PTO/AIA/80 (07-12)
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U.S. Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

■ Practitioners associated with Customer Number: 71562

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

☐ The address associated with Customer Number:

OR

☐	Firm or Individual Name		
	Address		
	City	State	Zip
	Country		
	Telephone	Email	

Assignee Name and Address: Becton Dickinson and Company
1 Becton Drive, Franklin Lakes, New Jersey

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be Filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of The practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record
The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	September 18, 2013
Name	David W. Highet	Telephone	201-847-5317
Title	Vice President and Chief Intellectual Property Counsel		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Filer:	Lloyd Craig Metcalf/Kris Haley
Attorney Docket Number:	P-6836C1

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1600**

Electronic Acknowledgement Receipt	
EFS ID:	17962294
Application Number:	14159959
International Application Number:	
Confirmation Number:	1050
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836C1
Receipt Date:	21-JAN-2014
Filing Date:	
Time Stamp:	15:44:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1600
RAM confirmation Number	2018
Deposit Account	500843
Authorized User	METCALF, L CRAIG
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	P_6836C1_AppDataSheet.pdf	840708 f33caccd92336e8e7b7cb3fd774f8f213aacb181	no	7
Warnings:					
Information:					
2		P_6836C1_AppDrwgs.pdf	418383 1f9ae9d37d1b7184cd2562415b4a4bf1404705cd	yes	24

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	11
Claims	12	16
Abstract	17	17
Drawings-only black and white line drawings	18	24

Warnings:					
Information:					
3	Oath or Declaration filed	P_6836C1_Declarations.pdf	136690 2ee6f52c38a9618c78ee3441a76a42769e003907	no	2
Warnings:					
Information:					
4	Power of Attorney	16081_AIA0080_GenPOA_091813.pdf	72586 8ba76f162ea6fdedceadff272a78b27f22afee48	no	1
Warnings:					
Information:					
5	PTO/SB/69-Authorize EPO Access to Search Results	P_6836C1_CertandAuth_sb0069.pdf	159288 da92d618af1d4bf0855e93c2c7ecc4bd0f177a85	no	2
Warnings:					
Information:					

6	Fee Worksheet (SB06)	fee-info.pdf	32956 d9e2b1c046a55c78752e1c4d178fb983d714923b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1660611	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt	
EFS ID:	17962294
Application Number:	14159959
International Application Number:	
Confirmation Number:	1050
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836C1
Receipt Date:	21-JAN-2014
Filing Date:	
Time Stamp:	15:44:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1600
RAM confirmation Number	2018
Deposit Account	500843
Authorized User	METCALF, L CRAIG
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	P_6836C1_AppDataSheet.pdf	840708 f33caccd92336e8e7b7cb3fd774f8f213aacb181	no	7
Warnings:					
Information:					
2		P_6836C1_AppDrwgs.pdf	418383 1f9ae9d37d1b7184cd2562415b4a4bf1404705cd	yes	24

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	11
Claims	12	16
Abstract	17	17
Drawings-only black and white line drawings	18	24

Warnings:					
Information:					
3	Oath or Declaration filed	P_6836C1_Declarations.pdf	136690 2ee6f52c38a9618c78ee3441a76a42769e003907	no	2
Warnings:					
Information:					
4	Power of Attorney	16081_AIA0080_GenPOA_091813.pdf	72586 8ba76f162ea6fdedceadff272a78b27f22afee48	no	1
Warnings:					
Information:					
5	PTO/SB/69-Authorize EPO Access to Search Results	P_6836C1_CertandAuth_sb0069.pdf	159288 da92d618af1d4bf0855e93c2c7ecc4bd0f177a85	no	2
Warnings:					
Information:					

6	Fee Worksheet (SB06)	fee-info.pdf	32956 d9e2b1c046a55c78752e1c4d178fb983d714923b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1660611	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

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National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P-6836C1
	Application Number	
Title of Invention	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Minh	Quang	Hoang	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Sandy	State/Province	UT	Country of Residence i	US

Mailing Address of Inventor:

Address 1	7954 English Oaks Cove		
Address 2			
City	Sandy	State/Province	UT
Postal Code	84093	Country i	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jonathan	Karl	Burkholz	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Salt Lake City	State/Province	UT	Country of Residence i	US

Mailing Address of Inventor:

Address 1	3610 Hermes Drive		
Address 2			
City	Salt Lake City	State/Province	UT
Postal Code	84124	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P-6836C1
	Application Number	
Title of Invention	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	

☐ **An Address is being provided for the correspondence Information of this application.**			
Customer Number	71562		
Email Address	IP_docket@bd.com	Add Email	Remove Email

Application Information:

Title of the Invention	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER		
Attorney Docket Number	P-6836C1	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter			
Total Number of Drawing Sheets (if any)	7	**Suggested Figure for Publication (if any)**	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	71562		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	11281711	2005-11-17

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

PTO/AIA/14 (03-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P-6836C1
	Application Number	
Title of Invention	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) [i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Access Code [i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P-6836C1
	Application Number	
Title of Invention	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(•) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. [X]

Organization Name	Becton, Dickinson and Company		
Mailing Address Information:			
Address 1	1 Becton Drive		
Address 2			
City	Franklin Lakes	**State/Province**	NJ
Country [i]	US	Postal Code	07417
Phone Number	201-847-6800	Fax Number	201-848-9228

PTO/AIA/14 (03-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P-6836C1
	Application Number	
Title of Invention	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	

Email Address	IP_docket@bd.com

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information:

Address 1	
Address 2	

City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications

Signature	/Craig Metcalf/			Date (YYYY-MM-DD)	2014-01-21
First Name	Craig	Last Name	Metcalf	Registration Number	31398

Additional Signature may be generated within this form by selecting the Add button. Add

PTO/AIA/14 (03-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P-6836C1
	Application Number	
Title of Invention	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PATENT APPLICATION
Our File No. 16081.1018
BD Reference No.: P-6836C1

UNITED STATES CONTINUATION PATENT APPLICATION

Of

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and

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For

PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

RELATED APPLICATIONS

[0001] This application is a continuation of United States Application No. 11/281,711, filed November 17, 2005, titled PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER, which is incorporated herein in its entirety.

BACKGROUND OF THE INVENTION

[0002] Catheter-related bloodstream infections are caused by bacteria/fungi in patients with intravascular catheters. These infections are an important cause of illness and excess medical costs, as approximately 80,000 catheter-related bloodstream infections occur in U.S. intensive care units each year. In addition to the monetary costs, these infections are associated with anywhere from 2,400 to 20,000 deaths per year.

[0003] Guidelines from the Centers for Disease Control and Prevention describe various ways to limit catheter-related bloodstream infections in hospital, outpatient and home care settings. The guidelines address issues such as hand hygiene, catheter site care and admixture preparation. Despite these guidelines, 15 catheter-related bloodstream infections continue to plague our healthcare system.

[0004] Impregnating catheters with various antimicrobial agents is one approach that has been implemented to prevent these infections. These catheters, however, have given less than satisfactory results. In addition, some microbes have developed resistance to the various antimicrobial agents in the system.

[0005] In another system that is commercially available in Europe, a catheter hub containing an antiseptic chamber is filled with three percent iodinated alcohol. Though it has

shown to be effective, the catheter hub is expensive and does not fare as well in a formal cost-benefit analysis. Therefore, there is a need for an effective and inexpensive way to reduce the number of catheter-related infections.

BRIEF SUMMARY OF THE INVENTION

[0006] The present invention is a device for antiseptically maintaining a patient fluid line access valve. The device includes a housing for covering the access portion of the access valve. A pad within the housing contacts the surface of the access portion of the access valve prior to (and optionally after) accessing the patient fluid line via the access valve to reduce the amount of microbes on the valve's access portion.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Figure 1 is an exploded view of a first representative embodiment of a cap/cleaner device and a patient fluid line access valve.

[0008] Figure 2 is a cross-sectional side view of the first representative embodiment of the cap/cleaner device.

[0009] Figure 3 is a cross-sectional side view of the first cap/cleaner device capping a patient fluid line access valve.

[0010] Figure 4 is a cross-sectional side view of the first cap/cleaner device cleaning a patient fluid line access valve.

[0011] Figure 5 is a flow chart illustrating representative embodiments of methods of using the cap/cleaner device.

[0012] Figure 6 is a perspective view of a second representative embodiment of a cap/cleaner device.

[0013] Figure 7 is a cross-sectional side view of the second cap/cleaner device.

[0014] Figure 8 is a cross-sectional view of a first separable connector.

[0015] Figure 9 is a side view of a second separable connector.

[0016] Figure 10A is a cross-sectional view of cleaning device.

[0017] Figure 10B is a cross-sectional view of a capping device.

DETAILED DESCRIPTION

[0018] Figure 1 shows an exploded view of patient fluid line access valve cap/cleaner device 10 with patient fluid line access valve A and patient fluid line B. Cap/cleaner 10 includes housing 12 with cap end 14, cleaning end 16 and thread 18; and lid 20. Access valve A includes housing A2 with thread A4 and septum A6 with slit A8. The exposed surface of septum A6 A10ng with at least a portion of the exposed surface of housing A2 that surrounds septum A6, form access portion A10of access valve A. Line B may be any of a number of types that include, for example, intravascular (IV) lines and catheters, saline wells, arterial lines and hemodialysis lines.

[0019] As will be described in more detail below, cap end 14 of cap/cleaner 10 attaches to access portion A10 of access valve A. Housing 12 is made from any of a number of types of plastic materials such as polycarbonate, polypropylene, polyethylene, glycol-modified polyethylene terephthalate, acrylonitrile butadiene styrene or any other moldable plastic material used in medical devices.

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[0020] Cap end 14 of housing 12 is open and contains thread 18 A10ng the inside of the opening. Cleaning end 16 is covered by lid 20. Lid 20 is typically made of foil or similar type material and completely seals the opening (not shown) of cleaning end 16. Any type of material or seal may be used as long as a moisture barrier is provided.

[0021] Figure 2 shows cap/cleaner 10 in more detail. In addition to the structures shown in Figure 1, cap/cleaner 10 also includes internal wall 12a, hood 16a and chamber 16b of cleaning end 16, cap 14a and cavity 14b of cap end 14, wet pad 22 within chamber 16b and dry pad 24 within cavity 14b. Internal wall12a separates cap end 14 and cleaning end 16.

[0022] Cap/cleaner 10 is typically distributed and stored in a sterile, sealed package either A10ne or paired with a patient fluid line access valve. One such type of valve is the BD Q-Syte™ valve from Becton, Dickinson and Company (illustrated in Figure 1). However, cap/cleaner 10 is useful with any type of needleless or needle required access valve. Once removed from the package, cap/cleaner 10 is ready for use.

[0023] Figure 3 illustrates cap/cleaner 10 covering access portion A10 of access valve A. Septum A6 provides an accessible seal for either a needle or a male luer taper. In the case of a needleless access device, such as that shown in Figure 3, slit A8 extends through septum A6 to provide a port for insertion of the male luer taper.

[0024] As shown, cap end 14 includes cap l4a with cavity l4b, which contains dry pad 24. Dry pad 24 is impregnated with an antimicrobial agent to aid in maintaining antiseptic conditions of access portion A10of valve A. Suitable material for dry pad 24 includes non-woven material or a foam sponge pad made of polyurethane, polyester, cotton or any bioengineered plastic material such as silicone. Any of a number of antimicrobial agents may be used to impregnate dry pad 24. Some examples include chlorhexidine gluconate, chlorhexidine diacetate,

chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, etc. Alternatively, cap end 14 does not contain dry pad 24 and aids in maintaining antiseptic conditions by simply covering access portion A10.

[0025] In use, cap end 14 of cap/cleaner 10 is placed over access portion A10 such that access portion A10 is within cavity 14b of cap end 14. Cap/cleaner 10 may be attached either prior to or after placement of valve A for the patient. As shown in Figure 3, valve A includes thread A4. By rotating cap/cleaner 10 or valve A relative to one another, threads A4 and 18 (of cap/cleaner 10) interlock to provide a secured attachment. It is not necessary, however, for valve A to include thread A4. Cap end 14 will also attach and hold a luer slip, which does not have a thread. In other embodiments, cap/cleaner 10 may be manufactured without a thread.

[0026] The amount of material used for dry pad 24 can vary. Typically, there is enough material for dry pad 24 to contact at least septum A6 of valve A. Enough space should be left in cavity 14b of cap end 14 for access portion A10of valve A to be encompassed by cap end 14, thus, maintaining antiseptic conditions of the surface. By maintaining antiseptic conditions of the surface, the risk of microbes penetrating into valve A is minimized.

[0027] To further minimize the opportunity for penetration by microbes, access portion A10is cleaned prior to accessing valve A with a needle or male luer taper. Figure 4 illustrates cap/cleaner 10 cleaning access portion A10 of valve A.

[0028] As shown in Figure 4, cleaning end 16 includes hood 16a and chamber 16b, which contains wet pad 22. Wet pad 22 is impregnated with a cleaning agent and optionally, an antimicrobial agent. Wet pad 22 may be made from materials similar to those described for dry pad 24.

[0029] The cleaning solution is typically an alcohol- or water-based solution. A suitable alcohol-based solution contains about 50% to about 100% (no additional water) of an alcohol solution. The balance of solutions that are less than 100% alcohol contain water and other optional materials such as fragrance, dye, surfactant, emollient, etc.

[0030] Suitable water-based solutions contain about 1% to about 10% alcohol solvent as a wetting agent and about 90% to about 99% water. Again, optional materials may also be added such fragrance, dye, surfactant, emollient, etc.

[0031] In an alternative embodiment, the cleaning solution also includes an antimicrobial agent. Any of a number of antimicrobial agents may be used in wet pad 22. Some examples include chlorhexidine gluconate, chlorhexidine diacetate, chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, etc. Wet pad 22 and dry pad 24 may be impregnated with the same or different antimicrobial agents.

[0032] As shown in the Figures, cleaning end 16 is larger than cap end 14. The hood of cleaning end 16 loosely encompasses at least access portion A10of valve A, and chamber 16b is sized to allow some movement when access portion Al0 is inserted. The amount of material used for wet pad 22 will vary, but the amount should hold enough cleaning solution and allow enough movement for thorough cleaning. Wet pad 22 should be contained entirely within hood 16a such that it is recessed inside chamber 16b of cleaning end 16.

[0033] In preparation for accessing valve A, cap end 14 is removed from valve A either by rotating cap/cleaner 10 to release threads 18 and A4 or by simply pulling if valve A does not have a thread. Lid 20 is removed from cleaning end 16. Cleaning end 16 is then placed over at least access portion A10, such that wet pad 22 contacts septum A6. Though Figure 4 only shows

contact with septum A6, additional pressure may be applied such that wet pad 22 extends beyond the edges of septum A6 to contact portions of the exposed surface of housing A2.

[0034] Next, for thorough cleaning, wet pad 22 should scrub access portion A10 of valve A. Scrubbing may be accomplished by, for example, rotational movement or back and forth movement. Scrubbing should be carried out for a time long enough to allow the cleaning solution to at least disinfect access portion A10 of valve A.

[0035] Once cleaned, valve A is ready to use. A needle or male luer taper is inserted to either infuse or withdraw fluid from the patient fluid line.

[0036] Figure 5 is a flowchart illustrating representative embodiments of methods for using cap/cleaner 10. Capping step 34, cleaning step 36 and accessing step 38 were described above and are the same in each embodiment. However, upon withdrawal after accessing the patient fluid line, access portion A10 of valve A may either be immediately capped or cleaned again prior to capping. If immediately capped, a new, second cap/cleaner 10A is obtained and removed from its package. This is represented by step 40. Cap end 14 of cap/cleaner 10A is placed over access portion Al0 as described above. Cleaning end 16 of cap/cleaner 10A is sealed and ready for the next time valve A is utilized.

[0037] Alternatively, access portion A10 may be cleaned again prior to capping. This can be performed in one of the following ways. First, in step 42, cleaning end 16 of cap/cleaner 10 is reused to clean access portion Al0, which is then capped, at step 44, with cap end 14 of a new, second cap/cleaner 10A. Second, in step 46, cleaning end 16 of a new, second cap/cleaner 10A is used to clean access portion A10. Then, valve A maybe capped either with cap end 14 of cap/cleaner 10A (step 48) or of a new, third cap/cleaner 10B (step 50). Third, in step 52, access portion A10 may be cleaned with an alternative disposable cleaning device that is well known in

the art. Examples of such cleaning devices include alcohol wipes, iodine swabs, etc. Once cleaned, cap end 14 of a new, second cap/cleaner 10A may be attached to valve 26 (step 50).

[0038] Additional embodiments of the present invention include separable and individual, uncoupled devices. Figure 6 shows separable cap/cleaner 56. Separable cap/cleaner 56 includes cap end 58, cleaning end 60 and gap 62. Gap 62 is the separation between cap end 58 and cleaning end 60.

[0039] Figure 7 shows separable cap/cleaner 56 in more detail and further includes dry pad 64 within cap end 58, wet pad 66 within cleaning end 60 and breakable connector 68. In use, separable cap/cleaner 56 operates as described above for 10 cap/cleaner 10 except that cleaning end 60 may be removed after cleaning access portion A10 of valve A. Detaching cleaning end 60 reduces bulkiness from separable cap/cleaner 56 by only maintaining cap end 58 over access portion A10.

[0040] Figure 8 shows a representative embodiment of breakable connector 68. Connector 68 is typically made of the same material from which housing 12 is fabricated. Torsional shearing caused by twisting cap end 58 and/or cleaning end 60 relative to each other may be used to break connector. Alternatively, a three-point bending force, which consists of a fulcrum (connector 68) that directs a force vector contralateral to the direction of the terminal (cap end 58 and cleaning end 60) force vectors, may be applied for breaking connector 68. Once removed, cleaning end 60 may be discarded.

[0041] Figure 9 is an alternate embodiment showing notched breakable connector 70. Notch 72 within connector 70 is an area of reduced cross-sectional area, which acts as a score to facilitate breaking of connector 70.

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[0042] Other separation mechanisms may also be used to remove cleaning end 60 from cap end 58. For instance, a luer lock type mechanism can be utilized to separate ends 58 and 60 from each other.

[0043] Figure 10A shows a representative embodiment of cleaning device 74 with lid 74a and wet pad 76. Here, cleaning device 74 is a stand-alone device that is used as described above for cleaning end 16.

[0044] Figure 10B shows a representative embodiment of cap device 78 with lid 78a and pad 80. Cap device 78 is a stand-alone device where pad 80 may either be a wet pad or a dry pad. Where pad 80 is a dry pad, cap device 78 is used as described above for cap end 14.

[0045] Where pad 80 is a wet pad, cap device 78 may be used to clean access portion A10 of valve A in addition to its capping function. The twisting motion involved in removing and placing cap device 78 with respect to access potion A10 provides friction for cleaning. Additional cleaning can be accomplished by twisting cap device 78 in one direction and then in the reverse direction for a desired amount of time.

[0046] Cap device 78 further comprises an inner circumference 82 that defines a cavity in which pad 80 is housed. In some instances, cap device 78 comprises a thread or threading 18 having a length that is less than inner circumference 82.

[0047] With either cleaning device 74 or cap device 78, additional gripping surface may be added by extending the length of the housing. The increased gripping surface would provide easier handling of devices 74 and 78.

[0048] Cap/cleaner 10 cleans and maintains access valves in antiseptic or aseptic condition. This substantially decreases the risk of patient infections caused by the ingress of microbes into the access valves, particularly for needleless access valves.

[0049] Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

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CLAIMS:

1. A device for maintaining a patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face, the device comprising:

a housing having an opening to an inner cavity for receiving the access portion of the access valve;

a wet pad holding a cleaning solution prior to receiving the access portion of the access valve;

threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening, the threading to engage the external threads of the access portion of the access valve as the housing is placed over the access portion of the access valve to contact the wet pad with the distalmost end face of the access portion of the access valve, and to disinfect the distalmost end face and at least a portion of the external threads of the access portion of the access valve with the cleaning solution from the wet pad, wherein the threading receives the external threads of the access portion of the access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the wet pad; and

a removable lid enclosing the inner cavity to maintain the wet pad and cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve.

2. The device of claim 1, wherein a threaded interaction between the threading and the external threads provides adjustable positioning of the septum within the inner cavity.

3. The device of claim 2, wherein adjustable positioning of the septum within the inner cavity allows the septum to contact the wet pad, and further allows the septum to contact and compress the wet pad between the septum and the inner cavity.

4. The device of claim 1, wherein the wet pad is a sponge.

5. The device of claim 1, wherein the housing comprises a polyethylene or polypropylene material.

6. The device of claim 1, wherein the cleaning solution comprises an antimicrobial agent.

7. The device of claim 6, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

8. The device of claim 6, wherein the cleaning solution is an alcohol-based cleaning solution.

9. A device for maintaining a patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face, the device comprising:

a housing for covering the access portion of the access valve, the housing having an open end, a closed end, and a cavity, the housing including a thread on an inner wall of the cavity

proximate the open end for engaging the external threads on the access portion of the access valve;

a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve, the wet pad being positioned within the cavity for contacting the end face of the access portion of the access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion; and

a lid over the open end of the housing to close the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the access valve into the cavity such that the thread engages the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide cleaning solution to the septum and at least a portion of the external threads.

10. The device of claim 9, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.

11. The device of claim 9, wherein the cleaning solution comprises an antimicrobial agent.

12. The device of claim 11, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

13. The device of claim 11, wherein the cleaning solution is an alcohol-based cleaning solution.

14. A device for maintaining a threaded patient fluid line access valve having an access portion with distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face, the device comprising:

a housing having an inner cavity for covering the access portion of the access valve;

a wet pad within the housing and impregnated with a cleaning solution prior to contacting the access valve, the wet pad being configured to contact at least a portion of the threaded patient fluid line access valve and the end face of the access valve to reduce the amount of microbes on the access valve;

a thread within the inner cavity of the housing and positioned between the wet pad and an opening to the inner cavity, the thread for engaging the external threads of the threaded patient fluid line access valve to cause the wet pad to contact the distalmost end face of the access valve; and

a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the access valve, the lid being removable to allow the distalmost end face of the access valve to be inserted into the housing and contact the wet pad to provide cleaning solution to the septum and at least a portion of the external threads.

15. The device of claim 14, wherein the inner cavity comprises an inner circumference and the internal thread comprises a length that is less than the inner circumference.

16. The device of claim 14, wherein the wet pad is a sponge.

17. The device of claim 14, wherein the housing comprises a polyethylene or polypropylene material.

18. The device of claim 14, wherein the cleaning solution is an alcohol-based cleaning solution.

19. The device of claim 14, wherein the cleaning solution comprises an antimicrobial agent.

20. The device of claim 19, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

ABSTRACT OF THE DISCLOSURE

[0050] Cap and cleaning devices antiseptically maintain patient fluid line access valves to minimize the risk of infection via catheters. The devices have a cap that may contain a dry pad impregnated with an antimicrobial agent. The cap covers the access portion of the access valve when not in use. The devices have a hood that contains a wet pad impregnated with a cleaning solution and, optionally, an antimicrobial agent. The wet pad cleans the access portion of the access valve prior to and optionally, after the access valve is utilized to access the patient fluid line.

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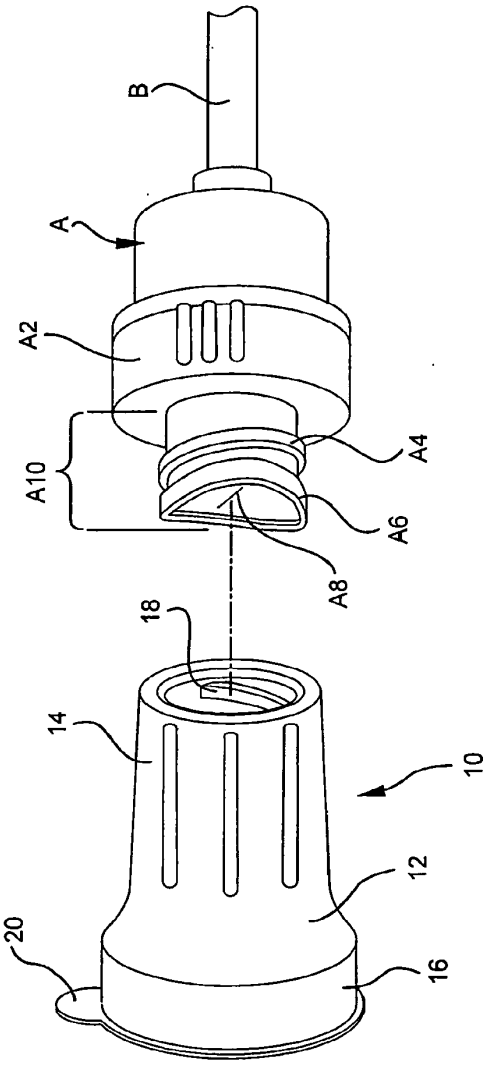


FIG. 1

FIG. 2

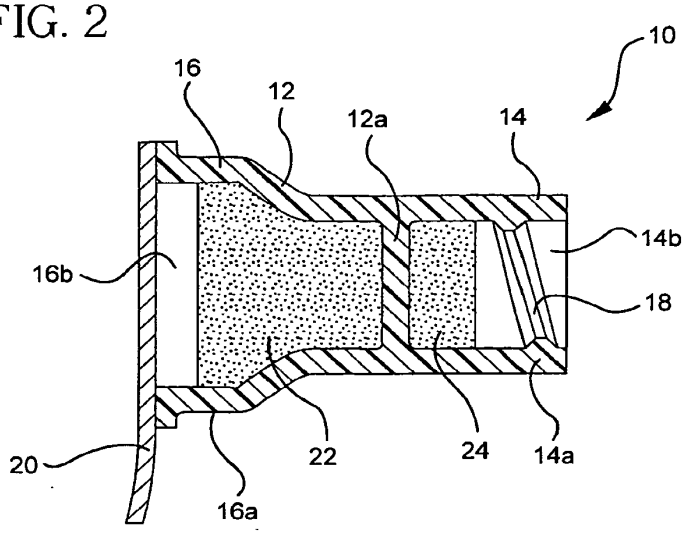

10
16
12
12a
14
14b
16b
18
20
22
24
14a
16a

FIG. 3

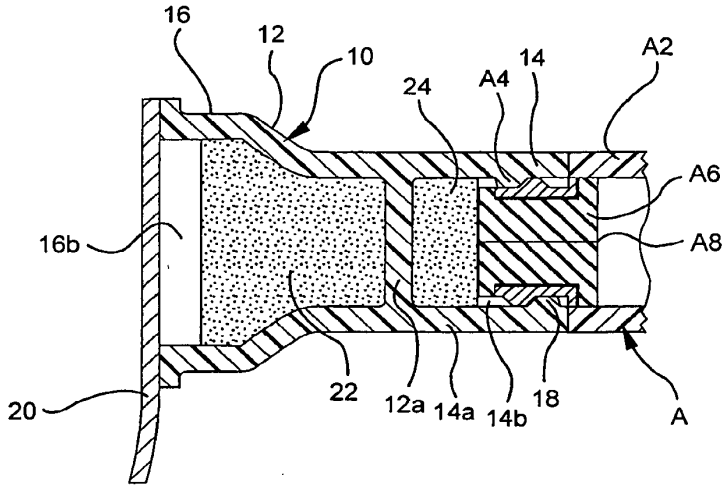

16
12
10
24
A4
14
A2
A6
16b
A8
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22
12a
14a
14b
18
A

FIG. 4

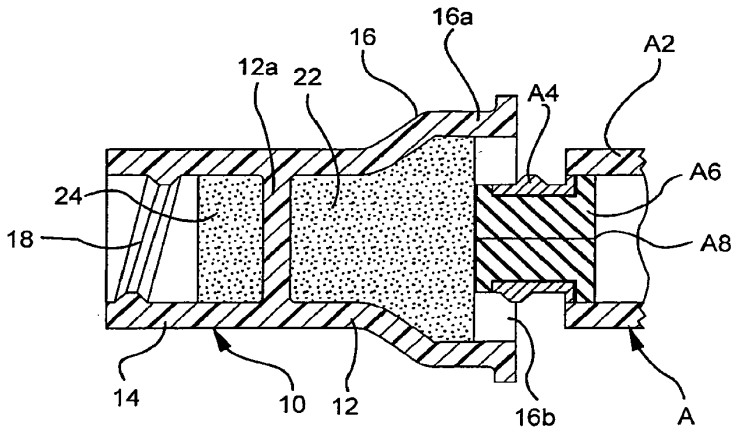


FIG. 5

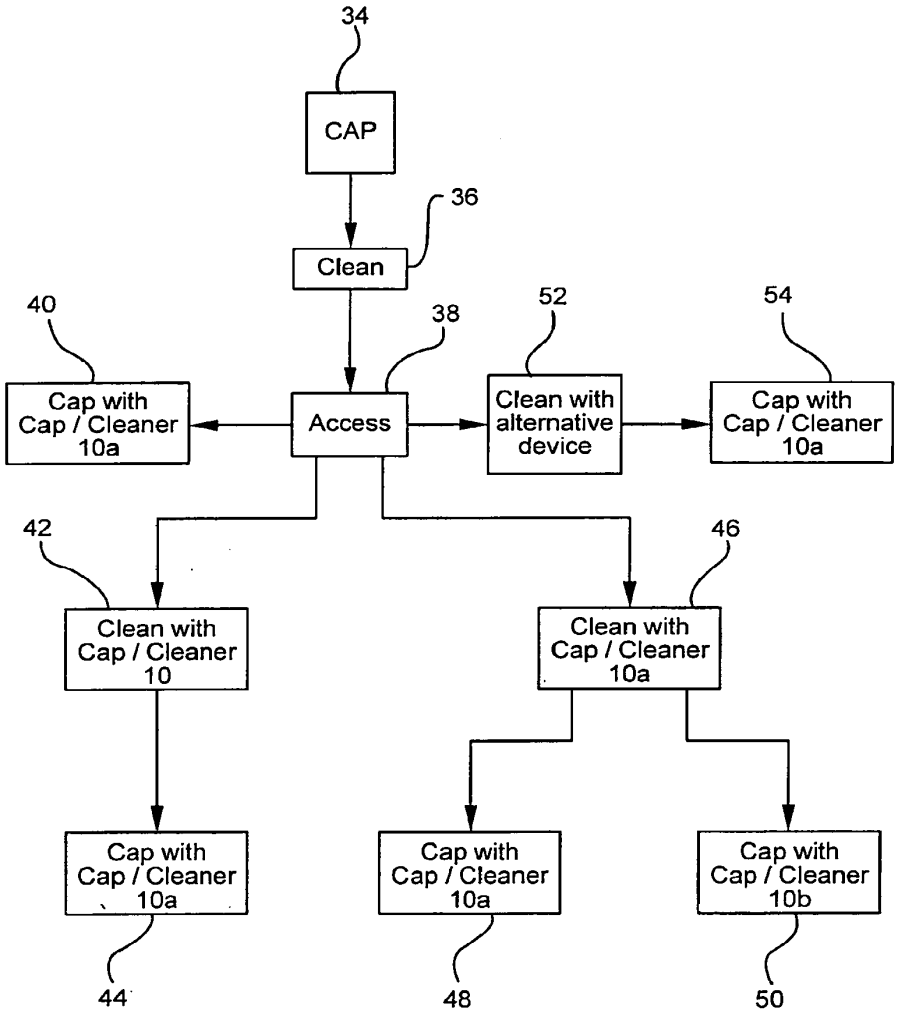

34
CAP
36
Clean
40
38
52
54
Cap with Cap / Cleaner 10a
Access
Clean with alternative device
Cap with Cap / Cleaner 10a
42
46
Clean with Cap / Cleaner 10
Clean with Cap / Cleaner 10a
Cap with Cap / Cleaner 10a
Cap with Cap / Cleaner 10a
Cap with Cap / Cleaner 10b
44
48
50

FIG. 6

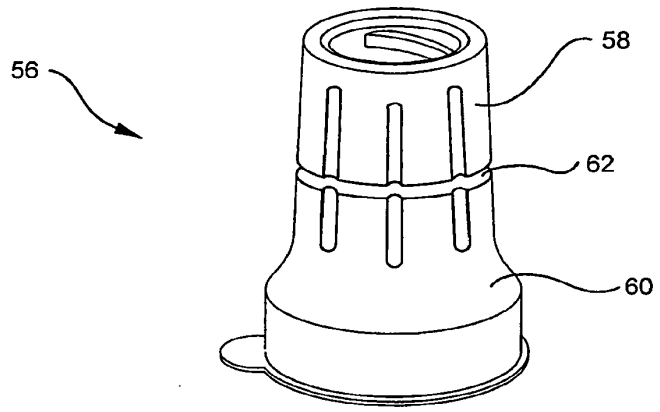


FIG. 7

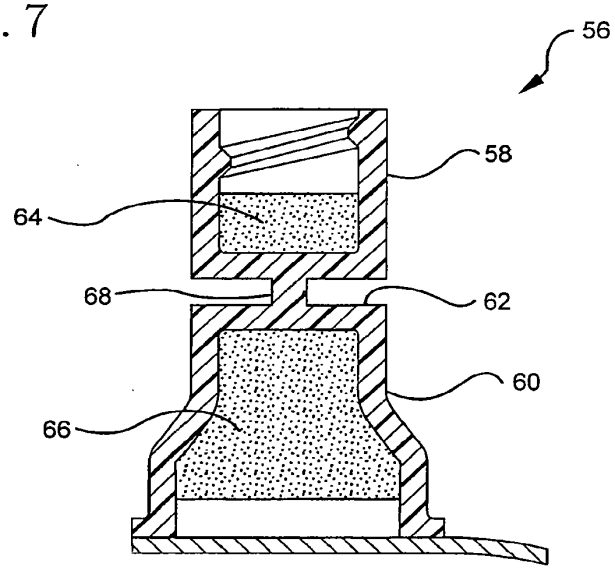


FIG. 8

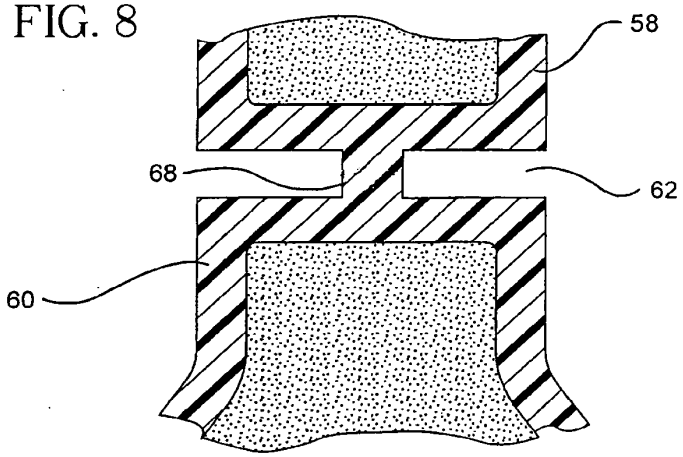


FIG. 9

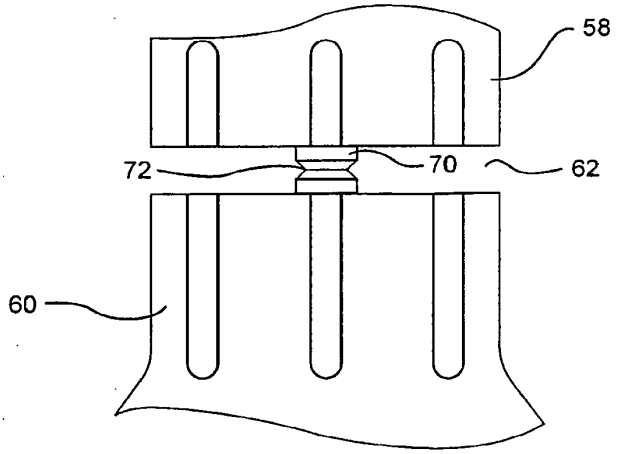


FIG. 10A

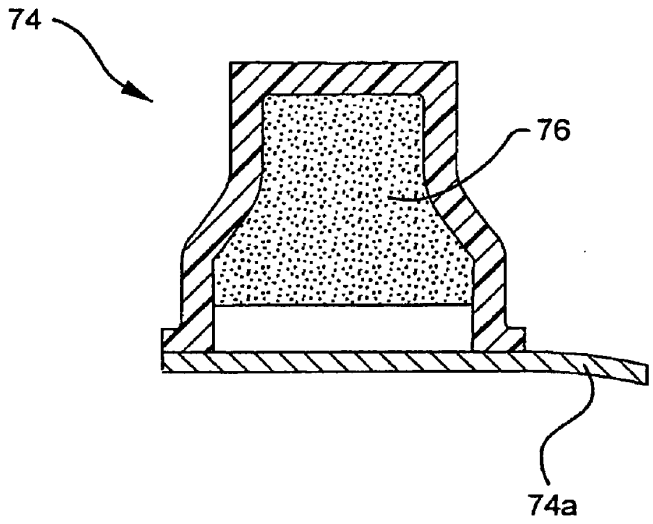
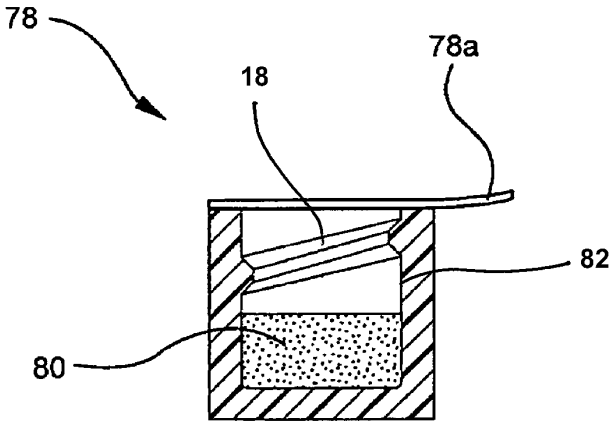


FIG. 10B



PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [■] The attached application, or
- [ ] United States application or PCT international application number _____

filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Jonathan Karl Burkholz Date (Optional) :_____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [■] The attached application, or
- [ ] United States application or PCT international application number _____

  filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

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LEGAL NAME OF INVENTOR

Inventor: Ming Quang Hoang Date (Optional) :_____

Signature: Mingquanghoang 12/5/2013

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/159,959	01/21/2014	3761	1600	P-6836C1	20	3

CONFIRMATION NO. 1050

71562
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

FILING RECEIPT

OC000000066423880

Date Mailed: 02/06/2014

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)
Minh Quang Hoang, Sandy, UT;
Jonathan Karl Burkholz, Salt Lake City, UT;

Applicant(s)
Becton, Dickinson and Company, Franklin Lakes, NJ

Assignment For Published Patent Application
Becton, Dickinson and Company, Franklin Lakes, NJ

Power of Attorney: The patent practitioners associated with Customer Number 71562

Domestic Priority data as claimed by applicant
This application is a CON of 11/281,711 11/17/2005

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/159,959**
Projected Publication Date: 05/15/2014
Non-Publication Request: No

Early Publication Request: No
Title

PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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Title 35, United States Code, Section 184

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/159,959

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*			OR	x 80 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 420 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1600

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/159,959	01/21/2014	Minh Quang Hoang	P-6836C1

CONFIRMATION NO. 1050

71562
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

POA ACCEPTANCE LETTER

OC000000066423971

Date Mailed: 02/06/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/21/2014.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/bmnguyen/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/159,959	01/21/2014	Minh Quang Hoang	P-6836C1

CONFIRMATION NO. 1050

71562
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

PUBLICATION NOTICE

OC000000068455662

Title:PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

Publication No.US-2014-0135710-A1
Publication Date:05/15/2014

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8491546	B2	2013-07-23	Hoang et al.	
	2	8167847	B2	2012-05-01	Anderson et al.	
	3	8162899	B2	2012-04-24	Tennican	
	4	8113731	B2	2012-02-14	Cable, Jr. et al.	
	5	8065773	B2	2011-11-29	Vaillancourt et al.	
	6	7922701	B2	2011-04-12	Buchman	
	7	7828186	B2	2010-11-09	Wales	
	8	7704935	B1	2010-04-27	Davis et al.	

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	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	9	7682561	B2	2010-03-23	Davis et al.	
	10	7452349	B2	2008-11-18	Miyahara	
	11	7282186	B2	2007-10-16	Lake, Jr. et al.	
	12	7268165	B2	2007-09-11	Greten et al.	
	13	7198800	B1	2007-04-03	Ko	
	14	7198611	B2	2007-04-03	Connell et al.	
	15	7083605	B2	2006-08-01	Miyahara	
	16	6994315	B2	2006-02-07	Ryan et al.	
	17	6911025	B2	2005-06-28	Miyahara	
	18	6861060	B1	2005-03-01	Luriya et al.	
	19	6846846	B2	2005-01-25	Modak et al.	

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	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	20	6708363	B2	2004-03-23	Larsen	
	21	RE38145	E	2003-06-17	Lynn	
	22	6488942	B1	2002-12-03	Ingemann	
	23	6413539	B1	2002-07-02	Shalaby	
	24	6337357	B1	2002-01-08	Fukunishi et al.	
	25	6227391	B1	2001-05-08	King	
	26	6117114		2000-09-12	Paradis	
	27	6116468		2000-09-12	Nilson	
	28	6051609		2000-04-18	Yu et al.	
	29	6045539		2000-04-04	Menyhay	
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	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	31	5861440		1999-01-19	Gohla et al.	
	32	5817344		1998-10-06	Hoang et al.	
	33	5792120		1998-08-11	Menyhay	
	34	5722537		1998-03-03	Sigler	
	35	5706944		1998-01-13	Hoang et al.	
	36	5694978		1997-12-09	Heilmann et al.	
	37	5686096		1997-11-11	Khan et al.	
	38	5641464		1997-06-24	Briggs, III et al.	
	39	5639310		1997-06-17	Giampaolo, Jr.	
	40	5620424		1997-04-15	Abramson	
	41	5616338		1997-04-01	Fox, Jr. et al.	

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	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	42	5569207		1996-10-29	Gisselberg et al.	
	43	5554135		1996-09-10	Menyhay	
	44	5554106		1996-09-10	Layman-Sipllar et al.	
	45	5547662		1996-08-20	Khan et al.	
	46	5512199		1996-04-30	Khan et al.	
	47	5335373		1994-08-09	Dangman et al.	
	48	5334388		1994-08-02	Hoang et al.	
	49	5242425		1993-09-07	White et al.	
	50	5195957		1993-03-23	Tollini	
	51	5023082		1991-06-11	Friedman et al.	
	52	4991629		1991-02-12	Ernesto et al.	

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	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	53	4989733		1991-02-05	Patry	
	54	4925668		1990-05-15	Khan et al.	
	55	4915934		1990-04-10	Tomlinson	
	56	4778447		1988-10-18	Velde et al.	
	57	4716032		1987-12-29	Westfall et al.	
	58	4671306		1987-06-09	Spector	
	59	4655762		1987-04-07	Rogers	
	60	4626664		1986-12-02	Grise	
	61	4624664		1986-11-25	Peluso et al.	
	62	4584192		1986-04-22	Dell et al.	
	63	4444310		1984-04-24	Odell	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	64	4440207		1984-04-03	Genatempo et al.	
	65	4432764		1984-02-21	Lopez	
	66	4417890		1983-11-29	Dennehey et al.	
	67	4354490		1982-10-19	Rogers	
	68	4282891		1981-08-11	Duceppe	
	69	4280632		1981-07-28	Yuhara	
	70	2961682		1960-11-29	Wurmbock et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20120283693	A1	2012-11-08	Anderson et al.	
	2	20120216360	A1	2012-08-30	Rogers et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
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	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	3	20120039765	A1	2012-02-16	Solomon et al.	
	4	20120016318	A1	2012-01-19	Hoang et al.	
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	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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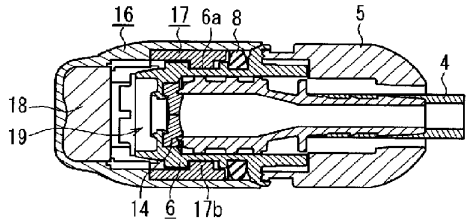
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添付公開書類:
— 国際調査報告（条約第 21 条(3)）

(54) **Title**: MEDICAL DEVICE FOR FORMING LIQUID COMMUNICATION PATH

(54) 発明の名称 : 医療用液体連通装置

[図5C]



(57) **Abstract**: A medical device for forming a liquid communication path, comprising: joining members (1, 3) for forming the communication flow path between objects to be communicated with each other; and a protective cap (2) having a tubular shape with a closed end, holding a germicide-impregnated member (18) at the deepest end of the protective cap, and capable of being mounted to at least one of the joining members which are being separated from each other. The inner peripheral surface of the protective cap forms a space (19) for surrounding the tip of the joining member, and the dimensional relationship between the joining member and the protective cap is set so that the germicide-impregnated member (18) faces the tip of the joining member with a spacing between the members. A sealing member (8) is mounted to the inner peripheral surface of the opening end of the protective cap or to the outer peripheral surface of that portion of the joining member which corresponds to the opening end of the protective cap, and when the protective cap is in a mounted state, the sealing member is pressed between the outer peripheral surface of the joining member and the inner peripheral surface of the protective cap to form an airtight structure for the space. The mounting of the cap on the joining member effectively sterilizes the tip of the joining member and, in addition, avoids leakage of the germicide due to the contact of the joining member with the germicide-impregnated member.

(57) 要約:

[続葉有]

WO 2010/143693 A1

連通対象間の連通流路を形成する結合部材１、３と、一端が閉塞された筒形状を有して殺菌剤含浸部材１８を最奥部に保持し、互いに分離された状態の結合部材の少なくとも一方に装着可能な保護キャップ２とを備えた医療用液体連通装置。保護キャップの内周面は結合部材の先端部を包囲する空間１９を形成し、殺菌剤含浸部材が間隔を保持して結合部材の先端部と対向するように、結合部材と保護キャップの相互の寸法関係が設定される。保護キャップの開口端部の内周面または結合部材における保護キャップの開口端部に対応する部位の外周面に装着された封止部材８を備え、保護キャップの装着状態で、結合部材の外周面と保護キャップの内周面間に封止部材が押圧されて空間の気密構造が形成される。保護キャップの装着により結合部材の先端部を効果的に殺菌し、しかも、結合部材が殺菌剤含浸部材に接触することに起因する殺菌剤の漏出を回避可能である。

明　細　書

発明の名称 ： 医療用液体連通装置

技術分野

[0001] 本発明は、例えば医療用のチューブを接続するためのコネクタ装置のような、連通対象の要素に各々装着された結合部材を互いに結合させることにより連通流路を形成するための医療用液体連通装置に関する。特に、互いに分離された状態の結合部材の少なくとも一方に装着可能で殺菌機能を備えた保護キャップを含む構成の液体連通装置に関する。

背景技術

[0002] 医療用液体連通装置の一例である医療用のコネクタとして、例えば、腹膜透析用の透析液交換に際して患者側トランスファーチューブ（エキステンションチューブ）と透析液の入ったバッグとを接続するためのコネクタが知られている。腹膜透析（ＰＤ）療法は、あらかじめ患者の腹腔に外科的に埋植した腹膜カテーテルを介して透析液を腹腔内に貯留し、腹膜の毛細血管を利用して体内に溜まった不純物をろ過する療法である。患者は、腹膜灌流カテーテルの体外側に、連続使用するトランスファーチューブ（エキステンションチューブ）を接続した状態で、日常の生活を送る。そして、患者自身が一日数回、透析液バッグをトランスファーチューブの先端に接続して、腹腔内の透析液を交換する。

[0003] この腹膜透析を行う上で最も問題となるのは、この１日数回行う透析液交換時に、誤って空気中や皮膚に付着した細菌が透析液と共に腹腔内に入ってしまうことである。仮に細菌が腹腔内に入ると、腹膜が炎症を起こし腹膜炎を発症するおそれがある。

[0004] そこで、腹膜透析を行う場合、透析液バッグとの接続のためにトランスファーチューブの先端に取り付けられたコネクタについて、細菌による汚染を低減することが重要である。器具あるいは組織等を殺菌する場合には、通常、ポビドンヨード溶液が用いられる。その場合、対象物に溶液を塗布して作

用させる方法が一般的である。従って、上述のような医療用コネクタの場合にも、トランスファーチューブの先端に設けられたコネクタに、ポビドンヨード等の殺菌剤を含浸したスポンジなどの多孔質物質（以下、含浸部材とする）を備えたキャップを被せることで、コネクタ先端部の殺菌が行なわれてきた（特許文献１～３参照）。

[0005] 特許文献２に開示された医療用コネクタ装置について、図１３、図１４に示した断面図を参照して説明する。図１３の（ａ）は、透析液バッグに設けられる雌型コネクタであるバッグ側コネクタ１１０を示す。図１４の（ｂ）は、雄型コネクタとして構成された患者側コネクタ１３０を示す。図１３の（ｂ）はバッグ側コネクタ用キャップ１２０、図１４（ａ）は患者側コネクタ用キャップ１４０を示す。

[0006] バッグ側コネクタ１１０は、第１環状ルアー部１１１と第１先端円筒部１１２の二重壁からなり、第１環状ルアー部１１１の基端部１１５には第１チューブ接続部１１６が設けられている。第１チューブ接続部１１６は、透析液バッグに接続されたチューブ１１９と接続される。基端部１１５の外周には凹部１１７が設けられ、第１先端円筒部１１２の基端には凸部１１８が設けられている。第１先端円筒部１１２は基端部１１５に嵌装され、凹部１１７と凸部１１８を介して、第１チューブ接続部１１６や第１環状ルアー部１１１に対し独立して回転可能に結合されている。第１先端円筒部１１２の内周には雌ねじ１１３が形成されている。また第１環状ルアー部１１１の先端付近の内周面には、弾性材料からなる封止部材１１４が埋め込まれている。

[0007] 一方、患者側コネクタ１３０は、先端円筒部１３２と、その内側に形成された第２環状ルアー部１３１と、第２チューブ接続部１３５を有する基端部１３４とからなる。第２チューブ接続部１３５は、チューブ１３６と接続される。先端円筒部１３２の基端は基端部１３４に結合されており、先端円筒部１３２は第２環状ルアー部１３１の先端を覆うように長く延出されている。先端円筒部１３２の外周には、バッグ側コネクタの先端円筒部１１２内周に設けられた雌ねじ１１３と螺合する雄ねじ１３３が形成されている。また

第２環状ルアー部１３１の外周が、バッグ側コネクタの第１環状ルアー部１１１の先端部内周に形成された封止部材と液密に周接することができる。

[0008] バッグ側コネクタと患者側コネクタを近接させて、先端円筒部１１２だけを独立に回転させることによって、チューブ１１９、１３６を捩れさせることなく、雌ねじ１１３と雄ねじ１３３を螺合させて、両コネクタを連結することが可能である。

[0009] 患者側コネクタキャップ１４０は、第３内筒１４１と、第３内筒１４１の回りに同心円状に形成された第３外筒１４２と、第３内筒先端に嵌接した栓１４６からなる。第３外筒１４２の内周には、患者側コネクタの先端円筒部１３２の外周に形成された雄ねじ１３３に螺合する雌ねじ１４３が形成され、雌ねじ１４３が終了する第３外筒先端の内縁部には弾性材料からなる封止部材１４５が配置されている。第３内筒１４１の基端には、殺菌剤を含有させた殺菌パッド１４４が装着されている。

[0010] 栓１４６は弾性材料から形成され、第２環状ルアー部１３１に押し付けられて液密に封止する。また殺菌パッド１４４は、患者側コネクタ１３０を患者側コネクタキャップ１４０に螺合した際に、先端円筒部１３２を殺菌する。封止部材１４５は、患者側コネクタと螺合した患者側コネクタキャップの中を外部からの汚染から保護するように封止する。

[0011] バッグ側コネクタキャップ１２０は、第４先端円筒部１２１と、第４キャップ基端部１２３を有する。第４先端円筒部１２１には、第１先端円筒部１１２の内周に形成された雌ねじ１１３に螺合させるための雄ねじ１２２が形成されている。

[0012] 上記構成のコネクタ装置により、透析液の注入が終了し、患者側コネクタ１３０とバッグ側コネクタ１１０の結合を解除したときには、患者側コネクタ１３０には新しい患者側コネクタキャップ１４０を装着して捩じ込む。この状態において、患者側コネクタ先端円筒部１３２は、患者側コネクタキャップ１４０内の殺菌パッド１４４に押圧されて、殺菌状態が保持される。

先行技術文献

特許文献

[0013] 特許文献1：特開昭５９－５００８０１号公報

特許文献2：特開平８－１５５０２５号公報

特許文献3：特開平８－２１５３１１号公報

発明の概要

発明が解決しようとする課題

[0014] 従来医療現場においては、殺菌剤と殺菌対象物とを直接接触させることで殺菌対象物の殺菌を行なうということが一般的であった。そのため、特許文献１、２に記載の構造では、キャップ中の含浸部材がコネクタの先端部と必ず接触する構造となっている。この構造により、コネクタの先端部によって含浸部材が押圧され、含浸部材中の殺菌剤が滲出する。

[0015] しかし、この構造により、滲出した殺菌剤が、コネクタの先端部からコネクタ・導管の内部流路に浸入したり、出した殺菌剤が、コネクタとキャップの接合部から外部に漏出し、周囲を汚染する、というような問題が発生するおそれがあった。その結果、トランスファーチューブの内部流路を経て患者体内に殺菌剤が浸入し、ＰＤ患者の健康に悪影響を及ぼすおそれがある。

[0016] また、特許文献３に記載の方法でも、保護キャップおよび閉鎖部材を導管から取り外す際に含浸部材（吸収材料１０）を押圧する必要があり、その際に滲出した防腐剤が保護キャップと閉鎖部材の間から漏出し、周囲を汚染するおそれがあった。

[0017] このような問題は、腹膜透析用のチューブを接続するコネクタに限らず、輸液チューブ等の、液体流路を接続することを要する箇所に用いられるコネクタについて共通する。更に一般的に言えば、連通対象に各々装着された結合部材により連通流路を形成するための医療用液体連通装置に共通する問題である。より詳しく言えば、互いに分離された状態の結合部材に装着可能で殺菌機能を備えた保護キャップを含む構成に共通する問題である。

[0018] そこで本発明は、殺菌剤含浸部材を奥部に保持する保護キャップを装着することにより、結合部材の先端部を十分に殺菌可能であって、しかも、結合

部材の先端部が殺菌剤含浸部材に接触することに起因する殺菌剤の漏出を回避可能な医療用液体連通装置を提供することを目的とする。

課題を解決するための手段

[0019] 本発明の医療用液体連通装置は、連通対象に各々装着され互いに結合されることにより前記連通対象間の連通流路を形成する結合部材と、一端が閉塞された筒形状を有して殺菌剤含浸部材を最奥部に保持し、互いに分離された状態の前記結合部材の少なくとも一方に装着可能な保護キャップとを備える。

[0020] 上記課題を解決するために、本発明の医療用液体連通装置は、前記保護キャップが前記結合部材に装着された状態において、前記保護キャップの内周面は前記結合部材の先端部を包囲する空間を形成し、前記殺菌剤含浸部材が間隔を保持して前記結合部材の先端部と対向するように、前記結合部材と前記保護キャップの相互の寸法関係が設定され、前記保護キャップの開口端部の内周面または前記結合部材における前記保護キャップの開口端部に対応する部位の外周面に装着された封止部材を備え、前記保護キャップの装着状態で、前記結合部材の外周面と前記保護キャップの内周面間に前記封止部材が押圧されて前記空間の気密構造が形成されることを特徴とする。

発明の効果

[0021] 上記構成によれば、殺菌剤含浸部材を奥部に保持する保護キャップを装着することにより、殺菌剤含浸部材と結合部材の先端部が接触しなくとも十分な殺菌効果を得ることが可能である。しかも、結合部材の先端部が殺菌剤含浸部材に接触することに起因する殺菌剤の漏出を回避することができる。

図面の簡単な説明

[0022] [図1A]図１Ａは、本発明の実施の形態１における医療用コネクタ装置を構成する雄型コネクタ及び保護キャップを分離状態で示す斜視図である。

[図1B]図１Ｂは、同医療用コネクタ装置における雄型コネクタに保護キャップが装着された状態を示す斜視図である。

[図2A]図２Ａは、同医療用コネクタ装置を構成する雌型コネクタを示す斜視

図である。

[図2B]図２Ｂは、図１Ａの雄型コネクタと図２Ａの雌型コネクタが接続された状態を示す斜視図である。

[図3A]図３Ａは、図１Ａの雄型コネクタの正面図である。

[図3B]図３Ｂは、図３Ａの雄型コネクタの右側面図である。

[図3C]図３Ｃは、図３Ａの雄型コネクタの断面図である。

[図4A]図４Ａは、図１Ａの保護キャップの正面図である。

[図4B]図４Ｂは、図４Ａの保護キャップの右側面図である。

[図4C]図４Ｃは、図４ＡにおけるＡ－Ａ線に沿った断面図である。

[図4D]図４Ｄは、図４ＢにおけるＢ－Ｂ線に沿った断面図である。

[図5A]図５Ａは、図１Ａにおける雄型コネクタ及び保護キャップを示す断面図である。

[図5B]図５Ｂは、図１Ｂにおける雄型コネクタ及び保護キャップを示す正面図である。

[図5C]図５Ｃは、図５Ｂの雄型コネクタ及び保護キャップの内部構造を示す断面図である。

[図6A]図６Ａは、図２Ａの雌型コネクタの正面図である。

[図6B]図６Ｂは、図６Ａの雌型コネクタの左側面図である。

[図6C]図６Ｃは、図６Ａの雌型コネクタの右側面図である。

[図6D]図６Ｄは、図６Ａの雌型コネクタの断面図である。

[図7A]図７Ａは、分解状態での雄型コネクタ及び雌型コネクタを示す断面図である。

[図7B]図７Ｂは、接続状態での雄型コネクタ及び雌型コネクタを示す正面図である。

[図7C]図７Ｃは、図７Ｂの雄型コネクタ及び雌型コネクタの断面図である。

[図8]図８は、本発明の実施の形態１における医療用コネクタ装置によるポビドンヨード溶液の滲出を抑止する効果を実証するための実験結果を示すグラフである。

[図9A]図９Ａは、同医療用コネクタ装置による殺菌能保持性能を実証するための加速保管の実験結果を示すグラフである。

[図9B]図９Ｂは、同医療用コネクタ装置による殺菌能保持性能を実証するための室温保管の実験結果を示すグラフである。

[図10A]図１０Ａは、本発明の実施の形態２における経腸栄養用コネクタ装置を構成するコネクタ及び保護キャップを示す正面図である。

[図10B]図１０Ｂは、同保護キャップの内部構造を示す断面図である。

[図10C]図１０Ｃは、コネクタに保護キャップが装着された状態を、保護キャップのみ断面で示す正面図である。

[図11A]図１１Ａは、本発明の実施の形態３における混注ポート装置を構成する混注ポート及び保護キャップを示す斜視図である。

[図11B]図１１Ｂは、同保護キャップの内部構造を示す断面図である。

[図12]図１２は、混注ポートの他の態様を示す斜視図である。

[図13]図１３は、従来例の医療用コネクタ装置の構成を示す断面図である。

[図14]図１４は、従来例の医療用コネクタ装置の構成を示す断面図である。

発明を実施するための形態

[0023] 本発明の医療用液体連通装置は、上記構成を基本として、以下のような態様をとることができる。

[0024] すなわち、前記結合部材の一方は雄型コネクタであり、その後端部に前記連通対象の一方と連結される装着部を有し、前記結合部材の他方は雌型コネクタであり、その後端部に第２の前記連通対象と連結される装着部を有する構成とすることができる。

[0025] 前記雄型コネクタは、内腔が液体流通用流路を形成する内筒と、内径が前記内筒の外径よりも大きく前記内筒の外側に同軸に結合された外筒とを有し、前記内筒の先端が前記外筒の先端よりも内部側に位置しており、前記保護キャップ及び前記雌型コネクタは、前記外筒の外側に装着される構成とすることができる。

[0026] 好ましくは、前記雄型コネクタは、先端部に内腔を遮蔽する密閉弁を有し

、前記雌型コネクタは、内腔が液体流通用流路を形成する内筒と、内径が前記内筒の外径よりも大きく前記内筒の外側に同軸に結合された外筒とを有して、前記外筒の内側に前記雄型コネクタが挿入されて接続され、前記雄型コネクタと前記雌型コネクタとが接続されたとき、前記雌型コネクタの前記内筒の先端が前記密閉弁を貫通して流路が開通する。

[0027] この場合、好ましくは、前記密閉弁よりも先端側に、前記雄型コネクタの内面に形成され前記密閉弁の外径よりも小さい開口を形成するフランジが設けられる。

[0028] また、好ましくは、前記フランジに、前記雄型コネクタの先端側に延びるリブが設けられる。

[0029] また、前記保護キャップの内部に、前記雄型コネクタの前記保護キャップ内の奥部に向かう移動位置を規制して前記空間を確保する位置規制部が設けられた構成とすることができる。

[0030] また、前記位置規制部は環状フランジにより形成され、前記雄型コネクタの先端部外面には前記環状フランジの内径よりも大きい外径を有する当接部が形成され、前記雄型コネクタと前記保護キャップとが接続されたとき、前記環状フランジと前記当接部の接触により前記雄型コネクタの前記保護キャップ内の奥部に向かう移動位置が規制される構成とすることができる。

[0031] また、前記雄型コネクタと前記保護キャップとは螺合により結合するように構成され、前記雄型コネクタと前記保護キャップの前記螺合の最深位置が前記位置規制部として機能し、前記雄型コネクタの前記保護キャップ内の奥部に向かう移動位置が規制される構成とすることができる。

[0032] また、前記保護キャップの内部にインナー部材が嵌入され、前記インナー部材により前記殺菌剤含浸部材が前記保護キャップの最奥部に保持されている構成とすることができる。

[0033] また、前記インナー部材は、前記雄型コネクタの前記保護キャップ内の奥部に向かう移動位置を規制して前記空間を確保する位置規制部を有する構成とすることができる。

[0034] また、前記保護キャップの最奥部に、開口部側よりも小径になった縮径部が設けられ、前記縮径部に前記殺菌剤含浸部材が配置されている構成とすることができる。

[0035] また、前記連通対象の一方は、経腸栄養法に用いられる栄養剤等を注入するための医療用容器のポート、他方は、前記医療用容器と患者の間を接続するためのチューブを含む経腸栄養セットである構成とすることができる。この場合、前記医療用容器のポートに設けられた経腸栄養用コネクタが前記結合部材の一方を構成し、前記栄養セットの一端に設けられ前記経腸栄養用コネクタと接続されるコネクタが、前記結合部材の他方を構成する。

[0036] また、前記結合部材の一方は混注ポートであり、前記混注ポートは、連通対象に設けられる台座と、前記台座に下面側から支持され中央部に挿入孔が形成されたディスク状の弁と、前記弁の中央部の上面を露出させる嵌合孔を有し前記弁の周縁を上面側から覆うカバーとを含み、前記結合部材の他方は、前記混注ポートに挿入可能でその内腔が液体流路を形成している挿入体である構成とすることができる。この場合、前記保護キャップは、前記混注ポートに対して装着されるように構成される。

[0037] 以下に、本発明の実施の形態における医療用液体連通装置について、図面を参照して具体的に説明する。

[0038] （実施の形態１）

本発明の実施の形態１における医療用液体連通装置は、腹膜透析におけるチューブ接続用の医療用コネクタ装置を適用例としたものである。まず、図１Ａ～図２Ｂを参照して、本実施の形態の医療用コネクタ装置の概要について説明する。図１Ａは、この医療用コネクタ装置を構成する雄型コネクタ１と保護キャップ２を、分解した状態で示す斜視図である。図１Ｂは、図１Ａの雄型コネクタ１と保護キャップ２が接続された状態を示す斜視図である。図２Ａは、この医療用コネクタ装置を構成する雌型コネクタ３を示す斜視図である。図２Ｂは、図１Ａに示した雄型コネクタ１と、図２Ａに示した雌型コネクタ３が接続された状態を示す斜視図である。

[0039] 本実施の形態では、雄型コネクタ１は患者側コネクタとして使用され、雌型コネクタ３は、透析液バッグに設けられるバッグ側コネクタとして使用される。雄型コネクタ１、保護キャップ２、及び雌型コネクタ３は全て樹脂により形成されている。

[0040] 図１Ａに示すように、雄型コネクタ１は後端部に、例えば、患者の腹腔に埋植された腹膜カテーテルに接続されるチューブ４が装着される。チューブ４の前部には、雄型コネクタ１を操作するための把持部５が設けられ、その先端側が保護キャップ２及び雌型コネクタ３との結合部を形成している。この結合部は、円筒部６と、円筒部６よりもやや小径に形成された先端小径部７から構成されている。円筒部６の外周面には、ねじ溝６ａが形成されている。円筒部６の基端には大径部６ｂにより段差が形成され、この大径部６ｂに当接させて、封止部材として機能する弾性リング８が装着されている。

[0041] 保護キャップ２は、一端が閉塞された略円筒形状を有し、図１Ｂに示すように、雄型コネクタ１の先端部外側に装着可能である。断面図を参照して後述するように、保護キャップ２は最奥部に、殺菌剤（例えば、ポビドンヨード溶液）を含浸した殺菌剤含浸部材が保持されている。保護キャップ２の内周面には、雄型コネクタ１に装着される際に、ねじ溝６ａと係合して雄型コネクタ１と保護キャップ２の結合を固定するための係合突起（後述）が設けられている。

[0042] 雌型コネクタ３は、例えばツインバッグ、Ｙセット、ＡＰＤ等の腹膜透析装置の回路先端等に接続される。図２Ａに示すように、後端部に、チューブ９が装着される。チューブ９の前部には、雌型コネクタ３を操作するための把持部１０が設けられ、その先端側が雄型コネクタ１との結合部を形成している。この結合部は、外筒１１の内部に形成されている。外筒１１の内周面には、雄型コネクタ１と接続される際に、ねじ溝６ａと係合して雄型コネクタ１と雌型コネクタ３の結合を固定するための係合突起１２が設けられている。保護キャップ２の内周面に設けられた係合突起も、この係合突起１２と同様である。

[0043] 外筒１１の内部に雄型コネクタ１が挿入され、ねじ溝６ａと係合突起１２が螺合することにより、図２Ｂに示すように、雄型コネクタ１と雌型コネクタ３が接続され固定される。雌型コネクタ３と雄型コネクタ１が接続されると、チューブ４、９間が、両コネクタ１、３の内腔を貫通する流路によって連通する。但し、図２Ｂでは、図２Ａに対して雌型コネクタ３が左右反転して描かれている。

[0044] 本実施の形態の特徴は、以下に説明するとおり、雄型コネクタ１と保護キャップ２の組み合わせに関連した構成にある。従って、図３Ａ～５Ｃを参照して、雄型コネクタ１と保護キャップ２の構造についてより詳細に説明する。まず、保護キャップ２の構造について説明する。

[0045] 図３Ａは、図１Ａの雄型コネクタ１の正面図、図３Ｂは、図３Ａの雄型コネクタ１の右側面図、図３Ｃは、図３Ａの雄型コネクタ１の断面図である。図３Ｃに示されるように、雄型コネクタ１は、円筒部６と、円筒部６の内腔に装着されたインナー部材１３と、円筒部６の後部に連結された把持部５に分けて形成されている。インナー部材１３の後部は把持部５の内部に延在して、チューブ接続部１３ａを形成しており、チューブ４が接続されている。また、インナー部材１３の内腔は、流路１３ｂを形成している。

[0046] 円筒部６の内腔の先端部には、内腔を遮蔽する密閉弁１４（例えばゴム製のスリット入りセプタム）が配置されている。円筒部６の先端部内周面には、密閉弁１４の外形よりも小さい開口を形成するフランジ１５が設けられ、インナー部材１３の先端とフランジ１５の間で、密閉弁１４が保持されている。フランジ１５には、先端側に延びるリブ１５ａが設けられている。

[0047] 密閉弁１４は、雄型コネクタ１と雌型コネクタ３が接続されていないときに、インナー部材１３内腔の流路を密閉する機能を有する。それにより、菌が雄型コネクタ１の外部から流路内に侵入することが防止される。また、可撓性のチューブ４側から液が漏出することも防止される。このように、密閉弁１４は、インナー部材１３内腔の流路の密閉状態を確保するためには有効であるが、必須ではない。また、他の方法で密閉状態を確保してもよい。

[0048] また、円筒部６の内周面に設けられたフランジ１５により、密閉弁１４を流路内に保持し易くなるとともに、雄型コネクタ１先端側から密閉弁１４に指で接触されることを抑制する効果が得られる。フランジ１５にリブ１５ａが設けられることにより、その効果をより向上させることができる。

[0049] 図４Ａは、保護キャップ２の正面図、図４Ｂは、図４Ａの保護キャップ２の右側面図、図４Ｃは、図４ＡにおけるＡ－Ａ線に沿った断面図、図４Ｄは、図４ＢにおけるＢ－Ｂ線に沿った断面図である。

[0050] 保護キャップ２は、図４Ｃ，図４Ｄに示されるように、一端が閉塞された略円筒形状の外筒１６と、外筒１６の内部に嵌入されたインナー部材１７とから形成されている。保護キャップ２の最奥部には、開口部側よりも小径になった縮径部１６ａが設けられ、縮径部１６ａ内に殺菌剤含浸部材１８が配置されている。殺菌剤含浸部材１８は、インナー部材１７の内端部１７ａの規制により最奥部に保持されている。縮径部１６ａを設け、その中に殺菌剤含浸部材１８を挿入することにより、保護キャップ２内に殺菌剤含浸部材１８を保持し易くなる。さらに、殺菌剤含浸部材１８が雄型コネクタ１の先端部に触れ難くなる効果も得られる。

[0051] インナー部材１７の開口側端部の内周面には、係合突起１７ｂが形成されている。雄型コネクタ１と保護キャップ２の結合は、雄型コネクタ１の外周面のねじ溝６ａと、係合突起１７ｂとの螺合により形成される。また、この螺合構造により、雄型コネクタ１と保護キャップ２の結合の最深位置が規制される。従って、雄型コネクタと保護キャップとが接続されるとき、螺合構造が、雄型コネクタ１の保護キャップ２内の奥部に向かう移動位置を規制する位置規制要素として機能する。

[0052] また、インナー部材１７の中間部内周面には環状フランジ１７ｃが形成され、同様の位置規制部として機能する。すなわち、雄型コネクタ１の先端部外面には、環状フランジ１７ｃの内径よりも大きい外径を有する当接部６ｂが形成されている。そのため、雄型コネクタ１に保護キャップ２が装着されたとき、環状フランジ１７ｃと当接部６ｂの接触により、雄型コネクタ１の

移動位置が規制される。

[0053] 殺菌剤含浸部材１８は、多孔質体、繊維体などの材質、例えばスポンジで形成することができる。含浸させる殺菌剤の例としては、ポビドンヨード溶液以外の殺菌剤を用いても良いが、人体への影響を考慮するとポビドンヨード溶液が望ましい。

[0054] 次に、図５Ａ～図５Ｃを参照して、雄型コネクタ１に保護キャップ２を装着した時の状態及び作用について説明する。図５Ａは、図１Ａの分解状態での雄型コネクタ１及び保護キャップ２を示す断面図、図５Ｂは、図１Ｂの結合状態での雄型コネクタ１及び保護キャップ２を示す正面図、図５Ｃは，図５Ｂの雄型コネクタ１及び保護キャップ２の断面図である。

[0055] 保護キャップ２は、雄型コネクタ１と雌型コネクタ３が接続されていないときに雄型コネクタ１に装着され、コネクタ先端を保護する。装着する時には、図５Ａに示すように、雄型コネクタ１の先端に保護キャップ２の開口部を対向させて、雄型コネクタ１を押し込みながら回転させる。それにより、保護キャップ２の内面に設けられた係合突起１７ｂと、雄型コネクタ１の外周面のねじ溝６ａとの係合を介して、雄型コネクタ１の先端に保護キャップ２が装着され固定される。

[0056] その際、上述のように、保護キャップのインナー部材１７の内周面に形成された環状フランジ１７ｃが位置規制部として機能し、また、雄型コネクタ１と保護キャップ２の螺合の最深位置による規制構造が位置規制部として機能する。それにより、雄型コネクタ１の先端部の周辺と保護キャップ２の内面との間に空間１９が形成される（図５Ｃ参照）。この空間の形成により、保護キャップ２に保持された殺菌剤含浸部材１８が、所定の間隔を保持して雄型コネクタ１の先端と接触することなく対向する状態が維持される。

[0057] また、雄型コネクタ１の外周面と保護キャップ３の内周面の間に弾性リング８が押圧され、それにより空間１９の気密が保持される。そのため、ポビドンヨード溶液が含浸された殺菌剤含浸部材１８からヨウ素が昇華して空間１９内に充満し、空間１９内に密閉された雄型コネクタ１の先端部に対する

殺菌作用が十分に得られる。なお、上述の例では、弾性リング８は雄型コネクタ１に外嵌されているが、空間１９を密閉するためには、弾性リング８は保護キャップ３の内部に嵌入されていてもよい。要するに、保護キャップ３を雄型コネクタ１に装着した際、弾性リング８が保護キャップ３と雄型コネクタ１の双方から押圧される構成であればよい。

[0058] 但し、弾性リング８は、腹膜透析用チューブのコネクタの場合、患者側のコネクタに外嵌されているほうが望ましい。保護キャップや透析液側のコネクタは１回限り使用であるのに対して、患者側のコネクタは半年に１回交換であるため、弾性リング８を設けるコストを削減できるからである。その他の使用目的のチューブであれば、この限りではない。

[0059] このように、殺菌剤含浸部材１８が雄型コネクタ１の先端と直接接触するのではなく、殺菌剤含浸部材１８と雄型コネクタ１の先端との間に所定の間隔を設けられていても、十分な殺菌効果が得られることが、後述する実験の結果により確認された。

[0060] 従って、本実施の形態の医療用コネクタ装置によれば、雄型コネクタ１の先端側に保護キャップ２を装着することにより、雄型コネクタの先端部の殺菌状態を容易に保持することができる。しかも、本実施の形態によれば、殺菌剤含浸部材１８と雄型コネクタ１の先端との間に所定の間隔が設けられるので、殺菌剤含浸部材１８が押圧力を受けることによる殺菌剤の滲出が回避される。従って、滲出した殺菌剤が、コネクタの先端部からコネクタ・導管の内部流路に浸入することや、滲出した殺菌剤が、コネクタとキャップの接合部から外部に漏出して、周囲を汚染するような不都合を回避することができる。

[0061] 次に、雌型コネクタ３の構造、及び作用について、図６Ａ～図７Ｃを参照して説明する。図６Ａは、図２Ａの雌型コネクタ３の正面図、図６Ｂは、図６Ａの雌型コネクタ３の左側面図、図６Ｃは同右側面図、図６Ｄは、図６Ａの雌型コネクタ３の断面図である。

[0062] 雌型コネクタ３は、内腔が液体流通用流路を形成する内筒２０と、内径が

内筒２０の外径よりも大きく内筒の外側に同軸に結合された外筒１１とを有する。外筒１１の後端部に把持部１０が形成され、また、内筒２０の中央部と結合している。外筒１１は、先端側が開口しており、内部にインナー部材２１が嵌込まれている。インナー部材２１の内周面には、係合突起１２が形成されている。内筒２０は、外筒１１の内部で開口に向かって延在する内筒先端部２０ａと、外筒１１の後方に延びて把持部１０の内側に位置するチューブ接続部２０ｂとを有する。

[0063] 次に、図７Ａ～図７Ｃを参照して、雄型コネクタ１と雌型コネクタ３を接続した時の状態及び作用について説明する。図７Ａは、分解状態での雄型コネクタ１及び雌型コネクタ３を示す断面図、図７Ｂは、接続状態での雄型コネクタ１及び雌型コネクタ３を示す正面図、図７Ｃは、図７Ｂの雄型コネクタ１及び雌型コネクタ３の断面図である。

[0064] 接続する時には、図７Ａに示すように、雄型コネクタ１の先端に雌型コネクタ３の先端開口部を対向させて、雄型コネクタ１を押し込みながら回転させる。それにより、雌型コネクタ３の内面に設けられた係合突起１２と、雄型コネクタ１の外周面のねじ溝６ａとの係合を介して、雄型コネクタ１の先端に雌型コネクタ３が装着され固定される。

[0065] その際、雌型コネクタ３への雄型コネクタ１の進入に伴い、内筒先端部２０ａは、雄型コネクタ１の先端に装着された密閉弁１４のスリットを押し広げながら貫通して雄型コネクタ１の内部に達し、流路を開通させる。

[0066] なお、以上のような保護キャップ２の装着、あるいは雌型コネクタ３との接続のためには、雄型コネクタ１は、他の形態とすることもできる。すなわち、雄型コネクタを、内腔が液体流通用流路を形成する内筒と、内径が内筒の外径よりも大きく内筒の外側に同軸に結合された外筒とから構成する。内筒の先端は外筒の先端よりも内部側に位置しており、保護キャップ及び雌型コネクタは、外筒の外側に装着される。この構成によれば、誤って雄型コネクタ先端部に触れた場合でも、液体が流通する内筒に触れることは回避でき、内筒を保護することができる。外筒に付着した菌は、保護キャップを被せ

れば上述のように殺菌することができるので、菌が流路内に侵入することがない。

[0067] 以下に、本実施の形態における医療用コネクタ装置において、雄型コネクタ１に保護キャップ２を装着した際に得られる効果について確認するための実験の結果について説明する。実験により、雄型コネクタ１の先端部の周辺と保護キャップ２の内面との間に密閉された空間１９が形成され、この密閉空間内で、殺菌剤含浸部材１８が所定の間隔を保持して雄型コネクタ１の先端と対向する状態が維持されることにより、十分な殺菌効果が得られることが実証された。また、その際、殺菌剤含浸部材１８と雄型コネクタ１の先端との接触に起因する殺菌剤の滲出が回避され、殺菌剤がコネクタの先端部からコネクタ・導管の内部流路に浸入する不都合を回避できることが実証された。

[0068] ［実験１：殺菌能の検証］

ポビドンヨード溶液が、雄型コネクタ１の先端部に非接触の状態で対向する構成により、雄型コネクタ１の先端部に存在する菌を殺菌する作用が得られることについて検証した。

[0069] 実験方法は以下のとおりである。まず、評価菌種として、Staphylococcus aureus、Staphylococcus epidermidis、Escherichia coli、Pseudomonas aeruginosa、Candida albicansの５菌種を用いた。ブドウ球菌属の場合は、Ｔｗｅｅｎ　８０（Polyoxyethylene Sorbitan Monooleate）を０．０１％添加した生理的食塩水、その他の菌種の場合は生理的食塩水に溶解させたものを用意した。

[0070] 次に、雄型コネクタ１の先端部に10^3ＣＦＵ／２０μＬの菌液を分注し、保護キャップ２を装着後、３０－３５℃の体温条件あるいは１０℃の低温条件で３ｈｒ静置した。その後、保護キャップ２を外し、雄型コネクタ１をリンス液（ＦＬＵＩＤ　Ｄ－ＳＴ液／ＢｉｏＭｅｒｉｅｕｘ）１０ｍＬ中に入れ３０ｓｅｃ攪拌後、φ０．４５μｍのフィルターで濾過を行った。これを３回繰り返した後、このフィルターをＳＣＤ寒天培地に載せて３０－３５℃

で培養後、生菌数を確認した。

[0071] 本実施の形態に基づく実施例１としては、保護キャップ２の殺菌剤含浸部材１８に１０%ポビドンヨード溶液を含浸させたもの、比較例１としては、保護キャップ２の殺菌剤含浸部材１８にポビドンヨード溶液に代えて生理的食塩水を含浸させたものを使用した。

[0072] 実験の結果について、（表１）を参照して説明する。比較例１については、どちらの温度条件下でも分注した菌数からの変化が認められなかったが、実施例１については、どちらの条件下でも全ての菌種を殺滅することが出来た。従って、ポビドンヨード溶液が雄型コネクタ１の先端部に非接触の状態でも、コネクタ先端部に存在する菌を殺菌可能であることを確認できた。

[0073] [表1]

評価菌種	生菌数(CFU)			
	体温条件（30－35℃）		低温条件（10℃）	
	実施例1	比較例1	実施例1	比較例1
Staphylococcus aureus	0	2.7×10^3	0	2.5×10^3
Staphylococcus epidermidis	0	1.1×10^3	0	3.1×10^3
Escherichia coli	0	4.2×10^3	0	3.3×10^3
Pseudomonas aeruginosa	0	1.5×10^3	0	2.2×10^3
Candida albicans	0	5.1×10^3	0	5.3×10^3

＊分注菌数１０^{3}ＣＦＵ

[0074] [実験２：ポビドンヨード溶液混入試験]

保護キャップ２を装着し外した後に、コネクタ導管部分に通液を行った場合に、保護キャップ２の殺菌剤含浸部材１８中のポビドンヨード溶液が通液内に混入するかどうか確認した。

[0075] 実験方法は以下のとおりである。すなわち、雄型コネクタ１の先端部に保護キャップ２を装着し４ｈｒ静置後、保護キャップ２を外し、この雄型コネクタ１に雌型コネクタ３を接続後、チューブ内に超純水を２０ｍＬ通液して

、実施例２とした。この超純水について０．０２Ｎチオ硫酸ナトリウム溶液を滴定液として用いた酸化還元滴定法にて有効ヨウ素の定量を行った。従来品のコネクタについて同様の試験を行ったものを、比較例２とした（従来品は全て、ポビドンヨード溶液にコネクタ先端が接触している）。

[0076] 実験の結果を示す図８から、実施例２では、比較例２Ａ～２Ｄと比較して、含浸部材内の有効ヨウ素量が多いにも関わらず、通液内への混入が認められなかったことが判る。

[0077] この結果により、殺菌剤含浸部材１８をコネクタと非接触とすることで、殺菌剤含浸部材１８中のポビドンヨード溶液の滲出が回避可能であることを確認できた。

[0078] ［実験３：殺菌能保持性能の検証］

雄型コネクタ１の先端部に存在する菌を殺菌可能な保存期間について確認した。実験方法は以下のとおりである。すなわち、雄型コネクタ１に保護キャップ２を装着し、アルミ包材に包装後４０℃／７５％ＲＨの条件下で加速保管を行い、殺菌能に重要なポビドンヨード溶液中の水分量及び有効ヨウ素量の経時変化の評価を行った。水分量については、保管前重量と保管後重量との差を測定することで算出した。

[0079] 有効ヨウ素量については、保護キャップ２を９９．５％エタノールに一晩浸漬後、さらに十分な共洗いによりポビドンヨードを抽出した後、０．０１Ｍチオ硫酸ナトリウム溶液を滴定液として用いた酸化還元滴定法にて有効ヨウ素の定量を行った。この時、試験毎にポビドンヨード溶液の検量線を作成し、これにより検体の有効ヨウ素量を算出した。これと同時に室温条件下でも同様に保管し、水分量・有効ヨウ素量データから加速保管と室温保管との関係を確認した。

[0080] また、これについて、実験１と同様の試験により殺菌能試験を行い、殺菌能保持可能期間を検討した。なお、温度条件は３０－３５℃の１条件とし、評価菌種はStaphylococcus epidermidisの１菌種とした。比較例３としては、保護キャップ２の含浸部材に含浸させているポビドンヨード溶液の代わり

に生理的食塩水を含浸させたものを使用した。

[0081] 加速保管の実験結果を図９Ａに、室温保管の実験の結果を図９Ｂに示す。この実験結果によれば、各保管期間の水分量及び有効ヨウ素量の対比から、室温保管１２Ｍ（月）は加速保管６Ｗ（週間）に、室温保管２４Ｍは加速保管１２Ｗにそれぞれ相当することが判る。従って、加速保管は室温保管の８倍相当の保管期間に相当することを確認できた。

[0082] また、殺菌能試験の結果を（表２）に示す。この試験の結果、加速保管１８Ｗで生菌が認められたことから、実施例３の場合は、加速保管１５Ｗまで十分な殺菌能が保持可能であることが確認された。

[0083] [表2]

保管期間 (W)	生菌数(CFU)	
	実施例3	比較例3
9	0	6.3×10^{3}
12	0	2.3×10^{3}
15	0	3.2×10^{3}
18	4.4×10^{1}	4.0×10^{3}
21	2.8×10^{2}	6.8×10^{3}
24	1.1×10^{2}	4.7×10^{3}
27	∞	2.7×10^{3}

＊分注菌数１０^{3}ＣＦＵ

[0084] 以上の結果により、加速保管１５Ｗは室温保管２年半相当に匹敵するため、殺菌能は約２年半保持することが可能であるということを確認できた。

[0085] [実験４：密閉空間内の殺菌剤濃度と非接触殺菌能の関係の検証]

密閉空間内での殺菌剤濃度による非接触殺菌能の変化について調べる実験を行った。

[0086] （１）ステップ１

先ず、ステップ１として以下の実験を行なった。すなわち、殺菌剤として１０%のポビドンヨード溶液を用い（実施例４）、評価菌種として１０^{3}ＣＦＵのS. epidermidisを用い、評価菌種との比較用に生理食塩水をそれぞれ用いた（比較例４）。

[0087] スポンジに、１０μｌ、５０μｌ、１５０μｌ、３００μｌのポビドンヨ

ード溶液をそれぞれ含浸させた。ポビドンヨード溶液が含浸したスポンジを５ｍｌシリンジのプランジャーのガスケットに装着し、空間が６３０ｍｌとなるようにプランジャーを調節した。

[0088] フォームと反対側（シリンジ先端細径部）に10^3ＣＦＵの菌液（Ｔｗｅｅｎ８０を０．０１%添加した生理食塩水で希釈）を２０μｌ分注し、密閉した。これを、室温で静置して、１時間後に生菌数を計測した。この実験の結果を（表３）に示す。

[0089] [表3]

ポビドンヨード溶液量（μl）	検体No.	生菌数（CFU）	
		実施例4	比較例4
10	1	0.6×10^2	1.9×10^3
	2	1.4×10^2	2.6×10^3
	3	3.7×10^2	2.6×10^3
	平均	1.9×10^2	2.4×10^3
50	1	0	1.4×10^3
	2	0	1.4×10^3
	3	0	1.8×10^3
	平均	0	1.5×10^3
150	1	0	2.4×10^3
	2	0	1.7×10^3
	3	0	2.1×10^3
	平均	0	2.1×10^3
300	1	0	1.3×10^3
	2	0	1.3×10^3
	3	0	1.6×10^3
	平均	0	1.4×10^3

＊分注菌数10^3ＣＦＵ

[0090] この実験結果から、菌を殺滅するために必要なポビドンヨード溶液の密閉空間体積に対する割合を算出した。空間体積が６３０mm^3の場合、１０%のポビドンヨード溶液が５０μｌ以上あれば10^3ＣＦＵのS. epidermidisを殺滅可能であることが判る。

[0091] （２）ステップ２

次に、ステップ２として以下の実験を行なった。すなわち、スポンジに、１０μｌ、５０μｌ、１５０μｌ、３００μｌのポビドンヨード溶液をそれぞれ含浸させた。ポビドンヨード溶液が含浸したフォームを５ｍｌシリンジのプランジャーのガスケットに装着し、空間が各評価体積となるようにプランジャーを調節した。各評価体積は、６３０mm^3、３７８mm^3、１８９mm^3、１２６mm^3とした。

[0092] フォームと反対側（シリンジ先端細径部）に10^3ＣＦＵの菌液（Ｔｗｅｅｎ８０を０．０１%添加した生理食塩水で希釈）を２０μｌ分注した。室温で静置後、各評価時間毎に生菌数を計測して殺滅完了時間を調べた。その結果を（表４）に示す。評価時間は０．５ｈｒ、及び１ｈｒとした。

[0093] [表4]

ポビドンヨード溶液量	検体 No.	殺菌時間(hr)			
		0.5		1.0	
		生菌数(CFU)		生菌数(CFU)	
		実施例	比較例	実施例	比較例
10μl/126mm^3	1	0	1.9×10^3	0	1.3×10^3
	2	26	1.8×10^3	0	1.5×10^3
	3	322	1.5×10^3	0	1.1×10^3
	平均	116	1.7×10^3	0	1.3×10^3
15μl/189mm^3	1	42	1.6×10^3	0	1.2×10^3
	2	2	2.1×10^3	0	1.0×10^3
	3	0	2.0×10^3	0	1.0×10^3
	平均	147	1.9×10^3	0	1.1×10^3
30μl/378mm^3	1	18	1.9×10^3	0	1.3×10^3
	2	2	2.0×10^3	0	1.2×10^3
	3	0	2.1×10^3	0	1.4×10^3
	平均	6.7	2.0×10^3	0	1.3×10^3
50μl/630mm^3	1	0	2.2×10^3	0	1.3×10^3
	2	0	1.8×10^3	0	1.4×10^3
	3	0	1.6×10^3	0	1.3×10^3
	平均	0	1.9×10^3	0	1.3×10^3

＊分注菌数10^3ＣＦＵ

[0094] この実験結果によれば、１０%ポビドンヨード溶液が空間体積に対して約８%以上存在すれば、10^3ＣＦＵのS. epidermidisを殺滅可能であることが判る。

[0095] （実施の形態２）

本発明の実施の形態２における医療用液体連通装置は、経腸栄養法に用いられるコネクタ装置を適用例とするものである。図１０Ａ～図１０Ｂを参照して、本実施の形態における経腸栄養用コネクタ装置の構成について説明する。

[0096] 経腸栄養法では、患者の鼻腔から胃又は十二指腸にまで通されたチューブを介して栄養剤、流動食、又は薬剤などの液状物が投与される。栄養剤等を投与する際には、まず、栄養剤等を医療用容器に注入する。次に、医療用容器のポート（通液部）に、チューブを含む注入路セットの一端に装着されたコネクタを接続する。さらに、医療用容器を、注入路セットが接続されたポートを下側にしてハンガーに吊り下げる。医療用容器をハンガーに吊り下げた状態で、注入路セットの他端に装着されたコネクタを、患者に装着されたチューブの端部のコネクタに接続し、医療用容器内の栄養剤等の液状物を患者に投与する。

[0097] 図１０Ａは、注入路セットが接続される医療用容器２２のポート２３を示す。ポート２３は、液状物が通過するための通液孔が形成された管状部２４と、管状部２４の先端を形成する経腸栄養用コネクタ２５を有する。コネクタ２５は、ルアー接続方式により注入路セットの一端のコネクタ（図示せず）と接続される。すなわち、コネクタ２５と注入路セットの一端に装着されたコネクタとが、本実施の形態における医療用液体連通装置を構成する。

[0098] この経腸栄養用コネクタ装置は更に、保護キャップ２６を含み、医療用容器２２が使用されていない状態では、コネクタ２５には、保護キャップ２６が装着される。保護キャップ２６の内部構造を、図１０Ｂに示す。保護キャップ２６は、一端が閉塞された筒形状を有しており、最奥部に殺菌剤含浸部材２７が保持されている。保護キャップ２６の開口端部の内周面には、封止部材２８が装着されている。

[0099] 図１０Ｃに示すように、保護キャップ２６はコネクタ２５に装着された状態において、コネクタ２５の先端の周囲を包囲する空間２９を形成し、殺菌剤含浸部材２７が所定の間隔を保持してコネクタ２５の先端と対向する。ま

た、保護キャップ２６がコネクタ２５に装着された状態で、コネクタ２５の外周面と保護キャップ２６の内周面間に封止部材２８が押圧されて、空間２９の気密構造が形成される。

[0100] 以上のような、本実施の形態の経腸栄養用コネクタ装置によれば、コネクタ２５の先端部に保護キャップ２６を装着することにより、当該部分の殺菌状態を容易に保持することができる。しかも、殺菌剤含浸部材２７と経腸栄養用コネクタ２５の先端との間に所定の空間２９が設けられるので、殺菌剤含浸部材２７が押圧力を受けることによる殺菌剤の滲出が回避される。従って、滲出した殺菌剤が、コネクタ２５の先端部からポート２３の内部流路に浸入することや、滲出した殺菌剤が外部に漏出して、周囲を汚染するような不都合を回避することができる。

[0101] なお、上述の構成では、医療用容器２２のポート２３に設けられた経腸栄養用コネクタ２５に保護キャップ２６が装着されるが、患者に装着されたチューブの端部のコネクタに保護キャップを装着するように構成して、同様の効果を得ることもできる。

[0102] （実施の形態３）

実施の形態３における医療用液体連通装置は、医療用混注ポート装置を適用例としたものである。図１１Ａ～図１１Ｂを参照して、本実施の形態における混注ポート装置の構成について説明する。

[0103] 医療用混注ポートは、患者に薬液等を投与する場合に、主たる薬液とは異なる薬液を、薬液供給用送液路に混注し、または、送液路を流れる液体をサンプル採取する場合等に用いられる。そのため、混注ポートは、先端が鋭利ではない挿入体を弁に形成された挿入孔に挿入して上記操作を行なうことができるように構成されている。

[0104] 図１１Ａに示す混注ポート３０は、連通対象であるチューブ３１の途中に装着されている。なお、連通対象はチューブに限られず、他のどのような形態のものであってもよい。チューブ３１には台座３２が設けられ、台座３２にカバー３４が装着されている。台座３２とカバー３３により、中央部に挿

入孔が形成されたディスク状の弁３４が保持されている。すなわち、台座３２により弁３４が支持され、カバー３３が弁３４に当接して、台座３２とカバー３３の間に弁３４が挟持されている。カバー３４は、中央部に弁３４の中央部上面を露出させる嵌合孔を有する。台座３２は、チューブ３１の内腔に通じる貫通孔を有する。

[0105] この混注ポート３０の弁３４を貫通してシリンジ先端部を構成するルアーのような挿入体（図示せず）が挿入されると、挿入体の内腔がチューブ３１の内腔と連通する。それにより、液体を注入および／または採取でき、弁３４からルアーを抜くと弁３４がその弾性により閉じる。すなわち、混注ポート３０と挿入体とから構成される混注ポート装置が、本実施の形態における医療用液体連通装置を構成する。

[0106] 混注ポート装置は更に、保護キャップ３５を含み、混注ポート３０が使用されていない状態では、混注ポート３０には、保護キャップ３５が装着される。

[0107] 図１１Ｂに、保護キャップ３５の内部構造を示す。保護キャップ３５は、一端が閉塞された筒形状を有しており、最奥部に殺菌剤含浸部材３６が保持されている。保護キャップ３５の開口端部の内周面には、封止部材３７が装着されている。

[0108] 保護キャップ３５は混注ポート３０に装着された状態において、混注ポート３０の上端の周囲を包囲する空間を形成し、殺菌剤含浸部材３６が所定の間隔を保持して混注ポート３０の上端と対向する。また、保護キャップ３５が混注ポート３０に装着された状態で、混注ポート３０の外周面と保護キャップ３５の内周面間に封止部材３７が押圧されて、空間の気密構造が形成される。

[0109] 以上のような、本実施の形態の医療用混注ポート装置によれば、混注ポート３０の上端部に保護キャップ３５を装着することにより、当該部分の殺菌状態を容易に保持することができる。しかも、殺菌剤含浸部材３６と混注ポート３０の先端との間に所定の空間が設けられるので、殺菌剤含浸部材３６

が押圧力を受けることによる殺菌剤の滲出が回避される。従って、滲出した殺菌剤が、混注ポート３０の先端部からチューブ３１の内部流路に浸入することや、滲出した殺菌剤が外部に漏出して、周囲を汚染するような不都合を回避することができる。

[0110] 図１２は、本実施の形態における他の態様の混注ポート装置を示す斜視図である。図１１Ａに示した混注ポート装置と同様の要素については、同一の参照符号を付して説明の繰り返しを省略する。この態様においては、チューブ３１の一端に混注ポート３０が装着されている。このような態様でも、上述と同様の保護キャップを用いることにより、上述と同様の効果を得ることができる。

産業上の利用可能性

[0111] 本発明の医療用液体連通装置によれば、殺菌剤含浸部材を奥部に保持する保護キャップを装着することにより、結合部材の先端部を十分に殺菌可能であって、しかも、結合部材の先端部が殺菌剤含浸部材に接触することに起因する殺菌剤の漏出が回避されるので、腹膜透析や輸液用等における流路接続のためのコネクタ装置等に有用である。

符号の説明

[0112] １　雄型コネクタ

２、２６、３５　保護キャップ

３　雌型コネクタ

４、９、３１　チューブ

５、１０　把持部

６　円筒部

６ａ　ねじ溝

６ｂ　当接部

７　先端小径部

８　弾性リング

１１、１６　外筒

１２、１７ｂ　係合突起

１３、１７、２１　インナー部材

１３ａ　チューブ接続部

１３ｂ　流路

１４　密閉弁

１５　フランジ

１５ａ　リブ

１６ａ　縮径部

１７ａ　内端部

１７ｃ　環状フランジ

１８、２７、３６　殺菌剤含浸部材

１９、２９　空間

２０　内筒

２０ａ　内筒先端部

２０ｂ　チューブ接続部

２１　インナー部材

２２　医療用容器

２３　ポート

２４　管状部

２５　経腸栄養用コネクタ

２８、３７　封止部材

３０　混注ポート

３２　台座

３３　カバー

３４　弁

請求の範囲

[請求項1] 連通対象に各々装着され互いに結合されることにより前記連通対象間の連通流路を形成する結合部材と、

一端が閉塞された筒形状を有して殺菌剤含浸部材を最奥部に保持し、互いに分離された状態の前記結合部材の少なくとも一方に装着可能な保護キャップとを備え、

前記保護キャップが前記結合部材に装着された状態において、前記保護キャップの内周面は前記結合部材の先端部を包囲する空間を形成し、前記殺菌剤含浸部材が間隔を保持して前記結合部材の先端部と対向するように、前記結合部材と前記保護キャップの相互の寸法関係が設定され、

前記保護キャップの開口端部の内周面または前記結合部材における前記保護キャップの開口端部に対応する部位の外周面に装着された封止部材を備え、前記保護キャップの装着状態で、前記結合部材の外周面と前記保護キャップの内周面間に前記封止部材が押圧されて前記空間の気密構造が形成されることを特徴とする医療用液体連通装置。

[請求項2] 前記結合部材の一方は雄型コネクタであり、その後端部に前記連通対象の一方と連結される装着部を有し、

前記結合部材の他方は雌型コネクタであり、その後端部に第２の前記連通対象と連結される装着部を有する請求項１に記載の医療用液体連通装置。

[請求項3] 前記雄型コネクタは、内腔が液体流通用流路を形成する内筒と、内径が前記内筒の外径よりも大きく前記内筒の外側に同軸に結合された外筒とを有し、

前記内筒の先端が前記外筒の先端よりも内部側に位置しており、

前記保護キャップ及び前記雌型コネクタは、前記外筒の外側に装着される請求項２に記載の医療用液体連通装置。

[請求項4] 前記雄型コネクタは、先端部に内腔を遮蔽する密閉弁を有し、

前記雌型コネクタは、内腔が液体流通用流路を形成する内筒と、内径が前記内筒の外径よりも大きく前記内筒の外側に同軸に結合された外筒とを有して、前記外筒の内側に前記雄型コネクタが挿入されて接続され、

前記雄型コネクタと前記雌型コネクタとが接続されたとき、前記雌型コネクタの前記内筒の先端が前記密閉弁を貫通して流路が開通する請求項２に記載の医療用液体連通装置。

[請求項5] 前記密閉弁よりも先端側に、前記雄型コネクタの内面に形成され前記密閉弁の外径よりも小さい開口を形成するフランジが設けられた請求項４に記載の医療用液体連通装置。

[請求項6] 前記フランジに、前記雄型コネクタの先端側に延びるリブが設けられた請求項５に記載の医療用液体連通装置。

[請求項7] 前記保護キャップの内部に、前記雄型コネクタの前記保護キャップ内の奥部に向かう移動位置を規制して前記空間を確保する位置規制部が設けられた請求項２～６のいずれか１項に記載の医療用液体連通装置。

[請求項8] 前記位置規制部は環状フランジにより形成され、前記雄型コネクタの先端部外面には前記環状フランジの内径よりも大きい外径を有する当接部が形成され、

前記雄型コネクタと前記保護キャップとが接続されたとき、前記環状フランジと前記当接部の接触により前記雄型コネクタの前記保護キャップ内の奥部に向かう移動位置が規制される請求項７に記載の医療用液体連通装置。

[請求項9] 前記雄型コネクタと前記保護キャップとは螺合により結合するように構成され、

前記雄型コネクタと前記保護キャップの前記螺合の最深位置が前記位置規制部として機能し、前記雄型コネクタの前記保護キャップ内の奥部に向かう移動位置が規制される請求項７に記載の医療用液体連通

装置。

[請求項10] 前記保護キャップの内部にインナー部材が嵌入され、前記インナー部材により前記殺菌剤含浸部材が前記保護キャップの最奥部に保持されている請求項２記載の医療用液体連通装置。

[請求項11] 前記インナー部材は、前記雄型コネクタの前記保護キャップ内の奥部に向かう移動位置を規制して前記空間を確保する位置規制部を有する請求項１０に記載の医療用液体連通装置。

[請求項12] 前記保護キャップの最奥部に、開口部側よりも小径になった縮径部が設けられ、前記縮径部に前記殺菌剤含浸部材が配置されている請求項２に記載の医療用液体連通装置。

[請求項13] 前記連通対象の一方は、経腸栄養法に用いられる栄養剤等を注入するための医療用容器のポート、他方は、前記医療用容器と患者の間を接続するためのチューブを含む経腸栄養セットであり、

前記医療用容器のポートに設けられた経腸栄養用コネクタが前記結合部材の一方を構成し、

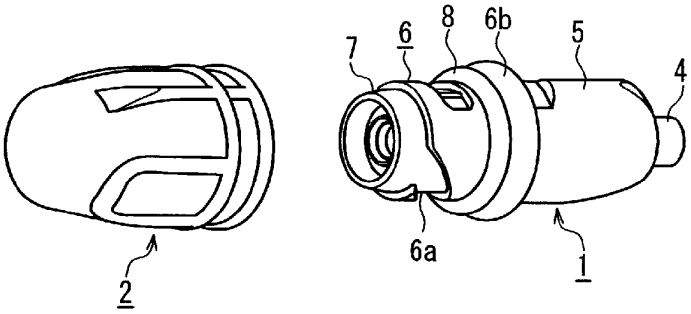
前記栄養セットの一端に設けられ前記経腸栄養用コネクタと接続されるコネクタが、前記結合部材の他方を構成する請求項１に記載の医療用液体連通装置。

[請求項14] 前記結合部材の一方は混注ポートであり、前記混注ポートは、連通対象に設けられる台座と、前記台座に下面側から支持され中央部に挿入孔が形成されたディスク状の弁と、前記弁の中央部の上面を露出させる嵌合孔を有し前記弁の周縁を上面側から覆うカバーとを含み、

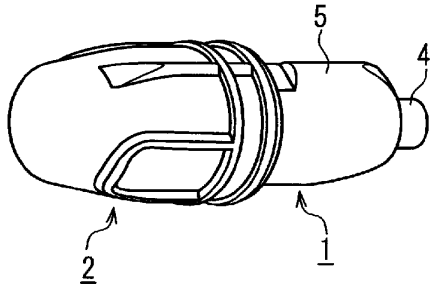
前記結合部材の他方は、前記混注ポートに挿入可能でその内腔が液体流路を形成している挿入体であり、

前記保護キャップは、前記混注ポートに対して装着されるように構成された請求項１に記載の医療用液体連通装置。

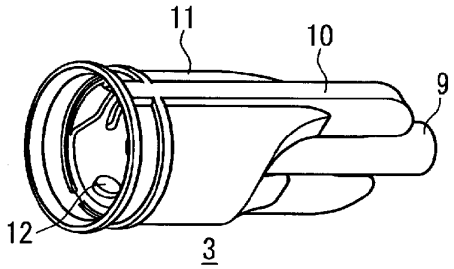
[図1A]



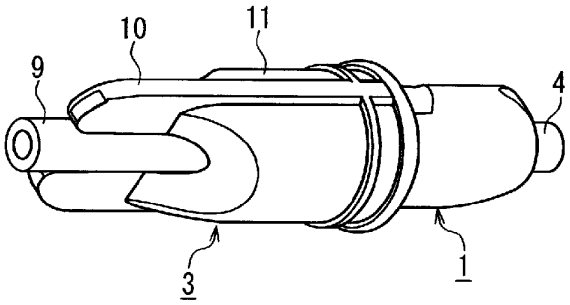
[図1B]



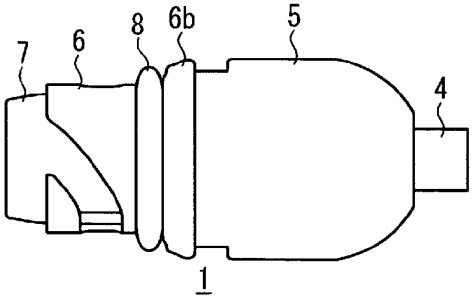
[図2A]



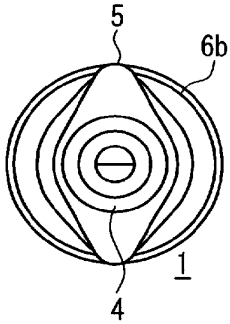
[図2B]



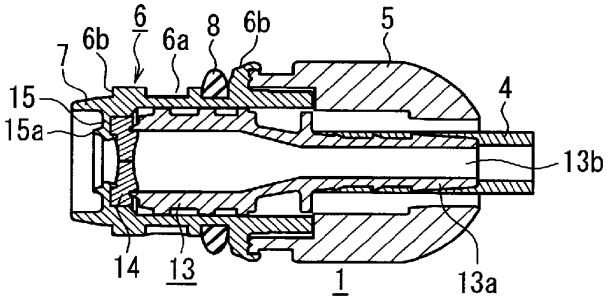
[図3A]



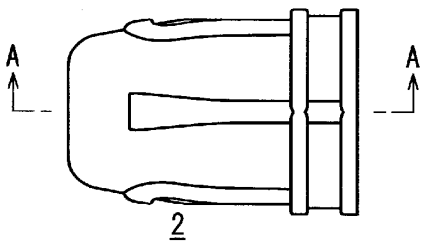
[図3B]



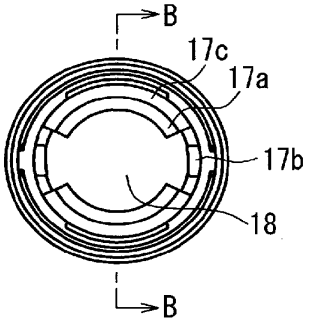
[図3C]



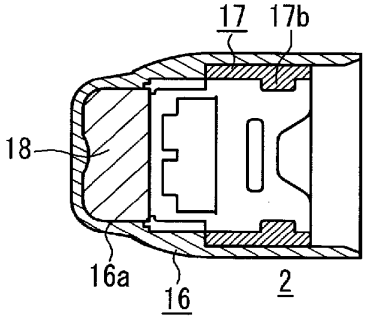
[図4A]



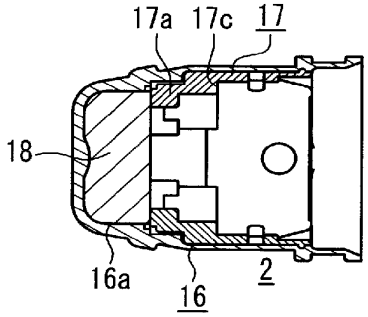
[図4B]



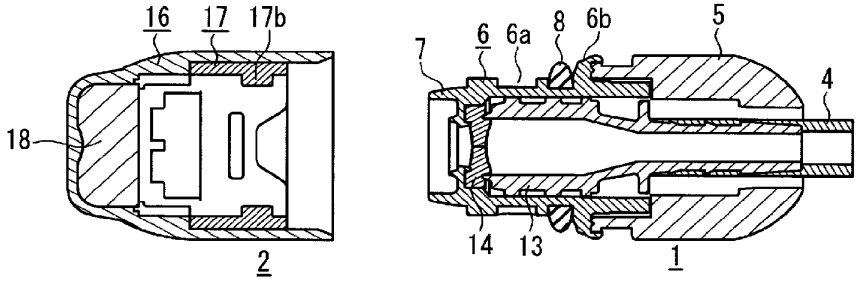
[図4C]



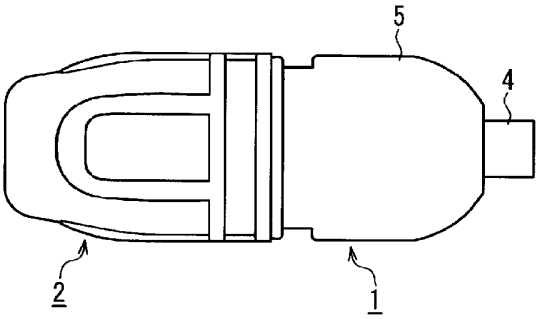
[図4D]



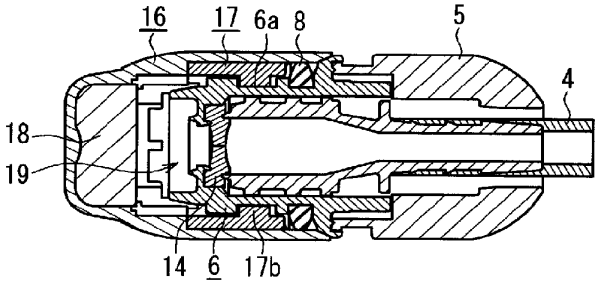
[図5A]



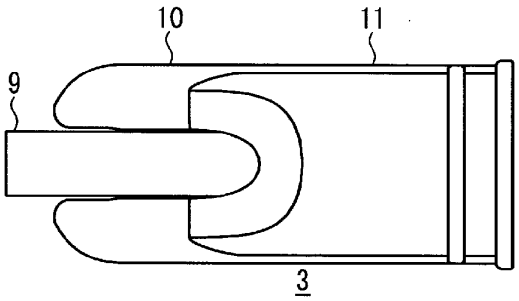
[図5B]



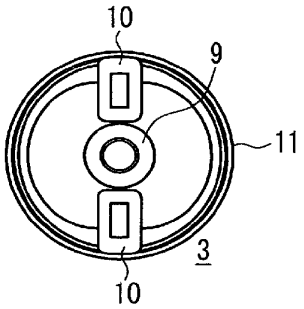
[図5C]



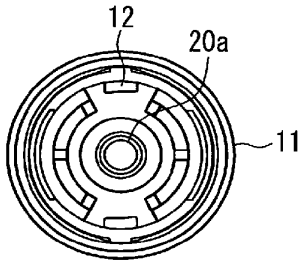
[図6A]



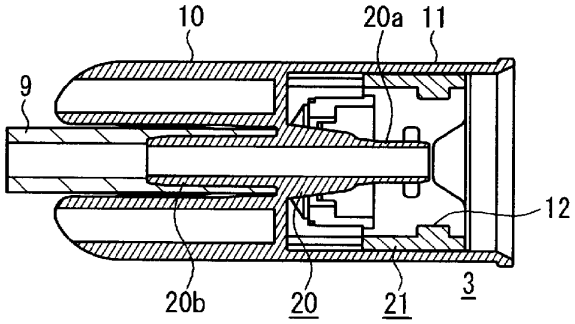
[図6B]



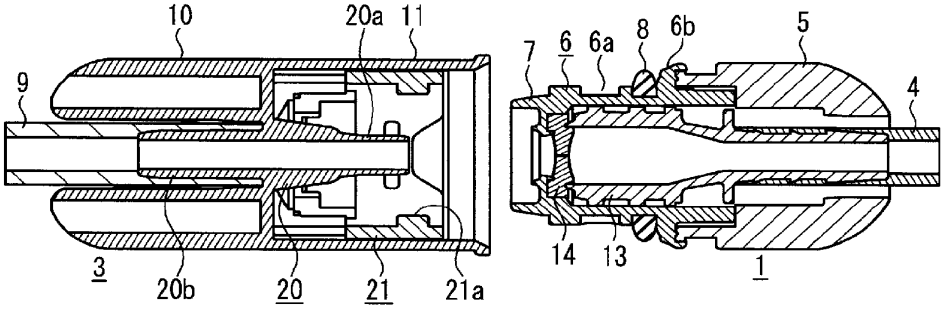
[図6C]



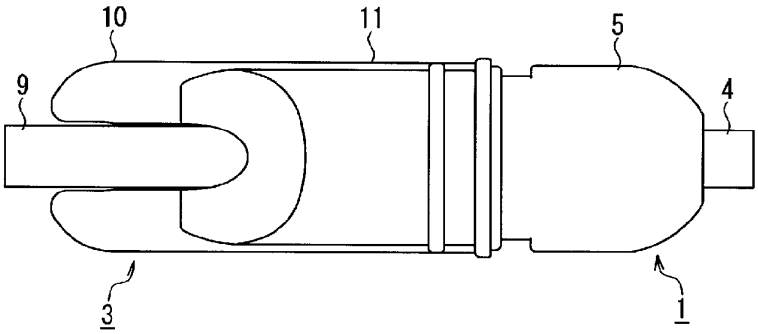
[図6D]



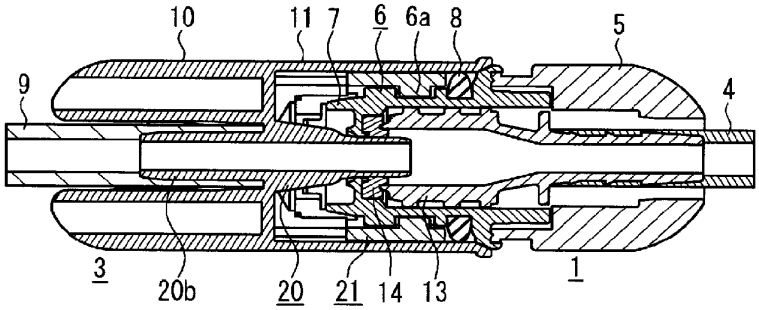
[図7A]



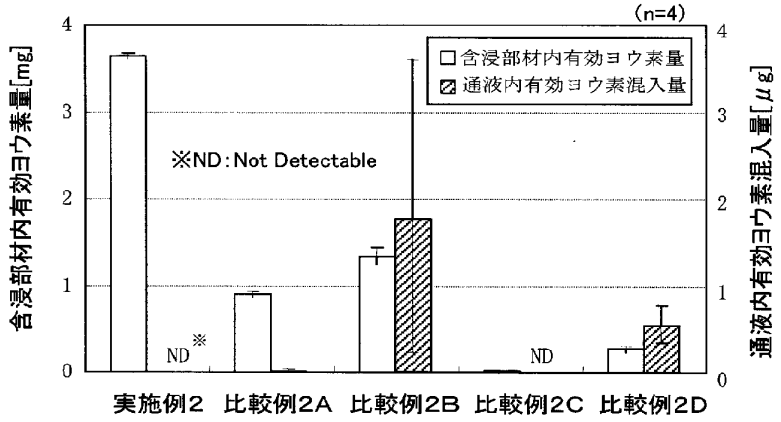
[図7B]



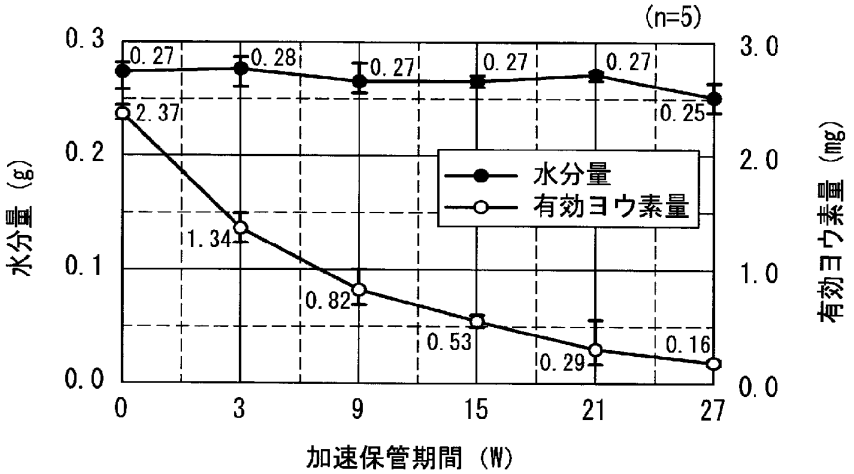
[図7C]


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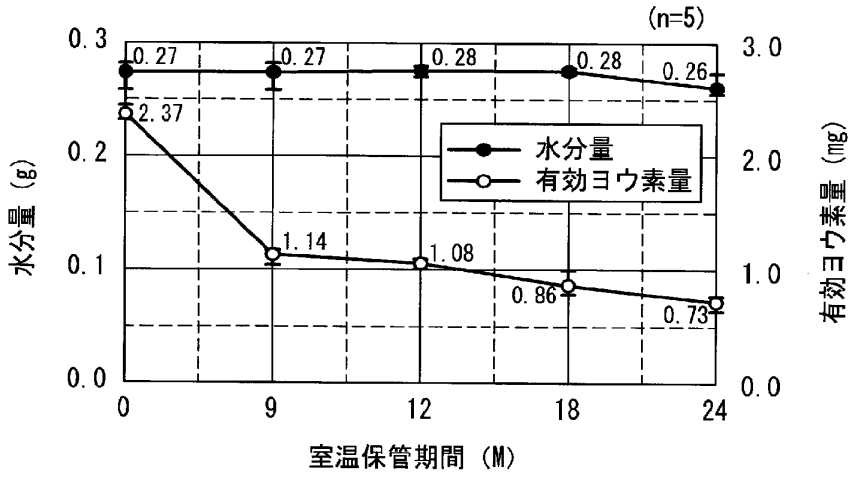
[図8]


(n=4)
含浸部材内有効ヨウ素量[mg]
通液内有効ヨウ素混入量[μg]
□含浸部材内有効ヨウ素量
▨通液内有効ヨウ素混入量
※ND:Not Detectable
ND※
ND
実施例2
比較例2A
比較例2B
比較例2C
比較例2D

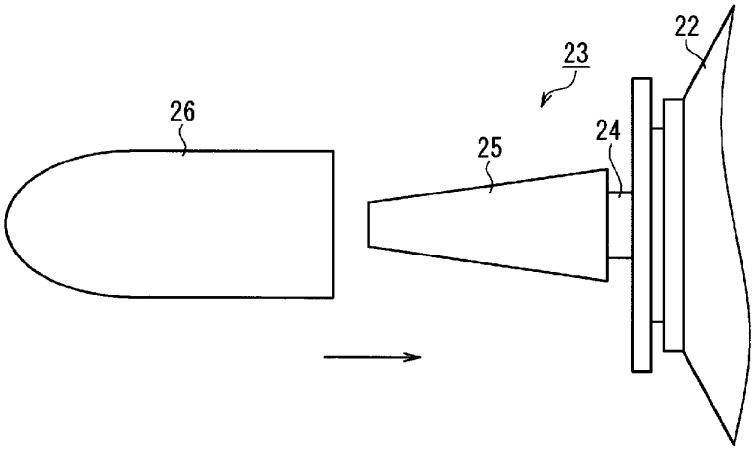
[図9A]


(n=5)
水分量(g)
有効ヨウ素量(mg)
水分量
有効ヨウ素量
0.27
0.28
0.27
0.27
0.27
0.25
2.37
1.34
0.82
0.53
0.29
0.16
加速保管期間(W)

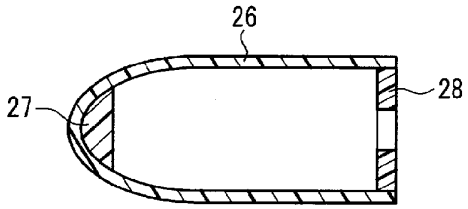
[図9B]



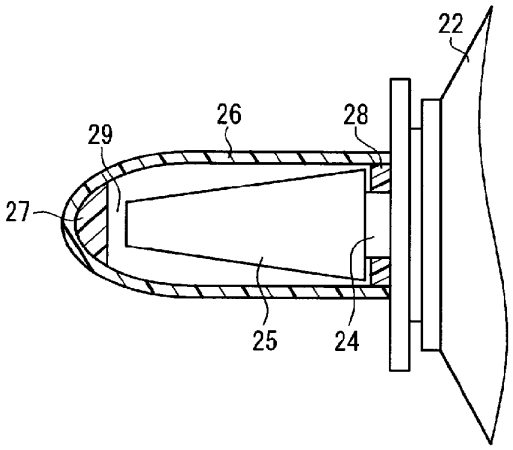
[図10A]



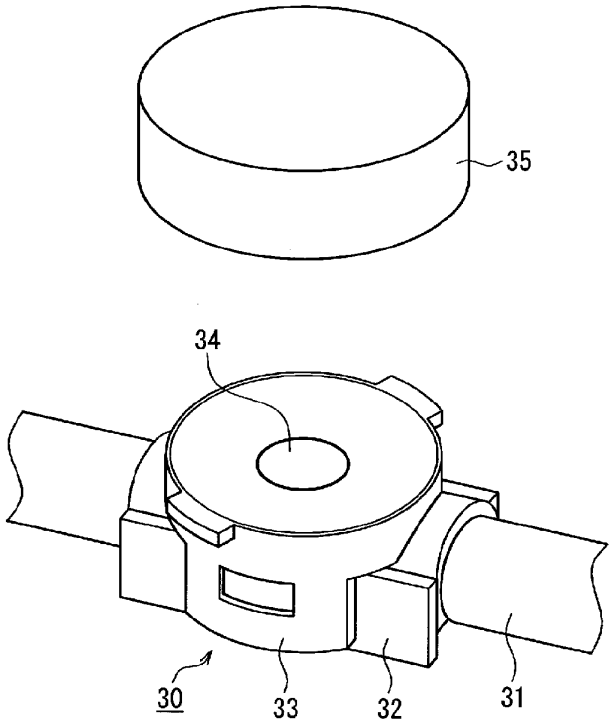
[図10B]



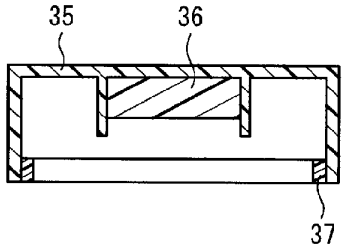
[図10C]



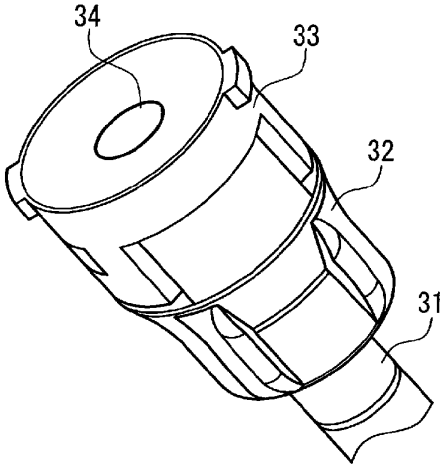
[図11A]



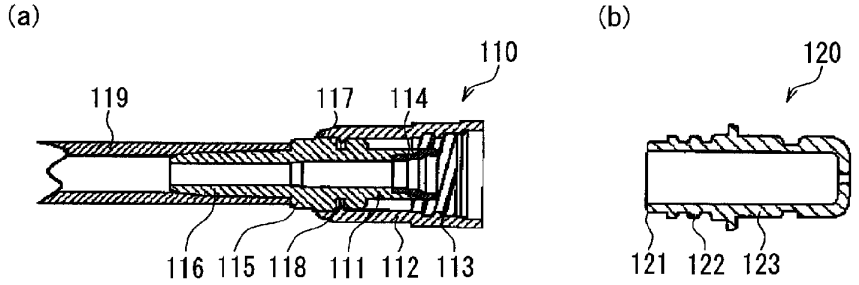
[図11B]


35
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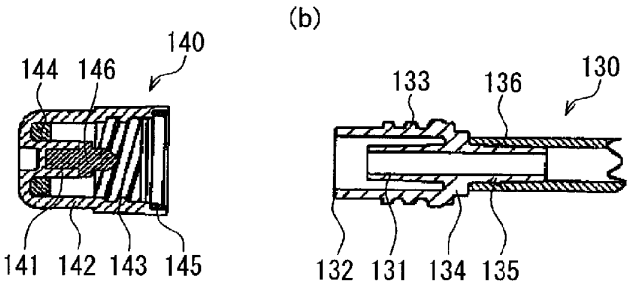
[図12]


34
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[図13]


(a)
(b)
110
119
117
114
116
115
118
111
112
113
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121
122
123

[図14]



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2010/059860

A. CLASSIFICATION OF SUBJECT MATTER
A61M1/14(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M1/14

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Jitsuyo Shinan Koho	1922-1996	Jitsuyo Shinan Toroku Koho	1996-2010
Kokai Jitsuyo Shinan Koho	1971-2010	Toroku Jitsuyo Shinan Koho	1994-2010

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/011798 A1 (JMS Co., Ltd.), 10 February 2005 (10.02.2005), page 8, lines 2 to 7; fig. 1C	1-14
X	page 8, line 20 to page 11, line 10; all drawings & US 2006/0189961 A1 & EP 1649890 A1 & CA 2534311 A & KR 10-2006-0034720 A & CN 1829551 A	2-12
A	JP 2001-309973 A (JMS Co., Ltd.), 06 November 2001 (06.11.2001), paragraph [0009] (Family: none)	1-14

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 July, 2010 (14.07.10)	27 July, 2010 (27.07.10)
Name and mailing address of the ISA/ Japanese Patent Office	Authorized officer
Facsimile No.	Telephone No.

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2010/059860

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 5-31178 A (Terumo Corp.), 09 February 1993 (09.02.1993), paragraph [0010] (Family: none)	1-14

Form PCT/ISA/210 (continuation of second sheet) (July 2009)

国際調査報告

国際出願番号　ＰＣＴ／ＪＰ２０１０／０５９８６０

Ａ．　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/14(2006.01)i

Ｂ．　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

Int.Cl.　A61M1/14

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報	１９２２－１９９６年
日本国公開実用新案公報	１９７１－２０１０年
日本国実用新案登録公報	１９９６－２０１０年
日本国登録実用新案公報	１９９４－２０１０年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

Ｃ．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求項の番号
X	WO 2005/011798 A1　（株式会社ジェイ・エム・エス）2005.02.10, 第８頁第2-7行,第1C図	1-14
X	第８頁第20行－第11頁第10行,全図 & US 2006/0189961 A1 & EP 1649890 A1 & CA 2534311 A & KR 10-2006-0034720 A & CN 1829551 A	2-12
A	JP 2001-309973 A　（株式会社ジェイ・エム・エス）2001.11.06, 段落【0009】（ファミリーなし）	1-14
A	JP 5-31178 A　（テルモ株式会社）1993.02.09,段落【0010】（ファミリーなし）	1-14

☐　Ｃ欄の続きにも文献が列挙されている。

☐　パテントファミリーに関する別紙を参照。

＊　引用文献のカテゴリー
「Ａ」特に関連のある文献ではなく、一般的技術水準を示すもの
「Ｅ」国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの
「Ｌ」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献（理由を付す）
「Ｏ」口頭による開示、使用、展示等に言及する文献
「Ｐ」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献
「Ｔ」国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの
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「＆」同一パテントファミリー文献

国際調査を完了した日 １４．０７．２０１０	国際調査報告の発送日 ２７．０７．２０１０
国際調査機関の名称及びあて先 日本国特許庁（ＩＳＡ／ＪＰ） 郵便番号１００－８９１５ 東京都千代田区霞が関三丁目４番３号	特許庁審査官（権限のある職員）　３Ｉ　８９１４ 高山　芳之 電話番号　０３－３５８１－１１０１　内線　３３４６

BAXTER EXHIBIT 1003
Page 106 of 484

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Published:

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(54) **Title**: SITE SCRUB BRUSH

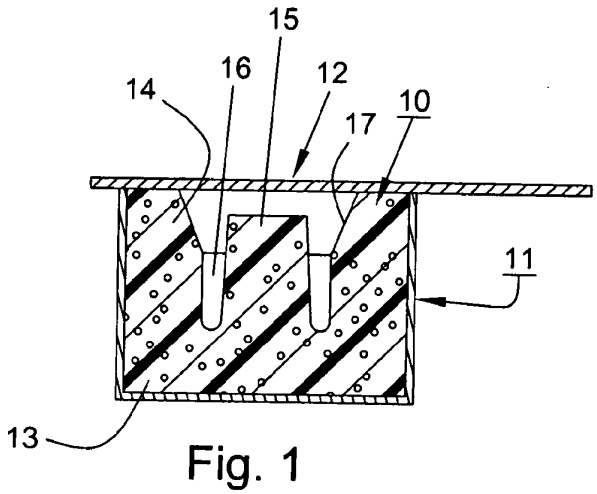


Fig. 1

(57) **Abstract**: The site scrub brush is made of a block of foam material, such as a semi-closed hydrophilic polyurethane medical grade foam, with a thin layer of sealing material, such as any plastic polymer which is non-permeable in nature, about the periphery and bottom. The brush is compressible under finger pressure to enhance the scrubbing action of the brush on the outer surfaces of a luer received by the brush.

WO 2010/039171 A1

Site Scrub Brush

This application claims the benefit of Provisional Patent Application 61/195,002, filed October 2, 2008.

This invention relates to an improvement of the microbial scrub brush described in pending US Patent Application 11/732,075 filed April 2, 2007.

As is known various products have been provided in an effort to sterilize the ports of various medical devices. For example, published US Patent Application 2008/0147047 describes a cap that has a threaded interior for threading onto a hub and that has one or more pillows saturated with disinfectant within the interior for engaging the hub. The cap is described as remaining on the hub.

Published US Patent Application 2007/0226660 describes a swab pouch that is to serve as a valve facial swab and a valve cover. As described, the swab pouch has a flattened configuration that can be dilated as by squeezing the pouch between thumb and forefinger. In one embodiment, the swab pouch includes an absorbent inner layer of elastic fabric or non-elastic comprised of absorbent cotton containing a disinfectant. The entire swab pouch may be elastic or the outer layer may be elastic. In one embodiment, the outer layer may be an elastic silicone sleeve, coating or molded component or may be molded with the fabric or molded into the fabric.

Published US Patent Application 2006/0030827 describes a luer cleaner that is described as being sized to receive a luer connector and that has bristles of polypropylene to engage and clean the outer surfaces of the luer connector.

It is an object of this invention to provide a site scrub brush that is relatively inexpensive to manufacture.

It is another object of the invention to provide a site scrub brush that can be manually compressed to enhance the scrubbing effect of the brush on the outer surfaces of a luer.

Briefly, the invention provides a site scrub brush that is formed of a foam material of block-like shape that can receive and retain a solution, such as a cleaning solution or disinfectant, and that is encased by a sealing material, but for one surface, to prevent loss of the solution. The unsealed surface may be covered by a removable cover, such as a foil of aluminum or other suitable material, such that upon removal of the cover, the foam material may be used to swab an instrumentality, such as a luer connector. The sealing material is characterized in being of a nature and/or thickness that is flexible and one that will allow the foam material to be compressed or deformed when squeezed when a connector is inserted into it.

The foam material may be open celled or semi-opened celled and may be molded or extruded or die cut from sheeting.

The sealing material may be polyurethane, polyester or any plastic polymer which is non-permeable in nature and which will act as a barrier preventing any solution from entering or leaving the foam material. The sealing material may be applied to the exposed surfaces of the foam material by being sprayed on or laminated onto the foam material or by dipping of the foam material into the sealing material in order to seal the perimeter and bottom surface of the foam material.

The solution can be a cleaning solution or disinfectant.

The foam material may be shaped and formed into sections, such as described in US Patent Applications 11/732,075 and 12/079,965 and used as described in each

Patent Application, the disclosure of each of which is incorporated herein.

These and other objects and advantages of the invention will become more apparent from the following detailed description taken in conjunction with the accompanying drawings wherein:

Fig. 1 illustrates a cross-sectional view of a site scrub brush in accordance with the invention;

Fig. 2 illustrates a cross-sectional view of a modified site scrub brush in accordance with the invention;

Fig. 3 illustrates a cross-sectional view of a modified site scrub brush in accordance with the invention having a conically tapered central section;

Fig. 4 illustrates a cross-sectional view of a modified site scrub brush in accordance with the invention having a conically tapered central portion defining an entrance between the annular portion and central portion;

Fig. 5 illustrates a cross-sectional view of a modified site scrub brush in accordance with the invention having an annular slit to define an annular portion and a central portion;

Fig. 6 illustrates a view similar to Fig. 5 with a slit extending throughout the length of an annular portion and a central portion; and

Fig. 7 illustrates a view similar to Fig. 6 with a cover in place.

Referring to Fig. 1, the site scrub brush is fabricated of a foam material 10 of block shape that is surrounded by a thin layer 11 of sealing material. In particular, the foam material is of cylindrical block-like shape and is made of a semi-open celled foam of medium density, such as a semi-closed hydrophilic polyurethane medical grade foam.

The foam material 10 is of a nature to receive a solution, such as a cleaning solution or antibacterial disinfectant solution, and may be used as described in US Patent Applications 11/732,075 and 12/079,965.

The sealing material 11 may be polyurethane, polyester or any plastic polymer which is non-permeable in nature and which will act as a barrier preventing any solution from entering or leaving the foam material.

The scrub brush is provided with a removable cover 12 that is secured over an open end of the foam material 10. The cover 12 may be a foil, such as an aluminum foil and is heat sealed to the exposed surface of the foam material 10. The cover (or foil lid) 12 would be peeled away prior to use and will prevent the solution in the foam material 10 from leaking out or drying out.

Alternatively, the cover 12 can be sealed to the thin barrier coating 11 of the sealing material.

In order to fabricate the scrub brush, the foam material 10 is molded or extruded or die cut from sheeting to form a cylindrical block shape. In particular, the foam material 10 is injection molded. Thereafter, the block of foam material 10 is dipped into a sealing material to form a thin layer 11 of the sealing material about the periphery and the bottom of the foam material 10 leaving the top surface exposed.

The thin layer 11 of sealing material is characterized in being of a nature and/or thickness that is flexible and one that will allow the foam material 10 to be compressed or deformed when squeezed when a connector is inserted into it. In particular, the layer 11 of sealing material is of a thickness to seal the peripheral surfaces and bottom of the block of foam material 10 while allowing the resultant scrub

brush to be compressed manually under the finger pressure of a user. For example, where the block of foam material has a diameter of 0.75 inches and a height of 0.87 inches, the thickness of the layer is from 0.050 inches to 0.080 inches.

Thereafter, the anti-bacterial disinfectant solution is placed in the foam material 10 and the cover 12 put into place to seal in the solution

The molded configuration of the foam material 10 is made to readily accept a medical type connector female luer. The shape configurations can be molded, burned or ground into the foam material 10. As shown, the foam material 10 has a base 13, an annular portion 14 extending upwardly, as viewed, from the base 13 and a central portion 15 extending upwardly from the base 13 in circumferentially spaced concentric relation to the annular portion 14 to define an annular gap 16. The annular portion 15 has a conical inwardly directed surface 17 that provides a narrowing entrance to the gap 16 and the central portion has a flat end 18.

Each of Figs. 2, 3, 4, 5 and 6, wherein like reference characters indicate like parts as above, displays different configurations in which the foam material 10 can be molded or extruded to form different shapes for various connectors.

Referring to Fig. 2, the central portion 15 of the scrub brush is made with a rounded end 19.

Referring to Fig. 3, the scrub brush has a gap 16' that extends the full depth of the central portion 14 without a conical entrance portion as in Fig. 1.

Referring to Fig. 4, the scrub brush has an annular slit 20 that separates the annular portion 14 from the central portion 15 so that the two portions are contiguous to each other. In addition, the central portion 15 is tapered at the end.

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As indicated in Fig. 5, the annular slit separating the annular portion of the foam material 10 from the central portion may extend half-way into the foam material or, as indicated in Figs. 6 and 7, the annular slit may extend completely through the foam material 10.

The construction of the scrub brush allows the scrub brush to be handled as a self contained individually sterile device. For example, since the surfaces of the foam material 10 are closed by the layer 11 of sealing material and the cover 12, the foam material can be maintained in a sterile condition until ready for use.

The outer barrier 11 and the foil lid 12 will keep the contents of the foam area sterile. The site scrub brush can be supplied in cases of 50 to 100 units. If the unit is dispensed in a sealed pouch with one or more units, the individual units remain sterile on their own merit.

In use, in order to clean a luer, the cover 12 is removed from the scrub brush and the luer inserted into the foam material 10. In this respect, the luer is inserted coaxially between the annular portion 14 and the central portion 15 such that the outer surfaces of the luer engage with the inner surfaces of the annular portion 14 and the inner surfaces of the luer engage with the outer surfaces of the central portion. Thereafter, the scrub brush is rotated about the luer to scrub the inside and outside surfaces of the luer via the foam material. During this time, debris from the luer is absorbed by the foam material. Due to the flexible nature of the layer 11 of sealing material and the compressibility of the foam material 10, the use may impose a compressive force on the scrub brush during rotation on the luer to enhance the scrubbing action of the annular portion of the foam material on the outside surfaces of

the luer.

The invention thus provides a site scrub brush that is relatively inexpensive to manufacture and one that can be manually compressed to enhance the scrubbing effect of the brush on the outer surfaces of a luer.

What is claimed is:

1. A site scrub brush comprising

a foam material of block-like shape for receiving and retaining a solution;

a sealing material encasing said foam material but for one surface thereof to prevent loss of the solution; and

a removable cover covering said one surface.

2. A site scrub brush as set forth in claim 1 wherein said cover is a foil of aluminum.

3. A site scrub brush as set forth in claim 1 wherein said sealing material is characterized in being flexible to a degree sufficient to allow said foam material to be deformed in response to insertion of a connector thereinto.

4. A site scrub brush as set forth in claim 3 wherein said sealing material is non-permeable.

5. A site scrub brush as set forth in claim 3 wherein said sealing material is made of a material selected from the group consisting of polyurethane and polyester.

6. A site scrub brush as set forth in claim 1 wherein said sealing material is a coating on said foam material.

7. A site scrub brush as set forth in claim 1 wherein said sealing material is laminated on said foam material.

8. A site scrub brush as set forth in claim 1 said foam material is of cylindrical shape about a longitudinal axis.

9. A site scrub brush as set forth in claim 1 wherein said foam material includes an

annular portion for enveloping an outer surface of a female luer and a central portion concentrically within said annular portion for insertion within a central passage of the female luer.

10. A site scrub brush as set forth in claim 9 wherein said central portion is circumferentially spaced from said annular portion.

11. A site scrub brush as set forth in claim 9 wherein said central portion is circumferentially contiguous to said annular portion.

12. A site scrub brush as set forth in claim 9 wherein said central portion has an outer conical surface.

13. A site scrub brush as set forth in claim 1 further comprising an anti-bacterial disinfectant solution impregnated in said foam material for disinfecting the outside surface and the interior of a female luer.

14. A site scrub brush as set forth in claim 1 wherein said foam material is a semi-closed hydrophilic polyurethane medical grade foam.

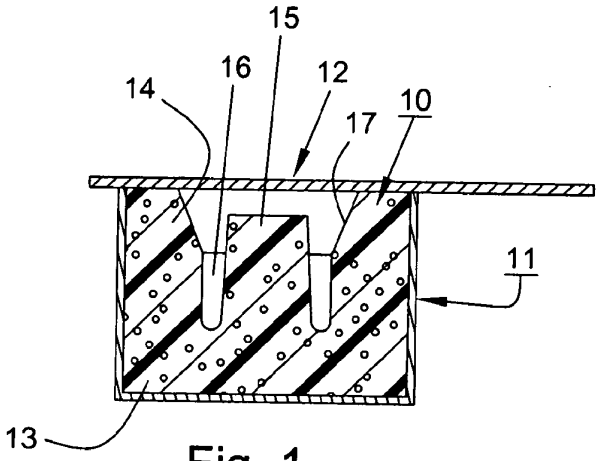


Fig. 1

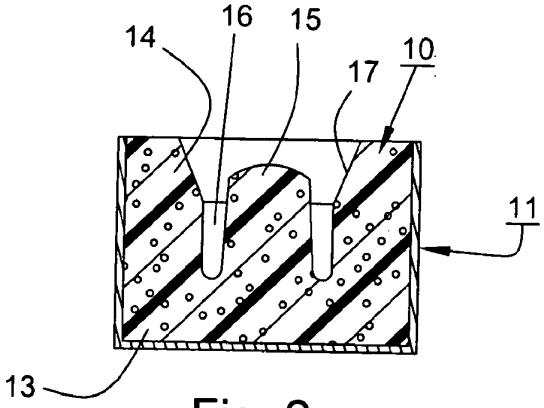


Fig. 2

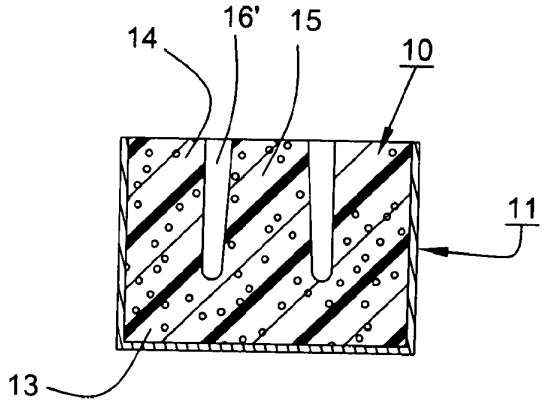


Fig. 3

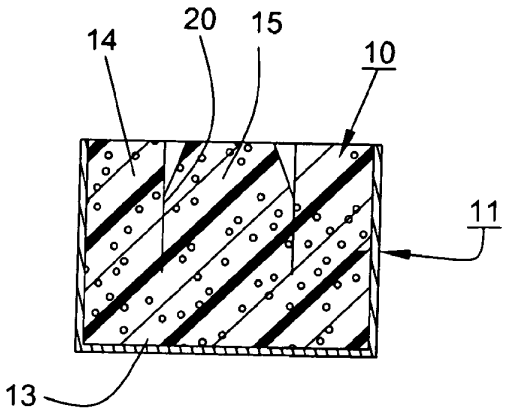


Fig. 4

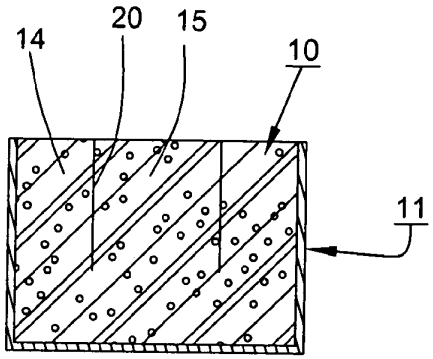


Fig. 5

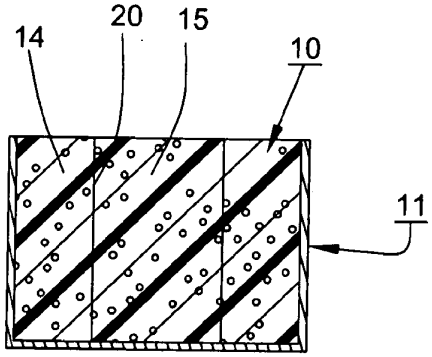


Fig. 6

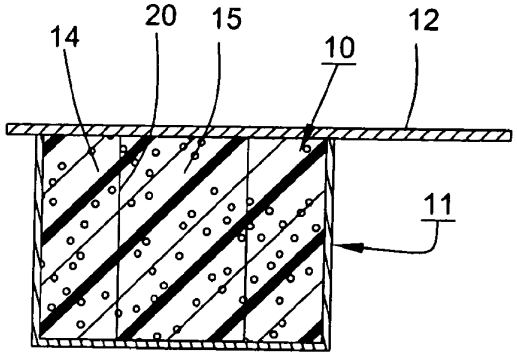


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 09/05120

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - B08B 9/04; A61M 39/10; A61M 39/16 (2009.01)
USPC - 15/104.16, 104.03, 104.05; 604/267
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC - 15/104.16, 104.03, 104.05; 604/267

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 15/104.16, 104.03, 104.05; 604/267; 134/8 (keyword limited, see terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(PGPB,USPT,EPAB,JPAB); Google.Search Terms Used: clean, swab, disinfectant, sterilize, aseptic, asepsis, luer, female, foam, semi-closed, hydrophilic, polyurethane, connector, connection, aluminum, cover, lip, top, cap, solution, liquid, polyurethane, PUR, polyester, non, not, permeable, cylindrical, tubular, cylinder, tube, swab, brush,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2008/0038167 A1 (Lynn) 14 February 2008 (14.02.2008) entire document, especially: Fig. 1, 2, 3, para. [0015], [0018], [0021], [0045]- [0048]	1, 3, 4, 6-8, 13 --- 2, 5, 9-12,14
Y	US 2,878,128 A (Jorgenson) 17 March 1959 (17.03.1959) Fig. 1, col. 1, ln 17-27, col. 2, ln 7-19	2
Y	US 2002/0062147 A1 (Yang) 23 May 2002 (23.05.2002) para. [0079], [0080]	5
Y	US 2006/0189961 A1 (Miyahara) 24 August 2006 (24.08.2006) Fig. 4B/C, para. [0045], [0050], [0051]	9-12
Y	US 3,961,629 A (Richter et al.) 08 June 1976 (08.06.1976) Abstract, col. 5, ln 30-49	14
Y	US 6,143,025 A (Stobie et al.) 07 November 2000 (07.11.2000) col. 8, ln 9-18	12
A	US 2007/0225660 A1 (Lynn) 27 September 2007 (27.09.2007) entire document	1-14

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 December 2009 (07.12.2009)	07 JAN 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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60/945,288 20 June 2007 (20.06.2007) US

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(54) Title: BIO-FILM RESISTANT SURFACES

(57) Abstract: The present invention relates to methods and compositions for rendering a surface resistant to bio-film formation by a combination of an alkanediol and an antimicrobial agent (and, optionally, an organic hydroxy acid). The invention provides for compositions which may be used to render surfaces bio-film resistant, articles having bio-film resistant surfaces, and methods for their preparation. The present invention may be advantageously applied to medical articles as well as articles used in non-medical contexts, such as child care or food preparation.

BIO-FILM RESISTANT SURFACES

PRIORITY CLAIM

This application claims priority to United States Provisional Application Serial No. 60/945,288 filed June 20, 2007, the contents of which are hereby incorporated in their entireties herein.

GRANT INFORMATION

Not applicable.

1. INTRODUCTION

The present invention relates to methods and compositions for rendering a surface resistant to bio-film formation by a combination of an alkanediol and an antimicrobial agent (and, optionally, an organic hydroxy acid).

2. BACKGROUND OF THE INVENTION

Whenever a medical article comes in contact with a patient, a risk of infection is created. Thus, a contaminated examination glove, tongue depressor, or stethoscope could transmit infection. The risk of infection dramatically increases for invasive medical articles, such as intravenous catheters, arterial grafts, endotracheal or intracerebral shunts and

prosthetic devices, which not only are, themselves, in intimate contact with body tissues and fluids, but also create a portal of entry for pathogens.

A number of methods for reducing the risk of infection have been developed which incorporate anti-infective compounds into medical articles. Ideally, such articles provide effective levels of an anti-infective compound during the entire period that the article is being used. This sustained release may be problematic to achieve, in that a mechanism for dispersing an anti-infective compound over a prolonged period of time may be required, and the incorporation of sufficient amounts of anti-infective compound may adversely affect the surface characteristics of the article. The difficulties encountered in providing effective anti-microbial protection increase with the development of drug-resistant pathogens.

Two well known anti-infective compounds are chlorhexidine and triclosan. The following patents and patent applications relate to the use of anti-microbial compounds in medical articles.

U.S. Pat. No. 4,723,950 by Lee relates to a microbicidal tube which may be incorporated into the outlet tube of a urine drainage bag. The microbicidal tube is manufactured from polymeric materials capable of absorbing and releasing antimicrobial substances in a controllable, sustained, time-release mechanism, activated upon contact with droplets of urine, thereby preventing the retrograde migration of infectious organisms into the drainage bag. The microbicidal tube may be produced by one of three processes: (1) a porous material, such as poly-propylene, is impregnated with at least one microbicidal compound, and then coated with a hydrophilic polymer which swells upon contact with urine, causing the leaching-out of the microbicidal compound; (2) a porous material, such as high density polyethylene, is impregnated with a hydrophilic polymer and at least one microbicidal compound; and (3) a polymer, such as silicone, is compounded and co-extruded with at least one microbicidal compound, and then coated with a hydrophilic polymer. A broad range of microbicidal compounds are disclosed, including chlorhexidine and triclosan, and combinations thereof. The purpose of Lee's device is to allow the leaching out of microbicidal compounds into urine contained in the drainage bag; similar leaching of microbicidal compounds into the bloodstream of a patient may be undesirable.

U.S. Pat. No. 5,091,442 by Milner relates to tubular articles, such as condoms and catheters, which are rendered antimicrobially effective by the incorporation of a non-ionic sparingly soluble antimicrobial compound, such as triclosan. The tubular articles are

made of materials which include natural rubber, polyvinyl chloride and polyurethane. Antimicrobial compound may be distributed throughout the article, or in a coating thereon. A condom prepared from natural rubber latex containing 1% by weight of triclosan, then dipped in an aqueous solution of chlorhexidine, is disclosed. U.S. Pat. Nos. 5,180,605 and 5,261,421, both by Milner, relate to similar technology applied to gloves.

U.S. Pat. Nos. 5,033,488 and 5,209,251, both by Curtis et al, relate to dental floss prepared from expanded polytetrafluoroethylene (PTFE) and coated with microcrystalline wax. Antimicrobial compounds such as chlorhexidine or triclosan may be incorporated into the coated floss.

U.S. Pat. No. 5,200,194 by Edgren et al. relates to an oral osmotic device comprising a thin semipermeable membrane wall surrounding a compartment housing a "beneficial agent" (that is at least somewhat soluble in saliva) and a fibrous support material composed of hydrophilic water-insoluble fibers. The patent lists a wide variety of "beneficial agents" which may be incorporated into the oral osmotic device, including chlorhexidine and triclosan.

International Patent Application No. PCT/GB92/01481, Publication No. WO 93/02717, relates to an adhesive product comprising residues of a co-polymerizable emulsifier comprising a medicament, which may be povidone iodine, triclosan, or chlorhexidine.

U.S. Pat. Nos. 5,019,096 and 5,616,338, both by Fox, Jr. et al. relate to infection-resistant medical articles comprising a synergistic combination of a silver compound (such as silver sulfadiazine) and chlorhexidine and their methods of manufacture, respectively. U.S. Pat. No. 5,334,588 by Fox, Jr. et al. relates to methods of inhibiting transmission of Hepatitis B virus using compositions comprising silver sulfadiazine and preferably further comprising a biguanide such as chlorhexidine and/or a detergent such as sodium deoxycholate.

U.S. Pat. Nos. 5,567,495, 5,772,640, 6,083,208 and 6,106,505 and U.S. patent publication Ser. Nos. 2001/0010016, 2001/0024661, 2002/0122876 and 2002/0173775, all by Modak et al., provide inter alia for anti-infective medical devices, either hydrophobic or hydrophilic, impregnated, coated, or impregnated and coated with various combinations of chlorhexidine, a silver salt such as silver sulfadiazine, silver oxide, silver carbonate or silver nitrate among others, a bismuth salt such as bismuth nitrate, bismuth citrate or bismuth

salicylate among others, a zinc salt, a cerium salt, triclosan, combinations of chlorhexidine free base and chlorhexidine acetate, benzalkonium chloride, citrate, povidone iodine, parachlorometaxylene, gramicidin, polymixin, norfloxacin, tobramycin, sulfamylon, polyhexamethylene biguanide, alexidine, iodine, rifampicin, miconazole, bacitracin, and minocycline.

United States Patent Application Publication No. US 20060099237 A1 relates to combinations of octoxyglycerin and anti-infective compounds that synergistically increase the anti-infective properties of medical articles impregnated and/or coated with various combinations of octoxyglycerin and anti-infective compounds relative to the anti-infective properties of medical articles impregnated and/or coated with the same anti-infective compounds without octoxyglycerin.

Salicylic acid, an organic β-hydroxy acid, traditionally used as an antithrombogenic agent, has been recently shown to affect bacterial infection and virulence. In endocarditis, *Staphylococcus aureus* causes endovascular infections, damaging endothelial cells of valvular tissue. Salicylic acid appears to mitigate the virulent effects, reducing growth and cellular density of *S. aureus*-induced infective endocarditis in an animal model (Kupferwasser et al., 1999 "Acetylsalicylic Acid Reduces Vegetation Bacterial Density, Hematogenous Bacterial Dissemination, and Frequency of Embolic Events in Experimental *Staphylococcus aureus* Endocarditis Through Antiplatelet and Antibacterial Effects," Circulation, 99:2791-2797; Kupferwasser et al., "Salicylic acid attenuates virulence in endovascular infections by targeting global regulatory pathways in *Staphylococcus aureus*," J Clin Invest. 2003; 112(2):222-33). In fact, salicylic acid modulates virulence by suppressing expression of adherence factors (Kupferwasser et al., "Salicylic acid attenuates virulence in endovascular infections by targeting global regulatory pathways in *Staphylococcus aureus*," J Clin Invest. 2003;112(2):222-33).

U.S. Pat. No. 6,582,719, International Patent Application No. PCT/US02/03087, and pending U.S. patent application Ser. No. 10/633,204, filed Jul. 30, 2003, all of which are incorporated by reference, disclose antimicrobial compositions comprising antiseptics, such as chlorhexidine, triclosan, and benzalkonium chloride, and antibiotics, such as minocycline, which may be particularly useful against antibiotic-resistant microorganisms. It has been discovered, however, that although certain of the chlorhexidine-containing solutions exhibited a broad spectrum of activity against many organisms, the

solutions became unstable, forming precipitates after a few days at room temperature. Having a short shelf life limits the application of these compositions in coating and impregnating medical devices.

Alkanediols are emollient solvents used in various applications, including in the cosmetics industry. Alkanediols are reported to have anti-fungal activity (Gershon, 2006, J. Pharm. Sci. 69(4):381-384).

3. SUMMARY OF THE INVENTION

The present invention relates to methods and compositions for rendering a surface resistant to bio-film formation by a combination of an alkanediol and an antimicrobial agent (and, optionally, an organic hydroxy acid). It is based, at least in part, on the discovery that a combination of octanediol, chlorhexidine, and lactic acid was observed to inhibit the adherence of certain bacteria and yeast to a catheter surface.

In one set of non-limiting embodiments, the present invention provides for compositions which may be used to render a surface resistant to bio-film formation. Such compositions may be solutions for impregnating or coating an article, or wipes comprising such solutions.

In another set of non-limiting embodiments, the present invention provides for methods of rendering a surface resistant to bio-film formation which utilize the aforementioned solutions or wipes.

In yet another set of non-limiting embodiments, the present invention provides for articles having a bio-film resistant surface created according to the invention.

The present invention may be used in the context of surfaces of medical articles or other surfaces which are desirably protected from microbe adherence, such as surfaces in an environment associated with child care, food preparation, etc..

4. DETAILED DESCRIPTION OF THE INVENTION

For clarity of description and not by way of limitation, the detailed description of the invention is divided into the following subsections:

(i) antimicrobial agents;

(ii) alkanediols;

(iii) hydroxy acids;

(iv) compositions for preparing a bio-film resistant surface;

(v) methods for producing a bio-film resistant surface; and

(vi) articles having a bio-film resistant surface.

"Bio-film resistant" as that term is used herein means that adherence of a microbe to the surface is inhibited.

4.1 ANTIMICROBIAL AGENTS

The present invention utilizes one or more biguanide, including, but not limited to, chlorhexidine, either as a free base, or a salt thereof, or a combination of free base and a chlorhexidine salt. Non-limiting examples include chlorhexidine diphosphanilate, chlorhexidine digluconate, chlorhexidine diacetate (also known as chlorhexidine acetate or CHA), chlorhexidine dihydrochloride, chlorhexidine dichloride, chlorhexidine dihydroiodide, chlorhexidine diperchlorate, chlorhexidine dinitrate, chlorhexidine sulfate, chlorhexidine sulfite, chlorhexidine thiosulfate, chlorhexidine di-acid phosphate, chlorhexidine difluoro-phosphate, chlorhexidine diformate, chlorhexidine dipropionate, chlorhexidine di-iodobutyrate, chlorhexidine di-n-valerate, chlorhexidine dicaproate, chlorhexidine malonate, chlorhexidine succinate, chlorhexidine malate, chlorhexidine tartrate, chlorhexidine dimonoglycolate, chlorhexidine monodiglycolate, chlorhexidine dilactate, chlorhexidine di-.alpha.-hydroxyisobutyrate, chlorhexidine diglucoheptonate, chlorhexidine di-isothionate, chlorhexidine dibenzoate, chlorhexidine dicinnamate, chlorhexidine dimandelate, chlorhexidine di-isophthalate, chlorhexidine di-2-hydroxynaphthoate, and chlorhexidine embonate and combinations thereof. Other examples of biguanides are polyhexamethylene biguanide and alexidine biguanide.

Other antimicrobial agents which may, in addition to a biguanide, be used according to the invention include, but are not limited to, triclosan, phenoxyethanol, a tetracycline compound such as minocycline, polymixin, octoxyglycerine, a chlorinated phenol such as parachlorometaxylenol and a quaternary ammonium compound such as benzalkonium chloride or benzethonium chloride. Combinations of such agents may also be used.

In preferred non-limiting embodiments, an antimicrobial agent to be used together with a biguanide is a silver compound. The term silver compound, as used herein, refers to a compound comprising silver, either in the form of a silver atom or a silver ion

unlinked or linked to another molecule via a covalent or noncovalent (e.g. ionic) linkage, including but not limited to covalent compounds such as silver sulfadiazine ("AgSD") and silver salts such as silver oxide ("Ag_2O"), silver carbonate ("Ag_2CO_3"), silver deoxycholate, silver salicylate, silver iodide, silver nitrate ("$AgNO_3$"), silver paraaminobenzoate, silver paraaminosalicylate, silver acetylsalicylate, silver ethylenediaminetetraacetic acid ("AgEDTA"), silver picrate, silver protein, silver citrate, silver lactate and silver laurate and combinations thereof.

4.2 ALKANEDIOLS

Examples of alkanediols which may be used, according to the invention, include alkanediols having between about five and twenty-five carbon atoms in the backbone, including but not limited to pentanediol, hexanediol, heptanediol, octanediol, nonanediol, decanediol, undecanediol, dodecanediol, cyclodecanediol, tridecanediol tetradecanediol, pentanedecanediol, hexadecanediol, heptadecanediol, octadecanediol, nonadecanediokl, eicosanediol, heneicosanediol, docosanediol, tricosanediol, and pentacosanediol, where the preferred alkanediols include 1,2 decanediol, 1,10 decanediol, 1,2 dodecanediol, 1,12 dodecanediol, cyclododecanediol, 1, 13 tridecanediol, 1,2 tetradecanediol, 1,14 tetradecanediol, and especially preferred are 1,2 decanediol, 1,2 dodecanediol, 1,12 dodecanediol, and 1,2 tetradecanediol.

4.3 HYDROXY ACIDS

Organic hydroxy acids which may be used according to the invention include α-hydroxy acids as well as β-hydroxy acids. Non-limiting examples of such hydroxyacids include α-hydroxy acids such as lactic acid, glycolic acid, and citric acid and β-hydroxy acids such as salicylic acid, betahydroxybutanoic acid, tropic acid, and trethocanic acid.

4.4 COMPOSITIONS FOR PREPARING A BIO-FILM RESISTANT SURFACE

The present invention provides for compositions that may be used to prepare a bio-film resistant surface.

In a particular set of non-limiting embodiments, the present invention provides for a composition for preparing a bio-film resistant surface comprising a biguanide, an alkanediol, and a solvent, where the biguanide is present at between about 0.1 and 5 percent

(weight/volume), or between about 2.5 and 4 percent (weight/volume), or between about 0.5 and 3 percent (weight/volume), and the alkanediol is present at between about 0.5 and 5 percent (volume/volume), and the solvent is selected from the group consisting of an alcohol (*e.g.* methanol, ethanol, isopropanol, and mixtures thereof) and tetrahydrofuran. In preferred non-limiting embodiments of the invention, the biguanide is chlorhexidine, such as chlorhexidine free base, chlorhexidine diacetate, chlorhexidine gluconate, or a mixture thereof, and the alkanediol is octanediol. Such compositions may further comprise one or more additional antimicrobial agent (in an amount between about 0.05 and 3 percent, preferably between about 0.2 and 1.5 percent (weight/volume), one or more hydroxy acid (in an amount between about 0.5 and 3 percent, preferably between about 0.2 and 2 percent (volume/volume), and/or one or more polymer (in an amount between about 1 and 3 percent or between about 1 and 20 percent or between about 1 and 10 percent, or between about 3 and 6 percent (weight/volume). In preferred non-limiting embodiments, the additional antimicrobial agent may be a silver compound, such as, but not limited to, silver sulfadiazine, the hydroxy acid may be lactic acid, and/or the polymer may be 93A polyurethane, 60D polyurethane, silastic medical adhesive type A, or a mixture thereof.

The term "about", as used throughout this document, means plus or minus 20 percent of the recited value.

The term "percent (weight/volume)" means the [weight of the referenced substance divided by the volume of the composition] multiplied by 100, or, in other words, the number of grams of the referenced substance in 100 milliliters of the composition.

As a specific non-limiting example, 100 ml of a composition comprising A percent biguanide (weight/volume), B percent alkanediol (volume/volume), C percent organic acid (volume/volume), D percent polymer (weight/volume) and E percent non-biguanide antimicrobial (weight/volume), in a solvent (which can be a mixed solvent), may be prepared by providing A grams of biguanide, D grams of polymer, E grams of non-biguanide antimicrobial, B mls of liquid form (*e.g.* melted) of alkanediol, and C mls of organic acid, adding each of these to solvent to form a solution and then solvent may be used to bring the total volume of the composition to 100 ml.

In non-limiting embodiments of the invention, a composition may be prepared by (i) dissolving biguanide, alkanediol, and optionally organic acid in an alcohol such as

ethanol or methanol; (ii) dissolving polymer in tetrahydrofuran or equivalent solvent; and then (iii) mixing the solutions prepared in (i) and (ii).

In specific, non-limiting examples, the present invention provides for the follwing impregnation solutions, which may be used, not by way of limitation, to impregnate catheters such as polyurethane catheters, and also provides for medical articles, such as catheters (e.g. polyurethane catheters) impregnated therewith:

2% CHX + 1.5% CHA + 0.75% AgSD + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 60.75% THF ("CHX-CHA-AgSD-L");

2% CHX + 1.5% CHA + 0.75% AgSD + 1% 1,2 Decanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF ("CHX-CHA- AgSD-L-D");

2% CHX + 1.5% CHA + 0.75% AgSD + 1% 1,12 Dodecanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU +30% Methanol + 59.75% THF ("CHX-CHA- AgSD-L-1,2 Dod");

2% CHX + 1.5% CHA + 0.75% AgSD + 1% 1,12 Dodecanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF ("CHX-CHA- AgSD-L-1,12 Dod");

2% CHX + 1.5% CHA + 0.75% AgSD + 1% 1,2 Tetradecanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF ("CHX-CHA- AgSD-L-1,14 TD");

2% CHX + 1.5% CHA + 0.75% AgSD + 1% 1,2 Octanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF ("CHX-CHA- AgSD-L-O");

3.5% CHX + 0.75% AgSD + 1% 1,2 Octanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF ("CHX- AgSD-L-O"); and

3.5% CHA + 0.75% AgSD + 1% 1,2 Octanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF ("CHA- AgSD- L-O").

In specific, non-limiting examples, the present invention provides for the following impregnation solutions, which may be used, not by way of limitation, for the impregnation of soft tissue patches (e.g., polytetrafluoroethylene ("PTFE") soft tissue patches ("STPs"), and also provides for medical articles, such as STPs (e.g. PTFE STPs) impregnated therewith:

0.1% Silver carbonate + 0.2% CHX + 0.15% CA + 1% O ("S-CHX-CHA-O");

0.1% Silver carbonate + 0.2% CHX + 0.15% CHA + 1% D ("S1-CHX-CHA-D"); and

0.05 % Silver carbonate + 0.2% CHX + 0.15% CHA +1% D (S2-CHX-CHA-D), where S = Silver carbonate, D = 1,2 Decanediol, and O = 1,2 Octanediol.

In specific, non-limiting embodiments, the present invention provides for the following impregnation solutions which may be applied to silicone articles, e.g., urinary catheters, for example but not limited to as part of a two-step method, and also provides for medical articles, such as catheters, e.g. urinary catheters, e.g. silicone urinary catheters, impregnated therewith:

CHX-O: 2% (w/v) CHX + 1% O + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF;

CHX-D: 2% (w/v) CHX + 1% D + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF;

CHX-1,2Dod: 2% (w/v) CHX + 1% 1,2 Dodecandiol + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF;

CHX-1,12Dod: 2% (w/v) CHX + 1% 1,12 Dodecanediol + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF; OR

CHX-TD: 2% (w/v) CHX + 1% TD + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF

In specific, non-limiting embodiments, the present invention provides for the following impregnation solutions which may be applied to wound coatings, and also provides for wound coverings impregnated therewith:

Antimicrobial composition 1

Ingredients	**(% w/w)**
CHA	0.15
CHX	0.15
AgSD	0.30
Lactic Acid	0.50
1,2 Decanediol	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10

Methanol	30.00
Tetrahydrofuran	67.90

Antimicrobial composition 2

Ingredients	**(% w/w)**
CHA	0.15
CHX	0.15
AgSD	0.30
Lactic Acid	0.50
1,12 Dodecanediol	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10
Methanol	30.00
Tetrahydrofuran	67.90

Antimicrobial composition 3

Ingredients	**(% w/w)**
CHA	0.15
CHX	0.15
Silver Carbonate	0.30
Lactic Acid	0.50
1,2 Decanediol	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10
Methanol	30.00
Tetrahydrofuran	67.90

Antimicrobial composition 4

Ingredients	**(% w/w)**
Polyhexamethylene biguanide	0.30
Silver Carbonate	0.30
1,2 Decanediol	0.50

Lactic Acid	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10
Methanol	30.00
Tetrahydrofuran	67.90

Antimicrobial composition 5

Ingredients	**(% w/w)**
CHA	0.15
CHX	0.15
1,2 Decanediol	0.50
Lactic Acid	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10
Methanol	30.00
Tetrahydrofuran	68.20

Antimicrobial composition 6

Ingredients	**(% w/w)**
Polyhexamethylene biguanide	0.30
1,2 Decanediol	0.50
Lactic Acid	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10
Methanol	30.00
Tetrahydrofuran	68.20

In a particular, non-limiting set of embodiments, a composition described in this section may be comprised in a wipe or a wound dressing.

4.5 METHODS FOR PRODUCING A BIO-FILM RESISTANT SURFACE

The present invention provides for methods of producing a bio-film resistant surface, comprising exposing the surface to a composition comprising a biguanide, an alkanediol, and a solvent, where the biguanide is present at between about 0.1 and 5 percent (weight/volume), or between about 2.5 and 4 percent (weight/volume) (where the article is to be "dipped" in the composition for a period of between about 5 seconds and 5 minutes or between about 5 seconds and 1 minute) or between about 0.5 and 3 percent (weight/volume), and the alkanediol is present at between about 0.5 and 5 percent (volume/volume) (Note that octanediol, for example, is a waxy solid but may be melted prior to adding to the solvent), and the solvent is selected from the group consisting of an alcohol (*e.g.* methanol, ethanol, isopropanol, and mixtures thereof), tetrahydrofuran and mixtures thereof. In preferred non-limiting embodiments of the invention, the biguanide is chlorhexidine, such as chlorhexidine free base, chlorhexidine diacetate, chlorhexidine gluconate, or a mixture thereof, and the alkanediol is octanediol. Such compositions may further comprise one or more additional antimicrobial agent (in an amount between about 0.05 and 3 percent, preferably between about 0.2 and 1.5 percent (weight/volume), one or more hydroxy acid (in an amount between about 0.5 and 3 percent, preferably between about 0.2 and 2 percent (volume/volume), and/or one or more polymer (in an amount between about 1 and 20 percent or between 1 and 30 percent or between about 1 and 10 percent, or between about 3 and 6 percent (weight/volume). In preferred non-limiting embodiments, the additional antimicrobial agent may be a silver compound, such as, but not limited to, silver sulfadiazine, the hydroxy acid may be lactic acid, and/or the polymer may be 93A polyurethane, 60D polyurethane, silastic medical adhesive type A, or a mixture thereof.

The surface may be exposed to the composition by immersing the surface in the composition or by applying the composition to the surface, for example by a spray, a stream, or a wipe.

In non-limiting embodiments of the invention, the composition may be exposed to the surface for a period of time such that the biguanide impregnates the surface.

In non-limiting embodiments of the invention, the composition may be exposed to the surface for a period of time such that the physical properties of the surface are

altered, for example, where there is swelling of the surface; such alteration should not be such that the surface is damaged with regard to its intended use.

For example, where the surface is a surface of a catheter fabricated from a polymer, the catheter may be immersed in the composition and/or the composition may be introduced into the interior of the catheter. In one non-limiting embodiment, the ends of the catheter are sealed to prevent entry of the composition into the lumen. In another non-limiting embodiment, the composition is introduced into the interior of the catheter. In another non-limiting embodiment, the catheter may be briefly dipped into the composition. In non-limiting embodiments, a catheter surface is exposed to the composition for a period of between about 5 seconds and 5 hours, or between about 1 minute and 2 hours, or between about 5 seconds and 5 minutes, or between about 5 seconds and 1 minute.

In one particular set of embodiments, the present invention provides for a two-step method for providing a bio-film resistant surface. In the first step, an additional antimicrobial agent as set forth above, (for example, but not limited to, triclosan or a silver compound such as silver sulfadiazine), may be applied as a first solution comprising the antimicrobial agent at a concentration between about 0.05 and 3 percent (weight/volume), said solution optionally further comprising a hydroxy acid at a concentration between about 0.5 and 3 percent (volume/volume), in a solvent selected from the group consisting of an alcohol (*e.g.* methanol, ethanol, isopropanol, and mixtures thereof), tetrahydrofuran and mixtures thereof (preferably methanol). Biguanide, alkanediol, polymer and optionally hydroxy acid are applied in the second step, comprised in a solution wherein biguanide is present at between about 0.1 and 5 percent (weight/volume), or between about 0.5 and 3 percent (weight/volume), alkanediol is present at between about 0.5 and 5 percent (volume/volume), polymer is present at a concentration between about 1 and 20 percent or between about 1 and 10 percent or between about 3 and 6 percent (weight/weight) and the solvent is selected from the group consisting of an alcohol (*e.g.* methanol, ethanol, isopropanol, and mixtures thereof), tetrahydrofuran and mixtures thereof; hydroxy acid, where present, is in an amount of between about 0.5 and 3 percent (volume/volume). In each step, soaking may be for time intervals between about 5 seconds and 5 hours, or between about 1 minute and 2 hours, or between about 5 seconds and 5 minutes, or between about 5 seconds and 1 minute.

In a specific, non-limiting embodiment of the two-step method, in the first step, a solution containing about 30 percent THF (volume/volume), about 65 percent methanol (volume/volume), about 3 percent triclosan (TC) (weight/volume), and about 2 percent lactic acid (L) (volume/volume), may be used, into which a polyurethane catheter may be dipped for a time period of at least about 30 seconds or at least about one minute, and then allowed to dry, for example (but not by way of limitation) 48 hours (or however long drying requires). For the second step, a solution may be prepared containing about 30 percent methanol (volume/volume), about 63 percent THF (volume/volume), about 2 percent octanediol (O) (volume/volume), about 1 percent lactic acid (L)(volume/volume), about 4 percent chlorhexidine free base (CHX)(weight/volume), about 4 percent 93A polyurethane (weight/volume), and about 1 percent 60D polyurethane (weight/volume). (The polyurethanes may be first dissolved in THF and the other components may be dissolved in methanol and then the two resulting solutions may be mixed). The catheter resulting from the first step may be dipped into this solution for at least about 5 seconds, and then allowed to dry.

In another specific, non-limiting embodiment of the two-step method, in step 1, a silicone article (*e.g.* a catheter) or portion thereof may be soaked for 1 hour in a solution comprising about 0.3 percent triclosan (weight/volume) and about 1.0 percent lactic acid (volume/volume) in about 30 percent methanol (volume/volume) / about 67 percent THF (volume/volume). The catheter may be removed, dried, rinsed in water and dried again. In step 2, the catheter resulting from step 1 may be dipped in a solution comprising about 2 percent chlorhexidine free base (weight/volume), about 10 percent Silastic Medical Adhesive Type A (weight/volume), about 2 percent octanediol (volume/volume) and about 88 percent THF (volume/volume) (where THF is used to bring the volume to 100 percent) and dried.

In yet further specific non-limiting examples of the invention, silicone catheters, for example urinary catheters, may be impregnated by a two-step method as follows. **Step 1:** Catheters may be soaked for 1 hour in 0.3% Triclosan (T) (w/v) + 1.0 % L (Lactic Acid) (v/v) in 30% Methanol (v/v) + 68.7% (v/v) THF. The catheters may be removed, dried for 1 hour, rinsed in water and dried for another hour. **Step 2:** Catheters may be dipped in the following solutions and dried for 24 hours and then used for testing:

CHX-O: 2% (w/v) CHX + 1% O + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF;

CHX-D: 2% (w/v) CHX + 1% D + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF;

CHX-1,2Dod: 2% (w/v) CHX + 1% 1,2 Dodecandiol + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF;

CHX-1,12Dod: 2% (w/v) CHX + 1% 1,12 Dodecanediol + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF; OR

CHX-TD: 2% (w/v) CHX + 1% TD + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF.

4.6 ARTICLES HAVING A BIO-FILM RESISTANT SURFACE

The present invention provides for an article having at least one surface which is rendered bio-film resistant using the compositions and methods set forth above.

In non-limiting embodiments, the present invention provides for an article having at least one surface comprising, as active agents, a biguanide (*e.g.* chlorhexidine free base or a chlorhexidine salt) at between about 250 and 5000 $\mu g/cm^2$ of surface or between about 500 and 1000 $\mu g/cm^2$ of surface and an alkanediol (*e.g.* octanediol) at between about 200 and 1500 $\mu g/cm^2$ of surface, and optionally a hydroxy acid (*e.g.* lactic acid) at between about 100 and 800 $\mu g/cm^2$ of surface, and/or optionally a silver compound (*e.g.* AgSD) at between about 0-200 $\mu g/cm^2$ of surface.

Medical articles that may be treated according to the invention are either fabricated from or coated or treated with biomedical polymer and include, but are not limited to, catheters including urinary catheters and vascular catheters (e.g. peripheral and central vascular arterial and venous catheters), wound drainage tubes, arterial grafts, soft tissue patches, gloves, shunts, stents, tracheal catheters, wound dressings, bandages, drapes, intrauterine devices, intravaginal devices, sutures, staples, guide wires and prosthetic devices (e.g. heart valves and LVADs). Vascular catheters that may be prepared according to the present invention include, but are not limited to, single and multiple lumen central venous catheters, peripherally inserted central venous catheters, emergency infusion catheters, percutaneous sheath introducer systems and thermodilution catheters, including the hubs and ports of such vascular catheters.

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In non-limiting embodiments, articles made of substrates such as polyurethane, silicone rubber, natural rubber latex, polyvinyl chloride, as well as cotton, silk (wound dressings) can be treated with a composition of the invention.

Below are a series of working examples. The compositions, methods and articles described in the below working examples are hereby incorporated into this detailed description.

5. EXAMPLE 1: EFFECT ON ZONE OF INHIBITION

Polyurethane (PU) 7 Fr. central venous catheters (CVC) were treated with octanediol ("O"), lactic acid ("L") and chlorhexidine ("C")- containing solutions, in the presence or absence of other active agent.

Preparation of coating solution. Two separate solutions were prepared, Solution A and Solution B, as follows:

Solution A: Chlorhexidine, octanediol, with or without lactic acid, in methanol; and

Solution B: 93A polyurethane and 60D polyurethane in THF,

and then the two solutions were mixed thoroughly prior to treatment. The amounts of active agents are set forth in Table 1, below, and the amount of polymer in the final solution, which was about 65 percent THF (volume/volume ("v/v")) and about 30 percent methanol (v/v) was 4 percent (weight/volume ("w/v")) 93A polyurethane and 1 percent (w/v) 60D polyurethane.

Impregnation of catheters. Catheters (6 cm in length, both ends sealed) were dipped in coating solutions prepared as above, containing active ingredients as indicated in Table 1. The catheters were dipped for 5 seconds in the solution and dried at room temperature for 24 hours and then used for testing.

TABLE 1

Group	Composition
1)	4% CHX
2)	4% CHX + 3% L
3)	4% CHX + 3% O
4)	4% CHX + 2% O + 1% L
5)	3% CHX + 1% TC
6)	3% CHX + 1% TC + 2% O + 1% L

7) 3% CHX + 1% AgSD

8) 3% CHX + 1% AgSD + 2% O + 1% L

NOTE: CHX = Chlorhexidine free base

Zone of Inhibition (ZOI)Test . Three 0.5cm segments of each group of catheters, prepared as described above, were embedded vertically in modified trypticase soy agar (TSA) media seeded on the surface with 0.3 ml of 10^8 colony forming units (CFU) per ml of bacteria or 10^5 cfu/ml of yeast and the plates were incubated at 37°C for 24 hours. The diameters of zones of inhibition of bacterial growth around the catheter segments were measured. The results are presented in Table 2.

TABLE 2

Group	Active Agents	Zone of Inhibition (mm) *P. aeruginosa*	*S. aureus*	*C. albicans*
1)	4% CHX	11.0	13.0	12.0
2)	4% CHX + 3% O	11.5	13.0	12.0
3)	4% CHX + 3%L	11.0	13.0	12.0
4)	4% CHX + 2%O+1%L	11.0	13.5	12.0
5)	3% CHX + 1% TC*	9.5	14.0	12.0
6)	3% CHX + 1% TC + 2% O + 1% L	11.0	15.0	12.0
7)	3% CHX + 1% AgSD	9.5	12.0	11.0
8)	3% CHX + 1% AgSD + 2% O + 1% L	11.5	13.5	13.0
9)	5% O + 3% L	0	8.0	0

* TC is triclosan.

Conclusion: The zone-inhibiting activity was not significantly different between the group containing O + L and the group without O + L.

6. EXAMPLE 2: EFFECT ON MICROORGANISM ADHERENCE

Bacterial adherence on Polyurethane (PU) 7 Fr.(white) central venous catheters (CVC) treated with O + L + C and other antiseptics, as set forth in the preceding section, was evaluated using an *in vitro* agar track model.

Agar tract model. The medium used was 0.5% agar (w/v) 20% bovine adult serum (BAS) (v/v) + 0.5% milk (v/v) + 0.03 % trypticase soy broth medium powder (TSB) (w/v) in phosphate buffered saline (PBS). First, agar and TSB was dissolved in PBS, and a magnetic stirring rod was included in the flask. The medium was sterilized by autoclaving at 121°C for 20 min. After autoclaving, it was allowed to cool down to 45 – 48° C in a water bath put on a magnetic stirrer. Then, BAS and milk were warmed to room temperature, and 5 ml of milk were mixed with 5 ml BAS in a sterile culture tube and added to the agar/TSB-containing flask with gentle stirring. Then the remaining amount of BAS was added to the flask. The medium was maintained at 45-48° C. 12.5 ml aliquots of medium were dispensed into different culture tubes and allowed to solidify at room temperature.

Evaluation of bacterial adherence. Catheter segments, 4 cm long and sealed at both ends, were inserted vertically into the center of the medium in each tube with 0.5 cm of the catheter protruding out of the medium. The caps of each tube were sealed with parafilm to prevent dessication. 5 catheter segments were used for each test. Untreated catheter segments were used as the control.

After 30 minutes, each catheter segment was lifted up (approximately 0.5 cm) and 25 µl of the culture (1-3x 10^8 cfu/ml of *P. aeruginosa* or 1-3x10^6 cfu/ml *C. albicans*) was added on the catheter just near the surface of the medium so that the inoculum was also spread on medium surface. The catheter was then placed back to its original position and incubated at 37°C for 7 days.

Then, the catheter segments were removed from the tubes and blotted on tissue. They were rinsed twice in 10 ml saline (6 segments/10 ml saline) and blotted dry. 0.5 cm was then cut off from both the ends of each catheter segment. Each catheter segment was then put in 4 ml LTSB (drug inactivating medium) in a culture tube and sonicated for 20 min. 0.5 ml aliquot from each tube was then plated out on TSA plates and incubated for 24-48 h. The results are shown in Table 3 (adherence of *P. aeruginosa*) and Table 4 (adherence of *C. albicans*).

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TABLE 3 *P. aeruginosa* adherence (infected 30 minutes after implantation)

Group	Active agents	Adherence of *P.aeruginosa*	
		CFU/cm	Log10 Reduction from control counts
Control	(uncoated)	1.1×10^4	----
1)	4% CHX	1.8×10^3	0.78
2)	4% CHX + 3% L	8.3×10^2	1.14
3)	4% CHX + 3% O	1.8×10^2	1.78
4)	4% CHX + 2% O + 1% L	92	2.08
5)	3% CHX + 1% TC	8.9×10^2	1.04
6)	3% CHX + 1% TC + 2% O + 1% L	1.1×10^2	2.0
7)	3% CHX + 1% AgSD	5.8×10^2	1.28
8)	3% CHX + 1% AgSD + 2% O + 1% L	4	3.44
9)	3% O + 3% L	9×10^3	0.1

TABLE 4

C. albicans adherence (infected 30 minutes after implantation)

Group	Active agents	Adherence of *C.albicans*	
		CFU/cm	Log10 Reduction from control counts
Control	(uncoated)	2.9×10^3	----
1)	4% CHX	1.0×10^3	0.5
2)	4% CHX + 3% L	1.1×10^3	0.46
3)	4% CHX + 3% O	1.9×10^2	1.2

4)	4% CHX + 2% O + 1% L	4	2.9
5)	3% CHX + 1% TC	90	1.5
6)	3% CHX + 1% TC + 2% O + 1% L	0	3.5
7)	3% CHX + 1% AgSD	44	1.9
8)	3% CHX + 1% AgSD + 2% O + 1% L	0	3.5

Conclusions. As regards *P. aeruginosa* adherence, catheters having surfaces treated with C + O and C + O + L showed lower adherence. Of all the groups C and AgSD with O and L had significantly lower adherence. This result indicates that biofilm formation and bacterial adherence on medical devices can be significantly reduced by treating the device with an antimicrobial solution containing C + O + L.

As regards *C. albicans* adherence, the group of catheters having surfaces treated with O and L showed significantly lower adherence.

7. EXAMPLE 3: TWO-STEP COATING METHOD

In the preceding sections, catheters were coated with CHX+T+O+L along with a polymer by a dip method. With dipping, the percent of CHX in the solution is preferably in the range of 2.5-4 % , for the catheter to be effective especially against *P.aeruginosa* (ZOI more than 10 mm) and *C.albicans* (ZOI more than 13 mm). For long term efficacy against *S.aureus*, a ZOI greater than 15mm is most preferred. The catheters coated by the one step dipping method show effective ZOI against *P. aeruginosa* and *C.albicans*. However the ZOI against *S.aureus* is about 15 mm when CHX+Triclosan is 3%+1% (w/v) in the coating solution. Increasing the Triclosan in the coating solution can increase the efficacy against *S.aureus*. However, Triclosan has essentially no activity against *P.aeruginosa*. Furthermore, coating catheters with solutions containing higher concentrations of Triclosan may lower the amount of CHX uptake by the catheter(since the ratio of CHX to Triclosan will be lower) which results in lower efficacy against *P.aeruginosa*.

In order to provide a catheter which is effective, for extended periods, against *P.aeruginosa*,*C.albicans* and *S.aureus*, a two step method was developed by which higher

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concentrations of both triclosan and chlorhexidine could be incorporated along with octanediol and lactic acid.

According to the two-step method, triclosan and lactic acid is applied to the surface in the first step, and chlorhexidine, octanediol, lactic acid and polymer is applied in the second step.

For the first step, a solution containing about 30 percent THF (v/v), about 65 percent methanol (v/v), about 3 percent triclosan (TC) (w/v), and about 2 percent lactic acid (L) (v/v), was prepared. For example, for each about 100 ml of solution to be prepared, 30 ml THF, 65 ml Methanol, 3 g Triclosan, and 2 ml Lactic acid are mixed. A portion of a polyurethane 7 fr. blue catheter, with the top end sealed to prevent entry of liquid into the catheter, was soaked in this solution for 1 minute and then allowed to dry for 48 hours.

For the second step, a solution was prepared containing about 30 percent methanol (v/v), about 63 percent THF (v/v), about 2 percent octanediol (O) (v/v), about 1 percent lactic acid (L)(v/v), about 4 percent chlorhexidine free base (CHX)(w/v), about 4 percent 93A polyurethane (w/v), and about 1 percent 60D polyurethane (w/v). This solution was first prepared by dissolving the chlorhexidine, lactic acid and octanediol in the methanol, dissolving the polyurethanes in the THF, and then mixing the solutions together. For example, for each about 100 ml of solution to be prepared, 2 ml octanediol, 1 ml lactic acid, and 4 mg chlorhexidine are dissolved in 30 ml methanol, and 4 g 93A polyurethane and 1 g 60D polyurethane are dissolved in 63 ml THF, and then the methanol and THF solutions are mixed. Then, the catheter from Step 1 was dipped into this solution for 5 seconds and dried at room temperature overnight.

Control (uncoated) catheters, catheters treated by a one-step method, or by the two-step method described above, were prepared, as follows:

1) Control (uncoated catheter)
2) Catheter by 2 steps (Step 1 3% T+2% L) and Step 2(4% CHX+1% L+ 2%O)
3) Catheter by 1 step (3% CHX+1.0%T +2% O+1% L)

The zones of inhibition for each of these catheters were then determined, using methods as set forth in Example 1, above. The results are presented in Table 5.

TABLE 5

Group	Zone of Inhibition (mm) *P. aeruginosa*	*S. aureus*	*C. albicans*
1 (control)	0	0	0
2 (2-step)	12.5	17.0	14.5
3 (1-step)	11.0	15.0	12.0

Conclusion : The two- step method produced a catheter which showed higher activity against all the organisms tested.

Bacterial adherence to the three catheters tested above was also determined, using methods described in Example 2. The results are shown in Table 6.

TABLE 6

Group	*P. aeruginosa* adherence (cfu/cm)
1 (control)	6.4×10^3
2 (2-step)	1.7×10^2
3 (1 step)	1.0×10^3

Conclusion Catheters prepared by the two-step method showed lower adherence of *P. aeruginosa*.

8. EXAMPLE 4. FURTHER BACTERIAL ADHERENCE STUDIES

Further studies evaluated bacterial adherence on polyurethane (PU) 4 Fr. peripherally inserted central venous catheters treated with O + L + C and other antiseptics using an *in vitro* agar tract model. Preparation of catheters, and the agar tract model, were as described in Examples 1 and 2 above, respectively. The results are shown in Table 7.

TABLE 7

P. aeruginosa adherence (infected 30 minutes after implantation)

Group	Adherence of P. aeruginosa

	(cfu/cm)
Control(uncoated catheters)	$1x10^3$
2.5% CHX + 1% TC	96
2.5% CHX + 1% TC + 2% L	92
2.5% CHX + 1% TC + 3% O	23
2.5% CHX + 1% TC + 2% O + 1%L	0

Conclusion : Catheters treated with C+O and C+O+L showed significantly lower adherence.

9. EXAMPLE 5: CATHETERS TREATED WITH TWO FORMS OF CHLORHEXIDINE

Studies were performed to evaluate adherence of *P. aeruginosa* on catheters treated with solutions containing chlorhexidine acetate (CHA) + chlorhexidine free base(CHX)

The method of coating and testing of adherence were the same as described in Examples 1 and 2 above, respectively. The results are shown in Table 8.

TABLE 8

P. aeruginosa adherence (infected 30 minutes after implantation)

Group	Adherence of *P. aeruginosa* (cfu/cm)
Control(uncoated catheters)	3.1×10^3
2% CHA+1.5% CHX	3.7×10^2
2% CHA+1.5% CHX+3% O	58
2% CHA+1.5%CHX +0.5% TC	1×10^2
2% CHA+1.5%CHX +0.5% TC+3% O	23

Conclusion: Catheters Coated with solutions containing CHA + CHX + O or with CHA + CHX + T C+ O showed significantly lower adherence.

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10. EXAMPLE 6: COMPARISON OF OCTOXYGLYCERINE AND OCTANEDIOL

Studies were performed to evaluate adherence of *P aeruginosa* on central venous catheters (CVC) impregnated with chlorhexidine, with or without either octoxyglycerine ("OCG") or octanediol. The catheters were prepared essentially as described in Example 1 and adherence was measured using the agar tract model as set forth in Example 2. Results, measured 7 days post-infection, are shown in Table 9.

TABLE 9

P. aeruginosa adherence (infected 30 minutes after implantation)

Group	(cfu/cm)
Control(uncoated catheters)	4.1×10^3
3% CHX	3.8×10^2
3% CHX+3% O	8
3% CHX+3% OCG	1×10^2

Conclusion The adherence was significantly lower in the Octanediol group 7days post infection. Without being bound by any particular theory, it is believed these results may be caused by octoxyglycerin, which is viscous fluid, remaining on the surface of the catheter as an oily coating which has diffused into the agar by the 7th day. In contrast, octanediol, which is a waxy powder, remains on the catheter surface and does not diffuse into the agar, so that bacteria which comes in contact with the surface of an octanediol coated catheter gets killed .

11. EXAMPLE 7: EVALUATION OF *S. AUREUS* ADHERENCE

Studies were performed to evaluate adherence of *S. aureus* to *p*olyurethane(PU) 4 Fr. central venous catheters (CVC) treated with C+ T+O+L (prepared as in Example 1), using an in vitro agar track model (as described below).

Catheter segments, 4 cm long and sealed at both ends, were inserted vertically into the center of medium in each tube with 0.5 cm of the catheter protruding out of the medium (as in Example 2). The caps of each tube were sealed with parafilm to prevent

dessication. 5 catheter segments were used for each test. Untreated catheter segments were used as the control.

After 21 days, the catheters were transferred to fresh agar tracts and after 30 minutes each catheter segment was lifted up (approximately 0.5 cm) and 25 ul of the culture (1-3x 10^8 cfu/ml of *S. aureus*) was added on the catheter just near the surface of the medium so that the inoculum was also spread on medium surface. The catheter was then placed back into its original position and incubated at 37°C for 7 days

The catheter segments were removed from the tubes and blotted on tissue. They were rinsed twice in 10 ml saline (6 segments/10 ml saline) and blotted dry. 0.5 cm was then cut off from both the ends of each catheter segment. Each catheter segment was then put in 4 ml LTSB (drug inactivating medium) in a culture tube and sonicated for 20 min. 0.5 ml aliquot from each tube was then plated out on TSA plates and incubated for 24-48 h. The results are shown in Table 10.

TABLE 10

S. aureus adherence (infected 21 day post implantation)

Group	Adherence of *S. aureus* (cfu/cm)
Control(uncoated catheters)	1.0×10^4
2.5% CHX+1% TC	2.8×10^2
2.5% CHX+1% TC +2%O+1%L	0

Conclusion: Group containing O + L showed no adherence even after infected 21 days post implantation.

12. EXAMPLE 8: TREATED SILICONE CATHETERS

Studies were performed to evaluate the antimicrobial efficacy of silicone urinary catheters impregnated with chlorhexidine, triclosan, octanediol and lactic acid.

One set of catheter portions was treated by a one-step method, as follows. Catheters were soaked in solutions comprising active agents dissolved in about 60 percent THF(v/v) + about 30 percent methanol (v/v) and the total volume was made up to 100% with THF. The catheters were soaked for 1 hour, dried at room temperature for 1 hour, rinsed in water and then dried for another hour and used for testing.

Another set of catheter portions was treated by a two-step method, as follows. In step 1, portions of silicone urinary catheters were soaked for 1 hour in 0.3% TC (w/v) + 1.0 % L (v/v) in 30% Methanol (v/v) + 67% (v/v) THF. The catheters were removed, dried for 1 hour, rinsed in water and dried for another hour. In step 2, catheters were dipped in 2% CHX (w/v) + 2% O (v/v) + 10% (w/v) Silastic Medical Adhesive Type A THF (THF used to bring the volume to 100%) and air dried at room temperature for 24 hours and then used for testing.

Bacterial adherence was evaluated using an *in vitro* urinary tract model, as follows. The model consists of two tubes one of which was an open cylindrical tube with one end capped and the other end sealed with a rubber cork with a hole in the center (Tube 1). The tube was crimped from both the sides at the center. The second tube was open at one end and was used for collection of urine (Tube 2). Both the tubes were sterilized with ethylene dioxide. Catheter segments of 6 cm in length, with both the ends sealed with silicone to prevent intraluminal contamination with bacteria, were sterilized and were inserted from top end of Tube 1 after lifting the cap aseptically and placed in the hole of the rubber cork at the end.

The sterile modified Trypticase Soya Agar was cooled to 40°C and then poured along the sides of the tube around the catheter leaving the upper 1cm of the catheter protruding out in the space above the agar tract, which represented the bladder. When the medium solidified in the tube, the cork at the bottom of the tube was removed gently without disturbing the agar column on the top thus exposing the lower end of the catheter. This lower end of the agar column with the catheter protruding represented the meatus and the agar surrounding the catheter simulated the urethra. This tube was then fixed on "Tube 2" to collect small amount of urine that flowed down the agar tract.

The "meatus" was inoculated daily with 20µl of 10^6 cfu/ml of *C. albicans* after dismantling the collection tube (Tube 2). The "bladder" was filled daily with fresh sterile urine. The "bladder" and the "meatus" were cultured daily on TSA to determine the presence of bacterial growth. On the day a positive "bladder" culture was found, the catheter segment was also processed for determination of bacterial colonization on the catheter surface. This was done by removing the catheter segment from the "bladder" end of the model, rinsing with saline and rolling it on a D/E agar plate followed by incubation for 24

hours at 37°C to semi-quantitatively determine the bacterial growth on the surface of the catheter.

The results are shown in Table 11.

TABLE 11

Duration of activity against C.albicans for 1-step vs 2-step Preparation Method (Days)

Active agents	1-step	2-step
Control	1	1
2% CHX + 0.3% TC	3	8
2% CHX + 0.3% TC + 1.% L+2%O	10	30

Conclusion: Silicone urinary catheters treated with C + TC + O + L showed longer activity. Catheters prepared by the two step method where the CHX was coated on the outer surface along with a silicone matrix showed superior activity. The two-step method was found to be better for releasing CHX from silicone rubber catheters. Incorporation of chlorhexidine on the outer coating of the silicone matrix appears to release an effective amount of chlorhexidine.

13. EXAMPLE 9: TREATMENT OF PTFE PATCHES

Studies were performed to evaluate the antimicrobial effect of surface treatment of polytetrafluoroethylene ("PTFE") soft tissue patches. In particular, such patches were impregnated with CHX + Silver Carbonate (AgC) and CHX + AgC + O + L.

1 cm^2 pieces were soaked in solutions comprising about 60 percent THF (v/v), about 20 percent Methanol (v/v) and about 20 percent ammonium hydroxide (v/v) as well as the active agents indicated below, then suctioned using a vacuum pump and left for 5 minutes. The pieces were removed, dried and rinsed in water. After 24 hours the patches were tested.

The following Adherence Testing Method was used. 4 pieces of PTFE tissue patch, each 1cm^2, were soaked in medium containing 50% TSB + 50% BAS (v/v) (1ml per 1 cm^2 of each piece) and placed on an orbital shaker at 37° C for 7 days. The pieces were removed, and transferred to a fresh media containing 10^5 cfu of *S. aureus*/ml (1ml/1cm^2) and

incubated for 24 hours at 37°C. The pieces were removed and rinsed twice in (2ml/1cm^2) saline) by vortexing at low speed, blotted dry and suspended in drug inactivating media (4.ml /1piece) and sonicated. 0.5 ml.aliqouts were plated. The results are shown in Table 12.

TABLE 12

Group	Adherence(Cfu/cm^2)
Control (untreated Patch)	>105
0.3% CHX +0.1% AgC	66
0.3%CHX + 0.1% AgC + 1% L+2%+O	5

Conclusion: The Group containing O + L showed lower adherence.

14. EXAMPLE 10: AGENTS AT CATHETER SURFACE

Pre-weighed 7 Fr catheters having an outer diameter measured to be 0.092" or 0.234 cm diameter were dipped in coating solution comprising 1) 4% CHX+2% Octanediol+1% Lactic acid, in about 30% methanol, about 63% THF and 2) 3.5% CHX+ 0.75% AgSD+ 2% Octanediol+1% Lactic acid in about 30% methanol, about 62.75% THF.

The catheters were dipped and immediately wrapped in pre-weighed aluminum foil to prevent any solvent evaporation and the weight of the coating solution on the catheter was determined.

The coating weights were found to be:

1) 0.022 grams total coating per cm^2

2)0.021 grams total coating per cm^2

Based on these weights and the percentages of active agents present, the following amounts of active agents were calculated to be present:

(1) LA = 1% => 220 micrograms/cm^2 Surface

CHX = 4% => 880 micrograms/cm^2 Surface

1,2-Octanediol = 2% => 440 micrograms/cm^2 Surface

(2) LA = 1% => 210 micrograms/cm^2 Surface

CHX = 3.5% => 735 micrograms/cm^2 Surface

1,2-Octanediol = 2% => 420 micrograms/cm^2 Surface

AgSD = 0.75% => 158 micrograms/cm^2 Surface

15. EXAMPLE 11: ZONES OF INHIBITION

Zones of inhibition associated with catheters treated with the active agents indicated in Table 13 were measured. The methods of preparing the catheters and for measuring zones of inhibition were essentially as set forth in Example 1 (for the particular combinations of active agents tested).

TABLE 13

	Zone of Inhibition (mm)		
Active Agents	*P. aeruginosa*	*S. aureus*	*C. albicans*
3.5% CHX + 2%O+1%L	11.0	12.5	11.5.
3.5% CHX + 2% O + 1% Salicylic acid	11.0	13.0	13.5.
3.5% CHX + 2% OCG+1%L	11.0	12.5	11.5
3.5% CHX + 1% O + 1% OCG +1% L	11.5	13.0	13.0

Conclusion: The activity of catheters with O+OCG was slightly higher than that with O or OCG alone against *C.albicans*.

16. EXAMPLE 12: BACTERIAL ADHERENCE TO IMPREGNATED CATHETERS

Polyurethane catheter segments were impregnated with the following solutions.

1) 2% CHX + 1.5% CHA + 0.75% AgSD + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 60.75% THF (CHX-CHA-AgSD-L)

2) 2% CHX + 1.5% CHA + 0.75% AgSD + 1% 1,2 Decanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF (CHX-CHA- AgSD-L-D)

3) 2% CHX + 1.5% CHA + 0.75% AgSD + 1% 1,12 Dodecanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU +30% Methanol + 59.75% THF (CHX-CHA- AgSD-L-1,2 Dod)

4) 2% CHX + 1.5% CHA + 0.75% AgSD + 1% 1,12 Dodecanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF (CHX-CHA- AgSD-L-1,12 Dod)

5) 2% CHX + 1.5% CHA + 0.75% AgSD + 1% 1,2 Tetradecanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF (CHX-CHA- AgSD-L-1,14 TD)

6) 2% CHX + 1.5% CHA + 0.75% AgSD + 1% 1,2 Octanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF (CHX-CHA- AgSD-L-O)

7) 3.5% CHX + 0.75% AgSD + 1% 1,2 Octanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF (CHX- AgSD-L-O)

8) 3.5% CHA + 0.75% AgSD + 1% 1,2 Octanediol + 1% Lactic acid + 3% 93A PU + 1% 60D PU + 30% Methanol + 59.75% THF (CHA- AgSD- L-O)

9) 3.5% CHA + 0.75% AgSD + 3% 93A PU + 1% 60D PU + 30% Methanol + 61.75% THF (CHA-AgSD)

To test bacterial adherence, the following experiments were performed.

Preparation of Agar tract model:

0.5% agar + 20 % bovine adult serum (BAS) + 0.5% milk + 0.03 % trypticase soy broth (TSB) in phosphate buffered saline (PBS). The necessary amounts of agar and TSB were weighed and suspended in PBS with a magnetic stirring bar in the flask. The medium was sterilized by autoclaving at 121° C for 20 min. After autoclaving, the medium was allowed to cool down to 45 – 48° C in a water bath put on a magnetic stirrer. BAS and milk

were warmed to room temperature. 5 ml of milk was mixed with 5 ml BAS in a sterile culture tube and added to the flask with gentle stirring. The remaining amount of BAS was added to the flask. The medium was maintained at 45-48° C. 2.5 ml aliquots of medium were dispensed in different culture tubes and allowed to solidify at room temperature.

Evaluation of bacterial adherence

Catheter segments, 4 cm long and sealed at both ends, were inserted vertically into the center of the medium in each tube with 0.5 cm of the catheter protruding out of the medium. The caps of each tube were sealed with Parafilm to prevent dessication. 5 catheter segments were used for each test. Untreated catheter segments were used as the control. After 30 minutes, each catheter segment was lifted up (approximately 0.5 cm) and 25 ul of the bacterial culture (1-3x 10^8 cfu/ml) was added on the catheter just near the surface of the medium so that the inoculum was also spread on medium surface. The catheter was then placed back to its original position and incubated at 37^0C for 7 days. The catheter segments were removed from the tubes and blotted on tissue. They were rinsed twice in 10 ml saline (6 segments/10 ml saline) and blotted dry. 0.5 cm was then cut off from both the ends of each catheter segment. Each catheter segment was then put in 4 ml LTSB (drug inactivating medium) in a culture tube and sonicated for 20 min. 0.5 ml aliquot from each tube was then plated out on TSA plates and incubated for 24-48 hours.

MRSA adherence On central venous catheter coated with various salts of Chlorhexidine along with silver salt and Octanediol was tested, using materials prepared as set forth above. To determine which Chlorhexidine salt would show better efficacy, catheters were coated with CHA, CHX, and a combination of CHA + CHX along with a silver salt and Octanediol and lactic acid was evaluated. Using MRSA as the test organism and adherence was evaluated 21 days post infection. The results are shown in TABLE 14.

TABLE 14: MRSA adherence (21 days after implantation and infection)

Group	**Adherence (Cfu/cm)**	**Log_{10} Reduction from Control Counts**
Control (uncoated catheters)	$3.8x10^4$	----
CHX- AgSD-L-O	77	2.7

CHX-CHA- AgSD-L-O	38	3.0
CHA-AgSD-L-O	$3.9x10^2$	2.0
CHA-AgSD-L	6.1x102	1.8

These data indicate that the groups containing CHX or CHX + CHA showed higher activity than the groups with CHA alone.

To evaluate bacterial adherence to central venous catheter (CVC) segments coated with various alkanediols along with CHX-CHA-AgSD-L, experiments were performed using the impregnation solutions set forth in TABLE 15, below, which also shows the results of these experiments..

TABLE 15: P. aeruginosa adherence (10 days after implantation and infection)

Group	Cfu/cm	Log_{10} Reduction from Control Counts Control
(uncoated catheters)	$1.0x10^4$	----
CHA-AgSD	$3.4x10^3$	0.52
CHX-CHA-AgSD-L-O	$1.5x10^2$	1.80
CHX-CHA-AgSD-L-D	20	3.20
CHX-CHA-AgSD-L-1,2 Dod	15	2.80
CHX-CHA-AgSD-L-1,12 Dod	18	2.70
CHX-CHA-AgSD-L-TD	32	2.50

These data indicate that each of the alkanediols tested enhanced the efficacy when used along with CHX-CHA-AgSD-L.

17. EXAMPLE 13: BACTERIAL ADHERENCE TO IMPREGNATE SOFT TISSUE PTFE PATCHES

The following impregnation solutions were prepared:

0.1% Silver carbonate + 0.3% CHA (S-CHA)

0.1% Silver carbonate + 0.2% CHX + 0.15% CHA (S-CHX-CHA)

0.1% Silver carbonate + 0.2% CHX + 0.15% CA (S-CHX-CHA)

0.1% Silver carbonate + 0.2% CHX + 0.15% CA + 1% O (S-CHX-CHA-O)
0.1% Silver carbonate + 0.2% CHX + 0.15% CHA + 1% D (S1-CHX-CHA-D)
0.05 % Silver carbonate + 0.2% CHX + 0.15% CHA +1% D (S2-CHX-CHA-D)
(all of them contain 1% Lactic acid)
(S = Silver carbonate, D = 1,2 Decanediol, O = 1,2 Octanediol)

1 cm^2 pieces of PTFE soft tissue patches ("STPs") were soaked in solutions comprising about 60 percent THF (v/v), about 20 percent Methanol (v/v) and about 20 percent ammonium hydroxide (v/v) as well as the active agents indicated above, then suctioned using a vacuum pump and left for 5 minutes. The pieces were removed, dried and rinsed in water. After 24 hours the patches were tested.

To evaluate bacterial adherence to the STPs, the following experiments were performed. Several 3 piece sets of PTFE tissue patch from each group and unimpregnated control, each 1 cm^2, were soaked in medium containing 50% TSB + 50% BAS (1ml per 1 cm^2 of each piece) and placed on an orbital shaker at 37° C. Adherence was tested after seven days as follows: one set from each group was removed, and transferred to a fresh media containing 10^5 cfu of organisms (1ml/1cm^2) and incubated for 24 hours at 37°C. The pieces were then removed and rinsed twice in saline at the rate of 2ml/cm^2 by vortexing at low speed, blotted dry and suspended in drug inactivating media (4.ml /1piece) and sonicated. 0.5 ml.aliquots were plated.Adherence after 14 days was tested as follows. patches were transferred to fresh media on the 7th day and continued orbital shaking for 14 days and then transferred to fresh media containing bacteria and processed as before. Adherence after 21 days was tested as follows: patches were transferred to fresh media on the 7th and 14th days with continuous shaking. On the 21st day, they were transferred to fresh media containing bacteria and processed as before.

The results obtained using different test organisms and after different periods of time are shown in TABLES 16-18, below.

TABLE 16: P. aeruginosa adherence (cfu/cm^2) on STPs 7 days after soaking in S.TSB

Group	Adherence (cfu/cm^2)
Control	$2.0x10^5$

S-CHA	$6.0x10^4$
S-CHX-CHA	$5.0x10^4$
S-CHX-CHA-O	630
S-CHX-CHA-D	43

TABLE 17: S. aureus adherence (cfu/cm^2) on STPs various days after soaking in S.TSB

	Chlorhexidine level	Bacterial Adherence (cfu/cm^2)		
Group	**(ug/cm^2)**	**7 day**	**14 day**	**21 day**
Control	----	$2.3x10^5$	$1.9x10^5$	$3.6x10^5$
S-CHA	86	0	$1.2x10^5$	$2.6x10^5$
S-CHX-CHA	94	0	$1.2x10^5$	N.D
S1-CHX-CHA-D	96	0	0	$6.3x10^1$
S2-CHX-CHA-D	94	0	73	$3.4x10^2$

ND = Not Determined

TABLE 18: P. aeruginosa adherence (cfu/cm^2) on STPs, various days after soaking in S.TSB

Group	**7 day**	**14 day**
Control	$2.0x10^5$	$1.5x10^6$
S-CA	$6.0x10^4$	$3.7x10^5$
S-CX-CA	$5.0x10^4$	3.0x105
S1-CX-CA-D	43	$3.0x10^4$
S2-CX-CA-D	101	$3.1x10^4$

18. EXAMPLE 14. BACTERIAL ADHERENCE TO SILICONE URINARY CATHETER SEGMENTS

Bacterial adherence to silicone urinary catheters impregnated using a two-step method with various alkanediols along with Chlorhexidine, Silver carbonate and Lactic Acid was evaluated.

Catheter segments were impregnated as follows.

Step 1: Catheters were soaked for 1 hour in 0.3% Triclosan (T) (w/v) + 1.0 % L (Lactic Acid) (v/v) in 30% Methanol (v/v) + 68.7% (v/v) THF. The catheters were removed, dried for 1 hour, rinsed in water and dried for another hour.

Step 2: Catheters were dipped in the following solutions and dried for 24 hours and then used for testing.

CHX: 2% (w/v) CHX + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 82% (v/v) THF

CHX-O: 2% (w/v) CHX + 1% O + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF

CHX-D: 2% (w/v) CHX + 1% D + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF

CHX-1,2Dod: 2% (w/v) CHX + 1% 1,2 Dodecandiol + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF

CHX-1,12Dod: 2% (w/v) CHX + 1% 1,12 Dodecanediol + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF

CHX-TD: 2% (w/v) CHX + 1% TD + 15% (w/v) Silastic Medical Adhesive Type A + 1% glycerin + 81% (v/v) THF

Duration of resistance of adherence of bacteria on the catheters was tested in the in vitro urinary tract model described above in Section 12. The results are shown in TABLE 19.

TABLE 19: Duration of activity against S. aureus

Group *	**(Days)**
Control	1
T-CHX-L	8
T-CHX-L-O	30
T-CHX-L-D	> 50
T-CHX-L-1,2 Dod	> 50
T-CHX-L-1,12 Dod	> 50
T-CHX-L-TD	> 50

* The letters for each catheter group denote the anti-infectives in the catheter

These data indicate that silicone urinary catheters containing alkanediols along with T + CHX + L showed longer activity than T + CHX + L.

19. EXAMPLE 15: BACTERIAL ADHERENCE TO IMPREGNATED WOUND DRESSINGS

Wound dressings were impregnated with the following solutions:

Antimicrobial composition 1

Ingredients	(% w/w)
CHA	0.15
CHX	0.15
AgSD	0.30
Lactic Acid	0.50
1,2 Decanediol	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10
Methanol	30.00
Tetrahydrofuran	67.90

Antimicrobial composition 2

Ingredients	(% w/w)
CHA	0.15
CHX	0.15
AgSD	0.30
Lactic Acid	0.50
1,12 Dodecanediol	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10
Methanol	30.00

Tetrahydrofuran	67.90

Antimicrobial composition 3

Ingredients	(% w/w)
CHA	0.15
CHX	0.15
Silver Carbonate	0.30
Lactic Acid	0.50
1,2 Decanediol	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10
Methanol	30.00
Tetrahydrofuran	67.90

Antimicrobial composition 4

Ingredients	(% w/w)
Polyhexamethylene biguanide	0.30
Silver Carbonate	0.30
1,2 Decanediol	0.50
Lactic Acid	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10
Methanol	30.00
Tetrahydrofuran	67.90

Antimicrobial composition 5

Ingredients	(% w/w)
CHA	0.15
CHX	0.15
1,2 Decanediol	0.50
Lactic Acid	0.50
Polyurethane 93A	0.40

Polyurethane 60D	0.10
Methanol	30.00
Tetrahydrofuran	68.20

Antimicrobial composition 6

Ingredients	**(% w/w)**
Polyhexamethylene biguanide	0.30
1,2 Decanediol	0.50
Lactic Acid	0.50
Polyurethane 93A	0.40
Polyurethane 60D	0.10
Methanol	30.00
Tetrahydrofuran	68.20

Wound dressings (Dukal Non-Adherent Pad) were dipped into the antimicrobial impregnation solution and dried for 24 hours. The dressings were cut into1cm^2 pieces and the Zones of Inhibition against various bacteria were determined. For the Zones of Inhibition Test, 1 cm^2 piece of each dressing was placed on a Trypticase Soy Agar plate seeded on the surface with 0.3mL of 10^8 colony forming units (CFU)/mL) of the test organism. The plates were incubated at 37^0C for 24hours. The Zone of Inhibition around the dressing was measured. The results are shown in TABLE 20, below.

TABLE 20: Zone of Inhibition (mm) testing of Dressings treated with Antimicrobial Composition (AC) 1, 2, 5 and 6

	AC 1		AC 2		AC 5		AC 6	
Organism	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**
S. aureus	15.0	15.0	15.0	15.0	14.5	11.0	13.5	6.5
MRSA	15.5	14.0	15.0	12.5	14.5	10.5	13.0	6.5
P aeruginosa	14.0	14.0	15.0	15.0	13.0	5.5	8.5	5.5
C. albicans	16.0	13.0	16.0	13.0	15.5	9.0	12.0	7.0

These data indicate that dressings impregnated with antibacterial agents and alkanediols exhibit broad spectrum antimicrobial activity.

Various publications are cited herein, the contents of which are incorporated by reference in their entireties.

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WHAT IS CLAIMED:

1. A composition for preparing a bio-film resistant surface comprising a biguanide, an alkanediol, and a solvent, where the biguanide is present at between about 0.1 and 5 percent (weight/volume), the alkanediol is present at between about 0.5 and 5 percent (volume/volume), and the solvent is selected from the group consisting of an alcohol, tetrahydrofuran, and mixtures thereof.

2. The composition of claim 1, wherein the biguanide is selected from the group consisting of chlorhexidine free base, chlorhexidine diacetate, chlorhexidine gluconate, polyhexamethylene biguanide, and a mixture thereof.

3. The composition of claim 1, wherein the alkanediol is octanediol.

4. The composition of claim 1, further comprising an additional antimicrobial agent in an amount between about 0.05 and 3 percent (weight/volume).

5. The composition of claim 4, wherein the additional antimicrobial agent is a silver compound.

6. The composition of claim 5, wherein the silver compound is silver sulfadiazine.

7. The composition of claim 1 or 4, further comprising one or more hydroxy acid in an amount between about 0.5 and 3 percent (volume/volume).

8. The composition of claim 7, wherein the hydroxy acid is selected from the group consisting of lactic acid, citric acid, and salicylic acid.

9. The composition of claim 1, comprised in a wipe.

10. The composition of claim 2, comprised in a wipe.

11. The composition of claim 3, comprised in a wipe.

12. The composition of claim 4, comprised in a wipe.

13. The composition of claim 5, comprised in a wipe.

14. The composition of claim 6, comprised in a wipe.

15. The composition of claim 7, comprised in a wipe.

16. The composition of claim 8, comprised in a wipe.

17. The composition of claim 1, comprised in a wound dressing.

18. The composition of claim 2, comprised in a wound dressing.

19. The composition of claim 3, comprised in a wound dressing.

20. The composition of claim 4, comprised in a wound dressing.

21. The composition of claim 5, comprised in a wound dressing.

22. The composition of claim 6, comprised in a wound dressing.

23. The composition of claim 7, comprised in a wound dressing.

24. The composition of claim 8, comprised in a wound dressing.

25. A method of producing a bio-film resistant surface, comprising exposing the surface to a composition for preparing a bio-film resistant surface comprising a biguanide, an alkanediol, and a solvent, where the biguanide is present at between about 0.1 and 5 percent (weight/volume), the alkanediol is present at between about 0.5 and 5 percent (volume/volume), and the solvent is selected from the group consisting of an alcohol, tetrahydrofuran, and mixtures thereof.

26. The method of claim 25, wherein the biguanide is selected from the group consisting of chlorhexidine free base, chlorhexidine diacetate, chlorhexidine gluconate, polyhexamethylene biguanide, and a mixture thereof.

27. The method of claim 25 wherein the alkanediol is octanediol.

28. The method of claim 25, further comprising an additional antimicrobial agent in an amount between about 0.05 and 3 percent (weight/volume).

29. The method of claim 28, wherein the additional antimicrobial agent is a silver compound.

30. The method of claim 29, wherein the silver compound is silver sulfadiazine.

31. The method of claim 25 or 28, further comprising one or more hydroxy acid in an amount between about 0.5 and 3 percent (volume/volume).

32. The method of claim 31, wherein the hydroxy acid is selected from the group consisting of lactic acid, citric acid, and salicylic acid.

33. An article having a surface rendered bio-film resistant by the method of claim 25.

34. An article having a surface rendered bio-film resistant by the method of claim 26.

35. An article having a surface rendered bio-film resistant by the method of claim 27.

36. An article having a surface rendered bio-film resistant by the method of claim 28.

37. An article having a surface rendered bio-film resistant by the method of claim 29.

38. An article having a surface rendered bio-film resistant by the method of claim 30.

39. An article having a surface rendered bio-film resistant by the method of claim 31.

40. An article having a surface rendered bio-film resistant by the method of claim 32.

41. A method of rendering a surface of an article resistant to bio-film formation, comprising:

(i) applying a first solution to the surface, said first solution comprising an antimicrobial agent, other than a biguanide, at a concentration of between about 0.05 and 3 percent (w/v), and optionally further comprising a hydroxy acid at a concentration between about 0.5 and 3 percent (v/v), in a solvent selected from the group consisting of an alcohol (*e.g.* methanol, ethanol, isopropanol, and mixtures thereof), tetrahydrofuran and mixtures thereof;

(ii) allowing the first solution to dry;

(iii) applying a second solution to the surface, said second solution comprising a biguanide at a concentration between about 0.1 and 5 percent (weight/volume), alkanediol at a concentration between about 0.5 and 5 percent (volume/volume), polymer at a concentration between about 1 and 20 percent (weight) volume, a solvent selected from the group consisting of an alcohol (*e.g.* methanol, ethanol, isopropanol, and mixtures thereof), tetrahydrofuran and mixtures thereof; and optionally hydroxy acid in an amount of between about 0.5 and 3 percent (volume/volume).

42. An article having at least one surface comprising, as active agents, a biguanide at between about 250 and 5000 $\mu g/cm^2$ of surface and an alkanediol at between about 200 and 1500 $\mu g/cm^2$ of surface, and optionally a hydroxy acid at between about 100 and 800 $\mu g/cm^2$ of surface, and/or optionally a silver compound at between about 0-200 $\mu g/cm^2$ of surface.

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received by the International Bureau on 26 September 2008 (26.09.2008)

1. A composition for preparing a bio-film resistant surface comprising a biguanide, an alkanediol, and a solvent, where the biguanide is present at between about 0.1 and 5 percent (weight/volume), the alkanediol is present at between about 0.5 and 5 percent (volume/volume), and the solvent is selected from the group consisting of an alcohol, tetrahydrofuran, and mixtures thereof.

2. The composition of claim 1, wherein the biguanide is selected from the group consisting of chlorhexidine free base, chlorhexidine diacetate, chlorhexidine gluconate, polyhexamethylene biguanide, and a mixture thereof.

3. The composition of claim 1, wherein the alkanediol is selected from the group consisting of octanediol, 1,2-decanediol, 1,2-dodecanediol, 1,12-dodecanediol and 1,2 tetradecanediol.

4. The composition of claim 1, further comprising an additional antimicrobial agent in an amount between about 0.05 and 3 percent (weight/volume).

5. The composition of claim 4, wherein the additional antimicrobial agent is a silver compound.

6. The composition of claim 5, wherein the silver compound is silver sulfadiazine.

7. The composition of claim 1 or 4, further comprising one or more hydroxy acid in an amount between about 0.5 and 3 percent (volume/volume).

8. The composition of claim 7, wherein the hydroxy acid is selected from the group consisting of lactic acid, citric acid, and salicylic acid.

9. The composition of claim 1, comprised in a wipe.

10. The composition of claim 2, comprised in a wipe.

11. The composition of claim 3, comprised in a wipe.

12. The composition of claim 4, comprised in a wipe.

13. The composition of claim 5, comprised in a wipe.

14. The composition of claim 6, comprised in a wipe.

15. The composition of claim 7, comprised in a wipe.

16. The composition of claim 8, comprised in a wipe.

17. The composition of claim 1, comprised in a wound dressing.

18. The composition of claim 2, comprised in a wound dressing.

19. The composition of claim 3, comprised in a wound dressing.

20. The composition of claim 4, comprised in a wound dressing.

21. The composition of claim 5, comprised in a wound dressing.

22. The composition of claim 6, comprised in a wound dressing.

23. The composition of claim 7, comprised in a wound dressing.

24. The composition of claim 8, comprised in a wound dressing.

25. A method of producing a bio-film resistant surface, comprising exposing the surface to a composition for preparing a bio-film resistant surface comprising a biguanide, an alkanediol, and a solvent, where the biguanide is present at between about 0.1 and 5 percent (weight/volume), the alkanediol is present at

between about 0.5 and 5 percent (volume/volume), and the solvent is selected from the group consisting of an alcohol, tetrahydrofuran, and mixtures thereof.

26. The method of claim 25, wherein the biguanide is selected from the group consisting of chlorhexidine free base, chlorhexidine diacetate, chlorhexidine gluconate, polyhexamethylene biguanide, and a mixture thereof.

27. The method of claim 25, wherein the alkanediol is selected from the group consisting of octanediol, 1,2-decanediol, 1,2-dodecanediol, 1,12-dodecanediol and 1,2 tetradecanediol.

28. The method of claim 25, said composition further comprising an additional antimicrobial agent in an amount between about 0.05 and 3 percent (weight/volume).

29. The method of claim 28, wherein the additional antimicrobial agent is a silver compound.

30. The method of claim 29, wherein the silver compound is silver sulfadiazine.

31. The method of claim 25 or 28, further comprising one or more hydroxy acid in an amount between about 0.5 and 3 percent (volume/volume).

32. The method of claim 31, wherein the hydroxy acid is selected from the group consisting of lactic acid, citric acid, and salicylic acid.

33. An article having a surface rendered bio-film resistant by the method of claim 25.

34. An article having a surface rendered bio-film resistant by the method of claim 26.

35. An article having a surface rendered bio-film resistant by the method of claim 27.

36. An article having a surface rendered bio-film resistant by the method of claim 28.

37. An article having a surface rendered bio-film resistant by the method of claim 29.

38. An article having a surface rendered bio-film resistant by the method of claim 30.

39. An article having a surface rendered bio-film resistant by the method of claim 31.

40. An article having a surface rendered bio-film resistant by the method of claim 32.

41. A method of rendering a surface of an article resistant to bio-film formation, comprising:

(i) applying a first solution to the surface, said first solution comprising an antimicrobial agent, other than a biguanide, at a concentration of between about 0.05 and 3 percent (w/v), and optionally further comprising a hydroxy acid at a concentration between about 0.5 and 3 percent (v/v), in a solvent selected from the group consisting of an alcohol (*e.g.* methanol, ethanol, isopropanol, and mixtures thereof), tetrahydrofuran and mixtures thereof;

(ii) allowing the first solution to dry;

(iii) applying a second solution to the surface, said second solution comprising a biguanide at a concentration between about 0.1 and 5 percent (weight/volume), alkanediol at a concentration between about 0.5 and 5 percent (volume/volume), polymer at a concentration between about 1 and 20 percent (weight) volume, a solvent selected from the group consisting of an alcohol (*e.g.* methanol, ethanol, isopropanol, and mixtures thereof), tetrahydrofuran and mixtures thereof; and optionally hydroxy acid in an amount of between about 0.5 and 3 percent (volume/volume).

42. An article having at least one surface comprising, as active agents, a biguanide at between about 250 and 5000 $\mu g/cm^2$ of surface and an alkanediol at between about 200 and 1500 $\mu g/cm^2$ of surface, and optionally a hydroxy acid at between about 100 and 800 $\mu g/cm^2$ of surface, and/or optionally a silver compound at between about 0-200 $\mu g/cm^2$ of surface.

43. The composition of claim 1, further comprising a polymer.

44. The composition of claim 43, comprised in a wipe.

45. The composition of claim 43, comprised in a wound dressing.

46. The composition of claim 4, wherein the additional antimicrobial agent is a chlorinated phenol.

47. The composition of claim 4, wherein the additional antimicrobial agent is triclosan.

48. The method of claim 25, said composition further comprising a polymer.

49. The method of claim 28, wherein the additional antimicrobial agent is a chlorinated phenol.

50. The method of claim 28, wherein the additional antimicrobial agent is triclosan.

51. An article having a surface rendered bio-film resistant by the method of claim 41.

52. An article having a surface rendered bio-film resistant by the method of claim 48.

53. An article having a surface rendered bio-film resistant by the method of claim 49.

54. An article having a surface rendered bio-film resistant by the method of claim 50.

55. The article of claim 33, 34, 35, 36, 37, 38, 40, 51, 52, 53 or 54 which is a wound dressing.

56. The article of claim 33, 34, 35, 36, 37, 38, 40, 51, 51, 52, 53 or 54 which is selected from the group consisting of a vascular catheter, a urinary catheter, a wound drainage tube and a tracheal catheter.

57. The article of claim 33, 34, 35, 36, 37, 38, 40, 51, 51, 52, 53 or 54 which is selected from the group consisting of an arterial graft, a soft tissue patch, a glove, a shunt, a stent, an intravaginal device, a suture, a staple, a guide wire, a heart valve, and a left ventricular assist device.

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB); Google Scholar
Search Terms Used: bio-film, resistant, biguanide, infect, microb, inhibit, anti, resistant, chlorhexidine, octanediol, silver, sulfadiazine

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/0020342 A1 (MODAK et al.) 25 January 2007 (25.01.2007) entire document, especially para [0013], [0014], [0031], [0119], [0160], [0198], [0202]	1-42
A	US 2007/0003538 A1 (MADHYASTHA) 04 January 2007 (04.01.2007) entire document	1-42

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

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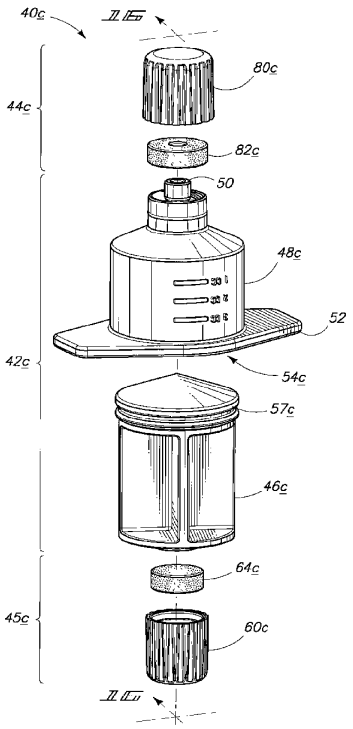
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[Continued on next page]

(54) Title: INTRAVASCULAR LINE AND PORT CLEANING METHODS, METHODS OF ADMINISTERING AN AGENT INTRAVASCULARLY, METHODS OF OBTAINING/ TESTING BLOOD, AND DEVICES FOR PERFORMING SUCH METHODS



(57) Abstract: An intravascular port access device includes a first component having a chamber configured to attach reversibly to an intravenous line port. A second component reversibly attaches to the first component and contains a disinfecting agent and an applicator material. The second component is configured to be reversibly received over external surfaces of the intravenous line port. A method of cleansing an intravenous line port includes providing a port cleaning device having a first component with a chamber containing a first cleaning agent. A second component includes a second cleaning agent. A third component has a microbiocidal agent and is reversibly attached to the first component. The second component is removed from the device, the external surfaces of the port are contacted with the second cleaning agent, the first cleaning agent is ejected from the chamber into the port, and the third component is used to cap the port.

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INTRAVASCULAR LINE AND PORT CLEANING METHODS, METHODS OF ADMINISTERING AN AGENT INTRAVASCULARLY, METHODS OF OBTAINING/TESTING BLOOD, AND DEVICES FOR PERFORMING SUCH METHODS

TECHNICAL FIELD

[0001] The invention pertains to intravascular port access devices, intravascular port cleaning devices, methods of cleaning an intravascular port, methods of administering an agent into an intravascular line port, methods of obtaining a blood sample from an individual, and sets of intravascular line port caps.

BACKGROUND OF THE INVENTION

[0002] Intravenous lines, such as peripheral IV lines and central IV lines, are common intravenous access methods for administering medicants, nutrient solutions, blood products, or other substances into a vein. Arterial lines are used, for example, in monitoring physiological parameters by arterial blood sampling during coronary, intensive or critical care. However, microorganism intravascular device colonization or infection can occur as a result from a patients' own endogenous flora or from microorganisms introduced from contaminated equipment or other environmental contamination sources. As a result, localized or systemic infection or septicemia can occur and can be life threatening.

[0003] Introduction of microorganisms into an intravenous line can be initiated or facilitated during handling of a catheter, hub, associated tubing, equipment, or injection ports, especially during manipulation of lines in preparation and during initiation of fluid administration into or withdrawal from the line. Microorganisms present on a surface of an injection port can be introduced through the port during administration. Microorganisms present on contaminated equipment utilized for administration can be introduced through the port causing colonization or infection. Bacterial growth and/or aggregation in a port or catheter can serve as the nidus for clotting, embolization and/or occlusion of the port or catheter. Further manipulation or administration through the port can facilitate spreading of microorganisms within the port, catheter, and lines, and ultimately into the patient's vein/artery and/or surrounding tissue. Accordingly, it would be advantageous to develop methods and devices for cleaning of external surfaces of

intravascular access ports and/or internal port areas to reduce risks of colonization and infection.

[0004] Another complication that can occur in association with an intravascular line, catheter or access port is clot formation due to blood return. Initial clot formation could extend and/or embolize into the superior vena cava and/or the right atrium and/or right ventricle of the heart, and subsequently into the pulmonary system circulating to the lungs. It would be advantageous to develop methodology and devices to deliver clot dissolving or clot inhibitory agents through intravascular ports to minimize or eliminate intravascular port associated clotting.

[0005] Yet another issue that can be associated with intravascular lines is lipid accumulation or build-up within the line or port. It would be advantageous to develop methodology and devices to deliver lipolytic agents through intravascular ports to minimize or eliminate port associated lipid build up.

SUMMARY OF THE INVENTION

[0006] In one aspect the invention pertains to an intravascular port access device. The device includes a first component having a chamber and being configured to attach reversibly to an intravenous line port. The second component reversibly attaches to the first component and contains a disinfecting agent and an applicator material selected from the group consisting of polyethylene felt sponge, polyethylene foam sponge, plastic foam sponge and silicon foam sponge. The second component is configured to be reversibly received over external surfaces of the intravenous line port.

[0007] In one aspect the invention encompasses an intravascular line port cleaner including a syringe barrel having a first end and a second end. A slideable piston is received into the barrel through the second end. The line port cleaner includes a first cap containing a cleansing agent and a second cap containing a microbiocidal agent.

[0008] In one aspect the invention encompasses a method of cleansing an intravenous line port. The method includes providing a port cleaning device comprising a first component having a chamber with a first cleaning agent. A second component includes a second cleaning agent. A third component has a microbiocidal agent and is reversibly attached to the first component. The method includes removing a second component from the device, contacting the external surfaces of the port with the second cleaning agent, injecting the first cleaning agent from the chamber into the port,

removing the third component from the device, and capping the port with the third component.

[0009] In one aspect the invention encompasses a method of obtaining a blood sample from an individual. The method includes providing a port access device having a first component including a chamber, a second component containing a cleaning agent and a third component comprising a microbiocidal agent. The third component is reversibly attached to the first component. The method includes removing the second component from the device and contacting the external surfaces of the port with the cleaning agent. The method further includes drawing blood from the individual through the port into the chamber of the first component removing the third component from the device and capping the port with the third component.

[0010] In one aspect the invention includes a set of intravascular line port caps. The set of caps includes a first port cap containing a first agent and a first applicator material. The set further includes a second port cap containing a second agent and a second applicator material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Preferred embodiments of the invention are described below with reference to the following accompanying drawings.

[0012] Fig. 1 is a diagrammatic isometric view of a device in accordance with one aspect of the invention.

[0013] Fig. 2 is a diagrammatic side view of the device shown in Fig. 1.

[0014] Fig. 3 is a diagrammatic exploded view of the device shown in Fig. 1.

[0015] Fig. 4 is a diagrammatic cross-sectional view of the device shown in Fig. 1.

[0016] Fig. 5 is a diagrammatic cross-sectional view of the device shown in Fig. 1 after repositioning relative to the positioning depicted in Fig. 4.

[0017] Fig. 6 is a diagrammatic isometric view of a device in accordance with another aspect of the invention.

[0018] Fig. 7 is a diagrammatic side view of the device shown in Fig. 6.

[0019] Fig. 8 is a diagrammatic exploded view of the device of Fig. 6.

[0020] Fig. 9 is a diagrammatic cross-sectional view of the device shown in Fig. 6.

[0021] Fig. 10 is a diagrammatic view of an exemplary packaging concept for the device shown in Fig. 6.

[0022] Fig. 11 shows a multi-pack packaging concept for the device shown in Fig. 6.

[0023] Fig. 12 is a diagrammatic exploded view of a device in accordance with another aspect of the invention.

[0024] Fig. 13 is a diagrammatic cross-sectional view of the device shown in Fig. 12.

[0025] Fig. 14 is a diagrammatic exploded view of a device in accordance with another aspect of the invention.

[0026] Fig. 15 is a diagrammatic exploded view of a device in accordance with another aspect of the invention.

[0027] Fig. 16 is a diagrammatic cross-sectional side view of the device shown in Fig. 15.

[0028] Fig. 17 is a diagrammatic isometric view of a packaging concept in accordance with one aspect of the invention.

[0029] Fig. 18 is a diagrammatic isometric view of the packaging concept shown in Fig. 17.

[0030] Fig. 19 is another diagrammatic isometric view of the packaging concept shown in Fig. 17.

[0031] Fig. 20 is a diagrammatic isometric view of a set of components in accordance with one aspect of the invention.

[0032] Fig. 21 is an exploded view of the set of components depicted in Fig. 20.

[0033] Fig. 22 is a diagrammatic exploded view of a packaging concept in accordance with one aspect of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0034] In general the invention includes devices and methodology for cleaning and/or accessing intravascular line ports. In particular applications devices of the invention can be used for cleaning external surfaces of a intravascular line port followed by cleaning of the port itself and in particular instances cleaning of intravascular lines.

[0035] In other applications devices of the invention can be utilized for administering an agent intravascularly. During these applications, the devices in accordance with the invention can typically be utilized to cleanse external surfaces of

the port prior to utilizing the device for administering of an agent intravascularly. In another application devices of the invention can be utilized to obtain a blood sample from an individual. A device in accordance with the invention is typically utilized to cleanse external surfaces of a port prior to utilizing the device to withdraw a sample of blood from the port. The invention also includes methodology for such port cleansing agent administration and blood sampling techniques.

[0036] In one embodiment, the device comprises two components. An example two component device is described with reference to Figs. 1-5.

[0037] Referring initially to Fig. 1, a port access device 10 comprises a first component 12 at a first end 14 of the device, and a second component 16 at a second end 18 of the device. Second component 16 can have a tab 20 or other extension feature for assisting removal of the second component from the first component. First component 12 has a chamber housing 22 which can be a collapsible housing. First component 12 can also comprise an extension portion 24. Referring to Fig. 2, as depicted device 10 can have second portion 16 insertable within connector portion 24. It is to be understood however that the invention contemplates other configurations wherein second portion 16 fits over or caps extension portion 24. It is also to be understood that the shape and dimension of collapsible housing 22 is but an example with alternative shapes, sizes and configurations contemplated.

[0038] Referring to Fig. 3 such shows an exploded view of the device depicted in Figs. 1 and 2. As illustrated chamber housing 22 of device 10 can house a chamber 23. Connector 24 can comprise a separator 25 having an opening 29 passing therethrough. Connector 24 can further comprise a receiving port 30 for receiving a dispenser 26. Dispenser 26 in turn can comprise a valve portion 28. Second component 16 can comprise a container 21.

[0039] Referring next to Fig. 4, such shows dispenser 26 with valve 28 seated within receiving port 30. As depicted such valve mechanism is in the "closed" position where contents of chamber 23 are blocked from passing into or through connector 24. Referring next to Fig. 5, application of force upon collapsible housing 22 such as a downward pressure upon a top surface of the housing can be utilized to displace valve device 28 from receiving port 30 as illustrated. Such displacement can allow passage of the contents of chamber 23 into or through connector portion 24.

[0040] As depicted in Fig. 4, second component 16 can contain an applicator material 32. Such applicator material can be for example, a sponge or sponge-type

material. Exemplary sponge-type materials can include but are not limited to polyethylene felt sponge, polyethylene foam sponge, plastic foam sponge and silicon foam sponge.

[0041] Where device 10 is to be utilized for port cleansing applications, container 21 of second component 16 will typically contain a cleansing agent. The cleansing agent can be a disinfecting agent for cleansing external port surfaces. The agent is not limited to a particular cleaning or disinfecting agent and can comprise for example alcohol, preferably contained in an alcohol solution comprising from about 5% to about 99% alcohol. In particular applications the alcohol solution will comprise 25% to 90% alcohol. The sponge-type applicator material can be utilized to assist in containing the cleansing agent and can further assist in applying the agent to external surfaces of the intravascular port. Second component 16 is removably attached to the device 10. For cleansing of the port, removable component 16 is removed from first component 12 and is utilized to contact external port surfaces for cleansing of external portions of an intravascular line port.

[0042] After cleansing of external portions of the port, the first component of the device, which in cleansing/disinfecting applications can be utilized for internal cleansing of the intravascular port, can be reversibly attached to the port to be cleansed. The chamber volume can be for example up to 3.5 ml; a preferred volume range can be from about 1 to about 3 ml. although alternative chamber sizes for smaller or larger volumes are contemplated. The chamber can have appropriate calibration marks relative to the total volume of the chamber. For example, a 3.5 ml. fluid volume chamber can have volume markings every 1 ml, every 0.5 ml, every 0.1 ml, etc. In particular embodiments, the connector portion can have a LEUR-LOK® (Becton, Dickinson and Company Corp., Franklin Lakes NJ) fitting (not shown) for connection to a LEUR-LOK® type port. A cleansing agent can be provided within chamber 23 and can be an antibiotic or an alternative appropriate disinfectant. An exemplary agent can be an alcohol or alcohol solution such as described above relative to the second component container 21. In cleansing applications chamber 22 can alternatively or additionally contain chemical agents including ethylene diamine tretaacetic acid (EDTA) and/or sodium citrate.

[0043] Once connected to the line port external pressure can be applied to collapsible housing 22 by for example squeezing, pinching, or pushing inward on the housing to displace dispenser 26 thereby opening or displacing valve 28 from receiving port 30. Continued squeezing or external force can be utilized to dispel or eject

contents of chamber 23 through connector 24 and into the connected port. Depending upon the volume of chamber 23 the injected cleansing solution may extend into the intravascular line itself. After dispelling the contents of chamber 23 device component 12 can be removed from the port to allow administration of fluids to be delivered intravascularly (for example). If such delivery is not to be performed immediately upon cleansing, component 12 of the cleansing device can be retained on the port until such time as intravascular delivery is desired.

[0044] In another aspect, the above-described device and methodology can be utilized for administering an anti-clot agent to minimize or prevent intravascular associated clot formation or to dissolve an existing clot. In this aspect, rather than or in addition to the antimicrobial agent, chamber 23 can contain an appropriate anticoagulant agent or clot dissolving agent. Exemplary anti-clot agents which can be utilized include but are not limited to anticoagulants such as EDTA, sodium citrate, heparin and heparin derivatives, and anti-thrombolytic agents such as tissue plasminogen activator. Where lipid accumulation is an issue an appropriate dispersion or lipolytic agent can be administered, either independently or in combination with antimicrobial agent and/or anti-clot agent. Injection of any such agents can be achieved in a manner analogous to that described above relative to the cleansing agent. These applications may also be accomplished utilizing the embodiments illustrated and described below.

[0045] An alternative embodiment of a device in accordance with the invention is illustrated and described with reference to Figs. 6-11. Referring to Fig. 6, such illustrates an alternative example port access device 40 having a syringe-like first component 42 and a second component 44. Referring to Fig. 7 syringe-like first component 42 includes a plunger 46. An exploded view of the port access device is depicted in Fig. 8. First component 42 includes a syringe barrel-like housing 48 having a first end 50 and a second end 52 with an internal chamber 54. Chamber 54 can preferably have a fluid volume of from 1 to about 3.5 ml. Housing 48 can have appropriate calibration marks as discussed above with respect to the earlier embodiment.

[0046] Plunger 46 can include a stem portion 56 having a seal 57. Plunger 46 can be insertable into second end 52 of housing 48. A second seal 59 can be associated with the larger diameter body of the plunger. Seal 59 is preferably present to form a seal between the plunger and an internal surface of the device chamber. Seal

59 can preferably be an elastameric seal which is over molded onto the piston (which can preferably be a molded hard plastic material). However, the invention contemplates alternative seal material and use of non-overmolded techniques.

[0047] Seal 57 can be a single seal or a set of seals and can be for example a set of two o-rings, a single broad overmolded elastameric o-ring or sleeve or a hard plastic seal molded integrally with the piston stem. The presence of seal 57 can advantageously inhibit or prevent unwanted or unintentional backflow of fluid into the device chamber thereby decreasing the risk of contamination of the device and/or its contents. Alternatively relative to the depicted configuration a single seal can be over molded to have a base portion which forms the seal between an internal wall of the device chamber and the large diameter portion of the piston and a sleeve portion which covers the walls of the smaller diameter portion of the piston (not shown).

[0048] The second component 44 is a removable cap portion having a housing 60 and an internal container 62. Container 62 can contain an applicator material 64. The applicator material can be, for example, any of those materials discussed above with respect to the earlier embodiment. The second component 44 can additionally contain a cleansing agent such as those cleansing agents discussed above. Second component 44 preferably can be configured to fit over or onto an intravascular port such that the cleansing agent can be applied to external surfaces of the port. Such cleaning preferably can be conducted prior to administering the contents of chamber 54 (for example, an anti-clot, antimicrobial or other cleansing agent) into the port. However, the invention contemplates post-administration cleansing of the port utilizing the removable cap portion.

[0049] Referring next to Fig. 9, such shows a cross-sectional view of the embodied device 40 in an intact configuration. For utilization second component 44 can be removed and utilized to cleanse external surface of the port. Subsequently, first end 50 of the second component can be attached to the port and contents of the chamber 54 can be administered into the port by application of force to plunger 46. Alternatively, chamber 54 can be provided empty or can be provided to contain, for example, an anticoagulant agent and device 40 can be provided with plunger 46 in a forward position. Thus device 40 can be utilized for applications such as obtaining and/or testing of a blood sample from an individual by attaching first end 50 of the device to the port and repositioning of plunger 46 to draw fluid through the port into chamber 54.

[0050] Referring to Fig. 10 packaging 70 for delivery, storage and/or disposal of the component for access device 40 is illustrated. Such packaging includes a lid 72 and a tray portion 74. Tray portion 74 has a cavity 76 with molded retainers 78 for positioning/retaining of the device and assisting in maintaining the integrity of the device and proper positioning of the plunger relative to the device chamber. Such packaging can be sealed and can be utilized to provide a sterile environment for device 40. As shown in Fig. 11 a series 71 of individual packaging unit 70 can be provided with individually sealed units to allow individual removal of units while maintaining sterility of additional units in the series.

[0051] Another alternative embodiment is described with reference to Figs. 12-13. In this embodiment first component 42a is the same as the immediately preceding embodiment. However, referring to Fig. 12 second component 44a comprises a "dual cap" system. Cap housing 60a includes container portion 62 and a second cap extension 65 which houses a second container 66. Container 62 can contain an applicator material 64 such as the sponge-like materials described above. Similarly container 66 can also contain a sponge or other applicator material 67. Container 62 can further contain a cleansing agent such as those described above.

[0052] Container 66 can preferably contain one or more microbiocidal agents that differ in composition from the cleaning solution contained in the cleansing cap 62. An example agent composition within cap portion 65 can include from about 3% to about 11% H_2O_2. Additional components of the agent can include for example ethanol (from about 30% to about 40%) sodium citrate (from about 1% to about 4%), EDTA, and/or peracetic acid (less than or equal to about 11%). Preferably, the pH will be between 5 and 10 and can be adjusted with NaOH or other appropriate base/acid to about ph 7.4 as needed based upon the physiological pH and biocidal activity. The presence of EDTA can provide sporocidal activity against for example bacillus spores by complexing Mn and can additionally help stabilize H_2O_2. In combination with H_2O_2 in the solution a synergistic and/or additive effect can be achieved. The invention does contemplate use of alternative chelators and pH stabilizers relative to those indicated.

[0053] It is to be noted that in some instances a similar solution having lower peroxide content may be included within the first container 62 and in particular instances may be present within the chamber of the first component.

[0054] Referring to Fig. 13 such shows an intact device prior to use. In port cleansing applications second component 44a is removed from the device and portion

60a is utilized to cover a port thereby contacting the port with the contents of container 62. Applicator material 64 can assist in applying the cleaning agent to external port surfaces. When the contents of chamber 54 are to be administered, component 44a is removed from the port and first component is attached to the port. Plunger 46 is depressed thereby injecting the contents of chamber 54 into the port. The syringe component is then removed from the port. A removable seal 68 can then be removed from second cap portion 65. Cap portion 65 can be placed over the port such that the contents of container 66 contact the port. Second component 44 can then be removed from the port or can be retained on the port until further port access or manipulation is desired.

[0055] Referring to Fig. 14 such shows an alternative embodiment wherein port access device 40b comprises a first component 42b, a second component 44b and a third component 45b where second component 44b and third component 45b are independently removable caps. As illustrated the caps are disposed initially at opposing ends of the device and are of differing size. However, alternative relative size and positioning of the caps on the device is contemplated. For example, first component 44b and second 45b can be disposed on top-side or bottom-side of wing extensions 51, 53 of chamber housing 48b.

[0056] For the example configuration illustrated, the larger cap (first component 44b) can be removed from the device and can be utilized for external port cleaning in a manner analogous to that described above. The second smaller cap (third component 45b) can be removed from the device after administration of the chamber contents and can be subsequently utilized as a port cap to protect the port until subsequent port access is desired as described above. Third component 45b optionally can contain an applicator material 82 and/or cleansing agent or microbiocidal agent as described above.

[0057] Alternative two-cap configurations include a device having a larger cap external to a smaller internal cap, the first cap being removable from the second cap where one of the first and second caps is configured for utilization as a port cap.

[0058] In the device shown in Fig. 14, cap housing 60b of second component 44b and cap housing 80 of third component 45b can be of differing colors. As such, the caps can be color coded (or otherwise coded) to notify the user or other personnel of the status of the port or intravascular line. For example, a first color such as green can be utilized on all or a portion of cap housing 80 which will be retained on the port after

use of the device to signify a properly sterilized port. Cap housing 60b can be a second color (e.g., yellow or red) signifying the cleansing or other procedure being performed has not yet been completed. Accordingly, the caps can be utilized as an added safety measure to help ensure proper use and assist in maintaining sterility and appropriate record keeping. For example, the caps can allow visual monitoring and can be tracked by hospital pharmacy and/or central auditing software.

[0059] In addition to visual auditing of compliance to proper cleaning and maintenance of sterility, a barcode, radio frequency identification (RFID) and/or other pharmacy dispensary or inventory control system associated with the device can be utilized to provide an independent audit/compliance system.

[0060] Referring next to Fig. 15 such depicts an additional alternate embodiment which can utilize a conventional type syringe and plunger design and can utilize caps in accordance with the invention. Accordingly, first component 42c comprises a syringe housing 48c and can have a LEUR-LOK® fitting at first end 50. Plunger 46c can have a conventional type piston seal 57c configured to insert into second end 52 of housing 48c and form a seal with the walls of chamber 54c. Second component 44c can comprise a housing 60c which can for example have an internal receiving port which fits either internally relative to the LEUR-LOK® fitting or which fits over and covers the LEUR-LOK® fitting at first end 50 of first component housing 48c. Third component 45c can also have housing 80c configured such that it comprises an internal receiving port which fits either internally relative to a LEUR-LOK® fitting or which fits over and covers the LEUR-LOK® fitting (or which can have an alternative type fitting) based upon the type of port being cleansed.

[0061] A cross-sectional view of the device shown in Fig. 15 is illustrated in Fig. 16. Such shows the exemplary type of cap housings for covering LEUR-LOK®-type fittings. For example third component 45c has housing 80c comprising a portion of such housing which fits internally within a LEUR-LOK® type fitting thereby capping such fitting. In contrast second component 44c has housing 60c which is threaded to thread onto LEUR-LOK® type fitting. It is to be understood that the depiction is for illustrative purposes only and that either or both caps can have the threaded configuration or the snap in configuration. Cap housing 60c and 80c can further be color coded as described above.

[0062] The invention also contemplates dual cap system disposed at the distal (non-administration) end of the port cleaner device (not shown). In this dual cap system

a first "green" cap can be reversibly joined to both the device and also back to front in a stack relationship relative to a second "yellow" cap. Each of the two caps can be, for example, a LEUR-LOK® type fitting cap, friction fit cap, etc. The green cap can contain the microbiocide composition described above. The yellow cap can contain for example the cleaning compositions discussed earlier or the microbiocide composition as contained in the green cap since in this configuration the yellow cap is not in contact with the administration end of the device.

[0063] Possible materials for caps include, but are not limited to, polyethylene, polypropylene, and/or copolymer materials. Further, the caps can preferably comprise a material or agent that is UV protective to preserve the integrity of hydrogen peroxide during storage, shipping, etc. Packaging may also contain UV protective materials to inhibit peroxide breakdown.

[0064] As mentioned above, devices of the invention can be utilized for withdrawing blood from an individual through an intravascular catheter or intravascular port. In particular applications, the device can be utilized directly for blood testing purposes. The device chamber can preferably have a chamber size in the range of 1 to 3 ml, with appropriate calibration marks as discussed above. Where whole blood is desired, depending upon the particular purpose for drawing, blood can be drawn into either a device having an empty chamber or into a device containing an anticoagulant such as EDTA, sodium citrate or alternative coagulant (such as discussed above). The device containing blood and anticoagulant can then be utilized directly in blood testing equipment or blood can be transferred to an alternative device for testing.

[0065] In applications where serum is desired, whole blood can be drawn into the device chamber and, after coagulation, the device containing the blood sample can be spun to separate the serum from the red blood cells. If anticoagulant is present in the device chamber, further separation can occur to isolate plasma. Alternatively, a filter such as a MILLIPORE® (Millipore Corp., Bedford MA) filter can be fitted onto the device after a sample is drawn into the device chamber. Such technique can filter out red blood cells, white blood cells and platelets allowing serum to flow from the chamber while retaining the blood cells within the filter. Anticoagulants can optionally be provided within the chamber to allow transfer of blood cells or plasma if such is desired based upon the testing or other procedure to be performed (i.e., complete blood count, CBC, platelet count, reticulocyte count, T and B lymphocyte assays and chemistries).

[0066] An appropriate filter can also be utilized to filter out particulates during drawing of a blood sample from an individual into the chamber.

[0067] It is to be understood that any of the devices above can be utilized for cleansing purposes, for administration purposes or for blood drawing/testing purposes. Methodology will be analogous with variation based upon the particular device utilized as described above.

[0068] Example device packaging is illustrated in Figs. 17-19. Packaging 100 can include a lid portion 102 and a packaging tray 104 as shown in Fig. 17. Referring to Fig. 18 and 19 packaging tray 104 can be a molded tray which has integrally molded retaining features which conform to the shape of a device 40c in accordance with the invention. Preferably the molded features conform to the shape of the device in the non-deployed position for shipment, storage, etc. Accordingly tray 104 can have one or more integrally molded retainer features 106, 107, 108 and 109. Tray 104 can also comprise an integrally molded receiving stand 110 which can be configured to receive device 40c in an upright position as depicted in Fig. 18. Such receiving stand can allow device 40c to be inserted and retained during administrative procedures or after use. Tray 104 may also be used for device disposal purposes.

[0069] Device caps in accordance with the invention can be utilized independent of the devices for cleansing and protection of alternative access catheters and ports such as intravascular, peritoneal dialysis, urinary ports and catheters, etc. Accordingly, the caps can be packaged independently in pairs (one each of two differing sizes, colors, etc., in groups or in bulk, of one or more colors). Figs. 20-21 show an example two cap packaging system 115 having a first cap 117 which can be for example a yellow cap and which can preferably be a LEUR-LOK® type cap and a second cap 118 which can be, for example, a green cap and which can also be a LEUR-LOK®. Packaging system 115 can comprise a packaging tray 120 and as illustrated in Fig. 21 can include integrally molded appropriate receiving ports/receiving rings 122, 124. Where additional or fewer caps are to be packaged together tray 120 can have an appropriate number of receiving ports for receiving and reversibly retaining the caps. Where the caps differ in size (diametric), the ports can also be of differing size as appropriate. It is to be understood that the caps may be provided in groups such as one green and four yellow caps per package or any other appropriate number depending upon the particular procedure for which they will be utilized with the number and size of package ports corresponding to the number and size of various caps.

[0070] Referring next to Fig. 22 an alternative packaging system 130 is illustrated. Packaging system 130 comprises a lid 132 and a tray 130 having integral receiving ports 136 and 138 for receiving caps 117 and 118. As discussed above alternative numbers and sizes of receiving ports can be provided based upon the number and sizes of caps to be utilized.

[0071] Where caps are provided in bulk, such may be individually packaged and may be provided individually in sheets or on strips. Caps can alternatively be provided with catheter or line/import devices. Such can be included in common packaging either loose or attached to a port catheter or line to be used for port cleaning and/or protection after package opening and/or while the device is in use. In some instances the cap(s) can be packaged in one or more sub-packages included within a larger package enclosing the catheter device.

CLAIMS

The invention claimed is:

1. An intravascular port access device comprising:

a first component having a chamber and being configured to attach reversibly to an intravenous line port; and

a second component reversibly attached to the first component and containing a disinfecting agent and an applicator material selected from the group consisting of polyethylene felt sponge, polyethylene foam sponge, plastic foam sponge and silicone foam sponge; the second component being configured to be reversibly received over external surfaces of the intravenous line port.

2. The device of claim 1 wherein the chamber has a volume of less than or equal to about 3.5 ml.

3. The device of claim 1 wherein the chamber contains a cleansing agent.

4. The device of claim 1 wherein the chamber contains an anticoagulant.

5. The device of claim 1 wherein the chamber contains a lipolytic agent.

6. The device of claim 1 further comprising a third component reversibly attached to the first component.

7. The device of claim 6 wherein the third component contains a microbiocidal agent.

8. The device of claim 7 wherein the microbiocidal agent comprises H_2O_2.

9. The device of claim 1 wherein the first component comprises a collapsible chamber housing.

10. The device of claim 1 wherein the first component comprises a syringe barrel chamber housing.

11. An intravascular line port cleaner, comprising:

a syringe barrel having a first end and a second end;

a slideable piston received into the barrel through the second end;

a first cap containing a cleansing agent; and
a second cap containing a microbiocidal agent.

12. The port cleaner of claim 11 wherein the syringe barrel contains a cleansing agent.

13. The port cleaner of claim 11 wherein the syringe barrel contains an anticoagulant.

14. The port cleaner of claim 11 wherein the syringe barrel contains a lipolytic agent.

15. The port cleaner of claim 11 wherein the first and second caps each contain an applicator material.

16. A method of cleansing an intravenous line port, comprising:
providing a port cleaning device comprising:
a first component having a chamber comprising a first cleaning agent;
a second component comprising a second cleaning agent; and
a third component comprising a microbiocidal agent reversibly attached to the first component;
removing the second component from the device;
contacting external surfaces of the port with the second cleaning agent;
injecting the first cleaning agent from the chamber into the port;
removing the third component from the device; and
capping the port with the third component.

17. The method of claim 16 wherein prior to removal the second component is reversibly attached to the third component.

18. The method of claim 17 wherein the first cleansing agent and the microbiocidal agent comprise H_2O_2.

19. The method of claim 16 wherein prior to removal the second component is reversibly attached to the first component.

20. The method of claim 16 wherein the first component is a syringe device.

21. The method of claim 12 wherein the second component comprises a first color and the third component comprises a second color differing from the first color.

22. The method of claim 12 wherein the second and third components are caps.

23. The method of claim 12 wherein the second and third components are caps comprising synthetic sponge material.

24. The method of claim 12 wherein the second and third components are LEUR-LOK® fitting caps and wherein the port is a LEUR-LOK® type port.

25. A method of administering an agent into an intravascular line port, comprising:

providing a port access device comprising:

a first component having a chamber comprising an agent to be administered into an intravascular line port;

a second component comprising a cleaning agent; and

a third component comprising a microbiocidal agent reversibly attached to the first component;

removing the second component from the device;

contacting external surfaces of the port with the second cleaning agent;

injecting the agent to be administered from the chamber into the port;

removing the third component from the device; and

capping the port with the third component.

26. The method of claim 25 wherein the agent to be administered is selected from the group consisting of an anticoagulant, an acidic solution, a basic solution, and a lipolytic agent.

27. The method of claim 25 wherein the first component is a syringe device.

28. The method of claim 25 wherein the first component comprises a collapsible chamber housing.

29. The method of claim 28 wherein the first component further comprises a sildeable valve and a delivery channel.

30. A method of obtaining a blood sample from an individual , comprising:

providing a port access device comprising:

a first component having a chamber;

a second component comprising a cleaning agent; and

a third component comprising a microbiocidal agent reversibly attached to the first component;

removing the second component from the device;

contacting external surfaces of the port with the second cleaning agent;

drawing blood from the individual through the port into the chamber of the first component;

removing the third component from the device; and

capping the port with the third component.

31. The method of claim 30 wherein the chamber comprises an anticoagulant.

32. A set of intravascular line port caps, comprising:

a first port cap containing a first agent and a first applicator material; and

a second port cap containing a second agent and a second applicator material.

33. The set of caps of claim 32 wherein the first agent is a cleansing agent and the second agent is a microbiocidal agent.

34. The set of caps of claim 32 wherein at least one of the first agent and the second agent comprises H_2O_2.

35. The set of caps of claim 32 wherein the first and second caps differ in color relative to each other.

36. The set of caps of claim 32 wherein the first and second caps differ in size relative to each other.

37. The set of caps of claim 32 further comprising a packaging component having a first receiving port and a second receiving port.

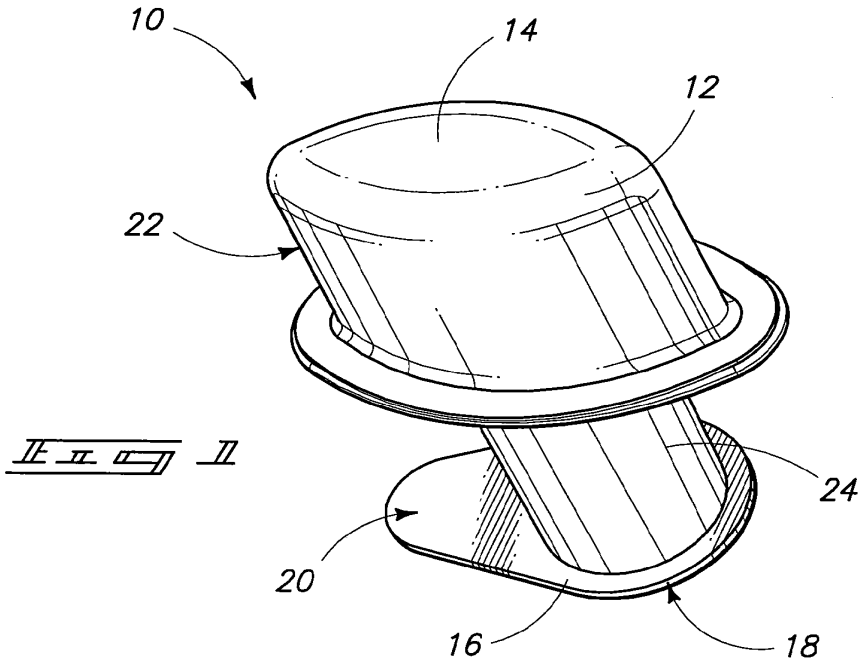


Fig 1

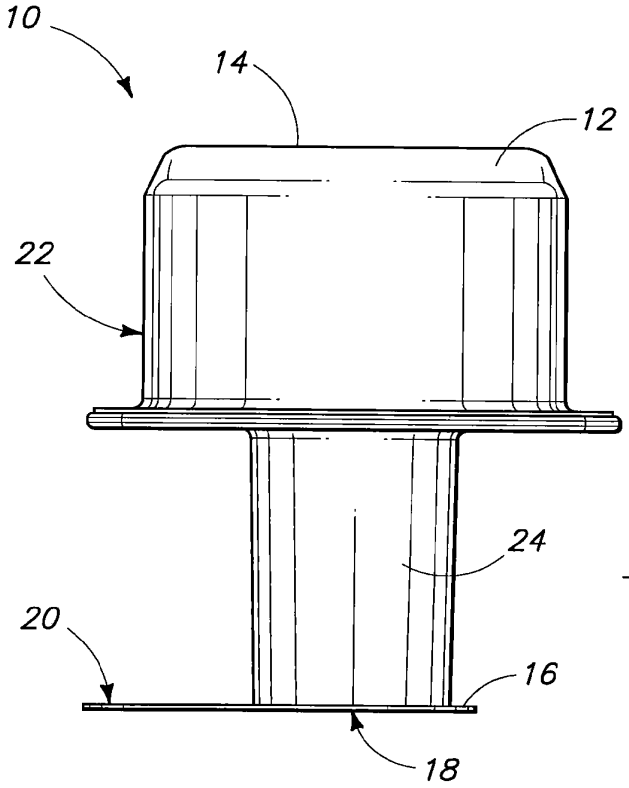


Fig 2

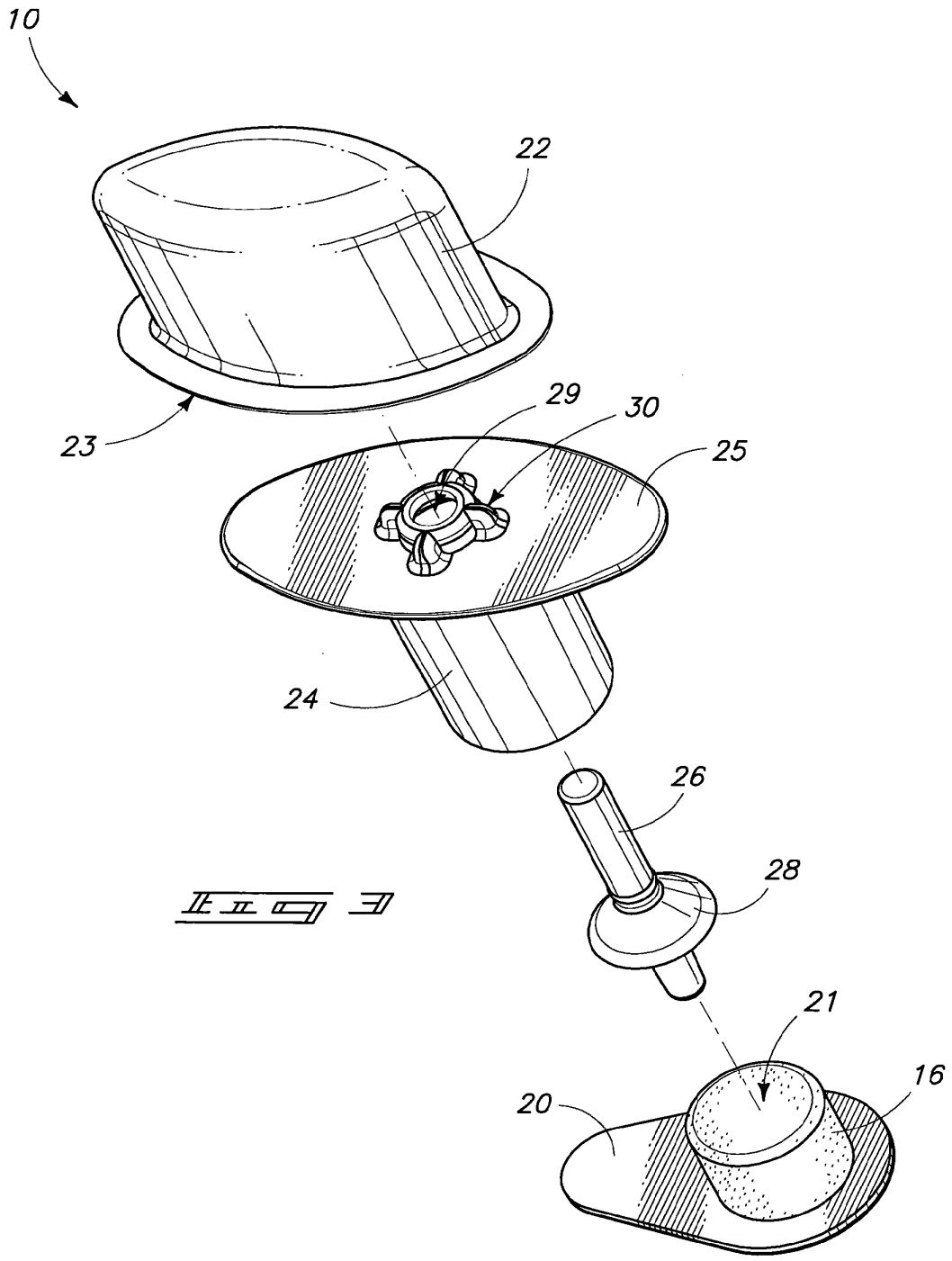


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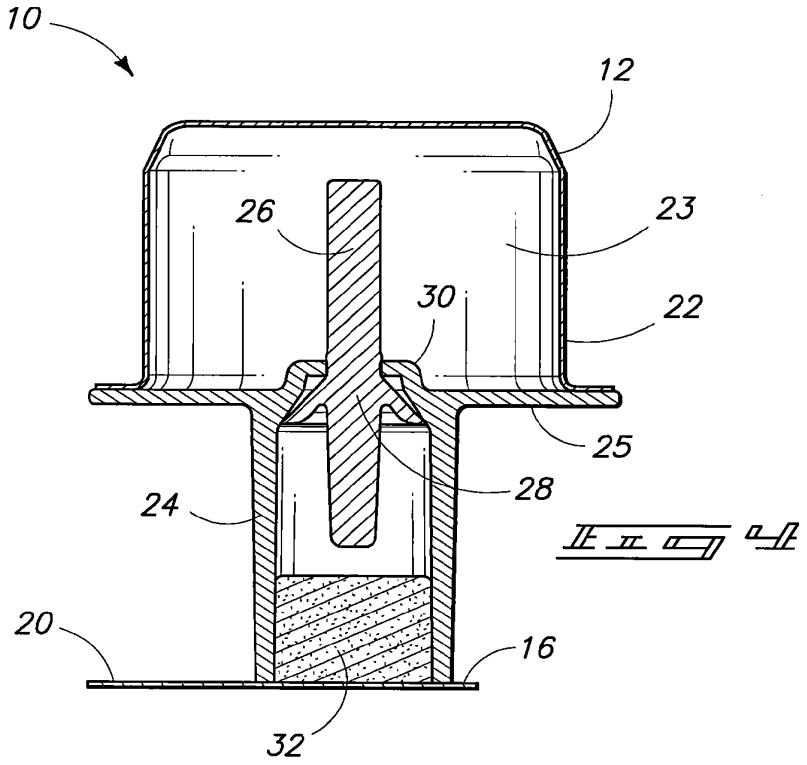


Fig 4

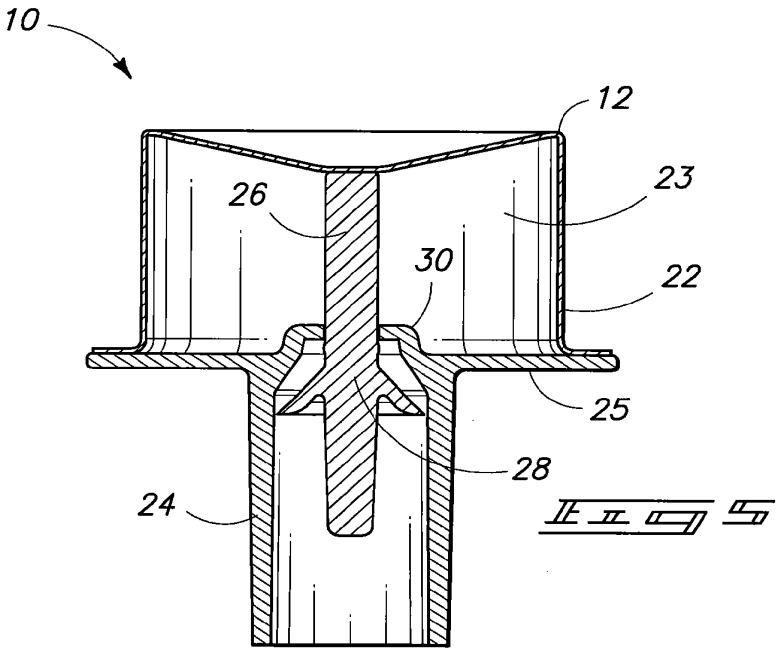


Fig 5

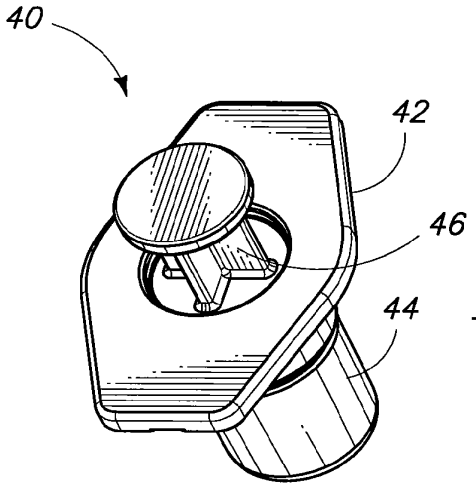


Fig 6

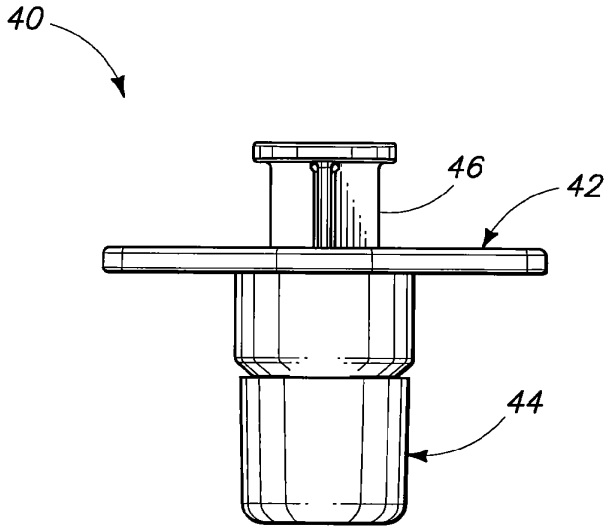


Fig 7

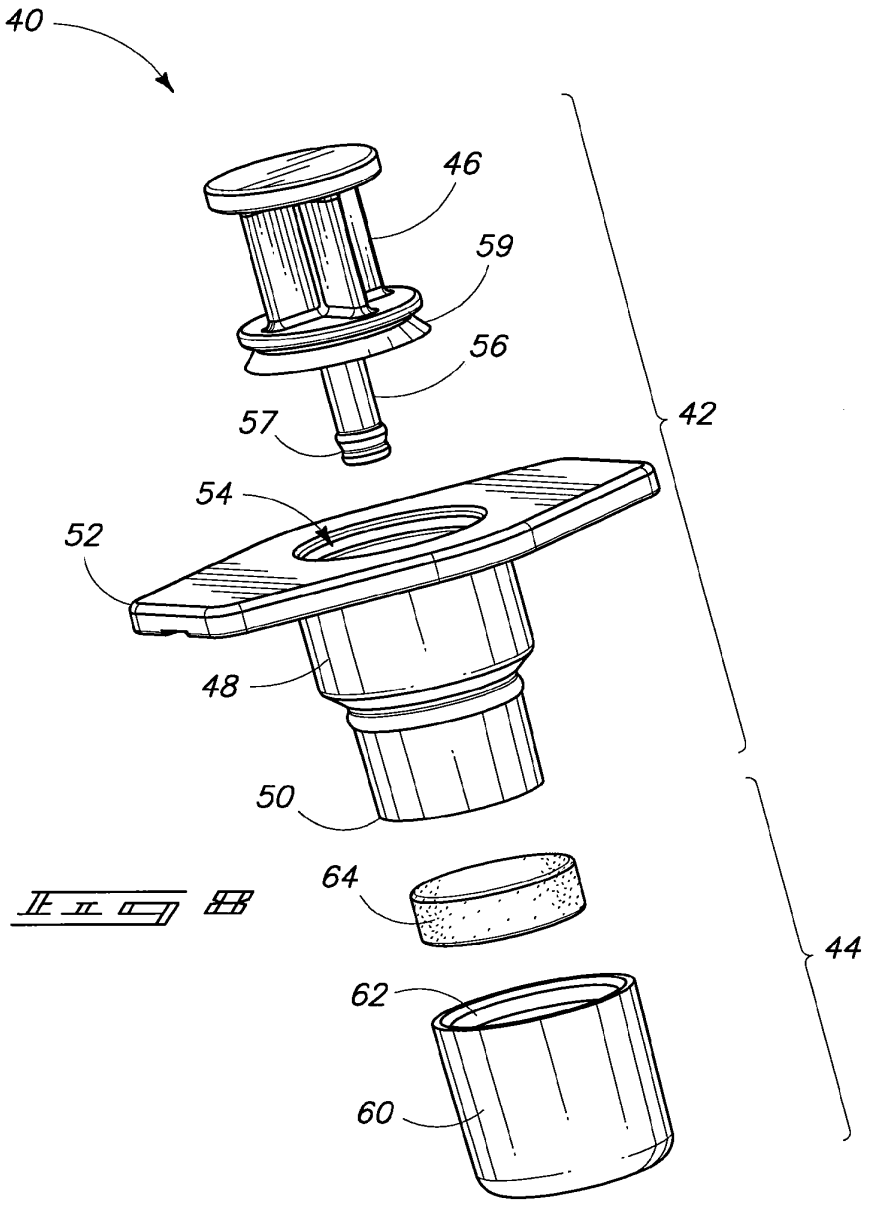


Fig. 8

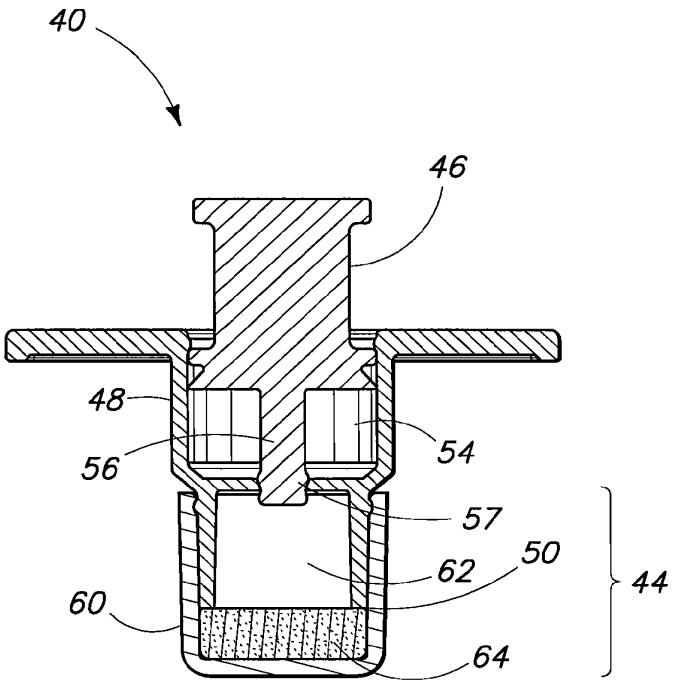


Fig 9

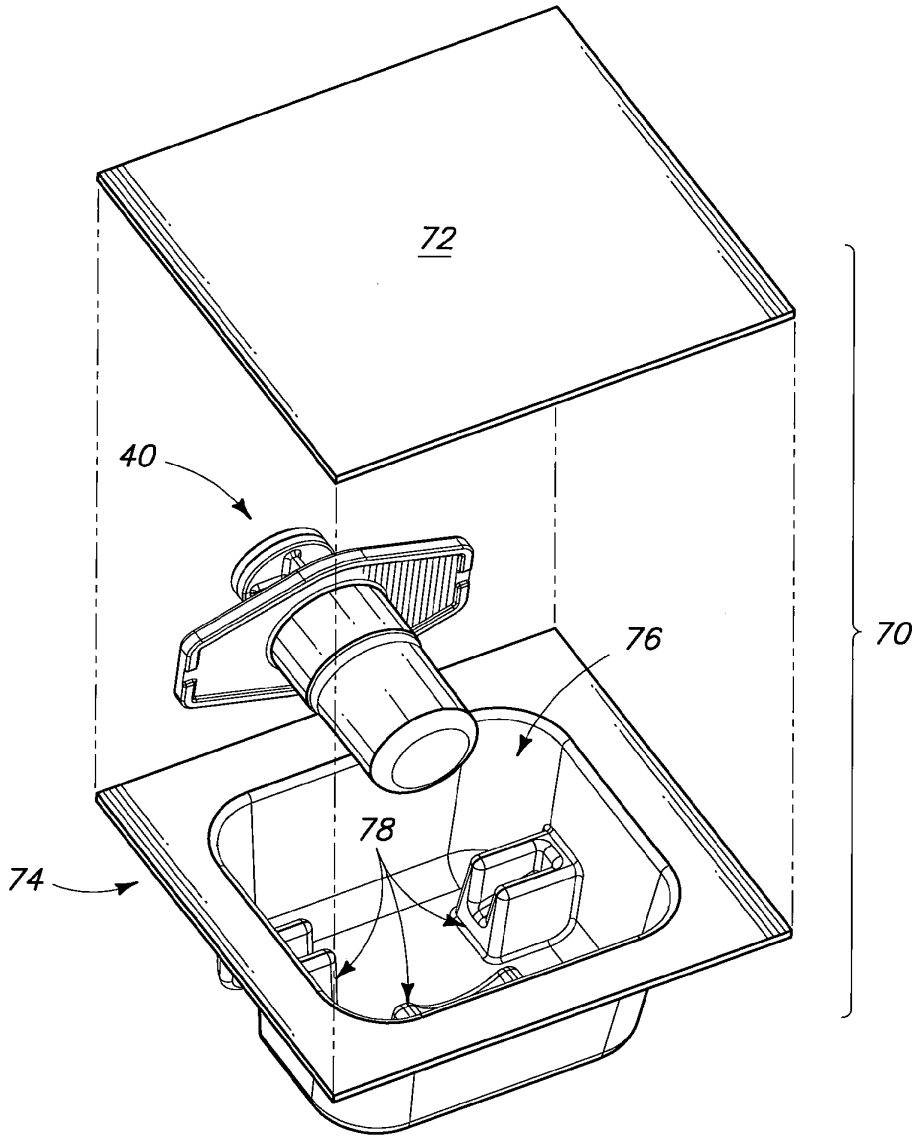


Fig 10

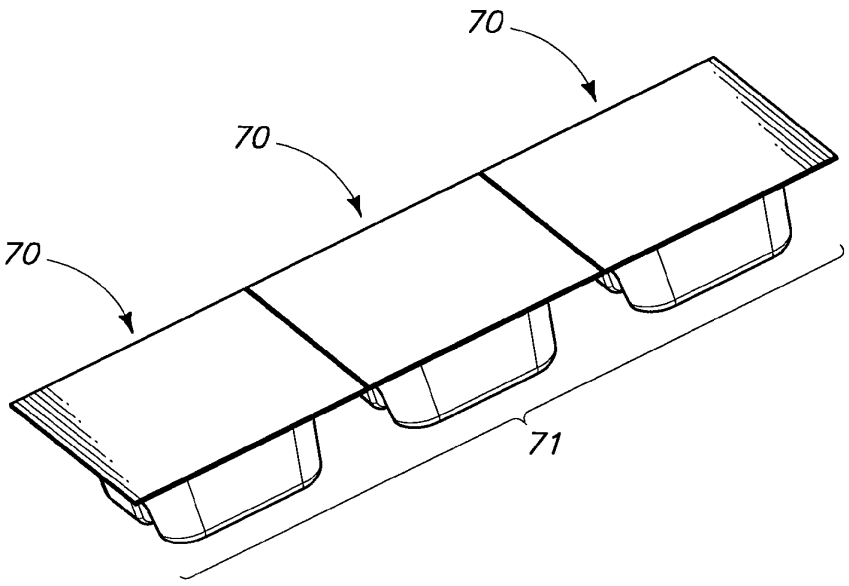


Fig 11

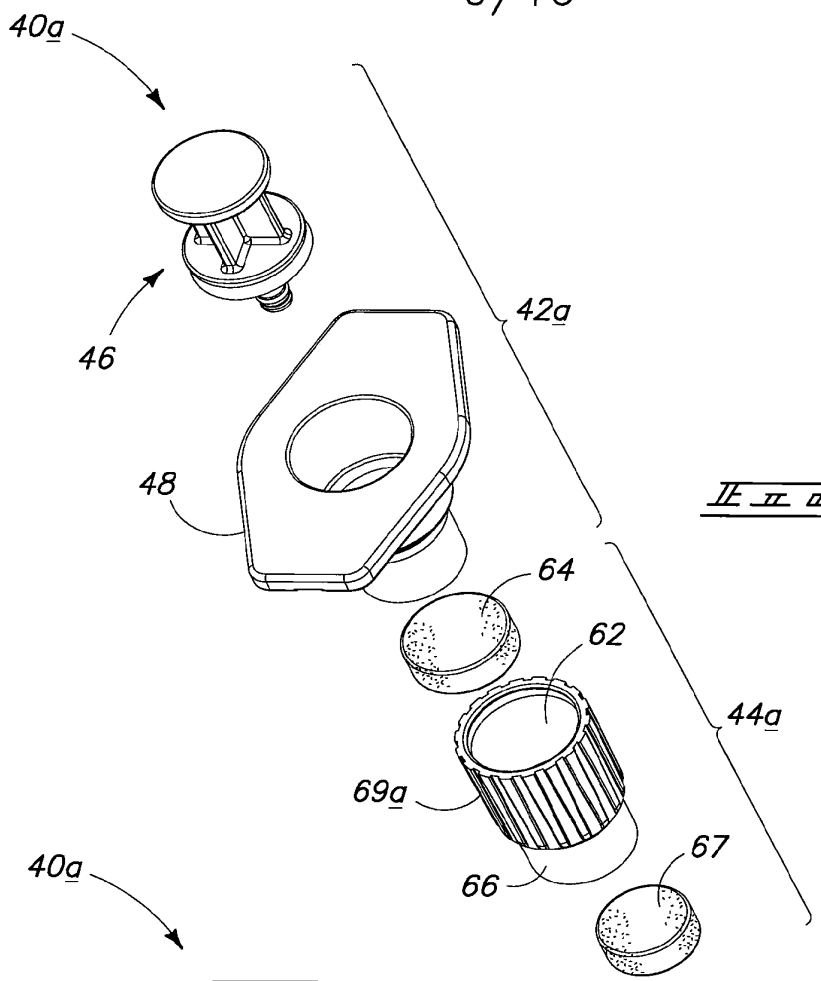

40a
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62
44a
69a
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66

Fig 12

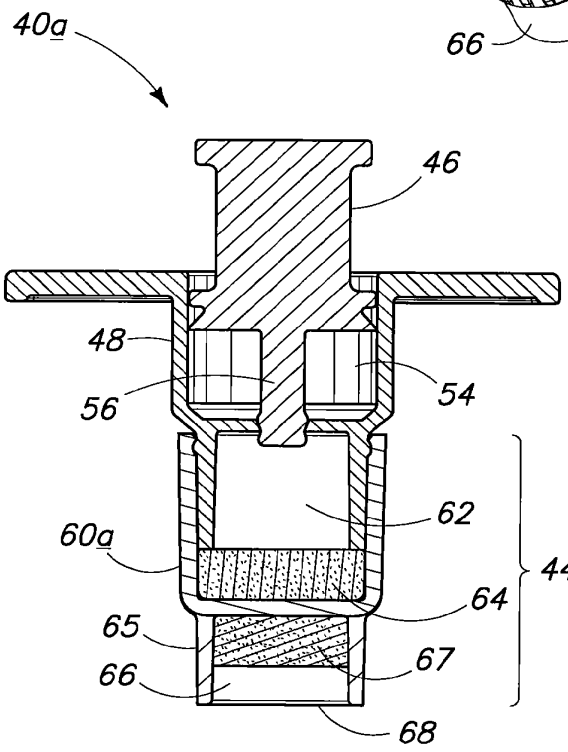

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Fig 13

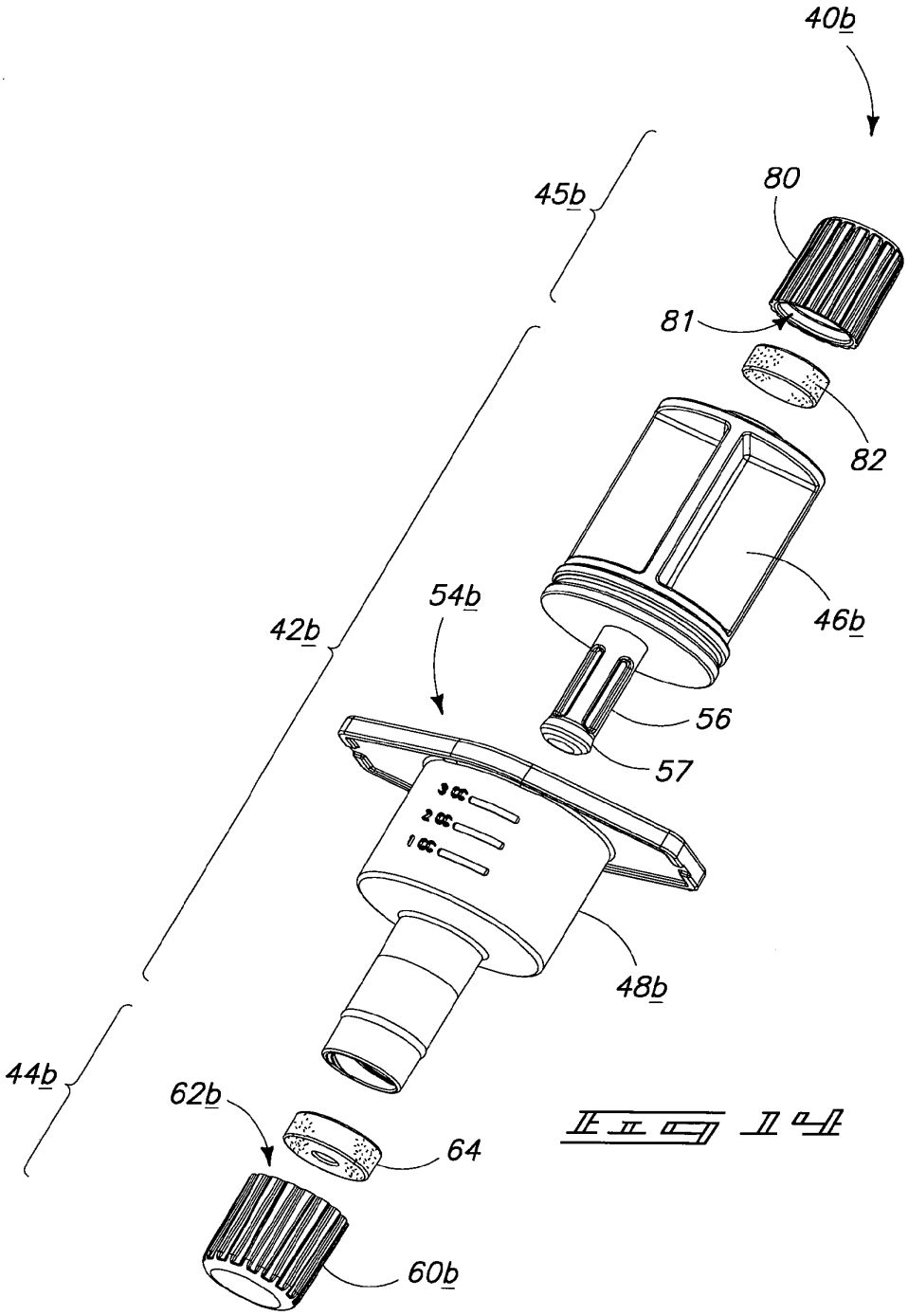


Fig. 11

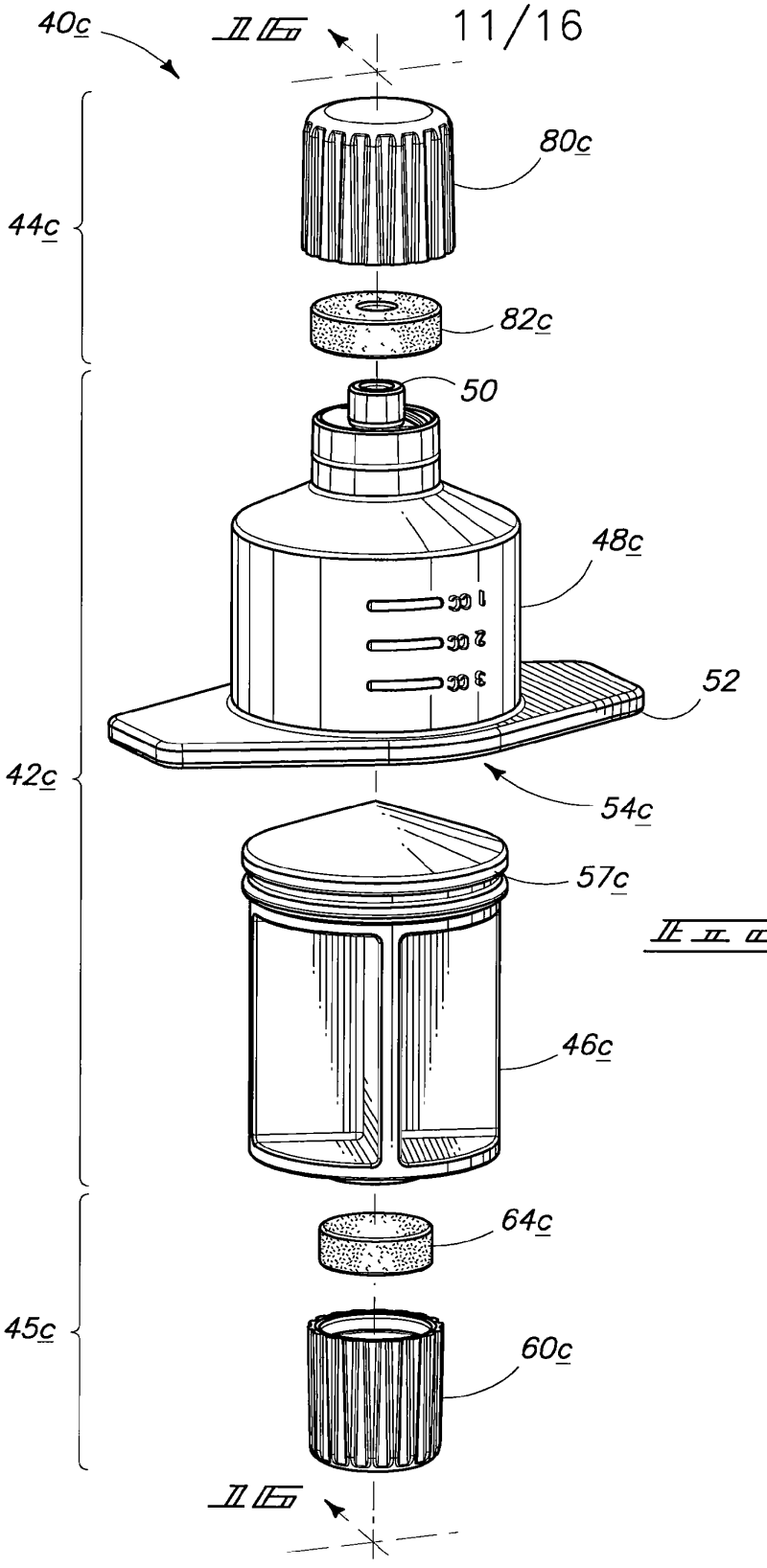


Fig. 15

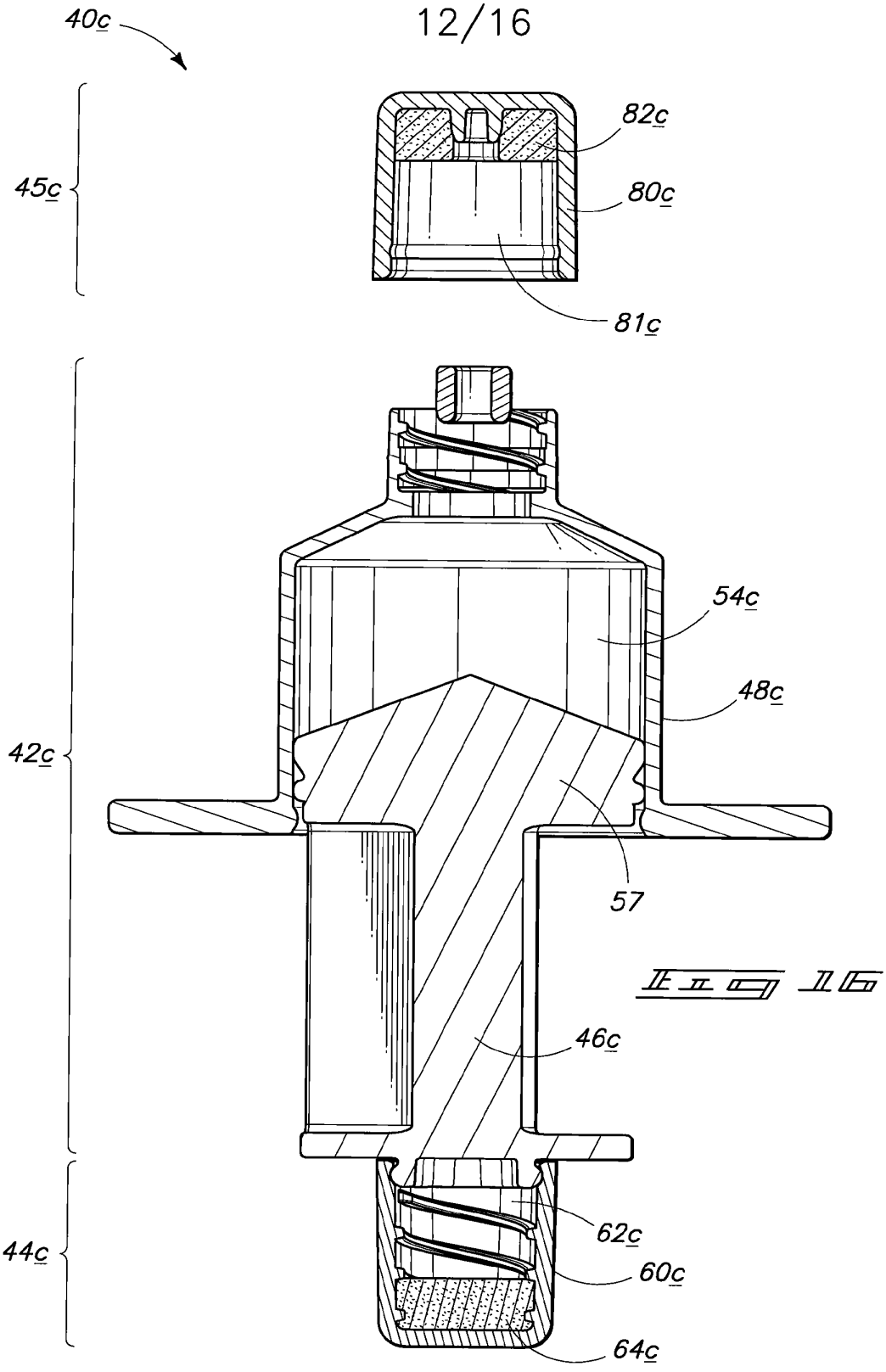


Fig 16

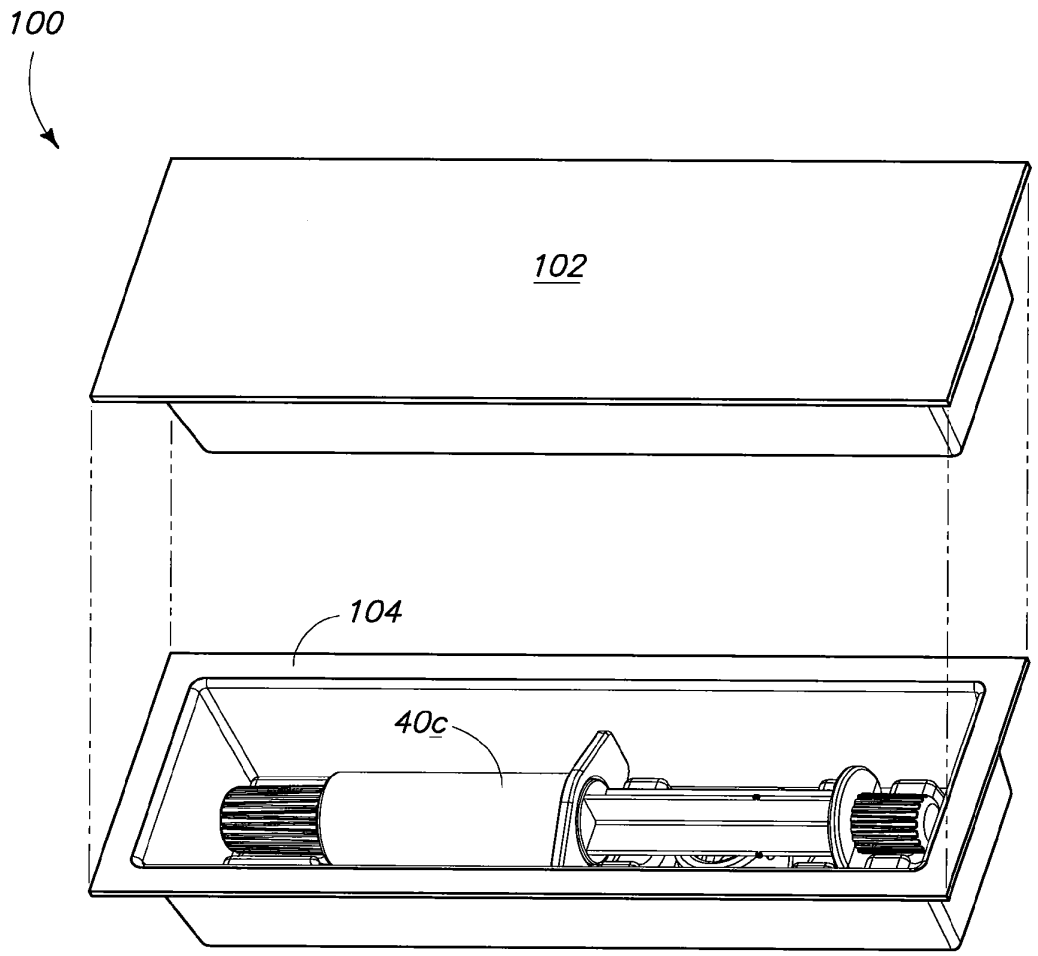


Fig 17

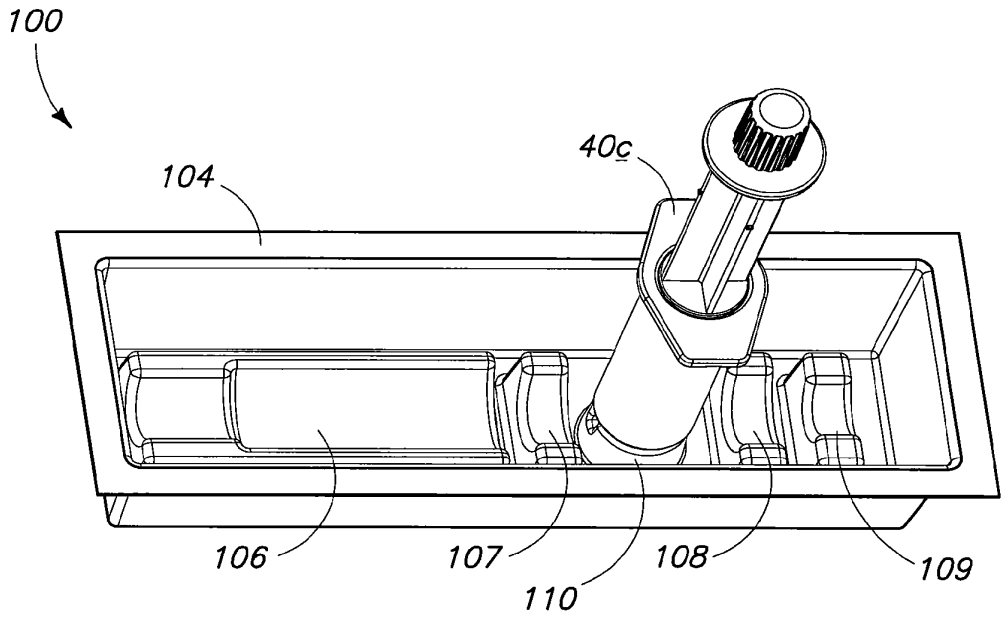


Fig. 18

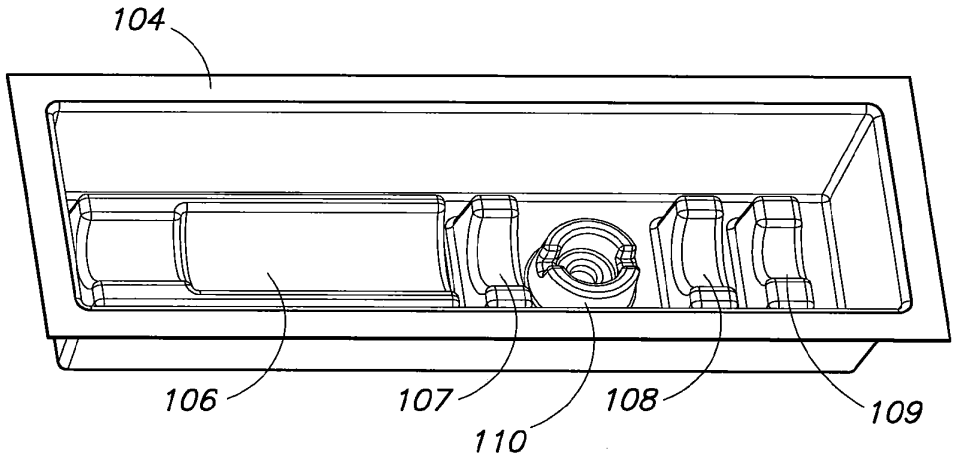


Fig. 19

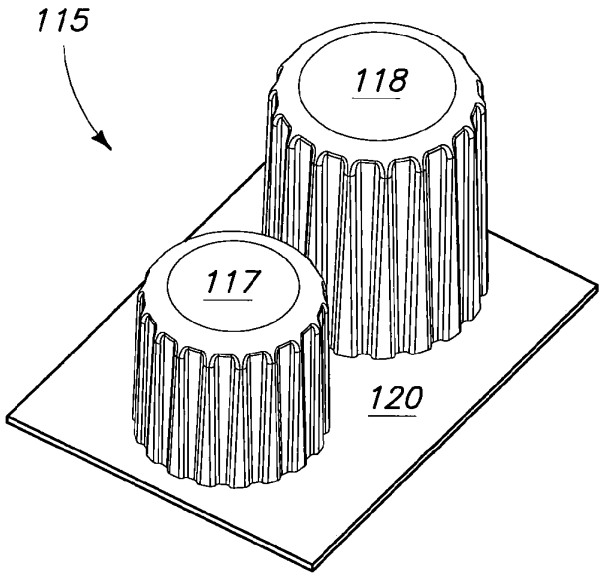


Fig 20

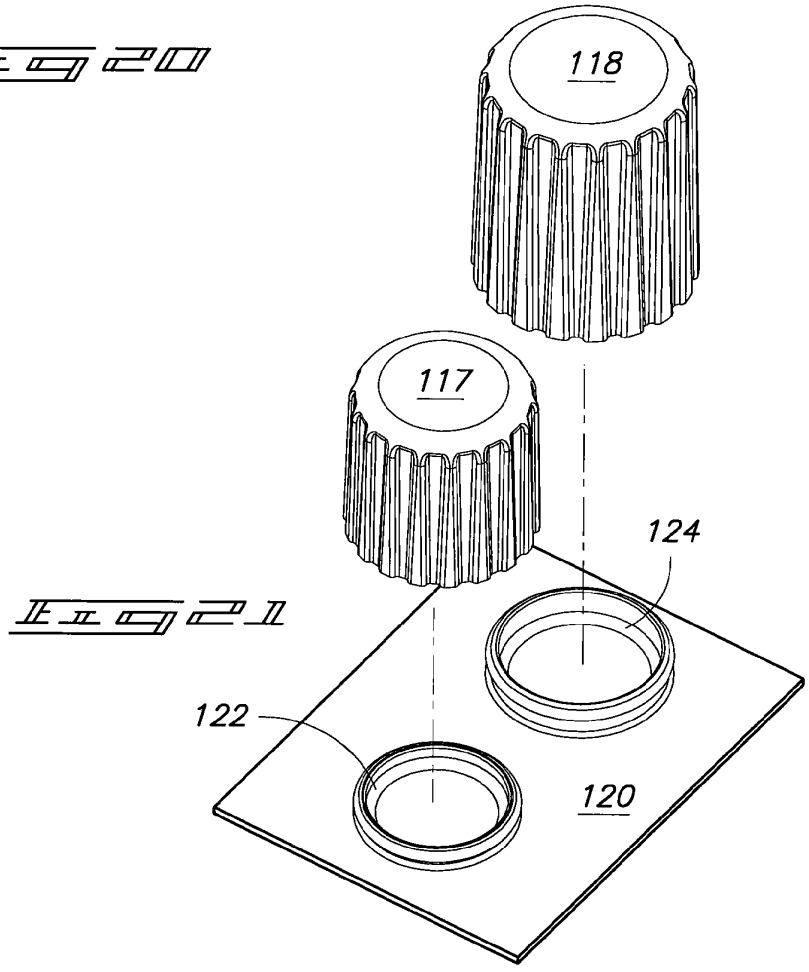


Fig 21

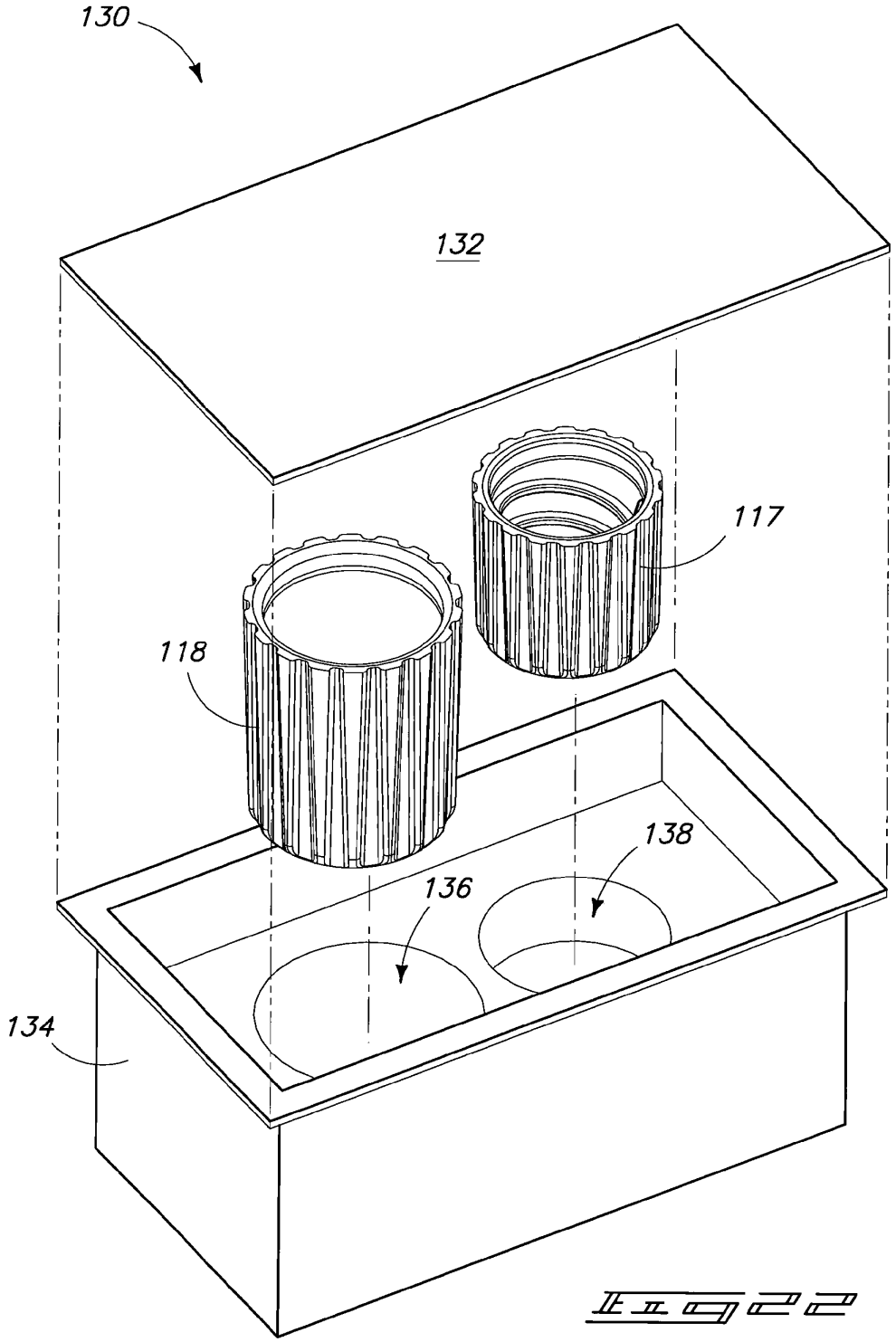


Fig 2

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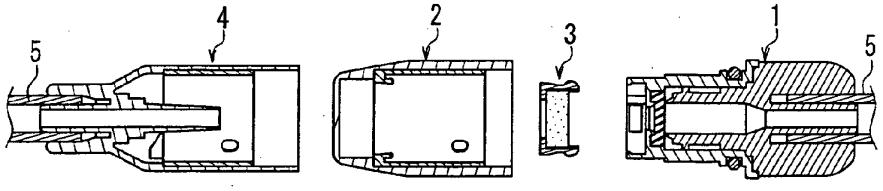
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(54) **CONNECTOR SYSTEM FOR MEDICAL USE**

(57) There are provided a male type connector (1), a protective cap (2), an inner cap (3) that supports a disinfectant-impregnated member therein and is retained in the protective cap, and a female type connector (4) in which an inner cylinder is fixed at an end of an outer cylinder, the inner cylinder including an internal end portion located inside the outer cylinder and an exposed external end portion. The inner cap includes engaging legs at each of which an engaging convexity is formed. A front end portion of the male type connector allows the engaging convexities at the engaging legs to engage therewith from inside. An inner cap retaining portion is formed on an inner wall surface of the protective cap, and a force exerted by the engagement between the inner cap and the male type connector is larger than a force exerted by the inner cap retaining portion to retain the inner cap. When the protective cap with the inner cap retained therein is fitted with the male type connector, and then is removed from the male type connector, the inner cap is retained in the male type connector and is detached from the protective cap. When the male type connector is connected with the female type connector, the internal end portion of the inner cylinder penetrates through the disinfectant-impregnated member, so that a channel is opened. When the connecting and detaching are repeated, the bacterial contamination can be reduced with a simple operation.

FIG. 1A



EP 1 649 890 A1

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Description

Technical Field

[0001] The present invention relates to a medical connector system for connecting a tube or the like that forms a channel for a solution for medical use, for example. In particular, the present invention relates to a medical connector system provided with a function of securely disinfecting a connecting portion with a simple operation when the connecting and detaching are repeated.

Background Art

[0002] Known examples of medical connectors include a connector for connecting a patient side transfer tube (extension tube) with a peritoneal dialysis unit when a dialysis solution for peritoneal dialysis is exchanged. Peritoneal dialysis is a medical treatment method in which a dialysis solution is stored in a patient's abdominal cavity by way of a peritoneal catheter that is implanted surgically in the patient's abdominal cavity beforehand, so that impurities accumulated in the body are filtered using capillary vessels in the peritoneum. The patient undertakes daily activities while a transfer tube (extension tube), which is used continuously for a half year, is connected to the end of the catheter. Then, the patient himself/herself connects a bag containing a dialysis solution with a front end of the transfer tube four times per day to exchange the dialysis solution in the abdominal cavity.

[0003] The most serious problem to be addressed for carrying out the peritoneal dialysis is bacteria in the air or attached to the skin inadvertently entering into the abdominal cavity with the dialysis solution during the operation of exchanging the dialysis solution, which is required four times per day. If bacteria enter into the abdominal cavity, these bacteria cause inflammation of the peritoneum to develop peritonitis.

[0004] Thus, in the peritoneal dialysis, it is important, when the dialysis solution is exchanged, to reduce the bacterial contamination of a connector that connects a transfer tube and a peritoneal dialysis unit. Conventionally, products for connecting tubes by melting with a heated copper plate or for disinfecting a connecting portion with ultraviolet rays are available commercially for preventing the bacterial contamination. However, since these products necessarily require units dedicated to the products, a patient always has to carry the unit. Moreover, in the event of problems with the unit, serious problems might occur.

[0005] Meanwhile, as for connecting members that do not require the units and can prevent the bacterial contamination, various structures have been examined. Examples of those ideas are a structure using a septum, which is pushed open to realize the fitting for connection and a structure where fitting is realized by breaking a film covering a connecting portion (see, for example, U.S. Patent No. 4,610,469 A and JP 6(1994)-312014 A).

[0006] However, all of those connectors known conventionally have problems that their mechanism is complicated, their size is large, and the required functions cannot be obtained sufficiently, and therefore none of them have been put into practical use. In particular, there is no connector that is constructed by paying sufficient attention to the structure for preventing the bacterial contamination when the connecting and detaching are repeated.

[0007] These problems are not peculiar to connectors that connect a tube for peritoneal dialysis but are common to connectors for use in places where the connection between channels for a solution, such as a usual infusion solution, is required.

Disclosure of Invention

[0008] It is an object of the present invention to provide a medical connector system that is capable of reducing the bacterial contamination with a simple operation when a channel for a solution is connected.

[0009] A medical connector system according to the present invention includes: a male type connector including a tube connecting portion at a rear end portion of the male type connector; a protective cap having a substantially cylindrical shape with a closed end and being capable of connecting and disconnecting with/from a front end side of the male type connector; an inner cap including an annular portion that supports a disinfectant-impregnated member in the annular portion, the inner cap being retained inside the protective cap in an initial state; and a female type connector having a double-cylinder structure in which an inner cylinder is fixed at one end portion of an outer cylinder. The inner cylinder includes an internal end portion located inside the outer cylinder and an external end portion that is exposed outside the outer cylinder and is capable of connecting with a tube.

[0010] The inner cap includes a plurality of engaging legs extending from the annular portion in a direction along an axis of the annular portion. An engaging convexity is formed at an outside of a front end portion of each of the engaging legs, the front end portion of the male type connector has a cylindrical shape and includes engaging concavities so as to allow the engaging convexities at the engaging legs to engage with the engaging concavities from inside, and an inner cap retaining portion is formed on an inner wall surface of the protective cap. A force exerted by the engagement between the engaging convexity of the inner cap and the engaging concavity of the male type connector is larger than a force exerted by the inner cap retaining portion to retain the inner cap.

[0011] When the protective cap with the inner cap retained in the protective cap is fitted with the male type connector, the engaging convexities at the engaging legs engage with the engaging concavities of the male type connector. When the protective cap is removed from the

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male type connector, the inner cap is retained at the front end of the male type connector and is detached from the protective cap. When the male type connector with the inner cap retained in the male type connector is connected with the female type connector, the internal end portion of the inner cylinder penetrates through the disinfectant-impregnated member, so that a channel is opened.

Brief Description of Drawings

[0012]

Figure 1A is a front cross-sectional view showing respective elements constituting a medical connector system according to an embodiment of the present invention.

Figures 1B to 1G are front cross-sectional views showing the operation of the medical connector system.

Figure 2A is a perspective view showing a male type connector constituting the medical connector system, Figure 2B is a front view of the same, and Figure 2C is a cross-sectional view of the same.

Figure 3A is a cross-sectional view showing a protective cap constituting the medical connector system.

Figure 3B is a cross-sectional view showing a state where an inner cap is retained in the protective cap.

Figure 4A is a perspective view showing the inner cap constituting the medical connector system, Figure 4B is a plan view of the same, and Figure 4C is a cross-sectional view of the same.

Figure 5A is a cross-sectional view showing a state where the inner cap is fitted with the male type connector constituting the medical connector system, Figure 5B is a front view of the same, and Figure 5C is a cross-sectional view of the same.

Figure 6A is a cross-sectional view showing a female type connector constituting the medical connector system.

Figure 6B is a cross-sectional view showing a state where the inner cap is retained in the female type connector.

Figures 7A to 7E are cross-sectional views for explaining the operation for fitting and detaching the protective cap with/from the male type connector constituting the medical connector system.

Figures 8A to 8E are cross-sectional views for explaining the operation for connecting and disconnecting the male type connector with/from the female type connector constituting the medical connector system.

Description of the Invention

[0013] According to the medical connector system of the present invention having the above configuration, the disinfectant-impregnated member in the inner cap can prevent the bacterial contamination of the front end portion of the male type connector. Further, every time the protective cap is exchanged, the inner cap is exchanged into a new one, and therefore this system can be disinfected by a new disinfectant-impregnated member without a complicated procedure.

[0014] In the medical connector system according to the present invention, preferably, the female type connector includes an inner cap retaining portion, and when the connection between the male type connector and the female type connector is released, the inner cap is retained inside the female type connector by the inner cap retaining portion and is detached from the front end of the male type connector.

[0015] Preferably, the male type connector includes a septum member at the front end portion of the male type connector for shielding an inner cavity, and when the male type connector with the inner cap retained at the front end of the male type connector is connected with the female type connector, the internal end portion of the inner cylinder penetrates through the disinfectant-impregnated member in the inner cap and the septum member of the male type connector, so that a channel is opened.

[0016] Preferably, on an outer surface of the male type connector, a circumferential step portion extending in a circumferential direction is formed so that a diameter at the front end side of the male type connector is smaller than that at a base end side, and a guide groove is formed so as to extend from the circumferential step portion toward the base end, the guide groove including an inclined portion that is inclined with respect to an axis of the male type connector. On the inner wall surface close to an opening end portion of the protective cap, a guide protrusion is formed. When the male type connector is inserted from an opening of the protective cap with the guide protrusion of the protective cap facing the guide groove of the male type connector, and then the protective cap and the male type connector are rotated while being urged axially toward each other, the guide protrusion slides along the guide groove, so that the male type connector is pulled into an inside of the protective cap by a driving force resulting from a screw action by the inclined portion of the guide groove, and the engaging convexities of the inner cap engage with the engaging concavities of the male type connector.

[0017] Preferably, the male type connector includes a blocking protrusion on an inner circumferential surface of the front end portion of the male type connector, which is capable of contacting with a side face portion of the engaging leg of the inner cap when the inner cap is fitted with the male type connector, the outer cylinder of the female type connector includes a guide protrusion formed on an inner wall surface close to an open end portion of the outer cylinder and a guide step portion including an inclined portion that is inclined with respect to an axis of the female type connector, and the inner cap includes protrusions on an outer circumferential surface

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of the annular portion. When the male type connector with the inner cap retained in the male type connector is inserted from an opening of the female type connector with the guide protrusion of the outer cylinder facing the guide groove of the male type connector, and then the female type connector and the male type connector are rotated while being urged axially toward each other, the guide protrusion slides along the guide groove, so that the male type connector is pulled into an inside of the female type connector by a driving force resulting from a screw action by the inclined portion of the guide groove. At the same time the protrusions of the annular portion slide along the inclined portion of the guide step portion of the female type connector while rotation of the engaging legs of the inner cap relative to the male type connector is blocked by the blocking protrusion of the male type connector, so that a force in the axis direction acts on the inner cap so as to separate the inner cap from the male type connector, resulting in release of the engagement between the inner cap and the male type connector, and further the inner cap assumes a state of being retained by the inner cap retaining portion of the outer cylinder.

[0018] Preferably, the inner cap retaining portion of the female type connector is configured with a horizontal step portion provided continuously at an inside of the inclined portion of the guide step portion, and when the protrusions of the annular portion of the inner cap contact with the horizontal step portion, the inner cap is prevented from moving in the axis direction toward the opening of the outer cylinder so as to be retained in the female type connector.

[0019] Preferably, the inner cap retaining portion of the female type connector is configured by setting dimensions of constituting elements so that portions of the inner wall of the outer cylinder contact with the outer circumferential surface of the annular portion of the inner cap or so that portions of an outer wall of the internal end portion of the inner cylinder contact with an inner circumferential surface of the annular portion of the inner cap, whereby the inner cap is retained by the thus exerted frictional force.

[0020] A protective cap assembled member used in the medical connector system having the above configuration includes: the protective cap having a substantially cylindrical shape with a closed end; and the inner cap retained at an inside of the protective cap and including an annular portion with a disinfectant-impregnated member supported in the annular portion. On an inner wall surface of the protective cap, an inner cap retaining portion for retaining the inner cap is formed. The inner cap includes a plurality of engaging legs extending from a circumferential edge portion of the annular portion in a direction along an axis of the annular portion, and an engaging convexity is formed at a front end of each of the engaging legs so as to protrude outward. The inner cap is retained in the inner cap retaining portion so that the front ends of the engaging legs are directed toward an opening of the protective cap.

[0021] The following describes specifically a configuration of a medical connector system according to an embodiment of the present invention with reference to Figures 1A to 1G, Figures 2A to 2C, Figures 3A and 3B, Figures 4A to 4C, Figures 5A to 5C, and Figures 6A and 6B. The description of the present embodiment is given taking as an application example connectors for connecting tubes in peritoneal dialysis.

[0022] As indicated by an exploded view of Figure 1A, this medical connector system includes a male type connector 1, a protective cap 2, an inner cap 3, and a female type connector 4. The male type connector 1 is connected to a front end of an extension tube 5 that leads to a peritoneal catheter implanted in a patient's abdominal cavity, for example. The female type connector 4 is connected to an extension tube 5 as a front end of a circuit in a peritoneal dialysis unit, such as a twin bag, BF, and APD, for example. The inner cap 3 initially is supplied in a state of being retained in the protective cap 2 as shown on the right side of Figure 1B. The inner cap 3 is equipped with a disinfectant-impregnated member, such as a disinfecting sponge impregnated with a disinfectant, which will be described later. The outline of a function of each of the elements constituting this medical connector system will be described below with reference to Figures 1B to 1G.

[0023] The protective cap 2 is fitted with the male type connector 1 when the male type connector 1 is not connected with the female type connector 4, for protecting a front end of the connector. For this purpose, as shown in Figure 1B, the protective cap 2 that retains the inner cap 3 therein is opposed to the male type connector 1, and they are fitted with each other as shown in Figure 1C. In this state, the disinfectant-impregnated member provided in the inner cap 3 covers the front end portion of the male type connector 1 so as to perform a disinfecting function.

[0024] When the male type connector 1 is to be connected with the female type connector 4, firstly, the protective cap 2 is detached and removed from the male type connector 1. In this detachment operation, the inner cap 3 is transferred from the protective cap 2 to the male type connector 1 as shown in Figure 1D. As shown in Figure 1E, the female type connector 4 is opposed to the male type connector 1 and, as shown in Figure 1F, is connected with the male type connector 1, thus forming a channel. As shown in Figure 1G, when the connection between the male type connector 1 and the female type connector 4 is released, the inner cap 3 finally is transferred to the inside of the female type connector 4 in accordance with the operation that will be described later, and is discarded together with the female type connector 4.

[0025] Each of the above constituting elements will be described below in detail. Firstly, the male type connector 1 will be described with reference to Figures 2A to 2C. Figure 2A is a perspective view of the male type connector 1, Figure 2B is a front view of the same, and Figure

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2C is a cross-sectional view of the same.

[0026] A main body of the male type connector 1 is made of resin, has a substantially cylindrical shape, and includes a front end portion 10, a guide portion 11 in the middle, and a base end portion 12 on a rear end side. As shown in Figure 2C, an inner cavity is formed so as to penetrate the front end portion 10, the guide portion 11, and the base end portion 12. Figures 2B and 2C illustrate the male type connector 1 in a state rotated around the axis of the main body by 90° from the state shown in Figure 2A.

[0027] A septum member 13 such as a rubber septum (with a slit) is fitted with the front end portion 10 so as to shield and protect a channel formed by the inner cavity and ensure liquid-tightness. Note here that the septum 13 is effective for ensuring liquid-tightness in the connecting state with the female type connector 4, but this element is not essential. Therefore, the liquid-tight seal may be ensured by other methods. At a boundary portion between the guide portion 11 and the base end portion 12, an annular groove 14 and a flange 15 are formed, and an O ring 14a is mounted on the annular groove 14 (not illustrated in Figure 2A).

[0028] In the front end portion 10, a concavity 101 is formed so as to hold the inner cap 3 therein. A pair of engaging holes 102 are provided on a side wall of the front end portion 10. These engaging holes 102 are used to lock the inner cap 3. This operation will be described later. Blocking protrusions 103 are formed adjacent to the respective engaging holes 102.

[0029] A guide groove 111 is formed on an outer circumferential surface of the guide portion 11. A pair of the guide grooves 111 are provided symmetrically with respect to the axis of the main body, and one of the guide grooves 111 is located on the reverse side of Figure 2A. The pair of guide grooves 111 are not necessarily required, and only one guide groove may function sufficiently. The guide groove 111 includes an axis direction portion 111a extending in the axis direction of the main body, an inclined portion 111b that is inclined, and a circumferential portion 111c extending along the circumferential direction. In the circumferential portion 111c, a locking convex stripe 111d is formed so as to separate a trailing end portion 111e of the guide groove 111. The front end portion 10 has a smaller outer diameter than that of the guide portion 11, so that an annular step portion 112 extending in the circumferential direction is formed on an outer surface of a boundary between the front end portion 10 and the guide portion 11. A front end of the axis direction portion 111a of the guide groove 111 leads to the annular step portion 112.

[0030] In the base end portion 12, a tube-shaped tube connecting portion 121 is formed for the connection with the extension tube (not illustrated). A protective cylinder 122 is formed around the tube connecting portion 121, and a knob 123 is provided on either side of the protective cylinder 122. The knob 123 is used for supporting firmly when the male type connector 1 is rotated.

[0031] In the present embodiment, as shown in Figure 2C, the base end portion 12 is formed separately from the front end portion 10 and the guide portion 11 with a part thereof being fitted with an inner cavity of the guide portion 11. This structure constitutes means for supporting the septum 13 in the front end portion 10. More specifically, the septum 13 is interposed between a flange-shaped septum supporting portion 104 formed in an inner cavity of the front end portion 10 and a pressing end 124 of the base end portion 12. A hook portion 105 is formed on an inner circumferential edge of the septum supporting portion 104 for engaging with a step portion formed on a surface of the septum 13 to suppress the deformation of the septum 13. The septum supporting portion 104 preferably has this structure for convenience in resin molding, but other structures also may be adopted for supporting the septum 13.

[0032] Next, the protective cap 2 will be described with reference to the cross-sectional views shown in Figures 3A and 3B. Figure 3A shows a state where the inner cap is not retained, and Figure 3B shows a state where the inner cap is retained. The protective cap 2 is made of resin and has a hollow structure with a substantially cylindrical shape whose front end is closed. On an inner wall surface close to an opening 20 of the protective cap 2, a guide protrusion 21 is formed. Although a pair of the guide protrusions 21 are provided symmetrically, only one of them is illustrated in the figures. On an inner circumferential surface on the closed end side of the protective cap 2, a retaining detent 22 is formed, where the inner cap 3 is retained as shown in Figure 3B.

[0033] When the male type connector 1 is inserted from the opening 20 of the protective cap 2, the guide protrusion 21 engages with the guide groove 111 in the male type connector 1, and a guiding function for adjusting a mutual positional relationship between the protective cap 2 and the male type connector 1 is obtained by the engagement. This operation will be described later.

[0034] Next, the inner cap 3 will be described with reference to Figures 4A to 4C. Figure -4A is a perspective view of the inner cap 3, Figure 4B is a front view of the same, and Figure 4C is a cross-sectional view of the same taken along a line A-A in Figure 4B. The inner cap 3 is made of resin and includes an annular portion 30 and two engaging legs 31. On an outer circumferential surface of the annular portion 30, a pair of protrusions 32 are formed between the pair of engaging legs 31 in the circumferential direction. A step portion 32a is formed on one side of the protrusion 32. At a front end of each of the engaging legs 31, an engaging convexity 33 is formed so as to protrude outward.

[0035] Inside the annular portion 30, a disinfecting sponge 34 is installed (illustrated only in Figures 4B and 4C and not illustrated in Figure 4A). The disinfecting sponge 34 is arranged so as to shield an opening 30a of the annular portion 30 and is fixed to a flange 30b of the annular portion 30 by ultrasonic welding, for example. A straight-line or cross-shaped slit (not illustrated) is pro-

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vided in the disinfecting sponge 34 so that an internal end portion 41b of the female type connector 4, which will be described later, can penetrate therethrough, and the disinfecting sponge 34 is impregnated with a disinfectant such as povidone iodine.

[0036] As previously described, the inner cap 3 initially is held in the protective cap 2 as shown in Figure 3B. The annular portion 30 of the inner cap 3 is held tight by the retaining detent 22, so that the inner cap 3 is retained by the frictional engagement therebetween. When the protective cap 2 is fitted with the male type connector 1, the engaging convexities 33 of the engaging legs 31 slide on an inner circumferential surface of the front end portion 10 of the male type connector 1 while the protective cap 2 and the male type connector 1 are rotated relative to each other. In order to prevent the retaining of the inner cap 3 by the retaining detent 22 of the protective cap 2 from being released by the frictional force exerted when the engaging convexities 33 slide on the inner circumferential surface of the front end portion 10, a force to retain the inner cap 3 is required to be set properly. Preferably, a rotation-blocking portion is provided in the protective cap 2 so as to block the rotation of the inner cap 3 by contacting with the step portions 32a formed of the protrusions 32 of the inner cap 3.

[0037] Figures 5A to 5C show a state where the inner cap 3 is retained in the front end portion 10 of the male type connector 1. In a state where the protective cap 2 is fitted with the male type connector 1, the engaging convexities 33 of the engaging legs 31 of the inner cap 3 engage with the engaging holes 102 in the front end portion 10 of the male type connector 1. This engagement allows the inner cap 3 to be retained in the front end portion 10. The engaging holes 102 are not necessarily through holes, and recessed portions may be available that are formed so that the engaging convexities 33 of the inner cap 3 can engage therewith.

[0038] As stated above, the inner cap 3 is retained in the protective cap 2 by the frictional engagement with the retaining detent 22 of the protective cap 2. Further, the engagement between the engaging holes 102 of the male type connector 1 and the engaging convexities 33 of the inner cap 3 allows the inner cap 3 to be retained in the male type connector 1. A force exerted by the engaging holes 102 of the male type connector 1 to retain the inner cap 3 is set to be larger than a force exerted by the retaining detent 22 of the protective cap 2 to retain the inner cap 3.

[0039] Next, the female type connector 4 will be described with reference to the cross-sectional views shown in Figures 6 A and 6B. Figure 6A shows a state where the inner cap is not retained, and Figure 6B shows a state where the inner cap is retained.

[0040] The female type connector 4 has a double-cylinder structure including an outer cylinder 40 and an inner cylinder 41 made of resin, the inner cylinder 41 being fixed at one end portion of the outer cylinder 40. The outer cylinder 40 has an opening 42 on the opposite side to the side where the inner cylinder 41 is fixed, to define a front end portion of the female type connector 4. The inner cylinder 41 includes an external end portion 41a exposed outside the outer cylinder 40 and an internal end portion 41b located inside the outer cylinder 40. The external end portion 41a is capable of connecting with the tube as a front end of a circuit in a peritoneal dialysis unit, for example. The external end portion 41a is surrounded by a protective cylinder 40a, which is formed of protruding one end portion of the outer cylinder 40. On either side of an outer circumferential surface of the protective cylinder 40a, a knob is formed in the same manner as the knob 123 in the male type connector 1, which is not illustrated in Figures 6A and 6B. When the female type connector 4 is connected with the male type connector 1, the internal end portion 41b pushes and expands the slit in the disinfecting sponge 34 in the inner cap 3 fitted at the front end of the male type connector 1 and the slit in the rubber septum 13 supported in the front end portion 10 so as to penetrate through the male type connector 1, whereby the channel is opened.

[0041] On an inner wall close to the opening 42 of the outer cylinder 40, a guide protrusion 43 is formed. The guide protrusion 43 has the same shape and function as those of the guide protrusion 21 formed in the protective cap 2. On an inner wall at an inside of the outer cylinder 40, a guide step portion 44 is formed. The guide step portion 44 includes an inclined portion 44a inclined with respect to the axis direction of the outer cylinder 40, and a horizontal step portion 44b that is orthogonal to the axis direction. The horizontal step portion 44b functions as means for retaining the inner cap 3 at the inside of the outer cylinder 40. That is, when the inner cap 3 is pushed into the inside of the outer cylinder 40, and the protrusions 32 contact with the horizontal step portion 44b, the inner cap 3 is retained in this state. The operation for the same will be described later.

[0042] Means for retaining the inner cap 3 may be configured so that portions of an inner wall of the inside of the outer cylinder 40 contact with an outer circumferential surface of the annular portion 30 of the inner cap 3, whereby the inner cap 3 is retained by the thus exerted frictional force. Alternatively, an outer circumferential surface of the inner cylinder 41 may be configured so as to contact with an inner circumferential surface of the flange 30b of the inner cap 3, whereby the inner cap 3 is retained by the thus exerted frictional force.

[0043] In Figures 6A and 6B, the guide protrusion 43 and the guide step portion 44 are formed on a member separated from a wall material of the outer cylinder 40. Although this structure may be preferable for convenience in resin molding, the guide protrusion 43 and the guide step portion 44 may be formed on the wall material of the outer cylinder 40 integrally. Further, preferably, in a state before use, a breakable film (not illustrated) is provided at a front end portion of the outer cylinder 40 of the female type connector 4 for protecting the inner cylinder and the channel in the female type connector 4 until

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immediately before use.

[0044] Next, the operation of the medical connector system having the above configuration will be described below.

[0045] Firstly, the operation for fitting the protective cap 2 with the male type connector 1 and further detaching the protective cap 2 from the male type connector 1 will be described with reference to Figures 7A to 7E. For the details of the structures of the male type connector 1, the protective cap 2, and the inner cap 3, see Figures 2A to 2C, Figures 3A and 3B, and Figures 4A to 4C, respectively.

[0046] Figures 7A to 7D show states at respective angular positions during an operation in which the male type connector 1 is rotated while the protective cap 2 is fixed. The male type connector 1 in Figure 7A is at the angular position in Figure 2A. From this state, by rotating the male type connector 1 by 90° clockwise when viewed from the base end side, the state of Figure 7D is obtained. Figure 7E shows a state where the protective cap 2 is rotated by 90° from the state shown in Figure 7D.

[0047] To begin with, as shown in Figure 7A, the protective cap 2 that retains the inner cap 3 therein is opposed to the male type connector 1, and then as shown in Figure 7B, the male type connector 1 is inserted into the protective cap 2. During this operation, the guide protrusion 21 formed on the inner wall surface of the protective cap 2 contacts with the annular step portion 112 on the outer circumferential surface of the male type connector 1 (see Figures 2A to 2C, Figures 3A and 3B, and Figures 4A to 4C).

[0048] By rotating the male type connector 1 relative to the protective cap 2, the guide protrusion 21 slides along the annular step portion 112, so that the guide protrusion 21 faces a position of the axis direction portion 111a of the guide groove 111. With this operation, the male type connector 1 becomes capable of being inserted further into the protective cap 2. From this position, as shown in Figure 7C, the male type connector 1 is pushed inside, while being rotated clockwise. Accordingly, the guide protrusion 21 slides along the inclined portion 111b of the guide groove 111. With this operation, by a screw action through the engagement between the guide protrusion 21 and the guide groove 111, the male type connector 1 is pulled into the innermost part of the protective cap 2. By rotating further, the guide protrusion 21 enters into the circumferential portion 111c, and goes further beyond the locking convex stripe 111d to reach the trailing end portion 111e. As a result, by the engagement between the guide protrusion 21 and the trailing end portion 111e, the protective cap 2 and the male type connector 1 are combined so as not to separate from each other in the axis direction.

[0049] During this operation, the engaging legs 31 of the inner cap 3 enter into the concavity 101 in the front end portion 10 of the male type connector 1. Since the inner cap 3 is retained by the retaining detent 22 of the protective cap 2, the engaging convexities 33 of the engaging legs 31 slide on the inner circumferential surface of the front end portion 10 of the male type connector 1. Finally, as shown in Figure 7D, the engaging convexities 33 engage with the engaging holes 102 of the male type connector 1, thus establishing the connection. In this state, the disinfecting sponge 34 supported in the inner cap 3 disinfects the front end portion of the male type connector 1. In addition, since an inner circumferential surface at the open end of the protective cap 2 contacts with the O ring 14a, the liquid-tightness inside the protective cap 2 can be maintained and the front end of the male type connector 1 can be protected from the air.

[0050] From the state shown in Figure 7D, by rotating the protective cap 2 relative to the male type connector 1 opposite to the direction for the connection, the inner cap 3 rotates with respect to the protective cap 2 together with the male type connector 1 by the engagement between the engaging convexities 33 and the engaging holes 102 of the male type connector 1. With this rotation, the guide protrusion 21 of the protective cap 2 slides along the guide groove 111 and reaches the axis direction portion 111a. From this state, by separating the male type connector 1 from the protective cap 2 in the axis direction, the male type connector 1 is removed from the protective cap 2 while the inner cap 3 is fitted with the front end of the male type connector 1 so as to assume a state shown in Figure 7E.

[0051] Next, the operation for connecting the male type connector 1 and the female type connector 4 will be described below with reference to Figures 8A to 8E. For the details of the structures of the male type connector 1, the inner cap 3, and the female type connector 4, see Figures 2A to 2C, Figures 4A to 4C, and Figures 6A and 6B, respectively.

[0052] Figures 8A to 8D show states at respective angular positions during an operation in which the female type connector 4 is rotated while the male type connector 1 is fixed in the same angle as shown in Figure 7E. The female type connector 4 of Figure 8A is illustrated in the angle of Figures 6A and 6B. By rotating the female type connector 4 by 90° clockwise when viewed from the side of the internal end portion 41b, the state of Figure 8D is obtained. Figure 8E shows a state where the male type connector 1 is rotated by 90° counterclockwise when viewed from the side of the tube connecting portion 121 from the state shown in Figure 8D.

[0053] Firstly, as shown in Figure 8A, the male type connector 1 and the female type connector 4 are opposed to each other. In this state, the inner cap 3 is fitted with the front end of the male type connector 1. Next, as shown in Figure 8B, the male type connector 1 is inserted into the outer cylinder 40 of the female type connector 4. In this operation, the guide protrusion 43 formed on the inner wall surface of the female type connector 4 contacts with the annular step portion 112 on the outer circumferential surface of the male type connector 1. The female type connector 4 is rotated properly so that the guide protrusion 43 faces the axis direction portion 111a of the

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guide groove 111 of the male type connector 1, whereby the male type connector 1 becomes capable of being inserted further into the female type connector 4. Since the engaging legs 31 of the inner cap 3 are located in the concavity 101 in the front end portion 10 of the male type connector 1, the engaging legs 31 do not protrude from the outer circumferential surface of the male type connector 1. Therefore, when the male type connector 1 is inserted into the outer cylinder 40 of the female type connector 4, less interference occurs with the inner wall surface of the outer cylinder 40, so that a smooth inserting or rotating operation can be realized.

[0054] In order to insert the male type connector 1 into an inside, the male type connector 1 is pushed inward, while rotating the female type connector 4 clockwise. With this operation, the guide protrusion 43 slides along the inclined portion 111b of the guide groove 111. According to a screw action generated between the guide protrusion 43 and the guide groove 111, the male type connector 1 reaches the innermost part of the female type connector 4 as shown in Figure 8C. In this state, the protrusions 32 of the inner cap 3 that is fitted with the front end portion of the male type connector 1 are located on the right side of the inclined portion 44a of the guide step portion 44 shown in Figure 6A in the circumferential direction.

[0055] By rotating further, the guide protrusion 43 enters into the circumferential portion 111c. During the process of the guide protrusion 43 sliding along the circumferential portion 111c, the protrusions 32 provided in the annular portion 30 of the inner cap 3 contact with the inclined portion 44a. By the rotational force exerted through the contact between the side surfaces of the engaging legs 31 and the blocking protrusions 103 of the male type connector 1, the protrusions 32 slide along the inclined portion 44a. Thereby, the inner cap 3 receives a force in the axis direction toward an inside of the female type connector 4 from the inclined portion 44a. As a result, as shown in Figure 8D, the engagement between the engaging convexities 33 formed at the engaging legs 31 of the inner cap 3 and the engaging holes 102 of the male type connector 1 is released. Finally, the protrusions 32 of the inner cap 3 reach the horizontal step portion 44b of the guide step portion 44 of the female type connector 4. The inner cap 3 is retained in the female type connector 4 in this state. That is to say, when the male type connector 1 is rotated counterclockwise as described later to release the connection between the male type connector 1 and the female type connector 4, the inner cap 3 is not rotated because the engagement between the engaging holes 102 and the engaging convexities 33 has been released. Moreover, since the protrusions 32 of the inner cap 3 and the horizontal step portion 44b are engaged, the inner cap 3 does not move in the axis direction so as to be detached from the female type connector 4.

[0056] In addition, when the female type connector 4 and the male type connector 1 are connected as described above, the internal end portion 41b of the inner cylinder 41 of the female type connector 4 pushes and expands the slit in the disinfecting sponge 32 in the inner cap 3 and the slit in the septum 13 supported in the front end portion 10 of the male type connector 1 so as to penetrate through the male type connector 1, whereby the channel is opened. In this process, the inner cylinder 41 of the female type connector 4 is disinfected by the disinfecting sponge 32.

[0057] When the connection between the female type connector 4 and the male type connector 1 is released, the male type connector 1 is rotated counterclockwise. With this operation, the engagement between the guide protrusion 43 and the guide groove 111 is released, and therefore both connectors can be separated in the axis direction. In this operation, as described above, the inner cap 3 is left in the female type connector 4 (Figure 8E).

[0058] After that, by fitting a newly-prepared protective cap 2 with the male type connector 1, a new inner cap 3 is fitted with the front end of the male type connector 1, whereby as stated above the front end portion of the male type connector 1 continues to be disinfected.

Industrial Applicability

[0059] According to the medical connector system of the present invention, the disinfectant-impregnated member in the inner cap prevents the contamination of the front end portion of the male type connector. Further, every time the protective cap is exchanged, the inner cap is exchanged into a new one, and therefore this system can be disinfected by a new disinfectant-impregnated member at times without a complicated procedure. Therefore, this system is suitable as a connector for connecting a channel for peritoneal dialysis, infusion, and the like.

Claims

1. A medical connector system comprising:

   a male type connector including a tube connecting portion at a rear end portion of the male type connector;
   a protective cap having a substantially cylindrical shape with a closed end and being capable of connecting and disconnecting with/from a front end side of the male type connector;
   an inner cap including an annular portion that supports a disinfectant-impregnated member in the annular portion, the inner cap being retained inside the protective cap in an initial state; and
   a female type connector having a double-cylinder structure in which an inner cylinder is fixed at one end portion of an outer cylinder, the inner cylinder including an internal end portion located inside the outer cylinder and an external end por-

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tion that is exposed outside the outer cylinder and is capable of connecting with a tube,
wherein the inner cap includes a plurality of engaging legs extending from the annular portion in a direction along an axis of the annular portion,
an engaging convexity is formed on an outer surface of a front end portion of each of the engaging legs,
the front end portion of the male type connector has a cylindrical shape and includes engaging concavities so as to allow the engaging convexities at the engaging legs to engage with the engaging concavities from inside,
an inner cap retaining portion is formed on an inner wall surface of the protective cap, and
a force exerted by the engagement between the engaging convexity of the inner cap and the engaging concavity of the male type connector is larger than a force exerted by the inner cap retaining portion to retain the inner cap,
when the protective cap with the inner cap retained in the protective cap is fitted with the male type connector, the engaging convexities at the engaging legs engage with the engaging concavities of the male type connector,
when the protective cap is removed from the male type connector, the inner cap is retained at the front end of the male type connector and is detached from the protective cap, and
when the male type connector with the inner cap retained in the male type connector is connected with the female type connector, the internal end portion of the inner cylinder penetrates through the disinfectant-impregnated member, so that a channel is opened.

2. The medical connector system according to claim 1, wherein the female type connector includes an inner cap retaining portion, and
when the connection between the male type connector and the female type connector is released, the inner cap is retained inside the female type connector by the inner cap retaining portion and is detached from the front end of the male type connector.

3. The medical connector system according to claim 1, wherein the male type connector includes a septum member at the front end portion of the male type connector for shielding an inner cavity, and
when the male type connector with the inner cap retained at the front end of the male type connector is connected with the female type connector, the internal end portion of the inner cylinder penetrates through the disinfectant-impregnated member in the inner cap and the septum member of the male type connector, so that a channel is opened.

4. The medical connector system according to claim 2, wherein on an outer surface of the male type connector, a circumferential step portion extending in a circumferential direction is formed so that a diameter at the front end side of the male type connector is smaller than that at a base end side, and a guide groove is formed so as to extend from the circumferential step portion toward the base end, the guide groove including an inclined portion that is inclined with respect to an axis of the male type connector,
on the inner wall surface close to an opening end portion of the protective cap, a guide protrusion is formed, and
when the male type connector is inserted from an opening of the protective cap with the guide protrusion of the protective cap facing the guide groove of the male type connector, and then the protective cap and the male type connector are rotated while being urged axially toward each other, the guide protrusion slides along the guide groove, so that the male type connector is pulled into an inside of the protective cap by a driving force resulting from a screw action by the inclined portion of the guide groove, and the engaging convexities of the inner cap engage with the engaging concavities of the male type connector.

5. The medical connector system according to claim 4, wherein the male type connector includes a blocking protrusion on an inner circumferential surface of the front end portion of the male type connector, which is capable of contacting with a side face portion of the engaging leg of the inner cap when the inner cap is fitted with the male type connector,
the outer cylinder of the female type connector includes a guide protrusion formed on an inner wall surface close to an open end portion of the outer cylinder and a guide step portion including an inclined portion that is inclined with respect to an axis of the female type connector,
the inner cap includes protrusions on an outer circumferential surface of the annular portion, and
when the male type connector with the inner cap retained in the male type connector is inserted from an opening of the female type connector with the guide protrusion of the outer cylinder facing the guide groove of the male type connector, and then the female type connector and the male type connector are rotated while being urged axially toward each other, the guide protrusion slides along the guide groove, so that the male type connector is pulled into an inside of the female type connector by a driving force resulting from a screw action by the inclined portion of the guide groove, and at the same time the protrusions of the annular portion slide along the inclined portion of the guide step portion of the female type connector while rotation of the engaging legs of the inner cap relative to the male type connector is blocked by the blocking protrusion of the male type connector, so that a force in the axis direction acts

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on the inner cap so as to separate the inner cap from the male type connector, resulting in release of the engagement between the inner cap and the male type connector, and the inner cap assumes a state of being retained by the inner cap retaining portion of the outer cylinder.

6. The medical connector system according to claim 5, wherein the inner cap retaining portion of the female type connector is configured with a horizontal step portion provided continuously at an inside of the inclined portion of the guide step portion, and
when the protrusions of the annular portion of the inner cap contact with the horizontal step portion, the inner cap is prevented from moving in the axis direction toward the opening of the outer cylinder so as to be retained in the female type connector.

7. The medical connector system according to claim 5, wherein the inner cap retaining portion of the female type connector is configured by setting dimensions of constituting elements so that portions of the inner wall of the outer cylinder contact with the outer circumferential surface of the annular portion of the inner cap or so that portions of an outer wall of the internal end portion of the inner cylinder contact with an inner circumferential surface of the annular portion of the inner cap, whereby the inner cap is retained by the thus exerted frictional force.

8. A protective cap assembled member used in the medical connector system according to claim 1, comprising:

the protective cap having a substantially cylindrical shape with a closed end; and
the inner cap retained at an inside of the protective cap and including an annular portion with a disinfectant-impregnated member supported in the annular portion,
wherein on an inner wall surface of the protective cap, an inner cap retaining portion for retaining the inner cap is formed,
the inner cap includes a plurality of engaging legs extending from a circumferential edge portion of the annular portion in a direction along an axis of the annular portion, and an engaging convexity is formed at a front end of each of the engaging legs so as to protrude outward, and
the inner cap is retained in the inner cap retaining portion so that the front ends of the engaging legs are directed toward an opening of the protective cap.

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FIG. 1A

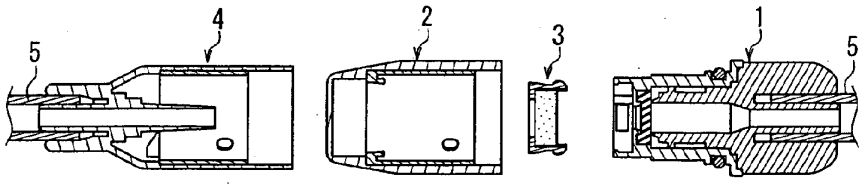


FIG. 1B

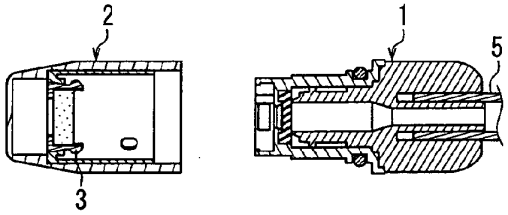


FIG. 1C

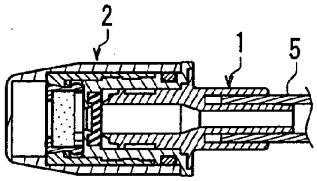


FIG. 1D

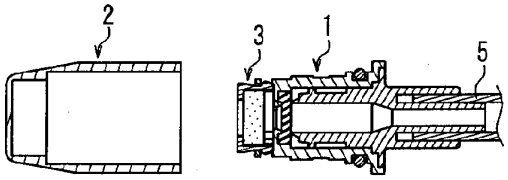


FIG. 1E

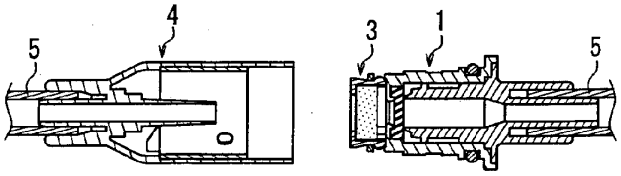


FIG. 1F

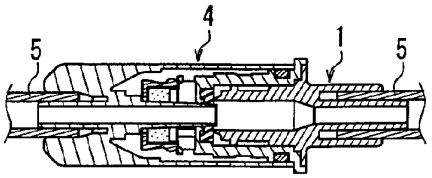
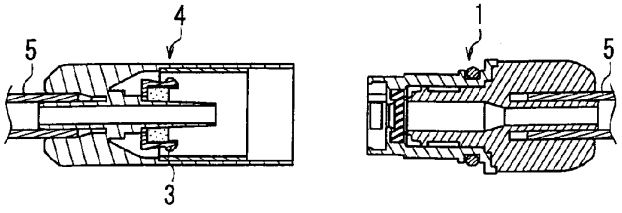


FIG. 1G



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FIG. 2A

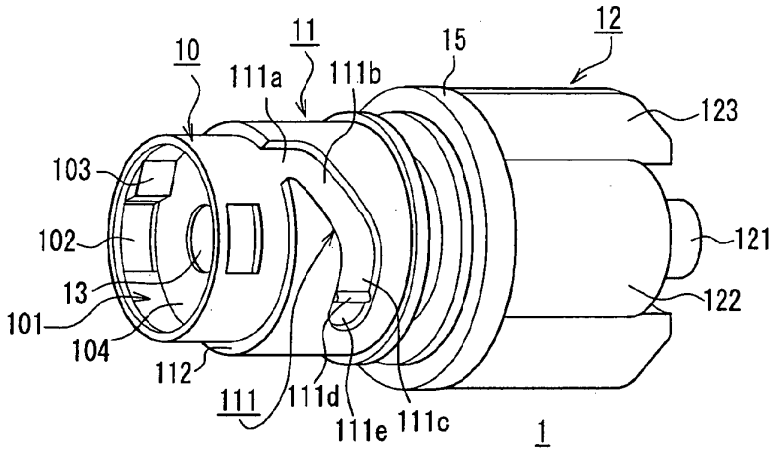


FIG. 2B

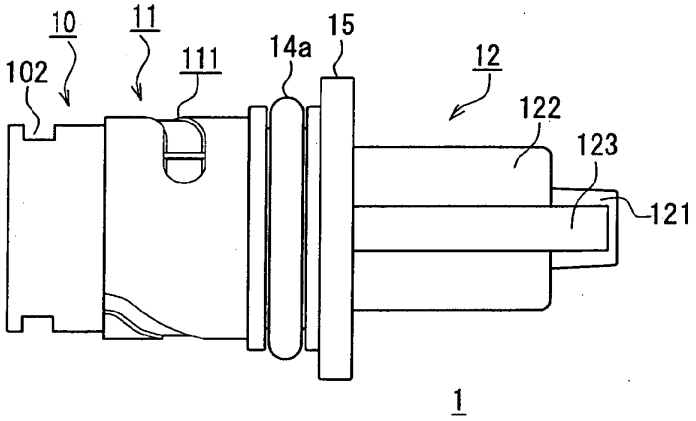
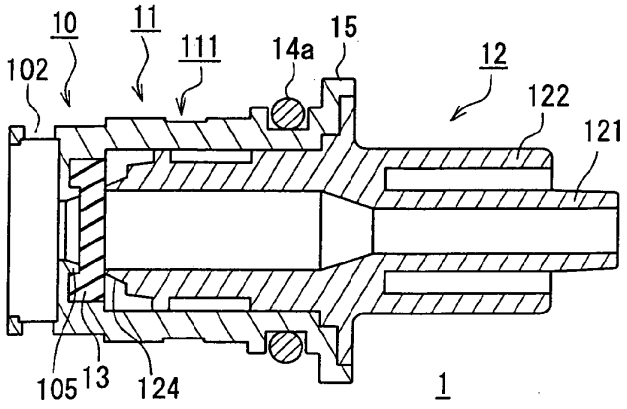


FIG. 2C



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FIG. 3A

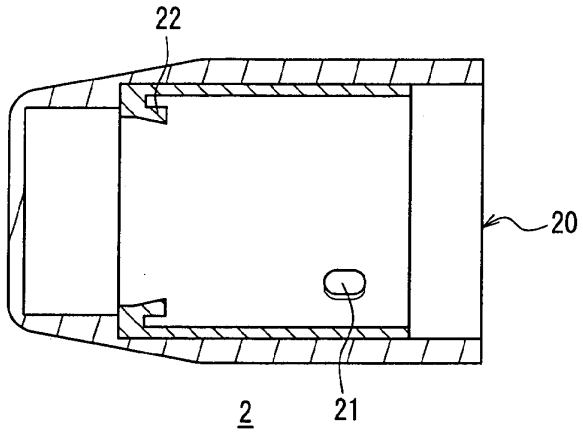
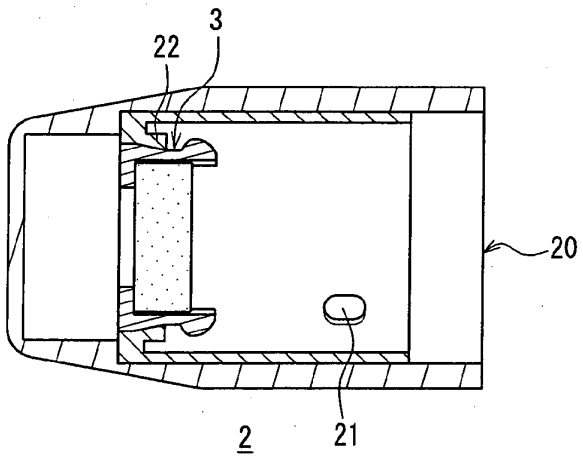


FIG. 3B



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FIG. 4A

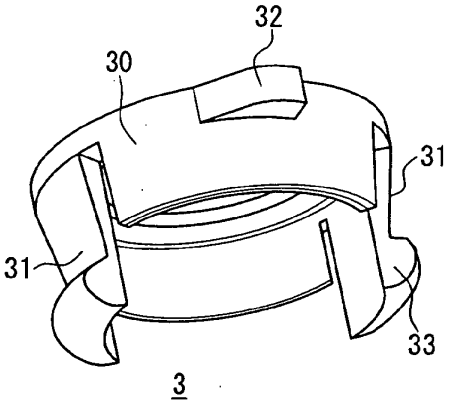


FIG. 4B

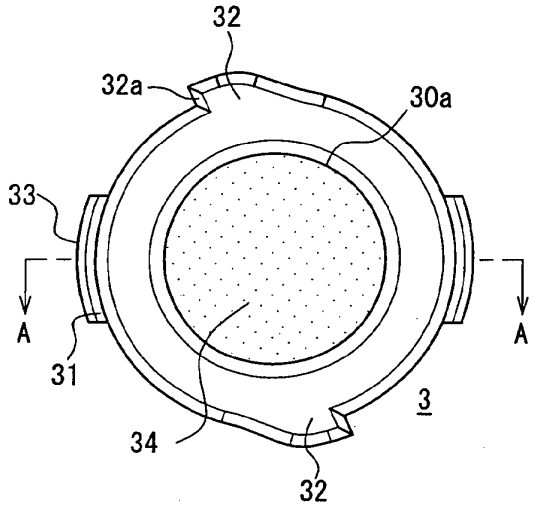
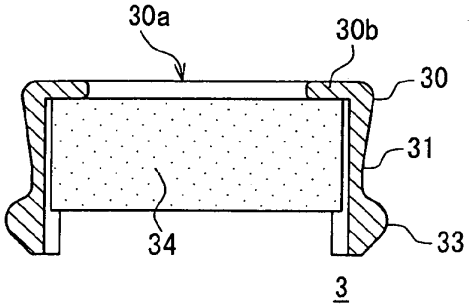


FIG. 4C



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FIG. 5A

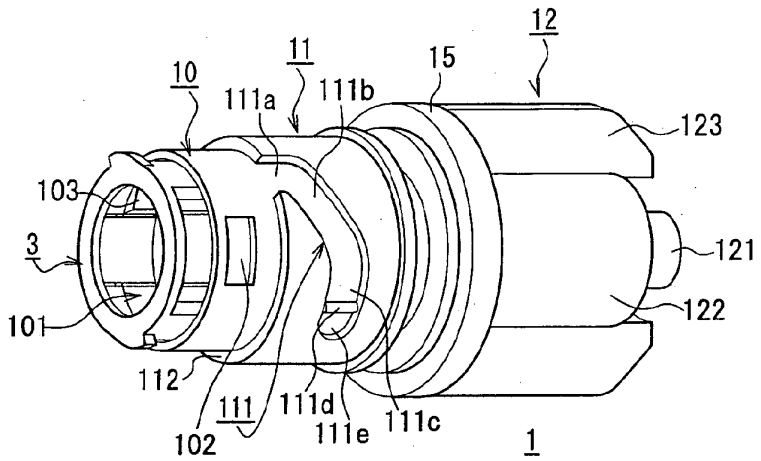


FIG. 5B

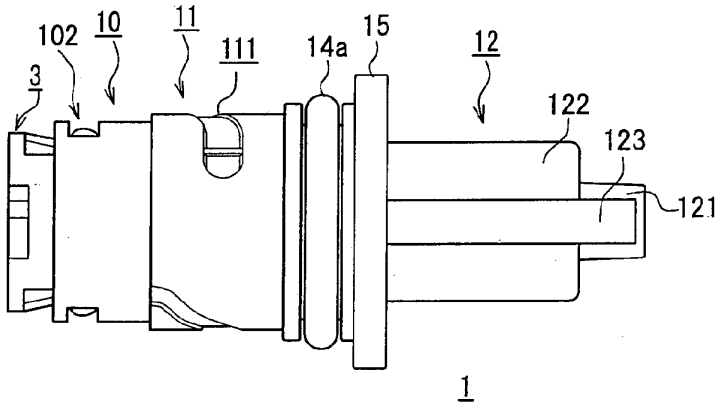
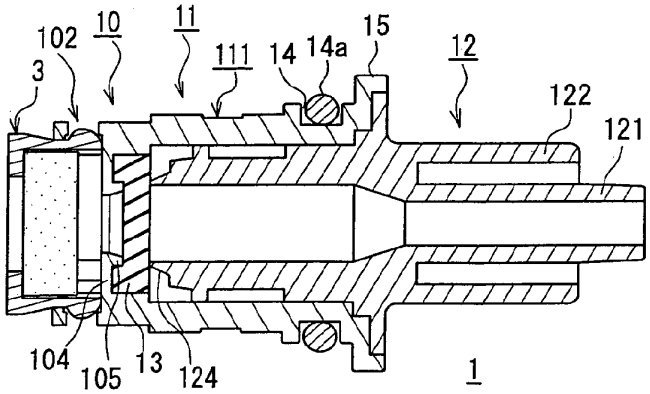


FIG. 5C



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FIG. 6A

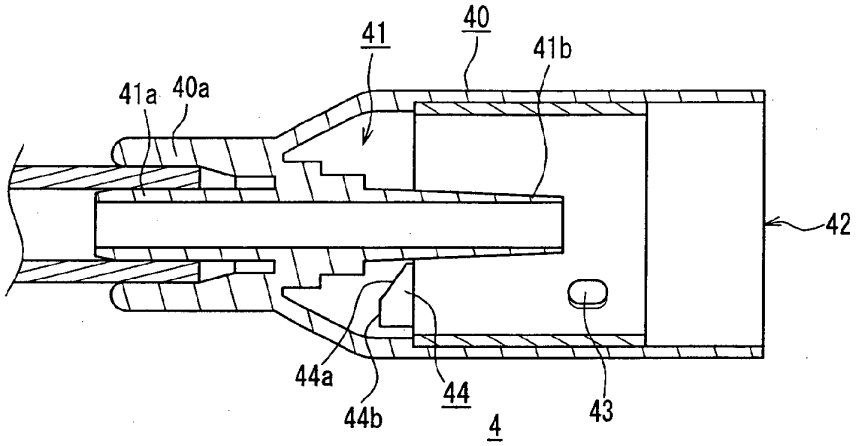
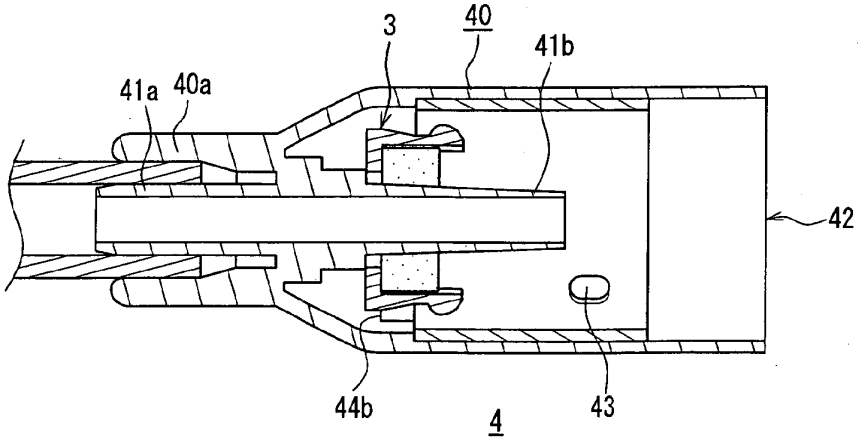


FIG. 6B



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FIG. 7A

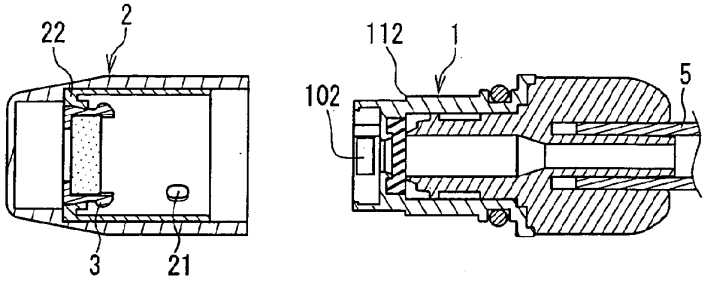


FIG. 7B

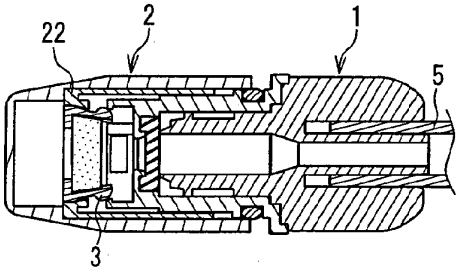


FIG. 7C

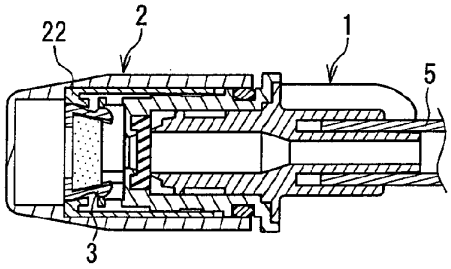


FIG. 7D

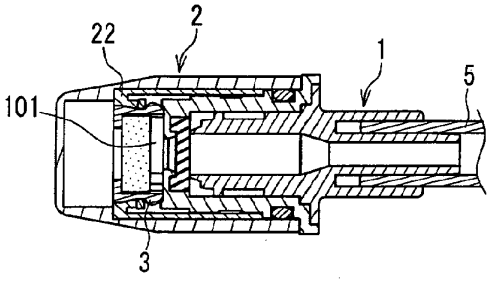
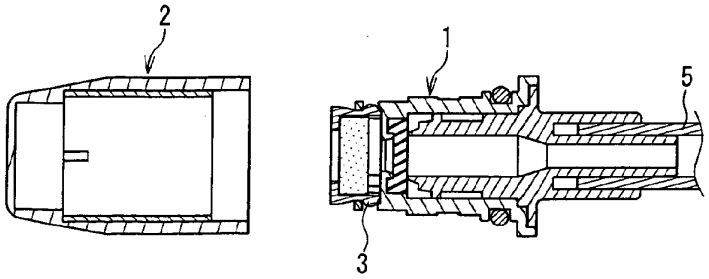


FIG. 7E



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FIG. 8A

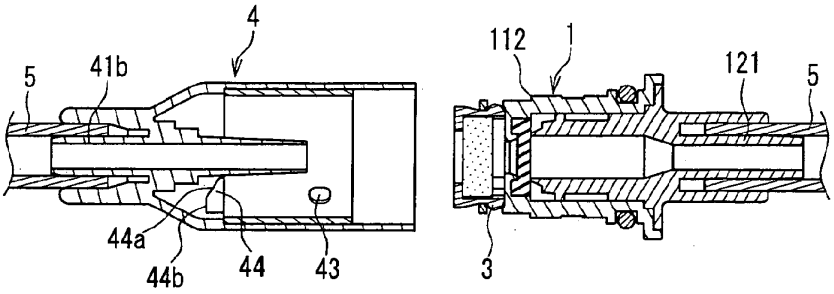


FIG. 8B

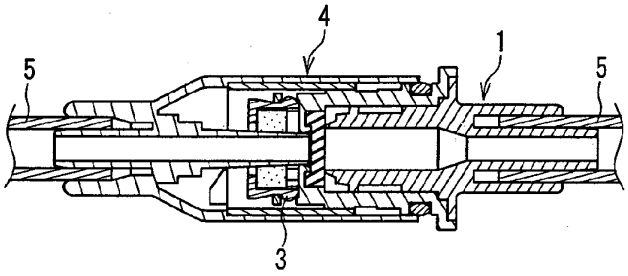


FIG. 8C

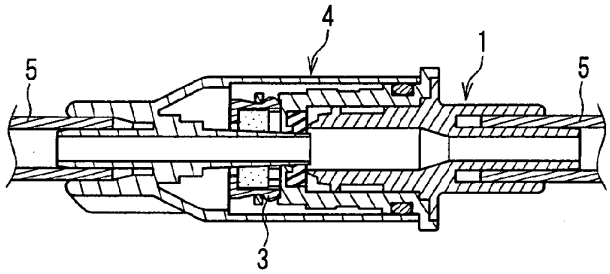


FIG. 8D

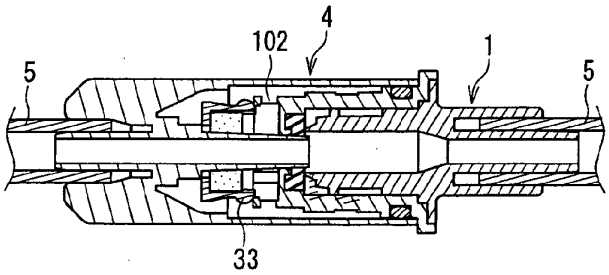
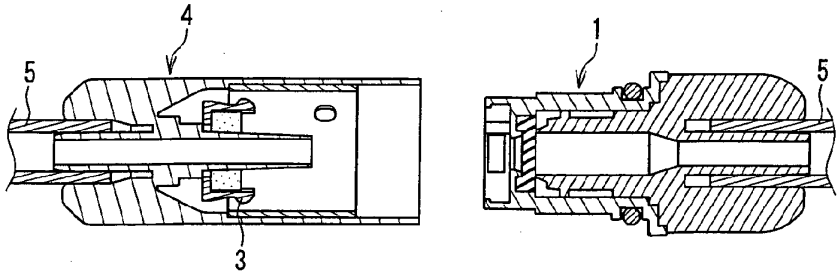


FIG. 8E



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INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2004/011114

A. CLASSIFICATION OF SUBJECT MATTER
Int.Cl[7] A61M39/10, A61M5/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Int.Cl[7] A61M39/00-39/20, A61M5/14, A61M1/14-1/18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1922-1996 Toroku Jitsuyo Shinan Koho 1994-2004
Kokai Jitsuyo Shinan Koho 1971-2004 Jitsuyo Shinan Toroku Koho 1996-2004

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 2003-210574 A (JMS Co., Ltd.), 29 July, 2003 (29.07.03), Full text; all drawings & US 2003/0144647 A1 & EP 1331020 A1	1-8
A	JP 2002-345952 A1 (Shimizu Pharmaceutical Co., Ltd.), 03 December, 2002 (03.12.02), Full text; all drawings (Family: none)	1-8
A	JP 3058205 B2 (Terumo Corp.), 04 July, 2000 (04.07.00), Full text; all drawings (Family: none)	1-8

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search	Date of mailing of the international search report
29 November, 2004 (29.11.04)	14 December, 2004 (14.12.04)
Name and mailing address of the ISA/ Japanese Patent Office	Authorized officer
Facsimile No.	Telephone No.

Form PCT/ISA/210 (second sheet) (January 2004)

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Page 225 of 484

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60/587,790 14 July 2004 (14.07.2004) US

(71) Applicant *(for all designated States except US)*: **MEDICAL COMPONENTS, INC.** [US/US]; 1499 Delp Drive, Harleysville, PA 19438 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **RAULERSON, Daniel, J.** [US/US]; 1205 Belleville Avenue, Brewton, AL 36426 (US). **SCHWEIKERT, Timothy** [US/US]; 121 North Park Drive, Levittown, PA 19054 (US). **WALL, William, Shaun** [US/US]; 215 Becker Road, North Wales, PA 19454 (US). **FISHER, Mark, S.** [US/US]; 118 Mountain View Road, Sellersville, PA 18960 (US).

(74) Agent: **NESS, Anton, P.**; Monte & McGraw, P.C., 4092 Skippack Pike, P.O. Box 650, Skippack, PA 19474 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LUER CLEANER

(57) Abstract: A luer cleaner (100) including a generally hollow body (112) having an open first end (104), a closed second end (106), and a longitudinal axis extending therethrough between the first end and the second end. The first end (104) is sized to receive therein a luer connector (190) proximal end and includes a plurality of bristles (134) extending generally toward the longitudinal axis sufficiently to engage the outer surfaces of the luer proximal end disposed therein. The second end comprises a compressible reservoir (166) containing a fluid (168), wherein, when the second end is compressed, the fluid is transmitted from the reservoir toward the first end through passageways to wet the luer proximal end. A method for cleaning luer connectors is also disclosed.

WO 2006/019782 A2

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This relates to and claims priority from Provisional U.S. Patent Application Serial No. 60/587,790 filed July 14, 2004.

FIELD OF THE INVENTION

[0002] The present invention relates to medical device, and more particularly to an apparatus for cleaning a luer connector that is attached to a catheter assembly implanted on a patient.

BACKGROUND OF THE INVENTION

[0003] In catheter assemblies such as are used in hemodialysis, proximal ends of the catheters are terminated in luer connectors that are disposed outside of the patient, and the luer connectors enable easy and rapid connection to respective fluid lines of the hemodialysis apparatus in a manner permitting easy and rapid disconnect. Of course, when unconnected to the fluid lines, the ends of the luer connectors are exposed to debris and contamination and they require cleaning and decontamination prior to each connection.

SUMMARY OF THE INVENTION

[0004] The present invention is a luer cleaner that includes a generally hollow body having an open first end, a closed second end, and a longitudinal axis extending therethrough between the first end and the second end. The first end is sized to receive therein the proximal end of the luer

connector and includes a plurality of bristles extending generally toward the longitudinal axis sufficiently to engage the luer connector disposed therein. The second end comprises a compressible reservoir containing a fluid, wherein, when the second end is compressed, the fluid is transmitted from the reservoir toward the first end. When the luer cleaner is inserted over the proximal end of the luer connector and preferably is rotated reciprocally several times about the luer's axis, the bristles engage and mildly scrub the outer surfaces of the luer connector's proximal end, including the male connector threads, to dislodge debris, and the fluid washes and thus cleans and decontaminates the luer connector end when the luer cleaner is removed from the luer connector. The method of the present invention includes: inserting a luer connector proximal end into a luer cleaner open end so that bristles within the luer cleaner engage the luer proximal end outer surfaces to scrub them; compressing the luer cleaner closed second end to force fluid toward the open first end through passageways to wash the luer connector end; and rotating the luer cleaner about the luer connector to scrub and clean it.

[0005] Other embodiments of the luer cleaner provide a frangible capsule within the reservoir at the second luer cleaner end that contains the fluid and that expresses the fluid when crushed; and provide a pair of frangible capsules within the reservoir, that contain the fluid and together express the fluid.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The accompanying drawings, which are incorporated herein and constitute part of this specification, illustrate the presently preferred embodiments of the invention, and together with the general description given above and the detailed description given below, serve to explain the features of the invention. In the drawings:

[0007] Fig. 1 is a perspective view of a luer cleaner according to a first preferred embodiment of the present invention, with a luer being inserted into the luer cleaner;

[0008] Fig. 2 is an exploded view of the luer cleaner shown in Fig. 1;

[0009] Fig. 3 is a sectional view of the luer cleaner shown in Fig. 1;

[0010] Fig. 4 is an enlarged front view of a scrubber disc shown inside the luer cleaner;

[0011] Fig. 5 is a sectional view of the scrubber disc of Fig. 4, taken along line 5--5 of Fig. 4; and

[0012] Figs. 6 and 7 are sectional views of luer cleaners according to second and third embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0013] In the drawings, like numerals indicate like elements throughout. Certain terminology is used herein for convenience only and is not to be taken as a limitation on the present invention. The terminology includes words specifically mentioned, derivatives thereof, and words of similar import. The following describes preferred embodiments of the invention. However, it should be understood based on this disclosure that the invention is not limited by the preferred embodiments described herein.

[0014] Referring now to Fig. 1, a luer cleaner 100 according to a first embodiment of the present invention is shown. The luer cleaner 100 is insertable over the proximal end of a luer connector 190 and rotatable axially about the luer. Luer connector, or luer, 190 is preferably connected to a medical device, such as a hemodialysis catheter 194. The proximal end of luer 190 includes male threads 192 that are used to secure luer 190 to a second medical device (e.g., a hemodialysis apparatus) having fluid lines each terminating in a corresponding luer connector that

incorporates internal female threads. Prior to connection of the luer 190 with the second medical device, the proximal end of luer 190 is inserted into an open end of the luer cleaner 100. As the luer cleaner 100 is rotated about the luer 190, antiseptic fluid contained in the luer cleaner 100 is forced from a reservoir in the luer cleaner 100 such as by manually applied pressure, over the luer 190, to clean debris and other contaminants that may be present on or around the luer threads 192. Also shown, along with Figs. 2 and 3, is a body 160 defining a reservoir 166 for a fluid 168.

[0015] Referring now to Figs. 2 and 3, the luer cleaner 100 includes an open end 104, a closed end 106, and a longitudinal axis 107 extending therethrough between the open end 104 and the closed end 106. The open end 104 includes a generally tubular body 108 having a longitudinal passage 110 that extends toward the closed end 106. Preferably, the body 108 is constructed from polyvinyl chloride or some other suitable biocompatible material. The body 108 includes an exterior portion 112 that may optionally include a plurality of gripping ribs 114 extending therefrom, away from the longitudinal axis 107. The gripping ribs 114 allow a user to grip the body 108 during use of the cleaner 100. The interior of the body 108 includes at least one, and preferably two, diametrically opposed alignment notches 116 that extend from the longitudinal passage 110 away from the longitudinal axis 107.

[0016] The body 108 further includes a guide member 117 that extends partially into the longitudinal passage 110 along the longitudinal axis 107 toward the open end 104. The guide member 117 preferably includes a male luer taper 118 to engage a female luer connection on the luer 190. The guide member 117 prevents fluid from entering the catheter 194 through the interior of the luer 190 after the fluid has been forced into the longitudinal passage 110 from the reservoir. The guide member 117 is preferably integrally molded with the body 108, as seen in the cross-section view of Fig. 3.

[0017] At least one and preferably four passages 119 are disposed within the body 108 between the exterior portion 112 of the body 108 and the guide member 117 (although only two passages 119 are shown in Fig. 3). The passages 119 are preferably parallel to the longitudinal axis 107 and each passage 119 is disposed ninety degrees apart from each adjacent passage 119.

[0018] The body 108 also includes an annular flange 120 that extends from the body 108, away from the open end 104 of the luer cleaner 100. The flange 120 extends outwardly of the passages 119, with a lip 122 being formed between the flange 120 and the exterior portion 112 of the body 108.

[0019] A tubular collar 123, having an approximately "T-shaped" cross section, is fixedly connected to the body 108, distal from the open end 104 of the luer connector 100. The collar 123 includes a corresponding lip 124 that extends circumferentially therearound and that is sized to surround and engage with the flange 120 of the body 108, as is seen in Fig. 3. The connection between the collar 123 and the body 108 may be an interference fit, a threaded connection, an adhesive-based connection, or some other suitable connection known to those skilled in the art.

[0020] The collar 123 also includes a connecting passage 125 that extends through the collar 123, generally along the longitudinal axis 107. When the collar 123 and the body 108 are engaged with each other, a generally circular throughway 126 is formed between the body 108 and the collar 123 that provides fluid communication between the connecting passage 125 and the passages 119 in the body 108.

[0021] A scrubber 130 is disposed within the longitudinal passage 110 and is preferably constructed from at least one, and preferably a plurality, of scrubber discs 131. Details of a scrubber disc 131 are shown in Figs. 4 and 5; each scrubber disc 131 includes an annular ring 132, with each ring 132 having a plurality of scrubber bristles 134 extending therefrom toward the

longitudinal axis 107. Preferably, the rings 132 and scrubber bristles 134 are constructed from polypropylene or some other suitable biocompatible material. The bristles 134 extend sufficiently far toward the center of each ring 132 so as to engage the luer threads of the luer when the luer is inserted into the luer cleaner 100.

[0022] Preferably, the ring 132 for each scrubber disc 131 includes at least one, and preferably two diametrically opposed, alignment posts 136 that extend from the outer perimeter of the ring 132 away from the center of the ring 132. Each post 136 is sized and shaped to fit into a respective alignment notch 116 cut into the body 108. Each post 136 engages the alignment notch 116 in a generally tight, frictional fit so that each ring 132 remains within the longitudinal passage 110 after insertion thereinto.

[0023] Each ring 132 also includes at least one, and preferably, a plurality of through-passages 140 that allow fluid to pass from one side of each ring 132 to an opposing side of each ring 132. Four through-passages 140 are preferred, as shown in Fig. 4, with each through-passage 140 being disposed at ninety degree spacings from each adjacent through-passage 140, although those skilled in the art will recognize that more or less than four through-passages 140 may be used. However, it is preferred that each through-passage 140 fluidly communicates with a passage 119 in the body 108, so that fluid communication exists between all of the passages 140 and the connecting passage 125.

[0024] Further, a plurality of radially extending channels 142 extends along an exterior of each ring 132 from the outer perimeter of the ring 132 to the inner diameter of the ring 132, with each channel 142 fluidly communicating with a through-passage 140. As can be discerned from Figs. 4 and 5, four channels 142 are disposed at ninety degree spacings apart from each adjacent channel 142, with channels 142 disposed on either side of each ring 132, although those skilled in

the art will recognize that, for each through-passage 140, a channel 142 is preferably disposed on either face of the ring 132.

[0025] With a plurality of rings 132 disposed adjacent one another, as shown in Fig. 3, the radially extending channels in adjacent rings 132 form radial passages 146 that provide fluid communication between each through-passage 140 and the longitudinal passage 110 to allow fluid to be transmitted through the radial passages 146 to the longitudinal passage 110. Fluid communication is now present between the longitudinal passage 110 and the connector passage 125.

[0026] Again referring to Fig. 3, a sealing ring 150 is disposed between the array of rings 132 and the open end 104 of the luer cleaner 100. The sealing ring 150 preferably has an internal diameter that is approximately the same as the external diameter of the luer 190 (see Fig. 1) to prevent fluid forced manually from the reservoir 168 within bulbous body 160 and into the longitudinal passage 110, from flowing out of the luer cleaner 100 between the luer 190 and the body 108 of the cleaner 100. The sealing ring 150 is preferably constructed from KRATON™ or other suitable, flexible material, so that the sealing ring 150 generally provides a seal around the luer when the luer is inserted into the luer cleaner 100.

[0027] A cap 152 is disposed on the open end 104 of the luer cleaner 100 to retain the sealing ring 150 and the array of scrubber rings 132 within the luer cleaner 100. The cap 152 is preferably annular, with a generally circular central opening 154 that is sized to allow the luer to be inserted therethrough. The cap 152 is preferably fixedly connected to the body 108, such as with an adhesive, although those skilled in the art will recognize that the cap 152 may be retained by other methods, such as by interference fit, or a threaded connection.

[0028] The closed end 106 of the luer cleaner 100 includes a generally bulbous body 160 constructed from KRATON™, 1064 PVC, or some other suitable, compressible material. The body 160 includes an open end 162 that is fixedly and sealingly connected to the collar 123 and a closed end 164 disposed away from the open end 162. The interior of the bulbous body 160 defines a compressible reservoir 166. A fluid 168 is disposed within the reservoir 166 such that the reservoir 166 fluidly communicates with the longitudinal passage 110 of the generally tubular body 108 through the connecting passage 125, the circular throughway 126, the passages 119, the through-passages 140, and the radial passages 146.

[0029] Preferably, the fluid 168 is a fluid having antiseptic properties, such as alcohol. More preferably, the fluid 168 is sufficiently viscous to remain in the reservoir 166 in the absence of a compressive force on the body 160 of the reservoir 166. Such a preferred fluid 168 is isopropyl alcohol in a polymer suspension, such as polyvinyl alcohol, sold commercially by GOJO Industries as PURELL®, although those skilled in the art will recognize that other fluids, including, but not limited to, povodine iodine or hydrogen peroxide, or any combination thereof, may be used instead.

[0030] In use, and referring to Figs. 1 and 3, the luer 190, such as on a proximal end of a catheter 194, is inserted into the open end 104 of the luer cleaner 100. The sealing ring 150 engages the external portion of the luer 190, restricting fluid 166 from being forced out of the open end 104 of the luer cleaner 100.

[0031] After the luer 190 is fully inserted into the open end 104 of the luer cleaner 100, the bulbous body 160 is then compressed, forcing the fluid 168 in the reservoir 166 from the reservoir 166 and eventually into the longitudinal passage 110 of the generally tubular body 108 through the connecting passage 125, the circular throughway 126, the passages 119, the through-passages 140, and the radial passages 146, to the longitudinal passage 110 and thus to the exterior of the luer 190.

The luer 190 is rotated about the longitudinal axis 107 of the luer cleaner 100, in a preferably back-and-forth motion, so that the bristles 134 on the scrubber discs 131, in conjunction with the fluid 168, clean contaminants from the exterior of the luer 190, including the luer threads 192. After several seconds of scrubbing the luer 190, the luer is removed from the luer cleaner 100, and the luer cleaner 100 may be discarded. Luer 190 is now disinfected and may be connected to an external medical device.

[0032] In an alternate embodiment of a luer cleaner 200, shown in Fig. 6, a fluid 268 may be retained in a frangible container 270 disposed within the reservoir 166. The fluid 268 may be significantly less viscous than the fluid 168 described above with respect to the luer cleaner 100 (Fig. 1). The frangible container 270 prevents the fluid 268 from flowing out of the reservoir 166 prior to use.

[0033] To use the luer cleaner 200, the luer is inserted into the open end 104 as described above with respect to the luer cleaner 100. The user compresses the reservoir 166 toward the longitudinal axis 107, breaking the frangible container 270, and allowing the fluid 268 to flow from the reservoir 166 and to the longitudinal passage 110 as described above with respect to the luer cleaner 100.

[0034] The frangible container 270 may be constructed from a material that is easily broken open under compression. The fluid 268 may be the same as the fluid 168 described above, or the fluid 268 may be a less viscous fluid, such as, for example, isopropyl alcohol without any suspension.

[0035] In Fig. 7, a third embodiment of luer cleaner 300 is shown. A pair of frangible containers 370 are secured to opposite sides of a tab 372, each containing quantities of fluid 368 that will be expressed into and forwardly through channel 376 of tab 372 when the closed end 360

ones of frangible containers 370, to enable the user to compress those indicated surfaces to crush and open the frangible containers, which are pressed against tab 372.

[0036] It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

CLAIMS

What is claimed is:

1. A luer cleaner comprising:

a generally hollow body having:

an open first end, a closed second end, and a longitudinal axis extending therethrough between the first end and the second end,

wherein the first end is sized to receive therein a luer and wherein the first end includes a plurality of bristles extending generally toward the longitudinal axis sufficiently to engage the luer disposed therein; and

wherein the second end comprises a compressible reservoir containing a fluid, wherein, when the second end is compressed, the fluid is transmitted from the reservoir toward the first end.

2. The luer cleaner according to claim 1, wherein the fluid is an antiseptic fluid.

3. The luer cleaner according to claim 1, wherein the plurality of bristles comprises at least one ring disposed in the open end, and wherein the plurality of bristles extend from the at least one ring toward the longitudinal axis.

4. The luer cleaner according to claim 3, wherein the at least one ring comprises a plurality of rings.

5. The luer cleaner according to claim 1, wherein the reservoir is defined within an initially separate compressible body joined to the hollow cleaner body remote from the open first end.

6. The luer cleaner according to claim 5, wherein the separate compressible body further comprises a collar disposed thereon forwardly of the reservoir, for being joined sealingly with the hollow cleaner body.
7. The luer cleaner according to claim 1, wherein the body further comprises an exterior portion, wherein the exterior portion comprises a plurality of ribs extending therefrom, away from the longitudinal axis.
8. The luer cleaner according to claim 1, further comprising a centering post disposed along the longitudinal axis and within the open first end, complementary to the open proximal end of a luer connector that closes the open proximal end upon full insertion of the luer connector proximal end into the open first end of the luer cleaner body.
9. The luer cleaner according to claim 1, wherein the fluid is retained in a frangible capsule within the compressible reservoir.
10. The luer cleaner according to claim 1, wherein the fluid is retained in two frangible capsules within the compressible reservoir, separated from each other by a tab having a channel extending forwardly toward the luer cleaner first end.
11. The luer cleaner according to claim 1, wherein, in the absence of compression of the reservoir, the fluid is sufficiently viscous to remain within the reservoir.
12. The luer cleaner according to claim 1, comprising at least one passageway for communicating the fluid from the reservoir to the first end.
13. A method of cleaning a luer comprising the steps of:

(a) providing a luer cleaner comprising:

a generally hollow body having an open first end, a closed second end, and a longitudinal axis extending therethrough between the first end and the second end,

wherein the first end is sized to receive therein a luer and wherein the first end includes a plurality of bristles extending generally toward the longitudinal axis sufficiently to engage the luer disposed therein; and

wherein the second end comprises a compressible reservoir adapted to receive and retain a fluid, wherein, when the second end is compressed, the fluid is transmitted toward the first end;

(b) inserting a luer into the open end, wherein the plurality of bristles engage an exterior of the luer; and

(c) compressing the second end and transmitting the fluid to the luer and to the plurality of bristles.

14. The method according to claim 13, further comprising rotating the luer about the longitudinal axis.

15. The method according to claim 14, wherein rotating the luer about the longitudinal axis further comprises reciprocally rotating the luer in each of two directions.

16. A luer cleaner comprising:

a generally hollow body having:

an open first end, a closed second end, and a longitudinal axis extending therethrough between the first end and the second end,

means for scrubbing a luer disposed at the first end; and

a reservoir for retaining a fluid at the second end and for transmitting the fluid from the second end toward the first end.

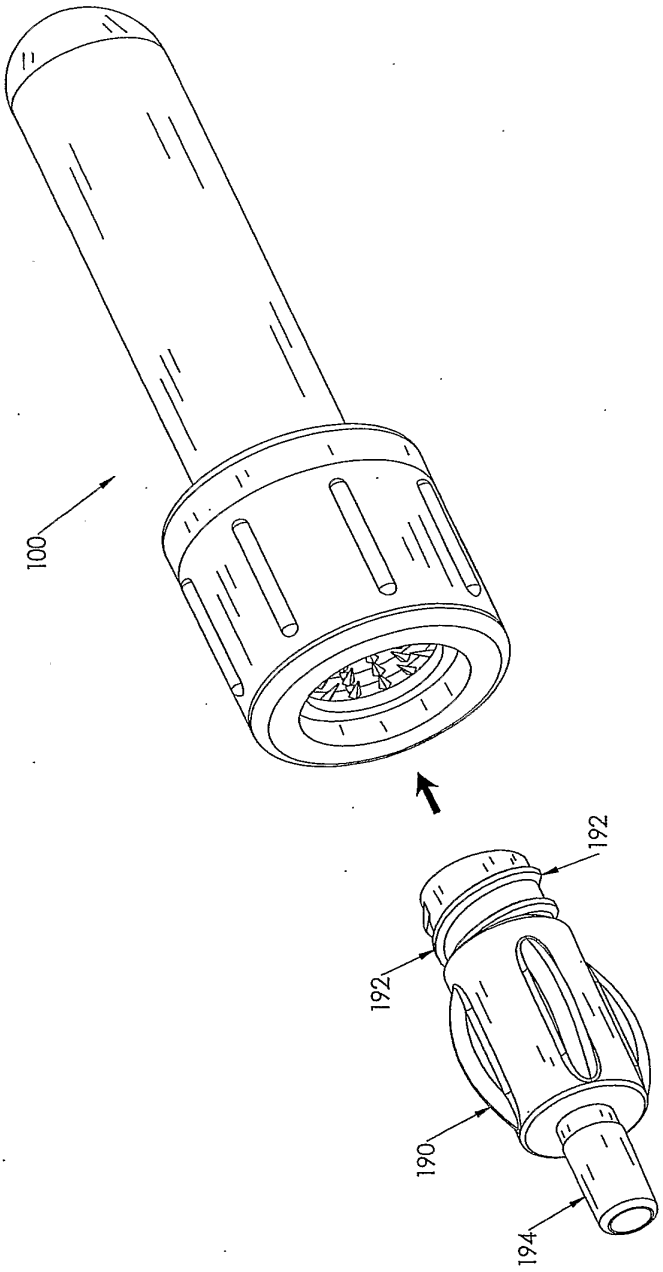


FIG. 1

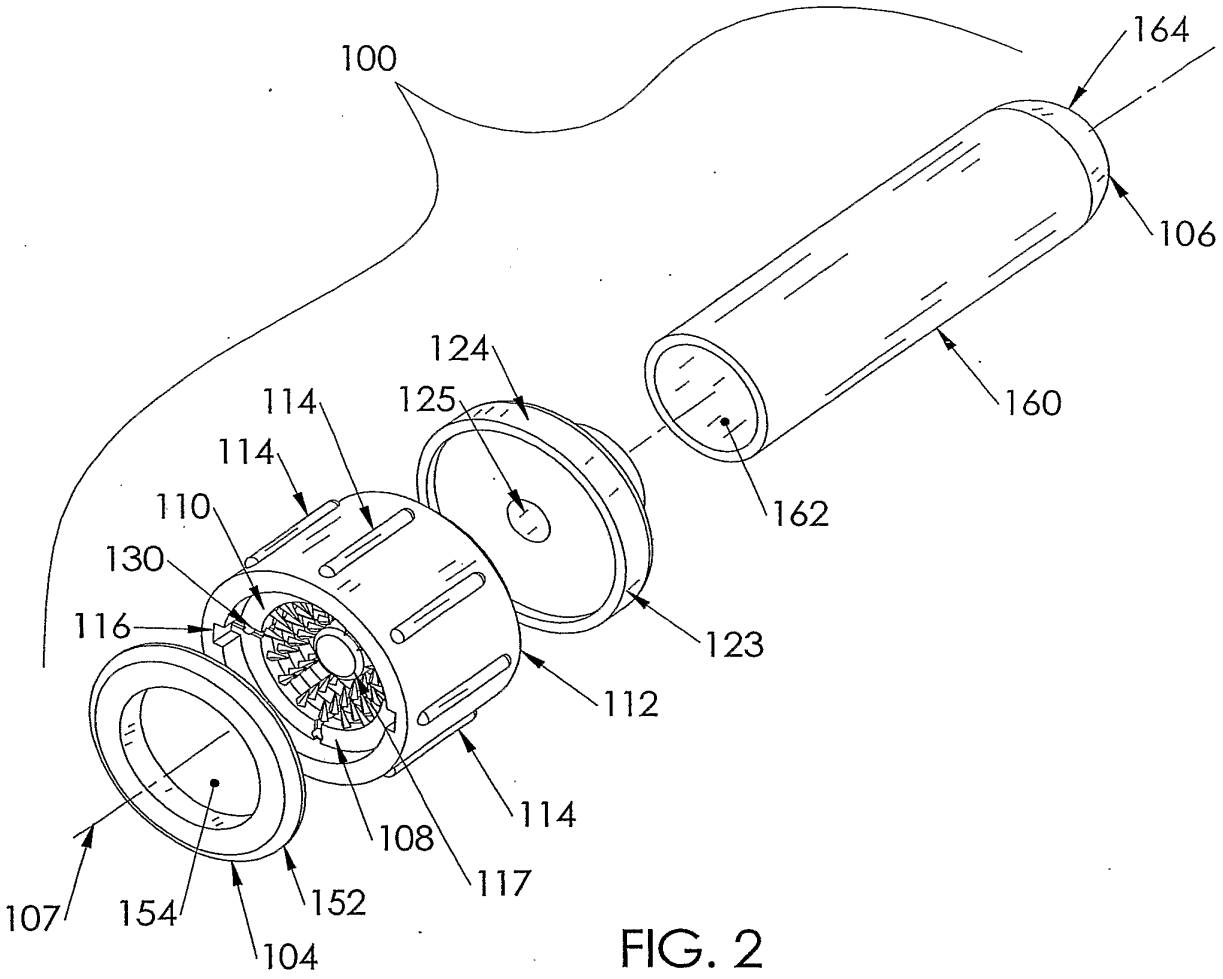

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FIG. 2

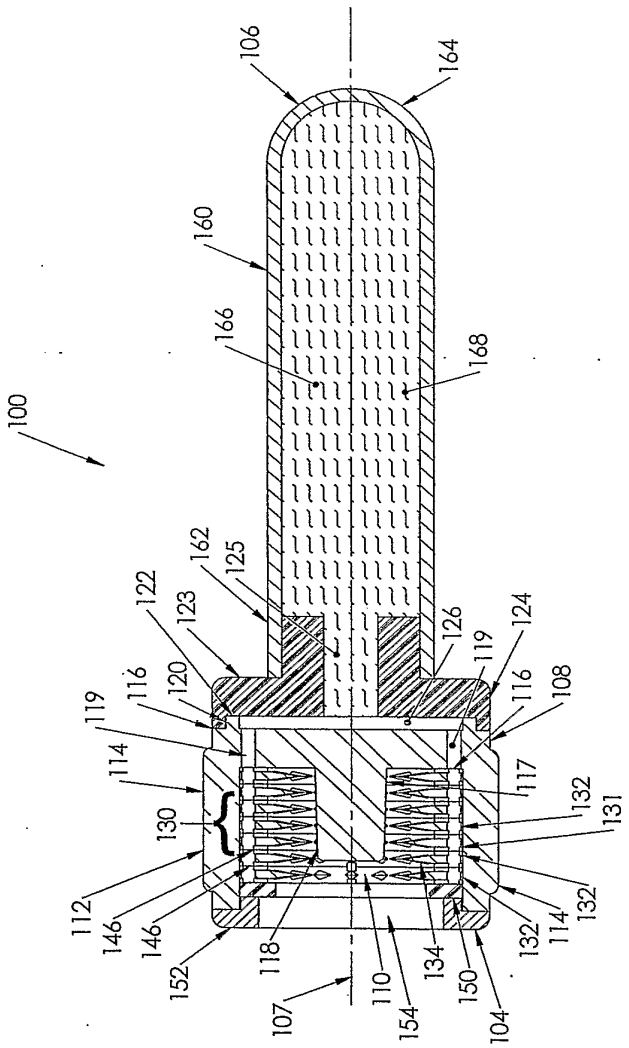

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FIG. 3

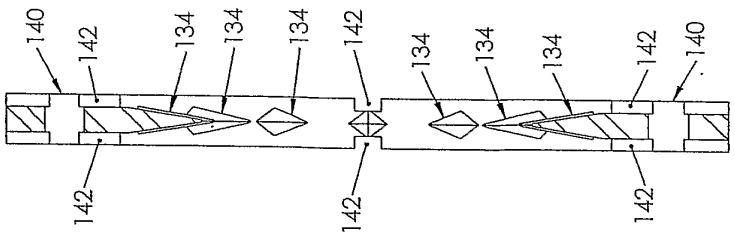

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FIG. 5

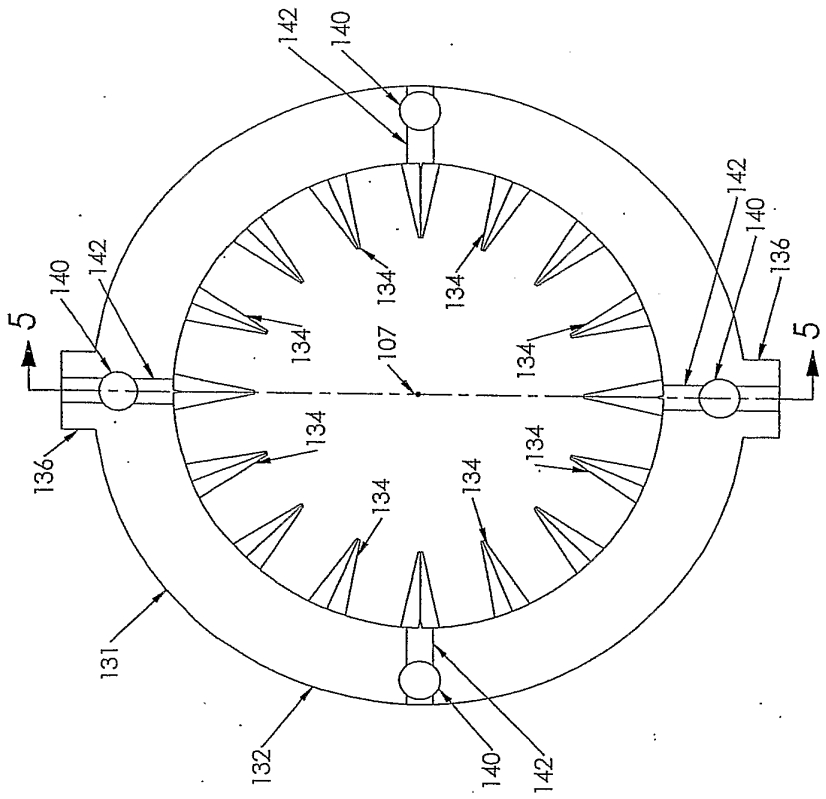

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FIG. 4

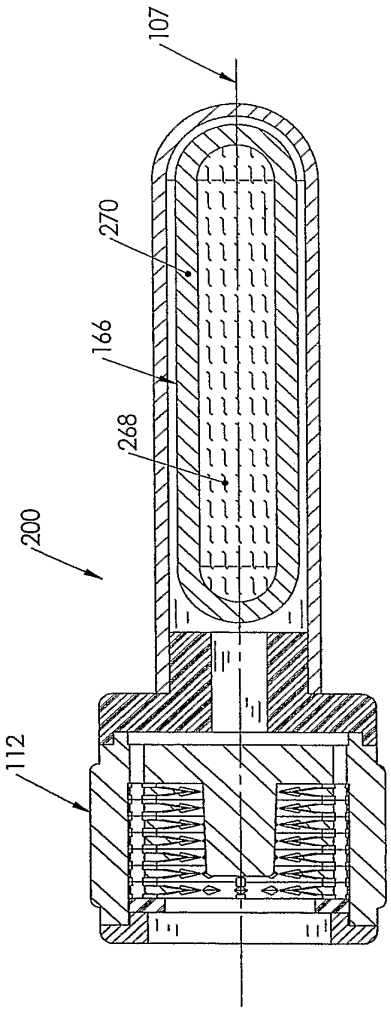


FIG. 6

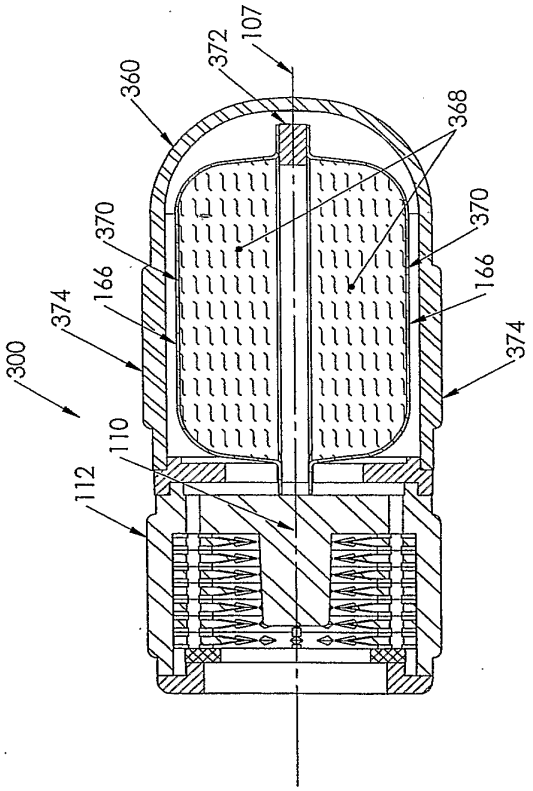


FIG. 7

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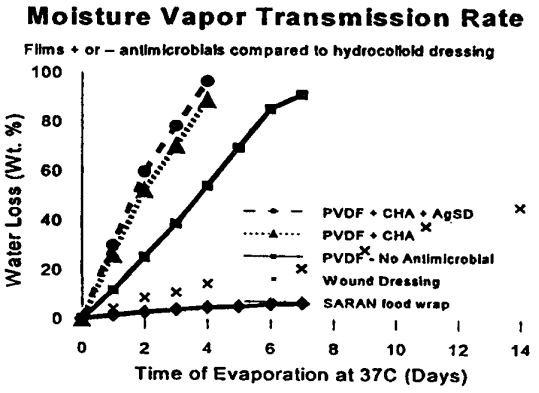
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(54) Title: COMPOSITION USEFUL FOR PROVIDING ONE–STEP SURGICAL PREPARATION AND DRAPE

(57) Abstract

This invention relates to an improved polyvinylidene fluoride–based composition useful for forming a flexible, tack–free, nonflammable, substantially fluid resistant barrier film with substantially improved durability and skin–adhesion properties. The composition providing a long–lasting protective barrier film capable of disinfecting the skin surface of normally present microorganisms upon initial application, and the film imparting continuous and prolonged antimicrobial agent. The barrier film is further capable of remaining substantially adherent to the skin surface after prolonged exposure to biological fluids. A kit and methods of use for the composition are disclosed. The figure illustrates the moisture vapor transmission rate (MTVR) for the present invention. The MTVR of the present invention containing both chlorhexidine acetate (CHA) and silver sulfadiazine (AgSD), chlorhexidine alone, and with no antimicrobial agent present is compared against BLISTER-FILM^TM hydrocolloid wound dressing and Saran(R) food wrap. The percent of water loss is plotted versus time in days. The data illustrating the present invention is breathable, thereby providing patient comfort and promotion of wound healing. See Test #3 for details.



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"COMPOSITION USEFUL FOR PROVIDING ONE-STEP SURGICAL PREPARATION AND DRAPE"

The government owns certain rights in the present invention pursuant to grant number 1R41 AR/AG44435-01 from the National Institutes of Health.

FIELD OF THE INVENTION

The present invention relates to an improved polyvinylidene fluoride-based film forming composition, and a one-step method of use providing a combination preoperative skin preparation and surgical incise drape. More specifically, the invention relates to an improved polyvinylidene fluoride-based composition useful in eliminating normally present microorganisms and imparting prolonged protection against microbial rebound growth on the skin surface. The invention further relates to preventing exposure of the skin surface to biological fluids, such as, blood, urine, and fecal waste.

BACKGROUND OF THE INVENTION

Surgical wound infections are an important cause of morbidity, mortality, and excess hospital costs. Surgical wound infections are the second most frequently found nosocomial infection overall, and among surgical patients, surgical site infections are the most common nosocomial infection site. Three factors contribute to the risk of developing a surgical wound infection: 1) the amount of and type of microbial contamination of the wound; 2) the condition of the wound at the end of the operation; and 3) host susceptibility, that is, the patient's intrinsic ability to deal with microbial contamination. In immuno-compromised patients, a greater tendency for infections caused by resident skin bacteria exists. Surgical site infections, which

may, for the most part be benign in normal patients, may be fatal to the immuno-compromised. It is therefore a goal of the present invention to control resident skin bacteria at the site of an invasive surgical procedure.

Illustrating the gravity of the problem, the Centers for Disease Control and Prevention reported the number of sepsis cases tripled from 1979 to 1992 due to increased invasive procedures in older and immune-suppressed patients. In the U.S., every year roughly 500,000 people acquire sepsis and 175,000 die. One conservative estimate of the average cost of a surgical site infection, as determined on the basis of an average extra length of hospital stay of five days is $7,500. In addition to these direct costs, there are significant consequences such as lost productivity due to missed workdays, emotional trauma inflicted on patients and health provider as a result of the development of surgical site infections, patient dissatisfaction with the outcome of the operation, and the fear of malpractice on the part of the health care provider.

In order to reduce the risk of wound infection and maximize primary healing, a preoperative skin preparation seeks to create a clean operative field while minimizing damage to the skin. The preoperative skin preparation reduces the risk of postoperative wound infection by removing soil and transient microorganisms from the skin, by reducing the resident microbial count to subpathogenic amounts in a short period of time, and by inhibiting rapid rebound growth of microorganisms.

The surgical site preparation objectives (scrub, antimicrobial painting of skin and draping of the surgical site) are to remove dirt, skin oil and microbes from the skin while also providing a barrier against microbial migration into the incision. It is desired these objectives be achieved with the least amount of skin irritation. It is suggested that the agent used for scrubs and painting

be a broad-spectrum antimicrobial, provide residual protection, and be nontoxic. An ideal antiseptic solution leaves a residue on the skin surface that continues to exert antimcrobial activity throughout the surgical period. This residual film should inhibit recolonization of the skin flora from environmental contact, from centripetal spread of microbes originating outside the field of prepared skin, and from the resident flora within the prepared field.

Many of the common surgical skin preparation protocols employ a topical application of an antimicrobial agent. Typically, topical application of antimicrobial agents is accomplished using, for example, lotions, ointments, and preoperative skin preps. The initial application of the antimicrobial agent, however, frequently does not impart the desired antimicrobial properties and requires continued application. During a surgical procedure the antimicrobial agent may also be removed by the action of blood, biological fluids and saline washes applied to the site. These two problems may lead to a rebound of the microorganism flora, and result in postoperative wound infection. It is therefore advantageous to have a one-step antimicrobial delivery system capable of maintaining an aseptic environment at the surgical site before and following the surgical procedure.

Other surgical skin preparation protocols employ a preopertive scrub, paint and drape procedure. The preoperative scrub is generally performed with antibacterial compounds such as povidone-iodine, chlorhexidine and hexachlorophene for varied periods of time (2-10 minute scrubs). The skin is then painted (or sprayed) with the antimicrobial. Povidone-iodine preparations are most widely used. 3M Corporation has developed a one-time skin preparatory solution, DURAPREP™ (U.S. Pat. No. 4,584,192), that is painted on and dries within 2 minutes.

Although skin scrubs and painting demonstrate initial microbial inhibtion, none have proven efficacious for longer surgical time periods.

Adhesive-backed film incise drapes are often applied after conventional skin preparation, and surgical incisions are made through the drape. Adhesive drapes have proven to be effective in preventing resident flora from migrating into the wound as long as they are not peeled back from the wound edges or loosened by trapped fluids or air. The intrinsic benefits and antimicrobial effectiveness of the traditional adhesive-backed incise drape, however, are negated by its problems with creasing, wrinkling, and separation from the wound edge.

Eliminating the current practice of using separate antimicrobial preparations and adhesive incise drapes would cut down on the cost of materials, reduce prep time, and decrease the time needed for anesthesia. A combination antimicrobial preparation and incise drape that could be uniformly applied would benefit the patient by reducing the incidence of infection, thereby improving the chances of successful surgery and limiting prolonged post-operative hospital stay due to nosocomial surgical infection.

Polyvinylidene fluoride (hereinafter occasionally abbreviated as PVDF) is a mechanically tough thermoplastic that readily and stably polymerizes without low molecular weight contaminants or chemical stabilizers. PVDF is approved for use by the Food and Drug Administration for repeated contact with food and by the National Sanitation Foundation under Standard 61 for high purity water systems. KYNAR® brand PVDF homopolymers and copolymers (Elf Atochem ATO, Philadelphia, PA) are also in compliance with US Pharmacopeia Classification VI. Materials safety sheets (MSDS) provided with the KYNAR® products indicate 100% of the respective polymer compound to be present with no detectable impurities.

The present invention addresses the problems in the art with an improved PVDF-based film-forming composition and one-step method of use for a combination preoperative skin preparation and surgical incise drape. No one before the present inventors realized and demonstrated that PVDF-based coatings could provide an excellent combination preoperative skin preparation and surgical incise drape as provided herein.

DESCRIPTION OF THE PRIOR ART

Various compositions are known in the art for forming a barrier film when applied to the skin surface. It is known that film forming compositions are useful for providing the skin with protection against irritants, biological fluids and microorganisms, and for forming protective wound bandages, and gloves. A desired film forming composition should be easily applied to the skin surface, substantially fluid resistant, tack-free, sufficiently permeable to water vapor transmission, adherent, long-lasting and flame resistant. Another preferred feature is the barrier films ability to serve as a vehicle for delivery of an antimicrobial agent and medicament to the skin surface.

For example, U.S. Pat. No. 3,987,000 teaches a film forming polymer composition for providing a protective bandage when applied to a wound site by spraying from an aerosol container. The composition comprises one or more esters of acrylic or methacrylic acid with one or more straight-chain or branched monovalent, primary or secondary aliphatic alcohols having one to four carbon atoms; one or more maleic acid monalkyl esters with 1 to 12 carbon atoms in the alkly moiety; and isobutene. The composition is solubilized in a solvent, such as ethanol, acetone or methylene chloride. The solution is sprayed onto the skin surface using a liquefied propellant gas, such as a halogen hyrocarbon.

U.S. Pat. No. 4,374,126 teaches a composition and method of forming a film on a mammalian skin surface for providing long term protection against microorganisms. The composition comprises an alcohol soluble carboxylated polyacrylate including an antimicrobial agent, a topical adhesion promoter, and a difunctional amide for crosslinking the polymer upon evaporation of the alcohol solvent. The film is inert to body fluids, and provides prolonged antimicrobial properties to the skin by remaining adherent to the skin surface in excess of two days.

U.S. Pat. No. 4,379,863 teaches a copolymer-based composition for forming a breathable, water-insoluble barrier film providing the skin with protection from irritants, such as, urine or fecal waste. The copolymer comprises a solution of 50/50 n-butyl/iso-butyl methacrylate, and a plasticizer dissolved in isopropanol. It is further taught that the barrier film is useful for providing protection at an interface between the skin surface and the adhesive of a prosthetic appliance.

U.S. Pat. No. 4,584,192 teaches a composition and method for forming a film containing complexed iodine as a broad spectrum antimicrobial for providing asesptic conditions on mammalian skin. The film-forming composition consist of monomers of an acrylic or methacrylic acid ester of an alkyl alcohol, and N-vinyl lactam. The composition is dissolved in an alcohol, such as, ethanol and isopropanol.

U.S. Pat. No. 4,914,140 teaches a composition for forming a protective barrier film on the skin that is less irritative because it contains no surfactants. The film is comprised of an acrylic copolymer of ethyl acrylate and methacrylate acid, and a cellulose derivative dissolved in an alcohol and water solvent mixture.

U.S. Pat. No. 5,547,662 teaches a composition for preparing a skin surface as a surgical site and includes the film forming material and an antimicrobial agent. The preferred embodiment of the invention consisting of a dye color change reactive to the elimination of the fugitive solvent. The said color change indicating the site is ready. The invention also teaches a use of the invention and a kit for its use.

U.S. Pat. No. 5,041,287 teaches a composition for forming a. tough, flexible film providing spray-on bandages for mammalian skin surfaces, as well as, spray-on gloves and coatings for medical parts and/or electonic devices. The composition comprises polyvinylidene diflouride, an aqueous emulsion of acrylates and methacrylates, an unsaturated carboxylic acid and/or acrylamide, and a plasticizer dissolved in a fugitive solvent. The composition is applied to the skin and forms a film upon evaporation of the solvent. The composition forms a coating suitable for providing a non-notching polymeric coating which is readily removable and does not adhere to a wound area.

The inventors of the present invention sought to improve upon the composition of U.S. Pat. No. 5,041,287 in order to achieve a composition that formed a film with substantially greater toughness, adhesion, and durability in a humid environment. A film-forming composition useful as an effective one-step preoperative skin preparation and surgical incise drape must embody a large number of characteristics. It must be substantially adherent to the skin surface in the presence of biological fluids, and be substantially resistant to degradation upon exposure to skin secretions and body oils. The composition must rapidly dry upon application to the skin surface providing a tough, flexible, thin long-lasting film. After forming, the film must adapt well to all skin movements, and be free of wrinkling, tearing, lifting or bubbling. The film must have a

substantial moisture vapor transmission rate preventing interference with normal skin respiratory processes. Further, the film must be highly resistant to burning when exposed to the high energy lasers frequently employed in modern surgical suites for performing an incision. The application of the film composition should also be convenient, cost-effective, and capable of providing a film with sufficient microporosity for both maintaining the skins respiratory processes and supporting the release of an encapsulated antimicrobial agent.

The present inventors have actively investigated for a composition that satisfies the above requirements for use as a combination preoperative skin preparation and surgical incise drape. Satisfying the many above stated requirements, the inventors disclose a materially improved PVDF-based composition comprising an amine-substitued acrylic polymer component. The composition of the present invention provides a film with substantially enhanced durability and skin-adhesion promoting characteristics over the prior art. The present invention represents an unforeseen improvement over U.S. Pat. No. 5,041,287, and these improvements provide a film forming composition suitable for use as a combination surgical preparation and drape.

SUMMARY OF THE INVENTION

In accordance with one embodiment of the invention, an improved PVDF-based composition comprising an amine-substitued acrylic polymer component is provided that forms a barrier film with substantial improvements in skin-adhesion, toughness and durability over the prior art. The improved durability and skin-adhesion characteristics providing a longer lasting film for imparting prolonged delivery of an encapsulated antimicrobial agent to the skin surface. The durability of the film is further illustrated by its resistance to physical removal.

The present invention provides an advantageous one-step method for eliminating surgical site microbial growth, and forming a surgical incise drape. The surgical incise drape rendering the interface between the skin and the film an aseptic environment before, during and following the surgical operation. In general the method involves applying the film forming composition to the surgical incision site, allowing the solvent to evaporate to form a thin, durable, substantially adherent film free of wrinkles and bubbles. The surgical incise drape being highly resistant to degradation and removal by biological fluids. The surgical incise drape being sufficiently microporous to sustain the release of an encapsulated antimicrobial agent while not interfering with the skin surfaces necessary respiratory processes. Further, the surgical drape is highly nonflammable.

Another embodiment of the invention is a method of use providing a protective barrier film on the skin surfaces of incontinent patients. The barrier film providing protection to the patients skin surface from body excretions, such as, urine, fecal matter and perspiration. The present invention being substantially resistant to degradation by said body excretions. The microporosity of the protective barrier film prevents interference with the skins respiratory processes, thus, allowing the application of large skin surface areas.

A preferred film forming composition comprising:

(a) about 30 to 60% by weight of solids selected from the group consisting of polyvinylidene diflouride and the copolymers thereof;

(b) about 10 to 20% by weight of solids of a polymer of monomers selected from the group consisting of an alkylacrylate, an alkyl (meth)acrylate, and the copolymers thereof;

(c) about 30 to 60% by weight of solids of a polymer of monomers selected from the group

consisting of a dialkylaminoalkyl (meth)acrylate and the active salts thereof, and a lower alkyl (meth)acrylate;

(d) about 0.5 to 2.0% of water based on total composition weight;

(e) an effective amount of an antimicrobial agent; and

(e) an aqueous organic solvent for dissolving all components;

wherein, said composition when applied to a skin surface from said solvent dries in less than one minute forming a substantially durable, substantially fluid resistant, tack-free barrier film substantially adherent to said skin surface, said barrier film capable of releasing said antimicrobial agent in an amount effective to substantially impart prolonged antimicrobial properties on said skin surface.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates the moisture vapor transmission rate (MTVR) for the present invention. The MTVR of the present invention containing both chlorhexidine acetate (CHA) and silver sulfadiazine (AgSD), chlorhexidine alone, and with no antimicrobial agent present is compared against BLISTERFILM™ hydrocolloid wound dressing and SARAN® food wrap. The percent of water loss is plotted versus time in days. The data illustrate the present invention is breathable, thereby providing patient comfort and promotion of wound healing. See Test #3 for details.

FIG. 2 illustrates a drug diffusion assay showing the ability of the coating of the present invention to release an antimicrobial agent for providing microbicidal activity against *S. epidermidis* (diagonal hatch) and *C. albicans* (horizontal hatch). The assay was performed with the present invention containing both chlorhexidine acetate (CHA) and silver sulfadiazine

(AgSD), chlorhexidine alone, silver sulfadiazine alone, and with no antimicrobial agent present. The measure of microbicidal activity released by the coating of the present invention is plotted as the zone of inhibition in millimeters. The composition of the present invention with the highest microbicidal activity is characterized by a larger numerical value for the zone of inhibition. See Test #7 for details.

DETAILED DESCRIPTION OF THE INVENTION

A problem addressed and resolved by the present invention is reducing the number of surgical wound associated infections with an improved PVDF-based composition comprising an admixture of PVDF, acrylic polymers, and an amine-substituted acrylic polymer. The composition of the present invention resulting in unforeseen improvements over the prior art (U.S. Pat. No. 5,041,287). The improvements including substantial increases in the PVDF-based films resistance to biological fluids, durability, and skin-adhesion properties. The improvements over the prior art forming a film having the desired features necessary for providing an effective one-step, preoperative skin preparation and surgical incise drape with sustained release of an antimicrobial agent. The antimicrobial agent eliminates microbes present on the skin surface and continues to inhibit any rapid rebound microbial growth over an extended period. The improved composition is soluble in a solvent, and when applied to the surgical incision site dries in less than a minute to form a substantially nonflammable surgical drape. Further, the improved composition does not cause primary irritancy and allergic sensitivity when contacted with skin.

The film forming composition of the invention is further suitable for use as a protective barrier on incontinent patients. The substantial skin-adhesion and durability of the invention achieves long-lasting protection against biological fluids, such as, urine, and resistance to

detachment from the skin by body oils, perspiration and hot water. The coating has further applicability as both a protective barrier and a delivery system for preventing infection at the site of a dialysis artero-venous shunt, feeding tube, colostomy conduit, urinary catheter or the like.

A preferred embodiment of the invention is a barrier film with sufficient moisture vapor permeability supporting reduction of excessive moisture buildup that could macerate the skin and loosen the adhesion of the film. Another feature of the invention is a coating suitable for maintaining the isothermic environment appropriate for an individual's body temperature. To sustain both the desired isothermic environment and moisture vapor permeability, it is preferred the microporosity provide a moisture vapor transmission rate of 0.1 to 1.0 g/cm^2/day. The preferred composition forming a film with a suitable microporosity includes water. Use of an aqueous acrylic emulsion, such as Rhoplex B-15J, is an advantageous method for preparing a composition having the desired microporosity. Rhoplex B-15J, is an acrylic polymer available from Rohm & Hass, Philadelphia, Pa.

It is another feature of the invention that the microporosity characteristic enhances diffusion to the skin surface of the antimicrobial agent or medicament encapsulated within the barrier film. Typical antimicrobial agents deliverable to the skin surface from the film include antibiotics, iodophors, silver sulfadiazine, chlorhexadine and biologically active salts thereof. An effective antibiotic for preventing antimicrobial growth is nystatin utilized in the concentration ranging from about 0.5 to 2.0% of the total weight of said film forming composition. A more preferrable antibiotic is chlorhexidine acetate, or a chlorhexidine acetate and silver sulfadiazine combination with each at an effective concentration in the range of about 0.5 to 2.0%. The preferred composition comprising chlorhexidine and silver sulfadiazine

provides a film having the desired microbicidal activity without altering film integrity or the desired microporosity. The improved skin-adhesion property allows the film to remain attached to the skin for an extended time period allowing the prolonged delivery of a preferred antimicrobial agent.

A suitable medicament for delivery the skin surface includes an anti-inflammatory agent, a steroid, an antiviral agent, an antifungal, an anticoagulant, an antiphlogisitic, a chemotherapeutic, a hemostatic, a cytostatic, and a hormone.

A preferred embodiment of the composition further includes a dye soluble in the organic solvent for visually ascertaining the location of the skin surface coated with the composition. The dye can act as a visual indicator during the course of a surgical operation, or provide a means for determining when a new coating may be required. Suitable dyes having virtually no effect upon the characteristics of the film include the Drug and Cosmetic class of dyes, such as, Drug and Cosmetic Green No. 6. The preferred range of dye concentration is between 0.01% and 0.1% (w/w).

The preferred solvent provides a drying time of less than one minute, and compromises neither film toughness, resistance to detachment in a wet/humid environment, nor the microporous film morphology. Exemplary solvents providing the above stated requirements include acetone, ethyl acetate and mixtures thereof. The most preferrable of the solvents is acetone because of its excellent disinfectant qualities and its volatility provides a preferrable drying time of less than one minute.

Another preferred embodiment of the invention is the adventageous inclusion of a lipid component in the composition. The lipid component provides protection from irritation of the

skin surface caused by the defatting action of the solvent. Suitable lipids are unsaturated fatty acids, saturated fatty acids, and sphingolipids. The most preferrable of the lipids include ceramide Type III, ceramide Type IV, cholesterol, and linoleic acid. The preferred range of lipid concentration is between 0.25 and 2.0 parts by weight per 10,000 parts by weight of polymer solids.

It is a preferred feature of the invention that the surgical incision drape formed by the composition be nonflammable. Most modern surgical suites employ high energy devices to perform an incision at the surgical site. It is highly desirable that the film be substantially resistant to burning and charring when exposed to common high energy surgical devices.

The present invention provides a coating that is free of dermal irritation upon contact with the skin surface. It is a further feature of the invention that the improved composition does not elicit skin sensitization or delayed contact hypersensitivity.

Preferrably the composition is composed of a solids content of about 5 to 10% by weight, providing suitable films with a thickness of about 0.010 mm to 0.015 mm when applied in single coatings to the skin surface. Films of varied thickness can be obtained using different methods of application that include painting, spreading, swapping, dipping or spraying. Alternatively, the thickness of the coating may be increased using multiple applications.

The preferred composition of the invention utilizes polyvinylidene diflouride homopolymer or a copolymer thereof. Suitable copolymers include tetrafluoroethane and hexafluoropropylene. The greater the PVDF concentration, the tougher the coating and ease with which it separates from the skin. For applications requiring flexibility, skin-adhesion and durability in a humid environment, it is preferrable to dilute the PVDF component by altering the

copolymer content or by combination with an acrylic, such as, alkyl (meth)acrylate. For the present invention, other halogen based polyvinylidene homopolymers, such as polyvinylidene chloride (PVC) may also be utilized. For purposes of the present invention, a suitable range of PVDF is determined to be about 30 to 60% by weight of solids.

The composition of the invention comprises about 10 to 20% by weight of solids of a polymer of acrylic monomers selected from the group comprising alkyl (meth)acrylates. It is known that typical alkyl (meth)acrylates suitable for use in the invention comprise methyl acrylate, ethyl acrylate, butyl acrylate, methyl methacrylate, propyl methacrylate, ethoxyethyl acrylate, methoxyethyl acrylate, methoxyethyl methacrylate, ethoxyethyl methacrylate, and the like.

To prepare the composition of the invention it is beneficial to prepare an aqueous emulsion of the acrylic compounds prior to combining with the polyvinylidene fluouride. Preferred acrylic polymer dispersants include the following:

1. methyl methacrylate, butyl acrylate and acrylic acid
2. propyl methacrylate, butyl acrylate and acrylic acid
3. methoxyethyl methacrylate, butyl acrylate and acrylic acid
4. methyl methacrylate, 2-ethylhexyl acrylate and methacrylic acid.

The film forming composition of the present invention represents an unforeseen improvement over the prior art in it could not be foreseen that the addition of an amine-substituted acrylic polymer of monomers selected from a group consisting of dialkylaminoalkyl (meth)acrylate, and a lower alkyl (meth)acrylate would provide a composition forming a protective coating with substantial increases in skin-adhesion and durability in a humid

environment. A preferred coating for forming a surgical drape comprises about 30 to 60% by weight of the amine-substituted acrylic polymer.

The inclusion of an amine-substitued acrylic polymer into the composition of the prior art provides a film capable of remaining substantially intact and 100% attached to a glass slide during 14 to 19 days of submersion in 37°C water (Formulation in EXAMPLE 1). This represents a substantial increase in skin-adhesion and durability over the prior art (U.S. Pat. No. 5,041,287). Which appears to be capable of remaining intact and 100% attached to a glass slide for 24 to 48 hours of submersion in 37°C water. When tested on human skin, the film of the present invention remained intact and 100% attached for at least 34 hours, while the film prepared from the prior art composition began to show separation at 20 hours. The preferred embodiment of skin-adhesion allows for greater retention of the film during a surgical procedure, providing the means for release of an encapsulated antimicrobial agent and protection of the surgical site from contamination.

Suitable dialkylaminoalkyl (meth)acrylates which can be used to prepare the amine-substituted acrylic polymer include N,N-dimethylaminoethyl (meth)acrylate, N,N-diethylaminoethyl (meth)acrylate, t-butylaminoethyl (meth)acrylate and active salts thereof. About 20 to 30% by weight the amine-substituted acrylic polymer to total solids content has been found suitable for the coatings of the present invention.

Suitable lower alkyl (meth)acrylates which can be used to prepare the amine-substitued acrylic polymer comprise those having 1 to 8 carbon atoms in the alkyl group such as methyl acrylate, ethyl acrylate, isopropyl acrylate, methyl methacrylate, propyl methacrylate, ethoxyethyl methacrylate, and the like.

A preferred composition for forming a surgical drape has a solids content of about 5 to 10%, and comprisises about 30 to 60% by weight of polyvinylidene difluoride, 10 to 20% by weight of a mixture of methyl acrylate, and methyl methacrylate, and 30 to 60% by weight of a polymer comprising N,N-dimethylaminoethyl methacrylate, and methyl methacrylate.

It is a feature of the invention that the improved composition be used as a one-step method for a combination surgical site preparation and drape. The present invention can be applied by either painting, spreading, or spraying. After the composition is applied to the selected surgical site, the solvent is allowed to evaporate. The time allowed for evaporation is rapid, occurring in less than one minute. The presence of the dye in the composition provides the individual applying the film with the means to visualize whether the surgical site is adequately covered. Once the desired surgical site is covered, the film provides a substantially durable surgical incise drape that promotes aseptic conditions on the skin surface through the combined action of the solvent and sustained release of an encapsulated antimcrobial agent. The surgical incision can next be made through the surgical drape without burning or charring the film.

In practice, another feature of the invention is a kit for applying the composition to the skin surface including a sealed container having an application means. Preferrably the application means is coupled to the container and comprises a pump spray, sponge, cloth, gauze, cotton, wool, brush, or roller ball applicator. A preferred feature of the kit is it can be contained within a sealed package that is capable of being sterilized, thus, providing a suitable and convenient means for applying the composition in the sterile environment of a surgical suite.

The following example compositions are provided to illustrate the invention, but are not to be considered to limit the invention. By way of example, a list of useful components and their sources is provided in Table I.

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TABLE I. Commercially available sources of Components

Ingredient	Product Identification	Source
Vinylidene Fluouride -Tetra Fluoroethylene Copolymer	Kynar 7201	Elf Atochem ATO Philadelphia, PA
Acrylic Copolymer	Rhoplex B-15J emulsion	Rohm and Haas Company Philadelphia, PA
Butylmethacrylate,2-Dimethylamino-ethyl Methacrylate, and Methyl Methacrylate Acrylic Copolymer	®Eudragit E100	Hüls America, Inc. Somerset, NJ
Acetone	dimethylketone: 2-propanone	Mallinckrodt Baker Inc. Paris, KY

EXAMPLE 1

A composition suitable for forming a surgical incise drape was prepared as follows utilizing commercially available compositions.

Component	Weight
Kynar 7201	5 g.
Rhoplex BJ-15	2.5 g.
Eudragit E 100	2.5 g.
Acetone	90 g.

The preparation of the composition is performed at room temperature with an anchor stirrer. The listed components are sequentially placed into a beaker, and the composition thoroughly mixed by stirring overnight to prepare a 10% by weight of polymer solids composition. The prepared composition readily forms a substantially adherent, durable film upon application to the skin surface and evaporation of the solvent.

EXAMPLE 2

Following the procedure of EXAMPLE 1, a film forming composition with the desired microbicidal activity was prepared comprising by weight both 0.5% chlorhexidine acetate and 0.5% silver sulfadiazine. 0.5 grams of each antimicrobial agent provides a PVDF-based coating suitable for eliminating normally present microbes from the surgical incision site, and preventing rapid rebound microbial growth. This composition providing a preferred one-step combination surgical site preparation and drape.

EXAMPLE 3

Following the procedure of EXAMPLE 1, a composition containing Chlosterol, Palmitic acid, Ceramide III and Ceramide IV was prepared. The resulting film provides a surgical incision drape that wards off the defatting action of the solvent in the composition. The quantities of the lipid in this example are provided in TABLE II.

TABLE II.

Lipid	mg of lipid/100g of composition
Cholesterol	0.4 mg
Palmitic acid	0.09 mg
Ceramide III	0.03 mg
Ceramide IV	0.03 mg

The invention is further illustrated by the following testing objectives.

TEST #1 -- FLAME PROPAGATION TEST

The tendency of the dried film of the invention to propagate a flame was determined using a modification of Underwriters Laboratory standard test UL94 "Plastics materials for parts in devices and appliances" (1991).

Using the composition described in Example 1, a 75x25x1 mm glass microsope slide is coated by wiping with a composition flooded sponge. Either immediately, or after fully drying, the coated slide is passed through a Bunsen Burner flame to ignite the composition. The coated slide is inserted into the flame at varying angles to observe the extent to which a flame consumes the composition. In the 180° flame-propagation test, at 0°, the specimen points upward ("North") and a flame is carried away from the film. Thus, at 0° the coating is subjected to the mildest condition in the test. Highly flammable materials will support a flame at 0°. Slightly flammable materials will support a flame at 180°, but inflammable materials will not. At progressively decreasing intermediate angles (135°, 90°, 45°), less of the specimen is contacted by the flame; so the severity of the test is reduced as the angle is decreased. Therefore, the smaller the angle which supports the propagation of a flame, the greater the hazard.

Another aspect of fire hazard is the time during which initially flammable materials, such as solvent-based coatings, remain flammable after they are applied. This was evaluated by allowing the coatings to dry for varying periods of time, at room temperature, and then subjecting them to the flame-propagation test at 180°. This test provides a measure of the time in which the coating remains a fire hazard. It is preferred that the coating be inflammable a short period of time after application.

The results of the two flammability tests are described in Tables III and IV.

TABLE III. Flammability of PVDF-based Skin Preparation Coating Materials

Composition	Coating Wet/Dry	Flame Angle (°)	Specimen Consumed (%)	No. of Trials
Example 1	Wet	180	100	2
		90	100	2
		45	100	2
		0	100	2
Example 1	Dry	180	0	3
		90	0	2
		45	0	2
		0	0	2

The results of the flame propagation test demonstrate that the PVDF-based coating will propagate a flame prior to drying, but quickly becomes inflammable. As shown in Table IV, the composition provides a surgical incision drape inflammable at the 180° test angle after a drying time of less than 15 seconds.

TABLE IV. Drying time required for surgical coating to become inflammable at 180° test angle

Composition	Drying time (sec.)	No. of Trials
Example 1	8-13	5

TEST #2 -- FILM FLAMMABILITY WIHT HIGH ENERGY SURGICAL TOOLS

Films formed from the composition of this invention may be subjected to modern high energy surgical instruments, and must therefore be flame resistant. To determine the film's flame resistance, the composition described in EXAMPLE 2 was applied to the skin of an orange and the exterior skin portion of a ham hock, and allowed to dry for one minute. Following this dry time, commonly used surgical lasers (TABLE V) were employed to test their burn effect on the film coating. Neither laser resulted in burning or charring of the film coating. Dry films of

the invention therefore do not pose a fire hazard when used in conjunction with the high energy devices present in modern surgical suites.

Table V. Flammability of PVDF-based coating used with High Energy Surgical Instruments

Instrument and Setting	Orange Flame		Ham Hock Flame	
	yes	no	yes	no
Coherent VersaPlus Select Nd-Yag, Neodymium 1.06 μm laser:				
Setting: High; Time: 120 seconds; Power: 60 watts		X		X
Coherent VersaPlus Select Nd-Yag, Holmium 2.1 μm laser:				
Setting: High; Energy: 28 Joules; Rate: 20 pulses/second		X		X
ConMed Excalibur Plus Bovie:				
Setting Standard; 50 coagulation		X		X
Setting Standard; 25 cut		X		X
Setting High; 120 coagulation		X		X
Setting High; 180 cut		X		X
Storz Fiber Optic:				
100% Illumination (max.); 1 minute		X		X

TEST #3 -- MICROPOROSITY AND MOISTURE VAPOR TRANSMISSION RATE

Microporosity is an essential feature of a surgical incise drape. The moisture vapor transmission rate (hereinafter will be abbreviated as MTVR) is the measure of a films ability to allow air and water vapor to pass through while preventing the passage of liquid water. The MTVR is directly related to the microporous morphology of a film, and is defined by the presence of pores extending throughout the film. The MTVR provides a physical barrier to moisture while allowing moisture vapor to permeate through. The microporosity, and, thus the MTVR of the invention can be adjusted over a wide range of compositional variations. When examined under an electron microscope at 10,000X, a coating prepared form the composition in EXAMPLE I is found to contain pores of about 0.1 to 2.0 μm in diameter.

For the present test, several coating compositions were tested to determine the effect an amine-substituted acrylic monomer would have upon the formation of the microporous morphology required for a suitable surgcial drape. It was found that the presence of the amine substituted acrylic monomer in combination with an aqueous acrylic emulsion (Rhoplex-R B-15J emulsion, Rohm and Haas Company, Philadelphia, PA), formed a film with the appropriate MTVR.

To test the MTVR of the present invention PVDF-based films having 0.5% w/w chlorhexidine acetate, PVDF-based films containing a combination of 0.5% w/w chlorhexidine acetate and 0.5% w/w silver sulfadiazine, PVDF-based films without antimicrobial, BLISTERFILM™ hydrocolloid wound dressing, and SARAN® food wrap were tested to determine which had the greatest MTVR (see FIG. 1). BLISTERFILM™ is a commercial hydrocolloid wound dressing that is described as having a relatively high MVTR that is adquate to promote wound healing.

The PVDF-based films were prepared following EXAMPLE 1 and EXAMPLE 2, respectively. Three replicates of each test sample were stretched over the mouths of 28.5 mm diameter tubes filled with 30 grams of distilled water. The tubes were clamped in an inverted position, and placed in a controlled environment room at 37°C and 24% relative humidity for seven days. The amount of water loss due to evaporation was monitored over several days. The improved composition (EXAMPLE 1 and 2) demonstrated a relatively high moisture vapor transmission rate. As shown in FIG. 1, the percent of water lost over time remained linear up to 100% water loss. Furthermore, FIG. 1 illustrates the MTVR of the present invention is substantially greater than both the BLISTERFILM™ hydrocolloid wound dressing, and

SARAN® food wrap. This result illustrates that a preferred feature of the invention is a substantially porous and breathable film. This preferred feature maintains the isothermic environment appropriate for a patient's body temperature, ensures adequate adhesion by preventing moisture buildup, and provides a route for the release of antimicrobial agents encapsulated within the coating.

TEST #4 – EVALUATION OF INVENTION AS A PRIMARY IRRITANT

To determine whether the preferred composition of the invention causes skin irritation the following test was performed. One day prior to the application of the coating, the hair on the back of six New Zealand White rabbits was removed with clippers. The skin surface on one side of the shaved area was left untouched while the other side was irritated by scratching with a sharp object. A 0.5 mL portion of the PVDF-based coating from EXAMPLE 1 was applied to both the untouched and the irritated skin, and covered with one inch square pieces of gauze sponges. The application sites were further protected by wrapping the trunks of the animals with gauze, and securing with elastic bandage.

The untouched and irritated test sites were given a pre-assigned score for both erythema and edema formation 24 hours and 72 hours after application of the coating (TABLE VI). The sum of the eight erythema and edema values was divided by four to give a Primary Irritation score. The Mean Primary Irritation Index was determined by dividing the Primary Irritation score by six, the number of test animals. The coating reaction was then assigned a descriptive rating, from this Index, providing a Mean Primary Dermal Irritation score (TABLE VII).

TABLE VI: Evaluation of Skin Reations

Erythema and Eschar Formation	Value
No Erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema to slight eschar formation	4
Edema Formation	**Value**
No Edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined)	2
Moderate edema (raised about 1 mm)	3
Severe edema (raised more than 1 mm)	4

TABLE VII: Mean Primary Irritation Index/Descriptive Rating

Range of Values	Descriptive Rating
0	Non-Irritating
0.1 - 1.9	Mildly Irritating
2.0 - 5.9	Moderately Irritating
6.0 - 8.0	Severely Irritating

Seven of the possible 48 test sites scored a one having only a barely visible erythema formation present (see Table VI). Thus, the composition of the invention had a Mean Primary Dermal Irritation score of 0.3. As shown in Table VII, mild irritants have values ranging from 0.1 to 1.9, indicating that the composition of the invention falls into the lowest end of the "mildly irritating" category. The slight irritation is expected with the introduction of a solvent to an area subjected to prior irritation. The results of this test demonstrate that the preferred composition of the invention does not cause any substantial skin irritation, but shows only mild signs of irritation when applied to previously irritated skin.

TEST # 5 -- *IN VIVO* DURABILITY

A preferrable feature of a PVDF-based composition useful for a one-step skin-preparation and surgical drape is sufficient durability and adhesion under end-use conditions. To determine whether the invention provided the desired durability and adhesion, the coating was applied to the skin of human volunteers and subjected to end-use conditions.

The volunteers applied to the anti-cubital fossa of both the left and right arms the composition prepared in EXAMPLE I. The coatings were observed for eight hours or longer before the volunteer either showered or bathed. Each volunteer subjectively evaluated the results of the experiment according to a rating scale. The rating scale was the percentage of coating remaining intact at each examination.

The coatings remained 90% to 100% intact with no separation or detachment after bathing. After continuing to wear the coating for a total of 24 hours, no more than 10% of the film had lifted up along the edges of the coated area. The film was found to gradually detach and flake away after 48 hours of wear. The results of *in vivo* durability test demonstrate that the invention provides a substantially durable film coating resistant to body oils, perspiration, and hot water.

TEST #6 -- RESISTANCE OF THE COATING TO BIOLOGICAL FLUIDS

For use of the composition as a surgical drape it is highly desirable that the film remain substantially adherent and maintain adequate moisture vapor transmission in the presence of biological fluids. The PVDF-based coating prepared in EXAMPLE 1 was evaluated for its resistance to detachment in the presence of biological fluids by submersion of a film-coated

microscope slide into blood, distilled water, saline, urine, and sodium heparin blood for three days at 37°C. The integrity of the coatings was rated daily according to a five-point scale, ranging from zero to four where zero represented 100% separation, and four represented no separation (0%) of the film from the slide. Following this protocol, the surgical drape coating remained fully adhered to the slide after three days continuous submersion in water, saline, and blood. In urine, slight lifting at the edges occurred after two days (rating of 3), which progressed to a rating of 2 (25-50% separation) after three days of continuous submersion.

To evaluate the films MTVR after exposure to biological fluids the test procedure described in TEST #3 was followed. The films compared were initially subjected to a 7 hour exposure to blood, urine, and water in a closed environment at 37°C, followed by a saline solution rinse. The films were then stretched over the mouths of 28.5 mm diameter tubes filled with saline solution to test the MTVR. After the 7 hour exposure, there was a small but non-significant decrease in the moisture vapor transmission rate, and no visible indications of leakage through the film.

The results of the resistance to biological fluids test demonstrate the integrity and continued protective function of the composition when used as a surgical drape or protective barrier for an incontinent individual.

TEST #7 – DRUG DIFFUSION ASSAY

The ability of a film coating to release antimicrobial agents to the skin surface is a preferred embodiment of the present invention. To evaluate the ability of the present invention to deliver encapsulated antimicrobial agents to the skin surface, a zone of inhibition test was

performed. For this test, the EXAMPLE 1 formulation containing either 0.5% chlorhexidine acetate, 0.5% chlorhexidine acetate and 0.5% silver sulfadiazine, or 2.0% silver sulfadiazine was analyzed. Two coatings of the improved formulation were applied on one side of a 9.8 mm polyethylene disc to an average thickness of 0.014 mm. Five discs were prepared for each test solution. Five disc coated with the improved composition without an encapsulated antimicrobial agent were included as controls.

The coatings were allowed to completely dry and then inverted on buffered yeast morphology agar plates swabbed with an inoculum of *C. albicans* or *S. epidermidis*. This placed the film coating in direct contact with the inoculated yeast morphology agar plates. The plates were incubated at 37°C for 24 hours. Determining the distance in millimeters from the periphery of the film coated disc to the sites of active microbial growth provides a measure of the zone of inhibition. The zone of inhibition is produced by diffusion out of the film of an encapsulated antimicrobial to the agar substrate, thereby eliminating any microbial growth that surrounds the film coated disc. Thus, the ability of a film to release increasing amounts of antimicrobial agent is characteristized by an expanded zone of inhibition. As shown in FIG. 2, the improved composition containing the 0.5% chlorhexidine acetate and 0.5% silver sulfadiazine combination provided the greatest zone of inhibition with a 16 mm zone of *S. epidermidis* inhibition. The results demonstrate that the improved PVDF-based coating can effectively release chlorhexidine acetate, silver sulfadiazine and a combination of chlorhexidine acetate and silver sulfadiazine. The control disc exhibited no inhibition and therefore no antimicrobial activity.

TEST #8 -- MICROBICIDAL ACTIVITY OF DRIED COATINGS

An effective surgical drape provides the desired microbicidal activity against a variety of microorganisms. To evaluate the microbicidal activity of the composition including an antimicrobial agent, a modified *in vitro* test found in the technical literature supplied by 3M Corporation for DURAPREP™ was utilized. In the 3M study design, coatings were applied to filters pre-seeded with microorganisms followed by 5 minute homogenization of the filters. The homogenized filters were then plated on nutrient substrates. 3M's technical literature reports a 100% kill within 1 minute of application using this method. These results, however, are to be expected considering the 3M solution contains 74% isopropyl alcohol (w/w). Thus, the inventors were concerned that the improved compositions's high concentration of acetone, with its inherent microbicidal properties, would eliminate all viable microorganisms regardless of the encapsulated antimicrobial agent. The modified version of the *in vitro* test therefore involves coating the filter with the test composition, allowing the acetone to completely evaporate, and then seeding the filter with microorganisms.

The modified version provides a stringent test of the microbicidal properties of one of the desired compositions including an antimicrobial agent. The test was performed using the formulation prepared in EXAMPLE 1 containing by weight either 0.5% chlorhexidine acetate, or 0.5% chlorhexidine acetate and 0.5% silver sulfadiazine. The test for *Escherichia coli* was performed as follows:

1. *E. coli* was grown overnight on Trypticase Soy Agar (TSA) at 37°C.
2. The following morning, colonies of *E. coli* were swabbed from the plate and diluted to an O.D. 530 of 0.05 with phosphate buffered saline (PBS).

3. Gelman hydrophilic polypropylene membrane filters (47 mm, .045μm) were placed on support and uniformly painted with the PVDF and antimicrobial combination using an artist brush. The polymer-coated membranes were allowed to air dry for 2 minutes at room temperature.

4. The bacterial suspension (0.1ml) described above was placed on the coated membrane and aseptically spread uniformly across the film coated membrane.

5. At 0 minutes, 2 minutes, 10 minutes and 30 minutes the filters were aseptically place in 10 ml of Letheen + 0.1% sodium thiosulfate to inactive the antimicrobial agent, and vortexed 30 seconds to dislodge the bacteria.

6. The suspension of dislodged bacteria was serially diluted in Phosphate buffered dilution water and plated on TSA plates for determination of the number of viable bacteria per ml.

7. Colonies were counted and recorded as the number of viable bacteria (per ml) dislodged from the surface of the PVDF-coated membranes. The log reduction in viability was determined by comparing the number of viable bacteria dislodged from the surface of the coating with and without an antimicrobial.

The results of the test show that the microbicidal activity of the dried PVDF-based composition containing a combination chlorhexidine acetate and silver sulfadiazine has substantial *in vitro* microbicidal activity. The test composition providing substantial reductions in colony forming units at 0, 2, 10 and 30 minute incubations.

The test was performed with similar results for *Staphylococcus epidermidis, Pseudomonas aeruginosa, Staphylococcus aureus, Proteus vulgaris, Candida albicans, Serratia marcesens*, and *Trichophyton mentagrophytes*. The results of the test demonstrate that antimicrobial agents encapsulated within the improved PVDF-based coating of the present invention provide substantial microbicidal activity *in vitro* against a variety organisms.

What is claimed is:

1. A film forming composition for providing a protective coating on a skin surface, comprising:

(a) about 30 to 60% by weight of solids selected from the group consisting of polyvinylidene diflouride and the copolymers thereof;

(b) about 10 to 20% by weight of solids of a polymer of monomers selected from the group consisting of a lower alkylacrylate, a lower alkyl (meth)acrylate, a hydroxy lower alkylacrylate, an alpha beta unsaturated carboxylic acid having an acid number of about 20 to 150, and the copolymers thereof;

(c) about 30 to 60% by weight of solids of a polymer of monomers selected from the group consisting of a dialkylaminoalkyl (meth)acrylate and, a lower alkyl (meth)acrylate;

(d) about 0.5 to 2.0% of water based on total composition weight;

(e) an effective amount of an antimicrobial agent; and

(f) an aqueous organic solvent for dissolving all components.

2. The composition of claim 1, further comprising a medicament.

3. The composition of claim 2, wherein said medicament is selected from the group consisting of an anti-inflammatory agent, a steroid, an antiviral agent, an antifungal, an anticoagulant, an antiphlogisitic, a chemotherapeutic, a hemostatic, a cytostatic, and a hormone.

4. The composition of claim 3, wherein said cytostatic is a silver compound.

5. The composition of claim 1, wherein said antimicrobial agent is substantially releasable in an amount sufficient to substantially impart prolonged antimicrobial properties on said skin surface, said antimicrobial agent selected from the group consisting of antibiotics, iodophors, silver sulfadiazine, chlorhexadine and biologically active salts thereof.

6. The composition of claim 5, wherein said antibiotic is nystatin present in a quantity ranging from about 0.5 to 2.0% of the total weight of said film forming composition.

7. The composition of claim 1, wherein said solvent is selected from the group consisting of acetone, ethyl acetate, and mixtures thereof.

8. The composition of claim 1, wherein said solids comprise between about 5 to 10% of the total weight of said film forming composition.

9. The composition of claim 1, further comprising a dye soluble in said organic solvent.

10. The composition of claim 9, wherein said dye is Drug and Cosmetic Green No. 6.

11. The composition of claim 1, further comprising a lipid component.

12. The composition of claim 11, wherein said lipid component is selected from the group consisting of an unsaturated fatty acid, a saturated fatty acid, and a sphingolipid.

13. The composition of claim 11, wherein said lipid component is selected from the group consisting of ceramide Type III, ceramide Type IV, cholesterol, and linoleic acid.

14. The composition of claim 11, wherein said lipid component being present in an amount of about 0.25 to 2.0 parts by weight per 10,000 parts by weight of polymer solids in said composition.

15. The composition of claim 1, wherein said dialkylaminoalkyl methacrylate being about 6 to 16% of the total weight of all solids in the composition.

16. The composition of claim 1, wherein said dialkylaminoalkyl (meth)acrylate is selected from the group consisting of N,N-dimethylaminoethyl (meth)acrylate, N,N-diethylaminoethyl (meth)acrylate, t-butylaminoethyl (meth)acrylate and active salts thereof.

17. The composition of claim 1, wherein said protective coating having a moisture vapor transmission rate of about 0.1 to 1.0 g/cm^2/day, said moisture vapor transmission rate sufficient to substantially maintain the isothermic environment of said skin surface.

18. A method for eliminating and inhibiting microbial growth at a skin surface site, comprising the steps of:

(a) applying to said skin surface site said film forming composition in claim 1;

(b) allowing evaporation of solvent from said film forming composition to form a protective film coating;

(c) allowing said protective coating to remain on said skin surface site for releasing antimicrobial agents in a quantity sufficient to substantially eliminate present microbes and inhibit microbial rebound growth on said skin surface site.

19. The method claimed in claim 18, wherein said site is a surgical procedure site and said film forming composition forms a substantially fluid resistant, substantially durable, substantially adherent surgical incise drape, said surgical incise drape capable of releasing a medicament, and an antimicrobial agent in a quantity capable of substantially imparting prolonged antimicrobial properties on said surgical procedure site.

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20. The method claimed in claim 18, wherein said film forming composition is applied to the skin surface of an incontinent person forming a substantially fluid resistant barrier film capable of imparting prolonged antimicrobial properties on the skin surface of said incontinent person.

21. The method claimed in claim 18, wherein said applying is by painting, spreading, swapping, dipping or spraying.

22. The method claimed in claim 18, wherein said barrier film is about 0.010 mm to 0.015 mm thick, when dry, on the skin surface.

23. A kit for applying the film forming composition to a skin surface site, said kit comprising:

(a) a sealed container for containing said film forming composition in claim 1;

(b) coating means for applying to said skin surface site said film forming composition; and

(c) a sealed package for holding said sealed container and said means for applying said film forming composition.

24. The kit claimed in claim 23, wherein said kit is sterilizable.

25 The kit claimed in claim 23, wherein said coating means is selected from the group consisting of a pump-spray, sponge, cloth, gauze, cotton, wool, brush and roller-ball applicator.

26 A film forming composition for providing a protective coating on a skin surface, comprising:

(a) about 30 to 60% by weight of solids selected from the group consisting of polyvinylidene diflouride and the copolymers thereof;

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(b) about 10 to 20% by weight of solids of a polymer of monomers selected from the group consisting of a lower alkylacrylate, a lower alkyl (meth)acrylate, a hydroxy lower alkylacrylate, an alpha beta unsaturated carboxylic acid having an acid number of about 20 to 150, and the copolymers thereof;

(c) about 30 to 60% by weight of solids of a polymer of monomers selected from the group consisting of a dialkylaminoalkyl (meth)acrylate, and a lower alkyl (meth)acrylate;

(d) about 0.5 to 2.0% of water based on total composition weight;

(e) a lipid component being present in an amount of about 0.25 to 2.0 parts by weight per 10,000 parts by weight of polymer solids;

(f) an effective amount of an antimicrobial agent; and

(g) an aqueous organic solvent for dissolving all components.

27. The composition of claim 1, wherein said composition when applied to a skin surface from said solvent dries in less than one minute forming a substantially durable, substantially fluid resistant, tack-free barrier film substantially adherent to said skin surface, said barrier film capable of releasing said antimicrobial agent in an amount effective to substantially impart prolonged antimicrobial properties on said skin surface, said barrier film being substantially porous, said pores ranging in dimension from about 0.1 microns to 2.0 microns in diameter.

28. The composition of claim$_{26}$, wherein said composition when applied to a skin surface from said solvent dries in less than one minute forming a substantially durable, substantially fluid resistant, tack-free barrier film substantially adherent to said skin

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surface, said barrier film capable of releasing said antimicrobial agent in an amount effective to substantially impart prolonged antimicrobial properties on said skin surface, said barrier film being substantially porous, said pores ranging in dimension from about 0.1 microns to 2.0 microns in diameter.

29. A film forming composition for providing a protective coating on a skin surface, comprising:

(a) about 30 to 60% by weight of solids selected from the group consisting of polyvinylidene diflouride and the copolymers thereof;

(b) about 10 to 20% by weight of solids of a polymer of monomers selected from the group consisting of a lower alkylacrylate, a lower alkyl (meth)acrylate, a hydroxy lower alkylacrylate, an alpha beta unsaturated carboxylic acid having an acid number of about 20 to 150, and the copolymers thereof;

(c) about 30 to 60% by weight of solids of a polymer of monomers selected from the group consisting of a dialkylaminoalkyl methacrylate, and a lower alkyl (meth)acrylate;

(d) about 0.5 to 2.0% of water based on total composition weight;

(e) an aqueous organic solvent for dissolving all components;

wherein, said composition when applied to a skin surface from said solvent dries in less than one minute forming a substantially durable, substantially fluid resistant, tack-free film substantially adherent to said skin surface.

30. The composition of claim 1, wherein said antimicrobial agent further comprises chlorhexidine acetate and silver sulfadiazine in a quantity ranging from about 0.5 to 2.0% of the total weight of said film forming composition.

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FIGURE 1

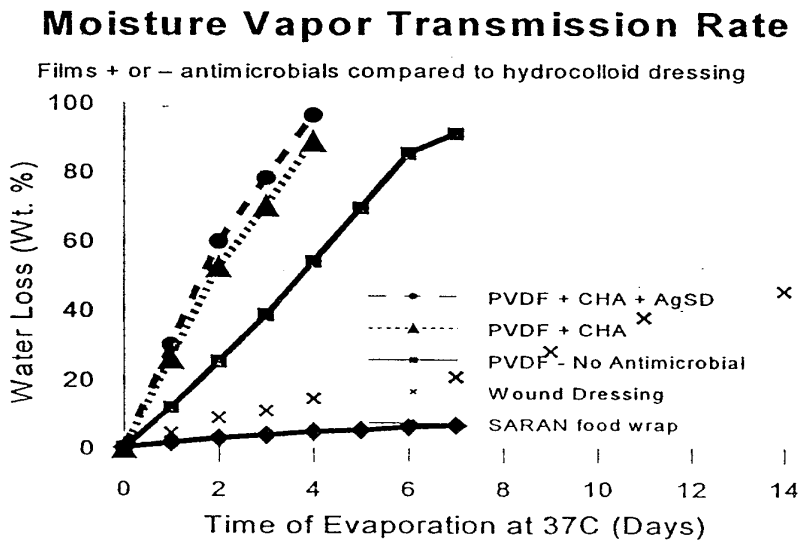
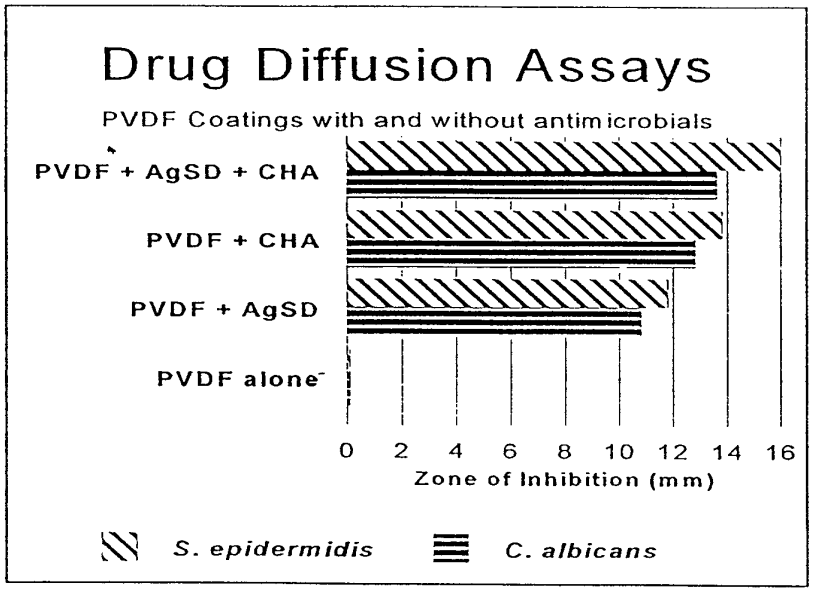


FIGURE 2



INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A01N 25/34
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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X - Y	US 5,041,287 A (DRIGGERS et al) 20 AUGUST 1991, column 2, lines 23-61; column 3, lines 3-13; column 3, lines 36-60; column 4, lines 48-57.	1-31 ----- 1-31
X - Y	US 4,374,126 A (CARDARELLI et al) 15 FEBRUARY 1983, column 2, lines 30-31 and 46-54; column 5, lines 3-19.	1-31 ----- 1-31

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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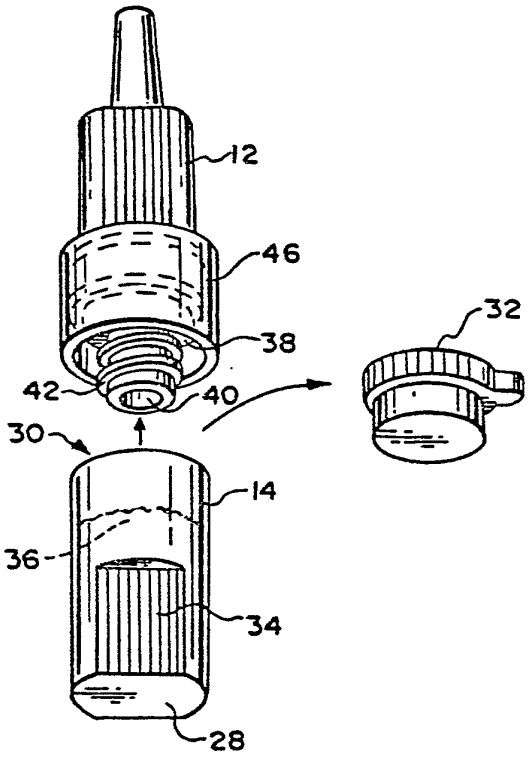
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(54) Title: ANTIBACTERIAL CLOSURE SYSTEM

(57) Abstract

A closure system (10) includes a connector (12) and a protective cap (14) in which there is a liquid antiseptic. As the cap and connector are joined together, multiple seals (56, 60) are formed to trap the liquid antiseptic (36) within the cap and force the antiseptic into the bore (40) of the connector.



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ANTIBACTERIAL CLOSURE SYSTEM

FIELD OF THE INVENTION:

This invention relates to closure systems for medical tubing or for ports on medical apparatus. The invention particularly relates to closure systems which provide an antibacterial effect.

BACKGROUND OF THE INVENTION:

Medical procedures often require a connection where the bioburden (i.e., bacterial population) is minimized. Closure systems containing an antibacterial agent can reduce the bioburden by providing a bacteriocidal or bacteriostatic effect to the connection site prior to and after use. Closure systems having an antibacterial effect are particularly desirable for components used in peritoneal dialysis.

At the present time thousands of patients who have limited or nonexistent kidney function due to end state renal disease are being maintained by continuous ambulatory peritoneal dialysis (CAPD), along with other forms of peritoneal dialysis.

In the CAPD procedure, connections between dialysis solution containers and administration sets which communicate with the peritoneal catheter must be routinely made and broken, normally several times a day. Particularly when the patient is doing the CAPD exchanges alone, there is the possibility that the sterility of the flow path between the various solution containers and the peritoneal cavity may be compromised. Airborne bacteria or the accidental contamination of an open connector by the patient can contaminate the flow path. The result of such a contamination can be peritonitis.

Closure systems for medical connectors, such as CAPD connectors, have been developed.

For example, in the Quinton Cap manufactured by Quinton Instrument Co., a liquid antiseptic such as povidone iodine, is injected into the lumen of the catheter by means of a syringe and then covered with a cap.

As another example, Lopez U.S. Patent 4,432,764 discloses an antiseptic end cap for a catheter. The end cap has a reservoir, in which a liquid antiseptic is retained. A movable wall can be displaced to force the liquid antiseptic from the reservoir into the bore of the catheter.

As yet another example, Genatempo et al U.S. Patent 4,440,207, which is assigned to the assignee of the present invention, discloses an end cap for a connector which is lined with an absorbent material containing an antiseptic.

BRIEF SUMMARY OF THE INVENTION:

The present invention provides a closure system which combines simplicity of operation with an enhanced antibacterial effect.

The closure system which embodies the features of the invention includes a connector and an associated protective cap. The connector includes a luer fitment having an interior bore and a skirt which peripherally surrounds the luer fitment. The cap has an exterior wall surface and an interior wall surface defining an interior chamber. A liquid antiseptic is retained in the interior chamber.

As the cap and connector are joined together, the luer fitment is moved progressively into the antiseptic-filled chamber. A first seal area is formed between the exterior cap wall surface and the skirt surrounding the fitment. In addition, a second seal area is formed between the interior cap wall surface and the luer fitment itself. These dual seal areas trap the liquid antiseptic within the cap cavity. As the advancing luer fitment occupies more and more of the double-sealed cap chamber, the trapped liquid antiseptic is forced into the bore of the luer fitment.

In the preferred embodiment, the luer fitment includes external threads. The cap further includes internal threads which engage the external threads of the luer fitment to provide a secure threaded connection between the connector and cap.

Other features and advantages of the invention will be pointed out in, or will be apparent from, the specification and claims, as will obvious modification of the embodiments shown in the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS:

Fig. 1 is a plan view of a closure system which embodies the features of the invention and in which the associated connector and cap are joined together;

Fig. 2 is another view of the closure system shown in Fig. 1 with the cap removed and the connector joined to a second mating connector;

Fig. 3 is another view of the closure system shown in Fig. 2 after the mating connectors have been disconnected and prior to the attachment of a new cap;

Fig. 4 is an enlarged perspective view of the closure system shown in Fig. 1; and

Figs. 5 to 7 are side views, partly in section, of the closure system as the connector and cap are being progressively brought together.

Before explaining the embodiments of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components as set forth in the following description or as illustrated in the accompanying drawings. The invention is capable of other embodiments and of being practiced or carried out in various ways. Furthermore, it is to be understood that the phraseology and terminology employed is for the purpose of description and should not be regarded as limiting.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A closure system 10 which embodies the features of the invention is shown in Fig. 1. The system 10 includes a luer-type connector 12 and a removable protective cap 14 for the connector 12.

The system 10 can be used in different operative environments. In the illustrated embodiment, the system 10 is used in conjunction with a peritoneal dialysis procedure. In this modality, the connector 12 is carried at the end of a catheter 16 which communicates with the peritoneal cavity of a patient. An extension set (not shown) can be used to interconnect the connector 12 with the end of the catheter 16. The cap 14 not only serves to protect the interior portions of the connector 12 from touch contact, but it also serves to provide an active antibacterial effect to prevent contamination of the connector 12 and adjacent portions of the catheter 16 or extension set. The closure system 10 thus reduces the potential for peritonitis, which is always a matter of paramount concern in peritoneal dialysis.

In use, the protective cap 14 is removed to expose the connector 12, when desired. This is shown in Fig. 2. The connector 12 can then be conveniently attached to suitable mating connector 18. As shown in Fig. 2, the mating connector 18 is carried at the end of a fluid administration set 20.

Once the resulting connection has been made between the connectors 12 and 18, spent peritoneal dialysis solution can be conducted out of the peritoneal cavity of the patient. Fresh peritoneal dialysis solution can then be conducted back into the peritoneal cavity so that the peritoneal dialysis process can continue. Upon the introduction of fresh dialysis solution, the two connectors 12 and 18 are separated, breaking the connection. This is shown in Fig. 3.

A new protective cap 14 is now attached to the connector 12. The protective cap 14 remains on the connector 12 (as shown in Fig. 1) while the just-freshly introduced peritoneal solution dwells within the peritoneal cavity for a predetermined period, typically about six hours. During this dwell period, the patient is free to carry on his or her activities, with the closure system 10 unobtrusively hidden beneath his or her clothing.

At the end of the dwell period, the cap 14 is removed and, preferably, discarded. Another exchange of spent-for-fresh peritoneal solution is made in the manner just described.

As best shown in Figs. 4 and 5, the protective cap 14 comprises a generally cylindrical body having an exterior wall surface 22 and an interior wall surface 24. The interior wall surface 24 defines an interior chamber 26. The chamber 26 has a closed end 28 and an open end 30. As shown in Fig. 3, the open end 30 is sealed prior to use by a removable plug 32.

The exterior wall surface 22 of the cap 14 may include a flattened, roughened portion 34 to facilitate the patient's grip on the cap 14 during its attachment and removal from the connector 12.

A liquid antiseptic 36 is carried within the cap chamber 26 to provide an active bacteriocidal effect when the cap 14 is attached to the connector 12. Prior to use, the plug 32 retains the antiseptic 36 within the chamber 26.

As is also best shown in Figs. 4 and 5, the connector 12 includes a luer fitment 38 and an annular skirt 46 which peripherally surrounds the fitment 38. While the luer fitment 38 may vary, in the illustrated embodiment, the fitment 38 comprises a female luer having a standard tapered interior bore 40. In the illustrated embodiment, the fitment 38 also includes a threaded distal end 42.

In this arrangement, the mating connector 18 comprises a suitably threaded male luer fitment 44 (shown in phantom lines in Fig. 1) which threadably engages the threaded distal end 42 within the skirt 46 and which sealingly occupies the bore 40 of the female luer fitment 38.

As best shown in Fig. 5, the threaded distal end 42 of the luer fitment 38 has an outer diameter which is less than the outer diameter of the rest of the fitment 38. An annular shoulder 48 is thus created on the fitment 38 near the threaded distal end 42.

Near this annular shoulder 48 there is also an upstanding ridge 50 formed on the fitment 38. This ridge 50 has a further increased outer diameter, compared to the rest of the fitment 38.

As can also be seen in Fig. 5, the interior cap wall surface 24 includes an interior threaded portion 52. This threaded portion 52 mates with the threaded distal end 42 of the luer fitment 38. The inner diameter of the threaded portion 52 is generally equal to the outer diameter of the threaded distal end 42 of the fitment 38.

An annular lip 54 extends outwardly from the exterior cap wall surface 22 at the open end 30 of the cap 14. As shown in Fig. 5, the lip 54 contacts the interior of the skirt 46, there forming a first sealed area 56.

As can be seen in Figs. 6 and 7, as the luer fitment 38 is progressively advanced into the interior chamber 26 of the cap 14, the first sealed area 56 formed between the annular lip 54 and the interior of the skirt 46 is continuously maintained.

As shown in Fig. 5, the region 58 of the cap 14 between its threaded portion 52 and its open end 30 has a larger inner diameter than the inner diameter of the threaded portion 52. This larger inner diameter is generally equal to the outer diameter of the ridge 50 formed on the fitment 38. Thus, as the luer fitment is progressively advanced into the interior chamber 26, a second sealed area 60 is formed between this cap region 58 and the ridge 50.

Also, as can be seen in Figs. 6 and 7, as the fitment 38 is progressively advanced into the cap chamber 26, this second sealed area 60, like the heretofore described first sealed area 56, is continuously maintained.

By continously maintaining the first and second sealed areas 56 and 60 as the luer fitment 38 is progressively threaded onto the cap 14, leakage of the liquid antiseptic 36 from the cap chamber 26 is prevented.

Since leakage is prevented, the antiseptic is effectively trapped within the cap chamber 26. Thus, as the threaded distal end 42 of the fitment is progressively advanced, the incompressible liquid antiseptic 36 trapped in the cap chamber 26 is directed out of the cavity 26 and into the bore 40 of the fitment 38. This is shown in Figs. 6 and 7.

When the cap 14 is fully threaded upon the connector 12 (see Fig. 7), the liquid antiseptic 36 occupies substantially all of the bore 40 of the fitment 38 and the adjacent portion of the extension set on catheter 16. As shown in Fig. 1, a clamp 62 is used to prevent the undesired transport of either the peritoneal dialysis solution out of the peritoneal cavity or the antiseptic 36 into the peritoneal cavity.

Because the inner diameter of the cap 14 in the region 88 is larger than the inner diameter in the threaded portion 52, an internal shoulder 64 is formed within the cap chamber 26. As shown in Fig. 7, when the cap 14 is fully threaded upon the luer fitment 38, the fitment shoulder 48 seats against the cap shoulder 64.

Together, the first and second sealed areas 56 and 60 effectively trap the antiseptic 36 within the confines of the cap chamber 26 as the fitment 38 is advanced to occupy more and more of the chamber 26. As a result, the antiseptic 36 has no place to escape other than into the bore 40 of the fitment 38.

Thereafter, when the cap 14 is completely attached to the connector 12, the first and second sealed areas 56 and 60 prevent leakage of the antiseptic 36 from the closure system 10 during use. Upon separation of the cap 14 from the connector 12, the skirt 46 serves to collect drops of antiseptic which may escape as the double seal arrangement is broken during separation, thereby preventing contact between the antiseptic and the user.

While, in the illustrated embodiment, the connector and the cap 14 are threaded together, the invention is operative in other configurations. For example, the luer fitment 38 can take the form of a spike member, and the cap 14 can be placed onto and off of the spike with a push-pull motion. As in the illustrated embodiment, by providing two seal areas between the spike and cap, the antiseptic can be trapped within the cap chamber 26 as the spike is inserted therein. The antiseptic will be directed onto the lumen of the spike as the spike and cap are joined, just as the antiseptic is directed into the bore 40 of the fitment 38 in the illustrated configuration.

An alternate embodiment of the cap 14 is shown in phantom lines in Fig. 5. There, the cap 14 includes a frangible membrane 68 which seals the antiseptic 36 within the cap chamber 26.

In this arrangement, because the antiseptic 36 is sealed within the cap chamber 26 by the membrane 68, a separate plug 36 need not be used.

As the threaded distal end 42 of the fitment 38 is advanced into the chamber 26, the frangible membrane 68 is broken by the fitment end 42. The liquid antiseptic 36 is then directed into the bore 40 of the fitment 38 in the manner heretofore described.

The components of the closure system 10 can be made of various materials, depending upon the operative environment in which they are used. In the context of peritoneal dialysis, the cap 14 is made of a suitable thermoplastic material which is capable of being sterilized and which is inert to the liquid antiseptic used. Antiseptics which may be used include sodium chloride and povidone iodine. The luer fitment 38 of the connector 12 can likewise be made of a sterilizable and inert thermoplastic material. Alternately a sterilizable and inert metallic material may be used, such as titanium or stainless steel. Preferably, the remainder of the connector 12 is made of a sterilizable and inert thermoplastic material.

Various features of the invention are set forth in the following claims.

CLAIMS

1. A closure system comprising

a connector including means for defining a luer fitment having an interior bore and wall means for defining a skirt peripherally surrounding said luer fitment,

a cap for joining to said connector, said cap having an exterior wall surface and an interior wall surface defining an interior chamber into which said luer fitment is advanced as said cap and connector are joined and in which a liquid antiseptic is retained, and

means associated with said cap and said connector forming a continuous first seal area between said exterior cap wall surface and said connector skirt and a continuous second seal area between said interior cap wall surface and said luer fitment for trapping the retained liquid antiseptic within said cap chamber as said cap and said connector are joined and for directing the liquid antiseptic from said cap chamber into said interior bore of said luer fitment as said luer fitment is advanced into said interior cap chamber.

2. A closure system according to claim 2

wherein said luer fitment includes an external threaded portion, and

wherein said interior cap wall includes a threaded portion which threadably engages said threaded portion of said luer fitment as said luer fitment is advanced into said interior cap chamber.

3. A closure system according to claim 1

wherein said means for forming said first seal area includes a lip formed on said exterior cap wall surface which sealingly contacts said connector skirt and which is continuously maintained as said luer fitment is advanced into said interior cap chamber.

4. A closure system according to claim 1 wherein said means for forming said second seal area includes a ridge formed on said luer fitment which sealingly contacts said interior cap wall surface and which is continuously maintained as said luer fitment is advanced into said interior cap chamber.

5. A closure system according to claim 1 wherein said cap includes a removable plug member for sealing said interior cap chamber prior to use.

6. A closure system according to claim 1 wherein said cap includes membrane means disposed within said interior cap chamber for normally sealing said interior cap chamber, and

wherein said luer fitment breaks said membrane to open said interior cap chamber as said luer fitment is advanced into said interior cap chamber.

FIG. 1

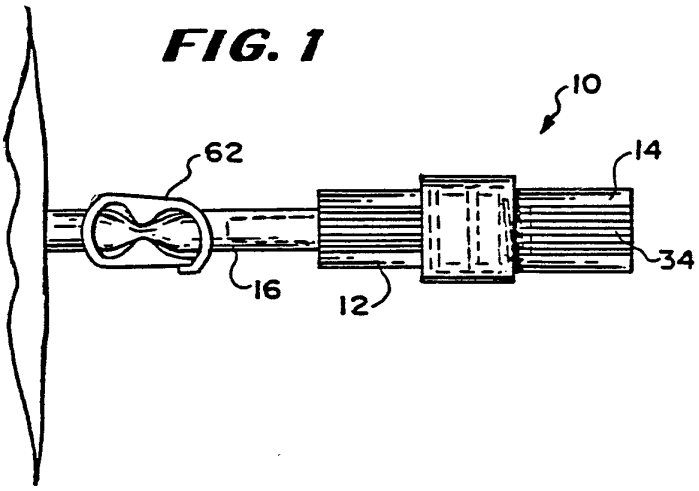


FIG. 2

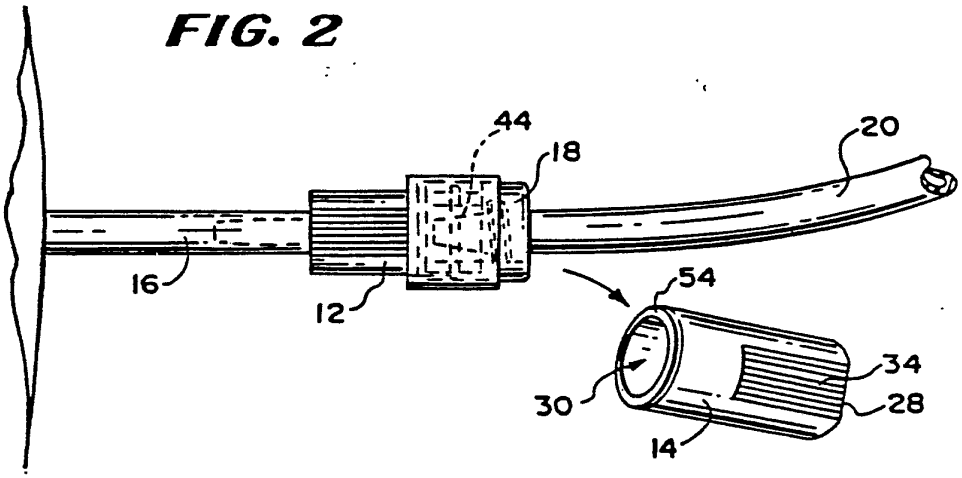


FIG. 3

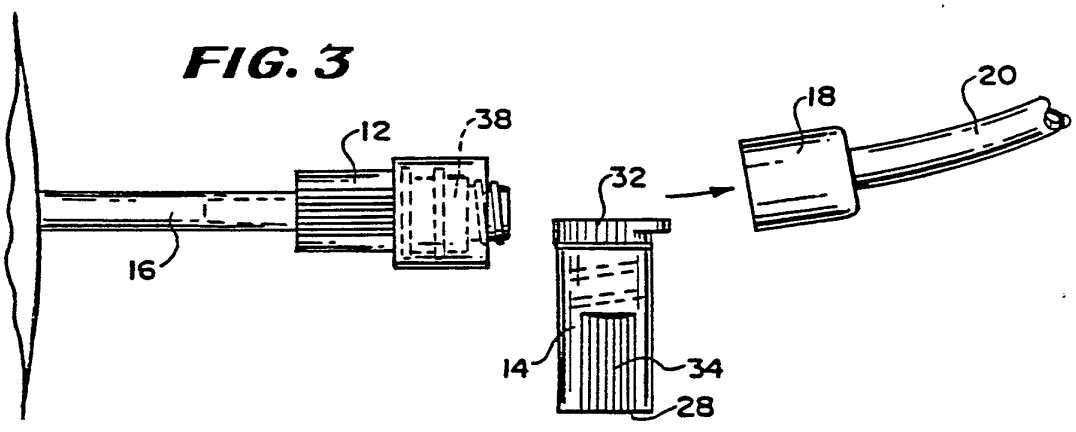


FIG. 4

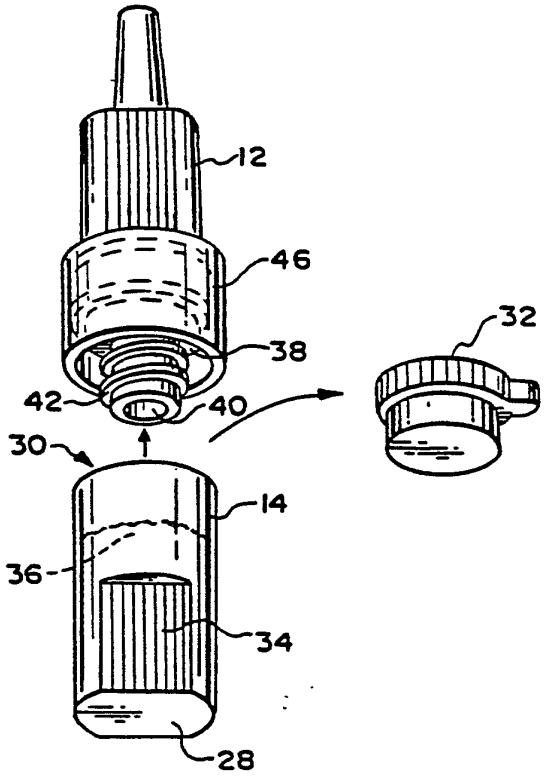


FIG. 5

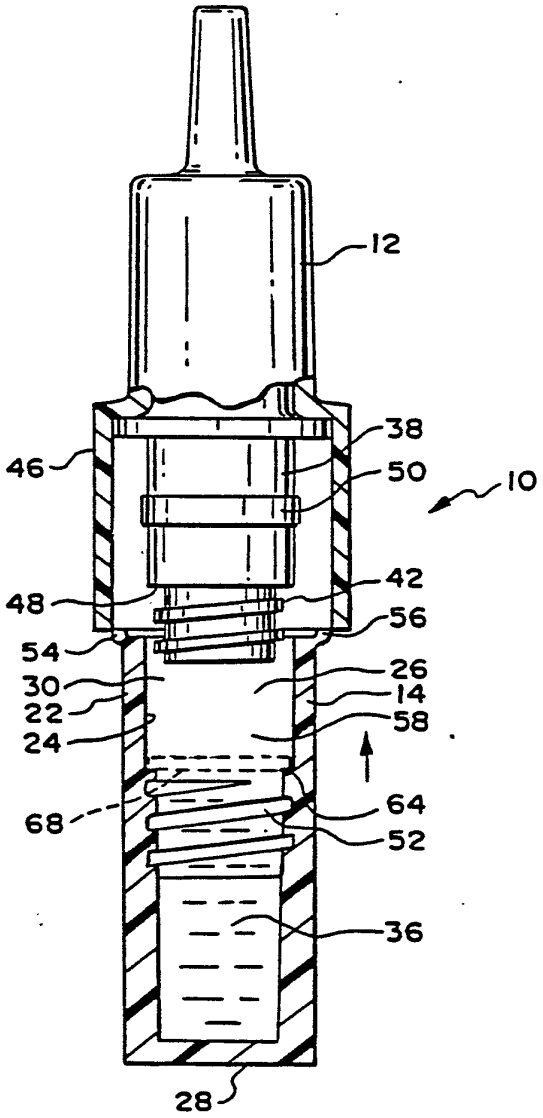


FIG. 6

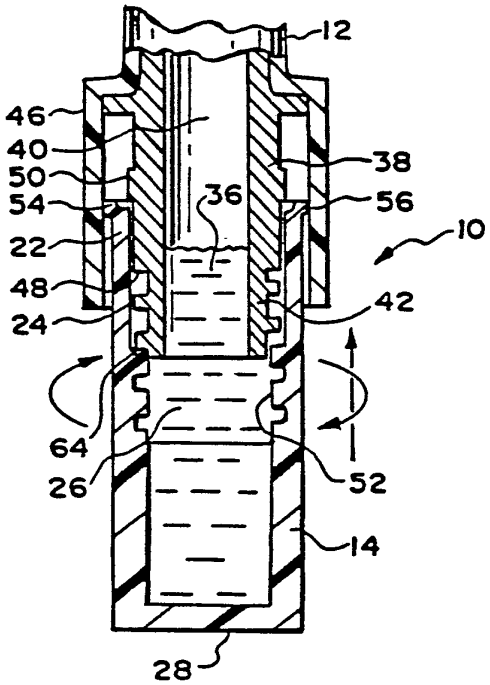
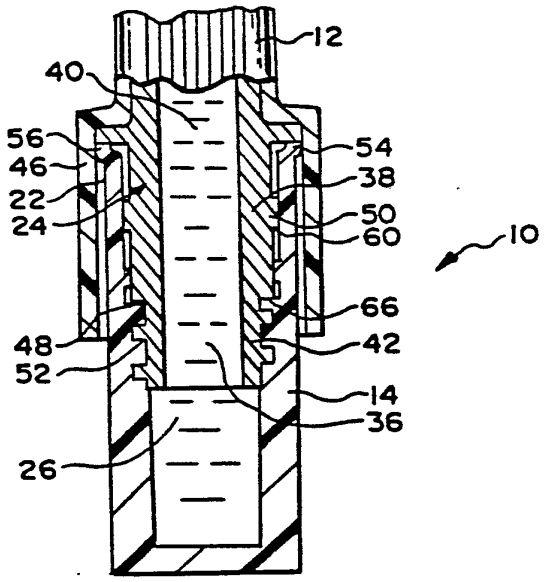


FIG. 7



INTERNATIONAL SEARCH REPORT

International Application No PCT/BE 86/00025

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 M 25/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	FR, A, 2493149 (SMAD) 7 May 1982, see figures 3-6; page 8, line 28 - page 9, line 13 & US, A, 4432764 cited in the application	1,2,5
Y	US, A, 4187848 (TAYLOR) 12 February 1980, see figures 3,5,6; column 3, lines 5-48	1,2,5
A	WO, A, 83/03975 (BAXTER TRAVENOL) 24 November 1983 & US, A, 4440207 cited in the application	
A	US, A, 4346703 (BAXTER TRAVENOL) 31 August 1982	
A	NL, A, 7301986 (INTERPHARM B.V.) 15 August 1974	

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* Special categories of cited documents: [10]

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"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
13th October 1986	17 NOV 1986
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	M. VAN MOL

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/BE 86/00025 (SA 14035)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 17/10/86

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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
FR-A- 2493149	07/05/82	DE-A,C	3143329	09/06/82
		US-A-	4432764	21/02/84
US-A- 4187848	12/02/80	BE-A-	869026	03/11/78
		GB-A,B	2000976	24/01/79
		NL-A-	7807375	22/01/79
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		GB-A,B	2040379	28/08/80
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		CA-A-	1158511	13/12/83
		CH-B-	648758	15/04/85
		US-A-	4439188	27/03/84
NL-A- 7301986	15/08/74	None		

For more details about this annex :
see Official Journal of the European Patent Office, No. 12/82

Electronic Acknowledgement Receipt

EFS ID:	19796234
Application Number:	14159959
International Application Number:	
Confirmation Number:	1050
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836C1
Receipt Date:	06-AUG-2014
Filing Date:	21-JAN-2014
Time Stamp:	18:57:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P_6836C1_IDS_080614.pdf	636267 e5040f51cb8a73253dd45dff0e71c51d8bf56e4a	no	14

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2	Foreign Reference	WO2010143693A1.pdf	1624707 4e6cfbf63c1ddbe53f3a7dcd9dea5cdc5aa2694d	no	44
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3	Foreign Reference	WO2010039171A1.pdf	450173 dc96c6ca96b7e1ba4da1eabd9f03fa324ecbba09	no	13
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4	Foreign Reference	WO2008157092A1.pdf	2122928 a10f257ce6b71a0129e0344df741c2b75d93f7a0	no	51
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5	Foreign Reference	WO2007137056A2.pdf	1213720 3fcf0119029f150261499b716c2f857b12ed1277	no	36
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6	Foreign Reference	EP1649890A1.pdf	1095020 5a2370 69b492d2a40417011ae4a1554c0e7c5cf4	no	19
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7	Foreign Reference	WO2006019782A2.pdf	727692 f03d0485c71c775eaa281d434e8362dd043e13da	no	20
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8	Foreign Reference	WO9929173.pdf	1636219 c211bcd02c72c319517319ec4ef04c48cb1ff193	no	41
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(Not for submission under 37 CFR 1.99)

Application Number	14159959
Filing Date	2014-01-21
First Named Inventor	Minh Quang Hoang
Art Unit	3763
Examiner Name	Andrew M. Gilbert
Attorney Docket Number	P-6836C1

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	2	20100172794	A1	2010-07-08	Ferlic et al.	
	3	20070282280	A1	2007-12-06	Tennican	

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	Application Number	14159959
	Filing Date	2014-01-21
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	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2014-10-29
Name/Print	Craig Metcalf	Registration Number	31398

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Electronic Acknowledgement Receipt

EFS ID:	20554824
Application Number:	14159959
International Application Number:	
Confirmation Number:	1050
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836C1
Receipt Date:	29-OCT-2014
Filing Date:	21-JAN-2014
Time Stamp:	18:57:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P_6836C1_SupplDS_102914.pdf	614569 2459e7c03727416d20cf5f808234277f4a47732e	no	4
Warnings:					
Information:					

Total Files Size (in bytes):	614569

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6523686	B1	2003-02-25	Bae	
	2	6196998	B1	2001-03-06	Jansen et al.	
	3	5989229		1999-11-23	Chiappetta	
	4	5702017		1997-12-30	Goncalves	
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U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040258560	A1	2004-12-23	Lake, Jr. et al.	
If you wish to add additional U.S. Published Application citation information please click the Add button.						Add

FOREIGN PATENT DOCUMENTS								Remove
Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2015-02-12
Name/Print	Craig Metcalf	Registration Number	31398

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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Electronic Patent Application Fee Transmittal

Application Number:	14159959
Filing Date:	21-Jan-2014
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Filer:	Lloyd Craig Metcalf/Kris Haley
Attorney Docket Number:	P-6836C1

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt	
EFS ID:	21490096
Application Number:	14159959
International Application Number:	
Confirmation Number:	1050
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836C1
Receipt Date:	12-FEB-2015
Filing Date:	21-JAN-2014
Time Stamp:	18:51:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	5460
Deposit Account	500843
Authorized User	METCALF, L CRAIG
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P_6836C1_SupplDS_021215.pdf	612250 f27730457ce6ad0a240cd243f8c969a4522d797f	no	4
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30730 e27ca9b4042dd3969346bb34798d507b8355e66e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	642980		

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5743884		1998-04-28	Hasson et al.	
If you wish to add additional U.S. Patent citation information please click the Add button.						Add

U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20100204648	A1	2010-08-12	Stout et al.	
If you wish to add additional U.S. Published Application citation information please click the Add button.						Add

FOREIGN PATENT DOCUMENTS								Remove
Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2007/044760	WO	A2	2007-04-19	DSU Medical Corporation		☐
If you wish to add additional Foreign Patent Document citation information please click the Add button								Add

NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	1		☐

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
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CERTIFICATION STATEMENT

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2015-04-29
Name/Print	Craig Metcalf	Registration Number	31398

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 April 2007 (19.04.2007)

PCT

(10) International Publication Number
WO 2007/044760 A2

(51) International Patent Classification:
A61M 5/14 (2006.01)

(21) International Application Number:
PCT/US2006/039633

(22) International Filing Date: 10 October 2006 (10.10.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/247,931 11 October 2005 (11.10.2005) US

(71) Applicant *(for all designated States except US)*: **DSU MEDICAL CORPORATION** [US/US]; 101 Convention Center Drive, Suite 850, Las Vegas, NV 89109 (US).

(72) Inventors; and
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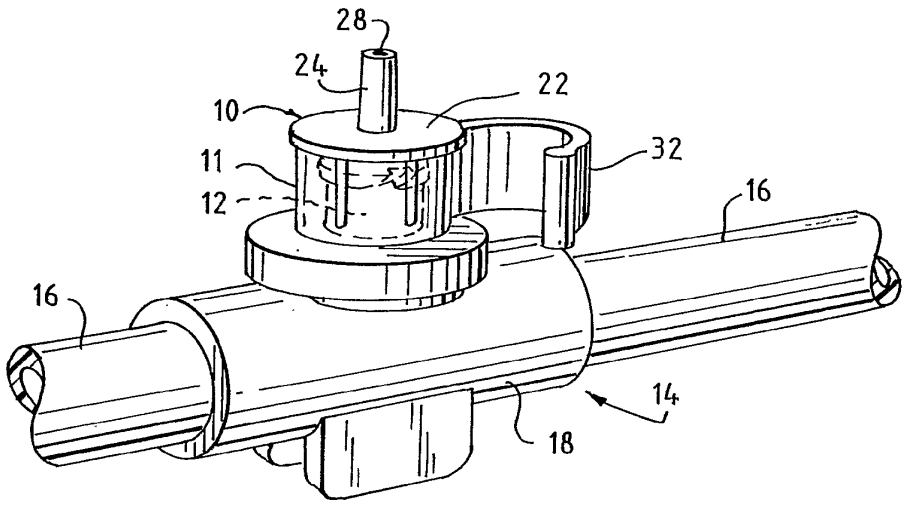
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(54) Title: CLOSURE FOR TUBULAR ACCESS PORT



(57) Abstract: A closure for a tubular access port in a medical fluid flow line or other container comprises a removable cap for enclosing and sealing the tubular access port. The cap has a closed end wall. The end wall carries an extending poker to facilitate the pushing of an antiseptic-carrying material into a lumen of the access port. The poker has an outer diameter that is less than the inner diameter of the access port. A method of using the poker is also described.

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CLOSURE FOR TUBULAR ACCESS PORT

BACKGROUND OF THE INVENTION

Tubular access ports are used in medical fluid flow lines and other medical fluid containers such as blood and parenteral solution bags, syringe chambers for administration of liquids, and various tube sets such as hemodialysis arterial and venous sets, plus other extracorporeal blood flow sets, and parenteral solution administration sets. The tubular portion of the access port is designed to receive a mating connector of another device which fits within the lumen of the tubular portion. To preserve sterility prior to use, the tubular access port may have a closure of conventional design, typically a removable, tubular cap comprising an end wall covering the opening of the lumen, a tubular wall fitting around the outer portion of said tubular portion and, also, typically, a male member attached to the inner face of the end wall that fits down into the lumen of said tubular portion. The tubular access ports themselves may be on the end of a branch tubing which connects to a tube set or other medical fluid container, or the access port may be directly carried on main flow tubing of a branch tubing set, a medical solution bag, a cap of another kind of container such as a dialyzer housing, a drip chamber, or the like.

Specifically, such tubular access ports may comprise a simple, open tubular end having a cylindrical lumen, or it may comprise a female luer or luer lock connector. Also, the tubular access port may be of a design as illustrated in U.S. published patent applications 2004/0068238 or 2004/0068239.

Additionally, such tubular access ports may contain any partial or complete wall which is recessed below the outer end of the port, and which partially or completely blocks or bridges a recessed portion of the lumen of the tubular access port, such as a one-way valve, check valve or a three-way rotary valve and the like.

As a problem with these designs, when the access port is opened, sterility of course is lost in the lumen of the access port and any barriers, valves or mechanisms within the flow pathway of the port, and the port should be resterilized or disinfected if it is to be reused. Typically, only the external portions of tubular and non-tubular access ports, for example, the elastomeric surface and outer housing of resealable elastomeric injection sites for needles are disinfected, typically with a conventional alcohol "prep pad".

In accordance with this invention, a closure is provided for a tubular access port in which disinfection of the lumen of the access port is greatly facilitated at low cost and with great ease, without the need of extra equipment except for, typically, a conventional alcohol "prep pad", or the like, such pads being generally ubiquitous at clinical and medical facilities.

DESCRIPTION OF THE INVENTION

In accordance with this invention, a closure for a tubular access port in a medical fluid flow line or other container comprises: a removable, tubular cap for enclosing the tubular access port. The cap has a closed end wall, with or without a male member attached to its inner face, while typically the end wall's outer face, in turn, carries an outwardly extending poker to facilitate the pushing of an antiseptic-containing material, typically an alcohol "prep pad", into a lumen of the access port to disinfect at least that portion of such lumen that will mate with the connector of a connecting device, for example, a syringe. Preferably, the entire recessed lumen or flow path of the access port receives disinfectant including portions proximal to any barrier or valve mechanisms that are recessed in the lumen and may become contaminated with use. The poker has an outer diameter that is less than the inner diameter of the access port, to provide space in the access port lumen for both the poker and the antiseptic-containing material. The antiseptic containing material may comprise fluid or gelled antiseptics, or antiseptic impregnated materials. Any appropriate antiseptic may be used, such as ethyl or isopropyl alcohol.

To practice this invention in some embodiments, an antiseptic-impregnated material may be placed across or in the open lumen of the access port. This material may comprise, a conventional, alcohol-soaked fabric prep pad, typically isopropanol, but, alternatively, it may comprise a small piece of alcohol-soaked cotton, or other woven or non-woven material. Other antiseptics such as povidone iodine may be used, if desired.

The poker, which generally comprises a small, projecting, semi-rigid or rigid stick of circular cross section (or any other desired cross sectional shape), is inserted into the open lumen of the access port, to force at least a portion of the antiseptic-containing material into the same open lumen to come in contact with the lumen wall, thereby coating such wall with the antiseptic. (If there is a recessed wall within the lumen of the access port that at least partially blocks or bridges the lumen, the poker may preferably be long enough such that this wall is coated with disinfectant material also.) There, the antiseptic-containing material is allowed to reside for a desired period of time, sufficient to provide a chosen antimicrobial effect by either fluid contact or gaseous effect. Thereafter, the antiseptic-containing material and poker may be removed from the open mouth, leaving at least a film of antiseptic remaining in at least the lumen of the access port and the access port is ready for connection in aseptic manner with another connector for the transfer of fluid therethrough.

While occupying the access port, the antiseptic and/or the antiseptic-impregnated material and the poker can provide closure and sealing, preventing ingress of infective materials, as well as delaying evaporation, thereby increasing the persistence of the antiseptic causing antimicrobial effect to any infective materials already in the lumen. As an advantage of the method of this invention, at least the antiseptic-impregnated material, and optionally the poker, may remain in the access port for a substantial period of time prior to removal and use of the access port. In other words, the antiseptic impregnated material and poker can be applied, for example, immediately after disconnection of the initial, sterile connection of a device to the access port. Such persistence of antiseptic within the access port can provide a degree of disinfection which is substantially higher than the conventional exposed

swabbing of a site immediately before use by accessing with a needle in that the kill time by this invention can be greatly extended, resulting in a much more reliable disinfection without a change of disinfectant. In other words, isopropyl alcohol may be used, but the level of disinfection is significantly raised by the extended period of exposure of the injection site or the like to the isopropyl alcohol, when compared with disinfection of the site immediately before access is effected, as is now the common practice. Thus, this exposure time to the antiseptic may be minutes and even hours between access events.

Typically, the poker is carried on a cap which is proportioned to cover the access port. This cap may be the original cap that is covering and optionally sealing the access port as it comes from the factory, typically maintaining aseptic conditions within the access port, with the poker extending outwardly from the cap. The same cap may be used to cover and optionally close the access port after the access port has been used, for example by connection with, and then disconnection from, a male luer or other tubular connector. In some embodiments, the poker has a length that is at least approximately the length of the tubular access port, to assure that the antiseptic and/or antiseptic-carrying fabric is driven completely into the access port to engage all of the inner surfaces of the lumen.

The tubular access port may define a female luer shape, and may thus be capable of sealing connection with a male luer or luer lock connector.

Furthermore, in some embodiments, the cap may also define an attached, outwardly extending, typically C-shaped projection which is proportioned to releasably grip a component of a fluid flow set that carries the access port, to releasably attach the cap to the flow set, with the cap being spaced from the access port. Thus, while the access port is in use, for example in a connection with a connector such as a male luer or luer lock connector, the cap may be hung onto medical tubing of the fluid flow set, to retain the cap nearby for convenient, subsequent use. Then, when the connection between the access port and the other connector is broken, the cap may be used as described above to again disinfect the access port, making use of an antiseptic and/or antiseptic-soaked material as described above,

typically removing the cap from its connection with the medical tubing, and using the (typically) outwardly projecting poker of the cap to force an antiseptic and/or antiseptic-impregnated material fabric into the lumen of the access port.

Accordingly, by this invention, a multiple use cap is provided which can initially close off an access port and optionally hold it in sterile condition, and the same cap may be used in a simple process to exert antimicrobial effect in the lumen of the access port, while serving as a temporary closure for the access port in conjunction with the antiseptic-carrying material, for a desired period of time to provide the desired antimicrobial effect, and longer if desired. Typically, the cap is positioned backwards, with the poker extending into the access port, until such time as the cap and antiseptic impregnated material may be removed. Then, the cap may be inverted, and may reclose the access port once again in a normal manner.

Additionally, for heightened disinfection, prior to replacing the cap on the disinfected access port, the interior of the cap may first be swabbed with the same or other antiseptic-impregnated material or disinfected by the insertion of antiseptic. Thus the inside of the access port, its external opening, and adjacent locking threads, if any, as well as the inner surfaces of its protective cap may be disinfected before or after each use.

The access port may carry a slit diaphragm or any other partial or full barrier at a recessed point within the access port, examples of this being disclosed in the above cited published patent applications.

The invention also comprises a method of disinfecting an access port of a medical fluid flow line or another container, the access port having an open mouth. The method comprises: inserting at least a portion of a fibrous or spongy, antiseptic-impregnated material, or antiseptic oil or gel on or into the open mouth of an access port with the poker of the above invention to disinfect at least some recessed portions of a tubular access port.. Thereafter, the poker and antiseptic material or gel can be removed from the open mouth, when a desired degree of disinfection has been achieved, which may be a matter of minutes and even hours as previously discussed. Alternatively, the antiseptic oil or gel may not need removal.

Examples on how this might be accomplished, as stated above, includes any of the steps of: placing an antiseptic-containing material across the open mouth prior to insertion of the poker; placing an antiseptic-containing material over or around the poker of the cap prior to inserting the poker into the open mouth of the access port; wadding up an antiseptic impregnated fabric or fibrous material such as a cotton ball, and placing it into the lumen of the access port, then using the poker to drive it further inwardly; taking a non-woven fabric or cotton ball impregnated with disinfectant and placing it over the opening, followed by using the poker to drive it in; using an alcohol gel as disclosed in U.S. Patent Publication 2005/0042240 (the disclosures of which are incorporated by reference), or a commercial hand sterilizing gel, and placing it at or into the opening of the access port followed by using the poker to push the antiseptic gel into the port and cover internal surfaces; using the alcohol gel or the like to coat the poker and then inserting the poker into the access port without a fibrous or spongy material present.

Additionally, the interior and/or exterior of the cap which carries the poker may be disinfected before or after disinfecting of the access port, making use of a conventional swab or the like, and then replacing the disinfectant cap on the disinfected access port.

Typically, the fibrous or spongy, antiseptic-impregnated material is a separate item, but such material may be attached to the poker or the like. The antiseptic-impregnated fabric or other material may be placed across or in the open mouth, inserting a poker into the open mouth to force at least a portion of the fabric into the open mouth. Thereafter, the fabric and poker can be removed from the open mouth, when the desired degree of disinfection has been achieved.

DESCRIPTION OF THE DRAWINGS

In the drawings, Fig. 1 is a perspective view of a portion of a medical fluid flow line which carries a tubular access port, which is closed by the closure cap of this invention.

Fig. 2 is a top plan view of the closure cap of Fig. 1, taken partly in section.

Fig. 3 is a perspective view of the flow tube and access port of Fig. 1 with the cap hanging on the tubing by means of the C-shaped projection.

Fig. 4 is a perspective view of the flow tubing and access port of Fig. 1, showing how the lumen of the access port may be covered with an antiseptic-carrying fabric, and with the cap accompanying, in inverted position.

Fig. 5 shows the cap, flow tube and access port of Fig. 4, connected together with the poker driving the antiseptic-carrying fabric into the lumen of the access port.

Fig. 6 is a perspective view of access port at Fig. 5, showing the access port lumen being filled with antiseptic-containing fabric, driven in by the poker of the closure cap, to provide antimicrobial effect in the bore.

Fig. 7 is an enlarged, fragmentary, sectional view taken along line 7-7 of Fig. 6, with a portion removed.

Fig. 8 is a fragmentary sectional view similar to Fig. 7 showing a conventional sealing cap for a female luer in accordance with the prior art, but also carrying a poker in accordance with this invention.

Fig. 9 is a longitudinal sectional view of a female luer connector on tubing, with the poker of a sealing cap extending into the female luer, and carrying an antiseptic-soaked fabric surrounding the poker.

Fig. 10 is a longitudinal sectional view of another embodiment of this invention, in which a female luer connector attached to tubing receives an outwardly extending poker of a sealing cap for the connector.

Fig. 11 is a perspective view of another embodiment of the cap of this invention.

Fig. 12 is a longitudinal sectional view of the cap of Fig. 11.

DESCRIPTION OF SPECIFIC EMBODIMENTS

Referring to the drawings, a closure 10, in closure cap form for a tubular access port 12 of a medical fluid flow assembly 14 is shown, all being of any

known type, but for the novel features of this invention. Medical fluid flow assembly 14 may comprise separate lengths 16 of flexible tubing conventionally sealed into a tubular housing 18, which carries tubular access port 12 having lumen 30 extending through outer end 13 of port 12. Access port 12 (and housing 18) may be of generally conventional design, and is particularly shown to be in the form of a female luer lock connector, having threads 20 or alternatively opposed lugs, to secure a male luer lock connector of another device, for example a syringe, in conventional manner.

Alternatively, closure 10 may be used in conjunction with a corresponding tubular access port that is attached to a solution or blood bag, a drip chamber, a housing, or another kind of medical container. Closure 10 can be seen to define a removable, typically tubular cap for covering tubular access port 12 and optionally sealing lumen 30. Closure cap 10 has a closed end wall 22 and an annular side wall 11 which attaches to the outside of tubular access port 12. Alternatively, attached to end wall 22 is a male member (not shown in Figs. 1-7) which extends inwardly into and grips at least a portion of the inner lumen of tubular access port 12, or both an annular side wall and male member can be employed to retain closure 10 on access port 12. When the internal male member is absent, as in Figs. 1-7, the interior 23 of closure 10 can be easily disinfecting-swabbed, being typically large enough for that, permitting reuse.

End wall 22, in turn, can carry an outwardly extending poker 24 (i.e. extending in opposite direction from annular wall 11 or the male member). Poker 24 is shown to be tubular in structure for the saving of material in manufacture, but its lumen 28 typically does not extend through closed end wall 22. Alternatively, poker 24 may be solid, and it also may be of square, triangular, or other cross section if desired, rather than being substantially cylindrical. Also, poker 24 may taper if desired.

It can be seen particularly from Fig. 7 that the portion of poker 24 that is inserted into lumen 30 of access port 12 has an outer diameter that is less than the inner diameter of the lumen 30 of access port 12. Also, it can be seen that poker 24 has a length that is approximately or almost the same as the length of

lumen 30 of tubular access port 12, extending from outer end 13 to an optional recessed internal, slit, elastomeric barrier wall 31, for example similar to those described in the above cited, published patent applications 2004/0068238 and 2004/0068239 (the disclosures of which are incorporated by reference). In this embodiment, the female lumen 30 of access port 12 has a terminus, i.e. slit elastomeric wall 31. Alternatively, lumen 30 has no nearby terminus, and may comprise a standard female luer on a fistula needle. Here, poker 24 may optionally only be at least as long as the mating length of lumen 30 which is in contact with a connected male luer, so poker 24 and antiseptic or antiseptic-impregnated material can disinfect at least this crucial portion of lumen 30. However, if desired, poker 24 may be much longer than this, and even may swab down into the lumen tubing to which the female luer connector is bonded.

In some embodiments, the poker outer diameter is about 0.1-3 mm. less than the inner diameter of lumen 30, preferably about 0.5 to 2 mm. less.

Furthermore, closure cap 10 defines an attached, outwardly extending, typically C-shaped projection 32, which is proportioned to releasably grip medical tubing 16 of fluid flow set 14, as particularly shown in Fig. 3. Thus, cap 10 can be releasably attached to flow set 14 at tubing 16 thereof, with the cap being spaced from access port 12, as in Fig. 3. This prevents caps 10 from being lost when not in use, for example when access port 12 is in connection with another connector of another medical device. When access port 12 comprises a female luer lock connector, it may thus connect with a male luer or luer lock connector of a flow line from a medical solution bag or a syringe, to provide medication to tubular set 14, or the like.

As shown in Fig. 1, closure cap 10 may initially provide a sterile barrier, by sealing or tortuous pathway, to tubular access port 12, as provided from the manufacturer. When use of the access port is desired, closure cap 10 can be removed, as indicated in Fig. 3, being preferably hung along tubing 16 by the use of C-shaped projection, as shown. Then, a male luer or luer lock connector may be applied to access port 12 in a conventional manner, not shown.

After the male luer or luer lock connector has been used and then disconnected, a fluid transfer having been made, cap 10 may be placed again on access port 12 in a normal manner. However, if and when it is contemplated that access port 12 might be reused, and that it is desirable for aseptic conditions to be provided once again to access port 12, as shown in Figs. 4-7 a conventional, alcohol-soaked pad 34 may be placed over the outer end of access port 12, this being one of the examples of inserting of fibrous or spongy, antiseptic-impregnated materials listed above. Closure cap 10 may be removed from its position of Fig. 3, and inverted so that poker 24 points toward access port 12 (Fig. 4). The poker 24 of cap 10 is then advanced into lumen 30 of access port 12 because its diameter is somewhat less than the inner diameter of lumen 30, thus allowing space for both the poker 24 and the material of pad or swab 34 to enter the lumen 30. This has the effect of driving a portion of the alcohol soaked pad 34 into lumen 30, as particularly shown in Fig. 7, with poker 24 pointing inwardly, and open mouth 36 of closure cap 10 pointing outwardly. Since poker 24 has an outer diameter that is less than the inner diameter of lumen 30, alcohol soaked pad 34 is urged into lumen 30, as shown in Fig. 7, as poker 24 is pressed into lumen 30.

Cap 10 and antiseptic impregnated pad 34 may be retained in their access port-closing position shown in Figs. 6 and 7 for a length of time which is sufficient to assure a high level of disinfection of lumen 30 and at least some outer surfaces of access port 12, typically two minutes or more. Particularly, cap 10 may remain in closing relationship as in Figs. 6 and 7 for an indeterminate period of time, for example hours, while set 14 is in use, since it provides a sealing function as well as an antimicrobial function.

In some embodiments, lumen 30 of tubular access port 12 may also comprise an inner, slit barrier wall or diaphragm 31 (Fig. 7), so that an internal closure is provided, to restrict the passage of antiseptic into the main flow path of set 14, while still permitting the flow of fluids through the slit of diaphragm wall 31 in either direction when access port 12 is properly connected with a male connecting device which opens such slit such as a male luer. For

example, such tubular access ports are disclosed in the previously cited U.S. published patent applications 2004/0068238 and 2004/0068239.

Then, if and when it is desired to reuse access port 12, closure cap 10 and fabric 34 can be removed, presenting an open access port as in Fig. 3, which may then be connected with a conventional connector such as a male luer or luer lock connector while closure cap 10 may preferably be placed on tube 14 by clip 32.

Subsequent to this, access port 12, if desired, may be again treated in the manner described above for antimicrobial effect, making use of the inverted cap closure 10 and poker 24, plus a new antiseptic-carrying fabric 34. Alternatively, access port 12 may be simply reclosed with closure cap 10, to assume once again the configuration of Fig. 1.

Referring to Fig. 8, a cap 41 is disclosed in which a projecting member 40 extends into lumen 30 of access port 12. It can be seen that, in accordance with the prior art, tapered, luer like projecting member 40 is of substantially the same outer diameter as the diameter of lumen 30 to provide abutting surfaces, with projecting member 40 substantially filling lumen 30 thereby sealing lumen 39 and/or providing retention of the cap to access port 12 with or without annular wall 42.

This comprises a difference between the prior art and this present invention, in which the portion of poker 24a used to insert antiseptic material into lumen 30 is of reduced diameter, to make room for antiseptic-impregnated fabric 34 or other antiseptic material, as shown in Fig. 7. Alternatively, poker 24a may extend inwardly, as a replacement for projecting member 40, being of lesser diameter, to create a space in lumen 30 that receives an antiseptic-impregnated fabric, sponge, or gel, in the manner of this invention. In that circumstance, room may have to be allotted between the tubular flange 42 of cap 38 and access port 12 for an excess of antiseptic-impregnated fabric 34, or the like.

Alternately, poker 24a may be mounted on an optional, larger diameter base 27 such as an annular ring, to provide frictionally or snap-fit abutting surfaces with an optionally slightly recessed outer portion of lumen 30, for

temporary securance of connector 12 and cap 41 together. Such base 27 with surmounted poker 24a may be either outwardly extending or inwardly extending.

Thus, Fig. 8 shows an embodiment of a closure cap in accordance with this invention, having a poker 24a on the cap 41 in a position opposed to projecting member 40, in which poker 24a is of reduced outer diameter relative to projecting member 40, and may be used in a manner similar to that which is disclosed above, by inverting of cap 41, but projecting internal sealing member 40 of cap 41 may be inserted into access port 12 without an intervening, antiseptic-impregnated fabric, in a releasably retained manner.

Referring to Fig. 9, another embodiment of the invention is shown in which closure cap 50 comprises a tubular cap body with a closed end 52 and an attached, tubular cap body wall 54, in a manner similar to the previous embodiments. Cap 50 defines a poker 24b, in a manner similar to previous embodiments, which extends outwardly from wall 52.

As shown in Fig. 9, a connector port 12b comprises a female luer, which is attached to flexible tubing 56 in a conventional manner within a rear recess 58 of female connector 12b.

Cap 50 has been, if desired, previously been carried on female connector 12b in a manner which is inverted from the position shown in Fig. 9, and analogous to that of Fig. 1, in its original configuration, as provided to the user. Then, cap 50 is removed, and female connector 12b is used in conventional manner, typically by connection with a male luer connector. Thereafter, the male luer connector is removed, and cap 50 is applied in the manner shown in Fig. 9, with a piece of antiseptic soaked fabric 60 applied between poker 24b and the inner diameter of lumen 62 of female connector 12b, for antibacterial effect. This permits reuse of the connector at a subsequent time, with an exponentially reduced level of microorganisms remaining therein.

In this embodiment, poker 24b is long enough so that it crosses junction 64 within recess 58 between connector 12b and the flexible, plastic tubing 56 upon which connector 12b is carried, for antimicrobial effect in that area.

Referring to Fig. 10, in another embodiment, cap 70, of broadly similar design to the previously described caps, comprises a tubular cap body 72 having a closed end wall 74. Poker 24c is carried by wall 74, as in previous embodiments, and extends, in this embodiment, for a distance that is substantially the distance through lumen 30 which is in contact with a typical connecting male connector member, such as a male luer, and not substantially farther. This is in contrast with the embodiment of Fig. 9. It can be seen that cap 70 is in connection with the same or a similar female connector 12b as in the previous embodiment.

Also, cap 70 carries an annular, proximally extending wall 74a, which serves to enclose the outer end 76 of female connector 12b in the position shown. Cap 70 can originally be used to close connector 12b in the position that is inverted from that shown in Fig. 10.

In this particular embodiment, the narrow space between poker 24c and the inner diameter wall of lumen 30 may be filled with a fluid antiseptic agent 78, which may have been applied as a coating to poker 24c immediately prior to placement into connector 12b. Such a fluid material may comprise an oil like Betadine, or a gelled alcohol, for example, similar to those of the previously cited published applications, or it may comprise an antiseptic-impregnated fabric which is permanently attached to poker 24c. Alternatively, a fabric like fabric 60 may be used.

Referring to Figs. 11 and 12, another embodiment of the cap of this invention, broadly similar to the cap of Fig. 8, is shown. Cap 80, comprises a tubular cap body with a closed end 82 and an attached, tubular cap body wall 84. Tubular cap body wall 84 defines retention ribs 86 outside of wall 84 and more retention ribs 88 inside of wall of 84. Cap 80 is shown in an inverted condition from its normal use for closing an open end tube. As in previous embodiments, cap 80 may be furnished to the user in closed, sealing relation with an open ended tube for sterile closure or the like. Central tube 90 is provided for improved sealing of such an open ended tube. In this embodiment, central tube 90 has a lumen 96 that extends through closed end wall 82 into an outwardly projecting poker section 92 having a closed end 94,

for the purpose of reduction of the amount of material needed in the manufacture of cap 80.

Poker 92 may be used in the manner previously described with respect to other embodiments of the cap of this invention.

Outer ribs 86 and the flat faces 98 of the periphery of closed end wall 82 are used to improve the gripping characteristics of cap 80, the periphery 98 being a polygon as shown.

Accordingly, by this invention, a closure cap is provided which permits the repeated usage of a tubular access port of a medical fluid flow line or other container, where the closure cap remains accessible and not easily lost, and participates in the antimicrobial treatment of the recessed portions of the access port, as desired, between uses of the port.

The above has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application, which is as defined in the claims below.

THAT WHICH IS CLAIMED IS

1. A closure for a lumen-defining access port of a medical fluid flow line or other container, which comprises:

a removable cap for enclosing and sealing said tubular access port, said cap having a closed end wall, said end wall carrying an extending poker to facilitate the pushing of an antiseptic-containing material into a lumen of said access port, the poker having an outer diameter that is less than the inner diameter of said access port.

2. The closure of claim 1 in which said poker has a length that is at least approximately the length of the lumen of said tubular access port, said cap being carried on said access port.

3. The closure of claim 1 in which said lumen of the tubular access port defines a female luer shape.

4. The closure of claim 1 in which said tubular access port is part of a medical tubing-containing fluid flow set.

5. The closure of claim 4 in which said cap defines an attached, outwardly extending projection proportioned to releasably grip the medical tubing of said fluid flow set, to releasably attach said cap to the flow set with the cap being spaced from the access port.

6. The closure of claim 1, positioned with said poker penetrating the lumen of a lumen-defining access port, said poker being surrounded by said antiseptic-containing material which occupies said lumen.

7. The closure of claim 6 in which said antiseptic-containing material comprises an alcohol-soaked pad.

8. The closure of claim 1 in which the poker has an outer diameter along its length that is at least 0.5 mm less than the diameter of the access port lumen.

9. The closure of claim 8 in which said tubular access port is part of a medical tubing-containing fluid flow set.

10. The closure of claim 9 in which said cap defines an attached, outwardly extending, C-shaped projection proportioned to releasably grip

medical tubing of said fluid flow set, to releasably attach said cap to the flow set with the cap being spaced from the access port, and in which said lumen of the tubular access port defines a female luer shape.

11. The closure of claim 10 in which said poker has a length that is at least approximately the length of said tubular access port.

12. The closure of claim 11, positioned with said poker penetrating the lumen of said access port, said poker being surrounded by a portion of an alcohol-soaked pad which occupies said lumen.

13. The closure of claim 1, in which a base is present surrounding said poker to provide temporary frictional or snap-fit retention of said cap and access part.

14. The method of disinfecting an access port of a medical fluid flow line or other container, said access port having an open mouth, which comprises:

placing an antiseptic-containing material at or in said open mouth;

inserting a poker into the open mouth, to force at least a portion of the material into the open mouth; and thereafter removing the material and poker from the open mouth.

15. The method of claim 14 in which the poker is carried on a cap which is proportioned to close said access port.

16. The method of claim 15 in which said cap is used to close the access port, prior to inserting said poker into the open mouth.

17. The method of claim 16 in which the cap carries an attached, outwardly extending projection proportioned to releasably grip a component of a fluid flow set that includes said access port.

18. The method of claim 14 in which the lumen of the tubular access port defines a female luer shape.

19. The method of claim 14 in which the cap carries an attached, outwardly extending C-shaped projection proportioned to releasably grip medical tubing of a fluid flow set that includes said access port.

20. The method of claim 19 in which the poker is carried on said cap, and the cap is used to close the access port.

21. A removable cap for enclosing and sealing an access port of a medical fluid flow line or another container, which cap defines an attached, outwardly extending, C-shaped projection proportioned to releasably grip medical tubing of said medical fluid flow line, to releasably attach said cap to the flow line with the cap being spaced from the access port.

22. The closure of claim 1 in which said poker extends outwardly from the remainder of said cap.

FIG. 1

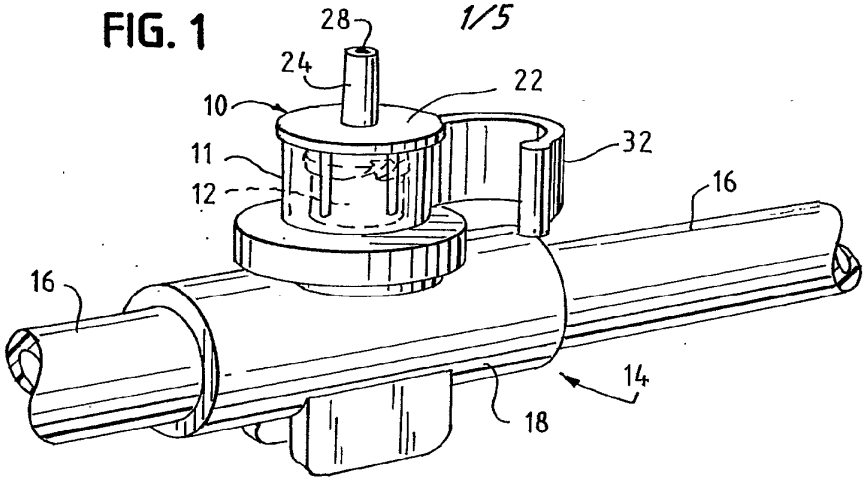


FIG. 2

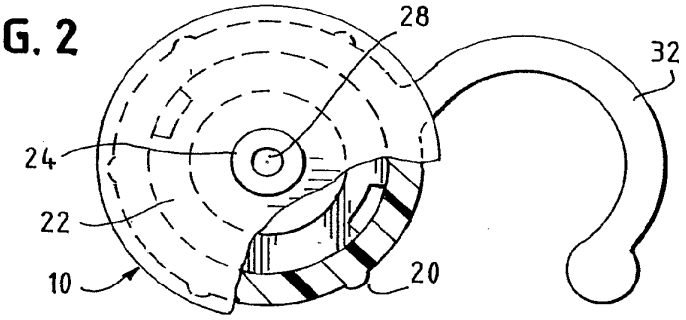


FIG. 3

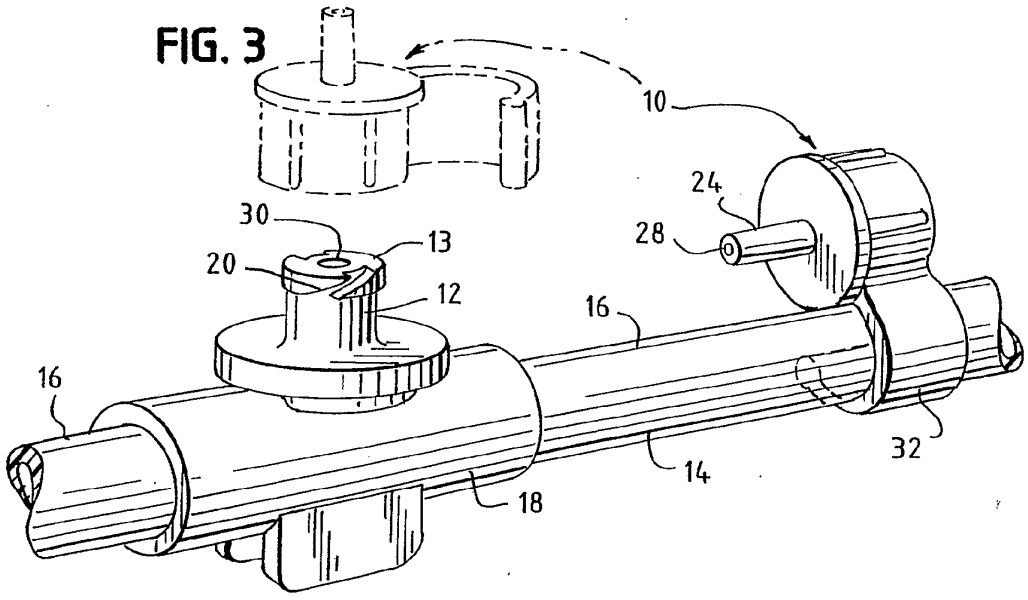


FIG. 4

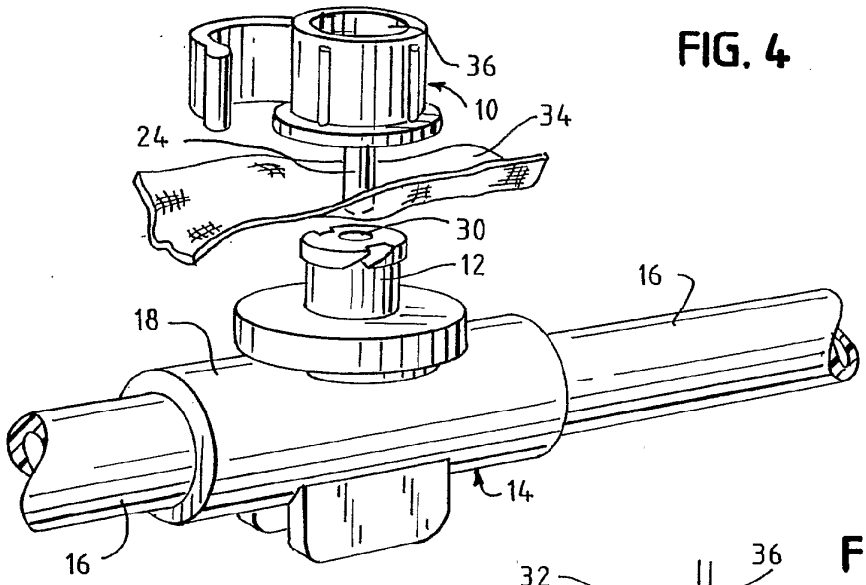


FIG. 5

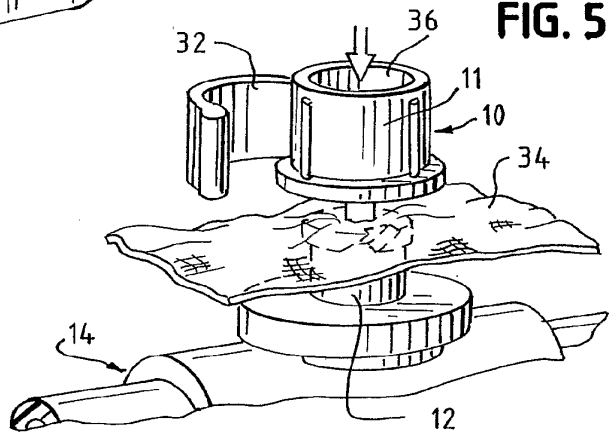


FIG. 6

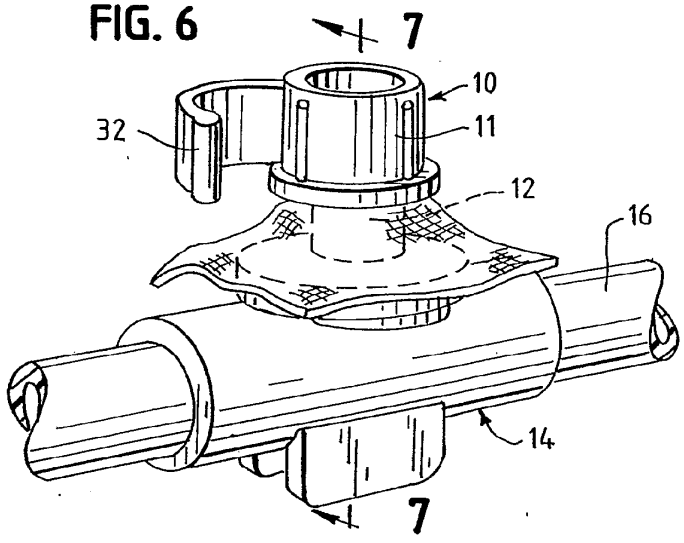


FIG. 7

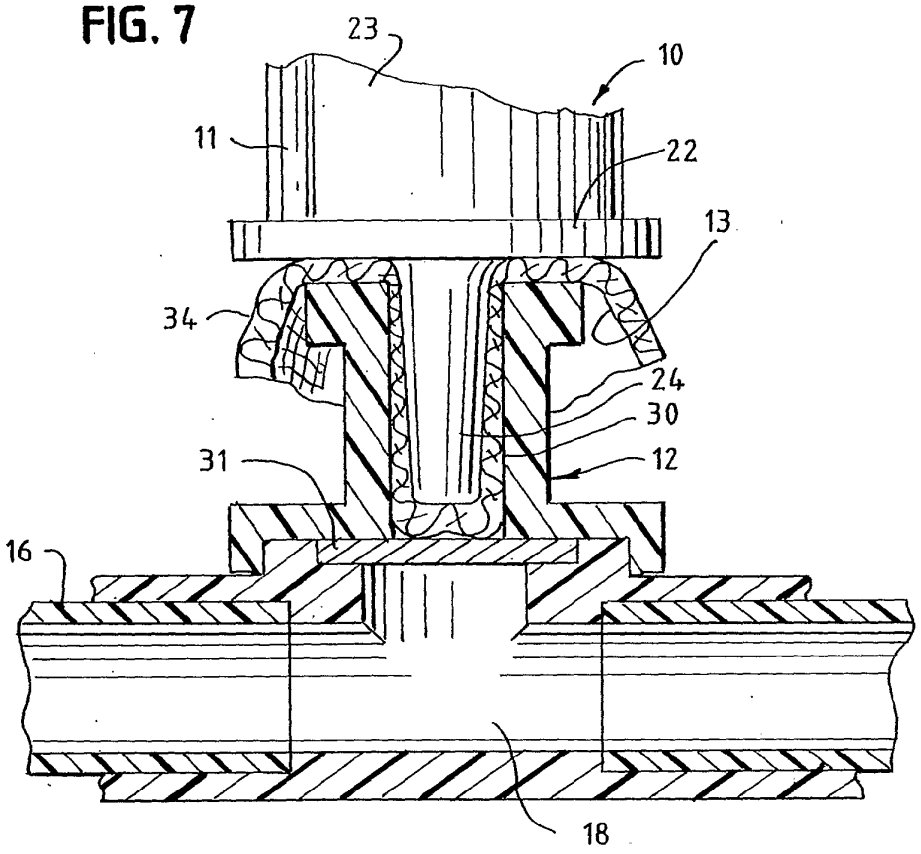


FIG. 8

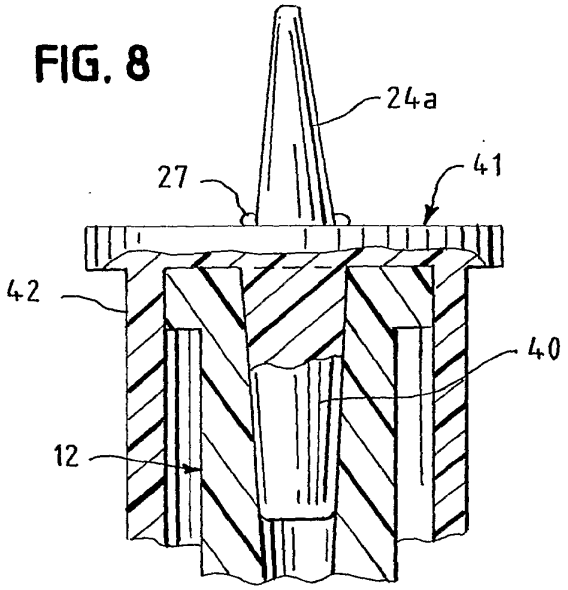


FIG. 9

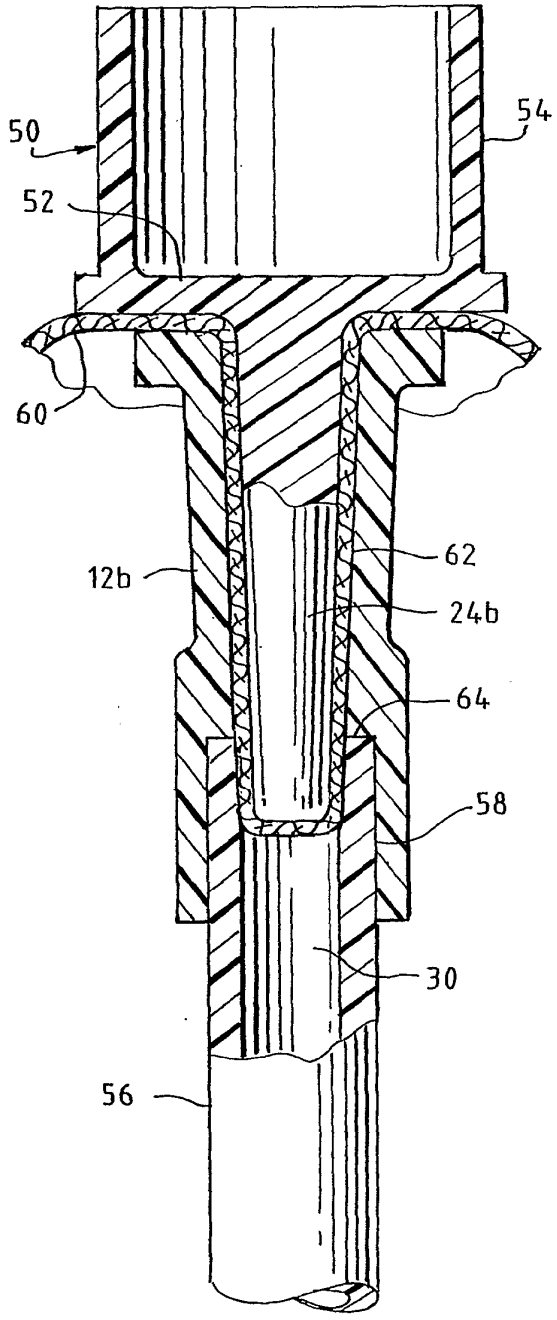


FIG. 10

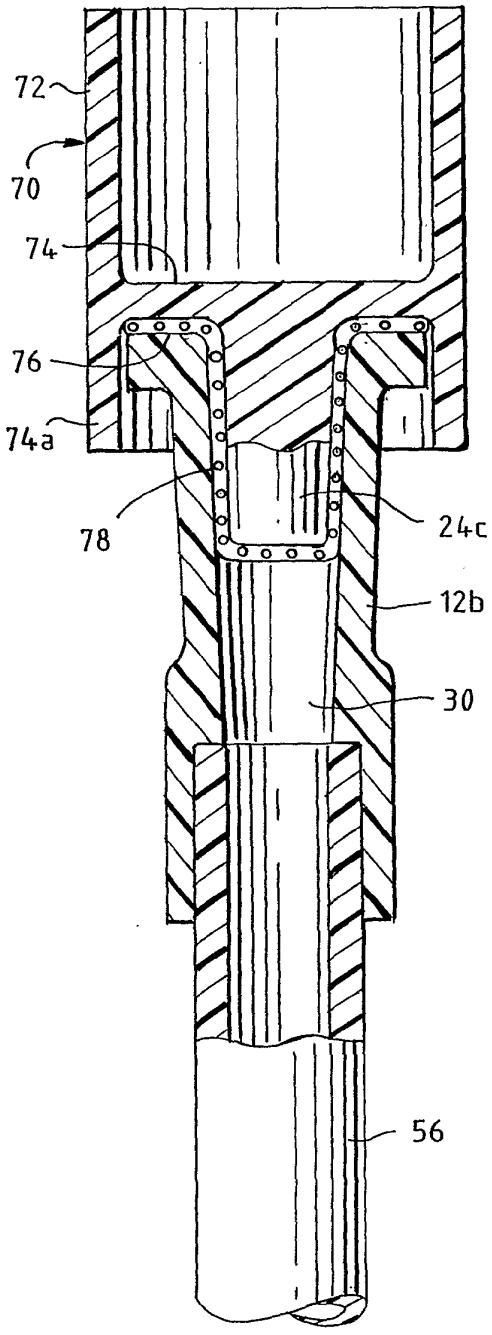


FIG. 11

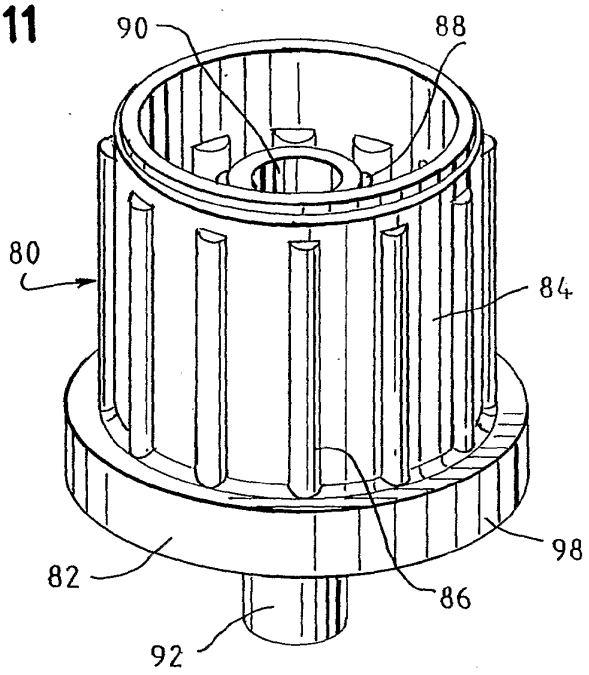
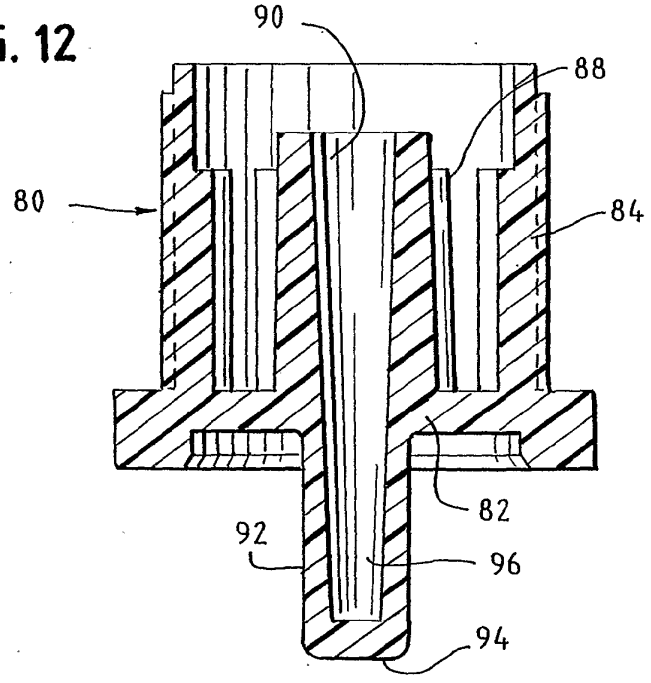


FIG. 12



Electronic Acknowledgement Receipt

EFS ID:	22208880
Application Number:	14159959
International Application Number:	
Confirmation Number:	1050
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836C1
Receipt Date:	29-APR-2015
Filing Date:	21-JAN-2014
Time Stamp:	17:25:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	P_6836C1_SupplDS_042915.pdf	612243 afc74736da2db4d5023301fca4e32b75f8b1de40	no	4

Warnings:	
Information:	

2	Foreign Reference	WO2007044760A2.pdf	1044329 bc27b49a70dfd9a61261eb0e72e948e70eb62756	no	23

Warnings:	
Information:	
Total Files Size (in bytes):	1656572

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/159,959	01/21/2014	Minh Quang Hoang	P-6836C1	1050

71562 7590 07/28/2015

David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
07/28/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip_docket@bd.com
cmetcalf@kmclaw.com

Office Action Summary	Application No. 14/159,959	Applicant(s) HOANG ET AL.	
	Examiner ANDREW GILBERT	Art Unit 3763	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/21/2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-20* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-20* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *1/21/2014* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Acknowledgments

2. The present application is a continuation of USPN 8740864. *The applicant is strongly advised to review the case history in the parent patent and updated the continuity data in the specification to expedite prosecution.*

3. The examiner notes that '864 had an IPR petition instituted with a Request for Trial Granted on 11/25/2014 (see IPR2014-00880). The trial was terminated on 1/5/2015 in view of a confidential settlement. The Board instituted in '864 on (i) claims 10 and 12 in view of 35 USC by White, Harding, and Genatempo, and (ii) claims 10, 12, 14, in view of 35 USC by Menyhay and Genatempo. However, settlement occurred prior to any final determination on the patentability of the challenged claims. ***The applicant is strongly advised to review the IPR2014-00880 file history*** and present to the examiner any documentation material to patentability of the present claims.

4. Claims 1-20 are pending for examination.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 4/29/15, 2/12/15, 10/29/14, 8/6/14 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

6. Claims 1-20 are objected to because of the following informalities:

7. In regards to claim 1, the term “and cleaning solution” in ln 16 should be changed to “and the cleaning solution”. Claims 2-8 are objected to by virtue of depending on claim 1.

8. In regards to claim 9, the term “the end face” in ln 10 should be changed to “the distalmost end face”. Claims 10-13 are objected to by virtue of depending on claim 9.

9. In regards to claim 9, the term “to provide cleaning solution” in ln 17-18 should be changed to “to provide the cleaning solution”.

10. In regards to claim 14, the term “with distalmost end face” in ln 2 should be changed to “with the distalmost end face”. Claims 15-20 are objected to by virtue of depending on claim 14.

11. In regards to claim 14, the term “the end face” in ln 7 should be changed to “the distalmost end face”.

12. In regards to claim 14, the term “to provide cleaning solution” in ln 15-16 should be changed to “to provide the cleaning solution”.

13.

14. In regards to claim 15, the term “the internal thread” in ln 2 should be changed to “the thread” in view of the recitation in ln 9 of claim 14.

15. **Furthermore, in claims 1-20 each subsequence reference to “a patient fluid line access valve” or "a threaded patient fluid line access valve" (i.e. claim 14) should be changed to "the patient fluid line access valve" or "the threaded patient**

fluid line access valve" accordingly instead of present recitations of "the access valve" to use clear and consistent terminology throughout the claims.

16. Appropriate correction is required.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

18. Claims 1-20 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 8740864. Although the claims at issue are not identical, they are not patentably distinct from each other because the claims are substantially similar in language and scope.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. ***See PTO 892 Form***.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ANDREW GILBERT/
Primary Examiner, Art Unit 3763

Notice of References Cited	Application/Control No. 14/159,959	Applicant(s)/Patent Under Reexamination HOANG ET AL.	
	Examiner ANDREW GILBERT	Art Unit 3763	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-8,740,864	06-2014	Hoang et al.	604/267
*	B	US-8,491,546	07-2013	Hoang et al.	604/267
*	C	US-4,440,207	04-1984	Genatempo et al.	150/154
*	D	US-4,432,764	02-1984	Lopez, Georges	604/533
*	E	US-4,778,447	10-1988	Velde et al.	604/29
*	F	US-5,242,425	09-1993	White et al.	604/256
*	G	US-5,554,135	09-1996	Menyhay, Steve Z.	604/256
*	H	US-2008/0019889	01-2008	Rogers et al.	422/292
*	I	US-2009/0062766	03-2009	Howlett et al.	604/411
*	J	US-2008/0086091	04-2008	Anderson et al.	604/192
*	K	US-2009/0028756	01-2009	Shahriari, Mahmoud R.	422/83
*	L	US-2004/0004019	01-2004	Busch, L. John	206/571
*	M	US-2003/0109853	06-2003	Harding et al.	604/536

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8491546	B2	2013-07-23	Hoang et al.	
	2	8167847	B2	2012-05-01	Anderson et al.	
	3	8162899	B2	2012-04-24	Tennican	
	4	8113731	B2	2012-02-14	Cable, Jr. et al.	
	5	8065773	B2	2011-11-29	Vaillancourt et al.	
	6	7922701	B2	2011-04-12	Buchman	
	7	7828186	B2	2010-11-09	Wales	
	8	7704935	B1	2010-04-27	Davis et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.G./

Receipt date: 08/06/2014	Application Number	14159959	14159959 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2014-01-21	
	First Named Inventor	Minh Quang Hoang	
	Art Unit	3763	
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6836C1	

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	10	7452349	B2	2008-11-18	Miyahara	
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	17	6911025	B2	2005-06-28	Miyahara	
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	19	6846846	B2	2005-01-25	Modak et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.G./

Receipt date: 08/06/2014	Application Number	14159959 14159959 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
(Not for submission under 37 CFR 1.99)	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	20	6708363	B2	2004-03-23	Larsen	
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Receipt date: 08/06/2014	Application Number	14159959 14159959 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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	35	5706944		1998-01-13	Hoang et al.	
	36	5694978		1997-12-09	Heilmann et al.	
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	38	5641464		1997-06-24	Briggs, III et al.	
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	40	5620424		1997-04-15	Abramson	
	41	5616338		1997-04-01	Fox, Jr. et al.	

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.G./

Receipt date: 08/06/2014	Application Number	14159959 14159959 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
(Not for submission under 37 CFR 1.99)	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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Receipt date: 08/06/2014	Application Number	14159959	14159959 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-01-21	
	First Named Inventor	Minh Quang Hoang	
	Art Unit	3763	
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6836C1	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20120283693	A1	2012-11-08	Anderson et al.	
	2	20120216360	A1	2012-08-30	Rogers et al.	

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	Examiner Name	Andrew M. Gilbert	
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	3	20120039765	A1	2012-02-16	Solomon et al.	
	4	20120016318	A1	2012-01-19	Hoang et al.	
	5	20110290799	A1	2011-12-01	Anderson et al.	
	6	20110150958	A1	2011-06-23	Davis et al.	
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	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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	36	20010016589	A1	2001-08-23	Modak et al.	

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	1	2010/143693	WO	A1	2010-12-16	JMS Co., Ltd.		☐
	2	2010/039171	WO	A1	2010-04-08	Bard Access Systems, Inc.		☐
	3	2008/157092	WO	A1	2008-12-24	Trustees of Columbia University City in New York		☐
	4	2007/137056	WO	A2	2007-11-29	Hyprotek, Inc.		☐
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	6	2006/019782	WO	A2	2006-02-23	Medical Components, Inc.		☐
	7	99/29173	WO		1999-06-17	FAN, Ming		☐
	8	87/00441	WO		1987-01-29	Baxter Travenol Laboratories, Inc.		☐

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	Examiner Name	Andrew M. Gilbert
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	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2014-08-06
Name/Print	Craig Metcalf	Registration Number	31398

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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	1	20100292673	A1	2010-11-18	Korogi et al.	
	2	20100172794	A1	2010-07-08	Ferlic et al.	
	3	20070282280	A1	2007-12-06	Tennican	

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Receipt date: 10/29/2014	Application Number	14159959 14159959 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
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	1	6523686	B1	2003-02-25	Bae	
	2	6196998	B1	2001-03-06	Jansen et al.	
	3	5989229		1999-11-23	Chiappetta	
	4	5702017		1997-12-30	Goncalves	

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	1	20040258560	A1	2004-12-23	Lake, Jr. et al.	

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EXAMINER SIGNATURE

Examiner Signature	/Andrew Gilbert/ (07/23/2015)	Date Considered	07/23/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.G./

Receipt date: 02/12/2015	Application Number	14159959	14159959 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2014-01-21	
	First Named Inventor	Minh Quang Hoang	
	Art Unit	3763	
	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6836C1	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2015-02-12
Name/Print	Craig Metcalf	Registration Number	31398

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.G./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5743884		1998-04-28	Hasson et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20100204648	A1	2010-08-12	Stout et al.	

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	1	2007/044760	WO	A2	2007-04-19	DSU Medical Corporation		☐

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Receipt date: 04/29/2015	Application Number	14159959 14159959 - GAU: 3763
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
(Not for submission under 37 CFR 1.99)	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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Examiner Signature	/Andrew Gilbert/ (07/23/2015)	Date Considered	07/23/2015

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	Examiner Name	Andrew M. Gilbert	
	Attorney Docket Number	P-6836C1	

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2015-04-29
Name/Print	Craig Metcalf	Registration Number	31398

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	6	(("5242425") or ("20030109853") or ("4440207") or ("6117114") or ("20040004019") or ("5554135")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/23 10:24
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S2	16	((JONATHAN) near2 (BURKHOLZ)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:30
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S6	9	("20060024372" | "5763412" | "6617294" | "6299610" | "6350251" | "6482197" | "6592564" | "6679870" | "6685694").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:51
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S9	124	(604/267).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
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S11	107	S10 and connector	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:55
S12	16	S10 and pad	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:55
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S19	13	(("4354490") or ("4432764") or ("4440207") or ("4655762") or ("4778447") or ("5554135") or ("5334388") or ("5792120") or ("6045539") or ("20070202177") or ("20080027399") or ("20080177250") or ("20090149819")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 14:27
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S31	20	("4346703" | "4417890" | "4431424" | "4432764" | "4439188" | "4440207" | "4551146").PN. OR ("4624664").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:27
S32	24	("2636644" | "2727516" | "4022206" | "4417890" | "4431424" | "4432764" | "4432766" | "4439188" | "4440207" | "4551146" | "4588402" | "4624664" | "4642091" | "4738668" | "4778447" | "4983161" | "5053003").PN. OR ("5195957").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:34
S33	11	("3986508" | "4511359" | "4610469" | "4878516" | "5190534" | "5195957" | "5334188" | "5423775" | "5792120").PN. OR ("6911025").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:42
S34	28	("20010016962" | "20030060781" | "20040021000" | "20050124970" | "20060030827" | "3971376" | "4301567" | "4624664" | "5048547" | "5375589" | "6045539" | "6086275" | "6450810" | "6602219" | "6673031" | "6813797" | "6813798" | "7198611" | "D176310" | "D214555" | "D258762" | "D305261" | "D325443" | "D527461" | "RE39499").PN. OR ("D596308").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:48
S35	8	("D176310").URPN.	USPAT	OR	ON	2010/06/08 10:48
S36	17	("1951099" | "1994206" | "2088658" | "2471303" | "2501193" | "3984656" | "D176310").PN. OR ("D296239").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:50
S37	40	("3502097" | "4346703" | "4417890" | "4440207" | "4559043" | "4610469" | "4752292" | "4781693" | "4919658" | "5139483").PN. OR ("5242425").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 11:06
S38	22	(("7452349") or ("7083605") or ("6911025") or ("4624664") or ("5195957") or ("7682561") or ("4432764") or ("20030153865") or ("7198611") or ("6994315") or ("2961682") or ("4282891") or ("4671306") or ("4778447") or ("20050124970") or ("20060030827") or ("20070225660") or ("5242425") or ("5694978") or ("6708363") or ("20040258560")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/06/08 11:20
S39	0	S38 and chlorohexidine	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:18

S40	1	S38 and chlorhexidine	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S41	0	S38 and (diacetate gluconate)	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S42	6	S38 and (polyethlyene polypropylene)	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S43	2	S38 and polyester	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S44	69	("2961682" | "20030153865" | "20040258560" | "20050124970" | "20060030827" | "20070202177" | "20070225660" | "20080027399" | "20080177250" | "20090149819" | "4282891" | "4354490" | "4432764" | "4440207" | "4624664" | "4655762" | "4671306" | "4778447" | "5195957" | "5242425" | "5334388" | "5554135" | "5694978" | "5792120" | "6045539" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561").PN.	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2010/09/09 10:00
S45	11	("2007/0112333").URPN.	USPAT	OR	ON	2012/04/04 15:07
S46	22	("2961682" | "20030153865" | "20040258560" | "20050124970" | "20060030827" | "20070225660" | "4282891" | "4432764" | "4624664" | "4671306" | "4778447" | "5195957" | "5242425" | "5694978" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:24
S47	88	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:35

		5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$).did. or (US-2961682-$).did.				
S48	7	S47 and (sponge polyurethane polyester cotton silicone) and alcohol with solution and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:36
S49	7	(S46 S47) and (sponge polyurethane polyester cotton silicone) and alcohol with solution and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:36
S50	14	(S46 S47) and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:41
S51	7	S50 not S49	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:41
S52	22	("2961682" | "20030153865" | "20040258560" | "20050124970" | "20060030827" | "20070225660" | "4282891" | "4432764" | "4624664" | "4671306" | "4778447" | "5195957" | "5242425" | "5694978" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34
S53	88	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34

		6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$).did. or (US-2961682-$).did.				
S54	14	(S52 S53) and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34
S55	22	("2961682" | "20030153865" | "20040258560" | "20050124970" | "20060030827" | "20070225660" | "4282891" | "4432764" | "4624664" | "4671306" | "4778447" | "5195957" | "5242425" | "5694978" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:35
S56	160	medical and connector and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:44
S57	26	("20010016589" | "20020144705" | "20030072781" | "20030162839" | "20040039349" | "20060165751" | "20060239954" | "20080075761" | "20080182921" | "4584192" | "4716032" | "4915934" | "4925668" | "5023082" | "5512199" | "5547662" | "5616338" | "5861440" | "6051609" | "6337357" | "6413539" | "6488942" | "6846846" | "6861060" | "7198800" | "7268165").PN. OR ("7704935").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:55
S58	3	(("4440207") or ("4778447") or ("5242425")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/04/05 11:01
S59	22	("2007/0112333").URPN.	USPAT	OR	ON	2012/09/19 13:58
S60	1	("5554135").PN.	US-PGPUB;	OR	OFF	2012/09/19

			USPAT; USOCR			14:25
S61	24	("4335756" | "4402691" | "4432766" | "4440207" | "4507111" | "5190534" | "D342134").PN. OR ("5554135").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/09/19 14:25
S62	3	(("5554135") or ("20040004019") or ("4778447")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/15 10:30
S63	65	("7780794" | "D607325" | "20070167910" | "7731679" | "7776011" | "20070249996" | "4432764" | "4728321" | "4983161" | "7431712" | "7922701" | "5554135" | "20070282280" | "7749189" | "4243035" | "4440207" | "20070112333" | "4507111" | "7753891" | "3977401" | "5827244" | "6045539" | "4402691" | "20090012426" | "20040258560" | "20050147524" | "4778447" | "20050013836" | "4335756" | "4432766" | "20090093757" | "7635344" | "7799010" | "7857793" | "4417890" | "4957637" | "20050203460" | "4624664" | "20070265578" | "6126640" | "20060030827" | "20100160894" | "4703762" | "4811847" | "5989229" | "6116468" | "0877946" | "4439184" | "20070249966" | "7731678" | "7763006" | "3270743" | "5954957" | "5820604" | "20050065479" | "4317446" | "20090099529" | "5190534" | "5792120" | "4041934" | "4799926" | "20110290799" | "4989733").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/15 10:49
S64	8	"US 8167847"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/01/15 10:49
S65	1	("4440207").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/15 11:48
S66	32	("2007/0112333").URPN.	USPAT	OR	ON	2013/08/07 15:27
S67	1	("20060048313").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 15:37
S68	8	("4624664").PN. ("20050013836" | "4317446" | "4440207" | "5827244" | "6045539" | "0877946").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:40
S69	15	("20050124970" | "20080038167" | "3987930" | "4354490" | "4440207" | "4450624" | "4778447" | "4838875" | "5951519" | "6045539").PN. ("2351804" | "4402691" | "5792120").PN. ("4346703").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:49
S70	2	"US 20080177250"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/07 15:50
S71	3	("20050065479" | "4440207" | "4989733").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:58

S72	4	("20020168530" | "20080107564" | "20090137969" | "20090297400").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:59
S73	2	("20030217423" | "20060030827").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:06
S74	12	("20050038397" | "20080132880" | "20080190485" | "20100063482" | "5439451" | "5492147" | "5536258" | "5738663" | "6932795" | "7014169" | "7762524" | "7922701").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:08
S75	2	(("4402691") or ("4440207")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 16:10
S76	3	("20070112333" | "20100172794" | "5554135").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:16
S77	3	("20110054440" | "4667837" | "7762988").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:17
S78	0	("8491546").URPN.	USPAT	OR	ON	2013/08/07 16:19
S79	4	("20100047123" | "20100049170" | "20120039765" | "4444310" | "4626664" | "5547662" | "5706944").PN.	USPAT	OR	ON	2013/08/07 16:20
S80	7	("20100047123" | "20100049170" | "20120039765" | "4444310" | "4626664" | "5547662" | "5706944").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:21
S81	124	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$ or US-20040004019-$).did. or (US-20060039742-$ or US-20080021392-$ or US-20080021381-$ or US-20080107564-$ or US-20090024096-$ or US-20090041619-$ or US-20090297400-$ or US-20100049170-$ or US-20100047123-$ or US-20100064456-$ or US-20100100056-$ or US-20100242993-$ or US-20100286637-$ or US-20100292673-$ or US-20100296968-$ or US-20110054440-$ or US-20110150958-$ or US-20110184382-$ or US-20110236258-$ or US-20110314619-$ or US-20120039765-$ or US-20010016589-$ or US-20030162839-$ or US-20080075761-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/07 16:22

		6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$ or US-7704935-$ or US-7866907-$ or US-8113731-$ or US-6488942-$ or US-6846846-$ or US-8167847-$ or US-8206514-$ or US-8252247-$ or US-8388894-$).did. or (US-2961682-$ or US-0877946-$).did. or (US-20080086091-$).did.				
S82	66	S81 and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:22
S83	56	("2436291" | "2596725" | "2629124" | "2673362" | "2713693" | "2722719" | "2774093" | "3316922" | "3369553" | "3375538" | "4117566").PN. OR ("4282891").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:23
S84	87	("3396727" | "4232677" | "4273247" | "4306976" | "4340052" | "4354490" | "4403992").PN. OR ("4440207").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:29
S85	46	("4346703" | "4417890" | "4431424" | "4432764" | "4439188" | "4440207" | "4551146").PN. OR ("4624664").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:32
S86	83	("3502097" | "4346703" | "4417890" | "4440207" | "4559043" | "4610469" | "4752292" | "4781693" | "4919658" | "5139483").PN. OR ("5242425").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:35
S87	44	("3557989" | "3595419" | "3612320" | "3715063" | "3973690" | "4019646" | "4210251" | "4394923" | "4597758" | "5014869" | "5060813").PN. OR ("5694978").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:37
S88	8	("6446659" | "4874377" | "RE33971" | "5122123" | "5733503" | "5139483" | "5047021" | "4614514").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:47

S89	1	("4610469").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 16:51
S90	195	("3986508" | "4022205" | "4030494" | "4143853" | "4161949" | "4334551" | "4431424" | "4508367" | "4511359").PN. OR ("4610469").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:52
S91	60	("1152286" | "1282679" | "20030105452" | "20030153865" | "20030229312" | "20040215170" | "20050017380" | "20060270990" | "20070106205" | "20080095680" | "2582109" | "3160327" | "3458080" | "4334551" | "4346703" | "4432764" | "4440207" | "4551146" | "4573983" | "4624664" | "4642091" | "4810241" | "4919658" | "4921491" | "4983161" | "5053003" | "5056464" | "5195957" | "5301849" | "5332113" | "5435358" | "5531810" | "5536258" | "5554135" | "5792120" | "5875942" | "5894015" | "5921425" | "5971965" | "6045539" | "6113068" | "6207201" | "6299131" | "6648158" | "6706022" | "6732876" | "6875205" | "7100890" | "7198611" | "7232419").PN. OR ("7682561").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:53
S92	270	(S83 S84 S85 S86 S87 S90 S91) and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:54
S93	1774	(fluid and valve and (medical patient) and thread and (pad sponge foam swab) and (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:39
S94	6	(fluid and valve and (medical patient) and (thread threading) same (pad sponge foam swab) with (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:40
S95	121	((cap cover) and (thread threading) same (pad sponge foam swab) with (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:42
S96	23	((medical patient user) with (port valve connector connection) and (thread threading) same (pad sponge foam swab) with (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:45
S97	109	((medical patient user) with (port valve connector connection) same (thread threading) same (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS;	OR	ON	2013/08/07 19:46

			EPO; JPO; DERWENT; IBM_TDB			
S98	42	((medical patient user) same (cap cover) same (thread threading) same (clean$3 steriliz$3 disinfect$3) with (solution liquid)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:49
S99	1011	((medical patient user) same (cap cover) same (clean$3 steriliz$3 disinfect$3) with (solution liquid)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:49
S100	103	((medical patient user) same (cap cover) same (clean$3 steriliz$3 disinfect$3) with (solution liquid) with (pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:50
S101	125	(valve and (cap cover) same (clean$3 steriliz$3 disinfect$3) with (solution liquid) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:51
S102	99	S101 not S100	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:51
S103	129	((fluid patient) with (line tube tubing) with (valve port connector luer) and (cap cover) same (clean$3 steriliz$3 disinfect$3) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:53
S104	0	(luer near3 (clean$3 steriliz$3 disinfect$3) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:56
S105	49	(luer near3 (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:56
S106	12	(("4232677") or ("4610469") or ("4624664") or ("4440207") or	US-PGPUB; USPAT;	OR	OFF	2013/08/07 20:33

		("4432764") or ("4778447") or ("5242425") or ("5694978") or ("6911025") or ("20060030827") or ("5554135") or ("20040004019")).PN.	USOCR			
S107	18	("20040004019" | "20050124970" | "4440207" | "4626664" | "4778447" | "5242425" | "5547662" | "5706944" | "6911025" | "6994315").PN. ("4444310" | "5554135").PN. ("20080177250" | "20090062766" | "20090149819" | "20100047123" | "20100049170" | "20120039765").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 20:45
S109	1148	(604/533).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S110	156	(604/534).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S111	312	(604/535).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S112	45	(604/536).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S113	337	(604/537).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S114	190	(15/104.03).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:40
S115	797	(15/104.04).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:41
S116	398	(15/104.062).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:41
S117	493	(15/104.92).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S118	941	(15/104.93).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S119	917	(15/104.94).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S120	2913	(422/28).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:46
S121	2	(("4440207") or ("5242425")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 15:15
S122	128	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/08 20:13

		$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$ or US-20040004019-$).did. or (US-20060039742-$ or US-20080021392-$ or US-20080021381-$ or US-20080107564-$ or US-20090024096-$ or US-20090041619-$ or US-20090297400-$ or US-20100049170-$ or US-20100047123-$ or US-20100064456-$ or US-20100100056-$ or US-20100242993-$ or US-20100286637-$ or US-20100292673-$ or US-20100296968-$ or US-20110054440-$ or US-20110150958-$ or US-20110184382-$ or US-20110236258-$ or US-20110314619-$ or US-20120039765-$ or US-20010016589-$ or US-20030162839-$ or US-20080075761-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$ or US-7704935-$ or US-7866907-$ or US-8113731-$ or US-6488942-$ or US-6846846-$ or US-8167847-$ or US-8206514-$ or US-8252247-$ or US-8388894-$ or US-4610469-$ or US-3595419-$ or US-4800904-$ or US-7857793-$).did. or (US-2961682-$ or US-0877946-$).did. or (US-20080086091-$).did.				
S124	0	S122 and (partial half) near2 thread$3	US-PGPUB;	OR	ON	2013/08/08

			USPAT; USOCR			20:14
S125	0	S122 and (partial half quarter length) near2 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14
S126	6	S122 and (partial half quarter length) with thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14
S127	2605	(cap connector) with (partial half quarter length) near3 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:16
S128	918	(cap connector) with (partial half quarter) near3 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:16
S129	68	valve same (cap connector) with (partial half quarter) near3 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:17
S130	6	medical and valve same (cap connector) with (partial half quarter) near3 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:17
S131	9	valve same (cap connector) with (partial half quarter) near3 thread$3 with inner	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:22
S132	5	("20040004019" | "4440207" | "4778447" | "5242425" | "6117114").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 10:31
S133	7	("20050147524" | "4280632" | "4671306" | "4991629" | "5954957" | "6116468" | "6227391").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 10:32
S134	129	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$ or US-20040004019-$).did. or (US-20060039742-$ or US-20080021392-$ or US-20080021381-$ or US-20080107564-$ or US-20090024096-$ or US-20090041619-$ or US-20090297400-$ or US-20100049170-$ or US-20100047123-$ or US-20100064456-$ or US-20100100056-$ or US-20100242993-$ or US-20100286637-$ or US-20100292673-$ or US-20100296968-$ or US-20110054440-$ or US-20110150958-$ or US-20110184382-$ or US-20110236258-$ or US-20110314619-$ or US-20120039765-$ or US-20010016589-$ or US-20030162839-$ or US-20080075761-$).did. or (US-5334388-$ or US-5439681-	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2014/01/13 10:34

		$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$ or US-7704935-$ or US-7866907-$ or US-8113731-$ or US-6488942-$ or US-6846846-$ or US-8167847-$ or US-8206514-$ or US-8252247-$ or US-8388894-$ or US-4610469-$ or US-3595419-$ or US-4800904-$ or US-7857793-$ or US-6117114-$).did. or (US-2961682-$ or US-0877946-$).did. or (US-20080086091-$).did.				
S135	22	(US-20070225660-$ or US-20060030827-$ or US-20050124970-$ or US-20040258560-$ or US-20030153865-$).did. or (US-7682561-$ or US-7452349-$ or US-7198611-$ or US-7083605-$ or US-6994315-$ or US-6911025-$ or US-6708363-$ or US-5694978-$ or US-5242425-$ or US-5195957-$ or US-4778447-$ or US-4671306-$ or US-4624664-$ or US-4432764-$ or US-4282891-$ or US-2961682-$).did. or (US-2961682-$).did.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 10:34
S136	1	("8491546").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/01/13 13:08
S137	0	(fluid and (set line tube tubing) and valve and septum and threads and internal and external and (pad sponge foam) and (clean$4 disinfect$4 steriliz$3)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:16
S138	1	(fluid and (set line tube tubing) and valve and septum and threads and (pad sponge foam) and (clean$4 disinfect$4 steriliz$3)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:16

S139	1	(fluid and (set line tube tubing) and valve and septum and threads and (pad sponge foam)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:16
S140	1	((fluid medical infusion infusing liquid medicament drug) and (set line tube tubing) and valve and septum and threads and (pad sponge foam)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:17
S141	2	((fluid medical infusion infusing liquid medicament drug) and (set line tube tubing) and valve and septum and threads and (clean$4 steriliz$4 disinfect$4)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:17
S142	2	"US 20140135710"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2015/07/22 22:44
S143	101	((Minh) near2 (Hoang)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:45
S144	63	((Jonathan) near2 (Burkholz)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:45
S145	117	("20020144705" | "20050147525" | "20080033371" | "20100049170" | "20100050351" | "20110290799" | "4444310" | "4778447" | "4915934" | "5620424" | "5641464" | "5817344" | "5954957" | "7198611" | "7268165" | "7922701" | "8167847" | "20100204648" | "20030072781" | "20040039349" | "20050147524" | "20080147047" | "20120016318" | "20120283693" | "5195957" | "5334388" | "5686096" | "6116468" | "6413539" | "7083605" | "7828186" | "20070225660" | "20090062766" | "20120216360" | "4282891" | "4584192" | "4991629" | "5547662" | "5639310" | "5706944" | "5792120" | "6337357" | "7282186" | "7452349" | "7704935" | "8162899" | "20090028750" | "20090149819" | "4626664" | "4655762" | "4716032" | "4925668" | "5554135" | "6051609" | "6488942" | "20010016589" | "20040004019" | "20060030827" | "20070112333" | "20080027399" | "20090008393" | "20100047123" | "2961682" | "4432764" | "4440207" | "5861440" | "6117114" | "6846846" | "6861060" | "7198800" | "20100172794" | "20040258560" | "20050124970" | "20080177250" | "4417890" | "4989733" | "5335373" | "5616338" | "5694978" | "6045539" | "6708363" | "6994315" | "8065773" | "8491546" | "20070282280" | "20100292673" | "5989229" | "5743884" | "20060165751" | "20060239954" | "20070202177" | "20080075761" | "20080095680" | "20100000040" | "4354490" | "4624664" | "5023082" | "5242425" | "5512199" | "5554106" | "5722537" | "6227391" |	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:45

		"6911025" | "8113731" | "5702017" | "6196998" | "6523686" | "20030162839" | "20080182921" | "20110150958" | "20120039765" | "4280632" | "4671306" | "5569207" | "7682561" | "RE38145").PN.				
S146	130	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$ or US-20040004019-$).did. or (US-20060039742-$ or US-20080021392-$ or US-20080021381-$ or US-20080107564-$ or US-20090024096-$ or US-20090041619-$ or US-20090297400-$ or US-20100049170-$ or US-20100047123-$ or US-20100064456-$ or US-20100100056-$ or US-20100242993-$ or US-20100286637-$ or US-20100292673-$ or US-20100296968-$ or US-20110054440-$ or US-20110150958-$ or US-20110184382-$ or US-20110236258-$ or US-20110314619-$ or US-20120039765-$ or US-20010016589-$ or US-20030162839-$ or US-20080075761-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2015/07/22 22:45

		7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$ or US-7704935-$ or US-7866907-$ or US-8113731-$ or US-6488942-$ or US-6846846-$ or US-8167847-$ or US-8206514-$ or US-8252247-$ or US-8388894-$ or US-4610469-$ or US-3595419-$ or US-4800904-$ or US-7857793-$ or US-6117114-$ or US-8491546-$).did. or (US-2961682-$ or US-0877946-$).did. or (US-20080086091-$).did.				
S147	2	(("8740864") or ("8491546")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/22 22:45
S148	54	("20040004019" | "20050124970" | "20060030827" | "20070112333" | "20070202177" | "20070225660" | "20080027399" | "20080147047" | "20080177250" | "20090028750" | "20090062766" | "20090149819" | "20090175759" | "20100047123" | "20100049170" | "20120039765" | "2961682" | "4282891" | "4354490" | "4432764" | "4440207" | "4444310" | "4624664" | "4626664" | "4655762" | "4671306" | "4778447" | "5195957" | "5242425" | "5334388" | "5547662" | "5554135" | "5639310" | "5641464" | "5694978" | "5706944" | "5722537" | "5792120" | "5817344" | "6045539" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7282186" | "7452349" | "7704935" | "7828186" | "7922701" | "8065773" | "8113731").PN. OR ("8491546").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:47
S149	0	("8740864").URPN.	USPAT	OR	ON	2015/07/22 22:47
S150	57	("20030153865" | "20040004019" | "20040258560" | "20050124970" | "20050147524" | "20060030827" | "20070202177" | "20070225660" | "20080027399" | "20080147047" | "20080177250" | "20090028750" | "20090062766" | "20090149819" | "20100047123" | "20100049170" | "20120039765" | "2961682" | "4280632" | "4282891" | "4354490" | "4432764" | "4440207" | "4444310" | "4624664" | "4626664" | "4655762" | "4671306" | "4778447" | "4991629" | "5195957" | "5242425" | "5334388" | "5547662" | "5554135" | "5639310" | "5694978" | "5706944" | "5792120" | "5817344" | "5954957" | "6045539" | "6116468" | "6117114" | "6227391" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561" | "7704935" | "7922701" | "8065773" | "8113731").PN. OR ("8740864").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:47
S151	10	S150 not S148	US-PGPUB;	OR	ON	2015/07/22

			USPAT; USOCR			22:47
S152	259	A61M39/16.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:51
S153	226	A61M39/162.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:51
S154	161	A61M39/165.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:51
S155	550	A61M39/02.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:51
S156	468	A61M39/20.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:52
S157	547	A61M2039/1033.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:52
S158	341	A61M2039/1072.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:52
S159	533	(S152 S153 S154)	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:52
S160	63	S153 and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:52
S161	183	(S152 S153 S154) and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:53
S162	795	(S152 S153 S154 S155 S156 S157 S158) and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:53
S163	44	("20040004019" | "4440207" | "4778447" | "5242425" | "6117114").PN. ("5554135").PN. ("20040004019" | "20080147047" | "20090028750" | "20090062766" | "4440207" | "4778447" | "5242425" | "5639310" | "5817344" | "7704935" | "7922701" | "8065773" | "8113731").PN. ("20070202177" | "20080027399" | "20080177250" | "20090149819" | "4354490" | "4432764" | "4440207" | "4655762" | "4778447" | "5334388" | "5554135" | "5792120" | "6045539").PN. ("2961682" | "20030153865" | "20040258560" | "20050124970" | "20060030827" | "20070225660" | "4282891" | "4432764" | "4624664" | "4671306" | "4778447" | "5195957" | "5242425" | "5694978" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:54
S164	0	("2014/0135710").URPN.	USPAT	OR	ON	2015/07/23 08:20
S165	1	2014-M07698.NRAN.	DERWENT	OR	ON	2015/07/23

						08:20
S166	2	"US 20140135711"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2015/07/23 08:31
S167	0	("2014/0135711").URPN.	USPAT	OR	ON	2015/07/23 08:31

EAST Search History (Interference)

< This search history is empty>

7/ 23/ 2015 10:26:29 AM
C:\ Users\ agilbert\ Documents\ EAST\ Workspaces\ Workspaces\ 14159959.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14159959	HOANG ET AL.
	Examiner	Art Unit
	ANDREW GILBERT	3763

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/23/2015								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
	10	✓								
	11	✓								
	12	✓								
	13	✓								
	14	✓								
	15	✓								
	16	✓								
	17	✓								
	18	✓								
	19	✓								
	20	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14159959	HOANG ET AL.
	Examiner	Art Unit
	ANDREW GILBERT	3763

CPC- SEARCHED		
Symbol	Date	Examiner
A61M39/16,162,165,02,20	7/23/2015	AG
A61M2039/1033,1072	7/23/2015	AG

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Searched EAST CPC class/subclass and keyword search - see attached sheets	7/23/2015	AG
Inventor Name search	7/23/2015	AG
Forward/backward citation searches	7/23/2015	AG
Updated search in related USPNs 8740864, 8491546	7/23/2015	AG

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/ANDREW GILBERT/ Primary Examiner.Art Unit 3763

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/159,959	01/21/2014	Minh Quang Hoang	P-6836C1	1050

71562 7590 09/30/2015

David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
09/30/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip_docket@bd.com
cmetcalf@kmclaw.com

Applicant-Initiated Interview Summary	**Application No.** 14/159,959	**Applicant(s)** HOANG ET AL.	
	Examiner ANDREW GILBERT	**Art Unit** 3763	

All participants (applicant, applicant's representative, PTO personnel):

(1) *ANDREW GILBERT*. (3)_____.

(2) *Brian Tucker (Reg. No. 61550)*. (4)_____.

Date of Interview: *24 September 2015*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1*.

Identification of prior art discussed: *USPN 8740864*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant and examiner discussed proposed amendments to the claim that would obviate all claim objections in the Non-Final Rejection mailed on 7/28/2015. Further, applicant and examiner discussed filing a e-Terminal Disclaimer to USPN 8740864 to obviate the previous double patenting rejection.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/ANDREW GILBERT/ Primary Examiner, Art Unit 3763	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	14/159,959	Confirmation No.: 1050
Applicant	:	Minh Quang Hoang	
Title	:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER	
Filed	:	January 21, 2014	
TC/A.U.	:	3763	
Examiner	:	Andrew M. Gilbert	
Docket No.	:	P-6836C1	
Customer No.	:	71562	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

Dear Sir:

This paper is filed in response to the Office Action of July 28, 2015 (the "Office Action"). Please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 9 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please amend paragraph 0001 of the specification as shown below:

[0001] This application is a continuation of United States Application No. 11/281,711, filed November 17, 2005 and issued on June 3, 2014 as United States Patent No. 8,740,864, titled PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER, which is incorporated herein in its entirety. This application is also related to United States Application No. 12/802,512, filed June 8, 2010 and issued on July 23, 2013 as United States Patent No. 8,491,546 and United States Application No. 14/159,991, filed January 21, 2014 both of which are titled PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A device for maintaining a patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face, the device comprising:

a housing having an opening to an inner cavity for receiving the access portion of the patient fluid line access valve;

a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve;

threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening, the threading to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access portion of the patient fluid line access valve to contact the wet pad with the distalmost end face of the access portion of the patient fluid line access valve, and to disinfect the distalmost end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad, wherein the threading receives the external threads of the access portion of the patient fluid line access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the wet pad; and

a removable lid enclosing the inner cavity to maintain the wet pad and the cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve.

2. (Original) The device of claim 1, wherein a threaded interaction between the threading and the external threads provides adjustable positioning of the septum within the inner cavity.

3. (Original) The device of claim 2, wherein adjustable positioning of the septum within the inner cavity allows the septum to contact the wet pad, and further allows the septum to contact and compress the wet pad between the septum and the inner cavity.

4. (Original) The device of claim 1, wherein the wet pad is a sponge.

5. (Original) The device of claim 1, wherein the housing comprises a polyethylene or polypropylene material.

6. (Original) The device of claim 1, wherein the cleaning solution comprises an antimicrobial agent.

7. (Original) The device of claim 6, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

8. (Original) The device of claim 6, wherein the cleaning solution is an alcohol-based cleaning solution.

9. (Currently Amended) A device for maintaining a patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face, the device comprising:

a housing for covering the access portion of the patient fluid line access valve, the housing having an open end, a closed end, and a cavity, the housing including a thread on an inner wall of the cavity proximate the open end for engaging the external threads on the access portion of the patient fluid line access valve;

a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve, the wet pad being positioned within the cavity for contacting the distalmost end face of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion; and

a lid over the open end of the housing to close the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the patient fluid line access valve into the cavity such that the thread engages the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads.

10. (Original) The device of claim 9, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.

11. (Original) The device of claim 9, wherein the cleaning solution comprises an antimicrobial agent.

12. (Original) The device of claim 11, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

13. (Original) The device of claim 11, wherein the cleaning solution is an alcohol-based cleaning solution.

14. (Currently Amended) A device for maintaining a threaded patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face, the device comprising:

a housing having an inner cavity for covering the access portion of the threaded patient fluid line access valve;

a wet pad within the housing and impregnated with a cleaning solution prior to contacting the threaded patient fluid line access valve, the wet pad being configured to contact at least a portion of the threaded patient fluid line access valve and the distalmost end face of the threaded patient fluid line access valve to reduce the amount of microbes on the threaded patient fluid line access valve;

a thread within the inner cavity of the housing and positioned between the wet pad and an opening to the inner cavity, the thread for engaging the external threads of the threaded patient

fluid line access valve to cause the wet pad to contact the distalmost end face of the threaded patient fluid line access valve; and

a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the threaded patient fluid line access valve, the lid being removable to allow the distalmost end face of the threaded patient fluid line access valve to be inserted into the housing and contact the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads.

15. (Currently Amended) The device of claim 14, wherein the inner cavity comprises an inner circumference and the ~~internal~~ thread comprises a length that is less than the inner circumference.

16. (Original) The device of claim 14, wherein the wet pad is a sponge.

17. (Original) The device of claim 14, wherein the housing comprises a polyethylene or polypropylene material.

18. (Original) The device of claim 14, wherein the cleaning solution is an alcohol-based cleaning solution.

19. (Original) The device of claim 14, wherein the cleaning solution comprises an antimicrobial agent.

20. (Original) The device of claim 19, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

REMARKS/ARGUMENTS

This paper is submitted in response to the Office Action mailed July 28, 2015.

Interview Summary

Applicant expresses appreciation for the telephonic interview conducted on September 24, 2015. During the interview, Examiner Gilbert indicated that the claims would be allowable.

Claim Objections

By this response, the claims have been amended as suggested by the Office.

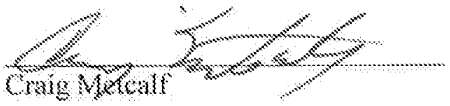
Double Patenting

A terminal disclaimer is filed herewith to address the double patenting rejection.

Conclusion

Applicant respectfully request that a Notice of Allowance be issued in this case. If there are any remaining issues preventing allowance of the pending claims that could be clarified by telephone, the Examiner is requested to contact the undersigned attorney.

Respectfully submitted,



Craig Metcalf
Reg. No. 31,398
Attorney for Applicant

Date: October 27, 2015

KIRTON | MCCONKIE
50 East South Temple
Salt Lake City, Utah 84111
Telephone: 801-328-3600

PTO/AIA/26 (04-14)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) P-6836C1

In re Application of: Minh Quang Hoang

Application No.: 14/159,959

Filed: January 21, 2014

For: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

The applicant, Becton, Dickinson and Company, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 8,740,864 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

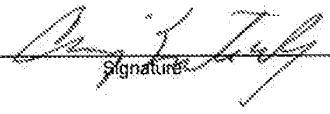
expires for failure to pay a maintenance fee;
is held unenforceable;
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is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 31,398



Signature

9/27/15
Date

Craig Metcalf
Typed or printed name

Attorney
Title

801-328-3600
Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	1	"Corrected Petition for Inter Partes Review Under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42,100 et seq.," USPTO, Patent Trial and Appeal Board, Excelsior Medical Corporation v. Becton, Dickinson and Company, Case IPR2014-00880, Patent No. 8,740,864, pp. 1-48, June 23, 2014.	☐
	2	"Patent Owner's Preliminary Response Under 37 C.F.R. § 42,10," USPTO, Patent Trial and Appeal Board, Excelsior Medical Corporation v. Becton, Dickinson and Company, Case IPR2014-00880, Patent No. 8,740,864, pp. 1-30, September 16, 2014.	☐
	3	"Decision, Institution of Inter Partes Review, 37 C.F.R. § 42,108," USPTO, Patent Trial and Appeal Board, Excelsior Medical Corporation v. Becton, Dickinson and Company, Case IPR2014-00880, Patent No. 8,740,864, pp. 1-21, November 25, 2014.	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2015-10-27
Name/Print	Craig Metcalf	Registration Number	31398

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	14159959
Filing Date:	21-Jan-2014
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Filer:	Lloyd Craig Metcalf/Kris Haley
Attorney Docket Number:	P-6836C1

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Statutory or Terminal Disclaimer	1814	1	160	160
		Total in USD ($)		**340**

Electronic Acknowledgement Receipt	
EFS ID:	23903439
Application Number:	14159959
International Application Number:	
Confirmation Number:	1050
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836C1
Receipt Date:	27-OCT-2015
Filing Date:	21-JAN-2014
Time Stamp:	14:55:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$340
RAM confirmation Number	1148
Deposit Account	500843
Authorized User	METCALF, L CRAIG
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		P_6836C1_OAResp_102715.pdf	293714 8dc4fbf377fc0975481dea4dee1cf84d84a63d24	yes	9

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Specification	2	2
Claims	3	8
Applicant Arguments/Remarks Made in an Amendment	9	9

Warnings:					
Information:					
2	Terminal Disclaimer Filed	P_6836C1_TermDisc_Pat_8740864_102715.pdf	295722 29ee6af652b1a3ecdd2cf16949d1d0d85db5f133	no	1
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	P_6836C1_SuppIDS_102715.pdf	612449 e0e0da62b54376f865145b709eec285f6f76e465	no	4
Warnings:					
Information:					

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

4	Non Patent Literature	P_6836_IPR_reply.pdf	1261019 bc6eaa4d4d5170c686b0841b9f4fbe9417bbd070	no	48
Warnings:					
Information:					
5	Non Patent Literature	P_6836_IPR_PreliminaryResponse.PDF	402614 dc5ec8b24df04fcca0fd7153fc48b84fc4ddd0cf	no	30

Warnings:					
Information:					
6	Non Patent Literature	P_6836_IPR_InstitutionDecision.pdf	8302608 e594f18cafd6e0d9104212004b6d38f5bc7d7d23	no	21
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	32126 cc839a9fc01fd2d2a1b812a61d8f1656dbe4043b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	11200252	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/159,959	Filing Date 01/21/2014	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)		
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	10/27/2015	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/STEFANIE BRYCE/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	14/159,959	HOANG ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 10/27/15	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

ANDRE ROBINSON

U.S. Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

71562 7590 11/17/2015

David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

EXAMINER
GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 11/17/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/159,959	01/21/2014	Minh Quang Hoang	P-6836C1	1050

TITLE OF INVENTION: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	02/17/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 02/11)

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

71562 7590 11/17/2015
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/159,959	01/21/2014	Minh Quang Hoang	P-6836C1	1050

TITLE OF INVENTION: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	02/17/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
GILBERT, ANDREW M	3763	604-533000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/159,959	01/21/2014	Minh Quang Hoang	P-6836C1	1050

71562 7590 11/17/2015

David W. Highet, VP & Chief IP Counsel
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(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 11/17/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/159,959	Applicant(s) HOANG ET AL.	
	Examiner ANDREW GILBERT	Art Unit 3763	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the reply filed on 10/27/2015*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-20*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/ANDREW GILBERT/
Primary Examiner, Art Unit 3763

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Acknowledgments

2. This office action is in response to the reply filed on 10/27/2015.

3. In the reply, the applicant amended claims 1, 9, 14, and 15.

4. Thus, claims 1-20 are pending for examination.

Terminal Disclaimer

5. The terminal disclaimer filed on 10/27/2015 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of USPN 8740864 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 10/27/2015 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Allowable Subject Matter

7. Claims 1-20 are allowed.

8. The following is an examiner's statement of reasons for allowance:

9. The subject matter of the independent claim could either not be found or was not suggested in the prior art of record. The present claims are substantially similar to

those previously allowed in USPN 8740864, to which a terminal disclaimer has been filed and approved on 10/27/2015. See Notice of Allowance mailed on 1/21/2014 for discussion of reasons for allowance and closest prior art as well as the comments below.

10. The examiner notes that '864 had an IPR petition instituted with a Request for Trial Granted on 11/25/2014 (*see IPR2014-00880*). The trial was terminated on 1/5/2015 in view of a confidential settlement. The Board instituted in '864 on (i) claims 10 and 12 in view of 35 USC 103(a) by White, Harding, and Genatempo, and (ii) claims 10, 12, 14, in view of 35 USC 103(a) by Menyhay and Genatempo. However, settlement occurred prior to any final determination on the patentability of the challenged claims by the Board.

11. Independent claim 10 in '864 differs from present independent claim 9 in several ways. Present claim 9 is different in the following manner (additions underlined; deletions ~~struck though~~):

> 9. (Currently Amended) A device for maintaining a patient fluid line access valve having an access portion with a~~n~~ distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face~~septum~~, the device comprising:
>
> a housing for covering the access portion of the patient fluid line access valve, the housing having an open end, a closed end, and a cavity, the housing including a thread on an inner wall of the cavity proximate the open end for engaging the external threads on the access portion of the patient fluid line access valve;
>
> a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve, the wet pad being positioned within the cavity for contacting the distalmost end face ~~to disinfect the end face and at least a portion of the external threads~~ of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion; and
>
> a lid over the open end of the housing to close~~seal~~ the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the patient fluid line access valve into the cavity such that the thread engages the external threads on the access portion as the access portion is advanced into the

inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads.

12. The differences in present independent claim 9 are in line with subject matter included in the other allowed independent claims 1 and 15 in '864 that were not challenged by IPR petitions. For example, the recitation in present claim 9 of "…such that the thread engages the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads." resembles subject matter recited in claim 1 of '864: "… the threading to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access portion of the patient fluid line access valve to contact the wet pad with the end face of the access portion of the patient fluid line access valve, and to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad…"

13. For this distinction in subject matter alone the examiner finds the institution of the IPR petition on independent claim 10 to be moot. However, the examiner will comment further on (i) White, Harding, and Genatempo in view of present claim 9, and (ii) Menyhay and Genatempo in view of present claim 9, in view of the remarks by the Board in the IPR2014-00880 decision.

a. (i) White, Harding, and Genatempo in view of present claim 9

14. Regarding (i), White (USPN 5242425) fails to teach or suggest a lid, a distalmost end face including external threads proximate to the distalmost end face, or the thread engaging the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the

wet pad to provide the cleaning solution to the septum and at least a portion of the external threads. For example:

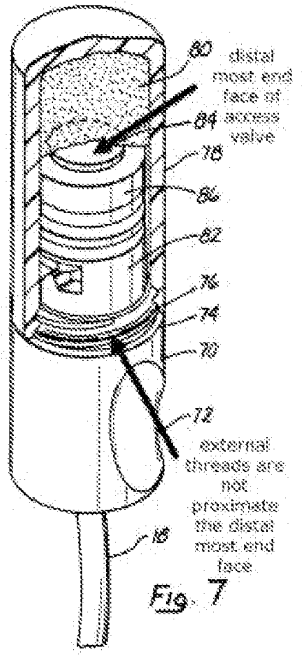


Fig. 7

FIG. 7 shows an alternate embodiment of the invention. As shown the distal member 70 with finger grip 72 is provided with an externally threaded shoulder 74. Threaded shoulder 74 is adapted to receive internal threads 76 of outer protective cap 78. Outer protective cap 78 preferably contains a sponge 80 saturated with an antiseptic. The outer protective cap 78 is spaced from proximal member or injection cap 82 to permit antiseptic to bathe the exterior surfaces of distal member 70, proximal member 82, and self-sealing septum 84. This maintains the self-sealing septum 84, proximal member 82 and interconnection between proximal member 82 and distal member 70 in aseptic conditions.

15. While White disclose an antiseptic may bath exterior surfaces of the septum, and member 82, there is no teaching or suggestion that the thread 76 engages the external threads 74 as the access portion is advanced into the inner cavity to cause the distalmost end face 84 to contact the wet pad 80 to provide the cleaning solution/antiseptic to at least a portion of the external threads. Rather, the engagement between the thread and the external threads forms an interconnection that seals and maintains the connection between the distal member 70 and cap 78 in aseptic conditions, i.e. sealed from the environment. The placement of the thread and external threads opposite from the distalmost end face and septum and sponge as disclosed and illustrated do not teach or suggest that any antiseptic contacts at least a portion of the

external threads to reduce the amount of microbes on the access portion. Rather, the thread 76 and external threads 74 appear to form a sealed connection that would maintain the antiseptic within the spaced between cap 78 and access valve so that septum and outer surface of the access valve are maintained in aseptic condition.

16. Harding (US 20030109853 A1) fails to teach or suggest numerous claim limitations and was cited in the petitioners IPR petition for the purpose of modifying the external threads to be proximate the septum rather than opposite the septum/distal end face as taught by White. However, the petition cites no teaching or motivation to make such a modification to the external threads of White except for it being a predictable variation that under *KSR, 550 U.S. 398, 417 (2007)* would bar patentability. Briefly, the examiner finds several reasons why such a modification would not be a predictable variation and why White would teach away from moving the external threads proximate to the septum/distal end face. First, Harding is not concerned with cleaning or aseptic sterilization of an access valve and consequently the location of the threads in Harding are not designed for such considerations. Second, one of ordinary skill in the art would find that White teaches away from moving the external threads to be proximate to the septum/end face for at least the face moving the external threads would result in a smaller area of the exterior surface of access valve being bathed in antiseptic. Thus, the outer surfaces of, i.e. 86 or 82, would no longer be kept in aseptic condition increasing the possibility of contamination and introduction of pathogens into the body of a patient. Since such a result is in direct conflict with the express teachings and purpose of

White's design, one of ordinary skill in the art would not be motivated to make such a modification to the location of the external threads.

17. Furthermore, even if the external threads are move to be proximate to the distalmost end face, White in view of Harding does not teach or suggest the claimed invention in present claim 9 because there is not teaching or suggestion that the thread engages the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads. Even if the external thread 76 of White was moved proximate to the distalmost end face 84 in view of Harding (which the examiner strongly believes White teaches directly away from doing), there is still no teaching or suggestion that any antiseptic solution will be provided to at least a portion of the external threads as claimed. Rather, the external threads 76 would still engage with corresponding threads 74, which would also have to be moved, to form a sealed engagment to maintain aseptic conditions. There is no teaching or suggestion that antiseptic from the sponge would contact the external threads in any manner and White arguably teaches away from such contact as that could threaten the threads ability to maintain an aseptic interconnection.

18. The IPR petition then turned to Genatempo (US 4440207) to teach that it is known to have a disinfecting cap that provides cleaning to both a connector end face and threads via an application of an antiseptic from a sponge. However, how Genatempo is structured and performs the cleaning of both a connector end face and

threads is vastly different from the septum and exterior surface of White's valve being bathed. Rather, Genatempo discloses a complete differently structured antiseptic cap where the cleaning pad is located near the open end and the thread is located opposed of the open end such that when the connector is inserted the outer surface of the connector having the external threads rub and come into contact with the antiseptic pad which performs a cleaning. Then after passing through the pad, then the external threads engage the thread of the housing of the antiseptic cap.

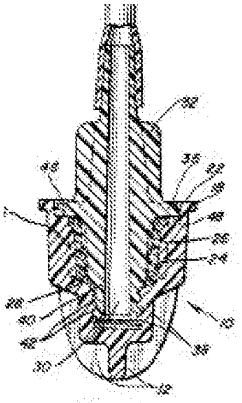


FIG. 3

19. Thus, Genatempo fails to teach or suggest that the thread engages the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads. Further, Genatempo fails to teach or suggest how an antiseptic contained in a sponge as taught by White would be able to contact the external thread of White by running on the exterior surface of White's access valve. Rather, Genatempo teaches that to clean an external thread the cleaning should occur prior to any engagement of the external

thread with a thread on the antiseptic cap since that threaded engagement prevents antiseptic from contacting the threads. Thus, the examiner finds that the present claims, including present claim 9, are allowable over the prior art of White, Harding, and Genatempo.

b. (ii) Menyhay and Genatempo in view of present claim 9

20. Regarding (ii), Menyhay (US 5554135) fails to teach or suggest, among other limitations, a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion or that the thread engages the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads.

21. As discussed above, Genatempo does not teach or suggest that the thread engages the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads and thus fix the missing limitations of Menyhay. Again, Genatempo is structured in a vastly different manner and the method Genatempo utilizes to apply antiseptic to the external threads is one where the threads come into contact with the wet pad prior to contacting any thread of the cap. Thus, even if Menyhay was modified to include a wet pad as taught by Genatempo instead of a dry pad, the resulting modification would not have the thread engaging the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end

face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads since the cleaning of the wet pad as taught by Genatempo occurs prior to any engagement of the thread and external threads. Thus, the examiner finds that the present claims, including present claim 9, are allowable over the prior art of Menyhay and Genatempo.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ANDREW GILBERT/
Primary Examiner, Art Unit 3763

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14159959	HOANG ET AL.
	Examiner	**Art Unit**
	ANDREW GILBERT	3763

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/23/2015	11/10/2015							
	1	✓	=							
	2	✓	=							
	3	✓	=							
	4	✓	=							
	5	✓	=							
	6	✓	=							
	7	✓	=							
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	14	✓	=							
	15	✓	=							
	16	✓	=							
	17	✓	=							
	18	✓	=							
	19	✓	=							
	20	✓	=							

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14159959	HOANG ET AL.
	Examiner	**Art Unit**
	ANDREW GILBERT	3763

CPC								
Symbol							**Type**	**Version**
A61M		39	/	162			F	2013-01-01
Y10T		137	/	4259			A	2015-04-01
A61M		39	/	02			I	2013-01-01
A61M		39	/	045			A	2013-01-01
A61M		39	/	16			I	2013-01-01
A61M		39	/	20			I	2013-01-01
A61M		2039	/	1033			A	2013-01-01
A61M		2039	/	1072			A	2013-01-01
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CPC Combination Sets								
Symbol							**Type**	**Set**	**Ranking**	**Version**
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			/							

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/ANDREW GILBERT/ Primary Examiner.Art Unit 3763	11/10/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	10A, 10B

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14159959	HOANG ET AL.
	Examiner	**Art Unit**
	ANDREW GILBERT	3763

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
		A	6	1	M	39 / 16 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/ANDREW GILBERT/ Primary Examiner.Art Unit 3763	11/10/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	10A, 10B

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	ANDREW GILBERT	3763

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 20	
/ANDREW GILBERT/ Primary Examiner.Art Unit 3763 (Primary Examiner)	11/10/2015 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 10A, 10B

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14159959	HOANG ET AL.
	Examiner	Art Unit
	ANDREW GILBERT	3763

CPC- SEARCHED		
Symbol	Date	Examiner
A61M39/16,162,165,02,20	11/10/2015	AG
A61M2039/1033,1072	11/10/2015	AG

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Updated EAST CPC class/subclass and keyword search done on 7/23/2015	11/10/2015	AG
Inventor Name search	11/10/2015	AG
Forward/backward citation searches	11/10/2015	AG
Updated search in related USPNs 8740864, 8491546	11/10/2015	AG
Interference search of PGPubs - see attached sheets	11/10/2015	AG

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	See above	11/10/2015	AG
	Interference search of PGPubs - see attached sheets	11/10/2015	AG

	/ANDREW GILBERT/ Primary Examiner.Art Unit 3763

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14159959
Filing Date	2014-01-21
First Named Inventor	Minh Quang Hoang
Art Unit	3763
Examiner Name	Andrew M. Gilbert
Attorney Docket Number	P-6836C1

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	1							☐

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AG/

Receipt date: 10/27/2015 14159959 - GAU: 3763

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Application Number	14159959
	Filing Date	2014-01-21
	First Named Inventor	Minh Quang Hoang
	Art Unit	3763
	Examiner Name	Andrew M. Gilbert
	Attorney Docket Number	P-6836C1

	1	"Corrected Petition for Inter Partes Review Under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42,100 et seq.," USPTO, Patent Trial and Appeal Board, Excelsior Medical Corporation v. Becton, Dickinson and Company, Case IPR2014-00880, Patent No. 8,740,864, pp. 1-48, June 23, 2014.	☐
	2	"Patent Owner's Preliminary Response Under 37 C.F.R. § 42,10," USPTO, Patent Trial and Appeal Board, Excelsior Medical Corporation v. Becton, Dickinson and Company, Case IPR2014-00880, Patent No. 8,740,864, pp. 1-30, September 16, 2014.	☐
	3	"Decision, Institution of Inter Partes Review, 37 C.F.R. § 42,108," USPTO, Patent Trial and Appeal Board, Excelsior Medical Corporation v. Becton, Dickinson and Company, Case IPR2014-00880, Patent No. 8,740,864, pp. 1-21, November 25, 2014.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/ANDREW GILBERT/	Date Considered	11/10/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AG/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	14159959
Filing Date	2014-01-21
First Named Inventor	Minh Quang Hoang
Art Unit	3763
Examiner Name	Andrew M. Gilbert
Attorney Docket Number	P-6836C1

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Craig Metcalf/	Date (YYYY-MM-DD)	2015-10-27
Name/Print	Craig Metcalf	Registration Number	31398

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AG/

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AG/

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	56	((MINH) near2 (HOANG)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:29
S2	16	((JONATHAN) near2 (BURKHOLZ)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:30
S3	2	"US 20070112333"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2009/11/20 13:30
S4	0	("2007/0112333").URPN.	USPAT	OR	ON	2009/11/20 13:30
S5	1	2007-373158.NRAN.	DERWENT	OR	ON	2009/11/20 13:31
S6	9	("20060024372" | "5763412" | "6617294" | "6299610" | "6350251" | "6482197" | "6592564" | "6679870" | "6685694").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:51
S7	803	(604/533).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
S8	766	(604/265).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
S9	124	(604/267).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 13:53
S10	237	(S7 S8 S9) and (antiseptic$4 clean$4 antimicrobial antibacterial) and valve	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:54
S11	107	S10 and connector	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:55
S12	16	S10 and pad	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 13:55
S13	32	("20020066702" | "20020091424" | "20020123787" | "20020193752" | "20040116845" | "20050038376" | "20050038376" | "20050095351" | "20050256500" | "4765588" | "5251873" | "5260020" | "5295657" | "5295658" | "5312813" | "5342316" | "5441487" | "5474544" | "5501426" | "5533708" | "5549651" | "5957898" | "6171287" | "6261282" | "6282444" | "6344033" | "6428491" | "6562295" | "6595964" | "6651956" | "6669681" | "6866656" | "6908459").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:01

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S17	50	("5531341" "4326569" "5203771" "20070112333" "20070176117" "6027492" "4375849" "4867309" "5913631" "6245056" "20030233074" "5401239" "5505695" "6206854" "4293898" "4324516" "4368737" "4368730" "4384590" "4392326" "4405313" "4407429" "4417888" "4453636" "4465200" "4484595" "4496349" "4503560" "4513888" "4537273" "4538564" "4546944" "4602654" "4763648" "4801029" "4846191" "4847597" "4920970" "4923059" "4957484" "4974280" "4981140" "4981230" "4988073" "5016799" "5018794" "5193525" "5202849" "5218736" "5267968").pn.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:08
S18	62	(S13 S15 S16 S17) and (antiseptic$4 clean$4 antimicrobial antibacterial steriliz$4)	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/20 14:11
S19	13	((("4354490") or ("4432764") or ("4440207") or ("4655762") or ("4778447") or ("5554135") or ("5334388") or ("5792120") or ("6045539") or ("20070202177") or ("20080027399") or ("20080177250") or ("20090149819")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/20 14:27
S20	23	("20050124970" | "20080038167" | "3987930" | "4354490" | "4440207" | "4450624" | "4778447" | "4838875" | "5951519" | "6045539").PN. ("2351804" | "4402691" | "5792120").PN. ("20020093192" | "20040201216" | "20050266714" | "20080132880" | "4324239").PN. ("20020093192" | "20040201216" | "20050266714" | "20080105704" | "20080132880" | "20080235888" | "4324239" | "7040598" | "7316669").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 09:35
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S26	3	("4417890" | "4440207" | "5620424").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:11
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S32	24	("2636644" | "2727516" | "4022206" | "4417890" | "4431424" | "4432764" | "4432766" | "4439188" | "4440207" | "4551146" | "4588402" | "4624664" | "4642091" | "4738668" | "4778447" | "4983161" | "5053003").PN. OR ("5195957").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:34
S33	11	("3986508" | "4511359" | "4610469" | "4878516" | "5190534" | "5195957" | "5334188" | "5423775" | "5792120").PN. OR ("6911025").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:42
S34	28	("20010016962" | "20030060781" | "20040021000" | "20050124970" | "20060030827" | "3971376" | "4301567" | "4624664" | "5048547" | "5375589" | "6045539" | "6086275" | "6450810" | "6602219" | "6673031" | "6813797" | "6813798" | "7198611" | "D176310" | "D214555" | "D258762" | "D305261" | "D325443" | "D527461" | "RE39499").PN. OR ("D596308").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:48
S35	8	("D176310").URPN.	USPAT	OR	ON	2010/06/08 10:48
S36	17	("1951099" | "1994206" | "2088658" | "2471303" | "2501193" | "3984656" | "D176310").PN. OR ("D296239").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 10:50
S37	40	("3502097" | "4346703" | "4417890" | "4440207" | "4559043" | "4610469" | "4752292" | "4781693" | "4919658" | "5139483").PN. OR ("5242425").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 11:06
S38	22	(("7452349") or ("7083605") or ("6911025") or ("4624664") or ("5195957") or ("7682561") or ("4432764") or ("20030153865") or ("7198611") or ("6994315") or ("2961682") or ("4282891") or ("4671306") or ("4778447") or ("20050124970") or ("20060030827") or ("20070225660") or ("5242425") or ("5694978") or ("6708363") or ("20040258560")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/06/08 11:20
S39	0	S38 and chlorohexidine	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:18
S40	1	S38 and chlorhexidine	US-PGPUB;	OR	ON	2010/06/08

			USPAT; USOCR			12:19
S41	0	S38 and (diacetate gluconate)	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S42	6	S38 and (polyethlyene polypropylene)	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S43	2	S38 and polyester	US-PGPUB; USPAT; USOCR	OR	ON	2010/06/08 12:19
S44	69	("2961682" | "20030153865" | "20040258560" | "20050124970" | "20060030827" | "20070202177" | "20070225660" | "20080027399" | "20080177250" | "20090149819" | "4282891" | "4354490" | "4432764" | "4440207" | "4624664" | "4655762" | "4671306" | "4778447" | "5195957" | "5242425" | "5334388" | "5554135" | "5694978" | "5792120" | "6045539" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561").PN.	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2010/09/09 10:00
S45	11	("2007/0112333").URPN.	USPAT	OR	ON	2012/04/04 15:07
S46	22	("2961682" | "20030153865" | "20040258560" | "20050124970" | "20060030827" | "20070225660" | "4282891" | "4432764" | "4624664" | "4671306" | "4778447" | "5195957" | "5242425" | "5694978" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:24
S47	88	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:35

		7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$).did. or (US-2961682-$).did.				
S48	7	S47 and (sponge polyurethane polyester cotton silicone) and alcohol with solution and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:36
S49	7	(S46 S47) and (sponge polyurethane polyester cotton silicone) and alcohol with solution and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:36
S50	14	(S46 S47) and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:41
S51	7	S50 not S49	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/04 15:41
S52	22	("2961682" | "20030153865" | "20040258560" | "20050124970" | "20060030827" | "20070225660" | "4282891" | "4432764" | "4624664" | "4671306" | "4778447" | "5195957" | "5242425" | "5694978" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34
S53	88	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34

		4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$).did. or (US-2961682-$).did.				
S54	14	(S52 S53) and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:34
S55	22	("2961682" | "20030153865" | "20040258560" | "20050124970" | "20060030827" | "20070225660" | "4282891" | "4432764" | "4624664" | "4671306" | "4778447" | "5195957" | "5242425" | "5694978" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:35
S56	160	medical and connector and (sponge polyurethane polyester cotton silicone) and alcohol and (chlorhexidine with gluconate chlorhexidine with diacetate)	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:44
S57	26	("20010016589" | "20020144705" | "20030072781" | "20030162839" | "20040039349" | "20060165751" | "20060239954" | "20080075761" | "20080182921" | "4584192" | "4716032" | "4915934" | "4925668" | "5023082" | "5512199" | "5547662" | "5616338" | "5861440" | "6051609" | "6337357" | "6413539" | "6488942" | "6846846" | "6861060" | "7198800" | "7268165").PN. OR ("7704935").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/04/05 10:55
S58	3	(("4440207") or ("4778447") or ("5242425")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/04/05 11:01
S59	22	("2007/0112333").URPN.	USPAT	OR	ON	2012/09/19 13:58
S60	1	("5554135").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/19 14:25

S61	24	("4335756" | "4402691" | "4432766" | "4440207" | "4507111" | "5190534" | "D342134").PN. OR ("5554135").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/09/19 14:25
S62	3	(("5554135") or ("20040004019") or ("4778447")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/15 10:30
S63	65	("7780794" | "D607325" | "20070167910" | "7731679" | "7776011" | "20070249996" | "4432764" | "4728321" | "4983161" | "7431712" | "7922701" | "5554135" | "20070282280" | "7749189" | "4243035" | "4440207" | "20070112333" | "4507111" | "7753891" | "3977401" | "5827244" | "6045539" | "4402691" | "20090012426" | "20040258560" | "20050147524" | "4778447" | "20050013836" | "4335756" | "4432766" | "20090093757" | "7635344" | "7799010" | "7857793" | "4417890" | "4957637" | "20050203460" | "4624664" | "20070265578" | "6126640" | "20060030827" | "20100160894" | "4703762" | "4811847" | "5989229" | "6116468" | "0877946" | "4439184" | "20070249966" | "7731678" | "7763006" | "3270743" | "5954957" | "5820604" | "20050065479" | "4317446" | "20090099529" | "5190534" | "5792120" | "4041934" | "4799926" | "20110290799" | "4989733").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/15 10:49
S64	8	"US 8167847"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/01/15 10:49
S65	1	("4440207").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/15 11:48
S66	32	("2007/0112333").URPN.	USPAT	OR	ON	2013/08/07 15:27
S67	1	("20060048313").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 15:37
S68	8	("4624664").PN. ("20050013836" | "4317446" | "4440207" | "5827244" | "6045539" | "0877946").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:40
S69	15	("20050124970" | "20080038167" | "3987930" | "4354490" | "4440207" | "4450624" | "4778447" | "4838875" | "5951519" | "6045539").PN. ("2351804" | "4402691" | "5792120").PN. ("4346703").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:49
S70	2	"US 20080177250"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/07 15:50
S71	3	("20050065479" | "4440207" | "4989733").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 15:58
S72	4	("20020168530" | "20080107564" | "20090137969" | "20090297400").PN.	US-PGPUB; USPAT;	OR	ON	2013/08/07 15:59

			USOCR			
S73	2	("20030217423" | "20060030827").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:06
S74	12	("20050038397" | "20080132880" | "20080190485" | "20100063482" | "5439451" | "5492147" | "5536258" | "5738663" | "6932795" | "7014169" | "7762524" | "7922701").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:08
S75	2	(("4402691") or ("4440207")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 16:10
S76	3	("20070112333" | "20100172794" | "5554135").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:16
S77	3	("20110054440" | "4667837" | "7762988").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:17
S78	0	("8491546").URPN.	USPAT	OR	ON	2013/08/07 16:19
S79	4	("20100047123" | "20100049170" | "20120039765" | "4444310" | "4626664" | "5547662" | "5706944").PN.	USPAT	OR	ON	2013/08/07 16:20
S80	7	("20100047123" | "20100049170" | "20120039765" | "4444310" | "4626664" | "5547662" | "5706944").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:21
S81	124	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$ or US-20040004019-$).did. or (US-20060039742-$ or US-20080021392-$ or US-20080021381-$ or US-20080107564-$ or US-20090024096-$ or US-20090041619-$ or US-20090297400-$ or US-20100049170-$ or US-20100047123-$ or US-20100064456-$ or US-20100100056-$ or US-20100242993-$ or US-20100286637-$ or US-20100292673-$ or US-20100296968-$ or US-20110054440-$ or US-20110150958-$ or US-20110184382-$ or US-20110236258-$ or US-20110314619-$ or US-20120039765-$ or US-20010016589-$ or US-20030162839-$ or US-20080075761-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/07 16:22

		4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$ or US-7704935-$ or US-7866907-$ or US-8113731-$ or US-6488942-$ or US-6846846-$ or US-8167847-$ or US-8206514-$ or US-8252247-$ or US-8388894-$).did. or (US-2961682-$ or US-0877946-$).did. or (US-20080086091-$).did.				
S82	66	S81 and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:22
S83	56	("2436291" | "2596725" | "2629124" | "2673362" | "2713693" | "2722719" | "2774093" | "3316922" | "3369553" | "3375538" | "4117566").PN. OR ("4282891").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:23
S84	87	("3396727" | "4232677" | "4273247" | "4306976" | "4340052" | "4354490" | "4403992").PN. OR ("4440207").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:29
S85	46	("4346703" | "4417890" | "4431424" | "4432764" | "4439188" | "4440207" | "4551146").PN. OR ("4624664").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:32
S86	83	("3502097" | "4346703" | "4417890" | "4440207" | "4559043" | "4610469" | "4752292" | "4781693" | "4919658" | "5139483").PN. OR ("5242425").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:35
S87	44	("3557989" | "3595419" | "3612320" | "3715063" | "3973690" | "4019646" | "4210251" | "4394923" | "4597758" | "5014869" | "5060813").PN. OR ("5694978").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:37
S88	8	("6446659" | "4874377" | "RE33971" | "5122123" | "5733503" | "5139483" | "5047021" | "4614514").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:47
S89	1	("4610469").PN.	US-PGPUB; USPAT;	OR	OFF	2013/08/07 16:51

			USOCR			
S90	195	("3986508" | "4022205" | "4030494" | "4143853" | "4161949" | "4334551" | "4431424" | "4508367" | "4511359").PN. OR ("4610469").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:52
S91	60	("1152286" | "1282679" | "20030105452" | "20030153865" | "20030229312" | "20040215170" | "20050017380" | "20060270990" | "20070106205" | "20080095680" | "2582109" | "3160327" | "3458080" | "4334551" | "4346703" | "4432764" | "4440207" | "4551146" | "4573983" | "4624664" | "4642091" | "4810241" | "4919658" | "4921491" | "4983161" | "5053003" | "5056464" | "5195957" | "5301849" | "5332113" | "5435358" | "5531810" | "5536258" | "5554135" | "5792120" | "5875942" | "5894015" | "5921425" | "5971965" | "6045539" | "6113068" | "6207201" | "6299131" | "6648158" | "6706022" | "6732876" | "6875205" | "7100890" | "7198611" | "7232419").PN. OR ("7682561").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:53
S92	270	(S83 S84 S85 S86 S87 S90 S91) and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 16:54
S93	1774	(fluid and valve and (medical patient) and thread and (pad sponge foam swab) and (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:39
S94	6	(fluid and valve and (medical patient) and (thread threading) same (pad sponge foam swab) with (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:40
S95	121	((cap cover) and (thread threading) same (pad sponge foam swab) with (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:42
S96	23	((medical patient user) with (port valve connector connection) and (thread threading) same (pad sponge foam swab) with (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:45
S97	109	((medical patient user) with (port valve connector connection) same (thread threading) same (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2013/08/07 19:46

			IBM_TDB			
S98	42	((medical patient user) same (cap cover) same (thread threading) same (clean$3 steriliz$3 disinfect$3) with (solution liquid)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:49
S99	1011	((medical patient user) same (cap cover) same (clean$3 steriliz$3 disinfect$3) with (solution liquid)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:49
S100	103	((medical patient user) same (cap cover) same (clean$3 steriliz$3 disinfect$3) with (solution liquid) with (pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:50
S101	125	(valve and (cap cover) same (clean$3 steriliz$3 disinfect$3) with (solution liquid) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:51
S102	99	S101 not S100	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:51
S103	129	((fluid patient) with (line tube tubing) with (valve port connector luer) and (cap cover) same (clean$3 steriliz$3 disinfect$3) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:53
S104	0	(luer near3 (clean$3 steriliz$3 disinfect$3) with (swab pad foam sponge)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:56
S105	49	(luer near3 (clean$3 steriliz$3 disinfect$3)) and @ad<="20051117"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2013/08/07 19:56
S106	12	(("4232677") or ("4610469") or ("4624664") or ("4440207") or ("4432764") or ("4778447") or ("5242425") or ("5694978") or	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/07 20:33

		("6911025") or ("20060030827") or ("5554135") or ("20040004019")).PN.				
S107	18	("20040004019" | "20050124970" | "4440207" | "4626664" | "4778447" | "5242425" | "5547662" | "5706944" | "6911025" | "6994315").PN. ("4444310" | "5554135").PN. ("20080177250" | "20090062766" | "20090149819" | "20100047123" | "20100049170" | "20120039765").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/07 20:45
S109	1148	(604/533).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S110	156	(604/534).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S111	312	(604/535).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S112	45	(604/536).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S113	337	(604/537).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:38
S114	190	(15/104.03).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:40
S115	797	(15/104.04).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:41
S116	398	(15/104.062).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:41
S117	493	(15/104.92).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S118	941	(15/104.93).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S119	917	(15/104.94).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:43
S120	2913	(422/28).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 14:46
S121	2	(("4440207") or ("5242425")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/08/08 15:15
S122	128	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2013/08/08 20:13

		US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$ or US-20040004019-$).did. or (US-20060039742-$ or US-20080021392-$ or US-20080021381-$ or US-20080107564-$ or US-20090024096-$ or US-20090041619-$ or US-20090297400-$ or US-20100049170-$ or US-20100047123-$ or US-20100064456-$ or US-20100100056-$ or US-20100242993-$ or US-20100286637-$ or US-20100292673-$ or US-20100296968-$ or US-20110054440-$ or US-20110150958-$ or US-20110184382-$ or US-20110236258-$ or US-20110314619-$ or US-20120039765-$ or US-20010016589-$ or US-20030162839-$ or US-20080075761-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$ or US-7704935-$ or US-7866907-$ or US-8113731-$ or US-6488942-$ or US-6846846-$ or US-8167847-$ or US-8206514-$ or US-8252247-$ or US-8388894-$ or US-4610469-$ or US-3595419-$ or US-4800904-$ or US-7857793-$).did. or (US-2961682-$ or US-0877946-$).did. or (US-20080086091-$).did.				
S124	0	S122 and (partial half) near2 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14

S125	0	S122 and (partial half quarter length) near2 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14
S126	6	S122 and (partial half quarter length) with thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:14
S127	2605	(cap connector) with (partial half quarter length) near3 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:16
S128	918	(cap connector) with (partial half quarter) near3 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:16
S129	68	valve same (cap connector) with (partial half quarter) near3 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:17
S130	6	medical and valve same (cap connector) with (partial half quarter) near3 thread$3	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:17
S131	9	valve same (cap connector) with (partial half quarter) near3 thread$3 with inner	US-PGPUB; USPAT; USOCR	OR	ON	2013/08/08 20:22
S132	5	("20040004019" | "4440207" | "4778447" | "5242425" | "6117114").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 10:31
S133	7	("20050147524" | "4280632" | "4671306" | "4991629" | "5954957" | "6116468" | "6227391").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 10:32
S134	129	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$ or US-20040004019-$).did. or (US-20060039742-$ or US-20080021392-$ or US-20080021381-$ or US-20080107564-$ or US-20090024096-$ or US-20090041619-$ or US-20090297400-$ or US-20100049170-$ or US-20100047123-$ or US-20100064456-$ or US-20100100056-$ or US-20100242993-$ or US-20100286637-$ or US-20100292673-$ or US-20100296968-$ or US-20110054440-$ or US-20110150958-$ or US-20110184382-$ or US-20110236258-$ or US-20110314619-$ or US-20120039765-$ or US-20010016589-$ or US-20030162839-$ or US-20080075761-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2014/01/13 10:34

		5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$ or US-7704935-$ or US-7866907-$ or US-8113731-$ or US-6488942-$ or US-6846846-$ or US-8167847-$ or US-8206514-$ or US-8252247-$ or US-8388894-$ or US-4610469-$ or US-3595419-$ or US-4800904-$ or US-7857793-$ or US-6117114-$).did. or (US-2961682-$ or US-0877946-$).did. or (US-20080086091-$).did.				
S135	22	(US-20070225660-$ or US-20060030827-$ or US-20050124970-$ or US-20040258560-$ or US-20030153865-$).did. or (US-7682561-$ or US-7452349-$ or US-7198611-$ or US-7083605-$ or US-6994315-$ or US-6911025-$ or US-6708363-$ or US-5694978-$ or US-5242425-$ or US-5195957-$ or US-4778447-$ or US-4671306-$ or US-4624664-$ or US-4432764-$ or US-4282891-$ or US-2961682-$).did. or (US-2961682-$).did.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 10:34
S136	1	("8491546").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/01/13 13:08
S137	0	(fluid and (set line tube tubing) and valve and septum and threads and internal and external and (pad sponge foam) and (clean$4 disinfect$4 steriliz$3)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:16
S138	1	(fluid and (set line tube tubing) and valve and septum and threads and (pad sponge foam) and (clean$4 disinfect$4 steriliz$3)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:16
S139	1	(fluid and (set line tube tubing) and valve and septum and threads and (pad sponge foam)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:16

S140	1	((fluid medical infusion infusing liquid medicament drug) and (set line tube tubing) and valve and septum and threads and (pad sponge foam)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:17
S141	2	((fluid medical infusion infusing liquid medicament drug) and (set line tube tubing) and valve and septum and threads and (clean$4 steriliz$4 disinfect$4)).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2014/01/13 13:17
S142	2	"US 20140135710"	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2015/07/22 22:44
S143	101	((Minh) near2 (Hoang)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:45
S144	63	((Jonathan) near2 (Burkholz)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:45
S145	117	("20020144705" | "20050147525" | "20080033371" | "20100049170" | "20100050351" | "20110290799" | "4444310" | "4778447" | "4915934" | "5620424" | "5641464" | "5817344" | "5954957" | "7198611" | "7268165" | "7922701" | "8167847" | "20100204648" | "20030072781" | "20040039349" | "20050147524" | "20080147047" | "20120016318" | "20120283693" | "5195957" | "5334388" | "5686096" | "6116468" | "6413539" | "7083605" | "7828186" | "20070225660" | "20090062766" | "20120216360" | "4282891" | "4584192" | "4991629" | "5547662" | "5639310" | "5706944" | "5792120" | "6337357" | "7282186" | "7452349" | "7704935" | "8162899" | "20090028750" | "20090149819" | "4626664" | "4655762" | "4716032" | "4925668" | "5554135" | "6051609" | "6488942" | "20010016589" | "20040004019" | "20060030827" | "20070112333" | "20080027399" | "20090008393" | "20100047123" | "2961682" | "4432764" | "4440207" | "5861440" | "6117114" | "6846846" | "6861060" | "7198800" | "20100172794" | "20040258560" | "20050124970" | "20080177250" | "4417890" | "4989733" | "5335373" | "5616338" | "5694978" | "6045539" | "6708363" | "6994315" | "8065773" | "8491546" | "20070282280" | "20100292673" | "5989229" | "5743884" | "20060165751" | "20060239954" | "20070202177" | "20080075761" | "20080095680" | "20100000040" | "4354490" | "4624664" | "5023082" | "5242425" | "5512199" | "5554106" | "5722537" | "6227391" | "6911025" | "8113731" | "5702017" | "6196998" | "6523686" | "20030162839" | "20080182921" | "20110150958" |	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:45

		"20120039765" | "4280632" | "4671306" | "5569207" | "7682561" | "RE38145").PN.				
S146	130	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$ or US-20040004019-$).did. or (US-20060039742-$ or US-20080021392-$ or US-20080021381-$ or US-20080107564-$ or US-20090024096-$ or US-20090041619-$ or US-20090297400-$ or US-20100049170-$ or US-20100047123-$ or US-20100064456-$ or US-20100100056-$ or US-20100242993-$ or US-20100286637-$ or US-20100292673-$ or US-20100296968-$ or US-20110054440-$ or US-20110150958-$ or US-20110184382-$ or US-20110236258-$ or US-20110314619-$ or US-20120039765-$ or US-20010016589-$ or US-20030162839-$ or US-20080075761-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2015/07/22 22:45

		7704935-$ or US-7866907-$ or US-8113731-$ or US-6488942-$ or US-6846846-$ or US-8167847-$ or US-8206514-$ or US-8252247-$ or US-8388894-$ or US-4610469-$ or US-3595419-$ or US-4800904-$ or US-7857793-$ or US-6117114-$ or US-8491546-$).did. or (US-2961682-$ or US-0877946-$).did. or (US-20080086091-$).did.				
S147	2	(("8740864") or ("8491546")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/22 22:45
S148	54	("20040004019" | "20050124970" | "20060030827" | "20070112333" | "20070202177" | "20070225660" | "20080027399" | "20080147047" | "20080177250" | "20090028750" | "20090062766" | "20090149819" | "20090175759" | "20100047123" | "20100049170" | "20120039765" | "2961682" | "4282891" | "4354490" | "4432764" | "4440207" | "4444310" | "4624664" | "4626664" | "4655762" | "4671306" | "4778447" | "5195957" | "5242425" | "5334388" | "5547662" | "5554135" | "5639310" | "5641464" | "5694978" | "5706944" | "5722537" | "5792120" | "5817344" | "6045539" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7282186" | "7452349" | "7704935" | "7828186" | "7922701" | "8065773" | "8113731").PN. OR ("8491546").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:47
S149	0	("8740864").URPN.	USPAT	OR	ON	2015/07/22 22:47
S150	57	("20030153865" | "20040004019" | "20040258560" | "20050124970" | "20050147524" | "20060030827" | "20070202177" | "20070225660" | "20080027399" | "20080147047" | "20080177250" | "20090028750" | "20090062766" | "20090149819" | "20100047123" | "20100049170" | "20120039765" | "2961682" | "4280632" | "4282891" | "4354490" | "4432764" | "4440207" | "4444310" | "4624664" | "4626664" | "4655762" | "4671306" | "4778447" | "4991629" | "5195957" | "5242425" | "5334388" | "5547662" | "5554135" | "5639310" | "5694978" | "5706944" | "5792120" | "5817344" | "5954957" | "6045539" | "6116468" | "6117114" | "6227391" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561" | "7704935" | "7922701" | "8065773" | "8113731").PN. OR ("8740864").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:47
S151	10	S150 not S148	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:47
S152	259	A61M39/16.cpc.	US-PGPUB;	OR	ON	2015/07/22

			USPAT; USOCR			22:51
S153	226	A61M39/162.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:51
S154	161	A61M39/165.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:51
S155	550	A61M39/02.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:51
S156	468	A61M39/20.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:52
S157	547	A61M2039/1033.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:52
S158	341	A61M2039/1072.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:52
S159	533	(S152 S153 S154)	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:52
S160	63	S153 and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:52
S161	183	(S152 S153 S154) and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:53
S162	795	(S152 S153 S154 S155 S156 S157 S158) and @ad<="20051117"	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:53
S163	44	("20040004019" | "4440207" | "4778447" | "5242425" | "6117114").PN. ("5554135").PN. ("20040004019" | "20080147047" | "20090028750" | "20090062766" | "4440207" | "4778447" | "5242425" | "5639310" | "5817344" | "7704935" | "7922701" | "8065773" | "8113731").PN. ("20070202177" | "20080027399" | "20080177250" | "20090149819" | "4354490" | "4432764" | "4440207" | "4655762" | "4778447" | "5334388" | "5554135" | "5792120" | "6045539").PN. ("2961682" | "20030153865" | "20040258560" | "20050124970" | "20060030827" | "20070225660" | "4282891" | "4432764" | "4624664" | "4671306" | "4778447" | "5195957" | "5242425" | "5694978" | "6708363" | "6911025" | "6994315" | "7083605" | "7198611" | "7452349" | "7682561").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/22 22:54
S164	0	("2014/0135710").URPN.	USPAT	OR	ON	2015/07/23 08:20
S165	1	2014-M07698.NRAN.	DERWENT	OR	ON	2015/07/23 08:20
S166	2	"US 20140135711"	US-PGPUB; USPAT;	OR	ON	2015/07/23 08:31

			USOCR; DERWENT			
S167	0	("2014/0135711").URPN.	USPAT	OR	ON	2015/07/23 08:31
S168	6	(("5242425") or ("20030109853") or ("4440207") or ("6117114") or ("20040004019") or ("5554135")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/23 10:24
S170	0	(("(20030109853" | "20040004019" | "20080019889" | "20080086091" | "20090028756" | "20090062766" | "4432764" | "4440207" | "4778447" | "5242425" | "5554135" | "8491546" | "8740864").PN.").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/23 21:27
S171	13	("20030109853" | "20040004019" | "20080019889" | "20080086091" | "20090028756" | "20090062766" | "4432764" | "4440207" | "4778447" | "5242425" | "5554135" | "8491546" | "8740864").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/23 21:27
S172	1	("8740864").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/24 14:17
S173	105	((MINH) near2 (HOANG)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/11/10 22:14
S174	74	((JONATHAN) near2 (BURKHOLZ)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/11/10 22:14
S175	1	("8740864").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/11/10 22:15
S176	0	("8740864").URPN.	USPAT	OR	ON	2015/11/10 22:15
S177	13	("20030109853" | "20040004019" | "20080019889" | "20080086091" | "20090028756" | "20090062766" | "4432764" | "4440207" | "4778447" | "5242425" | "5554135" | "8491546" | "8740864").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/11/10 22:15
S178	6	(("5242425") or ("20030109853") or ("4440207") or ("6117114") or ("20040004019") or ("5554135")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/11/10 22:15
S179	132	(US-20070112333-$ or US-20020123440-$ or US-20070202177-$ or US-20080027399-$ or US-20080177250-$ or US-20090149819-$ or US-20050222542-$ or US-20070176117-$ or US-20050124970-$ or US-20080038167-$ or US-20080132880-$ or US-20080235888-$ or US-20060048313-$ or US-20070225660-$ or US-20070093762-$ or US-20080086091-$ or US-20090008393-$ or US-20080095680-$ or US-20090028750-$ or US-20090062766-$ or US-20080147047-$ or US-20060030827-$ or US-20030153865-$ or US-20040258560-$ or US-20050147524-$ or US-20040004019-$).did. or (US-20060039742-$ or US-20080021392-$ or US-20080021381-$ or US-20080107564-$	US-PGPUB; USPAT; USOCR; DERWENT	OR	ON	2015/11/10 22:15

		or US-20090024096-$ or US-20090041619-$ or US-20090297400-$ or US-20100049170-$ or US-20100047123-$ or US-20100064456-$ or US-20100100056-$ or US-20100242993-$ or US-20100286637-$ or US-20100292673-$ or US-20100296968-$ or US-20110054440-$ or US-20110150958-$ or US-20110184382-$ or US-20110236258-$ or US-20110314619-$ or US-20120039765-$ or US-20010016589-$ or US-20030162839-$ or US-20080075761-$ or US-20140135711-$).did. or (US-5334388-$ or US-5439681-$ or US-5512199-$ or US-5547662-$ or US-5706944-$ or US-5817344-$ or US-6723689-$ or US-4655762-$ or US-5607683-$ or US-6651956-$ or US-4232677-$ or US-6089541-$ or US-4354490-$ or US-4402691-$ or US-4432764-$ or US-4440207-$ or US-4778447-$ or US-5554135-$ or US-5792120-$ or US-6045539-$ or US-6171287-$ or US-4243035-$ or US-5433705-$ or US-0877946-$ or US-7198611-$ or US-4417890-$).did. or (US-7682561-$ or US-6994315-$ or US-4624664-$ or US-4431424-$ or US-4439188-$ or US-5195957-$ or US-2636644-$ or US-4022206-$ or US-4432766-$ or US-4738668-$ or US-6911025-$ or US-7083605-$ or US-7452349-$ or US-7232419-$ or US-D596308-$ or US-4301567-$ or US-6813797-$ or US-7704002-$ or US-6207201-$ or US-4282891-$ or US-4671306-$ or US-5274874-$ or US-5639310-$ or US-5694978-$ or US-6708363-$ or US-5242425-$ or US-5989229-$).did. or (US-7763006-$ or US-7780794-$ or US-7794675-$ or US-7799010-$ or US-7922701-$ or US-7972322-$ or US-7985302-$ or US-8065773-$ or US-8069523-$ or US-7704935-$ or US-7866907-$ or US-8113731-$ or US-6488942-$ or US-6846846-$ or US-8167847-$ or US-8206514-$ or US-8252247-$ or US-8388894-$ or US-4610469-$ or US-3595419-$ or US-4800904-$ or US-7857793-$ or US-6117114-$ or US-8491546-$ or US-8740864-$).did. or (US-2961682-$ or US-0877946-$).did. or (US-20080086091-$).did.				
S180	6	(("5242425") or ("20030109853") or ("4440207") or ("6117114") or ("20040004019") or ("5554135")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/11/10 22:16
S181	4	(valve and wet near2 pad and thread$3 and housing and lid).clm.	US-PGPUB; USPAT; USOCR	OR	ON	2015/11/10 22:16

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	5	(valve and (clean$3 asceptic steriliz$3) near2 pad and thread$3 and housing and lid).clm.	US-PGPUB; USPAT	OR	ON	2015/11/10 22:21
L3	28	(valve and (clean$3 asceptic steriliz$3) and thread$3 and housing and lid).clm.	US-PGPUB; USPAT	OR	ON	2015/11/10 22:21
L4	24	(cavity and (clean$3 asceptic steriliz$3) and thread$3 and housing and lid).clm.	US-PGPUB; USPAT	OR	ON	2015/11/10 22:21
L5	4	(cavity and (clean$3 asceptic steriliz$3) and thread$3 and housing and end and face and lid).clm.	US-PGPUB; USPAT	OR	ON	2015/11/10 22:22
S182	4	(valve and wet near2 pad and thread$3 and housing and lid).clm.	US-PGPUB; USPAT	OR	ON	2015/11/10 22:16

11/ 10/ 2015 10:22:16 PM
C:\ Users\ agilbert\ Documents\ EAST\ Workspaces\ Workspaces\ 14159959.wsp

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

71562 7590 11/17/2015
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Craig Metcalf	(Depositor's name)
	(Signature)
February 3, 2016	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/159,959	01/21/2014	Minh Quang Hoang	P-6836C1	1050

TITLE OF INVENTION: PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	02/17/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
GILBERT, ANDREW M	3763	604-533000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Jeanne Lukasavage
2 Craig Metcalf
3 Kirton McConkie

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Becton, Dickinson and Company
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Franklin Lakes, New Jersey

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☒ Advance Order - # of Copies 2

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 50-0843 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature [signature] Date 2/3/16
Typed or printed name Craig Metcalf Registration No. 31,398

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	14159959
Filing Date:	21-Jan-2014
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Filer:	Lloyd Craig Metcalf/Kris Haley
Attorney Docket Number:	P-6836C1

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
Printed Copy of Patent - No Color	8001	2	3	6
		Total in USD ($)		**966**

Electronic Acknowledgement Receipt

EFS ID:	24815176
Application Number:	14159959
International Application Number:	
Confirmation Number:	1050
Title of Invention:	PATIENT FLUID LINE ACCESS VALVE ANTIMICROBIAL CAP/CLEANER
First Named Inventor/Applicant Name:	Minh Quang Hoang
Customer Number:	71562
Filer:	Lloyd Craig Metcalf/Kris Haley
Filer Authorized By:	Lloyd Craig Metcalf
Attorney Docket Number:	P-6836C1
Receipt Date:	03-FEB-2016
Filing Date:	21-JAN-2014
Time Stamp:	19:11:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$966
RAM confirmation Number	5458
Deposit Account	500843
Authorized User	METCALF, L CRAIG

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 CFR 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 CFR 1.19 (Document supply fees)

Charge any Additional Fees required under 37 CFR 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	P_6836C1_IssueFeeTrans_020316.pdf	1118879 a1dbfc7425d2f5dd763c9615b410fdab01d9f8ea	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32250 6c1df001886a28808a8f5b34439d9b12dc555e3b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1151129		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/159,959	03/15/2016	9283367	P-6836C1	1050

71562 7590 02/24/2016

David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Kirton & McConkie)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 129 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Becton, Dickinson and Company, Franklin Lakes, NJ;
Minh Quang Hoang, Sandy, UT;
Jonathan Karl Burkholz, Salt Lake City, UT;

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