

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BAXTER INTERNATIONAL INC.,  
Petitioner,

v.

BECTON, DICKINSON AND COMPANY,  
Patent Owner.

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Case IPR2020-00025  
Patent 9,283,367

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**DECLARATION OF MICHAEL PLISHKA**

I, Michael Plishka, submit this report on behalf of Patent Owner Becton, Dickinson And Company (“Patent Owner”) in the matter of *Inter Partes* Review of U.S. Patent No. 9,283,367 (the “’367 patent”), No. IPR2020-00025, challenging claims 1-20 (the “Challenged Claims”). I make this declaration based on personal knowledge and I am competent to testify about the matters set forth herein.

## **I. INTRODUCTION**

### **A. Engagement**

1. I have been retained on behalf of Patent Owner to consider the allegations made by Petitioner Baxter International Inc. (“Petitioner”) in the Petition for the *Inter Partes Review* of the ’367 patent (“Petition”) and the asserted prior art. My opinions are set forth below.

2. I am being compensated at the rate of \$400 per hour for my work performed, and \$475 per hour for deposition testimony offered, in connection with this matter. My compensation is in no way contingent on the results of these or any other proceedings relating to the above-captioned patent. I have no expectation or promise of additional business with Patent Owner in exchange for the positions explained herein. I do not have any direct financial interest in any of the parties.

### **B. Background and Qualifications**

3. A detailed description of my professional qualifications, including a listing of my specialties, expertise and professional activities, and a list of cases in which I

have testified in the last ten years, is contained in my curriculum vitae, a copy of which is attached as **Appendix A**. Below is a short summary of my professional qualifications.

**4.** I am the founder of ZenStorming™ LLC, a Chicago-based company focused on consulting with respect to innovation and design. I work primarily with medical device companies. My clients include: Carefusion (now owned by Becton, Dickinson and Company), Surgimatix, Hines VA, TransMax, Xavier Moreno, AOK Inc, King Systems, Hollister, Ferring Pharmaceuticals, Testicular Cancer Society, and Baxter Healthcare.

**5.** I have extensive design and engineering experience with respect to medical devices. For example, I have worked with clinicians to develop, design, prototype, and test numerous medical devices, including interventional drainage catheters. I also have experience designing, manufacturing, and testing patient fluid line access valves.

**6.** I have worked in the medical device industry since 1991, when I started as a Biomedical Engineer for Hines VA Hospital/Loyola Medical Center. At Hines VA Hospital, I performed engineering work related to multiple medical devices, including urinary catheters. In particular, I designed a supra-pubic indwelling catheter for use in bladder studies with animal test subjects. I also developed an implantable “mesh” electrode for use on the bladder wall and assisted with computer

simulations of the bladder in cooperation with the University of Illinois. Additionally, many of the patients at the VA were catheterized with Foley catheters, and I learned about Foley catheterization procedures with a doctor during my tenure at the VA.

7. From 1995 to 1999, I worked as a New Product Development Engineer for Manan Medical Products. At Manan, I designed multi-lumen tubes to be used in interventional drainage catheters and built prototype devices. Some of these catheters were used for draining abscesses from the abdomen. I also developed a drainage bag (“The Manan D Bag”) that was used to capture fluid draining from an organ (e.g., pus, bile, urine, etc.). This bag contained an anti-reflux valve to prevent drained liquids (which included urine) from re-entering the drainage line and catheter. The Manan D Bag also had a strap on it to attach it to a patient’s leg to prevent excess movement. Also, I designed the “Manta Disk.” The disk was placed at an exit site to anchor the catheter in place and prevent dislodgement. My work further included designing manufacturing processes and fixtures, and selecting particular materials for the finished products.

8. Next, I worked as an Engineering Specialist for Allegiance Healthcare (now Cardinal Health and Carefusion due to mergers and divestitures) from 1999 to 2006, where, in addition to interventional biopsy and spinal repair devices, I designed new types of catheters for thoracic and pleural drainage. I prototyped and improved tipping processes for over-the-needle drainage catheters. During my tenure at

Allegiance Healthcare, as at Manan, I observed clinicians to understand medical procedural flow. In 2006, I joined Baxter Healthcare, where I also worked as an Engineering Specialist. I worked with the venous access group focusing on luer activated devices. I worked there until 2008, when I founded ZenStorming™.

9. I hold a Bachelor of Science degree in mechanical engineering from the University of Illinois at Chicago. I obtained a Masters of Arts degree from Loyola University of Chicago.

10. In total, I have seven issued U.S. patents relating to medical devices. Two of my patents relate to a drainage catheter apparatus: U.S. Patent No. 5,730,724 “Drainage Catheter Apparatus” and U.S. Patent No. 5,989,241 “Drainage Catheter Apparatus.” I also am an author of several published articles. *See*, for example, Walter, J. S., Wheeler, J. S., Morgan, C., Zaszczurynski, P., & Plishka, M. “Measurement of total urethral compliance in females with stress incontinence.” *Neurourology and Urodynamics* 12.3 (1993): 273-276; and Walter, J. S., Wheeler, J. S., Cogan, S. F., Plishka, M., Riedy, L. W., & Wurster, R. D. “Evaluation of direct bladder stimulation with stainless steel woven eye electrodes.” *The Journal of Urology* 150.6 (1993): 1990-1996.

### **C. Basis of My Opinion and Materials Considered**

11. In preparing this declaration, I have considered exhibits and documents cited in this IPR, including the '367 patent and other documents and materials cited herein:

| Document | Description  |
|----------|--|
| Paper 1  | Petition IPR2020-00025   |
| Ex. 1001 | U.S. Patent No. 9,283,367 to Hoang et al. (“the ’367 Patent”)  |
| Ex. 1002 | Declaration of Mr. Richard Meyst   |
| Ex. 1003 | Prosecution History for the ’367 Patent  |
| Ex. 1006 | U.S. Patent No. 4,440,207 to Genatempo et al. (“ <i>Genatempo</i> ”)   |
| Ex. 1007 | U.S. Patent No. 5,554,135 to Menyhay (“ <i>Menyhay</i> ”)  |
| Ex. 1009 | U.S. Patent Publication No. 2004/0111078 to Miyahara (“ <i>Miyahara</i> ”)   |
| Ex. 1010 | U.S. Patent Publication No. 2003/0153865 to Connell et al. (“Connell”)   |
| Ex. 1011 | U.S. Patent Publication No. 2006/0030827 to Raulerson et al. (“Raulerson”)   |
| Ex. 2003 | S. Menyhay, RN, BSN <i>et al.</i> , “Preventing central venous catheter-associated bloodstream infections: Development of an antiseptic barrier cap for needleless connectors,” American Journal of Infection Control, Dec. 2008, Vol. 36, Issue 10, pp. S174.e1-e5. |
| Ex. 2004 | Plastics International - Chemical Resistance Chart   |
| Ex. 2005 | Overview of Clearances of Section 510(k) of the Food, Drug and Cosmetic Act  |

My opinions in this declaration are based on my review of these documents, as well as upon my education, training, research, knowledge, and experience.

**12.** Throughout this Declaration, all emphasis and annotations are added unless noted.

## **II. LEVEL OF ORDINARY SKILL IN THE ART**

**13.** I understand that my comments and opinions regarding the scope and content of the prior art should be from the prospective of one of ordinary skill in the art (“POSITA”) at the time of the invention.

**14.** I have been informed that a POSITA is a hypothetical person to whom one could assign a routine task with reasonable confidence that the task would be successfully carried out. I am informed that a POSITA must be sufficiently skilled to understand the specification and to make and use the invention without undue experimentation. Counsel has informed me that certain factors may be considered in determining the level of ordinary skill in the art: (1) the type of problems encountered in the art; (2) prior art solutions to these problems; (3) the rapidity with which inventions are made; (4) the sophistication of the technology; and (5) the educational level of active workers in the field.

**15.** Based on my knowledge and experience, and taking into account each of the above factors, it is my opinion that a POSITA at the time of the filing of the application that led to the '367 patent would have had an undergraduate degree or equivalent thereof in mechanical engineering or biomedical engineering with at least three years of experience in product design with experience in, but not limited to, for example, catheters, medical ports, and other patient fluid line access valve caps. Additional graduate education might substitute for experience and vice-versa. A POSA would have had knowledge of design considerations known in the industry and would have been familiar with then existing products and solutions, and would have understood how to search available literature for relevant publications.

**16.** Based on my educational background and work experience, I am and was familiar with the technology at issue as of the 2005 time frame in which the priority application of the '367 patent was filed. My educational background and experience also allow me to evaluate what knowledge a POSITA, as defined above, would have because I have worked with many people with similar qualifications. My educational background and experience also provide me with insight into the educational level and familiarity of a person working in the field of medical devices at the time of the 2005 priority date. As of the November 17, 2005 priority date, I met the foregoing standard for a POSITA.

### **III. CLAIM INTERPRETATION**

**17.** I understand that the *Philips* claim construction standard applies in this proceedings before the USPTO. Under this standard, claims are given their ordinary and customary meaning.

### **IV. REFERENCES AND GROUNDS SET FORTH IN PETITION.**

**18.** Petitioner advances six grounds for unpatentability of the Challenged Claims of the '367 Patent. These six grounds, along with the prior art references supporting those grounds, are set forth in the table below:

| Ground | Basis | Relied-On References   | Claims        |
|--------|-------|--|---------------|
| 1      | § 103 | <i>Menyhay</i> and <i>Genatempo</i>  | 1-20          |
| 2      | § 103 | <i>Menyhay</i> , <i>Genatempo</i> , and <i>Raad</i>                        | 7, 12, and 20 |
| 3      | § 103 | <i>Menyhay</i> , <i>Genatempo</i> , and <i>Miyahara</i>                    | 10, 15        |
| 4      | § 103 | <i>Connell</i> , <i>Raulerson</i> , and <i>Genatempo</i>                   | 1-20          |
| 5      | § 103 | <i>Connell</i> , <i>Raulerson</i> , <i>Genatempo</i> , and <i>Raad</i>     | 7, 12, and 20 |
| 6      | § 103 | <i>Connell</i> , <i>Raulerson</i> , <i>Genatempo</i> , and <i>Miyahara</i> | 10, 15        |

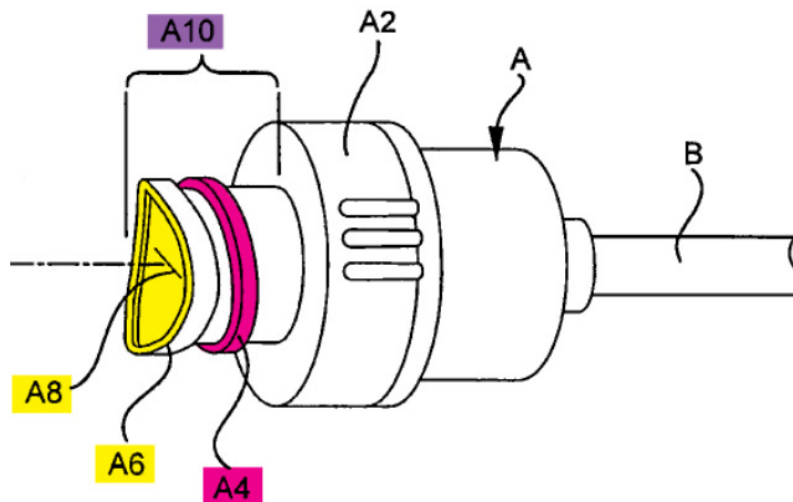
## V. THE '367 PATENT

19. The '367 patent describes a novel solution to the problem of catheter related bloodstream infections caused by the use of Intravenous (“IV”) access valves. This problem is solved by the claimed device, which is a cleaning cap for disinfecting an IV access valve (such as a Luer activated valves (“LAV”)).

20. In these types of access valves, the only barrier between the patient’s bloodstream and outside contaminants is the septum. Ex. 2003, 1. As typically used, the injection ports remain exposed until use. Ex. 1007, 1:61-2:3. Any septal-surface contaminants present on the septum-surface would be forced into the patient and could trigger a potentially fatal bloodstream infection. Ex. 2003, 1. This is particularly concerning when the connectors are frequently accessed and handled. *Id.*, 2. To prevent this, disinfection protocols are employed. *Id.*, 1-2; *see also* Ex. 1001, 1:20-33 (describing CDC guidelines for preventing bloodstream

infections including hand hygiene, catheter site care, and admixture preparation); Ex. 1007, 2:25-3:6 (describing typical cleaning procedures followed each time the injection port is accessed and cleaned). However, consistently following these multi-step procedures is difficult, even for experienced medical professionals attending to a patient in an intensive care unit. *Id.* In a study published by the American Journal of Infection Control, 67% of the connectors cleaned with alcohol wipes still showed transmission of bacterial contaminants. Ex. 2003, 4. The '367 patent describes one way to reduce these contaminants.

**21.** The access valve that needs to be disinfected is shown below in the color-annotated partial Figure 1:

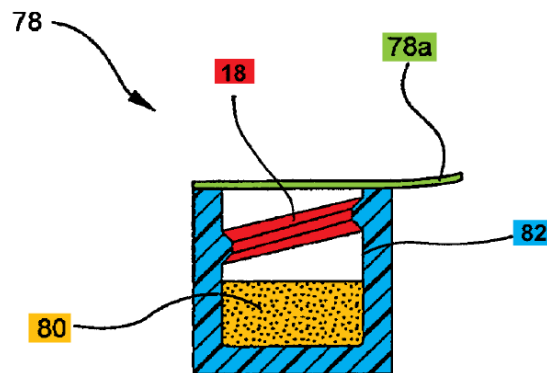


The patient fluid line access valve (A) has an **access portion (A10)** with an **end face** that includes a **septum (A6)**, and **external threads (A4)** on the access portion of the valve proximate the septum. (See also Ex. 1001, 2:19-25). It is particularly important to clean the end face of the access portion because the septum of the end

face provides a port for insertion of a needle or a male luer taper that would have access to a patient fluid line. (Ex. 1001, 2:52-57).

22. The claimed device for cleaning such access valve is shown below in color-annotated Figure 10b:

FIG. 10B



The cleaning cap includes a housing, a wet pad (80), internal threading (18), and a removable lid (78a). Figure 10B shows that the housing has a cavity for covering the access portion of the access valve. (Ex. 1001, 1:50-51). The wet pad (80) is impregnated with a cleaning agent, such as an alcohol-based solution, and optionally, an antimicrobial agent. (Ex. 1001, 3:30-51); it is used to clean the access portion of a patient fluid line access valve. (Ex. 1001, 5:14-16). The cap also has internal threads (18), which engage external threads on the patient fluid line access valve, advancing the end face of the valve into the cavity. (Ex. 1001, 3:5-11, 5:21-24). When the internal threads (18) of the cap are engaged with the external threads

(A4) of the access valve (A), the end face of the valve contacts the **wet pad (80)**. (Ex. 1001, Fig. 3). The contact between the pad and the end face of the access portion allows the antiseptic condition of the surface to be maintained, thereby minimizing the risk of microbes penetrating into the access valve (A). (Ex. 1001, 2:59-61, 3:16-24). Figure 10B also shows a **removable lid (78a)**, which “is typically made of foil or similar type material” and which “completely seals the opening” of the cap; it provides a moisture barrier to maintain the wet pad and cleaning solution in the cavity before use. (Ex. 1001, 2:34-38, 5:9-10).

## **VI. PROPOSED GROUNDS 1-3**

**23.** Grounds 1-3 presented by Petitioner proposed modifying Menyhay with the teachings of Genatempo. However, Menyhay and Genatempo describe covers that operate in very different ways and that are designed for very different types of catheters. I am therefore of the opinion that the modifications to Menyhay proposed by Petitioner would not have been obvious to a POSITA.

### **A. Overview of Menyhay**

**24.** Menyhay (Ex. 1007) discloses a “unique external injection port cover” for protecting and sterilizing vascular catheter ports. *See, e.g.*, Ex. 1007, 3:66-4:4, 4:8-11, 4:46-49, 4:50-67.

**25.** Menyhay explains that typically, injection ports remained completely uncovered and exposed, and required numerous steps to sterilize. *Id.*, 1:61-2:1, 2:25-

3:14. Menyhay provides a one-step, breakable capsule containing sterilization agents, and a projection that breaks the capsule when an appropriately firm and absorbent sponge applies sufficient pressure to rupture the capsule against the projection. *Id.*, 4:8-19, 6:50-52.

**26.** Upon insertion and tightening of the injection port 19, the cover breaks a capsule 11 to release the aseptic solution contained within so that a **sponge 12** is soaked. *Id.* The aseptic solution is released when the septum 18 of the port 19 applies sufficient pressure onto **sponge 12** to break capsule 11 against projection 13. *Id.*, 6:61-64. Menyhay states that grooves 9 “act as channels that allow the antiseptic agents escaping from the ruptured capsule 11 to flow around the capsule and soak into sponge.” *Id.*, 6:64-7:3.

**27.** The aseptic solution is absorbed by the **sponge 12** in accordance with its porosity so that the sponge bathes the septum 18 of the port in the aseptic solution. *Id.*, 6:67-7:3. The **sponge 12** included in the cover is specifically selected to have an absorption capacity “roughly equal to or slightly less than the volume of the fluid contained in the capsule” while being “firm enough to transmit pressure to the capsule” placed between the projection 13 and the flat face of a septum 18. *Id.*, 7:51-56. Menyhay specifically describes selecting the absorption capacity and porosity of the sponge to ensure bathing and decontaminating of the port. *Id.*; *see also id.*, 4:28-32.

28. Menyhay states that grooves 9 “act as channels that allow the antiseptic agents escaping from the ruptured capsule 11 to flow around the capsule and soak into sponge.” *Id.*, 6:64-7:3.

29. The **sponge** cleans the septum of the catheter when fully engaged (tightened to rupture the capsule 12 of aseptic solution) as it contacts and scrubs against the septum. *Id.*, 7:4-6. Fig. 3 of Menyhay (below) shows the arrangement when the capsule 11 is broken by projection 13 to release aseptic agent into the **sponge 12**.

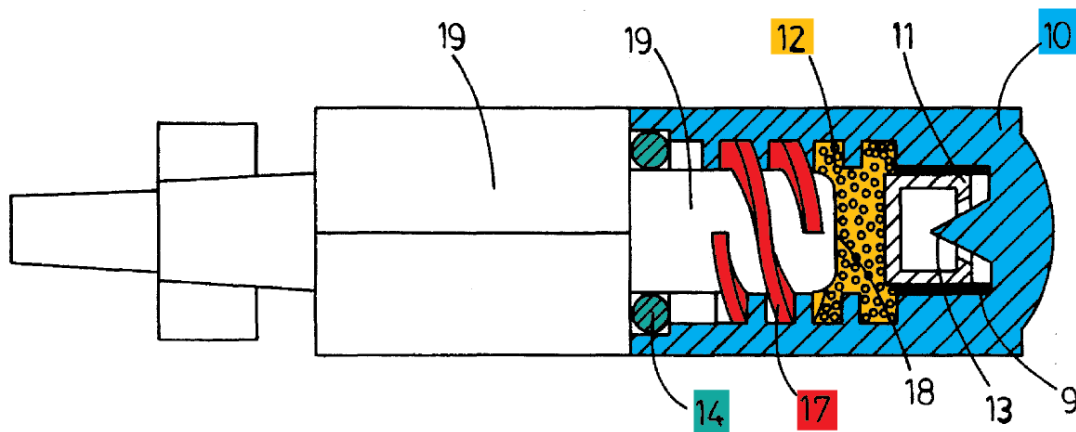


FIG. 3

30. Menyhay’s aseptic solution is retained in breakable capsule 11 until ruptured. *Id.* 4:8-19, 6:50-52. This ensures the aseptic contained within the capsule 11 does not evaporate, spill, or become contaminated. Menyhay states that the capsule can be formed of acrylic or another thin-layered brittle plastic that ruptures under

nominal pressure, but “should not be made of glass.” *Id.*, 7:47-51. Since the **sponge 12** remains dry until rupture, the **cover 10** can remain open ended.

### **B. Menyhay’s Capsule-Based Design**

**31.** Menyhay’s operating principle is based on storing aseptic solution in a breakable capsule. Menyhay’s capsule 11 serves to “releas[e] the antiseptic agents inside to be soaked up by sponge 12.” Ex. 1007, 6:61-64. The aseptic solution is released when the cover is tightened onto the port and the capsule breaks. *Id.*, 4:8-19, 6:50-52. Menyhay includes a projection 13 immediately adjacent to the capsule, and a sponge with appropriate firmness to apply the needed pressure to break the capsule against the projection 13. *Id.*, 7:51-56. The absorption capacity and porosity of the sponge are chosen to ensure bathing and decontaminating of the port. *Id.*; *see also id.*, 4:28-32.

**32.** Menyhay explains that the capsule contains the aseptic solution. *Id.*, 4:8-19, 6:50-52. By sealing the aseptic solution in this manner, it is not possible for the solution to evaporate, spill, or become contaminated.

**33.** Another benefit is the capsule allows for the open ended design of Menyhay’s cover, allowing it to protect the port septum from the elements and prevent the latex of the port septum from degrading or being contaminated because no lid is needed. *Id.*, 1:61-2:10. There is no risk of the aseptic solution evaporating, so no lid or other

cover is needed. No risk of spillage or contamination of the solution prior to breaking the capsule is possible.

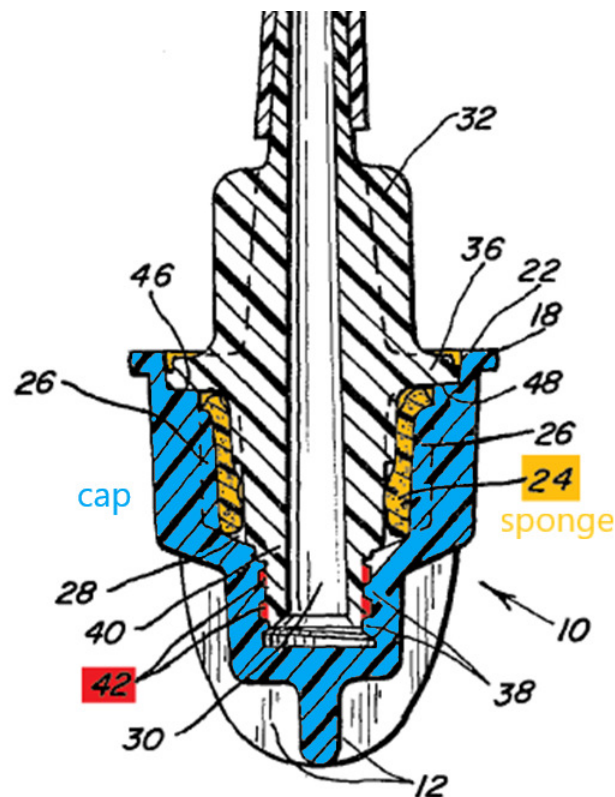
**34.** This open-ended design also avoids the need to perform a time-consuming cleaning procedure consisting of eighteen steps and involving two medical professionals. *See id.*, 2:25-3:6 (describing typical cleaning procedures followed each time the injection port is accessed and cleaned). Menyhay's described cleaning procedure is a typical example of the steps performed that would be performed to sterilize a port septum. Other benefits are that capsule based designs can give haptic feedback and audible confirmation of when the aseptic liquid is being released as the capsule fractures. Since a lid is not required to seal the cap and prevent spillage or evaporation, there is no need to develop and validate manufacturing processes to assure that the bond of the lid to the plastic is air tight. A POSITA would not pursue such a modification when Menyhay teaches fine tuning the components (*e.g.*, capsule materials, sponge firmness) to achieve the desired result.

**35.** In clinical studies accepted by the American Journal of Infection Control, only 1.6% of the tested Menyhay connectors indicated any transmission of bacterial contaminants, confirming the reliability of Menyhay's design. Ex. 2003, 4. The American Journal of Infection Control ("AJIC") is a peer-reviewed scientific journal. It is the official publication of the Association for Professionals in Infection Control and Epidemiology. As such it is the premier journal for sharing and

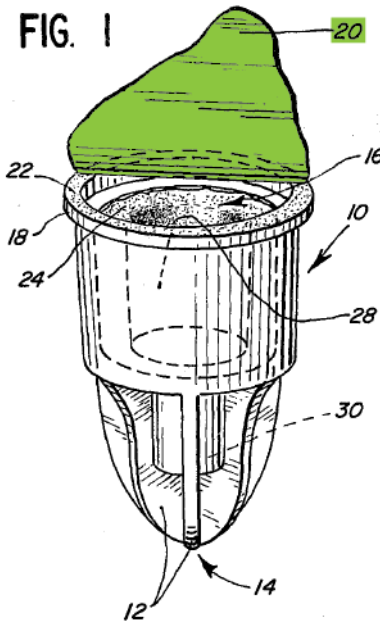
understanding advances in technologies and best practices in infection control. I have personally referenced this journal many times for information regarding new devices as would a POSITA. The study did not mention any reliability issues tied to the Menyhay device. *Id.*

### C. Overview of Genatempo

36. Genatempo (Ex. 1006) describes a sealed, wetted sponge solution for a peritoneal dialysis catheter cap. Fig. 3 of Genatempo (below) depicts how a portion of the **cap** is lined with **absorbent material 24** that is “filled with an antiseptic.” Ex. 1006, 3:22-23.



37. Prior to use, a **peelable lid 20** is removed from Genatempo's cap 10. The **peelable lid 20** serves to reduce the evaporation of the antibacterial agent retained in the **absorbent material 24**. *Id.*, 3:1-5.



38. When inserted, **threads 42** of the connector 32 engage with internal threads 38 of the **cap 10** after passing by the **absorbent material 24**. *Id.*, 3:36-39. Fig. 3 of Genatempo shows the **absorbent material 24** contacts and provides antiseptic agent to the tubular portion 40 of the connector 32. *Id.*, 3:40-45. The threads 42 are also only provided with antiseptic agent as the antiseptic flows or migrates downward. *Id.* Any antibacterial effect from the **pre-wetted material 24** that is provided to threads 42 would occur through migration of the antiseptic. *Id.*

39. Genatempo's operating principle is based on pre-wetting the sponge so that antiseptic agent can clean tubular portions of the connector. The lid of Genatempo serves to prevent the antiseptic agent in the sponge from evaporating.

**D. Petitioner's Proposed Modification of Menyhay with the Teachings of Genatempo**

40. I understand that Petitioner proposes modifying Menyhay to preload the sponge 12 with the antiseptic solution as taught by Genatempo. Pet., 22, 25-26. Petitioner alleges that this would "ensure full-wetting of the sponge and thus avoid[] dry spots in the event that the capsule of *Menyhay* fails to break sufficiently to wet sponge 12." *Id.* Petitioner alleges this would have enhanced patient safety because of "additional disinfection of the exposed surfaces" that would occur from the compression of pre-wetted sponges. *Id.*, 23.

**E. This Modification Changes Menyhay's Operating Principle**

41. Menyhay's capsule 11 serves to "releas[e] the antiseptic agents inside to be soaked up by sponge 12." Ex. 1007, 6:61-64. Projection 13 is immediately adjacent to the capsule 11 and serves to break the capsule under nominal pressure. *Id.*, 6:45-46, 7:47-51. It is my opinion these features serve only to break the capsule and wet the sponge. There would be no purpose for these features if the sponge was pre-wetted.

42. Petitioner's declarant does not mention the capsule when describing the "resulting combination." Ex. 1002, ¶79. I understand this to mean that what

Petitioner envisions does not include Menyhay's capsule and therefore operates very differently.

**F. Menyhay Teaches Adjustments Overlooked by Petitioner that a POSITA Would Employ**

**43.** If there were issues with Menyhay's operation or performance, there are several items that are identified by Menyhay that a POSITA would attempt to adjust. A POSITA would perform these modifications before exploring a more significant change to Menyhay's design.

**1. Menyhay Identifies Specific Capsule Materials that Rupture Under Nominal Pressure**

**44.** Menyhay identifies capsule materials that "break sufficiently." Menyhay discloses acrylic as an example of a brittle plastic from which the thin-layered capsule can be formed. Ex. 1007, 7:47-51. Clinical studies accepted by the American Journal of Infection Control confirmed the reliability of Menyhay's device. Ex. 2003, 4.

**45.** Paragraphs 75 and 76 of Petitioner's declarant's declaration do not support the statement that Menyhay's capsule would not "break sufficiently". Ex. 1002, ¶¶75-76. These paragraphs simply state that wetting only occurs after the Menyhay capsule is broken. *Id.*

**2. Menyhay Specifies Absorption Capacities and Suggests This May be Adjusted**

**46.** Menyhay says how the absorption capacity may be “roughly equal to or slightly less than the volume of fluid contained in the capsule.” Ex. 1007, 7:51-54. It is my opinion that Menyhay intends its sponge to be saturated once the capsule has been broken. If dryness was a concern, a POSITA would consider the suggestion by Menyhay that a smaller sponge absorption capacity may be desirable and make this type of an adjustment.

**G. Petitioner Does Not Explain How its Combination Would Successfully Solve its Identified Problems**

**47.** Menyhay specifies its sponge should be “firm enough to transmit pressure to the capsule.” Ex. 1007, 7:54-56. Menyhay states this pressure should be a “nominal pressure.” *Id.*, 7:47-51. Pre-wetting the sponge would change the sponge’s firmness and likely prevent the capsule from breaking reliably. As the hub is screwed into the cap, repeatable breakage occurs when the septum face contacts a relatively stiff sponge, transferring the force of advancement directly to the capsule enabling capsule breakage. Prewetting the sponge unnecessarily complicates the system by allowing the sponge to collapse before sufficient breakage forces are conveyed to the capsule. Instead, the sponge fills the threads, and conforms to and around the capsule. This is not a solution that is reliably predictable. A pre-wetted, compressed sponge actually hinders translation of the hub and thus, breaking of the capsule. This

proposed modification, argued as necessary to address an alleged unreliability in capsule rupture, would only aggravate such a problem.

**48.** It is not clear how much aseptic solution should be in the capsule now that the sponge is pre-wetted. To perform the sterilization properly, sufficient aseptic solution must be provided in the capsule to replace solution previously stored in the sponge before pressure was applied, squeezing some portion of the solution out.

**49.** Any excess fluid would leak from the cap and onto the patient, which would be unpleasant and/or uncomfortable. This excess solution may also interfere with the interfaces between the cap and the connector due to the solution's incompressibility and could contribute to incomplete fractures of the capsule. Also, the excess solution could cause suction between different components, making it difficult to separate the cap and connector. Alternatively, excess solution may spill when the caps are unassembled, thus spilling additional fluid onto the patient. In some situations, it is possible the aseptic solution may come into contact with components of the catheter that are not as compatible with the aseptic solution resulting in modified physical properties and possible part failure. *See* Ex. 2004. It is therefore important to minimize the amount of excess fluid utilized.

**H. Including Genatempo's Pre-Wetted Sponge Necessitates a Lid**

**50.** In a capsule based system like Menyhay, the aseptic solution cannot evaporate, spill, or become contaminated. There is no need for a lid of any sort. Only when a pre-wetted sponge is introduced does there exist a need for a lid.

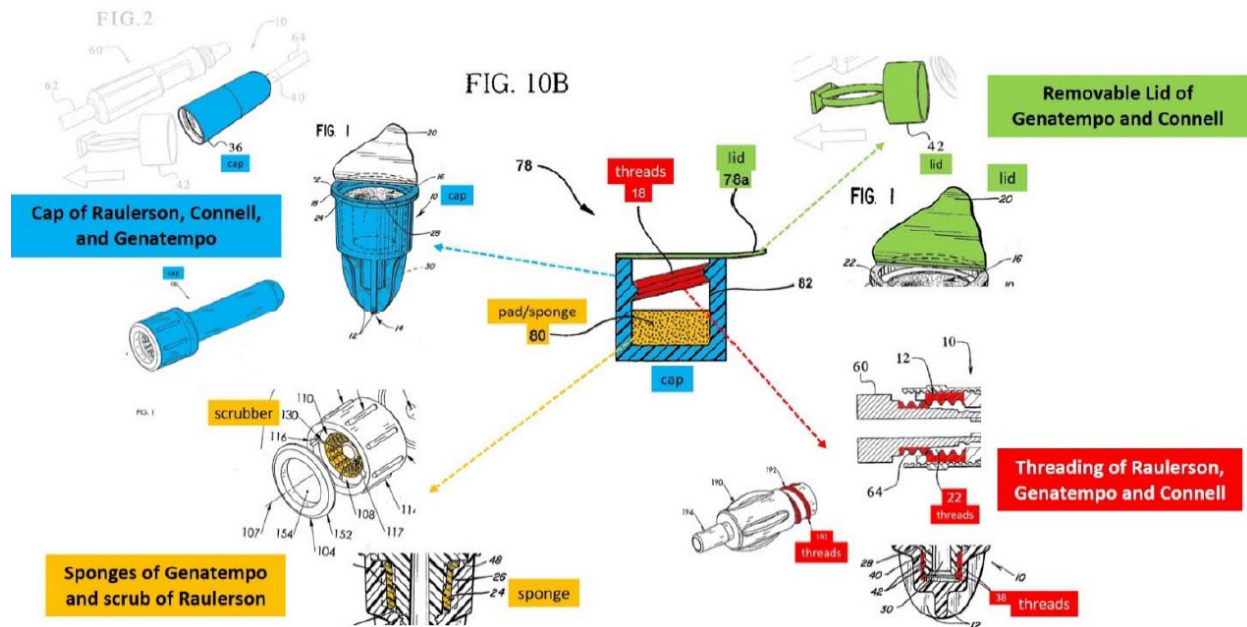
**51.** Adding steps that must be performed is not desirable. In general, it is better to reduce the number of steps that a practitioner must perform. Menyhay is evidence of such a desire. *See* Ex. 1007, 2:25-3:65. Menyhay explains two medical professionals are needed to ensure a sterile environment because the outsides of packages containing iodine and alcohol swabs are not sterile. *Id.*, 2:16-20. The second person opens the packages for the first person to remove the contents. *Id.*, 2:20-24. Menyhay's cap simplifies this procedure to a one-step process that can be executed by anyone, including the patients themselves. *Id.*, 4:46-49. As discussed earlier, the reconfiguration of an existing design to add additional components, where calibration of existing components such as Menyhay's sponge and capsule are known to achieve the same purpose, is completely illogical. Each new medical device requires extensive regulatory review and approval. In the case of the added lid, determining the optimum bonding parameters and validating the manufacturing process, as is required in medical device development, may require the approval of various stakeholders including government agencies, hospitals, standards organizations, etc. *See* Ex. 2005. For example, the Food and Drug Administration

("FDA") must receive a "Premarket Notification" from the manufacturer at least 90 days in advance of any marketing of the device. The manufacturer must generate and provide data to the FDA showing that the device is sterile, functions as intended, and is safe for use. If the FDA concurs, then the device is granted a 510(k) and can be commercialized. To the extent sponge "drying" or capsule breaking issue were encountered in the device of Menyhay, the "obvious" fix is to a POSITA is to recalibrate the properties of the sponge and capsule as taught by Menyhay, not to embark on a time consuming, and costly re-engineering of the product to the point that it is transformed to a competing solution already in the market with significant drawbacks that Menyhay does not provide. *See, e.g.,* Ex. 1010, [0053], [0066] (describing disadvantages in the prior art).

**52.** By including a lid, an extra step is added to a simple one-step process. This goes against the principle of simplification that Menyhay confirms. In addition, the addition of a lid and of a step of removing the lid reintroduces the possibility of contamination that Menyhay's design sought to reduce. *See id.*, 2:16-24. It should also be remembered that these caps relatively small. Peeling a lid from a tiny device is an additional burden and could result in dropped caps and therefore the need to use multiple caps.

## VII. PROPOSED GROUNDS 4-6

53. Petitioner has a diagram that tries to show where each claim element can be found in prior art:

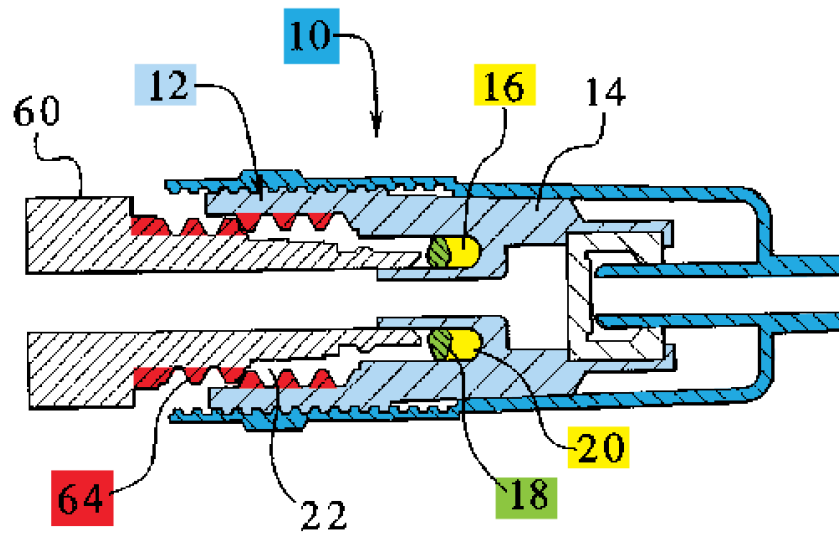


(Pet. 57).

54. I provide below an overview of each reference in an attempt to understand how Petitioner and its declarant propose to put the combinations together.

A. Overview of Connell

FIG. 4



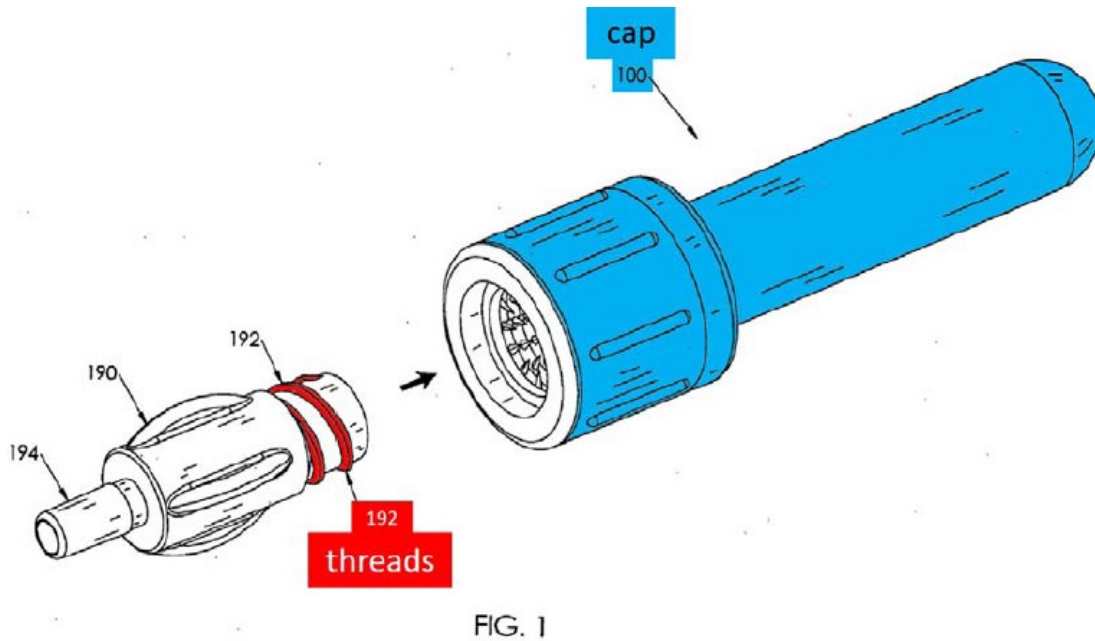
55. Connell describes a connector cap for cleaning a connector. The connect cap “easily and readily attaches to a dialysate container and a catheter inserted into a patient’s peritoneal cavity.” (Ex. 1010, Abstract). The color-annotated Figure 4 shows the connector cap (10) includes a **shell** that encloses a **cap (12)**. The **cap (12)** includes a disinfectant receptacle (16) that houses the **disinfectant (20)**. (Ex. 1010, [0016], [0071]). A **seal (18)** is also included to cap off the receptacle (16). (Ex. 1010, [0071]). The connector cap (10) has **internal threads (22)** that can mate with the **external threads (64)** of connector (60). (Ex. 1010, [0100]).

56. When in use, the connector (60) is inserted into the connector cap (10) by engaging the **threads (22) and (64)** together, such that the ends of the connector (60) would press against the **seal (18)** causing it to move or rupture, thereby releasing

the **disinfectant (20)**. The **disinfectant (20)** would then run out to clean the **external threads (64)** of the connector (60). (Ex. 1010, [0101]).

57. Connell's operating principle is to release disinfectant from a sealed receptacle to run out and clean the external threads of a connector. (Ex. 1010, [0101]). Connell has considered a prior art system using sponges to hold the disinfectant, but it steered away from that design for the need "to improve the efficiency, effectiveness and cost of providing sterile connections..." (Ex. 1010, [0012]). Connell states that the advantage of its sealed disinfectant design is that it "does not require an absorbent material to hold the disinfectant." (Ex. 1010, [0053]). Connells explains that its capsule-release design does not "create a mess" or "make the user/patient perform special handling in order not to spill the disinfectant." (Ex. 1010, [0066]). With this design, Connell explains that its connector cap provides "a safe and easy connection" for "introducing a disinfectant for a user/patient." (Ex. 1010, [0066]).

## B. Overview of Raulerson



58. Raulerson teaches a luer cleaner having a circular scrubber. The circular scrubber cleans a luer connector by rotating over and about the luer connector to dislodge any debris on the luer connector. (Ex. 1011, [0004]). Figure 1 above (annotated by Petitioner) illustrates a **luer cleaner (100)** that uses a scrubber for cleaning the **external threads (192)** of a luer connector (190).

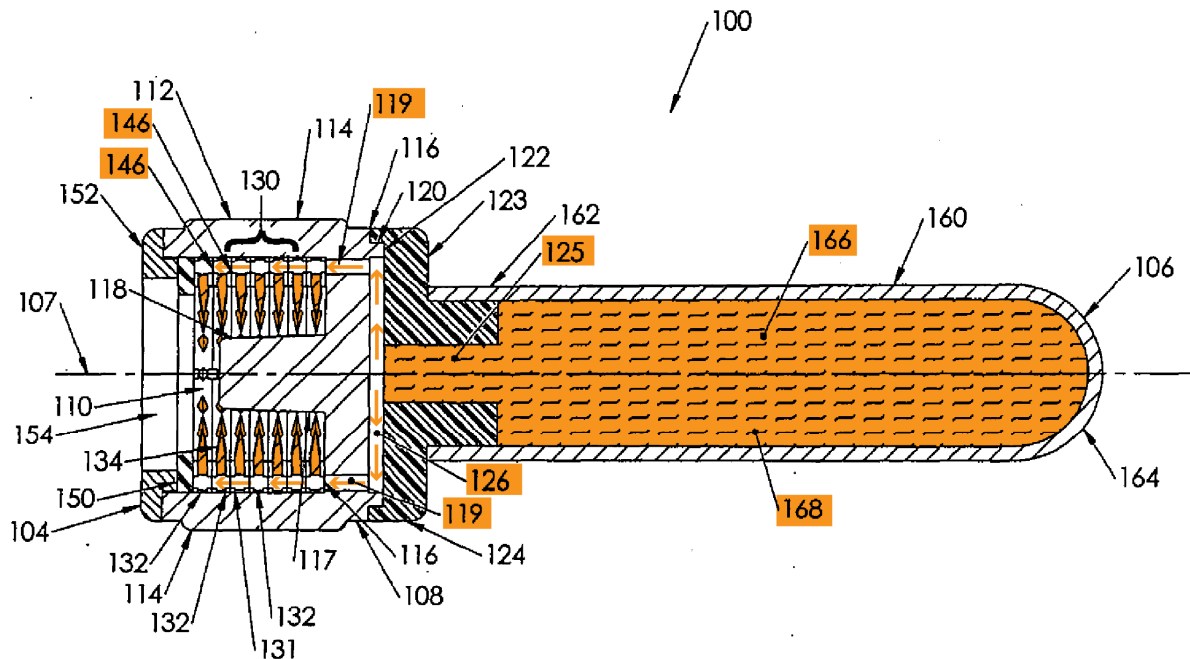


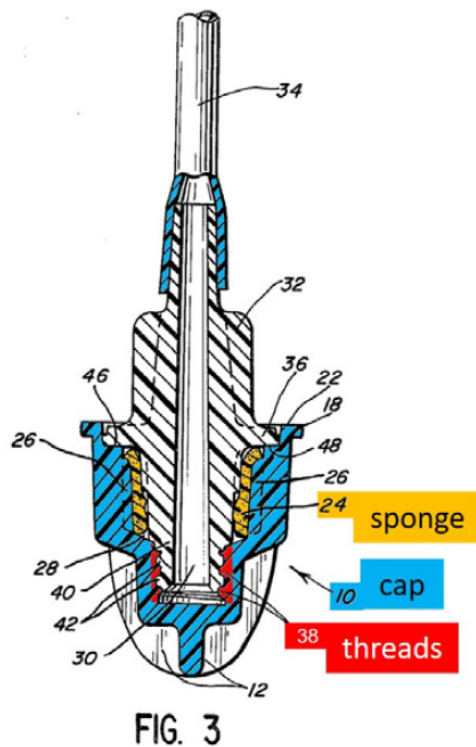
FIG. 3

**59.** As shown in color-annotated Figure 3 of Raulerson above, the luer cleaner (100) includes a scrubber (130) having “bristles 134.” The bristles (134) of the scrubber (130) line the inner side walls of the luer cleaner (100). When a luer connector (190) is inserted onto the center guide member (117) of the luer cleaner (100), only the side surfaces (where the external threads are located), and not the end surface, of the luer connector (190), would be in contact with the bristles (134) of the scrubber (13). (Ex. 1011, [0021]).

**60.** Raulerson further teaches the use of a large reservoir (166) of antiseptic fluid (168), and discloses multiple passages (*e.g.*, connecting passage 125, circular throughway 126, passage 119, radial passage 146, etc.) that allow the fluid to flow to the scrubber, as shown in the color-annotated Figure 3 above. (Ex. 1011, [0028]),

[0031]). There is no barrier that separates the disinfectants in the reservoir (166) and the body of the luer cleaner (108). (Ex. 1011, Fig. 3, [0031]). In operation, the reservoir is compressed, forcing the fluid from the reservoir into the passages, and leading the fluid to the scrubber (130) for cleaning the luer connector (190). (*Id.*)

### C. Overview of Genatempo



**61.** Genatempo is a peritoneal dialysis catheter cap that utilizes a pre-wetted sponge to clean the body of a connector.

**62.** As shown in Figure 3 (annotated by Petitioner), the **cap (10)** includes an **absorbent material (24)** and inner threads (42). The **absorbent material (24)** is located closer to the opening of the **cap (10)**; and the internal threads (42) are located near the closed end of the **cap (10)**.

**63.** In operation to clean a connector (32), the internal threads (42) of the **cap (10)** are engaged with the **threads (38)** of the connector (32). When the threads are engaged, Genatempo discloses that **absorbent material (24)** contacts the main tubular member 40 of the connector 32. (Ex. 1006, 3:43-45).

**64.** Figure 3 does not show any contact between the **absorbent material (24)** and the end face (*i.e.* the bottom surface) of the connector (32). Figure 3 also does not show any gap between the end face of the connector (32) and the inside bottom of the **cap (10)**.

#### **D. Petitioner's Combinations Are Incomplete**

**65.** Petitioner's presentation of the proposed combinations is incomplete. Petitioner does not explain what structure they are taking from which reference, where the structure they are taking would go into another structure, and how all the structures they are using would all fit together.

**66.** Petitioner proposes making its combination by taking very different elements from Connell, Raulerson, and Genatempo. Specifically, as illustrated in its diagram, Petitioner suggests to combine “[c]ap of Raulerson, Connell, and Genatempo,” “sponges of Genatempo and scrub of Raulerson,” “[t]hreading of Raulerson, Genatempo and Connell,” and “[r]emovable [l]id of Genatempo and Connell” together. (Pet. 57 (citing Ex. 1002, ¶ 100)).

**67.** As shown in the exploded diagram, Petitioner suggests to take the threading from all three references. It is unclear whether the proposed combinations would have one, two, or all three sets of threading arrangement, or some combined features of the threading arrangements. It is also unclear where the threads would be located relative to the cap, for example, whether the threads would be located closer to the opening of the cap as disclosed in Connell, or closer to the inside bottom of the cap as disclosed in Genatempo. (Pet. 57-58).

**68.** As another example, Petitioner suggests to adopt “sponges of Genatempo” in its proposed combinations. Petitioner states that the sponges are wet and impregnated with an antiseptic cleaning solution. But Petitioner does not explain where the sponges would be located, and why Connell’s cap would need a sponge at all given the sealed disinfectant already cleans the threads. (Pet. 57-58). Indeed, that is the entire point of the Connell’s capsule-release design.

**69.** Therefore, given these cursory explanations, I find the proposed grounds to be incomplete.

**E. Petitioner’s Combinations Would Change Connell’s Operating Principle**

**70.** In its proposed combinations, Petitioner argues that a POSITA would adopt the wet sponges from Genatempo to modify Connell’s cap so that the sponge can be sufficiently wetted in advance to avoid any “dry spots” or other issues with “failure to break a seal.” But it would not make any sense to a POSITA to make these

changes because they modify Connell's capsule-release operating principle, which is specifically designed to avoid absorbent materials (i.e., sponges).

**71.** Connell is a capsule-release design. Adding a sponge to replace the capsule-release design would change its operating principle. For example, Petitioner argues that adopting Genatempo's sponge would ensure "sufficient wetting of the sponge in advance." (Pet. 56). But Connell does not have or need any sponge for its described cleaning. Connell releases disinfectant from a sealed capsule allowing fluid to run through and clean the threads of a connector. (Ex. 1010, [0101]). A POSITA would not alter Connell to a sponge-based design to clean threads already cleaned by fluid flow. Especially given that Connell touts its ability to avoid such absorbent materials.

**72.** Connell explains that not having a sponge is an advantage. It states that the "advantage of the present invention is to provide a cap... that... does not require an absorbent material to hold the disinfectant." (Ex. 1010, [0053]). Connell explains that the use of "absorbent material with disinfectant" was attempted in prior art, but "[a] need still exists however to improve the efficiency, effectiveness and cost of providing sterile connections..." (Ex. 1010, [0012]) Petitioner's proposal to adopt the "absorbent material, such as that of *Genatempo*" (Pet. 56) would not make any sense. A POSITA would not add a sponge to a competing, and systemically different design, but simply switch to the sponge design itself if the capsule-release did not

perform. Indeed, one of the design principles is to keep the design elements simple and go with what works, as opposed to modifying a design with duplicative, or even competing, elements that have the same function. Adding a sponge to Connell would destroy its operating principle.

**F. Petitioner's Combinations Do Not Disclose a Wet Pad Contacting and the End Face as Required by the Claims**

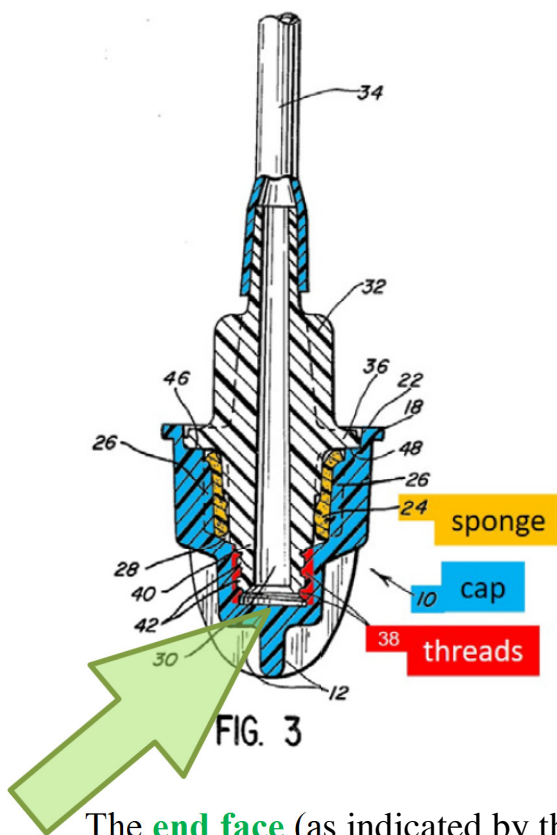
**73.** The claims of the '367 patent require contact between the claimed wet pad and the “end face” of the access portion of the patient fluid line access valve to be disinfected. The three independent claims recite such required contact: claim 1 recites “contact the wet pad with the distalmost end face of the access portion of the patient fluid line access valve, and to disinfect the end face” (Ex. 1001, 5:54-56); claim 9 recites “the wet pad being positioned within the cavity for contacting the distalmost end face of the access portion” (Ex. 1001, 6:31-33); and claim 14 recites “the wet pad being configured to contact... the distalmost end face of the threaded patient fluid line access valve.” (Ex. 1001, 6:66-7:246).

**74.** Petitioner's Proposed Grounds 4-6 all rely on the combination of Connell, Raulerson, and Genatempo. Petitioner does not explain where such contact is disclosed. Indeed, the proposed combinations do not disclose such required contact.

**75.** In its proposed combinations, Petitioner points to “[s]ponges of Genatempo and scrub of Raulerson” as disclosing the claimed wet pad. (Pet. 57 (*citing* Ex. 1002, ¶ 100)). But neither “sponges of Genatempo” or “scrub of Raulerson” is disclosed

as having contact with the end face of the access portion of the access valve as required by the claims, and Petitioner does not explain any modification to provide such in these grounds.

76. The lack of contact between the sponge and the end face of a connector is clearly shown in in Petitioner's own annotated Figure 3 of Genatempo below (Pet. 14):



The **end face** (as indicated by the arrow I have annotated) of the connector contacts the inside bottom of the cap. Figure 3 shows that the **absorbent material (24)** is located near the opening of the cap. Therefore, when the connector is inserted into the cap and the threads are engaged, the **end face** of the connector would not make contact with the **absorbent material (24)**.

77. The specification of Genatempo confirms what I see in Figure 3. It states that “[t]he tube of absorbent material 24 is shown contacting main tubular member 40 of connector 32, as well as threads 42.” (Ex. 1006, 3:43-45). The absorbent material 24 touches the main tubular member of the connector, and not the end face of the connector, which is what the claims require.

78. Petitioner suggests to adopt the wet sponges from Genatempo in the proposed combinations such that “when the sponge is compressed, [it would] release liquid to flow throughout the threading portions of the coupling.” (Pet. 56-57 (*citing* Ex. 1002, ¶ 99)). But Claim 1 requires “contact the wet pad with the end face.” The threads are not situated on the end face; the threads are situated on the side surfaces of the connector. Therefore, whether the liquid released from the sponge would flow through the threads is irrelevant to show that there is contact between the sponges and the end face. Figure 3 shows that there is no gap between the end face of the connector and the inside bottom of the cap. Even assuming the liquid released from the sponge contacts the end face (it does not), there is no physical contact between the sponge and the end face.

**G. A POSITA Would Not Have Been Motivated to Add a Sponge in a Capsule-Release System**

79. Claim limitation 1[b] requires “a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve.” (Ex. 1001, 5:47-

48). Petitioner argues that there is motivation to modify the combination of Connell and Raulerson with the teachings of Genatempo to add a wet pad. (Pet. 55, 61-62).

**80.** Petitioner argues that a POSITA “would understand that the use of a pre-impregnated absorbent material, such as that of *Genatempo* (Ex. 1006, Abstract), would provide the added benefit of ensuring sufficient wetting of the sponge in advance. (Ex. 1002, ¶99)... in such a combination, there would be no dry spots or other infirmities associated with a failure to break the seal. (Ex. 1002, ¶99)” (Pet. 56). Petitioner’s declarant makes a similar argument: “by adopting the pre-impregnated sponge of *Genatempo*, a POSA would understand that additional liquid can be provided that, when the sponge is compressed, is sufficient to release liquid to flow throughout the threading portions of the coupling. Additionally, *Genatempo* describes the use of a removable lid, which a POSA would recognize the necessity of to ensure that the pre-impregnated sponge of *Genatempo* does not dry out or expel its liquid prematurely.” (Ex. 1002, ¶99).

**81.** But this motivation is contradicted by the references themselves, a POSITA would not have been motivated to add a sponge taught by Genatempo in the proposed combination of Connell and Raulerson because neither Connell nor Raulerson is faced with the purported “dry spots” issue or “other deficiencies associated with failure of breaking.” No such issues confronted Connell or Raulerson.

82. On the “dry spots” issue, Connell does not have a sponge at all. Indeed, it identifies the lack of a sponge such as an advantage. (Ex. 1010, [0053]). Connell also explains that once the seal is moved or ruptured, the receptacle releases the disinfectant that would run through and clean the external threads of the connector. “[D]ry spots” is simply not an issue in Connell’s design.

83. In Raulerson, the luer cleaner 100 has a large reservoir (166) of antiseptic fluid (168), and multiple passages (*e.g.*, connecting passage 125, circular throughway 126, passage 119, radial passage 146, etc.) that allow the fluid to flow to the scrubber. (Ex. 1011, [0028], [0031]). This is shown in the color-annotated Figure 3:

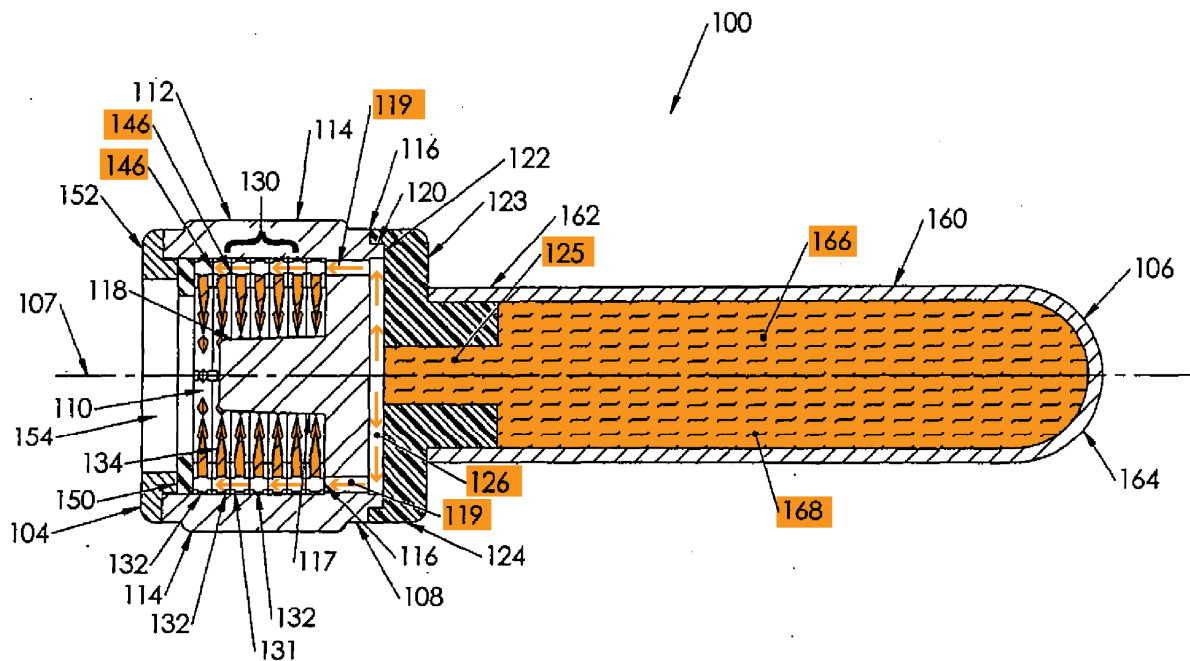


FIG. 3

There are no mentions of “dry spots” issue in Raulerson’s scrubber. For example, Raulerson does not express any concern with the antiseptic fluid fails to sufficiently

wet the scrubber bristles for cleaning the luer connector. To the contrary, there is so much antiseptic fluid that Raulerson is worried about the fluid entering “the interior of the luer 190” after it has been released from the reservoir. (Ex. 1011, [0016]). It designs a center guide member 117 that would engage with the luer 190 to prevent this overflow issue. (*Id.*)

**84.** The concern for “failure of breaking” is not disclosed anywhere in Connell. Rather, Connell discloses the “seal 18” to be “thin or otherwise frangible” in some embodiments. (Ex. 1010, [0074]). Connell seems to be concerned with the opposite of the problem identified by Petitioner and its declarant. It is that the seal would be loose or destroyed during shipment prior to using the connector 10. (Connell, [0095]).

**85.** A POSITA would not be motivated by the issues of “dry spots” or “other infirmities associated with a failure to break the seal” to adopt “the pre-impregnated sponge of Genatempo” because those issues are not applicable to Connell, which is specifically designed to avoid such absorbent materials. Petitioner has not sufficiently explained a rationale that would motivate a POSITA to adopt Genatempo’s sponge in the proposed combination of Connell and Raulerson.

## **VIII. CONCLUDING STATEMENT**

**86.** This declaration represents my opinions that I have formed up to date and based on the material currently available to me. I reserve the right to supplement this

Declaration to address any new information offered by Petitioner or provided by the Board. I also reserve the right to supplement this Declaration insofar as Petitioner is permitted to supplement the record with any additional opinions or arguments.

**87.** In signing this declaration, I understand that the declaration will be filed as evidence in a review proceeding before the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office. I acknowledge that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

I declare under penalty of perjury under the laws of the United States of America  
that the foregoing is true and correct.

Executed on January 21, 2020 at Lake Villa, Illinois.

A handwritten signature in black ink, reading "Michael Plishka", written over a horizontal line.

Michael Plishka

# APPENDIX

## A

**Michael Plishka | President**

**ZenStorming™, LLC**

michael@zenstorming.com, Cell: (847)791-3655

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### **Professional Experience Summary**

Founder and President of ZenStorming™, a Design and Innovation Consultancy.  
Twenty-Five+ years designing, developing and launching medical products

#### **FOCUS ON THE CUSTOMER**

*Clinical Relationship Builder*

*Extensive experience in Sterile Environments*

*Trained clinicians and sales staff on device use in cadaver and mock labs*

*Established hospital based training programs for engineers*

*Market Research studies*

*Product Research = Product Requirements = New Product Directions*

*Product Complaint Support*

*Assembled Clinical Advisory Boards to guide product portfolio strategy*

*Instructional Videos and Label Copy*

#### **APPLIED CREATIVITY**

*Idea Generation*

*Innovator for Next Generation Products*

*Product Platform Development*

*Strategic Technology Planning*

*Technology Assessment*

*Intellectual Property Portfolio Development*

*Expedited Project Feasibility*

*3D Printing and Prototyping*

*Product Problem Solving*

#### **REGULATORY SPECIALISMS**

*Presenter at 2017 Midwest Sensors Conference,*

*“Sensor-Driven Healthcare: Innovative Applications Today & Tomorrow”*

*Presenter at 2008 International Silicone Conference,*

*“Working with Medical Device Companies – The Essentials”*

*QSR Procedures (Design Controls, GMP, GLP, etc.)*

*Validation and testing protocols for  
packaging, new products and processes*

*Risk Assessment Process development*

*Authorship of 510 (k) submissions*

*Engineering Regulatory Compliance*

## PROFESSIONAL EXPERIENCE

### *Expert Witness*

- Bard – Expert Witness (IPR – Bard v Medline) – 2019
- Nevro – Expert Witness (IPR plus Court Case– Nevro v. Boston Scientific) – Current/Stayed
- Endoscopic Device Company – Expert Witness - Arbitration (2017)
- Carefusion– Expert Witness Support (Willie Harris v Carefusion; 2014)
- Hologic - Expert Witness (Ethicon EndoSurgery v. Hologic Inc and Suros Surgical Systems, Case No. 1:07-CV-00834; 2010)

### *ZenStorming Solutions, LLC*

*4/08 to Present*

- Carefusion/BD/Bard (2010-Present) – New Product Conception/Strategy/Design/Development, Research/Development of Disruptive Innovation Portfolio, Technology Assessment, IP Development, Sales/Clinical Training, Mobile App Story-Boarding
- Zavation (2019-Present) – Bone Cement Delivery System Development
- Matnovation (2015-Present)- Design and development of a bronchoscope (endoscope) with disposable components
- Surgimatix(2011-Present) – Endoscopic Suture Device Development, Quality System Development, Validation Support
- Hines VA (2009-Present) – Electrode Deployment Device Development, Grant Funding and Engineering Support
- TransMax(2016-Present) – Product Development, Engineering Advisor for CPR Training Device
- Xavier Moreno (2017-Present)– Epidural Catheter Measurement Device, Engineering Design and Development
- AOK Inc. – (2011-Present) New Product Development: Thoracic Access, Toy Robot Development
- 510(k) Authorship and Patent Research for Entrepreneurs (Ongoing)
- King Systems (Ambu) (2011-Present) – Respiratory Products and Emergency Airway Access, New Product Design/Development
- Inventor Anesthesiologist (2015) – Technical Guidance on Development and Licensing of Drug Dispenser Adapter
- Hollister (2010-Present)– New Product Idea Generation - Brainstorming Moderation
- Ferring Pharmaceuticals – (2009-2012)Developed Marketing Awareness Campaign
- Testicular Cancer Society (2009-10)- Developed Marketing Awareness Campaign
- Baxter Healthcare (2008)– IP Portfolio Development

### *Baxter Healthcare*

*6/06 to 4/08*

#### *Position: Engineering Specialist; Access Systems Business Unit*

- Lead Innovator for generating IP for Next Generation Vascular Access Products such as luer activated devices, resulting in multiple cross platform patent applications in heavily populated patent landscape
- Spearheaded development of resources that enabled manufacture of prototypes in half the time at a cost savings of 50%.
- Determined feasibility of new IV Access product and benchmarked against key competitive products in six months
- Engineering Lead for Market Research Studies
- Developed relationships with clinicians resulting in six new hospital sites for engineers to study clinician behaviors.
- Led Clinical Advisory Board Meetings in conjunction with Marketing.
- Drafted business unit plan for World Wide Technology/Product Planning Committees
- Mentor for younger engineers
- Company Representative in off-site college recruitment program.
- Direct Supervisory Responsibility for Junior Engineer

### *Cardinal Health (Allegiance Healthcare Corporation)*

*4/99 to 6/06*

#### *Position: Engineering Specialist; Special Procedures Business Unit*

- Engineering Project Lead driving the development of products from conception through launch while meeting aggressive timelines. Products included drainage catheters, biopsy devices and interventional vertebral repair.
- Physician Advisory Board Team Leader for new product development projects
- Technical Expert assessed and recommended new technologies and/or products for business development
- Developed patented, product platforms/line-extensions that provided 35% of all revenues in the Special Procedures

business unit.

- Developed training materials and trained Sales Staff /Clinicians on new products in cadaver labs and lecture settings
- Developed and updated Quality System/Design Controls, minimizing documentation volume and time without sacrificing safety (Design Controls, Risk Analysis, GMP, GLP, etc.)
- Authored and performed validation and testing protocols for new products and processes
- Supported 510 (k) regulatory submissions
- Developed company-wide Technical Development Career track for non-degreed Designers/Technicians
- Direct supervisory responsibility for Designer and EDP (Engineering Development Program) Engineer
- Mentor for younger engineers
- Indirect managerial responsibility for cross-cultural Project Team
- Company Representative in off-site college recruitment program.

***Manan Medical Products***

***3/95 to 4/99***

***Position: New Product Development Engineer***

- Worked with clinicians to develop novel and patented drainage catheters/accessories and biopsy products
- Managed manufacturing scale-up through product launch.
- Developed advertising, labeling (instructions), packaging and manufacturing procedures for new products.
- Filed and successfully received 510(k) approval on new and modified products.
- Wrote and performed validation and testing protocols for products, packaging and processes.
- Head of Engineering Regulatory Compliance Team achieving ISO registration and passing FDA audit with no corrective action taken
- Developed Design Control and Hazard Analysis procedures as per QSR and ISO

***Hines VA Hospital/Loyola Medical Center***

***3/91 to 5/94***

***Position: Biomedical Engineer***

- Developed bi-polar surface electrode for use on perineum.
- Co-developed implantable "mesh" electrode for use on bladder wall.
- Co-designed supra-pubic indwelling catheter for use in bladder studies.
- Generated computer simulation of bladder in cooperation with University of Illinois.
- Co-authored papers which applied research to practical, diagnostic use.

**INVENTIONS (Partial List)**

US5730724 Drainage Catheter Apparatus  
US5989241 Drainage Catheter Apparatus  
US 7018343 Biopsy Needle and Device Containing the Same  
D478987S Biopsy device  
CA2413665 Multi-Use Surgical Cement Dispenser Apparatus And Kit For Same  
CA2429357 Improved Paracentesis Device Having Multiple Detachable Components  
WO03086201 Improved Biopsy Needle And Biopsy Device Containing The Same  
WO03000121 Multi-Use Surgical Cement Dispenser Apparatus And Kit For Same  
WO03022337 Improved Paracentesis Device Having Multiple Detachable Components  
Curable Material Injection Device-Pending  
Curable Material Mixing and Delivery Device -Pending  
Paracentesis Device - Pending  
Luer Activated Device –Three Patents Pending  
Biopsy Devices – Two Pending

## **EDUCATION**

### ***Bachelor of Science Mechanical Engineering***

*University of Illinois at Chicago*

*Honors: Phi Eta Sigma for Honor Roll in multiple consecutive semesters*

### ***Master of Arts***

*Loyola University of Chicago*

## **PROFESSIONAL SOCIETIES**

***IDSA – Industrial Design Society of America***

***IEEE - Institute of Electrical and Electronics Engineers***

***EMBS – Engineering in Medicine and Biology Society***

***RSNA – Radiological Society of North America***

## **PUBLICATIONS**

“Mind Opening Exercise” Illustration in "Lifespan Human Development" (Sigelman, Rider, De George-Walker, 2013)

Walter, J. S., Wheeler, J. S., Zaszczurynski, P., & Plishka, M. "Urodynamic measure of urethral cross-sectional area: Application for obstructive uropathy." *Neurourology and urodynamics* 13.5 (1994): 571-582.

Damaser, M. S., Walter, J. S., & Plishka, M. "Letter." *International Urogynecology Journal* 5.3 (1994): 191-191.

Walter, J. S., Wheeler, J. S., Morgan, C., Zaszczurynski, P., & Plishka, M. "Measurement of urethral compliance in females with stress incontinence." *Engineering in Medicine and Biology Society, 1992 14th Annual International Conference of the IEEE*. Vol. 4. IEEE, 1992.

Walter, J. S., Wheeler, J. S., Morgan, C., Zaszczurynski, P., & Plishka, M. "Measurement of total urethral compliance in females with stress incontinence." *Neurourology and urodynamics* 12.3 (1993): 273-276.

Walter, J. S., Wheeler, J. S., Cogan, S. F., Plishka, M., Riedy, L. W., & Wurster, R. D. "Evaluation of direct bladder stimulation with stainless steel woven eye electrodes." *The Journal of urology* 150.6 (1993): 1990-1996.

## **HONORS/SKILLS**

### ***Presentations:***

- Presenter at 2017 Midwest Sensors Conference, “Sensor-Driven Healthcare: Innovative Applications Today & Tomorrow”
- Presenter at 2008 International Silicone Conference, “Working with Medical Device Companies – The Essentials”

### ***Awards:***

- Received Foster G. McGaw Contribution for Ava-Tex™ Bone Cement Delivery System (2005).
- Received Karl D. Bays New Product Award for development of Temno Evolution Biopsy Device (2004).
- Received Karl D. Bays New Product Award for development of Safe-T-Centesis Drainage System (2003).
- Received Allegiance Innovation Award for development and launch of Ava-Tex™ Bone Cement Delivery System in nine months (2001).
- Received Technical Excellence Award from Technical Council in 2001 and 2003.

## ITEMIZED PROJECT EXPERIENCE ADDENDUM

**Innovation:** Worked with clinicians to design the following:

- Biliary Catheters
- General Drainage Catheters
- Nephrostomy Catheters
- Guide Wire Introducers and Introducer sheaths
- MRI Compatible Biopsy Needles
- Vertebroplasty Systems
  - Delivery System
  - Mixing System
  - Access System
- Repositionable Para/thoracentesis Catheters
- Drainage Systems (Bottle and Bag based)
- Fully Automatic Breast Biopsy Device
- Catheter Fixation Disk
- Interventional Drainage Bag
- Laryngoscope
- Anesthesia Filters
- Tissue/Fiducial Markers
- Surgical Heating Systems
- Thoracic Entry Systems
- Laparoscopic Suturing Device

*Electrodes*

- Perineal
- Implantable Woven Mesh

*Vascular Access*

- Luer Activated Devices

**Clinical Procedural Attendance:**

- Biopsy
- Vertebroplasty
- PICC Placement
- Kyphoplasty
- Angioplasty/Stent Placement
- Interventional Drainage Catheter Placement
- Interventional Diagnostics
- Vascular Access

**Materials Knowledge:** Partial list of materials used in product developed:

- Implant grade steels
- MRI Compatible Materials
- Polycarbonate
- Polyurethane
- PMMA
- ABS
- Polypropylene
- Silicones
- PEEK
- Nylon

**Innovation Process:**

- Improved Brainstorming Processes
- Technical Expert involved in cross-business innovation
- Independent Reviewer of Cross-business products
- IP Generation and Portfolio Management
- Key Opinion/Clinical User Boards

**Process Engineering:** Manufacturing of the following devices:

- Interventional Drainage Catheters
- Needles
- Hand Held Injectors
- Cement Delivery Tubes
- Hot and Cold Pads
- Drainage Bags
- Guide Wire Catheters
- Luer Activated Devices
- Tissue Markers

**Anatomy/Physiology:** Working knowledge in the following areas:

- Human physiology
- Spine Mechanics
- Interventional Visualization Systems
- Vascular Biology
- Modelling of Heat Transfer under Anesthesia

**Coating/Impregnated Materials:** Experience with the following coatings:

- Hydrophilic Coating
- Antimicrobial Silver Coatings
- Parylene & PTFE Coating
- Lubricious materials (Impregnated)
- Antimicrobials (Impregnated)