

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti

Confirmation No.: 6375

Application No.: 10/722,102

Attorney Docket No: 780-A03-012C

Filed: November 25, 2003

Group Art Unit: 3733

For: KNEE ARTHROPLASTY METHOD

Examiner: P. Philogene

RESPONSE TO FINAL OFFICE ACTION

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Responsive to the Advisory Action mailed January 21, 2010 and in further reply to the Final Office Action mailed September 22, 2009, please enter the following amendments and remarks into the file of the above-entitled application.

This Response is being filed after the Final Office Action in order to place the application in condition for allowance or alternatively, in a better form for appeal. The amendments to the claims require only a cursory review by the Examiner, and thus, should be entered.

In accordance with USPTO practice, each section of this Response begins on a separate sheet. Applicant submits, these remarks serve to clarify the present invention, and are independent of patentability.

S&N 1017

Amendments to the Claims:

1. (Currently amended) A method of replacing at least a portion of a patient's knee, the method comprising the steps of:

making an incision in a knee portion of a leg of the patient ~~sized smaller than the portion of the knee to be replaced;~~

~~expanding the incision from an unexpanded configuration to an expanded configuration by applying force against opposite edge portions of the incision;~~

determining a position of a cutting guide using references derived independently from an intramedullary device;

positioning a cutting guide using the determined position, passing the cutting guide through the ~~expanded~~ incision and on a surface of a distal end portion of an unresected femur, the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod, ~~the cutting guide sized to be received in the expanded configuration;~~

moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; and

forming at least an initial cut on the femur by moving the cutting tool along the guide surface;

attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

2. (Previously presented) The method of claim 1 wherein the surface is a medial or lateral side of the distal end portion of the femur.

3. (Canceled)

4. (Previously presented) The method of claim 1 wherein a computer navigation system is used in the determining step.

5. (Original) The method of claim 1 wherein the positioning step includes removably

attaching the cutting guide to the side surface of the distal end portion of the femur.

6. (Original) The method of claim 5 wherein the cutting guide is removably attached with first and second pins extending through holes in the cutting guide and into the femur.

7. (Original) The method of claim 1 wherein the guide surface comprises a plurality of straight guide segments.

8. (Original) The method of claim 7 wherein the plurality of straight guide segments comprises:

- a distal guide segment disposed in a plane which extends perpendicular to a longitudinal central axis of the femur and extends through lateral and medial condyles of the femur;

- an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

- a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

- an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the femur; and

- a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

9. (Canceled)

10. (Original) The method of claim 1 wherein said step of cutting the femur includes utilizing the guide surface on the cutting guide to guide the cutting tool during making of an initial portion of a cut in the femur, and completing the cut in the femur while guiding the cutting tool with a surface formed during making of the initial portion of the cut in the femur.

11. (Canceled)

12. (Previously presented) The method of claim 10 wherein the cutting guide is removed from a side surface of the distal end portion of the femur after making the initial portion of the cut and before completion of the cut.

13-18. (Canceled)

19. (Currently amended) A method of replacing at least a portion of a joint in a patient, the method comprising the steps of:

obtaining a customized cutting guide fabricated for the patient based on preoperative ~~and clinical~~ information, the cutting guide positionable in a pre-determined position on a bone of the joint using references derived independently from an intramedullary device;

making an incision ~~proximal~~ adjacent to the joint in the patient, ~~the incision sized smaller than the portion of the joint to be replaced;~~

~~determining a position of a cutting guide using references derived independently from an intramedullary device;~~

positioning the cutting guide ~~using~~ in the pre-determined position[[,]] by passing the cutting guide through the incision and on a surface of an end portion of an unresected bone of the joint;

moving a cutting tool through the incision into engagement with a guide surface on the positioned cutting guide;

cutting the unresected bone of the joint for the first time, by moving the cutting tool along the guide surface;

attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface; and

disposing of the cutting guide, as it is no longer safely usable ~~or useful in a subsequent procedure, the cutting guide having been contaminated, or~~ the bone for which it was custom fabricated having been cut and therefore changed.

20. (Previously presented) The method of claim 19 wherein the side surface is a medial or lateral side of the end portion of the first bone.

21-22. (Canceled)

23. (Original) The method of claim 19 wherein the positioning step includes removably attaching the cutting guide to the side surface of the end portion of the first bone.

24. (Original) The method of claim 23 wherein the cutting guide is removably attached with first and second pins extending through holes in the cutting guide and into the first bone.

25. (Original) The method of claim 19 wherein the guide surface comprises a plurality of straight guide segments.

26. (Original) The method of claim 25 wherein the plurality of straight guide segments comprises:

- a distal guide segment disposed in a plane which extends perpendicular to a longitudinal central axis of the first bone;

- an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

- a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

- an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the first bone; and

- a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

27. (Canceled)

28. (Original) The method of claim 19 wherein said step of cutting the first bone includes utilizing the guide surface on the cutting guide to guide the cutting tool during making of an initial portion of a cut in the first bone, and completing the cut in the first bone while guiding the cutting tool with a surface formed during making of the initial portion of the cut in the first bone.

29. (Original) The method of claim 28 wherein the cutting guide is positioned on the side surface of the end portion of the first bone during completion of the cut.

30. (Original) The method of claim 29 wherein the cutting guide is removed from the side surface of the end portion of the first bone after making the initial portion of the cut and before completion of the cut.

31-32. (Canceled)

33. (Previously presented) The method of claim 1, wherein in said step of making an incision, said incision is offset from the center of said knee area.

34. (Canceled)

35. (Previously presented) The method of claim 19, wherein after said step of cutting, further including the steps of:

removing said cutting guide; and,

guiding said cutting tool using cuts formed in said cutting step to complete said cuts.

36. (Previously presented) The method of claim 19, wherein in said step of positioning, said cutting guide is sized smaller than said side surface.

37. (Previously presented) The method of claim 19, wherein after said step of positioning, further including the step of:

aligning said cutting guide using markings on said side surface.

38-39. (Canceled)

40. (Previously presented) The method of claim 1, wherein the determining step includes adjusting the determined position to correct a deformity of the joint.

41. (Previously presented) The method of claim 1, wherein the portion of a patient's knee replaced is at least a portion of an articulating surface of the joint.

42. (Canceled)

43. (Previously presented) A method of replacing at least a portion of a patient's knee, the method comprising the steps of:

making an incision in a knee portion of a leg of the patient;

expanding the incision from an unexpanded configuration to an expanded configuration by applying force against opposite edge portions of the incision;

determining a position of a cutting guide using references derived independently from an intramedullary device;

positioning a cutting guide using the determined position, passing the cutting guide through the expanded incision and on a surface of a distal end portion of an unresected bone, the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod, the cutting guide sized to be received in the expanded configuration;

moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; and

forming at least an initial cut on the bone by moving the cutting tool along the guide surface;

attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.

44. (Previously presented) The method of claim 43, wherein the cutting guide is customized to a patient's bone, and further including the step of disposing of the cutting guide, as the cutting guide is no longer useful as the bone for which it has been customized has been cut and thereby changed.

45. (Previously presented) The method of claim 43, wherein the cutting guide is fabricated from a plurality of cutting guide parts, and further including the step of disposing of at least one of said plurality of cutting guide parts.

46. (Previously presented) The method of claim 43, wherein the replacement portion of the knee is attached without dislocating the knee joint.

47. (Previously presented) The method of claim 43, wherein the bone is cut with a mill.

48. (Previously presented) The method of claim 43, wherein the bone is cut using a robotic arm.

49. (Previously presented) The method of claim 43, wherein in said forming step, a recess is formed in the bone, and in said attaching step, at least a part of the replacement portion is inlaid into the recess.

50. (Previously presented) The method of claim 43, wherein the replacement portion of the knee includes a plurality of segments having an articulating surface.

51. (Previously presented) The method of claim 43, further including the step of inserting a guide wire in bone of the knee, and wherein the replacement portion of the knee is provided with an opening through which the guide wire is passed.

52. (Previously presented) The method of claim 43, wherein the guide surface operates to capture the cutting tool within a slot.

53. (Previously presented) The method of claim 43, wherein at least a portion of the cutting guide is polymeric.

54. (Previously presented) The method of claim 43, wherein in carrying out the method, the quadriceps mechanism is not cut.

55. (Previously presented) The method of claim 43, wherein in carrying out the method, the articulating surface of the patella is maintained facing the femur.

56. (Previously presented) The method of claim 43, further including the step of unpacking a sterile package containing only one cutting guide.

57. (Previously presented) The method of claim 43, further including the step of unpacking a sterile package containing only one each of a cutting guide and a replacement portion of the knee.

58. (Currently amended) A method of replacing at least a portion of a joint in a patient, the method comprising the steps of:

~~determining a position for~~ obtaining an alignment guide positionable on a bone using references derived independently of an intramedullary device, wherein the alignment guide is custom fabricated for the patient based on patient imaging information;

positioning the alignment guide ~~using the determined position~~ in relation to the surface of an unresected bone of the joint;

referencing a cutting guide with respect to the alignment guide; and

cutting the unresected bone of the joint for the first time, by moving a cutting tool along a guide surface of the cutting guide.

59. (Previously presented) The method of claim 58, wherein the joint is a knee joint and a

total knee replacement is performed.

60. (Previously presented) The method of claim 58, wherein referencing the cutting guide includes positioning a pin into the bone to secure the cutting guide to the bone and wherein the pin position is determined by the alignment guide.

61. (Previously presented) The method of claim 58, wherein the guide surface has a width less than the width of the cut portion of the bone.

62. (Previously presented) The method of claim 58, wherein the joint is selected from the group consisting of: finger, wrist, elbow, shoulder, spine, hip, knee, ankle, toe.

63. (Previously presented) The method of claim 58, wherein at least a portion of the articulating surface of the joint is replaced within the cut bone.

64. (Previously presented) The method of claim 63, wherein the at least a portion of the articulating surface is replaced with a material selected from the group consisting of: biological, metal, composite, polymeric, ceramic, metal/ceramic, metal/polymer, polymer/ceramic, polymer/polymer, ceramic/ceramic, and ceramic/composite.

65. (Previously presented) The method of claim 58, wherein the joint has a plurality of articulating surface compartments, and at least a portion of the articulating surface is not replaced in all articulating surface compartments.

66. (Previously presented) The method of claim 58, wherein the cutting guide or the alignment guide is passed into the body through a cannula.

Remarks

Claims 1-2, 4-8, 10, 12, 19-20, 23-26, 28-30, 33, 35-37, 40-41, and 43-66 are presented for the Examiner's review and consideration. In this response, claims 1, 19, and 58 are amended, and claims 13-18, 22, 34, and 39 are cancelled. Applicant believes the claim amendments and accompanying remarks serve to clarify the present invention, and are independent of patentability. No new matter has been added.

35 U.S.C. §102

Claims 13-18, and 39, were rejected under 35 U.S.C. §102(b) as being anticipated by Jenkins, Jr. (U.S. 5,722,978), and under 35 U.S.C. §102(e) as being anticipated by Mansmann (U.S. 6,132,468). Without prejudice and without conceding the validity of the rejections, in order to expedite prosecution, Applicant has herein cancelled claims 13-18, 22, 34, and 39.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the §102 rejections.

With respect to comments made in the Advisory Action mailed January 4, 2010, it is asserted that any device or component could be adjusted to a single patient's bone. Applicant respectfully submits, however, that "custom fabricated" is clearly distinct from "adjusted". As to the assertion that the claims do not define structure as to how the cutting guide is "custom fabricated for a single patient's bone", Applicant notes, at least, that the claims recite a custom guide fabricated based on "preoperative" or "patient imaging information", neither of which are suggested or taught by the cited references. The foregoing arguments additionally apply to the travelling guide of Mansmann.

Amendment After Final Rejection

Although the Examiner has discretion over entry of amendments submitted after final rejection, any amendment that will place the application either in condition for allowance or in better form for appeal may be entered. *See* MPEP 714.12. Any amendment after final rejection should require only a cursory review by the Examiner, such as an amendment cancelling claims, adopting Examiner suggestions, and/or removing issues for appeal. *See* MPEP 714.13 II.

Applicant respectfully requests entry of the amendments and remarks presented herein into the file for the above-identified application.

In this response, claims 13-18, 22, 34 and 39 have been cancelled, and claims 1 and 19 have been amended to incorporate subject matter from allowed claim 43.

Accordingly, the claim amendments made herein are acceptable for entry as, in accordance with the guidelines, the amendments only cancel claims and incorporate allowed subject matter.

Furthermore, all subject matter presented in the claims (as amended herein) has been previously presented. No new matter, which would require a further search by the Examiner, has been added.

Based upon all the above, it is clear that the amendments made herein require only a cursory review by the Examiner. Therefore, the instant Response places the application in condition for allowance or alternatively, in a better form for appeal, and should be entered.

Allowable Subject Matter

Applicant acknowledges with appreciation that claims 1-2, 4-8, 10-12, 19-20, 22-26, 28-30, 33-37, 40-41, and 43-66 were allowed.

Applicant(s): P. Bonutti
Application No.: 10/722,102
Examiner: P. Philogene

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$1,110 is believed to be due for a three month extension. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A03-012C).

Respectfully submitted,

/ Paul D. Bianco /

Paul D. Bianco, Reg. #43,500

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NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES		Docket Number (Optional) 780-A03-012C				
<p>I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____</p> <p>Signature _____</p> <p>Typed or printed name Dinah Fuentes</p>		<p>In re Application of Peter Bonutti</p> <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Application Number 10/722,102</td><td style="width: 50%;">Filed November 25, 2003</td></tr></table> <p>For KNEE ARTHROPLASTY METHOD</p> <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Art Unit 3733</td><td style="width: 50%;">Examiner PHILOGENE, PEDRO</td></tr></table>	Application Number 10/722,102	Filed November 25, 2003	Art Unit 3733	Examiner PHILOGENE, PEDRO
Application Number 10/722,102	Filed November 25, 2003					
Art Unit 3733	Examiner PHILOGENE, PEDRO					
<p>Applicant hereby appeals to the Board of Patent Appeals and Interferences from the last decision of the examiner.</p> <p>The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) \$ <u>540</u></p> <p><input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: \$ _____</p> <p><input type="checkbox"/> A check in the amount of the fee is enclosed.</p> <p><input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.</p> <p><input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. <u>503410</u>.</p> <p><input checked="" type="checkbox"/> A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.</p> <p style="text-align: center;">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.</p> <p>I am the</p> <table style="width: 100%;"><tr><td style="width: 50%; vertical-align: top;"><p><input type="checkbox"/> applicant/inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p><p><input checked="" type="checkbox"/> attorney or agent of record. <u>43500</u> Registration number _____</p><p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p></td><td style="width: 50%; vertical-align: top;"><p><u>/Paul D. Bianco/</u> Signature</p><p><u>Paul D. Bianco</u> Typed or printed name</p><p><u>305 830-2600</u> Telephone number</p><p><u>March 22, 2010</u> Date</p></td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <div style="border: 1px solid black; padding: 5px;"><p><input type="checkbox"/> *Total of _____ forms are submitted.</p></div>			<p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. <u>43500</u> Registration number _____</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p>	<p><u>/Paul D. Bianco/</u> Signature</p> <p><u>Paul D. Bianco</u> Typed or printed name</p> <p><u>305 830-2600</u> Telephone number</p> <p><u>March 22, 2010</u> Date</p>		
<p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. <u>43500</u> Registration number _____</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p>	<p><u>/Paul D. Bianco/</u> Signature</p> <p><u>Paul D. Bianco</u> Typed or printed name</p> <p><u>305 830-2600</u> Telephone number</p> <p><u>March 22, 2010</u> Date</p>					

This collection of information is required by 37 CFR 41.31. 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, 1.14 and 41.6. 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.

Electronic Patent Application Fee Transmittal				
Application Number:		10722102		
Filing Date:		25-Nov-2003		
Title of Invention:		Knee arthroplasty method		
First Named Inventor/Applicant Name:		Peter M. Bonutti		
Filer:		Paul David Bianco		
Attorney Docket Number:		780-A03-012C		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Notice of appeal	1401	1	540	540
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 3 months with \$0 paid	1253	1	1110	1110
Miscellaneous:				
Total in USD (\$)				1650

Electronic Acknowledgement Receipt	
EFS ID:	7258668
Application Number:	10722102
International Application Number:	
Confirmation Number:	6375
Title of Invention:	Knee arthroplasty method
First Named Inventor/Applicant Name:	Peter M. Bonutti
Customer Number:	33771
Filer:	Paul David Bianco
Filer Authorized By:	
Attorney Docket Number:	780-A03-012C
Receipt Date:	22-MAR-2010
Filing Date:	25-NOV-2003
Time Stamp:	17:09:03
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1650
RAM confirmation Number	3987
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Extension of Time	extend.pdf	45980 c03378296511da584248f2c7c39f44ca87123190	no	1
Warnings:					
Information:					
2		AppealAmend.pdf	195657 b9c18811944017c7a19a02e23e6047e05d0f0299	yes	13
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment After Final		1	1	
	Claims		2	10	
	Applicant Arguments/Remarks Made in an Amendment		11	13	
Warnings:					
Information:					
3	Notice of Appeal Filed	AppealNote.pdf	41675 8bf72ed78a38bdf185994c6a9d4cc120088b41abe68	no	1
Warnings:					
Information:					
4	Fee Worksheet (PTO-875)	fee-info.pdf	31621 9bf779eac4b02460135d0f6801136407c12f79e2	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			314933		