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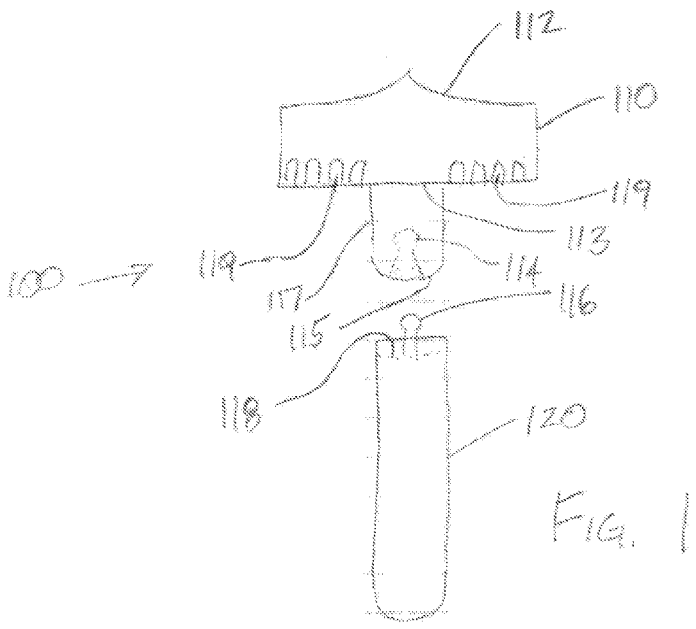

FIG. 1

(57) Abstract: A temporary joint replacement implant (100, 200, 300, 400, 500, 600, 700, 800, 900, 1000, 1100) including a temporary joint replacement component (110, 210, 310, 410, 510, 610, 710, 810, 910, 1010, 1110) and an intramedullary shaft (120, 220, 320, 420, 520, 620, 720, 820, 920, 1020, 1120) that are coupled together. The intramedullary shaft and temporary joint replacement component may be coupled together by a connection (114, 214, 314, 510, 516, 614, 714, 814, 914, 1014, 1114) that does not transmit an appreciable moment force. The intramedullary shaft may be made from cement, such as polymethylmethacrylate (PMMA), and may include an intermixed antibiotic or other therapeutic pharmaceutical agents.

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BONE CEMENT SPACER WITH FLEXIBLE STEM

BACKGROUND

[0001] The present invention generally relates to the field of medical implants for surgical use, and more particularly relates to providing structurally adequate implants that deliver a pharmaceutical, such as an antibiotic, to a surgical site.

[0002] Temporary spacers are sometimes utilized for approximately 45-60 days or more in two-stage joint replacement revisions where infection has become a problem. Some such spacers are formed from polymethylmethacrylate (PMMA) cement. Once infection has been confirmed in a joint containing implants, a two-stage joint revision may be implemented. In a first stage, joint replacement implants are removed and replaced with temporary implants, such as a cement spacer, which may contain antibiotics. The spacer of many existing protocols is a PMMA cement device that has been mixed with an antibiotic prior to polymerization. Typically, a patient is given intravenous antibiotics for a period of 45-60 days or more that work in combination with the antibiotic released from the spacer. After the infection has been cleared, a second stage of the revision surgery is performed where the spacer is removed and replaced with standard joint replacement implants.

[0003] Hand-molding a cement spacer is a time-consuming process, and quality control is difficult to maintain, which sometimes leads to less than desirable results. Preformed antibiotic containing cement spacers have been developed to address these shortcomings. It may also be desirable to provide articular joint components with functioning bearing surfaces so that the patient can move the joint during the temporary implantation period. However, due to the inherent structural limitations of cement, preformed cement spacers without significant internal metallic supports have not proven adequate to survive the normal cyclic loads applied to a weight bearing joint like a knee. This is especially true with designs that have long intramedullary stems. In particular, the coupling between an articular component and the proximal end of a long intramedullary stem is subject to significant moment loading, which is sometimes more than the cement material can withstand without fracturing. As a result, preformed, current articulating, cement spacers typically do not include long stems. Many existing cement spacers have been developed without intramedullary stems or with short stems that do not extend into the intramedullary canal. A lack of a long stem that can reach deeply into

the intramedullary canal may compromise the effectiveness of antibiotic delivery from the spacer because antibiotic loaded cement is not positioned deeply enough into the intramedullary canal to reside adjacent to all infection sites. Some surgeons hand-mold spacers with stems during surgery that may include long intramedullary stems. However, these spacers have not been mechanically tested, are subject to considerable variability, and have no regulatory clearance.

[0004] Thus, there is a continuing need to provide long intramedullary stems on spacer implants for use in two-stage revision procedures that are structurally adequate to allow a patient to continue to mobilize and bear weight on a joint during the time infections are being cleared from an implant site. Such long intramedullary stems should be long enough to position antibiotic delivering stem components deep within an intramedullary canal. Improved mechanisms may also provide consistently formed and quality controlled implants, even where the implants are formed from a setting material, such as cement, during an operation.

SUMMARY

[0005] One embodiment is directed to a joint replacement implant that includes a first joint replacement component with an articular surface on one side of the component configured to articulate with another component of the joint replacement implant or an anatomical surface, and an intramedullary shaft configured to couple with the first joint replacement component on a side of the first joint replacement component other than the one side of the component with an articular surface and configured to penetrate a medullary canal of a bone to which the joint replacement implant is configured to attach. The intramedullary shaft may be coupled to the first joint replacement component by a coupling that does not transmit an appreciable moment force between the first joint replacement component and the intramedullary shaft.

[0006] Another embodiment is directed to a joint replacement system that includes a first joint replacement component with an articular surface on one side of the component. The first joint replacement component is configured to couple with a bone. The system also includes a second joint replacement component that articulates with the first joint replacement component and is configured to couple with a different bone from the first joint replacement component. The system also includes at least one intramedullary shaft configured to couple with the first joint replacement component or the second joint replacement component. The at least one intramedullary shaft may be coupled to the first or second joint replacement component by a

coupling that does not transmit an appreciable moment force between the first joint replacement component and the intramedullary shaft, and the shaft may include an antibiotic agent.

[0007] Yet another embodiment is directed to a device for making an intramedullary shaft. The device may include a tubular shell configured to contain a setting material placed within the tubular shell, and an insert sized to fit at least partially within the tubular shell. Some insert embodiments include a coupling mechanism to which another component may be coupled to form a coupling that does not, in at least one plane, transmit an appreciable moment force.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The accompanying drawings are incorporated herein and form a part of the specification, illustrate the embodiments of the invention, and together with the written description serve to explain the principles, characteristics, and features of the invention. In the drawings:

[0009] FIG. 1 is a side elevation view, with hidden lines, of an embodiment of a tibial joint replacement component and an intramedullary shaft.

[0010] FIG. 2 is a perspective view of an embodiment of a femoral joint replacement component and an intramedullary shaft.

[0011] FIG. 3 is a cross-sectional elevation view of the femoral joint replacement component and the intramedullary shaft of FIG. 2.

[0012] FIG. 4 is a plan view of an embodiment of a tibial joint replacement component.

[0013] FIG. 5 is a cross-sectional elevation view of the tibial joint replacement component of FIG. 4.

[0014] FIG. 6 is a perspective view of an embodiment of a tibial joint replacement component and an intramedullary shaft in position within a tibia with a defect.

[0015] FIG. 7 is a plan view of the tibial joint replacement component and tibia of FIG. 6.

[0016] FIG. 8 is a cross-sectional view of the tibial joint replacement component, intramedullary shaft, and tibia of FIG. 6.

[0017] FIG. 9 includes three different views of a shroud, as shown in use in FIG. 8.

[0018] FIG. 10 is a plan view of an embodiment of a tibial joint replacement component.

[0019] FIG. 11 is a cross-sectional elevation view of the tibial joint replacement component of FIG. 10 including an intramedullary shaft.

[0020] FIG. 12 is an elevation view of the tibial joint replacement component and intramedullary shaft of FIG. 11.

[0021] FIG. 13 is a side elevation view of the tibial joint replacement component and intramedullary shaft of FIG. 11.

[0022] FIG. 14 is a perspective view of an embodiment of a femoral joint replacement component and a portion of an intramedullary shaft with part of an articular portion of the femoral joint replacement component made invisible for clarity of other portions of the device.

[0023] FIG. 15 is a perspective view of the femoral joint replacement component and portion of an intramedullary shaft shown in FIG. 14.

[0024] FIG. 16 is a cross-sectional view of an embodiment of a tibial joint replacement component and an intramedullary shaft.

[0025] FIG. 17 is a cross-sectional view of an embodiment of a tibial joint replacement component and an intramedullary shaft.

[0026] FIG. 18 is a plan view of an embodiment of a tibial joint replacement component.

[0027] FIG. 19 is a cross-sectional elevation view of the tibial joint replacement component of FIG. 18 including an intramedullary shaft.

[0028] FIG. 20 is an elevation view of the tibial joint replacement component and intramedullary shaft of FIG. 19.

[0029] FIG. 21 is a plan view of an embodiment of a tibial joint replacement component.

[0030] FIG. 22 is an elevation view of the tibial joint replacement component of FIG. 21 including an intramedullary shaft.

[0031] FIG. 23 is a cross-sectional side elevation view of the tibial joint replacement component and intramedullary shaft of FIG. 22.

[0032] FIG. 24 is a cross-sectional view of an embodiment of a tibial joint replacement component including an intramedullary shaft.

[0033] FIG. 25 is an elevation view of an embodiment of a tubular shell.

[0034] FIG. 26 is a cross-sectional view of the tubular shell of FIG. 25 and an insert.

[0035] FIG. 27 is an elevation view of an embodiment of a tubular shell.

[0036] FIG. 28 is a cross-sectional view of the tubular shell of FIG. 27 including an insert.

[0037] FIG. 29 is a perspective view of the insert of FIG. 28.

[0038] FIG. 30 is an elevation view of an embodiment of a tubular shell and an insert.

[0039] FIG. 31 is a cross-sectional view of the tubular shell and insert of FIG. 30.

[0040] FIG. 32 is an elevation view of an embodiment of a tubular shell and an insert.

[0041] FIG. 33 is a cross-sectional view of the tubular shell and insert of FIG. 32.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0042] The following descriptions of the depicted embodiments are exemplary in nature and are in no way intended to limit the scope of the invention, its application, or uses.

[0043] A joint replacement implant 100 is illustrated in FIG. 1. The joint replacement implant 100 includes a first joint replacement component 110 and an intramedullary shaft 120. Embodiments of joint replacement implants and component parts disclosed herein may act as temporary replacement components in some embodiments. The first joint replacement component 110 includes an articular surface 112 on one side of the component 110. In the illustrated embodiment, the first joint replacement component 110 is a tibial component. The articular surface 112 is configured to articulate with another component of the joint replacement implant or with an anatomical surface. For example, the articular surface 112 may articulate with a surface of a femoral component, such as the femoral component 210 illustrated in FIGS. 2 and 3. By way of another example, certain implant articular surfaces may be configured to interact with an anatomical surface in partial joint replacement procedures. The first joint replacement component 110 includes a stub shaft 117 with a coupling mechanism 114 at a distal end 115 of the stub shaft 117. In the illustrated embodiment, the coupling mechanism 114 is a snap fit connection into which a ball may be press fit for a secure connection. The first joint replacement component 110 also includes multiple cutouts 119 that are in some embodiments useful for increasing the surface area for adhesion of the first joint replacement component 110 in a setting substance such as, for example, bone cement.

[0044] The intramedullary shaft 120 shown in FIG. 1 is configured to couple with the first joint replacement component 110 on a side 113 of the first joint replacement component 110 that is opposite from the articular surface 112. The intramedullary shaft 120 is coupled to the first joint replacement component 110 by a coupling element that does not transmit an appreciable moment force between the first joint replacement component 110 and the intramedullary shaft 120. In this embodiment, such coupling is achieved by press fitting the ball 116 of the intramedullary shaft 120 into the coupling mechanism 114 of the first joint

replacement component 110. In the embodiment illustrated in FIG. 1, the distal end 115 of the stub shaft 117 is curved to allow for cooperative movement within arc 118 near the proximal end of the intramedullary shaft 120. By this coupling, the ball 116 is allowed to rotate within the coupling mechanism 114, which within the operational scope of the movement of the joint replacement implant does not transmit any appreciable moment force between the first joint replacement component 110 and the intramedullary shaft 120. As used herein the term "appreciable" moment force means a moment force that is enough to potentially break or significantly damaged the coupling between the first joint replacement component 110 and the intramedullary shaft 120. Another way to describe an acceptable coupling between the first joint replacement component 110 and intramedullary shaft 120 would be any coupling or configuration that allows rotational displacement under loading such that an appreciable moment force is not transferred.

[0045] A joint replacement implant 200 is illustrated in FIGS. 2 and 3. The joint replacement implant 200 includes a first joint replacement component 210 and an intramedullary shaft 220. Embodiments of joint replacement implants and component parts disclosed herein may act as temporary replacement components in some embodiments. The first joint replacement component 210 includes an articular surface 212 on one side of the component 210. In the illustrated embodiment, the first joint replacement component 210 is a femoral component. The articular surface 212 is configured to articulate with another component of the joint replacement implant or with an anatomical surface. For example, the articular surface 212 may articulate with a surface of a tibial component, such as the component 110 illustrated in FIG. 1. By way of another example, certain implant articular surfaces may be configured to interact with an anatomical surface in partial joint replacement procedures. The first joint replacement component 210 includes a coupling mechanism 214 on the side of the first joint replacement component 210 opposite from the articular surface 212. In the illustrated embodiment, the coupling mechanism 214 is a snap fit connection into which a ball may be press fit to provide a secure connection.

[0046] The intramedullary shaft 220 shown in FIGS. 2 and 3 is configured to couple with the first joint replacement component 210 on a side 213 of the first joint replacement component 210 that is opposite from the articular surface 212. The intramedullary shaft 220 is coupled to the first joint replacement component 210 by a coupling element that does not transmit an

appreciable moment force between the first joint replacement component 210 and the intramedullary shaft 220. In this embodiment, such a coupling is achieved by press fitting the ball 216 of the intramedullary shaft 220 into the coupling mechanism 214 of the first joint replacement component 210. By this coupling, the ball 216 is allowed to rotate within the coupling mechanism 214, which within the operational scope of the movement of the joint replacement implant does not transmit any appreciable moment force between the first joint replacement component 210 and the intramedullary shaft 220. As used herein the term "appreciable" moment force means a moment force that is enough to potentially break or significantly damaged the coupling between the first joint replacement component 210 and the intramedullary shaft 220. Another way to describe an acceptable coupling between the first joint replacement component 210 and intramedullary shaft 220 would be any coupling or configuration that allows rotational displacement under loading such that an appreciable moment force is not transferred.

[0047] A joint replacement implant 300 is illustrated in FIGS. 4 and 5. The joint replacement implant 300 includes a first joint replacement component 310 and an intramedullary shaft 320. Embodiments of joint replacement implants and component parts disclosed herein may act as temporary replacement components in some embodiments. The first joint replacement component 310 includes an articular surface 312 on one side of the component 310. In the illustrated embodiment, the first joint replacement component 310 is a tibial component. The articular surface 312 shown is configured to articulate with another component of the joint replacement implant or with an anatomical surface. For example, the articular surface 312 may articulate with a surface of a femoral component, such as the femoral component 210 illustrated in FIGS. 2 and 3. By way of another example, certain implant articular surfaces may be configured to interact with an anatomical surface in partial joint replacement procedures. The first joint replacement component 310 includes a stub shaft 317 with a coupling mechanism 314 at a distal end of the stub shaft 317. In the illustrated embodiment, the coupling mechanism 314 is ball that may be pressed into a snap fit connection to connect the components. The first joint replacement component 310 also includes multiple cutouts 319 that are in some embodiments useful for increasing the surface area for adhesion of the first joint replacement component 310 in a setting substance such as, for example, bone cement.

[0048] The intramedullary shaft 320 shown in FIG. 5 is configured to couple with the first joint replacement component 310 on a side 313 of the first joint replacement component 310 that is opposite from the articular surface 312. The intramedullary shaft 320 is coupled to the first joint replacement component 310 by a coupling element that does not transmit an appreciable moment force between the first joint replacement component 310 and the intramedullary shaft 320. In this embodiment, such coupling is achieved by press fitting the ball of the coupling mechanism 314 of the stub shaft 317 into the snap fit connection 316 of the intramedullary shaft 320. By this coupling, the ball of the coupling mechanism 314 is allowed to rotate within the snap fit connection 316, which within the operational scope of the movement of the joint replacement implant does not transmit any appreciable moment force between the first joint replacement component 310 and the intramedullary shaft 320. As used herein the term "appreciable" moment force means a moment force that is enough to potentially break or significantly damaged the coupling between the first joint replacement component 310 and the intramedullary shaft 320. Another way to describe an acceptable coupling between the first joint replacement component 310 and intramedullary shaft 320 would be any coupling or configuration that allows rotational displacement under loading such that an appreciable moment force is not transferred. The intramedullary shaft 320 retrieval connector 325 is distal of the coupling mechanism 316. The retrieval connector 325 in this embodiment is a threaded hole and may be used to create a secure connection between a retrieval instrument (not shown) and the intramedullary shaft 320 to pull the intramedullary shaft 320 from an intramedullary canal.

[0049] A joint replacement implant 400 is illustrated in FIGS. 6-8, and is structured and configured very similar to the joint replacement implant 300 described immediately above. Thus, the joint replacement implant 400 will not be described separately herein except features that are different from the joint replacement implant 300. The illustrations of FIGS. 6-8 are instructive regarding an exemplary interaction of the joint replacement implant 400 with a tibia 20. In the illustrated embodiment, the tibia 20 includes a defect 25 (FIGS. 6 and 8) near its proximal end. The defect 25 may be filled with cement intraoperatively. However, there may be a significant chance that cement would enter the coupling between the first joint replacement component 410 and the intramedullary shaft 420 to stiffen the coupling and increase the risk of moment transfer between the components and subsequent breakage. To avoid this potential problem, a shroud 470 may be attached around the coupling between the first joint replacement

component 410 and the intramedullary shaft 420 to restrict setting material, such as cement, from entering the coupling between the first joint replacement component 410 and the intramedullary shaft 420. Some embodiments of the shroud 470 may be made from an elastomeric material that can be fit tightly around at least a portion of the first joint replacement component 410. Any other effective shape or type of material may be used with other embodiments.

[0050] A joint replacement implant 500 is illustrated in FIGS. 10-13. The joint replacement implant 500 includes a first joint replacement component 510 and an intramedullary shaft 520. Embodiments of joint replacement implants and component parts disclosed herein may act as temporary replacement components in some embodiments. The first joint replacement component 510 includes an articular surface 512 on one side of the component 510. In the illustrated embodiment, the first joint replacement component 510 is a tibial component. The articular surface 512 shown is configured to articulate with another component of the joint replacement implant or with an anatomical surface. For example, the articular surface 512 may articulate with a surface of a femoral component, such as the femoral component 210 illustrated in FIGS. 2 and 3. By way of another example, certain implant articular surfaces may be configured to interact with an anatomical surface in partial joint replacement procedures. The first joint replacement component 510 includes a stub shaft 517 with a socket 514. The first joint replacement component 510 also includes multiple cutouts 519 that are in some embodiments useful for increasing the surface area for adhesion of the first joint replacement component 510 in a setting substance such as bone cement.

[0051] The intramedullary shaft 520 shown in FIGS. 11-13 is configured to couple with the first joint replacement component 510 on a side 513 of the first joint replacement component 510 opposite from the articular surface 512. The intramedullary shaft 520 is coupled to the first joint replacement component 510 by a coupling element that does not transmit an appreciable moment force between the first joint replacement component 510 and the intramedullary shaft 520. In this embodiment, such a coupling is achieved by passing a partial ball 516 with a diameter near the proximal end of the intramedullary shaft 520 through an opening in the socket 514, where the diameter of the partial ball 516 near the proximal end of the intramedullary shaft 520 will pass into the socket but will not pass through a distal end of the stub 517.

[0052] By this coupling, the partial ball 516 is allowed to rotate within the socket 514, which within the operational scope of the movement of the joint replacement implant does not

transmit any appreciable moment force between the first joint replacement component 510 and the intramedullary shaft 520. As used herein the term "appreciable" moment force means a moment force that is enough to potentially break or significantly damaged the coupling between the first joint replacement component 510 and the intramedullary shaft 520. Another way to describe an acceptable coupling between the first joint replacement component 510 and intramedullary shaft 520 would be any coupling or configuration that allows rotational displacement under loading such that an appreciable moment force is not transferred.

[0053] A joint replacement implant 600 is illustrated in FIGS. 14 and 15. The joint replacement implant 600 includes a first joint replacement component 610 and an intramedullary shaft 620. Embodiments of joint replacement implants and component parts disclosed herein may act as temporary replacement components in some embodiments. The first joint replacement component 610 includes an articular surface 612 on one side of the component 610. In the illustrated embodiment, the first joint replacement component 610 is a femoral component. The articular surface 612 is configured to articulate with another component of the joint replacement implant or with an anatomical surface. For example, the articular surface 612 may articulate with a surface of a tibial component, such as the component 110 illustrated in FIG. 1. By way of another example, certain implant articular surfaces may be configured to interact with an anatomical surface in partial joint replacement procedures. The first joint replacement component 610 includes a coupling mechanism 614 on the side of the first joint replacement component 610 opposite from the articular surface 612. In the illustrated embodiment, the coupling mechanism 614 is a slotted connector.

[0054] The first joint replacement component 610 illustrated in FIG. 15 includes a removal connector 619 to which an instrument may be coupled to detach the first joint replacement component 610 from a bone against which the first joint replacement component 610 is placed. The illustrated removal connector 619 is configured as a slot, but may have any other effective or suitable shape.

[0055] The intramedullary shaft 620 shown in FIGS. 14 and 15 is configured to couple with the first joint replacement component 610 on a side 613 of the first joint replacement component 610 that is opposite from the articular surface 612. The intramedullary shaft 620 is coupled to the first joint replacement component 610 by a coupling element that does not transmit an appreciable moment force between the first joint replacement component 610 and the

intramedullary shaft 620 in at least the medial-lateral direction. In this embodiment, such a coupling is achieved by providing a slotted connector that has a slot with a wider deep portion 630 and a narrower portion 631 located further away from a center of the first joint replacement component 610. The intramedullary shaft 620 includes a cylinder 616 with a longitudinal axis arranged substantially perpendicular to a longitudinal axis of the intramedullary shaft 620, wherein the cylinder 616 is configured to fit longitudinally in the wider deep portion 630 of the slot, but will not pass through the narrower portion 631 of the slot.

[0056] By this coupling, the cylinder 616 is allowed to rotate within the slot, which within the operational scope of the movement of the joint replacement implant does not transmit any appreciable moment force between the first joint replacement component 610 and the intramedullary shaft 620. As used herein the term "appreciable" moment force means a moment force that is enough to potentially break or significantly damaged the coupling between the first joint replacement component 610 and the intramedullary shaft 620. Another way to describe an acceptable coupling between the first joint replacement component 610 and intramedullary shaft 620 would be any coupling or configuration that allows rotational displacement under loading such that an appreciable moment force is not transferred.

[0057] A group of similar joint replacement implants 700, 800, 900, 1100 is illustrated in FIGS. 16-20 and 24. The implants are similar in that couplings between a first joint replacement component 710, 810, 910, 1110 and an intramedullary shaft 720, 820, 920, 1120 are made with flexible connectors that achieve the goal of a lowered moment connection stress by allowing the respective connectors to flex. The embodiments differ relative to the specific configurations of the connectors. The group will be discussed collectively herein with indications regarding differences among the group.

[0058] The joint replacement implant 700, 800, 900, 1100 includes a first joint replacement component 710, 810, 910, 1110 and an intramedullary shaft 720, 820, 920, 1120. Embodiments of joint replacement implants and component parts disclosed herein may act as temporary replacement components in some embodiments. The first joint replacement component 710, 810, 910, 1110 includes an articular surface 712, 812, 912, 1112 on one side of the component 710, 810, 910, 1110. In the illustrated embodiment, the first joint replacement component 710, 810, 910, 1110 is a tibial component. The articular surface 712, 812, 912, 1112 shown is configured to articulate with another component of the joint replacement implant or

with an anatomical surface. For example, the articular surface 712, 812, 912, 1112 may articulate with a surface of a femoral component, such as the femoral component 210 illustrated in FIGS. 2 and 3. By way of another example, certain implant articular surfaces may be configured to interact with an anatomical surface in partial joint replacement procedures.

[0059] The intramedullary shaft 720, 820, 920, 1120 is configured to couple with the first joint replacement component 710, 810, 910, 1110 on a side 713, 813, 913, 1113 of the first joint replacement component 710, 810, 910, 1110 that is opposite from the articular surface 712, 812, 912, 1112. The intramedullary shaft 720, 820, 920, 1120 is coupled to the first joint replacement component 710, 810, 910, 1110 by a coupling that does not transmit an appreciable moment force between the first joint replacement component 710, 810, 910, 1110 and the intramedullary shaft 720, 820, 920, 1120. As used herein the term "appreciable" moment force means a moment force that is enough to potentially break or significantly damaged the coupling between the first joint replacement component 710, 810, 910, 1110 and the intramedullary shaft 720, 820, 920, 1120. Another way to describe an acceptable coupling between the first joint replacement component 710, 810, 910, 1110 and intramedullary shaft 720, 820, 920, 1120 would be any coupling or configuration that allows rotational displacement under loading such that an appreciable moment force is not transferred.

[0060] In the embodiment of FIG. 16, such coupling is achieved with a first joint replacement component 710 that includes a hole 717, and the intramedullary 720 shaft includes a flexible element 714 that passes through the length of the intramedullary shaft 720 and couples with the first joint replacement component 710 through the hole 717 in the first joint replacement component 710. The flexible element 714 may be a cable or other multi-strand component, or may be configured as a monofilament. The flexible element 714 may be made of any effective or suitable material type to provide coupling while allowing some movement between the components. A nut 715 is shown that may be used to secure the flexible element 714 in place at any desired level of tension within the strength capabilities of the flexible element 714. By this coupling, the first joint replacement component 710 is allowed to rotate relative to the intramedullary shaft 720 according to the flexibility of the flexible element 714, and consequently does not transmit any appreciable moment force between the first joint replacement component 710 and the intramedullary shaft 720.

[0061] In the embodiment of FIGS. 17-19, such coupling is achieved with a resilient connector 814, 914 between the first joint replacement component 810, 910 and the intramedullary shaft 820, 920. In this configurations, the resilient connector 814, 914 bends in response to moment forces in the intramedullary shaft 820, 920 relative to the first joint replacement component 810, 920. The resilient connector 814 is molded into the intramedullary shaft 820 and includes a threaded end 819 on which a nut 815 may be placed to secure the components. The resilient connector 914 is placed through a hole in the first joint replacement component 910 and threaded into the intramedullary shaft 920 to secure the components. In these embodiments, the moment strength of the coupling between the first joint replacement component 810, 910 and the intramedullary shaft 820, 920 is controlled by the flexibility of the resilient connector 814, 914. Therefore, with the selection of appropriately flexible materials for the resilient connector 814, 914, the coupling does not transmit any appreciable moment force between the first joint replacement component 810, 910 and the intramedullary shaft 820, 920.

[0062] In the embodiment of FIG. 24, such a coupling is achieved with a resilient washer 1114 positioned between the coupling of the first joint replacement component 1110 and the intramedullary shaft 1120. The resilient washer 1114 is compressible and allows relative movement between the intramedullary shaft 1120 and the first joint replacement component 1110 in response to moment forces between the intramedullary shaft 1120 and the first joint replacement component. A bolt 1116 is embedded in the intramedullary shaft 1120, the first joint replacement component 1110 is placed over the bolt 1116 and against the resilient washer 1114, and a nut 1115 is put on the bolt 1116 to secure the components. Therefore, with the selection of appropriately flexible materials for the resilient washer 1114, the coupling does not transmit any appreciable moment force between the first joint replacement component 1110 and the intramedullary shaft 1120.

[0063] A joint replacement implant 1000 is illustrated in FIGS. 21-23. The joint replacement implant 1000 includes a first joint replacement component 1010 and an intramedullary shaft 1020. Embodiments of joint replacement implants and component parts disclosed herein may act as temporary replacement components in some embodiments. The first joint replacement component 1010 includes an articular surface 1012 on one side of the component 1010. In the illustrated embodiment, the first joint replacement component 1010 is a tibial component. The articular surface 1012 is configured to articulate with another component

of the joint replacement implant or with an anatomical surface. For example, the articular surface 1012 may articulate with a surface of a femoral component, such as the femoral component 210 illustrated in FIGS. 2 and 3. By way of another example, certain implant articular surfaces may be configured to interact with an anatomical surface in partial joint replacement procedures.

[0064] The first joint replacement component 1010 includes a hole with an articular surface along walls of the hole, which is configured as a slot 1013 in the illustrated embodiment. The implant also includes a connector 1014 with an articular surface portion 1015 that may be spherical or tapered. The connector 1014 passes through the first joint replacement component 1010 and couples with the intramedullary shaft 1020. The articular surface along walls of the slot 1013 through the first joint replacement component 1010 provides an articulating joint with the articular surface 1015 of the connector 1014. By this coupling, first joint replacement component 1010 and the intramedullary shaft 1020 are allowed to articulate relative to one another, and do not transmit any appreciable moment force between them. As used herein the term "appreciable" moment force means a moment force that is enough to potentially break or significantly damaged the coupling between the first joint replacement component 1010 and the intramedullary shaft 1020. Another way to describe an acceptable coupling between the first joint replacement component 1010 and intramedullary shaft 1020 would be any coupling or configuration that allows rotational displacement under loading such that an appreciable moment force is not transferred.

[0065] An intramedullary shaft 120, 220, 320, 420, 520, 620, 720, 820, 920, 1020, 1120 is configured to penetrate a medullary canal of the bone to which a joint replacement implant or one of its components 110, 210, 310, 410, 510, 610, 710, 810, 910, 1010, 1110 is configured to attach. In some embodiments, the intramedullary shaft is at least 100 mm long, while in other embodiments the intramedullary shaft is at least 200 mm long. In still further embodiments, the intramedullary shaft may be at least 300 mm long, or as long as necessary to reach the extents of the intramedullary canal.

[0066] Any disclosed intramedullary shaft 120, 220, 320, 420, 520, 620, 720, 820, 920, 1020, 1120 may be made at least in part from cement. In particular, an intramedullary shaft may be made at least in part from polymethylmethacrylate (PMMA). As noted above with regard to prior art temporary spacers, the intramedullary shaft 120, 220, 320, 420, 520, 620, 720, 820, 920,

1020, 1120 may include therapeutic pharmaceuticals. In particular the therapeutic pharmaceutical included may include an antibiotic.

[0067] Devices for making a cement intramedullary shaft are illustrated in FIGS. 25-33. A tubular shell 40, 49 configured to contain a setting material that may be placed within the tubular shell 40, 49 is illustrated in each of the four embodiments. An insert 50 sized to fit at least partially within the tubular shell 40 is depicted in FIG. 26. The insert 50 also includes a coupling mechanism 16 to which another component may be coupled to form a coupling that does not, in at least one plane, transmit an appreciable moment force. The coupling mechanism 16 is a snap fit connection into which a ball may be press fit to provide a secure connection, as shown in a similar connection illustrated in FIG. 5. A retrieval connector 25 positioned distal of the coupling mechanism 16 is also shown in FIG. 26. The retrieval connector 25 in this embodiment is a threaded hole and may be used to create a secure connection between a retrieval instrument (not shown) and the intramedullary shaft to pull the intramedullary shaft from an intramedullary canal. In other embodiments, rather than a socket, the coupling mechanism may be configured as a ball, a partial ball, a loop, a threaded socket, a threaded bolt, or any other effective mechanism. The insert 50 includes shapes 55 along its length that resist pullout from a setting material. The shapes 55 provide flat faces against which the insert 50 is anchored in the setting material. Other embodiments may include any other configurations that provide resistance to pullout.

[0068] An insert 60 sized to fit at least partially within the tubular shell 40 is illustrated in FIGS. 28 and 29. The insert 60 also includes a coupling mechanism 16 to which another component may be coupled to form a coupling that does not, in at least one plane, transmit an appreciable moment force. The coupling mechanism 16 is a snap fit connection into which a ball may be press fit to provide a secure connection, as shown in a similar connection illustrated in FIG. 5. A retrieval connector 25 positioned distal of the coupling mechanism 16 is also shown in FIG. 28. The retrieval connector 25 in this embodiment is configured as a threaded hole, and may be used to create a secure connection between a retrieval instrument (not shown) and the intramedullary shaft to pull the intramedullary shaft from an intramedullary canal. In other embodiments, rather than a socket, the coupling mechanism may be configured as a ball, a partial ball, a loop, a threaded socket, a threaded bolt, or any other effective or suitable mechanism. The insert 60 includes shapes 65, 66 along its length that resist pullout from a setting material. The

shapes 65, 66 provide flat faces against which the insert 60 is anchored in the setting material. There are gaps 67 between the shapes 66 that provide channels for flow of the setting material. Other embodiments may include any other configuration that provides resistance to pullout.

[0069] An insert 70 at least partially positioned within the tubular shell 40 is illustrated in FIGS. 30 and 31. The insert 70 also includes a coupling mechanism 76 to which another component may be coupled to form a coupling that does not, in at least one plane, transmit an appreciable moment force. The coupling mechanism 76 is configured as a loop to which another component may be coupled. In other embodiments, rather than a loop, the coupling mechanism may be configured as a ball, a partial ball, a socket, a threaded socket, a threaded bolt, or any other effective or suitable mechanism. The insert 70 includes shapes 75 that resist pullout from a setting material. Other embodiments may include any other configuration that provides resistance to pullout.

[0070] An insert 80 at least partially positioned within the tubular shell 49 is illustrated in FIGS. 32 and 33. The insert 80 also includes a coupling mechanism 86 to which another component may be coupled to form a coupling that does not, in at least one plane, transmit an appreciable moment force. The coupling mechanism 86 is configured as a loop to which another component may be coupled. In other embodiments, rather than a loop, the coupling mechanism may be configured as a ball, a partial ball, a socket, a threaded socket, a threaded bolt, or any other effective mechanism. The insert 80 includes shapes 85 and a cable 87 that resist pullout from a setting material. In addition to providing surface area for pullout resistance and additional structural strength to the intramedullary shaft, the cable 87 extends beyond the distal end of the setting material, and may be used as a structural element beyond the end of the setting material. Other embodiments may include any other configuration of shapes to provide resistance to pullout.

[0071] Embodiments of the tubular shell 40, 49 are frangible along its length at predetermined lengths, as illustrated in FIGS. 25, 27, 30, and 32 by lines 41, 42, and 43. The tubular shell 40, 49 may be a reduced thickness at these locations so that a designate length intramedullary shaft may be created by removing portions of the tubular shell. In other embodiments, the lines or marks 41, 42, and 43 may be markings at designated lengths at which cuts may be made with another instrument to select a length of tubular shell to be used to make an intramedullary shaft.

[0072] Various embodiments of devices described herein wholly, or their parts individually, may be made from any biocompatible material. The medical implant of some embodiments is capable of undergoing one or more steam sterilization cycles, or other sterilization procedures, without degrading in a manner that would make the implant unsuitable for use in a medical procedure. For example and without limitation, biocompatible materials may include, in whole or in part, non-reinforced polymers, reinforced polymers, metals, ceramics and/or combinations of these materials. Reinforcing of polymers may be accomplished with carbon, metal, or glass or any other effective material. Examples of biocompatible polymer materials include polyamide base resins, polyethylene, low density polyethylene, polymethylmethacrylate (PMMA), polyetheretherketone (PEEK), polyetherketoneketone (PEKK), a polymeric hydroxyethylmethacrylate (PHEMA), and polyurethane, any of which may be reinforced. Example biocompatible metals include stainless steel and other steel alloys, cobalt chrome alloys, tantalum, titanium, titanium alloys, titanium-nickel alloys such as Nitinol and other superelastic or shape-memory metal alloys. Components described herein may be formed by conventional milling or casting processes, by any type of three-dimensional printing or deposition based processes, or by any effective process.

[0073] Terms such as proximal, distal, side, and the like have been used relatively herein. However, such terms are not limited to specific coordinate orientations, but are used to describe relative positions referencing particular embodiments. Such terms are not generally limiting to the scope of the claims made herein. Any embodiment or feature of any section, portion, or any other component shown or particularly described in relation to various embodiments of similar sections, portions, or components herein may be interchangeably applied to any other similar embodiment or feature shown or described herein.

[0074] As various modifications could be made to the exemplary embodiments, as described above with reference to the corresponding illustrations, without departing from the scope of the invention, it is intended that all matter contained in the foregoing description and shown in the accompanying drawings shall be interpreted as illustrative rather than limiting. Thus, the breadth and scope of the invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the claims and their equivalents.

What is claimed is:

1. A joint replacement implant, comprising:

a first joint replacement component with an articular surface on one side configured to articulate with another component of the joint replacement implant or an anatomical surface; and

an intramedullary shaft configured to couple with the first joint replacement component on another side of the first joint replacement component other than the one side with an articular surface and configured to penetrate a medullary canal of a bone to which the joint replacement implant is configured to attach;

wherein the intramedullary shaft is coupled to the first joint replacement component by a coupling that does not transmit an appreciable moment force between the first joint replacement component and the intramedullary shaft.

2. The joint replacement implant of claim 1, wherein the first joint replacement component is a tibial component.

3. The joint replacement implant of claim 1, wherein the first joint replacement component is or a femoral component.

4. The joint replacement implant of claim 1, wherein the first joint replacement component includes a stub shaft with a coupling at a distal end of the stub shaft configured to couple with the intramedullary shaft.

5. The joint replacement implant of claim 4, wherein the stub shaft includes a socket and the intramedullary shaft includes a partial ball with a diameter near its proximal end that is configured to couple with the socket in the stub shaft by passing through an opening to the socket in a side of the stub shaft, but not passing through a distal end of the stub shaft.

6. The joint replacement implant of claim 1, wherein the first joint replacement component includes a removal connector to which an instrument may be coupled to detach the first joint replacement component from a bone against which the first joint replacement component is configured to be placed.

7. The joint replacement implant of claim 6, wherein the removal connector is a slot.

8. The joint replacement implant of claim 6, wherein the removal connector is a threaded hole.

9. The joint replacement implant of claim 6, wherein the removal connector is a threaded bolt.

10. The joint replacement implant of claim 1, wherein the intramedullary shaft is at least 100 mm long.

11. The joint replacement implant of claim 1, wherein the intramedullary shaft is at least 200 mm long.

12. The joint replacement implant of claim 1, wherein the intramedullary shaft is at least 300 mm long.

13. The joint replacement implant of claim 1, wherein the intramedullary shaft is coupled with the first joint replacement component on the opposite side of the first joint replacement component from the articular surface.

14. The joint replacement implant of claim 1, wherein the intramedullary shaft is made at least in part from cement.

15. The joint replacement implant of claim 14, wherein the cement includes polymethylmethacrylate (PMMA).

16. The joint replacement implant of claim 1, wherein the intramedullary shaft includes therapeutic pharmaceuticals.

17. The joint replacement implant of claim 16, wherein the therapeutic pharmaceuticals include antibiotics.

18. The joint replacement implant of claim 1, wherein the first joint replacement component includes a socket and the intramedullary shaft includes a ball near its proximal end that is configured to couple with the socket in the first joint replacement component.

19. The joint replacement implant of claim 1, wherein the first joint replacement component includes a ball and the intramedullary shaft includes a socket near its proximal end that is configured to couple with the ball in the first joint replacement component.

20. The joint replacement implant of claim 1, wherein the first joint replacement component includes a slot with a wider deep portion and a narrower portion positioned further away from a center of the first joint replacement component, wherein the intramedullary shaft includes a cylinder with a longitudinal axis arranged substantially perpendicular to a longitudinal axis of the intramedullary shaft, and wherein the cylinder is configured to fit longitudinally in the slot but will not pass through the narrower portion of the slot.

21. The joint replacement implant of claim 1, wherein the first joint replacement component includes a hole and the intramedullary shaft includes a flexible element that passes through a length of the intramedullary shaft and couples with the first joint replacement component through the hole in the first joint replacement component.

22. The joint replacement implant of claim 1, further comprising a resilient connector between the first joint replacement component and the intramedullary shaft, and wherein the resilient connector bends in response to moment forces in the intramedullary shaft relative to the first joint replacement component.

23. The joint replacement implant of claim 1, further comprising a resilient washer disposed between the connection of the first joint replacement component and the intramedullary shaft, and wherein the resilient washer is compressible and allows relative movement between

the intramedullary shaft and the first joint replacement component in response to moment forces between the intramedullary shaft and the first joint component.

24. The joint replacement implant of claim 1, further comprising a connector with an articular surface portion, wherein the connector passes through the first joint replacement component and couples with the intramedullary shaft, and wherein the first joint component includes a cooperating articular surface to provide an articulating joint with the articular surface of the connector.

25. The joint replacement implant of claim 1, further comprising a shroud configured to attach around the coupling between the first joint replacement component and the intramedullary shaft to restrict setting material from entering the coupling between the first joint replacement component and the intramedullary shaft.

26. The joint replacement implant of claim 1, further comprising a second joint replacement component that articulates with the first joint replacement component and is configured to couple with a different bone.

27. The joint replacement implant of claim 1, further comprising an intramedullary shaft configured to couple with the second joint replacement component and also configured to penetrate a medullary canal of a bone to which the second joint replacement component is configured to attach.

28. A joint replacement system, comprising:

a first joint replacement component with an articular surface on one side of the component, wherein the first joint replacement component is configured to couple with a bone;

a second joint replacement component that articulates with the first joint replacement component and is configured to couple with a different bone;

at least one intramedullary shaft configured to couple with the first joint replacement component or the second joint replacement component;

wherein the at least one intramedullary shaft is coupled to the first or second joint replacement components by a coupling that does not transmit an appreciable moment force between the first joint replacement component and the intramedullary shaft; and

wherein the at least one intramedullary shaft includes an antibiotic agent.

29. The joint replacement system of claim 28, wherein the intramedullary shaft is at least in part made from cement.

30. The joint replacement system of claim 28, wherein there are two intramedullary shafts, one configured to couple with the first joint replacement component, and another configured to couple with the second joint replacement component.

31. A device for making an intramedullary shaft, comprising:

a tubular shell configured to contain a setting material that may be placed within the tubular shell; and

an insert sized to fit at least partially within the tubular shell, wherein the insert includes a coupling mechanism to which another component may be coupled to form a coupling that does not, in at least one plane, transmit an appreciable moment force.

32. The device of claim 31, wherein the tubular shell is frangible along its length at predetermined lengths so that a designated length intramedullary shaft may be created by removing portions of the tubular shell.

33. The device of claim 31, wherein the tubular shell is marked along its length at predetermined lengths so that a designated length intramedullary shaft may be created by cutting the tubular shell at the marks.

34. The device of claim 31, wherein the coupling mechanism of the insert includes one or more of a ball, a partial ball, a socket, a loop, a threaded socket, and a threaded bolt.

35. The device of claim 31, wherein the insert includes a shape along its length that resists pullout from the setting material.

36. The device of claim 31, wherein the insert includes an elongated element that extends beyond the distal end of the setting material.

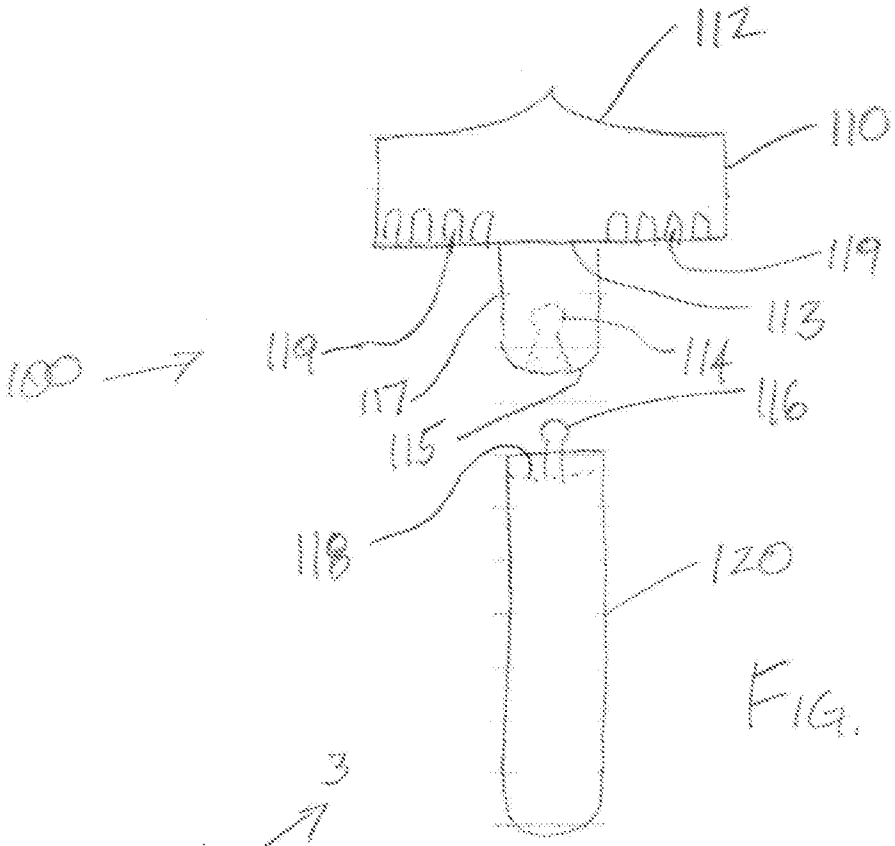

FIG. 1

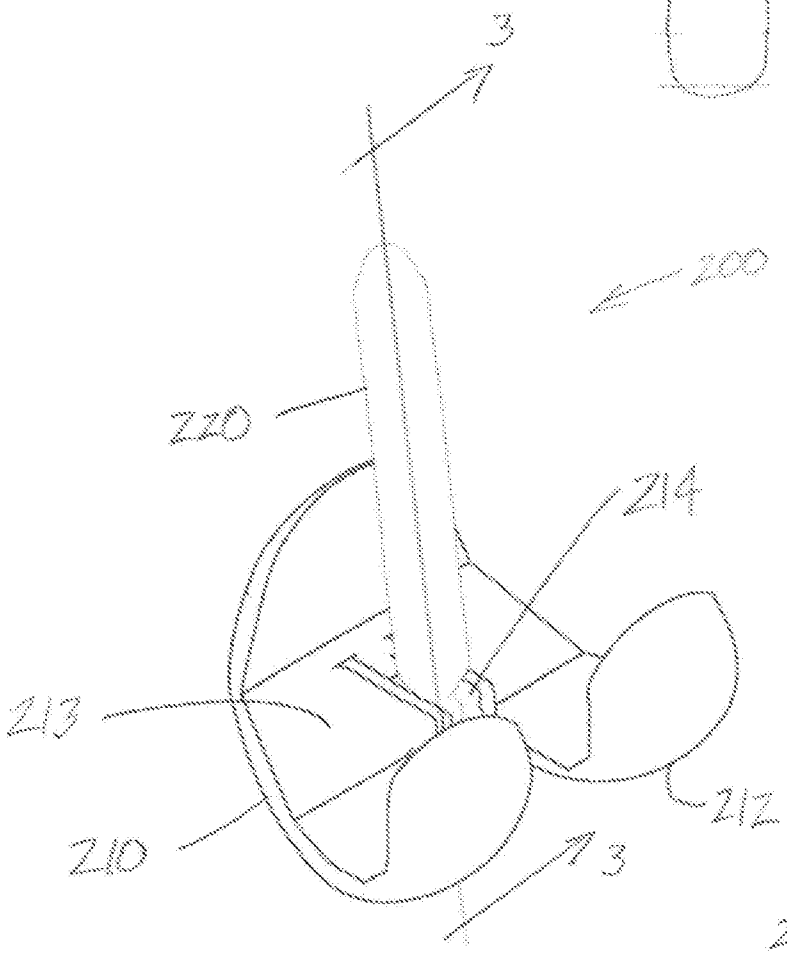

FIG. 2

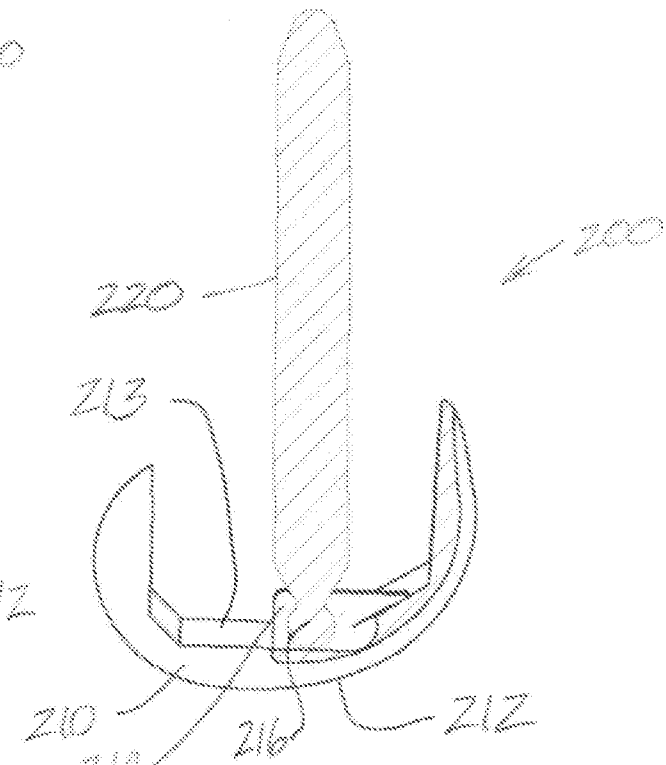

FIG. 3

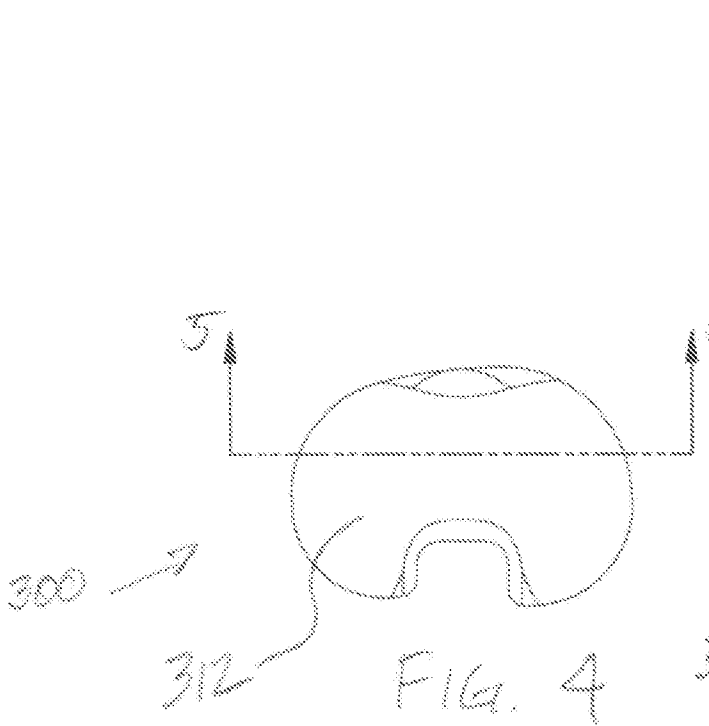

Fig. 4

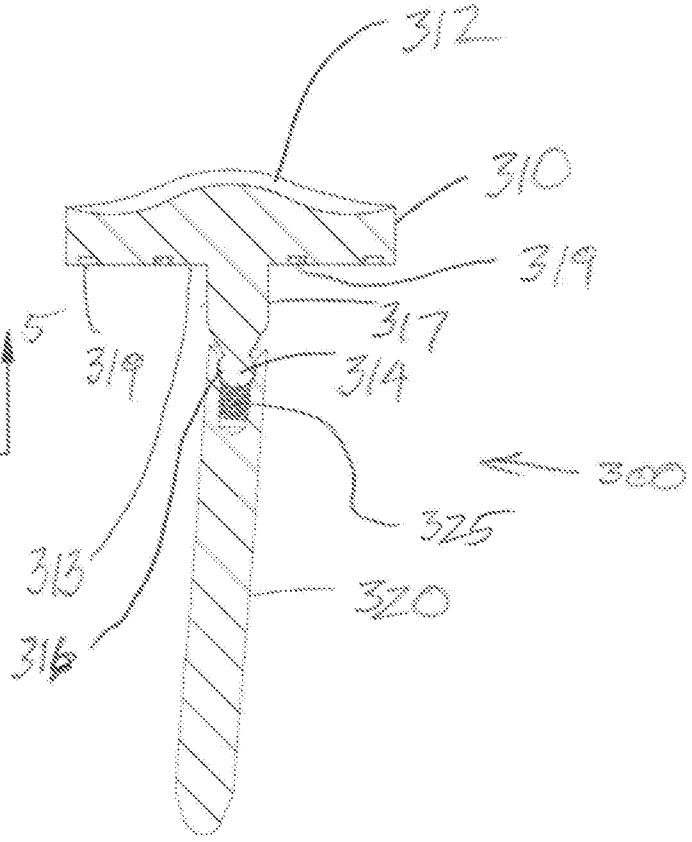

Fig. 5

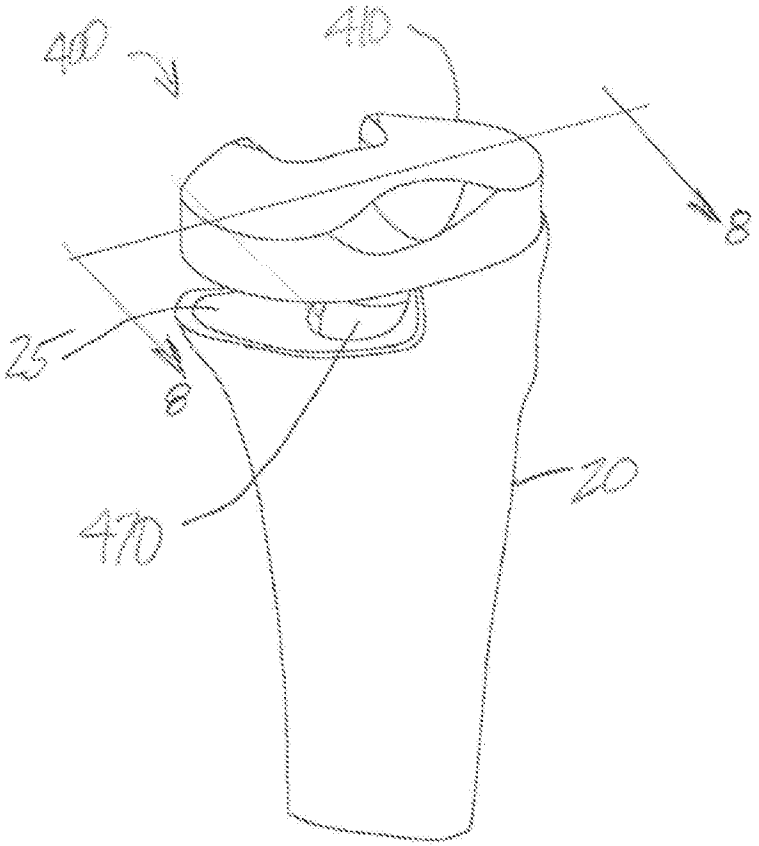

Fig. 6

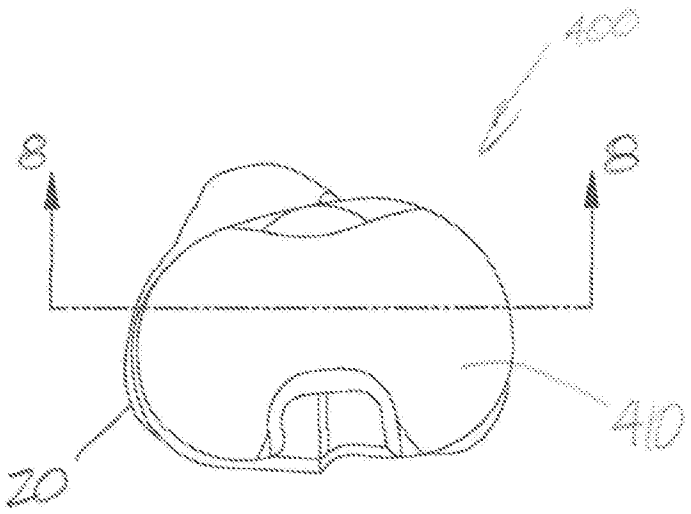

Fig. 7

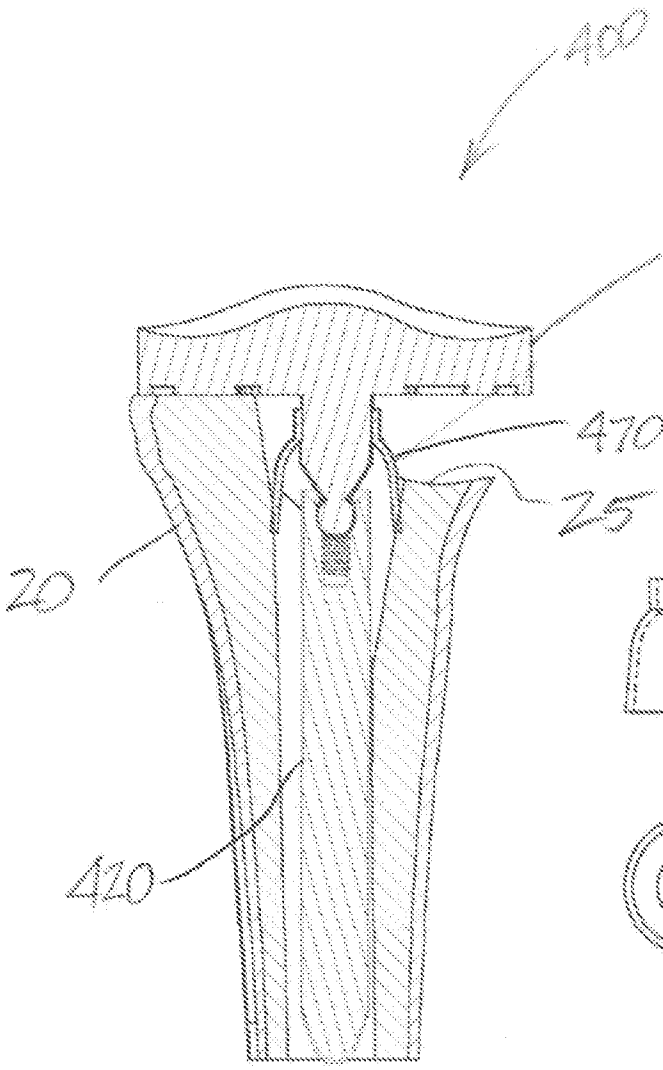

Fig. 8

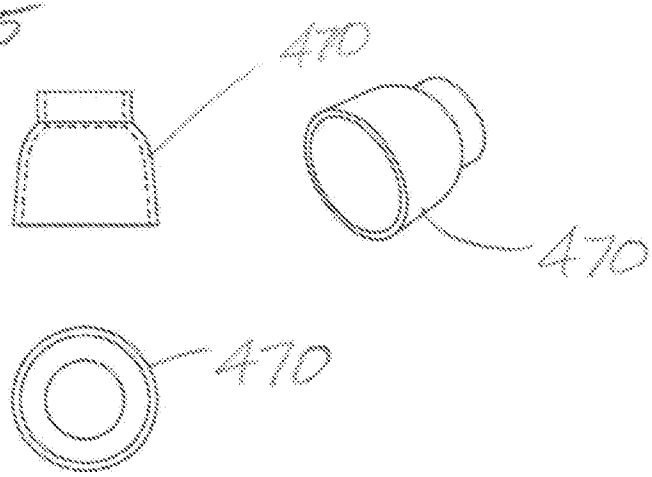

Fig. 9

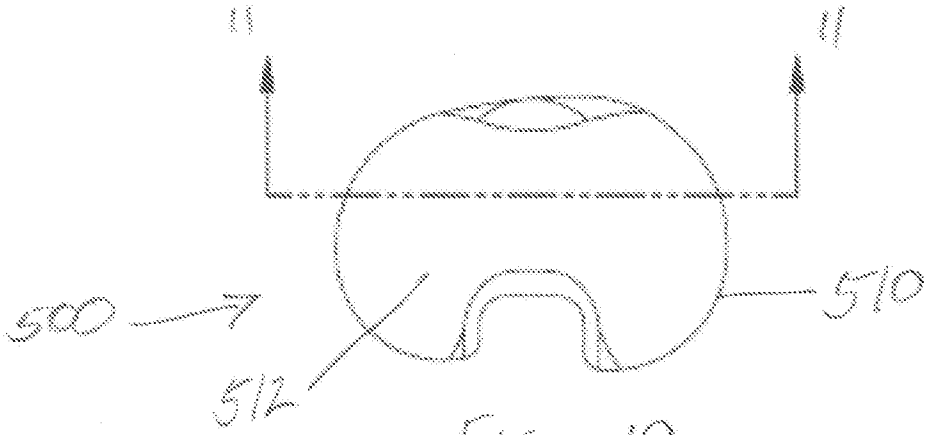

Fig. 10

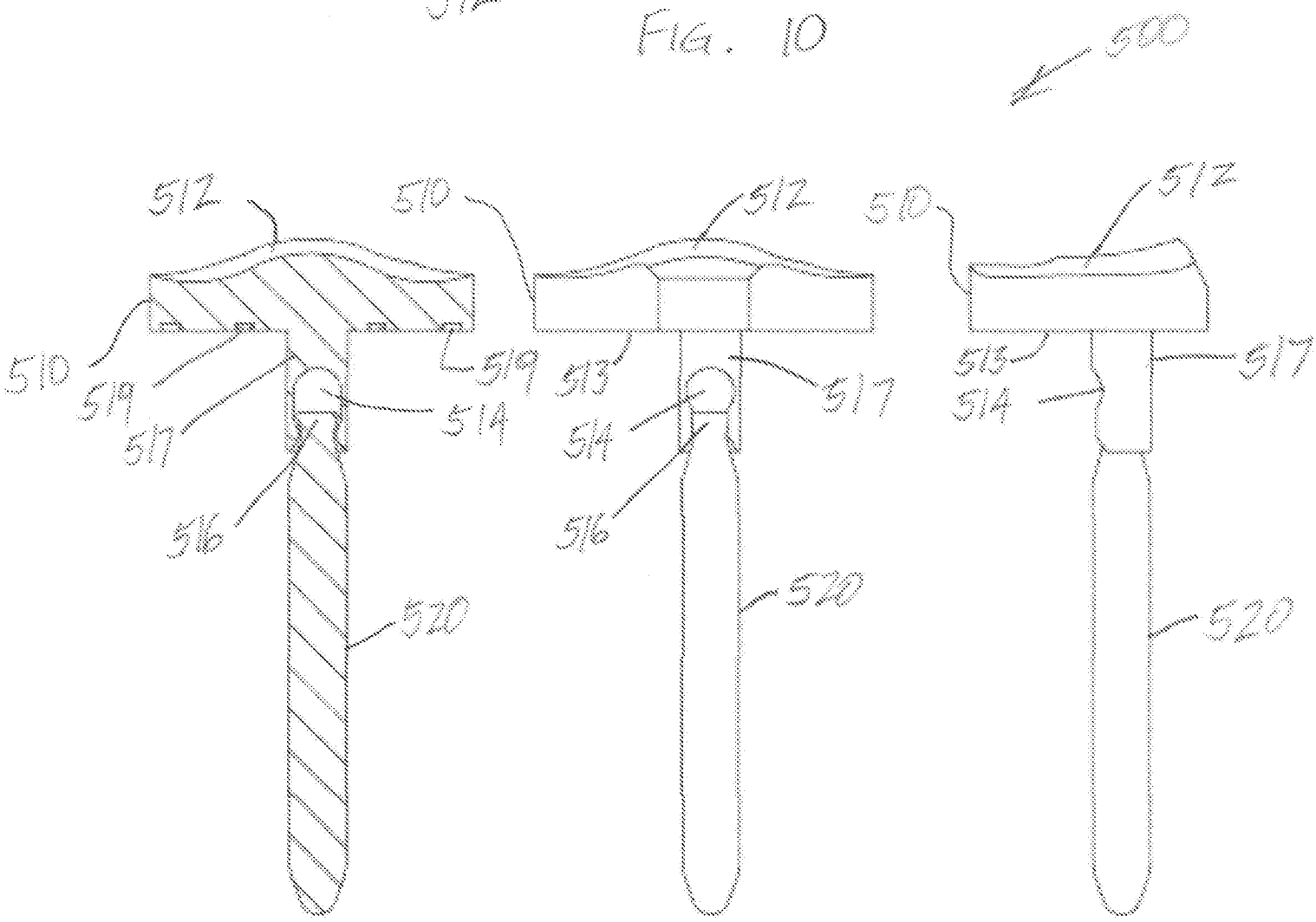

Fig. 11 Fig. 12 Fig. 13

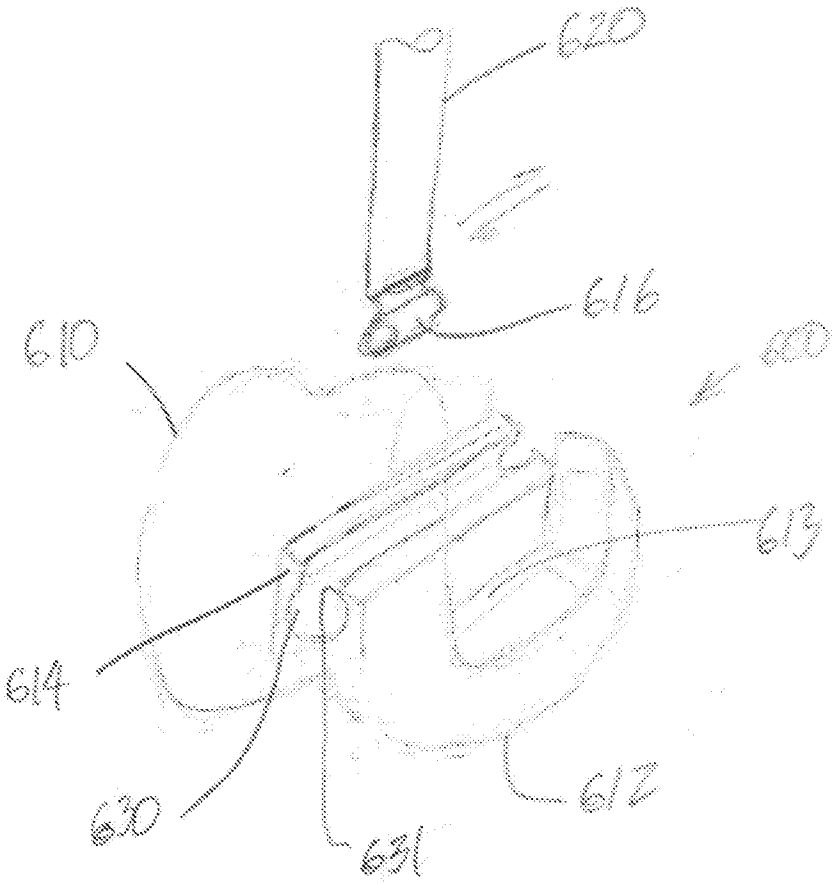

FIG. 14

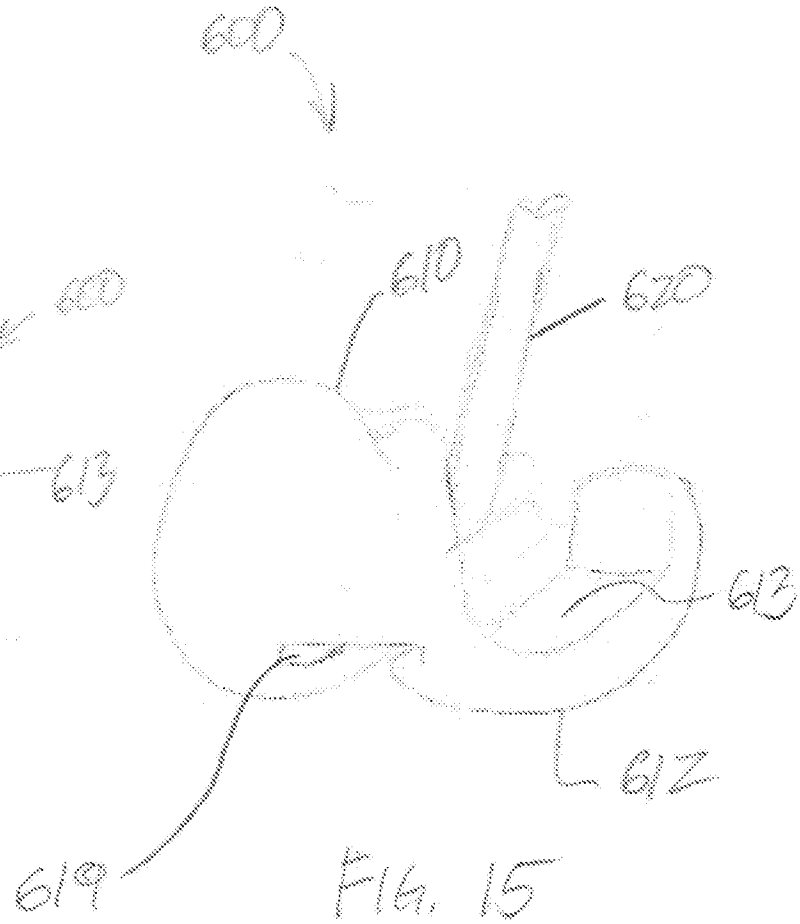

FIG. 15

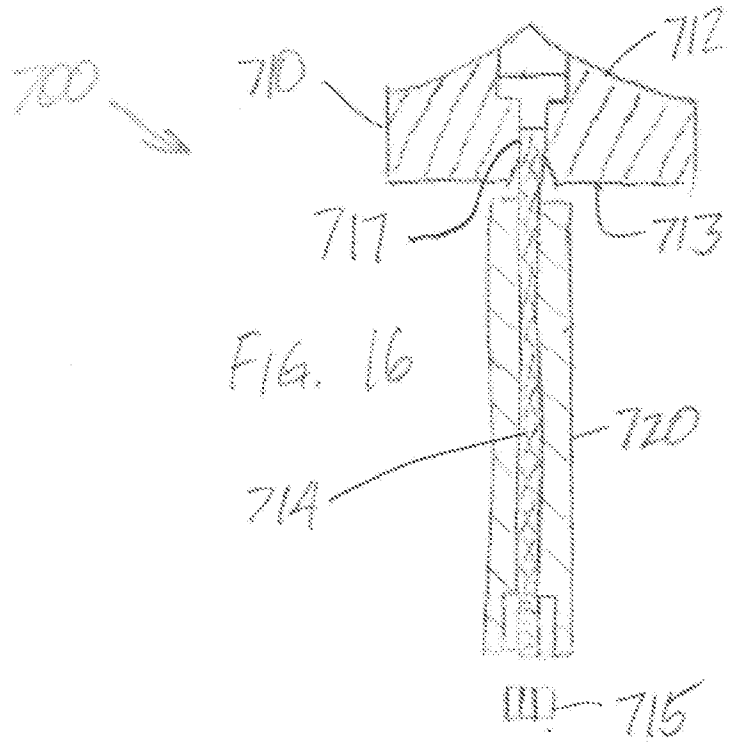

FIG. 16

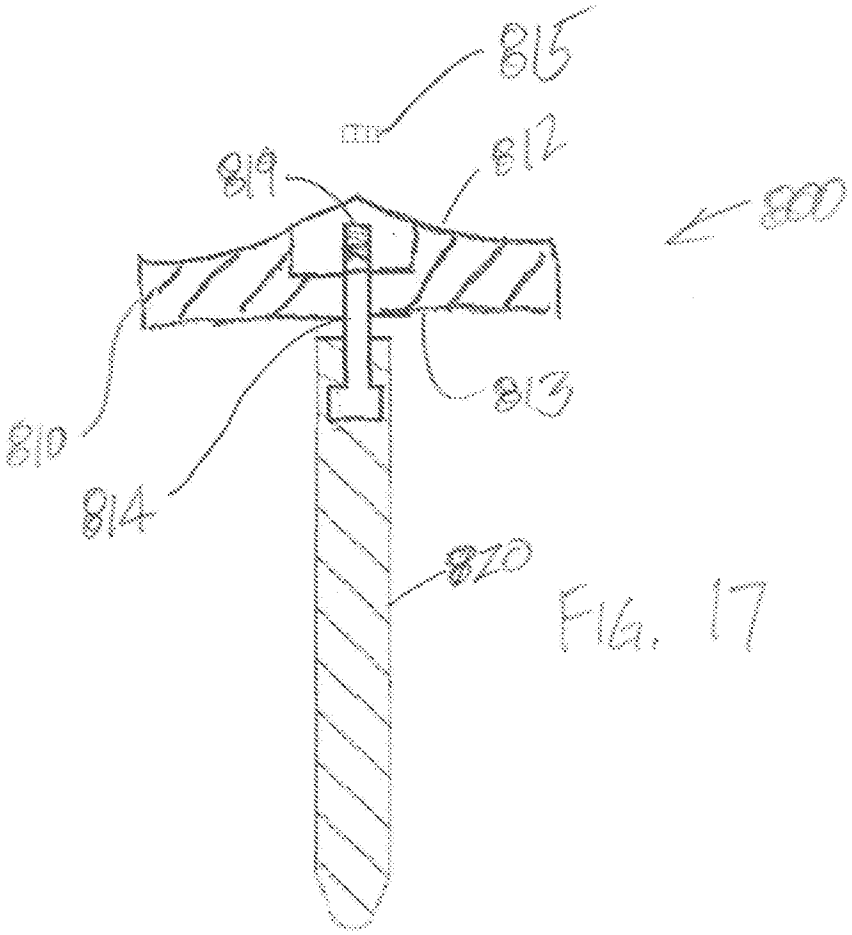

FIG. 17

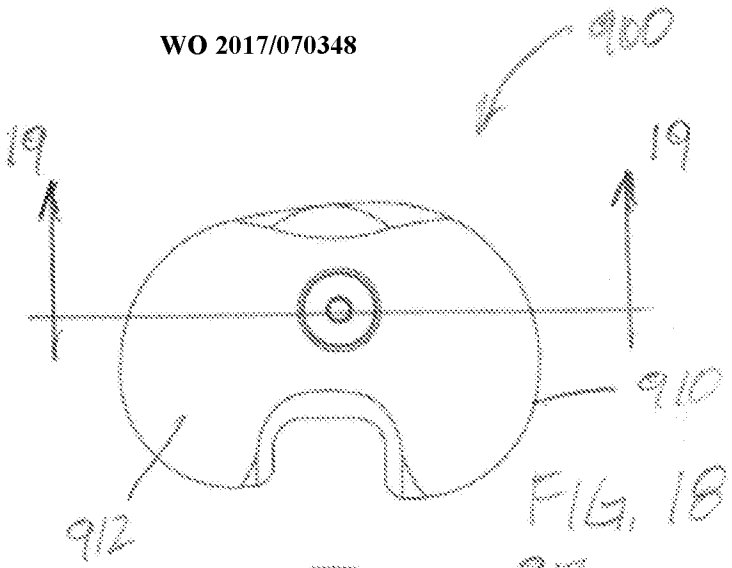

FIG. 18

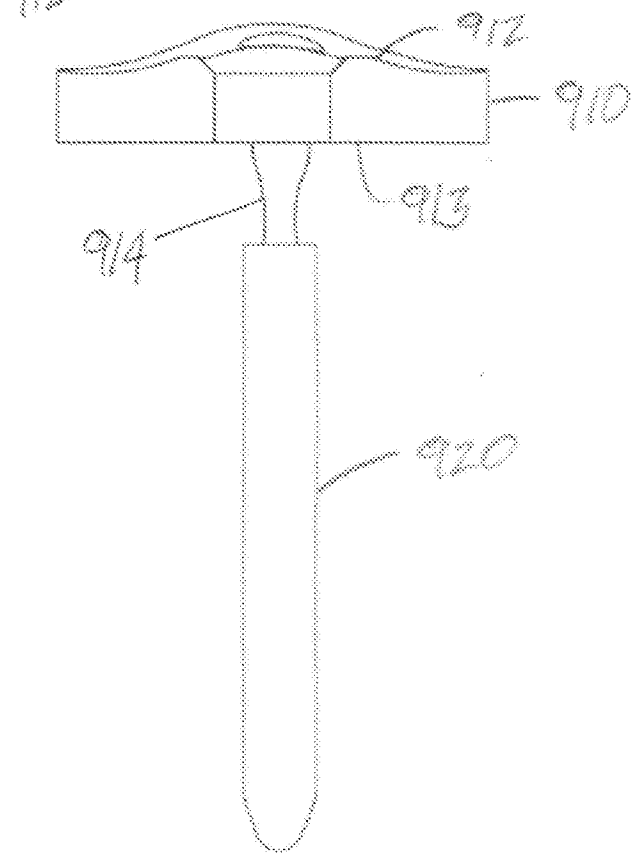

FIG. 20

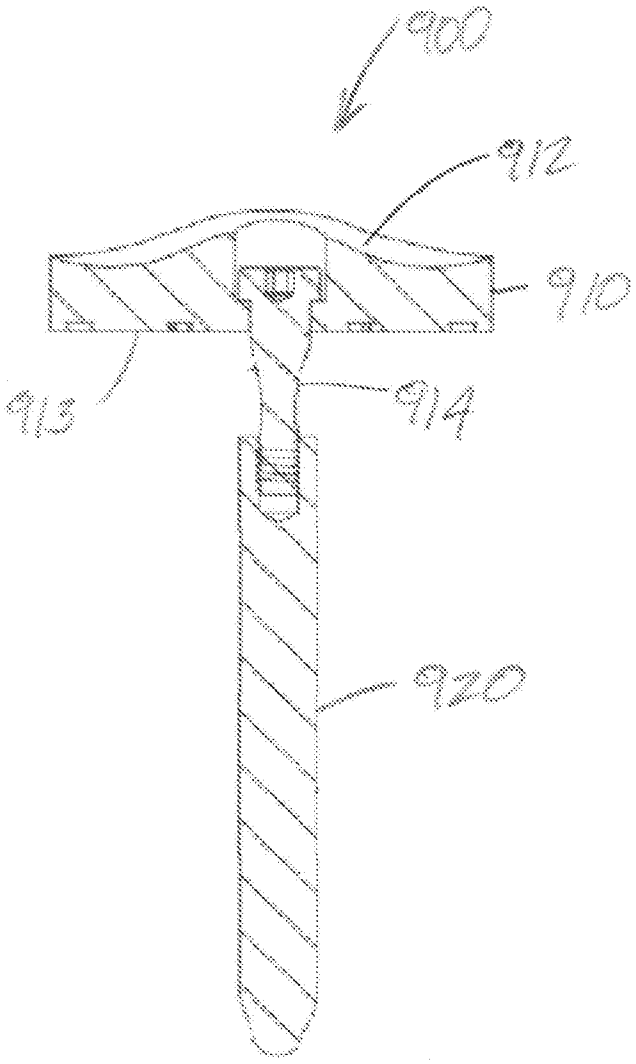

FIG. 19

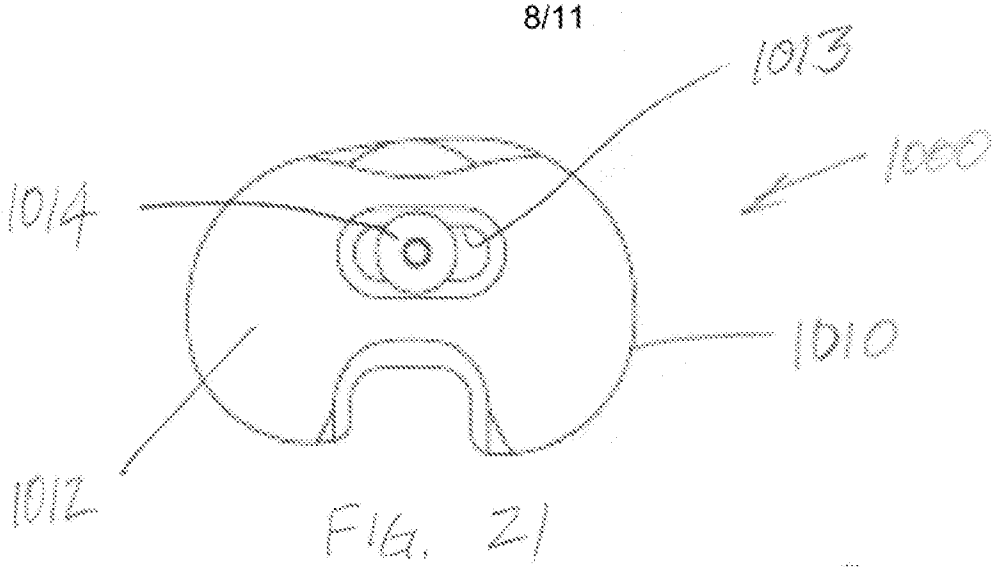

Fig. 21

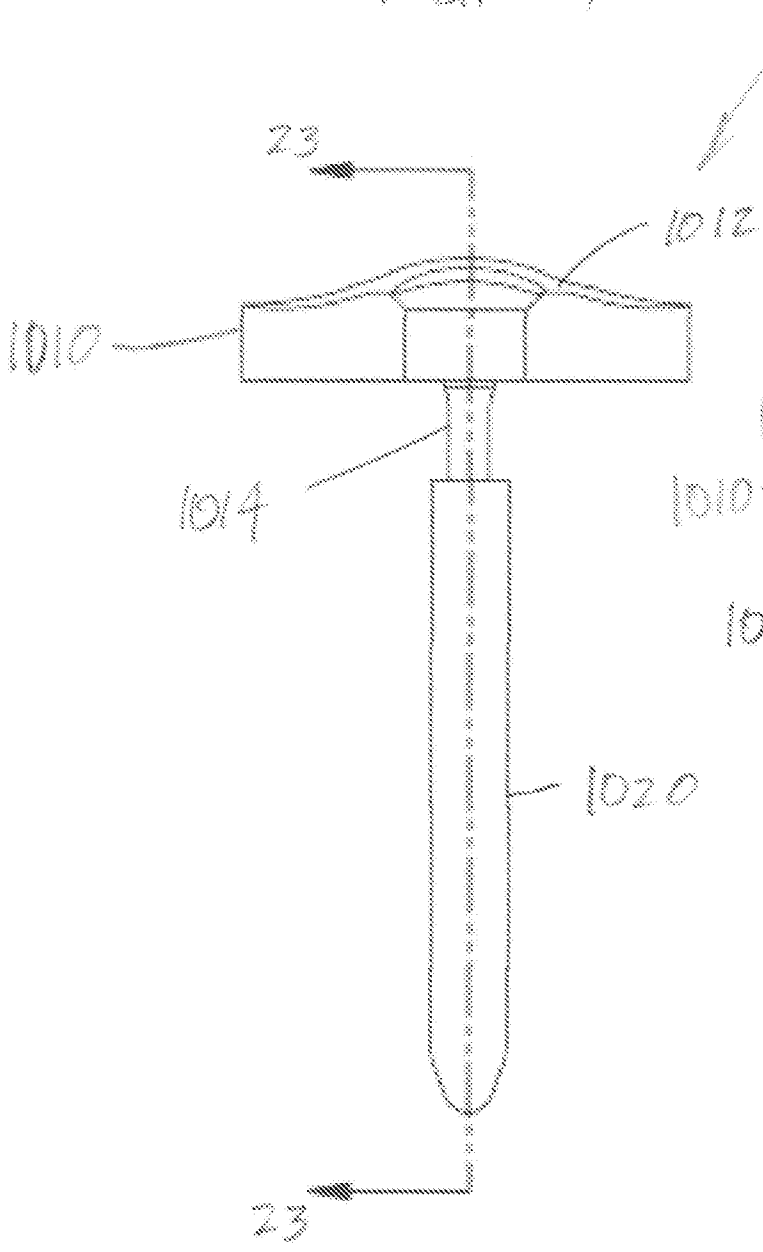

Fig. 22

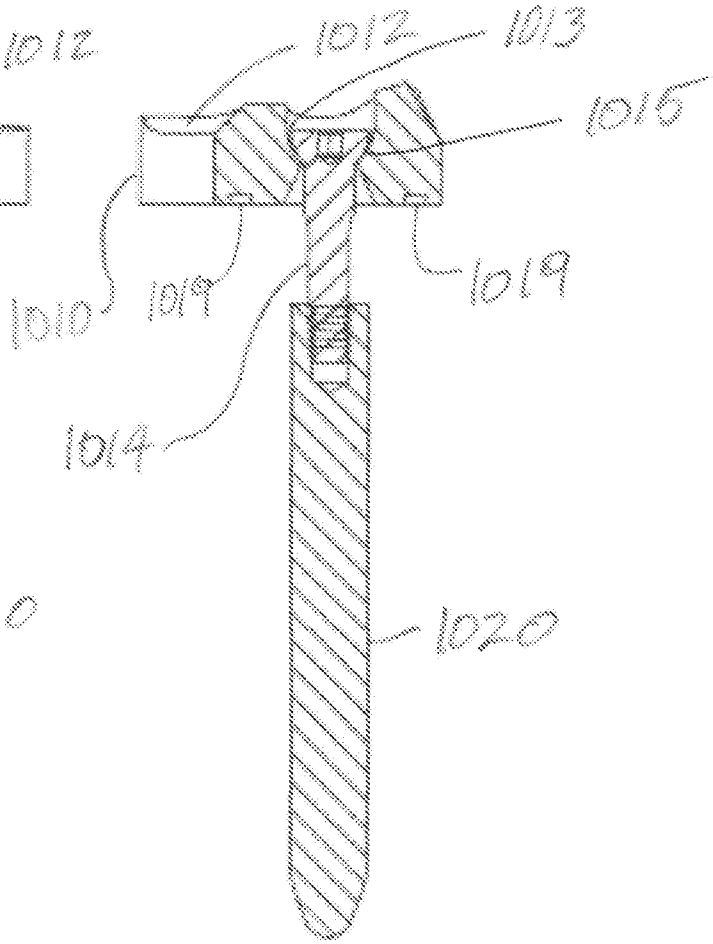

Fig. 23

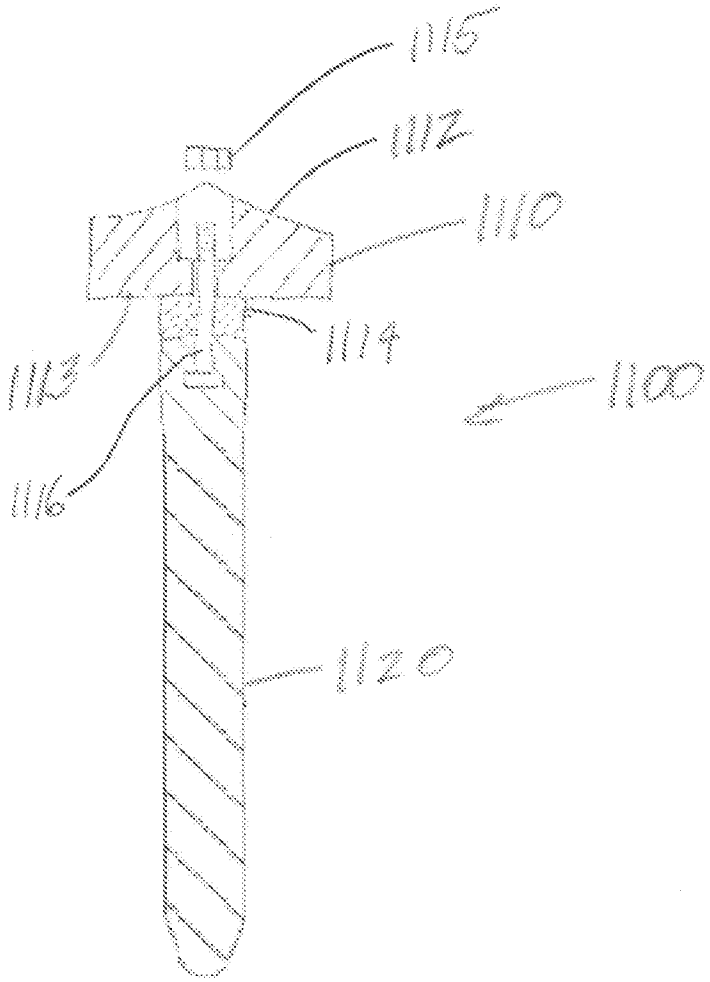

FIG. 24

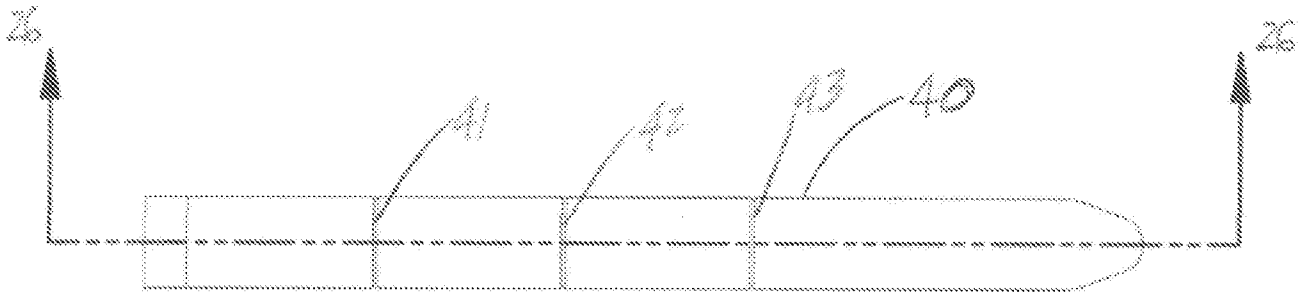

FIG. 25

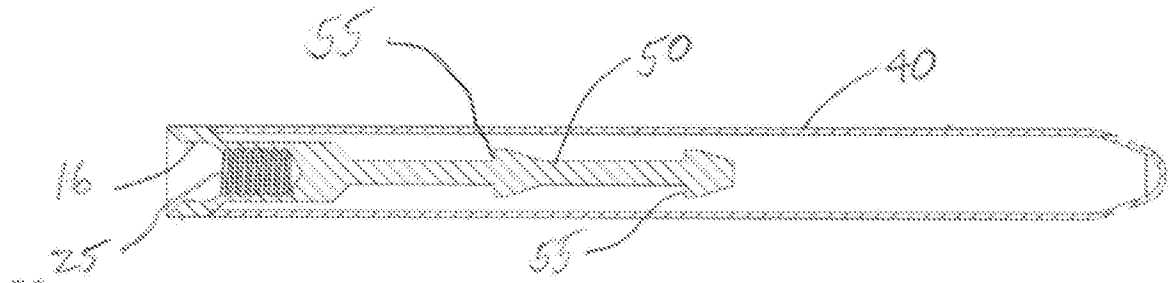

FIG. 26

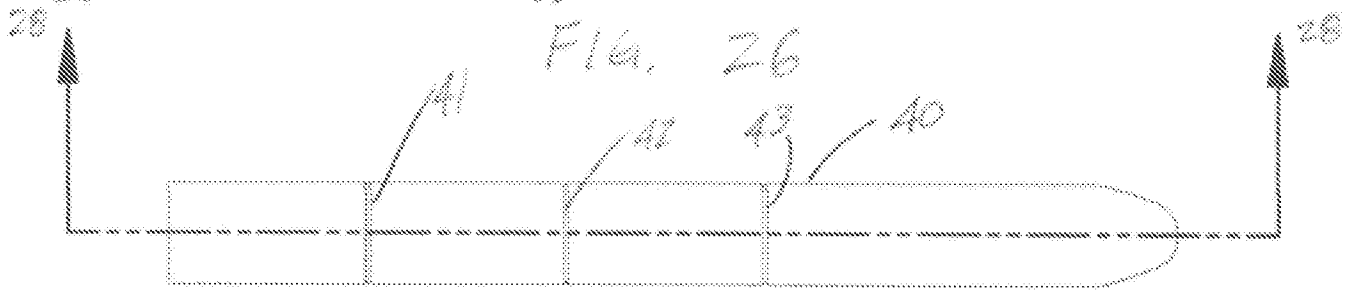

FIG. 27

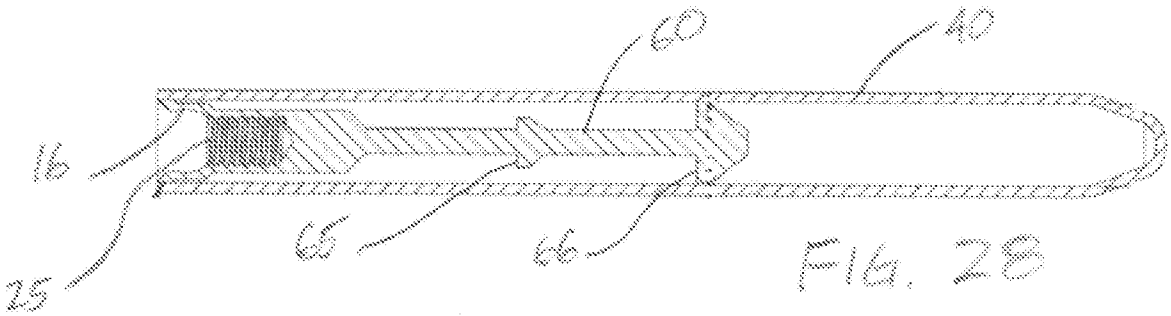

FIG. 28

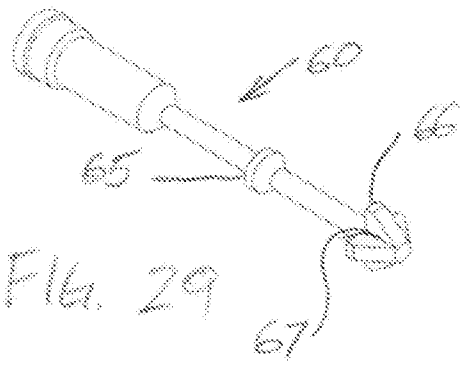

FIG. 29

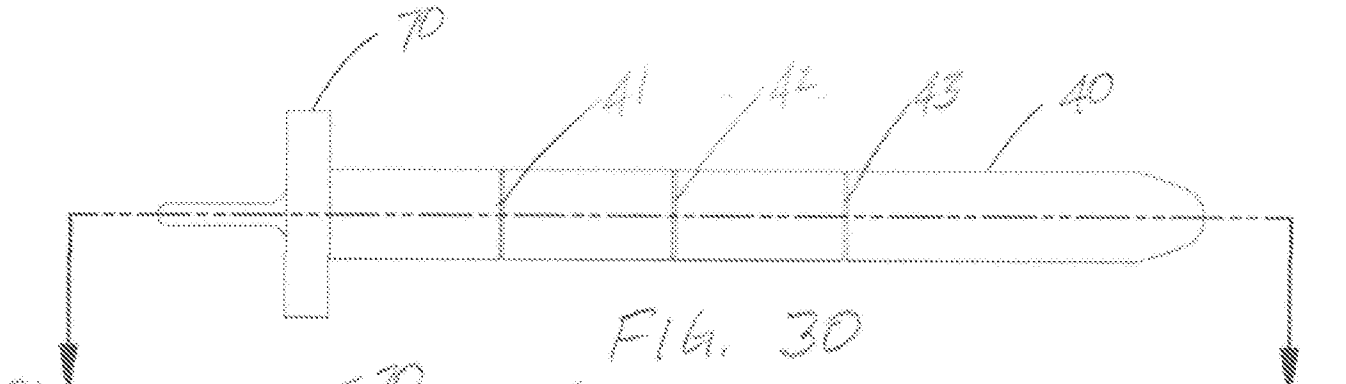

FIG. 30

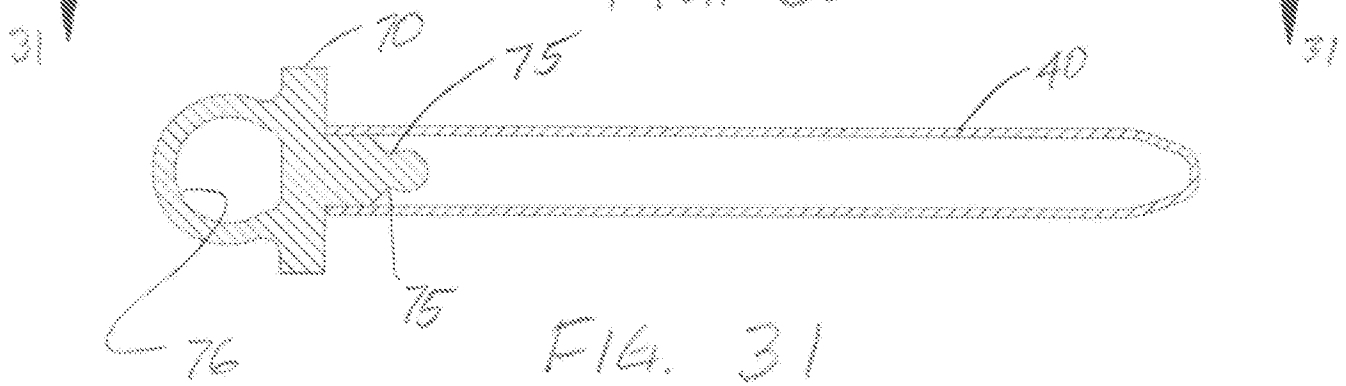

FIG. 31

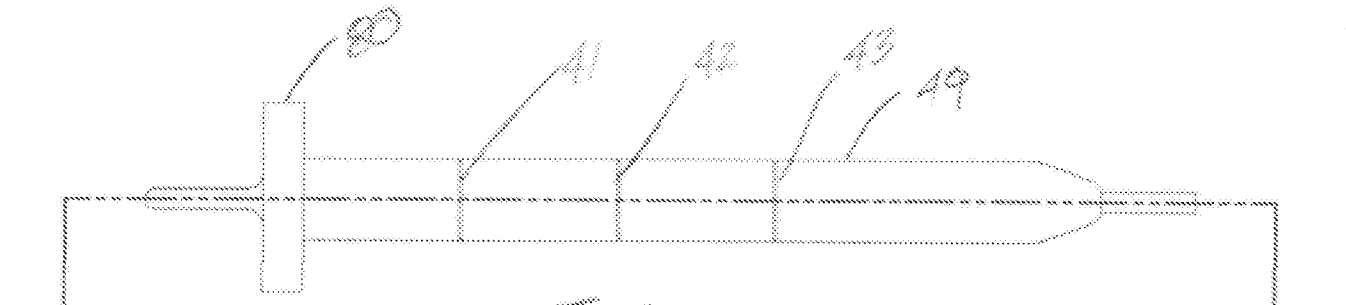

FIG. 32

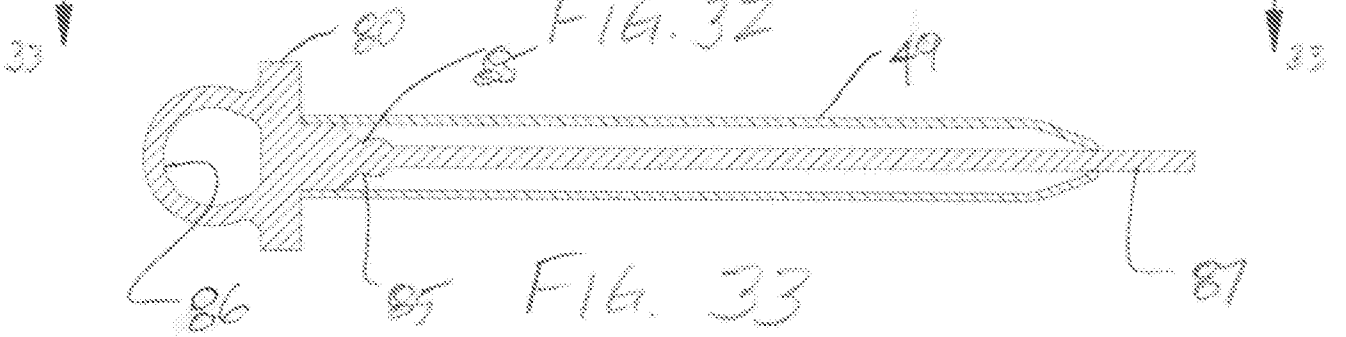

FIG. 33

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/057917

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-30

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/057917

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/38 A61F2/30
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2007/150065 A1 (ANGIBAUD LAURENT [US]) 28 June 2007 (2007-06-28) paragraph [0025] - paragraph [0039]	1-13,18, 19,26,27 14-17, 28-30

X Y	EP 2 008 621 A1 (DEPUY PRODUCTS INC [US]) 31 December 2008 (2008-12-31) paragraphs [0011] - [0014]	1,3,4,13 14-17

Y	WO 2010/015877 A1 (TECRES SPA [IT]; FACCIOLI GIOVANNI [IT]; SOFFIATTI RENZO [IT]) 11 February 2010 (2010-02-11) page 5, line 15 - page 9, line 10	14-17, 28-30

A	US 2011/112650 A1 (MASINI MICHAEL A [US]) 12 May 2011 (2011-05-12) the whole document	1-30

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

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 January 2017	13/03/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Mingrino, Alessandra

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2016/057917

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007150065 A1	28-06-2007	AU 2006344060 A1	29-11-2007
		BR PI0618305 A2	23-08-2011
		CA 2628841 A1	29-11-2007
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		CN 103239304 A	14-08-2013
		EP 1945147 A2	23-07-2008
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		NZ 568134 A	27-05-2011
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		BR PI0822625 A2	16-06-2015
		CA 2729866 A1	11-02-2010
		CN 102088931 A	08-06-2011
		EP 2326287 A1	01-06-2011
		ES 2586246 T3	13-10-2016
		KR 20110050425 A	13-05-2011
		US 2011118848 A1	19-05-2011
		US 2015351919 A1	10-12-2015
		WO 2010015877 A1	11-02-2010
US 2011112650 A1	12-05-2011	NONE	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-30

A joint replacement system including a first joint component and an intramedullary shaft configured to couple with the joint component by means of a coupling that does not transmit an appreciable moment force between the first joint replacement component and the intramedullary shaft.

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2. claims: 31-36

A device for making an intramedullary shaft, comprising a tubular shell configured to contain a setting material, and an insert sized to fit at least partially within the tubular shell, the insert including a coupling mechanism to which another component may be coupled to form a coupling that does not transmit an appreciable moment force in at least one plane.
