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(54) **PROSTHESIS INSTALLATION SYSTEMS
AND METHODS**

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(56) **References Cited**

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U.S. PATENT DOCUMENTS

5,007,936 A 4/1991 Woolson
5,019,083 A 5/1991 Klapper et al.
(Continued)

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FOREIGN PATENT DOCUMENTS

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which is a continuation-in-part of application No.
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9,168,154.

OTHER PUBLICATIONS

U.S. Appl. No. 14/585,056, filed Dec. 29, 2014, Kambiz Behzadi et
al.

(Continued)

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(57)

ABSTRACT

A system and method for allowing any surgeon, including
those surgeons who perform a fewer number of a replace-
ment procedure as compared to a more experienced surgeon
who performs a greater number of procedures, to provide an
improved likelihood of a favorable outcome approaching, if
not exceeding, a likelihood of a favorable outcome as
performed by a very experienced surgeon with the replace-
ment procedure.

(51) **Int. Cl.**

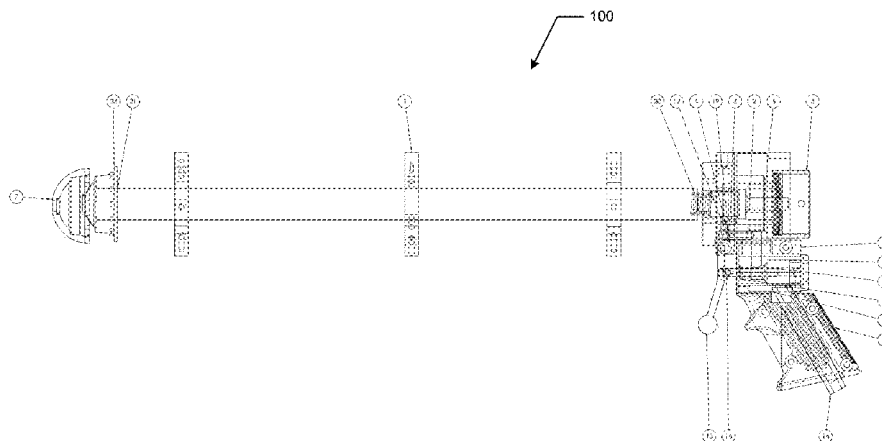
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19 Claims, 14 Drawing Sheets



(56)

References Cited**U.S. PATENT DOCUMENTS**

5,061,270 A 10/1991 Aboczky
 5,112,338 A 5/1992 Anspach, III
 5,169,399 A 12/1992 Ryland et al.
 5,236,433 A 8/1993 Salyer
 5,318,570 A 6/1994 Hood et al.
 5,456,686 A 10/1995 Klapper et al.
 5,540,697 A 7/1996 Rehmann et al.
 5,571,111 A 11/1996 Aboczky
 5,683,395 A 11/1997 Mikhail
 6,228,092 B1 5/2001 Mikhail
 6,723,102 B2 4/2004 Johnson et al.
 6,884,264 B2 4/2005 Spiegelberg et al.
 6,917,827 B2 7/2005 Kienzle, III
 7,220,264 B1 5/2007 Hershberger
 7,326,217 B2 2/2008 Bubb
 7,559,931 B2 7/2009 Stone
 7,604,637 B2 10/2009 Johnson et al.
 7,645,281 B2 1/2010 Marik
 7,727,282 B2 6/2010 Slone et al.
 3,057,479 A1 11/2011 Stone
 8,057,482 B2 11/2011 Stone et al.
 8,118,815 B2 2/2012 van der Walt
 8,128,631 B2 3/2012 Johnson et al.
 8,167,823 B2 5/2012 Nycz et al.
 8,206,405 B2 6/2012 Beverland et al.
 8,216,286 B2 7/2012 Aeschlimann et al.
 8,496,657 B2 7/2013 Bonutti et al.
 8,556,909 B2 10/2013 Giersch et al.
 8,783,378 B2 7/2014 Zhou
 8,801,724 B2 8/2014 Zumsteg et al.
 8,888,786 B2 11/2014 Stone et al.
 8,911,447 B2 12/2014 van der Walt et al.
 8,974,467 B2 3/2015 Stone
 8,974,468 B2 3/2015 Borja
 8,998,910 B2 4/2015 Borja et al.
 9,168,154 B2 10/2015 Behzadi
 9,192,392 B2 11/2015 van der Walt et al.
 9,220,612 B2 12/2015 Behzadi
 9,271,756 B2 3/2016 van der Walt et al.
 9,649,202 B2 5/2017 Behzadi et al.
 2002/0193797 A1 12/2002 Johnson et al.
 2005/0119666 A1 6/2005 Bubb
 2006/0100548 A1 5/2006 Ferguson
 2008/0109008 A1 5/2008 Schwager et al.
 2008/0119845 A1 5/2008 Stone et al.
 2009/0318836 A1 12/2009 Stone et al.
 2009/0318930 A1 12/2009 Stone et al.
 2009/0318931 A1 12/2009 Stone et al.
 2010/0016705 A1 1/2010 Stone
 2010/0063508 A1 3/2010 Borja et al.
 2010/0063509 A1 3/2010 Borja et al.
 2010/0064216 A1 3/2010 Borja et al.
 2010/0069911 A1 3/2010 Borja et al.
 2010/0076505 A1 3/2010 Borja
 2010/0100139 A1 4/2010 Young
 2010/0137869 A1 6/2010 Borja et al.
 2010/0137871 A1 6/2010 Borja
 2010/0249796 A1 9/2010 Nycz
 2011/0208093 A1 8/2011 Gross et al.
 2011/0218543 A1 9/2011 van der Walt
 2011/0251600 A1 10/2011 Giersch et al.
 2012/0130279 A1 5/2012 Stone
 2012/0136361 A1 5/2012 Aux Epaulles et al.
 2012/0209277 A1 8/2012 Leparmentier et al.
 2012/0283599 A1 11/2012 Borja
 2012/0316567 A1 12/2012 Gross et al.
 2013/0066323 A1 3/2013 Nycz et al.
 2013/0149660 A1 6/2013 Pruckner et al.
 2013/0282014 A1 10/2013 Haimerl et al.
 2014/0012391 A1 1/2014 Gugler et al.
 2014/0052149 A1 2/2014 van der Walt et al.
 2014/0058526 A1 2/2014 Meridew et al.
 2014/0135791 A1 5/2014 Nikou et al.
 2015/0182350 A1 7/2015 Behzadi
 2015/0182351 A1 7/2015 Behzadi

2015/0320428 A1 11/2015 Roger
 2016/0095720 A1 4/2016 Behzadi
 2016/0100958 A1 4/2016 Behzadi et al.
 2016/0175110 A1 6/2016 Behzadi et al.
 2016/0199199 A1 7/2016 Pedicini
 2016/0213493 A1 7/2016 Behzadi
 2017/0065428 A1 3/2017 Behzadi
 2017/0065429 A1 3/2017 Behzadi et al.
 2017/0071759 A1 3/2017 Behzadi et al.
 2017/0196705 A1 7/2017 Behzadi
 2017/0202683 A1 7/2017 Behzadi
 2017/0290666 A1 10/2017 Behzadi

FOREIGN PATENT DOCUMENTS

FR 2741523 A1 5/1997
 JP 2017500984 A 1/2017
 WO 8802246 A2 4/1988
 WO 9740785 11/1997
 WO 0108569 A1 2/2001
 WO 2008003962 A1 1/2008
 WO 2015100461 A1 7/2015
 WO 2017176905 A1 10/2017

OTHER PUBLICATIONS

International Search Report for International application No. PCT/US2017/026180 dated Sep. 8, 2017.

Written opinion of the international searching authority regarding International application No. PCT/US2017/026180 dated Sep. 8, 2017.

International Search Report for International Application No. PCT/US17/19940 dated Jul. 13, 2017.

Written Opinion of the International Searching Authority for International application No. PCT/US17/19940 dated Jul. 13, 2017.

The WoodPecker, Total Hip Broaching System, General Information, 1992, [retrieved on Feb. 13, 2015], Retrieved from the Internet: <www.imt-medicalusa.com/products/woodpecker-hip-broaching-system.aspx>.

The WoodPecker, Total Hip Broaching System, Specification, 1992, [retrieved on Feb. 13, 2015], Retrieved from the Internet: <www.imt-medicalusa.com/products/woodpecker-specifications.aspx>.

The WoodPecker, Total Hip Broaching System, Operation Manual, 1992, [retrieved on Feb. 13, 2015], Retrieved from the Internet: <www.plusmed.si/uploads/datoite/Pnevmatisko%20kladivo%20-%20navodilo%20za%20uporabo.pdf>.

The WoodPecker, Total Hip Broaching System, YourTube Reference—Total Hip Replacement with the Woodpecker Pneumatic Broaching System (2002), Uploaded Nov. 4, 2009, [retrieved on Feb. 13, 2015], Retrieved from the Internet: <www.youtube.com/watch?v=KisN6_M-xS0>.

Written Opinion of the International Searching Authority regarding International Application No. PCT/US2014/072609, dated Apr. 1, 2015.

International Search Report regarding International Application No. PCT/US2014/072609, dated Apr. 7, 2015.

U.S. Appl. No. 16/278,093, filed Feb. 16, 2019, Kambiz Behzadi.

U.S. Appl. No. 16/280,044, filed Feb. 20, 2019, Kambiz Behzadi.

U.S. Appl. No. 61/921,528, filed Dec. 29, 2013, Kambiz Behzadi.

U.S. Appl. No. 61/980,188, filed Apr. 16, 2014, Kambiz Behzadi.

U.S. Appl. No. 14/584,656, filed Dec. 29, 2014, Kambiz Behzadi.

U.S. Appl. No. 14/585,056, filed Dec. 29, 2014, Kambiz Behzadi.

U.S. Appl. No. 14/923,203, filed Oct. 26, 2015, Kambiz Behzadi.

U.S. Appl. No. 14/965,851, filed Dec. 10, 2015, Kambiz Behzadi.

U.S. Appl. No. 14/969,721, filed Dec. 15, 2015, Kambiz Behzadi et al.

U.S. Appl. No. 15/055,942, filed Feb. 29, 2016, Kambiz Behzadi et al.

U.S. Appl. No. 15/092,384, filed Apr. 6, 2016, Kambiz Behzadi.

U.S. Appl. No. 15/235,078, filed Aug. 11, 2016, Kambiz Behzadi et al.

U.S. Appl. No. 15/235,086, filed Aug. 11, 2016, Kambiz Behzadi.

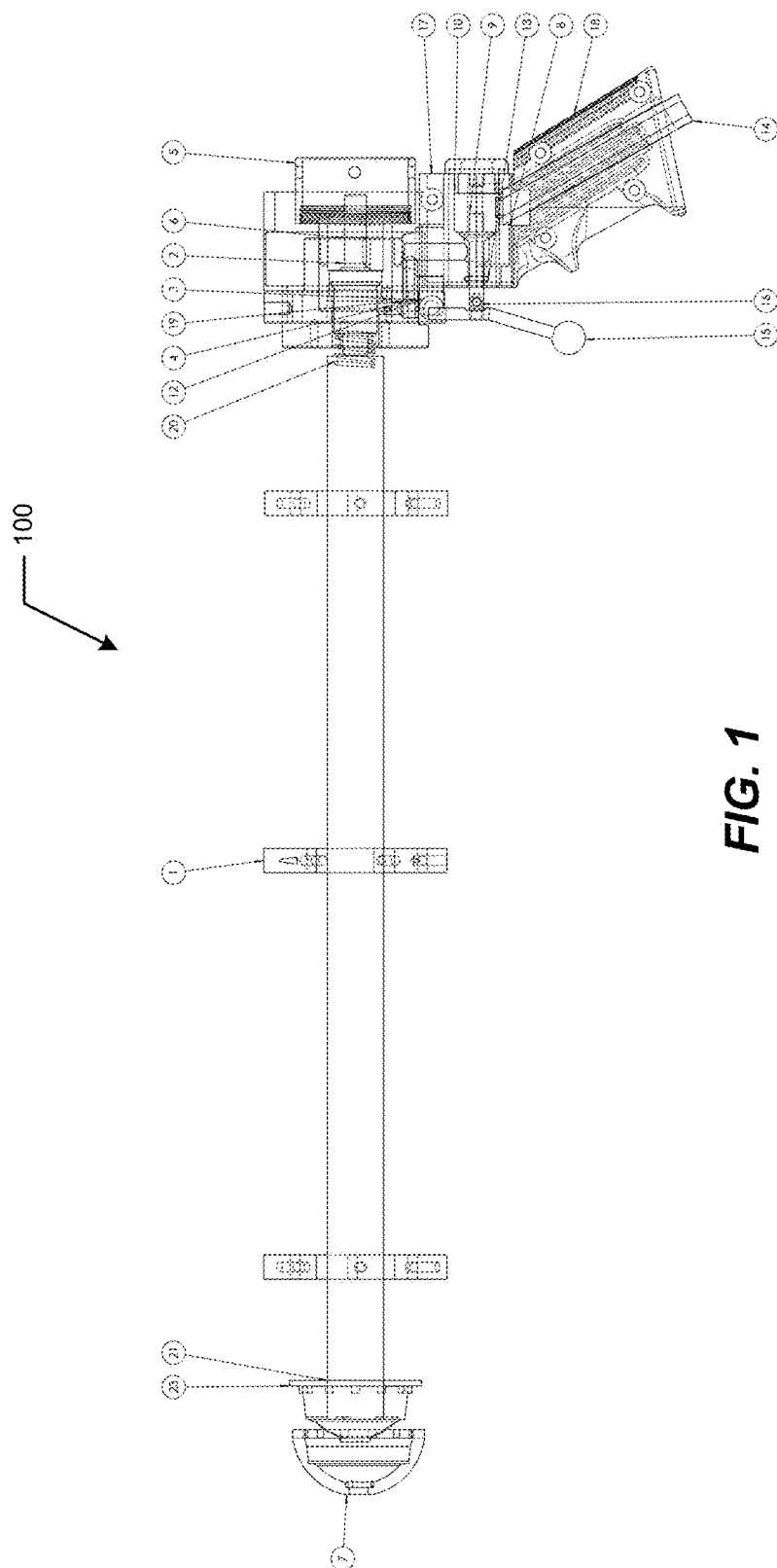
U.S. Appl. No. 15/479,716, filed Apr. 5, 2017, Kambiz Behzadi.

(56)

References Cited

OTHER PUBLICATIONS

U.S. Appl. No. 16/050,662, filed Jul. 31, 2018, Kambiz Behzadi et al.



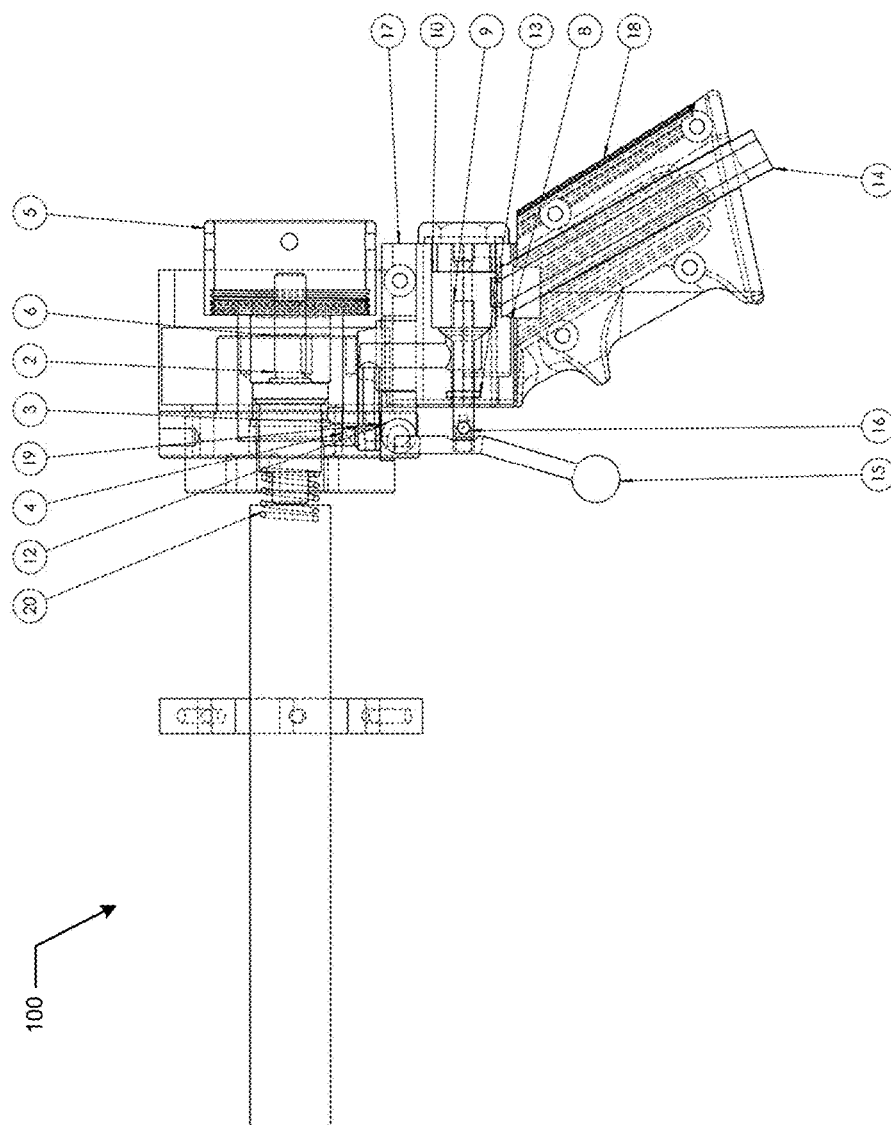


FIG. 2

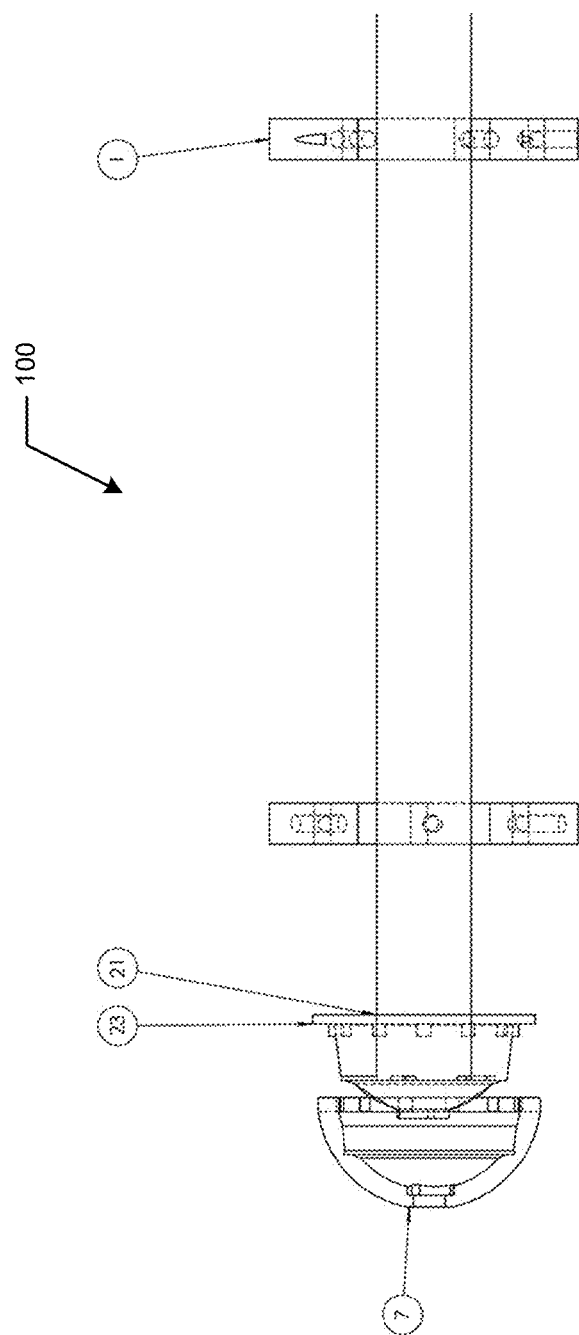


FIG. 3

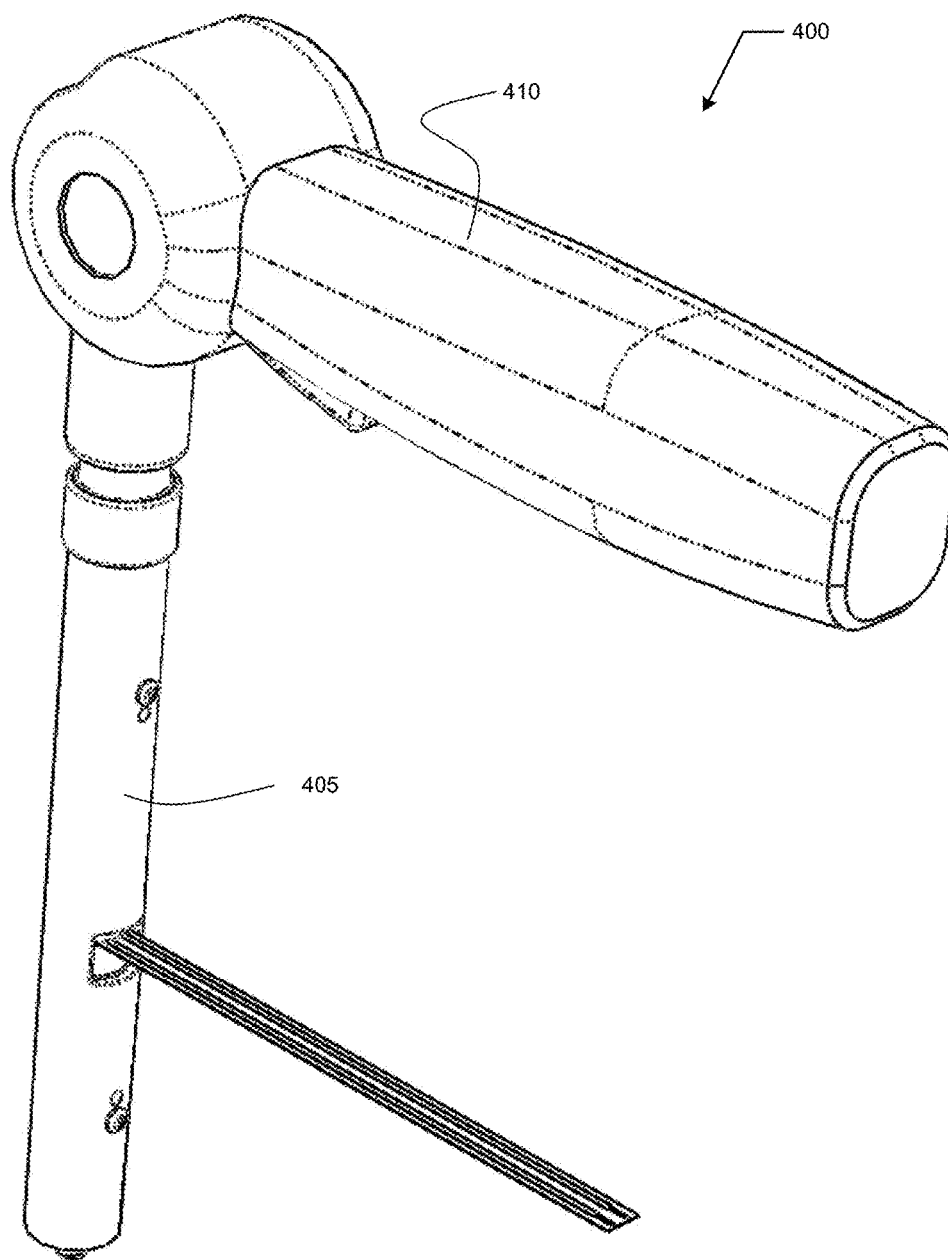


FIG. 4

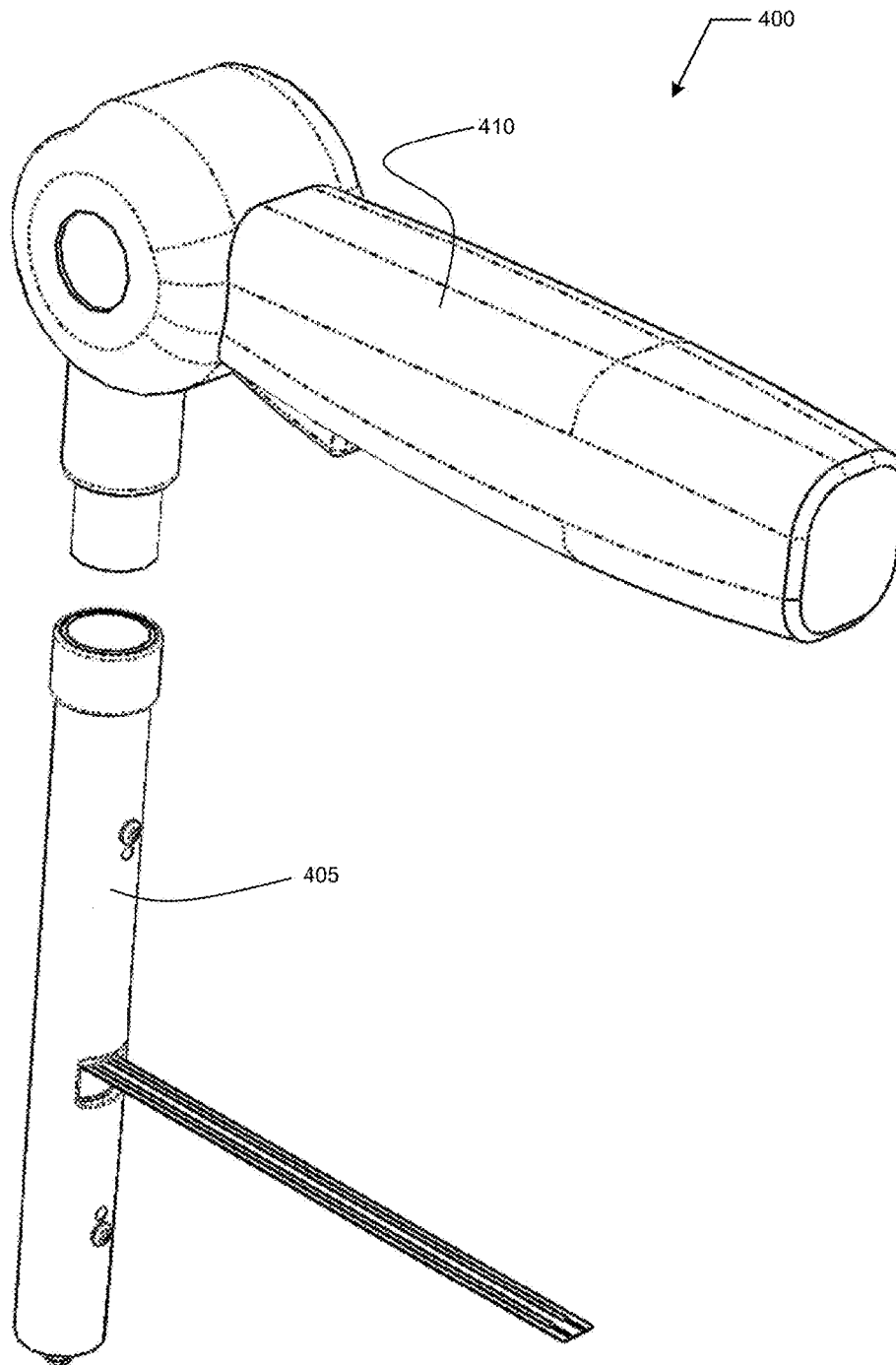


FIG. 5

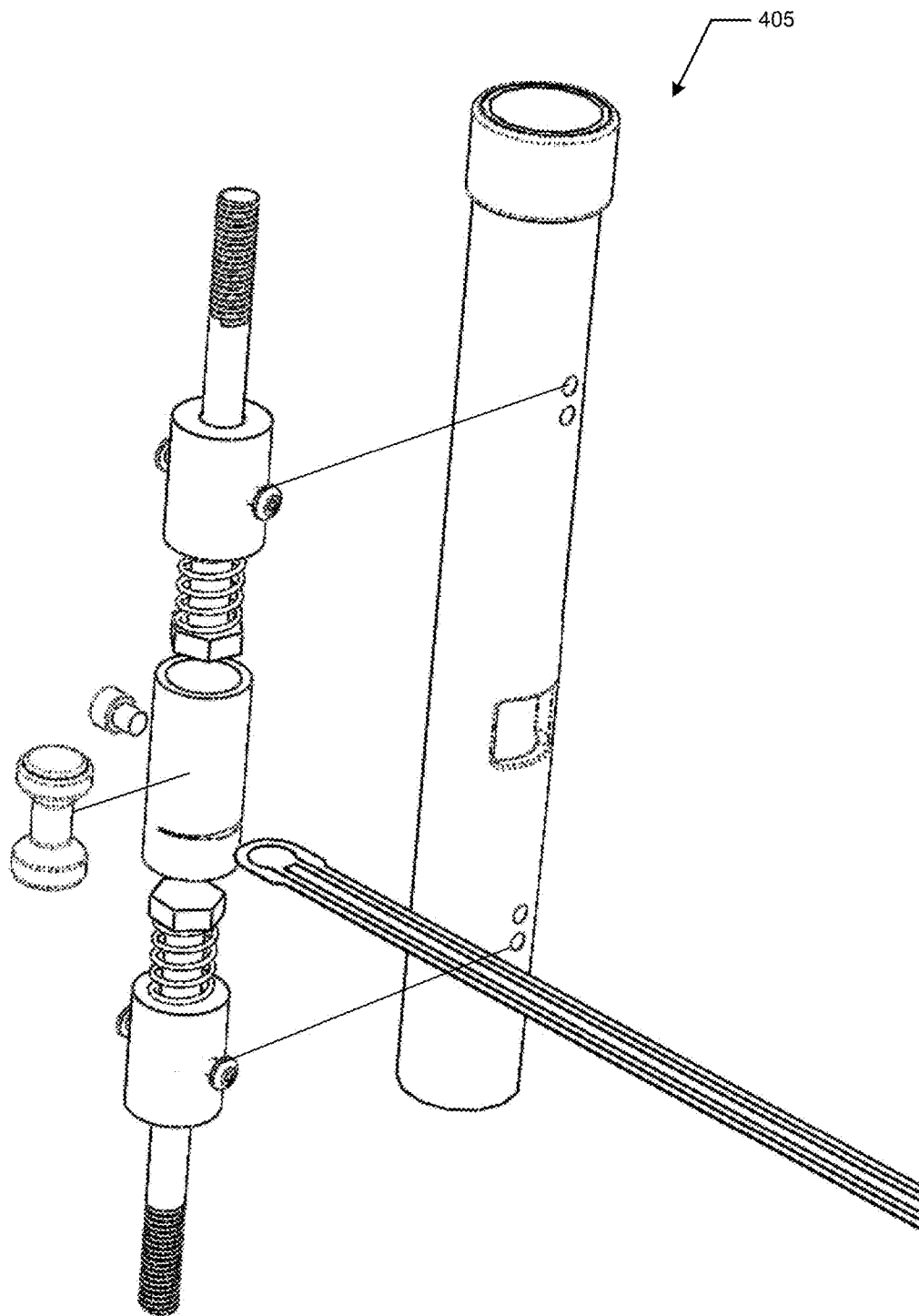


FIG. 6

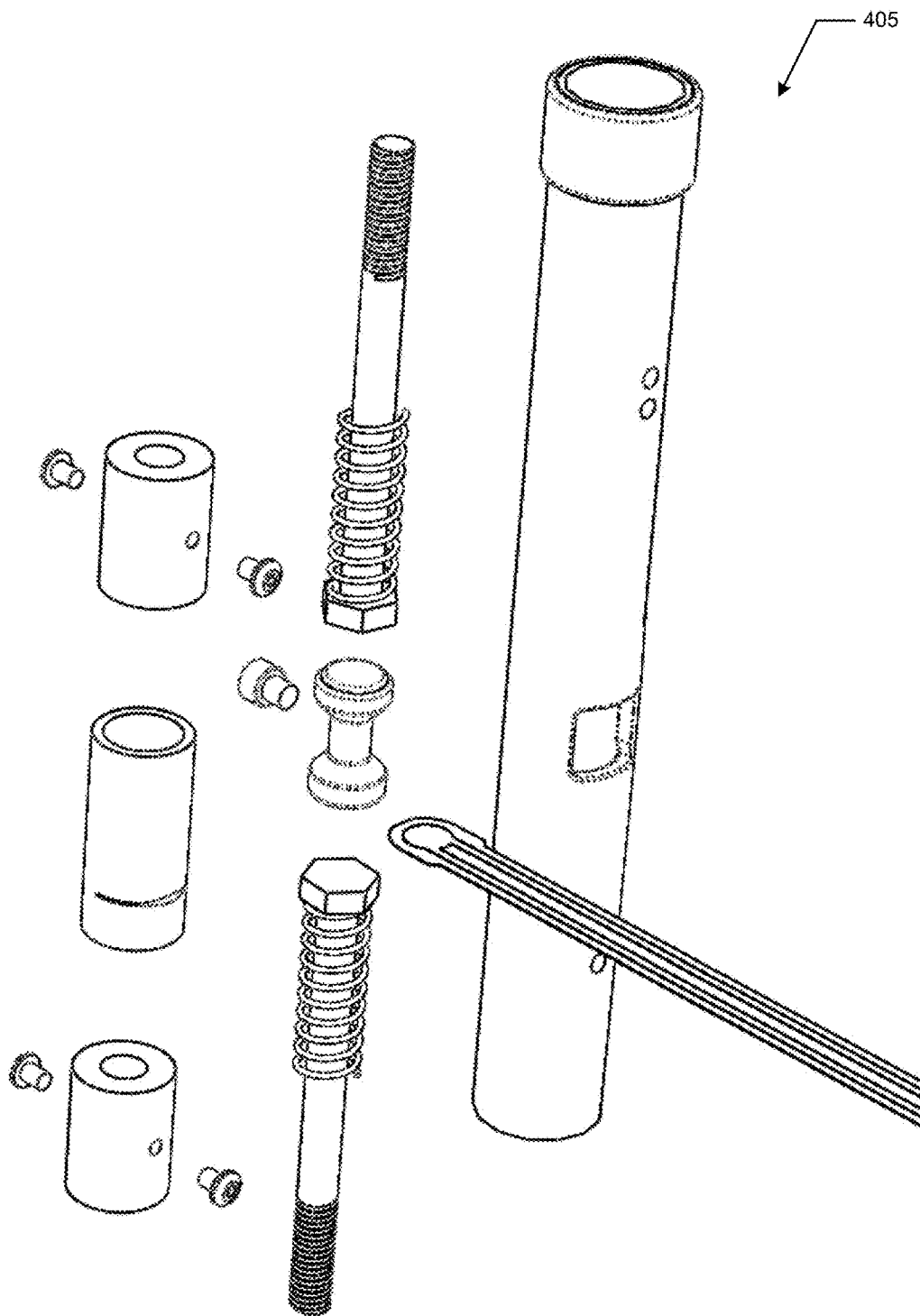


FIG.7

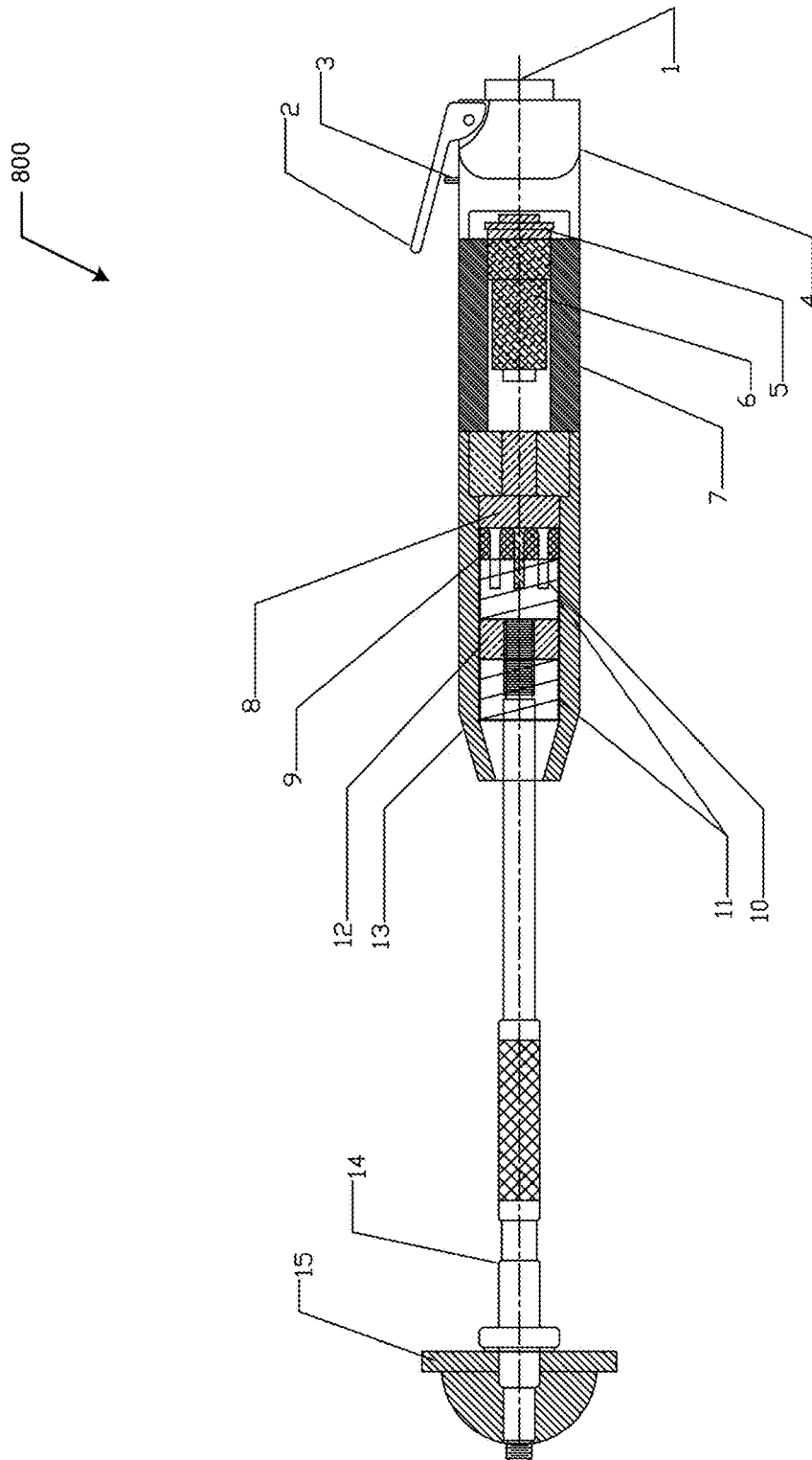


FIG. 8

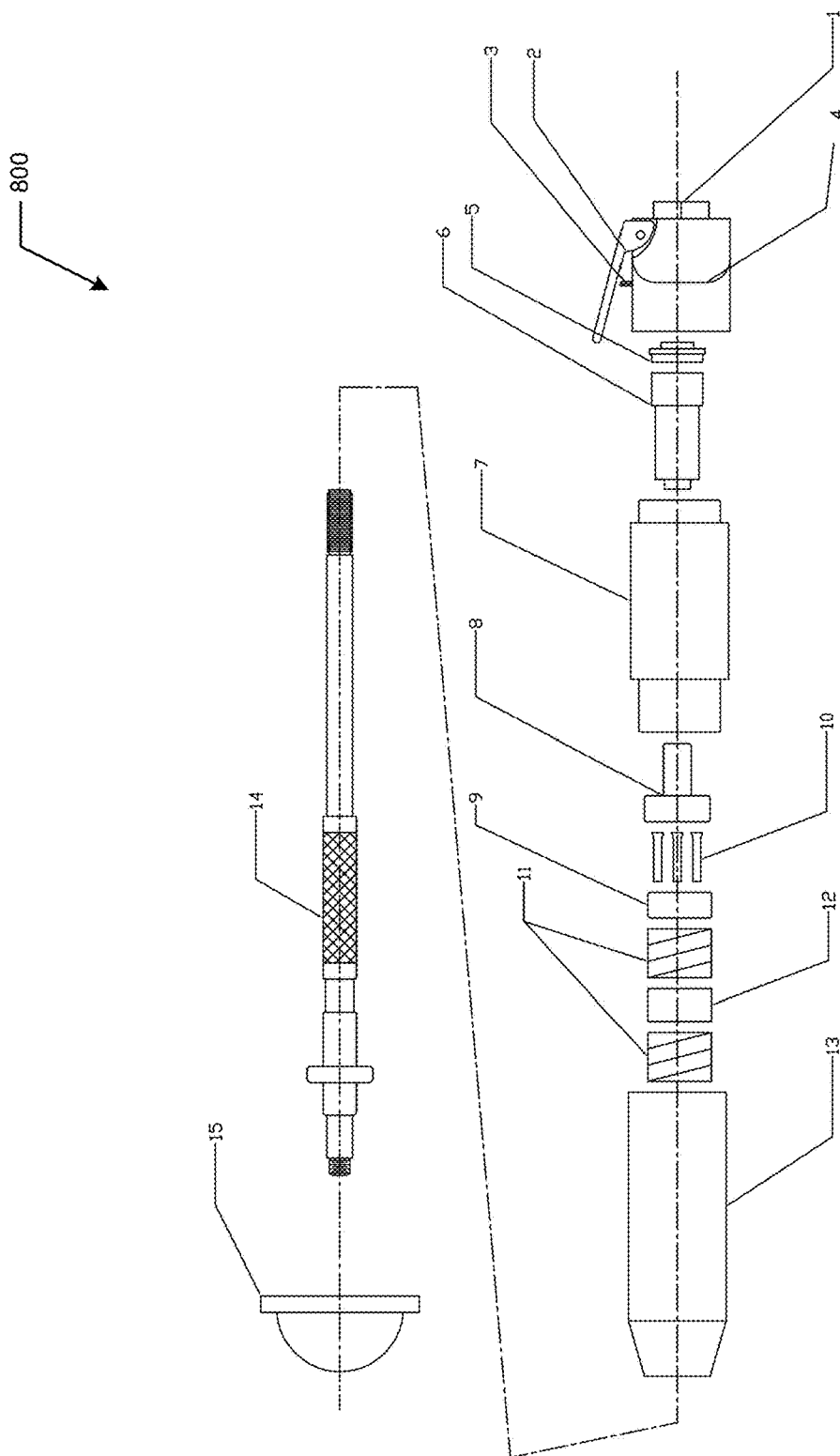


FIG. 9

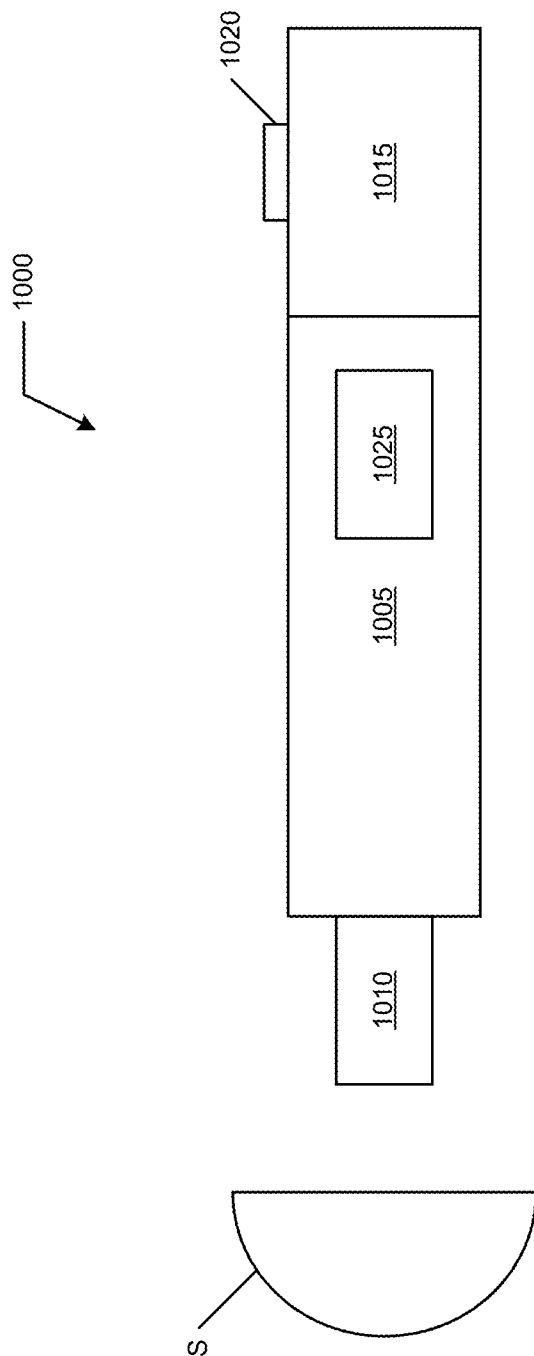


FIG. 10

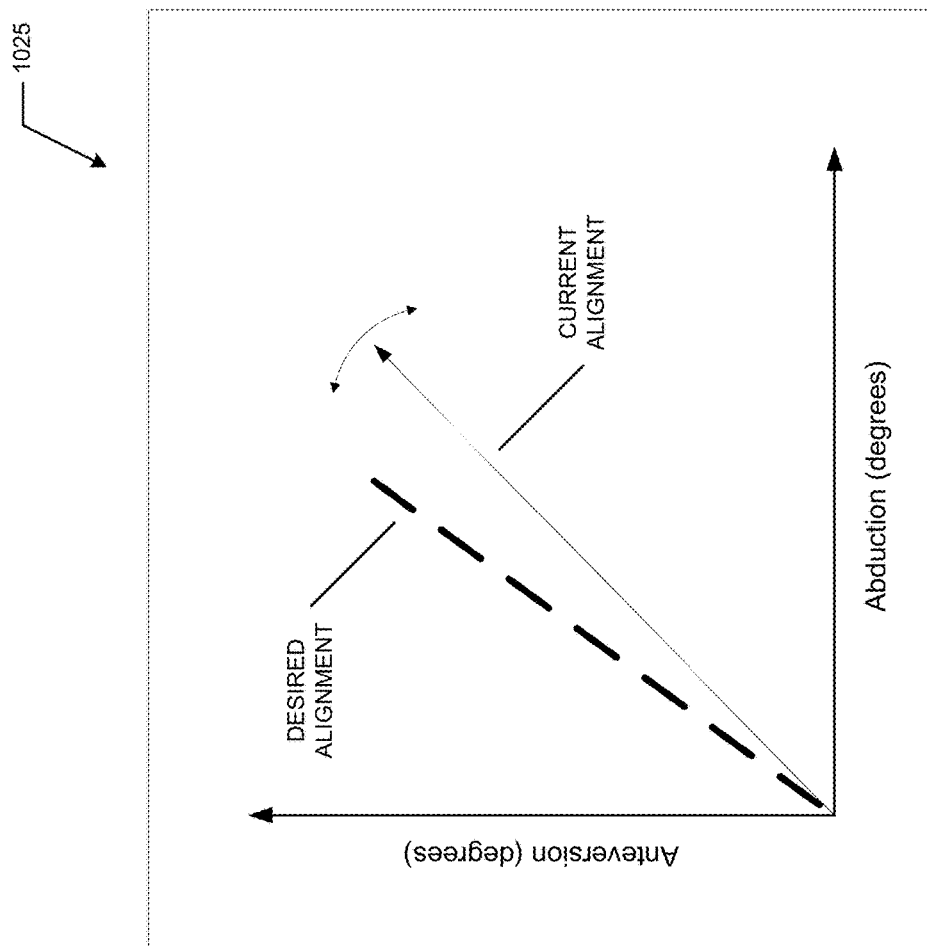


FIG. 11

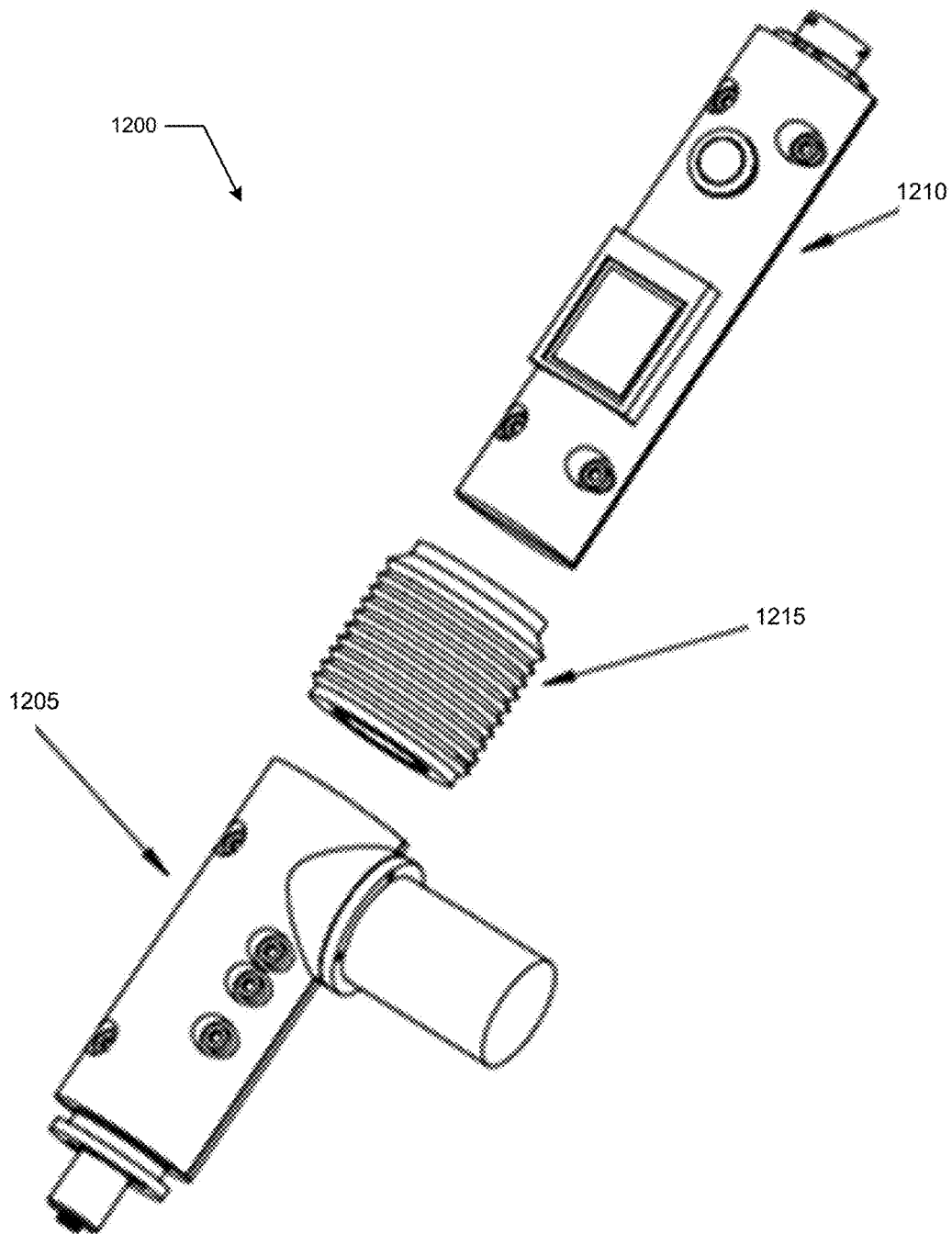


FIG. 12

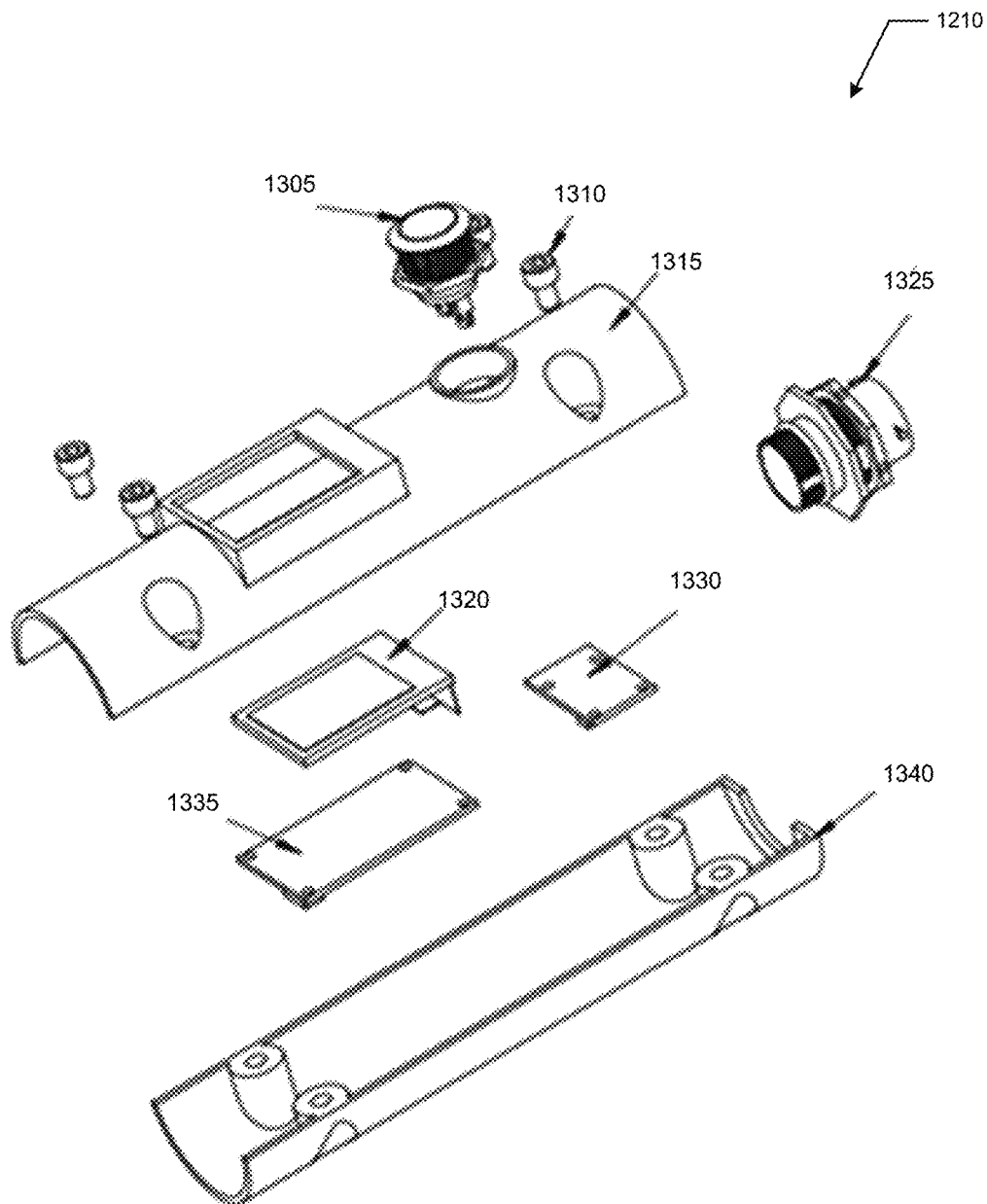


FIG. 13

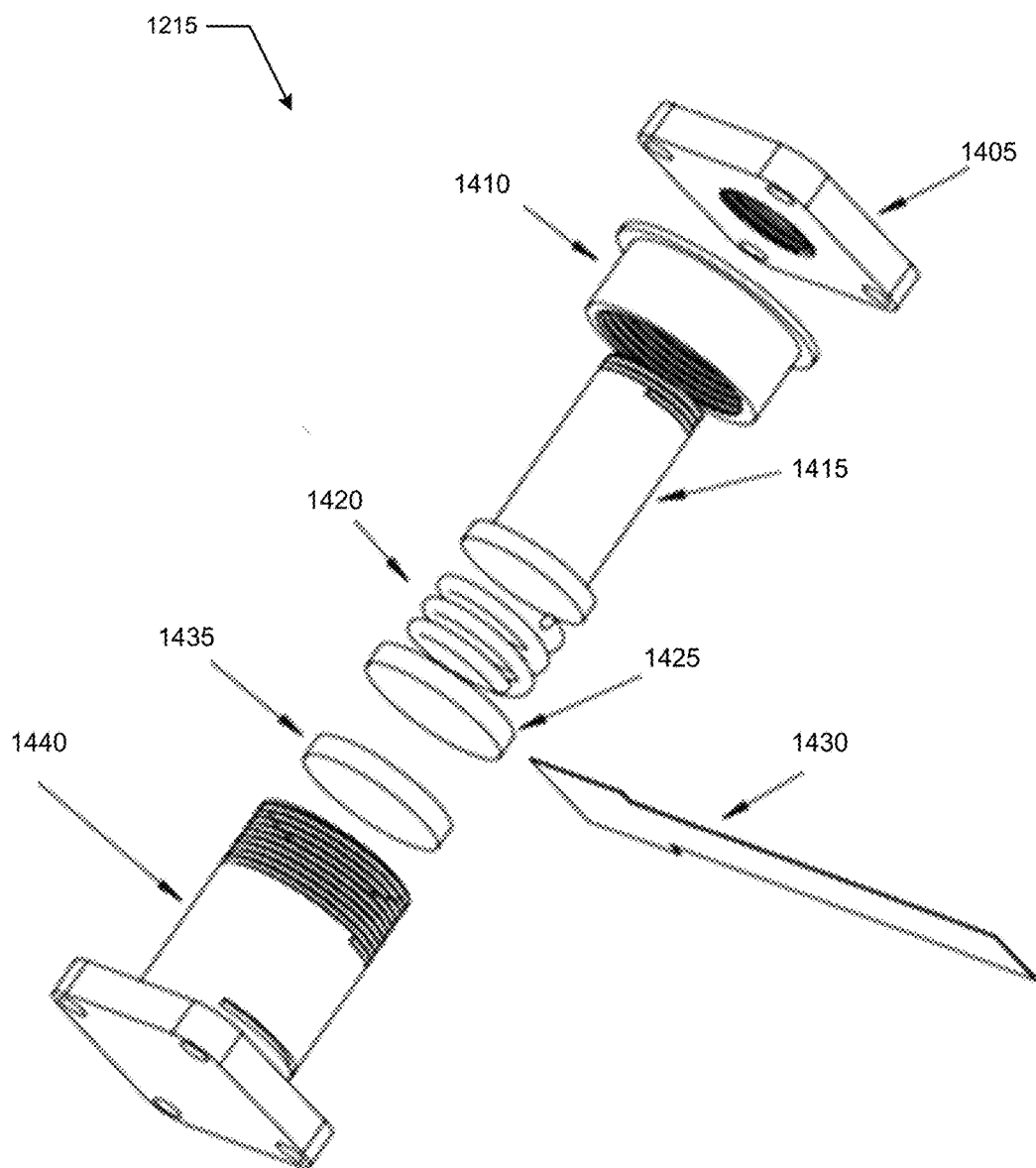


FIG. 14

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PROSTHESIS INSTALLATION SYSTEMS AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 15/055,942 filed 29 Feb. 2016 which is a continuation-in-part of U.S. patent application Ser. No. 14/923,203 filed 26 Oct. 2015 which is a continuation-in-part of U.S. patent application Ser. No. 14/584,656, filed 29 Dec. 2014 (now U.S. Pat. No. 9,168,154) that in turn claims benefit of both U.S. Patent Application No. 61/921,528 and U.S. Patent Application No. 61/980,188, and is related to U.S. patent application Ser. No. 14/965,851 filed 10 Dec. 2015, the contents of these applications in their entireties are hereby expressly incorporated by reference thereto for all purposes.

FIELD OF THE INVENTION

The present invention relates generally to orthopedic surgical systems and procedures employing a prosthetic implant for, and more specifically, but not exclusively, to joint replacement therapies such as total hip replacement including controlled installation and positioning of the prosthesis such as during replacement of a pelvic acetabulum with a prosthetic implant.

BACKGROUND OF THE INVENTION

The subject matter discussed in the background section should not be assumed to be prior art merely as a result of its mention in the background section. Similarly, a problem mentioned in the background section or associated with the subject matter of the background section should not be assumed to have been previously recognized in the prior art. The subject matter in the background section merely represents different approaches, which in and of themselves may also be inventions.

Total hip replacement refers to a surgical procedure where a hip joint is replaced using a prosthetic implant. There are several different techniques that may be used, but all include a step of inserting an acetabular component into the acetabulum and positioning it correctly in three dimensions (along an X, Y, and Z axis).

In total hip replacement (THR) procedures there are advantages to patient outcome when the procedure is performed by a surgeon specializing in these procedures. Patients of surgeons who do not perform as many procedures can have increased risks of complications, particularly of complications arising from incorrect placement and positioning of the acetabular component.

The incorrect placement and positioning may arise even when the surgeon understood and intended the acetabular component to be inserted and positioned correctly. This is true because in some techniques, the tools for actually installing the acetabular component are crude and provide an imprecise, unpredictable coarse positioning outcome.

Some techniques may employ automated and/or computer-assisted navigation tools, for example, x-ray fluoroscopy or computer guidance systems. A computer assisted surgery technique may help the surgeon in determining the correct orientation and placement of the acetabular component. However, current technology provides that at some point the surgeon is required to employ a hammer/mallet to physically strike a pin or alignment rod. The amount of force

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applied and the location of the application of the force are variables that would not be controlled by these navigation tools. Thus even when the acetabular component is properly positioned and oriented, when actually impacting the acetabular component into place the actual location and orientation can differ from the intended optimum location and orientation. In some cases the tools used can be used to determine that there is, in fact, some difference in the location and/or orientation. However, once again the surgeon employs an impacting tool (e.g., the hammer/mallet) to strike the pin or alignment rod to attempt an adjustment. However the resulting location and orientation of the acetabular component after the adjustment may not be, in fact, the desired location and/or orientation. The more familiar that the surgeon is with the use and application of these adjustment tools can reduce the risk to a patient from a less preferred location or orientation. In some circumstances, quite large impacting forces are applied to the prosthesis by the mallet striking the rod; these forces make fine tuning difficult at best and there is risk of fracturing and/or shattering the acetabulum during these impacting steps.

Installation and assembly systems for a prosthesis that have employed a guidance system may typically require that the surgeon divert attention from the installation/assembly when accessing information from the navigation system to establish or check the installation/assembly.

For some navigation/guidance systems, each operating room could define a frame of reference with the navigation system calibrated into this frame of reference. Such a use makes it difficult to use the navigation system in a different operating room without first performing calibration procedures. Thus the navigation system imposes an additional cost on the surgeon and the facilities management in implementing these types of solutions.

Different intra-operative evaluation and alignment of a prosthesis, e.g., an acetabular cup during THR, may include use of an A-frame, Fluoroscopy, Computer navigation, and patient specific instrumentation (PSI). Use of devices such as this may allow a surgeon to determine a position/alignment of the prosthesis and provide a map, such as of the pelvis, allowing the surgeon to decide on how to align the prosthesis to the pelvis.

Two processes, considered separate and distinct, are implicated in the installation and positioning of a prosthesis: i) preparation of the installation location, e.g. the acetabulum for the acetabular cup in THR, and ii) insertion of the prosthesis. While many focus on ii) for determining accurate installation, both i) and ii) may be important as errors in alignment and directionality during site preparation, e.g., reaming, could adversely affect the final outcome and which may require more extensive processing in process ii) than may be the case when care is also taken during process i).

Some of the patent applications incorporated above address improvement over the use of a mallet impacting/striking an alignment pin to adjust an orientation of a mispositioned prosthesis.

What is needed is a system and method for improving upon prosthesis installation, such as including a real-time evaluation of tool and/or prosthesis alignment or position.

BRIEF SUMMARY OF THE INVENTION

Disclosed is a system and method for improving upon prosthesis installation, such as including a real-time evaluation of tool and/or prosthesis alignment or position. The following summary of the invention is provided to facilitate an understanding of some of technical features related to

total hip replacement, and is not intended to be a full description of the present invention. A full appreciation of the various aspects of the invention can be gained by taking the entire specification, claims, drawings, and abstract as a whole. The present invention is applicable to other surgical procedures, including replacement of other joints replaced by a prosthetic implant in addition to replacement of an acetabulum (hip socket) with an acetabular component (e.g., a cup), and other processes in the procedure in addition to installation, including site preparation.

Some of the disclosed concepts involve creation of a system/method/tool/gun that vibrates an attached prosthesis, e.g., an acetabular cup, while an integrated alignment system, e.g., an inertial measurement unit (IMU) and display, measures and reports real-time alignment status. The gun would be held in a surgeon's hands and deployed. It could use a vibratory energy to insert (not impact) and position the cup into desired alignment (using current intra-operation measurement systems, navigation, fluoroscopy, integrated alignment system, and the like).

In one embodiment, a first gun-like device (e.g., a BMD1) is used for accurate impaction of the acetabular component at the desired location and orientation.

In another embodiment, a second gun-like device (e.g., a BMD2) is used for fine-tuning of the orientation of the acetabular component, such as one installed by the first gun-like device, by traditional mallet and tamp, or by other methodology. However the second gun-like device may be used independently of the first gun-like device for adjusting an acetabular component installed using an alternate technique. Similarly the second gun-like device may be used independently of the first gun-like device, particularly when the initial installation is sufficiently close to the desired location and orientation. These embodiments are not necessarily limited to fine-tuning as certain embodiments permit complete re-orientation. Some implementations allow for removal of an installed prosthesis.

Another embodiment includes a third gun-like device that combines the functions of the first gun-like device and the second gun-like device. This embodiment enables the surgeon to accurately locate, insert, orient, and otherwise position the acetabular component with the single tool.

Another embodiment includes a fourth device (e.g., a BMD3) that installs the acetabular component without use of the mallet and the rod, or use of alternatives to strike the acetabular component for impacting it into the acetabulum. This embodiment imparts a vibratory motion to an installation rod coupled to the acetabular component that enables low-force, impactless installation and/or positioning.

A positioning device for an acetabular cup disposed in a bone, the acetabular cup including an outer shell having a sidewall defining an inner cavity and an opening with the sidewall having a periphery around the opening and with the acetabular cup having a desired abduction angle relative to the bone and a desired anteversion angle relative to the bone, including a controller including a trigger and a selector; a support having a proximal end and a distal end opposite of the proximal end, the support further having a longitudinal axis extending from the proximal end to the distal end with the proximal end coupled to the controller, the support further having an adapter coupled to the distal end with the adapter configured to secure the acetabular cup; and a number N, the number N, an integer greater than or equal to 2, of longitudinal actuators coupled to the controller and disposed around the support generally parallel to the longitudinal axis, each the actuator including an associated impact head arranged to strike a portion of the periphery,

each impact head providing an impact strike to a different portion of the periphery when the associated actuator is selected and triggered; wherein each the impact strike adjusts one of the angles relative to the bone.

An embodiment of an installation or assembly device may include a vibratory installation system that facilitates installation or assembly of a prosthesis, or portion thereof, using a vibratory Behzadi Medical Device (BMD) including a coupled oscillation engine and pulse transfer assembly. This embodiment may further include an alignment system, e.g., an inertial measurement unit (IMU) and display/indicator system, coupled to the vibratory BMD. Further, the display is preferably coupled to the vibratory BMD. Thus the IMU and the display system would be available on the BMD and directly accessible in real-time, without attention diversion, as the surgeon continuously operates the BMD to install and/or assembly the prosthesis or portion thereof.

Some embodiments include the alignment system provided with other tools, such as a reamer, cutter, or other power device which cuts, abrades, planes, removes, or otherwise removes or shapes tissue at a prosthesis installation site.

An installation device for an acetabular cup disposed in a pelvic bone, the acetabular cup including an outer shell having a sidewall defining an inner cavity and an opening with the sidewall having a periphery around the opening and with the acetabular cup having a desired installation depth relative to the bone, a desired abduction angle relative to the bone, and a desired anteversion angle relative to the bone, including a controller including a trigger; a support having a proximal end and a distal end opposite of said proximal end, said support further having a longitudinal axis extending from said proximal end to said distal end with said proximal end coupled to said controller, said support further having an adapter coupled to said distal end with said adapter configured to secure the acetabular cup; and an oscillator coupled to said controller and to said support, said oscillator configured to control an oscillation frequency and an oscillation magnitude of said support with said oscillation frequency and said oscillation magnitude configured to install the acetabular cup at the installation depth with the desired abduction angle and the desired anteversion angle without use of an impact force applied to the acetabular cup.

An installation system for a prosthesis configured to be implanted into a portion of bone at a desired implantation depth, the prosthesis including an attachment system, including an oscillation engine including a controller coupled to a vibratory machine generating an original series of pulses having a generation pattern, said generation pattern defining a first duty cycle of said original series of pulses; and a pulse transfer assembly having a proximal end coupled to said oscillation engine and a distal end, spaced from said proximal end, coupled to the prosthesis with said pulse transfer assembly including a connector system at said proximal end, said connector system complementary to the attachment system and configured to secure and rigidly hold the prosthesis producing a secured prosthesis with said pulse transfer assembly communicating an installation series of pulses, responsive to said original series of pulses, to said secured prosthesis producing an applied series of pulses responsive to said installation series of pulses; wherein said applied series of pulses are configured to impart a vibratory motion to said secured prosthesis enabling an installation of said secured prosthesis into the portion of bone to within 95% of the desired implantation depth without a manual impact.

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A method for installing an acetabular cup into a prepared socket in a pelvic bone, the acetabular cup including an outer shell having a sidewall defining an inner cavity and an opening with the sidewall having a periphery around the opening and with the acetabular cup having a desired installation depth relative to the bone, a desired abduction angle relative to the bone, and a desired anteversion angle relative to the bone, including (a) generating an original series of pulses from an oscillation engine; (b) communicating said original series of pulses to the acetabular cup producing a communicated series of pulses at said acetabular cup; (c) vibrating, responsive to said communicated series of pulses, the acetabular cup to produce a vibrating acetabular cup having a predetermined vibration pattern; and (d) inserting the vibrating acetabular cup into the prepared socket within a first predefined threshold of the installation depth with the desired abduction angle and the desired anteversion angle without use of an impact force applied to the acetabular cup.

This method may further include (e) orienting the vibrating acetabular cup within the prepared socket within a second predetermined threshold of the desired abduction angle and within third predetermined threshold of the desired anteversion angle.

A method for inserting a prosthesis into a prepared location in a bone of a patient at a desired insertion depth wherein non-vibratory insertion forces for inserting the prosthesis to the desired insertion depth are in a first range, the method including (a) vibrating the prosthesis using a tool to produce a vibrating prosthesis having a predetermined vibration pattern; and (b) inserting the vibrating prosthesis into the prepared location to within a first predetermined threshold of the desired insertion depth using vibratory insertion forces in a second range, said second range including a set of values less than a lowest value of the first range.

An apparatus, including a prosthetic tool; and a set of sensors mechanically coupled to the prosthetic tool, the set of sensors including one or more structures selected from the group consisting essentially of one or more accelerometers, one or more gyro meters, and combinations thereof.

An installation device for an acetabular cup disposed in a pelvic bone, the acetabular cup including an outer shell having a sidewall defining an inner cavity and an opening with the sidewall having a periphery around the opening and with the acetabular cup having a desired installation depth relative to the bone, a desired abduction angle relative to the bone, and a desired anteversion angle relative to the bone, including a controller including a trigger; a support having a proximal end and a distal end opposite of the proximal end, the support further having a longitudinal axis extending from the proximal end to the distal end with the proximal end coupled to the controller, the support further having an adapter coupled to the distal end with the adapter configured to secure the acetabular cup; an oscillator coupled to the controller and to the support, the oscillator configured to control a series of vibratory pulses having an oscillation frequency and an oscillation magnitude of the support with the oscillation frequency and the oscillation magnitude configured to install the acetabular cup at the installation depth with the desired abduction angle and the desired anteversion angle responsive to the series of vibratory pulses; and an alignment system mechanically coupled to the support, wherein the alignment system includes a set of sensors and a feedback system configured to provide a direct real-time alignment variation indication during operation.

An installation system for a prosthesis configured to be installed into a portion of bone at a desired installation

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depth, the prosthesis including an attachment system, including an oscillation engine including a controller coupled to a vibratory machine generating an original series of pulses having a generation pattern, the generation pattern defining a first duty cycle of the original series of pulses; a pulse transfer assembly having a proximal end coupled to the oscillation engine and a distal end, spaced from the proximal end, coupled to the prosthesis with the pulse transfer assembly including a connector system at the proximal end, the connector system complementary to the attachment system and configured to secure and rigidly hold the prosthesis producing a secured prosthesis with the pulse transfer assembly communicating an installation series of pulses, responsive to the original series of pulses, to the secured prosthesis producing an applied series of ultrasonic pulses responsive to the installation series of pulses; and an alignment system mechanically coupled to the support, wherein the alignment system includes a set of sensors and a feedback system configured to provide a direct real-time alignment variation indication during operation; wherein the applied series of ultrasonic pulses are configured to impart a vibratory motion to the secured prosthesis enabling an installation of the secured prosthesis into the portion of bone to within 95% of the desired implantation depth.

A method for installing an acetabular cup into a prepared socket in a pelvic bone, the acetabular cup including an outer shell having a sidewall defining an inner cavity and an opening with the sidewall having a periphery around the opening and with the acetabular cup having a desired installation depth relative to the bone, a desired abduction angle relative to the bone, and a desired anteversion angle relative to the bone, including (a) generating an original series of pulses from an oscillation engine included in a prosthetic tool; (b) communicating the original series of pulses to the acetabular cup producing a communicated series of pulses at the acetabular cup; (c) vibrating, responsive to the communicated series of pulses, the acetabular cup to produce a vibrating acetabular cup having a predetermined vibration pattern; (d) inserting the vibrating acetabular cup into the prepared socket within a first predefined threshold of the installation depth with the desired abduction angle and the desired anteversion angle; and (e) monitoring directly a real-time alignment system coupled mechanically to the prosthetic tool to produce an installed alignment for the acetabular cup at a desired alignment with respect to the pelvic bone.

A method for inserting an implant into a prepared location in a live bone of a patient at a desired insertion depth at a desired relative alignment wherein non-vibratory insertion forces for inserting the prosthesis to the desired insertion depth are in a first range, the method including (a) vibrating the implant using a tool to produce a vibrating implant having a predetermined vibration pattern including an oscillation; (b) inserting the vibrating implant into the prepared location to within a first predetermined threshold of the desired insertion depth using vibratory insertion forces in a second range, the second range including a set of values less than a lowest value of the first range; and (c) aligning the vibrating implant to within a second threshold of the desired relative alignment using a direct view real-time alignment system mechanically coupled to the tool.

Any of the embodiments described herein may be used alone or together with one another in any combination. Inventions encompassed within this specification may also include embodiments that are only partially mentioned or alluded to or are not mentioned or alluded to at all in this brief summary or in the abstract. Although various embodi-

ments of the invention may have been motivated by various deficiencies with the prior art, which may be discussed or alluded to in one or more places in the specification, the embodiments of the invention do not necessarily address any of these deficiencies. In other words, different embodiments of the invention may address different deficiencies that may be discussed in the specification. Some embodiments may only partially address some deficiencies or just one deficiency that may be discussed in the specification, and some embodiments may not address any of these deficiencies.

Special sensors are added to an impact device having a separate device would provide feedback of the orientation of the impact device as measured by the sensors. The surgeon would position the impact device, divert attention from the device to review the orientation and make any desired correction to the orientation, and then bring attention back to the impact device trying to maintain the corrected orientation before striking the impact device.

Other features, benefits, and advantages of the present invention will be apparent upon a review of the present disclosure, including the specification, drawings, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying figures, in which like reference numerals refer to identical or functionally-similar elements throughout the separate views and which are incorporated in and form a part of the specification, further illustrate the present invention and, together with the detailed description of the invention, serve to explain the principles of the present invention.

FIG. 1 illustrates a representative installation gun;

FIG. 2 illustrates a right-hand detail of the installation gun of FIG. 1;

FIG. 3 illustrates a left-hand detail of the installation gun of FIG. 1 and generally when combined with FIG. 2 produces the illustration of FIG. 1;

FIG. 4 illustrates a second representative installation system;

FIG. 5 illustrates a disassembly of the second representative installation system of FIG. 4;

FIG. 6 illustrates a first disassembly view of the pulse transfer assembly of the installation system of FIG. 4;

FIG. 7 illustrates a second disassembly view of the pulse transfer assembly of the installation system of FIG. 4;

FIG. 8 illustrates a third representative installation system;

FIG. 9 illustrates a disassembly view of the third representative installation system of FIG. 8;

FIG. 10 illustrates a prosthetic tool;

FIG. 11 illustrates a representative direct view real-time display for an alignment system used in cooperation with a prosthetic tool;

FIG. 12 illustrates a representative prosthesis processing tool coupled to a set of accessories to improve performance, the set including a mechatronic handle and a damper;

FIG. 13 illustrates a perspective view of the mechatronic handle of FIG. 12; and

FIG. 14 illustrate a perspective view of the damper of FIG. 12.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the present invention provide a system and method for improving upon prosthesis installation, such

as including a real-time evaluation of tool and/or prosthesis alignment or position. The following description is presented to enable one of ordinary skill in the art to make and use the invention and is provided in the context of a patent application and its requirements.

Various modifications to the preferred embodiment and the generic principles and features described herein will be readily apparent to those skilled in the art. Thus, the present invention is not intended to be limited to the embodiment shown but is to be accorded the widest scope consistent with the principles and features described herein.

Definitions

Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this general inventive concept belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and the present disclosure, and will not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

The following definitions apply to some of the aspects described with respect to some embodiments of the invention. These definitions may likewise be expanded upon herein.

As used herein, the term “or” includes “and/or” and the term “and/or” includes any and all combinations of one or more of the associated listed items. Expressions such as “at least one of,” when preceding a list of elements, modify the entire list of elements and do not modify the individual elements of the list.

As used herein, the singular terms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to an object can include multiple objects unless the context clearly dictates otherwise.

Also, as used in the description herein and throughout the claims that follow, the meaning of “in” includes “in” and “on” unless the context clearly dictates otherwise. It will be understood that when an element is referred to as being “on” another element, it can be directly on the other element or intervening elements may be present therebetween. In contrast, when an element is referred to as being “directly on” another element, there are no intervening elements present.

As used herein, the term “set” refers to a collection of one or more objects. Thus, for example, a set of objects can include a single object or multiple objects. Objects of a set also can be referred to as members of the set. Objects of a set can be the same or different. In some instances, objects of a set can share one or more common properties.

As used herein, the term “adjacent” refers to being near or adjoining. Adjacent objects can be spaced apart from one another or can be in actual or direct contact with one another. In some instances, adjacent objects can be coupled to one another or can be formed integrally with one another.

As used herein, the terms “connect,” “connected,” and “connecting” refer to a direct attachment or link. Connected objects have no or no substantial intermediary object or set of objects, as the context indicates.

As used herein, the terms “couple,” “coupled,” and “coupling” refer to an operational connection or linking. Coupled objects can be directly connected to one another or can be indirectly connected to one another, such as via an intermediary set of objects.

As used herein, the terms “substantially” and “substantial” refer to a considerable degree or extent. When used in

conjunction with an event or circumstance, the terms can refer to instances in which the event or circumstance occurs precisely as well as instances in which the event or circumstance occurs to a close approximation, such as accounting for typical tolerance levels or variability of the embodiments described herein.

As used herein, the terms “optional” and “optionally” mean that the subsequently described event or circumstance may or may not occur and that the description includes instances where the event or circumstance occurs and instances in which it does not.

As used herein, the term “bone” means rigid connective tissue that constitute part of a vertebral skeleton, including mineralized osseous tissue, particularly in the context of a living patient undergoing a prosthesis implant into a portion of cortical bone. A living patient, and a surgeon for the patient, both have significant interests in reducing attendant risks of conventional implanting techniques including fracturing/shattering the bone and improper installation and positioning of the prosthesis within the framework of the patient’s skeletal system and operation.

As used herein, the term “prosthetic tool” refers to an implement, which may be powered using hydraulics, pneumatics, electricity, magnetics, mechanics, or combination, adapted for operating on, with, or in conjunction with, all or a portion of a prosthesis with regard to its assembly, installation, and/or positioning.

As used herein, the term “size” refers to a characteristic dimension of an object. Thus, for example, a size of an object that is spherical can refer to a diameter of the object. In the case of an object that is non-spherical, a size of the non-spherical object can refer to a diameter of a corresponding spherical object, where the corresponding spherical object exhibits or has a particular set of derivable or measurable properties that are substantially the same as those of the non-spherical object. Thus, for example, a size of a non-spherical object can refer to a diameter of a corresponding spherical object that exhibits light scattering or other properties that are substantially the same as those of the non-spherical object. Alternatively, or in conjunction, a size of a non-spherical object can refer to an average of various orthogonal dimensions of the object. Thus, for example, a size of an object that is a spheroidal can refer to an average of a major axis and a minor axis of the object. When referring to a set of objects as having a particular size, it is contemplated that the objects can have a distribution of sizes around the particular size. Thus, as used herein, a size of a set of objects can refer to a typical size of a distribution of sizes, such as an average size, a median size, or a peak size.

As used herein, mallet or hammer refers to an orthopedic device made of stainless steel or other dense material having a weight generally a carpenter’s hammer and a stonemason’s lump hammer.

As used herein, an impact force for impacting an acetabular component (e.g., an acetabular cup prosthesis) includes forces from striking an impact rod multiple times with the orthopedic device that are generally similar to the forces that may be used to drive a three inch nail into a piece of lumber using the carpenter’s hammer by striking the nail approximately a half-dozen times to completely seat the nail. Without limiting the preceding definition, a representative value in some instances includes a force of approximately 10 lbs/square inch.

As used herein, the term “vibration” or “vibratory” refers to a mechanical displacement oscillations (repetitive positional variation in time) about an equilibrium point that includes one or more axes of motion. The equilibrium point

may, in turn, move, such as for impactless implantation in which the equilibrium point is deeper into an installation site, for example, a desired depth into live bone. These vibrations are forced and responsive to a time-varying disturbance from an oscillation engine or the like applied, directly or indirectly, to a structure (e.g., a prosthesis or other implant) to be installed. The disturbance can be a periodic input, a steady-state input, a transient input, and/or a random input. A periodic input may include a harmonic or non-harmonic disturbance. Oscillation about the equilibrium point may be different, or similar, for each degree of freedom available for the vibratory motion. For example, there may be one oscillation profile longitudinally and a second oscillation profile laterally (e.g., perpendicular to the longitudinal axis), the two profiles generally matching, related, derived, or independent. An amount of displacement of an oscillation is generally less than a dimension of the implant, and may be much less, on the order of about a millimeter or less.

As used herein, the term “ultrasonic” refers to a vibration in which at least one oscillation component operates at a frequency greater than about 20 kHz, and more specifically in a range of 20 kHz to 2-3 GHz, and in some instances in a range of about 20 kHz to about 200 kHz.

The following description relates to improvements in a wide-range of prostheses installations into live bones of patients of surgeons. The following discussion focuses primarily on total hip replacement (THR) in which an acetabular cup prosthesis is installed into the pelvis of the patient. This cup is complementary to a ball and stem (i.e., a femoral prosthesis) installed into an end of a femur engaging the acetabulum undergoing repair.

As noted in the background, the surgeon prepares the surface of the hipbone which includes attachment of the acetabular prosthesis to the pelvis. Conventionally, this attachment includes a manual implantation in which a mallet is used to strike a tamp that contacts some part of the acetabular prosthesis. Repeatedly striking the tamp drives the acetabular prosthesis into the acetabulum. Irrespective of whether current tools of computer navigation, fluoroscopy, and robotics (and other intra-operative measuring tools) have been used, it is extremely unlikely that the acetabular prosthesis will be in the correct orientation once it has been seated to the proper depth by the series of hammer strikes. After manual implantation in this way, the surgeon then may apply a series of adjusting strikes around a perimeter of the acetabular prosthesis to attempt to adjust to the desired orientation. Currently such post-impaction result is accepted as many surgeons believe that post-impaction adjustment creates an unpredictable and unreliable change which does not therefore warrant any attempts for post-impaction adjustment.

In most cases, any and all surgeons including an inexperienced surgeon may not be able to achieve the desired orientation of the acetabular prosthesis in the pelvis by conventional solutions due to unpredictability of the orientation changes responsive to these adjusting strikes. As noted above, it is most common for any surgeon to avoid post-impaction adjustment as most surgeons understand that they do not have a reliable system or method for improving any particular orientation and could easily introduce more/greater error. The computer navigation systems, fluoroscopy, and other measuring tools are able to provide the surgeon with information about the current orientation of the prosthesis (in real time) during an operation and after the prosthesis has been installed and its deviation from the desired orientation, but the navigation systems (and others) do not protect against torsional forces created by the

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implanting/positioning strikes. The prosthesis will find its own position in the acetabulum based on the axial and torsional forces created by the blows of the mallet. Even those navigation systems used with robotic systems (e.g., MAKO) that attempt to secure an implant in the desired orientation prior to impaction are not guaranteed to result in the installation of the implant at the desired orientation because the actual implanting forces are applied by a surgeon swinging a mallet to manually strike the tamp.

A Behzadi Medical Device (BMD) is herein described and enabled that eliminates this crude method (i.e., mallet, tamp, and surgeon-applied mechanical implanting force) of the prosthesis (e.g., the acetabular cup). A surgeon using the BMD is able to insert the prosthesis exactly where desired with proper force, finesse, and accuracy. Depending upon implementation details, the installation includes insertion of the prosthesis into patient bone, within a desired threshold of metrics for insertion depth and location) and may also include, when appropriate and/or desired, positioning at a desired orientation with the desired threshold further including metrics for insertion orientation). The use of the BMD reduces risks of fracturing and/or shattering the bone receiving the prosthesis and allows for rapid, efficient, and accurate (atraumatic) installation of the prosthesis. The BMD provides a viable interface for computer navigation assistance (also useable with all intraoperative measuring tools including fluoroscopy) during the installation as a lighter more responsive touch may be used.

The BMD encompasses many different embodiments for installation and/or positioning of a prosthesis and may be adapted for a wide range of prostheses in addition to installation and/or positioning of an acetabular prosthesis during THR.

FIG. 1 illustrates a representative installation gun 100; FIG. 2 illustrates a right-hand detail of the installation gun 100; and FIG. 3 illustrates a left-hand detail of installation gun of 100 and generally when combined with FIG. 2 produces the illustration of FIG. 1. Installation gun 100 is represented as operable using pneumatics, though other implementations may use other mechanisms for creating a desired vibratory motion of prosthesis to be installed.

Installation gun 100 is used to control precisely one or both of (i) insertion, and (ii) abduction and anteversion angles of a prosthetic component. Installation gun 100 preferably allows both installation of an acetabular cup into an acetabulum at a desired depth and orientation of the cup for both abduction and anteversion to desired values. The following reference numbers in Table I refer to elements identified in FIG. 1-FIG. 3:

TABLE I

Device 100 Elements	
102	Middle guide housing
104	Klip
106	Kuciste
108	CILINDAR
110	Cjev
112	Poklopac
114	54 mm acetabular cup
116	Body
118	Valve
120	Bottom cap
122	Upper guide housing
124	Handle cam
126	DIN 3771 6 × 1.8-N—NBR 70
128	Main Air Inlet-Input Tube
130	Trigger

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TABLE I-continued

Device 100 Elements	
132	Trigger pin
134	DIN 3771 6 × 1.8-N—NBR 70
136	MirrorAR15-Hand Grip 1
138	Crossover Tube
140	9657K103 compression spring
142	Elongate tube
144	Lower guide housing
146	Primary adapter
148	Housing

Installation gun 100 includes a controller with a handle supporting an elongate tube 142 that terminates in adapter 146 that engages cup 114. Operation of trigger 130 initiates a motion of elongate tube 142. This motion is referred to herein as an installation force and/or installation motion that is much less than the impact force used in a conventional replacement process. An exterior housing 148 allows the operator to hold and position prosthesis 114 while elongate tube 142 moves within. Some embodiments may include a handle or other grip in addition to or in lieu of housing 148 that allows the operator to hold and operate installation gun 100 without interfering with the mechanism that provides a direct transfer of installation motion to prosthesis 114. The illustrated embodiment includes prosthesis 114 held securely by adapter 146 allowing a tilting and/or rotation of gun 100 about any axis to be reflected in the position/orientation of the secured prosthesis.

The installation motion includes constant, cyclic, periodic, and/or random motion (amplitude and/or frequency) that allows the operator to install cup 114 into the desired position (depth and orientation) without application of an impact force. There may be continuous movement or oscillations in one or more of six degrees of freedom including translation(s) and/or rotation(s) of adapter 146 about the X, Y, Z axes (e.g., oscillating translation(s) and/or oscillating/continuous rotation(s) which could be different for different axes such as translating back and forth in the direction of the longitudinal axis of the central support while rotating continuously around the longitudinal axis). This installation motion may include continuous or intermittent very high frequency movements and oscillations of small amplitude that allow the operator to easily install the prosthetic component in the desired location, and preferably also to allow the operator to also set the desired angles for abduction and anteversion.

In some implementations, the controller includes a stored program processing system that includes a processing unit that executes instructions retrieved from memory. Those instructions could control the selection of the motion parameters autonomously to achieve desired values for depth, abduction and anteversion entered into by the surgeon or by a computer aided medical computing system such as the computer navigation system. Alternatively those instructions could be used to supplement manual operation to aid or suggest selection of the motion parameters.

For more automated systems, consistent and unvarying motion parameters are not required and it may be that a varying dynamic adjustment of the motion parameters better conform to an adjustment profile of the cup installed into the acetabulum and status of the installation. An adjustment profile is a characterization of the relative ease by which depth, abduction and anteversion angles may be adjusted in positive and negative directions. In some situations these values may not be the same and the installation gun could be

enhanced to adjust for these differences. For example, a unit of force applied to pure positive anteversion may adjust anteversion in the positive direction by a first unit of distance while under the same conditions that unit of force applied to pure negative anteversion may adjust anteversion in the negative direction by a second unit of distance different from the first unit. And these differences may vary as a function of the magnitude of the actual angle(s). For example, as the anteversion increases it may be that the same unit of force results in a different responsive change in the actual distance adjusted. The adjustment profile when used helps the operator when selecting the actuators and the impact force(s) to be applied. Using a feedback system of the current real-time depth and orientation enables the adjustment profile to dynamically select/modify the motion parameters appropriately during different phases of the installation. One set of motion parameters may be used when primarily setting the depth of the implant and then another set used when the desired depth is achieved so that fine tuning of the abduction and anteversion angles is accomplished more efficiently, all without use of impact forces in setting the depth and/or angle adjustment(s).

This device better enables computer navigation as the installation/adjustment forces are reduced as compared to the impacting method. This makes the required forces more compatible with computer navigation systems used in medical procedures which do not have the capabilities or control systems in place to actually provide impacting forces for seating the prosthetic component. And without that, the computer is at best relegated to a role of providing after-the-fact assessments of the consequences of the surgeon's manual strikes of the orthopedic mallet. (Also provides information before and during the impaction. It is a problem that the very act of impaction introduces variability and error in positioning and alignment of the prosthesis.

FIG. 4 illustrates a second representative installation system 400 including a pulse transfer assembly 405 and an oscillation engine 410; FIG. 5 illustrates a disassembly of second representative installation system 400; FIG. 6 illustrates a first disassembly view of pulse transfer assembly 405; and FIG. 7 illustrates a second disassembly view of pulse transfer assembly 405 of installation system 400.

Installation system 400 is designed for installing a prosthesis that, in turn, is configured to be implanted into a portion of bone at a desired implantation depth. The prosthesis includes some type of attachment system (e.g., one or more threaded inserts, mechanical coupler, link, or the like) allowing the prosthesis to be securely and rigidly held by an object such that a translation and/or a rotation of the object about any axis results in a direct corresponding translation and/or rotation of the secured prosthesis.

Oscillation engine 410 includes a controller coupled to a vibratory machine that generates an original series of pulses having a generation pattern. This generation pattern defines a first duty cycle of the original series of pulses including one or more of a first pulse amplitude, a first pulse direction, a first pulse duration, and a first pulse time window. This is not to suggest that the amplitude, direction, duration, or pulse time window for each pulse of the original pulse series are uniform with respect to each other. Pulse direction may include motion having any of six degrees of freedom—translation along one or more of any axis of three orthogonal axes and/or rotation about one or more of these three axes. Oscillation engine 410 includes an electric motor powered by energy from a battery, though other motors and energy sources may be used.

Pulse transfer assembly 405 includes a proximal end 415 coupled to oscillation engine 410 and a distal end 420, spaced from proximal end 420, coupled to the prosthesis using a connector system 425. Pulse transfer assembly 405 receives the original series of pulses from oscillation engine 410 and produces, responsive to the original series of pulses, an installation series of pulses having an installation pattern. Similar to the generation pattern, the installation pattern defines a second duty cycle of the installation series of pulses including a second pulse amplitude, a second pulse direction, a second pulse duration, and a second pulse time window. Again, this is not to suggest that the amplitude, direction, duration, or pulse time window for each pulse of the installation pulse series are uniform with respect to each other. Pulse direction may include motion having any of six degrees of freedom—translation along one or more of any axis of three orthogonal axes and/or rotation about one or more of these three axes.

For some embodiments of pulse transfer assembly 405, the installation series of pulses will be strongly linked to the original series and there will be a close match, if not identical match, between the two series. Some embodiments may include a more complex pulse transfer assembly 405 that produces an installation series that is more different, or very different, from the original series.

Connector system 425 (e.g., one or more threaded studs complementary to the threaded inserts of the prosthesis, or other complementary mechanical coupling system) is disposed at proximal end 420. Connector system 425 is configured to secure and rigidly hold the prosthesis. In this way, the attached prosthesis becomes a secured prosthesis when engaged with connector system 425.

Pulse transfer assembly 405 communicates the installation series of pulses to the secured prosthesis and produces an applied series of pulses that are responsive to the installation series of pulses. Similar to the generation pattern and the installation pattern, the applied pattern defines a third duty cycle of the applied series of pulses including a third pulse amplitude, a third pulse direction, a third pulse duration, and a third pulse time window. Again, this is not to suggest that the amplitude, direction, duration, or pulse time window for each pulse of the applied pulse series are uniform with respect to each other. Pulse direction may include motion having any of six degrees of freedom—translation along one or more of any axis of three orthogonal axes and/or rotation about one or more of these three axes.

For some embodiments of pulse transfer assembly 405, the applied series of pulses will be strongly linked to the original series and/or the installation series and there will be a close, if not identical, match between the series. Some embodiments may include a more complex pulse transfer assembly 405 that produces an applied series that is more different, or very different, from the original series and/or the installation series. In some embodiments, for example one or more components may be integrated together (for example, integrating oscillation engine 410 with pulse transfer assembly 405) so that the first series and the second series, if they exist independently are nearly identical if not identical).

The applied series of pulses are designed to impart a vibratory motion to the secured prosthesis that enable an installation of the secured prosthesis into the portion of bone to within 95% of the desired implantation depth without a manual impact. That is, in operation, the original pulses from oscillation engine 410 propagate through pulse transfer assembly 405 (with implementation-depending varying levels of fidelity) to produce the vibratory motion to the prosthesis secured to connector system 425. In a first imple-

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mentation, the vibratory motion allows implanting without manual impacts on the prosthesis and in a second mode an orientation of the implanted secured prosthesis may be adjusted by rotations of installation system 400 while the vibratory motion is active, also without manual impact. In some implementations, the pulse generation may produce different vibratory motions optimized for these different modes.

Installation system 400 includes an optional sensor 430 (e.g., a flex sensor or the like) to provide a measurement (e.g., quantitative and/or qualitative) of the installation pulse pattern communicated by pulse transfer assembly 405. This measurement may be used as part of a manual or computerized feedback system to aid in installation of a prosthesis. For example, in some implementations, the desired applied pulse pattern of the applied series of pulses (e.g., the vibrational motion of the prosthesis) may be a function of a particular installation pulse pattern, which can be measured and set through sensor 430. In addition to, or alternatively, other sensors may aid the surgeon or an automated installation system operating installation system 400, such as a bone density sensor or other mechanism to characterize the bone receiving the prosthesis to establish a desired applied pulse pattern for optimal installation.

The disassembled views of FIG. 6 and FIG. 7 detail a particular implementation of pulse transfer assembly 405, it being understood that there are many possible ways of creating and communicating an applied pulse pattern responsive to a series of generation pulses from an oscillation engine. The illustrated structure of FIG. 6 and FIG. 7 generate primarily longitudinal/axial pulses in response to primarily longitudinal/axial generation pulses from oscillation engine 410.

Pulse transfer assembly 405 includes an outer housing 435 containing an upper transfer assembly 640, a lower transfer assembly 645 and a central assembly 650. Central assembly 650 includes a double anvil 655 that couples upper transfer assembly 640 to lower transfer assembly 645. Outer housing 635 and central assembly 650 each include a port allowing sensor 630 to be inserted into central assembly 650 between an end of double anvil 655 and one of the upper/lower transfer assemblies.

Upper transfer assembly 640 and lower transfer assembly 645 each include a support 660 coupled to outer housing 435 by a pair of connectors. A transfer rod 665 is moveably disposed through an axial aperture in each support 660, with each transfer rod 665 including a head at one end configured to strike an end of double anvil 655 and a coupling structure at a second end. A compression spring 670 is disposed on each transfer rod 665 between support 660 and the head. The coupling structure of upper transfer assembly 640 cooperates with oscillation engine 410 to receive the generated pulse series. The coupling structure of lower transfer assembly 645 includes connector system 425 for securing the prosthesis. Some embodiments may include an adapter, not shown, that adapts connector system 425 to a particular prosthesis, different adapters allowing use of pulse transfer assembly 405 with different prostheses.

Central assembly 650 includes a support 675 coupled to outer housing 435 by a connector and receives double anvil 655 which moves freely within support 675. The heads of the upper transfer assembly and the lower transfer assembly are disposed within support 675 and arranged to strike corresponding ends of double anvil 655 during pulse generation.

In operation, oscillation engine 410 generates pulses that are transferred via pulse transfer assembly 405 to the pros-

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thesis secured by connector system 425. The pulse transfer assembly 405, via upper transfer assembly 640, receives the generated pulses using transfer rod 665. Transfer rod 665 of upper transfer assembly 640 moves within support 660 of upper transfer assembly 640 to communicate pulses to double anvil 655 moving within support 675. Double anvil 655, in turn, communicates pulses to transfer rod 665 of lower transfer assembly 645 to produce vibratory motion of a prosthesis secured to connector system 425. Transfer rods 665 move, in this illustrated embodiment, primarily longitudinally/axially within outer housing 435 (a longitudinal axis defined as extending between proximate end 415 and distal end 420). In this way, the surgeon may use outer housing 435 as a hand hold when installing and/or positioning the vibrating prosthesis.

The use of discrete transfer portions (e.g., upper, central, and lower transfer assemblies) for pulse transfer assembly 405 allows a form of loose coupling between oscillation engine 410 and a secured prosthesis. In this way pulses from oscillation engine 410 are converted into a vibratory motion of the prosthesis as it is urged into the bone during operation. Some embodiments may provide a stronger coupling by directly securing one component to another, or substituting a single component for a pair of components.

FIG. 8 illustrates a third representative installation system 800; and FIG. 9 illustrates a disassembly view of third representative installation system 800.

The embodiments of FIG. 4-FIG. 8 have demonstrated insertion of a prosthetic cup into a bone substitute substrate with ease and a greatly reduced force as compared to use of a mallet and tamp, especially as no impaction was required. While the insertion was taking place and vibrational motion was present at the prosthesis, the prosthesis could be positioned with relative ease by torquing on a handle/outer housing to an exact desired alignment/position. The insertion force is variable and ranges between 20 to 800 pounds of force. Importantly the potential for use of significantly smaller forces in application of the prosthesis (in this case the acetabular prosthesis) in bone substrate with the present invention is demonstrated to be achievable.

Similarly to installation system 100 and installation system 400, installation system 800 is used to control precisely one or both of (i) installation and (ii) abduction and anteversion angles of a prosthetic component. Installation system 800 preferably allows both installation of an acetabular cup into an acetabulum at a desired depth and orientation of the cup for both abduction and anteversion to desired values. The following reference numbers in Table II refer to elements identified in FIG. 8-FIG. 9:

TABLE II

Device 800 Elements	
802	Air Inlet
804	Trigger
806	Needle Valve
808	Valve Body
810	Throttle Cap
812	Piston
814	Cylinder
816	Driver
818	Needle Block
820	Needles
822	Suspension Springs
824	Anvil
826	Nozzle
828	Connector Rod
830	Prosthesis (e.g., acetabular cup)

Installation system **800** includes a controller with a handle supporting an elongate rod that terminates in a connector system that engages prosthesis **830**. Operation of trigger **804** initiates a motion of the elongate rod. This motion is referred to herein as an installation force and/or installation motion that is much less than the impact force used in a conventional replacement process. An exterior housing allows the operator to hold and position prosthesis **830** while the elongate rod moves within. Some embodiments may include a handle or other grip in addition to or in lieu of the housing that allows the surgeon operator to hold and operate installation system **800** without interfering with the mechanism that provides a direct transfer of installation motion. The illustrated embodiment includes prosthesis **830** held securely allowing a tilting and/or rotation of installation system about any axis to be reflected in the position/orientation of the secured prosthesis.

The actuator is pneumatically operated oscillation device that provides the impact and vibration action this device uses to set the socket (it being understood that alternative motive systems may be used in addition to, or alternatively to, a pneumatic system). Alternatives including mechanical and/or electromechanical systems, motors, and/or engines. The actuator includes air inlet port **802**, trigger **804**, needle valve **806**, cylinder **814**, and piston **812**.

Air is introduced through inlet port **802** and as trigger **804** is squeezed needle valve **806** admits air into the cylinder **814** pushing piston **812** to an opposing end of cylinder **814**. At the opposite end piston **812** opens a port allowing the air to be admitted and pushing the piston **812** back to the original position.

This action provides the motive power for operation of the device and functions in this embodiment at up to 70 Hz. The frequency can be adjusted by trigger **804** and an available air pressure at air inlet port **802**.

As piston **812** impacts driver **816**, driver **816** impacts needles **820** of needle block **818**. Needles **820** strike anvil **824** which is directly connected to prosthesis **830** via connecting rod **828**.

Suspension springs **822** provide a flexibility to apply more or less total force. This flexibility allows force to be applied equally around prosthesis **830** or more force to one side of prosthesis **830** in order to locate prosthesis **830** at an optimum/desired orientation. Installation system **800** illustrates a BMD having a more strongly coupled pulse transfer system between an oscillation engine and prosthesis **830**.

The nature and type of coupling of pulse communications between the oscillation engine and the prosthesis may be varied in several different ways. For example, in some implementations, needles **820** of needle block **818** are independently moveable and respond differently to piston **812** motion. In other implementations, the needles may be fused together or otherwise integrated together, while in other implementations needles **820** and needle block **818** may be replaced by an alternative cylinder structure.

As illustrated, while both embodiments provide for a primarily longitudinal implementation, installation system **800** includes a design feature intended to allow the inserting/vibratory force to be "steered" by applying forces to be concentrated on one side or another of the prosthesis. Implementations that produce a randomized vibrational motion, including "lateral" motion components in addition to, or in lieu of, the primarily longitudinal vibrational motion of the disclosed embodiments may be helpful for installation of prosthesis in a wide range of applications including THR surgery.

Installation system **400** and installation system **800** included an oscillation engine producing pulses at approximately 60 Hz. System **400** operated at 60 Hz while system **800** was capable of operating at 48 to 68 Hz. In testing, approximately 4 seconds of operation resulted in a desired insertion and alignment of the prosthesis (meaning about 240 cycles of the oscillation engine). Conventional surgery using a mallet striking a tamp to impact the cup into place is generally complete after 10 blows of the mallet/hammer.

Experimental

Both system **400** and system **800** were tested in a bone substitute substrate with a standard Zimmer acetabular cup using standard technique of under reaming a prepared surface by 1 mm and inserting a cup that was one millimeter larger. The substrate was chosen as the best option available to us to study this concept, namely a dense foam material. It was recognized that certain properties of bone would not be represented here (e.g. an ability of the substrate to stretch before failure).

Both versions demonstrated easy insertion and positioning of the prosthetic cup within the chosen substrate. We were able to move the cup in the substrate with relative ease. There was no requirement for a mallet or hammer for application of a large impact. These experiments demonstrated that the prosthetic cups could be inserted in bone substitute substrates with significantly less force and more control than what could be done with blows of a hammer or mallet. We surmise that the same phenomena can be reproduced in human bone. We envision the prosthetic cup being inserted with ease with very little force.

Additionally we believe that simultaneously, while the cup is being inserted, the position of the cup can be adjusted under direct visualization with any intra-operative measurement system (navigation, fluoroscopy, etc.). This invention provides a system that allows insertion of a prosthetic component with NON-traumatic force (insertion) as opposed to traumatic force (impaction).

Experimental Configuration—System **400**

Oscillation engine **410** included a Craftsman G2 Hammerhead nailer used to drive fairly large framing nails into wood in confined spaces by applying a series of small impacts very rapidly in contrast to application of few large impacts.

The bone substitute was 15 pound density urethane foam to represent the pelvic acetabulum. It was shaped with a standard cutting tool commonly used to clean up a patient's damaged acetabulum. A 54 mm cup and a 53 mm cutter were used in testing.

In one test, the cup was inserted using a mallet and tamp, with impaction complete after 7 strikes. Re-orientation of the cup was required by further strikes on a periphery of the cup after impaction to achieve a desired orientation. It was qualitatively determined that the feel and insertion were consistent with impaction into bone.

An embodiment of system **400** was used in lieu of the mallet and tamp method. Several insertions were performed, with the insertions found to be much more gradual; allowing the cup to be guided into position (depth and orientation during insertion). Final corrective positioning is easily achievable using lateral hand pressure to rotate the cup within the substrate while power was applied to the oscillation engine.

Further testing using the sensor included general static load detection done to determine the static (non-impact) load to push the cup into the prepared socket model. This provided a baseline for comparison to the impact load testing. The prosthesis was provided above a prepared

socket with a screw mounted to the cup to transmit a force applied from a bench vise. The handle of the vice was turned to apply an even force to compress the cup into the socket until the cup was fully seated. The cup began to move into the socket at about an insertion force of ~200 pounds and gradually increased as diameter of cup inserted into socket increased to a maximum of 375 pounds which remained constant until the cup was fully seated.

Installation system **400** was next used to install the cup into a similarly prepared socket. Five tests were done, using different frame rates and setup procedures, to determine how to get the most meaningful results. All tests used a 54 mm acetabular Cup. The oscillation engine ran at an indicated 60 impacts/second. The first two tests were done at 2,000 frames/second, which wasn't fast enough to capture all the impact events, but helped with designing the proper setup. Test 3 used the oscillation engine in an already used socket, 4,000 frames per second. Test 4 used the oscillation engine in an unused foam socket at 53 mm, 4,000 frames per second.

Test 3: In already compacted socket, the cup was pulsed using the oscillation engine and the pulse transfer assembly. Recorded strikes between 500 and 800 lbs., with an average recorded pulse duration 0.8 ms.

Test 4: Into an unused 53 mm socket, the cup was pulsed using the oscillation engine and the pulse transfer assembly. Recorded impacts between 250 and 800 lbs., and an average recorded pulse duration 0.8 ms. Insertion completed in 3.37 seconds, **202** impact hits.

Test 5: Into an unused 53 mm socket, the cup was inserted with standard hammer (for reference). Recorded impacts between 500 and 800 lbs., and an average recorded pulse duration 22.0 ms. Insertion completed in 4 seconds using 10 impact hits for a total pressure time of 220 ms. This test was performed rapidly to complete it in 5 seconds for good comparability with tests 3 and 4 used 240 hits in 4 seconds, with a single hit duration of 0.8 ms, for a total pressure time of 192 ms.

In non-rigorous comparison testing without a direct comparison between system **400** and system **800**, generally it appears that the forces used for installation using system **800** were lower than system **400** by a factor of 10. This suggests that there are certain optimizing characteristics for operation of an installation system. There are questions such as to how low these forces can be modulated and still allow easy insertion of the prosthetic cup in this model and in bone. What is the lowest force required for insertion of a prosthetic cup in to this substrate using the disclosed concepts? What is the lowest force required for insertion of a prosthetic cup into hard bone using these concepts? And what is the lowest force required for insertion of a prosthetic cup into soft and osteoporotic bone using these concepts? These are the questions that can be addressed in future phase of implementations of the present invention.

Additionally, it is believed possible to correlate a density and a porosity of bone at various ages (e.g., through a cadaver study) with an appropriate force range and vibratory motion pattern required to insert a cup using the present invention. For example a surgeon will be able to insert sensing equipment in patient bone, or use other evaluative procedures, (preoperative planning or while performing the procedure for example) to assess—porosity and density of bone. Once known, the density or other bone characteristic is used to set an appropriate vibratory pattern including a force range on an installation system, and thus use a minimal required force to insert and/or position the prosthesis.

FIG. **10** illustrates a prosthetic tool **1000**. Tool **1000** may be configured to operate on a structure S, such as an acetabular cup for total hip arthroplasty. In other embodiments, tool **1000** may be configured to secure and operate a processing head, for example a reamer, cutter, or other tissue manipulation device. Structure S may include a mounting system, such as a threaded cavity or other mechanical coupling system allowing selective engagement and disengagement or structure S may be integrated with tool **1000**.

Tool **1000** includes a housing **1005** that includes a motor, for example an electric, hydraulic, pneumatic, and/or spring powered assembly, and the like. Some embodiments may not include a motor with housing **1005** including use as a support structure for other components and/or a hand-held. Housing **1005** includes a proximal end and a distal end with a mount **1010** coupled to the distal end and an alignment system **1015** coupled to the proximal end. Mount **1010** provides a mechanism to join, attach, fix, and/or mount structure S to tool **1000**. When structure S includes a threaded cavity, mount **1010** may include a complementary threaded shaft. There are a wide range of possible embodiments for tool **1000** and for structure S, therefore the mounting/attachment specifics are configured to allow tool **1000** to properly operate and manipulate structure S.

Alignment system **1015** includes an implementation of an inertial measurement system (IMU) for real-time intra-procedure feedback to the surgeon of a current orientation of tool **1000**. One problem for a surgeon is to know exactly the absolute attitude (pointing of tool **1000** in three dimensional space). There are tracking systems that are based on machine-readable markers that do this, but require cameras, calibration, and special procedures to configure them (for a particular 3D space like a single operating room). Once well configured, they work nicely, but need those markers and supporting external equipment which is inconvenient, especially limiting in moving the tool to another 3D space for another procedure. Alignment system **1015** may include an IMU, a variation of systems used in satellites, airplanes, and missiles, and the like. Alignment system **1015** may thus include one or more accelerometers, gyrometers, magnetic sensors, positional sensors, orientation sensors, combinations of these, and other inertial measurement devices.

Alignment system **1015** allows the surgeon using tool **1000** to improve tissue preparation or prosthesis insertion according to real-time steering data. Embodiments may include a distinction in outputting measurements/feedback directly to the surgeon during use. The process is half physical (measurement) and half mathematical (filtering and estimation) in order to fuse information and get a precise pointing.

For example: the surgeon uses the navigation to see correct inclination and anteversion. Once it is achieved, the surgeon may actuate a control **1020**, e.g., a small button, on tool **1000**. The orientation of tool **1000** at the time of actuation of control **1020** would become the orientation target, available to a feedback system **1025**, e.g., a display, coupled to or part of, alignment system **1015**. Now the surgeon does not need to look anywhere other than at feedback system **1025**, or at the site where tissue or the prosthesis is being processed. The surgeon easily references feedback system **1025** as necessary or desirable in real-time which indicates how far a current orientation of tool **1000** is from the desired inclination/anteversion values. Alignment system **1015** may operate as a relative orientation to localized 3D space of the procedure or it may operate as an absolute orientation referenced into a larger 3D space, such as the operating room.

FIG. 11 illustrates a representative direct view real-time feedback system 1025, e.g., a display, for alignment system 1015 used in cooperation with tool 1000. In operation, a surgeon locates tool 1000 with a desired orientation alignment and then operates control 1020. Operation of control 1020 sets the desired alignment indicator element of feedback system 1025. Subsequent manipulation of tool 1000 is reflected in a current alignment indicator element of feedback system 1025. As an orientation of tool 1000 changes in 3D space, current alignment indicator element changes. The surgeon can visualize how closely a current alignment of tool 1000 is to the desired orientation by referencing feedback system 1025 at any time to check on any differences between the indicators. When there is a difference, the surgeon easily reorients tool 1000 to the desired orientation by aligning the current alignment indicator element to the desired alignment indicator element.

Feedback system 1025 may include alternative indication systems that include various visual,

Tool 1000 allows a surgeon to have additional options and methods for evaluation, operation, and/or installation of structure S during intra-operative procedures.

For example, with regards to a reaming process, it may be noted that reaming is traditionally performed with little attention to directionality and alignment. Processing in this way may cause the preparation of the acetabulum to be imprecise and lead to a “predetermined path of sinking” that is less than ideal as it can result in an installed acetabular cup in an orientation that is not desired and which could cause compounding problems to correct. Tool 1000 allows for a concept of “directionality for reaming” in which structure S includes a reaming head and tool 1000 is used to maintain a desired orientation during reaming. Tool 1000 allows the surgeon to pay attention to alignment not just during the impaction process but also while reaming or other processing.

Non-tool 1000 methods for assessing alignment include A-frame, computer navigation, anterior approach with fluoroscopy, and patient specific instrumentation. Tool 1000 provides an alternative that is superior for many reasons.

1. The A-frame is a simple mechanical carpenter’s device with known angles and orthogonals, attached to the impaction rod, that allows the surgeon to ascertain 45 degree of abduction and 20 degrees of anti-version, as the surgeon holds the cup in the acetabulum ready for impaction. It is used only during the impaction process. Surgeons who use this technique do not routinely apply the A-frame to the reamer and therefore have no clue of the direction of reaming while performing the operation.

2. Computer Navigation is a process that allows the surgeon to know the planes of the pelvis, patient’s body, the OR table and the acetabular cup in the OR space. It allows the surgeon to have a sense of the direction of the reaming as well as the alignment of the cup. It is a very useful method that provides good intra-operative real time information. However, few surgeons have adopted this technique due to added OR time and its bulky presence in the OR theater.

3. Anterior Approach with fluoroscopy. The patient is supine and the surgeon has immediate visual information about the position of the reamer and the cup (sometimes computer software may be available that allows exact calculation of the cup’s inclination and ante-version angles it is not routinely used). The flow of real time visual information is easily processed in the surgeon’s brain and much more usable to many surgeons than navigation. The surgeon has a sense of the direction of reaming and the alignment of the cup during impaction. This is the primary reason fluoros-

copy has been adopted. The secondary reason is that the surgeon has an immediate sense of the leg lengths.

4. PSI or patient specific Instrumentation. This process has been more popular in total knees replacement; however, it has application in total hip replacement as well. Through a CT scan or MRI, a 3D model of the acetabulum is created. This 3D model allows the desired central axis of impaction to be set. A 3D custom guide is made that fits into the acetabulum. Through the computer software the desired angle of ante-version and inclination is predetermined and set on the 3D guide. Once the guide is seated within the patient’s acetabulum the desired alignment is set. A double laser system is then used to maintain this alignment throughout the operation, with the reaming and impaction process.

Irrespective of how a surgeon attains and sets a desired alignment, tool 1000 allows the surgeon to maintain the desired alignment without use of bulky equipment in the OR theater.

The IMU technique as described can take the alignment that is set and maintain that vector memorized in the OR space. All measurement equipment and techniques may thereafter be quickly removed from the OR setting (Computer navigation, C-Arm, A-Frame, and the like). All that is used is a small screen or other feedback device attached to tool 1000 (e.g., a reamer, an impactor, a BMD, or the like) that shows the three-dimensional deviation of the axis of the tool from the desired/set axis.

The surgeon can then be fully aware of the directionality and alignment of the reaming during processing. Finishing every reaming in the final desired alignment is expected to improve the placement of the prosthesis by helping “predetermine” the sinking path. Similarly when the surgeon impacts or inserts the cup, an IMU device attached to the impactor/insertor provides immediate real time information as to the three-dimensional position of the cup. The surgeon can watch ONLY the feedback screen and make real-time changes as the prosthesis is impacted or inserted.

The 5th technique of setting the desired alignment is a novel technique that utilizes tool 1000 to assess, choose, and set alignment. An embodiment of this method may revolutionize (unify) the way hip replacement surgery is done. Currently about 20% of surgeons have adopted anterior approach with fluoroscopy. However, many surgeons believe this technique is harder and less intuitive. For example, an embodiment may include a system or method that uses a single X-ray in the lateral position with tool 1000 to set the alignment. The patient can be positioned in the standard lateral decubitus position as is commonly done in posterior approach hip replacement surgery. Once the acetabulum is exposed, the surgeon will hold a “preliminary cup” with IMU monitor attached in the acetabular fossa and get an X-ray. As the X-ray is done, a button is pushed on the IMU to set the position of the cup in the OR space. X-ray software exists that can calculate the exact alignment of the “preliminary cup” in the acetabulum. From here on forward, mathematical calculations can be done in the IMU to determine the position of the cup in the OR space. For example when the IMU knows where 5 degrees of ante-version and 30 degrees of inclination is in the OR space, it can calculate 20 degrees of ante-version and 40 degrees of inclination internally and let you know how to hold the impaction rod to achieve that alignment for the cup. There is no further need for X-ray or C-arm machines (or Navigation units) to remain in the OR. There is no further need to continuously irradiate the patient, the surgeon and the OR staff. At the time the single X-ray is taken the IMU is calibrated in the OR space, and all other points/lines in the OR can be

determined by the calculations within the IMU. This technique may allow some of the surgeons who feel uncomfortable with the C-Arm unit and Navigation to utilize a simple X-ray along with the IMU to access the spatial map of the OR.

Incorporated U.S. patent application Ser. No. 14/965,851 includes a tool **1000**, e.g., an installing BMD, that uses a visual line of sight to assure co-axiality for installation forces. Use of an alignment system **1015** in cooperation with the installing BMD may provide improved performance of prosthesis-to-prosthesis and prosthesis to bone/tissue.

BMD is a "must have" device for all medical device companies and surgeons. Without BMD the Implantation problem is not addressed, regardless of the recent advances in technologies in hip replacement surgery (i.e.; Navigation, Fluoroscopy, MAKO/robotics, accelerometers/gyro meters, etc.). Acetabular component (cup) positioning remains the biggest problem in hip replacement surgery. Implantation is the final step where error is introduced into the system and heretofore no attention has been brought to this problem. Current technologies have brought significant awareness to the position of the implants within the pelvis during surgery, prior to impaction. However, these techniques do not assist in the final step of implantation.

BMD allows all real time information technologies to utilize (a tool) to precisely and accurately implant the acetabular component (cup) within the pelvic acetabulum. BMD device coupled with use of navigation technology and fluoroscopy and (other novel measuring devices) is the only device that will allow surgeons from all walks of life, (low volume/high volume) to perform a perfect hip replacement with respect to acetabular component (cup) placement. With the use of BMD, surgeons can feel confident that they are doing a good job with acetabular component positioning, achieving the "perfect cup" every time. Hence the BMD concept eliminates the most common cause of complications in hip replacement surgery which has forever plagued the surgeon, the patients and the society in general.

Some use of ultra sound devices, generally, may be used in connection with some aspects of THR, such as for implant removal (as some components may be installed using a cement that may be softened using ultrasound energy). There may be some suggestion that some ultrasonic devices that employ "ultrasound" energy could be used to insert a prosthesis for final fit, but it is in the context of a femoral component and it is believed that these devices are not presently actually used in the process). Some embodiments of BMD, in contrast, can simply be a vibratory device (non ultrasonic), and may not be ultrasonic and some implementations may include ultrasonic operation, and may be more profound than simply an implantation device as it is most preferably a positioning device for the acetabular component in THR. Further, there is a discussion that ultrasound devices may be used to prepare bones for implanting a prosthesis. BMD does not address preparation of the bone as this is not a primary thrust of this aspect of the present invention. Some implementations of BMD may include a similar or related feature. The forces applied by the vibration will be less than an impact force and preferably enable installation without requiring impact forces applied to the mechanism by which the equilibrium point is moved during installation of the vibrating implant. That mechanism may be hand pressure from the surgeon guiding the vibrating implant into a desired depth and orientation or may include some other mechanical application of less-than-impact force to adjust the equilibrium point.

Some embodiments BMD include devices that concern themselves with proper installation and positioning of the prosthesis (e.g., an acetabular component) at the time of implanting of the prosthesis. Very specifically, it uses some form of vibratory energy coupled with a variety of "real time measurement systems" to POSITION the cup in a perfect alignment with minimal use of force. A prosthesis, such as for example, an acetabular cup, resists insertion. Once inserted, the cup resists changes to the inserted orientation. The BMDs of the present invention produce an insertion vibratory motion of a secured prosthesis that reduces the forces resisting insertion. In some implementations, the BMD may produce a positioning vibratory motion that reduces the forces resisting changes to the orientation. There are some implementations that produce both types of motion, either as a single vibratory profile or alternative profiles. In the present context for purposes of the present invention, the vibratory motion is characterized as "floating" the prosthesis as the prosthesis can become much simpler to insert and/or re-orient while the desired vibratory motion is available to the prosthesis. Some embodiments are described as producing vibrating prosthesis with a predetermined vibration pattern. In some implementations, the predetermined vibration pattern is predictable and largely completely defined in advance. In other implementations, the predetermined vibration pattern includes randomized vibratory motion in one or more motion freedoms of the available degrees of freedom (up to six degrees of freedom). That is, whichever translation or rotational freedom of motion is defined for the vibrating prosthesis, any of them may have an intentional randomness component, varying from large to small. In some cases the randomness component in any particular motion may be large and in some cases predominate the motion. In other cases the randomness component may be relatively small as to be barely detectable.

FIG. 12 illustrates a processing system **1200** including representative prosthesis processing tool **1205** coupled to a set of accessories to improve performance, the set including a mechatronic handle **1210** and a damper **1215**. System **1200** is representative of certain BMD3 subsonic, or sonic, and perhaps BMD4 devices, and the like, which are mechanisms that may be made compatible with accessories that introduce intelligent behavior to the insertion procedure. The idea is to develop new mechanisms and house them as replaceable heads. FIG. 12 illustrates the mechanism of the BMD3 processing head as a replaceable/substitutable head. There are two accessories attached to the replaceable head, they are: shock absorber (damper) **1215** and mechatronic handle **1210**.

FIG. 13 illustrates a perspective view of mechatronic handle **1210** of FIG. 12. Handle **1210** includes a push button **1305**, a set of M5 screws **1310**, an MH Housing Bed **1315**, a TFT display **1320**, a connector **1325**, an IMU **1330**, a TFT controller **1335**, and an MH Housing roof **1340**.

The mechatronic handle **1210** houses additional sensors (e.g. gyros, accelerometers, inclinometers, etc.), support circuitry, cabling, TFT screen for visual feedback, and pushbutton to allow surgeon interaction during operation of this device.

The mechatronic handle **1210** is not expected to be a source of mechanical power. In order to minimize any discomfort during operation of the device under vibration, there is damper **1215**. Its primary function is to couple replaceable head **1205** and mechatronic handle **1210** to each other while damping vibrations generated by the replaceable head **1205**.

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FIG. 14 illustrate a perspective view of damper 1215 of FIG. 12. Damper 1215 includes a top support 1405, a bump stop cap 1410, a bump stop pin 1415, a spring 1420, a puck stop 1425, a sensor 1430, a puck bottom 1435, and a bottom support 1440. Note that a force sensor can be introduced in the damper in order to provide feedback about the preload (load provided by the surgeon directly while pressing the device against the cavity).

Damper 1215 and mechatronic handle 1210 can be used with several configurations of replaceable heads, this is what makes the device more versatile. Implementations of a Force Sensor System for Controlled in Insertion, navigation assisted insertion, and hybrid mechanism operation can be made possible by the use of a mechatronic handle.

The system and methods above has been described in general terms as an aid to understanding details of preferred embodiments of the present invention. In the description herein, numerous specific details are provided, such as examples of components and/or methods, to provide a thorough understanding of embodiments of the present invention. Some features and benefits of the present invention are realized in such modes and are not required in every case. One skilled in the relevant art will recognize, however, that an embodiment of the invention can be practiced without one or more of the specific details, or with other apparatus, systems, assemblies, methods, components, materials, parts, and/or the like. In other instances, well-known structures, materials, or operations are not specifically shown or described in detail to avoid obscuring aspects of embodiments of the present invention.

Reference throughout this specification to “one embodiment”, “an embodiment”, or “a specific embodiment” means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention and not necessarily in all embodiments. Thus, respective appearances of the phrases “in one embodiment”, “in an embodiment”, or “in a specific embodiment” in various places throughout this specification are not necessarily referring to the same embodiment. Furthermore, the particular features, structures, or characteristics of any specific embodiment of the present invention may be combined in any suitable manner with one or more other embodiments. It is to be understood that other variations and modifications of the embodiments of the present invention described and illustrated herein are possible in light of the teachings herein and are to be considered as part of the spirit and scope of the present invention.

It will also be appreciated that one or more of the elements depicted in the drawings/figures can also be implemented in a more separated or integrated manner, or even removed or rendered as inoperable in certain cases, as is useful in accordance with a particular application.

Additionally, any signal arrows in the drawings/Figures should be considered only as exemplary, and not limiting, unless otherwise specifically noted. Combinations of components or steps will also be considered as being noted, where terminology is foreseen as rendering the ability to separate or combine is unclear.

The foregoing description of illustrated embodiments of the present invention, including what is described in the Abstract, is not intended to be exhaustive or to limit the invention to the precise forms disclosed herein. While specific embodiments of, and examples for, the invention are described herein for illustrative purposes only, various equivalent modifications are possible within the spirit and scope of the present invention, as those skilled in the

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relevant art will recognize and appreciate. As indicated, these modifications may be made to the present invention in light of the foregoing description of illustrated embodiments of the present invention and are to be included within the spirit and scope of the present invention.

Thus, while the present invention has been described herein with reference to particular embodiments thereof, a latitude of modification, various changes and substitutions are intended in the foregoing disclosures, and it will be appreciated that in some instances some features of embodiments of the invention will be employed without a corresponding use of other features without departing from the scope and spirit of the invention as set forth. Therefore, many modifications may be made to adapt a particular situation or material to the essential scope and spirit of the present invention. It is intended that the invention not be limited to the particular terms used in following claims and/or to the particular embodiment disclosed as the best mode contemplated for carrying out this invention, but that the invention will include any and all embodiments and equivalents falling within the scope of the appended claims. Thus, the scope of the invention is to be determined solely by the appended claims.

The invention claimed is:

1. An apparatus, comprising:

a prosthetic tool;

a set of sensors mechanically coupled to said prosthetic tool, said set of sensors including one or more structures selected from the group consisting essentially of one or more accelerometers, one or more gyro meters, one or more magnetic sensors, and combinations thereof; and

a damper coupling said tool to said set of sensors wherein said prosthetic tool includes a housing, further comprising:

an alignment system mechanically coupled to said housing, wherein said alignment system includes said set of sensors and a feedback system configured to provide an alignment variation indication during operation wherein said prosthetic tool includes a mounting system securing a prosthesis and wherein said housing contains an oscillation motor configured to vibrate said mounting system with a predetermined vibration profile.

2. The apparatus of claim 1 wherein said tool includes a replaceable tool.

3. The apparatus of claim 2 wherein said replaceable tool is selected from a set of replaceable tools including one or more of a BMD1, a BMD2, a BMD3, a BMD4, and a BMD5.

4. An apparatus, comprising:

a prosthetic tool;

a set of sensors mechanically coupled to said prosthetic tool, said set of sensors including one or more structures selected from the group consisting essentially of one or more accelerometers, one or more gyro meters, one or more magnetic sensors, and combinations thereof; and

a damper coupling said tool to said set of sensors wherein said prosthetic tool includes a housing, further comprising:

an alignment system mechanically coupled to said housing, wherein said alignment system includes said set of sensors and a feedback system configured to provide an alignment variation indication during operation wherein said prosthetic tool includes a mounting sys-

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tem securing a tissue processing head and wherein said housing contains a motor configured to operate said tissue processing head.

5. The apparatus of claim 4 wherein said tissue processing head includes a tissue reaming configuration.

6. An installation device for an acetabular cup disposed in a pelvic bone, the acetabular cup including an outer shell having a sidewall defining an inner cavity and an opening with the sidewall having a periphery around the opening and with the acetabular cup having a desired installation depth relative to the bone, a desired abduction angle relative to the bone, and a desired anteversion angle relative to the bone, comprising:

a controller including a trigger;

a support having a proximal end and a distal end opposite of said proximal end, said support further having a longitudinal axis extending from said proximal end to said distal end with said proximal end coupled to said controller, said support further having an adapter coupled to said distal end with said adapter configured to secure the acetabular cup;

an oscillator coupled to said controller and to said support, said oscillator configured to control a series of vibratory pulses having an oscillation frequency and an oscillation magnitude of said support with said oscillation frequency and said oscillation magnitude configured to install the acetabular cup at the installation depth with the desired abduction angle and the desired anteversion angle responsive to said series of vibratory pulses; and

an alignment system mechanically coupled to said support, wherein said alignment system includes a set of sensors and a feedback system configured to provide a direct real-time alignment variation indication during operation; and

a damper coupling said oscillator to said set of sensors.

7. The installation device of claim 6 wherein said support includes one to six degrees of freedom relative to an X-axis, a Y-axis, and a Z-axis, and wherein said oscillation magnitude includes one or more oscillation directions selected from the group consisting of a translation direction, a rotation direction, an X-axis translation direction, a Y-axis translation, a Z-axis translation, a pitch direction about said X-axis, a yaw direction about said Y-axis, a roll direction about said Z-axis, and combinations thereof.

8. The installation device of claim 6 wherein said series of vibratory pulses includes a vibratory motion having a frequency greater than or equal to about 20 kHz.

9. An installation system for a prosthesis configured to be installed into a portion of bone at a desired installation depth, the prosthesis including an attachment system, comprising:

an oscillation engine including a controller coupled to a vibratory machine generating an original series of pulses having a generation pattern, said generation pattern defining a first duty cycle of said original series of pulses;

a pulse transfer assembly having a proximal end coupled to said oscillation engine and a distal end, spaced from said proximal end, coupled to the prosthesis with said pulse transfer assembly including a connector system at said proximal end, said connector system complementary to the attachment system and configured to secure and rigidly hold the prosthesis producing a secured prosthesis with said pulse transfer assembly communicating an installation series of pulses, responsive to said original series of pulses, to said secured prosthesis

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producing an applied series of ultrasonic pulses responsive to said installation series of pulses; and

an alignment system mechanically coupled to said support, wherein said alignment system includes a set of sensors and a feedback system configured to provide a direct real-time alignment variation indication during operation;

wherein said applied series of ultrasonic pulses are configured to impart a vibratory motion to said secured prosthesis enabling an installation of said secured prosthesis into the portion of bone to within 95% of the desired implantation depth; and

wherein a damper couples said oscillator to said set of sensors.

10. The installation system of claim 9 wherein said pulse transfer assembly receives said original series of pulses from said oscillation engine and produces, responsive to said original series of pulses, an installation series of pulses having an installation pattern, said installation pattern defining a second duty cycle of said installation series of pulses including a second pulse amplitude, a second pulse direction, a second pulse duration, and a second pulse time window with said pulse transfer assembly communicating said installation series of pulses to said secured prosthesis producing said applied series of ultrasonic pulses responsive to said installation series of pulses.

11. The installation system of claim 10 wherein said pulse transfer assembly includes a body and an elongate vibration assembly having a proximal end and a distal end opposite of said proximal end, said proximal disposed within said body and coupled to said oscillation engine with said distal end extending outside said body and including said connector system;

said elongate vibration assembly configured to move relative to said body and having one or more degrees of freedom.

12. The installation system of claim 9 wherein said pulse transfer assembly includes a body and an elongate vibration assembly having a proximal end and a distal end opposite of said proximal end, said proximal disposed within said body and coupled to said oscillation engine with said distal end extending outside said body and including said connector system;

said elongate vibration assembly configured to move relative to said body and having one or more degrees of freedom.

13. A method for installing an acetabular cup into a prepared socket in a pelvic bone, the acetabular cup including an outer shell having a sidewall defining an inner cavity and an opening with the sidewall having a periphery around the opening and with the acetabular cup having a desired installation depth relative to the bone, a desired abduction angle relative to the bone, and a desired anteversion angle relative to the bone, comprising:

(a) generating an original series of pulses from an oscillation engine included in a prosthetic tool;

(b) communicating said original series of pulses to the acetabular cup producing a communicated series of pulses at said acetabular cup;

(c) vibrating, responsive to said communicated series of pulses, the acetabular cup to produce a vibrating acetabular cup having a predetermined vibration pattern;

(d) inserting the vibrating acetabular cup into the prepared socket within a first predefined threshold of the installation depth with the desired abduction angle and the desired anteversion angle; and

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- (e) monitoring directly a real-time alignment system coupled mechanically to said prosthetic tool to produce an installed alignment for the acetabular cup at a desired alignment with respect to the pelvic bone; and
- (f) isolating said real-time alignment system from said prosthetic tool using a damper.

14. The method of claim **13** further comprising:

- (f) orienting, responsive to a feedback system of said alignment system, the vibrating acetabular cup within the prepared socket within a second predetermined threshold of the desired abduction angle and within third predetermined threshold of the desired anteversion angle.

15. A method for inserting an implant into a prepared location in a live bone of a patient at a desired insertion depth at a desired relative alignment wherein non-vibratory insertion forces for inserting the prosthesis to the desired insertion depth are in a first range, the method comprising:

- (a) vibrating the implant using a tool to produce a vibrating implant having a predetermined vibration pattern including an oscillation;
- (b) inserting the vibrating implant into the prepared location to within a first predetermined threshold of the desired insertion depth using vibratory insertion forces

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in a second range, said second range including a set of values less than a lowest value of the first range; and

- (c) aligning the vibrating implant to within a second threshold of the desired relative alignment using a direct view real-time alignment system mechanically coupled to said tool; and
- (d) isolating said direct view real-time alignment system from said tool using a damper.

16. The method of claim **15** wherein said second range is less than first range.

17. The method of claim **15** wherein said inserting step (b) includes:

- (b1) determining automatically, using an automated depth determining tool, a current insertion depth of said vibrating prosthesis; and
- (b2) increasing automatically, using an intraoperative robotic tool, said current insertion depth until said current depth is within said first predetermined threshold.

18. The method of claim **15** wherein the implant includes an acetabular cup prosthesis.

19. The method of claim **15** wherein said vibrating implants includes a vibration having an ultrasonic oscillation.

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