



(19) **United States**

(12) **Patent Application Publication**
Ferko et al.

(10) **Pub. No.: US 2012/0089146 A1**

(43) **Pub. Date: Apr. 12, 2012**

(54) **SYSTEM AND METHOD OF BONE PREPARATION**

Publication Classification

(51) **Int. Cl.**
A61B 17/56 (2006.01)

(52) **U.S. Cl.** **606/87**

(57) **ABSTRACT**

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(21) Appl. No.: **12/898,937**

(22) Filed: **Oct. 6, 2010**

The invention includes a system, method and kit for preparation of a bone. One aspect of the present invention is a bone preparation system comprising a cutting instrument and a guiding element. The cutting instrument includes a distal attachment feature and a distal region. The guiding element includes a proximal attachment feature and a guiding surface. When the proximal attachment feature of the guiding element is engaged with the distal attachment feature of the cutting instrument, the cutting instrument can pivot about the proximal attachment feature until the distal region contacts the guiding surface.

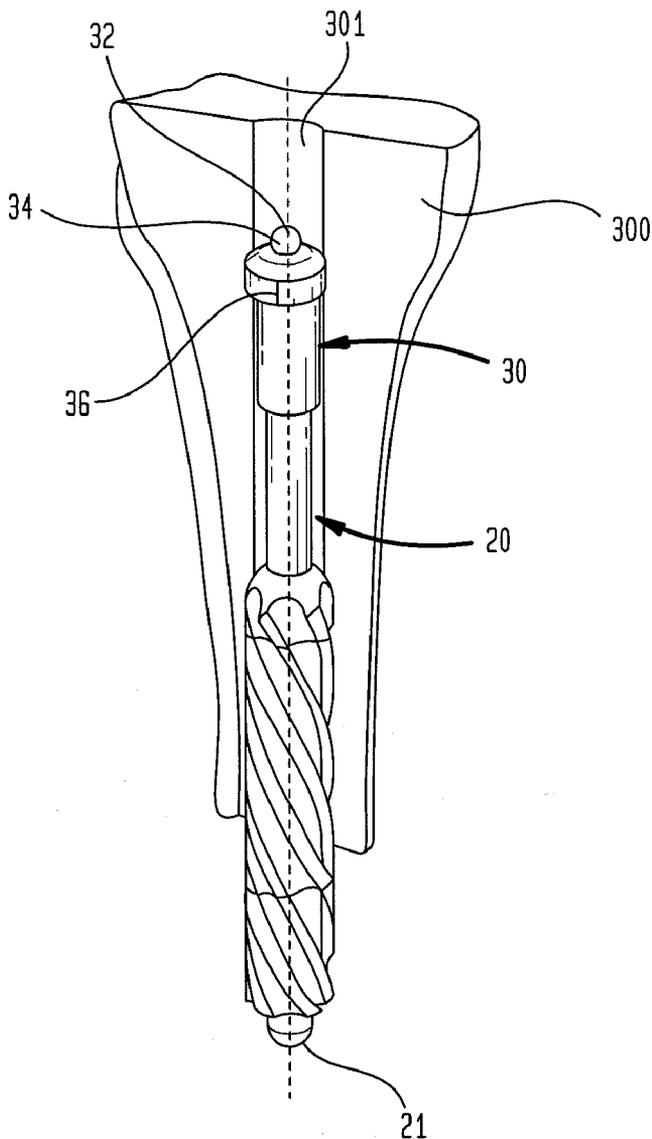


FIG. 1

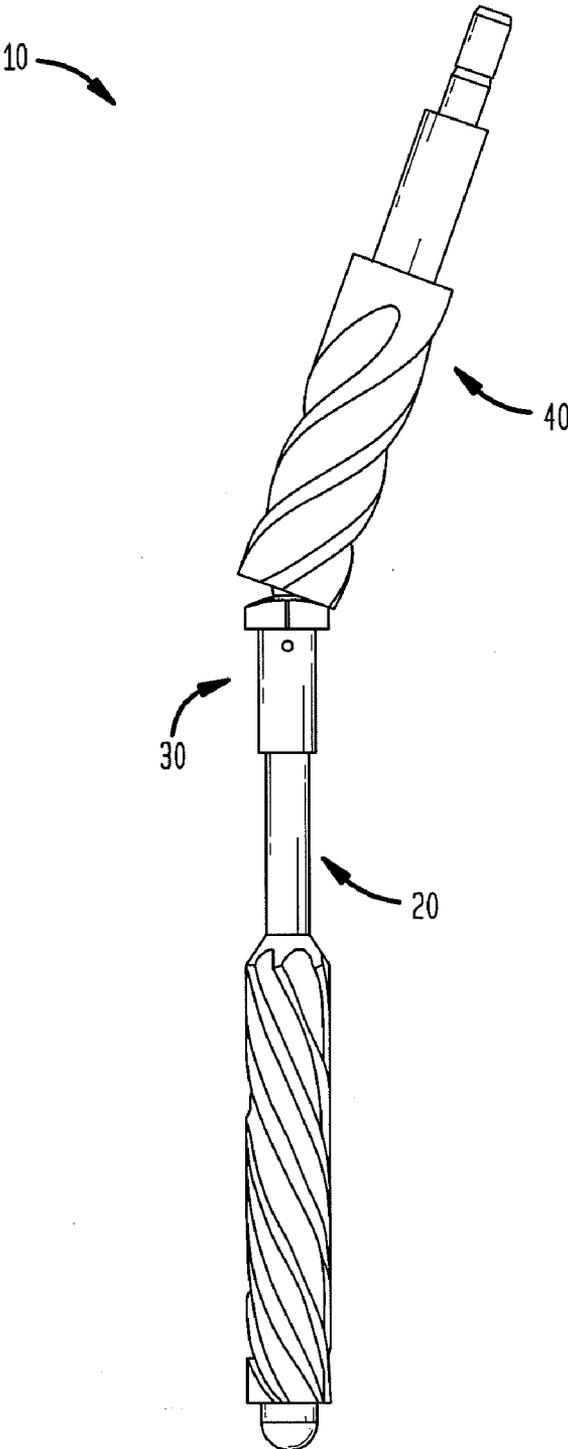


FIG. 2

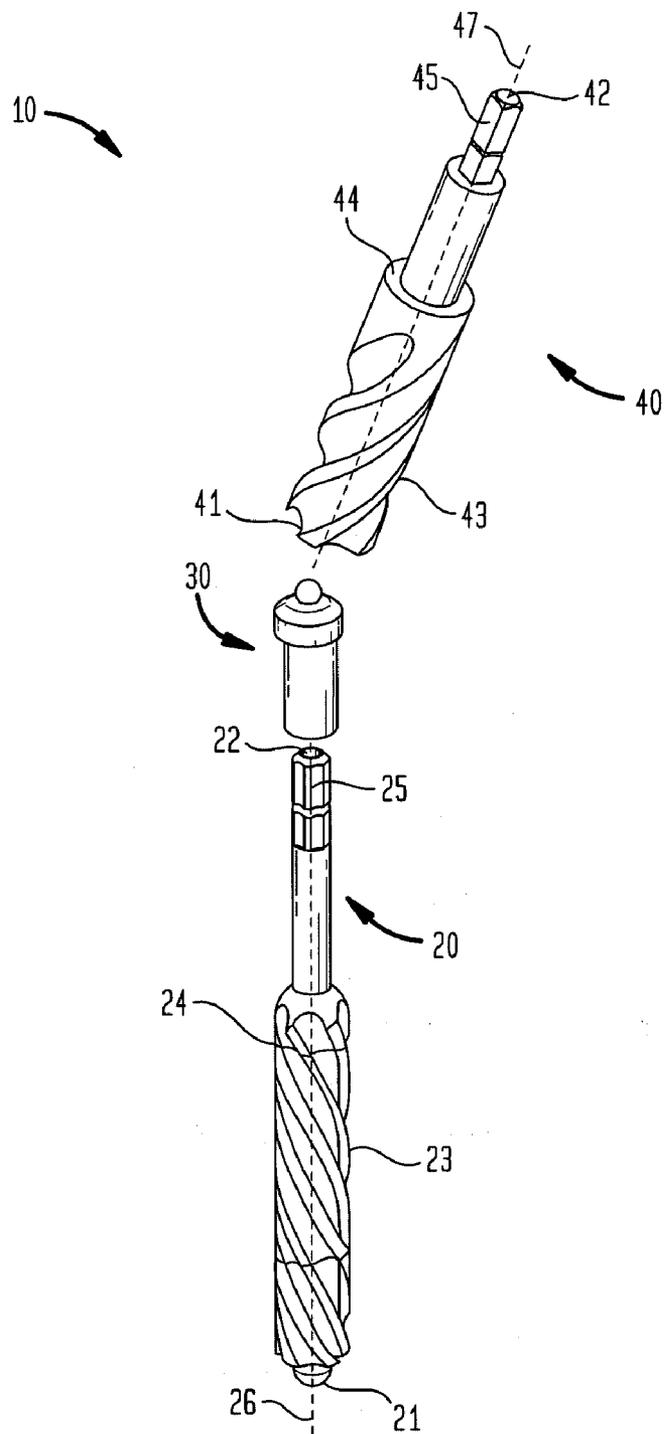


FIG. 3

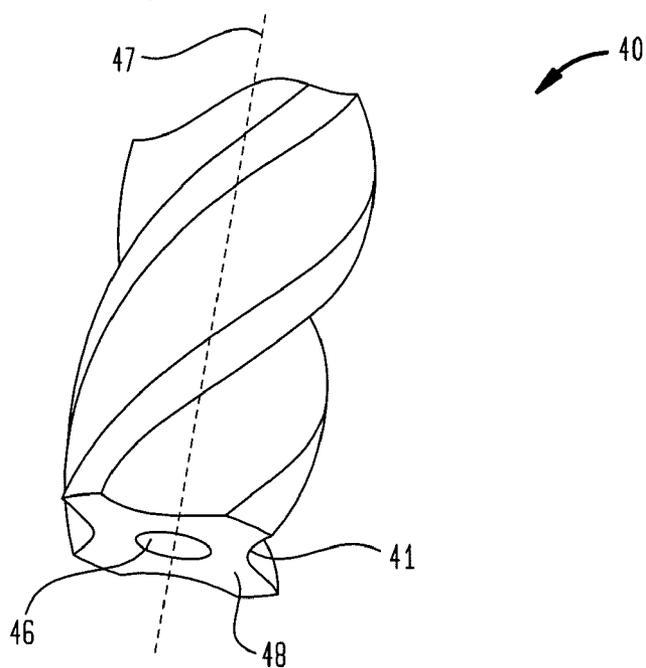


FIG. 4

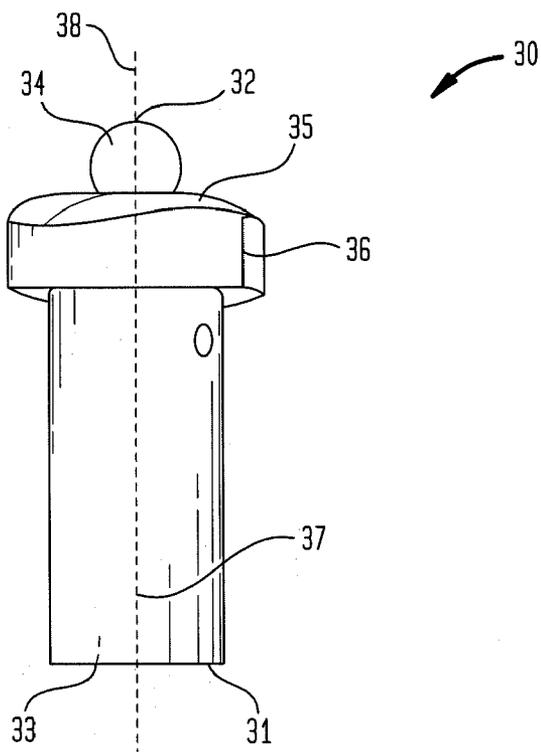


FIG. 5

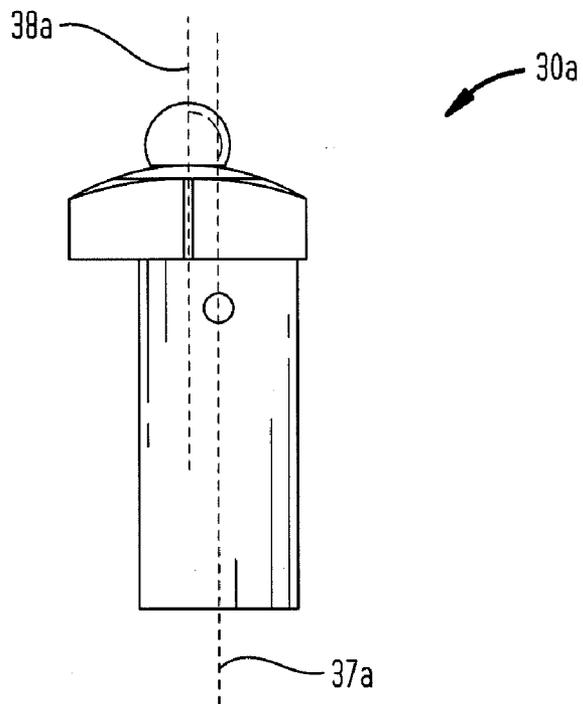


FIG. 6

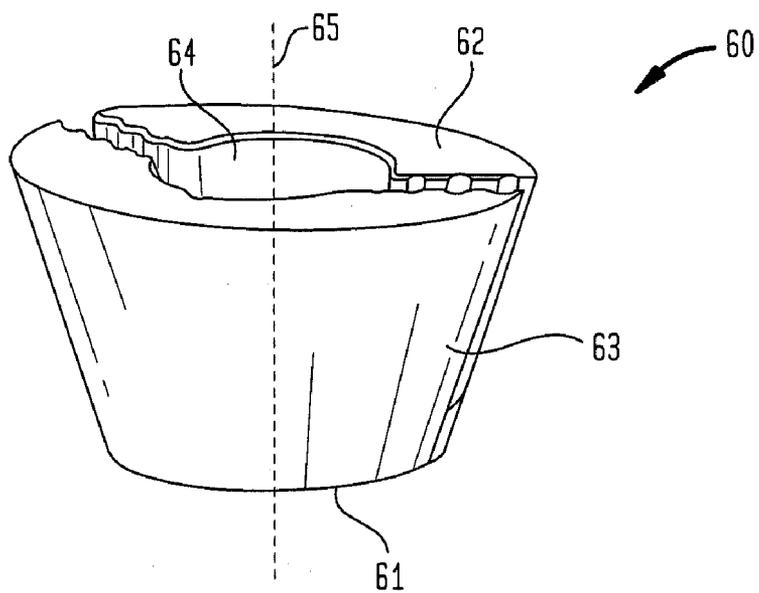


FIG. 7

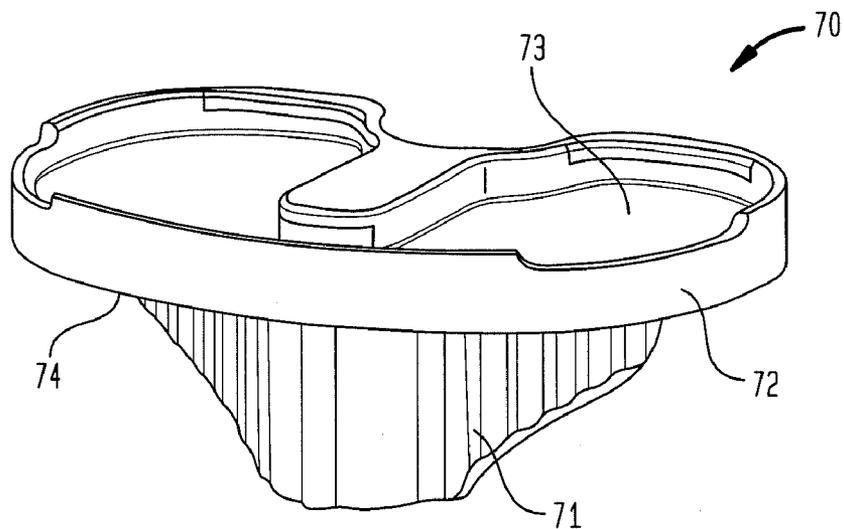


FIG. 8

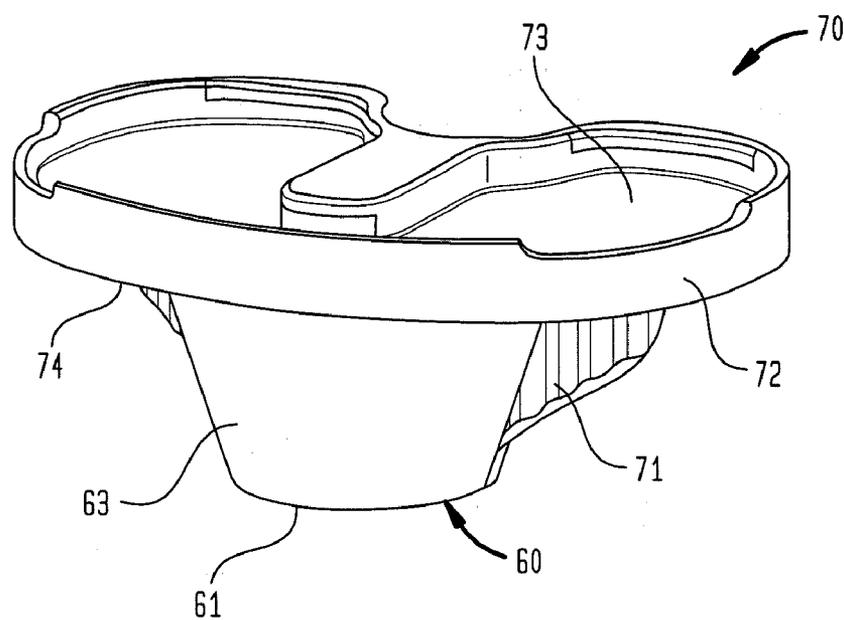


FIG. 9

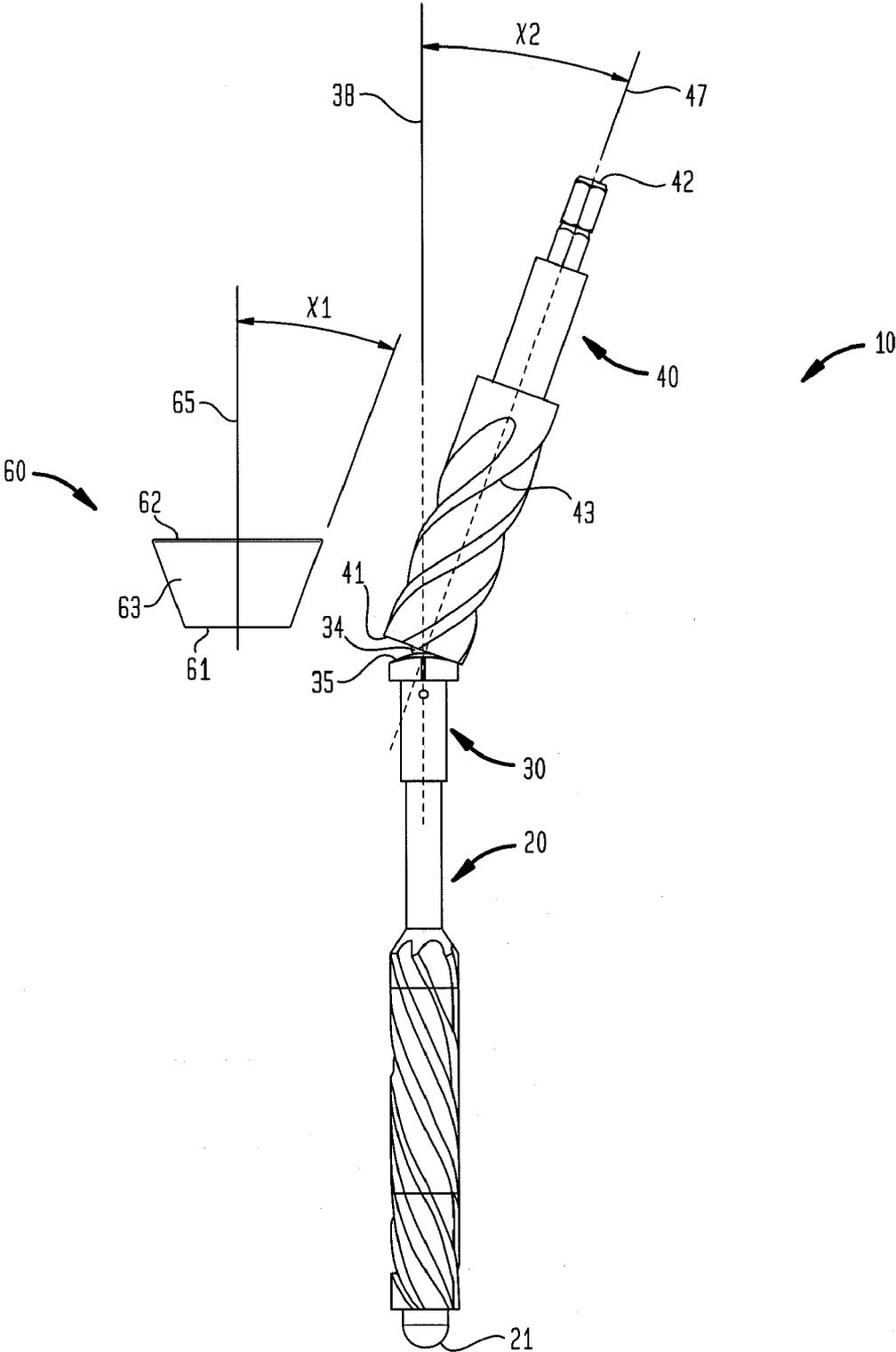
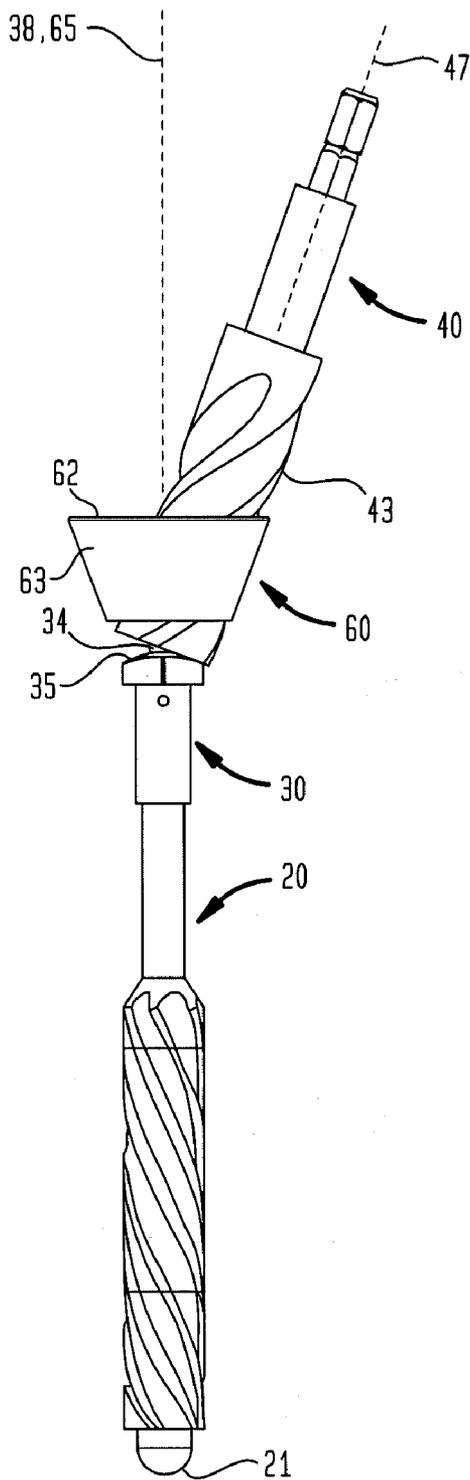


FIG. 10



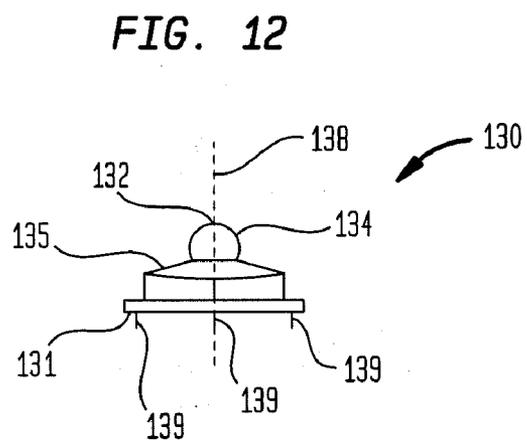
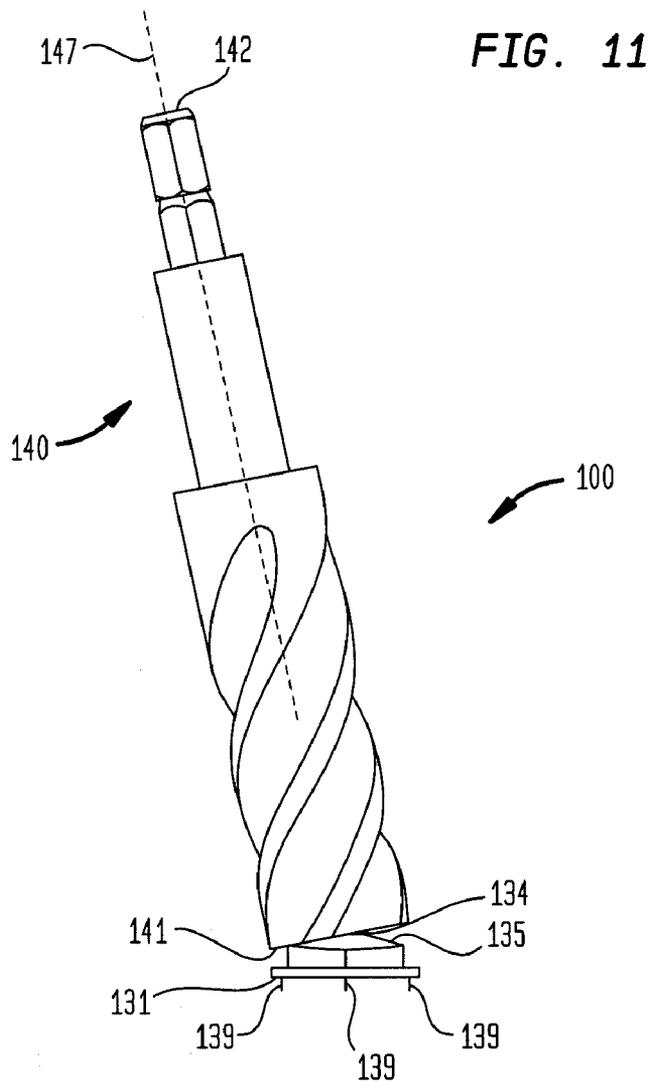


FIG. 13

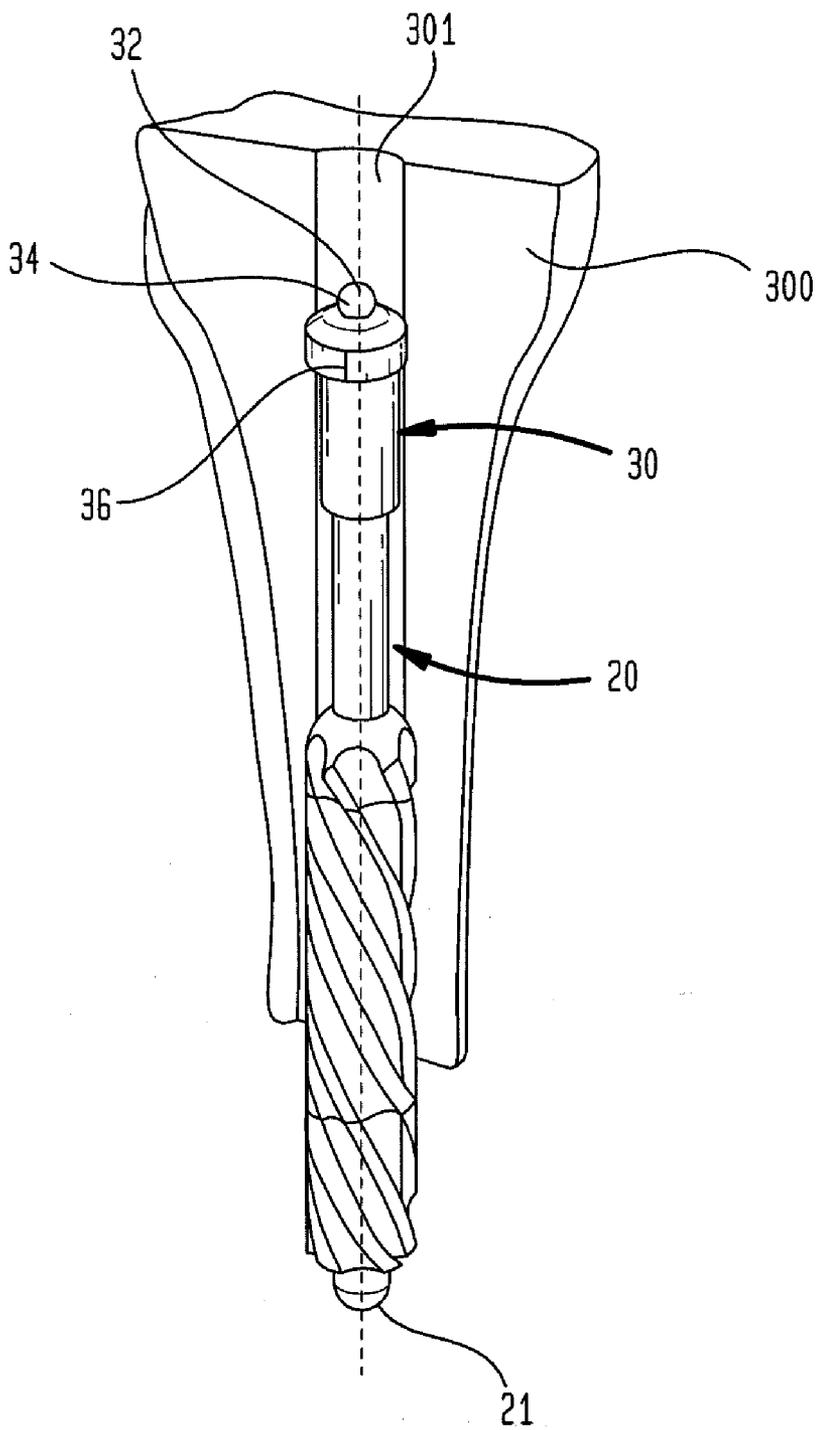


FIG. 14

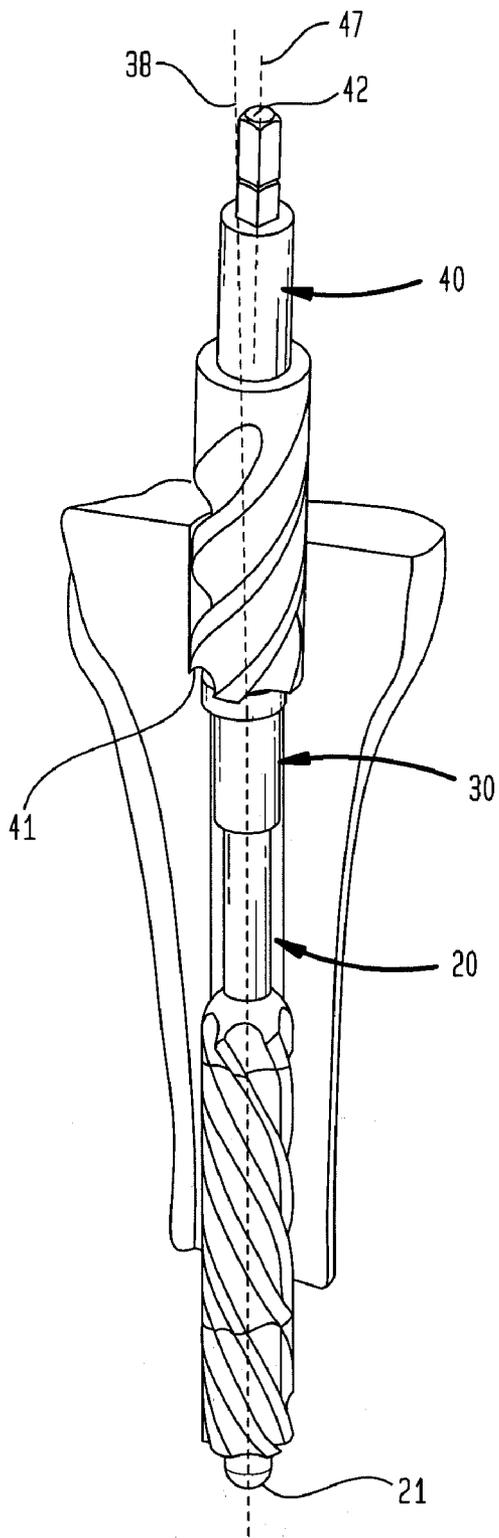
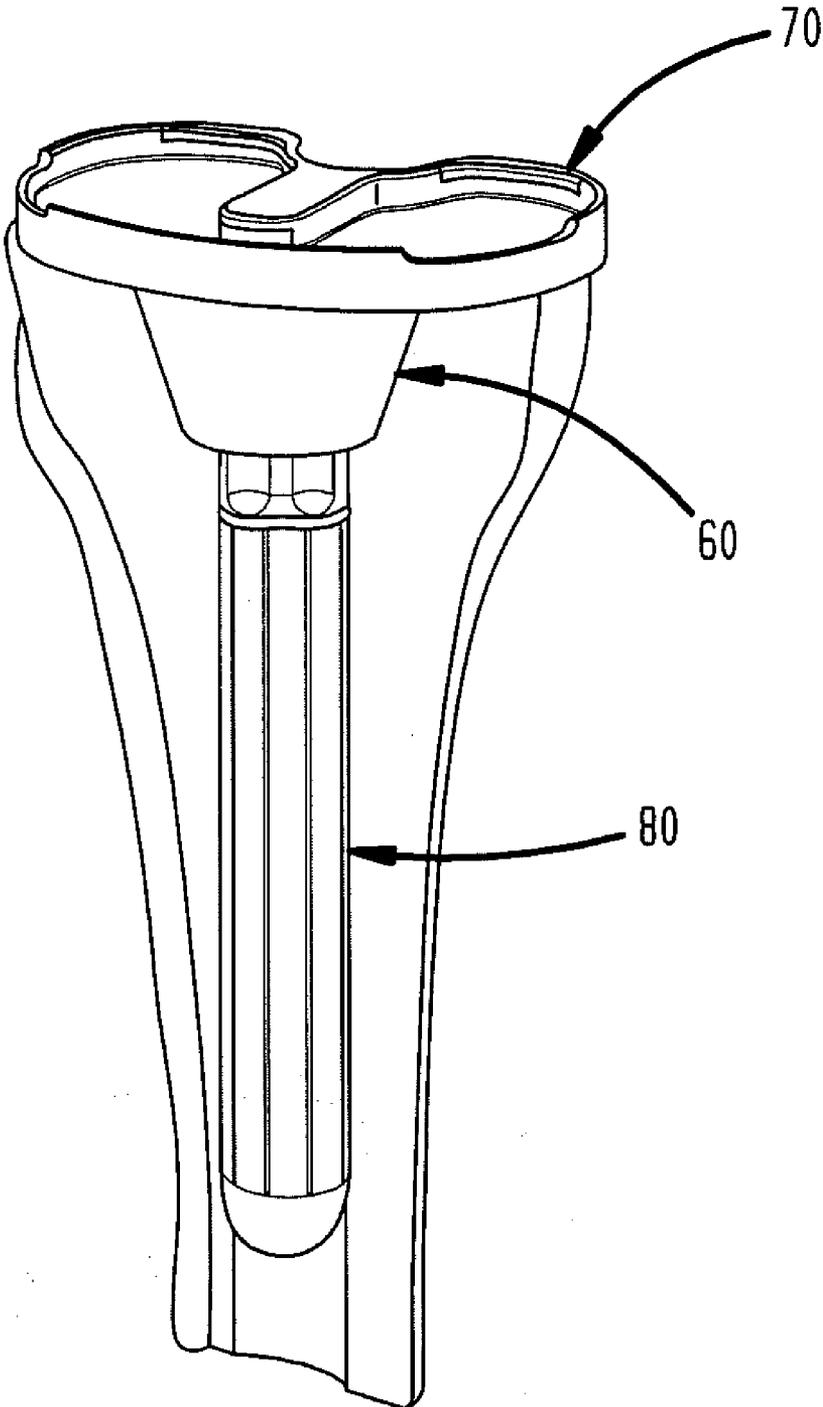


FIG. 15



SYSTEM AND METHOD OF BONE PREPARATION

BACKGROUND OF THE INVENTION

[0001] The present invention relates to a bone reaming system, and more particularly, to an apparatus and method for preparing specific geometries in the metaphyseal region of long bones.

[0002] Orthopedic surgery has been prevalent in recent years and the number of joint arthroplasty procedures is projected to grow exponentially in the future. Total knee replacement (TKR) is an example of joint arthroplasty. In TKR, the end surfaces of the femoral and tibial bones are resected and replaced with implants that may be made from metal, ceramic, polyurethane, or some combination thereof. In this procedure, the femoral and tibial implants may be fixed to the bone using cement, cementless biologic fixation or other known fixation means. While good TKR survivorship has been reported, it is known that these procedures may fail for reasons including incorrect alignment, loosening, osteolysis, infection, and the like. If a TKR procedure fails, a revision TKR procedure may be required.

[0003] In revision TKR, the primary implant components typically need to be removed, leaving defects or voids in the metaphyseal regions of the long bones on which they were implanted. Defects may be the result of removing the implants, the cement, other fixation means such as screws, or bone regions compromised by infection. The void size and geometry are unique for each patient and it is critical to augment these defect regions to ensure proper structural support for revision TKR implants.

[0004] In these revision TKR procedures, the augments available to address these bone defects are generally offered in limited sizes and shapes which do not consider the unique defect geometries of a particular patient. At least in part, the limitation of augment offerings is due to inability of current preparation instrument systems to prepare complex and non-uniform geometries. Thus, it is common place for patients to have excessive bone removed from their specific defect region in order to receive standard augment prostheses. Moreover, in some cases, an impaction based preparation technique such as broaching is used to prepare a bone defect region during revision surgery. Given that the bone in the defect region is already compromised, this impaction technique may lead to bone fractures which further worsen the patient condition and require addition intervention.

[0005] Therefore there exists a need for bone preparation system that will allow for complex and non-uniform geometries to be created during a preparation of the bone using non-impaction means.

BRIEF SUMMARY OF THE INVENTION

[0006] One aspect of the present invention is a bone preparation system comprising a cutting instrument and a guiding element. The cutting instrument includes an attachment feature and a first region. The guiding element includes an attachment feature and a guiding surface. When the attachment feature of the guiding element is engaged with the distal attachment feature of the cutting instrument, the cutting instrument can rotate and pivot about the guiding element. Contact between the first region and the guiding surface determines the amount of pivot of the cutting instrument about the guiding element.

[0007] Alternate embodiments of the bone preparation system may include any of, or any combination of the following: the cutting instrument attachment feature is a distal attachment feature and the first region is a distal region, the guiding surface attachment feature is a proximal attachment feature; the distal region of the cutting instrument may be comprised of a distal end and a distal surface; the guiding surface of the guiding element may extend 360 degrees around or around a portion of the attachment feature of the guiding element; the guiding surface may be derived from an outer profile of an augment implant which may be derived from a pre-operative patient specific imaging process; the guiding element may further include an aperture designed to engage a stem wherein the stem may include a cutting feature; the central axis of the guiding element, aperture and stem have various alignments; or the attachment feature of the guiding element may be a sphere and the distal attachment feature is a spherical female indentation.

[0008] Another aspect of the present invention is a method of bone preparation. Here, a guiding element is inserted into the canal of a bone and a cutting instrument is attached to the guiding element. The bone is prepared by pivoting the cutting instrument about the guiding element. The cutting instrument and guiding element are removed from the prepared bone.

[0009] Alternate embodiments of the method bone preparation system may include any of, or any combination of the following methods: preparing the canal of the bone using a reamer, engaging the guiding element with the reamer, inserting a prosthetic implant into the prepared bone, rotating the cutting instrument about the central axis, pivoting the cutting instrument about the guiding element, imaging of the patient, or developing a pre-operative patient specific implant based on the imaging of the bone of a patient.

[0010] A further aspect of the present invention is a bone preparation kit comprising an augment implant and a guiding element. The augment implant is for the metaphyseal region of a long bone. The guiding element includes a guiding surface where the guiding surface is derived from an outer profile of the augment implant.

[0011] Alternate embodiments of the bone preparation kit may further comprise any of the following: the augment implant includes a geometry based on patient imaging, the guiding surface includes a distal having at least one fixation feature, the guiding element further includes an aperture designed to engage a stem.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The present invention will be better understood on reading the following detailed description of non-limiting embodiments thereof, and on examining the accompanying drawings, in which:

[0013] FIG. 1 is a perspective view of a bone preparation system in accordance with one embodiment of the present invention.

[0014] FIG. 2 is an exploded view of the bone preparation system shown in FIG. 1.

[0015] FIG. 3 is an enlarged perspective view of a portion of a cutting instrument included in the bone preparation system shown in FIG. 1.

[0016] FIG. 4 is a perspective view of a guiding element included in the bone preparation system shown in FIG. 1.

[0017] FIG. 5 is a perspective view of an alternate embodiment of a guiding element.

[0018] FIG. 6 is a perspective view of a tibial augment in accordance with one embodiment of the present invention.

[0019] FIG. 7 is a perspective view of tibial baseplate implant in accordance with one embodiment of the present invention.

[0020] FIG. 8 is a perspective view of the tibial augment shown in FIG. 6 assembled with the tibial baseplate implant shown in FIG. 7.

[0021] FIG. 9 is a view illustrating the relationship of the geometry of the tibial augment shown in FIG. 6 to the bone preparation system shown in FIG. 1.

[0022] FIG. 10 is another view illustrating the relationship of the geometry of the tibial augment shown in FIG. 6 to the bone preparation system shown in FIG. 1.

[0023] FIG. 11 is a perspective view of an alternate embodiment bone preparation system in accordance with the present invention.

[0024] FIG. 12 is a perspective view of a guiding element included in the bone preparation system shown in FIG. 11.

[0025] FIG. 13 is a cross-sectional view of a tibial bone with a portion of the bone preparation system shown in FIG. 1 included therein.

[0026] FIG. 14 is a cross-sectional view of a tibial bone with the bone preparation system shown in FIG. 1 included therein.

[0027] FIG. 15 is a cross-sectional view of a tibial bone with the construct shown in FIG. 8 implanted thereon.

DETAILED DESCRIPTION

[0028] As used herein, the term “distal” means more distant from the heart and the term “proximal” means closest to the heart. The term “inferior” means toward the feet and the term “superior” means towards the head. The term “anterior” means towards the front part of the body or the face and the term “posterior” means towards the back of the body. The term “medial” means toward the midline of the body and the term “lateral” means away from the midline of the body.

[0029] Referring to the drawings, FIGS. 1-2 illustrate one embodiment bone preparation system 10 including a stem 20, guiding element 30 and a cutting instrument 40. The stem 20 has a distal end 21, proximal end 22 and a central axis 26. The stem 20 is designed to fit within the intramedullary canal of a long bone, for example, the tibia (shown in FIGS. 12 and 13). The stem 20 may include features such as an outer profile 23, depth references 24 and attachment geometries 25 for interfacing with other instruments. The attachment geometries 25 are designed to allow for assembly with other instruments as well as to provide rotational constraint during subsequent bone preparation, which will be further described. In the embodiment shown, a powered reaming instrument, which is not shown but is known in the art, would interface with the attachment geometries 25 and rotate the stem 20 about its central axis 26 within the intramedullary canal. Further, in this embodiment, outer profile 23 is a cutting surface that prepares the intramedullary canal as the stem 20 rotates. In an alternate embodiment, the stem 20 may have a smooth outer profile 23 dimensioned to reference a previously prepared intramedullary canal. Further in this alternate embodiment, the attachment geometries 25 may allow interface with an insertion-extraction instrument. In one or more embodiments, depth references 24 may be located anywhere on stem 20 and serve as an indicator of location to the user.

[0030] The cutting instrument 40 has a distal end 41, a proximal end 42 and a central axis 47. Cutting instrument 40

may include features such as an outer profile 43, a depth reference 44 and proximal attachment geometries 45 for interfacing with other instruments. Outer profile 43 preferably contains a cutting geometry and may have a single diameter throughout the cutting region. In alternate embodiments, outer profile 43 may have a non-constant diameter, stepped diameter or other geometric configuration to allow variable bone preparation. In the embodiment shown, cutting instrument 40 is a reamer and a powered reaming instrument would interface with the proximal attachment geometries 45 to rotate the reamer about central axis 47 to prepare the bone. In other embodiments, other instruments may interface with attachment geometries 45 to allow for rotational bone preparation, such as devices facilitating manual rotation. Further, in alternate embodiments, cutting instrument 40 may be a burr or other cutting geometry that rotates in order to prepare bone.

[0031] Depth reference 44 serves as a location indicator to the user and can take the form of engraved marks, steps, or the like. In the particular embodiment shown in FIGS. 1 and 2, depth reference is a step. Further, there may be multiple depth references 44 on the cutting instrument 40. FIG. 3 further illustrates the distal region of cutting instrument 40, which includes a distal surface 48 and a distal end 41. In the embodiment shown the attachment feature 46 is a spherical female indentation designed to engage with a male feature of guiding element 30 (described below). The stem 20, guiding element 30 and cutting instrument 40 are constructed of known instrument or implant material, such as stainless steel or titanium.

[0032] FIG. 4 illustrates, in more detail, guiding element 30, which includes a distal end 31 and proximal end 32. Distal end 31 may have an aperture 33 including an aperture central axis 37. Preferably, aperture 33 is designed to interface over proximal end 22 of stem 20, thereby engaging attachment geometries 25. When engaged, central axis 26 of stem 20 is aligned with the aperture central axis 37. In the depicted embodiment, guiding element 30 also preferably includes an alignment feature 36 taking the form of an engraved line which allows for orientation reference of the guiding element 30 as it is assembled with stem 20. Of course, in other embodiments, alignment feature 36 may be different elements, including, a notch, protrusion, or the like. Also in other embodiments, guiding element 30 may include a structure designed to affix it with stem 20. For example, a ball/detent or male/female connection may be employed.

[0033] Guiding element 30 in FIG. 4 also includes a proximal attachment feature 34 designed to interface with attachment feature 46 of a cutting instrument 40. In the embodiment shown, the proximal attachment feature 34 is a protrusion having a spherical geometry and includes an attachment feature central axis 38 that is aligned with aperture central axis 37. In an alternate embodiment shown in FIG. 5, attachment feature central axis 38a may be offset and therefore not aligned with the aperture central axis 37a. Further regarding guiding element 30, proximal attachment feature 34 and attachment feature 46 may be other known mechanisms used for removable attachment. In addition, while attachment features 34 and 46 are shown as male and female elements, respectively, this may be the opposite in other embodiments. In other words, cutting instrument 40 could include a male attachment feature, while guiding element 30 includes a female attachment feature.

[0034] The guiding element 30 may further include a guiding surface 35 designed to allow for a specified bone preparation. The geometry of guiding surface 35 may be derived

from a pre-operative scan, such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT), X-ray or similar known technology. Here, a bone model is generated from the pre-operative scan. The guiding surface **35** is preferably derived from the bone model as a mathematically sweeping geometry between multiple cross sections of a patient specific defect and can range from zero to 360 degrees around the attachment feature central axis **38**. In an alternate embodiment, guiding surface **35** may be derived from a standard augment implant design.

[0035] As noted above, proximal attachment feature **34** of the guiding element **30** is preferably engaged with the attachment feature **46** of the cutting element **40**. When engaged, the attachment feature central axis **38** intersects with the central axis **47** of the cutting instrument **40**. During bone preparation, the cutting instrument **40** is angled until the distal end **41** or distal surface **48** of the distal region engages with the guiding surface **35**, thus establishing an outer bound for the bone preparation.

[0036] Further on the bone preparation, cutting instrument **40** rotates its central axis **47**, and also pivots about proximal attachment feature **34**. Then, as either, or both the distal end **41** or distal surface **48** references the path of guiding surface **35**, thus establishing an outer bound for the bone preparation. The prepared bone geometry governed by guiding surface **35** is based on an augment implant designed to fill a patient specific defect and may be any unique geometry, including symmetric, asymmetric or offset.

[0037] In this bone preparation system, the geometry of the bone preparation is thusly governed by the geometry of the guiding surface **35**, which is located distal to the cutting instrument **40**. Further, the guiding surface **35** is located within the cortical perimeters of a long bone. Also of note, the attachment feature central axis **38** of guiding surface **35** may or may not be aligned with the central axis **26** of stem **20** which allows for asymmetric, offset and non-uniform preparation of the metaphyseal region of the long bone.

[0038] The stem **20**, guiding element **30** and cutting instrument **40** are illustrated in FIGS. 1-4 as independent structures. Other embodiments of this invention may include: the stem **20** and guiding element **30** being a single structure, the guiding element **30** and the cutting instrument **40** being a single structure, or the stem **20**, guiding element **30** and cutting instrument **40** being a single instrument structure.

[0039] FIG. 6 illustrates a tibial augment **60** having a distal end **61** and a proximal end **62**. Tibial augment **60** is preferably utilized to replace cancellous bone that was removed as the result of primary TKR implant removal, infection or the like. The tibial augment **60** is designed to provide the structural support for the revision TKR baseplate components. It has an outer profile **63**, a central aperture **64** and a central axis **65**. Central aperture **64** is designed to interface with prosthesis such as revision TKR baseplate component **70**, as shown in FIG. 6.

[0040] As shown in FIG. 7, the tibial baseplate component **70** may include a distal feature **71**, such as a keel, and a tray component **72** that has a proximal surface **73** and a distal surface **74**. FIG. 8 illustrates an example of a tibial augment **60** assembled with a tibial baseplate component **70**. A tibial augment may be assembled with tibial baseplate component **70** using cement, mechanical attachment or other known means.

[0041] FIG. 9 shows the relationship between the geometry of tibial augment **60** and bone preparation system **10**, in

particular, the geometrical relationship between outer profile **63** of tibial augment **60** and the guiding surface **35** of guiding element **30**. Here, tibial augment **60** has an outer profile **63** defined by an angle **X1** measured from a central axis **65**. Guiding surface **35** has a geometry that allows for a defect specific path for the cutting instrument **40**. Attachment feature **46** of cutting instrument **40** is engaged to proximal attachment feature **34** and distal end **41** references guiding surface **35**. **X2** represents an angular relationship between the attachment feature central axis **38** and cutting instrument **40** central axis **47**. Angles **X1** and **X2** have a mathematical relationship with respect to central axes **65** and **38**.

[0042] FIG. 10 provides an overlaid perspective of the relationship between the specific outer profile **63** of tibial augment **60** and the outer bounds of the bone preparation governed by the guiding surface **35**. This relationship is demonstrated by aligning the attachment feature central axis **38** and the central axis **65** of the tibial augment **60**. It is understood the mathematical relationship relates to multi-dimensional implant structures and may involve any unique geometry that would be different from patient to patient.

[0043] Guiding element **30** may be distributed as a standard instrument, a disposable instrument or a custom single use instrument. With a standard augment product offering, such as a tibial augment **60**, the guiding element **30** may be included as a standard instrument in an instrument kit. Also with a standard tibial augment **60**, the guiding element **30** may be a disposable instrument, designed for a single use, and to be used with standard stem **20** and cutting instrument **40**. In an alternate scenario, patient specific augments and may be created using scans, such as a pre-operative MRI, CT, X-ray or any combination thereof. Then a patient specific kit would be provided which includes, for example, a patient specific tibial augment **60**, and a guiding element **30**. The patient specific preparation would be guided thru the unique guiding surface **35** geometry that is designed to match patient specific augment geometry. Here, the patient specific tibial augment and augment specific guiding element **30** may be packaged together for a specific surgery.

[0044] FIGS. 11-12 illustrate an alternate embodiment of a bone preparation system **100** consisting of a cutting instrument **140** and a guiding element **130**. While each are not discussed, like elements to that of system **10** are labeled in FIGS. 11 and 12 with like reference numerals within the 100-series of numbers. For instance, similar to the embodiment previously described, cutting instrument **140** engages with a proximal attachment feature **134** on the guiding element **130**. The cutting instrument **140** rotates about its central axis **147**, and then pivots about attachment element **134** until either the distal end **141** or distal surface **148** contacts guiding surface **135**, thus establishing the outer bounds for the bone preparation. The significant difference with this alternate embodiment is that the guiding element **130** does not get assembled with a stem component **20**, but rather attaches directly to bone within the intermedullary canal. For example if the intermedullary canal is prepared to a certain depth using a reamer instrument or the like, the guiding element **130** would be placed at the interface between the prepared intermedullary bone and the unprepared intermedullary bone where there is a natural cortical bone "shelf". Fixation features **139** affix guiding element **130** to the bone and provides rotational constraint during bone preparation. These fixation features are shown as teeth, but may be other known fixation features, such as screws, pins or the like.

[0045] A method of preparing a bone utilizing system **10** is illustrated in FIGS. **13-15**. In this method, the intermedullary canal of tibial long bone **300** has been prepared using stem **20**, resulting in a prepared intramedullary canal region **301**. This is best shown in FIG. **13**, where stem **20** remains in the prepared central region **301**. Aperture **33** and alignment feature **36** of guiding element **30** are then removably attached with the attachment geometry **25** of stem **20**, as shown in FIG. **14**. Also shown in that figure, the attachment feature of cutting instrument **40** is then assembled to proximal attachment feature **34** of guiding element **30**. Cutting instrument **40** is then rotated about its central axis **47**, thus establishing a rotational cutting motion. The cutting instrument is then angled, by pivoting about attachment feature central axis **38**, until distal end **41** contacts guiding surface **35**. The rotating and pivoting of cutting instrument is continued until the metaphyseal region of the bone is prepared to receive and augment, such as tibial augment **60**.

[0046] As shown in FIG. **15**, a prosthetic implant construct is then inserted into the prepared bone, for instance, an assembled tibial baseplate component **70** and tibial augment **60** (as described above) with a stem implant **80**. It is understood that other known implant components such as stem extensions and offsets may further contribute to the implant assembly. Further, the implant components described may alternatively be inserted as individual components.

[0047] An alternate method of preparing bone, which is not illustrated, would involve preparing a long bone utilizing the system depicted in FIGS. **11** and **12**. Guiding element **130** would be inserted into an already prepared central canal region **301**, so that fixation features **139** stabilize the guiding element **130**. Attachment feature **146** of cutting instrument **140** is then assembled with proximal attachment feature **134** of guiding element **130**, so that distal end **141** references the guiding surface **135**. The method thereafter closely mirrors that described above in connection with the use of system **10**.

[0048] Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. For example, where the tibial preparation system includes a guiding element having a proximal attachment feature, a femoral preparation system may include a guiding element having a distal attachment feature. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

1. A bone preparation system comprising:
 - a cutting instrument including a first attachment feature and a first region; and
 - a guiding element including a second attachment feature and a guiding surface,
 wherein the second attachment feature is engaged with the first attachment feature so that the cutting instrument can rotate and pivot about the guiding element, contact between the first region and the guiding surface determining the amount of pivot of the cutting instrument about the guiding element.
2. The bone preparation system of claim 1, wherein the first attachment feature is a distal attachment feature and the first region is a distal region; and the second attachment feature is a proximal attachment feature.

3. The bone preparation system of claim 2, wherein the distal region includes a distal end and a distal surface.

4. The bone preparation system of claim 1, wherein the guiding surface extends 360 degrees around the second attachment feature.

5. The bone preparation system of claim 1, wherein the guiding surface extends around a portion of the second attachment feature.

6. The bone preparation system of claim 1, wherein the guiding surface is derived from an outer profile of an augment implant.

7. The bone preparation system of claim 6, wherein the augment profile is derived from a pre-operative patient specific imaging process.

8. The bone preparation system of claim 1, wherein the guiding element includes a first end having at least one fixation feature.

9. The bone preparation system of claim 1, wherein the guiding element further includes an aperture for engaging a stem.

10. The bone preparation system of claim 9, wherein the stem further includes an outer profile having a cutting feature.

11. The bone preparation system of claim 9, wherein the second attachment feature has a central axis and the guiding element aperture has a central axis,

the stem has a central axis,

wherein the second attachment feature central axis, aperture central axis and stem central axis are aligned.

12. The bone preparation system of claim 9, wherein the second attachment feature has a central axis and the guiding element aperture has a central axis,

the stem has a central axis,

wherein the second attachment feature central axis is offset from the aperture central axis, and the aperture central axis and stem central axis are aligned.

13. The bone preparation system of claim 1, wherein the second attachment feature is a sphere and the first attachment feature is a spherical female indentation.

14. A method of bone preparation comprising:
 inserting a guiding element into a canal of a bone;
 attaching a cutting instrument with a central axis to the guiding element;
 preparing the bone by pivoting the cutting instrument about the guiding element; and
 removing the cutting instrument and the guiding element from the prepared bone.

15. The method of bone preparation of claim 14, further comprising the step of preparing the canal of the bone.

16. The method of bone preparation of claim 15, wherein the preparing the canal step includes utilizing a reamer.

17. The method of bone preparation of claim 16, wherein the inserting step includes engaging the guiding element with the reamer.

18. The method of bone preparation of claim 15, further comprising the step of inserting a prosthetic implant into the prepared bone.

19. The method of bone preparation of claim 14, further comprising the step of rotating the cutting instrument about the central axis.

20. The method of bone preparation of claim 19, further comprising the step of pivoting the cutting instrument about the guiding element.

21. The method of bone preparation of claim 14, further comprising the step of imaging of the bone of a patient.

22. The method of bone preparation of claim 21, further comprising the step of developing a patient specific implant based on the pre-operative imaging of the bone of a patient.

23. A bone preparation kit comprising:

an augment implant for the metaphyseal region of a long bone; and

a guiding element including a guiding surface,

wherein the guiding surface is derived from an outer profile of the augment implant.

24. The bone preparation kit of claim 23, wherein the augment implant includes a geometry based on pre-operative patient imaging.

25. The bone preparation kit of claim 23, wherein the guiding surface includes a distal end having at least one fixation feature.

26. The bone preparation kit of claim 23, wherein the guiding element further includes an aperture designed to engage a stem.

27. The bone preparation kit of claim 26, wherein the stem is a reamer.

* * * * *