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(71) Applicant: UNIVERSITY OF CINCINNATI [US/US];
51 Goodman Drive, Suite 240, Cincinnati, Ohio 45221
(US).

(72) Inventor: BRANAM, Barton; 7959 Shelldale Way, Cin-
cinnati, Ohio 45242 (US).

(74) Agents: EVERETT, Denise M. et al.; 255 East Fifth
Street, Suite 1900, Cincinnati, Ohio 45202 (US).

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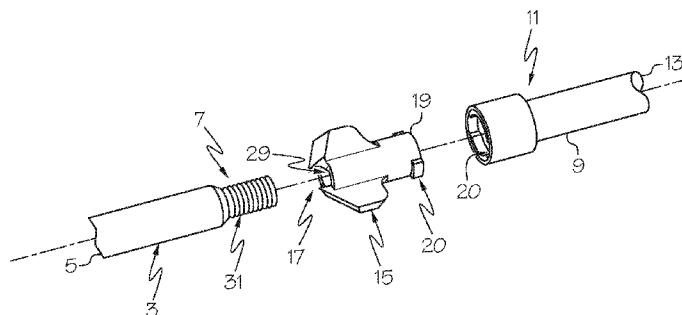


FIG. 5A

(57) Abstract: A modular reamer system that allows for intra-articular assembly of a low profile reamers for drilling bone tunnels in joint ligament reconstruction, and having particular utility in a retrograde technique for drilling a femoral tunnel in anterior cruciate ligament reconstruction. The reamer system components include a holder that may be detachably coupled to a reamer, and a guide pin that may be detachably coupled to the reamer, utilized in a surgical method that then permits the joint space to be free of tools during femoral drilling, enabling the knee to be held in a more relaxed surgical position, increasing fluid flow and therefore visibility during the drilling operation.

Retrograde Reamer System and Methods for Providing Bone Tunnels in Ligament Reconstruction Surgery

Priority Claim

5 This application claims priority under 35 U.S.C. §119(b) to U.S. provisional serial no. 62/133,310 filed on March 14, 2015, the entire disclosure of which is incorporated herein by this reference.

Technical Field

10 The subject matter of this disclosure relates to devices and methods useful for drilling bone tunnels in joint reconstruction surgery, and more specifically provides a novel reamer system with particular utility in a retrograde technique for drilling the femoral tunnel in an anterior cruciate ligament reconstruction.

Background

15 Anterior cruciate ligament (ACL) reconstruction is a commonly performed procedure in the young active population. Traditionally, the transtibial approach for drilling the femoral tunnel has been popular and widely accepted. However, modifying the tibial tunnel to appropriately transtibially drill the femoral tunnel may lead to a change in the tibial tunnel aperture. Recent literature suggests that anatomic ACL reconstruction may be more easily performed by drilling the femoral tunnel through an
20 accessory anteromedial portal. This led to development of an alternative surgical approach of drilling the femoral tunnel either through an accessory anteromedial portal or through a two-incision, outside-in approach.

Drilling the femoral tunnel through an accessory anteromedial portal allows for the placement of the femoral tunnel or tunnels independently of the tibial tunnel and in the location of the anatomic attachment of the ACL. However, to effectively create the tunnel, the knee must be hyperflexed, creating difficulty with flow of the arthroscopic fluid and also requiring the blind passage of large, sharp instruments across the often
5 pristine cartilage of the medial femoral condyle. Several investigators have described safer techniques for protecting medial structures when drilling the femoral tunnel through an accessory anteromedial portal.

One such recently developed independent femoral tunnel drilling technique is the
10 “retrograde technique”, as disclosed by Branam et al., "Retrograde technique" for drilling the femoral tunnel in an anterior cruciate ligament reconstruction", *Arthroscopy Techniques* 2013 Nov; 2(4): e395–e399, the entire disclosure of which is incorporated herein by this citation, which uses an accessory anteromedial portal. According to this technique, a guide pin is drilled from the lateral femoral condyle through the thigh inside
15 out with the knee in hyperflexion. The entry point of the pin on the lateral femoral condyle and the exit point on the lateral aspect of the thigh are reviewed to ensure proper orientation of the femoral tunnel. A reamer is inserted through the anteromedial portal and passed across the medial femoral condyle while the knee is extended. The sharp reamer is passed across the knee with the knee extended to avoid injury to the medial
20 femoral condyle. With the knee hyperflexed, the reamer is passed over the guide pin. A power unit held outside the anteromedial portal drives the reamer as it reams the tunnel to the required depth.

Although safety is enhanced, a remaining challenge of this technique is the need to hyperflex the knee to drill through the femur. First, an inability to hyperflex the knee is a contraindication to this technique because lack of hyperflexion makes placement of the pin in the proper trajectory virtually impossible. The most common reason for inability to flex the knee is obesity, a common condition of the general population. Next, the technique is technically demanding and requires a reasonably skilled assistant to hold the camera with a hyperflexed knee and also to assist in the retrograde passage of the guide pin into the reamer. Further, hyperflexion reduces visibility with diminished flow through the knee, making it even more difficult for an inexperienced assistant to properly navigate the instruments. As the bone is initially drilled, the bone fragments can often obscure visibility as well. Poor visibility limits evaluation of precise tunnel depth and may require uncoupling of the reamer pin device, extension of the knee and repeat hyperflexion in order to flush out the bone dust from the initial reaming. Precise depth measurement is critical to successful surgery. Drilling in hyperflexion requires several skilled assistants familiar with the technique meticulous attention to detail. Finally, drilling from the anteromedial portal still poses some risks to the anteromedial cartilage as instruments are utilized over the medial femoral condyle.

Clearly, there is a need for modification of this promising technique to reduce the need for multiple re-adjustment of the knee position and to reduce the need generally for hyperflexion of the knee.

20 **Summary**

Accordingly, an improved retrograde technique for joint ligament reconstruction is provided that allows for the reproducible safe passage of instrumentation through an accessory portal and drilling of the bone tunnel while the joint is in a relatively extended

position, thus permitting drilling of the tunnel with increased fluid flow and improved visibility. Specific embodiments relate to a reamer system adapted for drilling a tunnel through the femur in ACL reconstruction surgery without a need to hyperflex the patient's knee.

5 One embodiment is directed to a modular reaming system specifically adapted for creation of bone tunnels in joint ligament reconstruction surgery. The system comprises: (i) a substantially rigid elongate guide pin having a leading end and a trailing end; (ii) an elongate holder having an inserting end and an exterior end; and (iii) a reamer element having an advancing end and a retracting end. The advancing end of the reamer and the
10 trailing end of the guide pin are configured to detachably couple, and the inserting end of the elongate holder and the retracting end of the reamer element are configured to detachably couple.

Other embodiments are directed to methods for femoral tunnel reaming during anterior cruciate ligament reconstruction of a knee using the specially adapted reamer
15 system. The methods are provide enhanced safety; yet eliminate some of the need to hyperflex the patient's knee, and eliminate some of the transitioning between knee positions during surgery. Methods comprise: (a) hyperflexing the knee and advancing the leading end of the guide pin through a knee space access portal to a ligament insertion site to develop a femoral entrance hole; (b) further advancing the guide pin
20 retrograde until the trailing end extends a distance from the femoral entrance hole; (c) inserting the reamer assembly until the advancing end of the reamer element abuts the trailing end of the guide pin; (d) coupling the reamer to the guide pin; (e) decoupling the

elongate holder from the reamer and removing the elongate holder from the knee space;
(f) releasing the hyperflexion of the knee; (g) engaging power to the reamer and
advancing the guide pin retrograde to drill the femoral tunnel a desired tunnel depth; (h)
disengaging power to the reamer and retracting the reamer element into the knee space;
5 (i) inserting the holder into the knee space until the inserting end of the holder abuts the
retracting end of the reamer element; (j) coupling the holder and the reamer element; (k)
decoupling the reamer and the guide pin; and (l) retracting the reamer assembly from the
knee space and removing the guide pin.

Embodiments providing surgical kits are also provided. A surgical kit for
10 assembling embodiments of the adaptable reamer system may comprise any or all of the
reamer system components as disclosed herein. The kits may be targeted to specifically
or generally sized patients, or may comprise a variety of component sizes to
accommodate a wide range of joint sizes and/or patient sizes.

Embodiments provide methods for tunnel reaming during retrograde ligament
15 reconstruction of a joint that simplify and streamline known methods, while retaining
and enhancing the safety due to increased fluid flow and visibility during a larger
percentage of the total surgical effort. With respect to ACL reconstruction, embodiments
of the method enable elimination of a need to hyperflex the knee while drilling a femoral
tunnel. This is achieved by utilizing a specially adapted reamer system of modular
20 components that may be engaged and disengaged during the surgery such that tools may
be removed from the knee space during drilling. In other embodiments, access portals
may be selected at a wider variety of locations relative to the ligament insertion site in

order to minimize tool obstruction of the knee space and minimize potential for inadvertent injury to surrounding tissue.

These and other embodiments will be further explained and clarified by reference to the Figures and detailed description, below. While embodiments of the invention may
5 be illustrated by specific example for understanding, these should not be construed as limiting the full scope of the invention as defined by the appended claims.

Brief Description of the Figures

Fig. 1A-1G: Schematic illustration of tool location during femoral tunnel drilling according to a PRIOR ART procedure. **1A)** guide pin head is placed at
10 entrance location for femoral tunnel while knee is hyperflexed; **1B)** guide pin is moved through the femoral bone, exiting the thigh during hyperflexion; **1C)** hyperflexion is released and reamer is moved into the knee space; **1D)** knee is hyperflexed and reamer is engaged to guide pin;
15 **1E)** drilling is completed during hyperflexion; **1F)** reamer is guided back into the knee joint space; **1G)** hyperflexion is released and the reamer and guide pin are removed.

Fig. 2A-2G: Schematic illustration showing tool location during femoral tunnel drilling according to one embodiment of the invention. **2A)** guide pin
20 head is placed at entrance location for femoral tunnel while knee is hyperflexed; **2B)** guide pin is moved through the femoral bone, exiting

the thigh during hyperflexion; **2C)** hyperflexion is released and reamer-holder assembly is moved into the knee space; **2D)** knee is hyperflexed and reamer is engaged to guide pin, disengaged from holder, and holder is removed from knee space; **2E)** hyperflexion is released and drilling takes place; **2F)** knee is hyperflexed, reamer is guided back into the knee joint space, holder is guided to the reamer and reamer is re-engaged to the holder; **2G)** hyperflexion is released and the reamer-holder assembly and guide pin are removed.

Fig. 3A-3H: Schematic illustration showing tool location during femoral tunnel

drilling according to another embodiment of the invention. **3A)** guide pin head is placed at entrance location for femoral tunnel while knee is hyperflexed; **3B)** guide pin is moved through the femoral bone, exiting the thigh during hyperflexion; **3C)** hyperflexion is released and reamer-holder assembly is moved into the knee space; **3D)** while the knee remains at about a 90 ° flexion angle, the reamer is engaged to guide pin, disengaged from holder, and holder is removed from knee space; **3E)** 90° flexion is maintained and drilling takes place; **3F)** 90° flexion is maintained and the reamer is guided back into the knee joint space, holder is guided to the reamer and the reamer is re-engaged to the holder; **3G)** 90° flexion is maintained and the reamer-holder assembly and guide pin are removed; **3H)** compares hyperflexion with an approximately 90 degree flexion of the knee

- Fig. 4A-4D:** Perspectives of two reamer elements according to different embodiments of the invention. **4A)** lateral view of reamer element with external threads on male member for mated screw-type coupling to a guide pin; **4B)** iso-view of same reamer element; **4C)** lateral view of reamer element used in interlocking coupling to a guide pin; **4D)** iso-view of same reamer element.
- Fig 5A:** Illustration of a specific embodiment of a reamer system showing guide pin to reamer element to elongate holder couplings.
- Fig 5B:** Illustration of a specific embodiment showing a couple reamer and holder portion.
- Fig. 6A-6C:** Illustration of specific embodiments of **6A)** reamer assembly and guide pin; **6B)** reamer assembly engaged to guide pin; **6C)** reamer element engaged to guide pin and detached from elongate holder.
- Fig. 6D:** Illustration of a specific embodiment showing a guide pin-to-reamer element coupling.
- Fig. 7:** Illustration of a specific embodiment showing de-coupled guide pin, reamer element and angled elongate holder.
- Fig. 8A-8B:** **8A)** side view of a specific embodiment of a holder portion apart from the rod portion of an elongate holder; **8B)** iso-view of holder portion configured for interlocking coupling to reamer element and female coupling to rod portion.

Fig. 8C-8E: **8C)** illustration of a specific embodiment of a straight rod portion of an elongate holder; **8D)** illustration of a specific embodiment of an angled rod portion of an elongate holder; and **8E)** close-up view of male member of rod portion for coupling to female member of holder portion.

5

Detailed Description

Many surgeons have recently abandoned transtibial drilling of the femoral tunnel in anterior cruciate ligament (ACL) reconstruction because of potentially negative side effects on the tibial tunnel, and because the alternative of drilling the femoral tunnel independently of the tibial tunnel allows for improved flexibility in placing the femoral tunnel(s) in an ideal location. In double-bundle reconstruction, there is little margin for error in femoral tunnel placement. The commonly implemented “outside-in technique” also allows for creation of the femoral tunnel(s) independently of the tibial tunnel; however, it requires an outside-in guide. If the initial pass of the guide pin misses the tip of the guide, the position of the tunnel will be suboptimal. The position of the pin will be very difficult to change, and the path of the pin will tend to follow the same course. More recently, a technique of drilling the femoral tunnel through an accessory anteromedial (AM) portal was developed to permit the precise placement of the guide pin at the level of the intra-articular lateral femoral condyle. A second tunnel is easily placed from this direction as well.

A primary difficulty experienced in drilling the femoral tunnel from an accessory medial portal, however, results from the need to hyperflex the knee to appropriately

create the tunnel. There is little margin for error in drilling the femoral tunnel through an accessory anteromedial portal because the femoral tunnel is considerably shorter than when drilling the tunnel transtibially. If the pin is not directed anterior and distal, the result will be either a short femoral tunnel or back wall blowout. Hyperflexion of the knee results in poor flow of arthroscopic fluid through the knee and poor visibility. Further, hyperflexion of the knee results in difficulty passing even small instruments over a guide pin because the skin and subcutaneous tissue are impediments. It can often be difficult to tell whether the resisting structure is soft tissue or the articular cartilage on the medial femoral condyle. Forcing instruments may result in iatrogenic articular cartilage damage. Thus it can be difficult to pass even small, specialized, commercially designed low-profile reamers across this flexed knee over a pin.

More recently a retrograde drilling technique was developed that overcomes many of the disadvantages (Branam et al. *Arthroscopy Techniques* 2013 Nov; 2(4): e395–e399). The position of the tunnel placement is very precise and can be re-evaluated from several perspectives. The pilot hole allows for picking the exact desired spot on the femoral condyle and does not require an outside-in guide. Leaving the pin in the femur allows for several opportunities to evaluate the proposed trajectory of the tunnel. The spade-tip guide pin has a larger tip than the diameter of the wire, making maneuverability of the pin easier after placement because the shaft of the pin more easily slides through a larger hole. In contrast to a previously described “composite method,” the smaller guide pin is passed independently, thus allowing the surgeon's hand to be as far inferior and posterior as possible, with the resultant tunnel being as long as possible. The position of the tunnel intra-articularly can be easily evaluated from the excellent

visibility through the central portal, and the exit point of the pin on the lateral thigh gives the surgeon another opportunity to make certain that the pin is not too posterior before drilling.

An additional advantage of the retrograde drilling technique is that, in contrast to previously reported techniques, all instruments and reamers are passed into and out of the knee independently of one another large, and sharp instruments can be easily passed into and out of the non-hyperflexed knee under direct visualization, making certain that the medial structures are left in optimal condition. Moreover, the depth of the tunnel drilling can be perfectly evaluated. With poor fluid flow, the bone remnants from initial femoral tunnel drilling (i.e., the first 10 mm) can obscure visibility. In retrograde drilling, the reamer and guide pin can be withdrawn in opposite directions into the notch, the knee extended, and the joint flushed. The knee is then hyperflexed, and the reamer can be re-advanced antegrade over the guide pin as the guide pin is re-advanced retrograde through the reamer. With markedly improved visibility, the exact depth of the tunnel can be determined off the reamer. This technique allows the instruments to be left within the notch without crossing the notch as the knee is flexed or extended. This allows for meticulous creation of the tunnel with exact measurements while minimizing the number of times the instruments are passed into the knee, across the medial femoral condyle, and passing a structure by the medial femoral condyle over the guide pin is completely avoided.

However, some risks and limitations of this technique remain. First, an inability to hyperflex the knee is a contraindication to use of the technique, because lack of

hyperflexion makes placement of the pin in the proper trajectory virtually impossible. The most common reason for inability to flex the knee is obesity, a relatively common patient condition. The technique is also technically demanding and requires a reasonably skilled assistant to hold the camera with a hyperflexed knee and also to assist
5 in the retrograde passage of the guide pin into the reamer. Significantly, hyperflexion during drilling reduces visibility with diminished fluid flow through the knee, making it even more difficult for an inexperienced assistant to properly navigate the instruments. As the bone is initially drilled, the bone fragments can often obscure visibility as well.

The novel system and technique disclosed herein is safe and reproducible and
10 allows for very specific tunnel placement and measurement. The technique also allows the surgeon more flexibility with femoral tunnel placement and for evaluation without concern for iatrogenic injury or malpositioning of critically important tunnels. In addition, the number of steps is minimized because each instrument is only passed a single time across the knee. The disclosed modular and adaptable reamer system results
15 in fewer steps and simplifies the 'retrograde technique' for ACL reconstruction surgery.

Although the devices and methods of the present disclosure are described primarily with respect to knee ACL reconstruction surgery, it will be readily apparent to the ordinary practitioner that the concepts underpinning the invention and the advantages conferred by the invention may be realized by analogous considerations and practice on
20 other joint ligament reconstruction. In particular, where access to a ligament insertion site is through an access portal that requires intrusion and manipulation of tools in the joint space, embodiments of the invention may be applied to surgical advantage.

Embodiments of the novel modular reamer system provide generally for advantageous intra-articular assembly of a low profile reamers, regardless of the joint at issue.

One embodiment is directed to a reaming system for creation of bone tunnels in joint ligament reconstruction surgery. The system comprises: (i) a substantially rigid
5 elongate guide pin having a leading end and a trailing end; (ii) an elongate holder having an inserting end and an exterior end; and (iii) a reamer element having an advancing end and a retracting end; wherein the advancing end of the reamer and the trailing end of the guide pin are configured to detachably couple, and the inserting end of the elongate holder and the retracting end of the reamer element are configured to detachably couple.

10 The term “end” in the context of the embodiments described herein is not limited to an absolute end, but is meant to describe opposite end regions of an elongate member. Elongate has its ordinary meaning in the art to refer to a member having a length greater than a width. An elongate member that is angled is described so relative to a straight configuration of the same member. The term “substantially” is used herein merely to
15 avoid strict numerical boundaries where such boundaries are recognized by a person of skill in the art as unnecessary to comprehending intended scope.

According to embodiments of the invention, the elongate holder, guide pin and reamer elements may be provided as separate components capable of coupling or as detachably coupled components. When two or more components are coupled, the
20 components may be collectively referred to as an assembly. For example, when the reamer element is coupled to the elongate holder, it may be referred to as a reamer assembly. The couplings of the components are detachable. That is, the components

may be readily coupled or uncoupled/detached in operational use, and in particular, in the intra-articular space. A “coupling” may be achieved by any of numerous methods known in the art, wherein coupling and uncoupling are effectuated by substantially reverse manipulations. For example, if an externally threaded element couples to an internally threaded element by counter-clockwise turning of one relative to the other, then uncoupling is effectuated by clockwise turning. If interlocking members are coupled/engaged by a series of sequential movements of the interlocking elements on one member relative to the other, then disengagement occurs by a reverse sequence of the movements. One operational guide for selecting suitable coupling mechanisms is the recognition, for example, that de-coupling of a reamer-guide pin assembly after coupling of the reamer-holder assembly, must not reverse, loosen, or interfere with the reamer-holder assembly coupling. The coupling mechanisms at these two component junctures must be fully independent under the operational constraints of surgery. Different mechanisms may be employed at each of the coupling positions of the same assembly. A person of ordinary skill in the art, however, will readily understand that providing components which may be readily and independently coupled and uncoupled under operational conditions may be effectuated by a wide variety of coupling mechanisms.

According to specific embodiments, the configuration of the detachable coupling between the inserting end of the holder and the retracting end of the reamer element comprises corresponding mating members that may be secured by, for example, corresponding rotationally engaging interlocking elements or corresponding complementary threading on the mating members. In a specific embodiment, the mating members are secured by rotationally engaging interlocking elements. In more specific

embodiments the retracting end of the reamer element comprises a male mating member that mates with a corresponding female member on the inserting end of the holder and in very specific embodiments the male and female members are secured by corresponding interlocking elements that engage upon relative rotation of the holder and reamer element subsequent to mating. According to other specific embodiments, the configuration of the detachable coupling between the advancing end of the reamer element and the trailing end of the guide pin comprises corresponding mating members. For example, the female member may be internally threaded with the male member being externally threaded such that the mating members engage upon relative rotation of the corresponding mating members. In very specific embodiments the advancing end of the reamer element is configured as the female mating member. These mechanisms may readily be combined or interchanged in other embodiments, with the caveat being that engaging one coupling must not affect the engagement of the other coupling. For example, if corresponding threading is selected as a coupling mechanism at both couplings, threading will have to be reversed at one coupling relative to the other to avoid loosening of one coupling while tightening the other. This is similar with respect to selecting couplings reliant on locking by rotating interlocking elements. In a specific embodiment, an interlocking coupling is designed to require an additional manipulation to secure prior to relative rotation, and in a preferred embodiment, the coupling mechanism of the holder – reamer assembly is different than the coupling mechanism of the reamer – guide pin assembly.

According to specific embodiments, the elongate holder may comprise a rod portion and a holding portion as separate/separable components, wherein the rod portion

is detachably coupled to the holding portion. The elongate holder may be provided as a kit comprising separate/separable and interchangeable rod and holder portions. An elongate holder may be straight or angled depending on location of a joint space access portal relative to a desired ligament insertion site. Where placement or traversal of tools
5 in/across a region of a joint space is sought to be minimized or avoided for surgical efficiency and/or for minimizing potential for inadvertent damage to traversed joint tissue, the elongate holder rod portion may be angled for insertion into a joint space access portal having a more desirable proximity to the desired ligament insertion site.

Generally, an elongate holder may be made of any of a number of known
10 materials that provides a substantially “rod” shaped, and in specific embodiments may be cannulated, in whole or in part, for example, to accommodate power source connectors or as an aspect of a coupling mechanism. The elongate holder may be provided in a kit of rod portions of varying lengths, widths, and angles, and holder portions of various sizes, depending on surgical/patient need. In another alternative, an elongate holder rod
15 portion, may be provided as rigid but non-elastically pliable. The rod portion may be fabricated from a metal, polymeric, or hybrid material that is sufficiently pliable to bend to a desired angle; however not so pliable that the desired angle could be deformed during operational pressures. Such materials are well-known in the art. In another specific embodiment, the elongate holder may be provided as a modular system with
20 straight and angled components which may be assembled in whole or in part to form a straight or angled elongate holder having a particular desired overall geometry.

According to general embodiments, a guide pin is rigid in contrast to prior art reaming systems comprising flexible reamer guide pins and which also purport to permit drilling of the femoral tunnel without hyperflexion of the joint/knee. (See, e.g. Rasmussen et al. *Arthrosc Tech.* 2013 Nov; 2(4): e319–e322.) Such systems have

5 inherent difficulties, in particular with location precision and deformation into vulnerable tissue upon resistance to advancement. Specifically in the context of ACL reconstruction, specific embodiments of the presently disclosed reamer system permit insertion of a substantially rigid guide pin from the anteromedial access portal and an ability to drill the tunnel over/with the rigid guide pin with the knee in a resting position

10 of approximately 90 degrees flexion. In preferred embodiments, the entire guide pin is configured to rotate, for example, to effectuate coupling and uncoupling to the reamer element, and in certain cases as the reamer element is advanced across/with the guide pin. This is in contrast to systems providing a rotationally stationary guide pin and rotating cannulated instruments over a stationary guide wire.

15 Other embodiments of the invention are directed to methods for bone tunnel reaming during ligament reconstruction of a joint using embodiments of the novel reamer system disclosed herein. In specific embodiments, bone tunnel reaming comprises femoral tunnel reaming during anterior cruciate ligament reconstruction of a knee. According to one embodiment, the methods comprise: (a) hyperflexing the knee

20 and advancing the leading end of the guide pin through a knee space access portal to a ligament insertion site to develop a femoral entrance hole; (b) further advancing the guide pin until the trailing end extends a distance from the femoral entrance hole; (c) inserting the reamer assembly until the advancing end of the reamer element abuts the

trailing end of the guide pin; (d) coupling the reamer to the guide pin; (e) decoupling the elongate holder from the reamer and removing the elongate holder from the knee space; (f) releasing the hyperflexion of the knee; (g) engaging power to the reamer and advancing the guide pin to drill the femoral tunnel a desired tunnel depth; (h)

- 5 disengaging power to the reamer and retracting the reamer element into the knee space; (i) inserting the holder into the knee space until the inserting end of the holder abuts the retracting end of the reamer element; (j) coupling the holder and the reamer element; (k) decoupling the reamer and the guide pin; and (l) retracting the reamer assembly from the knee space and removing the guide pin.

- 10 For semantic precision it is noted that advancement of the guide pin in accordance with embodiments of the inventive methods is described as antegrade if power is attached on the trailing end side, and retrograde if the power is attached to the leading end.

- According to specific embodiments, the detachable coupling of the elongate
15 holder and reamer element comprises a male member on the retracting end of the reamer element mated to a corresponding female member on the inserting end of the holder, and rotationally engaged corresponding interlocking elements. In specific examples, the advancing end of the reamer element is configured as an internally threaded female mating member and the trailing end of the guide pin is configured as an externally
20 threaded male mating member such that the coupling of step (d), above comprises rotating the corresponding mating members relative to one another, and the decoupling of step (k), above, comprises rotating the corresponding mating members in a direction

opposite to (d). It may be readily envisioned that the respective parts may be reversed with respect to the coupling mechanism and still be within the scope of the instant systems, components and methods. According to specific embodiments, the decoupling of step (e) comprises disengaging the corresponding interlocking elements by relative
5 rotation of the reamer element and holder followed by disengaging the mated members, and the coupling of step (j) comprises mating the male member on the retracting end of the reamer to the corresponding female member on the inserting end of the holder to align the interlocking elements and rotating the reamer and holder relative to one another to engage the interlocking elements.

10 According to surgical needs and proximity of a ligament insertion site to a target access portal, the elongate holder may be straight or angled. A holder may be disassembled from a reamer and removed from the joint space prior to drilling, enabling drilling to take place while the knee is not hyperflexed, and in specific embodiments drilling takes place while the knee is at a “resting position” of approximately 90 degrees
15 flexion. In some embodiments knee space access portal comprises an anteroomedial portal and the elongate holder is substantially straight and hyperflexion is avoided during drilling.

Hyperflexing of the knee may be additionally avoided at every surgical step subsequent to insertion of the guide pin in accordance with other preferred embodiments.
20 Specifically, an elongate holder may be angled to be greater than zero and less than 90 degrees. In very specific embodiments the holder is angled approximately 45 degrees and insertion is via the anteromedial portal. Other insertion sites are contemplated and it

is understood that an ideal angle of the elongate holder may vary in accordance with selection of access portal, portal to insertion site proximity, and relevant geometries of the bone. For example, a central or lateral access portal may be selected, requiring an elongate holder angled from between about 10 degrees to about 90 degrees. In very
5 specific embodiments the elongate holder is angled to provide coupling of the reamer to the guide pin while avoiding hyperflexion of the knee for performance of every surgical step of femoral tunneling subsequent to insertion of the guide pin.

Embodiments providing surgical kits for use in association with joint ligament reconstruction are also provided. According to one embodiment, a kit comprises
10 components for assembling an adaptable reamer system selected from both straight and angled single unit elongate holders, separated/separable holders comprising straight or angled rod portions and holder portions, reamer elements, guide pins, providing the practitioner with a variety of sizes, coupling mechanisms, geometries and power connecting configurations to adapt to a wide variety of joint applications, and to provide
15 flexibility as to joint space access port location. Kits may be assembled for precise joint reconstruction applications (for example, a kit may provide only those elements needed/sized for ACL reconstruction via the anteromedial access portal) or broad joint reconstruction applications and may or may not include all components of a reamer system, for example, a kit may provide only variously sized reamer elements or only
20 variously configured elongate holders, and the like). Any combination of components of a reamer system as described herein is contemplated.

Examples

The following examples are set forth to illustrate specific embodiments of the invention and should not be construed as limiting the scope thereof as defined by the appended claims.

5 Example 1

Referring to **Figures 2A-2G**, a very specific embodiment of a surgical procedure for creating a femoral tunnel **43** utilizing an embodiment of the novel reamer system **1** is illustrated. **Fig. 2A)** A guide pin **3** is inserted at the anatomical insertion site of the ACL and **Fig. 2B)** a pilot hole is drilled through the femur **28**. Both steps require hyperflexion of the knee **26** (not shown). **Fig. 2C)** A reamer assembly **2** The reamer element **15** is secured onto the elongate holder **9** forming a reamer assembly **2** outside the joint space and then the reamer assembly **2** is inserted into the joint space across the medial femoral condyle with the knee flexed at 90° (relative extension) through the anteromedial portal. **Fig. 2D)** The trailing end **7** of the guide pin **3** is secured into the advancing end **17** of the reamer element **15** by use of a coupling mechanism such as complementary threads while the reamer element **15** is held in place by the holder **9**. This step requires hyperflexion of the knee **26**. **Fig. 2E)** The holder **9** is disengaged from the reamer element **15** and removed from the joint space and the femoral tunnel **43** is drilled to a required depth **45** with the knee in 90° flexion. The reamer **15** is advanced in the reverse direction to cut through the bone. **Fig. 2F)** After the tunnel is drilled, the reamer element **15** and guide pin **3** (also referred to as a reamer-guide pin assembly **4** when coupled are retracted into the joint space and the holder **9** is reintroduced into the joint space. The

knee is hyperflexed as the holder **9** engages with the reamer **15** to effectuate disassembly of the reamer-guide pin assembly **4**. **Fig. 2G**) The guide pin **3** is removed through the patient's thigh. The reamer assembly **2** is retracted to remove the reamer **15** from the joint space. The knee is flexed at 90° during this step.

5 For comparison purposes, **Figure 1** shows a prior art schematic of the process, which is substantially the same until **1E**. Notably, the elongate holder and reamer are not detachably coupled and are manipulated as a single unit. Since the hold remains in the knee space during the tunnel drilling, the knee must remain hyperflexed during the drilling. Further, other vulnerable tissues of the knee are subject to contact and potential
10 injury during the drilling by the holder.

Example 2

Referring to **Figures 3A-3G**, another very specific embodiment of the inventive system and methods is illustrated. **Fig. 3A** and **Fig. 3B** are the same steps as set forth in **Example 1** for **2A** and **2B**. **Fig. 3C** depicts the reamer **15** inserted into the joint space
15 with the knee flexed at 90°. The reamer element **15** is secured onto the holder **9** outside the joint space and then inserted through a central or lateral access portal. **Fig. 3D**) The trailing end of the guide pin is assembled in the internally threaded portion of the reamer element as the reamer is held in place with the holder. The Elongate holder is angled **32**.
And angle of approximately 90 degrees is shown; however other preferred angles include
20 a range from about 10 to about 90 degrees, with specific embodiments of 15, 30, 45 and 90 degrees. Due to the use of an angled elongate holder **9**, this step does not require hyperflexion of the knee and the knee is held in resting condition, flexed at

approximately 90°. **Fig. 3E)** The holder **9** is disengaged from the reamer **15** and removed from the joint space. Power is engaged to the guide pin and the femoral tunnel **43** is drilled to a desired depth **45** with the knee still flexed at 90°. The reamer **15** is advanced in the reverse direction to cut through the femur **28**. **Fig. 3F)** After the tunnel **43** is drilled, the reamer and guide pin assembly **4** is retracted into the joint space and the holder **9** is reintroduced into the joint space while the knee remains flexed at 90°. The holder re-engages with the reamer **15** and the reamer **15** and guide pin **3** are decoupled. **Fig. 3G)** The guide pin **3** is removed through the thigh and the reamer assembly **2** is retracted to remove the reamer **15** from the joint space, while the knee remains flexed at 90°. **Fig. 3H)** Compares hyperflexion of a knee with an approximately 90 degree flexion

Example 3

One embodiment of the reamer system is described with reference to **Figure 5A and 5B**. **Fig. 5A** depicts three separated components of the reamer system **1**, namely the reamer element **15**, guide pin **3** and a straight elongate holder **9**. The trailing end **7** of the guide pin **3** is provided with clockwise external threads **34**, which engage with the corresponding internal threads **30** on the reamer element **15**. A hand-held power unit **41** can drive the reamer-guide pin assembly on the outside of the lateral aspect of the thigh. Location of the power unit **41** may vary. **Fig. 5B** shows an enlarged and transparent view of a reamer element **15** coupled to a holder portion **12** of a holder **9** via an interlocking coupling mechanism **20**. The elongate holder **9** permits the technician/surgeon to insert and retract the reamer element **15** from the joint space.

Example 4

Figure 4A-4D illustrates specific embodiments of the low-profile reamer element 15 useful for creating the femoral tunnel. In very specific exemplary embodiments the reamer elements **15** are provided in diameters ranging from 7 mm to 13 mm with 0.5 mm increments. The reamer **15** enlarges the hole created by the guide pin to drill a tunnel with a required tunnel diameter up to a desired tunnel depth. In some exemplary methods, the tunnel can be further enlarged up to 13 mm in steps of 0.5 mm with the use of sequentially larger reamers. The reamer **15** cuts through the bone with the advancing end **17** coupled to the guide pin **3**, and the retracting end **19** de-coupled from the holder **9**, advancing/drilling in the reverse direction to prior art techniques, which permits removal of the holder **9** and elimination of hyperflexion during tunnel creation. The small size reduces the possibility of iatrogenic damage to the medial femoral condyle during insertion into joint space. In very specific embodiments, a male coupling member **21** on the retracting end **19** of the reamer **15** allows for easy assembly and disassembly with a corresponding female coupling member **23** on the holder **9**. **Figs. 4A and 4B** exemplify corresponding threaded members **34, 30** with rotational screwing as the coupling mechanism to a holder **9** (not shown), and **Figs. 4C and 4D** exemplify interlocking parts **20** which lock and un-lock the reamer element **15** to the holder **9** (not shown) by rotational movement relative to the holder.

Example 5

Figure 8 exemplifies an elongate holder embodiment having separated/separable rod portions and holder portions. **Figs. 8A and 8B** depict a holder portion **12** having interlocking elements **20** for coupling with the retracting end **19** of a reamer element **15** (not shown), and an internal female member **16** for engaging with (**Figs. 8C, 8D and 8E**)

the male member **14** on a rod portion **10** of an elongate holder **9**. The holder and reamer are coupled prior to insertion of the reamer assembly **2** into the knee space. The reamer **15** is held in place as the trailing end **7** of the guide pin **3** (not shown) is coupled to the advancing end **17** of the reamer **15**. Once coupled to the guide pin, counter-clockwise rotation of the reamer allows disassembly of the reamer from the holder and retraction of the holder from the joint space.

Example 6

Figure 7 illustrates another embodiment of the modular reamer system comprising a modification of the elongate holder **9** such that it is angled **32**, permitting insertion into the joint space through other access portals, including the central or lateral portal. This angled elongate holder eliminates traversing of delicate tissues by the reamer assembly **2** upon insertion, and further eliminates the need to hyperflex the knee at any time subsequent to insertion of the guide pin **3** into proper position. In the exemplary embodiment, the trailing end **7** of the guide pin **3** couples to the advancing end **17** of the reamer element **15** by rotating corresponding threaded members **21/23** relative to one another and the holder **9** couples to the retracting end **19** of the reamer **15** by rotating aligned corresponding interlocking elements **20** until they lock.

A person of ordinary skill in the art will understand that specific attributes of the reaming system, components, and methods may be altered or adapted without departing from the spirit nor limiting the scope of the instant invention as defined by the claims. Nor is the scope of the present invention intended to be limited to the above Description; but rather is as set forth in the appended claims. It will be appreciated that the invention

is in no way dependent upon particular results achieved. Articles such as “a”, “an” and “the” may mean one or more than one unless indicated to the contrary or otherwise evident from the context. Claims or descriptions that include “or” between one or more members of a group are considered satisfied if one, more than one, or all of the group members are present in, employed in, or otherwise relevant to a given product or process unless indicated to the contrary or otherwise evident from the context. The invention includes embodiments in which exactly one member of the group is present in, employed in, or otherwise relevant to a given product or process. The invention also includes embodiments in which more than one, or all group members are present in, employed in, or otherwise relevant to a given system or methods. Furthermore, it is to be understood that the invention encompasses all variations, combinations, and permutations in which one or more limitations, elements, clauses, descriptive terms, etc., from one or more of the listed claims or from the description above is introduced into another claim. For example, any claim that is dependent on another claim can be modified to include one or more elements, limitations, clauses, or descriptive terms, found in any other claim that is dependent on the same base claim.

Where elements are presented as lists, it is to be understood that each subgroup of the elements is also disclosed, and any element(s) can be removed from the group. For purposes of conciseness only some of these embodiments have been specifically recited herein, but the invention includes all such embodiments. It should also be understood that, in general, where the invention, or aspects of the invention, is/are referred to as comprising particular elements, features, etc., certain embodiments of the invention or aspects of the invention consist, or consist essentially of, such elements, features, etc.

Where ranges are given, endpoints are included. Furthermore, it is to be understood that unless otherwise indicated or otherwise evident from the context and understanding of one of ordinary skill in the art, values that are expressed as ranges can assume any specific value or subrange within the stated ranges in different embodiments

5 of the invention, to the tenth of the unit of the lower limit of the range, unless the context clearly dictates otherwise. Any particular embodiment, aspect, element, feature, etc., of the present invention, or any combination thereof, may be explicitly excluded from any one or more claims whether or not such exclusion is expressly recited herein. For example, any component or component feature can be explicitly excluded. Applicants

10 reserve the right to proviso out of the claims any specific component, component feature, configuration, process step and/or combination thereof, whether or not such component, component feature, configuration, process step thereof, is recited herein.

Claims

1. A reaming system for creation of bone tunnels in joint ligament reconstruction surgery, the system comprising: (i) a substantially rigid elongate guide pin having a leading end and a trailing end; (ii) an elongate holder having an inserting end and an exterior end; and (iii) a reamer element having an advancing end and a retracting end;
5 wherein the advancing end of the reamer and the trailing end of the guide pin are configured to detachably couple, and the inserting end of the elongate holder and the retracting end of the reamer element are configured to detachably couple.
2. The reaming system according to claim 1, wherein the configuration of the
10 detachable coupling between the inserting end of the holder and the retracting end of the reamer element comprises corresponding mating members and corresponding rotationally engaging interlocking elements.
3. The reaming system according to claim 2, wherein the retracting end of the reamer element comprises a male mating member that mates with a corresponding
15 female member on the inserting end of the holder, and the corresponding interlocking elements engage upon relative rotation of the holder and reamer element subsequent to mating.
4. The reaming system according to claim 1, wherein the elongate holder may be straight or angled depending on location of a joint space access portal relative to a
20 ligament insertion site.

5. The reaming system according to claim 4 wherein the elongate holder is angled to avoid hyperflexing the joint for insertion into the joint space access portal.
6. The reaming system according to any of the above claims 1-5, wherein the configuration of the detachable coupling between the advancing end of the reamer
5 element and the trailing end of the guide pin comprises corresponding mating members, the female member being internally threaded and the male member being externally threaded such that the mating members engage upon relative rotation of the corresponding mating members.
7. The reaming system according to claim 6, wherein the advancing end of the
10 reamer element is configured as the female mating member.
8. The reaming system according to claim 4, wherein the elongate holder is fabricated to bend to a desired angle.
9. The reaming system according to claim 4, wherein the elongate holder comprises multiple components which may be assembled in whole or in part to provide a straight
15 elongate holder or an angled elongate holder.
10. The reaming system according to any of claims 1-9, wherein the elongate holder comprises a rod portion and a holding portion as separable components, wherein the rod portion is detachably coupled to the holding portion.
11. A method for femoral tunnel reaming during anterior cruciate ligament
20 reconstruction of a knee using a reamer system, the system comprising (i) a substantially rigid elongate guide pin having a leading end and a trailing end; (ii) a reamer assembly

comprising an elongate holder having an inserting end and an exterior end, and a reamer element having an advancing end and a retracting end, and the inserting end of the holder and the retracting end of the reamer element are detachably coupled and wherein the advancing end of the reamer and the trailing end of the guide pin are configured to detachably couple, the method comprising: (a) hyperflexing the knee and advancing the leading end of the guide pin through a knee space access portal to a ligament insertion site to develop a femoral entrance hole; (b) further advancing the guide pin until the trailing end extends a distance from the femoral entrance hole; (c) inserting the reamer assembly until the advancing end of the reamer element abuts the trailing end of the guide pin; (d) coupling the reamer to the guide pin; (e) decoupling the elongate holder from the reamer and removing the elongate holder from the knee space; (f) releasing the hyperflexion of the knee; (g) engaging power to the reamer and advancing the guide pin retrograde to drill the femoral tunnel a desired tunnel depth; (h) disengaging power to the reamer and retracting the reamer element into the knee space; (i) inserting the holder into the knee space until the inserting end of the holder abuts the retracting end of the reamer element; (j) coupling the holder and the reamer element; (k) decoupling the reamer and the guide pin; and (l) retracting the reamer assembly from the knee space and removing the guide pin.

12. The method according to claim 11, wherein the detachable coupling of the elongate holder and reamer element comprises a male member on the retracting end of the reamer element mated to a corresponding female member on the inserting end of the holder, and rotationally engaged corresponding interlocking elements.

13. The method according to claim 11, wherein the advancing end of the reamer element is configured as an internally threaded female mating member and the trailing end of the guide pin is configured as an externally threaded male mating member such that the coupling of step (d) comprises rotating the corresponding mating members
5 relative to one another, and the decoupling of step (k) comprises rotating the corresponding mating members in a direction opposite to (d).
14. The method of claim 12, wherein the decoupling of step (e) comprises disengaging the corresponding interlocking elements by relative rotation of the reamer element and holder followed by disengaging the mated members, and the coupling of
10 step (j) comprises mating the male member on the retracting end of the reamer to the corresponding female member on the inserting end of the holder to align the interlocking elements and rotating the reamer and holder relative to one another to engage the interlocking elements.
15. The method according to claim 11, wherein the elongate holder may be straight
15 or angled depending on location of a knee space access portal relative to the ligament insertion site.
16. The method according to claim 15, wherein the knee space access portal comprises an antereomedial portal and the elongate holder is substantially straight or angled.
- 20 17. The method according to claim 15, wherein the knee space access portal comprises a central or lateral access portal and the elongate holder is angled.

18. The method according to claims 16 or 17, wherein the elongate holder is angled from between about 10 degrees to about 90 degrees.
19. The method according to claims 16 or 17, wherein the elongate holder is angled approximately 45 degrees.
- 5 20. The method according to any of claims 15-19, wherein hyperflexing the knee is avoided subsequent to step (b).
21. The method according to any of claims 15-19, wherein the elongate holder comprises multiple components which may be assembled in whole or in part to provide a straight elongate holder or an angled elongate holder.
- 10 22. The method according to any of claim 15-19, wherein the elongate holder is fabricated to bend at a desired angle.
23. The method according to any of claims 11-22, wherein the elongate holder comprises a rod portion and a holding portion as separable components, wherein the rod portion is detachably coupled to the holding portion.
- 15 24. A surgical kit for assembling an adaptable reamer system, the kit comprising elements selected from the elements of the reamer system according to any of claims 1-10.
25. The surgical kit according to claim 24 comprising more than one of any specific element in varying sizes.

26. A method for femoral tunnel reaming during retrograde anterior cruciate ligament reconstruction of a knee, the method comprising: drilling a femoral tunnel without hyperflexion of the knee.
27. The method according to claim 26, further comprising performing all steps of the
5 femoral tunnel reaming subsequent to insertion of a guide pin into a femoral position without hyperflexion of the knee.

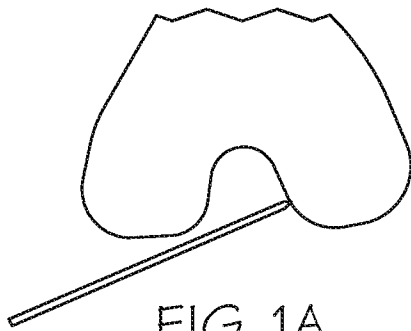


FIG. 1A
(PRIOR ART)

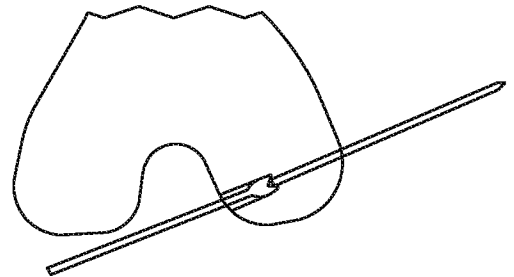


FIG. 1E
(PRIOR ART)

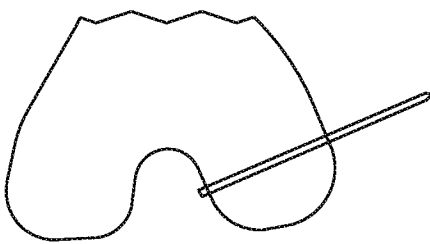


FIG. 1B
(PRIOR ART)

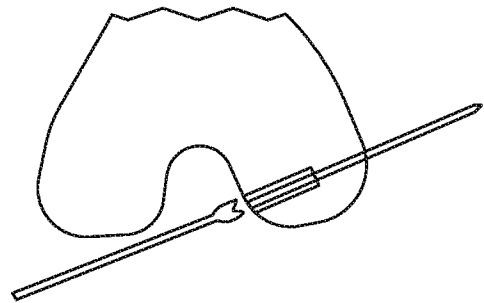


FIG. 1F
(PRIOR ART)

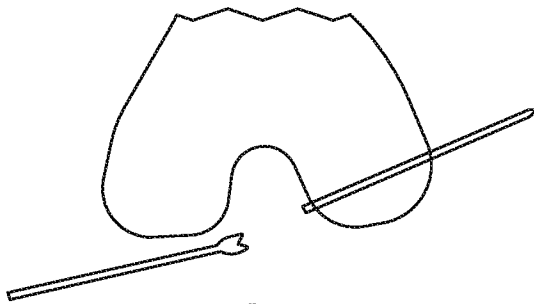


FIG. 1C
(PRIOR ART)

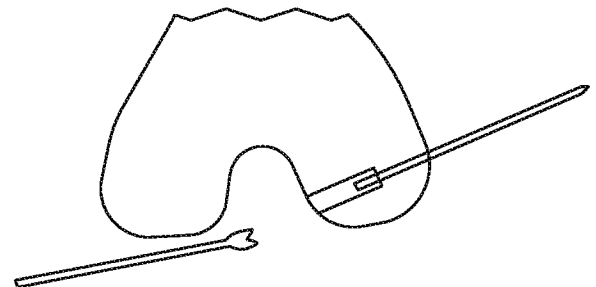


FIG. 1G
(PRIOR ART)

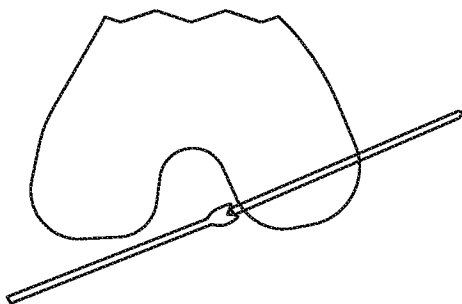
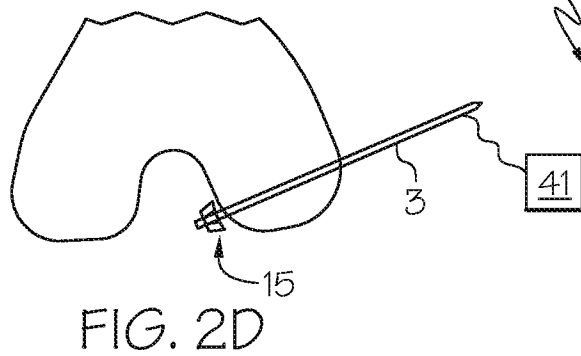
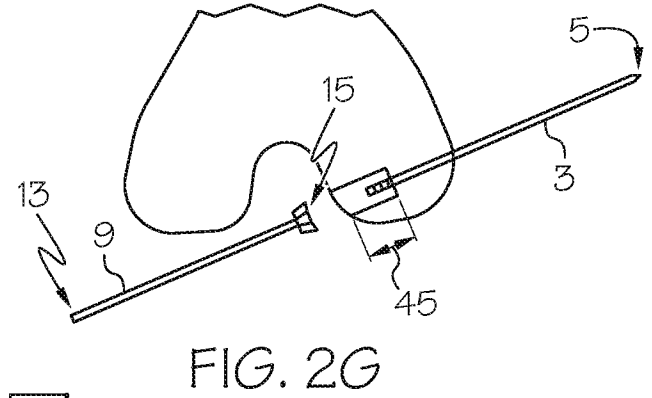
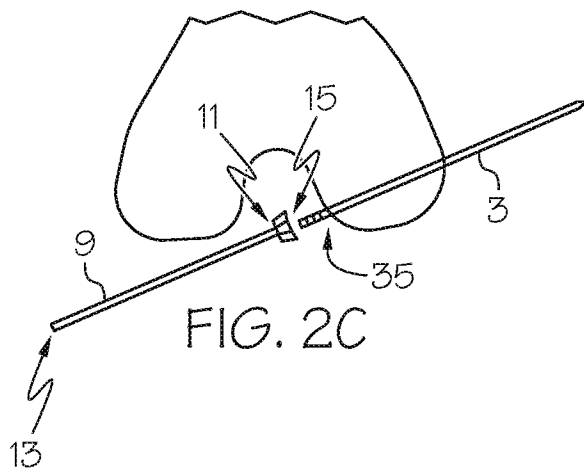
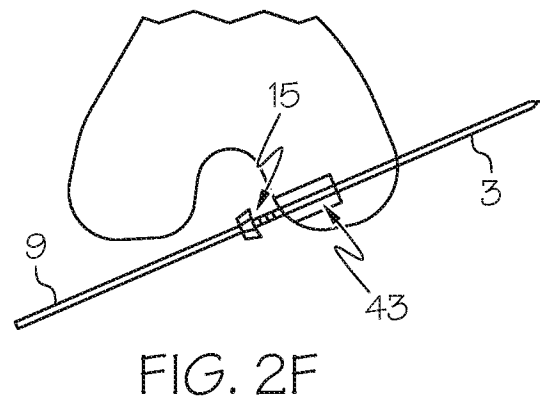
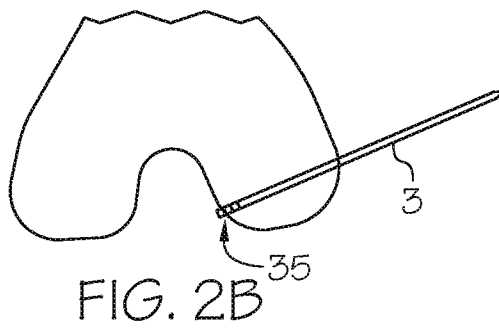
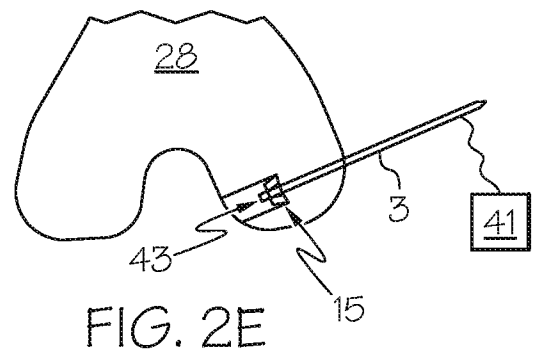
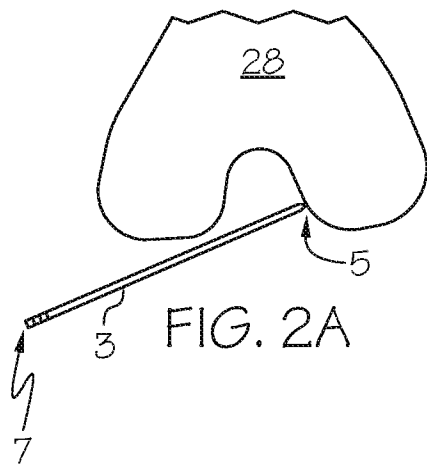
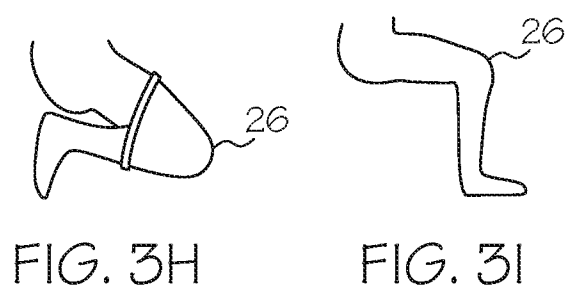
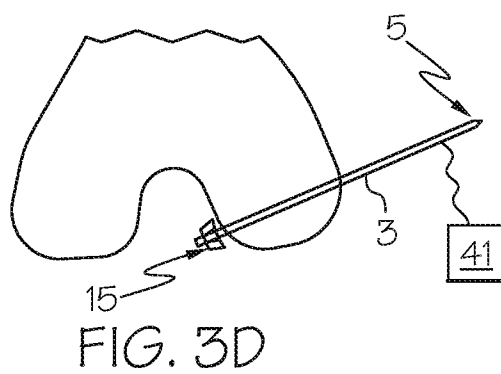
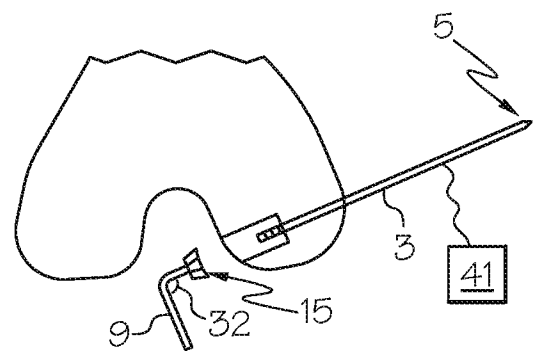
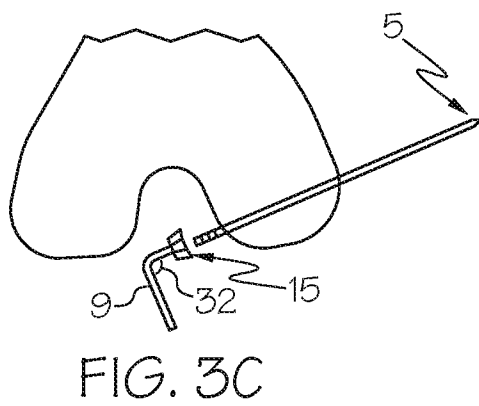
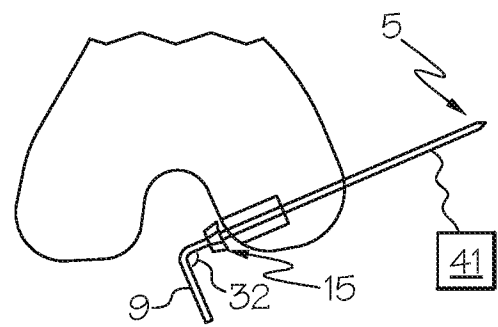
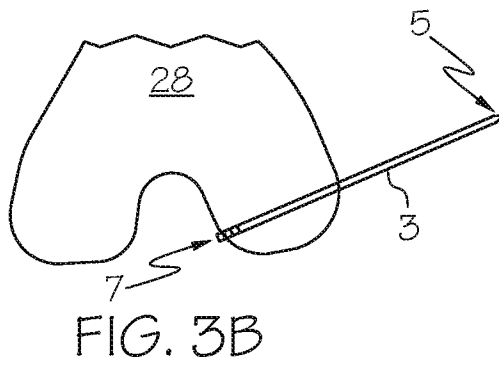
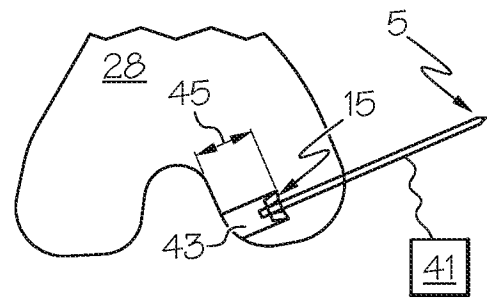
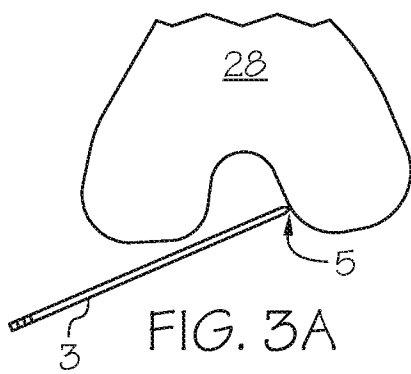


FIG. 1D
(PRIOR ART)

2 / 8





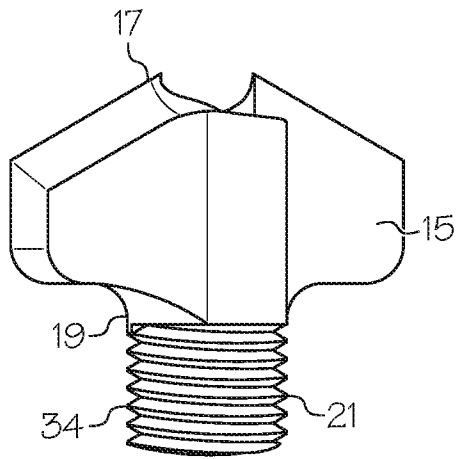


FIG. 4A

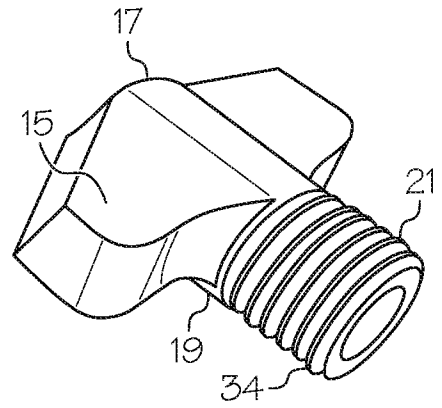


FIG. 4B

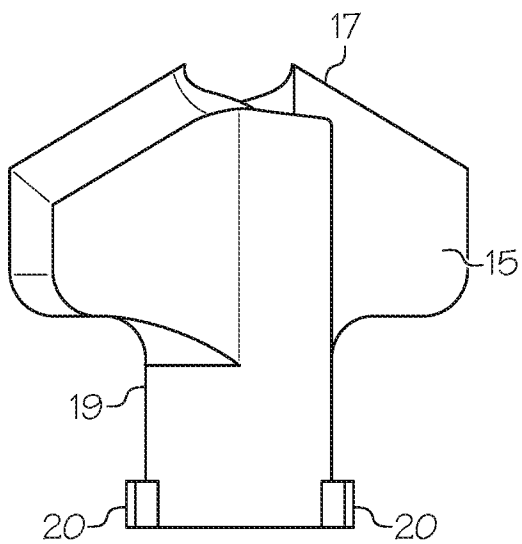


FIG. 4C

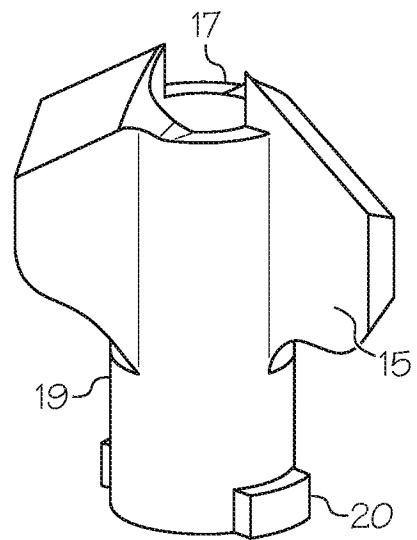


FIG. 4D

5 / 8

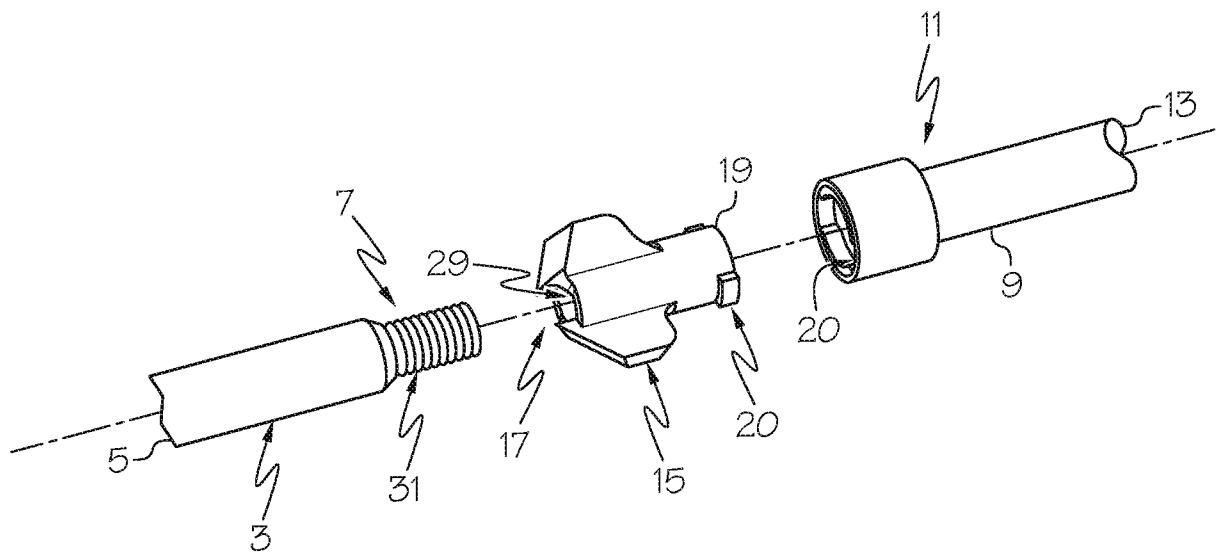


FIG. 5A

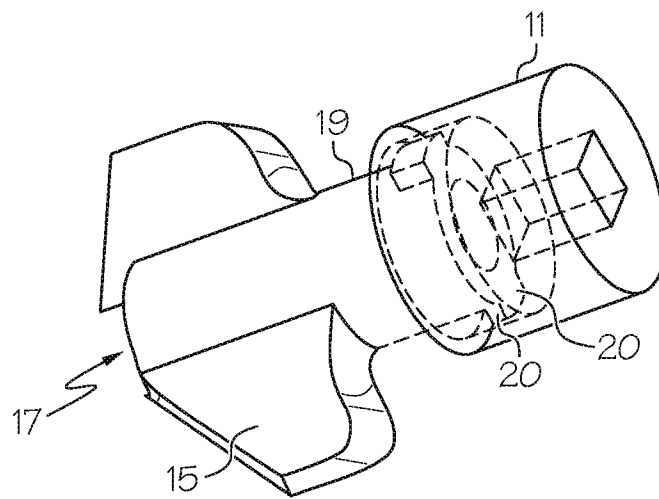


FIG. 5B

6 / 8

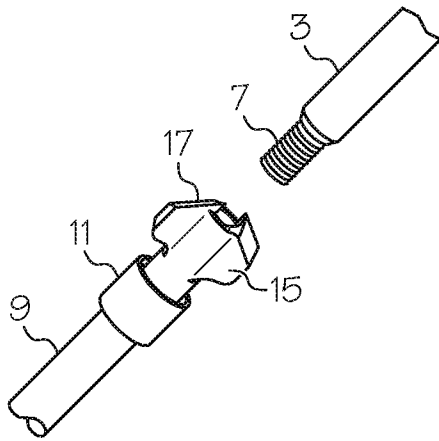


FIG. 6A

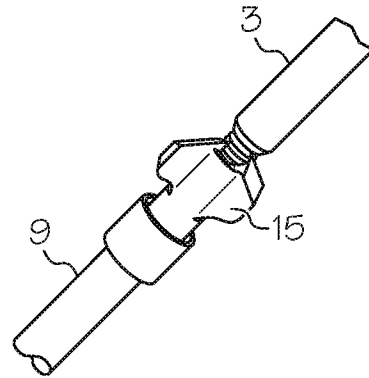


FIG. 6B

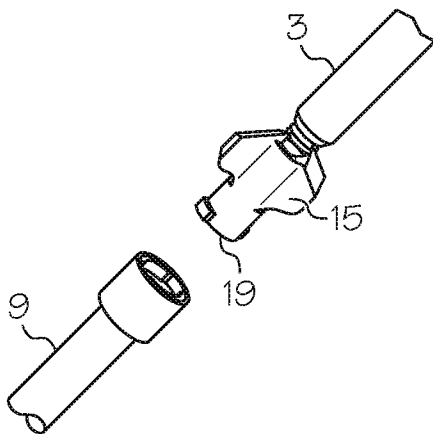


FIG. 6C

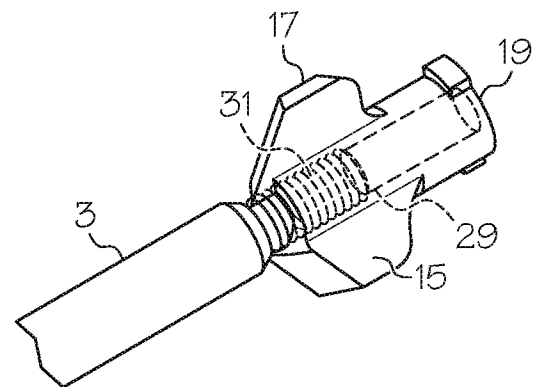


FIG. 6D

7 / 8

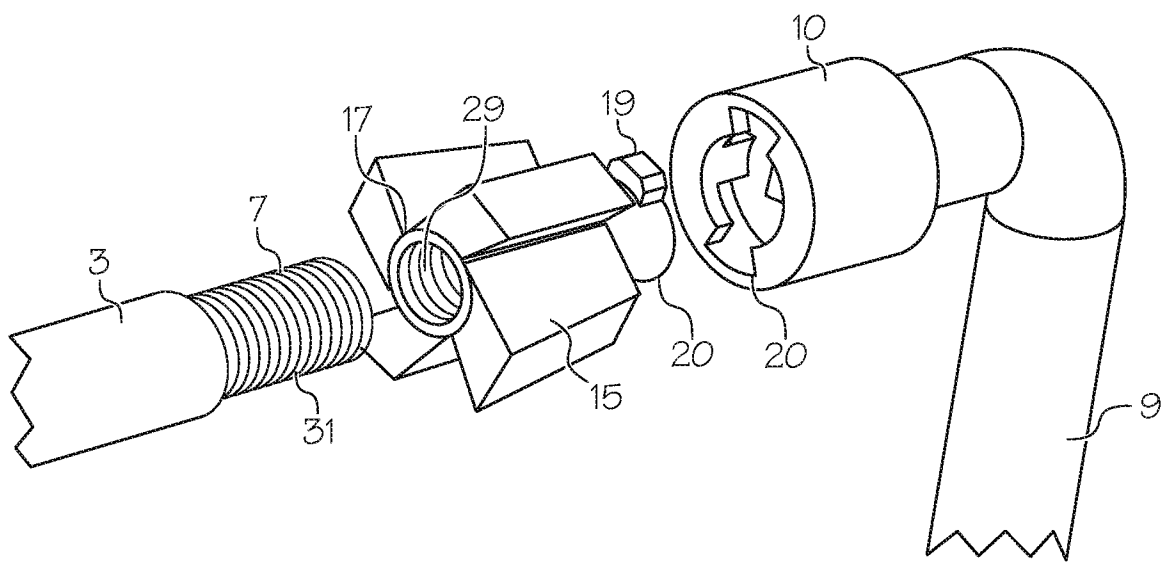


FIG. 7

8 / 8

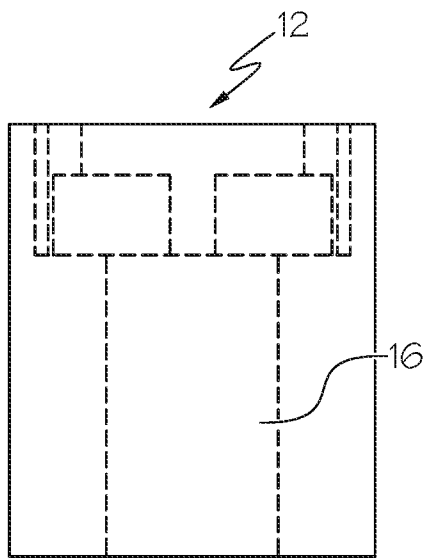


FIG. 8A

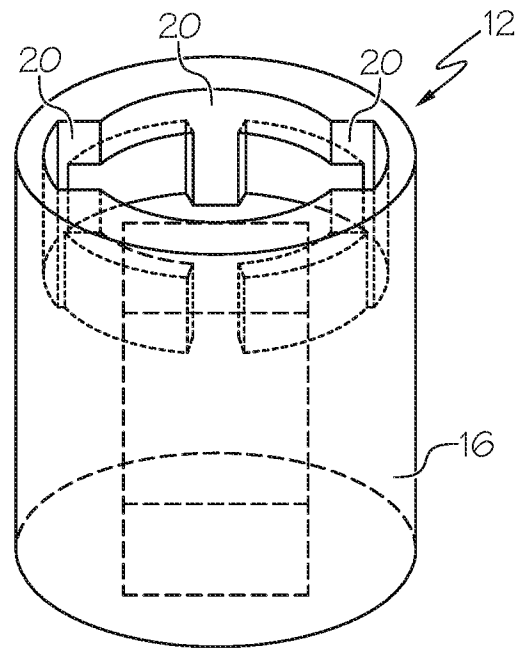


FIG. 8B

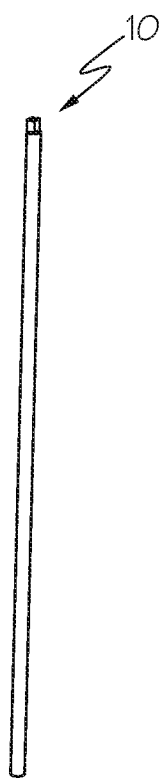


FIG. 8C

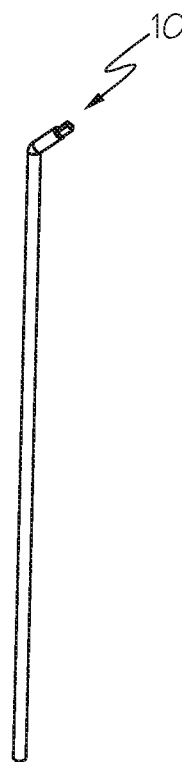


FIG. 8C

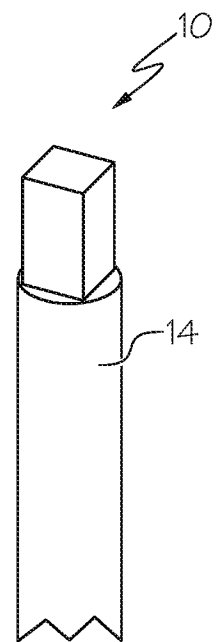


FIG. 8E

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US16/22269

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B17/16, A61B17/17, A61B17/56 (2016.01)

CPC - A61B17/16, A61B17/1615, A61B17/1617, A61B17/1675, A61B17/1631, A61B17/17, A61B17/1764

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8): A61B17/16, A61B17/17, A61B17/56 (2016.01); CPC: A61B17/16, A61B17/1615, A61B17/1617, A61B17/1675, A61B17/1631, A61B17/17, A61B17/1764, A61B17/56, A61F2/30, A61F2/38 A61F2/46, A61F2/461, A61F2/4603

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); PubMed; EBSCO; Google/Google Scholar; KEYWORDS: knee, ACL, anterior cruciate ligament, bone, ream*, mill*, drill*, cut*, pin, guid*, coupl*, connect*, detach*, attach*, thread*, hyper_flex*, femoral, tunnel*, external, internal, flex*, angle, degrees, bend*, retrograde, release

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/0233128 A1 (SCHMIEDING, R et al.) 4 October 2007; figures 1A-C, 2A, 3B, 13-17; paragraphs 32-35, 37, 46-50,	1-2, 6/1, 6/2, 7/6/1, 7/6/2
Y		3-5, 6/3-6/5, 7/6/3-7/6/5, 8, 9
X	WILSON, A et al. Anatomic All-Inside Anterior Cruciate Ligament Reconstruction Using the Translateral Technique. Arthroscopy Techniques. May 2013, Vol. 2, No. 2; pages e99-e104; pages e100-e101; page e103; column 1, paragraph 1	26, 27
Y	US 5,971,670 A (PANTZAR, G et al.) 26 October 1999; figure 1; column 2, lines 30-50;	3, 6/3, 7/6/3
Y	US 2011/0208194 A1 (STEINER, M et al.) 25 August 2011; figure 35A; paragraphs 5, 84, 123	4-5, 6/4, 6/5, 7/6/4, 7/6/5, 8-9
A	US 6,149,654 A (JOHNSON, L) 21 November 2000; figures 2, 4A-G; column 1, lines 63-65; column 2, lines 25-50	11-19
A	BRANAM, B et al. "Retrograde Technique" for Drilling the Femoral Tunnel in an Anterior Cruciate Ligament Reconstruction. Arthroscopy Techniques. November 2013, Vol. 2, No. 4, pages e395-e399; page e396-e397	11-19
A	US 2013/158555 A1 (BOURQUE, B et al.) 20 June 2013; entire document	1-9, 11-19, 26, 27
A	WO 2013/192080 A1 (SMITH & NEPHEW, INC.) 27 December 2013; entire document	1-9, 11-19, 26, 27

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

16 May 2016 (16.05.2016)

Date of mailing of the international search report

30 JUN 2016

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US16/22269

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

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

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

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

3. ☒ Claims Nos.: 10, 20-25
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.