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[54] **METHOD AND APPARATUS FOR OSTEOCHONDRAL AUTOGRAFT TRANSPLANTATION**

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[21] Appl. No.: **08/885,752**

[22] Filed: **Jun. 30, 1997**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/801,635, Feb. 18, 1997, Pat. No. 5,785,714, which is a continuation of application No. 08/389,492, Feb. 16, 1995, Pat. No. 5,603,716

[60] Provisional application No. 60/024,045, Aug. 16, 1996.

[51] **Int. Cl.**[6] **A61F 5/00**

[52] **U.S. Cl.** **606/86**; 606/88; 606/96

[58] **Field of Search** 606/86, 79, 69, 606/83, 84, 85, 87, 88, 96, 75; 623/13

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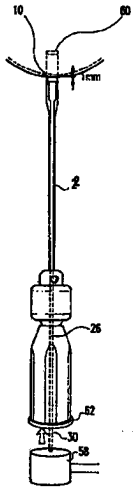
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[57] **ABSTRACT**

A method and apparatus for autogenous transplantation of articular cartilage with bone from one site, such as in the knee, to another to treat chondral defects. Graft harvesters and recipient site harvesters create identically-sized donor graft osteochondral cores and recipient sockets. Collared pins disposed within the harvesters facilitate removal of the harvested cores. Windows formed in the side of the harvester tubes allow visualization of the graft, such as when being inserted into the recipient socket. A removable three-piece driver/extractor is provided to allow for impact-driving and depth control of the harvesters into the selected sites.

20 Claims, 12 Drawing Sheets



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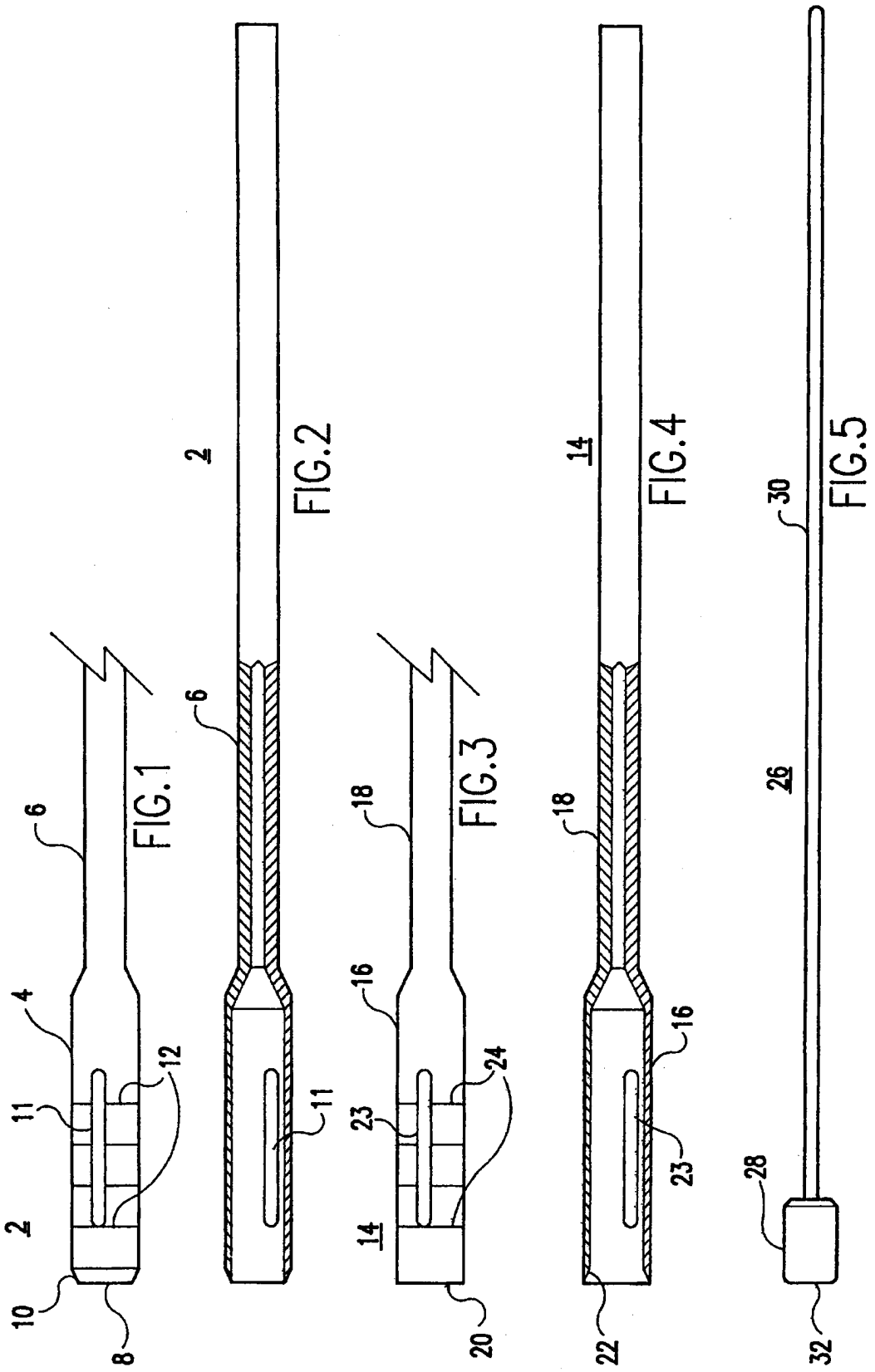
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FIG.1
6
4
12
11
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FIG.2
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FIG.3
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FIG.5
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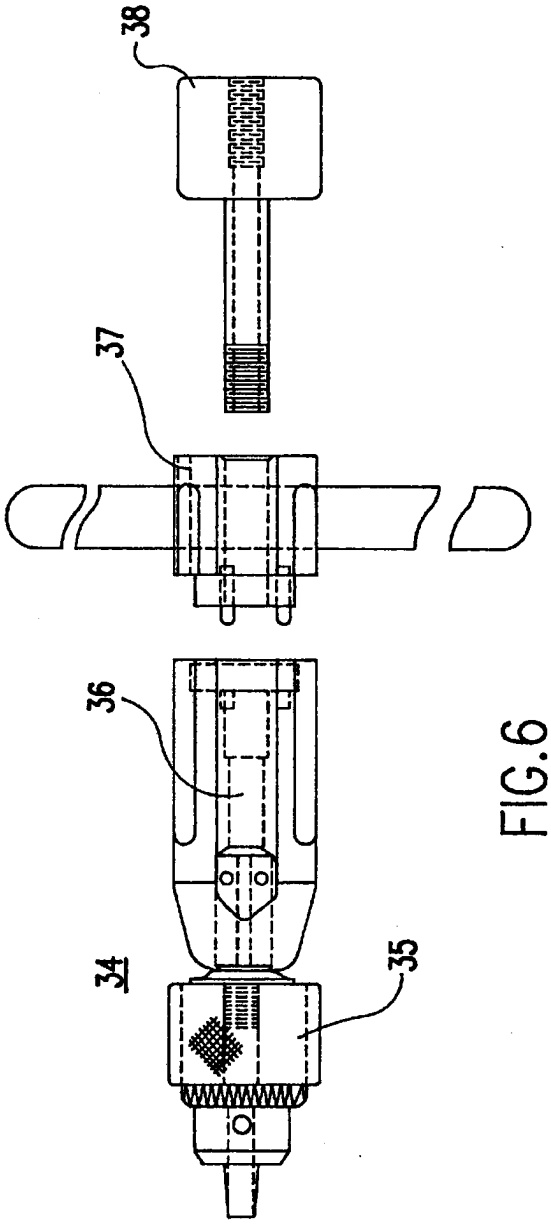


FIG.6

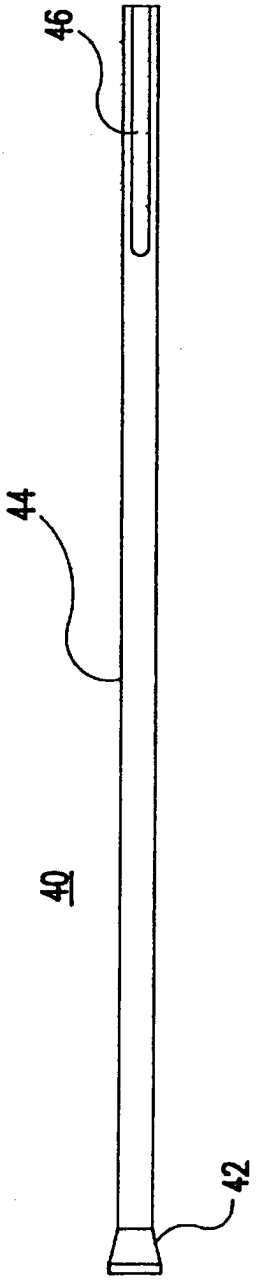


FIG.7

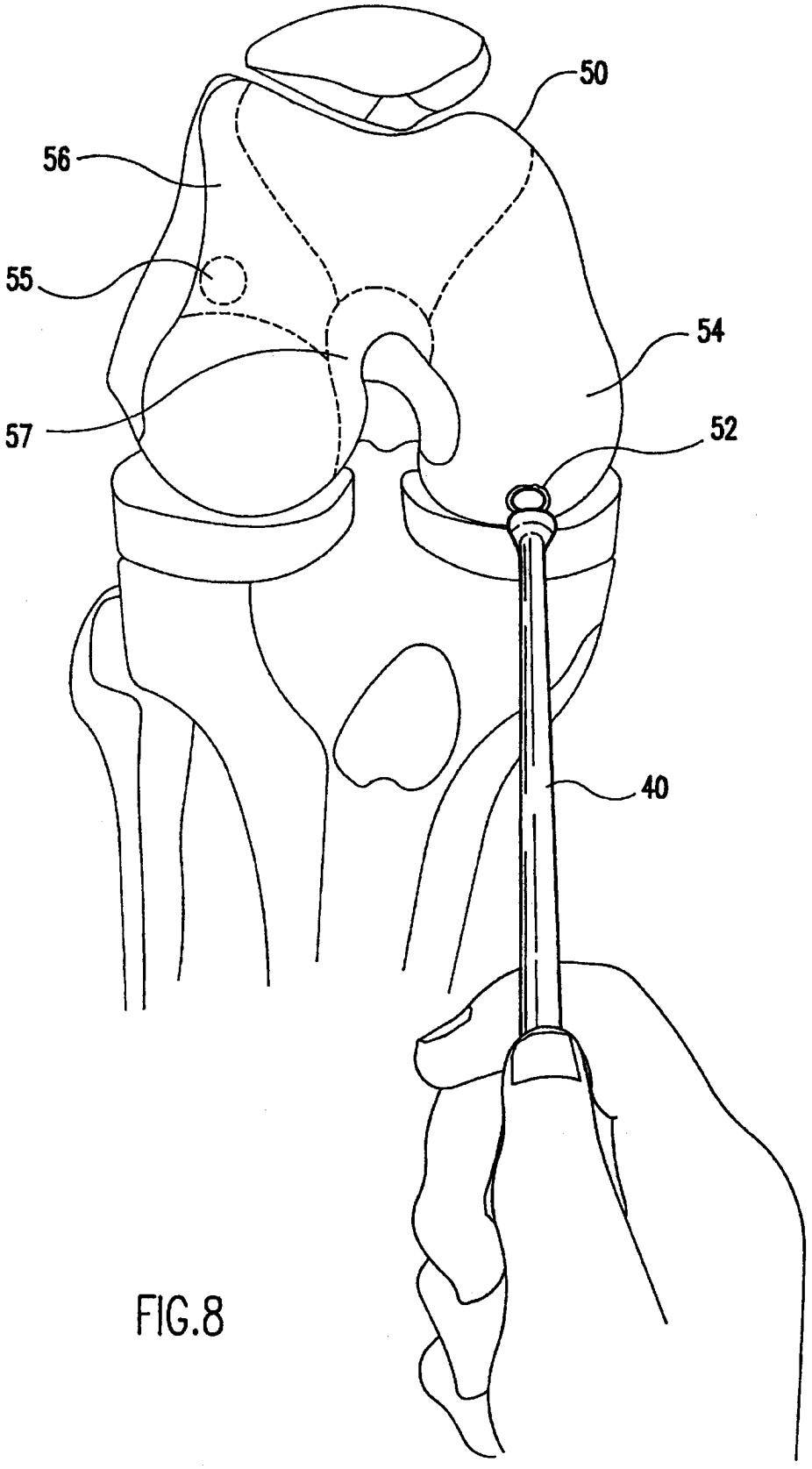


FIG.8

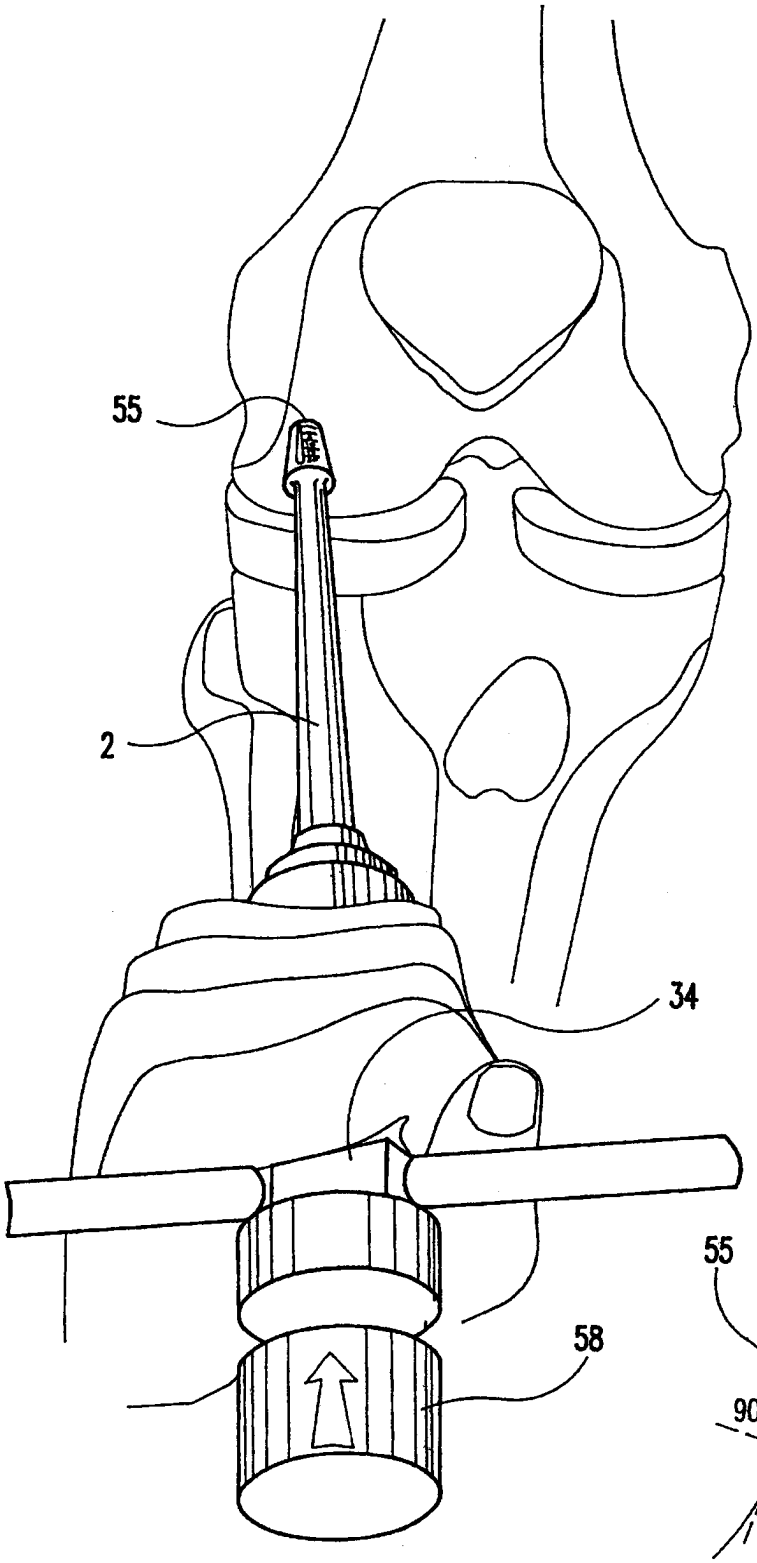


FIG.9

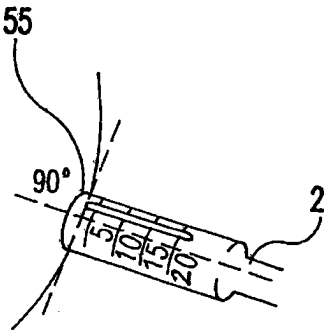


FIG.10

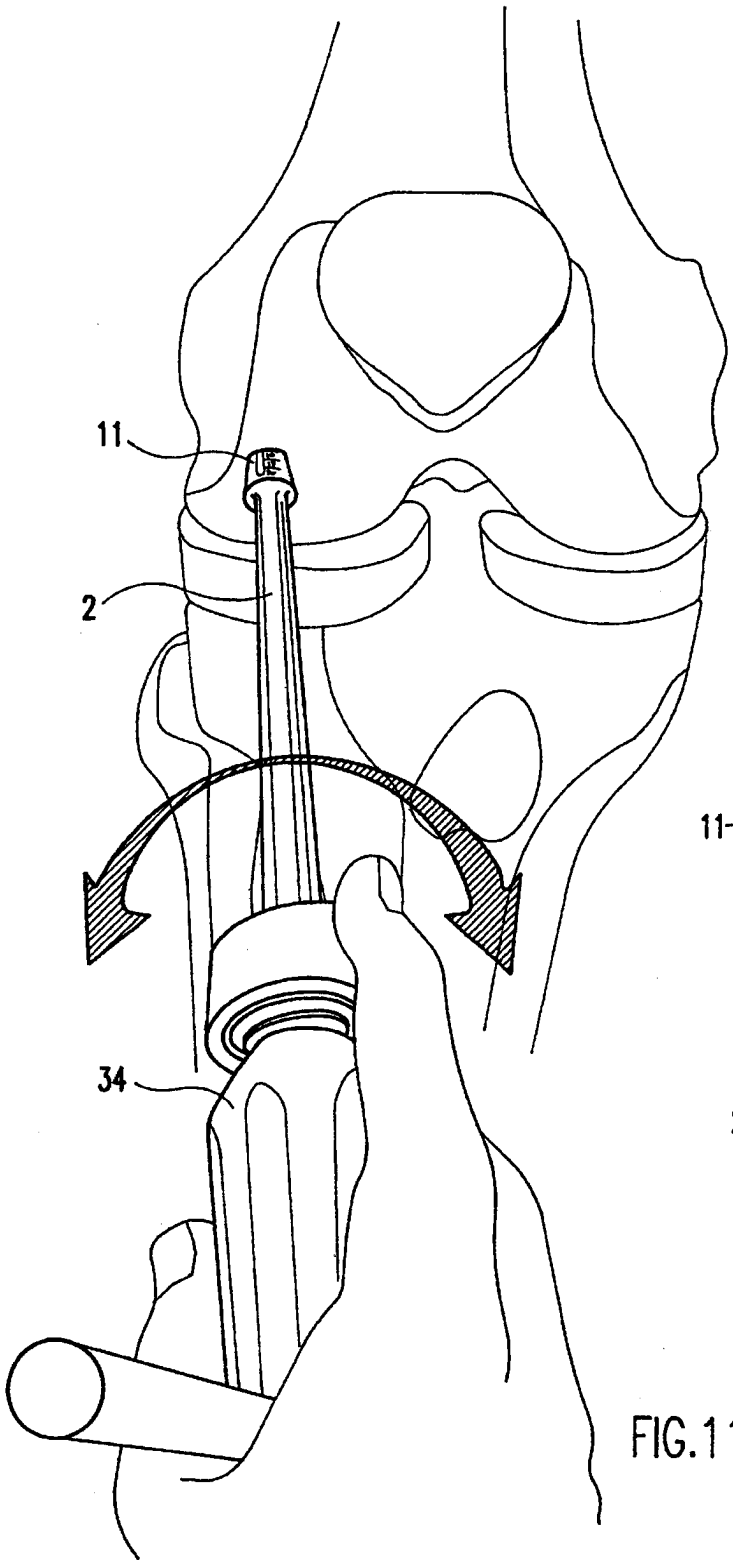


FIG.11

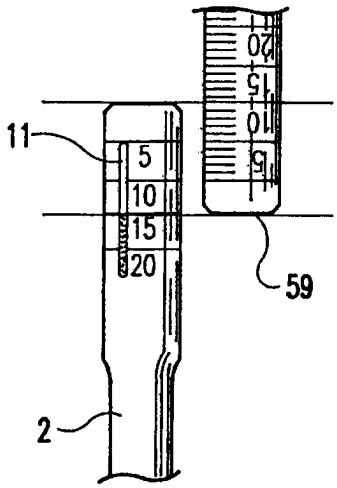


FIG.12

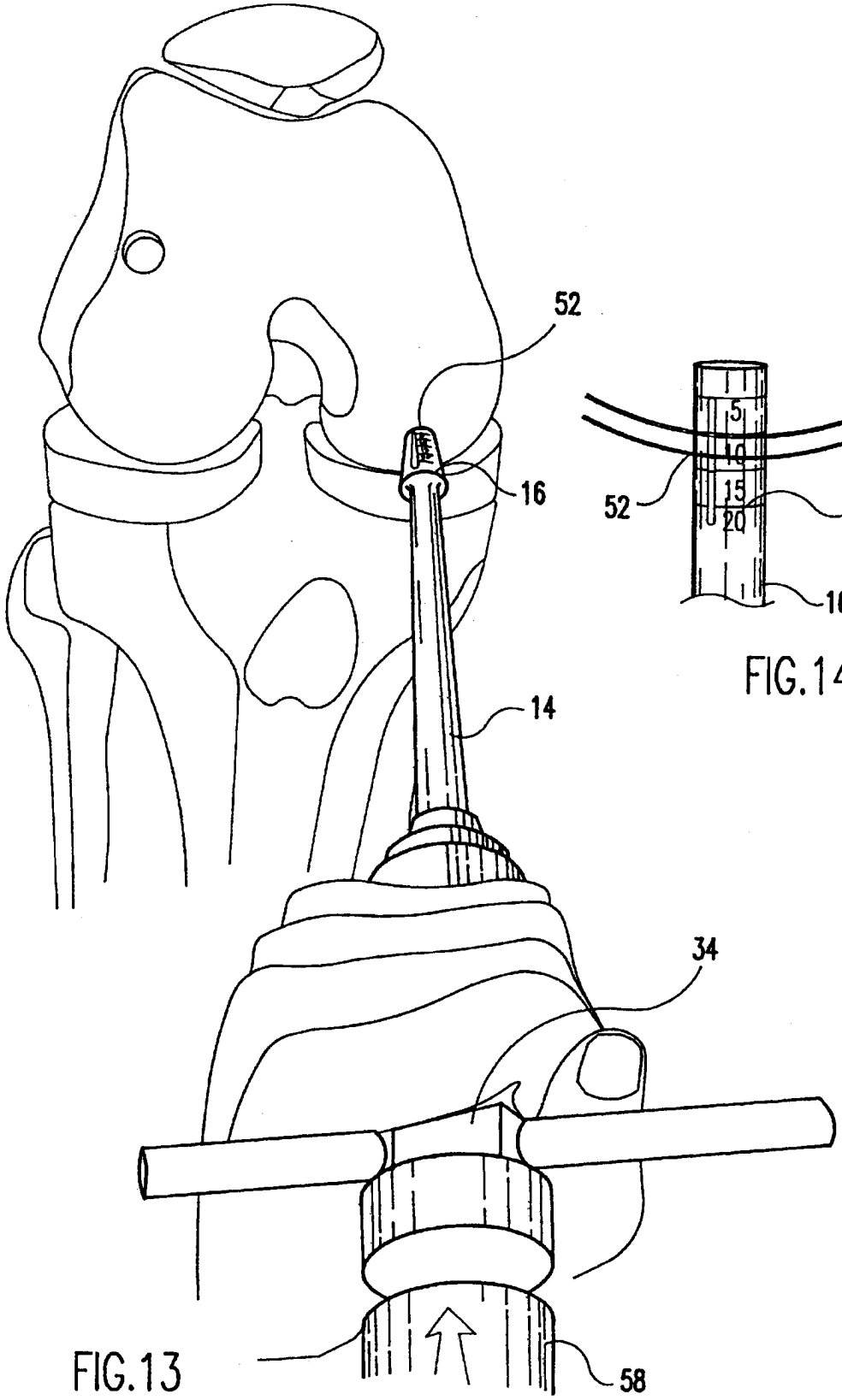


FIG.13

FIG.14

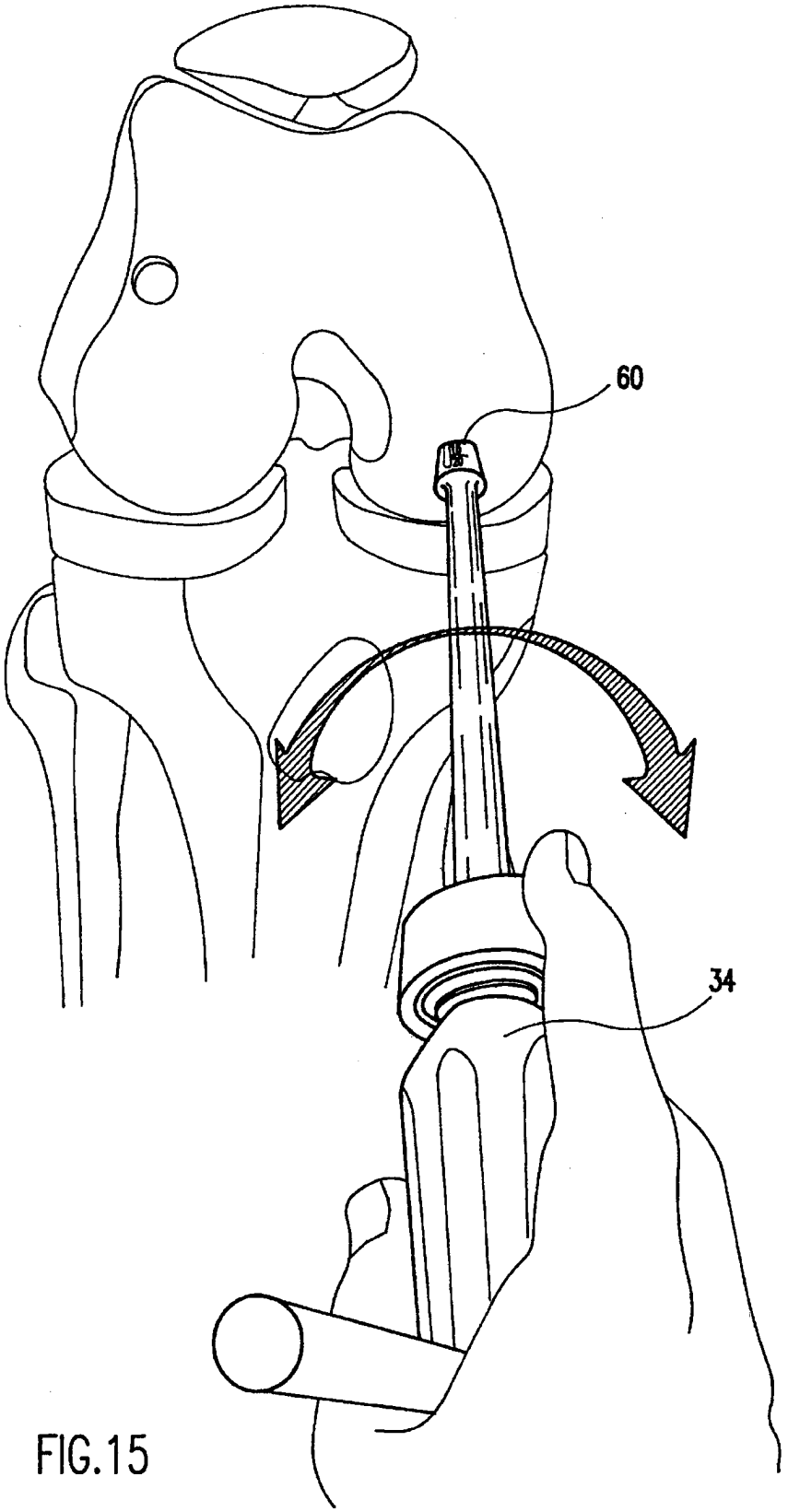


FIG.15

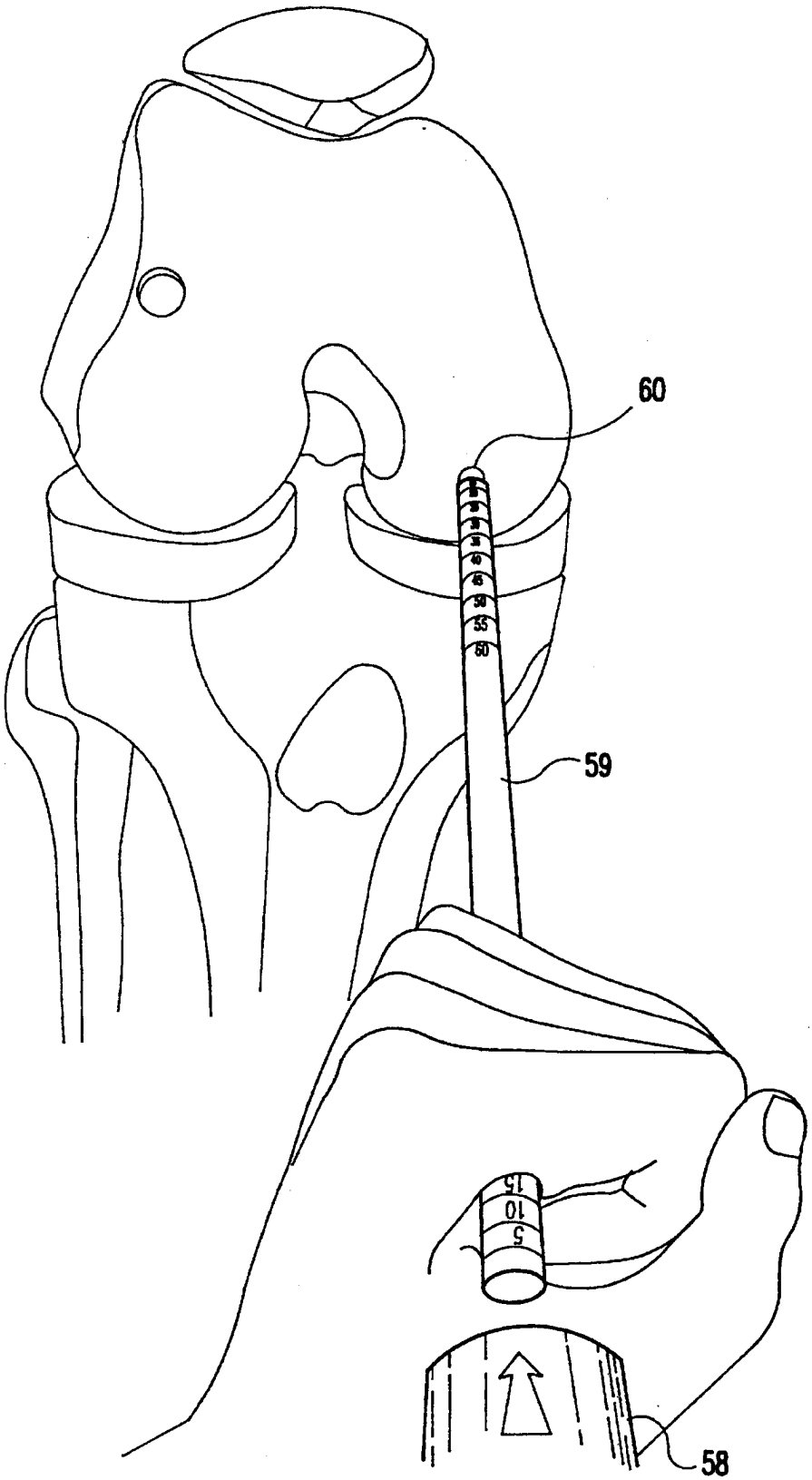


FIG.16

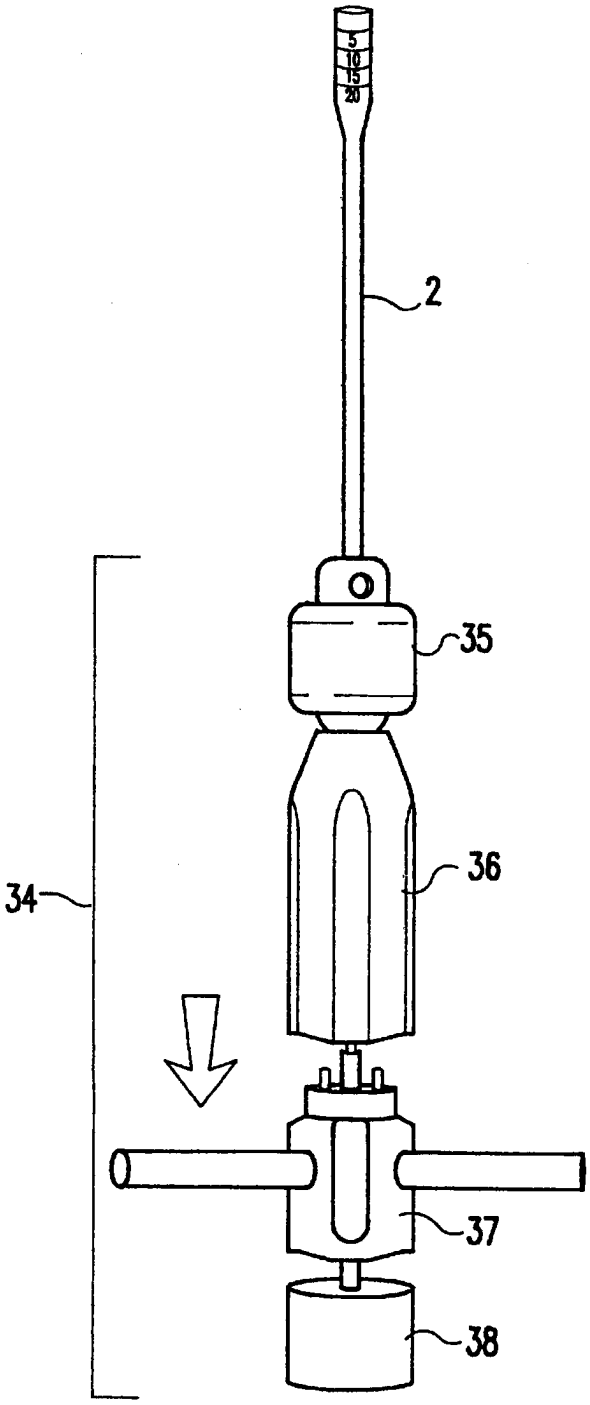


FIG.17

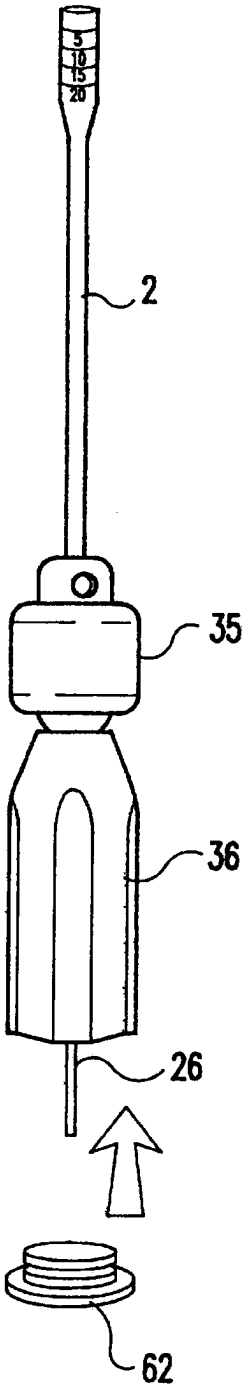


FIG.18

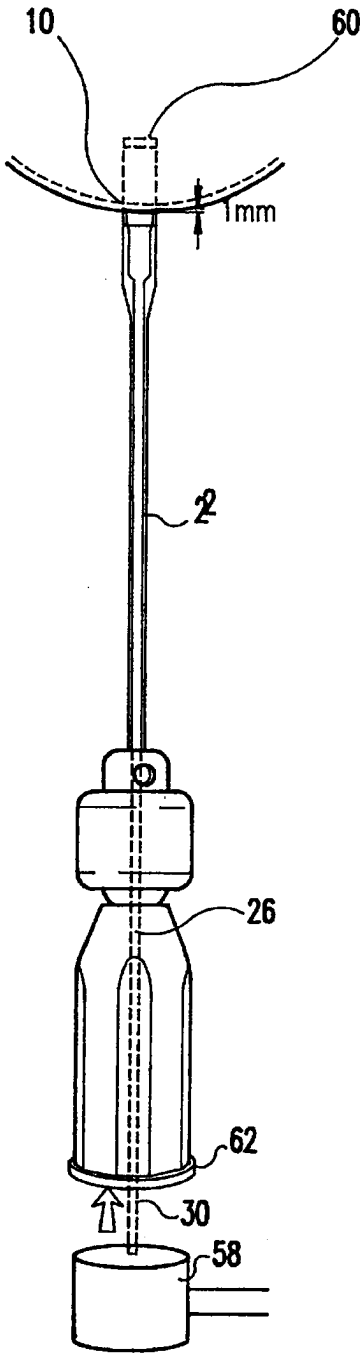


FIG.19

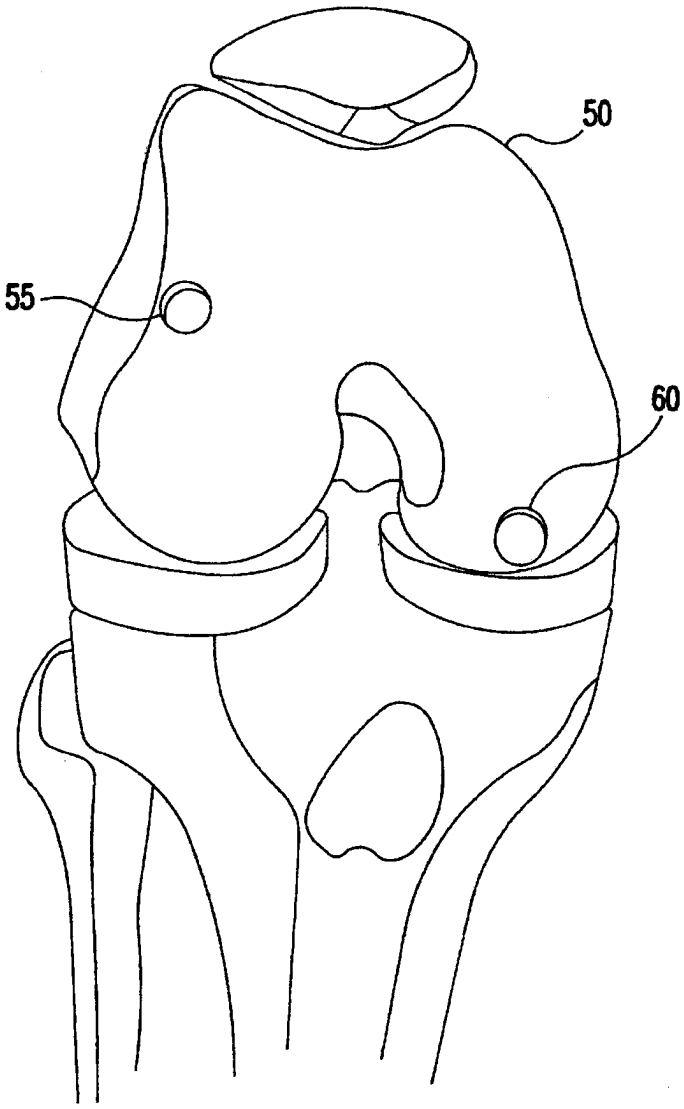


FIG.20

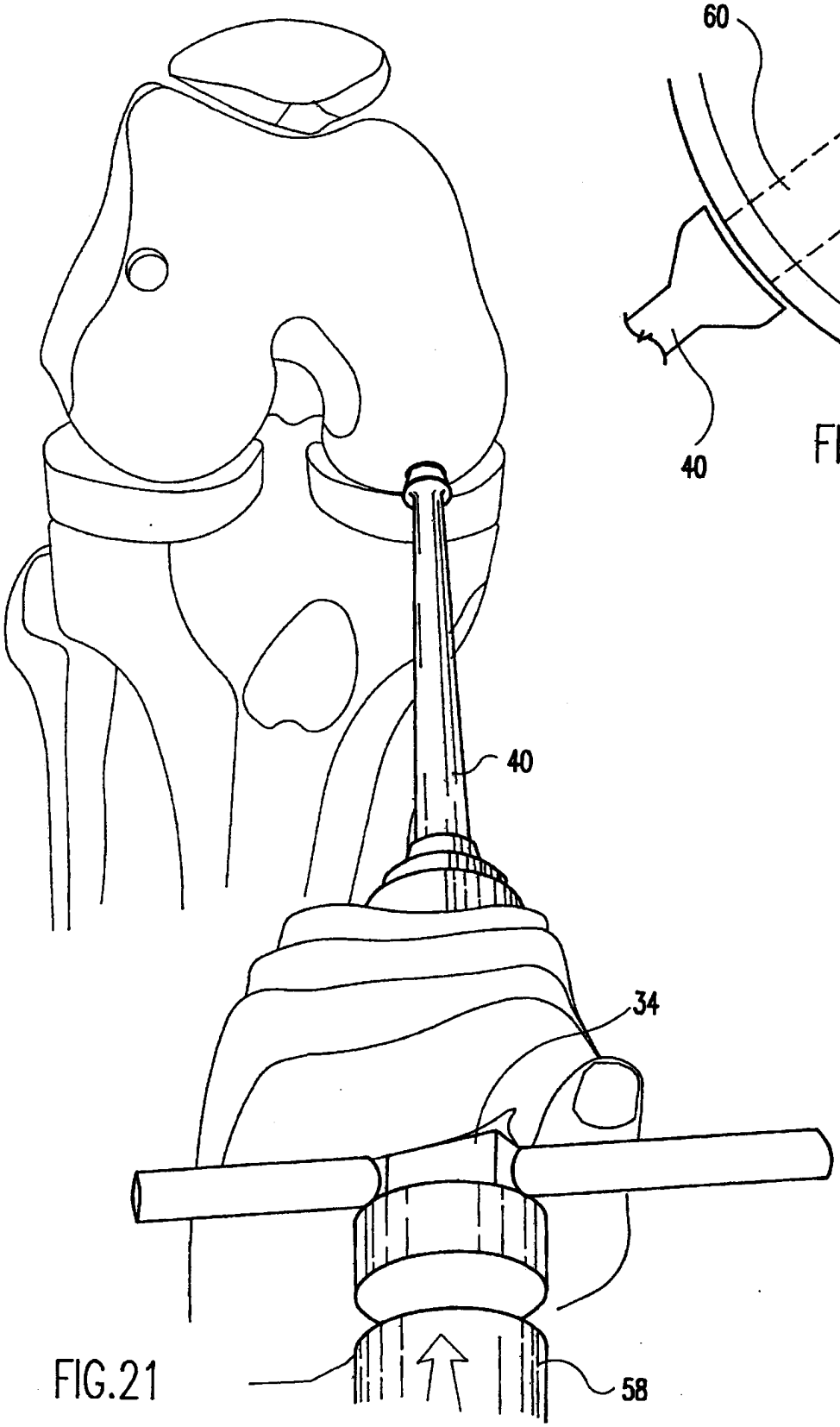


FIG.21

FIG.22

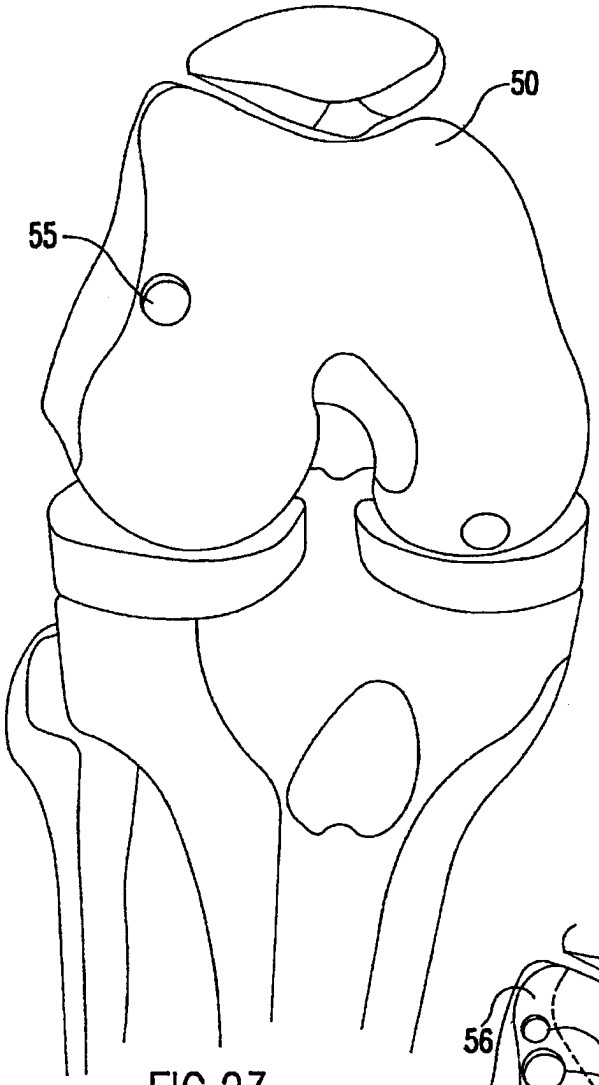


FIG.23

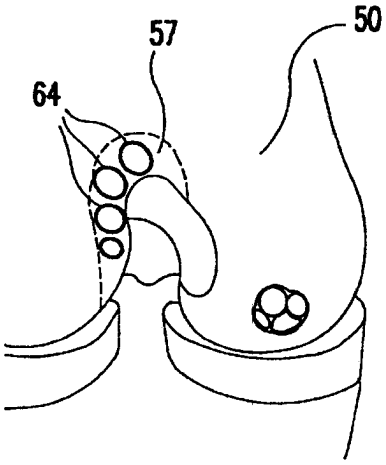


FIG.24

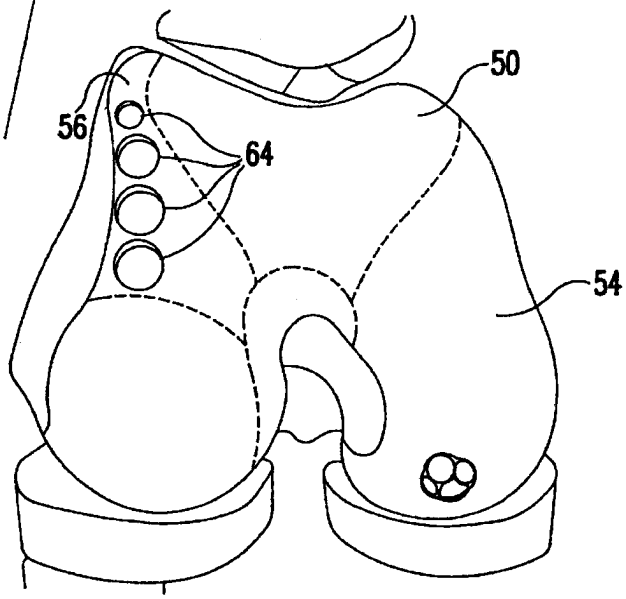


FIG.25

METHOD AND APPARATUS FOR OSTEOCHONDRAL AUTOGRAFT TRANSPLANTATION

This application is a continuation-in-part of application Ser. No. 08/801,635, filed Feb. 18, 1997, now 5,785,714 which is a continuation of application Ser. No. 08/389,492, filed Feb. 16, 1995 now U.S. Pat. No. 5,603,716, the disclosures of which are incorporated by reference herein. This application also claims the benefit of U.S. provisional application Serial No. 60/024,045, filed Aug. 16, 1996.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to the surgical treatment of chondral defects and, more specifically, to a method and apparatus for autogenous transplantation of articular cartilage/bone cores in knees having chronic anterior cruciate ligament (ACL) deficiency, or isolated articular defects.

2. Description of the Related Art

Chronic ACL deficiency can result in a wide range of chondral damage, varying from superficial blemishes and fissures, to large, full-thickness defects. These lesions may also occur as isolated pathology in cruciate normal knees.

Chondral defects of the femoral condyles are widely recognized indications which comprise approximately 5% of all knees undergoing arthroscopy. Treatment, however, is difficult and controversial. In earlier known methods, meniscal pathology was treated, and the ACL was reconstructed, but the chondral lesion usually was left untreated. This approach leads to lesion enlargement and ultimately an advancing arthritic condition.

A protocol of arthroscopic osteochondral autograft transplantation for repairing chondral defects has been developed and tested in knees having chronic ACL deficiency by Vladimir Bobić, as reported in Arthroscopic Osteochondral Autograft Transplantation In ACL Reconstruction: A preliminary clinical study; Knee Surgery, Sports Traumatology Arthroscopy (1996), incorporated herein by reference.

The transplantation procedure, which is intended to prevent further joint degeneration and possible development of osteoarthrosis, involves selecting donor sites for osteochondral cores, capped with intact cartilage, prior to notchplasty. Donor sites are selected along the anterolateral and superior aspect of the notchplasty area, or on the superolateral and anterolateral aspect of the lateral femoral condyle in the non-weightbearing area above the sulcus terminalis. At the donor sites, multiple osteochondral cores 5 mm to 9 mm in diameter and 10 to 15 mm long, are harvested using tubular cutting instruments.

Recipient repair sites typically are located on the weight-bearing area of the medial and lateral femoral condyles. Full-thickness chondral defects, typically larger than 10 mm in diameter, and up to 20 mm, are selected for treatment. Recipient sockets at the repair sites are prepared, and the donor cores are transferred and press-fitted into the recipient sockets.

The transplantation procedure described above has various difficulties associated with it. For example, removing the osteochondral cores from the tubular cutting instruments is difficult. In addition, improvements are needed in the formation of the donor cores and recipient sockets, especially to facilitate depth control during harvest as well as transplant insertion. In general, improvements are required in the instrumentation and techniques available to perform the transfer procedure.

SUMMARY OF THE INVENTION

The present invention overcomes the deficiencies in the prior art by providing surgical instruments and protocols for performing osteochondral transplant procedures using a series of thin-walled (0.5 mm) cutting tubes. Osteochondral cores, made up of hyaline cartilage capping subchondral bone, are harvested, preferably autogenously. The osteochondral cores, preferably 10 to 15 mm in length, are transplanted into sockets created in the defect to accept the transplanted core, or multiple cores, in a press-fit manner. The technique of the present invention may be carried out as either an open procedure or arthroscopically. Determinations regarding the protocol used will be based, for example, on the location, geometry, and extent of the chondral defect and the harvest sites.

The instrumentation of the present invention includes a series of core harvesters. The harvester of the present invention preferably includes a hollow tube having a distal cutting edge and a cannulated handle attached proximally. Within each core harvester, a collared pin is disposed slidably to facilitate removal of the harvested osteochondral core. The collared pin acts as a plunger to urge the harvested core from the lumen of the core harvester tube.

Preferably, two types of harvesters are provided: a donor harvester for obtaining donor osteochondral cores, and a recipient site harvester for forming recipient sockets at repair sites. Advantageously, the inner diameter of the donor harvester is equal to the outer diameter of the recipient site harvester. The outer diameters differ by 1 mm to accommodate the 0.5 mm wall thickness. The thin walls minimize bone and tissue damage.

The harvesters are provided in a range of sizes. To assist in harvesting to the proper depth, markings are provided on the instruments. The markings preferably are located on the outer surface of the harvester tubes for direct visual alignment with the surface of the tissue being harvested. Slotted windows are provided through the side walls of the tube to allow visualization of the harvested osteochondral core within the lumen of the harvester tube, allowing for visual confirmation of core length and surface geometry, for example, and for visual confirmation of depth during insertion.

The two types of bone harvesters can be distinguished by the formation of the sharp, distal cutting edge. On the donor graft harvesters, the distal cutting edge preferably is formed as an inward bevel, such that the cutting edge is formed by a slanted surface that slopes distally and inward, toward the central axis, from the outer surface to the inner surface of the harvester tube wall. Accordingly, the acutely-angled cutting edge is formed at the junction between the outer, beveled surface and the inner surface of the harvester tube wall.

On the recipient site harvesters, the distal cutting edge preferably is formed with a bevel opposite to that of the donor graft harvester. That is, the cutting edge is formed by a slanted surface that slopes distally and outward from the central axis, from the inner surface to the outer surface of the harvester tube wall. Accordingly, the acutely-angled cutting edge is formed between the inner, beveled surface and the outer surface of the harvester tube wall.

The two harvesters cooperate for precise correspondence in size between the donor graft and the recipient site. Correct sizing avoids problems associated with an improper fit of the graft in the recipient site, including compression or insufficiency of the repair.

According to a preferred method, the donor harvester is inserted into a tube harvester driver/extractor and placed

over the selected hyaline cartilage harvest site. The donor harvester is placed flush with the articular cartilage surface and impacted, using a mallet for example, to a selected depth of approximately 10 to 15 mm. After complete insertion to the selected depth, the driver/extractor is twisted and gently rocked to fracture the cancellous base for removal of the osteochondral core.

A recipient site is prepared with a recipient site harvester using a similar method. Alternatively, recipient sockets can be formed using various techniques, such as by drilling. The donor core preferably is pressed into the recipient site directly from the donor harvester.

Prior to insertion, size correlation between the donor core and the recipient site is provided by using a graft sizer and an alignment stick. The depth of the recipient site is determined using the alignment stick. If the graft osteochondral core is too long, adjustment of the core length or the length of the recipient site can be effected accordingly.

Using the driver/extractor, the donor osteochondral core is advanced with the collared pin so that the distal end of the core is flush with the end of the cutting edge of the harvester tube. As a manual aid to insertion depth control, the collared pin is sized so that the proximal end comes flush with the proximal end of the harvester handle when the distal end of the collared pin is 1 mm recessed from the cutting edge of the cutting end of the bone harvester. Accordingly, nearly-flush, anatomical insertion of the cartilage/bone core can be obtained without direct visual observation, and over-insertion is avoided.

After insertion, the osteochondral core insert is brought flush anatomically using a sizer/tamp. The graft is pressed with the sizer/tamp such that the surface of the graft comes into flush alignment with the normal articular cartilage surrounding the recipient repair site.

Although the instruments and techniques are described herein in connection with a specific autograft application in the ACL-deficient knee, they can be applied to ACL-normal knees, for treatment of joints other than the knee, and for xenogenous procedures. In addition, indications for the instrumentation and techniques of the invention can be extended to include other treatments, such as, for example, osteochondritis dissecans, allograft transplantation, bone grafting, graft fixation, and focused bone core biopsy.

Other features and advantages of the present invention will become apparent when the following description is read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a partial side view of a donor graft harvester according to the present invention.

FIG. **2** is a cut-away side view of the donor graft harvester of FIG. **1**.

FIG. **3** is a partial side view of a recipient site harvester according to the present invention.

FIG. **4** is a cut-away side view of the recipient site harvester of FIG. **3**.

FIG. **5** is a side view of a collared pin according to the present invention.

FIG. **6** is a cut-away side view of a driver/extractor handle according to the present invention.

FIG. **7** is a side view of a graft sizer/tamp according to the present invention.

FIG. **8** illustrates chondral defect size determination and surgical planning according to the present invention.

FIG. **9** illustrates donor harvester tube impaction according to the present invention.

FIG. **10** illustrates proper alignment of the donor harvester tube according to the present invention.

FIG. **11** illustrates donor core harvesting according to the present invention.

FIGS. **12** illustrates bone core sizing according to the present invention.

FIG. **13** illustrates recipient socket harvester impaction according to the present invention.

FIG. **14** illustrates recipient socket depth control according to the present invention.

FIG. **15** illustrates recipient socket core extraction according to the present invention.

FIG. **16** illustrates recipient socket sizing and preparation according to the present invention.

FIG. **17** illustrates assembly preparation of the driver/extractor of the present invention.

FIG. **18** illustrates preparation of the driver/extractor and donor core harvester for insertion in the recipient site according to the present invention.

FIG. **19** illustrates donor core insertion according to the present invention.

FIG. **20** illustrates insertion of the donor core according to the present invention.

FIG. **21** illustrates final donor core seating according to the present invention.

FIG. **22** is a detailed closeup of the donor core seating step of FIG. **21**.

FIG. **23** illustrates a completed transplantation according to the present invention.

FIG. **24** illustrates multiple transfers according to the present invention.

FIG. **25** illustrates multiple transfers according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. **1** and **2**, a donor graft harvester **2** is shown. The donor graft harvester includes a hollow tube **4** attached to a cannulated handle **6**.

The graft harvester tube has a sharp cutting edge **8** formed on the distal end thereof. The sharp edge is formed by a beveled surface **10** sloping inward distally from the outer surface to the inner surface of tube **4**.

The donor harvester preferably is provided in a range of sizes. Accordingly, the inner diameters of hollow tubes **4** are, for example, 5, 6, 7, 8, and 9 millimeters. The walls of the harvester tubes are typically 0.5 millimeter thick. The thin walls minimize bone and tissue damage.

As shown in FIG. **1**, windows **11** and depth markings **12** are provided on the tube of the donor site harvester to assist the surgeon during insertion of the harvester into the bone at the donor site. A longitudinal marking line (not shown) provided at the tip of each harvester facilitates core alignment in the recipient socket.

Windows **11** allow for arthroscopic confirmation of donor bone plug extraction prior to complete removal of the donor harvester, as discussed below. In addition, windows **11** allow a comparison of overall core length between donor and recipient cores. Windows **11** also allow visual control of core insertion depth by calibrating the collar and tube laser marks. Also, windows **11** provide increased surface friction

between the tube and the osteochondral core to ensure core extraction, especially at lengths over 10 mm.

Referring to FIGS. **3** and **4**, a recipient site harvester **14** according to the present invention is shown. The recipient site harvester includes a hollow tube **16** attached to a cannulated handle **18**. The harvester has a sharp cutting edge **20** formed on the distal end of tube **16**. The sharp edge is formed by a beveled surface **22** sloping outward distally from the inner surface to the outer surface of tube **16**. See FIG. **4**.

The recipient site harvester also is provided in a range of sizes. Accordingly, the outer diameters of hollow tubes **16** are, for example, 5, 6, 7, 8, and 9 millimeters, in correspondence with the inner diameter of the associated donor graft harvester described above. As with the donor harvester, the walls of the recipient harvester tubes are thin, and windows **23** and depth markings **24** are provided on the tube, in a manner and for reasons similar to those described above with respect to donor harvester **2**.

Referring to FIG. **5**, a collared pin **26** according to the present invention is shown. Pin **26** is made up of a collar **28** disposed on a distal end of a handle **30**. The surface **32** at the distal end of collar **28** is smooth to prevent damage to the cartilaginous surface of the graft core.

Pin **26**, having a collar **28** of appropriate size approximating the inner diameter of the harvester, is received within handle **6** of the donor graft harvester, or handle **18** of the recipient site harvester, prior to insertion of the respective harvester into the selected harvesting or donation site. Accordingly, the proximal end of pin **28** is inserted through hollow tube **4**, **16**, respectively, such that the collar is disposed within the tube prior to harvesting cores at the donor graft or recipient sites.

The proximal end of the pin extends beyond the proximal end of the harvester to an extent at least equal to the length of the tube, such that the harvested core can be removed easily from the lumen of the harvester tube by urging the handle of the collared pin distally to advance the harvested core. In this respect, the harvesters of the present invention are similar to the coring reamer of co-owned U.S. Pat. No. 5,423,823, the disclosure of which is incorporated herein by reference, and the bone harvester disclosed in co-owned U.S. Pat. No. 5,603,716.

Referring to FIG. **6**, a tube harvester driver/extractor **34** according to the present invention is shown. Cannulated tube harvester driver/extractor **34** preferably is assembled of three sections including a chuck end **36**, a handle **37** and an impact end **38**. Chuck **35** at the distal end of driver/extractor **34** secures onto the proximal end of harvesters **2**, **14**, and is cannulated to receive the proximal end of pin **26**. Removable handle **37** is used to manipulate the driver/extractor assembly.

According to the inventive procedure, as described more fully below, impact end **38** is struck with a mallet to drive the harvester/driver assembly into the selected harvesting site. Upon removal of end **38** and handle **37**, the proximal end of pin **28** of collared pin **26** is exposed for removal of the harvested cores from the harvester tubes, also set forth more fully below. Alternatively, the entire driver/extractor can be removed from the harvester prior to transfer.

Referring to FIG. **7**, a graft sizer/tamp **40** is shown. Sizer/tamp **40** has a tamp head **42** disposed on a shaft **44**. Three flats **46** are formed on the proximal end so that sizer/tamp **40** can be chucked into driver/extractor **34**.

The method according to a preferred embodiment of the present invention will be described with reference to FIGS. **8** through **18**.

Referring to FIG. **8**, an anterior aspect of a right knee **50** is shown diagrammatically. A chondral defect **52** in femoral condyle **54** is inspected arthroscopically and the extent of the lesion assessed with sizer/tamp **40**. Tamp **40** has the appropriate 5, 6, 7, 8, or 9 mm diameter Delrin head, which correlates with the diameter of the cutting tube harvesters.

A tamp **40** of appropriate size also can be used to evaluate potential harvest donor sites, such as site **55**, in an area **56** along the outer edges of the non-articulating margin of the lateral femoral condyle above the sulcus terminalis or directly adjacent to the superolateral margin **57** of the intraarticular notch.

Surgical planning with respect to transferring single or multiple osteochondral cores, appropriate osteochondral core diameter, and whether to proceed with an arthroscopic versus an open procedure must be assessed prior to further surgical transplantation intervention. Selection and size of single or multiple core grafts should be based on harvest site accessibility and the convex/concave surface shape relationship of the available donor and recipient sites.

The appropriate, single-use tube harvester set of one-each donor harvester **2** and one-each recipient harvester **14** with respective collared pins **26** is selected based on defect and harvest site measurements. The donor tube harvester is selected to have an outer diameter 1 mm larger than the recipient tube harvester. The inner diameter of the donor tube is thus equal to the recipient outer tube diameter to assure a press fit fixation of the donor core in the recipient site. Tube harvester sets consist of 5 and 6 mm, 6 and 7 mm, 7 and 8 mm, 8 and 9 mm, or 9 and 10 mm sizes.

Referring to FIG. **9**, the donor tube harvester **2** of the appropriate diameter and labeled "DONOR" is inserted fully into the tube harvester driver/extractor **34** (see FIG. **6**) and placed over the hyaline cartilage harvest site **55**. Care must be taken to adjust the insertion and/or knee flexion angle so that the tube harvester end is flush with the articular cartilage prior to impaction. See FIG. **10**. The tube harvester is driven into subchondral bone with a mallet **58** to a depth of approximately 15 mm. Care should be taken not to rotate the harvester during insertion so as to avoid damaging the core to be harvested.

During an arthroscopic procedure, a slotted cannula (not shown) may be used to facilitate larger diameter tube harvester insertion into the joint. After insertion, the slotted cannula is pulled back along the tube harvester shaft and removed sideways through the slot to increase intraarticular visualization, tube harvester mobility, and fluid distension.

Referring to FIG. **11**, driver/extractor **34** is rotated, preferably about 90° clockwise, about 90° counter-clockwise, and then gently rocked, superior and inferior, to fracture the cancellous base for removal of the osteochondral core. Donor tube harvester **2** is then retrograded from the donor site with the harvested core captured within the tube.

The harvested core can be visualized through windows **11** to verify that the core has been captured successfully within the harvester. If rotation and extraction of the tube harvester should fail to capture the core for removal, reinsertion and further impaction of the tube harvester up to 20 mm with subsequent rotation and extraction steps may be indicated.

Once the donor core is removed, its length and hyaline cartilage thickness can be seen through the windows **11** in the harvester, as shown in FIG. **12**. Accurate measurements can be obtained using a calibrated alignment stick **59**, discussed further below. After extraction, the donor tube harvester **2** and the captured core are removed from the driver/extractor and placed in a secure, sterile holding area.

Referring to FIG. **13**, the appropriately-sized tube harvester **14** labeled "RECIPIENT" and collared pin **26** from the tube harvester set are inserted fully into the tube harvester driver/extractor **34**. If a single core transfer is indicated to replace the surface of the defect **52**, recipient tube harvester **14** is placed over the defect and driven into the subchondral bone with mallet **58**. Again, rotation of the recipient harvester is avoided during insertion of the harvester, as noted above with respect to insertion of the donor harvester. The preferred depth of about 13 mm. is determined with the tube harvester millimeter depth markings **24** on the outer surface of tube **16**, as shown in FIG. **14**.

Care should be taken to select the proper insertion angle and knee flexion to allow the tube harvester to sit flush to the chondral surface prior to impaction. If multiple core transplantation is desired, the tube harvester is placed over the appropriate quadrant in the defect.

Also, during socket creation, attention to maintaining the harvester at a 90° angle to the articular surface, in both the sagittal and coronal planes, is very important to obtain a flush transfer. See FIG. **14**.

If angled harvesting must be performed due to anatomical obstruction to 90° placement of tube harvester flush with hyaline cartilage, a longitudinal marking line (not shown) at the tip of each tube harvester should be rotated to align with the leading cutting edge into cartilage during donor core harvesting. Recipient harvesting should be performed at an angle as close as possible to the angle used during donor core harvesting. This facilitates close approximation of the angled hyaline cartilage donor surface with the surrounding cartilage of the angled recipient socket by aligning the longitudinal marking line and leading cutting edge of the donor tube against the recipient socket rim during donor core insertion.

Referring to FIG. **15**, after sufficient tube harvester depth is determined, the tube harvester driver/extractor **34** is rotated and gently rocked, as with the donor harvester above, to fracture the cancellous bone at the distal end of the tube. Extraction of the tube harvester and core can be facilitated by simultaneous counter rotation and extraction of the tube driver so as to form recipient socket **60**.

After extraction of the harvester and its captured osteochondral core, the lengths of the donor and recipient cores can be compared directly by placing the donor and recipient harvesters side by side. The harvested cores can be visualized through windows **11** and **23** in the donor and recipient harvesters, respectively. Adjustments to the length of the harvester autograft donor core can be made accordingly. Preferably, the distal end of the donor core is smoothed prior to insertion into the recipient site.

Referring to FIG. **16**, calibrated alignment stick **59** of an appropriate diameter can be used to measure the depth of recipient socket **60**. The alignment stick also can align correctly the angle of the recipient socket with respect to the position of an insertion portal when an arthroscopic approach is used. Advantageously, the alignment stick also can be used to fine tune the recipient socket length as desired to match the length of the donor core. Accordingly, alignment stick **59** is impacted with mallet **58** until the desired depth is achieved.

For insertion of the autograft core, the recipient tube harvester **14** is replaced with the 1 mm diameter-larger donor tube harvester **2** and collared pin with the captured autograft core. The donor tube harvester is inserted fully into the tube harvester driver/extractor **34**.

Referring to FIGS. **17** and **18**, after donor tube harvester **2** reinsertion into the driver/extractor **34**, the driver/extractor impaction cap **38** is unscrewed and the T-handled midsection **37** is removed. Accordingly, the proximal end of collared pin **26** is exposed, which is used to advance the core into the recipient socket **60**.

A stainless steel pin calibrator **62** is applied onto the open handle end for protection during further impaction, to maintain alignment of the collared pin, and to provide mechanical control of the bone core insertion. The pin calibrator preferably has an O-ring that press fits into the handle, and a small hole in the center that is threaded, so that the calibrator can be pulled out of the handle with a threaded retriever.

As shown in FIG. **19**, the distal end of donor harvester **2** is inserted into recipient site **60**. The beveled surface **10** helps to guide the harvester at the recipient site and assists in providing a secure fit and alignment of the donor harvester. A mallet is used to tap lightly onto the proximal end of handle **28** of collared pin **26** to drive the core into the recipient socket **60** while maintaining stable positioning of the harvester tube and knee flexion angle.

The core is advanced so that 1 mm of core remains proud, as shown in FIGS. **19** and **20**. Accordingly, the collared pin **26** is advanced until the end of the pin is flush with the pin calibrator **62**. The pre-determined length of the collared pin is designed to advance the bone core so that 1 mm of the graft will be exposed outside the recipient socket when the pin is driven flush with the end of the proximal face of the pin calibrator. Control of the core insertion also can be obtained by visualizing the core and collared pin advancement through windows **11** in the side of the harvester.

Advantageously, incomplete insertion of the core avoids driving the core too far, which could result in a counter-sunk cartilage surface, requiring further invasive steps to pull back the core so as to be flush to surrounding articular cartilage. Over-insertion also is prevented by proper recipient socket preparation using the alignment stick, as set forth above.

Referring next to FIG. **21**, sizer/tamp **40** is chucked into driver/harvester **34** for seating the core flush with the surrounding hyaline cartilage. According to one embodiment of the method of the present invention, the sizer/tamp diameter is at least 1 mm larger than the diameter of the core. As shown in FIG. **22**, the larger diameter tamp provides complete control of proper core insertion depth flush to surrounding articular cartilage and eliminates any potential of overdriving.

According to another embodiment of the inventive method, sizer/tamp **40** is the same as that used to determine the core size required, and is the same size as the osteochondral core. The tamp is used in an off-center position with respect to the core, so that the overhanging edge of the sizer/tamp encounters the surrounding cartilage area and prevents overinsertion of the bone core. The face of the core is seated flush with the surrounding cartilage surface, which is achieved by light tapping with the mallet **58**. The completed transfer is shown in FIG. **23**.

When multiple cores of various diameters are to be harvested and transferred into specific quadrants of the defect, each core transfer should be completed prior to proceeding with further recipient socket creation. See FIGS. **24** and **25**. This prevents potential recipient tunnel wall fracture and allows subsequent cores to be placed directly adjacent to previously inserted cores when desired.

Donor sockets **64** are routinely left open after harvesting and fill in with cancellous bone and fibrocartilage within 8 to 12 weeks. Alternatively, cancellous bone harvested from the defect may be inserted into donor sites, and should be

tamped firmly into the donor socket with a sizer/tamper or alignment stick to compress the cancellous bone for enhanced fixation.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. Therefore, the present invention is to be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A method of transplanting osteochondral cores in a joint having articular cartilage and subchondral bone, using a cutting tube having a distal end and a pin, the method comprising the steps of:

a. inserting the pin into the cutting tube to form a cutting tube and pin assembly;

b. introducing the cutting tube into the joint;

c. placing the distal end of the cutting tube and pin assembly prior to introducing the pin into the joint over a selected site in the joint; and

d. driving the distal end of the cutting tube into the subchondral bone to a predetermined depth to form an osteochondral core.

2. The method of claim 1, further comprising the step of removing the cutting tube from the joint with the osteochondral core.

3. The method of claim 2, wherein the osteochondral core has a cancellous base, the method further comprising the step of rotating the cutting tube having been driven to the specified depth to fracture the cancellous base.

4. The method of claim 2, further comprising the steps of:

forming a socket in the joint, the socket having an opening;

introducing the cutting tube with the osteochondral core into the joint;

positioning the distal end of the cutting tube at the opening of the socket; and

urging the pin distally so as to advance the osteochondral core into the socket.

5. The method of claim 4, wherein the step of forming socket in the joint is performed by removing a bone core.

6. The method of claim 4, further comprising the step of seating the osteochondral core so that a proximal surface of the osteochondral core is flush with the opening of the socket.

7. The method of claim 4, wherein the step of forming the socket comprises performing steps a through d of claim 1 using a cutting tube having an outer diameter equal to an outer diameter of the osteochondral core.

8. The method of claim 4, further comprising the step of measuring the socket with an alignment stick.

9. The method of claim 4, further comprising the step of shaping the socket with an alignment stick.

10. The method of claim 1, wherein the cutting tube is driven without rotation.

11. The method of claim 1, wherein the step of driving the cutting tube comprises impacting the cutting tube.

12. The method of claim 1, wherein the pin has a collar.

13. A method of transplanting osteochondral cores in a joint having articular cartilage and subchondral bone, using a cutting tube having a distal end and slotted windows, and a pin slidably disposed within the tube, the method comprising the steps of:

a) introducing the cutting tube into the joint;

b) placing the distal end of the cutting tube over a selected site in the joint;

c) driving the cutting tube into the subchondral bone to form an osteochondral core;

d) removing the cutting tube with the osteochondral core from the selected site;

e) visualizing the osteochondral core within the cutting tube; and

f) advancing the pin with respect to the cutting tube so as to urge the osteochondral core from the cutting tube.

14. The method of claim 13, wherein the cutting tube has an inner diameter, and the method further comprises the step of:

forming a socket at a recipient site using a recipient tube having an outer diameter equal to the inner diameter of the cutting tube; and

wherein, in the step of advancing the pin with respect to the cutting tube, the osteochondral core is urged from the cutting tube into the socket formed at the recipient site.

15. A method of transplanting osteochondral cores in a joint having articular cartilage and subchondral bone, using a tube having means for visualizing an osteochondral core contained within the tube, the method comprising the steps of:

a) introducing an osteochondral core into the tube;

b) introducing the tube to a socket formed at a recipient site within the joint;

c) urging the osteochondral core from the tube into the socket;

d) visualizing the osteochondral core within the tube by way of the visualization means; and

e) orienting the osteochondral core with respect to the socket at the recipient site.

16. The method of claim 15, wherein the step of introducing the osteochondral core into the tube comprises the step of:

cutting the osteochondral core from a donor site using the tube, the tube comprising a donor tube having an inner diameter; and

wherein the socket formed at the recipient site within the joint is formed using a recipient tube having an outer diameter equal to the inner diameter of the donor tube.

17. A method of transplanting osteochondral cores in a joint having articular cartilage and subchondral bone, using a tube having a distal end and a pin, the method comprising the steps of:

inserting the pin into the tube;

placing the distal end of the tube over a selected site in the joint;

introducing an osteochondral bone core into the tube;

removing the tube from the selected site with the bone core remaining within the tube;

positioning the distal end of the tube at an opening of a bone socket; and

urging the pin distally so as to advance the bone core into the bone socket.

18. The method of claim 17, wherein the pin has a collar.

19. The method of claim 17, wherein the bone socket is formed by cutting with a tube having an outer diameter equal to an outer diameter of the osteochondral core.

20. The method of claim 17, wherein the step of inserting the pin into the tube is performed prior to the step of introducing the osteochondral bone core into the tube.

* * * * *

B-10

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United States Patent [19]

Hart et al.

[11] Patent Number: 6,017,348

[45] Date of Patent: *Jan. 25, 2000

[54] APPARATUS AND METHODS FOR ARTICULAR CARTILAGE DEFECT REPAIR

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[73] Assignee: Innovasive Devices, Inc., Marlborough, Mass.

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: 08/866,830

[22] Filed: May 30, 1997

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/399,428, Mar. 7, 1995, Pat. No. 5,782,835.

[51] Int. Cl.[7] A61B 17/00

[52] U.S. Cl. 606/79; 606/179; 606/88

[58] Field of Search 606/80, 79, 96, 606/88, 86, 167, 179, 180, 184

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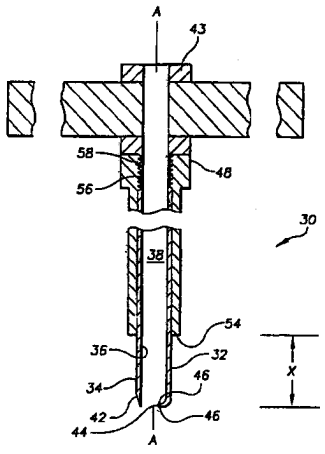
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Primary Examiner—Michael Buiz
Assistant Examiner—David O. Reip
Attorney, Agent, or Firm—Choate, Hall & Stewart

[57] ABSTRACT

A bone plug removal and emplacement tool includes a cylindrical cutting element having a proximal cutting edge and a cutting tooth. The outer surface of the cutting element can include an integral shoulder (e.g., in lieu of a replaceable outer sheath) that is spaced-apart from the proximal cutting edge and that engages the surface of the bone to define a depth stop for the cutting edge. An additional cylindrical element can be disposed within the cutting element. The proximal end of that additional element, which is referred to as a "harvester," is substantially aligned with the proximal end of the cutting element to receive a plug cut from the bone. The harvester can be slidably withdrawn from the cutting element to facilitate transplating the bone plug at another location. For this purpose, a stem or plunger can be slidably inserted and moved in the harvester to dislodge the plug.

24 Claims, 14 Drawing Sheets



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FIG. 1

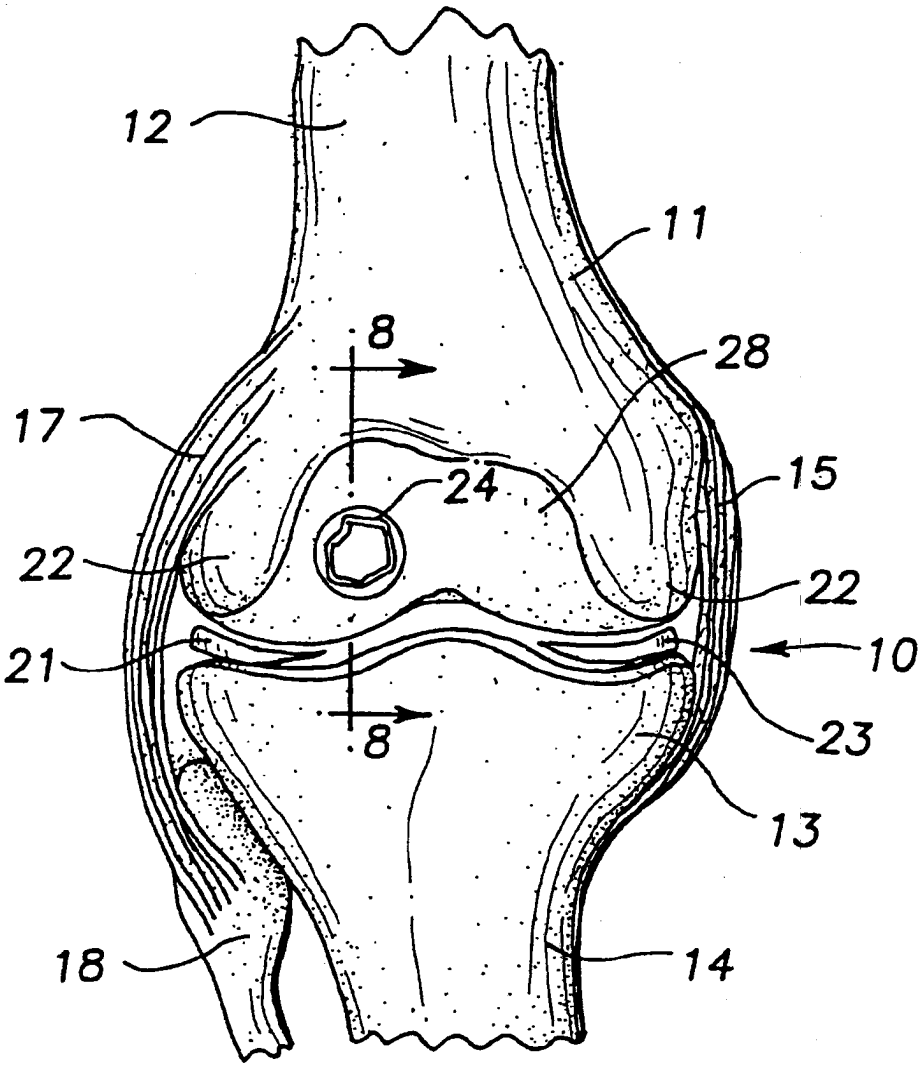


FIG. 2

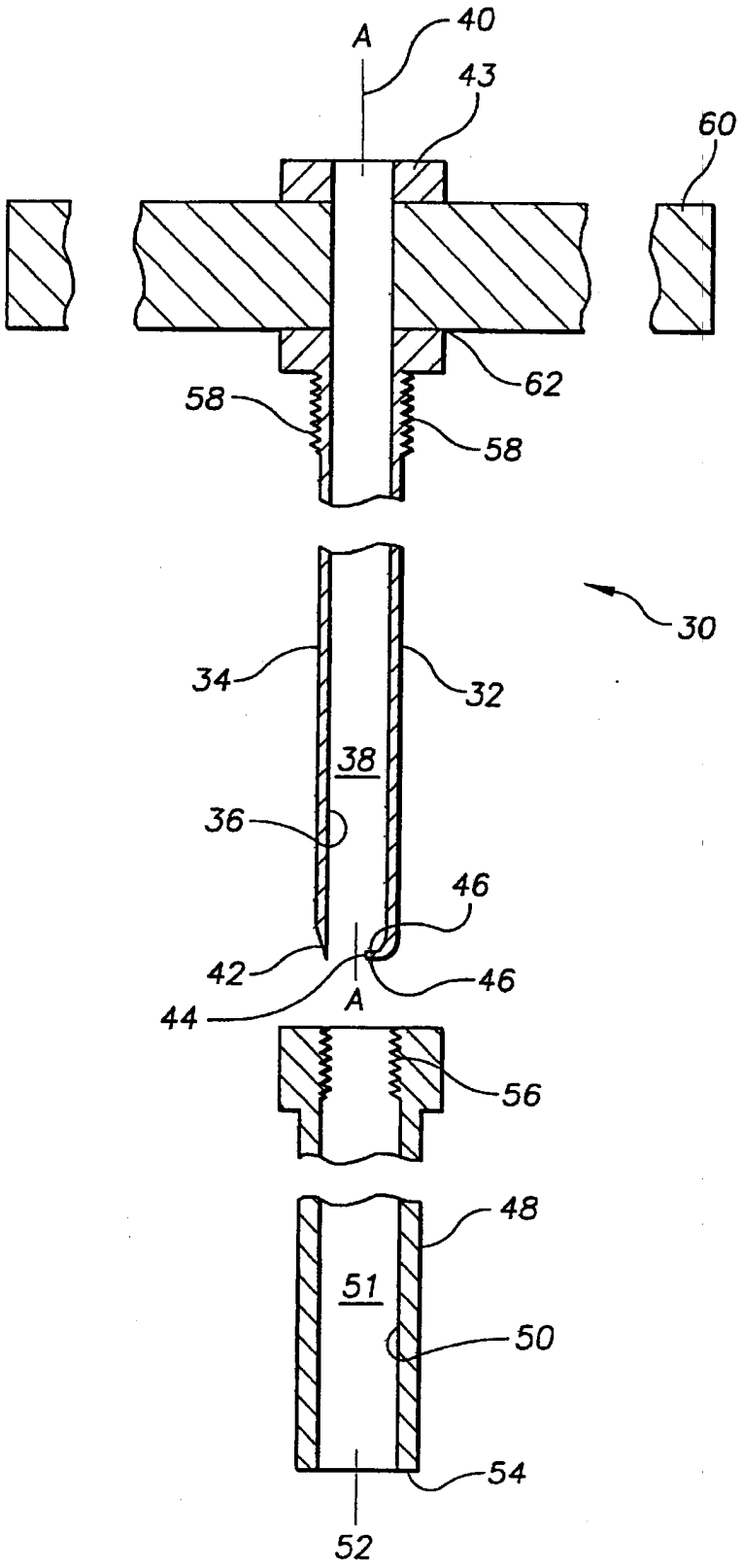


FIG. 3

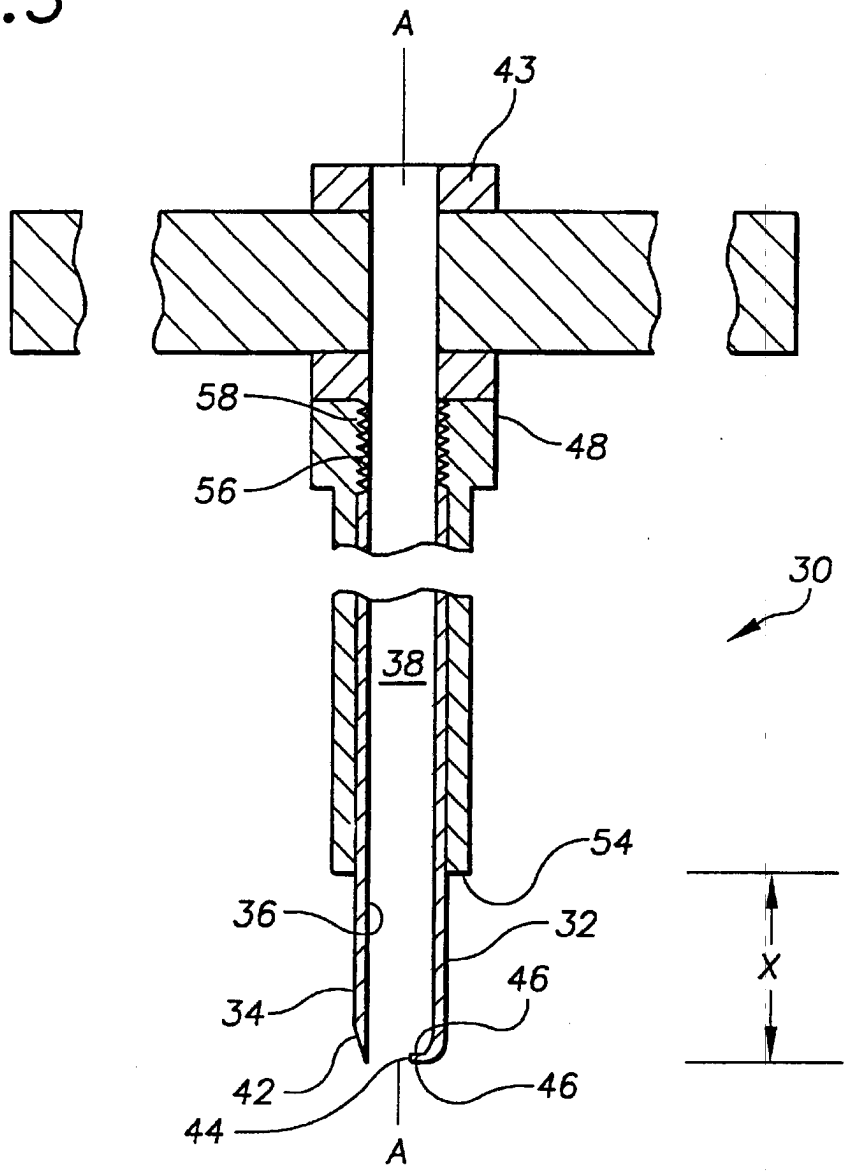


FIG. 4A

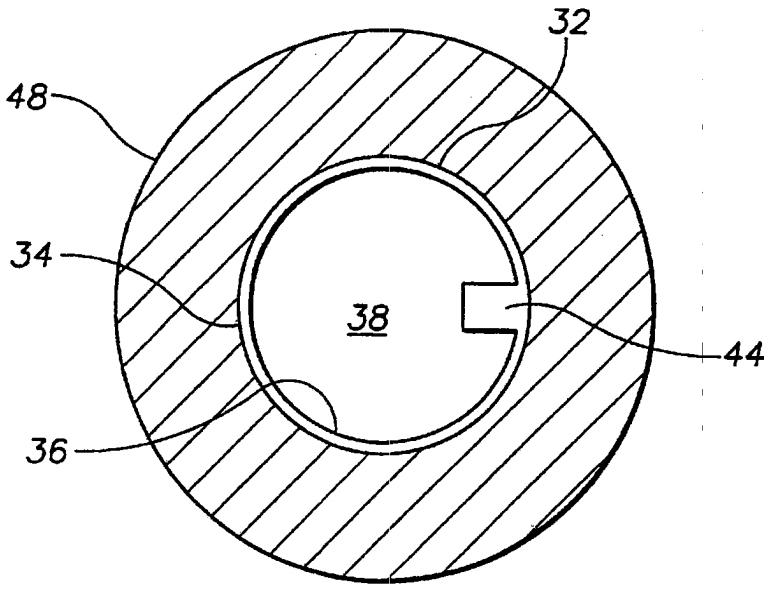


FIG. 4B

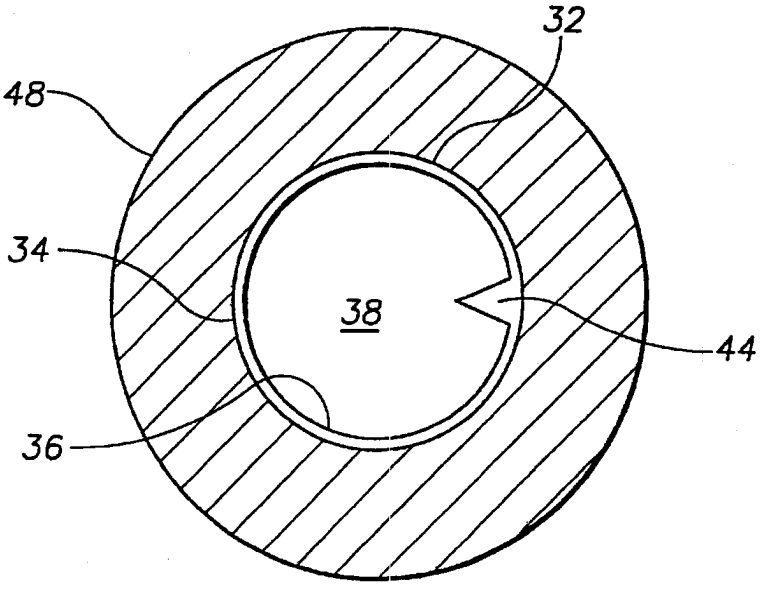


FIG.5

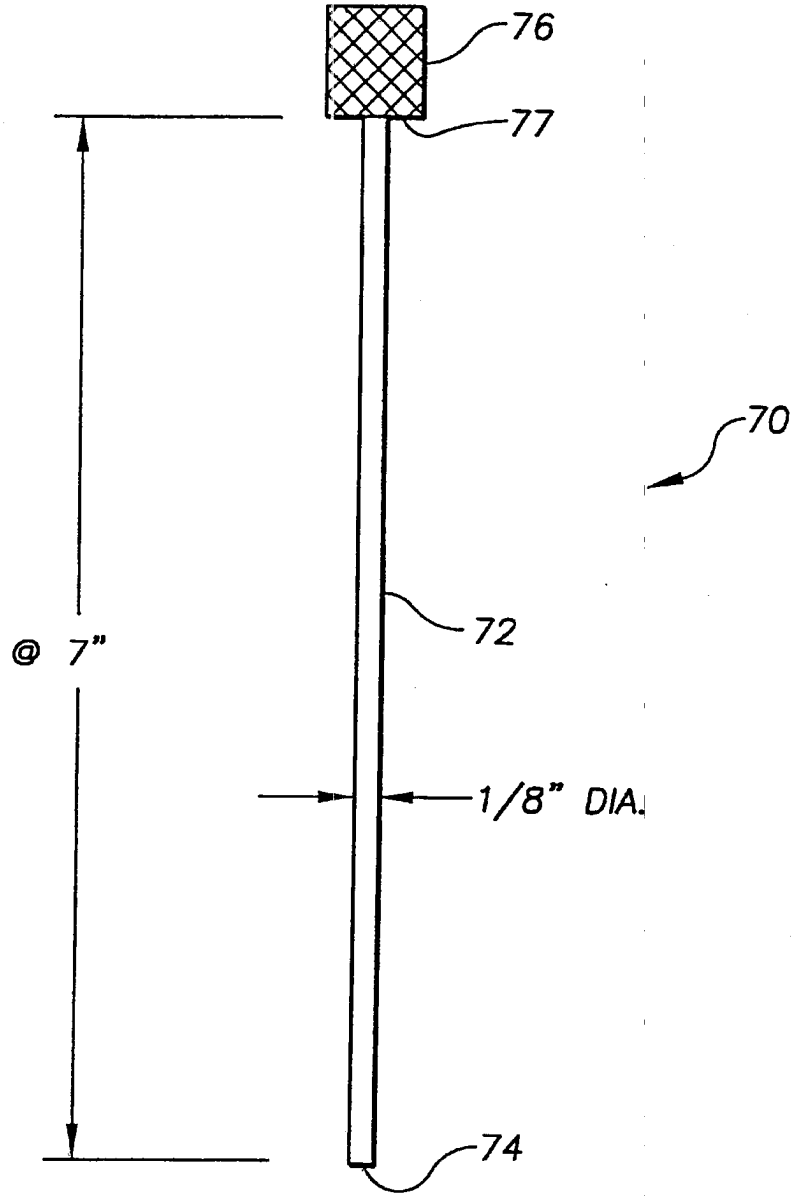


FIG. 6

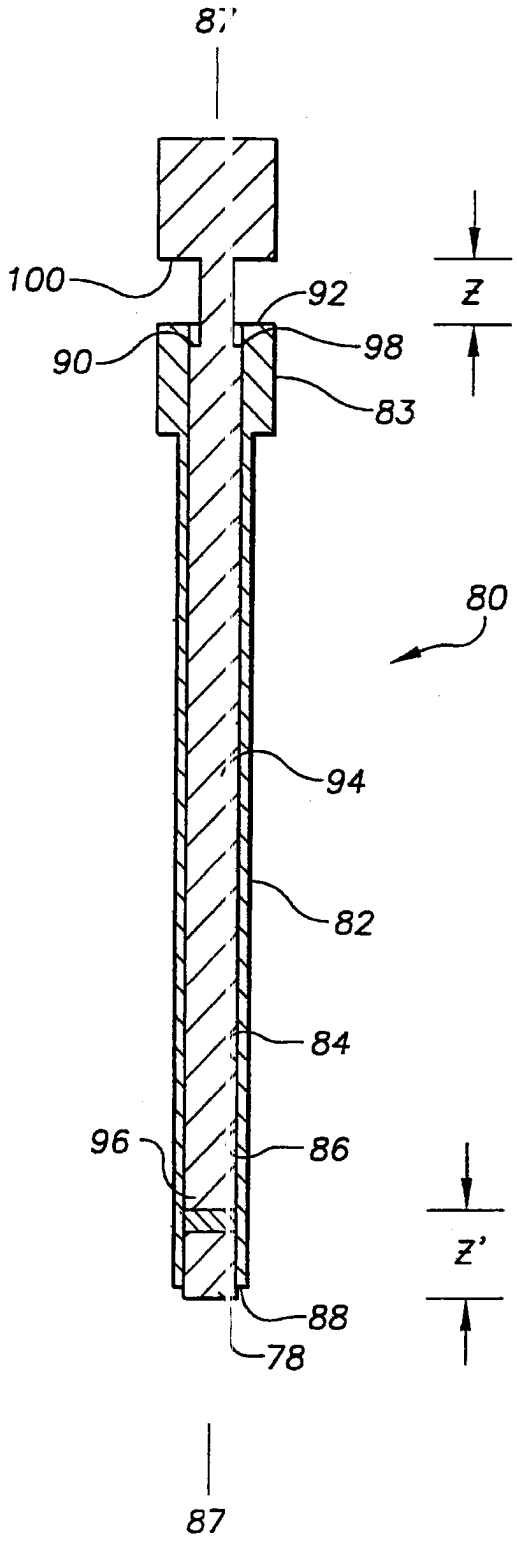


FIG. 7

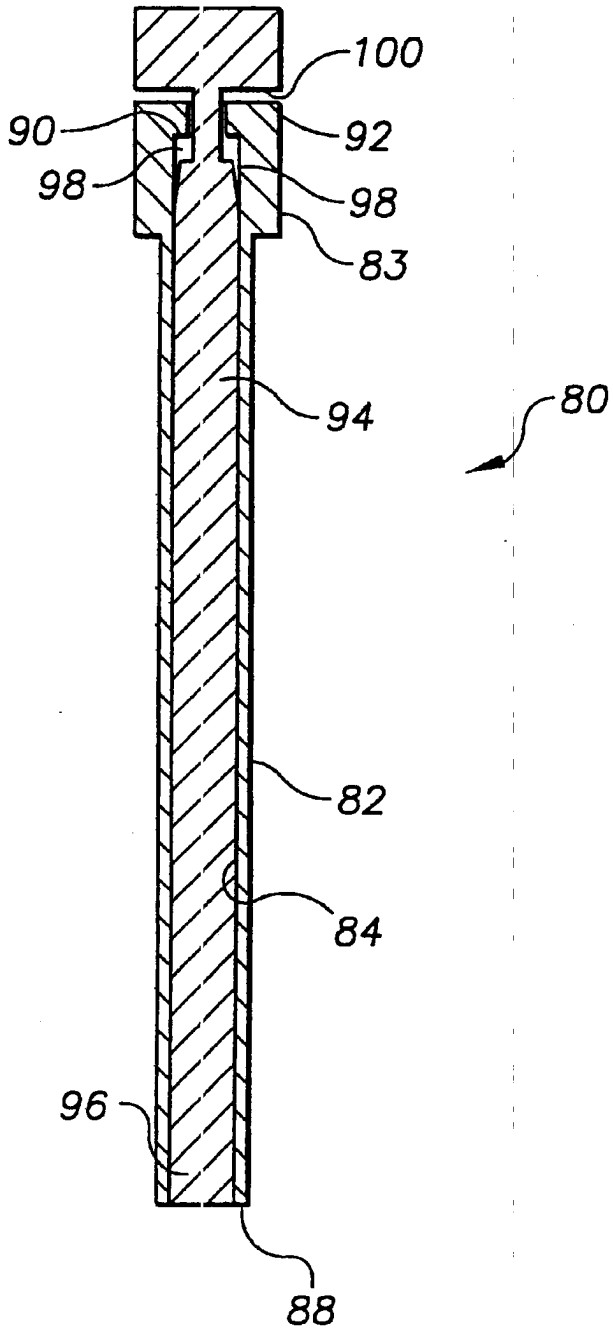


FIG.8A

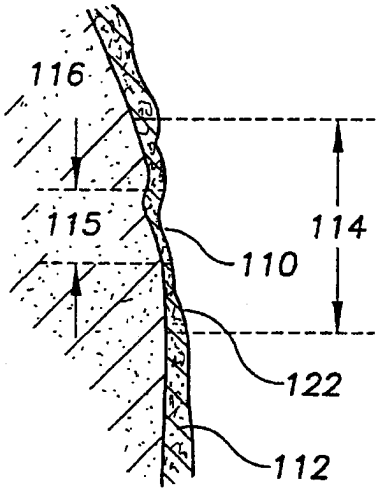


FIG.8B

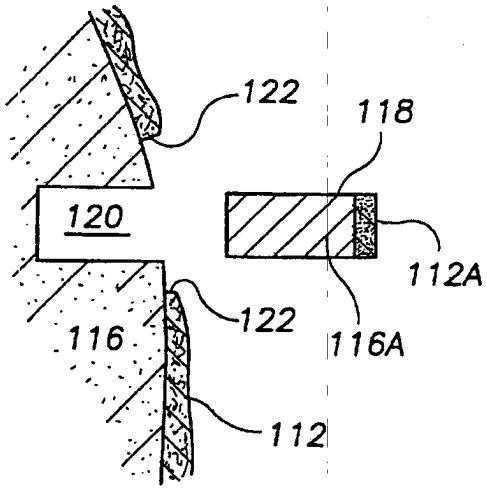


FIG.8C

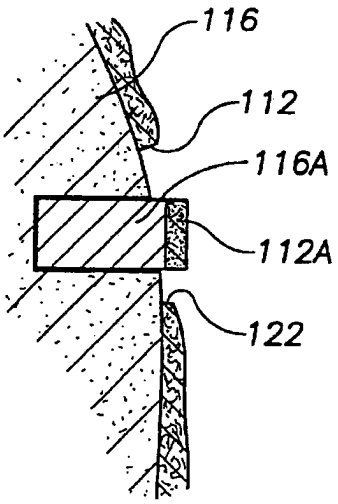


FIG.8D

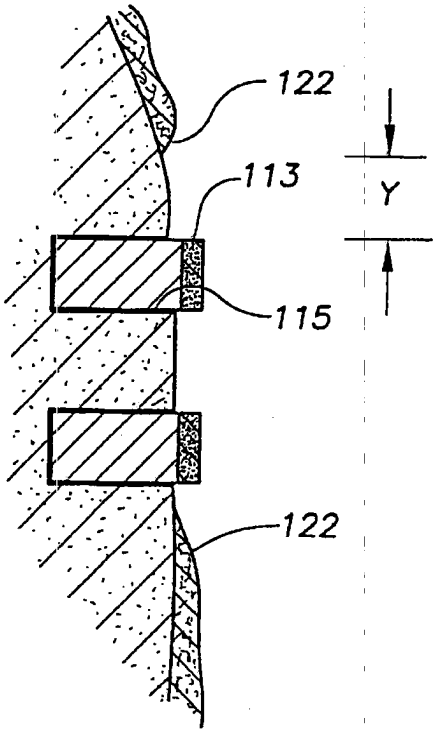


FIG. 9

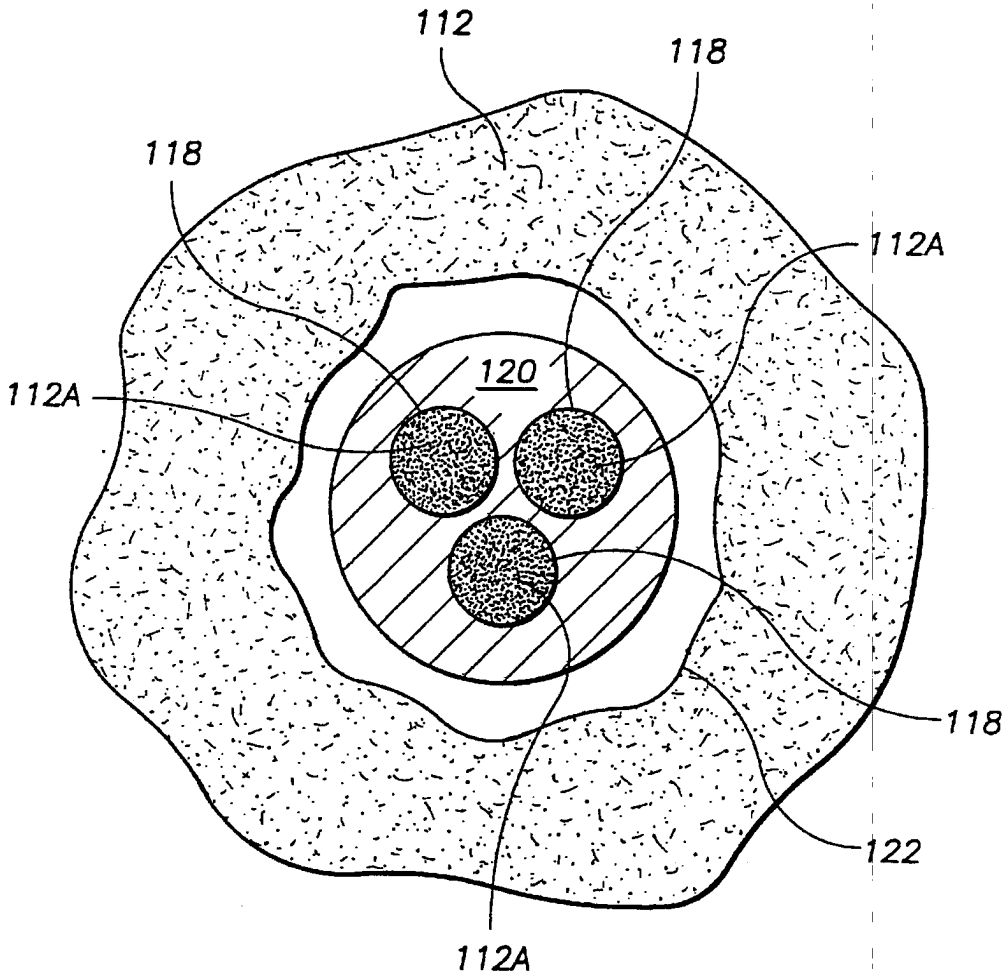


FIG. 10

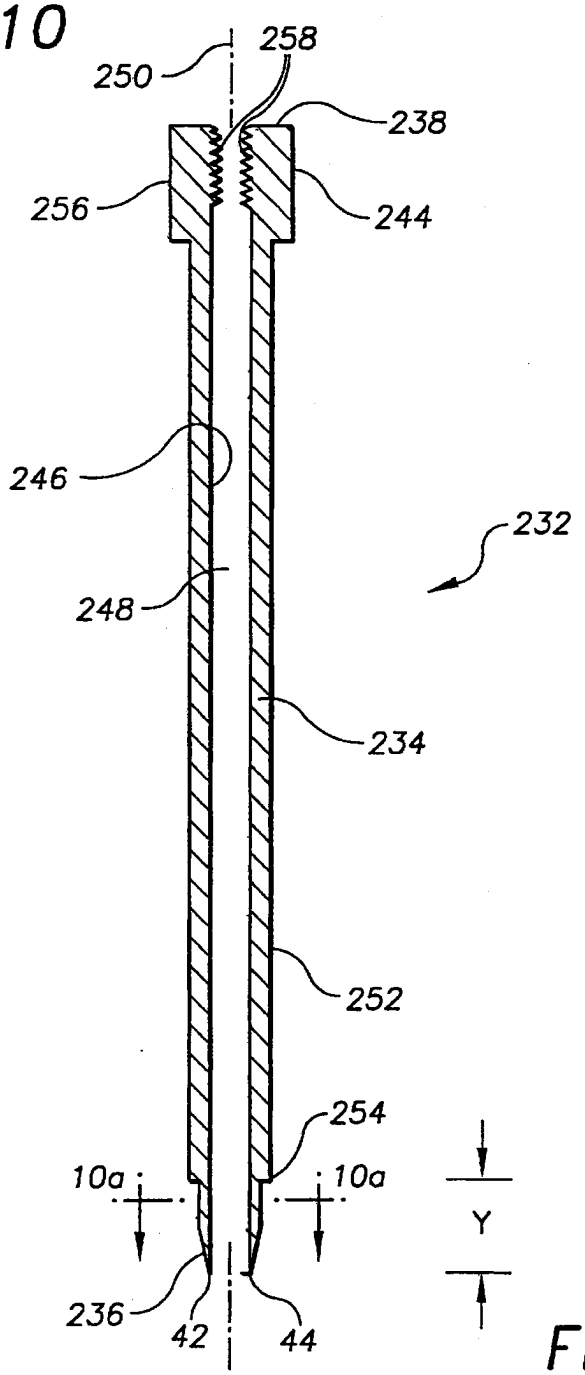


FIG. 10A

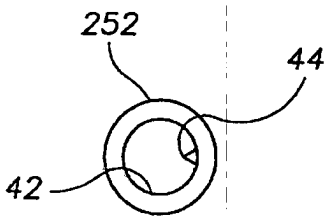


FIG. 11

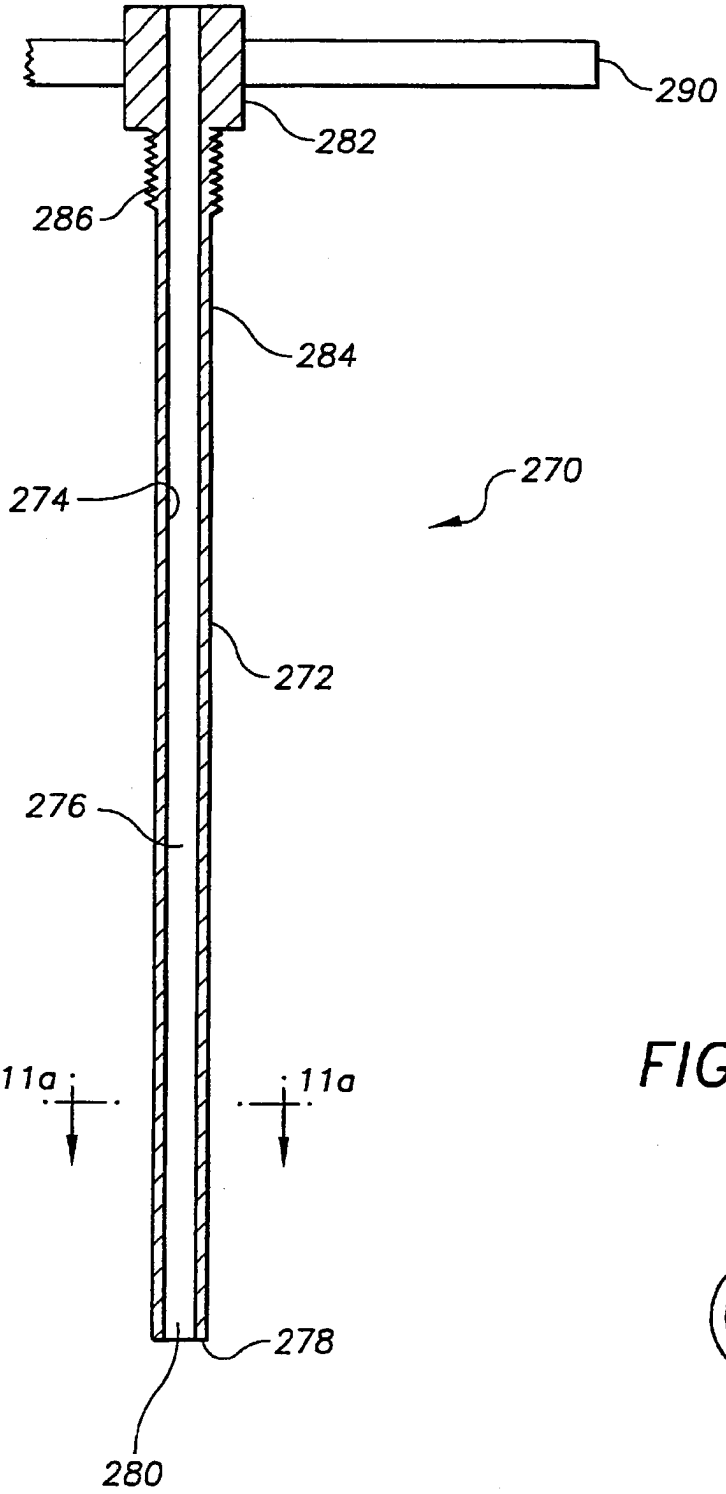


FIG. 11A

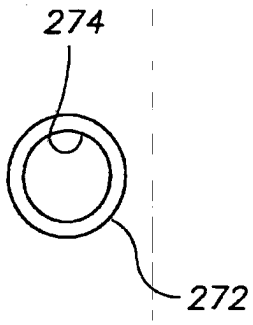


FIG. 12

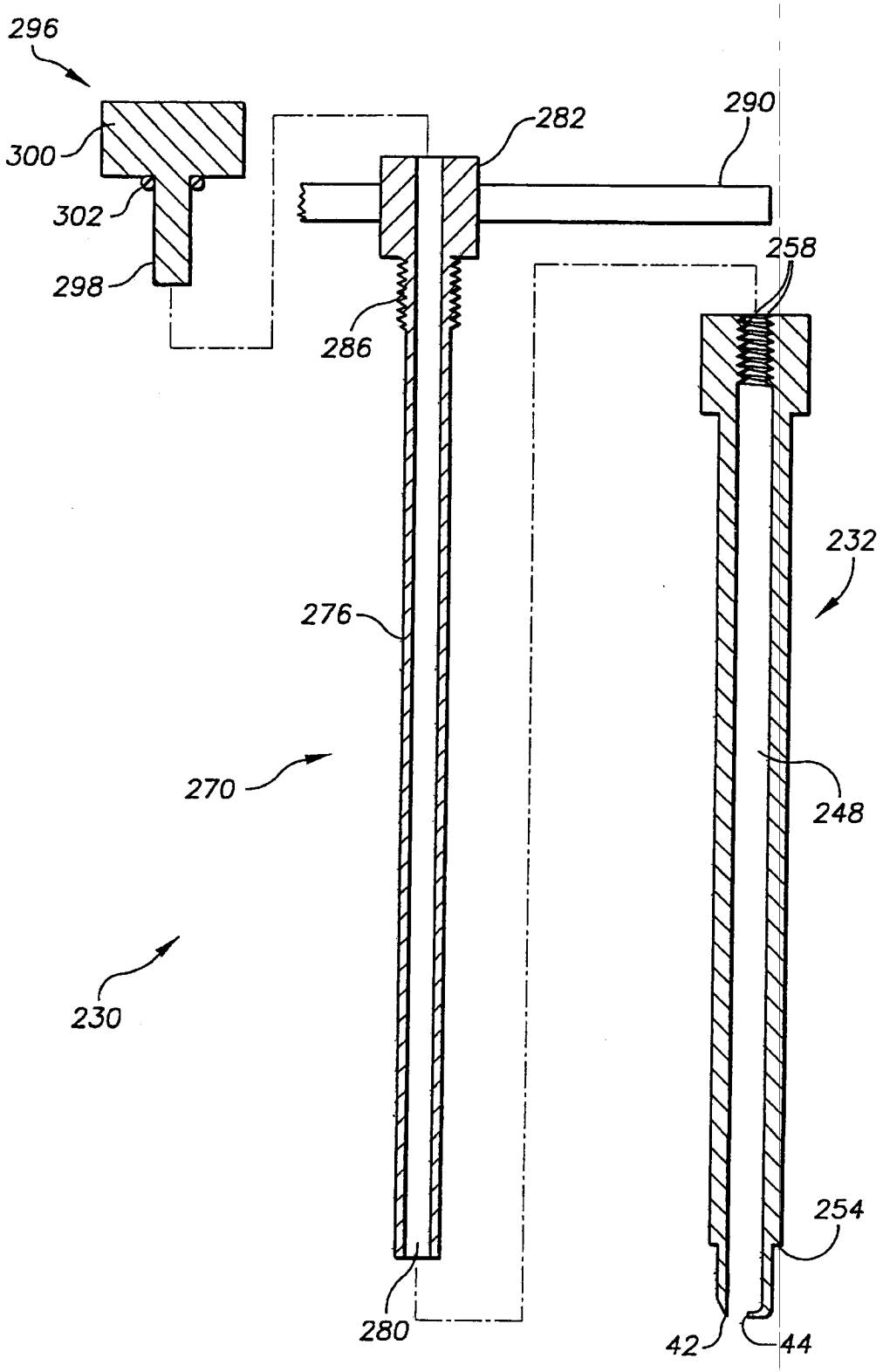


FIG. 13

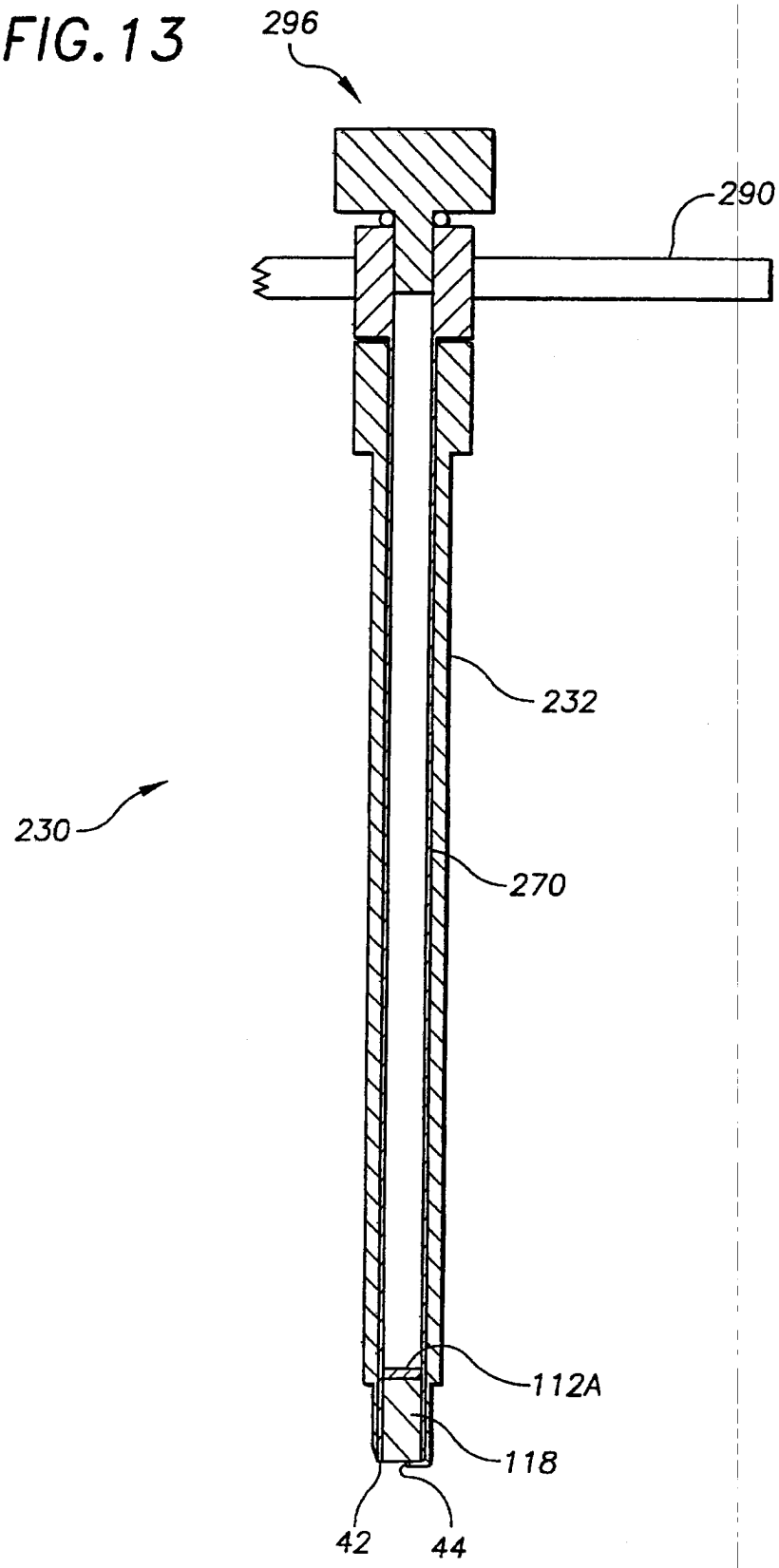
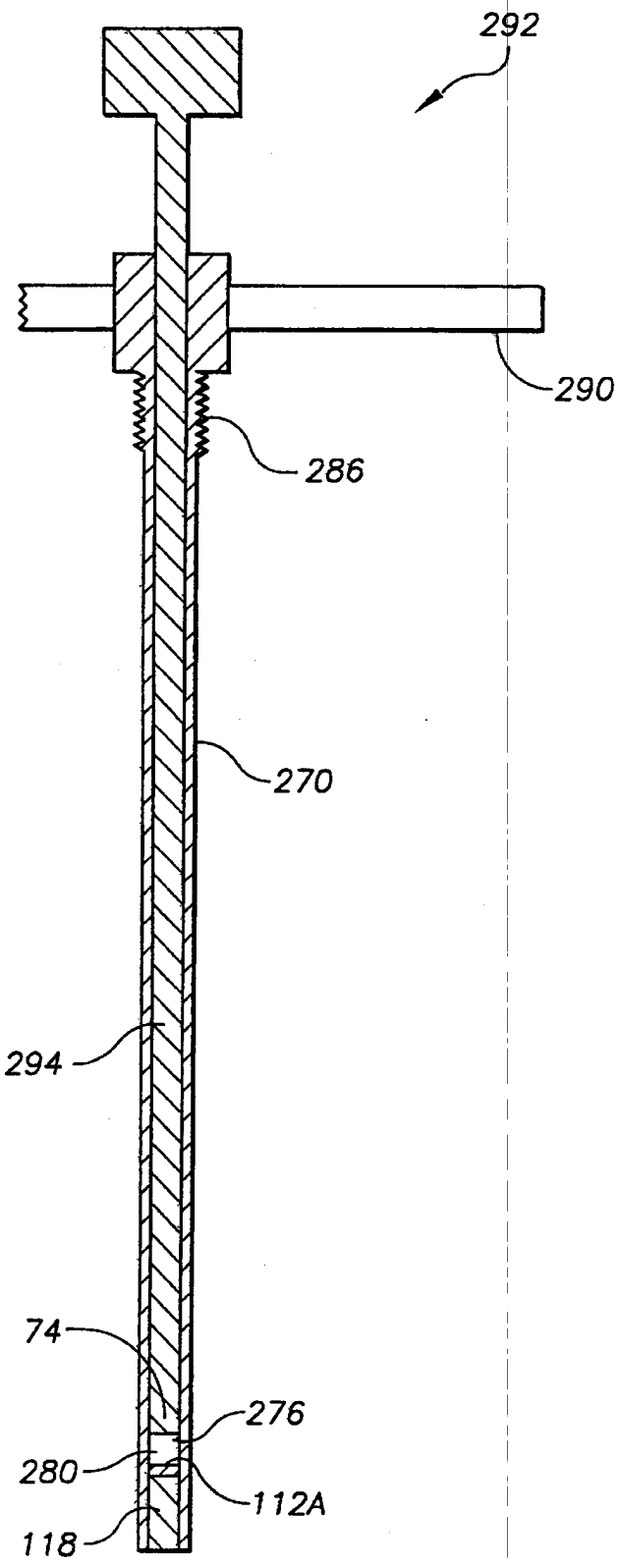


FIG. 14



APPARATUS AND METHODS FOR ARTICULAR CARTILAGE DEFECT REPAIR

REFERENCE TO RELATED APPLICATIONS

This application is a continuation in part of, commonly assigned U.S. patent application Ser. No. 08/399,428 filed Mar. 7, 1995 now U.S. Pat. No. 5,782,835, the teachings of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates to articular cartilage defects and their repair and more particularly to apparatus and methods for effecting such repair.

Defects in articular cartilage associated with trauma and osteochondritis dissecans represent a difficult challenge for surgeons. The patient can expect to face progressive deterioration over time leading to advanced osteochondritis, arthritis and the possibility of joint replacement. The knee as a weight-bearing joint is particularly susceptible to this problem, although similar injuries to the articular cartilage of other joints in humans and other mammals also occur with regularity.

FIG. **1** illustrates a knee joint **10** between the distal end **11** (i.e., that surface farthest from the center of the body) of a femur **12** and the proximal end **13** (i.e., that surface closest to the center of the body) of the tibia **14**. Portions **15**, **17** of the connective tissue which movably ties the femur **12** to the underlying tibia **14** and fibula **18** are shown. Normally interposed between opposing surfaces of the femur **12** and tibia **14** are lateral and medial meniscus cartilages, **21** and **23**, respectively. The condyles **22** at the distal end **11** of the femur **12** are normally supported by the meniscus cartilages **21** and **23** on the proximal end **13** of the tibia **14**. Normally, the distal end **11** of femur **12**, including the condyles **22** is covered by a layer **28** of cartilaginous material about 5 mm thick, referred to as the articular cartilage. Articular cartilage **28** forms a generally resilient pad which is fixed on the distal surface **11** of the femur **12** to protect the femur from wear and mechanical shock. The articular cartilage **28**, when lubricated by fluid in the knee joint **10**, provides a surface which is readily slidable on the underlying surfaces of the meniscus cartilages **21** and **23** or on the proximal surface **13** of the tibia **14** if one or both of the meniscus cartilages **21**, **23** should be partially or totally absent. Nevertheless, the articular cartilage **28** may become damaged in that it may be torn **24** or holed or become excessively worn.

Methods have been used to repair such articular cartilage damage before it can spread or result in eventual injury or wear to the underlying condyles **22**, meniscus cartilages **21**, **23**, or tissues associated with the tibia **12**. It has been known to replace damaged articular cartilage with a layer of fibrous material. See U.S. Pat. No. 5,067,964. Repairing defects in articular cartilage in human or other mammalian joints therefore requires materials that have been approved by the FDA for use in the human body. Is often problematic to find such materials that are commercially available and relatively low in cost in which completion of the repairs are within the skills of qualified orthopedic surgeons. Another repair method involves packing an articular cartilage defect with bits of cancellous and cortical bone (Soviet Patent SU 1454423, Jun. 27, 1986) that have been chipped from defect-free bone. This latter technique avoids using foreign materials but, like the former methods, does not preserve the original orientation of bone and cartilage.

Prostheses have also been used for replacement of the joint itself. Problems encountered after implanting such prostheses are usually caused by the cements used to attach the prostheses to the host bone. Further, some prostheses associated with joint replacements are actually much larger than the degenerated tissue that needs to be replaced so that extensive portions of healthy bone are typically removed to accommodate the prostheses.

The need remains to develop apparatus and methods which are suitable for articular cartilage repair and which avoid problems associated with prior art methods, such as those discussed above.

SUMMARY OF THE INVENTION

The present invention is an apparatus for repairing articular cartilage defects, and methods of using the apparatus, that harvest and utilize intact bone and intact articular cartilage plugs that preserve the natural orientation of the bone and articular cartilage.

One embodiment of the invention is a bone plug removal tool that includes a cylindrical cutting element having an external surface and having an internal surface defining an internal bore extending along a longitudinal axis of the cutting element from a proximal cutting edge. A cutting tooth is engaged with the internal surface at the proximal cutting edge and extends into the internal bore. The tooth is substantially orthogonal to the longitudinal axis of the cutting element and is defined between orthogonally extending surfaces disposed in parallel. A replaceable outer cylindrical sheath is arranged concentrically around the external surface of the cylindrical cutting element. The sheath also has an internal surface defining an internal bore extending along a longitudinal axis of the sheath. The sheath has a proximal terminus that is spaced-apart from the proximal cutting edge of the cylindrical cutting element and the terminus is designed to engage a surface of the bone to define a depth stop for the cutting edge. In preferred embodiments, the cutting tooth is a single tooth and screw threads are disposed on the external surface of the cylindrical cutting element for mating with corresponding screw threads on the internal surface of the cylindrical sheath. A handle may be engaged with a distal end of the tool for turning the tool into the bone once it has been driven to the desired depth. Thus, one aspect of the invention is a bone plug remover having an elongated body including two concentric elements in which an inner element is a cutting element and an outer element is replaceable and defines a depth stop for cutting.

Another embodiment of the invention is a bone plug emplacement tool to be used in conjunction with the bone plug removal tool. The preferred emplacement tool includes a cylindrical element having an internal surface defining an internal bore extending along a longitudinal axis of the element from a proximal end. The internal surface further defines an internal step adjacent a distal end of the element. A stem is disposed for co-axial movement within the element, the stem having a proximal end disposed within the internal bore. A shoulder is defined in the stem for mating engagement with the internal distal step of the element in order to limit distal movement of the stem within the internal bore. The proximal end of the stem, at the limit of distal movement, is spaced-apart from the proximal end of the co-axial element, the respective proximal ends defining between them an internal bone plug receiving space for receiving a bone plug of a certain length. The stem may be moved from a distal position, where the shoulder and step are engaged and the respective proximal ends define the space for receiving a bone plug, to a proximal position,

where the stem is moved proximally within the internal bore and the bone plug is driven from the internal bone plug receiving space. A second step may be defined in the stem for limiting proximal movement. This second step is located distal to the first step and external to the cylindrical element. It is preferred that, in the distal position, the second step and the distal end of the element are at a distance from each other that is equal to, or less than, the length of the bone plug.

A further embodiment is a kit incorporating the various tools. The kit for repair of an articular cartilage includes the bone plug removal tool of the invention, an elongated plunger for insertion into the proximal end of the cutting element and for coaxial movement within it, the plunger for displacing a bone plug from the distal end of the cutting element and the bone plug emplacement tool of the invention. Kits may also include a drill bit containing a depth stop for removing a portion of damaged articular cartilage.

A further embodiment of the invention also includes the combination of the bone plug emplacement tool of the invention and an excised bone plug contained within the internal bone plug receiving space of the emplacement tool.

In yet another embodiment, the invention provides a bone plug removal and emplacement tool that includes a cylindrical cutting element having a proximal cutting edge and a cutting tooth, as described above. The outer surface of the cutting element can include an integral shoulder (e.g., in lieu of a replaceable outer sheath) that is spaced-apart from the proximal cutting edge and that engages the surface of the bone to define a depth stop for the cutting edge.

An additional cylindrical element can be disposed within the cutting element. The proximal end of that additional element, which is referred to as a "harvester," is substantially aligned with the proximal end of the cutting element to receive a plug cut from the bone. The harvester can be slidably withdrawn from the cutting element to facilitate transplanting the bone plug at another location. For this purpose, a stem or plunger can be slidably inserted and moved in the harvester to dislodge the plug.

The invention also pertains to a method of repairing a defective articular cartilage. The method includes the steps of removing a section of defective articular cartilage from a site of cartilage damage and forming a hole of sufficient depth to penetrate bone underlying the site of defective articular cartilage. Next, a bone plug comprising intact bone and intact articular cartilage adhering thereto is removed from a bone lacking defective articular cartilage and is placed into the hole at the site of articular cartilage damage, so that the intact articular cartilage of the bone plug is co-extensive, and in lateral registration (i.e., aligned) with, articular cartilage external to the bone hole at the site of cartilage damage. The term "intact" in this context means that the bone and overlying articular cartilage undergo minimal physical disturbance during the removal process.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and purposes of the invention will be apparent to persons knowledgeable in this art upon reading the following description and inspecting the accompanying drawings which show:

FIG. **1** is a fragmentary front elevation view of a human knee joint with sufficient tissue removed to show the articular cartilage on the condyles of the femur, and further showing a damaged area in the articular cartilage.

FIG. **2** is an exploded cross sectional view of a bone plug removal tool of the present invention.

FIG. **3** is the bone plug removal tool of FIG. **2** with the cylindrical sheath and cylindrical cutting element joined.

FIG. **4A** is a proximal end view of the bone plug removal tool of the present invention illustrating one embodiment of the cutting tooth.

FIG. **4B** is a proximal end view of the bone plug removal tool of the present invention illustrating another embodiment of the cutting tooth.

FIG. **5** is a side elevation view of a plunger of the present invention that is designed to remove a bone plug from within the bone plug removal tool.

FIG. **6** is a cross sectional view of a bone plug emplacement tool in its distal position.

FIG. **7** is a cross sectional view of the bone plug emplacement tool of FIG. **6** in its proximal position.

FIGS. **8A** through **8D** are cross-sectional views of a fragment of bone through section **8**—**8** of FIG. **1** illustrating the orientation of the bone hole and bone plug of the present surgical technique.

FIG. **8A** is a cross section through a bone that contains a defect in the articular cartilage.

FIG. **8B** is a cross section through a bone whose defective cartilage area has been removed and into which a bone hole has been drilled. A bone plug is illustrated in proper orientation for insertion.

FIG. **8C** illustrates a bone plug received within a drilled bone hole.

FIG. **8D** illustrates a plurality of drilled bone holes within an articular cartilage defect.

FIG. **9** is a front elevation view of a plurality of bone plugs received within a single drilled bone hole within an articular cartilage defect.

FIGS. **10**–**10A** are cross sectional views of the cutting element of a bone plug removal and emplacement tool according to the invention.

FIGS. **11**–**11A** are cross sectional views of a harvester element of a bone plug removal and emplacement tool according to the invention.

FIG. **12** is an exploded view of a bone plug removal and emplacement tool configured for bone plug removal.

FIG. **13** is a cross sectional view of the tool of FIG. **12**.

FIG. **14** is a cross sectional view of a bone plug removal and emplacement tool configured for bone plug emplacement.

DETAILED DESCRIPTION OF THE INVENTION

Reference is now made to FIGS. **2**–**3** which illustrate one embodiment of the present bone plug removal tool. The bone plug removal tool **30** is a substantially cylindrical device made out of two pieces of surgical stainless steel. The tool **30** is formed into a cylindrical cutting element **32** and a cylindrical sheath **48** that is arranged concentrically around the cylindrical cutting element **32**. Cutting element **32** has an external surface **34** and an internal surface **36**. The internal surface **36** further defines an internal bore **38** extending along a longitudinal axis **40** (arrows A—A) of the cylindrical cutting element **32**. The bore **38** extends distally away from a proximal cutting edge **42**. In the present context, the term "proximal" refers to those portions of the apparatus that are closest to the center of the body or, alternately, are furthest away from the operator of the apparatus. The term "distal" refers to those portions of the apparatus that are furthest from the center of the body or, alternately, are closest to the operator of the apparatus. The internal bore **38** extends from the proximal cutting edge **42** to the distal end

43 of the cylindrical cutting element 32 from which a bone plug can be removed by the operator after bone plug extraction has been completed.

The proximal cutting edge 42 is sharpened so that any bone entering the internal bore 38 is cut from the surrounding bone. An excised bone plug trapped within bore 38 can move freely into this space and out the distal end 43 after the plug excision procedure has been completed, as discussed in more detail below.

At least one cutting tooth 44 is engaged with the internal surface 36 of the cylindrical cutting element 32 at the proximal cutting edge 42. This tooth 44 extends into the internal bore 38 in a direction that is substantially orthogonal to longitudinal axis 40 of the cylindrical cutting element 32. The cutting tooth 44 is defined by orthogonally extending tooth surfaces 46 that are disposed in parallel. Although a plurality of such teeth may be orthogonally disposed at the proximal cutting edge 42, in the most preferred embodiments of the present invention, only a single cutting tooth is necessary. As shown in FIG. 4A, the cutting tooth 44 is preferably rectangular or square in shape. It is also understood, however, the cutting tooth 44 may be generally triangular in shape as shown in FIG. 4B. The cutting tooth 44, moreover, preferably extends one-fifth of the diameter of the bore 38, although it may range from approximately 1/16 to 1/4 of the bore 38. When the bone plug removal tool 30 is rotated after insertion (to be described in more detail below), the core bone is forced to break loose from the surrounding bone at the cutting edge 42 and the cutting tooth 44 is embedded into the bone. When the tool 30 is extracted, the bone plug is extracted with it. The cutting tooth 44 will also cut a groove along the length of the bone plug which provides additional bone strength when the bone plug is emplaced into a bone hole, as discussed more fully below.

Referring again to FIGS. 2 and 3, the outer cylindrical sheath 48 is arranged concentrically around the external surface 34 of the cylindrical cutting element 32. The sheath has an internal surface 50 that also defines an internal bore 51 extending along longitudinal axis 52 of the sheath 48. In the embodiment illustrated, the outer cylindrical sheath 48 is removably engaged with the cylindrical cutting element 32 by way of matching screw threads 56, 58 located on the internal surface 50 of the cylindrical sheath 48 and on the external surface 34 of cylindrical cutting element 32, respectively. Therefore, the outer cylindrical sheath 48 is removable and may be replaced by another outer sheath having different dimensions by mating the corresponding screw threads. It is particularly preferred that outer cylindrical sheath 48, when engaged with the cylindrical cutting element 32, have a proximal terminus 54 that is not co-extensive with the proximal cutting edge 42 of the cutting element 32. Specifically, the proximal terminus 54 of outer cylindrical sheath 48 is spaced apart from the proximal cutting edge 42 by a distance that defines a depth stop distance X. The depth stop distance X defines the length of the bone plug that is to be removed.

As shown in FIG. 2, an elongated, preferably cylindrical handle 60 may cooperate with the adjacent distal end 43 of the cutting element 32 by way of a second bore 62 that extends through the cutting element 32 orthogonally to the longitudinal axis 40 of the cylindrical cutting element 32. Handle 60 may be inserted after the tool has been driven to the desired depth and is used for rotating the tool to cause the bone to break at proximal cutting edge 42.

It will be appreciated that various other embodiments are intended to be encompassed by the present bone plug tool. For example, handle 60 may be replaced by a conventional screw head (not shown) having a slot defined in it for receiving a screw driver or other, similar device. Handle 60 may also be replaced by a conventional hexagonal nut (not shown) which designed to receive a conventional socket wrench, socket driver or attached drill head. Moreover, although the cutting element 32 is preferably driven into the bone without any rotational movement, such as by hammering or tapping, it is also understood that the cutting element 32 may be screwed or twisted into the bone by means of a screwdriver, socket wrench or other similar device (not shown). In addition, corresponding threads 56, 58 may be replaced in other embodiments by conventional spring loaded snap-fit linkages (not shown). The exact nature of the handle and the nature of the removable coupling between the cylindrical cutting element and the outer cylindrical sheath is not intended to limit the scope of the invention in any way.

The dimensions of the plug removal tool 30 may vary according to the surgical procedures. In preferred embodiments, however, the bone plug removal tool 30 is about 6 inches (152.4 mm) in overall length. If a handle is used, the handle 60 is about 4 inches (101.6 mm) in total length with a diameter of about 0.31 inches (7.9 mm). The outer cylindrical sheath 48 has an outside diameter of 0.30 inch (7.6 mm) to provide sufficient surface area to effectively limit the depth of penetration of the internal cylindrical cutting element 32. The distance between the respective proximal ends of the cylindrical sheath 48 and the cylindrical cutting element 32 will of necessity vary according to the depth of the bone plug. It is contemplated that this distance will vary between 5 mm and 15 mm.

The outside diameter of the cylindrical cutting element 32 at the proximal cutting edge 42 may also vary but is most preferably about 0.25 inches (6.3 mm) with a bore of about 0.196 inches (4.9 mm) inside diameter. Although the bore will preferably range between 4.5 mm and 10 mm, it will again be appreciated that this inside diameter can be smaller or larger depending upon the circumstances.

As discussed above, the bone plug can move freely through internal bore 38 and pass out from the distal end 43 of cutting element 32 after the plug removal procedure has been completed. FIG. 5 illustrates a plunger 70 that is designed to accomplish this. Plunger 70 includes a shaft 72 having a proximal end 74 and a distal portion 76 whose outside diameter is significantly larger than the outside diameter of the rest of the shaft. The differences in outside diameter between the shaft 72 and the distal portion 76 form a step 77 at the junction of the distal portion 76 and shaft 72. The outside diameter of the shaft is sufficiently small so that shaft 72 can be passed between the cutting tooth 44 and the opposite, internal surface 36 of the cylindrical cutting element 32. An exemplary plunger that may be used with the bone plug removal tool has a shaft of about 0.125 inches (3.17 mm) in diameter and at length of about 7 inches (177.8 mm) between its proximal end 74 and the step 77.

FIGS. 6 and 7 illustrate a bone plug emplacement tool 80 used to drive an excised bone plug into a drilled bone hole so that defective articular cartilage may be repaired. FIG. 6 also shows a bone plug 78 in place within the emplacement tool 80. Bone plug emplacement tool 80 includes cylindrical element 82 having an internal surface 84 defining an internal bore 86. Element 82 has an expanded section 83 adjacent distal end 92. The internal bore 86 extends along a longitudinal axis 87 of the element 82 from a proximal end 88 of the element 82. Element 82 has a distal end 92. The internal surface 84 further defines, adjacent the distal end 92 of the element 82, an internal step 90.

A stem **94**, which may be solid, is disposed within the internal bore **86** and is adapted for co-axial (i.e. distal-proximal) movement. Stem **94** does not have an uniform outside diameter but includes a first shoulder **98** that is designed to mate in facing relationship to the internal step **90** of the cylindrical element **82**. When first shoulder **98** and internal step **90** are thus engaged, distal movement of the stem within the internal bore is halted. In this position (FIG. **6**), the proximal end **96** of stem **94** is located within internal bore **86** and is spaced apart from the proximal end **88** of the cylindrical element **80**. The respective proximal ends **88, 96**, define between them an internal bone plug receiving space that is configured to receive the bone plug **78** that is to be emplaced. In the embodiment illustrated, the stem **94** extends distally from the distal end **92** of cylindrical element **82**.

At some distance from distal end **92**, the stem **94** has defined in it a second shoulder **100**. The second shoulder **100** is designed to engage with the distal end **92** of element **82** and this engagement limits the proximal movement of the stem **94** within the internal bore **86**. The distance (Z) between the second shoulder **100** and distal end **92** of the cylindrical element **82** is designed to be at least equal to the longest dimension of the bone plug **78**. Similarly, the distance (Z') between the proximal end **96** of stem **94** and the proximal end **88** of the cylindrical element **82** is also at least equal to the longest dimension of the bone plug **78** and equal in length to the length of the internal bone plug receiving space. Proximal movement of the stem **94** within the internal bore **86** of the emplacement tool **80** will completely disgorge the bone plug **78** into a drilled bone hole. In preferred embodiments, the distance (Z) between the second shoulder **100** and the distal end **92** of the cylindrical element **82** is slightly less than the bone plug depth. For instance, in a 5 mm long bone plug, Z is 4 mm; for a 10 mm long bone plug, distance Z is 9 mm; for a 15 mm bone plug, distance Z is 14 mm, and so on. Thus, the distance (Z') between the proximal end **96** of the stem **94** and the proximal end **88** of the cylindrical element **82** is also slightly less than the bone plug depth. Specifically, if the bone plug is 5 millimeters long, the distance (Z') between the respective proximal ends **88, 96** is 4 millimeters so that one millimeter of bone will protrude from the proximal end **88** of the cylindrical element **82**. This protruding section assists the operator in finding the drilled bone hole prior to emplacement.

The stem **94** is adapted for movement from a distal position (FIG. **6**), where the first shoulder **98** and the internal step **90** are engaged and the respective proximal ends **88, 96** define between them the internal bone plug receiving space. The stem **94** then moves to a proximal position (FIG. **7**) where the second shoulder **100** engages with the distal end **92** of cylindrical element **82** and the bone plug is disgorged from within the internal bone plug receiving space, as described below. An exemplary emplacement tool that is compatible with the bone plug removal tool discussed previously has a cylindrical element that defines an internal bore of about 0.196 inches (4.9 mm) inside diameter. The outside diameter of the cylindrical element may be about 0.25 inches (6.3 mm) in diameter. The length of the cylindrical element from its proximal end to the beginning of the expanded section **83** may be about 5.5 inches (139.7 mm) in length.

The surgical technique described herein is preferably performed arthroscopically using conventional equipment, although open techniques may be utilized should proper bone plug insertion prove impossible by arthroscopic means. Before surgery, a bone plug removal tool of the present invention is prepared. A standard anterolateral or medial or superior portal is used to introduce a 4.5 mm, 30° oblique arthroscope, and a shaver is applied through an anteromedial portal to prepare the articular cartilage defect. After shaving the degenerated cartilage in the vicinity of the defect, an 8 mm skin incision is made on the superolateral corner of the patellofemoral joint. The bone plug removal tool **30** is inserted through this portal and at least one cylindrical bone plug (5 mm in diameter and 10 mm in length) is taken from the lateral wall of the patellar groove, located outside the patellofemoral joint. A bone plug may also be taken from the anterolateral side of the intercondylar area. Three holes, each with a diameter of 4.8 mm, are then made using a drill bit through the anteromedial portal. The bone plug is removed from the removal tool **30** using the plunger **70** and positioned within the emplacement tool **80**, as described below. The bone plug emplacement tool **80** of the invention containing the bone plug in its correct orientation is placed over the hole through this portal and the bone plug is pushed into the hole using the emplacement tool **80**, as described herein.

Referring generally to FIGS. **8A–8D**, the present invention contemplates repairing a defect or damaged area **110** in an articular cartilage **112** by removing a conveniently shaped (for example circular) portion **114** of the defective articular cartilage layer **112** and a portion **15 115** of the underlying bone **116**. FIG. **8A** illustrates the general principle, discussed more fully below, that the surface area of the bone portion removed **115** is not necessarily coextensive with the surface area **114** of cartilage removed. The edges **122** of the defect **110** are debrided to create vertical walls and sharp edges. The base of the defect is shaved smooth but is not abraded through to the subchondral bone. The size of the removed portion **114** is kept to a minimum but is large enough to include the whole of the damaged cartilage area.

The bone is drilled with a hand or power drill containing a drill bit that most preferably has an expanded outside diameter (i.e., a depth stop countersink) located some distance distal to the proximal end of the drill bit. An exemplary drill bit used with the present methodology has a cutting surface exactly equal to the chosen length of the bone plug. That is, the cutting surface can be between about 5 mm and 15 mm in length. The outside diameter of such an exemplary drill bit is very slightly undersized relative to the inside bore diameter of the bone core removal tool. In particular, an internal bore of 0.196 (4.97 mm) inside diameter for the cylindrical cutting element of a bone core removal tool would require a drill bit of 0.190 (4.82 mm) inches outside diameter. The difference of 0.006 (0.15 mm) inches is necessary for the required interference fit of the bone plug within the drilled bone hole. The outside diameter of the drill bit begins its expanded depth stop section at a distance above the proximal end that is equal to the depth of the bone plug. This expanded section may be 0.25 inches (6.35 mm) in diameter and can be about 6 inches (152.4 mm) long.

Bone holes drilled into the underlying bone may be of any depth but are most preferably about 5 mm to about 15 mm in depth. It is most preferred that excised plugs of articular cartilage with the underlying subchondral cancellous bone attached have a total length of about 10 mm. This will provide individual bone plugs having about 5 mm of cartilage and 5 mm of bone or other similar combinations such as 2 mm of cartilage and 8 mm of bone, 3 mm of cartilage and 7 mm of bone, etc.

Depending on the size of the defect and of the underlying bone hole, several bone holes may be drilled, each bone hole designed to receive a single bone plug (FIG. **8D**) or a single bone hole may be drilled to receive a plurality of bone plugs (FIG. **9**).

Following removal of the articular cartilage portion of the damaged area **110**, as well as the underlying bone, a correspondingly sized and shaped bone plug **118** is inserted, first into and through the opening **114** left in the articular cartilage layer **112**, and then into the underlying drilled bone hole **120**. The bone plug **118** contains both bone **116**A and its overlying articular cartilage **112**A. These plugs will most preferably be taken from the non weight-bearing surfaces of the joint principally in the intracondylar notch and the periphery of the condyle. The bone plug **118** is inserted into the drilled bone hole **120** so that the articular cartilage layer **112**A of bone plug **118** is in lateral registration with (i.e., is aligned with) the articular cartilage layer **112** surrounding the drilled bone hole **120**.

The bone plug **118** is of sufficient shape to maintain a frictional fit within the drilled bone hole **120** and will remain there until such time as tissue ingrowth from the surface of the bone and peripheral, cut edges **122** of the articular cartilage layer **112** surrounding the bone hole **120** more permanently fix the bone plug **118** in place.

Bone plugs **118** may be positioned within a single bone hole **120** so that their respective outer peripheral edges are not in contact with each other. More preferably, individual bone plugs **118** located in their respective bone holes **120** may have their centers between 3 mm and 5 mm apart (See FIG. **8**D). The peripheral edges **113**, **115** of a given bone plug **118** are preferably positioned at some distance (Y) from the cut edges **122** of the defect and it is preferred that this distance be no further than about 5 mm.

These rules for bone plug spacing and orientation allow for a variety of possible configurations. For example, an articular cartilage defect 10 mm in diameter may accommodate one 5 mm diameter plug in the center of the defect. A defect 20 mm in diameter may be divided into four, 10 mm diameter quadrants and four holes drilled in the underlying bone. The defect therefore receives a total of four bone plugs.

Although the bone plug **118** is designed to have a friction fit into the drilled bone hole **120**, several temporary fixation techniques are available. One such technique involves sewing sutures through the respective peripheral edges **113** of the articular cartilage layer **112**A adhering to the bone plug and the articular cartilage **122** of the surrounding tissue. Alternatively, an adhesive layer (not shown) may be provided between the bone plug **118** and drilled bone hole **120**. This adhesive layer allows time for sufficient ingrowth of tissue from the surrounding environment so that bone plug is locked into place in the bone hole. Various bio-adhesives are well known in the art. See for example U.S. Pat. No. 5,067,964 (fibrinogen and thrombin sealant). Bone growth or cartilage growth promoting chemical factors may also be added. These may include cartilage-derived growth factor (CDGF—See U.S. Pat. No. 5,376,636), various inteleukins, colony-stimulating factor (CSF), osteopontin, platelet-derived growth factor (PDGF) and bone morphogenic protein (BMP-1). See also U.S. Pat. No. 5,373,503, incorporated herein by reference.

In use, the bone plug removal tool **30** is positioned above the bone/cartilage surface and the proximal cutting edge **40** of the cylindrical cutting element is preferably tapped with a hammer (not shown) to seat the proximal cutting edge **40**. When the tool **30** is fully seated in the bone, the handle **60** is turned a minimum of 360° degrees and the cylindrical cutting element **32** engages the bone down to a depth that is limited by contact of the proximal terminus of the outer sheath **54** with the bone surface. The outer sheath **54** does not cut into the bone. The tool **30** is then pulled distally away from the bone with a twisting action to remove the bone plug. The plunger **70** is then inserted through the proximal cutting edge **42** of the bone plug removal tool **30** to push or tap the bone plug through the internal bore **38** and out the distal end **43** of the bone plug removal tool **30**. The excised bone plug is then manually inserted, typically by the surgeon, into the receiving space of the emplacement tool **80**, articular cartilage surface **112**A first. This insures proper orientation of the bone plug within the receiving space so that the excised articular cartilage layer **112**A is engaged with the proximal end of the stem **96**. It is particularly preferred that about one millimeter (1 mm) of underlying bone protrude from the proximal end **88** of the cylindrical element **82**. This configuration allows the operator to find the drilled bone hole more easily. Once located, the bone plug is pressed into the drilled bone hole by moving the stem **94** from the distal to the proximal position so that the excised bone plug can be disgorged into the bone hole. The holes drilled in the donor defects are filled with collagen plugs.

Post operative rehabilitation may include nonweight bearing for eight weeks with crutches. Full active motion of the knee will be encouraged such as "nonweight bearing" exercise with a stationary bike using minimal resistance but high speed. This is useful for thigh rehabilitation as soon as pain and swelling permits. Running and pivoting activities should not be allowed until after healing is confirmed either radiographically or by relook arthroscopy.

An exemplary prospective study to assess the effectiveness of this technique is now described. Patients are selected with significant full thickness articular cartilage defects located on the weight bearing surface of the femur. To be included in the study, patients are a minimum age of 14 years, have a thickness defect in the distal femoral condyle that includes those caused by osteochondritis dissecans and trauma that is at least 10 mm but no larger than 30 mm in diameter, adequate bone density, a willingness to comply with the study protocol, and a commitment to return for at least two years follow up. No patient with an active infection, who does not meet all of the inclusion criteria, or who has had prior knee surgery that would compromise the vascular supply is included.

Preoperative assessment includes a history including any identifiable etiology of the defect, a physical and radiographic evaluation, and the completion of both the Lysholm knee scoring scale and Tegner activity level scale. The objective evaluation includes tests for mensical signs, range of motion, atrophy, effusion, instability (Lachman, anterior drawer, and pivot shift), and patellofemoral problems. Baseline radiographs are obtained. The findings at surgery and procedures performed are recorded.

Post operative assessments occur at intervals of 1, 2, 3, 6, 12, and 24 months. These assessments are essentially the same as the preoperative evaluations and include the data for the Lysholm and Tegner scale and knee radiographs.

Additional Embodiments

FIGS. **10**–**14** illustrate a bone plug removal and emplacement tool according to a further embodiment of the invention. In this embodiment, a harvesting tube is disposed within the cutting element to facilitate removal and emplacement of a plug cut from the bone. That tube, which receives the plug as it is cut, can be slidably withdrawn from the cutting element and evacuated by a plunger that forces the plug, into a recipient bone hole.

Cutting Element

With particular reference to FIG. **10**, there is shown a cannulated cylindrical cutting element **232** used in connec-

tion with the bone plug removal and emplacement tool, particularly, for bone plug removal and harvesting. The element **232** is configured substantially like the cutting element **32** of FIGS. **2**, **3** and **4**, except insofar as its distal end includes a collar and internal threading, rather than a handle and external threading, and except insofar as described below. The body **234** of cutting element **232** is generally cylindrical in shape, though, conical and other shapes may be employed as well. At the proximal end **236** of element **232** are cutting edge **42** and one or more teeth **44**, which are constructed and utilized as described in the embodiments above. A cross-sectional view of the distal end of element **232** is provided in FIG. **10A**.

The cutting element **232** is dimensioned in accord with type of surgery with which it will be used, as well as the size of the bone plug to be removed. In a typical configuration for arthroscopic knee surgery, the element **232** is machined from surgical stainless steel (or other appropriate material) and is approximately 5 to 10 inches in length and, preferably, around 6 inches in length. The outside diameter of the cylindrical cutting element **232** at the proximal cutting edge **42** may also vary but is most preferably about 0.25 inches (6.3 mm). The bore diameter ranges between 4.5 mm and 10 mm and, preferably, 4.9 mm, depending upon the circumstances of use.

Cutting element **232** can include a removable outer cylindrical sheath that serves as a depth stop in the manner of sheath **48** described above. Alternately, as shown in FIG. **10**, the cutting element **232** can include an integral step **234** to define such a depth stop. That step can be machined or molded in the conventional manner. Those skilled in the art will appreciate that other configurations, such as protruding pins, can be employed to serve as depth stops, as well.

Illustrated depth stop **234** has sufficient surface area to stop that portion of the cutting element **232** distal to it from penetrating into the bone. Thus, for example, in an embodiment in which the outer diameter of the cutting element **232** proximal to the step is, e.g., about 0.25 inches (6.3 mm), that distal to the step is, e.g., 0.30 inch (7.6 mm). As with sheath **48**, the distance Y between the proximal end of cutting element **232** and step **234** will of necessity vary according to the depth of the desired bone plug, though, typically falls between 5 mm and 15 mm and, preferably, is 8 mm.

A collar **244** disposed at the distal end **238** of the cutting element **232** effects a further step in the outer surface of **252**. The collar **244**, which too is preferably integral to element **232**, provides reinforcement and aids in gripping the cutting element **232**. For the latter purpose, the surface of collar **244** is preferably knurled or roughened. Those skilled in the art will appreciate that the collar **244** is optional and, if employed, can utilize other configurations as well.

An internal surface **246**, which extends from the proximal end **236** to the distal end **238** of the cutting element **232**, defines a bore **248** that runs the length of the cutting element **232** about a longitudinal axis **250**. Threads **258** are provided on the internal surface **246** at the distal end of the bore **248**. The threads **258** provide a means for locking engagement, e.g., with a harvester as described below.

Harvester

FIG. **11** shows a harvester **270** used in connection with a bone plug removal and emplacement tool according to the invention. A cross-section of the harvester is shown in FIG. **11A**. The harvester **270** comprises a cannulated tube **272** that is adapted to be slidably received in the cutting element bore **248**. It includes an inner surface **274**, defining bore **276** whose distal end comprises a cavity **280** for receiving a bone plug cut by the cutting element **232**.

At the distal end of the tube **272** is a collar **282** and, proximal thereto, threads **286** for engagement with the threads **258** of the cutting element **232**. Upon mating the harvester threads **286** with the cutting element threads **258**, the harvester **270** and cutting element **232** become fixedly engaged for cutting and harvesting a bone plug. Those skilled in the art will appreciate that the threads **258**, **286**, though preferred, are optional and are not required to maintain the harvester **270** in engagement with the cutting element **232** during plug cutting and harvesting. Thus, for example, the harvester **270** and cutting element **232** can be mated by spring loaded snap-fit linkages, interference fit, etc.

The harvester **270** may also include a handle **290** located at the distal end **280** of the harvester and preferably mounted through the harvester collar **282**. As with handle **60**, described above, handle **290** may be mounted at different locations on the harvester or on the cutting element **232**. The handle **290** provides leverage for turning the cutting element **232** about its longitudinal axis **250**. As above, the exact nature of the handle and the nature of the removable coupling between the harvester **270** and the cylindrical cutting element **232** is not intended to limit the scope of the invention in any way.

The harvester **270** is sized in accord with the bone cutting element **232**. Thus, tube **272** is of a length such that its proximal ends is substantially aligned with the proximal end of cutting element **232** (with respect to longitudinal axis **250**) when the tool **230** is assembled tool. Put another way, in the assembled device, the proximal end of the tube **272** substantially abuts the cutting edge **42** and the distal surface of tooth **44**, without interfering with operation of either of them. In alternate embodiments, the proximal end of the tube is set back from that of the cutting element **232**. Preferably, that set back is less than 50% and, preferably, less than 10% of the depth stop distance Y, so that harvested bone plugs are adequately protected by the tube **272**. The outer diameter of the harvester proximal end **278** is substantially equal to, though slightly smaller (e.g., 1%–15% and, preferably, 5%) than the inner diameter of cutting element bore **248**. The wall of tube **272** at the proximal end (or cavity) is 0.1–0.5 mm and, preferably, about 0.3 mm. This is sufficiently thick to protect the bone plug during removal and emplacement, yet not so thick as to cause it to be crushed or deformed during harvesting.

In the illustrated embodiment, bore **276** is of constant diameter from the proximal end **278** to the distal end **280** of the harvester **270**. In alternate embodiments, the diameter of the bore **276** distal to the cavity may be smaller than that of cavity **280** itself. As the cavity **280** defines the region in which removed bone plugs reside, the cavity length (along longitudinal axis **250**) is preferably substantially equal to or greater than depth stop distance Y.

Bone Plug Removal Configuration and Operation

FIG. **12** shows an exploded view of the aforementioned bone plug removal and emplacement tool **230** configured for bone plug removal. The assembled tool is shown in cross-section in FIG. **13**. These drawings show that the harvester **270** is inserted in the bore **248** of cutting element **232** and, preferably, maintained there by cooperative action of threads **258**, **286**.

As above, assembled tool **230** may be driven into the bone in numerous ways, e.g., via screwing or twisting it into the bone by means of a screwdriver, socket wrench or other similar device (not shown). Preferably, however, it is driven into the bone without any rotational movement, such as by hammering or tapping. Transmission of such force from the

distal end of the tool **230** is facilitated by illustrated anvil **296** having a stem **298** extending from its body **300**. The anvil **296** may comprise metal, rubber, plastic, or other suitable material. The anvil **296** is mounted to the harvester **270** by inserting the stem **298** of the anvil **296** into the distal end of the bore **276** of the harvester **270**. Optional o-ring **302**, preferably made of rubber or plastic, provides a buffer between the anvil **296** and the harvester **270**.

The assembly **230** can be utilized in open or, preferably, arthroscopic surgery to remove and harvest a bone plug, generally as described above. Thus, a skin incision is made and the proximal end of the assembled tool **230** is inserted therethrough. The cutting edge **42** of the cutting element **232** is positioned on the bone surface from which the plug is to be taken, e.g., superior and lateral aspects of the interchondular notch. The edge **42** is preferably positioned perpendicular to the bone surface, e.g., via line-of-sight viewing or via use of the indicator element described in copending commonly assigned U.S. patent application Ser. No. 08/399,428. Upon tapping the anvil **296**, e.g., with a mallet (not shown) or other such object, the proximal ends of the cutting element **232** and harvester **270** are driven, e.g., 8 mm into the bone, until stopped by depth stop **254**.

Once its proximal end is inserted into the bone, the tool **230** is rotated as described above, e.g., via handle **290**, so that tooth **44** undercuts the bone plug, forcing it to break loose from the surrounding bone. FIG. **13** shows such a bone plug **118** and its overlying articular cartilage **112A** contained within harvester cavity **280** of the assembled tool **230**.

Bone Emplacement Configuration and Operation

After a bone plug is harvested, the harvester **270** is separated from the cutting element **232**, e.g., by unscrewing the harvester and slidably removing it. The bone plug **118** with articular cartilage **112A** remains protected in the cavity **280** at the proximal end of the harvester until it is ready for transplant into the recipient bone hole. If additional bone plugs are required, additional harvesters **270** can be assembled to the cutting element **232** and the foregoing process repeated.

Harvester **270** containing bone plug **118** (with cartilage **112A**) is positioned over a recipient bone hole **120**, which is created and prepared as discussed above. This can be facilitated by, first, screwing the harvester **270** into an optional endoscopic delivery guide (not shown) configured, dimensioned and constructed like cutting element **232**, but without cutting edge **42** and tooth **44**. After the harvester **270** is positioned, a removable plunger **292** is inserted into bore **276** in pushed in the proximal direction to disgorge bone plug **118** into the bone hole **120**.

Plunger **292** is constructed substantially like plunger **70**, described earlier, sans shoulder **98**. Particularly, shaft **294** of plunger **292** has an outer diameter between 25% and 99% and, preferably, between 80% and 90% of the inner diameter bore **276**. Shaft **294** also has a length sufficient to push the bone plug **118** out of cavity **80** and, preferably, about 1–5 mm further into bone hole **120**.

A further appreciation of the construction and operation of the embodiment shown in FIGS. **10–14** may be attained by reference to the schematics and other materials provided in the Appendices filed herewith.

Conclusion

It should be understood that the preceding is merely a detailed description of certain preferred embodiments. It therefore should be apparent to those skilled in the art that various modifications and equivalents can be made without departing from the spirit or scope of the invention.

What is claimed is:

1. A surgical assembly comprising a bone plug removal tool including:

a cylindrical cutting element having an internal surface defining an internal bore extending along a longitudinal axis of the cutting element from a proximal end;

a first cutting edge located at the proximal end of the cutting element for cutting a plug of bone as the cutting element is driven into a bone;

at least one cutting tooth located substantially at the proximal end of the cutting element and extending into the internal bore of the cutting element in a direction that is substantially orthogonal to the longitudinal axis of the cylindrical cutting element; and

the cutting tooth being defined by at least two planar and parallel surfaces extending substantially orthogonal to the longitudinal axis of the cutting element so as to form a second cutting edge for undercutting the bone plug when the first cutting edge is rotated inside the bone.

2. A surgical assembly according to claim **1**, wherein the cutting element comprises a plurality of cutting teeth substantially at the proximal end of the cutting element.

3. A surgical assembly according to claim **1**, wherein the cutting tooth is any of substantially rectangular and substantially square in shape.

4. A surgical assembly according to claim **1**, the cutting tooth is substantially triangular in shape.

5. A surgical assembly according to any of claims **3** and **4**, wherein the cutting tooth extends between 1/16 and 1/4 of a diameter of the internal bore of the cutting element.

6. A surgical assembly according to claim **5**, wherein the cutting tooth extends one-fifth of the diameter of the diameter of the internal bore.

7. A surgical assembly comprising a bone plug removal tool including:

a a cylindrical cutting element having an internal surface defining an internal bore extending along a longitudinal axis of the cutting element from a proximal end to a distal end of the cutting element,

a cutting edge located at the proximal end of the cutting element for cutting a plug of bone as the cutting element is driven into a bone,

at least one cutting tooth located substantially at the proximal end of the cutting element and extending into the internal bore of the cutting element in a direction that is substantially orthogonal to the longitudinal axis of the cylindrical cutting element, and

a harvester disposed within the internal bore of the cutting element, the harvester having a proximal end with an internal surface defining a cavity for receiving the plug of bone cut by the cutting edge.

8. A surgical assembly according to claim **7**, wherein the havester is removably disposed within the cutting element.

9. A surgical assembly according to claim **7**, wherein the havester is slidably disposed within the cutting element.

10. A surgical assembly according to claim **7**, wherein the cavity of the harvester has a proximal end that is substantially aligned with the proximal end of the cutting element.

11. A surgical assembly according to claim **10**, wherein the proximal end of the cavity is substantially aligned with the cutting edge of the cutting element.

12. A surgical assembly according to claim **10**, wherein the proximal end of the cavity is substantially aligned with the proximal end of the tooth of the cutting element.

13. The assembly of claim **7**, wherein the inner surface of the harvester comprises a bore in communication with the harvester cavity and extending the longitudinal length of the harvester.

14. The assembly of claim 7, further comprising a plunger disposed within at least the harvester cavity for dislodging the bone plug therefrom.

15. A surgical assembly according to claim 14, wherein the havester is removably disposed within the cutting element.

16. A surgical assembly according to claim 15, wherein the havester is slidably disposed within the cutting element.

17. A surgical assembly according to claim 7, wherein the bone plug removal tool comprises an anvil engaged at a distal end thereof for transmitting a driving force to the cutting element.

18. A surgical assembly according to claim 17, wherein the anvil is removably mounted to a distal end of the harvester.

19. A surgical assembly according to claim 17, wherein the anvil includes a stem concentrically mounted within a harvester bore for radially securing the anvil to the tool.

20. A surgical assembly according to claim 19, further comprising a buffer of resilient material located between the anvil and the harvester.

21. A bone plug remover comprising

an outer element having a cutting portion disposed at a proximal end thereof for cutting a plug from a bone,

an inner element having a receiving portion, substantially aligned with the cutting portion of the first element, for receiving the plug cut thereby,

the inner element being removably disposed within the outer element.

22. A method of repairing a defective articular cartilage, comprising

removing a plug from bone with the bone plug remover of claim 21,

disengaging the inner element of that bone plug remover from the outer element,

positioning the receiving portion of the inner element substantially adjacent a bone hole and disgorging the plug from the inner element into that hole.

23. A method according to claim 22, comprising the step of disgorging the plug into the hole by pushing the plug with a plunger.

24. A method according to claim 23, comprising the steps of

forming the hole in the bone at a site of articular cartilage damage,

cutting the plug from the bone at a site that is substantially free of such damage, and

placing the plug into the hole so that articular cartilage affixed to the plug is coextensive with, and in lateral registration with, articular cartilage external to the hole at the site of cartilage damage.

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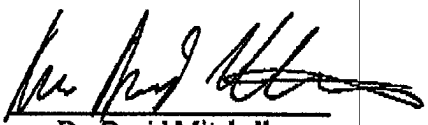
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON INC., Plaintiff, v. DISC-O-TECH MEDICAL TECHNOLOGIES LTD., and DISC ORTHOPAEDIC TECHNOLOGIES, INC., Defendants.	C.A. No. 04-204-JJF

DECLARATION OF DAVID MITCHELL, M.D.

I, Dr. David Mitchell, state under penalty of perjury that the attached **Rebuttal Expert Report of Dr. David Mitchell Regarding the Non-Infringement of U.S. Patent Nos. 5,108,404, 4,969,888 and 6,235,043 (B1)**, dated March 23, 2005, is true and correct to the best of my knowledge, information and belief. If asked, I am prepared to testify as to the matters contained within my expert report.

Dated: April 6, 2005



Dr. David Mitchell