US 20030009147A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2003/0009147 A1

Bonutti (43) Pub. Date: Jan. 9, 2003

(54) BIODEGRADABLE SAC AND METHOD OF USING SAME

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(21) Appl. No.: **10/233,866**

(22) Filed: **Sep. 3, 2002**

Related U.S. Application Data

(60) Division of application No. 09/483,676, filed on Jan. 14, 2000, now Pat. No. 6,468,289, which is a continuation of application No. 09/323,326, filed on Jun. 1, 1999, now Pat. No. 6,174,313, which is a continuation of application No. 08/834,835, filed on Apr. 11, 1997, now Pat. No. 5,935,131, which is a division of application No. 08/695,274, filed on Aug. 9, 1996, now Pat. No. 5,694,951, which is a division of application No. 08/353,494, filed on Dec. 9, 1994, now Pat. No. 5,577,517, which is a division of application No. 08/134,914, filed on Oct. 12, 1993, now Pat. No. 5,403,317, which is a division of application No. 07/545,908, filed on Jun. 28, 1990, now Pat. No. 5,269,785.

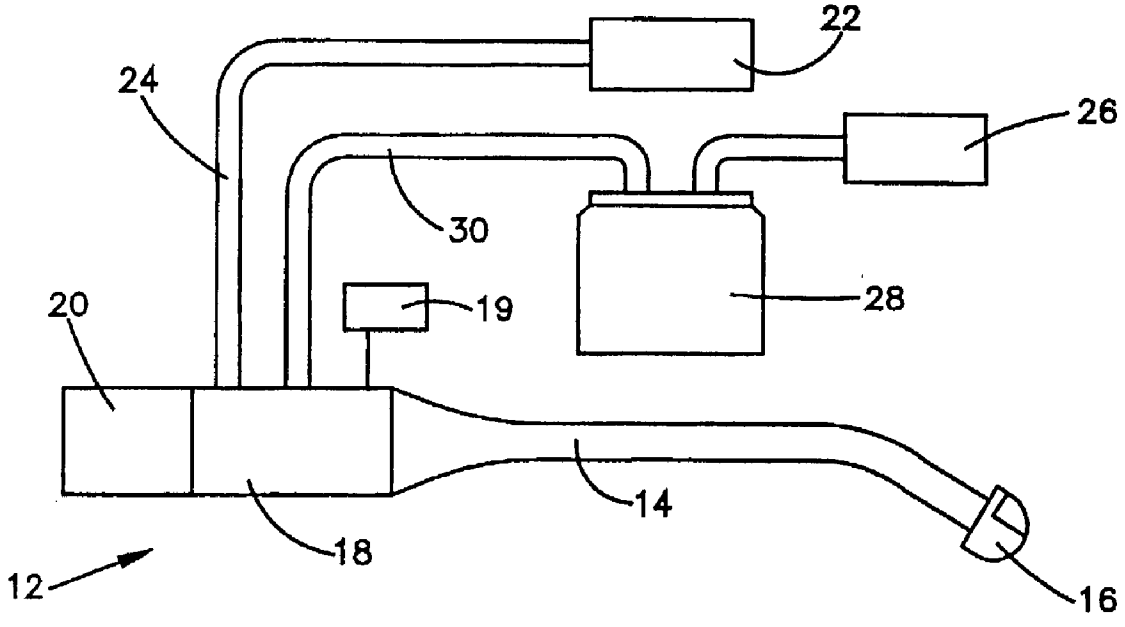
Publication Classification

(51) **Int. Cl.**[7] **A61M 31/00**

(52) **U.S. Cl.** **604/500**

(57) **ABSTRACT**

A percutaneous tissue removal apparatus having a flexible drill shaft, a cutting tip mounted on the shaft a power source for transmitting motion to the shaft to move the cutting tip against tissue and a suction source for removing tissue fragments along the shaft to a location outside the tissue mass while cutting. The apparatus may include a container for collecting one or more selected components of the harvested tissue fragments for implantation of the fragments preferably into the body of the patient from whom they were removed. Where the tissue to be cut is bone, a cutting tip is preferably made of a polymeric material which is softer than the cortical portion of the bone, although the cutting tip may be made of a ceramic or a composite material. A second flexible shaft may be provided either within or about the flexible drill shaft.



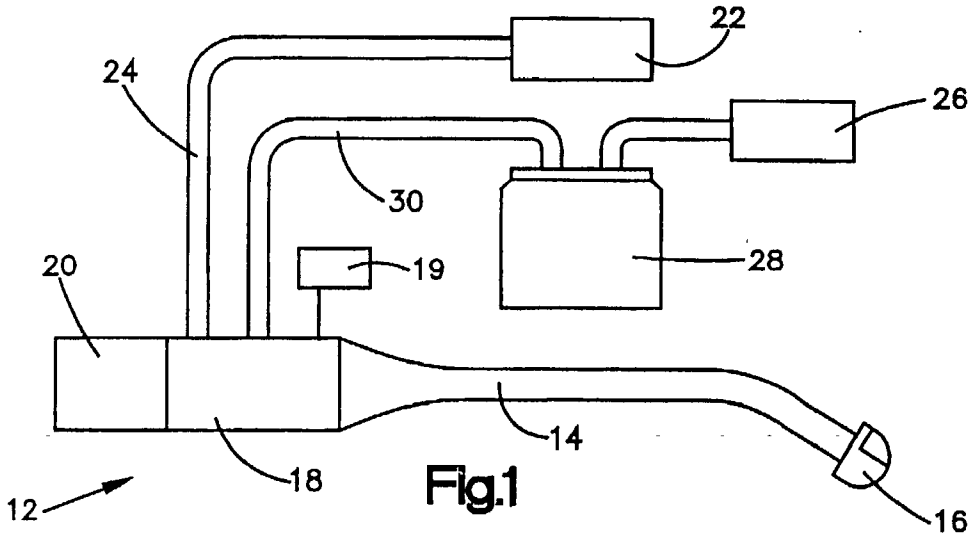


Fig.1

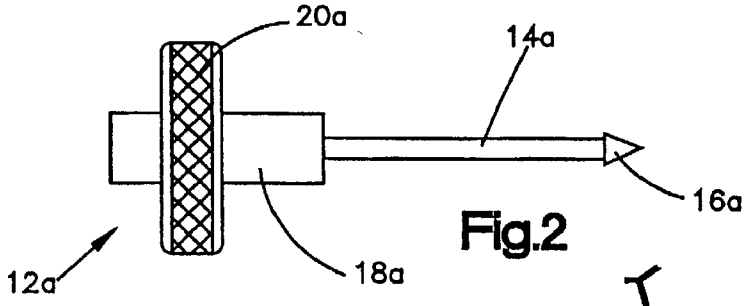


Fig.2

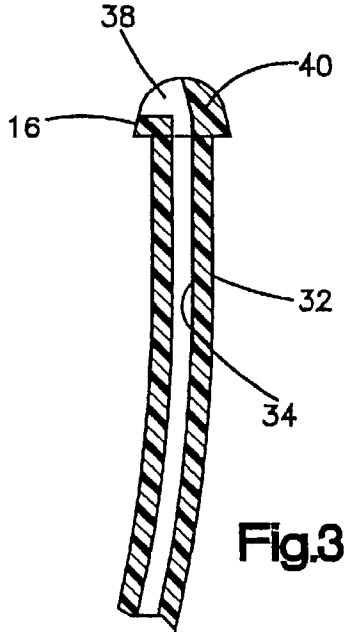


Fig.3

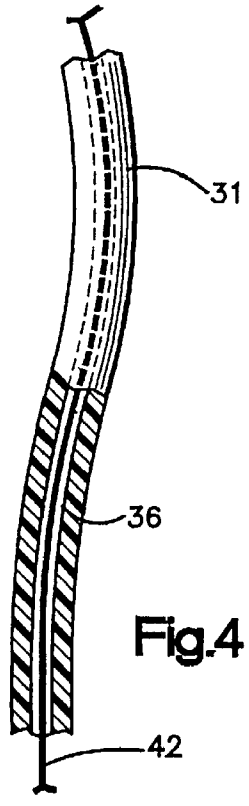


Fig.4

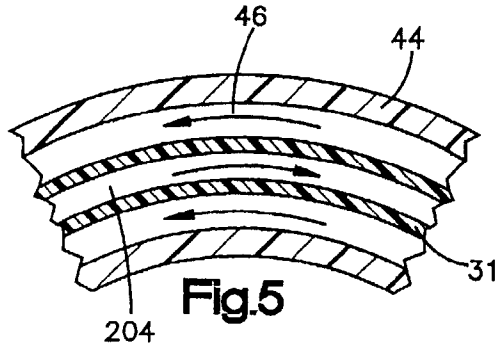


Fig.5

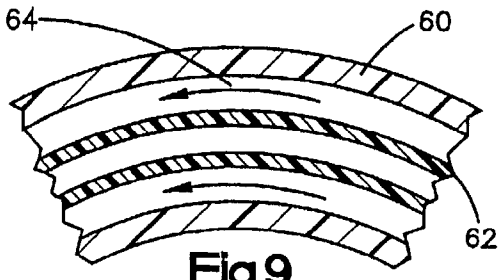


Fig.9

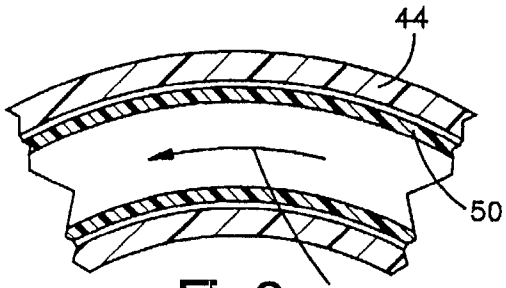


Fig.6

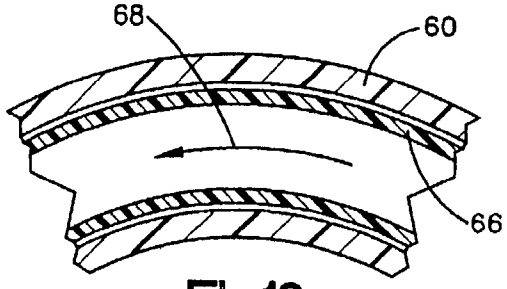


Fig.10

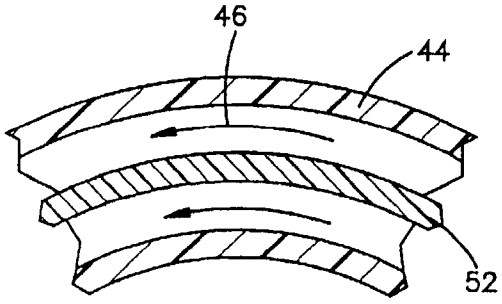


Fig.7

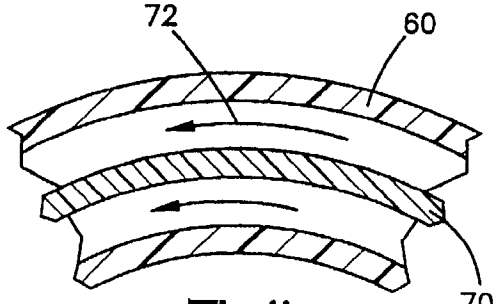


Fig.11

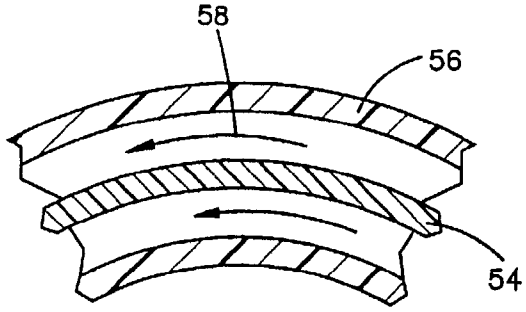


Fig.8

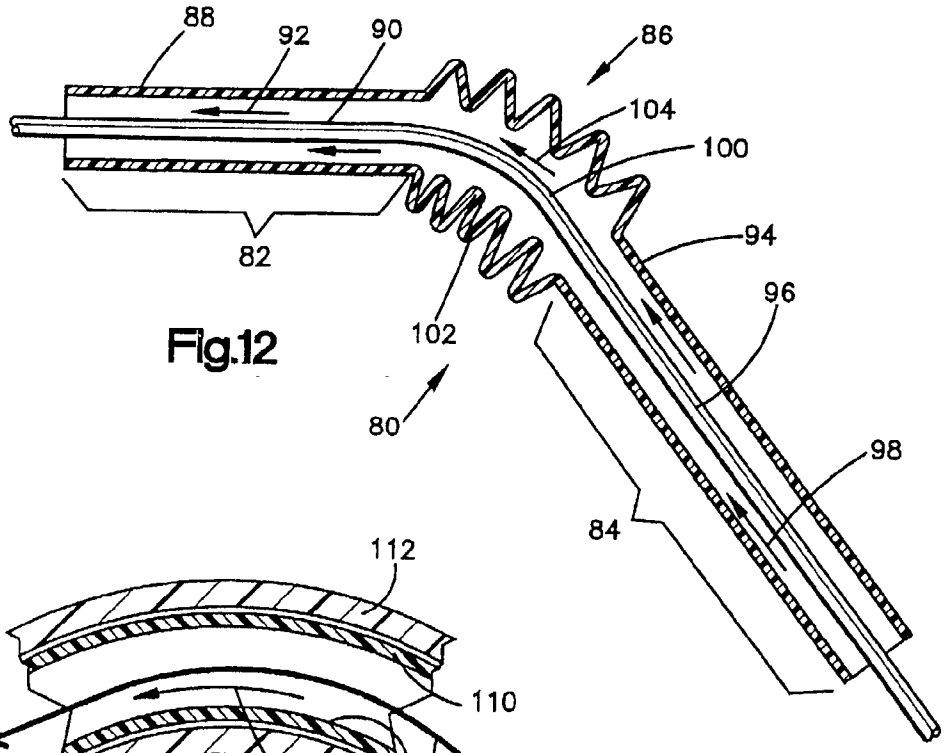


Fig.12

Fig.13

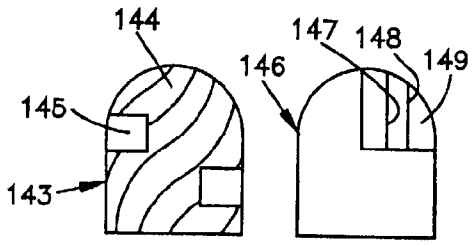


Fig.14F Fig.14G

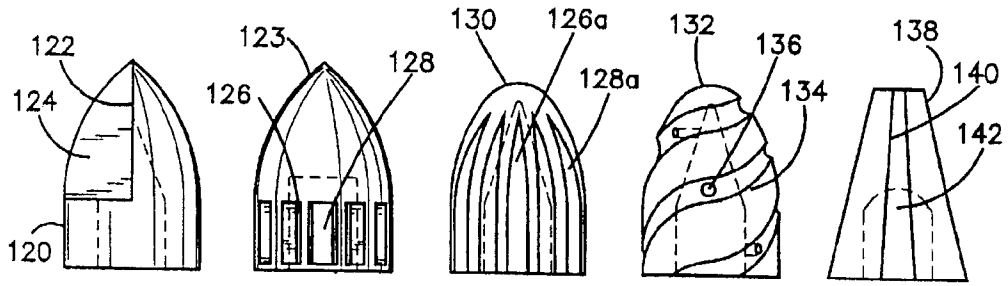


Fig.14A Fig.14B Fig.14C Fig.14D Fig.14E

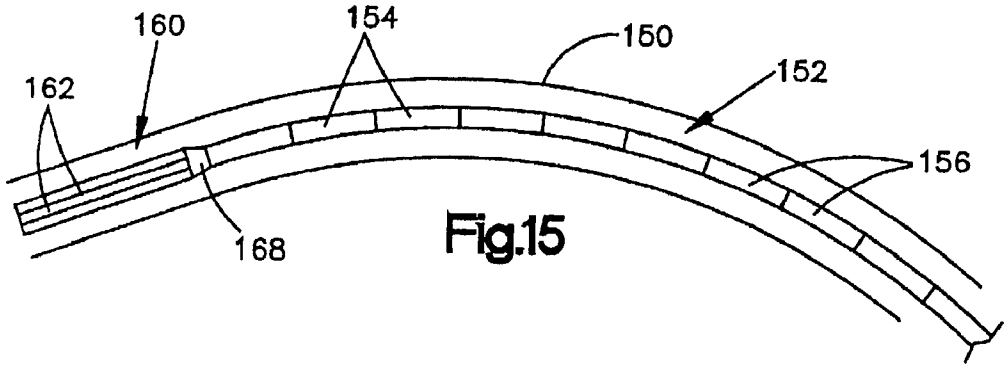


Fig.15

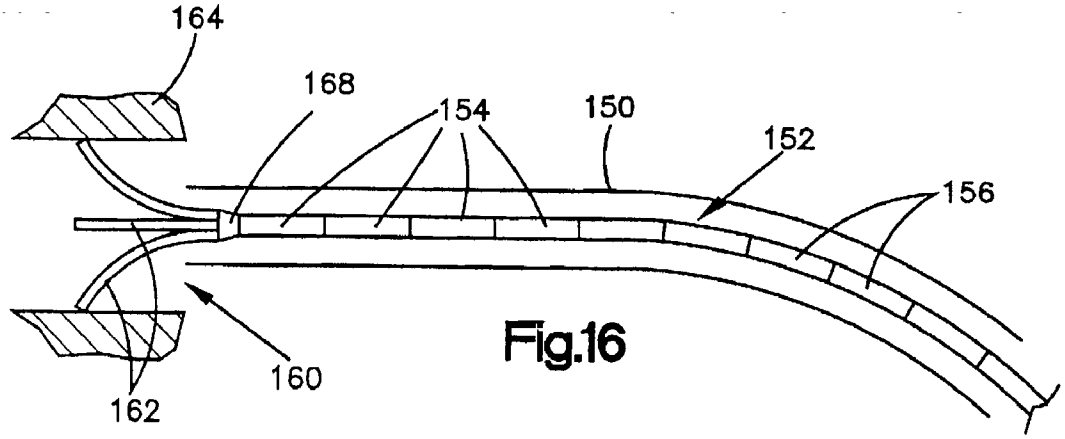


Fig.16

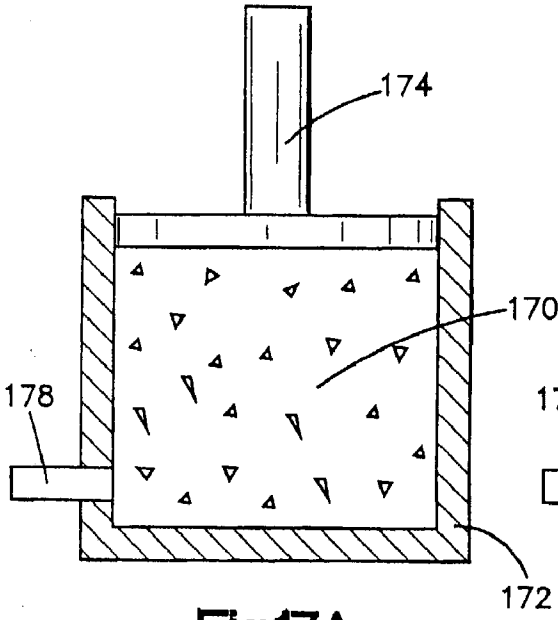


Fig.17A

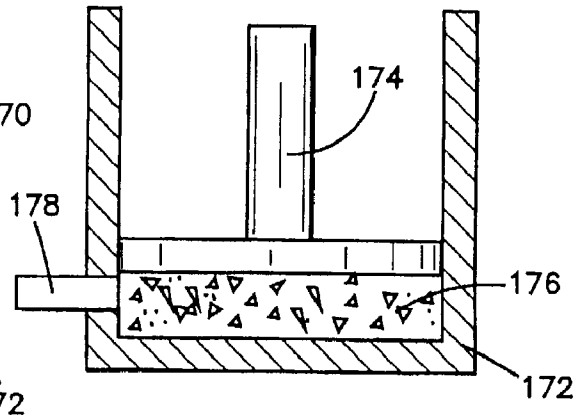


Fig.17B

Fig.18

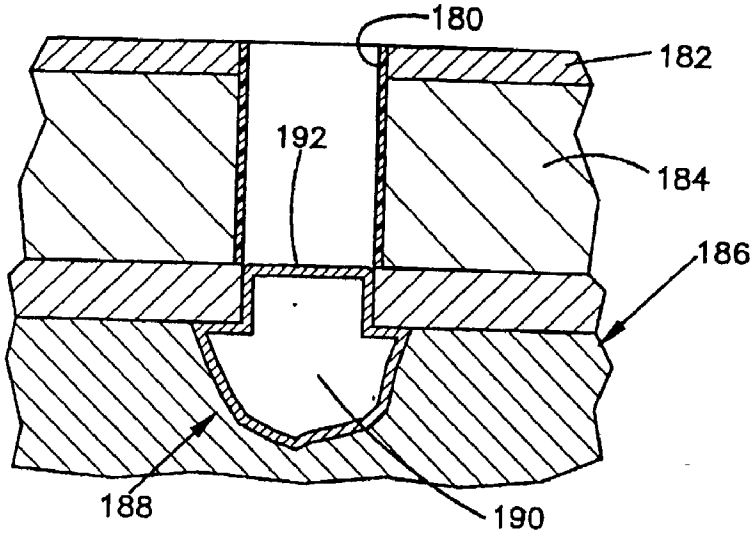


Fig.19A

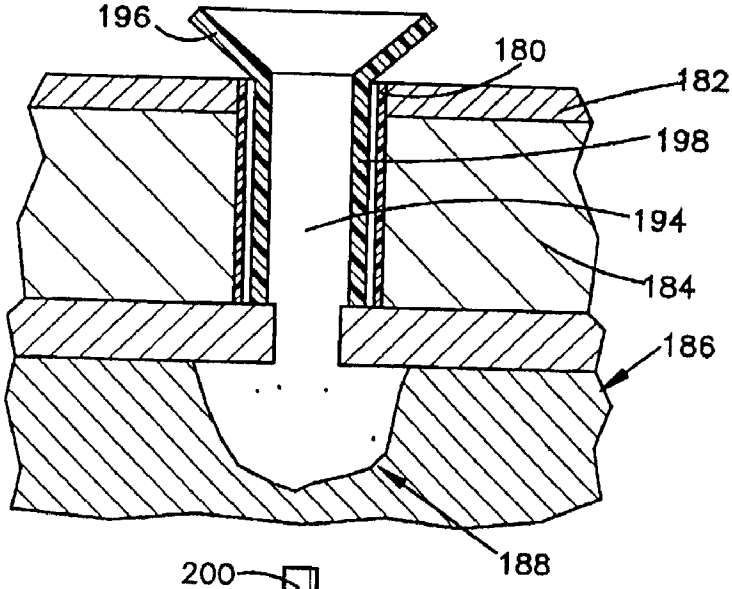
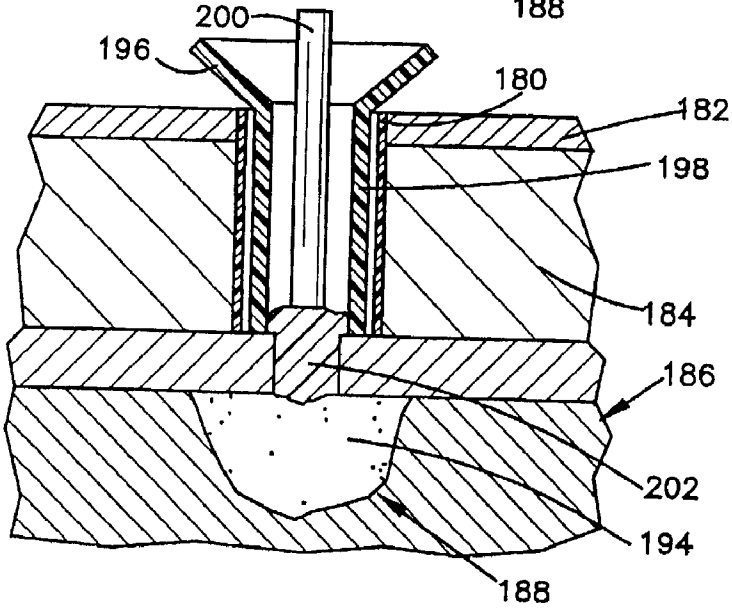


Fig.19B



BIODEGRADABLE SAC AND METHOD OF USING SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a divisional of U.S. patent application Ser. No. 09/483,676, filed Jan. 14, 2000, which in turn is a continuation of U.S. patent application Ser. No. 09/323,326, filed Jun. 1, 1999 (now U.S. Pat. No. 6,174,313 B1). The aforementioned application Ser. No. 09/323,326 is itself a continuation of U.S. patent application Ser. No. 08/834,835, filed Apr. 11, 1997 (now U.S. Pat. No. 5,935,131). The aforementioned application Ser. No. 08/834,835 is itself a divisional of U.S. patent application Ser. No. 08/695,274, filed Aug. 9, 1996 (now U.S. Pat. No. 5,694,951). The aforementioned application Ser. No. 08/695,274 is itself a divisional of U.S. patent application Ser. No. 08/353,494, filed Dec. 9, 1994 (now U.S. Pat. No. 5,577,517). The aforementioned application Ser. No. 08/353,494 is itself a divisional of U.S. patent application Ser. No. 08/134,914, filed Oct. 12, 1993 (now U.S. Pat. No. 5,403,317). The aforementioned application Ser. No. 08/134,914 is itself a divisional of U.S. patent application Ser. No. 07/545,908, filed Jun. 28, 1990 (now U.S. Pat. No. 5,269,785).

BACKGROUND OF THE INVENTION

[0002] 1. Technical Field

[0003] The present invention relates to the field of tissue removal and tissue grafting. More particularly, the present invention relates to an apparatus and method for the percutaneous cutting and removal of selected portions of tissue from a patient and the possible harvesting and implantation of the tissue portion in the donor.

[0004] 2. Description of the Prior Art

[0005] There are various known methods and apparatus for the cutting and removal of tissue fragments from a human. Each of these, however, suffers from one or more deficiencies.

[0006] U.S. Pat. No. 4,832,683 shows an instrument for ultrasonic cutting of bones, with irrigation or suction. However, there is no suction while cutting, no removal of the cut bone or tissue, and no flexibility in the instrument.

[0007] U.S. Pat. No. 4,265,231 shows apparatus for drilling a curved hole having a flexible shaft confined in a rigid tubular sheath, but which shows no removal of cut bone or tissue.

[0008] U.S. Pat. No. 4,541,423 shows apparatus for drilling a curved hole having a flexible shaft confined in a semi-rigid tubular sheath, but which shows no removal of cut bone or tissue.

[0009] U.S. Pat. No. 4,589,414 shows a surgical cutting instrument with a reciprocatory cutting motion, but which has no removal of cut bone or tissue, and no flexibility in the instrument.

[0010] U.S. Pat. No. 4,603,694 shows a rotating arthroscopic shaver with suction, but which is not flexible and which has no removal of cut bone or tissue.

[0011] U.S. Pat. No. 4,751,922 shows a flexible medullary reamer with a plastic shaft and a guide rod, but which has no suction and no removal of the cut bone or tissue.

[0012] U.S. Pat. Nos. 4,798,213, 4,649,918, and 4,142,517 show various apparatus for bone coring.

SUMMARY OF THE INVENTION

[0013] The present invention is a percutaneous tissue removal apparatus including a flexible drill shaft and means for transmitting motion to the shaft. A cutting tip is mounted on the shaft to cut tissue fragments from the tissue. The tissue fragments are removed by suction along the flexible drill shaft to a location outside the body while cutting. One or more selected components of the removed tissue fragments may be collected for implantation, preferably into the body of the patient from whom they were removed. Because the drill shaft is flexible, the surgeon can guide the cutting tip into various locations within the tissue from a small (percutaneous) incision. The surgeon can cut around arcs or angles, rather than only being able to go in a straight line, to reach any desired location, and to avoid vital tissue which would otherwise be in the cutting path. For example, when removing unwanted tissue inside a knee joint the drill shaft can deform, and is therefore less likely to damage normal tissue or joint surfaces. None of these functions is possible with a straight line system.

GENERAL DESCRIPTION OF THE INVENTION

[0014] The present invention is a percutaneous tissue removal device and method. In the preferred embodiments described below, the apparatus and method are illustrated as used for removal of bone tissue, but such description is for illustrative purposes only. The invention is not limited to the removal of bone tissue and may be used for removal of cartilage, muscle, fetal tissue, etc. It may be used to break up and remove kidney stones, in the gall bladder for a stone or tumor, in the stomach, in the colon to remove a polyp or tumor, etc. It can reach spaces not currently available with the straight line systems currently available.

[0015] A percutaneous tissue removal apparatus in accordance with the present invention includes a flexible drill shaft for insertion inside a tissue. A cutting tip is mounted on the drill shaft for cutting the tissue. Either rotating motion or reciprocating motion is transmitted to the drill shaft to move the cutting tip against the tissue to cut tissue fragments from the tissue. While cutting, the tissue fragments are removed by suction to a location outside the body. The drill shaft and cutting tip are small enough to be usable percutaneously. They may also be used for endoscopic, arthroscopic or fiberoptic or open surgery.

[0016] Because the drill shaft is flexible, the surgeon can guide the cutting tip into various locations within the tissue from one percutaneous incision. The surgeon can cut around arcs or angles, rather than only being able to go in a straight line, to reach any desired location, and to avoid vital tissue which would otherwise be in the cutting path. The flexible drill shaft also allows the surgeon when working inside a bone, for example, to keep the cutting tip away from the harder outer cortical bone and to remove only the softer inner cancellous bone. None of these features is available with the current straight line cutting devices.

[0017] The drill shaft may be made of metal, of polymeric material to reduce friction, or of a composite material. Extensive use of polymers in the drill shaft, its housing if provided, and the cutting tip area reduces friction substan-

tially, thus requiring less energy and generating less heat within the tissue. The drill shaft is drivable by hand (for improved feel) or by motor, at variable speeds based on the need for the tissue removed.

[0018] To provide for the collection of the tissue fragments to be harvested, the removal apparatus has an axially extending suction passage along the drill shaft through which the tissue fragments are removed. The suction passage has a smooth lining to keep the tissue fragments or graft material contained and to reduce friction of the harvested tissue fragments. This lining may be the inside diameter of the flexible drill shaft itself, or may be a separate liner sleeve which can be removed and disposed of when it becomes unsanitary or clogged, without having to remove the drill shaft and cutting tip. Alternatively, if a separate guide sleeve or guide rod is used the suction passage may be formed between the drill shaft and the guide sleeve or guide rod. In such a case, the drill shaft may be solid rather than hollow.

[0019] The cutting tip is made of a material which is harder than the material to be cut. The cutting tip may be slightly larger in diameter than the drill shaft. The cutting tip may be made of a polymeric material or a composite material. Alternatively, the cutting tip may be made of a ceramic material. The cutting tip is separable from the drill shaft, and several different cutting tips may be provided in varying hardnesses, so that the surgeon can selectively remove various portions of tissue as desired.

[0020] By virtue of its flexibility, the flexible drill shaft, when removing bone tissue, may stay within the cortical confines of the bone. Alternatively, it may work with a guide device to control the location of the cutting tip within the bone. The guide means may be a guide rod extending within the flexible drill shaft, or a hollow guide sleeve outside the flexible drill shaft. The guide rod or guide sleeve may be rigid in a particular shape, to fit a particular application; or it may be bendable into a particular shape which it will hold; or it may be selectively rigidifiable into a particular shape in situ. The guide means may include structure for positioning the tip of the flexible drill shaft. The guide means may also be inserted into a separate flexible tube system to guide it to a specific location, then removed, allowing the flexible drill to be inserted.

[0021] Fluid may be injected through the flexible drill shaft to a location adjacent the cutting tip to increase the efficiency of the tissue removal and to limit thermal necrosis. Alternatively, a fluid injection passage may extend axially along the flexible drill shaft, the drill shaft. Alternatively, fluid may be injected through the suction passage, alternating with the suction. The fluid injection may be constant or it may be pulsatile in nature. If fluid injection is used, centrifuging of the harvested material may be performed.

[0022] Means for collecting one or more selected components of the harvested tissue fragments may include a known trap or filter connected to the outlet of the suction passage. Removed tissue may be centrifuged to separate its components. Thus, the tissue fragments are not merely removed from the body and may be harvested for implantation of the fragments, preferably into the body of the patient from whom they were removed. In order to maintain the sterility of the tissue removed, the entire suction apparatus including the suction passage and the trap or filter is sterilized, and, if necessary, is disposable.

[0023] With the present invention all work is done by going percutaneously through the skin to a specific tissue area to minimize the damage to skin, muscle, and bone. For example, when removing bone tissue, trauma is limited to a small opening in the hard outer structural cortical bone, limiting postoperative bleeding from the bone which is difficult to stop, because the small operative hole can easily be plugged after the grafting procedure is completed, preventing postoperative bleeding into soft tissue. There is only intraosseous bleeding, so that fewer complications, and less pain, are likely to arise. The operation does not create stress risers which would weaken the bone. Thus, the present invention provides a safe and efficient way to collect and reuse a patient's own tissue.

[0024] Human tissue grafting works best using the patient's own tissue as donor material. Therefore, the harvested tissue may be implanted in the donor's own body for grafting. To implant one or more selected components of harvested bone fragments, for example, a cannula is inserted through the skin and muscle to the area of the bone where the graft is to be placed. A drill or curette is then used to remove a portion of the outer cortical bone. A curette or probe is inserted through the cannula to clear out the area where the graft is to be placed, either in open surgery or through X-ray guidance in percutaneous surgery. The harvested tissue fragments may be packed or compressed into a plug of tissue graft material, of a specific shape, with or without blood or fibrin for adhesion. Or, a retaining material such as a biodegradable mesh may be used to hold the graft material together as a unit. The graft material and its retaining material are then inserted at the graft location in the bone. Alternatively, the graft material is inserted and then sealed in place with a mass of formable polymeric material inserted over the graft material to hold the graft together in position.

[0025] A method of percutaneous tissue removal in accordance with the present invention includes the steps of placing within a tissue mass a flexible drill shaft having mounted thereon a cutting tip for cutting the tissue; transmitting motion to the drill shaft to move the cutting tip against the tissue to cut tissue fragments from the tissue; and removing the tissue fragments by suction to a location outside the tissue mass while cutting the tissue. The method may further include the step of controlling the location of the cutting tip within the tissue with a guide rod, the step of collecting one or more selected components of the harvested tissue fragments, and/or the step of implanting the fragments into the body of the patient from whom they were removed.

BRIEF DESCRIPTIONS OF THE INVENTION

[0026] Further features of the present invention will become apparent to those skilled in the art to which the present invention relates from reading the following specification with reference to the accompanying drawings, in which:

[0027] **FIG. 1** is a schematic view of a tissue removal system in accordance with the present invention and including a flexible drill;

[0028] **FIG. 2** is a schematic view of a hand-powered flexible drill for use in the system of **FIG. 1**;

[0029] **FIG. 3** is a schematic view of a portion of a hollow flexible drive shaft for the flexible drill;

[0030] **FIG. 4** is a schematic view similar to **FIG. 3** and showing a guide rod inside the hollow flexible drive shaft;

[0031] **FIG. 5** illustrates a portion of a flexible drill including a hollow flexible inner cutting shaft within a flexible outer sleeve and a suction passage between the two shafts;

[0032] **FIG. 6** is a view similar to **FIG. 5** with a suction passage within the inner shaft;

[0033] **FIG. 7** illustrates a portion of a flexible drill including a solid flexible inner cutting shaft within a flexible outer sleeve and a suction passage between the two shafts;

[0034] **FIG. 8** illustrates a portion of a flexible drill including a solid formable inner guide rod within a flexible outer cutting sleeve and a suction passage between;

[0035] **FIG. 9** illustrates a portion of a flexible drill including a hollow flexible inner cutting shaft within a solid formable outer sleeve and a suction passage between;

[0036] **FIG. 10** is a view similar to **FIG. 9** with a suction passage within the inner shaft;

[0037] **FIG. 11** illustrates a portion of a flexible drill including a solid flexible inner cutting shaft within a solid formable outer sleeve and a suction passage between;

[0038] **FIG. 12** illustrates a portion of a flexible drill including a relatively flexible portion between two relatively rigid portions;

[0039] **FIG. 13** illustrates the use of a liner sleeve in a suction passage;

[0040] **FIG. 14** is a view illustrating a number of different cutting tips usable with the flexible drill;

[0041] **FIGS. 15 and 16** are schematic views illustrating the provision of a plurality-y of separately inflatable bladders as a guide mechanism for a flexible structure and the operation of a guidance system for locating the tip of the flexible structure;

[0042] **FIGS. 17A and 17B** are schematic views illustrating the forming of harvested tissue fragments into a compressed plug suitable for implantation;

[0043] **FIG. 18** is a schematic view illustrating the implantation of harvested bone fragments using a polymeric mesh as a retainer; and

[0044] **FIGS. 19A and 19B** are schematic views illustrating the implantation of harvested tissue fragments using a formable polymeric sealant as a retainer.

DETAILED DESCRIPTION OF THE INVENTION

[0045] The present invention is described herein with reference to a percutaneous bone removal and harvesting apparatus and method. It should be understood that the present invention is not limited to the removal of bone tissue, but is useful in the removal of any hard or soft tissue in the body such as excess, unwanted, or tumorous tissue or tissue used for reimplantation or grafting.

[0046] A percutaneous bone removal apparatus **10** (**FIG. 1**) in accordance with the present invention includes a flexible drill **12**. The flexible drill **12** has a flexible shaft **14** and a cutting tip **16** at the distal end of the shaft **14**. The proximal end of the flexible shaft **14** is connected by a housing **18** to a motor or other power source **20** to provide rotational motion or reciprocating motion in a manner known in the art. Alternatively, the drill **12** may have an angled drive, such as 90.degree. drive or any angle, with the motor drive connected at an angle to the longitudinal extent of the suction and cutting apparatus.

[0047] Control means indicated schematically at **21** may include one or more switches or valves to turn on or off the suction, irrigation, and motor drive. control A fluid injection source **22** is connected by a fluid injection line **24** to the housing **18** of the flexible drill **12**. A suction source **26** acts through a trap or filter or strainer **28** and a suction line **30** to provide suction capabilities for the flexible drill **12**.

[0048] **FIG. 2** illustrates a flexible drill **12***a* in which the housing **18***a* is connected to a hand controller **20***a*. The hand controller **20***a* allows the surgeon to operate the flexible drill **12***a* by hand, imparting either rotational or reciprocating movement to the flexible shaft **14***a* and cutting tip **16***a*.

[0049] **FIG. 3** illustrates a portion of a basic version of a flexible drill having a cutting tip **16** mounted on a flexible drive shaft **31**. The drive shaft **31** has an outer surface **32** and an inner surface **34** defining a longitudinally extending suction passage **36**. The cutting tip **16** has a cutting edge **40** and an opening **38** through which tissue fragments cut by the cutting tip **16** may be aspirated. The tissue fragments are drawn through the suction passage **36** in the flexible drive shaft **31** and thence into the suction line **30** (**FIG. 1**) for collection in the trap or filter or strainer **28**.

[0050] **FIG. 4** illustrates the use of a pre-inserted guide rod **42** with a flexible drill of the present invention. The guide rod **42** extends through the suction passage **36** of the flexible drive shaft **31**. The guide rod **42** may be any suitable structure including a K-wire or other known device. The cutting tip **16** may have a centrally located opening in its distal end to allow insertion of the flexible drill over the guide rod **42**. The guide rod **42** is first placed in the body, then the flexible drill is inserted over the guide rod **42** and guided to the location from which tissue is to be harvested.

[0051] **FIG. 5** illustrates an embodiment of a flexible drill having an outer sleeve **44** circumscribing a flexible drill shaft **41**. The flexible outer sleeve **44** may be formed of a metal or composite material or may be formed of a polymeric material which may be the same as or different from the material of the flexible inner cutting shaft **31**. The outer sleeve **44** is fixed (non-moving) to minimize tissue damage. A suction passage **46** is defined between the outer surface of the flexible inner shaft **31** to which the cutting tip is attached, and the inner surface of the flexible outer sleeve **44**. Alternatively, as shown in **FIG. 6, a** suction passage **48** may be defined within the flexible inner cutting shaft **50**. In this case, the outer surface of the flexible inner shaft **50** is preferably, as illustrated in **FIG. 6**, in close proximity to the inner surface of the outer sleeve **44** to increase stability. The use of polymeric materials for both the inner shaft **50** and the outer sleeve **44** provides for reduced friction between the sleeve **44** and the shaft **50** for ease of operation and reduced heat generation.

[0052] **FIG. 7** illustrates an alternate embodiment of the apparatus of **FIG. 5** in which the flexible inner cutting shaft

52 is formed as a solid shaft rather than a hollow shaft. The harvested tissue fragments travel through the suction passage **46** between the inner shaft **52** and the outer sleeve **44**.

[**0053**] **FIG. 8** illustrates apparatus similar to **FIG. 7** in which a fixed (nonmoving) inner shaft **54** is made of a solid, formable, material and the cutting tip is mounted on a flexible rotating outer sleeve **56**. Suction is drawn through a suction passage **58** between the shaft **54** and the sleeve **56**. The inner shaft **54** is made from a semi-rigid material which is bendable to a desired curvature, at the use site, to select the curvature of the hole to be drilled, and which is rigid enough to retain that curvature in use while the drill shaft **56** rotates around it. Such material is disclosed in U.S. Pat. No. 4,541,423, the disclosure of which is incorporated herein by reference.

[**0054**] **FIGS. 9, 10** and **11** illustrate embodiments of the flexible drill of the present invention in which a flexible inner cutting shaft, which may be hollow or solid, is disposed within a non-moving formable outer sleeve. The formable outer sleeve **60** is made of a semi-rigid bendable shape retaining material as described above with reference to **FIG. 8**. In **FIG. 9, a** hollow flexible inner cutting shaft **62** is disposed within the outer sleeve **60** and defines therebetween a suction passage **64**. In **FIG. 10, a** hollow flexible inner cutting shaft **66** is disposed in close proximity to and within the outer sleeve **60**, with a suction passage **68** formed within the flexible inner cutting shaft **66**. In **FIG. 11, a** solid flexible inner cutting shaft **70** is disposed within the outer sleeve **60**, defining therebetween a suction passage **72**.

[**0055**] **FIG. 12** illustrates a portion of a flexible drill shaft **80** in accordance with the present invention in which a pair of relatively rigid drill portions **82** and **84** are joined by a relatively flexible drill portion **86**. The relatively rigid drill portion **82** includes an outer sleeve **88**, an inner shaft **90**, and a suction passage **92** therebetween. The relatively rigid drill portion **84** includes an outer sleeve **94** like the outer sleeve **88**, an inner shaft **96** like the inner shaft **90**, and a suction passage **98** therebetween. The drill portion **86** includes a relatively flexible inner shaft portion **100** disposed within a relatively flexible outer sleeve portion **102**, defining therebetween a suction passage **104**. The relatively flexible inner shaft portion **100** connects the relatively rigid inner shaft portions **90** and **96**. The relatively flexible outer sleeve portion **102** connects the relatively rigid outer sleeve portions **88** and **94**. The suction passage **104** in the relatively flexible drill shaft portion **86** connects the suction passages **92** and **98**. Either the inner shaft or the outer sleeve of the flexible drill **80** may have a cutting tip mounted thereon. Thus, with a flexible drill shaft made in this manner, it is not necessary that the entire drill shaft be made of flexible materials, but rather "joints" such as are formed by the relatively flexible portion **86** may be placed along the longitudinal extent of a relatively rigid drill shaft as desired.

[**0056**] **FIG. 13** illustrates how a disposable single-use liner sleeve **110** may be used in a flexible drill of the present invention. The liner sleeve **110** shown in **FIG. 13** is located within an outer sleeve **112** and is shown about a guide rod or guide wire **114**. Suction is drawn through a passage **116** within the liner sleeve **110**. The disposable single-use liner sleeve **110** provides an absolutely sterile environment through which harvested tissue fragments may pass. The inner surface **118** of the liner sleeve **110** is extremely smooth in order to facilitate passage of the harvested tissue fragments therethrough. It should be understood that a liner sleeve like the liner sleeve **110** may be used with any suitable flexible drill shaft configuration in accordance with the present invention, and not merely with the configuration shown in **FIG. 13**.

[**0057**] **FIG. 14** illustrates several different cutting tips which may be attached in a known manner to a flexible drill shaft in accordance with the present invention. The technology for the cutting tips is not specific to the present invention, but rather the cutting tips may be designed in accordance with known principles.

[**0058**] The cutting tip **120** (**FIG. 14**) has a cutting edge **122** at least partially defining an opening **123** through which suction is drawn. The cutting tip **124** includes a plurality of cutting edges **126** defining a plurality of suction openings **128** disposed along the outer circumferential portion of the cutting tip **124**. The cutting tip **130** is similar to the cutting tip **124** but includes cutting edges **126***a* and suction openings **128***a* which extend to the end of the cutting tip **130**. Furthermore, the cutting tip **130** is blunt rather than sharp, to avoid perforation of tissue, such as bones.

[**0059**] The cutting tip **132** has a spiral cutting edge **134** defining a spiral suction opening **136**. The cutting tip **138** has at least one longitudinally extending cutting edge **140** at least partially defining a longitudinally extending suction opening **142**. The cutting tip **143** is formed as a burr with fluted cutting edges **144** and suction openings **145**, and is especially suited for shaving operations such as removal of bone spurs, etc. The cutting tip **146** has twin cutting edges **147** and **148** and a suction opening **149**. The cutting edges **157** and **148** can be configured with the leading edge to grab the tissue and the trailing edge to cut the tissue.

[**0060**] The configuration of a cutting tip for use in accordance with the present invention is a design choice within the skill of the art. The goals to be met are proper cutting and suction capabilities, controllability and shape so as to avoid unwanted damage to areas of tissue not to be cut. For example, when removing the softer cancellous portion of bone, the cutting tip may be made of a material which is harder than the cancellous material of the bone but softer than the cortical portion of the bone to avoid damage thereto. Metal may be useful, and suitable polymers are also readily available. Ceramic materials and composites are also suitable. Also, the cutting tip may be arranged as a rotating flexible shaft within a fixed flexible outer shaft, with a cutting edge on the rotating shaft to cut tissue off against the fixed edge. In such a case, the apparatus may be advantageously configured with one shaft being metal and the other polymeric, to minimize friction and heat buildup.

[**0061**] **FIGS. 15 and 16** illustrate an alternate guidance system for positioning a flexible drill shaft **152** and its associated cutting tip. Disposed within the sleeve **150** is a guidance mechanism **152** including a plurality of inflatable elements spaced serially. The inflatable elements, when inflated, rigidify and become straight, while when in the deflated condition they are soft and flexible and may be curved or bent. Thus, as seen in **FIG. 15**, both the inflatable elements designated **154** and the inflatable elements **156** are curved. In **FIG. 16**, the inflatable elements **154** have rigidified and straightened, while the inflatable elements **156** remain in their curved position. The inflatable elements may

also be accordion shaped, expanding in length as they are inflated. The mechanism **152** may be augmented with a known cable guidance system.

[**0062**] By selectively and individually controlling the rigidification of any or all of the inflatable elements of the mechanism **152**, the inflatable mechanism **152** and its associated outer sleeve **150** may be selectively formed into almost any desired shape or position. Suitable control and valving apparatus is provided for controlling the inflation of the inflatable elements. Such apparatus may be, when only a few elements are present, a simple mechanical valving apparatus. When more elements are present, or more sophisticated or complex control thereof is desired, a microprocessor may be used to control the inflation of each segment. Separate inflation and deflation lines can be used, or one line can, by alternating valving, serve both functions. In such case, the control signals may be multiplexed down the structure via electric wire, optical fiber, or radio control, for example.

[**0063**] At the distal end of the mechanism **152** is a tip guidance mechanism **160** including a plurality of inflatable members **162**. The inflatable members **162** when in a deflated condition are flexible and relatively straight. When inflated, as shown in **FIG. 16**, the members **162** assume a preformed shape which may be curved or straight and which is illustrated herein as a curved shape, bending radially outwardly to engage the surface of adjacent tissue **164** and curve the end of the device into an appropriate position. The members **162** may be constructed, using known principles, to assume any desired shape. By controlling the positioning of one or more of the elements **162**, the tip portion **168** of the guidance mechanism **152** may be selectively placed in any position relative to the tissue **164**, thus positioning the end of the sleeve **150**. The air bladder guidance system as described may be used in conjunction with a flexible tube separate from the flexible drill shaft, order to guide the flexible tube to a specific location and position it there, thereafter removing the guidance system and allowing a flexible drill to be inserted.

[**0064**] Means for collecting one or more selected components of the harvested tissue fragments includes a mechanism **28** (**FIG. 1**) which may be a known trap or filter connected to the outlet of the suction passage **30**. Removed tissue may also be centrifuged if necessary or desired, keeping the components such as bone, cells, and blood and discarding fluid. These components and connections, and their uses, are well known in the art and thus are not described herein in greater detail. The harvested tissue fragments are not merely removed from the body of the patient, but are also collected in the structure **28** and thus harvested or saved for later implantation of the fragments, preferably into the body of the patient from whom they were removed. Such harvesting and implantation are desirable because human tissue grafting works best using the patient's own tissue as donor material.

[**0065**] In preparing the harvested graft material for implantation, the tissue fragments alone are spun or compressed (see **FIG. 17B**) to form them into the desired shape. When the tissue is harvested, blood and blood clots are often drawn along with the tissue fragments. The blood component fibrin is a sticky clotting component, and can be used to aid in holding the tissue fragments together for implantation. Thus, the blood can be is separated from the tissue fragments and then spun to separate the fibrin for use with the tissue fragments. Alternatively, the entire mass of tissue fragments and blood is compressed into a specific shape to form the mass into a specific, appropriate shape for implantation into the body.

[**0066**] The surgeon can also place other substances into the graft material to be implanted, such as other tissue graft material, collagen, antibiotics, or ceramic hydroxyapatite or tricalcium phosphate to aid in bone ingrowth. In such a case, when the blood or fibrin is used also, the graft has the adhesive qualities of the blood or fibrin and the biological properties of the bone (or other) tissue, along with the appropriate medical properties of any other material included.

[**0067**] Harvested tissue fragments before implantation are preferably packed or compressed into a plug of tissue graft material. Alternatively, the tissue fragments may be left in a more loose state, or only certain selected cells, components, or tissue fragments are used. Any suitable means of packing or compressing fragments may be used. **FIGS. 17A and 17B** illustrate schematically a simple apparatus for doing so. As viewed in **FIGS. 17A and 17B**, the harvested tissue pieces **170** are placed into a form or mold **172** and then compressed by a movable compressor **174** to form a plug **176** of a desired shape or size. Unwanted fluid drains out through one or more fluid outlets **178**, while the graft, cells, fibrin, and blood clot tissues remain within the form **172**.

[**0068**] To implant one or more selected components of the harvested tissue fragments, for example in grafting bone tissue onto a bone, a cannula **180** is inserted through the skin **182** and muscle **184** to the area of the bone **186** where the graft is to be placed. A curette or probe is then inserted through the cannula **182** to clear out the area **188** where the graft is to be placed.

[**0069**] The harvested tissue fragments are compacted or compressed into a plug **190** of tissue graft material. A retaining material such as a known biodegradable or other polymeric mesh **192** is then used to hold the graft material **190** together as a unit. The retaining material may also be a sac of biodegradable material used to hold the graft material. The sac can be closed by a clamp or by crimping or heat sealing. The graft material **190** and its retaining material **192** are then inserted into the graft area of the bone. The cannula **180** may then be removed. Alternatively, the tissue graft material may be held in place by a mass of biodegradable or other polymeric material used as a sealant for the opening in the bone **186**. The graft material can be compressed or spun into a specific shape. Thus, if an implant is needed to fit a specific shape of bone defect, the graft material can be formed in the shape needed and packed directly into the bone gap.

[**0070**] The bone graft material may also be implanted in the loose condition as described above. The bone graft material **194**, if loose, can be inserted through a funnel **196** and a sleeve **198** located within the cannula **180** to the area **188** to be grafted. It is then packed in place as desired using a suitable instrument. Next, an injector **200** is used to inject a mass of flowable biodegradable or other polymeric material **202** for use as a sealant to seal the bone graft material **194** in position. The use of a flowable biodegradable material is preferable in that it allows the surgeon to form in situ

a custom shaped sealant plug to seal the opening in the tissue graft area, which will eventually resorb as new tissue grows into its place.

[0071] The apparatus may include, as noted above, fluid injection means **22** and **24** for injecting fluid through the flexible drill to a location adjacent the cutting tip to aid in cutting and removal of the harvested tissue fragments. For example, in the drill shaft structure illustrated in **FIG. 5**, fluid may be injected through a fluid injection passage **204** within the flexible inner cutting shaft **31**, while suction is drawn in the opposite direction through the suction passage **46**. Alternatively, the suction may be intermittently discontinued and fluid may be injected through the suction passage, alternating with the suction. The fluid injection may be constant or it may be pulsatile in nature.

[0072] The present invention thus provides a method of percutaneous tissue removal which includes the steps of placing adjacent to a tissue mass a flexible drill shaft **14** having mounted thereon a cutting tip **16** for cutting the tissue; transmitting motion to the drill shaft **14** to move the cutting tip **16** against the tissue to cut tissue fragments from the tissue; and removing the tissue fragments by suction to a location outside the tissue mass while cutting the tissue. The method may further include the step of controlling the location of the cutting tip within the tissue with a guide mechanism, the step of collecting one or more selected components of the harvested tissue fragments, and/or the step of implanting the fragments into the body of the patient from whom they were removed.

[0073] From the above description of the invention, those skilled in the art will perceive improvements, changes and modifications. Such improvements, changes and modifications within the skill of the art are intended to be covered by the appended claims.

What is claimed is:

1. A surgical method comprising the steps of:

creating a space in a tissue; and

introducing a biodegradable sac into the created space.

2. The method of claim 1 wherein the sac contains fluid.

3. The method of claim 2 wherein the sac is closed by clamping, crimping, or heat sealing.

4. The method of claim 2 wherein the sac contains a material selected from the group consisting of tissue grafts, collagen, antibiotics, and bone growth promoting substances.

5. The method of claim 1 wherein the space is created by inserting an inflatable member into the tissue and inflating the inflatable member.

6. The method of claim 5 further comprising the step of at least partially deflating the inflatable member.

7. The method of claim 6 further comprising the step of removing the inflatable member from the tissue prior to introduction of the sac.

8. The method of claim 5 further comprising the step of inserting at least a portion of a sleeve into a patient's body and wherein the inflatable member is inserted into tissue through the sleeve.

9. The method of claim 8 further comprising the step of guiding the sleeve to the tissue with a guide wire.

10. The method of claim 8 further comprising the step of removing tissue fragments from the tissue.

11. The method of claim 8 wherein the sleeve is inserted percutaneously through skin.

12. The method of claim 5 wherein the tissue is bone tissue.

13. The method of claim 5 wherein the tissue is selected from the group consisting of bone, cartilage, muscle, and fetal tissue.

14. The method of claim 5 wherein at least one of the steps of inserting and inflating is performed under x-ray guidance.

15. The method of claim 5 wherein at least one of the steps of inserting and inflating is performed under endoscopic, arthroscopic, or fiber optic guidance.

16. The method of claim 5 wherein the inflatable member includes a plurality of inflatable elements.

17. The method of claim 16 wherein the inflatable elements are selectively inflated so that the inflatable member assumes a predetermined shape.

18. The method of claim 17 wherein a microprocessor is used to control the selective inflation.

19. The method of claim 5 wherein the inflatable member is flexible and substantially straight when deflated and assumes a preformed shape when inflated.

20. The method of claim 19 wherein the inflatable member bends radially outward.

21. A surgical method comprising the steps of:

inserting at least a portion of an elongate member into tissue;

inflating an inflatable member extending beyond a distal end of the elongate member so that the inflatable member engages a surface of tissue when inflated;

at least partially deflating the inflatable member; and

introducing a sac into at least a portion of space previously occupied by the inflatable member.

22. The method of claim 21 further comprising the step of inserting at least a portion of a sleeve into a patient's body and wherein the elongate member is inserted into tissue through the sleeve.

23. The method of claim 22 wherein the elongate member includes a plurality of inflatable elements.

24. The method of claim 23 wherein the inflatable elements are substantially accordion shaped and expand in length when inflated.

25. The method of claim 23 wherein the inflatable elements are selectively inflated so that the elongate member assumes a predetermined shape.

26. The method of claim 25 wherein a microprocessor is used to control the selective inflation.

27. The method of claim 21 wherein the inflatable member is flexible and substantially straight when deflated and assumes a preformed shape to engage a surface of tissue when inflated.

28. The method of claim 27 wherein the inflatable member bends radially outward.

29. The method of claim 21 further comprising the step of guiding the elongate member to tissue with a guide wire.

30. The method of claim 21 further comprising the step of removing tissue fragments from tissue.

31. The method of claim 21 wherein the elongate member is inserted percutaneously through skin.

32. The method of claim 21 wherein the surface of tissue includes tissue selected from the group consisting of bone, cartilage, muscle, and fetal tissue.

33. The method of claim 21 wherein at least one of the steps of inserting and inflating is performed under x-ray guidance.

34. The method of claim 21 wherein at least one of the steps of inserting and inflating is performed under endoscopic, arthroscopic, or fiber optic guidance.

35. A surgical method comprising the steps of:

implanting a pouch made of a biodegradable material into a body of a patient;

introducing a fluid into the pouch; and

closing the pouch to retain the fluid in the pouch.

36. The method of claim 35 wherein the pouch is closed by clamping, crimping, or heat sealing.

37. The method of claim 35 wherein the pouch contains a calcium-containing material.

38. The method of claim 35 wherein the pouch is implanted into bone.

39. The method of claim 35 wherein the pouch is implanted into a space surgically created in a tissue.

40. The method of claim 39 wherein the space is created by inserting an inflatable member into the tissue and inflating the inflatable member.

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