



(11) **EP 1 845 862 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention
of the grant of the patent:
30.07.2014 Bulletin 2014/31

(21) Application number: **06720112.9**

(22) Date of filing: **02.02.2006**

(51) Int Cl.:
A61B 17/00 (2006.01)

(86) International application number:
PCT/US2006/003616

(87) International publication number:
WO 2006/083988 (10.08.2006 Gazette 2006/32)

(54) **ULTRASONIC CUTTING DEVICE**

ULTRASCHALLSCHNEIDVORRICHTUNG

DISPOSITIF DE COUPE A ULTRASONS

(84) Designated Contracting States:
**AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI
SK TR**

(30) Priority: **02.02.2005 US 50265**
02.02.2005 US 50158

(43) Date of publication of application:
24.10.2007 Bulletin 2007/43

(73) Proprietor: **DePuy Spine, Inc.**
Raynham, MA 02767-0350 (US)

(72) Inventors:
• **JONES, Bryan S.**
West Roxbury, MA 02132 (US)

• **RAMSAY, Christopher**
West Wareham, Massachusetts 02576 (US)

(74) Representative: **Orr, Robert et al**
Urquhart-Dykes & Lord LLP
Tower North Central
Merrion Way
Leeds LS2 8PA (GB)

(56) References cited:
EP-A1- 0 482 195 WO-A-01/60268
WO-A-99/51149 US-A- 5 382 251
US-A- 5 792 044 US-A- 5 938 633
US-A- 5 938 633 US-B1- 6 425 906
US-B1- 6 440 138

EP 1 845 862 B1

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] The present invention relates to an ultrasonic cutting device, and more particularly to a system for cutting bone using an ultrasonic cutting device while preventing heat damage to the bone and neighboring tissue.

[0002] The use of ultrasonic medical devices in surgery is widely known in various surgical fields. Traditional surgical instruments using ultrasonic frequencies typically use the ultrasonic energy to dissect, coagulate, and cut living tissue during surgery. Existing ultrasonic surgical devices typically employ an ultrasonic transducer to translate electrical energy provided to the transducer into mechanical energy for use in the intended surgical procedure. The mechanical vibratory motion is typically delivered to a distal end of the surgical instrument where a cutter is located. Due to the mechanical vibratory motion, heat is generated at the cutter. In traditional medical procedures this heat is a sought after byproduct of the ultrasonic mechanical energy delivered to the cutter, as the heat aids in the coagulation of tissue that is cut by the surgical instrument.

[0003] The heated output of traditional ultrasonic surgical devices, however, does introduce several inherent problems when used in various forms of surgery. If these devices are used to attempt to cut bone, for example, the high concentrated heat and mechanical vibration can result in the temporary or permanent loss of blood supply to the region of bone in contact with the surgical device. This loss of blood supply in the bone is associated with necrosis of the bone, wherein bone tissue dies. Such death of bone tissue is not clinically desirable. In light of this, the use of ultrasonic cutting techniques with dense materials such as bone is not practical and is generally avoided. When faced with a need to cut bone, traditional invasive procedures are generally used. These invasive procedures generally require a larger incision and expose a patient to a greater risk of injury or infection. Furthermore, traditional mechanical means used to cut bone often employ vibrating or rotating instruments. Such instruments may not differentiate between bone and surrounding soft tissue, therefore the potential remains for unintentional damage to the surrounding soft tissue which may result in permanent injury to a patient.

[0004] Furthermore, existing bone cutting surgical devices use a combination of low frequency, located outside of the ultrasonic range, and low amplitude levels to slowly cut through bone. With such an approach, however a long period of time is required to cut through a region of bone. During a surgical procedure where the patient is under the effects of anesthesia, a surgeon generally wishes to minimize the time that the procedure takes to perform. While increasing the frequency or amplitude of a bone cutting device would decrease the time required to cut through the bone, such an increase of frequency or amplitude results in excessive heat generation at the cutter and the problems discussed above. Additionally, the high heat of the device results in cauterization of soft

tissue which may result in irreversible damage to a patient.

[0005] International Patent Application No. PCT/US99/07652 to Kyphon Inc. (Publication No. WO-99/51149) discloses structures and methods for creating cavities in interior body regions. In one embodiment, a linear movement tool capable of forming a cavity in a targeted treatment area is disclosed which has a stylet that carries a transmitter capable of transmitting energy that cuts tissue. A connector couples the transmitter to a source of energy through a suitable energy controller. The transmitter can propagate ultrasonic energy at harmonic frequencies suitable for cutting the targeted tissue.

[0006] EP 0482195 discloses a device according to the preamble of claim 1.

[0007] According to an aspect of the present invention, there is provided an ultrasonic surgical cutting system as claimed in claim 1.

[0008] In light of the inherent problems and concerns of existing surgical cutting techniques, a cooling mechanism attached to the cutter of an ultrasonic surgical device is beneficial. When the ultrasonic device is used to cut bone, reduction of heat at the cutter prevents bone necrosis. Additionally, as the cutter is operating at a less elevated temperature, damage to tissue surrounding the cutter is less of a concern. In light of this, should a cooled ultrasonic cutter stray from the intended subject and accidentally come into contact or close contact with an unintended region of tissue, the likelihood of damage to this tissue is reduced.

[0009] The present invention may relate to surgical cutting devices wherein ultrasonic vibration can be used in conjunction with a cooling mechanism. Using a cutting and cooling arrangement, as provided in the present invention, a cooled cutter can be used in cutting hard tissues such as bone, and is further capable of preventing heat related damage to hard or soft tissue surrounding the site of intended use.

[0010] Providing an ultrasonic cutting device wherein the cutter is maintained at a reduced temperature offers numerous advantages as compared to existing surgical devices. Firstly, the combination of ultrasonic cutting frequencies provides for speedy removal of bone during a surgical procedure. Additionally, as the cutting tip is at a reduced operating temperature, traditional problems with bone necrosis due to heat are reduced. In light of this, damage to the region of hard or soft tissue surrounding the location of the cut are minimized.

[0011] Additionally, the inherent concerns of a surgeon when using a high-heat ultrasonic cutting device in close proximity to hard or soft tissue that is not being cut are further eliminated by a ultrasonic surgical device that maintains a reduced cutter temperature. For example, extensive necrosis to cortical bone has been reported at temperatures of 70° C. The temperature threshold where tissue damage occurs has been found to be 56° C. Some studies have correlated thermal damage to tissue to the magnitude of temperature and the period of time during

which the tissue is subjected to damaging temperatures. This thermal damage has been shown to affect bone reformation. Heating bone to 47°C or 50°C for 1 minute can cause significantly reduced bone reformation. Furthermore, nervous tissue is particularly sensitive to elevated temperatures and may become damaged at temperature at 42° C. In light of this, the present invention may provide a reduced heat cutting tip such that damage to hard of soft tissue in the region to be cut is prevented.

[0012] In one embodiment of the present invention, during a surgical procedure where bone is to be cut, should a surgeon accidentally stray from the intended target bone and come into contact with surrounding nervous tissue, a reduced temperature ultrasonic cutting device is less likely to cause damage to the nervous tissue. In light of this, unintended nerve damage and paralysis is subsequently avoided while using a reduced temperature ultrasonic cutting device.

[0013] The ultrasonic cutting system of the present invention can perform lateral cutting operations. For example, using the present invention, a surgeon can laterally cut a region of bone from within a predefined hollow provided in the bone. For example, when used during spinal surgery, the present invention offers a surgeon the benefit of a compact ultrasonic device that can be readily guided down a predefined hollow pathway to a fixed depth. In one such surgical procedure, namely a stenosis correction procedure, the pedicles of a vertebrae are cut at corresponding points such that the pedicle can be separated from the main portion of the vertebral segment. Such a procedure is defined in U.S. Patent Application No. US 2003/0212400 to Bloemer, and US Patent No. US 6,358,254 B1 to Anderson. In accordance with the Bloemer application and Anderson patent, a hollow pathway is provided in the pedicle region of a vertebra. This hollow pathway can be generated using existing drilling techniques. Following the drilling of a hollow pathway, a need exists to cut through the material of the pedicle region such that an expandable screw may be placed within the hollow pathway. The required cutting, if completed from within the predefined hollow region, must be lateral in nature. The present invention, and its lateral cutting aspects, allows for the predefined hollow in the bone to be used to properly orient the surgical instrument. This expandable screw, placed in the now severed pedicle, allows for the separation of the pedicle from the main portion of the vertebrae such that stenosis is eliminated.

[0014] Using the present invention, the pedicle region can be carefully cut at fixed locations in a lateral manner such that the expandable screw can later be implanted and expand. Such an arrangement eliminates the potential for error in cutting a region of a vertebra, as the predefined hollow is used to orient the cutter, and further provides a readily repeatable cut along various regions of a vertebra. Additionally, the present ultrasonic cutter is easily operable by a surgeon, requiring only a simple insertion and revolution of a hand piece assembly. In light of this, when used in conjunction with a predefined hollow

pathway, spinal surgery can be performed in a minimally invasive manner such that repeatable results can be obtained without unintended damage to surrounding soft tissue. As the surgical procedure can be less invasive than traditional techniques, unnecessary trauma to a patient is prevented and the potential for infection is greatly reduced.

[0015] Additionally, when the device is employed using a high amplitude signal, soft tissue can be cut. As the present invention can include a cooled cutter, the cooled cutter arrangement is such that soft tissue cut by the present invention does not unnecessarily stick to the cutter.

[0016] The present invention will become better understood with reference to the following description and accompanying drawings, wherein:

FIGURE 1 is a is an illustrative graphical embodiment of a system for use with the present invention in accordance with one aspect of the present invention.

FIGURE 2A is an illustrative embodiment of the present invention in a state where the cutter is retracted while located in a predefined hollow.

FIGURE 2B is an illustrative embodiment of the present invention in a state where the cutter is extended while located in a predefined hollow.

FIGURE 2C is a detailed view of an illustrative embodiment of a portion of the system, wherein the internal workings of the rotatable hand piece are detailed.

FIGURE 3A is a flowchart illustrating the steps required in spinal stenosis correction when the pedicle region of a vertebrae is cut.

FIGURE 3B is an illustrative graphical embodiment of the present invention when used in stenosis correction surgery within a vertebrae of a patient.

FIGURE 4 is a cutaway view of the lateral cutter of the present invention when disposed upon a hollow vibratory shaft for use in convective cooling of the lateral cutter.

[0017] The present invention generally relates to an ultrasonic surgical cutting system, wherein a lateral cutter is used to cut through hard tissue such as bone, while simultaneously preventing unintended damage to tissue adjacent to the intended tissue to be cut. Additionally, the present invention provides for cutting of an intended material using a lateral cutter, wherein the lateral cutter can have a reduced temperature. Because the device employs a cooled cutter arrangement, inherent problems of ultrasonic cutting instruments are reduced. For exam-

ple, using a cooled cutter arrangement coupled with a low initial amplitude, bone may be cut in a manner such that necrosis does not develop. Additionally, while cutting a hard tissue such as bone, should the cooled cutter contact surrounding soft tissue, damage to the soft tissue will not result. Furthermore, coupled with an increase in amplitude to cut soft tissue, the cutter's temperature is reduced so that soft tissue cut by the present invention does not unnecessarily stick to the cutter.

[0018] FIGURE 1 is a is an illustrative graphical embodiment of a system for use with the present invention in accordance with one aspect of the present invention. The present system includes an ultrasonic generator 100 capable of producing an ultrasonic frequency. The generator's frequency is in the range of about 22Khz to 45Khz and contains a variable amplitude component. For example, a low amplitude can be employed while cutting a hard tissue such as bone, and a higher amplitude can be employed when the intended tissue to be cut is soft. Associated with the generator 100 is an ultrasonic transducer 104. The ultrasonic transducer allows for the conversion of electrical energy supplied by the ultrasonic generator 100 into mechanical energy which can be transmitted to a vibratory shaft 112 associated with the transducer 104. The transfer of energy between the ultrasonic generator 100 and the transducer 104 occurs using a electrical pathway 102. The electrical pathway can be a electrical connector between signal generator 100 and transducer 104 such that electrical energy can be delivered to the transducer 104. In the alternative, the electrical pathway 102 can be eliminated and the remotely located ultrasonic generator 100 can be integrated directly into the surgical cutting system. The coupling between the transducer 104 and the vibratory shaft 112 is such that mechanical motion generated by the transducer 104 is transferred directly to the vibratory shaft 112. The vibratory shaft 112 is therefore sized and constructed of an appropriate material to sufficiently transmit the mechanical motion of the transducer 104 without unnecessary attenuation of the ultrasonic signal. For example, surgical grade stainless steel or titanium may be used in construction of the vibratory shaft 112. The ultrasonic generator 100, transducer 104 and electrical pathway 102 may take numerous forms as understood by one skilled in the art. For example, existing commercially available surgical instruments including the aforementioned elements may be used in practicing the present invention.

[0019] The vibratory shaft 112 is contained within a guide tube 108. The guide tube 108 is sized such that the guide tube 108 can be readily placed down a predefined hollow pathway (not shown) such that the hollow pathway serves to orient the guide tube 108 and associated ultrasonic surgical cutting system. Furthermore the guide tube serves to contain the vibratory shaft 112 such that the vibratory shaft does not come in contact with surrounding tissue or bone. The predefined hollow pathway can be readily provided using existing techniques

such as drilling. For example, during use in stenosis correction surgery, a hollow pathway can be provided in each pedicle of a vertebra such that upon cutting the pedicle an anterior and posterior region is formed. Using a mechanical means, these anterior and posterior regions may be separated such that nervous tissue compression within the vertebrae is eliminated.

[0020] Associated with the distal end of the vibratory shaft 112 is a cutter 114. The cutter is a lateral cutter located perpendicular to the vibratory shaft 112. One skilled in the art, however, will readily recognize that the cutter may be placed at a variety of angles in relation to the vibrator shaft 112 such that the circumferential cut traced by the cutter 114 is at the required angle specific to the surgical procedure to be performed. Such systems do not fall within the scope of the present invention. The cutter 144 is sized and oriented such that while in the stored position the footprint of the cutter remains within the region defined by the guide tube. The cutter can be formed of any biocompatible material such as titanium or surgical grade stainless steel, and may be of various thicknesses. In one embodiment of the present invention, when used in stenosis correction the cutter is in the range of 2 to 3 millimeters thick. One skilled in the art will readily recognize, however, that the cutter thickness can be readily varied based upon the surgical needs of the intended procedure. The guide tube may be inserted into the hollow pathway such that the cutter 114 does not contact the walls of the hollow pathway during insertion. For illustrative purposes, the cutter 114 is shown as permanently affixed to the vibratory shaft 112. One skilled in the art will readily recognize that the cutter 114 may be affixed to the vibratory shaft 112 using various arrangements such as mechanical fastening means like screws. In the alternative, the distal end of the vibratory shaft 112 may contain a threaded section, such that an intended cutter 114 can simply be threaded onto the ultrasonic cutting system based upon the pending surgical procedure. Using such an arrangement, a surgeon can use the present invention during a plurality of surgical procedures which require specialized cutters 114 for use in the cutting of bone.

[0021] In conjunction with the insertion of the guide tube 108 into the hollow pathway, an adjustable stop 110 located on the guide tube 108 can be utilized in defining the depth of penetration of the guide tube 108 within the hollow pathway. The adjustable stop 110 can be preconfigured by a surgeon prior to insertion of the guide tube 108 into a hollow pathway. In one embodiment of the present invention, a set of calibration markings can be located along the length of the guide tube 108 such that a distance from cutter 114 to adjustable stop 110 can be easily set. In light of this, repeatable cuts at a fixed depth can be readily performed. When used in connection with stenosis correction surgery, for example, the depth of cut in both regions of the pedicle can be easily maintained using the adjustable stop 110. The adjustable stop 110 can be fixed using several means as understood by one

skilled in the art. For example, a simple set screw arrangement can be employed wherein a surgeon can use a supplied tool to lock the adjustable stop in place on the guide tube 108. In the alternative, the adjustable stop 110 can simply be retained along the length of the guide tube 108 using a friction fit.

[0022] The vibratory shaft 112 of the present invention is located in an offset manner to the centerline of the guide tube 108 such that the cutter 114 is located within the periphery of the guide tube while stored in the retracted portion. FIGURE 2A illustrates a retracted view of the cutter 114 prior to deployment of the cutter. FIGURE 2A further illustrates the eccentrically mounted vibratory shaft 112 located on an eccentric axis 152 of the present invention in relation to the longitudinally axis 150 of the guide tube 108. The eccentrically mounted vibratory shaft 112 allows for the deployment of the cutter to a deployed position, as illustrated in FIGURE 2B, upon rotation of the vibratory shaft 112. Upon extension of the cutter 114, as illustrated in FIGURE 2B, the ultrasonic surgical cutting system can be rotated about the central axis of the guide tube such that the cutter 114 provides a circumferential groove in the surrounding bone 120.

[0023] The cutter 114 of the present invention can be deployed into an extended position via operation of a rotatable hand piece 116. In one embodiment, the rotatable hand piece 116 includes a geared mechanism in communication with the vibratory shaft 112 such that upon rotation of the rotatable hand piece 116 the cutter 114 is rotated along an eccentric axis 152 located parallel to the guide tube 108. Upon rotation of the vibratory shaft and the attached cutter 114, the cutter can be deployed a variety of levels of extension beyond the exterior wall of the guide tube 108, such that the cutter can cut a variety of depths in the surrounding bone or tissue. Following the deployment of the cutter 114, the entire ultrasonic surgical cutting system can be rotated, using the supplied rotatable hand piece 116 such that the cutter sweeps through a circumferential path. The circumferential sweep of the cutter 114 results in a circumferential cut in the surrounding bone or tissue with a width of cut corresponding to the width of the cutter 114 and a depth of cut related to the depth of the extended cutter beyond the exterior of the guide tube 108.

[0024] Using such an arrangement, cuts of varying depths in the surrounding bone or tissue can be made using an incremental approach. An initial cutter depth can be set and the ultrasonic surgical cutting system can be revolved, thereby resulting in a first circumferential cut in the surrounding bone or tissue. The cutter 114 depth can then be increased, and the cutter swept through a second revolution, thereby creating a depth increase as compared to the initial cut in the surrounding bone or tissue. Using such an approach, one skilled in the art will readily recognize that deep cuts in the surrounding bone or tissue can be performed using a multi-pass arrangement such that cutter amplitude and frequency can be kept to a minimum, as a minimal amount

of material are removed in each pass, thereby reducing heat buildup at the cutter 114. Such an arrangement offers the benefit of decreased potential for necrosis development in surrounding bone, as the cutter tip is maintained at a reduced temperature. In the alternative, one skilled in the art will recognize that a full depth cut can be performed in a single pass using the present invention in a situation where such a cut is surgically necessary and acceptable. In addition, in the alternative, the radius of the cut can be varied during the single pass to accommodate the shape of the pedicle region. Due to the oblong shape of the pedicle cross-section, the desire to control the cutting depth is optimal. As the axis of the vibratory shaft 112 is offset from the axis of the guide tube 108 the radius of the cut can be varied by simultaneously manipulating the extent of cutter extension beyond the guide tube 108 and the rotation of the ultrasonic cutting device. For example, the cutter extension can be infinitely varied as the ultrasonic cutting instrument is rotated along the central axis of the guide tube 108. Such an arrangement creates an infinite depth of cut up to the maximum extended length of the cutter 114.

[0025] When used in spinal stenosis correction surgery, for example, a circumferential cut originating from within a predefined hollow pathway region can be made at a fixed depth. This circumferential cut through the pedicle region can be made in a single pass using a fully deployed lateral cutter, or can be made in several circumferential passes during which the cutter is deployed at an increasing depth along each pass. As the guide tube 108 is located within the predefined hollow pathway, the ultrasonic surgical cutter relationship is maintained throughout the cutting procedure such that a uniform cut results. Additionally, as the cutting originates from within the predefined hollow region, the cutting procedure remains minimally invasive.

[0026] The ultrasonic generator 100 provided a signal containing both a known amplitude and frequency. In one embodiment, a frequency of 22 kHz, and amplitude of 80 microns, can be utilized for ultrasonic cutting. As understood by one skilled in the art, both amplitude and frequency can be varied based upon the specific use of the ultrasonic surgical cutting system. For example, when used to cut bone, a low amplitude of the generated signal can be maintained such that excessive heating does not occur at cutter 114. Excessive heating at the cutter 114, when used in cutting bone, can result in bone necrosis. Additionally, using a low amplitude will reduce the likelihood of cutting soft tissue in which the cutter may come in contact once the outer edge of bone is reached. Employing a low amplitude signal therefore reduces excessive tip heating and the onset of necrosis. In the alternative, when the present ultrasonic surgical cutting system is employed to cut through soft tissue, the amplitude of the supplied signal can be increased such that the performance of the present invention when used to cut soft tissue is increased. For example, an increase in the speed of the blade, as governed by increases in the as-

sociated amplitude and frequency, offers increased ability to cut through soft tissue such as bone, while the cutter temperature remains reduced due to the cooling mechanism associated with the cutter. Employing a higher amplitude results in increased cutter 114 temperature, which serves to cauterize the region cut by the ultrasonic surgical cutting system, thereby preventing blood loss.

[0027] FIGURE 2C of the present invention is an illustrative cutaway example of the rotatable hand piece assembly 116 of the present invention. The rotatable hand piece assembly 116 performs the dual function of both extending the cutter 114 of FIG. 2B to a predetermined depth of cut beyond the confines of the external surface of the guide tube 108, as well as allowing a surgeon to rotate the entire ultrasonic surgical cutter system, such that the cutter 114 of FIG. 2B sweeps through an intended range of motion. The movement of the cutter 114 of FIG. 2B thereby creates a circumferential groove in the surrounding bone or tissue in contact with the cutter. For illustrative purposes, cutter is herein described in relation to a full circular sweep, yet one skilled in the art will readily recognize that the cutter can be swept through an isolated range of motion. In light of this, detailed removal of regions of bone can be effectuated using the present invention. As illustrated in FIGURE 2C, the transducer 104 and associated vibratory shaft 112 are located in an offset manner in relation to the centerline 150 of the rotatable hand piece 16 and guide tube 108 such that the cutter 114 of FIG. 2B maintains an eccentric range of motion when moved from the retracted position within the guide tube to the extended position. Furthermore, in the illustrative embodiment, the rotatable hand piece 116 includes a geared mechanism for deploying the cutter from the stowed position. As illustrated in the present embodiment the geared mechanism 200 includes a ring gear 210 associated with the rotatable hand piece. This ring gear, upon rotation of the rotatable hand piece, provides for transmission of rotational energy to an intermediate spur gear 212. The intermediate spur gear 212 further transfer the initial rotation of the rotatable hand piece 116 to a pinion gear 214 associated with the vibratory shaft. Such a transfer of rotational energy results in the rotation of the vibratory shaft 112 and the subsequent deployment of the attached cutter 114. One skilled in the art will readily recognize that the sizing and tooth count of the illustrated gears can be sized and specified such that the requisite mechanical advantage and rotational speeds are provided in accordance with the needs of the present invention.

[0028] The geared mechanism 200 of the present embodiment is used solely for illustrative purpose. One skilled in the art will readily recognize that the geared mechanism 200 may be replaced by numerous alternative mechanisms capable of extending the cutter 114. For example, a rack and pinion arrangement can be utilized in place of the circular gear train of the present embodiment. In the alternative, a planetary gear arrangement can be utilized for use in extending the cutter 114 and providing for a means by which the ultrasonic surgical

cutting system can be rotated along the longitudinal axis of the guide tube 108.

[0029] Furthermore, upon deploying the cutter 114 of FIG. 2B, the rotatable hand piece 116 is further rotated such that the entire ultrasonic surgical cutting system is rotated about the longitudinal axis (not shown) of the guide tube 108. Rotation of the ultrasonic surgical cutting system, and eccentric mounted vibratory shaft 112 and attached cutter 114, results in the removal of material from the surrounding hollow pathway 122. A full rotation of the rotatable hand piece 116 thereby results in a circular groove in the material surrounding the hollow pathway 122. Additionally, the cutter 114 depth can be gradually advanced such that that a deepening circular groove can be traced following several rotations of the rotatable hand piece 116.

[0030] FIGURE 3A is a flowchart illustrating the steps necessary in using the present invention to correct stenosis by cutting a pedicle region of a vertebrae. In accordance with step 300 a hollow pathway is initially provided in a pedicle region of the vertebrae to be cut. This hollow pathway can be provided using numerous existing techniques, as understood by one skilled in the art. For example, a drilling mechanism can be used such that a circular hole is bored into the intended region to be cut. In accordance with step 302, a lateral ultrasonic cutter is oriented within the hollow pathway at a fixed distance such that the cutter is appropriately located for cutting of the pedicle region of a vertebrae. The lateral ultrasonic cutter is then extended (304) beyond the hollow region of the hollow pathway and into the surrounding bone of the vertebrae. Following the extension of the lateral ultrasonic cutter, the cutter is rotated in a circumferential manner such that a circumferential groove is cut within the surrounding bone of the hollow pathway. (step 306) The ultrasonic lateral cutter may cut through the pedicle region in a single pass, or the depth of cut may be incrementally increased such that the ultrasonic lateral cutter cuts through the pedicle region in multiple revolutions.

[0031] FIGURE 3B illustrates an embodiment of the present invention when used in stenosis correction in a lower vertebrae of a human patient. The lower vertebra is provided with a hollow pathway 122 which can be drilled using existing bone drilling techniques. Following the provision of the hollow pathway, the guide tube, and associated cutter 114 can be inserted into the hollow pathway 122 using the surrounding bone 120 as a guide to locate the guide tube 108 against. The guide tube 108 can be deployed to a fixed distance either manually, or can be placed within the hollow pathway 122 until the adjustable stop 110 comes in contact with the upper region of the hollow pathway 122. Following insertion of the guide tube within the hollow pathway 122, the presently retracted cutter 114 can be deployed upon rotation of the eccentrically mounted vibratory shaft 112. Rotation of the vibratory shaft 112 occurs following rotation of the hand piece assembly 116 of FIG. 2C. Due to the eccentric location of the vibratory shaft 112, when viewed relative

to the guide tube 108 centerline, the cutter 114 is deployed in a manner where the cutter extends beyond the confines of the guide tube 108. Using such an arrangement, the cutter, which is receiving an ultrasonic vibration comprising an amplitude and frequency, can be rotated in a circumferential manner, thereby producing a groove in the surrounding bone 120. One skilled in the art will readily recognize that the present cutter 114 is oriented perpendicular to the vibratory shaft 112 but any number of relative angles between cutter 114 and vibratory shaft 112 can be employed.

[0032] FIGURE 4 of the present invention illustrated the use of a convective cooling mechanism for use with the present invention. The convective cooling pathway 400 is located internal to the vibratory shaft 112 and extend along the vibratory shaft 112 for a sufficient distance to adequately cool the cutter 114 associated with the vibratory shaft 112. As the cutter 114 of the present invention is in thermal contact with the vibratory shaft 112 of the present embodiment, heat generated in the cutter during operation is passed to the vibratory shaft through conduction. Heat passed to the distal end of the vibratory shaft adjacent to the cutter 114 is then passed to the convective cooling pathway 400 located internal to the vibratory shaft 112. Within the convective cooling pathway 400 a thermal gradient is established such that a working fluid is circulated along the thermal gradient from the cutter region 114 to the opposing end of the convective cooling pathway.

[0033] In one embodiment the convective cooling pathway includes a cellular matrix arrangement disposed within the convective cooling pathway 400. Existing conductive cooling pathways for use in surgical forceps are recognizable by one skilled in the art. One such example of convective cooling pathways is exhibited in the IsoCool™ Bipolar Forceps, offered by Codman, a Johnson & Johnson Company. The cellular matrix has a hollow central region parallel to the centerline of the vibratory shaft 112 such that a heated working fluid may travel up the hollow central region. In operation, the working fluid is instantly evaporated at the interface between vibratory shaft 112 and cutter 114. This now gaseous working fluid travels up the hollow central region of the convective cooling pathway 400 wherein it slowly cools as it moves further from the heated vibratory shaft 112 cutter 114 interface. The working fluid may then return to the interface 402 by passing through the cellular matrix of the convective cooling pathway. In one embodiment the cellular matrix may be made of a copper compound. In the present embodiment, the movement of the working fluid within the convective cooling pathway 400 is driven by the associated thermal gradient provided between the heated interface 402 region and the cool opposing end of the conductive cooling pathway 400. Those skilled in the art will readily recognize that the described cellular matrix arrangement is solely used for illustrative purposes and may be substituted by numerous convective cooling mechanisms as understood by one skilled in the art.

[0034] The use of the convective cooling pathway 400 with the present invention allows for the cooling of the cutter 114 such that heat generated at the cutter during use is partially or fully removed. In light of this, the cooled cutter 114 therefore reduces inherent problems with bone necrosis or inadvertent damage to soft tissue in regions surrounding the cutter 114. Furthermore, should the present invention be used in the cutting of soft tissue, the use of a cooled cutter prevents the inherent problems with tissue sticking to the cutter due to the high temperature associated with existing cutters.

[0035] FIGURES 1 through 4, wherein like parts are designated by like reference numerals throughout, illustrate an example embodiment of an ultrasonic cutting device according to the present invention. Although the present invention will be described with reference to the example embodiments illustrated in the figures, it should be understood that many alternative forms can embody the present invention. One of ordinary skill in the art will additionally appreciate different ways to alter the parameters of the embodiments disclosed, such as the size, shape, or type of elements or materials, in a manner still in keeping with the spirit and scope of the present invention.

[0036] Numerous modifications and alternative embodiments of the present invention will be apparent to those skilled in the art in view of the foregoing description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the best mode for carrying out the present invention.

[0037] Embodiments of the present invention may have a utility in the following methods.

[0038] A method for removing heat from the ultrasonic surgical cutter, comprising:

providing a vibratory shaft which is hollow, associated with the ultrasonic transducer and the cutter, wherein said ultrasonic transducer is associated with a first end of the vibratory shaft and the cutter is associated with a second end of the hollow vibratory shaft;

providing a thermally conductive cellular matrix within a region of the vibratory shaft, said cellular matrix having a hollow central region disposed within the cellular matrix; and

providing a working fluid for use with said cellular matrix, such that a convective thermal gradient is established through the cellular matrix originating at the second end associated with the cutter such that heat is removed from the second end associated with the cutter.

[0039] The ultrasonic surgical cutter may be used in the cutting of bone. The cellular matrix can be a copper based compound. The thermally conductive cellular matrix can provide for the removal of heat generated at the cutter.

[0040] A method of performing a surgical procedure comprising:

creating an access passage from a skin incision to proximate a vertebra,
introducing an ultrasonic cutting tool of the ultrasonic surgical cutting system through the access passage, and
cutting a portion of the vertebra or disk material proximate the vertebra with the ultrasonic cutting tool.

[0041] The method can further comprise inserting at least one dilator through the skin incision and advancing a distal end of the dilator into proximity to the vertebra to expand the incision and create the access passage. The method can further comprise delivering an access port over the dilator, the access port defining the access passage to proximate a vertebra. The method can further comprise inserting a retractor through the skin incision, advancing a distal end of the retractor into proximity to the vertebra, and expanding the retractor to create the access portal.

[0042] A method of performing a surgical procedure comprising,
delivering a cutting tip of an ultrasonic cutting tool of an ultrasonic surgical cutting system proximate a vertebra; cutting a portion of the vertebra with the cutting tip of the ultrasonic cutting tool; and
cooling the cutting tip to temperature sufficient to inhibit necrosis of tissue proximate the cutting tip.

[0043] The cutting tip can be cooled to a temperature less than approximately 50°C. The cutting tip can be cooled to a temperature less than approximately 45°C. The cutting tip can be cooled to a temperature less than approximately 40°C. The cutting tip can be cooled to a temperature approximate to body temperature. The cutting tip can be cooled by a convection cooling system coupled to the ultrasonic cutting tool.

[0044] The system of the present invention may have a transducer capable of transmitting an ultrasonic signal in the frequency range in between about 22Khz and about 45Khz. The system may have a transducer capable of transmitting an ultrasonic signal with an amplitude in the range between about 50 to about 100 microns. The vibratory shaft may be housed within a guide tube such that the ultrasonic lateral cutter associated with the vibratory shaft is eccentrically oriented to the guide tube. The vibratory shaft may further include a convective cooling pathway located internal to the vibratory shaft. The convective cooling pathway may remove heat generated at the lateral cutter during surgical cutting operations. The convective cooling pathway may maintain a lateral cutter temperature less than approximately 50°C. The convective cooling pathway may maintain a lateral cutter temperature less than approximately 45°C. The convective cooling pathway may maintain a lateral cutter temperature less than approximately 40°C. An adjustable stop may be associated with the guide tube, such that

the adjustable stop may be oriented at a plurality of points along the length of the guide tube. Calibration markings may be provided along the length of the guide tube for use in determining penetration depth of the guide tube in an associated cavity. The system may be capable of cutting bone using a predetermined amplitude and frequency signal. The ultrasonic lateral cutter may be made of a biocompatible material. The ultrasonic lateral cutter may be modular, such that a plurality of differently sized and oriented lateral cutters can be attached to the vibratory shaft. The ultrasonic cutter may be able to trace a variable radius depth of cut in the material surrounding the cutter. The system may be used in stenosis correction surgery.

[0045] An ultrasonic cutting device for use in cutting bone is also disclosed herein, the device having a cooled cutter, said device comprising:

an ultrasonic transducer for generating an ultrasonic output;
a ultrasonic cutter associated with said ultrasonic transducer; and
a convective cooling mechanism associated with the ultrasonic cutter and ultrasonic transducer, wherein the convective cooling mechanism provides for a cooled cutter in the ultrasonic cutting device.

[0046] The device may further comprise an ultrasonic generator capable of producing a signal with a frequency in the range between about 22Khz and about 45Khz. The device may further comprise an ultrasonic generator capable of producing a signal with an amplitude in the range between about 50 to about 100 microns. The convective cooling mechanism may comprise a thermally conductive cellular matrix disposed within the convective cooling mechanism. The convective cooling mechanism may include a working fluid, wherein the working fluid undergoes a fluid reflux within the convective cooling mechanism. The convective thermal gradient may originate at the cutter and extend toward the ultrasonic transducer and may be established within the convective cooling mechanism. The thermally conductive cellular matrix may include a hollow central region capable of passing a heated working fluid originating at the cutter end of the convective cooling mechanism. A cooled working fluid may return to the end of the convective cooling mechanism associated with the cutter via the cellular matrix of the convective cooling mechanism.

[0047] A tool for cutting tissue is also disclosed herein, the tool comprising:

a mechanical cutting tip and
a convection cooling system incorporated within the tool to cool the mechanical cutting tip to a temperature sufficient to inhibit tissue necrosis.

[0048] The mechanical cutting tip may be a drill bit. The mechanical cutting tip may be a burr. The mechanical

cutting tip may be a blade. The mechanical cutting tip may be an ultrasonic cutting tip. The tool may further comprise a tool body having a proximal end and a distal end, wherein the convection cooling system is positioned within the tool body. The convection cooling system may comprise a thermally conductive cellular matrix, and a working fluid.

Claims

1. An ultrasonic surgical cutting system, said system comprising:

an ultrasonic transducer element (104) for producing an ultrasonic output;
a rotatable handpiece (116) sized and oriented to contain the ultrasonic transducer element;
and

an ultrasonic lateral cutter (114) which can be oriented for use in lateral surgical cutting from within a hollow pathway, the ultrasonic lateral cutter associated with the ultrasonic transducer element by a vibratory shaft (112) sized and oriented to transmit a mechanical motion produced by the ultrasonic transducer element to the ultrasonic lateral cutter, the ultrasonic lateral cutter located perpendicular to the vibratory shaft;

characterised in that the system further comprises a guide tube (108) which can be placed down the predefined hollow pathway;
and **in that** the ultrasonic lateral cutter is sized and oriented such that in a stored position a footprint of the cutter remains within a region defined by the guide tube, and in a deployed position the ultrasonic lateral cutter extends beyond an exterior wall of the guide tube;
and further **in that**, following deployment of the cutter to the deployed position, the ultrasonic surgical cutting system can be rotated using the rotatable handpiece such that the cutter sweeps through a circumferential path.

2. The system of claim 1, which includes an ultrasonic generator (100), in which said ultrasonic generator is capable of producing an ultrasonic signal for use with the ultrasonic transducer.
3. The system of claim 1, in which the handpiece further comprises gears (210, 212, 214) in which upon rotation of the handpiece the vibratory shaft and associated attached cutter is rotated such that the circumferential path is traced by the lateral ultrasonic vibratory cutter.
4. The system of claim 1, in which the vibratory shaft is housed within the guide tube (108) such that the

ultrasonic lateral cutter associated with the vibratory shaft is eccentrically oriented to the guide tube.

5. The system of claim 1, in which the vibratory shaft further includes a convective cooling pathway (400) located internal to the vibratory shaft.
6. The system of claim 1, in which the ultrasonic lateral cutter is adapted to be orientated at a plurality of angles relative to the ultrasonic transducer.
7. The system of claim 1, in which the ultrasonic cutter is adapted to trace a variable radius depth of cut in the material surrounding the cutter.

Patentansprüche

1. Chirurgisches Ultraschallschneidsystem, wobei das System umfasst:

ein Ultraschallwandlerelement (104) zum Erzeugen einer Ultraschallausgabe;
ein drehbares Handstück (116), das zur Aufnahme des Ultraschallwandlerelements dimensioniert und orientiert ist; und

eine laterale Ultraschallschneideinrichtung (114), die zur Verwendung bei lateralem chirurgischen Schneiden innerhalb eines hohlen Durchgangs orientiert werden kann, wobei die laterale Ultraschallschneideinrichtung mit dem Ultraschallwandlerelement durch einen Schwingschaft (112) verbunden ist, der zum Übertragen einer von dem Ultraschallwandlerelement erzeugten mechanischen Bewegung auf die laterale Ultraschallschneideinrichtung dimensioniert und orientiert ist, wobei sich die laterale Ultraschallschneideinrichtung senkrecht zum Schwingschaft befindet;

dadurch gekennzeichnet, dass das System ferner ein Führungsrohr (108) umfasst, das in den vordefinierten hohlen Durchgang eingelassen werden kann;

und dass die laterale Ultraschallschneideinrichtung so dimensioniert und orientiert ist,

dass in einer eingefahrenen Position eine Grundfläche der Schneideinrichtung innerhalb einer von dem Führungsrohr definierten Region bleibt und in einer ausgefahrenen Position sich die laterale Ultraschallschneideinrichtung über eine äußere Wand des Führungsrohres erstreckt;

und ferner dass, im Anschluss an ein Ausfahren der Schneideinrichtung in die ausgefahrene Position, das chirurgische Ultraschallschneidsystem unter Verwendung des drehbaren Handstückes gedreht werden kann, so dass die Schneideinrichtung eine umlaufende Bahn durchläuft.

2. System nach Anspruch 1, das einen Ultraschallgenerator (100) enthält, wobei der Ultraschallgenerator zur Erzeugung eines Ultraschallsignals zur Verwendung mit dem Ultraschallwandler fähig ist. 5
3. System nach Anspruch 1, wobei das Handstück ferner Zahnräder (210, 212, 214) umfasst, wobei bei Drehung des Handstücks der Schwingschaft und die zugehörige befestigte Schneideinrichtung so gedreht werden, dass die umlaufende Bahn von der lateralen Ultraschallschwingungseinrichtung gezeichnet wird. 10
4. System nach Anspruch 1, wobei der Schwingschaft in dem Führungsrohr (108) so untergebracht ist, dass die mit dem Schwingschaft verbundene laterale Ultraschallschneideinrichtung zum Führungsrohr exzentrisch orientiert ist. 15
5. System nach Anspruch 1, wobei der Schwingschaft ferner einen konvektiven Kühldurchgang (400) enthält, der innerhalb des Schwingschafts angeordnet ist. 20
6. System nach Anspruch 1, wobei die laterale Ultraschallschneideinrichtung gestaltet ist, um unter einer Vielzahl von Winkeln relativ zum Ultraschallwandler orientiert zu werden. 25
7. System nach Anspruch 1, wobei die Ultraschallschneideinrichtung gestaltet ist, um eine Schnitttiefe mit variablem Radius in das die Schneideinrichtung umgebende Material zu zeichnen. 30

Revendications

1. Système de coupe chirurgical à ultrasons, ledit système comprenant : 40
 - un élément transducteur ultrasonique (104) pour produire une sortie ultrasonique ;
 - une pièce à main tournante (116) dimensionnée et orientée pour contenir l'élément transducteur ultrasonique ; et 45
 - un dispositif de coupe latéral à ultrasons (114) qui peut être orienté pour l'utilisation dans la coupe chirurgicale latérale depuis l'intérieur d'un chemin creux, le dispositif de coupe latéral à ultrasons associé à l'élément transducteur ultrasonique par un arbre de vibration (112) dimensionné et orienté pour transmettre un mouvement mécanique produit par l'élément transducteur ultrasonique au dispositif de coupe latéral ultrasonique, le dispositif de coupe latéral ultrasonique étant situé d'une manière perpendiculaire à l'arbre de vibration ; 50
 - caractérisé en ce que** le système comprend en

outre un tube de guidage (108) qui peut être placé en bas dans le chemin creux prédéfini ;
et en ce que le dispositif de coupe latéral ultrasonique est dimensionné et orienté de telle sorte que dans la position stockée, une empreinte du dispositif de coupe subsiste dans une région définie par le tube de guidage, et dans une position déployée, le dispositif de coupe latéral ultrasonique s'étend au-delà d'une paroi extérieure du tube de guidage ;
 et en outre **en ce que**, à la suite du déploiement du dispositif de coupe à la position déployée, le système de coupe chirurgical à ultrasons peut être amené à tourner en utilisant la pièce à main tournante de telle sorte que le dispositif de coupe parcourt un chemin circonférentiel.

2. Système selon la revendication 1, qui comprend un générateur ultrasonique (100), où ledit générateur ultrasonique est apte à produire un signal ultrasonique pour utilisation avec le transducteur ultrasonique.
3. Système selon la revendication 1, dans lequel la pièce à main comprend en outre des roues dentées (210, 212, 214) dans lequel, à la suite de la rotation de la pièce à main, l'arbre de vibration et le dispositif de coupe attaché associé est amené à tourner de telle sorte que le chemin circonférentiel est tracé par le dispositif de coupe latéral à ultrasons.
4. Système selon la revendication 1, dans lequel l'arbre de vibration est logé dans le tube de guidage (108) de telle sorte que le dispositif de coupe latéral à ultrasons associé à l'arbre de vibration est orienté d'une manière excentrique au tube de guidage. 35
5. Système selon la revendication 1, dans lequel l'arbre de vibration comprend en outre un chemin de refroidissement convectif (400) situé à l'intérieur de l'arbre de vibration.
6. Système selon la revendication 1, dans lequel le dispositif de coupe latéral à ultrasons est apte à être orienté à une pluralité d'angles relativement au transducteur ultrasonique.
7. Système selon la revendication 1, dans lequel le dispositif de coupe à ultrasons est apte à tracer une profondeur de coupe d'un rayon variable dans le matériau entourant le dispositif de coupe. 55

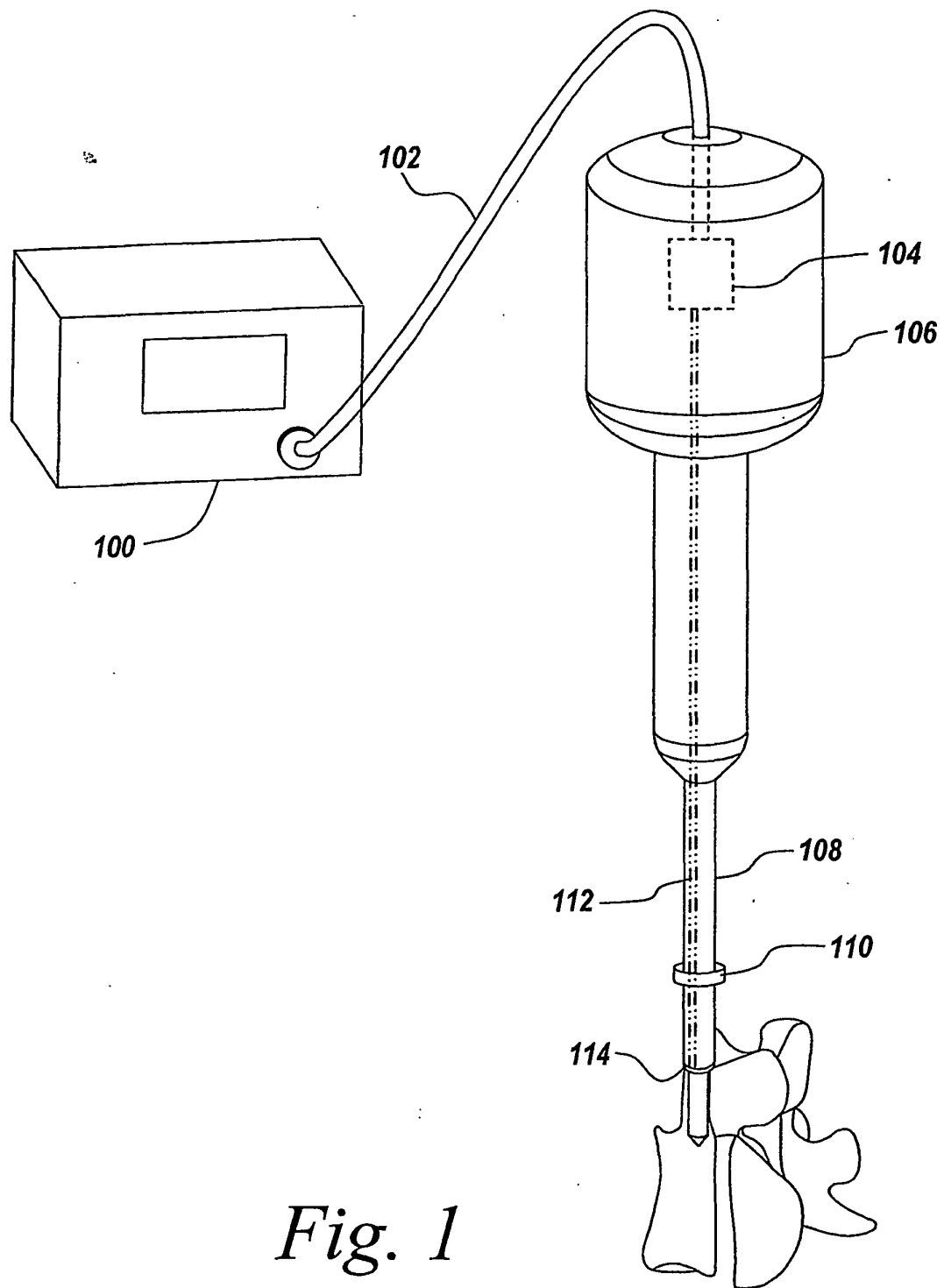


Fig. 1

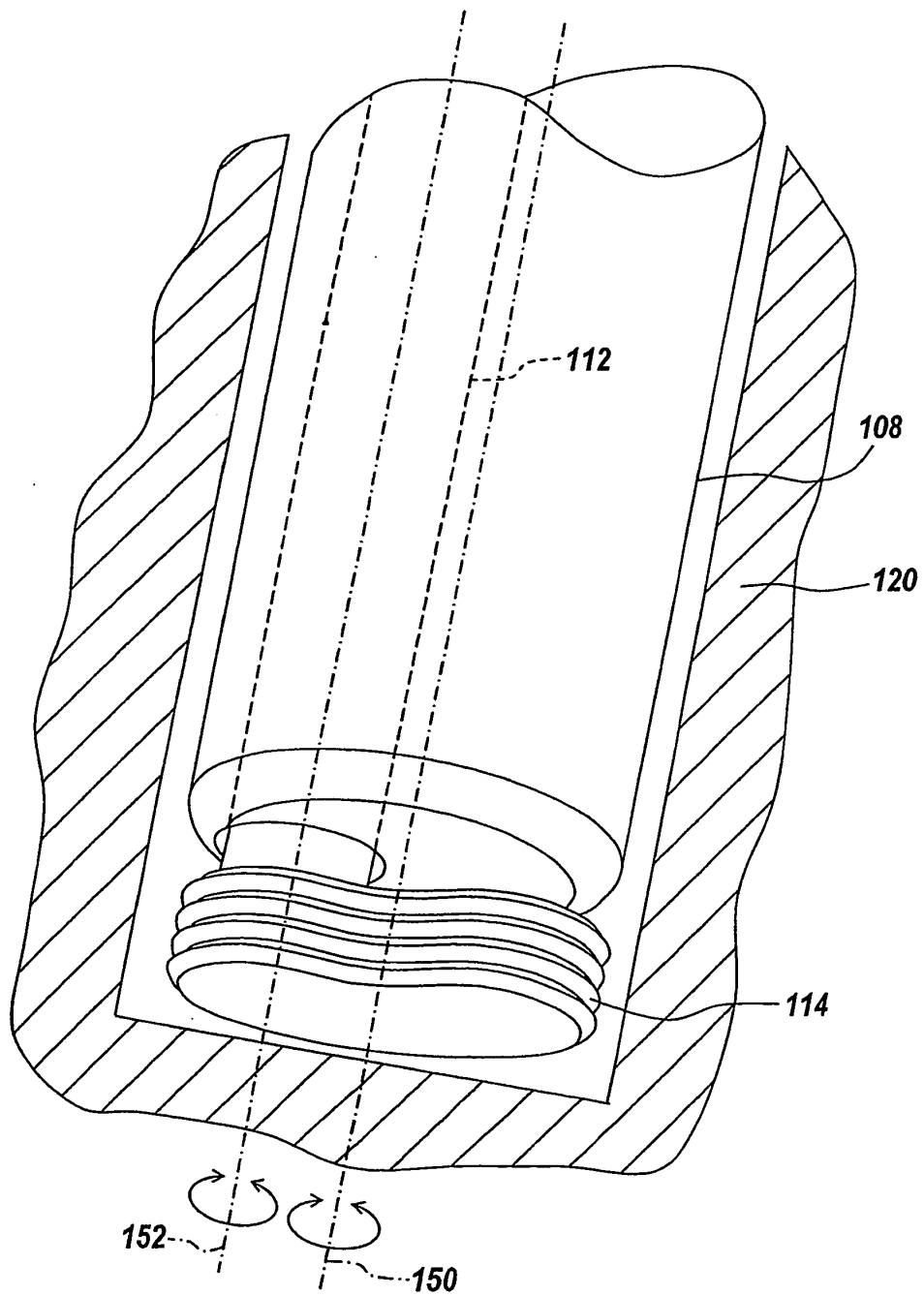


Fig. 2A

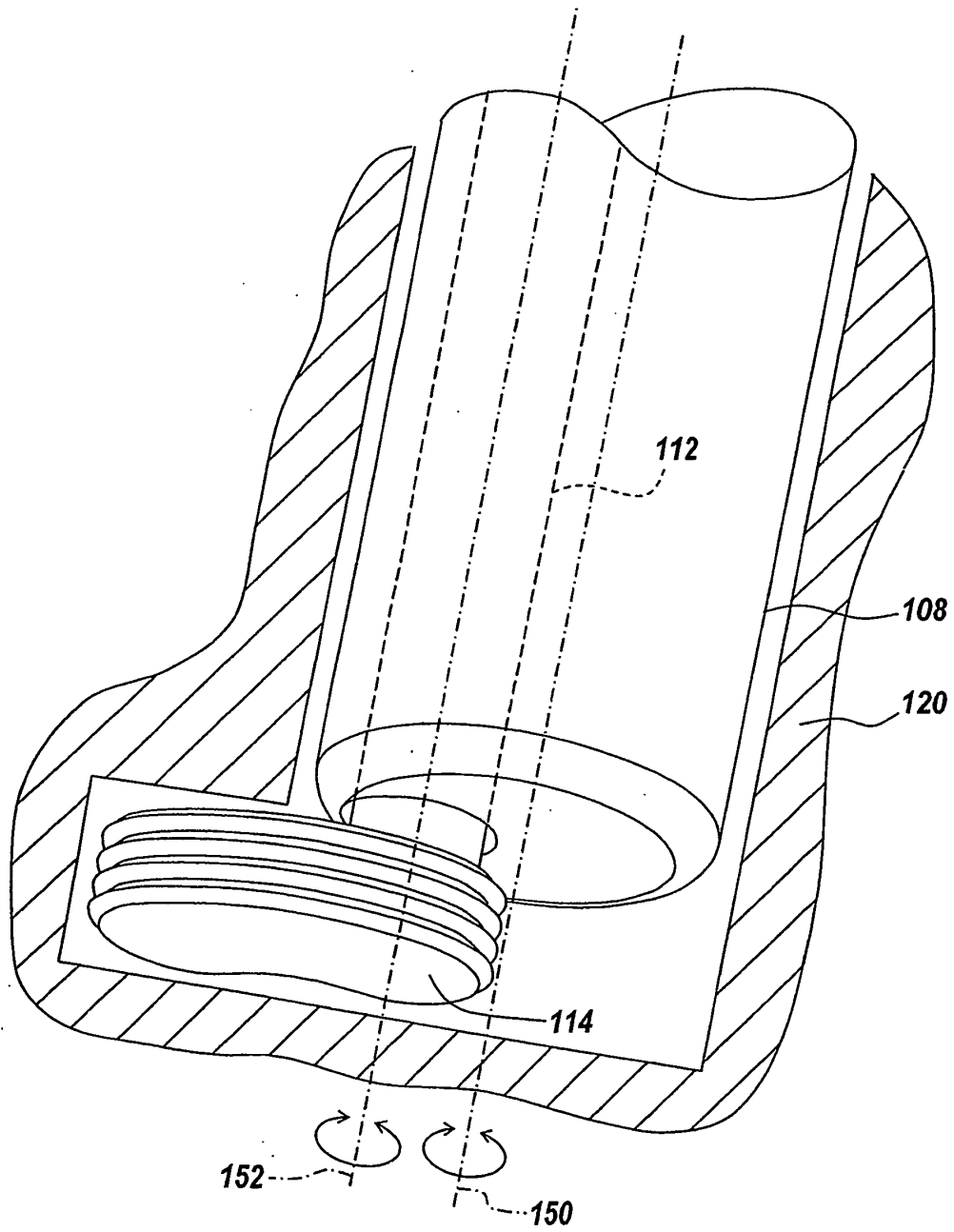
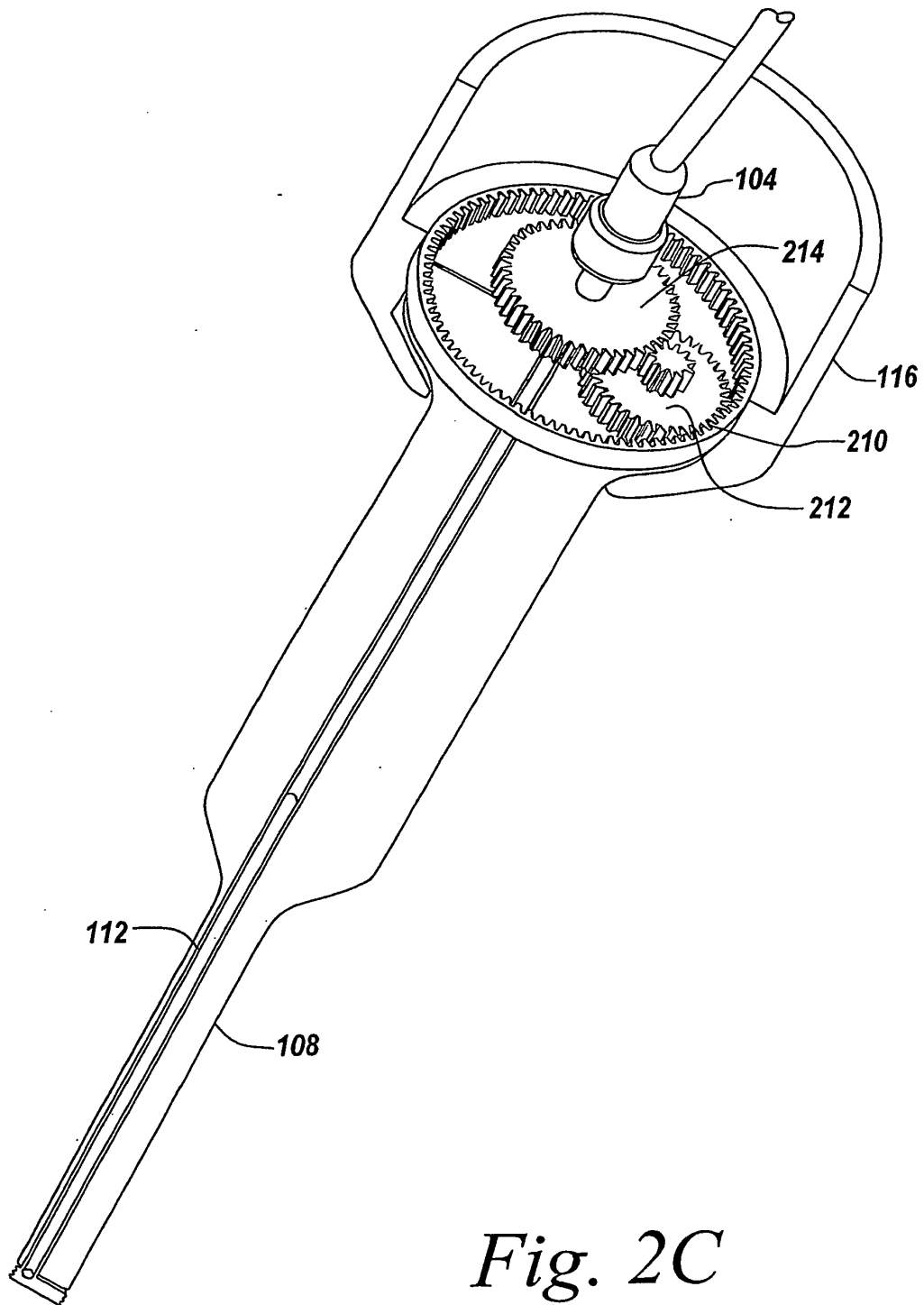


Fig. 2B



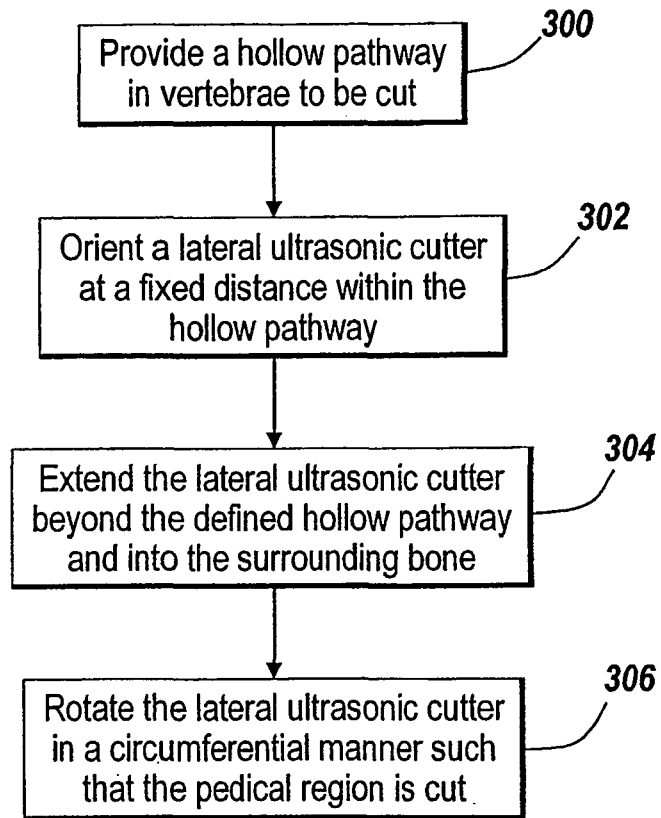


Fig. 3A

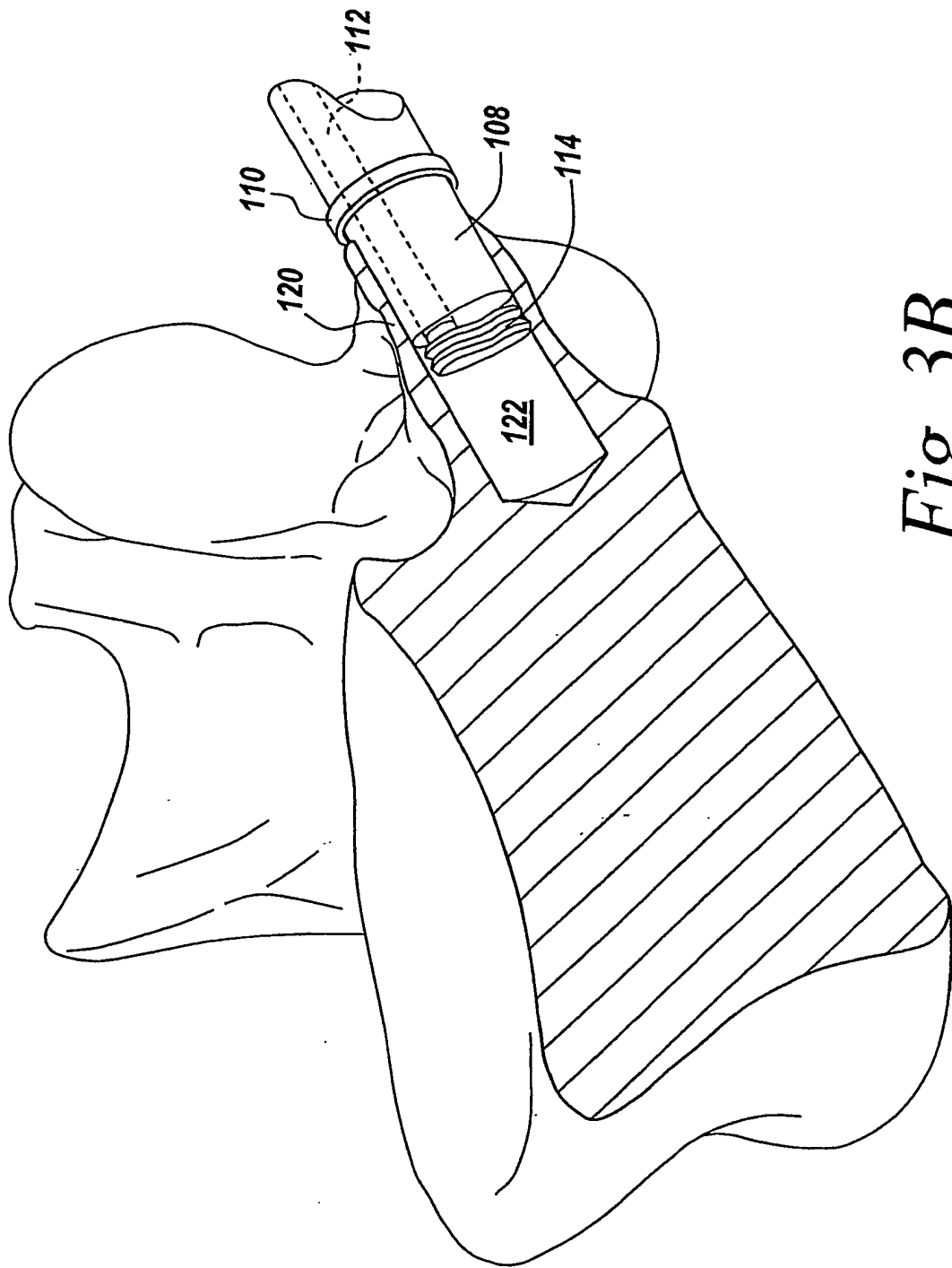


Fig. 3B

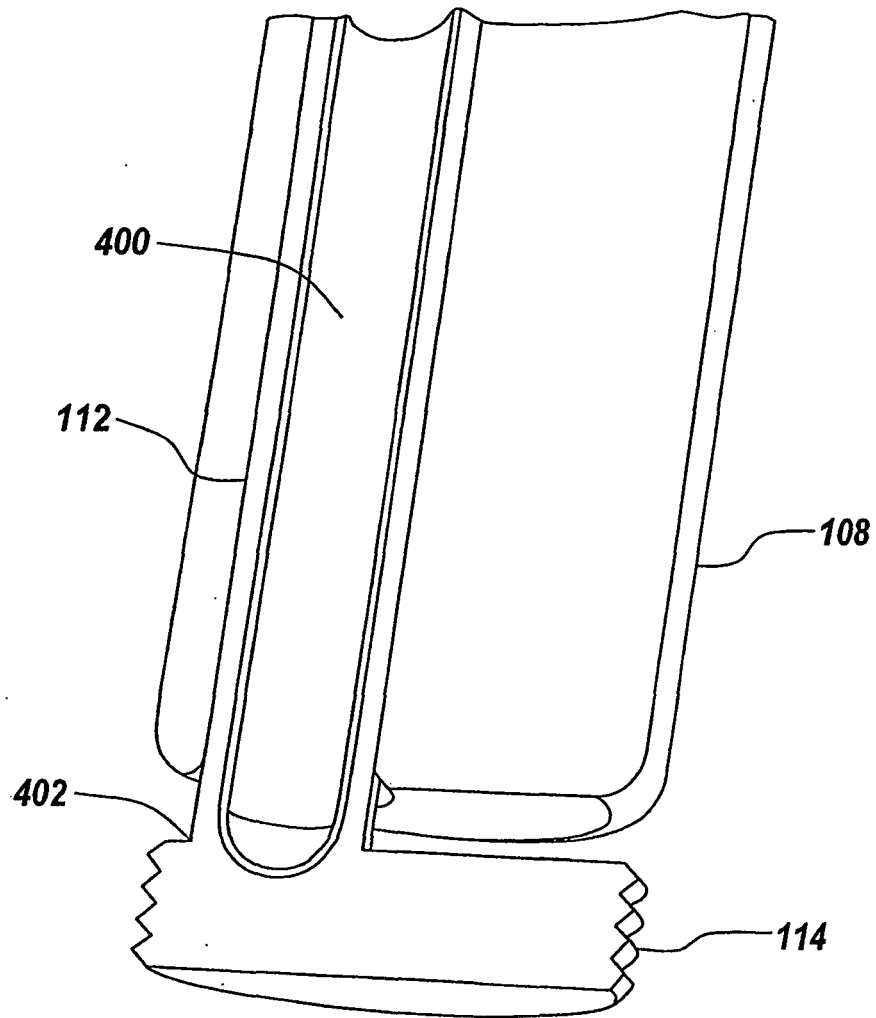


Fig. 4

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 9907652 W [0005]
- WO 9951149 A [0005]
- EP 0482195 A [0006]
- US 20030212400 A, Bloemer [0013]
- US 6358254 B1, Anderson [0013]

专利名称(译)	超声波切割装置		
公开(公告)号	EP1845862B1	公开(公告)日	2014-07-30
申请号	EP2006720112	申请日	2006-02-02
[标]申请(专利权)人(译)	德普伊斯派尔公司		
申请(专利权)人(译)	DePuy公司脊柱，INC.		
当前申请(专利权)人(译)	DePuy公司脊柱，INC.		
[标]发明人	JONES BRYAN S RAMSAY CHRISTOPHER		
发明人	JONES, BRYAN S. RAMSAY, CHRISTOPHER		
IPC分类号	A61B17/00		
CPC分类号	A61B17/320068 A61B17/1624 A61B17/1644 A61B17/1671 A61B17/22 A61B17/22004 A61B2017/1651		
代理机构(译)	ORR，ROBERT		
优先权	11/050158 2005-02-02 US 11/050265 2005-02-02 US		
其他公开文献	EP1845862A4 EP1845862A1		
外部链接	Espacenet		

摘要(译)

提供了一种超声外科手术切割方法和设备，其中该方法和设备允许从中空路径内切割骨头，使得与超声方法和设备相关联的切割器保持足够冷以防止被切割的骨坏死。此外，超声设备和方法可以用于切割软组织，其中使用冷却的切割器以防止在使用过程中软组织粘附到设备的切割刀片上。

