[19] Patents Registry
The Hong Kong Special Administrative Region
香港特別行政區
專利註冊處

[11] 1197964 A

[12] **SHORT-TERM PATENT SPECIFICATION**
短期專利說明書

[21] Application No. 申請編號
14100237.7

[51] Int.Cl.[8] A61B

[22] Date of filing 提交日期
09.01.2014

[30] Priority 優先權
03.12.2011 US 61/566,629
09.02.2012 US 61/596,865

[45] Publication Date of granted patent 批予專利的發表日期
27.02.2015

CN Application No. & Date 中國專利申請編號及日期
CN 201280005026.4 22.08.2012

CN Publication No. & Date 中國專利申請發表編號及日期
CN 103327913 25.09.2013

[86] International Application No. 國際申請編號
PCT/US2012/051952

[87] International Publication No. 國際申請發表編號
WO2013/081691 (06.06.2013)

[73] Proprietor 專利所有人
OUROBOROS MEDICAL, INC.
47757 Fremont Boulevard Fremont
CA 94538
UNITED STATES/UNITED STATES OF AMERICA

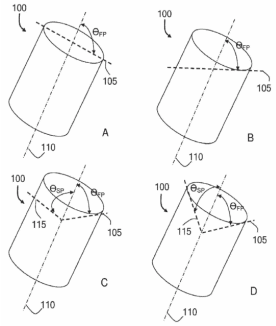
[72] Inventor 發明人
TO, John

[74] Agent and / or address for service 代理人及/或送達地址
Melvin Li Intellectual Property Limited
Level 8 Admiralty Centre Tower 2
18 Harcourt Road
Admiralty HONG KONG

[54] SAFE CUTTING HEADS AND SYSTEMS FOR FAST REMOVAL OF A TARGET TISSUE 用於快速移除靶組織的安全刀頭和系統

[57] A safe and efficient cutting heads for removing a target tissue from a subject during a surgical procedure are provided, the cutting heads composing a part of systems that address several problems, including clogging of state-of-the-art systems during removal of such tissue, for example. The target tissue can include any tissue that is accessible through a small surgical opening, for example, a joint tissue such as a meniscus or an intervertebral tissue, such as a nucleus pulposus. The devices can be referred to as orthopedic tissue removal devices having cutting heads associated with vacuum systems, making the systems useful in several procedures, including X-LIF (lateral approach to an intervertebral fusions) procedures, T-LIF (transforaminal approach to intervertebral fusions) procedures, P-LIF (posterior approach to intervertebral fusions), and a percutaneous, transforaminal approach (Kambin triangle access).

提供一種安全有效的刀頭，該刀頭用於在外科手術中從目標上移除靶組織，所述刀頭包括解決多個問題的系統的一部分，所述多個問題包括例如在現有系統在移除所述組織的堵塞問題 。所述靶組織可以包括通過較小的外科手術開口可以進入的組織，例如，關節組織（例如，半月板）或椎間盤組織（例如，髓核） 。所述裝置可以指骨科組織移除裝置，該骨骼組織移除裝置具有與真空系統相連的刀頭，使得所述系統在多種手術過程中是有用的，所述多種手術過程包括 X-LIF（椎間融合的側入）過程、T-LIF（椎間融合的穿入）過程、P-LIF（椎間融合的後入）過程或經皮的椎間進入（卡賓三角進入） 。



This print reflects an amendment of specification under section 120 of the Patents Ordinance.
本文件顯示，說明書已根據專利條例第 120 條修訂 。

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 June 2013 (06.06.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/081691 A1

(51) International Patent Classification:
A61B 17/3205 (2006.01) *A61B 17/34* (2006.01)
A61B 17/3209 (2006.01) *A61B 17/70* (2006.01)

(21) International Application Number:
PCT/US2012/051952

(22) International Filing Date:
22 August 2012 (22.08.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/566,629 3 December 2011 (03.12.2011) US
61/596,865 9 February 2012 (09.02.2012) US

(71) Applicant *(for all designated States except US)*: **OUROBOROS MEDICAL, INC.** [US/US]; 47757 Fremont Boulevard, Fremont, CA 94538 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **TO, John** [US/US]; 36514 Dijon Drive, Newark, CA 94560 (US).

(74) Agent: **BOYER, Brian, S.**; Syndicated Law, 460 Seaport Court, Suite 101, Redwood City, CA 94063 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

(54) **Title**: SAFE CUTTING HEADS AND SYSTEMS FOR FAST REMOVAL OF A TARGET TISSUE

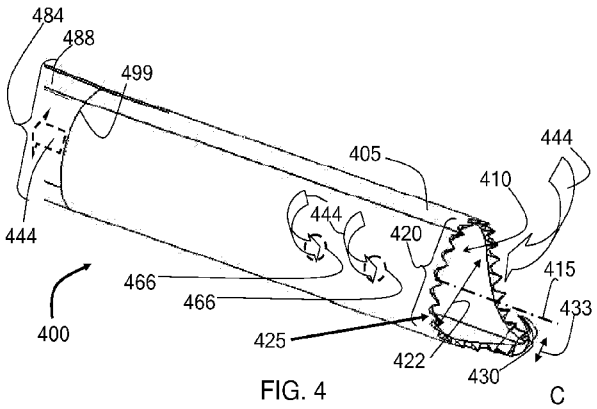


FIG. 4

(57) **Abstract**: A safe and efficient cutting heads for removing a target tissue from a subject during a surgical procedure are provided, the cutting heads composing a part of systems that address several problems, including clogging of state-of-the-art systems during removal of such tissue, for example. The target tissue can include any tissue that is accessible through a small surgical opening, for example, a joint tissue such as a meniscus or an intervertebral tissue, such as a nucleus pulposus. The devices can be referred to as orthopedic tissue removal devices having cutting heads associated with vacuum systems, making the systems useful in several procedures, including X-LIF (lateral approach to an intervertebral fusions) procedures, T-LIF (transforaminal approach to intervertebral fusions) procedures, P-LIF (posterior approach to intervertebral fusions), and a percutaneous, transforaminal approach (Kambin triangle access).

WO 2013/081691 A1

SAFE CUTTING HEADS AND SYSTEMS FOR FAST REMOVAL OF A TARGET TISSUE

JOHN TO

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/566,629, filed December 3, 2011, and U.S. Provisional Application No. 61/596,865, filed February 9, 2012, each application of which is hereby incorporated herein by reference in its entirety.

BACKGROUND

Field of the Invention

[0002] The teachings provided herein are generally directed to a safe and efficient cutting head for removing a target tissue from a subject during a surgical procedure.

Description of the Related Art

[0003] Intervertebral disc disease is a major worldwide health problem. In the United States alone almost 700,000 spine procedures are performed each year and the total cost of treatment of back pain exceeds $30 billion. Age related changes in the disc include diminished water content in the nucleus and increased collagen content by the 4.sup.th decade of life. Loss of water binding by the nucleus results in more compressive loading of the annulus. This renders the annulus more susceptible to delamination and damage. Damage to the annulus, in turn, accelerates disc degeneration and degeneration of surrounding tissues such as the facet joints.

[0004] The two most common spinal surgical procedures performed are discectomy and spinal fusion. These procedures only address the symptom of lower back pain, nerve compression, instability and deformity. The objective of the spinal disc fusion procedure is to restore, maintain and stabilize disc height, and/or reduce back pain. The procedure is generally performed by removing central disc material such and inner annulus, nucleus pulposus and the cartilage on the endplates before replacing with bone graft and a scaffold to effect fusion of the vertebral bodies within the treated disc for height stabilization. This removal process is called a discectomy and is both tedious and frequently inadequate which can result in compromised fusion, as well as traumatic and time consuming due to the large incision and dissections required to expose the disc for discectomy.

[0005] In a typical discectomy procedure, a nucleotomy is first performed in which the nucleus is loosened by using a curette or a manual shaver to shear the nucleus loose and then removed using a rigid grasper called a rongeur. The surgeon has to insert the rongeur through an opening in the disc called an anulotomy, grasp nucleus and remove out of the disc and the surgical access, clean the jaws and reinsert for more grasping of disc repeatedly. This process can pose safety issues for tissues in between tool passage such as nerves. Furthermore, disc debris left behind can hinder efficient subsequent tissue removal and insertion of the discectomy tools into the disc. The second step is decortication in which cartilage attached to the bone (cartilaginous endplate) is removed by the use of rigid scrapers such as a curette or a rasp to help promote a strong intervertebral fusion. Peeled cartilage are removed by scooping with a curette and withdrawn out of the body by the use of a rongeur. Tissue debris left behind can also compromise efficiency and effectiveness of the decortication resulting in a weaker fusion. Moreover, corners inside the discs are often hard to reach by current state-of-the art tools, often leaving additional areas of inadequate disc removal.

[0006] In addition, state-of-the-art systems using a combination of suction and cutting suffer clogging problems due to excised tissue becoming lodged in the system. One of skill will appreciate that problems with clogging during a surgical procedure can be problematic, and a solution to such clogging problems is highly desired.

[0007] Although several advanced tools have been developed, none have addressed all of these issues adequately. One of skill in the art would certainly appreciate a discectomy system that is (i) less tedious and time consuming to use, (ii) less prone to clogging by excised tissue; (iii) safer to the subject undergoing the surgery, and (iv) more effective in promoting a strong intervertebral fusion.

SUMMARY

[0008] The teachings provided herein are generally directed to a safe and efficient cutting head for removing a target tissue from a subject during a surgical procedure. The target tissue can include any tissue that is accessible through a small surgical opening, for example, a joint tissue such as a meniscus, in some embodiments, or an intervertebral tissue, such as a nucleus pulposus, in other embodiments.

[0009] The cutting head can be tubular with a cutting surface forming at least a first plane on a distal perimeter of cutting head, the cutting head in operable communication with a suction device to excise a target tissue in a manner that facilitates an ease of removal of the tissue with the suction. The cutting surface can be flat, sinusoidal, or serrated, for example, and the first plane of the cutting surface may be at an angle, Θ_{FP}, that deviates up to 75° from a position that is orthogonal to the central axis of the cutting head. In some embodiments, the cutting surface can have a second plane may be at an angle, Θ_{SP}, that deviates up to 75° from a position that is orthogonal to the central axis of the cutting head. In some embodiments, the cutting head has a cutting blade and a blade guard for guarding a perimeter tissue from the cutting blade.

[00010] As such, the teachings include a tubular cutting head for removing a target tissue of a subject. In these embodiments, the cutting head can have an outer perimeter that circumscribes a lumen through the cutting head, the lumen having a central axis. The cutting head can also have a forward cutting blade on a distal edge of the outer perimeter, the forward cutting blade configured for (i) cutting a target tissue in a forward stroke of the cutting head and (ii) directing the cut tissue into the lumen. And, the cutting head can also have a blade guard positioned distal to the forward cutting blade and configured to guard a perimeter tissue from the forward cutting blade upon the forward stroke the blade guard having a width that is smaller than the width of a transverse cross-section of the lumen to facilitate entry of the target tissue into the lumen on the forward stroke.

[00011] In some embodiments, the cutting head can have a backward cutting blade for cutting the target tissue in a backward stroke of the cutting head, a transverse cutting blade for cutting the target tissue in a transverse stroke of the cutting head, or a combination thereof. In some embodiments, a transverse cutting blade can be positioned on the blade guard for cutting the target tissue in a transverse stroke of the cutting head.

[00012] In some embodiments, the backward cutting blade can be positioned on the distal edge of the outer perimeter for cutting the target tissue in the backward stroke of the cutting head. In some embodiments, the backward cutting blade can be positioned on the blade guard for cutting the target tissue in the backward stroke of the cutting head, the blade guard having a double-edged blade tip point back into the lumen at an angle, Θ_2, of greater than 90° to trap and/or cut tissue in the lumen in the backwards stroke of the cutting head.

[00013] Since the cutting head can be designed to remove tissue through use of a suction, the teachings are also directed to systems of a cutting head that operably connect the cutting head with a suction assembly. As such, the teachings include a such a surgical, tissue removal system that includes a tubular cutting head for removing a target tissue of a subject. The system can include a cutting head having an outer perimeter that circumscribes a flow of suction through the cutting head; a lumen circumscribed by the outer perimeter, the lumen guiding the flow of suction and having a central axis; a forward cutting blade on a distal edge of the outer perimeter, the forward cutting blade configured for (i) cutting the target tissue in a forward stroke of the cutting head and (ii) directing the cut tissue into the lumen; and, a blade guard positioned distal to the forward cutting blade and configured to guard a perimeter tissue from the forward cutting blade upon the forward stroke the blade guard. In some embodiments, the blade guard can have a width that is smaller than the width of a transverse cross-section of lumen to facilitate entry of the target tissue into the lumen on the forward stroke.

[00014] The cutting head can be configured for an operable communication between the lumen and a source of a suction, such that the systems include a suction assembly in operable communication with the cutting head for creating the flow of suction for removing the target tissue through the lumen and out of the subject, the suction assembly comprising a rigid suction tube with a central axis. In some embodiments, the operable communication includes the use of one or more suction ports positioned just proximal to the most proximal point of the distal edge of the out perimeter of the cutting head. In some embodiments, the one or more ports can be located from about 3mm to about 20mm proximal to the most proximal point of the distal edge.

[00015] In some embodiments, the suction assembly comprises an at least substantially rigid suction tube having a proximal end and a distal end, the distal end in the operable communication with the cutting head, and the distal end configured for communicating with a source of suction for the suction assembly. In some embodiments, the at least substantially rigid suction tube can be formed as a single unit with the cutting head.

[00016] In some embodiments, the central axis of the lumen is at an angle, Θ_1, ranging from about 5° to about 90° from the central axis of the rigid suction tube, and the forward cutting blade is located about 3mm to about 25mm from the vertex of the angle, Θ_1.

[00017] The system of claim 10, the central axis of the lumen has a point of exit at the forward cutting blade, and the point of exit is located at a transverse distance of about 3mm to about 25mm that is orthogonal to the central axis of the rigid suction tube.

[00018] In some embodiments, the central axis of the lumen can be at an angle, Θ_1, ranging from about 5° to about 90° from a central axis of the flow of suction at the distal end of the suction assembly, and the forward cutting blade can be located about 3mm to about 25mm from the vertex of the angle, Θ_1. In some embodiments, the operable communication between the cutting head and the suction assembly can be articulating, and the angle can be adjustable. In some embodiments, the operable communication between the cutting head and the suction assembly can be rigid, and the angle can be fixed.

[00019] In some embodiments, the central axis of the lumen is at an angle, Θ_1, ranging from 1° to 180° from a central axis of the flow of suction at the distal end of the suction assembly, and the forward cutting blade is located 3mm to 25mm from the vertex of the angle, Θ_1. In these embodiments, additional angle, Θ_3, is located 5mm to 25mm proximal to Θ_1, and angles Θ_1 and Θ_3 are independently selected to range from about 0° to about 180°, with the limitation that (i) the net angle, Θ_4, between the central axis of the lumen of the cutting head and the central axis of a rigid suction tube located proximal to Θ_3 ranges from 0° to 90°; and, (ii) the distance between the central axis of the lumen of the cutting head and the central axis of the rigid suction tube ranges from 2mm to 30mm.

[00020] It should be appreciated that the cutting heads and systems taught herein have a variety of applications known to one of skill. In some embodiments, the target tissue can be a nucleus pulposus, and the perimeter tissue can be an annulus fibrosis, for example.

[00021] As such, the teachings are also directed to a surgical, tissue removal system for a discectomy, and the systems can comprise a tubular cutting head for removing a nucleus pulposus from a subject. In these embodiments, the systems can include a cutting head having an outer perimeter that circumscribes a flow of suction through the cutting head; a lumen circumscribed by the outer perimeter, the lumen guiding the flow of suction; a forward cutting blade on a distal edge of the outer perimeter, the forward cutting blade configured for (i) cutting the nucleus pulposus in a forward stroke of the cutting head and (ii) directing the cut nucleus pulposus into the lumen; a backward cutting blade for cutting the nucleus pulposus in a backward stroke of the cutting head; a transverse cutting blade for cutting the nucleus pulposus in a transverse stroke of the cutting head; and, a blade guard positioned

distal to the forward cutting blade and configured to guard an annulus fibrosis tissue from the forward cutting blade upon the forward stroke. And, the blade guard can have a width, for example, that is smaller than the width of a transverse cross-section of the lumen to facilitate entry of the target tissue into the lumen on the forward stroke.

[00022] The teachings also include a method of removing a target tissue from a subject. In these embodiments, the method can comprise creating an opening in a subject for access to a target tissue; inserting a cutting head taught herein through the opening to access the target tissue in the subject; and, forcing the cutting head in a forward direction on a surface comprising the target tissue to remove the target tissue. The forward direction can include a force vector that moves (i) at least substantially on a plane containing the central axis of the lumen of the cutting head, (ii) at least substantially on the surface comprising the target tissue, and (iii) toward the perimeter tissue that is protected by the blade guard. And, the method can include capturing the target tissue in the lumen of the cutting head, as well as removing the target tissue through the lumen and out of the subject.

[00023] In some embodiments, the method comprises forcing a cutting head taught herein in a backward direction on a surface comprising the target tissue to remove the target tissue. The backward direction can include a force vector that moves (i) at least substantially on a plane containing the central axis of the lumen of the cutting head, (ii) at least substantially on the surface comprising the target tissue, and (iii) away from the perimeter tissue that is protected by the blade guard.

[00024] In some embodiments, the method comprises forcing a cutting head taught herein in a transverse direction on a surface comprising the target tissue to remove the target tissue. The transverse direction can include a force vector that moves (i) at an angle ranging from about 15° to about 150° from a plane containing the central axis of the lumen of the cutting head, (ii) at least substantially on the surface comprising the target tissue, and (iii) in contact with the perimeter tissue that is protected by the blade guard.

[00025] The teachings are also directed to an obturator, guard cannula to protect a subject during entry and exit of an elongated surgical cutting device having a non-linearity. In these embodiments, the guard cannula can comprise an entry hub having an inner perimeter, an outer perimeter, and an irrigation port that communicates between the inner perimeter with the outer perimeter; and, a linear, elongated split-tube having a proximal end, a distal end, and a lumen. In these embodiments, the proximal end of the split-tube can (i)

circumscribe at least a portion of the inner perimeter of the hub and (ii) be in operable communication with the irrigation port. In these embodiments, the communication can be operable to receive an irrigation fluid from the irrigation port, the transport of the irrigation fluid to a target tissue including, for example, a movement of the irrigation fluid from the irrigation port to the distal end of the split-tube on a luminal surface of the split-tube.

[00026] The distal end of the split-tube can also have any configuration desired by one of skill. For example, the distal end can at least substantially pointed and/or sharp. In some embodiments, the distal end can be at least substantially blunt to avoid damage to an entry tissue upon contact of the distal end with the entry tissue. The split-tube can also have a length ranging from about 10cm to about 60 cm and a width ranging from about 5mm to about 16mm. Moreover, the split in the split-tube can compose a gap having a width ranging from about 4mm to about 14mm, the split accommodating a non-linearity in the surgical device.

[00027] As described above, the systems taught herein can be used in a variety of procedures for removal of a target tissue from a subject including, for example, removal of a meniscus or a discectomy. In some embodiments, the surgical cutting device used with the guard cannula can be a discectomy device. And, in some embodiments, the entry tissue includes the subject's epithelial tissue, muscle tissue, nerve tissue, connective tissue, a blood vessel, bone, cartilage, or a combination thereof, leading to the nucleus pulposus. As such, the target tissue can include the nucleus pulposus in some embodiments.

[00028] The teachings are also directed to a surgical tissue removal kit having a surgical tissue removal system and a guard cannula, using any combination of system and cannula embodiments taught herein. In some embodiments, the kits can be a discectomy kit. As such, in some embodiments, the entry tissue includes the subject's epithelial tissue, muscle tissue, nerve tissue, connective tissue, a blood vessel, bone, cartilage, or a combination thereof, leading to the nucleus pulposus. As such, the target tissue can include the nucleus pulposus in some embodiments.

[00029] The teachings are also directed to a method of using the kits to remove a target tissue. In some embodiments, the method comprises creating an opening in a subject for access to a target tissue; inserting the cutting head of the kit through the entry hub and the elongated split-tube of the guard cannula of the kit; inserting the cutting head of the kit through the opening to access the target tissue in the subject while protecting the entry

tissue with the blunt, distal end of the split-tube. Otherwise, methods of using the tissue removal systems are the same or similar to those taught herein. One of skill will appreciate having such kits for discectomies, for example, in which the target tissue can be a nucleus pulposus, and the perimeter tissue can be an annulus fibrosis. One of skill will also appreciate having a kit with a guard cannula that helps protect the subject's epithelial tissue, muscle tissue, nerve tissue, connective tissue, a blood vessel, bone, cartilage, or a combination thereof, leading to the nucleus pulposus in such procedures.

[00030] One of skill will appreciate that the embodiments taught herein are provided for purposes of outlining general concepts, and that several additional embodiments are included in, and can be derived from, the teachings provided herein.

BRIEF DESCRIPTION OF THE FIGURES

[00031] FIGs. 1A-1D illustrates a variety of tubular cutting head configurations that can be fabricated from stock tube, according to some embodiments.

[00032] FIGs. 2A-2E show blade configurations, according to some embodiments.

[00033] FIGs. 3A-3C show cross section of individual blade profiles, according to some embodiments.

[00034] FIGs. 4A-4C illustrate a cutting head, according to some embodiments.

[00035] FIGs. 5A and 5B illustrate the angulation of a cutting head 500, according to some embodiments.

[00036] FIG. 6 illustrates an obturator, guard cannula, according to some embodiments.

[00037] FIG. 7 illustrates a surgical tissue removal kit, according to some embodiments.

[00038] FIGs. 8A-8C illustrate a system or kit that can irrigate concurrent with application of suction, and without the obturator, guard cannula in place, according to some embodiments.

[00039] FIGs. 9A-9G show cutting head designs that were tested, according to some embodiments.

[00040] FIGs. 10A-10E illustrate the advancements in the cutting head, according to some embodiments.

[00041] FIGs. 11A-11C illustrate a bayonet-type communication between a cutting head and a suction assembly, according to some embodiments.

DETAILED DESCRIPTION OF THE INVENTION

[00042] The teachings provided herein are generally directed to a safe and efficient cutting head for removing a target tissue from a subject during a surgical procedure. The target tissue can include any tissue that is accessible through a small surgical opening, for example, a joint tissue such as a meniscus or an intervertebral tissue, such as a nucleus pulposus. In some embodiments, the devices taught herein can be referred to as an orthopedic tissue removal device. In some embodiments, the devices taught herein are useful in X-LIF (lateral approach to an intervertebral fusions) procedures, T-LIF (transforaminal approach to intervertebral fusions) procedures, P-LIF (posterior approach to intervertebral fusions), or a percutaneous, transforaminal approach (Kambin triangle access).

[00043] The term “subject” and “patient” can be used interchangeably in some embodiments and refer to an animal such as a mammal including, but not limited to, non-primates such as, for example, a cow, pig, horse, cat, dog, rat and mouse; and primates such as, for example, a monkey or a human. As such, the terms “subject” and “patient” can also be applied to non-human biologic applications including, but not limited to, veterinary, companion animals, commercial livestock, and the like.

[00044] The cutting head can be tubular with a cutting surface forming at least a first plane on a distal perimeter of cutting head, the cutting head in operable communication with a suction device to excise a target tissue in a manner that facilitates an ease of removal of the tissue with the suction.

[00045] The cutting surface can be flat, sinusoidal, or serrated, for example, and the first plane of the cutting surface may be at an angle, Θ_{FP}, that deviates up to 75° from a position that is orthogonal to the central axis of the cutting head. In some embodiments, the cutting surface can have a second plane may be at an angle, Θ_{SP}, that deviates up to 75° from a position that is orthogonal to the central axis of the cutting head. In some embodiments, the cutting head has a cutting blade and a blade guard for guarding a perimeter tissue from the cutting blade. In some embodiments, Θ_{FP} and Θ_{SP} can be independently selected to range from 0° to about 75°, from about 5° to about 75°, from about 10° to about 70°, from about 15°

to about 65°, from about 10° to about 60°, from about 5° to about 55°, from about 15° to about 50°, from about 20° to about 45°, from about 15° to about 40°, from about 25° to about 35°, or any angle or range of angles therein in increments of 1°.

[00046] FIGs. 1A-1D illustrates a variety of tubular cutting head configurations that can be fabricated from stock tube, according to some embodiments. FIG. 1A shows a cutting head stock tube 100 having a first plane 105 at an angle, Θ_{FP}, that is orthogonal to the central axis 110 of the lumen of the stock tube 100. FIG. 1B shows a cutting head stock tube 100 having a first plane 105 at an acute angle, Θ_{FP}, to the central axis 110 of the lumen of the stock tube 100, the acute angle ranging from 1° to about 75°. FIG. 1C shows a cutting head stock tube 100 having a first plane 105 at an acute angle, Θ_{FP}, to the central axis 110 of the lumen of the stock tube 100, the acute angle, Θ_{FP}, ranging from 1° to about 75°; and, having a second plane 105 at an angle, Θ_{SP}, that is orthogonal to the central axis 110 of the lumen of the stock tube 100. FIG. 1D shows a cutting head stock tube 100 having a first plane 105 at an acute angle, Θ_{FP}, to the central axis 110 of the lumen of the stock tube 100, the acute angle ranging from 1° to about 75°; and, having a second plane 105 at an angle, Θ_{SP}, to the central axis 110 of the lumen of the stock tube 100, the acute angle, Θ_{SP}, ranging from 1° to about 75°.

[00047] The cutting head can be fabricated from any material known to one of skill to be suitable in a surgical environment for the uses taught herein. For example, a hard material with hardness greater than Rockwell C 30 or greater than Rockwell C 45 can be suitable in some embodiments. In some embodiments, the cutting head can be comprised of a component selected from the group consisting of tempered steel, stainless steel, high carbon steel, titanium or titanium alloy, ceramic, diamond and obsidian. In some embodiments, the stainless steel can comprise 304 stainless steel, 316 stainless steel, 17-4 PH stainless steel, 400 series stainless steel, or any other stainless steels known to one of skill to be suitable for the cutting functions taught herein. In some embodiments, the cutting head can be made of cobalt chromium, tungsten carbide, or a ceramic.

[00048] The tube forming the cutting head can have a wall thickness, for example, from 0.003" to 0.020" or more specifically 0.005" to 0.012". The cross-sectional area of the cutting head can range from 0.120 inches^2 to 1.5 inches^2 or, in some embodiments, from 0.180 in^2 to 0.400 in^2. The width in any direction can range from 0.080" to 0.400" or more and, in some embodiments, 0.160" to 0.250". In some embodiments, the cutting head can

have a maximum transverse cross section dimension ranging from about 3.0mm to about 20.0mm, from about 4.0mm to about 15.0mm, from about 4.0mm to about 12.0mm, from about 5.0mm to about 10.0mm, about 5.0mm to about 8.0mm, or any range therein in increments of 0.1mm. In some embodiments, the cutting heads have diameters of about 4.8mm, about 5.0mm, about 5.2mm, about 5.4mm, about 5.8mm, about 6.0mm, about 6.2mm, about 6.4mm, about 6.6mm, about 6.8mm, about 7.0mm, about 7.2mm, about 7.4mm, about 7.6mm, about 7.8mm, about 8.0mm, about 8.2mm, and any 0.1mm increment therein.

[00049] The distal perimeter of a cutting head can be on the first plane or the second plane, or a combination thereof, and the cutting surfaces can be any cutting surface known to one of skill, such as a razor surface, a serrated surface, or a sinusoidal surface, in some embodiments. There are a variety of possible blade configurations known to one of skill in the art of cutting blade design, and any such configuration may be used. For example, the cutting surface can have teeth and gullets between the teeth. The spacing between the teeth can be equal or variable, and the depth of the gullets can be equal or variable, and any combination of teeth and gullets can be used. In some embodiments, the direction of the protrusion of the teeth can be offset from the direction of the remainder of the walls of the cutting head. In some embodiments, the teeth are in the same direction as the remainder of the walls of the cutting head, such that the teeth are merely an extension of the walls of the cutting head, with no shift in direction toward the lumen of the cutting head or away from the lumen of the cutting head. In some embodiments, there is a pattern of directional shift of the teeth away from, or toward, the lumen of the cutting head. For example, the pattern can be a sequence of toward, away, toward, away, no shift, and the sequence is repeated around the distal edge of the outer perimeter of the cutting head. In some embodiments, all teeth can point toward the lumen, and in some embodiments, all teeth can point away from the lumen. In some embodiments, the teeth alternate toward the lumen and away from the lumen tooth-by-tooth. And, in some embodiments, the teeth are gradually toward and away from the lumen at gradually increases and decreasing angles, tooth-by-tooth, to create an appearance of waves as the teeth circle the distal edge of the outer perimeter. The sequence can also be entirely random.

[00050] FIGs. 2A-2E show blade configurations, according to some embodiments. FIG. 2A shows a 5 tooth shift pattern of toward, away, toward, away, no shift, repeat. FIG. 2B shows a random shift pattern. FIG. 2C shows a wavy shift pattern. FIG. 3D shows a 3 tooth

shift pattern of away, toward, no shift, repeat. And, FIG. 3E shows a simple away, toward, repeat shift pattern.

[00051] The choice of blade configuration can be combined with a choice of blade profile, in some embodiments. Those of skill in the art of designing cutting blades will appreciate that the cutting heads taught herein can have a variety cutting actions, such as a chisel action, sawing action, slicing action, and ripping action, for example. As such, the blade profile chosen can be varied to use any blade profile known to one of skill. In some embodiments, the teeth are beveled. In some embodiments, the cutting heads have teeth that point backward as well as forward to include forward cutting surfaces in addition to backward cutting “spurs.”

[00052] As such, the teachings include a tubular cutting head for removing a target tissue of a subject. And, the tube can be an elongated, tubular structure of any shape, such as circular tube, a square tube, a rectangular tube, an elliptical tube, a pentagonal tube, a hexagonal tube, heptagonal, an octagonal tube, and the like, such that any number of sides, curvatures, or combinations thereof can be used in some embodiments. In some embodiments, a circular tube is used.

[00053] The cutting heads can have a combination of blade types, for example, forward-cutting blades, backward-cutting blades, and transverse cutting blades, as well as protrusions, hooks, and the like, for grabbing, ripping, or otherwise removing tissue. In some embodiments, the cutting head can have a backward cutting blade for cutting the target tissue in a backward stroke of the cutting head, a transverse cutting blade for cutting the target tissue in a transverse stroke of the cutting head, or a combination thereof. In some embodiments, a transverse cutting blade can be positioned on the blade guard for cutting the target tissue in a transverse stroke of the cutting head.

[00054] FIGs, 3A-3C show cross section of individual blade profiles, according to some embodiments. FIG. 3A shows a planar-concave blade profile. FIG. 3B shows a wedge blade profile. And, FIG. 3C shows a chisel blade profile. Likewise, it should be appreciated that the blades can be designed to have any configuration, including a single-edge, double-edge, single barb, double-barb, straight tip, barbed tip, and the like, to assist with any form of tissue removal, including cutting, slicing, chiseling, scraping, gouging, sawing, grinding, and ripping of a tissue for efficiency in removal during a surgery, for example.

[00055] FIGs. 4A-4C illustrate a cutting head, according to some embodiments. FIG. 4A shows an oblique view of the cutting head, and FIG. 4B shows a lateral view. The cutting head 400 can have an outer perimeter 405 that circumscribes a lumen 410 through the cutting head 400, the lumen 410 having a central axis 415. The cutting head 400 can also have a forward cutting blade 420 on a distal edge 425 of the outer perimeter 405, the forward cutting blade 420 configured for (i) cutting a target tissue (not shown) in a forward stroke of the cutting head 400 and (ii) directing the cut tissue into the lumen 410. And, the cutting head 400 can also have a blade guard 430 positioned distal to the forward cutting blade 420 and configured to guard a perimeter tissue (not shown) from the forward cutting blade 420 upon the forward stroke the blade guard 430 having a width 433 that is smaller than the width 422 of a transverse cross-section of the lumen 410 to facilitate entry of the target tissue into the lumen 410 on the forward stroke. And, as shown in FIGs. 4A-4C, the lateral surfaces 409 of the blade guard can also be serrated, or otherwise sharp cutting surfaces, for transverse cutting.

[00056] Since the cutting head can be designed to remove tissue through use of a suction 444, the teachings are also directed to systems of a cutting head that operably connect the cutting head with a suction assembly 484 (distal end only shown). As such, FIG. 4C also shows such a surgical, tissue removal system that includes a tubular cutting head 400 for removing a target tissue (not shown) of a subject. The system can include a cutting head 400 having an outer perimeter that circumscribes a flow of suction 444 through the cutting head 400; a lumen 415 circumscribed by the outer perimeter 405, the lumen 410 guiding the flow of suction 444 and having a central axis 415; a forward cutting blade 420 on a distal edge 425 of the outer perimeter 405, the forward cutting blade 420 configured for (i) cutting the target tissue in a forward stroke of the cutting head 400 and (ii) directing the cut tissue into the lumen 410; and, a blade guard 430 positioned distal to the forward cutting blade 420 and configured to guard a perimeter tissue (not shown) from the forward cutting blade 420 upon the forward stroke the blade guard 430.

[00057] The cutting head can be configured for an operable communication between the lumen 410 and a source of the suction 444, such that the systems 400 include the suction assembly 484 in operable communication with the cutting head 400 for creating the flow of suction 444 for removing the target tissue through the lumen 410 and out of the subject, the suction assembly 484 comprising a rigid suction tube 488 with a central axis. In some embodiments, the operable communication includes the use of one or more suction ports

466 positioned just proximal to the most proximal point of the distal edge of the out perimeter of the cutting head. In some embodiments, the one or more suction ports 466 can be located from about 3mm to about 20mm proximal to the most proximal point of the distal edge 425. While not intended to be bound by any theory or mechanism of action, one of skill will appreciate that a source of additional air can be useful when suctioning within a region that can create vacuum which would otherwise impede or cease the flow of suction that transports excised tissue away from the surgical space during the removal of the tissue. The suction ports 466 can be used to provide the additional air to avoid creating of the vacuum in the surgical space.

[00058] Any suction assembly construction known to one of skill can be used in many embodiments. In some embodiments, the suction assembly 484 comprises an at least substantially rigid suction tube 488 having a proximal end (not shown) and a distal end 499, the distal end 499 in the operable communication with the cutting head 400, and the distal end 499 configured for communicating with a source of suction 444 for the suction assembly 484. In some embodiments, the at least substantially rigid suction tube 488 can be formed as a single unit with the cutting head 400. The phrase, “at least substantially rigid” can refer a component that is rigid, or sufficiently rigid such that the desired function is obtained, under the forces that are created with normal use. For example, a desired function may be to prevent or inhibit the occurrence of a bending moment of the rigid component at one or more points along the length of a rigid suction tube upon use of the cutting head in the subject.

[00059] The following table describes the dimensional ratios of the cutting head 400 that were found to facilitate fast-and-efficient tissue removal in a discectomy. The “Label” is used to show the components and measures that form the ratios in a small device and a large device.

Label->	402	403	404	401			
	Cutter Diameter (in)	Pincer Height (in)	Pincer Width at the peak of the arch(in)	ID-Pincer Tip gap (in)	403/402	404/402	401/402
Small Device	0.203	0.098	0.080	0.085	0.483	0.394	0.419
Large Device	0.250	0.140	0.125	0.104	0.560	0.500	0.416
				Mean-->	0.521	0.447	0.417
				Theoretical Upper Limit	0.7	0.7	0.6
				Theoretical Lower Limit	0.3	0.3	0.3

[00060] The rigid suction tube can comprise any material known to one of skill to be suitable for the uses taught herein. For example, the rigid suction tube can comprise any surgical steel, plastic or resin considered desirable to one of skill for the devices taught herein. In some embodiments, the rigid suction tube can comprise the same or similar materials as the cutting head. In some embodiments, the rigid suction tube can comprise a stainless steel, polyetheretherketone (PEEK), polyimide, or carbon fiber. The wall thickness of the shaft can be any thickness at which a select material will have the physical properties desired. In some embodiments, the wall thickness can range, for example, from 0.003” to 0.020,” and from 0.005” to 0.010” in some embodiments. The luminal surface of the tube can be coated with TEFLON, a hydrophobic coating such as parylene, or a hydrophilic coating such as polyvinyl alcohol or polyethylene glycol.

[00061] In some embodiments, the rigid suction tube can comprise a polymer tube reinforced with a metal braid, a coiled tube, or a tube with transverse slots to facilitate articulation, should articulation be desired in some embodiments. In such embodiments, the cutting head can be angled relative to the axis of the rigid suction tube by, for example,

pulling on a tendon attached to the cutting head on one side, the tendon running-along a guide on the side of the rigid suction tube.

[00062] FIGs. 5A and 5B illustrate the angulation of a cutting head 500, according to some embodiments. FIG. 5A shows that the central axis 515 of the lumen 510 can be at an angle, Θ_1, ranging from about 5° to about 90° from a central axis 555 of the flow of suction 544 at the distal end 599 of the suction assembly (partially shown) 584, and the forward cutting blade 520 can be located about 2mm to about 25mm from the vertex of the angle, Θ_1. . In some embodiments, Θ_1 can range from about 2mm to about 30mm, from about 2mm to about 30mm, from about 2.5mm to about 25mm, from about 3mm to about 25mm, from about 4mm to about 20mm, from about 5mm to about 15mm, from about 3mm to about 25mm, from about 7mm to about 12mm, from about 8mm to about 10mm, or any range therein in increments of 0.5mm.

[00063] In some embodiments, the central axis of the lumen is at an angle, Θ_1, ranging from about 5° to about 90° from the central axis of the rigid suction tube, and the forward cutting blade is located about 3mm to about 25mm from the vertex of the angle, Θ_1. And, in some embodiments, the central axis of the lumen has a point of exit at the forward cutting blade, and the point of exit is located at a transverse distance of about 3mm to about 25mm that is orthogonal to the central axis of the rigid suction tube

[00064] In some embodiments, the central axis of the lumen is at an angle, Θ_1, ranging from 1° to 180° from a central axis of the flow of suction at the distal end of the suction assembly, and the forward cutting blade is located 3mm to 25mm from the vertex of the angle, Θ_1. In these embodiments, additional angle, Θ_3, is located 5mm to 25mm proximal to Θ_1, and angles Θ_1 and Θ_3 are independently selected to range from about 0° to about 180°, with the limitation that (i) the net angle, Θ_4, between the central axis of the lumen of the cutting head and the central axis of a rigid suction tube located proximal to Θ_3 ranges from 0° to 90°; and, (ii) the distance between the central axis of the lumen of the cutting head and the central axis of the rigid suction tube ranges from 2mm to 30mm. As such, the distance in the flow of suction between angles Θ_1 and Θ_3 can range from about 5mm to about 30mm, from about 5mm to about 25mm, from about 5mm to about 20mm, from about 6mm to about 18mm, from about 7mm to about 15mm, or any range or distance therein in increments of 1mm.

[00065] In some embodiments, the operable communication between the cutting head 500 and the suction assembly 584 can be articulating, and the angle, Θ_1, can be adjustable. In some embodiments, the operable communication between the cutting head 500 and the suction assembly 584 can be rigid, and the angle, Θ_1, can be fixed. In some embodiments, the angle, Θ_1, can range from 0° to about 45°, from about 1° to about 40°, from about 5° to about 35°, from 10° to about 35°, from 15° to about 40°, from 20° to about 30°, or any range therein in increments of 1°. In some embodiments, the angle, Θ_1, can be about 3°, about 5°, about 10°, about 15°, about 20°, about 25°, about 30°, about 35°, about 40°, about 45°, or any angle therein in increments of 1°.

[00066] In some embodiments, the backward cutting blade can be positioned on the distal edge 525 of the outer perimeter 505 for cutting the target tissue in the backward stroke of the cutting head 500. In some embodiments, the backward cutting blade 531 can be positioned on the blade guard 530 for cutting the target tissue in the backward stroke of the cutting head 500. FIG. 5B shows that the blade guard 530 can have a double-edged blade tip as the backward cutting blade 531 point back into the lumen 515 at an angle, Θ_2, of greater than 90° from the central axis 515 of the lumen 500 to trap and/or cut tissue in the lumen 510 in the backwards stroke of the cutting head 500. The backward cutting blade 531 can be referred to as a “talon” in some embodiments, or “pincer”, as it can function to grab, shear, and hook tissue for removal.

[00067] It should be appreciated that the cutting heads and systems taught herein have a variety of applications known to one of skill. In some embodiments, the target tissue can be a nucleus pulposus, and the perimeter tissue can be an annulus fibrosis, for example.

[00068] A surgical, tissue removal system for a discectomy is provided, and the systems can comprise a tubular cutting head for removing a nucleus pulposus from a subject. In these embodiments, the systems can include a cutting head having an outer perimeter that circumscribes a flow of suction through the cutting head; a lumen circumscribed by the outer perimeter, the lumen guiding the flow of suction; a forward cutting blade on a distal edge of the outer perimeter, the forward cutting blade configured for (i) cutting the nucleus pulposus in a forward stroke of the cutting head and (ii) directing the cut nucleus pulposus into the lumen; a backward cutting blade for cutting the nucleus pulposus in a backward stroke of the cutting head; a transverse cutting blade for cutting the nucleus pulposus in a transverse stroke of the cutting head; and, a blade guard positioned distal to the forward cutting blade

and configured to guard an annulus fibrosis tissue from the forward cutting blade upon the forward stroke.

[00069] Another valuable feature is that the devices taught herein can operate without substantial clogging from the flow of excised tissue from the cutting head, and this was accomplished by design. Without intending to be bound by any theory or mechanism of action, it was discovered that the area of a transverse cross-section of the distal end of the cutting head should be at least substantially equal to, or less than, the transverse cross-sectional area of any point that is positioned proximal to the distal end of the cutting head leading to collection of the flow of excised tissue from the cutting head. Such points would include, for example, any such point of cross-section along the rigid suction tube, or any other component of the section assembly leading to the point of collection of the excised tissue, for example, the most proximal orifice at which the pressure difference dumps the excised tissue into a collection canister in some embodiments. The term “at least substantially equal to” means that there may be a smaller transverse cross-sectional area, as long as it is limited in magnitude, in some embodiments. In some embodiments, the transverse cross-sectional area can be at least substantially equal to the transverse cross-sectional area of the cutting head if it is no more than 20% less in transverse cross-sectional area at the proximally located cross-section. In some embodiments, the transverse cross-sectional area can be at least substantially equal to the transverse cross-sectional area of the cutting head if it is no more than about 3%, about 5%, about 7%, about 9%, about 11%, about 13%, about 15%, about 17%, about 19%, about 21% less in transverse cross-sectional area at the proximally located cross-section. Any percent therein in increments of 1%, less in transverse cross-sectional area at the proximally located cross-section.

[00070] The teachings also include a method of removing a target tissue from a subject. In these embodiments, the method can comprise creating an opening in a subject for access to a target tissue; inserting a cutting head taught herein through the opening to access the target tissue in the subject; imaging the depth of the tip of the cutting head using a suitable imaging technique, such as fluoroscopy; and, forcing the cutting head in a forward direction on a surface comprising the target tissue to remove the target tissue while vacuum is activated to suck cut tissue proximally. The forward direction can include a force vector that moves (i) at least substantially on a plane containing the central axis of the lumen of the cutting head, (ii) at least substantially on the surface comprising the target tissue, and (iii) toward the perimeter tissue that is protected by the blade guard. And, the method can

include capturing the target tissue in the lumen of the cutting head, as well as removing the target tissue through the lumen and out of the subject.

[00071] The phrase, "at least substantially on…," can refer to a position or movement that is sufficient close to the exact desired position such that the desired function is obtained, under the forces and conditions that are created with normal use of the systems and devices taught herein. For example, "at least substantially on a plane containing the central axis of the lumen of the cutting head" or at least substantially on the surface comprising the target tissue" can refer to a position or movement that is parallel or substantially parallel to the plane or surface but perhaps off by about 1um to about 15mm from the actual plane, or perhaps off by about 0.1° to about 20° in direction of movement. The measure of "at least substantially" is used to approximate situations in which the exact measure or position is not obtained, but function desired by a person of ordinary skill is obtained. For example, a reduction of outcome when compared to the best possible outcome can be used to determine what is "at least substantially" the desired outcome. In some embodiments, the desired outcome is at least substantially obtained where the best possible outcome is reduced by less than 10%, less than 15%, less than 20%, less than 30%, less than 40% or less than 50%. In some embodiments, the desired outcome is at least substantially obtained where the best possible outcome is reduced by an amount of about 5% to about 30%, about 7% to about 35%, about 10% to about 25%, or any range therein in increments of 1%.

[00072] In a discectomy, the opening in the subject can vary, depending on the disk height of the subject, which is often in the range of about 5mm-7mm. In some embodiments, the opening in the subject can range in size from about 4mm x 4mm to about 14mm x 14mm. In some embodiments, the opening can be about 10mm x 7mm.

[00073] In some embodiments, the method comprises forcing a cutting head taught herein in a backward direction on a surface comprising the target tissue to remove the target tissue. The backward direction can include a force vector that moves (i) at least substantially on a plane containing the central axis of the lumen of the cutting head, (ii) at least substantially on the surface comprising the target tissue, and (iii) away from the perimeter tissue that is protected by the blade guard.

[00074] In some embodiments, the method comprises forcing a cutting head taught herein in a transverse direction on a surface comprising the target tissue to remove the

target tissue. The transverse direction, for example, can include a force vector that moves (i) at an angle ranging from about 15° to about 165° from a plane containing the central axis of the lumen of the cutting head, (ii) at least substantially on the surface comprising the target tissue, and (iii) in contact with the perimeter tissue that is protected by the blade guard.

[00075] The cutting heads taught herein are sharp and can be harmful to tissues during entry and exit of the cutting heads through the surgical opening. An obturator, guard cannula is provided in some embodiments to protect a subject during entry and exit of an elongated surgical cutting device having a non-linearity.

[00076] FIG. 6 illustrates an obturator, guard cannula, according to some embodiments. The guard cannula 600 can comprise an entry hub 605 having an inner perimeter 615, an outer perimeter 625, and an irrigation port 635 that communicates between the inner perimeter 615 with the outer perimeter 625; and, a linear, elongated split-tube 650 having a proximal end 655, a distal end 665, and a lumen 675. In these embodiments, the proximal end 655 of the split-tube 650 can (i) circumscribe at least a portion of the inner perimeter 615 of the hub 605 and (ii) be in operable communication with the irrigation port 635. In these embodiments, the communication can be operable to receive an irrigation fluid 690 from the irrigation port 635, the transport of the irrigation fluid 690 to a target tissue (not shown) including, for example, a movement of the irrigation fluid 690 from the irrigation port 635 to the distal end 665 of the split-tube 650 on a luminal surface 680 of the split-tube 650.

[00077] One of skill will appreciate that the “irrigation fluid” can be any fluid desired by one of skill, including liquids and gases. In some embodiments, the irrigation fluid can be aqueous. In some embodiments, the irrigation fluid can be non-aqueous. And, in some embodiments, the irrigation fluid can be an emulsion. In some embodiments, the irrigation fluid can comprise a gas. Examples of aqueous irrigation fluids include water, saline, or an aqueous surfactant containing liquid. Examples of non-aqueous fluids can include any oil-based liquid that may help facilitate tissue extraction during a surgical procedure. Examples of gases can include carbon dioxide, nitrogen, air, and any inert or at least substantially non-reactive gases. In some embodiments, the irrigation fluid can include a lubricant, such as glycerin, silicon oil, and the like. Irrigation fluids can be used as a carrier to help remove an excised tissue, or to help inhibit the creation of a vacuum within a surgical site that can inhibit the removal of the excised tissue. An example of such as a vacuum is one that may

be created during use of a suction within a closed cavity such as an intervertebral space within an annulus during a discectomy.

[00078] The distal end 665 of the split-tube 650 can also have any configuration desired by one of skill. For example, the distal end 665 can be at least substantially pointed and/or non-blunt. In some embodiments, the distal end 665 can be at least substantially blunt to avoid damage to an entry tissue upon contact of the distal end 665 with the entry tissue. The split-tube 650 can also have a length ranging from about 10cm to about 60 cm and a width ranging from about 5mm to about 16mm. Moreover, the split in the split-tube 650 can compose a gap 667 having a width ranging from about 4mm to about 14mm, the split accommodating a non-linearity in the surgical device. In some embodiments, the cutting heads taught herein can have a diameter that is smaller than that of the portion of the suction assembly that passes through the lumen of the guard cannula, such that the guard cannula holds the suction assembly 484 but allows the cutting head 400 to pass through the gap 667. As such, the gap 667 can have a width that exceeds the diameter of the cutting head 400 but is less than the diameter of the rigid suction tube 488, and the lumen of the guard cannula 600 has a diameter that exceeds the diameter of the rigid suction tube 488.

[00079] As described above, the systems taught herein can be used in a variety of procedures for removal of a target tissue from a subject including, for example, removal of a meniscus or a discectomy. In some embodiments, the surgical cutting device used with the guard cannula can be a discectomy device. And, in some embodiments, the entry tissue includes the subject's epithelial tissue, muscle tissue, nerve tissue, connective tissue, a blood vessel, bone, cartilage, or a combination thereof, leading to the nucleus pulposus. As such, the target tissue can include the nucleus pulposus in some embodiments.

[00080] A surgical tissue removal kit having a surgical tissue removal system and a guard cannula is provided, the kit using any combination of system and cannula embodiments taught herein. In some embodiments, the kits can be a discectomy kit. As such, in some embodiments, the entry tissue includes the subject's epithelial tissue, muscle tissue, nerve tissue, connective tissue, a blood vessel, bone, cartilage, or a combination thereof, leading to the nucleus pulposus. As such, the target tissue can include the nucleus pulposus in some embodiments.

[00081] FIG. 7 illustrates a surgical tissue removal kit, according to some embodiments. The kit 700 includes a cutting head 400, a suction assembly 484, and an obturator, guard

cannula 600. A flow of suction 444 from the suction assembly 484 enters the cutting head 400 to remove a target tissue excised by the cutting head. Irrigation water 690 can enter irrigation valve 795 and/or the irrigation port 635, the irrigation water 690 coming from the irrigation valve 795 is used when the suction 444 is off, and the irrigation water 690 coming from the irrigation port 635 can be used when the suction 444 is on, during which the suction 444 draws the irrigation water 690 between the luminal surface of the guard cannula 600 and the suction assembly 484 into the surgical area (not shown). The guard cannula 600 protects the entry tissue (not shown) while the cutting head 400 and suction assembly 484 moves relative to the entry tissue during a surgical procedure, the cutting head 400 moving, for example, in a forward, backward, and/or transverse motion to excise and remove the target tissue.

[00082] A method of using the kits to remove a target tissue is provided. In some embodiments, the method comprises creating an opening in a subject for access to a target tissue; inserting the cutting head of the kit through the entry hub and the elongated split-tube of the guard cannula of the kit; inserting the cutting head of the kit through the opening to access the target tissue in the subject while protecting the entry tissue with the blunt, distal end of the split-tube. Otherwise, methods of using the tissue removal systems are the same or similar to those taught herein. One of skill will appreciate having such kits for discectomies, for example, in which the target tissue can be a nucleus pulposus, and the perimeter tissue can be an annulus fibrosis. One of skill will also appreciate having a kit with a guard cannula that helps protect the subject's epithelial tissue, muscle tissue, nerve tissue, connective tissue, a blood vessel, bone, cartilage, or a combination thereof, leading to the nucleus pulposus in such procedures.

[00083] FIGs. 8A-8C illustrate a system or kit that can irrigate concurrent with application of suction, and without the obturator, guard cannula in place, according to some embodiments. FIG. 8A shows the complete discectomy system 800 including the cutting head 400, a means for applying suction through the suction assembly 884, a control handle 886 and a vacuum attachment 892, an irrigation tube 804, an irrigation control 802, and an optional vacuum control 888.

[00084] In embodiments in which the cutting head angle is adjustable, the handle 886 can have a knob (not shown) that turns to tension a pull cable to flex or straighten the cutting head relative to the rigid suction tube, or a slide that tensions the cable to flex or

straighten the cutting head relative to the rigid suction tube. The cables to flex and straighten can be on opposing sides of the shaft constrained to small side lumens attached to the outer surface of the shaft to flex and straighten out the cutting head.

[00085] FIG. 8B shows a cross-sectional view of the irrigation tube 804 relative to the rigid suction tube 894. And, FIG. 8C shows a cross-sectional view of the control handle 886 and internal piping.

[00086] One of skill will appreciate that the teachings and examples provided herein are directed to basic concepts that can extend beyond any particular embodiment, embodiments, figure, or figures. It should be appreciated that any examples are for purposes of illustration and are not to be construed as otherwise limiting to the teachings.

Example 1. Testing of cutter head designs

[00087] A variety of cutter heads were tested in 3 cadaver laboratories on 28 discs. The results were compared to determine the most efficient cutter head design. A desirable cutter head design was one that would cut well on all target tissues, including the nucleus pulposus, vertebral endplates, and inner annulus tissue. However, the cutter head should also cut the target tissues in a desired manner while providing little to no damage to the perimeter tissue, such tissue including the perimeter annulus fibrosis tissue that should be preserved as a desirable perimeter structure. In addition, the design should remove tissue quickly under suction, such that the configuration of the head facilitates the removal of the tissue under suction.

[00088] FIGs. 9A-9G show cutting head designs that were tested, according to some embodiments. The design in FIG. 9A cut well but it was not as safe to the annulus as other designs. The design in FIG. 9B was safe to the annulus but it did not cut tough tissue well and showed too much resistance. The design in FIG. 9C also did not penetrate tough tissue well. The design in FIG. 9D did cut and decorticate well, but it clogged on soft/elastic tissue. The design in FIG. 9E cut tough tissue well and did not clog, and it also decorticates really well. It was also safe to the annulus. The shape of the device however, did not reach the far side of the nucleus pulposus. The design in FIG. 9F shows a bend that was introduced to the device to enable the cutting head of FIG. 9E to reach the far side of the nucleus pulposus. The design in FIGs. 9G and 9H, however, showed the most efficient cutting head performance identified in the testing, removing 23cc of material in 5 minutes.

Example 2.

[00089] This example further developed the designs of the cutting heads. The design in FIGs. 8G and 8H were further investigated in 7 cadaver labs and 28 discs.

[00090] FIGs. 10A-10E illustrate the advancements in the cutting head, according to some embodiments. The design in FIG. 10A shows a cutting head having a bevel on the outer surface of the cutting teeth, and the device cut poorly and gouged soft bone. The design in FIG. 10B shows an oval cutting head not having the bevel on the outer surface of the cutting teeth, and the device had inconsistent cutting and gouged soft bone. The design in FIG. 10C was shown for a comparison result using a ring curette, and the device gouged soft bone. The design in FIG. 10D shows a short cutting head with a single “talon” or pincer, and the device showed the most appealing results to date with optimal cutting and no gouging. FIG. 10E is another proposed design, configured to perform with the efficiency of the design of FIG. 10D, with the addition of a second talon that bends away from the lumen of the cutting head to serve as an additional talon and blade guard.

[00091] The method used in this example was as follows:

1. Cutting a pilot hole of a 5-8mm dimension in height and width;
2. Pointing a 15° tip parallel to the vertebral endplates to cut and expand the cavity medially and laterally;
3. Gradually shaving down the endplates to hard tissue (cartilage or bone); fluoroscopy was used to verify the depth of the tip; the tip was used to shave along the curvature of the endplate; shaving was stopped where bone was exposed (hard, rough, sticky, and red aspirate identified as the endpoint); and, the handle of the device is tilted (i) medially to decorticate lateral side, and (ii) laterally to decorticate medial side;
4. Sweeping the cutting head medially-lateraly against anterior annulus to remove nucleus attached to the annulus and inner annulus as needed;
5. Pointing a 40° tip contralaterally and start shaving from posterior annulus while tilting handle laterally to remove bulk nucleus; and,
6. Rotating the handle toward the endplate to further decorticate.

Example 3.

[00092] This example describes an alternate embodiment that was tested, referred to as the serpentine or bayonet configuration, in which the rigid suction tube 488 can have at least two angles; an angle Θ_1, and an angle Θ_3.

[00093] FIGs. 11A-11C illustrate a bayonet-type communication between a cutting head and a suction assembly, according to some embodiments. It was discovered that the distal end of the rigid suction tube 488 can be redirected in bayonet, or serpentine, fashion in order to facilitate an improved access of the cutting head to a target tissue during a discectomy, for example. As shown in FIGs. 11A-11C, Angles Θ_1 and Θ_3 can each be independently selected to range from about 0° to about 180°, with the limitation that (i) the net angle, Θ_4, that is realized between the central axis 415 of the lumen 410 of the cutting head 400 and the central axis 497 of the rigid suction tube 488 (extended as directed proximal to Θ_1) ranges from 0° to 90°; and, (ii) the distance 498 between the central axis 415 of the lumen 410 of the cutting head 400 and the central axis 497 of the rigid suction tube 488 can range from about 2mm to about 30mm. And, in these embodiments, the central axis of the lumen can have a point of exit at the forward cutting blade, and the point of exit is located at a transverse distance of about 3mm to about 25mm

[00094] In some embodiments, the distance 498 between the from about 2.5mm to about 25mm, from about 3mm to about 25mm, from about 4mm to about 20mm, from about 5mm to about 15mm, from about 3mm to about 25mm, from about 7mm to about 12mm, from about 8mm to about 10mm, or any range therein in increments of 0.5mm. As such, the distance 498 can be about 2mm, about 3mm, about 4mm, about 5mm, about 6mm, about 7mm, about 8mm, about 9mm, about 10mm, about 12mm, about 14mm, about 16mm, about 18mm, about 20mm, about 22mm, about 24mm, about 26mm, about 28mm, about 30mm, and any distance or range therein in increments of 0.5mm. In some embodiments, the distance between the vertex of Θ_3 and the distal end of the cutting head 400 can range from about 5mm to about 25mm, from about 6mm to about 20mm, from about 7mm to about 15mm, or any range therein in increments of 1mm.

Amended Claims

WE CLAIM

1. A surgical, tissue removal system for removing a target tissue of a subject, the system comprising a cutting head having

   an outer perimeter that circumscribes a lumen through the cutting head, the lumen having a central axis;

   a forward cutting blade on a distal edge of the outer perimeter, the forward cutting blade configured for (i) cutting a target tissue in a forward stroke of the cutting head and (ii) directing the cut tissue into the lumen; and,

   a blade guard positioned distal to the forward cutting blade and configured to guard a perimeter tissue from the forward cutting blade upon the forward stroke the blade guard having a width that is smaller than the width of a transverse cross-section of the lumen to facilitate entry of the target tissue into the lumen on the forward stroke.

2. The system of claim 1, wherein the cutting head also has a backward cutting blade for cutting the target tissue in a backward stroke of the cutting head.

3. The system claim 1, wherein the cutting head also has a transverse cutting blade for cutting the target tissue in a transverse stroke of the cutting head.

4. The system of claim 1, wherein the cutting head also has a transverse cutting blade on the blade guard for cutting the target tissue in a transverse stroke of the cutting head.

5. The system of claim 1, wherein, the cutting head is further configured for an operable communication between the lumen and a source of a suction;

and,

a suction assembly in operable communication with the cutting head, the suction assembly providing the source of the suction and comprising an at least substantially rigid suction tube with a central axis and creating the flow of suction for removing the target tissue through the lumen and out of the subject.

6. The system of claim 5, wherein the at least substantially rigid suction tube is formed as a single unit with the cutting head.

7. The system of claim 5, wherein the cutting head also has a backward cutting blade for cutting the target tissue in a backward stroke of the cutting head.

Amended Claims

8. The system of claim 5, wherein the cutting head also has a transverse cutting blade for cutting the target tissue in a transverse stroke of the cutting head.

9. The system of claim 5, wherein the central axis of the lumen is at an angle, Θ_1, ranging from about 5^o to about 90^o from the central axis of the rigid suction tube, and the forward cutting blade is located about 3mm to about 25mm from the vertex of the angle, Θ_1.

10. The system of claim 9, wherein the operable communication between the cutting head and the suction assembly is articulating, and the angle, Θ_1, is adjustable.

11. The system of claim 9, wherein the operable communication between the cutting head and the suction assembly is rigid, and the angle, Θ_1, is fixed.

12. The system of claim 9, wherein the central axis of the lumen has a point of exit at the forward cutting blade, and the point of exit is located at a transverse distance of about 3mm to about 25mm that is orthogonal to the central axis of the rigid suction tube.

13. The system of claim 5, wherein the central axis of the lumen is at an angle, Θ_1, ranging from 1^o to 180^o from the central axis of the rigid suction tube, and the forward cutting blade is located 3mm to 25mm from the vertex of the angle, Θ_1; wherein,

    an additional angle, Θ_3, is located 5mm to 25mm proximal to Θ_1;

    angles Θ_1 and Θ_3 are independently selected to range from about 0^o to about 180^o, with the limitation that

    (i) the net angle, Θ_4, between the central axis of the lumen of the cutting head and the central axis of the rigid suction tube located proximal to Θ_3 ranges from 0^o to 90^o; and,

    (ii) the central axis of the lumen has a point of exit at the forward cutting blade, and the point of exit is located at a transverse distance of about 3mm to about 25mm that is orthogonal to the central axis of the rigid suction tube.

14. The system of claim 5, wherein the target tissue is a nucleus pulposus, and the perimeter tissue is an annulus fibrosis.

15. The system of claim 5, the cutting head also having a backward cutting blade for cutting the nucleus pulposus in a backward stroke of the cutting head;

    a transverse cutting blade for cutting the nucleus pulposus in a transverse stroke of the cutting head; and,

Amended Claims

wherein, the cutting head is configured for an operable communication between the lumen and a source of a suction;

and,

a suction assembly in operable communication with the cutting head, the suction assembly providing the source of the suction and comprising an at least substantially rigid suction tube with a central axis and creating the flow of suction for removing the nucleus pulposus through the lumen and out of the subject.

16. The system of claim 15, wherein the at least substantially rigid suction tube is formed as a single unit with the cutting head.

17. The system of claim 15, wherein the central axis of the lumen is at an angle, Θ_1, ranging from about 5^o to about 90^o from the central axis of the rigid suction tube, and the forward cutting blade is located about 3mm to about 25mm from the vertex of the angle, Θ_1.

18. The system of claim 15, wherein the central axis of the lumen has a point of exit at the forward cutting blade, and the point of exit is located at a transverse distance of about 3mm to about 25mm that is orthogonal to the central axis of the rigid suction tube.

19. The system of claim 17, wherein the operable communication between the cutting head and the suction assembly is articulating, and the angle, Θ_1, is adjustable.

20. The system of claim 17, wherein the operable communication between the cutting head and the suction assembly is rigid, and the angle, Θ_1, is fixed.

21. The system of claim 15, wherein the central axis of the lumen is at an angle, Θ_1, ranging from 1^o to 180^o from the central axis of the rigid suction tube, and the forward cutting blade is located 3mm to 25mm from the vertex of the angle, Θ_1; wherein,

an additional angle, Θ_3, is located 5mm to 25mm proximal to Θ_1;

angles Θ_1 and Θ_3 are independently selected to range from about 0^o to about 180^o, with the limitation that

(i) the net angle, Θ_4, between the central axis of the lumen of the cutting head and the central axis of the rigid suction tube located proximal to Θ_3 ranges from 0^o to 90^o; and,

Amended Claims

(ii) the central axis of the lumen has a point of exit at the forward cutting blade, and the point of exit is located at a transverse distance of about 3mm to about 25mm that is orthogonal to the central axis of the rigid suction tube.

22. The system of claim 15, wherein the backward cutting blade is positioned on the distal edge of the outer perimeter for cutting the target tissue in the backward stroke of the cutting head.

23. The system of claim 15, wherein the backward cutting blade is positioned on the guard for cutting the target tissue in the backward stroke of the cutting head, the guard having a double-edged blade tip point back into the lumen at an angle, Θ_2, of greater than 90^o to trap and/or cut tissue in the lumen in the backwards stroke of the cutting head.

24. The system of claim 15, wherein the transverse cutting blade is positioned on the blade guard for cutting the target tissue in the transverse stroke of the cutting head.

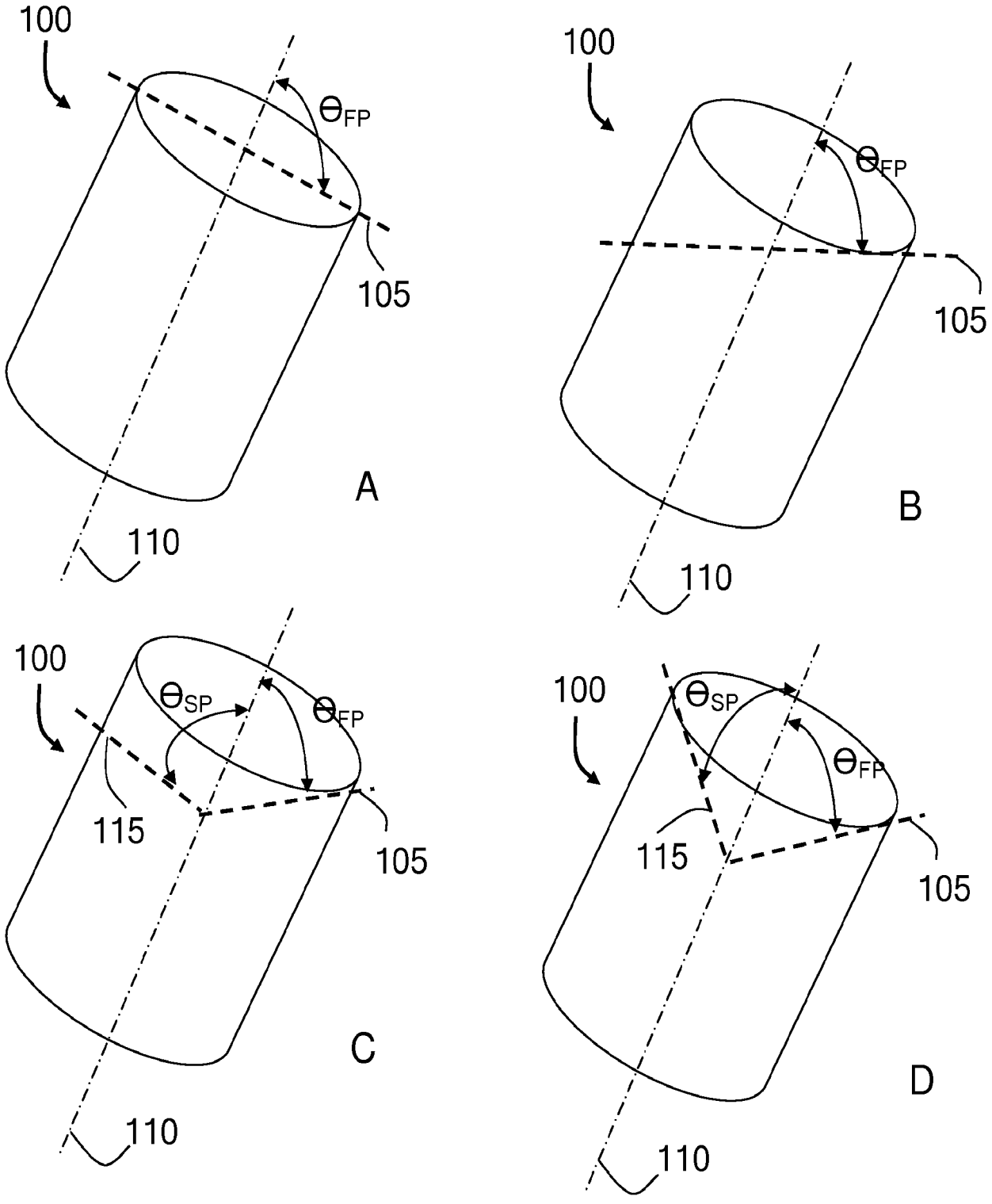

100
Θ_{FP}
105
A
110
100
Θ_{FP}
105
B
110
100
Θ_{SP}
Θ_{FP}
115
105
C
110
100
Θ_{SP}
Θ_{FP}
115
105
D
110

FIG. 1

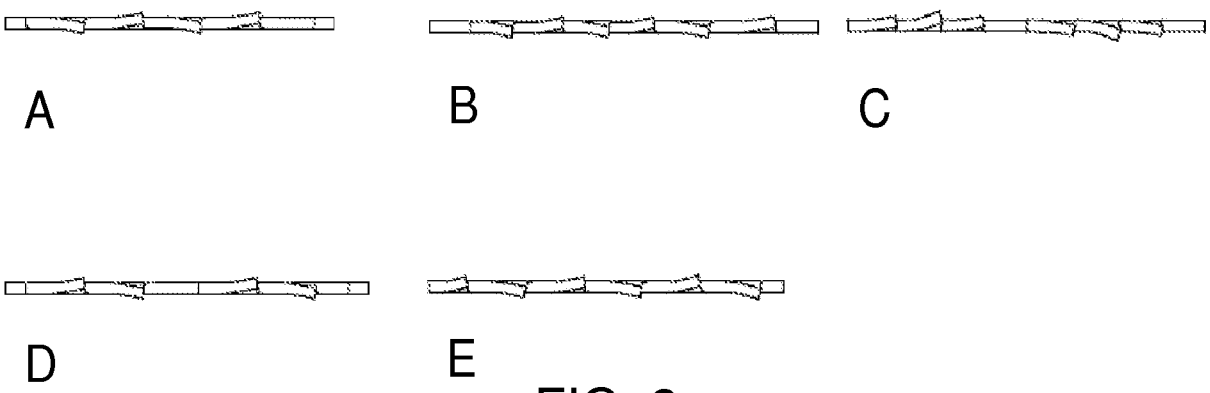


FIG. 2

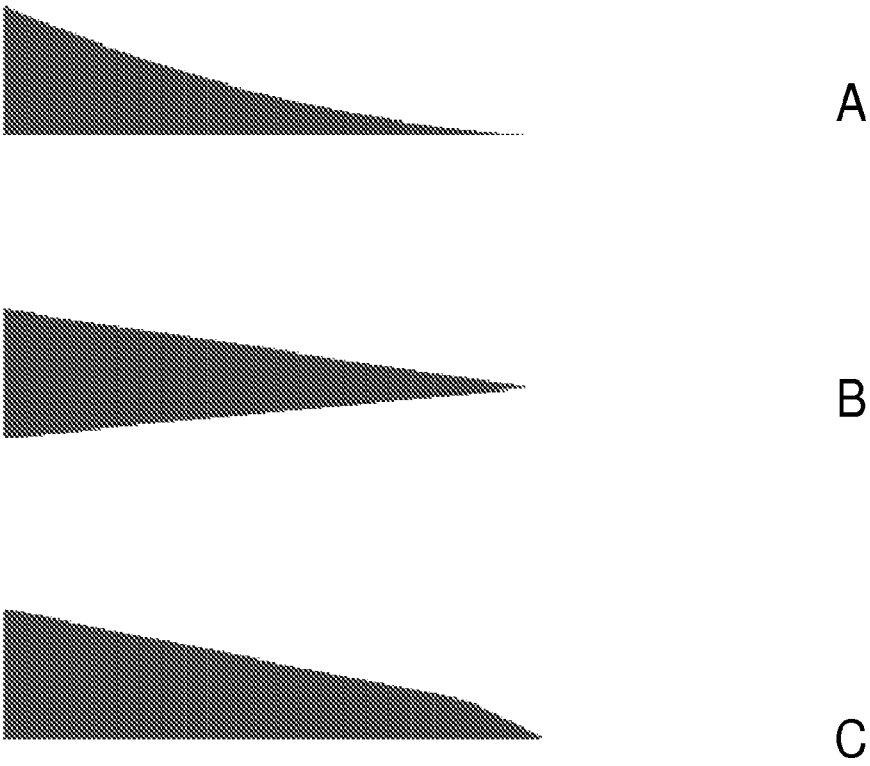


FIG. 3

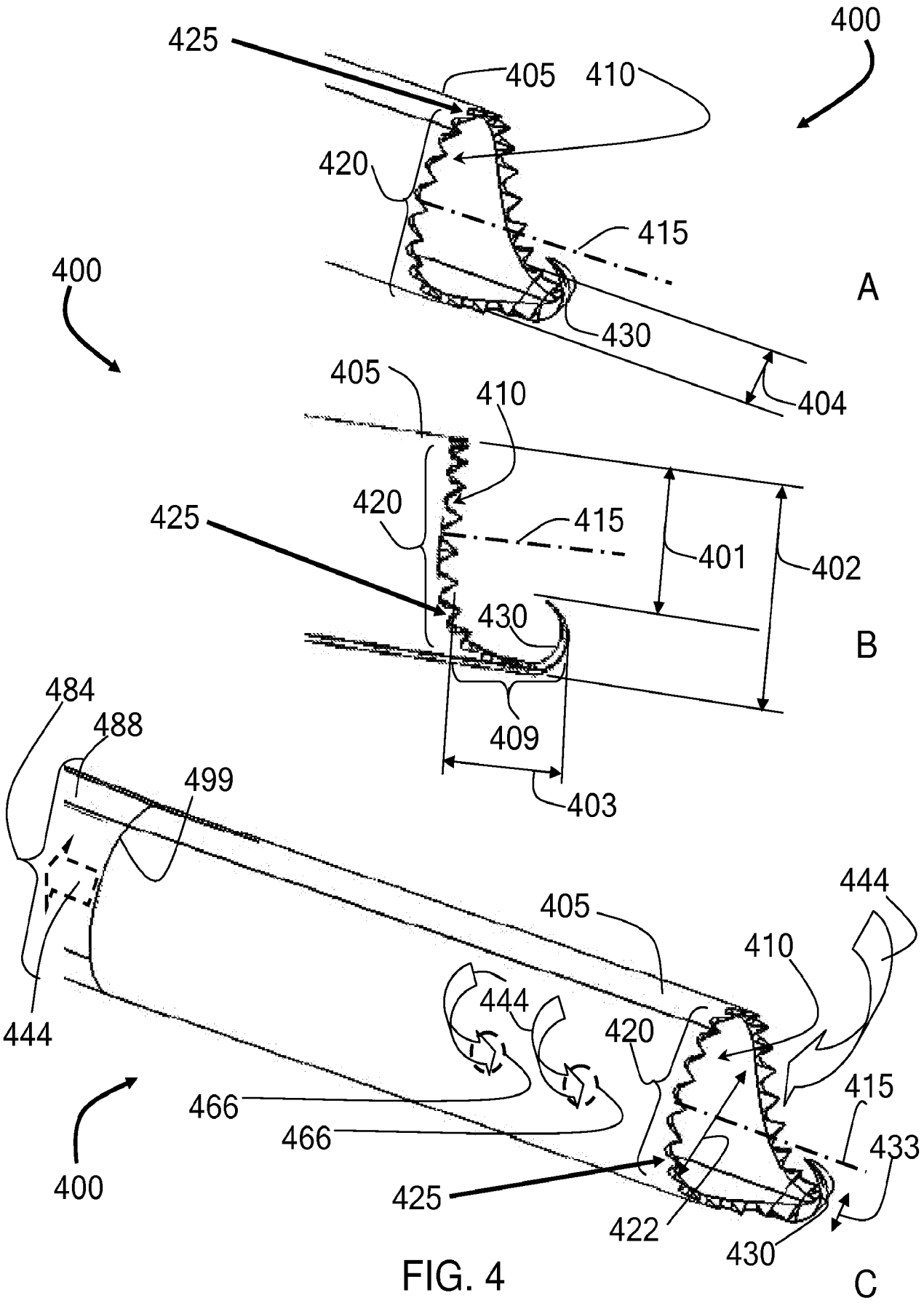

425
400
405
410
420
415
A
430
404
405
410
420
425
415
401
402
B
430
409
403
484
488
499
444
405
444
410
444
420
415
466
466
433
400
425
422
430
C

FIG. 4

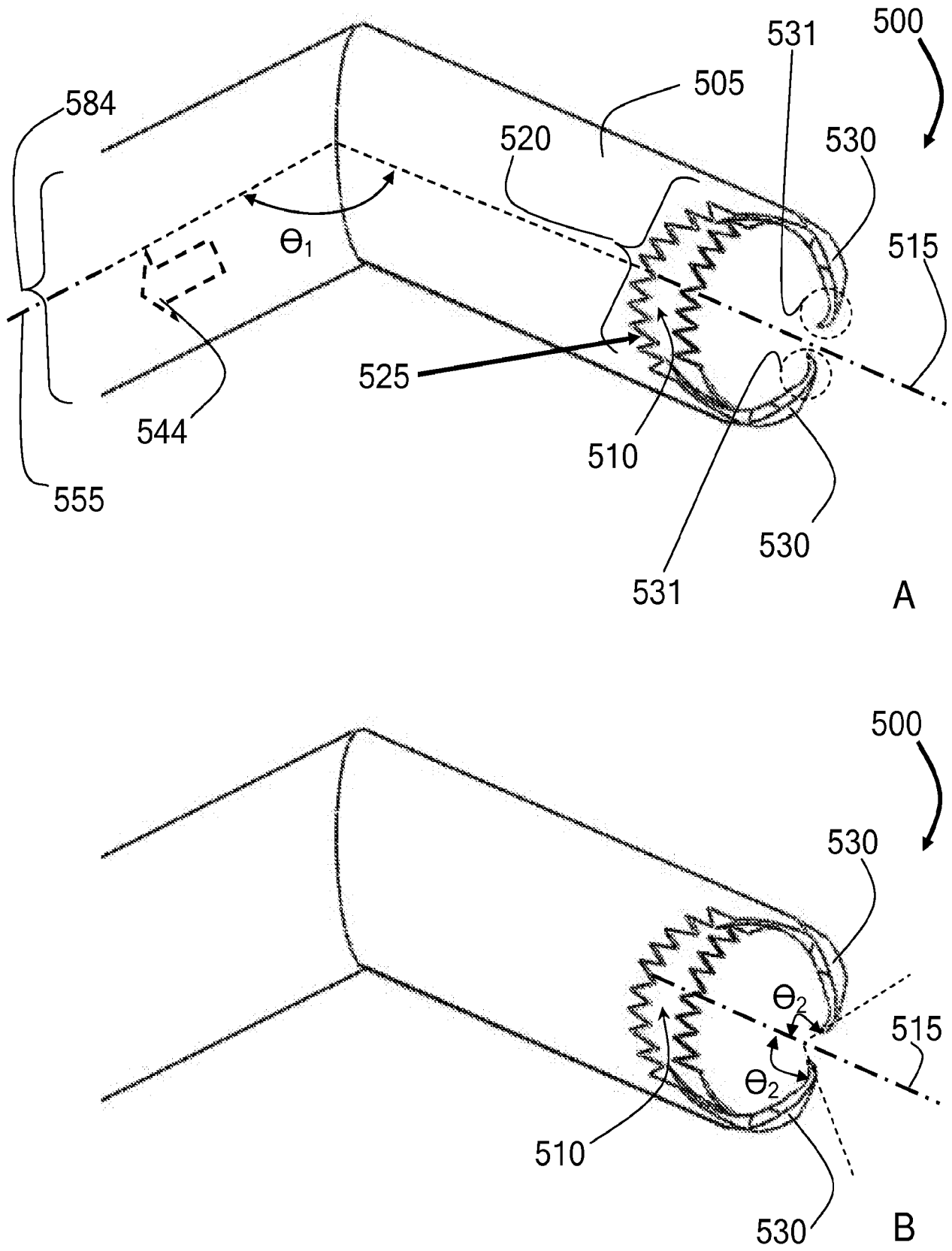

584
505
531
500
520
530
515
Θ_1
525
544
510
555
530
531
A
500
530
Θ_2
515
Θ_2
510
530
B

FIG. 5

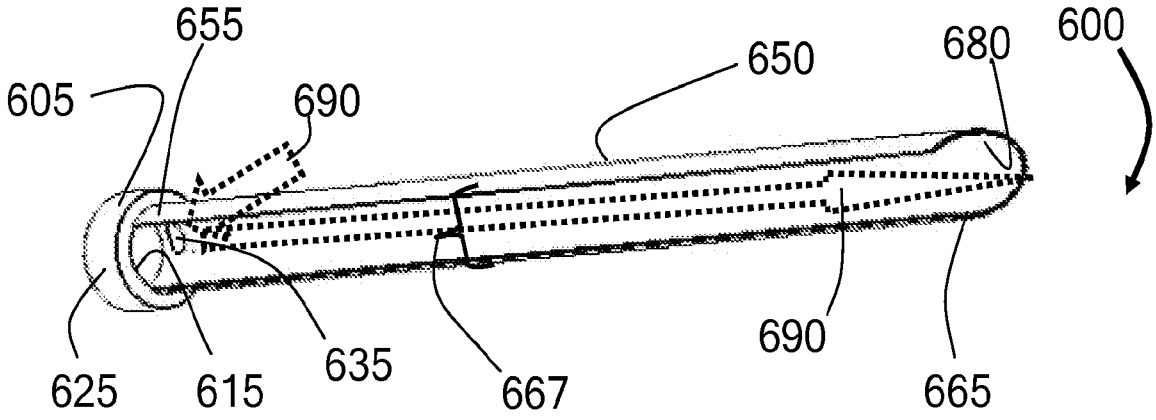

655
605
690
650
680
600
625
615
635
667
690
665

FIG. 6

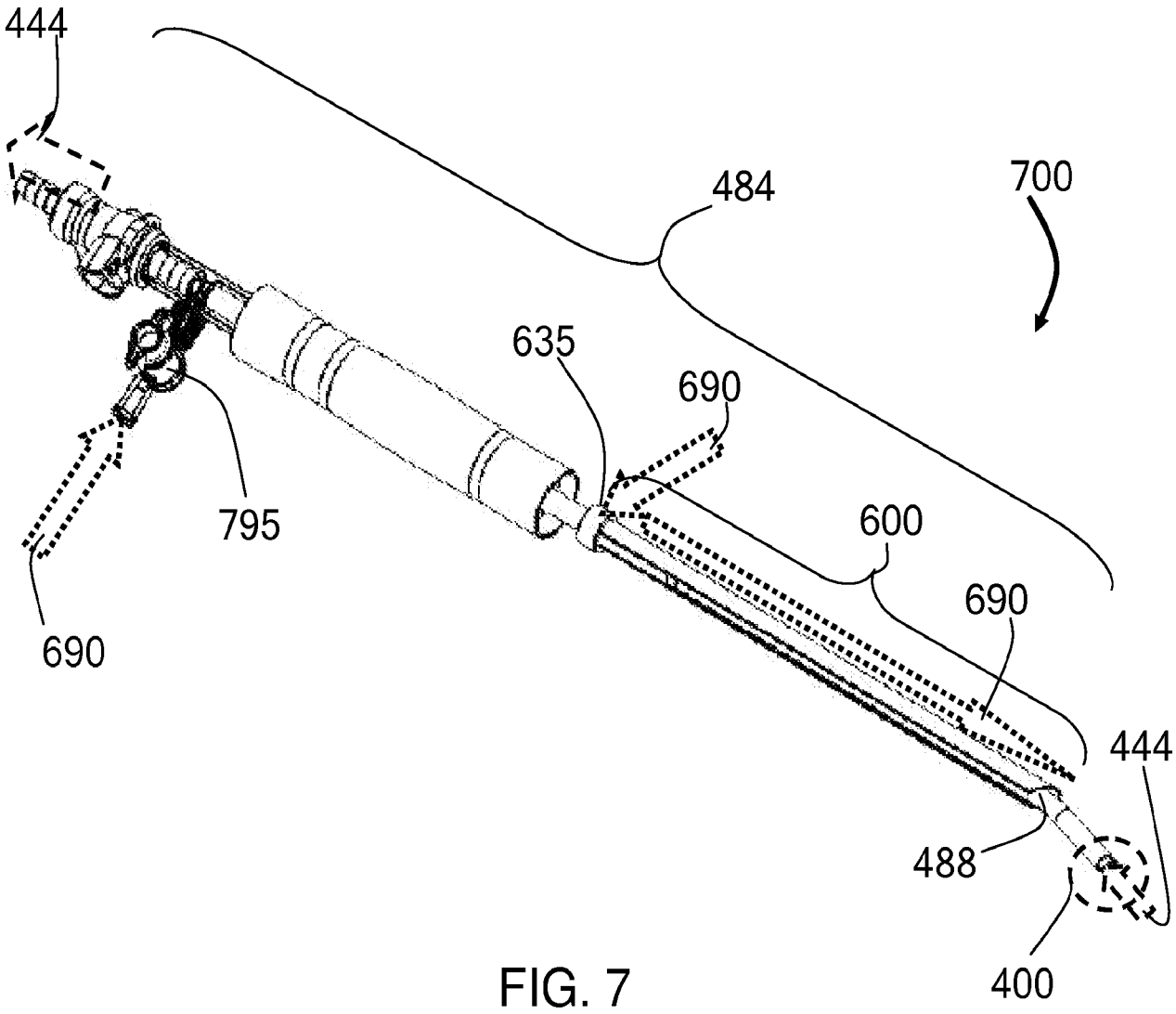

444
484
700
635
690
795
600
690
690
444
488
400

FIG. 7

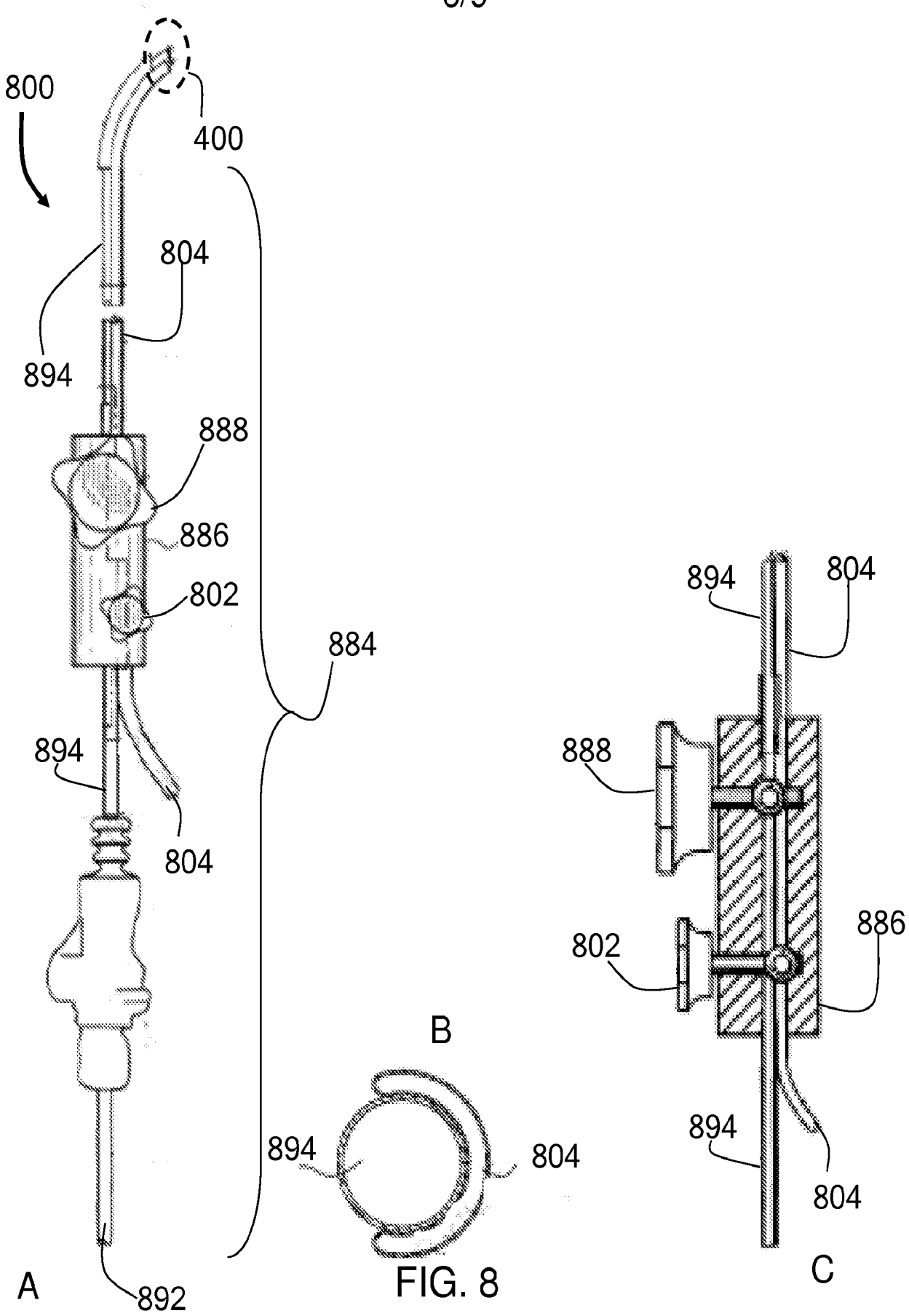
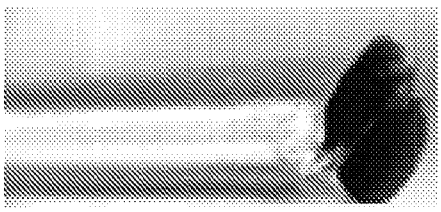
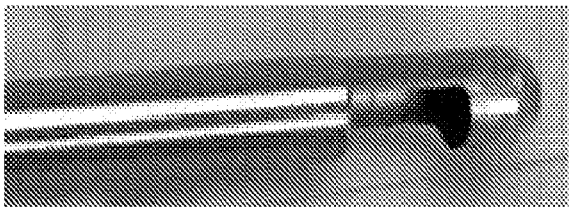

800
400
804
894
888
886
802
884
894
804
892
A
B
894
804
894
804
888
802
886
C

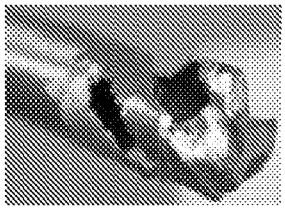
FIG. 8



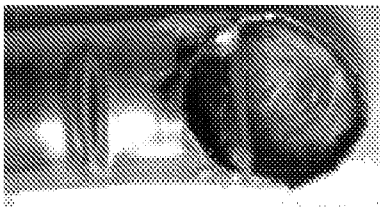
A



B

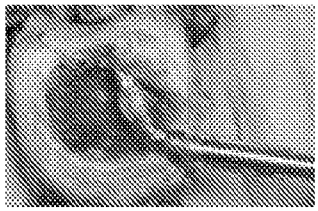


C

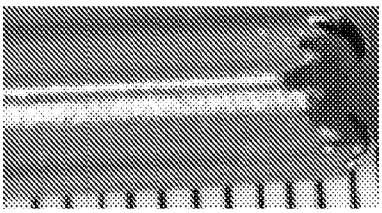


D

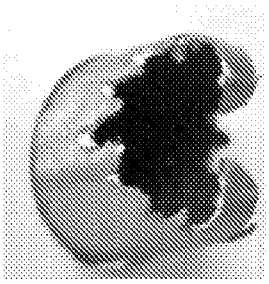
E



F

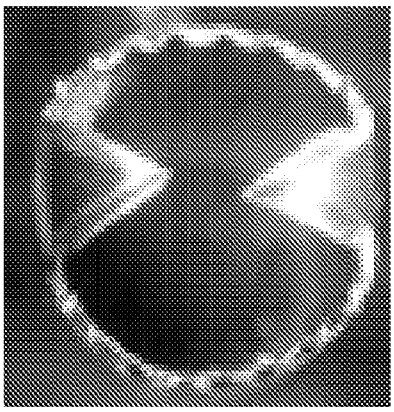


G

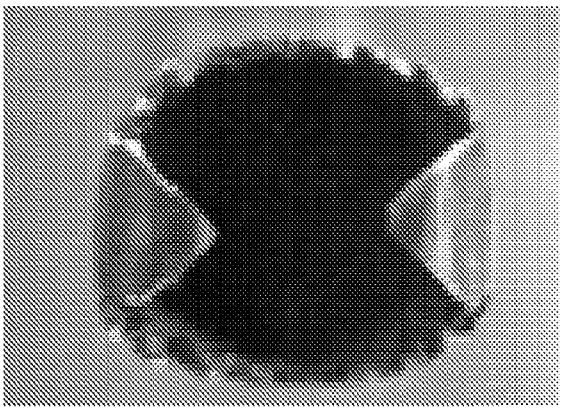


H

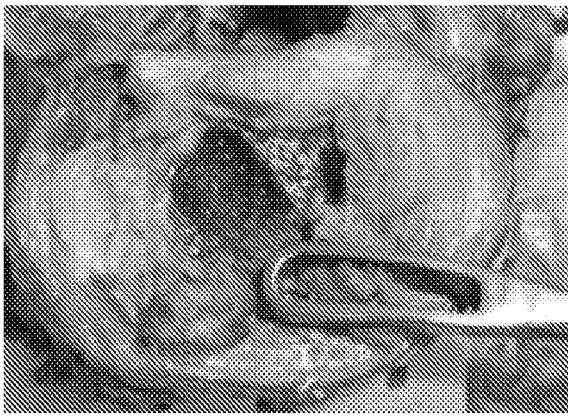
FIG. 9



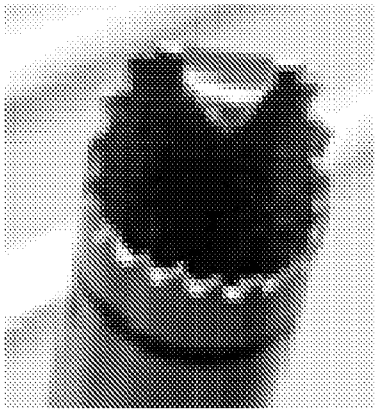
A



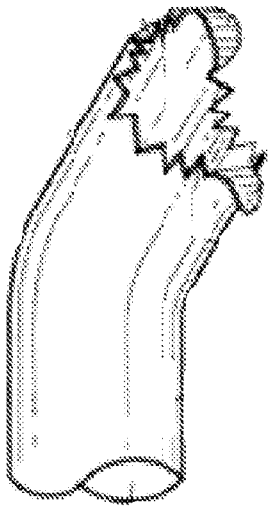
B



C

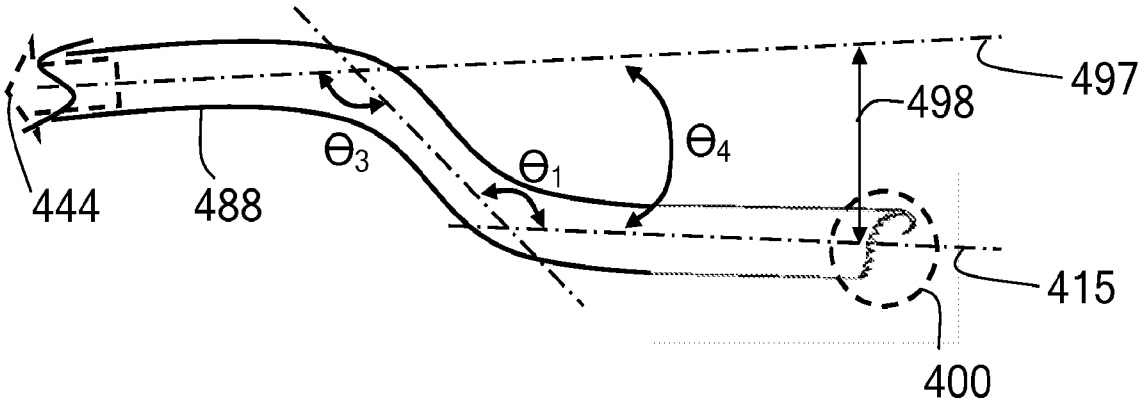


D

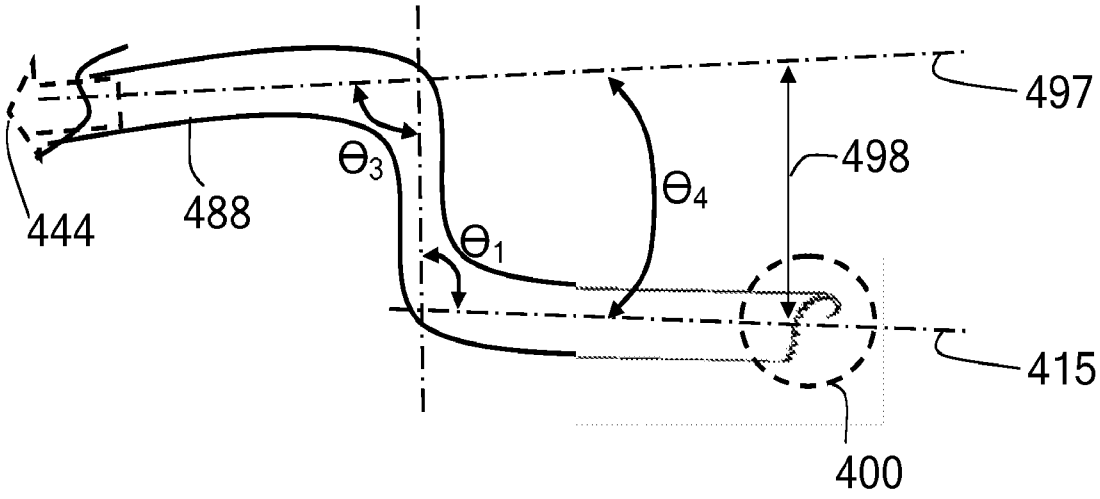


E

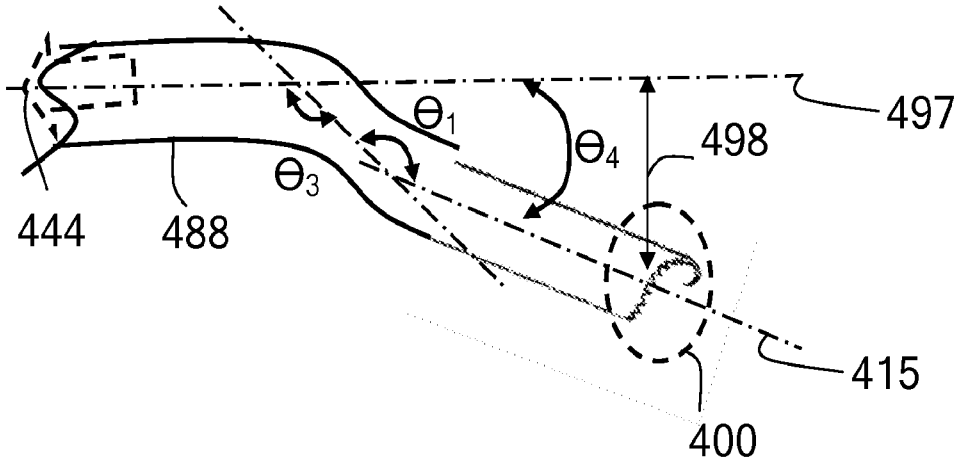
FIG. 10


497
498
Θ_3
Θ_1
Θ_4
444
488
415
400

A


497
498
Θ_3
Θ_4
444
488
Θ_1
415
400

B


497
Θ_1
Θ_4
498
Θ_3
444
488
415
400

C

FIG. 11

HK 1197964 A

(19)中华人民共和国国家知识产权局

(12)发明专利申请

(10)申请公布号 CN 103327913 A
(43)申请公布日 2013.09.25

(21)申请号 201280005026.4
(22)申请日 2012.08.22
(30)优先权数据
61/566,629 2011.12.03 US
61/596,865 2012.02.09 US
(85)PCT申请进入国家阶段日
2013.07.10
(86)PCT申请的申请数据
PCT/US2012/051952 2012.08.22
(87)PCT申请的公布数据
WO2013/081691 EN 2013.06.06
(71)申请人 欧罗波罗斯医学有限公司
地址 美国加利福尼亚州
(72)发明人 J·图
(74)专利代理机构 北京润平知识产权代理有限公司 11283
代理人 施娥娟 董彬
(51)Int.Cl.
A61B 17/3205(2006.01)
A61B 17/3209(2006.01)
A61B 17/34(2006.01)
A61B 17/70(2006.01)

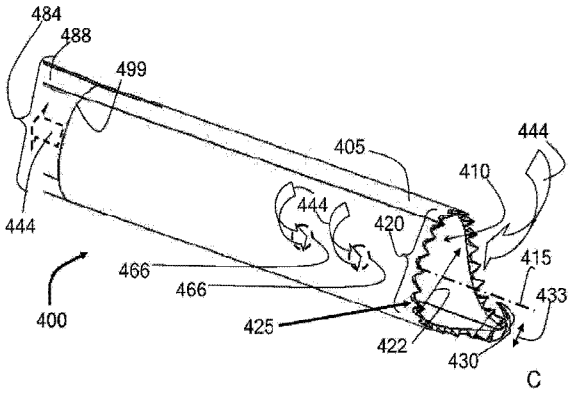
权利要求书7页 说明书16页 附图9页

(54)发明名称

用于快速移除靶组织的安全刀头和系统

(57)摘要

提供一种安全有效的刀头，该刀头用于在外科手术中从目标上移除靶组织，所述刀头包括解决多个问题的系统的一部分，所述多个问题包括例如在现有系统在移除所述组织的堵塞问题。所述靶组织可以包括通过较小的外科手术开口可以进入的组织，例如，关节组织(例如，半月板)或椎间盘组织(例如，髓核)。所述装置可以指骨科组织移除装置，该骨骼组织移除装置具有与真空系统相连的刀头，使得所述系统在多种手术过程中是有用的，所述多种手术过程包括X-LIF（椎间融合的侧入）过程、T-LIF（椎间融合的穿入）过程、P-LIF（椎间融合的后入）过程或经皮的椎间进入（卡宾三角进入）。



CN 103327913 A

用于快速移除靶组织的安全刀头和系统

[0001] 相关申请的交叉引用

[0002] 本申请要求申请日为2011年12月3日的美国临时申请No.61/566,629和申请日为2012年2月9日的美国临时申请No.61/596,865的优先权，上述两个申请中公开的所有内容均以引用的方式整体结合于此。

技术背景

技术领域

[0003] 此处的教导通常是指一种安全有效的刀头，该刀头用于在外科手术过程中切除目标上的靶组织。

[0004] 背景技术

[0005] 椎间盘疾病是一种主要的全球健康问题。仅在美国，每年都进行将近700,000例脊柱手术，并且治疗背痛的总费用已经超过了300亿美元。椎间盘中与年龄有关的变化包括细胞核内水分消失以及生命中每4个十年(the 4.sup.th decade)胶原蛋白成分的增加。细胞核锁住的水分的减少导致环形物(annulus)上更多的压缩负荷。这导致所述环形物更易于脱层(delamination)和损伤。所述环形物的损伤结果加速了椎间盘变性以及周围组织(例如，椎间关节)的变性。

[0006] 进行的两种最常见的椎柱外科手术为椎间盘切除术和椎柱融合术(spinal fusion)。这些手术仅解决了下背痛、神经压迫、失稳(instability)和畸形的症状。椎间盘的融合过程的目的为恢复、保持和稳定椎间盘的高度和/或降低背痛。所述过程通常实施为：为了稳定高度，在换上移植骨和支架之前移除中间椎间盘材料(例如，内部环形物(inner annulus)、髓核和终板(endplate)上的软骨)，以在被治疗的椎间盘内有效地融合椎体。这种移除过程被称作椎间盘切除术(discectomy)，并且该移除过程既冗长又频繁产生不足，由于用于椎间盘切除术时暴露椎间盘所需的大切口和剖开，上述不足可能导致不良融合(compromised fusion)、外伤和耗时。

[0007] 在典型的椎间盘切除术过程中，首先进行髓核摘除术(nuclemotomy)，在髓核摘除术中，利用刮匙或手动刮刀(manual shaver)使细胞核游离，以剪切游离的细胞核(nucleus loose)，并且随后利用被称作咬骨钳的硬的抓紧器移除所述游离的细胞核。外科医生必须将所述咬骨钳插入穿过椎间盘上的被称作切口(anulotomy)的开口，抓紧细胞核，并将该细胞核移出所述椎间盘和手术通路，清理钳口(jaw)并重复地重新插入，以抓取更多的椎间盘。这个过程可能造成工具通道之间的组织(例如，神经)的安全问题。此外，残留的椎间盘碎片可以阻碍后续组织的有效移除以及椎间盘切除工具在所述椎间盘中的插入。第二步为去皮质术(decortication)，在去皮质术中，利用刚性的刮刀(例如，刮匙或锉刀)移除附着在骨头上的软骨，以有助于促进牢固的椎间融合。通过利用刮匙舀出剥离的软骨，并且利用咬骨钳将剥离的软骨从椎体中取出。残留的组织碎片也可能降低去皮质术的效率和效果，从而导致较弱的融合。此外，现有技术中的工具通常难以到达所述椎间盘中的角部，并且通

常留下移除不充分的椎间盘区域。

[0008] 此外，利用抽吸和切割的结合的现有系统承受因切除的组织在所述系统中聚集而导致的堵塞问题。本领域技术人员将理解，外科手术过程中的上述堵塞问题悬而未决，并且非常需要上述堵塞的解决方案。

[0009] 虽然已经开发了多种先进的工具，但是并没有任何一种完全充分解决这些组织的工具。本领域技术人员当然希望有一种椎间盘切除术系统，该椎间盘切除术系统(i)使用时不太冗长且耗时较少的；(ii)不易于被切除的组织堵塞；(iii)使进行手术的目标更安全；以及(iv)更有效地促进牢固的椎间盘融合。

发明内容

[0010] 此处提供的教导通常是指一种安全有效的刀头，该刀头用于在外科手术过程中切除目标上的靶组织。该靶组织可以包括通过小的外科手术开口能够到达的任意组织，例如，在某些实施方式中的关节组织(例如，半月板)，或者在其他实施方式中的椎间盘组织(例如，髓核)。

[0011] 刀头可以是具有切割表面的管状，所述切割表面在所述刀头的远端周边上至少形成第一面，所述刀头与抽吸装置可操作地连通，以通过抽吸容易地移除所述组织的方式切除靶组织。切割表面可以是例如平的、正弦曲线形的或锯齿形的，并且所述切割表面的第一面可以形成角 θ_{FP}，该角 θ_{FP} 从与所述刀头的中心轴线正交的位置偏离达到 75° 。在某些实施方式中，所述切割表面可以具有第二面，该第二面可以形成角 θ_{SP}，该角 θ_{SP} 从与所述刀头的中心轴线正交的位置偏离达到 75° 。在某些实施方式中，所述刀头具有切割刃和切割刃防护件，该切割刃防护件用于防止所述切割刃切割周边组织。

[0012] 因此，本教导包括管状的刀头，该刀头用于移除目标的靶组织。在这些实施方式中，所述刀头可以具有外周，该外周限定了穿过所述刀头的内腔，所述内腔具有中心轴线。所述刀头的外周的远端边缘可以具有朝前的切割刃，所述朝前的切割刃构造为(i)在所述刀头的前进冲程中切割靶组织并且(ii)将切割的靶组织引导至所述内腔中。并且，所述刀头可以具有切割刃防护件，该切割刃防护件位于所述朝前的切割刃的远端，并且所述切割刃防护件构造为在所述前进冲程中防止所述朝前的切割刃切割周边组织，所述切割刃防护件的宽度小于所述内腔的横截面的宽度，以以便于所述靶组织在所述前进冲程中进入所述内腔中。

[0013] 在某些实施方式中，所述刀头可以具有朝后的切割刃、横切割刃或者二者的组合，所述朝后的切割刃用于在刀头的返回冲程中切割靶组织，所述横切割刃用于在刀头的横向冲程中切割靶组织。在某些实施方式中，横向切割刃可以位于所述切割刃防护件上，以在所述刀头的横向冲程中切割所述靶组织。

[0014] 在某些实施方式中，所述朝后的切割刃可以位于所述外周的远端边缘上，以在所述刀头的返回冲程中切割所述靶组织。在某些实施方式中，所述朝后的切割刃可以位于所述切割刃防护件上，以在所述刀头的返回冲程中切割所述靶组织，所述切割刃防护件具有双刃尖端，该双刃尖端以大于 90° 的角 θ_2 朝后指向所述内腔中，以在所述刀头的返回冲程中在所述内腔中抓紧和/或切割组织。

[0015] 由于可以将所述刀头设计为通过抽吸而移除组织，本教导还指导一种将刀头与抽

吸组件的刀头可操作地连接的刀头的系统。因此，本教导包括这种外科组织移除系统(a surgical, tissue removal system)，该外科组织移除系统包括管状的刀头，该刀头用于移除目标的靶组织。所述系统可以包括刀头，该刀头具有：外周，该外周限定了穿过所述刀头的抽吸流；内腔，该内腔由所述外周限定，所述内腔引导所述抽吸流，并且所述内腔具有中心轴线；朝前的切割刃，该朝前的切割刃位于所述外周的远端边缘上，所述朝前的切割刃构造为(i)在所述刀头的前进冲程中切割所述靶组织和(ii)将切割的靶组织引导至所述内腔中；和切割刃防护件，该切割刃防护件位于所述朝前的切割刃的远端，并且所述切割刃防护件构造为在所述刀头的前进冲程时防止所述朝前的切割刃切割周边组织(perimeter tissue)。在某些实施方式中，所述切割刃防护件的宽度小于所述内腔的横截面的宽度，以以便于所述靶组织在所述前进冲程中进入所述内腔中。

[0016] 所述刀头可以构造为在可操作地在所述内腔和所述抽吸源之间连通，因此，所述系统包括抽吸组件，该抽吸组件与所述刀头可操作地连通，以制造用于使所述靶组织穿过所述内腔并移出所述目标的抽吸流，所述抽吸组件包括刚性的抽吸管，该抽吸管具有中心轴线。在某些实施方式中，可操作地连通包括使用一个或多个抽吸口，该抽吸口设置于靠近所述刀头外周的远端边缘的最近点。在某些实施方式中，一个或多个口可以位于距离所述远端边缘的最近点大约 3mm 至大约 20mm 处。

[0017] 在某些实施方式中，所述抽吸组件包括至少大致刚性的抽吸管，该抽吸管具有近端和远端，该远端与所述刀头可操作地连通，并且所述远端构造为与所述抽吸组件的抽吸源连通。在某些实施方式中，所述至少大致刚性的抽吸管可以与所述刀头形成为一个整体。

[0018] 在某些实施方式中，所述内腔的中心轴线与所述刚性的抽吸管的中心轴线形成角 θ_1，该角 θ_1 在 5° 至 90° 的范围内，并且所述朝前的切割刃位于距离所述角 θ_1 的顶点大约 3mm 至大约 25mm 的位置。

[0019] 权利要求 10 的系统，所述内腔的中心轴线具有在所述朝前的切割刃上的出口点，并且所述出口点位于正交于所述刚性的抽吸管的中心轴线的横向距离处，该横向距离大约 3mm 至 25mm。

[0020] 在一些实施方式中，所述内腔的中心轴线在所述抽吸组件的远端与所述抽吸流的中心轴线成一定角 θ_1，该角 θ_1 在大约 5° 至大约 90° 的范围内，并且所述朝前的切割刃位于与所述角 θ_1 的顶点相距大约 3mm 至大约 25mm 的位置。在某些实施方式中，所述刀头与所述抽吸组件之间的可操作连通可以为铰接(articulating)，并且所述角可为可调节的。在某些实施方式中，所述刀头与所述抽吸组件之间的可操作连通可以是刚性的，所述角为固定的。

[0021] 在某些实施方式中，所述内腔的中心轴线与在所述抽吸组件的远端的所述抽吸流的中心轴线之间形成角 θ_1，该角 θ_1 在 1° 至 180° 的范围内，并且所述朝前的切割刃位于距离所述角 θ_1 的顶点 3mm 至 25mm 的位置。在这些实施方式中，靠近角 θ_1 大约 5mm 至 25mm 处为额外的角 θ_3，并且角 θ_1 和角 θ_3 互相独立地选自大约 0° 至大约 180° 的范围内，并且角 θ_1 和角 θ_3 的限制为(i)所述刀头的内腔的中心轴线与靠近角 θ_3 的刚性的抽吸管的中心轴线之间的净角 θ_4 在 0° 至 90° 的范围内；并且(ii)所述刀头的的内腔的中心轴线与所述刚性的抽吸管的中心轴线之间的距离在 2mm 至 30mm 的范围内。

[0022] 应当理解的是，此处教导的所述刀头和系统具有本来领域技术人员已知的多种用

途。例如，在某些实施方式中，所述靶组织可以为髓核，并且所述周边组织可以为纤维环。

[0023] 因此，本教导还指一种用于椎间盘切除术的外科组织移除系统，并且该外科组织移除系统可以包括管状的刀头，该刀头用于从目标上移除髓核。在这些实施方式中，所述系统可以包括刀头，该刀头具有：外周，该外周限定了穿过所述刀头的抽吸流；内腔，该内腔由所述外周限定，所述内腔引导所述抽吸流；朝前的切割刃，该朝前的切割刃位于所述外周的远端边缘上，所述朝前的切割刃构造为(i)在所述刀头的前进冲程中切割所述髓核和(ii)将切下的髓核引导至所述内腔中；朝后的切割刃，该朝后的切割刃用于在所述刀头的返回冲程中切割所述髓核；横向切割刃，该横向切割刃用于在所述刀头的横向冲程中切割所述髓核；和切割刃防护件，该切割刃防护件位于所述朝前的切割刃的远端，并且所述切割刃防护件构造为在所述前进冲程时防止所述朝前的切割刃切割环纤维。并且，所述切割刃防护件的宽度，例如，可以小于所述内腔的横截面的宽度，以以便于所述靶组织在所述前进冲程中进入所述内腔中。

[0024] 所述教导还包括一种从目标上移除靶组织的方法。在这些实施方式中，所述方法可以包括在目标上制造用于接近靶组织的开口；将此处教导的刀头插入穿过所述开口，以接近所述目标中的所述靶组织；和在包括所述靶组织的表面上沿朝前的方向推进所述刀头，以移除所述靶组织。所述朝前的方向可以包括力矢量，该力矢量在(i)至少大致在包括所述刀头的所述内腔的中心轴线的面上移动，(ii)至少大致在包括所述靶组织的所述表面上移动，和(iii)朝向由所述切割刃防护件保护的周边组织移动。并且，所述方法可以包括抓取所述刀头的所述内腔内的所述靶组织，并且使所述靶组织移动穿过所述内腔并移出所述目标。

[0025] 在某些实施方式中，所述方法包括在包括所述靶组织的表面上沿朝后的方向推进此处教导的刀头，以移除所述靶组织。所述朝后的方向包括力矢量，该力矢量(i)至少大致在包括所述刀头的所述内腔的中心轴线的面上移动，(ii)至少大致在包括所述靶组织的所述表面上移动，并且(iii)移动离开从由所述切割刃防护件保护的周边组织。

[0026] 在某些实施方式中，所述方法包括在包括所述靶组织的表面上沿横向方向推进此处教导的刀头，以移除所述靶组织。所述横向方向可以包括力矢量，该力矢量(i)以与包括所述刀头的所述内腔的中心轴线的面成大约 15° 至大约 150° 的范围内的角移动，(ii)至少大致在包括所述靶组织的表面上移动，并且(iii)移动至与由所述切割刃防护件保护的所述周边组织接触。

[0027] 本教导还指一种闭孔防护插管(obturator, guard cannula)，该闭孔防护插管在细长的外科手术切割装置进入和离开时保护目标，所述细长的外科手术切割装置具有非线性度。在这些实施方式中，所述防护插管可以包括入口毂，该入口毂具有内周、外周和冲洗口(irrigation port)，该冲洗口连通在所述内周和所述外周之间；和线性的细长的对开管(split-tube)，该对开管具有近端、远端和内腔。在这些实施方式中，所述对开管的近端可以(i)限定所述入口毂的所述内周的至少一部分，并且(ii)与所述冲洗口可操作地连通。在这些实施方式中，所述连通为可操作地，以接收来自所述冲洗口的冲洗流体，将所述冲洗流体运送至靶组织包括，例如，在所述对开管的内腔表面上将所述冲洗流体从所述冲洗口移动至所述对开管的远端。

[0028] 所述对开管的远端还可以具有本领域技术人员所需的任意结构。例如，所述远端

可以为至少大致尖的和/或锐利的。在一些实施方式中，所述远端可以为至少大致钝的，以避免在所述远端与入口组织接触时损坏所述入口组织。所述对开管的长度可以在大约10cm至大约60cm的范围内，并且所述对开管的宽度可以在大约5mm至大约16mm的范围内。此外，所述对开管的裂缝（split）可以构成间隙，该间隙的宽度在大约4mm至大约14mm的范围内，所述裂缝在所述外科手术装置中具有非线性度。

[0029] 如上所述，此处教导的系统可以用于从目标上移除靶组织的各种手术过程中，该手术过程包括例如，半月板的移除或椎间盘切除术。在某些实施方式中，利用防护插管的所述外科切割装置可以为椎间盘切除装置。并且，在某些实施方式中，所述入口组织包括通向所述髓核的所述目标的上皮组织、肌肉组织、神经组织、结缔组织、血管、骨骼、软骨或上述组织的结合。因此，在某些实施方式中，所述靶组织可以包括所述髓核。

[0030] 所述教导还指一种外科组织移除工具，该外科组织移除工具具有外科组织移除系统和防护插管，该外科组织移除工具利用此处教导的系统和防护插管实施方式的任意结合。在某些实施方式中，所述外科组织移除工具可以为椎间盘切除工具。因此，在某些实施方式中，所述入口组织包括通向所述髓核的所述目标的上皮组织、肌肉组织、神经组织、结缔组织、血管、骨骼、软骨或上述组织的结合。因此，所述靶组织可以包括某些实施方式中的髓核。

[0031] 所述教导还指一种利用所述工具移除靶组织的方法。在某些实施方式中，所述方法包括在目标上制造用于接近靶组织的开口；将所述工具的刀头插入穿过所述工具的防护插管的入口毂和细长的对开管；将所述工具的插入穿过所述开口，以接近所述目标中的靶组织，同时利用所述对开管的钝的远端保护所述入口组织。在其他方面，利用所述组织移除系统的方法与此处教导的那些方法相同或相似。本领域技术人员可以理解的是将这种工具用于椎间盘切除术，例如，在所述椎间盘切除术中，所述靶组织可以为髓核，并且所述周边组织可以为纤维环。本领域技术人员还可以理解的是使得所述工具具有防护插管，该防护插管有助于保护通向这种手术中的髓核的所述目标的上皮组织、肌肉组织、神经组织、结缔组织、血管、骨骼、软骨，或上述组织的结合。

[0032] 本领域技术人员将理解，出于一般指导概念的目的提供此处教导的实施方式，并且本领域技术人员还应理解，此处提供的教导包括多种其他的实施方式，并且可以从此处提供的教导中得出。

附图说明

[0033] 图1A至图1D展示了根据某些实施方式的多种管状的刀头结构，可以利用管材（stock tube）制造所述刀头结构；

[0034] 图2A至图2E展示了根据某些实施方式的切割刃结构；

[0035] 图3A至图3C展示了根据某些实施方式的独立的切割刃轮廓的横截面；

[0036] 图4A至图4C展示了根据某些实施方式的刀头；

[0037] 图5A和图5B展示了根据某些实施方式的刀头500的角度（angulation）；

[0038] 图6展示了根据某些实施方式的闭孔防护插管；

[0039] 图7展示了根据某些实施方式的外科组织移除工具；

[0040] 图8A至图8C展示了根据某些实施方式的外科组织移除系统或工具，该外科组织

移除系统或工具可以利用抽吸的同时进行冲洗，并且不需要闭孔防护插管安装就位；

[0041] 图 9A 至图 9G 展示了根据某些实施方式的经过测试的刀头设计；

[0042] 图 10A 至图 10E 展示了根据某些实施方式的刀头的改进(advancement)；

[0043] 图 11A 至图 11C 展示了根据某些实施方式的刀头和抽吸组件之间的卡口式连通(bayonet-type communication)。

具体实施方式

[0044] 此处提供的教导通常是指一种安全有效的刀头，该刀头用于在外科手术中切除目标上的靶组织。所述靶组织可以包括任意可以通过小的外科手术开口到达的组织，例如，关节组织(例如，半月板)或椎间盘组织(例如，髓核)。在某些实施方式中，此处教导的装置可以指一种骨科组织移除装置(orthopedic tissue removal device)。在某些实施方式中，此处教导的装置在 X-LIF(椎间融合的侧入)过程、T-LIF(椎间融合的穿入(transforaminal approach to intervertebral fusions))过程、P-LIF (椎间融合的后入)过程或经皮的椎间进入(a percutaneous, transforaminal approach)(卡宾三角进入(Kambin triangle access))中是有用的。

[0045] 在某些实施方式中，术语“目标”和“患者”可以交换，并且“目标”和“患者”是指动物，该动物例如为哺乳动物，该哺乳动物包括但不限于非灵长类(诸如牛、猪、马、猫、狗、鼠类)和灵长类(诸如，猴或人类)。因此，术语“目标”和“患者”还可以应用于非人类生物场合，该非人类生物场合包括但不限于疾病动物、宠物、商业牲畜等。

[0046] 所述刀头可以为具有切割表面的管状，该切割表面在所述刀头的远端周边上至少形成第一面，所述刀头与抽吸装置可操作地连通，以通过抽吸容易地移除所述组织的方式切除靶组织。

[0047] 所述切割表面可以为，例如，平的、正弦曲线形的或锯齿形的，并且所述切割表面的第一面可以形成角 θ_{FP}，该角 θ_{FP} 从与所述刀头的中心轴线正交的位置偏离达到 75°。在某些实施方式中，所述切割表面可以具有第二面，该第二面可以形成角 θ_{SP}，该角 θ_{SP} 从与所述刀头的中心轴线正交的位置偏离达到 75°。在某些实施方式中，所述刀头具有切割刃和切割刃防护件，该切割刃防护件用于防止周边组织被所述切割刃切割。在某些实施方式中，角 θ_{FP} 和角 θ_{SP} 可以独立地选自 0° 至大约 75°、大约 5° 至大约 75°、大约 10° 至大约 70°、大约 15° 至大约 65°、大约 10° 至大约 60°、大约 5° 至大约 55°、大约 15° 至大约 50°、大约 20° 至大约 45°、大约 15° 至大约 40°、大约 25° 至大约 35° 的范围，或者可以独立地选自任意角或此处增加 1° 的任意角范围。

[0048] 图 1A 至图 1D 展示了根据某些实施方式的多种管状的刀头结构，该刀头结构可以由管材(stock tube)制成。图 1A 展示了具有第一面 105 的刀头管材 100，第一面 105 形成角 θ_{FP}，该第一面 105 正交于管材 100 的内腔的中心轴线 110。图 1B 展示了具有第一面 105 的刀头管材 100，第一面 105 与管材 100 的内腔的中心轴线 110 形成锐角 θ_{FP}，该锐角 θ_{FP} 在 1° 至大约 75° 的范围内。图 1C 展示了刀头管材 100，该刀头管材具有第一面 105，该第一面 105 与管材 100 的内腔的中心轴线 110 之间形成锐角 θ_{FP}，该锐角 θ_{FP} 在 1° 至大约 75° 的范围内；并且所述刀头管材具有第二面 105，该第二面 105 形成角 θ_{SP}，第二面 105 与管材 100 的内腔 110 的中心轴线正交。图 1D 展示了刀头管材 100，该刀头管材 100 具有

第一面 105，该第一面 105 与管材 100 的内腔 110 的中心轴线形成锐角 θ_{FP}，该锐角 θ_{FP} 在 1° 至大约 75° 的范围内；并且所述刀头管材具有第二面 105，该第二面 105 与管材 100 的内腔的中心轴线 110 之间形成锐角 θ_{SP}，该锐角 θ_{SP} 在 1° 至大约 75° 的范围内。

[0049] 可以利用本领域技术人员已知的适于使用此处的教导的外科环境的任意材料制造所述刀头。例如，在某些实施方式中适用硬度大于洛氏硬度 C30 或硬度大于洛氏硬度 C45 的硬质材料。在某些实施方式中，所述刀头可以包括选自下组的成分，该组包括：回火钢、不锈钢、高碳钢、钛或钛合金、陶瓷、金刚石和黑曜石。在某些实施方式中，不锈钢可以包括 304 不锈钢、316 不锈钢、17-4PH 不锈钢、400 系列的不锈钢或者任意本领域技术人员已知的适于此处教导的切割功能的不锈钢材料。在某些实施方式中，可以利用铬化钴（cobalt chromium）、碳化钨（tungsten carbide）或陶瓷材料制作所述刀头。

[0050] 形成所述刀头的管的壁厚可以为，例如，0.003″ 至 0.020″ 之间，更具体地，为 0.005″ 至 0.012″ 之间。所述刀头的横截面积可以在 0.120 平方英寸至 1.5 平方英寸的范围内，或者，在某些实施方式中，所述刀头的横截面积可以在 0.180 平方英寸至 0.400 平方英寸的范围内。任意方向的宽度可以在 0.080″ 至 0.400″ 或更大的范围内，在某些实施方式中，可以在 0.160″ 至 0.250″。在某些实施方式中，所述刀头的最大横截面尺寸在 3.0mm 至大约 20.0mm 之间，在 4.0mm 至大约 15mm 之间，在大约 4.0mm 至大约 12.0mm 之间，在大约 5.0mm 至大约 10.0mm 之间，在大约 5.0mm 至大约 8.0mm 之间，或在此处增加 0.1mm 的任意范围内。在某些实施方式中，所述刀头的直径为大约 4.8mm、大约 5.0mm、大约 5.2mm、大约 5.4mm、大约 5.8mm、大约 6.0mm、大约 6.2mm、大约 6.4mm、大约 6.6mm、大约 6.8mm、大约 7.0mm、大约 7.2mm、大约 7.4mm、大约 7.6mm、大约 7.8mm、大约 8.0mm、大约 8.2mm，以及此处增加 0.1mm 的任意直径。

[0051] 刀头的远端周长可以在所述第一面上或者所述第二面上，或者在二者的结合上，并且所述切割表面可以为任意本领域技术人员已知的任意切割表面，例如，在某些实施方式中，所述切割表面可以为剃刀表面（razor surface）、锯齿形表面或正弦表面（sinusoidal surface）。有很多本领域技术人员已知的切割刃设计，并且可以利用这些结构中的任意一种。例如，所述切割表面可以具有齿和在齿之间的齿槽。多个所述齿之间的间隔可以相等或可以变化，并且所述齿槽的深度可以相等，也可以变化，并且可以利用齿和齿槽的任意结合。在某些实施方式中，所述齿的凸起的方向可以从所述刀头的所述壁的其余部分（remainder）的方向偏移。在某些实施方式中，所述齿与所述刀头的所述壁的其余部分方向相同，使得所述齿仅为所述刀头的壁的延伸，而不会朝向所述刀头的内腔的方向改变，或者不会远离所述刀头的内腔改变。在某些实施方式中，具有所述齿远离或朝向所述刀头的内腔的方向变换图形。例如，所述图形可以为朝向、远离、朝向、远离、无偏移的顺序，并且该顺序环绕所述刀头的外周的远端边缘重复。在某些实施方式中，所有的齿都指向所述内腔，并且在某些实施方式中，所有的齿都远离所述内腔。在某些实施方式中，所述多个齿中，各个齿交替地朝向和远离所述内腔。并且，在某些实施方式中，所述多个齿中，各个齿以逐渐增加和逐渐减小的角逐渐朝向和远离所述内腔，以当所述齿环绕所述外周的远端边缘时产生波浪形的外观。所述顺序也可以为完全随机。

[0052] 图 2A 至图 2E 展示了根据某些实施方式的切割刃结构。图 2A 展示了重复朝向、远离、朝向、远离、无改变的 5 齿的变换图形。图 2B 展示了随机的变换图形。图 2C 展示了波

浪形的变换图形。图 3D 展示了重复远离、朝向、无改变的 3 齿的变换图形。并且，图 3E 展示了简单的重复远离、朝向的变换图形。

[0053] 在某些实施方式中，可以结合选择所述切割刃的轮廓选择切割刃的结构。设计切割刃的本领域技术人员将理解，此处教导的刀头可以具有多种切割动作，例如，凿的动作、锯切的动作、切片的动作和劈开的动作。因此，选择的切割刃的轮廓可以是改变为使用本领域技术人员已知的任意切割刃轮廓。在某些实施方式中，所述齿是斜面的。在某些实施方式中，所述刀头可以具有朝后的齿和朝前的齿，以除了朝后的切割“刺(spur)”之外还包括朝前的切割表面。

[0054] 因此，所述教导包括管状的刀头，该管状的刀头用于移除目标上的靶组织。并且，所述管可以为细长的、具有任意形状(例如，圆管、正方管、矩形管、椭圆管、五边形管、六边形管、七边形管、八边形管等)的管状结构，使得在某些实施方式中，可以利用管的任意数量的边、曲线或者二者的结合。在某些实施方式中，利用圆管。

[0055] 所述刀头可以具有多种类型的切割刃(例如，朝前的切割刃、朝后的切割刃和横向的切割刃，以及凸起、钩等)的结合，以抓取、劈开组织，或者其他方式地移除组织。在某些实施方式，所述刀头具有：朝后的切割刃，该朝后的切割刃用于在刀头的返后冲程中切割所述靶组织；横向的切割刃，该横向的切割刃用于在所述刀头的横向冲程中切割所述靶组织；或者朝后的切割刃和横向的切割刃相结合的切割刃。在某些实施方式中，横向的切割刃可以位于所述切割刃防护件上，用于在所述刀头的横向冲程中切割靶组织。

[0056] 图 3A 至图 3C 展示了根据某些实施方式的独立的切割刃轮廓的横截面。图 3A 展示了平面 - 内凹切割刃轮廓。图 3B 展示了楔形切割刃轮廓。并且，图 3C 展示了凿形切割刃轮廓。同样地，应当理解的是，所述切割刃可以被设计为具有任意结构(包括单边、双边、单倒钩、双倒钩、直尖端、倒钩尖端等)，以辅助任意形式的组织的移除(包括组织的切割、切片、凿、刮、刨、锯切、磨削和劈切)，以例如在手术过程中有效地移除所述组织。

[0057] 图 4A 至图 4C 展示了根据某些实施方式的刀头。图 4A 展示了所述刀头的斜视图，并且图 4B 展示了所述刀头的侧视图。刀头 400 可以具有外周 405，该外周 405 限定了穿过刀头 400 的内腔 410，该内腔 410 具有中心轴线 415。刀头 400 还可以具有朝前的切割刃 420，该朝前的切割刃 420 位于外周 405 的远端边缘 425 上，朝前的切割刃 420 构造为(i)在刀头 400 的前进冲程中切割靶组织(未示出)，并且(ii)将切下的靶组织引导至内腔 410 中。并且，刀头 400 可以具有切割刃防护件 430，该切割刃防护件 430 位于朝前的切割刃 420 的远端并且构造为在所述前进冲程中防止周边组织(未示出)被切割刃 420 切割，切割刃防护件 430 的宽度 433 小于内腔 410 的横截面的宽度 422，以以便于所述靶组织在所述前进冲程中进入内腔 410 中。并且，如图 4A 至图 4C 所示，所述切割刃防护件的侧表面 409 可以为锯齿形的，或者其他形状锋利的切割表面，以用于横向切割。

[0058] 由于所述刀头可以设计为通过利用抽吸 444 移除组织，所以所述教导还指一种刀头的系统，该系统将所述刀头与抽吸组件 484 (仅示出了远端)可操作地连接。因此，图 4C 还展示了外科组织移除系统，该外科组织移除系统包括管状的刀头 400，该刀头 400 用于移除目标的靶组织(未示出)。所述外科组织移除系统可以包括刀头 400，该刀头 400 具有：外周，该外周限定穿过刀头 400 的抽吸流 444；内腔 410，该内腔 410 由外周 405 限定，内腔 410 引导抽吸流 444 并且具有中心轴线 415；朝前的切割刃 420，该朝前的切割刃 420 在外周 405

的远端边缘 425 上，朝前的切割刃 420 构造为（i）在刀头 400 的前进冲程中切割靶组织，并且（ii）将切下的靶组织引导至内腔 410 中；和切割刃防护件 430，该切割刃防护件 430 位于相对于朝前的切割刃 420 的远端并且构造为在所述前进冲程中防止周边组织（未示出）被朝前的切割刃 420 切割。

[0059] 所述刀头可以构造为可操作地在内腔 410 和抽吸源 444 之间连通，因此，系统 400 包括抽吸组件 484，该抽吸组件 484 与刀头 400 可操作地连通，以产生抽吸 444 流，以使所述靶组织穿过内腔 410 移除至所述目标外，抽吸组件 484 包括刚性的抽吸管 488，该抽吸管 488 具有中心轴线。在某些实施方式中，所述可操作地连通包括利用一个或多个抽吸口 466，该抽吸口 466 位于靠近刀头外周的最远端边缘的最近点。在某些实施方式中，一个或多个抽吸口 466 可以位于靠近远端边缘 425 的最近点大约 3mm 至 20mm 处。由于并未受任何动作理论或动作机理限制，本领域技术人员将理解，在移除组织的过程中，当在可以形成真空的区域内抽吸时，额外的空气源可以是有用的，否则所述真空可以阻碍或者终止将切除的组织从手术区域运走的抽吸流。抽吸口 466 可以用于提供额外的空气，以避免在手术区域内产生真空。

[0060] 在很多实施方式中可以利用本领域技术人员已知的任意抽吸组件结构。在某些实施方式中，抽吸组件 484 包括至少大致刚性的抽吸管 488，该抽吸管 488 具有近端（未示出）和远端 499，该远端 499 可操作地连通刀头 400，并且该远端 499 构造为连通用于抽吸组件 484 的抽吸源 444。在某些实施方式中，至少大致刚性的抽吸管 488 可以与刀头 400 形成为一个整体。词组“至少大致刚性”可以指元件是刚性的，或者足够刚性的，使得在正常使用所产生的力的作用下获得所需的功能。例如，所需的功能可以为当在所述目标上使用所述刀头时阻止或防止刚性的元件在沿刚性抽吸管的长度方向的一个或多个点处产生弯矩。

[0061] 下表描述了被发现能够在椎间盘切除术中实现快速有效地移除组织的刀头 400 的尺寸比（dimensional ratio）。“标签”用于展示在小设备和大设备上形成所述尺寸比的元件和措施。

[0062]

标签→	402	403	404	401			
	刀盘直径（in）	夹钳高度（Pincers Height）（in）	夹钳在拱形的顶点处的宽度（in）	ID-夹钳尖端间隙（in）	403/402	404/402	401/402
小装置	0.203	0.098	0.080	0.085	0.483	0.394	0.419
大装置	0.250	0.140	0.125	0.104	0.560	0.500	0.416
				平均值→	0.521	0.447	0.417
				理论上限	0.7	0.7	0.6
				理论下线	0.3	0.3	0.3

[0063] 刚性的抽吸管可以包括本领域技术人员已知的适用于此处的教导的任意材料。例如，刚性的抽吸管可以包括本领域技术人员认为是此处教导的装置所需的任意手术钢（surgical steel）、塑料或树脂。在某些实施方式中，所述刚性的抽吸管可以包括与所述刀头相同或相似的材料。在某些实施方式中，刚性的抽吸管可以包括不锈钢、聚醚醚酮（PEEK）、聚酰亚胺或碳纤维。轴的壁厚可以为选定的材料在此将具有所需的物理性质的任意厚度。在某些实施方式中，所述壁厚可以在，例如，0.003”至0.020”的范围内，并且，在某些实施方式中，可以在0.005”至0.010”的范围内。所述抽吸管的内腔表面可以涂覆有聚四氟乙烯（TEFLON）、疏水涂层（例如，聚对二甲苯）或亲水涂层（例如，聚乙烯醇或聚乙二醇）。

[0064] 在某些实施方式中，刚性的抽吸管可以包括金属编制线增强的聚合物管、盘管或具有横向槽的管，以便于在某些需要铰接的实施方式中进行铰接。在这些实施方式中，通过例如，拉扯连接在所述刀头的一侧的肌腱（tendon）可以使所述刀头相对于所述刚性的抽吸管的轴线形成角，所述肌腱沿所述刚性的抽吸管的一侧上的导向件（guide）延伸。

[0065] 图5A和图5B展示了根据某些实施方式的刀头500的角度。图5A展示了内腔510的中心轴线515可以与在抽吸组件（局部示出）584的远端599的抽吸流544的中心轴线555形成角 θ_1，该角 θ_1 在大约5° 至大约90° 的范围内，并且朝前的切割刃520可以距离角 θ_1 的顶点大约2mm至大约25mm处。在某些实施方式中，θ_1 可以在大约2mm至大约30mm、大约2mm至大约30mm、大约2.5mm至大约25mm、大约3mm至大约25mm、大约4mm至大约20mm、大约5mm至大约15mm、大约3mm至大约25mm、大约7mm至大约12mm、大约8mm至大约10mm，或此处增加0.5mm的任意范围内。

[0066] 在某些实施方式中，所述内腔的中心轴线与所述刚性的抽吸管的中心轴线之间的角 θ_1 在大约5° 至大约90° 的范围内，并且所述朝前的切割刃距离角 θ_1 的顶点大约3mm至大约25mm。并且，在某些实施方式中，所述内腔的中心轴线具有在所述朝前的切割刃上的出口点，并且所述出口点位于大约3mm至大约25mm的横向距离处，所述横向距离正交于所

述刚性的抽吸管的中心轴线。

[0067] 在某些实施方式中，所述内腔的中心轴线与在所述抽吸组件的远端的抽吸流的中心轴线之间的角 θ_1 在 1° 至 180° 的范围内，并且朝前的切割刃距离角 θ_1 的顶点 3mm 至 25mm。在这些实施方式中，额外的角 θ_3 位于靠近角 θ_1 的 5mm 至 25mm 位置处，并且角 θ_1 和角 θ_3 互相独立地选自大约 0° 至大约 180° 的范围内，并限制为（i）所述刀头的中心轴线与靠近角 θ_3 的刚性的抽吸管的中心轴线之间的净角（net angle）θ_4 在 0° 至 90° 之间；并且（ii）所述刀头的内腔的中心轴线与所述刚性的抽吸管的中心轴线之间的距离在 2mm 至 30mm 之间。因此，在角 θ_1 和角 θ_3 之间的抽吸流的距离可以在大约 5mm 至大约 30mm 之间、大约 5mm 至大约 25mm 之间、大约 5mm 至大约 20mm 之间、大约 6mm 至大约 18mm 之间、大约 7mm 至大约 15mm 之间，或者此处增加 1mm 的任意范围内。

[0068] 在某些实施方式中，刀头 500 和抽吸组件 584 之间的可操作的连通可以是铰接的，角 θ_1 可以为可调节的。在某些实施方式中，刀头 500 和抽吸组件 584 之间的可操作的连通可以是刚性的，角 θ_1 可以为固定的。在某些实施方式中，角 θ_1 可以在 0° 至大约 45° 的范围内、在大约 1° 至大约 40° 的范围内、在大约 5° 至大约 35° 的范围内、在 10° 至大约 35° 的范围内、在 15° 至大约 40° 的范围内、在 20° 至大约 30° 的范围内，或者在此处增加 1° 的任意范围内。在某些实施方式中，角 θ_1 可以为大约 3° 、大约 5° 、大约 10° 、大约 15° 、大约 20° 、大约 25° 、大约 30° 、大约 35° 、大约 40° 、大约 45° ，或者此处增加 1° 的任意角。

[0069] 在某些实施方式中，所述朝后的切割刃可以位于外周 505 的远端边缘 525 上，以在刀头 500 的返回冲程中切割所述靶组织。在某些实施方式中，朝后的切割刃 531 可以位于切割刃防护件 530 上，以在刀头 500 的返回冲程中切割所述靶组织。图 5B 展示了防护件 530，该防护件 530 具有作为朝后的切削刃 531 的双刃尖端，该双刃尖端以与内腔 500 的中心轴线 515 成大于 90° 的角 θ_2 朝后指向内腔 515，以在刀头 500 的返回冲程中在内腔 510 中抓紧和 / 或切割组织。由于朝后的切割刃的功能可以为抓紧、剪切和钩住将被移除的组织，所以在某些实施方式中，朝后的切割刃 531 可以被称作“爪（talon）”或“夹钳（pincer）”。

[0070] 应当理解的是，此处教导的所述刀头和系统具有本领域技术人员已知的多种应用。在某些实施方式中，例如，所述靶组织可以为髓核，并且所述周边组织可以为例如纤维环。

[0071] 提供一种用于椎间盘切除术的外科组织移除系统，并且该外科组织移除系统可以包括用于从目标上移除髓核的管状的刀头。在这些实施方式中，外科组织移除系统可以包括：刀头，该刀头具有：外周，该外周限定穿过所述刀头的抽吸流；内腔，该内腔由所述外周限定，并且所述内腔引导所述抽吸流；朝前的切割刃，该朝前的切割刃位于所述外周的远端边缘上，该朝前的切割刃构造为（i）在所述刀头的前进冲程中切割所述髓核和（ii）将切下的髓核引导至所述内腔中；朝后的切割刃，该朝后的切割刃用于在所述刀头的返回冲程中切割所述髓核；横向的切割刃，该横向的切割刃用于在所述刀头的横向冲程中切割所述髓核；和切割刃防护件，该切割刃防护件位于所述朝前的切割刃的远端并且构造为在所述前进冲程中防止所述朝前的切割刃切割纤维环。

[0072] 另一个有价值的特征在于，可以操作此处所述教导的装置，而基本上不被所述刀头切除的组织流阻塞，并且通过设计达到此目的。由于并未受任何动作理论或动作机理

限制，将发现，所述刀头远端的横截面的面积将至少大致等于或小于靠近刀头远端的引起（leading to）刀头切除的组织流聚集的任意点的横截面积。这些点将包括，例如，沿所述刚性的抽吸管的截面上的任意点，或者，引起被切除的组织的聚集点的所述抽吸组件的任意其他元件，例如，在某些实施方式中，压差将切除的组织倾卸至收集罐（collection canister）中的最近的孔处。在某些实施方式中，术语“至少大致等于”意味着只要限定在较小的范围内，可以有较小的横截面积。在某些实施方式中，如果横截面积比位于近端的横截面的横截面积小的量不超过 20%，则所述横截面积可以至少大致等于刀头的横截面积。在某些实施方式中，如果横截面积比在近端横截面的横截面积小的量不超过大约 3%、大约 5%、大约 7%、大约 9%、大约 11%、大约 13%、大约 15%、大约 17%、大约 19% 或大约 21%，则所述横截面积可以至少大致等于所述刀头的横截面积。比近端横截面的横截面积小的量在此处可以是增加 1% 的任意百分比。

[0073] 所述教导还包括一种从目标上移除靶组织的方法。在这些实施方式中，所述方法可以包括在目标上制造用于接近靶组织开口；插入此处所教导的刀头穿过所述开口，以接近所述目标中的靶组织；利用合适的成像技术（例如，荧光透视法）对所述刀头的尖端的深度进行成像；和在包括所述靶组织的表面上沿朝前的方向推进所述刀头以移除所述靶组织，同时激活真空，以抽吸附近的切下的组织。所述朝前的方向可以包括力矢量，该力矢量在（i）至少大致在包括所述刀头的所述内腔的中心轴线的面上移动，（ii）至少大致在包括所述靶组织的表面上移动，和（iii）朝向由所述切割刃防护件保护的周边组织移动。并且，所述方法可以包括在所述刀头的内腔内抓取靶组织，并且将所述靶组织穿过所述内腔并移出所述目标。

[0074] 术语“至少大致在……上”可以指，在正常使用此处教导的系统所产生的力和条件下，位置或移动足够靠近精确所需的位置，从而可以获得所需的功能。例如，“至少大致在包括所述刀头的所述内腔的中心轴线的面上”或“至少大致在包括靶组织的表面上”可以指平行于或大致平行于所述面或表面的位置或移动，但是该位置可能偏离实际的面或表面大约 1um 至大约 15mm，或者移动方向可能偏离大约 0.1° 至大约 20° 。“至少大致”的测量（measure）用于近似的场合，该近似的场合中不能获得精确测量或精确位置，但是本领域普通技术人员可以获得所需的功能。例如，当与可能的最佳结果相比时，减弱的结果可以用来确定什么是“至少大致”的所需结果。在某些实施方式中，在可能的最佳结果减弱少于 10%、少于 15%、少于 20%、少于 30%、少于 40% 或少于 50% 的地方至少大致地获得所需的结果。在某些实施方式中，在可能的最佳结果减弱大约 5% 至大约 30%、大约 7% 至大约 35%、大约 10% 至大约 25%，或者此处增加 1% 的任意范围内的位置至少大致地获得所需的结果。

[0075] 在椎间盘切除术中，可以根据所述目标的椎间盘高度而改变所述目标中的所述开口，椎间盘的高度通常在大约 5mm 至 7mm 的范围内。在某些实施方式中，所述目标中的所述开口的尺寸可以在大约 4mm×4mm 至大约 14mm×14mm 的范围内。在某些实施方式中，所述开口可以为大约 10mm×7mm。

[0076] 在某些实施方式中，所述方法包括在包括所述靶组织的表面上沿朝后的方向推进此处教导的刀头，以移除所述靶组织。所述朝后的方向可以包括力矢量，该力矢量（i）在至少大致在包括所述刀头的内腔的中心轴线的面上移动，（ii）在至少大致在包括所述靶组织的表面上移动，和（iii）移动离开由所述切割刃防护件保护的周边组织。

[0077] 在某些实施方式中，所述方法包括在包括所述靶组织的表面上沿横向方向推进此处教导的刀头，以移除所述靶组织。例如，所述横向方向可以包括力矢量，该力矢量(i)以与包括所述刀头的内腔的中心轴线的面成大约 15° 至大约 165° 范围内的角移动，(ii)至少大致在包括所述靶组织的表面上移动，和(iii)移动至与由所述切割刃防护件保护的周边组织接触。

[0078] 此处教导的所述刀头为锋利的，并且在所述刀头穿过所述外科手术的开口而进入或离开时可能对组织有害。在某些实施方式中设置有闭孔防护插管(an obturator, guard cannula)，以在非线性的细长的外科切割装置进入或离开时保护目标。

[0079] 图 6 展示了根据某些实施方式的闭孔防护插管。闭孔防护插管 600 可以包括：入口毂 605，该入口毂 605 具有内周 615、外周 625 和冲洗口 635，该冲洗口 635 连通在内周 615 和外周 625 之间；和线性的细长的对开管(split-tube) 650，该对开管 650 具有近端 655、远端 665 和内腔 675。在这些实施方式中，对开管 650 的近端 655 可以(i)限定入口毂 605 的内周 615 的至少一部分，并且(ii)与冲洗口 635 可操作地连通。在这些实施方式中，所述连通为可操作地，以接收来自冲洗口 635 的冲洗流体 690，将冲洗流体 690 运送至靶组织(未示出)包括，例如，冲洗流体 690 在对开管 650 的内腔表面 680 上从冲洗口 635 移动至对开管 650 的远端 665。

[0080] 本领域技术人员将理解，所述“冲洗流体”可以为本领域技术人员所需的任意流体，包括液体和气体。在某些实施方式中，冲洗流体可以为含水的(aqueous)。在某些实施方式中，所述冲洗流体可以为非含水的(non-aqueous)。并且，在某些实施方式中，所述冲洗流体可以为乳剂。在某些实施方式中，所述冲洗流体可以包括气体。含水的冲洗流体的实例可以包括水、盐水(saline)或包括液体的水性表面活性剂(aqueous surfactant)。非含水流体的实例可以包括在外科手术中可以有助于实现组织提取的任意油基液体(oil-based liquid)。气体的实例可以包括二氧化碳、氮气、空气，和任何惰性或至少大致无反应性(non-reactive)的气体。在某些实施方式中，所述冲洗流体可以包括润滑剂，例如甘油、硅油等。冲洗流体可以用作载体，以助于移除切除的组织，或者助于防止在手术位置产生真空，该真空可能会妨碍所述切除的组织的移除。这种真空的实例为，在椎间盘切除术时，在封闭的腔(例如，环形物内的椎间隙)内采用抽吸时产生的真空。

[0081] 对开管 650 的远端 665 还可以具有本领域技术人员所需的任意结构。例如，远端 665 可以为至少大致尖的和 / 或非钝的。在某些实施方式中，远端 665 可以为至少大致钝的，以避免在远端 665 与入口组织接触时伤害入口组织。对开管 650 的长度还可以在大约 10cm 至大约 60cm 的范围内，并且对开管 650 的宽度可以在大约 5mm 至大约 16mm 的范围内。此外，对开管 650 中的裂缝(split)构成间隙 667，该间隙 667 的宽度在大约 4mm 至大约 14mm 的范围内，所述裂缝在外科手术装置中具有非线性度(non-linearity)。在某些实施方式中，此处教导的所述刀头的直径可以小于所述抽吸组件的穿过所述闭孔防护插管的内腔的部分的直径，使得所述闭孔防护插管保持抽吸组件 484，但是允许刀头 400 穿过间隙 667。因此，间隙 667 的宽度可以超过刀头 400 的直径，但是小于刚性的抽吸管 488 的直径，并且闭孔防护插管 600 的内腔的直径大于刚性的抽吸管 488 的直径。

[0082] 如上所述，此处教导的系统可以用于从目标上移除靶组织的各种手术过程，这些手术过程包括，例如，半月板的移除或椎间盘切除术。在某些实施方式中，与防护插管一起

使用的外科切除装置可以为椎间盘切除装置。并且，在某些实施方式中，入口组织包括所述目标上的通向所述髓核的上皮组织、肌肉组织、神经组织、结缔组织、血管、骨骼、软骨或者上述组织的结合。因此，在某些实施方式中，所述靶组织可以包括髓核。

[0083] 提供一种具有外科组织移除系统和闭孔防护插管的外科组织移除工具，该外科组织移除工具利用此处教导的所述系统和所述防护插管的实施方式的任意结合。在某些实施方式中，所述工具可以为椎间盘切除工具。因此，在某些实施方式中，入口组织包括所述目标上的通向所述髓核的上皮组织、肌肉组织、神经组织、结缔组织、血管、骨骼、软骨或者上述组织的结合。因此，在某些实施方式中，所述靶组织可以包括髓核。

[0084] 图 7 展示了根据某些实施方式的外科组织移除工具。该工具 700 包括刀头 400、抽吸组件 484 和闭孔防护插管 600。来自抽吸组件 484 的抽吸流 444 进入刀头 400，以移除由所述刀头切除的靶组织。冲洗水 690 可以进入冲洗阀 795 和 / 或冲洗口 635，当抽吸流 444 关闭时，利用来自冲洗阀 795 的冲洗水 690，并且当抽吸流 444 打开时，可以利用来自冲洗口 635 的冲洗水 690 在上述过程中，抽吸流 444 引导闭孔防护插管 600 的内腔表面和抽吸组件 484 之间的冲洗水 690 进入外科手术区域（未示出）内。在例如刀头 400 朝前、朝后和 / 或横向移动以切除并移除的靶组织的手术过程中，防护插管 600 用于在刀头 400 和抽吸组件 484 相对于入口组织（未示出）移动时保护该入口组织。

[0085] 提供一种利用所述外科组织移除工具移除靶组织的方法。在某些实施方式中，所述方法包括 ：在目标上制造开口，用于接近靶组织 ；将所述外科组织移除工具的刀头插入穿过所述外科组织移除工具的防护插管的入口毂和细长的对开管 ；将所述外科组织移除工具的所述刀头插入穿过所述开口，以接近所述目标中的靶组织，同时利用所述对开管的钝的远端保护所述入口组织。在其他方面，利用所述组织移除系统的方法与此处教导的相同或相似。本领域技术人员可以理解的是将上述外科组织移除工具用于例如，椎间盘切除术，在该椎间盘切除术中，所述靶组织可以为髓核，并且周边组织可以为纤维环。本领域技术人员还可以理解的是使得外科组织移除工具具有防护插管，该防护插管有助于在这种手术中保护所述目标的通向所述髓核的上皮组织、肌肉组织、神经组织、结缔组织、血管、骨骼、软骨或上述组织的结合。

[0086] 图 8A 至图 8C 展示了根据某些实施方式的外科组织移除系统或工具，该外科组织移除系统或工具可以应用抽吸的同时进行冲洗，并且不需要闭孔防护插管安装就位。图 8A 展示了完整的椎间盘切除系统 800，该椎间盘切除系统 800 包括刀头 400、用于通过抽吸组件 884 提供抽吸流的工具、控制手柄 886 和真空附件 892、冲洗管 804、冲洗控制件 802 和可选择的真空控制件 888。

[0087] 在所述刀头的角为可调节的实施方式中，手柄 886 可以具有旋钮（未示出），转动该旋钮，以张紧拉绳（pull cable）以使所述刀头相对于所述刚性的抽吸管收缩或伸直，或者手柄 886 可以具有滑动件，该滑动件张紧所述拉绳，以使所述刀头相对于所述刚性的抽吸管收缩或伸直。用于收缩或伸直的所述拉绳可以位于轴的相对的两侧，所述轴受到连接在该轴的外表面的小的侧腔的约束，以收缩并拉直所述刀头。

[0088] 图 8B 展示了相对于刚性的抽吸管 894 的冲洗管 804 的剖视图。并且，图 8C 展示了控制手柄 886 和内管的剖视图。

[0089] 本领域技术人员将理解，此处提供的所述教导和实施例是指基本概念，该基本概

念可以延伸超过任意特殊的一个或多个实施方式、一个或多个附图。应当理解的是，任意实施例都是出于说明的目的，并且并不解释为限制所述教导的其他方面。

[0090] 实施例 1，测试刀头设计

[0091] 在 3 个尸体实验（cadaver laboratory）的 28 个椎间盘上测试多个刀头。对结果进行比较以确定最有效率的刀头设计。理想的刀头设计为一种可以很好地切割所有靶组织（包括髓核、椎体终板（vertebral endplates）和内部环形组织）的刀头。然而，所述刀头还应当以所需的方式切割所述靶组织，同时对周边组织不提供损伤，所述周边组织包括应当作为所需的周边结构保存的周边纤维环。此外，所述刀头设计应当在抽吸的作用下快速地移除组织，因此，所述刀头的结构使得能够在抽吸作用下进行所述组织的移除。

[0092] 图 9A 至图 9G 展示了根据某些实施方式的被测试的刀头设计。图 9A 中的刀头设计能很好地切割，但是对于所述环形物不如其他刀头设计安全。图 9B 中的刀头设计对于所述环形物是安全的，但是不能很好地切割坚韧的组织，并且展示了太多阻力。图 9C 中的设计也未能很好地穿过坚韧的组织。图 9D 中的设计的确能很好地切割和剥皮，但是该设计在软的 / 弹性的组织上被堵塞。图 9E 中的设计能很好地切割坚韧的组织且不发生堵塞，并且所述设计也能真正很好地剥皮。所述设计对于所述环形物也是安全的。然而，所述装置的形状并不能到达所述髓核的远侧。图 9F 中的设计展示了引入所述装置的弯曲部（a bend），该弯曲部使得图 9E 中的刀头能够到达所述髓核的远侧。然而，图 9G 和图 9H 中的设计展示了测试中验证的最有效的刀头性能，图 9G 和图 9H 中的设计在 5 分钟内移除 23cc 材料。

[0093] 实施例 2

[0094] 本实施例进一步拓展了所述刀头的设计。进一步在 7 个尸体实验和 28 个椎间盘中研究了图 8G 和图 8H 中的设计。

[0095] 图 10A 至图 10E 展示根据某些实施方式的所述刀头中的改进。图 10A 中的设计展示了切割齿的外表面上具有倾斜角的刀头和切割较差并且需要开凿（gouge）软骨的装置。图 10B 中的设计展示了椭圆形的刀头和产生不一致的切割并且需要开凿软骨的装置，所述刀头在切割齿的外表面上不具有倾斜角。图 10C 中的设计展示了用于采用环形刮匙的对比结果和开凿软骨的装置。图 10D 中的设计展示了具有一个“爪”或夹钳的短刀头和展示了最吸引人的结果并实现了最佳的切割且无需进行开凿的装置。图 10E 为另一种推荐的设计，该设计构造为具有图 10D 中的设计的功效，图 10E 中的设计还具有第二爪，该第二爪弯曲离开所述刀头的内腔，以用作额外的爪和切割刃防护件。

[0096] 本实施例中使用的方法如下：

[0097] 1. 切割高度和宽度尺寸为 5mm 至 8mm 的导孔；

[0098] 2. 使平行于椎体终板的 15° 的尖端指向，以居中地且侧向地切割并扩展所述腔。

[0099] 3. 逐渐将所述椎体终板刮剃至坚硬的组织（软骨或骨骼）；利用荧光透视法确认所述尖端的深度；利用所述尖端沿所述椎体终板的曲线刮剃；当露出骨骼（认定为终点的硬的、粗糙的、粘的且红色的抽出物）时停止刮剃；并且使所述装置的手柄（i）居中倾斜，以剥除侧边，和（ii）侧向倾斜，以剥除中间侧。

[0100] 4. 根据需要抵靠前方的环形物居中地 - 侧向地推动所述刀头，以移除连接在所述环形物和内部环形物上的髓核；

[0101] 5. 使 40° 的尖端指向相对侧，并且在侧向地倾斜把手时开始从后方的环形物开始

刮剃，以移除大部分的髓核；和

[0102] 6. 朝向所述椎体终板旋转所述手柄，以进一步剥除。

[0103] 实施例 3

[0104] 本实施例描述了用于测试的可选实施方式，所述可选实施方式被称为弯曲或卡口结构(serpentine or bayonet configuration)，其中刚性的抽吸管488可以具有至少两个角：角 θ_1 和角 θ_3。

[0105] 图 11A 至图 11C 展示了根据某些实施方式的刀头和抽吸组件之间的卡口式连通。可以发现刚性的抽吸管 488 的远端可以以卡口或弯曲的方式改变方向，以在例如椎间盘切除术中使刀头更接近靶组织。如图 11A 至图 11C 所示，角 θ_1 和角 θ_3 可以分别独立地选自从大约 0° 至大约 180° 的范围内，并限制为(i)刀头 400 的内腔 410 的中心轴线和刚性的抽吸管 488 的中心轴线 497（延伸为朝向靠近角 θ_1）之间实现的净角(net angle) θ_4，该净角 θ_4 在 0° 至 90° 的范围内；和(ii)刀头 400 的内腔 410 的中心轴线 415 与刚性的抽吸管 488 的中心轴线 497 之间的距离 498 可以在大约 2mm 至大约 30mm 的范围内。并且，在这些实施方式中，所述内腔的中心轴线可以在所述朝前的切割刃处具有出口点，并且该出口点位于大约 3mm 至大约 25mm 的横向距离处。

[0106] 在某些实施方式中，距离 498 在大约 2.5mm 至大约 25mm 之间、大约 3mm 至大约 25mm 之间、大约 4mm 至大约 20mm、大约 5mm 至大约 15mm、大约 3mm 至大约 25mm、大约 7mm 至大约 12mm 之间、大约 8mm 至大约 10mm 之间，或者此处增加 0.5mm 的任意范围内。因此，距离 498 可以为大约 2mm、大约 3mm、大约 4mm、大约 5mm、大约 6mm、大约 7mm、大约 8mm、大约 9mm、大约 10mm、大约 12mm、大约 14mm、大约 16mm、大约 18mm、大约 20mm、大约 22mm、大约 24mm、大约 26mm、大约 28mm、大约 30mm，以及此处增加 0.5mm 的任意距离或范围。在某些实施方式中，角 θ_3 的顶点与刀头 400 的远端之间的距离可以在大约 5mm 至大约 25mm 之间、大约 6mm 至大约 20mm 之间、大约 7mm 至大约 15mm 之间，或此处增加 1mm 的任意范围内。

修 改 的 权 利 要 求 书

1、一种外科组织移除系统，该外科组织移除系统用于移除目标的靶组织，所述外科组织移除系统包括刀头，该刀头具有：

外周，该外周限定穿过所述刀头的内腔，所述内腔具有中心轴线；

朝前的切割刃，该朝前的切割刃位于所述外周的远端边缘，所述朝前的切割刃构造为（i）在所述刀头的前进冲程中切割靶组织并（ii）将切割的组织引导至所述内腔；和

切割刃防护件，该切割刃防护件位于所述朝前的切割刃的远端，并且所述切割刃防护件构造为在所述前进冲程中防止所述朝前的切割刃切割周边组织，所述切割刃防护件的宽度小于所述内腔的横截面的宽度，以便于所述靶组织在所述前进冲程中进入所述内腔中。

2、根据权利要求 1 所述的外科组织移除系统，其中，该刀头还具有朝后的切割刃，该朝后的切割刃用于在所述刀头的返回冲程中切割所述靶组织。

3、根据权利要求 1 所述的外科组织移除系统，其中，该刀头还具有横向切割刃，该横向切割刃用于在所述刀头的横向冲程中切割所述靶组织。

4、根据权利要求 1 所述的外科组织移除系统，其中，该刀头还具有位于所述切割刃防护件上的横向切割刃，该横向切割刃用于在所述刀头的横向冲程中切割所述靶组织。

5、根据权利要求 1 所述的外科组织移除系统，其中，所述刀头还构造为可操作地在所述内腔和抽吸源之间连通；

和，

抽吸组件，该抽吸组件与所述刀头可操作地连通，所述抽吸组件提供所述抽吸源并且包括至少大致刚性的抽吸管，该至少大致刚性的抽吸管具有中心轴线，并且所述抽吸组件制造抽吸流，该抽吸流用于使所述靶组织穿过所述内腔并移出所述目标。

6、根据权利要求 5 所述的外科组织移除系统，其中，所述至少大致刚性的抽吸管与所述刀头形成为一个整体。

7、根据权利要求 5 所述的外科组织移除系统，其中，所述刀头还具有朝后的切割刃，该朝后的切割刃用于在所述刀头的返回冲程中切割所述靶组织。

8、根据权利要求 5 所述的外科组织移除系统，其中，所述刀头还具有横向切割刃，该横向切割刃用于在所述刀头的横向冲程中切割所述靶组织。

9、根据权利要求 5 所述的外科组织移除系统，其中，所述内腔的中心轴线与所述刚性的抽吸管的中心轴线形成角 θ_1，该角 θ_1 在大约 5° 至大约 90° 的范围内，并且所述朝前的切割刃位于距离所述角 θ_1 的顶点大约 3mm 至大约 25mm 的位置。

10、根据权利要求 9 所述的外科组织移除系统，其中，所述刀头和所述抽吸组件之间的可操作的连通是铰接的，并且所述角 θ_1 为可调节的。

11、根据权利要求 9 所述的外科组织移除系统，其中，所述刀头和所述抽吸组件之间的可操作的连通是刚性的，并且所述角 θ_1 为固定的。

12、根据权利要求 9 所述的外科组织移除系统，其中，所述内腔的中心轴线在所述朝前的切割刃处具有出口点，并且该出口点位于大约 3mm 至大约 25mm 的横向距离处，所述横向距离正交于所述刚性的抽吸管的中心轴线。

13、根据权利要求 5 所述的外科组织移除系统，其中，所述内腔的中心轴线与所述刚性的抽吸管的中心轴线形成角 θ_1，该角 θ_1 在 1° 至 180° 的范围内，并且所述朝前的切割刃位于距离所述角 θ_1 的顶点 3mm 至 25mm 的位置；其中，

额外的角 θ_3，该额外的角 θ_3 位于靠近角 θ_1 的 5mm 至 25mm 处；

角 θ_1 和角 θ_3 互相独立地选自大约 0°至大约 180°的范围内，角 θ_1 和角 θ_3 限制为：

（i）所述刀头的内腔的中心轴线与靠近角 θ_3 的所述刚性的抽吸管的中心轴线之间的净角为 θ_4，该净角 θ_4 在 0°至 90°的范围内；和

（ii）所述内腔的中心轴线具有出口点，该出口点位于所述朝前的切割刃处，并且所述出口点位于大约 3mm 至大约 25mm 的横向距离处，所述横向距离正交于所述刚性的抽吸管的中心轴线。

14、根据权利要求 5 所述的外科组织移除系统，其中，所述靶组织为髓核，并且所述周边组织为纤维环。

15、根据权利要求 5 所述的外科组织移除系统，所述刀头还具有朝后的切割刃，该朝后的切割刃用于在所述刀头的返回冲程中切除所述髓核；

横向的切割刃，该横向的切割刃用于在所述刀头的横向冲程中切割

所述髓核；

其中，所述刀头构造为可操作地在所述内腔和抽吸源之间连通；和，

抽吸组件，该抽吸组件与所述刀头可操作地连通，所述抽吸组件提供所述抽吸源并且包括至少大致刚性的抽吸管，该至少大致刚性的抽吸管具有中心轴线，并且所述抽吸组件制造抽吸流，该抽吸流用于将所述髓核穿过所述内腔并移出所述目标。

16、根据权利要求 15 所述的外科组织移除系统，其中，所述至少大致刚性的抽吸管与所述刀头形成为一个整体。

17、根据权利要求 15 所述的外科组织移除系统，其中，所述内腔的中心轴线与所述刚性的抽吸管的中心轴线形成角 θ_1，该角 θ_1 在大约 5° 至大约 90° 的范围内，并且所述朝前的切割刃位于距离所述角 θ_1 的顶点大约 3mm 至大约 25mm 的位置。

18、根据权利要求 15 所述的外科组织移除系统，其中，所述内腔的中心轴线在所述朝前的切割刃处具有出口点，并且该出口点位于大约 3mm 至大约 25mm 的横向距离处，所述横向距离正交于所述刚性的抽吸管的中心轴线。

19、根据权利要求 17 所述的外科组织移除系统，其中，所述刀头和所述抽吸组件之间的可操作的连通是铰接的，并且所述角 θ_1 为可调节的。

20、根据权利要求 17 所述的外科组织移除系统，其中，所述刀头和所述抽吸组件之间的可操作的连通是刚性的，并且所述角 θ_1 为固定的。

21、根据权利要求 15 所述的外科组织移除系统，其中，所述内腔的中心轴线与所述刚性的抽吸管的中心轴线形成角 θ_1，该角 θ_1 在 1° 至 180° 的范围内，并且所述朝前的切割刃位于距离所述角 θ_1 的顶点 3mm 至 25mm 的位置；其中，

额外的角 θ_3，该额外的角 θ_3 位于靠近角 θ_1 的 5mm 至 25mm 处；

角 θ_1 和角 θ_3 互相独立地选自大约 0°至大约 180°的范围内，角 θ_1 和角 θ_3 限制为

（i）所述刀头的内腔的中心轴线与靠近角 θ_3 的所述刚性的抽吸管的中心轴线之间的净角为 θ_4，该净角 θ_4 在 0°至 90°的范围内；和

（ii）所述内腔的中心轴线具有出口点，该出口点位于所述朝前的切割刃处，并且所述出口点位于大约 3mm 至大约 25mm 的横向距离处，所述横向距离正交于所述刚性的抽吸管的中心轴线。

22、根据权利要求 15 所述的外科组织移除系统，其中，所述朝后的切割刃位于所述外周的远端边缘上，用于在所述刀头的返回冲程中切割所述靶组织。

23、根据权利要求 15 所述的外科组织移除系统，其中，所述朝后的切割刃位于所述切割刃防护件上，用于在所述刀头的返回冲程中切割所述靶组织，所述切割刃防护件具有双刃尖端，该双刃尖端以大于 90° 的角 θ_2 朝后指向所述内腔中，以在所述刀头的返回冲程中在所述内腔中抓紧和/或切割组织。

24、根据权利要求 15 所述的外科组织移除系统，其中，所述横向的切

割刃位于所述切割刃防护件上，用于在所述刀头的横向冲程中切割所述靶组织。

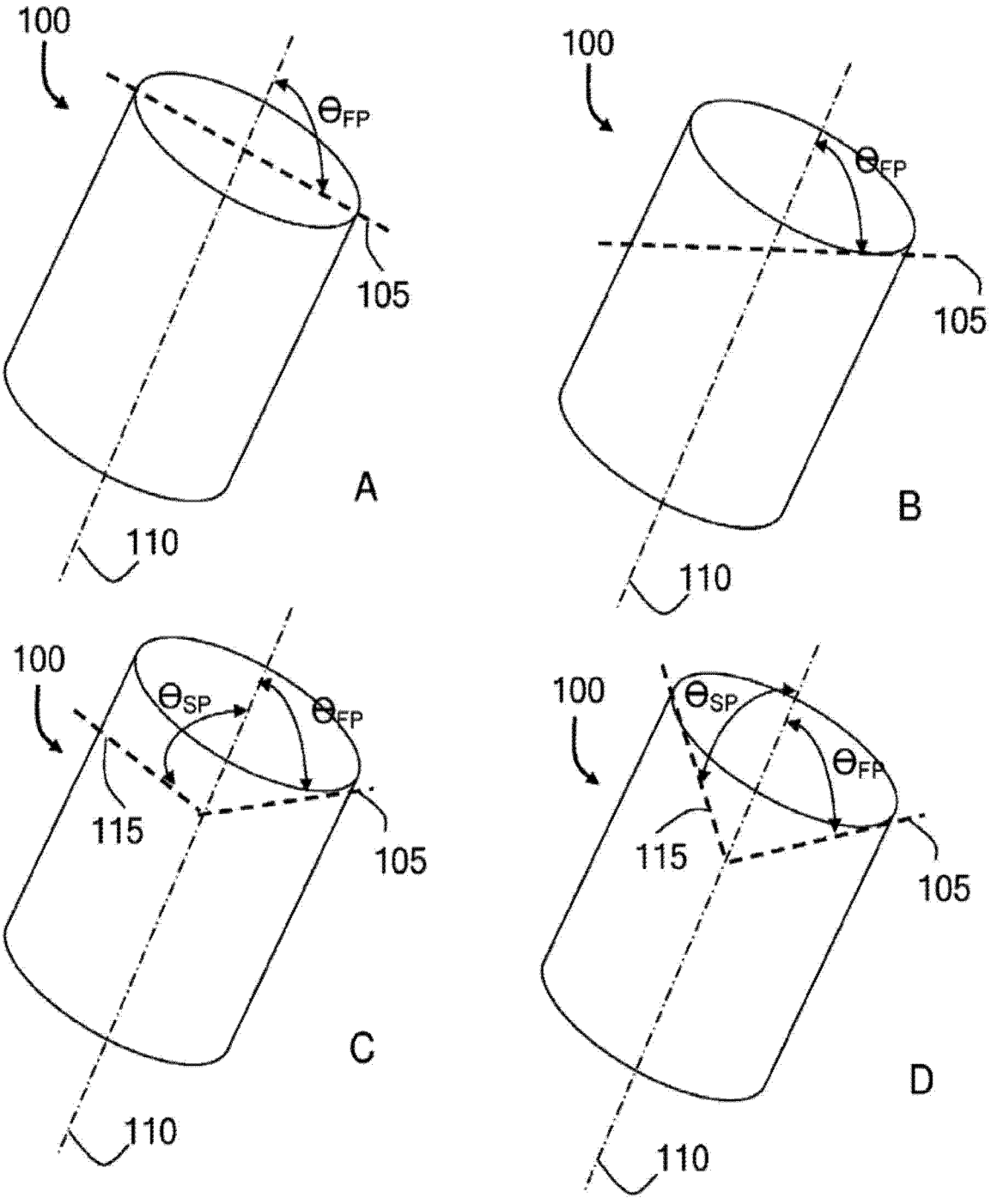

100
θFP
105
A
110
100
θFP
105
B
110
100
θSP
θFP
115
105
C
110
100
θSP
θFP
115
105
D
110

图 1

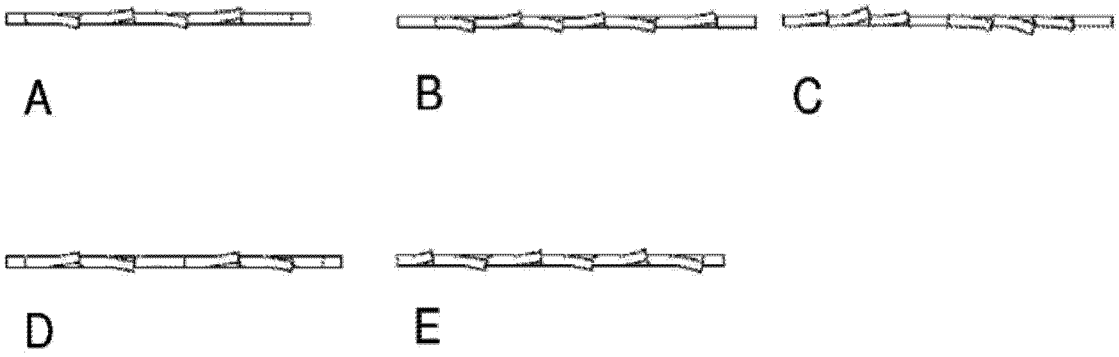


图 2

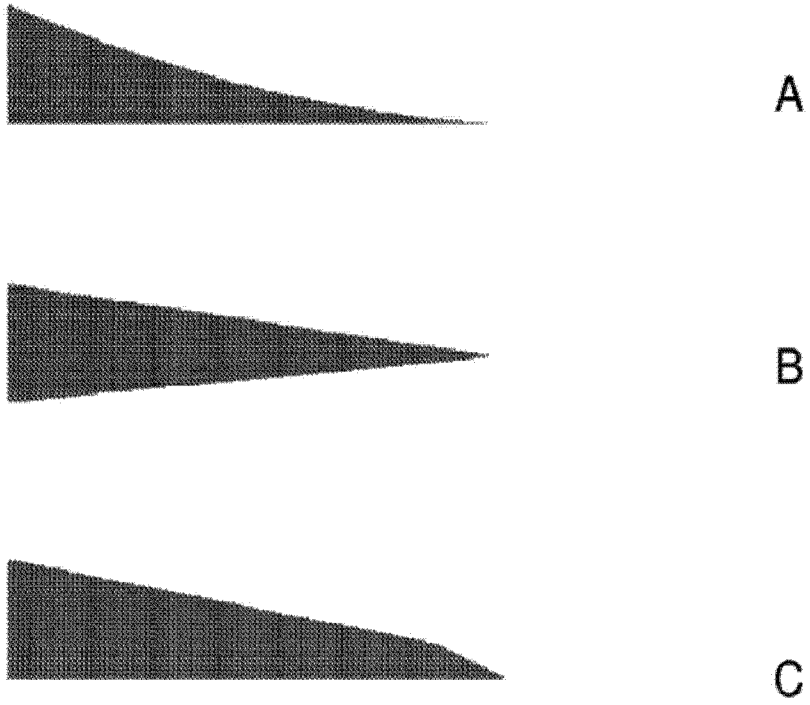


图 3

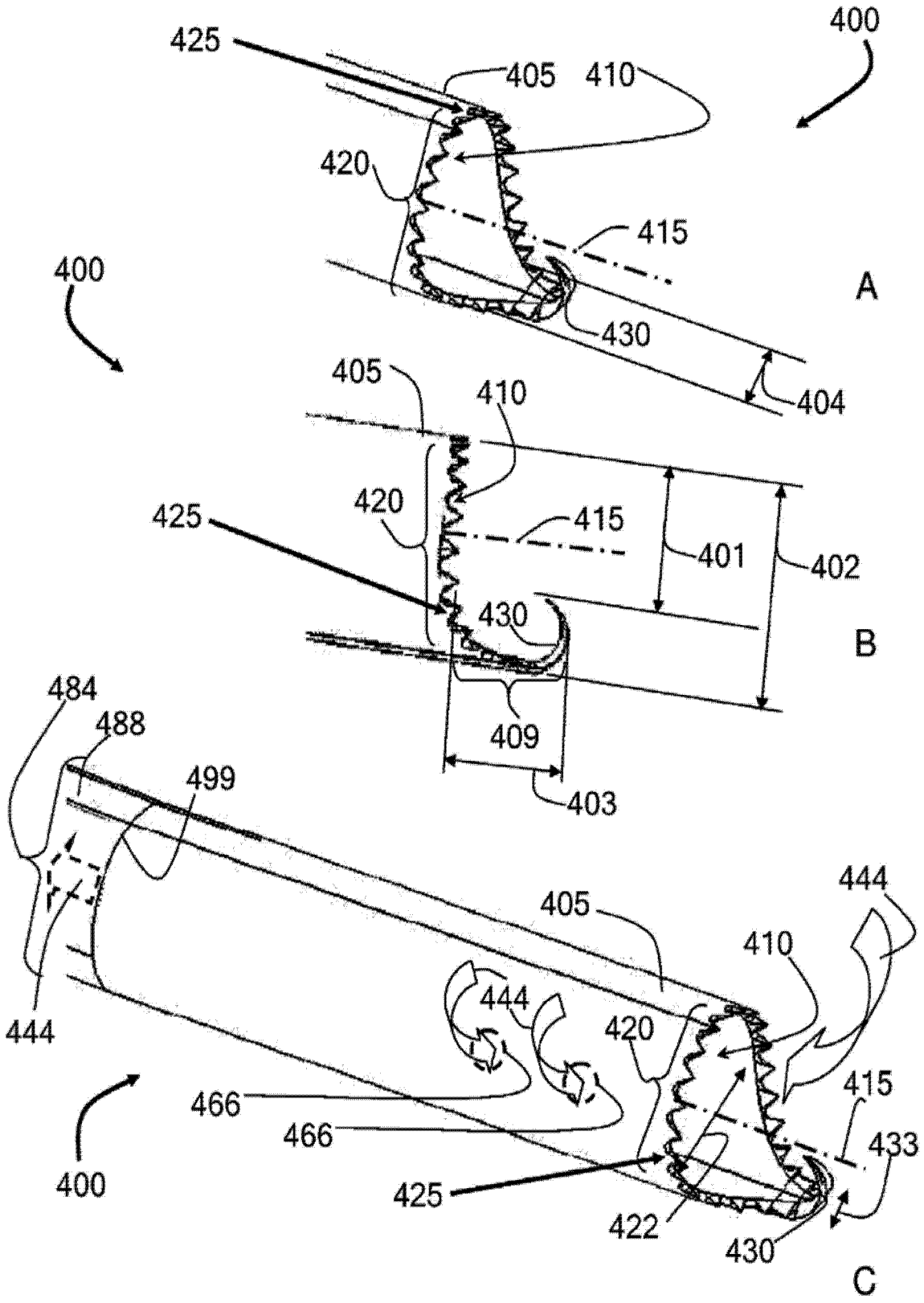

425
405
410
400
420
415
A
400
430
404
405
410
420
425
415
401
402
430
B
484
488
409
499
403
444
405
410
444
444
420
415
466
466
433
400
425
422
430
C

图 4

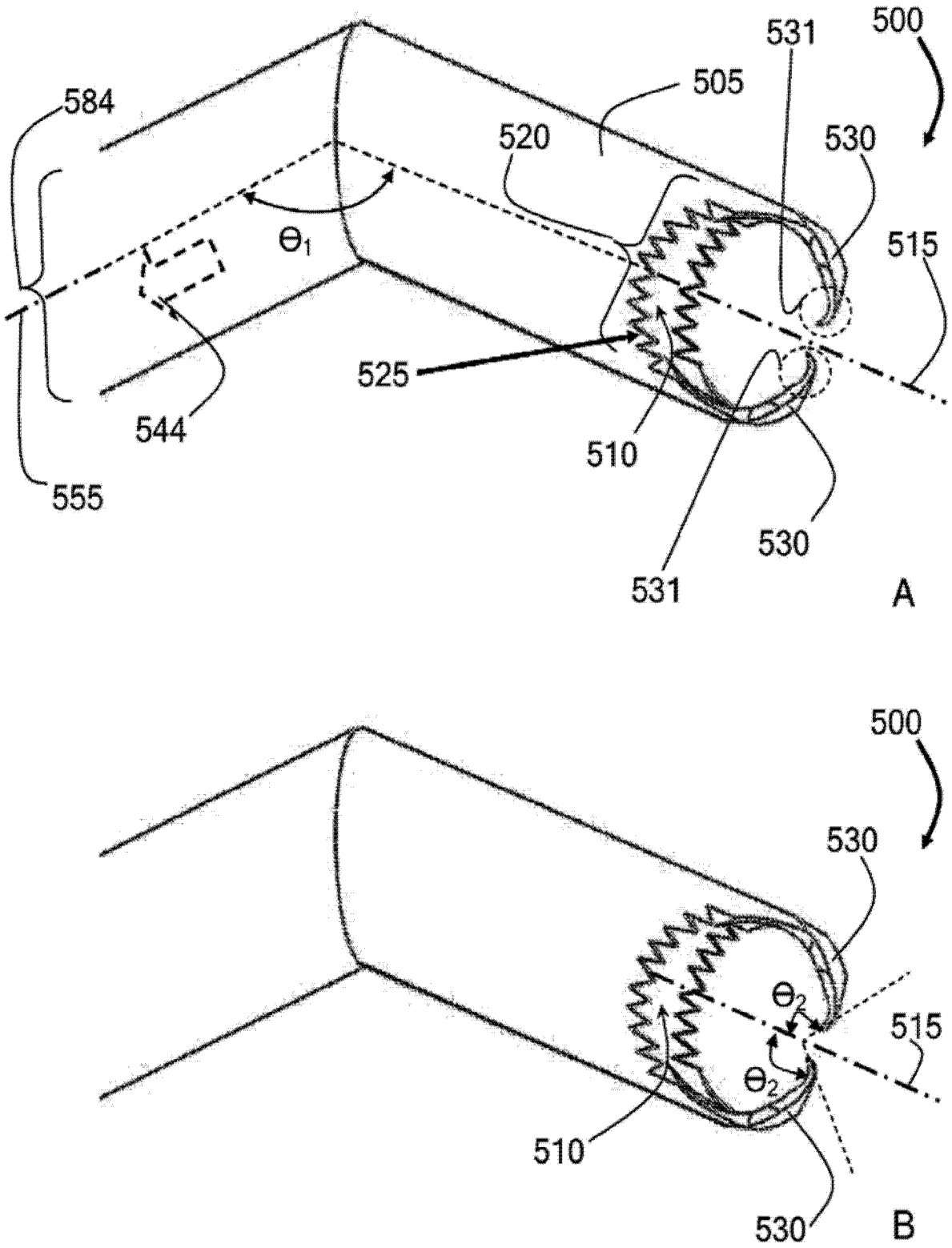

584
505
531
500
520
530
515
Θ_1
525
544
510
555
530
531
A
500
530
Θ_2
515
Θ_2
510
530
B

图 5

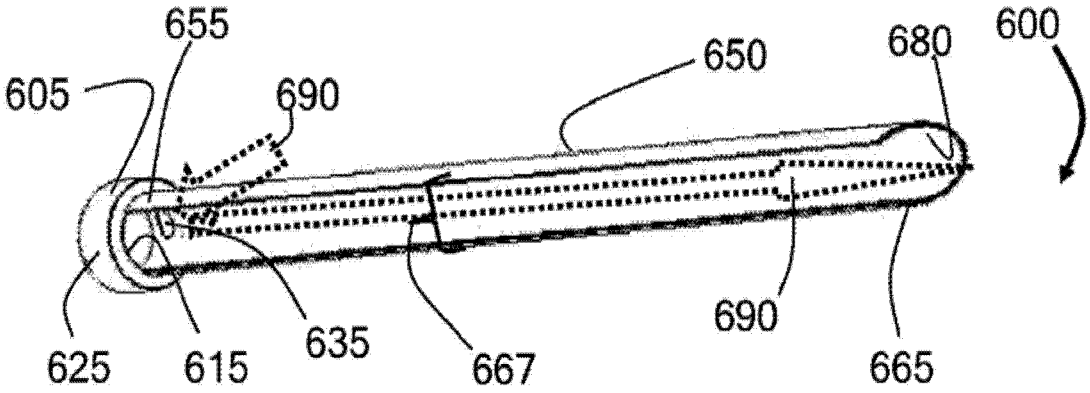

655
605
690
650
680
600
625
615
635
667
690
665

图 6

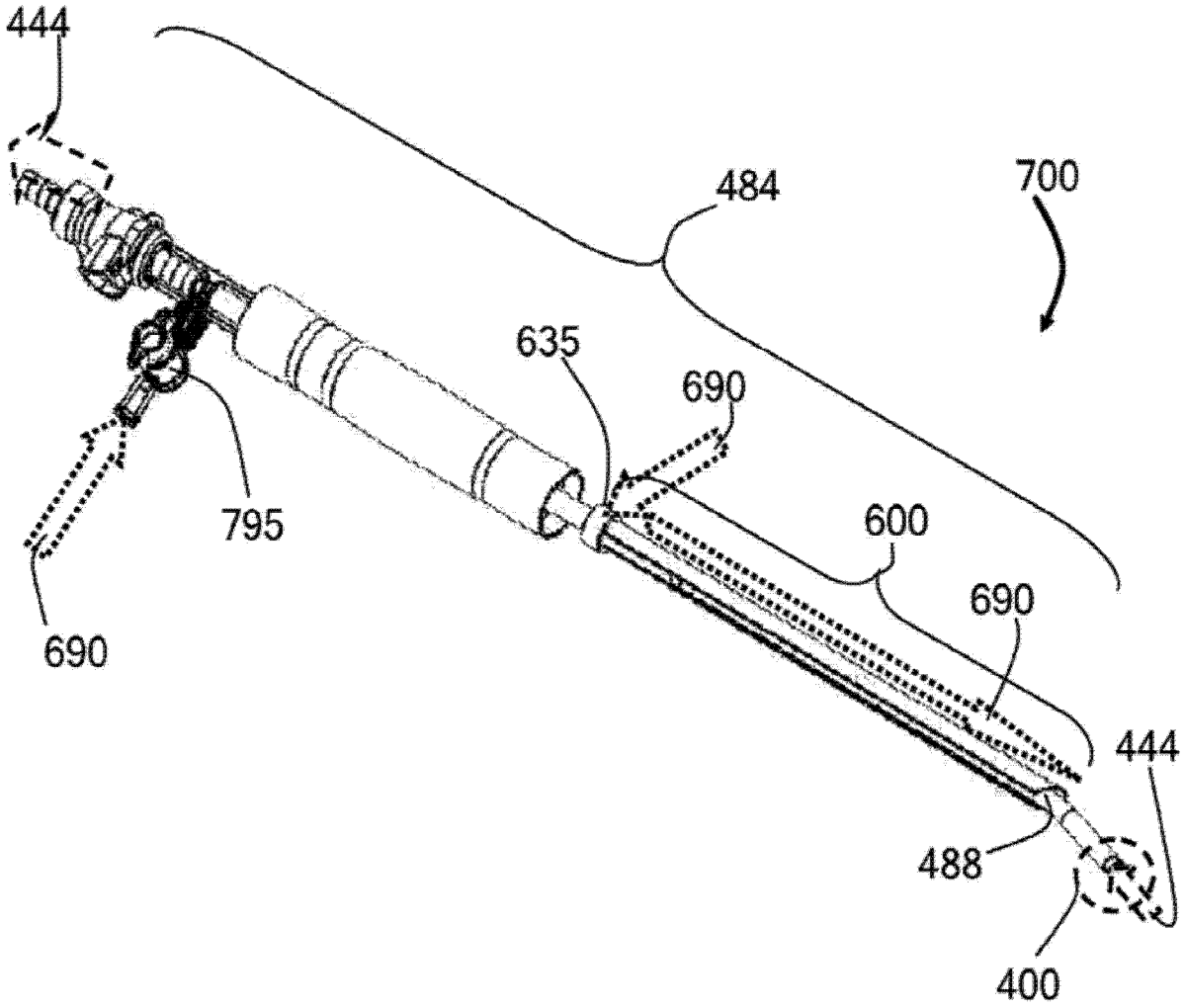

444
484
700
635
690
795
600
690
690
444
488
400

图 7

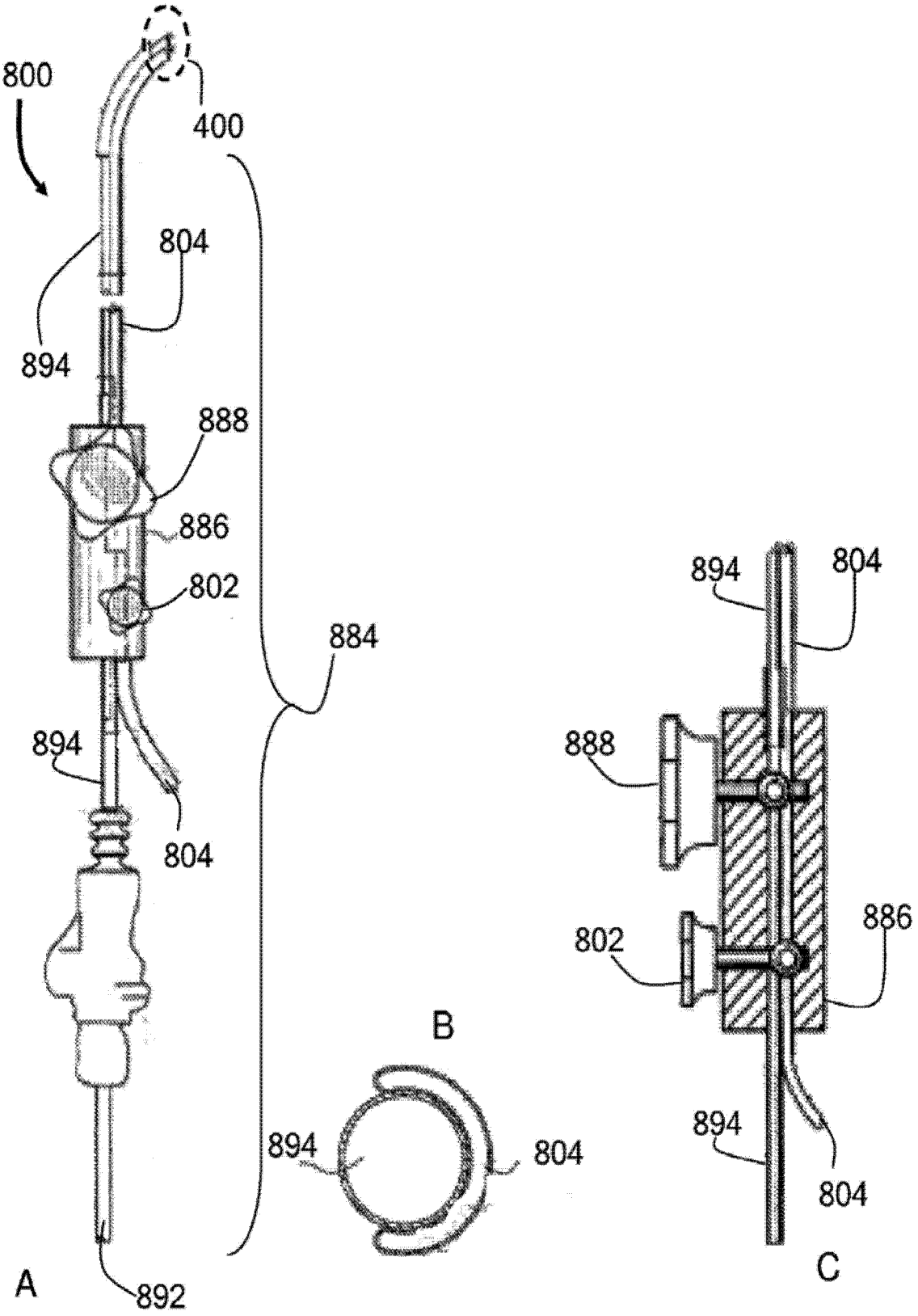

800
400
804
894
888
886
802
884
894
804
892
A
B
894
804
894
804
888
886
802
894
804
C

图 8

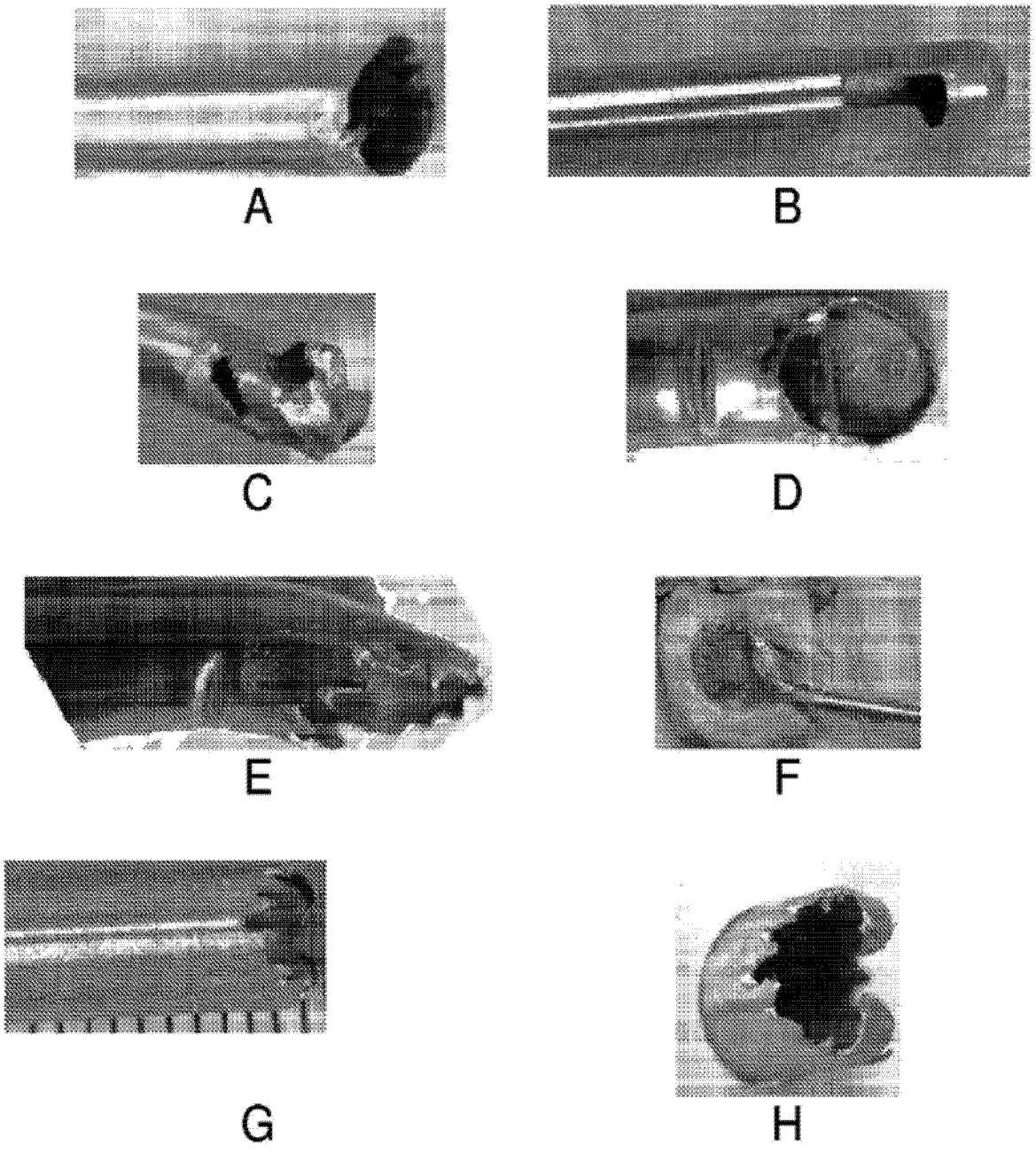
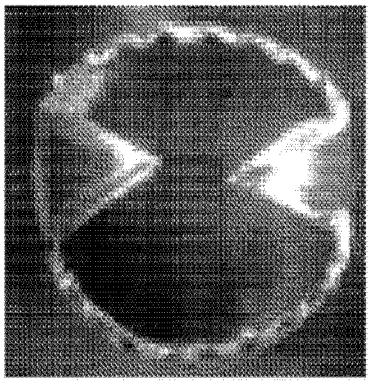
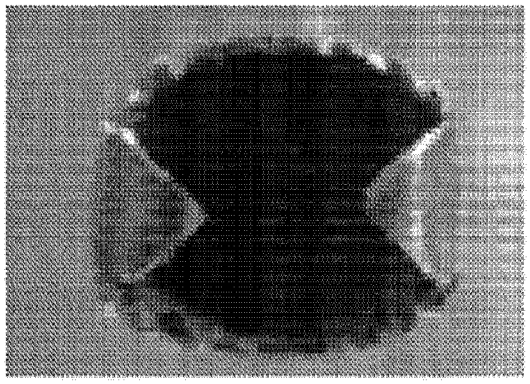


图 9

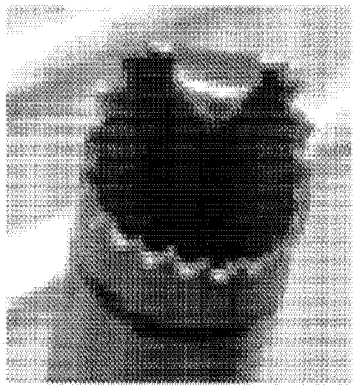


A

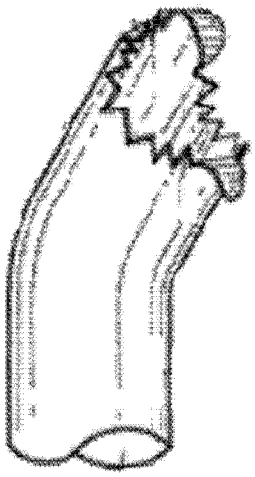


B

C



D



E

图 10

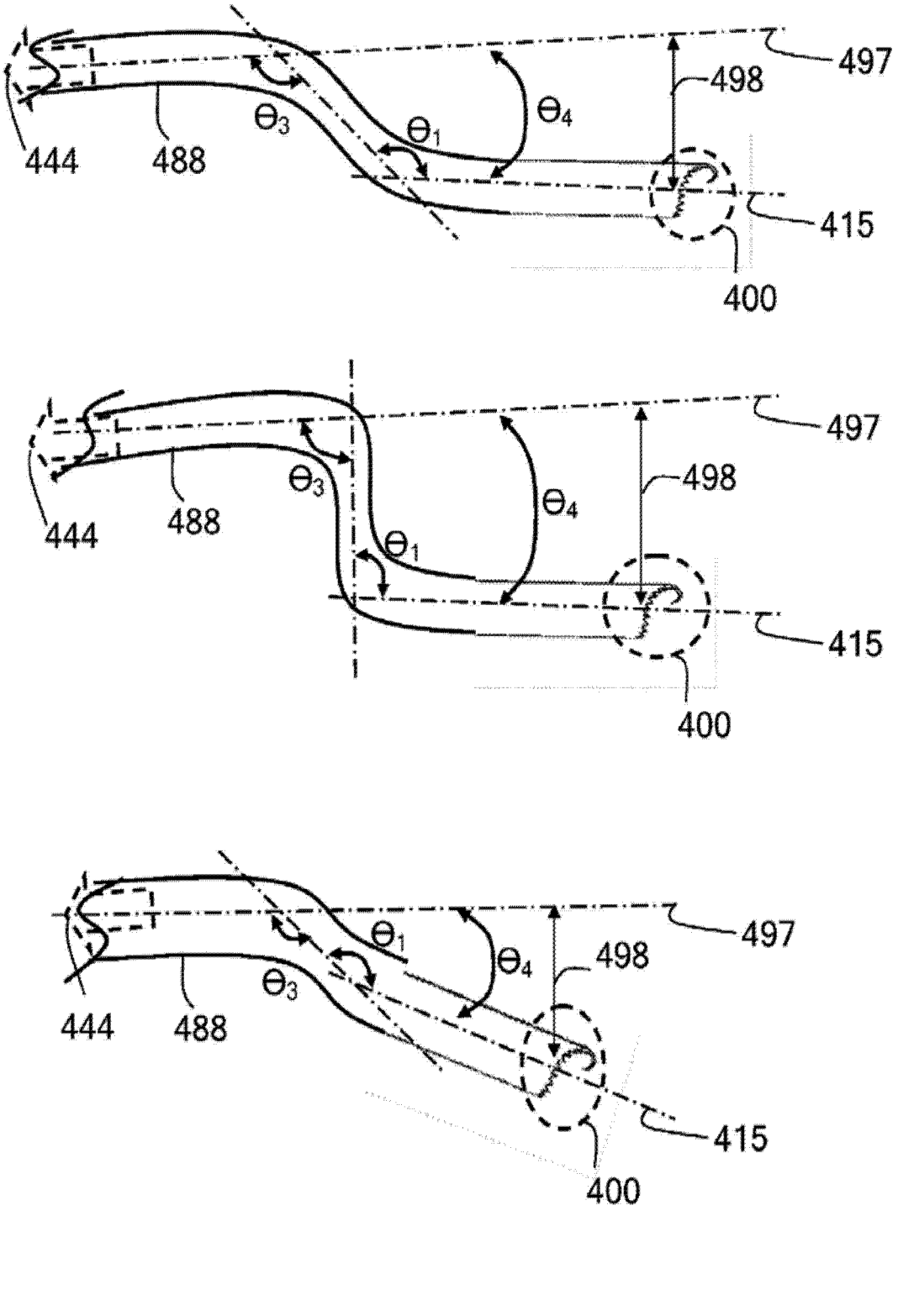

497
498
θ4
θ3
θ1
444
488
415
400
A
497
498
θ4
θ3
θ1
444
488
415
400
B
497
498
θ4
θ1
θ3
444
488
415
400
C

图 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/051952

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/3205(2006.01)i, A61B 17/3209(2006.01)i, A61B 17/34(2006.01)i, A61B 17/70(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 17/3205; A61B 1/00; A61F 9/007; A61B; A61B 17/32

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

Korean utility models and applications for utility models
Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: cutting, discectomy, tissue removal, blade, guard, suction

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO2004-110260 A2 (NEOMEDIX CORPORATION et al.) 23 December 2004 See abstract; page 11, lines 11-13, 28-30; page 12, lines 10-14; page 13, lines 31-32; page 16, lines 4-6; claims 1, 18-19, 24; fig. 2.	1-24,29-40
A	JP 2009-095662 A (NIDEK CO LTD) 07 May 2009 (NIDEK CO LTD) 7 May 2009 See abstract; figs. 1-2; paragraphs 11, 14-15, claims 1-3.	1-24,29-40
A	US 5456689 A (KRESCH, ARNOLD J. et al.) 10 October 1995 See abstract; figs. 1A, 2A, 5; column 4, lines 47-53; column 4, lines 59-65; column 5, lines 51-53; column 6, lines 26-31; claims 1, 9-10.	1-24,29-40
A	US 2008-0058842 A1 (MARK HANS EMANUEL, BLOEMENDAAL) 06 March 2008 See abstract; paragraphs 33, 40; claims 1, 6, 8, 12.	1-24,29-40
A	US 2006-0089527 A1 (FRANK DOLL et al.) 27 April 2006 See abstract; paragraphs 35, 37-39; claims 1-4, 7.	1-24,29-40
A	US 2008-0221605 A1 (SAAL JEFFREY ALAN et al.) 11 September 2008 See abstract; figs. 2E-3, 7, 9; paragraphs 95-97, 101, 121; claims 1, 8, 11-12, 17.	1-24,29-40

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 FEBRUARY 2013 (28.02.2013)	**04 MARCH 2013 (04.03.2013)**

Name and mailing address of the ISA/KR

Facsimile No. 82-42-472-7140

Authorized officer

LEE, Dong Yun

Telephone No. 82-42-481-8734

International application No.
PCT/US2012/051952

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

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

1. ☒ Claims Nos.: 25-28, 41-44
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 25-28 and 41-44 pertain to methods for treatment of human or animal body by therapy or surgery, thus relate to a subject matter which this international Searching Authority is not required to search under Article 17(2)(a)(i) of PCT and Rule 39.1(iv) of the Regulations under the PCT.

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

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2012/051952

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2004-110260 A2	23.12.2004	CA 2528056 A1	23.12.2004
		CA 2528060 A1	23.12.2004
		CA 2528060 C	11.12.2012
		CA 2528280 A1	23.12.2004
		CA 2528280 C	11.12.2012
		EP 1631204 A2	08.03.2006
		EP 1631204 B1	04.04.2012
		EP 1633236 A2	15.03.2006
		EP 1633236 A4	30.12.2009
		EP 1633267 A2	15.03.2006
		JP 2007-500582 A	18.01.2007
		JP 2007-501687 A	01.02.2007
		JP 2007-524472 A	30.08.2007
		JP 4611309 B2	22.10.2010
		JP 4685786 B2	18.02.2011
		JP 4685786 B2	18.05.2011
		JP 4704344 B2	18.03.2011
		JP 4704344 B2	15.06.2011
		MX PA05013310 A	19.05.2006
		MX PA05013311 A	18.08.2006
		MX PA05013313 A	18.08.2006
		US 2006-0241580 A1	26.10.2006
		US 2007-0010812 A1	11.01.2007
		US 2007-0276420 A1	29.11.2007
		US 7842034 B2	30.11.2010
		US 7959641 B2	14.06.2011
		WO 2004-110259 A2	23.12.2004
		WO 2004-110259 A3	23.12.2004
		WO 2004-110260 A3	16.04.2009
		WO 2004-110501 A2	23.12.2004
JP 2009-095662 A	07.05.2009	CN 101401755 A	08.04.2009
US 5456689 A	10.10.1995	CA 2230570 A1	20.03.1997
		CA 2230570 C	04.07.2006
		EP 0723422 A1	17.07.2002
		EP 0851786 A1	07.07.1999
		EP 0851786 B1	17.11.1999
		JP 09-503942 A	22.04.1997
		JP 11-511380 A	05.10.1999
		JP 3790803 B2	28.06.2006
		US 05527331 A	18.06.1996
		US 05531892 A	02.07.1996
		WO 95-10981 A1	27.04.1995
		WO 96-11638 A1	25.04.1996
		WO 97-10040 A1	20.03.1997
US 2008-0058842 A1	06.03.2008	AU 1998-90074 B2	02.05.2002
		CA 2302185 A1	11.03.1999

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2012/051952

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		EP 0996375 A1	03.05.2000
		EP 0996375 B1	15.03.2006
		JP 2001-514037 A	11.09.2001
		JP 4172910 B2	29.10.2008
		US 2008-0015621 A1	17.01.2008
		US 2008-0058588 A1	06.03.2008
		US 2012-0197280 A1	02.08.2012
		US 7249602 B1	31.07.2007
		US 8061359 B2	22.11.2011
		WO 99-11184 A1	11.03.1999
US 2006-0089527 A1	27.04.2006	DE 102004021713 A1	17.11.2005
		DE 502005000109 D1	02.11.2006
		EP 1610695 A1	04.01.2006
		EP 1610695 B1	20.09.2006
		WO 2005-104966 A1	10.11.2005
US 2008-0221605 A1	11.09.2008	EP 2109401 A2	21.10.2009
		EP 2109412 A1	21.10.2009
		US 2008-0183175 A1	31.07.2008
		US 2008-0183192 A1	31.07.2008
		WO 2008-094436 A1	07.08.2008
		WO 2008-094439 A2	07.08.2008
		WO 2008-094444 A2	07.08.2008