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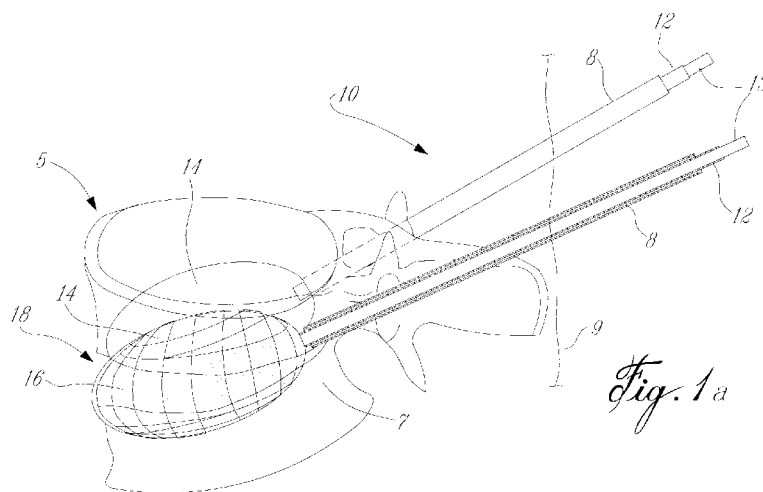
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(54) Title: DEVICE AND METHOD FOR PERCUTANEOUS INTRAVERTEBRAL OSTEOTOMY



(57) Abstract: A device (10) for percutaneously forming an osteotomy cavity (18) within a vertebral body (7) includes a working cannula (8) having a passage extending therethrough from a proximal end to a distal end thereof, and a membrane (16) releasably attached to the distal end of an insertion member (12, 144) received within the cannula such as to direct the membrane to the distal end of the cannula and into the osteotomy cavity formed within the vertebral body. The membrane is at least partially cement-impermeable and displaceable between a contracted position, wherein the membrane is configured to fit through the passage of the cannula (8) and into the cavity (18), and an extended position, wherein the membrane (16) extends to at least partially enclose the osteotomy cavity (18) and to thereby limit egress of bone cement out of the cavity (18) within the vertebral body (7).



DEVICE AND METHOD FOR PERCUTANEOUS INTRAVERTEBRAL OSTEOTOMY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present international application claims priority on United States Provisional Patent Application No. 61/119,413 file December 3, 2008, the entire content of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention relates generally to orthopedic surgery, and more particularly to a device and method for performing intravertebral osteotomy percutaneously.

BACKGROUND

[0003] Vertebroplasty and kyphoplasty are procedures currently performed on patients suffering from vertebral fractures, such as those caused by osteoporosis, cancer and/or trauma. During these procedures, bone cement is injected into the fractured vertebra in order to stabilize the vertebra and reduce pain felt by the patient. Kyphoplasty additionally attempts to restore the normal shape and height of the vertebra through the insertion and inflation of a balloon.

[0004] One of the main difficulties associated with these procedures is the lack of sufficient vertebral height gain for many patients. Fractures are typically stabilized and patient pain can be alleviated, but often the full vertebral height, and therefore the patient's own height, is not always restored

[0005] Post fracture kyphosis (curvature of the upper spine) affects a significant proportion of the population. While kyphoplasty procedures attempt to restore the original height and angle of kyphosis of a fractured vertebra, some sources have suggested that full vertebral height restoration is only achieved in about 50% of the cases that kyphoplasty is performed. One of the main reasons for this when using standard kyphosis techniques is that the compression fracture sites in the vertebra may have already healed in the deformed state by the time the procedure is conducted. This

occurs mainly because vertebral fractures are often not immediately detected, and by the time they are detected, the fracture sites have re-healed in whole or in part. Further, Kyphoplasty, however, cannot correct all vertebral fractures. The main reason for the lack of effectiveness in current treating methods and techniques is that the vertebrae have often already healed by the time the procedure is performed. In addition to this, there exists a relative lack of available tools, other than the standard kyphoplasty balloons, to readily lift the superior plate of the vertebra back to its original height.

[0006] Additional details regarding balloon kyphoplasty may be found, for example, in U.S. Patent nos. 6,423,083, 6,248,110, and 6,235,043, the specification of each of which is incorporated by reference herein in its entirety.

[0007] In order to treat a kyphotic wedged, but healed vertebra, the fracture must first be recreated. This new fracture creation is called an osteotomy. Osteotomies have been used to treat many different types of spine deformities, including excessive kyphosis and even lateral spine tilt. However, current spine osteotomy procedures require an invasive surgery carried out through large incisions, implying significant morbidity and mortality.

[0008] Several disadvantages exist with the standard kyphoplasty procedures used to date to treat fractured vertebra, including the high cost, the fact that positioning of the endplates of the vertebral body can be lost after the removal of the balloon catheter, and the risk of perforating the vertebral endplates during the procedure.

[0009] As with vertebroplasty, perhaps the most feared, albeit remote, complication related to kyphoplasty is the risk of bone cement leakage out of the vertebra and into the spinal canal. These leaks can lead, in the most extreme cases, to paralysis. Such a cement leak may occur through the low resistance veins of the vertebral body or through a crack in the bone which was not identified prior to the injection of the bone cement. Other complications associated with bone cement leakage include additional adjacent level vertebral fractures, infection and cement embolization.

[0010] Cement embolization occurs by a similar mechanism to a cement leak. The cement could be forced into the low resistance venous system and thus could travel to the lungs or brain, resulting in a pulmonary embolism or stroke.

[0011] Additionally, metastatic tumors may also lead to defects in vertebra, and these vertebral defects make kyphoplasty and vertebroplasty more difficult because the vertebral defect allows the free flow of cement preferentially away from the vertebra to be treated, and potentially into a dangerous zone.

[0012] US Patent Application Publication 2007/0067043 A1 by Dericks describes a sac to be place in a bone and filled with bone cement. In the preferred embodiment the sac is impermeable to prevent bone cement leakage into the vertebral body. US Patent Application Publication 2007/0233258 A1 by Hestad and al. describes a permeable bag. In the preferred embodiments described by Hestad, the bone cement material is inserted under pressure into the permeable bag causing the bag to expand and permeate the bag, such as to enter voids and fissures in the vertebral body simultaneously. International Patent Application WO 2007/067726 A2 by Dutoit et al. describes the insertion of a stent-like device into the fractured vertebral body. In a preferred embodiment described by Dutoit, a folded sheet metal device is said to be inserted into the vertebral body and subsequently expended. The various implants described are open at their respective ends and can be filled with bone cement.

[0013] Despite these systems, improvement of existing kyphoplasty devices and methods is sought.

SUMMARY OF THE INVENTION

[0014] There is provided, in accordance with one aspect of the present invention, a system for percutaneously forming an osteotomy cavity within a vertebral body, comprising: a working cannula having a passage extending therethrough from a proximal end thereof adapted to protrude beyond a skin surface to a distal end thereof adapted to be inserted within the vertebral body; and a membrane releasably attached to a distal end of an insertion member received within the cannula such as to direct the membrane to the distal end of the cannula and into the osteotomy cavity formed within the vertebral body, said membrane being at least partially cement-impermeable and displaceable between a contracted first position, wherein the membrane is configured to fit through the passage of the cannula and into the cavity, and an extended second position, wherein the membrane extends to at least partially enclose the osteotomy

cavity and to thereby limit egress of bone cement out of the cavity within the vertebral body.

[0015] There is also provided, in accordance with another aspect of the present invention, a percutaneous method to increase vertebral body height of a damaged vertebra, comprising the steps of: cannulating the vertebra with at least one working cannula inserted into the vertebral body; percutaneously cutting a cleavage plane between portions of the vertebral body using a cutting tool inserted through the working cannula, such as to percutaneously create an intravertebral osteotomy; separating the portions of the vertebral body to form an open sided cavity therein, thereby increasing the vertebral body height; inserting a first membrane cannula within the working cannula, said first membrane cannula having a first membrane attached at an extremity of the membrane cannula inserted into the vertebral body, the first membrane being substantially impermeable to a hardening material used to reinforce the vertebral body; positioning the first membrane in a first position within said cavity wherein the membrane partially encloses a first open side of said cavity; and injecting the hardening material through the first working cannula into the cavity.

[0016] There is further provided, in accordance with another aspect of the present invention, a percutaneous method to restore vertebral body height by vertebral osteotomy comprising the steps of: cannulating the vertebra with a first and a second working cannula inserted into the vertebral body; percutaneously cutting a cleavage plane in the vertebral body using a cutting tool inserted through at least one of the first and second working cannula; inserting a first deformable element through the first working cannula and a second deformable element in the second working cannula, the deformable elements permitting the perforation thereof in at least one region thereof; placing the first and second deformable elements in respective predetermined orientations; inflating the first and second deformable elements using a filler fluid injected therein to form an open-sided cavity within the vertebral body and thereby restore a height of the vertebral body; removing the filler fluid from the first deformable element, while ensuring that the second deformable element remains in the predetermined orientation, and injecting cement through the first working cannula into the first deformable element, thereby inflating the first deformable element a second time; perforating the first deformable element to increase the permeability thereof in at

least one preferred direction, and extruding the cement contained within the first deformable element into the cavity; removing the filler fluid from the second selectively deformable element while ensuring that the second selectively deformable element remains in the predetermined orientation, and injecting cement through the second working cannula into the second deformable element, thereby inflating the second deformable element a second time; and perforating the second deformable element thereby increasing the permeability thereof in at least one preferred direction, and extruding cement contained within the second deformable element into the cavity; wherein non-perforated regions of the first and second deformable elements are substantially impermeable to the cement to thereby at least partially enclose said cavity and contain the cement therewithin.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Reference will now be made to the accompanying drawings, in which:

[0018] Fig. 1a is a perspective side view of a vertebra in the process of being percutaneously restored to a normal height using the present system following a percutaneous intravertebral osteotomy;

[0019] Fig. 1b is a frontal view of the vertebra and the present system shown in Fig. 1a;

[0020] Fig. 1c is a perspective side view of vertebra and system of Fig. 1c, showing the osteotomy cavity being filled with cement after the cement-impermeable membranes of the present system have been positioned in place;

[0021] Fig. 2 is a partially sectioned side view of the working cannula, the membrane cannula and the balloon cannula which are received within each other as part of the present system;

[0022] Fig. 3 is a partially sectioned side view of the membrane cannula and the balloon cannula fitted together in a double-cannula package prior to insertion into the working cannula;

[0023] Fig. 4 is a side view of the working cannula, the membrane cannula and the balloon cannula fitted together, with the balloon of the balloon cannula shown in an inflated position;

[0024] Fig. 5a-5e show schematic top views of osteotomes of the present system used to perform the percutaneous intravertebral osteotomy;

[0025] Fig. 6 shows a top view of a vertebra in which the osteotomy is percutaneously formed using the osteotomes of the present system;

[0026] Fig. 7 shows a top view of a vertebra in which the intravertebral osteotomy is performed using a motorized cutting tool operated by a robotic system;

[0027] Figs. 8a is a perspective view of a cement impermeable membrane and associated deployment device;

[0028] Fig. 8b is a top view of the membrane of Fig. 8a;

[0029] Fig. 8c is a side view of the membrane of Fig. 8a;

[0030] Fig. 9a is a perspective view of the membrane and deployment device of Fig. 8a, inserted within a working cannula for insertion into a vertebral body;

[0031] Fig. 9b is a cross-sectional view of the membrane and deployment device within the working cannula, as shown in Fig. 9a;

[0032] Figs. 9c-9d show the membrane of Figs. 9a-9b being detached from the deployment device by a plunger inserted through the cement delivery tube;

[0033] Fig. 10 is a side perspective view of an alternate membrane shaped particularly for an anterior defect and having cement windows therein allowing controlled flow of cement therethrough;

[0034] Fig. 11 is a side perspective view of an alternate membrane shaped particularly for a lateral defect;

[0035] Fig. 12a shows a perspective view of an alternate membrane deploying device, including a ruptureable tubular envelope shown in an enclosed position and within which the membrane is contained;

[0036] Fig. 12b is a perspective view of the device of Fig. 12b, showing the tubular envelope in a ruptured position exposing the membrane therewithin;

[0037] Fig. 13a show a cross-sectional view of an alternate lift balloon shown in a compressed position, the lift balloon having side walls which are relatively more rigid than top and bottom walls;

[0038] Fig. 13b shows a cross-sectional view of the lift balloon of Fig. 13a, shown in an inflated position; and

[0039] Fig. 14 is a side view of an alternate lift balloon having an embedded electric device therein for varying the permeability of the balloon;

[0040] Fig. 15a is a side view of an alternate method of percutaneously restoring a vertebra to a normal height following a percutaneous intravertebral osteotomy, using additional trocars inserted into a vertebra of a lower level; and

[0041] Fig. 15b is a side view of the alternate method and system of Fig. 15a, shown with the working cannulae in the vertebra in which an osteotomy has been created and the trocars in the adjacent vertebra moved together such as to open the osteotomy.

DETAILED DESCRIPTION

[0042] A method and device is disclosed which enables the repair of vertebral fractures and re-establishment of the natural vertebral body height and kyphosis angle of one or more vertebrae while remaining minimally invasive and limiting the risk of bone cement leakage.

[0043] The presently disclosed method and system offers an improvement and modification of a kyphoplasty technique. Kyphoplasty generally involves performing the following steps: 1) percutaneously cannulating a vertebral body; 2) inserting bone tamps (cavity creating balloons for vertebral bodies); 3) expanding the bone tamps (bone balloons) and thereby 4) restoring some vertebral body height (angulation) or

creating a vertebral body cavity; and 5) filling the newly restored body (with a newly created cavity) with acrylic bone cement.

[0044] The presently disclosed method additionally includes, inter alia, creating an intravertebral osteotomy that is also percutaneously performed and which permits the fractured and/or deformed vertebra to be more fully and consistently repositioned such that the full height thereof is re-established. The osteotomy, or fracture creation, of the vertebra to be restored involves cutting the vertebral body, prior to the addition of any bone cement or a kyphoplasty-type balloon inflation, in order to permit the re-positioning of the damaged vertebra into its natural full height location. While osteotomies of have been used to treat spine deformities in the past, they have required making large incisions in the skin and soft tissue, which can cause significant morbidity and potentially mortality. To date, no known procedure and tool set exists for carrying out a vertebral osteotomy percutaneously. The present device and method, however, allows for such a percutaneously performed intravertebral osteotomy. Further, as will be seen, the present system and method also uses a percutaneously installed cement-impermeable membrane disposed in the osteotomy site within the vertebra in order to retain the injected bone cement within the vertebral body, thereby significantly reducing the likelihood of bone cement leaks.

[0045] Referring first to Figs. 1a - 1c, the device 10 is used to perform percutaneous intravertebral osteotomy and vertebral fracture fixation and height restoration without significant risk of bone cement leakage. The device 10 generally includes at least one working cannula 8 and an insertion member that is received within the working cannula and includes a cement-impermeable membrane 16 releasably attached thereto, the insertion member thereby directing the membrane to a distal (inner) end of the working cannula 8 for insertion and deployment of the membrane within the vertebral body cavity. The insertion member may include at least one membrane cannula 12 and/or at least one balloon cannula 13, having a selectively deformable element (such as a balloon 14) fixed thereto, which are sized to concentrically fit within each other such that one or both can be slid within the outer working cannula 8. In one particular embodiment, the balloon cannula 13 is received within the membrane cannula 12, such that the membrane cannula 12 and balloon cannula 13 are thus able to be inserted together and slid within the outer working cannula 12 as one. The system 10 also

includes tools for performing the percutaneous intravertebral osteotomy, which will be described in further detail below after the other elements of the system 10 have been first described.

[0046] The membrane cannula 12 is used to deploy a bone cement impermeable membrane 16 (i.e. a membrane that is substantially impermeable to bone cement) in a given region of the osteotomy site. The bone cement impermeable membrane 16 acts to retain the injected bone cement within the cavity formed in the vertebral body 7 by the osteotomy. The balloon cannula 13 is used to deploy and inflate a lift balloon 14 that acts to separate the cut portions of the vertebral body 7 such as to re-establish the natural height of the vertebra 5, as will be described in further detail below. The outermost working cannula 8 is inserted percutaneously (i.e. through the skin 9) and down into the vertebral body 7 of the vertebra 5 such that, once correctly positioned, the membrane cannula 12 and the balloon cannula 13 can be inserted down therethrough. As such, once the working cannula is positioned, the surgeon performing the present technique can readily percutaneously insert a variety of tools, catheters, cannulae and the like, including the membrane and balloon cannulae 12, 13, with accuracy from outside of the patient's body to the exact site selected within the vertebra 5.

[0047] Two sets of working, membrane and balloon cannulae 8, 12, 13 are shown in Figs. 1a -1c, as in at least one embodiment of the present system and method, two such sets of cannulae are provided (i.e. one set on each of the medial and lateral sides of the vertebra) for each procedure conducted on the vertebra 5. This permits accurate height and angle restoration, given that the two balloons 14 of the balloon cannulae 13, disposed on transverse sides opposite from each other within the cleavage plane formed in the vertebral body, can be independently expanded such as to raise the two sides of the vertebra different heights, as required in order to level the endplates of the vertebral body 7 and restore the complete height of the vertebra. For example, when fully restored, two planes, each defining one of the inferior and superior endplates of the vertebral body, may be approximately parallel to each other. In another embodiment, however, only one working cannula 8 is used and percutaneously inserted into place, and a lateral osteotomy can then be performed.

[0048] The terms proximal and distal as used herein are intended to refer to positions respectively closer to and further away from the vertebra when the cannulae in question are inserted down into the working cannulae 8 toward the vertebra 5.

[0049] The membrane cannula 12 includes a membrane element 16 on the proximal end thereof. The membrane 16 may be detachably engaged to the proximal end of the cannula 12 such that, once the membrane has been inserted through the working cannula and into position within the vertebral body cavity, as will be described, it can be detached from the main body of the membrane cannula 12 and left in position. This permits the membrane cannula 12 to be withdrawn if necessary. The membrane 16 is made of a material that is substantially impermeable and/or impervious to the material to be used to fill the cavity formed in the vertebral body, such as bone cement for example. Accordingly, the membrane 16 acts to block or limit the flow of bone cement out of the vertebra. This may be used to block the lateral egress of cement, or otherwise. The membrane 16 is thus used in the present procedure to help retain the injected bone cement within the osteotomy cavity 18 formed within the vertebra 5, thereby limiting the risk of bone cement leaking out of the vertebra.

[0050] The membrane 16, which is deployed by the membrane cannula 12 in one of several possible ways, as will be seen, is inserted into the cavity 18 formed in the vertebral body by the osteotomy cut in order to prevent or at least substantially limit any leakage of bone cement out of this cavity in the vertebral body. It is to be understood that the membrane 16 tailored or selected to fit any type and size of defect within the vertebra, and can be located at any necessary position therewithin in order to best prevent cement leakage. For example, if there is an anterior defect in the vertebra, an anterior impermeable membrane 16 is placed in position, if there is a posterior defect, the impermeable membrane 16 is posteriorly placed, if there is an equatorial defect you place an equatorial membrane, etc. Thus, the impermeable membrane 16 may be disposed at any suitable position such that it covers the areas where a cement leak is to be prevented.

[0051] As seen for example in Figs. 1a - 1c where an extension osteotomy has been carried out, the membrane 16 may be positioned about an outer edge of the vertebra 5 and of the cavity 18 formed therewithin, such as to at least partially enclose the cavity

18 by blocking the largest open side of the cavity. The cavity 18 may be formed by first making a lateral cut plane which extends completely through the anterior side of the vertebral body, and then vertically spreading apart the two cut apart end plates of the vertebral body, such as by inflating the lift balloons 14 or by using the trocars and working cannulas as shown in Fig. 15a-15b. In such an extension osteotomy, a larger opening to the cavity formed is created on the anterior side of the vertebra, and thus the one or two membranes 16 used are configured and positioned such as to substantially fill these openings surrounding the wedge shaped cavity within the vertebral body. In this case, each of the membranes 16 is preferably positioned about one of the sides (i.e. lateral or medial) and at least part of the anterior or front side of the vertebra, as best seen in Fig. 1c which shows two membranes 16 deployed about the anterior periphery of the cavity 18 after the balloons 14 have been inflated. The two membranes 16 thereby enclose a majority of the open outer periphery of the cavity 18. Although two membranes 16 are shown in the embodiment of Figs. 1a-1c, it is to be understood that a single cement impermeable membrane 16, sized to be sufficiently large to cover the anterior opening to the osteotomy cavity 18, can be used and positioned as required in order to substantially enclose the cavity formed in the vertebral body by the osteotomy.

[0052] Referring to Fig. 1c, once the lift balloons 14 have been inflated such as to re-establish the desired height of the vertebra, and the cement impermeable membranes 16 have been deployed into their desired positions as shown in Figs. 1a and 1b, the osteotomy cavity 18 formed in the vertebral body is then filled bone cement. This is accomplished, as shown in Fig. 1c, using a cement delivery tube 44 that is preferably sized such as to be able to be inserted down through the balloon cannula 13 or the membrane cannula 12, which are themselves disposed within the outer working cannula 8. In one embodiment, once the balloons 14 have been inflated, the cement delivery tube 44 is inserted through the balloon cannula 13, which is left in place within the membrane cannula 12 and therefore without the outer working cannula 8, until an outlet 45 at a proximal end 43 of the cement delivery tube 44 is disposed within the osteotomy cavity 18. Bone cement is then fed through the delivery tube 44 and flows out of the outlet 45 such as to fill the cavity 18. As can be seen in Fig. 1c, in at least one embodiment the outlet 45 in the cement delivery tube 44 is located in a side wall of the proximal end 43 such that the cement is ejected out of the tube radially, rather than the

tube simply being open at its end, although this of course remains possible also. In yet another embodiment, the proximal end 43 of the tube 44 is provided with two or more openings in the side wall thereof, such as to simultaneously dispense the cement in several directions at once. For example, the tube 44 may include four equally spaced apart openings in the side wall of the tube such that cement is ejected out of the tube into a cross-shaped configuration (i.e. four perpendicular directions at once). This accordingly makes the cement delivery tube 44 a directional injector, such that bone cement can be injected into the cavity 18 in a direction corresponding to the location of the outlet 45. For example, in order to be able to inject cement as required such as to fill the cavity, the surgeon needs only to rotate the delivery tube 44 thereby directing a flow of cement in one or more different directions. By varying the depth and angular position of the delivery tube within the cavity, a much more effective distribution of the bone cement within the vertebra is achieved. The cement delivery tube 44 can be either inserted with the balloon 14 in place, such that the balloon 14 is itself filled with bone cement and therefore left in position permanently, or alternately the lift balloon 14 is first deflated and withdrawn (such as by also withdrawing the balloon cannula 13 from the membrane cannula 12) before the cement delivery tube 12 is inserted down into the vertebra for percutaneous injection of the bone cement. In the first of these two embodiments (i.e. when the balloon is not removed), the balloon is made of a material which allows for inflation thereof while nonetheless being sufficiently porous such as to allow the bone cement to permeate through walls of the balloon and out into the remainder of the cavity 18. In the second of these two embodiments (i.e. when the balloon is first withdrawn after having been inflated to form the cavity), the cement delivery tube 44 is simply inserted directly within the membrane cannula. However, in this last case, as the balloon 14 has been removed, this necessitates that the second of the two lift balloons (i.e. the opposite side from the one being removed) within the vertebra is left in place and is sufficient to hold the spread apart sections of the vertebra in position until such time as the cavity created therebetween can be filled with cement.

[0053] In yet another embodiment, the lift balloon will break open in a specified direction by any one of a number of mechanisms which maintaining a substantially impermeable area. For example, these mechanism may include providing the balloon with one or more weak seams, or a rip out section or seam, in designated burst regions

while still having an impermeable non-burst region which will act as the impermeable membrane even after the other regions burst open. Thus, the burst regions will break open when the balloon is filled with cement which still maintaining at least one substantially impermeable area. The open burst areas therefore permit cement flow into the osteotomy cavity.

[0054] The presence of the cement impermeable membrane 16 about the periphery of the cavity 18 allows it to be subsequently filled with bone cement as described, with little risk of any substantial leakage of the bone cement out of the cavity thus enclosed by the impermeable membrane 16. Depending on the location and configuration of the osteotomy cut formed in the vertebra, which will itself depend on the deformity of the bone in question, the position of the membrane 16 may be altered as required in order to best surround and enclose the intravertebral cavity 18 created in the vertebra by the osteotomy, such as to retain the injected bone cement therein. It is also to be understood that the membrane 16 may be provided with any number of suitable configurations, shapes, sizes, materials, etc. and positioned as required by the surgeon in order to best enclose the osteotomy site formed within the vertebral body. The membrane 16 may be hydrophillic and is preferably substantially impermeable to the selected bone cement to be used.

[0055] The membrane 16 may be percutaneously inserted and positioned within the vertebral body in a number of possible manners. For example, these include the embodiments described below, whether by using the inflation of the lift balloon 14 to extend and position the membrane 16 in place, as shown in Figs. 1 and 4, or by deploying the membrane 16 in an alternate manner, such as shown in Figs. 8a – 12b for example. In either case the membrane cannula 12 having the un-deployed membrane 16 on a proximal end thereof is inserted through the outer working cannula 8, before the means for deploying the membrane 16 in place is activated to displace the membrane 16 from its compressed un-deployed shape to its expanded deployed shape.

[0056] The membrane cannula 12 is itself sized such as to be able to fit within a larger working cannula 8. As noted above, once the working cannulae 8 (two are preferably used) are positioned within the vertebral body 7 being repaired, the other components of the present system can be readily inserted into the exact predetermined

position within the vertebral body by simply inserting such components through the working cannulae 8, thereby permitting all of the steps described herein to be performed percutaneously.

[0057] Referring now to Figs. 2-4, one embodiment of the present system is depicted in which the membrane cannula 12 and the balloon cannula 13 are inserted together into the working cannula 8, such that the inflation of the balloon 14 of the balloon cannula 13 can be used to deploy the membrane 16 of the membrane cannula 12. The balloon cannula 13 has a selectively deformable element 14 disposed on a proximal end 15 thereof. The proximal end 15 of the balloon cannula 13, including this selectively deformable element 14 in its un-deployed or compressed shape such that it can fit within the membrane cannula 12, is inserted into the open end of the larger membrane cannula 12. The membrane cannula 12 has a membrane 16 disposed on a proximal end thereof, the membrane 16 being disposed in an un-deployed configuration such that it can pass through the working cannula 8.

[0058] As seen in Fig. 3, when so assembled the balloon and membrane cannulae 13, 12 form a double-cannulae package 11, wherein both the balloon 14 and the membrane 16 are both in their respective un-deployed configurations and disposed one within the other. In this embodiment, the membrane cannula 12 also includes a webbing 17 that surrounds the membrane 16. The webbing 17 acts to position the membrane 16 in place about the balloon 14 when the latter is inserted within the membrane and then inflated within the intravertebral cavity. The webbing 17 helps to restrain the membrane 16 in the desired location, such as about the exterior of the vertebral cavity for example, while the balloon 14 of the balloon cannula 14 inflates.

[0059] As seen in Fig. 4, as the balloon 14 inflates within the webbing 17, the bone cement impermeable membrane 16 is allowed to deploy between the surrounding webbing 17 and the inner inflated balloon 14. The membrane 16 may go from its un-deployed to its deployed position in a variety of manners, whether requiring the balloon to displace it into its deployed position or by having a "shape memory" such that it springs into its extended/deployed position when not restrained. These manners of deployment of the membrane 16 may include, for example, un-rolling, expanding, stretching, springing into a natural position and the like. Additionally, by being able to

insert or retract at least the membrane cannula 12, the exact position of the membrane 16, once deployed, within the cavity formed in the vertebral body can be varied by the surgeon as necessary. An alternate means for deploying the membrane 16 is described below with reference to Figs. 8a-12b. Although the membrane 16 is shown in Fig. 4 as extending transversely across the center of the lift balloon 14, it is to be understood that the cement impermeable membrane 16 may surround as much or as little of the lift balloon as required. For example, the membrane 16 may cover an entire half of the lift balloon, whether it being a lower hemisphere, an upper hemisphere, a proximal hemisphere or a distal hemisphere for example.

[0060] In at least the embodiment shown in Fig. 2-4, the selectively deformable element 14 of the balloon cannula 13 is an inflatable "lift" balloon, however it is to be understood that other alternatives are possible. Regardless, however, the selectively deformable element, or lift balloon, 14 is displaceable between a relaxed, or deflated, configuration as seen in Figs. 2-3 and an enlarged, or inflated, configuration as seen in Fig. 4. In the relaxed configuration, the lift balloon 14 is configured to fit, such as by being compressed, folded, etc. within the inner diameter of the membrane cannula 12, such as to form the combined double-cannula package 11 as seen in Fig. 3.

[0061] The combined package of the membrane cannula 12 having the relaxed selectively deformed element 14 thereon and the balloon cannula 13 therewithin, as seen in Fig. 3, is fed down the length of the working cannula 8. By so doing, the relaxed lift balloon 14 is inserted within a cut formed in the vertebra body by an osteotomy, as will be described in further detail below. Once so positioned in place within the vertebral body, the selectively deformable element 14 is displaced into its enlarged position, as shown in isolation in Fig. 4, such as by inflating the lift balloon 16. By being extended into this enlarged configuration, the vertebral body is spread apart and the osteotomy cut therein is enlarged such as to define a cavity 18 within the vertebral body 7. The balloon, which comprises the selectively deformable element 14, is controlled such as by introducing more or less fluid (such as, but not limited to, air) therein, such as to lift or spread apart the two portions of the vertebral body 7 disposed on opposite sides thereof and thereby expand the cavity 18 within the vertebral body a desired amount. This acts to lift a superior end place of the vertebral body 7 a height necessary to re-establish the natural height of the vertebra 5.

[0062] As noted above, the present method involves the percutaneously performed step of creating an intravertebral osteotomy. This is done after the cannulation of the vertebral body, i.e. after the working cannulae 8 have been installed in place, but prior to the insertion of the membrane and balloon cannulae 12, 13.

[0063] Referring to Figs. 5a-5e, a number of different configurations of cutting elements may be used, such as osteotomes (i.e. a tool used to cut the bone element), in order to be able to perform the osteotomy of the vertebra through the working cannulae 8, that is, percutaneously. Osteotomes of various geometries which can be inserted through the working cannulae 8, can be used such as to create a cleavage plane within the vertebral body 7, such that when the lift balloon(s) 14 are inserted in this cleavage plane and inflated, the cavity 18 within the vertebra is formed thereby re-establishing the full height of the vertebra.

[0064] Figs. 5a and 5b respectively show a straight segmented or hinged osteotome 30 and a straight multi-segmented or double-hinged osteotome 32, both of which are configured to be able to inserted through the working cannulae 8 in order to allow for percutaneous access to the site in the vertebral body that is to be cut. The hinged cutting tip 31 of the osteotomes 30, 32 allows for the osteotomy site 36 to be cut out within the vertebral body 7 of the vertebra 5, as seen in Fig. 6, while nonetheless still being able to be inserted down through the tubular working cannula 8 (when the tip is straightened out) in order for the cutting tip 31 to accurately access the selected intravertebral osteotomy site 36. Figs. 5c and 5d show two other possible osteotome configurations, namely curved osteotomes 34 and 35. Fig. 5e shows a detailed view of the pivoting cutting tip 31 of the multi-segmented osteotome 32, which is controlled via guide cables 37 which run through the interior of the hollow osteotome 32 and are fixed at two laterally spaced apart anchor points 39 on the tip 31. As such, by pulling on one or the other of the two guide cables 37, the pivoting tip 31 will swing back and forth, thereby permitting a cutting plane within the bone to be created. As seen in Fig. 5c, the curved osteotome 34 may also include a segmented tip 31 that pivots/hinges relative to the main curved body 33 of the osteotome. Both of the curved osteotomes 34, 35 are nonetheless receivable within the working cannulae 8, whether by being flexible or simply configured (such as, for example, by having a large-enough radius curve or a sufficiently small cross-section) such as to permit being slid through a straight working

cannula 8. Alternately, of course, the working cannulae 8 may be themselves provided with a curved configuration such as to allow for a similarly curved osteotome to be received therethrough.

[0065] Referring to Fig. 7, in an alternate embodiment, rather than using the above-described osteotomes to create the necessary cut(s) in the vertebra, the cutting element used includes motorized cutting tools, whether operated by the surgeon and/or by an automated robotic system, can similarly be employed in order to form the cut through the vertebral body, thereby permitting the re-establishment of the height of the vertebra using the lift balloons 16 as described above. More particularly, as shown in Fig. 7, a motorized cutting tool 40 is sized and configured to fit within the working cannula 8, such that the motorized cutting tool 40 can be inserted down through the working cannula 8 and into the vertebral body in order to percutaneously form the intravertebral osteotomy (i.e. cut) using the motorized milling tool 40 rather than the manual cutting osteotomes described above. The motorized cutting tool 40 may be a rotating cutting bit, such as a milling tool, including a high-speed burr for example. The milling tool 40 is, in one embodiment, operated by a robotic system 42, such as a 5-axis numerically-controlled robotic system for example. The robotic system may be fully automated, manually controlled by the surgeon or a combination thereof. The surgeon may for example configure the robotic system to displace the milling tool 40 along a predetermined path in space, wherein the milling tool 40 is inserted through the working cannula 8 to a given depth and activated (i.e. rotated at high speed such as to cut through the bone) and deactivated as required to form the cut in the vertebral body. During this process, of course, the surgeon has the control of the robotic system in order to vary the trajectory, position, orientation and/or cutting speed of the system as required. The robotic system 42 which operates the milling tool 40 in conjunction with the surgeon may also be provided with the necessary sensors and control mechanisms to allow the rotating milling tool 40 to cut only through bone material, in order to avoid nerves, blood vessels, etc. which surround the bone of the vertebrae and which are not to be damaged. This may also be done in conjunction with appropriate image guided devices. The robots may serve to actively cut the vertebrae, or may be used passively only to limit the area cut while the surgeon is moving the cutting tool himself. Although the milling tool 40 and robotic system 42 are described above, it is to be understood that a

variety of other motorized, or non motorized, automated and/or robotically controlled cutting tools can be used to carry out the percutaneously osteotomy of the vertebrae as described herein.

[0066] Referring now to Figs. 8a-12b, alternate bone cement impermeable membranes and means for deploying them will now be described. Rather than using the lift balloon 14 and the balloon cannula 13 to expand and deploy the membrane 16 as described above and shown in the embodiment of Figs. 1-4, in the present embodiments of Figs. 8a-12b the membrane 116 is deployed instead by another tube or cannula, acting as the insertion member, that is inserted through the working cannula 8, such as the cement delivery tube 44. The membranes in these embodiments all preferably are elastically deflectable such that they can be rolled or folded up for insertion through the working cannula 8 but nevertheless spring out to their deployed position and shape when released within the cavity such as to provide a stiff yet flexible barrier or “fence”. The membranes used within the present embodiments may be made of any number of cement impermeable elastically deformable and/or shape-memory materials, such as a thin nitinol shape memory alloy, a plastic or a thin biocompatible metal for example.

[0067] Referring to Figs. 8a-9d, a membrane 116 is removably mounted to the proximal end 143 of the cement delivery tube 144 (itself disposed within the outer working cannula 8), such that the cement delivery tube 144 is also used to insert and deploy the membrane 116 within the cavity of the vertebra, prior to the injection of bone cement in the cavity via the same tube 144. When disposed in its fully-extended or deployed position, the membrane 116 is as shown in Figs. 8a-8c. Although other shapes and configurations are possible, the membrane 116 forms a generally L-shaped configuration when disposed in the fully-extended or deployed position, thereby permitting it to at least partially enclose two sides of the cavity formed in the vertebral body. In order to be inserted down through the working cannula 8 before being deployed within the intravertebral cavity, the membrane must still be able to be rolled-up or otherwise compressed (i.e. disposed in an un-deployed or delivery configuration) such as to fit within the working cannula 8. Therefore, the flexible membrane 116 removably attached to the end of the bone cement delivery tube 144 is first rolled up and inserted within the outer working cannula 8, and the cement delivery tube is inserted down through the working cannula as shown in Figs. 9a-9b. Once the

membrane 116 is no longer confined within the working cannula 8, that is once it reaches the cavity in the vertebral, the membrane will spring freely out into its fully extended deployed position as shown in Fig. 8a. Once the surgeon has manipulated the cement delivery tube 144 such as to locate the now-extended membrane 116 in a desired location enclosing the cavity, the membrane 116 is preferably, but not necessarily, detached from the proximal end 143 of the cement delivery tube 144. The cement delivery tube 144 is then already in place to being the injection of the bone cement into the vertebral cavity. Although a number of possible release mechanisms can be used to detach the membrane 116 from the tube 144, in at least the embodiment of Figs. 8a-9d, one or more severable fasteners in the form of plastic rivets 146 are used to releasably fasten the membrane to the cement delivery tube. These rivets 146 are configured to fasten the membrane 116 to the delivery tube 144 until such time as they are severed or otherwise broken to disconnect the two components from each other. For example, this can be accomplished by using a plunger 148 which is inserted in a proximal direction 147 down through the cement delivery tube 144 and is used to forcibly contact the rivets 146, which project out into the internal space within the hollow delivery tube 144, thereby snapping off the rivets 146 and thus releasing the membrane 116. Other release mechanisms are of course also possible, and may even simply include the manual manipulation of the tube by the surgeon such as to break the rivets 146, which can be pre-weakened as required, thereby releasing the membrane 116 from the delivery tube 144.

[0068] Figs. 10 and 11 depict alternately shaped membranes 216 and 316 respectively, which are similar to the membrane 116, however the membranes 216 and 316 are configured/shaped specifically for enclosing the osteotomy cavities formed in vertebrae having anterior and lateral defects respectively. While other shapes and configurations are possible, these membranes include, for example, an enlarged barrier portion at a point thereon which is to be aligned with a targeted defect or other larger gap in the cavity. The enlarged barrier portion having a surface area that is greater than the central body portion of the membrane. The membrane 216 has an enlarged remote end region 217, adapted to cover the anterior vertebral defect and located on the end of the membrane opposite that removably fastened to the cement delivery tube, which is shaped to enclose the larger anterior cavity opening. The membrane 216 also includes

an additional feature, namely at least one cement window 218 through which a small and controlled amount of bone cement is allowed to flow. The membrane 316 is shaped for best use in lateral defect vertebra, and includes an enlarged central region 317 adapted to cover the lateral vertebral defect and a thinner stability tail 318 which helps to anchor the membrane in place.

[0069] Referring to Figs. 12a-12b, another alternative means for deploying the cement impermeable membrane is disclosed. Namely, in the present embodiment the cement impermeable membrane 416 is made up of a central flexible metal “backbone” 417 that is elastically deformable yet rigid and which is incorporated within a larger flexible tubular envelope 418. This composite membrane structure acts like a “bursting sausage”, wherein the tubular envelope 418 is fully enclosed (i.e. has a closed end) as shown in Fig. 12a, such that when it is filled with bone cement via the cement delivery tube 448, the tubular envelope 418 will fill up until the pressure therein is sufficiently high to cause the flexible tubular envelope to burst. Once this occurs, the more rigid backbone portion 417 is allowed to spring open to assume its deployed position, as shown in Fig. 12b. The flexible envelope may be made of a plastic or other suitable material, and may further be scored along a breach line 419, such that the plastic tubular envelope will be more likely to break or burst along this line when the pressure of the bone cement injected therein rises. This permits both a controlled burst and a predetermined amount of pressure to be established at which the tube is to break, thereby deploying the entire membrane structure 416 early enough for it to assume the desired position in order to close off the osteotomy cavity while nonetheless being actuated by the initiation of the bone cement injection.

[0070] In a normal procedure, the surgeon will insert the disclosed device 10 in a percutaneous access consisting of working cannula extending through the pedicles of vertebral bodies. Osteotomes of various geometries may be inserted through the working cannulae and into the vertebrae, so as to create the cleavage plane within the vertebral body.

[0071] The lift balloons 14 are then inserted between the vertebra adjacent the fractured site. When the devices 10 is located in the proper position, as shown in FIG. 4, the balloons 14 are inflated to expand the fractured vertebra 16. Thus, once the devices

10 are in place, the balloons 14 are then inflated simultaneously to open the osteotomy. The membranes 16 are then placed in the first position partially enclosing the cavity. Guide threads or webbing 17 are used to maintain the membrane 16 in place over the balloon 14.

[0072] Once the balloons 14 have been inflated, one balloon 14 is removed and the impermeable membrane is left behind. Cement is then injected into the cavity 18 through the membrane cannula 12 when the balloon 14 has been removed, and then allowed to cure. The membrane acts to help retain the cement within the cavity of the vertebra. The second balloon 14 is left inflated to maintain open the osteotomy.

[0073] The second balloon 14 is then removed and the cavity 18 left behind is then also filled with cement. Once the bone cement has cured, the osteotomies are secure, and the working cannula can then be removed, and the stab wounds can be closed.

[0074] Preferably, the membranes and osteotomy cavities are filled with in-situ curing PMMA. Bioactive "cements" such as calcium phosphate, hydroxyapatite, carbonated apatite cement, and glass-ceramic powders could be used rather than PMMA. Other bio-compatible in-situ curing materials may be used such as polyurethane, hydrogel, or bioactive glues. Resorbable cements of any type can also be used.

[0075] Furthermore, in one particular embodiment shown in Figs. 13a-13b, the balloons 114 may be formed with rigid side walls 115 (i.e. more rigid than the upper and lower walls 116 of the balloon), thereby substantially limiting the balloon deployment to the vertical direction (such as when performing an osteotomy expansion) by substantially limiting expansion in the lateral directions as a result of the more rigid lateral side walls of the balloon. As seen in Fig. 13a, when the balloon 114 is in a deflated position, such as to be inserted through the working cannula 8 for example, the more flexible top and bottom walls 116 thereof are compressed, while the side walls 115 substantially retain their shape given their more rigid structure. When in the inflated position, as shown in Fig. 13b, the more flexible top and bottom walls 116 expand upwards and downwards, while the more rigid side walls 115 maintain their shape and limit lateral expansion of the balloon. Although not depicted, it is also possible to provide a balloon which is configured such as to have one or more different

wall portions that is more rigid than the remaining walls, such as to control, as desired, the inflation of the balloon.

[0076] Referring back to Figs. 1a-1c, the membrane 16, once deployed in the desired position corresponding to the extended position, will substantially block the lateral egress of the cement. The membrane is impermeable to cement and may be made of thin nitinol shape memory alloy, plastic or thin biocompatible metal for example. The membrane 16 can be initially attached to one end of the device 10 by means such as rivets which can be used to retain the membrane in place until the cement is injected. Following the injection of the cement, the rivets are removed before the cement is hardened. Other means of attaching the membrane 16 to the device known in the art can also be used. Such means can include breakable joints for example.

[0077] The device 10 may be made from a material that expands. The device could be made of bio-resorbable materials including polylactic acid (PLA), polyglycolic acid (PGA), poly (ortho esters), poly (glycolide-co-trimethylene carbonate), poly-L-lactide-co-6-caprolactone, polyanhydrides, poly-n-dioxanone, and poly (PHB-hydroxyvaleric acid). It may also be constructed to allow more expansion of the device in a cranial to caudal direction than in a radial direction. The device may also be made of elastic or inelastic materials. The device is may, in one particular embodiment, be made of polymers.

[0078] The disclosed methodology requires the creation of an osteotomy that will permit fractured vertebrae to have a correction of their deformity. Blood loss would be minimal. The disclosed methodology is also an advance over conventional open surgical techniques that require major surgical incisions, large amounts of muscle dissection, major blood loss and is associated with high mortality and morbidity.

[0079] The advantage of the use of the disclosed device is that it would permit correction of all (100%) vertebral fractures and not just 50% of the fractures as has been demonstrated for kyphoplasty. Even healed fractures could be treated. In addition, lateral deviations of the spine could be treated, particularly those due to fracture. Metastatic tumors not previously amenable to kyphoplasty or vertebroplasty would now be amenable to percutaneous treatment. Scoliotic deformities could also be treated with this the present device in a percutaneous fashion.

[0080] The present device and methodology permit correction of both kyphotic and scoliotic deformities through minimally invasive, percutaneous techniques. Fusion is not required, so each vertebra is still permitted to articulate normally with adjacent vertebrae, in no way limiting overall spine motion. Vertebral levels adjacent to long fusions are subject to increased stresses and are at increased risk for fracture, hardware failure and disc degeneration. All of these events lead to further surgery. These risks do not exist with the described device and methodology that does not fuse vertebrae together. The minor surgical incisions mean that this type of surgery can be carried out in a greater proportion of patients presenting with spinal deformity. Patients previously considered too old or having too many co morbidities will now be eligible for surgery. Since the surgery is percutaneous and fusion of vertebrae is no longer required, rehab will be very rapid. Patients should be able to go back to their regular activities within days of having the surgery. Convalescence from the existing deformity surgery is on the order of 3-9 months depending on patient and required activities.

[0081] Accordingly, when using the presently described system, a percutaneously performed method of restoring vertebral body height by vertebral osteotomy includes the steps of: cannulating the vertebra with at least one working cannula inserted into the vertebral body; percutaneously cutting a cleavage plane in the vertebral body, using a cutting tool inserted through the working cannula; inserting a membrane cannula, having a selectively deformable element attached at an extremity thereof, into the working cannula, the selectively deformable element including a cement-impermeable membrane releasably attached thereto; inflating the selectively deformable element to expand the vertebral body thereby restoring a height of the vertebral body and forming an open-sided cavity therein; placing the cement-impermeable membrane in a position such that it at least partially encloses the cavity; and injecting cement through the working cannula into the cavity in the vertebral body. When two selectively deformable elements are used, i.e. through two separate working cannulae, one may be first removed before the cement is injected through the same working cannula.

[0082] Referring to Fig. 14, in accordance with another embodiment, a lift balloon 214 is used that is selectively permeable, in that the permeability of the balloon changes and can be controlled as desired. This is accomplished by making the balloon out of a material whose permeability varies in response to either a direct electric current or

temperature. For example, the balloon 214 may include an electric element 220 that is embedded therein and which is electrically connected to a power source such as to provide a selectively controlled electric current flow through the electric element 220 in the balloon wall. The electric element 220 may act as a heating element which increases the local temperature of the balloon 214 when the heating element is fed with current, thereby, for example, increasing the permeability of the balloon in these higher temperature areas. Alternately, the material of the balloon 214 may be such that when exposed to a current flow through the electric element 220, whether or not any temperature change occurs, the permeability of the balloon surrounding the electric element is varied as desired such as to increase or decrease the local permeability thereof. As such, using the balloon 214 of this embodiment, the permeability of the balloon is varied as desired by controlling the amount of electric current flowing through the electric element 220 embedded therein. Several advantages exist with this embodiment, such as being able to accurately control, and vary, both the quantity and direction of bone cement flow out of the inflated balloon 214, thereby allowing for controlled release of bone cement into certain specific regions within the vertebral body, as desired in order to be suit a given patient bone geometry and the requirements of each patient.

[0083] Referring to Figs. 15a-15b, an alternate embodiment is depicted in which one or more additional trocars 208 are used to open up the osteotomy site, either in lieu of or in addition to the lift balloons described above, such as to create the cavity 18 within the vertebral body. Trocars 208 may be inserted, percutaneously, into either the vertebra 5 in which the osteotomy has been created, for example above or below the osteotomy site, or alternately into an adjacent vertebra 6. Once in place, a movement of the exposed ends of the trocars 208 towards the exposed ends of the working cannulae 8 in opposed directions 210 will cause the lateral cut plane of the osteotomy within the vertebra 5 to move away from each other thereby forming the cavity 18 therebetween, as shown in Fig. 15b. Accordingly, angulation of the trocars 208 relative to the working cannulae 8 will allow the osteotomy to open up, thereby substantially restoring the original height and/or shape of the vertebra. The membranes 16 may then be positioned within this vertebral cavity 18 in a manner to best enclose the open side(s) of the cavity for retention of the bone cement to be injected therein.

[0084] While the use of the additional trocars 208 may be used without the lift balloons to open up the osteotomy cut within the vertebra, balloons can also be used in conjunction with the trocars 208, for example to maintain a portion of the vertebra in the opened position until such time as the cavity formed thereby can be filled with cement. The trocars 208 and the cannulae 8 may also be identical, and can include a slot at an inner end thereof for deployment of the balloons therefrom.

[0085] While the invention has been described in connection with specific embodiments thereof, it will be understood that it is capable of further modifications and this application is intended to cover any variations, uses, or adaptations of the invention following, in general, the principles of the invention and including such departures from the present disclosure as come within known or customary practice within the art to which the invention pertains and as may be applied to the essential features hereinbefore set forth, and as follows in the scope of the appended claims.

CLAIMS:

1. A device for percutaneously forming an osteotomy cavity within a vertebral body, comprising:

a working cannula having a passage extending therethrough from a proximal end thereof adapted to protrude beyond a skin surface to a distal end thereof adapted to be inserted within the vertebral body; and

a membrane releasably attached to a distal end of an insertion member received within the cannula such as to direct the membrane to the distal end of the cannula and into the osteotomy cavity formed within the vertebral body, said membrane being at least partially cement-impermeable and displaceable between a contracted first position, wherein the membrane is configured to fit through the passage of the cannula and into the cavity, and an extended second position, wherein the membrane extends to at least partially enclose the osteotomy cavity and to thereby limit egress of bone cement out of the cavity within the vertebral body.

2. The device as defined in claim 1, wherein the insertion member includes a selectively deformable element, the selectively deformable element being displaceable between a relaxed configuration, wherein the selectively deformable element is sized to be fed through the passage of the cannula, and an enlarged configuration, wherein the selectively deformable element expands to open the cavity within said vertebral body thereby restoring the height of the vertebral body.

3. The device as defined in claim 2, wherein the membrane is engaged with the selectively deformable element.

4. The device as defined in claim 2, wherein the expansion of the selectively deformable element from the relaxed configuration to the enlarged configuration acts to displace the cement-impermeable membrane from the contracted first position to the extended second position such as to position the cement-impermeable membrane within the cavity.

5. The device as defined in claim 2, wherein the membrane comprises at least one of a semi-permeable membrane, a fully impermeable membrane, and a compound membrane including both permeable and impermeable portions.
6. The device as defined in claim 2, wherein the selectively deformable element is an inflatable balloon and the insertion member includes a balloon cannula having a distal end to which the inflatable balloon is fixed and a membrane cannula to which the membrane is releasably attached, the membrane cannula being received within the balloon cannula, and the balloon cannula being received within the working cannula, wherein the membrane and balloon cannulae are insertable together within the working cannula such as to position both the inflatable balloon and the membrane within the cavity.
7. The device as defined in claim 2, wherein a webbing is releasably attached to the distal end of the insertion member, the webbing surrounding the membrane and retaining the membrane in position relative to the selectively deformable element while the selectively deformable element is expanded into the enlarged configuration thereof and the membrane is displaced into the extended second position thereof.
8. The device as defined in claim 1, wherein the insertion member includes a tube having the membrane releasably attached to a distal end thereof, the tube being received within the working cannula and operable for insertion and deployment of the membrane within the cavity.
9. The device as defined in claim 8, wherein the tube is a bone cement delivery tube, the tube being operable to insert and deploy the membrane within the cavity prior to delivery of the bone cement to the vertebral body.
10. The device as defined in any one of claims 1 to 9, further comprising a cutting element sized to be received within the working cannula and inserted in the proximal end of the working cannula and displaced therethrough such that a cutting tip of the cutting element is disposed within the vertebral body, the cutting tip of the cutting element being displaceable within the vertebral body to percutaneously create a cleavage plane cut in the vertebral body.

11. The device as defined in claim 10, wherein the cutting element includes one of a manually operated osteotome and a motorized cutting tool.
12. The device as defined in claim 11, wherein the manually operated osteotome includes an elongated body, the cutting tip being hingedly connected to a distal end of the elongated body to permit pivotable movement of the cutting tip.
13. The device as defined in claim 1, wherein the membrane is biased such as to be elastically deflectable into the extended second position where the membrane is not restrained by the working cannula, such that the membrane is deployed by spring action within vertebral body to at least partially enclose the osteotomy cavity.
14. The device as defined in claim 13, wherein the membrane is made of a shape-memory material.
15. The device as defined in claim 14, wherein the membrane is comprised of at least one of a nitinol shape memory alloy, a plastic and a thin biocompatible metal.
16. The device as defined in claim 1, wherein the membrane has an enlarged barrier portion with a greater surface area than a central body portion thereof, the enlarged barrier portion being adapted to be aligned with and cover a targeted defect or opening in the cavity.
17. The device as defined in claim 1, wherein the membrane defines a generally L-shaped configuration, such as to at least partially enclose two sides of the cavity within the vertebral body.
18. The device as defined in claim 8, wherein the membrane is releasably attached to a distal end of the tube of the insertion member by a severable fastener.
19. A percutaneous method to increase vertebral body height of a damaged vertebra, comprising the steps of:
 - cannulating the vertebra with at least one working cannula inserted into the vertebral body;

percutaneously cutting a cleavage plane between portions of the vertebral body using a cutting tool inserted through the working cannula, such as to percutaneously create an intravertebral osteotomy;

separating the portions of the vertebral body to form an open sided cavity therein, thereby increasing the vertebral body height;

inserting a first membrane cannula within the working cannula, said first membrane cannula having a first membrane attached at an extremity of the membrane cannula inserted into the vertebral body, the first membrane being substantially impermeable to a hardening material used to reinforce the vertebral body;

positioning the first membrane in a first position within said cavity wherein the membrane partially encloses a first open side of said cavity; and

injecting the hardening material through the first working cannula into the cavity.

20. The method as defined in claim 19, wherein the step of separating further comprises providing a first selectively deformable element, positioning the first selectively deformable element within the cleavage plane created in the vertebral body, and expanding the first selectively deformable element to increase the size thereof thereby separating the portions of the vertebral body to form said cavity and at least partially restoring the vertebral body height of the vertebra.

21. The method as defined in claim 20, wherein the selectively deformable element includes a balloon, the step of expanding comprising inflating the balloon.

22. The method as defined in claim 21, further comprising inserting a balloon cannula within the working cannula, the balloon cannula having the inflatable balloon at a distal end thereof and disposed in a non-inflated position for insertion within the working cannula and into the cleavage plane of the vertebral body.

23. The method of claim 22, further comprising, prior to inserting the first membrane cannula within the working cannula, mating the first membrane cannula and the balloon cannula such that the first membrane is disposed about the un-inflated balloon,

and wherein the step of inflating the balloon acts to position the first membrane in said first position within said cavity of the vertebral body.

24. The method as defined in claim 19, wherein the first membrane is releasably attached to the extremity of the membrane cannula.

25. The method as defined in claim 20, wherein the first membrane is attached to the first selectively deformable element and is integrally formed therewith, the step of position the first membrane comprising the step of expanding the selectively deformable element to deploying the first membrane attached therewith into the first position within the cavity.

26. The method as defined in claim 20, further comprising deflating the first selectively deformable element prior to the step of injecting the hardening material.

27. The method as defined in claim 19, further comprising inserting a second working cannula into the vertebral body, inserting a second membrane cannula into the second working cannula, the second membrane cannula having a second membrane attached thereto, the second membrane being substantially impermeable to the hardening material, and positioning the second membrane in a second position within said cavity to enclose a second open side of said cavity, the first and second membranes thereby enclosing a majority of said open sided cavity.

28. The method as defined in claim 27, further comprising providing a second selectively deformable element, positioning the second selectively deformable element within the cleavage plane on a transverse side opposite to the first selectively deformable element, and expanding the second selectively deformable element to increase the height of the vertebral body on at least said transverse side.

29. The method as defined in claim 28, further comprising angularly adjusting the vertebral body and the configuration of the cavity formed therein by independently inflating the second selectively deformable element relative to the first selectively deformable element.

30. The method as defined in claim 28, wherein the second membrane is releasably attached to the second selectively deformable element, further comprising independently releasing the second cement impermeable membrane within said vertebral body once the second selectively deformable element has been deflated.
31. The method as defined in claim 19, wherein the step of percutaneously cutting includes using an osteotome configured for being received through the working cannulae.
32. The method as defined in claim 19, wherein the step of percutaneously cutting includes using a motorized cutting tool controlled by a robotic system, the milling tool being configured for being received within the working cannulae.
33. The method as defined in claim 19, further comprising providing the first membrane with at least one of a semi-permeable membrane portion, a fully impermeable membrane portion, and a compound membrane portion including both permeable and impermeable regions.
34. The method as defined in claim 33, wherein the step of providing the first membrane further comprises providing at least one of a fully deformable membrane and a partially deformable membrane having selected portions thereof more rigid than others.
35. The method as defined in claim 19, further comprising altering a permeability of the first membrane.
36. The method as defined in claim 35, further comprising removing portions of the first membrane such as to increase the permeability of the first membrane in a predetermined direction corresponding to a location and orientation of the removed portions of the membrane.
37. The method as defined in claim 20, further comprising passing an electric current through regions of at least one of said first membrane and said first deformable element, the electric current locally varying a permeability of the at least one of said first membrane and said first deformable element in said regions.

38. The method as defined in claim 37, further comprising passing the electric current through the first deformable element in regions thereof located outside the first membrane.

39. The method as defined in claim 19, wherein the step of separating the portions of the vertebral body to form the open sided cavity further comprises inserting at least one trocar into one of an adjacent vertebra and the vertebral body at a location spaced apart from said working cannula, and bringing remote proximal ends of the trocar and the working cannula together to separate the portions of the vertebral body apart from each other.

40. The method as defined in claim 39, further comprising varying the size of the cavity and thus the height of the vertebral body by varying the relative angulation of the trocar and the working cannula.

41. A percutaneous method to restore vertebral body height by vertebral osteotomy comprising the steps of:

- cannulating the vertebra with a first and a second working cannula inserted into the vertebral body;

- percutaneously cutting a cleavage plane in the vertebral body using a cutting tool inserted through at least one of the first and second working cannula;

- inserting a first deformable element through the first working cannula and a second deformable element in the second working cannula, the deformable elements permitting the perforation thereof in at least one region thereof;

- placing the first and second deformable elements in respective predetermined orientations;

- inflating the first and second deformable elements using a filler fluid injected therein to form an open-sided cavity within the vertebral body and thereby restore a height of the vertebral body;

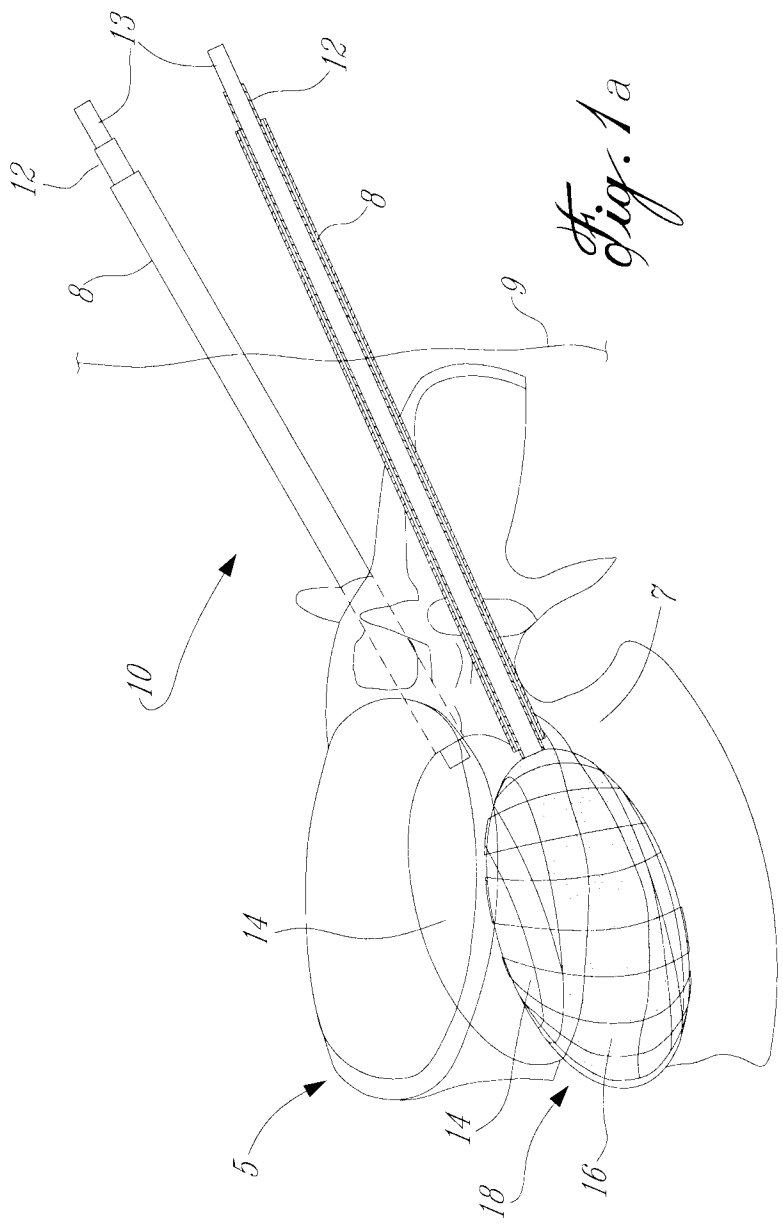
- removing the filler fluid from the first deformable element, while ensuring that the second deformable element remains in the predetermined orientation, and injecting cement through the first working cannula into the first deformable element, thereby inflating the first deformable element a second time;

perforating the first deformable element to increase the permeability thereof in at least one preferred direction, and extruding the cement contained within the first deformable element into the cavity;

removing the filler fluid from the second selectively deformable element while ensuring that the second selectively deformable element remains in the predetermined orientation, and injecting cement through the second working cannula into the second deformable element, thereby inflating the second deformable element a second time; and

perforating the second deformable element thereby increasing the permeability thereof in at least one preferred direction, and extruding cement contained within the second deformable element into the cavity;

wherein non-perforated regions of the first and second deformable elements are substantially impermeable to the cement to thereby at least partially enclose said cavity and contain the cement therewithin.



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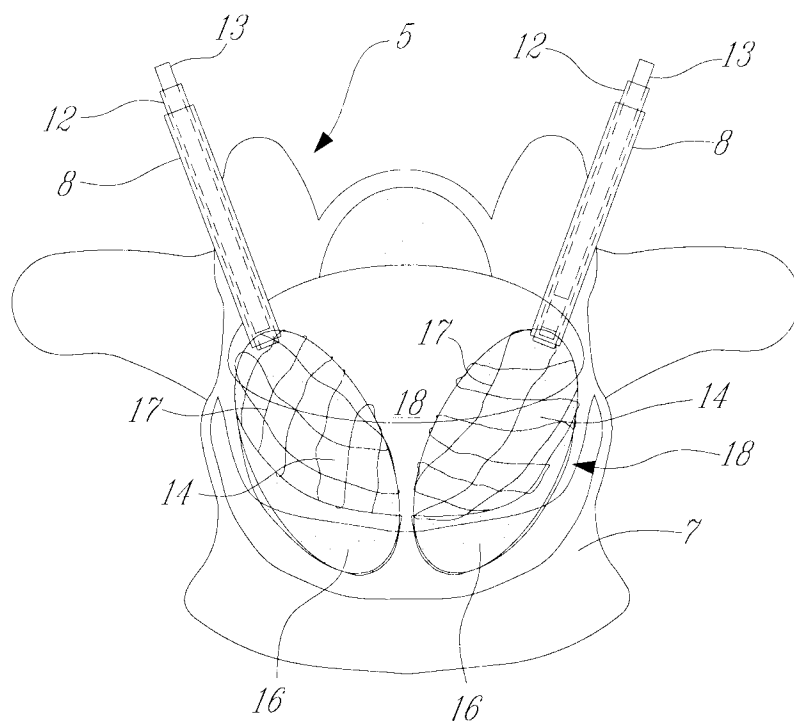
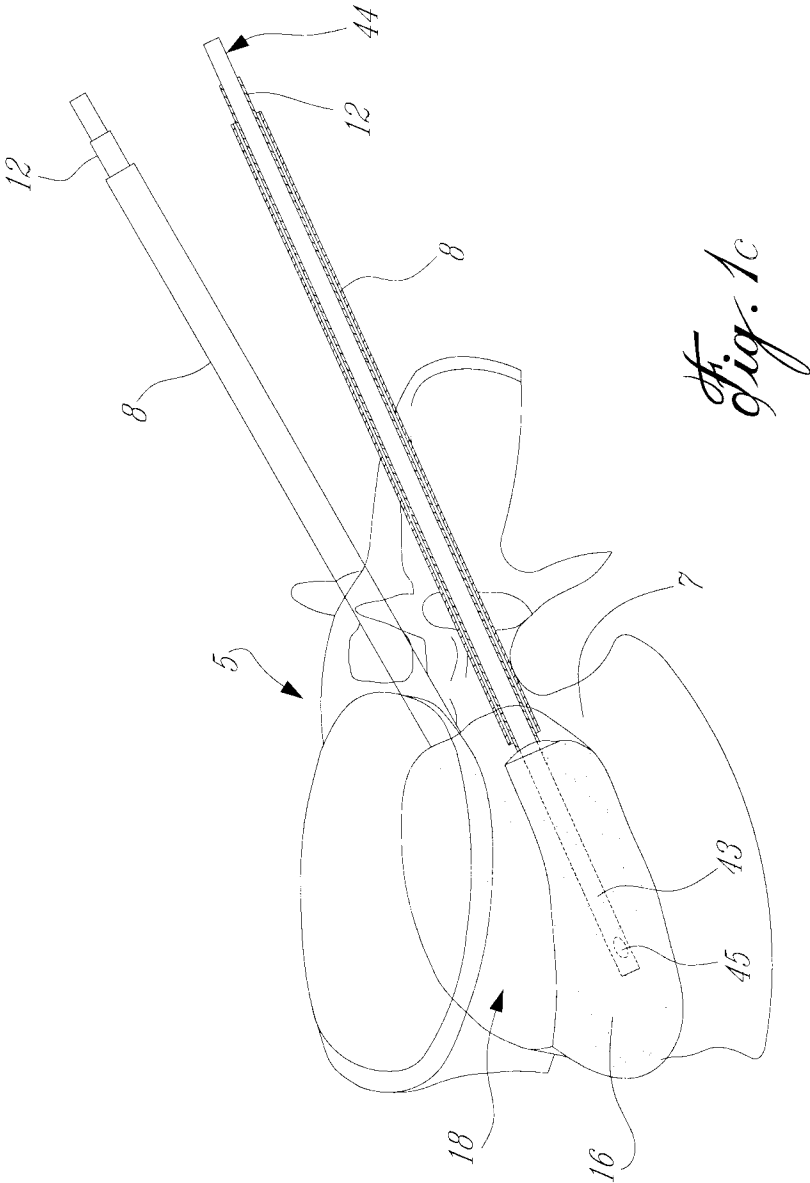
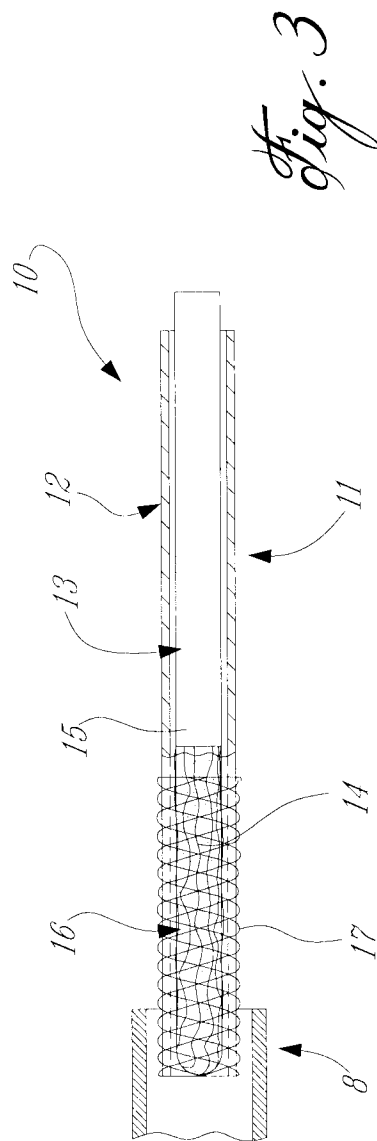
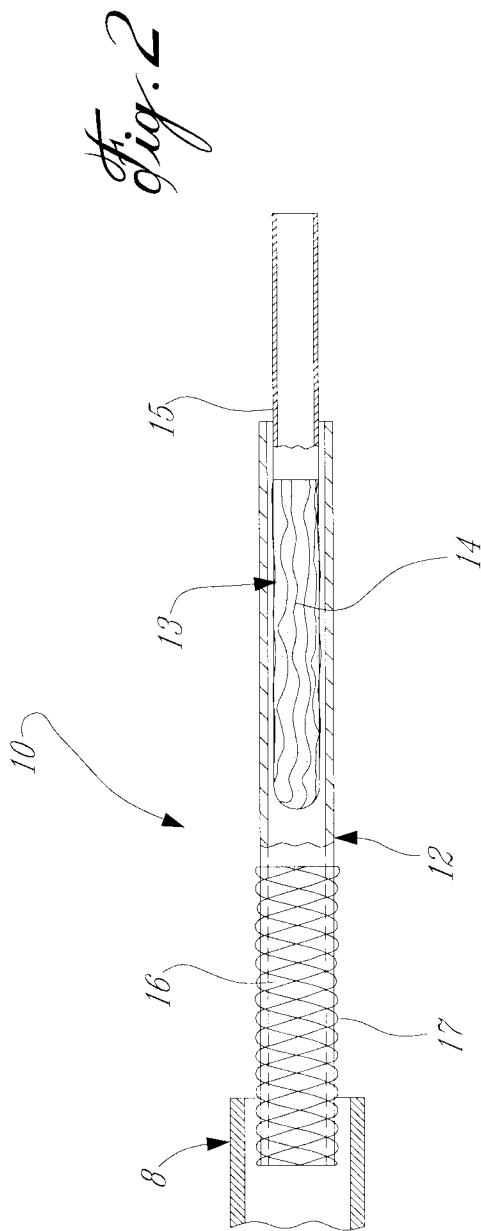


Fig. 1b





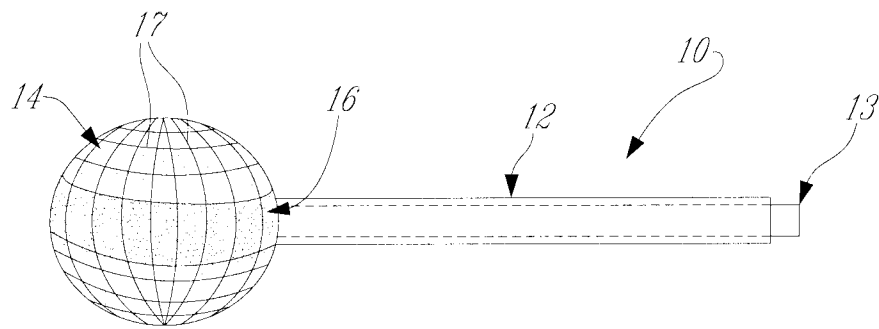


Fig. 4

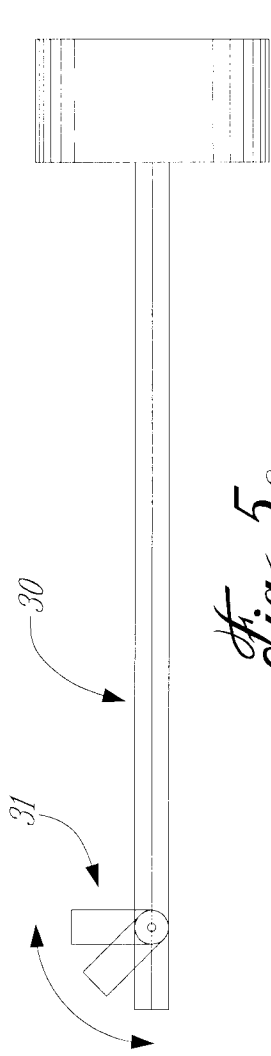


Fig. 5a

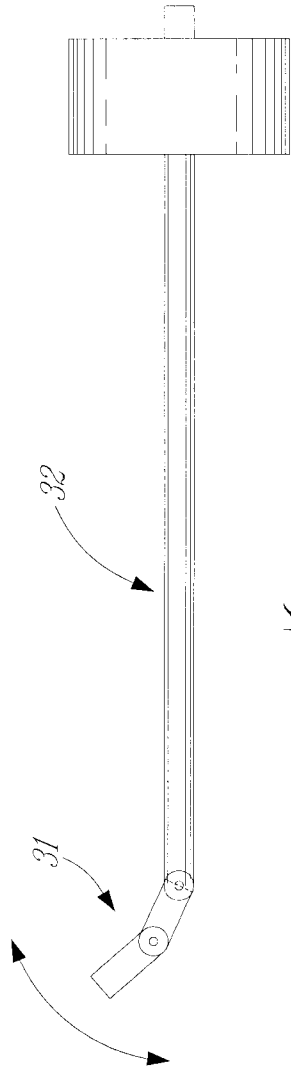


Fig. 5b

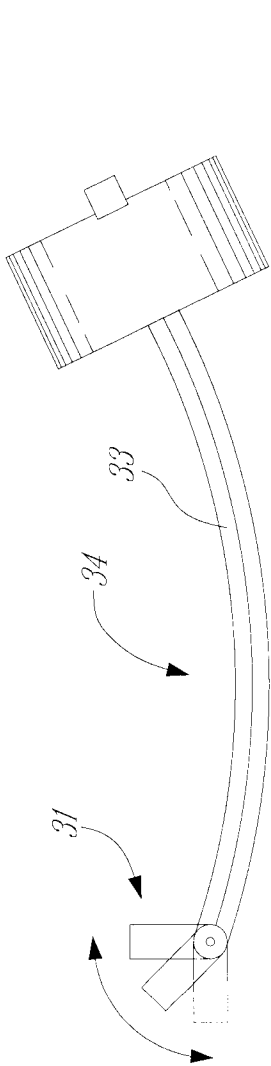


Fig. 5c



Fig. 5d

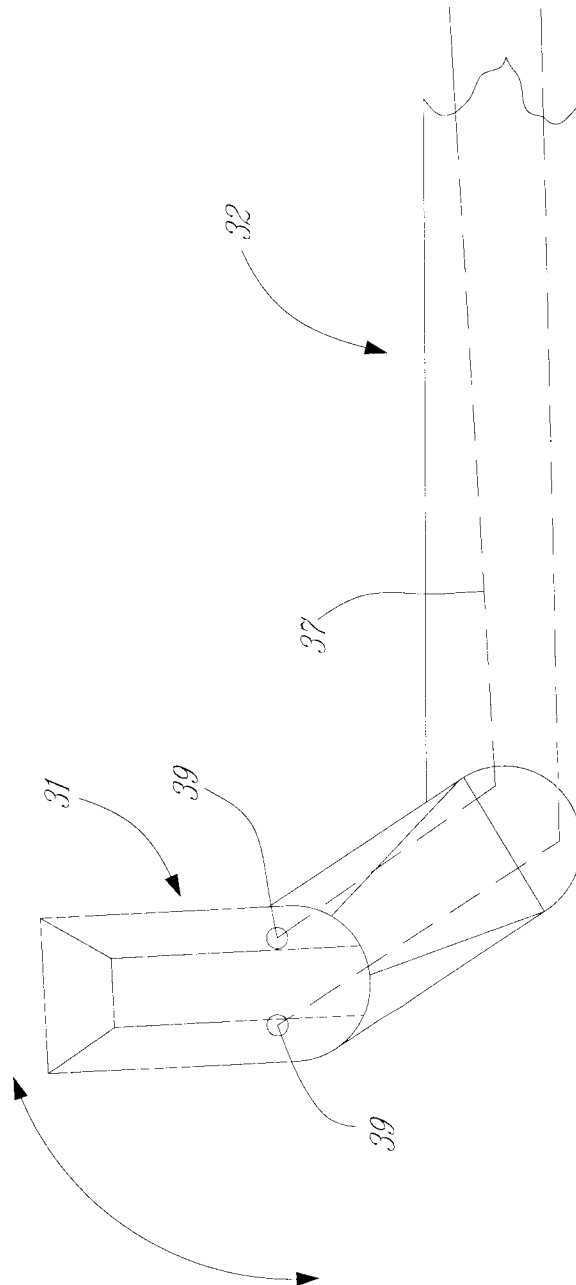


Fig. 5e

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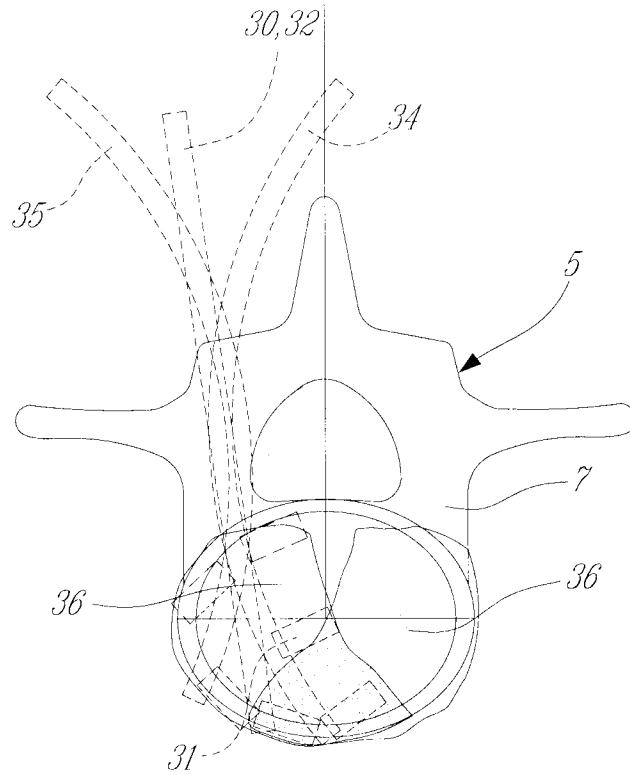
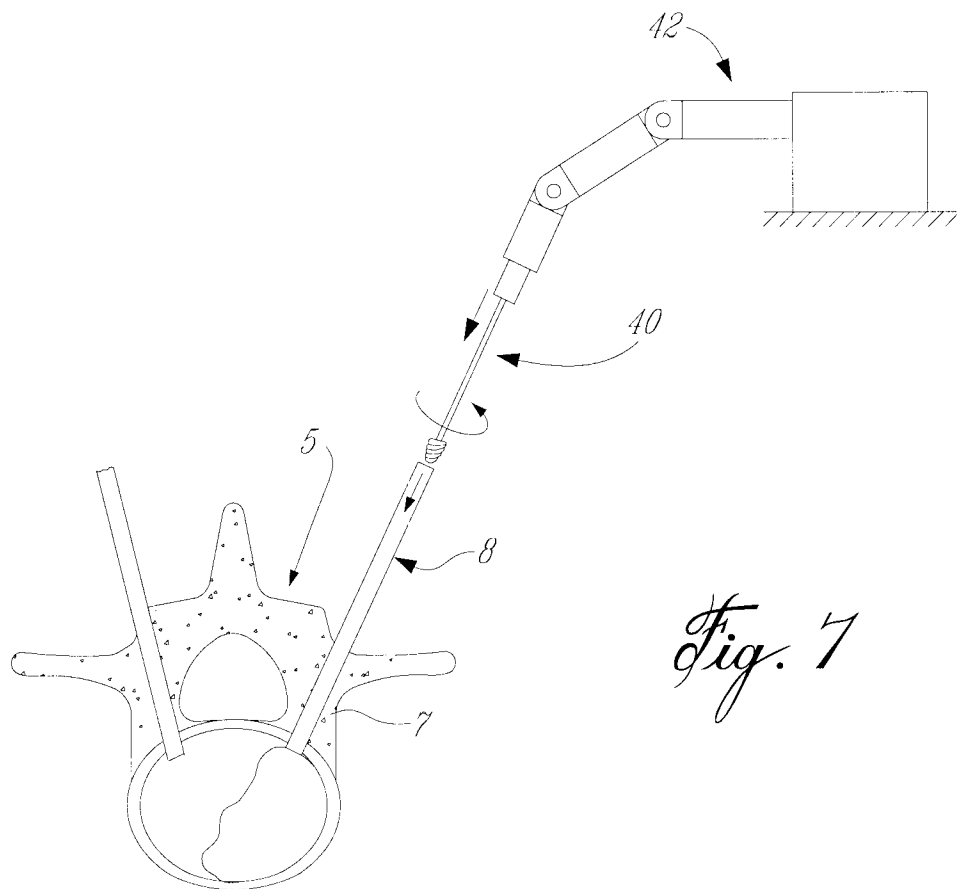
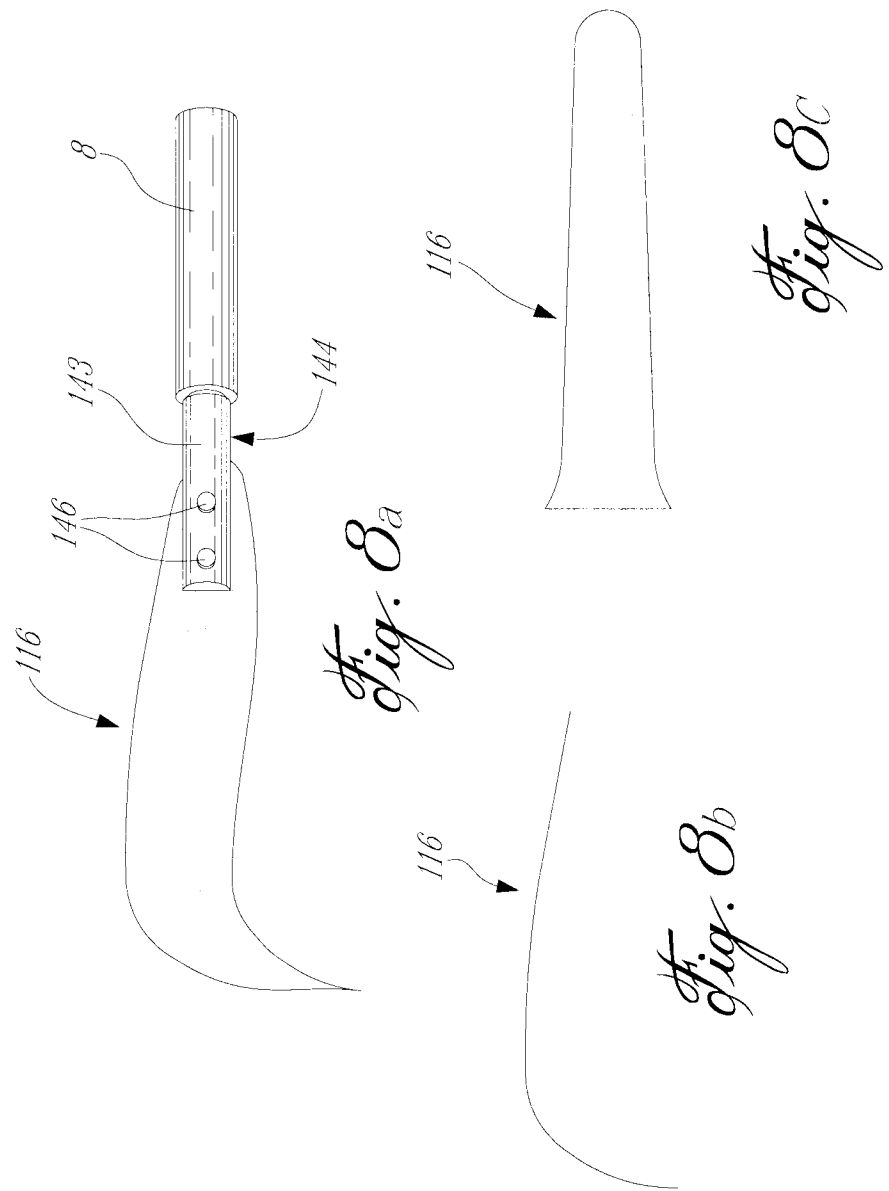


Fig. 6





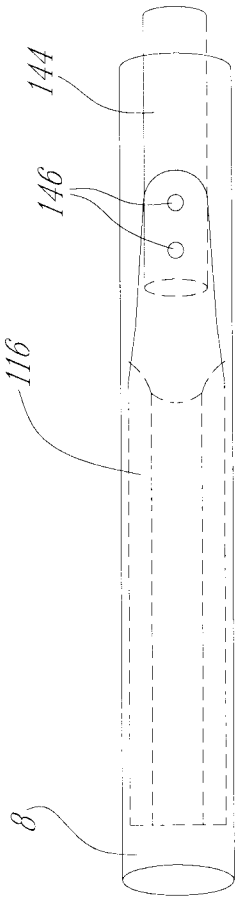


Fig. 9a

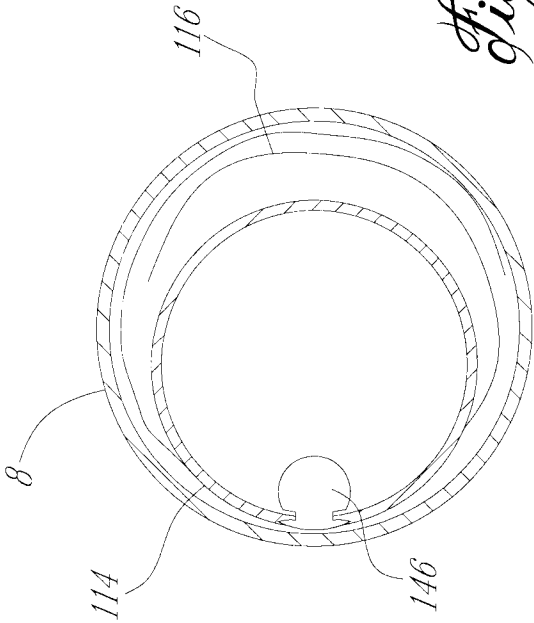


Fig. 9b

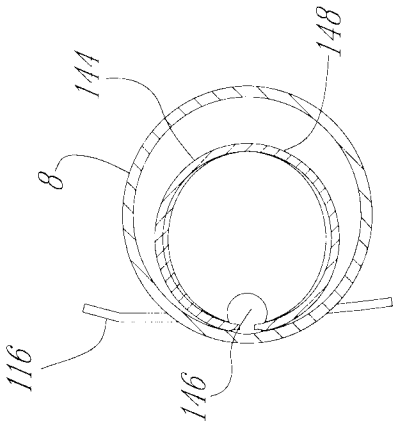


Fig. 9c

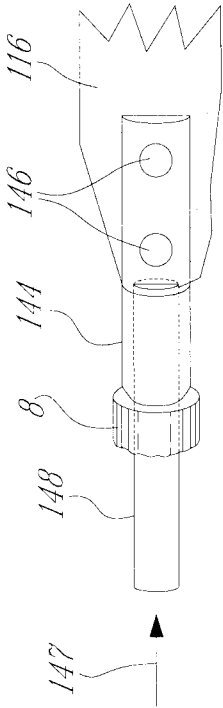
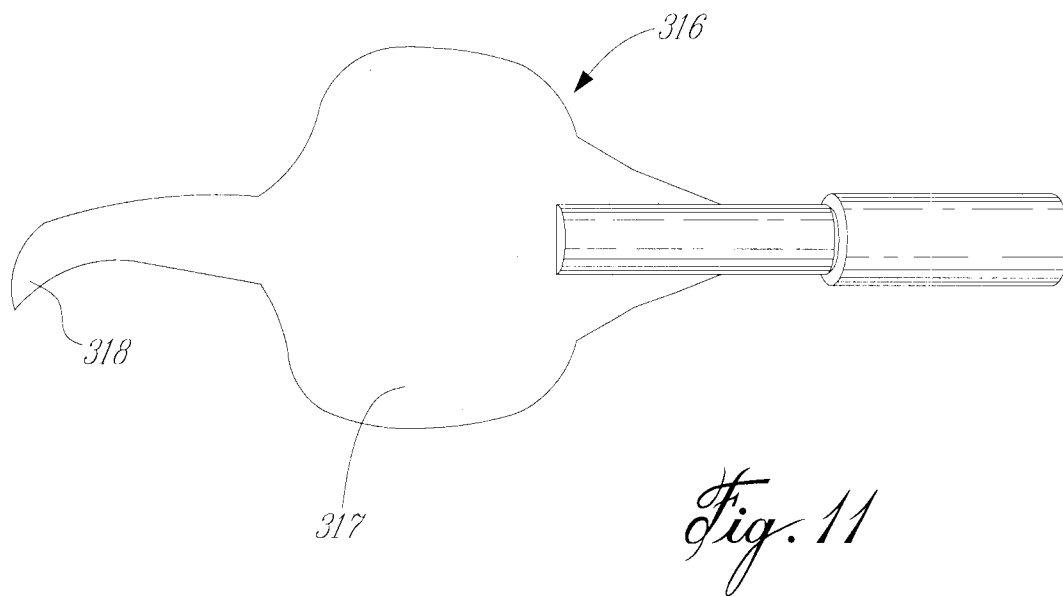
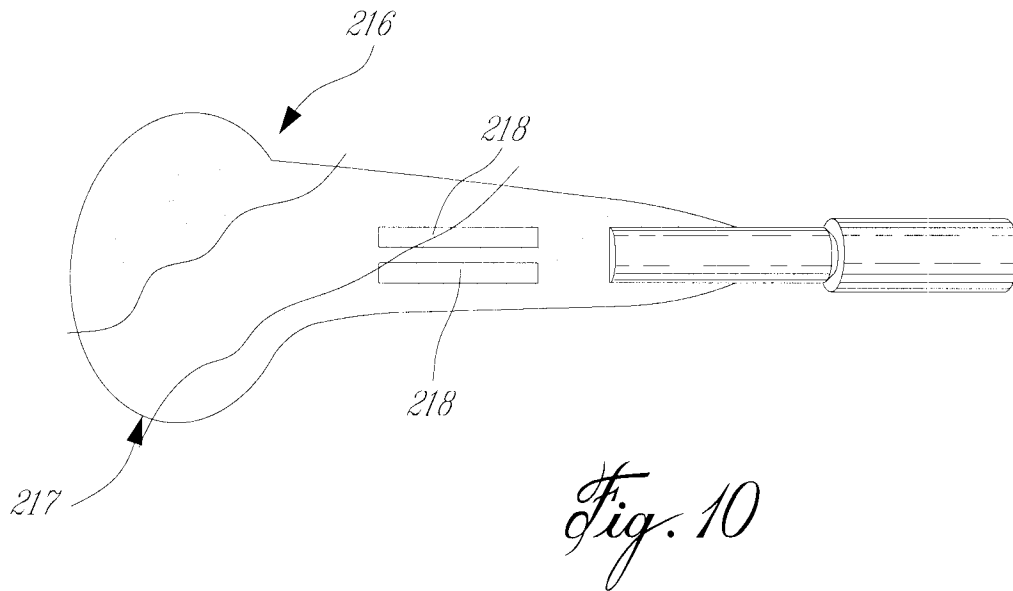
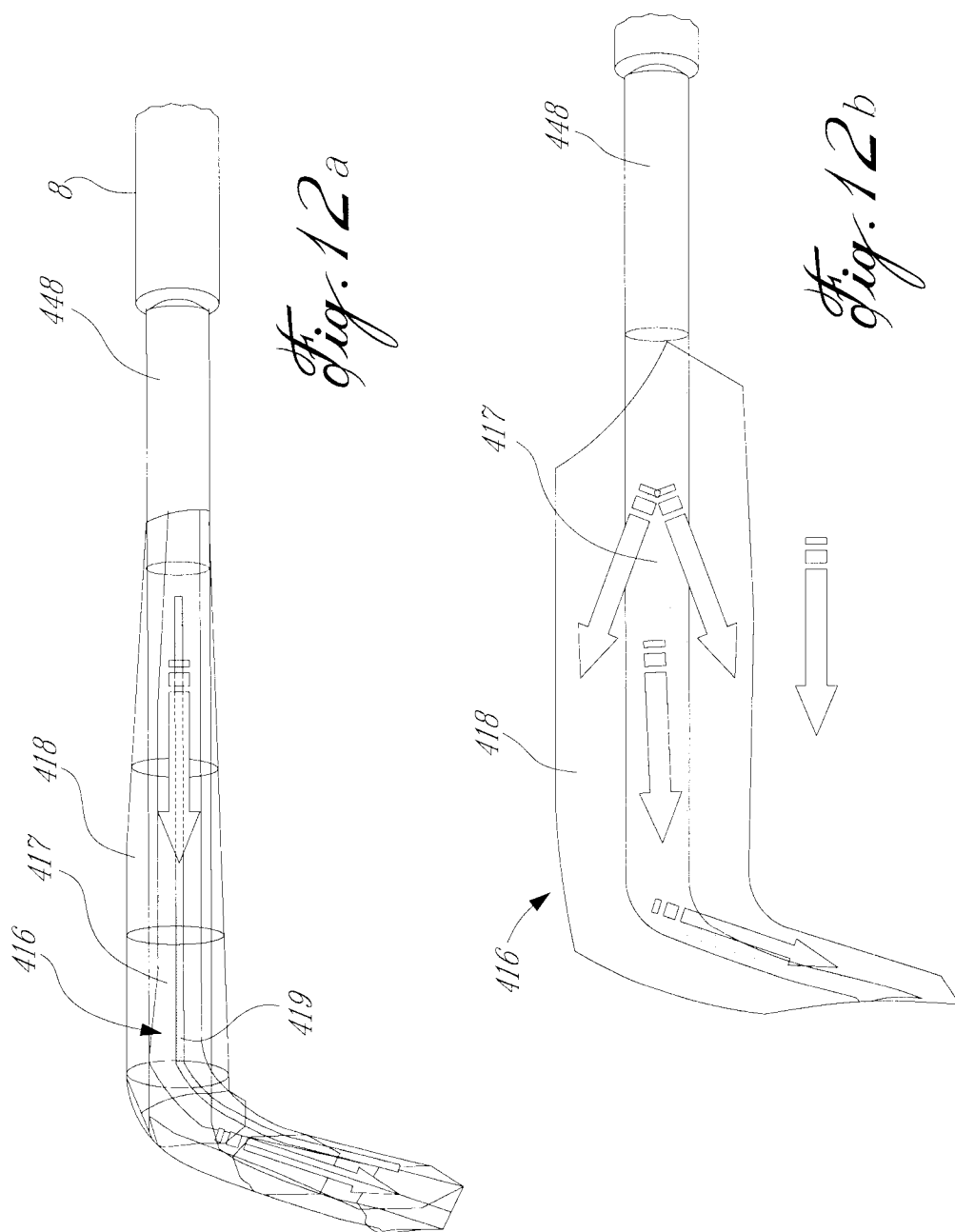


Fig. 9d

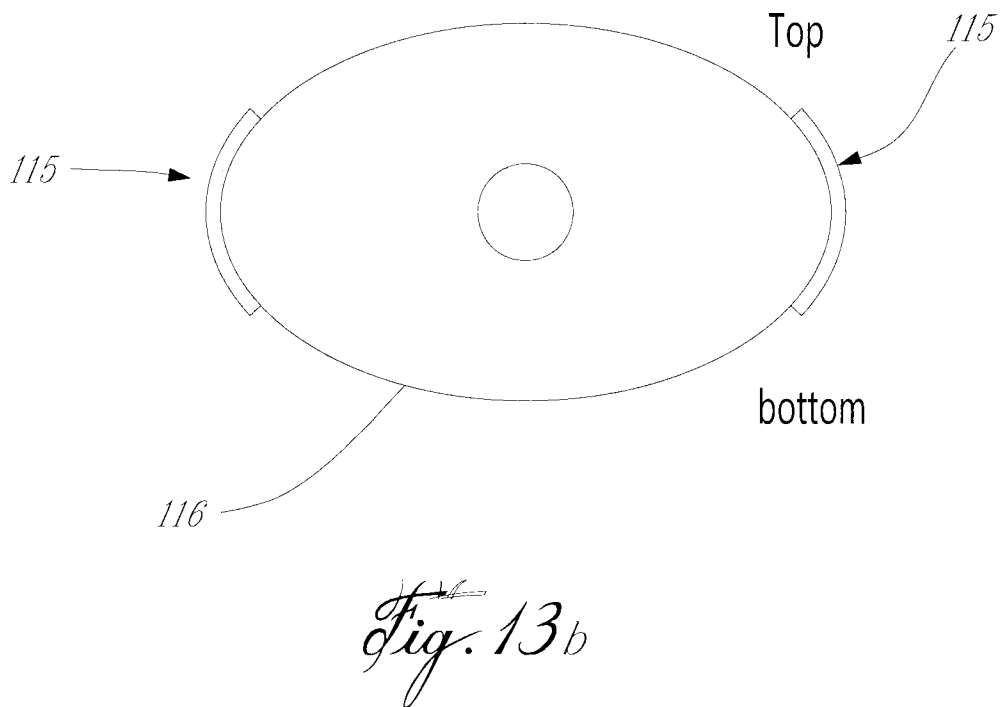
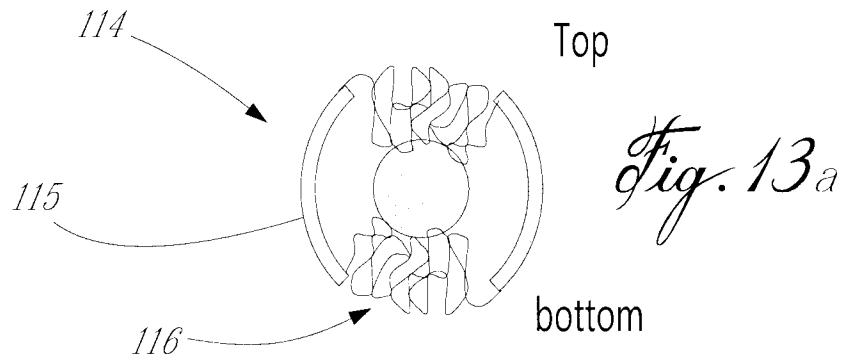
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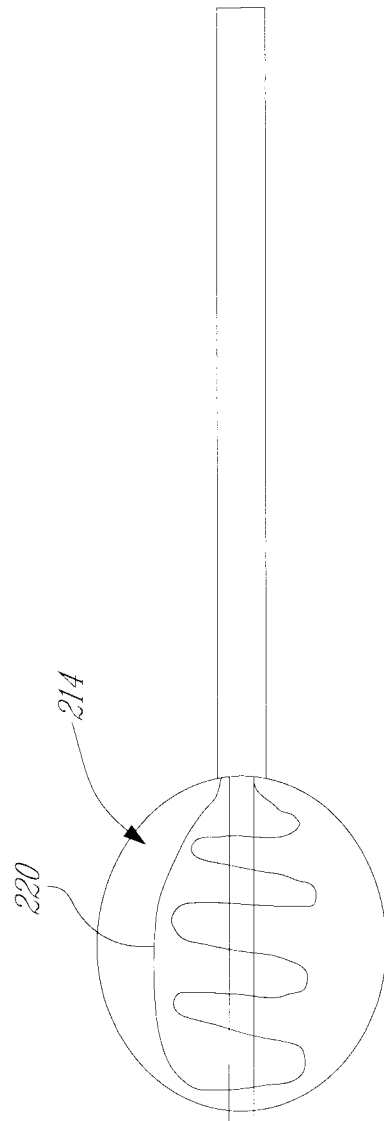


Fig. 14

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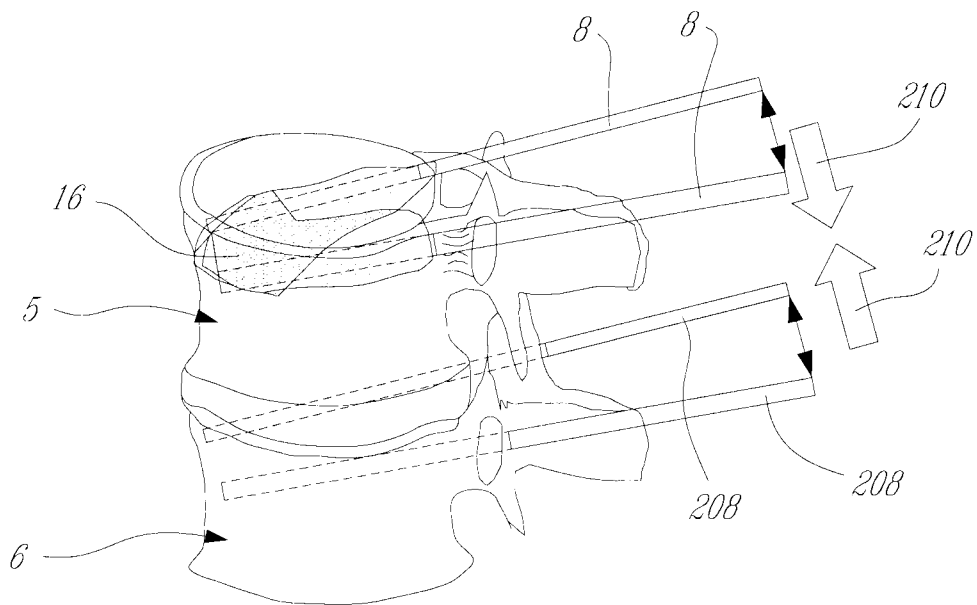


Fig. 15a

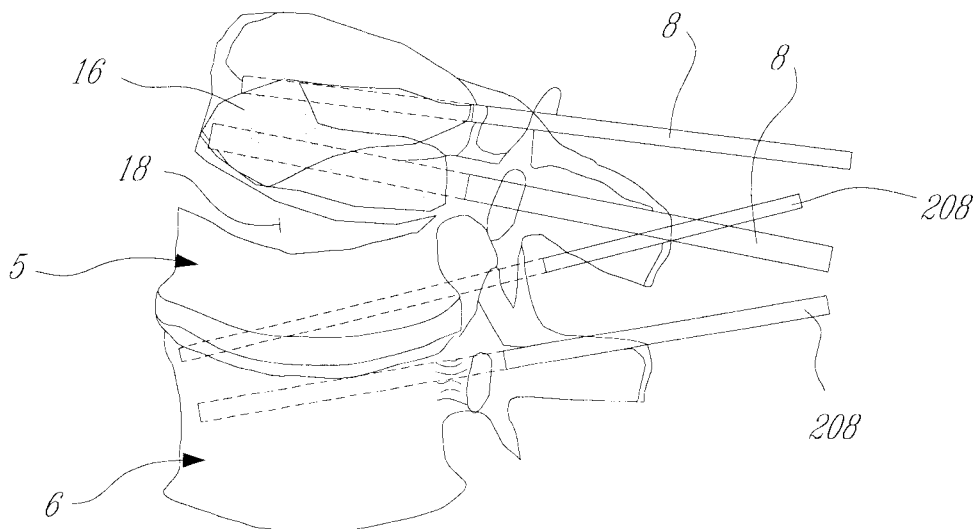


Fig. 15b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2009/001756

A. CLASSIFICATION OF SUBJECT MATTER IPC: A61B 17/68 (2006.01) , A61F 2/46 (2006.01) According to International Patent Classification (IPC) or to both national classification and IPC																	
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC(2006.01) A61B 17/68, A61F 2/46 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used) Delphion, Epoque (Epodoc database) Keywords: kyphoplasty, osteotomy, cement, membrane, vertebr, etc																	
C. DOCUMENTS CONSIDERED TO BE RELEVANT <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>WO2007067726A2 (DUTOIT, C. et al.) 14 June 2007 (14-06-2007) * [0055] - [0068], Fig. 10-11*</td> <td>1, 7, 8, 12-14</td> </tr> <tr> <td>X</td> <td>US20030088249A1 (FURDERER, F.) 8 May 2003 (08-05-2003) *Entire document*</td> <td>1, 7</td> </tr> <tr> <td>X</td> <td>US20040073308A1 (KUSLICH, S. D. et al.) 15 April 2004 (15-04-2004) *[0047] - [0056], Fig. 9-15*</td> <td>1</td> </tr> <tr> <td>A</td> <td>US20040215344A1 (HOCHSCHULER, S. et al.) 28 October 2004 (28-10-2004) * Entire document*</td> <td>1-17</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X	WO2007067726A2 (DUTOIT, C. et al.) 14 June 2007 (14-06-2007) * [0055] - [0068], Fig. 10-11*	1, 7, 8, 12-14	X	US20030088249A1 (FURDERER, F.) 8 May 2003 (08-05-2003) *Entire document*	1, 7	X	US20040073308A1 (KUSLICH, S. D. et al.) 15 April 2004 (15-04-2004) *[0047] - [0056], Fig. 9-15*	1	A	US20040215344A1 (HOCHSCHULER, S. et al.) 28 October 2004 (28-10-2004) * Entire document*	1-17
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X	US20040073308A1 (KUSLICH, S. D. et al.) 15 April 2004 (15-04-2004) *[0047] - [0056], Fig. 9-15*	1															
A	US20040215344A1 (HOCHSCHULER, S. et al.) 28 October 2004 (28-10-2004) * Entire document*	1-17															
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex. <table border="1"> <tbody> <tr> <td>* Special categories of cited documents :</td> <td>"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</td> </tr> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"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</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"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</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td></td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </tbody> </table>			* Special categories of cited documents :	"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	"A" document defining the general state of the art which is not considered to be of particular relevance	"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	"E" earlier application or patent but published on or after the international filing date	"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	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family	"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				
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family																
"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																	
Date of the actual completion of the international search 22 December 2009 (22-12-2009)		Date of mailing of the international search report 18 February 2010 (18-02-2010)															
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476		Authorized officer Daniel Cormier (819) 997-2754															

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/CA2009/001756**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the 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. ☒ Claim Nos. : 18-40
because they relate to subject matter not required to be searched by this Authority, namely :

Claims 18-39 are directed to a percutaneous method to increase vertebral body height of a damaged vertebra and claim 40 is directed to a percutaneous method to restore vertebral body height by vertebral osteotomy.
2. ☐ Claim 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. ☐ Claim 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 additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim 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 claim 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/CA2009/001756

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
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Continued on page 5

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/CA2009/001756

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