

(51) International Patent Classification:
A61F 2/44 (2006.01)(21) International Application Number:
PCT/CA2013/050810(22) International Filing Date:
25 October 2013 (25.10.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/718,337 25 October 2012 (25.10.2012) US
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ie, Montreal, Québec H3B 1R1 (CA).(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, IR, IS, JP, KE, KG, 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, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
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,

[Continued on next page]

(54) Title: EXPANDABLE PROSTHETIC VERTEBRAL IMPLANT

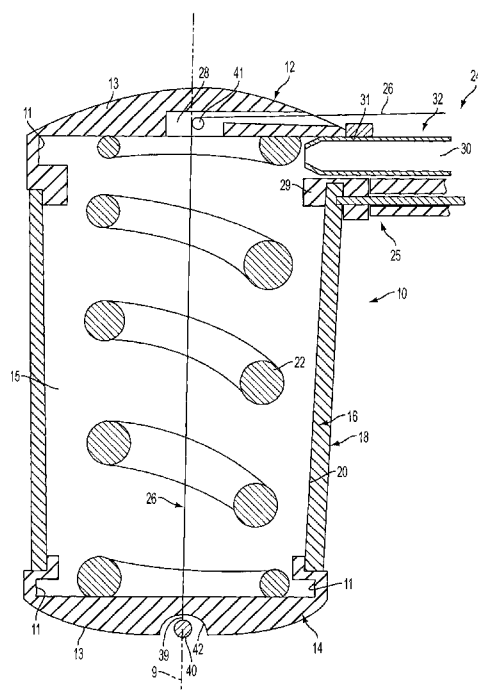


FIG. 1

(57) Abstract: The present expandable prosthetic vertebral implant includes at least one biasing member extending between opposed end plates, and an expansion controlling mechanism. The biasing member generates a distractive force between the end plates such as to force the end plates axially away from each other along a longitudinal axis thereby forcing expansion of the prosthetic implant from a collapsed position to an expanded position. The expansion controlling mechanism includes at least one cable operable to support only a tensile load which opposes the distractive force of the biasing member acting along the longitudinal axis. A distal end of the cable is anchored to a first one of the end plates by an anchor element and the cable extends through a pulley disposed within a guiding cavity defined in a second one of the end plates. The cable exerts a restraining force on the biasing member substantially opposed to the distractive force of the biasing member, and a length of the portion of the cable extending between the pulley and the anchor element being variable to thereby control at least one of an expansion rate and an expansion distance of the expandable prosthetic vertebral implant.



TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, **Published:**

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, KM, ML, MR, NE, SN, TD, TG).

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

EXPANDABLE PROSTHETIC VERTEBRAL IMPLANT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present patent application claims priority on United States Patent Application No. 61/718,337 filed October 25, 2012 and United States Patent Application No. 61/889,193 filed October 10, 2013, the entire contents of each which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention relates generally to spine prostheses, and more particularly relates to an expandable vertebral prosthetic implant.

BACKGROUND

[0003] Vertebrectomy, the excision of a vertebra, is often employed to address several conditions which severely weaken the spinal vertebrae, in order to decompress the spinal cord and/or to stabilize the vertebral column, and thereby reduce the likelihood that a weakened or fractured vertebra may cause significant nerve injury or severe back pain. These conditions can include, but are certainly not limited to, cancer, trauma, infection, bone disease and genetic bone malformation, for example. Trauma or fractures can also necessitate such an excision of a vertebra.

[0004] Corpectomy is a surgical procedure that involves removing part or all of a vertebral body, usually decompressing the spinal cord and nerves. Most known operative techniques for the excision of a vertebra, or a part thereof, are limited by the relatively restricted access to the vertebra that is to be removed and subsequently replaced and/or reconstructed. Most commonly, vertebrae are removed either from an anterior approach (i.e., via the front of a patient) or a posterior approach (i.e., via the back of the patient). Anterior approach techniques provide the widest access to the vertebra or vertebrae to be excised, however are sometimes associated with comorbidities with respect to the thoracotomy (i.e., the incision into the pleural space of the chest). Posterior approach techniques are generally preferred and are more frequently used as they are typically associated with lower morbidity rates, however they imply considerable constraints in terms of limited access, as the vertebra must be excised and replaced with a suitable prosthetic replacement without damaging the nerve

roots. Nerve root sacrifice is not a reasonable option in many regions of the spine as it can lead to loss of vital functions. The space made available by the corpectomy is normally filled using bone cement in a posterior intervention. Bone cement, while malleable and capable of being injected through a small access portal, is not easy to contain and may flow to areas of the spine or thoracic cage where it is not desired, causing complications. Further, it is very difficult to properly restore the complete normal height of the vertebral body and discs which have been removed during a corpectomy, as the bone cement is incapable of providing the necessary expansion force.

[0005] Discectomy is a surgical procedure that involves removing an intervertebral disc that is located between two vertebrae. Once the damaged disc is removed, it can be replaced by a disc replacement implant and/or the two vertebrae can be fused together by bridging the bony gap therebetween using a procedure such as intercorporal fusion.

[0006] Prosthetic vertebral implants, or “cages”, have been used to replace all or a portion of a weakened spinal motion segment, typically comprising a vertebral body and the two discs from either end thereof, that has been excised, or to replace a portion of such a spinal motion segment. However, in order to fill the space created by the excised vertebral body and the discs, such cages must be of sufficient height such as to be capable of filling the void left by an excised vertebral body and the two spinal discs on either side thereof. Thus, most known vertebral body replacement cages are intended to be placed using an anterior approach, which allows for greater access. Such known cages cannot easily be positioned using a posterior approach without causing unwanted damage, given the tight space constraints. The installation of such known vertebral cages using a posterior approach often requires resection of a nerve root in order to create a space large enough to permit cage entry. Existing cages do not have sufficiently small size envelopes (whether diameter, length, etc.), or sufficient collapsibility, to readily permit entry thereof between nerve roots if installed using a posterior approach. Additionally, these cages often require posterior fixation to aid with their stability and allow bone fusion across the void within which the cage is positioned.

[0007] While some known vertebral cages can be used for both trauma and tumour indications, many existing cages tend to be better suited for tumour indications but less practical for trauma indications. Additionally, in cases where the removal of the vertebra is required, existing vertebral cages that permit some, but often insufficient, expansion do not also lend themselves as well to efficient bone ingrowth.

[0008] Accordingly there remains a need for an improved prosthetic vertebral implant. Such an implant may, in particular, be optimized for installation using a posterior approach, although the ability to use the implant with an anterior approach may also be desired.

SUMMARY

[0009] In accordance with one aspect of the present invention, there is provided an expandable prosthetic vertebral implant adapted to be inserted within a space defined between two vertebral tissue surfaces, the prosthetic vertebral implant comprising: opposed end plates including outer surfaces thereon which face in opposite directions and are respectively adapted to abut said two vertebral tissue surfaces for engagement therewith, a longitudinal axis of the prosthetic vertebral implant extending between center points on each of the end plates; at least one biasing member extending between the end plates, the biasing member generating a distractive force between the end plates such as to force the end plates axially away from each other along said longitudinal axis thereby forcing expansion of the prosthetic bone implant from a collapsed position to an expanded position, the expanded position filling the space between the two vertebral tissue surfaces; and an expansion controlling mechanism including at least one cable operable to support only a tensile load which opposes the distractive force of the biasing member acting along said longitudinal axis, the cable having a distal end and a proximal end, the distal end anchored to a first one of said end plates by an anchor element and the cable extending through a pulley disposed within a guiding cavity defined in a second one of said end plates, the pulley through which the cable runs redirecting a direction of force of the cable from substantially axial, parallel to said longitudinal axis, for a portion of the cable extending between the pulley and the anchor element to a direction transverse to said longitudinal axis for a portion of the cable between the pulley and the proximal end of the cable, the cable exerting a restraining force on the biasing member substantially opposed to the distractive force of the biasing member, and a length of the portion of the cable extending between the pulley and the anchor element being variable to thereby control at least one of an expansion rate and an expansion distance of the expandable prosthetic vertebral implant.

[0010] There is also provided, in accordance with another aspect of the present invention, an expandable prosthetic vertebral implant system, the system comprising a prosthetic vertebral implant having a biasing member generating a distractive force

between end plates thereof thereby axially expanding the prosthetic vertebral implant from a collapsed position to an expanded position along a longitudinal axis; an expansion controlling mechanism including at least one cable operable to support only a tensile load and which opposes the distractive force of the biasing member, a length of a portion of the cable extending between the end plates being variable such as to control at least one of an expansion rate and expansion distance of the expandable prosthetic bone implant; and an installation tool in releasable engagement with the prosthetic vertebral implant, the installation tool comprising an elongated rigid arm having a distal end detachably engaged to one of the end plates such as to permit the prosthetic vertebral implant to be manipulated in space using the rigid arm.

[0011] There is further provided, in accordance with another aspect of the present invention a method of controlling expansion of an expandable prosthetic vertebral implant having opposed end plates adapted to be inserted within a space defined between two vertebral tissue surfaces, the method comprising: axially expanding the prosthetic vertebral implant from a collapsed position to an at least partially expanded position by generating a distractive force between the end plates using at least one biasing member extending therebetween, the distractive force displacing the end plates away from each other relative to a longitudinal axis of the implant, the end plates being free to be disposed at independent angular orientations relative to the longitudinal axis such as to respectively adapt to said two vertebral tissue surfaces; and controlling the axial expansion of the implant relative to said longitudinal axis by opposing the distractive force using a tensile-load supporting element extending between the end plates and having a variable length, the tensile-load supporting element exerting an opposed force on the biasing member, and varying said length of the tensile-load supporting element to control said axial expansion of the implant.

[0012] There is additionally provided a tool for installing a prosthetic vertebral implant adapted to be releasably attached to the tool, the prosthetic vertebral implant being expandable by a biasing member disposed within the implant and generating a distractive force between end plates thereof to expand the implant, the tool comprising: an elongated rigid arm having a distal end adapted for detachably engaging the prosthetic vertebral implant such as to permit the prosthetic vertebral implant to be manipulated in space using the rigid arm; a fluid inlet passage for injection of a viscous fluid therethrough, the fluid inlet passage being in fluid flow communication with a cavity

of the prosthetic vertebral implant when mounted to the distal end of the rigid arm; and an expansion controlling mechanism including a tensile-load supporting element acting to oppose the force of the biasing member, the control mechanism being operable to vary a length of the tensile-load supporting element such as to control at least one of an expansion rate and expansion distance of the expandable prosthetic bone implant.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Further features and advantages will become apparent from the following detailed description, taken in combination with the appended drawings, in which:

[0014] Fig. 1 is a cross-sectional view of a prosthetic vertebral implant in accordance with one aspect of the present disclosure, shown in an expanded position and mounted to an associated installation tool;

[0015] Fig. 2 is a partially sectioned side elevational view of the prosthetic vertebral implant of Fig. 1, shown with an outer containment sheath removed;

[0016] Fig. 3 is a partially sectioned side elevational view of the prosthetic vertebral implant of Fig. 1, shown with the outer containment sheath in place;

[0017] Fig. 4 is a perspective view of a prosthetic vertebral implant in accordance with an alternate aspect of the present disclosure, shown in an expanded position;

[0018] Fig. 5 is a side elevational view of the prosthetic vertebral implant and the installation tool of Fig. 1, which is used for installation of the implant;

[0019] Fig. 6 is a perspective view of the installation tool of the present disclosure shown in isolation;

[0020] Fig. 7 is a flow diagram providing steps undertaken when performing a method of installing the prosthetic vertebral implant in accordance with another aspect of the present disclosure;

[0021] Fig. 8A is a side view of a prosthetic vertebral implant in accordance with another embodiment of the present disclosure;

[0022] Fig. 8B is a top view of the prosthetic vertebral implant of Fig. 8A;

[0023] Fig. 9A is a side view of a prosthetic vertebral implant in accordance with another embodiment of the present disclosure;

[0024] Fig. 9B is a top view of the prosthetic vertebral implant of Fig. 9A;

[0025] Fig. 10A is a side view of a prosthetic vertebral implant in accordance with another embodiment of the present disclosure;

[0026] Fig. 10B is a top view of the prosthetic vertebral implant of Fig. 10A.

DETAILED DESCRIPTION

[0027] Referring to Fig. 1, the prosthetic spinal implant 10 of the present disclosure is adapted to replace one or more vertebral tissue elements such as, but not limited to, a vertebra bone excised in a vertebrectomy, a portion of a vertebra removed in a corpectomy, or an intervertebral disc which has been removed from between adjacent vertebrae. The prosthetic vertebral implant (PVI) 10 may be used to replace at least a portion of a vertebra and/or to stabilize and fix the disc spinal column of a patient by being used to replace an entire spinal motion segment, including the vertebral body itself and the spinal discs disposed on either side. Thus, when the PVI 10 is employed in conjunction with a spinal resection, the PVI 10 is braced between upper and lower vertebrae on either side of the resected vertebra and thus the PIV 10 replaces the entire spinal motion segment which was been removed, namely the excised vertebra itself and the discs on either side thereof. The PVI, which may also be referred to herein as a "cage" or a "spacer", 10 may be used alone to stabilize and fix the spinal column by replacing an excised vertebral body or a portion thereon, or alternately may be used in combination with supplemental fixation (not shown). The PVI 10 may also be used to replace an excised intervertebral disc, following a discectomy, in which case the implant is positioned within the bony gap between two adjacent vertebrae after the discectomy. While the overall height and amount of expansion of the implant required for such a disc-replacement implant application is smaller than for an application where the implant is being used to replace an entire vertebra, the features of the implant 10 as described herein remain otherwise the same. For example, when the implants described herein are used to replace intervertebral discs, rather than vertebrae, the overall height of the implant may only be about 15 mm, rather than 40-80 mm for example for the implant when used to replace a vertebra.

[0028] The present implant 10 may alternately be used to fill a space between any two hard tissues, and is not necessarily limited to use as a vertebral implant. For example, the present implant 10 may also be a space expander which can be used in other parts of the body, such as in compressed and/or fractured methaphyseal bone for example. While other applications of the present device are possible, the implant 10 of the present disclosure will be generally described in further detail below with respect to an embodiment whereby it is used as a vertebral implant.

[0029] As will be described in further detail below, the PVI 10 is releasably mounted to a remote end of a surgical installation tool 32, which is used to insert and position the PVI 10 within the desired space between two hard tissue surfaces and/or to otherwise manoeuvre, manipulate and control the PVI, while also providing filling and expansion functions, as will be seen.

[0030] The present PVI 10 is particularly well adapted to be used in applications where surgical access is very limited. For example, in patients with compromised spine stability, a vertebral body replacement could be carried out, using the present PVI 10, either from a minimally invasive posterior or anterior approach. In a particular embodiment, the PVI 10 is capable of collapsing into a sufficiently small fully-compressed space envelope such as to permit a posterior placement of the implant. The present PVI 10 is able to be implanted through a surgical access path that is much smaller than the space it is eventually capable of spanning, once implanted and expanded to fully fill the space of the missing native tissue structure, which may have been removed due to trauma, disease or otherwise. The PVI 10 is thus configured to be capable of expanding to several times its fully compressed height, and in one particular embodiment is capable of expanding to at least over three times its fully compressed height. In one particular embodiment, the PVI 10 is capable of expanding up to ten times its fully compressed height. Additionally, as will be seen, the degree of this expansion can be controlled, varied and even reduced during installation, as may be required.

[0031] Referring now to the structure of the present implant in greater detail, as seen in Figs. 1-3 the PVI 10 includes opposed first and second end plates 12 and 14 that are interconnected by a tubular body 16 formed by a flexible outer containment sheath, which together enclose a central cavity 15 within the implant. The implant 10 is used in conjunction with the surgical installation tool 32, which as seen in Fig. 1 is releasably engaged to one of the two end plates 12, 14. As will be seen, the surgical installation

tool 32 also acts as the bone cement injection device for injecting cement into the cavity 15 within the implant, and as a control mechanism which enables the amount of expansion of the PVI 10 to be controlled (i.e., increased or decreased as desired in order to expand or contract the entire implant).

[0032] As seen in Fig. 1, the upper end plate 12 includes a junction port 29 therein which is configured to matingly receive a distal end 31 of the surgical installation tool 32, in a manner which fixedly but releasably interconnects the PVI 10 and the surgical installation tool 32, such that manipulation of the implant in space is possible by the surgeon or operator. A releasable locking mechanism 25 is provided between the distal end 31 of the installation tool 32 and the end plate 12 of the PVI 10 with which it is engaged, which permits the two components to remain releasably fastened together until such time as the surgeon or operator wishes to disengage them. The locking mechanism 25 interconnecting the distal end 31 of the installation tool 32 and the junction port 29 of the PVI 10 may include quick-release type engagement 25 as shown in Fig. 1, or alternately a threaded engagement.

[0033] As such, the tool 32 is used to manipulate and position the implant 10 into a desired location between bone surfaces of the spine, inserted for example via a posterior approach, and subsequently to expand the PVI 10 and inject the bone cement into the internal cavity 15 of the PVI 10. Therefore, both the expansion and filling functions are accomplished using the installation tool 32, the distal end 31 of the tool 32 is detached from the end plate 12 of the PVI and withdrawn from the surgical field. More particularly, once the PVI 10 has been expanded in order to fill the space between the hard tissue of the spine within which it is installed, bone cement or other hardenable material is injected into the internal cavity 15 of the PVI 10 via a filler inlet passage 30 of the installation tool 32. The filler inlet passage 30 of the tool 32 is therefore in fluid communication with the internal cavity 15 of the PVI 10, when the tool 32 is in mated engagement with the implant as shown in Fig. 1.

[0034] The central cavity 15 defined within the PVI 10 is delimited by the internal side wall surface 20 of the tubular body 16 and by the first and second end plates 12, 14. The flexible outer containment sheath 18, which forms the outer wall of the tubular body 16, is preferably porous such as to allow air within the cavity 15 to be evacuated while still being able to seal bone cement or other hardenable, self-setting biocompatible material within the cavity 15. The pores formed through the flexible containment sheath

18 are therefore sufficiently large to permit air to be evacuated from the cavity by flowing therethrough while still being sufficiently small to prevent any outward leakage of the relatively more viscous bone cement. This therefore permits air to be evacuated from the cavity 15 when the implant is being compressed or expanded prior to or during installation, and/or during injection of the bone cement into the cavity. The central cavity 15 extends through the length of the device between each of the end plates 12,14, thus the PVI 10 is said to be "hollow", as the term is defined herein, prior to any injection of any cement into the cavity 15, i.e., the PVI 10 includes a longitudinally extending cavity, passage or channel therethrough, which is enclosed by the annular external side wall formed by the flexible outer containment sheath 18 and by the two end plates 12, 14 on either longitudinal end of the device.

[0035] In one particular embodiment the flexible containment sheath 18 forming the tubular body 16 of the PVI 10 comprises at least one of a polymeric material, and a fibre material which may be braded, woven, knitted or otherwise formed. However, in all cases the flexible containment sheath 18 is composed of a material such that it is sufficiently flexible to permit both the compression and expansion of the PVI 10 while still sealing the enclosed the cavity 15 within which the bone cement is received. The flexible containment sheath 18 may have a plurality of folds, or bellows, formed therein such as to be able to accommodate the compression and subsequent expansion of the implant. The flexible containment sheath 18 is attached at either axial end thereof to the first and second end plates, for example by cinching, and is configured to be able to expand axially (i.e., substantially parallel to the longitudinal axis 9). In one possible embodiment, the flexible containment sheath 18 is able to expand axially while still maintaining a relatively constant cross-section.

[0036] The end plates 12,14 of the PVI 10 may have D-shaped, kidney-shaped, clover leaf (i.e., having three leaves) shaped, oval, rectangular, square or other shaped perimeter profiles, and can be made of a suitable surgical and biocompatible rigid material, such as 316L Stainless steel or Titanium for example. As seen in Fig. 1, the outwardly facing surfaces 13 of each of the end plates 12, 14 may be curved, such as to form generally convex end surfaces 13 which are adapted to abut the bone or other hard tissue between which the implant is to be placed. The convex end surfaces 13 help the implant angularly adjust to a desired angle between the bone surfaces in a manner which best suits the particular anatomical structure of each case. It follows that the

cross-sectional shape of the tubular body 16 of the PVI 10 will have generally the same form and shape as that of the end plates 12, 14, and therefore a kidney shaped end plates will mean that the tubular body 16 formed by the flexible containment sheath will similarly have a generally kidney shaped cross-sectional profile. Kidney shaped end plates 12, 14 have been found particularly good for facilitating implantation through small surgical access portals.

[0037] Referring to Figs. 1 to 3, the PVI 10 includes at least one biasing member 22 which extends between and interconnects the end plates 12,14. In one particular embodiment of the present implant, the biasing member 22 is a separate component from the tubular body 16 of the implant and is disposed within the cavity 15 of the PVI 10. However, in an alternate embodiment (not depicted), the biasing member 22 can be integrated into the tubular body 16 itself of the implant, such that the flexible containment sheath 18 acts itself as a biasing member due to its spring-like material properties and/or configuration, whereby the outer tubular body 16 is itself a biasing member thereby obviating the necessity for a separate spring-like component 22 within the cavity 15 of the implant 10.

[0038] Returning back to the PVI 10 depicted in Figs. 1-3, the biasing member 22 is disposed within the cavity 15 and is generally concentric with a central longitudinal axis 9 of the implant 10, such that the two end plates 12, 14 interconnected by the biasing member 22 are displaceable relative to each other substantially along the longitudinal axis 9 of the implant. Each of the opposed ends of the biasing member 22 is fixed to the end plates 12, 14, such that compression and expansion of the spring will respectively bring the end plates together or apart. In the depicted embodiment, the biasing member 22 is a helical compression spring which acts to force the longitudinally outward expansion of the PVI 10, along the central longitudinal axis 9, from a collapsed position to an expanded position of the PVI 10 as shown in Fig. 1. The biasing member 22 permits the two end plates 12 and 14 to be able to move relative to each other along the central longitudinal axis 9 by a desired amount at least up to three times its fully compressed height (although greater expansion is also possible), such that the PVI can expand to fill any given space within which the implant is inserted. As will be seen below, however, this expansion is achieved in a controlled manner due to an expansion controlling mechanism 24 which is integrated into both the PVI 10 and the associated installation tool 32.

[0039] The biasing member 22 is preferably a compression spring which is configured so that a distractive force is generated and exists between the opposed first and second end plates 12, 14, such as to normally force them apart. The PVI 10 is, absent the controlling force acting counter to the spring force of the biasing member 22 which is provided by the expansion controlling mechanism 24 as will be seen, inclined to always expand to the maximum height possible within the anatomical space envelope of the spine within which it is inserted. The spring forming the biasing member 22 also allows the end plates 12, 14 to tilt as required such that they can automatically conform to the angulation of the native bone structure, permitting the end plates to be oriented such that the contact area with the adjacent hard surface is maximized, while still applying some pressure to the hard tissue of the bone.

[0040] In embodiment depicted in Figs. 1-3, the biasing member 22 is a linear helical compression spring, which generally has a circular radial cross-section. However, the biasing member 22 of the PVI 10 may comprise numerous other types of springs capable of being resistant to compression and thus which act to normally force the end plates apart. For example, the biasing member 22 of the present implant 10 may also include, in accordance with alternate embodiments, one or more of the following springs: a volute spring; a wave spring; and a torsion spring. These springs may not necessarily be linear, as per the helical compression spring, and in one embodiment a non-linear volute spring is provided between the two end plates. In another alternate embodiment, the biasing member 22 comprises a compression spring which has a variable pitch, such that the expansion force provided by the spring is as constant as possible. Alternately still, the biasing member 22 may include an elastomeric element which acts in a similar manner to a compression spring and performs a similar function of biasing the two end plates away from each other. Additionally, although only a single helical compression spring 22 is depicted in Figs. 1-3, several springs or biasing members 22 may be provided between the two end plates 12, 14.

[0041] For example, in one particular embodiment, two torsion springs are provided between the end plates 12, 14, which may be formed with a kidney shaped profile for example. In another possible embodiment, a single wave spring is provided between circular end plates. In yet another possible embodiment, three or four compression springs, all parallel to each other and to the longitudinal axis 9, are provided between the opposed end plates 12, 14, which may be formed having a multi-leaf configuration (ex:

trifolium or clover-shaped), such that each of the springs supports a different extremity of the end plates. Regardless of the configuration and type of biasing member 22 selected, however, the one or more biasing members 22 act to force the end plates 12, 14 in opposed directions away from each other, substantially along the longitudinal axis 9.

[0042] The presently described configuration of the PVI 10 having the biasing member 22 provides for excellent strength, and very little if any loss in strength occurs as a result of the cavity 15. The PVI 10 may in fact be able to support greater loads than comparable "solid" implants which have been previously used (i.e. without a central cavity 15 and biasing member 22 extending there through). Further, the tubular body 16 of the PVI 10 corresponds substantially to the vertebral bodies between which the PVI 10 is disposed, given that vertebrae have stronger bone material around their perimeter and softer bone near their centers.

[0043] As mentioned above, the expansion of the present PVI 10 is controlled by an expansion controlling mechanism 24. This mechanism 24 acts against the force of the biasing member 22, such as to control the amount of expansion and therefore the overall length thereof. This expansion controlling mechanism 24 accordingly permits the surgeon or operator of the present device to control the amount and rate of expansion of the PVI 10, by controlling the amount and rate of expansion of the biasing member 22 therewithin. Therefore, the mechanism 24 enables the operator to very accurately vary the overall height of the PVI 10, and allows a controlled expansion of the implant during its installation within the bone structures of the spine. Further still, the expansion controlling mechanism 24 also permits a reversal of the expansion of the PVI 10, i.e. it permits the PVI 10 be collapsed by any desired amount. This may be useful, for example, during the installation of the implant such as to compress the entire implant slightly, following an initial expansion, such as to readjust the implant in another position or to reduce the overall axial height of the implant if it has expanded beyond an amount desired by the surgeon. The expansion controlling mechanism 24 therefore acts against the force of the biasing member 22, such as to permit, prevent or reduce the amount of expansion of the biasing member 22.

[0044] Referring to Figs. 1-3, but as best seen in Fig. 1, the expansion-controlling mechanism 24 comprises an expansion-controlling and tensile-load supporting element 26 which extends through the cavity 15, and may in at least the depicted embodiment extend through the center of the cavity along the longitudinal axis 9. The tensile-load

supporting element 26 can be a string or cable, providing strength/resistance in tension but not compression, which controls the expansion of the biasing member 22 by providing resistance to the outwardly generated expansion force of the spring or biasing member 22. The tensile-load supporting element 26 will be generally referred to and described herein as a cable, wire rope or string, etc., however it is to be understood that other elements may also be used (such as an electric actuator or hydraulic piston which has a variable length that is able to be controlled) which similarly provide a counteracting force to the outwardly expanding force of the biasing member 22. The tensile-load supporting element 26 is therefore preferably, although not necessarily, a flexible cable having a distal end 39 thereof anchored to one of the end plates 14 by an anchor element and which extends through a guiding cavity 28 in the opposite end plate 12, such that the cable 26 is redirected toward a proximal end of the installation tool 32. In the depicted embodiment, a pulley 41 is disposed within this guiding cavity 28 along which the cable 26 runs, such that the cable "bends" 90 degrees between the portion thereof extending through the main cavity 15 of the body 16 of the device and the portion thereof extending out of the end plate 12 and along the handle of the tool 32. It is understood that the pulley 41 as defined herein may include a rotating pulley element or a rotationally stationary pin or cable guide about which the cable runs. The pulley 41 therefore allows for smooth axial translation of the endplates relative to one another, when the cable 26 is let out or wound in. Accordingly, the cable 26 is fixed relative to one of the two end plates but is able to be slid or otherwise displaced through the other of the two end plates, such that pulling or otherwise applying tension on the remote end of the cable 26 (i.e. the end opposite to that fastened to the end plate 14) will cause the end plate 14 move toward the end plate 12 as the length of the cable 26 extending therebetween is reduced.

[0045] The cable 26 may, in at least one embodiment, include a plurality of markings thereon disposed at regular and predefined intervals, such as to provide a visual indication to the operator of the device as to a distance between the endplates and increase therein. Accordingly, the operator is able to determine the expansion distance of the device, when being allowed to expand from a collapsed position to an extended position, and thus whether a full height of the void is filled by the expanded implant. Additionally, by being able to determine the expanded height of the implant via these markings on the cable, the operator is also able to determine a volume of cement which may be injected into the implant given the known expansion height thereof.

[0046] Although numerous ways exist to fasten the remote end 39 of the cable 26 to the remote end plate 14, in the embodiment depicted in Figs. 1-4 the remote end 39 of the expansion-controlling cable 26 has an anchor element comprising a spherical cable stop 40 thereon, which is concentrically received within a correspondingly shaped orifice 42 formed in the center of the end plate 14. This configuration, namely the cable stop 40 on the remote end 39 of the cable 26 which is attached at the outward side of the endplate 14, allows the end plates to assume an angular orientation as may be required by the given particular anatomical environment, however also means that the end plates may not expand and/or contract evenly. Thus, if it is desirable to be able to maintain the two end plates 12, 14 substantially parallel to each other during the expansion or contraction of the implant, the remote end 39 of the cable 26 may alternately be fastened to proximally projecting extension stub located an inward side of the endplate 14. This alternate configuration enables the endplates to remain substantially parallel to each other during the expansion of the device. In either case, however, winding in of the cable 26 will cause the remote distal end 39 of the cable 26 to pull the end plate 14 in the same direction towards the other end plate 12.

[0047] The cable 26 is configured (ex: has a sufficiently large diameter and/or is composed of a sufficiently strong material) such that it provides an appropriate factor of safety over the maximum load of the biasing member 22. In one particular embodiment, the cable which makes up the cable 26 has a diameter of approximately 1mm. In an alternate embodiment, the endplates can be fastened or otherwise locked together when the device 10 is in it fully compressed state, such as to permit storage of the device in this fully compressed state over periods of time, for example for storage, shipping, etc.

[0048] Referring now to Figs. 5 and 6 which show in further detail the installation tool 32 used, inter alia, for manipulating, expanding and filling the PVI 10, the tool 32 includes generally an elongated rigid arm 50 including a handle 52 at one end and having an implant engaging distal end 31 at the other end, the distal end 31 being releasably engaged with at least the end plate 12 of the PVI 10. As described with respect to Fig. 1, the distal end 31 of the tool 32 may be releasably fastened to the implant 10 by a releasable locking mechanism, which permits the tool 32 to be disengaged from the implant 10 and removed once the implant is positioned in place, expanded to fill the required space and filled with cement. The tool 32 also includes a hollow tube 54 which defines the filler inlet passage 30 therein, through which a viscous and hardenable fluid,

such as a self-hardening cement, is fed for injection into the internal cavity 15 of the implant 10. A connector 56 is provided on the flexible tube 54 such as to connect a source of the cement to the assembly.

[0049] The tool 32 also comprises at least a portion of an expansion controlling mechanism 60, which includes a tensile-load supporting element, in the form of a cable 26 in the depicted embodiment, and a mechanism for varying the length of this cable 26. The cable 26 which forms the tensile-load supporting element acts to oppose the force of the biasing member of the implant 10, and is either wound in or out by the expansion controlling mechanism 60 such as to vary a length of the cable extending between the two end plates 12, 14 of the PVI 10. Accordingly, by using the expansion controlling mechanism 60 to control the length of the cable between the end plates of the implant, at least one of the expansion rate and the expansion distance of the expandable prosthetic bone implant can be controlled by the expansion controlling mechanism 60. The action of the cable 26 required to lengthen or shorten the PVI 10, respectively the increasing or decreasing of the length of the cable 26, is therefore controlled by the expansion controlling mechanism 60 as shown in Figs. 5-6. This expansion controlling mechanism 60 may include a pulley system and/or a reel-like actuator 62 as shown in Fig. 6, comprising for example at least one of a locking or ratchet driven reel 64. In an alternate embodiment, the expansion controlling mechanism 60 may also include friction plates or discs, for example, which are similarly capable of controlling the length of cable within the implant. Regardless, the controlling member is capable of winding in or letting out the cable by small incremental amounts such as to either reduce the tension on the cable 26, to thereby allow expansion of the biasing member 22 (and therefore increase the axial length of the PVI 10), or to increase the tension on the cable 26, to thereby compress the biasing member 22 (and therefore reduce the axial length of the PVI 10). Therefore, applying or releasing the tension on the cable 26 acts (and thus winding-in or letting-out the cable) will increase or decrease the amount of force resisting against the axial expansion of the biasing member 22. In accordance with another embodiment, the expansion controlling mechanism includes one or more of a friction mechanism, a pulley mechanism, a ball/indent mechanism or any other equivalent mechanism operable to limit cable or string play out, and preferably, although not necessarily, permit the cable to be wound back in after an initial play out such as to permit adjustment of the length of the implant in both axial directions. In addition, the cable can be integrated as part of the elongated rigid control arm as shown in Fig. 5.

[0050] The cable 26 may thus be reversibly and gradually controlled and/or adjusted by the surgeon once the PVI 10 is inserted in place within the open space between hard tissue of the spine, in a manner which permits the surgeon to control the expansion of the PVI 10 within this space and even to reverse the expansion thereof when required. The control of the extension of the PVI 10 by the surgeon during a procedure is achieved by the activation of the tensioning controlling member, which provides a precise control on the extension of the implant. This is particularly useful when the PVI 10 is being inserted using a posterior approach.

[0051] The implant is thus configured to expand several times its fully compressed height by gradually allowing the cable 26 to be wound out thereby increasing the length of the cable extending between the two end plates of the implant 10, which in turn allows the spring 22 to expand at the same time. The operator of the device can therefore control the tension in the cable 26 and/or the length thereof in a reversible and gradual manner, using the same tool 32 which is also used for manipulation of the implant during insertion thereof and for the injection of the self-setting cement into the cavity 15 of the implant 10 once installed in place and expanded into position.

[0052] In an alternate embodiment (not shown), more than one cable 26 may be provided and used to control the expansion of the implant. For example, two or more separate cables or strings may be routed from the first end plate to the second end plate, either at circumferentially spaced apart points within the cavity 15 of the tubular body 16 or alternately along the outside of the spring 22 and/or the flexible containment sheath 18. In this embodiment, whereby multiple cables 26 are employed, they can be separately controlled such as to generate and control the angular orientation of at least the second end plate 14 relative to the first end plate 12. Alternately still, in an embodiment having multiple cables 26 acting counter to the spring 22, each of cables 26 can be individually controlled such as to adjust and/or control endplate tilt.

[0053] As noted above, self-setting cement or another suitable hardenable material (ex: polymerizing fluid) is injected into the cavity 15 of the PVI 10 via a filler inlet passage 30 of the tool 32, such as to stabilize and fix the implant 10 in its final, expanded, position. The self-setting cement, once injected into the implant 10, therefore bears the static loads imposed on the implant and the spring(s) 22 of the implant are therefore no longer exposed to any loads. The hardened bone cement completely fills the cavity 15 delimited by the end plates 12, 14 and the tubular wall 16 of the flexible containment

sheath 18. The internal surfaces of the first and second end plates 12, 14 which face the cavity 15 are thus configured such that the cement can positively form fit them once cured. Once the bone cement has cured within the PVI 10, the entire implant becomes rigid and is then capable of withstanding physiological loads.

[0054] In one particular embodiment, as shown in Figs. 1-4, each of the end plates 12, 14 has a lateral groove 11 formed in the inner surface of the end plate that is exposed to the cavity 15, which groove 11 allows the cement to form fit into the end plates 12, 14. The lateral groove 11, or "undercut", in the endplates extends about at least a portion of the periphery of the end plates 12, 14. In the depicted embodiment, this lateral groove 11 is annular and extends about the complete periphery of the end plates. These undercuts or lateral grooves 11 allow the cured cement injected into the cavity 15 to form fit with the end plates 12, 14, thereby firmly locking the endplates onto the cured cement core within the cavity 15. This advantageously increases the strength of the implant 10, particularly when undergoing severe bending and/or tension. In alternate embodiments, the end plates may be provide with other protruding and/or recessed features, surface roughness, etc., in lieu of the inner grooves 11, which similarly ensure that the cured cement within the cavity 15 forms a secure and rigid connection with the endplates.

[0055] The elongated control tool 32 includes a hollow tube which defines the filler inlet passage 30 therein, though which passage the hardenable filler material, such as polymerizing fluid, is fed for injection into the cavity 15 of the PVI 10. Preferably, the polymerizing fluid which is used is a bone cement paste that hardens once controlled expansion of the PVI into the expanded position has occurred. The filler inlet passage 30 thus communicates directly with the cavity 15, via the port 29 in the end plate 12, and the hardenable material is injected through this filler inlet passage 30 which extends along the center of a hollow tube of the control tool 32. The port 29 with which the remote end 31 of the tool 32 is mated, may also be disposed, for example, in the flexible containment sheath 18 forming the sidewall of the tubular body 16 or alternately proximate either one, or possibly also both, of the two end plates 12, 14. Other positions of the port 29 with which the filler inlet passage 30 of the tool 32 may be connected are of course also possible, provided that the cement inlet port is disposed in fluid flow communication with the internal cavity 15 defined within the PVI 10.

[0056] It is of note that although the end plates 12, 14 and the body 16 of the PVI 10 are depicted in Figs. 1-4 as being substantially circular in shape and peripheral profile, this

need not necessarily be the case. As noted above, the end plates and thus the tubular body of the implant may have numerous different shapes and cross-sectional profiles, such as kidney shaped, oval, clover leaf shaped, etc.

[0057] The first and second end plates 12 and 14 define outer surfaces 13, which form the two outwardly facing surfaces of the PVI 10 that are adapted to abut the two adjacent vertebrae or the two opposed hard tissues surfaces between which the implant 10 is to be installed. The end plates 12, 14 may be fastened or otherwise anchored to the adjacent vertebrae using surface features formed on their outer surfaces. These surface features may include, for example, projections which help to anchor the PVI 10 in place between the two next adjacent vertebral bone structures. In one embodiment, these surface features include a plurality of textured protrusions which extend from the outer surface of each of the end plates 12, 14, such as to permit the end plates to anchor and/or fasten to the bone structures surrounding the PVI 10. The protrusions can include: teeth, pins, barbs, spikes, and any combination thereof. The surface features can also include non-protruding surface feature elements, either in addition to or in place of the protrusions, which nonetheless help the end plates to be engaged, anchored and/or become fastened to the bone structure of the surrounding vertebrae. These non-protruding elements can include, for example, porous ingrowth surface regions, bioactive bone growth materials, etc.

[0058] The tubular body 16 of the PVI device 10 has an expanding configuration which allows at least for axial expansion, in a direction parallel to the longitudinal axis 9, of the body of the PVI 10 such as to fill any sized opening between vertebrae or between two hard tissue regions of the same vertebra. Particularly, while the tubular body 16 of the PVI generally may expand along the longitudinal axis 9, it is to be understood that deviations from the axis are of course possible, and particularly angular deviations which may be necessary given a particular anatomical environment for example. Regardless, the PVI 10 expands such that the end plates 12, 14 are generally displaced away from each other by virtue of the force of the biasing member 22, which force is controlled and counterbalanced by the cable 26 which helps control the expansion and modify it as necessary. The two end plates 12, 14 need not remain parallel to each other, and therefore the body can expand to accommodate any slope of the endplates 12,14 necessary for their outer surfaces to abut the adjacent vertebrae even a slope that is

significantly canted from a plane which is perpendicular to the longitudinal axis of the implant.

[0059] Although the internal side wall 20 and the external side wall of the tubular body 16 may be substantially parallel to each other, as is the case for sidewalls shown in Figs. 1 and 3 for example, they need not necessarily be identical in shape or form. In one preferred, but not essential, embodiment the internal and external side walls of the tubular body 16 substantially mirror each other such as to improve the structural integrity of the PVI 10. However, both the internal and external side walls must be able to substantially equally expand such as to permit the PVI 10 to be displaced from the very compact collapsed position to the significantly expanded position, as required.

[0060] In the embodiment described above, the flexible containment sheath 18 which expands axially and allows for the evacuation of air while containing the injected self-setting cement and/or bone growth stimulating material, the flexible sheath 18 is generally not a load carrying feature and once the biasing member 22 has expanded to the necessary height, the containment sheath serves as a container for retaining the injected self-setting cement and/or bone growth stimulating material within the cavity 15 of the implant 10. The porous nature of the flexible containment sheath 18 of the tubular body 16 may also allow for osteointegration.

[0061] Preferably, the combined axial height (i.e. thickness in a direction substantially parallel to the longitudinal axis 9 of the PVI 10) of the two end plates 12, 14 is relatively small compared to the total axial height of the implant when expanded. This enables the PVI 10 to be compressed into much smaller space envelopes than the devices of the prior art, thus enabling the placement of PVI 10 via much smaller surgical access openings, and in particular enabling the placement of the PVI 10 via a posterior approach without causing undue damage to the surrounding nerve and tissue structures. The PVI 10 thus provides an implant which can be inserted through a relatively small insertion opening, such as through a small posterior surgical access, between pairs of nerve roots, through a costotransversectomy or a wide transpedicular approach, for example. The PVI 10 thus has a collapsed position, which defines a small size envelope for ease of insertion, but which can subsequently be expanded to fill a much larger space, as shown in Figs. 1-3 for example. The surgeon inserts the PVI 10 in the body of the patient in the compressed or fully collapsed configuration and then release the tension applied by the cable 26 on the biasing member 22 by activating the tensioning

controlling member, thus releasing the biasing force of the biasing member 22 and thereby expanding the end plates 12,14 away from each other in a controlled way, since the surgeon controls precisely the amplitude of the PVI 10 versus the amount of actuated releasing to be applied on the cable 26.

[0062] The PVI 10 includes first and second end “plates” 12 and 14 which are interconnected by the generally tubular body 16, such as to define a cavity 15 within the implant. Although the term “plates” is used to define the end surfaces of the body which makes up the VP, it is to be understood that these plates may be integrally formed with the material of the body 16, and may also not necessarily be smooth or flat. The end plates 12 and 14 may also be disposed either externally or internally within an outer sheath or casing made up by the material of the body 16 which extends over the plates 12, 14 at either end. Thus, the plates can constitute a thin walled material, such as a metal or a polymer (such as a bioresorbable polymer for example), which is either integral with, or separate and fastened to, the material of the side walls. The end plates 12, 14 are however preferably, but not absolutely, harder and/or stiffer than the side walls 18, 20 of the body 16, whether the end plates are made of a different material or not.

[0063] Various configurations of body 16 are possible. The body 16 can comprise a bellows shape with a side wall which has a plurality of accordion type pleats which give the side wall an expanding bellows type folded shape. This folded, tubular side wall configuration thus enables the end plates 12 and 14 to be displaced towards and/or away from each other in a generally longitudinal direction. The accordion pleats of the side wall will prevent the device from unduly expanding in a radial direction and restricts most expansion to the opposed longitudinal directions, thus protecting the spinal cord from inadvertent injury when the PVI 10 is placed in position between vertebrae and expanded. Further, the flexibility provided by such a wall design permits the two end plates 12 and 14 to be angled, or canted, as required in order to accommodate the specific local topography of the vertebrae against which they are abutted when the PVI 10 is expanded *in situ*. Thus, the end plates 12, 14 are free to be disposed, when the PVI is expanded in place between the two adjacent vertebrae, at different angles relative to the longitudinal axis (i.e. the two end plates need not be parallel to each other).

[0064] In use, the PVI 10 collapses into a very small size envelope, such as to make its insertion into place between the nerve roots of two adjacent vertebrae possible without

causing damage, even upon a posterior placement. Additionally, matching features may be provided on one or both of the two end plates 12, 14 such that they can be fixed together in order to fasten the implant 10 in its fully collapsed position. This may be particularly useful, for example, for packaging, transport and/or storage purposes, such that the implant remains in its fully collapsed position.

[0065] Although the distance between adjacent nerve roots varies along the spine, this distance is generally between about 1 cm and about 2 cm. Accordingly, when the PVI 10 is disposed in its fully collapsed position, it preferably has a total collapsed height of less than about 1-2cm. The PVI 10 can be greatly collapsed, permitting significantly higher expansion ratios (i.e., the total expanded height divided by the collapsed height), such as, in one particular embodiment, expansion ratios ranging from about 200% to about 850%. In one particular embodiment of the PVI 10, however, this expansion ratio is at least 300%. In another embodiment, the expansion ratio is greater than 400%, and may be up to 1000% (i.e. 10 times its fully compressed height).

[0066] Referring now to the alternate embodiment as depicted in Fig. 4, the prosthetic vertebral implant (PVI) 110 is similar to the implant 10 described above, but has at least two biasing members 116 and 118 arranged in series (i.e. end to end) which extend between the opposed first and second end plates 112 and 114. A third biasing member 117 may also be provided in series (i.e. end to end) with the first and second biasing members 116, 118, and may be similar to upper biasing member 118 but disposed on the opposed end of the central biasing member 118, between the central biasing member 116 and the lower end plate 114. The biasing members 116, 117 and 118 in this embodiment comprise linear compression springs of different free heights (i.e. heights when uncompressed) and/or different spring coefficients, which are concentric about the central longitudinal axis 119 and joined together at one end to form a composite biasing member 122 formed of the different springs. Therefore, as demonstrated in this embodiment, rather than having a continuous spring as described above with respect to Figs. 1-3, a stack of springs may be provided end to end.

[0067] Having two biasing members in series allows the middle biasing member to be fixed in place, for example using cement, while allowing the outer one (or two) biasing members to remain free to compress and expand, as the physiologic forces act on the spine and the endplates. This may be achieved, for example, by enclosing the central spring by the sheath which contains the cement therewithin, but providing the outer

spring(s) which remain free to compress/expand outside the envelope of the cement enclosing sheath. In such a configuration, the "middle" spring would be selected such that it provides low force/high expansion, while the outer spring(s) would be selected such that they provide very high force but very low expansion. For example, the outermost springs may be so stiff that they permit only very small compressive motion, i.e. motion which is significantly less than that of the central spring. This may be, for example, less than half, less than one quarter, or less than ten percent of the motion of the central spring. Permitting such a "micro-motion" expansion/compression of the outer springs will help reduce stress-shielding of the bone graft material within the void, which may also improve the likelihood or quality of the eventual bone fusion across the void.

[0068] In another embodiment, a number of wave springs may alternately be provided between the end plates, and arranged for example such that each only completes one full 360 degree rotation and such that the peaks of one wave spring are joined (by weld or otherwise) to the peaks of the next wave spring in the stack. This configuration provides the same amount of expansion and compression ratio, but additionally serves to stabilize the spring against shear forces in comparison with a single, integrally formed, spring extending the full length of the implant. This improved resistance to shear forces is clearly only useful prior to the injection of the self-hardening cement into the cavity 15 of the implant 10, as once the implant is filled with cement it is the cement which bears all loads to which the implant is subjected.

[0069] The composite biasing member 122, formed of the springs 116, 117 and 118 stacked in series, extends between the end plates 112, 114 and forces the expansion of the PVI 110 from a collapsed position to an expanded position, such as shown in Fig. 4. A tensile-load supporting and expansion-controlling element 126 similarly extends through the center of the body of the implant and is collinear with the longitudinal axis 119. As per the cable 26 described above, the element 126 is similarly operable to control the extension height of the composite biasing member 122 formed of the two springs 116 and 118.

[0070] The PVI 110 can also comprise a flexible containment sheath (not shown in Fig. 4), which as per the flexible containment sheath 18 described above, encloses the composite biasing member 122 while permitting the springs of the biasing member to remain free to move and while still retaining the cement injected into the cavity defined within the containment sheath.

[0071] In another possible embodiment, the vertebral implants 10, 110 described above may also be provided with a central channel, formed by an inner tubular wall extending the length of the implant between in the two end plates, the central channel being in alignment with corresponding openings in each of the two end plates such as to form an annular body for the PVI 10, 110 having a hollow core defined by the central channel, in a manner similar to the implant described in International Patent Application No. PCT/CA2010/000957 filed June 18, 2010, published as WO 2010/145036, the entire contents of which are incorporated herein by reference. The openings in the end plates, which communicate with the longitudinally extending central channel extending through the center of the implant body, thereby permit bone ingrowth to occur through the end plates and through the length of the implant body. The expandable implant described in WO2010/145036 is an improvement of the expandable implant described in International Patent Application No. PCT/CA2008/001087 which was published WO2008/148210, the entire content of which is also incorporated herein by reference.

[0072] Fig. 7 shows the steps taken, in accordance with one possible implant installation method of the present disclosure, when installing the prosthetic vertebral implant 10 using the tool 32. Generally, the present method of controlling expansion of an expandable prosthetic vertebral implant 10, includes axially expanding the prosthetic vertebral implant from a collapsed position to an expanded position by generating a distractive force between the end plates of the implant, using for example a biasing member 22. The distractive force of the biasing member thus displaces the end plates 12, 14 of the implant 10 axially. The method further includes, in a most general form, controlling the axial expansion of the implant relative to its longitudinal axis by opposing the distractive force of the biasing member 22 using a tensile-load supporting 26 element extending between the end plates and having a variable length. The length of the tensile-load supporting element is then varied to control the axial expansion of the implant. The more detailed steps which make up each of these general steps of the presently described method are shown in detail in the flow diagram of Fig. 7.

[0073] Referring to Figs. 8A-8B, an alternate prosthetic vertebral implant (PVI) 210 is depicted which is generally similar to the implant 10 described above, but which has a number of biasing members 222 which are disposed between the opposed end plates 212 and 214. In the depicted embodiment, the biasing members 222 comprise four compression springs which are spaced apart about the annular shaped end plates 212,

214. The springs may be equally spaced apart about the end plates, or alternately they may be balanced (as per the embodiment of Figs. 8A-8B) such that they are symmetrical about one or both transverse cross-sectional planes (extending into the page in Fig. 8B and intersecting at the center of the endplate).

[0074] The distractive force of each of these springs is counteracted by corresponding separate cables 226, each being independently controlled, which together restrict and control the expansion of the implant 210. Because expansion controlling mechanism uses multiple cables, one for each of the springs 222, the relative orientation of the two end plates 212, 214 can be modified and controlled as required. When multiple springs and cables as used, as per the present embodiment, the sum of their forces should balance out. Each of these cables may run through a separate pulley disposed within one of the endplates. The force lines of each pair of spring and cable may also be coaxial, such as to ensure fully axial expansion of the implant. This configuration accordingly permits independent active control of the angular orientation of each of the end plates, in addition to their relative axial adjustment towards and away from each other. Unlike older expanding cage designs, where the relative angle between the two end plates are fixed, the PVI 210 of the present embodiment therefore not only permits the end plates to adopt different orientations relative to a common longitudinal axis of the implant, but also permits the orientation of one or both of the end plates to be actively controlled and modified, as needed, in order to achieve the best possible fit with the anatomical environment within which it is to be installed.

[0075] The PVI 210 of Figs. 8A-8B central graft channel 215 which is centrally disposed within the implant and which extends fully axially through both end plates 212, 214 and the implant body 216 which extends therebetween. This permits bone ingrowth and/or bone graft material to grow, or be inserted, into the center of the implant along the complete longitudinal length of the implant when in the expanded position. This may be particularly advantageous, for example, when the PVI 210 is being used to replace an intervertebral disc, following a discectomy, such as to allow bone growth between the two adjacent vertebrae and thereby help fuse these two vertebrae together with the implant therebetween. Accordingly, the implant body 216 is annular in shape, surrounding this central bone graft channel 215. The annular body 216 defines radially inner and outer walls 217 and 218, which are flexible or at least axially extendable such as to permit the longitudinal expansion of the implant 210. As best seen in Fig. 8A, the

biasing members (compression springs) 222 are disposed within this annular body 216, between the inner wall 217 and the outer wall 218. As such, the springs are encased within the body 216 and thus not exposed to bone graft or other environmental conditions following insertion of the implant 210. As the flexible inner and outer walls 217, 218 of the body 216 are free to axially expand or contract as required the angular orientation of the end plates 212, 214 can be different from each other and controlled by the biasing members 222 and the counteracting cables 226 of the expansion controlling mechanism, as described above, with the flexible walls 217, 218 of the annular implant body 216 being able to accommodate this angular difference between the endplates without requiring a radially outward or inward expansion.

[0076] Referring now to the embodiment of Figs. 9A-9B, the PVI 310 includes opposed end plates 312, 314 that are interconnected by captive infinite screws 317, or screw turnbuckles, which when rotated act to drive the end plates 312, 314 away from each other. These screws 317 may be double threaded (ex: Right-hand thread and left-hand thread on each screw) turnbuckle screws which push apart the end plates when they are rotated by the cables 326. The screws 317 therefore provide the distractive force which permits expansion of the implant 310. These screws 317 may be mounted in spherical joints in the end plates, such as to allow for angular misalignment and/or an angular orientation difference between the two end plates. As the screws are preferably, although not necessarily, independently actuated, an active control of the relative tilt angles of the two end plates 312, 314 is possible. The PVI 310 includes biasing members 322, in the form of torsion springs which, which generate torsion forces rather than linear forces as per the compression springs 222. The torsion springs 322 still help to force expansion and/or contraction of the implant 310, however they do so by acting on the screws 317 and causing the screws 317 to rotate. This may include, for example, that the torsion springs 322 cause the turnbuckle screws 322 to return to their original or natural positions (ex: fully expanded), unless acted upon by the cables 326 of the expansion controlling mechanism. The screws 317 and springs 322 accordingly act together to generate the distractive force which expands the implant. The implant 310 also includes an expansion controlling mechanism which similarly includes at least one cable 326, and more preferably one cable 326 per screw element 317. While the torsion springs 322 generate a rotational force on the screws 317 which attempts to expand the implant, rotation of each of the infinite screws 317 is controlled, or prevented when required, by one or more cables 326 having proximal ends anchored to the screws and

which are wrapped around each screw. As such, by controlling the winding out of the cables 326, rotation of the screws 317, driven by the torsion springs 322, is actuated and controlled as desired (ex: rotation of the screws can be started, stopped and controlled, as required). Much as per the embodiments described above, therefore, the cables 326 of the expansion controlling mechanism counteract the distractive force of the screws and springs 317, 322, much as per those of the other embodiments described above, and thus allow for controlled expansion of the implant 310. Because the cables 326 can be independently controlled, variable tilt of the end plates 312, 314, and thus active control of the relative angular orientation of each of the end plates, is also possible. For example, on side of the implant (ex: a posterior or an anterior side, for example) may be caused to expand more than the opposite side, in order to create a desired tilt on at least one, if not both, of the end plates.

[0077] As can be seen in Figs. 9A-9B, the implant 310 may have an annular implant body 316 which extends between the end plates 312, 314 and which defines at the center thereof a graft space or central graft channel 325 that extends fully axially through both end plates 312, 314 and the implant body 316 which extends therebetween. This central graft space or channel 325 permits bone ingrowth and/or bone graft material to grow, or be inserted, into the center of the implant and to extend along the complete longitudinal length of the implant when in the expanded position. Accordingly, the implant body 316 is annular in shape, surrounding this central bone graft channel 325. The annular body 316 defines radially inner and outer walls 318 and 319, which are flexible or at least axially extendable such as to permit the longitudinal expansion of the implant 310 as described above. As seen in Fig. 9A, the screws 317 and biasing members (torsion springs) 222 are disposed within this annular body 316, between the inner wall 318 and the outer wall 319. As such, the screws 317 and torsion springs 322 are encased within the implant body 316 and thus not exposed to bone graft or other environmental conditions following insertion of the implant 310. As the flexible inner and outer walls 318 and 319 of the body 316 are free to axially expand or contract as required. The flexible walls 318, 319 of the annular implant body 316 are thus able to accommodate an angular difference between the end plates, as described above, without requiring a radially outward or inward expansion.

[0078] Cement or other hardenable viscous material can be introduced into the annular cavity 315, or cement space, defined between the inner and outer flexible walls 318, 319

of the body 316, once the implant has been positioned in place and expanded as required to fill the gap between the vertebral tissues surfaces. It is to be understood, however, that for the implant 310 as well as all PVIs described herein, they do not necessarily need to use bone cement for the purposes of maintaining their expanded positions, and thus for certain applications it may not be desired or required to use bone cement in conjunction with the present expandable vertebral implants. If bone cement is used, however, it may be introduced into the annular cavity of the implant 310 via control handle 352 of an installation tool 332, which also acts as a cement filler by comprising a tubular conduit 330 within the handle 352, through which the hardenable cement may be injected. Further, much as per the embodiments described above, the cables 326 of the expansion controlling mechanism may also be fed through or along the handle 352 of the installation tool 332, and outward to a remote proximate end of the handle 352.

[0079] Referring now to the embodiment depicted in Figs. 10A-10B, the PVI 410 is similar to the implant 310 described above, however it includes wedges 460 in lieu of the screw turnbuckles 317. Similarly, however, biasing members (in this case driven by linear springs 422) act on the wedges 460, which in turn slide within ramps 462 that are fixed in place on the two end plates 412, 414. A cable 426 of the expansion controlling mechanism similarly controls expansion of the implant by resisting against, and controlling expansion of, the distractive force generated by the biased moving wedges 360 that slide along the ramps 362 to cause axial expansion of the implant 410. The implant 410 similarly includes, as per the implant 310 described above, a bone graft space or channel 425 centrally located within an annular body 416 defined by inner and outer flexible walls 418, 419. An annular cement space or enclosed cavity 415 is defined within the flexible walls 418, 419 of the annular body 416, within which cement or another suitable hardenable high vacuumity material may be introduced via the cement filler conduit 430 defined through the handle 452 of the installation tool 432. The sliding wedges 460, springs 422 and other components of the distractive force generating sub-assembly are contained within the annular cement cavity/space 415, and as such once the implant 410 has been expanded into its desired position, bone cement may be introduced into the cavity 415 such as to permanently fix the entire implant 410 in its desired final height and with the desired end plate orientations.

[0080] However, as is the case for all implants described herein, cement need not be used to fix or lock the implant in its desired final expanded position. This may be done

using a ratchet or other locking mechanism, such as to “freeze” or fix the implant in its expanded position without requiring the use of cement.

[0081] In all embodiments described herein, the end plates and other components of the present implants, including the springs, turnbuckle screws, wedges, etc, may be made of a suitable biocompatible material. In at least one embodiment, however, the material selected includes at least one of titanium and PEEK. As described above, the term “cable” is used herein as a generic term for any suitable elongated, flexible element that is a tensile-load supporting element (i.e. that it is only capable of supporting loads in tension, but not in compression). The “cables” as described herein may be made of a high strength polymer filament, or may be alternately made of a metal such as surgical steel. The cables may be braided, for improved strength, or simply a single filament element provided they are capable of supporting the required loads. In all cases, however, the cables/filaments used should be capable of being able to bend around a tight radius, of the order of 1-3 mm for example, and have sufficient tensile strength to oppose the spring force of the springs plus a suitable safety factor. This may be, for example only, 50-100 N (spring force) x 2 (safety factor).

[0082] It is also to be understood that all implants described herein may be used either as a full vertebrectomy device, i.e. the implant is used to replace an entire vertebra that has been excised, or may be used as a disc-replacement cage, i.e. the implant is used to replace an intervertebral disc.

[0083] Further, all implants described herein may be designed either for posterior or anterior approaches, however in many cases the VPIs may be more preferably intended for posterior use.

[0084] The embodiments of the invention described above are intended to be exemplary. Those skilled in the art will therefore appreciate that the foregoing description is illustrative only, and that various alternatives and modifications can be devised without departing from the spirit of the present invention. For example, although the present expandable prosthetic bone implant is described above with respect to embodiments whereby it is a vertebral implant, it is to be understood that the expanding implant of the present invention may also be a space expander which can be used in other parts of the body, such as in compressed and/or fractured metaphyseal bone for example. In another alternate embodiment, the tensioning element of the prosthetic bone implant is

disposed within the control tool, rather than in the prosthetic bone implant itself. In this embodiment, the elongated rigid arm is detachably engaged with both of the end plates of the implant, such that the tensioning element within the control arm can be operated to control the distraction of the two end plates away from each other. Accordingly, the present is intended to embrace all such alternatives, modifications and variances which fall within the scope of the appended claims.

CLAIMS:

1. An expandable prosthetic vertebral implant adapted to be inserted within a space defined between two vertebral tissue surfaces, the prosthetic vertebral implant comprising:
 - opposed end plates including outer surfaces thereon which face in opposite directions and are respectively adapted to abut said two vertebral tissue surfaces for engagement therewith, a longitudinal axis of the prosthetic vertebral implant extending between center points on each of the end plates;
 - at least one biasing member extending between the end plates, the biasing member generating a distractive force between the end plates such as to force the end plates axially away from each other along said longitudinal axis thereby forcing expansion of the prosthetic bone implant from a collapsed position to an expanded position, the expanded position filling the space between the two vertebral tissue surfaces; and
 - an expansion controlling mechanism including at least one cable operable to support only a tensile load which opposes the distractive force of the biasing member acting along said longitudinal axis, the cable having a distal end and a proximal end, the distal end anchored to a first one of said end plates by an anchor element and the cable extending through a pulley disposed within a guiding cavity defined in a second one of said end plates, the pulley through which the cable runs redirecting a direction of force of the cable from substantially axial, parallel to said longitudinal axis for a portion of the cable extending between the pulley and the anchor element, to a direction transverse to said longitudinal axis for a portion of the cable between the pulley and the proximal end of the cable, the cable exerting a restraining force on the biasing member substantially opposed to the distractive force of the biasing member, and a length of the portion of the cable extending between the pulley and the anchor element being variable to thereby control at least one of an expansion rate and an expansion distance of the expandable prosthetic vertebral implant.

2. The prosthetic vertebral implant as defined in claim 1, wherein the end plates are free to be disposed at independent angular orientations relative to the longitudinal axis, such as to respectively adapt to said two vertebral tissue surfaces.
3. The prosthetic vertebral implant as defined in claim 1 or 2, wherein the end plates are disposed at respective first and second angles relative to the longitudinal axis, the first and second angles being independently set and controllable by the expansion controlling mechanism.
4. The prosthetic vertebral implant as defined in any one of claims 1 to 3, wherein the pulley and the anchor element are aligned such that the direction of force of the cable extending therebetween is coaxial with the longitudinal axis.
5. The prosthetic vertebral implant as defined in claim 1, wherein the expansion controlling mechanism is operable to gradually increase a height of the prosthetic vertebral implant by gradually increasing the length of said portion of the cable extending between the pulley and the anchor element.
6. The prosthetic vertebral implant as defined in any one of claims 1 to 5, wherein the expansion controlling mechanism is operable to shorten said portion of the cable extending between the pulley and the anchor element such as to adjust or reduce the fully expanded position.
7. The prosthetic vertebral implant as defined in claim 1, further comprising an expandable body interconnecting the end plates and having a perimeter side wall defining therebetween a cavity axially extending between the end plates, the body being axially expandable along the longitudinal axis.
8. The prosthetic vertebral implant as defined in claim 7, wherein the biasing member extends between the end plates within the cavity of the expandable body.

9. The prosthetic vertebral implant as defined in any one of claims 1 to 8, wherein the biasing member comprises at least one compression spring disposed between the end plates.
10. The prosthetic vertebral implant as defined in any one of claims 1 to 8, wherein the biasing member comprises at least one torsion spring disposed between the end plates.
11. The prosthetic vertebral implant as defined in claim 9 or 10, wherein two or more of said springs are interconnected and arranged in series between the end plates.
12. The prosthetic vertebral implant as defined in claim 9 or 10, wherein two or more of said springs are arranged in parallel between the end plates.
13. The prosthetic vertebral implant as defined in claim 7, wherein the expandable body being tubular and comprising a flexible containment sheath enclosing said cavity.
14. The prosthetic vertebral implant as defined in claim 13, wherein the flexible containment sheath is substantially impermeable to a viscous fluid introduced into the cavity such as to prevent outward leading of the viscous fluid but remains porous to gas such as to allow air to be evacuated from the cavity.
15. The prosthetic vertebral implant as defined in claim 7, further comprising a fluid inlet port in fluid communication with the cavity to permit injection of a viscous fluid into the cavity.
16. The prosthetic vertebral implant as defined in claim 14 or 15, wherein the end plates include inner surfaces facing said cavity, the inner surfaces defining a lateral groove therein which extends about at least a portion of the periphery of the end plates, the lateral grooves being adapted to receive the viscous fluid therein such as to lock the end plates in position relative to the viscous fluid in the cavity when said viscous fluid hardens and form fits with the end plates.

17. The prosthetic vertebral implant as defined in any one of claims 14 to 16, wherein the viscous fluid is a self-setting cement.
18. The prosthetic vertebral implant as defined in any one of claims 1 to 17, wherein the expansion controlling mechanism includes at least one of a ratchet mechanism, a friction mechanism, a pulley mechanism and a ball/indent mechanism, operable to control wind-out of the string or cable.
19. The prosthetic vertebral implant as defined in claim 1, wherein the biasing member comprises a flexible containment sheath enclosing a cavity defined within a tubular body extending between the end plates.
20. The prosthetic vertebral implant as defined in any one of claims 1 to 19, wherein the prosthetic vertebral implant is one of a vertebral body implant adapted to replace a vertebra and a vertebral disc implant adapted to replace an intervertebral disc between adjacent vertebrae.
21. An expandable prosthetic vertebral implant system, the system comprising:
a prosthetic vertebral implant having a biasing member generating a distractive force between end plates thereof thereby axially expanding the prosthetic vertebral implant from a collapsed position to an expanded position along a longitudinal axis;
an expansion controlling mechanism including at least one cable operable to support only a tensile load and which opposes the distractive force of the biasing member, a length of a portion of the cable extending between the end plates being variable such as to control at least one of an expansion rate and expansion distance of the expandable prosthetic bone implant; and
an installation tool in releasable engagement with the prosthetic vertebral implant, the installation tool comprising an elongated rigid arm having a distal end detachably engaged to one of the end plates such as to permit the prosthetic vertebral implant to be manipulated in space using the rigid arm.

22. The system as defined in claim 21, wherein the installation tool further comprises a fluid inlet passage in fluid flow communication with a cavity of the prosthetic vertebral implant for injection of a viscous fluid through the fluid inlet passage and into the cavity of the prosthetic vertebral implant.
23. The system as defined in claim 21, wherein the installation tool includes an actuator operable to control the expansion controlling mechanism by shortening or lengthening the cable.
24. The system as defined in any one of claims 21 to 23, wherein the end plates are free to be disposed at independent angular orientations relative to the longitudinal axis, such as to respectively adapt to said two vertebral tissue surfaces.
25. The system as defined in any one of claims 21 to 23, wherein the end plates are disposed at respective first and second angles relative to the longitudinal axis, the first and second angles being independently set and controllable by the expansion controlling mechanism.
26. The system as defined in any one of claims 21 to 25, wherein the cable has a distal end and a proximal end, the distal end being anchored to a first one of said end plates by an anchor element and the cable extending through a pulley disposed within a guiding cavity defined in a second one of said end plates, the pulley redirecting a direction of force of the cable.
27. The system as defined in claim 26, wherein the direction of force of the portion of the cable extending between the end plates being substantially axial, parallel to said longitudinal axis, and the direction of force of the cable between the pulley and the installation tool being in a direction transverse to said longitudinal axis.
28. The system as defined in claim 21, wherein the prosthetic vertebral implant is as defined in any one of claims 1 to 20.

29. A method of controlling expansion of an expandable prosthetic vertebral implant having opposed end plates adapted to be inserted within a space defined between two vertebral tissue surfaces, the method comprising:

axially expanding the prosthetic vertebral implant from a collapsed position to an at least partially expanded position by generating a distractive force between the end plates using at least one biasing member extending therebetween, the distractive force displacing the end plates away from each other relative to a longitudinal axis of the implant, the end plates being free to be disposed at independent angular orientations relative to the longitudinal axis such as to respectively adapt to said two vertebral tissue surfaces; and

controlling the axial expansion of the implant relative to said longitudinal axis by opposing the distractive force using a tensile-load supporting element extending between the end plates and having a variable length, the tensile-load supporting element exerting an opposed force on the biasing member, and varying said length of the tensile-load supporting element to control said axial expansion of the implant.

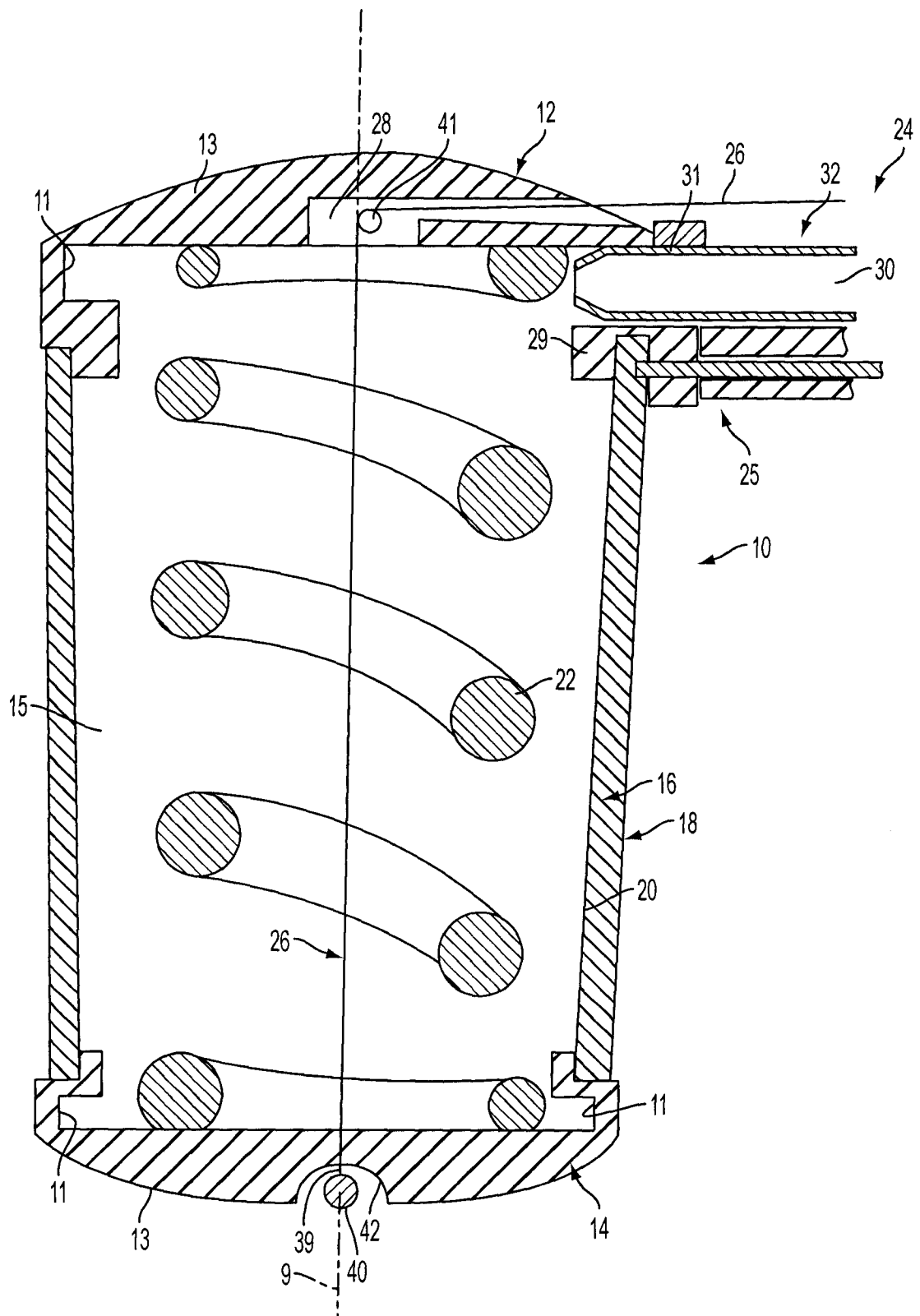


FIG. 1

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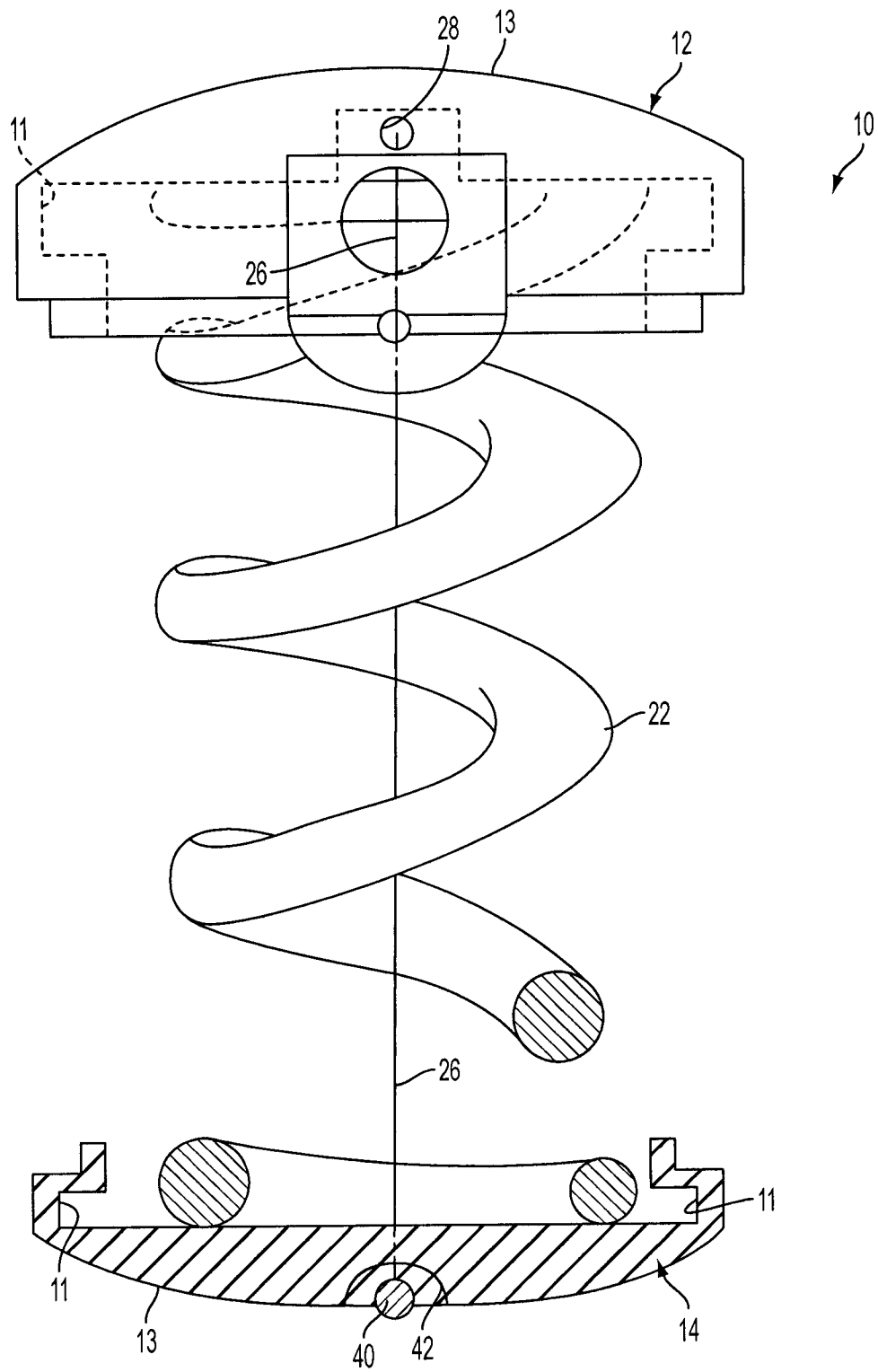


FIG. 2

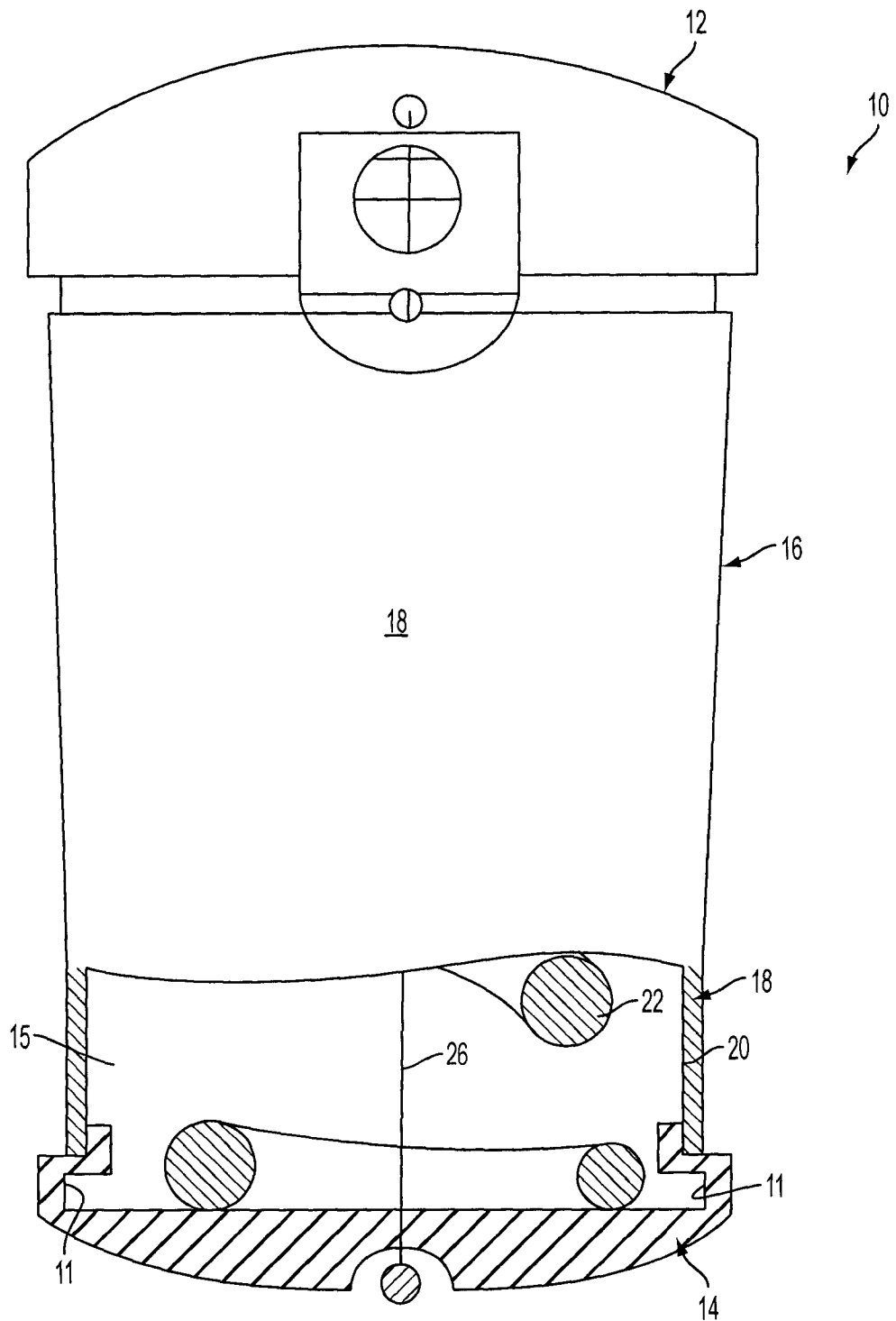


FIG. 3

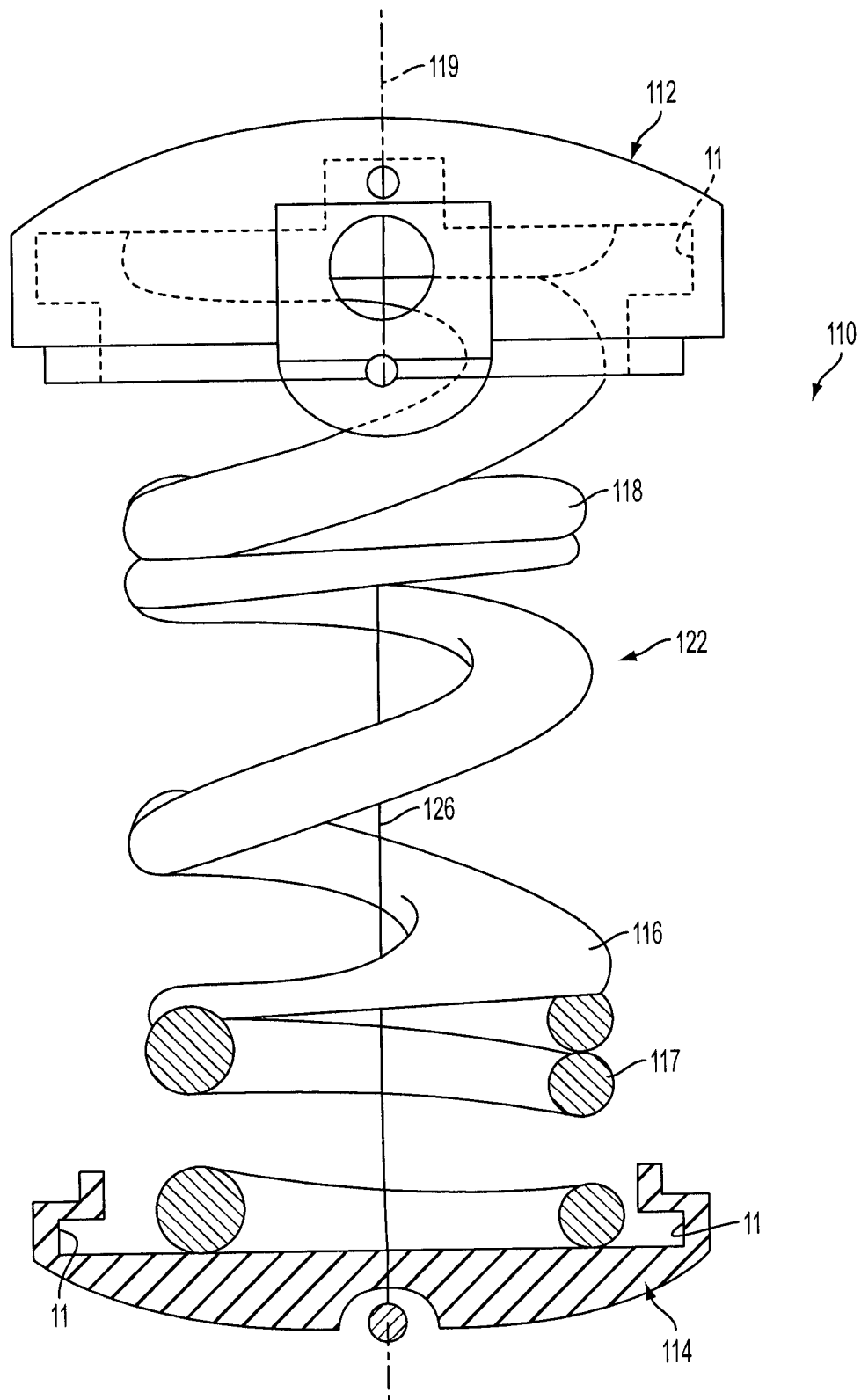


FIG. 4

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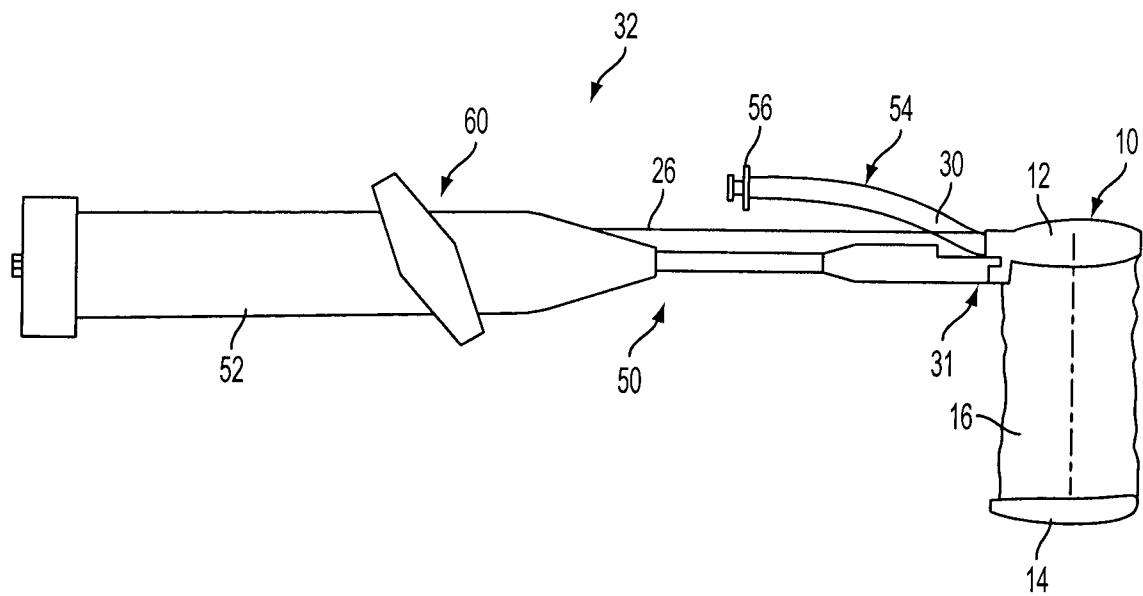


FIG. 5

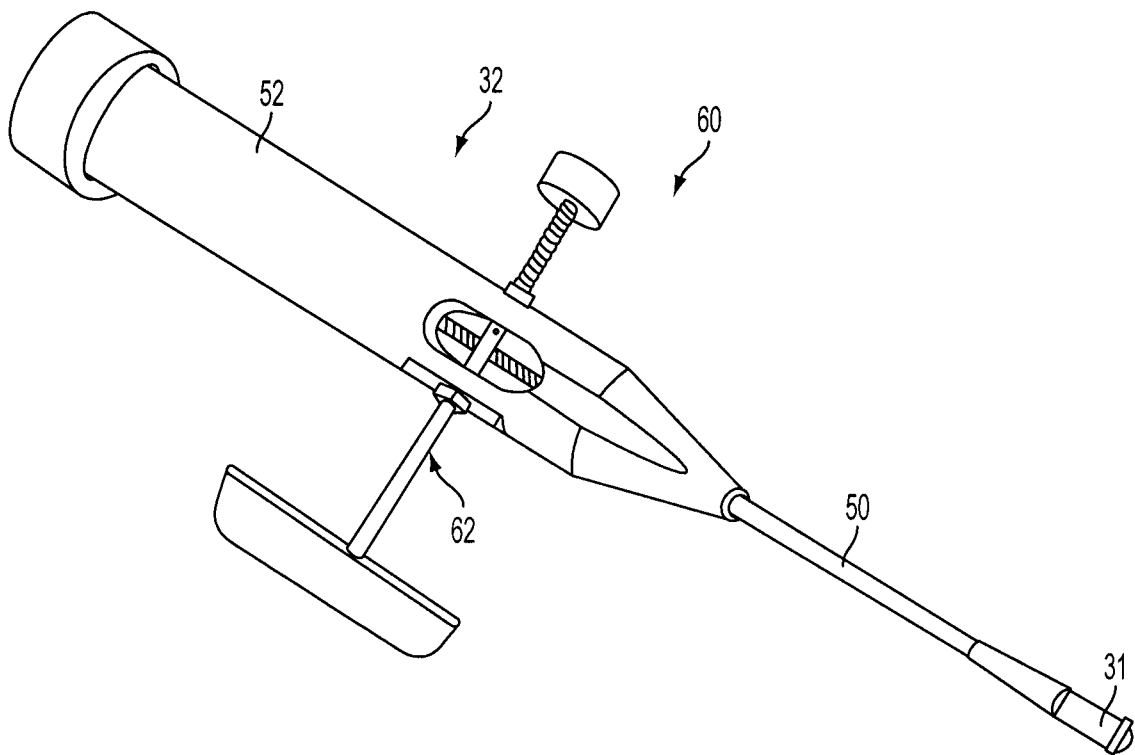


FIG. 6

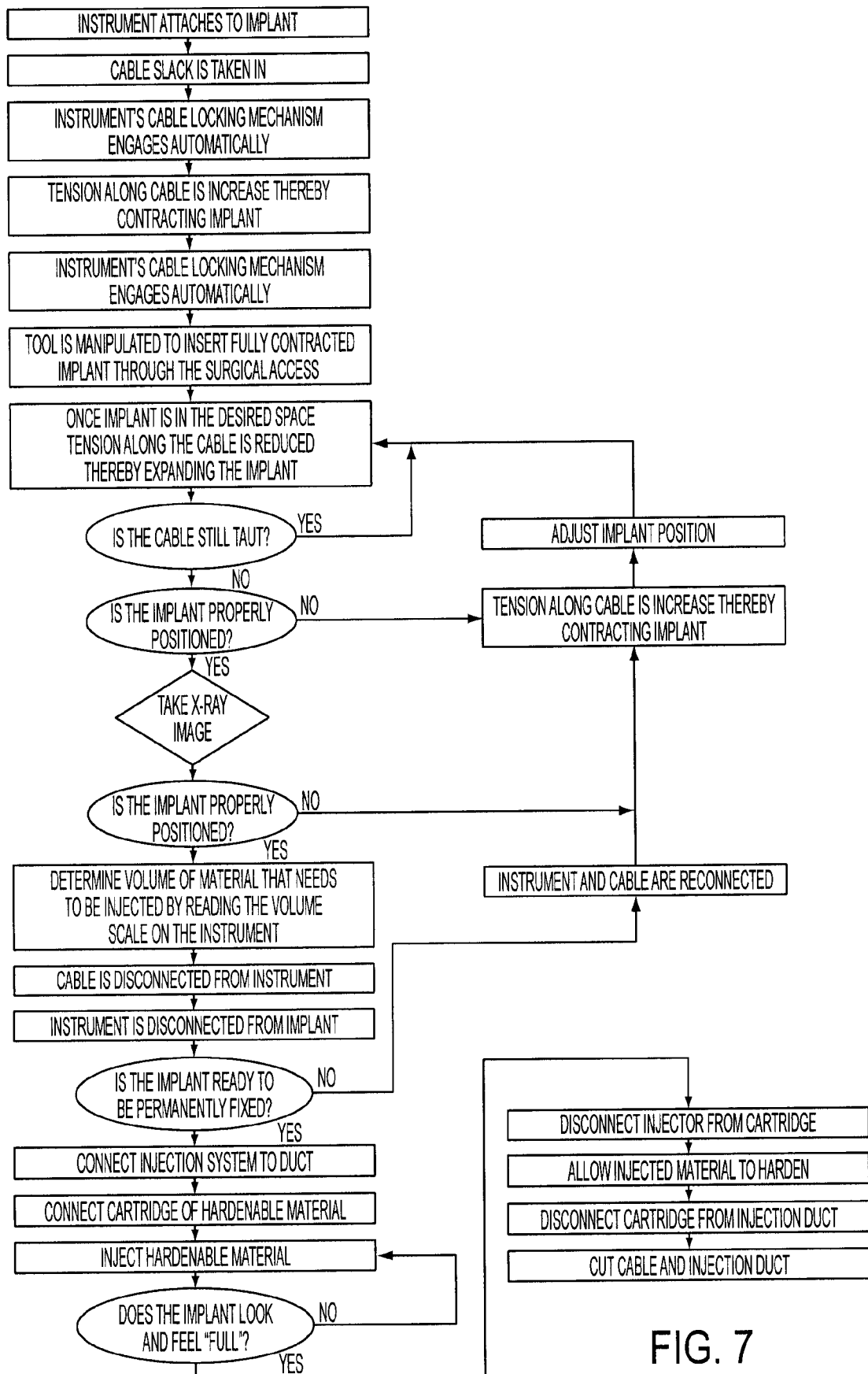


FIG. 7

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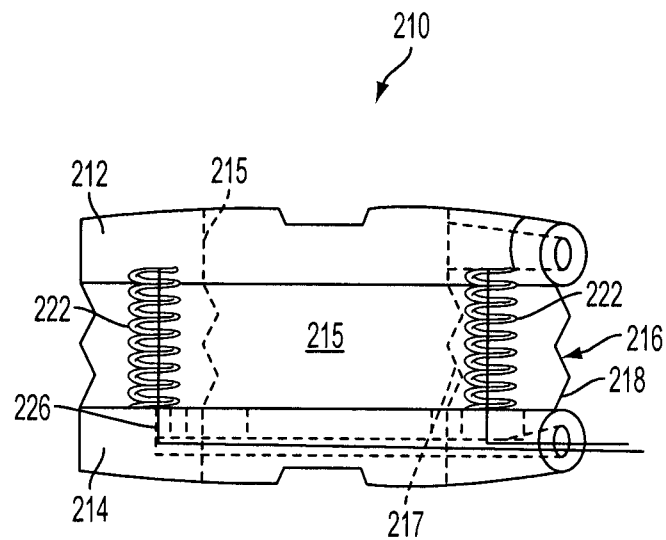


FIG. 8A

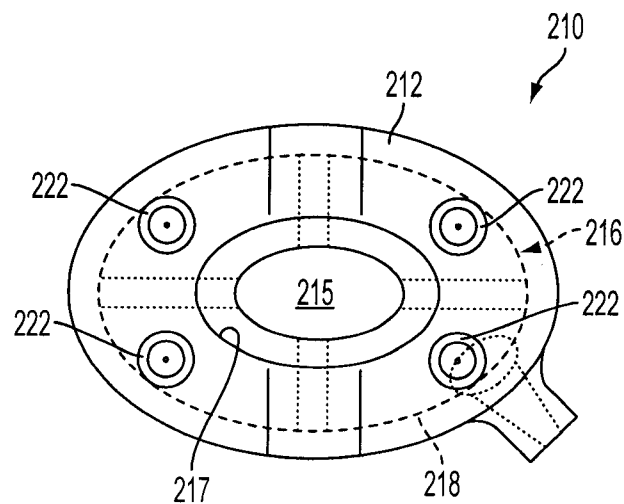


FIG. 8B

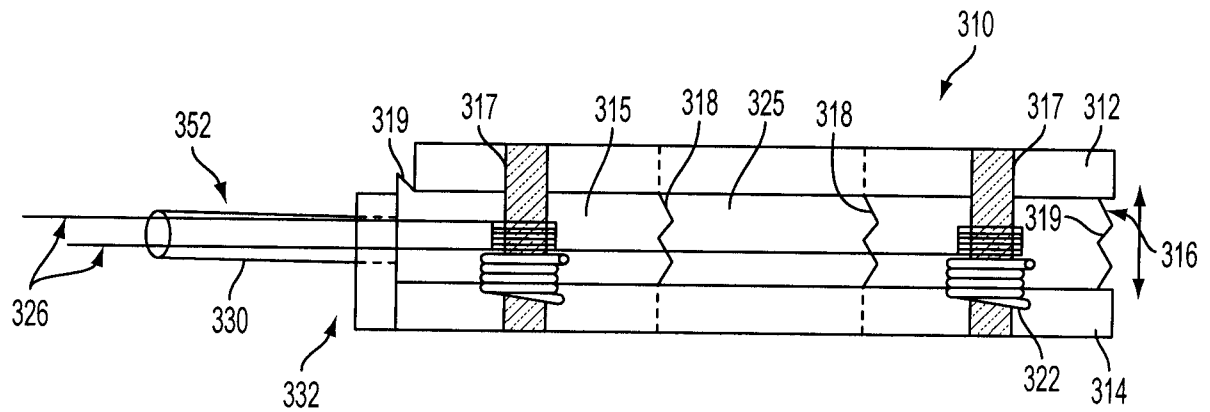


FIG. 9A

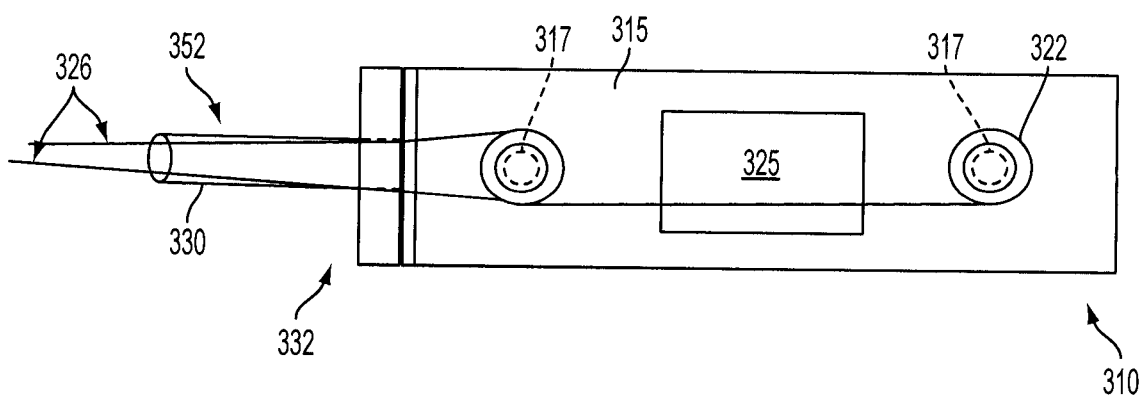


FIG. 9B

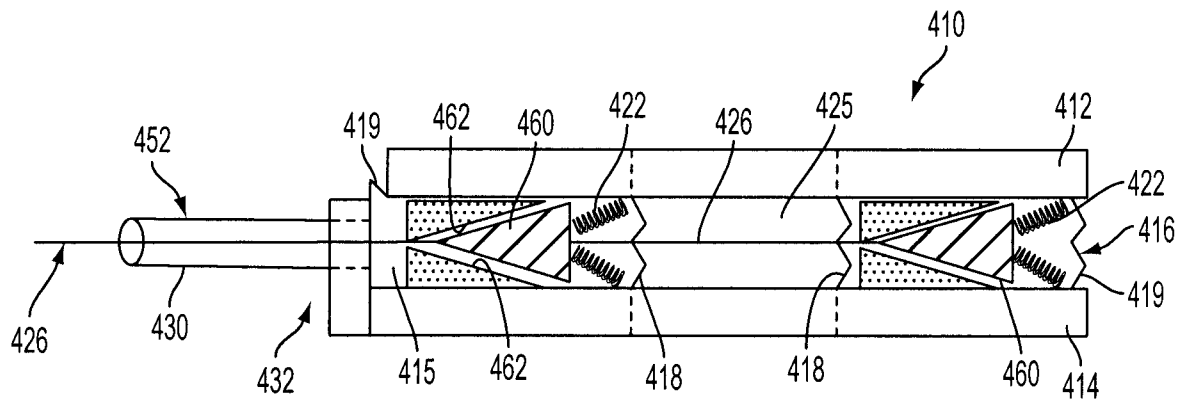


FIG. 10A

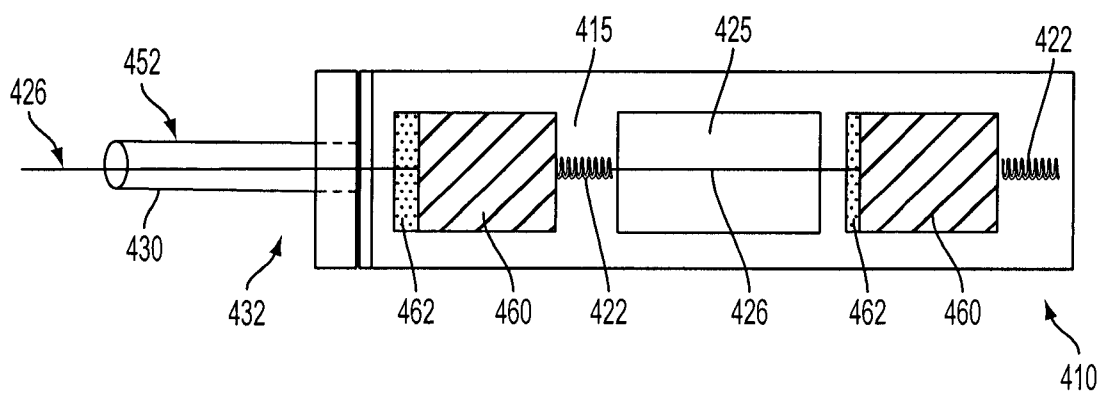


FIG. 10B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2013/050810

A. CLASSIFICATION OF SUBJECT MATTER IPC: A61F 2/44 (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: A61F - all (2006.01) USC: 623/17		
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) EPOQUE, TotalPatent, Canadian Patent Database, Google -Keywords: spinal, vertebral, end+plates, bias*, cable, tension, expansion+control, pulley		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US6063121 (XAVIER et al.) 16.May.2000 (16.05.2000) Figures 1-2	1-28
A	US2005/0165486 (TRIEU) 28.July.2005 (28.07.2005) Figure 13A	1-28
A	US2005/0033437 (BAO et al.) 10.February.2005 (10.02.2005) Figure 6	1-28
A	US2012/0016480 (GERBER et al.) 19.January.2012 (19.01.2012) Entire document	1-28
A	US2002/0055739 (LIEBERMAN) 09.May.2002 (09.05.2002) Entire document	1-28
☐ 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 another 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 04 December 2013 (04.12.2013)		Date of mailing of the international search report 05 December 2013 (05-12-2013)
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 Hoan Huynh (819) 934-3467

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/CA2013/050810**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. : 29
 because they relate to subject matter not required to be searched by this Authority, namely :

 Claim 29 is directed to a method for treatment of the human or animal body by surgery or therapy which the International Search Authority is not required to search.
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/CA2013/050810

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US6063121A	16 May 2000 (16-05-2000)	CA2300613A1 CA2300613C	14 September 2001 (14-09-2001) 23 September 2003 (23-09-2003)
US2005165486A1	28 July 2005 (28-07-2005)	AU2005209281A1 AU2005240008A1 CA2554576A1 CA2562476A1 CN1925317A CN1976650A EP1715819A1 EP1750623A1 US2005165485A1 US7250060B2 US2006259144A1 US8277508B2 US2005187631A1 WO2005072660A1 WO2005107654A1 WO2006107766A2 WO2006107766A3	11 August 2005 (11-08-2005) 17 November 2005 (17-11-2005) 11 August 2005 (11-08-2005) 17 November 2005 (17-11-2005) 07 March 2007 (07-03-2007) 06 June 2007 (06-06-2007) 02 November 2006 (02-11-2006) 14 February 2007 (14-02-2007) 28 July 2005 (28-07-2005) 31 July 2007 (31-07-2007) 16 November 2006 (16-11-2006) 02 October 2012 (02-10-2012) 25 August 2005 (25-08-2005) 11 August 2005 (11-08-2005) 17 November 2005 (17-11-2005) 12 October 2006 (12-10-2006) 15 February 2007 (15-02-2007)
US2005033437A1	10 February 2005 (10-02-2005)	AU2003245321A1 AU2004285471A1 AU2004285471B2 BRPI0415676A CA2543214A1 CN1668259A CN101193607A CN101193607B CN101534751A CN101534752A CN101534752B CN102038563A EP1513475A1 EP1513475A4 EP1682035A2 EP1682035A4 EP2063817A2 EP2063817A4 EP2066267A2 EP2066267A4 JP2005527296A JP2008502372A US2003220691A1 US7001433B2 US2010041777A1 US8114918B2 US2012108685A1 US8222306B2 US2009240333A1 US8231676B2 US2005192671A1 US8241360B2 US2005256581A1 US8262731B2 US2012108684A1 US8314158B2 US2010280619A1 US8377133B2 US8388684B2 US2008103598A1 US2008109081A1 US2010016974A1 US2012310287A1 WO03099172A1 WO2005041818A2 WO2005041818A3	12 December 2003 (12-12-2003) 12 May 2005 (12-05-2005) 25 November 2010 (25-11-2010) 19 December 2006 (19-12-2006) 12 May 2005 (12-05-2005) 14 September 2005 (14-09-2005) 04 June 2008 (04-06-2008) 27 March 2013 (27-03-2013) 16 September 2009 (16-09-2009) 16 September 2009 (16-09-2009) 04 January 2012 (04-01-2012) 04 May 2011 (04-05-2011) 16 March 2005 (16-03-2005) 19 March 2008 (19-03-2008) 26 July 2006 (26-07-2006) 25 April 2012 (25-04-2012) 03 June 2009 (03-06-2009) 18 April 2012 (18-04-2012) 10 June 2009 (10-06-2009) 06 March 2013 (06-03-2013) 15 September 2005 (15-09-2005) 31 January 2008 (31-01-2008) 27 November 2003 (27-11-2003) 21 February 2006 (21-02-2006) 18 February 2010 (18-02-2010) 14 February 2012 (14-02-2012) 03 May 2012 (03-05-2012) 17 July 2012 (17-07-2012) 24 September 2009 (24-09-2009) 31 July 2012 (31-07-2012) 01 September 2005 (01-09-2005) 14 August 2012 (14-08-2012) 17 November 2005 (17-11-2005) 11 September 2012 (11-09-2012) 03 May 2012 (03-05-2012) 20 November 2012 (20-11-2012) 04 November 2010 (04-11-2010) 19 February 2013 (19-02-2013) 05 March 2013 (05-03-2013) 01 May 2008 (01-05-2008) 08 May 2008 (08-05-2008) 21 January 2010 (21-01-2010) 06 December 2012 (06-12-2012) 04 December 2003 (04-12-2003) 12 May 2005 (12-05-2005) 15 November 2007 (15-11-2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2013/050810

US2012016480A1	19 January 2012 (19-01-2012)	AT400237T	15 July 2008 (15-07-2008)
		AU2003262694A1	03 March 2004 (03-03-2004)
		AU2003262694B2	23 October 2008 (23-10-2008)
		AU2003262695A1	03 March 2004 (03-03-2004)
		AU2003262695B2	04 December 2008 (04-12-2008)
		BR0313499A	05 July 2005 (05-07-2005)
		BR0313502A	12 July 2005 (12-07-2005)
		CA2495373A1	26 February 2004 (26-02-2004)
		CA2495373C	24 July 2012 (24-07-2012)
		CA2495404A1	26 February 2004 (26-02-2004)
		CA2495404C	03 May 2011 (03-05-2011)
		EP1531765A2	25 May 2005 (25-05-2005)
		EP1531765B1	09 July 2008 (09-07-2008)
		EP1542626A2	22 June 2005 (22-06-2005)
		EP1542626B1	26 September 2012 (26-09-2012)
		ES2310255T3	01 January 2009 (01-01-2009)
		US2005197702A1	08 September 2005 (08-09-2005)
		US7563284B2	21 July 2009 (21-07-2009)
		US2005251260A1	10 November 2005 (10-11-2005)
		US7563286B2	21 July 2009 (21-07-2009)
		US8435301B2	07 May 2013 (07-05-2013)
		US2009270992A1	29 October 2009 (29-10-2009)
		WO2004016205A2	26 February 2004 (26-02-2004)
		WO2004016205A3	27 May 2004 (27-05-2004)
		WO2004016205A9	08 July 2004 (08-07-2004)
		WO2004016217A2	26 February 2004 (26-02-2004)
		WO2004016217A3	22 July 2004 (22-07-2004)
		ZA200501542A	28 March 2007 (28-03-2007)
		ZA200501543A	28 March 2007 (28-03-2007)
US2002055739A1	09 May 2002 (09-05-2002)	AU1301402A	15 April 2002 (15-04-2002)
		AU9638001A	15 April 2002 (15-04-2002)
		CA2424173A1	11 April 2002 (11-04-2002)
		CA2424173C	17 April 2007 (17-04-2007)
		CA2424261A1	11 April 2002 (11-04-2002)
		CA2424261C	11 December 2007 (11-12-2007)
		CA2435694A1	06 February 2003 (06-02-2003)
		CA2440469A1	10 July 2003 (10-07-2003)
		CA2444698A1	24 October 2002 (24-10-2002)
		CA2444698C	29 August 2006 (29-08-2006)
		EP1322242A1	02 July 2003 (02-07-2003)
		EP1322242A4	07 June 2006 (07-06-2006)
		EP1322242B1	15 August 2007 (15-08-2007)
		EP1322263A1	02 July 2003 (02-07-2003)
		EP1322263A4	21 November 2007 (21-11-2007)
		EP1322263B1	02 September 2009 (02-09-2009)
		EP1370184A1	17 December 2003 (17-12-2003)
		EP1370184A4	21 June 2006 (21-06-2006)
		EP1377200A2	07 January 2004 (07-01-2004)
		EP1379183A1	14 January 2004 (14-01-2004)
		EP1379183A4	14 June 2006 (14-06-2006)
		EP1643921A1	12 April 2006 (12-04-2006)
		US6468309B1	22 October 2002 (22-10-2002)
		US6488683B2	03 December 2002 (03-12-2002)
		US2002055742A1	09 May 2002 (09-05-2002)
		US6527774B2	04 March 2003 (04-03-2003)
		US2002055737A1	09 May 2002 (09-05-2002)
		US6544265B2	08 April 2003 (08-04-2003)
		US2002055738A1	09 May 2002 (09-05-2002)
		US6551319B2	22 April 2003 (22-04-2003)
		US2002055740A1	09 May 2002 (09-05-2002)
		US6551320B2	22 April 2003 (22-04-2003)
		US6551322B1	22 April 2003 (22-04-2003)
		US2002183847A1	05 December 2002 (05-12-2002)
		US6689168B2	10 February 2004 (10-02-2004)
		US2003181913A1	25 September 2003 (25-09-2003)
		US6953462B2	11 October 2005 (11-10-2005)
		US2006009769A1	12 January 2006 (12-01-2006)
		US7601167B2	13 October 2009 (13-10-2009)
		US2004073216A1	15 April 2004 (15-04-2004)
		WO0228297A1	11 April 2002 (11-04-2002)
		WO0228323A1	11 April 2002 (11-04-2002)