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Michelson

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(54) **EXPANDABLE INTERBODY SPINAL FUSION IMPLANT WITH EXPANSION CONSTRAINING MEMBER AND METHOD FOR USE THEREOF**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 714 days.

This patent is subject to a terminal disclaimer.

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(60) Provisional application No. 60/274,869, filed on Mar. 9, 2001.

(51) **Int. Cl.**
A61F 2/44 (2006.01)
A61F 2/30 (2006.01)

(52) **U.S. Cl.** **623/17.11**; 623/17.15

(58) **Field of Classification Search** .. 623/17.11–17.16; 606/61
See application file for complete search history.

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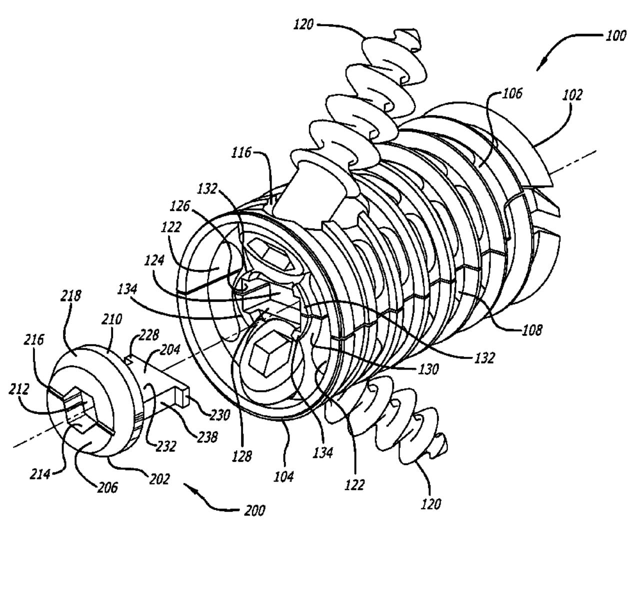
(57) **ABSTRACT**

An implant cap is disclosed for preventing the over-expansion of an expandable spinal implant and method for use therewith. An implant cap also is disclosed for moving an expandable spinal implant from a collapsed position to an expanded position with less than one full turn of the implant cap and a method for use therewith. A screw lock is disclosed for locking a bone screw to the trailing end of an expandable spinal implant and a method for use therewith.

43 Claims, 7 Drawing Sheets



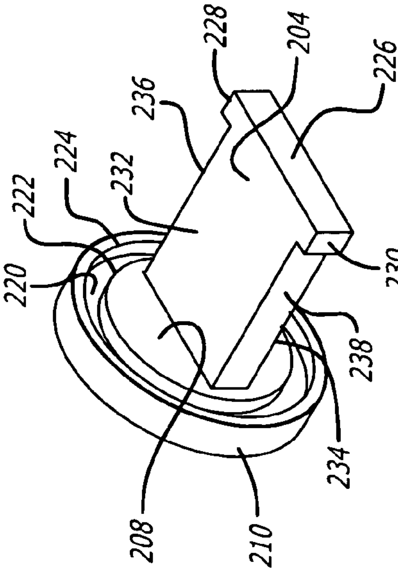

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FIG. 2

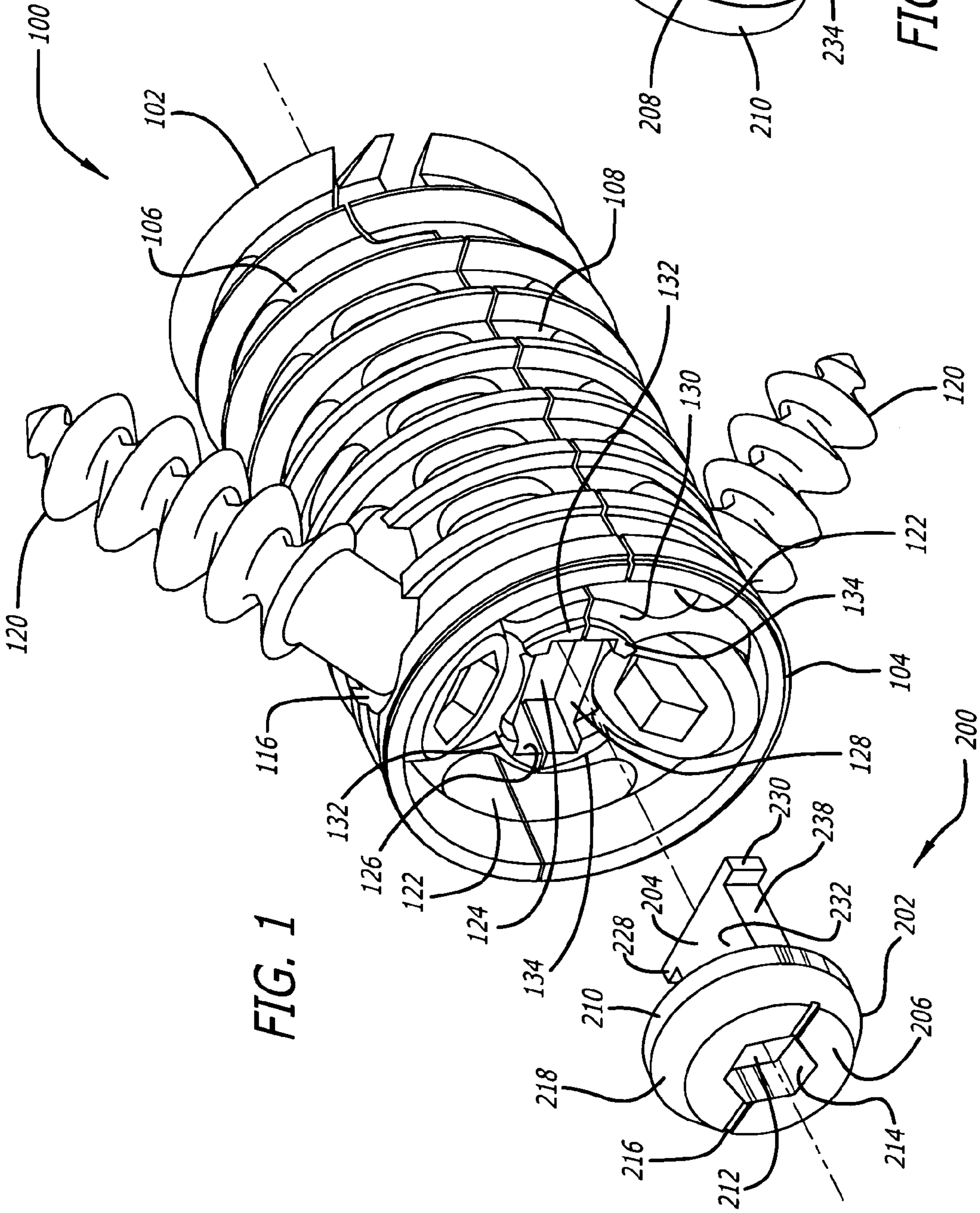
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FIG. 1

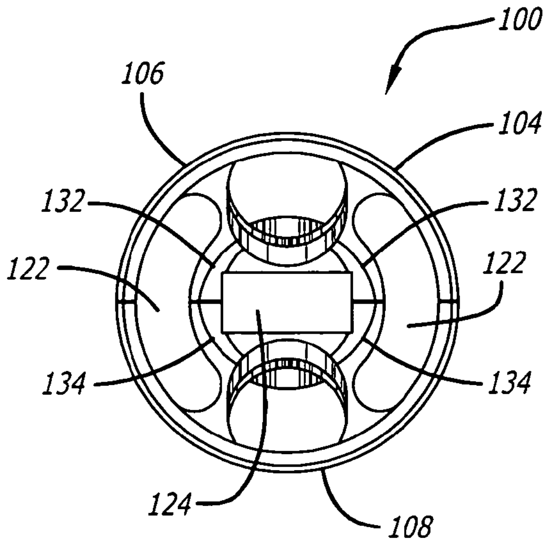


FIG. 3A

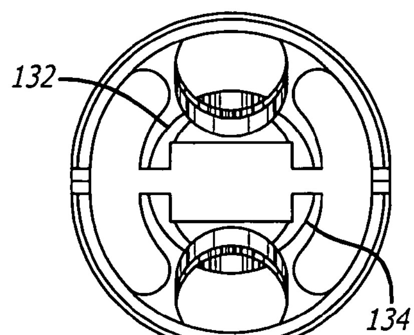


FIG. 3B

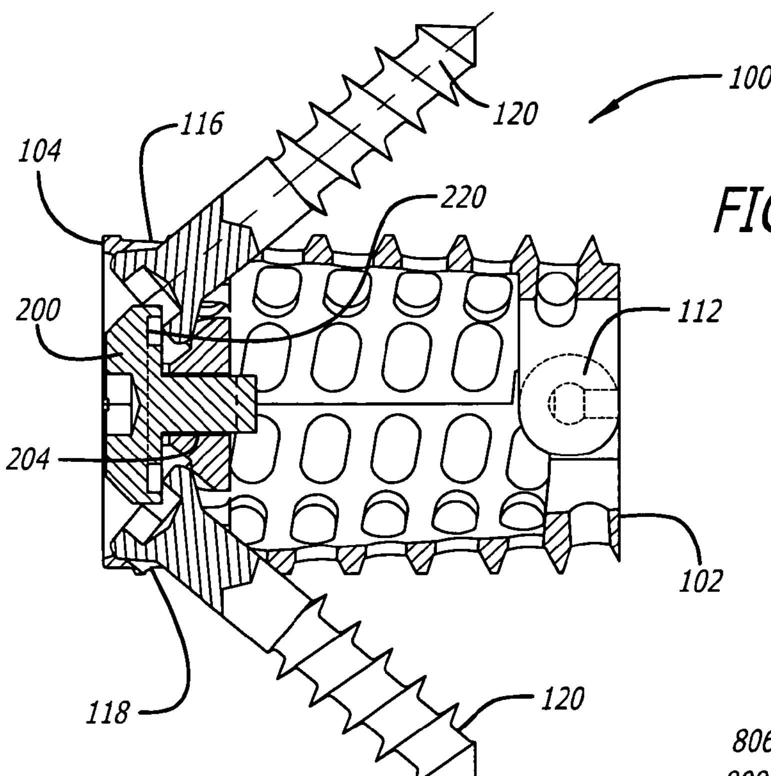
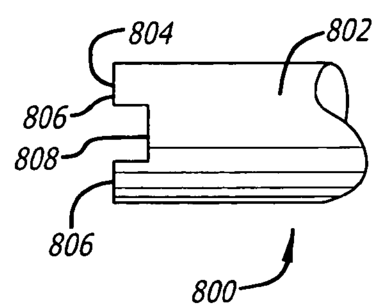


FIG. 4A

FIG. 4B



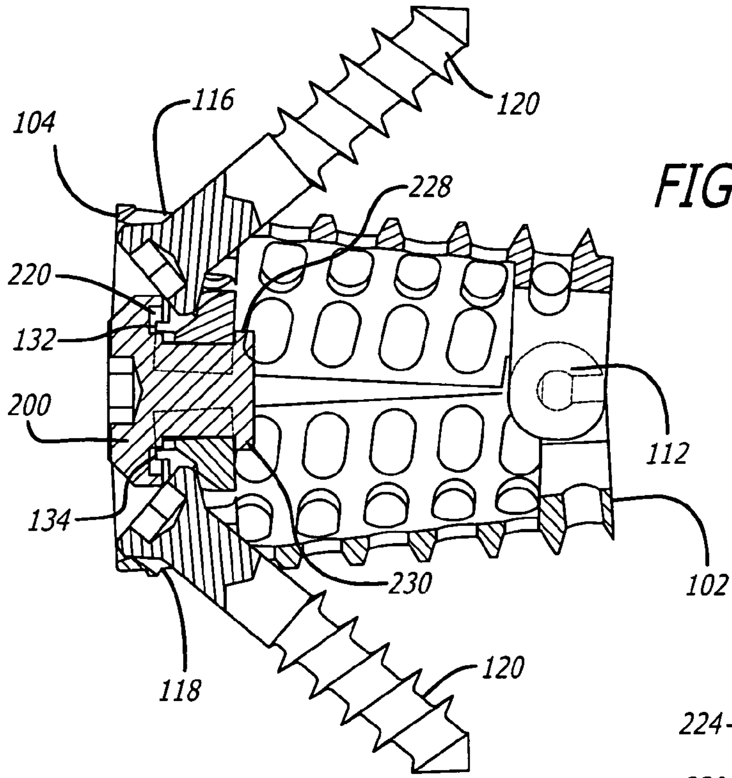


FIG. 5

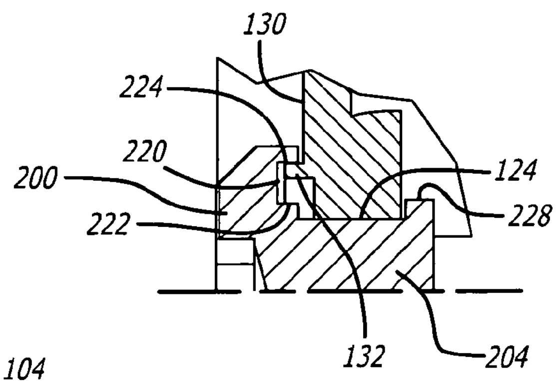


FIG. 7

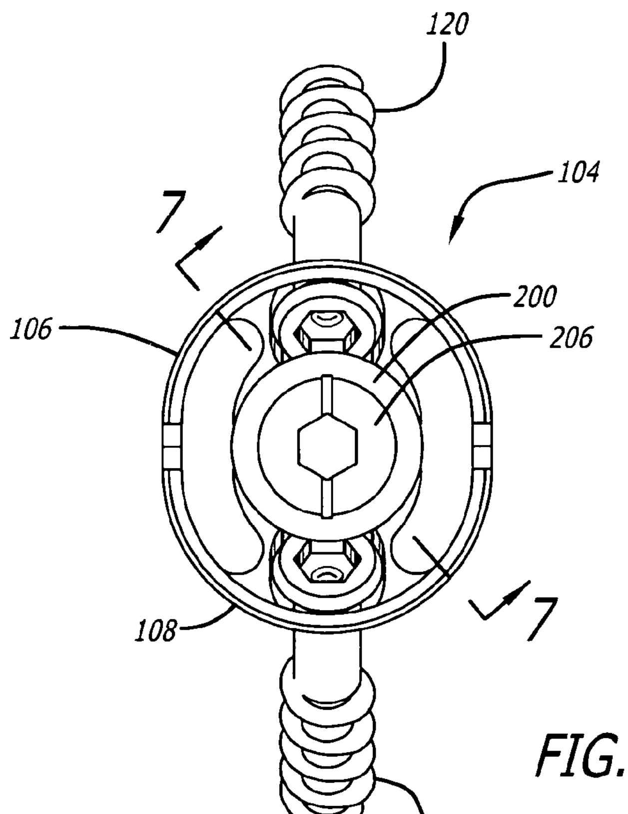
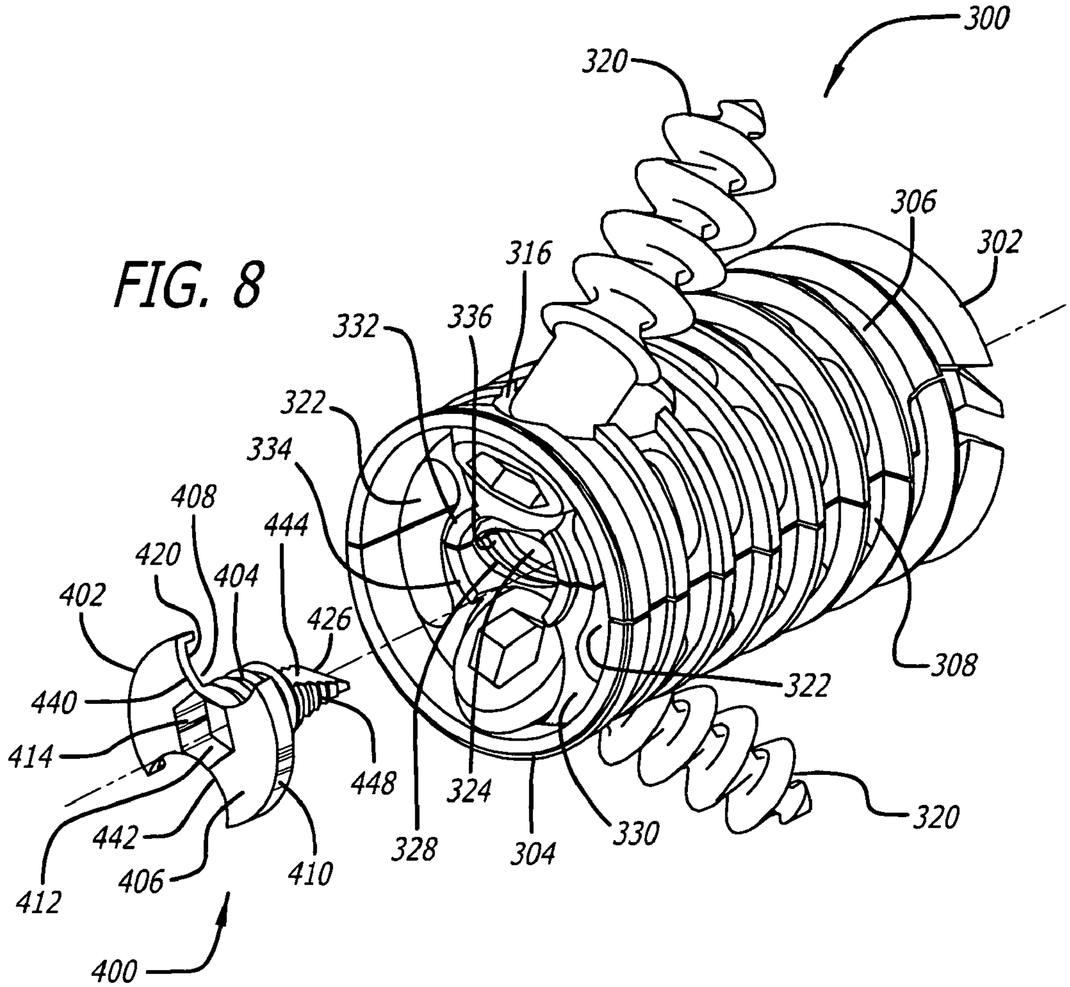


FIG. 6

FIG. 8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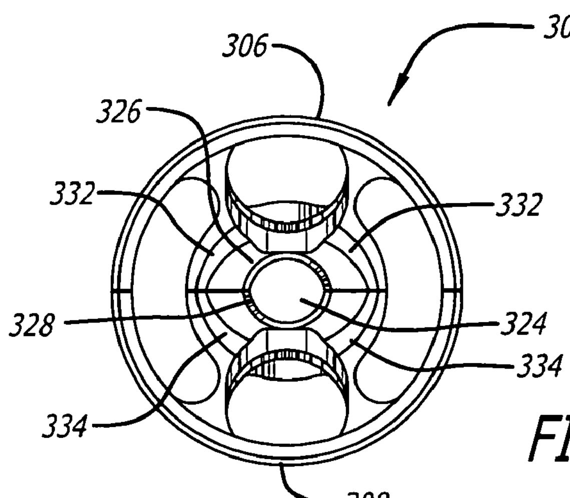
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FIG. 9

FIG. 10

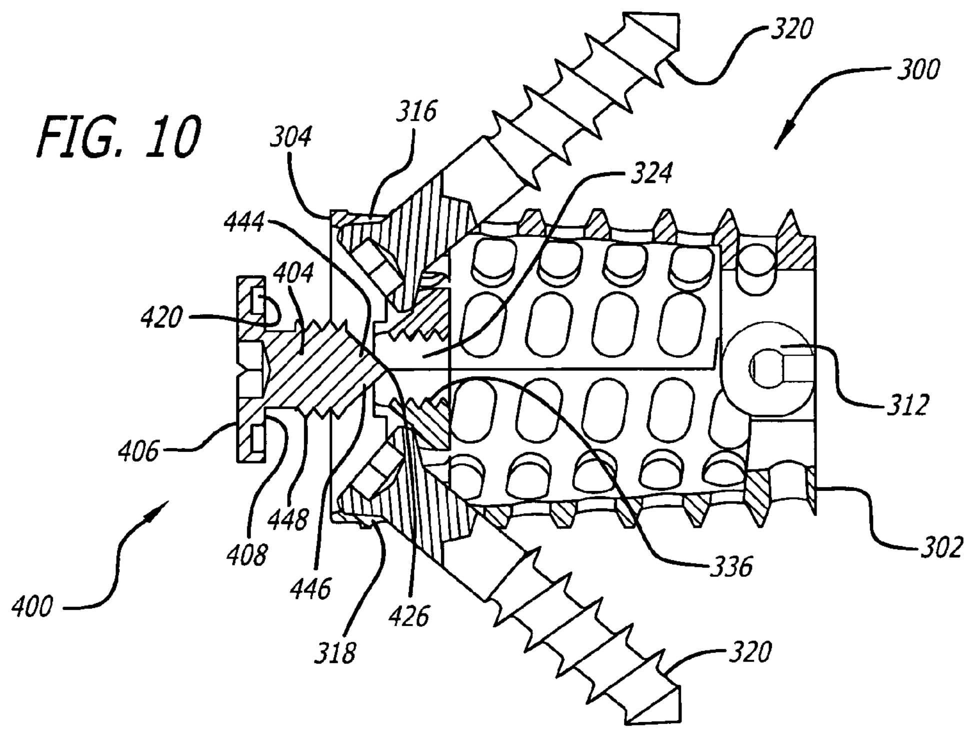
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FIG. 11

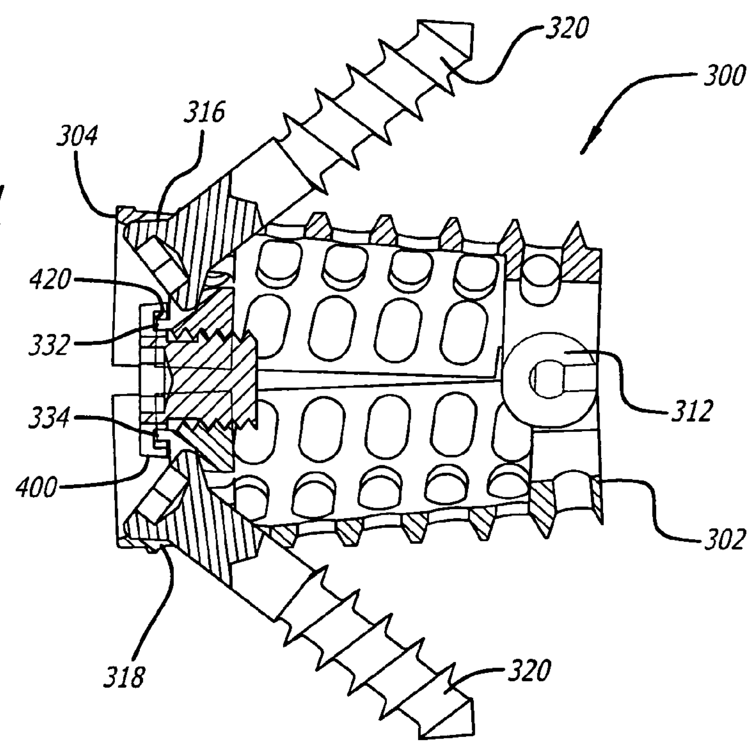
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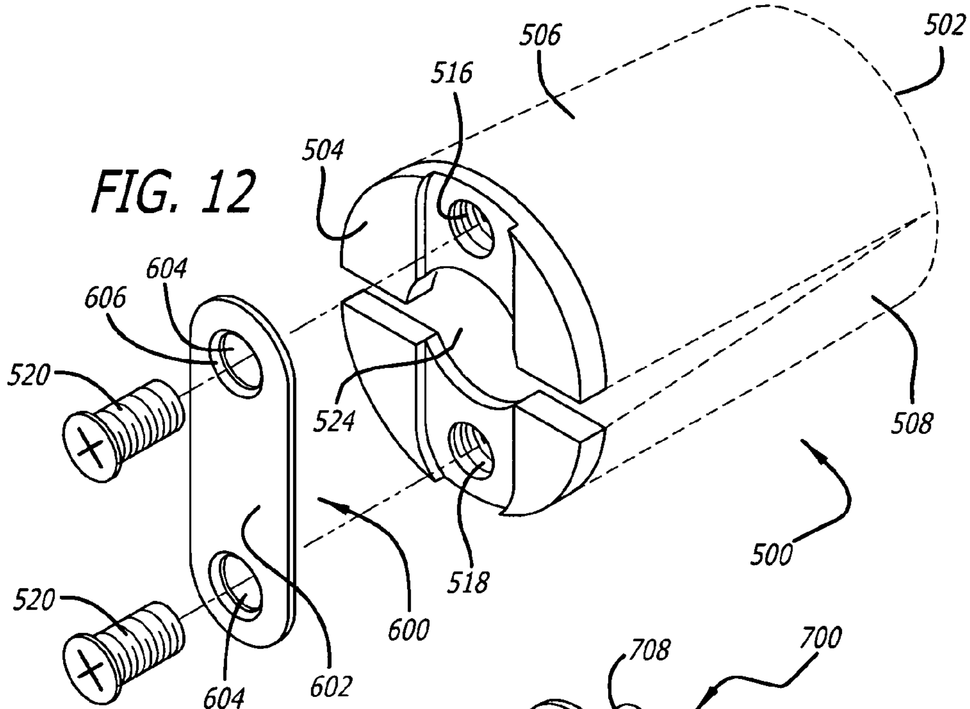
FIG. 12



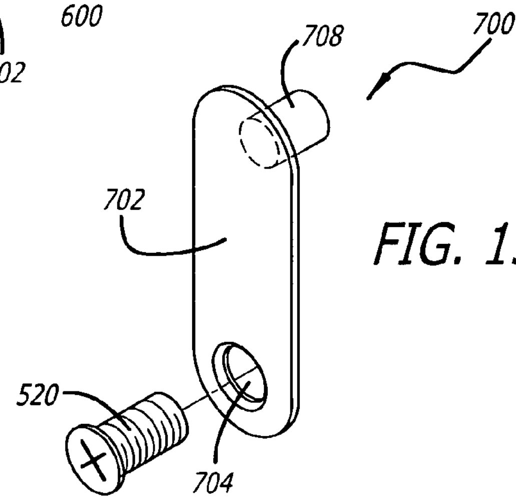


FIG. 13

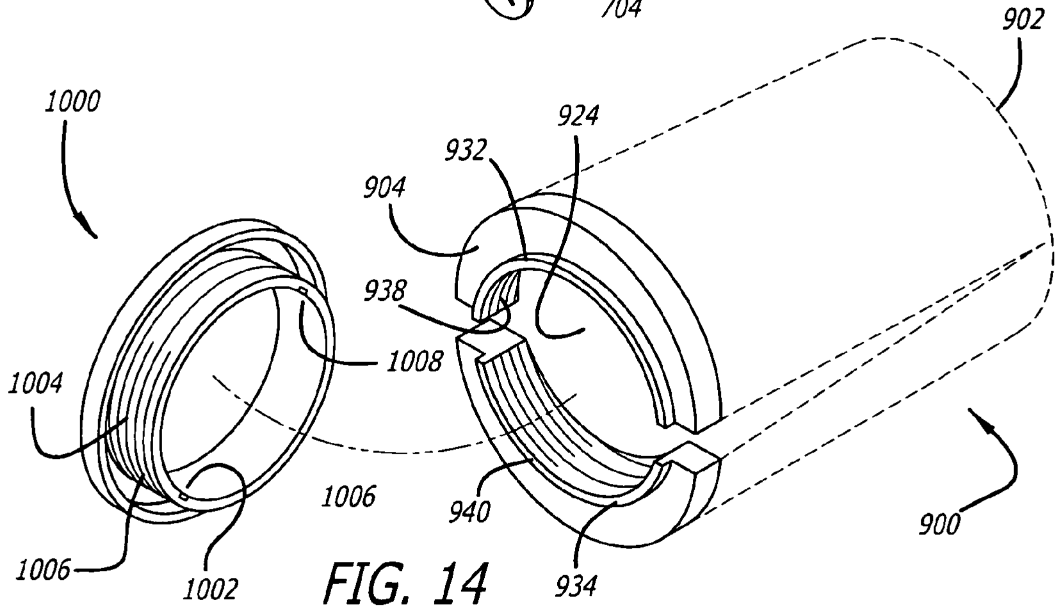


FIG. 14

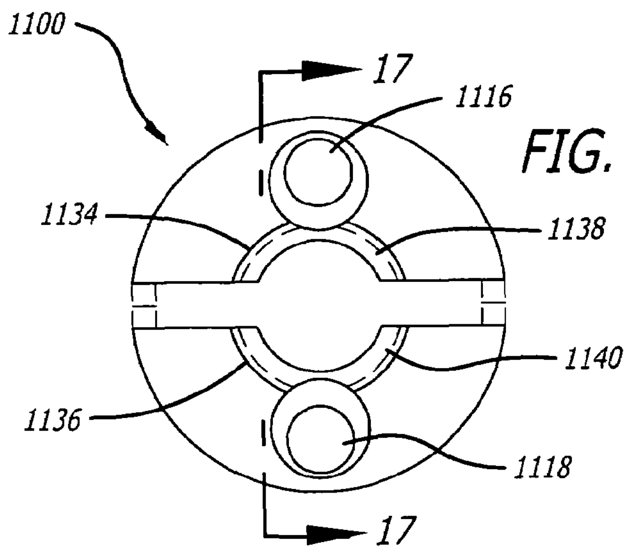


FIG. 15

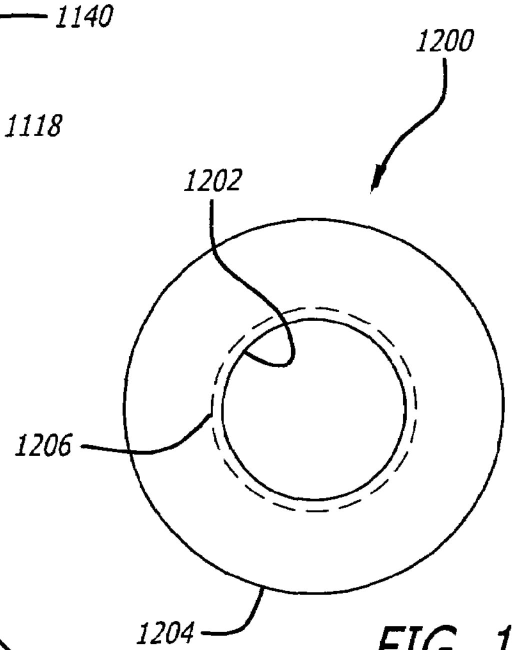


FIG. 16

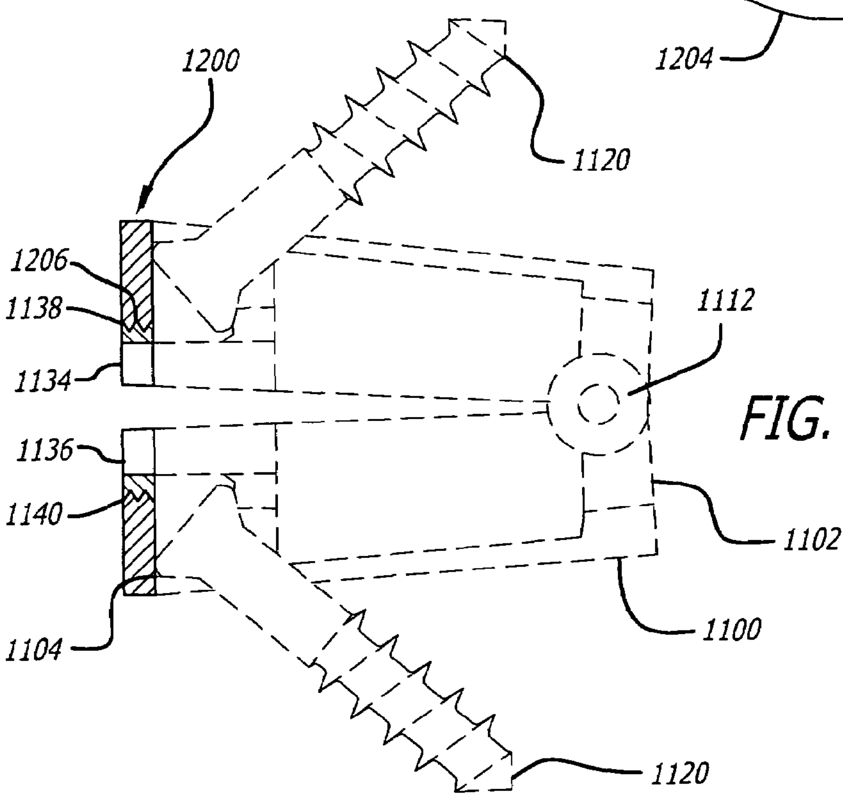


FIG. 17

EXPANDABLE INTERBODY SPINAL FUSION IMPLANT WITH EXPANSION CONSTRAINING MEMBER AND METHOD FOR USE THEREOF

RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 10/094,467, filed Mar. 8, 2002 now U.S. Pat. No. 6,849,093, which claims the benefit of U.S. provisional Application No. 60/274,869, filed Mar. 9, 2001, the disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Expandable implants are known in the field of spinal surgery. Many expandable implants require complex mechanisms in order to expand the implant. Greatly simplifying the expansion of an expandable implant is a device taught by Michelson in U.S. patent application Ser. No. 09/551,964, the disclosure of which is incorporated by reference herein, that moves the implant from a collapsed position to an expanded position with less than one full turn of an expander used to expand the implant. Expandable implants often have no provision for preventing the over-expansion of the implant while the implant is being expanded in the disc space. One of the embodiments of expandable implants taught by Michelson in the '964 application utilizes a hook and peg arrangement that is integral with the implant to prevent over-expansion.

In certain circumstances, the upper and lower members of the expandable implant can move away from one another and merely securing the upper and lower members to the adjacent vertebral bodies either with vertebral body engaging projections or with bone screws is not adequate. An example of such a circumstance occurs when the surgeon elects to approach the spine anteriorly, which generally requires severing, and/or removing substantial portions of the anterior longitudinal ligament over the operated area. The anterior longitudinal ligament is positioned along the anterior spinal surface and prevents hyperextension of the spine as an individual bends backward. Because the anterior longitudinal ligament covers the anterior spinal surface, the surgeon must cut through this tough ligament to access the disc space below, compromising the stability of the spine. Specifically, the anterior longitudinal ligament is generally lax, except when an individual leans backward, then the ligament acts as a tension band resisting elongation. If the anterior longitudinal ligament is damaged, there is no check on that spinal movement and the vertebral bodies may detrimentally angulate. Thus, what is needed is a simple, easy-to-use device that can either or both expand and prevent the over-expansion of an implant, and further can be used, if desired, to lock bone screws to an implant having bone screws therein.

SUMMARY OF THE INVENTION

The expansion constraining member of the present invention is capable of one or more of the following functions: (1) expands the implant by moving the upper and lower members apart, (2) maintains the implant in an expanded state by holding at least a portion of the upper and lower members apart so as to maintain the increased height of the implant and resist the collapse of the implant to the collapsed implant height, (3) prevents the implant from expanding beyond a predetermined amount by engaging at least a portion of the upper and lower members, and (4) locks bone screws to the implant by blocking the exit path of the bone screws in a direction opposite to the direction of insertion. Expansion of the implant preferably increases the implant height only, that is in a plane passing through the mid-longitudinal axis of the implant and the upper and lower members. The expansion constraining member preferably resists further expansion of the implant and makes possible vertical stability of the implant at its expandable end. The use of screws allows reconstruction of the function of the anterior longitudinal ligament. In a preferred embodiment, the expansion constraining member is capable of performing all four of the aforementioned enumerated functions.

The expansion constraining member of the present invention offers numerous advantages over devices of the prior art, a few of which include economy of parts, simplicity, and less mass occupying the interior of the implant. If the expansion constraining member is also a blocker to maintain the implant in an expandable state, an additional blocker is not needed in the implant itself. If the expansion constraining member is also an expander for expanding the implant to an expanded position, an additional expander is not needed. If the expansion constraining member is also a lock for locking the bone screws to the implant, an additional lock to lock the bone screws is not needed. An expansion constraining member capable of performing the aforementioned functions in one structure reduces the number of parts needed to perform additional functions. Further, the expansion constraining member of the present invention is preferably adapted to occupy less space of the implant interior, thereby increasing the available volume for holding fusion promoting materials in the implant.

In accordance with the purposes of the present invention, as embodied and broadly described herein, an implant cap of this invention is provided for use in expanding an expandable spinal implant having upper and lower portions adapted to move apart from one another to contact adjacent upper and lower vertebral bodies, respectively, of a human spine. The cap includes a head having a top surface and a bottom surface opposite the top surface. The head is configured to cooperatively engage an end of the implant to at least in part cover an opening in the end of the implant. The cap also includes a stem projecting from the bottom surface of the head. The stem has a distal end, opposed sides having a width therebetween, and upper and lower surfaces having a height therebetween. The width of the stem is greater than the height of the stem proximate the distal end of the stem when the cap is in an insertion position. The opposed sides are configured to move the upper and lower portions of the implant apart from one another when the cap is rotated from the insertion position to a deployed position.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an implant cap is provided for use in preventing the over-expansion of an expandable spinal implant having upper and lower portions adapted to move apart from one another to contact adjacent upper and lower vertebral bodies, respectively, in the human spine. The cap includes a head configured to cooperatively engage an end of the implant to at least in part cover an opening in the end of the implant. The head has a top surface and a bottom surface opposite the top surface. The bottom surface of the head of the cap has either a recess or a protrusion adapted to cooperatively engage either a protrusion or a recess, respectively, on the end of the implant to prevent the implant from expanding beyond a predetermined height. The cap also includes a stem projecting from the bottom surface of the head. The stem is adapted for insertion into the opening of the implant.

The implant cap may be part of an apparatus for insertion within an implantation space formed across the height of a disc space between vertebral bodies of a human spine. The apparatus includes an expandable spinal implant having upper and lower portions adapted to move apart from one another to contact adjacent upper and lower vertebral bodies, respectively. The implant has an end having an opening. Each of the upper and lower portions of the implant have either a recess or a protrusion to cooperatively engage either a protrusion or a recess, respectively, on the bottom surface of the cap to prevent the implant from expanding beyond a predetermined height.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, a method of this invention is provided for engaging an end cap having a stem to an expandable spinal implant having an end. The method includes the steps of inserting the stem of the end cap into the end of the implant; rotating the stem of the end cap to expand the height of the implant; and using a portion of the end cap to prevent the implant from expanding beyond a predetermined height.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, a method of this invention is provided for expanding an expandable spinal implant having an end. The method includes the steps of providing an end cap having a stem projecting therefrom; inserting at least a portion of the stem of the end cap into the end of the implant while the implant is in a collapsed position; and rotating the stem of the end cap less than one full turn to expand the implant from the collapsed position to an expanded position.

The accompanying drawings, which are incorporated in and constitute a part of this specification, are by way of example only and not limitation, and illustrate several embodiments of the invention, which together with the description, serve to explain the principles of the invention. The scope of the invention is limited only by the scope of the claims as from the present teachings other embodiments of the present invention shall be apparent to those skilled in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded trailing end perspective view of an expandable interbody spinal fusion implant with an expanding and constraining member in the form of an end cap for expanding the implant, blocking an opening to the implant, restraining over-expansion of the implant, and locking bone screws to the implant in accordance with a preferred embodiment of the present invention;

FIG. **2** is a leading end perspective view of the end cap of FIG. **1**;

FIG. **3**A is a trailing end elevation view of the implant of FIG. **1** in a collapsed state;

FIG. **3**B is a trailing end elevation view of the implant of FIG. **1** in an expanded state;

FIG. **4**A is a side elevation view in partial cross section of the implant of FIG. **1** in an unexpanded state and with the end cap inserted therein;

FIG. **4**B is a fragmentary side elevation view of an expander tool for expanding an expandable interbody spinal fusion implant from a posterior approach to the spine;

FIG. **5** is a side elevation view in partial cross section of the implant of FIG. **1** in an expanded state and with the end cap inserted therein;

FIG. **6** is a trailing end elevation view of the implant of FIG. **1** in an expanded state with the end cap inserted and in the locked position;

FIG. **7** is a fragmentary cross sectional side elevation view along line **7**-**7** of the implant of FIG. **6** showing a lip portion of the implant trailing end against the outer perimeter of a recess in the end cap for preventing over-expansion of the implant;

FIG. **8** is a trailing end perspective view of an expandable interbody spinal fusion implant with an expanding and constraining end cap for expanding the implant, blocking an opening to the implant, restraining over-expansion of the implant, and locking bone screws to the implant in accordance with another preferred embodiment of the present invention;

FIG. **9** is a trailing end elevation view of the implant of FIG. **8**;

FIG. **10** is a side elevation view in partial cross section of the implant of FIG. **8** in an unexpanded state and with the end cap being inserted therein;

FIG. **11** is a side elevation view in partial cross section of the implant of FIG. **8** in an expanded state with the end cap inserted therein;

FIG. **12** is a trailing end perspective view of an expandable interbody spinal fusion implant and an end member for constraining over-expansion of the implant in accordance with another preferred embodiment of the present invention;

FIG. **13** is a trailing end perspective view of an end member for constraining over-expansion of the implant in accordance with another preferred embodiment of the present invention;

FIG. **14** is a trailing end perspective view of an expandable interbody spinal fusion implant with an expansion constraining member in the form of a constraining ring for restraining over-expansion of the implant in accordance with another preferred embodiment of the present invention;

FIG. **15** is a trailing end elevation view of an expandable interbody spinal fusion implant in accordance with another preferred embodiment of the present invention;

FIG. **16** is a trailing end elevation view of an expansion constraining member in the form of a constraining ring for restraining over-expansion of the implant of FIG. **15** in accordance with another preferred embodiment of the present invention; and

FIG. **17** is a side elevation view in partial cross section and hidden line of the implant of FIG. **15** in an expanded state and with the constraining ring of FIG. **16** installed.

DETAILED DESCRIPTION OF THE DRAWINGS

Reference will now be made in detail to the present preferred embodiments (exemplary embodiments) of the invention, examples of which are illustrated in the accompanying drawings.

The expansion constraining member of the present invention is adapted for use with expandable interbody spinal fusion implants. To better understand the structure and interrelationship of the expansion constraining member and the expandable interbody spinal fusion implant, the structure and associated characteristics for one embodiment of an implant adapted to be used with the expansion constraining member of the present invention will be described first.

FIGS. **1**-**7** show a preferred embodiment of an expandable interbody spinal fusion implant **100** and an expansion constraining end cap **200** for use therewith in accordance with the present invention. The expansion constraining member of the present invention is not limited for use with implant

100 and may be used with other expandable interbody spinal fusion implants such as, but not limited to, those taught by Michelson in WIPO Publication No. 01/56513, entitled “Expandable Impacted Interbody Spinal Fusion Implant,” U.S. patent application Ser. No. 09/612,188, entitled “Expandable Push-In Arcuate Interbody Spinal Fusion Implant with Cylindrical Configuration During Insertion,” U.S. patent application Ser. No. 09/551,964, entitled “Expandable Threaded Arcuate Interbody Spinal Fusion Implant with Cylindrical Configuration During Insertion,” U.S. patent application Ser. No. 09/574,858, entitled “Expandable Threaded Arcuate Interbody Spinal Fusion Implant with Lordotic Configuration During Insertion,” U.S. patent application Ser. No. 09/772,309, entitled “Expandable Push-In Arcuate Interbody Spinal Fusion Implant with Tapered Configuration During Insertion,” the disclosures of which are incorporated by reference herein,

As shown in FIGS. **1**, **3**A, and **3**B, implant **100** has a leading end **102**, a trailing end **104**, an upper member **106**, and a lower member **108**. Upper and lower members **106**, **108** are each preferably arcuate at least in part and adapted for placement toward and at least in part within the upper and lower of two adjacent vertebral bodies, respectively. Upper and lower members **106**, **108** preferably include at least one opening adapted to communicate with one of the adjacent vertebral bodies, the openings being in communication with one another and adapted for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through the implant. Upper and lower portions **106**, **108** also preferably define a hollow interior therebetween for holding bone growth promoting material, the hollow interior preferably being in communication with the openings in upper and lower portions **106**, **108**. Trailing end **104** of implant **100** preferably includes openings **122** to permit for the packing of additional fusion promoting substances into the implant after the implant expansion and the application of the locking member, and to permit for the growth of bone through implant **100**.

As shown in FIGS. **4** and **5**, upper and lower members **106**, **108** are moveable relative to one another and have a first position that allows for a collapsed implant height and a second position that allows for an increased height. Upper and lower members **106**, **108** are preferably articulated at an articulation point proximate leading end **102** of implant **100**. Upper and lower members **106**, **108** are articulated to one another at a pivot point **112** so one of the respective ends of upper and lower members **106**, **108** remain articulated while the other of the respective ends of upper and lower members **106**, **108** are free to move away from one another. The cooperating rotational articulation **112** preferably is proximate one of the proximal end and the distal end of upper and lower members **106**, **108** at an end opposite to an end cap **200**. Other types of articulation as would be known to one of ordinary skill in the art are within the scope of the present invention.

Upper and lower members **106**, **108** preferably have an upper screw hole **116** and a lower screw hole **118**, respectively passing therethrough, each adapted to receive a bone screw **120** passing from the interior of implant **100** into an adjacent vertebral body to anchor implant **100** to an adjacent vertebral body. Bone screws are not essential to the operation of the implant, but are preferable for providing added securement of the implant to the adjacent vertebral bodies.

In certain circumstances, upper and lower members **106**, **108** can move away from one another and merely securing upper and lower members **106**, **108** to the adjacent vertebral bodies with bone screws is not adequate. An example of such a circumstance occurs when the surgeon elects to approach the spine anteriorly, which generally requires severing and/or removing substantial portions of the anterior longitudinal ligament over the operated area. The anterior longitudinal ligament is positioned along the anterior spinal surface and prevents hyperextension of the spine as an individual bends backward. Because the anterior longitudinal ligament covers the anterior spinal surface, the surgeon must cut through this tough ligament to access the disc space below, compromising the stability of the spine. Specifically, the anterior longitudinal ligament is generally lax, except when an individual leans backward, then the ligament acts as a tension band resisting elongation. If the anterior longitudinal ligament is damaged, there is no check on that spinal movement and the vertebral bodies may detrimentally angulate. Thus, a mechanism is needed to prevent movement of the upper and lower members relative to one another beyond a predetermined amount.

The expansion constraining member of the present invention is capable of one or more of the following functions: (1) expands the implant by moving the upper and lower members apart, (2) maintains the implant in an expanded state by holding at least a portion of the upper and lower members apart so as to maintain the increased height of the implant and resist the collapse of the implant to the collapsed implant height, (3) prevents the implant from expanding beyond a predetermined amount by engaging at least a portion of the upper and lower members, and (4) locks bone screws to the implant by blocking the exit path of the bone screws in a direction opposite to the direction of insertion. Expansion of the implant preferably increases the implant height only, that is in a plane passing through the mid-longitudinal axis of the implant and the upper and lower members. The expansion constraining member preferably resists further expansion of the implant and makes possible vertical stability of the implant at its expandable end. The use of screws allows reconstruction of the function of the anterior longitudinal ligament. In a preferred embodiment, the expansion constraining member is capable of performing all four of the aforementioned enumerated functions.

The expansion constraining member of the present invention offers numerous advantages over devices of the prior art, a few of which include economy of parts, simplicity, and less mass occupying the interior of the implant. If the expansion constraining member is also a blocker to maintain the implant in an expandable state, an additional blocker is not needed in the implant itself. If the expansion constraining member is also an expander for expanding the implant to an expanded position, an additional expander is not needed. If the expansion constraining member is also a lock for locking the bone screws to the implant, an additional lock to lock the bone screws is not needed. An expansion constraining member capable of performing the aforementioned functions in one structure reduces the number of parts needed to perform additional functions. Further, the expansion constraining member of the present invention is preferably adapted to occupy less space of the implant interior, thereby increasing the available volume for holding fusion promoting materials in the implant.

As shown in FIGS. **1**, **3**A, and **3**B, trailing end **104** also preferably has an opening **124** adapted to engage end cap **200** and may also provide access to the interior of implant **100** for the purpose of introducing bone growth promoting materials therein. Upper and lower interior surfaces **126**, **128** of opening **124** preferably have a portion that extends beyond exterior trailing end surface **130**, forming upper lip portions **132** and lower lip portions **134**, respectively. Upper and lower lip portions **132**, **134** can be arcs of a circle such that in the expanded state, the arcs would be part of the same circle. For example, when implant **100** is in an unexpanded state, the profile of upper and lower lip portions **132**, **134** preferably form the shape of at least a portion of an oval as shown in FIG. **3**A. In the expanded state of implant **100**, the profile of upper and lower lip portions **132**, **134** preferably becomes less oval and generally more circular in shape as shown in FIG. **3**B.

Cap **200** preferably has a head **202** and a stem **204**. Head **202** has a perimeter preferably sized and shaped to cover at least a portion of upper and lower bone screw holes **116**, **118** so as to lock bone screws **120** to implant **100**. Preferably, the perimeter of head **202** has at least one arcuate portion. Head **202** has a top surface **206**, a bottom surface **208**, and a rim **210**. Top surface **206** has a tool engagement area **212** that is preferably adapted to cooperatively engage an insertion tool. Tool engagement area **212** preferably includes a hex-shaped recess **214** adapted to engage the end of a correspondingly-shaped tool. A groove or marking **216** allows the surgeon to visually confirm the orientation of end **204** when hidden from view. Other shapes are possible for tool engagement area **212** depending upon the type of insertion tool used with the present invention, all of which are within the broad scope of the present invention.

Top surface **206** of cap **200** preferably has a bevel **218** extending around the perimeter thereof to form a reduced profile. Top surface **206** may have any shape suitable for its intended purpose though it is preferable that cap **206** generally not extend from trailing end **104** so as to avoid any undesired contact with delicate vascular and/or neurological structures adjacent thereto after implant **100** is installed in the spine.

As shown in FIG. **2**, bottom surface **208** of cap **200** has a recess **220** proximate the perimeter of bottom surface **208** that is adapted to interact with upper and lower lip portions **132**, **134** of implant **100**. As described in further detail below, the interaction of lip portions **132**, **143** and recess **120** limits any unwanted expansion or over-expansion of implant **100** beyond a predetermined height. Recess **220** has an inner perimeter **222**, an outer perimeter **224**, and a width therebetween adapted to accommodate the profiles of at least a portion of upper and lower lips **132**, **134** of implant **100** in both an unexpanded and expanded state. The surface of outer perimeter **224** forms a flange that acts as a stop against which upper and lower lip portions **132**, **134** of implant **100** are prevented from further movement away from the mid-longitudinal axis of implant **100** when implant **100** and cap **200** are engaged, as will be described in more detail below.

Stem **204** of cap **200** projects from bottom surface **208** and is sized and shaped to cooperatively engage opening **124** in trailing end **104** to expand implant **100** and to maintain implant **100** in an expanded state. Stem **204** preferably has a distal end **226** with tabs **228**, **230**, an upper surface **232**, a lower surface **234** opposite to upper surface **232**, and sides **236**, **238**. Tabs **228**, **230** are configured to engage the interior surface of trailing end **104** such that when properly positioned within opening **124**, tabs **228**, **230** prevent cap **200** from backing out of opening **124** and lock cap **200** to implant **100**.

Sides **236**, **238** of stem **204** are configured to cooperatively engage upper and lower interior surfaces **126**, **128** of opening **124**. Opening **124** may have any shape suitable for its intended purpose for interacting with stem **204**. For example, sides **236**, **238** may be beveled or rounded to accommodate rotational contact with upper and lower interior surfaces **126**, **128**. Stem **204** may have a generally rectangular cross-section or a generally circular cross-section along at least a portion of the length of the stem. Stem **204** may also have a cross-section with sides **236**, **238** intersecting the upper and the lower surfaces **232**, **234** at junctions, which may be two diametrically opposed corners and two diametrically opposed arcs. The two diametrically opposed arcs may be each of the same radius and, preferably, the diagonal or modified hypotenuse between the opposed arcs has a maximum dimension that generally approximates the distance between the upper and lower surfaces **232**, **234** such that when stem **204** is rotated from a first insertion position toward a second/deployed position, no substantial over-distraction occurs between the adjacent vertebral bodies as would occur if the height of the implant were to be increased markedly beyond that obtained in the second/deployed position. The two diametrically opposed corners may form a 90-degree angle. Additionally, sides **236**, **238** may be configured to be divergent away from distal end **226** to better accommodate engagement with upper and lower interior surfaces **126**, **128** while implant **100** is in the expanded state.

FIGS. **4-6** show a preferred expansion of implant **100** by cap **200**. In FIG. **4**, stem **204** of cap **200** is inserted through opening **124** in trailing end **104** of implant **100**. After stem **204** is inserted into opening **124**, tabs **228**, **230** extend beyond upper and lower interior surfaces **126**, **128** of opening **124** and into the interior of implant **100**. Upper and lower surfaces **232**, **234** of stem **204** are oriented toward upper and lower interior surfaces **126**, **128** of opening **124**, respectively, such that implant **100** is in a collapsed state. As cap **200** is rotated approximately 90° in either direction, sides **236**, **238** of stem **204** cooperatively engage with upper and lower interior surfaces **126**, **128** of opening **124**, forcing apart upper and lower members **106**, **108** away from the mid-longitudinal axis of implant **100** to position implant **100** in an expanded state. The configuration of stem **204** permits implant **100** to be expanded to a maximum implant height with less than one full turn. The rotation of cap **200** moves upper and lower members **106**, **108** from a generally parallel orientation shown in FIG. **4** to an angled orientation shown in FIG. **5** to expand or increase the height of implant **100**. During expansion of implant **100**, upper and lower lip portions **132**, **134** move within recess **220** of cap **200** until stem **204** ceases moving upper and lower interior surfaces **126**, **128** away from the mid-longitudinal axis of implant **100**. Tabs **228**, **230** move into cooperative engagement with an interior portion of upper and lower members **106**, **108** to lock cap **200** to implant **100** as well as lock implant **100** in an expanded state. A means to stop rotation of cap **200** when expansion is completed and secured to implant **200** may be employed. It is also within the broad scope of the present invention that cap **200** may be used to expand the implant from a first, collapsed lesser angled orientation to a second, expanded and more angled orientation.

For posterior spinal surgery, cap **200** may be preinstalled at the leading end of a posterior interbody spinal fusion implant. As shown in FIG. **4**B, by way of example and not limitation, an expander tool **800** may be used to cooperatively engage the stem of cap **200** from an opening in the implant trailing end. Expander tool **800** has a shaft **802** and a distal end **804**. Distal end **804** has a pair of prongs **806** and a recess **808** therebetween. Prongs **806** and recess **808** cooperate with the stem of cap **200** to rotate cap **200** and to move the implant from a collapsed state to an expanded state.

FIG. **7** shows a partial cross-section along line **7-7** of FIG. **6**. As shown in FIG. **7**, the maximum expansion of upper member **106** is reached when upper lip portions **132** are blocked from further motion away from the mid-longitudinal axis of implant **100** upon reaching outer perimeter **224** of recess **220**. Although not shown in FIG. **7**, lower lip portions **134** similarly contact outer perimeter **224** of recess **220**. In this manner, expansion of implant **100** beyond a predetermined amount is prevented. Tabs **228**, **230** of stem **204** bear against the interior of implant **100** and prevent removal of end cap **200** from opening **124**. In the deployed position, end cap **200** locks implant **100** in an expanded state, and is itself secured from inadvertent dislodgement.

As shown in FIGS. **8-11**, another preferred embodiment of the implant and end cap of the present invention is shown and generally referred to by the reference numbers **300** and **400**, respectively. Implant **300** is similar to implant **100**, except that opening **324** of implant trailing end **304** preferably has at least one thread **336** for cooperatively engaging with a threaded stem **404** of cap **400**.

Cap **400** is similar to cap **200**, except for differences noted below. Head **402** has a perimeter including an upper cutout portion **440** and a lower cutout portion **442**, each being adapted to allow the passage of a bone screw **320** into implant **300** after cap **400** has been attached to implant **300**. Once bone screws **320** are inserted, cap **200** may be rotated such that at least a portion of head **402** covers each of screws **320**. Upper and lower cutout portions **440**, **442** allow the surgeon the option of inserting bone screws **320** before or after attachment of cap **400** with implant **300**.

Stem **404** has at least one thread **448** along the mid-longitudinal axis of cap **400** for cooperatively engaging with threaded opening **324** of implant **300**. Distal end **426** of stem **404** has an upper surface **444** and a lower surface **446** that are at least in part tapered or convergent towards distal end **426** for assisting in the insertion of stem **404** into opening **324** of implant **300**.

As shown in FIGS. **10** and **11**, cap **400** is inserted into trailing end **304** of implant **300**, preferably by aligning the edge of distal end **426** with the plane separating upper and lower members **306**, **308**. Once upper and lower surfaces **444**, **446** of distal end **426** are sufficiently within threaded opening **324** of implant trailing end **304**, cap **400** is rotated to allow stem thread **448** of cap **400** to cooperatively engage with threaded opening **324**. The engagement of stem thread **448** with threaded opening **324** spreads apart upper and lower members **306**, **308** at least along a portion of the length of implant **300**. Continued rotation of cap **400** forces upper and lower lip portions **332**, **334** to contact recess **420** of cap **400**. The pitch of thread **448** is preferably such that as upper and lower lip portions **332**, **334** reach recess **420**, they come into contact with at least a portion of the outer perimeter of recess **420**. Upon contact with recess **420**, upper and lower lip portions **332**, **334** are prevented from further movement away from the mid-longitudinal axis of implant **300**. Cap **400** makes possible the full insertion of the bone screws either before or after the implant is expanded.

Those skilled in the art will appreciate that although it is preferred to use a cap to prevent over-expansion of an expandable implant, the invention is not so limited. For example, the implant trailing end may be adapted to have lip portions along the trailing end interior surface for cooperatively engaging with a recess and/or flange to prevent over-expansion of the implant. In such an instance, an over-expansion inhibiting surface may operate without a stem and/or head by relying on additional surface features of the implant trailing end, for example, a key-way entry along the opening leading to the interior lip portions or a circumferential barrier beyond the interior lip portions for preventing the over-expansion surface from traveling too far into the implant interior. It should also be apparent to those skilled in the art that the expander implant cap of the present invention may be adapted for use with a wide variety of expandable spinal implants, for example only, threaded cylindrical or frustoconical implants and impacted, push-in implants of various cross sectional shapes.

In other preferred embodiments, the expansion constraining member of the present invention need not be in the form of a cap. For example, FIGS. **12** and **13** show other preferred embodiments of expansion constraining member for constraining expansion of an implant **500**. Implant **500** has upper and lower screw holes **516**, **518** adapted to receive screws **520** to secure an expansion constraining member **600** to implant **500**.

Expansion constraining member **600** preferably has a bar **602** and two openings **604**. Screw openings **604** have an inner surface **606** adapted to accommodate screws **520** to lock expansion constraining member **600** to implant **500**. Inner surface **606** may be threaded or smooth. Those of ordinary skill in the art will appreciate that bar **602** may be of any shape suitable for the intended purpose of restraining the over-expansion of implant **500**.

Bar **602** may be planar or non-planar depending upon the orientation of the central axis of each of upper and lower screw holes **516**, **518** in relation to the plane of upper and lower members **506**, **508**. For example, bar **602** may be non-planar to accommodate implant **500** in an expanded state while aligning screw holes **604** with upper and lower screw holes **516**, **518** of implant **500** when upper and lower screw holes **516**, **518** each have a central axis generally parallel to the plane of upper and lower members **506**, **508**, respectively. Further, upper and lower screw openings **516**, **518** of implant **500** may have a central axis that is angled with respect to the plane of each of upper and lower members **506**, **508** of implant **500** so that screws **520** may assist in anchoring implant **500**, as with screws **120** and implant **100**.

After implant **500** is moved to its second, expanded state the surgeon positions bar **602** at trailing end **504** of implant **500** and aligns screw holes **604** with each of upper and lower screw holes **516**, **518**. Screws **520** are inserted to lock bar **602** to implant **500**.

In FIG. **13**, another preferred embodiment of the expansion constraining member of the present invention is shown and generally referred to by the reference number **700**. Expansion constraining member **700** is similar to expansion constraining member **600** except it has a peg **708** extending therefrom instead of a screw. A screw is passed through screw hole **704** to secure bar **702** to an implant.

FIG. **14** shows an implant **900** and expansion constraining member in the form of a ring **1000**. Implant **900** is similar to implant **500** except that opening **924** has upper and lower lip portions **932**, **934**. Lip portions **932**, **934** differ from those described in relation to implants **100** and **300** in that upper lip portion **932** has a thread **938** on the interior surface thereof, and lower lip portion **934** has a thread **940** on the interior surface thereof. Threads **938**, **940** are adapted to mate with a thread **1006** of constraining ring **1000**, described below.

Constraining ring **1000** has an inner surface **1002** and an outer surface **1004**. Outer surface **1004** has thread **1006** adapted to mate with threads **938**, **940** of implant **900**. Inner surface **1002** has a tool engagement area **1008** adapted to cooperatively engage a tool for attaching constraining ring **1000** to implant **900**. Constraining ring **1000** may be adapted to lock bone screws to implant **900** in a similar fashion as described in relation to implants **100** and **300**.

Implant **900** may be expanded to its second, expanded state. Thereafter constraining ring **1000** may be inserted into opening **924** of implant **900** and screwed around the inner perimeter of upper and lower lip portions **932**, **934**. While these later embodiments are shown in relationship to the trailing end of the implant without bone screws that has been done for simplicity and these and other means can be adapted to serve the purpose of locking the bone screws.

FIGS. **15-17** show an implant **1100** and expansion constraining member in the form of a ring **1200**. Implant **1100** is similar to implant **900** except that lip portions **1132**, **1134** differ from those described in relation to implant **900** in that upper lip portion **1132** and lower lip portion **1134** have a thread portion **1138**, **1140** respectively, on the exterior surface thereof. Implant **1100** also has upper and lower screw holes **1116**, **1118** that are adapted to receive bone screws **1120** in a similar fashion as described in relation to implants **100** and **300**.

Constraining ring **1200** is similar to constraining ring **1000** except that inner surface **1202** has thread **1206** adapted to mate with threads **1138**, **1140** of implant **1100**. Outer surface **1204** may have a tool engagement area adapted to cooperatively engage a tool for attaching constraining ring **1200** to implant **1100**.

Implant **1100** may be expanded to its second, expanded state. Thereafter, constraining ring **1200** is attached to implant **1100** by screwing ring **1200** around the outer perimeter of upper and lower lip portions **1132**, **1134** to lock bone screws **1120** to implant **1100** and constrain the over-expansion of implant **1100** as shown in FIG. **17**.

The expandable spinal implant and expander implant cap may be made of artificial or naturally occurring material suitable for implantation in the human spine. The implant and/or cap may comprise at least in part bone, metal including, but not limited to, titanium and its alloys, surgical grade plastics, plastic composites, ceramics, or any other material suitable for the intended purpose. The material may be bioresorbable.

The expandable spinal implant and/or cap of the present invention may be coated with, treated with, comprised of, be used in combination with, or have a hollow for containing bone growth promoting materials and/or substances, including but not limited to, bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic proteins, hydroxyapatite, and genes coding for the production of bone. The spinal implant and/or cap of the present invention can be formed of a material that intrinsically participates in the growth of bone from one of adjacent vertebral bodies to the other of adjacent vertebral bodies, can be a source of osteogenesis, or can be at least in part bioabsorbable or resorbable. The implant and/or cap of the present invention can be formed of a porous material.

At least one of the implant and cap of the present invention may be modified, or used in combination with materials to make it antimicrobial or antibacterial, such as, but not limited to, electroplating or plasma spraying with silver ions or other substance. The expandable spinal implant and/or cap of the present invention may be coated with, comprised of, be used in combination with, or have a hollow for containing one or more chemical substances and/or compounds adapted to inhibit scar formation.

While various embodiments of the present invention are presented by way of example only and not limitation, common to each of them, is that the expandable spinal implant for insertion across the disc space between two adjacent vertebral bodies of a human spine has surface features adapted to cooperatively engage with a recess of an attachable piece for inhibiting over-expansion of the implant.

There is disclosed in the above description and the drawings caps, a lock, expansion constraining members, expanders, and implants, which fully and effectively accomplish the objectives of this invention. However, it will be apparent that variations and modifications of the disclosed embodiments may be made without departing from the principles or the scope of the present invention.

What is claimed is:

1. An apparatus for insertion within an implantation space formed across the height of a disc space between vertebral bodies of a human spine, said apparatus comprising:

an expandable spinal implant having upper and lower portions adapted to move apart from one another to contact adjacent upper and lower vertebral bodies, respectively, said implant having an end having an opening, each of said upper and lower portions having a recess; and

an implant end cap having a head configured to cooperatively engage said end of said implant to at least in part cover said opening, said head having a top surface and a bottom surface opposite said top surface, said bottom surface having at least one protrusion adapted to cooperatively engage said recesses of said upper and lower portions of said implant to prevent said implant from expanding beyond a predetermined height by limiting movement of said upper and lower portions relative to one another, said implant end cap being rotated to engage said at least one protrusion and said recesses.

2. The apparatus of claim **1**, wherein said head is configured to cooperatively engage said end of said implant to completely cover said opening.

3. The apparatus of claim **1**, wherein said implant has a plurality of bone screw holes, said bottom surface of said head being configured to cover at least a portion of one of said bone screw holes when said cap is engaged to said implant.

4. The apparatus of claim **3**, wherein said bottom surface of said head is configured to cover a portion of more than one of said bone screw holes when said cap is engaged to said implant.

5. The apparatus of claim **3**, wherein said head is configured to allow the insertion of a bone screw into said implant after said cap is engaged with said implant.

6. The apparatus of claim **3**, wherein said head has a perimeter that is configured to permit the insertion of a bone screw into one of said bone screw holes after said cap is engaged with said implant, said head being movable to cover at least a portion of the bone screw after the bone screw is inserted in one of said bone screw holes.

7. The apparatus of claim **1**, wherein said upper and lower portions of said implant include at least one opening adapted to communicate with one of the adjacent vertebral bodies, said openings in said upper and lower portions being in communication with one another and adapted for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant.

8. The apparatus of claim **7**, wherein said implant includes a hollow interior for holding bone growth promoting material, said hollow interior being in communication with at least one openings in each of said upper and lower portions.

9. The apparatus of claim **1**, wherein said implant is in combination with a bone growth promoting material.

10. The apparatus of claim **9**, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

11. The apparatus of claim **1**, wherein said implant is treated with a bone growth promoting substance.

12. The apparatus of claim **1**, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.

13. The apparatus of claim **1**, wherein said implant is at least in part resorbable.

14. The apparatus of claim **1**, wherein said implant is formed of a porous material.

15. The apparatus of claim **1**, wherein said implant is in combination with a material adapted to inhibit scar formation.

16. The apparatus of claim **1**, wherein said implant is in combination with an antimicrobial material.

17. An apparatus for insertion within an implantation space formed across the height of a disc space between vertebral bodies of a human spine, said apparatus comprising:

an expandable spinal implant having upper and lower portions adapted to move apart from one another to contact adjacent upper and lower vertebral bodies, respectively, said implant having an end having an opening, each of said upper and lower portions having at least one protrusion; and

an implant end cap having a head configured to cooperatively engage said end of said implant to at least in part cover said opening, said head having a top surface and a bottom surface opposite said top surface, said bottom surface having a recess adapted to cooperatively receive said protrusions of said upper and lower portions of said implant to prevent said implant from expanding beyond a predetermined height by limiting movement of said upper and lower portions relative to one another, said implant end cap being rotated to facilitate receipt of said protrusions in said recess.

18. The apparatus of claim **17**, wherein said head is configured to cooperatively engage said end of said implant to completely cover said opening.

19. The apparatus of claim **17**, wherein said implant has a plurality of bone screw holes, said bottom surface of said head being configured to cover at least a portion of one of said bone screw holes when said cap is engaged to said implant.

20. The apparatus of claim **19**, wherein said bottom surface of said head is configured to cover a portion of more than one of said bone screw holes when said cap is engaged to said implant.

21. The apparatus of claim **19**, wherein said head is configured to allow the insertion of a bone screw into said implant after said cap is engaged with said implant.

22. The apparatus of claim **19**, wherein said head has a perimeter that configured to permit the insertion of a bone screw into one of said bone screw holes after said cap is engaged with said implant, said head being movable to cover at least a portion of the bone screw after the bone screw is inserted in one of said bone screw holes.

23. The apparatus of claim **17**, wherein said upper and lower portions of said implant include at least one opening adapted to communicate with one of the adjacent vertebral bodies, said openings in said upper and lower portions being in communication with one another and adapted for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant.

24. The apparatus of claim **23**, wherein said implant includes a hollow interior for holding bone growth promoting material, said hollow interior being in communication with at least one openings in each of said upper and lower portions.

25. The apparatus of claim **17**, wherein said implant is in combination with a bone growth promoting material.

26. The apparatus of claim **25**, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

27. The apparatus of claim **17**, wherein said implant is treated with a bone growth promoting substance.

28. The apparatus of claim **17**, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.

29. The apparatus of claim **17**, wherein said implant is at least in part resorbable.

30. The apparatus of claim **17**, wherein said implant is formed of a porous material.

31. The apparatus of claim **17**, wherein said implant is in combination with a material adapted to inhibit scar formation.

32. The apparatus of claim **17**, wherein said implant is in combination with an antimicrobial material.

33. A method for expanding an expandable spinal implant having an end, the method comprising the steps of:

providing an end cap having a stem projecting therefrom;

inserting at least a portion of the stem of the end cap into the end of the implant while the implant is in a collapsed position; and

rotating the stem of the end cap less than one full turn to expand the implant from the collapsed position to an expanded position.

34. The method of claim **33**, wherein the step of rotating the stem includes rotating the stem approximately 90 degrees.

35. The method of claim **33**, wherein the step of rotating the stem includes rotating a stem having no threads.

36. The method of claim **33**, further comprising the step of locking the cap to the implant.

37. The method of claim **33**, further comprising the step of locking the implant in an expanded position.

38. The method of claim **33**, wherein the implant has a plurality of bone screw holes, further comprising the step of covering at least a portion of the bone screw holes with at least a portion of the end cap.

39. The method of claim **33**, further comprising the step of inserting at least one bone screw in the implant after the stem of the end cap is inserted into the end of the implant.

40. The method of claim **33**, wherein the end of the implant includes an opening leading to an interior hollow having a bone growth promoting material therein, further comprising the step of covering at least a portion of the opening with the end cap.

41. The method of claim **33**, wherein the step of inserting includes inserting a non-threaded stem into the end of the implant.

42. An apparatus for insertion within an implantation space formed across the height of a disc space between vertebral bodies of a human spine, said apparatus comprising:

an expandable spinal implant having upper and lower portions adapted to move apart from one another to contact adjacent upper and lower vertebral bodies, respectively, said implant having an end having an opening, each of said upper and lower portions having a recess, said implant having a plurality of bone screw holes; and

an implant end cap having a head configured to cooperatively engage said end of said implant to at least in part cover said opening, said head having a top surface and a bottom surface opposite said top surface, said bottom surface having at least one protrusion adapted to cooperatively engage said recesses of said upper and lower portions of said implant to prevent said implant from expanding beyond a predetermined height by limiting movement of said upper and lower portions relative to one another, said bottom surface of said head being configured to cover at least a portion of one of said bone screw holes when said cap is engaged to said implant.

43. An apparatus for insertion within an implantation space formed across the height of a disc space between vertebral bodies of a human spine, said apparatus comprising:

an expandable spinal implant having upper and lower portions adapted to move apart from one another to contact adjacent upper and lower vertebral bodies, respectively, said implant having an end having an opening, each of said upper and lower portions having at least one protrusion, said implant having a plurality of bone screw holes; and

an implant end can having a head configured to cooperatively engage said end of said implant to at least part cover said opening, said head having a top surface and a bottom surface opposite said top surface, said bottom surface having a recess adapted to cooperatively receive said protrusions of said upper and lower portions of said implant to prevent said implant from expanding beyond a predetermined height by limiting movement of said upper and lower portions relative to one another, said bottom surface of said head being configured to cover at least a portion of one of said bone screw holes when said cap is engaged to said implant.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,326,248 B2
APPLICATION NO. : 10/719424
DATED : February 5, 2008
INVENTOR(S) : Gary K. Michelson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12:
Line 64: change "one openings" to --one opening--.

Column 13:
Line 58: change "that configured" to --that is configured--.

Column 14:
Line 6: change "one openings" to --one opening--.

Column 16:
Line 8: change "can" to --cap--; and
Line 9: change "least part" to --least in part--.

Signed and Sealed this

Twentieth Day of May, 2008

Jon W. Dudas

JON W. DUDAS
Director of the United States Patent and Trademark Office