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United States Patent [19]

Michelson

[11] **Patent Number: 6,136,001**

[45] **Date of Patent: Oct. 24, 2000**

[54] **APPARATUS AND METHOD FOR LINKING SPINAL IMPLANTS**

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[21] Appl. No.: **09/126,585**

[22] Filed: **Jul. 31, 1998**

Related U.S. Application Data

[63] Continuation of application No. 08/926,334, Sep. 5, 1997, which is a continuation of application No. 08/589,787, Jan. 22, 1996, abandoned, which is a continuation of application No. 08/219,626, Mar. 28, 1994, abandoned.

[51] **Int. Cl.**[7] **A61B 17/56**

[52] **U.S. Cl.** **606/61**

[58] **Field of Search** 606/61, 60, 72; 623/17, 16

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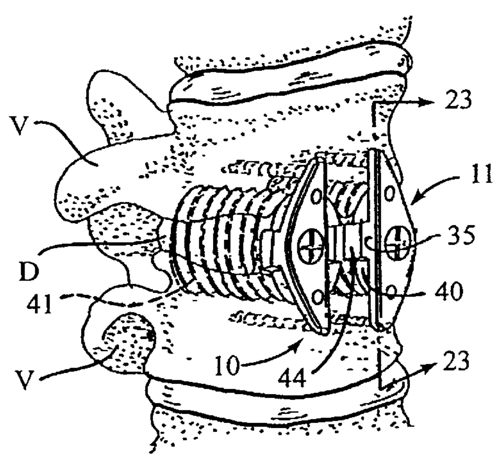
Primary Examiner—Michael Buiz
Assistant Examiner—(Jackie) Tan-Uyen T. Ho
Attorney, Agent, or Firm—Martin & Ferraro, LLP

[57] **ABSTRACT**

A spinal fixation device for stabilizing one or more segments of the human spine and for preventing the dislodgement of intervertebral spinal fusion implants, which remains permanently fixated once applied. The spinal fixation device of the present invention comprises of a staple member made of material appropriate for human surgical implantation which is of sufficient length to span the disc space between two adjacent vertebrae and to engage, via essentially perpendicular extending projections, the vertebrae adjacent to that disc space. A portion of the staple of the spinal fixation device interdigitates with an already implanted intervertebral spinal fusion implant which itself spans the disc space to engage the adjacent vertebrae, and the spinal fixation deice is bound to the spinal fusion implant by a locking means. The spinal fixation device of the present invention is of great utility in restraining the vertebrae adjacent to the spinal fusion implant from moving apart as the pine is extended and also serves as an anchor for a multi-segmental spinal alignment means for aligning more that one segment of the spine.

126 Claims, 10 Drawing Sheets



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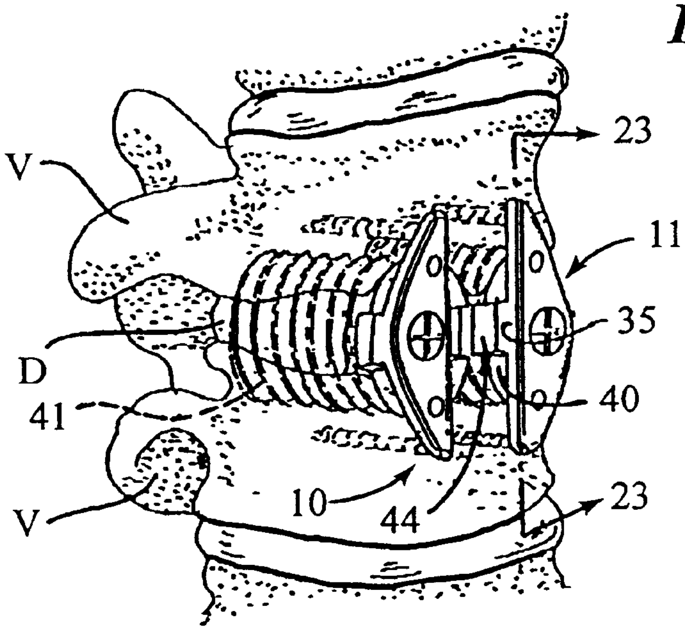


Fig. 1

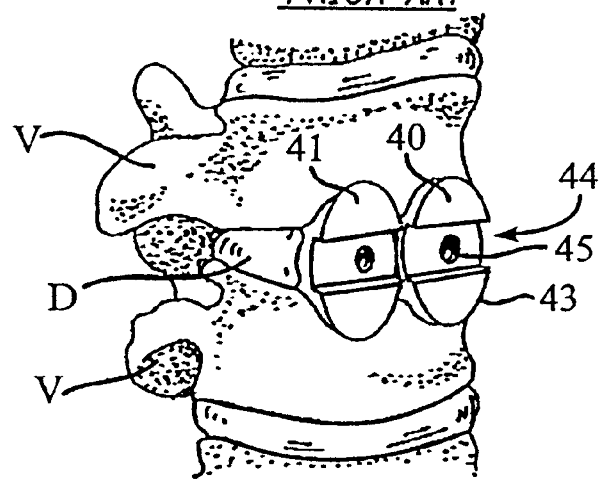


Fig. 2
PRIOR ART

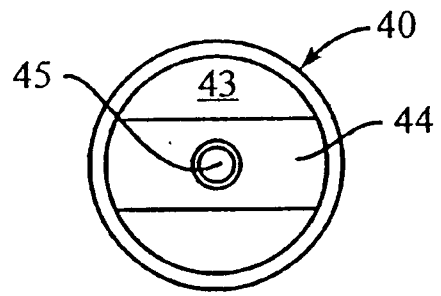


Fig. 4
PRIOR ART

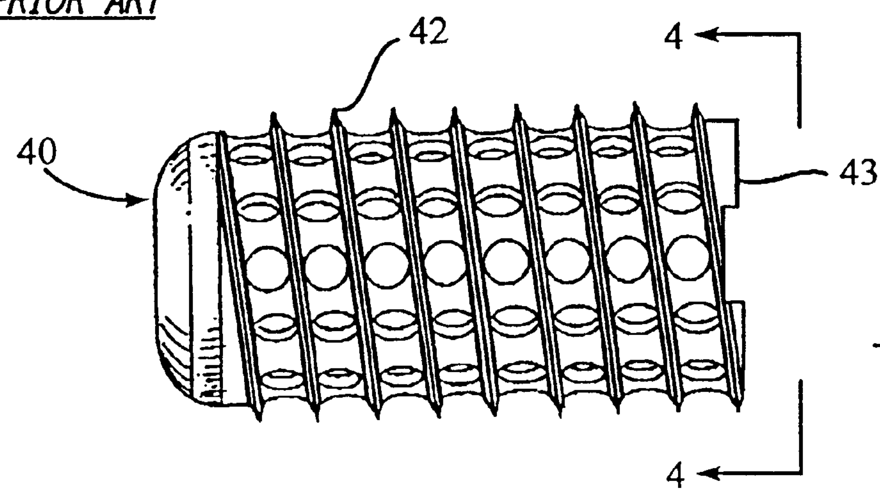
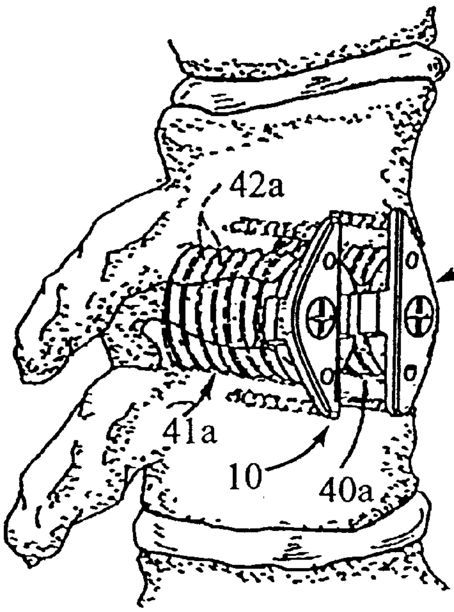


Fig. 3
PRIOR ART

Fig. 5



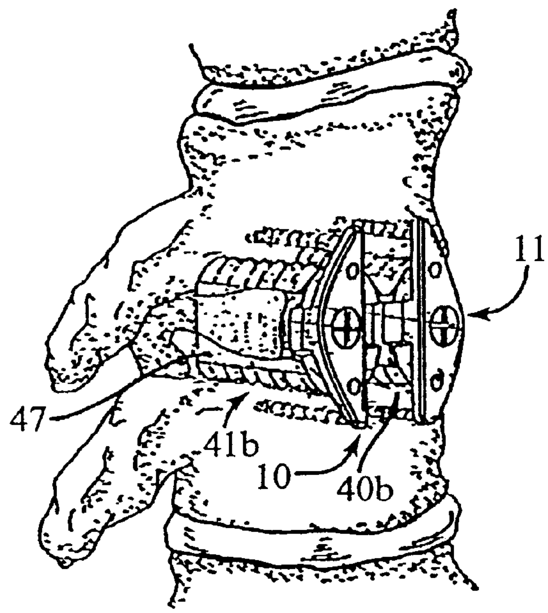


Fig. 6

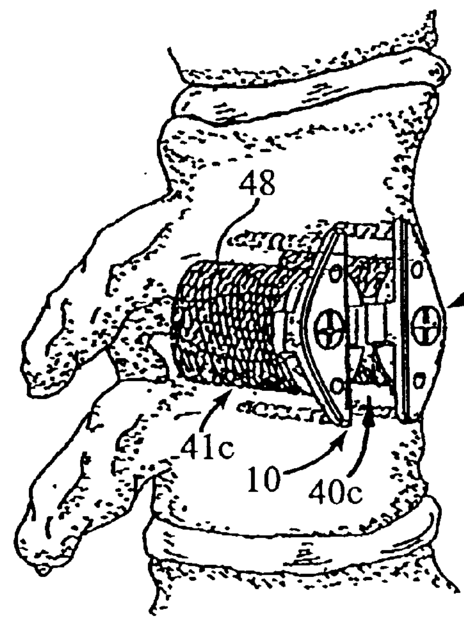


Fig. 7

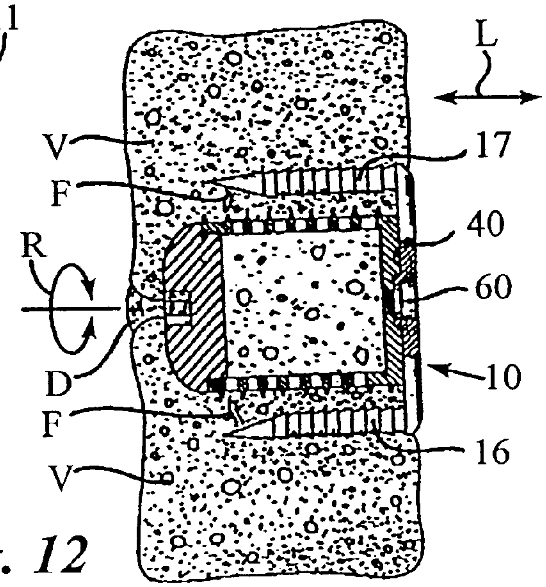


Fig. 12

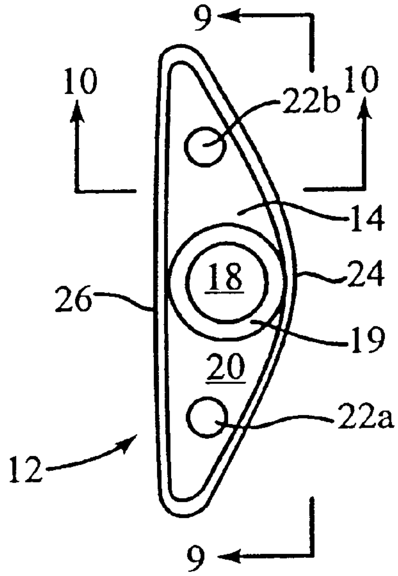


Fig. 8

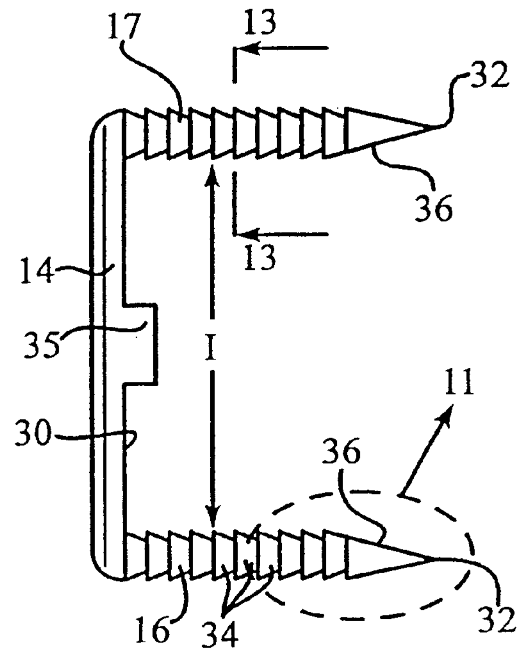


Fig. 9

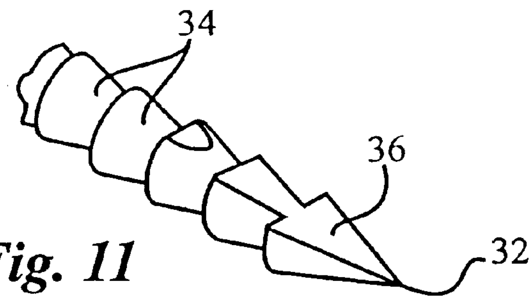


Fig. 11

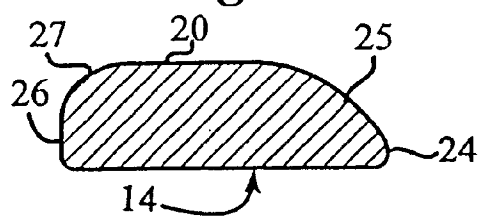


Fig. 10

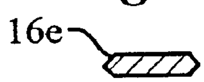


Fig. 13F

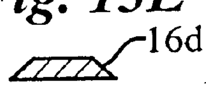


Fig. 13E

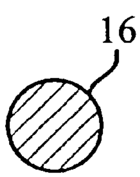


Fig. 13A

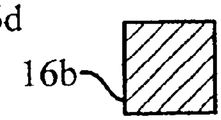


Fig. 13C

Fig. 13B

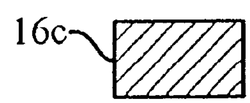


Fig. 13D

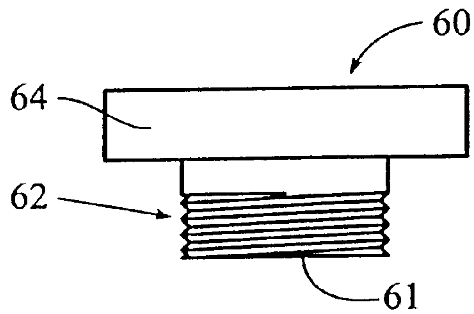
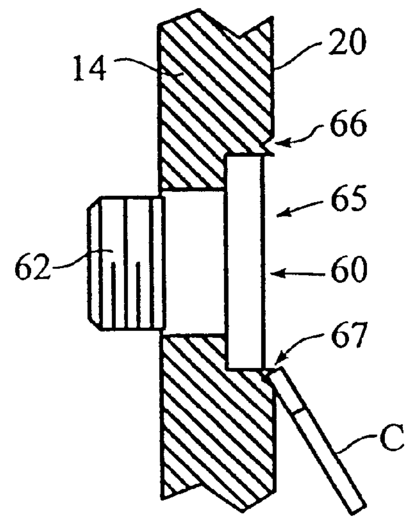


Fig. 14

Fig. 15A



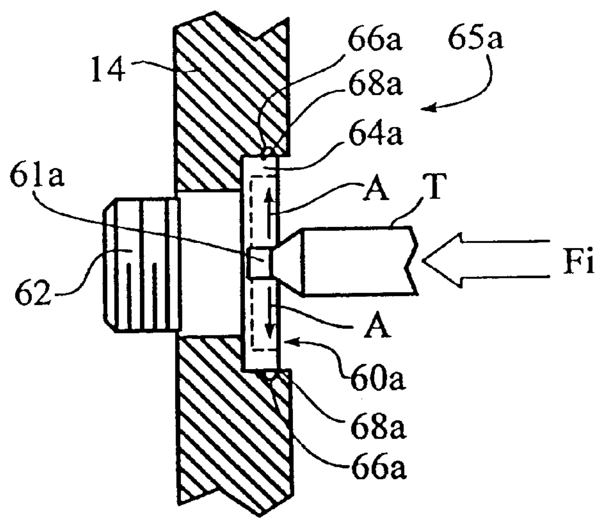


Fig. 15B

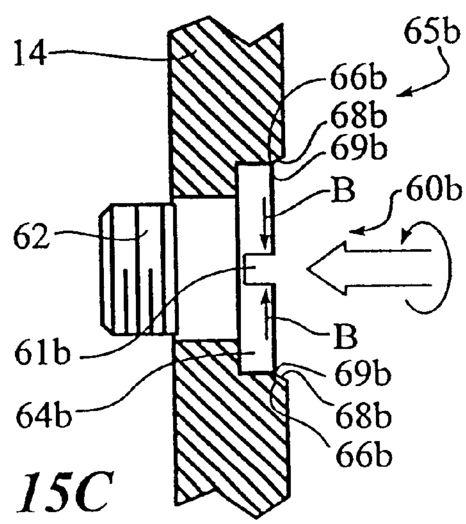


Fig. 15C

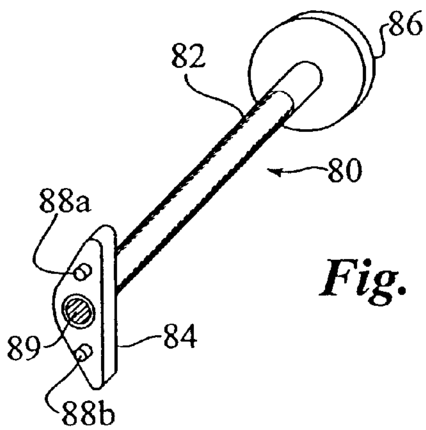
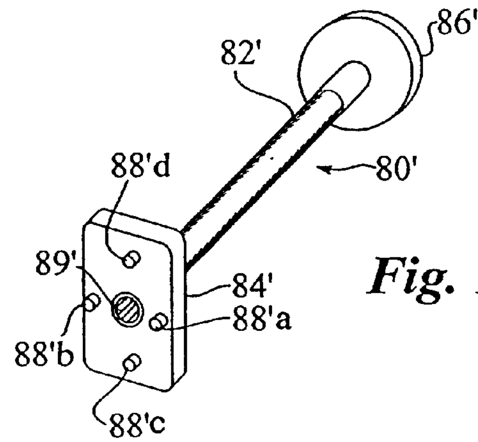


Fig. 16A



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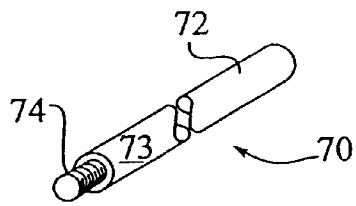


Fig. 17A

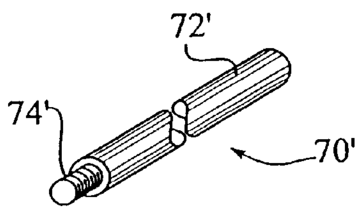
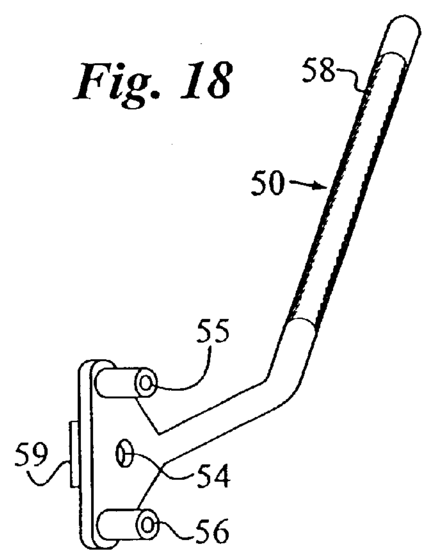


Fig. 17B

Fig. 18



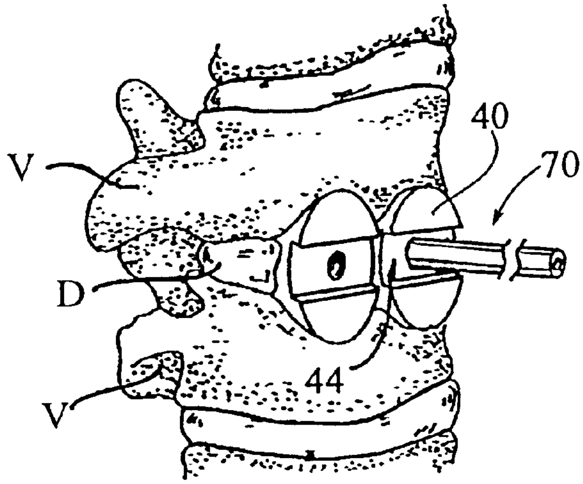


Fig. 19

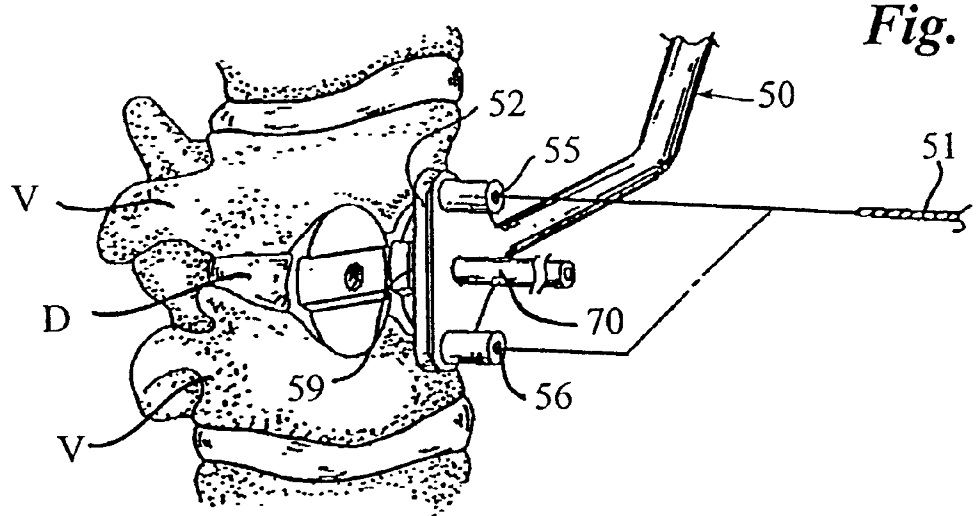


Fig. 20

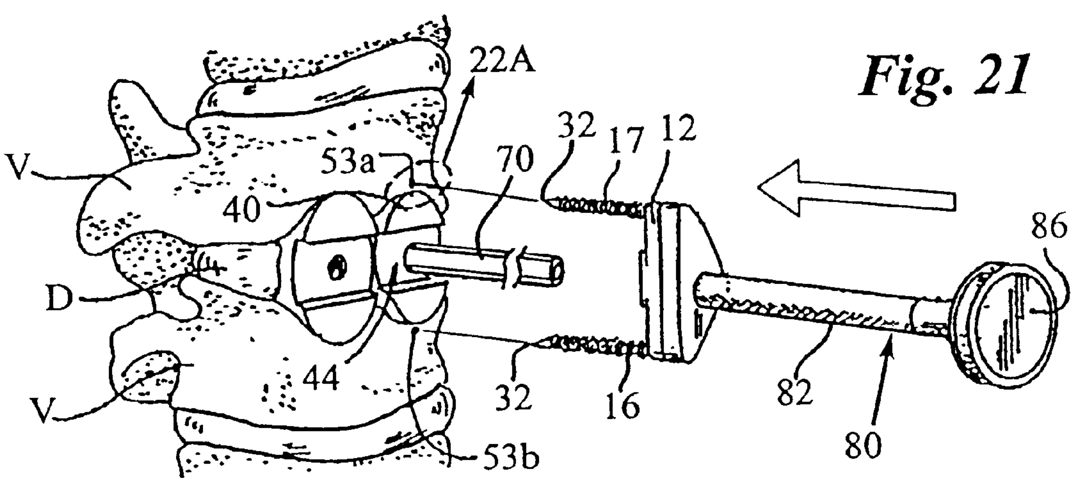


Fig. 21

Fig. 22

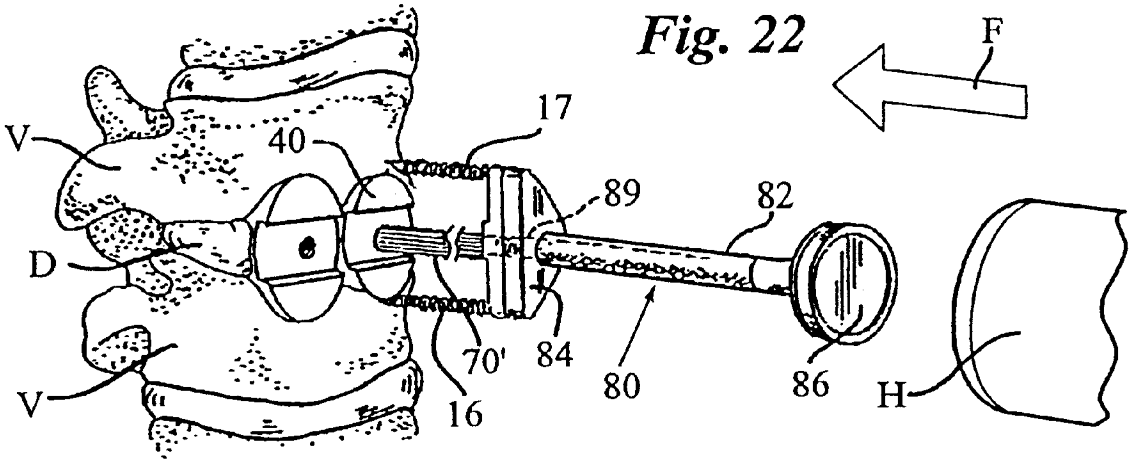
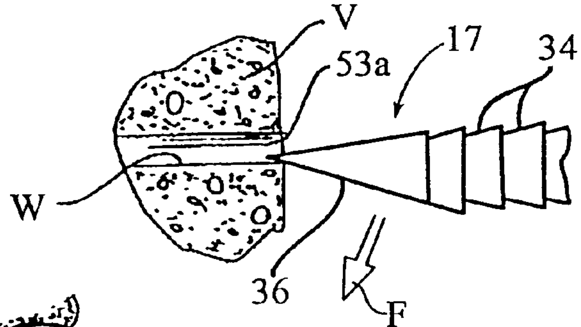


Fig. 22A



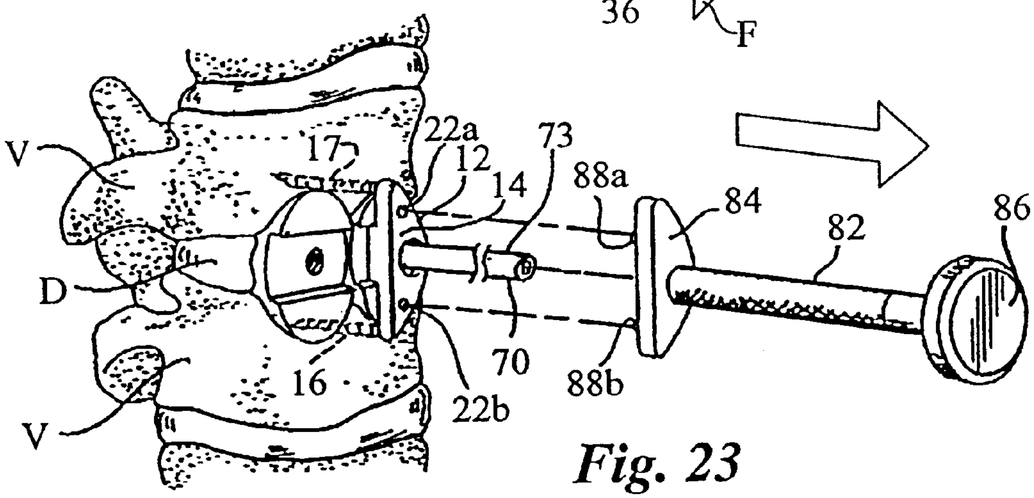


Fig. 23

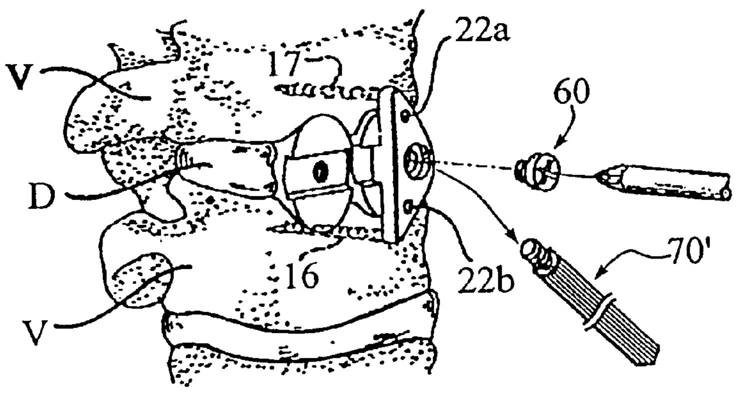
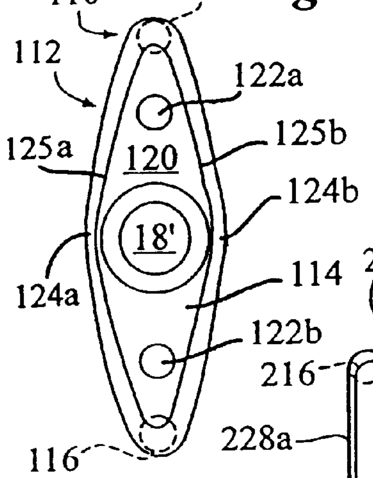


Fig. 24

Fig. 25



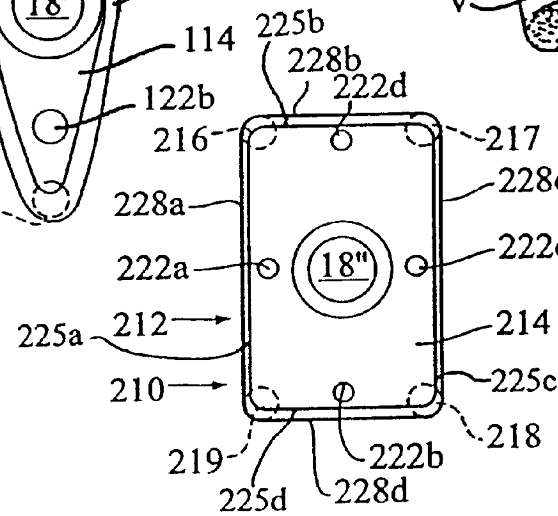


Fig. 26

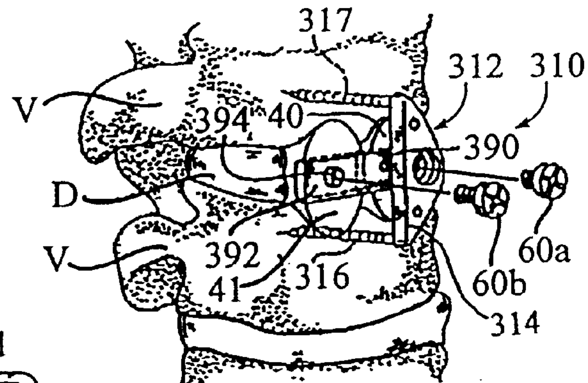


Fig. 27

Fig. 28

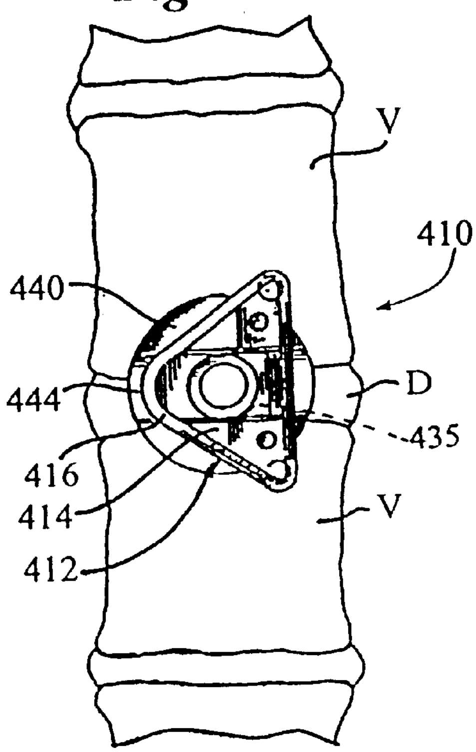


Fig. 29

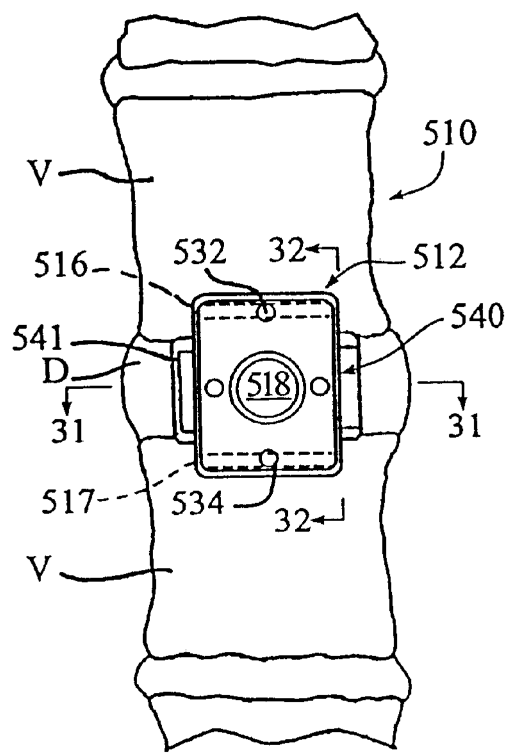
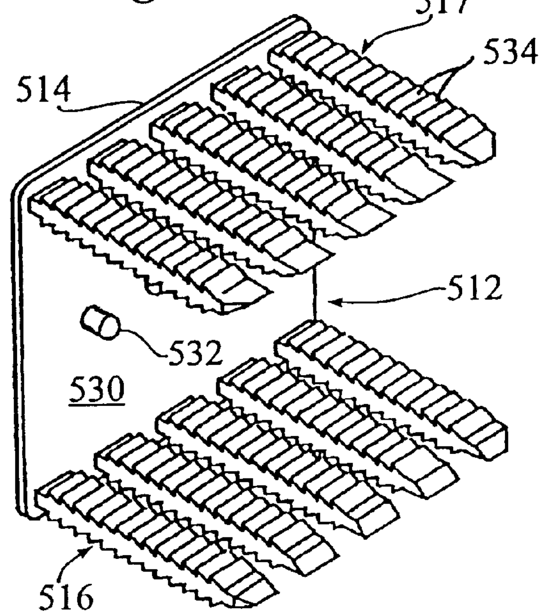


Fig. 30



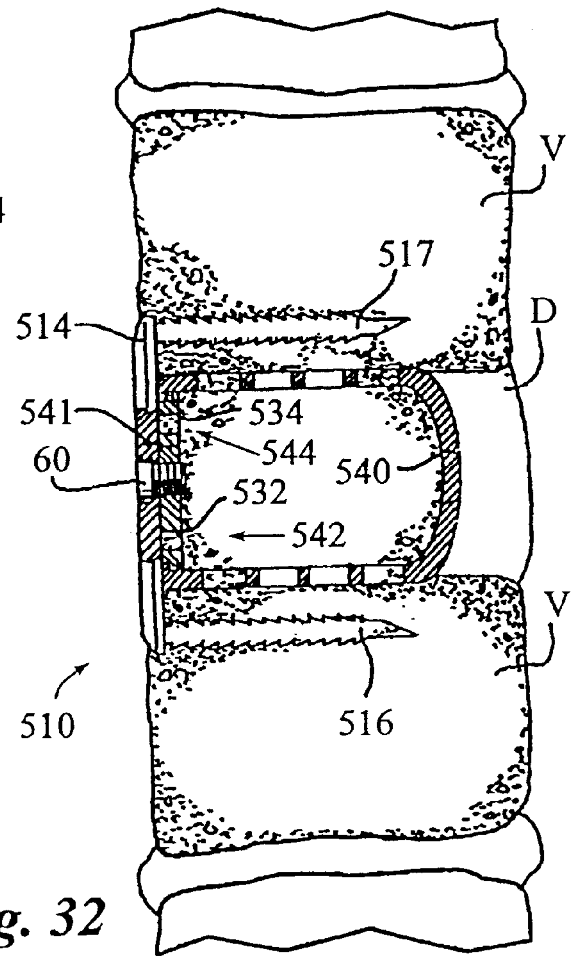


Fig. 32

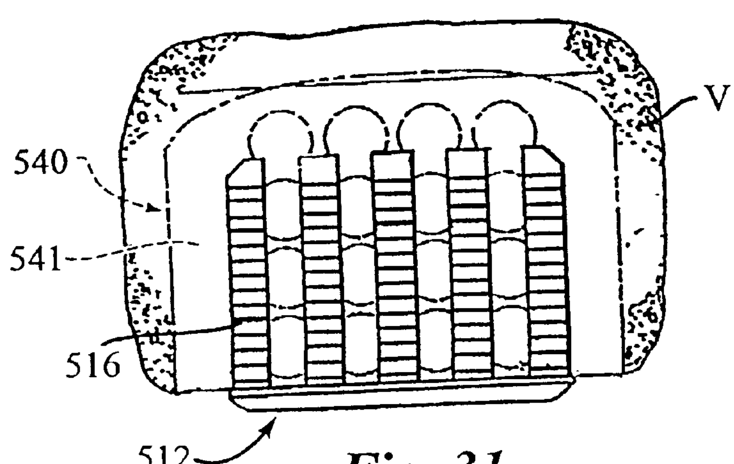
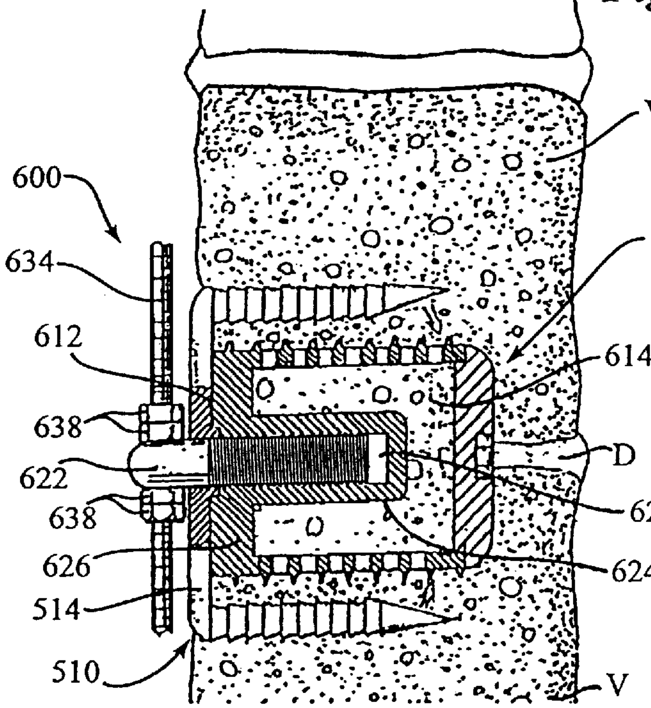


Fig. 31

Fig. 33



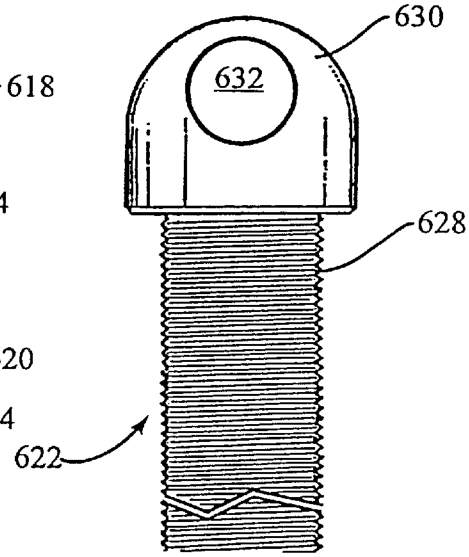


Fig. 34

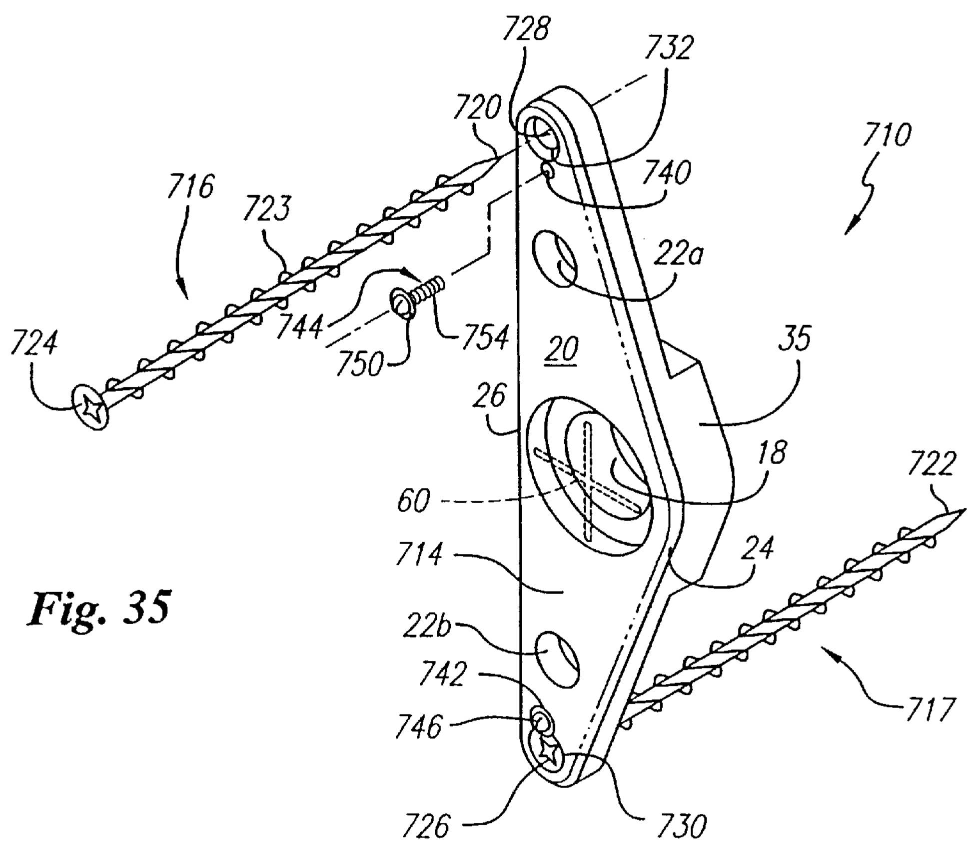


Fig. 35

APPARATUS AND METHOD FOR LINKING SPINAL IMPLANTS

This is a continuation of application Ser. No. 08/926,334, filed Sep. 5, 1997, which is a continuation of Ser. No. 08/589,787 abandoned filed Jan. 22, 1996 which is a continuation of 08/219,626 abandoned filed Mar. 28, 1994.—all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to surgical interbody fixation devices and in particular to a surgically implantable device for the stabilization of adjacent vertebrae of the human spine undergoing spinal arthrodesis and for the prevention of the dislodgement of spinal fusion implants used in the fusion process.

2. Description of the Related Art

When a segment of the human spine degenerates, or otherwise becomes diseased, it may become necessary to surgically remove the affected disc of that segment, and to replace it with bone for the purpose of obtaining a spinal fusion by which to restore more normal, pre-morbid, spatial relations, and to provide for enhanced stability across that segment. Performing such surgery of the spine from an anterior (front) approach offers the great advantage of avoiding the spinal cord, dural sac, and nerve roots. Unfortunately, in entering the disc space anteriorly a very important band-like structure called the anterior longitudinal ligament, is violated. This structure physiologically acts as a significant restraint resisting the anterior displacement of the disc itself and acting as a tension band binding the front portions of the vertebrae so as to limit spinal hyperextension.

Historically, various devices have been utilized in an attempt to compensate for the loss of this important stabilizing structure. These devices have assumed the form of blocks, bars, cables, or some combination thereof, and are bound to the vertebrae by screws, staples, bolts, or some combination thereof. The earliest teachings are of a metal plate attached to adjacent vertebrae with wood-type screws. Dryer teaches the use of a staple-screw combination. Brantigan U.S. Pat. No. 4,743,256 issued on May 10, 1988, teaches the use of a block inserted to replace the disc, affixed to a plate then screwed to the vertebrae above and below. Raezian U.S. Pat. No. 4,401,112 issued on Aug. 30, 1993, teaches the use of a turnbuckle affixed to an elongated staple such that at least one entire vertebral body is removed, the turnbuckle portion is placed within the spine, and the staple extends both above and below the turnbuckle and engages the adjacent vertebrae to the one removed.

Unfortunately, both staples and screws have quite predictably demonstrated the propensity to back out from the vertebrae. This is quite understandable as any motion, either micro or macro, tends to stress the interface of the metallic implant to the bone, and in doing so causes the bone to relieve the high stress upon it by resorbing and moving away from the metal. This entropic change is universally from the more tightened and thus well-fixated state, to the less tightened and less fixated state. For a staple, this is specifically from the more compressed and engaged state, to the less compressed and disengaged state. Similarly, screws in such a dynamic system loosen and back out.

The potential consequences of such loosening and consequent backing out of the hardware from the anterior aspect of the vertebral column may easily be catastrophic. Because of the proximity of the great vessels, aortic erosions and

perforations of the vena cava and iliac vessels have usually occurred with unfortunate regularity and have usually resulted in death.

Therefore, the need exists for a device which is effective in restoring stability to a segment of the spine such as, but not limited to, the anterior aspect of the human spine and which will without danger remain permanently fixated once applied.

SUMMARY OF THE INVENTION

The present invention is directed to a spinal fixation device for stabilizing a segment of the human spine and for preventing the dislodgement of intervertebral spinal fusion implants, which remains permanently fixated to the spine once applied. The spinal fixation device of the present invention comprises a staple member made of a material appropriate for human surgical implantation and which is of sufficient length to span the disc space between two adjacent vertebrae. The staple member engages, via essentially perpendicular extending projections, the vertebrae adjacent to that disc space. The projections are sharpened and pointed so as to facilitate their insertion into the vertebrae and are segmented or ratcheted to prevent the staple member from disengaging and backing out once inserted.

In the preferred embodiment of the spinal fixation device of the present invention, a portion of the staple member interdigitates with an already implanted intervertebral spinal fusion implant and the staple member is bound to the spinal fusion implant by a locking mechanism such as a screw with a locking thread pattern. The anchoring of the staple member via a locking mechanism to a spinal fusion implant protects the patient from the danger of the staple member itself disengaging and backing out. Further, if the spinal fusion implant is externally threaded, such as the spinal fusion implant taught by Michelson, U.S. Pat. No. 5,015,247 issued on May 14, 1991, then the staple member could only back out if the spinal fusion implant were free to rotate. However, the rotation of the spinal fusion implant in this instance is blocked by its connection to the staple member which is fixated across the disc space in such a way as to be incapable of rotation. Thus, the staple member is made safe against dislodgement by attachment to the spinal fusion implant and the stability of the spinal fusion implant is assured as it is also stabilized by the staple member and each works in connection with the other to remove the only remaining degree of freedom that would allow for the disengagement of either.

The spinal fixation device of the present invention is broadly applicable to the anterior, posterior and lateral aspects of the spinal column, be it the cervical, thoracic or lumbar area. In particular, the use of a staple member spanning the disc space and engaging the adjacent vertebrae which is applied to the anterior aspect of the spine is of great utility in restraining those vertebral bodies from moving apart as the spine is extended and thus is effective in replacing the anterior longitudinal ligament of the patient.

The spinal fixation device of the present invention provides the advantage of facilitating cross vertebral bony bridging (fusion via immobilization) which when achieved relieves all of the forces on the inserted spinal fusion implants. The spinal fixation device of the present invention may be coated with materials to promote bone fusion and thus promote the incorporation and ultimate entombment of the spinal fixation device into the bone fusion mass. The use of a bone fusion promoting material results in a speedier vertebra to vertebra fusion as bone may grow along the coated spinal fixation device bridging the two vertebrae so that the spinal fixation device acts as a trellis and supplies essential chemical elements to facilitate the bone fusion process.

Another advantage provided by the spinal fixation device of the present invention is that as it is inserted it compresses the adjacent vertebrae together, thus increasing the compressive load on the spinal fusion implants or implants within the disc space, such compression being beneficial to fusion and further stabilizing the spinal fusion implants.

A further advantage of the spinal fixation device of the present invention is that it may be used as an anchor such that a multiplicity of spinal fixation devices may then be interconnected via a cable, rod, bar, or plate, so as to achieve or maintain a multi-segmental spinal alignment.

Alternatively, the spinal fixation device of the present invention could be made of resorbable materials, such as bio-compatible resorbable plastics, that resorb at an appropriate rate such that once the spinal fixation device is no longer needed (i.e. when spinal fusion is complete) the body would resorb the spinal fixation device. The spinal fixation device could be only in part resorbable such that the projections of the staple member would be non-resorbable and would remain incarcerated in the vertebrae and sealed off once the resorbable portion of the staple is resorbed by the body.

As a further alternative, the spinal fixation device of the present invention could be made wholly of in part of ceramic and more particularly made of or coated with a ceramic such as hydroxyapatite that would actively participate in the fusion process.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal fixation device having a staple member spanning the disc space and engaging two adjacent vertebrae of the spine to restrain the vertebrae from moving apart as the spine is extended;

It is an another object of the present invention to provide a spinal fixation device that is effective in replacing the function of the anterior longitudinal ligament of a patient;

It is a further object of the present invention to provide a means for protecting the patient from the danger of the spinal fixation device itself disengaging and backing out by its being anchored to an intervertebral spinal fusion implant;

It is still another object of the present invention to provide a spinal fixation device that blocks the rotation of an intervertebral spinal fusion implant by its connection to the staple member which is fixated across the disc space in such a way as to be incapable of rotation thereby preventing the spinal fusion implant from backing out;

It is yet another object of the present invention to provide a spinal fixation device that is broadly applicable to the anterior aspect of the spinal column, be it the cervical, thoracic or lumbar area;

It is another object of the present invention to provide a spinal fixation device which may be applied longitudinally at any point about the circumference of the anterior aspect of the spine;

It is also another object of the present invention to provide a spinal fixation device that stabilizes a surgically implanted spinal fusion implant and works in connection with the spinal fusion implant to prevent disengagement of either;

It is another object of the present invention to provide a spinal fixation device that achieves cross vertebral bony bridging (fusion) which ultimately relieves all of the forces on inter-vertebral spinal fusion implants inserted within the disc space between two adjacent vertebrae, and provides for a permanently good result;

It is another object of the present invention to provide a spinal fixation device that serves as an anchor, such that a multiplicity of these anchors may then be interconnected via a cable, rod, bar, or plate, so as to achieve or maintain a multi-segmental spinal alignment; and

It is a further object of the present invention to provide a spinal fixation device that directly participates in the bony bridging of two adjacent vertebrae and participates in the spinal fusion process across those vertebrae.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective side view of a segment of the spinal column having two spinal fusion implants shown partially in hidden line inserted across the disc space between two adjacent vertebrae with each spinal fusion implant having a spinal fixation device of the present invention shown partially in hidden line secured thereto, spanning across the disc space and inserted into the vertebrae.

FIG. **2** is a perspective side view of a segment of the spinal column having two spinal fusion implants inserted across the disc space between two adjacent vertebrae.

FIG. **3** is an elevational side view of a cylindrical threaded spinal fusion implant.

FIG. **4** is an end view of the cylindrical threaded spinal fusion implant along lines **4**—**4** of FIG. **3**.

FIG. **5** is a perspective side view of a segment of the spinal column having two non-threaded spinal fusion implants with external ratchetings, shown in hidden line, inserted across the disc space between two adjacent vertebrae with each spinal fusion implant having a spinal fixation device of the present invention, shown partially in hidden line, coupled thereto, spanning across the disc space and inserted into the vertebrae.

FIG. **6** is a perspective side view of a segment of the spinal column having two spinal fusion implants having truncated sides with external ratchetings shown in hidden line inserted across the disc space between two adjacent vertebrae with each spinal fusion implant having a spinal fixation device of the present invention shown partially in hidden line coupled thereto, spanning across the disc space and inserted into the vertebrae.

FIG. **7** is a perspective side view of a segment of the spinal column having two spinal fusion implants having a knurled external surface shown in hidden line inserted across the disc space between two adjacent vertebrae with each spinal fusion implant having a spinal fixation device of the present invention shown partially in hidden line coupled thereto, spanning across the disc space and inserted into the vertebrae.

FIG. **8** is a top plan view of the spinal fixation device of the present invention.

FIG. **9** is a side view of the spinal fixation device of the present invention along lines **9**—**9** of FIG. **8**.

FIG. **10** is a cross sectional view taken along lines **10**—**10** of FIG. **8** showing the top member of the spinal fixation device of the present invention.

FIG. **11** is an enlarged fragmentary perspective side view of a projection of the spinal fixation device of the present invention taken along line **11** of FIG. **9**.

FIG. 12 is a cross sectional view of the spinal fixation device of the present invention inserted into the vertebrae and secured to the spinal fusion implant with the arrows showing the forces exerted, the rotational axis and the longitudinal axis of the spinal fusion implant.

FIG. 13A is a cross sectional view along line 13—13 of FIG. 9 of the preferred embodiment of the projections of the present invention.

FIGS. 13B, 13C, 13D, 13E, and 13F are cross sectional views taken along line 13—13 of FIG. 9 showing alternative embodiments of the projections of the spinal fixation device of the present invention.

FIG. 14 is an enlarged elevational side view of the locking screw used to secure the spinal fixation device of the present invention to a spinal fusion implant.

FIG. 15A is a cross sectional view of a securing means for locking the locking screw of the present invention.

FIG. 15B is a cross sectional view of a first alternative embodiment of the securing means for locking the locking screw of the present invention.

FIG. 15C is a cross sectional view of a second alternative embodiment of the securing means for locking the locking screw of the present invention.

FIG. 16A is a perspective side view of the instrumentation used for driving the spinal fixation device of the present invention into the vertebrae.

FIG. 16B is a perspective side view of a first alternative embodiment of the instrumentation used for driving the spinal fixation device of the present invention into the vertebrae.

FIG. 17A is a perspective side view of an alignment rod used to align the spinal fixation device of the present invention.

FIG. 17B is a perspective side view of an alternative embodiment of the alignment rod having splines used to align the spinal fixation device of the present invention.

FIG. 18 is a front perspective view of the drill template instrument.

FIG. 19 is a perspective side view of the alignment rod attached to a spinal fusion implant inserted in the disc space between two adjacent vertebrae.

FIG. 20 illustrates the step of drilling guide holes in the vertebrae adjacent to the spinal fusion implant with the drill template instrument of FIG. 18.

FIG. 21 illustrates a step of the method of inserting the spinal fixation device of the present invention with the alignment rod attached to the spinal fusion implant and the spinal fixation device placed on the driver instrumentation.

FIG. 22 illustrates a step of the short method of inserting the spinal fixation device of the present invention with the driver instrument engaging the splined alignment rod and a hammer for applying an impaction force and driving the driver instrument.

FIG. 22A is an enlarged fragmentary view of a projection being inserted into an insertion hole drilled within a vertebra shown in cross section taken along line 22A of FIG. 21.

FIG. 23 illustrates another step of the method of inserting the spinal fixation device of the present invention in which the spinal fixation device has been driven into the vertebrae and the driver instrumentation has been removed.

FIG. 24 illustrates another step of the method of inserting the spinal fixation device of the present invention with the splined alignment rod being removed from the spinal fusion implant and the locking screw being inserted and secured the spinal fixation device to the spinal fusion implant.

FIG. 25 is a top plan view of a first alternative embodiment of the spinal fixation device of the present invention.

FIG. 26 is a top plan view of a second alternative embodiment of the spinal fixation device of the present invention.

FIG. 27 is a perspective side view of a third alternative embodiment of the spinal fixation device of the present invention coupled to two spinal fusion implants and inserted in adjacent vertebrae of the spinal column.

FIG. 28 is a top plan view of a fourth alternative embodiment of the spinal fixation device of the present invention inserted into the vertebrae of the spinal column having a spinal fusion implant inserted in the disc space.

FIG. 29 is a top plan view of a fifth alternative embodiment of the spinal fixation device of the present invention inserted into the vertebrae of the spinal column having a spinal fusion implant inserted in the disc space.

FIG. 30 is a perspective bottom view of the fourth alternative embodiment of the spinal fixation device of the present invention.

FIG. 31 is a cross sectional view along lines 31—31 of FIG. 29 showing the fifth alternative embodiment of the spinal fixation device of the present invention inserted into the adjacent vertebrae and coupled to a spinal fusion implant.

FIG. 32 is a cross sectional view along lines 32—32 of FIG. 29 showing the projections of the fifth alternative embodiment of the present invention with respect to a spinal fusion implant inserted within the disc space.

FIG. 33 is a cross sectional view of a spinal fixation device of the present invention engaging two adjacent vertebrae and being attached to a spinal fusion implant, shown being used as an anchor for a multi-segmental spinal alignment means.

FIG. 34 is an enlarged elevational side view of a threaded post used to connect the spinal fixation device of the present invention to a multi-segmental spinal alignment means.

FIG. 35 is an exploded perspective view of a sixth alternative embodiment of the spinal fixation device of the present invention having independent projection members that are screws.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to FIG. 1 and 2, two identical spinal fixation devices of the present invention, each being generally referred to by the numerals 10 and 11, respectively, are shown inserted into two vertebrae V adjacent to a disc D of a segment of the human spine. Each spinal fixation device 10 and 11 is shown coupled to identical spinal fusion implants 40 and 41 that have been surgically implanted in the disc space between adjacent vertebrae V. In this manner, the spinal fixation devices 10 and 11 stabilize a segment of the spine, prevent the dislodgement of the spinal fusion implant 40, and remain permanently fixated to the spine once applied. The spinal fixation devices 10 and 11 are identical such that the description of one is equally applicable to the other. Thus, the description that follows will be directed to spinal fixation device 10.

Referring to FIGS. 3–4, the spinal fusion implant 40 such as, but not limited to, the spinal fusion implant described by Michelson, U.S. Pat. No. 5,015,247 issued on May 14, 1991, is shown. The spinal fusion implant 40 is cylindrical in shape and has external threads 42 at its outer perimeter for engaging the bone of the vertebrae V adjacent to the disc D. The spinal fusion implant 40 has an insertion end 43 having a depression **44** and a threaded aperture **45** for engaging a portion of the spinal fixation device **10** and also for engaging a portion of an instrument used to insert the spinal fixation device **10** into the vertebrae V.

Referring to FIGS. **5–7**, it is appreciated that the spinal fixation devices **10** and **11** of the present invention are not limited in use with a threaded spinal fusion implant **40** and **41**, but may be used with different types of spinal fusion implants. For example, the spinal fixation devices **10** and **11** may be coupled to spinal fusion implants **40***a* and **41***a*, respectively, each having external ratchetings **42***a* instead of external threads **42** as shown in FIG. **5**. Alternatively, the spinal fixation devices **10** and **11** may be coupled to spinal fusion implants **40***b* and **41***b*, respectively, each having a partially cylindrical shape with at least one truncated side **47** as shown in FIG. **6**. As a further alternative, the spinal fixation devices **10** and **11** may be coupled to spinal fusion implants **40***c* and **41**c, respectively, each having a knurled external surface **48** as shown in FIG. **7**. It is also appreciated that the spinal fixation devices may be used with a variety of other bone fusion implants without departing from the scope of the present invention.

Referring to FIGS. **8–9**, in the preferred embodiment, the spinal fixation device **10** of the present invention comprises a staple member **12** having a substantially planar top member **14** which is of sufficient length to span one intervertebral disc D and to engage, via a plurality of essentially perpendicular extending projections **16** and **17**, the vertebrae V adjacent to that disc D. The top member **14** has a central opening **18** within a concentric, countersunk recess **19** for receiving therethrough a screw or similar coupling means for coupling the spinal fixation device **10** to the spinal fusion implant **40**. The top member **14** has an upper surface **20** having a pair of openings **22***a* and **22***b* for receiving the posts **88***a* and **88***b* of a driving instrument **80** which is described in greater detail below in reference to FIGS. **16**A and **16**B.

Referring to FIG. **10**, a cross sectional view of the top member **14** is shown. In the preferred embodiment, the top member **14** is generally triangularly shaped and is radiused along curved side **24** and straight side **26**. The curved side **24** of the top member **14** is radiused at its upper edge **25** and at the upper edge **27** of straight side **26** to conform to the external curvature of the vertebrae V. In this manner, smooth surfaces are created at the upper edges **25** and **27** of the top member **14** that are contoured to the shape of the external curvature of the vertebrae V when the staple member **12** is in place. The smooth contoured surface of the upper edges **25** and **27** of the top member **14** prevent aortic erosions and perforations of the vessels proximate the vertebral column such as the vena cava and the iliac vessels which might otherwise result from friction.

In the preferred embodiment of the spinal fixation device **10**, the top member **14** has a width ranging from 6.0 mm to 28.0 mm, with 10.0 mm being the preferred width, and having a thickness in the range of 2.0 mm to 4.0 mm, with 3.0 mm being the preferred thickness. The staple member **12** is made of material appropriate for human surgical implantation including all surgically appropriate metals such as but not limited to, titanium, titanium alloy, chrome molybidium alloys, stainless steel; or non-metallic materials including permanent or resorbable substances or composites, carbon fiber materials, resins, plastics, ceramics or others.

Further, the staple member **12** of the present invention may be treated with, or even composed of, materials known to participate in or promote in the fusion process or bone growth. The spinal fixation device **10** may be coated with materials to promote bone fusion and thus promote the incorporation and ultimate entombment of the spinal fixation device **10** into the bone fusion mass. The use of a bone fusion promoting material such as, but not limited to hydroxyapatite, hydroxyapatite tricalcium phosphate or bone morphogenic protein, results in a speedier vertebra V to vertebra V fusion as bone may grow along the coated spinal fixation device **10** bridging the two vertebrae V so that the spinal fixation device **10** acts as a trellis and supplies essential chemical elements to facilitate the bone fusion process.

Referring again to FIG. **9**, the projections **16** and **17** are positioned at opposite ends of the top member **14** and depend downwardly and extend perpendicularly from the bottom surface **30** of the top member **14**. The projections **16** and **17** each terminate in a distal end **32** that is pointed and sharpened to facilitate the insertion of the projections **16** and **17** into the vertebrae V.

The staple member **12** is most effective when the interprojection distance I between projections **16** and **17** is at least 4.0 mm and preferably 6.0 mm greater than the diameter of the particular spinal fusion implant **40** for which the spinal fixation device **10** is being used so that at least 2.0 mm and preferably 3.0 mm of bone from the vertebrae V will be present between the spinal fusion implant **40** and each of the projections **16** and **17**. Typically, intervertebral spinal fusion implants have a diameter that ranges from 12.0 mm to 28.0 mm, therefore, the interprojection distance I typically will range from 18.0 mm to 34.0 mm for most applications.

In the preferred embodiment, the projections **16** and **17** comprise a series of segmented and ratcheted portions **34**. The segmented and ratcheted portions **34** provide for a "one way" insertion of the staple member **12** to prevent the backing-out of the projections **16** and **17** once they are inserted into the bone of the vertebrae V. In the preferred embodiment, each segmented and ratcheted portion **34** of the projections **16** and **17** is conical in shape and the diameter of each segmented and ratcheted portion **34** increases in the direction from the distal end **32** toward the top member **14** so that the projections **16** and **17** resemble a stack of cones. The segmented and ratcheted portions **34** are spaced approximately 2.0 mm to 4.0 mm apart, with 3.0 mm being the preferred distance between each segmented and ratcheted portion **34**.

Referring to FIG. **11–12**, in the preferred embodiment of the spinal fixation device **10**, in order to further facilitate the insertion of the projections **16** and **17** into the vertebrae V, the distal end **32** of each projection **16** has an eccentric, incline-planed inner surface **36** as shown in FIG. **11**. The eccentric, incline-planed inner surface **36** of each of the projections **16** and **17** create a force F which pushes the bone of the vertebrae V toward the spinal fusion implant **40** as the staple member **12** is inserted into each of the vertebrae V as shown in FIG. **12**.

Referring to FIGS. **13A–13F**, in the preferred embodiment of the spinal fixation device **10**, the projections **16** and **17** are cylindrical in shape having a circular cross section as shown for projection **16** in FIG. **13A**. Alternatively, the projection **16***a* may have a triangular cross section as shown in FIG. **13B**; the projection **16***b* may have a square cross section as shown in FIG. **13C**; the projection **16***c* may have a rectangular cross section as shown in FIG. **13D**; the projection **16***d* may have a trapezoidal cross section as shown in FIG. **13E**; or the projection **16***e* may have a cross section with a configuration as shown in FIG. **13F**.

In the preferred embodiment, the projections **16** and **17** each have a diameter of approximately 2.0 mm to 4.0 mm, with 3.0 mm being the preferred diameter at the widest point. The projection **16** and **17** each have a length ranging from 16.0 mm to 28.0 mm, with 22.0 mm being the preferred length when the spinal fixation device **10** is implanted in the direction of the anterior aspect of the vertebra V to the posterior aspect of the vertebrae V. Alternatively, it is appreciated that the projections **16** and **17** each could have a longer length depending on the diameter of the vertebrae V in which the projections **16** and **17** are implanted.

Referring again to FIG. **9**, the top member **14** of the staple member **12** has a central bar **35** extending from the center of its bottom surface **30**, for interdigitating and mating to an already implanted intervertebral spinal fusion implant **40**. In the preferred embodiment, the central bar **35** has a thickness in the range of 0.5 mm to 1.5 mm, with 0.5 mm being the preferred thickness.

Referring to FIG. **1**, the central bar **35** is configured so that it complements and engages the depression **44** at the insertion end **43** of the spinal fusion implant **40**. Once engaged to the depression **44**, the bar **35** interdigitates with the depression **44** of the spinal fusion implant **40** to lock and prevent the rotation of the spinal fusion implant **40**.

Referring to FIG. **14**, in the preferred embodiment, the staple member **12** is secured to the spinal fusion implant **40** by a screw **60** having threaded end **61** with a locking thread pattern **62** and screw head **64**. The locking thread pattern **62** has a reduced pitch at the bottom of the threaded end **61** such that the screw **60** is self-locking. However, it is appreciated that the threaded pattern **62** may be any of the means for locking a screw well known by those skilled in the art.

Referring to FIGS. **2** and **8**, the threaded end **61** of the screw **60** passes through the central opening **18** of the top member **14** and the threaded pattern **62** threads into the threaded aperture **45** of the spinal fusion implant **40**. The screw head **64** fits within the countersunk recess **19** of the top member **14** such that the screw head **64** is at or below the plane of the upper surface **20** of the top member **14**. In the preferred embodiment, the central opening **18** has a diameter ranging from 4.5 mm to 5.5 mm, with 5.0 mm being the preferred diameter. The countersunk recess **19** has a diameter in the range of 6.0 mm to 8.0 mm with 7.0 mm being the preferred diameter.

Referring to FIGS. **15**A, **15**B, and **15**C, an enlarged cross sectional view of three different embodiments of a securing means **65** for locking the screw **60** once it is threaded to the spinal fusion implant **40** are shown. In FIG. **15**A, the securing means **65** comprises a notch **66** in the surface **20** of the top member **14** which is preferably made of metal. Once the screw **60** is threaded and securely tightened to the spinal fusion implant **40**, a chisel C is used to bend a portion **67** of the top member **14** into the central opening **18** and against the screw head **64** so as to prevent the outward excursion and any unwanted loosening of the screw **60**.

In FIG. **15**B, a second embodiment of the securing means **65*a*** is shown comprising a central score **66*a*** concentric with the central opening **18**. A screw **60*a*** having a slot **61*a*** in the screw head **64*a*** is threaded and securely tightened to the spinal fusion implant **40**. An instrument T is partially inserted into slot **61*a*** after which an impaction force F_i is applied to the instrument T to spread apart the screw head **64*a*** in the direction of the arrows A so that the screw head **64*a*** becomes deformed from the impaction force F_i and fits within the central score **66*a***. Once the screw head **64*a*** is in the central score **66*a***, the outward excursion of the screw **60*a*** is prevented by the top lip **68** of the central score **66*a***.

In FIG. **15**C, a third embodiment of the securing means **65*b*** is shown comprising a screw **60*b*** having a screw head **64*b*** with a slightly flanged portion **69*b*** near the top and a slot **61*b***. The central opening **18** has along its circumference a recess **66*b*** for receiving the flanged portion **69*b*** of the screw head **64*b***. The securing means **65*b*** relies on the natural resiliency of the metal screw head **64*b*** such that when the screw **60*b*** is being driven by a screw driver, the screw head **64*b*** flexes in the direction of the arrows B. In this manner, the flanged portion **69*b*** of the screw head **64*b*** slides along the interior of the central opening **18** so that the screw head **64*b*** is below the top lip **68*b*** of the recess **66*b***. Once the screw driver is removed from the screw **60*b***, the screw head **64*b*** returns to its natural state in the direction opposite to the arrows B so that the flanged portion **69*b*** is within the recess **66*b***. The outward excursion of the screw **60** is thus prevented by the top lip **68*b*** which blocks the screw head **64*b*** by catching the flanged portion **69*b***.

FIGS. **16**A–**18** show the instrumentation used for installing the spinal fixation device **10**. Referring to FIG. **16**A, a driving instrument **80** used for inserting the spinal fixation device **10** into the vertebrae V is shown having a hollow tubular shaft **82** which terminates at one end to a bottom flat member **84** and terminates to a top flat member **86** at the other end. The bottom flat member **84** is preferably configured so that it conforms to the shape of the top member **14** of the staple member **12**.

The driving instrument **80** has a pair of short posts **88*a*** and **88*b*** extending from the bottom flat member **84**. The posts **88*a*** and **88*b*** are oriented on the bottom flat member **84** so as to correspond to the position of the openings **22*a*** and **22*b*** in the upper surface **20** of the top member **14** of the staple member **12**. Each of the posts **88*a*** and **88*b*** fit into each of the openings **22*a*** and **22*b*** and keep the staple member **12** aligned on the bottom flat member **84** of the driving instrument **80**. It is appreciated that the openings **22*a*** and **22*b*** in the top member **14** may be depressions within the surface **20** of the top member **14** or may be holes that pass through the top member **14**. In the preferred embodiment, the openings **22*a*** and **22*b*** gave a diameter ranging from 1.5 mm to 3.5 mm, with 2.5 mm being the preferred diameter.

Referring to FIG. **16**B, an alternative embodiment of the driving instrument **80'** which is used for inserting into the vertebrae V the spinal fixation device **210**, described in detail below in reference to FIG. **26**, is shown having a hollow tubular shaft **82'** which terminates at one end to a bottom flat member **84'** and terminates to a top flat member **86'** at the other end. The bottom flat member **84'** is rectangular in shape so that it conforms to the shape of the top member **214** of the spinal fixation device **210**.

The driving instrument **80'** has a pair of short posts **88'*a***, **88'*b***, **88'*c*** and **88'*d*** extending from the bottom flat member **84'**. The posts **88'*a*–88'*d*** are oriented on the bottom flat member **84'** so as to correspond to the position of the openings **222*a*–222*d*** of the spinal fixation device **210**. Each of the and keep the spinal fixation device **210** aligned on the bottom flat member **84'** of the driving instrument **80'**.

Referring to FIG. **17**A, an alignment rod **70** comprising a cylindrical shaft **72** having a smooth exterior surface **73** and a threaded end **74** may be threadably attached to the threaded aperture **45** of the spinal fusion implant **40** is shown. The alignment rod **70** fits through the central opening **18** of the spinal fixation device **10** and is used to properly align the projections **16** and **17** on each side of the spinal fusion implant **40** prior to engaging the vertebrae V. Further, the alignment rod **70** also serves as a guide post for the drilling template instrument **50** described in greater detail below.

Referring to FIG. **17**B, as an alternative embodiment of the alignment rod **70**, a splined alignment rod **70**' that has a finely splined surface **72**' along its longitudinal axis and a threaded end **74**' that may be attached to the threaded aperture **45** of the spinal fusion implant is shown.

Referring to FIG. **18**, a drilling template instrument **50** for creating a pair of insertion holes **53***a* and **53***b* in each of the vertebrae V for receiving each of the projection **16** and **17** respectively is shown. The drilling template instrument **50** has a template **52** with a central aperture **54** therethrough and guide passages **55** and **56** for guiding a drill bit **51** of a drilling tool. Attached to the template **52** is a handle **58** which angles away from the template **52** so as not to obstruct the line of sight of the surgeon and to allow easy access to the template **52** and easy access to the guide holes **55** and **56** for the drill bit **51**. Extending from the center of the bottom surface of the template **52** is a central member **59** (similar in structure and function to the central bar **35**) for mating to an already implanted intervertebral spinal fusion implant **40**. The central member **59** interdigitates with the depression **42** of the spinal fusion implant **40** so that the template **52** is properly oriented about the spinal fusion implant **40** and the guide holes **55** and **56** are properly oriented with respect to the vertebrae V adjacent to the spinal fusion implant **40**. The alignment rod **70** serves as a guide post for the drill template instrument **50** as it fits through the central aperture **54** of the template **52** and aligns the template **52** with respect to the spinal fusion implant **40** and insures that it is coaxial. The central aperture **54** of the drilling template instrument **50** is smooth so that if it is placed over a splined alignment rod **70**' the drilling template instrument **50** may be easily rotated about the splined alignment rod **70**' into position such that the central member **59** is able to mate and interdigitate with the depression **44** of the spinal fusion implant **40**.

Referring to FIGS. **19**–**24**, the spinal fixation device **10** of the present invention is inserted in the following manner: At least one spinal fusion implant **40** is surgically implanted so that it is substantially within the disc space between two adjacent vertebrae V and engages at least a portion of each of the two adjacent vertebrae V. Once the spinal fusion implant **40** is in place, the alignment rod **70** is attached to the threaded aperture **45** of the spinal fusion implant **40**. The alignment rod **70** serves as a guide post for the drilling template instrument **50** as it fits through the central aperture **54** of the template **52** and aligns the template **52** coaxially with respect to the spinal fusion implant **40**.

Referring to FIG. **20**, once the template **52** is properly aligned and the drilling template instrument **50** is seated so that the central member **59** interdigitates with the spinal fusion implant **40**, the insertion holes **53***a* and **53***b* are drilled in each of the adjacent vertebrae V with a drilling instrument having a drill bit **51** with a diameter that is substantially smaller than the diameter of each the projections **16** and **17** of the staple member **12**.

Once the drilling of the insertion holes **53***a* and **53***b* is completed, the drill template instrument **50** is removed from the spinal fusion implant **40** and from the alignment rod **70**. The alignment rod **70** is left in place attached to the threaded aperture **45** of the spinal fusion implant **40**.

Referring to FIG. **21**, the staple member **12** is placed onto the driving instrument **80** used for driving and fixing the staple member **12** into the vertebrae V so that the bottom flat member **84** and the posts **88***a* and **88***b* are aligned with the top member **14** and the depressions **22***a* and **22***b* of the top member **14**. The alignment rod **70** serves as a guide post for the staple member **12** as it fits through the central opening **18** of the staple member **12** and aligns the staple member **12** coaxially with respect to the spinal fusion implant **40**.

Referring to FIG. **22**, once the staple member **12** is properly placed onto the bottom flat member **84** of the driving instrument **80**, the staple member **12** and the driving instrument **80** are aligned with respect to the alignment rod **70** so that the alignment rod **70** passes through the central opening **18** of the staple member **12** and is inserted into the central hollow portion **89** of the driving instrument **80**. The staple member **12** and the driving instrument **80** are then lowered along the alignment rod **70** so that the sharp distal end **32** of each of the projections **16** and **17** comes into contact with the external surface of the vertebrae V and is aligned with the previously drilled insertion holes **53**A and **53**B

As shown in FIG. **22**A, it is preferred that the insertion holes **53***a* and **53***b* be drilled so that when the projections **16** and **17** are inserted into the holes **53***a* and **53***b*, the incline planed inner surface **36** of each of the projections **16** and **17** contacts the inner wall W of the insertion holes **53***a* and **53***b* that is closest to the spinal fusion implant **40**. In this manner a compression force F is created as each of the projections **16** and **17** of the staple member **12** is inserted into insertion holes **53***a* and **53***b*, respectively, compressing the bone of the vertebrae V toward the spinal fusion implant **40**.

Referring to FIG. **23**, the staple member **12** is then driven into the vertebrae V by applying a high impaction force to the driving instrument **80** with a hammer H or other impacting means against the top flat member **86** of the driving instrument **80**. The staple member **12** is driven into the vertebrae V such that the projections **16** and **17** are moved forward into the insertion holes **53***a* and **53***b*, respectively, until the bottom surface **30** of the top member **14** of the staple member **12** comes to rest against the surface of the vertebrae V.

Referring to FIGS. **23**–**24**, the driving instrument **80** is lifted away from the alignment rod **70** so that the alignment rod **70** is no longer within the central hollow portion **89** of the driving instrument **80**. The alignment rod **70** is unthreaded from the threaded aperture **45** and is removed from the spinal fusion implant **40**. The staple member **12** is secured to the spinal fusion implant **40** with the locking screw **60** which has a threaded pattern **62** with a reduced pitch. The reduced pitch of the locking screw **60** locks the locking screw **60** to the spinal fusion implant **40** with minimal turning of the locking screw **60** and prevents any unwanted loosening. Further, any of the three embodiments of the securing means **65**, **65***a* or **65***b* described above in reference to FIGS. **15**A–**15**C may be used to further prevent any unwanted loosening and outward excursion of the screw **60**.

Referring back to FIG. **12**, once the staple member **12** is driven into the vertebrae V and is secured to the spinal fusion implant **40**, the spinal fusion implant **40** is prevented from rotating along its rotational axis R by its connection to the staple member **12** which is fixated across the disc space between the vertebrae V. The staple member **12** is prevented from backing out from the vertebrae V along the longitudinal axis L by its connection to the spinal fusion implant **40** and by the segmented and ratcheted portions **34** of the projections **16** and **17**. In this manner, the staple member **12** and the spinal fusion implant **40** interact to prevent the dislodgement of each other from the vertebrae V in which they are implanted. Thus, the staple member **12** is made safe against dislodgement by attachment to the spinal fusion implant **40** and the stability of the spinal fusion implant **40** is assured as it is also stabilized by the staple member **12** and each works in connection with the other to remove the only remaining degree of freedom that would allow for the disengagement of either. In addition, the incline planed inner surface **36** at the distal end **32** of the projections **16** and **17** forces bone toward the spinal fusion implant **40** along force lines F to further secure the spinal fusion implant **40** and further prevent the dislodgement of the spinal fusion implant **40**.

It is appreciated by those skilled in the art that when the bone of the vertebrae V is sufficiently soft, a shorter method (hereinafter referred to as the "Short Method") of inserting the spinal fixation device **10** is possible by omitting the steps of drilling the insertion holes **53***a* and **53***b* prior to inserting the staple member **12** into the vertebrae V.

Referring to FIG. **22**, in the Short Method, the splined alignment rod **70'** that is finely splined along its longitudinal axis is used instead of the alignment rod **70**. Once the splined alignment rod **70'** has been attached to the spinal fusion implant **40**, the staple member **12** may be placed over the splined alignment rod **70'** so that the splined alignment rod **70'** passes through the aperture **18** and into the central aperture **89** of the driving instrument **80**. The central aperture **89** of the driving instrument **80** is correspondingly splined to the splines of the splined alignment rod **70'** so that the staple member **12** can be aligned with respect to the spinal implant **40**. The alignment of the staple member **12** and the driving instrument **80** is maintained as the corresponding splines of the central aperture **89** interdigitate with the splines of the splined alignment rod **70'** and prevent the rotation of the staple member **12** about the splined alignment rod **70'**. The prevention of rotation about the splined alignment rod **70'**is especially important when the Short Method is used to insert the spinal fixation device **10**, as no insertion holes **53***a* and **53***b* have been drilled in the vertebrae V. The staple **12** can be driven directly into the vertebrae V by the application of a high impaction force to the driving instrument **80** as described above and shown in FIG. **22**.

Once the staple member **12** is driven into the vertebrae V, the steps of the longer method described above are used to secure the spinal fixation device to the spinal fusion implant **40** are the same. The Short Method of inserting the staple member **12** reduces the amount of time required to insert and secure the spinal fixation device **10** of the present invention and thus reduces the overall duration of the spinal fixation surgical procedure.

While the present invention has been described with respect to its preferred embodiment, it is recognized that alternative embodiments of the present invention may be devised without departing from the inventive concept.

For example, referring to FIG. **25**, a first alternative embodiment of a spinal fixation device **110** having a staple member **112** with a top member **114** generally in the shape of an elongated oval having two curved sides **124***a* and **124***b* is shown. In this alternative embodiment, the curved sides **124***a* and **124***b* have upper edges **125***a* and **125***b*, respectively, that are radiused to conform to the external curvature of the vertebrae V thereby creating smooth contoured surfaces as described above for the spinal fixation device **10**, the preferred embodiment of the present invention. The top member **114** has openings **122***a* and **122***b* in the upper surface **120** of the top member **114** and has two projections **116** and **117** depending downwardly from the bottom surface **130** of the top member **114** at opposite ends of the staple member **112**. The projections **116** and **117** are the same as the projections **16** described above for the preferred embodiment.

Referring to FIG. **26**, a second alternative embodiment of the spinal fixation device **210** having a staple member **212** is shown with a top member **214** that is generally rectangular in shape and has an upper surface **220** with openings **222***a*, **222***b*, **222***c*, and **222***d*. The top member **214** has four projections **216**, **217**, **218**, and **219** depending from its bottom surface at each of its corners. The projections **216–217** are the same as the projections **16** and **17** described above in the preferred embodiment. The top member **214** has four straight sides **228***a*, **228***b*, **228***c*, and **228***d* having upper edges **225***a*, **225***b*, **225***c*, and **225***d*, respectively, that are radiused to conform to the to external curvature of the vertebrae V create a smooth surface as described above for the preferred embodiment. The driving instrument **80'** shown in FIG. **16**B is used to insert the spinal fixation device **210**.

Referring to FIG. **27**, a third alternative embodiment of the spinal fixation device **310** having a staple **312** with a top member **314** that is generally triangular is shown. The top member **314** has two projections **316** and **317** depending from the bottom surface of the top member **314** that engage the vertebrae V. Extending from the center of the bottom surface of the top member **314** is a central member **390** which is similar to the central bar **35** of the preferred embodiment of the spinal fixation device **10** in that the central member **390** interdigitates with the depression **44** of the spinal fusion implant **40**. However, the central bar **390** also has an extension arm **392** that extends laterally from the top member **314** to span the diameter of an adjacent spinal fusion implant **41**. The extension arm **392** interdigitates with the depression **44** of the spinal implant **41**. The extension arm **392** has a central aperture **394** for receiving a screw **60***b* used to couple the extension arm **392** to the spinal fusion implant **41**. In this manner, a single spinal fixation device **310** is capable of interdigitate with two adjacent spinal fusion implants **40** and **41** to lock and prevent the rotation and any excursion of the spinal fusion implants **40** and **41**. The fixation of two spinal fusion implants **40** and **41** is possible while leaving no protruding metal, such as the top member **314**, on the side of the spine where the vessels are located in close approximation to the vertebrae as is the case with the L_4 and L_5 vertebrae where the vessels are located over the left side of those vertebrae. It is appreciated that any of the securing means **65–65***b*, described above may be used to lock the screw **60***b* to the extension arm **392**.

Referring to FIG. **28**, a fourth alternative embodiment of the spinal fixation device **410** having a staple member **412** with a top member **414** that is generally triangular in shape is shown in the installed position. The top member **414** is wider and larger than top member **14** as it is used with an implant **440** having a large diameter in the range of 22.0 mm to 28.0 mm. The top member **414** needs to be wider when used with implant **440** in order to provide a central bar **435** of sufficient length to interdigitate and mate with the preferred embodiment of the present invention for use with a multi-segmental spinal alignment means **600** described in greater detail below in that the staple **512** provides a more solid anchoring means that can resist greater torsion forces resulting from the application of the multi-segmental spinal alignment means **600** to align the spine.

Alternatively, for all of the embodiments described above, the spinal fixation device **10** of the present invention could be made of resorbable materials, such as bio-compatible resorbable plastics, that resorb at an appropriate rate such that once the spinal fixation device **10** is no longer needed (i.e. when spinal fusion is complete) the body would resorb the spinal fixation device **10**. One such resorbable material is polygalactone, however any other resorbable plastic or other material safely usable within the human body are also within the scope of the present invention.

Further, the spinal fixation device could be only in part resorbable such that the projections **16** and **17** of the staple member **12** would be non-resorbable and would remain incarcerated in the vertebrae V and sealed off once the resorbable portion of the staple is resorbed by the body.

Referring to FIGS. **33** and **34**, as a further application, the spinal fixation device **510** of the present invention may be used as an anchor for a multi-segmental spinal alignment means **600**, such that a multiplicity of spinal fixation devices may then be interconnected via a cable, rod, bar, or plate, so as to achieve or maintain any desired multi-segment spinal alignment. In the preferred embodiment, the multi-segmental spinal alignment means **600** comprises more than one spinal fixation device **510** of the present invention placed in series along the spine such that each spinal fixation device **510** spans one disc D and engages two adjacent vertebrae V. The spinal fixation device **510** is preferred over the other embodiments of the present invention in that it has a greater area of engagement with the vertebrae V so as to provide a solid anchoring means for the multi-segmental spinal alignment means **600**. However, it is appreciated that other embodiments including but not limited to those described herein may be utilized as anchoring means for the multi-segmental spinal alignment means **600**

When used as an anchor, each spinal fixation device **510** interdigitates with and is connected to a spinal fusion implant **610** having an insertion end **612**, an interior chamber **614** and is inserted in the disc space between the two adjacent vertebrae. The spinal fusion implant **610** has a threaded blind hole **620** for receiving a threaded post **622** therein. The blind hole **620** has a casing that is made of strong surgically, implantable material such as, but not limited to titanium. The casing **624** extends from the insertion end **612** of the spinal fusion implant **610** into the interior central chamber **614**. The insertion end **612** has a rigid construction that is capable of withstanding high torsion forces resulting from the tensioning of the multi-segmental spinal alignment means to align segments of the spine. In the preferred embodiment, the insertion end **612** of the spinal fusion implant has an end portion **626** that closes the insertion end **612**. The end portion is substantially thicker than the rest of the spinal fusion implant **610** and in the preferred embodiment, the end portion **626** has thickness ranging from 1.5 mm to 4.0 mm, with 2.5 mm being the preferred thickness.

Referring to FIG. **34**, the threaded post **622** has a threaded end **628** with a locking thread pattern that is substantially longer than the locking thread pattern **62** of the screw **60** described above and a head portion **630** having a hole **632** for receiving a rod **634** or a cable therethrough. The head portion **630** has a rounded exterior surface to prevent any damage such as aortic erosion to the vessels in the area adjacent to the spine. In the preferred embodiment the threaded post has a diameter ranging from 3.0 mm to 6.0 mm, with 4.5 mm being the preferred diameter and has a length ranging from 15.0 mm to 25.0 mm, with 20.0 mm being the preferred length. The head portion **630** extends at a height above the top member **514** of the spinal fixation device **510** of approximately 8.0 mm to 16.0 mm, with 12.0 being the height preferred once it is threadably attached to the spinal fusion implant **610** such that it does not significantly protrude from the spinal column into the tissue and vessels adjacent thereto.

Once the threaded post **622** is attached to the spinal fusion implant **610**, the head portion **630** of each threaded post **622** are connected to one another by the rod **634** having a sufficient diameter to fit through the hole **632** of each head portion **630**. The rod **634** has at least a portion thereof that is threaded so that a plurality of lock nuts **638** may be used to secure the rod **634** to the head portions **630**. The lock nuts **638** may also be used as length adjusting means to adjust the length of the rod **634** between head portions **630** so that segmental portions of the spine may be held closer together or held further aport for the purposes of aligning the spine. It is appreciated that a plurality of multi-segmental spinal alignment means **600** may be placed in series either on one side or on opposite sides of the spine, such that one side of the spine may be extended while the other side may be held stationary or may be compressed in order to achieve proper spinal alignment. The multi-segment spinal alignment may be maintained by keeping the rod tensioned with the lock nuts **638** or by any other means well known by those skilled in the art. It is also appreciated that in place of a rod **634** a cable, a plate or any other means well known by those skilled in the art may be used to interconnect the multi-segmental spinal alignment means.

Referring to FIG. **35**, a sixth alternative embodiment of the spinal fixation device of the present invention is shown and generally referred to by the numeral **710**. The spinal fixation device **710** comprises a top member **714** that is similar to the top member **14** described above, except that it does not have projections **16** and **17** extending from the bottom surface. Like numbers are being used to designate identical features of the top members **14** and **714**.

In the top member **714**, instead of having projections **16** and **17**, independent projection members **716** and **717** in the form of screws are used to secure the top member **714** of the spinal fixation device **710** to the vertebrae V of the spine. The projection screw members **716** and **717** each terminate in a sharp distal end **720** and **722** respectively, have a threaded portion **723**, and have screw heads **724** and **726** for engaging a screw driver or similar driving instrument.

The top member **714** has a hole **728** on one end and a hole **730** at its other end through which each of the projection screw members **716** and **717** respectively, may pass. The projections screw members **716** and **717** pass through the holes **728** and **730** to engage the vertebrae V. Each of the holes **728** and **730** has a concentric counter sunk recess **732** and **734** for receiving and seating the screw heads **724** and **726** of the projection screw members **716** and **717** so that the screw heads **724** and **726** are flush or below the top surface **20** of the top member **714** once inserted into the vertebrae V.

As the projection screw members **716** and **717** are threaded, they can be rotationally advanced into the vertebrae instead of by way of an impaction force such that the potential for damage to the vertebrae V is reduced. The threads of the threaded portion **723** follow one another as the projection screw members **716** and **717** are being screwed into the bone such that the integrity of the vertebrae V is preserved. Also, as the projection screw members **716** and **717** are independent from the top member **714**, the penetration depth of the spinal fixation device **710** into the bone of the vertebrae V may be easily altered by selecting different sized projection screw members **716** and **717** appropriate for the particular vertebrae being fused. Further, it is possible to configure the holes **728** and **730** in the top member **714** such that the projection screw members **716** and **717** may be inserted into the vertebrae V from a number of different angles relative to the top member **714**.

Adjacent and proximate to each of the holes **728** and **730** are threaded openings **740** and **742**, respectively, for receiving locking screws **744** and **746** respectively. Each of the locking screws **744** and **746** have a head portion **750** and **752** and a locking thread portion **754** and **756** for threadably and lockably engaging the threaded openings **740** and **742**. The locking screws **744** and **746** are attached to the top member **714** after the projection screw members **716** and **717** have been inserted into the vertebrae V. At least a part of the head portion **750** and **752** blocks and preferably makes contact with the screw projections **716** and **717** to prevent any unwanted loosening and outward excursion of the screw projections **716** and **717**.

It is appreciated that the projection members **716** and **717**, instead of being threaded screws, may have a number of other configurations such as, but not limited to, the configurations of the projections described above for the various embodiments of the present invention. If the projections members **716** and **717** are ratcheted instead of being threaded, they can be driven into the vertebrae V with a driving instrument and impaction force as described above for the method of the present invention.

While the present invention has been described with respect to its preferred embodiment and a number of alternative embodiments, it is recognized that additional variations of the present invention may be devised without departing from the inventive concept and scope of the present invention.

What is claimed is:

1. A multi-segmental spinal alignment apparatus for linking segments of the spine, comprising:

a first spinal implant adapted to be surgically implanted at least in part within a first disc space between two adjacent vertebrae in a segment of the spine, said first spinal implant being adapted to contact both of the vertebrae adjacent to the first disc space when the disc space has been restored to approximate a normal height for the disc space, said first spinal implant having an end configured to receive a connector;

a second spinal implant adapted to be surgically implanted at least in part within a second disc space between two adjacent vertebrae in another segment of the spine, said second spinal implant being adapted to contact both of the vertebrae adjacent to the second disc space when the disc space has been restored to approximate a normal height for the disc space; and

a connector attached to said first and second spinal implants for connecting said first and second spinal implants.

2. The apparatus of claim **1**, wherein said second spinal implant has an end portion configured to receive said connector.

3. The apparatus of claim **2**, wherein each of said end portions has an aperture for receiving said connector.

4. The apparatus of claim **3**, wherein said apertures are generally aligned along the longitudinal axis of the spine.

5. The apparatus of claim **1**, wherein each of said end portions are detachable.

6. The apparatus of claim **1**, wherein each of said end portions is a coupler.

7. The apparatus of claim **6**, wherein each of said couplers are detachable.

8. The apparatus of claim **6**, wherein each of said couplers includes an aperture generally along the longitudinal axis of the spine for receiving said connector.

9. The apparatus of claim **6**, wherein each of said couplers has a head and a shank, said head having an aperture for receiving the connector.

10. The apparatus of claim **9**, wherein each of said first and second implants has an aperture for receiving said shanks.

11. The apparatus of claim **10**, wherein said shanks and said apertures have cooperating threads.

12. The apparatus of claim **1**, wherein said first and second implants include upper and lower portions with at least one opening in each of said upper and lower portions for permitting bone growth from one of the adjacent vertebrae through said spinal implant to the other of the adjacent vertebrae.

13. The apparatus of claim **12**, further comprising a hollow interior within each of said first and second implants for holding bone growth promoting material, said hollow interior being in communication with at least one opening in each of said upper an lower portions.

14. The apparatus of claim **1**, wherein said first and second implants include upper and lower portions that are arcuate.

15. The apparatus of claim **1**, wherein said first and second implants further comprise a protrusion for engaging the adjacent vertebrae.

16. The apparatus of claim **15**, wherein said protrusion is a thread.

17. The apparatus of claim **1**, wherein said connector is selected from one of a rod, a cable, a plate, and a bar.

18. The apparatus of claim **1**, further comprising means for adjusting the length of said connector between said first and second spinal implants for aligning segments of the spine.

19. The apparatus of claim **18**, wherein said length adjusting means includes a threaded member on said connector for varying the length of said connector between said first and second spinal implants.

20. The apparatus of claim **18** further comprising a means for locking said length adjusting means at a selected length.

21. The apparatus of claim **1**, further comprising a third spinal implant adapted to be surgically implanted in the first disc space, a fourth spinal implant adapted to be surgically implanted in the second disc space, and a second connector attached to both of said third and fourth implants.

22. The apparatus of claim **21**, wherein said first and second connectors are adapted to be placed on one side of the spine.

23. The apparatus of claim **21**, wherein said first and second connectors are adapted to be placed on opposite sides of the spine.

24. The apparatus of claim **21**, wherein said first and second connectors are selected from one of a rod, a cable, a plate, and a bar.

25. The apparatus of claim **1**, wherein said first and second spinal implants include an artificial material other than bone.

26. The apparatus of claim **1**, wherein said implants are configured for implantation across a disc space in the thoracolumbar region of the human spine.

27. A multi-segmental spinal alignment apparatus for linking multiple implants surgically implanted in the human spine, comprising:

a first spinal implant adapted to be surgically implanted within a first location of the spine;

a second spinal implant adapted to be surgically implanted within a second location of the spine, each of said first and second spinal implants having opposed arcuate portions over at least a portion of their length and at least one opening in each of said opposed arcuate portions along the length of said implants for permitting growth of bone into and through said implants, said implants having a hollow interior for holding bone growth promoting material, said hollow interior of each of said implants being in communication with at least one opening in each of said opposed arcuate portions; and a protrusion extending from the exterior of each of said implants for engaging bone in the spine; and

a connector having a width and a length, said connector being attached along its length to each of said implants for connecting said implants together, each of said implants having a width greater than said width of said connector measured transverse to the longitudinal axis of the spine.

28. The apparatus of claim **27**, wherein at least one of said insertion and trailing ends are open for loading bone growth promoting materials into said hollow interior.

29. The apparatus of claim **28**, further comprising an end cap for closing said open end.

30. The apparatus of claim **27**, wherein each of said implants has an end portion configured to receive said connector.

31. The apparatus of claim **27**, wherein each of said implants has an end portion configured to couple to said connector.

32. The apparatus of claim **31**, wherein each of said end portions has an aperture for receiving said connector.

33. The apparatus of claim **31**, wherein said apertures are generally aligned along the longitudinal axis of the spine.

34. The apparatus of claim **27**, wherein each of said end portions is detachable.

35. The apparatus of claim **27**, wherein each of said end portions is a coupler.

36. The apparatus of claim **35**, wherein each of said couplers is detachable.

37. The apparatus of claim **35**, wherein each of said couplers include an aperture generally along the longitudinal axis of the spine for receiving said connector.

38. The apparatus of claim **35**, wherein each of said couplers have a head and a shank, said head having an opening for receiving the connector.

39. The apparatus of claim **38**, wherein each of said implants has an aperture for receiving said shank.

40. The apparatus of claim **39**, wherein said shank and said apertures have cooperating threads.

41. The apparatus of claim **27**, wherein said protrusion of said opposed arcuate portions is a thread.

42. The apparatus of claim **27**, wherein said connector is selected from one of a rod, a cable, a plate, and a bar.

43. The apparatus of claim **27**, further comprising means for adjusting the length of said connector between said implants for aligning segments of the spine.

44. The apparatus of claim **43**, wherein said length adjusting means includes a threaded member on said connector for varying the length of said connector between said implants.

45. The apparatus of claim **43**, further comprising means for locking said length adjusting means at a selected length.

46. The apparatus of claim **27**, further comprising a third spinal implant adapted to be surgically implanted in a third location in the spine, a fourth spinal implant adapted to be surgically implanted in a fourth location in the spine, and a second connector attached to both of said third and fourth implants.

47. The apparatus of claim **46**, wherein said first and second connectors are adapted to be placed on one side of the spine.

48. The apparatus of claim **46**, wherein said first and second connectors are adapted to be placed on opposite sides of the spine.

49. The apparatus of claim **46**, wherein said second connector is selected from one of a rod, a cable, a plate, and a bar.

50. The apparatus of claim **27**, wherein said implants include an artificial material other than bone.

51. A multi-segmental spinal alignment apparatus for linking segments of the spine, comprising:

a first spinal implant adapted to be surgically implanted at least in part within a first disc space between two adjacent vertebrae in a segment of the spine, said first spinal implant being adapted to contact both of the vertebrae adjacent to the first disc space when the disc space has been restored to approximate a normal height of the disc space;

a second spinal implant adapted to be surgically implanted at least in part within a second disc space between two adjacent vertebrae in another segment of the spine, said second spinal implant being adapted to contact both of the vertebrae adjacent to the second disc space when the disc space has been restored to approximate a normal height of the disc space;

a connector having a length sufficient to span the distance from said first disc space to said second disc space to connect said implants; and

a plurality of couplers for coupling said connector to each of said spinal implants.

52. The apparatus of claim **51**, wherein each of said spinal implants has an end portion configured to receive said at least one of said couplers.

53. The apparatus of claim **51**, wherein each of said implants has an end portion configured to couple to said at least one of said couplers.

54. The apparatus of claim **52**, wherein each of said couplers has an aperture for receiving said connector.

55. The apparatus of claim **54**, wherein said apertures are generally aligned along the longitudinal axis of the spine.

56. The apparatus of claim **52**, wherein each of said couplers is detachable.

57. The apparatus of claim **52**, wherein each of said couplers has a head and a shank, said head having an opening for receiving the connector.

58. The apparatus of claim **57**, wherein each of said implants have an aperture for receiving said shank.

59. The apparatus of claim **58**, wherein each of said shanks and each of said apertures has cooperating threads.

60. The apparatus of claim **51**, wherein said implants include upper and lower portions with a plurality of openings for permitting bone growth from one of the adjacent vertebrae through each of said implants to the other of the adjacent vertebra.

61. The apparatus of claim **60**, further comprising a hollow interior for holding bone growth promoting material, said hollow interior within each of said implants being in communication with at least two of said plurality of openings.

62. The apparatus of claim **51**, wherein said implants include upper and lower portions that are arcuate.

63. The apparatus of claim **51**, wherein said implants further comprise a protrusion for engaging the adjacent vertebrae.

64. The apparatus of claim **63**, wherein said protrusion of said implants is a thread.

65. The apparatus of claim **51**, wherein said connector is selected from one of a rod, a cable, a plate, and a bar.

66. The apparatus of claim **51**, further comprising means for adjusting the length of said connector between said implants for aligning segments of the spine.

67. The apparatus of claim **66**, wherein said length adjusting means includes a threaded member on said connector for varying the length of said connector between said implants.

68. The apparatus of claim **66**, including means for locking said length adjusting means at a selected length.

69. The apparatus of claim **51**, further comprising a third spinal implant adapted to be surgically implanted in the first disc space, a fourth spinal implant adapted to be surgically implanted in the second disc space, and a second connector having a length sufficient to span the distance between said first and second disc spaces to connect said third and fourth spinal implants.

70. The apparatus of claim **69**, wherein said first and second connectors are adapted to be placed on one side of the spine.

71. The apparatus of claim **69**, wherein said first and second connectors are adapted to be placed on opposite sides of the spine.

72. The apparatus of claim **69**, wherein said first and second connectors are selected from one of a rod, a cable, a plate, and a bar.

73. The apparatus of claim **51**, wherein said implants include an artificial material other than bone.

74. The apparatus of claim **51**, wherein said implants are configured for implantation across a disc space in the thoracolumbar region of the human spine.

75. A method for linking multiple segments of a human spine, comprising the steps of:

implanting a first spinal implant adapted to be surgically implanted at least in part within a first disc space between two adjacent vertebrae in a segment of the spine, said first spinal implant being adapted to contact both of the vertebrae adjacent to the first disc space when the disc space has been restored to approximate a normal height for the disc space, said first spinal implant having a trailing end configured to receive a connector;

implanting a second spinal implant adapted to be surgically implanted at least in part within a second disc space between two adjacent vertebrae in a segment of the spine, said second spinal implant being adapted to contact both of the vertebrae adjacent to the second disc space, when the disc space has been restored to approximate a normal height for the disc space; and

attaching a connector to both of said first and second spinal implants.

76. The method of claim **75**, further comprising the step of positioning said implants in spatial relationship to each other.

77. The method of claim **75**, wherein the step of implanting said second implant includes implanting said second implant having a trailing end configured to receive a connector.

78. The method of claim **76**, wherein the positioning step includes the sub-step of varying the length of the connector between said implants.

79. The method of claim **76**, wherein the positioning step includes the sub-step of aligning segments of the spine.

80. The method of claim **76**, further comprising the step of locking said implants in a fixed spatial relationship to each other.

81. The method of claim **75**, further comprising the steps of implanting a third spinal implant in the first disc space and implanting a fourth spinal implant in the second disc space.

82. The method of claim **81**, wherein the attaching step includes attaching a second connector to both of said third and fourth spinal implants.

83. The method of claim **81**, further comprising the step of positioning on the same side of the spine first and second connectors for connecting spinal implants.

84. The method of claim **81**, further comprising the step of positioning on opposite sides of the spine first and second connectors for connecting spinal implants.

85. The method of claim **75**, further comprising the step of tensioning said connector between said implants.

86. The method of claim **75**, wherein the attaching step includes the sub-step of connecting at least three spinal implants in a series along segments of the spine.

87. The method of claim **75**, wherein the implanting steps include implanting said spinal implants including an artificial material other than bone.

88. The method of claim **75**, wherein the implanting steps include implanting said implants across a disc space in the thoracolumbar region of the human spine.

89. A method for linking multiple segments of the spine, comprising the steps of:

implanting a first spinal implant adapted to be surgically implanted in a first location of the spine, said first spinal implant having a maximum width and opposed arcuate portions over at least a portion of its length and a plurality of openings along the length of said implant passing therethrough for permitting growth of bone into said first implant, said first implant having a hollow interior for holding bone growth promoting material, said hollow interior being in communication with at least two of said plurality of openings, and a protrusion extending from the exterior of said first implant for engaging bone in the spine;

implanting a second spinal implant adapted to be surgically implanted in a second location in the spine, said second implant having a maximum width and opposed arcuate portions over at least a portion of its length and a plurality of openings along the length of said second implant passing therethrough for permitting growth of bone into said second implant, said second implant having a hollow interior for holding bone growth promoting material, said hollow interior being in communication with at least two of said plurality of openings, and a protrusion extending from the exterior of said second implant for engaging bone in the spine; and

aligning a connector to both of said implants, said connector having a width measured transverse to the longitudinal axis of the spine less than the maximum width of each of said implants.

90. The method of claim **89**, wherein the implanting steps include the sub-step of implanting said implants having at least one of said insertion and trailing ends open for loading bone growth promoting materials into said hollow interior.

91. The method of claim **90**, further comprising the step of providing an end cap for closing said open end.

92. The method of claim **89**, further comprising the step of positioning said implants in spatial relationship to each other.

93. The method of claim **92**, wherein the positioning step includes the sub-step of varying the length of the connector between said implants.

94. The method of claim **92**, wherein the positioning step includes the sub-step of aligning segments of the spine.

95. The method of claim **92**, further comprising the step of locking said implants in a fixed spatial relationship to each other.

96. The method of claim **89**, further comprising the steps of implanting a third spinal implant at a third location in the

spine and implanting a fourth spinal implant at a fourth location in the spine.

97. The method of claim **96**, wherein the attaching step includes attaching a second connector to both of said third and fourth spinal implants.

98. The method of claim **96**, further comprising the step of positioning on the same side of the spine first and second connectors for connecting spinal implants.

99. The method of claim **96**, further comprising the step of positioning on opposite sides of the spine first and second connectors for connecting implants.

100. The method of claim **89**, further comprising the step of tensioning said connector between said implants.

101. The method of claim **89**, wherein the attaching step includes the sub-step of connecting at least three spinal implants in a series along segments of the spine.

102. The method of claim **89**, wherein the implanting steps include implanting said spinal implants including an artificial material other than bone.

103. An apparatus for linking multiple spinal implants, comprising:

a first spinal implant adapted to be surgically implanted at least in part within a disc space between two adjacent vertebrae in a segment of the spine, said first spinal implant being adapted to contact both of the vertebrae adjacent to the disc space;

a second spinal implant adapted to be surgically implanted at least in part within the same disc space in which said first spinal implant is to be implanted, said second spinal implant being adapted to contact both of the vertebrae adjacent to the disc space; and

a connector attached to said first and second spinal implants for connecting said first and second spinal implants.

104. The apparatus of claim **103**, wherein each of said implants has an end portion configured to couple to said connector.

105. The apparatus of claim **104**, wherein each of said implants has an end portion configured to receive said connector.

106. The apparatus of claim **104**, wherein each of said end portions has an opening for receiving said connector.

107. The apparatus of claim **104**, wherein said end portions are detachable.

108. The apparatus of claim **104**, wherein each of said end portions is a coupler.

109. The apparatus of claim **108**, wherein each of said couplers are detachable.

110. The apparatus of claim **108**, wherein each of said couplers has a head and a shank, said head having an opening for receiving the connector.

111. The apparatus of claim **110**, wherein each of said implants has an aperture for receiving said shank.

112. The apparatus of claim **111**, wherein said shanks and said apertures have cooperating threads.

113. The apparatus of claim **103**, wherein said implants include upper and lower portions with a plurality of openings for permitting bone growth from one of the adjacent vertebrae through each of said implants to the other of the adjacent vertebrae.

114. The apparatus of claim **113**, further comprising a hollow interior within each of said implants for holding bone growth promoting material, said hollow interior being in communication with at least two of said plurality of openings.

115. The apparatus of claim **103**, wherein said implants have upper and lower portions that are arcuate.

116. The apparatus of claim **103**, wherein said implants further comprise a protrusion for engaging the adjacent vertebrae.

117. The apparatus of claim **116**, wherein said protrusion of said upper and lower portions of said implants is a thread.

118. The apparatus of claim **103**, wherein said connector is selected from one of a rod, a cable, a plate, and a bar.

119. The apparatus of claim **103**, wherein said implants include artificial material other than bone.

120. The apparatus of claim **103**, wherein said implants are configured for implantation across a disc space in the thoracolumbar region of the human spine.

121. An method for linking multiple spinal implants in the spine, comprising the steps of:

implanting a first spinal implant within a disc space between two adjacent vertebrae in a segment of the spine, said first spinal implant being adapted to contact both of the vertebrae adjacent to the disc space;

implanting a second spinal implant within the same disc space in which said first spinal implant is to be implanted, said second spinal implant being adapted to contact both of the vertebrae adjacent to the disc space; and

connecting said implants with a connector.

122. The method of claim **121**, wherein the implanting steps include implanting said implants having an end portion configured to couple to said connector.

123. The method of claim **121**, wherein the implanting steps include implanting each of said implants having an end portion configured to receive said connector.

124. The method of claim **121**, wherein the connecting step includes the sub-step of preventing rotation of said implants with said connector.

125. The method of claim **121**, wherein the implanting steps include implanting said spinal implants including an artificial material other than bone.

126. The method of claim **121**, wherein the implanting steps include implanting said implants across a disc space in the thoracolumbar region of the human spine.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,136,001
DATED : October 24, 2000
INVENTOR(S) : Gary Karlin Michelson

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

Title page,
Item [57], **ABSTRACT,**
Line 14, change "deice" to -- device --;
Line 17, change "pine" to -- spine --;

Column 18, claim 13,
Line 5, change "an" to -- and --;

Column 18, claim 20,
Line 1, after "18" insert -- , --;

Column 19, claim 40,
Line 1, change "shank" to -- shanks --;

Column 20, claim 60,
Line 5, change "vertebra" to -- vertebrae --;

Column 22, claim 89,
Line 28, change "aligning" to -- attaching --; and

Column 24, claim 121,
Line 1, change "An" to -- A --;

Signed and Sealed this

Twelfth Day of February, 2002

Attest:

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

Attesting Officer