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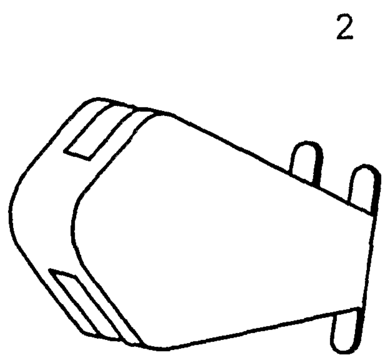
(54) **Title:** APPARATUS AND METHOD FOR SPINAL FUSION USING POSTERIORLY IMPLANTED DEVICES



(57) Abstract: An apparatus and method for spinal interbody fusion is disclosed. This implant includes fasteners which firmly attach it to vertebrae adjacent to excised tissue so as to transmit tension and torsional loads to and from those vertebrae. The instruments and methods are particularly adapted for interbody fusion from a posterior approach to the spine. One instrument is a vertebral spreader that is able to create anterior lift to a fixed or variable angle. Another instrument is a tome for cutting rectangular grooves in bone and preparing end plate surfaces. A method contemplates the use of these instruments to prepare a disk space and the insertion of the implant.

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APPARATUS AND METHOD FOR SPINAL FUSION USING POSTERIORLY IMPLANTED DEVICES

PRIORITY

This application is related to and claims priority from the United States Patent Application No. 10/379,609, filed March 5, 2003.

BACKGROUND OF INVENTION

Field Of Invention

This invention relates generally to the treatment of injured, degenerated, or diseased tissue in the human spine, for example, damaged intervertebral discs and vertebrae. It further relates to the removal of damaged tissue and to the stabilization of the remaining spine by fusion to one another of at least two vertebrae adjacent or nearly adjacent to the space left by the surgical removal of tissue. More particularly, this invention relates to the implantation of devices that can be inserted from the patient's posterior, that is, from the back, to take the structural place of removed discs and vertebrae during healing while simultaneously sharing compressive loads. This invention further relates to the implantation of devices that do not interfere with the natural lordosis of the spinal column. More particularly, while aspects of the present invention may have other applications, the invention also provides instruments and techniques especially suited for interbody fusion from a generally posterior approach to the spine.

Background of the Invention

For many years a treatment, often a treatment of last resort, for serious back problems has been spinal fusion surgery. Disc surgery, for example, typically requires removal of a portion or all of an intervertebral disc. Such removal, of course, necessitates replacement of the structural contribution of the removed disc. The most common sites for such surgery, namely those locations where body weight most concentrates its load, are the lumbar discs in the L1-2, L2-3, L3-4, L4-5, and L5-S1 intervertebral spaces.

In addition, other injuries and conditions, such as tumor of the spine, may require removal not only of the disc but of all or part of one or more vertebrae, creating an even greater need to replace the structural contribution of the removed tissue. Also, a number of degenerative diseases and other conditions such as scoliosis require correction of the relative orientation of vertebrae by surgery and fusion.

In current day practice, a surgeon will use one or more procedures currently known in the art to fuse remaining adjacent spinal vertebrae together in order to replace the structural contribution of the affected segment of the disc-vertebrae system. In general for spinal fusions a significant portion of the intervertebral disk and, if necessary, portions of vertebrae are removed and a stabilizing element, frequently including or composed entirely of bone graft material, is packed in the intervertebral space. In parallel with the bone graft material, typically additional external stabilizing instrumentation and devices are applied, in one method a series of pedicle screws and conformable metal rods. The purpose of these devices, among other things, is to prevent shifting and impingement of the vertebrae on the spinal nerve column. These bone graft implants and pedicle screws and rods, however, often do not provide enough stability to restrict relative motion between the two vertebrae while the bone grows together to fuse the adjacent vertebrae.

Various surgical methods have been devised for the implantation of fusion devices into the disk space. Both anterior and posterior approaches have been used for interbody fusions. The anterior approach requires the added costs and associated risks for a general surgeon and/or a vascular surgeon to open the patient's abdominal cavity in order for the back surgeon to operate on the spine from an anterior approach. As a result, many surgeons prefer a posterior approach.

The posterior surgical approach to the spine has often been used in the past. The primary difficulty of the posterior approach is that the spine surgeon must navigate past the spinal cord and subsidiary nerve structures. Also, unprotected drilling or trephining for implantation of cylindrical bone dowels carries risks to the patient.

U.S. Pat. No. 5,484,437 to Michelson discloses a technique and associated instrumentation for inserting a fusion device from a posterior surgical approach that provides greater protection for the surrounding tissues and neurological structures during the procedure. As described in more detail in the '437 patent, the surgical technique involves the use of a distractor having a penetrating portion that urges the vertebral bodies apart to facilitate the introduction of the necessary surgical instrumentation. The '437 patent also discloses a hollow sleeve having teeth at one end that are driven into the vertebrae adjacent the disc space created by the distractor. These teeth engage the vertebrae to maintain the disc space height during subsequent steps of the procedure following removal of the distractor. In accordance with one aspect of the '437 patent, a drill is passed through the hollow sleeve to remove portions of the disc material and vertebral bone to produce a prepared bore for insertion of the fusion device. The drill is then removed from the sleeve and the fusion device is positioned within the disc space using an insertion tool.

While the more recent techniques and instrumentation represent an advance over earlier surgical procedures for the preparation of the disc space and insertion of the fusion device, the need for improvement still remains. The present invention is directed to this need and provides convenient methods and instruments to insure safe and effective preparation of a disc space in conjunction with implant placement.

The restoration of normal anatomy is a basic principle of all orthopedic reconstructive surgery. Lordosis, which results in a pronounced forward curvature of the lumbar region of the spine, is a factor that needs to be taken into account in designing lumbar implants.

Therefore, there is a perceived need for a device which simultaneously and reliably attaches mechanically to the bony spinal segments on either side of the removed tissue so as to prevent relative motion in extension or torsion of the spinal segments during healing, provides spaces in which bone growth material can be placed to create or enhance fusion, and enables the new bony growth, and, in a gradually increasing manner if possible, shares the spinal compressive load with the bone growth material and the new growth so as to enhance bone growth and calcification. The needed device will usually require a modest taper to preserve natural lumbar spinal lordosis.

Thus, it is an object of the current invention to provide a stabilizing device for insertion in spaces created between vertebrae during spinal surgery. It is a further object to create a device implantable from the patient's posterior for stabilizing the spine by preventing or severely limiting relative motion between the involved vertebrae in tension (extension) and torsion loading during healing. It is a further object to provide a device which promotes growth of bone between vertebrae adjacent to the space left by the excised material by progressive sharing of the compressive load to the bone graft inserted in the space between the vertebrae. It is yet a further object to provide mechanical stability between adjacent vertebrae while bone grows and at the same time not diminish the natural lordosis of the lumbar spine. It is a further object to provide instrumentation that provides adequate protection for the sensitive vessels and neurological structures adjacent to the operating field. It is a further object to provide instrumentation that creates a significant bed of bleeding bone while also preserving endplate structure for strength. Another object of this invention is to provide a spreader instrument that provides sequential angular and translational distraction of the disk space from the posterior side to restore the natural height and angle of the disk space and to help facilitate insertion of the implant. It is yet another object of this invention for the implant to be capable of being fabricated from human bone allograft material.

SUMMARY OF THE INVENTION

The invention disclosed here is a novel implant and associated instrumentation designed to achieve the foregoing objects. The design of the new implant for spinal surgery includes the possibility of fabricating the device from human bone allograft material and from biocompatible manmade materials. The design is also such that the implant seats firmly in and mechanically mates with and ultimately fastens to adjacent vertebrae and stabilizes the involved vertebrae in tension and in torsion. Either the implant can be tapered or the vertebrae can be cut so as to preserve the natural lordosis of the spine. This invention also includes instrumentation necessary to effectively and safely prepare the intervertebral space, angularly distract the vertebrae and insert the implants.

The implants generally have a rectangular geometry, although in some embodiments an annular geometry is preferred, with a lordotic slope of approximately ten degrees, such that the opposing anterior side is taller than the posterior side. The slope can be reversed for use in other portions of the spine for lumbar use where the curvature is opposite The implant also incorporates an anti-expulsion feature, such as notches or teeth on the top and bottom surfaces of the stabilizing fins. The implant may also contain opposing slots on either side to facilitate gripping with a bone holder instrument.

The attachment portions of the implant are stabilizing fins projecting inferiorly and superiorly from the central one third of the wedge shaped implant. These stabilizing fins help stabilize the disk space in torsion, and help maintain a stable host-graft interface for fusion. The top and bottom surfaces of the implants, including the fins themselves, have a typically ten-degree lordosis. Therefore the anterior portion of the implant is a taller dimension than the posterior portion. This creates a challenge in the placement of the implant from the posterior direction. Therefore, for the lumbar region, the implant has an aggressive lead chamfer designed to further distract the endplates, as necessary to facilitate placement.

In its most general form, the invention is an implant for mechanically attaching to the ends of and promoting bony fusion of at least two vertebrae adjacent to a space left by surgically removed spinal tissue, comprising a load-sharing body; said load-sharing body further comprising opposing rectangular fins on the top and bottom surfaces of the implant capable of mechanically anchoring the device to said adjacent vertebrae and thereby transmitting tensile and torsional loads to and from said adjacent vertebrae. In another embodiment, the vertebrae may be cut at such an angle so as to preserve the natural lordosis of the spine, i.e. 0-18 degrees, once the implant is inserted.

In another embodiment, the invention generally is an implant for mechanically attaching to the ends of and promoting bony fusion of at least two vertebrae adjacent to a space left by surgically removed spinal tissue, comprising a structure formed from a single piece of bone allograft material having a top and bottom, said top and bottom surfaces including a stabilizing fin for mechanically interlocking with channels cut into said adjacent vertebrae.

An important aspect in the implant procedure is the preparation of the space to receive the implant and the grooves for the rectangular stabilizing fins. A spacer/osteotome guide system is used which distracts the vertebrae and stabilizes them during preparation and acts as a guide for precise cutting. Special tomes are designed to precisely cut the rectangular channels and prepare the end plate surface. The spacer/osteotome guide is designed to avoid the nerve root and limit the depth of the cut for safety. The tomes also have depth stops which limit the depth of the cut for safety.

Another important aspect of the implant procedure is an instrument system to facilitate translational and angular distraction from within the disk space to achieve the quality of distraction currently only obtained by the anterior approach. This provides a highly significant benefit to the surgeon. A double action vertebral spreader is provided that will penetrate more deeply into the disk space to create anterior lift to a fixed or variable angle. The design will allow the surgeon to set the lordotic angle prior to distraction of the vertebral endplates.

Brief Description of the Drawings

FIGURE 1A is an oblique view of the front and side of the spacer/osteotome guide part of the present invention;

FIGURE 1B is an orthogonal view of the side of the spacer/osteotome guide;

FIGURE 2 shows the osteotome in oblique view;

FIGURE 3A is a top view of the implant;

FIGURE 3B is a side view of the implant;

FIGURE 3C is a posterior view of the implant;

FIGURE 4A shows a posterior view of two vertebrae;

FIGURE 4B shows a posterior view of two vertebrae with spacer/osteotome guides installed between the vertebrae;

FIGURE 5A is an oblique view of the rear and side of the spacer/osteotome guide;

FIGURE 5B is an oblique view of the front and side of the spacer/osteotome guide;

FIGURE 5C shows a side view of the spacer/osteotome guide between two vertebrae;

FIGURE 6A is a detailed oblique view of the dual box osteotome;

FIGURE 6B shows the relationship of the dual box osteotome and the spacer/osteotome guide;

FIGURE 7A shows a posterior view of two vertebrae in which channels have been cut in adjacent endplates;

FIGURE 7B shows a posterior view of two vertebrae in which the implants have been installed;

FIGURE 7C shows a side view of the two vertebrae in which an implant has been installed;

FIGURE 8 is an oblique view of the vertebral body spreader;

FIGURE 9A is a view of the vertebral body spreader in a closed mode;

FIGURE 9B is a view of the vertebral body spreader with its jaws open at the lordotic angle;

FIGURE 9C is a view of the vertebral body spreader in its fully open mode;

FIGURE 10A is an oblique view of the rear and side of the spacer/osteotome guide;

FIGURE 10B is an orthogonal view of the side of the spacer/osteotome guide;

FIGURE 10C is an oblique view of the front and side of the spacer/osteotome guide part of the present invention;

FIGURE 10D is a posterior view of the spacer/osteotome guide;

FIGURE 10E is an oblique view of the front and side of the spacer/osteotome guide part of the present invention;

FIGURE 10F is a posterior view of the spacer/osteotome guide;

FIGURE 11A is a side view of the implant.

FIGURE 11B is a side view of the implant.

Identification of Items in the Figures

FIGURE 1A

2 -- spacer/osteotome guide

FIGURE 1B

2 -- spacer/osteotome guide

FIGURE 2

4 -- osteotome

6 -- blades of osteotome

8 -- handle of osteotome

15 -- end of handle portion of dual box osteotome

FIGURE 3A

7a,7b -- curved sides of bone implant

9 -- chamfer

10 -- bone implant

11 -- locking teeth

13 -- fins on implant

FIGURE 3B

7b -- curved sides of bone implant

9 -- chamfer

10 --bone implant

11 -- locking teeth

13 -- fins on implant

FIGURE 3C

7b -- curved sides of bone implant

7c,7d – opposing slots to facilitate gripping by a holding instrument

10 -- bone implant

11 -- locking teeth

13 – fins on implant

FIGURE 4A

12 -- upper vertebral body

14 -- lower vertebral body

16 -- spinal cord

18a,18b,18c,18d -- lateral nerves from spinal cord

20 -- intervertebral space

21 -- upper cortical endplate of lower vertebra

23 -- lower cortical endplate of upper vertebra

FIGURE 4B

2 -- spacer/osteotome guide

12 -- upper vertebral body

14 -- lower vertebral body

16 -- spinal cord

18a,18b,18c,18d -- lateral nerves from spinal cord

20' -- intervertebral space

21 -- upper cortical endplate of lower vertebra

30 -- stop taps on spacer/osteotome guide

FIGURE 5A

2 -- spacer/osteotome guide

30 -- stop tabs

32 -- angled side of spacer/osteotome guide

34 -- guide channels

36 -- hole that receives insertion handle

FIGURE 5B

2 -- spacer/osteotome guide

30 -- stop tabs

32 -- angled side of spacer/osteotome guide

34 -- guide channels

FIGURE 5C

2 -- spacer/osteotome guide

20'' -- intervertebral space

27 -- upper vertebral body

28 -- lower vertebral body

30 -- stop tabs

FIGURE 6A

4 – dual box osteotome

6 -- blades of osteotome

8 -- handle of osteotome

15 -- end of handle portion of dual box osteotome

40 -- front sides of osteotome blades

42 -- sharp cutting edges of osteotome

FIGURE 6B

2 -- spacer/osteotome guide

4 – dual box osteotome

6 -- blades of osteotome

8 -- handle of osteotome

34 -- osteotome guide channel

44 -- hollow centers of osteotome blades

45 -- arrow showing direction of cut

FIGURE 7A

12 -- upper vertebra

14 -- lower vertebra

16 -- spinal cord

21 -- upper cortical endplate of lower vertebra

23 -- lower cortical endplate of upper vertebra

50 -- cut channels that receive implants

FIGURE 7B

10 -- bone implants

12 -- upper vertebra

14 -- lower vertebra

16 -- spinal cord

21 -- upper cortical endplate of lower vertebra

23 -- lower cortical endplate of upper vertebra

50 -- cut channels that receive implants

FIGURE 7C

10 -- bone implants

12 -- upper vertebra

14 -- lower vertebra

20 -- intervertebral space

50 -- cut channels that receive implants

FIGURE 8

60 -- vertebral body spreader tool

61,61' -- pivot points, or hinge pins, of jaw actuation arms

62,62' -- jaws

64,64' -- jaw actuation arms

65,65' -- catch mechanisms

66,66' -- handles

68,68' -- locking stops

70,70' -- parallel rails

82, 82' -- guide slots for sliding pivot arms

FIGURE 9A

55 -- disc space

57 -- upper vertebral body

59 -- lower vertebral body

60 -- vertebral body spreader tool

62,62' -- jaws

64,64' -- jaw actuation arms

65,65' -- catch mechanisms

66,66' -- handles

68,68' -- locking stops

70,70' -- parallel rails

76,76' -- crossing slider mechanism

77,77' -- sliding pivot points

78 -- one arm of crossing slider

79 -- one arm of crossing slider

80 -- common pivot point of arms of crossing slider

FIGURE 9B

55 -- disc space

57 -- upper vertebral body

59 -- lower vertebral body

60 -- vertebral body spreader tool

62,62' -- jaws

64,64' -- jaw actuation arms

65,65' -- catch mechanisms

66,66' -- handles

68,68' -- locking stops

70,70' -- parallel rails

76,76' -- crossing slider mechanism

77,77' -- sliding pivot points

78 -- one arm of crossing slider

79 -- one arm of crossing slider

80 -- common pivot point of arms of crossing slider

FIGURE 9C

55 -- disc space

57 -- upper vertebral body

59 -- lower vertebral body

60 -- vertebral body spreader tool

62,62' -- jaws

64,64' -- jaw actuation arms

65,65' -- catch mechanisms

66,66' -- handles

68,68' -- locking stops

70,70' -- parallel rails

76,76' -- crossing slider mechanism

77,77' -- sliding pivot points

78 -- one arm of crossing slider

79 -- one arm of crossing slider

80 -- common pivot point of arms of crossing slider

FIGURE 10A

91 -- spacer/osteotome guide

92 -- stop tabs

93 -- hole

FIGURE 10B

91 -- spacer/osteotome guide

92 -- stop tabs

FIGURE 10C

94 -- spacer/osteotome guide

94' -- blunt nose on anterior end of guide

FIGURE 10D

94 -- spacer/osteotome guide

95 -- hole

FIGURE 10E

96 -- spacer/osteotome guide

96' -- blunt nose on anterior end of guide

97 -- main body of spacer

98 -- box guide for osteotome

FIGURE 10F

96 -- spacer/osteotome guide

97 -- main body of spacer

98 -- box guide for osteotome

99 -- hole for detachable handle

FIGURE 11A

102 -- implant

104,104' -- shelves

105,105' -- chamfers

106,106' -- fins

108 -- locking teeth

FIGURE 11B

110 -- implant

111 -- teeth

112,112' -- fins

114,114' -- shelves

115,115' -- chamfers

Detailed Description of the Preferred Embodiments

The implant itself is preferably allograft material but may also comprise a variety of presently acceptable biocompatible materials. The body of the implant may optionally have a modest taper to accommodate the natural lordosis of the lumbar spine. In a variant of one embodiment, locking notches or teeth may be located on the outer edge of both the stabilizing fins, to engage the cortical bone and prevent the implant from migrating out of the intervertebral space.

As previously noted, any of the embodiments of the interlocking implant can be fabricated from cadaver bone which is processed to form bone allograft material. Tissue grafting of living tissue from the same patient, including bone grafting, is well known. Tissue such as bone is removed from one part of a body (the donor site) and inserted into tissue in another (the host site) part of the same (or another) body. With respect to living bone tissue, it has been desirable in the past to be able to remove a piece of living tissue graft material which is the exact size and shape needed for the host site where it will be implanted, but it has proved very difficult to achieve this goal.

It is now possible to obtain allograft bone which has been processed to remove all living material which could present a tissue rejection problem or an infection problem. Such processed material retains much of the structural quality of the original living bone, rendering it osteoinductive. Moreover, it can be shaped according to known and new methods to attain enhanced structural behavior. In the present invention, allograft bone is reshaped into one of the spacer configurations for use as a spine implant.

In the current invention, a blank is cut from cortical allograft bone, generally from long bones of the leg. The blank is machined by conventional milling to form the fins, grooves and outer surfaces. Such processes in general are able to maintain the biological and structural properties of the allograft material.

FIGURES 3A, 3B, 3C and **7B** depict the implant and its position once inserted within two vertebrae.

FIGURES 1A, 1B, 2, 4B, and **5A – 6B** depict the surgical tools used to install the implant. This apparatus comprises a set of unique tools which will accurately cut the rectangular grooves in bone and prepare the endplate surfaces for the purpose of inserting an implant which locks adjacent vertebrae together.

FIGURES 8 and **9A – 9C** depict the surgical tool used to facilitate translational and angular distraction from within the disk space to achieve the quality of distraction currently only obtained by the anterior approach. A double action vertebral spreader is used that will penetrate more deeply into the disk space to create anterior lift to a fixed or variable angle. The design will allow the surgeon to set the lordotic angle prior to distraction of the vertebral endplates.

FIGURES 10A – F and **11A** and **B** depict the various embodiments of the spacer/osteotome guide and of the implant.

Overview of the Invention

Referring to **FIGURES 1A** through **3C** there are shown the three main components of the present invention. **FIGURE 1A** is an oblique view of a spacer/osteotome guide **2**, two each of which are inserted between adjacent vertebra **12, 14** as shown in **FIGURES 4A** and **4B**. **FIGURE 1B** shows the angle **α** of the taper of the spacer, said taper corresponding to the desired lordosis of the two vertebrae being fused. **FIGURE 2** is an oblique view of a dual box osteotome **4** comprised of a two-part osteotome blade **6** and a driver handle **8**. As will be explained below, the osteotome blade **6** is guided by the guide **2** when it cuts channels in adjacent vertebral endplates so as to accommodate the insertion of a spinal fusion implant **10** as shown in the three orthogonal views, **FIGURES 3A, 3B** and **3C**. **FIGURE 3A** shows curved sides **7a, 7b** which correspond to the edges of the source bone from which the implant **10** has been machined, specifically from cortical bone of the femur or tibia. **FIGURE 3B** is a side view showing the tapered side **7b** (with corresponding taper on unshown side **7a**), which has the same angle **α** that provides the desired angle or lordosis of the vertebrae being conjoined by the implants, specifically a lordotic angle of 2 **α** or about 10 degrees. **FIGURE 3C** shows the implant **10** from its posterior end, i.e., the end that, when installed corresponds to the posterior side of the spinal column. The serrations or locking teeth **11** provide a gripping effect when the implant has been installed in the channel that has been cut by the cutting tool **4**, said channels being visible in **FIGURE 7A**. During the implantation process, two implants are installed in each intervertebral space, more or less symmetrically about the spinal cord, as will be described in more detail below.

Use of the Invention

FIGURE 4A is a posterior view of two vertebra **12, 14** from which boney, muscle-supporting processes have been removed to expose the spinal cord **16**, the nerves **18a, 18b, 18c** and **18d** extending laterally outward therefrom, and the posterior portion of the intervertebral space **20**, within which two implants **10** are to be inserted, one on either side of spinal cord **16** within the specific locations occupied by the spacer/osteotome guides **2** in **FIGURE 4B**. Note that the respective vertebrae **12, 14** have been separated in **FIGURE 4B** compared to **FIGURE 4A** to accommodate the installation of the spacer/osteotome guides **2**, or, more specifically, the space **20'** in **FIGURE 4B** is larger than the corresponding space **20** in **FIGURE 4A**.

The Spacer/Osteotome Guide

Referring to **FIGURES 5A** and **5B**, the vertebral body spacer/osteotome guide **2** is shown in two oblique views, showing the length **L**, width **W** and height **H** dimensions. The spacer/osteotome guides **2** are made of stainless steel.

The spacer/osteotome guides **2** measure approximately 20- 30 mm long by 9- 12 mm wide, and they have heights that vary from 6 mm to 14 mm. The anterior or front part of the spacer is chamfered or curved to facilitate introduction past bony landmarks. The posterior end has features to allow connection to a drive handle, which is easily removed after the spacer is fully inserted into the disc space. There are two centrally located coplanar slots **34** on the superior and inferior surface of the spacers which are approximately 1 mm to 3 mm deep, defining a guide channel. The posterior origin of these slots **34** is easily viewed, even when the spacer is fully inserted. The spacers further have tabs **30** extending superiorly and inferiorly that contact the vertebral body's posterior wall to prevent over insertion. In a second embodiment, the spacers may have a centrally located, hollow tab projecting 2 mm to 5 mm posteriorly so as to guide the bone cutting tome blade on both sides and also to provide additional protection to adjacent neural structures. This second embodiment also includes a flange projection on one lateral side that, when fully inserted, retracts the central dura. The combination of the hollow tab and flange provide full protection while allowing the safe subsequent passage of the sharp bone- cutting tome, and prevents over-insertion.

FIGURES 5A and **5B** show details of the spacer/osteotome guide **2** in two oblique views. **FIGURE 5A** is a rear and side view of the spacer/osteotome guide **2**, showing the aforementioned stop tabs **30** which are contiguous with the main body **32**, and two osteotome guide channels **34**. The hole **36** receives the end of a detachable handle, not shown, which is used to insert the spacer/osteotome guide **2** between adjacent vertebrae **12, 14** as shown in **FIGURE 4B**. **FIGURE 5B** is a partial front and side view of the spacer/osteotome guide **2**. **FIGURE 5C** is a schematic cross-sectional side view of a spacer/osteotome guide **2** within the vertebral space **20''** between two vertebrae **27, 28**. **FIGURE 5C** is a side view of one of the installed spacers/osteotome guides **2** with stop tabs **30** abutting the posterior side of an upper vertebra **27** and a lower vertebra **28**. **FIGURE 5C** complements **FIGURE 4B** where the spacers/osteotome guides **2** are shown in posterior view between vertebrae designated as **12** and **14**. Note that, as shown in **FIGURE 5A**, the spacer/osteotome guide **2** has only three stops **30**. The reason for only three stops **30** is evident in **FIGURE 4B** where the nerves **18a, 18b** are in proximity to where the missing fourth stop would otherwise be. Note yet further in **FIGURE 4B** that the two spacers/osteotome guides **2** shown are not identical, but rather they are mirror images of each other with respect to the sagittal plane, or, in other words, in relation to the locations of the three respective stops tabs **30** on each spacer.

The Osteotome

The dual box osteotome **4**, i.e., the osteotome, is shown in oblique views in **FIGURES 2, 6A** and **6B**. The osteotome **4** is comprised of two parallel, hollow cutting blades **6** and a detachable handle **8**. The double blade portion is further connected to a male or female threaded boss to enable firm attachment to the handle **8**. Each box shape blade **6** is generally 4 mm wide by 4 mm tall on each side. Three sides of the box are sharpened and one side is blunt. The blunt side, generally the side closest to the central axis, may also protrude 1 mm to 3 mm from the sharp sides and may be chamfered. More specifically, as shown in **FIGURE 6A**, the front sides **40** of the hollow cutting blades **6** have sharp cutting edges **42**. **FIGURE 6B** shows in oblique view the way in which the osteotome and handle assembly **4** engages the channels **34** in the spacer/osteotome guide **2**. The arrow **45** shows the direction of the osteotome **4** when its blade portion **6** engages the spacer/osteotome guide **2** after the spacer/osteotome guide has been inserted between the vertebrae as shown in **FIGURE 4B**. The cutting force to drive the cutting blade assembly **4** is applied by way of the handle **8**, through the use of a mallet tapping against the end **15** of the handle portion **8** of the osteotome assembly **4** shown in **FIGURE 6A**.

As the hollow cutting edges or blades **6** of the osteotome cut into the adjacent vertebral end plates **21, 23**, the pieces of cut bone accumulate inside the hollow spaces **44** shown in **FIGURE 6B**. The open ended design of the cutting blade **6** facilitates removal of the bone chips and later cleaning of the instrument **4**.

The depth of cut of the cutting blade into the vertebral endplates is intended to be sufficient to remove the hard cortical bone of the endplates **21, 23** shown in **FIGURE 7A** of the vertebral bodies so as to expose blood-rich, underlying cancellous bone. **FIGURE 7A** shows, in a posterior view, the channels **50** that have been cut by the cutting blade assembly **4**. The objective of the cutting process is to expose a significant bed of bleeding bone while maintaining a sufficient portion of strong cortical endplate bone.

The Implants

Two implants are used between each the vertebral bodies being fused. Each one is to provide structural support and stabilization to a lumbar spinal motion segment subsequent to removal of protruding or deranged intervertebral disc material, and also to provide a substrate for new bone growth accompanying successful fusion of two adjacent vertebral body segments.

Referring to **FIGURES 3A** through **3C**, the implant **10** has fins **13** projecting inferiorly and superiorly from the central 1/3 of a wedge shaped block. When viewed from behind, as in **FIGURE 3C**, the geometry of the bone spacer **10** resembles a "cross". When viewed from the side **(FIGURE 3B)**, the implant **10** is wedge shaped, such that sides **7a, 7b**, including the fins **13**, diverge from the posterior side **10b** to the anterior side **10a** about a line of symmetry. The outermost finned surface has a series of locking teeth **11**, or grooves or projections, that aid in anchoring the implant and its fins that engage the channels **50** shown in **FIGURE 7A.** More specifically, the sharp, tooth – like projections **11** are about 1mm tall, which is adequate to penetrate exposed cancellous bone after the vertebral endplate cortices have been cut to accommodate the fin portion **13** of the implant **10** thereby increasing interface friction and minimizing the potential for translation after implantation.

The importance of achieving good fit of a spacer **10** within the disc space is essential. When the fit is maximized, the surface area of contact and resultant friction at the interface is maximized. Accordingly, for lordotic disc spaces, the anterior height of the spacer device **10** is taller than the posterior height. The anterior region **10a** has a slope or chamfer **9** to aid in initial insertion between the vertebrae. Alternatively, for parallel shaped disc spaces, a non-lordotic or parallel spacer (**Figures 10C-10F**) may provide a preferred fit.

The implant **10** shown in **FIGURES 3A** through **3C**, is cut from human donor bone, which accounts for the curved faces **7a, 7b** which are most evident in the top view shown in **FIGURE 3A**. More specifically, the implant **10** is cut from donor cortical bone of the femur or tibia. **FIGURE 7B** shows two inserted implants **10** in posterior view between the vertebral bodies. **FIGURE 7C** is a side view of an installed implant **10** within an intervertebral space **20** between two vertebrae **12, 14**. The respective posterior – to – anterior angles **α** are shown in **FIGURE 3B**, while the corresponding lordosis angles **α** are shown in **FIGURE 7C**.

In **FIGURE 3B**, the faces, or sides, **7a** and **7b** of the implant **10** are shown to be tapered at an angle **α** that corresponds to half of the desired lordosis of the vertebra. The angle **α** of the tapered side, shown in **FIGURE 3B** corresponds to the angle **α** of the spacer/osteotome guide **2** shown in **FIGURE 1B**. In **FIGURE 3C**, the implant **10** has opposing slots **7c, 7d** on either side to facilitate gripping with a holding instrument (not shown). The preferred configuration of the implant **10** is approximately 20 mm to 25 mm long by 9 mm to 12 mm wide by 6 mm to 14 mm high, as measured on the posterior region.

The Vertebral Body Spreader

FIGURE 8 shows in oblique view the vertebral body spreader tool **60** used to separate or distract two adjacent vertebral bodies prior to insertion of the spacers **2**. The spreader **60** enables sequential angular and translation distraction of the disc space from the posterior side of the spine.

More specifically, the spreader device **60** consists of two jaws **62, 62'** (which get inserted into an intervertebral disc space) connected to arms **64, 64'** each having a catch mechanism **65, 65'** that engages the respective locking stops **68, 68'**. The arms **64, 64'** and the contiguous jaws **62,62'** pivot about the hinge pins **61,61'**, respectively, so as to provide angular motion of the jaws. The handle grips **66, 66'** operate to displace the parallel rails **70, 70'** by way of the crossing slider mechanism **76,** the operation of which is shown in **FIGURES 9A** through **9C**. The crossing slider **76** consists of two arms **78, 79**, which pivot about a common pivot point **80** when the handles **66, 66'** are squeezed together. Two ends of the crossing slider mechanism **76** engage respectively the handles **66, 66'** at the respective pivot points **77, 77'**, which also slide forward (toward the jaws **62, 62'**) inside of slots **82, 82'** in the rails **70, 70'** (visible in **FIGURE 8**). The crossing slide mechanism maintains the rails **70, 70'** parallel with one another as they separate from one another when the handles **66, 66'** are squeezed together (**FIGURE 9C**).

A design criterion of the vertebral body spreader **60** is to take into account a common characteristic of the degenerated painful disc, namely loss of disc height and loss of lordotic orientation. The goal is to restore natural height and angle to a collapsed disc space. Since the greatest degree of angular collapse is anterior, it is particularly difficult to lift the anterior portion of the disc space with a device that is applied from the posterior direction.

Spreaders of the sort typically used in posterior operations make contact only the posterior wall of the vertebral body and therefore provide only posterior lift. A consequence of posterior lift is anterior settling, resulting in a flattening of the disc space beyond anatomical norms. The spreader device **60** in **FIGURE 8** overcomes these disadvantages by way of two cooperating mechanisms that allow the following sequence of events: insertion, followed by angular distraction and then translational distraction. Referring now to **FIGURES 9A** through **9C**, insertion of two opposed jaws **62, 62'** into the disc space **55** between two adjacent vertebral bodies **57, 59** is achieved when the device **60** is in the fully closed position, as shown in **FIGURE 9A**. The length of the jaws **62, 62'** is 24 mm, which is sufficient to ensure that the jaws make good contact with the anterior portion of the disc space. The locking pivot arms **64, 64 '** are then engaged into the position shown in **FIGURE 9B** with the catches **65, 65'** seated in the respective locking stops **68, 68'**, so as to angulate the jaws **62, 62'** at an approximately 10 degree angular distraction within the disc space **55**. With the jaws locked at 10 degrees, a second translational motion is brought about by means of the handles **66, 66'** which cause parallel translational spreading of the disc space, as shown in **FIGURE 9C**. This dual action ensures the disc space can be maintained at about 10 degrees while achieving maximum disc height restoration. Flattening of the disc height is prevented by maintaining of the 10 degree jaw position while distracting.

The spreader tool **60** may also be used to help facilitate insertion of the graft in the final stages of the operation. The dual action spreader **60** may be placed on the contralateral side of the disc space or directly adjacent to the graft if space is available, and it may be used to create additional lift and angulation, as required, to lessen the force required to insert the bone graft.

Summary of Operational Sequence

Referring to **FIGURES 4A** and **4B** as well as **FIGURES 7A** through **7C**, the installation of the implants **10** can be described in a general, summarizing way. First, the posterior faces of the vertebrae **12, 14** are exposed and then the vertebrae are forced apart to accommodate the insertion of the two spacer/osteotome guides **2**, as shown in **FIGURE 4B. FIGURE 6B** shows the relationship of the spacer/osteotome guide **2** and the osteotome **4** when the cut is made to create each channel **50** as shown in **FIGURE 7A**. The implants **10** are then installed as shown in **FIGURES 7B** and **7C**.

More specifically, prior to implantation, the disc material is removed from the intervertebral space **20**, shown in **FIGURE 4A**, exposing the cortical endplates **21, 23** of the adjacent vertebral bodies **12, 14**. The vertebral bodies are displaced from one another by use of the spreader tool **60** so that the intervertebral space **20** can receive the two rigid spacers/osteotome guides **2**, shown in **FIGURE 4B**, which are placed, one at a time, contralaterally in relation to the spinal cord **16**. Each spacer/osteotome guide **2**, upon being installed into the intervertebral space **20**, maintains contact with the strong, cortical, endplate bone.

After the spacers/osteotome guides **2** are in place, the endplates **21, 23** are further prepared by inserting the dual box osteotome **4, FIGURE 6A**, that simultaneously removes from the respective top and bottom vertebral bodies (**12, 14**, respectively) a 4 mm wide by 4 mm deep portion of each endplate and vertebral body bone. The resultant channels **50 (FIGURE 7A)** in the respective vertebral bodies **12, 14** are parallel to each other in a plane that is parallel to the sagittal plane. The resultant channels **50** define a placement axis for the finned implant device **10**.

The wedge-shaped implant **10**, as shown in **FIGURE 3B**, does not precisely match the geometry of the respective prepared bone slot in the endplates **21, 23**. More specifically, the channels or slots **50** are cut such that they are parallel, not dependent on the planes of the respective vertebral endplates **21, 23**. The maximum height of the fins on the anterior side **10a (FIGURE 3B)** is greater than the distance between the prepared slots **50**. (As measured across the parallel bottoms of the slots.) Engagement of the leading chamfer **9** **(FIGURE 3B)** into the prepared channels **50** locates the implant parallel to the sagittal plane. Subsequent impacting of the implant **10** causes the geometry of the initially parallel bottoms of the slots or channels **50** to assume the respective angles **α** of the implant fins **13** (carrying the teeth **11**). Distraction of adjacent vertebral bodies through impaction upon the implant **10** is possible because the adjacent vertebral bodies **12, 14** are non-constrained. Their relative positions are controlled primarily by soft tissue structures (not shown) that can be non-destructively stretched or altered. A consequence of full device impaction is translational and angular distraction of the disc space **20** so as, in the end, to yield the lordosis angle **2α**, shown in **FIGURE 7C/D**.

The two fins **13** of each implant **10** are also slightly wider than the prepared channel **50** shown in **FIGURE 7A**, creating a press fit when impacted. The tight fit achieves increased biomechanical stability and reduces the likelihood of migration of the implant after installation. Since the channels **50** in the vertebral endplates are only 4 mm wide, the endplate on either side of the channel retains its strength for good structural support.

EMBODIMENTS

FIGURES 10A through **10F** show three embodiments of the spacer/osteotome guide. **FIGURES 11A** and **11B** show two embodiments of the implant.

Spacer/Osteotome Guide -- First Embodiment

FIGURES 10A and **10B** show two views of the first embodiment of the spacer/osteotome guide **91**. One of the distinguishing characteristics of this embodiment is the angle **α** made by the top **T** and bottom **B** relative to the central axis **A-A'**, the angle **α** being half the desired angle of lordosis, which is about 10 degrees. The other distinguishing feature is the stop tabs **92**, located on the posterior end of the spacer block **91**. The stop tabs **92** prohibit the spacer from moving to deep into the intervertebral space during insertion or during the bone cutting process. The hole **93** receives a detachable handle, used during insertion and removal of the spacer.

Spacer/Osteotome Guide -- Second Embodiment

FIGURES 10C and **10D** show two views of the second embodiment of the spacer/esteotome guide **94**. Unlike the first embodiment above, the top **T** and bottom **B** of this embodiment are parallel, and no stop tabs are used. The hole **95** receives a detachable handle, used during insertion of the spacer and removal of the spacer. The blunt nose **94'**, located on the anterior end, aids in the spacer insertion process.

Spacer/Osteotome Guide -- Third Embodiment

FIGURES 10E and **10F** show two views of the third embodiment of the spacer/osteotome guide **96**. The main body **97** of the spacer is characterized by having a top **T** and bottom **B** that are parallel one another. The spacer is further characterized by an additional box guide **99** that receives the osteotome during bone cutting. The box guide **98** also serves to restrain the spacer block **96** from moving too deep into the intervertebral space during the bone cutting process. The hole **99** receives a detachable handle, used during insertion and removal of the spacer. The blunt nose **96'**, located on the anterior end of the spacer, serves to distract the respective vertebral bodies during the spacer insertion process.

Implant -- First Embodiment

FIGURE 11A is an orthogonal side view of the first embodiment of the implant **102**. The characterizing feature of this first embodiment is the angle **α'** which each shelf **104, 104'** (there are two shelves on each side, the second set is out of view in the **FIGURE**) makes relative to the main axis **B-B'**. Each angle **α'** is half the desired angle of lordosis, which is about 10 degrees. Chamfers **105, 105'**, which aid in the insertion process, are located on the anterior end of the implant. The two fins **106, 106'**, respectively at the top **T** and the bottom **B** and having locking teeth **108**, each make an angle **α''** relative to the axis **B-B'**. The angle **α''** is essentially equal to the angle **α'**, both being about half the angle of lordosis, or about 10 degrees.

Implant -- Second Embodiment

FIGURE 11B is an orthogonal side view of the second embodiment of the implant **110**. This second embodiment is characterized relative to the first embodiment in that the sets of teeth **111** located on the tops of the respective fins **112, 112'** are parallel to the main axis **C-C'**, whereas each shelf **114, 114'** (there are two shelves on each side, the second set is out of view in the **FIGURE**) makes an angle **α'''** relative to the main axis **C-C'**. Each angle **α'''** is half the desired angle of lordosis, which is about 10 degrees. Chamfers **115, 115'**, located on the anterior end of the implant, aid in the insertion process.

While the invention has been described in combination with embodiments thereof, it is evident that many alternatives, modifications, and variations will be apparent to those skilled in the art in light of the foregoing teachings. Accordingly, the invention is intended to embrace all such alternatives, modifications and variations as fall within the spirit and scope of the appended claims.

CLAIMS

We claim:

1. An implant for insertion into a space left by surgically removed spinal tissue, said implant comprising:
    a. a body having a top surface and a bottom surface and a distal end and a proximal end; and
    b. on each of the top surface and the bottom surface of the body, a stabilizing fin protrusion generally in the form of a rectangular parallelepiped, each said stabilizing fin protrusion having a height and width configured to slide matingly into a corresponding channel in an adjacent vertebra, said channels having been pre-established with substantially the same height and width as the stabilizing fin protrusion which is inserted into said channel, each said stabilizing fin protrusion further having a surface in a plane approximately perpendicular to the plane of the vertebral body endplate or disk after the implant is inserted into said space, whereby said implant attaches mechanically to the vertebrae adjacent to said space.

2. A matched pair of implants according to Claim 1 in which each member of the matched pair is substantially a mirror image of the other member of the matched pair, each member of the matched pair being separately implanted on opposite sides of the spinal column.

3. The implant of Claim 1 in which the body has the shape of a segment of an annulus.

4. The implant of Claim 1 in which the surface of each said stabilizing fin protrusion in a plane approximately perpendicular to the axis of the spine additionally comprises locking teeth.

5. The implant of Claim 1 in which the top surface and the bottom surface of the body have an angle with respect to one another which is predetermined to maintain after implantation the natural lordosis of the spinal segment in which the implant is being used.

6. The implant of Claim 5 in which the surface of each said stabilizing fin protrusion in a plane approximately perpendicular to the axis of the spine have an angle with respect to one another which is predetermined to maintain after implantation the natural lordosis of the spinal segment in which the implant is being used.

7. A combined spacer and osteotome guide for maintaining a proper intervertebral space and for preparation of an adjacent vertebrae to receive stabilizing fin protrusions of an implant, said spacer and osteotome guide comprising:
   a. a body generally in the shape of a rectangular parallelepiped and having a top surface and a bottom surface and a proximal end and a distal end;
   b. tabs at the proximal end of the body to prevent inserting the spacer and osteotome guide too far into the intervertebral space; and
   c. a guide channel in each of the top surface and the bottom surface matching in width and depth the outer dimensions of an osteotome to be inserted over the spacer and osteotome guide.
8. The spacer and osteotome guide of Claim 7 in which the top surface and the bottom surface have an angle with respect to one another which is predetermined to maintain the natural lordosis of the spinal segment in which the spacer and osteotome guide is being used.
9. The spacer and osteotome guide of Claim 7 in which the distal end of the body additionally has chamfer surfaces, whereby the adjacent vertebrae are temporarily pushed apart to facilitate insertion of the spacer and osteotome guide into the space.
10. An osteotome comprising:
    a. a handle; and
    b. a pair of osteotome blades, each blade in the shape of a hollow elongated rectangular box, said boxes being rigidly attached to the handle, said osteotome blades being configured so as to slide matingly into a spacer and osteotome guide.
11. The osteotome of Claim 10 in which the pair of hollow osteotome blades additionally comprises a structural member disposed transverse between the pair of hollow osteotome blades to comprise an assembly, said assembly comprising a dual box, said assembly further being rigidly attached to the handle.
12. A vertebral body spreader capable of producing sequential angular and translational distraction of a disk space comprising:
    a. a pair of jaw actuation arms, each said arm having a jaw at the proximal end;
    b. a crossing slider mechanism comprising two arms, the arms being pivotally connected at the mid point of each said arm;
    c. a pair of parallel rails, each said rail being connected pivotally at one end to one of the jaw actuation arms so as to provide angular of the jaws and near the other end being

connected both pivotally to the proximal end of one of the arms of the crossing slider mechanism and slidably connected to the distal end; and

d. a pair of handle grips pivotally connected near the proximal ends and each said handle grip being connected pivotally at the proximal end to the distal end of one of the arms of the crossing slider mechanism.

13. The vertebral body spreader of Claim 12 in which each of the jaws is about 24 mm in length.

14. The vertebral body spreader of Claim 12 in which each of the jaw actuation arms has a catch mechanism at the distal end.

15. The vertebral body spreader of Claim 14 in which the distal end of each of the parallel rails has a locking stop for engaging the catch mechanism on the jaw actuation arms.

16. The vertebral body spreader of Claim 15 in which the jaws are at an angular distraction with respect to one another which is predetermined to maintain the natural lordosis of the spinal segment in which the implant is being used when the a catch mechanisms of the jaw actuation arms are engaged by the locking stops of the parallel rails.

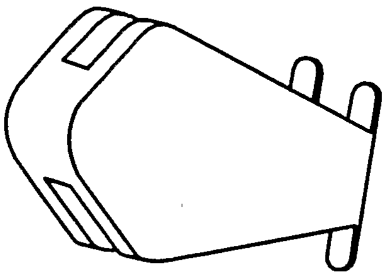

FIGURE 1A

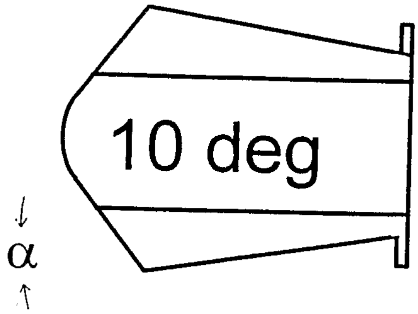

FIGURE 1B

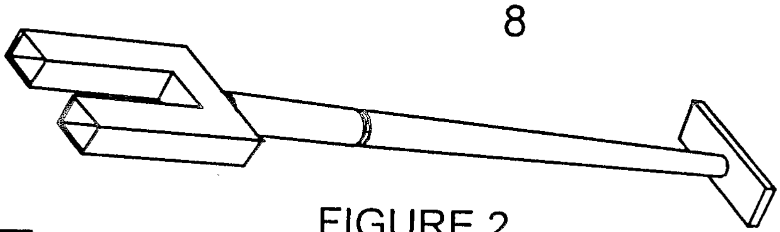

FIGURE 2

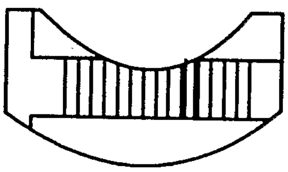

FIGURE 3A

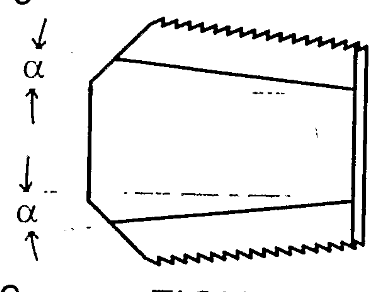

FIGURE 3B

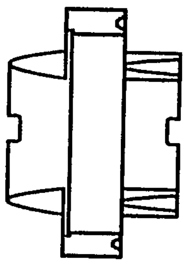

FIGURE 3C

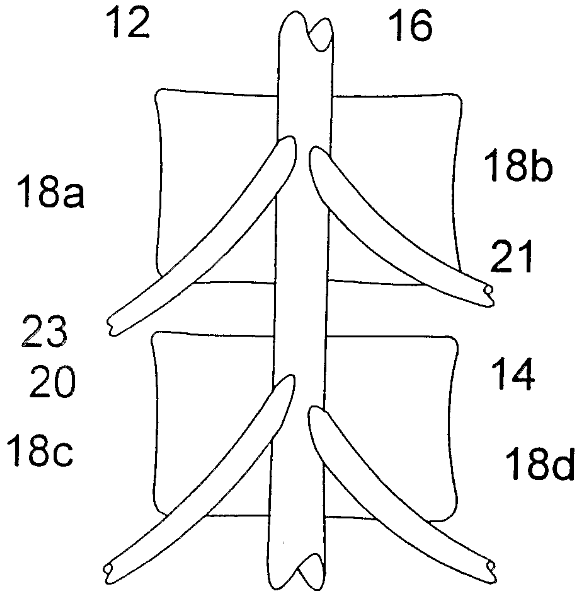

FIGURE 4A

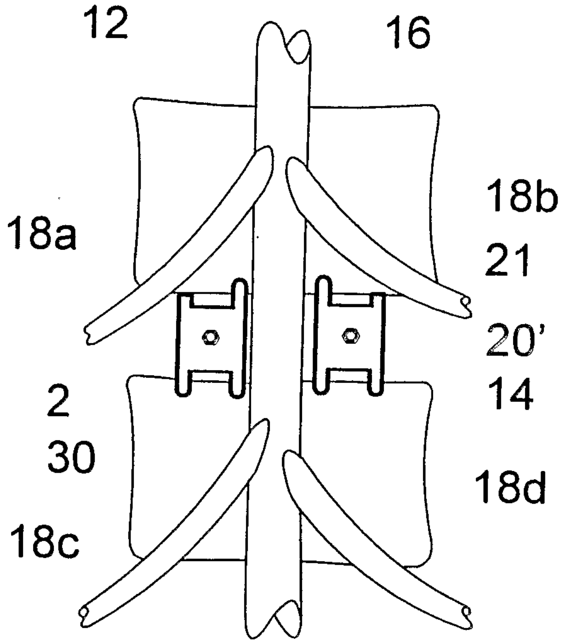

FIGURE 4B

lowery11

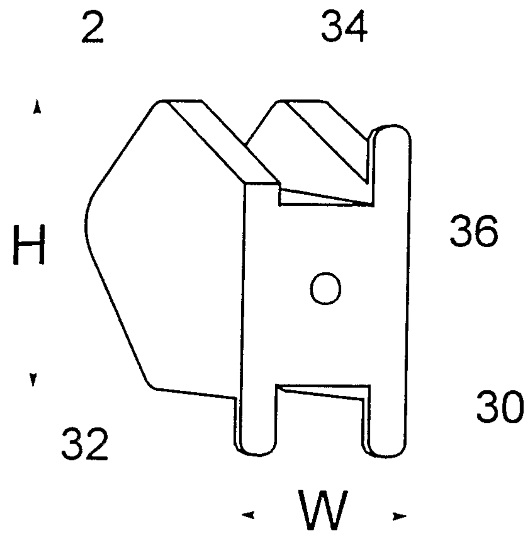

FIGURE 5A

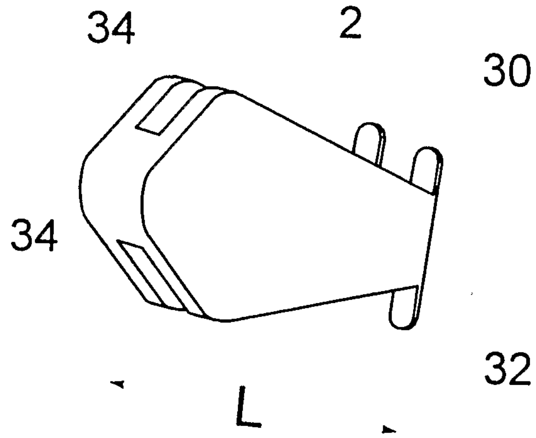

FIGURE 5B

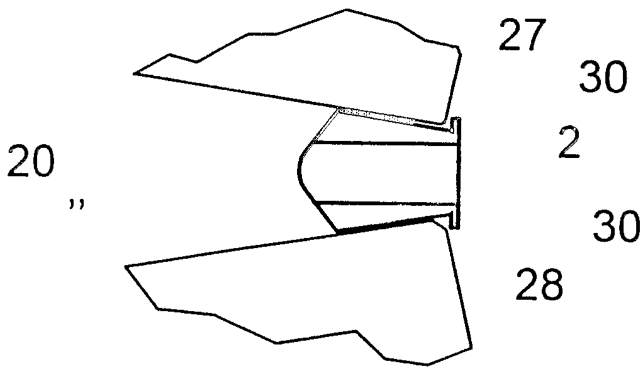

FIGURE 5C

lowery13

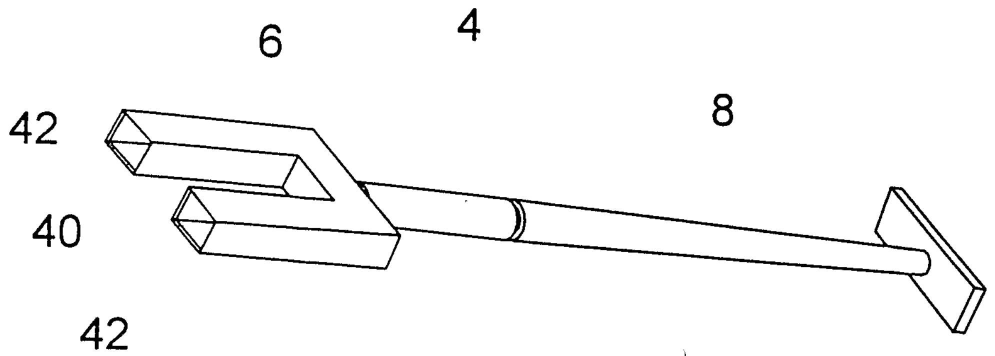

FIGURE 6A

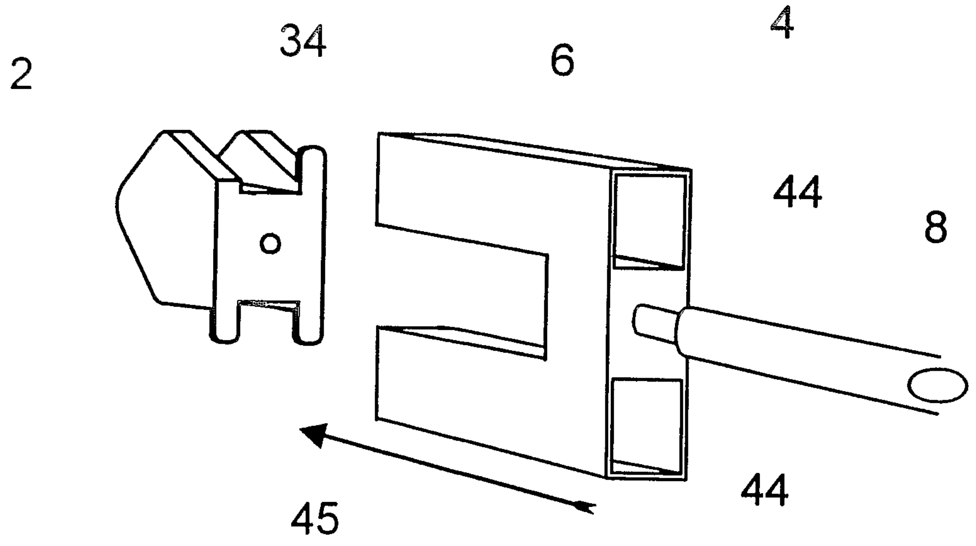

FIGURE 6B

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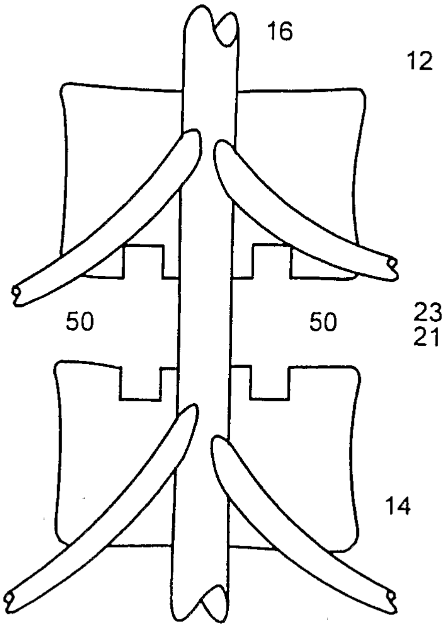

FIGURE 7A

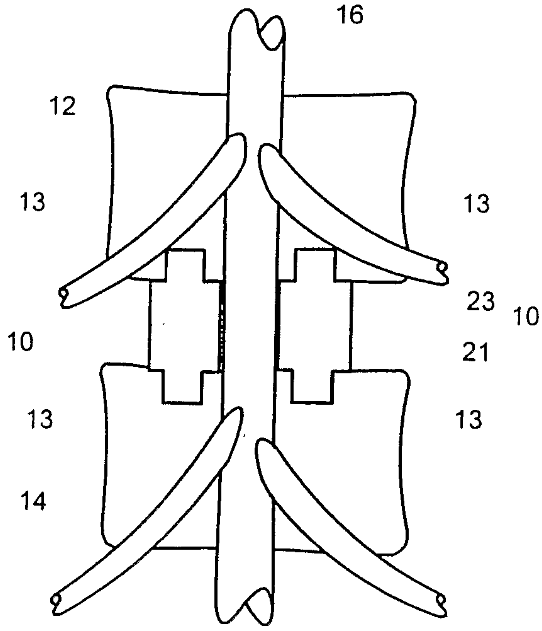

FIGURE 7B

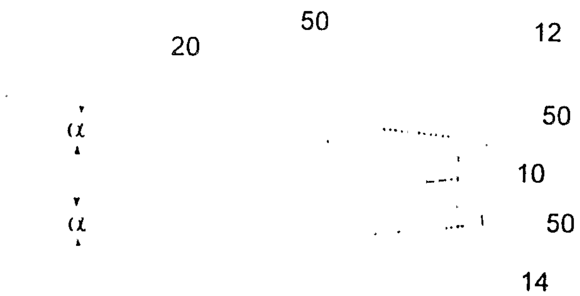

FIGURE 7C

lowery12

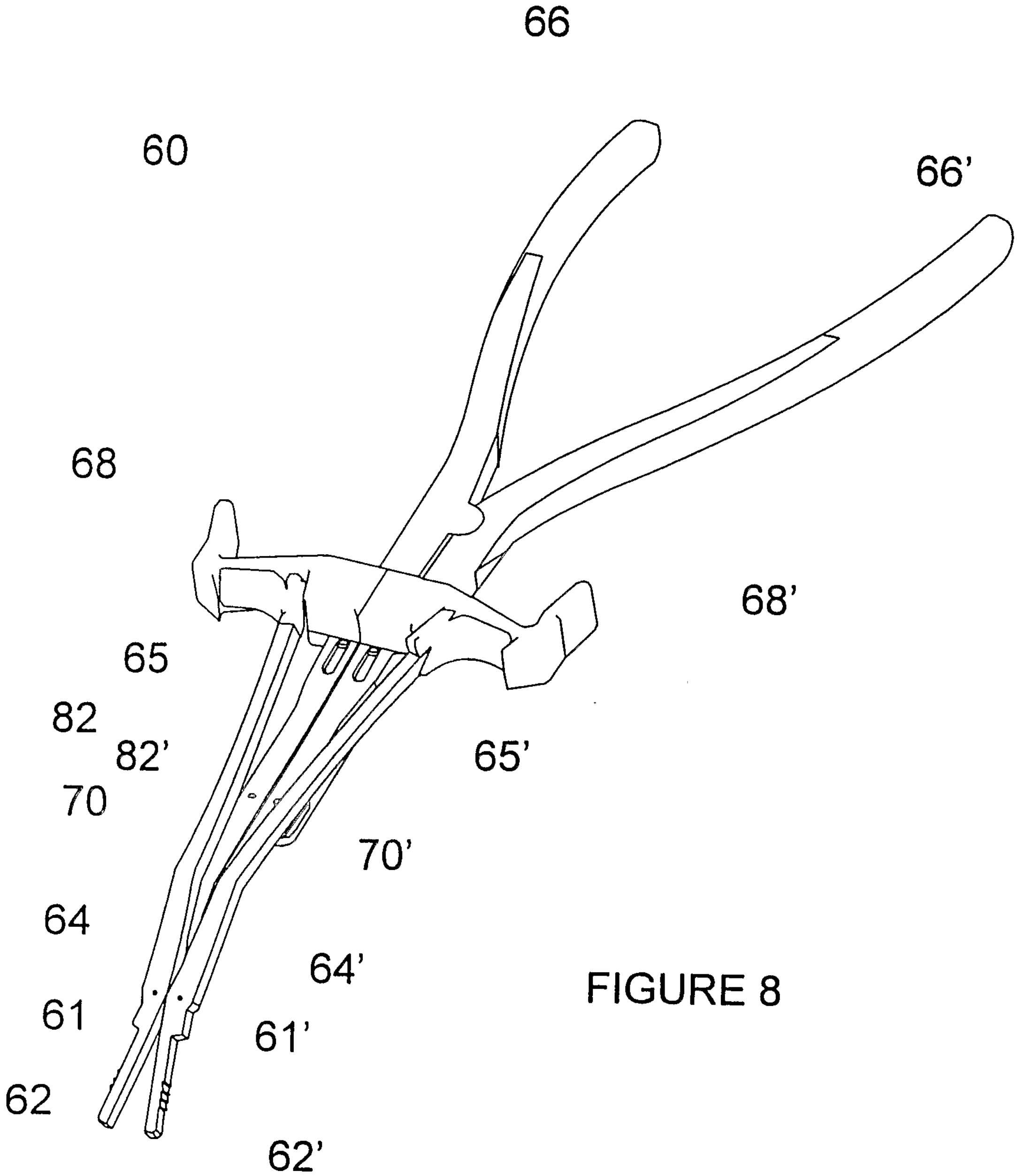

FIGURE 8

Lowery15a

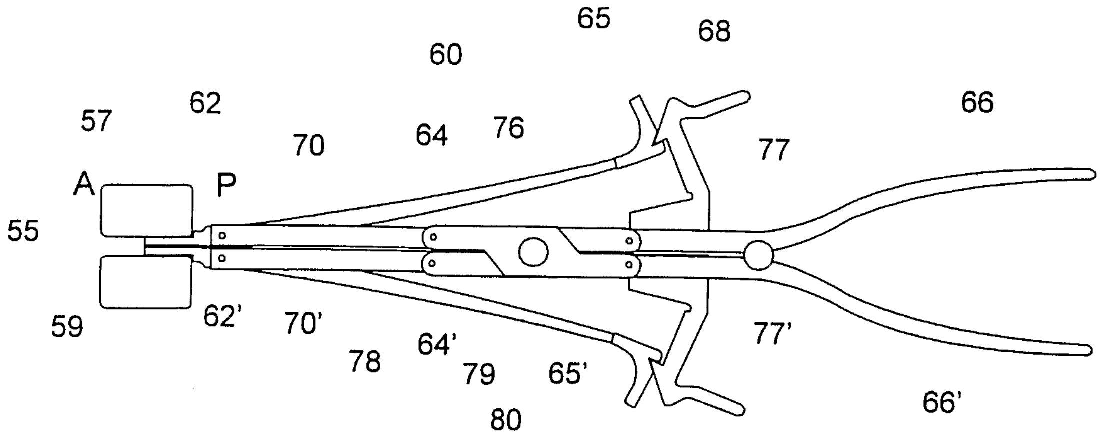

FIGURE 9A

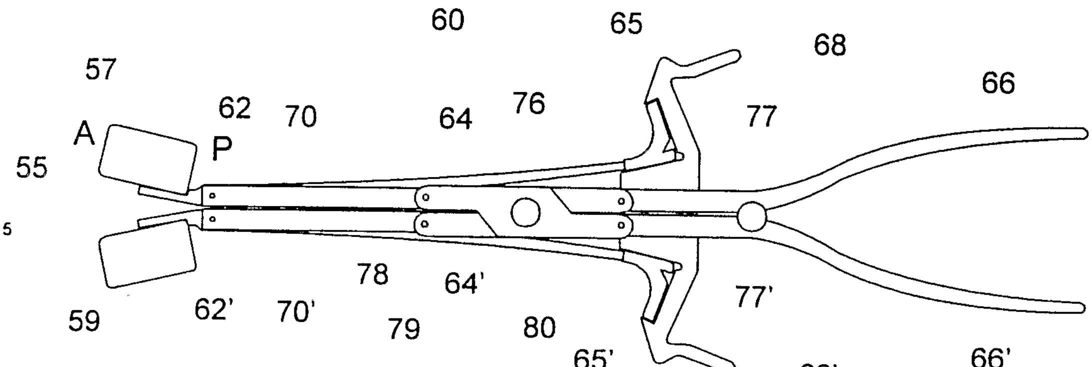

FIGURE 9B

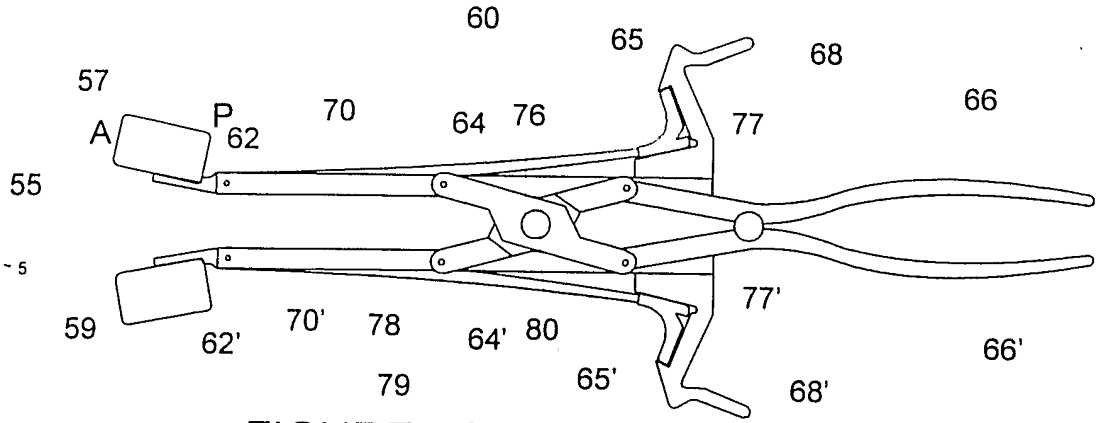

FIGURE 9C

Lowery14bwa

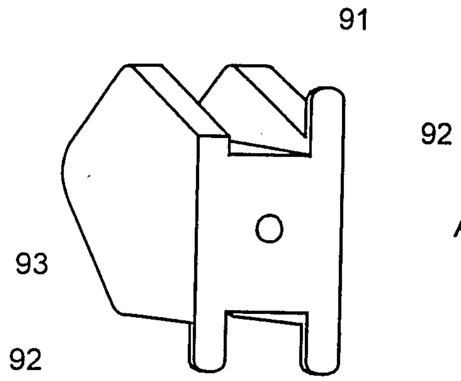

FIGURE 10A

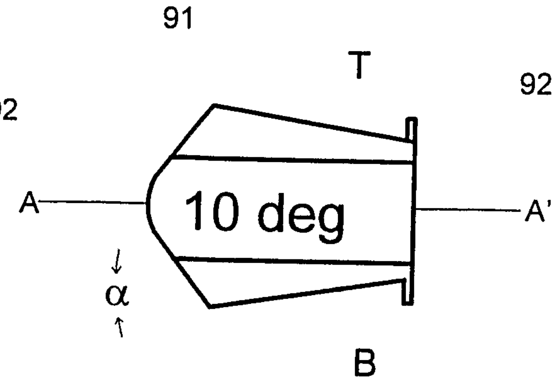

FIGURE 10B

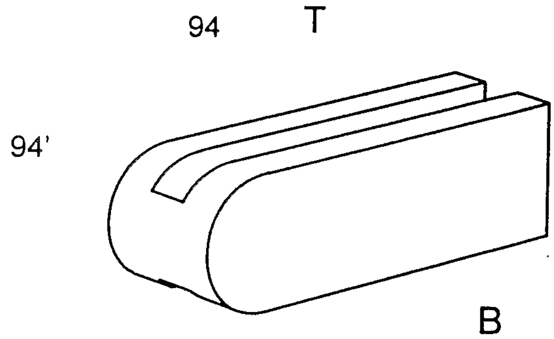

FIGURE 10C

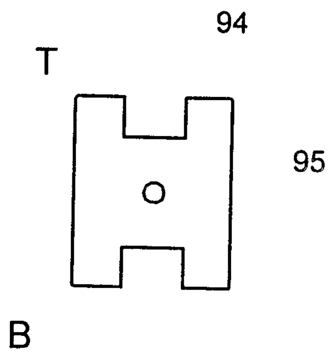

FIGURE 10D

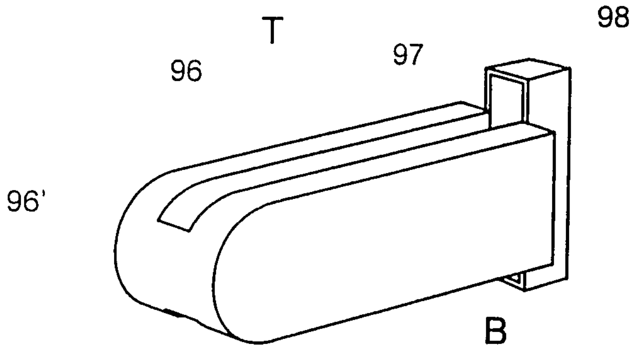

FIGURE 10E

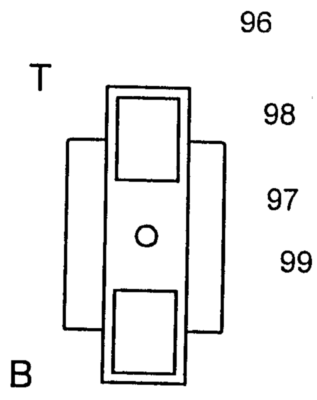

FIGURE 10F

lowery16

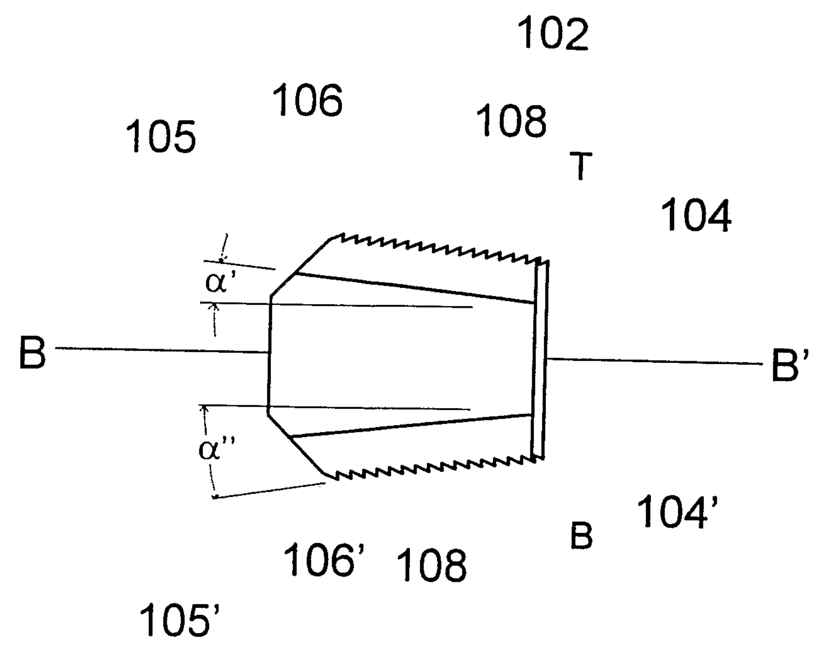

FIGURE 11A

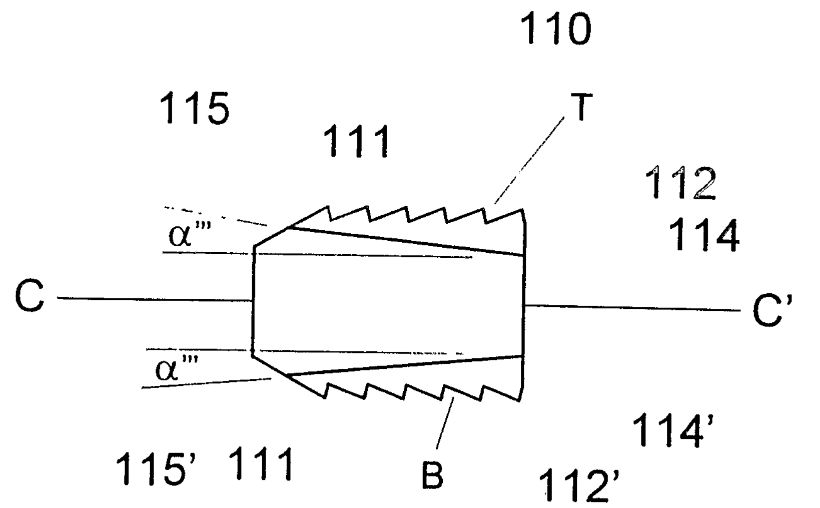

FIGURE 11B

lowery17