US007445636B2

(12) **United States Patent**
Michelson

(10) **Patent No.: US 7,445,636 B2**
(45) **Date of Patent: Nov. 4, 2008**

(54) **INSTRUMENTATION FOR USE WITH RADIALLY EXPANDING INTERBODY SPINAL FUSION IMPLANT**

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(73) Assignee: **Warsaw Orthopedic, Inc.**, Warsaw, IN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 552 days.

(21) Appl. No.: **10/914,847**

(22) Filed: **Aug. 10, 2004**

(65) **Prior Publication Data**

US 2005/0021041 A1 Jan. 27, 2005

Related U.S. Application Data

(62) Division of application No. 10/105,839, filed on Mar. 25, 2002, now Pat. No. 7,128,760.

(60) Provisional application No. 60/281,714, filed on Apr. 4, 2001, provisional application No. 60/279,205, filed on Mar. 27, 2001.

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

(52) **U.S. Cl.** **623/17.15**; 606/249

(58) **Field of Classification Search** 623/16.11, 623/17.11, 17.15, 17.16; 606/61, 248, 249
See application file for complete search history.

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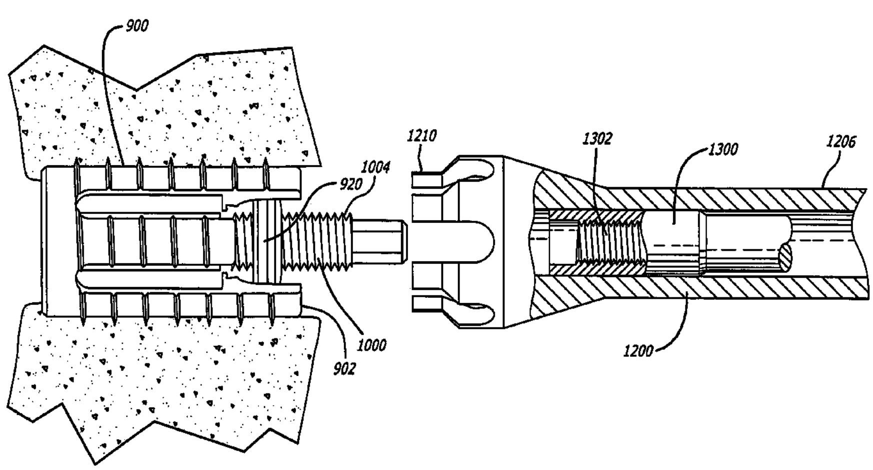
Primary Examiner—Ralph A Lewis
(74) *Attorney, Agent, or Firm*—Martin & Ferraro, LLP

(57) **ABSTRACT**

Interbody spinal fusion implants being at least in part radially expandable at one of the leading or trailing ends to expand both the height and at least a portion of the width of the implant, and instruments and methods for inserting the implants into an implantation space in the spine are disclosed.

13 Claims, 25 Drawing Sheets



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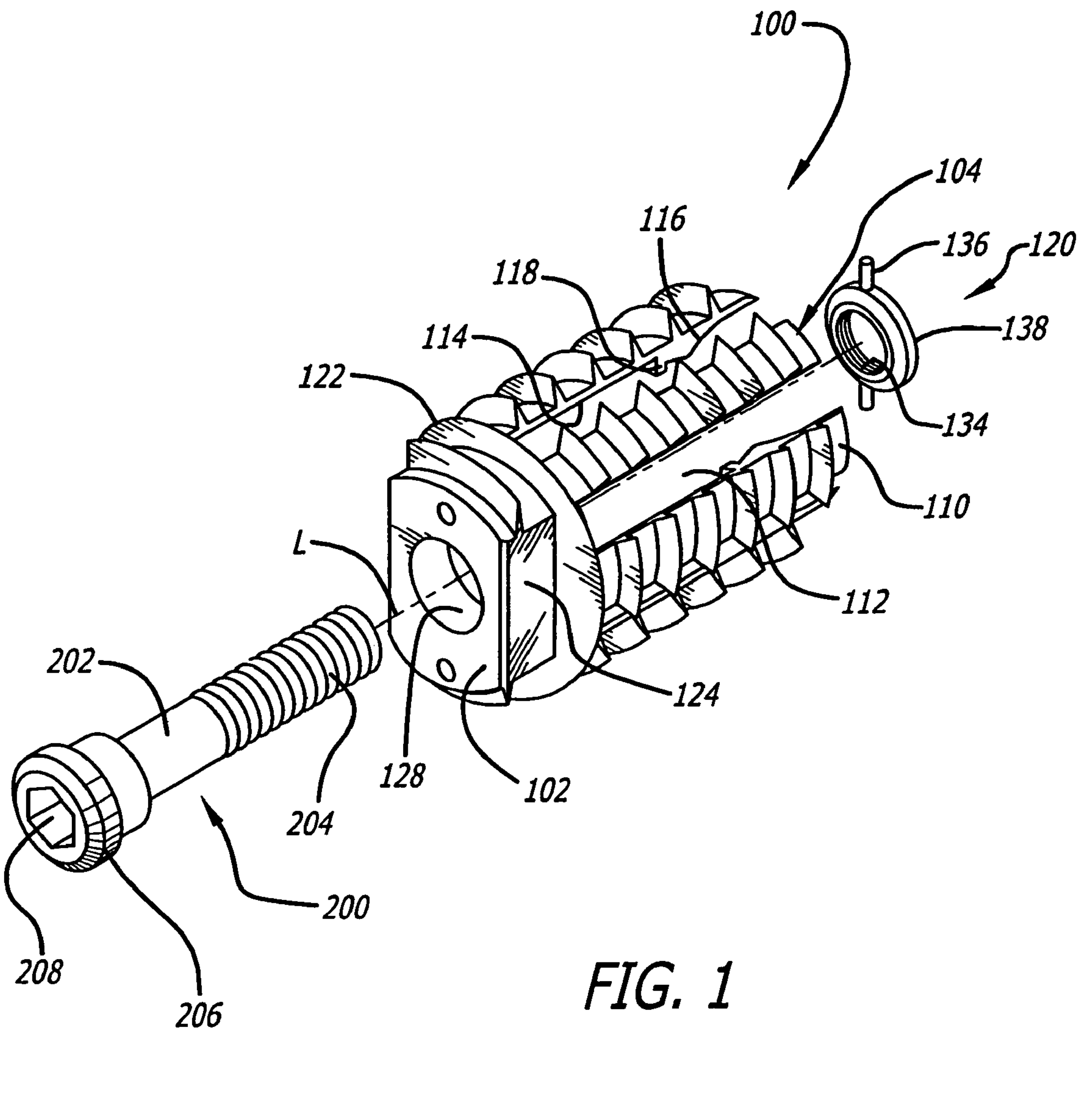
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FIG. 1

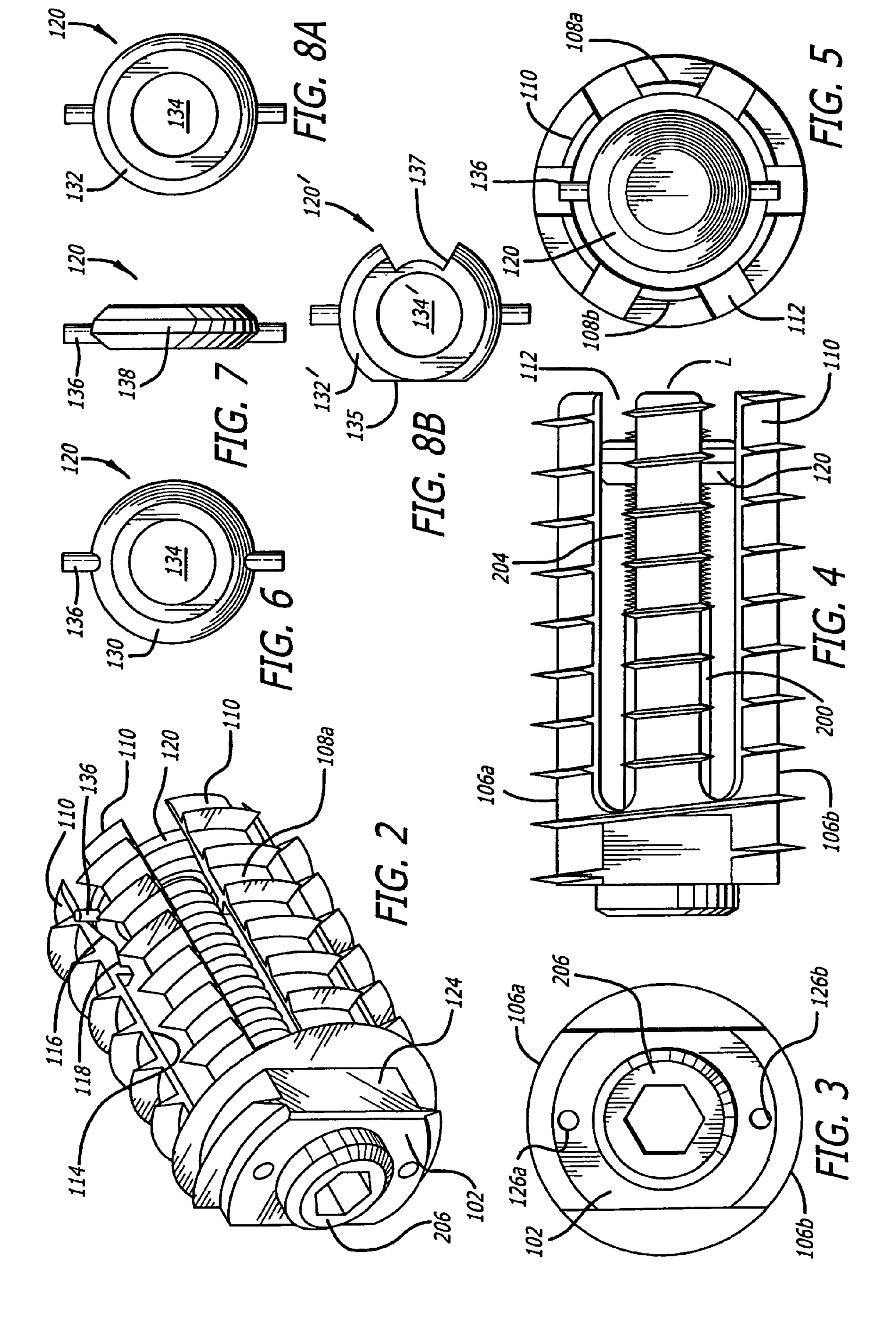


FIG. 8A

FIG. 7

FIG. 6

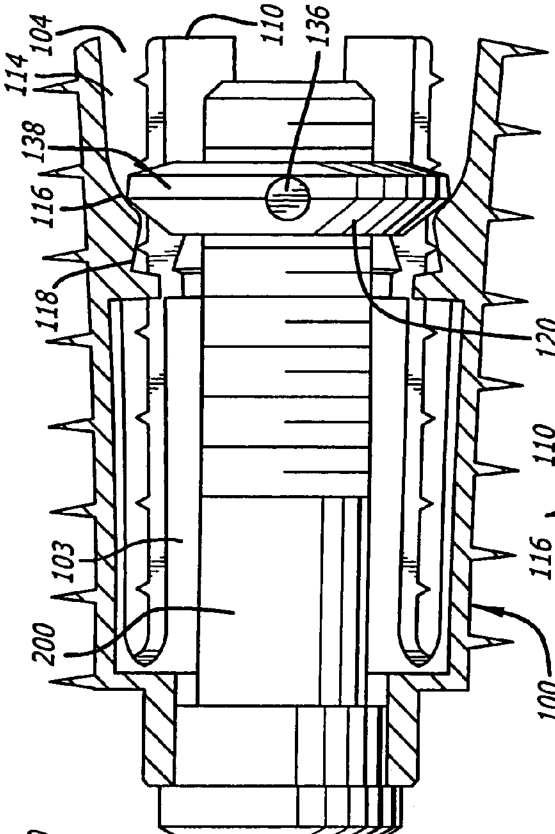
FIG. 8B

FIG. 5

FIG. 4

FIG. 2

FIG. 3



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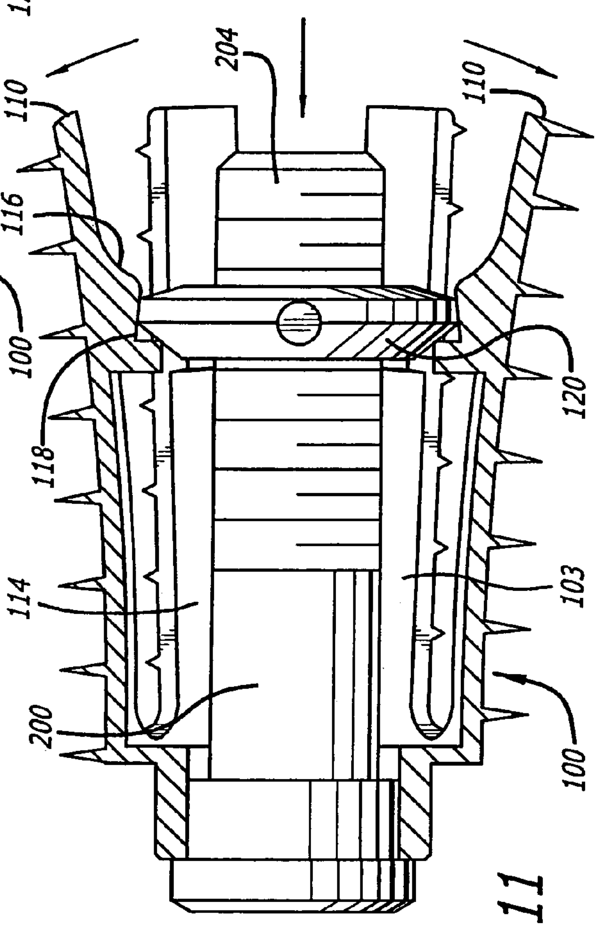

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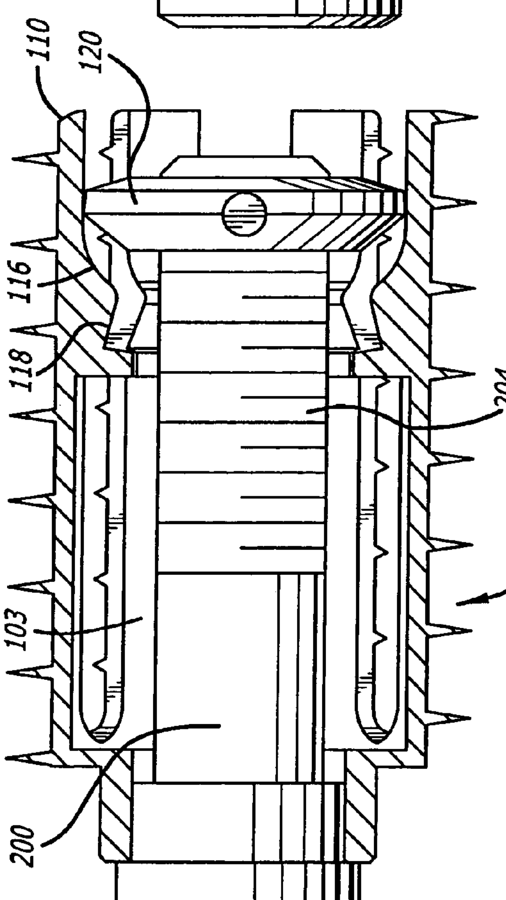

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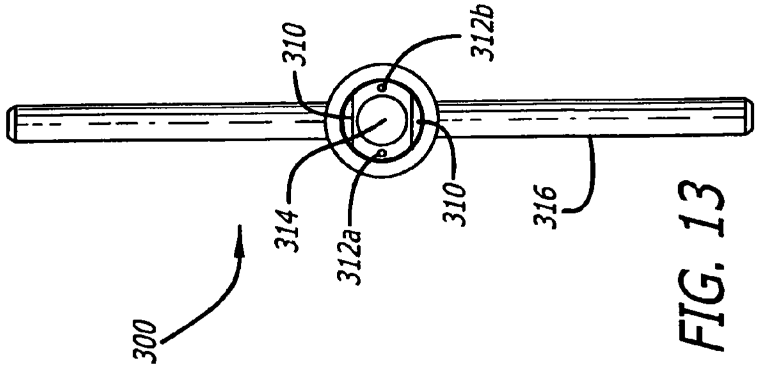

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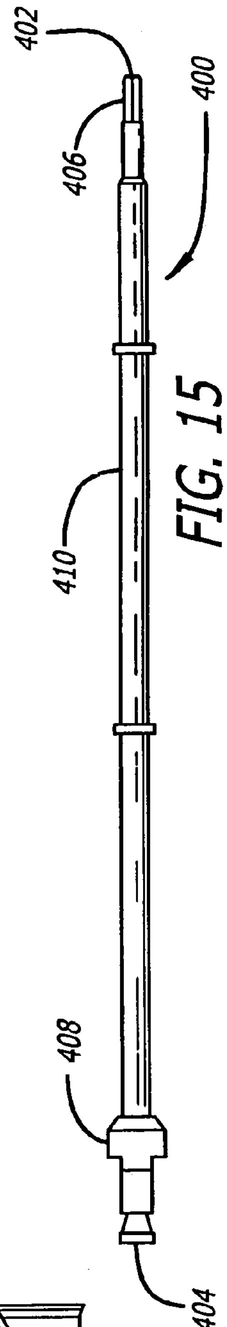

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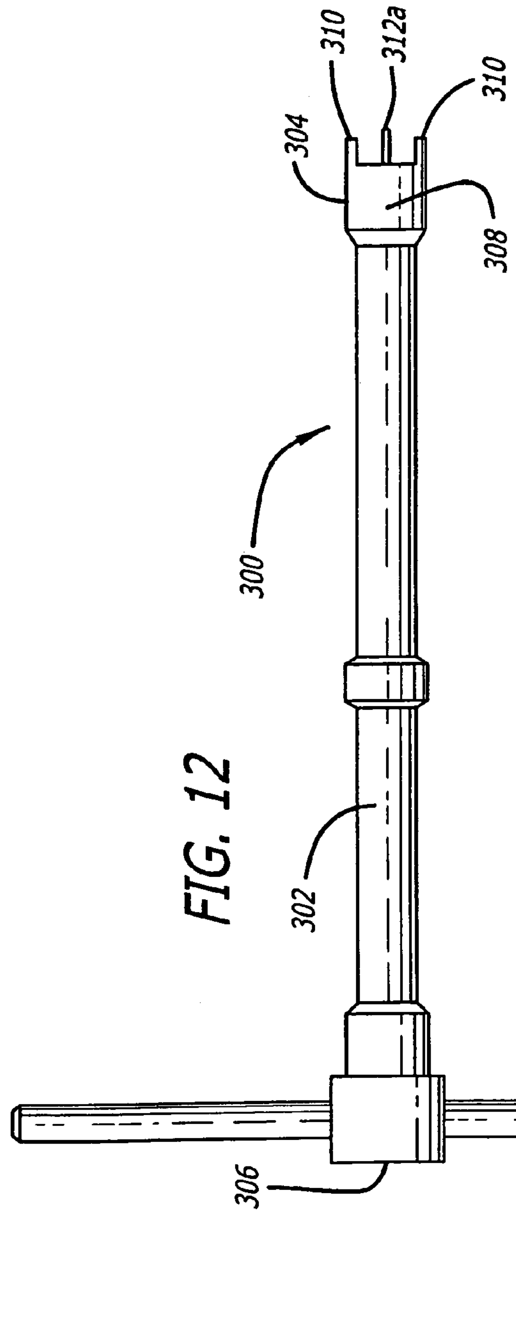

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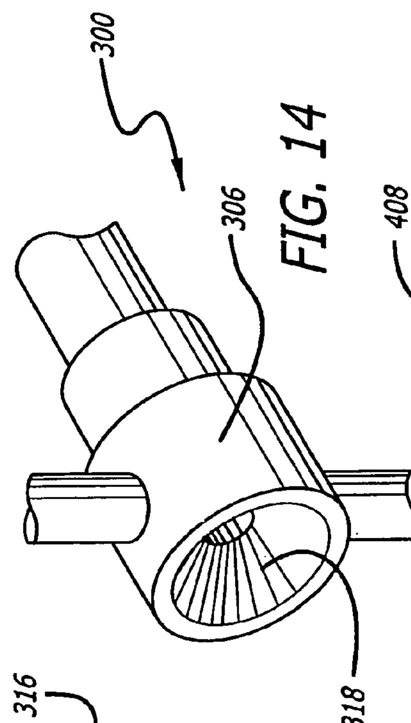

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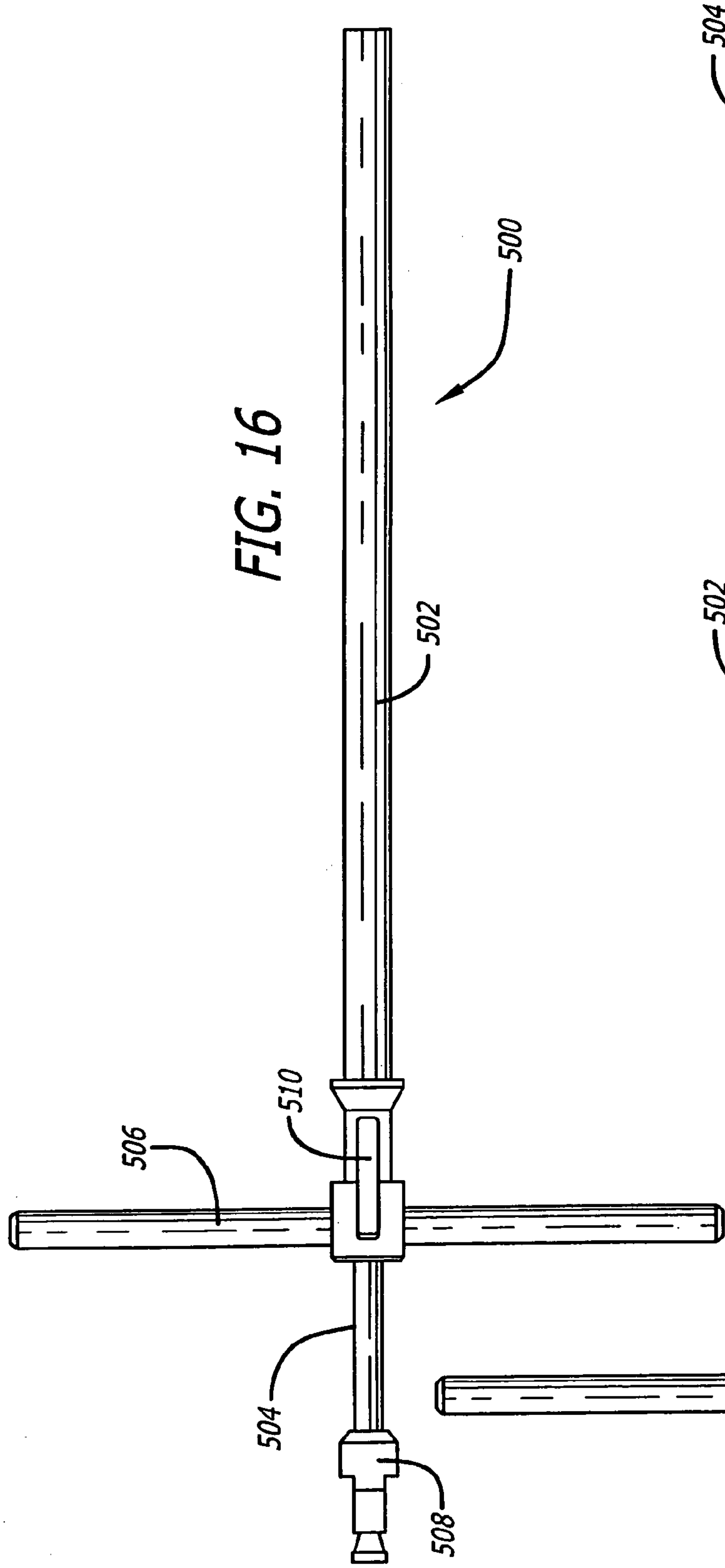

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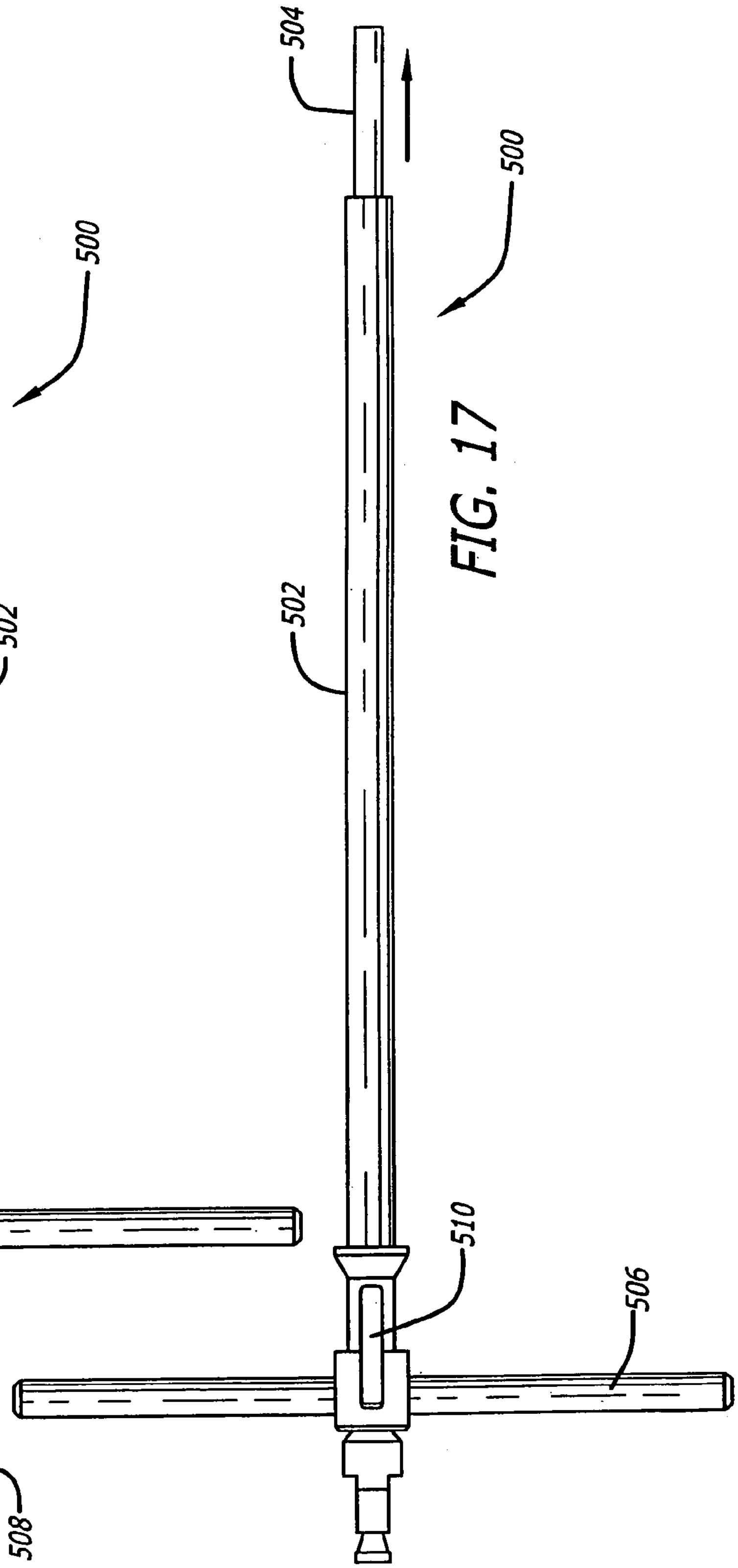

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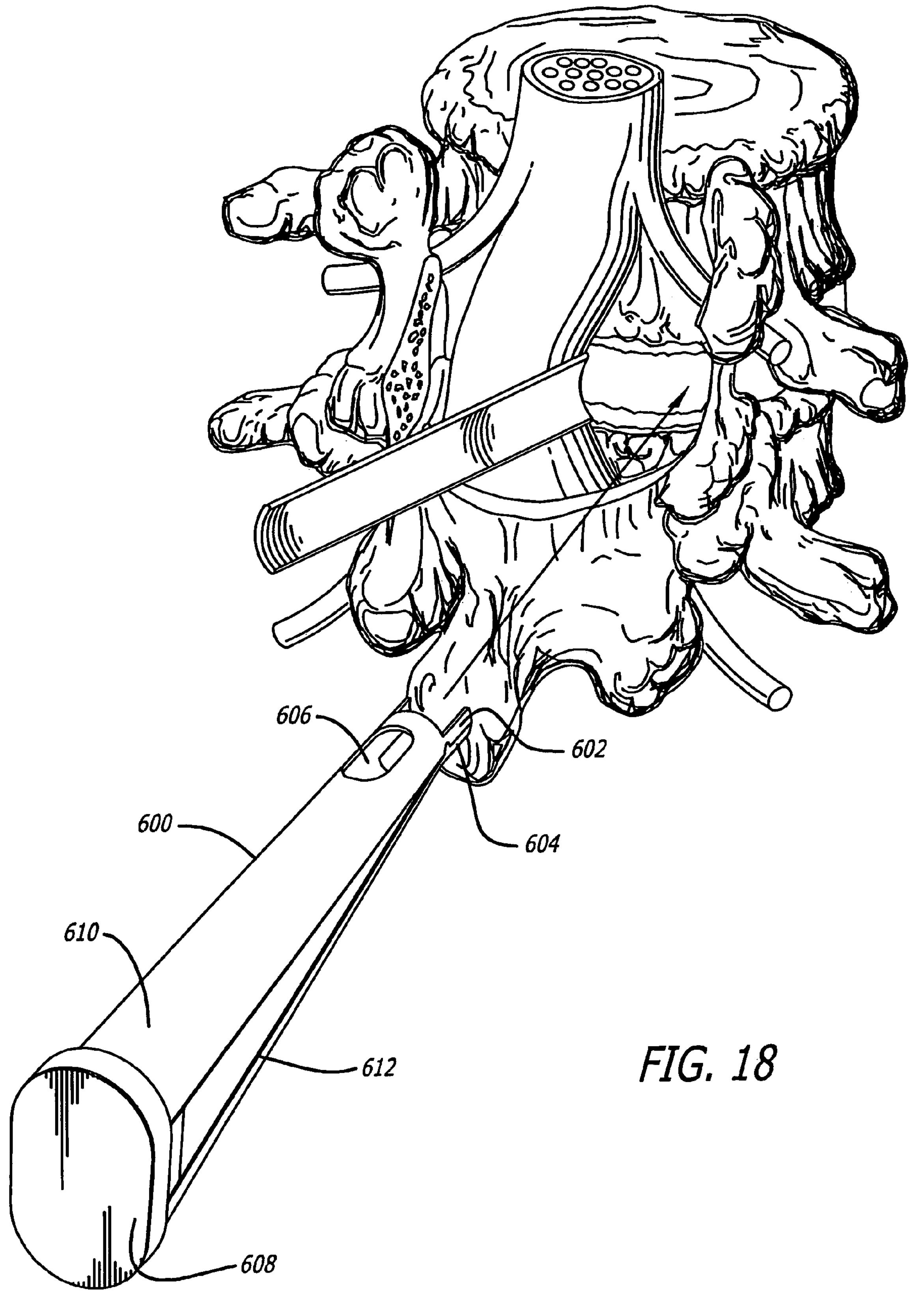

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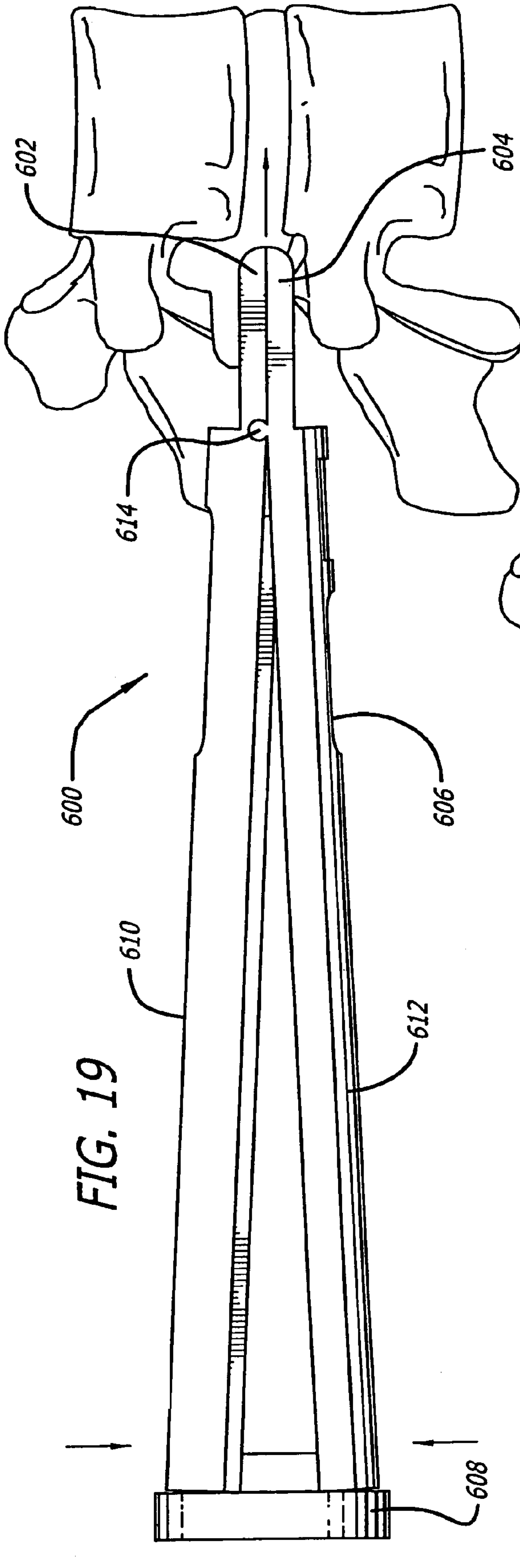

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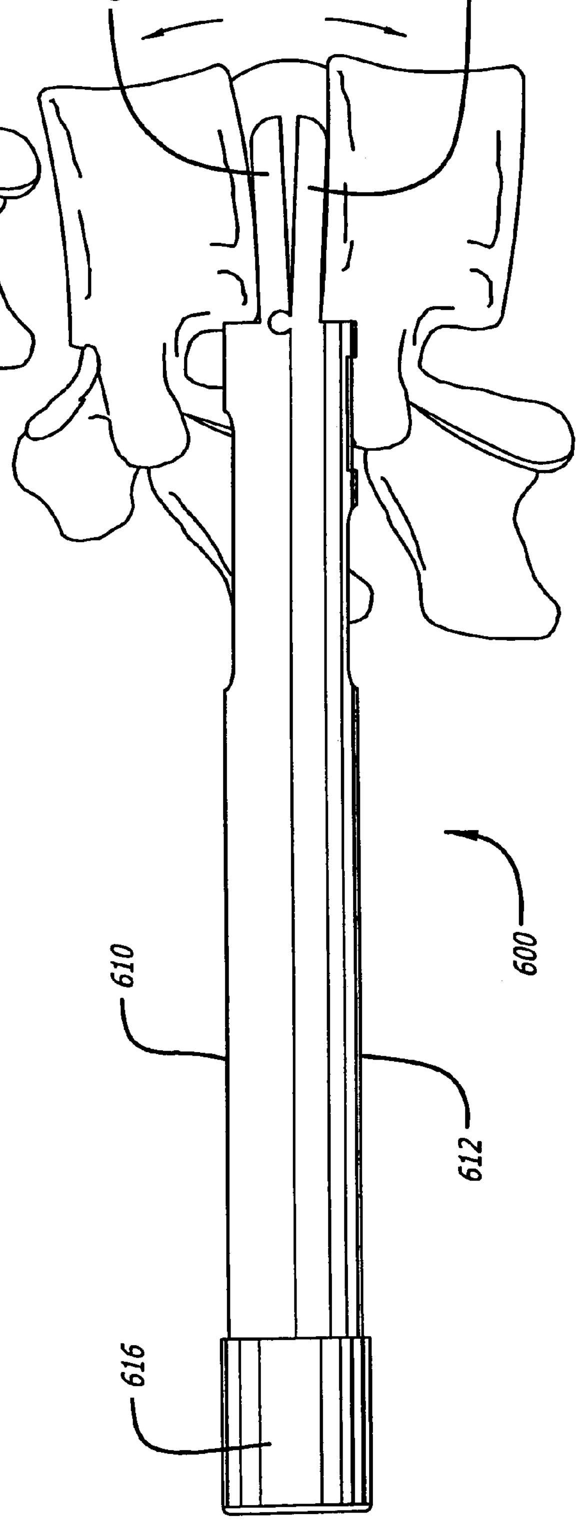

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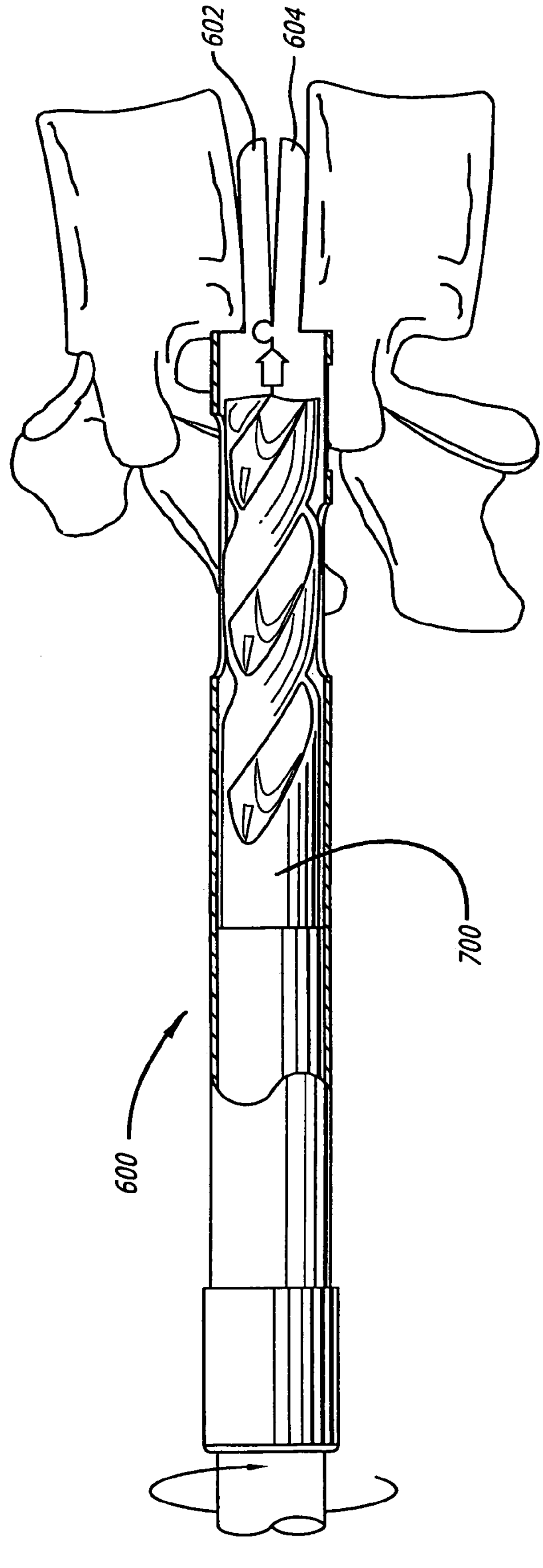

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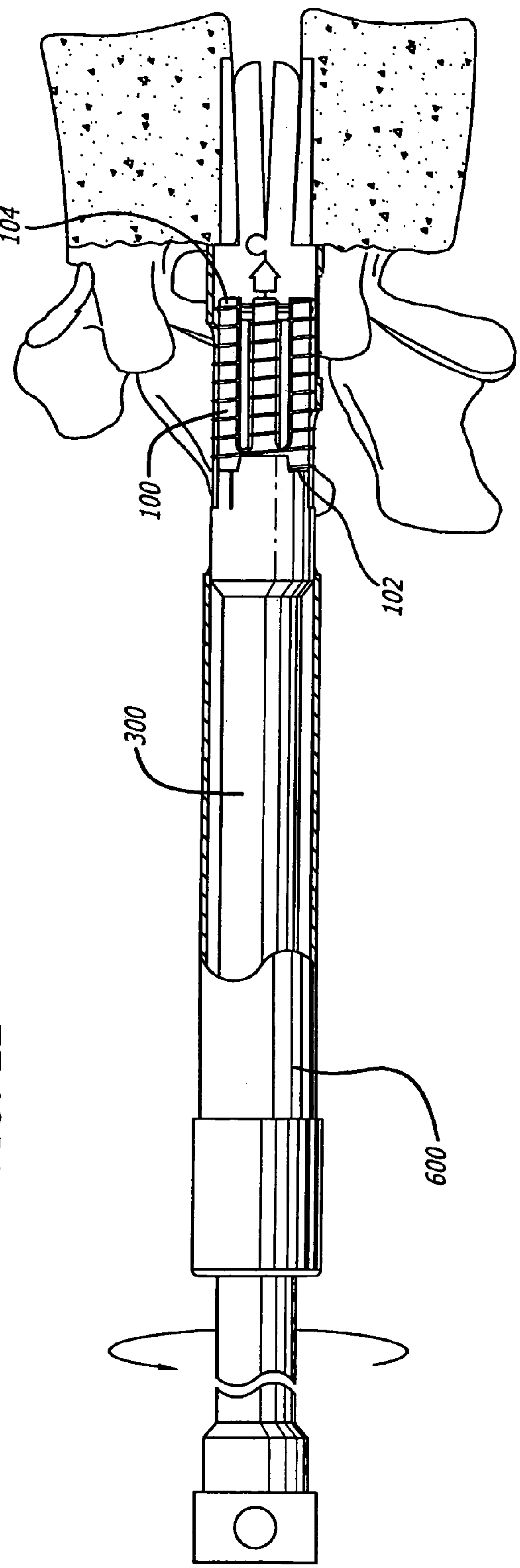

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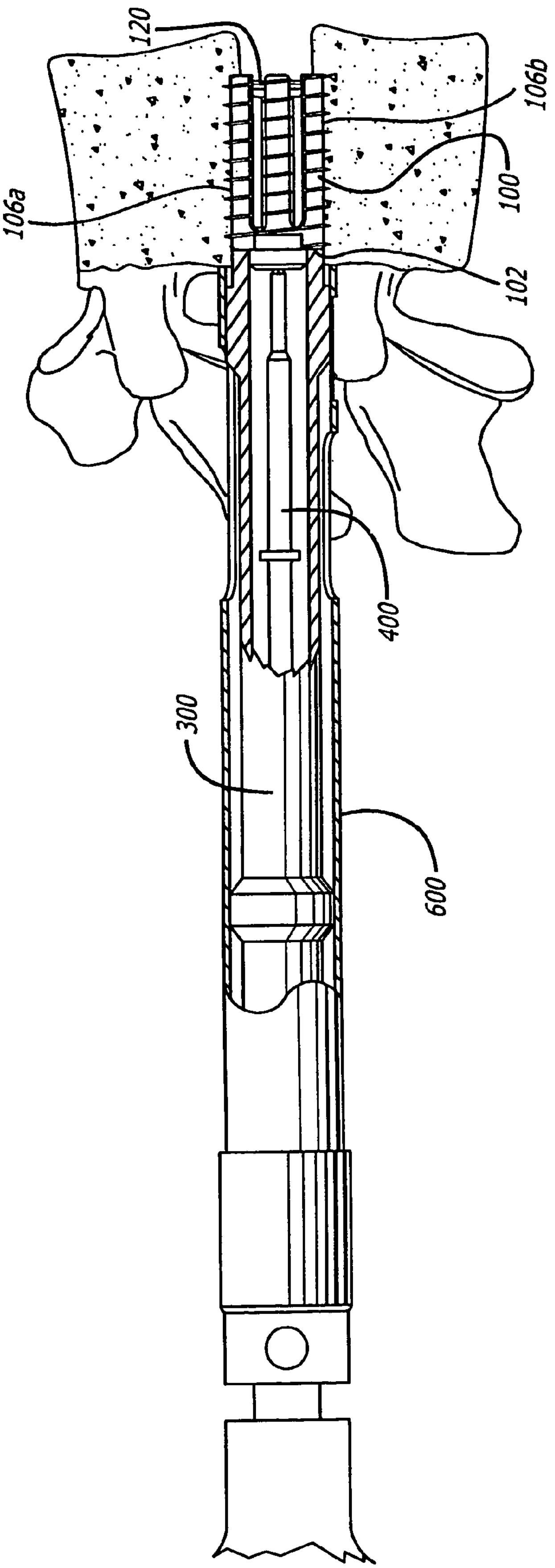

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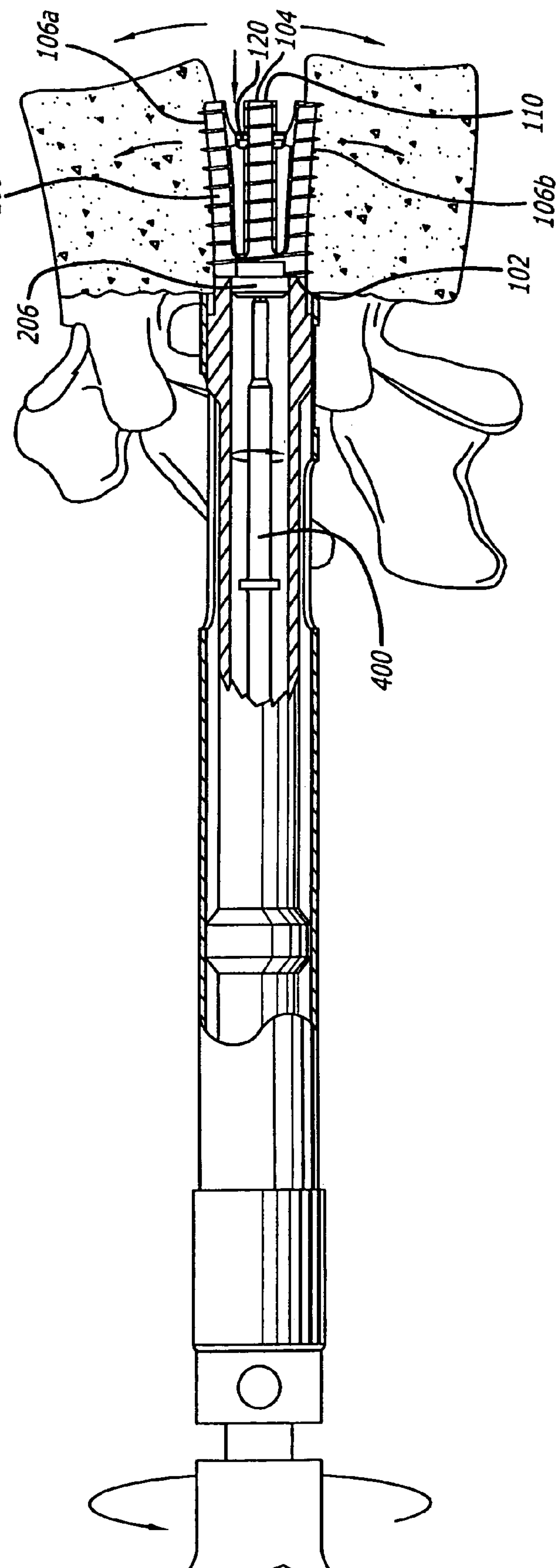

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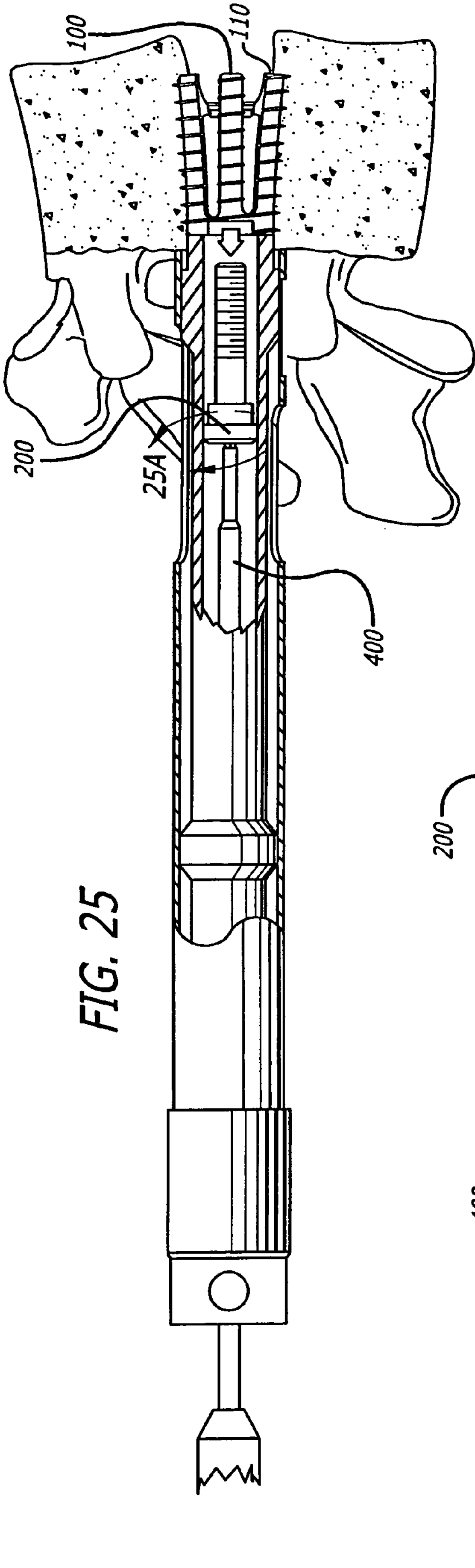

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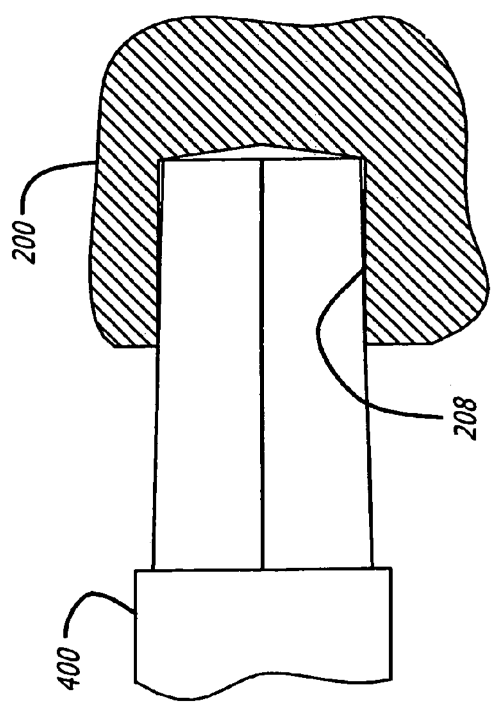

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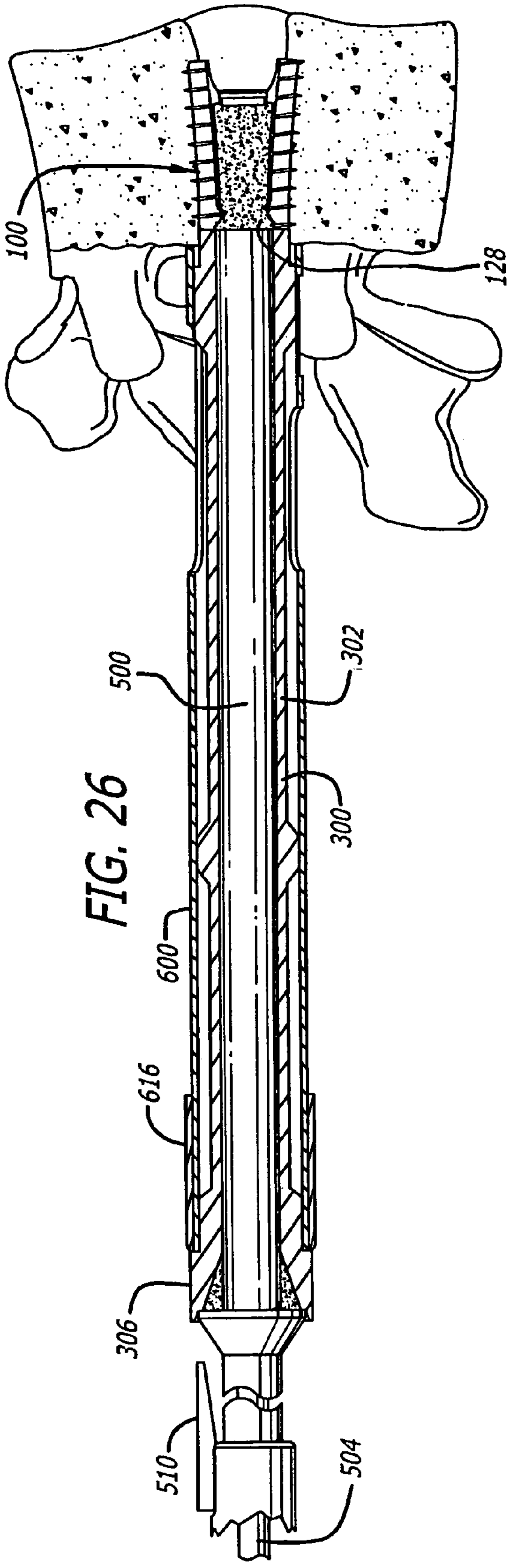
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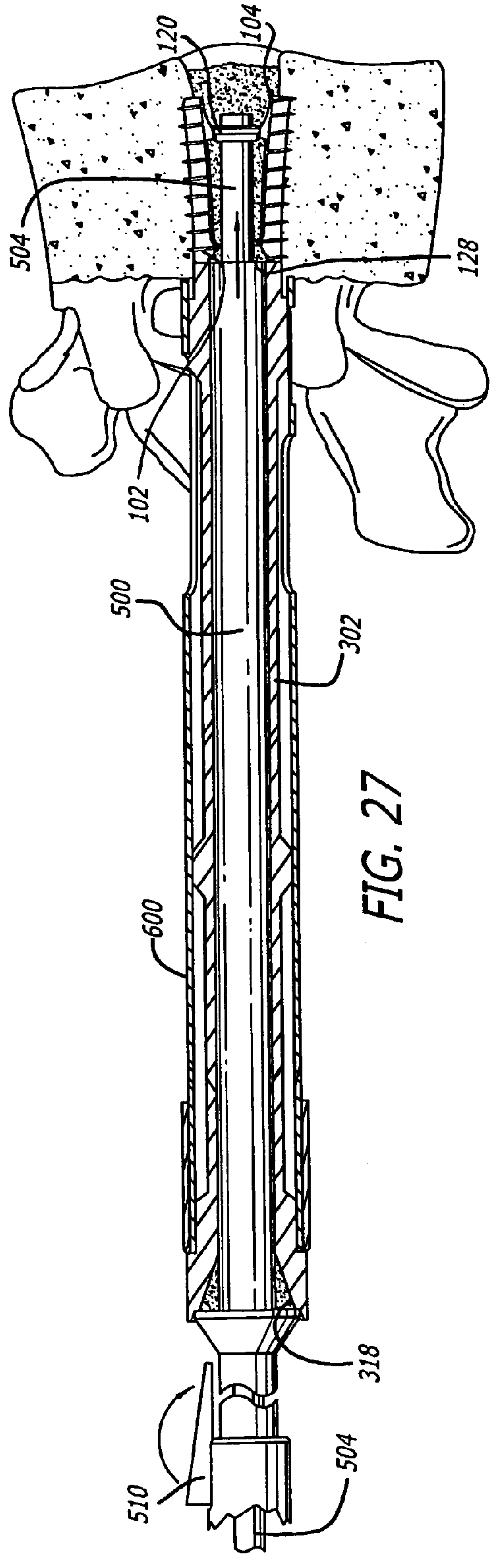
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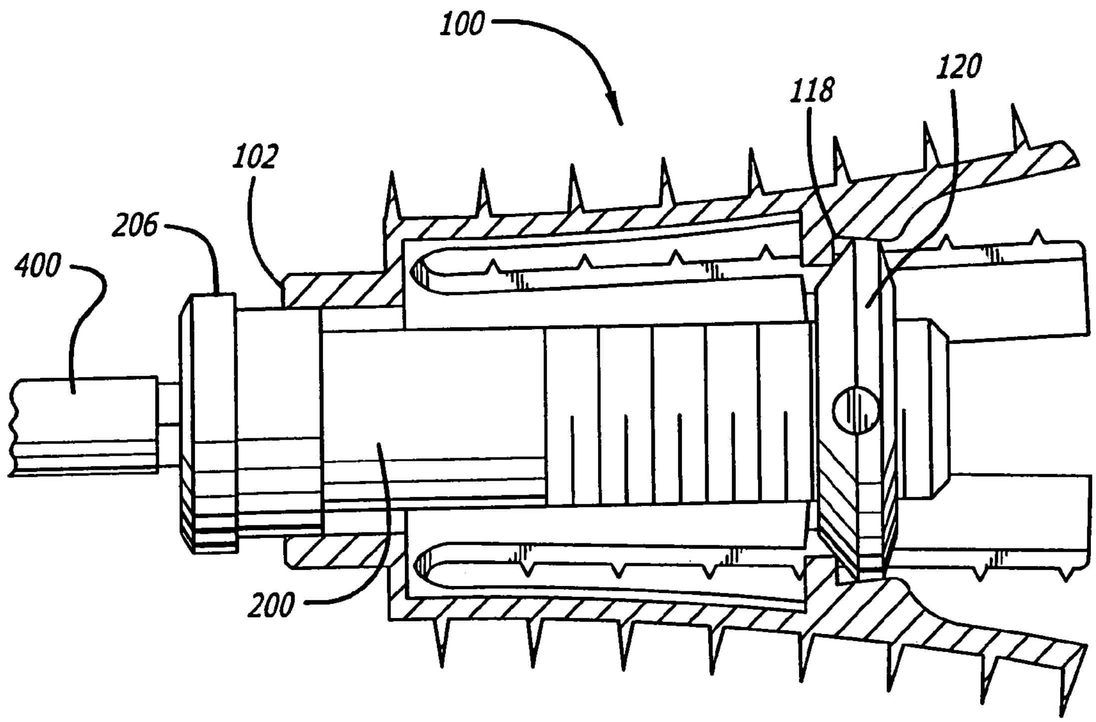
FIG. 27



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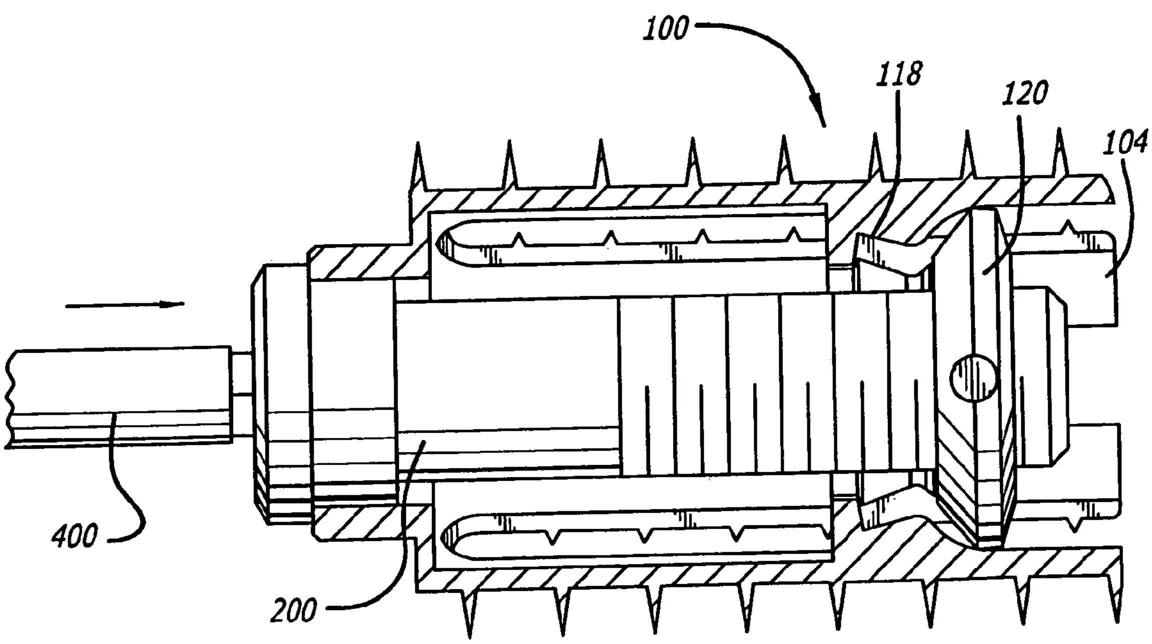

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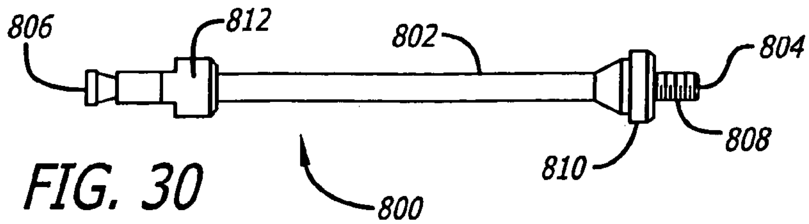

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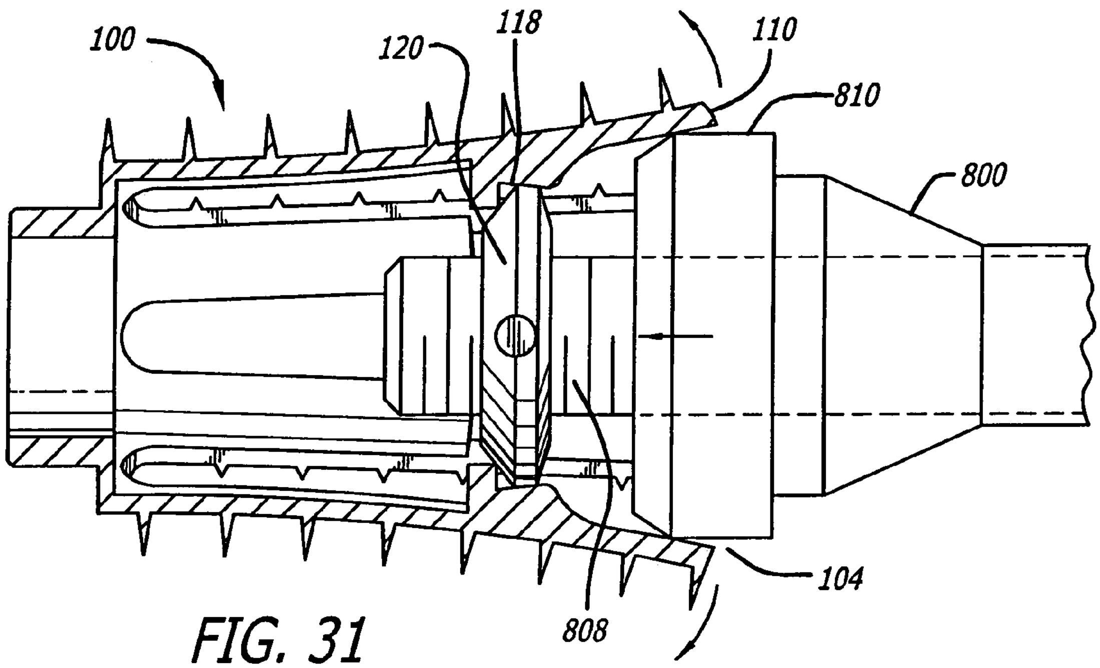

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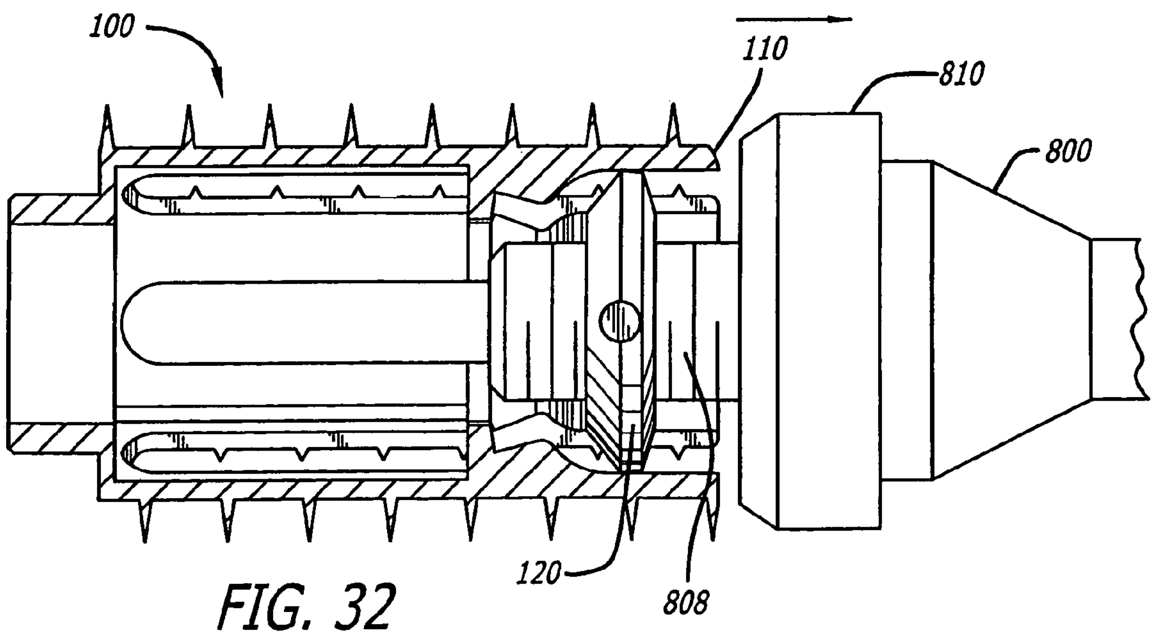
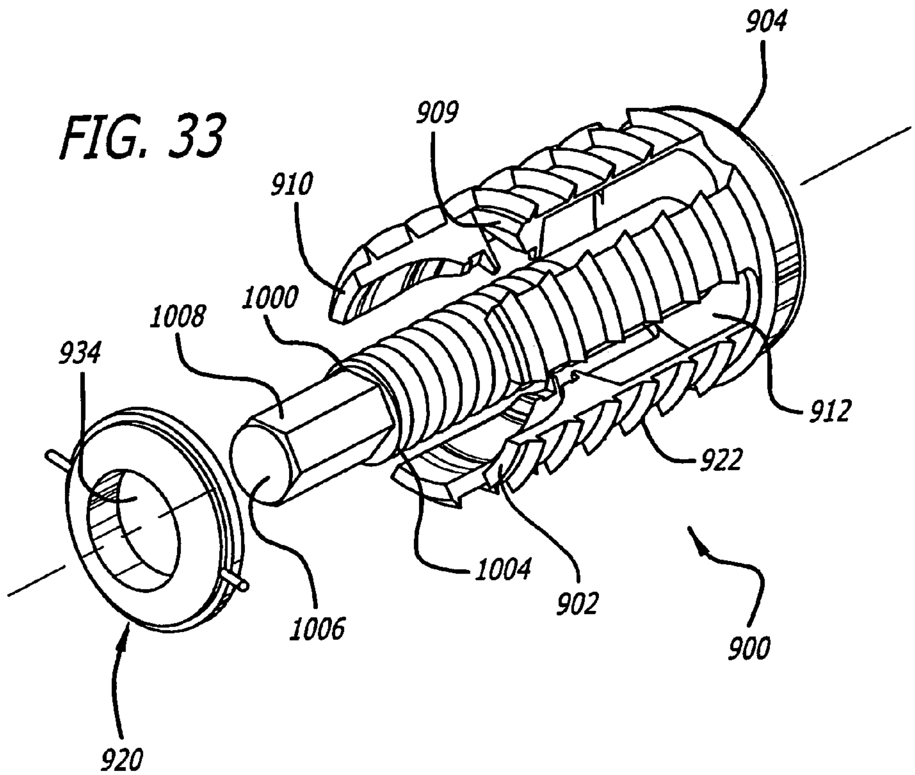


FIG. 32

FIG. 33



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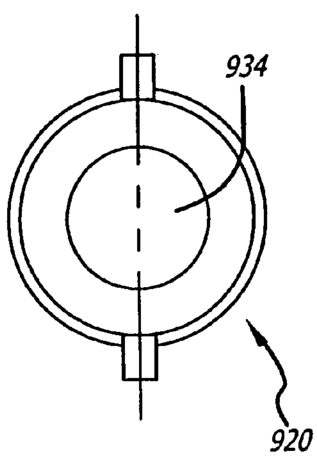

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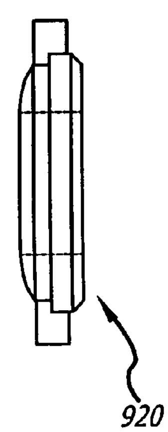

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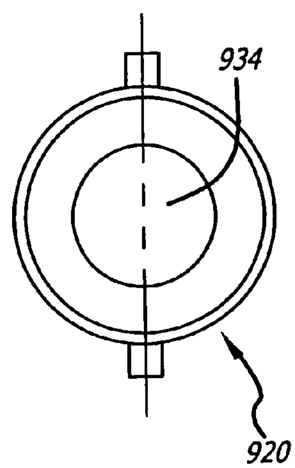

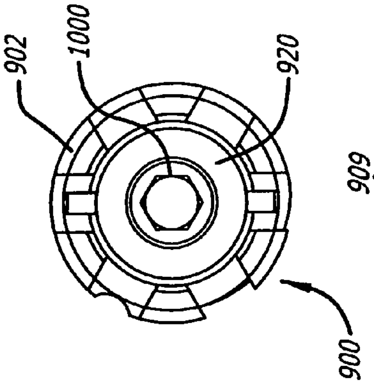

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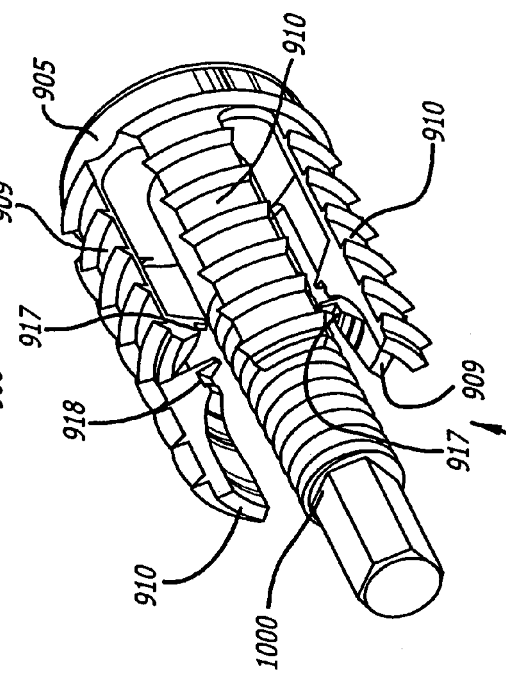

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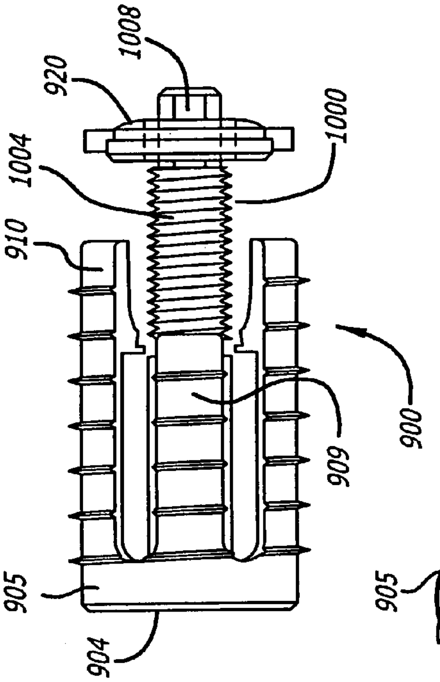

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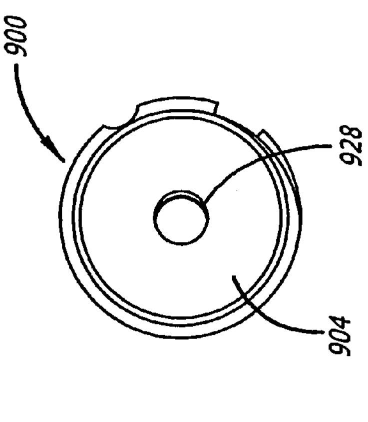

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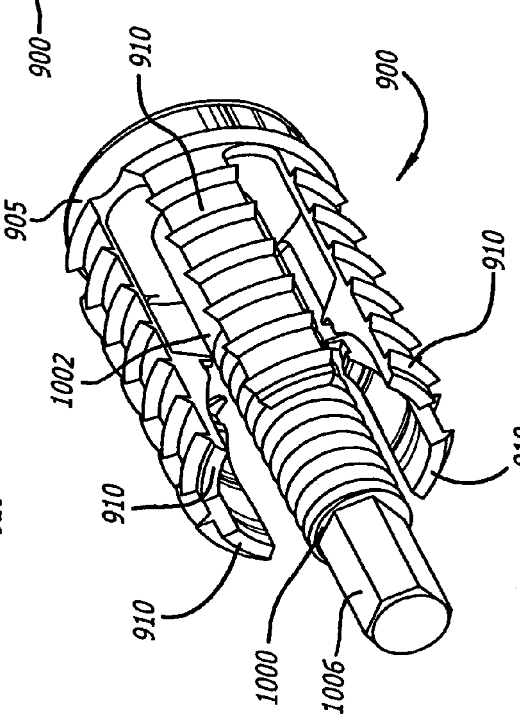
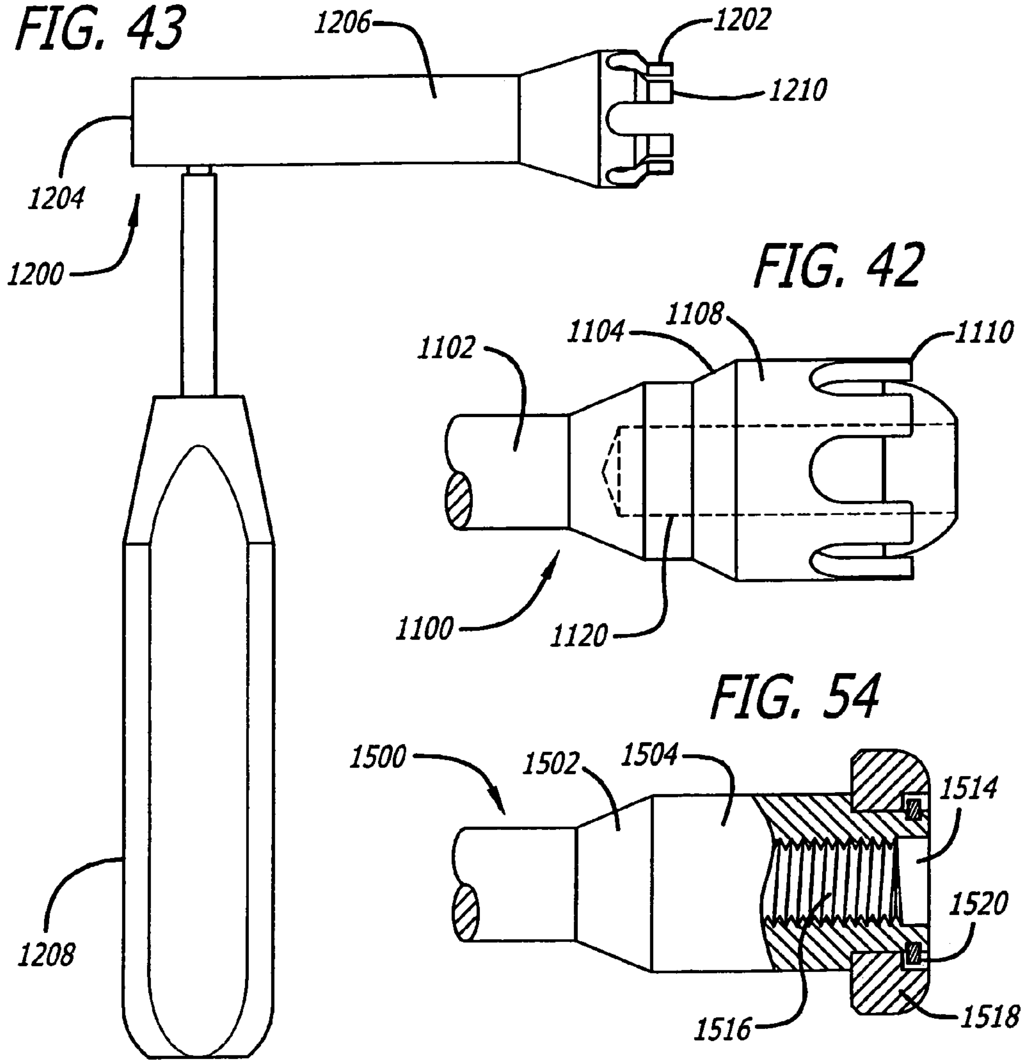


FIG. 38

FIG. 43

FIG. 42

FIG. 54



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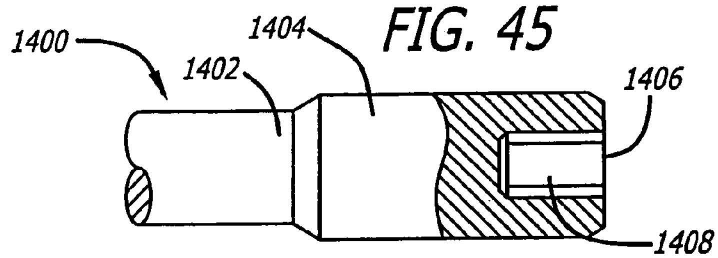

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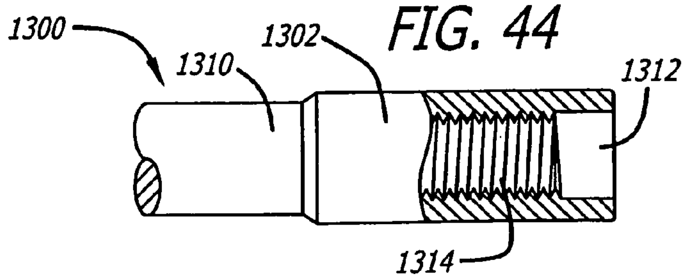

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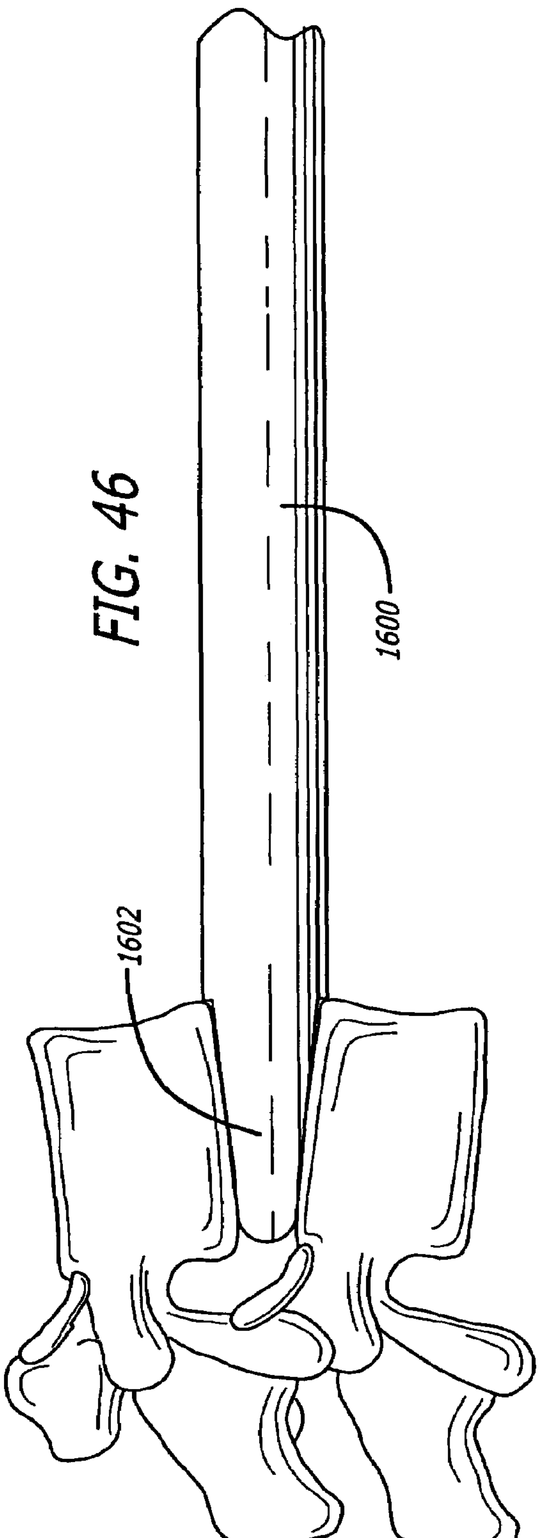

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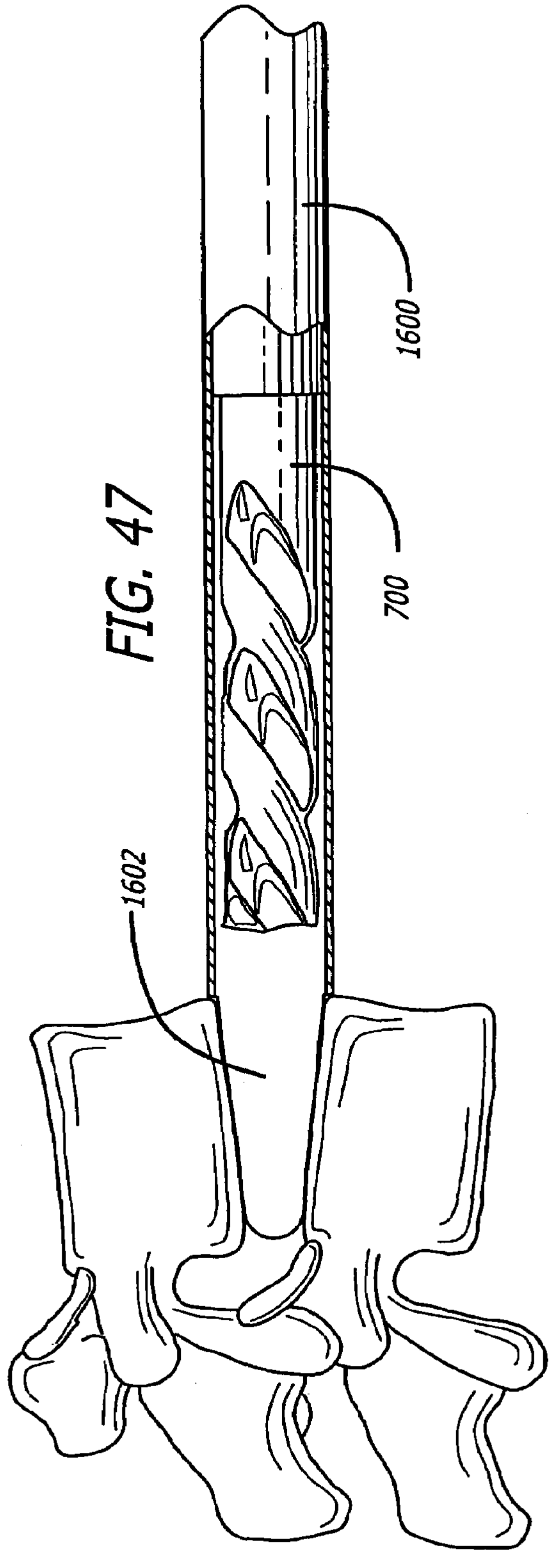


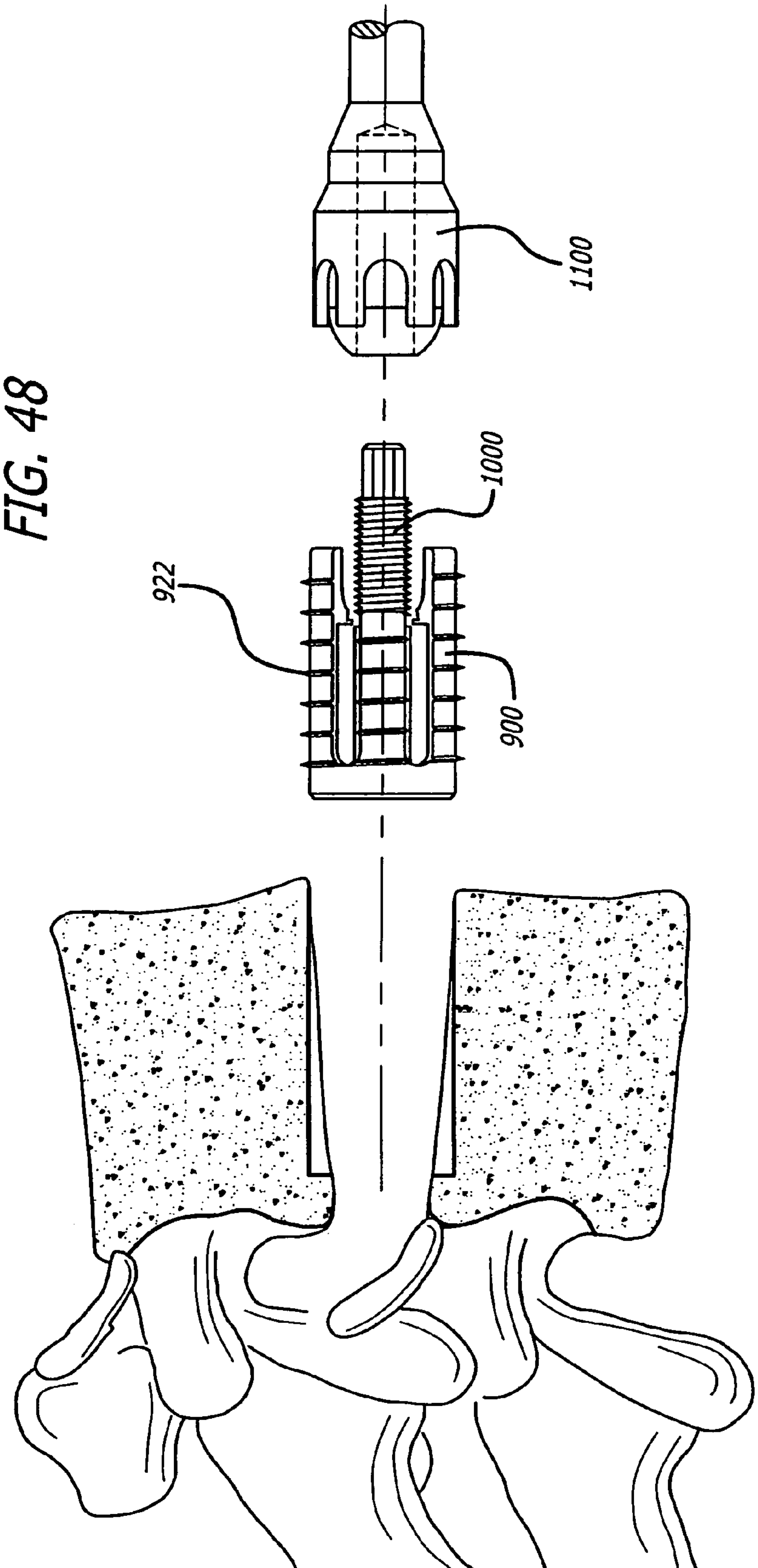
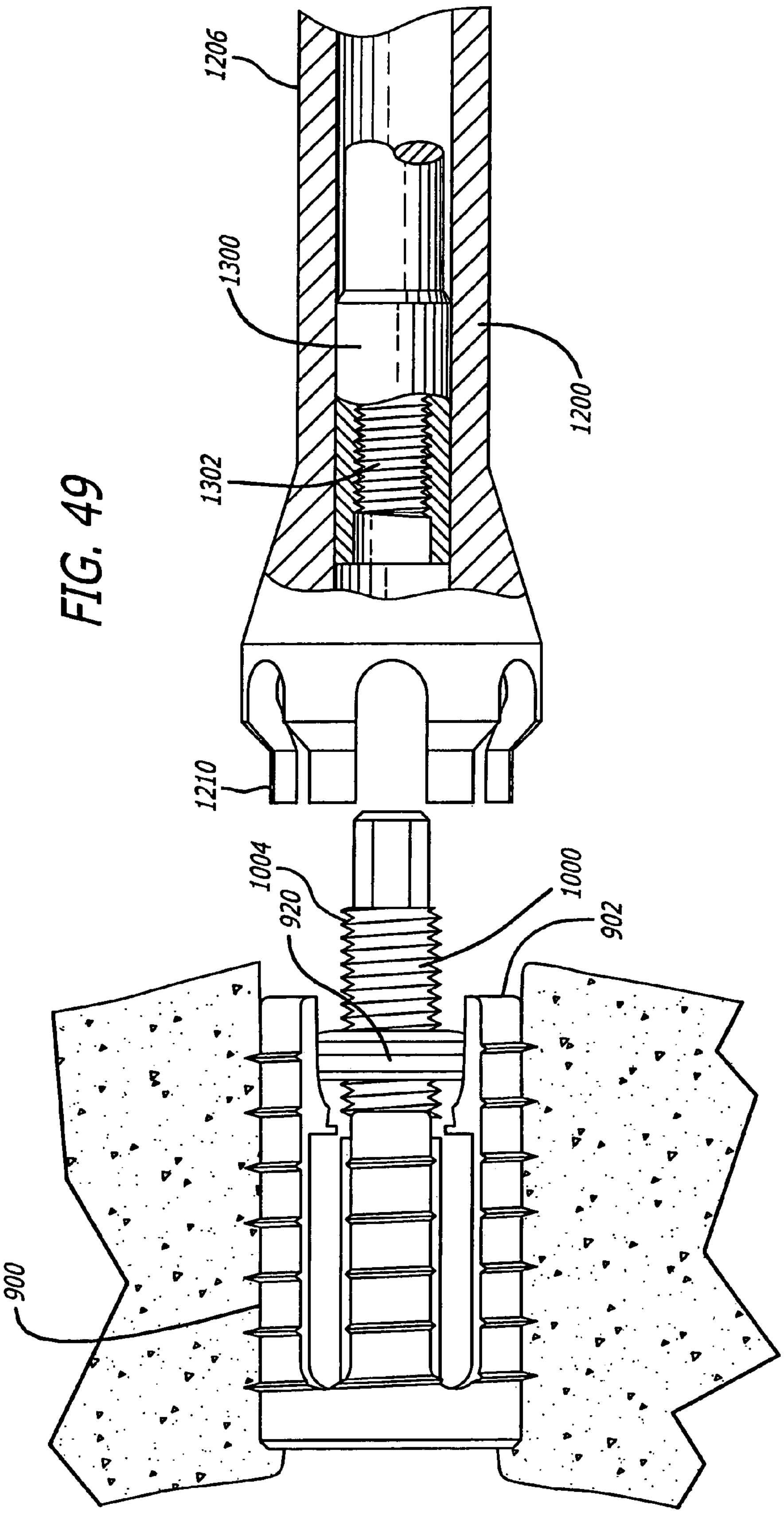
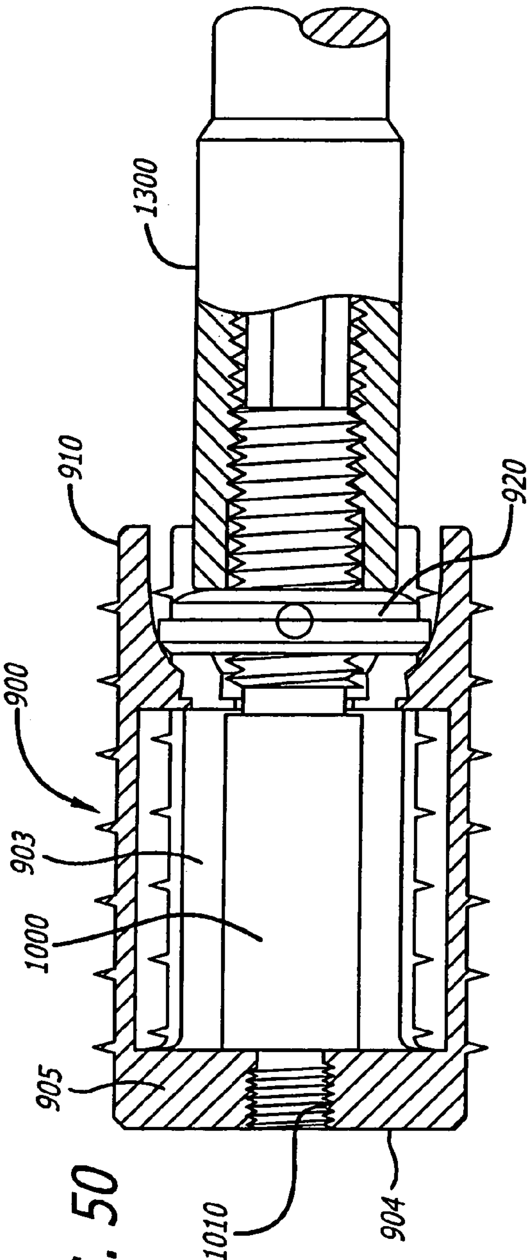


FIG. 48

FIG. 49

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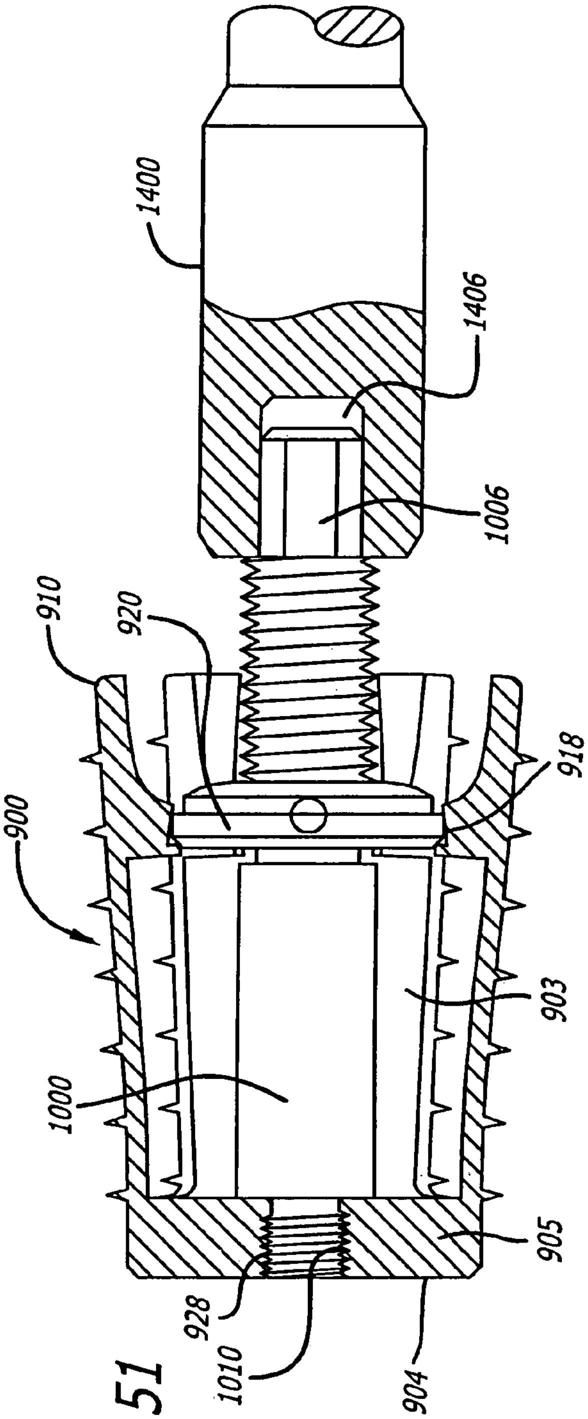
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FIG. 51

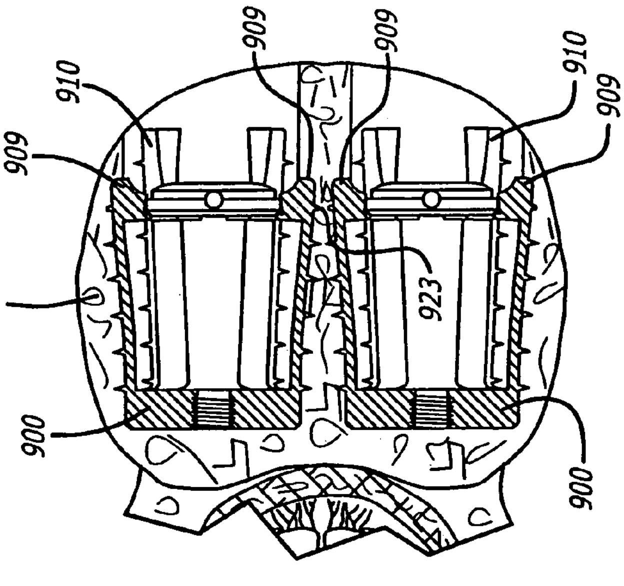


FIG. 53

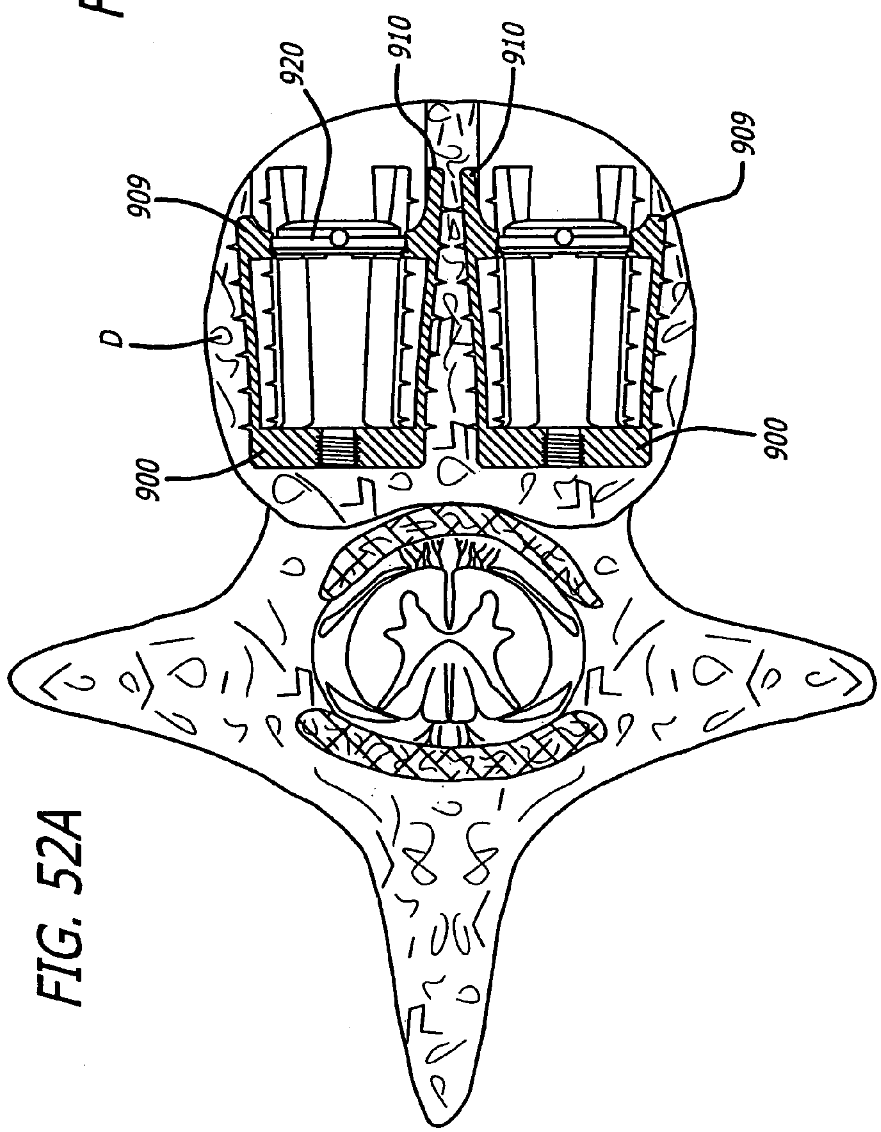
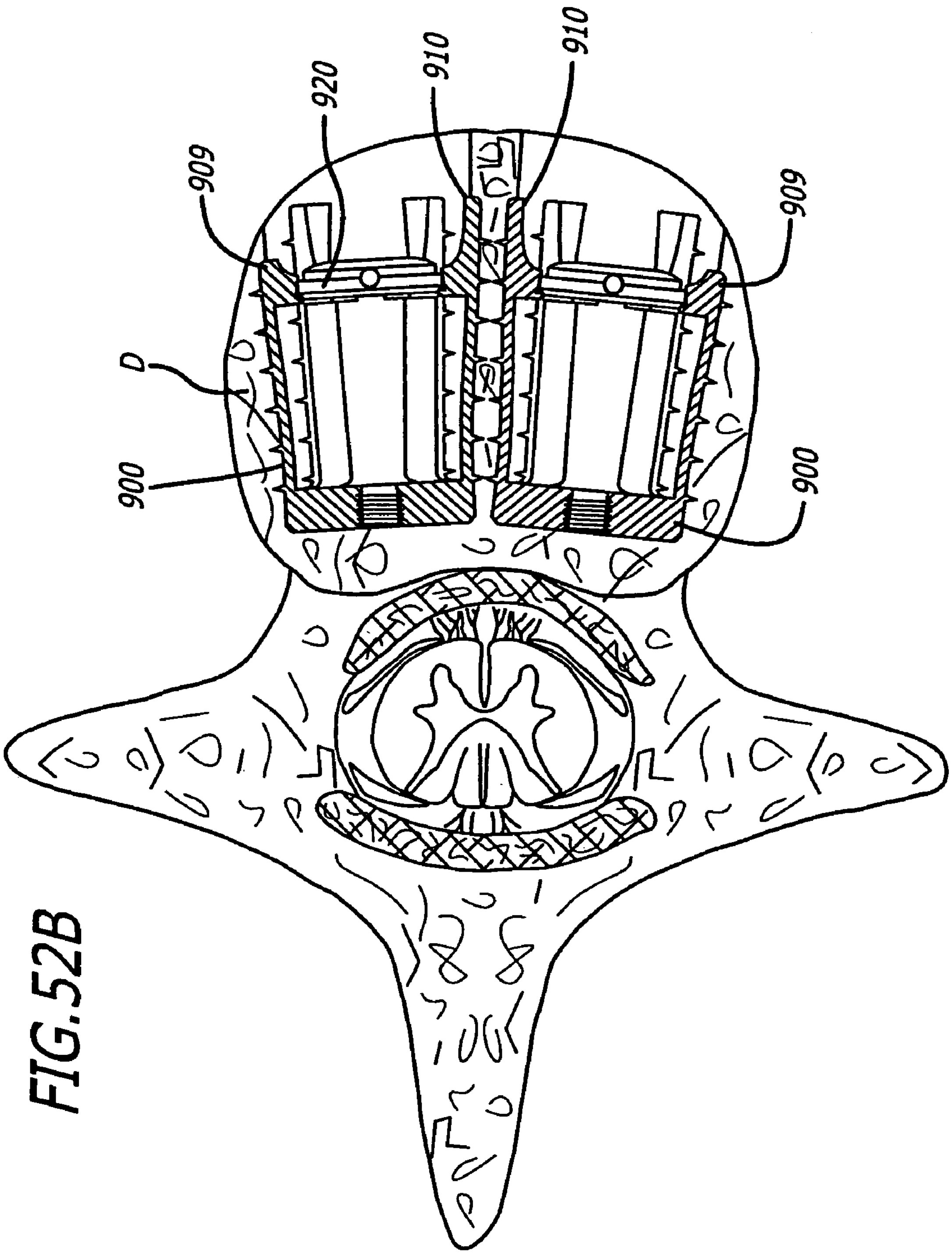


FIG. 52A



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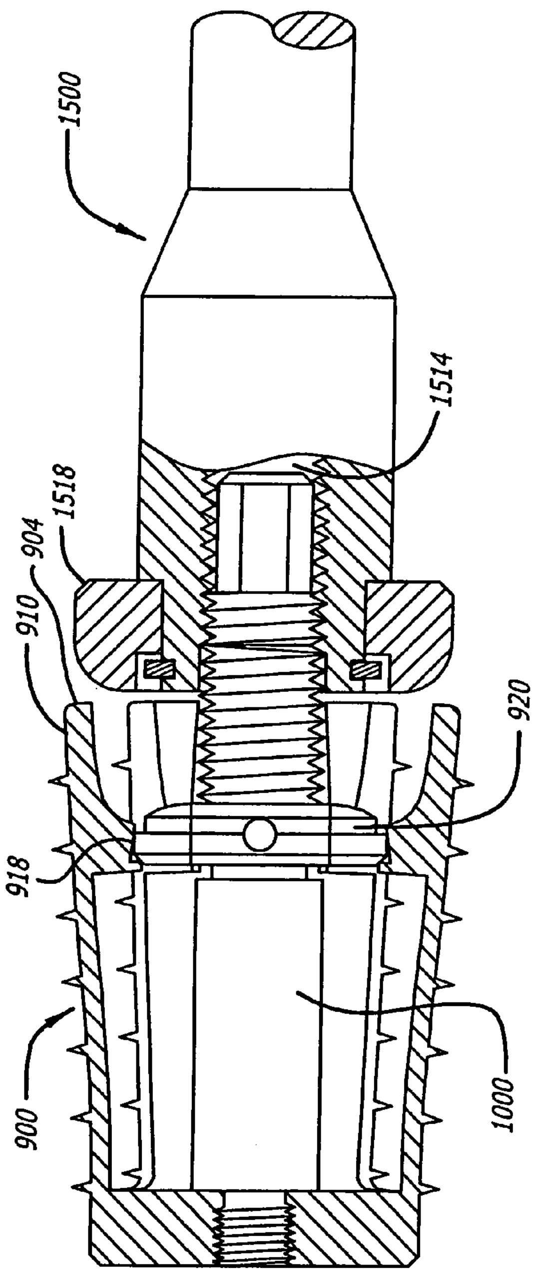
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FIG. 55

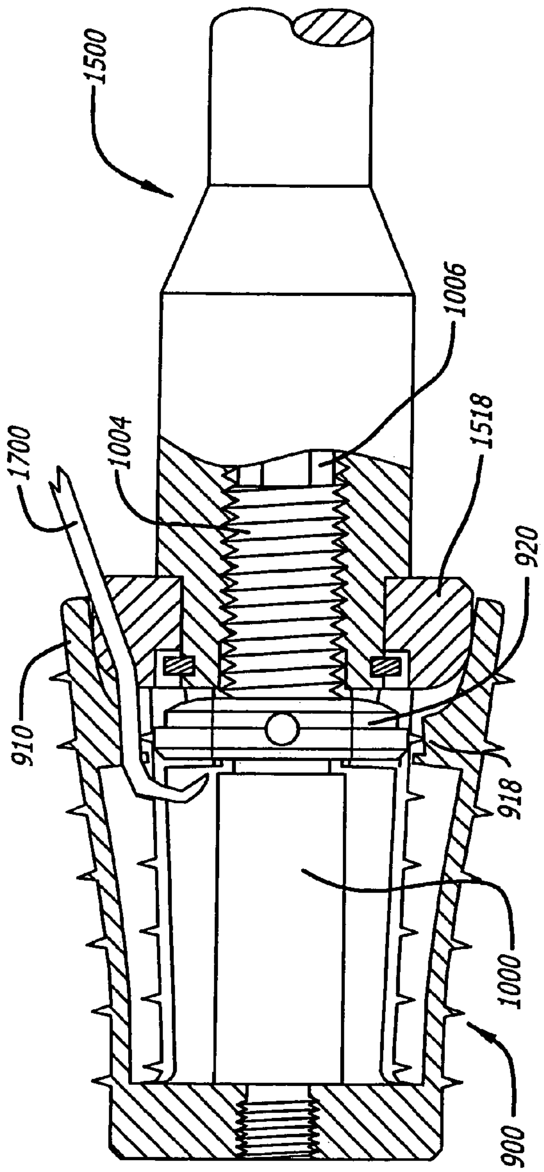
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FIG. 56

INSTRUMENTATION FOR USE WITH RADIALLY EXPANDING INTERBODY SPINAL FUSION IMPLANT

RELATED APPLICATIONS

This application is a divisional of application Ser. No. 10/105,839, filed Mar. 25, 2002; now U.S. Pat. No. 7,128, 760, which claims benefit of provisional Application No. 60/279,205, filed Mar. 27, 2001; and provisional Application No. 60/281,714, filed Apr. 4, 2001; all of which are incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to interbody spinal implants, and instruments and methods for inserting interbody spinal implants into an implantation space in the spine, and in particular to an expandable interbody (for placement at least in part between adjacent vertebral bodies in the space previously occupied by disc material) spinal fusion implants for the immobilization of adjacent vertebrae.

2. Description of the Related Art

Expandable spinal fusion implants have height raising capabilities that are utilized once the implant is initially positioned. Such height raising capability may be utilized within the spine anteriorly, posteriorly, or both and to various extents, respectively to raise the front or back of the implant. More particularly, such implants have upper and lower surfaces of upper and lower portions that in an insertion position are collapsed relative to one another and in a deployed position are spaced further away from one another than in the collapsed position.

Expandable fusion implants offer the advantage of allowing for the placement of a potentially larger implant through a smaller opening in a patient's body. The first expandable spinal fusion (allowing for the growth of bone from vertebral body to vertebral body through the implant) implant was invented by Michelson and also is disclosed in U.S. Pat. No. 5,776,199, filed Jun. 28, 1988, which is hereby incorporated by reference herein.

Expandable interbody spinal fusion implants preferably may be inserted from an anterior approach to the spine, an approach posterior to the vertebral transverse processes, or to either side of the spinal midline in pairs. Such expandable implants are adapted to increase in height at their leading ends or at their trailing ends from a collapsed state to an expanded state for the purpose of increasing spinal lordosis at that interspace. During installation of expandable interbody spinal fusion implants, it is desirable that the surgeon have the ability to precisely control the implant with the appropriate instruments and methods to load the implant with appropriate bone growth promoting material, to insert the implant into the implantation space, to deploy the implant to a final expanded state, and to further load the implant with bone growth material if so desired.

Also known in the art are expandable interbody spinal fusion implants that are circumferentially expandable at one of their leading or trailing ends to expand both the height and the width of the implant. Such implants have an expansion mechanism that is moved from the trailing end through the interior of the implant to reach the leading end to expand the implant. Any bone growth material present within the interior of the implant would be forced out of the interior of the implant by the expansion mechanism passing therethrough. Accordingly, such implants cannot be effectively preloaded with bone growth promoting material prior to expansion of the implant.

There exists a need for a circumferentially expanding implant that is substantially hollow and substantially devoid of any elaborate or substantial space occupying expansion mechanism to permit preloading of the implant with bone growth promoting material prior to expansion of the implant. The expansion mechanism would not interfere with the capacity to compressively load osteogenic material such as bone or any other suitable material through the length of the implant and to have it extrude from the implant. The extrusion of the osteogenic material from the implant provides an increased volume of osteogenic material over a greater surface area of the adjacent vertebral bodies adjacent the disc space to be fused and beyond the surface area of contact of the implant to the vertebral bodies themselves. Surrounding the implant itself with additional fusion promoting substances in contact with the adjacent vertebral bodies may enhance the fusion process.

There also exists a need for instruments and methods for use with expandable interbody spinal fusion implants providing for all of the aforementioned needs individually or in combination.

SUMMARY OF THE INVENTION

Additional objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

The present invention is directed to an interbody spinal fusion implant particularly adapted for anterior, posterior, and posterior lateral interbody spinal fusion; and methods and instrumentation for a preferred insertion of these implants.

The present invention implant is adapted to have a generally constant size at one end while allowing for a generally circumferential increase in size at the opposite end. This feature is particularly useful for posterior lumbar interbody fusion and posterior lateral interbody spinal fusion, where it is desirable to have the vertebral bodies spaced apart more anteriorly than posteriorly to restore the lumbar lordosis. The implant is preferably inserted in a generally cylindrical form or more particularly with the opposed surfaces of the implant adapted to contact each of the opposed adjacent vertebral bodies adjacent to the disc space to be fused being generally parallel. Subsequently, the implant is expanded at the leading end so that the opposed vertebral body engaging surfaces of the implant are then in a generally angular relationship to each other over a substantial portion of the length of the implants. The present invention methods and instrumentation in conjunction with the present invention implant allows for the installation of an implant that in its final implanted form is substantially hollow with the exception of an expander ring which is itself preferably hollow so as to not interfere with the full loading of the implant and the extrusion there through of the selected osteogenic material.

In accordance with the purposes of the present invention, as embodied and broadly described herein, an interbody spinal fusion implant is provided for implantation from at least in part a posterior approach at least in part within and across the height of a disc space between two adjacent vertebral bodies of an adult human spine. The implant includes a body having a leading end for insertion first into the disc space, a trailing end opposite the leading end, and a mid-longitudinal axis along the length of the body. The body has an upper portion adapted to contact one of the adjacent vertebral bodies, a lower portion opposite the upper portion adapted to contact another one of the adjacent vertebral bodies, and at least one side portion between the upper and lower portions. Each of the upper, lower, and side portions extend from the trailing end of the body and are spaced apart from one another to form a hollow interior therebetween. The hollow interior is configured to hold at least some bone growth promoting material therein. The upper and lower portions are configured to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through the body of the implant. Each of the upper, lower, and side portions are configured to move at least in part in a direction away from the mid-longitudinal axis of the body to allow for expansion of the height and at least a portion of the width of the body. The upper, lower, and side portions have a collapsed position relative to one another allowing for a collapsed height and width of the body, and an expanded position relative to one another allowing for an expanded height and width of the body. The expanded height and width of the body is greater than the collapsed height and width of the body, respectively.

The implant also includes an expander positioned at least in part within the hollow interior. The expander is configured to cooperatively engage an instrument adapted to be inserted through the trailing end of the body to engage and to move the expander from a position proximate the leading end when the body is in the collapsed position away from the leading end toward the trailing end of the body to place the body in the expanded position. The expander is adapted to contact and to move the upper, lower, and side portions away from the mid-longitudinal axis of the body. The upper, lower, and side portions of the body are adapted to cooperatively engage the expander to locate the expander at a location along the length of the body between and away from each of the leading and trailing ends and to resist dislodgment of the expander from that location when the implant is in use. The expander is adapted to hold at least a portion of the upper, lower, and side portions apart so as to maintain the expanded height and width of the body and to resist the collapse of the body to the collapsed body height and width when the body is in the expanded position.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an interbody spinal fusion implant is provided for implantation from at least in part an anterior approach at least in part within and across the height of a disc space between two adjacent vertebral bodies of an adult human spine. The body has a base proximate the leading end, an upper portion adapted to contact one of the adjacent vertebral bodies, a lower portion opposite the upper portion adapted to contact another one of the adjacent vertebral bodies, and at least one side portion between the upper and lower portions. Each of the upper, lower, and side portions extend from the base of the body and are spaced apart from one another to form a hollow interior therebetween. Each of the upper, lower, and side portions are configured to move at least in part in a direction away from the mid-longitudinal axis of the body to allow for expansion of the height and at least a portion of the width of the body. The upper, lower, and side portions have a collapsed position relative to one another allowing for a collapsed height and width of the body, and an expanded position relative to one another allowing for an expanded height and width of the body. The expanded height and width of the body is greater than the collapsed height and width of the body, respectively.

The implant also includes an expander at least in part within the hollow interior. The expander is configured to contact an instrument that is adapted to be inserted through the trailing end of the body to move the expander from a position proximate the trailing end when the body is in the collapsed position away from the trailing end and toward the base of the body to place the body in the expanded position. The expander is adapted to contact and to move the upper, lower, and side portions away from the mid-longitudinal axis of the body. The upper, lower, and side portions of the body are adapted to cooperatively engage the expander to locate the expander at a location along the length of the body between and away from each of the leading and trailing ends and to resist dislodgment of the expander from that location when the implant is in use. The expander is adapted to hold at least a portion of the upper, lower, and side portions apart so as to maintain the expanded height and width of the body and to resist the collapse of the body to the collapsed body height and width when the body is in the expanded position.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, a method of this invention is provided for inserting an interbody spinal fusion implant from at least in part a posterior approach at least in part within and across the height of a disc space between two adjacent vertebral bodies of an adult human spine. The method includes providing the spinal implant having a body with a leading end for insertion first into the disc space, a trailing end opposite the leading end, a mid-longitudinal axis, upper and lower portions, and at least one side portion. Each of the upper, lower, and side portions extend from the trailing end of the body. A hollow interior is between the upper and lower portions. The implant includes an expander for expanding the height and at least a portion of the width of the body. The method includes preparing an implantation space to receive the implant from a posterior approach to the spine; inserting the implant at least in part into the implantation space; and moving the expander from a position proximate the leading end toward the trailing end of the body along at least a portion of the length of the body of the implant to move the upper, lower, and side portions in a direction away from the mid-longitudinal axis of the body of the implant to expand the height and at least a portion of the width of the body of the implant.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, a method of this invention is provided for inserting an interbody spinal fusion implant from at least in part an anterior approach at least in part within and across the height of a disc space between two adjacent vertebral bodies of an adult human spine. The method includes providing the spinal implant having a body with a leading end for insertion first into the disc space, a trailing end opposite the leading end, a mid-longitudinal axis, upper and lower portions, and at least one side portion. Each of the upper, lower, and side portions extend from the leading end of the body. A hollow interior is between the upper and lower portions. The implant includes an expander for expanding the height and at least a portion of the width of the body. The method includes preparing an implantation space to receive the implant from an anterior approach to the spine; inserting the implant at least in part into the implantation space; and moving the expander from a position proximate the trailing end toward the leading end of the body along at least a portion of the length of the body of the implant to move the upper, lower, and side portions in a direction away from the mid-longitudinal axis of the body of the implant to expand the height and at least a portion of the width of the body of the implant.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an apparatus is provided for inserting at least in part within and across the height of a disc space between two adjacent vertebral bodies of the human spine a spinal implant having upper and lower portions, and an expander for expanding the height and at least a portion of the width of the implant from a collapsed position to an expanded position. The apparatus includes an inserter guide having a leading end and a trailing end. The leading end of the inserter guide is configured to cooperatively engage the trailing end of the implant. The inserter guide has a hollow interior forming a passage from the trailing end to the leading end through the inserter guide. The apparatus also includes a post adapted to be inserted at least in part through the trailing end of the implant and into a hollow interior of the implant for moving the expander along at least a portion of the length of the implant between the upper and lower portions of the implant. The post has a leading end configured to cooperatively engage the expander and a trailing end adapted to be coupled to the implant and cooperatively engage an instrument for moving the post. The apparatus also includes an inner shaft that is configured to be inserted at least in part within the passage of the inserter guide. The inner shaft has a leading end and a trailing end. The leading end of the inner shaft is configured to cooperatively engage the trailing end of the post. The inner shaft is adapted to move the post so as to move the expander toward the trailing end of the implant to expand the height and at least a portion of the width of the implant.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an apparatus is provided for use with a spinal implant having an expander for expanding the height of the implant from a collapsed position to an expanded position. The implant has a leading end for insertion first into a disc space between two adjacent vertebral bodies of the human spine and a trailing end opposite the leading end. The implant has at least upper and lower portions adapted to be moved away from one another by the expander when positioned therebetween. The apparatus includes an elongated shaft having a leading end and a trailing end opposite the leading end, and a mid-longitudinal axis. The apparatus also includes an enlarged head proximate the leading end of the shaft that is configured to be inserted at least in part between the upper and lower portions of the implant. The enlarged head is adapted to move apart the upper and lower portions to release the expander therebetween. The apparatus also includes a projection extending from the enlarged head that is adapted to cooperatively engage the expander for removal of the expander from within the implant.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an apparatus is provided for inserting at least in part within and across the height of a disc space between two adjacent vertebral bodies of the human spine a spinal implant having an expander for expanding the height and at least a portion of the width of the implant from a collapsed position to an expanded position. The implant has upper, lower, and side portions including a plurality of arms separated by spaces. The apparatus includes an inserter having a leading end and a trailing end opposite the leading end. The leading end of the inserter guide has a plurality of spaced apart portions that are configured to fit in the spaces between the arms of the spinal implant to cooperatively engage the inserter to the implant.

In accordance with the purposes of yet a further embodiment of the present invention, as embodied and broadly described herein, an apparatus is provided for holding a spinal implant having an expander for expanding the height and at least a portion of the width of the implant from a collapsed position to an expanded position. The implant has upper, lower, and side portions comprising a plurality of arms separated by spaces. The apparatus includes a sleeve having a leading end and a trailing end and a passageway from the trailing end to the leading end. The passageway provides access to the implant through the sleeve. The leading end of the sleeve has a plurality of spaced apart portions that are configured to fit in the spaces between the arms of the spinal implant to cooperatively engage the sleeve to the implant.

In accordance with the purposes of a further embodiment of the present invention, as embodied and broadly described herein, an apparatus is provided for use with a spinal implant having an expander for expanding the height of the implant from a collapsed position to an expanded position. The implant has a leading end for insertion first into a disc space between two adjacent vertebral bodies of the human spine and a trailing end opposite the leading end. The implant has at least upper and lower portions adapted to be moved away from one another by the expander when positioned therebetween. The apparatus includes an elongated shaft having a mid-longitudinal axis, a leading end, and a trailing end opposite the leading end. The leading end has a bore therein and an enlarged head with a collar in movable relationship to the head that permits rotational movement of the head independent of the collar. The collar and the head are configured to be inserted at least in part between the upper and lower portions of the implant. The collar is adapted to bear against and move apart the upper and lower portions of the implant to release the expander therebetween. The apparatus also includes a post that is adapted to be inserted at least in part through the trailing end of the spinal implant for guiding the elongated shaft along the mid-longitudinal axis between the upper and lower portions of the implant. The post has a leading end configured to cooperatively engage the implant and a trailing end that is adapted to be received within the bore of the elongated shaft. The head of the elongated shafted is adapted to rotate about the post.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate the embodiments of the invention and together with the description, serve to explain the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded perspective view of a spinal fusion implant, radial expander of the implant, and threaded post in accordance with a preferred embodiment of the present invention for posterior insertion into the spine;

FIG. **2** is an assembled trailing end perspective view of the embodiment of FIG. **1**;

FIG. **3** is a trailing end elevation view of the embodiment of FIG. **2**;

FIG. **4** is a side elevation view of the embodiment of FIG. **2**;

FIG. **5** is a leading end elevation view of the embodiment of FIG. **2**;

FIG. **6** is a leading end elevation view of a radial expander of the implant of FIG. **1**;

FIG. **7** is a side elevation view of the radial expander of FIG. **6**;

FIG. **8**A is a trailing end elevation view of the radial expander of FIG. **6**;

FIG. **8**B is a trailing end elevation view of a radial expander incorporating two alternative embodiments in accordance with the present invention;

FIG. **9** is a partial side sectional view of the embodiment of FIG. **2** prior to the implant being radially expanded;

FIG. **10** is a partial side sectional view of the embodiment of FIG. **2** with the implant in partial radial expansion;

FIG. **11** is a partial side sectional view of the embodiment of FIG. **2** with the implant in a radially expanded state;

FIG. **12** is a side elevation view of one embodiment of a driver instrument for inserting the implant of FIG. **1**;

FIG. **13** is a distal end view of the driver instrument of FIG. **12**;

FIG. **14** is a perspective proximal end view of the funnel-shaped end of the driver instrument of FIG. **12**;

FIG. **15** is a side elevation view of one embodiment of a rotating instrument used to rotate the threaded post to move the radial expander to radially expand the implant of FIG. **1**;

FIG. **16** is a side elevation view of one embodiment of a plunger instrument for inserting bone growth promoting material into the implant of FIG. **1** and the disc space;

FIG. **17** is a side elevation view of the plunger instrument of FIG. **16** in an extended state;

FIG. **18** is a perspective view of the posterior aspect of a lumbar segment of a spine with the dural sac retracted to the left showing a partial discectomy and an expandable guard with disc penetrating extensions approaching the disc space between the adjacent vertebral bodies with the disc penetrating extensions in an insertion position;

FIG. **19** is a side view of the guard of FIG. **18** being inserted within the spine with the disc penetrating extensions parallel to one another in the insertion position;

FIG. **20** is a side view of the guard of FIG. **18** in the deployed position with the disc penetrating extensions shown in an expanded position to induce angulation of the adjacent vertebral bodies;

FIG. **21** is a side view of the guard of FIG. **18** in the deployed position with the disc penetrating extensions in an expanded position to induce angulation of the adjacent vertebral bodies and in partial cross-section to show a side view of a drill being inserted through the guard;

FIG. **22** is a side view of the guard of FIG. **18** in partial cross-section showing the spinal fusion implant of FIG. **1** and the driver instrument of FIG. **12** passing through the guard to install the implant into a prepared implantation space across the height of the restored disc space and into the adjacent vertebral bodies;

FIG. **23** is a side view of the implant of FIG. **1** in a non-expanded state inserted into the implantation space and the rotating instrument of FIG. **15** passing through the driver instrument of FIG. **12** and guard of FIG. **18** both shown in partial cross section to engage the threaded post;

FIG. **24** is a side view of the implant of FIG. **1** radially expanded in the implantation space via the rotating instrument of FIG. **15** that passes through the driver instrument and guard both shown in partial cross section;

FIG. **25** is a side view of the rotating instrument of FIG. **15** removing the threaded post from the implant of FIG. **1** through the driver instrument and guard both shown in partial cross section;

FIG. **25**A is an enlarged fragmentary view along line **25**A of FIG. **25** showing the cooperative engagement of the driver instrument and threaded post;

FIG. **26** is a partial side sectional view of the guard and driver instrument with the plunger instrument of FIG. **16** inserted therein and being used to fill the interior of the implant of FIG. **1** with bone growth promoting material;

FIG. **27** is a partial side sectional view of the guard and driver instrument with the instrument of FIG. **16** in an extended state inserted therein for delivering bone growth promoting material beyond the radial expander and to regions of the disc space beyond the leading end of the implant not occupied by the implant;

FIG. **28** is a partial side sectional view of the implant of FIG. **1** in an expanded state with the threaded post being partially threaded into the radial expander;

FIG. **29** is a partial side sectional view of the implant of FIG. **1** with the post partially threaded into the radial expander being advanced toward the leading end of the implant to unseat the radial expander and return the implant to the non-expanded state for posterior extraction of the implant from the implantation space;

FIG. **30** is a side elevation view of one embodiment of a remover instrument used to unlock and remove a seated radial expander from an anterior approach and through the leading end of the implant to place the implant of FIG. **1** into a non-expanded state;

FIG. **31** is a partial side sectional view of the remover instrument of FIG. **30** being used to expand the implant anteriorly to unlock and displace the expander to allow for removal of the implant;

FIG. **32** is a partial side sectional view of the implant shown in FIG. **1** in a non-expanded state with the radial expander being removed from the leading end of the implant by the remover instrument of FIG. **30**;

FIG. **33** is an exploded perspective view of a spinal fusion implant, radial expander, and threaded post in accordance with another preferred embodiment of the present invention for anterior insertion into the spine;

FIG. **34** is a side elevation view of the embodiment of FIG. **33**;

FIG. **35** is a leading end elevation view of the embodiment of FIG. **33**;

FIG. **36** is a trailing end elevation view of the embodiment of FIG. **33**;

FIG. **37** is a perspective view of an alternative embodiment of the implant and threaded post of FIG. **33** having two diametrically opposed shortened arms;

FIG. **38** is a perspective view of an alternative embodiment of the implant of FIG. **33** having arms of generally the same length;

FIG. **39** is a trailing end elevation view of the radial expander of FIG. **33**;

FIG. **40** is a side elevation view of the radial expander of FIG. **33**;

FIG. **41** is a leading end elevation view of the radial expander of FIG. **33**;

FIG. **42** is a fragmentary side elevation view of the leading end of one embodiment of a driver instrument for inserting the implant of FIG. **33**;

FIG. **43** is a side elevation view of one embodiment of an instrument for holding the implant of FIG. **33** while the radial expander of FIG. **33** is advanced through the interior of the implant;

FIG. **44** is a fragmentary side elevation view in partial cross section of one embodiment of a rotating instrument used to linearly advance the radial expander along the threaded post and into the implant to radially expand the implant of FIG. **33**;

FIG. **45** is a fragmentary side elevation view in partial cross section of one embodiment of an instrument for use in removing the post from the implant of FIG. **33**;

FIG. **46** is a side elevation view of two adjacent vertebrae and a hollow guard for use in preparing a disc space to receive the implant of FIG. **33**;

FIG. **47** is a side elevation view of the adjacent vertebrae and guard of FIG. **46** in partial cross-section and a side view of a drill being inserted through the guard;

FIG. **48** is an exploded side view of the implant of FIG. **33**, the instrument of FIG. **42**, and an implant receiving space formed across the height of the disc space and the adjacent vertebral bodies shown in partial cross section;

FIG. **49** is a side elevation view of the implant of FIG. **33** in a non-expanded state inserted into the implant receiving space formed across the height of the disc space and two adjacent vertebral bodies in cross section and a fragmentary view of the instrument of FIG. **43** in partial cross section being positioned to engage the arms of the implant with the instrument of FIG. **44** shown in partial cross section being inserted therethrough for cooperative engagement with the post;

FIG. **50** is a side elevation view in partial cross section of the implant of FIG. **33** with the instrument of FIG. **44** in rotational engagement with the post of FIG. **33** moving the radial expander into the implant;

FIG. **51** is a side elevation view in partial cross section of the implant of FIG. **33** with the instrument of FIG. **45** being used to remove the post of FIG. **33** from the implant in the expanded state;

FIG. **52**A is a top plan view in partial cross section of a vertebra with two implants of FIG. **33** in an expanded state installed side-by-side into a disc space from an anterior approach with the trailing ends in close proximity to each other and the shortened arms oriented toward the antero-lateral aspects of the vertebral body;

FIG. **52**B is a top plan view in partial cross section of a vertebra with two implants of FIG. **33** in an expanded state installed side-by-side into a disc space from an anterior approach with the trailing ends in close proximity to each other in a toed-in orientation and the shortened arms oriented toward the antero-lateral aspects of the vertebral body;

FIG. **53** is a fragmentary top plan view in partial cross section of a vertebra with two implants of FIG. **37** in an expanded state installed side-by-side into a disc space from an anterior approach with the trailing ends in closer proximity to each other than in FIG. **52**A;

FIG. **54** is a side elevation view of a preferred embodiment of a remover instrument used to remove an installed radial expander from an implant to collapse the implant of FIG. **33** into a non-expanded state;

FIG. **55** is a partial side sectional view of the implant of FIG. **33** and the instrument of FIG. **54** being used to unlock the radial expander; and

FIG. **56** is a partial side sectional view of the implant of FIG. **33** with the instrument of FIG. **54** being fully deployed in the implant and a hook being used to extract the radial expander from the implant.

DETAILED DESCRIPTION OF THE DRAWINGS

The following description is intended to be representative only and not limiting and many variations can be anticipated according to these teachings, which are included within the scope of this inventive teaching. Reference will now be made in detail to the preferred embodiments of this invention, examples of which are illustrated in the accompanying drawings.

FIGS. **1-11** show a preferred embodiment of a radially expandable implant and threaded post used to expand the implant in accordance with the present invention. As shown in FIGS. **1-5**, implant **100** preferably is a spinal fusion implant adapted to be installed from at least in part a posterior approach to the spine into an implantation space formed across the height of a spinal disc and into two adjacent vertebral bodies. Implant **100** has a body with a trailing end **102**, a leading end **104** for insertion first into the disc space, and preferably has a hollow interior **103**. Leading end **104** is preferably open to permit access to hollow interior **103** of implant **100** through leading end **104**. Hollow interior **103** is preferably configured to hold at least some bone growth promoting material therein.

Implant **100** includes at least upper and lower arcuate portions **106***a* and **106***b* adapted to be oriented toward and contact adjacent upper and lower vertebral bodies, respectively, and preferably has opposite sides **108***a* and **108***b*. Arcuate portions **106***a*, **106***b* and sides **108***a*, **108***b* include arms **110** that extend from trailing end **102** along at least a part of the length of the implant toward leading end **104**. Arms **110** are preferably separated by a space **112**. Spaces **112** may be of different lengths and widths and may, for example, be in the shape of a slit, a slot, or any other shape suitable for the intended purpose of spacing apart arms **110**. Preferably, spaces **112** permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through the body of implant **100**.

As best shown in FIGS. **9-11**, arms **110** have an interior surface **114** facing hollow interior **103** of implant **100** configured to bear against and hold a radial expander for forcing apart arms **110** from within hollow interior **103**. Preferably, upper portion **106***a*, lower portion **106***b*, and at least one of sides **108***a*, **108***b* are configured to locate an expander along the length of the body of implant **100** between and away from each of trailing and leading ends **102**, **104** and to resist dislodgement of the expander when implant **100** is in use. Interior surface **114** of arms **110** of at least upper and lower arcuate portions **106***a*, **106***b* preferably has a ramped portion **116** and seat **118** for receiving an expander **120**. Each arm **110** preferably is of such length, thickness, and material to resist rotational torquing forces during rotation of implant **100** while being flexible enough to move in a radial direction away from the mid-longitudinal axis of implant **100** when forced apart from the interior of implant **100**. For example, one embodiment of implant **100** has six arms **110**, each of which flexes in a radial direction away from the mid-longitudinal axis; thus, each arm **110** moves in a direction different from that of any of the other arms **110** of implant **100**. Preferably, each arm **110** is sufficiently resilient so that each arm **110** may be moved away from the mid-longitudinal axis of implant **100** and may be permitted to return to its original orientation if desired without substantial deformation. Examples of preferred materials for arms **110** include, but are not limited to, metals such as titanium and stainless steel, plastics, and carbon fibers among others. Arms **110** may be engineered to have a flexibility and springiness optimal for the stiffness of the area of the spine into which they are to be implanted.

In the expanded position, arms **110** may be at least in part concave along at least a portion of the length of implant **100**. A concave configuration of arms **110** provides a desirable springiness and resilience for contacting and supporting the vertebral bodies adjacent implant **100**. Although it is preferred to have movable arms **110** spaced around the entire circumference of the implant, the invention is not so limited. By way of example only, one or more arms **110** may be truncated or omitted from a side or sides to limit the expansion of the width of the implant. A preferred embodiment of implant **100** would have at least two arms **110** on each of upper and lower arcuate portions **106***a*, **106***b*, each of arms **110** being adapted to be radially expanded in a direction away from the mid-longitudinal axis of implant **100**. To accommodate side-by-side placement of implants, arms **110** may be of different lengths. Implant **100** preferably includes at least one external thread **122** to permit for the rotational insertion of implant **100** into the disc space and between adjacent vertebral bodies a human spine. Although a preferred embodiment of the implant includes threads, the invention is not so limited. For example, the exterior of implant **100** may include other bone engaging surfaces such as projections, splines, knurling, ratchets, or other surface roughenings to resist expulsion of the implant from the implantation space after implantation.

As shown in FIGS. **1-4**, trailing end **102** preferably is configured to cooperatively engage a driver **300** shown in FIG. **12** used to install implant **100** into the disc space. For example, trailing end **102** may include truncated sides **124** for cooperatively engaging flanges **310** of driver **300** and recesses **126***a* and **126***b* for engaging pins **312***a* and **312***b*, respectively, of driver **300**. Trailing end **102** of implant **100** has an opening **128** sized for receiving a post **200** for engagement with radial expander **120**.

Post **200** is configured to be inserted into implant **100** through trailing end **102**. Post **200** preferably has a shaft **202** with at least one thread **204** and a head **206**. Head **206** includes a tool engagement area **208** for cooperatively engaging a tool used for inserting and removing post **200** from implant **100**. Area **208** is shown as having a hex-shaped engagement surface, but it is understood that area **208** may have any configuration suitable for its intended purpose. The distal end of post **200** passes through opening **128** of implant **100** and extends into the interior of implant **100** to engage radial expander **120**. Thread **204** is adapted to cooperatively engage radial expander **120** to move radial expander toward trailing end **102** of implant **100** and force arms **110** apart to expand implant **100**. Shaft **202** may be at least in part smooth to permit movement of shaft **202** within opening **128** without engagement to opening **128**.

As shown in FIGS. **6-8**A, radial expander **120** is configured to be inserted at least in part within hollow interior **103** of implant **100**. Expander **120** preferably has a leading face **130** adapted to be oriented toward trailing end **102** of implant **100** and an opposite trailing face **132** adapted to be oriented toward leading end **104** of implant **100** when inserted within hollow interior **103** of implant **100**. A preferred radial expander **120** has an opening **134**, guide pegs **136**, and a rim **138** adapted to bear against interior surface **114** of arms **110**. Radial expander **120** is preferably at least in part circular or may have any other configuration suitable for its intended purpose. Opening **134** is preferably threaded to cooperate with thread **204** of post **200** to move radial expander **120** toward trailing end **102** of implant **100**. Although threaded rotational engagement is preferred for moving radial expander **120**, the invention is not so limited. For example, post **200** may be configured to engage radial expander **120** with a retractable flange or projection and pull expander **120** into position to expand arms **110**. Preferably, expander **120** has a fixed shape.

Guide pegs **136** of radial expander **120** are adapted to fit within spaces **112** such that as post **200** is rotated, radial expander **120** advances in a linear direction away from leading end **104** towards trailing end **102** of implant **100**. Pegs **136** prevent substantial rotation of radial expander **120** during rotation of post **200**. Although two guide pegs **136** are shown extending from radial expander **120**, the number and shape of pegs **136** may be varied as suitable for their intended purpose.

FIG. **8**B shows a radial expander **120'** incorporating two alternative embodiments in accordance with the present invention. Radial expander **120'** is adapted to selectively expand the height of implant **100** and to limit or prevent the expansion of the width of implant **100**. The configuration of radial expander **120'** provides for the selective movement of one or more arms **110** away from the mid-longitudinal axis of implant **100** as radial expander **120'** is advanced into implant **100**. For example, radial expander **120'** may have one or more truncated sides **135** to form a reduced width portion of radial expander **120'**. Truncated side **135** is preferably configured to avoid contact with the interior surface **114** of arms **110** adjacent truncated side **135** and is preferably configured to clear interior surface projections such as, for example, ramp **116** of arm **110** during the advancement of radial expander **120'** toward leading end **102**. Instead of truncated side **135**, radial expander **120'** may include a groove **137** configured to receive at least a portion of an arm **110** adjacent thereto. In its preferred use, at least the upper and lower portions of rim **138** of radial expander **120'** bear against the interior surface **114** of arms **110** to expand the height of implant **100** so as not to induce expansion of any arm or arms **110** adjacent truncated side **135** or groove **137**, as the case may be. The expansion of the implant may be controlled by the interaction of the radial expander and arms of the implant to expand the width to only one side or to expand both sides by different amounts and involve one or more arms on a side of the implant. It is appreciated that other configurations of radial expander **120'** are possible to achieve its intended purpose without departing from the scope of the present invention.

FIG. **9** shows implant **100** in a collapsed state. After insertion into the disc space, post **200** is rotated, causing radial expander **120** to travel within the interior of implant **100** from a position proximate leading end **104** toward trailing end **102**. Pegs **136** travel within space **112** and can contact the sides of arms **110** to limit rotation of radial expander **120** during rotation of post **200**.

FIG. **10** shows rim **138** of radial expander **120** moved along interior surface **114** of implant **100** after post **200** is initially rotated, and shows rim **138** in contact with ramp portions **116** of implant **100**. Movement of radial expander **120** away from leading end **104** along ramp portions **116** forces arms **110** to move away from the mid-longitudinal axis of implant **100** and toward the adjacent vertebral bodies.

As shown in FIG. **11**, continued rotation of post **200** causes radial expander **120** to traverse ramp portions **116** and enter seat **118** of implant **100**. The entrance to seat **118** is narrower than the remainder of seat **118** to prevent radial expander **120** from backing-out. Radial expander **120** is further held into place within seat **118** by arms **110**. The sloped sides of seat **118** form an inclined plane that inhibits movement of radial expander **120** toward leading end **104** of implant **100**. With radial expander **120** seated in seat **118**, arms **110** are forced apart at a greater distance as measured from leading end **104** to the mid-longitudinal axis than from trailing end **102** to the mid-longitudinal axis to place implant **100** into an expanded state. After implant **100** is in the expanded state, post **200** can be removed from implant **100** by rotation in the opposite direction, and radial expander **120** remains in seat **118** to maintain the expanded height and width of implant **100**.

FIGS. **12-14** show an implant driver **300** for inserting implant **100** into a disc space. Implant driver **300** has a shaft **302**, a distal end **304**, and a proximal end **306**. Shaft **302** is preferably hollow and is adapted to permit the passage of other instruments therethrough as described below. Distal end **304** includes an implant engaging head **308** with flanges **310**, pins **312***a*, **312***b*, and an opening **314**. Implant engaging head

308 is sized and shaped to cooperatively engage an implant to hold and manipulate the implant during insertion into the disc space. Proximal end 306 includes a handle 316 for rotational and linear advancement of driver 300. Proximal end 306 preferably has a funnel-shaped opening 318 passing through shaft 302 and expanding through distal end 304. Funnel-shaped opening 318 is preferably configured as shown in FIG. 14 to facilitate the introduction of bone growth promoting material into shaft 302. Funnel-shaped opening 318 is preferably sized and shaped to receive other instruments therethrough, such as plunger 500 described in association with FIGS. 16 and 17 below.

FIG. 15 shows a rotating tool 400 for engaging and rotating post 200. Rotating tool 400 has a distal end 402 and a proximal end 404. Distal end 402 has a tip 406 adapted to cooperatively engage area 208 of post 200. In a preferred embodiment, tip 406 is hex-shaped, but may be of any shape suitable to engage post 200. Tip 406 is preferably adapted to engage area 208 of post 200 such that upon the disengagement of post 200 from implant 100, rotating tool 400 can withdraw post 200 through shaft 302 of driver 300. In order to facilitate the removal of post 200 such that post 200 and rotating tool 400 may be removed together, tip 406 may be adapted to cooperatively engage with area 208, for example, via an interference fit, detent, or retractable spring flange. Proximal end 404 is preferably configured to engage a handle and has a stop 408. Proximal end 404 is preferably adapted to engage with a mechanical or manual device for rotating shaft 410.

FIGS. 16 and 17 show a plunger instrument for inserting bone growth promoting material into implant 100 and into the surrounding disc space. Plunger 500 preferably has an outer shaft 502, an inner rod 504, and a handle 506. Inner rod 504 preferably has a proximal end configured to engage a handle, such as a T-handle for example, and a stop 508 for limiting the travel of inner rod 504 when placed within outer shaft 502. In use, plunger 500 may be inserted into an instrument adapted to deliver bone growth promoting material into implant 100 such as driver 300. Plunger 500 and driver 300 together may be placed within a guard such as guard 600 of FIG. 18 to introduce bone growth promoting material into hollow interior 103 of implant 100 and preferably the disc space surrounding the implant.

In a preferred embodiment, bone growth promoting material is introduced into hollow interior 103 of shaft 302 of driver 300 through funnel-shaped opening 318. Plunger 500 with inner rod 504 inserted therein, may be inserted into the interior of driver 300 to push bone growth promoting material therethrough and into the implant. Plunger 500 and inner rod 504 may further move bone growth promoting material into the remaining areas inside and around the implant not yet filled with bone growth promoting material.

Plunger 500 preferably has a clamp 510 and stop 508 to limit the extension of inner rod 504 from outer shaft 502. Stop 508 may have any configuration adapted to limit the travel of inner rod 504, for example, a shoulder, flange, or other projection. Although it is preferred that inner rod 504 is solid, the invention is not so limited. Clamp 510 in the tightened position holds inner rod 504 in fixed relationship to outer shaft 502 and preferably so as not to extend from the distal end of shaft 502. When clamp 510 is released, inner rod 504 is permitted to travel beyond the distal end of outer shaft 502 to the extent limited by stop 508.

FIGS. 18-30 show various steps of a preferred method for inserting implant 100 and using associated instrumentation disclosed herein.

FIG. 18 is a perspective view of a segment of a spine viewed from a posterior aspect with the dural sac retracted to the left showing that a partial discectomy has already been performed. Guard 600, with disc penetrating extensions 602, 604 and window 606, is shown approaching the disc space between the adjacent vertebral bodies with disc penetrating extensions 602, 604 in a first or insertion position.

It is appreciated that various types of guards may be used to provide protected access to the disc space including, but not limited to, those taught by Michelson in Application Ser. Nos. 10/085,731 and 10/085,406; and U.S. Pat. Nos. 5,015,247; 5,484,437; 6,080,155; and 6,210,412 all of which are incorporated herein by reference.

An impaction cap 608 is positioned on the proximal end of guard 600 to maintain it in the open position such that the disc penetrating extensions are closed into the insertion position. In this position, guard 600 is ready to be placed or driven into the disc space between the adjacent vertebral bodies.

In FIG. 19, the extensions of guard 600 are fully inserted into the spine with the disc penetrating extensions parallel to one another in the insertion position. Impaction cap 608 is shown holding the guard in the open position and the disc penetrating extension in the insertion position. Guard 600 rotationally articulates to permit movement of disc penetrating extensions 602, 604 in response to movement of a first portion 610 and a second portion 612 relative to one another. The rotational articulation preferably occurs about a hinge 614, which is preferably formed in first and second portions 610, 612.

In FIG. 20, guard 600 is shown in a closed position with the disc penetrating extensions shown in the inserted position to induce lordosis to the vertebral bodies. After closing guard 600, the proximal end has a lock collar 616 placed around it to maintain guard 600 in the closed position.

In FIG. 21, guard 600 is in a closed position with disc penetrating extensions 602, 604 in the inserted position to induce angulation to the adjacent vertebral bodies. At the distal end of guard 600 shown in cross-section is a side view of a bone removal device such as a drill 700 being inserted through guard 600. It is appreciated that other bone removal devices suitable for the intended purpose such as, but not limited to, burrs, reamers, mills, saws, trephines, chisels, and the like may also be used and would be within the scope of the present invention. Guard 600 provides protected access to the disc space and the adjacent vertebral bodies for drill 700 via the elongated opening in guard 600.

Drill 700 may have a reduced diameter-cutting portion relative to the shaft diameter of guard 600 or may be inserted through an inner sleeve that passes into guard 600 to guide drill 700 to form an implantation space smaller than the passage through guard 600. Thus, the guard opening may be taller than the height of the cutting portion of drill 700. Such a taller opening also allows the implantation of an implant taller than the height of the cutting portion of drill 700.

As best shown in FIG. 22, implant 100 and implant driver 300 may be passed through guard 600 to insert implant 100 in a collapsed position into the disc space between the adjacent vertebral bodies. The guard may be left in place throughout the procedure. Implant 100 is assembled with post 200 inserted through trailing end 102 of implant 100 to engage radial expander 120 inserted in the collapsed position into hollow interior 103 of implant 100 through leading end 104. Radial expander 120 in this position may bear against the interior surface 114 of arms 110 but does not yet force arms 110 apart so that implant 100 is in a non-expanded state. Implant 100 is preferably rotated into the disc space such that thread 122 penetrably engages the bone of the adjacent vertebral bodies.

As illustrated in FIG. **23**, after implant **100** is installed in the desired position in the implantation space between the adjacent vertebral bodies with opposed arcuate portions **106***a* and **106***b* oriented toward the adjacent vertebral bodies, rotating tool **400** is used to engage and rotate post **200** so as to pull radial expander **120** away from leading end **104** and toward trailing end **102** along the interior surface **114** of arms **110** to transition implant **100** from a collapsed position to an expanded position.

As shown in FIG. **24**, as rotating tool **400** is rotated, radial expander **120** moves toward trailing end **102** of implant **100** causing arms **110** to move radially outward away from the mid-longitudinal axis of implant **100**. The interaction between radial expander **120** and arms **110** is best shown in FIGS. **9-11**. The radial expansion of implant **100** results in a greater implant height and width proximate leading end **104** than the implant height and width proximate trailing end **102**. Upper and lower arcuate portions **106***a*, **106***b* are positioned in angular relationship to each other and position the vertebral bodies adjacent implant **100** in an angular relationship to each other.

As shown in FIGS. **25** and **25**A, after implant **100** is in the expanded state, post **200** is removed by rotating tool **400** from implant **100**. Rotating tool **400** is adapted to cooperatively engage tool engagement area **208** of post **200**. The leading end of rotating tool **400** may be tapered to allow the tip of tool **400** to slightly bind and positively engage tool engagement area **208**. Radial expander **120** remains seated within hollow interior **103** of implant **100** to hold arms **110** in a radially expanded state.

FIGS. **26** and **27** show a preferred method for insertion of bone growth promoting materials into implant **100** and the disc space surrounding implant **100**. Driver **300** is shown inserted into guard **600** with its distal end adjacent to and in communication with opening **128** of implant **100** to access hollow interior **103** of implant **100**. Bone growth material is introduced into funnel shaped end **318** of driver **300**. Plunger **500** with inner rod **504** in the retracted position is used to push and load the bone growth promoting material through shaft **302** of driver **300** and into implant **100**. Sufficient bone growth promoting material is introduced into driver **300** to at least partially fill implant **100**. Alternatively, the implant may be pre-loaded with bone growth promoting material prior to its insertion into the implantation space. Additional bone growth material may be added to fill any space within the implant created as a result of transitioning implant **100** to an expanded position as described below.

As shown in FIG. **27**, after the implant is at least partially filled with bone growth promoting material, inner rod **504** is moved forward in the extended position into implant **100** through opening **128** of trailing end **102** to push the bone growth promoting material in its path through opening **134** of radial expander **120**. Distributing bone growth promoting material beyond radial expander **120** fills the interior of implant **100** proximate leading end **104** and introduces bone growth promoting material further into the disc space beyond leading end **104** and unoccupied by implant **100**. After inner rod **504** is retracted from within the interior of implant **100** and plunger **500** is removed from driver **300**, additional bone growth promoting material may be inserted into driver **300**. Plunger **500** then may be used to fill the space left unoccupied by the removal of inner rod **504** with bone growth promoting material and further pack bone growth promoting material into implant **100**. After filling implant **100** and the surrounding disc space with bone growth promoting material, plunger **500** and driver **300** are removed from guard **600**. The trailing end of guard **600** is then opened to return disc penetrating extensions **602**, **604** to the closed position to facilitate the removal of guard **600** from the disc space.

FIGS. **28-32** show a preferred remover and methods of disengaging radial expander **120** from seat **118** of implant **100** if it is desired to uninstall implant **100** or other implants of the present invention designed for a generally posterior insertion. FIG. **28** shows post **200** being partially threaded into a seated radial expander **120** by rotating tool **400** such that a portion of post **200** extends from trailing end **102** of implant **100**. As shown in FIG. **29**, post **200** may then be advanced in a linear direction without substantial rotation toward leading end **104** of implant **100** such as, for example, with an impaction force. The linear advancement of post **200** toward leading end **104** moves expander **120** out of seat **118** and toward leading end **104**. This allows the implant arms to collapse inward to the unexpanded state, thereafter allowing the implant to be unthreaded or otherwise removed from the spine. The implant holder may be attached prior to collapsing the implant or thereafter. With expander **120** removed from the interior of implant **100**, arms **110** are no longer held in a radially expanded position, thereby causing implant **100** to collapse to an unexpanded state.

With reference to FIGS. **30-32**, in certain circumstances, for example, where it may be desirable to revise an instrumentation and to access implant **100** from an anterior aspect of the spine, radial expander **120** may be removed from the leading end **104** (oriented near the anterior aspect of the space) of implant **100**. FIG. **30** shows a remover **800** for removing radial expander **120** from hollow interior **103** of implant **100** through leading end **104**. Remover **800** has a shaft **802**, a distal end **804**, and a proximal end **806**. Distal end **804** has a threaded rod **808** and an enlarged head **810** with a diameter configured to enter hollow interior **103** of implant **100** in a radially expanded state and force apart arms **110**. Proximal end **806** is preferably configured to be attached to a removable handle for rotating remover **800**.

Threaded rod **808** of remover **800** threads into radial expander **120** causing forward movement of remover **800** toward leading end **104** of implant **100**. As remover **800** moves toward leading end **104**, enlarged head **810** contacts interior surface **114** of arms **110**, forcing arms **110** to move outward and further away from the mid-longitudinal axis of implant **100**. This movement in turn causes seat **118** to expand outward opening the entrance to seat **118**, thus permitting radial expander **120** to be removed from seat **118** of implant **100**. FIG. **32** shows remover **800** removing radial expander **120** from seat **118** to return arms **110** to their initial non-expanded position. The implant may then be removed from the implantation site if desired.

The method of the present invention may also be performed from an anterior approach to the spine. FIGS. **33-56** show various embodiments of an implant **900** for insertion from at least in part an anterior approach to the spine as well as instruments and the associated method for inserting and removing implant **900**. Implant **900** is similar to implant **100**, with certain differences noted below. As shown in FIGS. **33-36**, implant **900** has an open trailing end **902**, a leading end **904** shown closed in this embodiment, a base **905** proximate the leading end, and a shortened arm **909** and lengthened arms **910** extending from base **905**. FIG. **37** shows an alternative embodiment of implant **900** having two opposed shortened arms **909** and lengthened arms **910**. Shortened arms **909** are preferably located on at least one side of implant **900** when two implants are inserted side-by-side as shown in FIGS. **52**A, **52**B, and **53**. Shortened arms **909** provide for a reduced diameter of trailing end **902** such that trailing end **902** does not substantially protrude from the disc space to minimize the risk of interference with delicate vascular and neurological structures present adjacent to the disc space. Shortened arms **909** also permit two implants **900** in an expanded state to be placed side-by-side in close proximity to each other in the disc space. Although a combination of shortened arms **909** and lengthened arms **910** is preferred, the invention is not so limited. For example, in situations where the surgeon determines it is appropriate, implant **900** may have arms **910** of generally equal length as shown in another alternative embodiment of implant **900** in FIG. **38**.

The interaction between radial expander **920** and the interior surface of arms **909**, **910** is similar to that between radial expander **120** and arms **110** (described in relation to FIGS. **9-11**) except that unlike the interior surface of arm **110**, shortened arms **909** have a notched area **917** that functions to hold the radial expander **920** in seat **918** and maintain shortened arms **909** in a radially expanded state when radial expander **920** is seated in seats **918** of lengthened arms **910**.

In implant **900** a post **1000** is inserted through the trailing end **902**. Leading end **904** preferably has a threaded opening **928** for threadably engaging post **1000**. Post **1000** has a shaft **1002** with a first thread **1004** for cooperative engagement with a tool **1300** shown in FIG. **44** for pushing or otherwise moving radial expander **920** away from trailing end **902** and toward base **905** proximate leading end **904** of implant **900**. Post **1000** has a head **1006** with a tool engagement area **1008** that is preferably hex-shaped to engage a post remover **1400** shown in FIG. **45**, and a second thread **1010** shown in FIGS. **50**, **51** at the end opposite head **1006** for cooperative engagement with threaded opening **928** in leading end **904** of implant **900**.

As an alternative to using a post with a threaded end for engagement with the leading end of the implant, a post may be used having a leading end with a retractable flange or other projection for cooperative engagement with the leading end of the implant. Such a post may then be used to rotate the radial expander into position in a fashion similar to that described with reference to FIGS. **23** and **24**. Once the radial expander is seated, the flanges or other projections may be retracted , and the post may then be withdrawn.

As shown in FIGS. **33** and **39-41**, radial expander **920** is similar to radial expander **120** shown in FIGS. **6-8**. Opening **934** of radial expander **920** is preferably unthreaded. A threaded opening is not essential since radial expander **920** is moved by rotating tool **1300** and not by post **1000**, described in more detail below.

FIG. **42** shows an implant driver **1100** for inserting implant **900** into a disc space. Driver **1100** has a shaft **1102** and a distal end **1104**. Distal end **1104** preferably has an implant engaging head **1108** with flanges **1110** spaced apart by recessed areas and a bore **1120**. Implant engaging head **1108** is preferably sized and shaped to cooperatively engage trailing end **902** of implant **900** for insertion into the disc space. Implant engaging head **1108** preferably is tapered to facilitate insertion into the interior of implant **900** and to facilitate the placement of flanges **1110** into spaces **912**. Arms **909**, **910** fit into recessed areas between flanges **1110**. In this position, driver **1100** is engaged to implant **900** and can rotate implant **900**. Bore **1120** is preferably configured to receive post **1000** so that driver **1100** may insert implant **900** with post **1000** already attached thereto.

FIG. **43** shows an implant holder **1200** for holding implant **900** in a stable position while one or more tools, for example rotating tool **1300**, engages with post **1000** to move radial expander **920** toward leading end **904**. Implant holder **1200** has a distal end **1202**, a proximal end **1204**, a shaft **1206** therebetween, and a handle **1208**. Distal end **1202** preferably has a plurality of flanges **1210** that are configured for engagement with spaces **912** between arms **909**, **910**. Shaft **1206** is preferably hollow and sized to accommodate the passage of tools therethrough, for example, rotating tool **1300**. Flanges **1210** are adapted to fit in spaces **912** between arms **909**, **910** to hold implant **900**. Rotating tool **1300** is used to rotate post **1000** to move radial expander **920** while implant **900** is held stable by holder **1200** to resist the rotational forces bearing upon post **1000**.

FIG. **44** shows rotating tool **1300** for advancing radial expander **920** away from trailing end **902** and toward base **905** proximate leading end **904**. Rotating tool **1300** has a distal end **1302** and a shaft **1310**. Distal end **1302** has a bore **1312** with a thread **1314** adapted to cooperatively engage with first thread **1004** of post **1000**. Bore **1312** preferably has an unthreaded portion at its leading end that permits rotating tool **1300** to move over a portion of post **1000** such as post head **1006** prior to engagement of the thread. As tool **1300** is rotated onto post **1000**, distal end **1302** bears against radial expander **920** to advance radial expander **920** into implant **900**. After radial expander **920** is seated into seat **918**, rotating tool **1300** is unthreaded from post **1000** and removed from implant **900**.

FIG. **45** shows a post remover **1400** for removing post **1000** after radial expander **920** has been seated in seat **918** of implant **900**. Post remover **1400** has a shaft **1402** and a distal end **1404**. Distal end **1404** has a bore **1406** with a post engagement surface **1408** that is preferably hex-shaped to cooperatively engage with tool engagement area **1008** of post **1000**. Post remover **1400** removes post **1000** from implant **900** by unthreading post **1000** from opening **928** in leading end **904** of implant **900**.

FIGS. **46-51** show various steps of a preferred method for inserting implant **900** from an anterior approach to the spine and using associated instrumentation disclosed herein.

FIGS. **46** and **47** show insertion of a guard **1600** with disc penetrating extensions **1602** into the disc space and the use of drill **700** to prepare the disc space for implantation. Disc penetrating extensions **1602** need not be but are preferably angled to place the adjacent vertebral bodies in angular relationship to each other. As taught in U.S. Pat. No. 6,080,155 to Michelson incorporated by reference herein, the guard may have one or more extensions of any size or shape suitable for the intended purpose and one or more bores which could, but need not, be in part overlapping. It is understood that the use of such a guard is only preferred and not required. The guard may be of any type suitable for the purpose of providing protected access while the disc space is prepared and during implantation including, but not limited to, the guards incorporated by reference above.

In FIG. **48**, drill **700** and guard **1600** are withdrawn and driver **1100** is used to insert implant **900** into the prepared disc space. In this example, implant **900** is rotatably inserted so that thread **922** penetrably engages the bone of the adjacent vertebral bodies. At the option of the surgeon, guard **1600** may be left in place throughout the whole procedure, the procedure then being carried out through the hollow shaft of guard **1600**. Additionally, implant **900** may be installed without first installing post **1000** into implant **900**. However, it is preferred that post **1000** is installed in implant **900** before implant **900** is installed into the disc space.

As illustrated in FIG. **49**, radial expander **920** is moved onto post **1000** and implant holder **1200** is moved into position. After flanges **1210** of implant holder **1200** are engaged with arms **909**, **910** of implant **900**, rotating tool **1300** is inserted through the interior of shaft **1206** so that threaded bore **1302** of rotating tool **1300** cooperatively engages first thread **1004** of post **1000**. As shown in FIG. **50**, after rotating tool **1300** and post **1000** are rotationally engaged, continued rotation of rotating tool **1300** linearly forces radial expander **920** away from trailing end **902** and to bear against the interior surfaces of arms **909**, **910**, causing arms **909**, **910** to be forced away from the mid-longitudinal axis of the implant as described above in relation to implant **100** and FIGS. **9-11**.

As shown in FIG. **51**, after radial expander **920** is seated into seat **918** and implant **900** is placed in an expanded state, post remover **1400** is used to engage head **1006** of post **1000**. Rotating post remover **1400** disengages post **1000** from threaded opening **928** of implant **900**, allowing post **1000** to be withdrawn through opening **934** of radial expander **920** and from the interior of the implant.

FIGS. **52**A, **52**B, and **53** show two implants **900** in a radially expanded state placed in close proximity to one another within the perimeter of a disc space D. In FIG. **52**A and **52**B, implants **900** of FIG. **33** are preferably positioned such that shortened arms **909** face the antero-lateral aspect of the vertebral bodies such that the structure of each implant is kept substantially within the disc space to minimize the risk of interference with delicate vascular and neurological structures present adjacent to the disc space. In FIG. **52**B, implants **900** are oriented toward each other in a toed-in configuration permitting the implants to be closer to each other in a side-by-side placement. Such placement permits the use of larger implants to better fill the disc space than may be possible with implants positioned parallel to each other.

In FIG. **53**, two implants **900** of FIG. **37**, each having opposed shortened arms **909**, are preferably placed such that the mid-longitudinal axis of each implant are in closer proximity to one another than the embodiment shown in FIG. **52**A. Closer placement is made possible, by way of example only, by positioning each implant such that shortened arms **909** face each other within the disc space. Additionally, the size of thread **922** may be reduced towards trailing end **902** so that trailing end **902** has a reduced thread portion **923** to minimize contact with the thread of an adjacent implant. Such an orientation permits greater expansion to occur without a lengthened arm from one implant crossing the lengthened arm of an implant adjacent thereto. In all the embodiments described herein, it should be apparent that a number of arrangements of shortened and/or lengthened arms are possible and all within the broad scope of the present invention.

FIGS. **54-56** show a preferred remover and methods of disengaging radial expander **920** from seat **918** of implant **900** if it is desired to uninstall implant **900**. FIG. **54** shows a remover **1500** for removing radial expander **920** from hollow interior **903** of implant **900** through trailing end **902**. Remover **1500** has a shaft **1502** and a distal end **1504**. Distal end **1504** has a bore **1514** with a thread **1516** that is configured for cooperative engagement with first thread **1004** of post **1000**, a collar **1518** with an outer diameter slightly smaller than the diameter of hollow interior **903** of implant **900** in a radially expanded state, and a bearing **1520** that allows remover **1500** to rotate relative to collar **1518**. Bore **1514** preferably has an unthreaded portion at its leading end that permits remover **1500** to move over a portion of post **1000** prior to rotational engagement.

As shown in FIGS. **55** and **56**, threaded bore **1514** of remover **1500** threads onto post **1000** causing forward movement of remover **1500** into trailing end **904** of implant **900**. As remover **1500** moves into trailing end **904**, collar **1518** contacts arms **909**, **910**, forcing arms **909**, **910** to move outward away from the mid-longitudinal axis of the implant. This movement in turn causes seat **918** to expand outward to release radial expander **920**, thus permitting radial expander **920** to be removed from implant **900**.

FIG. **56** shows an instrument, for example a hook **1700**, for removing radial expander **920** from implant **900** to return arms **909**, **910** to their initial or non-expanded position.

The implants described herein preferably have a generally circular cross section transverse to the mid-longitudinal axis of the implant. In the collapsed position, the implants may have a generally cylindrical configuration or may be in the shape of a cylinder with at least a portion of a side removed. The implants may be tapered from trailing end to leading end and may have a generally frusto-conical configuration in the collapsed position to facilitate insertion into the implantation space.

In another embodiment, in the expanded position, the implants described herein may have a leading end or a trailing end tapered at an angle that matches the angle of the upper, lower, and side portions in the expanded position.

The radially expandable spinal fusion implant may include, be made of, treated, coated, filled, used in combination with, or have a hollow for containing artificial or naturally occurring materials and/or substances suitable for implantation in the human spine. These materials and/or substances include any source of osteogenesis, bone growth promoting materials, bone, bone derived substances or products, demineralized bone matrix, ossifying proteins, bone morphogenetic proteins, hydroxyapatite, genes coding for the production of bone, and bone including, but not limited to, cortical bone. The implant can also be formed of an artificial material stronger than bone such as metal including, but not limited to, titanium and its alloys, surgical grade plastics, plastic composites, ceramics, or other materials suitable for use as a spinal fusion implant. The implant can include at least in part of materials that are bioabsorbable and/or resorbable in the body such as bone and/or bone growth promoting materials. The implant of the present invention can be formed of a porous material or can be formed of a material that intrinsically participates in the growth of bone from one of adjacent vertebral bodies to the other of adjacent vertebral bodies. Where such implants are for posterior implantation, the trailing ends of such implants may be treated with, coated with, or used in combination with chemical substances to inhibit scar tissue formation in the spinal canal. The implants of the present invention may be adapted to facilitate the electrostimulation of the fusion area into which they are inserted and the proximate bone thereabout. The implant of the present invention may be modified, or used in combination with materials to make it antibacterial, such as, but not limited to, electroplating or plasma spraying with silver ions or other substance. At least a portion of the implant may be treated to promote bone ingrowth between the implant and the adjacent vertebral bodies. The implant of the present invention may be used in combination with spinal fixation hardware, bone screws, plates, rods, tethers of synthetic chords or wires.

Although various embodiments of the present invention have been disclosed, they are but preferred embodiments for the purpose of illustration by example and not limitation. It should be understood that any modifications of these teachings as would be known to one of ordinary skill in the art are anticipated and within the scope of the present inventive teachings.

What is claimed is:

1. A system for use in human spinal surgery, said system comprising:

a spinal implant having an expander for expanding the height and at least a portion of the width of said implant from a collapsed position to an expanded position, said implant having upper, lower, and side portions comprising a plurality of arms separated by spaces; and

a holder for holding said spinal implant, said holder including a sleeve having a leading end, a trailing end, a mid-longitudinal axis therebetween, and a passageway from said trailing end to said leading end, said passageway providing access to said implant through said sleeve, said leading end of said sleeve having spaced apart upper, lower, and side portions, said sleeve having a maximum cross-sectional dimension across the mid-longitudinal axis and through said upper, lower, and side portions of said sleeve, said maximum cross-sectional dimension through said upper and lower portions of said sleeve being substantially the same as the maximum cross-sectional dimension through said side portions of said sleeve, said maximum cross-sectional dimension through said upper, lower, and side portions of said sleeve increasing in a direction from said leading end of said sleeve toward said trailing end of said sleeve along at least a portion of the mid-longitudinal axis, said upper, lower, and side portions of said sleeve configured to fit in the spaces between said upper, lower, and side arms, respectively, of said spinal implant to cooperatively engage said sleeve to said implant.

2. The system of claim **1**, wherein said holder further comprises a handle proximate said trailing end of said sleeve.

3. The system of claim **1**, wherein said spaced apart portions of said sleeve are flexible at least in part.

4. The system of claim **1**, wherein said spaced apart portions of said sleeve when engaged to said implant are configured to resist rotational movement of said implant.

5. The system of claim **1**, wherein said passageway of said sleeve is configured to receive therethrough at least one tool adapted to engage said implant.

6. The system of claim **1**, wherein said passageway of said sleeve is configured to receive therethrough at least one tool adapted to engage said expander.

7. The system of claim **1**, in combination with a rotating tool configured to pass through said passageway of said sleeve for moving said expander along at least a portion of a length of said implant between said upper, lower, and side portions of said implant.

8. The system of claim **1**, in combination with a remover instrument configured to pass through said passageway of said sleeve for removing said expander from said Implant.

9. The system of claim **1**, in combination with a post adapted to be inserted at least in part within said implant for moving said expander along at least a portion of a length of said implant between the upper, lower, and side portions of said implant.

10. The system of claim **9**, in combination with a remover instrument configured to pass through said passageway of said sleeve for removing said post from within said implant.

11. The system of claim **1**, in combination with an instrument for loading bone growth promoting material into at least a portion of said implant.

12. The system of claim **1**, wherein said implant includes a hollow interior between said upper, lower, and side portions and in communication with said spaces separating said arms of said implant.

13. The system of claim **1**, wherein said implant has a mid-longitudinal axis and said upper, lower, and side portions of said implant are configured to move at least in part in a direction away from the mid-longitudinal axis to expand the height and at least a portion of the width of said implant.

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