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(54) **CONICALLY SHAPED ANTERIOR FUSION CAGE AND METHOD OF IMPLANTATION**

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(57) **ABSTRACT**

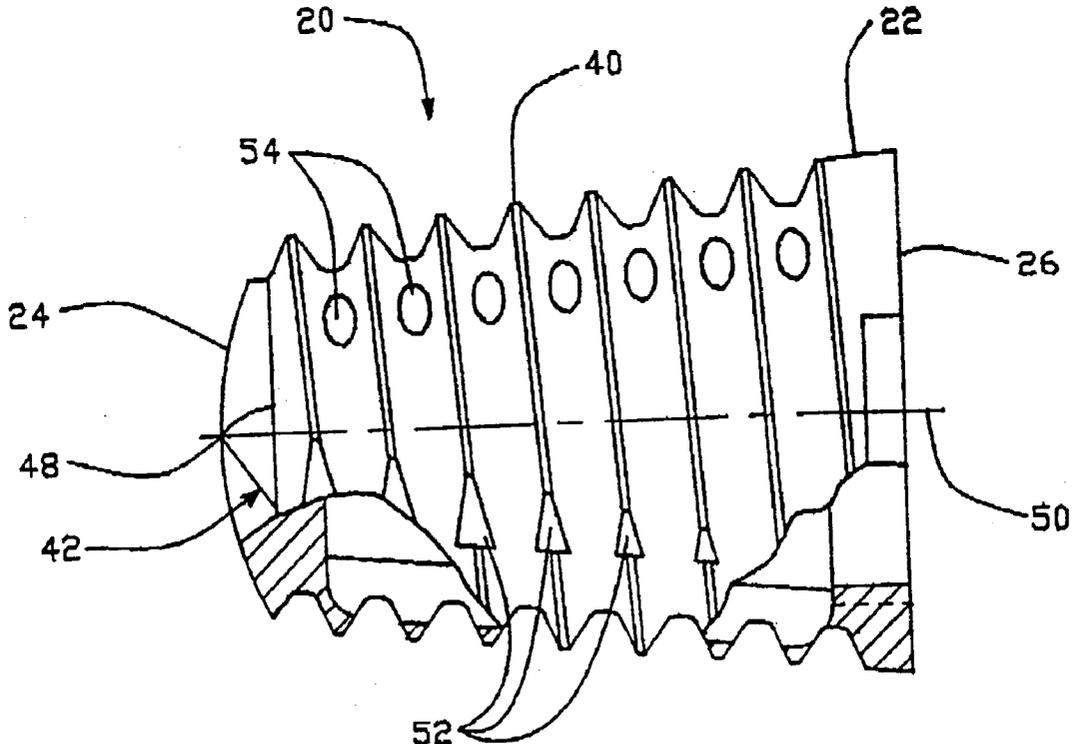
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A fusion cage for promoting fusion with one or more bone structures including a conically-shaped cage body including a proximal end having a first diameter and a distal end having a second diameter, wherein the first diameter of the proximal end is greater than the second diameter of the distal end.

**Related U.S. Application Data**

(63) Continuation of application No. 09/358,188, filed on Jul. 20, 1999, now abandoned, which is a continua



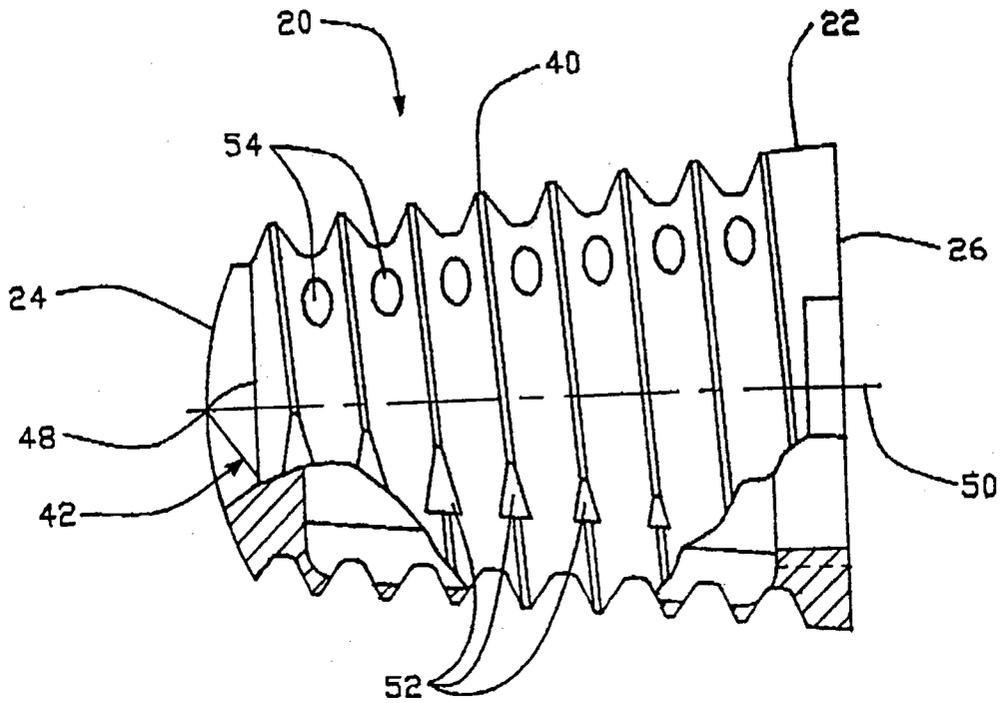


FIG. -1

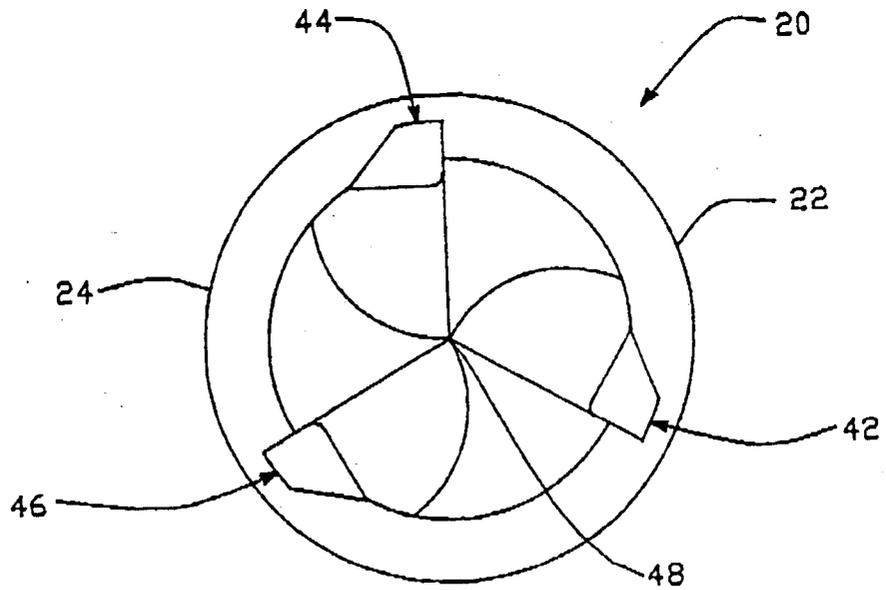


FIG. -2

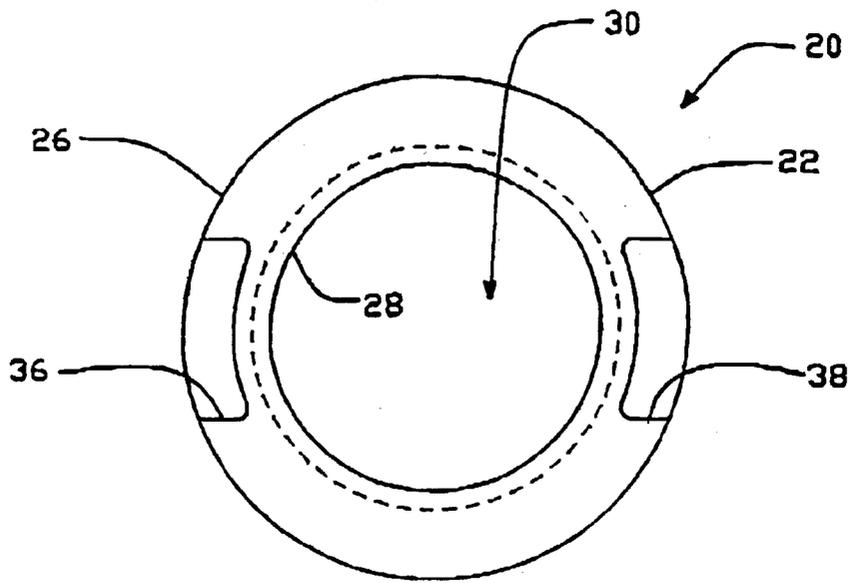


FIG. -3

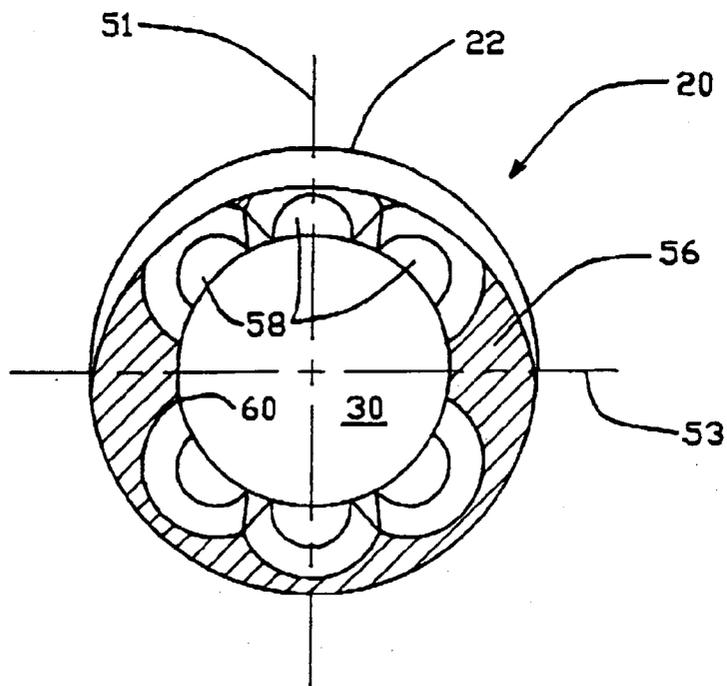


FIG. -4

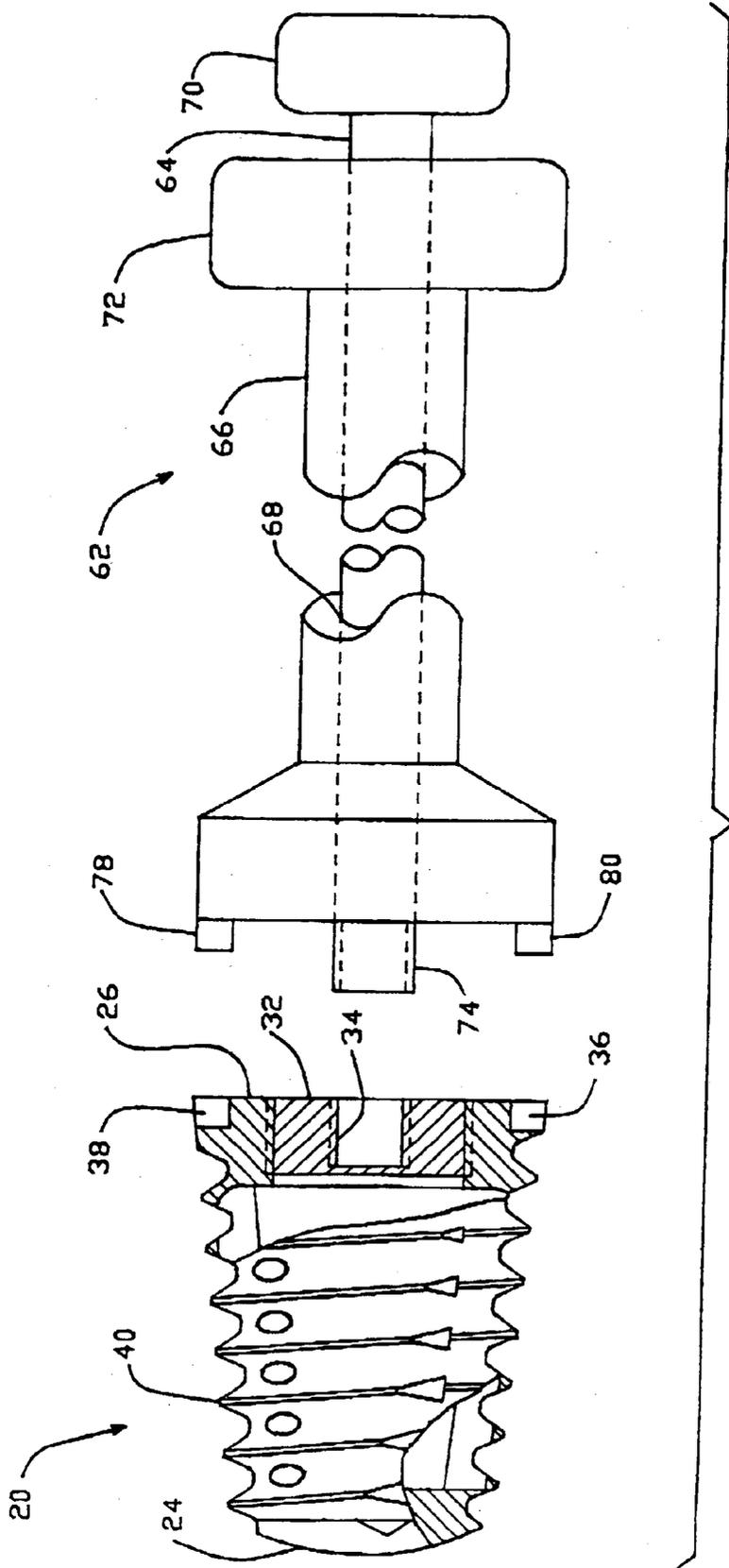


FIG.--5

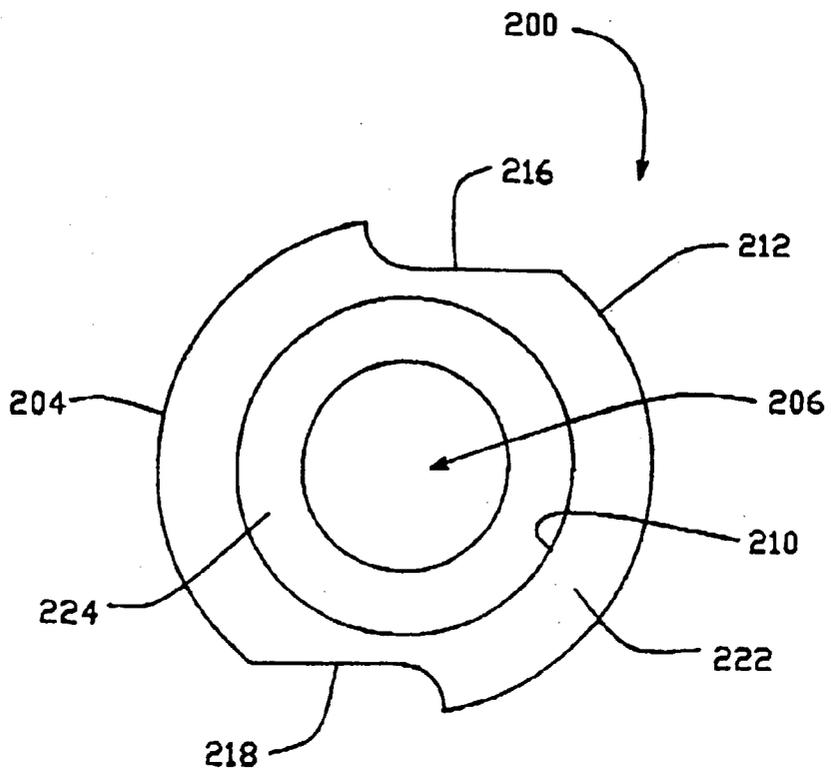


FIG.-12

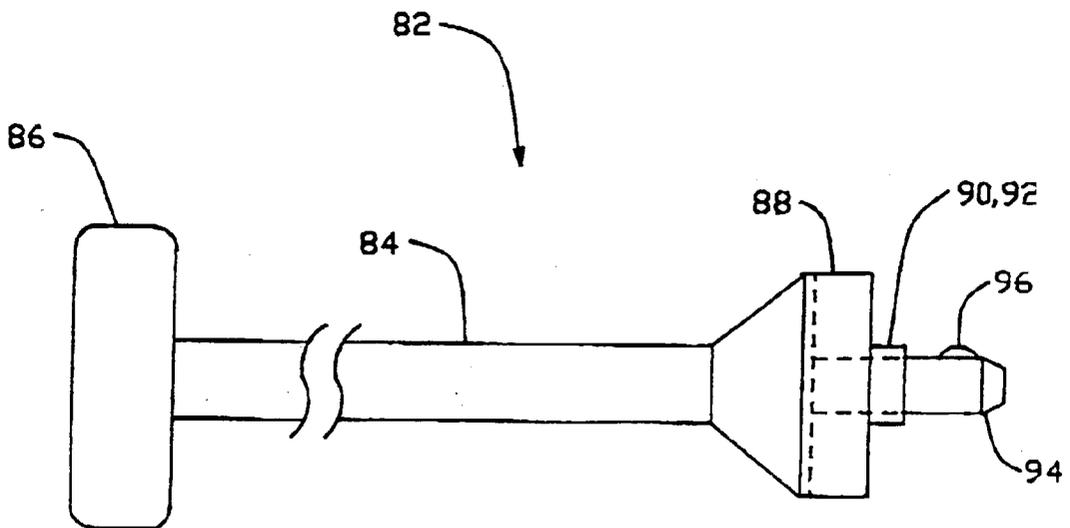


FIG.-6

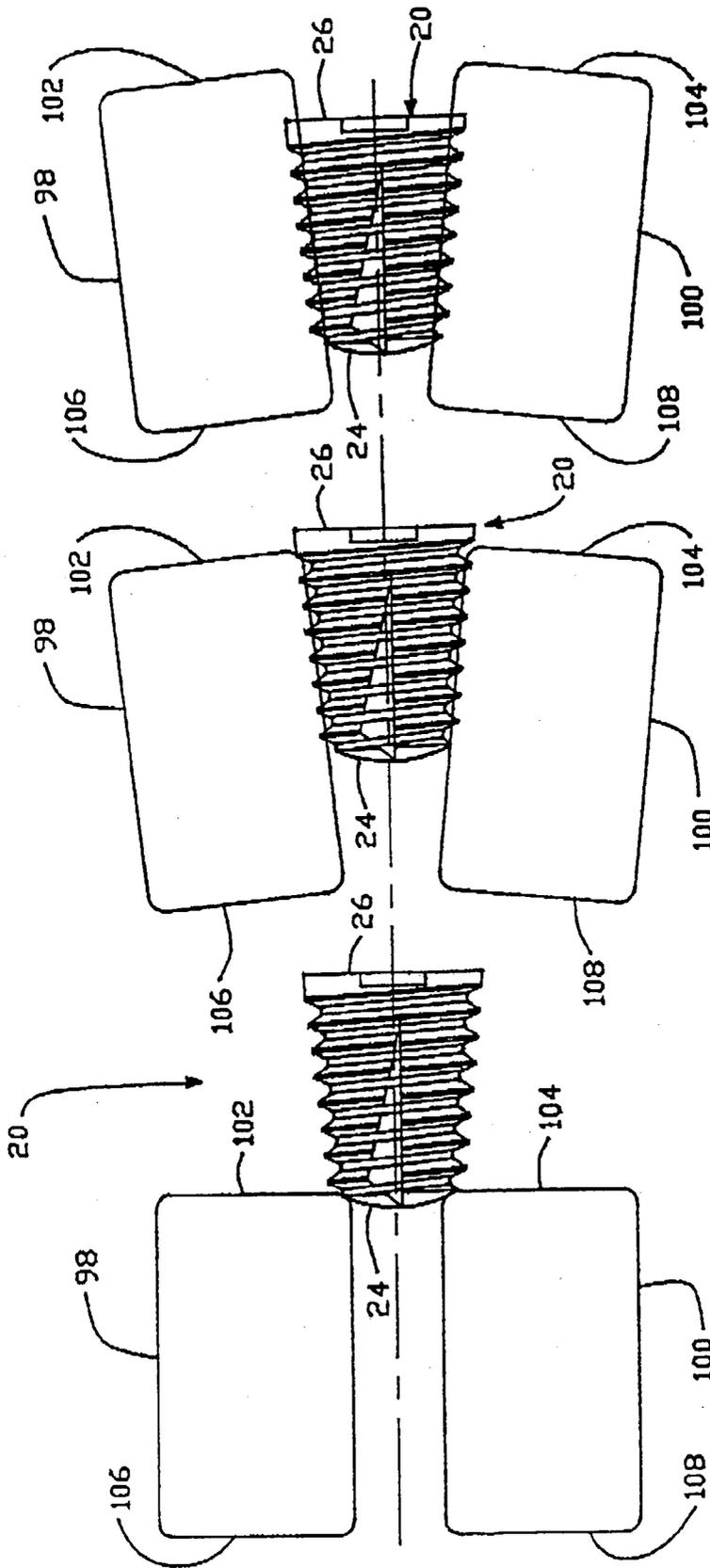


FIG.—7

FIG.—8

FIG.—9

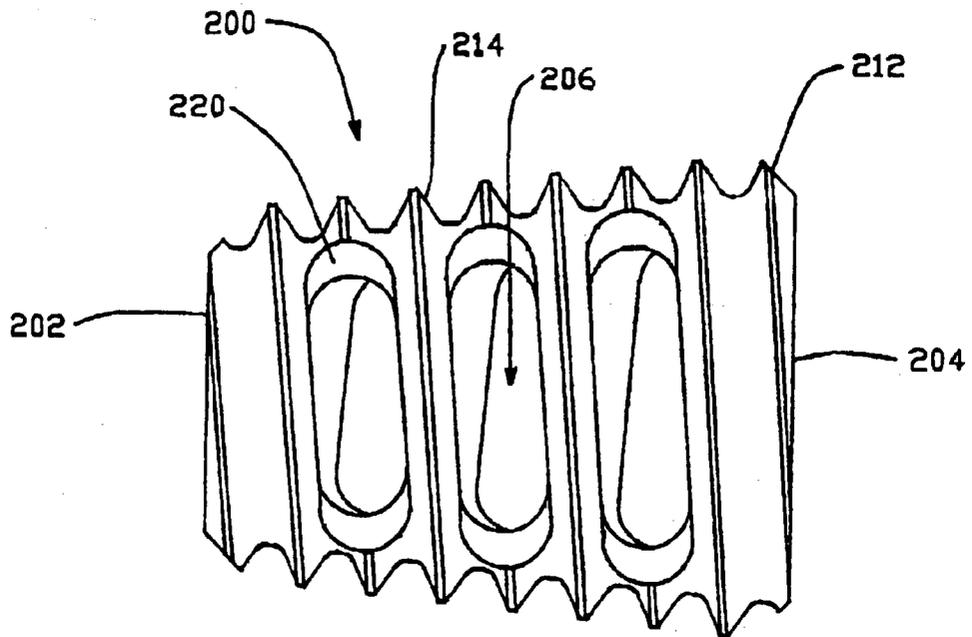


FIG. - 10

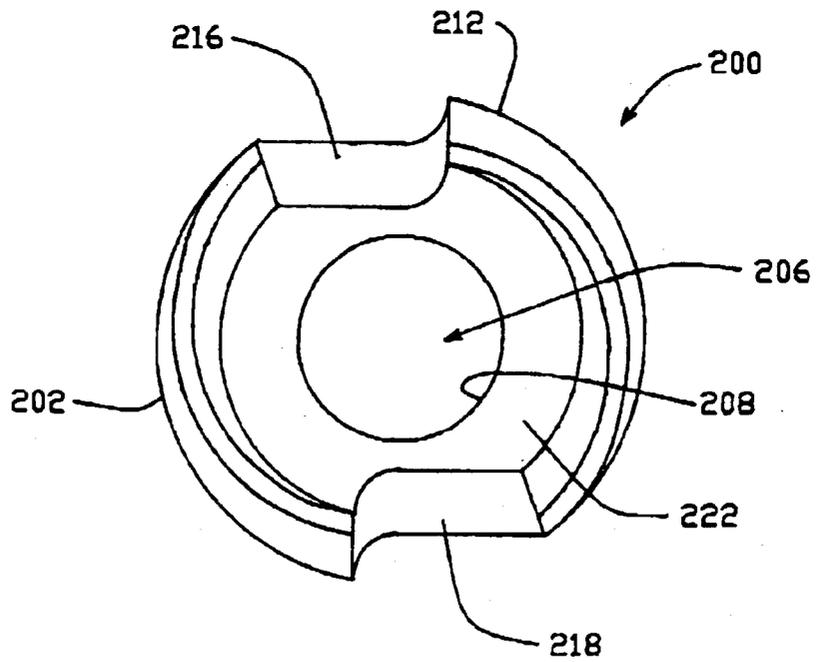


FIG. - 11

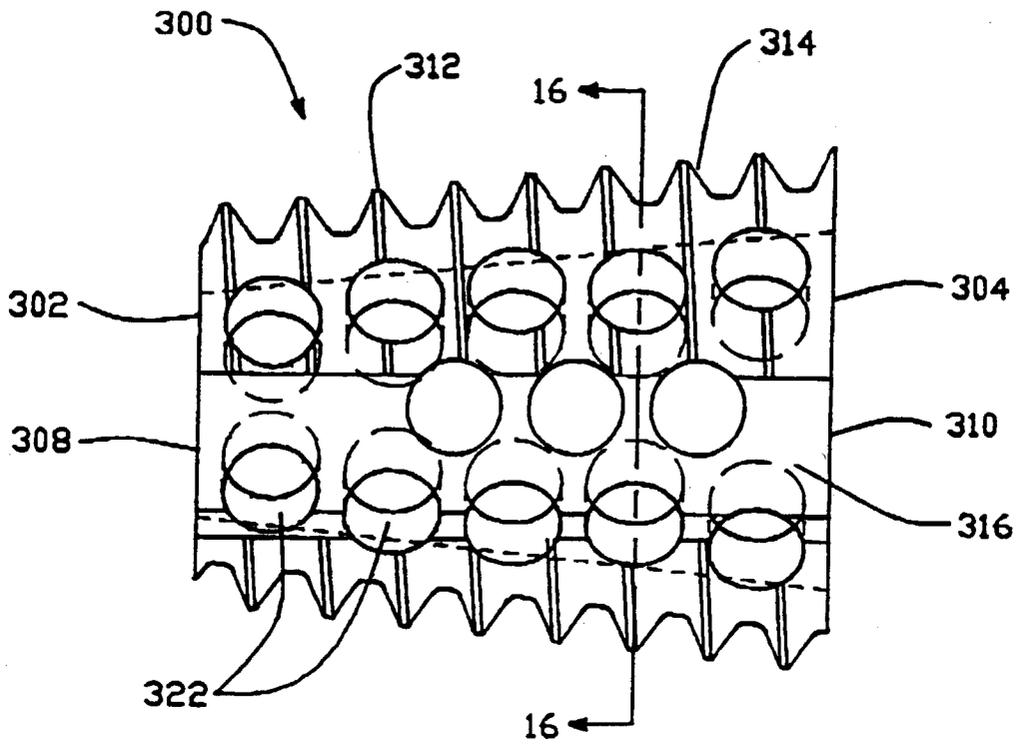


FIG. - 13

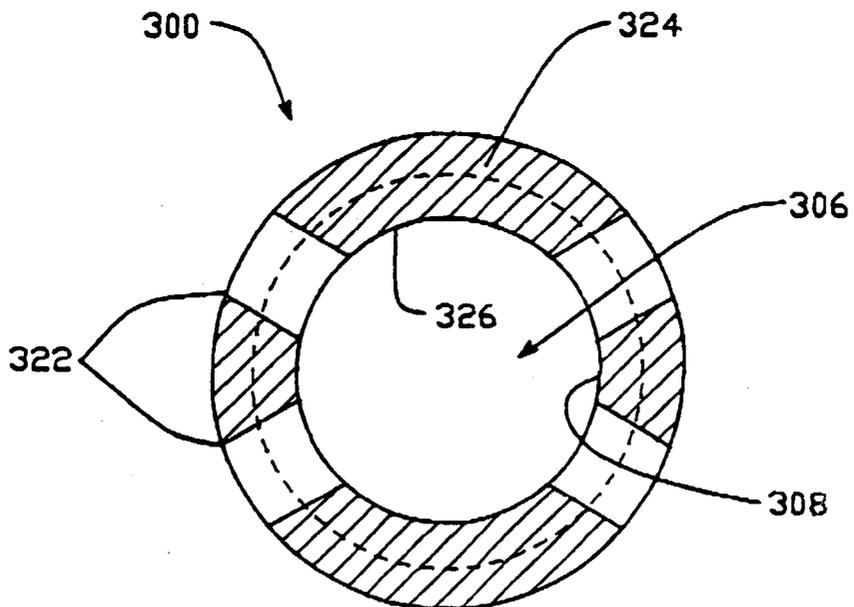


FIG. - 16

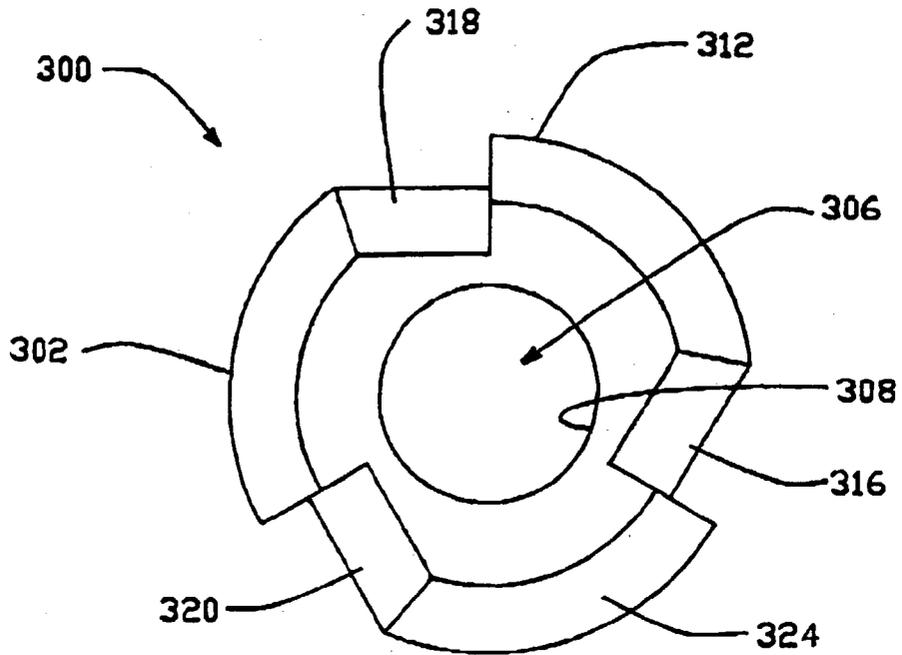


FIG. - 14

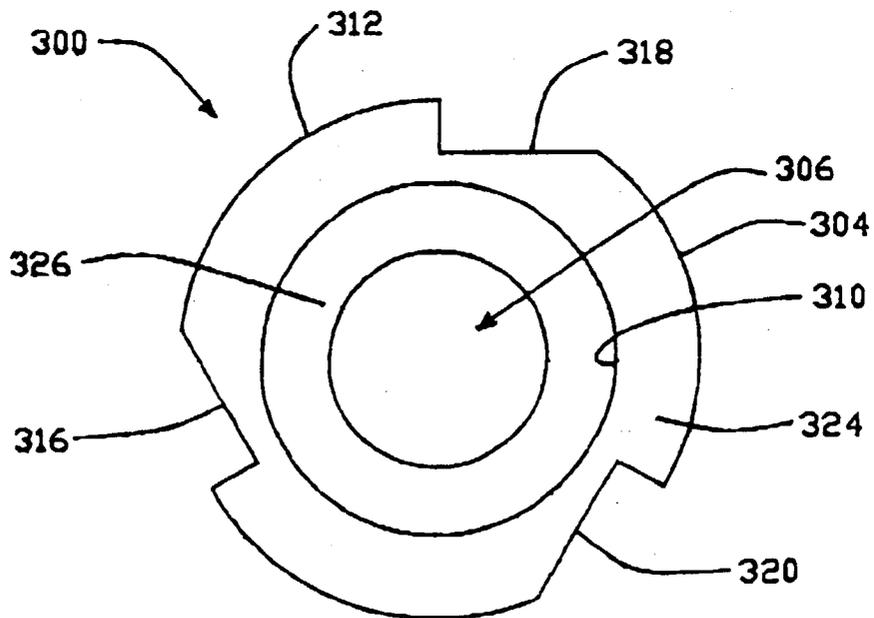


FIG. - 15

## CONICALLY SHAPED ANTERIOR FUSION CAGE AND METHOD OF IMPLANTATION

### CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present invention is a continuation of application Ser. No. 09/358,188, filed Jul. 20, 1999, which is a continuation of application Ser. No. 08/781,525 filed Jan. 9, 1997, which is a file wrapper continuation of application Ser. No. 08/306,879 filed Dec. 15, 1994 (now abandoned). The disclosures of the '188, '525 and '879 applications are hereby incorporated by reference herein.

### BACKGROUND OF THE INVENTION

[0002] This invention is directed to devices and methods for facilitating the fusing of bone structures and more particularly the fusing together of adjacent vertebral bodies or bone structures.

[0003] Technical literature and patent documents disclose a number of devices and methods for fusing bones together. One such device which has proven to be successful is disclosed in U.S. Pat. No. 4,961,740, entitled "V-THREAD FUSION CAGE AND METHOD OF FUSING A BONE JOINT," which patent has been assigned the present assignee and which patent is incorporated herein by reference. The referenced patent discloses a fusion cage which is preferably cylindrical and has threads formed as part of the external cylindrical surface. The fusion cage defines an internal cavity and apertures through the wall of the cage which communicate the external cylindrical surface with the internal cavity. The apertures are formed in the valleys of the threads. Normally two such cages are used to stabilized and fuse together adjacent vertebral bodies or bone structures.

[0004] In practice, using a posterior approach, a patient's vertebral bone structures are exposed and degenerate disk material located between the vertebral bone structures is removed. A threaded tap is used to tap complementary threads in the upper and lower vertebral bone structures preparatory to the insertion of the above fusion cage. Once such tapping has been accomplished, using an introduction tool, the fusion cage is screwed into the space between the adjacent vertebral bone structures. The threads bite into the bone of the upper and lower vertebral bone structures, stabilizing the bone structures, and preventing the fusion cage from working out of this position due to patient movement. Generally two such fusion cages are applied using this technique. Once the two implants have been positioned, then bone growth inducing substances, such as bone chips, are packed into the internal cavity of the fusion cages. These bone growth inducing substances come into immediate contact with the bone from the vertebral bone structures which project into the internal cavity through the apertures. Such projection of bone is due to the fact that the apertures are formed in the valleys of the external threads of the fusion cage. Such immediate bone to bone contact between the vertebral bone structures and the bone pack within the fusion cages results in more rapid propagation of bone cells between the adjacent vertebral bone structures and thus a more rapid fusion of the adjacent vertebral bone structures.

### SUMMARY OF THE INVENTION

[0005] The present invention is directed to a fusion cage which has been designed to be implanted using an anterior approach to the vertebral bone structures.

[0006] In a first embodiment of the present invention, the fusion cage includes a conically-shaped cage body having a proximal end and a distal end, said distal end having a diameter which is smaller than the diameter of the proximal end. The distal end further is rounded with for example a bull nose in order to facilitate the insertion of the cage body relative to one or more bone structures. The conically-shaped cage body is particularly advantageous for use with an anterior approach to vertebral bone structure fusion. This is due to the fact that the normal lordosis of the vertebral bone structures defines a wedged-shape space for a vertebral disk between, for example, lumbar vertebrae. Accordingly, the conically-shaped body cage can be sized and selected in order to maintain or enlarge upon the normal lordosis.

[0007] In a second embodiment of the present invention, a fusion cage includes a conically-shaped cage body having a proximal end and a distal end with the distal end having a diameter which is smaller than the diameter of the proximal end. The conically-shaped cage body has a conically-shaped outer surface and at least one flute formed in the conically-shaped outer surface. The flute acts as a relief much as the flute placed on self-tapping screws in order to facilitate the insertion of the fusion cage using a twisting motion between two vertebral bone structures.

[0008] In a third embodiment of the invention, a fusion cage includes a conically-shaped cage body having a proximal end and a distal end, the distal end having a diameter which is smaller than the diameter of the proximal end. The conically-shaped cage body has a conically-shaped outer surface and a plurality of threads formed as part of the conically-shaped outer surface. The plurality of threads allows the cage body to be inserted using an anterior approach. Due to the fact that the cage body is conically-shaped, the requirement for pretapping the vertebral bone structures to receive the fusion cage is eliminated with the fusion cage being self-tapping. Also the cage gradually spreads apart the vertebral bone structures as the cage is inserted in order to regain or enlarge the natural lordosis of the adjacent vertebral bone structures. As with other embodiments of the present invention, flutes can be provided through the plurality of threads in order to allow for enhanced thread tapping by the cage and for a smoother insertion of the fusion cage between the vertebral bone structures. Preferably two or three flutes would be formed spaced about the fusion cage in order that one flute would be engaging with or adjacent to an upper vertebral bone structures with another flute being engaging with or adjacent to a lower vertebral bone structure. Such a relationship maintains alignment of the fusion cage and prevent wandering as the fusion cage is introduced between the two vertebral bone structures. Without two or more flutes, wandering might occur due to the fact that the threads are only substantially engaged with the vertebral bone structures and not with the disk material between the vertebral bone structures, which disk material does not provide support to the threads.

[0009] In a further aspect of the invention, any of the above embodiments can be provided with a plurality of apertures through the fusion cage and an internal cavity with the apertures communicating between the internal cavity and the external surface of the fusion cage. Bone growth inducing substances, such as bone chips, can be packed into the internal cavity either before the fusion cage is inserted or after the fusion cage has reached a final insertion position.

The bone chips come in contact with the vertebral bone structures through the apertures in order to facilitate fusion between the adjacent vertebral bone structures.

[0010] In another aspect of the invention which can be included in any of the above embodiments, the cage body can have a round or bull nose distal end with one or more flutes formed in the round or bull nose distal end in order to enhance the self-tapping nature of the fusion cage.

[0011] In yet another aspect of the invention, introduction tools allow the fusion cage to be accurately positioned between the vertebral bone structures.

[0012] The method of the present invention affords access to adjacent vertebral bone structures using an anterior approach and procedure. Such anterior approach and procedure can be preferably performed laparoscopically using an introduction set including a cannula. A laparoscopic procedure is minimally invasive as the abdomen muscle tissue can be spread using a set of cannula of increasing size and a small opening thereby developed through which a fusion cage can be inserted. Such a procedure is less traumatic to the tissue than an alternate anterior approach and procedure, also known as an anterior lumbar interbody fusion, where an incision, perhaps up to five inches long is made, through the abdomen muscle tissue. It is to be understood however that either anterior approach and procedure can be used with the fusion cage and fall within the scope of the invention.

[0013] After such access, using preferably a laparoscopic technique, degenerate disk material can be removed and, using a cannula and insertion tool, an appropriately shaped fusion cage can be screwed into place between the vertebral bone structures in order to stabilize the vertebral bone structures and allow for fusion. Either preparatory to insertion of the fusion cage or after it has been inserted, bone chips or other bone growth inducing substances can be inserted into the fusion cage to promote bone to bone contact and subsequent fusion.

[0014] It is to be understood that although the above embodiments have been described with respect to the fusion of adjacent vertebral bodies or bone structures, that the present invention can be used to fuse together a variety of bone structures, in addition to being fused to one bone structure and used as, for example, a base for an implant.

[0015] Other objects and advantages of the invention can be obtained through a review of the specification and the figures.

#### BRIEF DESCRIPTION OF THE FIGURE

[0016] FIG. 1 is a partially sectional side view of an embodiment of the fusion cage of the invention.

[0017] FIG. 2 depicts a left end (distal end) view of the fusion cage of FIG. 1.

[0018] FIG. 3 depicts a right end (proximal end) view of the fusion cage of FIG. 1.

[0019] FIG. 4 depicts a view through line 4-4 of the fusion cage of FIG. 1.

[0020] FIG. 5 depicts fusion cage of FIG. 1 in conjunction with an introduction tool.

[0021] FIG. 6 depicts an alternative embodiment of the introduction tool.

[0022] FIGS. 7, 8, and 9 depict progressive stages in the method of inserting the fusion cage between adjacent vertebral bone structures.

[0023] FIG. 10 depicts a side view of an alternative embodiment of the fusion cage of the invention.

[0024] FIG. 11 depicts the left end (distal end) view of the fusion cage of FIG. 10.

[0025] FIG. 12 depicts the right end (proximal end) view of the fusion cage of FIG. 10.

[0026] FIG. 13 depicts a side view of yet another embodiment of the fusion cage of the present invention.

[0027] FIG. 14 depicts a left distal end (distal end) view of the fusion cage of the invention of FIG. 13.

[0028] FIG. 15 depicts a right end (proximal end) view of the fusion cage of the invention of FIG. 13.

[0029] FIG. 16 depicts a sectional view taken through line 16-16 of FIG. 13.

#### DETAILED DESCRIPTION

[0030] With respect to the figures in a particular FIG. 1, a side view of the preferred embodiment of the fusion cage 20 is depicted. Fusion cage 20 includes a fusion cage body 22 which in this preferred embodiment is provided in the shape of a cone. Fusion cage 20 includes a distal end 24 and a proximal end 26. The distal end 24 in a preferred embodiment is rounded or bull nosed in order to facilitate the insertion of the fusion cage 20 relative to one or more bone structures. The proximal end 26 includes an opening 28 which communicates with an internal cavity 30 defined by the fusion cage 20. The opening 28 in a preferred embodiment is threaded so that it can receive an end cap or plug 32 (FIG. 5). End cap 32 is used to close off the proximal end 26 and retain bone growth inducing substances packed therein as described hereinbelow. As can be seen in FIG. 5, end cap 32 includes a threaded bore 34 which is designed to receive an insertion tool. The threaded bore 34 has an initial unthreaded, hex-shaped section 35 which can be used with a socket wrench to tightly position end cap 32 in opening 28. The proximal end 26 further define first and second peripheral indentations 36, 38. These peripheral indentations 36, 38 receive tangs from an insertion tool as described hereinbelow for facilitating the insertion of the fusion cage 20.

[0031] A plurality of threads 40 is defined as part of the outer cylindrical surface 42 of the body 22. It is to be understood that the plurality of threads can be replaced with a plurality of interrupted or discrete threads or a plurality of projections, ridges, protrusions, barbs, or spurs and be within the spirit and scope of the invention.

[0032] The rounded distal end 24, and at least some of threads 40 defined flutes or relief grooves 42, 44, and 46. (FIGS. 1, 2.) In a preferred embodiment, flutes 42, 44, and 46 meet at a central point 48 of the distal end 24 on the longitudinal axis 50 of the fusion cage 20. In other embodiments the flutes can be smaller and not extend all the way to the central point 48 on the longitude axis 50. Still in other embodiments, the flutes can be eliminated from the distal end 24 and such embodiments are still within the spirit and

scope of the invention, the flutes extend from the distal end **24** toward the proximal end **26** as shown in **FIG. 1** with respect to flute **42**. These flutes are defined by the sections **52** which are removed from the threads. In a preferred embodiment, the flutes become narrower as they approach the proximal end **26** due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position. As shown in other embodiments, the flutes can be deeper and extend from the distal end completely to the proximal end. Still further in other embodiments the flutes can be confined to the first several threads adjacent to the distal end and/or to just the distal end.

[0033] As can be seen in **FIGS. 1, 4**, a plurality of apertures **54** are provided through wall **56** of the fusion cage **20**. In a preferred embodiment, these apertures **54** are formed by broaching grooves **58** in the internal surface **60** of the internal cavity **30**. The effect of such broaching is to remove material from the valleys between the threads **40**, thus defining the aperture **54**. The advantages of such an arrangement are taught by the above-referenced U.S. Pat. No. 4,961,740, which patent is incorporated herein by reference and allows for immediate bone to bone contact between the vertebral bodies or bone structures and the bone packed within the internal cavity **30** of the fusion cage **20**.

[0034] The apertures **54** in a preferred embodiment increase in size from smaller apertures closer to the distal end **24** to a larger aperture closer to the proximal end **26**. This increase in size allows for more bone to bone contact. Alternatively in the embodiment as shown in **FIG. 1**, all the apertures are of the same size.

[0035] As can be seen in **FIG. 4**, the apertures are clustered about a transverse axis **51**, both at the upper and lower end of the axis. This is so that in position, the apertures come into contact with the upper and lower vertebral bone structures (**FIG. 9**) to encourage bone growth through the fusion cage from the vertebral bone structures. The lateral section of the fusion cage found along the other transverse access **53** do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process.

[0036] A preferred embodiment of the conically-shaped fusion cage **20** includes a fusion cage which is 23 millimeters in length having a distal end **24** with a diameter of 14 millimeters and a proximal end **26** with a diameter of 18 millimeters. The cage body is a right circular cone. The threads have a pitch of **300** and there are ten threads per inch with a thread depth of 0.053 inches. Further the cage is made of a titanium material. Preferably this and the other disclosed fusion cages disclosed are machined. However, the processes such as molding can be used to accomplish formation of the fusion cages.

[0037] The cage is inserted between vertebral bodies using an insertion tool **62** (**FIG. 5**). Insertion tool **62** includes an inner handle **64** and an outer handle **66**. The outer handle includes a bore **68** for receiving the inner handle **64**. Handles **64, 66** include knobs **70, 72** respectively. The distal end of inner handle **64** defines a threaded shaft **74**, having a reverse thread to facilitate easy removal, and the distal end of handle **66** define a cylindrical disk **76** which has first and second tangs **78, 80**, projecting from the peripheral edge of the cylindrical disk **76**. These tangs **78, 80** are designed to mate with the peripheral indentation **36, 38** of the fusion cage **20**. For purposes of inserting the fusion cage between the

vertebral bodies, the end cap **32** is inserted into the fusion cage **20** as shown in **FIG. 5**. Then the threaded shaft **74** of the inner handle is introduced into the threaded bore **34** of the end cap **32**. After this is accomplished, the outer handle **66** is slid over the inner handle **64** and the tangs **78, 80** are positioned into engagement with the indentations **36, 38**. In this arrangement, the fusion cage **20** can be anteriorly inserted into the space between the vertebral body structure using the insertion tool **62**.

[0038] An alternative embodiment of the insertion tool is shown in **FIG. 6**. In this figure, insertion tool **82** includes a handle **84** with a knob **86**. At the end of the insertion tool **82** distal from the knob **86** is a cylindrical disk **88** which has first and second tangs **90, 92**, which have the same function as the above tangs **78, 80**. Extending from the center of the cylindrical disk **88** along the centerline of the insertion tool **82** is a shaft **94** which has a ball detent **96**. For use with insertion tool **82**, the threaded bore **34** of the end cap **32** would be replaced with a bore having a lip which could engage with the ball detent **96** of the insertion tool **82**.

[0039] The method for inserting the fusion cage **20** of **FIG. 1** using an anterior approach and procedure to the vertebral bodies is as follows. It is to be understood that although the focus of this discussion is on a laparoscopic procedure, that the anterior approach and procedure can also include a more invasive procedure where a long incision is made in the abdomen wall.

[0040] With an anterior approach, using an introduction set such as described by way of example only, in U.S. Pat. No. 4,863,430, entitled "INTRODUCTION SET WITH FLEXIBLE TROCAR WITH CURVED CANNULA," which is incorporated by reference, but however with larger diameter instruments, an amount of disk material is removed between the two vertebral bodies or bone structures which are to be fused together. This procedure is accomplished through a cannula position adjacent to the vertebral bone structures. With the same or a larger diameter cannula, the fusion cage **20** can be introduced adjacent to the vertebral bone structures. In a first procedure, the fusion cage is packed with bone growth substances and the end cap **32** is affixed to the fusion cage **20**. Insertion tool **62** is then secured to the fusion cage **20** and the fusion cage is guided through the cannula to a location adjacent to the upper and lower vertebral body such as presented schematically in **FIGS. 7, 8, 9**, by upper body **98** and lower body **100**. In the initial position as shown in **FIG. 7**, the fusion cage **20** is adjacent to the anterior surfaces **102, 104** of the vertebral bodies **98, 100**. As the introduction tool is turned, the threads **40** of the fusion cage **20** bite into the vertebral bodies **98, 100**. Further turning of the introduction tool causes the fusion cage to move through the position shown in **FIG. 8** to the final resting position shown in **FIG. 9**, where the distal end **24** is moved adjacent to the posterior sections **106, 108** of the vertebral bone structures **98, 100**. As this occurs, the fusion cage **20** increases the lordosis or spacing between the vertebral bodies, basically distracting the vertebral bodies and causing the vertebral bodies to pivot about the posterior sections **106, 108**, with such posterior sections acting like a hinge. It is noted that most of the distraction occurs adjacent to the anterior sections, but that distractions also occur at the posterior sections where the hinged effect is exhibited. Preferably, the lordosis is increased over the normal lordosis in order to stabilize the vertebral bone structures prior to

fusion occurring. Stabilization occurs due to the fact that increased lordosis places additional stress on the anterior longitudinal ligaments which are part of the anatomy holding the vertebral bodies in place.

[0041] Once the fusion cage 20 is appropriately positioned, the handle 64 of the insertion tool 62 is unscrewed from the cap 32 and the fusion handle 62 is pulled away from the fusion cage.

[0042] An alternative embodiment of a fusion cage 200 is shown in FIGS. 10, 11, and 12. Fusion cage 200 includes a distal end 202 and a proximal end 204. Fusion cage 200 includes an internal cavity 206. End caps not shown can be used to close the ports 208, 210 of distal and proximal ends 202, 204. A plurality of threads 212 are defined on the external conical surface 214 of the fusion cage 200. Defined by the threads 212 are first and second flutes 216, 218, which in this embodiment extend from the distal end 202 to the proximal end 204. These flutes provide thread relief allowing the fusion cage 200 to be self-tapping.

[0043] The fusion cage 200 includes a plurality of elongated apertures 220 which are formed through the side walls of a fusion cage 200. The elongated apertures 202 are formed in such a way that the internal conical surface 214 is spaced away from the internal surface 224 of the internal cavity 206 by the thickness of the sidewall 222.

[0044] A further embodiment of the invention is shown in FIGS. 13, 14, 15 and 16. In FIG. 16 the fusion cage 300 has distal and proximal ends 302 and 304 respectively. The fusion cage 300 defines an internal cavity 306, and ports 308 and 310 defined through the distal and proximal ends 302 and 304 respectively. A plurality of thread 312 is defined as part of the external conical surface 314 of the fusion cage 200. First, second and third flutes 316, 318, and 320, are defined in the threads 312 from the distal end 302 to the proximal end 304. These flutes give the fusion cage 300 an enhanced self-tapping advantage. These flutes are equally spaced about the fusion cage 300 in a manner similar to the flutes of the fusion cage embodiment 20 in FIG. 1.

[0045] A plurality of aperture 322 is provided through the external conical surface 314 of the fusion cage 300 and through the side wall 324 opening into the internal cavity 306. Accordingly, at the location of the aperture 322 the external surface 314 is held away from the internal surface 326 by the thickness of the side wall 324.

[0046] The present invention affords the advantages of a fusion cage which can be introduced through an anterior approach in order to maintain or increase lordosis between adjacent vertebral bodies. The fusion cage has the advantage of being conically-shaped and self-tapping through the use of external flutes. The flutes additionally assist in keeping the fusion cage aligned and centered as the cage is being inserted between the vertebral bone structures.

[0047] Other advantages, aspects, and objects of the invention can be obtained through a review of the claims and the appended figures.

[0048] It is to be understood that additional embodiments of the invention can be constructed and fall within the spirit and scope of the claims.

1. A fusion cage for promoting fusion with one or more bone structures comprising:

a conically-shaped cage body including a proximal end having a first diameter and a distal end having a second

diameter, wherein said first diameter of said proximal end is greater than said second diameter of said distal end.

2. The fusion cage as claimed in claim 1, wherein said distal end is rounded so as to facilitate insertion of said fusion cage relative to one or more bone structures.

3. The fusion cage as claimed in claim 1, wherein said conically-shaped cage body has a conically-shaped outer surface.

4. The fusion cage as claimed in claim 3, wherein said conically-shaped outer surface of said cage body has continuous threads.

5. The fusion cage as claimed in claim 3, wherein said conically-shaped outer surface has at least one flute formed therein.

6. The fusion cage as claimed in claim 5, wherein said flute extends from said distal end toward said proximal end of said cage body.

7. The fusion cage as claimed in claim 6, wherein said flute is formed in the rounded distal end of said cage body.

8. The fusion cage as claimed in claim 1, wherein said cage body further comprises:

an internal cavity surrounded by said conically-shaped outer surface of said cage body; and

a plurality of apertures formed through said conically-shaped body for providing communication between said conically-shaped outer surface and said internal cavity.

9. The fusion cage as claimed in claim 8, wherein said apertures increase in size from said distal end to said proximal end of said cage body.

10. The fusion cage as claimed in claim 8, further comprising a bone-growth inducing material disposed in said internal cavity of said cage body.

11. The fusion cage as claimed in claim 10, wherein said bone-growth inducing material includes bone.

12. The fusion cage as claimed in claim 10, wherein said proximal end includes an opening in communication with said internal cavity of said cage body so that said bone-growth inducing material may be disposed in said internal cavity of said cage body.

13. The fusion cage as claimed in claim 12, further comprising an end cap covering said opening for retaining said bone-growth inducing material in said internal cavity.

14. The fusion cage as claimed in claim 13, wherein said opening at the proximal end of said cage body includes internal threads and said end cap includes external threads adapted for meshing with the internal threads of said opening at said proximal end.

15. A fusion cage for promoting fusion with one or more bone structures comprising:

a conically-shaped cage body including a proximal end having a first diameter and a distal end having a second diameter, wherein said first diameter of said proximal end is greater than said second diameter of said distal end;

said cage body defining a conically-shaped outer surface surrounding an internal cavity of said cage body; and

a bone-growth inducing material disposed in said internal cavity of said cage body.

16. The fusion cage as claimed in claim 15, further comprising a plurality of apertures formed through said

conically-shaped body for providing communication between said conically-shaped outer surface and said internal cavity.

**17.** The fusion cage as claimed in claim 16, wherein said apertures increase in size from said distal end to said proximal end of said cage body.

**18.** The fusion cage as claimed in claim 17, wherein said bone-growth inducing material includes bone.

**19.** The fusion cage as claimed in claim 15, wherein said proximal end of said cage body includes an opening in

communication with said internal cavity of said cage body so that said bone-growth inducing material may be disposed in said internal cavity of said cage body.

**20.** The fusion cage as claimed in claim 19, wherein said opening at the proximal end of said cage body includes internal threads and said end cap includes external threads adapted for meshing with the internal threads of said proximal end opening.

\* \* \* \* \*