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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

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INVENTOR(S)					
Given Name (first and middle (if any))		Family Name or Surname		Residence (City and either State or Foreign Country)	
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Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
SYSTEM AND METHODS FOR SPINAL FUSION					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
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ENCLOSED APPLICATION PARTS (check all that apply)					
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Respectfully submitted,

[Page 1 of 2]

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SIGNATURE

REGISTRATION NO. 40,182

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Jonathan D. Spangler

**PROVISIONAL APPLICATION
FOR UNITED STATES LETTERS PATENT**

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SYSTEMS AND METHODS FOR SPINAL FUSION

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SYSTEMS AND METHODS FOR SPINAL FUSION

BACKGROUND OF THE INVENTION

I. Field of the Invention

5 The present invention relates generally to spinal surgery and, more particularly, to a system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites.

10

II. Discussion of the Prior Art

Currently there are nearly 500,000 spine lumbar and cervical fusion procedures performed each year in the United States. Such procedures are commonly performed to correct problems, such as chronic back or neck pain, which result from degenerated intervertebral discs or trauma. Generally, spinal fusion procedures involve removing some or all of the diseased or damaged disc, and inserting one or more intervertebral implants into the resulting disc space. Introducing the intervertebral implant serves to restore the height between adjacent vertebrae ("disc height"), which reduces if not eliminates neural impingement commonly associated with a damaged or diseased disc.

20

Autologous bone grafts are widely used intervertebral implant for lumbar fusion. Autologous bone grafts are obtained by harvesting a section of bone from the iliac crest of the patient and thereafter implanting the article of autologous bone graft to effect fusion. While generally effective, the use of autologous bone grafts suffers certain drawbacks. A primary drawback is the morbidity associated with harvesting the autologous graft from the patient's iliac crest. Another related drawback is the added surgical time required to perform the bone-harvesting.

Allograft bone grafts have been employed with increased regularity in an effort to overcome the drawbacks of autologous bone grafts. Allograft bone grafts are harvested from cadaveric specimens, machined, and sterilized for implantation. While allograft bone grafts eliminate the morbidity associated with iliac crest bone harvesting, as well as decrease the overall surgical time, they still suffer certain drawbacks. A primary drawback is supply constraint, in that the tissue banks that process and produce allograft bone implants find it difficult to forecast allograft given the inherent challenges in forecasting the receipt of cadavers. Another related drawback is that it is difficult to manufacture the allograft with consistent shape and strength characteristics given the variation from cadaver to cadaver.

The present invention is directed at overcoming, or at least improving upon, the disadvantages of the prior art.

SUMMARY OF THE INVENTION

The present invention overcomes the drawbacks of the prior art by providing
5 a spinal fusion system and related methods involving the use of a spinal fusion
implant of non-bone construction. The non-bone construction of the spinal fusion
implant of the present invention overcomes the drawbacks of the prior art in that it is
not supply limited (as with allograft) and does not require harvesting bone from the
patient (as with autograft). The spinal fusion implant of the present invention may
10 comprise of any suitable non-bone composition, including but not limited to polymer
compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone
(PEKK)), ceramic, metal or any combination of these materials.

The spinal fusion implant of the present invention may be provided in any
15 number of suitable shapes and sizes depending upon the particular surgical procedure
or need. The spinal fusion implant of the present invention may be dimensioned for
use in the cervical and/or lumbar spine without departing from the scope of the
present invention. For lumbar fusion, the spinal fusion implant of the present
invention may be dimensioned, by way of example only, having a length ranging
20 between 9 and 18 mm, a height ranging between 8 and 16 mm, and a width ranging
between 25 and 45 mm. For cervical fusion, the spinal fusion implant of the present

invention may be dimensioned, by way of example only, having a length about 11 mm, a height ranging between 5 and 12 mm, and a width about 14 mm.

The spinal fusion implant of the present invention may be provided with any
5 number of additional features for promoting fusion, such as apertures extending between the upper and lower vertebral bodies which allow a boney bridge to form through the spinal fusion implant of the present invention. Such fusion-promoting apertures may be dimensioned to receive any number of suitable osteoinductive agents, including but not limited to bone morphogenic protein (BMP) and bio-
10 resorbable polymers, including but not limited to any of a variety of poly (D,L-lactide-co-glycolide) based polymers, such as disclosed in U.S. Patent No. 6,013,853. The spinal fusion implant of the present invention is preferably equipped with one or more lateral openings which aid it provides in visualization at the time of implantation and at subsequent clinical evaluations.

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The spinal fusion implant of the present invention may be provided with any number of suitable anti-migration features to prevent spinal fusion implant from migrating or moving from the disc space after implantation. Suitable anti-migration features may include, but are not necessarily limited to, angled teeth formed along
20 the upper and/or lower surfaces of the spinal fusion implant and/or spike elements disposed partially within and partially outside the upper and/or lower surfaces of the

spinal fusion implant. Such anti-migration features provide the additional benefit of increasing the overall surface area between the spinal fusion implant of the present invention and the adjacent vertebrae, which promotes overall bone fusion rates.

5 The spinal implant of the present invention may be introduced into a spinal target site through the use of any of a variety of suitable instruments having the capability to releasably engage the spinal implant. In a preferred embodiment, The insertion instrument permits quick, direct, accurate placement of the spinal implant of the present invention into the intervertebral space. According to one embodiment, 10 the insertion instrument includes a threaded engagement element dimensioned to threadably engage into a receiving aperture formed in the spinal fusion implant of the present invention. According to another embodiment, the insertion instrument includes an elongate fork member and a generally tubular lock member.

15 **BRIEF DESCRIPTION OF THE DRAWINGS**

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

Figure 1 is a perspective view of a spinal fusion system of the present invention, including a lumbar fusion implant releasably coupled to an insertion instrument according to one embodiment of the present invention;

5 Figure 2 is a perspective view of the lumbar fusion implant of FIG. 1, illustrating (among other things) fusion apertures extending between top and bottom surfaces, a plurality of visualization apertures extending through the side walls, and a variety of anti-migration features according to one embodiment of the present invention;

10 Figure 3 is a top view of the lumbar fusion implant of FIG. 1, illustrating (among other things) the fusion apertures and the anti-migration features according to one embodiment of the present invention;

15 Figure 4 is a side view of the lumbar fusion implant of FIG. 1, illustrating (among other things) the visualization apertures, the anti-migration feature, and a receiving aperture for releasably engaging the insertion instrument of FIG. 1 according to one embodiment of the present invention;

20 Figure 5 is an end view of the lumbar fusion implant of FIG. 1, illustrating (among other things) the receiving aperture formed in the proximal end, the anti-

migration features, and the visualization apertures according to one embodiment of the present invention;

Figure 6 is an enlarged side view of the lumbar fusion implant of FIG. 1
5 releasably coupled to the distal end of the insertion instrument of FIG. 1 according to one embodiment of the present invention;

Figure 7 is a perspective view of the insertion instrument of FIG. 1 in a fully assembled form according to one embodiment of the present invention;

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Figure 8 is an enlarged perspective view of the distal region of the insertion instrument of FIG. 1 according to one embodiment of the present invention;

Figure 9 is a perspective exploded view of the insertion instrument of FIG. 1,
15 illustrating the component parts of the insertion instrument according to one embodiment of the present invention;

Figure 10 is a perspective view of a spinal fusion system of the present invention, including a cervical fusion implant releasably coupled to a cervical
20 insertion instrument according to one embodiment of the present invention;

Figure 11 is a perspective view of the proximal side of the cervical fusion implant of FIG. 10, illustrating (among other things) fusion apertures extending between top and bottom surfaces, a plurality of visualization apertures extending through the lateral walls, a plurality of receiving apertures, and a variety of anti-migration features according to one embodiment of the present invention;

Figure 12 is a perspective view of the distal side cervical fusion implant of FIG. 10, illustrating (among other things) the visualization apertures and anti-migration features;

Figure 13 is a top view of the cervical fusion implant of FIG. 10, illustrating (among other things) the fusion apertures and anti-migration features according to one embodiment of the present invention;

Figure 14 is a side view of the cervical fusion implant of FIG. 10, illustrating (among other things) the visualization apertures, the anti-migration features, and one of two receiving apertures provided in the proximal end for releasably engaging the cervical insertion instrument of FIG. 10 according to one embodiment of the present invention;

Figure 15 is a perspective view of the cervical fusion implant of the present invention just prior to attachment to the cervical insertion device according to one embodiment of the present invention;

5 Figure 16 is a perspective view of the insertion instrument of FIG. 10 in a fully assembled form according to one embodiment of the present invention;

Figure 17 is a perspective exploded view of the insertion instrument of FIG. 10, illustrating the component parts of the insertion instrument according to one
10 embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this
15 specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex
20 and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The system to facilitate

bone fusion and related methods disclosed herein boasts a variety of inventive features and components that warrant patent protection, both individually and in combination.

5 FIG. 1 illustrates, by way of example only, a spinal fusion system 5 for performing spinal fusion between adjacent lumbar vertebrae, including an exemplary spinal fusion implant 10 and an exemplary insertion instrument 20 provided in accordance with the present invention. The spinal fusion implant 10 may comprise of any suitable non-bone composition having suitable radiolucent characteristics, 10 including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-ether-ketone-ketone (PEKK)) or any combination of PEEK and PEKK. The spinal fusion implant 10 of the present invention may be dimensioned, by way of example only, having a length ranging between 9 and 18 mm, a height ranging between 8 and 16 mm, and a width ranging between 25 and 45 mm.

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As will be described in detail below, the insertion instrument 20 is configured to releasably maintain the exemplary spinal fusion implant 10 in the proper orientation during insertion into a lumbar disc space and thereafter released to deposit the implant 10. The exemplary spinal fusion implant 10, having been 20 deposited in the disc space, facilitates spinal fusion over time by maintaining a restored disc height as natural bone growth occurs through and/or past the implant

10, resulting in the formation of a boney bridge extending between the adjacent vertebral bodies.

The spinal fusion implant 10 of the present invention may be provided with
5 any number of additional features for promoting fusion, such as apertures 2
extending between the upper and lower vertebral bodies which allow a boney bridge
to form through the spinal fusion implant 10. According to a still further aspect of
the present invention, this fusion may be facilitated or augmented by introducing or
positioning various osteoinductive materials within the apertures 2 and/or adjacent to
10 the spinal fusion implant 10. Such osteoinductive materials may be introduced
before, during, or after the insertion of the exemplary spinal fusion implant 10, and
may include (but are not necessarily limited to) autologous bone harvested from the
patient receiving the spinal fusion implant 10, bone allograft, bone xenograft, any
number of non-bone implants (e.g. ceramic, metallic, polymer), bone morphogenic
15 protein, and bio-resorbable compositions, including but not limited to any of a
variety of poly (D,L-lactide-co-glycolide) based polymers, such as disclosed in U.S.
Patent No. 6,013,853.

The spinal fusion implant 10 of the present invention is preferably equipped
20 with one or more lateral openings 4 which aid it provides in visualization at the time
of implantation and at subsequent clinical evaluations. More specifically, based on

the generally radiolucent nature of the implant 10, the lateral openings 4 provide the ability to visualize the interior of the implant 10 during X-ray and/or other suitable imaging techniques which are undertaken from the side (or "lateral") perspective of the implant 10. If fusion has taken place, the lateral openings 4 will provide a method for the surgeon to make follow up assessments as to the degree of fusion without any visual interference from the spinal fusion implant 10. Further, the lateral openings 4 will provide an avenue for cellular migration to the exterior of the spinal fusion implant 10. Thus the spinal fusion implant 10 will serve as additional scaffolding for bone fusion on the exterior of the spinal fusion implant 10.

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FIGS. 2-5 depict various embodiments of the exemplary spinal fusion implant 10. Some common attributes are shared among the various embodiments. More specifically, each spinal fusion implant 10 has a top surface 31, a bottom surface 33, lateral sides 14, a proximal side 22, and a distal side 16. In one embodiment, the top and bottom surfaces 31, 33 are generally parallel. It can be appreciated by one skilled in the art that although the surfaces 31, 33 are generally parallel to one another, they may be provided in any number of suitable shapes, including but not limited to concave and/or convex. When provided as convex shapes, the top and bottom surfaces 31, 33 may better match the natural contours of the vertebral end plates.

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The exemplary spinal fusion implant 10 also preferably includes anti-migration features designed to increase the friction between the spinal fusion implant 10 and the adjacent contacting surfaces of the vertebral bodies so as to prohibit migration of the spinal fusion implant 10 after implantation. Such as anti-migration features may include ridges 6 provided along the top surface 31 and/or bottom surface 33. Additional anti-migration features may also include a pair of spike elements 7 disposed within the proximal region of the implant 10, a pair of spike elements 8 disposed within the distal region of the implant 10, and a pair of spike elements 9 disposed within the central region of the implant 10. Spike elements 7, 8, 9 may extend from the top surface 31 and/or bottom surface 33 within the respective proximal, distal and central regions of the implant 10. The spike elements 7, 8, 9 may be manufactured from any of a variety of suitable materials, including but not limited to a metal, ceramic, and/or polymer material, preferably having radiopaque characteristics. The spike elements 7, 8, 9 may also take any of a variety of suitable shapes, including but not limited to a generally elongated element disposed within the implant 10 such that the ends thereof extend generally perpendicularly from the upper and/or lower surfaces 31, 33 of the implant 10. As best appreciated in FIG. 4, the spike elements 7, 8, 9 may each comprise a unitary element extending through upper and lower surfaces 31, 33. Alternatively, each spike element 7, 8, 9 may comprise a shorter element which only extends through a single surface 31, 33 (that is, does not extend through the entire height of the implant 10).

The spinal fusion implant 10 has two large fusion apertures 2, separated by a medial support 50, extending in a vertical fashion through the top surface 31 and bottom surface 33. The fusion apertures 2 function primarily as an avenue for bony fusion between adjacent vertebrae. The fusion apertures 2 may be provided in any of a variety of suitable shapes, including but not limited to the generally rectangular shape best viewed in FIG. 3, or a generally circular, oblong and/or triangular shape or any combination thereof. The spinal fusion implant 10 may have a plurality of visualization apertures 4 which allow a clinician to make visual observations of the degree of bony fusion un-obscured by the lateral side 14 to facilitate further diagnosis and treatment. The visualization apertures 4 may be provided in any of a variety of suitable shapes, including but not limited to the generally oblong shape best viewed in FIG. 4, or a generally circular, rectangular and/or triangular shape or any combination thereof.

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The spinal fusion implant 10 may be provided with any number of suitable features for engaging the insertion instrument 20 without departing from the scope of the present invention. As best viewed in FIGS. 4-6, one engagement mechanism involves providing a threaded receiving aperture 12 in the proximal sidewall 22 of the spinal fusion implant 10 of the present invention. The threaded receiving aperture 12 is dimensioned to threadably receive a threaded engagement member 24

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on the insertion instrument 20 (as will be described in greater detail below). The receiving aperture 12 extends inwardly from the proximal side 22 in a generally perpendicular fashion relative to the proximal side 22. Although shown as having a generally circular cross-section, it will be appreciated that the receiving aperture 12 may be provided having any number of suitable shapes or cross-sections, including but not limited to rectangular or triangular. In addition to the receiving aperture 12, the spinal fusion implant 10 is preferably equipped with a pair of grooved purchase regions 60, 61 extending generally horizontally from either side of the receiving aperture 12. The grooved purchase regions 60, 61 are dimensioned to receive corresponding distal head slots 62, 63 on the insertion instrument 20 (as will be described in greater detail below), which collectively provide an enhanced engagement between the implant 10 and instrument 20.

FIGS. 6-8 detail the exemplary insertion instrument 20 according to one embodiment of the invention. The exemplary insertion instrument 20 includes an elongate tubular element 28 and an inserter shaft 44. The elongate tubular element 28 is constructed with a distal head 26 at its distal end, a distal head slot 62 at its distal end, a thumbwheel housing 38 at its proximal end and a handle 42 at its proximal end. The elongate tubular element 28 is generally cylindrical and of a length sufficient to allow the device to span from the surgical target site to a location

sufficiently outside the patient's body so the handle 42 and thumbwheel housing 38 can be easily accessed by a clinician or a complimentary controlling device.

The elongate tubular element 28 is dimensioned to receive a spring 46 and the proximal end of the inserter shaft 44 into the inner bore 64 of the elongate tubular element 28. The inserter shaft 44 is dimensioned such that the threaded connector 24 at the distal end of the inserter shaft 44 just protrudes past the distal head slots 62, 63 to allow engagement with the receiving aperture 12 of the spinal fusion implant 10. It should be appreciated by one skilled in the art that such a construction allows the inserter shaft 44 to be able to rotate freely within the elongate tubular element 28 while stabilized by a spring 46 to reduce any slidable play in the insertion instrument 20.

The handle 42 is generally disposed at the proximal end of the insertion instrument 20. The handle 42 is fixed to the thumbwheel housing 38 allowing easy handling by the clinician. Because the handle 42 is fixed the clinician has easy access to the thumbwheel 34 and can stably turn the thumbwheel 34 relative to the thumbwheel housing 38. Additionally, the relative orientation of the thumbwheel housing 38 to the handle 42 orients the clinician with respect to the distal head 26 and distal head slot 62. By way of example, the thumbwheel housing 38 holds a thumbwheel 34, a set screw 32, and a spacer 36. The inserter shaft 44 is attached to

the thumbwheel 34 and is freely rotatable with low friction due to the spacer 36. One skilled in the art can appreciate myriad methods of assembling a housing similar to the above described.

5 FIG. 6 details the distal head slot of the exemplary insertion instrument 20 coupled to the spinal fusion implant 10 through the purchase regions 60, 61. The distal head slots 62, 63 are dimensioned fit slidably into the purchase regions 60, 61 with low friction to allow accurate engagement of the threaded connector 24 to the receiving aperture 12 of the spinal fusion implant 10. In the presented embodiment,
10 the outer dimension of the threaded connector 24 is smaller than the largest outer dimension of the distal head 26 and elongate tubular element 28. Alternatively, other methods of creating a gripping surface are contemplated including but not limited to knurling or facets.

15 In order to use the system to perform a spinal fusion procedure, the clinician must first designate the appropriate implant size. After the spinal fusion implant 10 is chosen, the distal head slots 62, 63 of the inserter shaft 44 is inserted into the purchase regions 60, 61 of the spinal fusion implant 10. At that time the spinal fusion implant 10 and insertion instrument 20 are slidably engaged with one another.
20 Before the clinician can manipulate the combined spinal fusion implant 10 and insertion instrument 20, they must be releasably secured together. In order to secure

the spinal fusion implant 10 onto the threaded connector 24 of the inserter instrument 20, the clinician would next employ the thumbwheel 34 to rotate the inserter shaft 44 which in turn rotates the threaded connector 24. The rotation of the threaded connector 24 will releasably engage the receiving aperture of the spinal fusion implant 10 and stabilize the insertion instrument 20 relative to the spinal fusion implant 10.

A clinician can utilize the secured system in either an open or minimally invasive spinal fusion procedure. In either type of procedure, a working channel would be created in a patient that reaches the targeted spinal level. After the creation of that channel, the intervertebral space would be prepared. After preparation the secured device is used to place a spinal fusion implant 10 into the prepared intervertebral space. Once the implant 10 is inserted into the prepared space, the implant 10 is released from the insertion instrument 20 by rotating the thumbwheel 34 to disengage the threaded connector 24 from the receiving aperture 12. That motion removes the compressive force on the purchase regions 60, 61 between the distal head 26 and the distal head slots 62, 63 of the spinal fusion implant 10 and allows the insertion instrument to be slidably removed from the implant 10. After the threaded connector 24 is disengaged from the implant 10, the insertion instrument 20 is removed from the working channel and the channel is closed. As previously mentioned, additional materials may be included in the procedure before, during or

after the insertion of the spinal fusion implant 10 to aid the natural fusion of the targeted spinal level.

FIG. 10 illustrates a spinal fusion system 105 for performing spinal fusion
5 between adjacent cervical vertebrae, including an exemplary spinal fusion implant 110 and an exemplary cervical insertion instrument 120 provided in accordance with the present invention. The spinal fusion implant 110 may comprise of any suitable non-bone composition having suitable radiolucent characteristics, including but not limited to polymer compositions (e.g. poly-ether-ether-ketone (PEEK) and/or poly-
10 ether-ketone-ketone (PEKK)) or any combination of PEEK and PEKK. The spinal fusion implant 110 may be provided in any number of suitable sizes, such as, by way of example only, a length ranging between 11 to 14 mm, a height ranging between 5 and 12 mm, and a width ranging from 14 and 16 mm.

15 As will be described in detail below, the cervical insertion instrument 120 is configured to releasably maintain the exemplary cervical fusion implant 110 in the proper orientation for insertion. The cervical fusion implant 110 may be simultaneously introduced into a disc space while locked within the cervical insertion instrument 120 and thereafter released. The exemplary cervical fusion implant 110,
20 having been deposited in the disc space, effects spinal fusion over time as the natural bone healing process integrates and binds the implant with the adjacent vertebral

bodies. This fusion may be facilitated or augmented by introducing or positioning various materials in a space created within or adjacent to the cervical fusion implant 110. Those materials may be introduced before, during, or after the insertion of the exemplary cervical fusion implant 110. The additional material may include bone autograft harvested from the patient receiving the spinal fusion implant 10, one or more additional bone allograft, bio-resorbables or xenograft implants, any number of non-bone implants, and any number of fusion promoting compounds such as bone morphogenic protein.

10 FIGS. 11-14 depict various embodiments of the exemplary cervical fusion implant 110. Some common attributes are shared among the various embodiments. More specifically, each cervical fusion implant 110 has a top surface 31, a bottom surface 33, lateral sides 14, a proximal side 22, and a distal side 16. In one embodiment, the top and bottom surfaces 31, 33 are generally parallel. It can be appreciated by one skilled in the art that although the surfaces are generally parallel, 15 that the top 31 and bottom 33 surfaces may be angled with respect to one another to match the natural curve of the spine (i.e. lordosis or kyphosis). By way of example, implants for the cervical or lumbar regions of the spine will have anterior height greater than the posterior height to match the natural lordosis in those regions. 20 Inversely, the implants designed for implantation into the thoracic region will be manufactured with a posterior height greater than the anterior height to match the

natural kyphosis in that region. Additionally, the angled surface can aid in overall fit within the vertebral disc space.

The cervical fusion implant 110 preferably includes two receiving apertures 5 12 which are centrally aligned on the proximal side 22. The receiving apertures 12 extend inwardly from the proximal side 22 in a generally perpendicular fashion relative to the proximal side 22. Although shown as having a generally circular cross-section, it will be appreciated that the receiving aperture 12 may be provided having any number of suitable shapes or cross-sections, including but not limited to 10 rectangular or triangular.

The exemplary cervical fusion implant 110 also preferably includes anti-migration features such as anti-migration teeth 6 along the top surface 31 and bottom surface 33. Additional anti-migration features may include a plurality of proximal 15 anti-migration spikes 68 and/or distal anti-migration spikes 70 integrated vertically through the cervical fusion implant 110. The anti-migration features increase the friction between the cervical fusion implant 110 and the adjacent contacting surfaces of the vertebral bodies. That friction prohibits migration of the cervical fusion implant 110 during the propagation of natural bony fusion. It should be appreciated 20 by one skilled in the art that such anti-migration teeth 6 can be oriented in a

particular direction which will stabilize the cervical fusion implant 110 in several degrees of rotation during placement.

The cervical fusion implant 110 has one large fusion aperture 2, extending in a vertical fashion through the top surface 31 and bottom surface 33 which will function primarily as the avenue for bony fusion between adjacent vertebrae. The cervical fusion implant 110 may have a plurality of visualization apertures 4 which can also serve as an avenue of bony fusion on the lateral sides 14 via cell migration or additional adjuvants. The visualization apertures 4 serve an additional function of allowing a clinician to make visual observations of the degree of bony fusion unobscured by the lateral side 14 to facilitate further diagnosis and treatment.

FIG. 15 illustrates, by way of example, the orientation of the cervical fusion implant 110 prior to attachment to the cervical insertion instrument 120 by a clinician. One skilled in the art would appreciate that although the current embodiment shows a slidable engagement, various other methods of engagement are contemplated; such as, threadable or hooking features.

FIGS. 16-17 detail the tubular lock member 21 of the exemplary cervical inserter instrument 110. The tubular lock member 21 includes a central bore 25 dimensioned to receive the proximal end of the elongate fork member 11 therein.

The internal dimension of the central bore 25 is smaller than the largest freestanding outer dimension of the taper feature 19. As a result, the portion of the elongate fork member 11 that may be received by the central bore 25 of the tubular lock member 21 is limited by interference between the distal end of the tubular lock member 21 and the taper feature 19 of the elongate fork member 11. In the present embodiment, the outer dimension of the threaded feature 13 of the elongate fork member 11 is smaller than the largest outer dimension of the taper feature 19 on the elongate fork member 11. A thread feature 23 (not shown) is located at the proximal end of the tubular lock member 21 that in the central bore 25. The thread feature 23 matches the thread feature 13 on the elongate fork member 11 so that they can be threadably attached to one another. To ease the rotation of the tubular lock member 21 by hand, two semi-circular wings 27 may be provided protruding laterally outward from either side of the tubular lock member 21. Alternatively, other methods of creating a gripping surface are contemplated including but not limited to knurling or facets.

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A clinician can utilize the secured system in either an open or minimally invasive spinal fusion procedure. In either type of procedure, a working channel would be created in a patient that reaches the targeted spinal level. After the creation of that channel, the intervertebral space would be prepared. After preparation the secured device is used to place a cervical fusion implant 110 into the prepared intervertebral space. Once the cervical fusion implant 110 is inserted into the

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prepared space, the implant 110 is released from the cervical insertion instrument 120 by retracting the tubular lock member 21 from the elongate fork member 11 by rotating the tubular lock member 21 with respect to the elongate fork member 11 in the opposite direction from that used to initially secure the implant 110. That motion
5 removes the compressive force on the purchase region 39 between the apertures 12 of the cervical fusion implant 110 and allows the engagement features 17 to be slidably removed from the apertures 12. After the engagement features 17 are disengaged from the cervical fusion implant 110, the cervical inserter instrument 120 is removed from the working channel and the channel is closed. As previously mentioned,
10 additional materials may be included in the procedure before, during or after the insertion of the cervical fusion implant 110 to aid the natural fusion of the targeted spinal level.

In order to use the system to perform a spinal fusion procedure, the clinician
15 must first designate the appropriate implant size. After the cervical fusion implant 110 is chosen, the engagement features 17 of the elongate fork member 11 are inserted into the apertures 12 on the implant 110. At that time the cervical fusion implant 110 and elongate fork member 11 are slidably engaged with one another. Before the clinician can manipulate the combined cervical fusion implant 110 and
20 elongated fork member 11, they must be releasably secured together. In order to secure the cervical fusion implant 110 onto the elongate fork member 11, the

clinician would next employ the tubular lock member 21. The clinician would insert the proximal end of the elongate fork member 11 into the central bore 25 of the tubular lock member 21 at its distal end. The tubular lock member 21 would then be advanced over the elongate fork member 11 until the thread feature 13 of that member and the thread feature 23 of the tubular lock member 21 become engaged.

Once engaged, advancement of the tubular lock member requires rotation of the tubular lock member 21 with respect to the elongate fork member 11. Preferably, after only a small amount of engagement of the thread features the distal end of the tubular lock member 21 would contact the taper feature 19 of the elongate fork member 11. The tubular lock member 21 would be advanced creating greater interference as the distal end approaches the distal end of the taper feature 19 which has the larger outer dimension. The increasing interference would laterally displace the clamping arms 15 of the elongate fork member 11 towards each other. Since the engagement features 17 of the elongate fork member 11 were initially inserted into the apertures 12 of the exemplary cervical fusion implant 110, the displacement of the clamping arms 15 would create a compressive force on the purchase region 39 separating the apertures 12 of the exemplary cervical fusion implant 110. That compressive force allows a clinician to manipulate the system without the exemplary cervical fusion implant 110 from becoming disengaged from the cervical inserter instrument 120.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the description herein of specific embodiments is not intended to limit the invention to the particular forms disclosed, but on the contrary, the invention is to cover all modifications, equivalents, and alternative falling within the spirit and scope of the invention as defined by the appended claims.

For example, while described herein primarily with reference to the lumbar and cervical spinal surgery, it is to be readily appreciated that the spinal fusion implants of the present invention may be suitable for accomplishing fusion in the thoracic spine without departing from the scope of the present invention. Moreover, it is to be readily appreciated that the insertion tools described herein may be employed with implants of any number of suitable constructions, including but not limited to metal, ceramic, plastic or composite.

ABSTRACT

A system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites.

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28

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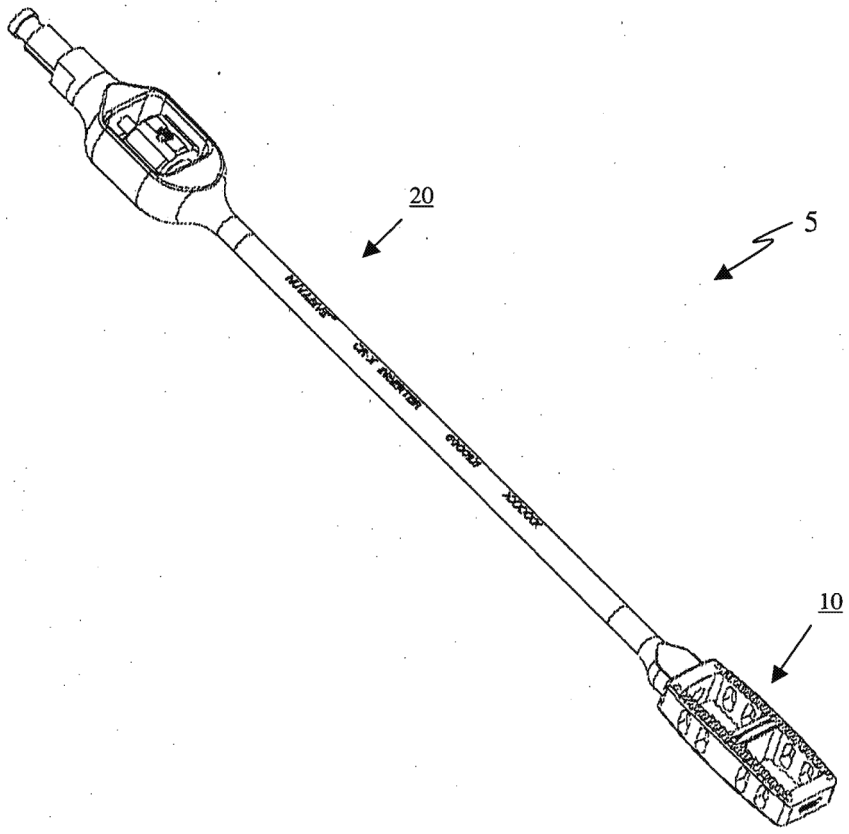


FIG. 1

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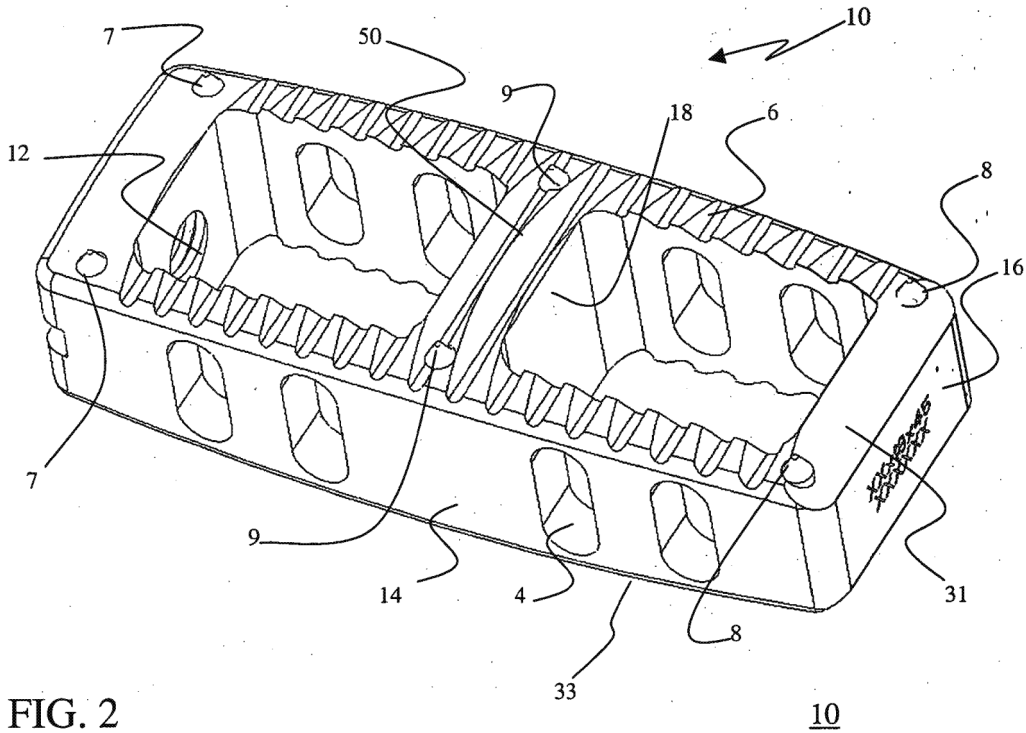


FIG. 2

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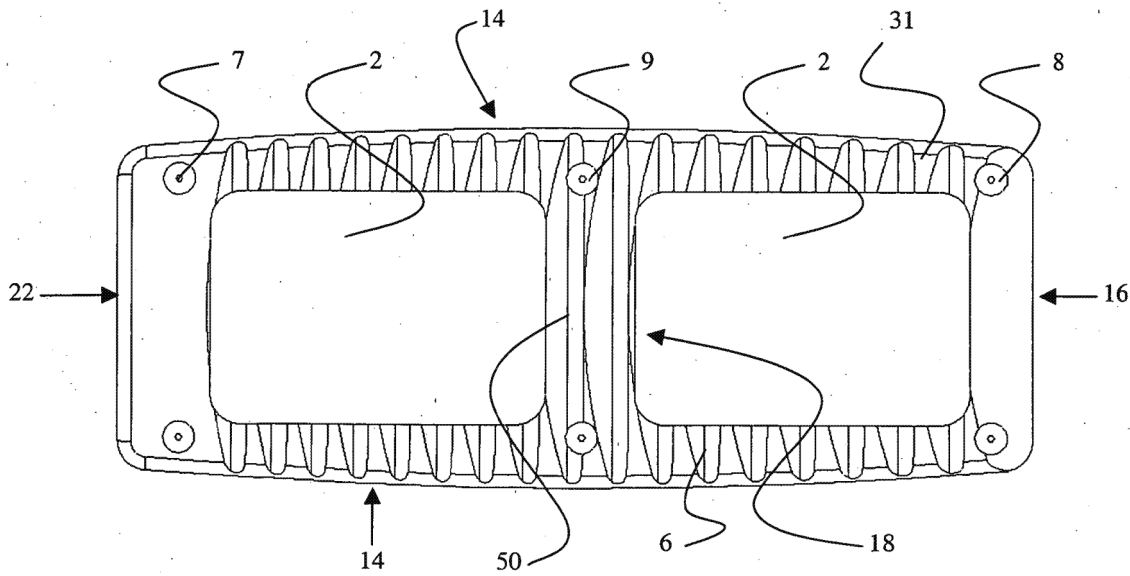


FIG. 3

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NUVA_ATEC0020837

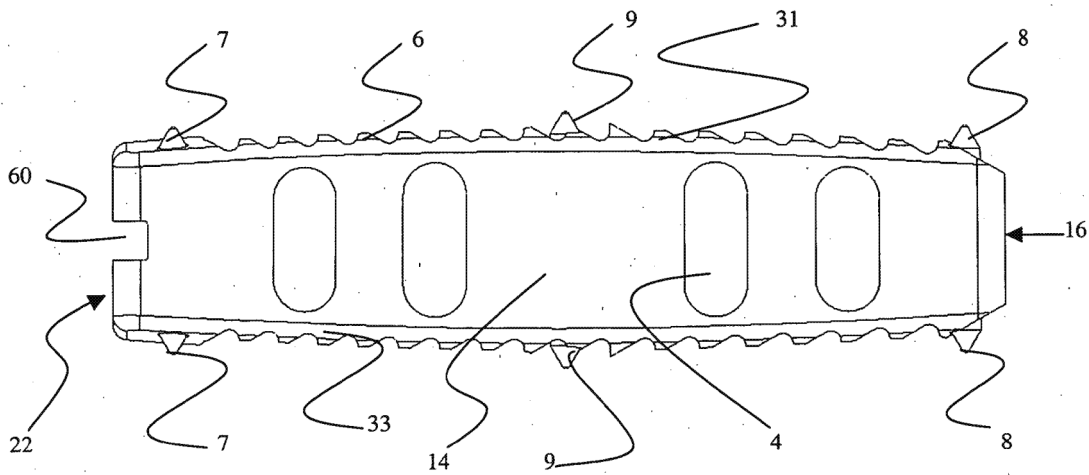


FIG. 4

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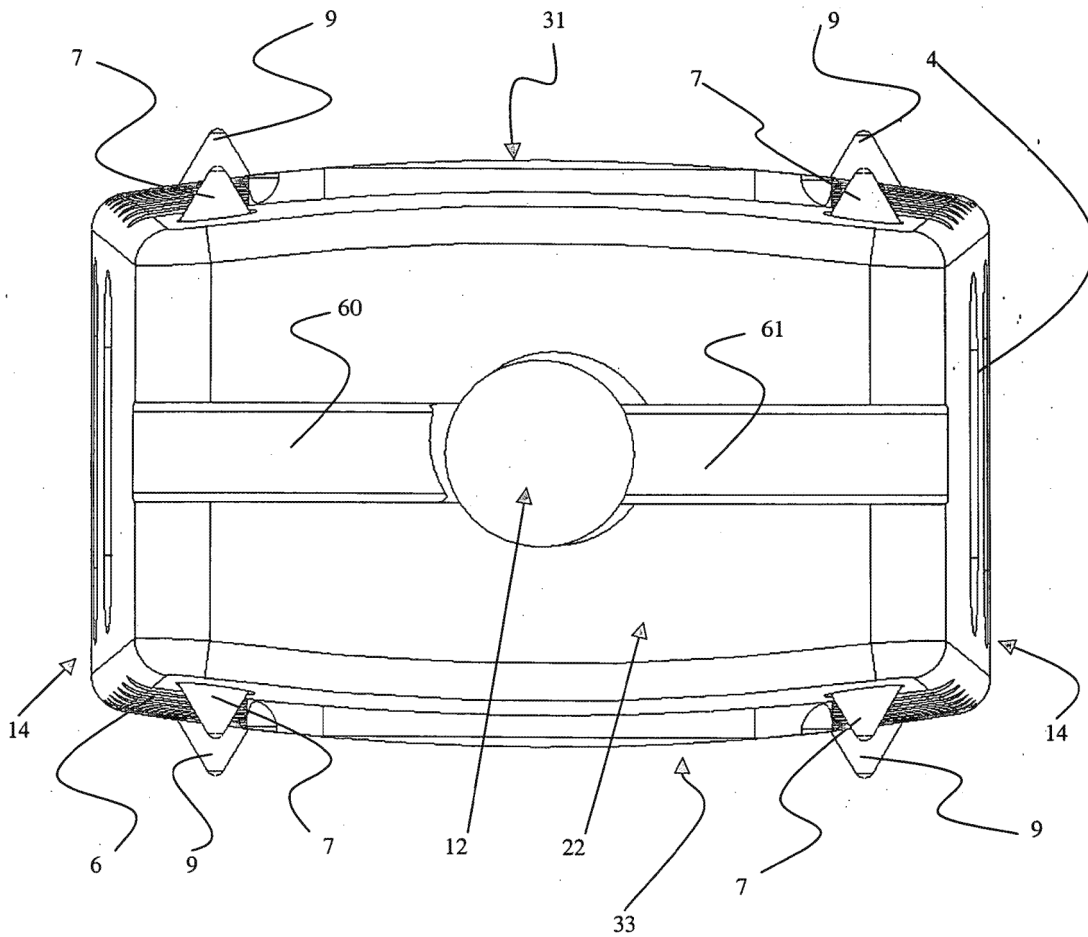


FIG. 5

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NUVA_ATEC0020839

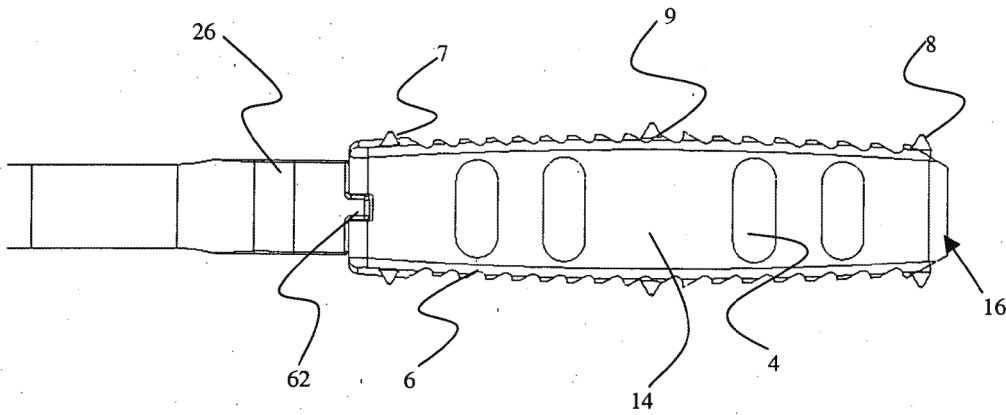


FIG. 6

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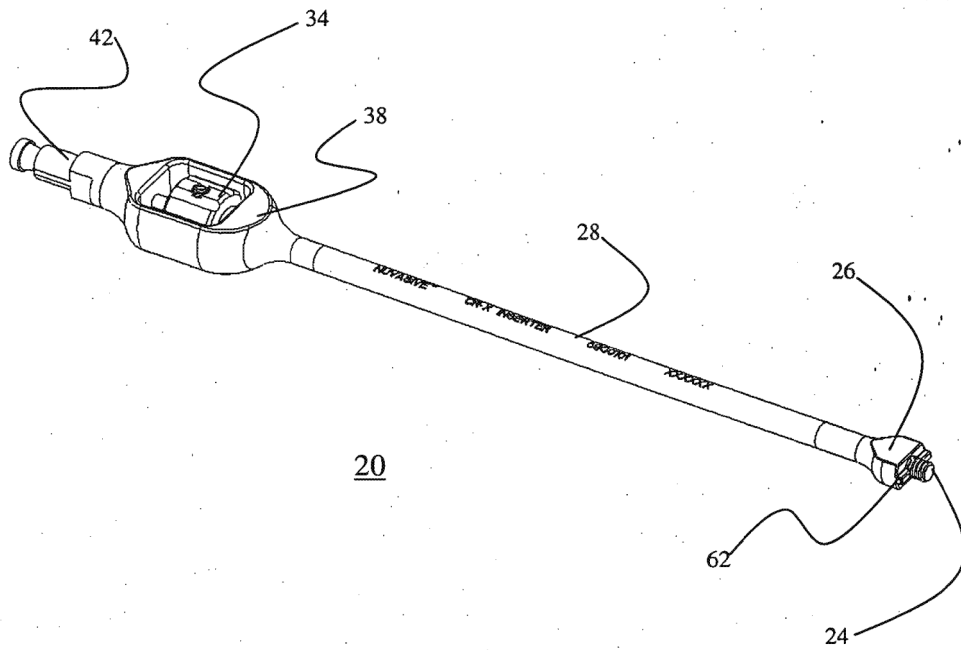


FIG. 7

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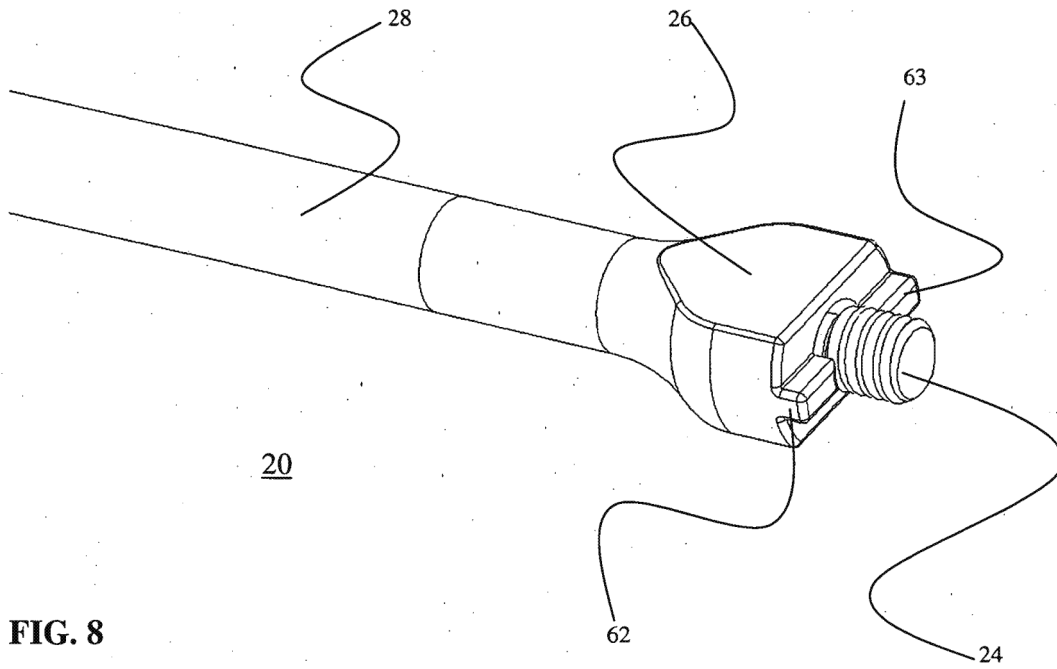


FIG. 8

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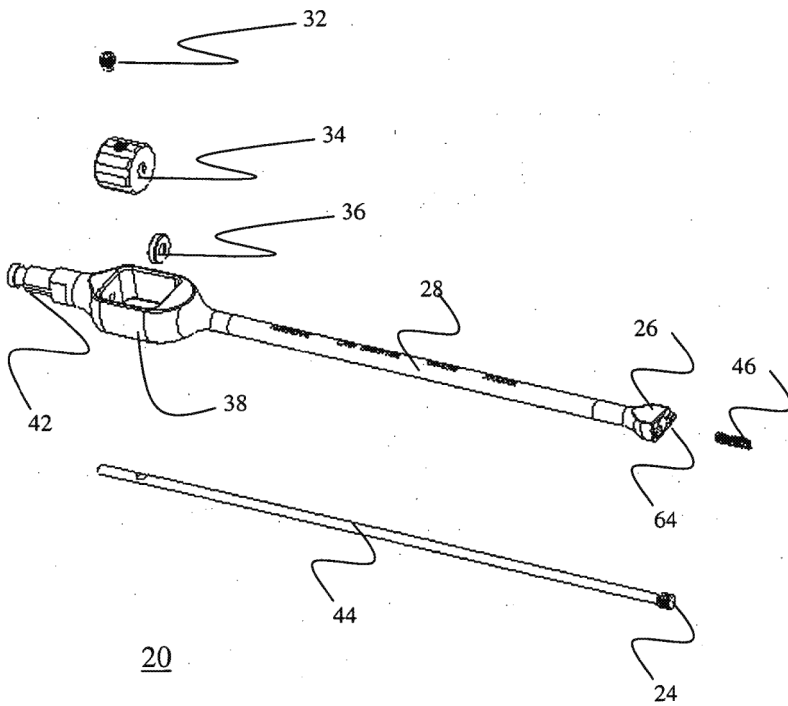


FIG. 9

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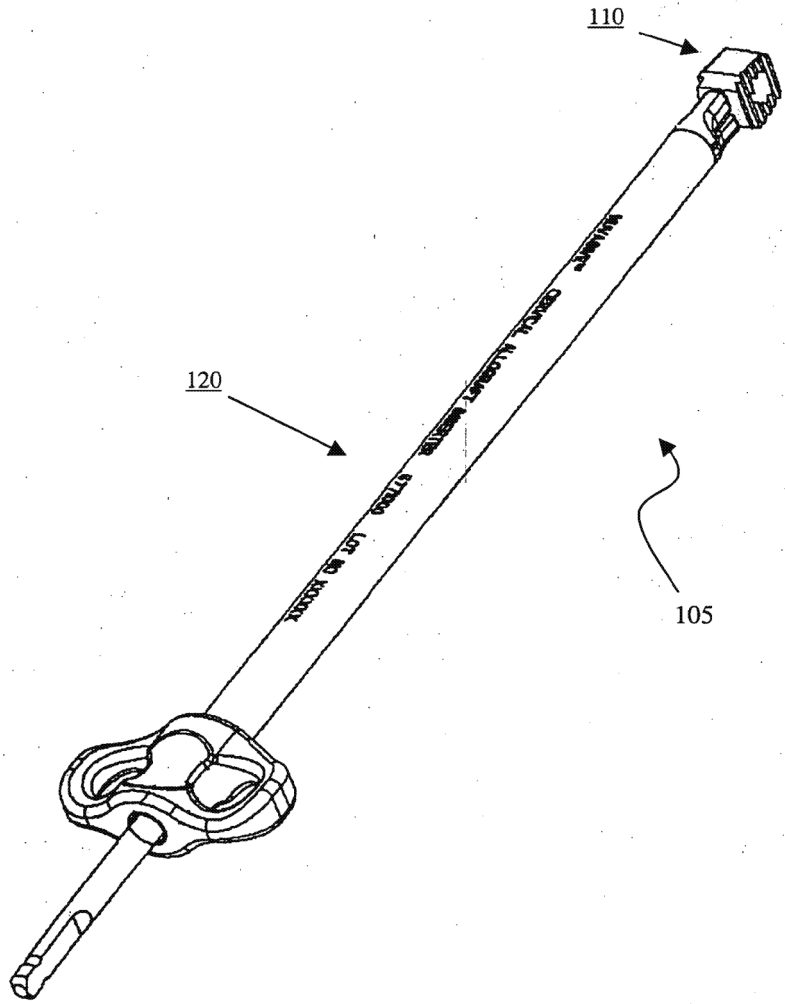


FIG. 10

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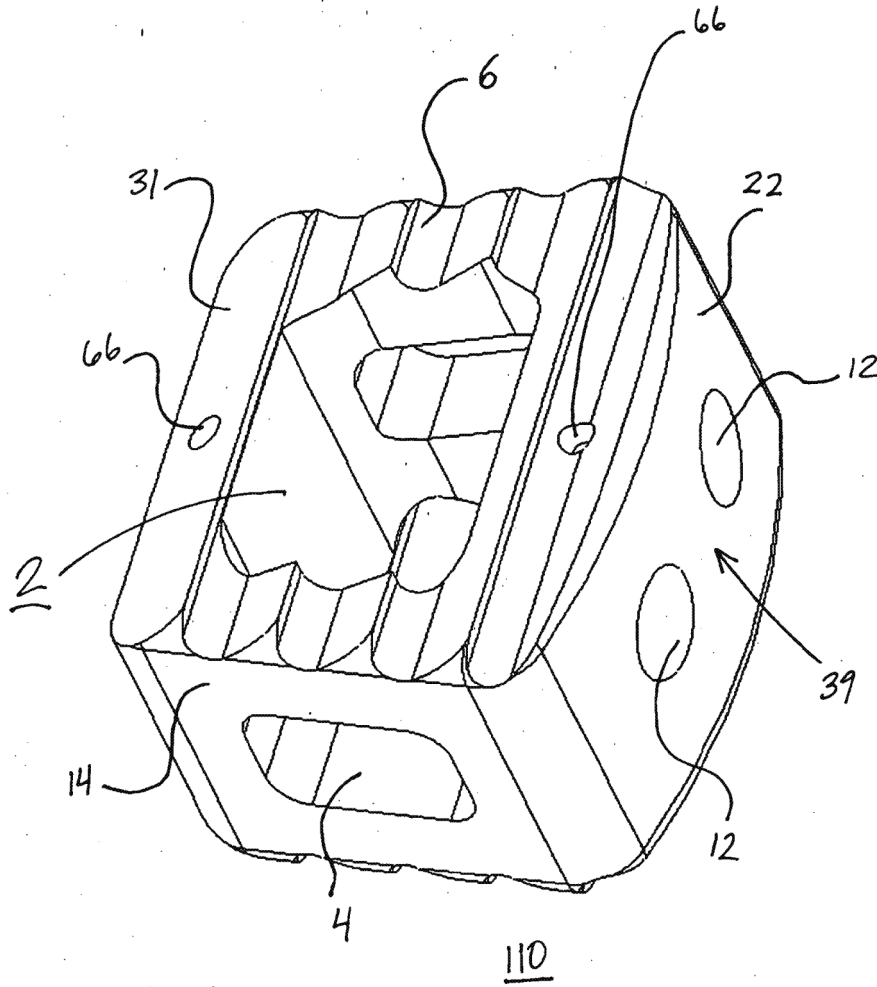
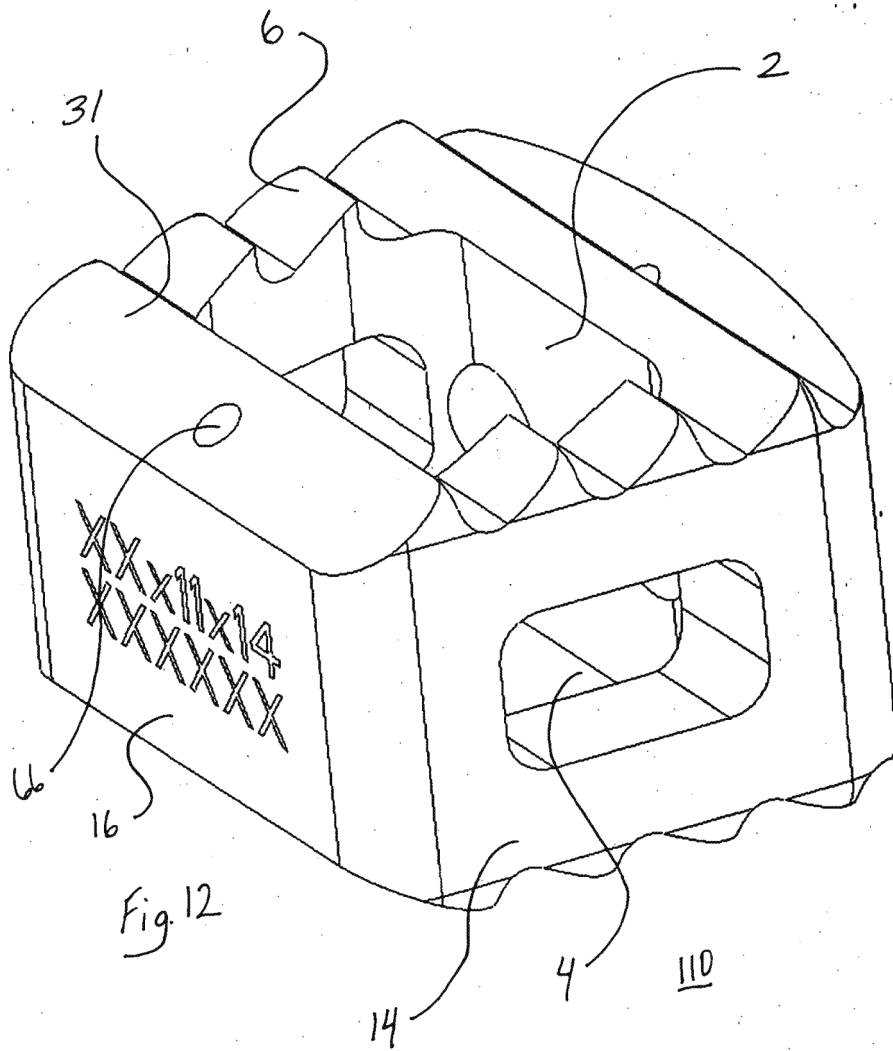


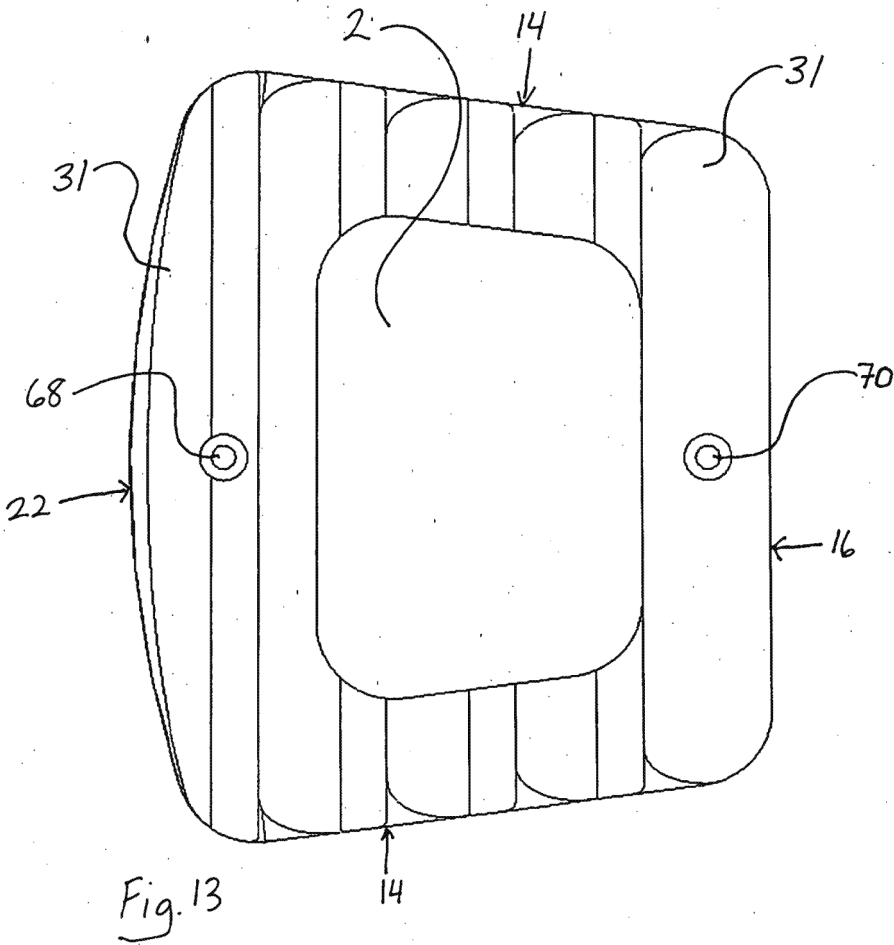
Fig. 11

110

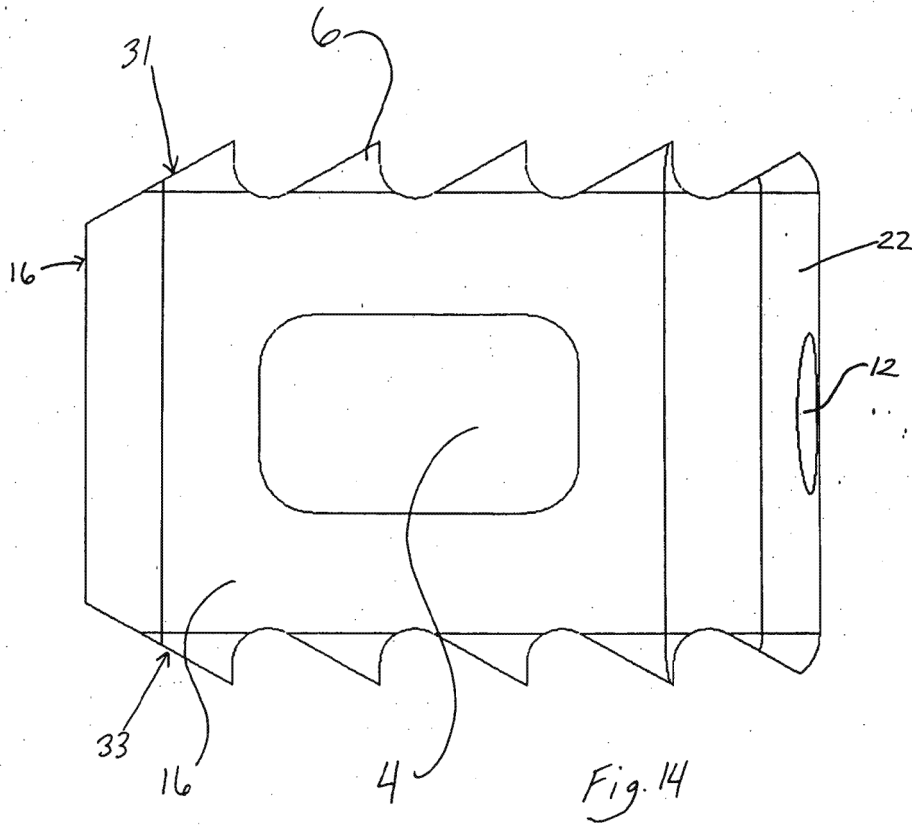
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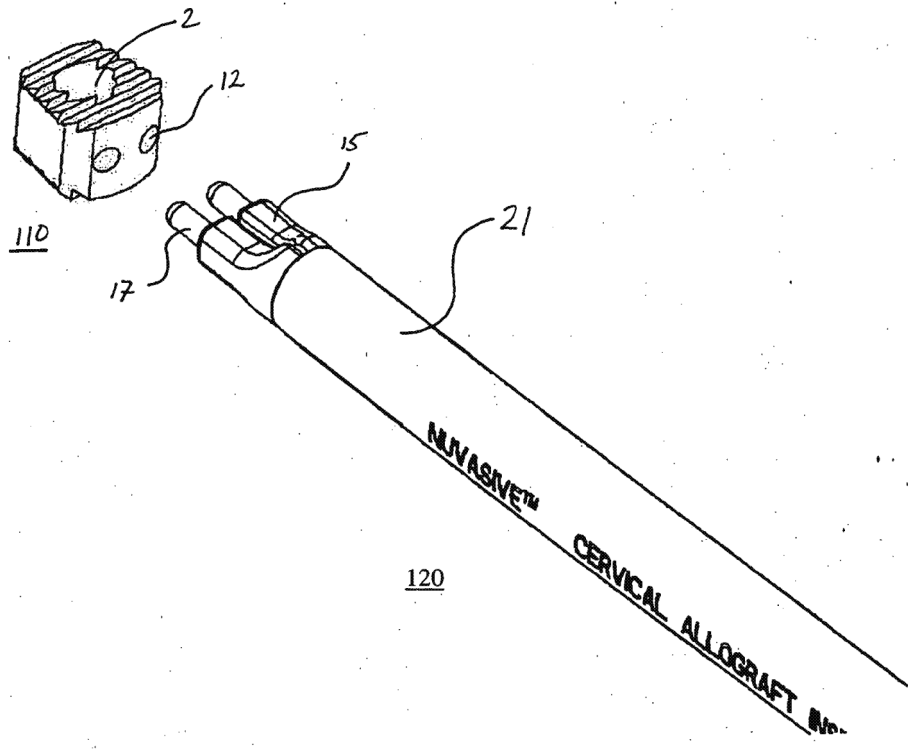


FIG. 15

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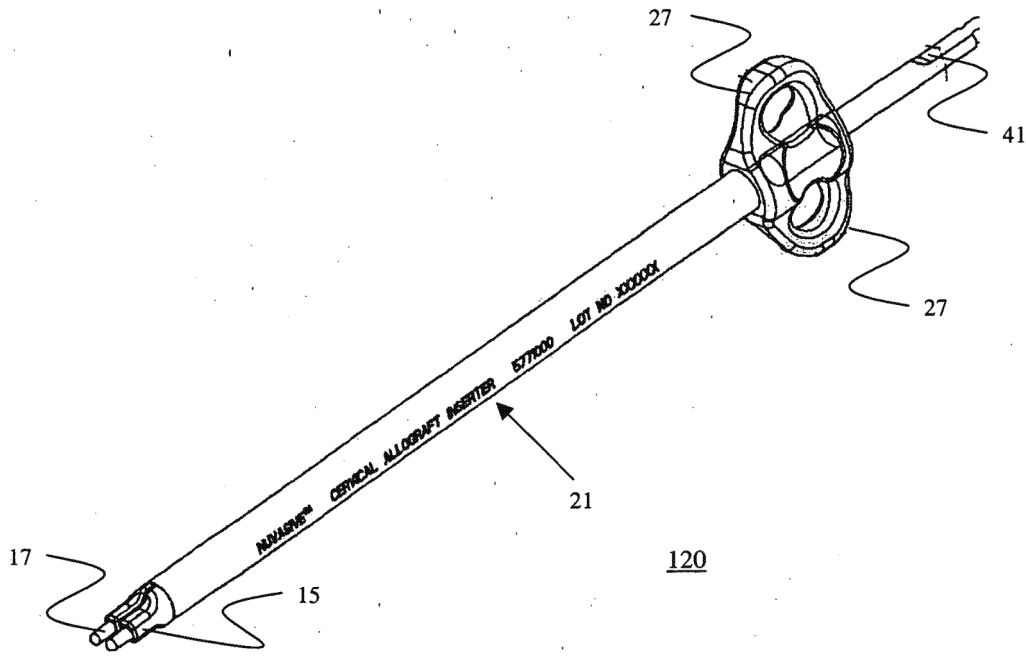


FIG. 16

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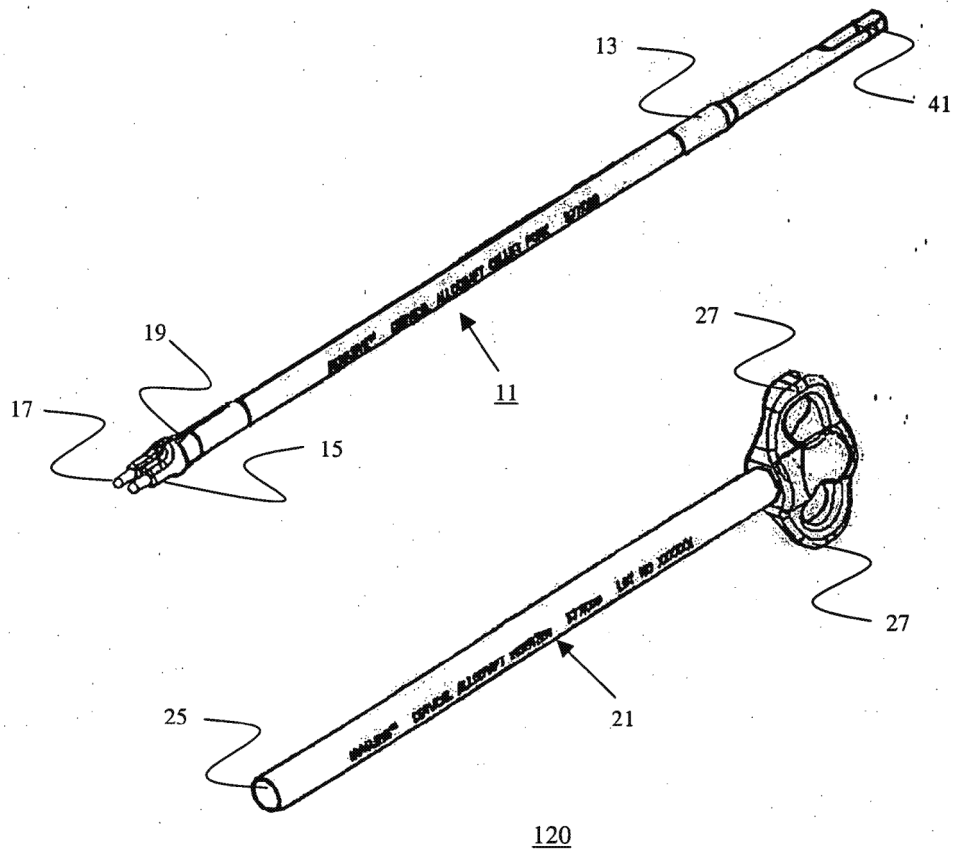


FIG. 17

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60/557,536	03/29/2004	Matthew Curran	104 PRV

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10065 OLD GROVE ROAD
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CONFIRMATION NO. 3587
FORMALITIES LETTER



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Date Mailed: 06/01/2004

NOTICE TO FILE MISSING PARTS OF PROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(c)

Filing Date Granted

An application number and filing date have been accorded to this provisional application. The items indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

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Applicant must submit \$ 80 to complete the basic filing fee for a small entity.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(l) of \$25 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

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