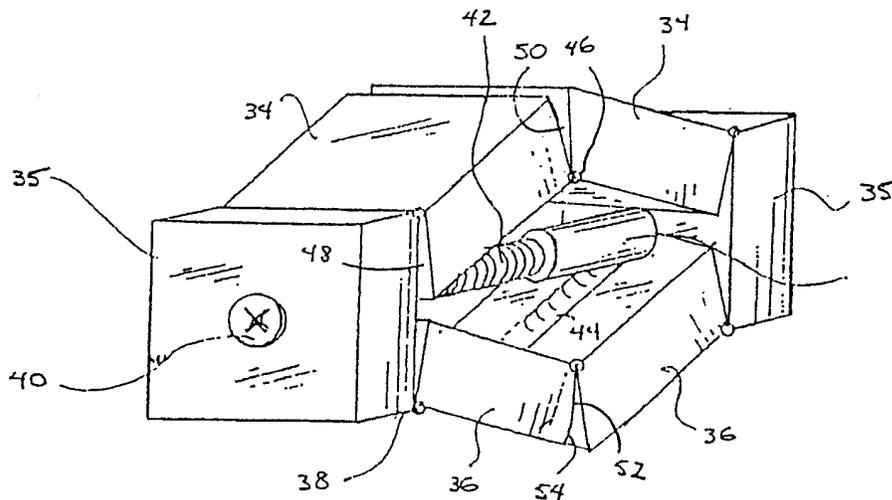




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(54) Title: MIDDLE EXPANDABLE INTERVERTEBRAL DISK IMPLANT AND METHOD



(57) Abstract

Artificial disk implant and methods for implanting same, the implant having a member (32, 34, 36, 77, 92, 94) for adapting in size and shape to the anatomical space between vertebrae, and apparatus (25, 42, 60, 112) for expanding the implant in the middle portion thereof to conform to the space. In one embodiment, there is provided an artificial intervertebral disk implant having a cylindrical body (20, 41, 56, 88) comprised of cylindrical subunits (32, 34, 36, 92, 94) capable of expansion. In another embodiment, rectangular members (34, 36) or elongate ribs (77) capable of expansion are provided. The implant can be used alone or in various combinations for the purpose of spinal fusion.

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MIDDLE EXPANDABLE INTERVERTEBRAL DISK IMPLANT AND METHOD

BACKGROUND OF THE INVENTION

This invention relates to an intervertebral disk implant and a method of implanting same. More specifically, the present invention relates to cylindrical and rectangular disk implants which are expandable in the middle portion which are used alone or in various combinations for the purpose of spinal fusion.

The spine is a flexible structure comprised of thirty-three vertebrae separated and cushioned from each other by fibrous intervertebral disks. If the spine is injured or becomes diseased, surgical intervention involving removal of one or more disks, and fusion of the adjacent vertebrae, may be indicated. The more frequent injuries are in the lower lumbar and in the lower cervical regions.

Treatment of a herniated disk in the neck and in the lumbar region continues to be a challenging field of medicine. The classical treatment for a ruptured disk continues to be diskectomy, i.e., removal of the disk from between the vertebrae. In this process, all or a portion of the intervertebral disk is removed, leaving a defect which continues to bother the patients throughout the rest of their lives. An additional procedure is to replace the disk space with a bone graft, usually bone chips cut from the patient's iliac crest, bringing about fusion of the vertebrae above and below the disk, eliminating the empty space between the vertebrae.

Theoretically, a diskectomy with fusion is a satisfactory procedure, though not ideal because the replaced bone does not have any of the functions of the cartilage tissue of the disk, i.e. no cushioning effect,

-2-

and has complications because of several factors. First, the bone plug used to pack the disk space does not conform to the shape of the disk because the disk bulges maximally in the center. The disk space is wider in the middle and narrower at its anterior and posterior ends. Consequently, a bone plug having its maximum width at the center, e.g., one which is shaped to fit the space, cannot be inserted through the narrow mouth of the disk space. For this reason, the various bone plugs which are currently available commercially have only four contact points, i.e. at the front and back of the disk space. Secondly, access to the disk is from one side or the other of the dorsal spine of the adjacent vertebrae, leaving a space that is "off-center" relative to the bodies of the adjacent vertebrae. An implant inserted into that off-center space, therefore, replaces only a portion of the disk and consequently contacts only a portion of the bodies of the adjacent vertebrae such that the stability of the implant is even more problematical than might be apparent from the limited contact resulting from the shape of the intervertebral space in the first place. Another complication is the possibility of infection or other conditions which may require the removal of the implant. Also, if the bone pieces do not fuse, they may eventually extrude out of the disk space, causing pressure on the nerve roots.

Various prosthetic disk plugs, or implants, are disclosed in the art, but all are characterized by limitations of not conforming to the shape of the disk space, lack of stability when inserted off-center, inability to be removed, or other disadvantages. For instance, U.S. Patent No. 4,863,476 describes an elongated body divided longitudinally into two portions having a cam device movable therebetween for increasing the space between the two body portions. However, that device is

-3-

generally cylindrical in shape such that the only contact points are at the front and back of the disk space, creating increased likelihood of instability and generally rendering that device unsuitable for use after partial
5 diskectomy. The art also discloses intervertebral disk prostheses (e.g., U.S. Patent Nos. 3,867,728, 4,309,777, 4,863,477 and 4,932,969 and French Patent Application No. 8816184) which may have more general contact with the adjacent disks, but which are not intended for use in
10 fusion of the disks. The art also includes spinal joint prostheses such as is described in U.S. Patent No. 4,759,769, which is again not indicated for use when fusion is the preferred surgical intervention.

From this prior art, it is apparent that there has
15 long been a need for a disk plug, or implant, capable of supporting the disk space after a simple diskectomy for fusion of adjacent vertebrae, and the object of the present invention is to provide such an implant.

SUMMARY OF THE INVENTION

20 An intervertebral disk implant is described for implantation into the disk space after surgical removal of all or a portion of a diseased or damaged disk. Implants according to this invention include means for changing the shape of the implant to adapt to the shape of the disk
25 space by expanding the implant to conform to the contour of that space, and are, for that reason, referred to herein as being "middle expandable".

In one embodiment, there is provided an intervertebral disk implant with a cylindrical body comprised of subunits
30 capable of radially outward expansion. In another embodiment, there is provided an implant having a substantially rectangular body likewise comprised of subunits capable of radially outward expansion. Both are disk plugs expandable in the middle portion to provide

-4-

contact with substantially the entire area of the disk space against the vertebral bodies.

In the method of the present invention, there is provided a method of fusing two adjacent vertebrae after
5 removal of all or a portion of the disk from therebetween which comprises inserting a disk implant into the space from which the disk has been removed, expanding the middle portion of the implant outwardly in a radial direction, injecting cancellous bone chips into the disk space medial
10 to the implant, and applying a physiologically compatible adhesive over the bone chips medial to the implant to close off the opening of the disk space.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, Figure 1 is a projected view of one
15 embodiment of the disk implant of the present invention.

Figure 2 is a cross sectional view of the disk implant of Fig. 1 taken along the line 2-2 in Fig. 1.

Figure 3 is a projected view of the central axis of the disk implant of Fig. 1 having the members coiled
20 therearound removed therefrom.

Figure 4 is a projected view of the implant of Fig. 1 after expansion of the middle portion thereof.

Figure 5 is a projected, exploded view of a second embodiment of the disk implant of the present invention.

25 Figure 6 is a projected view of the implant of Fig. 5 showing that implant after expansion thereof.

Figure 7 is a top, plan view of a lumbar vertebra of a human patient having a top, plan view of the implant of Fig. 6 superimposed thereon to show the spatial
30 relationship of the implant to the adjacent vertebrae after insertion into the disk space.

Figure 8 is a projected view of another embodiment of the implant of the present invention.

35 Figure 9 is a projected view of the disk implant of Fig. 8 after expansion of the middle portion thereof.

-5-

Figure 10 is an exploded, projected view of a fourth embodiment of the implant of the present invention.

Figure 10A is a side view of two hinged members comprising the middle portion of the implant of Fig. 10 and removed therefrom.

Figure 11 is a projected view of a fifth embodiment of the disk implant of the present application.

Figure 12 is a cross sectional view of the disk implant of Fig. 11 taken along the line 12-12 in Fig. 11.

Figure 13 is a side view of the disk implant of Fig. 11 showing a portion broken away therefrom.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 depicts a cylindrical embodiment of the disk implant of the present invention. The disk implant 20 shown in that figure is comprised of a strong, thin non-porous material. Suitable materials for the disk implant 20 include modified carbon, titanium, steel, metals and/or metal alloys having a memory (see below), physiologically inert and/or medically compatible polymers such as a urethane or DELRIN® polymer, or any generally rigid, biologically compatible material used for surgical implants. It is also useful to use a material which is compatible with magnetic resonance imaging (MRI) procedures. The disk implant 20 is comprised of a plurality of longitudinally aligned sections, or subunits 22, 24 and 26, and a screw 28 to which each section is mounted (as described below) is turned to cause differential, radially outward expansion of subunits 24 and 26. The subunits 24 and 26 are preferably comprised of a material capable of maintaining spring tension and are mounted to and wound around an elongate longitudinal axis in the form of central rod 25 (see Figs. 2 and 3) integral with screwhead 28. Because of this structure, each of the subunits is conveniently referred to as including a coiled member as identified at reference numeral 32.

-6-

Each coiled member 32 is mounted to central rod 25 by welding, riveting, or by other manner depending upon the material(s) comprising the sheet 32 and central rod 25 as known in the art. In the preferred embodiment shown in
5 Figures 1-4, the central rod 25 is provided with a flat 23 to provide a stable surface for mounting of the member 32 thereto by, for instance, welding. At the other, free end of each coiled member 32, the coiled member 32 is beveled as at reference numeral 33 so as to provide a smooth,
10 generally round exterior surface on each of the subunits 24 and 26 and to facilitate the sliding of the free end of coiled member 32 along the outside surface thereof as the subunits 24 and 26 are expanded radially outwardly as described below.

15 A Phillips head-type slot 18 is provided in the screwhead 28 for rotation of the rod 25 as described below, and the head 28 is provided with a plurality of teeth 19 for interdigitating with the reciprocal cavities in the lock nut 21 to prevent undesired rotation of central rod
20 25. The Allen screws 30 are loosened to force lock nut 21 away from the end surface 27 of subunit 22 so that the teeth 19 on the head 28 of central rod 25 are disengaged from the cavities in lock nut 21 to allow rotation of screwhead 28 and rod 25. Alternatively, either or both of
25 rod 25 or lock nut 21 is comprised of a resilient, medically compatible polymer material which allows rotation of the teeth 19 past the cavities in lock nut 21 in one direction but not the other. The expanded shape of a section of the disk implant 20 is shown in Figure 2.

30 Turning screwhead 28 and central rod 25 using the slot 18 expands the sections 24 and 26, which remain expanded due to the interaction of the teeth 19 and the cavities in lock nut 21 and the compression of the implant 20 between the bodies of the vertebrae above and below the implant 20
35 once inserted into the disk space. In other words,

-7-

engagement of the free end of coiled member 32 by the adjacent vertebrae prevents the slipping of the free end of the coiled member 32 around the outside circumference of implant 20 such that members 32 do not "re-wind" after
5 being expanded.

As shown in Figure 3, central rod 25 is provided with a portion 29 approximately mid-way between the ends thereof having a larger diameter than the rest of the central rod 25. By use of the central rod with sections of different
10 diameters and/or thicknesses of the cylindrically wound member 32, the subunits 24 and 26 are differentially expanded. Turning screw 28 allows for maximal expansion of the subunit 26 and moderate expansion of the subunit 24 because the member 32 comprising subunit 26 is mounted to
15 the rod 25 on the portion 29 of larger diameter while each of the members 32 comprising subunits 22 and 24 is mounted to central rod 25 between the portion 29 and the subunits 22. Turning the central rod 25 uncoils the members 32 because each member 32 is attached to the central rod 25.

20 Figure 4 illustrates the cylindrical disk implant 20 in its radially expanded form. Once expanded, the implant cannot be removed from the disk space except by turning the allen screws 30 to either back out or remove lock nut 21, thereby allowing rotation of rod 25.

25 Referring now to Figures 5 and 6, an alternative embodiment of the implant 20 is shown at reference numeral 56. Implant 56 is comprised of a single piece of metal, such as a titanium alloy, or medical grade polymeric plastic, such as DELRIN®, which is resilient and has a
30 memory for the shape in which it is molded, shown in Fig. 6. Implant 56 is molded in the same generally elongate, cylindrical shape as the implant 20 shown in Figs. 1-4, but is molded in a shape in which the middle portion 58 thereof is normally expanded radially outwardly from the central
35 axis of the cylinder. An elongate screw 60 is provided

-8-

having two sets of threads 62 and 66 thereon, the former for engaging the threads 68 formed in the bore 70 extending longitudinally through implant 56, the latter for engaging a similarly formed set of threads located in the bore 70 at the other end of implant 56 and therefore not visible in Figures 5 and 6. A slot 72 is formed in the head 74 of screw 60 for turning screw 60 to move the opposite ends 76a and 76b of implant 56 away from each other, thereby extending implant 56 and decreasing the radially outward expansion of the middle 58 thereof as shown in Fig. 5 for insertion into the disk space. Longitudinal slots 75 are molded into implant 56 to form ribs 77 which flex to allow the extension and outward expansion of implant 56 in this manner.

As noted above, the instability of prior implants once inserted into the disk space is problematical, and Fig. 7, showing the implant 56 in place relative to the body 78 of an adjacent lumbar vertebra 80 illustrates how the apparatus of the present invention overcomes this limitation of prior implants. The implant 56 is inserted into the disk space in an anterior-posterior (A-P) orientation, the dorsal spine 82 of vertebra 80 being pointed posteriorly. As clearly shown in Fig. 7, when so positioned, implant 56 occupies only a portion of the surface area of the vertebral body 78, the remainder of the area being occupied by that portion of the intervertebral disk (not shown) which is not removed during the diskectomy procedure (or, in a fusion procedure, this area is packed with cancellous bone chips). Access to that area is from the posterior aspect of the disk medial to the implant. In addition, the periphery 88 of vertebral body 78 is, as described above, thicker than the central portion 90 of body 78, further limiting access and creating an uneven surface on which the body 78 bears on the implant. However, because of the expansion of only the middle 58 of

-9-

implant 56, the implant 56 is stable in the A-P orientation shown. Once implanted, the screw 60 is backed out of the bore 70 in implant 56 and implant 56 assumes the shape shown in Figs. 6 and 7.

5 Figure 8 depicts a rectangular disk implant 31 constructed according to the present invention. Turning Phillips head 39 of screw 42 encapsulated in a sheath 44 (best shown in Fig. 9) formed in the hinged members 34 and 36 forming intermediate subunits in the same manner as the
10 subunits, or sections, 24 and 26 of implant 20 causes the radially outward expansion of superior hinged members 34 superiorly and inferior hinged members 36 inferiorly. Although shown in Figures 8 and 9 with two of the hinged members 34 and 36, it will be understood by those skilled
15 in the art who have the benefit of this disclosure that the plug, or implant, 31 may be provided with four, eight, or even more of the hinged members 34 and 36 as shown at reference numerals 92 and 94 in Figure 10 and numeral 41 in
20 Figures 11-13. The expanded shape of the rectangular disk plug 31 is illustrated in Figure 9. Hinged members 34 and 36 are secured to an end cap or subunit 33 by hinge 38 and to each other by hinge 46. Upon rotation of screw 42 using a conventional screwdriver and the Phillips head slot 39, the end caps 33 are drawn closer together by movement along
25 the threads of screw 42. To insure that the members 34 and 36 expand radially outwardly from screw 42, the ends 48 of each respective member 34 and 36 abutting the end caps 33 are angled so as to create a force vector outwardly away from screw 42 when end cap 33 exerts pressure on the
30 surface 48, the hinge 38 being mounted in the acute angle formed by surface 48 and end cap 33.

In one embodiment (best shown in Figures 11-13 and discussed below), the tendency of this force vector to cause the members 34 and 36 to expand is increased by
35 angling the face 50 of one member 34 or 36 in the same

-10-

direction as the angle in the surface 48. The surface 52 of the opposed member 34 and 36 is similarly angled, but with a bearing surface 54 formed therein that is angled in the same direction as the angle in surface 48 and face 50 so that the face 50 rides upwardly onto bearing surface 54 to translate the opposed, end-to-end force vectors applied to end caps 33 by rotation of screw 42 into a force vector having a radially outward (from screw 42) component. By referring to Figures 11-13, it can be seen that the radially outward expansion of the middle portion of implant 31 caused by rotation of the screw 42 effectively simulates the opening of two opposed umbrellas, and the particular embodiment shown in those figures may be conveniently referred to as having a "double umbrella" configuration.

A threaded lock nut 40 is inserted over Phillips screw head 39 (see Figure 8). Lock nut 40 prevents the members 34 and 36 from moving once expanded. Removing lock nut 40 provides access to screw head 39 to allow members 34 and 36 to return to the position shown in Figure 8.

The above-referenced, double-umbrella configuration of the implant of the present invention is illustrated at reference numeral 88 in Figure 10. In this embodiment, the hinged members 92 and 94 are mounted on pivot pins 96 to the first and second end members 90 and 98, respectively, as well as to each other, most of the pins 96 and all but two sets of the hinged members 92 and 94 being omitted from the figure for purposes of clarity. The pivot pins 96 which mount members 92 and 94 to the ends 90 and 98 are received within the bores 100 and 102 formed in each end member 90 and 98, the bores 100 and 102 being numbered separately to draw attention to their arrangement on the end members 90 and 98. The ears 104 on hinged members 92' and 94' are longer than the ears 106 on hinged members 92'' and 94'' and the bores 100, for receiving the pivot pin 96 are located closer to the end surface 108 of end member 90

-11-

(and the corresponding end surface of end member 98 at the opposite end of implant 88) than the bores 102. By this arrangement, the strength of the implant 88 is significantly increased.

5 Expansion of the middle portion of implant 88 is accomplished by turning the screw 112 using the hex head 114 formed at one end thereof, the other end of screw 112 being received by the threads 115 formed in the second end member 98. To increase the tendency of the hinged members
10 92 and 94 to expand in the radially outward direction, the holes in the hinged members 92 and 94 in which pivot pins 96 reside are offset along the longitudinal axis of implant 88. The offset holes are better shown in Figure 10A in which one pair of the members 92 and 94 is shown in side
15 view removed from implant 88. The direction of expansion is shown by the arrow 95 in Figure 10A and, as can be seen, the center holes 97 are offset outwardly (e.g., in the direction of arrow 95) relative to the holes 99 at the ends of hinged members 92 and 94 (e.g., in the ears 106).

20 A lock nut 116 having threads 118 formed in the outside surface thereof is received by the threads 120 formed in the bore 122 in end member 90 through which the screw 112 is received for preventing undesired rotation of screw 112. Lock nut 116 is provided with a hex slot 124 to
25 facilitate insertion and/or removal and hex slot 124 extends all the way through lock nut 116 and is of large enough size that a hex key can be inserted through slot 124 and into hex head 114 for turning screw 112 without adjustment of lock nut 116.

30 Another embodiment of the double-umbrella configuration of the implant of the present invention is shown at reference numeral 41 in Figures 11-13. As is the case with the implant 88 shown in Figure 10, the implant 41 is generally cylindrical in shape, yet utilizes the hinged
35 member 34 and 36 construction of implant 31 shown in

-12-

Figures 8 and 9. Figure 12 shows a projected view of the disk implant 41 shown in Figure 11 having the members 34 and 36 cut in section. This view shows how the hinged members 34 and 36 fit together in the unexpanded position due to their beveled sides 64, giving the implant 41 its generally cylindrical shape. The sides 110 of the hinged members 92 and 94 of implant 88 are similarly beveled (Figure 10).

All of the disk implants of the present invention are expandable in the middle portion, i.e., the portion intermediate the ends, to contact substantially the entire anterior-posterior dimension of the disk space against the vertebral bodies as described above in connection with the description of Figure 7. If a complete intervertebral fusion is being performed, the plug is used in conjunction with intervertebral cancellous bone packing. Because of the support provided by the plug, until fusion is established, the cancellous bone pieces have a better chance of fusion due to the presence of the implant, and the bone pieces and the disk implant have a better chance of staying in the intervertebral disk space. Alternatively, the plug is used to maintain the spacing between vertebrae and can be used in conjunction with intertransverse posterior lateral fusion. In short, the implant acts as a physiological support for the rest of the patient's life or until a bone fusion is established.

The disk implant of the present invention may have additional indications, e.g. short segment scoliosis, where the curvature of the spine can be corrected by distracting the vertebral bodies on the inside of the curvature. By expanding the middle portion of the plug inside the disk space, the vertebral bodies are distracted, thereby helping straighten the spinal column.

If no bone graft is planned, discectomy can be made minimally through one side exposure so that when the disk

-13-

plug is inserted and expanded, it will occupy the empty space. Because there is no further movement at this disk space, the chance of recurrent disk herniation is minimized. Also, the likelihood of recurrent disk herniation due to opening and closing of the space on the side of the diskectomy is reduced because the disk plug closes this mouth. Consequently, in addition to the advantages of a one sided, simple diskectomy, the risk of recurrent disk herniation can be reduced.

10 The cylindrical 20, 41, 56, and 88 and rectangular 31 implants are inserted after a simple diskectomy. Ordinarily, the size of the disk implant is approximately 2.5 to 3.5 centimeters in length and 1.0 to 1.5 centimeters in height and width. The same plug in smaller dimensions is used in thoracic and cervical levels where indicated.

15 By reference to the figures, it can be seen that both the rectangular and the cylindrical implants have the common feature of being expandable in the middle without changing the diameter of the dimensions of the two ends. Consequently, surgery is performed as in simple diskectomy, and the disk is exposed through a small laminotomy. The disk material is removed and any nerve root compression is corrected. The posterior longitudinal ligament and disk cartilage are removed until the vertebral surfaces are exposed above and below the disk space. The shape of the disk space determines whether the disk plug used is cylindrical or rectangular. The disk plug is then inserted and hammered into place so that the anterior end of the disk plug almost touches the anterior longitudinal ligament. Subsequently, using a Phillips screwdriver, the posterior screw end is turned. This implant method also gives good distraction to the vertebral bodies. In the case of simple disk problems, no further treatment may be required.

-14-

When used in interbody fusion, cancellous bone chips are made into very fine particles and pumped into the disk space medial to the disk plug and packed into the space. The posterior longitudinal ligament is intact to the opposite side and to the center of the disk space. These cancellous bone chips are held tightly in place. Since the mouth of the disk space is closed with the disk plug, the risk of the cancellous bone chips coming out is minimized. Also, the disk plug prevents the opening and closing of the disk space, thus preventing the bone chips coming out. If necessary, a small amount of a physiologically compatible adhesive of a type known in the art is applied over the cancellous bone chips just medial to the disk plug to close off the remaining portion of the opening of the disk space. The patient should be able to ambulate soon after the surgery because of the stability given by the disk plug. Before narrowing of the disk space occurs, the cancellous bone chips will have started the fusion process.

If a posterior lateral intertransverse fusion is desired, this procedure is also done in conjunction with the middle expandable disk plug. The disk plug is applied as explained above and the posterior lateral fusion performed. Since the disk plug provides stability to the spine until the posterior lateral fusion is solid, the patient can ambulate soon after the surgery. This procedure also prevents the disk space narrowing, which is a common problem with posterior lateral fusion.

-15-

WHAT IS CLAIMED IS:

1. An implant for disposition in the space between two vertebrae of a patient after removal of a portion of the disk therefrom comprising:

an elongate, threaded rod;

5 first and second end caps having holes there-
through for receiving said rod, the hole in said
second end cap being threaded for engaging the threads
on said rod to move said second end cap along said rod
relative to said first end cap when said rod is
10 rotated; and

an intermediate portion mounted between said
first and second end caps, whereby rotation of said
rod causes radially outward expansion of said
intermediate portion to conform the shape of the
15 expanded implant to the shape of the anatomical region
of the disk space.

2. An implant of claim 1, additionally comprising a lock nut for engaging said rod to prevent the rotation of said rod.

3. An implant of claim 1, wherein said intermediate portion comprises a plurality of members hingedly mounted to said end caps.

4. An implant of claim 3, wherein rotation of said rod causes said second end cap to move along said rod to move said second end cap toward said first end cap, thereby forcing said intermediate portion radially outwardly.

5. An implant of claim 3, wherein the edges of said hinged members are beveled.

6. An implant of claim 3, wherein the hinges between said hinged members are offset so as to cause said hinged members to expand radially outwardly when said rod is rotated.

7. An implant of claim 3, wherein a sheath is formed in said hinged members to allow said hinged members to

-16-

close around said rod before said hinged members are expanded so as to minimize the thickness of the implant.

8. An implant of claim 1 wherein said intermediate portion comprises a plurality of spring-tensioned members spaced along the length of and wound around said rod and having one end affixed thereto.

9. An implant of claim 8 wherein said rod is provided with a plurality of different diameters spaced along the length thereof and having the end of one of said spring-tensioned members affixed to each section thereof.

10. A method of maintaining the space between two adjacent vertebrae of a patient after removal of the disk from therebetween comprising the steps of:

5 inserting an elongate implant into the space between two vertebrae after removal of the disk therefrom, the implant having a length which approximates the anterior-posterior dimension of the body of the vertebrae and a vertical dimension small enough to allow the insertion of the implant;

10 expanding the implant radially outwardly in the portion intermediate the ends of the implant to conform the shape of the implant to the shape of the anatomical region of the disk space into which the implant is inserted; and

15 preventing the reversal of the outward radial expansion of the intermediate portion of the implant.

11. A method of claim 10 further comprising injecting cancellous bone chips into said disk space medial to the disk plug.

12. A method for fusing two adjacent vertebrae after removal of a portion of the disk from therebetween comprising the steps of:

5 inserting an elongate implant through an opening into a space between two adjacent vertebrae of a patient after removal of the disk from between the

-17-

vertebrae, the implant having a length which approximates the anterior-posterior dimension of the body of the vertebrae and a vertical dimension small enough to allow insertion of the implant;

10 expanding the middle portion of the implant outwardly in a radial direction to conform the shape of the implant to the shape of the space from which the disk has been removed;

15 injecting cancellous bone chips into the space between the vertebrae medial to the implant; and

 applying a physiologically compatible adhesive over the cancellous bone chips medial to the disk implant to close off the opening into the space from

20 which the disk has been removed.

1/4

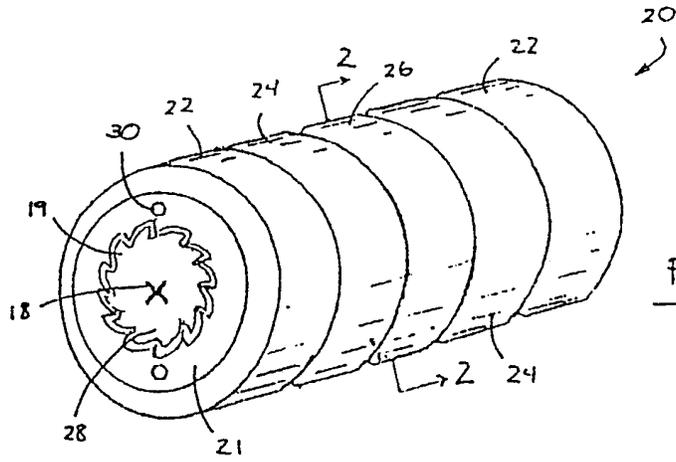


FIG. 1

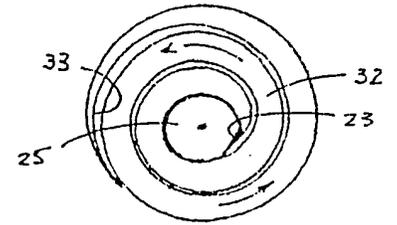


FIG. 2

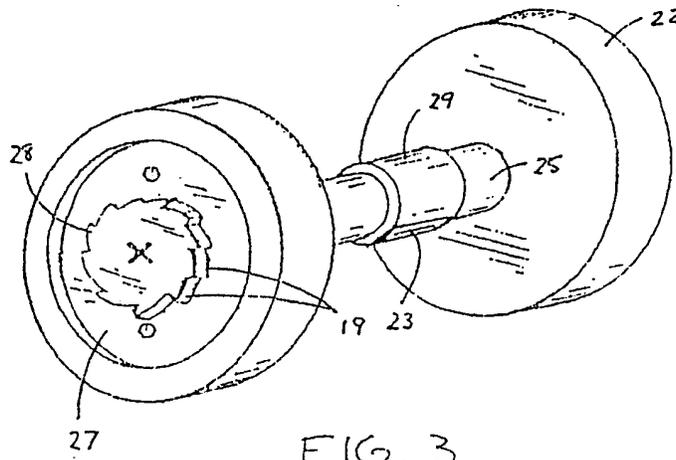


FIG. 3

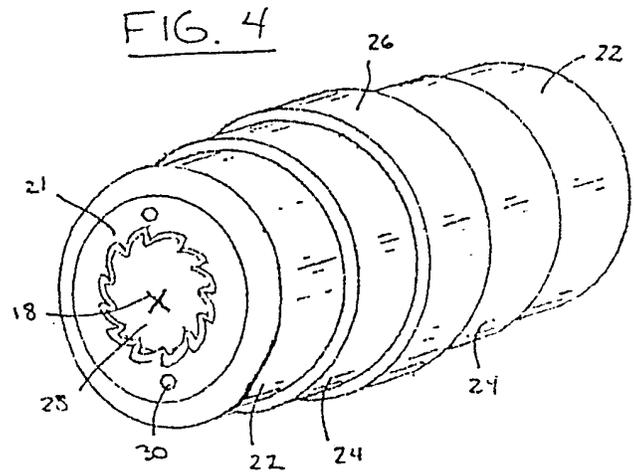


FIG. 4

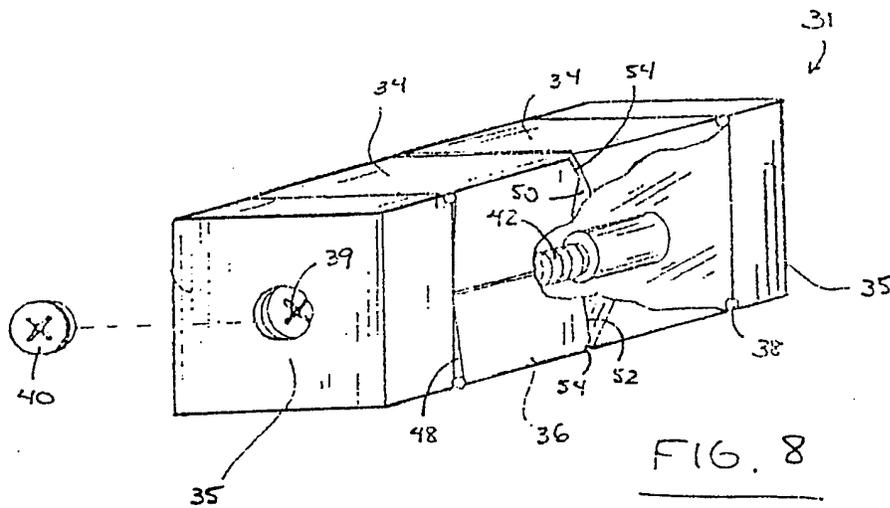


FIG. 8

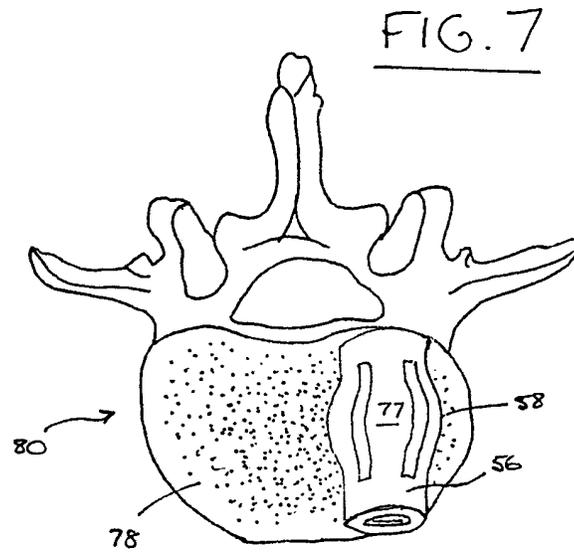
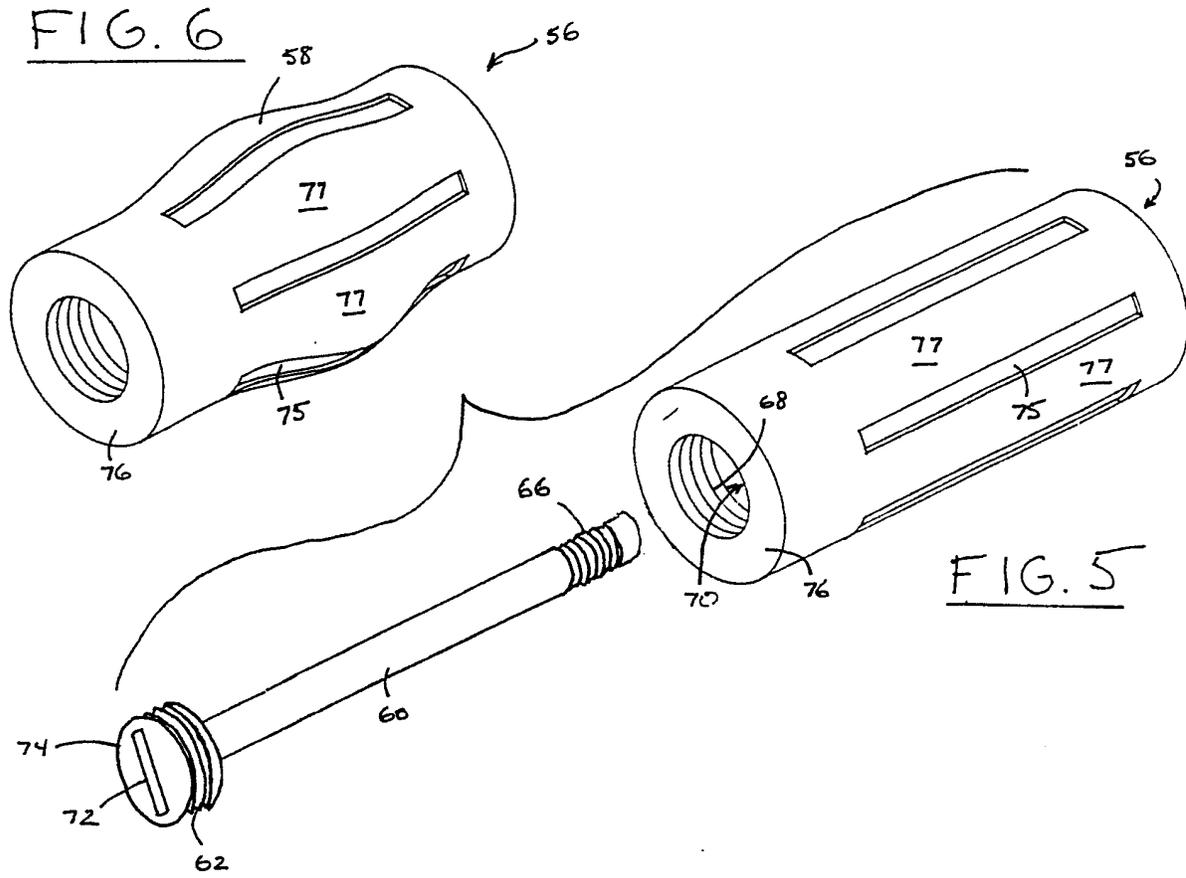


FIG. 9

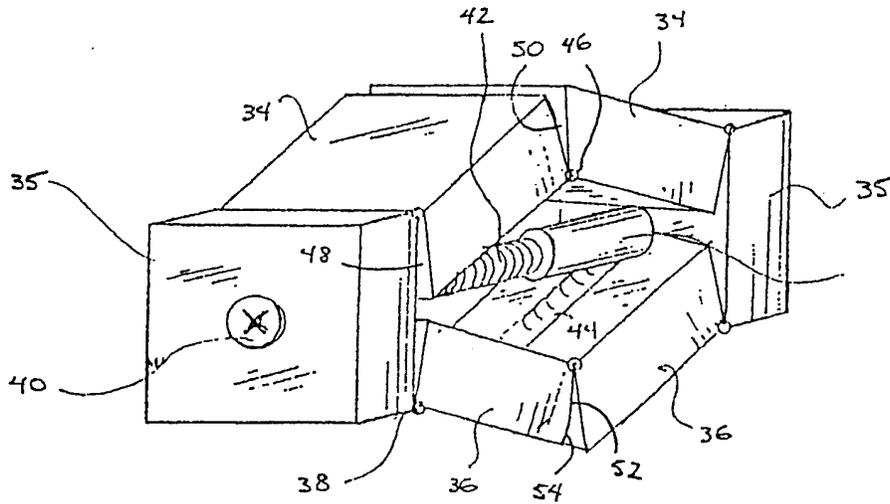


FIG. 11

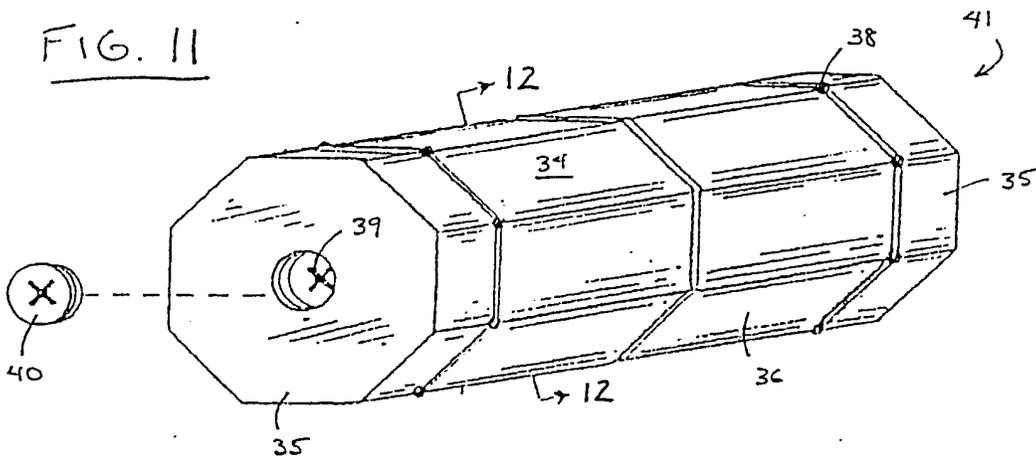


FIG. 12

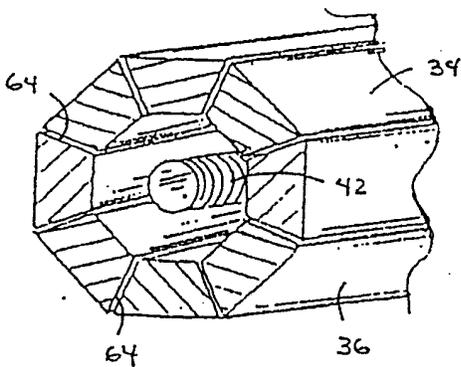
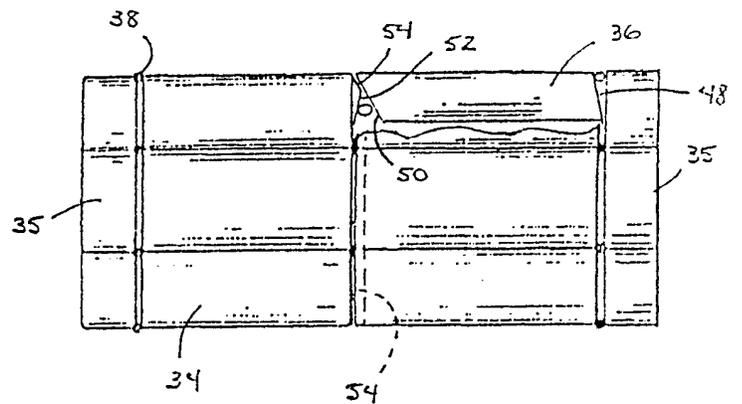
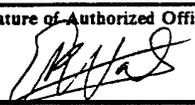


FIG. 13



INTERNATIONAL SEARCH REPORT

International Application No **PCT/US 92/01397**

| | | |
|---|--|---|
| I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ | | |
| According to International Patent Classification (IPC) or to both National Classification and IPC Int. Cl. 5 A 61 F 2/44 | | |
| II. FIELDS SEARCHED | | |
| Minimum Documentation Searched ⁷ | | |
| Classification System | Classification Symbols | |
| Int. Cl. 5 | A 61 F | A 61 B |
| Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸ | | |
| | | |
| III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹ | | |
| Category ^o | Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹² | Relevant to Claim No. ¹³ |
| A | EP, A, 0260044 (SHEPPERD) 16 March 1988, see abstract; figure 2 (cited in the application) ----- | 1 |
| A | EP, A, 0304305 (CEDAR SURGICAL) 22 February 1989, see column 4, lines 50-62; figure 1 ----- | 1 |
| <p>^o Special categories of cited documents :¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> | | |
| IV. CERTIFICATION | | |
| Date of the Actual Completion of the International Search | | Date of Mailing of this International Search Report |
| 05-06-1992 | | 14. 07. 92 |
| International Searching Authority | | Signature of Authorized Officer |
| EUROPEAN PATENT OFFICE | |  Els Vonk |

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9201397
SA 58198

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 03/07/92. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|--|------------------|-------------------------|------------------|
| EP-A- 0260044 | 16-03-88 | JP-A- 63145650 | 17-06-88 |
| | | US-A- 4863476 | 05-09-89 |
| EP-A- 0304305 | 22-02-89 | US-A- 4772287 | 20-09-88 |
| | | JP-A- 1070041 | 15-03-89 |
| | | US-A- 4904260 | 27-02-90 |

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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| | | | |
|--|----------------------|------------------------|--------|
| TRANSMITTAL FORM <small>(to be used for all correspondence after initial filing)</small> | Application Number | 11/093,409 | |
| | Filing Date | March 29, 2005 | |
| | First Named Inventor | Matthew Curran | |
| | Art Unit | 3733 | |
| | Examiner Name | Elana Beth Fisher | |
| Total Number of Pages in This Submission | 12 | Attorney Docket Number | 104US1 |

| ENCLOSURES (Check all that apply) | | |
|---|--|--|
| <input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input checked="" type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input checked="" type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Request for Continued Examination |
| <input type="text"/> Remarks | | |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | | | |
|---|-------------------|----------|--------|
| Firm Name | NUVASIVE INC. | | |
| Signature | /Jennifer Risser/ | | |
| Printed name | Jennifer Risser | | |
| Date | November 18, 2010 | Reg. No. | 60,059 |

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Electronic Patent Application Fee Transmittal

| | |
|---|---------------------------------------|
| Application Number: | 11093409 |
| Filing Date: | 29-Mar-2005 |
| Title of Invention: | Systems and methods for spinal fusion |
| First Named Inventor/Applicant Name: | Matthew Curran |
| Filer: | Jennifer Lynn Risser |
| Attorney Docket Number: | 104US1 |

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|--|----------|----------|--------|----------------------|
| Basic Filing: | | | | |
| Pages: | | | | |
| Claims: | | | | |
| Miscellaneous-Filing: | | | | |
| Petition: | | | | |
| Patent-Appeals-and-Interference: | | | | |
| Post-Allowance-and-Post-Issuance: | | | | |
| Extension-of-Time: | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
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| Miscellaneous: | | | | |
| Submission- Information Disclosure Stmt | 1806 | 1 | 180 | 180 |
| Total in USD (\$) | | | | 180 |

Electronic Acknowledgement Receipt

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|---|---------------------------------------|
| EFS ID: | 9203688 |
| Application Number: | 11093409 |
| International Application Number: | |
| Confirmation Number: | 6640 |
| Title of Invention: | Systems and methods for spinal fusion |
| First Named Inventor/Applicant Name: | Matthew Curran |
| Customer Number: | 30328 |
| Filer: | Jennifer Lynn Risser |
| Filer Authorized By: | |
| Attorney Docket Number: | 104US1 |
| Receipt Date: | 10-JAN-2011 |
| Filing Date: | 29-MAR-2005 |
| Time Stamp: | 23:22:06 |
| Application Type: | Utility under 35 USC 111(a) |

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| Submitted with Payment | yes |
| Payment Type | Deposit Account |
| Payment was successfully received in RAM | \$180 |
| RAM confirmation Number | 6763 |
| Deposit Account | 502040 |
| Authorized User | |

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| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|-----------------|----------------------|-----------|-------------------------------------|------------------|------------------|
| | | 1166 | | | |

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| 1 | Information Disclosure Statement (IDS) Filed (SB/08) | 2011-01-10- SupplementalIDS104US1.pdf | 613386 11ab68f6107f65ebb22cdd1141caf3b7b2198e5a | no | 6 |
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| Information: | | | | | |
| 2 | Foreign Reference | WO199000037A1.pdf | 917824 f3749d9e322fed8f3a2d9bc13aea22023dbe51a2 | no | 35 |
| Warnings: | | | | | |
| Information: | | | | | |
| 3 | Foreign Reference | WO1992014423A1.pdf | 683387 5b0541c7f41927bc20b449c7059194af2600fc77 | no | 25 |
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| Information: | | | | | |
| 4 | NPL Documents | Baulot.pdf | 2092847 3bdb52d5bd196ffaca8f70914f3ef246c6efe1dd | no | 6 |
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| Information: | | | | | |
| 5 | NPL Documents | Berry.pdf | 322776 5b8aca5ba082438377b6eada3c4a20e5c1167581 | no | 6 |
| Warnings: | | | | | |
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| 7 | NPL Documents | Edeland.pdf | 370458 44d387ba99c6b8fc227e7d982509298b50601a26 | no | 6 |
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| 8 | NPL Documents | KEMP.pdf | 2380605 89962bdfb44b9ac178166b5aca763cedbae8fad5 | no | 20 |
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| 9 | NPL Documents | 2010-06-14NUCorrectedFinalIn validityContentions.pdf | 282155 7de5c29b25facba8604fccbf9a30d997d5f2a51 | no | 17 |
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| 10 | NPL Documents | AppendixB3.pdf | 348228 | no | 55 |
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| 11 | NPL Documents | AppendixB4.pdf | 419619 | no | 61 |
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| 14 | NPL Documents | AppendixB8.pdf | 472690 | no | 53 |
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| 16 | NPL Documents | AppendixB1.pdf | 371014 | no | 63 |
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| 17 | NPL Documents | AppendixB2.pdf | 474505 | no | 61 |
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| 18 | NPL Documents | AppendixB7.pdf | 549703 | no | 61 |
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| 20 | NPL Documents | AppendixB17.pdf | 194806 | no | 12 |
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| Information: | | | | | |
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| | | | 9f4a1b2381d258e199c3314d30f8acc845f93985 | | |
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| Information: | | | | | |
| 23 | NPL Documents | AppendixB20.pdf | 144693 | no | 12 |
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| Information: | | | | | |
| 34 | Transmittal Letter | 2010-11-18-Transmittal104US1. pdf | 262867 | no | 2 |
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EXAMINER
FISHER, ELANA BETH
ART UNIT PAPER NUMBER

3733
DATE MAILED: 01/20/2011

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

11/093,409 03/29/2005 Matthew Curran 104US1 6640

TITLE OF INVENTION: SYSTEMS AND METHODS FOR SPINAL FUSION

Table with 7 columns: APPLN. TYPE, SMALL ENTITY, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL FEE(S) DUE, DATE DUE

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If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

30328 7590 01/20/2011

NuVasive
 c/o CPA Global
 P.O. Box 52050
 Minneapolis, MN 55402

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

| |
|-----------------------------|
| _____ (Depositor's name) |
| _____ (Signature) |
| _____ (Date) |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 11/093,409 | 03/29/2005 | Matthew Curran | 104US1 | 6640 |

TITLE OF INVENTION: SYSTEMS AND METHODS FOR SPINAL FUSION

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | YES | \$755 | \$0 | \$0 | \$755 | 04/20/2011 |

| EXAMINER | ART UNIT | CLASS-SUBCLASS |
|--------------------|----------|----------------|
| FISHER, ELANA BETH | 3733 | 623-017160 |

| | |
|---|---|
| <p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.</p> | <p>2. For printing on the patent front page, list</p> <p>(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____</p> <p>(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____</p> <p>3 _____</p> |
|---|---|

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE _____ (B) RESIDENCE: (CITY AND STATE OR COUNTRY) _____

Please check the appropriate assignee category or categories (will not be printed on the patent) : Individual Corporation or other private group entity Government

| | |
|---|--|
| <p>4a. The following fee(s) are submitted:</p> <p><input type="checkbox"/> Issue Fee</p> <p><input type="checkbox"/> Publication Fee (No small entity discount permitted)</p> <p><input type="checkbox"/> Advance Order - # of Copies _____</p> | <p>4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)</p> <p><input type="checkbox"/> A check is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).</p> |
|---|--|

5. Change in Entity Status (from status indicated above)

a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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UNITED STATES DEPARTMENT OF COMMERCE
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Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

Table with columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
Rows: 11/093,409 03/29/2005 Matthew Curran 104US1 6640
30328 7590 01/20/2011
NuVasive
c/o CPA Global
P.O. Box 52050
Minneapolis, MN 55402
EXAMINER FISHER, ELANA BETH
ART UNIT 3733 PAPER NUMBER
DATE MAILED: 01/20/2011

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 11 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 11 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.

11/093,409

Examiner

ELANA B. FISHER

Applicant(s)

CURRAN ET AL.

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1. This communication is responsive to the request for continued examination submitted on November 18, 2010.
- 2. The allowed claim(s) is/are 1-5 and 31-51.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 - 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
- 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 01/10/2011
- 4. Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- 6. Interview Summary (PTO-413), Paper No./Mail Date 20110112.
- 7. Examiner's Amendment/Comment
- 8. Examiner's Statement of Reasons for Allowance
- 9. Other _____.

/Elana B Fisher/
Examiner, Art Unit 3733

/EDUARDO C. ROBERT/
Supervisory Patent Examiner, Art Unit 3733

| | | | |
|---|--------------------------------------|--------------------------------------|--|
| Examiner-Initiated Interview Summary | Application No. 11/093,409 | Applicant(s) CURRAN ET AL. | |
| | Examiner ELANA B. FISHER | Art Unit 3733 | |

All Participants:

(1) ELANA B. FISHER.

(2) RORY SCHERMERHORN.

Status of Application: _____

(3) _____.

(4) _____.

Date of Interview: 28 December 2010

Time: 4 PM

Type of Interview:

- Telephonic
 Video Conference
 Personal (Copy given to: Applicant Applicant's representative)

Exhibit Shown or Demonstrated: Yes No

If Yes, provide a brief description: .

Part I.

Rejection(s) discussed:

N/A

Claims discussed:

36 & 37

Prior art documents discussed:

N/A

Part II.

SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:

Examiner contacted applicant's representative about antecedent basis issues with claims 36 and 37. Applicant's representative agreed to an examiner's amendment in order to place the application in condition for allowance.

Part III.

- It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.
 It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.

/Elana B Fisher/
Examiner, Art Unit 3733

(Applicant/Applicant's Representative Signature – if appropriate)

Art Unit: 3733

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rory Schermerhorn on December 28, 2010.

The application has been amended as follows:

Claim 36, line 1: "The implant of claim 31..." has been changed to "The implant of claim 2..."

Claim 37, lines 2-3: "said later side" has been changed to "said anterior side"

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/

Examiner, Art Unit 3733

/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733

| | | |
|---|--|---|
| Index of Claims  | Application/Control No. 11093409 | Applicant(s)/Patent Under Reexamination CURRAN ET AL. |
| | Examiner ELANA B FISHER | Art Unit 3733 |

| | |
|---|-----------------|
| ✓ | Rejected |
| = | Allowed |

| | |
|---|-------------------|
| - | Cancelled |
| ÷ | Restricted |

| | |
|---|---------------------|
| N | Non-Elected |
| I | Interference |

| | |
|---|-----------------|
| A | Appeal |
| O | Objected |

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

| CLAIM | | DATE | | | | | | | |
|-------|----------|------------|------------|------------|------------|------------|------------|--|--|
| Final | Original | 02/12/2007 | 02/27/2008 | 09/12/2008 | 08/16/2009 | 05/15/2010 | 01/12/2011 | | |
| | 1 | ÷ | ✓ | ✓ | ✓ | ✓ | = | | |
| | 2 | ÷ | ✓ | ✓ | ✓ | ✓ | = | | |
| | 3 | ÷ | ✓ | ✓ | ✓ | ✓ | = | | |
| | 4 | ÷ | ✓ | ✓ | ✓ | ✓ | = | | |
| | 5 | ÷ | ✓ | ✓ | ✓ | ✓ | = | | |
| | 6 | ÷ | ✓ | - | - | - | - | | |
| | 7 | ÷ | ✓ | - | - | - | - | | |
| | 8 | ÷ | ✓ | - | - | - | - | | |
| | 9 | ÷ | ✓ | - | - | - | - | | |
| | 10 | ÷ | ✓ | - | - | - | - | | |
| | 11 | ÷ | ✓ | ✓ | - | - | - | | |
| | 12 | ÷ | ✓ | ✓ | - | - | - | | |
| | 13 | ÷ | ✓ | ✓ | - | - | - | | |
| | 14 | ÷ | N | N | - | - | - | | |
| | 15 | ÷ | N | N | - | - | - | | |
| | 16 | ÷ | N | N | - | - | - | | |
| | 17 | ÷ | N | N | - | - | - | | |
| | 18 | ÷ | N | N | - | - | - | | |
| | 19 | ÷ | N | - | - | - | - | | |
| | 20 | ÷ | N | - | - | - | - | | |
| | 21 | ÷ | N | - | - | - | - | | |
| | 22 | ÷ | N | - | - | - | - | | |
| | 23 | ÷ | N | - | - | - | - | | |
| | 24 | ÷ | N | N | - | - | - | | |
| | 25 | ÷ | N | N | - | - | - | | |
| | 26 | ÷ | N | N | - | - | - | | |
| | 27 | | | ✓ | - | - | - | | |
| | 28 | | | ✓ | - | - | - | | |
| | 29 | | | N | - | - | - | | |
| | 30 | | | N | - | - | - | | |
| | 31 | | | | ✓ | ✓ | = | | |
| | 32 | | | | ✓ | ✓ | = | | |
| | 33 | | | | ✓ | ✓ | = | | |
| | 34 | | | | ✓ | ✓ | = | | |
| | 35 | | | | ✓ | ✓ | = | | |
| | 36 | | | | ✓ | ✓ | = | | |

| | | |
|---|--|---|
| Index of Claims  | Application/Control No. 11093409 | Applicant(s)/Patent Under Reexamination CURRAN ET AL. |
| | Examiner ELANA B FISHER | Art Unit 3733 |

| | |
|---|-----------------|
| ✓ | Rejected |
| = | Allowed |

| | |
|---|-------------------|
| - | Cancelled |
| ÷ | Restricted |

| | |
|---|---------------------|
| N | Non-Elected |
| I | Interference |

| | |
|---|-----------------|
| A | Appeal |
| O | Objected |

Claims renumbered in the same order as presented by applicant
 CPA
 T.D.
 R.1.47

| CLAIM | | DATE | | | | | | | |
|-------|----------|------------|------------|------------|------------|------------|------------|--|--|
| Final | Original | 02/12/2007 | 02/27/2008 | 09/12/2008 | 08/16/2009 | 05/15/2010 | 01/12/2011 | | |
| | 37 | | | | ✓ | ✓ | = | | |
| | 38 | | | | ✓ | ✓ | = | | |
| | 39 | | | | ✓ | ✓ | = | | |
| | 40 | | | | ✓ | ✓ | = | | |
| | 41 | | | | ✓ | ✓ | = | | |
| | 42 | | | | ✓ | ✓ | = | | |
| | 43 | | | | ✓ | ✓ | = | | |
| | 44 | | | | | ✓ | = | | |
| | 45 | | | | | ✓ | = | | |
| | 46 | | | | | ✓ | = | | |
| | 47 | | | | | ✓ | = | | |
| | 48 | | | | | ✓ | = | | |
| | 49 | | | | | ✓ | = | | |
| | 50 | | | | | ✓ | = | | |
| | 51 | | | | | ✓ | = | | |

| | | |
|--|--|---|
| Search Notes  | Application/Control No. 11093409 | Applicant(s)/Patent Under Reexamination CURRAN ET AL. |
| | Examiner JERRY CUMBERLEDGE | Art Unit 3733 |

| SEARCHED | | | |
|----------|----------------|------------|----------|
| Class | Subclass | Date | Examiner |
| 623 | 17.11-17.16 | 2/27/2008 | JLC |
| 606 | 99 | 2/27/2008 | JLC |
| | Updated Search | 9/12/2008 | JLC |
| | Above Updated | 08/16/2009 | EF |
| | Above Updated | 05/15/2010 | EF |
| | Above Updated | 01/12/2011 | EF |

| SEARCH NOTES | | |
|--------------------------------|------------|----------|
| Search Notes | Date | Examiner |
| Inventor Name Search Performed | 2/27/2008 | JLC |
| EAST classification search | 08/16/2009 | EF |
| EAST citation search | 08/16/2009 | EF |
| EAST text search | 08/16/2009 | EF |
| IDS reference search in EAST | 08/16/2009 | EF |
| Above Updated | 05/15/2010 | EF |
| Above Updated | 01/12/2011 | EF |

| INTERFERENCE SEARCH | | | |
|---------------------|--------------|------------|----------|
| Class | Subclass | Date | Examiner |
| | See Attached | 01/12/2011 | EF |

/ELANA B FISHER/
Examiner.Art Unit 3733

EAST Search History**EAST Search History (I nterference)**

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | Time Stamp |
|--------------|-------------|--|----------------|-------------------------|----------------|---------------------|
| L1 | 0 | ((spinal adj fusion adj implant) and (top adj surface) and (bottom adj surface) and (distal adj side) and (proximal adj side) and (first adj side adj wall) and (second adj side adj wall) and (anterior adj side) and (posterior adj side) and length and (fusion adj apertures) and (radiopaque adj marker) and three and (medial adj support)).clm. | USPAT; UPAD | OR | ON | 2011/01/12 15:00 |

1/ 12/ 2011 3:00:36 PM**C:\ Documents and Settings\ efisher1\ My Documents\ EAST\ Workspaces
\ 11093409.wsp**

Receipt date: 01/10/2011

11093409 - GAI: 3733

Doc code: IDS

Pat. Sec. 101 (11)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| | | | |
|---|------------------------|-------------------|------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | Application Number | | 11093409 |
| | Filing Date | | 2005-03-29 |
| | First Named Inventor | Matthew Curran | |
| | Art Unit | | 3733 |
| | Examiner Name | Elana Beth Fisher | |
| | Attorney Docket Number | | 104US1 |

| U.S. PATENTS | | | | | | | Remove |
|-------------------|---------|---------------|------------------------|------------|---|--|--------|
| Examiner Initial* | Cite No | Patent Number | Kind Code ¹ | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | |
| | 1 | 3867728 | | 1975-02-25 | Stubstad et al. | | |
| | 2 | 4501269 | | 1985-02-26 | Bagby | | |
| | 3 | 4834757 | | 1989-05-30 | Brantigan | | |
| | 4 | 5015247 | | 1991-05-14 | Michelson | | |
| | 5 | 5047055 | | 1991-09-10 | Bao et al. | | |
| | 6 | 5192327 | | 1993-03-09 | Brantigan | | |
| | 7 | 5263953 | | 1993-11-23 | Bagby | | |
| | 8 | 5397364 | | 1995-03-14 | Kozak | | |

| | | | |
|--|------------------------|-------------------|----------------------|
| Receipt date: 01/10/2011 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | Application Number | 11093409 | 11093409 - GAU: 3733 |
| | Filing Date | 2005-03-29 | |
| | First Named Inventor | Matthew Curran | |
| | Art Unit | 3733 | |
| | Examiner Name | Elana Beth Fisher | |
| | Attorney Docket Number | 104US1 | |

| | | | | | | |
|--|----|---------|--|------------|----------------|--|
| | 9 | 5489307 | | 1996-02-06 | Kuslich et al. | |
| | 10 | 5658337 | | 1997-08-19 | Kohrs et al. | |
| | 11 | 4545374 | | 1985-10-08 | Jacobson | |
| | 12 | 5026373 | | 1991-06-25 | Ray | |
| | 13 | 5071437 | | 1991-12-10 | Steffee | |
| | 14 | 4961740 | | 1990-10-09 | Ray et al. | |

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

| Examiner Initial* | Cite No | Publication Number | Kind Code ¹ | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
|-------------------|---------|--------------------|------------------------|------------------|---|--|
| | 1 | | | | | |

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

| Examiner Initial* | Cite No | Foreign Document Number ³ | Country Code ² ; | Kind Code ⁴ | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T ⁵ |
|-------------------|---------|--------------------------------------|-----------------------------|------------------------|------------------|---|--|----------------|
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|---|------------------------|-------------------|----------------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | Application Number | 11093409 | 11093409 - GAU: 3733 |
| | Filing Date | 2005-03-29 | |
| | First Named Inventor | Matthew Curran | |
| | Art Unit | 3733 | |
| | Examiner Name | Elana Beth Fisher | |
| | Attorney Docket Number | 104US1 | |

| | | | | | | |
|---|----------|----|--|------------|-----------|--------------------------|
| 1 | 90/00037 | WO | | 1990-01-11 | Michelson | <input type="checkbox"/> |
| 2 | 92/14423 | WO | | 1992-09-03 | Pisharodi | <input type="checkbox"/> |

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published. | T ⁵ |
|--------------------|---------|---|--------------------------|
| | 1 | BAULOT et al. "Complementary anterior spondylodesis by thoracoscopy. Technical note regarding an observation," Technical Designs and Experimental Research, 90(5):347-351 (1994). | <input type="checkbox"/> |
| | 2 | BERRY et al. "A morphometric study of human lumbar and selected thoracic vertebrae, study of selected vertebrae" (1986) | <input type="checkbox"/> |
| | 3 | CROCK, H.V., "Anterior Lumbar Interbody Fusion" Clinical Orthopaedics & Related Research (1982) | <input type="checkbox"/> |
| | 4 | CROCK, H.V., "A short practice of spinal surgery," Published 1993 by Springer-Verlag/Wien, New York | <input type="checkbox"/> |
| | 5 | EDELAND, H.G. "Some additional suggestions for a intervertebral disk prosthesis" 7 Journal of Biomedical Engineering 57 (1985) | <input type="checkbox"/> |
| | 6 | KEMP, H.B.S. "Anterior fusion of the spine for infective lesions in adults" 55B Journal of Bone & Joint Surgery 715 (1973) | <input type="checkbox"/> |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | Application Number | 11093409 | 11093409 - GAU: 3733 |
| | Filing Date | 2005-03-29 | |
| | First Named Inventor | Matthew Curran | |
| | Art Unit | 3733 | |
| | Examiner Name | Elana Beth Fisher | |
| | Attorney Docket Number | 104US1 | |

| EXAMINER SIGNATURE | | | |
|--------------------|----------------|-----------------|------------|
| Examiner Signature | /Elana Fisher/ | Date Considered | 01/12/2011 |

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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.



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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 11/093,409 | 03/29/2005 | Matthew Curran | 104US1 | 6640 |
| 30328 | 7590 | 02/16/2011 | EXAMINER | |
| NuVasive c/o CPA Global P.O. Box 52050 Minneapolis, MN 55402 | | | FISHER, ELANA BETH | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/16/2011 | PAPER |

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| 11093409 | 3/29/2005 | CURRAN ET AL. | 104US1 |

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Minneapolis, MN 55402

EXAMINER

ELANA B. FISHER

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Commissioner for Patents

The IDS submitted on April 22, 2005 has been reconsidered.

/EDUARDO C. ROBERT/
Supervisory Patent Examiner, Art Unit 3733

/Elana B Fisher/
Examiner, Art Unit 3733

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



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| Application Number | 11/093,409 |
| Filing Date | March 29, 2005 |
| First Named Inventor | Matthew Curran |
| Group Art Unit | Unknown |
| Examiner Name | Unknown |

Sheet 1 of 6

Attorney Docket No: 104US1

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| | Application Number | 11/093,409 |
| | Filing Date | March 29, 2005 |
| | First Named Inventor | Matthew Curran |
| | Group Art Unit | Unknown |
| | Examiner Name | Unknown |
| Sheet 2 of 6 | Attorney Docket No: 104US1 | |

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| | Application Number | 11/093,409 |
| | Filing Date | March 29, 2005 |
| | First Named Inventor | Matthew Curran |
| | Group Art Unit | Unknown |
| Examiner Name | Unknown | |
| Sheet 3 of 6 | Attorney Docket No: 104US1 | |

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| Application Number | 11/093,409 |
| Filing Date | March 29, 2005 |
| First Named Inventor | Matthew Curran |
| Group Art Unit | Unknown |
| Examiner Name | Unknown |
| Attorney Docket No: 104US1 | |

Sheet 4 of 6

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| | Filing Date | March 29, 2005 |
| | First Named Inventor | Matthew Curran |
| | Group Art Unit | Unknown |
| | Examiner Name | Unknown |
| Sheet 5 of 6 | Attorney Docket No: 104US1 | |

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| | Filing Date | March 29, 2005 |
| | First Named Inventor | Matthew Curran |
| | Group Art Unit | Unknown |
| | Examiner Name | Unknown |
| Sheet 6 of 6 | Attorney Docket No: 104US1 | |

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|--|----------------------|---|----------------|
| Examiner Initials* | Cite No ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
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|----------|----------------|-----------------|------------|
| EXAMINER | /Elana Fisher/ | DATE CONSIDERED | 02/12/2011 |
|----------|----------------|-----------------|------------|

Substitute Disclosure Statement Form (PTO-1449)
 * EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

| | |
|---|---------------------------------------|
| Application Number: | 11093409 |
| Filing Date: | 29-Mar-2005 |
| Title of Invention: | SYSTEMS AND METHODS FOR SPINAL FUSION |
| First Named Inventor/Applicant Name: | Matthew Curran |
| Filer: | Jennifer Lynn Risser |
| Attorney Docket Number: | 104US1 |

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|--|----------|----------|--------|----------------------|
| Basic Filing: | | | | |
| Pages: | | | | |
| Claims: | | | | |
| Miscellaneous-Filing: | | | | |
| Petition: | | | | |
| Patent-Appeals-and-Interference: | | | | |
| Post-Allowance-and-Post-Issuance: | | | | |
| Utility Appl issue fee | 1501 | 1 | 1510 | 1510 |

Extension-of-Time:

1198

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|--------------------------|----------|----------|--------|----------------------|
| Miscellaneous: | | | | |
| Total in USD (\$) | | | | 1510 |

Electronic Acknowledgement Receipt

| | |
|---|---------------------------------------|
| EFS ID: | 9560525 |
| Application Number: | 11093409 |
| International Application Number: | |
| Confirmation Number: | 6640 |
| Title of Invention: | SYSTEMS AND METHODS FOR SPINAL FUSION |
| First Named Inventor/Applicant Name: | Matthew Curran |
| Customer Number: | 30328 |
| Filer: | Jennifer Lynn Risser |
| Filer Authorized By: | |
| Attorney Docket Number: | 104US1 |
| Receipt Date: | 01-MAR-2011 |
| Filing Date: | 29-MAR-2005 |
| Time Stamp: | 15:01:30 |
| Application Type: | Utility under 35 USC 111(a) |

Payment information:

| | |
|--|-----------------|
| Submitted with Payment | yes |
| Payment Type | Deposit Account |
| Payment was successfully received in RAM | \$1510 |
| RAM confirmation Number | 1289 |
| Deposit Account | 502040 |
| Authorized User | |

File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|-----------------|----------------------|-----------|-------------------------------------|------------------|------------------|
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| 1 | Issue Fee Payment (PTO-85B) | 2011-03-01- IssueFeePartB104US1.pdf | 220605 | no | 2 |
| | | | d2a78f6098ca221198f36bb3c80b65d690c26b34 | | |

Warnings:

Information:

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|---|-------------------------|--------------|--|----|---|
| 2 | Fee Worksheet (PTO-875) | fee-info.pdf | 29641 | no | 2 |
| | | | 303aa4b86315230594d10dac4cd7006ca5aeef09 | | |

Warnings:

Information:

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|-------------------------------------|--|--|--------|--|--|
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Receipt date: 04/22/2005

11093409 - GAU: 3733

PTO/SBDBA(06-03)
Approved for use through 07/31/2006 OMB 0651-0031
US Patent & Trademark Office U.S. DEPARTMENT OF COMMERCE

| | | |
|--|---|----------------|
| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | <small>Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it carries a valid OMB control number.</small> Complete if Known | |
| | Application Number | 11/093,409 |
| | Filing Date | March 29, 2005 |
| | First Named Inventor | Matthew Curran |
| | Group Art Unit | Unknown |
| Examiner Name | Unknown | |
| Sheet 3 of 6 | Attorney Docket No: 104US1 | |

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EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional) Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /E.F./

Receipt date: 04/22/2005

11093409 - GAU: 3733

Substitute for form 1449A/PTO
INFORMATION DISCLOSURE STATEMENT BY APPLICANT
 (Use as many sheets as necessary)

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PTO/SB/08A(08-03)
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 US Patent & Trademark Office, U.S. DEPARTMENT OF COMMERCE

Complete if Known

| | |
|----------------------|----------------|
| Application Number | 11/093,409 |
| Filing Date | March 29, 2005 |
| First Named Inventor | Matthew Curran |
| Group Art Unit | Unknown |
| Examiner Name | Unknown |

Attorney Docket No: 104US1

| US PATENT DOCUMENTS | | | | |
|---------------------|---------------------|-----------------------|---|---|
| Examiner Initial * | USP Document Number | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
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Change(s) applied to document, /D.H.P./ 3/2/2011

EXAMINER /Elana Fisher/

DATE CONSIDERED 02/12/2011

* EXAMINER: Inval if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

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1449
02 16 11

Receipt date: 01/21/2009

11093409 - GAI: 3733

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 01/31/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| | | | |
|---|------------------------|----------------------|------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | Application Number | | 11093409 |
| | Filing Date | | 2005-03-29 |
| | First Named Inventor | Matthew Curran | |
| | Art Unit | 3733 | |
| | Examiner Name | Jerry L. Cumberledge | |
| | Attorney Docket Number | 104US1 | |

| U.S. PATENTS | | | | | | | Remove |
|---|---------|---------------|------------------------|---------------------------------|---|--|--------|
| Examiner Initial* | Cite No | Patent Number | Kind Code ¹ | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | |
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Bib Data Sheet

CONFIRMATION NO. 6640

Table with 5 columns: SERIAL NUMBER (11/093,409), FILING OR 371(c) DATE (03/29/2005), CLASS (623), GROUP ART UNIT (3733), ATTORNEY DOCKET NO. (104US1)

APPLICANTS
Matthew Curran, Carlsbad, CA;
Mark Peterson, Medford, OR;
** CONTINUING DATA *****
This appln claims benefit of 60/557,536 03/29/2004
** FOREIGN APPLICATIONS *****
IF REQUIRED, FOREIGN FILING LICENSE GRANTED
** 04/23/2005

Table with 5 columns: Foreign Priority claimed (checkboxes), 35 USC 119 (a-d) conditions met (checkboxes), STATE OR COUNTRY (CA), SHEETS DRAWING (20), TOTAL CLAIMS (26), INDEPENDENT CLAIMS (2)

ADDRESS
30328

TITLE
SYSTEMS AND METHODS FOR SPINAL FUSION

Table with 2 main columns: FILING FEE RECEIVED (715) and FEES: Authority has been given in Paper No. to charge/credit DEPOSIT ACCOUNT No. for following; and a list of checkboxes for fees: All Fees, 1.16 Fees (Filing), 1.17 Fees (Processing Ext. of time), 1.18 Fees (Issue), Other, Credit



| APPLICATION NO. | ISSUE DATE | PATENT NO. | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|------------|------------|---------------------|------------------|
| 11/093,409 | 04/05/2011 | 7918891 | 104US1 | 6640 |

30328 7590 03/16/2011
NuVasive
c/o CPA Global
P.O. Box 52050
Minneapolis, MN 55402

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 308 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Matthew Curran, Carlsbad, CA;
Mark Peterson, Medford, OR;

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Matthew Curran et al. Art Unit : 3733
Patent No. : 7,918,891 Examiner : Elana Beth Fisher
Issue Date : April 5, 2011 Conf. No. : 6640
Serial No. : 11/093,409
Filed : March 29, 2005
Title : SYSTEMS AND METHODS FOR SPINAL FUSION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST TO CORRECT INVENTORSHIP
UNDER 37 C.F.R. § 1.324(a)

Applicant requests correction of inventorship for the above-captioned issued patent by the addition of the following inventor:

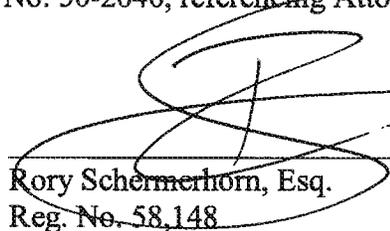
LUIZ PIMENTA

Applicant submits herewith the following:

- 1) Inventor's Declaration to Correct Inventorship by LUIZ PIMENTA ;
- 2) Declarations by current named Inventors: MATTHEW CURRAN and MARK PETERSON;
- 3) Consent of Assignee to Correct Inventorship;
- 4) Certificate Under 37 C.F.R. §3.73(b); and
- 5) Certificate of Correction.

A credit card payment of \$230 (\$130 in payment for the petition fee of §1.20(b), \$100 in payment for the Certificate of Correction fee of §1.20(a)) is submitted herewith. Please apply any other charges or credits to Deposit Account No. 50-2040, referencing Attorney Docket No. 104US1.

Date: June 21, 2013



Rory Schermerhorn, Esq.
Reg. No. 58,148

Customer Number 30328
NuVasive, Inc.
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P.O. Box 52050
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Matthew Curran et al. Art Unit : 3733
Patent No. : 7,918,891 Examiner : Elana Beth Fisher
Issue Date : April 5, 2011 Conf. No. : 6640
Serial No. : 11/093,409
Filed : March 29, 2005
Title : SYSTEMS AND METHODS FOR SPINAL FUSION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE UNDER 37 CFR §3.73(b)

Under 37 CFR §3.73(b) NUVASIVE, INC., a corporation, certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of assignments from the inventors of the patent application identified above. The assignments were recorded in the Patent and Trademark Office at

Reel 016832, Frame 0646 on August 4, 2005; and

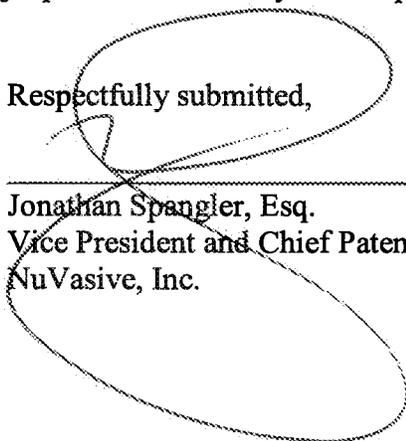
Reel 030212, Frame 0928 on April 15, 2003.

The undersigned, whose title is supplied below, is empowered to act on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief and believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: June 20, 2013


Jonathan Spangler, Esq.
Vice President and Chief Patent Counsel of
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Matthew Curran et al. Art Unit : 3733
Patent No. : 7,918,891 Examiner : Elana Beth Fisher
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

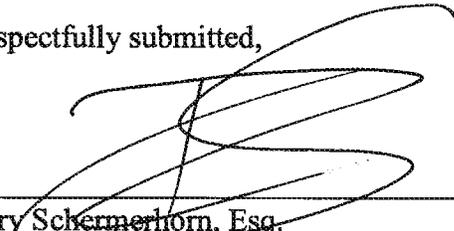
TRANSMITTAL OF REQUEST FOR CERTIFICATE OF CORRECTION

Applicant hereby requests that a certificate of correction be issued for the above patent in accordance with the attached request.

One or more of the errors sought to be corrected were made by Applicants, therefore a credit card payment of the \$100 required fee of 37 CFR §1.20(a) is submitted herewith. Please apply any other charges or credits to Deposit Account 50-2040, referencing Attorney Docket No.: 104US1.

Respectfully submitted,

Date: June 21, 2013



Rory Schermerhorn, Esq.
Reg. No. 58,148

Customer Number 30328
NuVasive, INC.
c/o CPA Global
P.O. Box 52050
Minneapolis, MN 55402
Telephone: (858) 909-1845

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1

PATENT NO. : 7,918,891
APPLICATION NO.: 11/093,409
ISSUE DATE : April 4, 2011
INVENTOR(S) : Matthew Curran et al.

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

Title Page, Inventors, please insert -- Luiz Pimenta, Sao Paulo, Brasil --

MAILING ADDRESS OF SENDER (Please do not use customer number below):

NuVasive, c/o CPA Global, P.O. Box 52050, Minneapolis, MN 55402

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

| | |
|---|---------------------------------------|
| Application Number: | 11093409 |
| Filing Date: | 29-Mar-2005 |
| Title of Invention: | SYSTEMS AND METHODS FOR SPINAL FUSION |
| First Named Inventor/Applicant Name: | Matthew Curran |
| Filer: | Rory A. Schermerhorn/Marjorie Jarvis |
| Attorney Docket Number: | 104US1 |

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|--|----------|----------|--------|----------------------|
| Basic Filing: | | | | |
| Pages: | | | | |
| Claims: | | | | |
| Miscellaneous-Filing: | | | | |
| Petition: | | | | |
| Patent-Appeals-and-Interference: | | | | |
| Post-Allowance-and-Post-Issuance: | | | | |
| Certificate of Correction | 1811 | 1 | 100 | 100 |
| Processing Fee Correcting Inventorship | 1816 | 1 | 130 | 130 |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|---------------------------|----------|----------|--------|----------------------|
| Extension-of-Time: | | | | |
| Miscellaneous: | | | | |
| Total in USD (\$) | | | | 230 |

Electronic Acknowledgement Receipt

| | |
|---|---------------------------------------|
| EFS ID: | 16125041 |
| Application Number: | 11093409 |
| International Application Number: | |
| Confirmation Number: | 6640 |
| Title of Invention: | SYSTEMS AND METHODS FOR SPINAL FUSION |
| First Named Inventor/Applicant Name: | Matthew Curran |
| Customer Number: | 30328 |
| Filer: | Rory A. Schermerhorn/Marjorie Jarvis |
| Filer Authorized By: | Rory A. Schermerhorn |
| Attorney Docket Number: | 104US1 |
| Receipt Date: | 21-JUN-2013 |
| Filing Date: | 29-MAR-2005 |
| Time Stamp: | 18:53:43 |
| Application Type: | Utility under 35 USC 111(a) |

Payment information:

| | |
|--|-------------|
| Submitted with Payment | yes |
| Payment Type | Credit Card |
| Payment was successfully received in RAM | \$230 |
| RAM confirmation Number | 17157 |
| Deposit Account | |
| Authorized User | |

File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|-----------------|----------------------|-----------|-------------------------------------|------------------|------------------|
| | | 1218 | | | |

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|--|--|---|---|----|---|
| 1 | Petition for review/processing depending on status | 2013-06-21_RqstCorrInventors hip_104US1.pdf | 24185 f50675827a24bab35cab4f47d600c475c29f be17 | no | 1 |
| Warnings: | | | | | |
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| 2 | Oath or Declaration filed | 2013-06-21_Declaration_Pimenta_104US1.pdf | 50213 cc235c351a7aa84d7570414d2fe7cd87bba 0ba5c | no | 1 |
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| 3 | Oath or Declaration filed | 2013-06-21_Declaration_Curran_104US1.pdf | 50340 945d6c4bc6573cfa09712d9eee56640dfe5 acfc | no | 1 |
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| 4 | Oath or Declaration filed | 2013-06-21_Declaration_Peterson_104US1.pdf | 75103 69a2af1fe34b3d1491ff49a31afe20c90f9ba d52 | no | 1 |
| Warnings: | | | | | |
| Information: | | | | | |
| 5 | Consent of Assignee accompanying the declaration | 2013-06-21_ConsentAssignee_104US1.pdf | 29947 47fb0b0ecbf41960d9654aa1d326f3d702f5 bf5c | no | 1 |
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| 6 | Assignee showing of ownership per 37 CFR 3.73. | 2013-06-21_Cert3-73b_104US1.pdf | 32291 dcb0731ba18272ede83fd0c015a86e05f56 bdb17 | no | 1 |
| Warnings: | | | | | |
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| 7 | Request for Certificate of Correction | 2013-06-21_COC_Transmittal_104US1.pdf | 25017 f571dd2476f9008dae3218aa3f706f4a89e1 9a1a | no | 1 |
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| Information: | | | | | |
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| 8 | Request for Certificate of Correction | 2013-06-21_COC_104US1.pdf | 164255 f7ea6632f26ee58eba723bd172b6b39afe8b0db | no | 2 |
| Warnings: | | | | | |
| Information: | | | | | |
| 9 | Fee Worksheet (SB06) | fee-info.pdf | 31854 d964adda40a4933659395d4d94f3b15766069708 | no | 2 |
| Warnings: | | | | | |
| Information: | | | | | |
| Total Files Size (in bytes): | | | 483205 | | |
| <p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p> | | | | | |



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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes application details for NuVasive, Inc. and examiner information for FISHER, ELANA BETH.

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip@nuvasive.com
docketing@cpaglobal.com



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ALEXANDRIA, VA 22313-1450
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| | | |
|--|---|--------------------------|
| <i>In re</i> Patent No. CURRAN ET AL. | : | |
| Issue Date: April 5, 2011 | : | DECISION GRANTING |
| Appl No.: 11/093,409 | : | PETITION |
| Filed: March 29, 2005 | : | <i>37 CFR 1.324</i> |
| For: SYSTEMS AND METHODS FOR SPINAL FUSION | : | |
| | : | |
| | : | |
| | : | |

This is a decision on the petition filed June 21, 2013 to correct inventorship under 37 CFR 1.324.

The petition is granted.

The patented file is being forwarded to Certificate of Corrections Branch for issuance of a certificate naming only the actual inventor or inventors.

/Eduardo C. Robert/

EDUARDO C. ROBERT
Supervisory Patent Examiner
Art Unit 3733
Technology Center 3700

NuVasive, Inc.
c/o CPA Global
P.O. Box 52050
Minneapolis, MN 55402

Art Unit: 3733



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ALEXANDRIA, VA 22313-1450
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DATE: August 6, 2013
TO: Certificates of Correction Branch
FROM: Eduardo C. Robert, SPE, Art Unit 3733
SUBJECT: Request for Certificate of Correction

Please issue a Certificate of Correction in U. S. Letters Patent No. 7,918,891 as specified on the attached Certificate.

/Eduardo C. Robert/

Eduardo C. Robert, SPE
Art Unit 3733

Art Unit: 3733

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE

Patent No. 7,918,891

Patented: April 5, 2011

On petition requesting issuance of a certificate for correction of inventorship pursuant to 35 U.S.C. 256, it has been found that the above identified patent improperly sets forth the inventorship. Accordingly, it is hereby certified that the correct inventorship of this patent is:

Matthew Curran, Carlsbad, CA; Mark Peterson, Medford, OR; Luiz Pimenta, Sao Paulo, Brasil

/Eduardo C. Robert/

Eduardo C. Robert, Supervisory Patent Examiner
Art Unit 3733