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Applicant

Priority

International

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International

END

Title: END DEVICE FOR A VERTEBRAL IMPLANT

Abstract: An end device (10) attached to an intervertebral implant (100) and methods of use. The end device comprises a base (20) having a receiving area, an opening (30), and at least one gate (40) that is selectively positionable between open and closed orientations. The implant is sized to fit through the opening and into the receiving area when the gate is in the open orientation. Once inserted, the gate is sized to extend across at least a section of the opening and prevent the implant from escaping.
before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
END DEVICE FOR A VERTEBRAL IMPLANT

Background

Various procedures include removing the entirety or a section of a vertebral member. The procedures may also include removing more than one section or entirety of vertebral members. These procedures may be required due to damage to the vertebral member, such as that caused by a specific event such as trauma, a degenerative condition, a tumor, or infection.

Once the vertebral member is removed, an implant is inserted to replace the removed member or members. The implant maintains the spacing of the remaining vertebral members providing for them to function properly. The positioning and size of the implant are carefully determined prior to insertion. Once inserted, the implant should remain in position.

One surgical concern is securely interposing a vertebral implant between the remaining vertebral members to ensure that the implant can resist axial, torsional, and shear loading without causing anterior displacement ("kick-out"), posterior retropulsion of the implant and any associated graft material, or subsidence. Existing vertebral implants which attempt to minimize these methods of failure can often result in other undesirable consequences such as instrumentation pull-out, graft dislodgment, or erosion of nearby vascular and soft tissue structures due to high profile design.

Summary

The present application is directed to devices and methods of an end device attachable to an implant. The end device comprises a base having a receiving area, an opening, and at least one gate that is selectively positionable between open and closed orientations. The implant is sized to fit through the opening and into the receiving area when the gate is in the open orientation. Once inserted, the gate is sued to extend across at least a section of the opening and prevent the implant from escaping.
Brief Description of the Drawings

Figure 1 is a perspective view of a pair of end devices mounted to an implant according to one embodiment;

Figure 2 is a perspective view of an end device in an open orientation according to one embodiment;

Figure 3 is a perspective view of an end device in a closed orientation according to one embodiment;

Figure 4 is a perspective view of a second side of the end device according to one embodiment;

Figure 5 is a perspective view of a pair of end devices mounted to an insertion device according to one embodiment;

Figure 6 is a perspective view of an end device having a sliding gate in an open orientation according to one embodiment;

Figure 7 is a perspective view of a second side of the end device having a sliding gate in a closed orientation according to one embodiment; and

Figure 8 is a perspective view of a removable gate according to one embodiment.

Detailed Description

Figure 1 illustrates a pair of end devices, generally illustrated as element 10, each attached to one end of a vertebral implant 100. The end device 10 includes a first side 11 that faces towards the implant 100, and a second side 12 that faces towards a vertebral member. A receiving mechanism within the end device 10 is selectively positionable between open and closed orientations. The open orientation provides for inserting the implant 100 within a receiving area of the end device 10. The closed orientation prevents the implant 100 from being removed from the receiving area of the end device 10.

The term "Implant" is used generally herein to describe a device that is inserted into a patient. Implant 100 may be inserted into a patient for a variety of purposes, and may have a variety of shapes and sizes. In the embodiment of Figure 1, implant 100 has a
cylindrical shape with a hollow interior for holding bone-growth material. One example
of such a cylinder is disclosed in U.S. Patent Nos. 5,897,556 and 6,149,651, which are
incorporated herein by reference. The cylindrical body may comprise angled, intersecting
elongate bats which form a plurality of \( \text{a} \text{r} \)angular apertures. The cylindrical body defines
a hollow bore configured to receive bone growth material.

Figures 2 and 3 illustrate the end device 10 with Figure 2 illustrating an open
orientation \( \text{m} \) Figure 3 a closed orientation. An end device 10 is connected to the
implant 100 and prevents subsidence, expulsion, and/or enables fusion. An implant 100
may be equipped with a single or multiple end devices 10. For implants 100 equipped
with multiple end devices 10, the devices may be the same or different in the
embodiments of Figures 2 and 3. End device 10 includes a base 20, opening 30, and a gate
40. Base 20 includes a bottom 21 and a sidewall 22. A receiving area 26 is framed by the
base 20 and gate 40 to receive the implant 100.

Bottom 21 shields the end members of the implant 100 from contacting the
vertebral member. Bottom 21 may be constructed of supports 23 spaced apart with gaps
24 for bone growth material in the implant 100 to reach the vertebral member for bone and
tissue ingrowth and vascularization. Supports 23 and gaps 24 may have a variety of
shapes and sizes. The bottom 21 may further have a roughened surface to connect with
the implant 100 such as when the implant 100 comprises a bone strut. Side-walls 22
extend outward from the bottom 21 forming the receiving area 26. Sidewalls 22 may
extend a variety of heights from the bottom 21 depending upon the context. Apertures 25
may extend through the sidewalls 22 and may be threaded to receive a fastener that
connects the end device 10 to the implant 100. Apertures 25 also provide for the bone
growth material to reach the vertebral member.

The outer surface of the bottom 21 is constructed to maintain the position
relative to the vertebral member. As illustrated in Figure 4, spikes 27 having a sharp tip
may be positioned at spaced intervals to bite into the vertebral member. Ridges 28 may
also be positioned along the surface to maintain the device position. The outer surface
may also be roughened such as by a grit blast to further maintain the device position.

Opening 30 is positioned within the sidewall 22 and sized for the insertion of the implant
100. Opening 30 is defined between a first edge 31 and a second edge 32,
Gate 40 is selectively positionable between open and closed orientations for positioning and containing the implant 100 within the receiving area 26. Gate 40 comprises first member 41 and second member 42. Each of the members 41, 42 is movably connected to the side-wall 22 at a pivot 43. This connection provides for movement between the open orientation as illustrated in Figure 2, and the closed orientation as illustrated in Figure 3. Each member 41, 42 has an elongated shape having a first end 44 and a second end 45. Pivot 43 is positioned at a point intermediate between the ends 44, 45. In the open orientation, the first ends 44 are positioned within the receiving area 26 defined within the sidewalls 22. In the open orientation, a distance between the first ends 44 is less than a distance between the edges 31, 32. In the open orientation, the second ends 45 are spaced away from the opening 30 with a distance between the second ends 45 being greater than the distance between the edges 31, 32. The extent of pivoting may vary depending upon the application. In one embodiment, the gates 40 have a swing of about 50° between the open and closed orientations.

Members 41, 42 have an arcuate shape that matches the side-walls 22 and extends around the periphery of the bottom 21 when in the closed orientation. In the embodiment of Figure 3, members 41, 42 have a length for the ends 45 to be in an overlapping configuration when in the closed orientation. One or both ends 45 may include a lock mechanism to maintain the members 41, 42 in the closed orientation. In the embodiment of Figures 2 and 3, the lock mechanism includes a ball and detent combination that mates together in the closed orientation. First and second edges 31, 32 of the sidewalls may further include a locking mechanism that engages the members 41, 42. In one embodiment, each edge 31, 32 includes an indent or aperture 49 that receives a mating tab located on the members 41, 42 to further secure the members 41, 42 in the closed orientation. A deformable spring interface and a fastener may also be used to keep the gate in the closed orientation.

Members 41, 42 may have the same or different height relative to the sidewalls 22. In the embodiments of Figures 2 and 3, members 41, 42 have a snailier height and are spaced upward from the bottom 21 with an upper edge of the members 41, 42 substantially matching an upper edge of the sidewalls 22. This gap between the members 41, 42 and the bottom 21 forms a space for the insertion device 80 as illustrated in Figure 5.
insertion device 80 is constructed to position the devices 10 relative to the vertebral members. Device 80 includes first and second arms 81, 82 each sized to hold an end device 10. Each arm 81, 82 has spaced-apart fingers 89 forming a capture area to receive the end devices 10. The fingers 89 form an opening 88 sized to slide the end devices 10 into the capture area. An adjustment mechanism 83 controls the distance between the arms 81, 82. In this embodiment, adjustment mechanism 83 is a jack device having pivoting linkages 84 attached to an arm 85. Handle 86 is operatively connected to the arm 85 to control the movement of the linkages 84 and thus the relative spacing of the arms 81, 82.

In use, one or two end devices 10 are slid through the openings 88 formed by the fingers 89 on the arms 81, 82. The end devices 10 are positioned in the capture area defined by the arms 81, 82 with the spikes 27 extending outward in preparation for positioning within the vertebral members. Further, the gates 40 are in the open orientation.

With the end devices 10 attached, the arms 81, 82 are positioned in a relatively closed orientation and are spaced apart a distance to fit between the remaining vertebral members. The surgeon then manipulates the handle 86 to insert the arms 81, 82 with the end devices 10 between the vertebral members. Once inserted, handle 86 is rotated to move apart the arms 81, 82. This movement causes the spikes 27 to be driven into the vertebral members to attach the end devices 10. The expansion movement may also distract the vertebral members.

With the end devices 10 in the open orientation, the implant 100 is moved through the gates 40 and into the receiving area 26. The gates 40 in the open orientation retract the soft tissue that may surround the vertebral members and keep open the line of sight for the surgeon. Once the end devices 10 are inserted, the implant 100 is inserted through the opening 30 and contacts the first ends 44 of the arms 41, 42. Further insertion of the implant 100 into the receiving area 26 causes the arms 41, 42 to move about their respective pivots 43 towards the closed orientation. In one embodiment, complete insertion of the implant 100 into the receiving area 26 results in the arms 41, 42 becoming locked together. In another embodiment, the surgeon locks the arms 41, 42 together after the insertion of the implant 100.
Once the implant 100 and end devices 10 are inserted, the insertion device 80 is removed from the end devices 10. The opening 88 in the amis SK 82 is aligned facing away from the handle 86. The surgeon manipulates the handle 86 and pulls the insertion device 80 in a proximal direction thus causing the end devices 10 and implant 10 to slide out of the fingers 89 and remain between the vertebral members.

The embodiments illustrated in Figures 2 and 3 include a gate 40 having first and second members 41, 42. Gate 40 may further comprise a single member that extends across the opening 30 to prevent escape of the implant 100. Both the single gate and multiple gate embodiments may extend across the entirety or a portion of the opening 30. The embodiment of Figures 2 and 3 illustrate the first and second members 41, 42 extending across the entirety of the opening 30. Other embodiments include the gate 40 being smaller than the opening leaving a gap that is of a smaller size than the implant 100 thus preventing escape.

Another embodiment of a gate 40 features a sliding attachment with the base 20. As illustrated in Figures 6 and 7, sidewalis 22 include a slot 71 within an inner face. First and second members 41, 42 are sized to slide within the slot between an open orientation as illustrated in Figure 6, and a closed orientation as illustrated in Figure 7. Slot 71 may extend around the entirety of the sidewall 22, or a limited section adequate to receive the members 41, 42 to an amount to clear the opening 30 for insertion of the implant 100. In the embodiment of Figure 6, the first ends 44 of the members 41, 42 make contact in the open orientation with the second ends 45 being within the sidewalis 22. In the closed orientation, second ends 45 are in contact. Members 41, 42 may be attached within the sidewall 22 to prevent full removal. In one embodiment as illustrated in Figure 7, pins 72 within the sidewall 22 are positioned within a groove 79 in the members 41, 42 to pi-event the complete removal.

In other embodiments of this sliding arrangement first ends 44 may be spaced apart in the open orientation, and second ends 45 may not be in contact in the closed orientation. In another embodiment, multiple members may be used, as opposed to the single member configuration illustrated in Figures 6 and 7. In another embodiment, slot 71 for receiving the members 41, 42 is positioned on an outer face of the sidewall 22.
Figure 8 illustrates another embodiment having a removable gate 40. Gate 40 includes first and second ends 44, 45 each having a locking mechanism that engages first and second edges 31, 32 of the sidewalls 22. In the open orientation, gate 40 is removed allowing for the implant to be inserted through the opening 30 into the receiving area 26.

In the closed orientation, gate 40 is mounted to the sidewalls 22 thereby enclosing the receiving area 26 and preventing escape of the implant. In another embodiment (not illustrated), the removable gate 40 is comprises of two or more sections. Each of the sections is separately removable from and attachable to the sidewalls.

In embodiments having a pivoting gate as illustrated in Figures 2 and 3, pivot 43 may be positioned at a variety of locations along the gate. In the embodiments of Figures 2 and 3, pivot 43 is positioned between the first and second ends 44, 45. In another embodiment, pivot 43 is positioned at the first end 45.

End device 10 may further include a combination of different gate configurations. By way of example, one section of the gate 40 may have a pivoting configuration, with a second section having a sliding or removable configuration. In one embodiment, gate 40 is configured for both sliding and pivoting.

In one embodiment of a pivoting gate as illustrated in Figures 2 and 3, one or both members 41, 42 have a tapered width that increases from the first end 44 towards the second end 45. Sidewall 22 includes a cutout section 96 into which the first end 44 is inserted when the gate 40 moves to the closed orientation. Cutout section 96 has a constant width. A section of the width of the members 41, 42 is slightly greater than the width of the cutout section 96. This causes the members 41, 42 to become slightly wedged into the cutout section 96 in the open orientation to maintain the members 41, 42 in the open orientation. The differences in widths between the cutout section 96 and the members 41, 42 is only slight thus not greatly increasing the amount of force required to move the members 41, 42 to the closed orientation. In another embodiment, the width of the members 41, 42 is constant and the cutout section 96 has a tapering width. In another embodiment, a bail detent mechanism is used to maintain one or both members 41, 42 in the open orientation.

A spacing device (not illustrated) may be positioned on a second side 12 of the end device 10. The spacing device may have an angled shape such that the end device 10
with implant 100 corresponds to the curvature of the spine. The spacing device may be separately attached to the bottom surface, or may be integral with the bottom surface.

The term "distal" is generally defined as in the direction of the patient, or away from a user of a device. Conversely, "proximal" generally means away from the patient, or toward the user. Spatially relative terms such as "under", "below", "lower", "over", "upper", and the like, are used for ease of description to explain the positioning of one element relative to a second element. These terms are intended to encompass different orientations of the device in addition to different orientations than those depicted in the figures. Further, terms such as "first", "second", and the like, are also used to describe various elements, regions, sections, etc and are also not intended to be limiting.

The present invention may be carried out in other specific ways than those herein set forth without departing from the scope and essential characteristics of the invention. In one embodiment, bottom 21 of base 20 is solid. In another embodiment, the supports 23 are deleted, and the bottom 21 of the base 20 is open, with only a rim remaining to support the implant 100. In another embodiment, supports 23 are removable, and connect to the bottom 21 as a separate element intended to contain bone fusion material. The individual members 41, 42 may have the same or different sizes and shapes. In one embodiment, sidevail 22 is positioned inward from an outer edge of the bottom 21. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.
Claims

What is claimed is:

1. A device for a vertebral implant comprising:
   - a base having a bottom and a sidewall that extends from the bottom to form a receiving area;
   - an opening in the sidewall that leads into the receiving area; and
   - a gate having a first end and a second end, the gate being attached to the sidewall and selectively positionable between a first orientation with the second end positioned clear of the opening and a second orientation with the second end positioned at the opening with the gate extending across a section of the opening to prevent the implant from escaping from the receiving area.

2. The device of claim 1, wherein the gate is pivotally attached to the sidewall at a point between the first end and the second end.

3. The device of claim 2, wherein the gate is attached to the sidewall at a point in closer proximity to the first end than to the second end.

4. The device of claim 2, wherein the first end extends into the receiving area when the gate is in the first orientation.

5. The device of claim 1, wherein the gate is removed from the sidewall in the first orientation.

6. The device of claim 1, wherein the gate is removably attached to the base, the gate comprises ends having locking mechanisms that each attach to the base.

7. The device of claim 1, wherein the sidewall further comprises a slot sized to receive the gate in the first orientation.
8. The device of claim 7, wherein a height of the gate is different than a height of the slot to maintain the gate in the first orientation.

9. The device of claim 1, further comprising spikes that extend outward from a second face of the bottom.

10. The device of claim 1, further comprising apertures on a second face of the bottom to receive another member.

11. The device of claim 1, further comprising a second gate with first and second ends, the second gate being attached to the sidewall and selectively positionable relative to the base.

12. The device of claim 1, wherein each of the first and second gates are pivotaly attached to the sklewail at a point between the first and second ends of the first and second gates.

13. The device of claim 11, wherein the second gate is sized to extend across at least a section of the opening.

14. The device of claim 11, wherein the first and second gates are substantially the same length.

15. The device of claim 11, further comprising slots within the sidewalls to at least in part house the first and second gates.

16. The device of claim 11, wherein the first and second gates are positionable between a first orientation with the first and second gates positioned clear of the opening, and a second orientation with the first and second gates positioned across at least a section of the opening.
17. The device of claim 16, wherein the first ends are positioned within the receiving area when the first aid second gates are in the first orientation, and aligned with the sidewall when the first and second gates are in the second orientation.

18. The device of claim 16, wherein second ends of the first and second gates comprise a Socking mechanism to maintain the gates in the second orientation.

19. The device of claim 16, wherein the second ends of the first and second gates are spaced apart in the first orientation.

20. The device of claim 16, wherein the first ends are positioned outside of the sidewalls in the first orientation, and aligned with the sidewalls in the second orientation.

21. The device of claim 16, wherein a distance between the second ends of the gates in the first orientation is greater than a width of the opening.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

According to International Patent Classification (IPC) or to both national classification and IPC

INV. A61F2/30 A61F2/44 A61F2/46

A61F

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents

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Date of the actual completion of the international search

23 March 2007

Date of mailing of the international search report

30/03/2007

Name and mailing address of the ISA/

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