US 20080228275A1

(19) United States

(12) Patent Application Publication

Cannon et al.

(10) Pub. No.: US 2008/0228275 A1

(43) Pub. Date: Sep. 18, 2008

(54) **INTERVERTEBRAL IMPLANT COMPONENT WITH THREE POINTS OF CONTACT**

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(21) Appl. No.: **11/686,021**

(22) Filed: **Mar. 14, 2007**

Publication Classification

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

(52) **U.S. Cl.** **623/17.16**

(57) **ABSTRACT**

An intervertebral implant is made up of components which each have an inner surface and an outer surface which engages an adjacent vertebra and presents only three distinct points of contact with a cortical rim of the vertebra. Preferably, the outer surface has a footprint which is sized to be within that of the cortical rim. In disclosed embodiments, the footprint can be convexo-concave shaped, D shaped, or kidney shaped. The intervertebral implant can be provided with upper and lower (or first and second) components which engage adjacent first and second vertebrae and which move relative to one another. The implant has both the first and second outer surfaces sized to present a respective footprint sufficient for two lateral-anterior and one posterior points of contact with an adjacent cortical rim of the respective first and second vertebra.

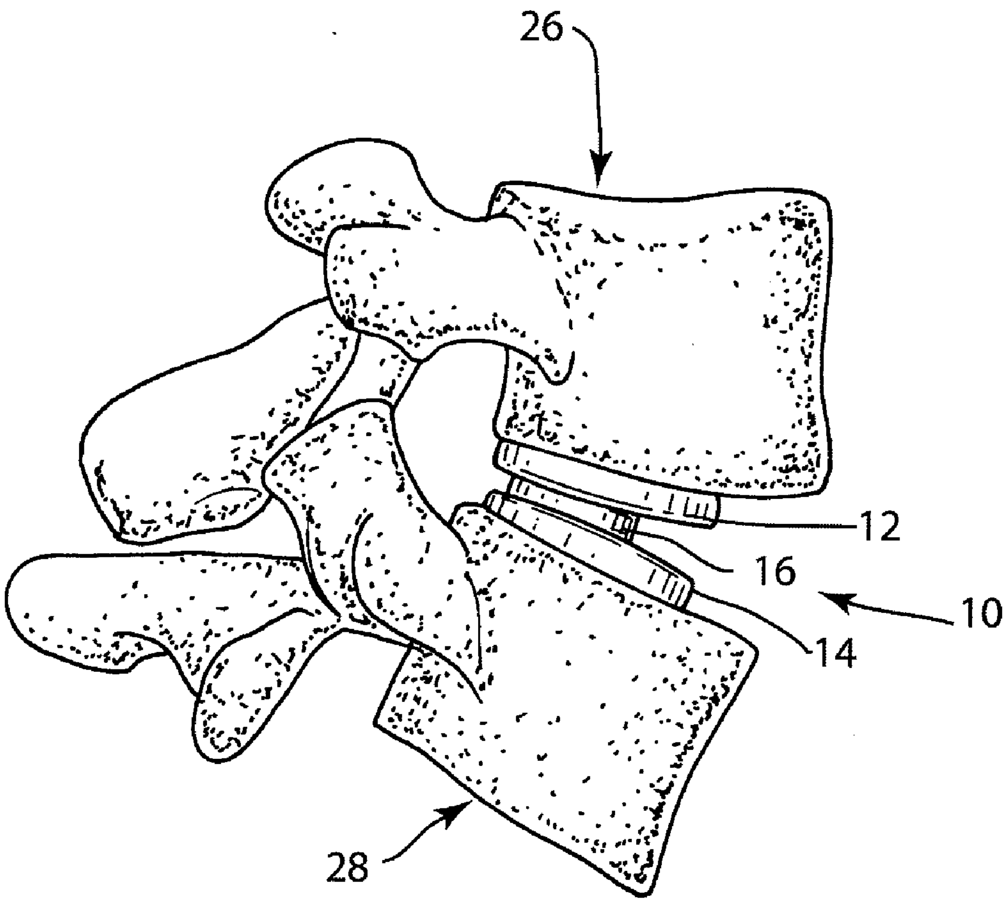
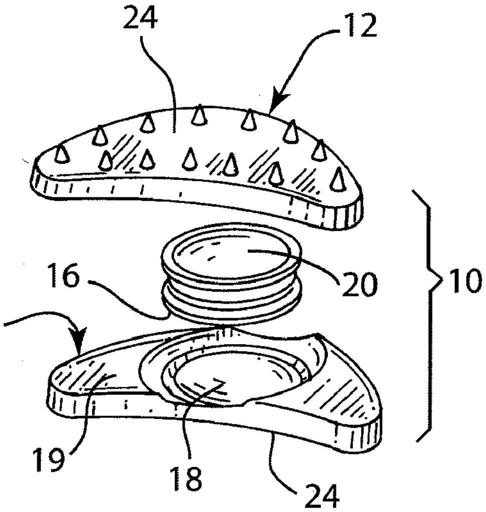


Fig. 1



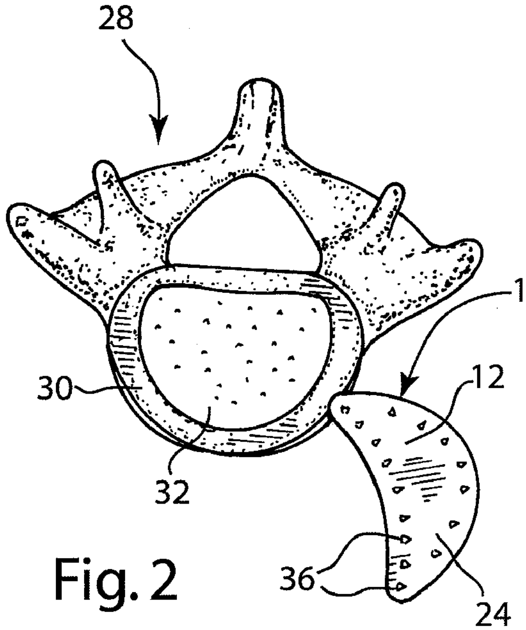
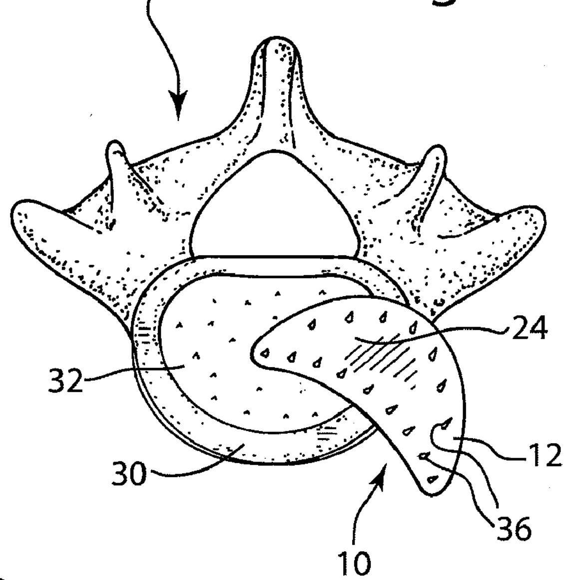


Fig. 2

Fig. 3



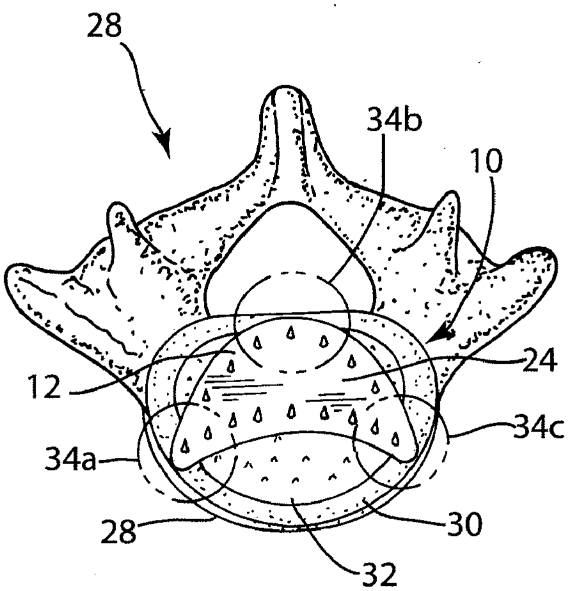


Fig. 4

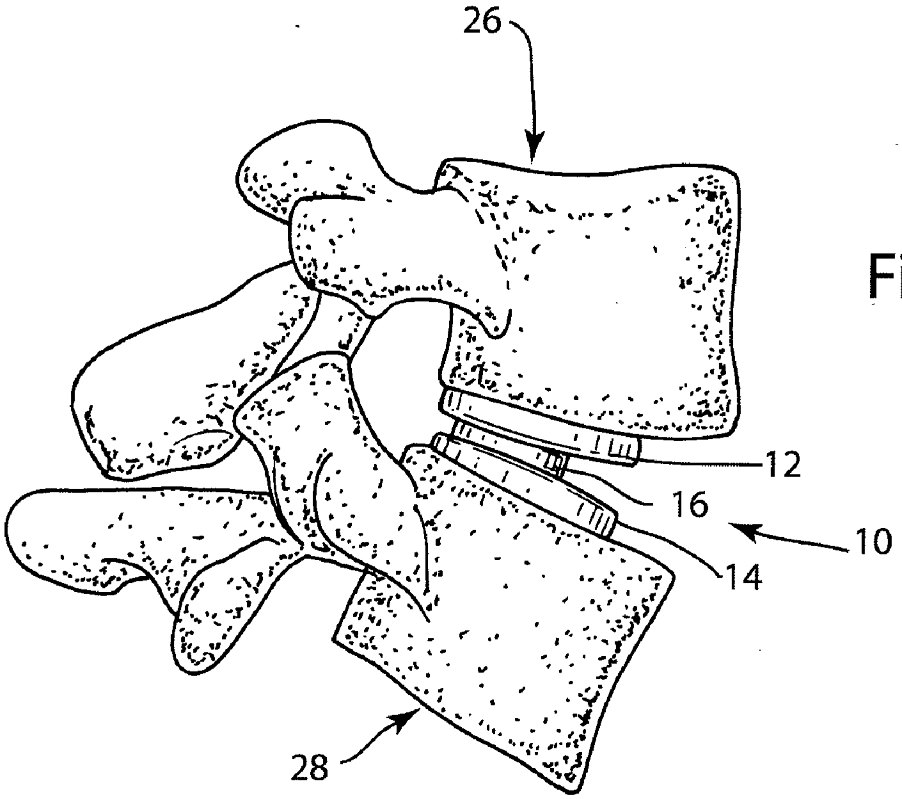


Fig. 5

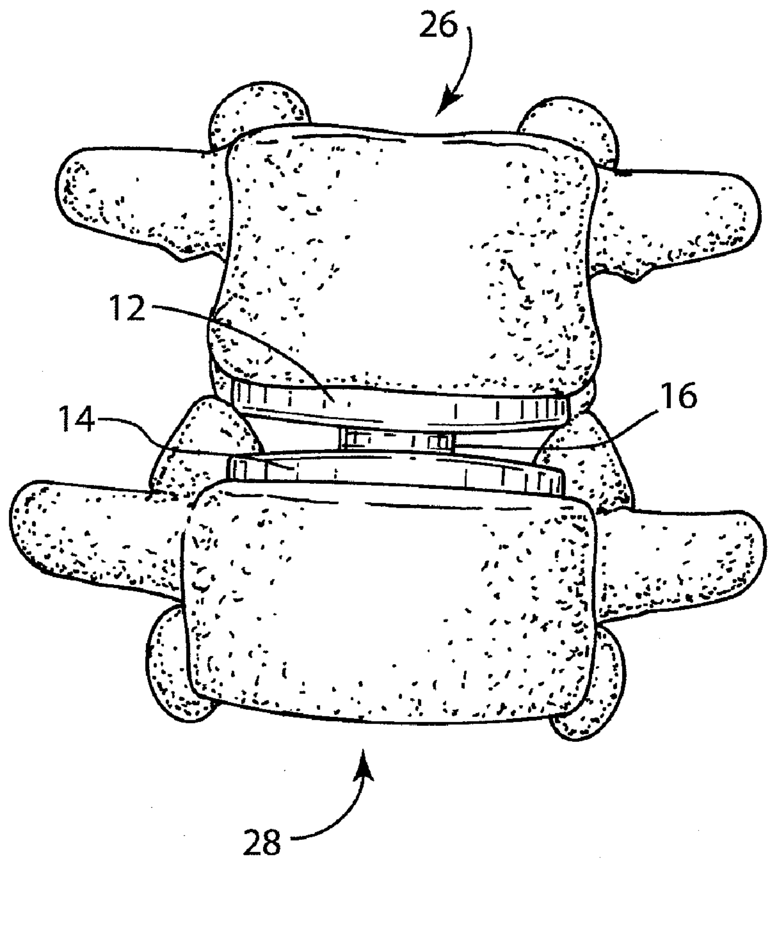


Fig. 6

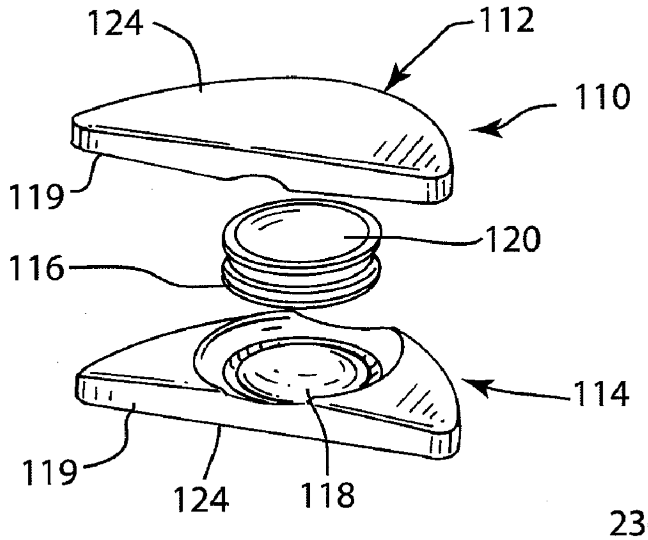


Fig. 7

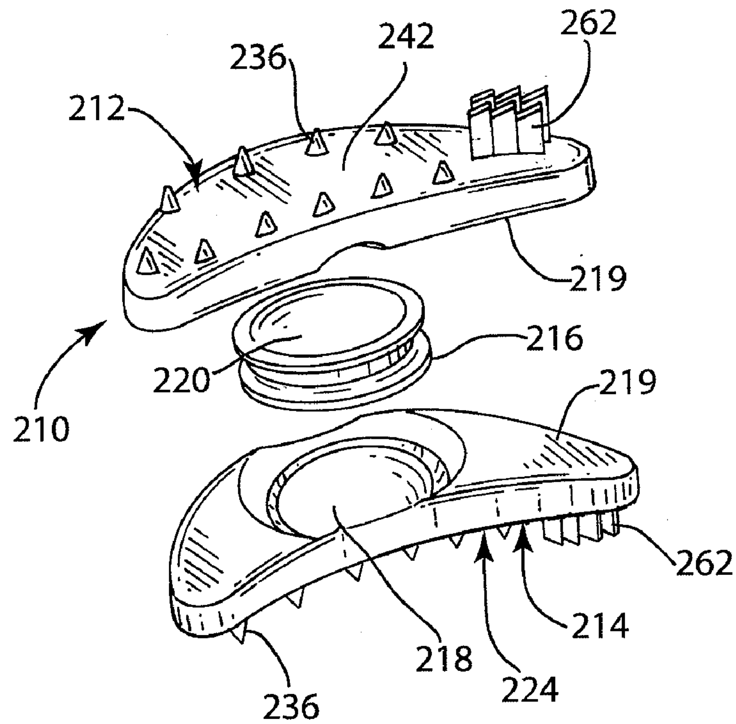


Fig. 8

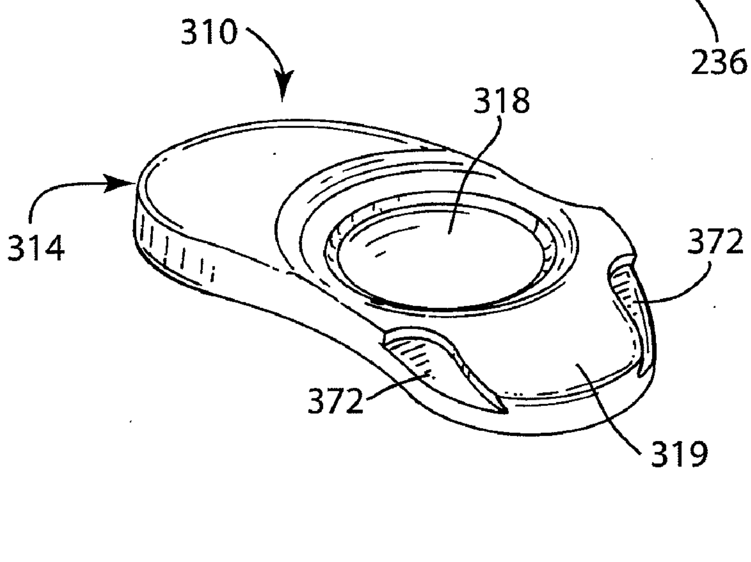


Fig. 9

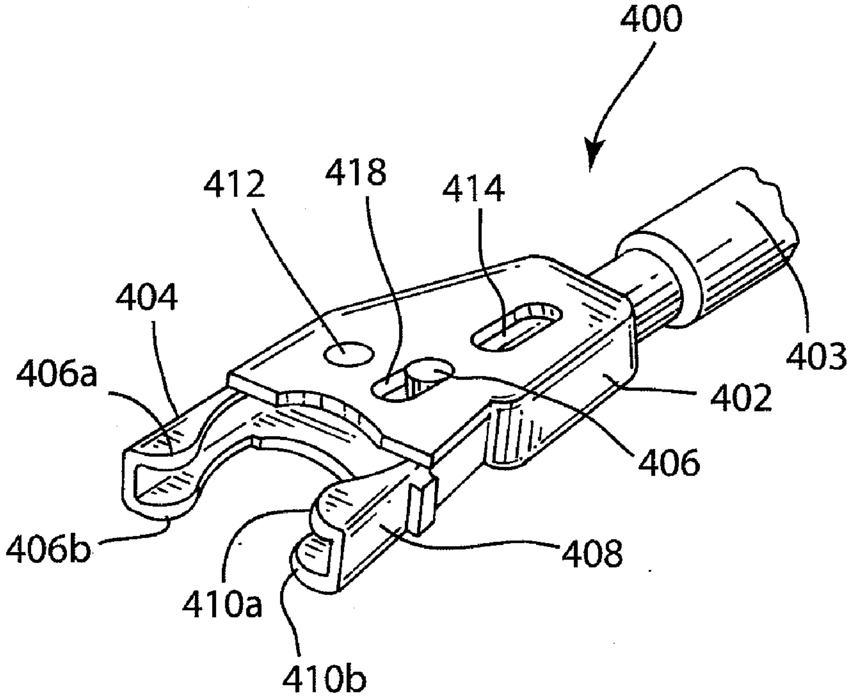

400
412
418
414
404
406a
403
402
406
406b
408
410a
410b

Fig. 10

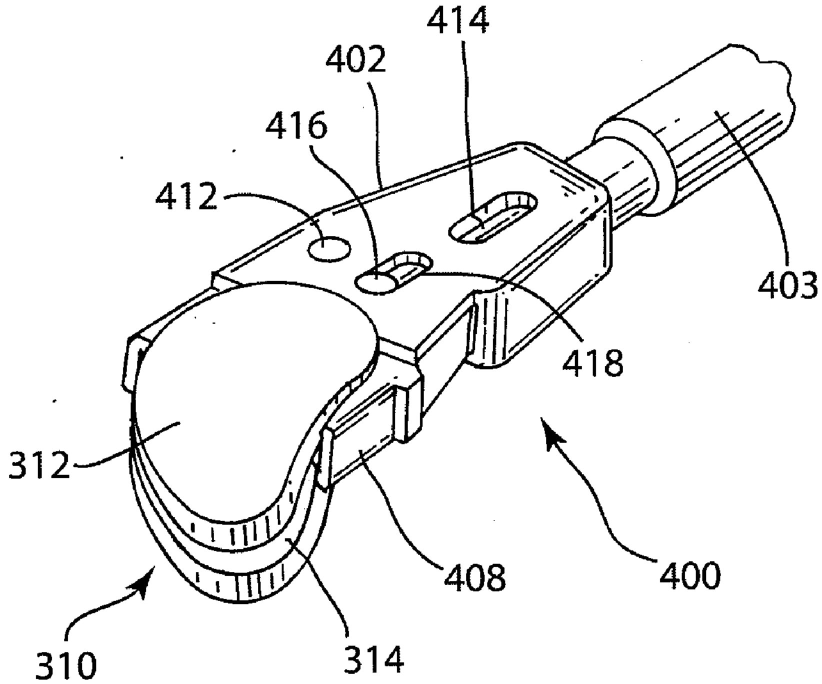

414
402
416
412
403
418
312
408
400
310
314

Fig. 11

INTERVERTEBRAL IMPLANT COMPONENT WITH THREE POINTS OF CONTACT

BACKGROUND OF THE INVENTION

[0001] Historically, when it was necessary to completely remove a disc from between adjacent vertebrae, the conventional procedure is to fuse the adjacent vertebrae together. This "spinal fusion" procedure, which is still in use today, is a widely accepted surgical treatment for symptomatic lumbar degenerative disc disease. However, reported clinical results vary considerably, and complication rates are considered by some to be unacceptably high.

[0002] More recently, there have been important developments in the field of disc replacement, namely disc arthoplasty, which involves the insertion of an artificial intervertebral disc implant into the intervertebral space between adjacent vertebrae, and which allows limited universal movement of the adjacent vertebrae with respect to each other. The aim of total disc replacement is to remove pain generation (caused by a bad disc), restore anatomy (disc height), and maintain mobility in the functional spinal unit so that the spine remains in an adapted sagittal balance. Sagittal balance is defined as the equilibrium of the trunk with the legs and pelvis to maintain harmonious sagittal curves. In contrast with fusion techniques, total disc replacement preserves mobility in the motion segment and mimics physiologic conditions.

[0003] One such intervertebral implant includes an upper part that can communicate with an adjacent vertebrae, a lower part that can communicate with an adjacent vertebrae, and an insert located between these two parts. An example of this type of implant is disclosed in U.S. Pat. No. 5,314,477 (Marnay).

[0004] While this and other known implants represent improvements in the art of artificial intervertebral implants, there exists a continuing need for improvements in this field.

BRIEF SUMMARY OF THE INVENTION

[0005] In accordance with the present invention, a component of an intervertebral implant is provided with an inner surface and an outer surface. The outer surface engages an adjacent vertebra and presents only three distinct points of contact with a cortical rim of the adjacent vertebra. Preferably, the outer surface has a footprint which is sized to be within that of the cortical rim. In disclosed embodiments, the footprint of the outer surface has a major convex side and can be convexo-concave shaped, D shaped, or kidney shaped.

[0006] Preferably, the three points of contact of the footprint of the outer surface with the cortical rim are two lateral-anterior points and one posterior point. In addition, the footprint of the outer surface includes opposed ends which provide the two lateral-anterior points of contact.

[0007] In a preferred embodiment, the outer surface of the component includes at least one vertebra engaging protrusion. The protrusion can include a protruding keel located adjacent an opposed or longitudinal end, which keel may be curved.

[0008] Also in a preferred embodiment, the inner surface includes a pair of cutouts extending to an adjacent outer edge thereof. The cutouts are preferably angled centrally inwardly and dovetail shaped in cross section.

[0009] Also in accordance with the present invention, an intervertebral implant can be provided with upper and lower (or first and second) components, each as described above and each of which engages an adjacent first and second vertebrae. The implant also includes a means for allowing the first and second components to move relative to one another. The implant would have the outer surfaces of both the first and second components sized to present a respective footprint sufficient for only three points of contact with an adjacent cortical rim of the respective first and second vertebra.

[0010] It is an advantage of the present invention that a minimally sized intervertebral implant is provided.

[0011] It is also an advantage of the present invention that the intervertebral implant has only three points of contact made at the cortical rim of the adjacent vertebrae.

[0012] It is a further advantage of the present invention that a major convex-sided shape of the intervertebral implant presents a small insertion size which can be inserted along an arc shaped path.

[0013] Other features and advantages of the present invention are stated in or apparent from detailed descriptions of presently preferred embodiments of the invention found hereinbelow.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0014] FIG. **1** is a perspective exploded view of an implant in accordance with the present invention.

[0015] FIG. **2** is a top plan view of the implant depicted in FIG. **1** adjacent a vertebra.

[0016] FIG. **3** is a top plan view of the implant depicted in FIG. **2** partially inserted into an intervertebral space.

[0017] FIG. **4** is a top plan view of the implant depicted in FIG. **2** fully inserted into an intervertebral space.

[0018] FIG. **5** is a left side view of the implant depicted in FIG. **2** inserted into an intervertebral space.

[0019] FIG. **6** is an anterior view of the implant depicted in FIG. **5**.

[0020] FIG. **7** is a perspective exploded view of an alternatively shaped implant of the present invention.

[0021] FIG. **8** is a perspective exploded view of an implant similar to FIG. **1** but showing a modification of the invention.

[0022] FIG. **9** is a perspective view of a component of an alternatively shaped implant of the present invention showing a modification of the invention.

[0023] FIG. **10** shows the operative portion of an instrument used for insertion of an implant according to the present invention.

[0024] FIG. **11** shows an implant having components as in FIG. **9** being engaged by the instrument depicted in FIG. **10**.

DETAILED DESCRIPTION OF THE INVENTION

[0025] With reference now to the drawings in which like numerals represent like elements throughout the views, an intervertebral implant **10** according to the present invention is depicted in FIGS. **1-6**. Broadly and as best shown in FIG. **1**, implant **10** is formed of three components or parts, an upper part **12**, a lower part **14** and a movable insert **16** allowing upper part **12** to move relative to lower part **14**. An opposed pair of convexities **18** are provided on respective inner surfaces **19** of upper and lower parts **12** and **14** (though only convexity **18** for lower part **16** is shown), and concavities **20** (only upper concavity **20** is shown) on opposite sides of insert **16** which concavities **20** mate with adjacent convexities **18**. Such parts **12**, **14** and **16** in general and the motions provided thereof are well known in the art, such as in USPA 2006/0116769 (Marnay et al.) which is herein incorporated by reference, and thus need not be discussed further. It will be noted that it is also known in the art that insert **16** could be a convexity extending integrally from one part which mates with a concavity integrally in the other part, so the separate depiction of an insert **16** for the present invention is only exemplary of one type of movable insert means known in the art.

[0026] Both upper and lower parts **12** and **14** each have an outer surface **24**. As known in the art, outer surfaces **24** are each designed to contact an adjacent vertebrae, such as upper and lower vertebrae **26** and **28** depicted in FIGS. **2-6**. As shown in FIGS. **2-4**, vertebra **28** (and similar vertebrae in general) includes a relatively rigid cortical rim **30** of bone which surrounds less rigid cancellous bone **32**. Prior art vertebral implants were designed to cover cortical rim **30**. However, such coverage results in multiple points (or areas) of contact which are not needed. Thus, implant **10** of the present invention provides a more compact and hence easier to insert implant which still has a good and sufficient contact with the adjacent vertebrae.

[0027] It is thus a feature of the present invention that outer surfaces **24** are designed or sized to provide three distinct points (or small areas) of contact **34***a*, **34***b* and **34***c* (or collectively, points **34**) with the adjacent cortical rim **30** as shown in FIG. **4**. It will be appreciated that points of contact **34** shown in FIG. **4** are those of outer surface **24** of upper part **12** which would contact upper vertebra **26** (not shown) but in the same manner as the underlying points of contact **34** of lower part **14** (which are not seen because they are covered by upper part **12**) contact lower vertebra **28** which is shown. It will be noted that outer surface **24** also includes a series of small teeth or spikes **36** or other such protrusions upstanding therefrom which serve to anchor upper and lower parts **12** and **14** in place after implantation as well known in the art.

[0028] As noted above, outer surface **24** is shaped with a major convex side according to the present invention to present a footprint so that only three points of contact **34** are provided thereby. As the size of vertebrae vary depending on location and on the individual user, implant **10** will be tailored to the individual so that only three points of contact **34** are made. This sizing of the footprint of outer surface **24** is conveniently determined by choosing the footprint of outer surface **24** to be located within the footprint of cortical rim **30** as shown. The points of contact **34** are left and right lateral-anterior points **34***a* and **34***c* which are preferably symmetrically located as shown, and a posterior point **34***b*. Conveniently, the footprint of the outer surface **24** includes opposed ends which provide the left and right lateral-anterior points **34***a* and **34***c*. Suitable footprints to provide the three points **34** of contact include: a) a convexo-concave footprint as shown by implant **10** in FIGS. **1-4** (and by implant **210** in FIG. **8**); b) a D-shaped footprint as shown by implant **110** in FIG. **7**; or c) a kidney shaped footprint as shown by implant **310** in FIGS. **9** and **11**.

[0029] The use of such a small footprint and only three points of contact **34** with one being posterior or anterior also makes it possible for implants **10**, **110**, **210** and **310** to have a relatively narrow or small maximum width between left and right points **34***a* and **34***c* as evident from the three footprints discussed above. This narrow maximum width, particularly where augmented by a longitudinal concavity or inward bowing as with implants **10**, **210** and **310**, permits implants **10**, **110**, **210** and **310** to be inserted between adjacent vertebrae **26** and **28** through a smaller incision than if the implant spanned cortical rim **30** in all directions. In FIGS. **2-4**, it will also be appreciated that the size and shape of implant **10** also makes the implanting of implant **10** from the angle shown and along the path depicted easy to accomplish.

[0030] Implant **110** depicted in FIG. **7** discloses upper and lower parts **112** and **114** having outer surfaces **124** which present a D shaped footprint. As with FIG. **1**, as noted above, insert **116** shows the upper concavity thereof (opposite the similar lower concavity thereof.

[0031] Depicted in FIG. **8** is an implant **210** which is also convexo-concave shaped like implant **10**. However, implant **210** includes a keel **262** extending from each of outer surfaces **224** adjacent an opposed or longitudinal end thereof, and preferably the opposed end which is inserted last between vertebrae **26** and **28** (see FIG. **3**) with the opposite longitudinal end then preferably having a slight chamfer to ease insertion. Each keel **262** serves to anchor the associated upper and lower parts **212** and **214** of implant **210** in place in a provided cutout or slot in adjacent vertebrae **26** and **28** after implantation as known in the art, in addition to the anchoring provided by the small spikes **236** also shown in FIG. **8**. Keel **262** is depicted as curved or arced to match arced insertion path along which implant **210** would be implanted between the vertebrae (as shown by the three positions of implant **10** shown in FIGS. **2-4**); though if implant **262** is implanted along a straight direction, keel **262** would instead be straight. If desired, two or more keels positioned along an arc or straight line could also be provided. The cutout required for keel **262** could be made in advance of implantation, or keel **262** could be self-cutting having chisel-like cutting edges at the introduction end as known in the art.

[0032] In FIG. **9**, an entire implant is identified by the numeral **310**, although only lower part **314** thereof is shown in detail. The upper part **312** is a mirror image thereof, and the insert the same as the above described insert **16**. Lower part **314** has an outer surface **324** which presents a kidney shaped footprint as shown. Also shown on lower part **314** are an opposed pair of cutouts **372** in inner surface **319**. Cutouts **372** are dovetail shaped, that is, the vertical walls thereof are angled inwardly (or each toward the other cutout **372**), and cutouts **372** are also preferably are longitudinally angled centrally inwardly or converging toward one another (or toward convexity **318**) as they extend from the adjacent opposed end. Cutouts **372** are provided so that an instrument with a pair of matingly shaped engaging members can securely grasp lower part **314** (and similarly upper part **312**) in order to insert implant **310** between vertebrae **26** and **28** as generally known in the art; and the added security of having both the dovetails shape and convergence allows cutouts **372** to be usable as well to reposition or even remove implant **310** as required. Of course, cutouts **372** could also be parallel to one another rather than converging if desired if less holding power is needed with the instrument.

[0033] Depicted in FIGS. **10** and **11** is a portion of an insertion instrument **400** which can be used for insertion of implant **310** (or the other disclosed implants if they are provided with cutouts **372**). Instrument **400** includes a base **402** attached to an inserter shaft **403**. Extending distally from base **402** (away from inserter shaft **403**) is a longitudinal fixed arm **404**. Fixed arm **404** is shaped with top and bottom laterally-inwardly directed projections **406***a* and **406***b*. Projections **406** are designed to fit matingly in cutouts **372**, and thus have a mating dovetail design. Laterally opposite to fixed arm **404** is a movable arm **408** having top and bottom laterally-inwardly directed projections **410***a* and **410***b* which are similarly shaped as projections **406** but oppositely directed. Like projections **406**, projections **410** are designed to fit matingly in cutouts **372** but on the opposite side of implant **310**. As known in the art, movable arm **408** is movable about a pivot **412** provided in base **402** toward fixed arm **404**, and this movement is accomplished by a rod **414** guided in inserter shaft **403** which is forced against a pin **416** integral with movable arm **408** and trapped in slot **418** of base **402**.

[0034] In use, instrument **400** is used to grasp implant **310** by placing projections **406** and **410** on either sides of implant **310** and adjacent respective cutouts **372**. Then, by manipulation of rod **414**, movable arm **408** is moved towards fixed arm **404** so that projections **406** and **410** are received in and then locked in cutouts **372**. Once projections **406** and **410** are locked in place in cutouts **372**, implant **310** is securely attached to base **402** so that implant **310** can be inserted between vertebrae by manipulation of inserter shaft **403** as known in the art.

[0035] While the present invention has been described with respect to exemplary embodiments thereof, it will be understood by those of ordinary skill in the art that variations and modifications can be effected within the scope and spirit of the invention.

1. An intervertebral implant component comprising:

an outer surface for engaging an adjacent vertebra and an inner surface;

wherein said outer surface is constructed to present only three distinct points of contact for engaging a cortical rim of the adjacent vertebra, and said outer surface has a footprint which is sized to be within that of the cortical rim to be engaged.

2. (canceled)

3. An intervertebral implant component as claimed in claim **21** wherein said footprint of said outer surface is convexo-concave shaped.

4. An intervertebral implant component as claimed in claim **1**, wherein said footprint of said outer surface is D shaped.

5. An intervertebral implant component as claimed in claim **1**, wherein said footprint of said outer surface is kidney shaped.

6. An intervertebral implant component as claimed in claim **1**, wherein said three points of contact of said footprint of said outer surface with the cortical rim are two lateral-anterior points and one posterior point.

7. An intervertebral implant component as claimed in claim **6**, wherein a footprint of said outer surface includes opposed ends which provide the two lateral-anterior points of contact.

8. An intervertebral implant component as claimed in claim **1**, wherein said outer surface includes at least one vertebra engaging protrusion.

9. An intervertebral implant component as claimed in claim **8**, wherein said at least one vertebra engaging protrusion includes a protruding keel located adjacent a longitudinal end of said outer surface.

10. An intervertebral implant component as claimed in claim **9**, wherein said keel is curved.

11. An intervertebral implant component as claimed in claim **1**, wherein said inner surface includes a pair of instrument receiving cutouts extending to an adjacent outer edge thereof.

12. An intervertebral implant component as claimed in claim **11**, wherein said cutouts are angled centrally inwardly.

13. An intervertebral implant component as claimed in claim **12**, wherein said cutouts are dovetail shaped in cross section.

14. An intervertebral implant comprising:

a first part which has a first outer surface for engaging a first vertebra and a first inner surface;

a second part which has a second outer surface for engaging a second vertebrae and a second inner surface; and

said first and second parts being moveable relative to one another;

wherein said first and second outer surfaces are sized to present a respective footprint sufficient for only three points of contact with an adjacent cortical rim of the respective first and second vertebra to be engaged, said footprints also being sized to be within that of the adjacent cortical rim to be engaged.

15. (canceled)

16. An intervertebral implant as claimed in claim **14**, wherein said footprints of said outer surfaces are convexo-concave shaped.

17. An intervertebral implant as claimed in claim **14**, wherein said footprints of said outer surfaces are D shaped.

18. An intervertebral implant as claimed in claim **14**, wherein said footprints of said outer surfaces are kidney shaped.

19. An intervertebral implant as claimed in claim **14**, wherein said three points of contact of each of said footprints of said outer surfaces with the adjacent cortical rims are two lateral-anterior points and one posterior point.

20. An intervertebral implant as claimed in claim **19**, wherein each of said footprints of said outer surfaces include opposed ends which provide the two lateral-anterior points of contact.

21. An intervertebral implant as claimed in claim **14**, wherein each of said outer surfaces includes at least one vertebra engaging protrusion.

22. An intervertebral implant as claimed in claim **21**, wherein each said at least one vertebra engaging protrusion includes a protruding keel located adjacent a longitudinal end of the respective said outer surface.

23. An intervertebral implant as claimed in claim **22**, wherein each said keel is curved.

24. An intervertebral implant as claimed in claim **14**, wherein each of said inner surfaces includes a pair of instrument receiving cutouts extending to an adjacent outer edge thereof.

25. An intervertebral implant as claimed in claim **24**, wherein each of said cutouts is angled centrally inwardly.

26. An intervertebral implant as claimed in claim **25**, wherein each of said cutouts is dovetail shaped in cross section.

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