(30) Priority data:

733,710

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5: WO 93/01771 (11) International Publication Number: A1 A61F 2/44 (43) International Publication Date: 4 February 1993 (04.02.93)

PCT/US92/05859 (21) International Application Number:

22 July 1992 (22.07.92) (22) International Filing Date: Published

US

(71) Applicant: CALCITEK, INC. [US/US]; 2320 Faraday Avenue, Carlsbad, CA 92008 (US).

22 July 1991 (22.07.91)

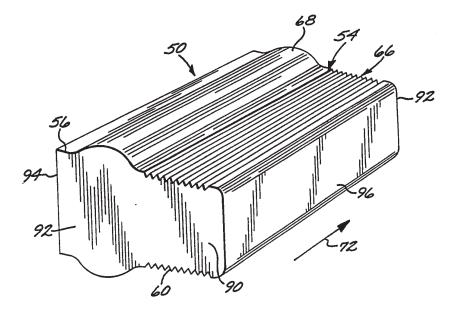
(72) Inventors: SENTER, Howard, J.; 1760 Beechwood Blvd., Pittsburgh, PA 15217 (US). WAGNER, William, R.; 1225 Via Ramon, Escondido, CA 92029 (US). LARIV-IERE, Richard, L.; 3515 Ryan Drive, Escondido, CA 92025 (US).

(74) Agents: GARMONG, Gregory, O.; 13126 Silver Saddle Lane, Poway, CA 92064 (US) et al.

(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE).

With international search report.

(54) Title: SPINAL DISK IMPLANT



(57) Abstract

۲

A spinal disk implant (50) comprises a solid body (90) having four sides (54, 54a, 94, 96) and a pair of spaced-apart, opposed bases (92). Each transverse face (54, 54a) has an anterior platform (56) adjacent to the anterior face (94). A posterior ledge (60) is oriented at an insertion angle (I) relative to an opposed posterior ledge (60a) of the opposed transverse face (54a). At least one of the posterior ledges (54, 54a) has a pattern of serrations (66). There is a ridge (68) on at least one of the transverse faces (54, 54a), positioned between the anterior platform (56) and the posterior ledge (60) and extending in the direction perpendicular to the bases (92). The implant (50) is desirably formed at least in part from a material that bonds with natural bone after implant, such as the ceramic hydroxylapatite.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

ΑT	Austria	FI	Finland	MI	Mali
AU	Australia	FR	France	MN	Mongolia
BB	Barbados	GA	Gabon	MR	Mauritania
BE	Belgium	GB	United Kingdom	MW	Malawi
BF	Burkina Faso	GN	Guinea	NL.	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	ΙE	Ireland	RO	Romania
CA	Canada	IT	Italy	RU	Russian Federation
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic	SE	Sweden
CH	Switzerland		of Korea	SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU	Soviet Union
CM	Cameroon	LI	Licchtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		
ES	Spain	MG	Madagascar		

-1-

Description

Spinal Disk Implant

Technical Field

This invention relates to implants surgically placed into the human body, and, more particularly, to an implant placed between two vertebrae to fuse them together.

Background Art

The human spine is composed of a column of 33 10 bones. termed vertebrae, and their joining structures. The 24 vertebrae nearest the head, collectively termed the presaccral vertebrae, are separate bones capable of individual movement. presaccral vertebrae are generally bodies of the 15 connected by anterior and posterior longitudinal ligaments and by discs of fibrocartilage, termed intervertebral disks, positioned between opposing faces of adjacent vertebral bodies. These mobile vertebrae may be classified by their position and 20 function into either cervical, thoracic, or lumbar vertebrae. The remaining 9 vertebrae are fused to form the saccrum (5 vertebrae) and the coccyx (4 vertebrae) and are incapable of individual movement. This column ofvertebrae and 25 intervertebral disks form a central axis for supporting the load of the head and torso. The vertebral body and the dorsal vertebral arch of each of the 24 mobile presaccral vertebrae enclose an opening, termed the vertebral foramen, through which spinal cord, a column of nerve tissue which communicates nerve impulses between the brain and the rest of the body, and the spinal nerve roots pass and are protected from damage.

The presaccral vertebrae are normally held in 35 a precise relation to each other by the intervertebral disks, the longitudinal ligaments,

the musculature of the body. These vertebrae and move relative to adjacent vertebrae in various can manners, permitting the head to be turned relative providing a wide range body and to the The movement between flexibility to the spine. individual pairs of vertebrae is limited to prevent local pressure on the spinal cord or excessive bending of the spinal cord. Such pressure possibly result in disorders bending could with blockage of the nerve impulses associated traveling along the spinal cord, in turn producing paresthesia, or loss of motor control which pain, resolved by removing the causative be must condition.

10

25

30

35

The nerve conduction disorders may also be 15 associated with the intervertebral disks or the such condition is a One bones themselves. intervertebral disk. in which a herniation of the amount of tissue protrudes from the sides of the disk into the foramen to compress the spinal 20 A second common condition involves cord. development of small bone spurs, termed osteophytes, the posterior surface of the vertebral body, again impinging on the spinal cord.

Upon identification of the abnormality causing the conduction disorders, surgery may be required to the problem if more conservative treatment correct For those problems associated with fails. of osteophytes or herniations of formation intervertebral disk, one such surgical procedure is In this procedure, the discectomy. intervertebral the are exposed and bodies involved vertebral thus removing the disk is removed, intervertebral or providing access for the offending tissue, osteophytes. A second the bone removal of spinal fusion, may then be procedure, termed a required to fix the vertebral bodies together to

5

10

15

20

25

-3-

prevent movement and maintain the space originally occupied by the intervertebral disk. Although there may result some minor loss of flexibility in the spine, because of the large number of vertebrae the loss of mobility is usually acceptable.

During a spinal fusion following a discectomy, an implant is inserted into the intervertebral This intervertebral implant is often a bone graft removed from another portion of the patient's body, termed an autograft. The use of bone taken from the patient's body has the important advantage avoiding rejection of the implant, but has some There is always a risk in opening a shortcomings. second surgical site for obtaining the implant, which can lead to infection or pain for the patient, site of the implant is weakened by the the removal of bony material. The bone implant may not perfectly shaped and placed, leading to slippage absorption of the or implant, or failure of the implant to fuse with the vertebrae.

options for a graft source for are bone removed from cadavers, termed an allograft, orfrom another species, termed xenograft. In these cases, while there is the benefit of not having a second surgical site as a possible source infection or pain, there is the of increased difficulty with graft rejection and the risk of transmitting communicable diseases.

alternative approach to using a bone graft is to use a manufactured implant made of a synthetic 30 that is biologically compatible with the material body and the vertebrae. Several compositions and geometries of such implants have been utilized, ranging from simple blocks of material to carefully 35 shaped implants, with varying success. No fully satisfactory implant has been reported. In some instances, the implanting surgery is readily

accomplished, but the results are unsatisfactory due to side effects or dislocation of the implant. In other instances, the implant requires a complex surgical procedure that is difficult to perform and still may not lead to correction of the problem for the reasons indicated.

There is therefore a need for an improved spinal disk implant, which is both readily utilized in a surgical procedure and has a high probability of success without undesirable side effects. The present invention fulfills this need, and further provides related advantages.

Disclosure of Invention

10

15

20

25

30

present invention provides a surgical The implant, and its method of use, that is implanted between two vertebrae during a procedure in which two vertebrae are fused together. The surgical disk implant is readily manufactured of biologically compatible materials in the required shape and with preselected dimensions. so that a properly dimensioned implant is available for the particular vertebrae being fused together. The disk implant of readily implanted invention may bе procedures, with established surgical chances of surgical difficulty. The geometry of the good load bearing and support implant ensures the fused vertebrae, and minimizes the through the implant dislocating relative to likelihood of during surgery or during the the vertebrae either post-operative fusing process.

In accordance with the invention, a spinal disk implant comprises a solid body having four sides and a pair of spaced-apart, opposed bases. The four sides include spaced-apart, opposed

-5-

anterior and posterior faces, and a pair of spaced-apart, opposed transverse faces. Each transverse face has an anterior platform adjacent to the anterior face. The anterior platform is spaced . 2 apart from the opposed anterior platform by maximum anterior platform spacing. A posterior ledge is oriented at an insertion angle relative to opposed posterior ledge of the opposed transverse least one of the posterior ledges has 10 thereon pattern of serrations. There is a ridge least one of the transverse faces, positioned between the anterior platform and the posterior ledge and extending in the direction perpendicular the bases. The top of the ridge is spaced apart 15 from the opposed transverse face by an amount than the anterior platform spacing. may be a ridge on one or both transverse faces.

spinal disk implant is a generally rectangular block of material, which has 20 distinct regions. The anterior platform on each transverse face are preferably, but not necessarily, parallel to each other and spaced apart by the desired spacing of the vertebrae. The disk implant surgically implanted SO that the anterior 25 cortical bone regions of the vertebrae contact the anterior platforms on the opposing transverse faces, precisely defining the final separation of vertebrae. This separation is maintained after implantation to a good degree of accuracy, because 30 majority of the load carried by the vertical spinal column is reacted through the anterior cortical bone of the vertebrae and the anterior platform region of the surgical disk implant.

The posterior ledge is preferably, although not necessarily, tapered inwardly to permit the implant to be inserted between the vertebrae during the surgical procedure. The surface of the

intermediate ridge is preferably smooth for the same The serrations of the posterior ledge, acting together with the intermediate ridge, key the engagement of the implant with each vertebra and prevent dislocation of the implant with respect to The principal keying engagement is vertebrae. the cancellous bone region of the vertebrae. Preferably, a relatively small portion of the load by the spine is carried through the posterior ledge and the ridge, because their contact with the cancellous bone makes settling in of the implant vertebrae a greater concern in this into the The anterior platform and/or the posterior region. the ridge can be bowed outwardly ledge and/or slightly, to match the shape of the contacted vertebrae more precisely.

10

15

30

spinal disk implant may alternatively be terms of the functional relations of described elements. In accordance with this structural aspect of the invention, a spinal disk implant is 20 placed between two adjacent vertebrae previously originally having a spinal disk therebetween, each vertebra having an anterior cortical bone region and central cancellous bone region. The disk implant comprises a solid body of substantially the same 25 height as the natural spacing between the anterior cortical bone regions of the two adjacent vertebrae of equal-to or lesser width than the spinal disk The disk two vertebrae. originally between the implant has means for supportively engaging the cortical bone regions of the adjacent vertebrae, the supportively engaging including opposing, means for apart anterior platforms, and means spaced achieving keying engagement of the implant with the cancellous bone region of each vertebra to prevent 35 implant with respect to the two dislocation of the vertebrae after implantation of the implant between

-7-

the two vertebrae.

spinal disk implant is preferably made in The whole or a ceramic material such as in part of (calcium) hydroxylapatite. Hydroxylapatite ("HA") 5 composition and crystal structure similar to that of mineral phase of natural bone, and has the proven biocompatibility with natural bone. Alternatively, the spinal disk implant may be made whole in part of a biocompatible orthopedic or 10 polymer ("BOP"), or other suitable material. implant may be made in its entirety of such materials, may be made of a metal such as a or titanium alloy, or a metal covered with a layer of the ceramic such as HA or BOP. Additionally, the 15 spinal disk implant may be made with its surface microporous so that it may be impregnated with therapeutic agents prior to implantation. implant may then function as a delivery vehicle for the impregnated therapeutic agents, such antibiotics 20 or bone stimulating factors such as bone morphogenic protein ("BMP") or osteogenin.

present invention provides an advance in the art of intervertebral disk implants. The implant of the invention may be readily placed 25 surgically, is designed to provide load bearing and capability to the spine while minimizing likelihood of dislocation of the implant. features and advantages of the invention will be apparent from the following more detailed 30 description of the preferred embodiments, taken in conjunction with the accompanying drawings illustrate, by way of example, the principles of the invention.

Brief Description of Drawings

15

20

25

30

Figure 1 is a side elevational view of the spine;

Figure 2 is a plan view of a cervical 5 vertebra;

Figure 3 is an elevational view of the spinal disk implant of the invention;

Figure 4 is a perspective view of the spinal disk implant of Figure 3;

Figure 5 is another embodiment of the spinal disk implant;

a diagrammatic depiction of the Figure 6 is implanting the spinal disk for surgical procedure the invention, wherein Figure 6A is a implant of Figure 1, Figure 6B is the same region as detail of after removing the natural intervertebral 6A Figure disk, Figure 6C depicts the formation of a retaining groove in the vertebrae, Figure 6D depicts placement the spinal implant of Figure 3, Figure 6E depicts spinal implant, and Figure 6F insertion of the depicts the implant in place between the vertebrae;

Figure 7 is a plan view of a cervical vertebra similar to the view of Figure 2, with the properly positioned spinal disk implant indicated in phantom lines;

Figure 8 is a perspective view similar to Figure 4 of another embodiment of the invention;

Figure 9 is an anterior elevational view of another embodiment of the spinal disk implant;

Figure 10 is a posterior elevational view of another embodiment of the spinal disk implant; and

Figure 11 is an anterior elevational view of another embodiment of the spinal disk implant.

Best Mode for Carrying Out The Invention

5

10

15

Figure 1 depicts a human spine 20. The spine 20 is formed from thirty-three individual vertebrae 22, with the 24 uppermost vertebrae in most cases separated by intervertebral disks 24. The spine 20 is described as having an anterior side 26 and a posterior side 28.

2 depicts one of the vertebrae, here Figure one of the cervical vertebrae 30. (A cervical vertebra has been chosen for illustration, but the other vertebra are similar in relevant aspects and differ primarily in details of geometry.) vertebra 30 includes a vertebral body region 32, and various processes 34. A cervical disk 36, indicated phantom lines, overlies the vertebral body region the natural condition. A central opening through the vertebra 30 is the foramen 38, through which the spinal cord and the spinal nerve roots pass.

20 vertebral body region 32 The includes distinct types of natural bone. A layer of cortical bone is found at an anterior edge 42 vertebral body region 32. The cortical bone is a hard, dense type of bone, having high strength. A central portion 44 of the vertebral body region 32 of cancellous bone, which is a resilient, weaker, and less dense type of bone.

implant 50, shown in Figures 3 spinal disk and 4, has \mathbf{a} structure designed for implantation between the vertebral body regions of two adjacent 30 vertebrae 22. This spinal disk implant readily inserted between the vertebrae during a surgical procedure, produces a load-bearing joint in which the majority of the load on the spine 20 is 35 borne through the cortical bone, and is highly resistant to dislocation away from its proper position between the vertebrae.

5

10

15

20

50 is a right-angled prismatic implant sides and a pair body 90 having four parallel bases 92. The four spaced-apart, opposed apart anterior and posterior sides include spaced 94 and 96, and a pair of spaced-apart, opposed faces faces 54. In the elevational view of transverse Figure 3, the preferred embodiment of the implant 50 bilaterally symmetric about a seen to be central plane 52 positioned between the transverse pair of opposing, spaced-apart transverse faces 54.

54 includes face transverse Each An anterior platform 56 of each transverse regions. is parallel (in the illustrated embodiment) an opposing anterior platform 56a on an opposing transverse face 54a. The two anterior platforms 56 56a are separated by a preselected distance 58, substantially equal to the natural spacing which is between the two vertebrae between which the implant is to be placed. This spacing criterion provides basis for selecting appropriately sized implants 50.

is tapered inwardly, posterior ledge 60 Α 52. The angular plane toward the central orientation between the two posterior ledges 60 and 25 insertion angle I. An end 62 of the is an posterior ledge 60 closest to the anterior platform spaced from a corresponding end 62a of the opposing posterior ledge 60a by a distance 64, which less than the distance is preferably equal to or 30 The angle I (between the two posterior ledges 58. 60 and 60a) is from 0 degrees (no taper) to about 10 is preferably from about 0.5 to about 10 degrees, is most preferably about 5.2 and degrees. The implant is operable with no taper. degrees. 35 testing has indicated that an insertion However. of more than about 0.5 degrees imparts a angle I

-11-

slight wedge shape to the implant and significantly aids in achieving a smooth surgical insertion of the implant between the vertebrae. If the insertion angle is more than about 10 degrees, the geometry of the implant makes achieving full contact with the vertebrae difficult, and can interfere with satisfactory post-operative fusion.

pattern of serrations 66, extending perpendicular to the plane of the illustration of Figure 3 and thence in the direction perpendicular the bases 92, is present on the posterior ledge The serrations are desirably in the form of protrusions outwardly from the posterior ledge 60 extending across a portion of the surface. serrations may be small teeth, continuous small ridges, bumps, or other equivalently performing structure. The serrations 66 interlock with the cancellous bone of the vertebrae to inhibit dislocation (movement) of the implant 50 relative to the vertebrae after implantation.

10

15

20

25

30

35

the transverse face 54, positioned between anterior platform 56 and the posterior ledge 60, the intermediate ridge 68. The ridge 68 extends perpendicular to the plane of the illustration of Figure 3 thus perpendicular to the bases 92. and top of the ridge 68 is separated from the top of ridge 68a on the opposing transverse face 54a by distance 70. The distance 70 is greater than either the distance 58 The ridge 68 is or64. preferably smooth, without serrations, to permit it surgically implanted bе in the manner described subsequently.

Dislocation (movement) of any spinal implant is a serious concern, and the present implant 50 is designed to avoid such movement. Dislocation of the implant 50 posteriorly toward the foramen 38 is of particular concern, because such dislocation could

implant 50 impinging against the result in the The combination of the ridge 68, the spinal cord. slightly wedge-shaped serrations 66, and the configuration of the implant 50 all aid in avoiding dislocation of the implant 50, and particularly in avoiding dislocation in the direction of the spinal cord.

implant may be interpreted as being formed extending a planar section of the shape shown in 3 in the direction perpendicular to the bases 92, sometimes termed a prism generator 72. the case of the preferred embodiment is a prismatic body that is bilaterally symmetric right transverse central plane 52, but other about the invention may not have the bilateral 15 forms of the symmetry about the plane 52.

the embodiment of Figures 3-5, In of each transverse face 54 is a mirror structure of the other, symmetric face 54a. 20 embodiments of the implant need not be symmetric about a central plane, but can be asymmetric for use particular procedures. Figure 8 illustrates an 50' asymmetric asymmetric implant having two (Features corresponding to those features. 25 Figures 3-5 bear the same numbering.) There is only ridge 68, and the pattern of serrations 66 is found on only one of the transverse faces 54. this case the serrations 66 are in the form of dimples rather than the form shown in Figures 3-5. 30 These asymmetries need not be used together, and, for example, an operable implant may have only one on both transverse faces. ridge but serrations example, there may be one ridge only, on one another the transverse faces, and one set of serrations 35 only, on the same or the opposed transverse face.

Figure 8 also shows another feature not found in the embodiment of Figures 3-5. A pattern of

-13-

serrations 100 is formed on at least one of the anterior platforms 56, to provide a gripping action with the cortical bone region of the vertebra. The pattern of serrations 100 can be placed on neither, one, or both of the anterior platforms 56.

5

Three other embodiments of the invention are in Figures 9-11. Figure 9 is an elevational view from the anterior face side of an implant 110, whose construction is similar to that shown 10 Figure 4, that one or both of the anterior except platforms 56 bowed outwardly (i.e., of convex is shape) relative to the body of the implant. Figure elevational view from the posterior face is an side of an implant 112, whose construction similar to that 15 shown in Figure 4, except that one of the posterior ledges 60 is (i.e., of convex shape) relative to the outwardly of the implant. Figure 11 is an elevational view of implant 116, except that one or both of an 20 the ridges 68 is bowed outwardly (i.e., of convex shape) relative to the body of the implant. the bowed anterior platform 56, posterior shape of ledge 60, or ridge 68 is not critical. It may be close arc of a circle, or not. The corners an 25 typically rounded slightly to reduce stresses. shape may be conveniently described as the ratio The the height of the bow above the end points, the dimension a in Figure 9-11, divided by the distance between the bases 92, the dimension b in Figures Preferably, for a bowed construction, the 30 9-11. degree of bowing as measured by a/b is more than 0and no greater than about 0.2.

The outward bowing of the anterior platform 56, the posterior ledge 60, or the ridge 68 can be provided to more closely match the available surface of the vertebra, and also reduce concentrated stresses on the surface of the implant that might

5

10

cause its premature failure. That is, in some instances it may be desirable to form the exposed face of the vertebra to a slightly concave shape, to which the convex shape of the implant conforms more closely.

The various features discussed in relation to the embodiments of Figures 3-5 and 8-11 may be used in various combinations for particular requirements and procedures, as long as the limitations of the invention as set forth herein are met.

Returning to a discussion of the preferred implant 50 of Figures 3-5 (which is also applicable other implants of Figures 8-10), the implant 50 is desirably made from a material that, after 15 surgical implantation, bonds to the natural bone of the adjacent vertebrae to form a rigid structure. implant is preferably made from a ceramic, most preferably the ceramic calcium hydroxylapatite. Ca10(PO4)6(OH)2. having chemical formula 20 use of such materials in implants is known, see The example US Patent 4,863,476, whose disclosure is incorporated by reference. The implant 50 may also made from a composite material such the carbon-fiber reinforced plastics disclosed in US Patent 4,904,261, whose disclosure is incorporated 25 reference. The implant may also be made from a biocompatible orthopedic polymer ("BOP"), such as a copolymer of methylmethacrylate and N-vinylpyrrolidone and calcium gluconate, reinforced polyamide fibers. Such a material is known in the 30 art, and is described, for example, in G. Lozes et "Discectomies of the Lower Cervical spine Using Interbody Biopolymer (BOP) Implants", Acta Neurochir 96, pages 88-93 (1989).(Wien), vol. In instances, the implant may be made from an uncoated 35 biocompatible metal. such as titanium or a titanium alloy such as Ti-6Al-4V, or a nonreactive metal such

-15-

as gold, or such a metal coated with a layer of the ceramic.

Another approach for the construction of the implant is shown in Figure 5. A coated implant 74 prepared by providing a piece of metal 76, such is titanium or titanium alloy, in the shape of the implant but slightly undersize in all dimensions. coating 78 of ceramic or polymer, ofthe types described previously, is applied over the piece of 10 metal 76 to enlarge the implant 74 to the proper final dimensions.

The implant 50 may be made microporous, so that functions a delivery as vehicle antibiotics or bone stimulating factors such as bone 15 morphogenic protein orosteogenin, which introduced into the implant before implantation surgery. In the case of the preferred ceramic hydroxylapatite construction of the implant. density and/or surface morphology of the ceramic can 20 be varied in the sintering process SO that retains the materials to be delivered. The delivery chemicals by this approach is known in the art, for example, H.A Benghuzzi et al., "The Effects of Density of the Ceramic Delivery Devices 25 Sustained Release of Androgens in Castrated Rodents," Annual Meeting of the Society for 17th Biomaterials, May 1-5, 1991, page 159.

Any of the implants discussed herein surgically implanted by a technique indicated schematically in Figure 6. Figure 6A is a detail of illustrating two vertebrae 1, 22 and the intervertebral disk 24 between them. In an anterior discectomy, the disk 24 is first removed, Figure 6B, and the facing surfaces of the vertebrae 35 smoothed. Α facing, opposed groove 80 is ground into both the superior vertebra 22a and the inferior vertebra 22b (or only one vertebra if the implant to

5

10

15

20

25

30

35

be used has only one ridge), using a drill 86 with a burr end, Figure 6C. The groove 80 extends transversely to the vertebrae, in a transverse direction 84 (shown in Figure 2). The groove 80 is positioned to produce a flush placement of the implant, in the manner to be described in relation to Figure 6F. The radius of the groove 80 is substantially the same as the radius of the ridge 68, ensuring a close contact between the ridge 68 and the inside of the groove 80.

implant of the geometry discussed herein selected with the spacing 58 about that of the 42 the anterior edges of spacing between The implant 50 is placed adjacent the vertebrae 22. vertebrae 22a and 22b, with the tapered end of the posterior ledge 60 inserted between the vertebrae shown in Figures 6D and 6E. and 22b as is then tapped with a surgical hammer on implant 50 the implant between the to drive the exposed end spine 20 vertebrae. The is typically distended slightly during this final stage of insertion to ease the insertion. Figure 6F illustrates the final implant 50 or 74 between the placement of the vertebrae 22a and 22b.

Figure 7 shows a plan view of the implant 50 respect to the vertebra properly positioned with The implant 50 is positioned in the anterior region of the vertebral body 32, well away from the 38 to avoid contact of the implant with the foramen The lateral width 82 of the implant 50 spinal cord. 74 is less than or equal to that of the vertebral body region 32 of the vertebra 22. The anterior platform 56 is aligned with the anterior edge 42 of is made of hard cortical 22, which vertebra The primary reaction path for the largest bone. loading is through the anterior edge regions spinal of the vertebrae and the anterior platform 56 of the

-17-

implant. The ridge 68, posterior ledge 60, and pattern of serrations 66 on the posterior ledge 60 aligned primarily with the central portion 44 of vertebra 22, which is made of softer and more 5 resilient cancellous bone. The ridge 68 and the serrations 66 tend to lock the implant 50 or 74 into place and prevent dislocation of the implant, by a keying action. The ridge 68 keys with the groove while the pattern of serrations 66 tends to 10 interlock with the cancellous bone. The serrations also increase the bonding area during subsequent interaction between the natural bone of the vertebra and the implant material.

The present approach provides an implant and process or technique for its use. The implant is of design and material of construction selected to improve the fusion of the adjacent vertebrae, and to permit the implant to be readily implanted. Although particular embodiments of the invention been described in detail for purposes of 20 have illustration, various modifications may be made without departing from the spirit and scope of the invention. Accordingly, the invention is not to be limited except as by the appended claims.

- 18-

Claims

1. A spinal disk implant, comprising a solid body having four sides and a pair of spaced-apart, opposed bases, the four sides including spaced-apart, opposed anterior and posterior faces, and

a pair of spaced-apart, opposed transverse faces, each transverse face having

5

10

15

20

25

an anterior platform adjacent to the anterior face, the anterior platform being spaced apart from an opposed anterior platform by a maximum anterior platform spacing, and

a posterior ledge oriented at an insertion angle relative to an opposed posterior ledge of an opposed transverse face, at least one of the posterior ledges having thereon a pattern of serrations; and

a ridge on at least one of the transverse faces positioned between the anterior platform and the posterior ledge and extending in a direction perpendicular to the bases, a top of the ridge being spaced apart from the opposed transverse face by an amount greater than the anterior platform spacing.

- 2. The implant of claim 1, wherein the implant is made of a material that bonds to natural bone.
 - 3. The implant of claim 1, wherein the implant is made at least in part of a biocompatible orthopedic polymer material, a ceramic or a ceramic-coated metal.
- 30 4. The implant of claim 3, wherein the ceramic is hydroxylapatite.
 - 5. The implant of claim 3, wherein the metal is selected from the group consisting of titanium and a titanium alloy.

- 6. The implant of claim 1, wherein the implant is microporous.
- 7. The implant of claim 1, wherein the insertion angle is from 0 to about 10 degrees.
- 8. The implant of claim 1, further including a pattern of serrations on at least one of the anterior platforms, the pattern of serrations extending in a direction perpendicular to the bases.
- 9. The implant of claim 1, wherein at least one of the anterior platforms, the posterior platforms, or the ridge is bowed outwardly when viewed perpendicular to the anterior face.
- 10. The implant of claim 1, wherein the ridge is bowed outwardly when viewed perpendicular to the anterior face.
 - 11. A process for implanting a spinal implant, comprising the steps of:

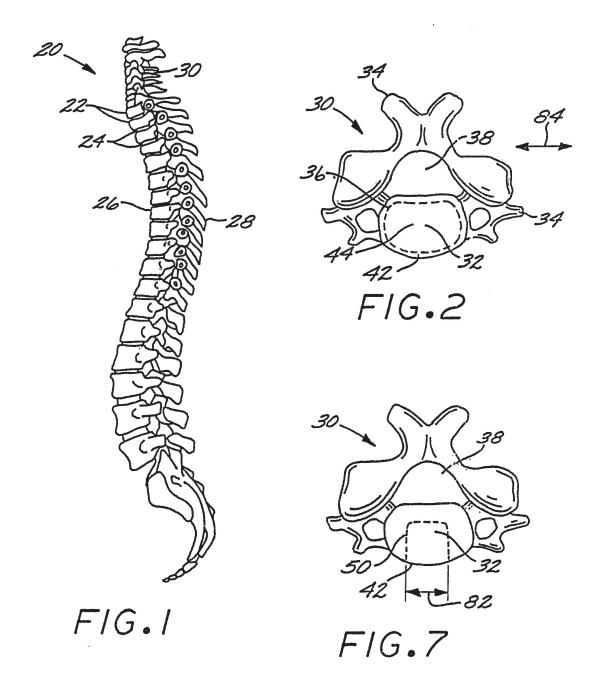
providing a spinal implant comprising a solid 20 body having four sides and a pair of spaced-apart, opposed bases, the four sides including spacedapart, opposed anterior and posterior faces, and a pair of spaced-apart, opposed transverse faces, each transverse face having an anterior platform 25 adjacent to the anterior face, the anterior platform being spaced apart from the opposed anterior platform by a maximum anterior platform spacing, and a posterior ledge oriented at an insertion angle relative to an opposed posterior 30 ledge of the opposed transverse face, at least one of the posterior ledges having thereon a pattern of serrations, and a ridge on at least one of the transverse faces positioned between the anterior platform and the posterior ledge and extending in 35 the direction perpendicular to the bases, the top

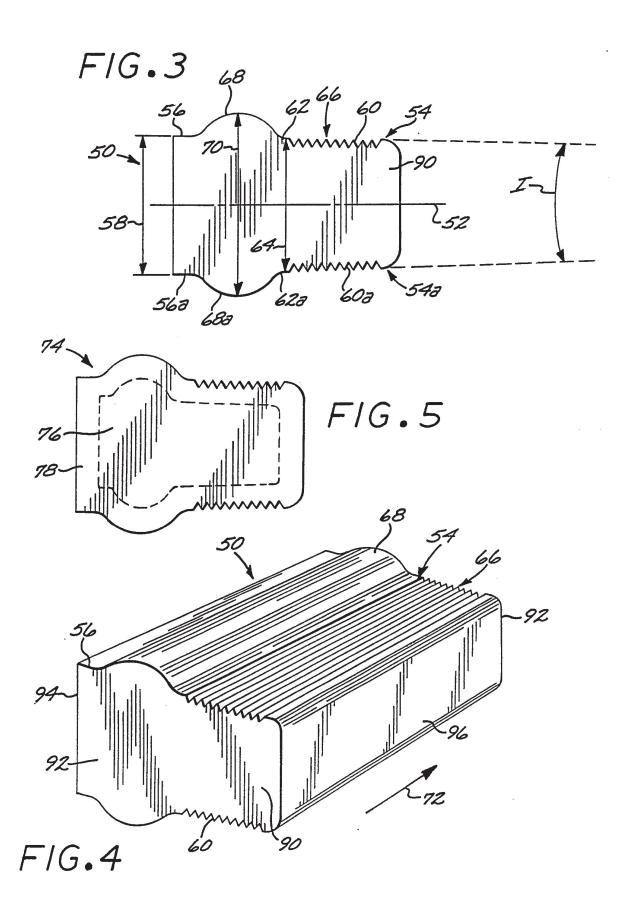
5

- 20 -

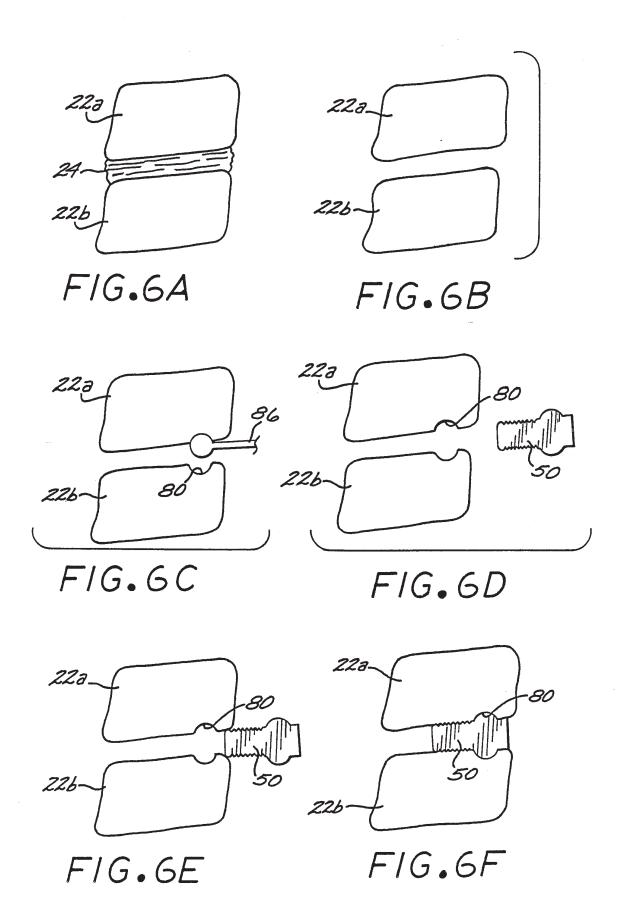
of the ridge being spaced apart from the opposed transverse face by an amount greater than the anterior platform spacing; and

placing the spinal implant between two vertebrae of a person's body, with the ridge of the spinal implant lying transverse to the vertebrae and the anterior platform placed between the anterior cortical bone regions of the vertebrae.





SUBSTITUTE SHEET



SUBSTITUTE SHEET 25

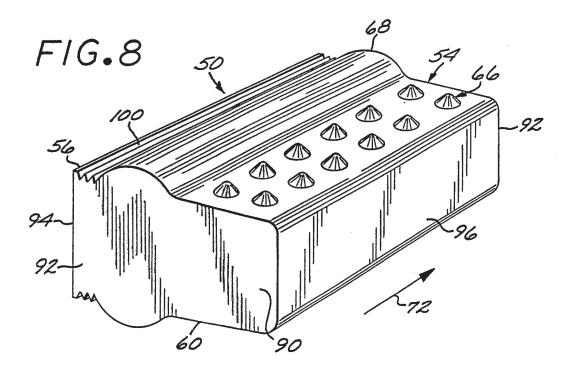
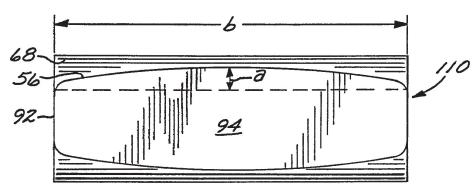
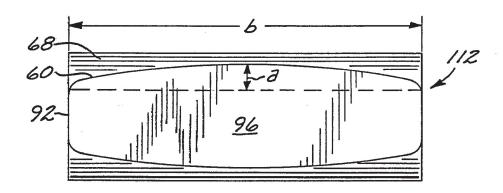


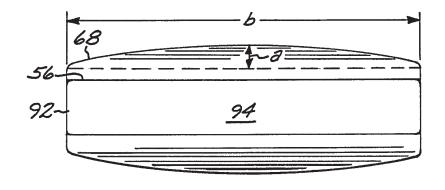
FIG.9



F1G.10



SUBSTITUTE SHEET 26



F1G.11

INTERNATIONAL SEARCH REPORT

International application No. PCT/US92/05859

A. CLASSIFICATION OF SUBJECT MATTER IPC(5) :A61F 2/44								
US CL :623/17 According to International Patent Classification (IPC) or to both national classification and IPC								
B. FIELDS SEARCHED								
Minimum documentation searched (classification system followed by classification symbols)								
U.S. :								
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched								
and the mental searched								
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)								
· , , , , , , , , , , , , , , , , , , ,								
-								
C. DOCUMENTS CONSIDERED TO BE RELEVANT								
Category*	Citation of document, with indication, where a	ppropriate, of the relevant passages	Relevant to claim No.					
X	EP, A, 0042271 (Kuntz) 23 December 1981, entir	e document.	1 & 9-11					
 Y			2-8					
v	NO A OLIGINAL CO.							
X 	WO, A, 91/05521 (Gross et al.) 02 May 1991.	intire document	1 & 9-11					
Y			2-8					
Furth	er documents are listed in the continuation of Box C	See patent family annex.						
	cial categories of cited documents:	"I" later document published after the inter date and not in conflict with the applica	mational filing date or priority					
to b	ument defining the general state of the art which is not considered e part of particular relevance	principle or theory underlying the inve	ntion					
	er document published on or after the international filing date ment which may throw doubts on priority claim(s) or which is	"X" document of particular relevance; the considered novel or cannot be consider when the document is taken alone	claimed invention cannot be ed to involve an inventive step					
cite	to establish the publication date of another citation or other ial reason (as specified)	"Y" document of particular relevance; the	claimed invention cannot be					
'O" doc:	ment referring to an oral disclosure, use, exhibition or other	considered to involve an inventive combined with one or more other such being obvious to a person skilled in the	documents, such combination					
'P" docu	ment published prior to the international filing date but later than priority date claimed	"&" document member of the same patent f						
	ctual completion of the international search	Date of mailing of the international sear	ch report					
21 AUGUS	T 1992	7 60CT 1992						
Name and m	ailing address of the ISA/ er of Patents and Trademarks	Authorized officer	P.O.					
Box PCT	D.C. 20231	ELIZABETH BURKE						
-	. NOT APPLICABLE	Telephone No. (703) 308-2006						