United States Patent [19]

Kuntz

[11] **4,349,921**

[45] **Sep. 21, 1982**

[54] **INTERVERTEBRAL DISC PROSTHESIS**

[76] Inventor: **J. David Kuntz,** 899 Lahakas Blvd., Kitimat, B.C., Canada

[21] Appl. No.: **159,843**

[22] Filed: **Jun. 16, 1980**

[51] **Int. Cl.**[3] **A61F 1/00**

[52] **U.S. Cl.** **3/1**

[58] **Field of Search** ..... 3/1, 1.9, 1.91, 1.911, 3/1.912, 1.913; 128/92 C, 92 CA, 92 R, 92 EC

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,677,369	5/1954	Knowles	128/92 R
3,685,058	8/1972	Tronzo	128/92 EC X
3,867,728	2/1975	Stubstad et al.	3/1.91
3,875,595	4/1975	Froning	3/1
4,040,131	8/1977	Gristina	3/1.91
4,245,359	1/1981	Stuhmer	3/1.9
4,257,129	3/1981	Volz	3/1.911

FOREIGN PATENT DOCUMENTS

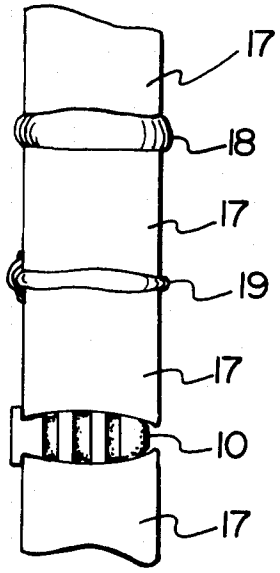
2263842	7/1974	Fed. Rep. of Germany	3/1.91
2804936	8/1979	Fed. Rep. of Germany	3/1.91
2372622	6/1978	France	3/1.9

Primary Examiner—Clifford D. Crowder

[57] **ABSTRACT**

An intervertebral disc prosthesis intended to replace a natural intervertebral disc and to restore the normal intervertebral spacing without complete loss of flexibility of the spinal joint. The prosthesis comprises a body of biologically-acceptable material suitably dimensioned and shaped to replace a natural disc. One of the longitudinal ends of the prosthesis has suitable means, e.g. a raised flange, to facilitate handling of the prosthesis and to prevent penetration to an excessive depth into the spinal joint. The other longitudinal end is preferably wedge-shaped to facilitate insertion into the intervertebral space. The superior and inferior surfaces are preferably provided with surface characteristics to produce a "friction-fit" and are convex to correspond to the adjacent vertebral surface. The prosthesis is inexpensive to manufacture and can be implanted quite easily with little danger to the patient. Moreover, the prosthesis maintains at least some of the flexibility of the joint while remaining firmly anchored in place.

52 Claims, 15 Drawing Figures



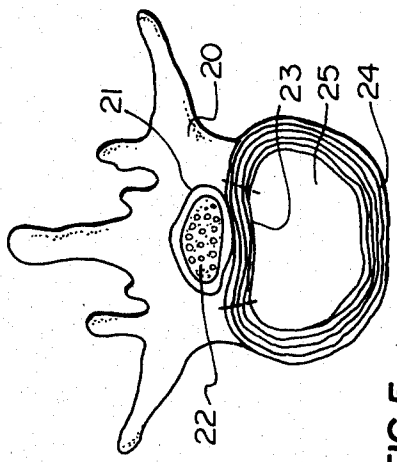


FIG. 5

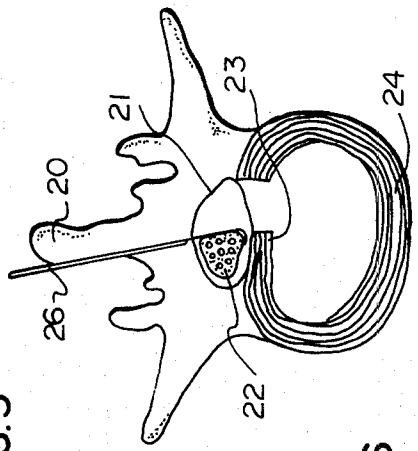


FIG. 6

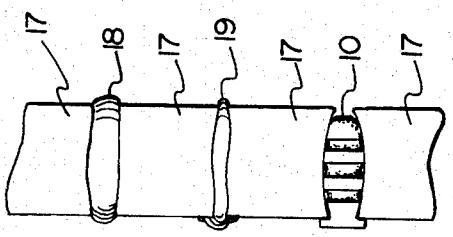


FIG. 4

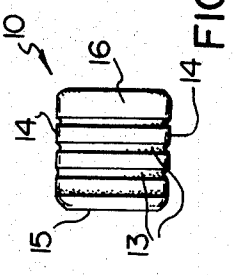


FIG. 1

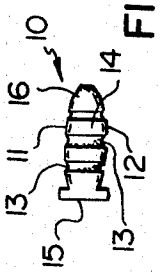


FIG. 2

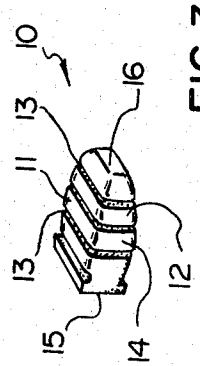


FIG. 3

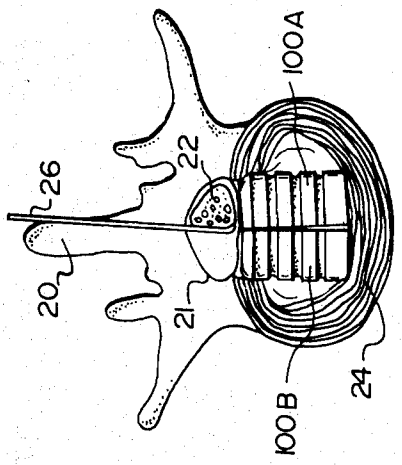


FIG. 9

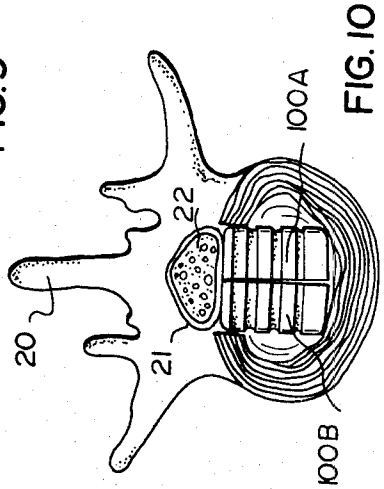


FIG. 10

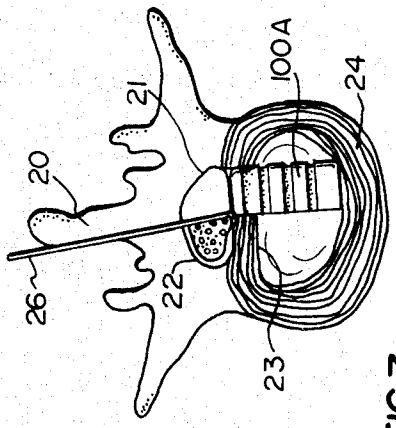


FIG. 7

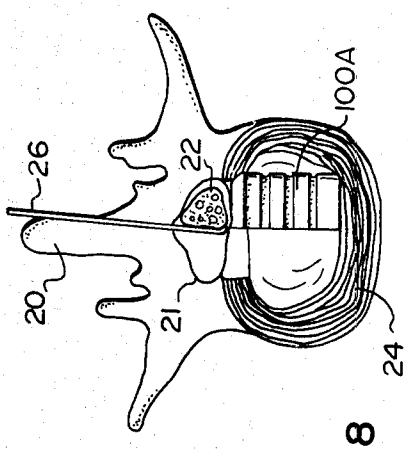


FIG. 8

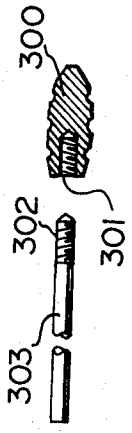


FIG. 15

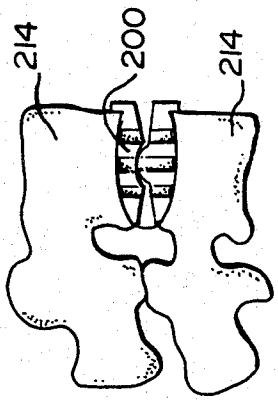


FIG. 13

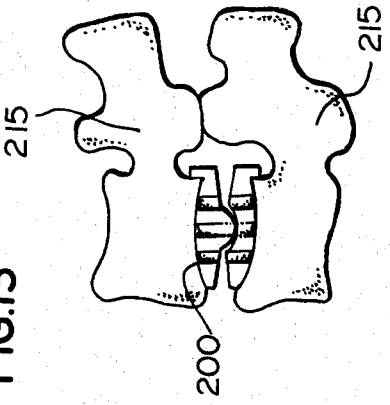


FIG. 14

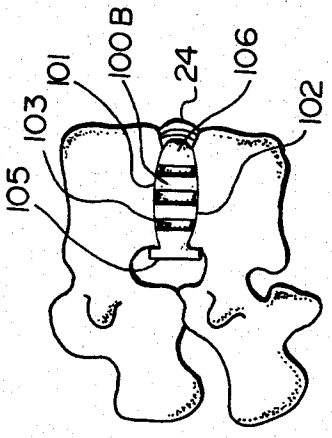


FIG. 11

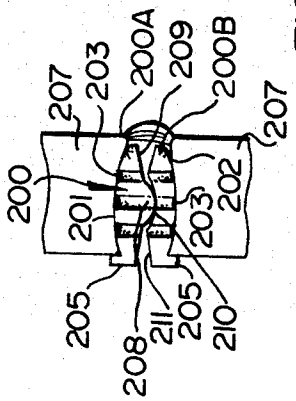


FIG. 12

INTERVERTEBRAL DISC PROSTHESIS

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to an intervertebral disc prosthesis and to surgical techniques for implanting the prosthesis.

The vertebrae of the spinal column are connected together by intervertebral fibrocartilaginous discs. The discs maintain a separation between the vertebrae, but occasionally become narrowed so that the intervertebral separation is reduced. This reduction in separation has a number of painful and unpleasant consequences, for example, in the cervical region of the spine, it can result in cervical spondylosis, vertebral artery syndrome and painful arc syndromes. These symptoms are described in more detail below.

1. Description of the Prior Art

Procedures have been developed in the prior art for alleviating the symptoms resulting from intervertebral disc failure.

One such procedure involves fusing the adjacent vertebrae by removing the damaged disc and inserting a plug or wedge of bone removed from another part of the patient's skeleton.

An example (known as the "Cloward technique") of such a procedure for the cervical vertebrae is described in "ORTHOPAEDICS—PRINCIPLES AND THEIR APPLICATION," Samuel L. Turek, M.D., Lippincott Company, Third Edition, pp. 761–763, in which a hole is drilled in the spinal column straddling the damaged disc space and including parts of the adjacent vertebrae. The hole is then filled with a cylindrical plug or dowel of bone in order to fuse the vertebrae together.

Fusion of vertebrae together necessarily results in complete loss of flexibility of the spinal column at this location and is thus disadvantageous. Accordingly, proposals have been made in the past to replace the damaged or diseased disc with a disc prosthesis intended to duplicate the function of the natural disc to some extent.

French patent application publication No. 2,372,622, of Bernard Fassio, published June 30, 1978, discloses one such disc prosthesis. This consists of a flat circular plate having central hemispherical projections on each face thereof. The hemispheres allow articulation of the joint while the flat plate maintains separation. It is believed, however, that such a prosthesis would not be entirely satisfactory because the hemispheres would not correspond closely to the shape of the adjacent vertebral surfaces. This could result in crushing of the cancellous vertebral bone by the hemispheres and consequent reduction in separation and articulation of the joint.

Another disc prosthesis is disclosed in U.S. Pat. No. 3,867,728 of Stubstad et al., issued Feb. 25, 1975, assigned to Cutter Laboratories Inc. The prosthesis is a flattened kidney shaped block of elastomeric synthetic resin. The shape of the prosthesis is intended to conform closely to the space in a spinal disc from which the necleus pulposus has been removed. One disadvantage of this type of prosthesis is that elastomeric materials have been known to disintegrate in the body and to break down under repeated stressing over prolonged periods. Moreover, it is disclosed that the surface of the prosthesis may be porous to allow tissue ingrowth, but a porous surface is more prone to harbor bacteria due to the large surface area involved. In a porous surface in which tissue ingrowth has occurred, there is also increased possibility of repeated injury at the interface between the bone and prosthesis due to tearing of fibrous tissue or prosthetic fibers with subsequent tissue reaction including foreign body rejection.

A major disadvantage of a porous material is that if there is actual tissue ingrowth into the prosthesis, removal could be difficult. Curetting out the prosthesis would lead to hemorrhage of a very vascular surface area, caused by the tissue ingrowth, with subsequent increased danger of cord compression secondary to hemorrhage.

Besides, any porous material allowing tissue ingrowth for stability in a cervical spine would be dangerous as the esophagus, which lies anteriorly, could become adhered to the prosthesis with resultant dysphagia or difficulty in swallowing.

There is consequently a need for a prosthesis that remains stably in place when implanted but does not have the difficulties referred to above associated with porous surfaces.

West German Offenlegungsschrift No. 2,263,842 in the name of Hoffmann-Daimler, published on July 4, 1974 discloses yet another type of disc prosthesis. In its simplest form, this prosthesis consists of a circular disc having smooth convex faces. The disc may be made of a synthetic material. This simple form, however, may become displaced when implanted and could possibly damage the neural canal.

The known prostheses are often made of different materials bonded together to allow movement within the prosthesis, but this weakens the overall loading strength of the prosthesis. This is particularly the case when the prosthesis is submitted to repeated stresses. Bonded materials can become fatigued under stress and, due to the very thin spaces involved, any multiple layered prosthesis would involve quite thin layers of material. This would increase the problem of breakage and migration of fragments which could have hazardous consequences in the spinal area.

It is believed that each of the prostheses referred to above is intended only for the lumbar area of the spine. For example, the Stubstad et al. patent describes insertion through an anterior approach which is, in fact, a 'retroperitoneal' approach. There is therefore a need for a disc prosthesis that can be used in the cervical area of the spine as well as just the lumbar area.

Another difficulty of the known prostheses is the difficulty of handling them during surgical implantation. In particular, difficulty is often encountered in removing the prostheses once implanted should adjustment or replacement be required.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an improved intervertebral disc prosthesis.

According to one aspect of the invention there is provided an intervertebral disc prosthesis, comprising a body of biologically compatible material having a superior surface, an inferior surface and opposed anterior and posterior ends, and means located at one of said opposed ends for facilitating holding of the prosthesis during its insertion into or removal from an intervertebral disc space.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.