



- [54] **PROSTHETIC IMPLANT FOR INTERVERTEBRAL SPINAL FUSION**
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- [21] Appl. No.: **123,191**
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- [52] U.S. Cl. **623/17; 606/61**
- [58] Field of Search **623/17; 606/61**

Attorney, Agent, or Firm—Hill, Steadman & Simpson

[57] **ABSTRACT**

Block or plug implants provide weight-bearing support for adjacent vertebrae in a vertebral column while allowing sufficient area between and beside the plugs for packing of autologous bone graft to allow bony healing and fusion. The plugs have a laterally directed slot to allow ingrowth of blood supply from the side and to allow locking the permanent device in place with living bone. The plugs have a patterned surface to grip the vertebrae. Plugs used for fusion in the L4-5 and L5-S1 levels are wedged-shaped to reproduce the normal shape of these discs, which are higher anteriorly than posteriorly. The height of the plugs is greater than the width. The implants are made of a biocompatible carbon fiber reinforced polymer or alternately made of traditional orthopaedic implant materials such as chrome cobalt, stainless steel or titanium. In the surgical procedure, undamaged annulus fibrous disc tissue connecting the adjacent vertebrae is preserved and a pair of side-by-side implant plugs are forced into side-by-side transverse channels in the adjoining vertebrae to stretch the remaining annulus and support body weight applied through the vertebrae. The plugs are bottomed in the channels on cortex bone and bone ingrowth and fusion is facilitated by packing a patient's own graft into the center of the plug and beside and between the two adjacent plugs.

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,349,921	9/1982	Kuntz	623/17
4,501,269	2/1985	Bagby	
4,743,256	5/1988	Brantigan	623/17
4,834,757	5/1989	Brantigan	623/17
4,878,915	11/1989	Brantigan	623/17
4,961,740	10/1990	Ray	606/61
5,015,247	5/1991	Michelson	606/61
5,147,402	9/1992	Bohler et al.	623/16
5,192,327	3/1993	Brantigan	623/17
5,320,644	6/1994	Baumgartner	623/17

FOREIGN PATENT DOCUMENTS

1007661	3/1983	U.S.S.R.	606/61
1175464	8/1985	U.S.S.R.	606/61
1424826	9/1988	U.S.S.R.	606/61
1650114	5/1991	U.S.S.R.	606/61

Primary Examiner—David H. Willse

11 Claims, 3 Drawing Sheets

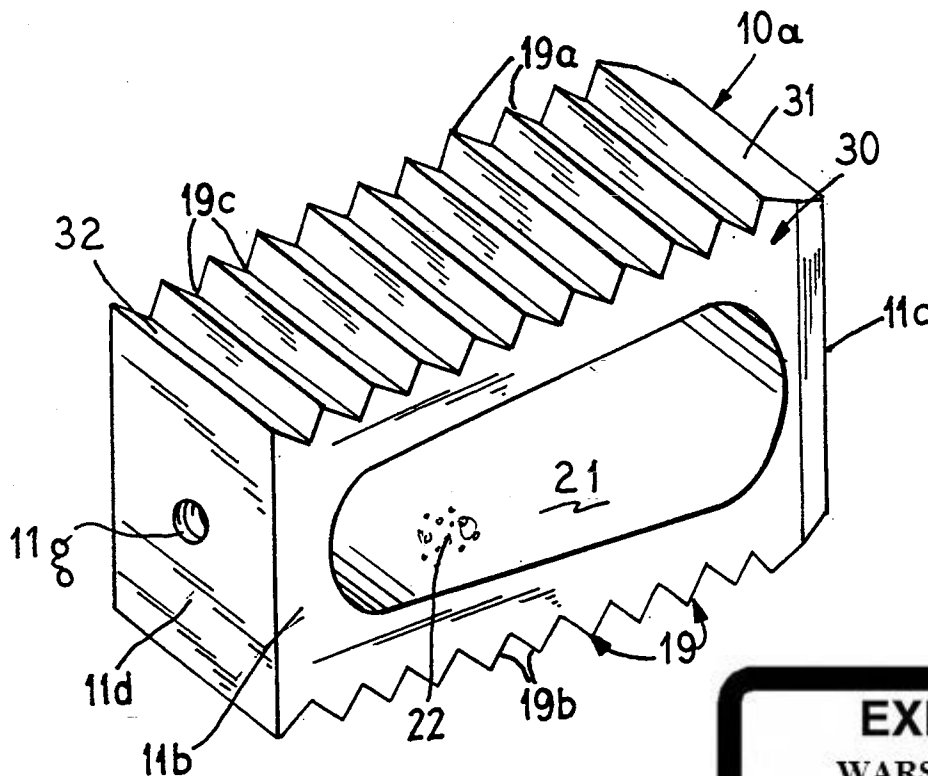


EXHIBIT
WARSAW2004
NuVasive, Inc. v.
Warsaw Orthopedic, Inc.
IPR2013 00305

FIG. 1

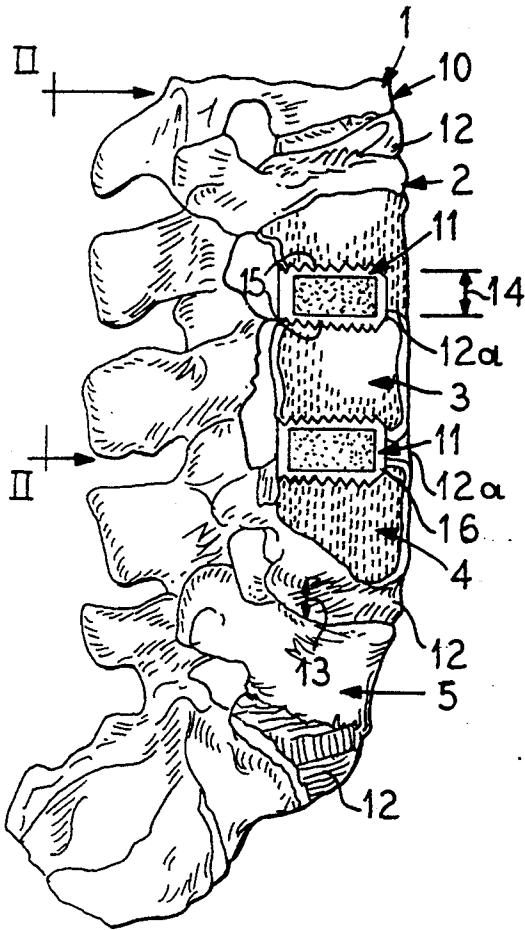


FIG. 2

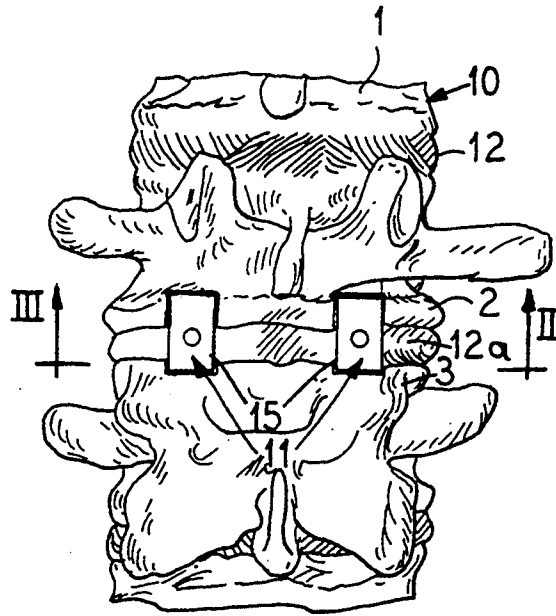


FIG. 3

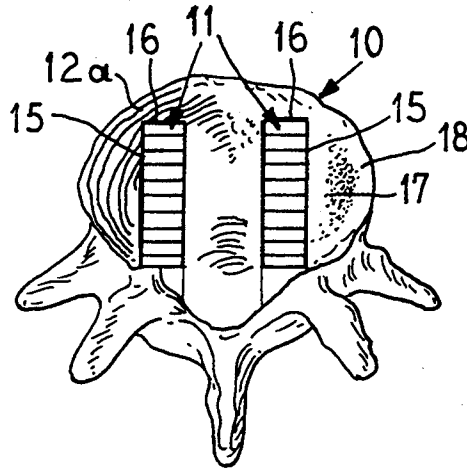


FIG. 4

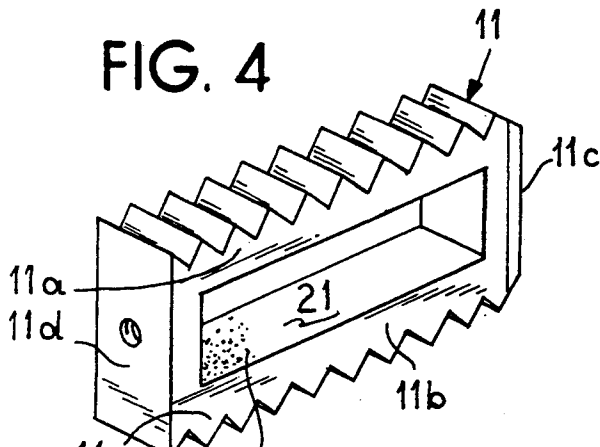


FIG. 6

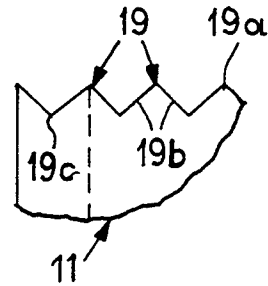


FIG. 5

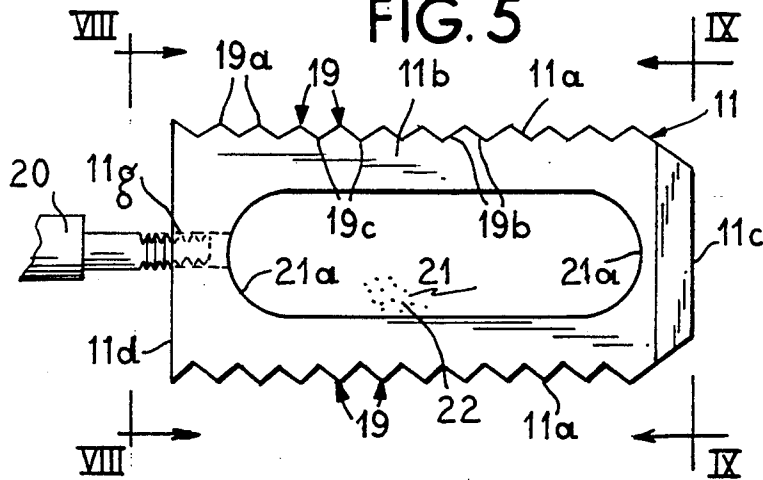


FIG. 7

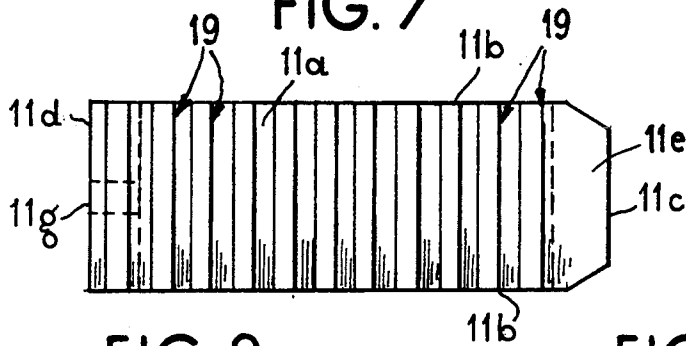


FIG. 8

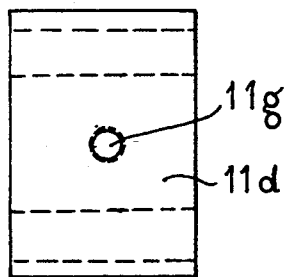
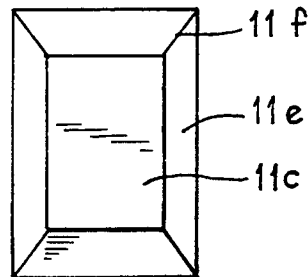
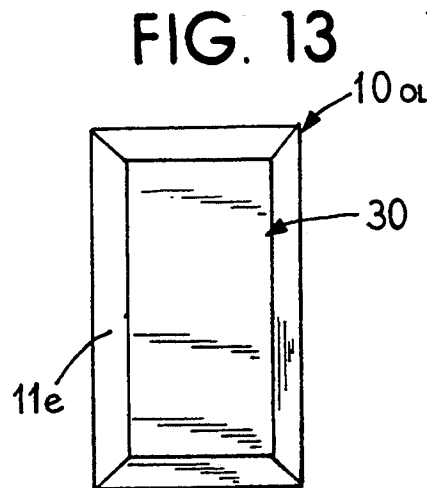
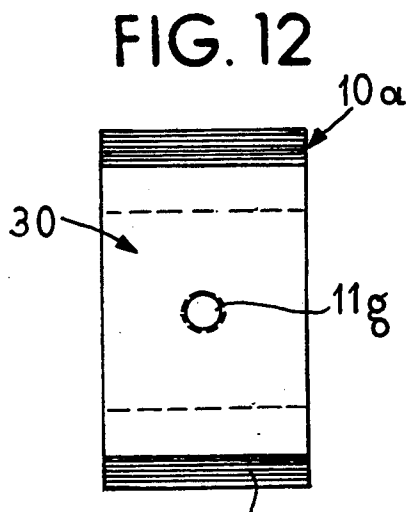
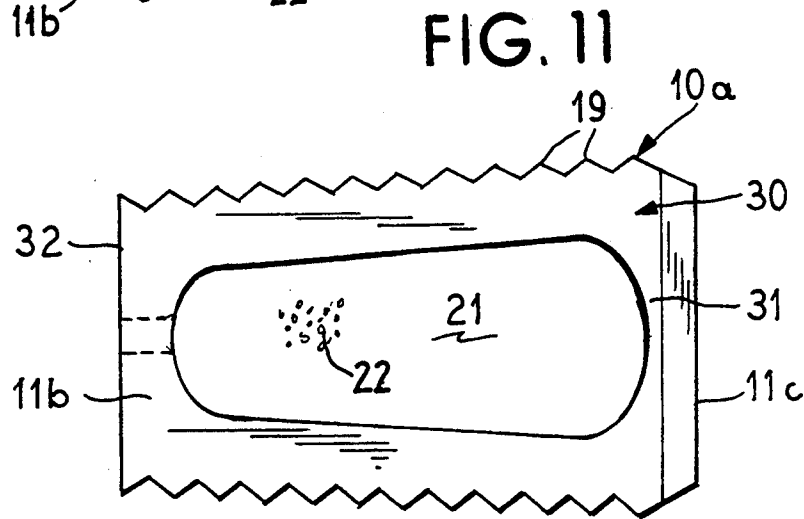
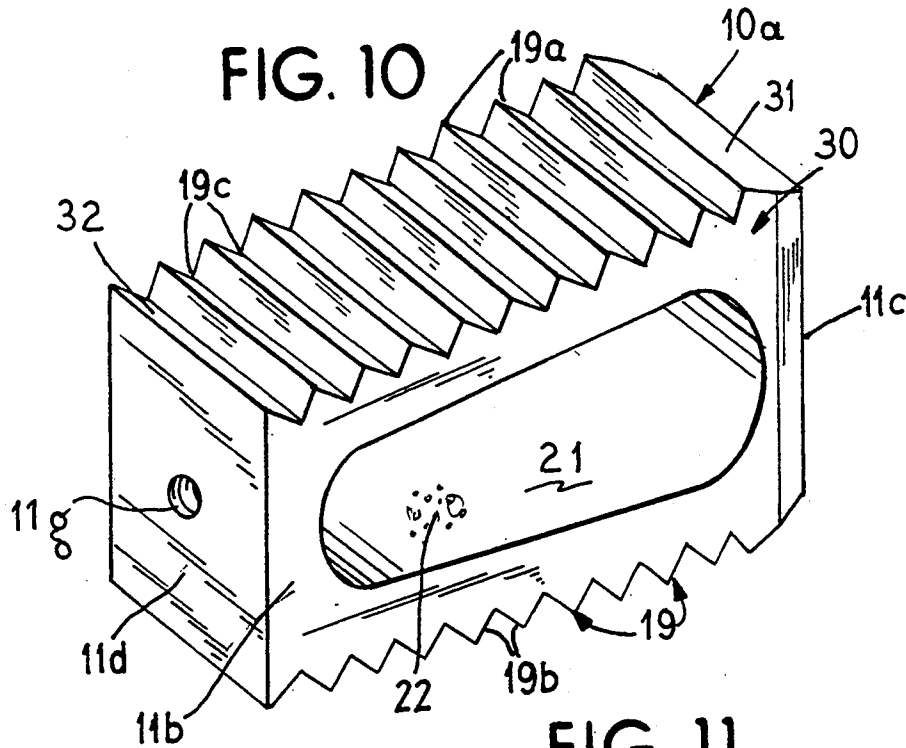


FIG. 9





PROSTHETIC IMPLANT FOR INTERVERTEBRAL SPINAL FUSION

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to the art of prosthetic devices implanted between adjacent vertebrae to treat or prevent back or neck pain in patients with ruptured or degenerated intervertebral discs. More specifically, the invention deals with improvements in prosthetic strut forming plugs or blocks facilitating bone ingrowth from adjoining vertebrae which are rectangular or, specifically, parallelepiped shaped, with height greater than width providing substantial wide roughened top and bottom surface areas for supporting adjacent vertebrae while having narrower smooth sides to minimize damaging surgical exposure and nerve root retraction required during their surgical implantation. The plugs have a horizontal or lateral slot providing a receptacle for packing bone graft material, have tapered leading ends, a tool receiving trailing end and are composed of radiolucent rigid inert material for visualization of post operative bone healing.

2. Description of the Prior Art

As pointed out in my U.S. Pat. Nos. 4,743,256, 4,834,757, 4,878,915, and 5,192,327, the leading cause of low back pain arises from rupture or degeneration of lumbar intervertebral discs. Pain in the lower extremities (sciatica) is caused by the compression of spinal nerve roots by damaged discs between the vertebrae and low back pain is caused by collapse of the disc and the adverse effects of bearing the majority of the body weight through a damaged unstable vertebral joint.

Disc excision with posterior lumbar interbody fusion (PLIF) reconstructs the normal anatomic relationships between the bony and the neural structures and has many advantages. Weight-bearing through a solid bony fusion mass between vertebral bodies relieves the mechanical pain of the traditional unstable degenerative disc and generally prevents long-term disc collapse or further degenerative changes. The complete disc excision prevents recurrent herniation of the same degenerated disc.

However, this PLIF procedure has several serious disadvantages in that it is technically very difficult, and, therefore not as successful or widely used as it might be. It requires interbody bone grafting to achieve both a strut-like support that bears the entire body's weight through the vertebral bodies, and it requires bony healing of the grafted bone to achieve permanent fusion.

It is well understood in orthopaedic surgery that grafted bone heals by a process known as "creeping substitution" in which blood capillaries first grow into the grafted bone, the grafted bone is reabsorbed, and then new bone cells are laid down along the bony matrix of the graft. During the time that the bone graft is being reabsorbed, the weight-bearing strength is reduced at least 50%, causing crushing of the graft and failure of the surgery.

My prior aforesaid U.S. Pat. No. 4,743,256 discloses an improved surgical method for eliminating spinal back pain caused by ruptured or degenerated vertebral discs by spanning the disc space between adjacent vertebrae with rigid inert implants having surfaces facilitating bone ingrowth and bottomed on prepared sites of the vertebrae to integrate the implant with the verte-

brae and to provide a permanent weight supporting strut maintaining the disc space.

My prior aforesaid U.S. Pat. No. 4,878,915 disclosed a further improved surgical procedure by providing the rigid implants or blocks with tool receiving end spaces facilitating their insertion onto the prepared sites and having geometric patterns of roughened surfaces on the peripheries of the implants enhancing the bone growth.

My prior aforesaid U.S. Pat. No. 4,834,757 discloses a further improved prosthetic implant having recesses in the form of through slots be packed with bone graft material.

My prior aforesaid U.S. Pat. No. 5,192,327 describes stackable oval implants for anterior lumbar interbody fusion or vertebral reconstruction of fracture or tumor.

The Bagby U.S. Pat. No. 4,501,269 discloses a cylindrical basket seated in a cylindrical hole bored transversely across the bones of a spinal joint of a bone which permits free rocking rotation between bone and basket and only communicates bone fragments packed in the basket through perforations in the basket. Nothing was provided to lock the basket against rotation and blood supply was limited by the perforations.

The Ray U.S. Pat. No. 4,961,740 discloses a cylindrical dowel-plug implant with a screw-thread surface to be threaded into a cylindrical drilled hole in the vertebrae. While this hollow implant permitted packing of bone graft material therein, it had very small perforations limiting ingrowth of blood supply and inhibiting bony healing. The device, being cylindrical and seated in a cylindrical hole, allowed relative rotation or rocking which inhibited or destroyed bone fusion.

The Michelson U.S. Pat. No. 5,015,247 also disclosed cylindrical dowel shaped plug implants in cylindrical drilled holes in vertebrae permitting rotation and a relative movement between the plug and vertebrae during healing. Bone graft material packed within the plug could only communicate with the vertebrae through small holes limiting blood supply and bone ingrowth.

The present invention now further improves this art by providing inert narrow rectangular or parallelepiped plugs or blocks implanted in mating grooves or channels of adjacent vertebrae in spaced side-by-side relation with imperforate continuous top and bottom faces providing a greater area of weight bearing support and an interior adapted to be fully packed with bone growth material fully exposed to the vertebrae without intervening obstructions. The narrow width dimension of the plug minimizes the widths of the plug receiving grooves, provides more spacing from adjacent nerves and increases the graft bone areas. The weight bearing top and bottom surfaces or faces are roughened preferably serrated, to provide teeth for biting into the vertebrae. The plugs also have smooth side faces to prevent damage to adjacent bone faces and to facilitate insertion. The invention includes wedge shaped plugs or blocks for restoring normal spinal alignment especially in the lower lumbar levels.

SUMMARY OF THE INVENTION

The present invention now provides rigid inert, narrow vertebral prosthetic implant plugs or blocks which are higher than wide, have imperforate top and bottom weight bearing surfaces with serrations or projecting peaks that bite into adjoining vertebrae surfaces, smooth side faces which will not damage adjacent vertebrae surfaces and an unimpeded open side lateral window or slot for bone graft material in full communica-

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