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<p>(21) International Application Number: PCT/US94/06345 (22) International Filing Date: 9 June 1994 (09.06.94) (30) Priority Data: 08/074,781 10 June 1993 (10.06.93) US (71) Applicant: KARLIN TECHNOLOGY, INC. [US/US]; 4929 Premiere Avenue, Lakewood, CA 90712 (US). (72) Inventor: MICHELSON, Gary, Karlin; 438 Sherman Canal, Venice, CA 90291 (US). (74) Agent: SCHELLIN, Eric, P.; Suite 704, 2121 Crystal Drive, Arlington, VA 22202 (US).</p>		<p>(81) Designated States: AU, BB, BG, BR, BY, CA, CN, CZ, FI, HU, JP, KP, KR, KZ, LK, LV, MG, MN, MW, NO, NZ, PL, RO, RU, SD, SK, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>Without international search report and to be republished upon receipt of that report.</i></p>
<p>(54) Title: APPARATUS AND METHOD OF INSERTING SPINAL IMPLANTS</p> <p>(57) Abstract</p> <p>Apparatus and a method of inserting spinal implants is disclosed in which an intervertebral space is first distracted, a hollow sleeve having teeth at one end is then driven into the vertebrae adjacent that disc space. A drill is then passed through the hollow sleeve removing disc and bone in preparation for receiving the spinal implant which is then inserted through the sleeve.</p>		

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APPARATUS AND METHOD OF INSERTING SPINAL IMPLANTS
RELATED APPLICATIONS

This application is a continuation in part of United States application serial no. 07/205,935, filed on
5 June 13, 1988, which is a divisional application of United States Patent Number 5,015,247 issued May 14, 1991, both of which are incorporated into this application by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

10 The present invention relates to artificial fusion implants to be placed into the intervertebral space left remaining after the removal of a damaged spinal disc and specifically to the apparatus for and method of, inserting the implants.

15 2. Description of the Prior Art

For the purpose of achieving long term stability to a segment of injured spine, a fusion (the joining together of two or more bones via a continuous bridge of incorporated bone) may be performed. Well-known to those
20 skilled in such art is the interbody fusion wherein the disc is partially excised and bone placed within that space previously occupied by that disc material (between adjacent vertebrae) for the purpose of restoring a more normal spatial relationship, and to provide for stability; short
25 term by mechanical support, and long term by the permanent cross bonding of bone from vertebra to vertebra. For fusion to occur within the disc space, it is necessary to

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prepare the vertebrae to be fused by breaking through, or cutting into, the hardened outside plates of bone (the endplates) to allow the interposed bone graft to come into direct contact with the more vascular cancellous (spongy) bone, and to thereby trick the body into attempting to heal this induced, but controlled, "fracturing" by both bone production and the healing of the grafts to both opposed vertebral surfaces such that they become one continuous segment of bone.

10 The purpose of the present invention is to provide an implant, and the apparatus and method of inserting the implant within the intervertebral space left after the removal of the disc material and permanently eliminate all motion at that location. To do so, the device of the present invention is space occupying within the disc interspace, rigid, self-stabilizing to resist dislodgement, stabilizing to the adjacent spinal vertebrae to eliminate local motion, and able to intrinsically participate in a vertebra to vertebra bony fusion so as to assure the permanency of the result.

15 At present, following the removal of a damaged disc, either bone or nothing is placed into the remaining space. Placing nothing into this space allows the space to collapse which may result in damage to the nerves; or the space may fill with scar tissue and eventually lead to a reherniation. The use of bone to fill the space is less than optimal in that bone obtained from the patient requires additional surgery and is of limited availability

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in its most useful form, and if obtained elsewhere, lacks living bone cells, carries a significant risk of infection, and is also limited in supply as it is usually obtained from accident victims. Furthermore, regardless of the source of the bone, it is only marginal structurally and lacks a means to either stabilize itself against dislodgement, or to stabilize the adjacent vertebrae.

a. Prior Art Implants

There have been an extensive number of attempts to develop an acceptable disc prosthesis (an artificial disc). Such devices by design would be used to replace a damaged disc and seek to restore the height of the interspace and to restore the normal motion of that spinal joint. No such device has been found that is medically acceptable. This group of prosthetic or artificial disc replacements, seeking to preserve spinal motion and so are different from the present invention, would include:

U.S. Patent No. 3,867,728 to STUBSTAD - describing a flexible disc implant.

U.S. Patent No. 4,349,921 to KUNTZ - describing a flexible disc replacement with file-like surface projections to discourage device dislocation.

U.S. Patent No. 4,309,777 to PATIL - describing a motion preserving implant with spiked outer surfaces to resist dislocation and containing a series of springs to urge the vertebrae away from each other.

U.S. Patent No. 3,875,595 to FRONING - describing

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