US008226652B2

(12) **United States Patent**
Michelson

(10) **Patent No.: US 8,226,652 B2**
(45) **Date of Patent: *Jul. 24, 2012**

(54) **THREADED FRUSTO-CONICAL SPINAL IMPLANTS**

(75) Inventor: **Gary Karlin Michelson**, Venice, CA (US)

(73) Assignee: **Warsaw Orthopedic, Inc.**, Warsaw, IN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/296,125**

(22) Filed: **Nov. 14, 2011**

(65) **Prior Publication Data**

US 2012/0053695 A1 Mar. 1, 2012

Related U.S. Application Data

(63) Continuation of application No. 12/942,671, filed on Nov. 9, 2010, now Pat. No. 8,057,475, which is a continuation of application No. 12/454,393, filed on May 18, 2009, now Pat. No. 7,828,800, which is a continuation of application No. 08/480,908, filed on Jun. 7, 1995, now Pat. No. 7,534,254.

(51) **Int. Cl.**
A61F 17/56 (2006.01)

(52) **U.S. Cl.** **606/60**; 606/246

(58) **Field of Classification Search** 606/60, 606/246–252, 279; 623/17.11, 17.16
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

350,420	A	10/1886	Dillon
1,137,585	A	4/1915	Craig
2,065,659	A	12/1936	Cullen
2,181,746	A	11/1939	Siebrandt
2,243,718	A	5/1941	De G. Moreira
2,372,622	A	3/1945	Fassio
2,514,665	A	7/1950	Myller
2,537,070	A	1/1951	Longfellow
2,543,780	A	3/1951	Hipps et al.
2,677,369	A	5/1954	Knowles
2,774,350	A	12/1956	Cleveland
2,789,558	A	4/1957	Rush
2,832,343	A	4/1958	Mose
2,842,131	A	7/1958	Smith

(Continued)

FOREIGN PATENT DOCUMENTS

DE 1 961 531 7/1970

(Continued)

OTHER PUBLICATIONS

Adams, et al.; Outline of Orthopaedics, Eleventh Edition; Trunk and Spine, p. 194.

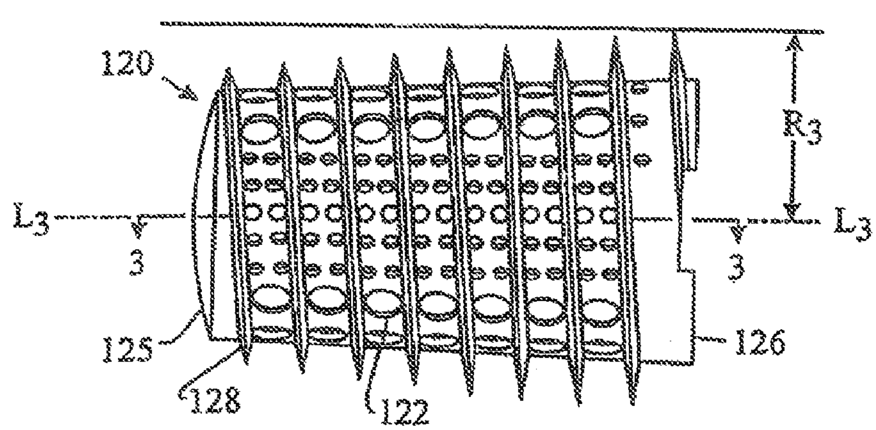
(Continued)

Primary Examiner — Michael A. Brown
(74) *Attorney, Agent, or Firm* — Martin & Ferraro, LLP

(57) **ABSTRACT**

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration. An external thread is employed to increase implant stability and implant surface area, and for the purpose of advancing the spinal fusion implant into the fusion site. The spinal fusion implants of the present invention may be relatively solid or hollow and may have surface roughenings to promote bone ingrowth and stability. The spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation.

16 Claims, 4 Drawing Sheets



U.S. PATENT DOCUMENTS

2,878,809 A 3/1959 Treace
3,128,768 A 4/1964 Geistauts
3,298,372 A 1/1967 Feinberg
3,426,364 A 2/1969 Lumb
3,486,505 A 12/1969 Morrison
3,604,487 A 9/1971 Gilbert
3,605,123 A 9/1971 Hahn
3,618,611 A 11/1971 Urban
3,709,219 A 1/1973 Halloran
3,719,186 A 3/1973 Merig, Jr.
3,720,959 A 3/1973 Hahn
3,750,652 A 8/1973 Sherwin
3,848,601 A 11/1974 Ma et al.
3,855,638 A 12/1974 Pilliar
3,866,510 A 2/1975 Eibes et al.
3,867,728 A 2/1975 Stubstad et al.
3,867,950 A 2/1975 Fischell
3,875,595 A 4/1975 Froning
3,888,260 A 6/1975 Fischell
3,892,232 A 7/1975 Neufeld
3,905,047 A 9/1975 Long
3,915,151 A 10/1975 Kraus
3,916,907 A 11/1975 Peterson
3,918,440 A 11/1975 Kraus
3,942,535 A 3/1976 Schulman
3,948,262 A 4/1976 Zaffaroni
3,952,334 A 4/1976 Bokros et al.
3,987,499 A 10/1976 Scharbach et al.
4,003,287 A 1/1977 Ziaylek, Jr.
4,016,651 A 4/1977 Kawahara et al.
4,027,392 A 6/1977 Sawyer et al.
D245,259 S 8/1977 Shen
4,051,905 A 10/1977 Kleine
4,059,115 A 11/1977 Jumashev et al.
4,070,514 A 1/1978 Eatherly et al.
4,082,097 A 4/1978 Mann et al.
4,086,701 A 5/1978 Kawahara et al.
4,124,026 A 11/1978 Berner et al.
4,142,517 A 3/1979 Stravropoulos et al.
4,168,326 A 9/1979 Broemer et al.
4,175,555 A 11/1979 Herbert
4,177,524 A 12/1979 Grell et al.
4,181,457 A 1/1980 Holmes
4,197,850 A 4/1980 Schulman et al.
4,206,516 A 6/1980 Pilliar
4,222,128 A 9/1980 Tomonaga et al.
D257,511 S 11/1980 Zahn
4,232,679 A 11/1980 Schulman
4,237,948 A 12/1980 Jones et al.
4,258,716 A 3/1981 Sutherland
4,259,072 A 3/1981 Hirabayashi et al.
4,262,369 A 4/1981 Roux
4,271,832 A 6/1981 Evans et al.
D260,525 S 9/1981 Lassiter
4,289,123 A 9/1981 Dunn
4,293,962 A 10/1981 Fuson
4,309,777 A 1/1982 Patil
4,328,593 A 5/1982 Sutter et al.
4,333,469 A 6/1982 Jeffcoat et al.
4,341,206 A 7/1982 Perrett et al.
4,349,921 A 9/1982 Kuntz
4,356,572 A 11/1982 Guillemin et al.
4,401,112 A 8/1983 Rezaian
4,405,319 A 9/1983 Cosentino
4,414,979 A 11/1983 Hirshorn et al.
4,423,721 A 1/1984 Otte et al.
4,439,152 A 3/1984 Small
4,450,834 A 5/1984 Fischer
4,484,570 A 11/1984 Sutter et al.
4,492,226 A 1/1985 Belykh et al.
4,497,320 A 2/1985 Nicholson et al.
4,501,269 A 2/1985 Bagby
4,507,115 A 3/1985 Kambara et al.
RE31,865 E 4/1985 Roux
4,530,360 A 7/1985 Duarte
4,535,374 A 8/1985 Anderson et al.
4,535,485 A 8/1985 Ashman et al.
4,542,539 A 9/1985 Rowe, Jr. et al.
4,545,374 A 10/1985 Jacobson
4,547,390 A 10/1985 Ashman et al.
4,549,547 A 10/1985 Brighton et al.
4,552,200 A 11/1985 Sinha et al.
4,553,273 A 11/1985 Wu
4,554,914 A 11/1985 Kapp et al.
D281,814 S 12/1985 Pratt et al.
4,570,623 A 2/1986 Ellison et al.
4,570,624 A 2/1986 Wu
4,592,346 A 6/1986 Jurgutis
4,599,086 A 7/1986 Doty
4,600,000 A 7/1986 Edwards
4,602,638 A 7/1986 Adams
4,604,995 A 8/1986 Stephens
4,608,052 A 8/1986 Van Kampen et al.
4,611,581 A 9/1986 Steffee
4,619,264 A 10/1986 Singh
4,628,921 A 12/1986 Rousso
4,634,720 A 1/1987 Dorman et al.
4,636,217 A 1/1987 Ogilvie et al.
4,636,526 A 1/1987 Dorman et al.
4,645,503 A 2/1987 Lin et al.
4,653,486 A 3/1987 Coker
4,655,777 A 4/1987 Dunn
4,661,536 A 4/1987 Dorman et al.
4,664,567 A 5/1987 Edwards
4,665,920 A 5/1987 Campbell
4,677,883 A 7/1987 Lee
4,677,972 A 7/1987 Tornier
4,693,721 A 9/1987 Ducheyne
4,696,290 A 9/1987 Steffee
4,698,375 A 10/1987 Dorman et al.
4,710,075 A 12/1987 Davison
4,713,004 A 12/1987 Linkow et al.
4,714,469 A 12/1987 Kenna
4,721,103 A 1/1988 Freedland
4,736,738 A 4/1988 Lipovsek et al.
4,743,256 A 5/1988 Brantigan
4,743,260 A 5/1988 Burton
4,759,766 A 7/1988 Buettner-Janz et al.
4,759,769 A 7/1988 Hedman et al.
4,769,881 A 9/1988 Pedigo et al.
4,781,591 A 11/1988 Allen
4,790,303 A 12/1988 Steffee
4,805,602 A 2/1989 Puno et al.
4,820,305 A 4/1989 Harms et al.
4,830,000 A 5/1989 Shutt
4,834,757 A 5/1989 Brantigan
4,848,327 A 7/1989 Perdue
4,851,008 A 7/1989 Johnson
4,863,476 A 9/1989 Shepperd
4,863,477 A 9/1989 Monson
4,865,603 A 9/1989 Noiles
4,877,020 A 10/1989 Vich
4,878,915 A * 11/1989 Brantigan 623/17.11
4,903,882 A 2/1990 Long
4,904,260 A 2/1990 Ray et al.
4,904,261 A 2/1990 Dove et al.
4,911,718 A 3/1990 Lee et al.
4,913,144 A 4/1990 Del Medico
4,936,848 A 6/1990 Bagby
4,943,291 A 7/1990 Tanguy
4,955,885 A 9/1990 Meyers
4,955,908 A 9/1990 Frey et al.
4,957,495 A 9/1990 Kluger
4,960,420 A 10/1990 Goble et al.
4,961,740 A * 10/1990 Ray et al. 606/247
4,968,316 A 11/1990 Hergenroeder
4,969,888 A 11/1990 Scholten et al.
4,987,904 A 1/1991 Wilson
5,015,247 A 5/1991 Michelson
5,015,255 A * 5/1991 Kuslich 128/898
5,026,373 A 6/1991 Ray et al.
5,030,236 A 7/1991 Dean
5,055,104 A * 10/1991 Ray 606/247
5,059,193 A 10/1991 Kuslich
5,062,845 A 11/1991 Kuslich et al.
5,071,437 A 12/1991 Steffee
5,084,050 A 1/1992 Draenert

5,102,414	A	4/1992	Kirsch	
5,108,422	A	4/1992	Green et al.	
5,112,336	A	5/1992	Krevolin et al.	
5,116,304	A	5/1992	Cadwell	
5,122,130	A	6/1992	Keller	
5,123,926	A	6/1992	Pisharodi	
5,133,755	A	7/1992	Brekke	
5,171,278	A	12/1992	Pisharodi	
5,192,327	A *	3/1993	Brantigan	623/17.11
5,246,458	A	9/1993	Graham	
5,258,031	A	11/1993	Salib et al.	
5,263,953	A	11/1993	Bagby	
5,279,292	A	1/1994	Baumann et al.	
5,282,861	A	2/1994	Kaplan	
5,292,252	A	3/1994	Nickerson et al.	
5,306,309	A	4/1994	Wagner et al.	
5,314,427	A	5/1994	Goble et al.	
5,324,295	A	6/1994	Shapiro	
5,352,229	A	10/1994	Goble et al.	
5,360,430	A	11/1994	Lin	
5,364,399	A	11/1994	Lowery et al.	
5,370,662	A	12/1994	Stone et al.	
5,370,697	A	12/1994	Baumgartner	
5,393,036	A	2/1995	Sheridan	
RE34,871	E	3/1995	McGuire et al.	
5,396,880	A	3/1995	Kagan et al.	
5,397,359	A	3/1995	Mittelmeier et al.	
5,397,364	A	3/1995	Kozak et al.	
5,425,772	A	6/1995	Brantigan	
5,435,723	A	7/1995	O'Brien	
5,443,514	A	8/1995	Steffee	
5,458,638	A	10/1995	Kuslich et al.	
5,489,307	A	2/1996	Kuslich et al.	
5,489,308	A	2/1996	Kuslich et al.	
5,571,109	A	11/1996	Bertagnoli	
5,571,189	A	11/1996	Kuslich	
5,669,909	A	9/1997	Zdeblick et al.	
5,683,463	A	11/1997	Godefroy et al.	
5,766,252	A	6/1998	Henry et al.	
5,782,919	A	7/1998	Zdeblick et al.	
D397,439	S	8/1998	Koros et al.	
5,800,547	A	9/1998	Schafer et al.	
5,906,616	A	5/1999	Pavlov et al.	
6,118,043	A	9/2000	Nies et al.	
7,534,254	B1	5/2009	Michelson	
7,828,800	B2	11/2010	Michelson	
8,057,475	B2	11/2011	Michelson	
2002/0138144	A1	9/2002	Michelson	

FOREIGN PATENT DOCUMENTS

DE	24 46 039		4/1975
DE	29 10 627		9/1980
DE	31 01 333	A1	12/1981
DE	31 32 520	A1	6/1982
DE	35 05 567	A1	6/1986
DE	36 08 163	A1	9/1987
DE	41 04 359	A1	8/1992
DE	43 02 397	A1	7/1993
EP	0 077 159		4/1983
EP	0 162 005		11/1985
EP	0 179 695		4/1986
EP	0 260 044		3/1988
EP	0 303 241	A2	2/1989
EP	0 307 241		3/1989
EP	0 499 465	A1	8/1992
EP	0 551 187	A1	7/1993
EP	0 577 179	A1	1/1994
EP	0 599 419	A2	6/1994
EP	0 732 093	A2	9/1996
ES	283078		5/1985
FR	2 295 729		7/1976
FR	2 581 336		11/1986
FR	2 703 580		10/1994
GB	1 291 470		10/1972
GB	1 492 990		11/1977
GB	1 531 487		11/1978
GB	2 076 657	A	12/1981
GB	2 083 754		3/1982
GB	2 126 094	A	3/1984
GB	2 164 277	A	3/1986
JP	57-29348		2/1982
JP	60-31706		2/1985
JP	60-43984		3/1985
JP	61-122859		6/1986
JP	62-155846		7/1987
SE	106 101		7/1939
SU	1107854		8/1984
SU	1124960		11/1984
SU	1217374		3/1986
SU	1222254		4/1986
WO	WO 84/01298		4/1984
WO	WO 91/06266		5/1991
WO	WO 92/14423		9/1992
WO	WO 93/01771		2/1993

OTHER PUBLICATIONS

Herkowitz, et al.; Principles of Bone Fusion; The Spine, Third Edition; Chapter 44, p. 1739.

Muschler, et al.; The Biology of Spinal Fusion; Spinal Fusion Science and Technique, Cotler and Cotler, pp. 9-13.

Zindrick, et al.; Lumbar Spine Fusion: Different Types and Indications; The Lumbar Spine, vol. 1, Second Editon, pp. 588-593 (1996).

Gillingham, F.J., et al., Automatic Patient Monitoring in the Ward; Brit. J. Surg., vol. 53, No. 10, pp. 864-866 (Oct. 1966).

Maloney, A.F.J., et al.; Clinical and Pathological Observations in Fatal Head Injuries, Brit. J. Surg., vol. 56, No. 1, pp. 23-31 (Jan. 1969).

Harris, P., et al.; Spinal Deformity After Spinal Cord Injury; Paraplegia, vol. 6, No. 4, pp. 232-238 (Feb. 1969).

Gillingham, F.J., et al.; Head injuries; Proceedings of the 18th World Congress of the International College of Surgeons, Rome, pp. 68-71 (May 28-31, 1972).

Whatmore, W. J.; Sincipital Encephalomenigoceles; Brit. J. Surg., vol. 60, No. 6, pp. 261-270 (Apr. 1973).

Whatmore, W. J.; Meninigioma Following Trauma; Brit. J. Surg., vol. 60, No. 6, pp. 496-498 (Jun. 1973).

Bagby, George W.; Wobbler Syndrome in Horses (the Ataxic Horse); Spokane County Medical Society Bulletin; Spring 1979.

Rathke, F.W., et al.; Surgery of the Spine; Atlas of Orthopaedic Operations, vol. 1, p. 137, W.B. Sauders Co., Philadelphia (1979).

Albrektsson, T., et al.; Osseointegrated Titanium Implants; Acta. Orthop. Scand.; vol. 52:55-170 (1981).

Raveh, J., et al.; Neue Rekonstruktionsmoglichkeiten des Unterkiefers bei knochernen Defekten nach Tumorresektionen; Der Chirug vol. 53:459-467 (1982).

Crock, H. V.; Practice of Spinal Surgery; Springer-Velag/Wien, New York (1983).

DeBowes, R.M., et al.; Study of Bovine . . . Steel Baskets; Transactions of the 29th Annual Meeting; Orthopaedic Research Society, vol. 8, p. 407, Mar. 8-10, 1983.

O'Neill, P., et al.; Spinal Meningoceles in Association with Neurofibromatosis; Neurosurgery, vol. 13, No. 1, pp. 82-84 (Jul. 1983).

Brandt, L., et al.; A Dowel Inserter for Anterior Cervical Interbody Fusion; J. Neurosurg. 61:793-794 (Oct. 1984).

Whatmore, W.J., et al.; The Coventry Cervical Spreader and Dowel Inserter; ACTA Neurochirurgica, vol. 70, FASC. 1-2 (1984).

Raveh, J., et al.; Use of the Titanium-coated Hollow Screw and Reconstruction Plate System in Bridging of Lower Jaw Defects; J. Oral Maxillofac Surg. 42:281-294 (1984).

Otero-Vich, Jose M.; Anterior Cervical Interbody Fusion with Threaded Cylindrical Bone; J. Neurosurg 63:750-753 (Nov. 1985).

Morscher, E., et al.; Die vordere Verplattung der Halswirbeisäule mit dem Hohlschrauben-Plattensystem aus Titanium, Der Chirurg, vol. 57, pp. 702-707 (1986) with English Translation.

Bagby, G.W.; Basket Implant Facillitates Spinal Fusion; Orthopedics Today, vol. 7, No. 10 (Oct. 1987).

Butts, M. L., et al.; Biomechanical Analysis of a New Method for Spinal Interbody Fixation; 1987 Symposium, American Society of Mechanical Engineers, "Advances in Bioengineering", Boston, MA (Dec. 13-18, 1987).

Crawley et al.; A Modified Cloward's Technique for Arthrodesis of the Normal Metacarpophalangeal Joint in the Horse; Veterinary Surgery, vol. 17, No. 3, pp. 117-127 (1988).
Raveh, J., et al.; Surgical Procedures for Reconstruction of the Lower Jaw Using the Titanium-Coated Hollow-Screw Reconstruction Plate System: Bridging of Defects; Otolaryngologic Clinics of North America; vol. 20, No. 3 (Aug. 1987).
Whatmore, W. J.; Proceedings of the Society of British Neurological Surgeons; Journal of Neurology, Neurosurgery, and Psychiatry, 50:1093-1100 (1987).
Goldthwaite, N., et al.; Toward Percutaneous Spine Fusion; Ch. 45; Lumbar Spine Surgery; C.V. Mosby Company, pp. 512-522 (1987).
Bagby, G.W.; Arthrodesis by the Distraction-Compression Method Using a Stainless Steel Implant; Orthopedics, vol. II, No. 6, pp. 931-934 (Jun. 1987).
Itoman, M., et al.; Banked Bone Grafting for Bone Defect Repair—Clinical Evaluation of Bone Union and Graft Incorporation; J. Jpn. Orthop. Assoc. 62:461-469 (1988).
Kane, W.J.; Direct Current Electrical Bone Growth Stimulation for Spinal Fusion; Spine, vol. 13, No. 3, pp. 363-365 (Mar. 1988).
The SpF-T Spinal Fusion Stimulator: An Efficacious Adjunct that Meets the Diverse Needs of Spine Patients; EBI Medical Systems; (Aug. 1991).
Schmitz et al.; Performance of Alioplastic Materials and Design of an Artificial Disc; The Artificial Disc, Brock, Mayer, Weigel; pp. 23-34 (1991).
The Use of Direct Current for Electrically Induced Osteogenesis; The Positive Effect of an Electronegative charge on Bone Growth; EBI Medical Systems (Feb. 1993).
Mylonas, C., et al.; Anterior Cervical Decompression and Fusion Using the Coventry Cervical Spreader and Dowel Inserter; British Journal of Neurosurgery, 7:545-549 (1993).
Fusion of the Lumbar Spine; Anterior Monosegmental Fusion L5-S1, Atlas of Spinal Operations, Thieme, pp. 270-274 (1993).
Spine Basics, Danek Group, Inc., Glossary (1993).
Lumbar Spine Surgery, Techniques & Complications; History of Lumbar Spine Surgery (1994) pp. 11-15; 27; 30; 35-45; 265-268.
European Search Report dated Aug. 4, 1999.
Cloward, Ralph B.; Surgical Techniques for Lumbar Disc Lesions; Codman; Signature Series 3.
Cloward, Ralph B.; Ruptured Cervical Intervertebral Discs: Removal of Disc & Osteophytes & Anterior Cervical Interbody Fusion (A.C.I.F.); Codman; Signature Series 4.
Cloward, Ralph B.; Recent Advances in Surgery of the Cervical Spine; pp. 285-293; German Society For Neurosurgery: vol. 2 Cervical Spine Operations; Excerpta Medica.
Hutter, Charles George; Spinal Stenosis and Posterior Lumbar Interbody Fusion; pp. 103-114; Clinical Orthopaedics and Related Research; No. 193; The Association of Bone and Joint Surgeons.
Lin, Paul M.; Posterior Lumbar Interbody Fusion; pp. 114-122; Charles C. Thomas; Springfield, Illinois.
Lin, Paul M.; Lumbar Interbody Fusion: Principles and Techniques in Spine Surgery; Techniques and Complications; pp. 81, 98, 120, 146, 173, 180-184, 204, 224, 225, 231; Aspen Publishers, Inc.; 1989.
Tan, S.B.; A Modified Technique of Anterior Lumbar Fusion with Femoral Cortical Allograft; pp. 83-93; The Journal of Orthopaedic Suroical Techniques, vol. 5, No. 3, 1990.
Muller, M.E.; Manual of Internal Fixation: Techniques Recommended by the AO Group; Second Edition, Expanded and Revised; pp. 3-20, 27-41, 53-58, 71-78, 94, 311, 320; Springer-Verlag; 1979.
Hierholzer, G.; Manual on the AO/ASIF Tubular External Fixator; pp. 85-91; Springer-Verlag; 1985.
Helm, Urs, Small Fragment Set Manual: Technique Recommended by the ASIF-Group; pp. 5-7, 10, 20, 21, 30; Springer-Verlag, 1974.
Harmon, Paul H.; Anterior Excision and Vertebral Body Fusion Operation for Intervertebral Disk Syndromes of the Lower Lumbar Spine: Three- to Five-Year Results in 244 Cases; pp. 107-127, Clinicai Orthopaedics and Related Research, No. 26, J.B. Lippincott.
Harmon, Paul H.; A Simplified Surgical Technic for Anterior Lumbar Diskectomy and Fusion; Avoidance of Complications; Anatomy of the Retroperitoneal Veins; pp. 130-143; Clinical Orthopaedics and Related Research, No. 37, J.B. Lippincott Company, 1964.
Bullough, Peter G.; Atlas of Spinal Diseases; Figure 5.7; J.B. Lippencott Company; 1988.
Canale, S. Terry; Campbell's Operative Orthopaedics; vol. 3, 9th Edition; pp. 2191, 2216, 2459; Mosby, 1998.

* cited by examiner

Fig.1

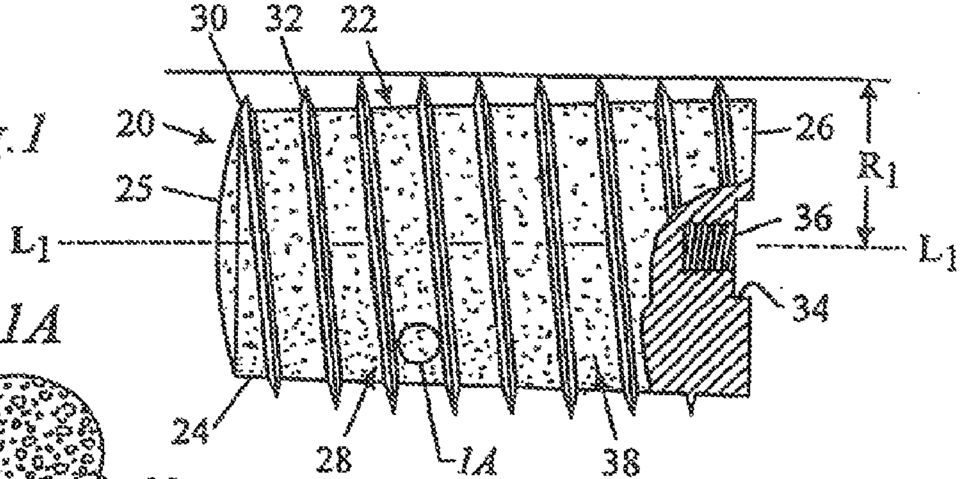


Fig.1A

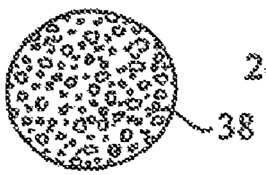


Fig.2

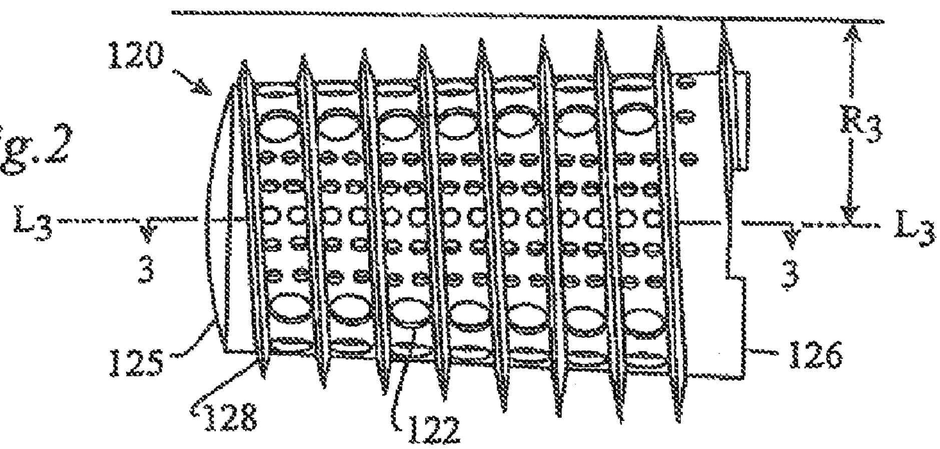


Fig.3

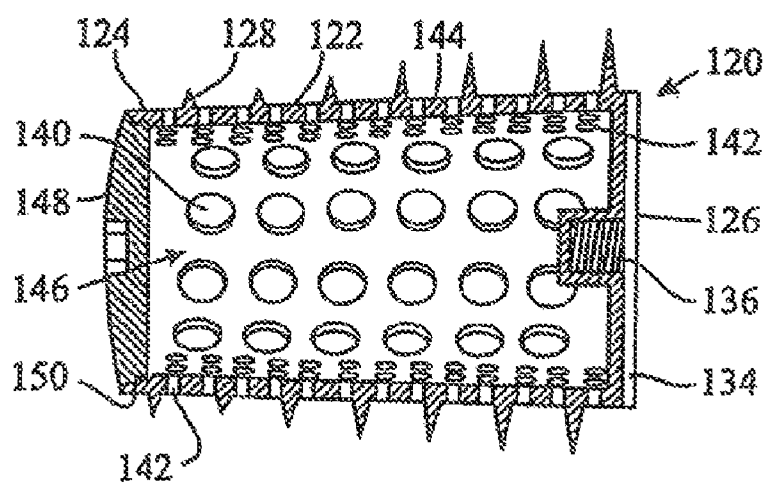


Fig. 1B

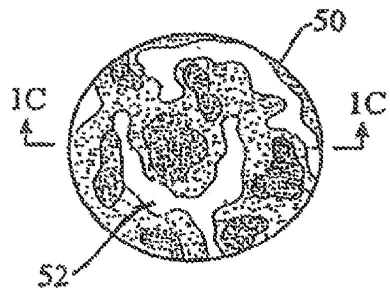


Fig. 1C

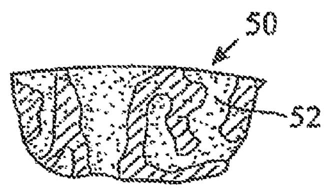


Fig. 1D

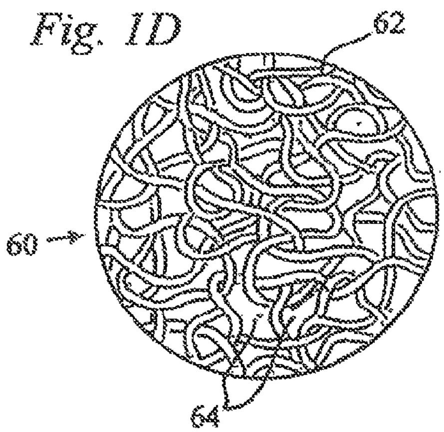


Fig. 1E

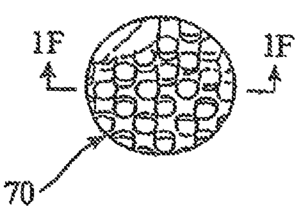


Fig. 1F

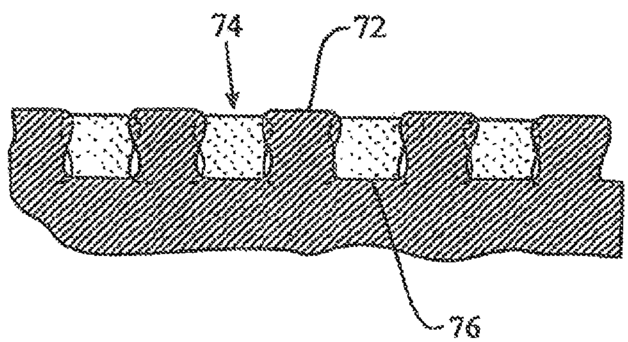


Fig. 4

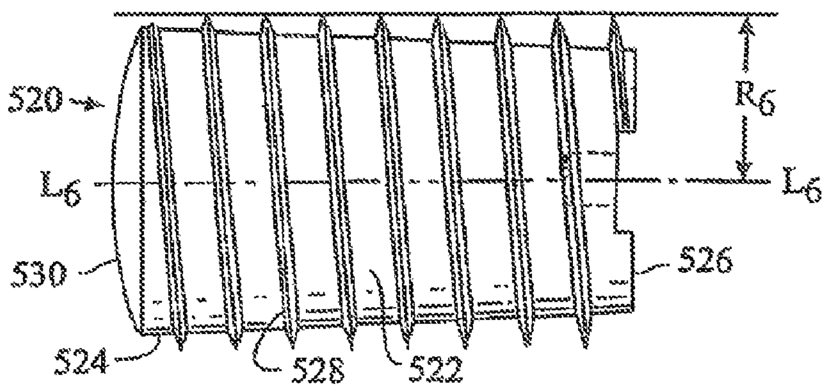


Fig. 5

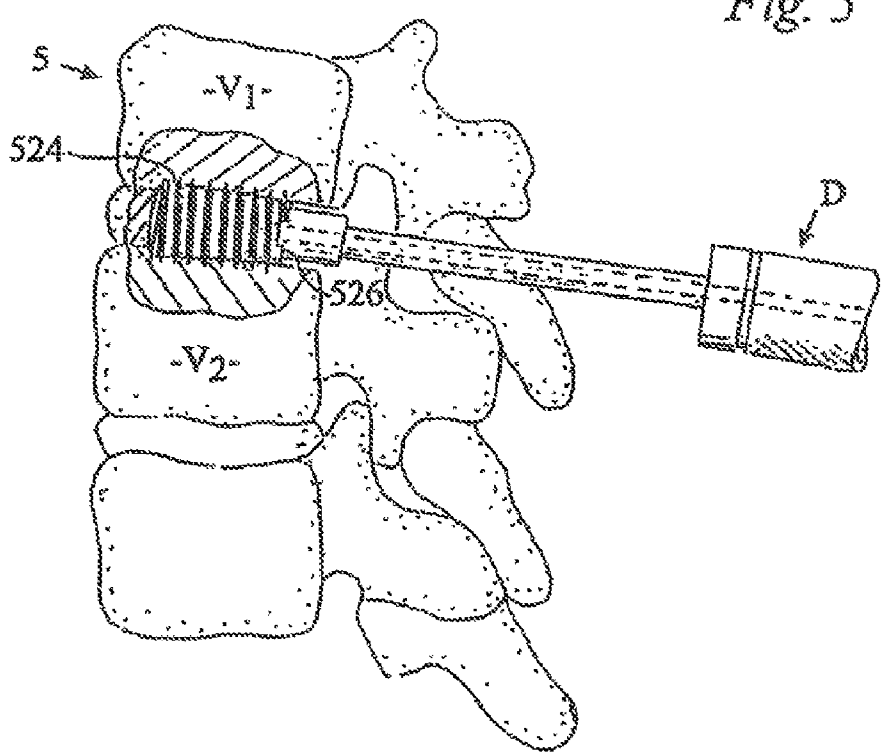


Fig. 6

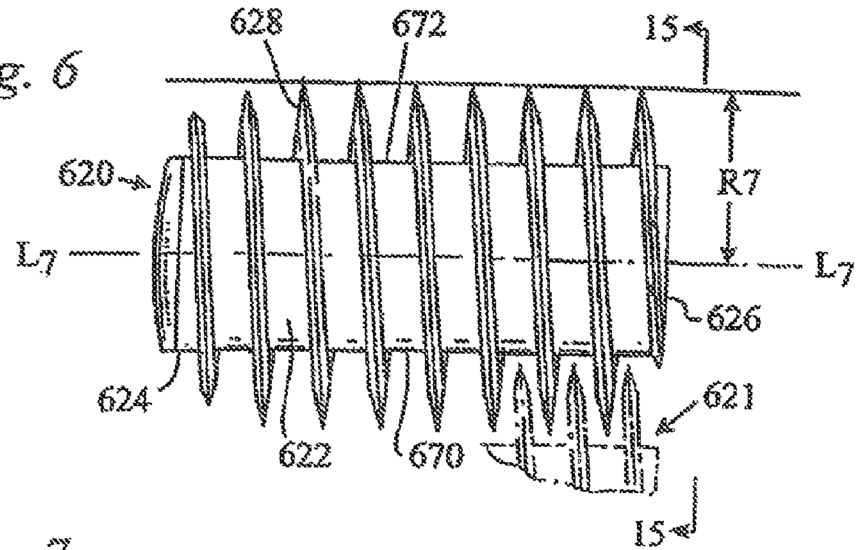


Fig. 7

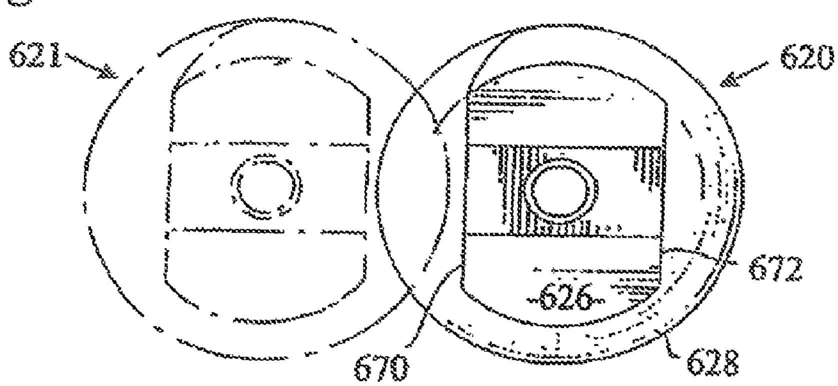
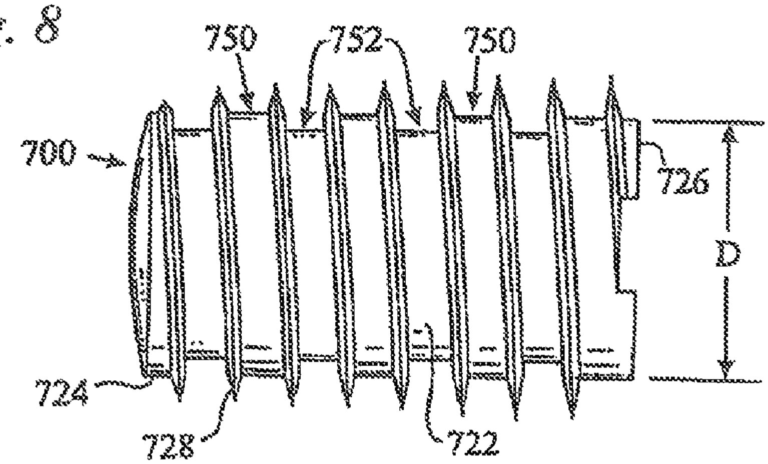


Fig. 8



THREADED FRUSTO-CONICAL SPINAL IMPLANTS

The present application is a continuation of application Ser. No. 12/942,671, filed Nov. 9, 2010 now U.S. Pat. No. 8,057,475; which is a continuation of application Ser. No. 12/454,393, filed May 18, 2009, now U.S. Pat. No. 7,828,800; which is a continuation of application Ser. No. 08/480,908, filed Jun. 7, 1995, now U.S. Pat. No. 7,534,254; which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in anatomical lordosis.

2. Description of the Prior Art

Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space, the space between adjacent vertebrae normally occupied by a spinal disc. Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae. Such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the lumbar spine are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated with a loss of lordosis.

Therefore, there exists a need for spinal fusion implants that permit for the restoration of anatomical lordosis.

SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration. In the preferred embodiment, the spinal fusion implants of the present invention have a body that is partially or fully frusto-conical shape substantially along the portion of the implant in contact with the adjacent vertebrae of the spine. The spinal fusion implants of the present invention have an external thread for engaging the adjacent vertebrae of the spine and have an insertion end and a trailing end. The external thread may have a variable or constant thread radius and/or a constant or variable thread height measured from the body of the implant.

The spinal fusion implants of the present invention may be further modified so that while the upper and lower surfaces are portions of a frusto-cone, at least one side portion may be truncated to form a planar surface that is parallel to the central longitudinal axis of the implant to form straight walls. These implants may have a more tapered aspect at the insertion end of the implant to facilitate insertion. The spinal fusion implants of the present invention may be relatively solid and/or porous and/or hollow, and may have surface roughenings to promote bone ingrowth and stability.

The spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. These wells, or holes, may pass either into or through the implant and may or may not intersect. The spinal fusion implants of

the present invention may have at least one chamber which may be in communication through at least one opening to the surface of the implant. Said chamber may have at least one access opening for loading the chamber with fusion promoting substances. The access opening may be capable of being closed with a cap or similar means.

The spinal fusion implants of the present invention offer significant advantages over the prior art implants:

1. Because the spinal fusion implants of the present invention are at least partially frusto-conical in shape, those that taper from the leading edge to the trailing edge are easy to introduce and easy to fully insert into the spinal segment to be fused. In another embodiment, where the trailing edge of the implant is larger than the leading edge, the implant utilizes a tapered forward portion and an increasing thread height relative to the body from the leading edge to the trailing edge to facilitate insertion.
2. The shape of the implants of the present invention is consistent with the shape of the disc, which the implants at least in part replace, wherein the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The implants of the present invention are similarly taller anteriorly than they are posteriorly.
3. The spinal fusion implants of the present invention conform to a geometric shape, which shape is readily producible at the site of fusion, to receive said spinal fusion implants.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose of spinal fusion, including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bioabsorbable, and various ceramics or combination sufficient for the intended purpose. Further, the spinal fusion implants of the present invention may be made of a solid material, a mesh-like material, a porous material and may comprise, wholly or in part, materials capable of directly participating in the spinal fusion process, or be loaded with, composed of, treated of coated with chemical substances such as bone, morphogenic proteins, hydroxyapatite in any of its forms, and osteogenic proteins, to make them bioactive for the purpose of stimulating spinal fusion. The implants of the present invention may be wholly or in part bioabsorbable.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal fusion implant that is easily inserted into the spine, having a tapered leading end;

It is another object of the present invention to provide a spinal fusion implant that tapers in height from one end to the other consistent with the taper of a normal spinal disc;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

It is still another object of the present invention to provide a spinal fusion implant that is self stabilizing within the spine;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of providing stability between adjacent vertebrae when inserted;

It is still another object of the present invention to provide a spinal fusion implant that is capable of participating in the fusion process by containing, being composed of, or being treated with fusion promoting substances;

It is further another object of the present invention to provide a spinal fusion implant that is capable of spacing apart and supporting adjacent vertebrae during the spinal fusion process;

It is still further another object of the present invention to provide a spinal fusion implant that is consistent in use with the preservation of a uniform thickness of the subchondral vertebral bone;

It is another object of the present invention to provide a spinal fusion implant having a shape which conforms to an easily produced complementary bore at the fusion site; and

It is a further object of the present invention to provide a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual heights of each implant.

It is a further object of the present invention to provide a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual lengths of each implant.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side elevational view of the spinal fusion implant of the present invention having a body that is frusto-conical with an external thread having a substantially uniform radius.

FIG. **1**A is an enlarged fragmentary view along line **1**A of FIG. **1** illustrating the surface configuration of the implant of FIG. **1**.

FIG. **1**B is an enlarged fragmentary view along line **1**A of FIG. **1** illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

FIG. **1**C is a cross sectional view along lines **1**C-**1**C of FIG. **1**B illustrating the alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

FIG. **1**D is an enlarged fragmentary view along line **1**A of FIG. **1** illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a fibrous mesh-like material.

FIG. **1**E is a fragmentary view along line **1**A of FIG. **1** illustrating an alternative embodiment of the surface configuration, of the implant of the present invention comprising a plurality of spaced apart posts.

FIG. **1**F is an enlarged fragmentary sectional view along lines **1**F-**1**F of FIG. **1**E illustrating the surface configuration of the implant of FIG. **1**E.

FIG. **2** is an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body with an external thread radius and thread height that are not constant.

FIG. **3** is as cross sectional view along line **3**-**3** of the implant of FIG. **2**.

FIG. **4** is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention.

FIG. **5** is a side elevational view and partial cut-away of a segment of the spinal column in lordosis showing the spinal fusion implant of FIG. **4** being implanted with a driving instrument from the posterior approach to the spinal column.

FIG. **6** is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body and truncated sides.

FIG. **7** is an end view along line **7**-**7** of the spinal fusion implant of FIG. **6** shown placed beside a second identical implant shown in hidden line.

FIG. **8** is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body with an irregular configuration.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. **1**, a side elevational view of the spinal fusion implant of the present invention generally referred to by numeral **20** is shown. The implant **20** has a body **22** that is frusto-conical in shape such that the body **22** has a diameter (root diameter) that is generally frusto-conical. The body **22** has an insertion end **24** and a trailing end **26**. The insertion end **24** may include a tapered portion **25** to facilitate insertion of the spinal implant **20**. In the preferred embodiment, when the implant **20** is inserted from the anterior aspect of the spine, the body **22** of the implant **20** has a maximum diameter at a point nearest to the trailing end **26** and a minimum diameter at a point nearest to the insertion end **24**.

The implant **20** has an external thread **28** having a substantially uniform radius R_1 measured from the central longitudinal axis L_1 of the implant **20**. The outer locus of the external thread **28** (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis L_1. While the major diameter of the implant **20** is substantially uniform, the external thread **28** may be modified at the leading edge by having initially a reduced thread radius to facilitate insertion of the implant **20** and may also be modified to make the external thread **28** self-tapping. In the preferred embodiment, the external thread **28** has a first thread **30** of a lesser radius than the radius R_1 of the remainder of the external thread **28** to facilitate insertion of the implant **20**. The second thread **32** has a greater radius than the first thread **30**, but is still shorter than the radius R_1 of the remainder of the external thread **28** which is thereafter of constant radius.

The body **22** is frusto-conical substantially along the portion of the body **22** in contact with the adjacent vertebrae of the spine which allows for creating and maintaining the adjacent vertebrae of the spine in the appropriate angular relationship to each other in order to preserve and/or restore the normal anatomic lordosis of the spine. The substantially uniform radius R_1 of the external thread **28** of the implant **20** allows engaging the bone of the adjacent vertebrae in a position that counters the forces which tend to urge the implant **20** from between the adjacent vertebrae in the direction opposite to which the implant **20** was implanted. The greater thread height measured from the body **22** near the leading end **24** of the implant **20** provides greater purchase into the vertebral bone and again enhances the stability of the implant **20**. Further, the configuration of the external thread **28** increases the surface area of the implant **20** in contact with the vertebrae to promote bone ingrowth.

The implant **20** has a recessed slot **34** at its trailing end **26** for receiving and engaging insertion instrumentation for inserting the implant **20**. The recessed slot **34** has a threaded opening **36** for threadably attaching the implant **20** to instrumentation used for inserting the implant **20**.

Referring to FIG. **1**A, the implant **20** has an outer surface **38** that is porous to present an irregular surface to the bone to promote bone ingrowth. The outer surface **38** is also able to hold fusion promoting materials and provides for an increased surface area to engage the bone in the fusion process and to provide further stability. The pores of the outer surfaces **38** are microscopic in size having a diameter that is less than 1 mm, in the range of 50-1000 microns, with 250-500 microns being the preferred diameter. It is appreciated that the outer surface **38**, and/or the entire implant **20**, may comprise any other porous material or roughened surface sufficient to hold fusion promoting substances and/or allow for bone ingrowth and/or engage the bone during the fusion process. The implant **20** may be further coated with bioactive fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins. The implant **20** is shown as being solid, however it is appreciated that it can be made to be substantially hollow or hollow in part.

Referring to FIG. **1**B, an enlarged fragmentary view along line **1**A of FIG. **1** illustrating an alternative embodiment of the surface configuration **38** of the implant of the present invention made of a cancellous material is shown. The cancellous material **50**, similar in configuration to human cancellous bone, having interstices **52** such that the outer surface **38** has a configuration as shown in FIGS. **1**B and **1**C. As the implant of the present invention may be made entirely or in part of the cancellous material **50**, the interstices **52** may be present in the outer surface **338** and/or within the entire implant to promote bone ingrowth and hold bone fusion promoting materials.

Referring to FIG. **1**D, an enlarged fragmentary view along line **1**A of FIG. **1** illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a fibrous mesh-like material is shown. The mesh-like material **60** comprises strands **62** that are formed and pressed together such that interstices **64**, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface **38** of implant of the present invention.

Referring to FIGS. **1**E and **1**F, a fragmentary view along line **1**A of FIG. **1** illustrating an alternative embodiment of the surface configuration **38** of the implant of the present invention comprising a plurality of spaced apart posts **70** is shown. The posts **70** have a head portion **72** of a larger diameter than the remainder of the posts **70**, and each of the interstices **74** is the reverse configuration of the posts **72**, having a bottom **76** that is wider than the entrance to the interstices **74**. Such a configuration of the posts **70** and interstices **74** aids in the retention of bone material in the surface **38** of the implant and further assists in the locking of the implant into the bone fusion mass created from the bone ingrowth. As the bone ingrowth at the bottom **76** of the interstices is wider than the entrance, the bone ingrowth cannot exit from the entrance and is locked within the interstice **74**. The surface of the implant provides for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non smooth surface.

In the preferred embodiment, the posts **70** have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of approximately 0.1-2 mm such that the interstices **74** have a width in the range of approximately 0.1 to 2 mm. The post sizes, shapes, and distributions may be varied within the same implant.

In the preferred embodiment, for use in the lumbar spine, the implant **20** has an overall length in the range of approximately 24 mm to 32 mm with 26 mm being the preferred length. The body **22** of the implant **20** has a root diameter at the insertion end **24** in the range of 8-20 mm, with 14-16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end **26** in the range of 10-24 mm, with 16-18 mm being the preferred diameter at the trailing end **26**, when said implants, are used in pairs. When used singly in the lumbar spine, the preferred diameters would be larger.

In the preferred embodiment, the implant **20** has a thread radius R_1 in the range of 6 mm to 12 mm, with 9-10 mm being the preferred radius R_1. For use in the cervical spine, the implant **20** has an overall length in the range of approximately 10-22 mm, with 12-14 mm being the preferred length. The body **22** of the implant **20** has a root diameter at the insertion end **24** in the range of 8-22 mm, with 16-18 mm being the preferred root diameter at the insertion end when used singly, and 8-10 mm when used in pairs. The body **22** of the implant **20** has a root diameter at the trailing end **26** in the range of 10-24 mm, with 18-20 mm being the preferred root diameter at the trailing end **26** when used singly, and 10-12 mm when used in pairs; a thread radius, R_1 in the range of approximately 4-12 mm, with 9-10 mm being the preferred radius R_1 when inserted singularly and 5-7 mm when inserted side by side in pairs.

Referring to FIG. **2**, an alternative embodiment of implant **20** is shown and generally referred to by the numeral **120**. The implant **120** has a body **122** similar to body **122** of implant **120** and has an external thread **128** having a radius R_3 measured from the central longitudinal axis L_3 of the implant **120**. The thread radius R_3 is not constant throughout the length of the implant **120** and the external thread **128** has a thread height that is also not constant with respect to the body **122** of the implant **120**. In the preferred embodiment, the implant **120** has an external thread **128** with a radius R_3 that increases in size from the insertion end **124** to the trailing end **126** of the implant **120**.

Referring to FIG. **3**, a cross sectional view along line **3**-**3** of the implant **120** is shown. The implant **120** has an outer wall **144** surrounding an internal chamber **146**. The large and small openings **140** and **142** may pass through the outer wall **144** to communicate with the internal chamber **146**. The internal chamber **146** may be filled with bone material or any natural bone growth material or fusion promoting material such that bone growth occurs from the vertebrae through the openings **140** and **142** to the material within internal chamber **146**. While the openings **140** and **142** have been shown in the drawings as being circular, it is appreciated that the openings **140** and **142** may have any shape, size configuration or distribution, suitable for use in a spinal fusion implant without departing from the scope of the present invention.

The openings **140** and **142** are macroscopic in size having a diameter that is greater than 1 mm. The large openings **140** have a diameter in the range of 206 mm, with the preferred diameter being 3.5 mm; and the small openings have a diameter in the range of 1-2 mm, with 1.5 mm being the preferred diameter.

The implant **120** has a cap **148** with a thread **150** that threadably attaches to the insertion end **124** of the spinal fusion implant **120**. The cap **148** is removable to provide access to the internal chamber **146**, such that the internal chamber **146** can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap **148** and/or the spinal fusion implant **120** may be made of any material appropriate for human implantation including metals such as cobalt chrome, stainless steel, titanium, plastics, ceramics, composites and/or may be made of, and/or filled, and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. The cap **148** and the implant **120** may be partially or wholly bioabsorbable.

Referring to FIG. **4**, a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention generally referred to by numeral **520** is shown. The implant **520** has a body **522** having a root diameter that is frusto conical in the reverse direction as that implant **20** shown in FIG. **1**, in order to preserve and/or restore lordosis in a segment of spinal column when inserted from the posterior aspect of the spine. The body **522** has an insertion end **524** and a trailing end **526**. In the preferred embodiment, the body **522** of the implant **520** has a minimum diameter at a point nearest to the trailing end **526** and a maximum diameter at a point nearest to the insertion end **524**. The insertion end **524** may have an anterior nose cone portion **530** presenting a tapered end to facilitate insertion.

The implant **520** has an external thread **528** having a substantially uniform radius R_6 measured from the central longitudinal axis L_6 of the implant **520** such that the external diameter of the external thread **528** (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis L_6. It is appreciated that the thread **528** can have a major diameter that varies with respect to the longitudinal axis L_6, such that the major diameter may increase from the insertion end **524** to the trailing end **526** or the reverse. The external thread **528** has a thread height measured from the body **522** that increases from the insertion end **524** to the trailing end **526**.

Referring to FIG. **5**, a segment of the spinal column S is shown with the vertebrae V_1 and V_2 in lordosis and an implant **520** shown being inserted from the posterior aspect of the spinal column S with an instrument driver D. The implant **520** is inserted with the larger diameter insertion end **524** first in order to in initially distract apart the vertebrae V_1 and V_2 which then angle toward each other posteriorly as the implant **520** is fully inserted. It is appreciated that the insertion of implant **520** does not require the adjacent vertebrae V_1 and V_2 to be placed in lordosis prior to insertion, as the full insertion of the implant **520** itself is capable of creating the desired lordotic angular relationship of the two vertebrae V_1 and V_2.

In the preferred embodiment, for use in the lumbar spine, the implant **520** has an overall length in the range of approximately 24 m 30 mm, with 26 mm being the preferred length. The body **522** of the implant **520** has a root diameter at the insertion end **524** in the range of 12-22 mm, with 16 mm being the preferred root diameter at the-insertion end, and a root diameter at the trailing end **526** in the range of 10-20 mm, with 14 mm being the preferred diameter at the trailing end **526**. In the preferred embodiment, the implant **520** has a thread radius R_6 in the range of 6 mm to 12 mm, with 8 mm being the preferred radius R_6.

Referring to FIG. **6**, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral **620** and a partial fragmentary view of a second identical implant, generally referred to by the numeral **621** are shown. The implant **620** has a body **622** that is partially frusto-conical in shape similar to body **22** of implant **20** shown in FIG. **1**, and has an insertion end **624** and a trailing end **626**. The body **622** of the implant **620** has truncated sides **670** and **672** forming planar surfaces that are parallel to the longitudinal axis L_7. In this manner, two implants **620** and **621** may be placed side by side, with one of the sides **670** or **672** of each implant with little space between them, such that the area of contact with the bone of the adjacent vertebrae is maximized. It is appreciated that the body **622** may also be cylindrical in shape and have truncated sides **670** and **672**.

The implant **620** has an external thread **628** having a radius R_6 measured from the central longitudinal axis L_7 that may be constant, such that the major diameter or outer locus-of the external thread **628** has an overall configuration that is substantially, cylindrical. It is appreciated that the external thread **628** may have a thread radius R_7 that is variable with respect to the longitudinal axis L_7 such that the major diameter or outer locus of the external thread **628** has an overall configuration that is substantially frusto-conical.

Referring to FIG. **7**, an end view of the implant **620** placed beside implant **621** is shown. The implant **620** has a thread radius that is substantially constant and has a thread height measured from the body **622** that is greater at the sides **670** and **672**. In this manner, two implants **620** and **621** can be placed beside each other with the external thread **628** of each implant interdigitated allowing for closer adjacent placement of the two implants as a result of the substantial overlap of the external thread **628** at the side **670** or **672** of the implants.

Referring to FIG. **8**, an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral **700**. The implant **700** is similar in configuration to implant **20** shown in FIG. **1**, except that the body **722** has an irregular configuration. The configuration of the body **722** has a root diameter D which is variable in size throughout the length of the implant **700** and, as shown in this embodiment, comprises larger diameter portions **750** and smaller diameter portions **752**. It is appreciated that each of the large diameter portions **750** may be of the same or different diameter and each of the smaller diameter portions **752** may be of the same or different diameter.

The outer surface of the body **722** of implant **720** may be filled with fusion promoting substances such that the smaller diameter portions **752** may hold such fusion promoting substances. If so filled, the composite of the implant **700** and the fusion promoting material could still produce an even external surface of the body **722** if so desired.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is appreciated that the various teachings described in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

Each of the features disclosed in the various embodiments and their functional equivalents may be combined in any combination sufficient to achieve the purposes of the present invention as described herein.

I claim:

1. A spinal implant for insertion within an implantation space formed into a segment of adjacent vertebral bodies of a human lumbar spine, said implant comprising:

a body having a leading end, a trailing end, a mid-longitudinal axis through said leading and trailing ends, a length parallel to the mid-longitudinal axis, and an arcuate sidewall surrounding the mid-longitudinal axis and extending from said leading end to said trailing end, said body having an interior surface and an opposite exterior surface, said arcuate sidewall having at least two apertures extending therethrough, said apertures being in communication with each other;

a first thread extending from said interior surface of said body proximate said trailing end, said first thread having a major diameter;

a second thread extending from said interior surface of said body, said second thread being spaced apart from said first thread, said second thread having a major diameter of a different size relative to the major diameter of said first thread; and

a third thread extending from said exterior surface of said body, said body having a frustoconical configuration along at least a portion of its length and over a plurality of turns of said third thread about the mid-longitudinal axis.

2. The implant of claim **1**, wherein said implant is configured to space apart the adjacent vertebral bodies.

3. The implant of claim **1**, wherein said implant is configured to distract apart the adjacent vertebral bodies using an element of rotation.

4. The implant of claim **1**, wherein said third thread has a variable height along each turn of said third thread about the mid-longitudinal axis of said body.

5. The implant of claim **4**, wherein said third thread has an outer locus with a substantially cylindrical configuration.

6. The implant of claim **1**, wherein an outer locus of one of said threads has a substantially cylindrical configuration.

7. The implant of claim **1**, wherein said first thread proximate said trailing end has an outer locus with a substantially cylindrical configuration.

8. The implant of claim **1**, wherein said body has the frustoconical configuration along its length over at least eight turns of said third thread about the mid-longitudinal axis.

9. The implant of claim **1**, wherein said body includes a central bore extending from said trailing end along the mid-longitudinal axis of said body, said central bore being configured to permit the delivery of bone growth promoting material to said apertures.

10. The implant of claim **1**, wherein said trailing end is closed.

11. The implant of claim **1**, wherein said leading end includes an aperture centered at the mid-longitudinal axis.

12. The implant of claim **1**, wherein said body includes a central bore extending from said trailing end along the mid-longitudinal axis of said body, said arcuate sidewall having at least one well passing through said body and forming opposed apertures at said exterior surface of said sidewall, said well intersecting said central bore, said central bore being configured to permit delivery of bone growth promoting material to said apertures.

13. The implant of claim **12**, wherein said leading end includes an aperture centered at the mid-longitudinal axis.

14. The implant of claim **12**, wherein said arcuate sidewall includes a second well passing through said body and forming opposed apertures at said exterior surface of said sidewall, said second well intersecting said well.

15. The implant of claim **1**, wherein the major diameter of said first thread proximate said trailing end is less than the major diameter of said second thread.

16. The implant of claim **1**, wherein said first thread proximate said trailing end is configured to threadably engage an instrument to insert said implant into the spine.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,226,652 B2
APPLICATION NO. : 13/296125
DATED : July 24, 2012
INVENTOR(S) : Gary Karlin Michelson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page 3, Item (56), Other Publications
Column 2, line 33: change “Encephalomenigoceles;” to --Encephalomeningoceles;--;
Column 2, line 34: change “No. 6” to --No. 4--;
Column 2, line 35: change “Meninigioma” to --Meningioma--;
Column 2, line 42: change “vol. 52:55-170” to --Vol. 52:155-170--;
Column 2, line 44: change “Der Chirug” to --Der Chirurg--;
Column 2, line 46: change “Springer-Velag/Wien” to --Springer-Verlag/Wien--;
Column 2, line 63: change “Halswirbeisäule” to --Halswirbelsäule--;
Column 2, line 66: change “Facillitates” to --Facilitates--; and
Column 2, line 68: change “Butts, M. L.,” to --Butts, M. K.,--.

Title Page 4, Item (56), Other Publications
Column 1, line 24: change “Alioplastic” to --Alloplastic--;
Column 2, line 19: change “Suroical” to --Surgical--;
Column 2, line 25: change “Helm” to --Heim--; and
Column 2, line 30: change “Clinicai” to --Clinical--.

Signed and Sealed this
Twelfth Day of March, 2013

Teresa Stanek Rea
Acting Director of the United States Patent and Trademark Office