

EXHIBIT 1

TO THE DECLARATION OF
BRIAN J. NISBET IN SUPPORT OF
DEFENDANTS' MOTION FOR
SUMMARY JUDGMENT

032904

16711 U.S. PTO

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. ER 310993525 US

INVENTOR(S)					
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)			
Matthew	Curran	San Diego, California			
Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
SYSTEM AND METHODS FOR SPINAL FUSION					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages	27	<input type="checkbox"/>	CD(s), Number _____		
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets	17	<input checked="" type="checkbox"/>	Other (specify) Postcard		
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.					FILING FEE Amount (\$) <div style="border: 1px solid black; width: 100px; height: 40px; margin: 0 auto; text-align: center;">80.00</div>
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<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
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60/557536

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Respectfully submitted,

SIGNATURE _____

TYPED or PRINTED NAME Jonathan D. Spangler

TELEPHONE (858) 243-0029

Date March 29, 2004

REGISTRATION NO. 40,182

(if appropriate)

Docket Number: ~~108PRV~~ 104PRV

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Jonathan D. Spangler

**PROVISIONAL APPLICATION
FOR UNITED STATES LETTERS PATENT**

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SYSTEMS AND METHODS FOR SPINAL FUSION

By Inventor:

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a citizen of the United States
Carlsbad, California

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Filed:

March 29, 2004

SYSTEMS AND METHODS FOR SPINAL FUSION

BACKGROUND OF THE INVENTION

I. Field of the Invention

5 The present invention relates generally to spinal surgery and, more particularly, to a system and method for spinal fusion comprising a spinal fusion implant of non-bone construction releasably coupled to an insertion instrument dimensioned to introduce the spinal fusion implant into any of a variety of spinal target sites.

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II. Discussion of the Prior Art

 Currently there are nearly 500,000 spine lumbar and cervical fusion procedures performed each year in the United States. Such procedures are commonly performed to correct problems, such as chronic back or neck pain, which
15 result from degenerated intervertebral discs or trauma. Generally, spinal fusion procedures involve removing some or all of the diseased or damaged disc, and inserting one or more intervertebral implants into the resulting disc space. Introducing the intervertebral implant serves to restore the height between adjacent vertebrae (“disc height”), which reduces if not eliminates neural impingement
20 commonly associated with a damaged or diseased disc.

Autologous bone grafts are widely used intervertebral implant for lumbar fusion. Autologous bone grafts are obtained by harvesting a section of bone from the iliac crest of the patient and thereafter implanting the article of autologous bone graft to effect fusion. While generally effective, the use of autologous bone grafts suffers certain drawbacks. A primary drawback is the morbidity associated with harvesting the autologous graft from the patient's iliac crest. Another related drawback is the added surgical time required to perform the bone-harvesting.

Allograft bone grafts have been employed with increased regularity in an effort to overcome the drawbacks of autologous bone grafts. Allograft bone grafts are harvested from cadaveric specimens, machined, and sterilized for implantation. While allograft bone grafts eliminate the morbidity associated with iliac crest bone harvesting, as well as decrease the overall surgical time, they still suffer certain drawbacks. A primary drawback is supply constraint, in that the tissue banks that process and produce allograft bone implants find it difficult to forecast allograft given the inherent challenges in forecasting the receipt of cadavers. Another related drawback is that it is difficult to manufacture the allograft with consistent shape and strength characteristics given the variation from cadaver to cadaver.

The present invention is directed at overcoming, or at least improving upon, the disadvantages of the prior art.

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