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Mit internationalem Recherchenbericht.

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(54) Title: DEVICE FOR SUCKING UP AND COLLECTING BONE PARTICLES

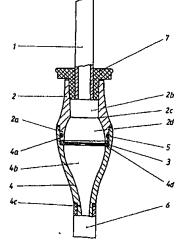
(54) Bezeichnung: VORRICHTUNG ZUM ABSAUGEN UND AUFFANGEN VON KNOCHENTEILCHEN

(57) Abstract

This invention concerns a device for sucking up and collecting bone particles, such as bone meal, and bore chips from cooling and/or rinsing liquids during dental interventions in implantology and in the field of bone regeneration periodontology. Said device essentially consists of an aspirator tip (1), an adapter (7), and a housing with an upper part (2), a lower part (4) and a filter sieve (3). A conical intake port (2b) leads past a sharp-edged transition section (2c) into a dome-shaped cavity (2d) in the upper part (2). A funnel-shaped cavity (4b) in the lower part (4) adjoins it. Between the cavities (2d; 4b), a filter sieve (3) is located. The upper part (2) is provided with a collar (2a) into which an O-ring (5) fits. The lower part (4) is provided with a recess with a wall (4a) and with a connecting port (4c) for a hose (6). The collar (2a), the O-ring (5) and the wall (4a) form the housing closure in which the filter sieve (3) is seated. The upper part (2) and the lower part (4) are made of pure titanium. The filter sieves(3) are graded in degree of fineness and soldered through the rim. The adapter (7) is provided with different inlet ports for different aspirator tips.

(57) Zusammenfassung

Die Erfindung betrifft eine Vorrichtung zum Absaugen und Auffangen von Knochenteilchen wie Knochenmehl und Bohrspänen aus der Kühl- bzw. Spülflüssigkeit bei zahnärztlichen Arbeiten in der Implantologie und im Bereich der Knochenregeneration der



Parodontologie. Die Erfindung besteht im Wesentlichen aus einer Saugkanüle (1), einem Adapter (7), einem Gehäuse mit dem Oberteil (2), dem Unterteil (4) und einem Filtersieb (3). Eine konisch gehaltene Einlaßöffnung (2b) geht an einem scharfkantigen übergang (2c) in einen domförmigen Hohlraum (2d) des Oberteils (2) über. Hieran schließt sich ein trichterförmiger Hohlraum (4b) des Unterteils (4) an. Zwischen den Hohlräumen (2d; 4b) ist ein Filtersieb (3) angeordnet. Das Oberteil (2) ist mit einem einen O-Ring (5) aufnehmenden Bund (2a) versehen. Das Unterteil (4) ist mit einem Einstich mit einer Wandung (4a) und mit einem Anschlußstutzen (4c) für einen Schlauch (6) versehen. Der Bund (2a), der O-Ring (5) und die Wandung (4a) bilden den Gehäuseverschluß, in dem das Filtersieb (3) arretiert ist. Das Oberteil (2) und das Unterteil (4) bestehen aus Reintitan. Die Filtersiebe (3) sind im Feinheitsgrad abgestuft und mit einem Rand verschweißt. Der Adapter (7) ist mit unterschiedlichen Einlaßöffnungen für verschiedene Saugkanülen (1) versehen.

LEDIGLICH ZUR INFORMATION

Codes zur Identifizierung von PCT-Vertragsstaaten auf den Kopfbögen der Schriften, die internationale Anmeldungen gemäss dem PCT veröffentlichen.

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Bezeichnung der Erfindung

Vorrichtung zum Absaugen und Auffangen von Knochenteilchen

5 Technisches Gebiet

Die Erfindung betrifft eine Vorrichtung zum Absaugen und Auffangen von Knochenteilchen wie Knochenmehl und Bohrspänen aus der Kühl- bzw. Spülflüssigkeit bei zahnärtzlichen Arbei-10 ten in der Implantologie und im Bereich der Knochenregeneration der Parodontologie.

Stand der Technik

- 15 Vorrichtungen zum Absaugen und Auffangen von Knochenteilchen wie Knochenmehl und Knochenspäne sind hinreichend bekannt.

 So ist aus dem DE GM 295 147 26 eine Vorrichtung zum Absaugen von Knochen- und Metallspänen bei zahnärztlichen Arbeiten bekannt, die aus einem Absaugrohr und einem Filtergehäuse mit
- 20 Saugschlauchanschluß besteht. Im Gehäuse sind eine Filter zum Auffangen der Knochenspäne und ein Rückschlagventil angeordnet. Zwischen diesen ist eine verstellbare Drosselklappe vorgesehen. Im Inneren des Gehäuses ist weiterhin ein bewegbarer Entleerungskolben zur Ausgabe der aufgefangenen Späne ange-
- 25 ordnet.

Diese Vorrichtung ist sehr aufwendig. Mit ihrer Verwendung treten Sterilitäts- und Reinheitsprobleme auf. So ist nach jeder Anwendung die gesamte Vorrichtung gründlich zu reinigen und zu sterilisieren. Sie ist nicht zum Auffangen kleinster

30 Knochenteilchen geeignet.

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Weiterhin ist aus dem DE GM 86 09 630 eine Vorrichtung zum Auffangen von Bohrmehl aus dem Spülwasser bei Operationen am knöchernen Skelett, insbesondere am Kopf bekannt, bei der im Gehäuse ein Knochenmehlfilter angeordnet ist. Das Gehäuse besteht aus zwei miteinander verbundenen zylindrischen Hälften und ist mit zwei Anschlußstutzen versehen, die an eine zur parallelen Spülwasserleitung verlaufende umschaltbare Bypassleitung angeschlossen sind. Das Knochenfilter ist als ein verstärktes Netz ausgebildet und aus dem Gehäuse herausnehm-

10 bar. Es besteht aus polymerem Material und hat variable Porengrößen.

15 die ungleichmäßige Schicht die Weiterverarbeitung.

Nachteilig bei dieser Vorrichtung ist die ungleichmäßige Ablagerung der aufgefangenen Knochenteilchen im Filter, wodurch eine ungleichmäßige Durchspülung auftritt. Außerdem erschwert

- Auch ist aus einem Prospekt der Firma S & W DENTAL MED, 47441 Moers, eine "Knochenfalle" bekannt. Diese Vorrichtung besteht aus einem als Griff fungierenden Aluminiumgehäuse mit einem Absaugschlauch. Das Gehäuse ist mit einer Verschlußkap-
- 20 pe mit chirurgischem Absauger versehen. Im Gehäuseinneren ist ein Auffangsieb (Filtereinsatz) für autologes Knochenmaterial angeordnet. Das Filtersieb besteht aus sterilisierbarem Kunststoff und dient zur mehrmaligen Verwendung.

Diese Vorrichtung ist mit einigen Nachteilen behaftet. So
25 können leicht Korrosionsteilchen des Aluminiumgehäuses mit
dem Augmentat in den OP-Bereich gelangen. Außerdem besteht
die Problematik der Mehrfachverwendung eines Kunststoffsiebes (Reinigung nahezu unmöglich). Weiterhin bereiten Kanten
und Rillen sowie die schwer zugängliche innenliegende Dich-

30 tung Probleme bei der Reinigung.

Darstellung der Erfindung

Der Erfindung liegt die Aufgabe zugrunde, die Nachteile des

3

Standes der Technik zu beseitigen und eine weitere Vorrichtung zum Absaugen und Auffangen von Knochenteilchen wie Knochenmehl und Knochenspäne zu schaffen, die einen gleichmäßigen Niederschlag des Filtrates auf der Sieboberfläche des 5 Filters ermöglicht.

Erfindungsgemäß geht eine konisch gehaltene Einlaßöffnung an einem scharfkantigen Übergang in einen domförmigen Hohlraum des Oberteils über. Hieran schließt sich ein trichterförmi10 ger Hohlraum des Unterteils an. Zwischen den Hohlräumen ist ein Filtersieb angeordnet. Das Oberteil ist mit einem einen O-Ring aufnehmenden Bund versehen. Das Unterteil ist mit einem Einstich mit einer Wandung und mit einem Anschlußstutzen für einen Schlauch versehen. Der Bund, der O-Ring und die
15 Wandung bilden den Gehäuseverschluß, in dem das Filtersieb arretiert ist. Das Oberteil und das Unterteil sind aus Reintitan gefertigt. Die Filtersiebe sind im Feinheitsgrad abgestuft. Das Filtersieb ist mit einem Rand verschweißt. Die Saugkanüle ist in einem Adapter des Oberteils befestigt, der

Kurze Beschreibung der Zeichnung

In der zugehörigen Zeichnung ist die erfindungsgemäße Lösung 25 im Schnitt dargestellt.

Bester Weg zur Ausführung der Erfindung

Die Erfindung besteht im Wesentlichen aus einer Saugkanüle 1, 30 einem Adapter 7, einem Gehäuse mit dem Oberteil 2, dem Unterteil 4 und einem Filtersieb 3. Das Oberteil 2 ist ein rotationssymmetrisches Drehteil mit einem Bund 2a, der mit einer Ringnut für einen O-Ring 5 versehen ist. Eine leicht konische Einlaßöffnung 2b führt über einen scharfkantigen Übergang 2c

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in einen domartigen Hohlraum 2d, der vom trichterförmigen Hohlraum 4b des ebenfalls rotationssymmetrischen Unterteils 4 durch ein Filtersieb 3 abgegrenzt ist. Das Filtersieb 3 ist aus sterilisierbarem Kunststoff gefertigt und mit einem 5 Verstärkungsrand verschweißt. Es können Filtersiebe 3 mit unterschiedlichen Porenöffnungen, also unterschiedlicher Feinheit, verwendet werden, z.B. solche mit Porenöffnungen von ca. 100 - 300 µm. Wegen der hohen Anforderungen an Sterilität und Reinheit kommen Filtersiebe 3 als Einwegartikel

10 zum Einsatz.

Das Unterteil 4 ist mit einem Einstich versehen, wodurch die Wandung 4a eine Anlage 4d für das Filtersieb 3 erhält. Der Hohlraum 4b mündet in einen Anschlußstutzen 4c für einen Schlauch 6 einer nicht näher bezeichneten Behandlungseinheit 15 mit Saugvorrichtung.

Oberteil 2 und Unterteil 4 werden miteinander verbunden, indem die Wandung 4a über den Bund 2a geschoben und somit der O-Ring 5 zusammengedrückt wird. Dabei wird das Filtersieb 3 durch die Stirnseite des Bundes 2a und die Anlage 4d in einer

- 20 Ringnut arretiert. Diese Elemente bilden den Verschluß des aus hochresistentem Reintitan gefertigten Gehäuses der Vorrichtung. Entsprechend seiner vielfältigen Verwendungsmöglichkeiten wird in der Einlaßöffnung 2b ein vorzugsweise aus Kunststoff bestehender Adapter 7 mit seinem ebenfalls koni-
- 25 schen Ansatz aufgenommen. Der Adapter 7 ist mit verschiedengroßen Bohrungen zur Aufnahme aller bekannten Saugkanülen 1 versehen. Diese können aus Metall oder Kunststoff gefertigt sein. Alle Bestandteile der Vorrichtung sind sterilisierbar. Sie ist ergonomisch vorteilhaft als Griff gestaltet.

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Die Wirkungsweise der erfindungsgemäßen Vorrichtung ist folgende:

Die Vorrichtung ist an eine nicht dargestellte Behandlungseinrichtung mit Sauganschluß angeschlossen. Knochenmehl bzw.

5

Knochenspäne entstehen im Behandlungsbereich durch den Einsatz von medizinischen Geräten mit materialabtragender Wirkung wie Sägen, Fräsen, Bohren usw., z.B. in der zahnärztlichen Implantologie beispielsweise nach Kavitätenpräparation für Implantate oder bei der gezielten Entnahme von Knochen für die Augmentation und im Bereich der Knochenregeneration in der Parodontologie. Dabei soll die Augmentation mit autologem Material immer Priorität haben.

Die Saugkanüle 1 wird hierzu in den OP-Bereich gebracht, so 10 daß das in einer Kühl- bzw. Spülflüssigkeit befindliche Knochenmaterial (Knochenmehl, Knochenspäne) angesaugt die konische Einlaßöffnung 2b passiert und am scharfkantigen Übergang 2c im domförmigen Hohlraum 2d strömungstechnisch verwirbelt wird. Diese technischen Maßnahmen bewirken, daß das

- 15 Filtrat gleichmäßig verteilt auf der etwa 3 cm² großen Sieboberfläche gesammelt wird. Die Entnahme des autologen Materials -etwa 3 cm³- ist anschließend einfach. Hierzu öffnet
 man das Gehäuse und gibt das Filtersieb 3 samt Augmentat in
 eine vorbereitete sterile Schale. Nach Einlegen eines neuen
- 20 sterilen Filtersiebes 3 ist die Vorrichtung wieder einsatzfähig. Sie wird durch ihre Konstruktion den Anforderungen an
 Sterilität und Reinheit gerecht. Ihr geringes Gewicht und die
 ergonomische Formgebung ermöglichen eine problemlose Handhabung. Aufgrund der geringen Anzahl an Bestandteilen ist sie
 25 preiswert in der Herstellung.

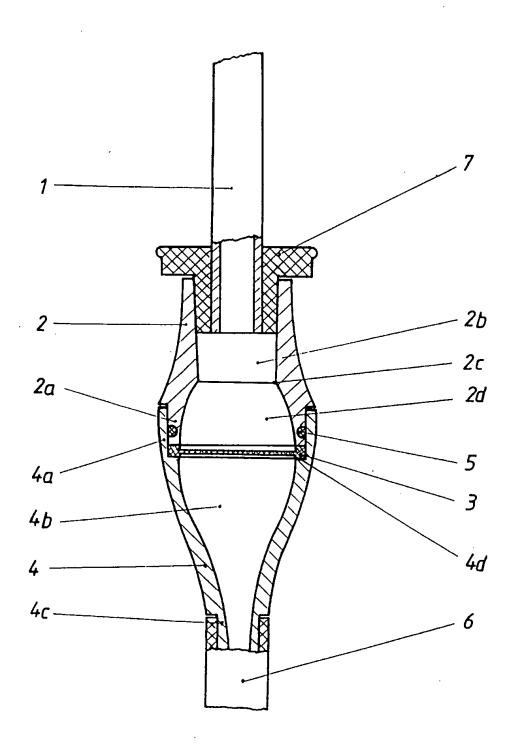
Gewerbliche Anwendbarkeit

Die Erfindung wird bei zahnärztlichen Arbeiten in der Implan-30 tologie und im Bereich der Knochenregeneration der Parodontologie in Verbindung mit anderen medizintechnischen Geräten gewerblich genutzt.

Schutzansprüche

- Vorrichtung zum Absaugen und Auffangen von Knochenteilchen wie Knochenmehl und Knochenspänen aus der Kühl- bzw. Spül- flüssigkeit bei zahnärztlichen Arbeiten, bestehend aus einer Saugkanüle und einem Gehäuse mit Auffangsieb, dadurch gekennzeichnet, daß eine konisch gehaltene Einlaßöffnung (2b) an einem scharfkantigen Übergang (2c) in einen domförmigen Hohlraum (2d) des Oberteils (2) übergeht, an die sich ein trichterförmiger Hohlraum (4b) des Unterteils (4) anschließt und daß zwischen den Hohlräumen (2d;4b) ein Filtersieb (3) angeordnet ist.
- Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß
 das Oberteil (2) mit einem einen O-Ring (5) aufnehmenden
 Bund (2a) versehen ist.
- Vorrichtung nach Anspruch 1 bis 2, dadurch gekennzeichnet, daß das Unterteil (4) einen Einstich mit einer Wandung
 (4a) und einem Anschlußstutzen (4c) für einen Schlauch (6) versehen ist.
- Vorrichtung nach Anspruch 1 bis 3, dadurch gekennzeichnet, daß der Bund (2a), der O-Ring (5) und die Wandung (4a) den
 Gehäuseverschluß bilden, in dem das Filtersieb (3) arretiert ist.
- Vorrichtung nach Anspruch 1 bis 4, dadurch gekennzeichnet, daß das Oberteil (2) und das Unterteil (4) aus Reintitan
 gefertigt sind.
 - 6. Vorrichtung nach Anspruch 1 bis 5, dadurch gekennzeichnet, daß die Filtersiebe (3) im Feinheitsgrad abgestuft sind.

- 7. Vorrichtung nach Anspruch 1 bis 6, dadurch gekennzeichnet, daß das Filtersieb (3) mit einem Rand verschweißt ist.
- 8. Vorrichtung nach Anspruch 1 bis 7, dadurch gekennzeichnet daß die Saugkanüle (1) in einem Adapter (7) des Oberteils (2) befestigt ist.
- Vorrichtung nach Anspruch 1 bis 8, dadurch gekennzeichnet, daß der Adapter (7) mit unterschiedlichen Einlaßöffnungen versehen ist.



INTERNATIONAL SEARCH REPORT

Inter 1al Application No PC1/DE 97/00668

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61C17/06 A61M1/ A61M1/00 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61C A61M Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Relevant to claim No. Category ' Citation of document, with indication, where appropriate, of the relevant passages PATENT ABSTRACTS OF JAPAN 1 vol. 095, no. 006, 31 July 1995 & JP 07 079997 A (YATARO KOMIYAMA; OTHERS: 01), 28 March 1995, see abstract DE 86 06 069 U (WINKEL) 24 April 1986 4,7 see claims 1,3; figure 2 Α 1 US 5 035 688 A (INUI MASAHIKO) 30 July A see column 2, line 4 - line 38; claim 1; figure 1 DE 82 36 368 U (WINKEL) 5 May 1983 1 Α see figure 3 -/--Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance invention "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "O" document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed "A" document member of the same patent family Date of mailing of the international search report Date of the actual completion of the international search 09.09.97 25 August 1997 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016 Kanal, P

INTERNATIONAL SEARCH REPORT

Inter 1al Application No PC1/DE 97/00668

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A	US 4 083 706 A (WILEY CORLESS W) 11 April 1978 see abstract; figure 2	1,8
P,A	EP 0 758 551 A (FRIATEC KERAMIK KUNSTSTOFF) 19 February 1997 see abstract	1

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INTERNATIONALER RECHERCHENBERICHT

Inter nales Aktenzeichen
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		<u> </u>	
A. KLASSI IPK 6	FIZIERUNG DES ANMELDUNGSGEGENSTANDES A61C17/06 A61M1/00		
Nach der Int	ternationalen Patentklassifikation (IPK) oder nach der nationalen Klas	sifikation und der IPK	
B. RECHE	RCHIERTE GEBIETE		
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C. ALS WI	ESENTLICH ANGESEHENE UNTERLAGEN		
Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe	der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	PATENT ABSTRACTS OF JAPAN vol. 095, no. 006, 31.Juli 1995 & JP 07 079997 A (YATARO KOMIYAM/ 01), 28.März 1995, siehe Zusammenfassung	A;OTHERS:	1
Y A	DE 86 06 069 U (WINKEL) 24.April : siehe Ansprüche 1,3; Abbildung 2	1986	1,7
A	US 5 035 688 A (INUI MASAHIKO) 30 1991 siehe Spalte 2, Zeile 4 - Zeile 3 Anspruch 1; Abbildung 1		1
A	DE 82 36 368 U (WINKEL) 5.Mai 198 siehe Abbildung 3	3 /	1
	itere Veröffentlichungen sind der Fortsetzung von Feld C zu	X Siehe Anhang Patentfamilie	I
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<u> </u>	25.August 1997		
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INTERNATIONALER RECHERCHENBERICHT

Inter sales Aktenzeichen
PC1/DE 97/00668

Kategorie*	ng) ALS WESENTLICH ANGESEHENE UNTERLAGEN Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
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Α .	US 4 083 706 A (WILEY CORLESS W) 11.April 1978 siehe Zusammenfassung; Abbildung 2	1,8
P,A	EP 0 758 551 A (FRIATEC KERAMIK KUNSTSTOFF) 19.Februar 1997 siehe Zusammenfassung	1

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Formblatt PCT/ISA/210 (Fortsetzung von Blatt 2) (Juli 1992)

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichu. 4 die zur seiben Patentfamilie gehören

Inter nales Aktenzeichen
PCT/DE 97/00668

Im Recherchenbericht ngeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
DE 8606069 U	24-04-86	KEINE	
US 5035688 A	30-07-91	KEINE	
DE 8236368 U		KEINE	
DE 29511026 U	26-10-95	KEINE	
US 4083706 A	11-04-78	KEINE	
EP 0758551 A	19-02-97	KEINE	

Formblatt PCT/ISA/210 (Anhang Patent/amilia)(Juli 1992)



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS PO. Box 1450 Alexandria, Viginia: 22313-1450

APPLICATION NUMBER

FILING OR 371 (c) DATE

FIRST NAMED APPLICANT

ATTORNEY DOCKET NUMBER

11/093,409

03/29/2005

Matthew Curran

104US1

30328

ATTN: LEGAL DEPARTMENT NU VASIVE, INC. 4545 TOWNE CENTRE COURT . SAN DIEGO, CA 92121

CONFIRMATION NO. 6640 FORMALITIES LETTER

OC000000015847518

Date Mailed: 04/25/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(f) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is \$65 for a Small Entity

• \$65 Late oath or declaration Surcharge.

Replies should be mailed to:

Mail Stop Missing Parts

Commissioner for Patents

P.O. Box 1450

Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

M-HAILE
Office of Initial Patent Examination (703) 308-1202
PART 3 - OFFICE COPY

OC000000015847518*

Page 1 of 2

hán 223 (3-(450

APPLICATION NUMBER

FELING OR 371 (c) DATE

FIRST NAMED APPLICANT

ATTORNEY DOCKET NUMBER

11/093,409

03/29/2005

Matthew Curren

104US1

30328

ATTN: LEGAL DEPARTMENT NU VASIVE, INC. 4545 TOWNE CENTRE COURT SAN DIEGO, CA 92121

CONFIRMATION NO. 6640 FORMALITIES LETTER

JUN, 25, 2015-2mo Nov. 25, 2015-7mo Date Mailed: 04/25/2005

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P.O. Box 1450

Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

08/05/2005 NNGUYEN1 00000040 502040 11093409

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65.00 DA

Page 2 of 2

M-WAILE
Office of Initial Patent Examination (703) 308-1202
PART 1 - ATTORNEY/APPLICANT COPY

(to be used for all co	SMITTAL FORM	Application Numb Filing Date First Named Invert Art Unit Examiner Name	nd to a collection of initer 11/093,40 March 29, ntor Matthew 0 3738 n/a	rademark Office; formation unless it 9 2005	PTO/SB/21 (09-04) through 07/31/2006. OMB 0651-0031 U.S. DEPARTMENT OF COMMERCE displays a valid OMB control number.
Fee Transmitte	Ī	Drawing(s)	Check all that apply		Allowance Communication to TC
Amendment/R After F Affidav Extension of T Express Aband Information Did Certified Copy Document(s) Reply to Missin Incomplete Ap Reply to Re	inal rits/declaration(s) rime Request donment Request sclosure Statement of Priority ng Parts/	Petition Petition to Convert to Provisional Application Power of Attorney, For Change of Corresponding Terminal Disclaimer Request for Refund CD, Number of CD(standscape Tail Remarks	o a on Revocation indence Address	of Appea (Appea Propri	
	SIGNATU	RE OF APPLICANT,	ATTORNEY, C	OR AGENT	
Signature Printed name	/asive, Inc.				
D-4-	just 1, 2005		Reg. No.	40,182	
I hereby certify that thi sufficient postage as fi the date shown below: Signature	s correspondence is being rst class mail in an envelo	TIFICATE OF TRAN a facsimile transmitted to the pe addressed to: Commis	he USPTO or depos	sited with the Un	ited States Postal Service with Alexandria, VA 22313-1450 on August 1, 2005

This collection of information is required by 37 CFR 1.5. 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 1.11 and1.14. This collection is estimated to 2 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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: 1	Patent Application of)		
Matthe	ew Curran, et al.) .	Group Art Unit:	3738
App. S	Ser. No. 11/093,409	Examiner:	TBD
Filed:	March 29, 2005		
For:	SYSTEMS AND METHODS) FOR SPINAL FUSION)		
)		

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on August 1, 2005.

Signature:

Jonathan Spangler

RESPONSE TO NOTICE TO FILE MISSING PARTS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir or Madam:

In response to a Notice to File Missing Parts mailed on April 25, 2005, having a two-month period for response that expired June 25, 2005, the applicant respectfully submits the following:

Application Serial No. 11/093,409 Attorney Ref. No. 104US1

(A) A copy of the Notice to File Missing Parts;

(B) A signed declaration by the inventors as required by the Notice to File Missing Parts;

and

(C) A Petition for Extension of Time for 2 months.

Furthermore, Applicant hereby authorizes a payment of \$65.00 fee for the late filed declaration and \$225.00 fee for the Extension of Time for a total of \$290.00. No other fees are deemed necessary at this time. However, in the event that there are any additional fees to be charged or payments to be credited, the applicant hereby request that any charges or credits be made to Deposit Account No.: 50-2040 for Customer No.: 30,328. In the event that there are any questions concerning the remarks above or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

NUVASIVE, INC.

By

Jonathan Spangler, Esq.

Registrat on No. 40,182

4545 Towne Centre Court San Diego, CA 92121

Tel.: (858) 243-0029

August 1, 2005



PTO/SB/22 (12-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE

Under the paper reputation Act of 1995, no persons are required to respond to a collection of information unless if displays a valid OMB control number.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional)		
FY 2005 (Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)	104451		
Application Number 11 093 409	Filed MARCH 29, 2005		
FOR SYSTEMS AND METHODS FOR SPINAL FUSIO			
Art Unit 3738	Examiner N/A		
This is a request under the provisions of 37 CFR 1.136(a) to extend the perioapplication.	od for filing a reply in the above identified		
The requested extension and fee are as follows (check time period desired a	and enter the appropriate fee below):		
<u>Fee</u>	Small Entity Fee		
One month (37 CFR 1.17(a)(1)) \$120	\$60 \$		
Two months (37 CFR 1.17(a)(2)) \$450	\$225 \$ 225.00		
Three months (37 CFR 1.17(a)(3)) \$1020	\$510 \$		
Four months (37 CFR 1.17(a)(4)) \$1590	\$795		
Five months (37 CFR 1.17(a)(5)) \$2160	\$1080 \$		
Applicant claims small entity status. See 37 CFR 1.27.			
A check in the amount of the fee is enclosed.			
Payment by credit card. Form PTO-2038 is attached.			
The Director has already been authorized to charge fees in this a	application to a Deposit Account.		
The Director is hereby authorized to charge any fees which may Deposit Account Number 50-2040 . I have			
WARNING: Information on this form may become public. Credit card inform	e enclosed a duplicate copy of this sheet.		
Provide credit card information and authorization on PTO-2038.			
	05/2005 NNGUYEN1 00000040 502040 11093409		
	C:2252 225.00 DA		
assignee of record of the entire interest. See 37 Cl Statement under 37 CFR 3.73(b) is enclosed (F	Form PTO/SB/96).		
attorney of agent of record. Registration Number _	40,182		
attorne or agent under 37 CFR 1.34. Registration number acting under 37 CFR 1.34			
	AUGUST 1, 2005		
Signature	Date		
JONATHAN SPANGLER	858-243-0029		
Typed or printed name	Telephone Number		
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their represen signature is required, see below.	tative(s) are required. Submit multiple forms if more than one		
Total of forms are submitted;			

This collection of information is required by 37 CFR 1.136(a). 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 1.11 and 1.14. This collection is estimated to take 6 minutes 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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduc ersons are required to res

PTO/SB/01 (04-05)

Approved for use through 07/31/2006. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN DATENT ADDITION

(37 CFR 1.63)									
	Declaration Submitted With Initial Filing	OR	/	Declaration Submitted after Initia Filing (surcharge (37 CFR 1.16 (e)) required)					

pond to a collection of information	unless it contains a valid OMB control number.
Attorney Docket Number	104US1
First Named Inventor	Matthew Curran
COMP	PLETE IF KNOWN
Application Number	11/093,409
Filing Date	March 29, 2005
Art Unit	3738
Examiner Name	n/a

I hereby declare that:								
Each inventor's residence, ma	Each inventor's residence, mailing address, and citizenship are as stated below next to their name.							
I believe the inventor(s) name which a patent is sought on the	ed below to be the invention enti	ne original and first in	ventor(s) of the subj	ect matter whi	ch is claime	ed and for		
Systems and Methods for Spinal Fusion								
the specification of which		(Title of the In	vention)					
the specification of which								
is attached hereto								
OR								
was filed on (MM/DD/)	YYY)	03/29/2005	as United States A	pplication Nur	mber or PC	T International		
Application Number 1	1/093,409	and was amended	on (MM/DD/YYYY)			(if applicable).		
I hereby state that I have revi amended by any amendment	ewed and under specifically refe	stand the contents of rred to above.	f the above identified	specification,	including th	ne claims, as		
I acknowledge the duty to d continuation-in-part application and the national or PCT international or PCT internat	ins, material info	ormation which beca	me available betwee	defined in 37 en the filing da	7 CFR 1.56 ate of the p	6, including for rior application		
I hereby claim foreign priorit	y benefits unde	r 35 U.S.C. 119(a)-(d) or (f), or 365(b)	of any foreign	application	n(s) for patent,		
inventor's or plant breeder's country other than the United	ights certificated	(s), or 365(a) of any	PCT international appropriate	oplication which	ch designate	ed at least one		
application for patent, invento	r's or plant bree	der's rights certificate	e(s), or any PCT inte	rnational appl	ication havi	ng a filing date		
before that of the application	on which priority			<u></u>	4151 1.0	A., 1 10		
Prior Foreign Application Number(s)	Country	Foreign Filing [(MM/DD/YYY			ertified Co YES	py Attached? NO		
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Additional foreign ap	plication numbe	ers are listed on a sup	pplemental priority da	ita sheet PTO	/SB/02B att	ached hereto.		

[Page 1 of 2]

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 21 minutes 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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance completion the form call 1-800-PTO-9199 and select option 2.

If you need assistance completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/01 (04-05)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DECLARATION — Utility or Design Patent Application

correspondence to:	e address sociated with istomer Number:	30),328			OR		Correspondence address below
Name		"						
Address								
City		-	State)				ZIP
Country	Те	elephone				Ema	il	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.								
NAME OF SOLE OR FIRST IN	VENTOR:	A pe	etition	has	been filed	for this	unsig	ned inventor
Given Name (first and middle [if	fany])	-		Family Name or Surname				
Matthew				Curran				
Inventor's Signature 7/26/05								Date 7/26/05
Residence: City	State			Country Citizer			nship	
Carlsbad CA			USA				US	
Mailing Address 3218 Rancho Quartillo								
City	State			Zip				Country
Carlsbad	CA			92009				USA
NAME OF SECOND INVENTO	R:		$ \Box$	l a	petition ha	as beer	n filed f	for this unsigned inventor
Given Name (first and middle [if	any])		<u> </u>		Family Na			•
Mark				Peterson				
Inventor's Signature						• •		Date
Residence: City	State		Cour	Country Citizen			nship	
Medford	edford OR I						US	
Mailing Address 840 Royal Avenue Suite #1								
City	State			Zip Count			ry	
Medford	OR				97504 USA			
Additional inventors or a legal representative are being named on thesupplemental sheet(s) PTO/SB/02A or 02LR attached hereto.								



PTO/SB/01 (04-05)
Approved for use through 07/31/2008, OMB 0851-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paparwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION - Utility or Design Patent Application

Direct all	The address			OR		Correspondence	
correspondence to:	associated with Customer Numbe	1	30,328		ш	address below	
Name						•	
Address					•		
City			State	····	٠.	ZIP	
Country		Telephone	.1	Ema	ij.	- In	
I hereby declare that all st and belief ere believed t statements and the like so false statements may jeop	o be true; and fur made are punishal ardize the validity of	ther that these str de by fine or impris	itements were conment, or bo	made with the thing in the made with the made in the m	the kno	owledge that willful false	
NAME OF SOLE OR FIRE		A:	petition has be				
Given Name (first and mid	dle [if any])		F	emily Name o	r Suma	ame	
/latthew	•	1	Cr	man			
Inventor's Signature						Date	
Residence: City	State		Country		Chize	nship	
Carlsbad	CA		USA US			,	
Mailing Address 218 Rancho Quartillo			·				
City	State		Zip			Country	
Carlebad	CA	•	92009	·	ļ	USA	
NAME OF SECOND INVE	NTOR:		A pe	titlori has bes	n filed	for this unsigned inventor	
Given Name (first and mid Mark		Family Name or Sumame Peterson					
Inventor's Signature	March Pe	lessen				Date 7/26/05	
Residence: City	State		Country	,	Citize	enship	
Medford	OR	, ,	ASU		บธ		
Malling Address 840 Royal Avenue Suite #1							
City	State		Zip		Country		
Mediand	OR	. ,	97504		USA	· ·	
Additional inventors or a le	cal recresentative are be	no named on the	supplemental shee	ot(s) PTQ/SB/02A	Or 021 R	attached hereto.	



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.			
11/093,409	03/29/2005 Matthew Curran		104US1 6640				
30328 7 JONATHAN SF	7590 02/20/2007 PANGLER	EXAMINER					
NU VASIVE, II	NC.		CUMBERLEDGE, JERRY L				
4545 TOWNE C SAN DIEGO, C	CENTRE COURT CA 92121		ART UNIT	PAPER NUMBER			
			3733				
SHORTENED STATUTORY PERIOD OF RESPONSE MAIL DATE			DELIVER	Y MODE			
31 DA	AYS	02/20/2007	PAI	PER			

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)
•	11/093,409	CURRAN ET AL.
Office Action Summary	Examiner	Art Unit
	Jerry Cumberledge	3733
The MAILING DATE of this communication app		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be to the apply and will expire SIX (6) MONTHS from the application to become ABANDON	N. imely filed in the mailing date of this communication. ED (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on		
,	action is non-final.	
3) Since this application is in condition for allowar	nce except for formal matters, pr	rosecution as to the merits is
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 4	153 O.G. 213.
Disposition of Claims		
4)⊠ Claim(s) <u>1-26</u> is/are pending in the application.		
4a) Of the above claim(s) is/are withdraw	vn from consideration.	
5) Claim(s) is/are allowed.		
6) Claim(s) is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) 1-26 are subject to restriction and/or e	election requirement.	
Application Papers	•	
9) The specification is objected to by the Examine	r	
10)☐ The drawing(s) filed on is/are: a)☐ acce		Examiner.
Applicant may not request that any objection to the		
Replacement drawing sheet(s) including the correct		
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Offic	e Action or form PTO-152.
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a	a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents	s have been received.	
2. Certified copies of the priority documents		•
Copies of the certified copies of the prior		red in this National Stage
application from the International Bureau	•	
* See the attached detailed Office action for a list	of the certified copies not receiv	ed.
Attachment(s)	-	
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) 	4) Interview Summar Paper No(s)/Mail [
3) Information Disclosure Statement(s) (PTO/SB/08)	5) 🔲 Notice of Informal	
Paper No(s)/Mail Date	6)	

Application/Control Number: 11/093,409

Art Unit: 3733

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 1. Claims 1-13, drawn to a system, classified in class 606, subclass 90.
- II. Claims 14-26 drawn to a method of spinal fusion, classified in class 623, subclass 17.16.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to distract adjacent vertebrae.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Application/Control Number: 11/093,409

Art Unit: 3733

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

Application/Control Number: 11/093,409

Art Unit: 3733

Page 4

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JI C

EDUARD C. ROBERT

SUPERVISOR PATENT EXAMINER

Index of Claims Application/Control No. Applicant(s)/Patent Under Reexamination CURRAN ET AL. Examiner Cumberledge, Jerry 3733

/	Rejected	-	Cancelled	N	Non-Elected	Α	Appeal
=	Allowed	÷	Restricted	1	Interference	0	Objected
					ПСВА		□ P147

☐ Claims	Claims renumbered in the same order as presented by applicant						☐ CPA	□ т.і	D. 🗆	R.1.47
CLAIM		DATE								
Final	Original	02/12/2007								
	1	÷								
	2	+								
	3	+								
	4	+		-						
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MAR 1 9 2007 PTO/SB/21 (09-06) Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number Application Number 11/093 409 **TRANSMITTAL** Filing Date 03/29/2005 **FORM** First Named Inventor Matthew Curran Art Unit 3733 **Examiner Name** Jerry L. Cumberledge (to be used for all correspondence after initial filing) Attorney Docket Number 104US1 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance Communication to TC Fee Transmittal Form Drawing(s) Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to TC ✓ Petition Amendment/Reply (Appeal Notice, Brief, Reply Brief) Petition to Convert to a After Final Proprietary Information Provisional Application Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Identify Terminal Disclaimer Extension of Time Request below): Request for Refund **Express Abandonment Request** CD, Number of CD(s) Information Disclosure Statement Landscape Table on CD Certified Copy of Priority Remarks Document(s) Return Postcard Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

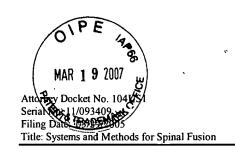
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Signature Printed name Jonathan Spangler

Jonathan Spangler

ed by 37 CER 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to This collection of information is red process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of	
Matthew Curran	Group Art Unit: 3733
App. Ser. No. 11/093,409)) Eveniner: Jerry I. Cumberledge
Filed: 03/29/2005	Examiner: Jerry L. Cumberledge Output
For: SYSTEMS AND METHODS FOR SPINAL FUSION	
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, Po Box 1450, Alexandria VA 22313-1450 on 03/15/2007:

Signature:

Jonathan Spangler

RESTRICTION RESPONSE

Mail Stop Amendment Commissioner for Patents PO Box 1450 Alexandria VA 22313-1450

Dear Sir:

In response to the Office Action mailed February 20, 2007, having a one month shortened period for response that expires on March 20, 2007, Applicants hereby respectfully submit that the apparatus cannot be used to distract adjacent vertebra and therefore Group I (claims 1-13) and Group II (claims 14-26) form an indivisible invention and therefore no election or restriction is required.

IN THE CLAIMS:

1. (Original) A spinal fusion system comprising:

> an interbody spinal fusion implant, including at least in part a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having at least one receiving aperture for engaging an insertion instrument, and two lateral sides; and

> an insertion instrument, including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature; and

a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant.

- 2. (Original) The spinal fusion system of Claim 1, wherein the implant is substantially radiolucent and composed of non-bone material.
- 3. (Original) The spinal fusion system of Claim 1, wherein the implant includes at least one visualization aperture extending through at least one of the lateral sides.
- 4. (Original) The spinal fusion system of Claim 1, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other to better match the natural curvature of the spine.

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- Original) The spinal fusion system of Claim 1, wherein the implant further includes antimigration features to increase friction between the implant and vertebral endplate minimizing unwanted movement, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.
- 6. (Original) The spinal fusion system of Claim 1, wherein the receiving aperture of the implant comprises a singular threaded aperture.
- 7. (Original) The spinal fusion system of Claim 6, wherein the insertion instrument engagement feature comprises a threaded connector dimensioned to engage the threaded receiving aperture of the implant.
- 8. (Original) The spinal fusion system of Claim 7, wherein the securing mechanism includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member such that turning the rotation device causes the generally elongated shaft member to turn, and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture, releasably securing the implant to the insertion instrument.
- 9. (Original) The spinal fusion system of Claim 8, wherein the proximal end of the implant further includes at least one purchase region adjacent to the receiving aperture and wherein the distal opening of the generally elongated tubular member is situated in a distal head, the distal head including at least one distal head slot, adjacent to the distal opening, for engaging the purchase region on the implant and enhancing the engagement between the implant and the insertion instrument.

Title: Systems and Methods for Spinal Fusion

- 10. (Original) The spinal fusion system of Claim 1, wherein the implant includes two receiving apertures positioned adjacent to each other on the proximal side of the implant.
- 11. (Original) The spinal fusion system of Claim 10, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.
- 12. (Original) The spinal fusion system of Claim 11, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.
- (Original) The spinal fusion system of Claim 12, wherein the securing mechanism includes, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device.

Filing Date: 03/29/2005

Title: Systems and Methods for Spinal Fusion

- 14. (Original) A method of spinal fusion, comprising the steps of:
 - (a) releasably securing a spinal fusion implant to an insertion instrument, the spinal fusion implant including a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having at least one receiving aperture for engaging an insertion instrument, and two lateral sides, and the insertion instrument including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature
 - (b) introducing the spinal fusion implant to a prepared space between adjacent vertebral end plates and properly positioning the implant within the space;
 - (c) releasing the insertion instrument from the properly positioned implant and withdrawing the insertion instrument from the surgical corridor.
- 15. (Original) The spinal fusion method of Claim 0, wherein the implant is substantially radiolucent and composed of non-bone material
- 16. (Original) The spinal fusion method of Claim 0, wherein the implant includes at least one visualization aperture extending through at least one of the lateral sides.
- 17. (Original) The spinal fusion method of Claim 0, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other, and generally angled with respect to each other to better match the natural curvature of the spine.

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Title: Systems and Methods for Spinal Fusion

- 18. (Original) The spinal fusion method of Claim 0, wherein the implant further includes anti-migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.
- 19. (Original) The spinal fusion method of Claim 0, wherein the receiving aperture of the implant comprises a singular threaded aperture.
- 20. (Original) The spinal fusion method of Claim 0, wherein the insertion instrument engagement feature comprises a threaded connector dimensioned to engage the threaded receiving aperture of the implant.
- 21. (Original) The spinal fusion method of Claim 0, wherein the means for releasably securing the threaded connector to the threaded receiving aperture of the implant includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member such that turning the rotation device causes the generally elongated shaft member to turn, and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture, releasably securing the implant to the insertion instrument.
- 22. (Original) The spinal fusion method of Claim 0, wherein the proximal end of the implant further includes at least one purchase region adjacent to the receiving aperture and wherein the distal opening of the generally elongated tubular member is situated in a distal head, the distal head including at least one distal head slot, adjacent to the distal

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Filing Date: 03/29/2005
Title: Systems and Methods for Spinal Fusion

opening, for engaging the purchase region on the implant and enhancing the engagement between the implant and the insertion instrument.

- 23. (Original) The spinal fusion method of Claim 0, wherein the implant includes two receiving apertures positioned adjacent to each other on the proximal side of the implant.
- 24. (Original) The spinal fusion method of Claim 0, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.
- 25. (Original) The spinal fusion method of Claim 0, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.
- (Original) The spinal fusion method of Claim 0, including a securing mechanism for releasably securing the engagement features in the receiving apertures of the implant, the securing mechanism including, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and

releasably securing the implant to the insertion device.

REMARKS

Claims 1-26 are currently pending in this application. In the Office Action mailed on February 20, 2007 ("Office Action"), claims 1-26 were subject to restriction and/or election. The restriction alleged that the present application contains an invention needing election of certain claims because the apparatus can also be used to distract adjacent vertebrae.

The apparatus cannot be used to distract adjacent vertebrae because a separate distracter is needed before the apparatus can insert the implant. The system and method in the Application claims of inserting the implant between two vertebrae, but does not claim, nor is the apparatus designed to be a distracter of adjacent vertebrae since a separate distracter is needed for proper distraction of the vertebrae before insertion of the apparatus. Applicants respectfully request favorable consideration of the present application in light of the restriction to the claims and the following remarks.

In the event the Examiner disagrees with the Applicants characterization of a single indivisible invention, the Applicants hereby provisionally elect – with traverse – a spinal fusion system, Group I (claims 1-13), as originally set forth in the Application.

Title: Systems and Methods for Spinal Fusion

CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. No other fees are deemed necessary at this time. However, in the event that there are any additional fees to be charged or payments to be credited, the applicant hereby request that any charges are credits be made to Deposit Account No.: 50-2040 for Customer No.: 30,328. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted, NUVASIVE, INC.

Bv.

Jonathan Spangler, Esq. Registration No. 40,182

4545 Towne Centre Court San Diego, CA 92121 Tel.: (858) 243-0029

March 15, 2007

PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 8, 2004

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/093,409 03/29/2005		Matthew Curran	104US1	6640
30328 JONATHAN S	7590 07/09/2007 SPANGLER		EXAM	INER
NU VASIVE,	INC.		CUMBERLED	GE, JERRY L
4545 TOWNE SAN DIEGO,	CENTRE COURT CA 92121	•	ART UNIT	PAPER NUMBER
			3733	·
			MAIL DATE	DELIVERY MODE
			07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of Non-Compliant	Application No.	Applicant(s)				
Amendment (37 CFR 1.121)	Examiner Ledge	Art Unit 3 13 3				
The MAILING DATE of this communication ap	ppears on the cover sheet with the c	correspondence address				
The amendment document filed on is considere 37 CFR 1.121 or 1.4. In order for the amendment docu						
THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE 1. Amendments to the specification: A. Amended paragraph(s) do not includ B. New paragraph(s) should not be und C. Other	e markings.	BE NON-COMPLIANT:				
2. Abstract:A. Not presented on a separate sheet.B. Other	37 CFR 1.72.	•				
☐ 3. Amendments to the drawings: ☐ A. The drawings are not properly identif	CFR 1.121(d). drawing correction has been elimi	nated. Replacement drawings				
showing amended figures, without m C. Other 4. Amendments to the claims: A. A complete listing of all of the claims B. The listing of claims does not include C. Each claim has not been provided w of each claim cannot be identified. In number by using one of the following (Previously presented), (New), (Not D. The claims of this amendment paper E. Other: 5. Other (e.g., the amendment is unsigned or	is not present. It the text of all pending claims (inclinity in the proper status identifier, and Note: the status of every claim mug status identifiers: (Original), (Curentered), (Withdrawn) and (Withdrawn have not been presented in asce	luding withdrawn claims) I as such, the individual status list be indicated after its claim rently amended), (Canceled), rawn-currently amended). Inding numerical order.				
For further explanation of the amendment format requi	red by 37 CFR 1.121, see MPEP	§ 714.				
TIME PERIODS FOR FILING A REPLY TO THIS NOT	TCE:					
Applicant is given no new time period if the non-filed after allowance. If applicant wishes to resubment entire corrected amendment must be resubmitted.	nit the non-compliant after-final an					
correction, if the non-compliant amendment is one (including a submission for a request for continued amendment filed within a suspension period under Quayle action. If any of above boxes 1. to 4. are continued to the continued of the continued						
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Failure to timely respond to this notice will respond to the application if the non-filed in response to a Quayle action; or Non-entry of the amendment if the non-companent mendment.	compliant amendment is a non-fina opliant amendment is a preliminary					
Legal Instruments Examiner (LIE), if applicable		one No.				
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TO TRA	DEMARK	. Ho belson	Application Number	11/093,40	9
	RANSMITTAL		Filing Date	March 29,	2005
	FORM		First Named Inventor	Matthew C	Curran
			Art Unit	3733	
(to be used for	all correspondence after initial	filing)	Examiner Name	Jerry L. Cu	umberledge
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Firm Name	SIGNA	TURE O	F APPLICANT, ATTO	RNEY, O	OR AGENT
riiii ivame	NuVasive, Inc.	_			
Signature		\mathcal{I}			
Printed name	Jonathan Spangler				
Date	July 13_2007	\supset	F	Reg. No.	40,182
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This collection of information is required by 37 CFR 1.5. 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 1.11 and1.14. This collection is estimated to 2 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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Title: Systems and Methods for Spinal Fusion

NITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of)
Matthew Curran) Group Art Unit: 3733
App. Ser. No. 11/093,409)) Eveninger James I. Comphaelladae
Filed: 03/29/2005) Examiner: Jerry L. Cumberledge)
For: SYSTEMS AND METHODS FOR SPINAL FUSION)))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria VA 22313-1450 on July 13, 2007: Signature: Jonathan Spangler

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT (37 CFR 1.121)

Mail Stop Amendment Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Non-Compliant Amendment (37 CFR 1.121) mailed on July 9, 2007, which relates to a non-final amendment, thus having a one month shortened period for response that expires on August 9, 2007, Applicants submit herewith a corrected section entitled IN THE CLAIMS, which contains a corrected claims listing believed to now be fully compliant with 37 CFR 1.121.

Title: Systems and Methods for Spinal Fusion

IN THE CLAIMS:

1. (Original) A spinal fusion system comprising;

an interbody spinal fusion implant, including at least in part a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having at least one receiving aperture for engaging an insertion instrument, and two lateral sides; and

an insertion instrument, including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature; and

a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant.

- 2. (Original) The spinal fusion system of Claim 1, wherein the implant is substantially radiolucent and composed of non-bone material.
- 3. (Original) The spinal fusion system of Claim 1, wherein the implant includes at least one visualization aperture extending through at least one of the lateral sides.
- 4. (Original) The spinal fusion system of Claim 1, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other to better match the natural curvature of the spine.
- 5. (Original) The spinal fusion system of Claim 1, wherein the implant further includes antimigration features to increase friction between the implant and vertebral endplate

Title: Systems and Methods for Spinal Fusion

minimizing unwanted movement, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.

- 6. (Original) The spinal fusion system of Claim 1, wherein the receiving aperture of the implant comprises a singular threaded aperture.
- 7. (Original) The spinal fusion system of Claim 6, wherein the insertion instrument engagement feature comprises a threaded connector dimensioned to engage the threaded receiving aperture of the implant.
- 8. (Original) The spinal fusion system of Claim 7, wherein the securing mechanism includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member such that turning the rotation device causes the generally elongated shaft member to turn, and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture, releasably securing the implant to the insertion instrument.
- 9. (Original) The spinal fusion system of Claim 8, wherein the proximal end of the implant further includes at least one purchase region adjacent to the receiving aperture and wherein the distal opening of the generally elongated tubular member is situated in a distal head, the distal head including at least one distal head slot, adjacent to the distal opening, for engaging the purchase region on the implant and enhancing the engagement between the implant and the insertion instrument.
- 10. (Original) The spinal fusion system of Claim 1, wherein the implant includes two receiving apertures positioned adjacent to each other on the proximal side of the implant.

Title: Systems and Methods for Spinal Fusion

11. (Original) The spinal fusion system of Claim 10, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.

- 12. (Original) The spinal fusion system of Claim 11, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.
- 13. (Original) The spinal fusion system of Claim 12, wherein the securing mechanism includes, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device.
- 14. (Original) A method of spinal fusion, comprising the steps of:
 - (a) releasably securing a spinal fusion implant to an insertion instrument, the spinal fusion implant including a top surface for contacting a first vertebral endplate, a

Title: Systems and Methods for Spinal Fusion

bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having at least one receiving aperture for engaging an insertion instrument, and two lateral sides, and the insertion instrument including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature

- (b) introducing the spinal fusion implant to a prepared space between adjacent vertebral end plates and properly positioning the implant within the space;
- (c) releasing the insertion instrument from the properly positioned implant and withdrawing the insertion instrument from the surgical corridor.
- 15. (Original) The spinal fusion method of Claim 14, wherein the implant is substantially radiolucent and composed of non-bone material
- 16. (Original) The spinal fusion method of Claim 14, wherein the implant includes at least one visualization aperture extending through at least one of the lateral sides.
- 17. (Original) The spinal fusion method of Claim 14, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other, and generally angled with respect to each other to better match the natural curvature of the spine.
- 18. (Original) The spinal fusion method of Claim 14, wherein the implant further includes anti-migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike

Title: Systems and Methods for Spinal Fusion

elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.

- 19. (Original) The spinal fusion method of Claim 14, wherein the receiving aperture of the implant comprises a singular threaded aperture.
- 20. (Original) The spinal fusion method of Claim 19, wherein the insertion instrument engagement feature comprises a threaded connector dimensioned to engage the threaded receiving aperture of the implant.
- 21. (Original) The spinal fusion method of Claim 20, wherein the means for releasably securing the threaded connector to the threaded receiving aperture of the implant includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member such that turning the rotation device causes the generally elongated shaft member to turn, and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture, releasably securing the implant to the insertion instrument.
- 22. (Original) The spinal fusion method of Claim 21, wherein the proximal end of the implant further includes at least one purchase region adjacent to the receiving aperture and wherein the distal opening of the generally elongated tubular member is situated in a distal head, the distal head including at least one distal head slot, adjacent to the distal opening, for engaging the purchase region on the implant and enhancing the engagement between the implant and the insertion instrument.
- 23. (Original) The spinal fusion method of Claim 14, wherein the implant includes two receiving apertures positioned adjacent to each other on the proximal side of the implant.

Title: Systems and Methods for Spinal Fusion

24. (Original) The spinal fusion method of Claim 23, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.

- 25. (Original) The spinal fusion method of Claim 24, wherein the elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature.
- (Original) The spinal fusion method of Claim 25, including a securing mechanism for releasably securing the engagement features in the receiving apertures of the implant, the securing mechanism including, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device.

Serial No. 11/093,409

Filing Date: 03/29/2005 Title: Systems and Methods for Spinal Fusion

Respectfully submitted, NUVASIVE, INC.

By:

Jonathan Spangler, Esq. Registration No. 40,182

4545 Towne Centre Court San Diego, CA 92121 Tel.: (858) 243-0029

July 13, 2007

	*PATENT APPLICATION FEE DETERMINATION RECORD Effective December 8, 2004 // 093409											
	CLAIMS AS FILED - PART I (Cotumn 1) (Column 2)							SMALL TYPE	ENTITY /	OR		THAN ENTITY
IJ	OTAL CLAIMS		24)				RATE	FEE		RATE	FEE
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Unitêd States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
11/093,409	03/29/2005	Matthew Curran	104US1	6640	
JONATHAN S NU VASIVE, 1	INC.	EXAMINER CUMBERLEDGE, JERRY L			
SAN DIEGO,	CENTRE COURT CA 92121		ART UNIT	PAPER NUMBER	
			3733		
			MAIL DATE	DELIVERY MODE	
•			10/01/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES DEPARTMENT OF COMMERCE U.S. Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS P.O. Box 1450

Alexandria, Virginia 22313-1450

APPLICATION NO.I CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
11093409	3/29/2005	CURRAN ET AL.	104US1

JONATHAN SPANGLER NU VASIVE, INC. 4545 TOWNE CENTRE COURT SAN DIEGO, CA 92121

EXAMINER

Jerry Cumberledge

PAPER ART UNIT 3733 20070919B

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

The reply filed on 03/19/2007 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Applicant has not included an election of invention with the response to the restriction requirement mailed on 02/20/2007. It is noted that the requirement to be complete must include (i) an election of species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

See 37 CFR 1.111. Since the above-mentioned reply appears to be bona fide, applicant is given ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

ERVISORY PATENT EXAMINER

ZDUARDO/CLROBERT



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.			
11/093,409	03/29/2005	104US1 6640					
30328 JONATHAN S	7590 03/18/200 PANGLER	EXAMINER					
NU VASIVE, I			CUMBERLEDGE, JERRY L				
SAN DIEGO, (CENTRE COURT CA 92121		ART UNIT PAPER NUMBER				
,			3733	 ,			
			MAIL DATE	DELIVERY MODE			
			03/18/2008	PAPER			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	1					
	Application No.	Applicant(s)				
	11/093,409	CURRAN ET AL.				
Office Action Summary	Examiner	Art Unit				
	JERRY CUMBERLEDGE	3733				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w. - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
Responsive to communication(s) filed on 19 Ma This action is FINAL . 2b) ☑ This Since this application is in condition for allowant closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro					
Disposition of Claims						
4) Claim(s) 1-26 is/are pending in the application. 4a) Of the above claim(s) 14-26 is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-13 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or	n from consideration.					
··· <u> </u>	_					
 9) The specification is objected to by the Examine 10) The drawing(s) filed on 29 March 2005 is/are: a Applicant may not request that any objection to the or Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examine 1. 	a) accepted or b) objected to drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some color None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 04/22/2005.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite				

DETAILED ACTION

Examiner Comment

On 10/01/2007 a miscellaneous office communication was sent to Applicant's representative indicating that Applicant's response to the restriction requirement (mailed on 02/20/2007) was incomplete. During a brief conversation with Applicant's representative in January 2008, Applicant's representative pointed out how the response was a complete response and the examiner confirmed that the response was fully responsive. As such, the miscellaneous letter mailed 10/01/2007 was mistakenly sent and is vacated. An office action responsive to Applicant's election filed 03/19/2007 follows.

Election/Restrictions

Applicant's election with traverse of claims 1-13 (Group 1) in the reply filed on 03/19/2007 is acknowledged. The traversal is on the ground(s) that the claimed invention cannot be used to distract adjacent vertebrae. This is not found persuasive because the claimed invention can be used to distract vertebrae by placing the end of the device between adjacent vertebrae which would cause them to separate or distract.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected method of spinal fusion, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/19/2007.

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Drawings

The drawings are objected to because Figs. 17-23 are blurry and indistinct. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Steffee (US Pat. 5,716,415).

Steffee discloses a spinal fusion system comprising; an interbody spinal fusion implant (Fig. 15), including at least in part a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate (Fig. 1, surfaces contacting the vertebral endplates), at least one fusion aperture (Fig. 15, ref. 160) extending between the top surface and the bottom surface (Fig. 15, ref. 160) to allow bony fusion between the first vertebral end plate and the second vertebral endplate (Fig. 15), a distal side (Fig. 15, ref. 32a), a proximal side (Fig. 15, ref. 30b) having at least one receiving aperture (Fig. 15, ref. 60b) for engaging an insertion instrument, and two lateral sides (Fig. 15, ref. 20b and opposite side); and an insertion instrument (Fig. 4), including a generally elongated tubular member (Fig. 4, ref. 108) having a distal opening and a proximal opening (Fig. 4, near ref. 96 and ref. 104), a generally elongated shaft

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member (Fig. 4, ref. 118) having a distal end and a proximal end (Fig. 4) and being generally dimensioned to be inserted through the elongated tubular member (Fig. 4) such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening (Fig. 4), and the distal end including an implant engagement feature (Fig. 4, near ref. 136); and a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant (column 4, lines 24-35). The implant is substantially radiolucent and composed of nonbone material (column 7, lines 13-22). The implant includes at least one visualization aperture extending through at least one of the lateral sides (Fig. 15, ref. 156b). The top and bottom surfaces of the implant are at least one of generally parallel with respect to each other to better match the natural curvature of the spine (Fig. 15). The implant further includes anti-migration features (Fig. 15, ref. 36b) to increase friction between the implant and vertebral endplate minimizing unwanted movement (Fig. 15), the antimigration features including at least one of ridges formed in the top surface (Fig. 15), ridges formed in the bottom surface (Fig. 15), one or more spike elements protruding from the top surface (Fig. 15), one or more spike elements protruding from the bottom surface (Fig. 15), and one or more spike elements protruding from the top and bottom surface (Fig. 15). The securing mechanism includes, at least in part, a rotation device attached near the proximal end of the generally elongated shaft member (Fig. 4, ref. 84) such that turning the rotation device causes the generally elongated shaft member to turn (Fig. 4), releasably securing the implant to the insertion instrument (Fig. 4) (column 4, lines 24-35). The proximal end of the implant further includes at least one purchase

region (Fig. 15, any of the portions near the receiving aperture) adjacent to the receiving aperture and wherein the distal opening of the generally elongated tubular member is situated in a distal head (Fig. 4, portion near ref. 104), the distal head including at least one distal head slot (Fig. 4, slot between refs. 130), adjacent to the distal opening (Fig. 4), for engaging the purchase region on the implant (Fig. 4) and enhancing the engagement between the implant and the insertion instrument (Fig. 4). The implant includes two receiving apertures (Fig. 15, ref. 60b and ref. 62b) positioned adjacent to each other on the proximal side of the implant (Fig. 15). The generally elongated tubular member comprises a tubular lock member (Fig. 5, near ref. 100, ref. 102), the generally elongated shaft member comprises an elongated fork member (Fig. 4, ref. 86), and the engagement feature comprises two prongs (Fig. 4, ref. 136) extending from a pair of clamping arms (Fig. 4, ref. 130) and dimensioned to engage the two receiving apertures of the implant (Fig. 4)(Fig. 15)(Fig. 10). The elongate fork member includes a taper feature (Fig. 7, ref. 132) situated between the clamping arms (Fig. 7, ref. 130) and the proximal end (Fig. 7, near ref. 128) of the elongate fork member and the tubular lock member (Fig. 5, near ref. 100), ref. 102) includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature (Fig. 5, ref. 100). The securing mechanism includes, at least in part, a threaded region situated near the proximal end of the elongated fork member (Fig. 7, ref. 128), and a complimentary threaded region (Fig. 4, ref. 120) near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary

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threaded regions to meet as the tapered region enters the central bore at the distal opening (Fig. 4), wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions (Fig. 4), advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device (Fig. 4)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffee (US Pat. 5,716,415) in view of Boyd et al. (US Pat. 5,797,917).

Steffee discloses the claimed invention except for the receiving aperture of the implant comprises a singular threaded aperture. The insertion instrument engagement feature comprises a threaded connector dimensioned to engage the threaded receiving aperture of the implant and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture. Steffe does disclose an engagement feature that is used to engage and manipulate a spinal implant (Steffee, column 4, lines 24-35).

Boyd et al. disclose a receiving aperture (Fig. 4, ref. 20) of a spinal implant (Fig. 4) that comprises a singular threaded aperture (Fig. 4, ref. 20). The insertion instrument

engagement feature comprises a threaded connector (Fig. 5, ref. 64) dimensioned to engage the threaded receiving aperture of the implant and wherein turning the elongated shaft member in relation to the implant threadably engages the threaded connector and threaded receiving aperture (Fig. 4). The connector is used to engage and manipulate a spinal implant (Boyd et al., column 8, lines 22-31).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the engagement feature of Steffee with the engagement feature Boyd et al., in order to achieve the predictable result of using the connector to engage and manipulate a spinal implant.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./ Examiner, Art Unit 3733

/Eduardo C. Robert/ Supervisory Patent Examiner, Art Unit 3733

Notice of References Cited Application/Control No. 11/093,409 Examiner JERRY CUMBERLEDGE Applicant(s)/Patent Under Reexamination CURRAN ET AL. Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	А	US-5,716,415	02-1998	Steffee, Arthur D.	623/17.16
*	В	US-5,797,917	08-1998	Boyd et al.	606/99
*	С	US-5,192,327	03-1993	Brantigan, John W.	623/17.11
*	D	US-6,206,922	03-2001	Zdeblick et al.	623/17.11
*	Е	US-2003/0149438 A1	08-2003	Nichols et al.	606/99
	F	US-			
	G	US-			
	Н	US-			
	I	US-			
	J	US-			
	К	US-			
	L	US-			
	М	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	Ν					
	0					
	Р					
	Q					
	R					
	S					
	Т					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)					
	C						
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)

Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	11093409	CURRAN ET AL.
	Examiner	Art Unit
	Cumberledge, Jerry	3733

✓	Rejected	-	Cancelled		N	Non-Elected		А	Ар	Appeal	
=	Allowed	÷	Restricted		ı	Interf	erence	0	Obje	ected	
	☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47							R.1.47			
	CLAIM DATE										
Ei	nal Original	02/12/2007	2272008								

Claims renumbered in the same order as presented by applicant						☐ CPA).	☐ R.1.47		
CLAIM		CLAIM DATE								
Final	Original	02/12/2007	02/27/2008							
	1	÷	✓							
	2	÷	✓							
	3	÷	✓							
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U.S. Patent and Trademark Office Part of Paper No.: 20080226

Search Notes



11093409

Applicant(s)/Patent Under Reexamination

CURRAN ET AL.

Examiner

JERRY CUMBERLEDGE

Art Unit

3733

SEARCHED

Class	Subclass	Date	Examiner
623	17.11-17.16	2/27/2008	JLC
606	99	2/27/2008	JLC

SEARCH NOTES

Search Notes	Date	Examiner
Inventor Name Search Performed	2/27/2008	JLC

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

TFW)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Matthew Curran et al.

Title:

System and Methods for Spinal Fusion

Docket No.:

104US1

Filed:

March 29, 2005

Examiner:

Unknown

MS Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Serial No.: 11/093,409

Due Date: N/A

Group Art Unit: Unknown

We are transmitting herewith the following attached items (as indicated with an "X"):

APR 2 2 2005

 \underline{X} A return postcard and this transmittal document.

X An Information Disclosure Statement (2 pgs.), Form 1449 (6 pgs.), and copies of 37 cited documents.

Customer Number: 30328

Jonathan Spangler Reg. No. 40,182

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this <u>20</u> day of April, 2005.

MEREDITH MESCHER

Name

Signature

(GENERAL)

S/N 11/093,409 **PATENT**

IN THE UNITE PATENT AND TRADEMARK OFFICE

Applicant: Matthew Curran et al.

Serial No.: 11/093,409

March 29, 2005

Examiner: Group Art Unit:

Unknown Unknown

Docket:

104US1

Filed: Title:

System and Methods for Spinal Fusion

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 et. seq., the referenced materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 50-2040 in order to have this Information Disclosure Statement considered.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office. Notification of this change was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004. Thus, Applicant has not included copies of any US Patents or Published Applications cited with this submission. Should the Office require copies to be provided, Applicant respectfully requests that notice of such requirement be directed to Applicant's belowsigned representative. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

INFORMATION DISCLOSURE STATEMENT

Serial No :11/093,409

Filing Date: March 29, 2005

Title: System and Methods for Spinal Fusion

Page Z Dkt: 104US1

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

MATTHEW CURRAN ET AL.

By their Representatives

CUSTOMER NUMBER: 30328

858-909-1807

Date 4.19. 05

By

Jonathan Spangler

Reg. No. 40,182

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MPREDITH MESCH

Signatur

Substitute for form 1449A/PTO
INFORMATION DISCLOSURE STATEMENT BY APPLOANS
(Use as many sheets as necessar) Attorney Docket No: 104US1 Sheet 1 of 6

Complete if Known	equired to respond to a collection of information unless it contains a valid OMB control number
Application Number	11/093,409
Filing Date	March 29, 2005
First Named Inventor	Matthew Curran
Group Art Unit	Unknown
Examiner Name	Unknown
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/Jerry Cumberledge/

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der the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.
Complete if Known Substitute for form 1449A/PTO INFORMATION DISCLOSURE **Application Number** 11/093,409 STATEMENT BY APPLICANT March 29, 2005 **Filing Date** (Use as many sheets as necessary) **First Named Inventor** Matthew Curran Unknown **Group Art Unit Examiner Name** Unknown Attorney Docket No: 104US1 Sheet 2 of 6

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INFORMATION DISCLOSURE	Application Number	11/093,409				
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, ,,	First Named Inventor	Matthew Curran				
	Group Art Unit	Unknown				
	Examiner Name Unknown					
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Complete if Known Substitute for form 1449A/PTO INFORMATION DISCLOSURE **Application Number** 11/093,409 STATEMENT BY APPLICANT March 29, 2005 **Filing Date** (Use as many sheets as necessary) **First Named Inventor** Matthew Curran **Group Art Unit** Unknown **Examiner Name** Unknown Attorney Docket No: 104US1 Sheet 4 of 6

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INFORMATION DISCLOSURE	Application Number	11/093,409			
STATEMENT BY APPLICANT (Use as many sheets as necessary)	Filing Date	March 29, 2005			
	First Named Inventor	Matthew Curran			
	Group Art Unit	Unknown			
	Examiner Name	Unknown			
Sheet 6 of 6	Attorney Docket No: 104US1				

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TITLE									
Systems and methods for spinal fusion									
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Attorney Docket No. 104US1 Page 1 of 13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of)
MATTHEW CURRAN) Group Art Unit: 3733
App. Ser. No. 11/093,409)) Examiner: Jerry L. Cumberledge,
Filed: March 29, 2005))
For: SYSTEMS FOR METHODS FOR)
SPINAL FUSION)
Certificate of Transmission: I hereby certify that this correspond	ondence is being transmitted to the USPTO via EFS-Web on June 19, 2008:
Signature: /rory schermerhorn/ Name: Rory Schermerhorn	

RESPONSIVE AMENDMENT

Mail Stop Amendment Commissioner for Patents PO Box 1450 Alexandria VA 22313-1450

Dear Sir:

In response to the Office Action mailed on March 18, 2008, having a three-month shortened period for response that expires on June 18, 2008, please amend the application as follows:

IN THE CLAIMS:

1. (Currently amended) A spinal fusion system comprising;

an interbody spinal fusion implant, including at least in part a top surface for

contacting a first vertebral endplate, a bottom surface for contacting a second vertebral

endplate, at least one fusion aperture extending between the top surface and the bottom

surface to allow bony fusion between the first vertebral end plate and the second vertebral

endplate, a distal side, a proximal side having at least one a pair of receiving apertures

separated by a distance and situated within the boundaries of the proximal side for

engaging an insertion instrument, and two lateral sides; and

an insertion instrument, including a generally elongated tubular member having a

distal opening and a proximal opening, a generally elongated shaft member having a distal

end and a proximal end and being generally dimensioned to be inserted through the

elongated tubular member such that the distal end extends beyond the distal opening and

the proximal end extends beyond the proximal opening, and the distal end including an

implant engagement feature; and

a securing mechanism for releasably securing the engagement feature in one or

more receiving apertures of the implant.

2. (Original) The spinal fusion system of Claim 1, wherein the implant is substantially

radiolucent and composed of non-bone material.

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3. (Original) The spinal fusion system of Claim 1, wherein the implant includes at

least one visualization aperture extending through at least one of the lateral sides.

4. (Original) The spinal fusion system of Claim 1, wherein the top and bottom

surfaces of the implant are at least one of generally parallel with respect to each other, and

generally angled with respect to each other to better match the natural curvature of the

spine.

5. (Currently amended) The spinal fusion system of Claim 1, wherein the implant

further includes anti-migration features to increase friction between the implant and

vertebral endplate minimizing unwanted movement., the anti-migration features including

at least one of ridges formed in the top surface, ridges formed in the bottom surface, one

or more spike elements protruding from the top surface, one or more spike elements

protruding from the bottom surface, and one or more spike elements protruding from the

top and bottom surface.

6. - 10. (Cancelled)

11. (Currently amended) The spinal fusion system of Claim $\underline{10}$, wherein the generally

elongated tubular member comprises a tubular lock member, the generally elongated shaft

member comprises an elongated fork member, and the engagement feature comprises two

prongs extending from a pair of clamping arms and dimensioned to engage the two

receiving apertures of the implant.

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12. (Original) The spinal fusion system of Claim 11, wherein the elongate fork

member includes a taper feature situated between the clamping arms and the proximal end

of the elongate fork member and the tubular lock member includes a central bore having

an internal dimension smaller than the largest outer dimension of the taper feature.

13. (Original) The spinal fusion system of Claim 12, wherein the securing mechanism

is, at least in part, a threaded region situated near the proximal end of the elongated fork

member, and a complimentary threaded region near the proximal opening of the tubular

lock member within the central bore, such that inserting the proximal end of the elongated

fork member into the distal end of the tubular lock member will cause the complimentary

threaded regions to meet as the tapered region enters the central bore at the distal

opening, wherein rotating the tubular lock member in relation to the elongated fork

member engages the threaded regions, advancing the central bore over the tapered region

and laterally displacing the clamping arms and engagement prongs to create a compressive

force on the interior surface of the receiving aperture and releasably securing the implant

to the insertion device.

14. (Withdrawn - Currently Amended) A method of spinal fusion, comprising the steps

of:

(a) releasably securing a spinal fusion implant to an insertion instrument, the

spinal fusion implant including a top surface for contacting a first vertebral endplate, a

bottom surface for contacting a second vertebral endplate, at least one fusion aperture

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extending between the top surface and the bottom surface to allow bony fusion between

the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side

having at least one a pair of receiving apertures separated by a distance and situated within

the boundaries of the proximal side for engaging an insertion instrument, and two lateral

sides, and the insertion instrument including a generally elongated tubular member having

a distal opening and a proximal opening, a generally elongated shaft member having a

distal end and a proximal end and being generally dimensioned to be inserted through the

elongated tubular member such that the distal end extends beyond the distal opening and

the proximal end extends beyond the proximal opening, and the distal end including an

implant engagement feature;

(b) introducing the spinal fusion implant to a prepared space between adjacent

vertebral end plates and properly positioning the implant within the space;

(c) releasing the insertion instrument from the properly positioned implant and

withdrawing the insertion instrument from the surgical corridor.

15. (Withdrawn) The spinal fusion method of Claim 14, wherein the implant is

substantially radiolucent and composed of non-bone material

16. (Withdrawn) The spinal fusion method of Claim 14, wherein the implant includes

at least one visualization aperture extending through at least one of the lateral sides.

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Title: SYSTEMS FOR METHODS FOR SPINAL FUSION

- 17. (Withdrawn) The spinal fusion method of Claim 14, wherein the top and bottom surfaces of the implant are at least one of generally parallel with respect to each other, and generally angled with respect to each other to better match the natural curvature of the spine.
- 18. (Withdrawn Currently Amended) The spinal fusion method of Claim 14, wherein the implant further includes anti-migration features to increase friction between the implant and vertebral endplate minimizing unwanted movement, the anti-migration features including at least one of ridges formed in the top surface, ridges formed in the bottom surface, one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surface.
- 19. 23. (Cancelled)
- 24. (Withdrawn Currently Amended) The spinal fusion method of Claim 2414, wherein the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant.

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Title: SYSTEMS FOR METHODS FOR SPINAL FUSION

25. (Withdrawn) The spinal fusion method of Claim 24, wherein the elongate fork

member includes a taper feature situated between the clamping arms and the proximal end

of the elongate fork member and the tubular lock member includes a central bore having

an internal dimension smaller than the largest outer dimension of the taper feature.

26. (Withdrawn) The spinal fusion method of Claim 24, including a securing

mechanism for releasbly securing the engagement features in the receiving apertures of the

implant, the securing mechanism including, at least in part, a threaded region situated near

the proximal end of the elongated fork member, and a complimentary threaded region near

the proximal opening of the tubular lock member within the central bore, such that

inserting the proximal end of the elongated fork member into the distal end of the tubular

lock member will cause the complimentary threaded regions to meet as the tapered region

enters the central bore at the distal opening, wherein rotating the tubular lock member in

relation to the elongated fork member engages the threaded regions, advancing the central

bore over the tapered region and laterally displacing the clamping arms and engagement

prongs to create a compressive force on the interior surface of the receiving aperture and

releasably securing the implant to the insertion device.

27. (New) The spinal fusion system of Claim 5, wherein the anti-migration features

are at least one of a set of ridges formed in the top surface, a set of ridges formed in the

bottom surface, and a set of ridges on the top and bottom surfaces.

28. (New) The spinal fusion system of Claim 5, wherein the anti-migration features are at least one of one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements

protruding from the top and bottom surfaces.

29. (Withdrawn - New) The spinal fusion method of Claim 18, wherein the anti-

migration features are at least one of a set of ridges formed in the top surface, a set of

ridges formed in the bottom surface, and a set of ridges on the top and bottom surfaces.

30. (Withdrawn - New) The spinal fusion method of Claim 18, wherein the anti-

migration features are at least one of one or more spike elements protruding from the top

surface, one or more spike elements protruding from the bottom surface, and one or more

spike elements protruding from the top and bottom surfaces.

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REMARKS

Claims 1-5, 11-13, 27, and 28 are currently pending in this application. Through this response claims 1, 5 and 11 are amended, claims 6-10, and 19-23 are cancelled without prejudice, and claims 27-28 are added. No new matter has been introduced. Claims 14-18, 24-26 and 29-30 currently stand as withdrawn. Withdrawn claims 14, 18, and 24 are amended, and new claims 29-30 were added and withdrawn. In the Office Action mailed on March 18, 2008 ("Office Action"), claims 1-13 were rejected and the drawings were objected to. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

In order to advance prosecution on the merits, Applicants have amended the pending independent claim 1 in order to define more particularly the subject matter sought to be patented, without prejudice to pursue the original subject matter, for example, in a continuation application.

Drawings

On page 3 of the Office Action, the Examiner objected to Figures 17-23, stating the figures were blurry and indistinct. In response, applicants have submitted replacement figures, including Figures 17-23 on 4 replacements sheets, and respectfully ask the Examiner to remove the objection of the figures.

Claim Rejections

A. 35 U.S.C. 102(b) - Steffee

Claims 1-5 and 10-13 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,716,415 to Steffee. The rejection of claim 10 is moot as claim 10 is now cancelled. Applicants respectfully traverse the remaining rejections as set forth below.

In order for a reference to anticipate the present claimed invention under 35 U.S.C. 102(b), it must be shown that each and every element of the claim can be found in the reference. Attorney Docket No. 104US1 Serial No. 11/093,409 Filing Date: March 29, 2005

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If it can be shown that one element of the claim is missing or not met by the cited reference, the rejection must be withdrawn as inappropriate.

Claim 1, as presently amended, describes a spinal fusion system comprising: an interbody spinal fusion implant, including at least in part a top surface for contacting a first vertebral endplate, a bottom surface for contacting a second vertebral endplate, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side having *a pair* of receiving apertures separated by a distance and situated within the boundaries of the proximal side for engaging an insertion instrument, and two lateral sides; and an insertion instrument, including a generally elongated tubular member having a distal opening and a proximal opening, a generally elongated shaft member having a distal end and a proximal end and being generally dimensioned to be inserted through the elongated tubular member such that the distal end extends beyond the distal opening and the proximal end extends beyond the proximal opening, and the distal end including an implant engagement feature; and a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant.

The Steffee reference appears to be silent with regard to at least one element found in amended claim 1, such that the rejection for anticipation should be withdrawn. The Steffee reference does not disclose at least the claim 1 element of having "a pair of receiving apertures separated by a distance and situated within the boundaries of the proximal side." On the contrary, Steffee discloses an implant that includes a pair of recesses in which an engagement instrument grasps the exterior side surfaces of the implant. The implant described in Steffee includes end surfaces (30, 32), side surfaces (20, 22), and upper and lower surfaces (24, 26). The end surfaces 30 and 32 of Steffee correlate to the proximal and distal sides of the implant of claim 1, respectively. Side surfaces 20, 22 and upper and lower surfaces 24, 26, correlate to the lateral sides and top and bottom surfaces of the implant of claim 1. Again, claim 1 requires a pair of receiving apertures to be situated in the proximal side. Steffee however, teaches that the recesses (60, 62) (for engaging an insertion instrument) are situated in the side surfaces of the implant.

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Title: SYSTEMS FOR METHODS FOR SPINAL FUSION

Col. 3, lns. 26-28; col. 3, ln. 37-38. "The recesses 60 and 60 may be located anywhere on the [side] surfaces 20 and 22." Col. 3, ln. 35, 35. To hold the implant, Steffee describes an insertion instrument with a pair of extensions (136) that clamp along the exterior of the implant and engaging the side surfaces 20, 22 in the recesses 60, 62. Assuming, *arguendo*, that the recesses 60, 62 are considered by the examiner to be included in the proximal side simply because they extend along the side surface and meet the end surface 30, the Applicants submit that this still lacks any teaching of the claim1 element of being situated "within the boundaries of the proximal side." Instead, each recess would only form a part of the outer boundary of the end surface.

The configuration of the implant of claim 1 with a pair of receiving apertures "situated within the boundaries of the proximal end" may provide significant advantages over that shown in Steffee. For example, by having the apertures of the implant located within the boundaries of the proximal side, the distal end of the insertion instrument can be created with a smaller profile than the implant (e.g. the engagement features of the insertion instrument do not need to have dimensions at least as big or bigger than an entire side of the implant), thus allowing the clinician to better visualize the implant and the surrounding tissue while inserting the implant. In comparison, the implant of Steffee requires an insertion instrument with a larger distal profile (see figures 10 and 12 in which the clamping extensions protrude from each side surface of the implant) in order to allow for the extensions to clamp the side surfaces. The smaller profile, with engagement features engaging the interior of the implant as opposed to the exterior (as in Steffee), provides further advantage in that it decreases the possibility of interference (such as, for example, friction between the engagement features and the adjacent vertebra during either insertion of the implant or removal of the insertion tool) or inadvertent contact between insertion instrument and surrounding body tissue (such as, for example, delicate nerves or blood vessels that may be proximate to the target site).

Because Steffee fails to teach or disclose at least one claimed feature in the independent claim 1, Applicants respectfully submit that the rejection under 35 USC 102(b) should be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.

Furthermore, claims 2-5,10-13, and 27-28 are dependent upon claim 1 and should be allowable at least for the reasons set forth for the allowability of claim 1, as well as the additional limitations they contain. The Applicants believe these claims to be in condition for allowance and respectfully request a favorable indication in that regard.

B. 35 U.S.C. 103(a) - Steffee in view of Boyd

Claims 6-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Steffee in view of US Patent No. 5,797,917 to Boyd. The rejection is now moot in light of the cancellation of claims 6-9.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Reconsideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

NUVASIVE, INC.

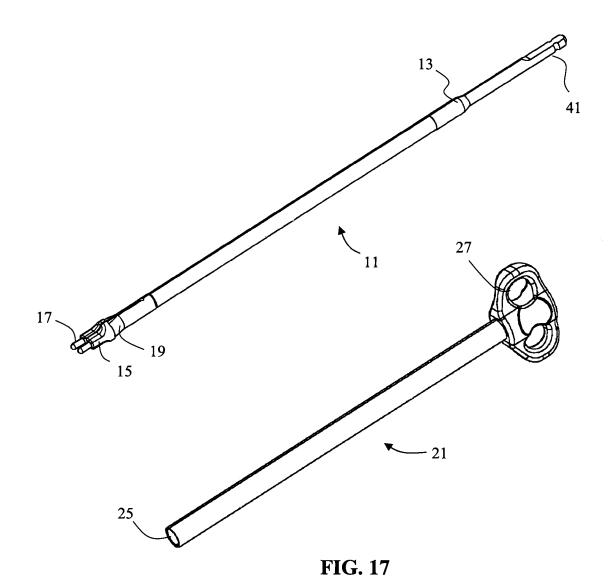
/rory schermerhorn/

By:

Rory Schermerhorn, Esq. Registration No. 58,148

4545 Towne Centre Court San Diego, CA 92121 Tel.: (858) 243-0029

June 19, 2008



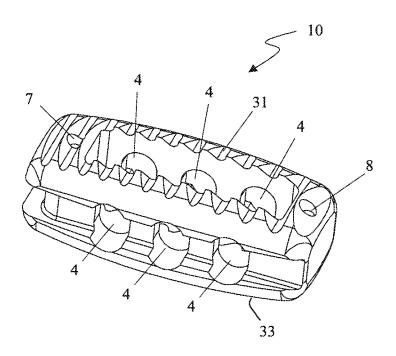


FIG. 18

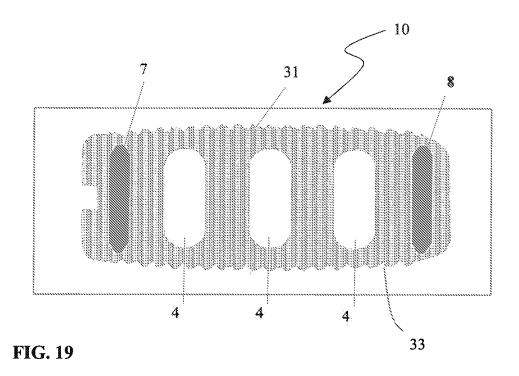
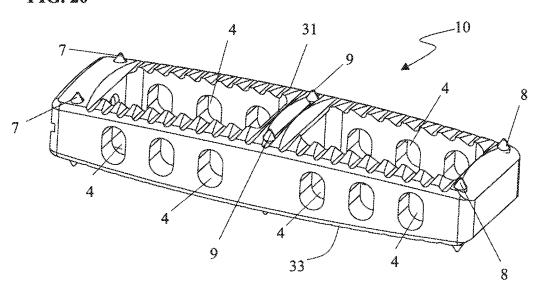


FIG. 20



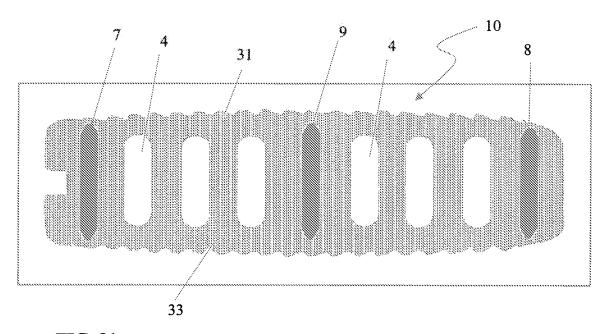
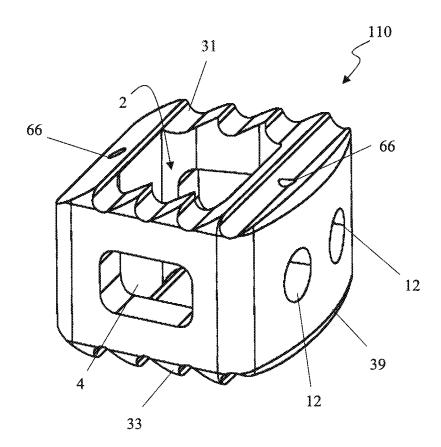
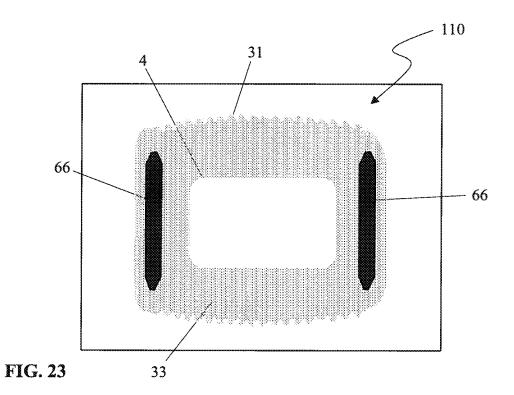


FIG. 21







Electronic Patent A	р	lication Fe	e Transı	mittal			
Application Number:	11093409						
Filing Date:	29-	Mar-2005					
Title of Invention:	Systems and methods for spinal fusion						
First Named Inventor/Applicant Name:	Matthew Curran						
Filer:	Rory A. Schermerhorn						
Attorney Docket Number:	104	·US1					
Filed as Small Entity							
Utility Filing Fees							
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)		
Basic Filing:							
Pages:							
Claims:							
Miscellaneous-Filing:							
Petition:							
Patent-Appeals-and-Interference:							
Post-Allowance-and-Post-Issuance:							
Extension-of-Time:							
Extension - 1 month with \$0 paid 966^{-2251} 1 60 60							

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
	Tota	al in USE	(\$)	60

Electronic Acknowledgement Receipt				
EFS ID:	3489512			
Application Number:	11093409			
International Application Number:				
Confirmation Number:	6640			
Title of Invention:	Systems and methods for spinal fusion			
First Named Inventor/Applicant Name:	Matthew Curran			
Customer Number:	30328			
Filer:	Rory A. Schermerhorn			
Filer Authorized By:				
Attorney Docket Number:	104US1			
Receipt Date:	20-JUN-2008			
Filing Date:	29-MAR-2005			
Time Stamp:	01:48:07			
Application Type:	Utility under 35 USC 111(a)			

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Payment Type	Deposit Account
Payment was successfully received in RAM	\$60
RAM confirmation Number	4820
Deposit Account	502040
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1			a60a58dc3f23662fc03f3b1e26e033bcf d4bba9e	yes	
	Multipa	rt Description/PDF files in	zip description		
	Document Description		Start	Е	nd
	Amendment - After No	1		1	
	Claims	2		8	
	Applicant Arguments/Remarks	9	13		
Warnings:					
Information:					
2	Drawings-only black and white line	104US1-RA-efiledrawings-6-	143220	no	4
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Warnings:					
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875			Δ	Application or Docket Number 11/093,409		Filing Date 03/29/2005		To be Mailed			
	APPLICATION AS FILED — PART I (Column 1) (Column 2) SMALL ENTITY ☑ OR SMALL ENTITY										
	FOR	N	JMBER FIL	.ED NU	IMBER EXTRA		RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)
	BASIC FEE (37 CFR 1.16(a), (b),	or (c))	N/A		N/A		N/A		1	N/A	
	SEARCH FEE (37 CFR 1.16(k), (i), (i)		N/A		N/A		N/A		1	N/A	
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A			N/A	
	ΓAL CLAIMS CFR 1.16(i))		mir	nus 20 = *			x \$ =		OR	x \$ =	
IND	EPENDENT CLAIM CFR 1.16(h))	IS	m	inus 3 = *			x \$ =		1	x \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s)) If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).											
	MULTIPLE DEPEN	NDENT CLAIM PR	ESENT (3	7 CFR 1.16(j))					l		
* If t	the difference in col	umn 1 is less than	zero, ente	r "0" in column 2.			TOTAL			TOTAL	
	APP	LICATION AS (Column 1)	AMEND	DED – PART I (Column 2)	(Column 3)		SMAL	L ENTITY	OR		ER THAN ALL ENTITY
AMENDMENT	06/20/2008	CLAIMS REMAINING AFTER AMENDMENT	AFTER PREV		PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
ME	Total (37 CFR 1.16(i))	* 20	Minus	** 26	= 0		X \$25 =	0	OR	x \$ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0		X \$105 =	0	OR	x \$ =	
\ME	Application S	ize Fee (37 CFR 1	.16(s))								
1	FIRST PRESEN	NTATION OF MULTIF	LE DEPEN	DENT CLAIM (37 CF	FR 1.16(j))				OR		
							TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	
		(Column 1)		(Column 2)	(Column 3)						
L		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
Z Z	Total (37 CFR 1.16(i))	*	Minus	**	=		x \$ =		OR	x \$ =	
AMENDMENT	Independent (37 CFR 1.16(h))	*	Minus	***	=		X \$ =		OR	x \$ =	
Z U	Application S	ize Fee (37 CFR 1	.16(s))								
AM	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR				
						• '	TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
** If	* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.							W. BADIE/		er:	

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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

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APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/093,409	03/29/2005 Matthew Curran		104US1	6640
30328 JONATHAN SI	7590 09/17/200 PANGLER	8	EXAM	INER
NuVasive, Inc.	_		CUMBERLED	GE, JERRY L
7475 LUSK BOULEVARD SAN DIEGO, CA 92121			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	DELIVERY MODE
			09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)				
Office Action Summary		11/093,409	CURRAN ET AL.				
		Examiner	Art Unit				
		JERRY CUMBERLEDGE	3733				
Period fo	The MAILING DATE of this communication app or Reply	pears on the cover sheet with the c	orrespondence address				
WHIC - Exter after - If NO - Failui Any r	A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status							
1) 又	Responsive to communication(s) filed on 20 Ju	ine 2008					
·		action is non-final.					
<i>'</i> —	Since this application is in condition for allowa		secution as to the merits is				
٥/١	closed in accordance with the practice under <i>E</i>	·					
	·	2. pares Quayre, 1000 0.21 1., 10	0.0.2.2.0.				
Dispositi	on of Claims						
4)🛛	Claim(s) 1-5,11-18 and 24-30 is/are pending in	n the application.					
•	4a) Of the above claim(s) <u>14-18,24-26,29 and .</u>	<u>30</u> is/are withdrawn from consider	ation.				
5)	Claim(s) is/are allowed.						
6)🖂	Claim(s) <u>1-5,11-13,27 and 28</u> is/are rejected.						
·	Claim(s) is/are objected to.						
·	Claim(s) are subject to restriction and/o	r election requirement.					
,—	, <u> </u>	·					
Applicati	on Papers						
9)□ .	The specification is objected to by the Examine	er.					
10)🛛	The drawing(s) filed on <u>20 June 2008</u> is/are: a)⊠ accepted or b)⊡ objected to	by the Examiner.				
	Applicant may not request that any objection to the						
	Replacement drawing sheet(s) including the correct						
11) 🗆 .	The oath or declaration is objected to by the Ex		, ,				
•	,						
Priority u	ınder 35 U.S.C. § 119						
	Acknowledgment is made of a claim for foreign ☐ All b)☐ Some * c)☐ None of: 1.☐ Certified copies of the priority document		-(d) or (f).				
			on No				
	2. Certified copies of the priority document	• •					
	3. Copies of the certified copies of the prio	•	d in this National Stage				
	application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment	t(s)						
	1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notic	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate				
	nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	5) Notice of Informal P 6) Other:	atent Application				
i ape	raper nots/initial date						

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (US Pub. 2002/0116008 A1).

Lin discloses a spinal fusion system comprising an interbody spinal fusion implant (Fig. 9, ref. 100), including at least in part a top surface for contacting a first vertebral endplate (Fig. 9), a bottom surface for contacting a second vertebral endplate (Fig. 9), at least one fusion aperture (Fig. 9, ref. 104) extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side (Fig. 9, lower portion), a proximal side (Fig. 9, upper portion) having a pair of receiving apertures (Fig. 9, ref. 106a,b) separated by a distance (Fig. 9)(Fig. 14) and situated within the boundaries of the proximal side (Fig. 9) for engaging an insertion instrument, and two lateral sides (Fig. 9); and an insertion instrument (Fig. 17, ref. 200), including a generally elongated tubular member (Fig. 17, ref. 212) having a distal opening (Fig. 17) and a proximal opening (Fig. 17), a generally elongated shaft member having a distal end and a proximal end (Fig. 17, ref. 214) and being generally dimensioned to be inserted through the elongated tubular member (Fig. 17) such that the distal end extends beyond the distal opening (Fig. 17, i.e. ref. 210) and

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the proximal end extends beyond the proximal opening (Fig. 17, near ref. 230), and the distal end including an implant engagement feature (Fig. 18, ref. 232); and a securing mechanism for releasably securing the engagement feature in one or more receiving apertures of the implant (paragraph 0036). The implant is substantially radiolucent and composed of non-bone material (paragraph 0039). The implant includes at least one visualization aperture (e.g. Fig. 26, ref. 310) extending through at least one of the lateral sides. The top and bottom surfaces of the implant are at least one of generally parallel with respect to each other, and generally angled with respect to each other to better match the natural curvature of the spine (Fig. 9). The implant further includes antimigration features to increase friction between the implant and vertebral endplate minimizing unwanted movement (Fig. 1, ref. 12). The anti-migration features are at least one of a set of ridges formed in the top surface, a set of ridges formed in the bottom surface, and a set of ridges on the top and bottom surfaces (Fig.1). The anti-migration features are at least one of one or more spike elements protruding from the top surface, one or more spike elements protruding from the bottom surface, and one or more spike elements protruding from the top and bottom surfaces (Fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (US Pub. 2002/0116008 A1) in view of Steffee (US Pat. 5,716,415).

Page 4

Lin et al. discloses the claimed invention except for the generally elongated tubular member comprises a tubular lock member, the generally elongated shaft member comprises an elongated fork member, and the engagement feature comprises two prongs extending from a pair of clamping arms and dimensioned to engage the two receiving apertures of the implant. The elongate fork member includes a taper feature situated between the clamping arms and the proximal end of the elongate fork member and the tubular lock member includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature. The securing mechanism is, at least in part, a threaded region situated near the proximal end of the elongated fork member, and a complimentary threaded region near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening, wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions, advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the receiving aperture and releasably securing the implant to the insertion device. Lin, however, does disclose a mechanism that comprises a threaded engagement (paragraph 0035) that includes

Art Unit: 3733

prongs that extend into apertures of an implant in order to grip and manipulate an implant (paragraph 0035)(paragraph 0036).

Steffee discloses a spinal fusion system that comprises a generally elongated tubular member which comprises a tubular lock member (Fig. 5, near ref. 100, ref. 102), the generally elongated shaft member comprises an elongated fork member (Fig. 4, ref. 86), and the engagement feature comprises two prongs (Fig. 4, ref. 136) extending from a pair of clamping arms (Fig. 4, ref. 130) and dimensioned to engage the two receiving apertures of the implant (Fig. 4)(Fig. 15)(Fig. 10). The elongate fork member includes a taper feature (Fig. 7, ref. 132) situated between the clamping arms (Fig. 7, ref. 130) and the proximal end (Fig. 7, near ref. 128) of the elongate fork member and the tubular lock member (Fig. 5, near ref. 100), ref. 102) includes a central bore having an internal dimension smaller than the largest outer dimension of the taper feature (Fig. 5, ref. 100). The securing mechanism includes, at least in part, a threaded region situated near the proximal end of the elongated fork member (Fig. 7, ref. 128), and a complimentary threaded region (Fig. 4, ref. 120) near the proximal opening of the tubular lock member within the central bore, such that inserting the proximal end of the elongated fork member into the distal end of the tubular lock member will cause the complimentary threaded regions to meet as the tapered region enters the central bore at the distal opening (Fig. 4), wherein rotating the tubular lock member in relation to the elongated fork member engages the threaded regions (Fig. 4), advancing the central bore over the tapered region and laterally displacing the clamping arms and engagement prongs to create a compressive force on the interior surface of the

Art Unit: 3733

receiving aperture and releasably securing the implant to the insertion device (Fig. 4). Steffee discloses that this mechanism is used to grip and manipulate an implant (column 4, lines 36-60).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted a mechanism as taught by Lin et al, with a mechanism as taught by Steffee, in order to achieve the predictable result of gripping and manipulating an implant.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Application/Control Number: 11/093,409

Art Unit: 3733

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the

Page 7

examiner should be directed to JERRY CUMBERLEDGE whose telephone number is

(571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM -

5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

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Application/Control Number: 11/093,409 Page 8

Art Unit: 3733

Notice of References Cited Application/Control No. 11/093,409 Examiner JERRY CUMBERLEDGE Applicant(s)/Patent Under Reexamination CURRAN ET AL. Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	Α	US-2002/0116008 A1	08-2002	Lin et al.	606/99
*	В	US-2003/0109928 A1	06-2003	Pasquet et al.	623/17.11
*	С	US-6,159,211	12-2000	Boriani et al.	606/279
*	D	US-2005/0203538 A1	09-2005	Lo et al.	606/099
	Е	US-			
	F	US-			
	G	US-			
	Н	US-			
	-	US-			
	J	US-			
	K	US-			
	L	US-			
	М	US-			

FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

	NON-FATENT BOCOMENTS							
*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)						
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)

Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office PTO-892 (Rev. 01-2001)

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	11093409	CURRAN ET AL.
	Examiner	Art Unit
	Cumberledge, Jerry	3733

✓	Rejected	-	Cancelled	N	Non-Elected	Α	Appeal
=	Allowed	÷	Restricted	I	Interference	0	Objected

☐ Claims	renumbered	in the same	order as pr	esented by a	applicant		□ СРА	□ т.с	D. 🗆	R.1.47
CL	ΔIM	DATE								
Final	Original	02/12/2007	02/27/2008	09/12/2008						
	1	÷	✓	✓						
	2	÷	✓	✓						
	3	÷	✓	✓						
	4	÷	✓	✓						
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	7	÷	✓	-						
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	9	÷	✓	-						
	10	÷	✓	-						
	11	÷	✓	✓						
	12	÷	✓	✓						
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	14	÷	N	N						
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	16	÷	N	N						
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	23	÷	N	-						
	24	÷	N	N						
	25	÷	N	N						
	26	÷	N	N						
	27			✓						
	28			✓						
	29			N						
	30			N						

U.S. Patent and Trademark Office Part of Paper No.: 20080912

Search Notes

Application/Control No.	Applicant(s)/Patent Under Reexamination
11093409	CURRAN ET AL.
Examiner	Art Unit
JERRY CUMBERLEDGE	3733

SEARCHED					
Class	Subclass	Date	Examiner		
623	17.11-17.16	2/27/2008	JLC		
606	99	2/27/2008	JLC		
	Updated Search	9/12/2008	JLC		

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search Performed	2/27/2008	JLC

	INTERFERENCE SEAF	RCH	
Class	Subclass	Date	Examiner

Doc code: IDS Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (12-08)
Approved for use through 01/31/2009. OMB 0651-0031
Formation Disclosure Statement (IDS) Filed
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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	Application Number		11093409	
	Filing Date		2005-03-29	
INFORMATION DISCLOSURE	First Named Inventor	Matth	ew Curran	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		3733	
(Not 10. Gabiniosion anagrae of Grant 1100)	Examiner Name	Jerry L. Cumberledge		
	Attorney Docket Number		104US1	

			PATENTS	Remove		
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4950296		1990-08-21	McIntyre, J. L.	
	2	5484437		1996-01-16	Michelson, Gary K.	
	3	5741253		1998-04-21	Michelson, Gary K.	
	4	5860973		1996-10-30	Michelson, Gary K.	
	5	6059829		2000-05-09 Schlapfer, F. et al.		
	6	6120503		2000-09-19	Michelson, Gary K.	
	7	6409766		2002-06-25	Brett, D. C.	
	8	6432140		2002-08-13	Lin, Chih-I	

984 EFS Web 2.1.9

(Not for submission under 37 CFR 1.99)

Application Number		11093409		
Filing Date		2005-03-29		
First Named Inventor Matthe		ew Curran		
Art Unit		3733		
Examiner Name Jerry		L. Cumberledge		
Attorney Docket Number		104US1		

9	6468311	2002-10-22	Boyd, L. M., et al.	
10	6491724	2002-12-10	Ferree, B.	
11	6672019	2004-01-06	Wenz, J. O.	
12	6676703	2004-01-13	Biscup, R. S.	
13	6706067	2004-03-16	Shimp, L. A., et al.	
14	6743255	2004-06-01	Ferree, B.	
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16	6761739	2004-07-13	Shepard, Y. D.	
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18	6942698	2005-09-13	Jackson, R. P.	
19	6964687	2005-11-15	Bernard, P. M., et al.	

EFS Web 2.1.9 985

(Not for submission under 37 CFR 1.99)

Application Number		11093409	
Filing Date		2005-03-29	
First Named Inventor Matthe		ew Curran	
Art Unit		3733	
Examiner Name Jerry		L. Cumberledge	
Attorney Docket Number		104US1	

	20	6979353		2005-12-27	Bresina, S.		
	21	6984245		2006-01-10	McGahan, T. V., et al.		
	22	6986788		2006-01-17	Paul, D. C., et al.		
	23	6989031		2006-01-24	Michelson, G. K.		
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	25	D472634		2003-04-01	Anderson, B. G.		
	26	D473650		2003-04-22	Anderson, B. G.		
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	28	D530423		2006-10-17	Miles, P. et al.		
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Application Number		11093409	
Filing Date		2005-03-29	
First Named Inventor	Matth	ew Curran	
Art Unit		3733	
Examiner Name	Jerry	L. Cumberledge	
Attorney Docket Number		104US1	

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(Not for submission under 37 CFR 1.99)

Application Number		11093409		
Filing Date		2005-03-29		
First Named Inventor	Matth	ew Curran		
Art Unit		3733		
Examiner Name Jerry		L. Cumberledge		
Attorney Docket Number	er	104US1		

	CERTIFICATION STATEMENT						
Plea	Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):						
	That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).						
OF	L						
	That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).						
	See attached ce	rtification statement.					
	Fee set forth in 3	37 CFR 1.17 (p) has been submitted herewith	1.				
×	None						
		SIGNA					
	A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.						
Sigi	Signature /roryschermerhorn/ Date (YYYY-MM-DD) 2009-01-21						
Nar	ame/Print Rory Schermerhorn Registration Number 58148						
pub 1.14	This collection of information is required by 37 CFR 1.97 and 1.98. 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 1 hour 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						

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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Electronic Patent Application Fee Transmittal							
Application Number:	11093409						
Filing Date:	ing Date: 29-Mar-2005						
Title of Invention:		Systems and methods for spinal fusion					
First Named Inventor/Applicant Name:	tthew Curran						
Filer:	Rory A. Schermerhorn						
Attorney Docket Number:	Attorney Docket Number: 104US1						
Filed as Small Entity							
Utility under 35 USC 111(a) Filing Fees							
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)		
Basic Filing:							
Pages:							
Claims:							
Miscellaneous-Filing:							
Petition:							
Patent-Appeals-and-Interference:							
Post-Allowance-and-Post-Issuance:							
Extension-of-Time:							
Extension - 1 month with \$0 paid		990 2251	1	65	65		

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Request for continued examination	2801	1	405	405
	Tot	al in USD	(\$)	470

Electronic Acknowledgement Receipt					
EFS ID:	4653620				
Application Number:	11093409				
International Application Number:					
Confirmation Number:	6640				
Title of Invention:	Systems and methods for spinal fusion				
First Named Inventor/Applicant Name:	Matthew Curran				
Customer Number:	30328				
Filer:	Rory A. Schermerhorn				
Filer Authorized By:					
Attorney Docket Number:	104US1				
Receipt Date:	21-JAN-2009				
Filing Date:	29-MAR-2005				
Time Stamp:	21:11:50				
Application Type:	Utility under 35 USC 111(a)				

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$470
RAM confirmation Number	7060
Deposit Account	502040
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

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File Listing	g:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)	
1		404154 BAF 4 24 00 15	48242		_	
1		104US1-RAF-1-21-08.pdf	81d7a97e81dbc77cdadbc0425e0341467cc c9816	yes	9	
	Multipa	art Description/PDF files in	.zip description	<u> </u>		
	Document Des	Start	E	nd		
	Amendment Submitted/Entered	1		1		
	Claims	2		5		
	Applicant Arguments/Remarks N	6	9			
Warnings:						
Information:						
2	Request for Continued Examination	104US1-RCE-1-21-08.pdf	697334	no	3	
_	(RCE)		6bcde52558e23bd033005aeea4ffdaefe34d 8a8f			
Warnings:			·			
Information:						
3	Information Disclosure Statement (IDS)	104US1-IDS-1-21-08-1.pdf	610263	no	6	
3	Filed (SB/08)	104031 103 1 21 00 1.pui	35987dce6a79d2014f2114f15b46f2b08758 e81e		J	
Warnings:						
Information:						
4	Fee Worksheet (PTO-06)	fee-info.pdf	31473	no	2	
7	i ee worksneet (i 10-00)	0dbff7c96703bd2a08237835f609c16ccbd4 d7ed				
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Attorney Docket No. 104US1 Page 1 of 9

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Matthew Curran Art Unit: 3733

Serial No.: 11/093,409 Examiner: Jerry L. Cumberledge

Filing Date: March 29, 2005

Title: Systems and Methods for Spinal Fusion

Certificate of Transmission: I hereby certify that this paper or fee is being transmitted to the United States Patent and Trademark Office, via EFS-Web, on <u>January 21, 2008</u>.

Signature: /roryschermerhorn/ Name: Rory Schermerhorn

RESPONSE AFTER FINAL WITH RCE

Mail Stop RCE Commissioner for Patents PO Box 1450 Alexandria VA 22313-1450

Dear Sir:

In response to the Final Office Action mailed on September 17, 2008, having a three-month shortened period for response that expires on December 17, 2008, please amend the application as follows:

IN THE CLAIMS:

1. (Currently amended) A spinal fusion system implant positionable within an interbody space between a first vertebral endplate and a second vertebral endplate, said interbody space being at least partially defined by a posterior aspect, and anterior aspect, and opposing lateral aspects, said implant comprising:

an interbody spinal fusion implant, including at least in part a top surface including a plurality of ridges to engage said for contacting a first vertebral endplate when said implant is positioned within the interbody space, a bottom surface including a plurality of ridges to engage said for contacting a second vertebral endplate when said implant is positioned within the interbody space, at least one fusion aperture extending between the top surface and the bottom surface to allow bony fusion between the first vertebral end plate and the second vertebral endplate, a distal side, a proximal side, having a pair of receiving apertures separated by a distance and situated within the boundaries of the proximal side for engaging an insertion instrument, and two lateral sides; and a first side wall defining an anterior side when said implant is positioned within the interbody space, and a second side wall defining a posterior side when said implant is positioned within the interbody space;

wherein said implant has a length extending from said proximal side to said distal side, a width extending from said first side wall to said second side wall, and a height extending from said top surface to said bottom surface;

wherein said length is so dimensioned as to extend between said lateral aspects of said interbody space when said implant is positioned within the interbody space and is at least two and a half times greater than said width;

wherein said width is greater than said height;

said implant further including first and second fusion apertures that each extend between the top and bottom surfaces and permit bone growth between the first vertebral endplate and the second vertebral endplate when said implant is positioned within the interbody space, said first and second fusion apertures being adjacent to one another and separated by a medial support;

said implant further including at least one radiopaque marker situated between said top and bottom surfaces.

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an insertion instrument, including a generally elongated tubular member having a distal

opening and a proximal opening, a generally elongated shaft member having a distal end and a

proximal end and being generally dimensioned to be inserted through the elongated tubular

member such that the distal end extends beyond the distal opening and the proximal end extends

beyond the proximal opening, and the distal end including an implant engagement feature; and

a securing mechanism for releasably securing the engagement feature in one or more

receiving apertures of the implant.

2. (Currently amended) The spinal fusion-system implant of Claim 1, wherein the said

implant is substantially radiolucent and composed of non-bone material.

3. (Currently amended) The spinal fusion system implant of Claim 1, wherein the said

implant includes at least one visualization aperture extending through at least one of said first

side wall and said second side wall the lateral sides.

4. (Currently amended) The spinal fusion system implant of Claim 1, wherein the top and

bottom surfaces of the implant are at least one of generally parallel with respect to each other,

and generally angled with respect to each other to better match the natural curvature of the spine.

5. (Currently amended) The spinal fusion system implant of Claim 1, wherein the implant

further includes anti-migration features to increase friction between the implant and vertebral

endplate minimizing unwanted movement said first and second fusion apertures are one of

generally rectangular and generally oblong in shape.

6–30. (Cancelled)

31. (New) The Spinal fusion implant of claim 1, further including at least one receiving

element at least partially defined along said proximal side.

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32. (New) The spinal fusion implant of claim 31, wherein said receiving element is engageable with an insertion instrument.

- 33. (New) The spinal fusion implant of claim 32, wherein said receiving element comprises a threaded aperture.
- 34. (New) The spinal fusion implant of claim 33, wherein said receiving implant further comprises a slot extending from said threaded aperture.
- 35. (New) A spinal fusion implant of non-bone construction postionable via a lateral transpsoas surgical approach to the spine into a position within an interbody space between a first vertebra and a second vertebra, wherein said interbody space being at least partially defined by a posterior aspect, and anterior aspect, and opposing lateral aspects, said implant comprising:

a top surface to contact said first vertebra when said implant is positioned within the interbody space, a bottom surface to contact said second vertebra when said implant is positioned within the interbody space, a distal side, a proximal side, a first side to face said anterior aspect of said disc space when said implant is positioned within the interbody space and a second side to face said posterior aspect of said disc space when said implant is positioned within the interbody space, wherein said implant is generally rectangular in shape having a length extending from said proximal side to said distal side of at least 40mm, a width extending from said first side to said second side of at least 15mm, and a height extending from said top surface to said bottom surface ranging from 8mm to 16mm, said implant further including a pair fusion apertures comprising one of a generally rectangular and generally oblong shape and extending between said top surface and bottom surface to permit bone growth between the first vertebra and the second vertebra, said implant further including a at least one radiopaque marker situated between said top and bottom surfaces.

36. (New) The implant of claim 31, wherein said non-bone material is one of PEEK and PEKK.

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37. (New) The implant of claim 31, wherein said implant includes at least one visualization

aperture extending through at least one of said posterior side and said lateral side.

38. (New) The implant of claim 31, wherein a portion of said implant adjacent said distal

side is tapered.

39. (New) The implant of claim 31, further including at least one anti-migration features

comprising at least one of a set of ridges formed in the top surface, a set of ridges formed in the

bottom surface, a set of ridges on the top and bottom surfaces, one or more spike elements

protruding from the top surface, one or more spike elements protruding from the bottom surface,

and one or more spike elements protruding from the top and bottom surface.

40. (New) The spinal fusion implant of claim 35, further including at least one receiving

element at least partially defined along said proximal side.

41. (New) The spinal fusion implant of claim 40, wherein said receiving element is

engageable with an insertion instrument.

42. (New) The spinal fusion implant of claim 41, wherein said receiving element comprises

a threaded aperture.

43. (New) The spinal fusion implant of claim 42, wherein said receiving implant further

comprises a slot extending from said threaded aperture.

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REMARKS

Claims 1-5 and 31-43 are currently pending in the application. Through this response

claims 1-5 are amended, new claims 31-43 are added, and claims 6-30 are cancelled without

prejudice. Applicants respectfully request favorable consideration of the present application in

light of the amendments to the claims and the following remarks.

In an effort to advance prosecution on the merits, the Applicants have amended

independent claim 1 and cancelled independent claim 14 in order to define more particularly the

subject matter sought to be patented. The amendments are made without prejudice and the

Applicants reserve the right to further pursue the original subject matter, for example, in a

continuation application.

Claim Rejections

A. 35 U.S.C. 102(b) - Lin

Claims 1-5, 27 and 28 were rejected under 35 U.S.C. 102(b) as being anticipated by Lin

et al. (US Pub. 2002/0116008 A1). With the cancellation of claims 27 and 28 the rejections of

those claims are now moot. The Applicants respectfully traverse the remaining rejections as set

forth below.

In order for a reference to anticipate the present claimed invention under 35 U.S.C.

102(b), it must be shown that each and every element of the claim can be found in the reference.

If it can be shown that one element of the claim is missing or not met by the cited reference, the

rejection must be withdrawn as inappropriate.

Claim 1, as currently amended, is directed to a spinal fusion implant positionable within

an interbody space between a first vertebral endplate and a second vertebral endplate, said

interbody space being at least partially defined by a posterior aspect, and anterior aspect, and

opposing lateral aspects. The implant comprises a top surface including a plurality of ridges to

engage said first vertebral endplate when said implant is positioned within the interbody space, a

bottom surface including a plurality of ridges to engage said second vertebral endplate when said

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implant is positioned within the interbody space, a distal side, a proximal side, a first side wall defining an anterior side when said implant is positioned within the interbody space, and a second side wall defining a posterior side when said implant is positioned within the interbody space; wherein said implant has a length extending from said proximal side to said distal side, a width extending from said first side wall to said second side wall, and a height extending from said top surface to said bottom surface; wherein said length is so dimensioned as to extend between said lateral aspects of said interbody space when said implant is positioned within the interbody space and is at least two and a half times greater than said width; wherein said width is greater than said height; said implant further including first and second fusion apertures that each extend between the top and bottom surfaces and permit bone growth between the first vertebral endplate and the second vertebral endplate when said implant is positioned within the interbody space, said first and second fusion apertures being adjacent to one another and separated by a medial support; said implant further including at least one radiopaque marker situated between said top and bottom surfaces.

The Lin reference is silent with regard to at least one element found in amended claim 1, such that the rejection for anticipation should be withdrawn. By way example, Lin is silent as to the claim 1 element of having a length that is at least two and a half times greater than the width, as well as having a length dimensioned to extend between the lateral aspects of the interbody space. By way of further example, Lin also fails to disclose, among other things, an implant where the width is greater than the height, an implant having first and second fusion apertures separated by a medial support, and an implant with at least one radiopaque marker situated between top and bottom surfaces.

Because the Lin reference is silent to at least one element of amended Claim 1, Applicants respectfully submit that the rejection under 35 USC 102(b) should be withdraw in favor of an indication of allowance, which is hereby earnestly solicited. Furthermore, claims 2-5 are dependent upon independent claim 1 and should be allowable at least for the reasons set forth for the allowability of claim 1, as well as the additional limitations they contain. New claims 31-

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34 also depend from claim 1 and should also be allowable for the reasons set forth for the allowability of claim 1 and the additional limitations they contain. The Applicants believe claims 1-5 and 31-34 are in condition for allowance and respectfully request a favorable indication to that effect.

The Applicants respectfully submit that Lin also fails to disclose at least one element of new claim 35. By way of example, Lin fails to disclose the claim 35 element of having an implant with a generally rectangular shape. Lin also fails to disclose at least the additional elements of having an implant with a length extending from a proximal side to a distal side that is at least 40mm, an implant having first and second fusion apertures separated by a medial support, and an implant with at least one radiopaque marker situated between top and bottom surfaces, among others. Claim 35 is believed to be in condition for allowance and an indication to that effect is earnestly solicited. Claims 36-43 depend from claim 35 and are also believed to be in condition for allowance and an indication to that effect is respectfully requested.

B. 35 U.S.C. 103(a) – Lin in view of Steffee

Claims 11-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lin in view of Steffee (US Pat. 5,716,415). The rejection is now moot in light of the cancellation of claims 11-13.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

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CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Reconsideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted, NUVASIVE, INC.

/roryschermerhorn/

By: _____

Rory Schermerhorn, Esq. Registration No. 58,148

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January 21, 2008

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (12-08) Approved for use through 01/31/2009. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL (Submitted Only via EFS-Web) Application Filing **Docket Number** Art 11/093,409 2005-03-29 104US1 3733 Number Date (if applicable) Unit First Named Examiner Matthew Curran Jerry L. Cumberledge Inventor Name This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV SUBMISSION REQUIRED UNDER 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s). Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked. Consider the arguments in the Appeal Brief or Reply Brief previously filed on Other **X** Enclosed ★ Amendment/Reply Information Disclosure Statement (IDS) Affidavit(s)/ Declaration(s) Other **MISCELLANEOUS** Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required) Other **FEES** The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed. The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to X Deposit Account No SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED Patent Practitioner Signature

Applicant Signature

Doc code: RCEX PTO/SB/30EFS (12-08)

Doc description: Request for Continued Examination (RCE)

Approved for use through 01/31/2009. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Signature of Registered U.S. Patent Practitioner								
S	Signature	/roryschermerhorn/	Date (YYYY-MM-DD)	2009-01-21					
1	Name	Rory Schermerhorn	Registration Number	58148					

This collection of information is required by 37 CFR 1.114. 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 1.11 and 1.14. This collection is estimated to take 12 minutes 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.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
- A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a
 court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement
 negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.			
11/093,409	03/29/2005	Matthew Curran	104US1 6640				
³⁰³²⁸ NuVasive	7590 08/27/200	9	EXAM	INER			
c/o CPA Global		FISHER, ELANA BETH					
P.O. Box 52050 Minneapolis, M			ART UNIT	PAPER NUMBER			
•			3733				
			MAIL DATE	DELIVERY MODE			
			08/27/2009	PAPER			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)				
	Office Action Comments	11/093,409	CURRAN ET AL.				
	Office Action Summary	Examiner	Art Unit				
		ELANA B. FISHER	3733				
Period fo	The MAILING DATE of this communication app r Reply	oears on the cover sheet with the c	orrespondence address				
WHIC - Exter after - If NO - Failui Any r	ORTENED STATUTORY PERIOD FOR REPLICATION OF THE MAILING DISTRICTORY IS LONGER, FROM THE MAILING DISTRICTORY IS LONGER, FROM THE MAILING DISTRICTORY IS STATED AND AND AND AND AND AND AND AND AND AN	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timwill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONEI	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status							
1) 又	Responsive to communication(s) filed on 21 Ja	anuary 2009.					
•	• • • • • • • • • • • • • • • • • • • •	s action is non-final.					
<i>'</i> —	Since this application is in condition for allowa		secution as to the merits is				
٥/١	closed in accordance with the practice under <i>E</i>						
			0.0.2.2.0.				
Dispositi	on of Claims						
4)🛛	Claim(s) 1-5 and 31-43 is/are pending in the a	pplication.					
	4a) Of the above claim(s) is/are withdra	wn from consideration.					
5)	Claim(s) is/are allowed.						
6)🖂	Claim(s) <u>1-5 and 31-43</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
8)□	Claim(s) are subject to restriction and/c	r election requirement.					
Applicati	on Papers						
		A.P.					
-	The specification is objected to by the Examine		- - - -				
•	The drawing(s) filed on is/are: a) _ acc						
	Applicant may not request that any objection to the	*	* *				
44)□:	Replacement drawing sheet(s) including the correct		, ,				
11)	The oath or declaration is objected to by the Ex	kaminer. Note the attached Office	Action of form PTO-152.				
Priority u	ınder 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
2) Notic 3) Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <u>01/21/2009</u> .	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate				

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 21, 2009 has been entered.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-5 and 31-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. Patent 5,860,973) in view of Frey et al. (U.S. Patent 6,830,570) and Kuntz (U.S. Patent 4,349,921).

Michelson discloses a spinal fusion implant (900) that is generally rectangular in shape and comprising parallel top and bottom surfaces (902, 904) comprising a plurality of ridges (FIG 16), a tapered distal side, a proximal side, and first and second sidewalls (see diagram provided), such that a length extends between the distal and proximal sides, a width extends between the first and second sidewalls, and a height extends between the top and bottom surfaces (902, 904). The length is at least 40mm, the width is at least 15mm and the height is in the range of 8mm to 16mm (Column 10, lines 42-47).

Additionally, the implant includes at least one visualization aperture extending through at least one of the first and second sidewalls (FIG 16).

However, Michelson fails to disclose that the spinal fusion implant (900) includes first and second fusion apertures extending between the top and bottom surfaces. Frey et al. disclose a spinal fusion implant (1000) comprising top and bottom surfaces (1010, 1012) including first and second fusion apertures (1018a, 1018b, 1020a, 1020b) that are adjacent to one another and separated by a medial support (1019, 1024), the apertures being generally rectangular and oblong in shape. It therefore would have been obvious to one skilled in the art to modify the spinal fusion implant taught by Michelson by adding fusion apertures that extend between the top and bottom surfaces, as is taught by Frey et al., because the apertures promote fusion of upper and lower vertebrae to one another (Frey et al.; Column 17, line 40).

Michelson further fails to disclose that the implant (900) comprises a least one receiving element. Frey et al. disclose a spinal fusion implant (1000) that additionally comprising a least one receiving element (1044) comprising a threaded aperture engagable with an insertion instrument and a slot (1046) extending from the threaded aperture. It therefore would have been obvious to one skilled in the art to modify the implant taught by Michelson by having at least one receiving element (1044) along its proximal side, as is taught by Frey et al., because it allows for an insertion instrument to securely attach to the implant for controlled insertion into the disc space.

Additionally, Michelson in view of Frey et al. fail to disclose the specific material of the implant. Kuntz discloses a spinal implant (10) made of a radiolucent material, such

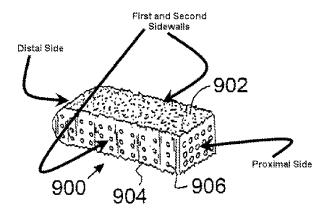
as high density polyethylene that additionally comprises a radiopaque marker (Column 7, lines 52-60). It therefore would have been obvious to one skilled in the art to modify the implant taught by Michelson in view of Frey et al. such that it is made up of a radiolucent material and also comprises a radiopaque marker between the top and bottom surfaces, as is taught by Kuntz, because the radiolucent material has "high strength and durability" and the radiopaque marker allows for "the position of the posthesis be confirmed radiologically" (Kuntz; Column 7, lines 52-60).

Michelson in view of Frey et al. and Kuntz further fail to disclose that the length of the implant is at least two and a half times greater that the width of the implant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the length be at least two and a half times greater than the width, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Finally, Michelson in view of Frey et al. and Kuntz fail to disclose that the implant is made of one of PEEK and PEKK. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the material of the implant be one of PEEK and PEKK, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

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Response to Arguments

4. Applicant's arguments with respect to claims 1-5 and 31-43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

Notice of References Cited Application/Control No. 11/093,409 Examiner ELANA B. FISHER Applicant(s)/Patent Under Reexamination CURRAN ET AL. Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	Α	US-5,860,973	01-1999	Michelson, Gary Karlin	606/247
*	В	US-4,349,921	09-1982	Kuntz, J. David	623/17.16
*	С	US-6,830,570	12-2004	Frey et al.	623/17.16
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Index of Claims Index of Claims Application/Control No. Applicant(s)/Patent Under Reexamination CURRAN ET AL. Examiner Cumberledge, Jerry 3733

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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	11093409	CURRAN ET AL.
	Examiner	Art Unit
	Cumberledge, Jerry	3733

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Search Notes

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Inventor Name Search Performed	2/27/2008	JLC					
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Becejpt date: 01/21/2009

Doc description Disclosure Statement (IDS) Filed

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	Application Number		11093409	
	Filing Date		2005-03-29	
INFORMATION DISCLOSURE	First Named Inventor Matthe		thew Curran	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		3733	
(Not for Submission under 67 Of K 1.33)	Examiner Name	Jerry	L. Cumberledge	
	Attorney Docket Number		104US1	

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