

Receipt Number  
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UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

ORTHOPEDIC DEVELOPMENT  
CORPORATION and MINSURG  
CORPORATION,

Plaintiffs,

v.

SILVER SURGICAL SUPPLY,

Defendant.

*Exhibits A-B*

Case: 4:08-cv-10696  
Judge: Gadola, Paul V  
Referral MJ: Majzoub, Mona K  
Filed: 02-19-2008 At 03:11 PM  
CMP ORTHOPEDIC DEVELOPMENT CORP., E  
T AL V SILVER SURGICAL SUPPLY (TAM)

BODMAN LLP

By: Dennis J. Levasseur (P39778)  
Candice B. Rusie (P70906)

6<sup>th</sup> Floor at Ford Field  
1901 St. Antoine Street  
Detroit, Michigan 48226  
(313) 259-7777

-and-

SHEPPARD, MULLIN, RICHTER &  
HAMPTON, LLP

By: Don J. Pelto, Esq.  
Kesari Ruza, Esq.  
1300 I Street, N.W., 11<sup>th</sup> Floor East  
Washington, DC 20005  
(202) 218-0000

Attorneys for Plaintiff

**COMPLAINT**

February 19, 2008

Plaintiffs Orthopedic Development Corporation ("ODC") and MinSURG Corporation ("MinSURG," and together with ODC sometimes referred to as "Plaintiffs") as and for its complaint ("Complaint") against defendant Silver Surgical Supply ("Silver Surgical" or "Defendant") alleges as follows:

### **PARTIES**

1. Plaintiffs ODC and MinSURG are corporations organized and existing under the laws of the State of Florida, with their principal place of business at 2730 McMullen Booth Road, Suite 203, Clearwater, Florida 33761. MinSURG is a wholly-owned subsidiary of ODC. MinSURG develops, manufactures, markets, and sells, in interstate commerce, human allograft tissue products (the "Allografts"), as well as associated surgical instrument sets (the "Instruments") under the trademark TruFUSE<sup>®</sup> (the "TruFUSE<sup>®</sup> Product(s)").

2. Upon information and belief, Defendant Silver Surgical is a corporation organized and existing under the laws of the State of Michigan, with its principal place of business at 1074 Center Ste B Auburn Hills, Michigan 48326. On or about March 9, 2007, Silver Surgical entered into a 12-month *Independent Distributor Agreement* with MinSURG (the "Distribution Agreement"), giving Silver Surgical the rights to market and distribute MinSURG's TRUFUSE<sup>®</sup> Products. In connection therewith, Silver Surgical provided TruFUSE<sup>®</sup> Instruments to various hospitals on consignment. Each hospital that received a set of TruFUSE<sup>®</sup> Instruments from Silver Surgical signed a TruFUSE<sup>®</sup> Allograft Consignment Inventory Agreement ("Consignment Agreement"). A copy of the Distribution Agreement in substantially the same form as entered into between the parties, along with a representative Consignment Agreement, are attached hereto as Exhibit "A"

**JURISDICTION AND VENUE**

3. The Court has personal jurisdiction over Silver Surgical because, upon information and belief, it is incorporated in the State of Michigan and transacts business in the State of Michigan.

4. The Court has subject matter jurisdiction over this action under 28 U.S.C. §§1331, 1338; Section 3 of the Lanham Act, 15 U.S.C. § 1121; 28 U.S.C. § 1332 (diversity); 28 U.S.C. § 1367 (supplemental jurisdiction). The amount in controversy exceeds \$75,000, exclusive of interest and costs. Venue is proper under 28 U.S.C. § 1391 (b) and (c).

**FACTS COMMON TO ALL CLAIMS**

**Back Pain and Spinal Facet Fusion**

5. Back pain is one of the most common ailments in adults, affecting an estimated 50 million people in the U.S. An estimated 80% of adults will experience back pain at some point in their life, while 50% of the working population have back pain every year. The National Center for Health Statistics reports that 14% of new patient visits to physician offices, or approximately 13 million annually, are for complaints of lower back pain. In the next 12 months, there will be more episodes of back pain than any other disease except the common cold. Facet joint disorders (degenerative conditions such as osteoarthritis) are among the most common of all the recurrent disabling lower back problems that cause serious symptoms. Facet joints are also gaining increasing favor as primary and supplementary fusion sites. The American Academy of Orthopedic Surgeons reports spinal fusion is the most commonly performed operation for back pain with approximately two million fusion procedures performed since 1990, and approximately 400,000 spinal fusions performed in 2007 in the U.S. alone.

**The TruFUSE<sup>®</sup> Products**

6. Plaintiffs' patent-pending TruFUSE<sup>®</sup> Product is a unique, novel spinal facet fusion system invented by Dr. David A. Petersen, M.D., FAAOS that offers a low-risk and minimally invasive surgical solution to back pain resulting from facet joint degeneration and from mild spinal instability. Among other things, the TruFUSE<sup>®</sup> Product significantly reduces a patient's time in the hospital, time off of work, recovery time, and rehabilitation time as compared to traditional spinal fusion surgeries. In most cases, the TruFUSE<sup>®</sup> surgery can be completed in less than an hour and requires no more than a one-night hospital stay. The TruFUSE<sup>®</sup> Product is sold through a network of over 40 distributors and is represented by some 300 sales representatives across the United States. As of January 15, 2008, over 2,500 TruFUSE<sup>®</sup> allograft sets have been sold in the United States, over 200 surgical instrument sets designed exclusively for use in implanting TruFUSE<sup>®</sup> allografts have been consigned to distributors, hospitals and surgeons. In addition, more than 100 surgeons have used TruFUSE<sup>®</sup> Products while more than 600 surgeons have been trained and certified in the technique and are awaiting hospital clearances. The overwhelming majority of patients treated with the TruFUSE<sup>®</sup> Products have reported a significant and lasting reduction in pain and a return to daily living routines with minimal recovery time.

7. TruFUSE<sup>®</sup> Products are packaged in three formats: (1) a single 5.0 mm dowel including two preformed Allografts and one drill bit per box; (2) a single spinal level 5.0 mm dowel including one preformed Allograft with one drill bit for every two boxes; and (3) a single 7.5 mm dowel including one preformed Allograft. Other Instruments designed for use with the Allografts (e.g., drill guides, holders, inserters and tamps) are reusable. One complete set of 5.0 mm Instruments is provided to each TruFUSE<sup>®</sup> certified surgeon upon completion of training. In addition, each distributor receives one 7.5 mm Instrument set for every ten 7.5 mm dowel sets

ordered. MinSURG also provides TruFUSE<sup>®</sup> Allografts and Instruments on consignment to both hospitals and distributors.

**The TRUFUSE<sup>®</sup> Trademark**

8. ODC is the owner of the TRUFUSE<sup>®</sup> mark, Registration No. 3,290,465, filed on November 16, 2005, for use in connection with "human allograft tissue" in International Class 5 (the "TRUFUSE<sup>®</sup> Mark"). The foregoing registration is current and valid. ODC has continuously offered and sold Allografts and associated Instruments under the TRUFUSE<sup>®</sup> Mark since at least January 1, 2006.

9. Plaintiffs have invested millions of dollars and have expended significant effort in developing and refining the product design, technique and surgical instruments in addition to advertising and promoting the TruFUSE<sup>®</sup> Products in conjunction with the TRUFUSE<sup>®</sup> Mark across the United States. Plaintiffs prominently display the TRUFUSE<sup>®</sup> Mark on all TruFUSE<sup>®</sup> Products, and clinical, training and marketing materials. As a result, TruFUSE<sup>®</sup> Products have become known and recognized by medical professionals throughout the United States as a symbol of unique, proprietary and effective surgical technique performed using high quality human allograft tissue products and surgical instruments.

**The Distribution Agreement**

10. On or about March 9, 2007, Silver Surgical entered into the Distribution Agreement with MinSURG whereby Silver Surgical became the exclusive licensee to promote, market, sell, and distribute TruFUSE<sup>®</sup> Products in Michigan (the "Territory").

11. The Distribution Agreement was structured to continue for a period of twelve months, and was renewable by MinSURG for additional twelve month periods, unless otherwise terminated by MinSURG.

12. Section 12 of the Distribution Agreement addresses Proprietary Rights and states:

Except as otherwise provided herein, MinSURG expressly retains title and ownership to all worldwide intellectual property rights, including without limitation, design, know-how, patent rights, trademarks, and copyrights in and to the Products, TruFUSE and MinSURG trademarks, service marks and logos, and any modifications, adaptations, derivative works, and enhancements made thereto.

13. Section 14.1 of the Distribution Agreement sets forth Silver Surgical's permitted use of the TRUFUSE<sup>®</sup> Mark, and prohibits Silver Surgical from "adopt[ing], us[ing] or register[ing] any words, phrases or symbols which are identical or confusingly similar to [the TRUFUSE<sup>®</sup> Mark] or oppose any such registration by MinSURG or it's [sic] affiliates."

14. Section 14.3 of the Distribution Agreement addressed any potential infringing products, and stated:

[Silver Surgical] shall provide prompt notice to MinSURG of any infringement or potential infringement of the TruFUSE Marks by a third party and of any challenge to its use of the TruFUSE marks by a third party...Distributor shall cooperate fully with MinSURG in any legal action taken by MinSURG against such third parties, provided that MinSURG shall pay all expenses of such action and all damages which may be awarded or agreed upon in settlement of such action shall accrue to MinSURG.

15. Upon commencement of the Distribution Agreement, ODC and MinSURG provided Silver Surgical with TruFUSE<sup>®</sup> Products, with training regarding the TruFUSE<sup>®</sup> Products and technical and sales literature to promote, market, and sell the TruFUSE<sup>®</sup> Products in the Territory. Silver Surgical then began distributing the TruFUSE<sup>®</sup> Products and provided Plaintiffs' Instruments on consignment with hospitals and medical professionals in the Territory. *See* Consignment Agreement, Exh. "A".

16. In or about November 2, 2007, MinSURG terminated the Distribution Agreement with Silver Surgical because Silver Surgical was providing its customers with significant discounts on TruFUSE<sup>®</sup> Products outside of MinSURG's approved pricing structure.

**Nutech Medical Inc.'s Competing Facet Fusion Product**

17. On or about September 17, 2007, Plaintiffs received a report from one of its distributors that another one of its distributors, Nutech Medical, Inc. ("Nutech"), was developing and marketing a "TruFUSE<sup>®</sup> knock-off" facet fusion product. Upon further investigation, Plaintiffs learned that Nutech was planning to market a competitive facet fusion product under the confusingly similar name "NUFUZE" and that the product, upon information and belief, incorporates Plaintiffs' proprietary information and trade secrets provided to Nutech pursuant to its distribution agreement with Plaintiffs and is a copy of the TruFUSE<sup>®</sup> Products. Among other things, ODC received reports from one of its new hires, that prior to commencing his employment with ODC, Nutech had engaged him as a consultant to review designs for a new spinal facet fusion product Nutech intended to market. After reviewing the product, the surgeon came to the conclusion that Nutech's new product was "essentially the same as TruFUSE<sup>®</sup>."

18. Upon hearing that the Nutech facet fusion product was to be marketed under the "NUFUZE" mark, Plaintiffs conducted a United States Patent and Trademark Office (the "USPTO") database search and confirmed that Nutech had indeed registered the trademark NUFUZE, along with the trademark BIOFUZE, in the category of "[s]urgical implants compromising allograft or other processed human or animal tissue and associated surgical instrument sets" (the "Nutech Trademark Applications"). On December 5, 2007, ODC filed a Notice of Opposition to the Nutech Trademark Applications with the Trademark Trial and Appeal Board. On January 14, 2008, Nutech filed an answer to ODC's Opposition to the Nutech Trademark Applications abandoning its application for registration of the NUFUZE and BIOFUZE marks.

19. Plaintiffs further learned that Kenneth Horton ("Horton"), Nutech's President and sole owner and an ODC shareholder, had incorporated NuFuze, Inc. as a corporate entity separate from Nutech in the State of Alabama on March 1, 2007 and that NuFuze, Inc.'s corporate name was changed to NuFix, Inc. on August 7, 2007. Horton is listed as the incorporator and sole shareholder of NuFix and the address of the corporation is the same as that of Nutech.

20. Beginning in or about December 2007, Plaintiffs learned that Nutech began marketing its competing allograft product to TruFUSE<sup>®</sup>-trained surgeons under the brand names "NuFuze" and/or "NuFix." On or about December 31, 2007, Plaintiffs received confirmation from its Los Angeles based distributor that a surgeon that uses TruFUSE<sup>®</sup> in his practice reported being contacted by a Nutech distributor offering "NUFUZE" at a "drastically reduced price."

21. On or about January 9, 2008, Plaintiffs received a report from its Michigan distributor that Silver Surgical had commenced marketing and selling Nutech's facet fusion product under the brand name "NuFix" to surgeons and hospitals in Ohio and Michigan. In addition, Plaintiffs' Michigan distributor reported that in connection with distributing NuTech's competing facet fusion product, Silver Surgical was making "disparaging comments directed toward the TruFUSE<sup>®</sup> Product, organization and clinical efficacy." Upon information and belief, the surgeons and hospitals targeted by Silver Surgical for distributing Nutech's facet fusion product use or used TruFUSE<sup>®</sup> Products.

22. On January 22, 2008, ODC received a report from its Ohio distributor that, according to a surgeon that uses TruFUSE<sup>®</sup> Products in his practice, a surgical product distribution company attempted to convince him to use NuFix instead of TruFUSE<sup>®</sup> Products on the same day as a planned surgery saying that "they use they same [surgical] instrumentation [as

TruFUSE<sup>®</sup>] and that the only difference is that the product has ridges.”

23. On February 7, 2008, ODC and MinSURG filed a complaint in the United States District Court, Middle District of Florida against Nutech, NuFix, Horton, and Todd Gilbert ("Gilbert"), another ODC shareholder involved in the creation of Nutech's/NuFix's facet fusion product ("Florida Complaint"). The Florida Complaint alleges, among other things, that the sale of Nutech's/NuFix's facet fusion product constitutes trademark infringement, unfair competition and false advertising under both the Lanham Act and state law, entitling Plaintiffs to both injunctive relief and damages. In addition, the Florida Complaint alleges misappropriation of trade secrets and breaches of contract against Nutech, Horton and Gilbert.

24. On the same day, Plaintiffs sent a letter to Silver Surgical putting Silver Surgical on formal notice of the claims asserted against Nutech, NuFix, Horton and Gilbert in connection with the sale of Nutech's/NuFix's facet fusion product, demanding that Silver Surgical discontinue all infringing activities related to Nutech's/NuFix's facet fusion product and provide assurances to Plaintiffs that it had ceased all of its infringing activities within ten (10) days, by February 18, 2008. A true and correct copy of Plaintiffs' cease and desist letter is attached hereto as Exhibit "B".

25. Plaintiffs did not receive the requested assurances by February 18, 2008, and upon information and belief, Silver Surgical continues to distribute Nutech's/NuFix's infringing facet fusion product.

26. Upon information and belief, Silver Surgical is marketing Nutech's/NuFix's facet fusion product to hospitals using Nutech/NuFix marketing, pitch and other presentation materials (the "Nutech Materials"). Upon information and belief, the Nutech Materials falsely claim, among other things, that (a) the TruFUSE<sup>®</sup> Allograft has a tendency to pop out after it is implanted and that the ridge design of NuFix reduces this occurrence; and that (b) NuFix is

designed to be used with TruFUSE<sup>®</sup> Instruments held on consignment by hospitals.

27. By virtue of the foregoing acts, Defendant has, among other things, contributed to the creation of a strong likelihood of consumer confusion as to the source of origin or relationship of TruFUSE<sup>®</sup> and Nutech's/NuFix's facet fusion product and has otherwise contributed to Nutech's/NuFix's unfair competition with Plaintiffs, which has caused and will continue to cause irreparable injury to Plaintiffs' brand, business reputation and good will, the loss of business and other damages.

**CAUSES OF ACTION**

**FIRST CAUSE OF ACTION**

(Lanham Act Unfair Competition -- False Designation of Origin)

(15 U.S.C. §1125(a)(1)(A))

28. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 28 of the Complaint as if fully set forth herein.

29. The foregoing conduct of Silver Surgical constitutes direct and contributory unfair competition, false designation of origin, and false and misleading descriptions and/or representations of fact that are likely to cause confusion or mistake, or to deceive consumers as to the affiliation, connection, or association of Nutech's competing facet fusion product with the TruFUSE<sup>®</sup> Products or as to the origin, sponsorship, or approval of Nutech's facet fusion product or other commercial activities, in violation of 15 U.S.C. § 1125(a)(1)(A).

30. Further, by virtue of having entered into the Distribution Agreement with Plaintiffs, Silver Surgical knew, or could have reasonably anticipated or expected, that its actions would contribute to and further Nutech's acts of unfair competition in violation of 15 U.S.C. § 1125(a)(1)(A).

31. As a result, Plaintiffs have suffered and continue to suffer monetary damages in an amount to be determined at trial, inclusive of attorneys' fees and costs under 15 U.S.C. § 1117.

32. The damage caused by Silver Surgical's actions is not entirely susceptible to ready or precise calculation in that such damage also involves lost profits, lost business opportunities, loss of goodwill and reputation, and confusion of consumers, such that monetary damages alone cannot adequately compensate Plaintiffs for Silver Surgical's misconduct. Unless permanently enjoined by the Court, Silver Surgical will continue to make false descriptions and representations and to pass off Nutech's competing facet fusion product as affiliated with Plaintiffs, all to Plaintiffs' irreparable injury.

### **SECOND CAUSE OF ACTION**

(Lanham Act Unfair Competition – False Advertising) (15 U.S.C. § 1125(a)(1)(B))

33. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 33 of Complaint as if fully set forth herein.

34. Silver Surgical, through its marketing activities set forth in Paragraphs 22 through 27 above, misrepresents the nature, characteristics and qualities Nutech's/NuFix's facet fusion product and the TruFUSE<sup>®</sup> Products, constituting unfair competition and false advertising in violation of 15 U.S.C. § 1125(a)(1)(B).

35. Further, by virtue of having entered into the Distribution Agreement with Plaintiffs, Silver Surgical knew, or could have reasonably anticipated or expected, that its actions would contribute to and further Nutech's acts of unfair competition and false advertising in violation of 15 U.S.C. § 1125(a)(1)(B).

36. As a result, Plaintiffs have suffered and continue to suffer monetary damages in an amount to be determined at trial, inclusive of attorneys' fees and costs under 15 U.S.C. §

1117.

37. The damage caused by Silver Surgical's actions is not entirely susceptible to ready or precise calculation in that such damage also involves lost profits, lost business opportunities, loss of goodwill and reputation, and confusion of consumers, such that monetary damages alone cannot adequately compensate Plaintiffs for Silver Surgical's misconduct. Unless permanently enjoined by the Court, Silver Surgical will continue to falsely advertise the nature, characteristics and qualities of Nutech's facet fusion product, all to Plaintiffs' irreparable injury.

**THIRD CAUSE OF ACTION**

(Common Law Unfair Competition)

38. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 38 of the Complaint as if fully set forth herein.

39. Silver Surgical has engaged in unfair competition under the common law of the State of Michigan by, among other things, causing confusion in the marketplace as to the origin of Nutech's/NuFix's facet fusion product, mistake or deception as to the nature and extent of an affiliation between Nutech/NuFix and Plaintiffs, or as to the origin, sponsorship or approval of Nutech's/NuFix's products and services.

40. By reason of the foregoing acts, Silver Surgical has willfully, intentionally and unfairly competed with Plaintiffs in violation of the common law of the State of Michigan.

41. By reason of Silver Surgical's actions alleged herein, Silver Surgical has caused, and is continuing to cause, monetary damage to Plaintiffs in an amount to be determined at trial, and will continue to cause irreparable injury to Plaintiffs unless and until such unfair activities are permanently enjoined by this Court.

**FOURTH CAUSE OF ACTION**

(Michigan Consumer Protection Act)

42. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 41 of the Complaint as if fully set forth herein.

43. The acts described above constitute violations of the Michigan Consumer Protection Act.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs requests the following relief:

- (a) That Silver Surgical and all persons acting in concert or privity with them, including their respective officers, agents, servants, employees, successors and assigns, jointly and severally, be permanently enjoined from committing any further acts constituting direct and/or contributory unfair competition and false advertising;
- (b) That Silver Surgical be directed to immediately cease distributing any infringing bone allograft products on behalf of Nutech/NuFix or any other entity;
- (c) That Silver Surgical be required to file with this Court and serve on Plaintiffs' counsel within 14 days after issuance of a permanent injunction herein, or within such reasonable time as this Court shall direct, a report in writing and under oath setting forth in detail the manner and form in which Silver Surgical has complied with such injunction;
- (d) That Plaintiffs have judgment against Silver Surgical for disgorgement of profits, lost profits and compensatory damages in connection with its distribution of Nutech's/NuFix's competing facet fusion product;

- (e) That Plaintiffs be awarded statutory damages, attorney's fees, costs, and prejudgment interest pursuant to 15 U.S.C. § 1117, including but not limited to damages for willful infringement under 15 U.S.C. § 1125(c);
- (f) That Plaintiffs be awarded the costs and disbursements of this action, together with reasonable attorney's fees; and
- (g) That Plaintiffs be awarded such other and further relief as the Court deems just and proper.

Respectfully submitted,

BODMAN LLP

By: 

Dennis J. Levasseur (P39778)

Candice B. Rusie (P70906)

6<sup>th</sup> Floor at Ford Field

1901 St. Antoine Street

Detroit, Michigan 48226

(313) 259-7777

[dlevasseur@bodmanllp.com](mailto:dlevasseur@bodmanllp.com)

[crusie@bodmanllp.com](mailto:crusie@bodmanllp.com)

-and-

SHEPPARD, MULLIN, RICHTER &  
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By: Don J. Pelton, Esq.

Kesari Ruza, Esq.

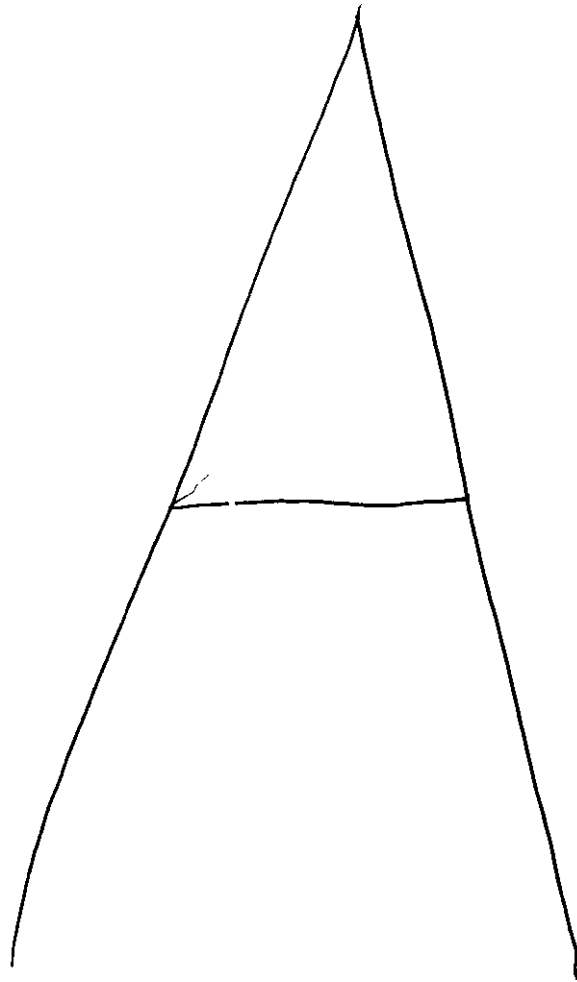
1300 I Street, N.W., 11<sup>th</sup> Floor East

Washington, DC 20005

(202) 218-0000

Attorneys for Plaintiffs

February 19, 2008





## INDEPENDENT DISTRIBUTOR AGREEMENT

THIS INDEPENDENT DISTRIBUTOR AGREEMENT is made as of the \_\_\_\_ day of \_\_\_\_\_, 2007 (the "Effective Date") by and between MinSURG Corporation, a Florida corporation, having its principal place of business at 2730 McMullen Booth Road, Suite 203, Clearwater, Florida 33761 ("MinSURG") and Silver Surgical a, having its principal place of business at Silver Surgical, 1074 Center, Suite B, Auburn Hills, MI 48326 ("Distributor"). MinSURG and the Distributor are sometimes referred to herein as the "Parties" and individually as "Party."

### RECITALS

**WHEREAS**, MinSURG is the sole and exclusive provider of the TruFUSE<sup>®</sup> spinal facet fixation system ("TruFUSE");

**WHEREAS**, Distributor desires to market and distribute TruFUSE; and

**WHEREAS**, MinSURG and Distributor deem it to be in their mutual best interests to enter into an agreement whereby Distributor shall be appointed as an exclusive distributor of TruFUSE in certain territories as hereinafter provided.

**NOW THEREFORE**, in consideration of the terms, conditions and mutual covenants contained herein, the Parties hereto agree as follows:

### 1. DEFINITIONS

For purposes of this Agreement, the following words shall have the following meanings:

1.1 "**Agreement**" means this Independent Distributor Agreement and all exhibits, schedules and annexes which are attached to this Agreement from time to time and form a part hereof.

1.2 "**Confidential Information**" is defined in Section 13.1.

1.3 "**Customer**" means any MinSURG approved medical doctor, clinic, and hospital purchasing Products in the Territory from Distributor.

1.4 "**TruFUSE Marks**" means the trademarks, trade names, service marks, domain names, logos and other commercial symbols identifying TruFUSE.

1.5 "**Prices**" mean the prices payable by Distributor to MinSURG as consideration for the purchase by Distributor of the Products, as set forth in Exhibit A.

1.6 "**Products**" mean the TruFUSE products described in Exhibit A.

1.7 "**Proprietary Information**" is defined in Section 13.1.

1.8 "**Territory**" means the specific states or geographic areas set forth in Exhibit A and any other geographic area designated by MinSURG for the exercise of Distributor's rights and obligations in this Agreement.

1.9 "**Trade Secrets**" is defined in Section 13.1.

1.10 “**Trained Surgeon**” is defined in Exhibit A.

1.11 “**Hospital**” or “**Provider**” means the hospital or surgery center responsible for payment of the Products where the Trained Surgeons practice.

## 2. APPOINTMENT

2.1 **Grant of Rights.** MinSURG hereby grants to Distributor, and Distributor hereby accepts, upon the terms and conditions set forth in this Agreement, the exclusive right to promote, market, sell, and distribute Products to Customers located within the Territory.

2.2 **Technical and Sales Literature License.** During the term of this Agreement, and subject to its terms and conditions, MinSURG grants to Distributor a nonexclusive, nontransferable, royalty free license, to use the TruFUSE sales and technical literature and materials to promote, market, sell and distribute the Products in the Territory. The Parties hereto hereby acknowledge that the provisions of this Agreement are also subject to the Policies and Procedures set forth in Exhibit A attached hereto.

2.3 **Sales Outside the Territory; Internet Sales.** Distributor shall not distribute, sell or otherwise provide the Products outside the Territory and shall not advertise, promote or solicit Customers for the Products outside the Territory, unless authorized in writing by MinSURG. Distributor may promote and sell Products using the Internet, provided however, Distributor shall not accept or fill orders for Products from Customers located outside the Territory and shall not deliver Product to or for a Customer outside the Territory. MinSURG and Distributor shall monitor the distribution and sale of Products within the Territory to insure that the Products are not, directly or indirectly, being redistributed or resold outside the Territory.

2.4 **Reserved Rights.** Except as otherwise set forth in this Agreement, no express or implied right is granted to Distributor regarding the Products, the TruFUSE technical and sales literature and the TruFUSE Marks and Distributor acknowledges that all copyright, patent, trade secret and other intellectual property rights in and to the Products, TruFUSE technical and sales literature and the TruFUSE Marks are the sole property of MinSURG. MinSURG reserves all rights not expressly granted herein.

2.5 **Sub-Distributors.** Distributor shall not, without the prior written consent of MinSURG, appoint any new sub-distributors to promote, market, distribute and sell the Products within the Territory. Distributor shall submit to MinSURG, for its prior approval, a copy of any written agreement, or the terms and conditions of any oral agreement, proposed to be entered into between Distributor and any proposed sub-distributor.

## 3. ADDITIONAL PRODUCTS

3.1 **Related Products.** MinSURG may from time to time offer related products for sale, which are not listed in Exhibit A (“Related Product(s)”). Such Related Product(s), new or not, may be incorporated into this Agreement by written amendment at any time during the term of this Agreement. If MinSURG, in its sole discretion, chooses to distribute such Related Products in the Territory during the term of this Agreement, MinSURG shall offer Distributor the exclusive right to promote, market, sell and distribute such Related Products in the Territory subject to this Agreement, which offer shall be open for acceptance for a period no longer than thirty (30) days. In the event that Distributor chooses not to accept MinSURG’s offer to include any such Related Products in this Agreement, MinSURG may use other persons or entities to act as distributors of such Related Product(s) to Customers in the Territory without further obligation to Distributor.

#### 4. GENERAL OBLIGATIONS OF DISTRIBUTOR

**4.1 Minimum Sales Requirement.** During the term of this Agreement, Distributor shall make the minimum sales of the Products from MinSURG set forth in Exhibit A ("Minimum Sales Requirement"). Sales counted toward the Minimum Sales Requirement for any period provided herein shall be based on the Products which are paid for prior to the expiration of the applicable period. Distributor understands and agrees that achievement of Minimum Sales Requirement is of the essence of this Agreement and the failure of Distributor to achieve at least eighty percent (80%) of the Minimum Sales Requirement conditions in Exhibit A in any three month period shall, upon thirty (30) days written notice by MinSURG, constitute grounds for the conversion of this contract from exclusive to a non-exclusive right to the channel and territory (all other provisions of the contract remaining unchanged), while failure to achieve the minimums in any 12 month period is grounds for non-renewal of the contract at the Company's option as of the renewal period following such failures. However, notice of intention not to renew based on performance must be given 30 days in advance of the new renewal period.

**4.2 Promotion and Marketing.** Distributor shall use commercially reasonable efforts to further the promotion, marketing, sale and distribution of the Products in the Territory, including but not limited to, building brand awareness and value. MinSURG may, in its reasonable discretion, prepare promotional programs for the Products in the Territory and Distributor agrees to cooperate with MinSURG in sales or promotional programs prepared by MinSURG. Distributor shall not make any materially misleading or untrue statements concerning the Products.

**4.3 Competing Products.** During the term of this Agreement, Distributor shall not, and shall cause its agents and representatives to not, sell, distribute, market, advertise or solicit sales orders for any product that MinSURG deems to be similar to or competitively positioned against the Products in the Territory.

**4.4 Business Plan.** During the term of this Agreement at such times as mutually agreed between the Distributor and MinSURG, the Distributor shall submit to MinSURG a mutually agreeable marketing and business plan ("Business Plan") for marketing, distribution and sale of the Products in the Territory. The Business Plan may include a description of the Distributor's sales organization, a competitive market analysis, methods of distribution, a marketing plan, projected quarterly sales by Product, and other information.

**4.5 Forecasts.** Distributor shall provide to MinSURG on a monthly basis a three (3) month rolling forecast of Distributor's projected purchase orders in a form acceptable to MinSURG. The forecasts are for planning purposes only and shall not be binding on Distributor or MinSURG.

**4.6 Personnel and Physician Training.** Distributor shall maintain competent and trained personnel for marketing and distribution of the Products in the Territory. Distributor shall be responsible for arranging personnel and physician training with MinSURG regarding the Products.

**4.7 Governmental Requirements.** In the event the Distributor shall be handling human tissue directly, the Distributor shall at all times be duly registered as a tissue bank under the laws of the United States and shall (i) comply with all applicable laws and regulations of the United States and the Territory, including but not limited to, laws and restrictions and regulations of the Food and Drug Administration ; (ii) in the event such regulations may be initiated at some time by regulating authorities, assist MinSURG in obtaining any required registrations, licenses and permits for the Products and the marketing, sale and distribution of the Products in the Territory by supplying such documentation or information as may be reasonably requested by

MinSURG; and (iii) obtain and maintain during the term of this Agreement all governmental approvals and licenses necessary to import the Products into the Territory. If any governmental registration, license or approval for the marketing, sale and distribution of the Products is required, Distributor shall obtain MinSURG written approval prior to commencing any registration or approval process. Unless otherwise required by applicable law, all registrations, licenses and approvals for the Products and the distribution of the Products in the Territory shall be in the name of and shall be solely owned by MinSURG. MinSURG will reimburse Distributor for any pre-approved and reasonable fees for such registrations, licenses and approvals that are in MinSURG's name or are transferred to MinSURG upon termination of the Agreement. Distributor shall provide MinSURG with a copy of all registrations, licenses and approvals obtained or received for the Products and distribution of the Products in the Territory within five (5) business days of Distributor's receipt of each such registration, license and approval.

**4.8 Distributor Expenses.** Except as otherwise specifically provided herein, Distributor assumes full responsibility for all its own costs and expenses incurred in carrying out its obligations under this Agreement, including but not limited to all rents, salaries, commissions, advertising, translations of documents and materials, demonstration, training, travel and accommodation for the employees, agents, representatives or other personnel of Distributor.

**4.9 Marketing Materials.** All marketing materials created by or for Distributor relating to the Products shall be approved by MinSURG prior to use by Distributor. Such marketing materials shall contain copyright, trademark and other notices as approved by MinSURG.

**4.10 Reports and Reviews.** Distributor shall provide MinSURG with reports of its activities, competitor activities, and other information regarding the Products and the markets for the Products in the Territory in such detail and with such frequency as MinSURG and Distributor shall mutually agree and as defined in Exhibit A. Distributor agrees to participate with MinSURG in quarterly reviews to discuss Distributor's sales, marketing, and business plan for distribution of the Products, and sales achievements and objectives no later than three weeks after the quarter end as defined in Exhibit A.

## 5. GENERAL OBLIGATIONS OF MINSURG

**5.1 General.** MinSURG shall use commercially reasonable efforts to maintain and enhance the reputation, usefulness, and acceptance of its Products and to assist Distributor in all reasonable ways to promote the sale of the Products in the Territory.

**5.2 Distributor Training.** MinSURG shall provide initial training on the Products for Distributor's sales force and subsequent training upon the release of new Products or Related Products subject to this Agreement. The date, duration, content and location of the initial training and training relating to any new Products or Related Products subject to this Agreement, shall be mutually agreed upon by the Parties. Unless otherwise agreed, initial training will be performed at the MinSURG training center in Clearwater, Florida. Notwithstanding the foregoing, Distributor shall bear all costs of travel and living expenses for Distributor's personnel to attend any training whether during the initial period or subsequent thereto. If training is provided at Distributor's location, Distributor shall provide reasonable training facilities without expense to MinSURG. For training in addition to that identified above, MinSURG and Distributor shall mutually agree in writing on the charges for such training, in advance of the training, including but not limited to MinSURG travel and other related expenses.

**5.3 Trained Surgeon Training; Hospital Approval.** Distributor shall be responsible to arrange physician training for those to become Trained Surgeons, which training shall be performed by MinSURG or its certified regional trainers, and will be performed by phone and, for more complicated techniques, either at the MinSURG training center or at the Trained

Surgeon's location as necessary. There will be no additional fee for training and certification of Trained Surgeons. It shall be the responsibility of Distributor to ensure that TruFUSE is approved for use in at least one hospital where each Trained Surgeon has admitting and Operating Room rights. Upon request, MinSURG will assist Distributor in obtaining such approval.

5.4 **Marketing Support.** MinSURG shall provide Distributor with an electronic and one hard copy of TruFUSE technical and sales literature and materials.

## 6. PURCHASE OF PRODUCTS AND SERVICES BY HOSPITALS AND OTHER APPROVED PROVIDERS

6.1 **Purchase Orders and Delivery.** MinSURG shall use its reasonable best efforts to deliver ordered Products timely upon receipt of a purchase order from Distributor's client hospitals or surgery centers.

6.2 **Modification of Orders.** Except as otherwise agreed to in writing or as otherwise set forth herein, all order(s) are non-cancelable, non-refundable and non-exchangeable. All order(s) placed with MinSURG for Products shall be made through the submission of a Purchase Order. Notwithstanding the content of Distributor's purchase order, this Agreement shall take precedence over Distributor's purchase order, and, subject to applicable law, in the event of any conflicting, inconsistent or additional terms of Distributor's purchase order, the terms of this Section 6 shall prevail.

6.3 **Delivery.** All deliveries of the Products to Hospitals and other Providers shall be FOB Tampa, FL.

6.4 **Product Changes.** MinSURG may do any of the following upon reasonable notice and without liability to Distributor:

- (a) Alter the specifications for any Product or any new Product or Related Product;
- (b) Discontinue the development of any new Product, whether or not such new Product has been announced publicly and discontinue the sale of any Product; and
- (c) Commence the development and distribution of new Products and Related Products which may make any Product obsolete.

## 7. COMMISSIONS

7.1 **Commissionable sales.** The Distributor shall be compensated according to the following formula, which compensation shall be paid monthly on or before the fifteenth of each succeeding month on Sales for which payment has actually been received by MinSURG during the preceding month. The Parties agree that their respective taxes shall be their sole responsibility.

**Commission Amount:** The Distributor shall receive 25% (twenty five percent) of Provider pricing for all Product sales actually made by the Distributor under terms and conditions accepted by MinSURG arising within the Distributor's Territory as defined in Exhibit A and amended or adjusted from time to time as provided herein. Such Commissions exclude charges for shipping and other ancillary costs of delivering Product to the Provider.

## 8. TERMS AND TERMINATION

8.1 **Term.** This Agreement shall commence on the Effective Date, shall continue in effect for a period of twelve (12) months and shall be automatically renewed for additional 12 month periods, unless otherwise terminated pursuant to the provisions hereof.

(a) Notwithstanding any other provision of this Agreement, either Party shall have the right to immediately terminate this Agreement for cause by giving written notice of such termination to the other Party, if the other Party fails to comply with any material term hereof and fails to correct such lack of compliance within thirty (30) days after receipt of written notice of such failure. Without limiting the foregoing, any failure by Distributor to pay amounts when due shall be deemed a failure to comply with a material term of this Agreement and MinSURG shall be entitled to immediately terminate this Agreement without further notice to Distributor and opportunity to cure.

(b) Either Party may immediately terminate this Agreement for cause by giving written notice of such termination to the other Party upon the occurrence of any of the following events:

(i) if the other Party makes a voluntary petition in bankruptcy, insolvency or similar petition;

(ii) an involuntary petition in bankruptcy, insolvency or similar petition is made against the other Party;

(iii) if the other Party becomes insolvent or makes a general assignment for the benefit of creditors, suffers or permits an appointment of a receiver for its business or assets or is liquidated; or

(iv) the enactment or adoption of any change in laws, rules, regulations or governmental policies or other change in circumstances that makes it illegal, impossible or impracticable to export, import, market, sell and distribute the Products to or in the Territory as contemplated in this Agreement.

(c) Either party may terminate this agreement upon thirty days written notice to the other party.

8.2 **Rights Upon Termination.** Upon termination or expiration of this Agreement: (a) all of Distributor's rights granted hereunder shall immediately cease; (b) Distributor shall return to MinSURG or destroy at MinSURG's direction any and all language translations of MinSURG's sales and technical literature and materials in Distributor's possession or control; (c) Distributor shall return to MinSURG any Products in its possession; (d) Distributor shall immediately return to MinSURG all other MinSURG property, including, but not limited to, all original documents and copies which contain MinSURG Proprietary Information; (e) Distributor shall deliver to MinSURG such documents and instruments as MinSURG may reasonably request in connection with the termination or expiration of this Agreement; and (f) Distributor shall remove from its facilities and other premises all signs, billboards and other similar items bearing any of the TruFUSE Marks or identifying Distributor as an authorized distributor of MinSURG or the Products and, within a reasonable period of time following such termination, withdraw or cancel any registrations or filings with governmental authorities relating to Distributor's use of any of the TruFUSE Marks. In the event of a termination of this Agreement under Section 8.1, subject to the applicable provisions of this Section 8.2, neither Party shall owe any compensation to the other Party for lost profits, lost opportunities, goodwill, or any other loss or damages as a result

of or arising from such termination. Except as required for Distributor's performance of obligations under this Section 8.2 or Section 8.3, upon expiration or earlier termination of this Agreement, Distributor shall immediately cease and desist from any further use of Proprietary Information of MinSURG.

8.3 **Surviving Terms.** The provisions of Sections 2.3, 2.4, 7, 8.2, 9, 10, 11, 12, 13, 14, and 15 shall survive the expiration or the termination of this Agreement by either Party for any reason.

## 9. MINSURG WARRANTY AND INDEMNITY.

9.1 **Limited Warranties.** Subject to Section 9.2, MinSURG represents and warrants to Distributor that (a) MinSURG has full authority to execute and perform this Agreement; (b) this Agreement has been duly executed and delivered by MinSURG and constitutes MinSURG's legal, enforceable and binding obligation; (c) MinSURG's execution and performance of this Agreement will not conflict with the terms or conditions of any other agreement or contract to which it is a party or is otherwise bound; and (d) no approval, action or authorization by any governmental authority or agency is required for MinSURG's execution and performance hereof (except for governmental certifications, registrations, licenses and approvals for the export of the Products to the Territory) which has not already been obtained.

9.2 **Disclaimer of Warranties.** MINSURG PROVIDES NO WARRANTIES, EITHER EXPRESS OR IMPLIED, WITH REGARD TO THE PRODUCTS OR THE TRUFUSE MARKS, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

### 9.3 MinSURG Indemnification.

(a) MinSURG shall defend, indemnify and hold harmless Distributor from and against any claim of a third party to the extent arising from the negligence or willful misconduct of MinSURG, its employees, agents, or contractors (other than Distributor) in the performance of its obligations under this Agreement. MinSURG will pay resulting court costs, damages and legal fees finally awarded, provided Distributor promptly notifies MinSURG in writing of any such claim, MinSURG has sole control of the defense and all related settlement negotiations, and Distributor provides MinSURG with such assistance and all related information for such defense as MinSURG may reasonably request.

(b) MinSURG shall defend, indemnify and hold Distributor harmless from and against any claim that the Products, TruFUSE technical and sales literature or the TruFUSE Marks infringe, in the Territory, a patent, trademark or copyright of a third party (a "Claim"), and pay resulting court costs, damages and legal fees incurred in connection with such Claim, provided (i) Distributor notified MinSURG promptly in writing of any such Claim and (ii) gives MinSURG sole control of the defense of the same and all negotiations for its settlement or compromise. Should any Products become, or in MinSURG's opinion be likely to become, the subject of a claim of infringement, Distributor shall permit MinSURG, at MinSURG's option and expense, to (x) procure for Distributor the right to continue using the Products, (y) replace or modify the Products to become non-infringing, or (z) if neither procurement or replacement are commercially reasonable, terminate this Agreement by giving written notice thereof to the Distributor, with no further obligation or liability to Distributor. Notwithstanding the foregoing, MinSURG shall have no liability for any claim of infringement to the extent based upon any modification of the Products, TruFUSE technical and sales literature and the

TruFUSE Marks not made by MinSURG or its authorized representatives. THE FOREGOING STATES THE ENTIRE LIABILITY OF MINSURG WITH RESPECT TO INFRINGEMENT IN THE TERRITORY OF ANY PROPERTY RIGHT OF A THIRD PARTY BY THE PRODUCTS, TRUFUSE TECHNICAL AND SALES LITERATURE AND THE TRUFUSE MARKS.

#### 10. DISTRIBUTOR WARRANTY AND INDEMNITY

10.1 **Limited Warranties.** Distributor represents and warrants to MinSURG that (a) Distributor has full authority to execute and perform this Agreement; (b) this Agreement has been duly executed and delivered by Distributor and constitutes Distributor's legal, enforceable and binding obligations; (c) Distributor's execution and performance of this Agreement will not conflict with the terms or conditions of any other agreement or contract to which Distributor is a party or is otherwise bound; and (d) no approval, action, registration, license or authorization by any governmental authority or agency is required for Distributor's execution and performance hereof which has not already been obtained.

10.2 **Distributor's Indemnification.** Distributor shall defend, indemnify and hold harmless MinSURG from and against any claim of a third party that is either reduced to final, non-appealable judgment or settled with Distributor's consent, not to be unreasonably withheld, to the extent arising out of or resulting from:

(a) Distributor's and sub-distributor's negligent acts or omissions or willful misconduct in the use, import, marketing, promotion, advertising, distribution and sale of the Products, including but not limited to Distributor's and sub-distributor's promotional or advertising materials for the Products;

(b) Any statements, claims, representations or warranties made by Distributor or sub-distributors relating to the Products, other than as authorized or made by MinSURG in writing, including but not limited to those made in the TruFUSE technical and sales literature and materials;

(c) Any breach by Distributor of it's obligations under this Agreement; and

(d) Any infringement or claim thereof of any patent, copyright, trademark, service mark, trade name, trade secret or any other property right of a third party arising from the use by Distributor of (i) any symbol, insignia, name or identifying characteristic other than the TruFUSE Marks, (ii) any combination of any TruFUSE Mark with any materials not provided or approved by , (iii) any modification to the Products not made by MinSURG, or (iv) any use of the Products not authorized or certified by MinSURG or by the TruFUSE technical and sales literature and materials.

#### 11. LIMITATION OF LIABILITY.

11.1 IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR CONSEQUENTIAL, EXEMPLARY, INCIDENTAL OR INDIRECT OR PUNITIVE DAMAGES OR LOSS OF GOODWILL, BUSINESS OPPORTUNITY OR PROFIT, IN CONNECTION WITH THE SUPPLY, USE OR PERFORMANCE OF THE PRODUCTS PROVIDED HEREUNDER, OR IN CONNECTION WITH ANY CLAIM ARISING FROM OR RELATED TO THIS AGREEMENT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR IF THE EXCLUSIVE REMEDIES STATED HEREIN FAIL OF THEIR ESSENTIAL PURPOSE.

11.2 Notwithstanding the provisions of this Section 11, this Agreement shall not limit the liability of either Party for personal injury, including death, arising from the negligence or willful misconduct of such Party or its employees acting within the scope of their employment.

## 12. PROPRIETARY RIGHTS.

Except as otherwise provided herein, MinSURG expressly retains title and ownership to all worldwide intellectual property rights, including without limitation, design, know-how, patent rights, trademarks, and copyrights in and to the Products, TruFUSE and MinSURG trademarks, service marks and logos, and any modifications, adaptations, derivative works, and enhancements made thereto.

## 13. CONFIDENTIALITY.

13.1 **Definitions.** For purposes of this Agreement, "Trade Secrets" means information which: (a) derives economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. "Confidential Information" means information, other than Trade Secrets, that is of value to its owner and is treated as confidential. "Proprietary Information" means Trade Secrets and Confidential Information.

13.2 **Nondisclosure Requirements.** Each Party agrees to hold Proprietary Information of the other Party in strictest confidence and not to copy, reproduce, distribute, manufacture, duplicate, reveal, report, publish, disclose, cause to be disclosed, or otherwise transfer the Proprietary Information of the other Party to any third party, or utilize such Proprietary Information for any purpose whatsoever other than as expressly contemplated by this Agreement or as otherwise agreed to in writing by the Parties. Each Party may only disclose the other Party's Proprietary Information to employees, representatives and consultants of such Party who are under a written obligation to comply with the nondisclosure obligations set forth herein. Each Party agrees to notify the other Party in writing of any suspected or known breach of the obligations or restrictions set forth in this Section 13. The obligations of this Section 13.2 shall continue for so long as such information constitutes a Trade Secret under applicable law and for Confidential Information, for the term of this Agreement and for a period of three (3) years following termination or expiration of this Agreement. Notwithstanding the foregoing, any previously executed nondisclosure agreement between the Parties shall continue in full force and effect, provided that to the extent of any inconsistency or ambiguity between such non-disclosure agreement and this Agreement, this Agreement shall take precedence and control and govern in all respects.

13.3 **Exceptions.** The foregoing obligations of this Section 13 shall not apply if and to the extent that: (i) the information communicated was already known to a Party without obligation to keep such information confidential at the time of a Party's receipt from the other Party; (ii) the information communicated was received by a Party in good faith from a third party lawfully in possession thereof and having no obligation to keep such information confidential, or (iii) a Party establishes that the information communicated was publicly known at the time of such Party's receipt from the other Party or has become publicly known other than by a breach of this Agreement. If either Party is required to disclose all or part of the Proprietary Information of the other Party pursuant to any legal requirement of any country which may have jurisdiction over that Party, such Party shall immediately upon becoming aware that such disclosure is required, give the other Party notice of the circumstances in which the disclosure is required and, subject to applicable law, agree with the other Party on the extent and timing of such disclosure.

**13.4 Statistical Information.** In addition to the exceptions of 13.3 hereof, Distributor hereby agrees to assist and cooperate with MinSURG, at MinSURG's sole cost and expense, in obtaining the cooperation of Trained Surgeons to provide or allow the review by MinSURG of patient redacted information to allow a statistical study of TruFUSE efficacy, cost and performance outcome including, but not limited to, pre-operative and post-operative radiograph copies, length of stay, rehabilitation requirements and whether TruFUSE was used as an adjunct to instrumented or interbody fusion or as a stand-alone procedure. All of the foregoing may be used by MinSURG for such purposes even though it might otherwise be considered Confidential or Proprietary Information.

#### **14. TRADEMARKS**

**14.1 Use of the TruFUSE Marks.** MinSURG hereby grants to Distributor, and Distributor hereby accepts from MinSURG, a nonexclusive, nontransferable, royalty-free license to use the TruFUSE Marks set forth on Exhibit A hereto, solely in connection with the marketing, distribution, promotion, advertising and sale of the Products in the Territory and in accordance with any MinSURG's standards and instructions, and for no other purpose. MinSURG may inspect and monitor Distributor's use of the TruFUSE Marks. Distributor shall not adopt, use or register any words, phrases or symbols which are identical to or confusingly similar to any of the TruFUSE Marks or oppose any such registration by MinSURG or its affiliates. Distributor is not granted any right, title or interest in the TruFUSE Marks other than the foregoing limited license, and Distributor shall not use the TruFUSE Marks as part of Distributor's business entity or trade name or permit any third party to do so.

**14.2 Markings.** Distributor shall not remove or alter any trade names, trademarks, copyright notices, serial numbers, labels, tags or other identifying marks, symbols or legends affixed to any Products, documentation or containers or packages.

**14.3 Infringements.** Distributor shall provide prompt notice to MinSURG of any infringement or potential infringement of the TruFUSE Marks by a third party and of any challenge to its use of the TruFUSE Marks by a third party. MinSURG reserves the right in its sole discretion to institute any proceedings against third party infringers of the TruFUSE Marks, and Distributor shall refrain from doing so. Distributor shall cooperate fully with MinSURG in any legal action taken by MinSURG against such third parties, provided that MinSURG shall pay all expenses of such action and all damages which may be awarded or agreed upon in settlement of such action shall accrue to MinSURG.

**14.4 Termination of Use.** Except as otherwise provided in Section 8.2(c) hereof, upon termination of this Agreement, Distributor shall immediately cease any use of the TruFUSE Marks in any manner. In addition, Distributor hereby appoints MinSURG its attorney in fact, which appointment is coupled with an interest, to allow MinSURG to cancel, revoke or withdraw any governmental registration or authorization permitting Distributor to use the TruFUSE Marks in the Territory. To effectuate the purposes of this provision, Distributor shall sign and deliver any documents and perform all further acts as may be reasonably requested by MinSURG.

**14.5 Distributor Web Sites.** Distributor shall not operate an Internet site that references any of the Products or the TruFUSE Marks ("Distributor Web Site") without the prior written consent of MinSURG. In consideration of MinSURG allowing Distributor to reference the Products or use the TruFUSE Marks in the Distributor Web Site, MinSURG may provide and Distributor shall post on the Distributor Web Site, mandatory content, including but not limited to privacy policies, terms of use, copyright and trademark notices, and graphics and trademark policies. Subject to MinSURG's prior written consent, Distributor shall prominently provide on the home page of the Distributor Web Site a link to MinSURG's Internet sites in location, style, size and manner specified by MinSURG.

14.6 **Internet Search Strategies.** Distributor may not use any TruFUSE Mark or any of the Products in connection with any domain name, directory, address, locator, linking, co-branding, meta-tag, or with any other Internet search strategy.

15. **MISCELLANEOUS.**

15.1 **Independent Contractors.** Notwithstanding anything set forth herein to the contrary, the relationship of the Parties is that of independent contractors, and nothing herein shall be construed to create a partnership, joint venture, franchise, employment or agency relationship between the Parties. Neither party shall have authority to enter into agreements of any kind on behalf of the other Party and shall not have the power or authority to bind or obligate the other Party in any manner to any third party.

15.2 **Assignment.** Neither Party shall assign or otherwise transfer its rights or obligations under this Agreement except with the prior written consent of the other Party, provided, however, either Party may assign or transfer all its rights and obligations under this Agreement to a successor in interest to all or substantially all of its assets or business by reason of sale, merger or operation of law, without the prior written consent of the other Party, if such successor affirms in writing that it will remain bound by all the terms and conditions of this Agreement.

15.3 **Notices.** Notices permitted or required to be given hereunder shall be deemed sufficient if given by (a) registered or certified mail, postage prepaid, return receipt requested, (b) private courier service, or (c) facsimile or e-mail sent to the respective addresses or facsimile numbers or e-mail addresses and to the attention of the representatives of the Parties or at such other addresses or facsimile numbers or e-mail addresses or representative as the respective Parties may designate by like notice from time to time. Notices so given shall be effective upon receipt by the Party to which notice is given.

15.4 **Arbitration.** If any dispute arises between the Parties relating to the subject matter of this Agreement, the Parties shall each make good faith efforts to negotiate an amicable settlement of such matter. The Parties agree that, except as otherwise provided below, any dispute, claim or controversy relating in any way to this Agreement shall be settled by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") in the state of Florida held in Pinellas County, Florida, with judgment upon the award rendered by the arbitrator to be entered in any court of competent jurisdiction. Notwithstanding the foregoing or the then-current specified Commercial Arbitration Rules, the following shall apply with respect to the arbitration proceeding: (i) the existence, subject, evidence, proceedings, and ruling resulting from the arbitration proceedings shall be deemed confidential information, and shall not be disclosed by either Party, their representatives, or the arbitrator (except: (a) to the professional advisers of the Parties; (b) in connection with a public offering of securities by either Party; (c) as ordered by any court of competent jurisdiction; or (d) as required to comply with any applicable governmental statute or regulation) and (ii) the arbitrator shall be required to prepare written findings of fact. Notwithstanding the foregoing, either Party may apply to a court of competent jurisdiction for a temporary restraining order, preliminary injunction or other equitable relief, as necessary, without breach of this arbitration agreement and without abridgement of the powers of the arbitrator.

15.5 **Governing Law, Jurisdiction and Venue.** This Agreement has been made, executed and delivered in Florida, in which state the offices of MinSURG are located. Accordingly, the Parties invoke the laws of Florida regarding the protection of their rights and enforcement of their obligations hereunder and they mutually stipulate and agree that this Agreement is in all respects (including, but not limited to, all matters of interpretation, validity,

performance and the consequences of breach) to be exclusively construed, governed and enforced in accordance with the internal laws (excluding all conflict of laws rules) of Florida and any applicable federal laws of the United States of America, as from time to time amended and in effect. The state and federal courts located in the Tampa Bay, Florida area shall have exclusive jurisdiction over the Parties and this Agreement and shall be the exclusive venue for any court proceedings.

15.6 **Force Majeure.** Except Distributor's obligation to pay under Section 7, neither Party shall be liable for any failure to perform or delay in performance of its obligations hereunder caused by circumstances beyond its reasonable control, including, but not limited to, fire, storm, flood, hurricane, explosion, accident, acts of a public enemy or rebellion, insurrection, riot, civil commotion, strikes or other labor disputes, sabotage, epidemic, quarantine or any agency thereof, judicial action and any other such external circumstances (a "Force Majeure").

15.7 **No Solicitation of Related Personnel.** During the term of this Agreement, and for a period of twelve (12) months after termination of this Agreement, neither Party, nor any subsidiary or parent thereof, shall, directly or indirectly, (i) solicit for employment or consulting engagement, (ii) offer employment to, or (iii) engage the related business services of any person who is or was an officer, employee or consultant of the other Party.

15.8 **Entire Agreement.** This Agreement constitutes the entire agreement between the Parties concerning the subject matter hereof, and supersedes and replaces all prior or contemporaneous understandings or agreements, written or oral, regarding such subject matter. No amendment to or modification of this Agreement, or any waiver of any term or condition of this Agreement will be binding unless in writing and signed by a duly authorized representative of both Parties. The section and subsection headings in this Agreement are inserted solely as a matter of convenience and for reference, and shall not be considered in the construction or interpretation of any provision hereof. If any provision hereof is declared invalid by a court or arbitral tribunal of competent jurisdiction, such provision shall be ineffective only to the extent of such invalidity, so that the remainder of that provision and all remaining provisions of this Agreement will continue in full force and effect.

15.9 **Execution.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original hereunder. Each Party agrees to be bound by its own facsimile or telecopy signature, and accepts the facsimile or telecopy signature of the other Party hereto.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date set forth above.

**MINSURG CORPORATION**

**DISTRIBUTOR**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

## EXHIBIT A

To Independent Distributor Agreement, dated as of \_\_\_\_\_, 2007, (the "Agreement") by and between MinSURG Corporation ("MinSURG") and Silver Surgical ("Distributor"). Except as otherwise indicated herein, all defined terms used herein shall have the definitions contained in the Agreement.

### PRODUCTS.

**TruFUSE Allograft System:** a proprietary, patent pending cortical cadaveric allograft spinal facet fusion dowel and technique with custom designed surgical instruments including a drill guide, compaction drill bit, allograft holder and allograft inserter and tamp.

**TruFUSE Packaging:** TruFUSE is packaged in three formats: a single spinal level 5.0 mm format including two preformed allograft dowels and one drill bit per box; a single 5.0mm dowel with one drill bit for every two boxes; and a single 7.5mm dowel (each of the three formats being referred to as "Units"). Other surgical instrumentation including drill guides, holders, inserters and tamps ("Instruments") are reusable and one complete set of 5.0 mm instruments will be provided to surgeons only upon completion of training and certification in a sterilizable case without charge to Trained Surgeons. The Distributor will receive one 7.5mm instrument set per ten (10) Units of 7.5 mm dowels. A "Trained Surgeon" is a qualifying physician who regularly performs spine surgery, typically an orthopedic or neurosurgeon, acceptable to MinSURG who has been trained in the TruFUSE technique by a certified TruFUSE trainer employed by MinSURG or the Distributor. Only Trained Surgeons are authorized to perform the TruFUSE technique and to receive Instruments and use Units. The Distributor shall maintain and provide MinSURG with a current list of all Trained Surgeons at all times including complete contact information, specialty and hospital affiliations.

**Consignment:** MinSURG may provide TruFUSE on a shelf consignment to hospitals and/or ambulatory surgery centers that have approved the use of TruFUSE within their institutions upon acceptance of its Consignment Agreement by the Provider, the par level of which shall be not less than 5 (five) 5.0mm two dowel Units per surgeon.

### TERRITORY.

See Schedule A- Distributor Territories and Sales Quotas attached hereto.

### PRICING AND INITIAL SALES.

**Unit Pricing:** MinSURG's Fee Schedule is attached hereto as Exhibit B, and pricing may be changed by MinSURG from time to time at its sole discretion.

**Instrument Pricing:** Instrument sets, including a sterile tray, will be provided without cost to each *certified* Trained Surgeon and each *registered* representative plus two spare sets for the distributorship. Additional sets are available for \$850.00. The Distributor will receive one 7.5mm instrument set per ten (10) Units of 7.5 mm dowels. Trained Surgeons may request a free replacement instrument set, not including a sterile tray, after 50 surgeries have been performed as determined by weekly case schedules.

### POLICIES AND PROCEDURES.

#### 1. Territories and Exclusivity

- a. New territories or expansion territories can only be acquired by permission. It is MinSURG's policy, and responsibility, to protect the interests of each of its distribution partners by enforcing territorial exclusivity. If Distributor identifies an opportunity outside of its Territory, it should contact MinSURG if Distributor is not sure who the distributor in that area is, or contact the distributor in that area directly to work out a mutually agreeable arrangement. If an acceptable arrangement cannot be reached, Distributor's corporate contact at MinSURG will arbitrate between the distributors.
- b. Territorial exclusivity is only preserved by maintaining Minimum Purchase Requirements.

**2. Case Schedules**

- a. MinSURG's rapid growth combined with long production lead times could lead to shortages. To ensure adequate supplies and deliveries, MinSURG has determined that working with weekly case schedules, a rolling 90 day forecast, and an accurate representative list is in everyone's best interest. Non-stocking distributors must also provide a monthly inventory log for all consigned levels in their possession including inventory at hospitals within their territory, a contractual obligation.
- b. MinSURG has requested Distributor's cooperation with the following, and, in return, it will guarantee priority shipment:
  - (1) Weekly case schedules will be due on the Thursday prior to the week reported. Previous schedules must be updated and returned by the close of the business day the Friday of the week reported.
  - (2) Rolling 90 day forecasts should be provided on the last Friday of every month.
  - (3) An accurate representative list, including contact information, must be given to MinSURG immediately, and be updated as changes arise.

**3. Collateral Materials**

- a. Collateral materials also have been ordered in large quantities with little or no notice. MinSURG works hard to provide industry leading distributor services. So that MinSURG will be able to continue to do so, the Parties agree to the following process:
  - i. Request forms must be filled out for all collateral, instrumentation, and email requests. Requests submitted any other way cannot be guaranteed.
  - ii. 25 pieces of each type of collateral per *registered representative* will be given free of charge per quarter. Anything over 25 will be charged as follows
    - 1. FAQ \$3.00
    - 2. Slick \$.40
    - 3. Physician Brochure \$0.40
    - 4. Hospital Approval Packets \$ 3.50
    - 5. Physician Packets \$3.50
    - 6. QUICK Reference Guide \$0.40

7. White paper and Slides \$1.50

8. Patient brochures will not be limited

- iii. A 5 business day lead time is required for all collateral and instrumentation requests. Products will then be shipped ground. Urgent deliveries will be billed at cost. A \$50 surcharge to accommodate for overtime will be assessed beginning with the second urgent delivery per quarter.
- iv. UPS will be the only shipping company used by MinSURG. If any other shipping company is requested an account number must be given and the distributor will be charged for any pick-up costs.
- v. Instrument sets, including a sterile tray, will be provided without cost to each *certified* Trained Surgeon and each *registered* representative plus two spare sets for the Distributor. Additional sets are available for \$850.00.
- vi. Trained Surgeons may request a free replacement instrument set, not including a sterile tray, after 50 surgeries have been performed as determined by weekly case schedules.
- vii. Demonstration sawbones and materials are a Distributor responsibility. If they are needed on an urgent basis they can be purchased from MinSURG at cost plus shipping. Cradles can be purchased from Sawbones directly.
  - Item # - 1524-1
  - [www.sawbones.com](http://www.sawbones.com) or (206)463-5551

All required forms may be submitted via fax or email. Electronic and hardcopy forms are located on the TruFUSE Toolbar or can be emailed upon request.

OCT-19-2007 08:58 FROM: SURGERY ADMIN

4192513819

TO: 917277974895

P.003/003

COPY

## TruFUSE<sup>®</sup> ALLOGRAFT CONSIGNMENT INVENTORY AGREEMENT

MinSurg Corporation agrees to provide a TruFUSE allograft consignment inventory to *St. Luke's Hospital*. TruFUSE Allografts placed in consignment inventory will be shipped to *St. Lukes Hospital, 5901 Monclova Road, Maumee, OH 43537* without charge and will remain the property of MinSurg Corporation until they are used.

MinSurg will honor its discounted price of \$2,932.50 per box (two TruFUSE allograft dowels and one drill bit) throughout the term of this agreement.

During the terms of this agreement, MinSurg agrees to the following:

- Make periodic visits to monitor consignment inventory
- Provide three business days notice, prior to each visit to appropriate hospital personnel
- During each visit perform the following:
  - Verify consignment inventory
  - Monitor par levels
  - Monitor expiration dates
  - Rotate inventory if necessary
- Bill and replace inventory in a timely manner
- Educate appropriate hospital personal on the management of consignment inventory
- Provide, on a monthly basis, a series of reports showing annual usage and current consignment inventory
- Provide proper documentation for maintaining a consignment inventory
- Eliminate shipping charges for consignment replacements
- Replace TruFUSE allografts at no charge should an issue arise where MinSurg is at fault
- Notify appropriate hospital personnel if for any reason a recall, either voluntary or mandated, should be necessary. It will be the responsibility of MinSurg to arrange for effected inventory to be returned to the processing facility. It will also be the responsibility for MinSurg to provide replacement TruFUSE allografts in an acceptable time frame.

During the term of this agreement *St. Luke's Hospital* agrees to the following:

MinSurg Corporation  
 2730 McMullen Booth Road, Suite 203, Clearwater, FL 33761  
 727-466-4550 -- 727-797-4895 Facsimile  
 www.minsurg.com

No. 2218

Oct. 19. 2007 8:31AM

OCT-19-2007 08:57 FROM: SURGERY ADMIN

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TO: 917277974895


P.002/003




No. 2218 2

- Maintain a list of all TruFUSE allografts in consignment inventory.
- Maintain proper storage conditions
- Allow MinSurg representative access to inventory to audit and evaluate storage conditions
- Provide a complete Allograft Implant Record and return the self-addressed, stamped section back to LifeLink Tissue Bank, MinSurg's designee, within 5 business days.
- Provide a purchase order number for implanted grafts either on an individual basis or a monthly basis (to be determined prior to signing) so that TruFUSE allografts can be billed and replaced
- Perform monthly in-house audits to verify consignment inventory
- Provide a purchase order number for TruFUSE allografts missing from inventory over thirty (30) days
- Obtain a return authorization number prior to returning any allograft back to MinSurg
- Allograft may be loaned to another facility with notification to MinSurg, by telephone at 727-466-4772, email at [compliance@minsurg.com](mailto:compliance@minsurg.com), or fax at 727-797-4895; however *St. Luke's Hospital, 5901 Monclova Road, Maumee, OH 43537* is responsible for all consigned inventory
- Notify MinSurg should any changes need to be made to par levels

Terms of this agreement, including fees, will continue through December 31, 2008.

  
 \_\_\_\_\_  
 Authorized Signature  
 MinSurg Corporation

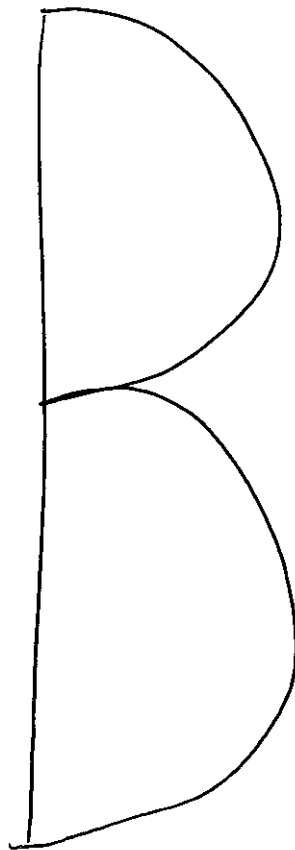
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 Date

  
 \_\_\_\_\_  
 Authorized Signature  
 St. Luke's Hospital  
 5901 Monclova Road  
 Maumee, OH 43537

3-5-07  
 \_\_\_\_\_  
 Date

MinSurg Corporation  
 2730 McMullen Booth Road, Suite 203, Clearwater, FL 33761  
 727-466-4550 - 727-797-4895 Facsimile  
[www.minsurg.com](http://www.minsurg.com)

Oct. 19. 2007 8:31AM





1300 I Street, NW | 11th Floor East | Washington, D.C. 20005-3314  
202-218-0000 office | 202-218-0020 fax | [www.sheppardmullin.com](http://www.sheppardmullin.com)

Don J. Pelto  
Writer's Direct Line: 202-772-5362  
[dpelto@sheppardmullin.com](mailto:dpelto@sheppardmullin.com)

February 7, 2008

Our File Number: 14XL-129844

***VIA FEDERAL EXPRESS AND FACSIMILE***

Ms. Kelly Matwiejcyk  
Silver Surgical  
1074 Center Ste.B  
Auburn Hills, MI 48326  
**Fax:** (248) 475-1801

Re: Orthopedic Development Corporation and MinSURG Corporation  
v. NuTech Medical, Inc., NuFix, Inc., Kenneth Horton, and Todd Gilbert  
Civil Action No. 8:08-cv-00262-T-30TGW  
United States District Court for the Middle District of Florida

Dear Ms. Matwiejcyk:

We represent Orthopedic Development Corporation ("ODC") and MinSURG Corporation ("MinSURG") in intellectual property matters.

ODC and MinSURG have initiated legal action against Nutech Medical, Inc. and NuFix, Inc. ("Nutech") and their principal, Ken Horton, and employee, Todd Gilbert, charging, among other things, trade secret misappropriation, trademark infringement, unfair competition, false advertising, and breach of contract. These claims are based, in part, on Nutech's marketing and selling a facet fusion device that is virtually identical to the MinSURG TRUFUSE® facet fusion product and on Nutech's use of the confusingly similar NUFUZE, BIOFUZE and/or NUFIX brand names to market and sell its competing facet fusion products ("Nutech Products"). It is our understanding that Nutech has contracted you to represent and sell the Nutech Products that are the subject of this litigation and that you are actively marketing them.

IF YOU DO NOT IMMEDIATELY CEASE AND DESIST MARKETING AND SELLING THE NUTECH PRODUCTS UNDER ANY BRAND NAME IN VIOLATION OF THE RIGHTS OF ODC AND MINSURG, OUR CLIENT HAS AUTHORIZED US TO TAKE ALL STEPS NECESSARY TO PROTECT ITS VALUABLE RIGHTS, INCLUDING BY COMMENCING LITIGATION AGAINST YOU.

SHEPPARD MULLIN RICHTER & HAMPTON LLP

Ms. Matwiejczyk  
February 7, 2008  
Page 2

Please be aware that if you should decide to continue these activities and to litigate this matter, under the Lanham Act, 15 U.S.C. §1117, ODC/MinSURG will be entitled to disgorge from you any profits from the sale of the Nutech Products. ODC/MinSURG will also be entitled to recover actual damages in addition to court costs and attorneys' fees.

In addition, ODC has a pending patent application covering the TruFUSE® facet fusion product and the associated method. This application was published under U.S. Patent Application Serial No. 11/232,519 (Publication No. 2006/0111782) on May 25, 2006. A copy of the published application is enclosed. If you are distributing the Nutech Products, you may also be liable for reasonable royalties for the infringement of ODC's systems, methods, and devices covered by the claims of the published patent application during the time beginning on the date the application was published. We expect to receive from the USPTO a Notice of Allowance in this application shortly.

ODC/MinSURG is hopeful that this matter can be resolved amicably with you without having to resort to costly and time-consuming litigation, however, we must have your reply to this letter within ten (10) calendar days. If we do not hear from you within this time period, we will assume that you are not interested in pursuing a settlement and we will advise ODC/MinSURG to proceed accordingly. The foregoing does not constitute a complete statement of the rights and remedies of ODC and MinSURG, none of which is waived or prejudiced hereby, and all of which are expressly reserved.

If you have any questions or wish more information on this matter, please contact me directly or through your legal counsel.

Very truly yours,



Don J. Pelto

for SHEPPARD, MULLIN, RICHTER & HAMPTON LLP

W02-EAST:9DJF1\200665874.1

Encl.



US 20060111782A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2006/0111782 A1**

**Petersen**

(43) **Pub. Date: May 25, 2006**

(54) **SPINAL PLUG FOR A MINIMALLY INVASIVE FACET JOINT FUSION SYSTEM**

**Publication Classification**

(75) **Inventor: David A. Petersen**, Clearwater, FL, (US)

(51) **Int. Cl. A61F 2/44** (2006.01)

(52) **U.S. Cl. 623/17.11**

Correspondence Address:  
**LARSON AND LARSON**  
 11199 69TH STREET NORTH  
 LARGO, FL 33773

(57) **ABSTRACT**

(73) **Assignee: ORTHOPEDIC DEVELOPMENT CORPORATION**

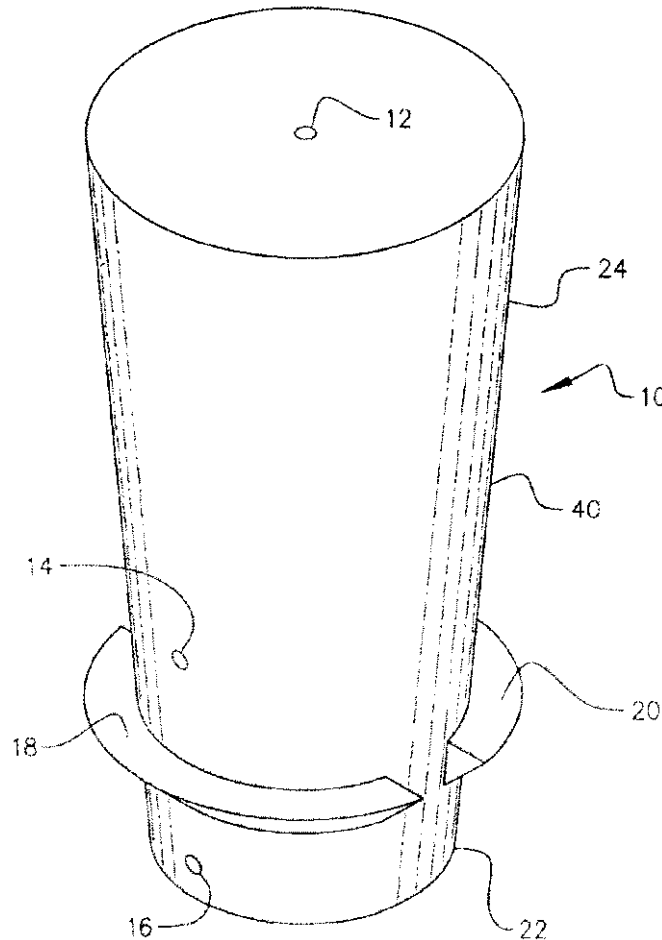
A frustum shaped body has an aperture in a top surface and a pair of first and second opposed apertures in a side surface, first and second horizontal internal channels connect both the first and second opposed apertures. A vertical channel from the top aperture connects with the first and second channels. After the body is inserted into a hole in a facet joint, compatible synthetic or biologic material is inserted into the vertical channel until the material exits from the first and second apertures in the side surface. At least one pair of flanges on a portion of an exterior side surface of the body acts as a detent to hold the body in place within the facet joint hole.

(21) **Appl. No.: 11/232,519**

(22) **Filed: Sep. 22, 2005**

**Related U.S. Application Data**

(63) **Continuation-in-part of application No. 10/992,720, filed on Nov. 22, 2004.**



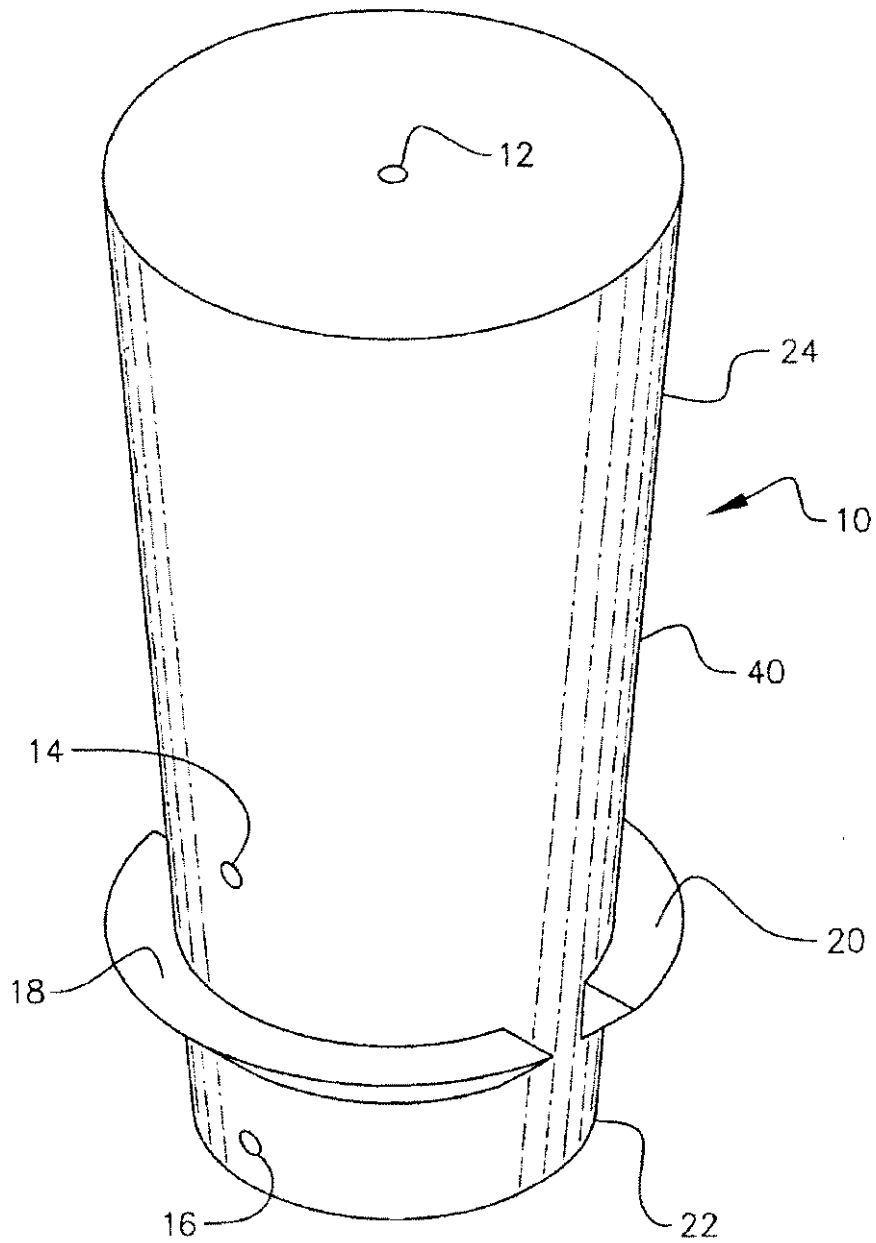


FIG. 1

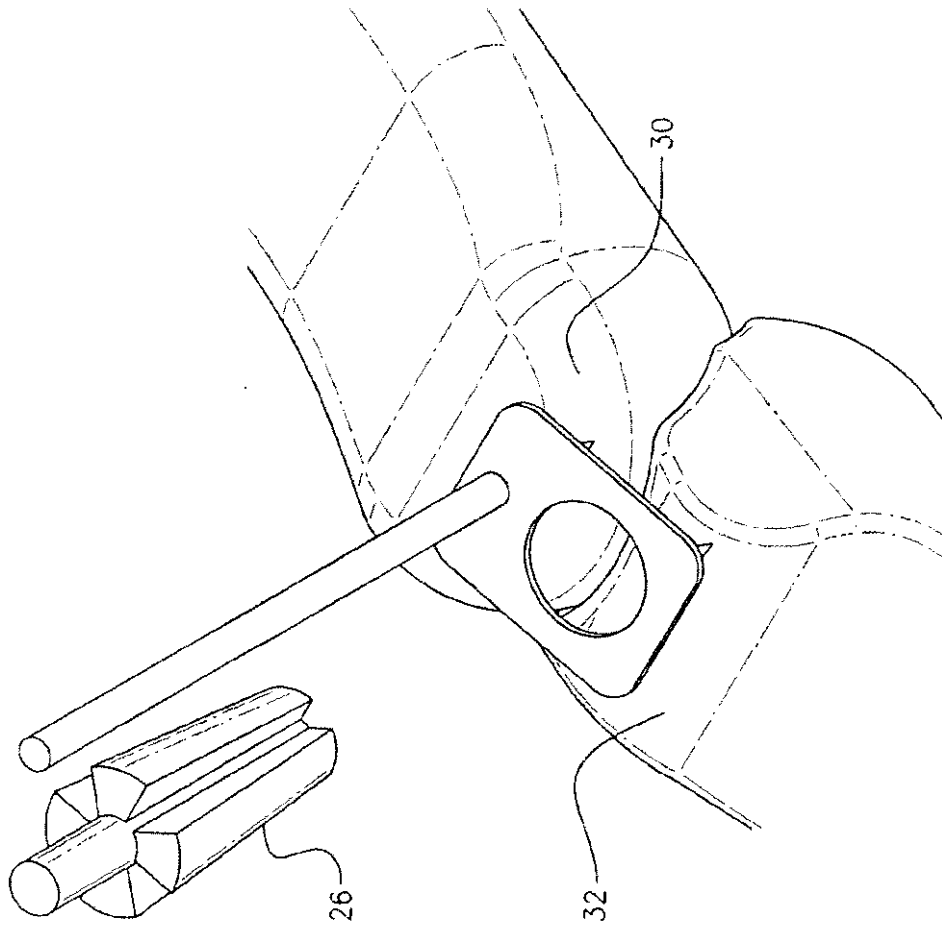


FIG. 2

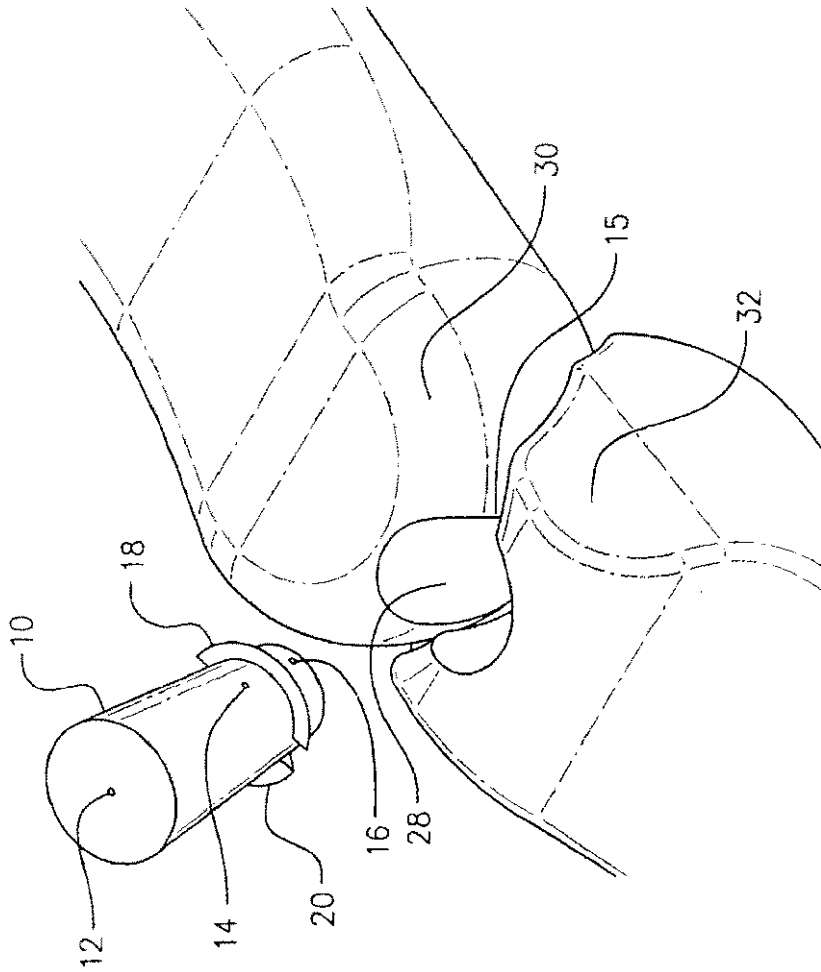


FIG. 3

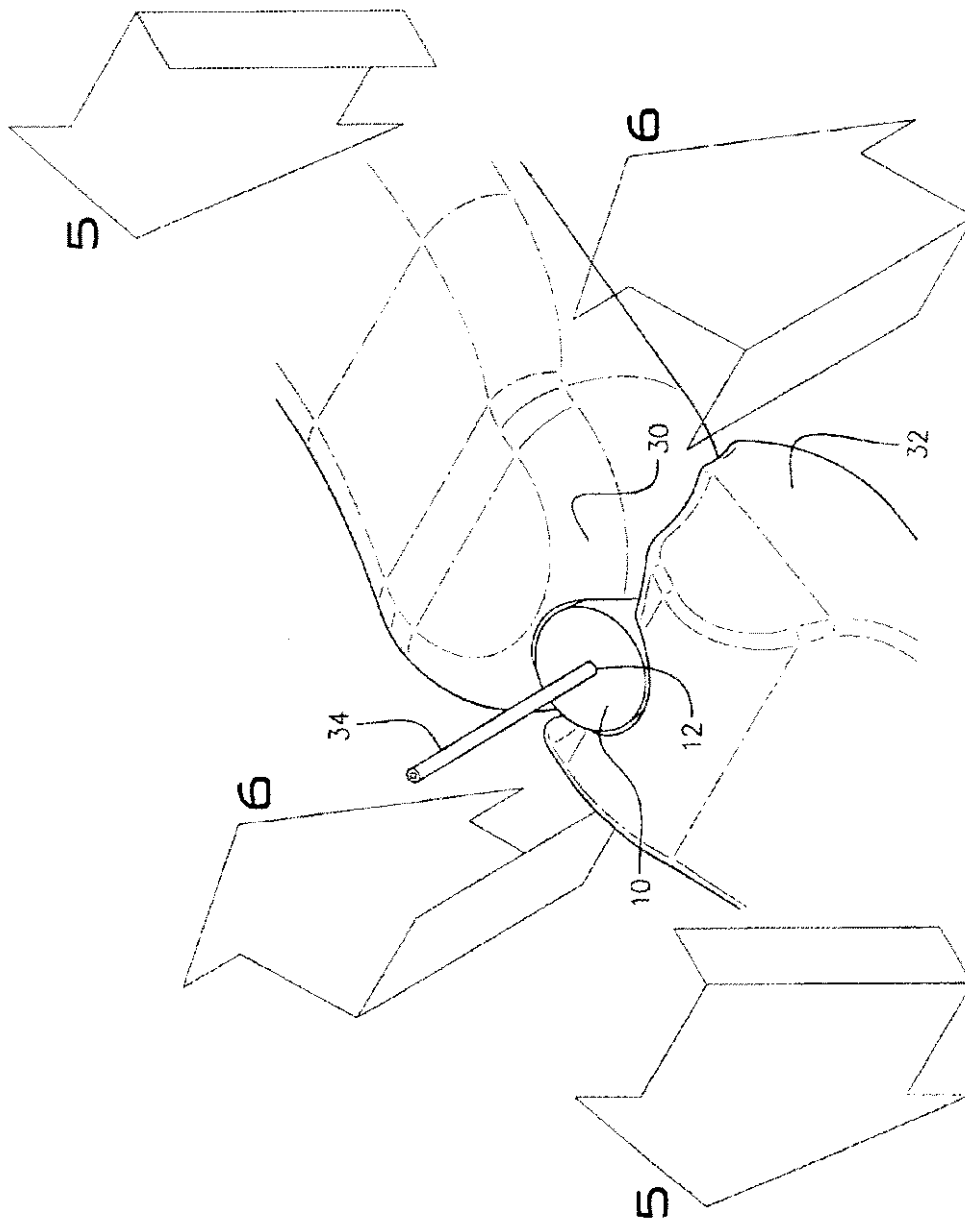


FIG. 4

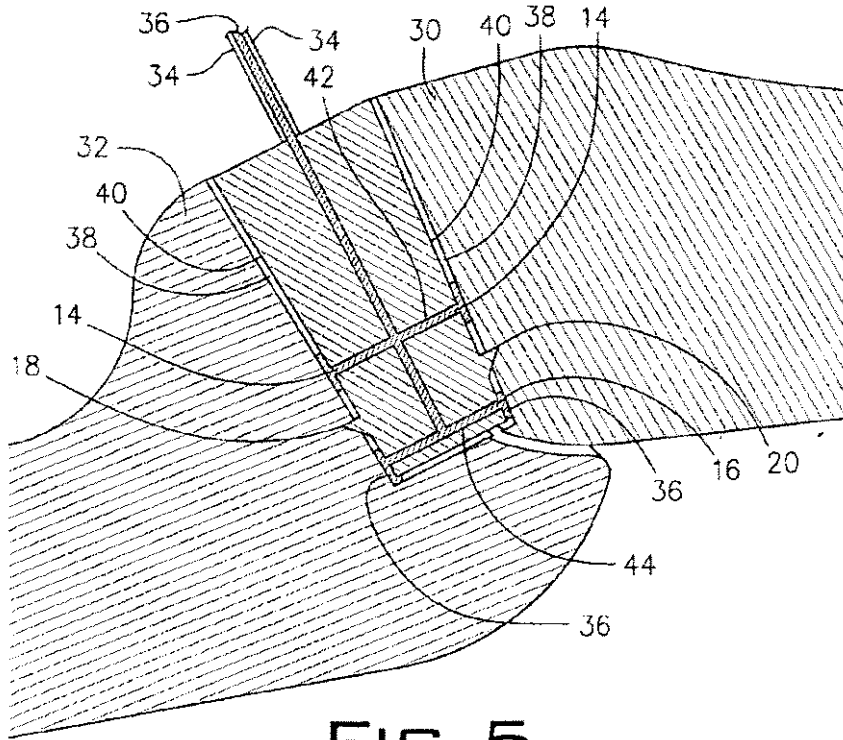


FIG. 5

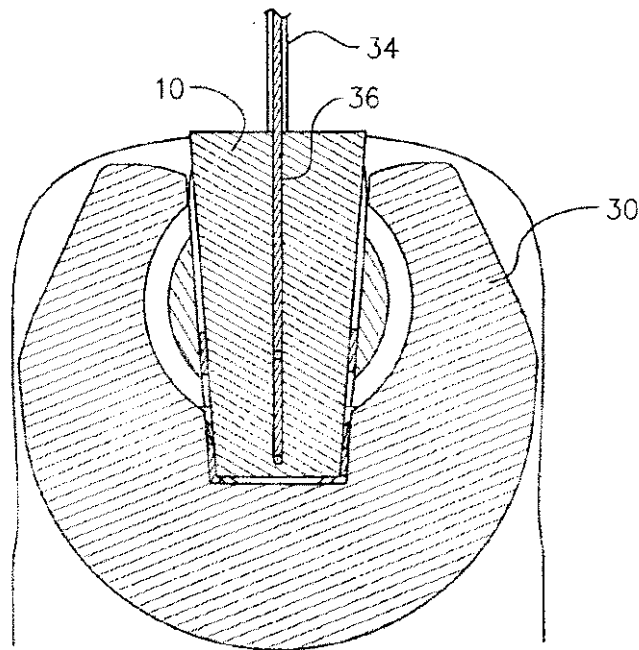


FIG. 6

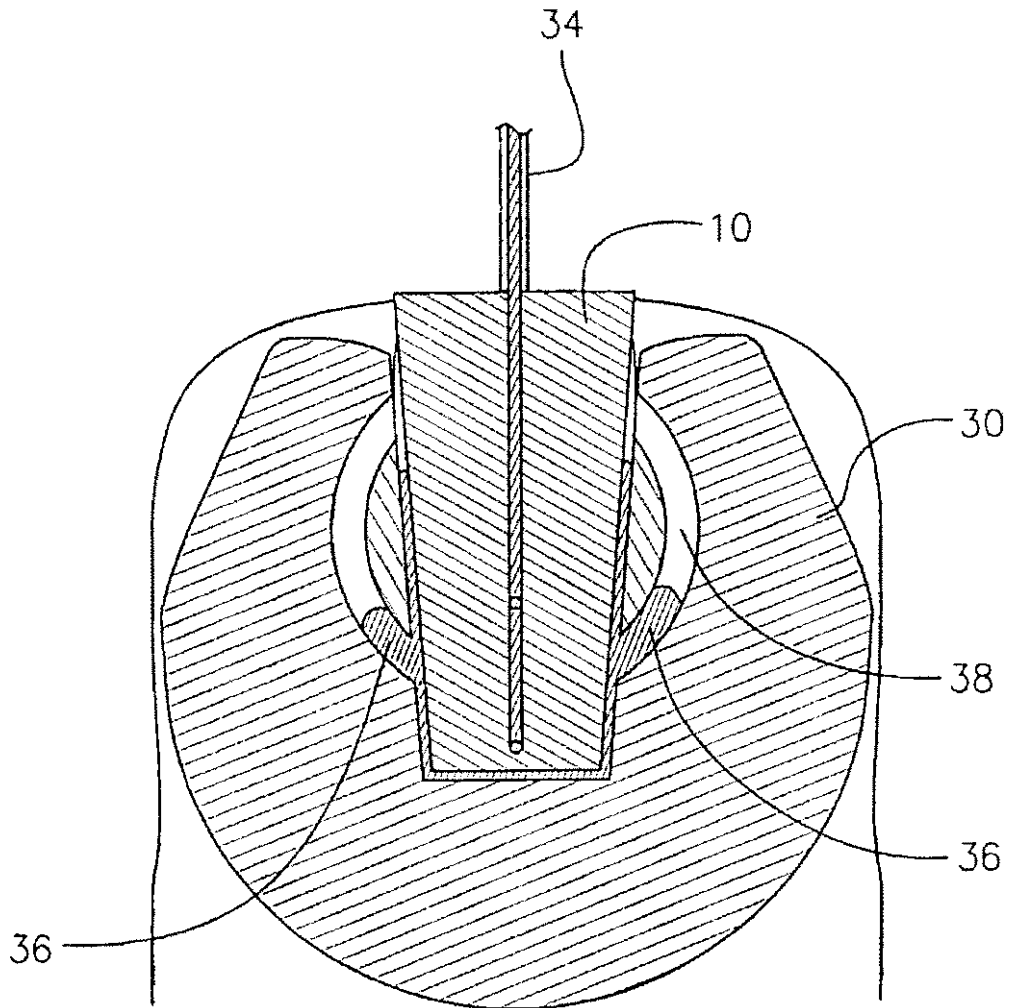


FIG. 7

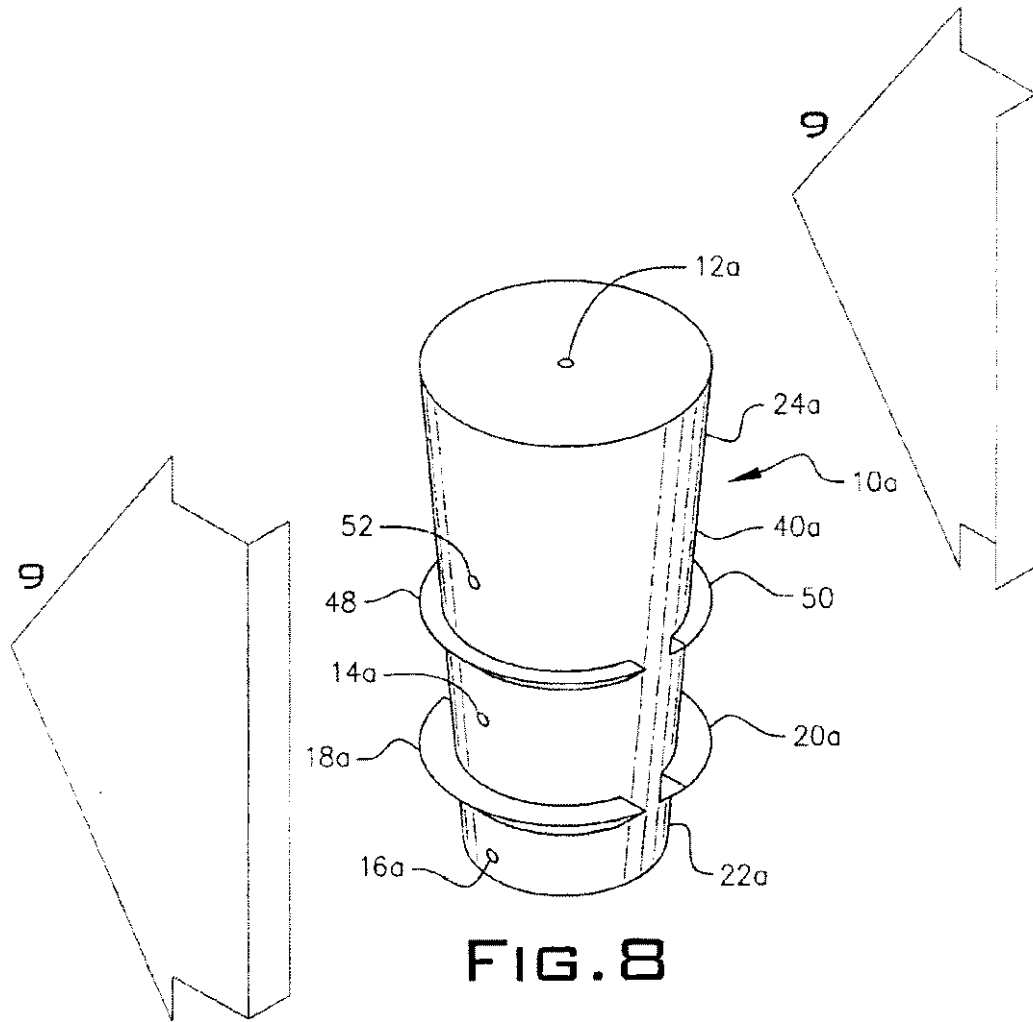
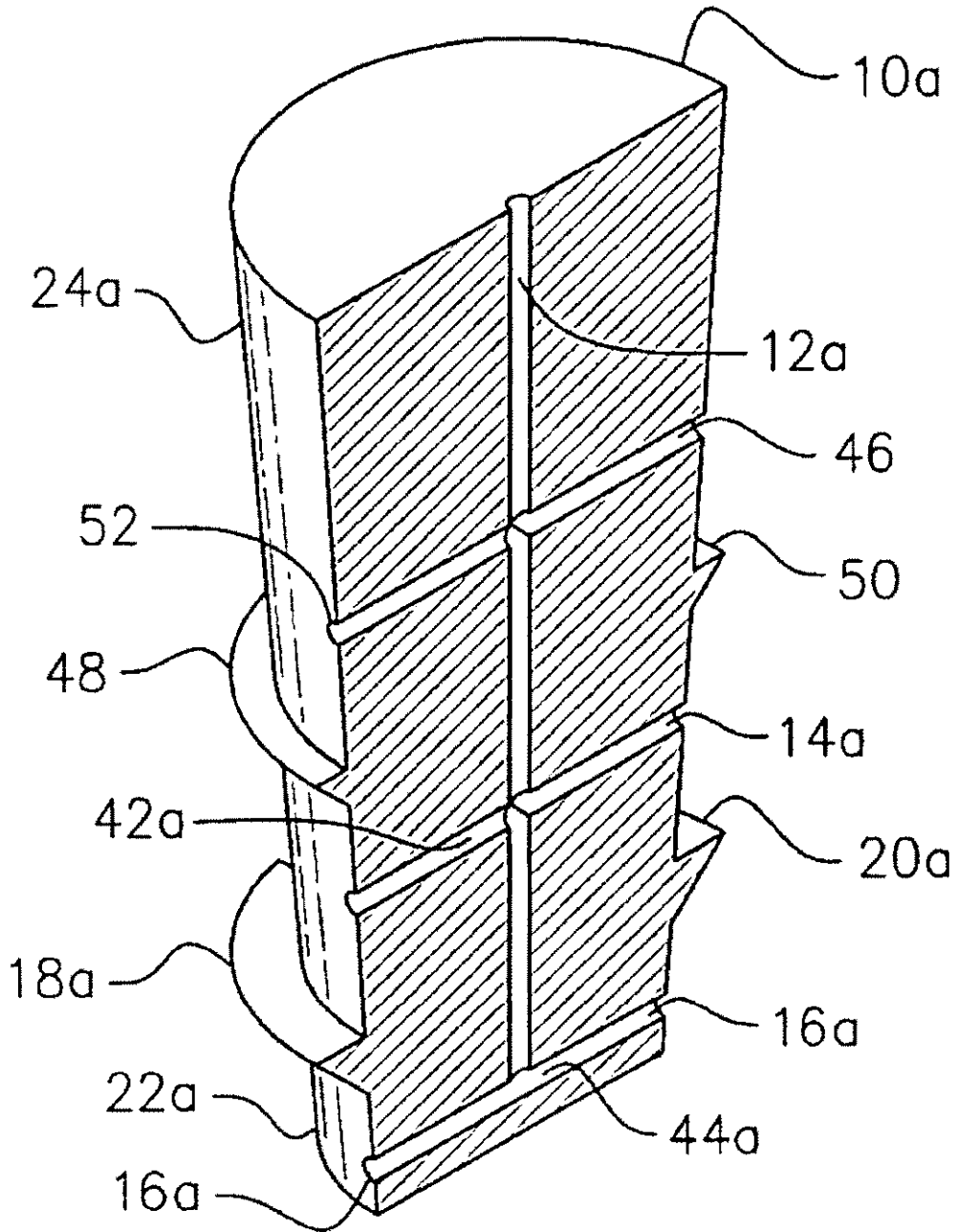
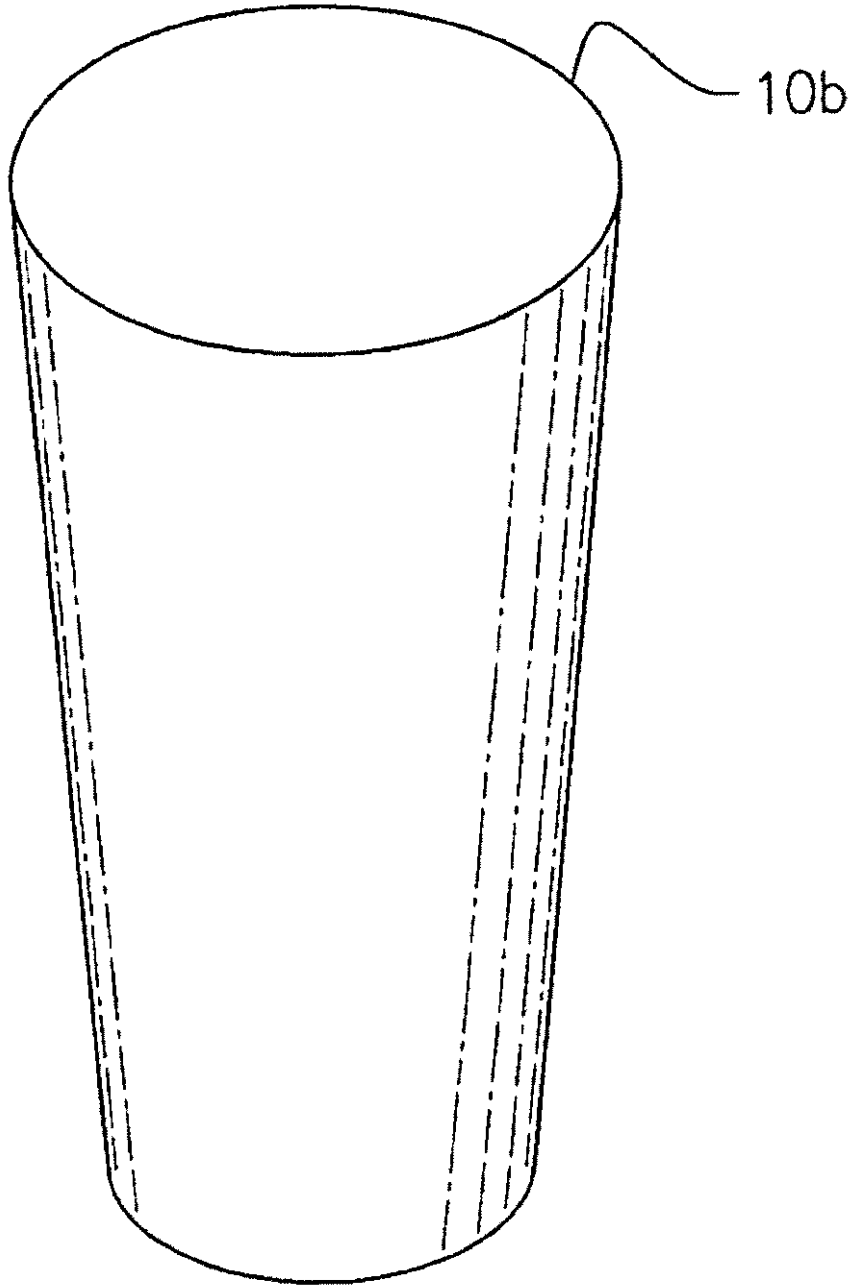


FIG. 8



**FIG. 9**



**FIG. 10**

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## SPINAL PLUG FOR A MINIMALLY INVASIVE FACET JOINT FUSION SYSTEM

### PRIOR APPLICATIONS

[0001] This application is a continuation-in-part from application Ser. No. 10/992,720, filed Nov. 22, 2004.

### BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates generally to minimally invasive spine surgery and, more particularly, to using an arthroscopic type portal or open facet joint fusion surgical instrumentation for insertion of either pre-made, pre-shaped synthetic cortical bone or harvested and compacted iliac crest grafts, autologous or cadaveric allografts. The graft and fusion system is limited to the forty-eight facet joints located on the spine, C1-C2 through L5-S1.

[0004] 2. Description of the Prior Art

[0005] In the United States alone, about 10% of the entire population will suffer from back pain sometime in the next twelve months. More people will contract back pain in the next year than any other injury or disease except the common cold and flu. About one-third will not recover and have to live with persistent, disabling symptoms. The number is cumulative year after year.

[0006] One of the root causes of back pain, particularly the persistent and disabling kind, are facet joints, small joints located behind adjacent vertebrae in the spine that allow for spinal motion.

[0007] Present surgical solutions available for the millions of people with facet joint dysfunctions are complex, invasive, pedicle screw based high-risk operations with prolonged recovery times, from 6 to 24 months, and uncertain outcomes. High risk equates to frequent litigation, which forces non-surgical symptomatic treatment while the disease or consequences of injury progressively worsen. Some of these efforts provide intervertebral fusion described in U.S. Pat. No. 6,485,518 and U.S. Patent Application Serial Number 2003/0032960. Numerous patents have been granted for general fusion of the spine that may or may not involve the facet joint by proximity or design.

[0008] With the advent of new, safer and less invasive surgical techniques and technology, the growth of spine surgery now outpaces every other orthopedic surgery segment. Its growth is further fueled by an enormous demand

### SUMMARY OF THE INVENTION

[0009] The use of pre-shaped, harvested or synthetic bone as a structural fixation for facet joint fusion offers three distinct advantages over pedicle or compression screws, which are presently used in facet fusion procedures; i.e., (1) using bone instead of metal allowing for natural bone ingrowth and a stronger, permanent fusion; and (2) the natural or synthetic graft cannot work its way loose over time, a concern with screw type fixation.

[0010] The grafts and system are specifically designed for use in a minimum invasive or an arthroscopic type portal for stand-alone procedures and provide a stronger, unique and superior fusion when used as an adjunct to instrumented

vertebral fusion by greatly reducing risk of facet joint pain resulting from persistent facet joint motion.

[0011] The minimally invasive facet joint fusion for the treatment of a diseased or painful facet joint that is not appropriate for resurfacing or replacement, involves the use of instrumentation and autograft, cadaveric allograft or FDA approved pre-made, pre-shaped synthetic cortical bone graft for use in minimally invasive, outpatient, arthroscopic spine surgery or classic open surgery and, more specifically, to fuse spinal facet joints from C1-C2 through L5-S1. This system serves as a primary or a revision surgery.

[0012] The present invention accomplishes a superior spinal facet joint fusion by providing a grafting alternative to facilitate fusion using arthroscopic portal or open surgical techniques of the C1-C2 through L5-S1 spinal facet joints.

[0013] According to one broad aspect of the present invention, the arthroscopic facet joint fusion system comprises a punch or drill that creates a hole through both sides of the facet joint in a conical pattern. The hole is filled with either the patient's own harvested and compacted bone plug using iliac crest autograft, pre-made, pre-shaped cortical cadaveric allograft (the autograft or allograft formed by bone plug press or machining) or FDA approved pre-made, pre-shaped synthetic grafts.

[0014] The punch or drill includes any number of components capable of performing the creation of a hole through both sides of the spinal facet joint using an arthroscope or similar portal to access the joint or during classic open surgery. By way of example only, the punch/drill includes a hand actuator that will create sufficient pressure to create a specific sized hole through both sides of the spinal facet joint using a mechanical arrangement similar to that of common pliers resized to work through an arthroscopic opening. Additionally, a drill guide can be placed and a specifically sized and shaped drill head can be used to create the opening, either in a horizontal or vertical direction through the facet joint.

[0015] The bone plug press (graft forming or compression instrument) includes any number of components capable of using harvested autograft, cadaveric allograft cortical bone or a synthetic alternative to match the bone tunnel made by the punch or drill. By way of example only, the bone plug press includes a mechanism similar to common pliers or a more standard hand press that will transfer sufficient force to form bone plugs by squeezing the handles together to form the bone plug and compress the bone or synthetic alternative to the proper density and shape.

[0016] The impactor or tamp includes any number of components capable of pushing and compressing the bone plug into the bone tunnels. A suture or metallic overlay also can be applied to provide additional structural stability to the joint during graft incorporation.

### BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

[0018] FIG. 1 shows a frustum shaped bone plug of this invention for employment in a facet joint fusion;

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[0019] FIG. 2 shows a tapered drill used to prepare for the bone plug;

[0020] FIG. 3 shows a hole prepared for the bone plug;

[0021] FIG. 4 shows a bone plug inserted in the hole of FIG. 3 and with an application tube for inserting synthetic or biologic material;

[0022] FIG. 5, is a cross-section along line 5-5 of FIG. 4;

[0023] FIG. 6 is a cross-section along line 6-6 of FIG. 4;

[0024] FIG. 7 is a cross-section according to FIG. 6 showing synthetic or biologic material cementing the bone plug in place;

[0025] FIG. 8 shows a first alternative frustum shaped bone plug;

[0026] FIG. 9 shows a cross-section of the frustum shaped bone plug of FIG. 8 along lines 9-9; and

[0027] FIG. 10 shows a second alternative frustum shaped bone plug.

#### DETAILED DESCRIPTION OF THE INVENTION

[0028] Referring to FIG. 1, the bone plug of this invention is an inverted frustum shaped device 10 having a vertical central channel 12 for insertion of a synthetic or biologic material to assist in fusing the bone plug 10 in place in a spinal joint 15. The bone plug 10 has multiple side parts 14 and 16 for excretion of the synthetic or biologic material from the central channel 12. A pair of opposed flanges 18 and 20 on the same plane partially circumvent the bone plug 10 near bottom end 22 having a smaller diameter than the top end 24.

[0029] In order to fuse a spinal facet joint, a tapered drill 26, shown in FIG. 2, is employed to prepare a hole 28 shown in FIG. 3 between two bones 30 and 32. As seen in FIG. 4, an application tube 34 is inserted in channel 12 to permit insertion of a synthetic or biologic material 36 into bone plug 10. The biologic material 36 flows down channel 12 as shown in FIG. 5, and excess biologic material flows out of side parts 14 and 16 through channels 42 and 44, respectively, into a space 38 between the bones 30 and 32, and an exterior side wall 40 of the bone plug 10. The flanges 18 and 20 act as detents to hold the bone plug 10 in place within hole 28. As seen further in FIG. 7, the biologic material 36 flows outwardly from openings 14 and 16 into a space 38 to cement the plug 10 in place.

[0030] An alternative plug 10a is shown in FIGS. 8 and 9. A central channel 12a feeds biologic material to side channels 46, 42 and 44a. In like manner, biologic material 36 flows out through openings 52, 14a and 16a and promotes bonding to the bone. A second parallel pair of flanges 48 and 50 are added to flanges 18a and 20a to increase the strength of the plug 10a in the hole 28. Side wall 40a in like manner to plug 10 is narrower in diameter at a bottom end 22a than its top end 24a.

[0031] If the joint is determined to be too badly damaged or diseased for present replacement methods or prospective methods such as facet joint hemi-arthroplasty, minimally invasive facet joint fusion is prospectively a superior alternative for three primary reasons:

[0032] 1. It is minimally invasive surgery that can be performed in an outpatient setting as opposed to major surgery performed in a hospital. This procedure can also be performed during open surgery if the facet joints need to be fused as determined by a physician particularly in conjunction with instrumented vertebral fusion;

[0033] 2. Recovery times are estimated to be a few weeks as opposed to 6 to 12 months; and

[0034] 3. It takes full advantage of advances in biomaterials and synthetic alternatives.

[0035] The present invention is directed at overcoming, or at least improving upon, the disadvantages of the prior art by achieving the following:

[0036] Reversal of the cost/benefit ratio of present procedures versus the invention;

[0037] A minimally invasive procedure versus major open surgery;

[0038] Outpatient versus inpatient surgery (about 20 minutes per joint versus hours). Note: this procedure may also be performed during open surgery at the discretion of the physician;

[0039] Can be used to augment present open fusion techniques to lessen the need for bone stimulation especially in high risk groups such as smokers and multi-level cases;

[0040] Reduced morbidity;

[0041] Reduced blood loss;

[0042] Reduced time under anesthesia;

[0043] Reduced risk;

[0044] Recovery time dramatically reduced;

[0045] Minimal scarring that decreases the risk of failed back syndrome and improves revision surgery outcome;

[0046] Reduced risk of post operative infection by significantly reducing operating room time and soft tissue destruction;

[0047] No preclusion of other surgical or non-invasive treatment options; and.

[0048] Projected high success rate by utilizing accepted arthroscopic procedures employing a new technique and taking advantage of either existing cortical bone harvesting procedures in combination with unique instrumentation to shape and prepare the bone or new pre-shaped, pre-made synthetic cortical bone alternatives as they are made generally available by FDA approval.

[0049] It is anticipated that the availability of this system and graft alternatives will dramatically increase the number of surgeries performed because they offer the first safe outpatient surgical solution to the predominant cause of spinal joint pain. It is expected that virtually all patients receiving this procedure will be able to walk out the same day and be fully functional within a few weeks. Present surgical solutions require hospitalization of about three days and six to twenty-four months recovery.

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[0050] Aside from the obvious positive clinical outcome, the significant favorable financial impact on disability, worker's compensation and health care insurers is considerable.

[0051] Spinal facet implant units are calculated per joint. Each patient has two joints per spinal segment and twenty-four segments, C1-C2 through L5-S1 for a total of forty-eight facet joints. Each surgery is likely to involve multiple joints.

[0052] The present invention is directed at overcoming, or at least improving upon, the disadvantages of the prior art.

[0053] In inserting the plug 10, the tapered drill is specifically used through an arthroscopic type portal allowing access to the joint through a small incision and progressive dilation of the intervening soft tissue. The instrument design does not preclude its use in a classic open surgery or by access to the facet joint through an otherwise limited incision. The opening 28 is marginally smaller than the bone plug 10 to create proper fixation of the plug 10 and the joint.

[0054] Referring again to FIGS. 1 and 8, a fused facet joint plug 10, 10a or 10b is shown with one shaped autograft, cadaveric allograft or FDA approved synthetic pre-made, pre-shaped cortical bone plug. The anterior end 22 or 22a of the plug 10 or 10a is 3-8 mm and the posterior end 24 or 24a of the plug 10, 10a or 10b is 4-12 mm in diameter in a frustum shape with the wider portion located in the posterior portion to facilitate fixation during bone graft incorporation. The procedure is envisioned to require only one bone plug per facet joint and two per level. Permanent fixation occurs when bone in-growth occurs into the joint itself and into the plug over time.

[0055] The frustum shaped bone graft 10b, as shown in FIG. 10, can be employed when no additional biologic material is required.

[0056] Other equivalent elements can be substituted for the elements disclosed herein to produce substantially the same results in substantially the same way.

Having thus described the invention what is claimed and desired to be secured by Letters Patent is:

I. A facet joint fusion plug comprising:

a substantially solid frustum shaped body having an aperture in a top surface and a pair of first opposed apertures in a side surface and a pair of second opposed apertures in the side surface, both the first and second opposed apertures positioned in a lower portion of the body distal from the top surface;

a vertical channel directed downwardly from the aperture in the top surface, the vertical channel intersecting with a first horizontal channel connecting the first opposed pair of apertures and terminating at a second horizontal channel connecting the second opposed pair of apertures;

at least one pair of flanges partially surrounding a bottom portion of an exterior surface of the body; and

the body formed from a material selected from the group consisting of synthetic cortical bone, a harvested synthetic cortical and compacted iliac crest graft and a cadaveric allograft.

2. The facet joint fusion plug according to claim 1, wherein there is a third pair of opposed apertures in a side surface of the body and the vertical channel intersects with a third horizontal channel connecting the third pair of apertures.

3. The facet joint fusion plug according to claim 1, wherein a second pair of flanges partially surrounds a bottom portion of the exterior surface of the body.

4. The facet joint fusion plug according to claim 2, wherein a second pair of flanges partially surrounds a bottom portion of the exterior surface of the body.

5. The facet joint fusion plug according to claim 1, wherein the first and second horizontal channels are on parallel horizontal planes.

6. The facet joint fusion plug according to claim 2, wherein the third horizontal channel is on a parallel horizontal plane above the first and second horizontal channels.

7. The facet joint fusion plug according to claim 1, wherein the body is formed from synthetic cortical bone.

8. The facet joint fusion plug according to claim 1, wherein the body is formed from a harvested and compacted iliac crest graft.

9. The facet joint fusion plug according to claim 1, wherein the body is formed from a cadaveric allograft.

10. A plug mounted in a hole between bones forming a facet joint, the plug comprising:

a substantially solid frustum shaped body having an aperture in a top surface, the top surface having a greater diameter than a bottom surface;

a first pair of opposed apertures in a side surface of the body, the first pair of apertures connected by a first horizontal channel;

a second pair of opposed apertures in a side surface of the body, the second pair of apertures connected by a second horizontal channel in a parallel plane to the first horizontal channel;

a vertical channel directed downwardly from the aperture in the top surface, the vertical channel intersecting with the first horizontal channel and terminating in the second horizontal channel;

at least one pair of flanges partially surrounding a bottom portion of an exterior surface of the body; and

a synthetic or biologic material compatible with bone passing through the top aperture and exiting from the first and second pair of apertures in the side surface of the body.

11. The plug mounted in a hole between bones forming a facet joint according to claim 10, wherein a third pair of opposed apertures are connected by a third horizontal channel intersecting with the vertical channel, the synthetic or biologic material exiting from the third pair of apertures.

12. The plug mounted in a hole between bones forming a facet joint according to claim 10, wherein there are two pair of flanges spaced apart partially surrounding a bottom portion of an exterior surface of the body.

13. The plug mounted in a hole between bones forming a facet joint according to claim 10, wherein the body is formed from a material selected from the group consisting of a synthetic cortical bone, a harvested and compacted iliac crest graft and a cadaveric allograft.

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14. The plug body according to claim 13, formed from a synthetic cortical bone.

15. The plug body according to claim 13, formed from a harvested and compacted iliac crest graft.

16. The plug body according to claim 13, formed from an iliac cadaveric allograft.

17. A method of mounting a plug in a facet joint C1-C2 and L5-S1, the method comprising:

cutting an arthroscopic type portal in the tissue of a patient outside a diseased or damaged facet joint;

creating a hole between two opposed bones forming the facet joint;

inserting a frustum preshaped plug into the hole, the plug having a shape substantially the same as the hole;

providing the plug with an aperture on a top surface, the top surface diameter being greater than a bottom surface diameter;

providing the plug with at least one pair of flanges partially surrounding an outside side wall and at least a first and second opposed pair of side apertures in the side wall of the plug;

providing an internal cortical channel from the top surface aperture to a first horizontal channel connecting the first

pair of apertures and a second horizontal channel connecting the second pair of apertures;

inserting an applicator tube into the aperture in the top surface;

inserting a synthetic or biologic material compatible with bone into the applicator tube; and

providing sufficient pressure on the synthetic or biologic material to cause egress of the material from the side wall apertures.

18. The method according to claim 17, wherein the preshaped plug is provided as a synthetic cortical bone.

19. The method according to claim 17, wherein the preshaped plug is provided as a compacted iliac crest graft.

20. The method according to claim 17, wherein the preshaped plug is provided as a cadaveric allograft.

21. A solid plug mounted in a hole between bones forming a facet joint, the plug consisting of a substantially frustum shaped body having a posterior end with a diameter of 4 to 12 mm and an anterior end with a diameter less than the posterior end.

\* \* \* \* \*

This US 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

**I. (a) PLAINTIFFS**  
 Orthopedic Development Corporation and MinSURG Corporation

**(b)** County of Residence of First Listed Plaintiff Clearwater, Florida  
 (EXCEPT IN U.S. PLAINTIFF CASES)

**(c)** Attorney's (Firm Name, Address, and Telephone Number)  
 Dennis J. Levasseur (P39778), Candice B. Rusie (P70906), Bodman LLP  
 6th Floor at Ford Field, 1901 St. Antoine Street, Detroit, Michigan 48226  
 (313) 2590777

**DEFENDANTS**  
 Silver Surgical Supply

County of Residence of First Listed Defendant Oakland County, Michigan  
 (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Select One Box Only)

1 U.S. Government Plaintiff  
 2 U.S. Government Defendant  
 3 Federal Question (U.S. Government Not a Party)  
 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Select One Box for Plaintiff and One Box for Defendant)  
 (For Diversity Cases Only)

Citizen of This State	<input type="checkbox"/> 1	<input checked="" type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input checked="" type="checkbox"/> 4
Citizen of Another State	<input checked="" type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

**IV. NATURE OF SUIT** (Select One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<b>PERSONAL INJURY</b> <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input checked="" type="checkbox"/> 840 Trademark	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	LABOR	SOCIAL SECURITY	
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<input type="checkbox"/> 510 Motions to Vacate Sentence <b>Habeas Corpus:</b> <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	<input type="checkbox"/> 710	<input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes	

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Case: 4:08-cv-10696  
 Judge: Gadola, Paul V  
 Referral MJ: Majzoub, Mona K  
 Filed: 02-19-2008 At 03:11 PM  
 CMP ORTHOPEDIC DEVELOPMENT CORP., E  
 T AL V SILVER SURGICAL SUPPLY (TAM)

**V. ORIGIN** (Select One Box Only)

1 Original Proceeding  
 2 Removed from State Court  
 3 Remanded from Appellate Court  
 4 Reinstated or Reopened  
 5 Transferred from another district (specify)  
 6 Multidistrict Litigation  
 7 Appeal to District Judge from Magistrate Judgment

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
 28 U.S.C. Sec. 1331, 1338, Section 3 of Lanham Act.

Brief description of cause:  
 Trademark infringement

**VII. REQUESTED IN COMPLAINT:**

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

**DEMANDS** CHECK YES only if demanded in complaint:  
**JURY DEMAND:**  Yes  No

**VIII. RELATED CASE(S) IF ANY** (See instructions): JUDGE \_\_\_\_\_ DOCKET NUMBER \_\_\_\_\_

DATE: February 19, 2008

SIGNATURE OF ATTORNEY OF RECORD: *Candice B. Rusie*

**FOR OFFICE USE ONLY**

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_