UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

NUVASIVE, INC.
Patent Owner

Case IPR2013-00506
Patent 8,361,156

SECOND DECLARATION OF RICHARD A. HYNES, M.D.

I. INTRODUCTION

1. On August 14, 2013, I provided a first Declaration in this matter. *See* Declaration of Richard A. Hynes, M.D. (Exhibit MSD 1101). This Second Declaration is in rebuttal to statements made in NuVasive, Inc.'s ("NuVasive" or "Patent Owner") Response (the "Response") (Paper No. 21) and the accompanying Declaration of Hansen A. Yuan, M.D. (the "Yuan Declaration") (Exhibit Nuvasive 2022) filed on May 22, 2014. In this Second Declaration, I will address some of the errors set forth in the Response and the Yuan Declaration. To the extent that I do not address a certain portion of the Yuan Declaration does not mean that I agree with that portion. Instead, I have limited my comments to what I believe are the most pertinent and egregious errors stated by Dr. Yuan.

2. In preparing this declaration, I have reviewed the following documents:

a. NuVasive's Preliminary Response (Paper No. 8);

b. NuVasive's Patent Owner Response (Paper No. 21);

c. Declaration of Hansen A. Yuan, M.D. (Exhibit 2020);

d. Exhibits 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, and 2030.

e. Transcript of the Deposition of Dr. Hansen A. Yuan (Exhibit MSD 1173)

3. I have also reviewed additional references cited in this Declaration.

II. REBUTTAL OF DR. YUAN'S TESTIMONY REGARDING BACKGROUND

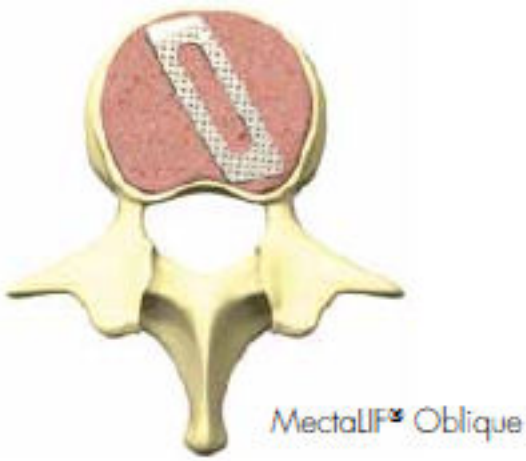
4. In ¶ 26 of the Yuan Declaration, Dr. Yuan states that "[h]istorically, ordinary surgeons before 2004 avoided approaching the lumbar spine from the lateral, transpsoas approach because of the fear of neurologic injury associated with penetrating the psoas muscle." This is incorrect as, prior to 2004, surgeons, such as myself, were not concerned with nor avoided the transpsoas approach, but rather performed surgeries on a regular basis using this approach. In fact, because the lateral transpsoas approach is considered an anterior approach by the North American Spine Society and within the field in general, surgeons have been utilizing transpsoas techniques at least since introduced by Meuler in 1906 when performing a retroperitoneal anterior approach. *See* NASS Memorandum Re: Lateral Interbody Fusion (XLIF, DLIF) of the Lumbar Spine, dated January 5, 2010 (a true and correct copy of which is attached hereto as Appendix A); Rick C. Sasso et al., *Anterior Lumbar Fusion,* Chapter 10 of "Surgical Management of Low Back Pain", 2d Edition (2008) (a true and correct copy of which is attached hereto as Appendix B) at 87; U.S. Patent No. 5,313,962 (attached hereto as Appendix C) at 6:1-58; LJ O'Hara and RW Marshall, *Far Lateral Lumbar Disc Herniation. The Key to the Intertransverse Approach*, 79(6) J. Bone Joint Surg. Br.

943, 943-47 (1997) (a true and correct copy of which is attached hereto as Appendix D); Ex. 1153. During his deposition, even Dr. Yuan testified that he had been performing surgeries using the transpsoas approach for the last 30 years. *See* Yuan Deposition, at 110-111. Accordingly, contrary to Dr. Yuan's statement, lateral transpsoas approaches are not a recent development, but instead are just similar to other anterior approaches that surgeons have been doing for quite some time (and prior to 2004).

5. In ¶ 35 of the Yuan Declaration, Dr. Yuan states that "[t]he maximum possible length for an implant that is inserted from either the front or the back of the patient is limited to the depth of the vertebrae, measured from the anterior to posterior end of the vertebrae." At the relevant time, this statement is incorrect because it overlooks the common occurrence, and prior art teachings, and very real possibility of inserting the implant at an angle (when beginning in the front or back of the patient). The maximum length of the implant depends on the starting point and the angle at which the surgeon inserts the implant, and the tools the surgeon uses in doing so. The maximum length that can be accommodated safely is dictated by the side-to-side (or "transverse") width of the vertebrae and the diagonal depth. In fact, Dr. Yuan's own article, in which an X-ray image shows an implant inserted obliquely, demonstrates that his noted statement is not true, because the length of the implant is plainly not limited by the depth of the vertebrae. *See* Ex. 1117 at 3.

Simple geometry dictates that the hypotenuse of the right triangle formed by the transverse width and depth is longer than the depth. Further, Dr. Yuan admitted his error during his deposition when he admitted that implants greater than 40 mm would fit in the disc space if inserted at an angle from the back. *See* Yuan Deposition at 245:9-16. Indeed I regularly perform oblique procedures, on average 5 or 6 per week over the last three to five years. Recently, I have been performing these procedures using the OLIF procedure as depicted in the brochure (attached hereto as Appendix E) and have taught at least 50 other surgeons how to perform this procedure. This is a completely safe procedure. Oblique procedures like the OLIF have been performed since the late 1990s and allow the use of a longer implant, such as with the Medtronic Clydesdale, which is accused of infringing the '156 patent claims. This oblique approach allows the use of a longer and wider implant and such larger implants are often preferred, especially considering that those of ordinary skill in the art have known since at least 2003 that a single long implant inserted obliquely may be preferable to a pair of shorter parallel implants inserted posteriorly. *See* Shih-Tien Wang et al., *Comparison of Stabilities between Obliquely and Conventionally Inserted Bagby and Kuslich Cages as Posterior Lumbar Interbody Fusion in a Cadaver Model*, 66 J. CHIN. MED. ASSOC. 676, 676-681 (2003) (filed with the Reply as Ex. 1136) (concluding that obliquely inserted implant is preferable to pair of posteriorly inserted implants, and as it provides

same stability while requiring less exposure, enabling precise implantation, and costing less); *see also* U.S. Patent No. 6,626,905 (attached hereto as Appendix F) at 9:32-39; Jie Zhao et al., *Posterior Lumbar Interbody Fusion Using One Diagonal Cage With Transpedicular Screw/Rod Fixation*, 12 EUR. SPINE J. 173, 175-77 (2003) (a true and correct copy of which is attached hereto as Appendix G). I, along with many other surgeons, also routinely approach the spine anterior to the psoas at the L4/L5 level using this and other MIS approaches. Numerous long spinal fusion implants that are inserted using this oblique technique are commercially available, including Medacta's MectaLIF oblique intervertebral body fusion device. These MectaLIF oblique implants are offered at lengths up to 40 mm. *See* Medacta MectaLIF Brochure (a true and correct copy of which is attached hereto as Appendix H) at 6, 18. Such oblique procedures are also very popular overseas, including, for example, in Japan, because no neuromonitoring is involved. I also note that NuVasive promotes a similar approach with its MAS TLIF device and approach and the implant, as mentioned in the associated patent, was at least considered in sizes up to 45 mm. *See* NuVasive Maximum Access Surgery Tranforaminal Lumbar Interbody Fusion Booklet (filed with the Reply as Ex. 1132); U.S. Patent



No. 8,623,088 (filed with the Reply as Ex. 1131), at 5:32-35. Similarly, NuVasive has admitted that its CoRoent XL can be used in TLIF and Posterior Lateral Approaches. *See* Excerpt of Transcript of Deposition of Patrick Miles, taken November 8, 2010 (filed with the Reply as Ex. 1172), at 85:1 to 86:25.

6. In ¶ 39 of the Yuan Declaration, Dr. Yuan states that

> the Telamon implant referenced in the Telamon literature cited by Petitioner and Dr. Hynes was designed to be used as a posterior or PLIF implant. That is, the implant was designed to be inserted from the posterior (or back) side of the patient in a posterior-anterior direction. This is confirmed by the surgical technique guide for the Telamon that shows the implant being inserted in a direct posterior-anterior direction via a PLIF procedure.

While the surgical technique guide cited by Dr. Yuan shows the Telamon implant being used in this manner, in my experience, the implant is not limited to a direct PLIF approach. In fact, the Telamon implant was initially approved as part of the Vertestack system, as indicated on the Telamon Brochure. *See* Telamon Brochure (Exhibit MSD 1107), at 1. The Vertestack System Brochure, submitted in this proceeding as Exhibit MSD 1120, as well as the 510k approval for the Vertestack System issued by the FDA, submitted in this proceeding as MSD 1134, sets out that the components of the Vertestack System can be inserted by anterior, oblique, or lateral approaches. *See* Ex. 1120, at 8, 11. Accordingly, one of ordinary skill in the art who had experience implanting the components of the Vertestack system would have known that not only could the Telamon Vertestack Vertebral Body

Spacer be inserted by anterior, oblique, or lateral approaches, but also that the use of such insertion techniques would have been proper and safe according to the FDA. Moreover, surgeons are entitled to perform surgeries off label (in a manner other than or in addition to those approved for marketing by the FDA) that the surgeon determines to be safe for their patients and would be motivated to do so in the appropriate situations.

7. In ¶ 40 of the Yuan Declaration, Dr. Yuan states that "small changes in design . . . can have significant impacts on the functionality of the implant as used by the surgeon and the clinical benefits of the implant to the patient population." This is an over exaggeration of the effect that certain small changes to an implant may have, especially when those changes are explicitly taught in the prior art, yield predictable and expected results, and involve nothing more than the application of common sense to obtain entirely predictable results. Small dimensional changes, such as those proposed in my first declaration, will not affect or change the function of the implant as the implant will still fit in the patient and will still promote fusion of the vertebrae and create stability in the disc space of the patient. Accordingly, the proposed changes do not create a problem and Dr. Yuan has not presented anything to substantiate his contrary opinion that goes against common sense and routine skill and understanding of a person of skill in this field of endeavor.

8. In ¶ 41 of the Yuan Declaration, Dr. Yuan states that

> [s]pinal interbody fusion implants have to be designed to support the heavy loads placed on the spine, to help align the spine and alleviate pain caused by misalignment, to prevent ejection from the disc space after insertion, and to promote fusion of the two adjacent vertebrae. While it is generally true that interbody fusion implant designers try to design implants with large surface areas, i.e., large footprints, the size of such implants remain limited by the above-described anatomical limitations and the original intended use (for example, the original intended use of Telamon as a PLIF implant). The large surface area of the implant can provide greater structural support and restoring proper spacing between the vertebrae. It is critically important that interbody fusion implants can be inserted along the intended insertion path, can be positioned in the disc space, support the intended load, stay in place after insertion, align the spine, and allow fusion of the vertebrae.

Dr. Yuan's opinion regarding the size of an implant being limited by its supposed "original intended use," and his opinion that it is "critically important that interbody fusion implants can be inserted along the intended insertion path," is without logical support and in fact is inconsistent with my knowledge and routine experiences. As Dr. Yuan and I agree, the goal of interbody fusion "is to induce bone growth between two vertebrae into a single bony bridge." *See* Yuan Declaration at ¶ 31. Accordingly, the intended purpose of any spinal fusion implant is to achieve this goal, and while proper positioning of the implant in the disc space is important, surgeons of ordinary skill in the art knew that there existed multiple insertion paths for a single type of implant, and that the use of one particular path over another was dependent upon the patient's anatomy, and the

specific physiological problem being addressed. Indeed, Dr. Yuan's experience shows that one implant, the Spine Tech BAK, although originally designed for PLIF or ALIF use was easily modified by elongation to be used by him in the angled/oblique approaches and laterally. Similarly, the NuVasive Triad implant was promoted for use laterally, posteriorly, and in postero-lateral procedures. *See* NuVasive XLIF 90 Surgical Technique Brochure (filed with the Reply as Ex. 1175); Malberg M., Extreme Lateral Interbody Fusion (XLIF), in Regan J, Lieberman I, eds. Atlas of Minimal Access Surgery, 2nd ed. St Louis: Quality Medical Publishing, 2004 (filed with the Reply as Ex. 1176); TLIF Surgical Technique Brochure (filed with the Reply as Ex. 1177); First Amendment to Agreement 550002080 By and Between the County of Santa Clara and NuVasive, Inc., dated October 25, 2011 (filed with the Reply as Ex. 1178), at 3. NuVasive has also indicated its CoRoent XL can be used posteriorly, anteriorly, and as a TLIF. *See* Ex. 1172, at 85:1 to 86:25.

9. In ¶ 45 of the Yuan Declaration, Dr. Yuan tries to take my deposition testimony out of context in stating that "[t]he complication with using markers, as identified by Dr. Hynes, is that the implant can have too many of them." It is important to note that the number of markers (four) in the proposed modified implants would not be too many. In particular, the placement of two markers along the medial plane of an implant is an obvious modification particularly when

the implant is made longer, because the markers provide additional information on the location and orientation of the implant that can assist the surgeon in properly positioning the larger implant. As Dr. Yuan testified, such placement of the markers would lead to the predictable result of being able to see the markers in an X-ray image of the implant. *See* Yuan Deposition at 319:8 to 320:6.

10. In ¶ 46 of the Yuan Declaration, Dr. Yuan states that "the strategic placement of radiopaque markers is essential to making radiolucent implants safe and effective for use in the human spine." There is no reason to think that the proposed addition of two markers would impact the safety or effectiveness of the implant, nor did I ever say so in my declaration or deposition testimony. In fact, Baccelli discloses the placement of the two markers along the medial plane. The addition of a marker along the medial plane of the implant is merely an obvious variant if one needs or otherwise wants to know where the middle of the implant is located and/or how the implant is oriented during or after the implant is placed in the disc space. By having two markers along the medial plane, the surgeon is able to tell if the implant has been inserted at an angle. Additionally, Dr. Yuan's statement is not true because it is not essential for some uses to have these markers, for example when used in scoliosis or other deformity applications or when no lamina is present or the vertebrae are otherwise misaligned and therefore cannot reliably be compared to the location of the markers. The markers are merely an

option that may be nice to have, are sometimes helpful, and that a person of skill in the art would include when wanting the information they provide.

11. In ¶ 47 of the Yuan Declaration, Dr. Yuan states that "[t]he claims of the '156 patent are directed to a combination of features for spinal interbody fusion implants particularly suited for insertion in a lateral, transpsoas surgical approach to the spine." Dr. Yuan omits that the specification of the '156 patent states that implant may also "be introduced in a variety of approaches, such as posterior, anterior, antero-lateral, and postero-lateral . . . ." '156 patent, at 5:31-33. In fact, Dr. Yuan later admitted that he now understands that the claims of the '156 patent do not require that implant to be inserted using a transpsoas approach. *See* Yuan Deposition at 94:17 to 97:13.

12. Additionally in ¶ 47 of the Yuan Declaration , Dr. Yuan incorrectly states "that the '156 patent presents novel dimensions and length-to-width proportions for implants that are greater than 40mm in length . . . ." With the assumption that Dr. Yuan was referring to the claimed length to width ratio of 2.5:1 as the "novel" length to width proportion, spinal implants greater than 40 mm in length and having this claimed length-to-width proportion have been known since at least 1997 as shown in BAK PMA Supplemental Decision (filed as Ex. 1118 with the Reply) (a Michelson disclosed implant), which lists approved spinal fusion implants having length-to-width dimensions of 44 mm x 15 mm and 44 mm

x 17 mm. *See* Ex. 1118. Additionally, the Michelson Butterfly was offered in that same size ratio of 2.5:1. *See* Exs. 1116 and 1123 filed with Reply.

13. In ¶ 48 of the Yuan Declaration, Dr. Yuan states that "[p]rior to March 29, 2004, the vast majority, if not all, commercially available spinal implants on the market were designed for insertion into the disc space in posterior or anterior approach, not a lateral approach." This statement is misleading. Prior to March 29, 2004, many implants could be inserted by an anterior or lateral approach. Indeed, as explained by NASS, a lateral approach is merely a variant of an anterior approach and is coded the same for purposes of reimbursement. *See* NASS Memorandum dated January 5, 2010, entitled "Re: Lateral Interbody Fusion (XLIF, DLIF) of the Lumbar Spine" (Exhibit MSD 1119); NuVasive 2014 Reimbursement Guide (a true and correct copy of which is attached hereto as Appendix I), at 3.

14. In ¶ 49 of the Yuan Declaration, Dr. Yuan states that "the direct lateral approach to the lumbar spine presents complications because of the presence of the psoas muscle." This statement is misleading because a direct lateral approach to the spine is not particularly complicated in comparison to other types of approaches, and surgeons trained to perform anterior surgeries, such as myself, should generally feel comfortable using such a lateral approach as of the time of this invention. This approach was often used to treat tuberculosis or other

spinal infection, tumors, or scoliosis, in conjunction with direct visualization as the nerves that a surgeon needs to avoid using this approach are clearly visible. *See e.g.,* Yuan Dep. at 109:20 to 111:1. Additionally, there was no need to perform a lateral surgery by going through the transpsoas muscle, as it was well known to be safe and effective to retract the psoas muscle when using a lateral approach prior to 2004, including in the lower lumbar region. *See, e.g.,* Paul C. McAfee et al., *Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine*, 23 SPINE 1476, 1478 (1998) (a true and correct copy of which is attached hereto as Appendix J).

15. In ¶ 50 of the Yuan Declaration, Dr. Yuan states that he

> would find it surprising if someone had used one of Dr. Michelson's illustrated implants to attempt a fusion on a live human patient because, in my opinion, the lumbar implants described by Dr. Michelson . . . were not useful and would have been readily recognized in March 2004 as being unnecessarily risky for use in a live human patient based on the surgical techniques practiced at the time.

This is an unexpected and uninformed opinion considering that Medtronic had commercialized a Michelson '973 implant that was inserted using a lateral technique as early as 2001. As one example, Medtronic's Butterfly Fusion System, first made available in 2001 utilized a variety of Michelson-style implants, with widths ranging from 14 to 16 mm, and lengths ranging from 30 to 40 mm. *See* Butterfly Fusion System Surgical Guide (Ex. 1123), at 2, 19. Additionally, long

BAK cages were commercialized well before 2004 and were approved by the FDA. Presumably the FDA, along with the surgeons who used these Michelson implants, did not think they were unnecessarily risky. Additionally, Dr. Yuan testified that it was reasonable given the level of knowledge in the late 1990s for him and Dr. McAfee to use such implants on living patients on at least two occasions. Yuan Dep. at 60:13 to 61:2. Further, I have personally treated a patient with a long lateral implant that was originally inserted in 2001. Attached hereto as Appendix K is a true and correct copy of an X-ray image of this patient.

16. In ¶ 51 of the Yuan Declaration, Dr. Yuan states he "perform[ed] a handful of lateral fusion procedures using the BAK cage," but that "those procedures were performed using a retracted psoas approach to the spine," "the implants were not commercially available," and the "results were not what we hoped for." To provide context to this statement, it is important to note that the BAK cage was an embodiment of an implant commensurate with the claims of Michelson and created by a licensee of Michelson. *See* Sulzer Spine-Tech 2000 Price List (filed with the Reply as Ex. 1159). Additionally, whether true or not, the assertions that these procedures were performed with a retracted psoas and that the implants were not commercially available, and whether the results were not what Dr. Yuan hoped for, are immaterial. What is important is that Dr. Yuan has admitted that such lateral procedures were being performed prior to 2004 with

implants that were historically inserted using an anterior or posterior approach and that when motivated to do so he and others obtained customized elongated PLIFs or ALIFs or used longer versions of those implants for lateral or angled approaches. *See* Yuan Dep. at 42:17 to 50:18; *id* at 62:14-19. Dr. Yuan also admitted that at the time, in the late 1990s, it was reasonable and believed to be safe by those reviewing the procedure, for him to proceed with implanting these devices in human patients using this approach. *See* Yuan Deposition at 60:13 to 61:2.

17. In ¶ 60 of the Yuan Declaration, Dr. Yuan states that "having two radiopaque markers also allows a surgeon to see . . . whether the implant is askew and the degree to which the implant is askew. These uses were not disclosed in the cited prior art references." This is an incorrect statement as the cited prior art reference Baccelli discloses the use of markers in this manner. *See* Baccelli at FIG. 2. Moreover, these markers provide an entirely predictable and expected result, as Dr. Yuan also admitted in his deposition. Yuan Dep. at 319:8 to 320:6. There is nothing new or nonobvious about using markers in the middle of the implant.

18. In ¶ 63 of the Yuan Declaration, Dr. Yuan notes that "the CoRoent XL spinal fusion implants are available with a longitudinal length greater than 40mm (e.g., 45mm, 50mm, and 55mm) extending from a proximal end of the

proximal wall to a distal end of the distal wall." Dr. Yuan, however, fails to note that 25% of the CoRoent XL spinal fusion implant sizes that have been offered by NuVasive have a longitudinal length of only 40 mm, and because these implants have lateral width of 18 mm, the implants have a length-to-width ration of 2.2 to 1. These facts contradict Dr. Yuan's earlier statement that the claimed longitudinal length of greater than 40 mm and length-to-width ratio of 2.5 to 1 are necessary to allow the implant to be inserted using a lateral, tranpsoas approach.

II. REBUTTAL OF DR. YUAN'S TESTIMONY REGARDING THE PRIOR ART RELIED ON BY THE PTAB FOR INSTITUTING IPR

19. In ¶ 79 of the Yuan Declaration, Dr. Yuan states that "the SVS-PR was designed to be an interbody spacer that is inserted using a PLIF (posterior) procedure in a direct posterior-anterior direction in the disc space," and that "a person of ordinary skill in the art would have recognized this fact." This is an incorrect and misleading statement based on a significant underestimation of the skill level of those of ordinary skill in the art and ignoring the description on the brochure and its relationship to the FDA clearance of this product. One of ordinary skill in the art, depending on the patient and the physiological condition to be corrected, would have known that besides being inserted in a "direct anterior-posterior direction in the disc space," the implant could also be inserted at an angle or laterally if desired. In fact, this angled approach was the technique utilized and

described in a journal article authored by Dr. Yuan. *See* Ex. 1117, at 1-6. Additionally, I also note that this implant was originally cleared by the FDA as a vertebral body replacement device, which, as Dr. Yuan noted, can also be put in anteriorly, laterally, or obliquely just like the CoRoent XL, which was also cleared as a vertebral body replacement device. *See* Yuan Dep. at 154:1-7; CoRoent 510k (Ex. 1143); Synthes Vertebral Spacer 510k (Ex. 1146); Miles Dep. Transcript 2010 (Ex. 1172), at 75:1-76:26; *id.* at 81:1 to 82:25; *id.* at 85:1 to 86:25. Further, as previously mentioned, surgeons are entitled to perform surgeries off label (in a manner other than or in addition to those approved for marketing by the FDA) that the surgeon determines to be safe for their patients and would be motivated to do so in the appropriate situations.

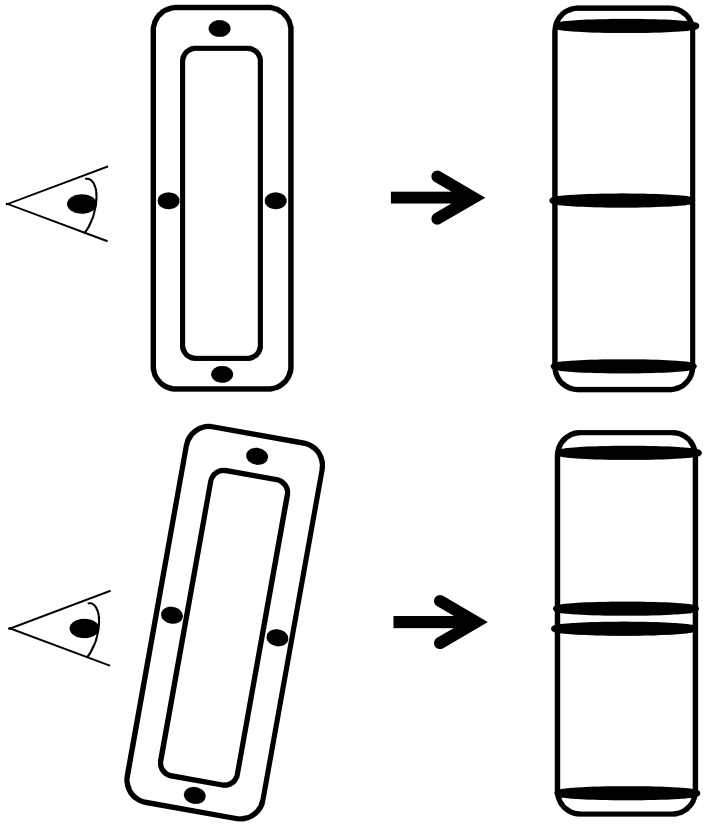
20. In ¶ 80 of the Yuan Declaration, Dr. Yuan states "a person of ordinary skill in the art would have recognized that the SVS-PR implant was intended for a PLIF procedure for final placement in a direct anterior posterior direction by the dimensions in which the SVS-PR was available." Again, as stated above, this is incorrect because one of ordinary skill in the art would have understood at the time of invention that the SVS-PR could be used not just as a PLIF, but also as an ALIF or laterally, as it was explicitly promoted in the brochure and as indicated by its FDA approval.

21. In ¶ 81 of the Yuan Declaration, Dr. Yuan states that "the pair of markers at the posterior and distal walls [of the SVS-PR] would provide surgeons with all of the requisite orientation and positioning information for a PLIF procedure." This statement is incorrect. The noted markers alone do not provide *all* of the requisite information a surgeon may desire. For example, the inclusion of marker along the medial plane of the implant allows the surgeon to accurately track the positioning of the implant as it inserted into the patient. In this way, the middle marker may be analogized to the light found at the center of a long vehicle, such as a stretch limousine, to indicate the presence of a long vehicle. *See e.g.*, 49 C.F.R. 571.108 at Table I-A - Required Lamps and Reflective Devices (requiring placement of intermediate side marker lamps "on each side [of a vehicle over 30 feet] located at or near the midpoint between the front and rear side marker lamps"); Trucks, Buses, MPVs: Federal Lighting Equipment Location Requirements, http://www.nhtsa.gov/Vehicle+Safety/Other+Equipment/Trucks,+Buses,+MPVs:+Federal+Lighting+Equipment+Location+Requirements (last visited Sept. 2, 2014) (noting "functional purpose" of intermediate side marker lamps on vehicles 30 feet or longer is to "indicate presence of a long vehicle.").

This is an especially apt comparison as it comports with NuVasive comparing its large CoRoent implants with stretch limousines. *See* NuVasive Press Release re: 60 mm CoRoent XL Implants (a true and correct copy of which is attached hereto as Appendix L).

CoRoent	Stretch Hummer	CoRoent XL 60mm Implant
		
Impressively Long	X	X
Market-leading Strength and Support	X	X
Large Apetures for Bony Through-Growth		X
Marker Rods for Optimal Visualization		X
Exceptionally Good Looking	X	X

Further, as depicted below, the addition of a second marker along the medial plane of the implant would inform the surgeon as to whether the implant was askew after insertion in the disc space.



22. In ¶ 82 of the Yuan Declaration, Dr. Yuan states that as proof of the SVS-PR's use as a PLIF only "[t]here are no instrument sets listed [in the SVS-PR Size and Instrument Set Brochure] for an anterior approach, let alone for a lateral approach." This fact is irrelevant, as it does exclude implantation of the SVS-PR using a different technique, such as an anterior, lateral or oblique technique.

23. In ¶ 85 of the Yuan Declaration, Dr. Yuan states that the "length and width dimensions are far smaller than what would be normally required for a

lateral, trans-psoas implant in the lumbar spine, and the width is much smaller than typical anterior insertion lumbar implants." This is irrelevant because there is no requirement in the claims of the '156 patent that the claimed implant be inserted using a lateral trans-psoas (or any other type of) approach and no reason why you could not apply the teachings of this reference to implants you might use or that are usable for such an approach. This statement also ignores the explicit disclosure on this brochure that it is also a vertebral replacement device, and like the similarly sized NuVasive Triad, could be inserted in various approaches including laterally and anteriorly. *See* Telamon Brochure (Ex. 1107), at 1; NuVasive XLIF 90 Surgical Technique Brochure; Malberg M., Extreme Lateral Interbody Fusion (XLIF), in Regan J, Lieberman I, eds. Atlas of Minimal Access Surgery, 2nd ed. St Louis: Quality Medical Publishing, 2004; TLIF Surgical Technique Brochure; First Amendment to Agreement 550002080 By and Between the County of Santa Clara and NuVasive, Inc., dated October 25, 2011, at 3; Deposition Transcript of Patrick Miles, taken September 4, 2014 (filed in Reply as Ex. 1174), at 121-124].

24. In ¶ 85 of the Yuan Declaration, Dr. Yuan also states that

> the Telamon implants are designed with a 3° lordosis sloped downwardly in the direction of the trailing end that mates with the inserter tool, thereby further indicating to a person of ordinary skill I the art that the Telamon implant should be inserted in a posterior path. If a Telamon implant were inserted laterally across the vertebrae, it would create a scoliotic deformity in the patient due to the sloped surface.

This statement is based on a substantial underestimation of the skill and knowledge of one of ordinary skill in the art. The proposed modification to the Telamon, as well as the SVS-PR, is to make the implant longer, thereby increasing its stability. One of ordinary skill in the art would have found it obvious to adjust the slope of the implant in the proper direction depending on how the modified implant was inserted. One of the functions of these types of implants is to restore the height of disc space. Therefore, one of ordinary skill in the art would have understood that if, for example, the implant was to be inserted using a lateral approach, one would simply change the relationship of the opposing side walls to make one side wall taller than the other, as was well known and common at the time of invention. Indeed, PLIF implants are rarely actually inserted straight. Rather they are typically inserted at an angle but do not create a scoliotic deformity. This is also clear from the fact that Telamon was originally approved by the FDA as a vertebral body replacement and in that capacity could be inserted at an angle. I do not believe the FDA would have approved this implant for this use if it determined that such use would create scoliosis.

25. In ¶ 86 of the Yuan Declaration, Dr. Yuan states that "the Telamon implant has a side aperture—often referred to as a visualization window—in the medial plane of the implant. As previously described, these windows are generally designed to help the surgeon visualize bone healing/fusion post-operatively, so

such visualization windows should not be obstructed by a radiopaque marker passing through." The placement of a single wire marker in that window would not present an obstruction and would not prevent a surgeon from observing the bone fusion/growth occurring post-implantation. Dr. Yuan's statement can be analogized to stating that a mullion on a window would not allow one to see through the window, which is simply not true. Similarly, the heads up display that pilots use to target does not preclude them from seeing the target, but rather merely provides additional information to accurately locate the target relative to the sites on their weapon systems, like the markings on the optics in a rifle scope.

26. In ¶ 88 of the Yuan Declaration, Dr. Yuan states that "[b]eing a cervical implant, the dimensions of Baccelli's implant are going to be significantly smaller than the dimensions of an implant used in the lumbar spine." The facts that the implant disclosed in Baccelli could be used as a cervical implant, and that it may have smaller dimensions than a lumbar implant when used in the cervical spine, are irrelevant because Baccelli has been cited by the Board for its disclosure of four radiopaque markers in the same arrangement as claimed in the '156 patent. The use and size of the implant of the Baccelli implant do nothing to negate the use of this reference for its teaching of four radiopaque markers arranged as claimed in the '156 patent, nor does it change the function of those markers, which is entirely predictable. In fact, the smaller sized embodiment of Bacelli that NuVasive relies

on shows that 4 markers (two being in the middle) are not confusing even on a smaller implant where the markers are physically closer together.

27. In ¶ 89 of the Yuan Declaration, Dr. Yuan states that "one of skill in the art would recognize that it would take a great deal of experimentation and modification to make Baccelli's cervical implant appropriate as a lumbar interbody fusion." Again, as stated above with respect to ¶ 88, the suitability of the Baccelli implant for use in the lumbar region is irrelevant to the instituted grounds. Further, to the extent that one of ordinary skill in the art would have wanted to modify the Baccelli implant for such use, I disagree that it would have taken a great deal of experimentation. The function of the implant would be unchanged, and the conditions to promote fusion would be unchanged. All that would have been required at the time is a simple resizing of the implant based on the known anatomical constraints of the lumbar disc space, and the known teachings of Michelson and the other cited prior art references.

28. In ¶ 93 of the Yuan Declaration, Dr. Yuan states that

> I believe that a person of ordinary skill in the art in March 2004 (and even today) would recognize that Michelson proposes implants in which the width (or diameter in the case of the dowel designs) is quite large even compared to the largest dimension (the length), thereby providing an implant that is both long and wide to fulfill Dr. Michelson's intended purpose of an "oversized" spinal implant.

This statement ignores the disclosure of long and narrow implants disclosed in Michelson, including the disclosure of applications incorporated by reference in Michelson, such as U.S. Pat. Appl. Ser. No. 08/394,836 and U.S. Pat. Appl. Ser. No. 08/074,081. For example, Figures 18 and 19 of Michelson depict such long and narrow implants. *See* Michelson, at Figs. 18 and 19. Michelson explicitly describes an alternative embodiment that "has a narrower width." *See* Michelson at 10:47-54. Moreover, it would be understood by the disclosure in Michelson, by the permissive language in this exemplary disclosure, that it could be used as a single narrow implant. *See* Michelson at 10:49-54 ("The spinal fusion implant 1000 is similar to the spinal fusion implant 900, but has a narrower width such that more than one spinal fusion implant 1000 *may* be combined in a modular fashion for insertion v.rithin the disc space D between the adjacent vertebrae."). Further, one of ordinary skill in the art, by comparing the relative sizes of the implants shown in Michelson would have readily understood that implant 900 had a width in the range of 12 mm to 16 mm, or approximately half that, or less, of implant 900, which Michelson describes as having a width "in the range of 24 mm to 32 mm." *See* Michelson at 10:41-44.

FIG. 18

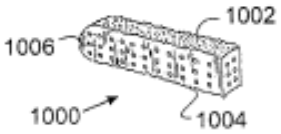
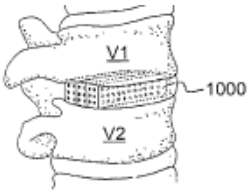


FIG. 19



29. In ¶ 91 of the Yuan Declaration, Dr. Yuan states that "nothing in Michelson '973 indicates that his implants are designed to be used in a posterior

approach to the spine." This statement is irrelevant and also ignores the posterior approach implants incorporated into the Michelson disclosure (a concept Dr. Yuan admits he does not understand). Michelson is being relied upon for its disclosure of implants having dimensions as claimed in the '156 patent. Again, the claims of the '156 patent are not limited the use of any particular approach to insert the implant.

30. In ¶ 92 of the Yuan Declaration, Dr. Yuan states that "the implants of Michelson '973 are made of titanium." This is incorrect and misleading. Titanium is merely one example of the materials disclosed by Dr. Michelson, as the specification discloses that the implants may be "made of a material appropriate for human implantation *such as* titanium *and/or may be made of*, and/or filled and/or coated with . . . ." Michelson, at 5:66-67 (emphasis added). Michelson also discloses that the implants "can be made of *any* material suitable for human implantation," and "may be made of *an* artificial material." *Id.* at 7:40; 6:37 (emphasis added). Michelson also discloses that the implants may also be made of "a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material." *Id.* at 5:67 to 6:5.

31. In ¶ 92 of the Yuan Declaration, Dr. Yuan also states that "it is my understanding that the implants illustrated in Michelson '973 have never been

commercialized and have never been inserted in a live human patient." This statement is incorrect because Michelson implants were commercialized, for example by Medtronic with its Butterfly system, as well as the long BAK cages that were sold by Spine Tech.

32. In ¶ 94 of the Yuan Declaration, Dr. Yuan states for some reason that I "do[] not do very many PLIF procedures." This statement is both irrelevant, and incorrect. I was trained to perform PLIF procedures by Dr. Cloward, the pioneer for such procedures, and while it is true that I prefer to perform ALIF procedures, I nevertheless have performed hundreds of PLIF procedures, and still routinely perform PLIF procedures.

33. In ¶ 95 of the Yuan Declaration, Dr. Yuan states that the Saber implant "is not made of PEEK." This is incorrect. The Saber implant is formed from "carbon fiber reinforced PEEK material." *See* Exhibit 2017, at 3.

34. In ¶ 98 of the Yuan Declaration, Dr. Yuan states that "[t]here would be no reason to place an additional marker near the middle or medial plane of the implant, as doing so would be redundant. In fact, doing so could cause problems, including confusing the surgeon," and that I somehow agreed with him on this point. This is a gross mischaracterization of my testimony. I testified that the placement of too many markers in different orientations may hypothetically create confusion sometimes, and analogized the situation of using too many markers to

that of the "big metal blob" that a surgeon would see when looking at an X-ray image of metal implants. *See* Hynes Deposition at 164:10-22. I do not believe that the placement of two markers on the medial plane of an implant would cause confusion to a surgeon of ordinary skill in the art.

35. In ¶ 99 of the Yuan Declaration, Dr. Yuan states that "redundancy or potential confusion . . . would be caused by excessive markers position[ed] in or near the medial plane of the PLIF implants." This is an exaggeration as well as an incorrect statement. The addition of two markers along the medial plane would not cause confusion. Additionally, the two additional markers would not be redundant because, as noted above, they would allow the surgeon to determine if an individual implant had been inserted askew.

36. In ¶ 101 of the Yuan Declaration, Dr. Yuan states

> In the PLIF procedure for SVS-PR and Telamon, the vertebrae cannot be distracted to the same degree from a posterior approach due to a number of anatomic structures. Thus, a person of ordinary skill in the art in March 2004 would have recognized that Baccelli's protruding metal spikes 24 should not be incorporated into PLIF implants such as SVS-PR or Telamon because the protruding metal spikes 24 would substantially impair posterior insertion of the PLIF implant into the disc space and/or potentially cause a significant amount of tissue damage during impaction into the disc space from the posterior path.

This is an incorrect statement because the spikes 24 of Baccelli are suitable for a PLIF procedure. It is irrelevant that the vertebrae might not be distracted to the same degree as the cervical vertebrae, and Dr. Yuan does not establish that this

difference in the degree of distraction would actually prevent insertion of an implant featuring such spikes. It is also not true that such spikes would potentially cause a significant amount of tissue damage, as these spikes are present on NuVasive's own CoRoent XL implants, and it is unlikely that such spikes would be included by NuVasive if they were unsafe. Moreover, even Michelson teaches, by incorporation, the distraction of the disc space by as much as 10 mm. *See* U.S. Patent No. 5,484,437 (the "'437 patent")) incorporated by reference in Michelson through its incorporation by reference in U.S. Patent No. 5,772,661, at 14: 61-62 ("[T]he distraction necessary to restore the height of the interspace would be approximately 10 mm."). Further, Dr. Yuan admitted in certain PLIF procedures in the lumbar spine the disc space may be distracted by as much as 5 mm. *See* Yuan Dep. at 186:4-15. These tiny spikes in Bacelli and the CoRoent XL are much smaller than 5 or 10 mm and can be implanted safely with no or little distraction.

37. In ¶ 102 of the Yuan Declaration, Dr. Yuan states

> I do not believe that a person of ordinary skill in March 2004, when lateral, trans-psoas procedures were not widely used and there was no commercial lateral, trans-psoas implant available, would have found it obvious to add two radiopaque markers in the medial plane of a PLIF implant such as SVS-PR or Telamon. Doing so would not provide any meaningful additional information regarding the implants location and orientation, and instead would provide imaging information that is redundant or possibly confusing in the X-ray or fluoroscope images, as described above. Moreover, one of ordinary skill in the art in

> March 2004 would not have had a rational basis to add Baccelli's protruding metal spikes 24 to the SVS-PR implant or the Telamon implant because of the increased difficulties associated with impacting a PLIF implant with such protruding spikes 24 into the disc space via the posterior insertion, and because of the increased risks of harm to the patient.

There are numerous errors with this statement. First, as discussed above, the statement "there was no commercial lateral, trans-psoas implant available" is both irrelevant to the current proceeding, and incorrect. Second, one of ordinary skill in the art would have been motivated to put in the radiopaque spikes disclosed in Baccelli on a longer SVS-PR or Telamon for the reasons stated above, especially if the implant was to be put in at an angle or if it was desired to set the implant in the disc space in a particular orientation. Therefore, it is incorrect to state that such a modification would be disadvantageous. Further, it is incorrect to say one of ordinary skill in the art would not have a rational basis to make such modification, as such a basis exists simply because the references are in the same field and share the same function of spinal fusion and these markers provide the predictable result of supplying information on location and orientation in such implants. This is just the basic application of common sense to a potential desire for more information on the location and orientation of an implant in the body as was known in the art.

38. In ¶ 103 of the Yuan Declaration, Dr. Yuan states

> that a person of ordinary skill in the art in March 2004 would recognize that the proposed modifications to the SVS-PR and

> Telamon PLIF implants (increasing the longitudinal length to be greater than 40 mm) would render each implant inoperable for its intended PLIF purpose and would furthermore require a change in the basic principle (a PLIF procedure) under which the SVS-PR or Telamon construction was designed to operate.

This statement is incorrect for multiple reasons. First, Dr. Yuan is ascribing the wrong "intended purpose" to these implants. The purpose any these types of implants, the SVS-PR and the Telamon and the claimed implants of the '156 patent, is to promote fusion of the vertebrae. Moreover, there is nothing in the claims of the '156 patent that is directed to or otherwise requires the use of any particular technique to insert the implant. With that in mind, it is important to note that Dr. Yuan has not indicated in any way that the proposed modifications to the Telamon and SVS-PR would render them inoperable for their intended purpose of fusing vertebrae. This is simply because he cannot legitimately make such a claim. Additionally, even if the intended purpose of these implants or the claim language necessitated insertion using a posterior approach (which they do not), modifying the implants as proposed would not render the implants inoperable for this purpose. As stated above, an implant inserted using a posterior approach does not have to be inserted in a direct anterior to posterior direction. Instead, a longer implant may be inserted posteriorly at an angle so as to fit within the disc space. Further, one of ordinary skill in the art would have been motivated to modify SVS-PR and Telamon to have a length greater than 40 mm, to make the implant more stable, and to provide

better structural support to the adjacent vertebrae while reducing patient exposure. Dr. Yuan is also ignoring the teachings in the Telamon and SVS-PR brochures that they are also used (or have a purpose) as vertebral body replacement devices and as he admitted in his deposition such devices may be inserted laterally, anteriorly, and at an angle or obliquely. Further, he ignores the fact that even CoRoent XL could be inserted posteriorly and was similarly originally approved as a vertebral body replacement device. *See* Ex. 1172, at 75:1 to 76:25, 81:1 to 82:25, and 85:1 to 86:25.

39. In ¶ 105 of the Yuan Declaration, Dr. Yuan states that "both SVS-PR and Telamon were designed to be PLIF implants with an intended use in a traditional PLIF procedure (direct posterior approach)." As noted above, this is incorrect, as both implants, in addition to being usable as a PLIF device, were also explicitly described in their brochures as, and originally cleared by the FDA as vertebral body replacement devices, which would include use for anterior, lateral and oblique procedures. *See* Telamon Brochure (Ex. 1107), at 1; SVS-PR Brochure (Ex. 1106), at 1; VerteStack 510k – K031780 (Ex. 1134), at 1; Synthes Vertebral Spacer 510k – K011037 (Ex. 1146), at 1; and Ex. 1172 at 30:5 to 34:6. Accordingly, the designs of the SVS-PR and Telamon allow for other approaches for insertion.

40. Also in ¶ 105 of the Yuan Declaration, Dr. Yuan misconstrues my testimony when he states

> I agree with Dr. Hynes, if a PLIF implant was modified to have a longitudinal length greater than 40 mm and then inserted in the traditional PLIF path (as shown on the cover of the SVS-PR surgical guide and the Telamon guide), the modified implant would indeed "protrude" from the anterior aspect of the disc space.

I did not say that say that a longer implant would necessary protrude, and, in fact, stated that it would not protrude if angled. Further, when posed with a hypothetical (that NuVasive characterized as an "absurd" question) necessitating that the implant protrude, I did explain that the implant could be safely placed in the space in the vertebral body where the surgeon approaches anteriorly if the surgeon inserted the implant posteriorly. Put another way, the oblique path of insertion from the anterior direction provides a safe space that the implant theoretically could protrude. While this may not be an optimal placement of the implant, nor one that I would necessarily recommend, when asked this hypothetical question I did explain that an implant could nevertheless still potentially be physically placed in this space.

41. In ¶ 106 of the Yuan Declaration, Dr. Yuan takes Dr. Sachs' testimony out of context and states that the insertion of "a greater-than-40mm PLIF implant from a posterior approach . . . [is] fraught with risk that would be avoided by a person of ordinary skill in the art." Dr. Sach's testimony was based on the

knowledge of one skilled in the art *prior* to the teachings provided in Michelson. With the benefit of the teachings of Michelson, one of ordinary skill in the art would have understood safe ways of inserting a long implant laterally and antero-laterally. Additionally, as noted above, the insertion and placement of a long implant at an angle using a posterior approach will also provide for a safe implantation as was done by Dr. Yuan himself. Accordingly, such a procedure would not be "fraught with risk." Additionally, while not in the Yuan Declaration, I note that the Patent Owner has included in its Response a distorted modified image taken from the Telamon Brochure. *See* Response at 52. Patent Owner states that the image has been modified to "show Petitioner's proposed modification to Telamon's implant–having a length increased from the original 26

mm to the proposed length of greater than 40 mm . . . ." *Id.* As shown below, Patent Owner's modified Telamon has an equivalent length of nearly 49 mm.

Original Image	Original image with length increased by 54% (assuming original image is 26 mm, equivalent to a length of 40 mm)	Manipulated image from Response (actual increase of length of 88%; assuming original image is 26 mm, equivalent to a length of 48.88 mm)
		

III. ADDITIONAL REMARKS

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: September 5, 2014

By: _____
Richard A. Hynes, M.D.

Appendices to Second Hynes Declaration

APPENDIX A: NASS Memorandum Re: Lateral Interbody Fusion (XLIF, DLIF) of the Lumbar Spine, dated January 5, 2010

APPENDIX B: Rick C. Sasso et al., *Anterior Lumbar Fusion,* Chapter 10 of "Surgical Management of Low Back Pain", 2d Edition (2008)

APPENDIX C: U.S. Patent No. 5,313,962

APPENDIX D: LJ O'Hara and RW Marshall, *Far Lateral Lumbar Disc Herniation. The Key to the Intertransverse Approach*, 79(6) J. Bone Joint Surg. Br. 943, 943-47 (1997)

APPENDIX E: OLIF25 Technique Brochure

APPENDIX F: U.S. Patent No. 6,626,905

APPENDIX G: Jie Zhao et al., *Posterior Lumbar Interbody Fusion Using One Diagonal Cage With Transpedicular Screw/Rod Fixation*, 12 EUR. SPINE J. 173, 175-77 (2003)

APPENDIX H: Medacta MectaLIF Brochure

APPENDIX I: NuVasive 2014 Reimbursement Guide

APPENDIX J: Paul C. McAfee et al., *Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine*, 23 SPINE 1476, 1478 (1998)

APPENDIX K: X-ray image of patient

APPENDIX L: NuVasive Press Release re: 60 mm CoRoent XL Implants

APPENDIX A

NASS
NORTH AMERICAN SPINE SOCIETY
7075 Veterans Boulevard, Burr Ridge, IL 60527
Toll-free: (866) 960-6277 Phone: (630) 230-3600
Fax: (630) 230-3700 Web: www.spine.org

January 5, 2010

Re: Lateral Interbody Fusion (XLIF, DLIF) of the Lumbar Spine

The North American Spine Society (NASS) has recently become aware that several insurance companies have proposed or are considering noncoverage/nonpayment of a technique of lumbar interbody fusion that utilizes a lateral approach with the use of specialized retractors. NASS is a multispecialty medical organization dedicated to fostering the highest quality, evidence-based, ethical spine care and wishes to provide comment on this technique and corresponding development.

While the concept of this technique, lumbar interbody fusion utilizing a lateral approach with the use of specialized retractors, is not proprietary, there are two commonly used proprietary retractor systems; XLIF, manufactured by Nuvasive (San Diego, CA) and DLIF Sofamor Danek manufactured by Medtronic (Memphis, TN).

In order to provide comment, it is necessary to fully comprehend the technical aspects of lateral interbody fusion (LIF), performed either using the XLIF or DLIF systems. The procedure utilizes a portal made in the lateral flank through which serial dilators and retractors are placed through the psoas muscle to be seated on the lateral aspects of the disc space and vertebral bodies. By utilizing a smaller incision than other open surgical techniques that often utilize a posterior or anterior approach, it is appropriately described as an open, minimally invasive operation that is performed under direct visualization (in contrast to a percutaneous procedures which are billed using unlisted CPT codes) . While the retractors systems are new in recent years, the approach is not novel. Open lateral approaches to the upper lumbar spine and thoracic spine are considered a standard method of accessing the discs and vertebral bodies in appropriately indicated cases. Such approaches have been used for the treatment of lumbar degenerative disorders, tumors, fractures, and infections of the spine. The major anatomical distinction between open anterior and lateral approaches is, notwithstanding the size of the incision, dissection being performed anterior or through the psoas muscle. As the psoas muscle is only present in the lumbar spine (L1 to S1), this discussion is most relevant to the lumbar spine.

Dictated by surgeon preference, there are variations in the exact manner in which open anterior or lateral exposure of the lumbar is executed. Based on the location of pathology, the patient's body habitus, and presence or absence of spinal deformity, a direct anterior or more lateral approach to the disc and vertebral bodies can be chosen. The marketed forms of LIF procedures in question (XLIF or DLIF) have standardized the approach to direct lateral access that utilizes dissection through the psoas muscle instead of anterior to the muscle.

Some insurance companies have ascribed such descriptors as "investigational" and "experimental" to XLIF and DLIF procedures. These terms do not seem to be justified. Prior to the introduction of XLIF and DLIF, a spinal surgeon could have chosen to perform an open procedure using a direct lateral corridor, as is performed in LIF, as part of standard customary practice, including transpsoas approaches. Anterior interbody arthrodesis (thoracic, lumbar, additional level) accurately describes these procedures and as such CPT codes 22556, 22558, and 22585 have been recommended. Regardless of the exact direction of accessing the lumbar spine from L1 to L5, the appropriate code has been that for ALIF, 22558. The technical aspects of XLIF and DLIF are not sufficiently distinct from an ALIF to justify another code. NASS has consistently held this position and addresses it in the attached 2006 *SpineLine* article.

In an illustrative comparison, describing a procedure such as lumbar artificial disc replacement (LADR) as "investigational" and "experimental" at the time of its introduction was completely justified. In the case of LADR, the risks, complications, and efficacy were unknown with no analogous procedure from which one could extrapolate results. Thus, randomized controlled trials were needed in order to introduce this novel implant and technique to the general population. Once the results of these studies were evaluated by the FDA, the procedure was approved. Although equivalency (noninferiority) was demonstrated, some payers have been reluctant to provide reimbursement for the newer procedure. Notwithstanding the details of the continued controversy, the course of LADR demonstrates appropriate early use of the terms "investigational" or "experimental" to the betterment of patient care.

In understanding the technical aspects of LIF as detailed above and the nuances of standard open anterior access to the lumbar spine, a major distinction must be made between a new procedure such as LADR and a modified approach for a standard, accepted procedure, such as LIF. LIF, in the form of XLIF or DLIF, is a method of performing an operation that has long been considered a standard practice. It is novel only in its use of a smaller incision and a different retractor system. If one were to consider LIF as experimental or investigational, than one would need to conclude that there is only one correct method of performing an anterior lumbar interbody fusion, that all surgeons access the spine through the exact same tissue planes, and that the disc and vertebral bodies are all accessed in the exact same orientation. Not only is this technically impossible, it is not verifiable.

It is true that accessing the lumbar spine by dissection of the psoas muscle has attendant risks. This is the case with other types of open anterior lumbar surgery as well. The known complications with standard anterior retroperitoneal or transperitoneal exposure of the lumbar spine include injury to the structures that reside within or on the psoas muscle, most notably the nerves of the lumbar plexus.

Because of its minimally invasive approach in which the psoas muscle and its associated structures are not widely dissected, surgeons who perform LIF routinely employ some type of neurological monitoring. The purpose of neurological monitoring is to detect if dilators or retractors are too close to a neurological structure in the psoas muscle and, if so, they are repositioned. Historically, this is analogous to neurological monitoring that is performed for any other type of spinal surgery in which the status of nerve function is assessed during the operation. Cadaveric studies have demonstrated the relationship of the neural structures in the psoas muscle which have identified that there is a safe corridor through which the lumbar spine can be accessed by a direct lateral approach.[i]

As such, approach-related nerve complications have been reported in the limited series available. Knight et al[ii] reported 9 approach-related complications in a series of 58 patients undergoing XLIF or DLIF. The authors compared this to a historical cohort of patients undergoing posterior lumbar fusion at the same institution, finding comparable rates of complications. The types of complications included ipsilateral L4 nerve root injuries, lateral femoral cutaneous nerve injuries, and psoas muscle spasm. In another report, Anand et al[iii] found 3 of 12 patients who underwent XLIF for degenerative scoliosis had new onset thigh dysasthesias, which resolved within six weeks. One of 12 had quadriceps weakness that resolved within six weeks. These types of complications have been reported with open anterior approaches to the lumbar spine.[iv]

Literature Review: In reviewing the literature, there are limited data concerning clinical outcomes specifically with XLIF or DLIF. In fact, the published series primarily report early outcomes and approach-related complications. Perhaps these two parameters are most pertinent, as there are a multitude of studies regarding the outcomes of lumbar interbody fusion, whether via an anterior or posterior technique. Anand et al[iii] published results from a prospective evaluation of 12 patients who underwent XLIF, in addition to other minimally invasive fusion techniques, for the treatment of degenerative scoliosis. At a mean follow-up of 75.5 days, the VAS pain score improved an average of 2.3 points. Complications in this series were detailed above. Knight et al[ii] retrospectively reviewed results of 58 patients who underwent DLIF or XLIF. Though clinical outcomes were not measured, the group found that blood loss, complication rates, and operative times were comparable between the DLIF and XLIF groups. These parameters were comparable to those in a historical cohort of patients who underwent posterior fusion at the same institution.

Based on the presentation of the aforementioned discussion points, NASS provides the following conclusions regarding coverage of XLIF and DLIF:

- *Lateral interbody fusion (LIF), in the form of XLIF, DLIF, would be inappropriately characterized as "experimental" or" investigational"*.

- *While additional clinical outcomes data would be helpful for any surgical procedure including (LIF), these data are not needed to endorse continued use and coverage of these forms of interbody fusion*.

- *XLIF and DLIF should be coded and reimbursed as an ALIF. The technical execution and surgical principles of LIF are sufficiently analogous to if not a variation of ALIF. It should not be coded as a percutaneous procedure (unlisted CPT code)*.

- *XLIF and DLIF, which are anterior procedures, should not be confused with posterior procedures that have similar sounding names, such as TLIF, PLIF, and GLIF (Trademark, Alphatec).*

After reviewing the above comments, it is hoped that UHC will concur that XLIF and DLIF are *not* investigational or experimental and thus provide coverage accordingly. NASS welcomes the opportunity to further elaborate on the comments provided herein.

Thank you for your consideration.

Regards,

Ray Baker, MD
President

c: Christopher Bono, MD, Chair, Professional Economic and Regulatory Committee
William Mitchell, MD, Director, Health Policy Council

Attachment

---

[i] Regev GJ, Chen L, Dhawan M, Lee YP, Garfin SR, Kim CW. Morphometric analysis of the ventral nerve roots and retroperitoneal vessels with respect to the minimally invasive lateral approach in normal and deformed spines. Spine. 2009; 34:1330–1335.

[ii] Knight RQ, Schwaegler P, Hanscom D, Roh J. Direct lateral lumbar interbody fusion for degenerative conditions: early complication profile. J Spinal Disord Tech. 2009; 22:34-37.

[iii] Anand N, Baron EM, Thaiyananthan G, Khalsa K, Goldstein TB. Minimally invasive multilevel percutaneous correction and fusion for adult lumbar degenerative scoliosis: a technique and feasibility study. J Spinal Disord Tech. 2008; 21:459-467.

[iv] Rauzzino MJ, Shaffrey CI, Nockels RP, Wiggins GC, Rock J, Wagner J. Anterior lumbar fusion with titanium threaded and mesh interbody cages. Neurosurg Focus. 1999; 15;7(6):e7.

APPENDIX B

AQ1

10 Anterior Lumbar Interbody Fusion

Rick C. Sasso, A. Kirk Reichard, and Shenil Shah

Historical Background

Anterior lumbar interbody fusion (ALIF) was first used in the treatment of tuberculosis and lumbar spondylolisthesis.[1–3] Although described by Capener[4] in 1932 as the "ideal" operation for spondylolisthesis, he further elaborated that "the technical difficulties of such procedure, however, preclude their trial." This statement was soon to be proven wrong by numerous technical advances in ALIF. When initially developed, the transperitoneal approach for lumbar arthrodesis was the norm, but was later replaced by the retroperitoneal approach. The first description of the transperitoneal approach was published in 1906 by Muller,[5] and Iwahara[6] first reported the later approach in 1944. Further broadening the scope of ALIF, Lane and Moore[7] in 1948 reported ALIF as a treatment for lumbar degenerative disk disease. Here they used the transperitoneal approach with an allogenic bone graft in 97 patients, reporting a 54% fusion rate after 8 months and a clinical success rate of 94%.

Further developing Iwahara's retroperitoneal approach, Hodgson and Stock[8,9] established the foundation for the modern era of ALIF while treating Pott's disease with different bone grafting materials. Debridement of the necrotic tissue, followed by decompression of the spinal canal, allowed them to place corticocancellous blocks of autogenous bone into the defect to obtain arthrodesis. The dowel technique, developed by Ralph Cloward in 1953, involved the use of cylindrical shaped corticocancellous dowels. Although Cloward[10–12] used a posterior approach, his methods for disk removal, end-plate preparation, and grafting were widely used. Following Cloward's dowel technique, four individuals adapted this to make their own innovations in bone grafting methods. Two of them, Harmon[13] in 1963 and Sacks[14] in 1965, were the first to utilize the dowel technique for an anterior lumbar fusion. The third, Crock, developed a cylindrical allograft for the anterior approach to the lumbar spine. Finally, the fourth, O'Brien et al,[15] modified a technique of using trapezoidal bone blocks for the treatment of lumbar discogenic pain through ALIF. They later developed a hybrid interbody graft using a biologic fusion cage (femoral cortical allograft ring) packed with autogenous cancellous bone graft. By using autogenous iliac crest bone graft, rapid incorporation and vascularization of the graft are achieved, as well as and long-term stability.[16] Furthermore, the femoral allograft ring allows for acute stability of the construct and a compatible framework for host bone ingrowth.[15]

Despite the success in safely exposing the anterior lumbar spine, in the 1970s and 1980s stand-alone ALIF was not a reliable procedure due to low fusion rates. Early in the development of the procedure, there was great discrepancy among success rates. The reported numbers were incredibly inconsistent, with some reporting huge success and others complete failure. For example, Lane and Moore,[7] as stated previously, reported a 94% clinical success rate. In contrast, though, Adkins[17] in 1955 had a fusion rate of l%. Early reports encompassing numerous surgical techniques and a heterogeneous group of patients demonstrated a fusion rate of 95% by Harmon,[13] 70% by Hoover,[18] 90% by Crock,[19] and 96% by Fujimaki et al.[20] However, other reports cited fusion rates of 19%, 40%, 45%, and 56% by Calandruccio and Benton,[21] Nisbet and James,[22] Raney and Adams,[23] and Flynn and Hoque,[24] respectively. A 1972 study conducted from the Mayo Clinic and authored by Stauffer and Conventry[25] concluded definitively that the stand-alone ALIF had a low success rate. After reporting on 83 patients who underwent ALIF without instrumentation between 1959 and 1967, they found an extremely low success rate, with pseudarthrosis occurring in 44%. The Mayo Clinic study resulted in a review of the ALIF as a stand-alone procedure, and it soon after fell out of favor, particularly for the indication of lumbar degenerative disk disease and lumbar axial back pain.

In response to these low fusion rates, a technique combining an ALIF with posterior fusion became very common.[26] Although the anterior approach continued to be utilized for the diskectomy, lordosis restoration, and fusion block insertion, a posterior approach was used to access the posterior elements for instrumentation and stabilization **(Fig. 10.1).** The addition of posterior instrumentation increases stability across the segment and decreases motion while the fusion solidifies. Despite having a very high fusion rate, the magnitude of the circumferential fusion increased morbidity. Although the ALIF usage had been revitalized with posterior instrumentation, the search for a better construct continued.

Fig. 10.1

These new innovations included anterior lumbar instrumentation, first reported by Humphries et al[27] in 1961. They developed a slotted, contoured plate that was placed over the anterior lumbar spine in an attempt to enhance arthrodesis. Another advance in anterior hardware was the cylindrical cage. The first cylindrical cages were modified from a smooth, stainless steel, fenestrated cylinder (Bagby

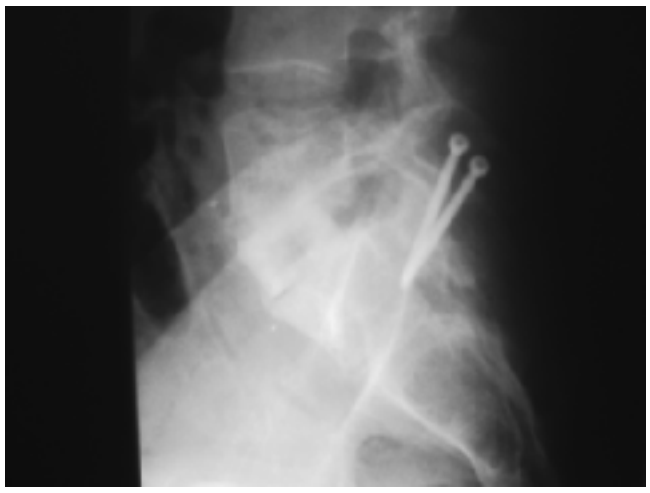


Fig. 10.1 Lateral radiograph of circumferential fusion using a femoral ring allograft for the anterior lumbar interbody fusion (ALIF) and translaminar facet screws for posterior stability.

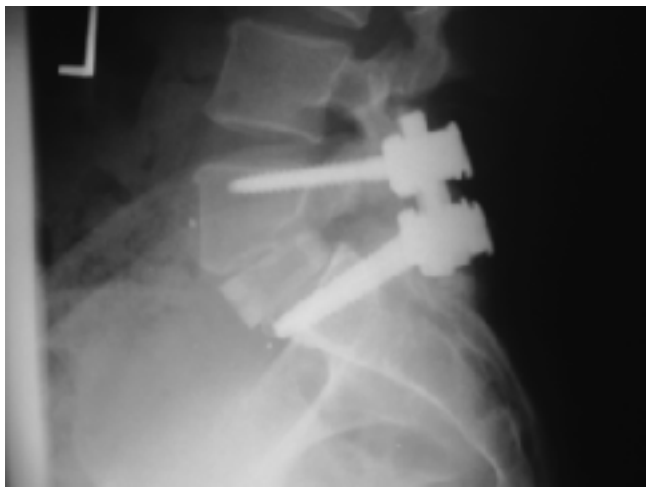


Fig. 10.2 Lateral radiograph of circumferential fusion using a femoral ring allograft for the ALIF and pedicle screws and rods for posterior stability.

basket) used by Bagby and colleagues in the mid-1970s and early 1980s to treat Wobbler syndrome, which is a chronic cervical instability causing myelopathy in thoroughbred horses.[28] In Bagby's procedure, he packed the cage with cancellous bone chips obtained from the reaming of the cervical decompression, thus eliminating the need for an autograft harvest. Further, the cage was developed with perforations in its walls to allow for bone ingrowth and to enhance fusion. This construct allowed for early stability and improved arthrodesis. Animals studies corroborated the success of this procedure with fusion rates as high as 88%.[28–31] Following the original cylindrical cage, more and more improvements in the design of the cages led to the Bagby and Kuslich design (BAK, Spine-Tech, Minneapolis, MN), which was first implanted in humans in 1992.[32] This BAK titanium cage was threaded and screwed into the end plates for stabilization and fusion of the segment. Another similar device developed by Ray[33] (Ray TFC, Surgical Dynamics, Norwalk, CT) was initially used in posterior lumbar interbody fusion (PLIF) but was later adapted to the ALIFs as well.

Although cylindrical cages were originally metal alloy, the development of machined bone dowels provided several advantages. Threaded bone dowels are similar in nature to a metal cage, but differ in that they are osteoconductive, incorporated over time, radiographically benign, and easier to revise.

Despite the rampant usage and initial success of the threaded cylindrical cage in the late 1990s, the next generation, the lumbar tapered (LT) cage, has several advantages over the cylindrical predecessor. It provides the same benefits of a cylindrical device, but allows the surgeon to symmetrically ream the end plate while restoring lordosis. Symmetric reaming prepares the end plate for fusion and preserves the strength.

In addition, LT cages packed with recombinant human bone morphogenetic protein (rhBMP-2) perform as well as those packed with autograft. AQ2

Other constructs include trapezoidal cages. Trapezoidal constructs can be made from various materials, but several features are shared, including a large footprint for maximum end-plate coverage and a large inner volume for bone graft and future fusion maturation.

Although cages continue to be widely used, femoral ring allografts (FRAs), as well as other trapezoidal implants are growing in popularity. The rhBMP-2 is also commonly used during all spinal fusions. Using rhBMP-2 decreases donor-site morbidity, as well as operating room time, and has proven to be as effective as autologous bone. Not surprisingly, the surgical approach has again been revisited, and recent research has shied away from laparoscopic approaches in favor of a retroperitoneal "mini" open approach. Although the ALIF was conceived over 100 years ago, it continues to be updated and improved with each new generation of implant and surgeon.

The ALIF has developed over decades, and specific attributes have been identified as primary contributors to a successful outcome. With the disk as the pain generator, removal of the pain source with a total diskectomy addresses the patient's presenting complaint. Also, restoration of disk height can alleviate foraminal stenosis. Re-creation of native lordosis may decrease juxtalevel stress. And lastly, posterior stabilization maximizes the likelihood of fusion **(Fig. 10.2).** Fig. 10.2

Biomechanics

The greatest strength of the vertebral body is present in the peripheral subchondral bone of the cortical end plate.

When threaded cages are used, the preparation process violates this peripheral ring of subchondral bone. Although this process compromises the strong ring of subchondral bone and theoretically raises the risk of subsidence, it also exposes vascular cancellous bone that may facilitate healing.

In contrast, to prepare the intervertebral space for a nonthreaded, trapezoidal implant, such as an FRA, the strong peripheral ring of subchondral bone is preserved and directly supports the graft while fusion occurs. In the past when FRAs were fashioned by the surgeon on the back table, the size and shape were difficult to match, and this strong ring of subchondral bone may not have been maximally utilized. Now, FRAs are more frequently manufactured, and thus size and shape are more predictable. This enables the surgeon to match the implant to the patient and build the most stable construct. In addition, manufactured FRAs have the benefit of insertion instruments that distract the adjacent vertebral bodies and ensure proper alignment and placement.

The spine endures a wide range of biomechanical forces, from 400 N while standing, to greater than 7000 N during heavy lifting,[34,35] with an maximum compression strength of 10,000 N.[36] The selected implant should not fail under these loads. When tested, modern-day implants usually sustain the maximum loads, with failure occurring at the end plate or the sacroiliac joint.[37] With implants infrequently failing, every effort must be made to utilize the intrinsic strength and healing potential of the end plate to promote rapid fusion. Considering that the implants usually do not fail, when constructs do fail, it generally results in subsidence of the implant into the vertebral body, or cavitation. As the end plate fails, either due to violation during preparation or after excessive loading, the implant migrates into the vertebral body and the segment collapses. Cavitation is addressed by choosing an implant with a large contact area, or footprint. A larger footprint provides a bigger foundation for the implant, decreasing the load per square inch **(Fig. 10.3).**

Fig. 10.3

Subsequently, a successful implant should be mechanically strong to withstand compressive loads while providing an osteogenic, osteoinductive, and osteoconductive matrix. Many metal alloy implants provide strength and stability but are unable to incorporate these other attributes. To compensate, metal implants provide an environment that allows the surgeon to place an autogenous cancellous bone graft, which does accomplish these later goals. Although metal implants can provide an environment that is fusion friendly, it is limited by the specific design and subsequent volume available for the fusion to traverse through the implant. To maximize the area available for fusion, the surgeon should expose the entire end plate with a total diskectomy,[38] as well as choose an implant that provides the most volume for the biologic substrate and future fusion block.

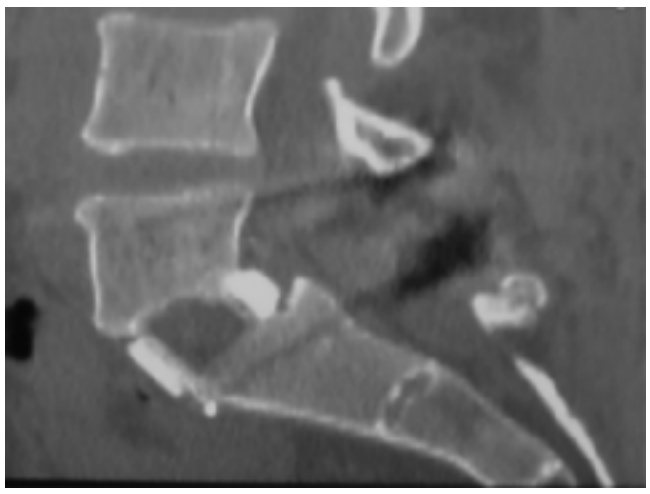


Fig. 10.3 Sagittal reconstruction of a computed tomography (CT) scan with a femoral allograft at L5-S1 demonstrating a large footprint and support on the peripheral endplate.

Implant design affects how the load is transmitted to the adjacent vertebra and may contribute to juxtalevel discogenic pain.[39] A recent biomechanical analysis revealed that greater implant contact area transmits loads to the adjacent segment in a more physiologic manner and could decrease adjacent level pain, as Kumar et al[39] found in 2005 that implants with smaller surface areas transmit loads in a similar manner to a degenerative disk that causes discogenic pain. In addition, physiologic stress patterns are better recreated when the patient's lordotic curve is restored. Consequently, when choosing a device, the largest appropriate implant should be carefully implanted after a total diskectomy. This would theoretically prepare the end plate in the correct fashion, load the adjacent vertebra more physiologically, and, when fused, minimize the risk of juxtalevel disease and pain.

Rh-BMP-2 is now routinely used for spinal fusions. The decrease in donor-site morbidity and operating room (OR) time are inviting; however, a recent study found a concerning trend. This prospective cohort study found a lower fusion rate with rhBMP in FRAs. Although, the ALIFs studied were stand-alone, the fusion rate was decreased with the use of rhBMP. The authors believe that the drop in fusion rate, although insignificant, may be secondary to rhBMP-induced resorption of the FRA **(Fig. 10.4).** If the ring is absorbed more quickly, the graft may weaken or fragment, which allows motion at the segment before fusion occurs, resulting in an unsatisfactory outcome.[40] This stand-alone study reinforces the significance of stabilizing the fusion segment. Although FRA implants are stable at the time of implantation, rhBMP may accelerate the resorption process and destabilize the segment before fusion can occur. Posterior stabilization with pedicle screws or translaminar facet screws provides the needed stability necessary for fusion.

Fig. 10.4

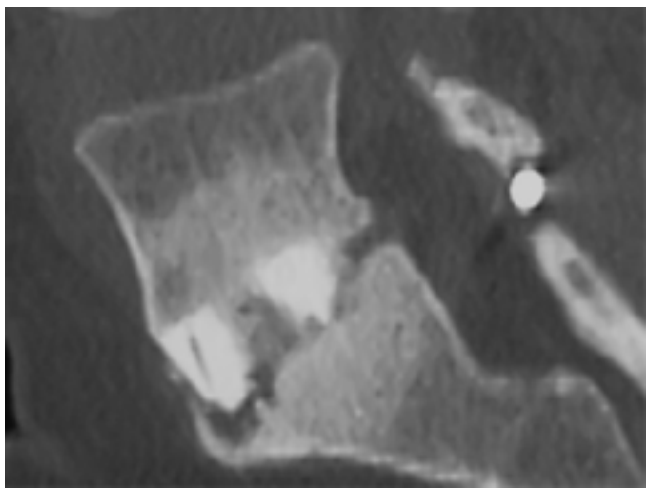


Fig. 10.4 Sagittal reconstruction of CT scan with a femoral allograft packed with recombinant human bone morphogenetic protein (rhBMP-2) demonstrating early resorption of bone at the caudal graft–host junction.

Although the ALIF was conceived as a stand-alone device, posterior instrumentation has proven to be optimal for reliable fusion. Even though the stand-alone ALIF does have intrinsic stability, posterior stabilization is recommended because posterior instrumentation provides stability in the range the cage does not.[41] Several implant options have been used, two of which are pedicle screws and translaminar facet screws. Ferrara et al[42] performed a biomechanical comparison of these two constructs and found both to be reliable constructs, with similar properties. After 180,000 cycles, both constructs were equivalent with regard to stiffness and motion. With similar biomechanical properties, implant choice can be determined by other factors, including surgeon preference, and patient-specific characteristics.

Although both constructs have similar integrity, multiple factors should be considered. Best and Sasso[43] recently reviewed 105 ALIF patients receiving translaminar screws or pedicle screws, and they found that the OR time was greatly reduced with translaminar screws, and the blood loss was significantly less.[43] Translaminar screw placement combines a midline incision and percutaneous screw placement, thus decreasing the overall incision length. To place translaminar facet screws, less muscle stripping is required, the cephalad facet joint is not disrupted, and instrumentation prominence is not an issue.[44] Despite the benefits of translaminar facet screws, patients with a prior complete laminectomy and removal of the spinous process or those with spondylolysis are not candidates.

Understanding the biomechanics of the spine is critical to interpreting the principles with the latest implants and techniques. Despite the ever-changing approach to lumbar disk disease, the ALIF relies on removal of the entire degenerative disk, preserving end-plate strength, re-creating physiologic lordosis, eliminating motion across the segment, and most importantly, achieving a stable fusion.

Patient Selection

Most low back pain is transient and self-limiting; however, 5% does not respond to nonoperative treatment.[45,46] Although this small percentage of patients does not improve with the most conservative measures, the surgeon must be confident that all conventional alternatives have been exhausted. Leaving options behind and moving ahead too quickly places risks on patients who would have improved without surgery and puts the surgeon at risk of an unacceptable outcome. Utilizing conservative methods and screening tests with high predictive value improves practice outcomes.

The ALIF is a commonly used surgical intervention to treat discogenic low back pain not controlled by nonoperative measures. Indications for an interbody fusion include degenerative disk disease of one or two adjacent levels of the lumbar spine, with severe, chronic, disabling, low back pain lasting longer than 6 months and unresponsive to adequate nonoperative therapy.[33,47] Less than three levels should be addressed at a time, as the risk of pseudarthrosis increases with each additional level fused and clinical success decreases.[48–50]

The pathophysiology of discogenic pain is poorly understood; however, we do know that other factors, such as compensation and pending litigation, affect outcomes.[51] These confounding variables must be accounted for prior to determination of the definitive therapy. The importance of the history and physical examination cannot be overstated; the interaction with the patient is an opportunity for the surgeon to assess the patient's expectations and determine if the patient is motivated by secondary gain.

Magnetic resonance imaging (MRI) is a sensitive and specific tool for diagnosing disk pathology[52]; however, asymptomatic disk pathology or herniation can be as high as 34%.[53] Boden et al[53] studied 20- to 39-year-olds, and found that more than one third had asymptomatic disk degeneration and more than one fifth had asymptomatic disk herniations. MRI should not be used as a screening tool and should be ordered only when clinical suspicion is high for spinal pathology.

Although controversial, diskography can provide the surgeon additional information prior to surgical intervention. Diskography is a diagnostic tool that many feel correlates pathoanatomy and symptomatology in patients with primary discogenic pain. Several studies suggest improved outcomes in interbody fusion patients after supportive preoperative diskography.[54–56] Re-creation of concordant pain with diskography especially under low pressures can verify the pain source or help rule out pathology at a specific level **(Fig. 10.5).**

Fig. 10.5

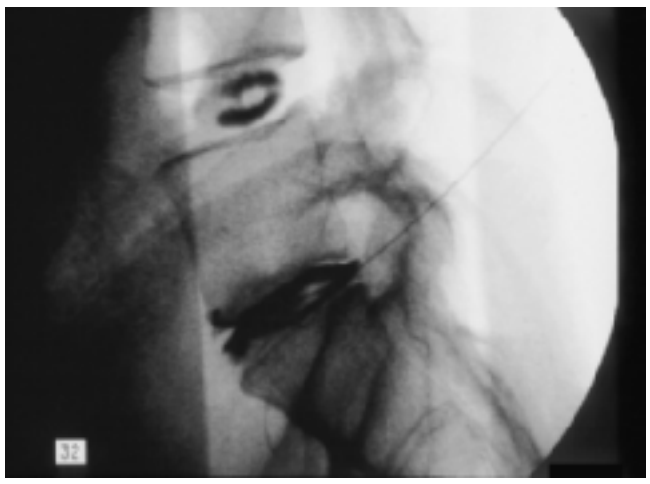


Fig. 10.5 Lateral radiograph during diskography with a morphologically abnormal L5-S1 disk and a normal L4-L5 disk.

Another provocative test with predictive value is the selective nerve root injection (SNRI), which can elucidate the pathophysiology of the pain generator in patients with complex disk disease or nontraditional radiculopathy. A positive result, meaning the patient has 100% relief of symptoms following the injection of anesthetic, correlates with the benefits achieved following surgical intervention of simply decompressing the offending nerve.[57] This procedure is easily performed by an experienced anesthesiologist and gives the surgeon an added layer of confidence before surgical intervention **(Fig. 10.6).**

Fig.10.6

Operative intervention for spinal pathology places the patient at risk. Utilizing available diagnostic tools improves patient outcome and avoids low-yield surgical intervention. The least expensive and most easily used tools likely are the history and physical examination of the patient.

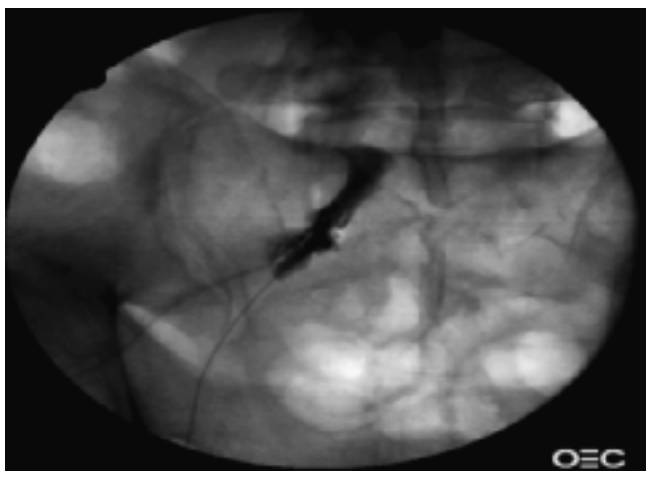


Fig. 10.6 Anteroposterior radiograph during selective nerve root injection (SNRI) of the left S1 nerve.

Clinical Studies

The ALIF has evolved over several decades through constant reevaluation and technique revision. To date, the most reliable constructs employ an anterior fusion that is stabilized posteriorly with instrumentation. Several attempts have been made to optimize an anterior-only, stand-alone technique; however, fusion rates have been less reliable. Posterior instrumentation provides the additional stability needed for rapid fusion, and now with the addition of rh-BMP, donor-site morbidity can be eliminated.

Despite the wide usage of cylindrical cages throughout the 1990s, no prospective fusion data was available until 2004. Starting in 2000, 140 patients were enrolled in a prospective, randomized, controlled, clinical trial comparing fusion rates of stand-alone threaded cages and stand-alone FRAs.[58] The 13 surgeons who took part in the trial implanted either a pair of cylindrical threaded titanium cages or an FRA. Both implants were packed with autograft, and fusion was evaluated at 6-month intervals by a board-certified radiologist. At 6 months, 95% of the threaded cages were fused as compared with only 10.9% of the FRAs, and the superior fusion rate remained in favor of threaded cages throughout the study. The highest fusion rate obtained by the FRA control group was 51.9% at 2 years, in contrast to the lowest fusion rate seen with the threaded cages was 95% at 6 months. Regardless of the outstanding fusion capacity of threaded cages, clinical outcomes remained equal between groups.[58] These surprising clinical findings may be explained by Fraser's[59] analysis in 1995, which attributes the clinical success of the ALIF to the surgical approach to the pathologic disk and not the fusion status.

The more recent emergence of LT cages enables surgeons to restore lumbar lordosis while achieving the similarly high fusion rates seen with cages. Burkus et al[60] compared LT cages implanted with rh-BMP-2 and FRA with autologous bone graft, and found no difference in outcomes, supporting the use of rh-BMP-2.[60] Having an off-the-shelf substitute for autologous bone graft allows surgeons to spare their patients the morbidity associated with donor sites, without sacrificing the osteoinductive properties needed for a fusion **(Fig. 10.7).**

Fig. 10.7

Although donor-site morbidity has overshadowed autologous bone grafting, a prospective analysis was lacking. The senior author of this chapter participated in the first prospective analysis of over 200 spinal fusion patients randomized to an autologous donor arm and an rh-BMP arm comparing postoperative pain. Nearly one third of the autologous donors had persistent donor-site pain 2 years postoperatively compared with zero pain in the rh-BMP randomized group.[61] The ability to eliminate donor-site pain is an appealing option for the spine surgeon, despite appearing to be an added expense.

A comparison of an off-the-shelf osteoinductive growth factor reveals that they are in fact a cost-effective way of

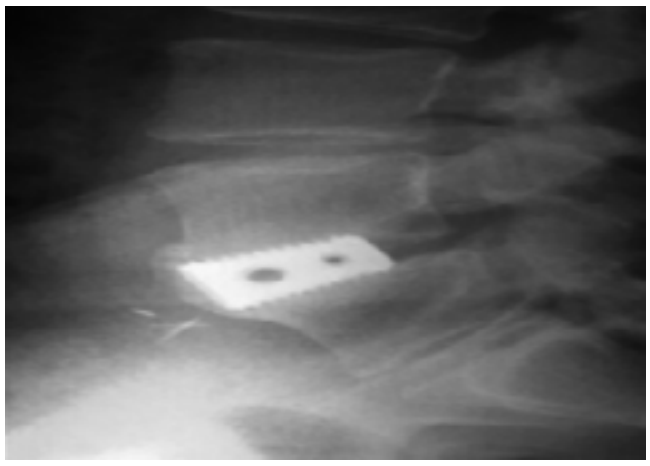


Fig. 10.7 Lateral radiograph of ALIF with an lumbar tapered (LT) cylindrical cage and BMP.

decreasing patient morbidity and maximizing patient outcomes. This 2003 evaluation found that the cost of BMP is offset by reductions in other care expenses. For example, valuable OR time is reduced with the use of a protein substitute, the postoperative period is less painful, and less nursing staff wound care is required for the patient.[62]

Reduction of OR time is beneficial for patients as well as for surgeons. Similar to using rhBMP, performing a 270-degree fusion (posterior instrumentation without fusion after an ALIF) versus a 360-degree fusion may be another effective way to trim OR time. A 2001 prospective randomized trial failed to reveal any clinical difference with the addition of the posterior instrumentation. The Oswestry Low Back Disability Index (ODI) and the Numerical Rating Scale (NRS) were used to evaluate outcomes following ALIF with or without posterior stabilization, and there were no statistical clinical differences.[63] Without clinical support of the posterior fusion, surgeons could choose to decrease operative supply cost (i.e., supplies needed for posterior fusion), shorten OR time, and decrease intra/postoperative complications.

Evaluation of patient success can be addressed from many perspectives. A clinical evaluation may reveal a pain-free patient with total resolution of symptoms despite a radiographic result that may be discordant, or vice versa. Using interval plain radiographs and computed tomography (CT) scans, a recent study shows that LT cages plus rhBMP compared favorably with LT cages plus autograft, and those supplemented with rhBMP achieved more bone formation outside of the cage. Both constructs formed bone similarly through the implant, but rhBMP improved bony fusion outside the cage. This confirms that rhBMP is not only comparable to autologous bone graft as an osteoinductive agent, but may be superior when specifically evaluating bone formation outside the stabilizing construct.[64]

Multiple papers support the stability of threaded cages and the clinical success[33,65,66]; however, a recent retrospective review revealed an increased complication rate with threaded devices compared with nonthreaded trapezoidal block-type constructs. This retrospective review identified a significantly higher number of intraoperative complications with threaded devices and the tools used to prepare the site and insert the devices. The study also found more postoperative complications; however, this was not statistically significant. The greatest numbers of complications seen were vascular in nature, including both intraoperative and postoperative. Most of these complications can be linked to the added steps required to prepare the level for the threaded device and the insertion instrumentation.[58]

The surgical techniques employed to expose the anterior lumbar spine focus on the preservation of adjacent structures to minimize long-term complications. The anterior lumbar spine can be approached via a transperitoneal or extraperitoneal approach using various incisions. As with other surgical disciplines, minimally invasive techniques have been pioneered with varying results. The laparoscopic anterior lumbar interbody fusion (LALIF) first appeared in the late 1990s,[67,68] with positive results presented by the early users. Initial LALIF reports indicated that the procedure was a safe, less invasive procedure, with less blood loss and faster patient recovery. However, follow-up reports found LALIF to be more time-consuming, and the touted benefits similar to those achieved with a "mini" open retroperitoneal approach.[69,70] In 2003, Chung et al[71] performed a 47-patient side-by-side comparison of the LALIF and the mini-ALIF and reported similar clinical and radiographic outcomes, with no identifiable advantages to the LALIF, despite the added technical challenge. Not only have the proclaimed benefits of the laparoscopic approach been challenged, but also specific complications are higher with the LALIF.

Two studies in 2003 reported a higher risk of retrograde ejaculation following a transperitoneal LALIF as compared with a mini-open retroperitoneal ALIF.[72,73] The delicate superior hypogastric plexus lies on top of the L4–S1 anterior spine and innervates the internal vesical sphincter. Damage to the plexus can cause retrograde ejaculation in men. The transperitoneal approach, either laparoscopic or open, dissects through this fragile web of nerves, whereas an open retroperitoneal approach, mini or traditional, sweeps the plexus from left to right. Retraction of the plexus as a whole versus dissection through it appears to decrease the risk of internal vesical sphincter denervation.

Imaging

Evaluation of interbody arthrodesis is difficult and controversial secondary to various fusion criteria.[50,59,74,75] Varying criteria include bridging bone and no motion on flexion and extension films, whereas others allow limited motion.

Radiographic assessment is also limited by the materials implanted.

Computed tomography and plain x-ray are traditionally used to assess fusion. Utilizing these tools, pseudarthrosis is identified by lucency around the cage, motion across the segment, or lack of bridging bone extending through the cage. Unfortunately, no study, other than histologic, is 100% reliable. Even with the improved quality of reconstructed, thin-segment, high-resolution CT, it is also unreliable in evaluation of fusion status.[38,74,76,77]

Post-ALIF pain is often attributed to pseudarthrosis. A follow-up study of patients with persistent back pain following ALIFs with radiographically confirmed fusions found a high rate of pseudarthrosis upon reoperation. Six of seven patients had pre-revision CT scans that failed to show peri-implant lucency. Seven of eight patients had pre-revision plain films showing no signs of loosening. The CT scan and plain films were both hindered with the use of a metal implant as compared with a bone allograft, making the predictive value of these screening tools low when metal implants were used.[74,77]

In addition, Cizek and Boyd[74] performed a cadaveric study on three different implant materials to determine the predictive value of CT scan versus plain radiographs for identification of a fusion. They compared bone cages, titanium cages, and carbon fiber cages, and found that neither CT scan nor plain radiograph was reliable. Fusions identified on CT were often refuted with plain films and vice versa.

Another study on pig-tailed macaques *(Macaca nemestrina)* reexamined this controversy, finding thin section helical CT better than plain films at identifying the presence of fusion; however, the extent of fusion was overestimated on CT when compared with histology. The predictive values of the CT results were greater in this nonhuman study with 83% concordance between the CT and the histology, versus 45% concordance with plain radiographs.

In summary, radiographic assessment of interbody fusions is suboptimal secondary to interpretation and implant artifact. Although these tools may be beneficial for identification of the grossly positive or negative result, the more difficult cases may require additional studies and possibly surgical exploration for definitive diagnosis.

Conclusion

Low back pain is generally treated with nonoperative measures, including nonsteroidal antiinflammatory drugs (NSAIDs), physical therapy, lifestyle modification, and time. Unfortunately, not all patients with discogenic pain respond to nonoperative treatment. A thorough preoperative evaluation should be able to determine patients with primary discogenic pain who may respond to operative arthrodesis.

The mini-open retroperitoneal ALIF approach allows the surgeon to maximize exposure without compromising the superior hypogastric plexus or the rectus muscles. The mini-ALIF approach is retroperitoneal and minimally invasive in nature with a low complication rate.

Choosing an implant is a personal decision and should be founded in clinical success. FRA has proven to be successful, especially with posterior instrumentation, and has unique benefits with regard to postoperative imaging. When an FRA is used in conjunction with posterior instrumentation and an off-the-shelf osteogenic biologic, an ideal construct for a 360-degree fusion has been created. Additionally, using translaminar facet screws to minimize soft tissue insult will optimize clinical success.

Our current assessment of spinal pathology will continue to change and our treatment options will too. Although spine surgery is an ever-changing world, the patient interactions and clinical success that motivate those involved is a constant.

References

1. Mercer W. Spondylolisthesis with a description of a new method of operative treatment and notes of ten cases. Edinburgh Med J 1936;43:545–572
2. Burns B. An operation for spondylolisthesis. Lancet 1933;224: 1233–1239
3. Ito H, Tsuchiya J, Asami G. A new radical operation for Pott's disease. J Bone Joint Surg Br 1934;16:499–515
4. Capener N. Spondylolisthesis. Br J Surg 1932;19:374–386
5. Muller W. Transperitoneale freilegung der wirbelsaule bei tuberkuloser spondylitis. Dtsch Z Chirop 1906;85:128–137
6. Iwahara T. A new method of vertebral body fusion. Surgery 1944;8:271–287
7. Lane JD, Moore E. Transperitoneal approach to the intervertebral disc in the lumbar area. Ann Surg 1948;127:537–551
8. Hodgson A, Stock F. Anterior spinal fusion. Br J Surg 1956;44:226–275
9. Hodgson AR, Stock FE. Anterior spine fusion for the treatment of tuberculosis of the spine. J Bone Joint Surg Br 1960;42:295–310
10. Cloward RB. Spondylolisthesis: treatment by laminectomy and posterior interbody fusion. Clin Orthop Relat Res 1981;154:74–82
11. Cloward RB. The treatment of ruptured lumbar intervertebral discs by vertebral body fusion. J Neurosurg 1953;10:154–168
12. Cloward RB. Lesions of the intervertebral disks and their treatment by interbody fusion methods. Clin Orthop Relat Res 1963;27:51–77
13. Harmon PH. Anterior excision and vertebral body fusion operation for intervertebral disc syndromes of the lower lumbar spine. Clin Orthop Relat Res 1963;26:107–127
14. Sacks S. Anterior interbody fusion of the lumbar spine. J Bone Joint Surg Br 1965;47:211–223
15. O'Brien JP, Dawson MH, Heard CW. Simultaneous combined anterior and posterior fusion. Clin Orthop Relat Res 1986;203:51–77
16. Holte DC, O'Brien JP, Renton P. Anterior lumbar fusion using a hybrid interbody graft. A preliminary radiographic report. Eur Spine J 1994;3:32–38

17. Adkins EWO. Lumbosacral arthrodesis after laminectomy. J Bone Joint Surg Br 1955;37:208–223
18. Hoover NW. Methods of lumbar spine fusion. J Bone Joint Surg Am 1968;50:194–210
19. Crock HV. Anterior lumbar interbody fusion: Indications for its use and notes on surgical technique. Clin Orthop Relat Res 1982;165:157–163
20. Fujimaki A, Crock H, Bedbrook G. The results of 150 anterior lumbar interbody fusion operations performed by two surgeons in Australia. Clin Orthop Relat Res 1982;165:164–167
21. Calandruccio RA, Benton BF. Anterior lumbar fusion. Clin Orthop Relat Res 1964;35:63–68
22. Nisbet NW, James A. Results of intervertebral bony fusions. J Bone Joint Surg Br 1956;38:952–953
23. Raney FL, Adams JE. Anterior lumbar disc excision and interbody fusion used as a salvage procedure. J Bone Joint Surg Am 1963;45:667–668
24. Flynn JC, Hoque MA. Anterior fusion of the lumbar spine. End-result study with long-term follow-up. J Bone Joint Surg Am 1979;61:1143–1150
25. Stauffer RN, Coventry M. Anterior interbody lumbar spine fusion: Analysis of Mayo Clinic studies. J Bone Joint Surg Am 1972;54:756–768
26. Kozak JA, O'Brien JP. Simultaneous combined anterior posterior fusion: An independent analysis of a treatment for the disabled low back pain patient. Spine 1990;15:322–328
27. Humphries AW, Hawk WA, Berndt AL. Anterior interbody fusion of lumbar vertebrae. Surg Clin North Am 1961;41:1685–1700
28. DeBowes RM, Grant BD, Bagby GW. Cervical vertebral interbody fusion in the horse: a comparative study of bovine xenografts and autografts supported by stainless steel baskets. Am J Vet Res 1984;45:191–199
29. Bagby GW. Arthrodesis by the distraction-compression method using a stainless steel implant. Orthopedics 1988;11:931–934
30. Crawley GR, Grant BD, White KK. A modified Cloward's technique for arthrodesis of the normal metacarpophalangeal joint in the horse. Vet Surg 1988;17:117–127
31. Wagner PC, Grant BD, Bagby GW, et al. Evaluation of spine fusion as treatment in the equine wobbler syndrome. Vet Surg 1979;8:84–88
32. Kuslich SD, Ulstrom CI, Griffith SL, et al. The Bagby and Kuslich method of lumbar interbody fusion. History, technique, and 2-year follow-up results of a United States prospective, multicenter trial. Spine 1998;23:1267–1278
33. Ray CD. Threaded fusion cages for lumbar interbody fusions. An economic comparison with 360 fusions. Spine 1997;22:681–685
34. Nachemson AL, Schultz AB, Berkson MH. Mechanical properties of human lumbar spine motion segments: influence of age, sex, disc level and degeneration. Spine 1979;4:1–8
35. White AA, Panjabi MM. Clinical Biomechanics of the Spine, 2nd ed. Philadelphia: Lippincott, 1990
36. Dolan P, Earley M, Adams MA. Bending and compressive stresses acting on the lumbar spine during lifting activities. J Biomech 1994;27:1237–1248
37. Haher TR, Yeung AW, Merola AA, et al. An in vitro biomechanical investigation of spinal interbody fusion devices. 14th Annual Meeting of the North American Spine Society, 1999, Chicago
38. McAfee PC, Lee GA, Fedder IL, et al. A prospective randomized study of 100 anterior interbody cage arthrodeses: complete versus partial discectomy. 14th Annual Meeting of North American Spine Society, 1999, Chicago
39. Kumar N, Judith MR, Kumar A, et al. Analysis of stress distribution in lumbar interbody fusion. Spine 2005;30:1731–1735
40. Pradhan BB, Bae HW, Dawson EG, et al. Graft resorption with the use of bone morphogenetic protein: lessons from anterior lumbar interbody fusion using femoral ring allografts and recombinant human bone morphogenetic protein-2. Spine 2006;31:E277–E284
41. Phillips FM, Cunningham B, Carandang G, et al. Effect of supplemental translaminar facet screw fixation on the stability of stand-alone anterior lumbar interbody fusion cages under physiologic compressive loads. Spine 2004;29:1731–1736
42. Ferrara LA, Secor JL, Jin BH, et al. A biomechanical comparison of facet screw fixation and pedicle screw fixation: effects of short-term and long-term repetitive cycling. Spine 2003;28:1226–1234
43. Best NM, Sasso RC. Efficacy of translaminar facet screw fixation in circumferential interbody fusions as compared to pedicle screw fixation. J Spinal Disord Tech 2006;19:98–103
44. Beaubien BP, Mehbod AA, Kallemeier PM, et al. Posterior augmentation of an anterior lumbar interbody fusion. Spine 2004;29:E406–E412
45. Deyo RA, Cherkin D, Conrad D, Volinn E. Cost, controversy, crisis: low back pain and the health of the public. Annu Rev Public Health 1991;12:141–156
46. Frymoyer JW, Pope MH, Clements JH, et al. Risk factors in low back pain. An epidemiological survey. J Bone Joint Surg Am 1983;65:213–218
47. Kuslich SD, Ulstrom CL, Griffith SL, et al. The Bagby and Kuslich method of lumbar interbody fusion. History, technique, and 2-year follow-up results of a United States prospective, multicenter trial. Spine 1998;23:1267–1278
48. Kozak JA, O'Brien JP. Simultaneous combined anterior and posterior fusion: an independent analysis of a treatment for the disabled low-back pain patient. Spine 1990;15:322–328
49. Goldner JL, Urbaniak JR, McCollum DE. Anterior disc excision and interbody spinal fusion for chronic low back pain. Orthop Clin North Am 1971;(2):543–568
50. Chow SP, Leong JC, Ma A, Yau AC. Anterior spinal fusion for deranged lumbar intervertebral disc. Spine 1980;5:452–458 AQ3
51.
52. Forristall RM, Marsh HO, Pay NT. MRI and contrast CT of the lumbar spine: comparison of diagnostic methods and correlation with surgical findings. Spine 1988;13:1049–1054
53. Boden SD, Davis DO, Dina TS, et al. Abnormal magnetic resonance scans of the lumbar spine in asymptomatic subjects: a prospective investigation. J Bone Joint Surg Am 1990;72:403–408
54. Gill K, Blumenthal S. Functional results after anterior lumbar fusions at L5–S1 in patients with normal and abnormal MRI scans. Spine 1992;17:940–942
55. Colhoun E, McCall IW, Williams L, et al. Provocation discography as a guide to planning operation on the spine. J Bone Joint Surg Br 1988;70B:267–271
56. Schwarzer AC, Aprill CN, Derby R, et al. The prevalence and clinical features of internal disc disruption in patients with chronic low back pain. Spine 1995;20:1878–1883
57. Sasso RC, Macadaeg K, Nordmann D, Smith M. Selective nerve root injections can predict surgical outcome for lumbar and cervical radiculopathy: comparison to magnetic resonance imaging. J Spinal Disord Tech 2005;18:471–478
58. Sasso RC, Kitchel SH, Dawson EG. A prospective, randomized controlled clinical trial of anterior lumbar interbody fusion using a titanium cylindrical threaded fusion device. Spine 2004;29:113–122

59. Fraser RD. Interbody, posterior and combined lumbar fusions. Spine 1995;20:S167–S177
60. Burkus JK, Gornet MF, Dickman CA, et al. Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages. J Spinal Disord Tech 2002;15:337–349
61. Sasso RC, LeHuec JC, Shaffrey C, et al. Iliac crest bone graft donor site pain after anterior lumbar interbody fusion. J Spinal Disord Tech 2005;18:S77–S81
62. Polly DW, Ackerman SJ, Shaffrey CI, et al. A cost analysis of bone morphogenetic protein versus autologous iliac crest bone graft in single-level anterior lumbar fusion. Orthopedics 2003;26:1027–1037
63. Schofferman J, Slosar P, Reynolds J, et al. A prospective randomized comparison of 270 degree fusions to 360 degree fusions (circumferential fusions). Spine 2001;26:E207–E212
64. Burkus JK, Dorchak JD, Sanders DL. Radiographic assessment of interbody fusion using recombinant human bone morphogenetic protein type 2. Spine 2003;28:372–377
65. Rajaraman V, Vingan R, Roth P, et al. Visceral and vascular complications resulting from anterior lumbar interbody fusion. J Neurosurg 1999;91:60–64
66. O'Brien JP, Dawson MH, Heard CW, et al. Simultaneous combined anterior and posterior fusion. A surgical solution for failed spinal surgery with a brief review of the first 150 patients. Clin Orthop Relat Res 1986;203:191–195
67. Regan JJ, Aronoff RJ, Ohnmeiss DD, Sengupta DK. Laparoscopic approach to L4–L5 for interbody fusion using BAK cages: experience in the first 58 cases. Spine 1999;24:2171–2174
68. Lieberman IH, Willsher PC, Litwin DE, et al. Transperitoneal laparoscopic exposure for lumbar interbody fusion. Spine 2000;25:509–514
69. Liu JC, Ondra SL, Angelos P, et al. Is laparoscopic anterior lumbar interbody fusion a useful minimally invasive procedure? Neurosurgery 2002;51:S155–S158
70. Zdeblick TA, David SM. Laparoscopic versus mini anterior lumbar interbody fusion. Spine 2000;25:2682–2687
71. Chung SK, Lee SH, Lim SR, et al. Comparative study of laparoscopic L5–S1 fusion versus open mini-ALIF, with a minimum 2-year follow-up. Eur Spine J 2003;12:613–617
72. Escobar E, Transfeldt E, Garvey T, et al. Video-assisted versus open anterior lumbar spine fusion surgery: a comparison of four techniques and complications in 135 patients. Spine 2003;28:729–732
73. Sasso RC, Burkus JK, LeHuec JC. Retrograde ejaculation after anterior lumbar interbody fusion. Spine 2003;28:1023–1026
74. Cizek GR, Boyd LM. Imaging pitfalls of interbody spinal implants. 14th Annual Meeting of North American Spine Society, 1999, Chicago
75. McAfee PC. Interbody fusion cages in reconstructive operations on the spine. J Bone Joint Surg Am 1999;81:859–880
76. Heithoff KB, Mullin JW, Holte D, et al. Failure of radiographic detection of pseudoarthrosis in patients with titanium anterior lumbar interbody fusion cages. 14th Annual Meeting of North American Spine Society, 1999, Chicago
77. Weiner BK, Fraser RD. Spine update: lumbar interbody cages. Spine 1998;23:634–640

Queries to Author

AQ1: AU: chapter title has been changed to be consistent with the title in TOC OK?
AQ2: AU: most later chapters use theabbreviation style rhBMP-2. OK?
AQ3: AU: Please supply ref. 51.

APPENDIX C

US005313962A

United States Patent [19]

Obenchain

[11] Patent Number: 5,313,962

[45] Date of Patent: May 24, 1994

[54] METHOD OF PERFORMING LAPAROSCOPIC LUMBAR DISCECTOMY

[76] Inventor: **Theodore G. Obenchain,** 12002 Royal Birkdale Row, #A, San Diego, Calif. 92128

[21] Appl. No.: **24,517**

[22] Filed: **Mar. 1, 1993**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 780,865, Oct. 18, 1991.

[51] **Int. Cl.**[5] **A61B 17/36**

[52] **U.S. Cl.** **128/898;** 606/1; 606/14

[58] **Field of Search** 128/898, 747, 4, 6, 128/362, 395, 397, 398; 606/15, 16, 13, 14, 45, 46

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,122,853	10/1978	Smith .	
4,545,374	10/1985	Jacobson	606/61
4,573,448	3/1986	Kambin	128/898
4,583,539	4/1986	Karlin et al. .	
4,638,799	1/1987	Moore	606/1
4,678,459	7/1987	Onik et al.	604/22
4,863,477	9/1989	Monson	623/17
4,984,563	1/1991	Renaud .	
4,998,527	3/1991	Meyer .	
5,027,792	7/1991	Meyer .	
5,084,043	1/1992	Hertzmann et al.	606/13
5,100,420	3/1992	Green et al.	128/4
5,131,382	7/1992	Meyer	604/22

OTHER PUBLICATIONS

Burton, "Surgical Diskectomy 1991: Status Report", *Seminars in Orthopedics,* vol. 16, No. 2, Jun. 1991, pp. 92–97.

Obenchain, "Journal of Laparoendoscopic Surgery", *Laparoscopic Lumbar Discectomy: Case Report,* vol. 1, No. 3, 1991 pp. 145–149.

Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Jeffery A. Schmidt
Attorney, Agent, or Firm—Jerry R. Seiler

[57] **ABSTRACT**

In one method for performing a laparoscopic lumbar discectomy an incision is created in the abdominal wall of a patient. The peritoneal lining is dissected from the abdominal wall while relocating the peritoneal lining toward the midline of the abdomen to create an expanded retroperitoneal space. A surgical apparatus is inserted into the incision comprising an endoscope and surgical means suitable for performing a lumbar discectomy. The surgical apparatus is directed through the expanded retroperitoneal space until the surgical apparatus approaches the anterior aspect of a vertebral body and a discectomy is performed on the vertebral body.

17 Claims, 4 Drawing Sheets

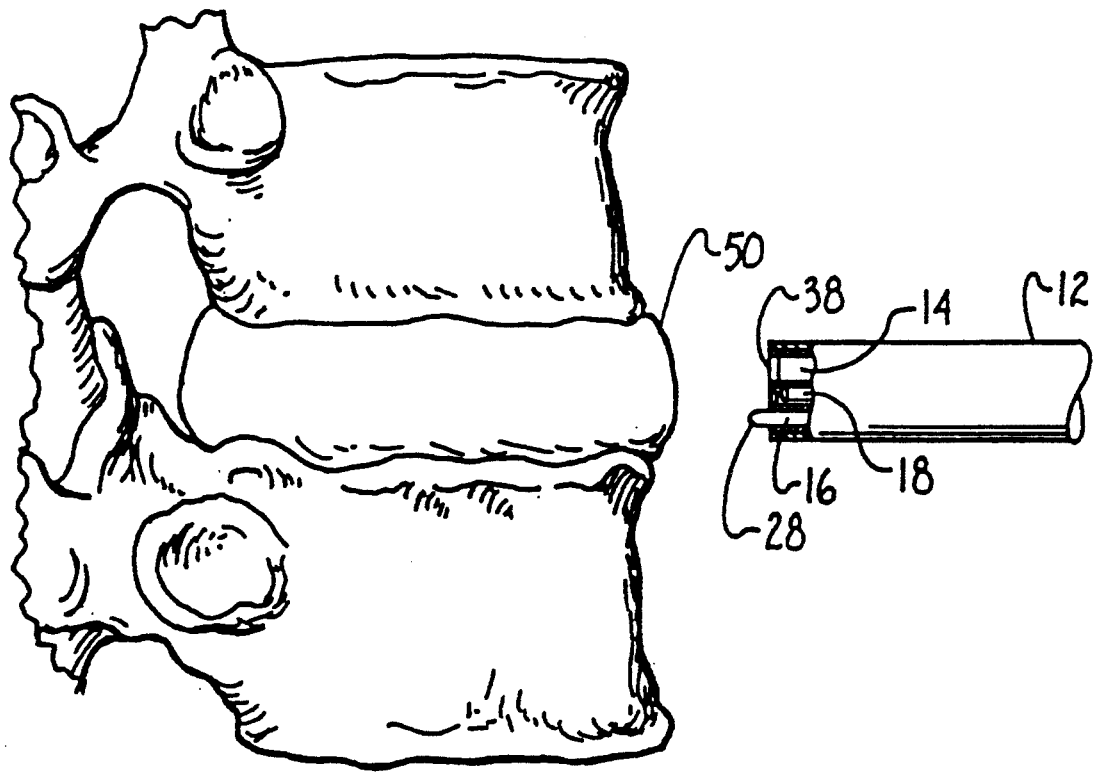


Fig.1

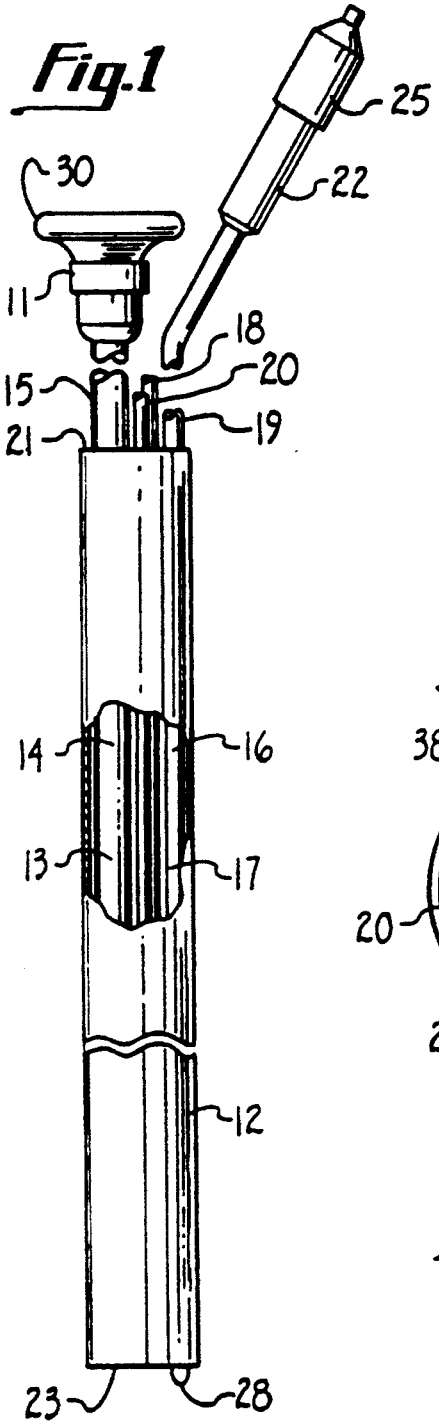


Fig.2

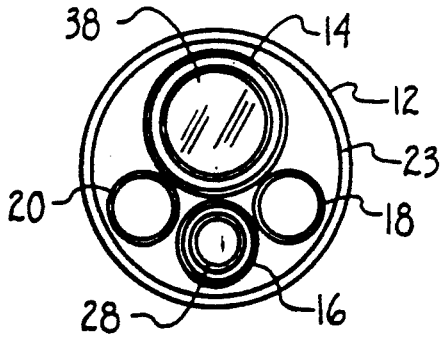


Fig.3

Fig.4

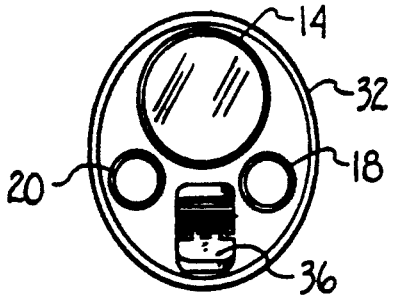
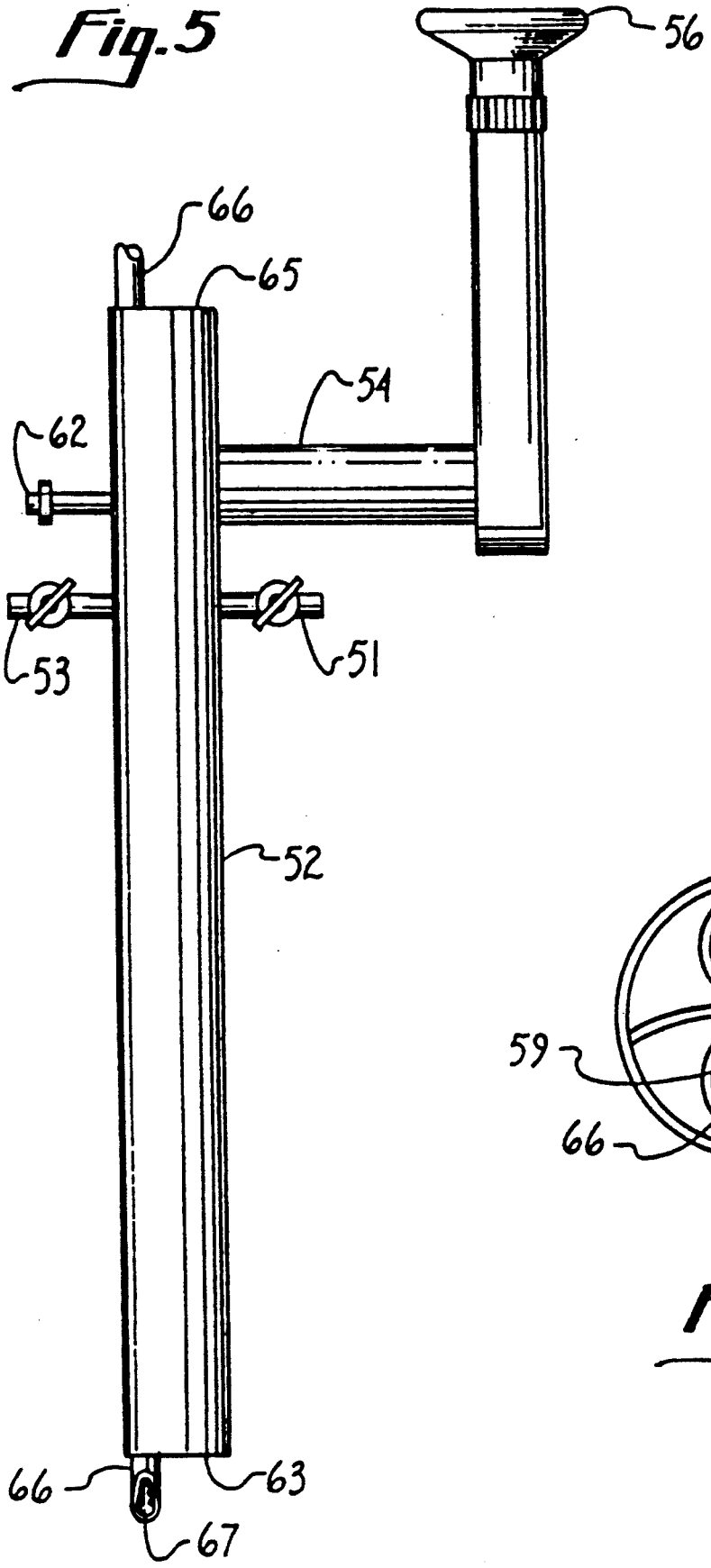


Fig. 5



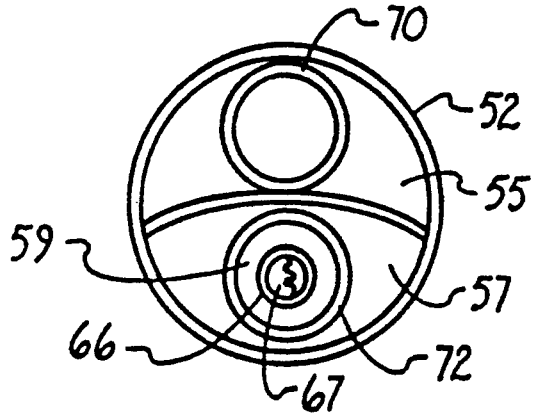


Fig. 6

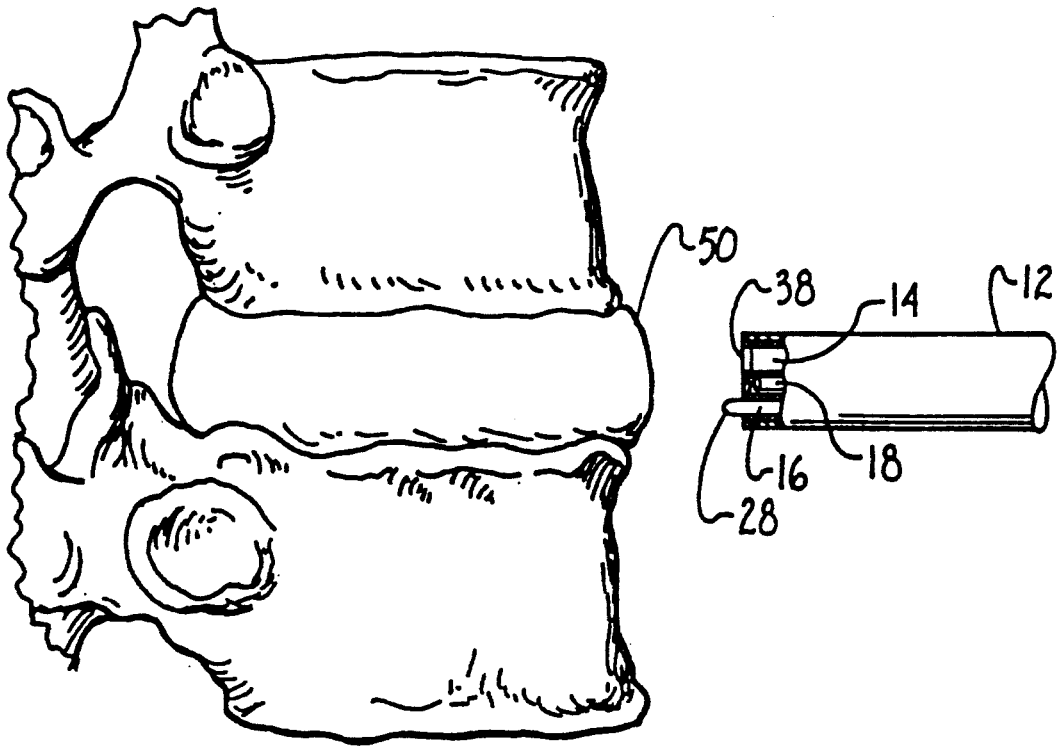


Fig. 7

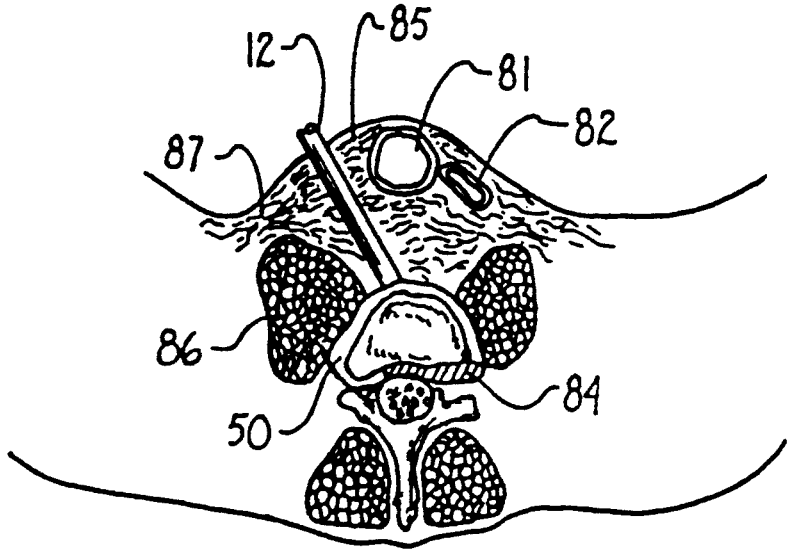


Fig. 8

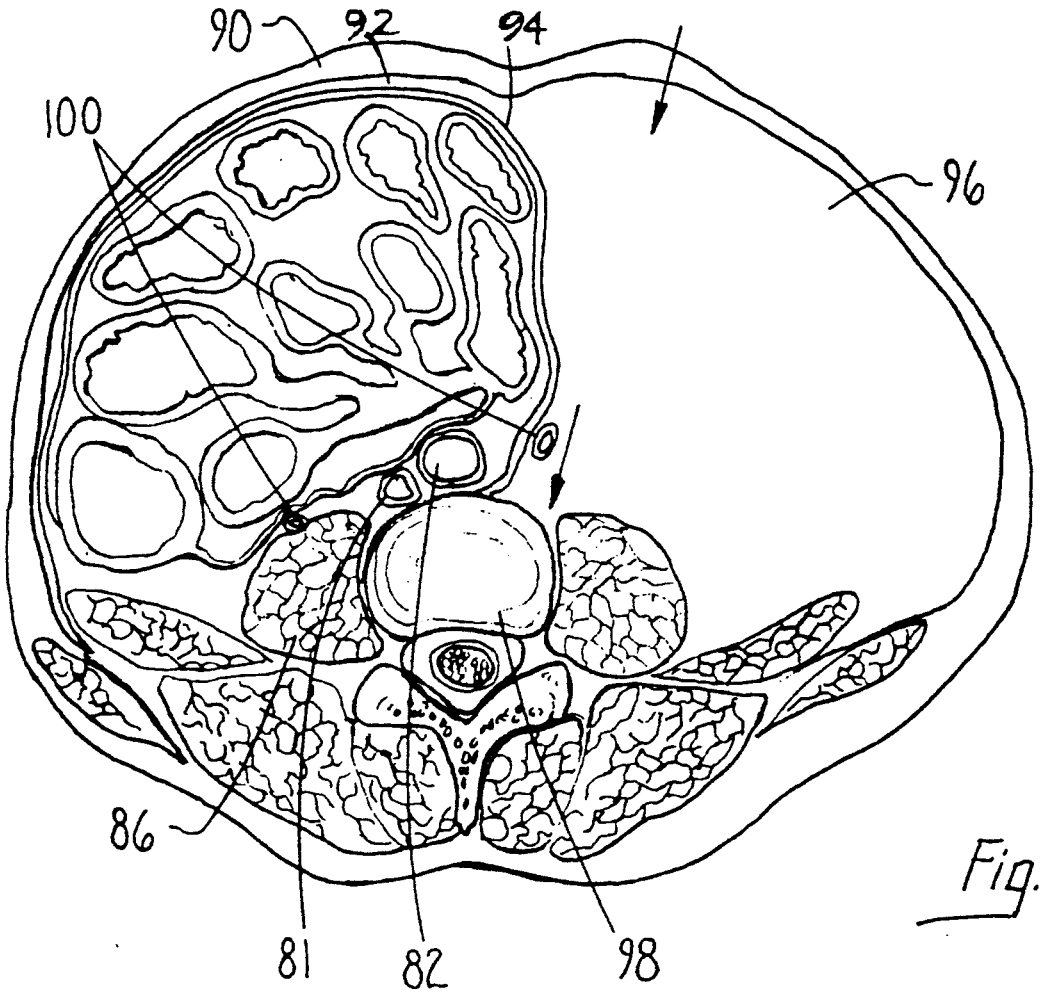


Fig. 9

METHOD OF PERFORMING LAPAROSCOPIC LUMBAR DISCECTOMY

BACKGROUND OF THE INVENTION

This application is a continuation-in-part of application number 07/780,865 to Obenchain, filed Oct. 18, 1991, the entire contents of Which is hereby incorporated by reference.

Lumbar surgery to remove discs or portions of discs which have herniated has heretofore generally involved posterior entry. More recently, surgery using both endoscopic observation and control and a laser fiber instrument for incising the annulus and removing disc tissue has involved entry from one or two different posterior angles. Using such a technique, the endoscope is viewed from one angle, while the laser surgical tool or other surgical instrument is directed and guided during the surgery from a different angle. Such a procedure requires two spinal punctures into the patient thereby doubling the risk of nerve root injury. It is to the elimination of a dual puncture surgery for lumbar discectomy and to improve the control and observation of a lumbar discectomy utilizing a single disc entry while the patient is in a supine position that the present invention is directed. Although endoscopic surgical devices are known, such devices comprise elongated surgical forceps having a built-in tube for receiving an endoscope. However, such devices do not provide an endoscopic tool having a feature which allows insertion and removal of different selected surgical instruments during the surgery while the device itself remains in the abdominal cavity.

Posterior entry for lumbar discectomy has a number of complications such as the development of epidural scar tissue, the manipulation of neural structures and the removal of bone. Therefore, an anterior method for lumbar discectomy is disclosed which provides a more conservative approach to such surgery.

SUMMARY OF THE INVENTION

This invention provides improved methods for performing lumbar discectomies. Laparoscopic lumbar discectomies reduce both the size and number of incisions required and minimize postoperative trauma while speeding recovery.

In a first preferred embodiment of this invention, a method of performing a laparoscopic lumbar discectomy comprises creating one or more incisions through the abdominal wall and into the preperitoneal space of a patient, inserting surgical apparatus comprising an endoscope, dissecting means suitable for separating the peritoneal lining from the abdominal wall in both the preperitoneal and retroperitoneal space, and surgical means suitable for performing a lumbar discectomy. The method further comprises instilling a pharmaceutically acceptable gas into the preperitoneal and retroperitoneal space, thereby expanding the space, and dissecting the peritoneal lining from the abdominal wall while relocating the peritoneal lining toward the midline of the abdomen. After the transperitoneal space has been suitably expanded the discectomy apparatus of the invention is inserted through the space approaching the anterior aspect of a vertebral body and thereafter the discectomy is performed on the vertebral body. Preferably the incision is created through the abdominal wall and into the preperitoneal space and is preferably lateral to the abdominal midline. Still more preferably, the incision is adjacent the abdominal midline.

In another preferred embodiment of this invention a method is provided for performing a laparoscopic lumbar discectomy comprising inserting a surgical apparatus through an abdominal incision into the preperitoneal space. The surgical apparatus comprises an elongated sleeve member having a first and a second end, endoscope receiving means and an endoscope secured therein, laser fiber receiving means having a laser fiber secured therein, suction and irrigation channel means, and dissecting means for separating the peritoneal lining from the abdominal wall, each of the means extending along the interior of the sleeve member between the first and second end through the abdominal incision. The method of this embodiment further comprises directing the sleeve member into the preperitoneal space, observing the direction of the sleeve using the endoscope, guiding the sleeve member through the preperitoneal space and into the retroperitoneal space while separating the peritoneal lining from the abdominal wall using the dissecting means until the second end thereof is adjacent the exterior annulus of a vertebral disc space, surgically entering the disc space and removing disc tissue by energizing and manipulating the laser fiber, directing irrigating fluid through one or more of the conduits and removing fluid with suctioning through one or more of the conduits. It is also contemplated that the method additionally include the step of instilling a pharmaceutically acceptable gas into the preperitoneal and retroperitoneal space. Preferably the abdominal incision is lateral to the abdominal midline. In one preferred embodiment, the pharmaceutically acceptable gas is CO_2 and in another preferred embodiment, the pharmaceutically acceptable gas is air.

In yet another preferred embodiment of this invention a method is provided for performing a laparoscopic lumbar discectomy on a patient comprising creating an incision through the abdominal wall and into the preperitoneal space, creating a retroperitoneal space, inserting a surgical apparatus comprising an endoscope, irrigation and suction means, and means suitable for performing a lumbar discectomy, traversing the preperitoneal space and retroperitoneal space toward a lumbar vertebral body with the surgical apparatus until the surgical apparatus approaches the anterior aspect of the vertebral body, entering the disk space of the vertebral body, and performing the discectomy. Preferably the abdominal incision is lateral to the abdominal midline and more preferably the incision is adjacent the abdominal midline.

In another preferred embodiment of this invention, a method is provided for performing a laparoscopic lumbar discectomy on a patient comprising creating an incision in the abdominal wall of a patient, instilling a pharmaceutically acceptable gas to expand the retroperitoneal region located between the incision and the lumbar vertebrae, without disecting the peritoneum, inserting a surgical apparatus comprising an endoscope and surgical means for performing a lumbar discectomy into the incision, directing the surgical apparatus through the regions and performing the discectomy on at least one vertebral body. Preferably the incision is adjacent the abdominal midline. In one embodiment the pharmaceutically acceptable gas is CO_2 and in another preferred embodiment, the pharmaceutically acceptable gas is air.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side view, partially broken away, illustrating the apparatus of the invention comprising an endoscope and fiber laser tool received therein;

FIG. **2** is an end view of the apparatus of FIG **1**;

FIG. **3** is a side view of another embodiment of the invention showing a device having a rongeur surgical instrument received therein;

FIG. **4** is an end view of the apparatus of FIG **3**;

FIG. **5** is a side view of another embodiment having a 90° endoscopic elbow, and light source port and mounting components;

FIG. **6** is an end view of the device of FIG. **5**;

FIG. **7** illustrates a method of using the apparatus of FIG. **1** for laparoscopic lumbar discectomy;

FIG. **8** further illustrates a method of performing surgery according to the invention; and

FIG. **9** illustrates another preferred method of performing a laparoscopic lumbar discectomy.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. **1** and **2**, there is illustrated a first embodiment of the apparatus of the invention having an endoscope and a fiber laser device received and secured therein. The specific components of the apparatus include a sleeve member **12** comprising an elongated cylinder having a first end **21** and a second end **23**. The sleeve may be any desired shape, preferably round or oval, and having a relatively smooth exterior surface, without sharp edges or corners. The relative size of the sleeve is important. The length between the first and second ends must be sufficient to allow the surgeon or user to insert the device into a cavity of a patient, with the second end **23** adjacent the specific site of the surgery being carried out, and with the outer or first end **21** extending outwardly of the patient's cavity. For example, in abdominal or thoracic surgery, sleeve **12** must be a length of between about 15 and about 38 cm. However, it will be understood that different lengths for different specific uses may be used, and the criticality of the length will primarily be defined by the surgical procedure for which the device is to be used.

The cross-sectional outer diameter dimensions are also important, and must be large enough to accommodate the interior conduits, tubes, pipes, and other components, and yet be small enough to allow insertion into a relatively small incision, obviously preferable to minimize trauma. It has been found that a sleeve having a maximum exterior cross-sectional dimension of about **10** mm, and preferably between about **5** or about **9** mm is quite suitable for lumbar discectomy and many other procedures.

Interiorly of the sleeve **12** are secured an endoscope receiving means comprising a channel member **14** extending substantially entirely along the interior length of the sleeve between ends **21** and **23**. Channel member **14** includes an interior portion **13**, and an exterior portion **15** terminating in an adaptor or fitting **11** for receiving eyepiece **30** of an endoscope. The fitting may threadedly engage the endoscope for securing it in place, or it may simply otherwise allow the endoscope eyepiece to be nested in its proper position for use during surgery. In either event, the endoscope must be rotatable in the apparatus, to enable the user to rotate the endoscope to view the surgical site from any angle. The endoscope receiving channel or tube must also be of a shape to adequately receive and hold the elongated endoscope in place in the apparatus, as well as to provide positioning of the lens **38** substantially coterminous with the end **23** of sleeve **12**. The channel also allows the user to conveniently grasp adaptor and/or eyepiece **30** for rotating the endoscope eyepiece to observe the surgical site as well as to direct the apparatus through an incision and into the cavity where the surgery is performed.

A second channel member **16** is provided and secured in sleeve **12** for receiving and directing a laser fiber therealong. As shown, a laser fiber device having a handle member **25** and a laser emitter **28** at the opposite end is received and secured in channel member **16** having an interior portion **17** extending between ends **21** and **23** of sleeve **12** and an exterior portion **19** terminating in a fitting or adaptor **22** for securing the laser handle member **25**. The laser fiber receiving means must be of sufficient length to allow the emitter **28** to be positioned properly adjacent sleeve end **23** when the fiber laser device is secured. It will be understood to those skilled in the art that different types of fiber lasers may be used and accommodated in the apparatus of the invention, including a free beam laser, such as CO_2, or a contact fiber laser, such as a Holmium or Nd:YAG type. Where a free beam laser is used, the fiber laser emitter **28** will usually extend beyond end **23** of sleeve **12** as illustrated in FIG. **1**, while in the latter case, the fiber laser emitter may be coterminous with the sleeve end. Any suitable type of adaptor or fitting member **22** for securing the fiber laser surgical tool in the apparatus may be incorporated.

A plurality of conduits **18** and **20** to provide irrigation of the surgical site and to suction tissue and fluid to be removed from the site are provided by conduits **18** and **20**. Any number of such irrigation and suction conduits may be installed in the device, depending on the type of surgery and needs of the surgeon and techniques or procedures in which the apparatus is to be used. The conduits may extend parallel adjacent the channel members as shown, or may be concentrically arranged as will be described hereinafter. The conduits preferably extend outwardly beyond first end **21** of sleeve **12**, as shown, to provide means for being secured to hoses or pipes for directing irrigating fluid into the surgical site and removal of the fluid material therefrom. The length of the fluid handling conduits provides ports coterminous with a second end **23** of sleeve **12** and the conduits are secured and extend substantially along the interior length of the sleeve **12** as illustrated.

In FIGS. **3** and **4**, there is illustrated another embodiment of the invention, also comprising a device having an endoscope securing feature as previously described, together with a plurality of fluid handling conduits for irrigating and suctioning the surgical site. In this embodiment, an alternative shape for sleeve **32** is illustrated, and is observed in FIG. **4** as being oval or oblong in cross-sectional shape. The device includes channel member **40** for receiving one or more of a plurality of different conventional surgical instruments. A conventional rongeur **34** is shown having blades **36** which may be actuated by the surgeon for cutting and removing bone or tissue. Although a rongeur is illustrated as being received in the device, it may be removed and other types of conventional surgical tools such as, for example, a free beam laser or a shaver, which may extend for some length beyond sleeve end **65** and substantially along the sleeve axis, and inserted, for example a tre-

phine, curette, shaver or a trocar or other similar surgical tools, well known to those skilled in the art. Thus, any one of these surgical instruments may be conveniently inserted in the device and guided and manipulated by the surgeon having endoscopic observation for directing the apparatus through a patient's cavity to the surgical site and for manipulating and controlling the instrument. During the surgery, different surgical instruments may be selected by the surgeon and received in and removed from elongated channel **40** as the procedure dictates, with irrigation and suction being performed via fluid handling channels **18** and **20** and endoscopic observation and monitoring of the procedure provided using endoscope **30**. Although both embodiments shown in FIGS. **1–4** illustrate the use of an eyepiece **30** on the endoscope, it will be understood that the endoscope will usually be attached to a video camera having projection means so that the surgeon may view and control the surgery by observing a conveniently located video screen.

Another embodiment of the apparatus of the invention is shown in FIGS. **5** and **6**. In the embodiment shown, sleeve **52** is provided with an elbow **54** which extends out of the way of the plane and axis of the sleeve so that substantially straight cutting or surgical tools can be used without interfering with the observation of the surgery using an endoscope or attachment for a video camera. In such an embodiment, a 90° elbow **54** extends from the sleeve and is provided with an attachment device **56** for securing a video camera, or the like. Although the endoscopic 90° elbow is shown, a straight or angled attachment may be used for the same purpose, so long as it provides for endoscopic, video or other observation away from the axis of the sleeve to allow the surgeon to conveniently manipulate the tool extending from the sleeve. In addition, in the embodiment illustrated, fittings **51** and **53** for attaching irrigation and suction components are also provided, as is a light source attachment component **62**. In this embodiment, a straight shaver apparatus **66** having a cutting end which can be extended outwardly up to a few centimeters from the end **63** of the sleeve is provided. Shaver **66** illustrated includes a port **67** and a hollow interior communicating with a suction port (not shown) for directing tissue suctioned from the surgical site through port **67**, along the hollow shaver interior and out through a suction port attached to a power source handle, (not shown), and well understood by those skilled in the art.

Observing also FIG. **6**, the sleeve of this embodiment may include one or more irrigation and/or suction conduits **55**, **57** and **59** for introducing irrigating fluids and/or removing the tissue from the surgical site. If the device of the invention is to be used with a hollow shaver or other hollow surgical device through which tissue can be suctioned, a single port or multiple irrigation ports for directing irrigation fluid to the surgical site may be used. Where the surgical tool, for example a free beam laser, is to be used, both irrigation and suctioning the conduits are provided in the sleeve apparatus of the invention. As illustrated, the shape of such channels is not critical and, for example, one or more annular conduits **59** concentrically located around the surgical instrument may be incorporated, or other shaped channels may be conveniently formed along the sleeve interior adjacent the guide channels **70** and **72** for the endoscope and surgical tool.

FIGS. **7** and **8** schematically illustrates the use of the apparatus of FIG. **1** in a laparoscopic lumbar discectomy procedure of the invention which is believed to offer substantial advantages over state of the art lumbar discectomy procedures. In such a procedure, the patient is placed in a supine or lithotomy position, and the abdomen preferably distended with air or carbon dioxide (CO_2). The surgeon observes the procedure preferably using a video camera attached to the endoscope and viewing the video screen. The surgeon directs the apparatus of the invention, including the cutting tool inserted in the appropriate channel of sleeve **12**, through an abdominal incision, for example, immediately above the pubic bone. Direction is continued through soft tissue, which may be teased, coagulated or vaporized using the laser or other surgical tool until it is adjacent the exterior of the disc space annulus **50**. Surgery carried out between lumbar vertebrae **L3–4** and **L4–5** may be accomplished by directing the sleeve **12** to the left of aorta **81** and inferior vena cava **82**, between the aorta and the psoas muscle **86**, and through the posterior peritoneum **87** and fatty tissue **85**. If desired, the surgery may traverse through the psoas muscle. Where the surgery site is between **L5** and **S-1**, the dissection is preferably generally close to the midline between the iliac branches of the great vessels. Alternatively, for example, where the patient has extensive abdominal adhesions, it may be preferred to use a lateral puncture of the abdomen to avoid bowel perforation, and entry into the disc space is lateral, transversing the psoas muscle, or immediately in front of it. Once the apparatus reaches the exterior of the disc space annulus or ligament, a trephine may be used to penetrate the annulus and traverse the disc space, again using endoscopic and fluoroscopic control and guidance, and then proceed with the discectomy for removing herniated disc material **84**. A fiber laser emitter **28** or other surgical device for cutting and removing bone and disc tissue is illustrated in FIG. **7**. It is to be understood that the surgery or portion of the surgery may be conducted by utilizing any one or more different surgical instruments selected and alternately inserted and removed from sleeve **16**. Concurrently with the cutting and removal of tissue, fluid is introduced into one or more of the channels for irrigating the surgical site, and suction is applied to one or more of the other conduits or through a shaver or other hollow cutting instrument for removing the fluid and tissue cut and loosened by the surgery. After the discectomy is complete, the surgeon removes the apparatus, applies appropriate sutures, and closes the wound incision in the abdomen. Conventional surgical techniques used as part of such a procedure are known to those skilled in the art. The improved laparoscopic lumbar discectomy of the invention avoids posterior dual puncture techniques used heretofore and may be accomplished in an outpatient setting with a minimum use of oral narcotics.

In another preferred surgical method using the laparoscopic lumbar discectomy technique of this invention, the lumbar discectomy procedure is performed by using a retroperitoneal technique in which the peritoneum remains intact. Like the transperitoneal approach disclosed above, the retroperitoneal approach is suitable for discectomy procedures involving any of the lumbar vertebrae. As an exemplary illustration, FIG. **9** provides a transverse section of the abdomen at approximately the L5 vertebral level.

Using the retroperitoneal method in a lumbar discectomy according to the invention, the patient is positioned in the supine or lithotomy position. While it is contemplated that the incision site for entry of the apparatus shown in FIGS. **1-6** can be located anywhere along the abdomen surface, the incision is preferably made below the epigastric and hypochondriac regions of the abdomen and is preferably lateral, that is, to the right or left of the abdominal midline. More preferably, the incision is directly adjacent the abdominal midline. For purposes of this application, the abdominal midline is a spatially defined line extending from the sternum through the umbilicus to the center of the pubic bone. As understood to those skilled in the art, laparoscopic trocars are punctured through the abdominal wall for insertion of multiple instruments for dissection and exposure of the front of the spine.

The retroperitoneal lumbar discectomy technique is particularly well-suited for discectomies involving the L3–4 and L4–5 vertebral spaces as well as L5–S1 spaces. Referring to FIG. **9**, the abdominal incision continues through the abdominal wall **90** through the muscle and connective tissue and into the preperitoneal space **92**. Care is taken to maintain the integrity of the peritoneal lining **94**. Dissection is continued along the inner surface of the abdominal wall, separating the peritoneal lining from the preperitoneal and retroperitoneal space **96** while guiding the peritoneum toward the abdominal midline. Instruments typically required during this portion of the procedure include blunt dissecting tools, bowel retractor, endoscope and discoscope. In order to facilitate this dissection, the retroperitoneal **94** and preperitoneal space **96** may be expanded by instilling a pharmaceutically acceptable gas such as CO_2, air, an inert gas such as helium or the like. Gas expansion and manual dissection are used to guide the peritoneum toward the midline while separating the lining **94** from the abdominal wall **90**. The dissection process continues until there is sufficient room in the retroperitoneal space **96** to access the targeted vertebral body **98** with the surgical apparatus of this invention. During the dissection process care is taken to avoid the ureters **100**, iliac vessels, **81** and **82**, and the psoas muscles **86**. Where this procedure is performed on the upper lumbar vertebrae, care is additionally taken to angle the channel member **40** and the dissecting tools away from the anterior surface of the kidney and associated vessels.

Upon accessing the vertebral body, surgical tools suitable for performing a lumbar discectomy are introduced either through the channel member or directly into the retroperitoneal space, thus permitting the surgeon to perform the discectomy procedure. The channel member additionally includes an endoscope or the like to permit the surgeon to visually guide the surgical apparatus. Similarly, the channel member is capable of being equipped with surgical means, such as a laser fiber or the like, suitable for performing a lumbar discectomy. Irrigation and suction means are also preferably available for use with the channel member. While this invention is described in association with an apparatus similar or identical to the apparatus of this invention, it is contemplated that any number of surgical apparatus may be used that are appropriate for traversing the abdomen of a patient to perform a discectomy while the patient is in a supine position.

A preferred discectomy procedure is described in association with the transperitoneal approach disclosed above. This procedure employs a laser fiber to disassociate disc tissue. While the retroperitoneal lumbar discectomy approach is described in association with FIG. **9** using a channel member device similar to the device of this invention, it is additionally contemplated that any suitable surgical apparatus, as determined by one with skill in the art, could similarly be used. Therefore, the device of this invention should not be construed as a limitation on the surgical methods of this invention. In addition, it is further contemplated that the retroperitoneal approach can be used for a variety of other spinal procedures including lumbar interbody fusions, sympathectomies, and vertebral biopsies.

Advantageously, the retroperitoneal discectomy approach permits the surgeon to reposition a portion of the intact peritoneal cavity including the bowel to access the damaged tissue. Thus, bowel retraction is not a problem. In addition, since the ureter and iliac vessels are closely associated with the peritoneal lining, repositioning of the peritoneum to the midline naturally relocates the ureter and iliac vessels as well. Further, the transperitoneal approach can involve tedious dissections and can, during some procedures, increase the likelihood of postoperative complications. The retroperitoneal approach minimizes these complications. However, both procedures have advantages based on the location of the particular damages disc in need of correction. For example, depending upon location, the retroperitoneal approach can provide easier access to the anterior aspect of the vertebra and the disc space than the transperitoneal approach. Thus, depending on location, a surgeon may select either the transperitoneal or the retroperitoneal as a preferred method for disc surgery. Selection may depend on patient history, the physical attributes of the patient, or the physical location of the particular vertebral body in need of a discectomy. For example, a surgeon may prefer to use the transperitoneal approach for discectomies at the L5–S1 level while preferring the retroperitoneal approach for discectomies involving the L3–L4 and L4–L5 levels.

While particular embodiments of this invention have been described in detail, it will be apparent to those skilled in the art that these embodiments are exemplary rather than limiting, and the true scope of the invention is that defined in the following claims.

What is claimed is:

1. A method of performing a laparoscopic lumbar discectomy comprising:

creating an incision through the abdominal wall and into the preperitoneal space of a patient;

dissecting said peritoneal lining from said abdominal wall and instilling a pharmaceutically acceptable gas into said preperitoneal and retroperitoneal space while relocating said peritoneal lining toward the midline of said abdomen thereby expanding said space;

inserting a surgical apparatus comprising an endoscope and surgical means suitable for performing a lumbar discectomy into said space until said surgical apparatus approaches the anterior aspect of a vertebral body; and

removing disc tissue utilizing said surgical apparatus.

2. The method of claim **1**, wherein said incision is created through said abdominal wall and into the preperitoneal space.

3. The method of claim **2**, wherein said incision is lateral to the abdominal midline.

4. The method of claim **3**, wherein said incision is adjacent to the abdominal midline.

5. A method of performing a laparoscopic lumbar discectomy comprising:

creating an expanded retroperitoneal space between the abdominal wall and peritoneal lining by separating said peritoneal lining from said abdominal wall using dissecting means and instilling a pharmaceutically acceptable gas into said retroperitoneal space;

inserting a surgical apparatus through an abdominal incision into the retroperitoneal space, said surgical apparatus comprising an elongated sleeve member having a first and a second end, endoscope receiving means and an endoscope secured therein, laser fiber receiving means having a laser fiber secured therein, suction and irrigation channel means, each of said means extending along the interior of said sleeve member between said first and second end through said abdominal incision;

directing said sleeve member into the retroperitoneal space;

observing the direction of said sleeve using said endoscope;

guiding said sleeve member through said retroperitoneal space until the second end thereof is adjacent the exterior annulus of a disc space;

surgically entering the disc space and removing disc tissue by energizing and manipulating said laser fiber;

directing irrigating fluid through one or more of said conduits; and

removing fluid with suctioning through one or more of said conduits.

6. The method of claim 5, wherein said abdominal incision is lateral to the abdominal midline.

7. The method of claim 5, wherein said pharmaceutically acceptable gas is CO_2.

8. The method of claim 5, wherein said pharmaceutically acceptable gas is air.

9. The method of claim 5, wherein said instilling step is performed prior to or during the guiding step.

10. A method of performing a laparoscopic lumbar discectomy on a patient comprising:

creating an incision through the abdominal wall and into the preperitoneal space;

inserting a surgical apparatus comprising an endoscope, irrigation and suction means, and means suitable for performing a lumbar discectomy into said preperitoneal space;

separating peritoneal ling from the abdominal wall and expanding the retroperitoneal space therebetween;

traversing said preperitoneal space and said retroperitoneal space toward a lumbar vertebral body with said surgical apparatus until said surgical device approaches the anterior aspect of said vertebral body;

entering the disk space of said vertebral body; and removing disc tissue utilizing said surgical apparatus.

11. The method of claim 10, wherein said abdominal incision is lateral to the abdominal midline.

12. The method of claim 11, wherein said incision is adjacent said abdominal midline.

13. The method of claim 10, wherein the traversing step additionally comprises the step of instilling a pharmaceutically acceptable gas into said preperitoneal space and said retroperitoneal space thereby expanding said space.

14. A method of performing a laparoscopic lumbar discectomy on a patient comprising:

creating an incision in the abdominal wall of a patient;

separating peritoneal lining from the abdominal wall and instilling a pharmaceutically acceptable gas to expand a retroperitoneal space located between said incision and the lumbar vertebrae;

inserting a surgical apparatus comprising an endoscope and surgical means for performing a lumbar discectomy into said incision;

directing said surgical apparatus through said expanded retroperitoneal space; and

removing disc tissue utilizing said surgical apparatus on at lest one vertebral body.

15. The method of claim 14, wherein said incision is adjacent the abdominal midline.

16. The method of claim 14, wherein said pharmaceutically acceptable gas is CO_2.

17. The method of claim 14, wherein said pharmaceutically acceptable gas is air.

* * * * *

APPENDIX D

FAR LATERAL LUMBAR DISC HERNIATION

THE KEY TO THE INTERTRANSVERSE APPROACH

L. J. O'HARA, R. W. MARSHALL

From the Royal Berkshire Hospital, Reading, England

Of a total of 330 patients requiring operation on a lumbar disc, 20 (6.1%) with lateral disc prolapse had a new muscle-splitting, intertransverse approach which requires minimal resection of bone.

There were 16 men and 4 women with a mean age of 52 years. All had intense radicular pain, 15 had femoral radiculopathy and 19 a neurological deficit. Far lateral herniation of the disc had been confirmed by MRI.

At operation, excellent access was obtained to the spinal nerve, dorsal root ganglion and the disc prolapse. The posterior primary ramus was useful in locating the spinal nerve and dorsal root ganglion during dissection of the intertransverse space.

At review from six months to four years, 12 patients had excellent results with no residual pain and six had good results with mild discomfort and no functional impairment. Two had poor results. There had been neurological improvement in 17 of the 20 patients.

We report a cadaver study of the anatomy of the posterior primary ramus. It is readily identifiable through this approach and can be traced down to the spinal nerve in the intertransverse space.

We recommend the use of a muscle-splitting intertransverse approach to far lateral herniation of the disc, using the posterior primary ramus as the key to safe dissection.

J Bone Joint Surg [Br] 1997;79-B:943-7.
Received 14 April 1997; Accepted after revision 18 July 1997

L. J. O'Hara, BSc, FRCS, Specialist Registrar
Southampton General Hospital, Tremona Road, Southampton SO16 6YD, UK.

R. W. Marshall, FRCS, Consultant Orthopaedic Surgeon
Royal Berkshire Hospital, London Road, Reading RG1 5AN, UK.

Correspondence should be sent to Mr R. W. Marshall.

0301-620X/97/67876 $2.00

The term 'far lateral' applies to prolapse of a lumbar disc which compresses the nerve root at the same level[1] irrespective of whether it is in the intervertebral canal, at the foramen or further laterally. Failure to recognise its presence has often been responsible for a poor outcome and persistent sciatica after operation.[2-6] CT and MRI now allow successful demonstration of protrusions of the lateral disc which account for between 6% and 10% of all lumbar discs which need operation.[7-10] Prolapse of a lumbar disc at this site, however, may still be overlooked.[11]

There has been discussion as to the most suitable surgical approach to a far lateral disc lesion.[12] Most surgeons use an interlaminar approach,[1,3,5,6-9,13-16] but full exposure of the nerve root requires total resection of the facet joint which may prejudice the subsequent stability of the spine. This has led to the development of approaches to expose the nerve root within the intertransverse space by a paramuscular[5,6,8,9,17] route with retraction of the erector spinae from the midline, or by muscle splitting, usually with a paramedian incision.[8,15,18-21] These require minimal resection of bone. The paramuscular route is preferred by many, despite its disadvantages, because surgeons are not familiar with the anatomy of the muscle-splitting approach. We found that the posterior ramus of the spinal nerve is a useful anatomical landmark in this approach, allowing early identification of the spinal nerve and dorsal root ganglion and safe dissection of the intertransverse space. We describe our experience in 20 operations and in a cadaver study.

PATIENTS AND METHODS

Between August 1992 and January 1996 out of a total of 330 patients with prolapse of the lumbar disc requiring operation, 20 with far lateral herniation (6.1%) were treated by the senior author (RWM). There were 16 men and four women with a mean age of 52 years (26 to 78), and a mean duration of symptoms of 23 weeks (4 weeks to 2 years).

All patients complained of intense, unilateral radicular pain which was either sciatic (25%) or femoral (75%). In 13 the onset was sudden. Only five had a history of injury; in the remainder the onset was insidious. Thirteen patients

Table I. Nerve-tension signs on clinical examination in 20 patients

Level	Number	SLR*	FST†	FST + SLR
L2/3	2	0	2	0
L3/4	7	2	6	1
L4/5	6	3	3	0
L5/S1	5	5	1	1
Total	20	10	12	2

* reduced straight-leg raising
† positive femoral stretch test

Table II. Number (%) of far lateral disc herniations as shown by MRI

Disc level	Number
L2/3	2 (*10*)
L3/4	7 (*35*)
L4/5	6 (*30*)
L5/S1	5 (*25*)
Total	20 (*100*)

had back pain (65%) but this was more intense than the radicular pain in only five. Nineteen patients had neurological deficits (95%); 17 had sensory loss and 14 had motor weakness. The motor deficit was usually mild; only two had weakness to MRC grade 3. Abnormal deep tendon reflexes were found in only five (25%) patients; all were absent knee reflexes in patients with prolapse of the L3/4 disc. All patients had a positive nerve-tension test (Table I). A positive femoral stretch test was present in 12 (60%), most of whom had a prolapse at L4/5 and above. Reduced straight-leg raising was found in ten patients (50%), including all five with an L5/S1 disc lesion (Table I).

Pain was assessed using a visual analogue scale before and after operation. Plain radiography showed a grade-2 spondylolisthesis at L5/S1 in two patients who had an extraforaminal prolapse at the same level. In one, who was awaiting spinal fusion before the sudden onset of intractable sciatica, fusion was performed at the same time as far lateral discectomy. Axial and sagittal MRI confirmed the diagnosis, and showed that 75% of far lateral disc herniations occurred at L4/5 and above (Table II and Fig. 1).

All patients were assessed clinically at the last review by the first author (LJO'H), who had not been involved in their treatment.

Operative technique. The patient is anaesthetised and placed prone on a Montreal mattress and antibiotic prophylaxis is given (1.5 g cefuroxime). The intertransverse space is approached through a paramedian incision 5 cm lateral to the midline, splitting multifidus and longissimus as described by Wiltse[22] for spinal fusion. The bases of the transverse processes are identified with a fingertip and a self-retaining retractor inserted. The level is checked by image intensifier.

We use binocular loupe magnification and a fibreoptic headlight to identify the posterior primary ramus of the spinal nerve where it passes through the medial aspect of the intertransverse membrane, before distributing its branches to the dorsal musculature. This nerve is a useful anatomical guide later in the dissection. The transverse process and the facet joint are exposed by reflecting soft tissue, and the isthmus is defined by reflecting muscle from the pars interarticularis.

The dorsal root ganglion and the spinal nerve are embedded in extraforaminal fat and connective tissue beneath the intertransverse membrane. Identification of the posterior primary ramus allows the surgeon to locate these vulnerable neural structures rapidly and safely (Figs 2 and 3) thus reducing the risk of avulsion injury. Overhanging isthmic

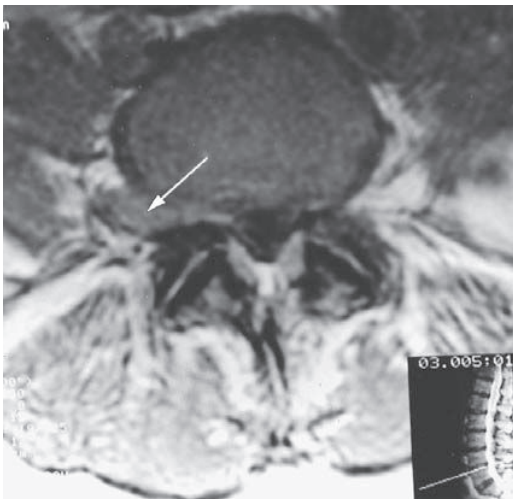


Fig. 1a

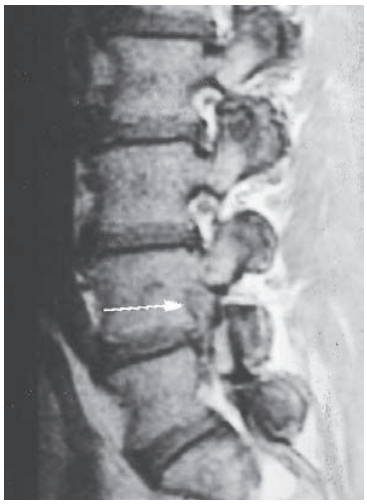


Fig. 1b

Axial (a) and sagittal (b) MRI showing an extraforaminal disc at L4/5. The disc prolapse displaces extraforaminal fat on the sagittal view.

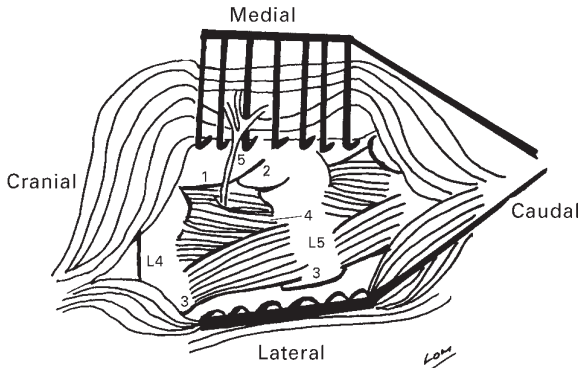


Fig. 2a

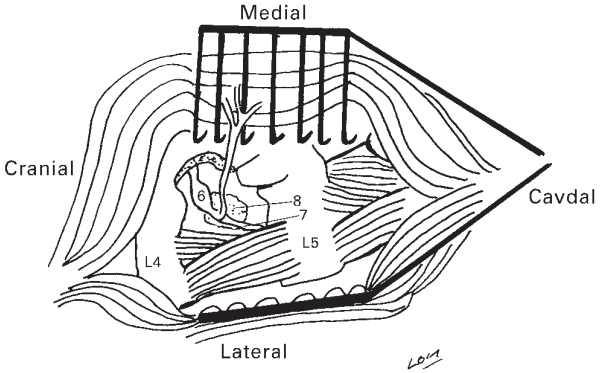


Fig. 2b

Diagrams showing the intertransverse space at L4/5 through the paramedian muscle-splitting approach (a) and the use of the posterior ramus as the key to its safe dissection (b) (1, isthmus; 2, facet joint; 3, transverse process; 4, intertransverse membrane; 5, posterior primary ramus; 6, dorsal root ganglion; 7, spinal nerve; 8, extraforaminal disc herniation).

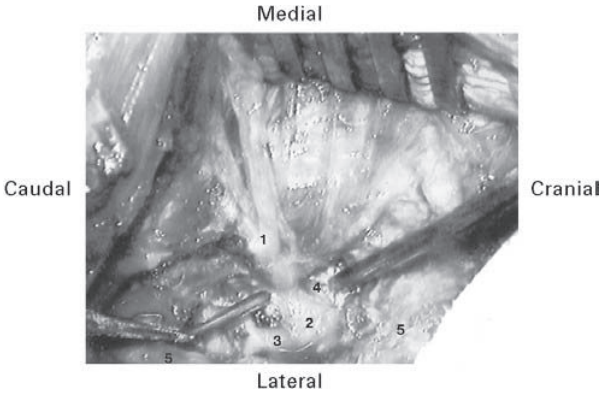


Fig. 3a

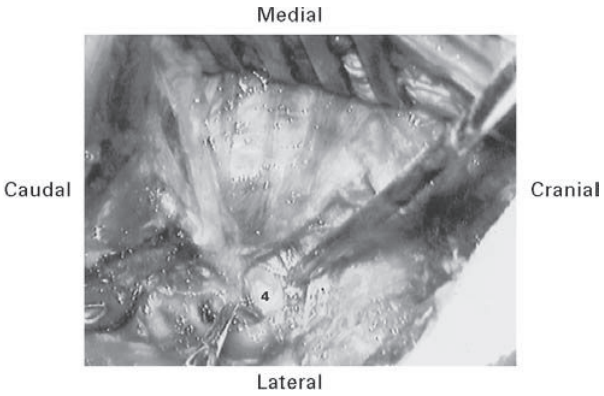


Fig. 3b

Photographs showing the exposure of the intertransverse space obtained by the muscle-splitting approach. The posterior primary ramus leading to the spinal nerve and dorsal root ganglion is clearly shown (a). Herniated extraforaminal disc material is removed by a pituitary rongeur after lateral retraction of the spinal nerve (b) (1, posterior primary ramus; 2, dorsal root ganglion; 3, spinal nerve; 4, sequestrated extraforaminal disc; 5, transverse process.

bone may be cleared, if necessary, with a high-speed burr while protecting the underlying nerves with a blunt dissector. Further access is obtained by trimming the most lateral aspect of the superior articular process of the facet with a burr without disturbing the joint itself. Resection of bone is not always needed, but trimming of the superior articular process is invariably required at the L5/S1 level because of the size of the facet.

The spinal nerve is usually found to be under tension from the herniated disc, which is often sequestrated. The nerve is carefully retracted laterally allowing access to the disc material which is removed with pituitary forceps, reducing the tension of the nerve. The remaining degenerative disc material is then cleared from the disc space itself. Further exploration beneath the dorsal root ganglion with a probe allows any residual, sequestrated material to be removed.

RESULTS

The results at six months to four years were excellent in 12 patients (60%) with no residual discomfort, and good in six (30%) who had only minor leg or back pain and no functional impairment. One patient with a long-standing far lateral protrusion of the L4/5 disc showed no improvement after surgery. Subsequent MRI indicated the possibility of residual extraforaminal disc material, but at a further operation only scar tissue was found. This was released but there was no improvement. The other patient with a poor outcome had increased radicular pain after operation although there was an improvement in neurological function.

Sequestrated disc material was found in 50% of cases. There was neurological improvement in 17 of 19 patients. Of 14 patients with motor weakness 12 showed improvement and 11 had complete resolution. A sensory deficit improved in 14 of 17 patients with total resolution in nine. The mean leg pain score improved from 8.0 preoperatively to 1.5 after operation.

Cadaver study. A cadaver was dissected to determine whether the medial branch of the dorsal primary ramus could be identified at every level of the lumbar spine. At five levels (L1 to S1) the medial branch of the dorsal

primary ramus was readily identified and traced down through the intertransverse membrane to the spinal nerve and its dorsal root ganglion.

DISCUSSION

Lindblom[23] demonstrated prolapse of the lumbar disc outside the confines of the vertebral canal in a cadaver study in 1944, but the clinical diagnosis has remained difficult, since these lateral protrusions could not be shown by myelography, or by limited operative exploration. In 1971 Macnab[2] reported two cases of compression of the L5 root by an extraforaminal protrusion of the L5/S1 disc after a failed exploration at L4/5. In 1974 Abdullah et al[1] described the clinical syndrome of the "extreme lateral" herniation of the lumbar disc as demonstrated by discography; they found herniations beneath or beyond the facet, compressing the nerve root at the same level, in 11.7% of prolapses of lumbar discs. The characteristic clinical findings included anterior thigh and leg pain, appropriate sensory loss, absence of back pain, an absent knee jerk and no reduction of straight-leg raising. Subsequent authors have described these discs as "extreme lateral",[3,8,10,13,14,19,21,24] "far lateral",[6,9,16,18] "extracanalicular"[5] and "foraminal" or "extraforaminal".[4,15,17,25-27] Larger series have reported incidences of between 5.8% and 10.3%[7-10] which agree with our figure of 6.1%.

The characteristic feature is that a far lateral disc compresses the nerve root which exits at the same level; this is in contrast to classic posterolateral disc compression which affects the nerve root leaving at the level below.

Far lateral herniation more often compromises the upper lumbar nerve roots[1,8,10] producing a femoral radiculopathy; in 75% of our patients the nerve root at L4 and above was affected. The femoral nerve traction test is often positive.[8,10,13,16] The Lasegue sign is less reliable in determining the level of root compression, but it is wrong to believe that straight-leg raising is usually normal.[1,7,19] In the series of Abdullah et al[1] there were no cases of compression of the L5 nerve root and the frequency of Lasegue's sign was only 4%. Since then far lateral herniation at L5/S1 has been found frequently[8-11,14,18] with an incidence of 38% in the 178 cases of Porchet et al[10] and 25% in our series. Since the L5 nerve root is compressed by L5/S1 far lateral protrusion, there is a high frequency of decreased straight-leg raising.

The intensity of the radicular pain in far lateral prolapse is particularly severe; this probably results from direct contact of nuclear or annular fragments with the dorsal root ganglion.[3] Instability[5,6] and severe back pain[8] have been reported after an interlaminar approach with facetectomy and spinal fusion has been advocated in every case.[27] An extraforaminal disc prolapse is often sequestrated[1,5,8,9,18,19] and many migrate superiorly and laterally. These sequestrated fragments may be missed even after full facetectomy, and are the cause of persistent radicular pain.[5]

The precise localisation of a far lateral disc by CT[11,24,28] and MRI[11,29] has allowed more direct and anatomically favourable approaches to be used. Since the mid 1980s the intertransverse route has been used to provide direct access to the extraforaminal area and the intervertebral foramen with minimal resection of bone. The paramuscular approach requires a larger incision and greater soft-tissue retraction, but exposes less of the foramen;[8] its advocates find the muscle-splitting approach disorientating because of the lack of anatomical landmarks.[6,9]

The course and relationship of the lumbar nerve are different at each level because of the variation in the structure of the lumbar vertebrae which is also altered by disc herniation.[21] A consistent anatomical landmark is of benefit. Fankhauser and de Tribolet[20] using the transmuscular approach observed the posterior ramus of the spinal nerve during operative dissection, but discounted it as an anatomical landmark because systematic identification of its branches was difficult and time-consuming. O'Brien et al[19] using the posterolateral approach of Watkins in far lateral herniation utilised the lateral branch of the posterior primary ramus to direct them to the spinal nerve and hence the intervertebral foramen. Since 1992, we have used the medial branch of the posterior primary ramus as an anatomical guide to the spinal nerve and the underlying disc prolapse.

The posterior primary ramus of the lumbar nerve arises immediately distal to the dorsal root ganglion and is directed backwards towards the upper border of the subjacent transverse process.[30] After piercing the intertransverse membrane it gives off three branches, medial, intermediate and lateral, each having a segmental muscular distribution.[31] The medial and intermediate branches supply multifidus and longissimus, respectively, and are represented at every level. The lateral branch, supplying iliocostalis, is absent at L5/S1 presumably because its segmental muscle has no fibres arising from the L5 transverse process.[31]

We have consistently identified the medial branch of the posterior primary ramus both at operation and in the cadaver (Fig. 3). It can then be traced to the intertransverse membrane allowing early identification of the underlying spinal nerve and safe dissection of the extraforaminal area. Identification of the posterior ramus may also reduce the risk of its avulsion from the dorsal root ganglion: this may be responsible for the dysaesthesia found after operation in some patients.[8,17,18]

The appearance of the intertransverse ligament has been described as being that of a membrane[30] and our operative and cadaver studies confirm that the term 'ligament' is a misnomer. The intertransverse 'ligament' consists of sheets of connective tissue extending from the upper border of one transverse process to the lower border of the one above. It lacks a distinct border medially or laterally, with less densely packed and more irregular collagen fibres than is found in a true ligament. It probably forms part of a complex fascial system separating the paravertebral com-

partments.[30] The membrane extends to the lateral aspect of the pars interarticularis and the facet. It can be incised safely provided that the underlying neural structures are protected after identification by tracing the posterior primary ramus into the intertransverse space.

We recommend the use of a muscle-splitting, intertransverse approach to a far lateral disc, with the posterior primary ramus providing the key to safe exposure of the spinal nerve and the underlying structures.

We are most grateful to Mr C. Sinnatamby, FRCS, for access to cadaver dissection at the Royal College of Surgeons of England, Mr Lionel Williams and the Photographic Department at the Royal Berkshire Hospital, and to Mrs. J Wood and Miss J. Deacon for collating medical records and arranging the patient assessments.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

REFERENCES

1. **Abdullah AF, Ditton EW III, Byrd EB, et al.** Extreme-lateral lumbar disc herniations: clinical syndrome and special problems of diagnosis. *J Neurosurg* 1974;41:229-34.
2. **Macnab I.** Negative disc exploration: an analysis of the causes of nerve-root involvement in sixty-eight patients. *J Bone Joint Surg [Am]* 1971;53-A:891-903.
3. **Patrick BS.** Extreme lateral ruptures of lumbar intervertebral discs. *Surg Neurol* 1975;3:301-4.
4. **Jackson RP, Glah JJ.** Foraminal and extraforaminal lumbar disc herniation: diagnosis and treatment. *Spine* 1987;12:577-85.
5. **Reulen HJ, Pfaundler S, Ebeling U.** The lateral microsurgical approach to the extracanalicular lumbar disc herniation. I: a technical note. *Acta Neurochir Wien* 1987;84:64-7.
6. **Siebner HR, Faulhauer K.** Frequency and specific surgical management of far lateral lumbar disc herniations. *Acta Neurochir Wien* 1990;105:124-31.
7. **Abdullah AF, Wolber PG, Warfield JR, Gunadi AK.** Surgical management of extreme lateral lumbar disc herniations: review of 138 cases. *Neurosurgery* 1988;22:648-53.
8. **Fankhauser H, de Tribolet N.** Extreme lateral lumbar disc herniation. *Br J Neurosurg* 1987;1:111-29.
9. **Hood RS.** Far lateral lumbar disc herniations. *Neurosurg Clin N Am* 1993;4:117-24.
10. **Porchet F, Fankhauser H, de Tribolet N.** Extreme lateral lumbar disc herniation: clinical presentation in 178 patients. *Acta Neurochir Wien* 1994;127:203-9.
11. **Osborn AG, Hood RS, Sherry RG, et al.** CT/MR spectrum of far lateral and anterior lumbosacral disk herniations. *Am J Neuroradiol* 1988;9:775-8.
12. **Getty CJM, Wiltse LL, Tarlov E, et al.** Discussion on extreme lateral lumbar disc herniation. *J Spinal Disord* 1989;2:133-41.
13. **Postacchini F, Montanaro A.** Extreme lateral herniations of lumbar disks. *Clin Orthop* 1979;138:222-7.
14. **Godersky JC, Erickson DL, Seljeskog EL.** Extreme lateral disc herniation: diagnosis by computed tomographic scanning. *Neurosurgery* 1984;14:549-52.
15. **Recoules-Arche D.** Surgery of disk hernia of the lumbar vertebral canal. *Neurochirurgie* 1985;31:61-4.
16. **Epstein NE, Epstein JA, Carras R, Hyman RA, Vishnubakhat SM.** Far lateral lumbar disc herniation: diagnosis and surgical management. *Neuroorthopaedics* 1986;1:37-44.
17. **Melvill RL, Baxter BL.** The intertransverse approach to extraforaminal disc protrusion in the lumbar spine. *Spine* 1994;19: 2707-14.
18. **Maroon JC, Kopitnik TA, Schulhof LA, Abla A, Wilberger JE.** Diagnosis and microsurgical approach to far-lateral disc herniation in the lumbar spine. *J Neurosurg* 1990;72:378-82.
19. **O'Brien MF, Peterson D, Crockard HA.** A posterolateral microsurgical approach to extreme-lateral lumbar disc herniation. *J Neurosurg* 1995;83:636-40.
20. **Fankhauser H, de Tribolet N.** Extraforaminal approach for extreme lateral lumbar disc herniation. In: Torrens MJ and Dickson RA, eds. *Operative spinal surgery (practice of surgery series).* Edinburgh: Churchill Livingstone, 1991:145-60.
21. **Schlesinger SM, Fankhauser H, de Tribolet N.** Microsurgical anatomy and operative technique for extreme lateral lumbar disc herniations. *Acta Neurochir Wien* 1992;118:117-29.
22. **Wiltse LL.** The paraspinal sacrospinalis splitting approach to the lumbar spine. *Clin Orthop* 1973;91:48-57.
23. **Lindblom K.** Protrusions of disks and nerve compression in the lumbar region. *Acta Radiol* 1944;25:195-212.
24. **Kornberg M.** Extreme lateral lumbar disc herniations: clinical syndrome and computed tomography recognition. *Spine* 1987;12:586-9.
25. **Novetsky GJ, Berlin L, Epstein AJ, Lobo N, Miller SH.** The extraforaminal herniated disc: detection by computed tomography. *AJNR* 1982;3:653-5.
26. **Kurobane Y, Takahashi T, Tajima T, et al.** Extraforaminal disc herniation. *Spine* 1986;11:260-8.
27. **Kunogi J, Hasue M.** Diagnosis and operative treatment of intraforaminal and extraforaminal nerve root compression. *Spine* 1991;16:1312-20.
28. **Williams AL, Haughton VM, Daniels DL, Thornton RS.** CT recognition of lateral lumbar disk herniation. *AJR* 1982;139:345-7.
29. **Dickman CA, Mamourian A, Drayer BP, et al.** MR imaging of lateral disc herniation (letter, comment). *J Neurosurg* 1990;73:642-3.
30. **Bogduk N, Twomey LT.** *Clinical anatomy of the lumbar spine*. 2nd Ed. Edinburgh: Churchill Livingstone, 1991.
31. **Bogduk N, Wilson AS, Tynan W.** The human lumbar dorsal rami. *J Anat* 1982;134:383-97.

APPENDIX E

Medtronic

OLIF25™

Procedure

Oblique Lateral Interbody Fusion For L2 to L5 Surgical Technique

As described by:

Richard A. Hynes, MD, FACS
The B.A.C.K Center
Melbourne, Florida

Michael MacMillan, MD
University of Florida
College of Medicine
Gainesville, Florida

Brian Kwon, MD
Tufts University
School of Medicine
Boston, Massachusetts

MICHELSON TECHNOLOGY AT WORK

The **Oblique Lateral Interbody Fusion (OLIF)** Procedure provides spine surgeons with a **complete minimally invasive solution** for the treatment of degenerative lumbar conditions. By utilizing an **oblique lateral approach to the spine**, this procedure enables placement of a large interbody graft into the disc space for anterior column support while avoiding obstacles associated with traditional anterior, posterior and/or direct lateral approaches. The OLIF25™ Procedure allows for **psoas-preserving access to the L2-L5 levels**. This procedure also incorporates a comprehensive set of instruments and implants including fully integrated neuromonitoring and navigation, streamlined access instrumentation, anatomically designed implants and percutaneous fixation systems.

Interbody
CLYDESDALE®
Spinal System*

Access
MAST QUADRANT™
Lateral Retractor System

Neuromonitoring
NIM-ECLIPSE® Spinal System**

Navigation
O-ARM® System and
StealthStation® System

Fixation
CD HORIZON® SEXTANT® Percutaneous
Rod Insertion Systems and
CD HORIZON® LONGITUDE™ Multi-level
Percutaneous Fixation System

There are some risks associated with minimally invasive spine surgery, including transitioning to a conventional open procedure, neurological damage, damage to the surrounding soft tissue, and, where used, instrument malfunction. Other risks associated with implants used include device migration, non-fusion, loss of spinal curvature, correction, height, and/or reduction. Minimally invasive procedures may be associated with longer operative times.

*The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.
**The NIM-ECLIPSE® System is manufactured by Medtronic Xomed, Inc. Distributed by Medtronic Sofamor Danek USA, Inc.

Medtronic

Oblique Lateral Interbody Fusion

Ante-Psoas Approach OLIF25™ Surgical Technique

Preoperative Planning

Preoperative planning can be useful in determining:

- Location of the iliac crest and lower ribs in relation to disc space of interest
- Position of the psoas, anterior vasculature, posterior nerve structures and the kidneys via axial MRI
- The oblique angle of entry into the disc space
- Curvature of the spine

Although the OLIF25™ Approach, which is lateral to the anterior vasculature is not recommended for use at L5-S1 in certain patients, it may be performed if the patient has a low bifurcation of anterior vasculature and a low iliac crest. Physicians should use preoperative planning to determine the location of anterior vasculature, the iliac crest, and the surgical trajectory to determine the appropriateness of this technique at the L5-S1 disc space.

Standard lateral surgical positioning is right lateral decubitus, or left side up, and is the preferred positioning for an oblique lateral approach based on vasculature positioning. However, the surgeon should consider ease of access, surgeon preference and the preoperative images in determining which side to approach. Correction can be achieved equally from either the convex or concave side of the curve.

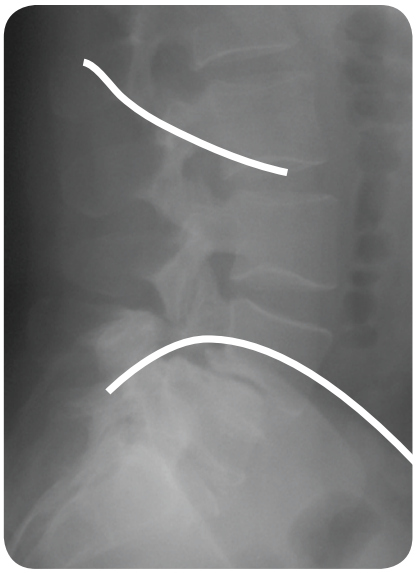


Figure 1

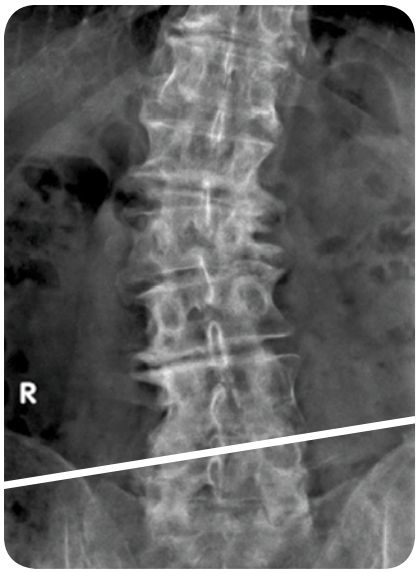


Figure 2

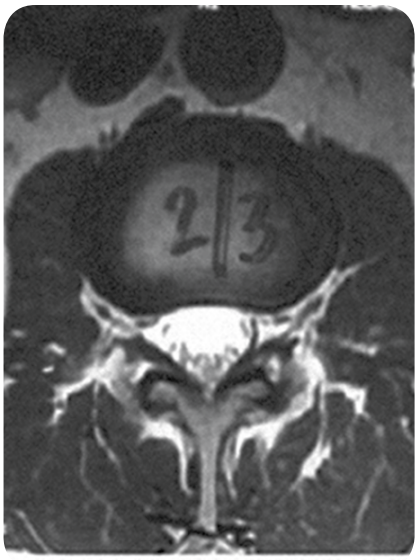


Figure 3

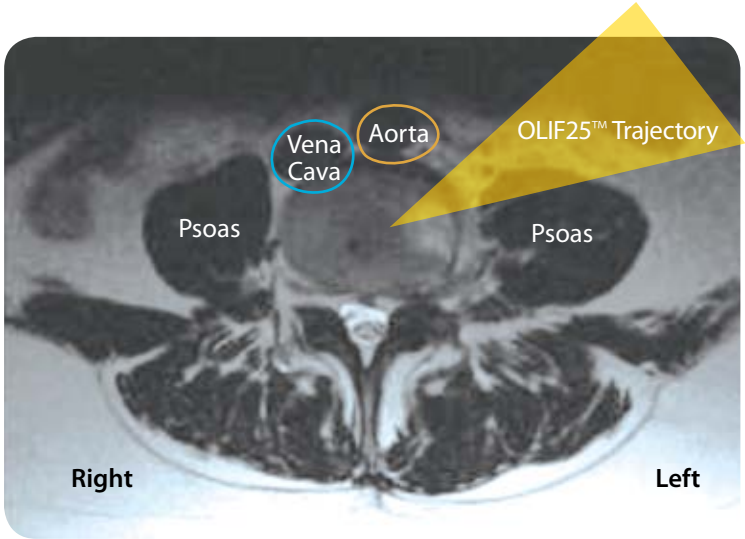


Figure 4

NIM-ECLIPSE® Spinal System Electrode Placement

After the patient is asleep, needle recording electrodes are placed in the innervated muscles in the legs to monitor the affected nerve roots during the procedure. Please follow the instructions below, as well as the accompanying electrode placement guide, to correctly place the electrodes in the appropriate muscles for the desired levels.

1. Electrodes are placed prior to patient draping and the establishment of the sterile field.
2. Clean the areas with alcohol wipes.
3. The green lead ground electrode should be placed between the stimulator and the monitoring electrodes in a location where the bone is close to the skin and the electrode will not contact muscle.
4. The white stimulus return electrode should be placed near the location of stimulation. Connect the Probe lead wire to the instrument jack of the Patient Interface Module.
5. Tape all of the electrodes securely in place and plug the leads into the Patient Interface Module. Power on the NIM-ECLIPSE® Spinal System* to begin monitoring.

Helpful Tip

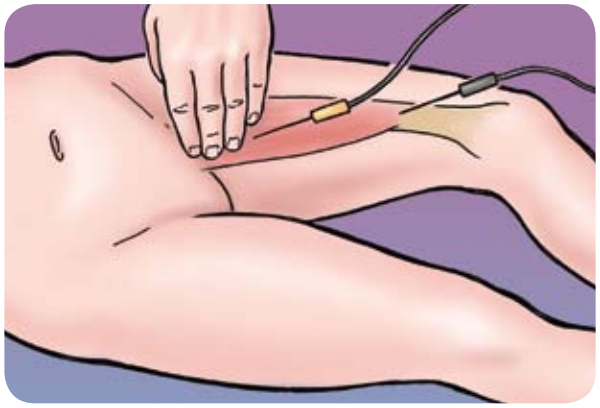
Let the anesthesiologist know EMG monitoring will be used during the procedure to ensure that no neuromuscular blocking agents are administered during monitoring. During intubation, a fast-acting neuromuscular blocking agent should be used.

Sample L2 – L5 Setup

Active: needle inserted four to five fingerbreadths (fb) below the pubic tubercle and deeply into the palpable muscle belly.

Reference: needle inserted subcutaneously above the active needle.

Channel 1	Left L2 – L3	AL
Channel 5	Right L2 – L3	AL

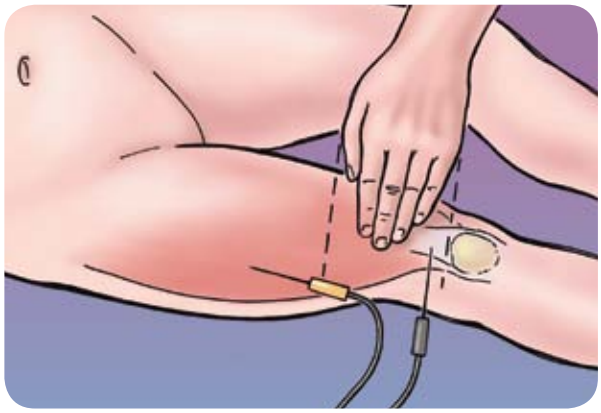


Adductor Longus (AL)

Active: insert needle tangentially but deep into muscle belly one handbreadth above the patella.

Reference: insert needle subcutaneously at patellar tendon.

Channel 2	Left L2 – L4	VL
Channel 6	Right L2 – L4	VL



Vastus Lateralis (VL)

*NIM-ECLIPSE® Spinal System is manufactured by Medtronic Xomed, Inc. Distributed by Medtronic Sofamor Danek USA, Inc.

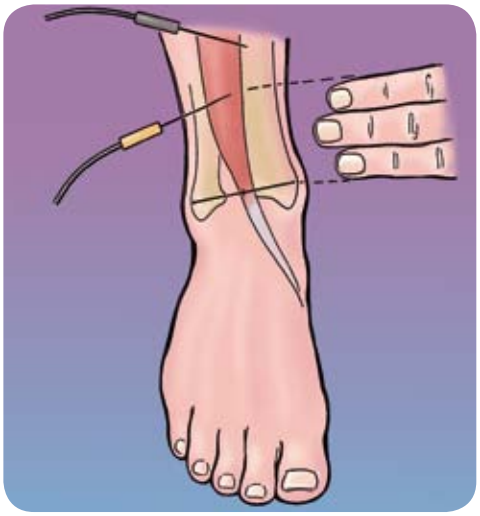
NIM-ECLIPSE® Spinal System Electrode Placement *continued*

Active: insert needle into muscle belly three fb above the midpoint of the bi-malleolar line (lateral to the tibial crest).

Reference: insert needle over the tibial crest (shin).

Channel 3 Left L5 EHL

Channel 7 Right L5 EHL



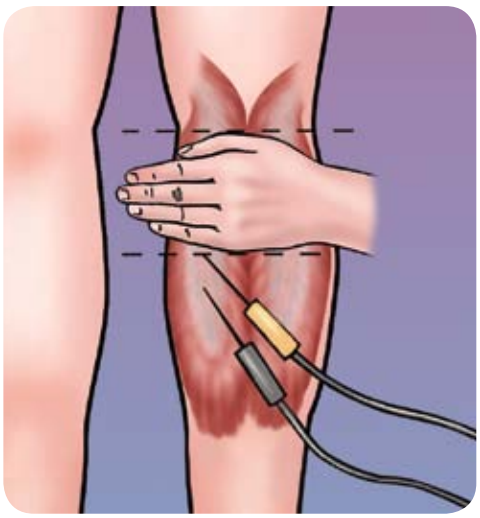
Extensor Hallucis Longus (EHL)

Active: insert needle into the muscle belly one handbreadth below the posterior crease of the knee.

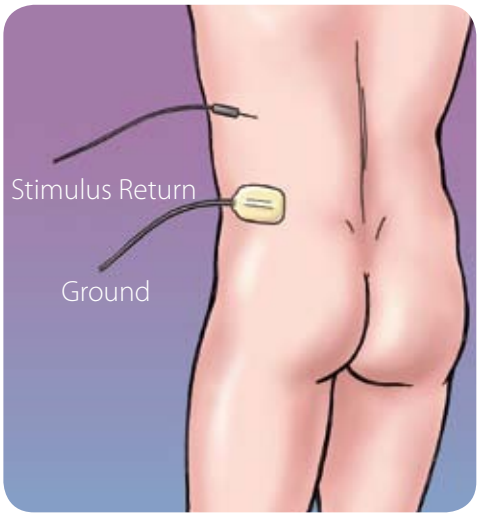
Reference: insert needle subcutaneously 2cm to 3cm away from the active electrode.

Channel 4 Left S1 – S2 GASTROC

Channel 8 Right S1 – S2 GASTROC



Medial Gastrocnemius (GASTROC)



Ground/Stimulus Return

Patient Positioning

The patient should be placed in the right lateral decubitus (left side up) position. An axillary roll is placed to protect the neurovascular structures in the axilla. Padding is placed between the arms to ensure they remain suspended in the neutral position. Padding is also placed beneath and in between the legs from the knees distally **(Figures 5 and 6)**.

The legs of the patient may be slightly flexed in order to prevent the patient from rolling on the bed. However, extreme flexion to relax the psoas is not required because the approach is outside or within the anterior portion of the psoas (ante-psoas).

Breaking of the surgical table is not required, even if the patient has a high iliac crest and deep seated L4-5 disc space, as the oblique lateral approach is anterior to the iliac crest.

The patient is secured to the surgical table with tape at four locations:

1. Just beneath the iliac crest
2. Over the thoracic region, just beneath the shoulder
3. From the back of the table, over the ankle, and past the knee to the front of the table
4. From the shin to the back of the table

The surgeon and operating team should be positioned to work on the abdominal side of the patient with the C-Arm positioned posterior to the patient.

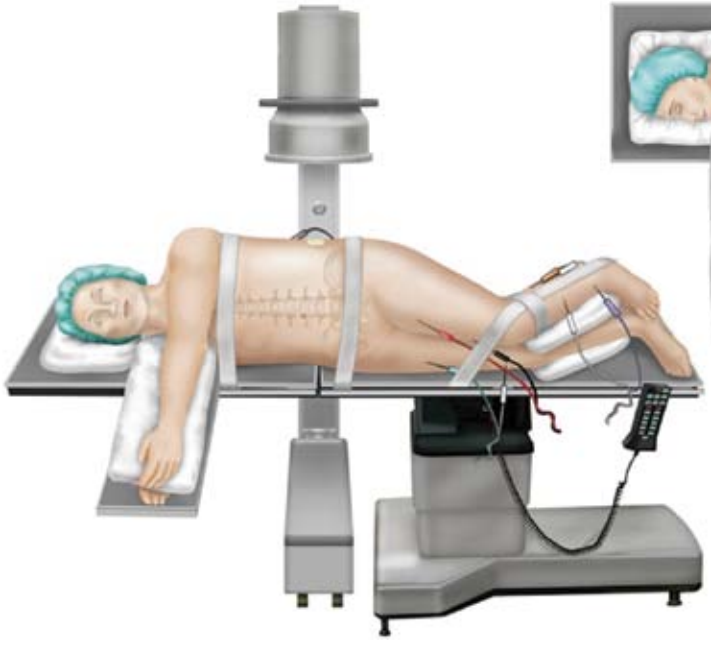


Figure 5

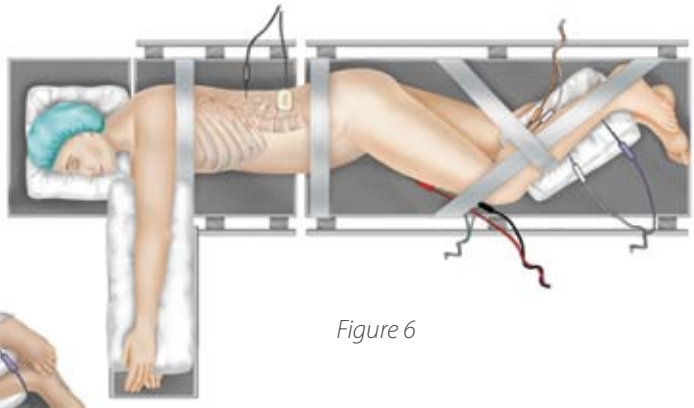


Figure 6

Patient Positioning *continued*

First, an AP image should be obtained to ensure the patient is positioned in a true lateral position **(Figure 7)**. On the AP x-ray clear, distinct pedicles that are equidistant from the spinous process should be visible. Then, a lateral x-ray is obtained and clean, distinct end plates should be seen **(Figure 8)**. Pedicles should overlap as should transverse processes to ensure a true lateral position has been achieved.

Important

It is critical the C-arm remain in the 0° and 90° positions at all times to ensure true lateral positioning and a safe lateral working channel across the disc space. For multilevel cases, rotate the surgical table independent of the C-arm for each level to obtain true images. Each disc space is measured on lateral fluoroscopy and line drawn on the patient to assist the radiology technician with lining up the angle specific to each disc.

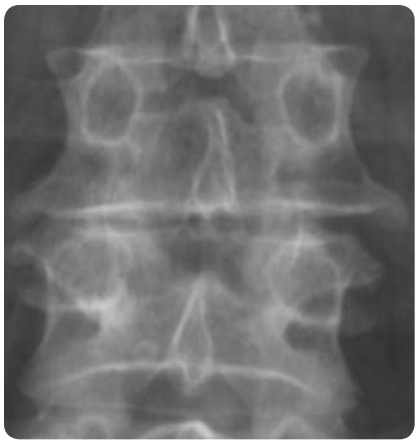


Figure 7

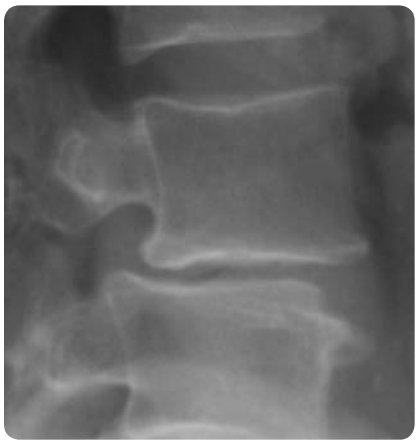


Figure 8

Localization

Fluoroscopy is used to confirm the target segment and mark the location for the initial incision. The disc spaces of interest, lower ribs and iliac crest can be marked on the skin as landmarks. For a single-level case the patient should be marked 4cm-10cm anterior to the midsection of the target disc (or approximately one third of the distance from the top of the iliac crest to the umbilicus).

A 3cm to 6cm vertical, horizontal or oblique incision can be made. For a two-level case, the patient should be marked 4cm-10cm anterior to the midsection of the intervening vertebral body. In addition, the lumbar lordosis of the operative levels can be marked on the skin to determine the angle in line with the disc space **(Figures 9–11)**.

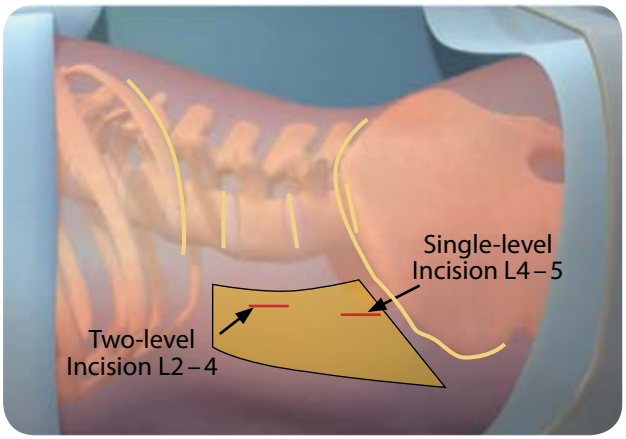


Figure 9

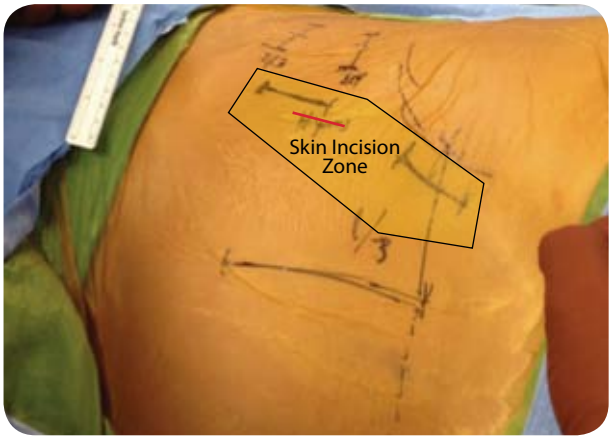


Figure 10

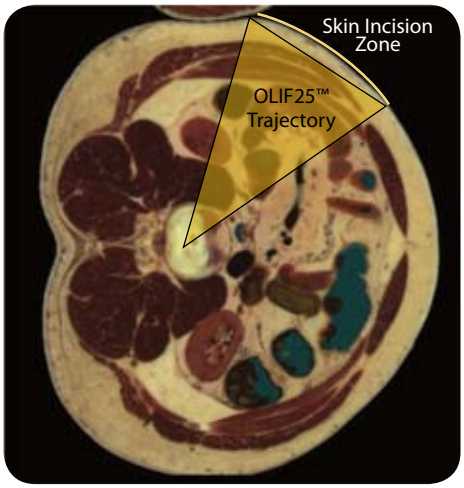


Figure 11

Localization *continued*

If image guidance is being used, a Navigation probe may be used to approximate the location of the initial skin incision based on the system images **(Figures 12 and 13)**.

Figure 12

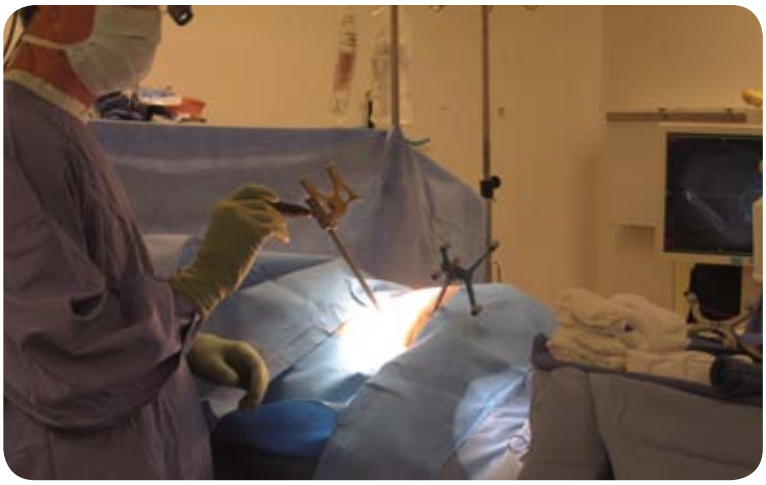
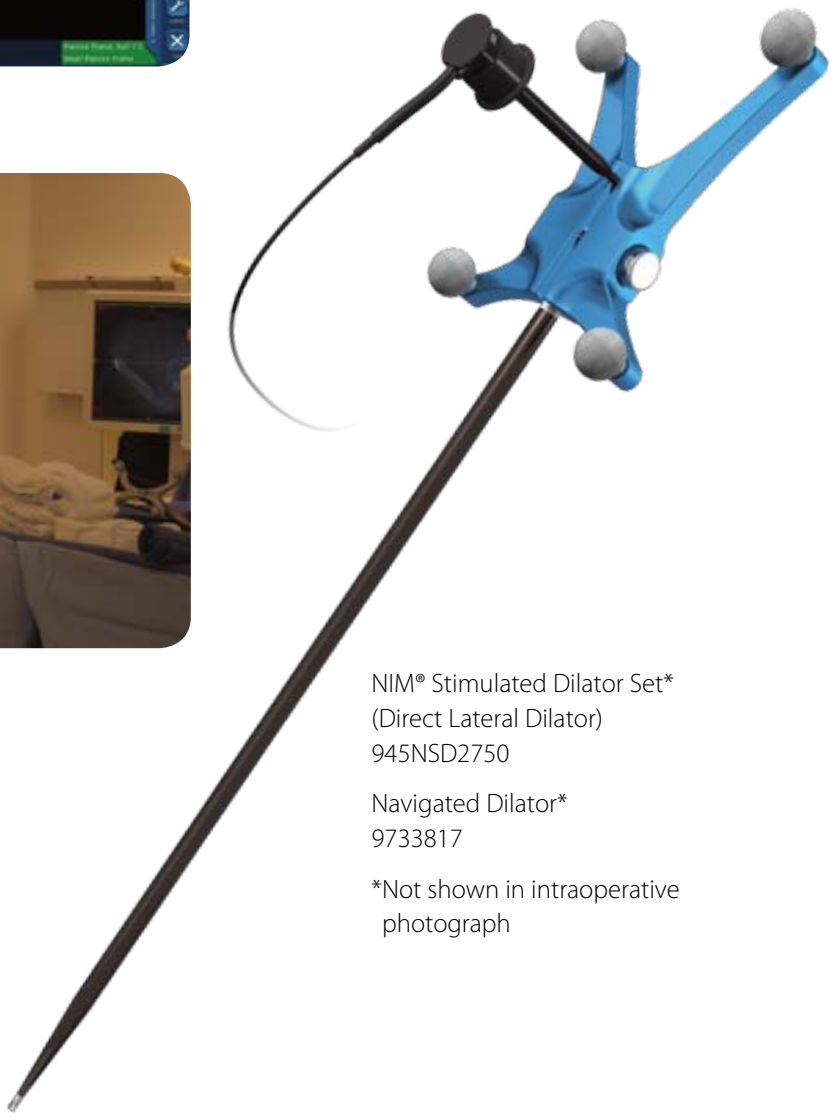


Figure 13



NIM® Stimulated Dilator Set*
(Direct Lateral Dilator)
945NSD2750

Navigated Dilator*
9733817

*Not shown in intraoperative photograph

Dissection

After making a single skin incision, the subcutaneous fat layers are dissected until the abdominal musculature is reached. A monopolar cautery may be used for hemostasis, and a small self-retaining retractor can be used for initial dissection of the skin and subcutaneous layer.

The external oblique fascia will be the first plane encountered and is the only layer that will need to be sharply incised. A Kelly Clamp is then used to bluntly spread through the fibers of the external oblique, internal oblique, and transversalis muscles. All dissection is done in line with the muscle fibers as these muscle layers run in opposite directions. After bluntly penetrating the transversalis fascia, the yellow retroperitoneal fat is exposed.

Once inside the retroperitoneal space, the index finger is used to follow the internal abdominal wall posteriorly down to the psoas muscle, which can be visualized.

The finger or a blunt instrument is used to sweep the peritoneal contents, including the ureter, which reflects with the peritoneum, and the retroperitoneal fat anteriorly past the anterior portion of the psoas clearing to the anterior vertebral body **(Figure 14)**.

Direct visualization may be employed in addition to tactile feel to ensure a safe approach to the disc space free from vascular, peritoneal and nerve obstructions. The fat overlying the psoas muscle can be swept in a cephalad and caudal direction as well as dorso-ventral with handheld retractors in order to visualize placement of the NIM® X-PAK Probe or the first Direct Lateral Dilator **(Figure 15)**. Use of hand-held retractors placed between peritoneal contents and the Probe will also minimize risk of injury to ureters and vascular structures anteriorly. A kitner or cloth-based dissector may be used to sweep soft tissue structures anteriorly.

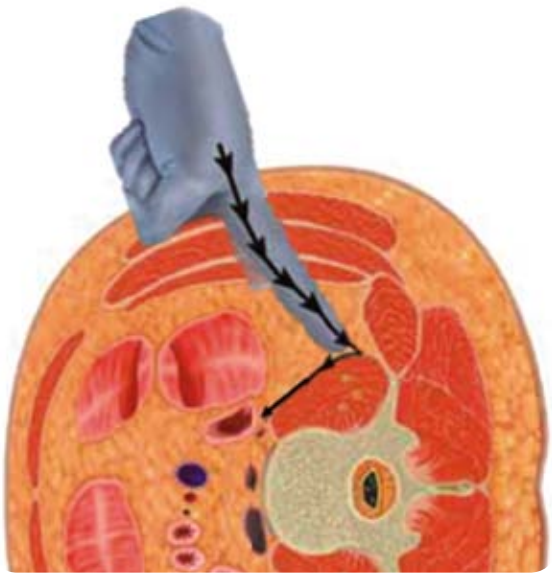


Figure 14

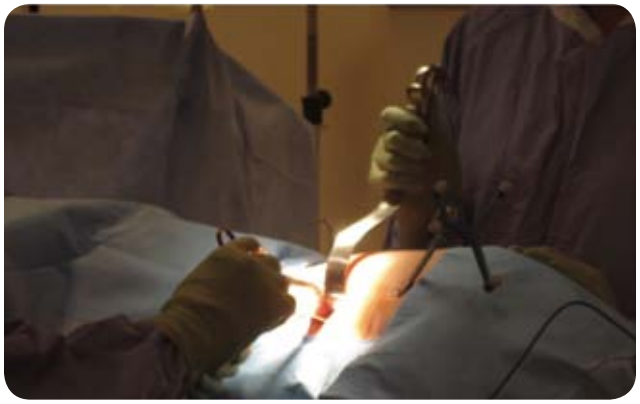


Figure 15

Helpful Tip

Entering the transversalis fascia obliquely from anterior in the incision to posterior to the quadratus muscle will prevent inadvertent entry into the peritoneum. Palpating the quadratus muscle, followed by the tip of the transverse process and finally the psoas muscle, will help verify that the correct retroperitoneal plane is being entered and ensures that the peritoneum is not compromised.

Placement of Initial Probe

After a safe retroperitoneal pathway to the anterior portion of the psoas has been established under direct visualization, a probe (NIM® X-PAK Probe or the first Direct Lateral Dilator) is guided down to the disc space in front or on the anterior portion of the psoas while using the finger or handheld retractors to protect the peritoneal membrane and retract retroperitoneal fat **(Figures 16 and 17)** (see Helpful Tip on Page 9). The NIM® X-PAK Probe and Direct Lateral Dilator include an insulated shaft that enables controlled electrification at the tip of the devices.

A Needle Driver is used to position the NIM® X-PAK Probe onto the disc space or psoas. The preferred starting position of the probe on the disc space is anterior to the psoas and away from the major vessels, although the probe may start on the anterior portion of the psoas muscle as well. Approaching the spine obliquely as opposed to direct lateral will further ensure the instruments work away from the peritoneum and anterior vascular structures. The oblique angle of the probe may be assessed preoperatively and measured intraoperatively using a mechanical or digital protractor. Probe position should be confirmed using lateral fluoroscopy or image-guided navigation (if using the Direct Lateral Dilator) **(Figure 18)**.

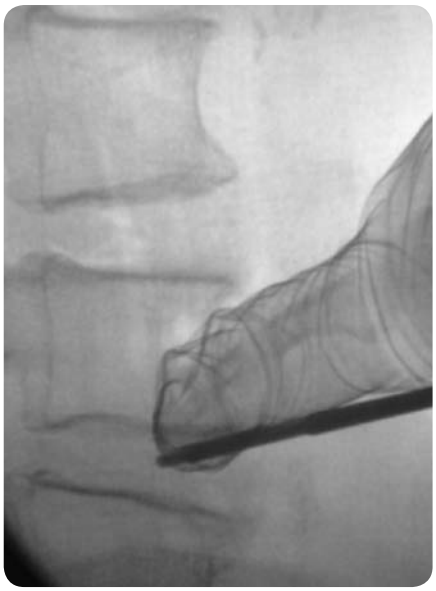


Figure 16

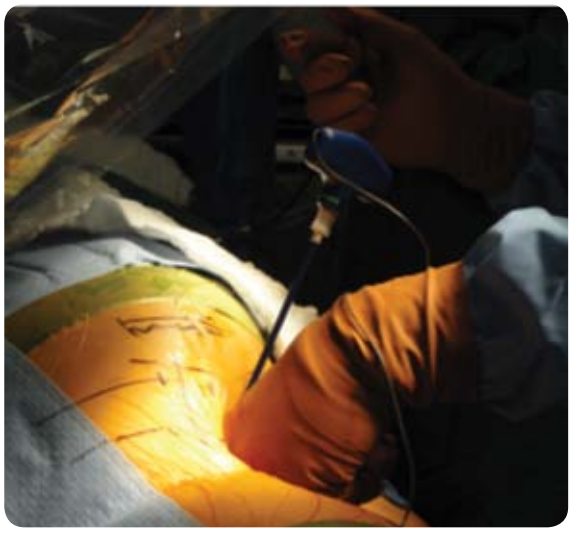


Figure 17

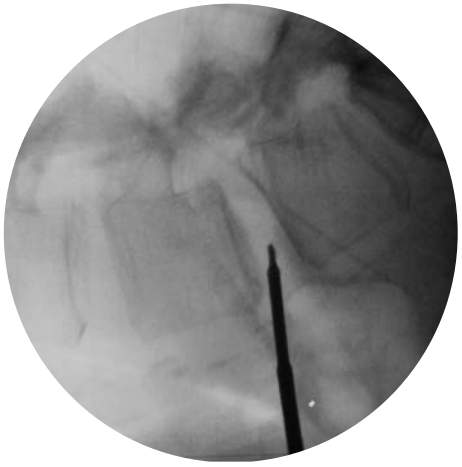


Figure 18

Placement of Initial Probe *continued*

Avoiding the posterior aspect of the psoas muscle or staying out of the psoas muscle completely will minimize the potential risk to the nerves within the psoas and to the psoas muscle itself. Cadaveric studies have shown that the motor nerves typically reside in the posterior one third of the psoas muscle **(Figure 19)**.

Note that the entry point into the disc may be slightly more anterior than the midpoint of the disc **(Figure 20)**. This will minimize the risk of injury to the contralateral foramen due to the oblique trajectory of disc preparation instruments and cage placement.

After the proper position has been established, carefully pass the probe into the disc space. If passing the probe through the anterior portion of the psoas, current is delivered to monitor for any neural structures as the fibers of the muscle are being split. The recommended stimulating current setting is between 6 milliamps and 8 milliamps. If an EMG response is generated at this level, the probe should be repositioned until a nerve-free pathway is located.

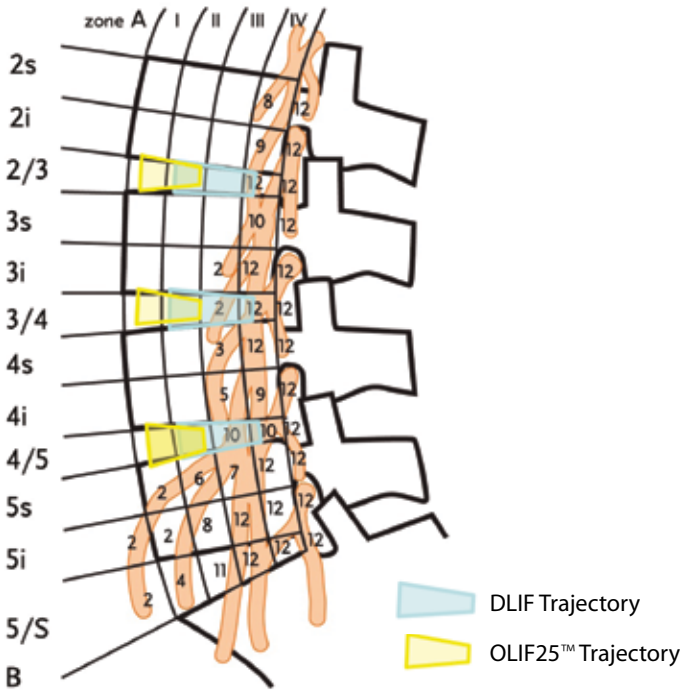


Figure 19

Helpful Tip

*When monitoring with the NIM-ECLIPSE® Spinal System, the surgeon has the additional option of setting the machine to nerve proximity mode. In this mode, the system will send out a cycling current to continuously search for the stimulus threshold required to elicit an EMG response. The displayed current value will decrease as the NIM® X-PAK Probe is moved closer to a nerve. Ensuring threshold values above 8 milliamps is recommended **(Figure 21)**.*

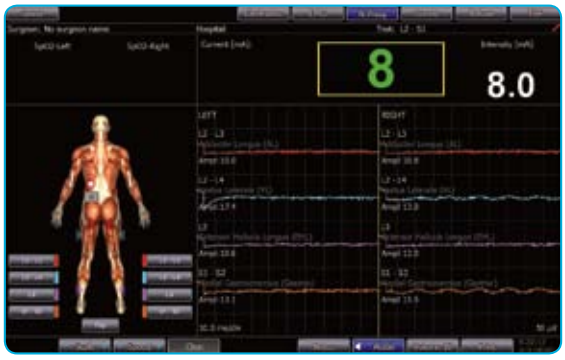


Figure 21

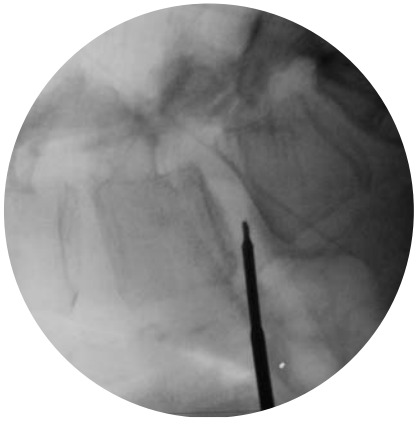


Figure 20

Important

Please see the NIM-ECLIPSE® Spinal System package insert and user's manual for complete instructions and a list of warnings, precautions, and other medical information. The NIM-ECLIPSE® Spinal System is intended for use to record, monitor, and stimulate/record biopotential signals including electromyograph (EMG), evoked response and nerve/muscle potentials, and intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. The system provides feedback to the surgeon and OR team to assist in the localization and assessment of spinal nerves and verification of placement of spinal instrumentation to avoid injury to at-risk nerve roots.

Placement of Initial Probe *continued*

After the probe has safely passed in front of or through the anterior portion of the psoas, the tip of the probe should be passed into the disc space to secure its location. The oblique angle and lordotic angle of the probe as it enters the disc space may be assessed preoperatively and measured intraoperatively using image guidance or using a mechanical or digital protractor.

Fluoroscopy or image guidance (if using the Direct Lateral Dilator) is used to confirm proper probe alignment into the disc space **(Figures 22 and 23)**. If the NIM® X-PAK Probe is used, the blue stimulating handle is then removed, leaving only the insulated cannula within the disc space. A guidewire is then placed through the cannula into the desired disc space and its position confirmed with fluoroscopy.

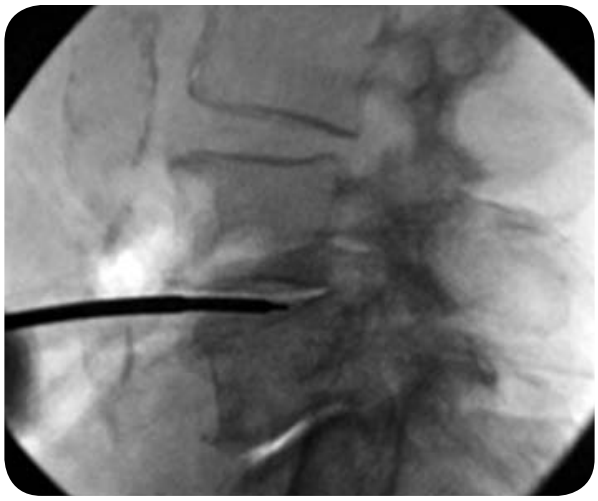


Figure 22

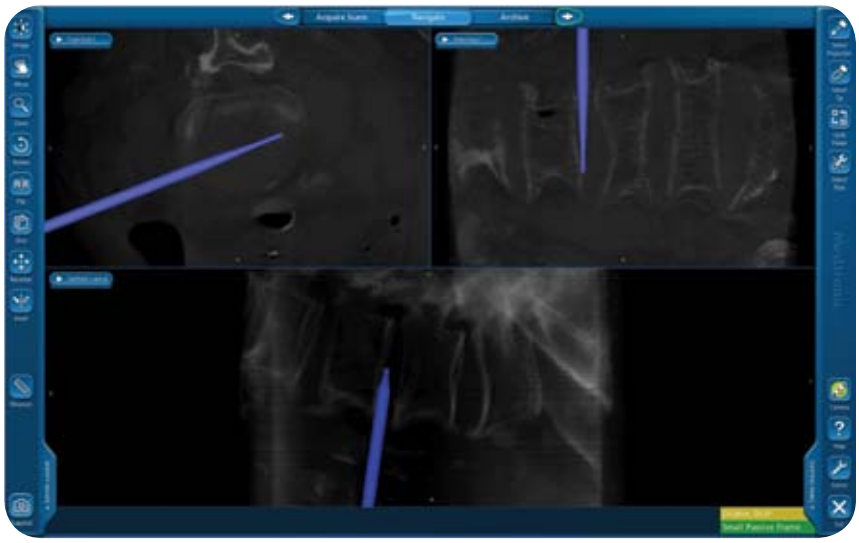


Figure 23

Dilation and Retractor Placement

With the guidewire or first dilator in place and impacted into the annulus for firm fixation, sequential dilation is used to spread the fibers of the abdominal musculature to a diameter of 22mm **(Figure 24)**. If the anterior portion of the psoas muscle is dilated, EMG is active to detect any mechanical and triggered effect to the nerve roots.

Measure the depth from the skin to the disc space using the graduated markings on the dilators and select the appropriate Retractor Blades. Attach the blades to the Lateral Retractor base and place the assembly over the Grooved Dilator **(Figures 25-27)**. The retractor should be advanced employing a back and forth twisting motion with only gentle downward pressure through the fascia and muscle. This technique helps to ensure the fascia and muscle fibers are not pulled down into the surgical corridor.

Helpful Tip

To minimize the amount of residual muscle, employ a back and forth twisting motion with each dilator and use AP fluoroscopy to confirm that each dilator has reached the disc space. The first dilator may be extended slightly into the disc space to ensure complete dilation through the psoas muscle.

Important

The grooves on the largest dilator should be aligned cephalad and caudal and must be aligned with the corresponding retractor Stability Pin channels on the blades. Failure to mate the grooves could cause the blades to splay.

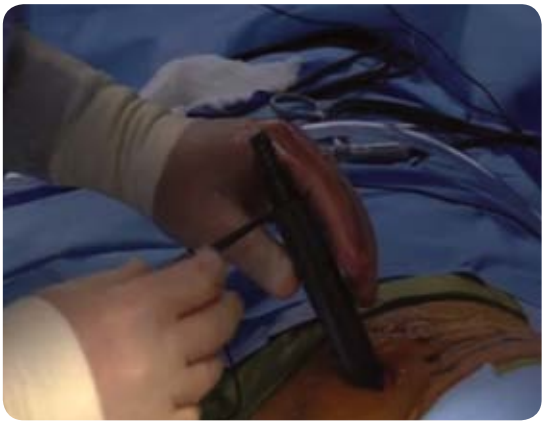


Figure 24

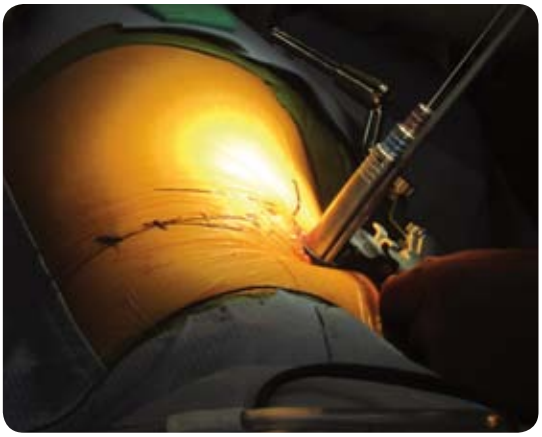


Figure 26

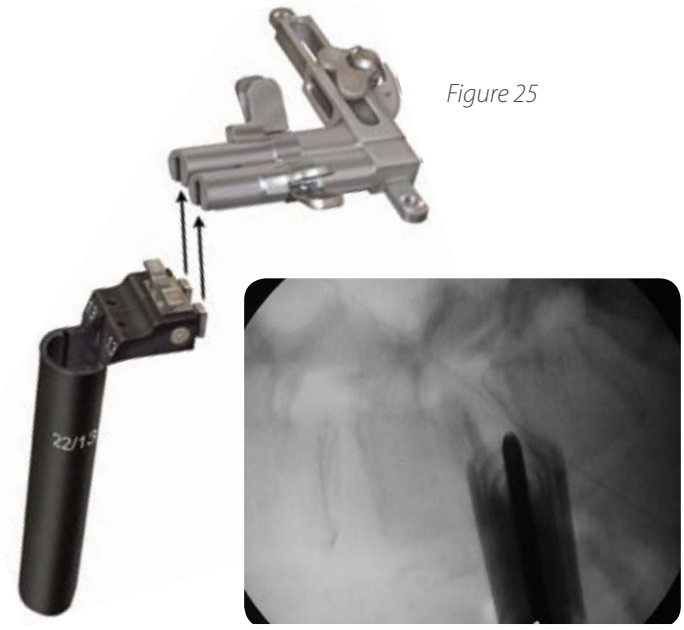


Figure 25

Figure 27

Dilation and Retractor Placement *continued*

The Retractor Assembly is then attached to the Flexible Arm using the Rotating Flex Arm Attachment to provisionally maintain retractor position.

It is important to align the retractor blades so that the opening between them is parallel to the disc space. Utilize the skin markings drawn during localization to orient the Retractor Blades. This will facilitate orthogonal disc preparation and final implant placement.

Use the NIM-SPINE® Ball-tip Probe to test both Stability Pin channels of the Retractor Blades to ensure a nerve-free pathway before placing a pin.

Insert a Stability Pin through one of the Retractor Blades to help prevent retractor migration during the procedure. Use the Stability Pin Driver to thread the pin in the channel of whichever blade is closest to the end plate **(Figure 28)**.

Fluoroscopy is recommended for placement of the Stability Pin to ensure it is not placed too far anteriorly risking injury to vascular structures.

With the Stability Pin in place, the Dilator Tubes are removed, leaving only the Retractor Assembly and Guidewire or first dilator. The Guidewire or first dilator may be left in place as a final reference point to verify position.

A final lateral fluoroscopic image is taken to confirm proper retractor placement over the spine.

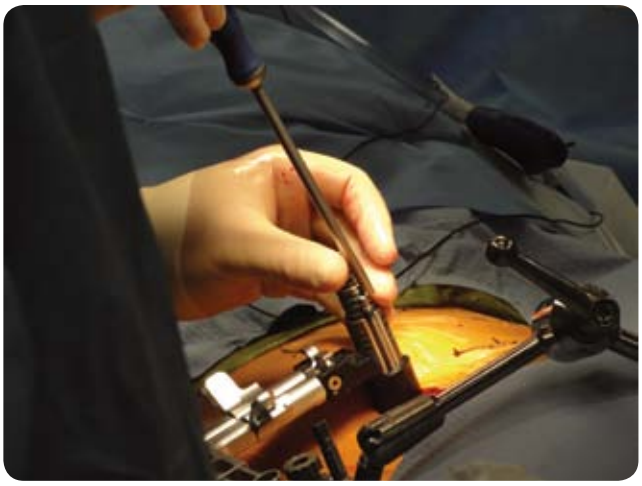


Figure 28

Disc Preparation

The MAST QUADRANT™ Illumination System is attached to the Retractor Blades by placing the metal tips of the light source into the holes on the top of the blades and then sliding the tips under the built-in retaining sleeves.

Typically a thin layer of soft tissue will remain at the base of the Retractor Blades. The NIM-SPINE® Ball-tip Probe is used to stimulate in all four quadrants at the Retractor Base in order to identify any nerve structures that may be present in the residual muscle.

A Penfield 4 is then used to sweep the residual muscle off of the disc space until the annulus is visualized.

The annulus is then incised and an annulotomy at least 18mm in length is created using the Bayoneted Knife **(Figure 29)**. Undercut, beneath the psoas, more annulus as needed with Kerrison rongeur which facilitates implant position and implantation and permits easy rotation of implant into orthogonal position.

A thorough discectomy is then performed using pituitaries and other disc preparation instruments **(Figure 30)**.

A large Cobb is passed along both end plates to the contralateral annulus. A mallet is then used to gently release both the superior and inferior aspects of the contralateral annulus. This step is critical to ensure that appropriate distraction and coronal alignment can be achieved.

A Paddle Style Shaver is placed into the disc space and rotated several times (clockwise and counterclockwise) to clean the end plates **(Figure 31)**. AP fluoroscopy should be used to center the shaver in the disc before turning **(Figure 32)**. The appropriately-sized shavers should be carefully selected to ensure the end plates are not compromised.

Serrated Curettes, Rasps, a Ring Curette, a Uterine Curette and Combo Tools are used to ensure proper end-plate preparation. It is extremely important that the end plates be meticulously prepared for fusion by removing the cartilaginous disc without destroying the cortical end plates.

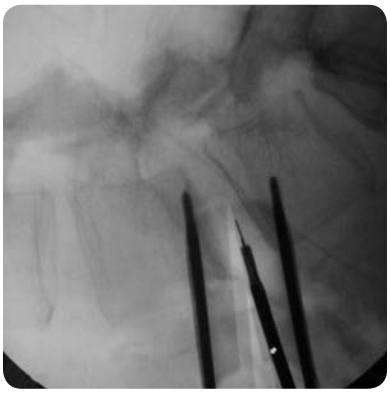


Figure 29

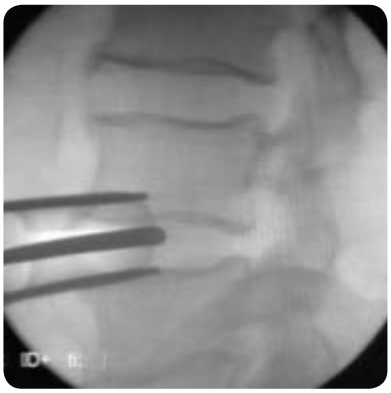


Figure 30

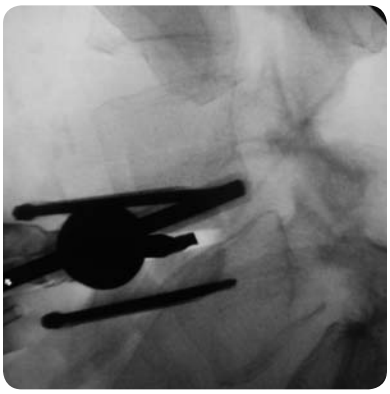


Figure 31

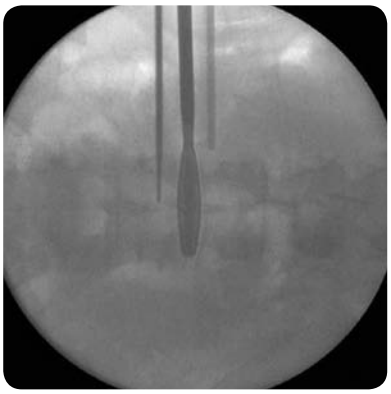


Figure 32

Important

All disc preparation instruments, including the Cobb and Shavers, can enter obliquely through the retractor and then be turned orthogonally to allow the surgeon to work orthogonally across the disc space and release the contralateral annulus. The retractor should be slightly opened to allow for the instruments to turn orthogonally. A mechanical or digital protractor may be used to assess the oblique and lordotic angles of entry into the disc space, but the location of the instruments is confirmed using fluoroscopy.

Trialing

The disc space is sequentially distracted with Trials until adequate disc space height is obtained and adequate foraminal size is restored.

The Trials are passed through the retractors obliquely and then are turned to allow the surgeon to place them orthogonally across the disc space. A mechanical or digital protractor may be used to further assess the oblique and lordotic angles of entry into the disc space, but the location of the trials is confirmed using fluoroscopy or image guidance **(Figures 33 – 35)**.

The Trial is impacted into the disc space. A properly-sized Trial should be centered with the spinous process and should span the entire ring apophysis in order to reach fully across the vertebral body end plate.

Helpful Tip

When using 22mm Trials, it may be necessary to open the Retractor Blades more to allow the passing of the larger Trial.

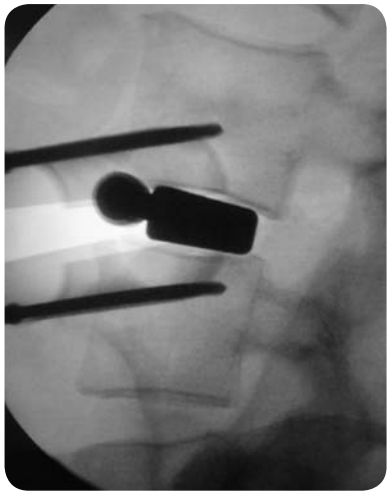


Figure 33

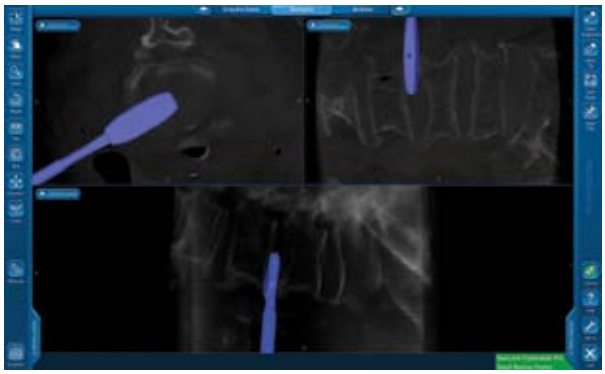


Figure 34

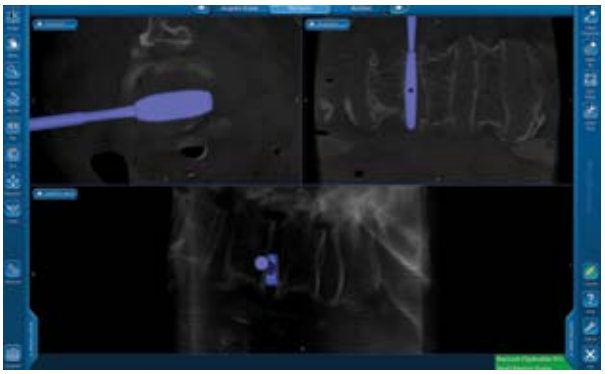


Figure 35

Implant Placement

Once trialing is complete, the corresponding CLYDESDALE® Spinal System implant is attached to the Inserter **(Figure 36)** or the optional DL Inserter. The DL Inserter utilizes sleeves for graft containment. The sleeves must be retracted to attach the implant. If using a lordotic implant, take note of the anterior side of the implant, marked **ANTERIOR**.

Before inserting the CLYDESDALE® Spinal System implant, place autograft in the implant's central cavity.

If using the DL Inserter, slightly extend the sleeves to cover the implant's graft chamber or fully extend the sleeves to cover the entire implant by unthreading the nut from the outer sleeve **(Figures 37 and 38)**.

Figure 36

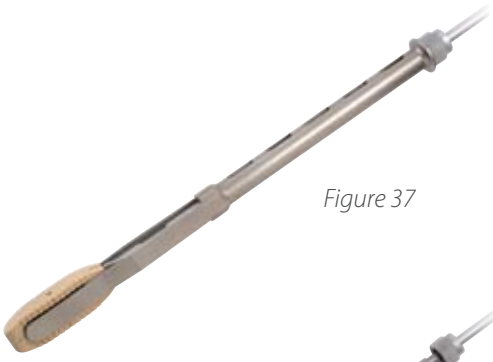


Figure 37

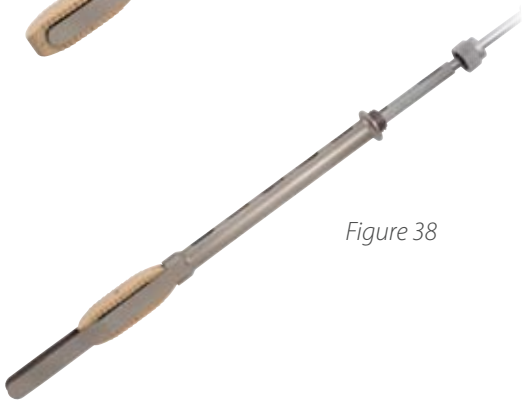


Figure 38

Important

For disassembly/reassembly and cleaning information on the DL Inserter (part number 2942001), refer to the Cleaning section of the CLYDESDALE® Spinal System Important Product Information beginning on page 27 of this surgical technique.

Implant Placement *continued*

A mallet is then used to gently insert the implant while monitoring placement under AP fluoroscopy. The inserter enters obliquely and can then be turned orthogonally to allow the surgeon to place it orthogonally across the disc space. A mechanical or digital protractor may be used to further assess the oblique and lordotic angles of entry into the disc space, but the location of the implant is confirmed using fluoroscopy or image guidance. Near complete rotation and alignment of the implant should be complete by the time approximately 50 – 75% of the implant is inserted into the disc space while fluoroscopy is in lateral position. The implant is easily viewed during this insertion due to the oblique view portal through the retractors. Then, the final positioning of implant should be completed under AP fluoroscopy. Care should be taken to ensure the CLYDESDALE® Spinal System implant is aligned properly.

After the implant is positioned in the center of the disc space from a medial/lateral perspective, the Inserter is unthreaded from the implant and removed **(Figures 39 – 44)**.

Figure 39

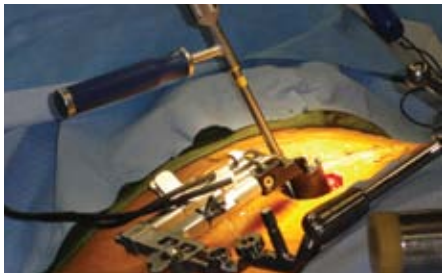


Figure 40

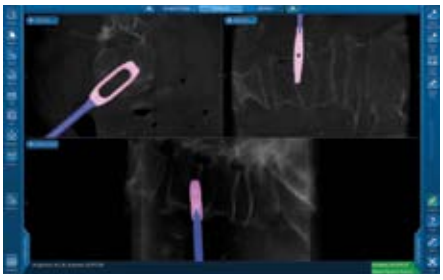


Figure 41

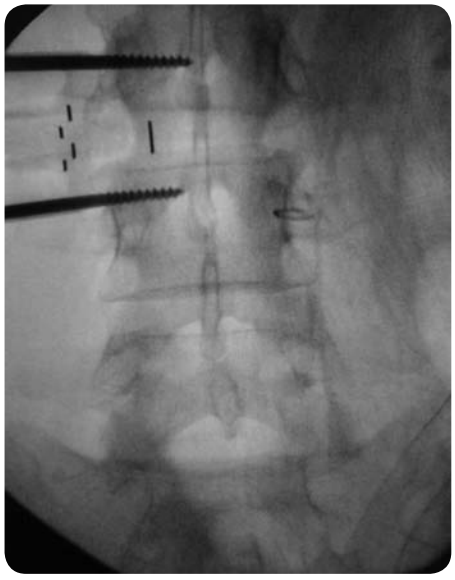


Figure 42

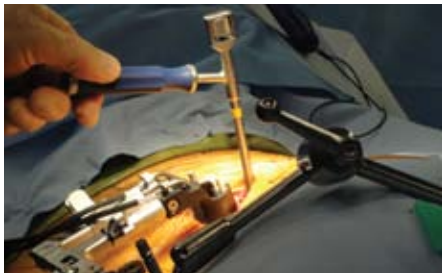


Figure 43

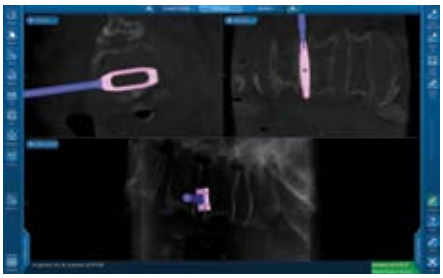
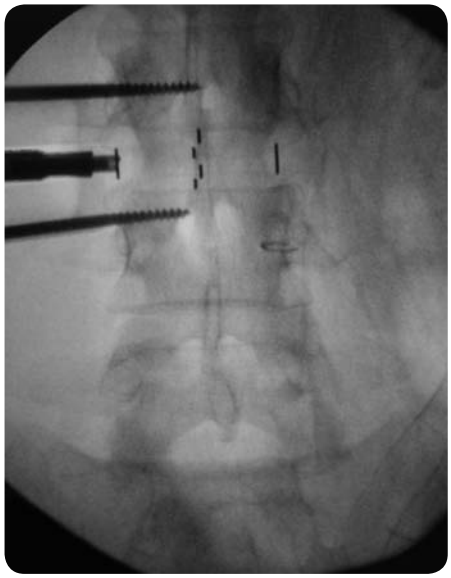


Figure 44



(For navigation use the Navigation Interbody inserter, Part Number 97344556. Instrument not shown in intraoperative photographs.)

Closure

After the autograft material has been inserted into the disc space, the Stability Pin may be unthreaded and removed.

The Retractor is then detached from the Flex Arm and the Retractor Blades are carefully withdrawn from the surgical site. As the Retractor is removed, the muscle and fat layers can be visualized closing back into place.

The surgical site is irrigated appropriately and the fascia over the external oblique is then closed with interrupted synthetic absorbable suture.

Finally, the subcutaneous layers and skin are closed and the skin is sealed with skin adhesive.

Explantation

Should it be necessary to remove or reposition the CLYDESDALE® Spinal System device, the Removal Tool may be used.

To remove the implant, first fit the tips of the Removal Tool with the divots at the end of the implant **(Figure 45)**. Next, depress the trigger to lock onto the implant. Finally, attach the Slap Hammer to the Removal Tool and gently impact the Slap Hammer to facilitate implant removal **(Figure 46)**.

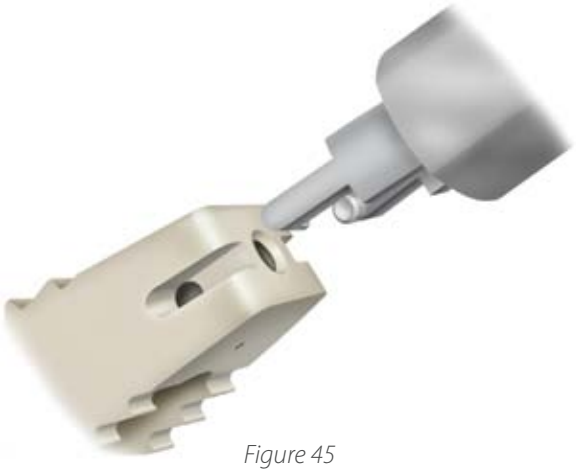


Figure 45

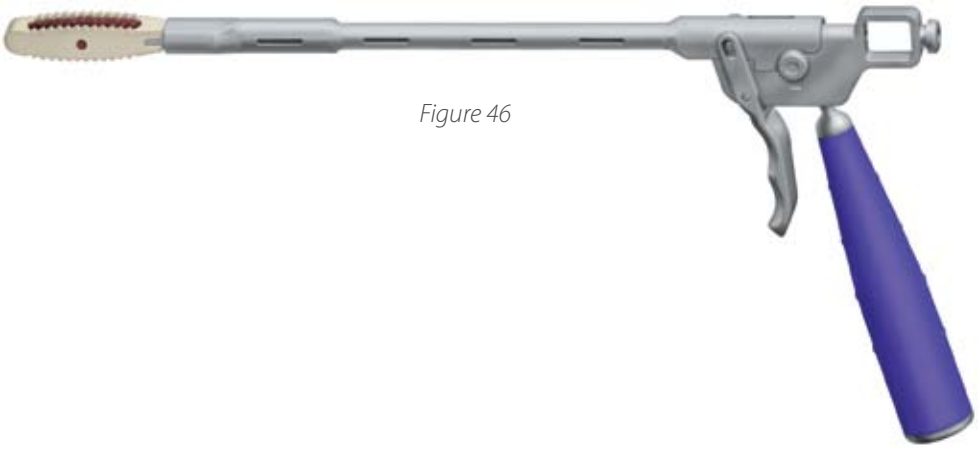
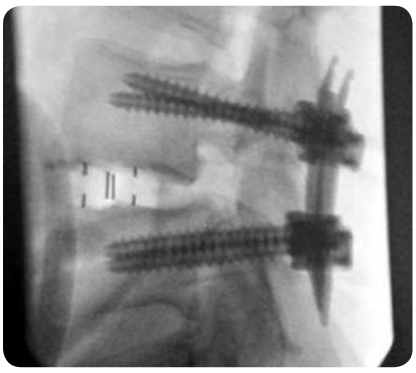


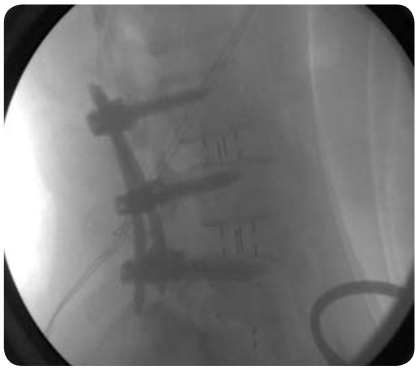
Figure 46

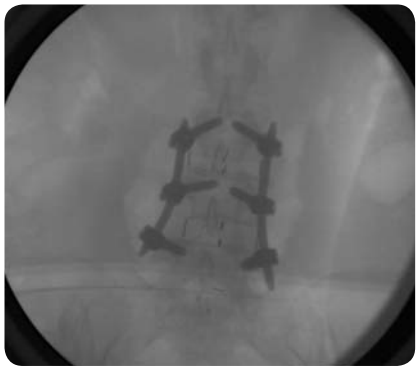
Fixation

Supplemental instrumentation is then placed according to the appropriate surgical technique. The CLYDESDALE® Spinal System can be used with any Medtronic posterior or anterior fixation system.



» CD HORIZON® SEXTANT® II Percutaneous Rod Insertion System





» CD HORIZON® LONGITUDE® Multi-level Percutaneous Fixation System

INDICATIONS FOR THE CD HORIZON® Spinal System

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON® SPIRE™ Plate is a posterior, single level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined); spondylolisthesis; trauma; and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

Warning: The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

Product Ordering Information

INSTRUMENT CASE 1

SPS02028 – Retractor and Kerrison Pituitary Trays

Part Number	Description	Set Quantity
Retractor, Blades, Pins, and Driver		
9569000	Retractor Base	1
9568010	Rotating Flex Arm Attachment	1
9567319	9cm Retractor Blade Internal Pin, Right	1
9567309	9cm Retractor Blade Internal Pin, Left	1
9567310	10cm Retractor Blade Internal Pin, Right	1
9567300	10cm Retractor Blade Internal Pin, Left	1
9567311	11cm Retractor Blade Internal Pin, Right	1
9567301	11cm Retractor Blade Internal Pin, Left	1
9567312	12cm Retractor Blade Internal Pin, Right	1
9567302	12cm Retractor Blade Internal Pin, Left	1
9567313	13cm Retractor Blade Internal Pin, Right	1
9567303	13cm Retractor Blade Internal Pin, Left	1
9567315	15cm Retractor Blade Internal Pin, Right	1
9567305	15cm Retractor Blade Internal Pin, Left	1
9569309	9cm Blade Pin	2
9569310	10cm Blade Pin	2
9569311	11cm Blade Pin	2
9569312	12cm Blade Pin	2
9569313	13cm Blade Pin	2
9569315	15cm Blade Pin	2
8970400	Stability Pin Driver	1
Dilators		
9560420	5.3mm Dilator	1
9561421	10.6mm Dilator	1
9561422	16.0mm Dilator	1
9561424	20.8mm Grooved Dilator	1
Guidewires		
8670002	Guidewire Sharp (long)	2
8670005	Guidewire – Trocar Tip 1.6mm, 350mm (short)	2
Kerrisons and Pituitaries		
2940068	3mm Rotate Kerrison Punch	1
2940069	5mm Rotate Kerrison Punch	1
2940075	Pituitary Rongeur, 4mm × 10mm Straight	1
2940076	Pituitary Rongeur, 4mm × 10mm Up	1

INSTRUMENT CASE 2

SPS02027 – CLYDESDALE® Trial and Inserter Removal Trays

Part Number	Description	Set Quantity
Trials		
2986845	8mm × 45mm DL Trial	1
2986850	8mm × 50mm DL Trial	1
2986855	8mm × 55mm DL Trial	1
2986045	10mm × 45mm DL Trial	1
2986050	10mm × 50mm DL Trial	1
2986055	10mm × 55mm DL Trial	1
2986245	12mm × 45mm DL Trial	1
2986250	12mm × 50mm DL Trial	1
2986255	12mm × 55mm DL Trial	1
2986445	14mm × 45mm DL Trial	1
2986450	14mm × 50mm DL Trial	1
2986455	14mm × 55mm DL Trial	1
2986645	16mm × 45mm DL Trial	1
2986650	16mm × 50mm DL Trial	1
2986655	16mm × 55mm DL Trial	1
Instruments		
9074002	Slap Hammer	1
2982002	DL Removal Tool	1
2982001	Threaded Inserter	1

DISPOSABLE CASES

SPS00589 – Disposables

Part Number	Description	Set Quantity
NIM-SPINE® Probes, Dilator, Light Source, and Knife		
9450015	NIM-SPINE® 23cm Ball-tip Probe	1
9450069	NIM® X-PAK Probe	1
9560658	MAST QUADRANT® Illumination System	1
9450070	5.3mm Dilator (Plastic)	1
9560659	Bayoneted Discectomy Knife	1

INSTRUMENT CASE 3

SPS00586 – Flex Arm Tray

Part Number	Description	Set Quantity
Flex Arm and Attachment		
9561523	Bed Rail Clamp	1
9561524	Flexible Arm	1

Product Ordering Information *continued*

INSTRUMENT CASE 4

SPS02029 – Instrument Trays 1 and 2

Part Number	Description	Set Quantity
Disc Preparation Instruments Tray 1		
2940050	Combo Tool	1
2940051	Angled Combo Tool	1
2940052	Reverse Angle Combo Tool	1
2940053	Straight Serrated Cup Curette	1
2940054	Angled Serrated Cup Curette	1
2940055	Reverse Angle Serrated Cup Curette	1
2940056	Straight Ring Curette	1
2940057	10mm Cobb Elevator	1
2940059	18mm Cobb Elevator	1
Disc Preparation Instruments Tray 2		
2940186	6/8mm Distractor	1
9561554	Wide Nerve Root Retractor, Long	1
9569650	Bayoneted Penfield 4 Push/Pull, Long	1
2940200	Long Suction	2
2900165	Cannulated Reamer T-Handle	2
2941608	8mm Shaver, 45mm length	1
2941610	10mm Shaver, 45mm length	1
2941612	12mm Shaver, 45mm length	1
2941614	14mm Shaver, 45mm length	1
2941616	16mm Shaver, 45mm length	1

DL SUPPORT SET - DISC PREPARATION INSTRUMENTS

SPS02408 - Disc Preparation Tray 1

Part Number	Description	Set Quantity
2942001	DL Inserter	1
2942049	DL Slap Hammer	1
2942037	10mm Endplate Protector	2
2942058	18mm Endplate Protector	2
2942026	8mm Rotate Distractor	1
2942028	10mm Rotate Distractor	1
2942030	12mm Rotate Distractor	1
2942032	14mm Rotate Distractor	1
2942020	Osteotome	1
2942017	Dilator Holder	1
74-619-106	6mm Pituitary Rongeur	1

DL SUPPORT SET - DISC PREPARATION INSTRUMENTS

SPS02408 - Disc Preparation Tray 2

Part Number	Description	Set Quantity
2942035	10mm Straight Cobb	1
2942036	18mm Straight Cobb	1
2942014	5.5mm 90 degree Push Curette	1
2942015	5.5mm 45 degree Pull Curette	1
2942016	5.5mm 90 degree Pull Curette	1
2942012	Uterine Curette	1
2942018	Flat Rasp	1
2942019	Curved Rasp	1
2942023	14mm Wedge Distractor	1
2942024	18mm Wedge Distractor	1

DL SUPPORT SET - ACCESS INSTRUMENTS

SPS02409 - Access Instrument Tray 1

Part Number	Description	Set Quantity
9569324	14mm Stability Pin	2
9569326	16mm Stability Pin	2
9569327	17mm Stability Pin	2
9567314	DL Blade Right 14cm	1
9567304	DL Blade Left 14cm	1
9567316	DL Blade Right 16cm	1
9567306	DL Blade Left 16cm	1
9567317	DL Blade Right 17cm	1
9567307	DL Blade Left 17cm	1
2942022	Access Handle Left	1
2942050	Access Handle Right	1
2942011	Retractor Opener	2

DL SUPPORT SET - ACCESS INSTRUMENTS

SPS02409 - Access Instrument Tray 2

Part Number	Description	Set Quantity
9568008	Medial Lateral Rack Assembly	1
2942002	9cm Anterior/Posterior Blade	2
2942003	10cm Anterior/Posterior Blade	2
2942004	11cm Anterior/Posterior Blade	2
2942005	12cm Anterior/Posterior Blade	2
2942006	13cm Anterior/Posterior Blade	2
2942007	14cm Anterior/Posterior Blade	2
2942008	15cm Anterior/Posterior Blade	2
2942009	16cm Anterior/Posterior Blade	2
2942010	17cm Anterior/Posterior Blade	2

Product Ordering Information *continued*

CLYDESDALE® 22mm DL Trials
SPS02418

Part Number	Description
6° CLYDESDALE® 22mm Trial Set	
2988845	8mm × 45mm
2988850	8mm × 50mm
2988855	8mm × 55mm
2988045	10mm × 45mm
2988050	10mm × 50mm
2988055	10mm × 55mm
2988245	12mm × 45mm
2988250	12mm × 50mm
2988255	12mm × 55mm
2988445	14mm × 45mm
2988450	14mm × 50mm
2988455	14mm × 55mm
2988645	16mm × 45mm
2988650	16mm × 50mm
2988655	16mm × 55mm

CLYDESDALE® 22mm DL Trials
SPS02419

Part Number	Description
12° CLYDESDALE® 22mm Trial Set	
2989045	10mm × 45mm
2989050	10mm × 50mm
2989055	10mm × 55mm
2989245	12mm × 45mm
2989250	12mm × 50mm
2989255	12mm × 55mm
2989445	14mm × 45mm
2989450	14mm × 50mm
2989455	14mm × 55mm
2989645	16mm × 45mm
2989650	16mm × 50mm
2989655	16mm × 55mm

Product Ordering Information *continued*

CLYDESDALE® SPINAL SYSTEM IMPLANTS

Part Number	Description
6° CLYDESDALE® Spinal System SPS02156	
2968840	8mm × 40mm
2968845	8mm × 45mm
2968850	8mm × 50mm
2968855	8mm × 55mm
2968860	8mm × 60mm
2968040	10mm × 40mm
2968045	10mm × 45mm
2968050	10mm × 50mm
2968055	10mm × 55mm
2968060	10mm × 60mm
2968240	12mm × 40mm
2968245	12mm × 45mm
2968250	12mm × 50mm
2968255	12mm × 55mm
2968260	12mm × 60mm
2968440	14mm × 40mm
2968445	14mm × 45mm
2968450	14mm × 50mm
2968455	14mm × 55mm
2968460	14mm × 60mm
2968640	16mm × 40mm
2968645	16mm × 45mm
2968650	16mm × 50mm
2968655	16mm × 55mm
2968660	16mm × 60mm

CLYDESDALE® SPINAL SYSTEM IMPLANTS

Part Number	Description
0° CLYDESDALE® Spinal System SPS02157	
2969840	8mm × 40mm
2969845	8mm × 45mm
2969850	8mm × 50mm
2969855	8mm × 55mm
2969040	10mm × 40mm
2969045	10mm × 45mm
2969050	10mm × 50mm
2969055	10mm × 55mm
2969240	12mm × 40mm
2969245	12mm × 45mm
2969250	12mm × 50mm
2969255	12mm × 55mm
2969440	14mm × 40mm
2969445	14mm × 45mm
2969450	14mm × 50mm
2969455	14mm × 55mm
2969640	16mm × 40mm
2969645	16mm × 45mm
2969650	16mm × 50mm
2969655	16mm × 55mm

Product Ordering Information *continued*

CLYDESDALE® SPINAL SYSTEM IMPLANTS

Part Number	Description
6° CLYDESDALE® 22mm Spinal System SPS02416	
2926840	8mm × 40mm
2926845	8mm × 45mm
2926850	8mm × 50mm
2926855	8mm × 55mm
2926860	8mm × 60mm
2926040	10mm × 40mm
2926045	10mm × 45mm
2926050	10mm × 50mm
2926055	10mm × 55mm
2926060	10mm × 60mm
2926240	12mm × 40mm
2926245	12mm × 45mm
2926250	12mm × 50mm
2926255	12mm × 55mm
2926260	12mm × 60mm
2926440	14mm × 40mm
2926445	14mm × 45mm
2926450	14mm × 50mm
2926455	14mm × 55mm
2926460	14mm × 60mm
2926640	16mm × 40mm
2926645	16mm × 45mm
2926650	16mm × 50mm
2926655	16mm × 55mm
2926660	16mm × 60mm

CLYDESDALE® SPINAL SYSTEM IMPLANTS

Part Number	Description
12° CLYDESDALE® 22mm Spinal System SPS02417	
2922040	10mm × 40mm
2922045	10mm × 45mm
2922050	10mm × 50mm
2922055	10mm × 55mm
2922060	10mm × 60mm
2922240	12mm × 40mm
2922245	12mm × 45mm
2922250	12mm × 50mm
2922255	12mm × 55mm
2922260	12mm × 60mm
2922440	14mm × 40mm
2922445	14mm × 45mm
2922450	14mm × 50mm
2922455	14mm × 55mm
2922460	14mm × 60mm
2922640	16mm × 40mm
2922645	16mm × 45mm
2922650	16mm × 50mm
2922655	16mm × 55mm
2922660	16mm × 60mm

Important Product Information

IMPORTANT INFORMATION ON CLYDESDALE® SPINAL SYSTEM

PURPOSE

This device is a PEEK (POLYETHERETHERKETONE) interbody fusion device intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

DESCRIPTION

The CLYDESDALE® Spinal System consists of PEEK cages of various widths and heights, which include Tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog or price list for further information about warranties and limitations of liability.

INDICATIONS

The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. **These implants may be implanted via a minimally invasive lateral approach.**

CONTRAINDICATIONS

This device is not intended for cervical spine use.

Contraindications include, but are not limited to:

- Infection, local to the operative site
- Signs of local inflammation,
- Fever or leukocytosis,
- Morbid obesity,
- Pregnancy,
- Mental illness,
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials,
- Any case not needing a fusion,
- Any case not described in the indications,
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem.
- Pediatric cases or where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- **Severe bone resorption.**
- **Osteomalacia**
- **Severe osteoporosis.**

POTENTIAL ADVERSE EVENTS

Adverse effects may occur when the device is used either with or without associated instrumentation.

The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

- Implant migration.
- Breakage of the device(s).
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis).
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury.
- Cerebral spinal fluid leakage.
- Haemorrhage of blood vessels and/or hematomas.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening or movement of the device(s).
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or pene¬tration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or be¬low the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise, including sterility, loss of con¬sortium, and sexual dysfunction.
- Development of respira¬tory problems, e.g. pul¬monary embolism, atelectasis, bron¬chitis, pneumonia, etc.
- Change in mental status.
- Cessation of any poten¬tial growth of the operated por¬tion of the spine.
- Death.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and / or alcohol / drug abuse patients and those with poor muscle and bone quality and / or nerve paralysis are also poor candidates for spinal fusion.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

A device that has been implanted should never be reused, reprocessed or resterilized under any circumstances. Sterile packaged devices should also never be resterilized. Reuse, reprocessing, or resterilization may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

!USA FOR US AUDIENCES ONLY

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

MRI INFORMATION

The CLYDESDALE® Spinal System has not been evaluated for safety,,compatibility, heating, or migration in the MR environment.

IMPLANT SELECTION

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the human anatomy. Unless great care is taken in patient selection, placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage or loosening of the device before the fusion process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by MEDTRONIC. In the interests of patient safety, it is therefore recommended that MEDTRONIC implants are not used with devices from any other source.

Never, under any circumstances, reuse a CLYDESDALE® Spinal System device. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and / or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be taken in the handling and storage of the device(s). They should not be scratched or damaged. Devices should be protected during storage especially from corrosive environments.
- Further information about this system will be provided upon request.
- The surgeon should be familiar with the various devices before use and should personally verify that all devices are present before the surgery begins.
- The size of device for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

Important Product Information *continued*

- Unless supplied sterile, all devices should be cleaned and sterilized before use. Additional sterile components should be available in case of any unexpected need.

INTRAOPERATIVE

- The instructions in any available CLYDESDALE® Spinal System surgical technique manual should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
- To assure proper fusion below and around the location of the fusion, autogenous bone graft must be used.
- Bone cement should not be used, because this material may make removal of these components difficult or impossible. The heat generated from the curing process may damage or deform the PEEK devices.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, and / or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity, or sudden jolts or shock to the spine.
- The patient should be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
- The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and / or break, the devices should be revised and / or removed immediately before serious injury occurs.
- CLYDESDALE® Spinal System implants are interbody devices and are intended to stabilize the operative area during the fusion process.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING

Devices may be supplied in a sterile or non-sterile form. Packages for each of the components should be intact upon receipt. Once the seal on the sterile package has been broken, the product should not be re-sterilized. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components, including instruments, should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to MEDTRONIC.

CLEANING

Disassembly/reassembly and cleaning instructions can be found at http://manuals.medtronic.com/. Refer to the "Reprocessing Instructions for the Direct Lateral (DL) Inserter– M708348B087" for disassembly and cleaning instructions specific to the DL Inserter instrument (part number 2942001). Refer to the "Reprocessing Instructions for the General Instruments" 0380035 for cleaning instructions for CLYDESDALE® Spinal System trials.

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

Table 1: Sterilization Cycle Parameters for the United States and Its Territories below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	MINIMUM DRY TIME[1]
Steam	Gravity Displacement	250°F (121°C)	30 Minutes	30 Minutes
Steam	Gravity Displacement	270°F (132°C)	15 Minutes	30 Minutes
Steam	Gravity Displacement	275°F (135°C)	10 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	270°F (132°C)	4 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	275°F (135°C)	3 Minutes	16 Minutes

For Medical Facilities Located Outside the United States and Its Territories: Some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

Table 2: Sterilization Cycle Parameters for Medical Facilities Outside the United States and Its Territories

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	MINIMUM DRY TIME[1]
Steam	Gravity Displacement	273°F (134°C)	20 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	273°F (134°C)	4 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	273°F (134°C)	20 Minutes	30 Minutes

1 The minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer's recommendations.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, exposure times) used for their equipment.

The sterilization cycles listed in Table 2 above are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Sterilization instructions can be found at http://manuals.medtronic.com/. Refer to the "Reprocessing Instructions for the Direct Lateral (DL) Inserter– M708348B087" for the sterilization instructions specific to the DL Inserter instrument (part number 2942001). Refer to the "Reprocessing Instructions for the General Instruments" 0380035 for sterilization instructions for CLYDESDALE® Spinal System trials.

SERVICING

Inspect all instruments prior to use. Please return the instrument to Medtronic if any of the following are observed: corrosion, discoloring, pitting, or any other signs of wear.

Inspect the threaded shaft of the inserter instrument. Please return the instrument to Medtronic if threads are damaged or distorted or if the shaft appears bent.

Inspect the silicone handle of the inserter instrument. Please return the instrument to Medtronic if the silicone handle is discolored, cut, or damaged in any way.

PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC. Further, if any of the implanted spinal system component(s) ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax, or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact MEDTRONIC.

EC REP

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: + 31 45 566 80 00

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone 800 933 2635 (In U.S.A.)
901 396 3133 (Outside of U.S.A.)
Fax 901 396 0356

EXPLANATION OF SYMBOLS

Symbol	Definition
Rx only	CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician
	Consult Instructions for Use
	Do Not Reuse.
	Use by
LOT	Batch Code
REF	Catalogue Number
NON STERILE	Non-sterile
!USA	For U.S. audiences only.
	Manufacturer
CE 0123	The device complies with European Directive MDD 93/42/EEC
CE	The device complies with European Directive MDD 93/42/EEC
EC REP	Authorised Representative in the European Community
STERILE R	Sterilized using irradiation

www.medtronic.com

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

For more information visit
www.myspinetools.com

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

APPENDIX F

US006626905B1

(12) **United States Patent**
Schmiel et al.

(10) **Patent No.: US 6,626,905 B1**
(45) **Date of Patent: Sep. 30, 2003**

(54) **POSTERIOR OBLIQUE LUMBAR ARTHRODESIS**

(75) Inventors: **Daniel G. Schmiel**, Edina, MN (US); **Rodney L. Houfburg**, Prior Lake, MN (US); **Daniel D. McPhillips**, Ham Lake, MN (US); **William C. Welch**, Sewickley Heights, PA (US)

(73) Assignees: **Sulzer Spine-Tech Inc.**, Minneapolis, MN (US); **University of Pittsburgh of the Commonwealth System of Higher Education**, Pittsburg, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 74 days.

(21) Appl. No.: **09/630,793**

(22) Filed: **Aug. 2, 2000**

(51) **Int. Cl.**[7] **A61B 17/56**
(52) **U.S. Cl.** **606/61**; 623/17.11
(58) **Field of Search** 606/60, 61; 623/17.11, 623/17.12, 17.13, 17.14, 17.15, 17.16

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,848,601	A	11/1974	Ma et al.
4,501,269	A	2/1985	Bagby
4,653,481	A	3/1987	Howland et al.
4,743,256	A	5/1988	Brantigan
4,805,602	A	2/1989	Puno et al.
4,834,757	A	5/1989	Brantigan
4,877,020	A	10/1989	Vich
4,961,740	A	10/1990	Ray et al.
5,000,165	A	3/1991	Watanabe
5,015,247	A	5/1991	Michelson
5,015,255	A	5/1991	Kuslich
5,026,373	A	6/1991	Ray et al.
5,055,104	A	10/1991	Ray
5,306,275	A	4/1994	Bryan
5,357,983	A	10/1994	Mathews
5,458,638	A	10/1995	Kuslich et al.
5,484,437	A	1/1996	Michelson
5,489,307	A	2/1996	Kuslich et al.
5,489,308	A	2/1996	Kuslich et al.
5,505,732	A	4/1996	Michelson
5,534,031	A	7/1996	Matsuzaki et al.
5,549,608	A	8/1996	Errico et al.
5,554,157	A	9/1996	Errico et al.
5,584,831	A	12/1996	McKay
5,586,984	A	12/1996	Errico et al.
5,609,636	A	3/1997	Kohrs et al.
5,645,598	A	7/1997	Brosnahan, III
5,658,337	A	8/1997	Kohrs et al.
5,722,977	A	3/1998	Wilhelmy

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

EP	0 307 241 A2	3/1989
WO	WO 98/48738	11/1998
WO	WO 99/59481	11/1999
WO	WO 01/28437 A3	4/2001
WO	WO 01/62166 A2	8/2001

OTHER PUBLICATIONS

Brochure "Posterior 4022 Paddle Tube Surgical Technique, BAK™ Lumbar Interbody Fusion System", *Sulzer Medica Sulzer Spine-Tech*, 25 pgs., (1998).

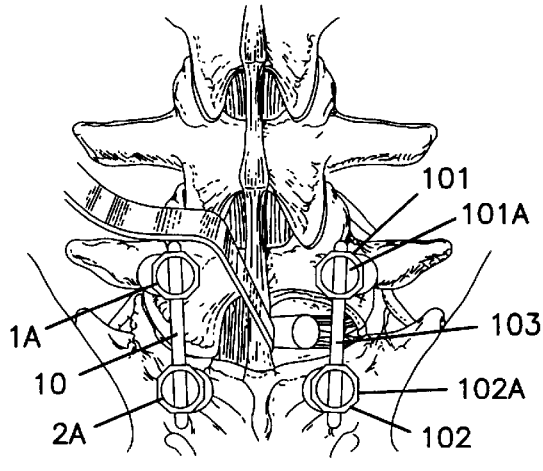
(List continued on next page.)

Primary Examiner—Ralph A. Lewis
(74) *Attorney, Agent, or Firm*—Merchant & Gould P.C.

(57) **ABSTRACT**

Instruments and methods for spinal stabilization are disclosed. In preferred embodiments, the invention provides greater stabilization of vertebral bodies through methods including combinations of bilateral external fixation systems and intervertebral implants to provide greater fusion stability, greater motion segment stability, faster fusion, reduced pain, reduced chance of migration, reduced chance of subsidence, etc.

15 Claims, 6 Drawing Sheets



U.S. PATENT DOCUMENTS

5,741,253	A	4/1998	Michelson	
5,749,916	A	5/1998	Richelsoph	
5,772,661	A	6/1998	Michelson	
5,776,196	A	7/1998	Matsuzaki et al.	
5,797,909	A	8/1998	Michelson	
5,800,550	A	9/1998	Sertich	623/17
5,860,973	A	1/1999	Michelson	
5,863,293	A	1/1999	Richelsoph	
5,865,847	A	2/1999	Kohrs et al.	
5,928,242	A	7/1999	Kuslich et al.	
5,947,971	A	9/1999	Kuslich et al.	
5,964,760	A	10/1999	Richelsoph	
5,984,922	A	11/1999	McKay	
6,010,503	A	1/2000	Richelsoph et al.	

OTHER PUBLICATIONS

Brochure "Posterior 4022 Tooth Tube Surgical Technique, BAK™ Lumbar Interbody Fusion System", *Sulzer Medica Sulzer Spine–Tech*, 26 pgs., (1998).

Brochure "Spine Care Sulzer Spine–Tech Surgical Technique For Posterior Lumbar Fixation, Silhouette", *Sulzer Medica Sulzer Spine–Tech*, 23 pages (1999).

Declaration of Daniel G. Schmiel and Brochure "Spine Care Sulzer Spine–Tech, POLAr™ Instrumentation Surgical Technique", *Sulzer Medica Sulzer Spine–Tech*, 9 pgs. (2000).

Brantigan et al., "Posterior Lumbar Interbody Fusion Technique Using The Variable Screw Placement Spinal Fixation System", *State of the Art Reviews*, vol. 6, No. 1, pp. 175–200 (Jan. 1992).

Cheng, B. et al., "Biomechanical Evaluation Of Transforaminal Oblique Cage Stability", *North American Spine Society Proceedings, 14th Annual Meeting*, 3 pgs. (Oct. 1999).

Harmes, J. et al., "Instrumented Spinal Surgery, Principles and Techniques", *Thieme*, pp. 136–139 (Date Unknown).

Patel, A. et al., "Posterior Lumbar Interbody Fusion With Metal Cages: Current Techniques", *Operative Techniques In Orthopaedics*, Vol 10, No. 4, pp. 311–319 (Oct., 2000).

Zhao, J. et al., "Posterior Lumbar Interbody Fusion Using Posterolateral Placement Of A Single Cylindrical Threaded Cage", *SPINE*, vol. 25, No. 4, pp. 425–430 (Feb. 2000).

Puno, R. et al., "The Puno–Winter–Byrd (PWB) Spinal System for Transpedicular Fixation of the Lumber Spine" pp. 281–296 (Mar. 18, 1997).

FIG. 1

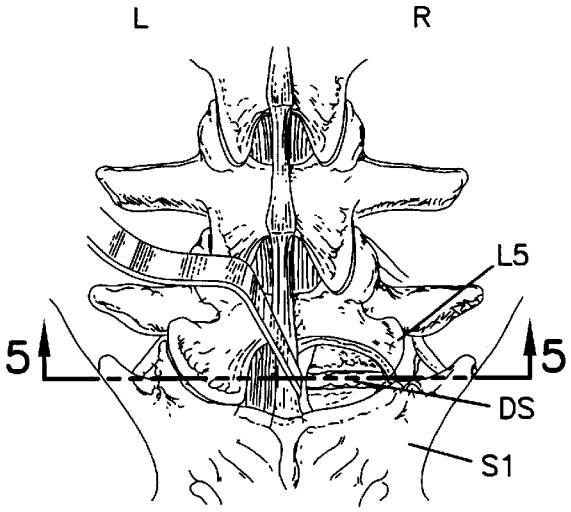


FIG. 2

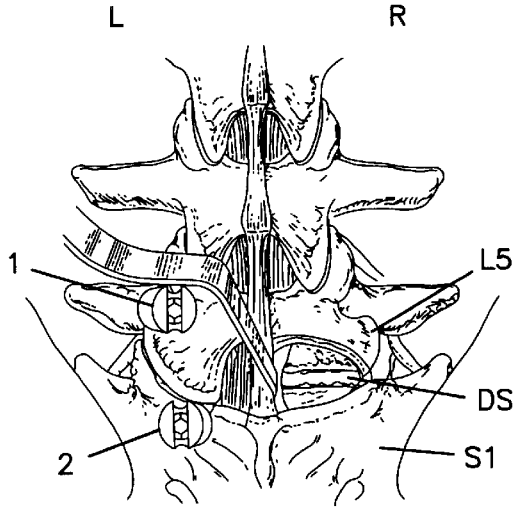


FIG. 3

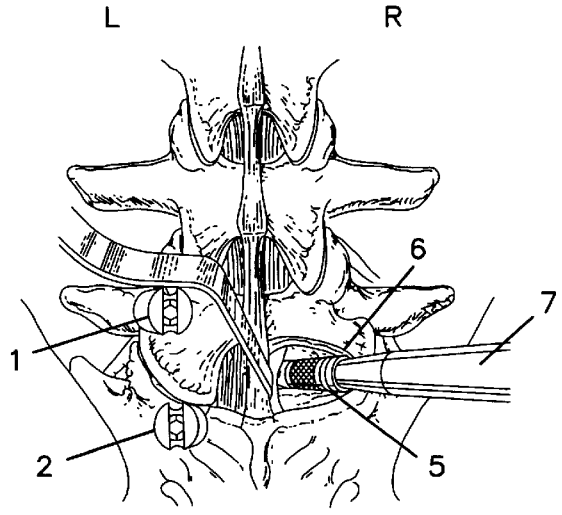


FIG. 4

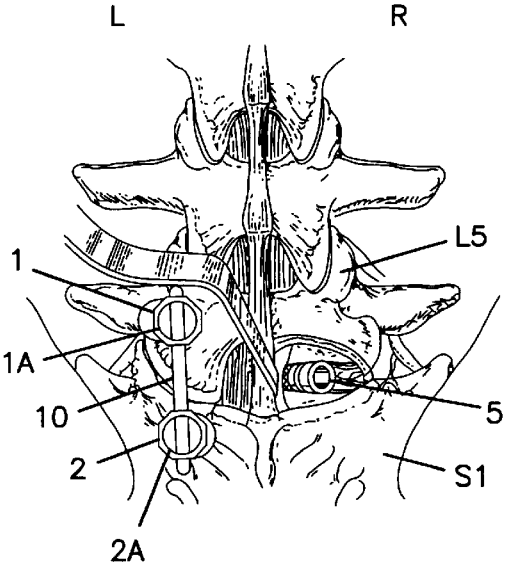


FIG. 5

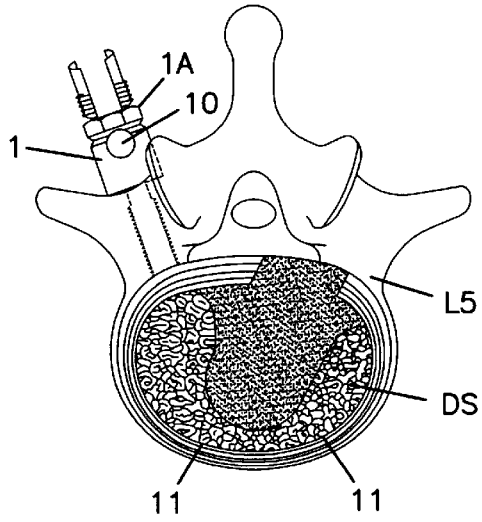


FIG. 6

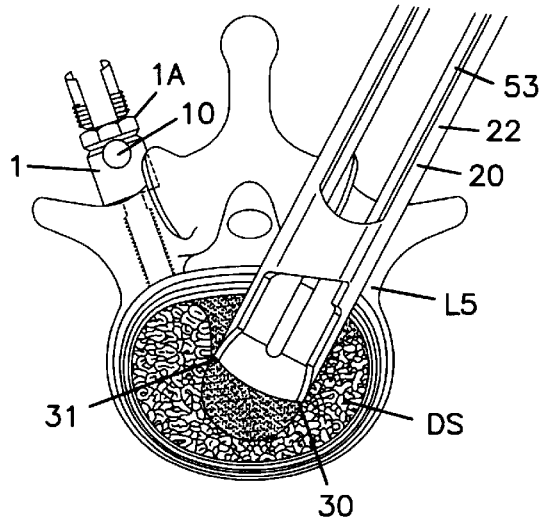


FIG. 7

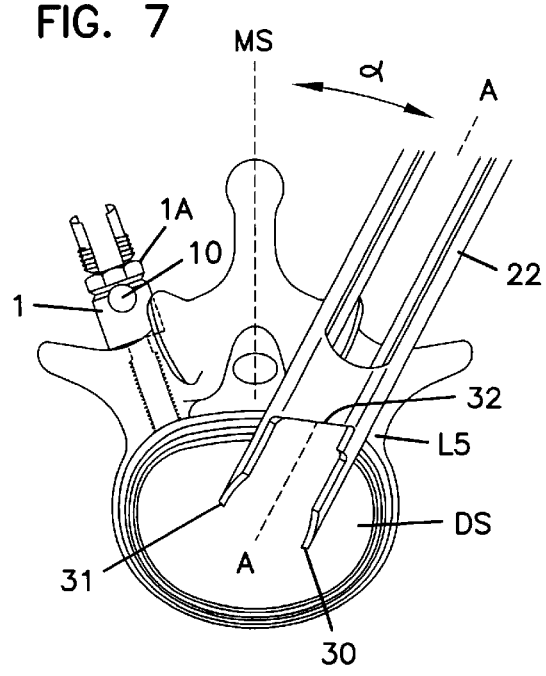


FIG. 8

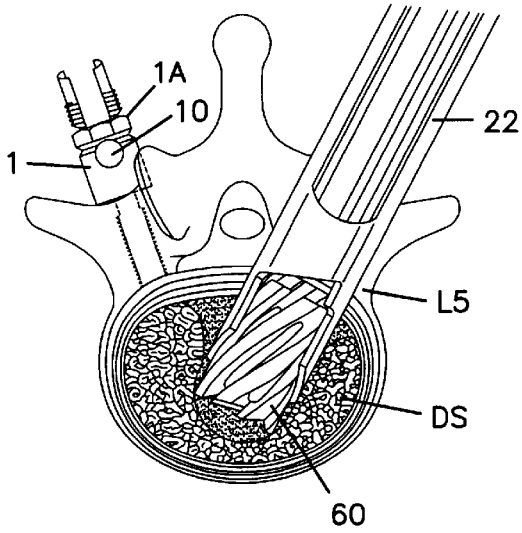


FIG. 9

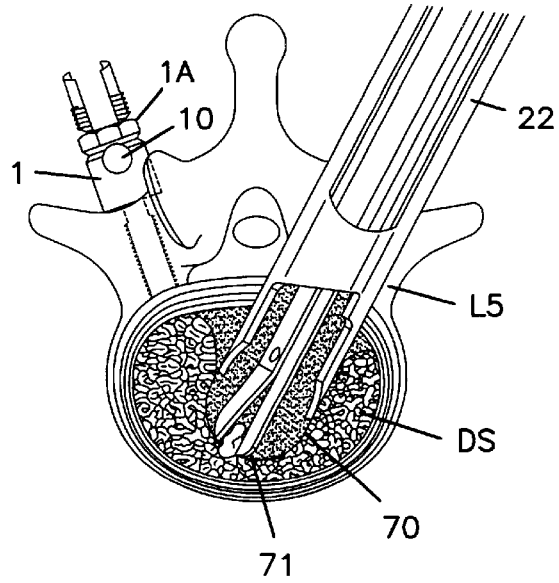


FIG. 10

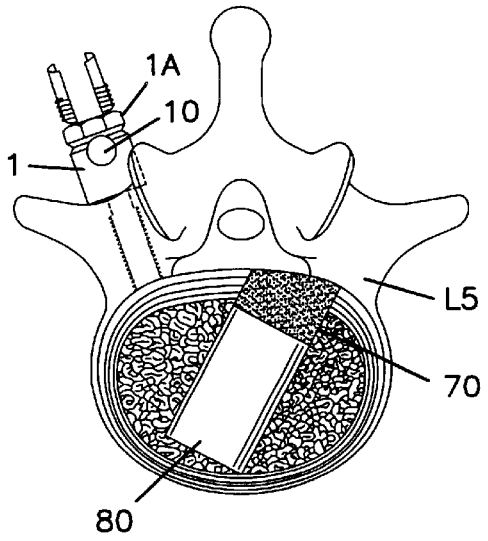


FIG. 11

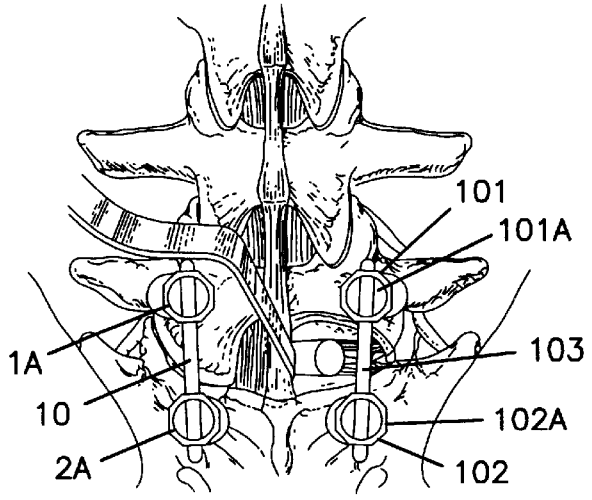


FIG. 12

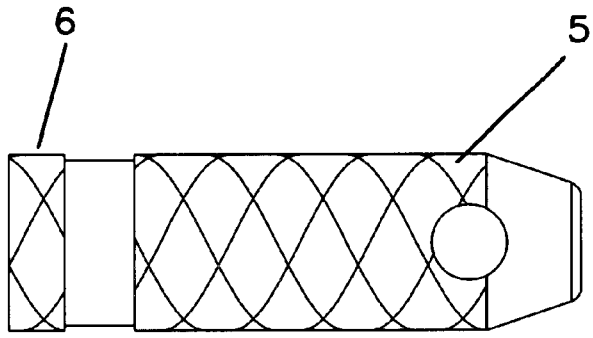
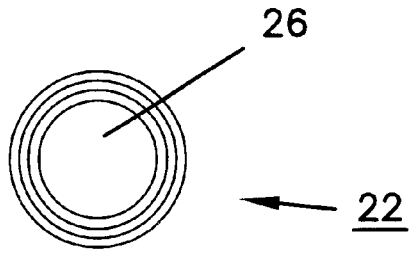


FIG. 15



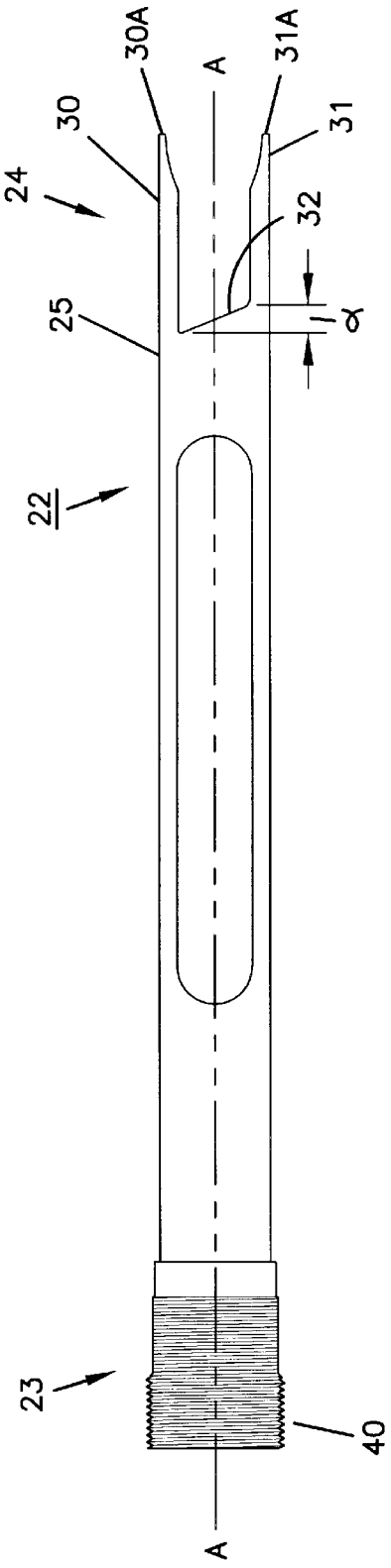

30A
A
31A
30
31
24
32
25
α
22
23
40
A

FIG. 13

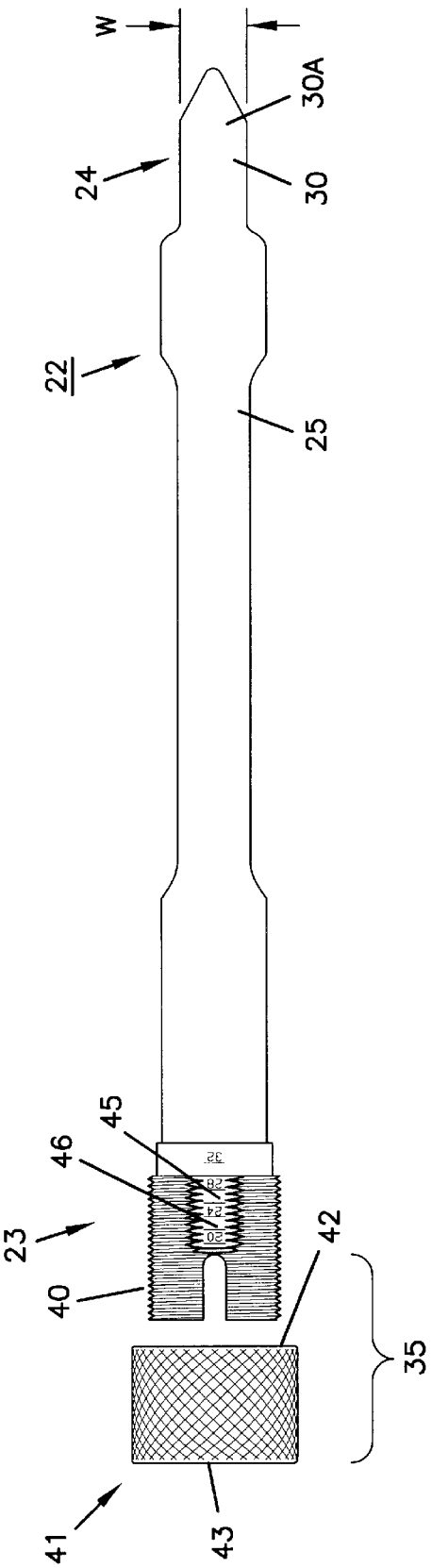

W
30A
24
30
22
25
45
46
23
42
40
35
41
43

FIG. 14

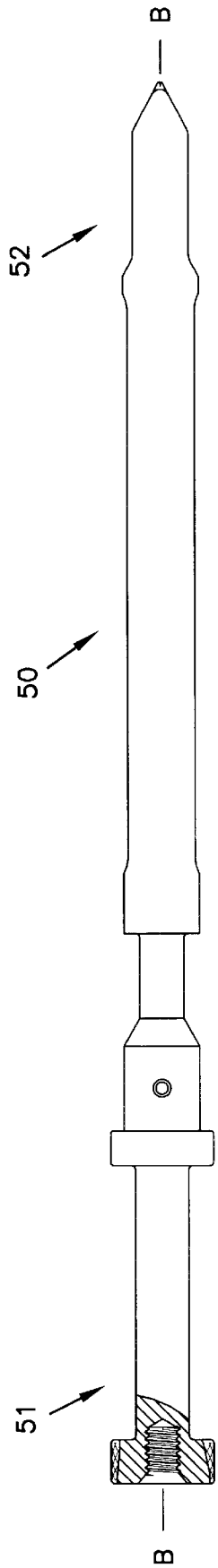


FIG. 16

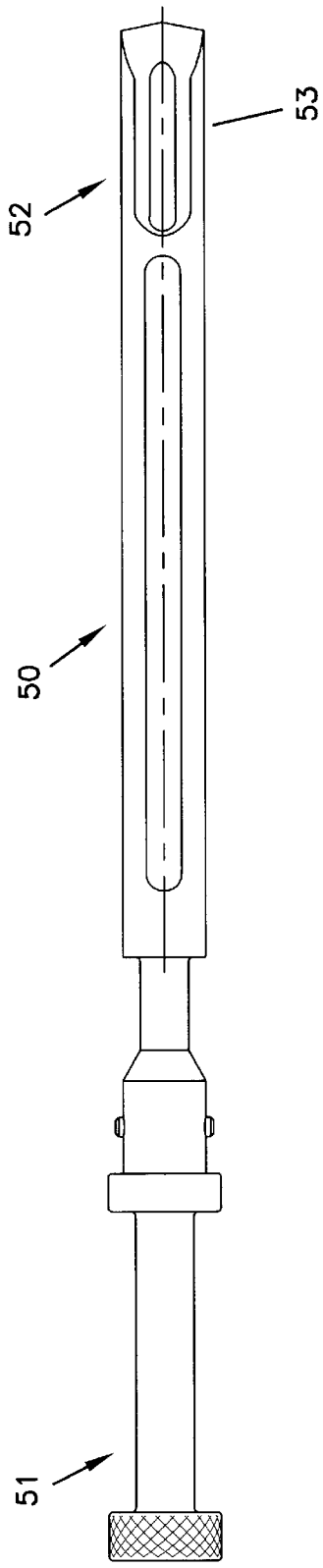


FIG. 17

POSTERIOR OBLIQUE LUMBAR ARTHRODESIS

FIELD OF THE INVENTION

The invention pertains to interbody vertebral stabilization. Specifically, the invention is directed to devices and procedures for stabilization of vertebral bodies using external and intervertebral stabilizing systems. The invention is particularly advantageous for stabilizing lumbar vertebrae.

BACKGROUND OF THE INVENTION

Chronic back problems cause pain and disability for a large segment of the population. In many cases, the chronic back problems are caused by intervertebral disc disease and loss of stability of the intervertebral joint. Stabilization and/or arthrodesis of the intervertebral joint can reduce the pain and debilitating affects associated with disc disease.

Spinal stabilization systems and procedures have been developed to stabilize diseased intervertebral joints and, in some cases, to fuse the vertebrae that are adjacent to the diseased joint space. Most fusion techniques include removing some or all of the diseased disc material from the affected joint, stabilizing the joint and inserting a bone graft or other material to facilitate bony fusion of the vertebrae.

One type of spinal stabilization system includes screws and connecting rods which can be used for stabilizing many spinal conditions including, for example, degenerative disc disease, scoliosis, spondylolithisis and spinal stenosis. Examples of such systems are disclosed in U.S. Pat. Nos. 6,010,503; 5,946,760; 5,863,293; 4,653,481, etc., the entire disclosures of which are incorporated herein by reference. In these systems, a bone screw (e.g., pedicle screw) is typically anchored into each vertebral body to be stabilized and a rigid connecting rod mounted to the screws to fix the vertebrae in a particular relative position. Generally, these systems provide posterior column support but lack anterior column support.

Another type of spinal stabilization system includes interbody implants such as disclosed in, for example, U.S. Pat. Nos. 5,458,638; 5,489,307; 5,055,104; 5,026,373; 5,015,247; 4,961,740; 4,877,020; 4,743,256; and 4,501,269, the entire disclosures of which are incorporated herein by reference. Some of these implants are bone, some are solid titanium or similar non-bone implant material and some are hollow implants that provide for inclusion of a bone graft or other suitable material to facilitate bony union of the vertebrae

Interbody implants can be inserted into the disc space through an anterior, posterior or lateral approach. When two implants are used, the implants are typically positioned parallel to one another on either side of a sagittal plane passing through the midline of the vertebral bodies. In some systems, the implants are inserted into a bore formed between adjacent vertebral bodies in the cortical endplates and can extend into the cancellous bone deep to the cortical endplates. Implant size is typically selected such that the implants force the vertebrae apart to cause tensing of the vertebral annulus and other soft tissue structures surrounding the joint space. Tensing the soft tissues surrounding the joint space results in the vertebrae exerting compressive forces on the implant to maintain the implant in place.

However, in some cases, the compressive forces exerted on the implant may cause undesired pressure induced changes to the bone adjacent the implant. Pressure induced changes can lead to reduced joint stability, increased fusion time and increased chance of subsidence or implant migration.

Accordingly, there is a continuing need for improved vertebral stabilizing devices and methods. The present invention is directed to addressing these needs.

SUMMARY OF THE INVENTION

The present invention is directed to instruments and methods for stabilization of vertebral bodies adjacent an intervertebral disc space using bilateral external stabilization systems and intervertebral implants.

In one embodiment, the invention provides a method for stabilizing an intervertebral joint between adjacent first and second vertebral bodies from a posterior approach. The method includes a step of forming an implant bore between the adjacent vertebrae for receiving an intervertebral implant. An intervertebral implant is then inserted into the implant bore. A bilateral external stabilization arrangement, such as known pedicle screw and rod fixation systems can be mounted to the adjacent vertebrae before or after preparing the implant bore and inserting the intervertebral implant.

In another embodiment, the invention provides a surgical procedure for stabilizing an intervertebral joint between adjacent first and second vertebral bodies using an interbody implant inserted into the intervertebral disc space with the longitudinal axis of the implant oriented at an angle oblique to a sagittal plane passing through the midline of the vertebral bodies. Bilateral external stabilization systems can be applied before or after insertion of the intervertebral implant.

The invention also provides new instruments including an instrument guide for guiding instruments for preparing an implant site and inserting the implant into the implant site. The instrument guides include a distal edge having an oblique angle that can rest on the exterior surface of the vertebrae such that the longitudinal axis of the guide can be at an angle oblique to a sagittal plane passing through the midline of the vertebral bodies. The instrument guides of the invention can also include distally extending paddles to stabilize the instrument guide during use and to distract and/or maintain distraction of the intervertebral disc space to a predetermined height during an implant procedure.

Kits will also be available including instrument guides of the invention having various sized lumens and paddle widths for corresponding to different implant diameters and disc space heights. The kits can also include boring instruments, taps, depth gauges, etc., which may be necessary to perform a procedure according to the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a posterior view of the L_5-S_1 vertebrae having a partial laminectomy and facetectomy on the right side;

FIG. **2** is the same view of the L_5-S_1 vertebrae after discectomy;

FIG. **3** is the same view of the L_5-S_1 vertebrae during insertion of a distraction plug into the disc space;

FIG. **4** is the same view of the L_5-S_1 vertebrae with the distraction plug in place;

FIG. **5** is an end-on view of the L_5-S_1 disc space taken through line **5**—**5** of FIG. **1**;

FIG. **6** is the same view of the L_5-S_1 disc space of FIG. **5** with an instrument guide and wedge distractor of the invention in place;

FIG. **7** is the same view of the L_5-S_1disc space as FIG. **5** with an instrument guide of the invention in place;

FIG. **8** is the same view of the L_5-S_1 disc space as FIG. **7** with a boring tool passed through the instrument guide;

FIG. **9** is the same view of the L_5-S_1 disc space as FIG. **5** after boring an implant bore and showing a pituitary rongeur passed through the instrument guide for removing debris in the implant bore;

FIG. **10** is the same view of the L_5-S_1 disc space as FIG. **5** with an implant passed into the implant site;

FIG. **11** is a posterior view of the L_5-S_1 vertebrae having a partial laminectomy and facetectomy on the right side after oblique insertion of an implant and bilateral pedicle screw and rod fixation;

FIG. **12** is a side view of one embodiment of a distraction plug suitable for the invention;

FIG. **13** is a side view of one embodiment of an instrument guide according to the invention;

FIG. **14** is a side view of the instrument guide of FIG. **13** rotated 90° around axis A-A;

FIG. **15** is a distal end-on view of the instrument guide of FIG. **13**;

FIG. **16** is a side view of one embodiment of a wedge distractor according to the invention; and

FIG. **17** is a top view of the wedge distractor of FIG. **16**.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to stabilization of vertebral bodies adjacent an intervertebral joint space. The invention provides new instruments and procedures for cooperative interaction of bilateral vertebral fixation systems, such as pedicle screws and rods, with interbody fusion systems to provide anterior and posterior column support which can result in greater fusion stability, greater motion segment stability, reduced fusion time, reduced pain, reduced chance of implant migration and reduced chance of subsidence.

It will be noted that in several places throughout the specification, guidance is provided through lists of examples. In each instance, the recited list serves only as a representative group. It is not meant, however, that the list is exclusive.

Screw and rod fixation systems suitable for the invention include known pedicle screw and rod fixation systems, non-limiting examples of which are disclosed in U.S. Pat. Nos. 6,010,503; 5,964,760; 5,863,293; the entire disclosures of which are incorporated herein by reference.

As used herein, an "implant" includes any interbody implant suitable for facilitating fusion between adjacent bones including intervertebral implants prepared from materials including non-bone implant materials such as titanium, stainless steel, porous titanium, ceramic, carbon fiber reinforced polymers, etc. or bone materials including heterologous, homologous, autologous, artificial bone, etc. The implants can be threaded or non-threaded. Non-limiting examples of implants suitable for the invention are disclosed in, for example, U.S. Pat. Nos. 5,865,847; 5,749,916; 5,722,977; 5,658,337; 5,609,636; 5,489,307; 5,484,638; 5,055,104; 5,026,373; 5,015,247; 4,961,740; 4,877,020; 4,848,757; 4,743,256; 4,501,269; and 3,848,601. The entire disclosure of each of these patents is incorporated herein by reference. A preferred embodiment of an implant is the BAK® available from Sulzer Spine-Tech Inc., Minneapolis, Minn.

An "implant site" refers to the location for placement of the implant between adjacent vertebrae. An "implant bore" refers to the bore formed for receiving the implant between adjacent vertebrae. The implant bore can be threaded or non-threaded depending on the type of implant to be inserted and/or the stage of preparation of the implant bore. The implant bore can be prepared using drills, reamers, chisels or other instruments used for cutting bone or preparing a bore for receiving an implant.

If a hollow non-bone implant is used, after inserting the implant into an implant bore, the implant can be filled with a bone support matrix. As used herein, a "bone support matrix" is a material that facilitates new bone growth between the opposing vertebral bodies. Suitable bone support matrices can be resorbable or nonresorbable and osteoconductive or osteoinductive. Examples of suitable matrices according to the invention include synthetic materials, such as Healos™, available from Orquest, Mountain View, Calif.; NeOsteo™, available from Sulzer Orthopedic Biologics, Denver, Colo.; or any of a variety of bone morphogenic proteins (BMPs). Suitable bone support matrices also include heterologous, homologous, or autologous bone and derivatives thereof.

Throughout the specification, unless stated otherwise, the terms "proximal" and "distal" are relative terms, the term "proximal" referring to a location nearest the surgeon and the term "distal" referring to a location farthest from the surgeon. So, in the case of performing a vertebral fusion from an anterior approach, the anterior surfaces of the vertebrae are "proximal" and the posterior surfaces of the vertebrae are "distal" relative to the surgeon performing the procedure. Likewise, in a posterior approach, the posterior vertebral surfaces are proximal and the anterior surfaces are distal.

As used herein, the "depth" of a vertebrae is defined as the anterior posterior dimension of the vertebrae. The "width" of the vertebrae is the dimension from the right lateral edge to the left lateral edge. The "height" of the disc space is the dimension from the superior endplate to the inferior endplate of opposing vertebrae.

In one embodiment, the invention is directed to a surgical procedure for stabilizing vertebral bodies adjacent to an intervertebral disc space. According to this embodiment, a bilateral vertebral fixation system is used to provide posterior spinal column support and an intervertebral implant used to provide anterior spinal column support. An example of a preferred bilateral vertebral fixation system is a pedicle screw and rod fixation system. According to this embodiment, typically, at least one pedicle screw is inserted into the posterior aspect of the right and left lateral side of each vertebrae to be stabilized. The pedicle screws positioned on the left lateral side of each of the vertebrae to be stabilized are fixed together using a rod. Likewise, the pedicle screws positioned on the right lateral side of the vertebrae to be stabilized are fixed together using a rod. It will be appreciated that either the right or left lateral sides of the vertebrae can be fixed together first.

Before or after positioning the pedicle screws, and before or after fixation of the pedicle screws and rods, a single interbody spinal implant is inserted obliquely into each of the intervertebral disc spaces between adjacent vertebrae to be stabilized. According to the invention, "oblique" insertion of the implant means that the longitudinal axis of the implant is positioned in the intervertebral disc space at an angle of about 10°–45°, typically about 20–25°, and preferably about 22.5° relative to a sagittal plane passing through the verte-

bral bodies. Because the implant is obliquely inserted, only a unilateral facetectomy or laminectomy is needed, thus preserving the existing facet joint of the contralateral side of the affected vertebrae.

In addition, while the pedicle screws can first be positioned and stabilized on either the right or left side, in one preferred embodiment, pedicle screw and rod stabilization can be performed first on the side of the vertebrae contralateral to the side from which the implant is inserted, prior to insertion of the implant. That is, if a right facetectomy and laminectomy is performed to insert the implant from the right side of the vertebrae, the left side of the vertebrae can be stabilized with the pedicle screw system prior to preparation of the implant site.

In some embodiments, it may be advantageous to distract the vertebral bodies prior to insertion of the spinal implant or pedicle screw fixation to change or restore the disc space to its normal height.

In another embodiment, the invention provides an instrument guide and kits including instrument guides, reamers, taps, distractors, etc. which are advantageous for performing the procedures of the invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

The invention will be described with reference to the accompanying drawings, wherein like reference numerals identify similar or corresponding components throughout the several views. The illustrated embodiments and description are for exemplary purposes to facilitate comprehension of the invention and should not be construed to limit the scope of the invention.

The invention can be used for stabilization of cervical, thoracic and lumbar vertebrae. For exemplary purposes, the invention will be described using a posterior approach to fuse the lumbosacral joint (i.e., L_5-S_1). It will be appreciated that in the lumbar region, insertion of an intervertebral implant according to the invention can be performed through an anterior approach and placement of the pedicle screw and rod through a posterior approach. However, combining an anterior and posterior approach requires repositioning of the patient during surgery, and thus, may not be preferred. In addition, although the following discussion exemplifies lumbar stabilization at a single level, multiple levels of vertebral stability can be performed using the herein described procedures.

For a posterior approach, the patient is placed in a prone position with the hips flexed and the legs adjusted to provide the desired sagittal alignment. Exposure of the disc space(s) to be fused can be made using known methods and decompression of the disc space can be performed as needed. An implant is selected that has the appropriate diameter and length for the patient. The diameter of the implant is preferably selected to provide sufficient distraction of the vertebrae to restore the normal disc height and to provide about 1 to 3 mm of purchase of the implant into the endplates of each of the superior and inferior vertebrae adjacent the affected disc space.

In one embodiment, a threaded implant having an external diameter of about 3–3.5 mm (i.e., outer thread diameter) greater than the distracted disc space height is selected to maximize disc space height while minimizing implant size. This embodiment provides about 1.5–1.75 mm of purchase of the threads into the endplates of each vertebrae. In an alternative embodiment, if a non-threaded implant is selected an implant having an external diameter of about 0.75–1.25 mm greater than the distracted disc space can be selected. In some embodiments, the external diameter of the implant can be about equal to the disc space height. In such an embodiment, the implant maintains the disc space height without having purchase into the endplates of the vertebrae.

The length of the implant can be selected to maximize the amount of cortical bone at the exterior margin of the vertebral bodies that contacts the implant while still permitting the implant to reside completely within the exterior margins of the vertebral bodies. In other embodiments, a shorter implant may be selected to permit use of a greater amount of a bone support matrix in the disc space. An appropriate implant size can be determined using known methods including measurements based on preoperative x-rays, CT images, MRI images or intra-operative x-rays. Templates can also be used such as, for example, BAK™, surgical measurement templates available from Sulzer Spine-Tech Inc., Minneapolis, Minn. Intraoperative fluoroscopy can also be used throughout the procedure.

FIG. **1** is a top view of the L_5-S_1 vertebrae and associated structures after partial unilateral laminectomy and facetectomy for exposure of the L_5 S_1 disc space DS for insertion of an implant from the right side of the disc space. While the implant can be inserted from either the right side or left side of the vertebrae, preferably the laminectomy and facetectomy are performed on the side with more symptomatic radiculopathic findings. Alternatively, the laminectomy and facetectomy can be performed in the side having less scar tissue if previous surgeries have been performed. In addition, while partial laminectomy may be performed on the side from which the implant will be inserted from, the entire lamina can be removed from the symptomatic side and some or all of the lamina can be removed on the contralateral side if believed to be necessary to obtain adequate disc and nerve root decompression. When using a hollow chambered implant, bone from the lamina and facet can be saved to pack into the chamber to facilitate new bone growth.

Referring to FIG. **2**, the exiting nerve root and thecal sac are retracted medially to provide exposure. Discectomy can then be performed as needed to remove disc material from the disc space DS. In the illustrated embodiment, a first pedicle screw **1** can be placed into left pedicle of the L_5 vertebrae and a second pedicle screw **2** can be placed into the left of the sacrum S_1. The pedicle screws are preferably positioned within the pedicle canal. In this embodiment, the pedicle screws are first placed on the side of the vertebrae contralateral to the side on which the laminectomy and facetectomy are performed. If the pedicle screws are placed prior to placement of the intervertebral implant, the vertebrae can be distracted and the rod secured between pedicle screws of the first side to maintain distraction of the vertebrae during preparation of the implant bore. Alternatively, as described below, distraction plugs can be used if needed to maintain distraction during preparation of the implant bore.

Referring now to FIG. **3**, the disc space DS can be sequentially distracted with distraction plugs **5** having incrementally increasing diameters to restore the disc space to a desired height. Distraction plugs suitable for the invention are known and disclosed in, for example, U.S. Pat. No. 5,489,307, the entire disclosure being incorporated herein by reference. A side view of an alternative embodiment of a distraction plug **5** suitable for the invention is shown in FIG. **12**. As illustrated in FIG. **3**, the proximal end **6** of distraction plug **5** can be mounted to a handle **7** for manipulating the distraction plug into the disc space DS. Also, as illustrated in FIG. **3**, in preferred embodiments, the longitudinal axis of

distraction plug **5** is inserted into disc space DS at an angle that is oblique to a sagittal plane passing through the midline of the vertebrae (i.e., mid-sagittal plane). As shown in FIG. **4**, once appropriate distraction is achieved, a rod **10** can be applied between first pedicle screws **1** and **2** and the rod **10** secured using, for example, lock nuts **1***a* and **2***a*. In this embodiment, securing rod **10** at this stage provides distraction that can be maintained throughout the procedure. After securing rod **10** in position, distraction plug **5** can be removed.

FIG. **5** is an end-on view of vertebral body L_5 taken through line **5**—**5** of FIG. **1**. As illustrated, after removal of distraction plug **5**, bone support matrix **11** can be packed into disc space DS lateral and anterior to the region where the implant site is to be formed. Referring to FIG. **6**, an instrument guide **20** can then be used to guide instruments for preparation of the implant site. A wedge distractor **53** is shown within the lumen of instrument guide **22** with paddles **30** and **31** passed into the disc space. Wedge distractor **53** fills the gap between paddles **30** and **31** and provides greater surface area contact with the vertebral endplates when the instrument guide is passed into the disc space.

FIGS. **13**–**15** illustrate one embodiment of a preferred instrument guide **22** according to the invention. FIG. **13** is a side view of instrument guide **22**, FIG. **14** is a side view of instrument guide **22** rotated 90° from the view of FIG. **13** and FIG. **15** is a distal end view of instrument guide **22**. Instrument guide **22** includes a proximal end **23**, a distal end **24**, a wall **25** surrounding a lumen **26** and having a longitudinal axis A-A passing therethrough. It will be appreciated that while instrument guide **22** has a circular cross-sectional configuration, an instrument guide of the invention can have other cross-sectional configurations including rectangular, oval, oblong, etc. The cross-sectional configuration of the instrument guide typically corresponds to the cross-sectional configuration of an implant to be inserted into an implant site prepared with the instrument guide.

Paddles **30** and **31** extend from the distal end **24** of instrument guide **22**. As best appreciated in FIG. **13**, the distal edge **32** of wall **25** of instrument guide **22** has an angle α, relative to longitudinal axis A-A, as distal edge **32** extends from paddle **30** to paddle **31**. The angle α of distal edge **32** corresponds to the oblique angle at which the implant will be inserted into the disc space as further discussed below. In general, the angle of distal edge **32** can be about 10°–30°, typically about 10°–25° and, in one preferred embodiment, about 22.5° relative to longitudinal axis A-A. Thus, as will be appreciated from the drawings, when paddles **30** and **31** are inserted into disc space DS until distal edge **32** rests against the posterior surface of the vertebrae, longitudinal axis A-A will be oriented at an angle of α° from the mid-sagittal plane of the vertebrae. In this orientation, instrument guide **22** provides for orientation of all instruments passing through instrument guide **22** to be positioned at the same angle α relative to the mid-sagittal plane.

Paddles **30** and **31** can also have a distal tapered tip, **30***a* and **31***a* respectively, to facilitate insertion of paddles **30** and **31** into disc space DS. In addition, each of paddles **30** and **31** have a width dimension W. A plurality of instrument guides **22** will be available having width dimensions W in about 1 mm increments to correspond with the disc height established by distraction plugs **5**. Ranges of paddle widths suitable for instrument guide **22** according to the invention are about 2 to 20 mm.

The paddle width dimension W can be equal to or less than the cross-sectional diameter of the lumen **26** of instrument guide **22**. Thus, in one embodiment, an instrument guide having a paddle width dimension W equal to the diameter of the lumen permits passage through the lumen of an implant having a diameter substantially equal to the disc space height formed by the paddle width dimension W.

In an alternative embodiment, the paddle width dimension W can be about 1 mm less than the diameter of the body of the implant. This relationship, referred to as "rule of one" distraction, provides for a smaller implant diameter to maintain a greater disc space height. According to the "rule of one," the lumen diameter of an instrument guide will typically be about 3.5 mm greater than the paddle width dimension W. As an example, for an instrument guide having a paddle width W of 12 mm, the lumen size of the instrument guide according to the "rule of one" can be calculated as follows. Assuming that the threads of the implant radially extend approximately 1.25 mm beyond the diameter of the body of the implant, an implant having a body diameter of 13 mm, such as a BAK™ 13 mm implant, has an overall diameter across the threads of 15.5 mm (13 mm+1.25 mm+1.25 mm). Accordingly, the lumen diameter of the instrument guide will be sized to permit passage of an implant diameter of 15.5 mm. Thus, the difference between the 12 mm paddle width dimension W and the lumen diameter of the instrument guide is about 3.5 mm. The difference between the 12 mm paddle width dimension W and the 13 mm body diameter is about 1 mm.

The proximal end **23** of instrument guide **22** can include a depth adjustment arrangement **35** for controlling the depth of penetration into the disc space of an instrument passed through instrument guide **22**. For example, in one embodiment, the depth adjustment arrangement can include threads **40** at the proximal end **23** of instrument guide **22** which mate with internal threads **42** of cap **41**. Thus, by threading cap **41** onto threads **40**, the proximal surface of cap **43** acts as an affirmative stop to stop distal travel of an instrument passed into the instrument guide **22** that has a proximal end arrangement configured to abut against proximal end **43** of cap **41**. An indicator arrangement **45** such as marks **46** can be used to indicate the depth of penetration of an instrument through the distal end **24** of instrument guide **33**.

FIGS. **16** and **17** illustrate a wedge distractor **50** that can be passed into lumen **26** of instrument guide **22**. As illustrated, wedge distractor **50** has a proximal end **51** and a distal end **52** and a longitudinal axis B—B passing therethrough. At distal end **52**, wedge distractor **50** includes distal extension **53** configured to fit within the contours of paddles **30** and **31** of instrument guide **22**.

Although the foregoing discussion of the method of the invention includes distraction with a distraction plug prior to insertion of the paddles of instrument guide **22**, in an alternative embodiment, the use of distraction plugs to distract the disc space may be omitted and distraction provided solely by insertion of the paddles of an instrument guide having a width dimension W equal to a desired disc space height.

Referring now to FIG. **7**, it will be appreciated that when instrument guide **22** is distally advanced into disc space DS until distal edge **32** is substantially flush along the posterior margin of the vertebrae, angle α provides for the longitudinal axis A-A to be positioned at an angle α relative to mid-sagittal plane MS passing through the mid-line of the vertebrae.

Referring to FIG. **8**, a reamer, drill, chisel or other boring instrument **60** can then be passed into instrument guide **22**

and operated using known methods to form an implant bore between the end plates of the vertebrae. An implant bore formed in a preferred embodiment of the invention has a longitudinal axis that is at an angle oblique to the mid-sagittal plane.

As shown in FIG. **9**, debris remaining in the implant bore **70** prepared by boring tool **60** can be removed through instrument guide **22** using, for example, a pituitary rongeur **71**. If a threaded implant is to be used, a tap can be passed through instrument guide **22** to tap threads into implant bore **70**.

As shown in FIG. **10**, once the implant bore **70** is complete, an implant **80** can be passed into the bore. Implant **80** can be inserted into implant bore **70** through instrument guide **22**, or instrument guide **22** can be removed and the implant inserted directly into the implant bore **70**. The area posterior to the implant can then be packed with a bone support matrix such as autologous bone.

Referring to FIG. **11**, a second pedicle screw **101**, **102** can then be inserted into the second side (right side) of vertebrae L_5 and S_1 and rod **103** applied between the pedicle screws and the rod secured in position, for example, by tightening lock nuts **101***a* and **102***a*.

If multiple levels are to be stabilized, the procedure described can be repeated at the additionally affected inter-vertebral disc space(s). While the preparation of the implant bore has been described using an instrument guide, such as instrument guide **22**, it will be appreciated that the implant bore can also be prepared using other guide instruments or, if the surgeon prefers, free hand without angular guidance of the instruments by an instrument guide.

Oblique placement of a single implant into the intervertebral space provides at least two advantages. First, oblique placement of the implant reduces side to side rocking of the joint space that can occur when the implant is positioned within and parallel to the mid-sagittal plane of the disc space. In addition, by using only a single implant, only a single lamina and posterior facet joint need be removed to perform the procedure.

From the foregoing detailed description and examples, it will be evident that modifications and variations can be made in to the instruments and methods of the invention without departing from the spirit or scope of the invention. Therefore, it is intended that all modifications and variations not departing from the spirit of the invention come within the scope of the claims and their equivalents.

What is claimed is:

1. A surgical procedure for stabilizing an intervertebral joint between adjacent first and second vertebral bodies, said first and second vertebral bodies each having a first lateral side and a second lateral side on opposite sides of a sagittal plane passing through a midline of said first and second vertebral bodies, the procedure comprising a step of:

anchoring a first pedicle screw into said first lateral side of said first vertebral body;

anchoring a first pedicle screw into said first lateral side of said second vertebral body;

forming an implant bore between said adjacent first and second vertebrae for receiving an intervertebral implant; and

inserting an intervertebral implant having a longitudinal axis into said implant bore, said longitudinal axis of said intervertebral implant oriented oblique to said sagittal plane.

2. The method according to claim **1** further comprising a step of fixing a connecting rod to said first pedicle screw of said first vertebral body and said first pedicle screw of said second vertebral body to stabilize said first and second vertebral bodies.

3. The method according to claim **1** wherein said step of fixing said connecting rod to said first pedicle screws to stabilize said first and second vertebral bodies is performed before forming said implant bore.

4. The method according to claim **1** wherein said implant bore has a longitudinal bore axis and said bore axis is formed at an angle oblique to said sagittal plane, said oblique angle being about 10°–45°.

5. The method according to claim **4** wherein said oblique angle is approximately 22° degrees to said sagittal plane.

6. The method according to claim **1** wherein said first and second vertebral bodies are distracted before forming said implant bore.

7. The method according to claim **1** further comprising steps of:

anchoring a second pedicle screw into said second lateral side of said first vertebral body;

anchoring a second pedicle screw into said second lateral side of said second vertebral body; and

fixing a connecting rod to said second pedicle screw of said first vertebral body and said second pedicle screw of said second vertebral body.

8. A surgical procedure for stabilizing an intervertebral joint between adjacent first and second vertebral bodies, said first and second vertebral bodies each having a first lateral side and a second lateral side on opposite sides of a sagittal plane passing through a midline of said first and second vertebral bodies, the procedure comprising a step of:

anchoring a first pedicle screw into said first lateral side of said first vertebral body;

anchoring a first pedicle screw into said first lateral side of said second vertebral body;

distracting said first and second vertebral bodies;

forming an implant bore between said adjacent first and second vertebrae for receiving an intervertebral implant;

inserting an intervertebral implant having a longitudinal axis into said implant bore, said longitudinal axis of said intervertebral implant oriented oblique to said sagittal plane; and

fixing a connecting rod to said first pedicle screw of said first vertebral body and said first pedicle screw of said second vertebral body to stabilize said first and second vertebral bodies.

9. The method according to claim **8** wherein said step of fixing said connecting rod to said first pedicle screws to stabilize said first and second vertebral bodies is performed before forming said implant bore.

10. The method according to claim **8** wherein said implant bore has a longitudinal bore axis and said bore axis is formed at an angle oblique to said sagittal plane, said oblique angle being about 10°–45°.

11. The method according to claim **10** wherein said oblique angle is approximately 22° degrees to said sagittal plane.

12. The method according to claim **8** further comprising steps of:

anchoring a second pedicle screw into said second lateral side of said first vertebral body;

anchoring a second pedicle screw into said second lateral side of said second vertebral body; and

fixing a connecting rod to said second pedicle screw of said first vertebral body and said second pedicle screw of said second vertebral body.

13. A surgical procedure for stabilizing an intervertebral joint between adjacent first and second vertebral bodies, said first and second vertebral bodies each having a first lateral side and a second lateral side on opposite sides of a sagittal plane passing through a midline of said first and second vertebral bodies, the procedure comprising a step of:

anchoring a first pedicle screw into said first lateral side of said first vertebral body;

anchoring a first pedicle screw into said first lateral side of said second vertebral body;

distracting said first and second vertebral bodies;

fixing a connecting rod to said first pedicle screw of said first vertebral body and said first pedicle screw of said second vertebral body to stabilize said first and second vertebral bodies;

forming an implant bore between said adjacent first and second vertebrae for receiving an intervertebral implant, wherein said implant bore has a longitudinal bore axis and said bore axis is formed at an angle oblique to said sagittal plane, said oblique angle being about 10°–45°; and

inserting an intervertebral implant having a longitudinal axis into said implant bore, said longitudinal axis of said intervertebral implant oriented oblique to said sagittal plane.

14. The method according to claim 13 wherein said oblique angle is approximately 22° degrees to said sagittal plane.

15. The method according to claim 13 further comprising steps of:

anchoring a second pedicle screw into said second lateral side of said first vertebral body;

anchoring a second pedicle screw into said second lateral side of said second vertebral body; and

fixing a connecting rod to said second pedicle screw of said first vertebral body and said second pedicle screw of said second vertebral body.

* * * * *

APPENDIX G

Eur Spine J (2003) 12 : 173–177
DOI 10.1007/s00586-001-0376-4

ORIGINAL ARTICLE

Jie Zhao
Tiesheng Hou
Xinwei Wang
Shengzhong Ma

Posterior lumbar interbody fusion using one diagonal fusion cage with transpedicular screw/rod fixation

Received: 15 December 2000
Revised: 9 November 2001
Accepted: 13 November 2001
Published online: 11 January 2003

J. Zhao · T. Hou · S. Ma
Orthopedic Surgery Department,
Changhai Hospital, 174 Changhai Road,
Shanghai 200433, P.R. China

X. Wang (✉)
Orthopedic Department,
Changzheng Hospital, 415 Feng yang
Road, Shanghai, 200003, P.R. China
e-mail: orth.wang@263.net,
Tel.: 86-21-25071456,
Fax: 86-21-25070583

Abstract Posterior lumbar interbody fusion (PLIF) using threaded cages has gained wide popularity for lumbosacral spinal disease. Our biomechanical tests showed that PLIF using a single diagonal cage with unilateral facetectomy does add a little to spinal stability and provides equal or even higher postoperative stability than PLIF using two posterior cages with bilateral facetectomy. Studies also demonstrated that cages placed using a posterior approach did not cause the same increase in spinal stiffness seen with pedicle screw instrumentation, and we concluded that cages should not be used posteriorly without other forms of fixation. On the other hand, placement of two cages using a posterior approach does have the disadvantage of risk to the bilateral nerve roots. We therefore performed a prospective study to determine whether PLIF can be accomplished by utilizing a single diagonal fusion cage with the application of supplemental transpedicular screw/rod instrumentation. Twenty-seven patients underwent a PLIF using one single fusion cage (BAK, Sulzer Spine-Tech, Minneapolis, MN, USA) inserted posterolaterally and oriented anteromedially on the symptomatic side with unilateral facetectomy and at the same level supplemental fixation with a transpedicular screw/rod system. The internal fixation systems included 12 SOCON spinal systems (Aesculap AG, Germany) and 15 TSRH spinal systems (Medtronic Sofamor Danek, USA). The inclusion criteria were grade 1 to 2 lumbar isthmic spondylolisthesis, lumbar degenerative spondylolisthesis, and recurrent lumbar disc herniations with instability. Patients had at least 1 year of low back pain and/or unilateral sciatica and a severely restricted functional ability in individuals aged 28–55 years. Patients with more than grade 2 spondylolisthesis or adjacent-level degeneration were excluded from the study. Patients were clinically assessed prior to surgery by an independent assessor; they were then reassessed at 1, 3, 6, 12, 18, and 24 months postoperatively by the same assessor and put into four categories: excellent, good, fair, and poor. Operative time, blood loss, hospital expense, and complications were also recorded. All patients achieved successful radiographic fusion at 2 years, and this was achieved at 1 year in 25 out of 27 patients. At 2 years, clinical results were excellent in 15patients, good in 10, fair in 1, and poor in 1. Regarding complications, one patient had a postoperative motor and sensory deficit of the nerve root. Reoperation was required in one patient due to migration of pedicle screws. No implant fractures or deformities occurred in any of the patients. PLIF using diagonal insertion of a single threaded cage with supplemental transpedicular screw/rod instrumentation enables sufficient decompression and solid interbody fusion to be achieved with minimal invasion of the posterior spinal elements. It is a clinically safer, easier, and more economical means of accomplishing PLIF.

Keywords Lumbar · Fusion cage · Implant · Transpedicular screw · Interbody

Introduction

Posterior lumbar interbody fusion (PLIF), introduced by Dr. Ralph Cloward in the 1940s [2], laid the foundations for future biomechanically ideal fusion. A successful PLIF has the advantages of restoring the disc height, immobilizing the unstable degenerated intervertebral disc, decompressing the dural sac and the nerve roots, and restoring load-bearing to anterior structures [1]. Numerous techniques have been described, including use of autologous iliac crest bone graft, allograft bone, dowel-shaped graft, key stone graft, tricortical graft, and bone chips. Threaded-cage PLIF has the advantages of minimizing complications of graft resorption and disc space collapse and has therefore been recommended [5, 7].

The PLIF method that was introduced involving implantation of two threaded cages [4, 7] lacked supplemental internal fixation with a pedicle screw system. Insertion of one anterior or lateral cage has been successful on a limited basis. It is challenging to insert two cages of appropriate size posteriorly during the surgical procedure without extensive laminectomy and bilateral facetectomy. From a mechanical point of view, posterior element deficiencies adversely affect the stiffness of intervertebral fusion cages immediately after insertion, as these structures provide resistance to flexion and torsion. In addition, there is the obvious potential for neurological damage during surgery [8].

The results of our biomechanical tests show that the posterolateral single threaded cage PLIF with unilateral facetectomy led to significantly higher postoperative stiffness than PLIF using two cages with bilateral facetectomy in pure compression, left bending, and left and right torsion. Flexion and extension loading modes also showed stiffer values in the single-cage group than in the two-cage group, but this was not statistically significant [9]. We therefore decided to perform PLIF utilizing a single diagonal cage with the application of supplementary transpedicular screw/rod instrumentation while maintaining minimal invasion of the posterior elements. This study concerns the first 27 patients who have reached the 2-year follow-up interval.

Patients and methods

From July 1997 to August 1998, 27 patients with symptomatic lumbar disease were treated by PLIF using single BAK (Bagby and Kuslich) and additional pedicle screw internal fixation. Nine patients with grade 1 to 2 lumbar isthmic spondylolisthesis, 11 with lumbar degenerative spondylolisthesis, and 7 with recurrent lumbar disc herniations with instability were treated prospectively. The internal fixation systems included 12 SOCON spinal systems (Aesculap AG, Germany) and 15 TSRH spinal systems (Medtronic Sofamor Danek, USA). There were 16 men and 11 women. The mean age was 46 years (range, 28–55 years). The minimum follow-up for review of 24 months.

Table 1 Data on 27 patients

	IS	DS	RDH
Patients (*n*)	9	11	7
Average age (years)	43±8	50±3	47±5
Sex			
Male (*n*)	7	2	2
Female (*n*)	2	9	5
Average blood loss (ml)	711±105	891±274	1000±327
Average surgery time (min)	201±31	225±72	225±56
Average hospital stay (days)	14±2	12±3	13±2
Average hospital costs (US dollars)	4975±318	4872±459	4872±459

IS, isthmic spondylolisthesis; DS, degenerative spondylolisthesis; RDH, recurrent disc herniation.

Table 2 Pre- and postoperative data on 27 patients

	Preoperative	Postoperative
Symptoms		
Low back pain (*n*)	27	8
Intermittent claudication (*n*)	6	2
Leg pain (*n*)	12	2
Fitness for work		
Disability (*n*)	7	0
Partial disability (*n*)	15	2
Restricted duty (*n*)	5	10
Return to previous work (*n*)	0	15
Clinical results		
Poor (*n*)	16	0
Fair (*n*)	10	2
Good (*n*)	1	10
Excellent (*n*)	0	15

Inclusion criteria

The inclusion criteria were grade 1 to 2 lumbar isthmic spondylolisthesis, lumbar degenerative spondylolisthesis, and recurrent lumbar disc herniations with instability. Patients had at least 1 year of low back pain and/or unilateral sciatica and a severely restricted functional ability in individuals under 60 years of age. The preoperative data on all 27 patients are shown in Table 1 and Table 2.

Exclusion criteria

The exclusion criteria included active infection, osteopenia, symptomatic vascular disease, active malignancy, gross obesity, greater than grade 2 spondylolisthesis, adjacent level degeneration, and pregnancy.

Surgical technique

The patient was placed in the kneeling/sitting position on an Andrew's frame under general anesthesia. The surgical procedure is illustrated in Fig. 1. For patients with stenosis, unilateral laminec-

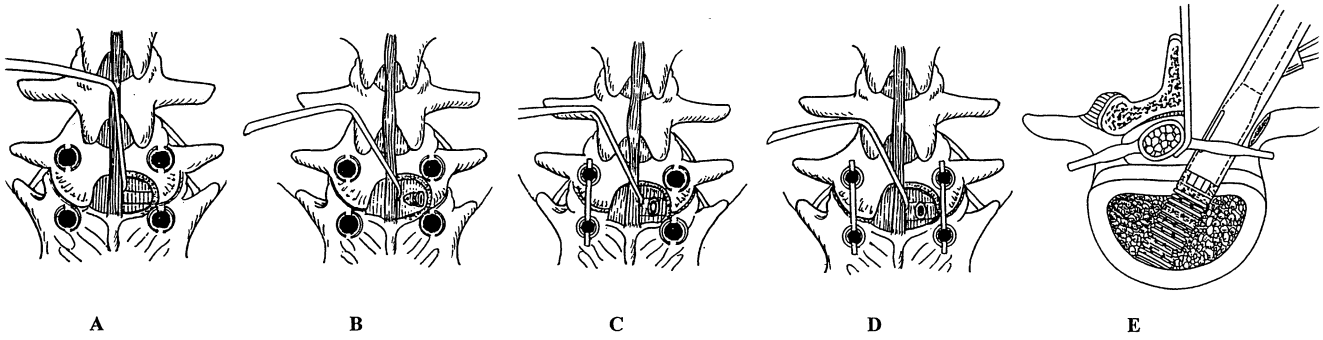


Fig. 1A–E Demonstration of the surgical procedure of posterior lumbar interbody fusion (PLIF) using one diagonal fusion cage with transpedicular screw fixation. **A** An appropriate hemi-laminectomy and unilateral partial facetectomy of the symptomatic side was performed, and pedicle screws were inserted bilaterally. **B** The disc space was then cleaned and the distraction plug gradually inserted until the desired annular tension was achieved. **C** A single rod was applied to the contralateral side of the distraction plug, and locking nuts were tightened to maintain distraction. **D** After bone grafting, the BAK was inserted diagonally; finally, the second rod was put in place, and all the nuts were tightened. **E** Cross-section of extra bone graft previous to the BAK (Bagby and Kuslich) insertion

tomy and facetectomy of the symptomatic side was able to achieve adequate decompression of the stenosis. For patients with spondylolisthesis, sequential distraction until the desired annular tensions were achieved was able to reduce slippage to some extent. Before cage insertion, the bone from laminectomy was grafted into the prepared disc space, while the iliac bone graft was placed in the cage. We believe that the bone outside the cage has greater fusion potential than the bone inside.

X-rays or fluoroscopic images were taken in both the anteroposterior and lateral planes. The size of the implanted cage was determined by both the templates for X-ray, computed tomography (CT) or magnetic resonance imaging (MRI) scans and the extent of distraction during surgery.

Patients' clinical symptoms were assessed prior to surgery by an independent assessor (the third author) and reassessed at 1, 3, 6, 12, 18, and 24 months postoperatively by the same assessor; patients were put into four categories: excellent, good, fair, and poor. Clinical results were rated as excellent if the patient was pain-free and had returned to work at their previous occupation. If the patient continued to have mild backache requiring non-narcotic medication only and had returned to full-time work, the results were rated as good. A fair result indicated that the patient's continuing back pain prevented him or her returning to work or narcotic medication was required. A poor result indicated that the patient's condition was worse than it was preoperatively or required additional surgery at the same level [10]. Operative time, blood loss, and hospital expense were also recorded (Table 1).

Fusion status was determined from the anteroposterior, lateral, and flexion–extension radiographs. All radiographs were reviewed by the blinded assessor (the forth author), who determined whether there was radiographic fusion or nonunion. For a fusion to be deemed solid, the anteroposterior or lateral radiograph had to show mature bony trabeculae bridging the fusion area. Flexion–extension films were considered to show fusion with less than 2° of motion on the lateral film. Fusion results were purely determined by radiographic means [3].

Results

All patients achieved successful radiographic fusion at 2 years, and 25 out of 27 patients at 1 year (Fig. 2). Clinical results at 2 years were excellent in 15 patients, good in 10, fair in 1, and poor in 1 (reoperation). Ten patients were able to return to work, but not to their previous occupation. Fifteen patients worked in their previous occupation. From a functional point of view, 12 patients had a mild level of low back pain, intermittent claudication, or sciatica, while 15 patients had no pain (Table 2). Regarding complications, one patient had a postoperative temporary motor and sensory deficit of the adjacent nerve root. Reoperation was required in one patient due to migration of pedicle screws. No implant fractures or deformities occurred in any of the patients.

Discussion

PLIF using threaded cages has gained wide popularity for lumbosacral spinal disease. Although many studies have concluded that threaded cages provide the same amount of stabilization as a PLIF bone graft with supplementary transpedicular screws/rod constructs, controversy still exists [6, 9]. The threaded fusion cages were originally designed to be placed anteriorly; they have also been used from a posterior lumbar approach, which often involves removal of much of the facet joints to allow safe implantation. Our biomechanical test [9] showed that PLIF using a single diagonal cage with unilateral facetectomy does add a little to spinal stability, but it provides equal or even higher postoperative stability than PLIF using two posterior cages with bilateral facetectomy. Tencer et al. [8] also found that posterior placement of an insert can compromise the facet and lamina structures by reducing torsion stiffness, which is further reduced when two inserts are used. They believe that these data can be interpreted as indicating that it may be better to use a single insert rather than two.

Oxland et al. [6] demonstrated that cages placed from both anterior and posterior directions provided good stability in flexion, but not in extension. Supplementary pos-

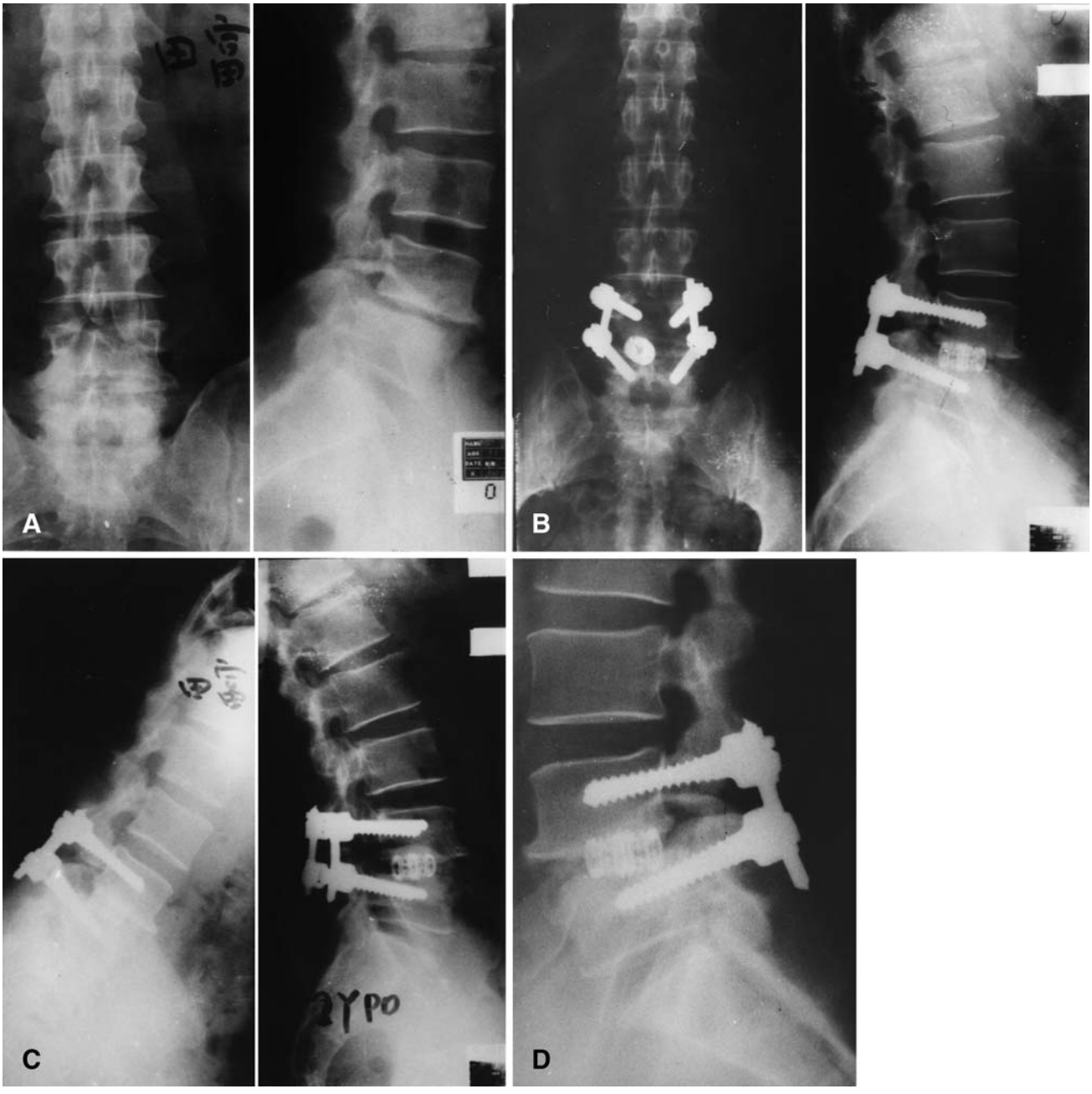


Fig. 2 **A** A 41-year-old man with symptomatic grade 1 isthmic spondylolisthesis. **B** He was treated with posterior lumbar interbody fusion (PLIF) using one diagonal BAK cage with unilateral facetectomy and with transpedicular screw fixation. **C** The result at 2-year follow-up. **D** The lateral radiograph at 2-year follow-up showed bony trabeculae bridging the fusion level

terior fixation with pedicle or translaminar screws substantially improves stability in all directions. On the other hand, placement of two cages from a posterior approach does have the disadvantage of risk to the bilateral nerve roots [4, 7]. Since posteriorly placed interbody fusion cages offer no significant increase in stiffness, their use as a stand-alone device may not be appropriate.

This method has some obvious advantages. It is an easier technique compared to routine two-cage PLIF. In treatment of patients with unilateral sciatica, the cage can be placed from the symptomatic side so as to avoid retraction of the nerve root and dural sac of the asymptomatic side. Since the application of the supplementary instrumentation can provide adequate postoperative stability immediately, an undersized cage can be used without worrying about its displacement. Regarding surgical procedure, sin-

gle-cage PLIF also has the advantages of less blood loss, shorter surgery time, and a shorter hospital stay.

Indications for PLIF using single threaded fusion cages with supplementary instrumentation in lumbar spine have not yet been fully established or proved by long-term outcome studies. They might include degenerative or less than grade 2 isthmic spondylolisthesis after completion of a decompressive laminectomy, iatrogenic instability after previous decompressive procedures, and certain cases of retrolisthetic instability with disc space collapse and restoration of alignment.

We conclude that PLIF using diagonal insertion of a single threaded cage with supplementary transpedicular screw/rod instrumentation enables sufficient decompression and solid interbody fusion to be achieved, while maintaining minimal invasion to the posterior elements. It is a clinically safer, easier, and more economical way of achieving PLIF.

References

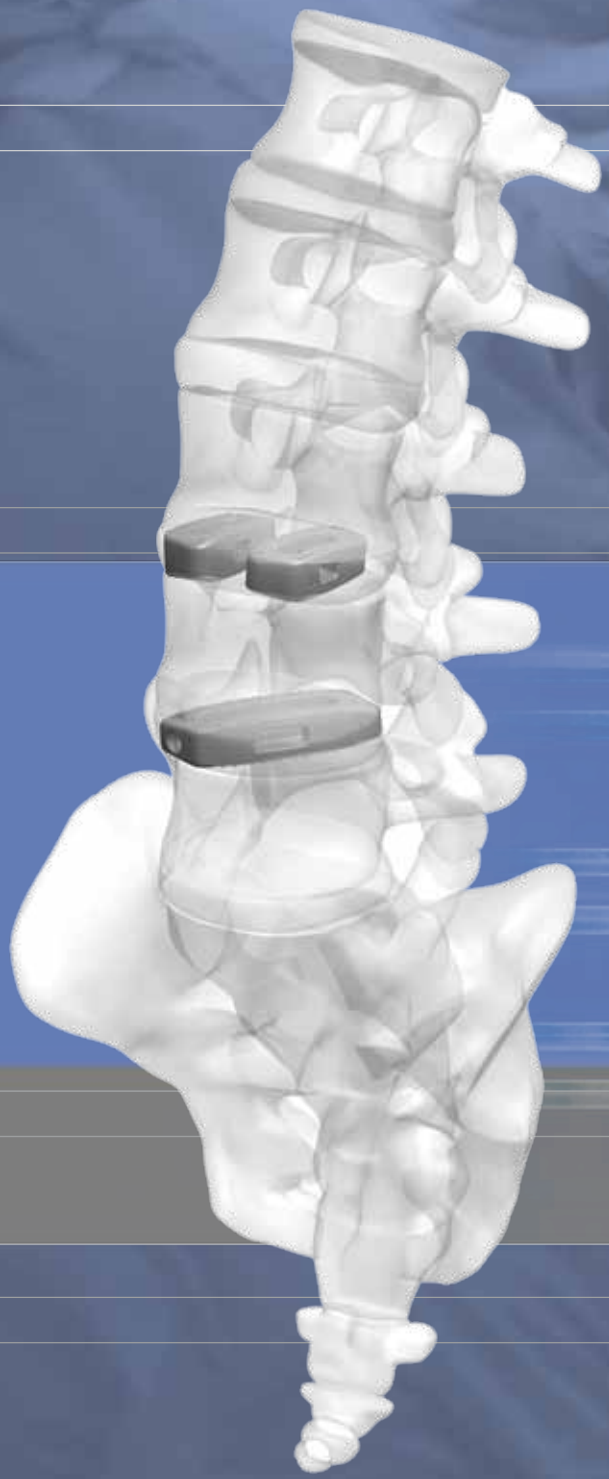
1. Bagby GW (1988) Arthrodesis by the distraction-compression method using a stainless steel implant. Orthopedics 11:931–934
2. Cloward RB (1953) The treatment of ruptured lumbar intervertebral discs by vertebral body fusion. Indications, operation technique, after care. J Neurosurg 10:154–168
3. Herkowitz HN, Kurz LT (1991) Degenerative lumbar spondylolisthesis with spinal stenosis. J Bone Joint Surg [Am] 73:802–808
4. Kuslich SD, Danielson G, Dowdle JD, Sherman J, Fredrickson B, Yuan H, Griffith SL (2000) Four-year follow-up results of lumbar spine arthrodesis using the Bagby and Kuslich lumbar fusion cage. Spine 25:2656–2662
5. Kuslich SD, Ulstrom CL, Griffith SL, Ahern JW, Dowdle JD (1998) The Bagby and Kuslich method of lumbar interbody fusion. History, techniques, and 2-year follow up results of a United States prospective, multicenter trial. Spine 23:1267–1278
6. Oxland TR, Lund T (2000) Biomechanics of stand-alone cages and cages in combination with posterior fixation: a literature review. Eur Spine J Suppl:S95–101
7. Ray CD (1997) Threaded titanium cages for lumbar interbody fusions. Spine 22:667–679, discussion 679–680
8. Tencer AF, Hampton D, Eddy S (1995) Biomechanical properties of threaded inserts for lumbar interbody spinal fusion. Spine 20:2408–2414
9. Zhao J, Hai Y, Ordway NR (2000) Posterior lumbar interbody fusion using posterolateral placement of a single cylindrical threaded cage. Spine 25: 425–433
10. Zdeblick TA (1993) A prospective, randomized study of lumbar fusion: preliminary results. Spine 18:983–991

APPENDIX H

MectaLIF®

OBLIQUE & POSTERIOR

INTERVERTEBRAL BODY FUSION DEVICE



Surgical Technique

Hip | Knee | Spine | Navigation

Medacta International

EACH TO THEIR OWN

The anatomical Solution for the posterior Interbody Fusion PLIF approach.

The clear Solution for the oblique Interbody Fusion OLIF approach.

The transparent Solution for the transforaminal Interbody Fusion TLIF approach.

CAUTION

Federal law (USA) restricts this device to sale distrribution and use by or on the order of a physician.

ACKNOWLEDGMENTS

Medacta® International would like to express its gratitude to

JOSHUA D. AUERBACH, MD
Bronx-Lebanon Hospital Center
affiliated with Albert Einstein College of Medicine
New York, USA

ZSOLT FEKETE, MD
Roland-Klinik
Bremen, Germany

CHRISTOPH-E. HEYDE, MD
Professor of University Medical Center
Leipzig, Germany

DEZSÖ JESZENSZKY, MD
Schulthess Klinik
Zürich, Switzerland

for their valuable and constant help in MectaLIF® implant, instruments and Surgical Technique development.

CONTENTS

1 INTRODUCTION

The anatomical design of our MectaLIF® Intervertebral Body Fusion Device matches the given biological conditions in each patient and pathology and meets the requirements of the treating surgeon.

The PLIF procedure, popularized in the 1950's and 1960's by Cloward, who inserted iliac crest bone into the intervertebral disc space, lost popularity because of the complication rate and technical difficulties. In the 1980's spacers made of titanium or carbon fiber reinforced PEEK were designed to overcome these challenges. However, bone from the iliac crest can be adjusted to the patient's anatomy, compared to metal spacers which are available in a predetermined design.
These thoughts led us to the development of our MECTALIF Posterior and MectaLIF® Oblique Intervertebral Body Fusion Device, whose anatomical design features offer distinctive benefits, including:

- Unilateral transforaminal/oblique approach (TLIF) or a bilateral posterior approach (PLIF).
- Biconvex superior/inferior surface that closely match the native anatomy.

MectaLIF® Posterior

MectaLIF® Oblique

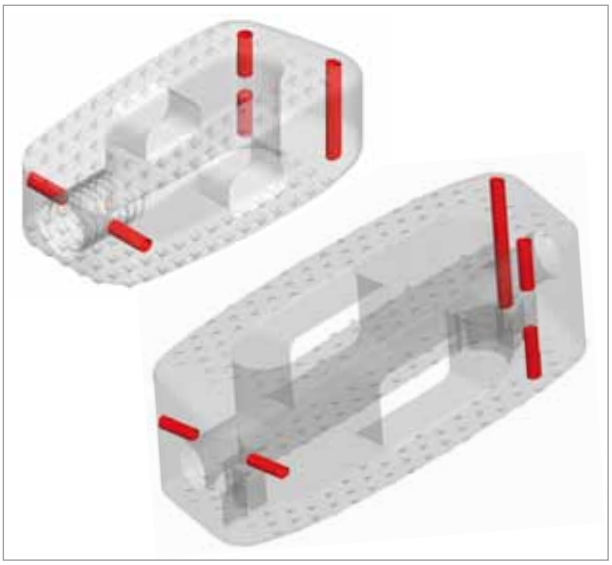
- Different footprints and five heights are offered to address individual patient anatomy.
- The footprint as well as the outer counter is anatomically shaped to facilitate optimal load transfer and maximize the implant-endplate contact surface.
- Large central as well as lateral window to receive filling material to accelerate the occurrence of fusion through the implant.
- Pyramid shaped teeth to enhance the resistance to implant migration.
- Shapes ranging from parallel to lordotic to restore natural sagittal alignment.
- Self-distracting nose for simplicity of insertion.
- PEEK, radiolucent and optimizes the load transfer between the cage and the adjacent vertebral bodies and reduces the affects of stress shielding on the graft material.

MectaLIF® Oblique

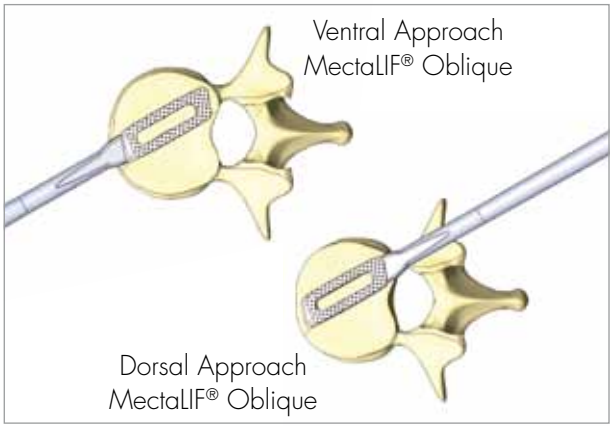
MectaLIF® Posterior

1.1 Material & Marker

- Biocompatible radiolucent PEEK-OPTIMA®[1] with a favorable modulus of elasticity allows a clear assessment of bony fusion.
- Posterior and anterior marker pins allow a easy and clear visualization.



Ventral/Dorsal Approach MectaLIF® Oblique



[1] PEEK-OPTIMA® polymer from Invibio Biomaterial Solutions

2 INDICATIONS

INTERVERTEBRAL BODY FUSION DEVICE
The MectaLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

The MectaLIF® Posterior Intervertebral Body Fusion Device is inserted bilaterally in pairs via posterior lumbar interbody fusion approach.
The MectaLIF® Oblique Intervertebral Body Fusion Device is inserted unilaterally via transforaminal lumbar interbody fusion approach in either open or minimal invasive technique.

3 CONTRAINDICATIONS

The MectaLIF® Posterior, MectaLIF® Oblique Intervertebral Body Fusion Device System in combination with a pedicle screw system should not be implanted in patients with active systemic infection or infection localized to the site of implantation.

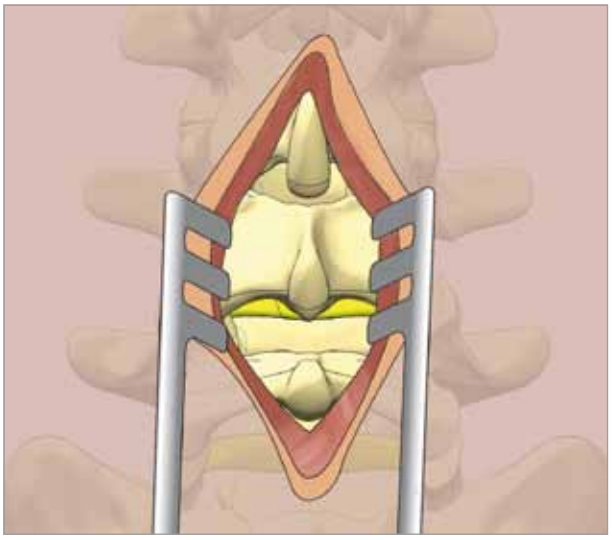
4 PRE-OPERATIVE PLANNING

This important step before each surgery includes the use of MRI and/or CT scans to template and determine the type and size of implant to be used to match the patient's anatomy.

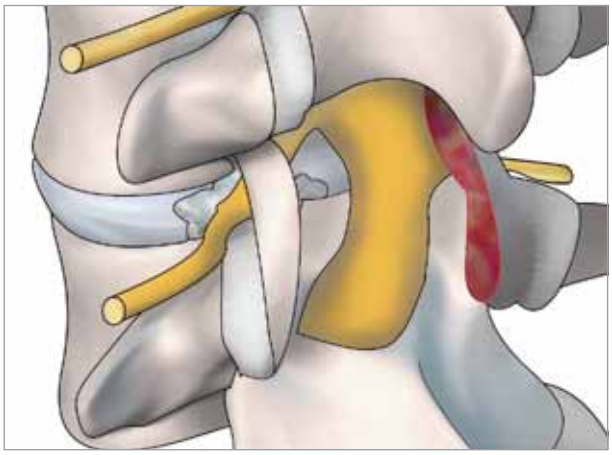
5 SURGICAL TECHNIQUE: POSTERIOR (PLIF)

5.1 Exposure and Preparation Posterior

Skin incision and dissection laterally from the midline. Locate the spinous process and the lamina of the corresponding level(s).



Perform a laminotomy sufficiently large enough for the PLIF preparation. Ensure that the neural structures are protected throughout the entire disc space exposure.



A conventional discectomy is performed by incising the annulus lateral to the dural sac.
Use the curette to remove the disc through the incision window leaving only the anterior and lateral annulus intact.

This is done bilaterally and then disc fragments from the intradiscal space are removed with disc rongeurs in standard fashion. The importance of this is to remove extruded fragments, to adequately decompress the neural elements, and to provide entry to the disc space for distraction with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished. It is also important to remove osteophytes and posterior lips of the adjacent vertebral body with an osteotome.

The disc space is sequentially distracted until original disc space height is obtained and normal foraminal heights are restored. It is critical to ensure that the segment is not overdistracted.

Depending on the pathology and the surgeon's preference there are two other methods to achieve disc space distraction: either via pedicle screws or using a lamina spreader.

Remaining soft tissue or cartilaginous endplate are removed with vigorous scraping or curettage, which is essential for good vascularization of the bone graft. Excessive endplate preparation, however, can weaken the endplates and predispose to fracture or device subsidence. It is therefore of paramount importance to remove only the cartilaginous portion of the endplates, and to maintain the integrity of the underlying bony endplate which provides compressive resistance.

5.2 Trial Insertion (PLIF)

Color code and sizes:

The lengths of the trials are 25 mm. The notch on the top of the trial indicates 22 mm which is equivilent to the shorter version of the cage.

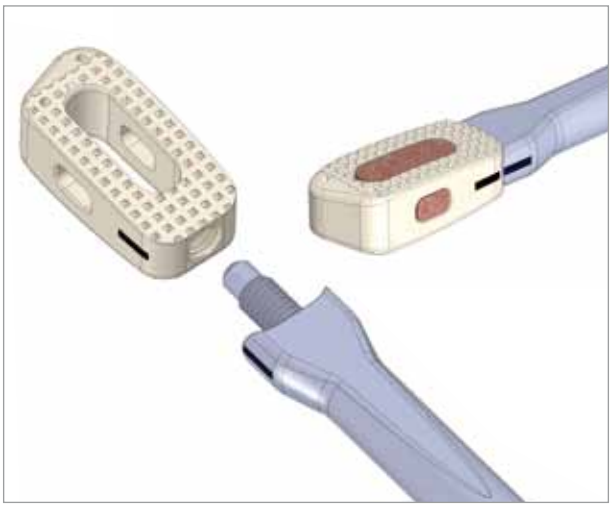
Select the size of the trial implant as determined during preoperative planning and confirmed by intraoperative fluoroscopy and attach it to the Cage Inserter. Markers on the trial, instrument, as well as the implant will align to confirm proper engagement of the trial/implant with the instrument.

The inserter to be used is marked "MectaLIF® Posterior" on the shaft. The mark "LATERAL" indicates the proper alignment of the instrument in respect to the patient. Insert the trial implant into the disc space by light impaction and confirm proper position, depth, and size with intraoperative fluoroscopy and tactile feel. If the trial implant is too loose or too tight, try the next larger/smaller size until a secure fit is achieved. Using the largest possible implant improves stability by creating tension on the ligaments and the annulus fibrosus.

Remove the trial implant assembly and select the matching implant. If necessary, the slap hammer is available to assist in safe removal of the trial implant.

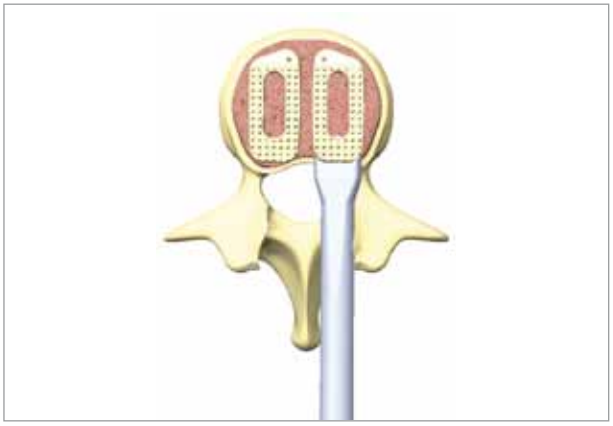
5.3 Implant Placement

Prepare autologous bone graft and freshly aspirated bone marrow, place it at the anterior rim of the vertebral body and impact it gently before inserting the implant. Different Bone Graft Impactors as well as a Bone Tamp are included in the instrument set.
Gently pack bone graft into the opening of the carefully selected cages using the filler block and bone tamp.



Attach the implant perpendicular to the Inserter by screwing the thread of the inner shaft into the threaded hole and secure it firmly. The cylindrical tip of the inserter simplifies the fixation of the implant.Ensure that the orientation of the implant is correct (see marker line on the implant which should line up with the corresponding line on the instrument).
Insert the implant straight into the intervertebral disc space by gentle impaction. Protect the nerve roots and thecal sac with a suitable instrument. Check the position of the implant with the image intensifier.

Remove the instrument if the implant position is to your satisfaction. Insert the second implant on the contralateral side as described before. If necessary tap lightly the implant into position with the cage impactor and the hammer.



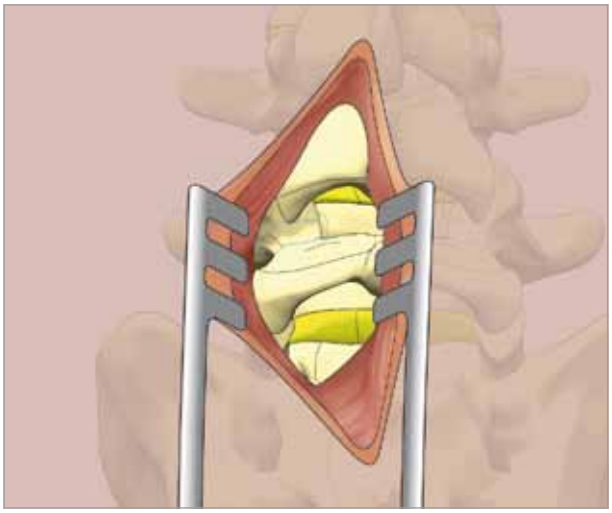
Check the position of the implant with the image intensifier. Remove the instrument if the implant is in satisfactory position.

Be careful to ensure proper alignment of the implants.

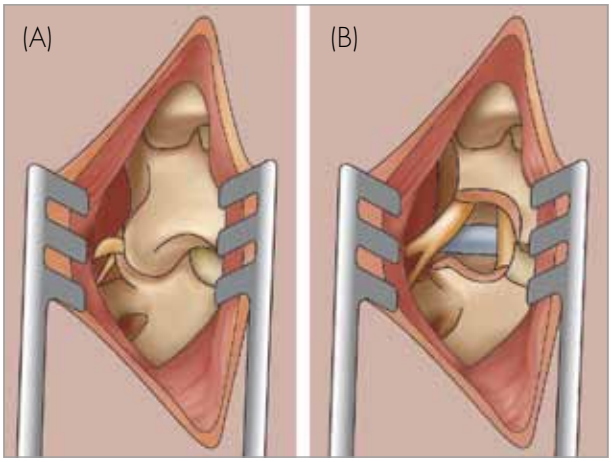
6 SURGICAL TECHNIQUE: TRANSFORAMINAL/OBLIQUE (TLIF)

6.1 Exposure and Preparation Transforaminal/Oblique

The TLIF technique can be performed either in open or mini-open approach.



Skin incision and dissection laterally from the midline. Locate the spinous process and the lamina of the corresponding layer(s) (A).
Prepare a window for transforaminal approach, using an osteotome or drill, to remove the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra (B). Ensure that the neural structures are spared as much as possible. Additional bone removal may be carried out using a Kerrison rongeur or drill.



Divide the ligamentum flavum from the inferior portion of the lamina. Expose the nerve root and dural tube from soft tissue, probe with ball point instrument. Gently retract the nerve root and dural tube. Then create the annular window with an annulus knife.
To assist distraction during disc space preparation, pedicle screws and rod can be inserted on the contralateral side.

Use the curette to remove the disc through the incision window. The annulus must be preserved to provide additional support. A combination of shavers, pituitary rongeurs, and curettes designed for intervertebral discs can facilitate removal of the nucleus pulposus and the surface layers of the cartilaginous endplates.

The critical steps include adequate removal of extruded disc fragments, adequate decompression of the traversing and exiting nerve roots, and to provide entry to the disc space for distraction with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished. Be sure to remove osteophytes and posterior lips of the adjacent vertebral body with an osteotome so as to avoid neural impingement or graft malalignment.

The disc space is sequentially distracted until adequate disc space height is obtained and normal foraminal heights are restored. Insert the distracters with the curved sides touching the endplates. Insert distracters sequentally until the desired height is obtained. It is critical to ensure that the segment is not overdistracted. Depending on the pathology and the surgeon's preference there are two other methods to achieve disc space distraction: either via pedicle screws or using a lamina spreader.

Remaining soft tissue or cartilaginous endplate are removed with vigorous scraping or curettage, which is essential for good vascularization of the bone graft. Excessive endplate preparation, however, can weaken the endplates and predispose to fracture or device subsidence. It is therefore of paramount importance to remove only the cartilaginous portion of the endplates, and to maintain the integrity of the underlying bony endplate which provides compressive resistance.

6.2 Trial Insertion Transforaminal/Oblique

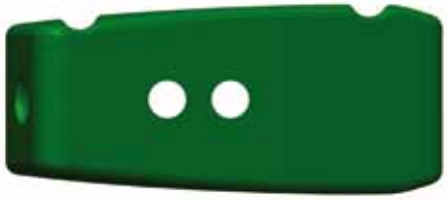
Color code and sizes:

7 mm light blue

9 mm violet

11 mm gold

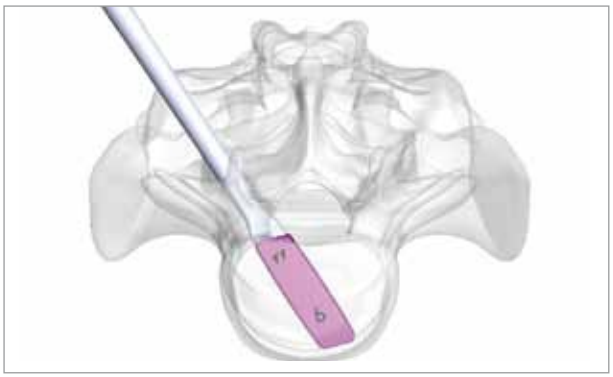
13 mm blue



15 mm dark green

The Trials as well as the implants have A (Anterior) and P (Posterior)markings to facilitate proper orientation. The lenghts of the trials are 36 mm and the two notches on the trial indicates 32mm. One when vetral access is used and one for dorsal access.

The mark "MEDIAL" indicates the proper alignment of the instrument in respect to the patient. Visualization of the two holes in the trial indicate on a true lateral x-ray that the trial is in the correct position, i.e. 30° in the sagittal plane. The medial mark on the instrument indicates correct alignment.



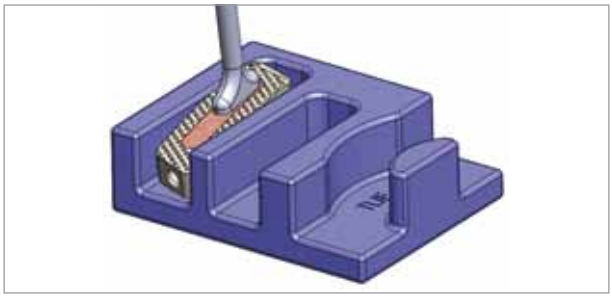
Select the size of the trial implant as determined during preoperative templating and confirmed intraoperatively by fluoroscopy and attach it to the Cage Inserter. Insert the trial implant into the disc space by light impaction and confirm the proper position with the aid of anterior-posterior and lateral fluoroscopy.
If the trial implant is too loose or too tight, try the next larger/smaller size until a secure fit is achieved. Using the largest possible implant improves stability by creating tension on the ligaments and the annulus fibrosus.

Remove the trial implant assembly and select the matching implant. If necessary, the slap hammer is available to assist in safe removal of the trial implant.

6.3 Implant Placement Transforaminal/Oblique

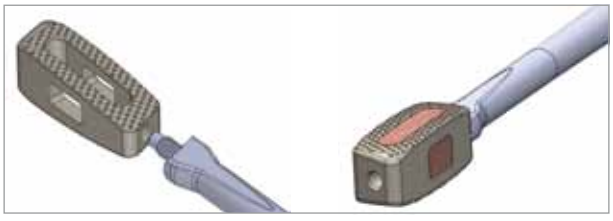
Prepare autologous bone graft and freshly aspirated bone marrow; place it anteriorly and contralaterally before inserting the implant.

Gently pack bone graft into the opening of the carefully selected cage using the filler block and bone tamp.



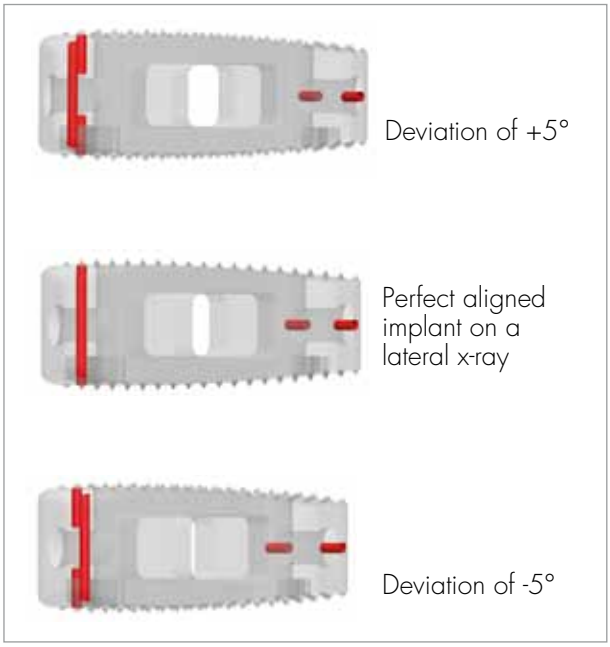
Different shapes of bone graft impactors are available in the set.

Attach the cage perpendicular to the Cage Inserter by screwing the thread of the inner shaft into the threaded hole and secure it firmly. Ensure that the orientation of the implant is correct (see illustration). The cylindrical guiding tip on the inserter simplifies the engaging of the instrument.



Insert the implant into the intervertebral disc space by gentle impaction. Protect the nerve root with a suitable instrument. If necessary tap lightly the implant into position with the cage impactor and the hammer.

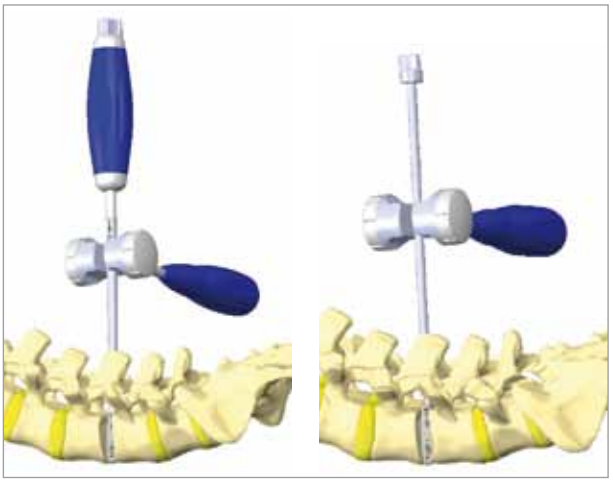
Check the position of the implant with the image intensifier. Remove the instrument if the implant is in satisfactory position. The broken line marker indicates the deviation of the implant position (see below).



Use bone tamp to pack graft material into disc space around the implant.
To achieve satisfactory immobilization of the grafted interbody space compression on the additional posterior fixation with a pedicle screw system is recommended.

7 REMOVAL OF AN INCORRETLY PLACED IMPLANT

Attach the Cage Inserter perpendicular to the implant and remove the implant from its site. If necessary, the slap hammer is available to assist in safe removal of the implant.



For any further information related to the MectaLIF® Intervertebral Body Fusion Devices please refer to the package insert.

The MectaLIF® Posterior and the MectaLIF® Oblique are supplied sterile in single-use packages; it should never be reimplanted.

8 INSTRUMENTATION NOMENCLATURE

GENERAL INSTRUMENTATION SET - TRAY N° 1

Ref.	Description	
03.22.10.0011	MectaLIF® Posterior Inserter	
03.22.10.0012	MectaLIF® Oblique Inserter	
03.22.10.0013	Bone Filler Block	
03.22.10.0014	Hammer	
03.22.10.0017	MectaLIF® Posterior Implant Impactor	
03.22.10.0018	MectaLIF® Oblique Implant Impactor	
03.22.10.0019	Strait Bone Graft Impactor	
03.22.10.0020	Curved Bone Graft Impactor	
03.22.10.0021	Angled Bone Graft Impactor	
03.22.10.0022	Flat Bone Graft Impactor	
03.22.10.0050	Implant Remover	

Ref.	Description	
03.22.10.0001	MectaLIF® Posterior Trial, 7 mm, 5°	
03.22.10.0002	MectaLIF® Posterior Trial, 9 mm, 5°	
03.22.10.0003	MectaLIF® Posterior Trial, 11 mm, 5°	
03.22.10.0004	MectaLIF® Posterior Trial, 13 mm, 5°	
03.22.10.0005	MectaLIF® Posterior Trial, 15 mm, 5°	
03.22.10.0006	MectaLIF® Oblique Trial, 7 mm, 0°	
03.22.10.0007	MectaLIF® Oblique Trial, 9 mm, 5°	
03.22.10.0008	MectaLIF® Oblique Trial, 11 mm, 5°	
03.22.10.0009	MectaLIF® Oblique Trial, 13 mm, 5°	
03.22.10.0010	MectaLIF® Oblique Trial, 15 mm, 5°	
03.22.10.0029	Implant Tray	
03.22.10.0300	Instrument Tray	
03.22.10.0054	Trial Cady	5° Trials
03.22.10.0051[i]	Addendum Trial Cady	0° and 10° Trials
03.22S.001	Instrument Set	MectaLIF® Posterior & MectaLIF® Oblique
03.22S.002	Instrument Set	MectaLIF® Posterior
03.22S.003	Instrument Set	MectaLIF® Oblique

MectaLIF® Posterior 0° AND 10° TRIALS [i]

Ref.	Description
03.22.10.0051	Addendum Trial Cady
03.22.10.0030	MectaLIF® Posterior Trial, 7 mm, 0°
03.22.10.0031	MectaLIF® Posterior Trial, 9 mm, 0°
03.22.10.0032	MectaLIF® Posterior Trial, 11 mm, 0°
03.22.10.0033	MectaLIF® Posterior Trial, 13 mm, 0°
03.22.10.0034	MectaLIF® Posterior Trial, 15 mm, 0°
03.22.10.0036	MectaLIF® Posterior Trial, 9 mm, 10°
03.22.10.0037	MectaLIF® Posterior Trial, 11 mm, 10°
03.22.10.0038	MectaLIF® Posterior Trial, 13 mm, 10°
03.22.10.0039	MectaLIF® Posterior Trial, 15 mm, 0°

MectaLIF® Oblique 0° AND 10° TRIALS [i]

Ref.	Description
03.22.10.0041	MectaLIF® Oblique Trial, 9 mm, 0°
03.22.10.0042	MectaLIF® Oblique Trial, 11 mm, 0°
03.22.10.0043	MectaLIF® Oblique Trial, 13 mm, 0°
03.22.10.0044	MectaLIF® Oblique Trial, 15 mm, 0°
03.22.10.0048	MectaLIF® Oblique Trial, 13 mm, 10°
03.22.10.0049	MectaLIF® Oblique Trial, 15 mm, 10°

[i] On request

9 IMPLANTS NOMENCLATURE

MectaLIF® Oblique

Code	Size	Lordosis	Color
03.20.001	12x32x7 mm	0°	Light Blue
03.20.002	12x32x9 mm	0°	Violet
03.20.003	12x32x11 mm	0°	Gold
03.20.004	12x32x13 mm	0°	Dark Blue
03.20.005	12x32x15 mm	0°	Dark Green
03.20.006	12x32x9 mm	5°	Violet
03.20.007	12x32x11 mm	5°	Gold
03.20.008	12x32x13 mm	5°	Dark Blue
03.20.009	12x32x15 mm	5°	Dark Green
03.20.010	12x32x13 mm	10°	Dark Blue
03.20.011	12x32x15 mm	10°	Dark Green
03.20.012	12x36x7 mm	0°	Light Blue
03.20.013	12x36x9 mm	0°	Violet
03.20.014	12x36x11 mm	0°	Gold
03.20.015	12x36x13 mm	0°	Dark Blue
03.20.016	12x36x15 mm	0°	Dark Green
03.20.017	12x36x9 mm	5°	Violet
03.20.018	12x36x11 mm	5°	Gold
03.20.019	12x36x13 mm	5°	Dark Blue
03.20.020	12x36x15 mm	5°	Dark Green
03.20.021	12x36x13 mm	10°	Dark Blue
03.20.022	12x36x15 mm	10°	Dark Green

On request

Code	Size	Lordosis	Color
03.20.023	12x40x7 mm	0°	Light Blue
03.20.024	12x40x9 mm	0°	Violet
03.20.025	12x40x11 mm	0°	Gold
03.20.026	12x40x13 mm	0°	Dark Blue
03.20.027	12x40x15 mm	0°	Dark Green
03.20.028	12x40x9 mm	5°	Violet
03.20.029	12x40x11 mm	5°	Gold
03.20.030	12x40x13 mm	5°	Dark Blue
03.20.031	12x40x15 mm	5°	Dark Green
03.20.032	12x40x13 mm	10°	Dark Blue
03.20.033	12x40x15 mm	10°	Dark Green

MectaLIF® Posterior

Code	Size	Lordosis	Color
03.21.001	11x22x7 mm	0°	Light Blue
03.21.002	11x22x9 mm	0°	Violet
03.21.003	11x22x11 mm	0°	Gold
03.21.004	11x22x13 mm	0°	Dark Blue
03.21.005	11x22x15 mm	0°	Dark Green
03.21.006	11x22x7 mm	5°	Light Blue
03.21.007	11x22x9 mm	5°	Violet
03.21.008	11x22x11 mm	5°	Gold
03.21.009	11x22x13 mm	5°	Dark Blue
03.21.010	11x22x15 mm	5°	Dark Green
03.21.011	11x22x9 mm	10°	Violet
03.21.012	11x22x11 mm	10°	Gold
03.21.013	11x22x13 mm	10°	Dark Blue
03.21.014	11x22x15 mm	10°	Dark Green
03.21.015	11x25x7 mm	0°	Light Blue
03.21.016	11x25x9 mm	0°	Violet
03.21.017	11x25x11 mm	0°	Gold
03.21.018	11x25x13 mm	0°	Dark Blue
03.21.019	11x25x15 mm	0°	Dark Green
03.21.020	11x25x7 mm	5°	Light Blue
03.21.021	11x25x9 mm	5°	Violet
03.21.022	11x25x11 mm	5°	Gold
03.21.023	11x25x13 mm	5°	Dark Blue
03.21.024	11x25x15 mm	5°	Dark Green
03.21.025	11x25x9 mm	10°	Violet
03.21.026	11x25x11 mm	10°	Gold
03.21.027	11x25x13 mm	10°	Dark Blue
03.21.028	11x25x15 mm	10°	Dark Green

10 RECOMMENDED FIXATION OPTIONS

Supplemental internal fixation e.g. pedicle screw fixation must be applied.

Part numbers subject to change.

NOTE FOR STERILIZATION

Note for sterilization: the instrumentation is not sterile upon delivery. It must be cleaned before use and sterilized in an autoclave respecting the regulations of the country, EU directives where applicable and following the instructions for use of the autoclave manufacturer.
For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilization of Medacta® International reusable orthopedic devices" available at www.medacta.com.

Medacta International SA
Strada Regina - 6874 Castel San Pietro
Switzerland
Phone +41 91 696 60 60
Fax +41 91 696 60 66
info@medacta.ch

DISTRIBUTED BY

Medacta USA
4725 Calle Quetzal Suite B - Camarillo
California 93012
Phone +1 805 437 7085
Fax +1 805 437 7089
info@medacta.us.com

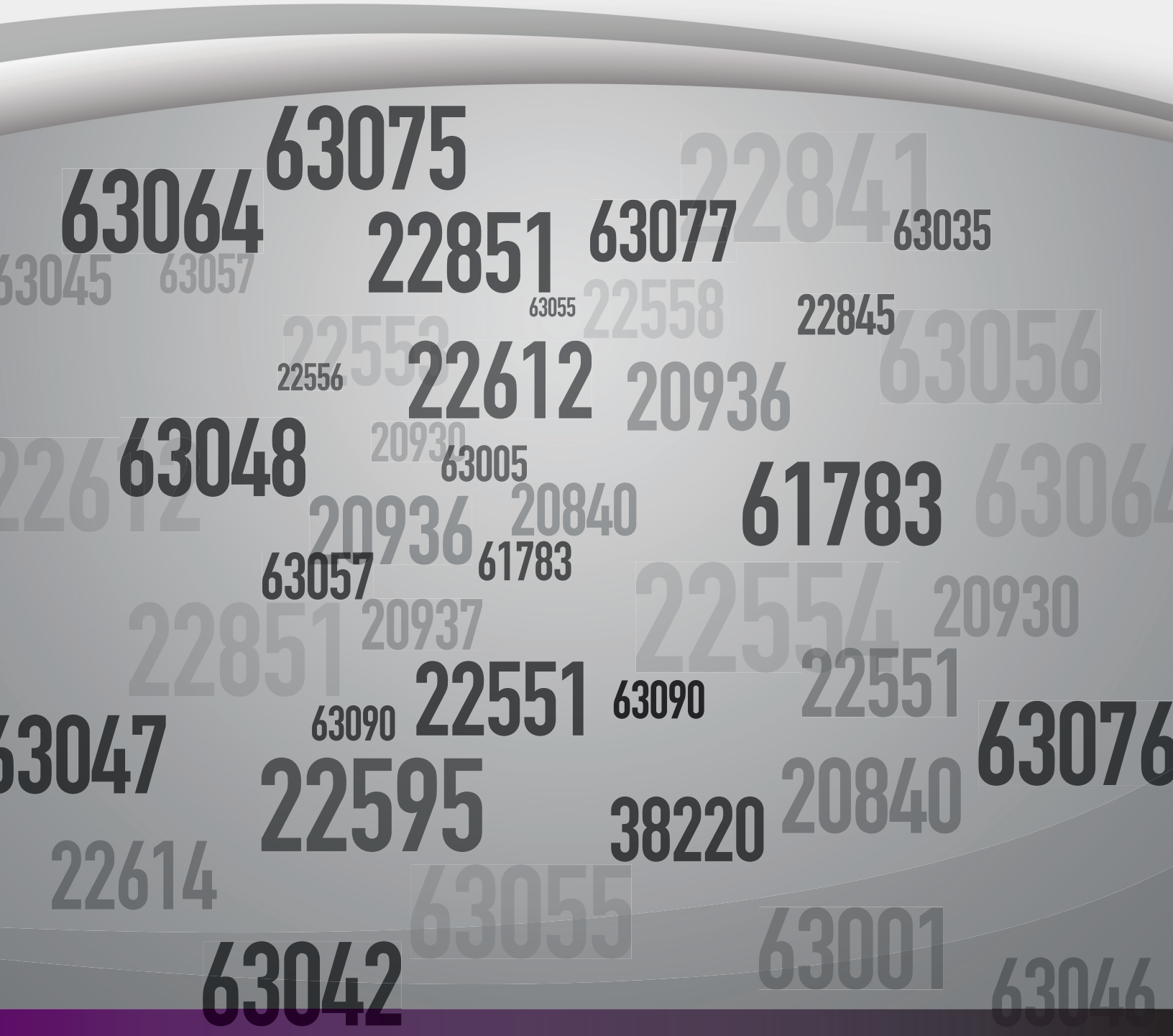
MectaLIF® Oblique
MectaLIF® Posterior
Surgical Technique
ref: 99.44.12US
rev. 00

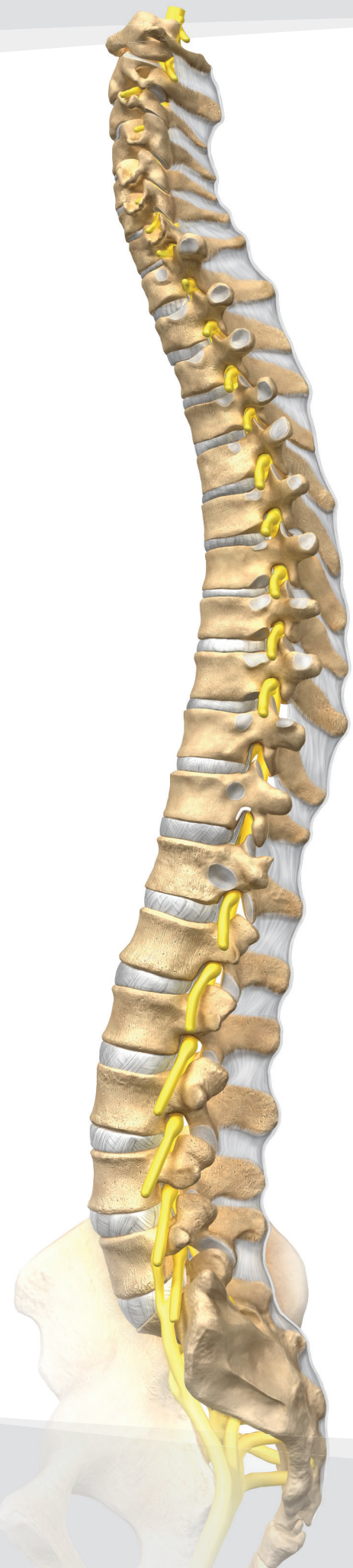
APPENDIX I

NUVASIVE
Speed of Innovation

2014

Reimbursement Guide





2014

Reimbursement Guide

CONTENTS

2014 Reimbursement Guide

I. INTRODUCTION

This Reimbursement Guide has been prepared to assist physicians and facilities ("providers") in accurately billing for NuVasive® implants and instrumentation systems. The NuVasive corporate headquarters houses a state-of-the-art education center and cadaver operating lab, designed to provide training and education to physicians on these technologies.

This information details our general understanding of the application of certain codes to NuVasive products. It is the provider's responsibility to determine and submit appropriate codes, charges, and modifiers for the products and services rendered. Payors may have additional or different coding and reimbursement requirements. Therefore, before filing any claim, providers should verify these requirements in writing with local payors. For more information, visit **www.nuvasive.com**.

Spine Reimbursement Support

800-211-0713 or **reimbursement@nuvasive.com**

Working with professional medical societies and legislators, NuVasive has taken an active role regarding reimbursement for spine products and procedures. To assist providers with coding and denial issues, NuVasive established Spine Reimbursement Support assistance, available at **800-211-0713** or **reimbursement@nuvasive.com**. Please use this resource for reimbursement questions regarding any of the NuVasive products and associated procedures.

II. PHYSICIAN CODING AND PAYMENT

When physicians bill for services performed, payors require the physician to assign a Current Procedural Terminology (or CPT®) code to classify or identify the procedure performed. These CPT codes are created and maintained by the American Medical Association (AMA) and are reviewed and revised on an annual basis. The most commonly used CPT codes are referred to as Category I codes and are five-digit codes accompanied by narrative descriptions.

The AMA assigns a number of relative value units (or RVUs) to most CPT codes to represent the physician work, malpractice costs, and practice expenses associated with a given procedure or service. Medicare annually revises a dollar conversion factor that, when multiplied by the code's RVUs, results in the national Medicare reimbursement for that procedure. Most private payors also consider a code's RVUs when establishing physician fee schedules.

Industrial or work-related injury cases are usually paid according to state-established fee schedules or percentage of billed charges. A state-appointed agency or private third party payors handle administration of workers' compensation benefits and claims.

1. FUSION FACILITATING TECHNOLOGIES

The following CPT codes are generally used to report a decompression and/or arthrodesis procedures. The codes listed here are examples only, not an exhaustive listing. It is always the physician's responsibility to determine and submit appropriate codes, charges, and modifiers for the services that were rendered.

CPT CODING FOR ARTHRODESIS USING THE NUVASIVE® MAXCESS® SYSTEM

NASS provided coding guidance for physicians when performing a fusion through an anterolateral approach. During an XLIF® lateral approach procedure, the patient is typically positioned laterally in order to spread the abdominal muscles to approach the lumber spine via a retroperitoneal exposure. The iliopsoas muscle is either split or mobilized to access the anterior spine from the lateral approach. The target of this approach is the vertebral body and anterior interspace. The physician is therefore performing an anterior fusion through an anterolateral approach. For this reason, NASS recommended the use of the anterior arthrodesis CPT code 22558, as well as the applicable instrumentation code(s) to describe the procedure.

When obtaining preauthorization for this procedure, please keep the following key points in mind:

- Include trade names of the devices to ensure appropriate review by payors. Payors may establish coverage criteria based on the specific devices/approach. In addition, utilize recognized correct coding nomenclature.
- Medical necessity for the fusion must be established through relevant patient diagnosis codes.
- Preauthorization should be requested for all relevant procedure codes for the case (e.g., anterior arthrodesis, posterior arthrodesis, instrumentation, graft material, nerve monitoring, etc.).

2014 Reimbursement Guide

Decompression Procedure Codes

CPT® CODE[1]	MODIFIER (IF WARRANTED)	PROCEDURE DESCRIPTION
63001		Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; cervical
63003		Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; thoracic
63005		Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis
63015		Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; cervical
63016		Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; thoracic
63017		Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; lumbar
63020	-50	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical
63030	-50	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar
63035	-50	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
63040	-50	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, re-exploration, single interspace; cervical
63042	-50	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, re-exploration, single interspace; lumbar
63043		Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, re-exploration, single interspace; each additional cervical interspace (List separately in addition to code for primary procedure)
63044	-50	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, re-exploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)
63045		Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), single vertebral segment; cervical

Decompression Procedure Codes (cont.)

CPT® CODE[1]	MODIFIER (IF WARRANTED)	PROCEDURE DESCRIPTION
63046		Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; thoracic
63047		Laminectomy, facetectomy and foraminotomy, (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar
63048		Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)
63055		Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; thoracic
63056		Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; lumbar (including transfacet or lateral extraforaminal approach) (e.g., far lateral herniated intervertebral disc)
63057		Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (List separately in addition to code for primary procedure)
63064		Costovertebral approach with decompression of spinal cord or nerve root(s) (e.g., herniated intervertebral disc), thoracic; single segment
63075		Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace
63076		Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (List separately in addition to code for primary procedure)
63077		Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; thoracic, single interspace
63078		Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; thoracic, each additional interspace (List separately in addition to code for primary procedure)
63081		Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment
63082		Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, each additional segment (List separately in addition to code for primary procedure)
63085		Vertebral corpectomy (vertebral body resection), partial or complete, transthoracic approach with decompression of spinal cord and/or nerve root(s); thoracic, single segment

2014 Reimbursement Guide

Decompression Procedure Codes (cont.)

CPT® CODE[1]	MODIFIER (IF WARRANTED)	PROCEDURE DESCRIPTION
63086		Vertebral corpectomy (vertebral body resection), partial or complete, transthoracic approach with decompression of spinal cord and/or nerve root(s); thoracic, each additional segment (List separately in addition to code for primary procedure)
63087		Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; single segment
63088		Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; each additional segment (List separately in addition to code for primary procedure)
63090		Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; single segment
63091		Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; each additional segment (List separately in addition to code for primary procedure)

Spine Arthrodesis and Arthroplasty Procedure Codes

PROCEDURE	CPT® CODE[1]	PROCEDURE DESCRIPTION
POSTERIOR FUSION	22595	Arthrodesis, posterior technique, atlas-axis (C1-C2)
	22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below C2 segment
	22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic, with lateral transverse technique, *when performed*
	22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar, with lateral transverse technique, *when performed*
	22614	Each additional vertebral segment (List separately in addition to code for primary procedure).
	0334T	Sacroiliac joint stabilization for arthrodesis, percutaneous or minimally disruptive (indirect visualization), includes obtaining and applying autograft or allograft (structured or morselized), when performed, includes image guidance when preformed (e.g., CT or fluoroscopic)
PLIF or TLIF	22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
	22632	Each additional interspace (List separately in addition to code for primary procedure)
ANTERIOR FUSION	22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy, and decompression of spinal cord and/or nerve root(s); cervical below C2
	22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)
	22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
	22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
	22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
	22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace
	22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1.
	0309T	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft, when performed, lumbar L4-L5 interspace

2014 Reimbursement Guide

Spine Arthrodesis and Arthroplasty Procedure Codes (cont.)

PROCEDURE	CPT® CODE[1]	PROCEDURE DESCRIPTION
COMBINED FUSION	22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique, including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression); single interspace and segment, lumbar (Do not report with 22612 or 22630 at the same level)
	22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique, including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression); each additional interspace and segment, lumbar (Do not report with 22612 or 22630 at the same level) (List separately in addition to code for primary procedure) (Use 22634 in conjunction with 22633)
CERVICAL DISC ARTHROPLASTY	22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical (Do not report 22856 in conjunction with 22554, 22845, 22851, 63075 when performed at the same level) (Do not report 22856 in conjunction with 69990) (For additional interspace cervical total disc arthroplasty, use 0092T)
	22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical (Do not report 22861 in conjunction with 22845, 22851, 22864, 63075 when performed at the same level) (Do not report 22861 in conjunction with 69990)
	22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical 22864 in conjunction with 22861, 69990) (For additional interspace removal of cervical total disc arthroplasty, use 0095T)

Grafting and Lumbar Instrumentation Procedure Codes

PROCEDURE	CPT® CODE[1]	PROCEDURE DESCRIPTION
ALLOGRAFT & AUTOGRAFT	20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)
	20931	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)
	20936	Autograft for spine surgery only (includes harvesting the graft); local (e.g., ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)
	20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
	20938	Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
POSTERIOR INSTRUMENTATION	0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar
	22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
	22841	Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
	22842	Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
	22843	Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
	22844	Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (List separately in addition to code for primary procedure)
ANTERIOR INSTRUMENTATION	22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
	22846	Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)
	22847	Anterior instrumentation; 8 or more vertebral segments (List separately in addition to code for primary procedure)
INTERVERTEBRAL DEVICES	22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)

2014 Reimbursement Guide

Surgical Modifiers in Spine Surgery

The following are surgical modifiers that may be used by spine surgeons to describe specific surgical circumstances.

Surgical Session or Same Day Modifiers

These modifiers are appended to indicate a specific circumstance that occurred during a surgical procedure or the same day as a surgical procedure.

Modifier 22 Increased Procedural Services

When the work required to provide a service is substantially greater than typically required, the service may be identified by adding modifier 22 to the usual procedure code. Documentation must support the substantial additional work and the reason for the additional work (i.e., increased intensity, time, technical difficulty of procedure, severity of patient's condition, physical and mental effort required). **Note:** This modifier should not be appended to an E/M service.

Modifier 50 Bilateral Procedure

Unless otherwise identified in the listings, bilateral procedures that are performed at the same session should be identified by adding modifier 50 to the appropriate 5-digit code.

Modifier 51 Multiple Procedures

When multiple procedures, other than E/M services, Physical Medicine and Rehabilitation services or provision of supplies (e.g., vaccines), are performed at the same session by the same provider, the primary procedure or service may be reported as listed. The additional procedure(s) or service(s) may be identified by appending modifier 51 to the additional procedure(s) or service code(s). **Note:** This modifier should not be appended to designated "add-on" codes.

Modifier 52 Reduced Services

Under certain circumstances, a service or procedure is partially reduced or eliminated at the physician's discretion. Under these circumstances, the service provided can be identified by its usual procedure number and the addition of modifier 52, signifying that the service is reduced. This provides a means of reporting reduced services without disturbing the identification of the basic service. **Note:** For hospital outpatient reporting of a previously scheduled procedure/service that is partially reduced or canceled as a result of extenuating circumstances, or those that threaten the well-being of the patient prior to or after administration of anesthesia, see modifiers 73 and 74.* (See modifiers approved for ambulatory surgery center (ASC)/outpatient hospital use.)

Modifier 53 Discontinued Procedure

Under certain circumstances, the physician may elect to terminate a surgical or diagnostic procedure. Due to extenuating circumstances or those that threaten the well-being of the patient, it may be necessary to indicate that a surgical or diagnostic procedure was started but discontinued. This circumstance may be reported by adding modifier 53 to the code reported by the physician for the discontinued procedure. **Note:** This modifier is not used to report the elective cancellation of a procedure prior to the patient's anesthesia induction and/or surgical preparation in the operating suite. For ASC/outpatient hospital reporting of a previously scheduled procedure/service that is partially reduced or canceled as a result of extenuating circumstances, or those that threaten the well-being of the patient prior to or after administration of anesthesia, see modifiers 73 and 74.* (See modifiers approved for ASC/outpatient hospital use.)

**For complete information on modifiers, see AMA CPT.*

Modifier 59 Distinct Procedural Service

Under certain circumstances, it may be necessary to indicate that a procedure or service was distinct or independent from other non-E/M services performed on the same day. Modifier 59 is used to identify procedures/services, (other than E/M services), that are not normally reported together, but are appropriate under the circumstances. Documentation must support a different session, different procedure or surgery, different site or organ system, separate incision/excision, separate lesion, or separate injury (or area of injury in extensive injuries) not ordinarily encountered or performed on the same day by the same individual. However, when another already established modifier is appropriate, it should be used rather than modifier 59. Only if no more descriptive modifier is available, and the use of modifier 59 best explains the circumstances, should modifier 59 be used. **Note:** Modifier 59 should not be appended to an E/M service. To report a separate and distinct E/M service with a non-E/M service performed on the same date, see modifier 25.*

**For complete information on modifiers, see AMA CPT.*

Modifier 76 Repeat Procedure or Service by Same Physician or Other Qualified Healthcare Professional

It may be necessary to indicate that a procedure or service was repeated by the same physician or other qualified healthcare professional subsequent to the original procedure or service. This circumstance may be reported by adding modifier 76 to the repeated procedure or service. **Note:** This modifier should not be appended to an E/M service.

Modifier 77 Repeat Procedure by Another Physician or Other Qualified Healthcare Professional

It may be necessary to indicate that a basic procedure or service was repeated by another physician or other qualified healthcare professional subsequent to the original procedure or service. This circumstance may be reported by adding modifier 77 to the repeated procedure or service. **Note:** This modifier should not be appended to an E/M service.

Global Period Modifiers

These modifiers are appended to a subsequent procedure performed during the global period of an original procedure.

Modifier 58 Staged or Related Procedure or Service by the Same Physician During the Postoperative Period

It may be necessary to indicate that the performance of a procedure or service during the postoperative period was: (a) planned or anticipated (staged); (b) more extensive than the original procedure; or (c) for therapy following a surgical procedure. This circumstance may be reported by adding modifier 58 to the staged or related procedure. **Note:** For treatment of a problem that requires a return to the operating/procedure room (e.g., unanticipated clinical condition), see modifier 78.

Modifier 78 Unplanned Return to the Operating/Procedure Room by the Same Physician or Other Qualified Healthcare Professional Following Initial Procedure for a Related Procedure During the Postoperative Period

It may be necessary to indicate that another procedure was performed during the postoperative period of the initial procedure (unplanned procedure following initial procedure). When this procedure is related to the first, and requires the use of an operating/procedure room, it may be reported by adding modifier 78 to the related procedure. (For repeat procedures, see modifier 76.)

Modifier 79 Unrelated Procedure or Service by the Same Physician During the Postoperative Period

The physician may need to indicate that the performance of a procedure or service during the postoperative period was unrelated to the original procedure. This circumstance may be reported by using modifier 79. (For repeat procedures on the same day, see modifier 76.)

Modifier 76 Repeat Procedure or Service by Same Physician or Other Qualified Healthcare Professional

It may be necessary to indicate that a procedure or service was repeated by the same physician or other qualified healthcare professional subsequent to the original procedure or service. This circumstance may be reported by adding modifier 76 to the repeated procedure or service. **Note:** This modifier should not be appended to an E/M service.

Modifier 77 Repeat Procedure by Another Physician or Other Qualified Healthcare Professional

It may be necessary to indicate that a basic procedure or service was repeated by another physician or other qualified healthcare professional subsequent to the original procedure or service. This circumstance may be reported by adding modifier 77 to the repeated procedure or service. **Note:** This modifier should not be appended to an E/M service.

Surgeon Role Modifiers

These modifiers are used when more than one surgeon participates in a surgical procedure.

Modifier 62 Two Surgeons

When 2 surgeons work together as primary surgeons performing distinct part(s) of a procedure, each surgeon should report his/her distinct operative work by adding modifier 62 to the procedure code and any associated add-on code(s) for that procedure, as long as both surgeons continue to work together as primary surgeons. Each surgeon should report the co-surgery once, using the same procedure code. If additional procedure(s), (including add-on procedure(s)), are performed during the same surgical session, separate code(s) may also be reported with modifier 62 added. **Note:** If a co-surgeon acts as an assistant in the performance of additional procedure(s) during the same surgical session, those services may be reported using separate procedure code(s) with modifier 80 or modifier 82 added, as appropriate.

Modifier 80 Assistant Surgeon

Surgical assistant services may be identified by adding modifier 80 to the usual procedure number(s).

Modifier 81 Minimum Assistant Surgeon

Minimum surgical assistant services are identified by adding modifier 81 to the usual procedure number.

Modifier 82 Assistant Surgeon (when qualified resident surgeon not available)

The unavailability of a qualified resident surgeon is a prerequisite for use of modifier 82, appended to the usual procedure code number(s).

2. NVM5® INTRAOPERATIVE MONITORING SYSTEM

For coding and billing information regarding physician-driven intraoperative monitoring during spinal surgery, please see the *2014 NVM5 Intraoperative Monitoring (IOM) Reimbursement Guide* (9501261 A).

Medicare Note:

In April 2004, CMS (Centers for Medicare & Medicaid Services) issued Correct Coding Initiative (CCI) edits for the nerve monitoring codes listed in the *2014 NVM5 Intraoperative Monitoring (IOM) Reimbursement Guide* (9501261 A). The edits indicate that nerve monitoring codes are to be bundled into ALIF, PLIF, and TLIF procedure codes in Section III when the primary spine physician is performing both services. Medicare does not reimburse the operative physician for physician-driven intraoperative monitoring when performing the arthrodesis procedure.

Additionally, general coding guidelines do not allow the operating surgeon, assistant surgeon, or co-surgeon to separately report intraoperative neuromonitoring.

- The American Medical Association (AMA) deleted CPT® code 95920 and replaced it with CPT codes 95940 and 95942. CPT codes 95940 and 95941 represent the IOM component of the study/studies and are add-on codes. CPT code 95940 or 95941 must always be billed together with the primary nerve monitoring procedure code.
  CPT code 95940: continuous IOM in the O.R., one-on-one monitoring requiring personal attendance, each 15 minutes.
  CPT code 95941: continuous IOM from outside the O.R. (remote or nearby) or for monitoring of more than one case while in the O.R., per hour.
- Additionally for Medicare cases, CMS invalidated CPT code 95941 and replaced it with HCPCS code G0453, which allows the remote physician to monitor one case at a time.
  HCPCS code G0453: continuous IOM from outside the O.R. (remote or nearby), per patient (attention directed exclusively to one patient), each 15 minutes.
- Prior to January 1, 2011, CPT code 61795 was used to describe intracranial, extracranial, or spinal navigation procedures.
- CPT code 61795 was deleted and code 61783 now covers spine procedures specifically, with codes 61781 and 61782 for intracranial and extracranial procedures, respectively.
- Below are some key descriptors of CPT code 61783:
  - Includes spinal applications, which allows for navigation using a stereotactic technique to identify anatomy for precise treatments and for avoidance of vital structures.
  - The application of the procedure is to help identify anatomy, and more specifically, to aid with instrument placement. Primary fusion procedure codes where pedicle screws are inserted to facilitate fusion are appropriate if covered by the payor.
  - Not applicable for spinal decompression for degenerative spine disease or disc replacement (codes 63030, 63042, 63047). Exceptions could include tumor-related surgeries.
  - Possible primary codes include: 22600, 22610, and 22612.

NVM5® Computer-Assisted Surgery Applications

- NVM5 Guidance aids physicians in the placement of pedicle screws through pre-planned angle measurements and integrated EMG information.

NVM5 COMPUTER-ASSISTED SURGERY PRIMARY CODE				
CPT	**DESCRIPTION**	**2014 CONVERSION FACTOR**	**RVU**	**NATIONAL MEDICARE COVERAGE**
61783	Stereotactic computer-assisted (navigational) procedure; spinal (List separately in addition to code for primary procedure)	$34.023	6.91	$235.10

III. HOSPITAL INPATIENT CODING AND PAYMENT

Payment under Medicare for inpatient hospital services is based on a classification system determined by patient diagnosis known as Medicare Severity – Diagnosis Related Groups (MS-DRGs). Under MS-DRGs, a hospital is paid at a predetermined, specific rate for each Medicare discharge. Fixed prices are established for hospital services, based on the patient diagnosis(es) and procedure(s) performed and are paid regardless of the actual cost the hospital incurs when providing the services.

MS-DRGs take into consideration length of stay, the number of services provided, and the intensity of services. The system was designed to give hospitals incentives to provide care more efficiently and appropriately document patient diagnoses and procedures performed.

Only one MS-DRG is assigned to a patient for a particular hospital admission, and determined by ICD-9-CM diagnoses and procedure codes.

2014 Reimbursement Guide

1. NUVASIVE® TECHNOLOGY
Possible ICD-9-CM Procedure Codes

The following ICD-9-CM procedure codes are often used to report a decompression and/or arthrodesis procedure. These procedures often include the use of the NuVasive MaXcess® system for surgical access and various NuVasive spine instruments. It is always the hospital's responsibility to determine and submit appropriate codes and modifiers for the services that were rendered.

ICD-9-CM PROCEDURE CODE	DESCRIPTION
	DECOMPRESSION
80.51	Excision of intervertebral disc
03.09	Other exploration and decompression of spinal canal
	FUSION, ARTHROPLASTY, INSTRUMENTATION, AND GRAFTING
81.00	Spinal fusion, not otherwise specified
81.01	Atlas-axis spinal fusion
81.02	Other cervical fusion, anterior technique
81.03	Other cervical fusion, posterior technique
81.04	Dorsal and dorsolumbar fusion, anterior technique
81.05	Dorsal and dorsolumbar fusion, posterior technique
81.06*	Lumbar and lumbosacral fusion, anterior technique
81.07	Lumbar and lumbosacral fusion, lateral transverse process technique
81.08	Lumbar and lumbosacral fusion, posterior technique
81.32	Refusion of other cervical spine, anterior technique
81.33	Refusion of other cervical spine, posterior technique
81.34	Refusion of dorsal and dorsolumbar spine, anterior technique
81.35	Refusion of dorsal and dorsolumbar spine, posterior technique
81.36	Refusion of lumbar and lumbosacral spine, anterior technique
81.37	Refusion of lumbar and lumbosacral spine, lateral transverse process technique
81.38	Refusion of lumbar and lumbosacral spine, anterior column posterior technique
81.62	Fusion or refusion of 2-3 vertebrae
81.63	Fusion or refusion of 4-8 vertebrae
81.64	Fusion or refusion of 9 or more vertebrae
84.62	Insertion of total spinal disc prosthesis, cervical
84.66	Revision or replacement of artificial spinal disc prosthesis, cervical
	INSTRUMENTATION AND GRAFTING
77.79	Excision of other bone for graft, except fascial bones
84.51	Insertion of interbody fusion device
84.55	Insertion of bone void filler
84.59	Insertion of other spinal devices
	INTRAOPERATIVE NERVE MONITORING
00.94	Intraoperative neurophysiologic monitoring

**The American Hospital Association's Coding Clinic Fourth Quarter 2010 edition identified XLIF® in the index of procedures reported using 81.06: Lumbar and lumbosacral fusion, anterior technique.*

1. NUVASIVE® TECHNOLOGY

Possible ICD-9-CM Procedure Codes (CONT.)

ICD-9-CM PROCEDURE CODE	DESCRIPTION
	SPINAL NAVIGATION
00.31	Computer-assisted surgery with CT/CTA
00.32	Computer-assisted surgery with MR/MRA
00.33	Computer-assisted surgery with fluoroscopy
00.34	Imageless computer-assisted surgery
00.35	Computer-assisted surgery with multiple datasets
00.39	Other computer-assisted surgery

MS-DRGs

The MS-DRGs most likely to be applicable for reporting a spine procedure utilizing NuVasive technology are:

MS-DRG[2]	DESCRIPTION	FY2014 SPINAL MS-DRG AND MEDICARE UNADJUSTED PAYMENT
	LAMINECTOMY/DISCECTOMY/DISC ARTHROPLASTY	
490	Back and Neck Procedures Except Spinal Fusion with CC and MCC or Disc Device/Neurostimulator	$10,929
491	Back and Neck Procedures Except Spinal Fusion without CC and MCC	$6,317
	ANTERIOR/POSTERIOR FUSION	
453	Combined Anterior/Posterior Spinal Fusion with MCC (360)	$68,118
454	Combined Anterior/Posterior Spinal Fusion with CC	$46,513
455	Combined Anterior/Posterior Spinal Fusion without CC and MCC	$36,469
	COMPLEX FUSION	
456	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or 9+ Fusions with MCC	$55,601
457	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or 9+ Fusions with CC	$39,546
458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, or 9+ Fusions without CC and MCC	$29,797
	LUMBAR FUSION	
459	Spinal Fusion Except Cervical with MCC	$39,532
460	Spinal Fusion Except Cervical without MCC	$23,327
	CERVICAL FUSION	
471	Cervical Spinal Fusion with MCC	$28,675
472	Cervical Spinal Fusion with CC	$16,986
473	Cervical Spinal Fusion without CC and MCC	$13,025

2. NON-MEDICARE REIMBURSEMENT

Many commercial payors reimburse hospitals using Medicare DRGs and associated payment rates as benchmarks for contracted rates while others reimburse on a per diem basis. Disposables, implants, or instrumentation associated with NuVasive® products generally are coded under Revenue Code 270: Medical/Surgical Supplies, 272: Sterile Medical/Surgical Supplies, or 278: Medical/Surgical Supplies and Devices, Other Implants. Payment will be according to the terms of the payor contract. For HCPCS codes (including C-codes) that may be relevant to NuVasive technology, see Section IV4 on page 17.

IV. OUTPATIENT FACILITY CODING AND PAYMENT

1. HOSPITAL OUTPATIENT

A procedure is considered to be performed in a hospital outpatient department when the procedure is performed in a facility that is administratively and financially linked to a hospital and the patient is registered at the hospital, but not admitted as an inpatient.

The Outpatient Prospective Payment System (OPPS) groups procedures into Ambulatory Payment Classifications (APCs).

- Each APC encompasses services that are clinically similar and require similar resources.
- APCs group together services, supplies, drugs, and devices that are used in particular procedures.
- Each APC has a separate payment rate that is meant to account for all of the items used in the procedure.
- Each APC is assigned a relative payment weight, based on the median costs of the services within the APC.
- A hospital receives multiple APC payments for a single visit if multiple services are delivered in that visit.
- Transitional pass-through payments have been established for certain approved "new or innovative medical devices" and allow for additional payment outside the APC.
- Many private payors use the APC payment rates established by Medicare to determine contracted rates with hospitals.

Decompression and Arthrodesis Codes

Under the Medicare OPPS, the following decompression CPT® codes map to the corresponding APC. When more than one procedure code is submitted, each additional APC is subject to multiple procedure reduction payments. For 2014, Medicare has bundled procedure payment for add-on codes into payment for the primary procedure.

CPT CODE[1]	APC[3]	APC DESCRIPTION	2014 NATIONAL MEDICARE AVERAGE REIMBURSEMENT[2]
63001	0208	Laminotomies and Laminectomies	$4,003.31
63005	0208	Laminotomies and Laminectomies	$4,003.31
63015	0208	Laminotomies and Laminectomies	$4,003.31
63017	0208	Laminotomies and Laminectomies	$4,003.31
63020	0208	Laminotomies and Laminectomies	$4,003.31
63030	0208	Laminotomies and Laminectomies	$4,003.31
63035	N/A	N/A	
63040	0208	Laminotomies and Laminectomies	$4,003.31
63042	0208	Laminotomies and Laminectomies	$4,003.31
63045	0208	Laminotomies and Laminectomies	$4,003.31
63046	0208	Laminotomies and Laminectomies	$4,003.31
63047	0208	Laminotomies and Laminectomies	$4,003.31
63048	N/A	N/A	
63055	0208	Laminotomies and Laminectomies	$4,003.31
63056	0208	Laminotomies and Laminectomies	$4,003.31
63057	N/A	N/A	
63064	0208	Laminotomies and Laminectomies	$4,003.31
63066	N/A	N/A	
63075	0208	Laminotomies and Laminectomies	$4,003.31
63076	N/A	N/A	
22551	0208	Laminotomies and Laminectomies	$4,003.31
22554	0208	Laminotomies and Laminectomies	$4,003.31
22612	0208	Laminotomies and Laminectomies	$4,003.31
22614	N/A	N/A	
22851	N/A	N/A	
22856	0208	Laminotomies and Laminectomies	$4,003.31

2. NON-MEDICARE REIMBURSEMENT

Commercial and work-related injury payors may reimburse fusion procedures on an outpatient basis. Facilities may choose to preauthorize (relative to benefits) prior to the procedure. Payors may allow additional payment for disposables, fixation, or instrumentation associated with procedures billed under Revenue Code 270: Medical/Surgical Supplies, 272: Sterile Medical/Surgical Supplies, or 278: Medical/Surgical Supplies and Devices, Other Implants. Payment will be according to the terms of the contract or as line item supplies at cost plus markup.

2014 Reimbursement Guide

3. AMBULATORY SURGERY CENTER

To be eligible to receive facility fees, a center must be certified and/or accredited as an Ambulatory Surgery Center (ASC).

Currently, none of the common procedures performed utilizing NuVasive® products are included on Medicare's list of approved procedures in an ASC. However, commercial and work-related injury payors may reimburse for these procedures in an ASC, which should obtain preauthorization of benefits to ensure that reimbursement is available. Some managed care payors and HMOs may use Medicare guidelines relative to site of service reimbursement. ASCs may use Revenue Code 270: Medical/Surgical Supplies, 272: Sterile Medical/Surgical Supplies, or 278: Medical/Surgical Supplies and Devices, Other Implants, for billing any disposables, instrumentation, or fixation associated with NuVasive technologies. Payment will be according to the terms of the contract, or as line item supplies at cost plus markup.

4. FACILITY DEVICE AND IMPLANT CODES

C-codes report drugs, biologicals, and devices eligible for transitional pass-through payments and for items classified in new technology Ambulatory Payment Classifications (APCs) under the Outpatient Prospective Payment System (OPPS).

The following information highlights certain product codes that may or may not be relevant to surgical cases performed using NuVasive products.

MASTER HCPCS SUPPLY LISTING[4]	
Surgical tray	A4550
Electrodes, per pair	A4556
Lead wires, per pair	A4557
Surgical supply, miscellaneous	A4649
Noncovered item or service	A9270
Anchor/Screw for opposing bone-to-bone or soft tissue-to-bone (implantable)	C1713
Connective tissue, non-human (includes synthetic)	C1763
Connective tissue, human	C1762
Prosthetic implant, not otherwise specified	L8699

REVENUE CODES[5]	
Medical/Surgical supplies	0270
Medical/Surgical supplies: Nonsterile supplies	0271
Medical/Surgical supplies: Sterile supplies	0272
Medical/Surgical supplies: Other implants	0278

1 *Current Procedural Terminology 2014, American Medical Association. Chicago, IL. CPT is a registered trademark of the American Medical Association. Current Procedural Terminology (CPT®) is copyright American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.*

2 *CMS FY2014 IPPS Final Rule; rates are not geographically adjusted.*

3 *CMS CY2014 OPPS Final Rule.*

4 *HCPCS codes are used for outpatient claims only and may or may not be reimbursed separately from the procedure payment.*

5 *Revenue codes are used on inpatient and outpatient claims for cost reporting. MS-DRG payments include the cost of all equipment and supplies associated with spine procedures.*

V. CODING AND PAYMENT SCENARIOS

The following scenarios provide examples of possible coding options when using NuVasive® technology. While each manufacturer has their own trademark or marketing names for various technology, it is important to use the appropriate clinical terminology when reporting procedures.

1. CERVICAL ANTERIOR SCENARIOS

a) Anterior cervical fusion, discectomy, and decompression, C5-C6, with NuVasive Helix ACP™ plate, structural allograft, and Osteocel® Cellular Allograft – Anterior cervical fusion and decompression (ACDF), anterior plate instrumentation, structural allograft, morselized allograft

CPT® CODE[1]	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2	81.02, 80.51	471, 472, or 473
22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)	Instrumentation is included in the fusion code.	N/A
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)	N/A	N/A
20931	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)	N/A	N/A

b) ACDF, C5-C6, with one of the NuVasive Helix ACP family of cervical plates – Anterior cervical discectomy, interbody fusion with a synthetic intervertebral device, anterior plate fixation, morselized allograft

CPT CODE	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2	81.02, 80.51	471, 472, or 473
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)	Instrumentation is included in the fusion code.	N/A
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)	N/A	N/A

c) ACDF, C5-C6, with NuVasive Helix ACP and CoRoent® Small and morselized autograft – Anterior cervical decompression, interbody fusion with a synthetic intervertebral device, and anterior plate fixation with morselized autograft from the iliac crest through a separate incision

CPT CODE	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2	81.02, 80.51	471, 472, or 473
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)	Instrumentation is included in the fusion code.	N/A
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)	77.79 Excision of bone for graft, other. Harvested from the iliac crest or locally.	N/A

2014 Reimbursement Guide

1. CERVICAL ANTERIOR SCENARIOS (CONT.)

d) ACDF, C5-C6, with CoRoent® Small Interlock™ and morselized autograft – Anterior cervical decompression, interbody fusion with a synthetic intervertebral device and morselized autograft from the iliac crest through a separate incision

CPT® CODE[1]	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2	81.02, 80.51	471, 472, or 473
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)	77.79 Excision of bone for graft, other. Harvested from the iliac crest or locally.	N/A

e) Cervical Disc Arthroplasty (CDA) with PCM® Cervical Disc

CPT CODE	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22856	Total disc arthroplasty (artificial disc) anterior approach, including discectomy to prepare interspace (other than for decompression) single interspace: cervical	81.62	490

2. CERVICAL POSTERIOR SCENARIOS

a) Posterior fusion with VuePoint® OCT and Osteocel® Cellular Allograft – Posterior cervical arthrodesis, C5-C6, using posterior non-segmental fixation and bone graft substitute

CPT CODE	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below C2 segment	81.03	471, 472, or 473
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)	Instrumentation is included in the fusion code.	N/A
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)	N/A	N/A

b) Cervical laminectomy and decompression, C5-C6, with Leverage® LFS fixation – Posterior cervical laminectomy, decompression, and fixation using posterior non-segmental instrumentation and bone marrow aspirated from the iliac crest through a separate fascial incision

CPT CODE	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
63001	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; cervical	03.09	490 or 491
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)	78.59	N/A
38220-59	Bone marrow, aspiration only	41.31	N/A

3. THORACOLUMBAR ANTERIOR SCENARIOS

a) Thoracic interbody fusion, T11-T12, through an anterolateral incision with grafting material – Anterior thoracic interbody arthrodesis with placement of a synthetic intervertebral device and an autograft from the same incision

CPT CODE[1]	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	81.04, 80.51	456, 457, 458, 459, or 460
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
20936	Autograft for spine surgery only (includes harvesting the graft); local (e.g., ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)	77.79 Excision of bone for graft, other. Harvested from the iliac crest or locally.	N/A

b) Lumbar fusion, L4-L5, through an anterior or anterolateral incision with CoRoent® XL, Triad,® and autograft – Anterior lumbar interbody fusion with placement of a synthetic intervertebral device and autograft obtained from the iliac crest through a separate incision

CPT CODE	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	80.51, 81.06	456, 457, 458, 459, or 460
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)	77.79 Excision of bone for graft, other. Harvested from the iliac crest or locally.	N/A
20931	Allograft, structural, for spine surgery only	N/A	N/A

2014 Reimbursement Guide

3. THORACOLUMBAR ANTERIOR SCENARIOS (CONT.)

c) Lumbar fusion, L4-L5, through an anterior or anterolateral incision with CoRoent® XL, Triad,® and XLIF Decade™ Plate, or CoRoent XLR, Triad, and Brigade® ALIF plate – Anterior lumbar interbody arthrodesis with placement of a synthetic intervertebral device, autograft obtained from the iliac crest through a separate incision, and an anterior plate

CPT® CODE[1]	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	80.51, 81.06	456, 457, 458, 459, or 460
22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)	Instrumentation is included in the fusion code.	N/A
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)	77.79 Excision of bone for graft, other. Harvested from the iliac crest or locally.	N/A
20931	Allograft, structural, for spine surgery only	N/A	N/A

d) Complete corpectomy, L2, and fusion through an anterior or anterolateral incision with X-CORE® and autograft (local) with Traverse® anterior plate – Corpectomy, anterior lumbar interbody fusion, L1-L2, L2-L3, placement of synthetic intervertebral devices, corpectomy defect, L1-L3, autograft from the same incision, and anterior plate

CPT CODE	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
63090	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; single segment	80.99	490 or 491
22558-51	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	81.06, 80.51	456, 457, 458, 459, or 460
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace	81.62	N/A
22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)	Instrumentation is included in the fusion code.	N/A
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
20936	Autograft for spine surgery only (includes harvesting the graft); local (e.g., ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)	77.79 Excision of bone for graft, other. Harvested from the iliac crest or locally.	N/A

3. THORACOLUMBAR ANTERIOR SCENARIOS (CONT.)

e) Costovertebral approach thoracic discectomy with X-CORE® Mini, autograft, and Osteocel® Cellular Allograft – Costovertebral thoracic discectomy, autograft, and morselized allograft

CPT® CODE[1]	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
63064	Costovertebral approach with decompression of spinal cord or nerve root(s) (e.g., herniated intervertebral disc), thoracic; single segment	03.09	490 or 491
20936	Autograft for spine surgery only (includes harvesting the graft); local (e.g., ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)	77.79 Excision of bone for graft, other. Harvested from the iliac crest or locally.	N/A
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)	N/A	N/A

f) Anterior fusion, L4-L5 through an anterior approach Brigade®-H and autograft, and PLF with Precept® or Spherx® DBR® III and Osteocel Cellular Allograft, with Anterior Longitudinal Ligament Release and Osteotomy (Osteotomy only with the determination of a rigid/ankylosed spine). Anterior lumbar interbody arthrodesis with placement of a synthetic intervertebral device and autograft from the iliac crest through a separate incision and posterolateral lumbar arthrodesis, L4-L5, with non-segmental instrumentation and morselized allograft.

CPT® CODE[1]	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22558-51	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	80.51, 81.06	456, 457, 458, 459, or 460
22224-51	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	77.39, 80.51	N/A
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
20936	Autograft for spine surgery only (includes harvesting the graft); local (e.g., ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)	77.79 Excision of bone for graft, other. Harvested from the iliac crest or locally.	N/A

2014 Reimbursement Guide

3. THORACOLUMBAR ANTERIOR SCENARIOS (CONT.)

g) Anterolateral fusion, L4-L5 through an anterior or anterolateral approach with CoRoent® XL-H, or Brigade®-H and autograft, and PLF with Precept® or Spherx® DBR® III and Osteocel® Cellular Allograft, with Anterior Longitudinal Ligament Release and Osteotomy (Osteotomy only with the determination of a rigid/ankylosed spine). Anterior lumbar interbody arthrodesis with placement of a synthetic intervertebral device and autograft from the iliac crest through a separate incision and posterolateral lumbar arthrodesis, L4-L5, with non-segmental instrumentation and morselized allograft with osteotomy.

CPT® CODE[1]	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22224	Lumbar	77.39, 80.51	N/A
22226	Each additional level	77.39, 80.51	N/A
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	81.06	453, 454, or 455
22612-51	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)	80.51, 81.08	N/A
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)	Instrumentation is included in the fusion code.	N/A
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)	77.79 Excision of bone for graft, other. Harvested from the iliac crest or locally.	N/A
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)	N/A	N/A

4. LUMBAR COMBINED ANTERIOR-POSTERIOR SCENARIOS

Anterolateral fusion, L4-L5, through an anterior or anterolateral approach with CoRoent® XL or XLR and autograft, and PLF with Precept® or SpheRx® DBR® III, Triad,® and Osteocel® Cellular Allograft – Anterior lumbar interbody arthrodesis with placement of a synthetic intervertebral device and autograft from the iliac crest through a separate incision and posterolateral lumbar arthrodesis, L4-L5, with non-segmental instrumentation and morselized allograft

CPT CODE	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	81.06	453, 454, or 455
22612-51	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)	80.51, 81.08	N/A
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)	Instrumentation is included in the fusion code.	N/A
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)	77.79 Excision of bone for graft, other. Harvested from the iliac crest or locally.	N/A
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)	N/A	N/A
20931	Allograft, structural, for spine surgery only	N/A	N/A

1 *Current Procedural Terminology 2014, American Medical Association. Chicago, IL. CPT is a registered trademark of the American Medical Association. Current Procedural Terminology (CPT®) is copyright American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.*

2014 Reimbursement Guide

5. LUMBAR POSTERIOR-POSTEROLATERAL SCENARIOS

PLIF/TLIF, L4-L5, with CoRoent,® Precept,® SpheRx,® or Armada,® and FormaGraft® collagen bone graft matrix – Combined posterior lumbar interbody arthrodesis and posterolateral lumbar arthrodesis with placement of a synthetic intervertebral device, non-segmental instrumentation, bone marrow aspirated from the iliac crest through a separate incision, and morselized allograft

CPT® CODE[1]	DESCRIPTION	HOSPITAL ICD-9-CM PROCEDURE CODE	POSSIBLE MS-DRG
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar (Do not report with 22612 or 22630 at the same level)	81.08 , 81.07, 80.51	456, 457, 458, 459, or 460
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	84.51	N/A
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)	Instrumentation is included in the fusion code.	N/A
38220-59	Bone marrow, aspiration only	41.31	N/A
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)	N/A	N/A

VI. TECHNOLOGY OVERVIEW

1. CERVICAL

A. Anterior/Interbody Procedures

i. The PCM® Cervical Disc is designed to replace the degenerated cervical disc at a single level from C3-C7, providing support for the vertebrae while allowing for movement of the joint.

ii. The *Gradient Plus® Anterior Cervical Plate system* is designed to stabilize the anterior column of the cervical spine after an ACDF (anterior cervical discectomy and fusion).

iii. The *NuVasive® Helix ACP™ (Anterior Cervical Plate) family of systems* (NuVasive Helix ACP, NuVasive Helix Mini ACP,™ NuVasive Helix-T ACP,™ and NuVasive Helix-Revolution ACP™) are designed to stabilize the anterior column of the cervical spine after an ACDF.

iv. The *CoRoent® Small Interlock™ system* is a standalone anterior cervical interbody fusion system indicated for use in a single level from C2-T1.

v. The *CoRoent Small family of implant systems* is designed to be placed in the interbody space in the cervical spine to help restore interbody height and stabilize the anterior column of the spine, and is indicated for use in a single level from C2-T1. (**Note:** Requires supplemental fixation.)

B. Posterior Procedures

i. The *VuePoint® OCT Fixation system* is designed to stabilize the posterior column of the cervical spine (via sub-laminar hooks) and upper thoracic spine (via pedicle screws or sub-laminar hooks).

ii. The *Leverage® LFS system* (allograft and plate) is designed to stabilize the posterior column of the cervical and upper thoracic spine via laminoplasty allograft and plates.

2. THORACOLUMBAR

A. Anterior/Lateral Procedures

i. The *XLIF Decade™ Plate system* is designed to stabilize the anterior column of the spine during a fusion via an anterolateral approach.

ii. The *Brigade® ALIF plate system* is designed to stabilize the anterior column of the spine from an anterior approach.

iii. The *CoRoent® XL/XLR Interbody Implant systems* are designed to be placed in the interbody space in the lumbar spine, along with supplemental fixation, to help restore interbody height and stabilize the anterior column of the spine. It is indicated for one or two contiguous levels from L2-S1.

iv. The *Brigade Standalone ALIF* is an interfixated thoracolumbar interbody fusion system.

v. The *X-CORE® Expandable VBR system* is designed to provide intervertebral anterior column support during corpectomy procedures.

vi. The *Traverse® Anterior Plating system* is designed to stabilize the anterior column of the spine during corpectomy procedures.

B. Posterior Procedures

i. The *SpheRx® and Armada® systems* are universal instrumentation sets consisting of pedicle screws, hooks, rods, and various other connectors.

ii. The *CoRoent® Large family* (Narrow, Wide, Tapered, Contoured, Impacted, Oblique, MP) of interbody products is designed for interbody stabilization during posterior interbody approaches, such as PLIF and TLIF. (**Note:** Requires supplemental fixation.) It is indicated for one or two contiguous levels from L2-S1.

iii. The *Affix® II Spinous Process Plating system* is used as posterior instrumentation to achieve posterior stabilization and fusion following either a posterior decompression (e.g., laminectomy) or interbody fusion (ALIF, PLIF, and TLIF).

iv. The *Precept® system* is a universal instrumentation set consisting of pedicle screws, rods, and various other connectors.

C. Instruments

i. The *MaXcess® systems* are universally applicable, full-featured, retractor systems which can be used to access the cervical, thoracic, and lumbar spine during a variety of spine procedures. The MaXcess systems give the physician direct, open visualization, including illumination, for the surgery while minimizing disruption to the patient's anatomy.

3. BIOLOGICS

A. *Osteocel® Cellular Allograft* is an allograft cellular bone matrix. Osteocel Plus and Osteocel Pro are product categories that utilize Osteocel technology.

B. *FormaGraft® Collagen Bone Graft Matrix* is a collagen- and mineral-based bone graft substitute for use in filling bony voids.

C. The *Triad® Allograft system* is comprised of machined, saline-packaged allograft, designed to be implanted in the intervertebral space in cervical or lumbar spinal fusion procedures.

D. The *ExtenSure® H2™ Allograft system* is implanted via a posterior approach during posterior decompression and fusion procedures.

4. NVM5® INTRAOPERATIVE MONITORING SYSTEM

A. The *NVM5 Intraoperative Monitoring system* is an innovative and versatile tool, housing the following surgical modalities: Stimulated EMG, Free Run EMG, Motor Evoked Potentials (MEPs), Somatosensory Evoked Potentials (SSEPs), Bendini®, and Guidance.

NVM5 combines intraoperative electrically stimulated EMG and spontaneous EMG activity to assess possible nerve root irritation or injury during spine surgery. Patented software algorithms* help provide the physician with real-time data to help assess a patient's neurophysiologic status. Spinal cord integrity is assessed using MEPs or SSEPs, whereby a controlled stimulation elicits a response that is transmitted through the spinal cord and measured at recording sites. Electrodes record activity during the procedure, providing information about the health and function of the spinal cord and/or specific spinal nerves.

**U.S. Patent No. 7,522,953*

2014 Reimbursement Guide

ADDENDUM A

HEALTHCARE ACRONYMS

A

AARP	American Association of Retired Persons
AHA	American Hospital Association
AHIP	America's Health Insurance Plans (formerly known as HIAA)
AHRQ	Agency for Healthcare Research and Quality
ALOS	Average Length of Stay
AMA	American Medical Association
APC	Ambulatory Payment Classification
ASC	Ambulatory Surgery Center

B

BCBS	BlueCross BlueShield

C

CC	Complications and Comorbidities
CMS	Centers for Medicare & Medicaid Services (formerly known as HCFA)
CMS-1500	Universal claim form for physician services (formerly known as HCFA-1500)
COB	Coordination of Benefits
COBRA	Consolidated Omnibus Budget Reconciliation Act
CPT®	Current Procedural Terminology

D

DME	Durable Medical Equipment
DOS	Date of Service
DRG	Diagnosis Related Group (now MS-DRG)

E

EDI	Electronic Data Interchange
EOB	Explanation of Benefits
ERISA	Employee Retirement Income Security Act

F

FDA	Food and Drug Administration
FEHBP	Federal Employees Health Benefits Program
FFS	Fee-for-Service
FI	Fiscal Intermediary

H

HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health & Human Services
HIAA	Health Insurance Association of America (now AHIP)
HMO	Health Maintenance Organization

I

ICD	International Classification of Diseases

M

MCC	Major Complications and Comorbidities
MCO	Managed Care Organization
MFS	Medicare Fee Schedule
MS-DRG	Medicare Severity – Diagnosis Related Group

N

Non-PAR	Non-Participating Physician
NOS	Not Otherwise Specified

O

OPPS	Outpatient Prospective Payment System

P

PAR	Participating Physician
PCP	Primary Care Physician
PHO	Physician Hospital Organization
POS	Point-of-Service
PPO	Preferred Provider Organization
PPS	Prospective Payment System
PRO	Peer Review Organization

R

RBRVS	Resource-Based Relative Value Scale
RVU	Relative Value Unit

T

TPA	Third-Party Administrator

U

UB-92	Uniform Billing 1992
UCR	Usual, Customary, and Reasonable
UPIN	Unique Physician Identification Number
UR	Utilization Review
URO	Utilization Review Organization

2014 Reimbursement Guide

ADDENDUM B

GLOSSARY OF REIMBURSEMENT TERMS

A

Allowed Charges: Charges for services furnished by a healthcare provider, which qualify as covered expenses, paid in whole or in part by an insurer. Charges are subject to deductibles and/or coinsurance.

Ambulatory Payment Classification (APC): The basic unit of payment in the Medicare Prospective Payment System for outpatient visits or procedures (similar to DRGs).

Ambulatory Surgery Center (ASC): An organization that provides surgical services on an outpatient basis for patients who do not need to occupy an inpatient, acute care hospital bed. May be a component of a hospital or a freestanding, privately owned center.

Ancillary Services: Services other than hospital room and board, nursing and physician services.

Appeal: A process whereby the provider and/or beneficiary (or representative) exercises the right to request a review of a contractor determination to deny commercial insurance, Medicare coverage, or payment for a service in full or in part.

Approved Charge: The amount Medicare pays a physician, based on the Medicare Fee Schedule or its transition rules. Physicians may bill beneficiaries for an additional amount, subject to the limiting charge.

Assignment: A decision by a healthcare provider made in advance of submitting a claim to an insurer to accept the allowed charge and subsequent payment as payment in full.

Automated Claim Review: Claim review and determination made using system logic (edits). Automated claim reviews never require human intervention to make a claim determination.

B

Balance Billing: Billing the beneficiary for any fee in excess of that allowed by the insurance carrier.

Beneficiary: A person eligible to receive benefits under a healthcare plan.

Benefit: The amount payable by the third-party payor to a claimant, assignee, or beneficiary.

Bundling: The use of a single payment for a group of related services or surgeries and principal procedures when performed together.

C

Capitation: A reimbursement system whereby a monthly payment is made to providers, based on membership rather than services provided. The payment covers contracted services and is paid in advance of care provided. Capitation is expressed as a "per member per month" amount. Under most capitation-based contracts, providers do not receive additional payment even if the costs of care exceed the fixed rate of payment.

Carrier: A commercial insurance company that writes and administers health insurance policies and pays claims. Also, under Medicare, a private contractor who administers claims for Part B Medicare services.

Centers for Medicare & Medicaid Services (CMS): The U.S. Government agency with responsibility for the administration of the Medicare and Medicaid programs (previously known as HCFA). www.cms.hhs.gov/center/physician.asp

CHAMPUS (TRICARE): The former Civilian Health and Medical Program of the Uniformed Services, now known as TRICARE. A federally funded comprehensive health benefits program administered by the Department of Defense and designed to provide healthcare benefits to eligible veterans and their dependents.

Claim: A demand to an insurer, by the insured person or provider acting on behalf of the insured, for payment of benefits under a policy.

CMS-1500 (HCFA-1500): A universal insurance claim form mandated for Medicare billing and generally accepted by all insurance carriers for outpatient-based healthcare providers. Physicians and medical suppliers use the CMS-1500 claim form (previously known as the HCFA-1500).

Coinsurance: Beneficiary is responsible for a percentage of the overall cost of care after the care has been provided; e.g., Medicare beneficiaries are responsible for a 20% coinsurance amount on all outpatient Part B services.

Complications and Comorbidities (CC): There are three levels of severity in MS-DRGs, based upon assignment of secondary diagnosis codes. CCs reflect the second highest severity assignment and are included on the list if they could demonstrate that their presence leads to substantially increased hospital resource use.

Consolidated Omnibus Budget Reconciliation Act (COBRA): A federal law that allows and requires past employees to be covered under company health insurance plans for a set premium. This program gives individuals the opportunity to retain insurance when their current plan or position has been terminated.

Coordination of Benefits (COB): A provision in an insurance plan wherein a person covered under more than one group plan has benefits coordinated such that all payments are limited to 100% of the actual charge or allowance. Most plans also specify rules whereby one insurer is considered primary and the other is considered secondary.

Copayment: Like coinsurance, copayment is a cost-sharing arrangement for the beneficiary, although typically paid at the time that a service is provided; e.g., a $10 copayment for an office visit or an outpatient drug prescription.

CPT® (Current Procedural Terminology): The coding system for physicians' services, developed by the American Medical Association and the basis of the HCPCS coding system for physicians' services. Each procedure or service rendered by a physician is identified with a five-digit code. CPT codes are revised annually by the American Medical Association. www.amapress.com

Customary Charge: The provider's standard charge for a given service. Typically calculated by insurance carriers as the provider's median charge for the service over a prior 12-month period.

D

Date of Service (DOS): The specific date a service was provided to an individual under a particular health plan.

Deductible: A stipulated amount that the insured is required to pay toward the cost of medical treatment before the benefits of the insurance policy or program take effect.

Denial: The refusal of an insurer to cover an item or service under a healthcare plan or program.

Dependents: The spouse and/or children of the insured, as defined in the insurance contract.

Diagnosis Related Group (DRG): A system of classifying medical cases for payment on the basis of diagnostic codes. Used under Medicare's inpatient prospective payment system (IPPS) for inpatient hospital services. (DRG is now referred to as MS-DRG.)

Durable Medical Equipment (DME): Any equipment that undergoes repeated use, is usable at home, and is not beneficial to a person without an illness or injury. Splinting, orthopaedic bracing, and wheelchairs are examples of DME.

E

Electronic Claim: A claim form that is processed and delivered from one computer to another via some form of magnetic media (e.g., magnetic tape, diskette) or via telecommunications.

Encounter Data: Claims that are not paid fee-for-service because they are the responsibility of the provider under the capitation agreement.

EOB (Explanation of Benefits): A form included with a check from the insurer explaining the benefits that were paid and/or charges that were rejected.

Evaluation & Management (E/M) Service: A nontechnical service provided by physicians for the purpose of diagnosing and treating diseases and counseling and evaluating patients.

Exclusion: Specific services or conditions that a health insurance policy or program will not cover or will only do so at a limited rate.

Experimental Procedures: Medical procedures for which basic safety or effectiveness is still in doubt.

2014 Reimbursement Guide

F

Fee-for-Service: Refers to paying medical providers a specified amount for individual services rendered.

Fee Schedule: A list of predetermined payments for medical services. For example, Medicare Part B reimburses physicians based on a fee schedule.

Fiscal Intermediary (FI): A health insurance plan contracted with the Department of Health & Human Services to process claims and perform other functions under Medicare's Part A hospital insurance program.

G

Global Surgery: The payment policy in the Medicare fee schedule stating that in addition to the procedure itself, the global surgical fee includes all related services and visits that occur within a designated time period (typically 90 days).

H

HCPCS (Healthcare Common Procedure Coding System): A two-level coding system, consisting of Level I CPT® codes and Level II codes for DME products, etc.

Health Maintenance Organization (HMO): Prepaid health plans that provide a range of services in return for fixed monthly premiums or other payment method. Virtually any organization can sponsor an HMO, including the government, hospitals, employers, labor unions, and insurance companies.

I

ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modifications): A standardized system of describing diagnoses and identifying codes for reporting treatment and diagnosis of health plan enrollees. The coding and terminology provide a uniform language that accurately designates primary and secondary diagnosis and ensures consistent communication on claim forms. Maintained jointly by the American Hospital Association and CMS.

Individual Practice Association (IPA) Model HMO: A healthcare model that contracts with an Individual Practice Association (IPA) entity to provide healthcare services in return for a negotiated fee. The IPA, in turn, contracts with physicians who continue in their existing individual or group practices.

Initial (Claim) Determination: The first adjudication made by a carrier or fiscal intermediary (FI) (i.e., the Medicare affiliated contractor) following a request for Medicare (or insurance) payment.

M

Major Complications and Comorbidities (MCC): There are 3 levels of severity in MS-DRGs, based upon assignment of secondary diagnosis codes. MCCs reflect the highest severity assignment and are included on the list if they could demonstrate that their presence leads to substantially increased hospital resource use.

Medicaid: A state/federal government sponsored medical assistance program to enable eligible recipients to obtain essential medical care and services.

Medical Necessity: Medical information justifying that a service rendered was reasonable and appropriate for the diagnosis or treatment of a medical condition.

Medicare: A federal health insurance program for people age 65 or older, for disabled persons, and for those with chronic renal disorders.

Medicare+Choice: Under the Balanced Budget Act of 1997 (BBA97), Congress created a new Medicare Part C, known as Medicare+Choice, which allows CMS to contract with a number of managed care organizations including, but not limited to, health maintenance organizations, preferred provider organizations, provider service organizations, and medical savings accounts.

Medicare Contractor: An organization that enters into a legal agreement with the Department of Health & Human Services to handle specified administrative, payment, and review functions. These organizations are charged with the responsibility of ensuring payments are made only for services covered under Medicare Part A or Part B. They determine whether a particular service is covered under Medicare in the course of adjudicating a Medicare claim or conducting utilization and quality review. Contractors include fiscal intermediaries (Part A contractors), carriers (Part B contractors), health maintenance organizations, competitive medical plans, utilization, and quality control peer review organizations.

Medi-Gap: Health insurance policies that provide benefits for services and costs, such as deductibles and coinsurance, not covered under the Medicare program.

N

Non-Participating Physician: A physician who does not sign a health plan participation agreement and therefore is not obligated to accept assignment on all claims.

P

Part A (Medicare): The Medicare hospital insurance program which covers hospital and related institutional care.

Part B (Medicare): The Medicare supplementary medical insurance program, which covers the costs of physician services, outpatient lab, x-ray, DME, and certain other healthcare services.

Participating Provider: A hospital, pharmacy, physician, or ancillary services provider who has contracted with a health plan to provide medical services for a determined fee or payment.

Point-of-Service Plan (POS): The newest type of managed care organization in which beneficiaries who decide to go outside the plan for healthcare services receive reduced benefits.

Preferred Provider Organization (PPO): An arrangement whereby an insurer or managing entity contracts with a group of healthcare providers who provide services at lower than usual fees in return for prompt payment and a guaranteed volume of patients.

Prior Authorization: An assessment of healthcare services by the insurer in advance of provision of services by the provider. This may be required under the healthcare plan or program, or may be performed routinely by the provider to ensure coverage and payment.

R

RBRVS (Resource-Based Relative Value Scale): A government mandated relative value system (implemented in 1992) that is used for calculating national fee schedules for services provided to Medicare patients. Physicians are paid on relative value units (RVUs) for procedures and services. The three components of each established value include: work expense, practice expense, and malpractice expense.

S

Secondary Insurer: The insurer that is second in responsibility under Coordination of Benefits.

Self-insured/Self-funded: Employers fund benefit plans from their own resources without purchasing insurance. Self-funded plans may be self-administered, or the employer may contract with a third-party administrator.

Staff Model HMO: This healthcare model employs physicians to provide healthcare to its members. The HMO compensates the physicians by salary and incentive programs (e.g., Kaiser Permanente).

T

Third-Party Administrator (TPA): An organization that processes healthcare claims without bearing any insurance risk.

TRICARE (formerly known as CHAMPUS): Formerly named the Civilian Health and Medical Program of the Uniformed Services, TRICARE is a federally funded comprehensive health benefits program administered by the Department of Defense and designed to provide healthcare benefits to eligible veterans and their dependents.

U

UB-92 and UB-04: A uniform billing form required for submitting and processing claims for institutional providers.

Usual, Customary, and Reasonable (UCR): A term indicating fees charged for medical services that are considered normal, common, and in line with the prevailing fees in the provider's area.

Utilization Management: Activities that include admission/pre-admission review, second surgical opinion, concurrent review, discharge planning, individual case management, focused review, and provider profiling.

Utilization Review: The process of reviewing services to determine if those services are or were medically necessary and appropriate. Utilization review may be performed in advance of services or retrospectively.

To order, please contact your NuVasive® Sales Consultant or Customer Service Representative today at:
NuVasive, Inc. 7475 Lusk Blvd., San Diego, CA 92121 • phone: 800-475-9131 fax: 800-475-9134
NuVasive UK Ltd. Suite B, Ground Floor, Caspian House, The Waterfront, Elstree, Herts WD6 3BS UK
EC REP phone: +44 (0) 208-238-7850 fax: +44 (0) 207-998-7818

www.nuvasive.com

9501260 A

CE 0086

APPENDIX J

SPINE Volume 23, Number 13, pp 1476–1484
©1998, Lippincott–Raven Publishers

Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine

Emphasis on the Lateral BAK

Paul C. McAfee, MD,* John J. Regan, MD,† W. Peter Geis, MD,‡ and Ira L. Fedder, MD*

Study Design. Eighteen patients with lumbar instability from fractures, postlaminectomy syndrome, or infection were treated prospectively with minimally invasive retroperitoneal lumbar fusions.

Objectives. To determine if interbody Bagby and Kuslich fusion cages and femoral allograft bone dowels can be inserted in a transverse direction via a lateral endoscopic retroperitoneal approach to achieve spinal stability.

Summary of Background Data. Endoscopic spinal approaches have been used to achieve lower lumbar fusion when instrumentation is placed through a laparoscopic, transperitoneal route. However, complications of using this approach include postoperative intra-abdominal adhesions, retrograde ejaculation, great vessel injury, and implant migration. This study is the first clinical series investigating the use of the lateral retroperitoneal minimally invasive approach for lumbar fusions from L1 to L5.

Methods. Eighteen patients underwent anterior interbody decompression and/or stabilization via endoscopic retroperitoneal approaches. In most cases, three 12-mm portals were used. Two parallel transverse interbody cages restored the neuroforaminal height and the desired amount of lumbar lordosis was achieved by inserting a larger anterior cage, distraction plug, or bone dowel.

Results. The overall morbidity of the procedure was lower than that associated with traditional "open" retroperitoneal or laparotomy techniques, with a mean length of hospital stay of 2.9 days (range, outpatient procedure to 5 days). The mean estimated intraoperative blood loss was 205 cc (range, 25–1000 cc). There were no cases of implant migration, significant subsidence, or pseudoarthrosis at mean follow-up examination of 24.3 months (range, 12–40 months) after surgery.

Conclusions. This preliminary study of 18 patients illustrates that endoscopic techniques can be applied effectively through a retroperitoneal approach with the patient in the lateral position. Unlike the patients who had undergone transperitoneal procedures described in previous reports, in these preliminary 18 patients, there were no cases of retrograde ejaculation, injury to the great vessels, or implant migration. [Key words: endoscopic retroperitoneal, minimally invasive retroperitoneal lumbar fusions, transverse axis BAK] **Spine 1998; 23:1476–1484**

From the *Scoliosis and Spine Center, St. Josephs Hospital, Baltimore, Maryland, the †Texas Back Institute and the Institute for Spine and Biomedical Research, Plano, Texas, and the ‡Minimally Invasive Services Training Institute, St. Josephs Hospital, Baltimore, Maryland.
Acknowledgment date: August 28, 1997.
First revision date: October 23, 1997.
Acceptance date: December 2, 1997.
Device status category: 9.

The use of minimally invasive and endoscopic approaches has been described for multiple abdominal procedures, including cholecystectomy,[29,31,32] appendectomy,[28] colon resection,[12] and Nisson fundoplication.[33] Recently, increased attention has been paid to the use of these approaches with lumbar discectomy[25,26] and lumbar anterior interbody arthrodesis.[1,4,8] Most endoscopic approaches described thus far have been transperitoneal and have depended on CO_2 insufflation to provide working space and to retract the small bowel out of the surgical field. Gaur[6] and McDougall et al[24] were the first to describe retroperitoneoscopy, an endoscopic retroperitoneal approach for urologic procedures. The current report describes the natural transition toward retroperitoneal minimally invasive endoscopic spinal surgery, which does not require CO_2 insufflation, Trendelenburg position, entrance into the peritoneum, or anterior dissection near the great vessels to provide safe exposure for spinal surgery.

Materials and Methods

Twelve minimally invasive retroperitoneal lumbar procedures were performed at St. Josephs Hospital in Baltimore, Maryland, and six were performed at Presbyterian Hospital of Plano, Texas, between March 1994 and September 1996. There were 6 female and 12 male patients, with a mean age of 53.4 years (range, 31–76 years).

The indications for surgery included 13 cases of degenerative conditions, three cases of infections, one unstable burst fracture, and one case of a retroperitoneal neurofibroma in-