

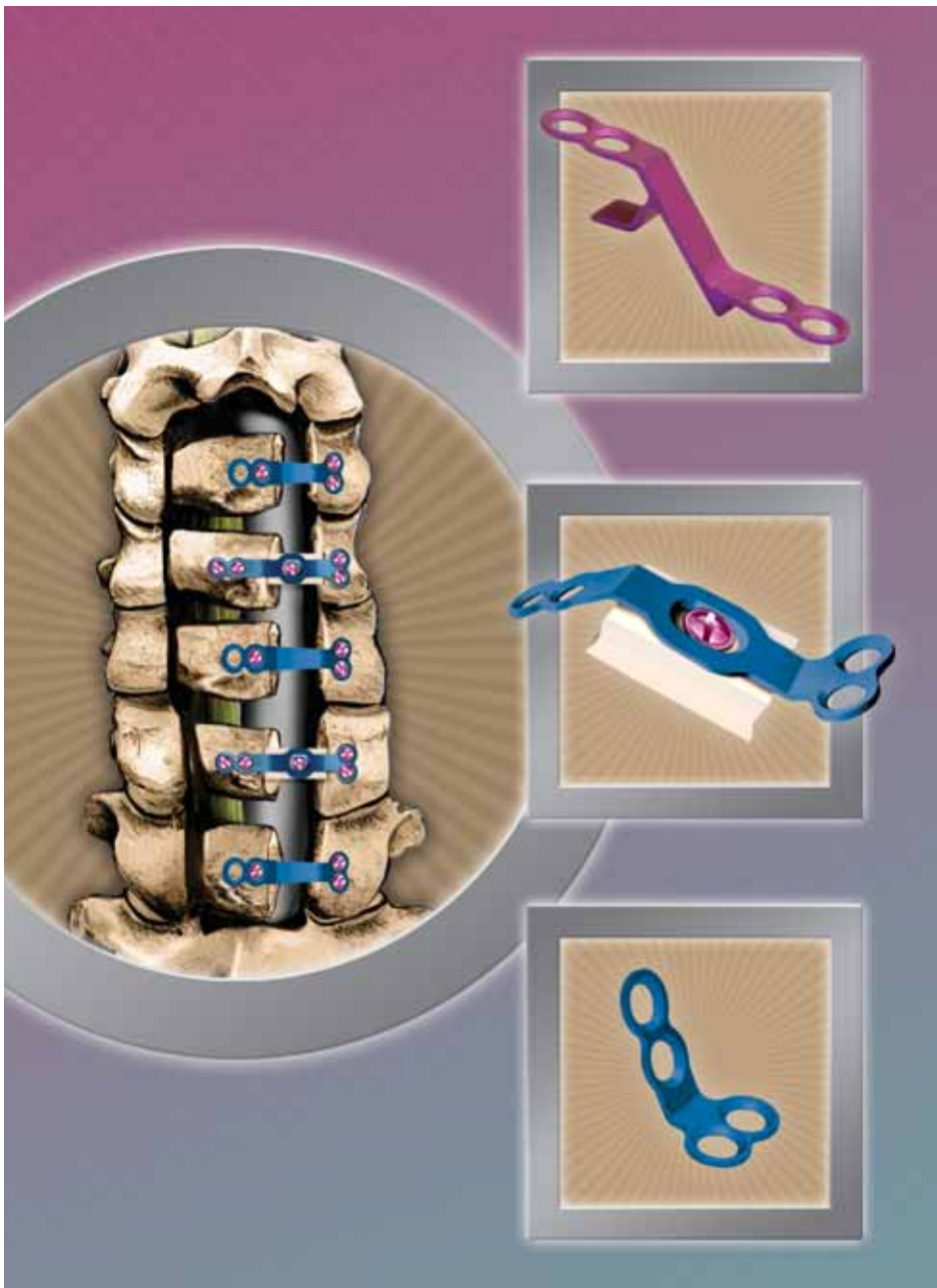


Medtronic

SOFAMOR DANEK

CENTERPIECE™ PLATE FIXATION SYSTEM

Surgical Technique



Dear Colleagues:

The preferred surgical procedure for the treatment of multi-level cervical myelopathy remains a matter of discussion. In selecting a procedure to recommend to their patients, surgeons must account for a number variables, such as the sources and location of compression, cervical alignment, segmental instability patterns, comorbid medical conditions, functional requirements of the host, degree of preoperative axial pain, etc. Laminoplasty has been proven to yield the same neurologic outcomes as multi-level anterior decompression and fusion procedures. However, the complication rates are lower with laminoplasty, and motion is preserved rather than sacrificed. Early active range of motion may also be encouraged, provided the position of the laminae is secured during surgery.

A myriad of laminoplasty techniques have been described, none of which appear to differ to any great extent in their success rates. The choice of which method a surgeon might use appears to be primarily a matter of training and familiarity, as are the details of how the laminae are maintained in their open position. The principle school of thought described in this technique is the Open Door procedure. We have worked closely with Medtronic Sofamor Danek to develop a system of implants to facilitate laminar fixation during Open Door laminoplasty procedures.

This monograph concerns the use of the CENTERPIECE™ Plate Fixation System with and without an interpositional allograft. We hope that you will note its potential advantages for your patients:

- Anatomic contouring
- Ease of application
- Secure laminar fixation
- Adaptability to procedures with and without allograft
- Facilitation of early active motion and rehabilitation

For those familiar with laminoplasty, we think that you will find the CENTERPIECE™ Plate Fixation System a welcome enhancement to your technique. For those considering adding laminoplasty to their surgical repertoire, we think that the CENTERPIECE™ System will enhance the appeal of the procedure and make it easier to perform.

Sincerely,

John G. Heller, MD

Jeffrey C. Wang, MD

Implant Features	3
Instruments	5
Overview	6
Patient Positioning	7
Surgical Exposure	8
Open Door Technique	
Open Side Trough Preparation	9
Hinge Side Trough Preparation	10
Opening the Laminoplasty	11
Keeping the Door Open	
A. Utilizing the Open Door Plate	12
B. Utilizing the Graft Plate	15
Use of Lateral Hole Plate	17
Use of Wide Mouth Plate	18
Use of Hinge Plate	19
Implant Removal	20
Product Ordering Information	21
Important Information on the CENTERPIECE™ Plate Fixation System	22

Open Door Plates

- Pre-cut, pre-contoured plate design
- Laminar shelf of plate allows for easy fixation to lamina
- Multiple screw hole options for flexibility in screw placement
- Intrinsic stability provided by design of plate
- “Kickstand” design of plate aids in stability when placed on lateral mass
- Color coded
- Available in 8mm – 18mm sizes in 2mm increments



Graft Plates

- Pre-cut, pre-contoured plate design
- Oval shaped center screw hole in the graft plate allows for fine adjustments of the plate on the allograft
- Multiple screw hole options for flexibility in screw placement
- Color coded
- Available in 8mm – 18mm sizes in 2mm increments



Lateral Hole Plates (in OD and GP)

- Medial/lateral orientation of the lateral mass screw holes allows for flexible screw placement in the event that the surface area of the lateral mass has been reduced in its cranial-caudal dimension, especially following supplemental foraminotomies
- Color coded
- Available in 8mm – 18mm sizes in 2mm increments



Hinge Plates

- Small angled plate designed to secure a floppy or displaced hinge



Wide Mouth Plates (OD Lateral Hole Plate and OD Standard Hole Plate)

- Wider laminar shelf used to accommodate thick laminae
- Color coded
- Available in 8mm - 18mm sizes in 2mm increments



Bone Screws

- Self-tapping
- Precision instrumentation with stab-and-grab feature
- Color coded
- Available in 2.6mm and 3.0mm diameters, 5mm - 11mm lengths in 2mm increments



Allograft

- All cortical graft for added stability
- Simplified surgical technique by eliminating the need to shape resected autograft
- Curved edges of allograft provide a secure fit between the lamina and lateral mass
- Pre-drilled center screw hole allows for immediate access for screw insertion, eliminating a procedural step
- Freeze-dried
- Available in 8mm - 18mm sizes in 2mm increments



Top View



Side View



Universal handle



Bone Trial



Plate Holder



*Drill Bit with
1.9 x 5.5mm
Depth Stop*



Screwdriver Sleeve



Screwdriver Shaft



Bone Cutter

Cervical laminoplasty can achieve spinal cord decompression in cases of multi-level myelopathy or myeloradiculopathy due to cervical spondylosis, ossification of the posterior longitudinal ligament (OPLL), and similar conditions. The most common reason for failure of laminoplasty has been re-stenosis due to hinge closure. Various techniques have been employed to hold the door open while the host heals the laminar hinge in the expanded position. Ideally, a method of achieving laminar fixation should be technically intuitive, provide secure laminar fixation, while minimizing the risk of iatrogenic injuries, blood loss and operative time. The authors describe the use of the novel CENTERPIECE™ Plate Fixation System designed to accomplish these goals during Open Door laminoplasty. The technical issues relevant to performing the laminoplasty and securing the laminae are discussed. The plates have been proven to be biomechanically equivalent to the currently-used techniques. The use of these plates will potentially allow the patient to engage in an early active rehabilitation protocol while minimizing the risk of re-stenosis of the canal. This may ultimately lead to better preservation of motion and decreased axial neck pain following laminoplasty.

The patient is positioned prone as for most other posterior cervical procedures, with the head secured in a Mayfield three-pin head-holder, preferably in slight flexion (Figures 1 and 1a). Some cervical flexion helps reduce the overlap of the laminae and facet joints, which facilitates the laminoplasty itself. A reverse Trendelenberg position may help decrease bleeding from epidural and paravertebral veins.

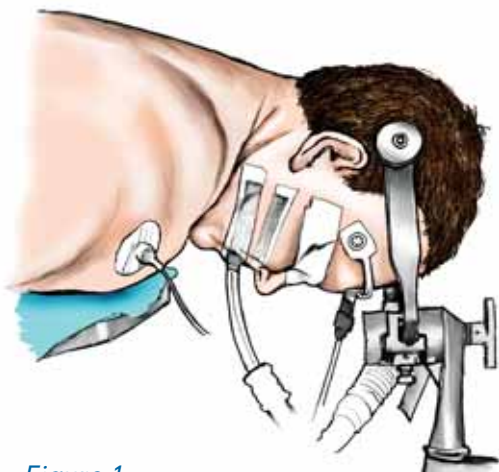


Figure 1



Figure 1a

The surgeon performs a midline posterior exposure from the inferior aspect of C2 to the superior aspect of T1 (Figures 2 and 3). The lateral dissection follows the subperiosteal plane out to the mid-portion of the lateral masses. Unlike the exposure required for a laminectomy and fusion, the muscle origins and insertions over the lateral half of the lateral masses are preserved. The insertion of the extensor muscles is only detached from the lower lamina margin of C2 to afford access to the C2-3 inter-laminar space. The junction of the medial aspect of the lateral mass with the lateral portion of the lamina is identified at each level planned in the decompression. At this point it is particularly helpful to correlate the local surface anatomy with the preoperative axial images.

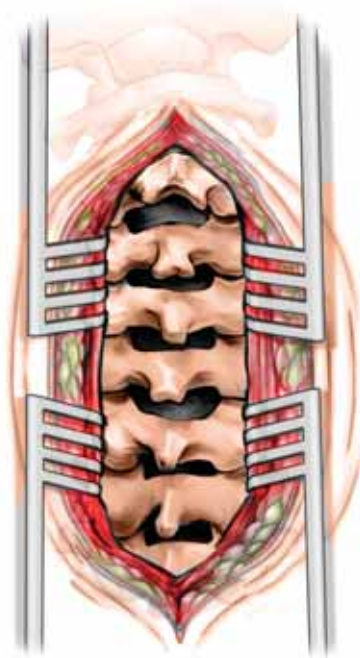


Figure 2



Figure 3

Note: In the event that the posterior decompression ought to extend to the C2 level, this can be accomplished while respecting the integrity of the C2 posterior arch and the majority of its muscular origins and insertions. A so-called dome laminectomy is performed by using a burr and Kerrison to remove the lower margin of C2, followed by the cancellous bone and ventral cortex (Figures 4, 4a and 4b).



Figure 4



Figure 4a



Figure 4b

Open Side Trough Preparation

The open side trough is prepared with a burr along the junction of the lamina and the lateral mass. Three layers of bone must be removed in turn: the dorsal cortex, followed by the cancellous layer and then the ventral cortex (Figure 5 and 5a). Hemostasis of the bone surfaces can be achieved with the use of thin bone wax “match sticks” or applying a slurry of powdered GelFoam™ and thrombin solution. The completion of the bone separation on the open side can be performed with a 1.0 millimeter Kerrison Rongeur. At this point, the objective is to ensure that bone separation has been achieved. This will permit one to assess the stiffness of the hinge as it is prepared for each lamina.

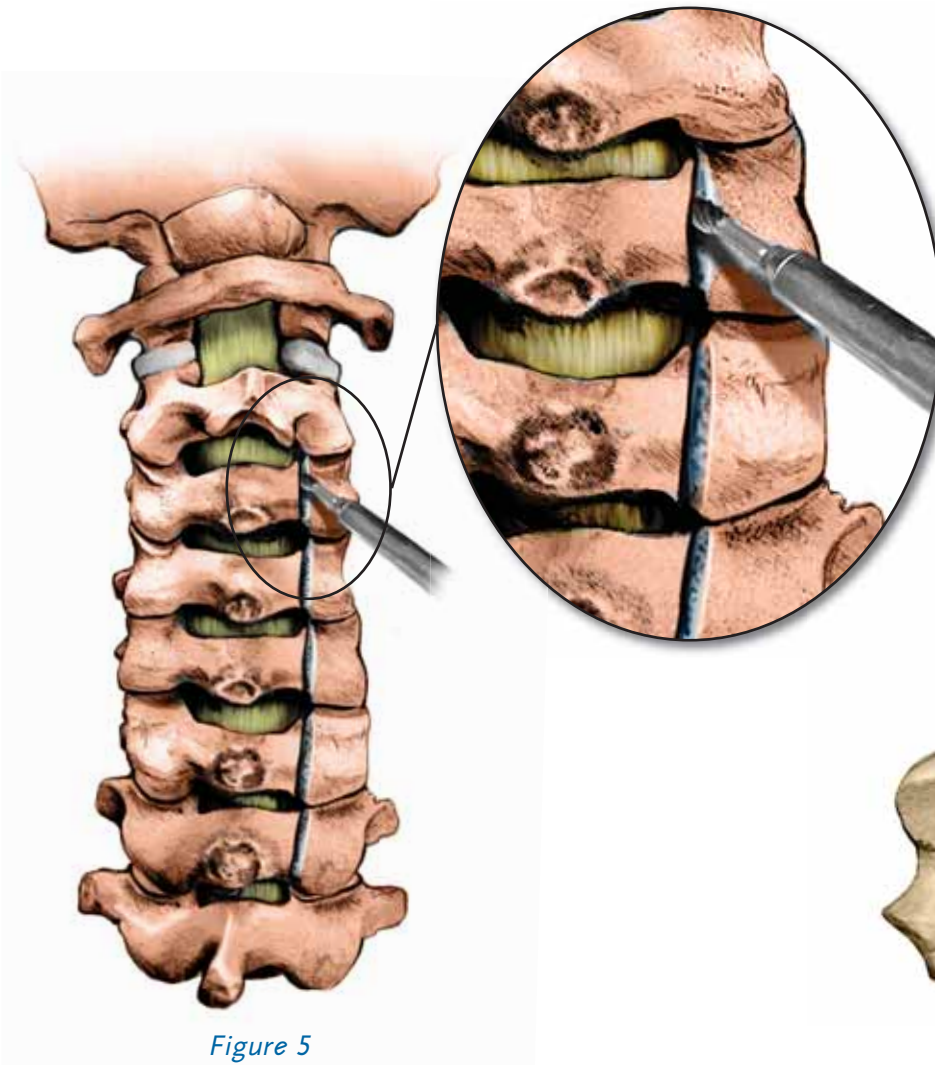


Figure 5

“I prefer to use a 3.0mm or 4.0mm cutting burr with low aggression teeth or a MIDAS® AM-8”

– John Heller, MD

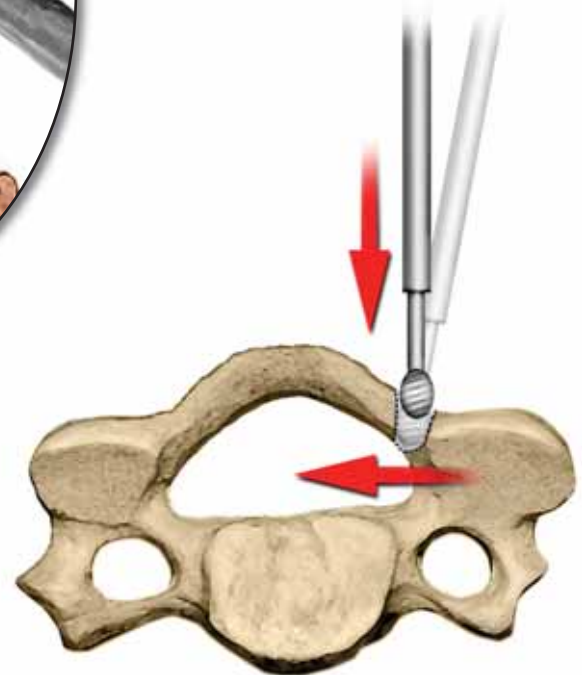


Figure 5a

Note: The side of the spinal canal to be opened may be chosen for a number of reasons. If supplemental foraminotomies are planned, then the open side should be ipsilateral to them. If the patient's myelopathy is asymmetric, some surgeons prefer to open the more involved side. Finally, all things being equal, the choice may be influenced by the surgeon's dominant hand. A right hand dominant surgeon will probably wish to stand on the patient's left and open the left side. The converse would be the case for a left-handed surgeon.

Hinge Side Trough Preparation

On the hinge side of the laminoplasty another trough is made with the burr of choice (Figure 6 and 6a). Care must be taken to avoid two common errors: placing the trough too medially over the laminae and/or removing excessive bone, either of which will lead to a floppy hinge. After removing the dorsal cortex and cancellous layer, one should pause to assess the stiffness of the hinge at each level. The laminar hinge should yield slightly with a moderate bending force. The surgeon should err on the side of leaving more bone, as fine-tuning can be done once every level is at or close to the desired thickness. If the hinge fails to bend despite resection of what seems to be an adequate amount of bone, check to be sure that the bone was completely divided on the open side.

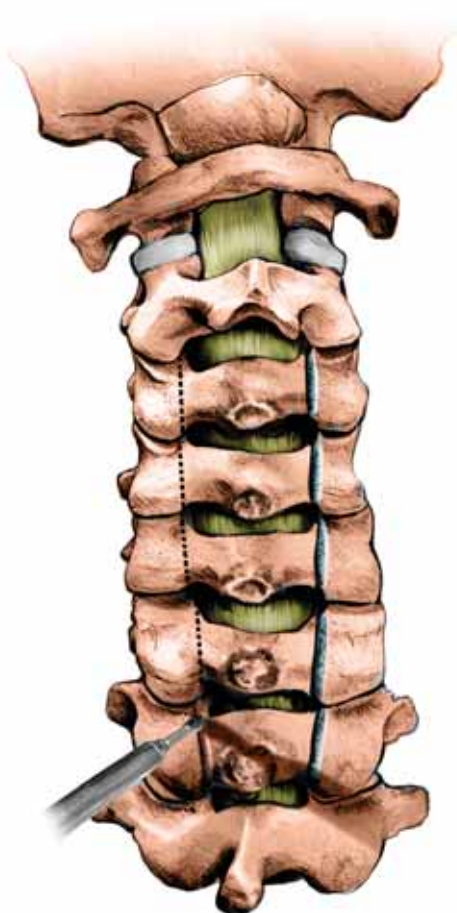


Figure 6

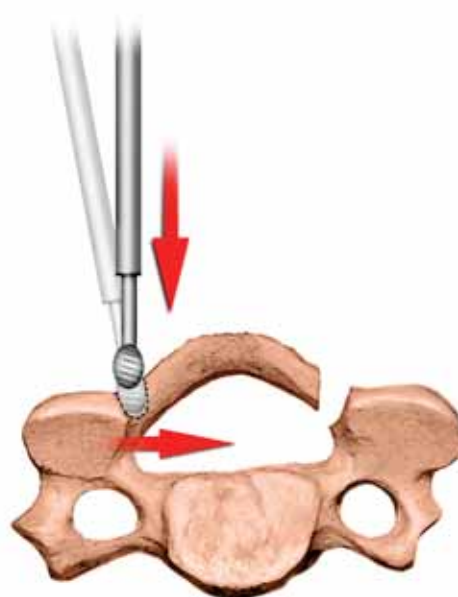


Figure 6a

Note: To resurrect a situation in which a hinge is either too floppy or displaced, one could opt to use the hinge plate. This small angled plate may be used to secure the hinge when it is thought to be necessary. (Refer to Page 19.)

Opening the Laminoplasty

Following the hinge side preparation, divide the ligamentum flavum, facet capsules and veins as required. A 2.0mm or 3.0mm Kerrison punch may be used to excise the ligamentum flavum at C2-C3 and C7-T1 (Figure 7). Division of the residual facet capsular tissue and the underlying epidural veins may be done in a number of ways. The authors prefer to do so with bipolar forceps and either a fine scissor or 1.0mm Kerrison punch (Figures 8). This may be facilitated by applying a slight opening force to the laminae while using a nerve hook to separate the veins from the dura. The laminae are now sequentially opened from one end to the other. The hinges are fashioned to be somewhat stiff. Use an angled probe to ensure that any epidural adhesions have been lysed beneath the laminae before fully opening the laminoplasty (Figure 9).

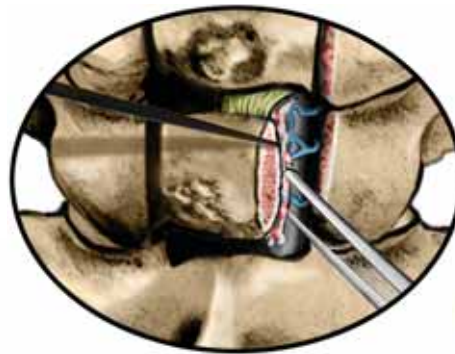


Figure 8

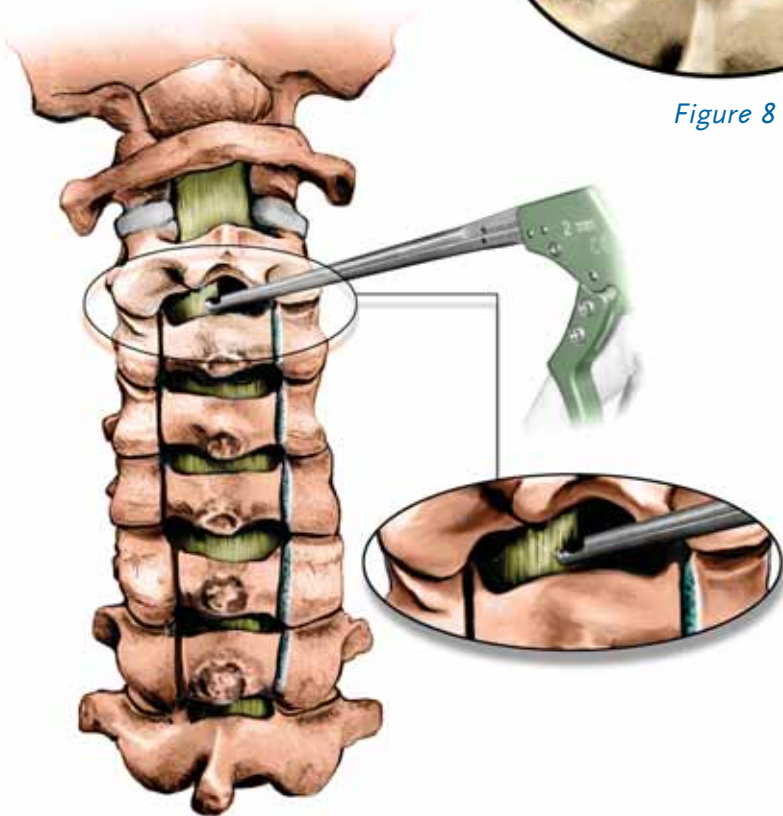


Figure 7



Figure 9

Keeping the Door Open

A. Utilizing the Open Door Plate

Plate Positioning

The appropriate size laminoplasty plate for each level is selected using the bone trials (Figure 10). Using the plate holder, the corresponding plate is then inserted by fitting the cut edge of the lamina into the laminar shelf of the plate, then seating the lateral portion of the plate down onto the edge of the lateral mass (Figure 11). The ventral prong on the under surface of the plate should catch the cut edge of the lateral mass. This helps to stabilize the plate's position while completing the fixation, as well as reducing any shear loads on the lateral fixation screws.



Figure 10

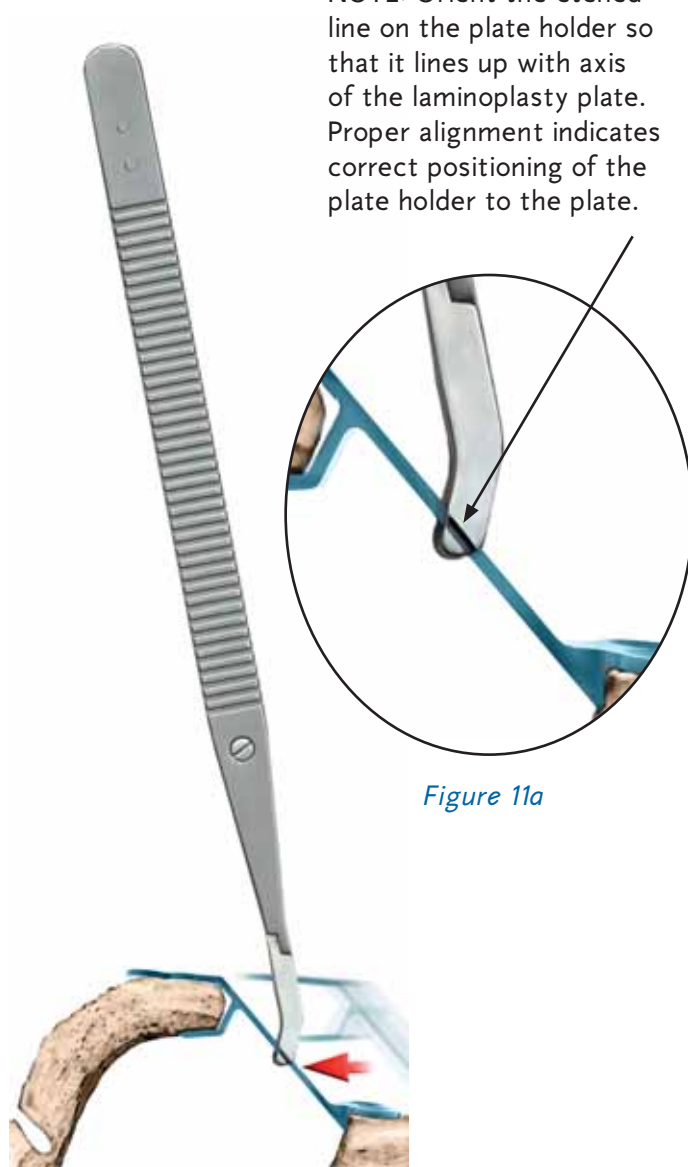


Figure 11a

Figure 11

NOTE: Orient the etched line on the plate holder so that it lines up with axis of the laminoplasty plate. Proper alignment indicates correct positioning of the plate holder to the plate.

Drill and Screw Insertion

Each of the lateral mass screw holes are made using the 1.9 x 5.5mm depth-stopped drill bit. The drill bit may be attached to the universal handle for manual drilling or attached to a power drill (Figure 12). Using the self-holding screwdriver, the self-tapping screws are inserted to anchor the plate to the lateral mass (Figure 13). The screwdriver sleeve is optional, and can be used to help secure the screw onto the screwdriver while inserting it into the bone. The sleeve can be placed over the screwdriver either before or after the screw has been loaded on the screwdriver (Figure 13a).



Figure 12



Figure 13



Figure 13a

The laminar hole may then be drilled using the same 1.9 x 5.5mm depth stopped drill bit and secured with a self-tapping screw (Figures 14 and 14a). A second screw may be placed in the lamina if desired. The assistant may want to hold the lamina with a clamp to prevent damage to the hinge if hard laminar bone causes a high torque of insertion for the screw.

"I typically use both lateral mass screw holes and one laminar screw hole"

– John Heller, MD

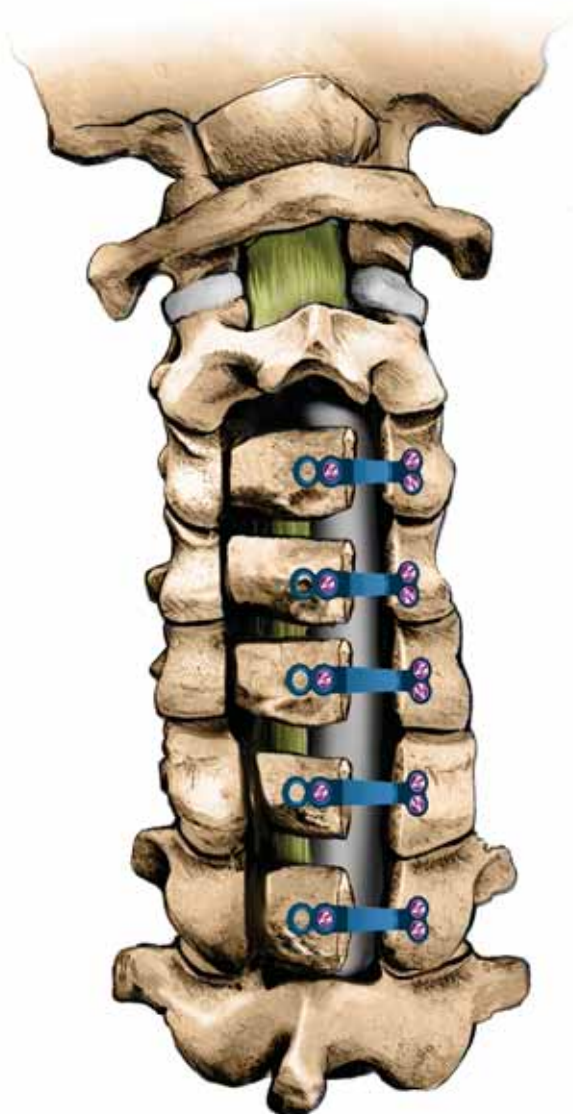


Figure 14

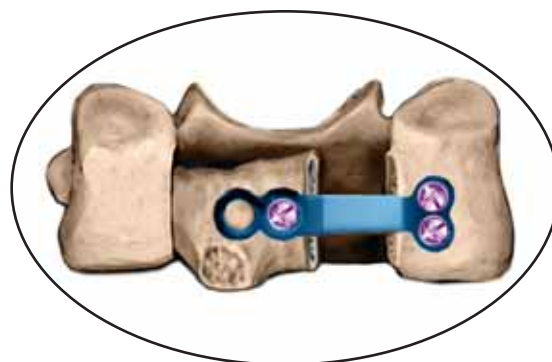


Figure 14a

B. Utilizing the Graft Plate

An alternative technique, which allows for the placement of allograft on the open side of the laminoplasty, can be performed using the graft plate.

The initial surgical procedure is performed in the same manner as if preparing to use the Open Door Plate (as described on pages 9-11). After the laminoplasty has been “opened”, the appropriate size allograft is selected using the bone trials (Refer to Figure 10). As an example, a 12mm trial corresponds to a 12mm allograft. The allograft is then attached to the graft plate and secured by inserting a 2.6 x 5mm screw through the pre-drilled center hole in the allograft (Figure 15 and 15a). The oval shaped center screw hole in the graft plate allows for fine adjustments of the plate on the allograft. The allograft/graft plate construct is inserted between the cut edge of the lamina and the lateral mass. To secure the allograft/graft plate construct to the bone and complete the fixation, drill and insert the self-tapping screws according to the procedural steps described on pages 13 and 14 (Figure 16).



Figure 15



Figure 15a



Figure 16

The allograft/graft plate construct can be used at every level of the laminoplasty (Figure 17), or may be alternated with the Graft Plate or Open Door Plate alone (Figures 17a and 17b).



Figure 17

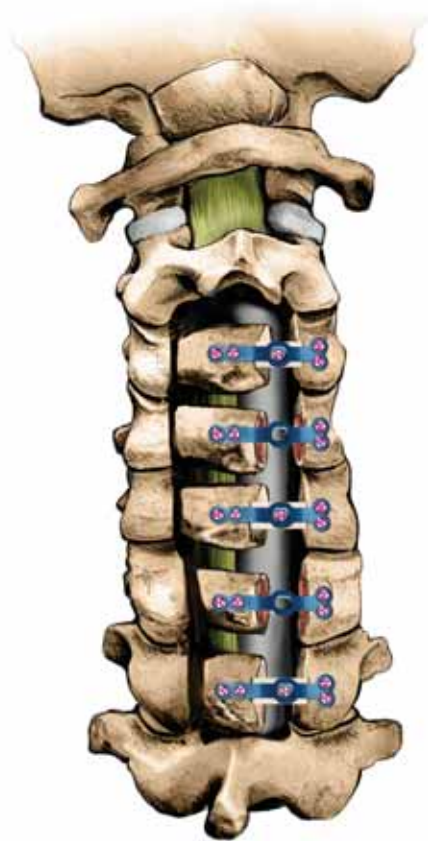


Figure 17a

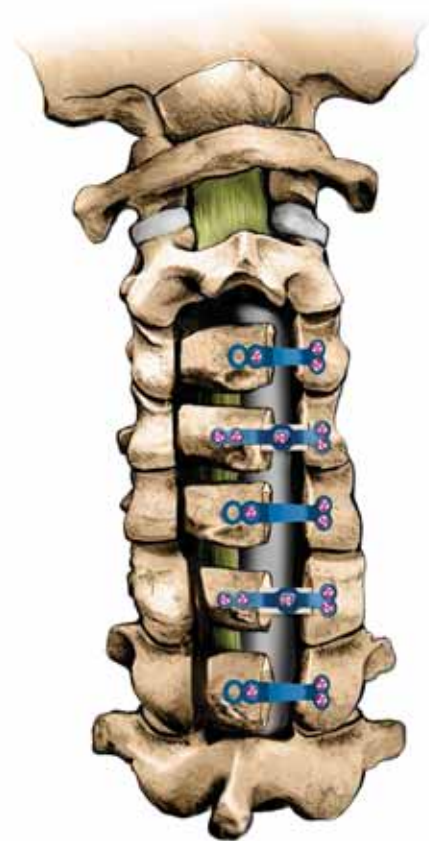


Figure 17b

The Lateral Hole Plate

In the event that the surface area of the lateral mass is either too small in its cranial-caudal dimension, or it has been reduced in the addition of one or more foraminotomies, one could opt to use the lateral hole plate. The sizing and method of insertion are the same as for the standard open door and graft plates, except that the orientation of the lateral mass screws is now parallel to the long axis of the plate. The exposure may need to be widened slightly at any level where the lateral hole plates are needed.

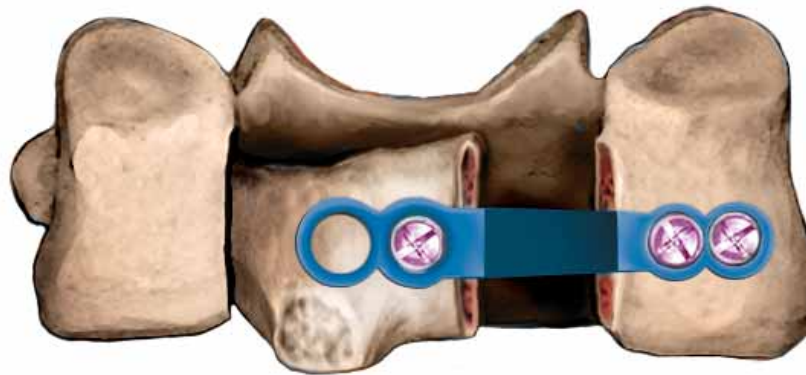


Figure 18

The Wide Mouth Plate

The Wide Mouth plate may be needed on occasion to accommodate thicker laminae. As an alternative to bending the laminar shelf of the standard open door plate, one could use the wide mouth plate to allow for easier placement onto the thicker laminae. The sizing and method of insertion are the same as for the standard open door plate.

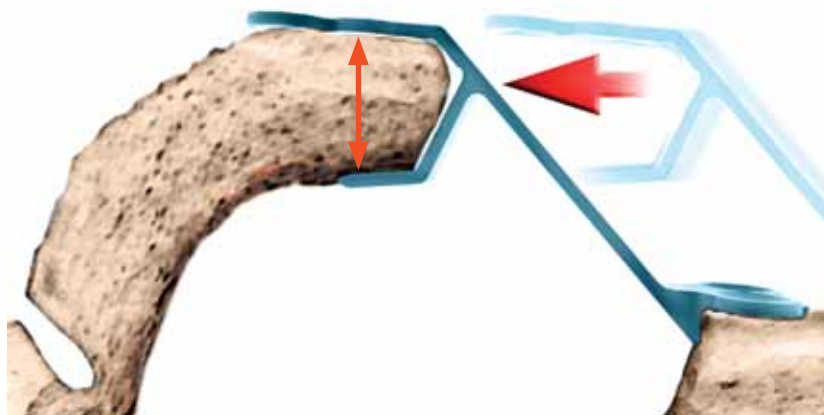


Figure 19

The Hinge Plate

The Hinge plate may be needed on occasion to secure a floppy or displaced hinge which threatens to impinge upon a nerve root or the dura. In the event that it is judged to be necessary, its application begins before opening the laminoplasty. The loose laminae should be grasped and stabilized with a suitable clamp (eg. A ligamentum flavum clamp). It is held firmly while the laminar side screws holes are drilled with the 1.9 x 5.5mm depth stopped drill bit. The hinge plate is then fastened to the lamina with two screws. The laminoplasty is then opened as usual. The lateral mass screw holes for the hinge plate are then drilled for two additional screws, firmly fixing the hinge in place.

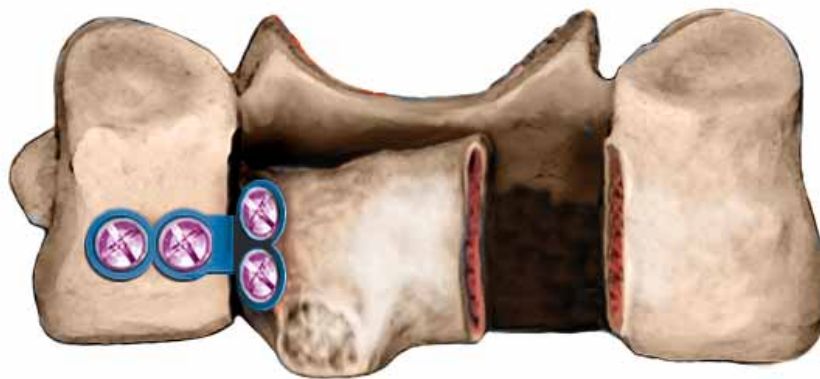


Figure 20

Implant Removal

To remove any of the laminoplasty plates described throughout this technique, engage the screw head with the Self-Holding Screwdriver, and in a counter clockwise motion, remove the screw from the bone. The plate can then be freely removed from the bone.

Implants	
Item Number	Description
Open Door Plates	
8530008	8mm Open Door Plate
853-010	10mm Open Door Plate
853-012	12mm Open Door Plate
853-014	14mm Open Door Plate
853-016	16mm Open Door Plate
853-018	18mm Open Door Plate

Graft Plates	
8530408	8mm Graft Plate
853-410	10mm Graft Plate
853-412	12mm Graft Plate
853-414	14mm Graft Plate
853-416	16mm Graft Plate
853-418	18mm Graft Plate

Lateral Hole Plates	
853008LH	8mm Open Door Lateral Hole Plate
853010LH	10mm Open Door Lateral Hole Plate
853012LH	12mm Open Door Lateral Hole Plate
853014LH	14mm Open Door Lateral Hole Plate
853016LH	16mm Open Door Lateral Hole Plate
853018LH	18mm Open Door Lateral Hole Plate
853408LH	8mm Graft Lateral Hole Plate
853410LH	10mm Graft Lateral Hole Plate
853412LH	12mm Graft Lateral Hole Plate
853414LH	14mm Graft Lateral Hole Plate
853416LH	16mm Graft Lateral Hole Plate
853418LH	18mm Graft Lateral Hole Plate

Wide Mouth Plates	
853008WM	8mm Open Door Wide Mouth Plate
853010WM	10mm Open Door Wide Mouth Plate
853012WM	12mm Open Door Wide Mouth Plate
853014WM	14mm Open Door Wide Mouth Plate
853016WM	16mm Open Door Wide Mouth Plate
853018WM	18mm Open Door Wide Mouth Plate
853008LW	8mm Open Door Lateral Hole Wide Mouth Plate
853010LW	10mm Open Door Lateral Hole Wide Mouth Plate
853012LW	12mm Open Door Lateral Hole Wide Mouth Plate
853014LW	14mm Open Door Lateral Hole Wide Mouth Plate
853016LW	16mm Open Door Lateral Hole Wide Mouth Plate
853018LW	18mm Open Door Lateral Hole Wide Mouth Plate

Hinge Plate	
8530000	Hinge Plate

Bone Screws	
853-465	2.6 x 5mm Bone Screw
853-467	2.6 x 7mm Bone Screw
853-469	2.6 x 9mm Bone Screw
853-471	2.6 x 11mm Bone Screw
853-505	3.0 x 5mm Bone Screw
853-507	3.0 x 7mm Bone Screw
853-509	3.0 x 9mm Bone Screw
853-511	3.0 x 11mm Bone Screw

Allograft	
853908	TISSUE 853908 CENTERPIECE™ Strut 8mm Service Fee
853910	TISSUE 853910 CENTERPIECE™ Strut 10mm Service Fee
853912	TISSUE 853912 CENTERPIECE™ Strut 12mm Service Fee
853914	TISSUE 853914 CENTERPIECE™ Strut 14mm Service Fee
853916	TISSUE 853916 CENTERPIECE™ Strut 16mm Service Fee
853918	TISSUE 853918 CENTERPIECE™ Strut 18mm Service Fee

Instrument Set	
Item Number	Description
8530810	8-10mm Bone Trial
8530812	12-14mm Bone Trial
8530814	16-18mm Bone Trial
853-620	Bone Cutter
853-622	Plate Holder
8530605	1.9 x 5.5mm Drill Bit, Sterile
6956016	Universal Handle
8530630	Screwdriver Shaft
8530631	Screwdriver Sleeve

PURPOSE:

The purpose of the Medtronic Sofamor Danek (MSD) CENTERPIECE™ Plate Fixation System is to provide a means to prevent expulsion of graft material after a laminoplasty has been performed.

DESCRIPTION:

The CENTERPIECE™ Plate Fixation System consists of a variety of sizes of plates and screws. The CENTERPIECE™ Plate Fixation System components are made of from medical grade titanium or titanium alloy.

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the Medtronic Sofamor Danek catalog and/or pricelist for further information about warranties and limitations of liability.

INDICATIONS:

The Medtronic Sofamor Danek CENTERPIECE™ Plate Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The CENTERPIECE™ Plate Fixation System is used to hold the graft material in place in order to prevent the graft material from expulsion, or impinging the spinal cord.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Fever or leukocytosis.
3. Morbid obesity.
4. Pregnancy.
5. Mental illness.
6. Any medical or surgical condition which would preclude potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevated white blood count (WBC), or a marked left shift in the WBC differential count.
7. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
8. Suspected or documented metal allergy or intolerance.
9. Any case needing to mix metals from different components.
10. Any case not needing a laminoplasty procedure.
11. Any patient having inadequate tissue coverage over the operative site, or inadequate bone stock or bone quality
12. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
13. Any patient who will not follow postoperative instructions, such as drug/alcohol abuse patients, and are unwilling to restrict postoperative activities.
14. Any case not described in the Indications.
15. Any patient unwilling to follow the postoperative instructions.

Contraindications of this device are consistent with those of other anterior spinal instrumentation systems. This spinal implant system is not designed, intended, or sold for uses other than those indicated.

POSSIBLE ADVERSE EFFECTS:

1. Early or late loosening of the components.
2. Implant migration.
3. Disassembly, bending, loosening, slippage, and/or breakage of any or all of the components or instruments.
4. Foreign body reaction to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring.
5. Pressure on the skin possibly resulting in skin breakdown from component parts where there is inadequate tissue coverage over the implant. Implant or graft extrusion through the skin. Wound complications.
6. Loss of proper spinal curvature, correction, height, and/or reduction.
7. Infection.
8. Bone fracture or stress shielding at, above, or below the level of surgery.
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis or other types of serious injury. Cerebral spine fluid leakage.
10. Gastrointestinal, urological, and/or reproductive system compromise, including sterility, impotency, and/or loss of consortium.
11. Hemorrhage of blood vessels and/or hematomas.
12. Discitis, arachnoiditis, and/or other types of inflammation.
13. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
14. Inability to resume activities of normal daily living.
15. Death.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse reactions.

WARNINGS AND PRECAUTIONS:

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This system is intended to be used to provide protection of the spinal canal. The safety and effectiveness of the device when implanted in the anterior spine have not been established.

Preoperative and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the CENTERPIECE™ Plate Fixation System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results.

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.



For US Audiences Only

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Other preoperative, intraoperative, and postoperative warnings are as follows:

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. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending, loosening, or migration of the device, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Use care in the handling and storage of implant components. Implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The CENTERPIECE™ Plate Fixation System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. Unless sterile packaged, all parts should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

1. Any instruction manuals, if available, should be carefully followed.
2. 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.
3. Implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
4. Never over-tighten screws so as to prevent stripping of the threads. Recheck the tightness of all screws after finishing to ensure that none have loosened during the tightening of the other screws. Failure to do so may cause loosening.

POSTOPERATIVE:

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

1. Detailed instructions on the use and limitations of the device should be given to the patient. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls, sudden jolts, or sudden blows to the spine.
2. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation that may cause sharp forces to the posterior cervical spine.

PACKAGING:

Packages for each of the components should be intact upon receipt. If a loaner, earn-out or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to Medtronic Sofamor Danek.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic Sofamor Danek. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

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. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270 °F (132 °C)	4 Minutes
Steam	Gravity	250 °F (121 °C)	30 Minutes
Steam*	Gravity*	273 °F (134 °C)*	20 Minutes*

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

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, Medtronic Sofamor Danek. Further, if any of the implanted CENTERPIECE™ Plate Fixation 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 Sofamor Danek 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:

USA

1800 Pyramid Place
Memphis, Tennessee 38132
USA
Telephone: 800-876-3133 or 901-396-3133

EUROPE

SOFAMOR SNC*
13, rue de la Perdrix
93290 TREMBLAY
FRANCE
Telephone: (33) 1.49.38.80.00

*authorized representative
RCS Bobigny B 617 320 486
NAF 331 B

listen. respond. deliver.

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

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