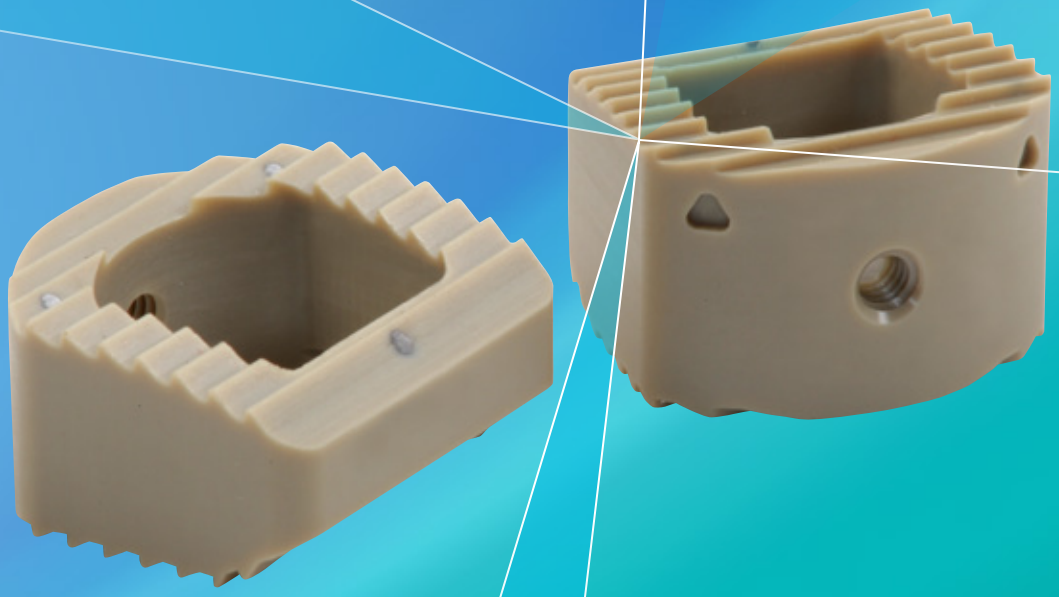
Medtronic

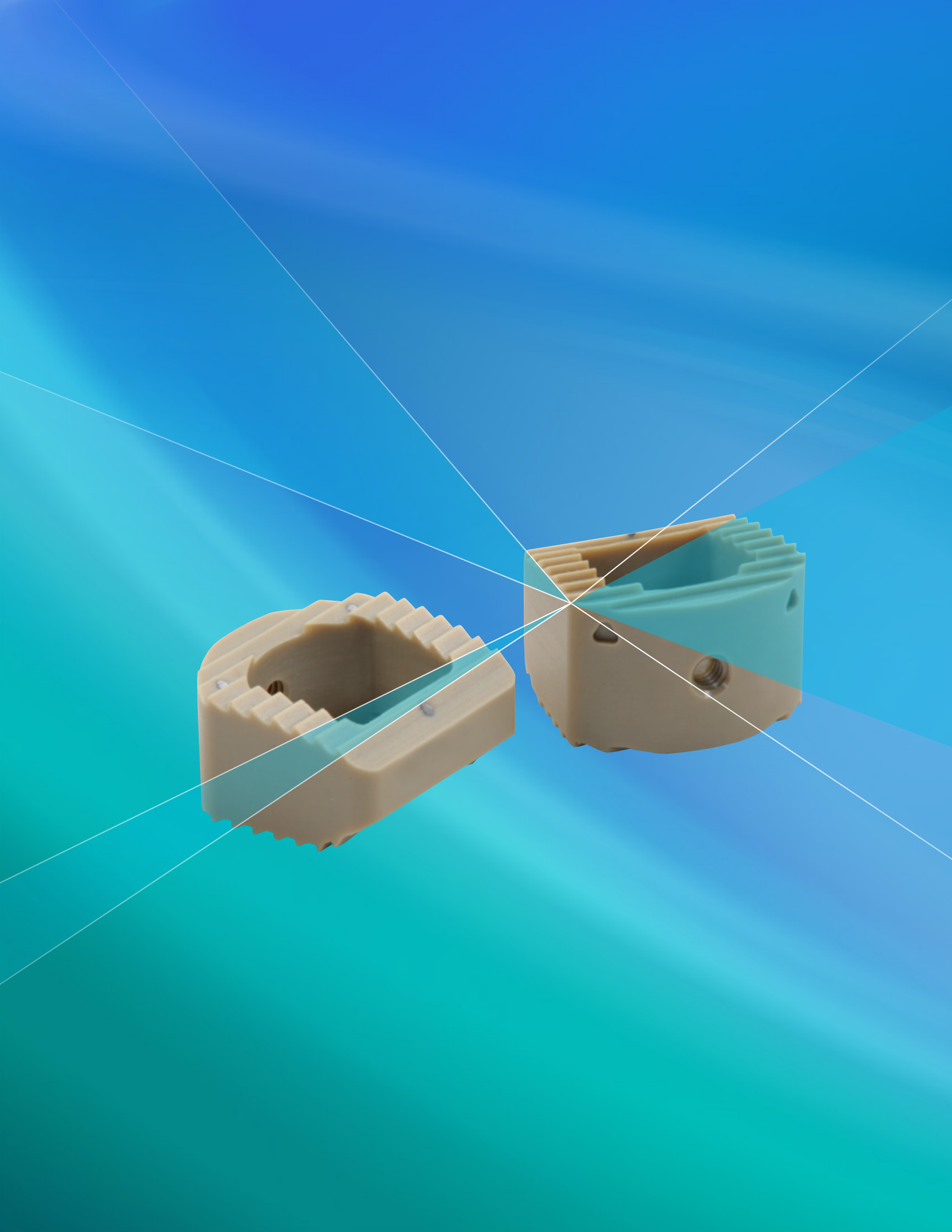
ANATOMIC PEEK

Cervical Fusion System

Surgical Technique



MICHELSON TECHNOLOGY AT WORK



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Patient Positioning/Approach

The patient is placed in the supine position with the neck in slight extension. The posterior cervical spine is supported to establish and maintain normal lordosis. The surgeon selects a right- or left-sided approach to the cervical spine **(Figure 1)**.

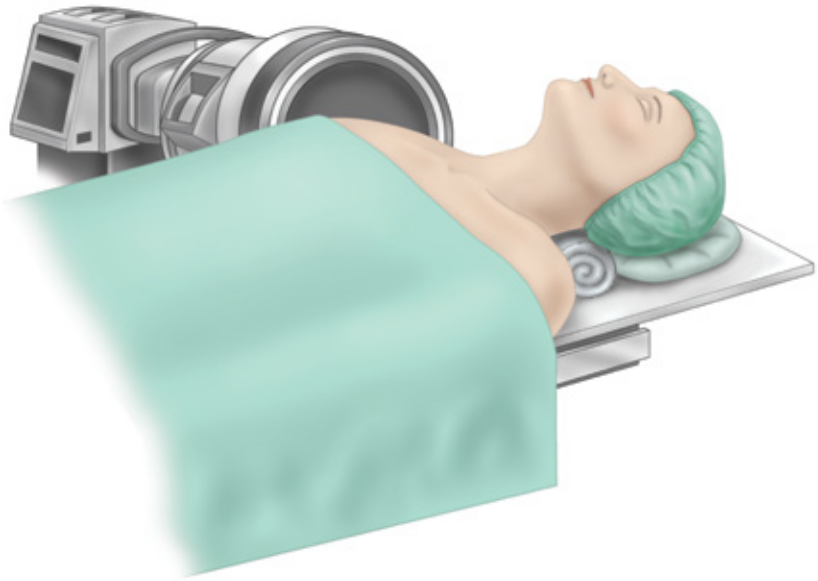

Figure 1

The platysma muscle is split. The superficial layer of the deep cervical fascia is opened along the anterior border of the sternocleidomastoid muscle. Using finger dissection, the plane between the tracea and esophagus medially and the carotid sheath laterally is established to expose the prevertebral fascia. Hand-held retractors are utilized to provide initial exposure of the anterior vertebral column and the adjacent longus colli muscles. **(Figure 2)**.

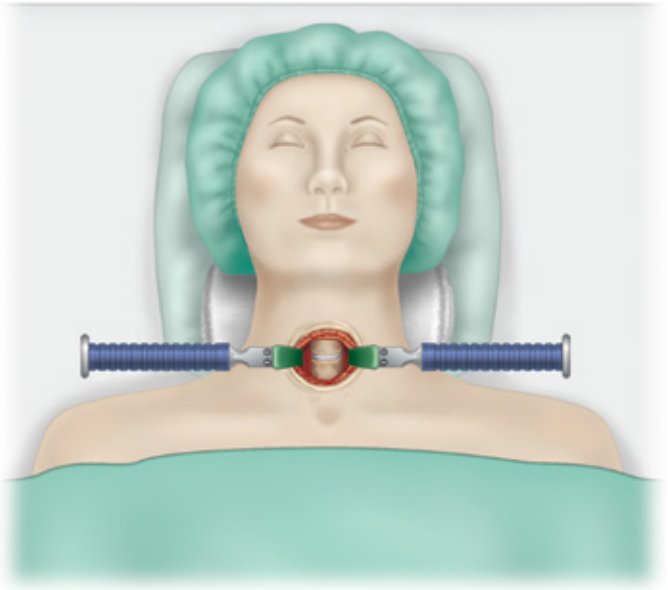

Figure 2

Exposure

After the prevertebral fascia has been opened, the disc space level is confirmed on x-ray. The longus colli muscles are subperiosteally elevated, and self-retaining retractor blades are securely positioned beneath them. A slotted blade may be used if an anterior osteophyte prevents proper positioning. A longitudinal self-retaining retractor may be placed to provide optimal visualization **(Figure 3)**. If distraction pins are used, they are positioned midline in the vertebral bodies adjacent to the disc. The distractor is placed over the pins, and gentle distraction is applied. Alternatively, a cervical halter and weights may be used for traction.

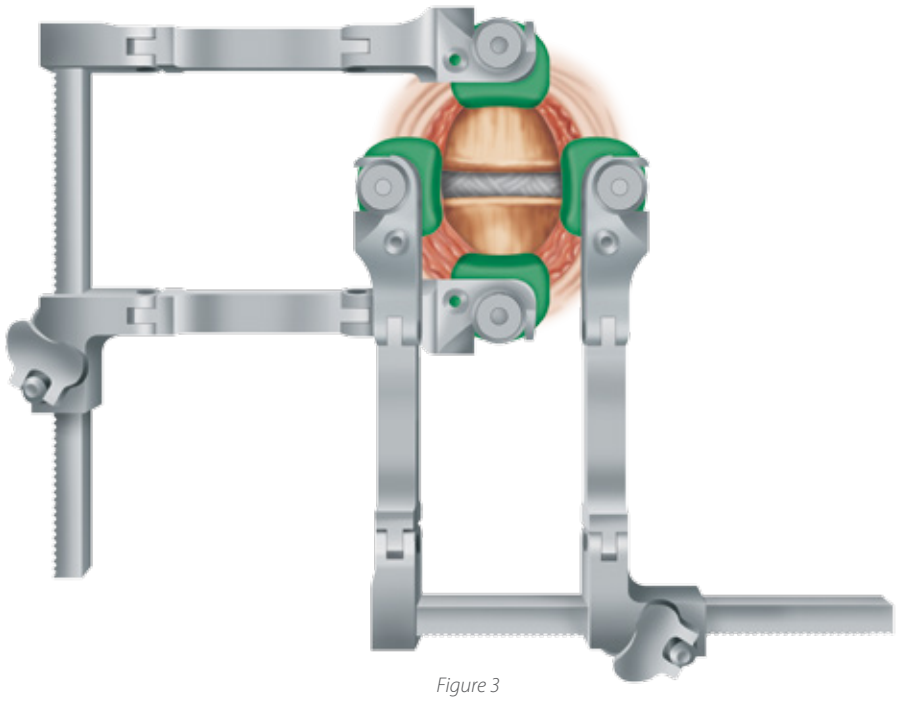

Figure 3

Discectomy

Pituitaries, curettes, and thin-footed Kerrison rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament **(Figures 4 and 5)**.

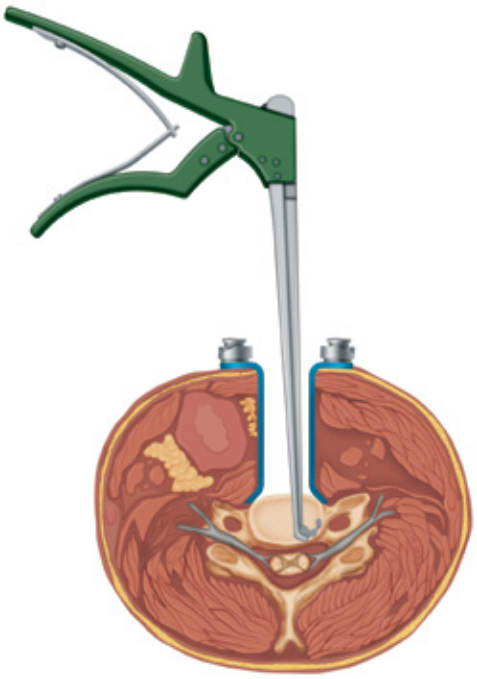

Figure 4

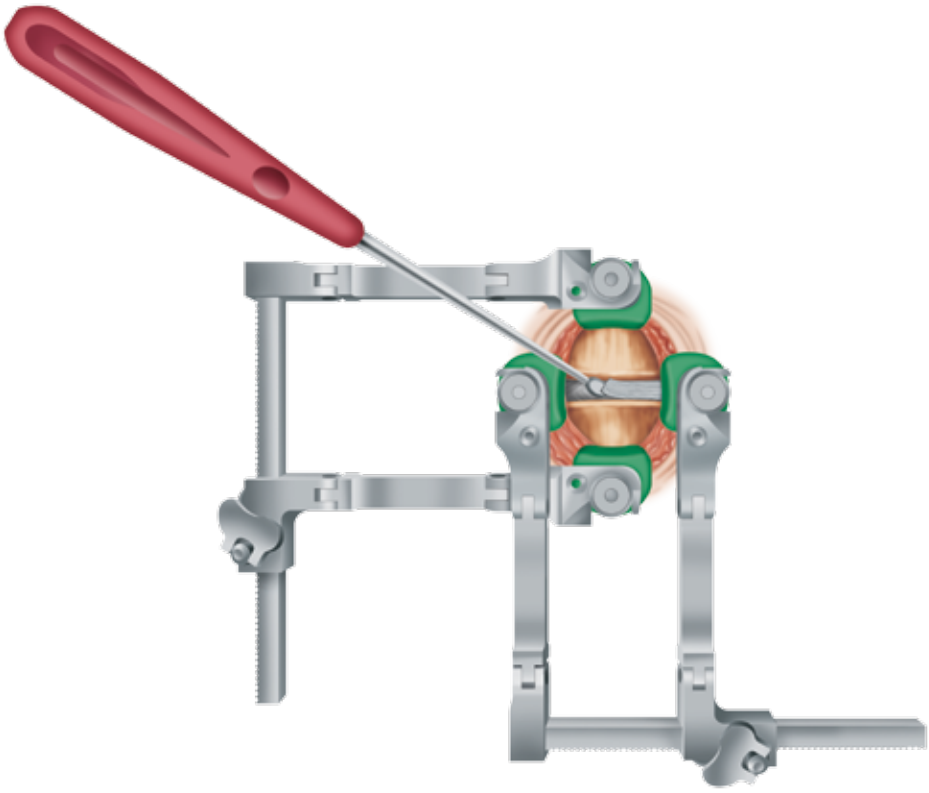

Figure 5

Discectomy *continued*

A high-speed drill with a burr (match tip/round) may be utilized for removal of the posterior disc and osteophytes to achieve neural decompression **(Figure 6)**. The posterior longitudinal ligament and osteophytes are then carefully removed.

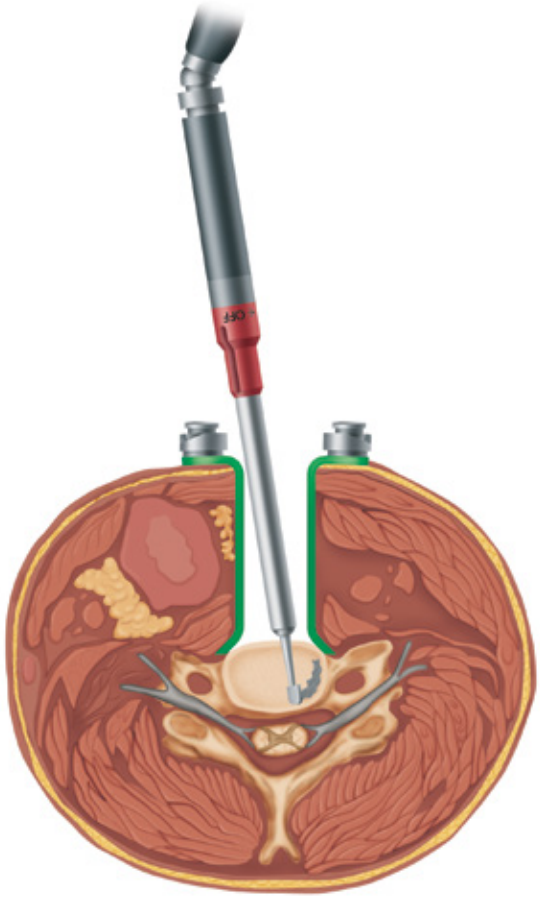

Figure 6

End-plate Preparation

Once the decompression and end-plate preparation are completed, the ANATOMIC PEEK spacer sizing is determined by selecting the lordotic trial that provides the most satisfactory fit in the prepared disc space **(Figures 7 and 8)**. The trial should fit flush against the end plates and produce a tight interference fit while restoring and maintaining adequate interbody height. If it does not, choose a taller trial and/or re-evaluate the end-plate preparation. The trials come in three "footprints;" 14mm wide by 11mm deep (purple trials), 16mm wide by 14mm deep (green trials), and 18mm wide by 16mm deep (blue). Choose the footprint that best matches the width and depth of the prepared interbody space. The trials for use with the Anatomic PEEK Cervical Fusion system match the geometry of the cervical spacers in the system.

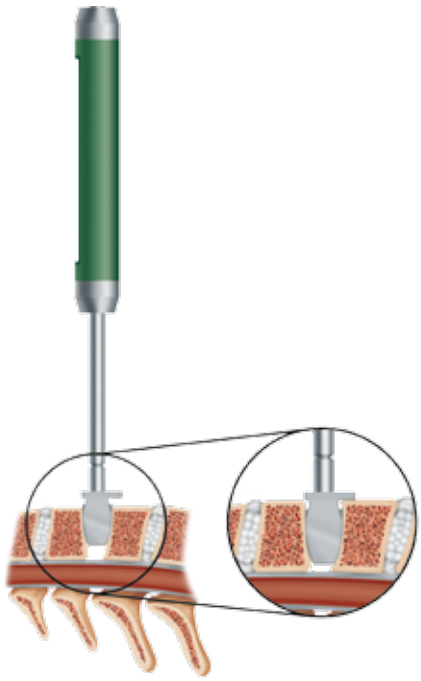

Figure 7

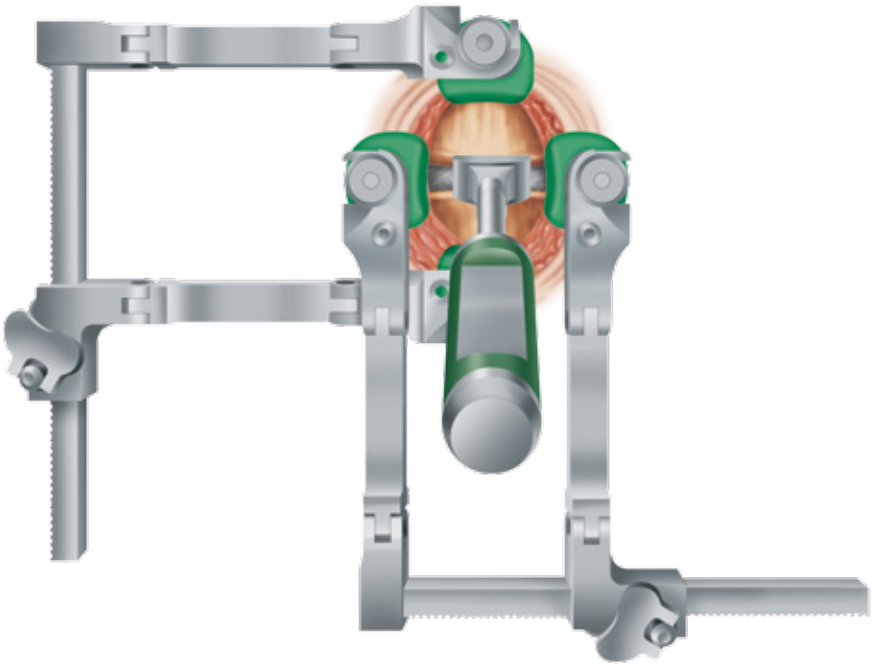

Figure 8

End-plate Preparation *continued*

Final end-plate preparation may be carried out with a rasp. Select the rasp that will decorticate the end plates with minimal bone removal. The rasp will help ensure end-plate preparation is complete. **(Figures 9 and 10)**.

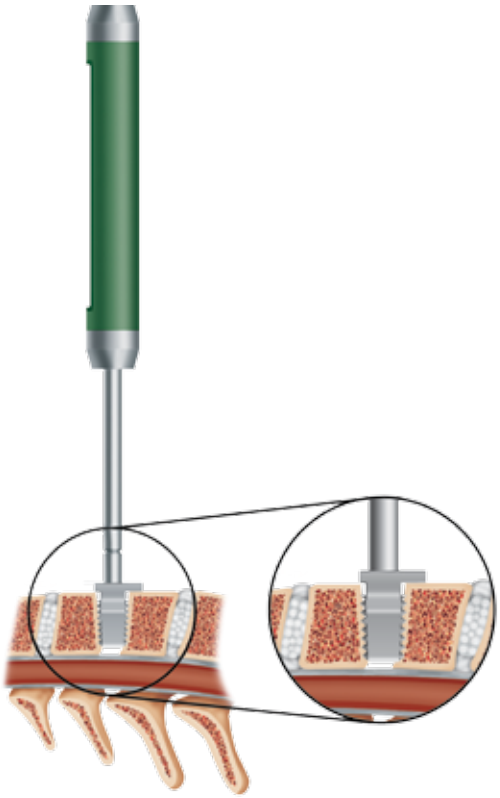

Figure 9

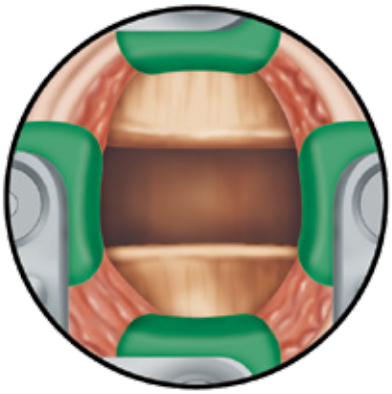

Figure 10

Implant Placement

Select the ANATOMIC PEEK Cervical Fusion Spacer that corresponds to the final trial.

The ANATOMIC PEEK spacer is attached to the Threaded Inserter **(Figure 11)**. The center of the implant is then packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The directional arrows on the anterior surface of the spacer should point superiorly.

Figure 11

The implant is introduced into the prepared interbody space and gently tapped into position using a mallet. A tamp may be used for final positioning **(Figure 12)**.

If necessary, the spacer can be repositioned by reattaching the Threaded Inserter.

Figure 12

Application of Anterior Cervical Plate

Select an anterior cervical plate with the appropriate length **(Figure 13)**. Ensure that the plate contour matches the desired lordosis. If the lordosis of the plate needs adjusting, use the plate bender to increase or decrease the lordotic curve **(Figure 14)**.

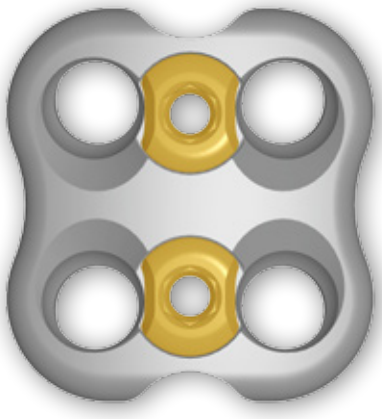

Figure 13

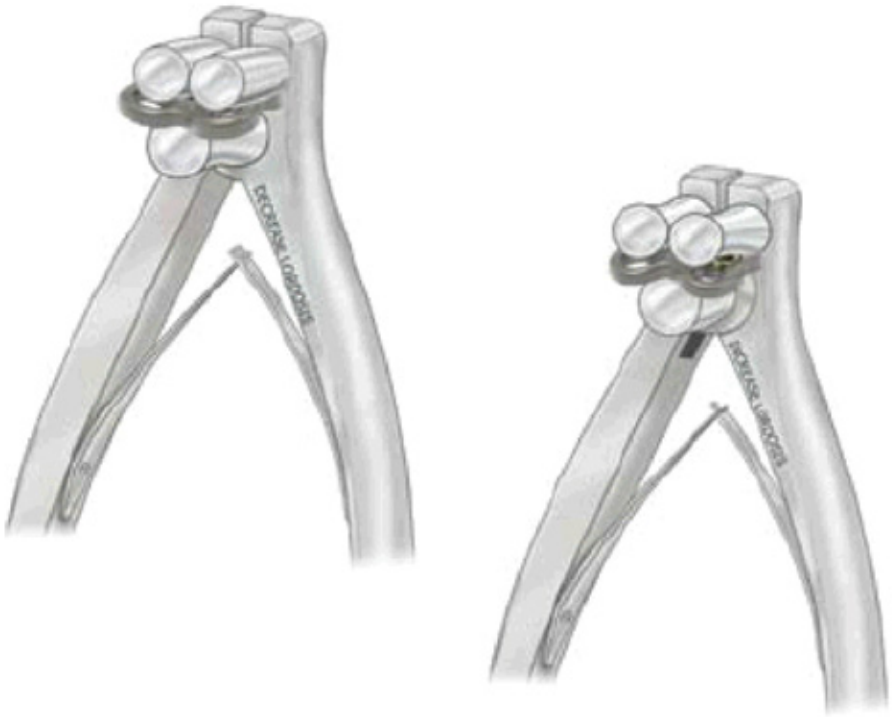

Figure 14

Application of Anterior Cervical Plate *continued*

Secure the plate with prefixation pins. Select the drill guide to begin drilling, tapping, and inserting the screws **(Figure 15)**.

Ensure that screws are locked into the plate with the anti-back out mechanism for the appropriate plate. Refer to the appropriate supplemental fixation surgical technique for proper construct insertion.

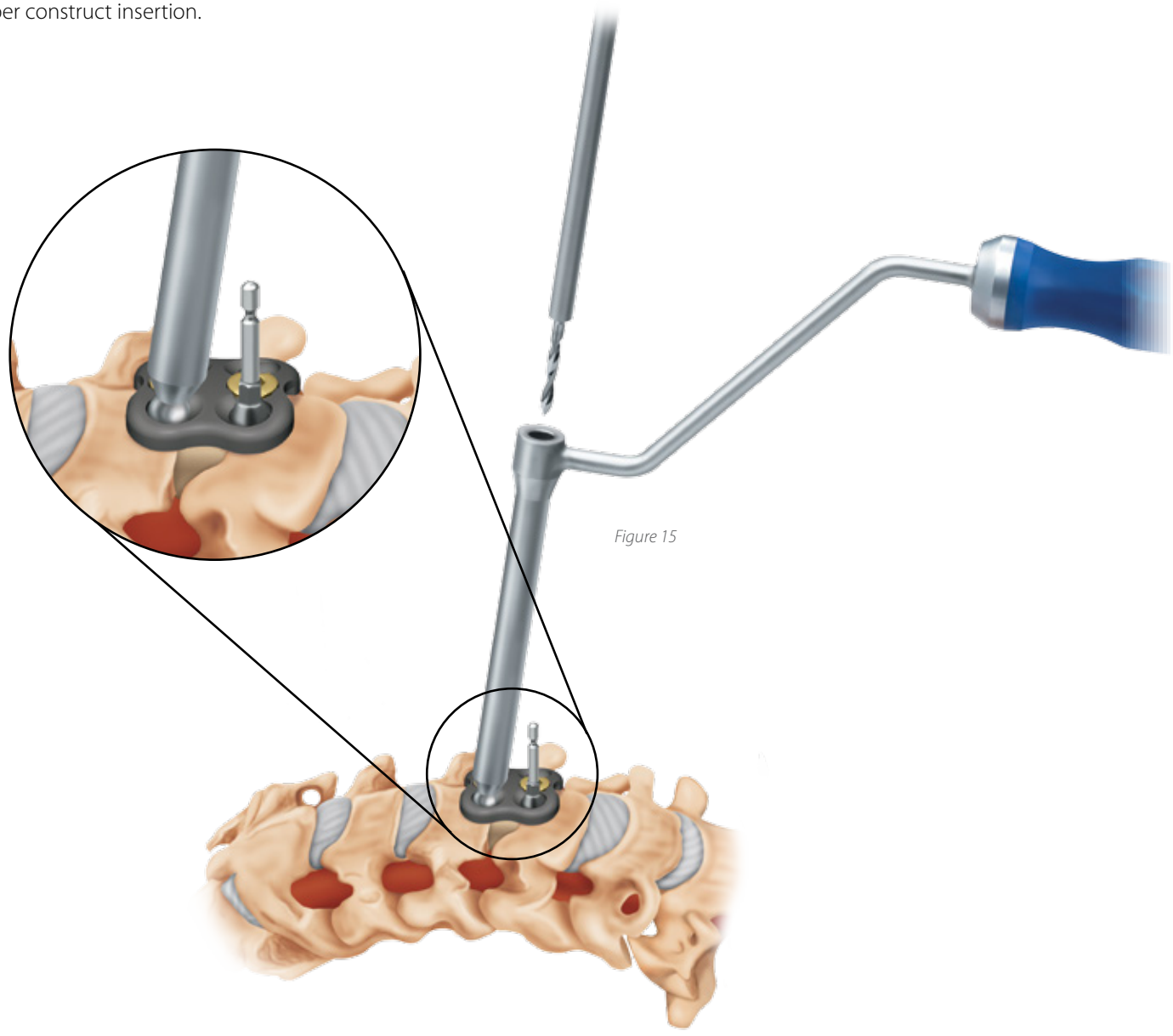

Figure 15

Explantation

First remove the plate. Removal of the implant can be accomplished by using a high-speed burr to resect the implant. The spacer can be removed intact by exposing the anterior surface of the implant and creating a clear plane around the implant by removing surrounding bone with a high-speed burr or osteotomes. The implant inserter/holder can then be reattached to the spacer, and the implant can be removed intact with an in-line slap hammer.

Ordering Information

ANATOMIC PEEK 14mm × 11mm IMPLANT SET

Product Number	Description	Total Internal Volume
4240541	14mm x 11mm x 5mm	0.22cc
4240641	14mm x 11mm x 6mm	0.26cc
4240741	14mm x 11mm x 7mm	0.31cc
4240841	14mm x 11mm x 8mm	0.36cc
4240941	14mm x 11mm x 9mm	0.40cc
4240041	14mm x 11mm x10mm	0.45cc
4240141	14mm x 11mm x 11mm	0.50cc
4240241	14mm x 11mm x 12mm	0.54cc
4240341	14mm x 11mm x 13mm	0.59cc
4240441	14mm x 11mm x 14mm	0.64cc

ANATOMIC PEEK 16mm × 14mm IMPLANT SET

Product Number	Description	Total Internal Volume
4240564	16mm x 14mm x 5mm	0.36cc
4240664	16mm x 14mm x 6mm	0.44cc
4240764	16mm x 14mm x 7mm	0.51cc
4240864	16mm x 14mm x 8mm	0.59cc
4240964	16mm x 14mm x 9mm	0.67cc
4240064	16mm x 14mm x 10mm	0.74cc
4240164	16mm x 14mm x 11mm	0.82cc
4240264	16mm x 14mm x 12mm	0.90cc
4240364	16mm x 14mm x 13mm	0.97cc
4240464	16mm x 14mm x 14mm	1.05cc

ANATOMIC PEEK 18mm × 16mm IMPLANT SET

Product Number	Description	Total Internal Volume
4240586	18mm x 16mm x 5mm	0.48cc
4240686	18mm x 16mm x 6mm	0.58cc
4240786	18mm x 16mm x 7mm	0.69cc
4240886	18mm x 16mm x 8mm	0.79cc
4240986	18mm x 16mm x 9mm	0.89cc
4240086	18mm x 16mm x 10mm	1.00cc
4240186	18mm x 16mm x 11mm	1.10cc
4240286	18mm x 16mm x 12mm	1.20cc
4240386	18mm x 16mm x 13mm	1.31cc
4240486	18mm x 16mm x 14mm	1.41cc

VERTE-STACK® ANATOMIC PEEK™ INSTRUMENT SET

Product Number	Description
6246011	Inserter Handle
6279017	Threaded inner shaft
6246041	Rasp 14mm x 11mm
6246064	Rasp 16mm x 14mm
6246084	Rasp 18mm x 16mm
875-725	Curved Tamp
6472061	Mallet
6279004	Caliper
6248541	Trial 14mm x 11mm, 5mm
6248641	Trial 14mm x 11mm, 6mm
6248741	Trial 14mm x 11mm, 7mm
6248841	Trial 14mm x 11mm, 8mm
6248941	Trial 14mm x 11mm, 9mm
6248041	Trial 14mm x 11mm, 10mm
6248141	Trial 14mm x 11mm, 11mm
6248241	Trial 14mm x 11mm, 12mm
6248564	Trial 16mm x 14mm, 5mm
6248664	Trial 16mm x 14mm, 6mm
6248764	Trial 16mm x14mm, 7mm
6248864	Trial 16mm x 14mm, 8mm
6248964	Trial 16mm x 14mm, 9mm
6248064	Trial 16mm x 14mm, 10mm
6248164	Trial 16mm x 14mm, 11mm
6248264	Trial 16mm x 14mm, 12mm
6248364	Trial 16mm x 14mm, 13mm
6248464	Trial 16mm x 14mm, 14mm
6248586	Trial 18mm x 16mm, 5mm
6248686	Trial 18mm x 16mm, 6mm
6248786	Trial 18mm x 16mm, 7mm
6248886	Trial 18mm x 16mm, 8mm
6248986	Trial 18mm x 16mm, 9mm
6248086	Trial 18mm x 16mm, 10mm
6248186	Trial 18mm x 16mm, 11mm
6240004	Anatomic Upper Tray
6240005	Anatomic Lower Tray
6240007	Anatomic Lid
6240008	Anatomic Case

Important Product Information for ANATOMIC PEEK Cervical Fusion System

PURPOSE

This device is a 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. This device is manufactured from medical grade POLYETHERETHERKETONE (PEEK) with tantalum markers and is provided sterile.

DESCRIPTION

The ANATOMIC PEEK Cervical Fusion System consists of cages of various widths and heights which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The ANATOMIC PEEK™ devices must be used with supplemental fixation.

No warranties, express or implied, are made. 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.

Medical grade titanium and medical grade PEEK may be used together. Never use titanium or titanium alloy implants with stainless steel in the same construct.

Indications

The ANATOMIC PEEK Cervical Fusion System is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2 – C3 disc to the C7 – T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK device is to be used with supplemental fixation. The ANATOMIC PEEK Cervical Fusion System is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open anterior approach.

CONTRAINDICATIONS

The ANATOMIC PEEK device is not intended for posterior surgical implantation. Contraindications also include, but are not limited to:

1. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
2. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
3. Any patient unwilling to cooperate with postoperative instructions.
4. Fever or leukocytosis.
5. Infection local to the operative site and/or signs of local inflammation.
6. Mental illness.
7. Morbid obesity.
8. Pregnancy.
9. Any case not requiring fusion.
10. Suspected or documented allergy or intolerance to the component materials.
11. This device must not be used for pediatric cases, or where the patient still has general skeletal growth.
12. Patients with a known hereditary or required bone friability or calcification problem should not be considered for this type of surgery.
13. Prior fusion at the level to be treated.
14. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
15. Spondylolisthesis unable to be reduced to Grade 1 (when used as a cervical interbody device).
16. Any case that requires the mixing of metals from two different components or systems.

NOTA BENE

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

1. Severe bone resorption.
2. Osteomalacia
3. Severe osteoporosis.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:

1. Bone loss or decrease in bone density possibly caused by stress shielding.
2. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
3. Loss of spinal mobility or function.
4. Inability to perform the activities of daily living.
5. Change in mental status.
6. Death.
7. Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
8. Disassembly, bending, and/or breakage of any or all of the components.
9. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and/or meningitis.
10. Early or late loosening of the components.
11. Implant migration.
12. Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation, and/or autoimmune disease.
13. Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the autograft, or at the bone graft harvest site at, above, and/or below the level of surgery.
14. Ileus, gastritis, bowel obstruction or other types of gastrointestinal complications.
15. Graft donor site complications including pain, fracture, infection, or wound healing problems.
16. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.
17. Wound necrosis or wound dehiscence.
18. Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
19. Infection.
20. Loss of neurologial function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss, and/or spasms.
21. Non-union (or pseudarthrosis), delayed union, and/or mal-union.
22. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
23. Scar formation possibly causing neurological compromise around nerves and/or pain.
24. Subsidence of the device into vertebral body(ies).
25. Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.

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

WARNING(S)

This system was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

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 in cervical interbody fusion procedures without autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

This system should not be used in any case not described in the indications.

Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.

PRECAUTION(S)

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.

Based on fatigue testing results, when using the ANATOMIC PEEK™ CERVICAL FUSION SYSTEM, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of this system.

!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 ANATOMIC PEEK Cervical Fusion System has not been evaluated for safety, heating, migration, or compatibility in the magnetic resonance environment.

Based on fatigue testing results, when using the ANATOMIC PEEK Cervical Fusion System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of this system.

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.

Important Product Information for ANATOMIC PEEK Cervical Fusion System *continued*

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 ANATOMIC PEEK Cervical Fusion 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 used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.

Further information on the use of this system will be made available on request.

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 type of construct to be assembled 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.

This device is provided sterile. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

The instructions in any available applicable 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 implant components may cause injury to the patient or operative personnel.

To ensure proper fusion below and around the location of the instrumentation, autograft, allograft or a combination of autograft and allograft must be used in all cervical interbody procedures. In cervical interbody procedures, autograft and/or allogenic bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

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. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, or breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary 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 or sudden jolts in spinal position.

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. The patient should be advised not to smoke or consume excess alcohol during the bone healing process.

Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual bending, loosening, or breakage of the device. It is important that immobilization of the union is established and confirmed by roentgenographic examination. Where there is a non-union, or if the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs.

Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING

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.

STERILIZATION: ANATOMIC PEEK CERVICAL FUSION SYSTEM DEVICES ARE PROVIDED STERILE VIA GAMMA IRRADIATION.

Only sterile products should be placed in the operative field. Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company.

Refer to the package insert of the supplemental instrumentation for sterilization information.

No implant should be re-used once it comes into contact with human tissue or body fluid. Always immediately clean and re-sterilize instruments that have been used in surgery. This process must be performed before handling or (if applicable) before returning the product to Medtronic.

Sterilization instructions for instruments used with this system can be found at http://manuals.medtronic.com/. Refer to the reprocessing instructions for general instruments– 0380035 for cleaning and sterilization instructions.

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, contact Medtronic.

EXPLANATION OF SYMBOLS

Rx only	Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.
	Consult Instructions for Use
	Do Not Reuse
	Batch Code
	Manufacturer
REF	Catalogue Number
	Sterilized using Irradiation
	Use By

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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.

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