Medtronic

ANATOMIC PEEK PTC- Pure Titanium Coating

Cervical Fusion System

Surgical Technique

MICHELSON TECHNOLOGY AT WORK

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Cervical Fusion System

Surgical Technique

Patient Positioning/Approach

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

Figure 1

Split the platysma muscle. Open the superficial layer of the deep cervical fascia along the anterior border of the sternocleidomastoid muscle. Using finger dissection, expose the prevertebral fascia by establishing the plane between the trachea and esophagus medially and the cartoid sheath laterally. Utilize hand-held retractors to provide initial exposure of the anterior vertebral column and the adjacent longus colli muscles. **(Figure 2)**.

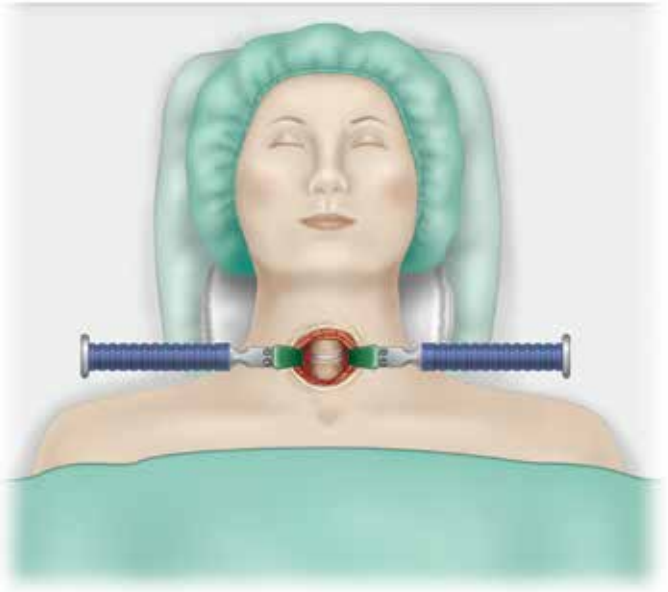

Figure 2

Exposure

After opening the prevertebral fascia confirm the disc space level on x-ray. Elevate the longus colli muscles subperiosteally, and securely position the self-retaining retractor blades beneath them. A slotted blade may be used if an anterior osteophyte prevents proper positioning. Place a longitudinal self-retaining retractor to provide optimal visualization **(Figure 3)**. This may be done with the assistance from retracting and distracting instruments such as the Medtronic TRIMELINE® Anterior Cervical Instrument System. If distraction pins are used, they are positioned midline in the vertebral bodies adjacent to the disc. Place the distractor over the pins, and apply gentle distraction. Alternatively, a cervical halter and weights may be used for traction.

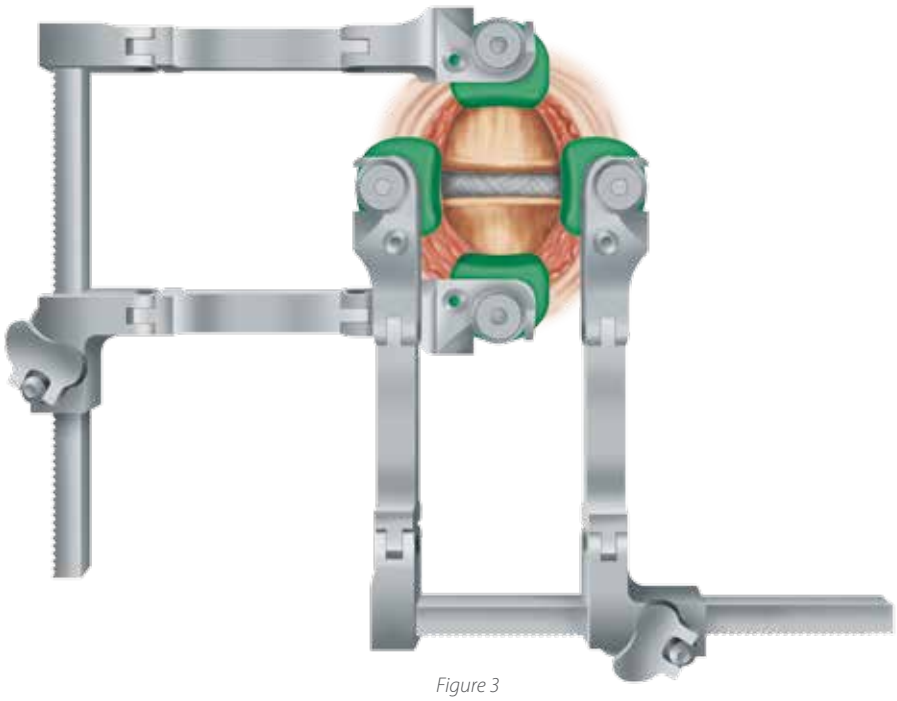

Figure 3

Discectomy

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

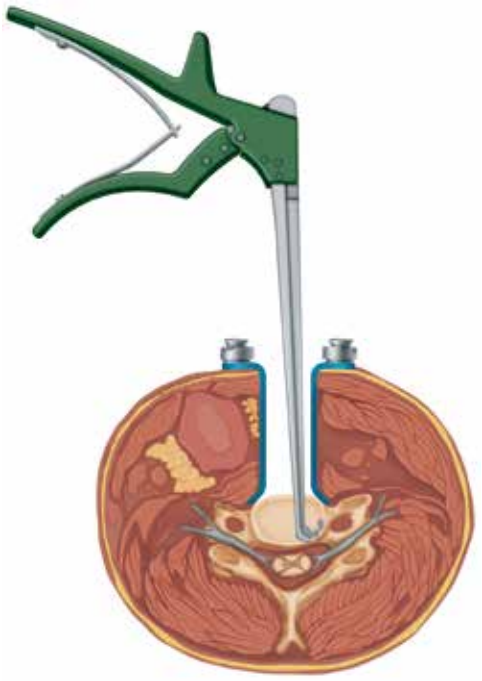

Figure 4

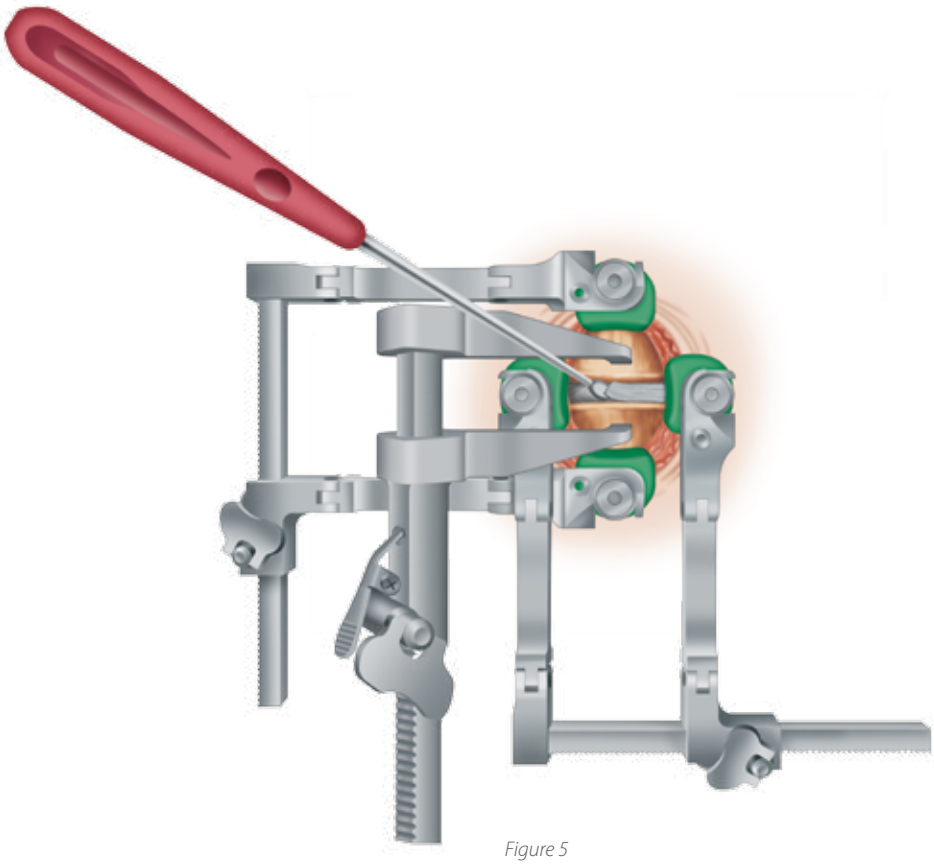

Figure 5

Discectomy *continued*

Utilize a high-speed drill with a burr (match tip/round) for removal of the posterior disc and osteophytes to achieve neural decompression **(Figure 6)**. Then carefully remove the posterior longitudinal ligament and osteophytes.

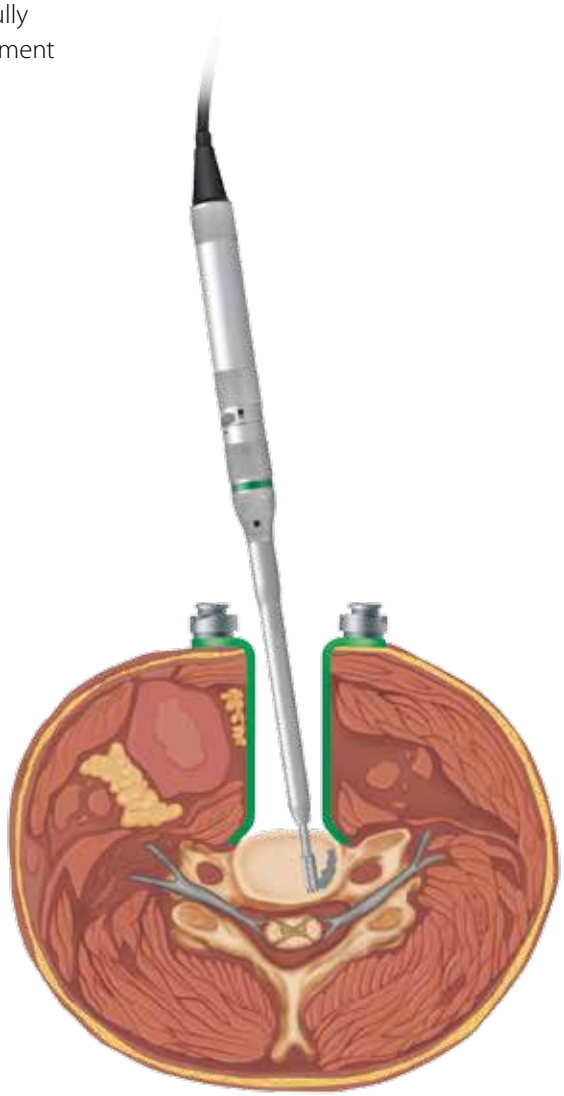

Figure 6

End-plate Preparation

Once the decompression and end-plate preparation are completed, determine the ANATOMIC PEEK PTC spacer size 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 PTC Cervical Fusion System match the geometry of the cervical spacers in the system.

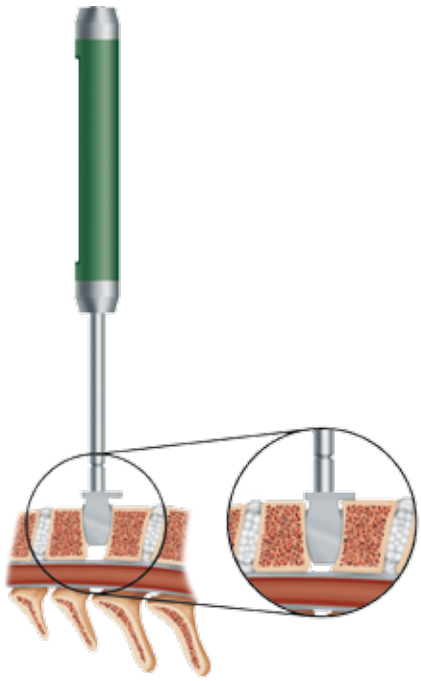

Figure 7

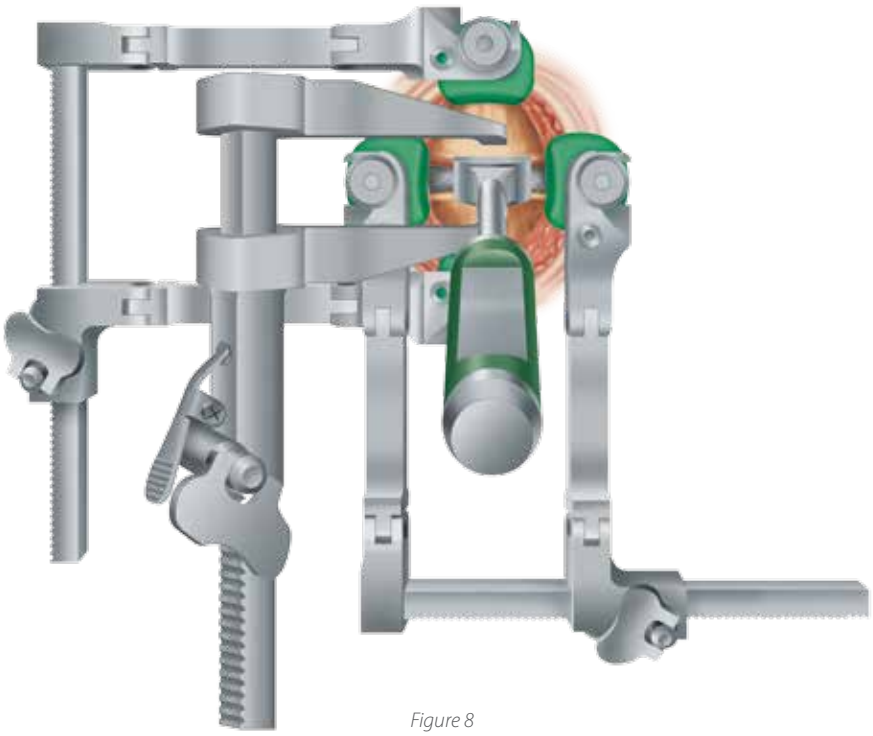

Figure 8

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)**.

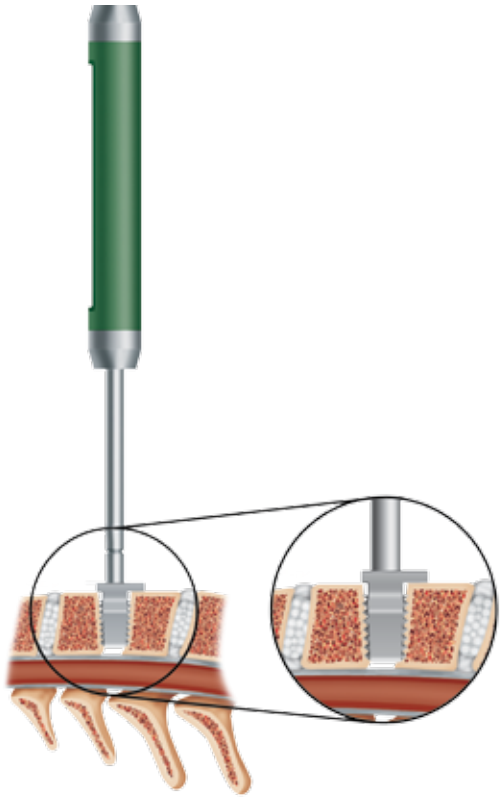

Figure 9

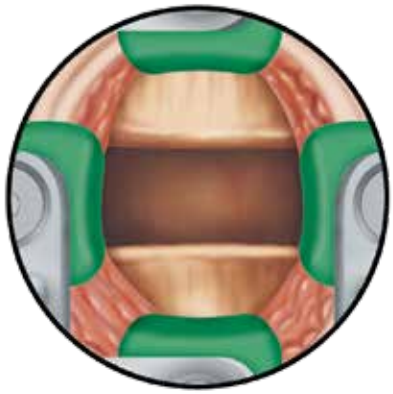

Figure 10

Implant Placement

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

Attach the ANATOMIC PEEK PTC spacer to the Threaded Inserter. Then pack the center of the implant with autograft and/or allogenic bone graft comprised of corticocancellous bone chips such as XPANSE® C Bone Insert* **(Figure 11)**. The directional arrows on the anterior surface of the spacer should point superiorly.

Figure 11

Introduce the implant into the prepared interbody space and gently tap into position using a Mallet. A tamp may be used for final positioning **(Figure 12)**.

If necessary, reposition the spacer by reattaching the Threaded Inserter.

Figure 12

*For additional information on the XPANSE® C Bone Insert, please refer to the product brochure.

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 **(Figure 16)**. Refer to the appropriate supplemental fixation surgical technique for proper construct insertion.

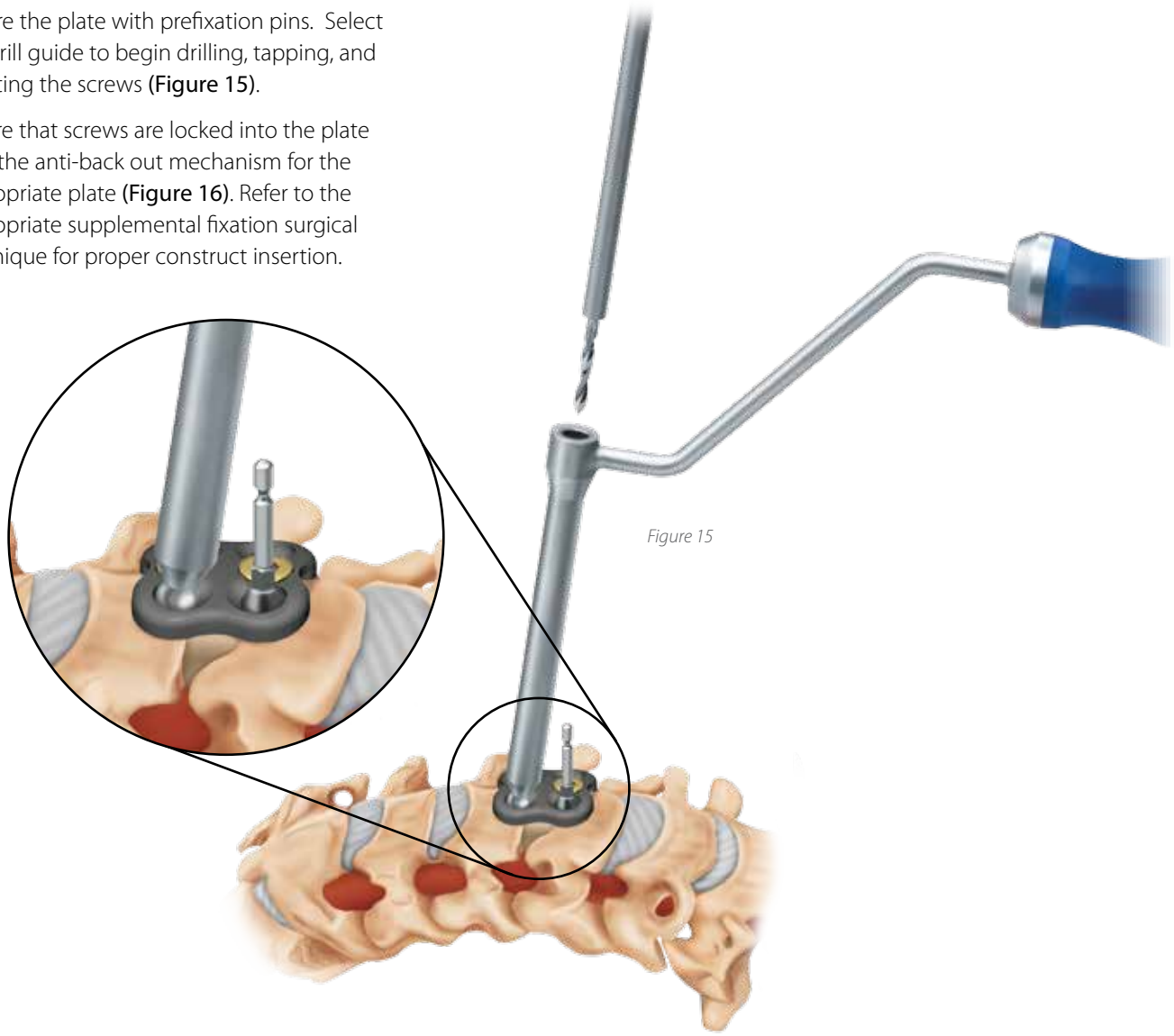

Figure 15

Final Construct

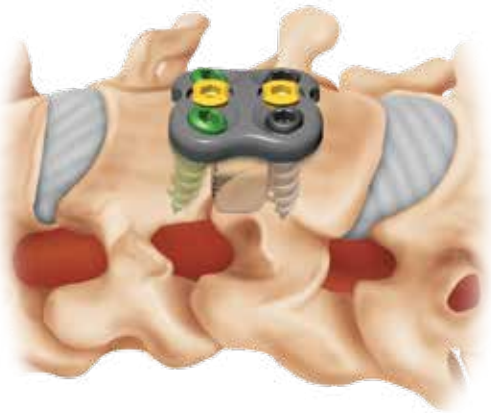

Figure 16

Application of Anterior Cervical Plate *continued*

Multi-level Implantation

When preforming a two-level procedure with an Anatomic PEEK PTC Interbody Cage, refer to the initial steps as described in this technique. To ensure sufficient access to the affected disc spaces, make the skin incision centered at the middle vertebral body. A standard incision for the exposure of two contiguous levels is required **(Figures 17a and 17b)**.

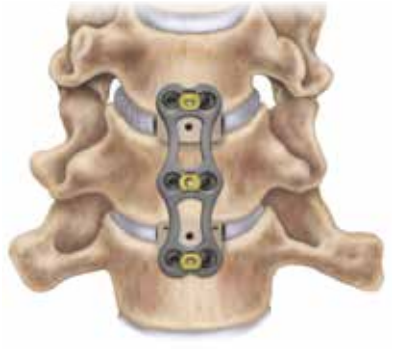

Figure 17a

Figure 17b

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 PTC IMPLANT SET

Product Number	Description (Width x Depth x Posterior Height)	Total Internal Volume
5030541	14mm × 11mm × 5mm	0.22cc
5030641	14mm × 11mm × 6mm	0.26cc
5030741	14mm × 11mm × 7mm	0.31cc
5030841	14mm × 11mm × 8mm	0.36cc
5030941	14mm × 11mm × 9mm	0.40cc
5030564	16mm × 14mm × 5mm	0.36cc
5030664	16mm × 14mm × 6mm	0.44cc
5030764	16mm × 14mm × 7mm	0.51cc
5030864	16mm × 14mm × 8mm	0.59cc
5030964	16mm × 14mm × 9mm	0.67cc

Optional Implants

Product Number	Description (Width x Depth x Posterior Height)	Total Internal Volume
5030041	14mm × 11mm × 10mm	0.45cc
5030141	14mm × 11mm × 11mm	0.50cc
5030241	14mm × 11mm × 12mm	0.54cc
5030341	14mm × 11mm × 13mm	0.59cc
5030441	14mm × 11mm × 14mm	0.64cc

VERTE-STACK ANATOMIC PEEK INSTRUMENT SET

Product Number	Description
6246011	Inserter Handle
6279017	Threaded Inner Shaft
6246041	Rasp 14mm × 11mm
6246064	Rasp 16mm × 14mm
6246084	Rasp 18mm × 16mm
875-725	Curved Tamp
6472061	Mallet
6279004	Caliper
6248541	Trial 14mm × 11mm, 5mm
6248641	Trial 14mm × 11mm, 6mm
6248741	Trial 14mm × 11mm, 7mm
6248841	Trial 14mm × 11mm, 8mm

VERTE-STACK ANATOMIC PEEK INSTRUMENT SET

continued

Product Number	Description
6248941	Trial 14mm × 11mm, 9mm
6248041	Trial 14mm × 11mm, 10mm
6248141	Trial 14mm × 11mm, 11mm
6248241	Trial 14mm × 11mm, 12mm
6248564	Trial 16mm × 14mm, 5mm
6248664	Trial 16mm × 14mm, 6mm
6248764	Trial 16mm × 14mm, 7mm
6248864	Trial 16mm × 14mm, 8mm
6248964	Trial 16mm × 14mm, 9mm
6248064	Trial 16mm × 14mm, 10mm
6248164	Trial 16mm × 14mm, 11mm
6248264	Trial 16mm × 14mm, 12mm
6248364	Trial 16mm × 14mm, 13mm
6248464	Trial 16mm × 14mm, 14mm
6248586	Trial 18mm × 16mm, 5mm
6248686	Trial 18mm × 16mm, 6mm
6248786	Trial 18mm × 16mm, 7mm
6248886	Trial 18mm × 16mm, 8mm
6248986	Trial 18mm × 16mm, 9mm
6248086	Trial 18mm × 16mm, 10mm
6248186	Trial 18mm × 16mm, 11mm
6240004	Anatomic Upper Tray
6240005	Anatomic Lower Tray
6240007	Anatomic Lid
6240008	Anatomic Case

Important Information for ANATOMIC PEEK PTC 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), tantalum markers, a commercially pure titanium (CP Ti) coating, and is provided sterile.

DESCRIPTION

The ANATOMIC PEEK PTC Cervical Fusion System consists of cages of various widths and heights which can be inserted between one disc level or two contiguous levels 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 PTC 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.

Medical grade tantalum, medical grade CP Ti, 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 PTC Cervical Fusion System is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one disc level or two contiguous levels 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 PTC device is to be used with supplemental fixation. The ANATOMIC PEEK PTC 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 PTC device is not intended for posterior surgical implantation. Contraindications also include, but are not limited to:

- 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.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any patient unwilling to cooperate with postoperative instructions.
- Fever or leukocytosis.
- Infection local to the operative site and/or signs of local inflammation.
- Mental illness.
- Morbid obesity.
- Pregnancy.
- Any case not requiring fusion.
- Suspected or documented allergy or intolerance to the component materials.
- This device must not be used for pediatric cases.
- Patients with a known hereditary or required bone friability or calcification problem should not be considered for this type of surgery.
- Prior fusion at the level to be treated.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- 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:

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

POTENTIAL ADVERSE EVENTS

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

- Bone loss or decrease in bone density possibly caused by stress shielding.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
- Loss of spinal mobility or function.
- Loss of spinal mobility or function.
- Inability to perform the activities of daily living.
- Change in mental status.
- Death.
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Disassembly, bending, and/or breakage of any or all of the components.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and/or meningitis.
- Early or late loosening of the components.
- Implant migration.
- Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation, and/or autoimmune disease.
- 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.
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal complications.
- Graft donor site complications including pain, fracture, infection, or wound healing problems.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.
- Wound necrosis or wound dehiscence.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Infection.
- 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.
- Non-union (or pseudarthrosis), delayed union, and/or mal-union.
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Subsidence of the device into vertebral body(ies).
- 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 place- ment 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 PTC 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.1

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

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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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