Medtronic

PEEK PREVAIL™

Cervical Interbody Device

Surgical Technique

As described by:

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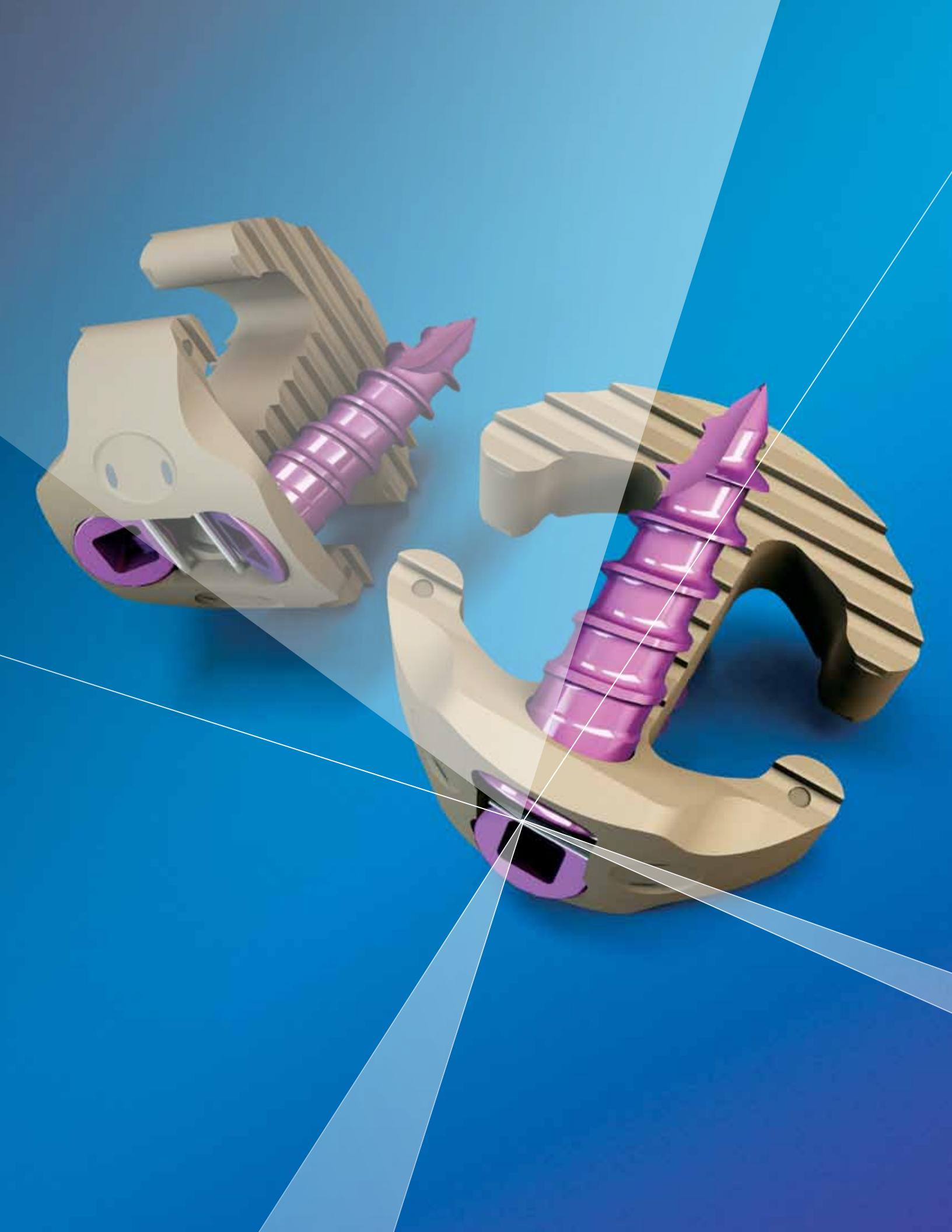
ZEPHIR® System incorporates technology developed by Gary K. Michelson, MD.

MICHELSON TECHNOLOGY AT WORK



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Cervical Interbody Device

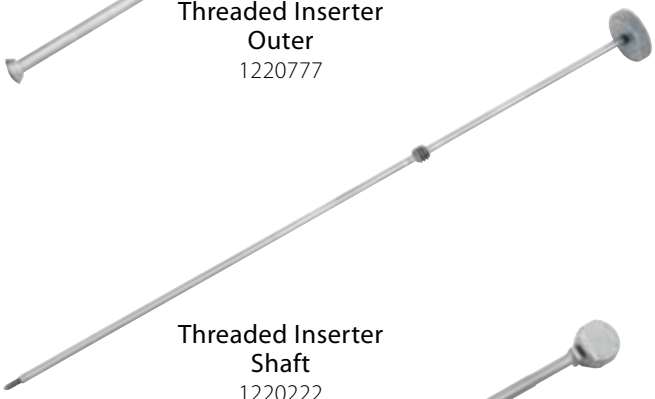
Surgical Technique

Instrument Set

Mallet
6472061

Awl
6650165

Threaded Inserter
Outer
1220777



Threaded Inserter
Shaft
1220222

Trasp
5mm, 5220564
6mm, 5220664
7mm, 5220764
8mm, 5220864
9mm, 5220964

Quad Drive
Screwdriver
1204444

Flexdriver
1209999

Universal Handle
6650250

Revision Tool
1201111

Quad Driver Sleeve
1206666

Patient Positioning and Approach

The patient is placed in the supine position with the head in slight extension. The mandible is tilted out of the surgical field. 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)**.

A transverse or oblique skin incision is made. A muscle-splitting approach is made to the spine through an avascular dissection plane. The strap muscles, trachea and esophagus are retracted medially, and the carotid sheath is retracted laterally. Hand-held retractors are used to provide initial exposure of the anterior vertebral column and the adjacent longus coli muscles **(Figure 2)**. After the anterior longitudinal ligament, disc spaces and central portions of the vertebral bodies have been exposed, the longus coli 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. Longitudinal self-retaining retractors are then placed to provide visualization **(Figure 3)**. A vertebral body distractor may also be used. The distraction pins are positioned midline in the vertebral bodies adjacent to the disc **(Figure 4)**. The distractor is placed over the pins, and gentle distraction is applied.

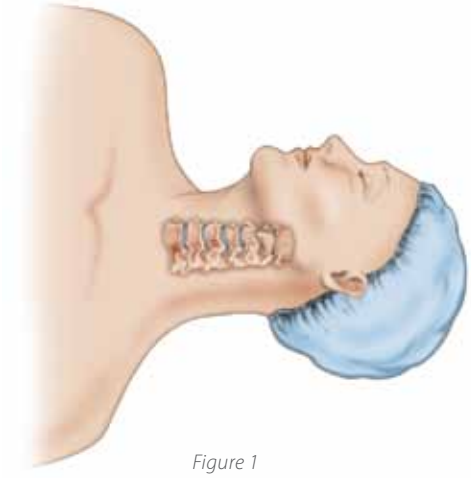


Figure 1

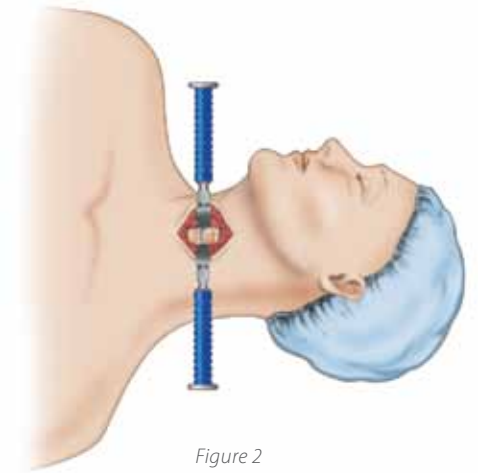


Figure 2

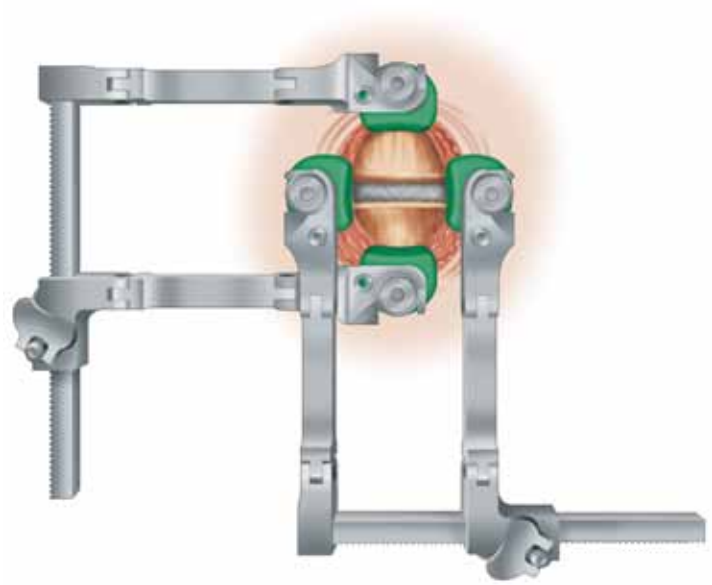


Figure 3

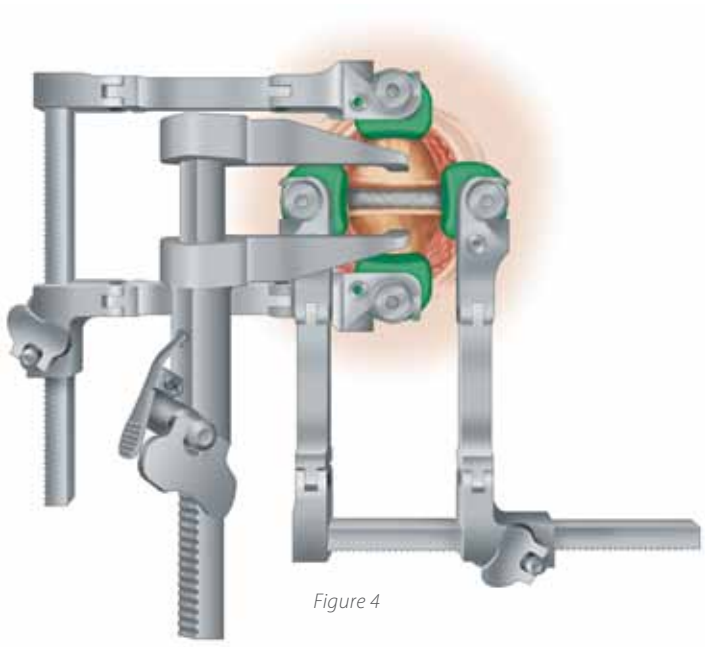


Figure 4

Discectomy

Pituitaries, curettes, and thin-footed Kerrison rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament. A high-speed drill with a burr (match tip/round) may be used for removal of the posterior disc and osteophytes to achieve neural decompression **(Figures 5a and 5b)**. The posterior longitudinal ligament and osteophytes are then carefully removed.

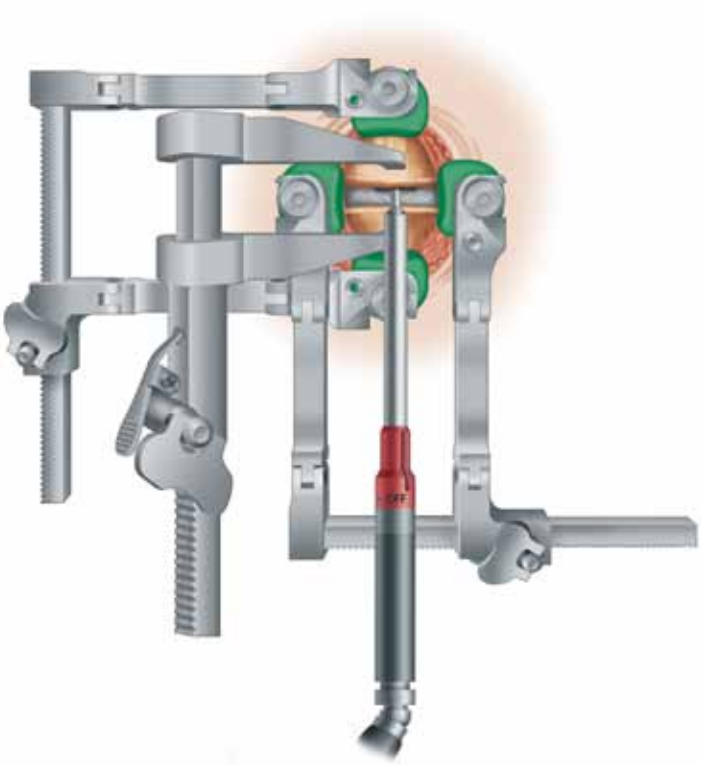


Figure 5a

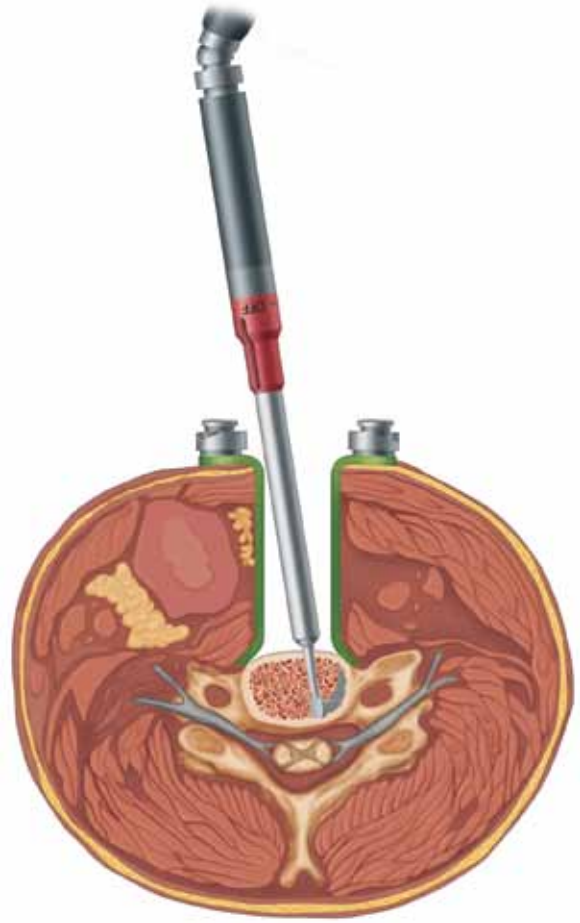


Figure 5b

Anterior Vertebral Body Preparation

Once the discectomy is complete, a high-speed drill with a burr is used to carefully shape the inferior lip of the superior vertebral body and the superior lip of the inferior vertebral body to match the flanges found on both the trial and implant.

This chamfer must be cut at an angle to allow each screw to be inserted at an angle into the vertebral bodies **(Figure 6)**. It is important that the chamfer match the angle of the flange to ensure proper screw placement.

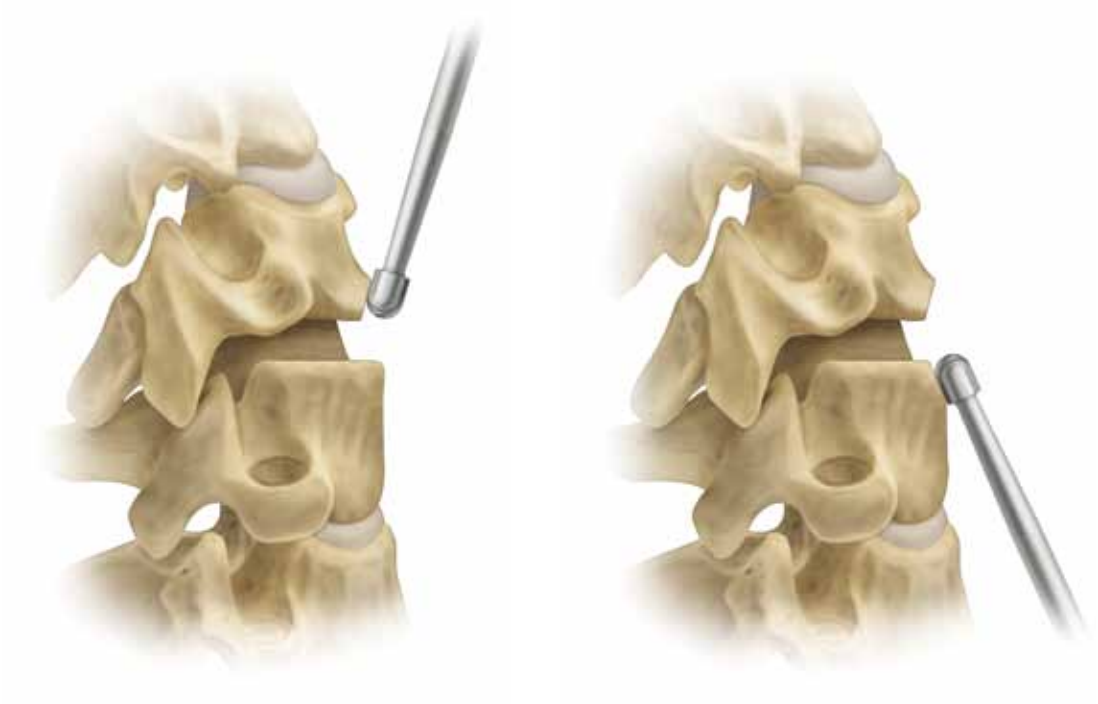


Figure 6

Trialing and End-plate Preparation

Once the decompression and anterior vertebral body preparation are completed, a PEEK PREVAIL™ Cervical Interbody Device size is determined by selecting the Trasp that provides the most satisfactory fit in the prepared disc space. The Trasp is a dual-purpose instrument with a Trial on one end and a Rasp on the other.

Final end-plate preparation is carried out with the Rasp. The Rasp creates a mortise for the PEEK PREVAIL™ Cervical Interbody Device. The Rasp will decorticate the end plates with minimal bone removal. Additionally, the Rasp will help ensure adequate end-plate preparation **(Figure 7)**.

Confirm the implant size and height by reinserting the Trial head after using the Rasp head **(Figure 8)**. Once the appropriate height is identified, choose the corresponding PEEK PREVAIL™ Cervical Interbody Device.

Helpful Hint

While the Trial is inserted, use fluoroscopy to ensure there are no visible gaps between the flange and bone.

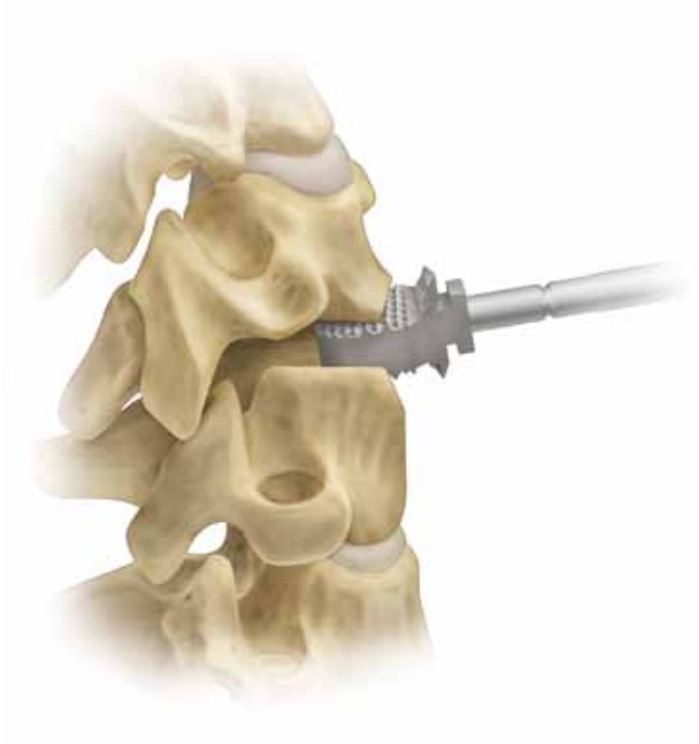


Figure 7

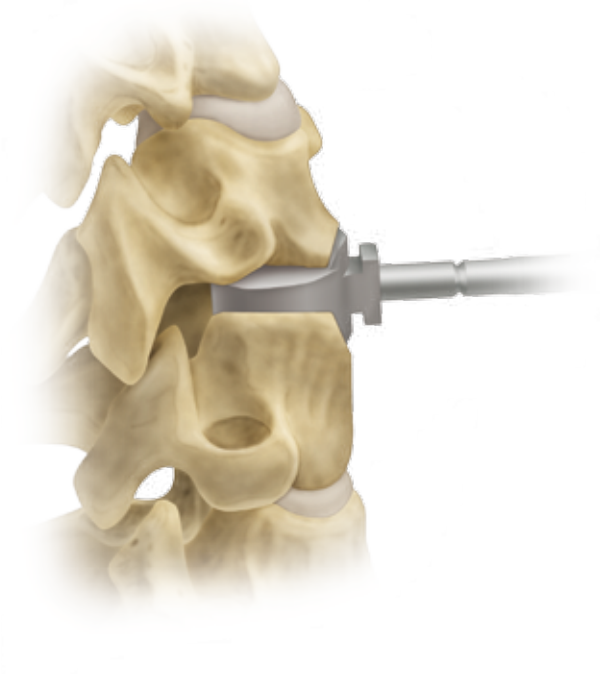


Figure 8

Implant Placement

Select the appropriately sized implant that corresponds to the final Trasp used in the end-plate preparation step. Pack the implant with autograft and attach it to the Threaded Inserter **(Figures 9a and 9b)**.

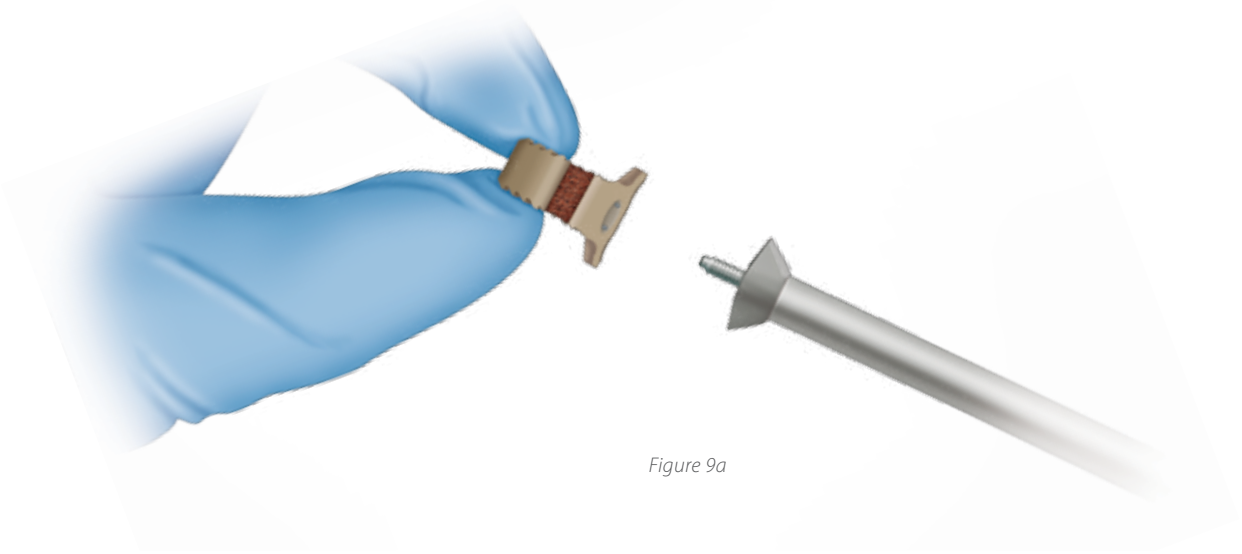


Figure 9a

Figure 9b

Implant Placement *continued*

The device should be oriented with the flanged surface positioned anteriorly **(Figures 10a and 10b)**. It is important to ensure the implant is seated in the disc space as close to midline as possible **(Figures 11a and 11b)**. This midline placement will facilitate proper insertion of the screws.

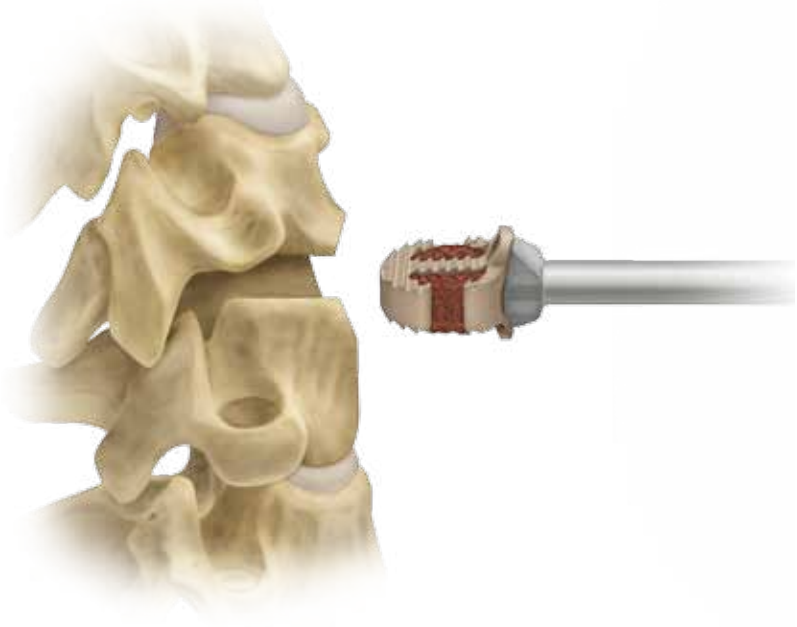


Figure 10a

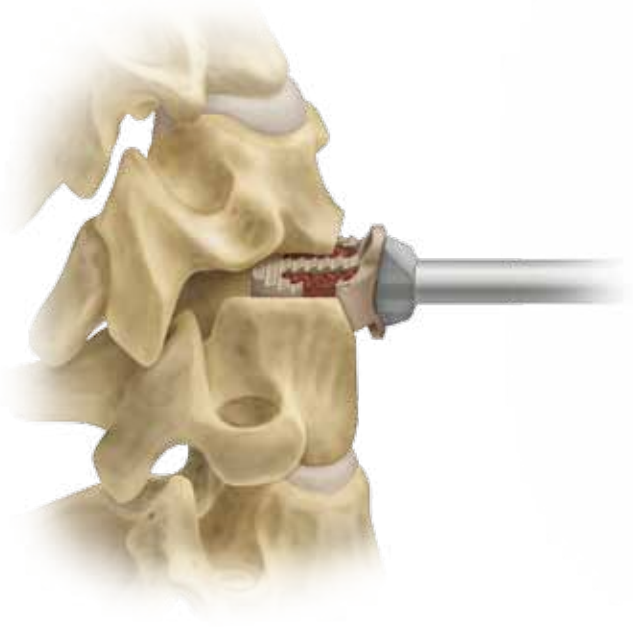


Figure 10b

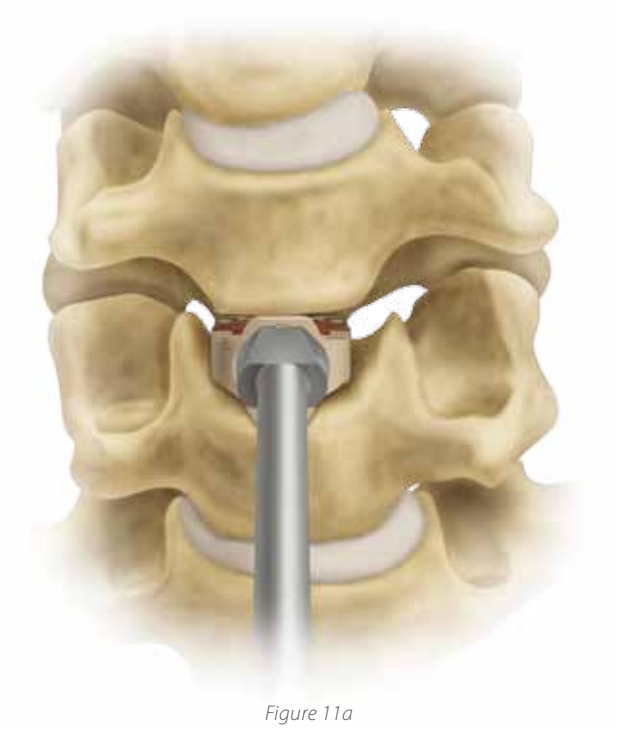


Figure 11a

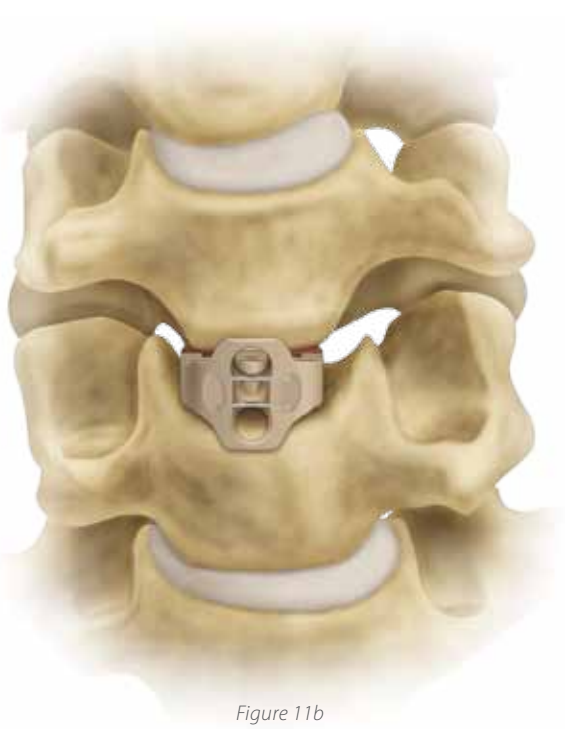


Figure 11b

ZEPHIR® Anterior Cervical Screw Placement

Select the Self-Drilling Screw length that is most appropriate for the patient's anatomy. Using a "stab-and-grab" Quad Drive Screwdriver, pick up the appropriate screw with the quad drive portion of the screwdriver shaft in the screw head **(Figure 12)**. Before placing the screws, release the cephalad/caudal distraction. Insert each screw and stop right before it passes the Nitinol locking wire to ensure the implant remains centered. The screw should be inserted at a angle, perpendicular to the chamfered lip **(Figure 13a)**. The Flexdriver can be used for screw insertion to accommodate a patient's anatomy if needed **(Figure 13b)**.

Figure 12

Important

Prior to insertion of the screws, using the Awl is recommended to establish the trajectory and ensure proper placement of the screws.

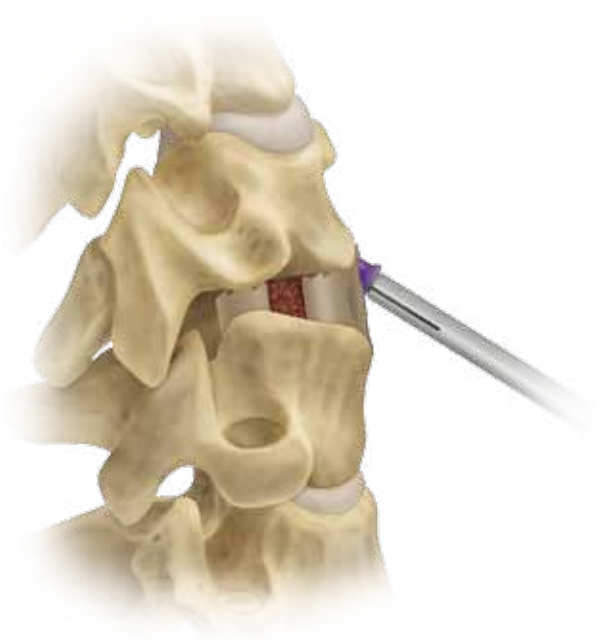


Figure 13a

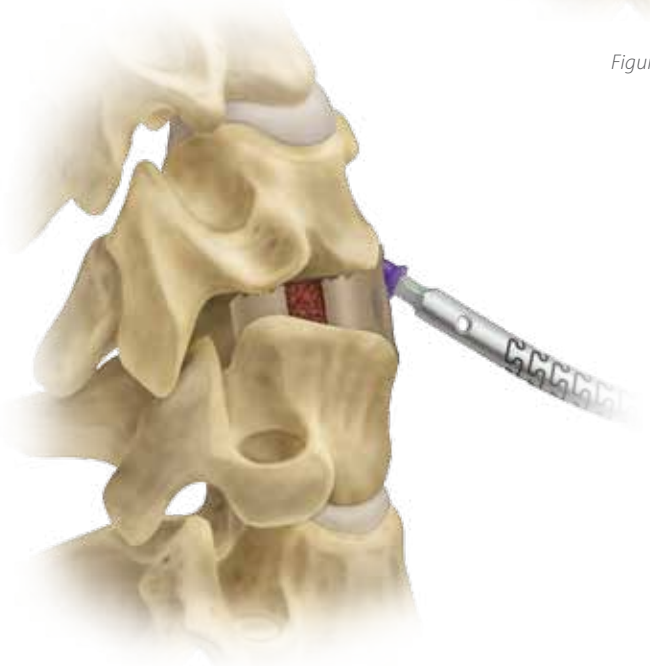


Figure 13b

ZEPHIR® Anterior Cervical Screw Placement *continued*

With the screw in place, just above the Nitinol wire, tighten the screw to engage the locking mechanism **(Figures 14a and 14b)**. Once the screw head passes the Nitinol wire, do not drive the screw further into the vertebral body. Only a quarter to a half turn is recommended. This will prevent the screws from stripping.

As the screw is inserted, the Nitinol locking wire will deflect and allow the screw to continue until fully inserted. When the screw head is seated, the Nitinol locking wire will retract over the head of the screw to prevent the screw from backing out.

Repeat the screw insertion step to secure the final construct **(Figure 15)**.

Figure 14a

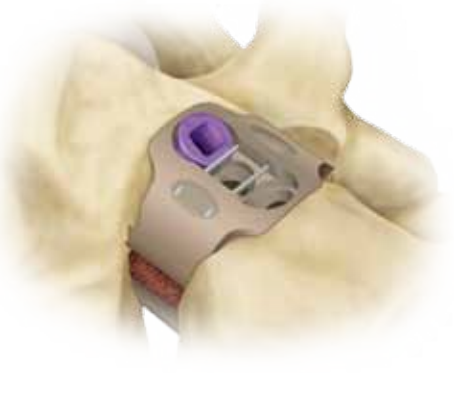


Figure 14b

Important

Once the screw head passes the Nitinol wire, do not drive the screw further into the vertebral body. Only a quarter to a half turn is recommended.

Figure 15

Revision Tool

Removal of the screws from the PEEK PREVAIL™ Cervical Interbody Device can be accomplished using the Revision Tool. The "stab-and-grab" end of the Revision Tool is inserted into the head of the screw and rotated counterclockwise. The Revision Tool must be held flush against the head of the screw for it to work properly **(Figure 16)**. Begin with the flat surface side of the Revision Tool oriented toward the Nitinol wire. As the Revision Tool is rotated, it will deflect the wire from the head of the screw and will allow the screw to be removed from the implant **(Figures 17a and 17b)**. Once the head of the screw is past the Nitinol locking wire the screw can be removed with the Revision Tool or a standard screwdriver **(Figure 18)**.

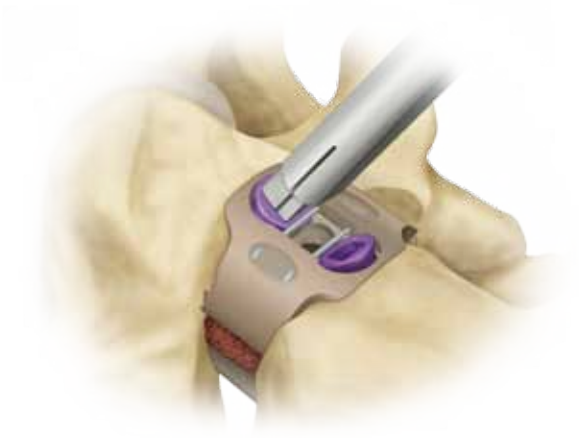


Figure 16

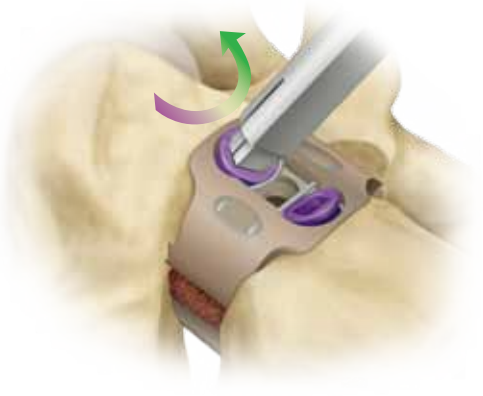


Figure 17a

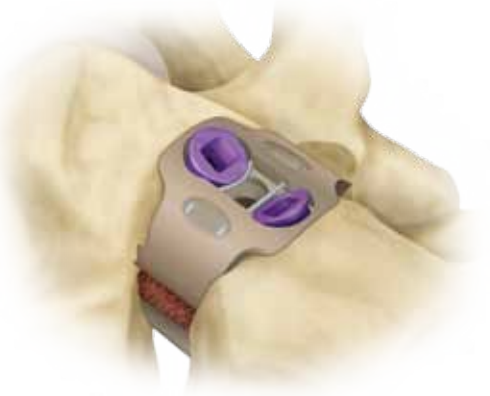


Figure 17b

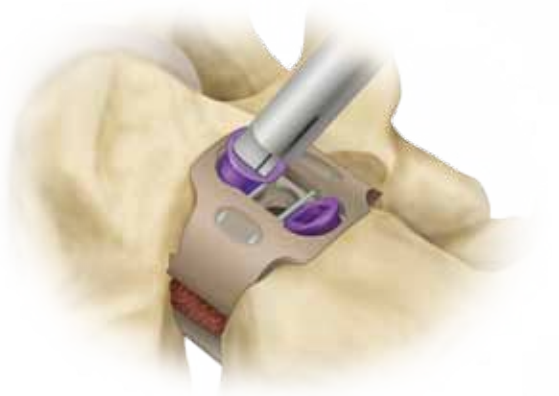


Figure 18

Explantation

Removal of the implant can be accomplished by using a high-speed burr to resect the implant. The implant can be removed 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. Once the screws have been removed, the Threaded Inserter can be reattached to the implant, still intact, and removed with an in-line slap hammer.

Product Ordering Information

Implant Measurements

Part Number	Posterior Height	Anterior Height	Inner Volume
4210564	5mm	6mm	0.4cc
4210664	6mm	7mm	0.5cc
4210764	7mm	8mm	0.6cc
4210864	8mm	9mm	0.7cc
4210964	9mm	10mm	0.8cc

Implant Set Configuration
Set Type 2096

Part Number	Description	Qty.
4210564	5mm × 16mm × 14mm	2
4210664	6mm × 16mm × 14mm	2
4210764	7mm × 16mm × 14mm	2
4210864	8mm × 16mm × 14mm	1
4210964	9mm × 16mm × 14mm	1
11000000	Implant Case	1

Instrument Set Configuration
Set Type 2125

Part Number	Description	Qty.
5220564	5mm Trasp, 16mm × 14mm	1
5220664	6mm Trasp, 16mm × 14mm	1
5220764	7mm Trasp, 16mm × 14mm	1
5220864	8mm Trasp, 16mm × 14mm	1
5220964	9mm Trasp, 16mm × 14mm	1
1220777	Threaded Inserter Outer	1
1220222	Threaded Inserter Shaft	2
1209999	Flexdriver	1
1206666	Quad Driver Sleeve	2
1204444	Quad Drive Screwdriver	2
6650250	Universal Handle	2
8792811	3.5mm Self-Drilling ZEPHIR® System Screw, 11mm Length	6
8792813	3.5mm Self-Drilling ZEPHIR® System Screw, 13mm Length	6
8792815	3.5mm Self-Drilling ZEPHIR® System Screw, 15mm Length	6
8792911	4.0mm ZEPHIR® System Rescue Screw, 11mm Length	3
8792913	4.0mm ZEPHIR® System Rescue Screw, 13mm Length	3
8792915	4.0mm ZEPHIR® System Rescue Screw, 15mm Length	3
8797033	ZEPHIR® System Screw Caddy	1
1201111	Revision Tool	1
6650165	Awl	1
6472061	Mallet	1
1207777	Upper Tray	1
1850079	Instrument Lid	1
1850076	Instrument Base	1

Important Product Information

PURPOSE

The PEEK PREVAIL™ Cervical Interbody Device is indicated for anterior 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. This system is indicated for single-level use only in the cervical and thoracic anterior spine.

DESCRIPTION

The PEEK PREVAIL™ Cervical Interbody Device is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is "I-Beam" shaped with a 2 screw midline configuration. This device is intended to be radiolucent and the interior space of the product is to be used with autograft.

The PEEK PREVAIL™ Cervical Interbody device implant is manufactured from PEEK OPTIMA® and contains tantalum radiopaque markers and a Nitinol screw locking mechanism. The screws used with this device (ZEPHIR® Anterior Cervical Screws) are manufactured from Titanium Alloy.

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

INDICATIONS

The PEEK PREVAIL™ Cervical Interbody Device is indicated for anterior 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. The PEEK PREVAIL™ Cervical Interbody Device must be used with internal screw fixation provided by ZEPHIR® Anterior Cervical Screws. The PEEK PREVAIL™ Cervical Interbody Device implants are to be used with autograft and implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

CONTRAINDICATIONS

The PEEK PREVAIL™ Cervical Interbody device is not intended for posterior surgical implantation.

Contraindications include, but are not limited to:

1. Any case needing to mix metals from different components.
2. Any case not described in the indications.
3. 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.
4. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
5. Any patient unwilling to co-operate with postoperative instructions.
6. Fever or leukocytosis.
7. Infection, local to the operative site.
8. Mental illness.
9. Morbid obesity.
10. Pregnancy.
11. 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.
12. Signs of local inflammation.
13. Suspected or documented metal allergy or intolerance.

These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Contraindications of this device are consistent with those of other spinal systems.

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. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
4. Change in mental status.
5. Death.
6. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
7. Disassembly, bending, and/or breakage of any or all of the components.
8. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
9. Early or late loosening of the components. Implant migration.
10. Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
11. 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.
12. Gastrointestinal complications.
13. Graft donor site complications including pain, fracture, infection, or wound healing problems.
14. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
15. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
16. Infection.
17. 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.
18. Non-union (or pseudarthrosis). Delayed union. Mal-union.
19. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
20. Scar formation possibly causing neurological compromise around nerves and/or pain.
21. Subsidence of the device into vertebral body(ies).
22. Tissue or nerve damage, irrigation, 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)

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. The PEEK PREVAIL™ Cervical Interbody Device must be used with the ZEPHIR® Anterior Cervical Screws to augment stability. Use of this product without autograft 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.

Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage of the thread will reduce the stability of the instrumentation.

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.

!USA FOR US AUDIENCES ONLY

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

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. Plastic polymer 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 material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, 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. 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.
4. Further information on the use of this system will be made available on request.
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.
6. 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.
7. 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. The instructions in any available applicable surgical technique manual 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. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the instrumentation, autograft should be used. Autograft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused. When using the PEEK PREVAIL™ Cervical Interbody device, autograft should be used.
5. 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.

1. 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.
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. The patient should be advised not to smoke or consume excess alcohol during the bone healing process.
3. The 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.
4. 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.
5. 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. 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.

Important Product Information *continued*

CLEANING AND DECONTAMINATION

Unless just removed from an unopened Medtronic 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. 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

The contents of the implant package for the PEEK PREVAIL™ Cervical Interbody Device are provided sterile via gamma irradiation. The ZEPHIR® Anterior Cervical Screws and general instruments used with the PEEK PREVAIL™ Cervical Interbody Device are provided non-sterile.

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:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 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.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. 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) returning to Medtronic.

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.

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Please contact Customer Service or your Sales Representative for the most up-to-date package insert.

Important Product Information

GENERAL INSTRUMENTS

PURPOSE:

This instrument is intended for use in surgical procedures.

DESCRIPTION:

Unless otherwise stated, instruments are made out of a variety of materials commonly used in orthopedic and neurological procedures including stainless steel and acetyl copolymer materials which meet available national or international standards specifications. Some instruments are made out of aluminium, and some with handles made of resin bonded composites, and while these can be steam autoclaved, certain cleaning fluids must not be employed. None of the instruments should be implanted.

INTENDED USE:

This instrument is a precision device which may incorporate a measuring function and has uses as described on the label. Unless labeled for single use, this instrument may be re-used. If there is any doubt or uncertainty concerning the proper use of this instrument, please contact Medtronic Customer Service for instructions. Any available surgical techniques will be provided at no charge.

WARNINGS:

The methods of use of instruments are to be determined by the user's experience and training in surgical procedures. Do not use this instrument for any action for which it was not intended such as hammering, prying, or lifting. This instrument should be treated as any precision instrument and should be carefully placed on trays, cleaned after each use, and stored in a dry environment. To avoid injury, the instrument should be carefully examined prior to use for functionality or damage. A damaged instrument should not be used. Additional back-up instruments should be available in case of an unexpected need. Medtronic does not and cannot warrant the use of this instrument nor any of the component parts upon which repairs have been made or attempted except as performed by Medtronic or an authorized Medtronic repair representative. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the Medtronic catalog for further information about warranties and limitations of liability. DO NOT IMPLANT THE INSTRUMENTS.

POSSIBLE ADVERSE EFFECTS:

Breakage, slippage, misuse, or mishandling of instruments, such as on sharp edges, may cause injury to the patient or operative personnel. Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose, or even dangerous to the patient or surgical staff. Proper patient selection and operative care are critical to the success of the device and avoidance of injury during surgery. Read and follow all other product information supplied by the manufacturer of the implants or the instruments. Special precautions are needed during pediatric use. Care should be taken when using instruments in pediatric patients, since these patients can be more susceptible to the stresses involved in their use. There are particular risks involved in the use of instruments used for bending and cutting rods. The use of these types of instruments can cause injury to the patient by virtue of the extremely high forces which are involved. Do not cut rods in situ. In addition, any breakage of an instrument or the implant in this situation could be extremely hazardous. The physical characteristics required for many instruments does not permit them to be manufactured from implantable materials, and if any broken fragments of instruments remain in the body of a patient, they could cause allergic or infectious consequences.

Over-bending, notching, striking and scratching of the implants with any instrument should be avoided to reduce the risk of breakage.

Under no circumstances should rods or plates be sharply or reverse bent, since this would reduce the fatigue life of the rod and increase the risk of breakage. When the configuration of the bone cannot be fitted with an available device and contouring of the device is absolutely necessary, contouring should be performed only with proper bending equipment, and should be performed gradually and with great care to avoid notching or scratching the device.

Extreme care should be taken to ensure that this instrument remains in good working order. Any surgical techniques applicable for use of this system should be carefully followed. During the procedure, successful utilization of this instrument is extremely important. Unless labeled for single use, this instrument may be reused. This instrument should not be bent or damaged in any way. Misuse of this instrument, causing corrosion, "freezing-up", scratching, loosening, bending and/or fracture of any or all sections of the instrument may inhibit or prevent proper function.

It is important that the surgeon exercise extreme caution when working in close proximity to vital organs, nerves or vessels, and that the forces applied while correcting the position of the instrumentation is not excessive, such that it might cause injury to the patient. Excessive force applied by instruments to implants can dislodge devices, particularly hooks. Never expose instruments to temperatures in excess of 134° C that may considerably modify the physical characteristics of the instruments.

!USA For US Audiences Only

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

This device should be used only by physicians familiar with the device, its intended use, any additional instrumentation and any available surgical techniques. For the best results Medtronic implants should only be implanted with Medtronic instruments.

Other complications to the patient and/or hospital staff may include, but are not limited to:

1. Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs or joints.
2. Breakage of the device, which could make necessary removal difficult or sometimes impossible, with possible consequences of late infection and migration. Breakage could cause injury to the patient or hospital staff.
3. Infection, if instruments are not properly cleaned and sterilized.
4. Pain, discomfort, or abnormal sensations resulting from the presence of the device.
5. Nerve damage due to surgical trauma.
6. Dural leak in cases of excessive load application.
7. Impingement of close vessels, nerves and organs by slippage or misplacement of the instrument.
8. Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.
9. Cutting of skin or gloves of operating staff.
10. Bony fracture, in cases of deformed spine or weak bone.
11. Tissue damage to the patient, physical injury to operating staff and/or increased operating time that may result from the disassembly of multi-component instruments occurring during surgery.

OTHER PRECAUTIONS:

1. Excessive forces when using bending or fixation instruments can be dangerous especially where bone friability is encountered during the operation.
2. Any form of distortion or excessive wear on instruments may cause a malfunction likely to lead to serious patient injury.
3. Regularly review the operational state of all instruments and if necessary make use of repair and replacement services.

DEVICE FIXATION:

Some surgeries require the use of instruments which incorporate a measuring function. Ensure that these are not worn, that any surface engravings are clearly visible. Where there is a need for a specified tightening torque, this may normally be achieved with torque setting instruments supplied by Medtronic; the pointer on these instruments must indicate ZERO before use. If not, return for recalibration. With small instruments, excess force, beyond the design strength of the instrument, can be caused even by simple manual overloading. Do not exceed recommended parameters. To determine the screw diameter with the screw gauge, start with the smallest test hole.

PACKAGING:

Medtronic instruments may be supplied as either sterile or non- sterile. Sterile instruments will be clearly labeled as such on the package label. The sterility of instruments supplied sterile can only be assured if the packaging is intact. Packages for both sterile and non-sterile components should be intact upon receipt. All sets should be carefully checked for completeness and all components should be carefully checked for signs of damage, prior to use. Damaged packages or products should not be used and should be returned to Medtronic. Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately re-sterilize all instruments used in surgery. Instruments should be thoroughly cleaned prior to re-sterilization. This process must be performed before handling, or before returning product to Medtronic.

EXAMINATION:

Instruments must always be examined by the user prior to use in surgery. Examination should be thorough, and in particular, should take into account a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, bruising or distortion, and that all components of the instrument are complete.

Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise unfunctional.

Cleaning and Decontamination:

Unless just removed from an unopened Medtronic package, all instruments 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. 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. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the set of process parameters below:

Method	Cycle	Temperature	Exposure Time
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 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.**

It is important to note that a sterilization wrap, package or sterilization container system should be used to enclose the case or tray in order to maintain sterility.

Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be resterilized.

OPERATIVE USE:

The physician should take precautions against putting undue stress on the spinal area with instruments. Any surgical technique instruction manual should be carefully followed. If an instrument breaks in surgery and pieces go into the patient, these pieces should be removed prior to closure and should not be implanted.

REMOVAL OF IMPLANTS:

For the best results, the same type of Medtronic instruments as used for implantation should be used for implant removal purposes. Various sizes of screwdrivers are available to adapt to the removal drive sizes in auto break fixation screws.

It should be noted that where excessive bone or fibrous growth has occurred from the first surgery, there may be added stress on the removal instruments and the implants. Both instrument and implant may be prone to possible breakage. In this case it is necessary to first remove the bone and/or tissue from around the implants.

FURTHER INFORMATION:

In case of complaint, or for supplementary information, please contact Medtronic.

PRODUCT COMPLAINT:

Any Health Care Professionals (e.g., customer users of Medtronic instruments), who have any complaint or who have experienced dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Medtronic. Further, if any instrument "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 or Medtronic 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 or Medtronic should be notified as soon as possible 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, and the nature of the complaint.

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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.