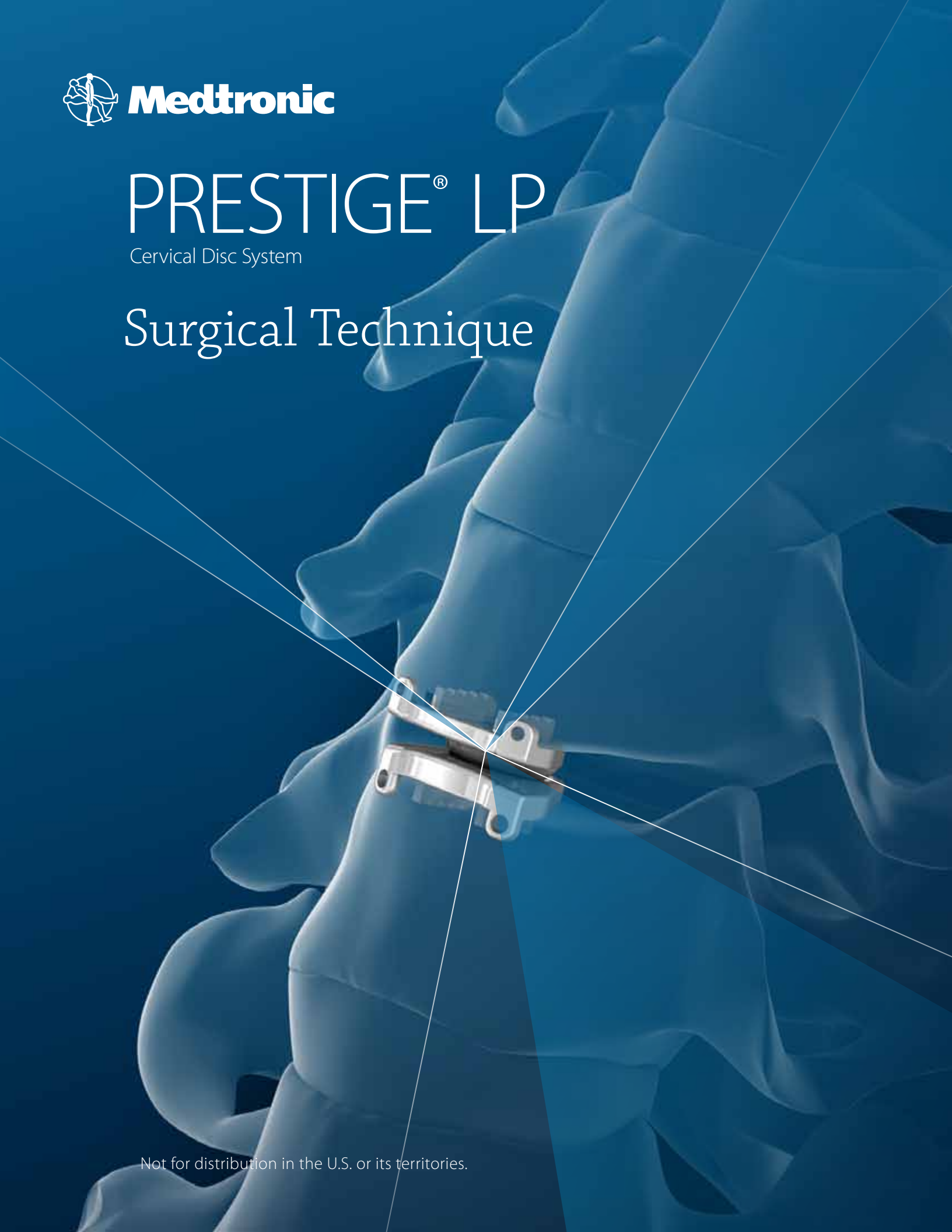
Medtronic

PRESTIGE® LP

Cervical Disc System

Surgical Technique



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Introduction

The surgical benefits of an anterior approach to the cervical spine in the management of the intractable symptoms and signs associated with cervical disc disease are widely appreciated. Usually, the symptomatic functional spinal unit (FSU) is mobile and mechanically stable preoperatively. Anterior cervical disc fusion, although providing symptomatic relief, has the disadvantage of converting the operated segment to a non-functional spinal unit.

Surgical Technique

Step 1 Preoperative Measurement

Use computed tomography (CT) or magnetic resonance image (MRI) so that the slices are parallel to the vertebral body end plates, determine the smaller of the two vertebral body end plates at the target disc space. The use of a CT image is preferred. Do not include spurs or ridges that will be removed in the subsequent burring/ decompression process. Determine the magnification factor of the image using the PRESTIGE® LP Cervical Disc Template Set **(Figure 1a)**. Choose the prosthesis template corresponding to the measured magnification factor, and follow the instructions on the template to select the prosthesis size **(Figure 1b)**. This templating process will determine the appropriate footprint of the implant, but not the height **(Figures 1c and 1d)**.

Note

Templating provides only approximate sizing. This initial assessment may vary because of magnification factors inherent in CT or MRI images. The final selection of implant size should be based on clinical judgement, disc space preparation, and trialing.

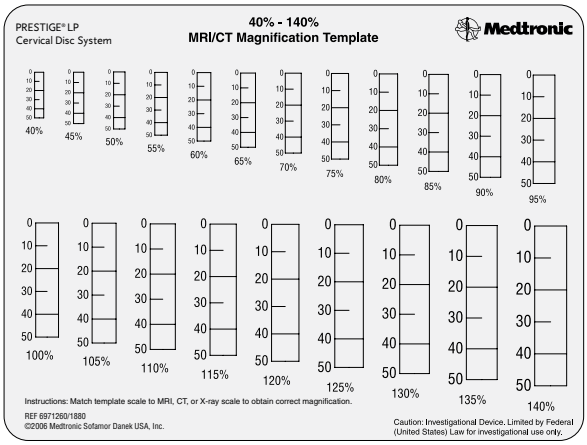

Figure 1a

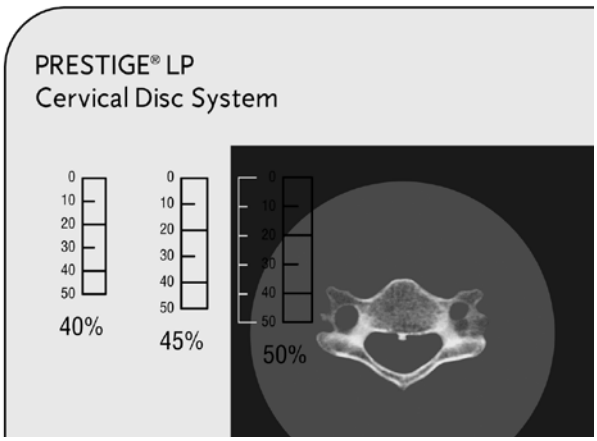

Figure 1b

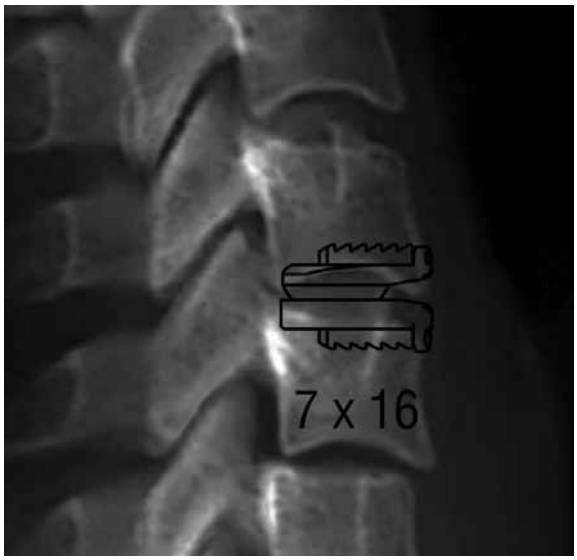

Figure 1c

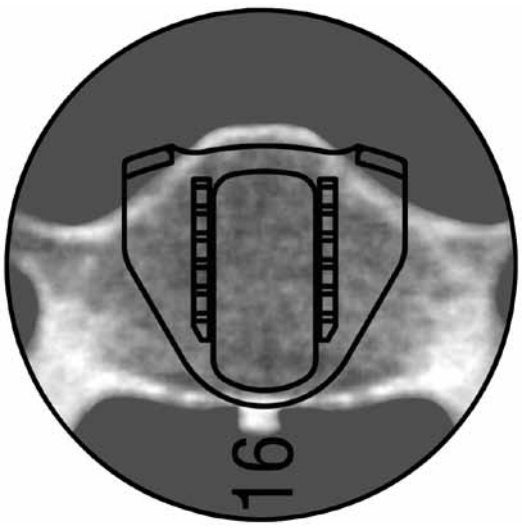

Figure 1d

Step 2 Patient Positioning

The patient is placed in the supine position with the head and neck in a neutral position **(Figure 2)**. The posterior cervical spine should be supported to establish and maintain this position. A standard right-sided or left-sided approach may be used.

Note

Neck position should mirror the preoperative standing neutral lateral x-rays and remain fixed throughout the procedure. Failure to reproduce preoperative neutral neck position may result in improper implant position or improper sagittal balance of the cervical spine at the operative level.

Note

Both shoulders may be pulled down and secured for better visualization of the lower cervical spine during fluoroscopy, if necessary. It will be necessary to perform a fusion procedure if visualization of the target disc space does not allow for an optimal lateral view.

Note

Use standard methods to identify the correct disc level.

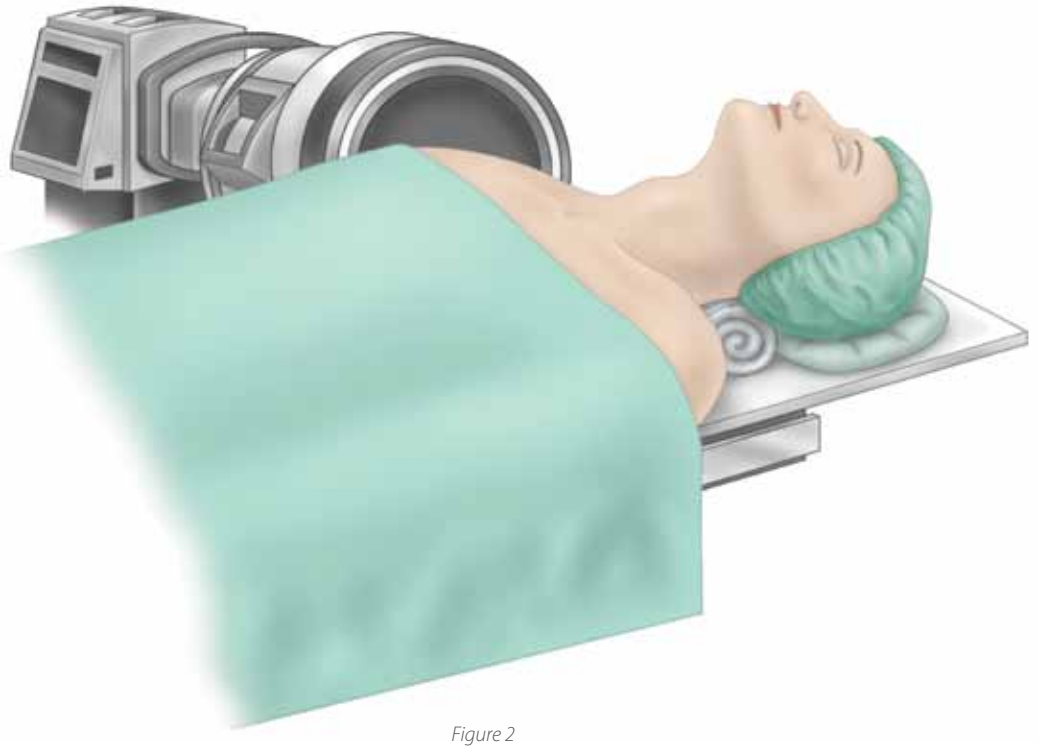

Figure 2

Step 3 Exposure

Typically, a transverse skin incision is made. An avascular dissection plane is developed between the trachea and the esophagus medially, and the carotid sheath laterally. Hand-held retractors are utilized to provide exposure of the anterior vertebral column and the adjacent longus colli muscles **(Figure 3)**.

After the anterior vertebral column has been exposed, the longus colli muscles are elevated and the medial/lateral self-retaining retractor blades are positioned beneath them. This can be done with the help of Medtronic TRIMLINE® ACDF Retractor Set.

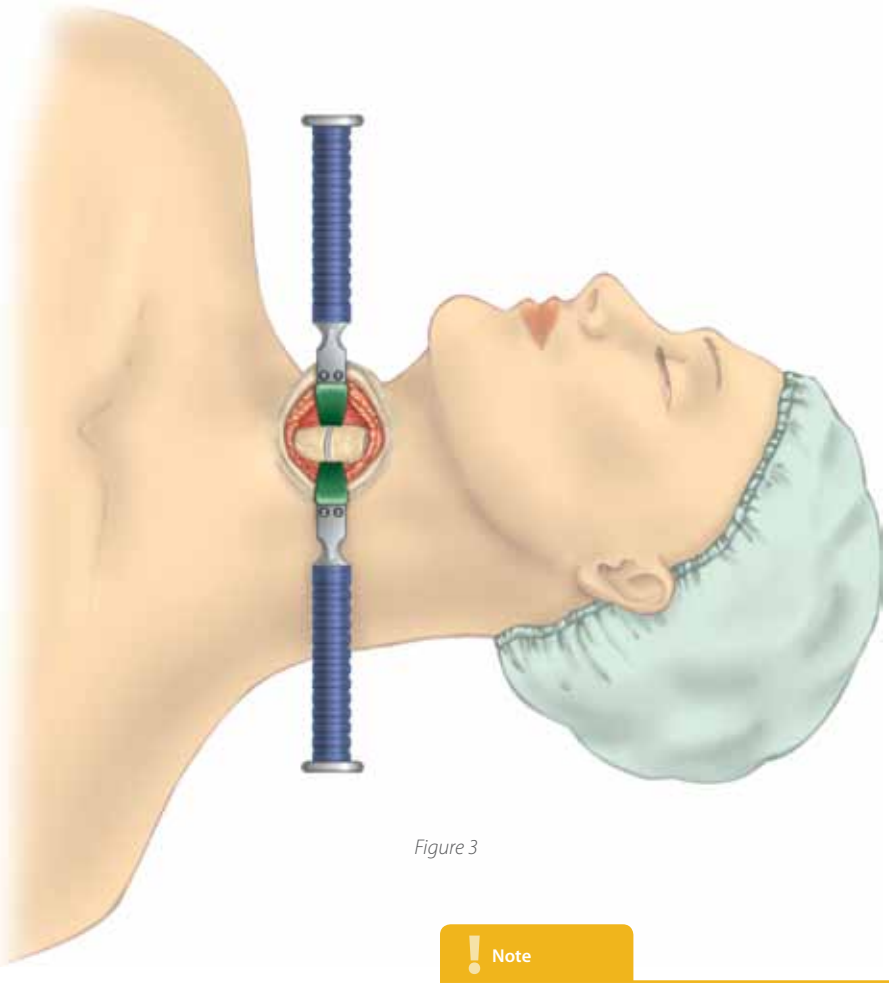

Figure 3

Note

The presence of anatomical abnormalities and/or deformities may reduce the ability to ensure proper placement of the instrumentation and/or prosthesis. Under such circumstances, it may be necessary to perform a fusion procedure.

Step 4 Discectomy/Decompression

The discectomy is completed at the indicated level. Pituitaries, curettes, and kerrisons may be used to remove the disc material and cartilage and expose the posterior longitudinal ligament **(Figure 4)**.

To obtain a complete and thorough decompression, a vertebral body or halter distractor may be used. Vertebral body distraction pins are positioned midline in the vertebral bodies adjacent to the discectomy. The distractor is placed over the pins and the appropriate amount of distraction is applied. 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. The posterior longitudinal ligament is carefully removed. Lightly burr the anterior surface of the vertebral bodies to remove any soft tissue and bony protrusions to create a flat surface.

Figure 4

Note

Take care to prevent excessive anterior bone removal.

Note

A complete and thorough discectomy and bilateral decompression are essential.

Step 5 End-Plate Preparation

After the discectomy and decompression is complete, relax or remove exterior distraction devices. Using either a round or cylindrical burr (surgeon preference), prepare the end plates so that they are flat and parallel **(Figure 5)**. Take care to preserve as much cortical bone as possible. It is important to complete the end-plate preparation to the posterior aspects of the vertebral bodies to ensure maximum implant/end plate interface **(Figure 6)**. The appropriately sized Shim Distractor can be used during any step of the procedure to assist in the introduction of instruments into the disc space, or during end-plate preparation, should the disc space collapse without external distraction **(Figure 7)**.

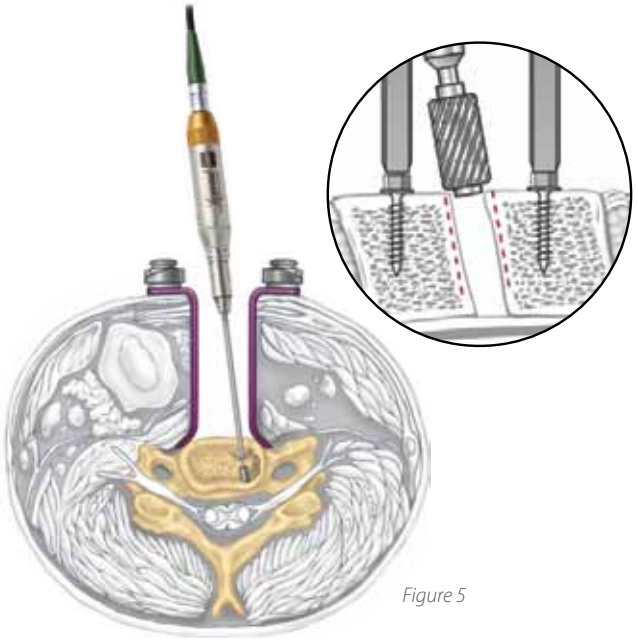

Figure 5

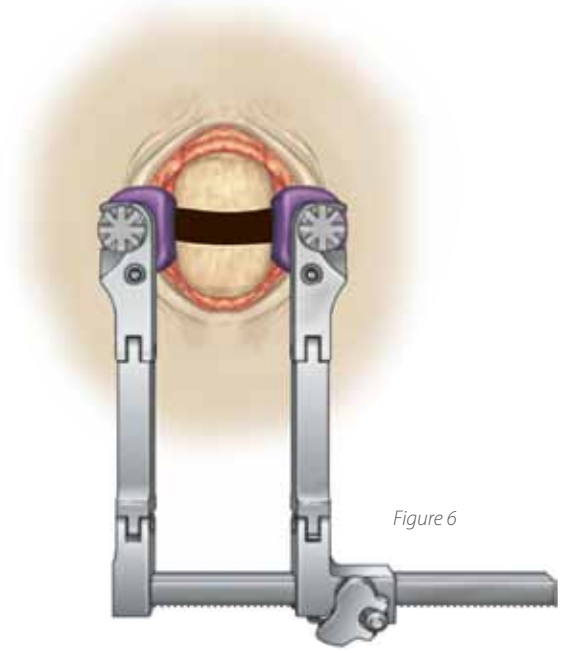

Figure 6

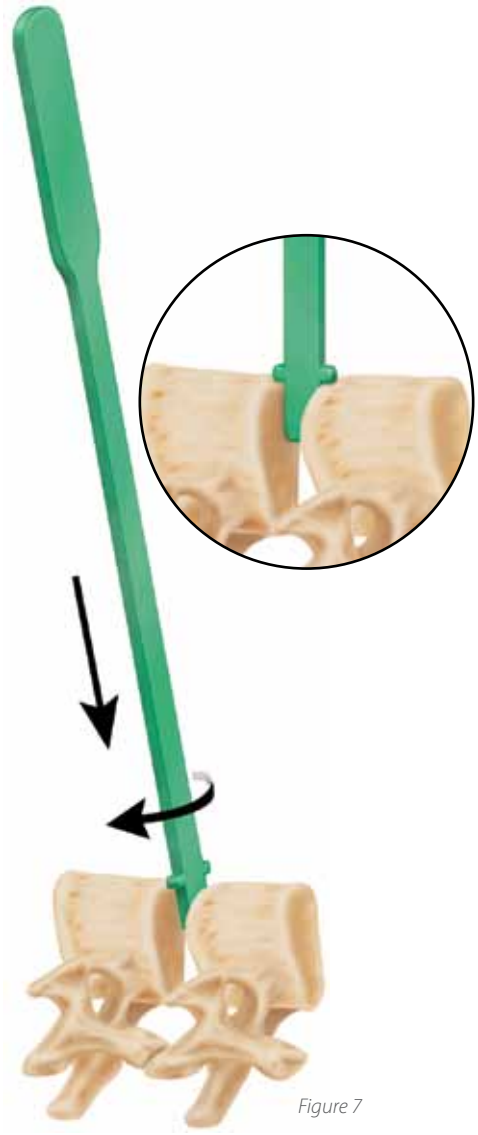

Figure 7

Step 5 End-Plate Preparation *Continued*

The appropriately sized Rasp can also be used, or used in conjunction with a burr, for completing this step. The appropriately sized Rasp should maximize end plate contact. Introduce the Rasp into the disc space with the positive stop positioned superiorly. The Rasp can be moved in an in-and-out manner, with slight medial/lateral rocking **(Figure 8)**. The Handle Extension can be used to remove the Rasp if necessary **(Figure 9)**. The size dimensions of the Rasp head will precisely match the end plate interfacing dimensions of the implant ensuring adequate end-plate preparation.

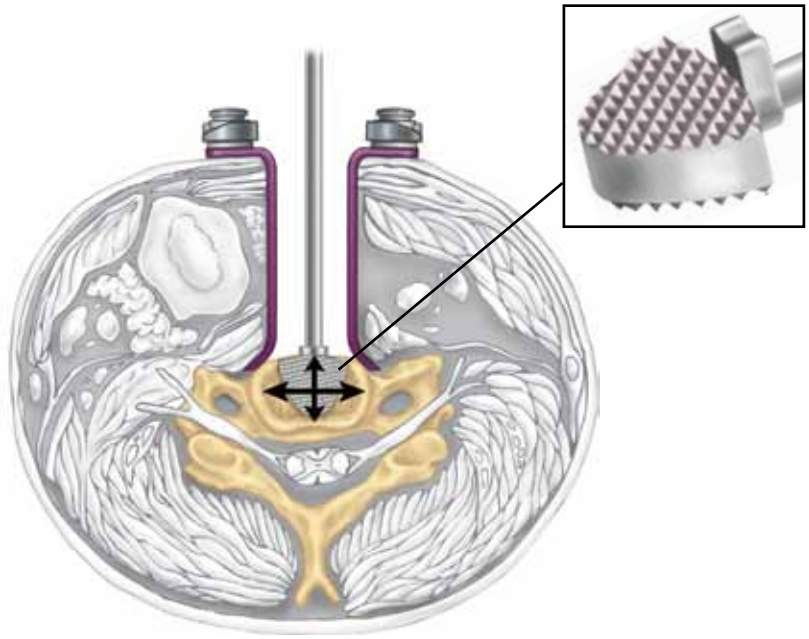

Figure 8

Note

Rasping will help remove any protrusions remaining after parallel burring.

Figure 9

Step 6 Implant Size Selection

Once the end plates are prepared in a flat, parallel fashion, utilize the appropriately sized Implant Trial to confirm the size of the prepared disc space. The size dimensions of the Implant Trial head also precisely match the end-plate interfacing dimensions of the implant. The Implant Trial, which measures the disc space height, depth, and width should fit snug without distracting the disc space. If more than gentle tapping is required to insert the Implant Trial into the disc space, consider a smaller Implant Trial or additional end-plate preparation. Verify fit of the Implant Trial with fluoroscopy. The Implant Trial has four anterior tabs that match the anterior tabs of the PRESTIGE® LP Cervical Disc. Double check the anterior vertebral body surfaces to ensure no protruding bone interferes with the placement of the Implant Trial tabs flush with the anterior surface.

Note

It is important that the prepared end plates be in complete contact with the flat portions of the Implant Trial and that the posterior tip of the Implant Trial reaches the posterior aspects of the disc space ***(Figure 10)****.*

Figure 10

Step 7 Rail Preparation

Once the appropriate PRESTIGE® LP Disc size is determined through the Implant Trial step, select the corresponding Trial/Cutter Guide to prepare the implant fixation channels in the end plates. Gently impact the Trial/Cutter Guide into the prepared disc space. It is important that the Trial/Cutter Guide be centered on the midline of the vertebral bodies.

Note

The Trial/Cutter Guide should be impacted until the four drill guide ports on the head of the Trial/Cutter Guide touch the anterior surface of the spine ***(Figure 11)****.*

Figure 11

Step 7 Rail Preparation *Continued*

Attach the Rail Cutter Bit to the Universal Handle. Insert the Rail Cutter Bit into one port on the Trial/Cutter Guide. Drill the first fixation channel into the end plate. While holding the Trial/Cutter Guide firmly in place, remove the bit and place a Temporary Fixation Pin in the channel. Drill the next channel in the contralateral port. Place the second Fixation Pin. Repeat the process for the third, and finish by drilling the fourth channel **(Figure 12)**. Remove the Fixation Pins and Trial/Cutter Guide. Each properly prepared end plate should have two parallel channels as shown **(Figure 13)**. If this is not the case, double check to ensure the end plates were properly paralleled and repeat this step.

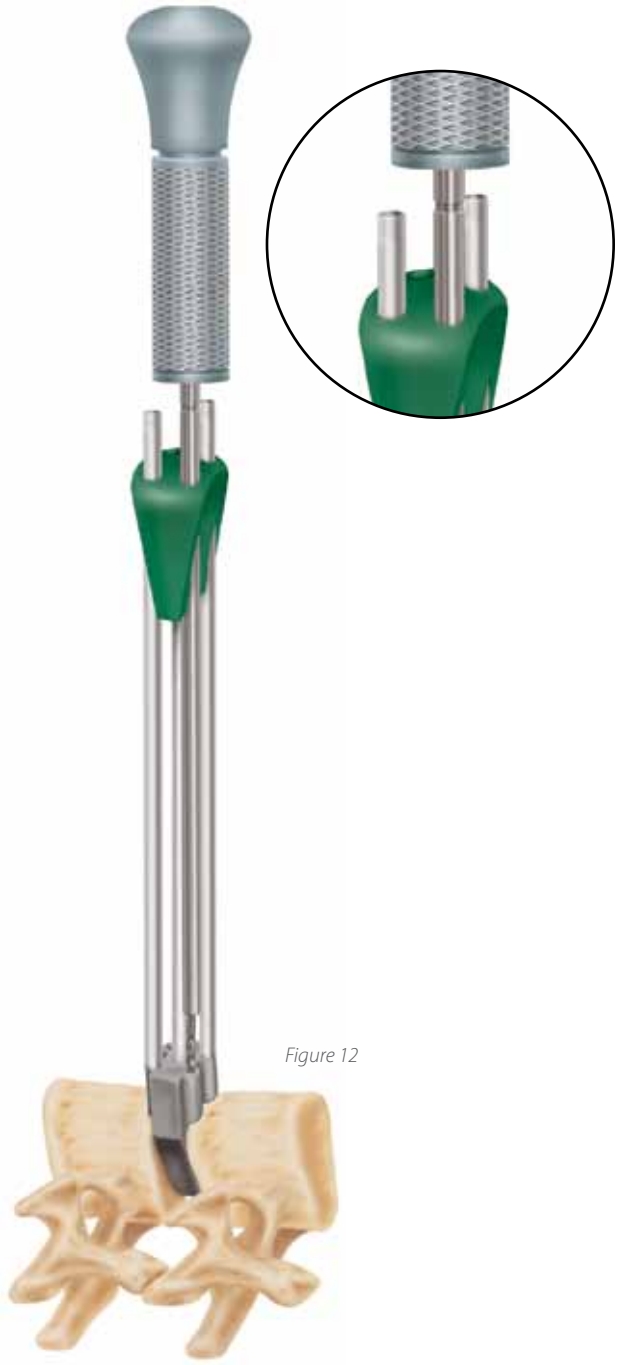

Figure 12

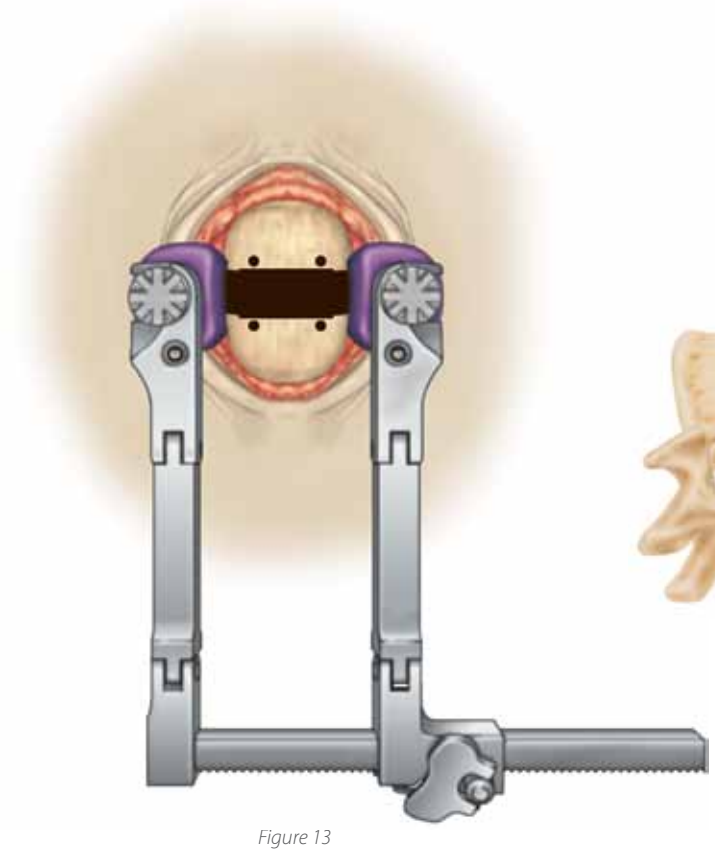

Figure 13

Step 8 Rail Cutting

Align the four cutting blades of the Rail Punch into the four pilot holes made by the Trial/Cutter Guide **(Figure 14)**. Gently tap into the disc space until depth stops contact the anterior surface of the spine **(Figure 15)**. The Handle Extension may be used to remove the Rail Punch **(Figure 16)**. This should complete the preparation of the four channels into the end plates as shown **(Figure 17)**.

Figure 15

Figure 16

Figure 14

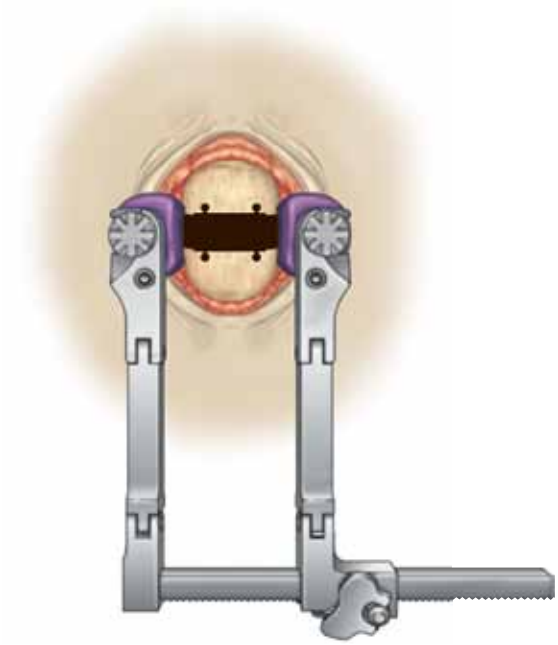

Figure 17

Step 9 Implantation

Place the appropriately sized PRESTIGE® LP Disc in the corresponding slot of the Loading Block **(Figure 18)**. Attach the PRESTIGE® LP Cervical Disc onto the Implant Inserter by placing the four inserter prongs into the ports on the anterior disc tabs **(Figure 19)**. Advance the outer sheath toward the disc. Rotate the sheath clockwise to lock in position **(Figure 20)**.

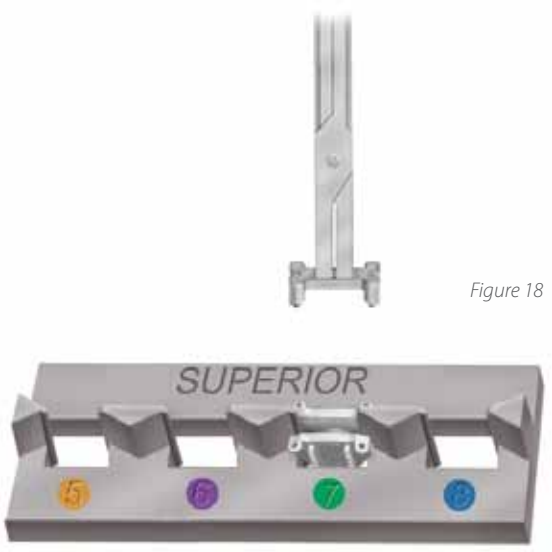

Figure 18

Figure 19

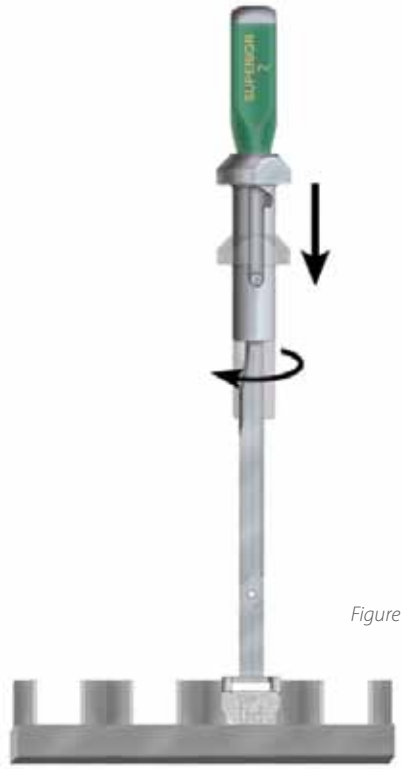

Figure 20

Note

The ball portion of the implant should be superior.

Step 9 Implantation *Continued*

With the ball portion of the prosthesis positioned superiorly, align the PRESTIGE® LP Disc rails with the channels on the end plates. Insert the prosthesis into the prepared disc space. Gently tap into place with a mallet until the anterior tabs come into contact with the anterior surface of the vertebral bodies. When tapping the device into place, care should be taken to exert gentle pressure in a direction perpendicular to the anterior surface of the device to avoid the possibility of breaking an anterior disc tab. A slight gap may remain between the tabs and anterior surface on either the inferior or superior body if the anterior surfaces are not exactly level. This is acceptable. Rotate the sheath counterclockwise to release **(Figure 21)**. Slide the outer sheath back and gently remove the Inserter **(Figure 22)**.

Note

*Utilize the Final Impactor to fully seat the PRESTIGE® LP Disc if necessary by aligning it with the anterior aspects of the implant and gently tapping with a mallet **(Figure 23)**.*

Figure 21

Figure 22

Figure 23

Step 10 Placement Verification

Following implantation **(Figure 24)**, lateral and AP radiographs should be taken to verify proper placement. Complete the surgery using standard anterior cervical closure procedures.

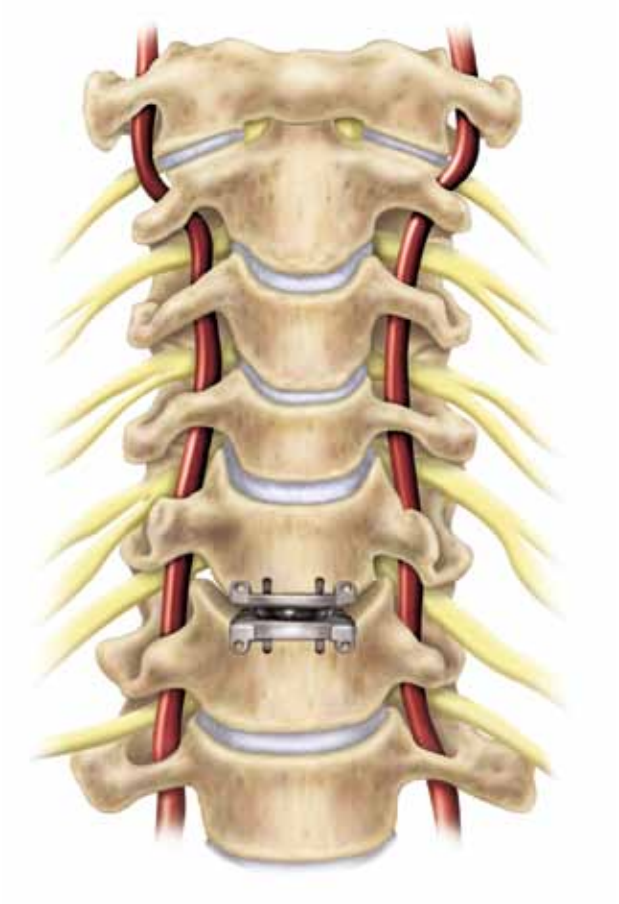

Figure 24

Note

If explantation of the PRESTIGE® LP Cervical Disc is required, separation of the implant from the end plate can be achieved utilizing standard surgical instruments. If removal is required after the implant has bonded with the end plates, a small osteotome may be used, along with an angled curette and forceps to separate the fixation surface from the bone.

Bi-Level Implantation

If/when treating more than one level with a PRESTIGE® LP Cervical Disc, the following bi-level surgical technique describes implantation at two adjacent levels. When performing a bi-level implantation procedure, refer to the initial steps described in the PRESTIGE® LP single-level surgical technique.

Specific preoperative planning is necessary when performing a bi-level procedure. The following should be considered during your preoperative planning:

» To ensure sufficient access to the two affected disc spaces, make the skin incision centered at the middle vertebral body. A standard incision for the exposure of two levels is required **(Figure 25)**.

» When placing the first implant, pay special attention to implant height selection. The goal is to balance the discs to achieve normal sagittal balance and disc space height. Before placing the first implant, it is important to verify normal sagittal balance and disc space height by using the Implant Trials.

  Achieve this by:

  - Preoperative templating
  - Careful trialing under lateral fluoroscopy comparing the facet and intradiscal heights in healthy adjacent levels
  - Implant Trials should fit snugly without distracting the disc space

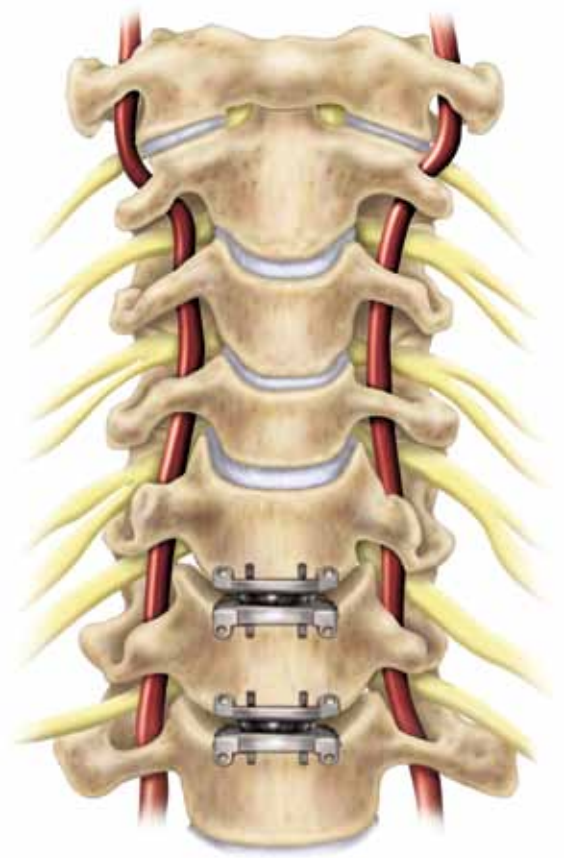

Figure 25

Product Ordering Information

PRESTIGE® LP System Insert Tray with Instruments

Item Number	Description	Size
6971411	5mm Tray	-
6971412	5mm Base	-
6971413	5mm Lid	-
6971225	Implant Trial	5mm × 12mm
6971245	Implant Trial	5mm × 14mm
6971265	Implant Trial	5mm × 16mm
6971325	Rasp	5mm × 12mm
6971345	Rasp	5mm × 14mm
6971365	Rasp	5mm × 16mm
6971425	Rail Punch	5mm × 12mm
6971445	Rail Punch	5mm × 14mm
6971465	Rail Punch	5mm × 16mm
6971525	Trial Cutter Guide	5mm × 12mm
6971545	Trial Cutter Guide	5mm × 14mm
6971565	Trial Cutter Guide	5mm × 16mm
6791105	Shim Distractor	5mm
6971155	Implant Inserter	5mm

PRESTIGE® LP System Upper Insert Tray with Instruments

Item Number	Description	Size
6971405	Outer Case	-
6971410	Outer Lid	-
6971416	6mm Upper Insert Tray	-
6971226	Implant Trial	6mm × 12mm
6971246	Implant Trial	6mm × 14mm
6971266	Implant Trial	6mm × 16mm
6971326	Rasp	6mm × 12mm
6971346	Rasp	6mm × 14mm
6971366	Rasp	6mm × 16mm
6971426	Rail Punch	6mm × 12mm
6971446	Rail Punch	6mm × 14mm
6971466	Rail Punch	6mm × 16mm
6971156	Implant Inserter	6mm
6971106	Shim Distractor	6mm
6971526	Trial/Cutter Guide	6mm × 12mm
6971546	Trial/Cutter Guide	6mm × 14mm
6971566	Trial/Cutter Guide	6mm × 16mm
6971112	Drill Bit Handle	-
6971160	Final Impactor	-
6971115	Slap Hammer	-
6971114	Mallet	-
6971152	Loading Block	5mm – 8mm
6971116	Temporary Fixation Pin	-
6971118	Rail Cutter Bit, Standard	
6971119	Rail Cutter Bit, Diamond Point (Optional)	

Product Ordering Information *Continued*

PRESTIGE® LP System Middle Insert Tray with Instruments

Item Number	Description	Size
6971407	Inner Tray Middle	-
6971227	Implant Trial	7mm × 12mm
6971247	Implant Trial	7mm × 14mm
6971267	Implant Trial	7mm × 16mm
6971287	Implant Trial	7mm × 18mm
6971327	Rasp	7mm × 12mm
6971347	Rasp	7mm × 14mm
6971367	Rasp	7mm × 16mm
6971387	Rasp	7mm × 18mm
6971527	Trial/Cutter Guide	7mm × 12mm
6971547	Trial/Cutter Guide	7mm × 14mm
6971567	Trial/Cutter Guide	7mm × 16mm
6971587	Trial/Cutter Guide	7mm × 18mm
6791427	Rail Punch	7mm × 12mm
6971447	Rail Punch	7mm × 14mm
6971467	Rail Punch	7mm × 16mm
6971487	Rail Punch	7mm × 18mm
6971107	Shim Distractor	7mm
6971157	Implant Inserter	7mm

PRESTIGE® LP System Lower Insert Tray with Instruments

Item Number	Description	Size
6971406	Inner Tray Lower	-
6971248	Implant Trial	8mm × 14mm
6971268	Implant Trial	8mm × 16mm
6971288	Implant Trial	8mm × 18mm
6971348	Rasp	8mm × 14mm
6971368	Rasp	8mm × 16mm
6971388	Rasp	8mm × 18mm
6971548	Trial/Cutter Guide	8mm × 14mm
6971568	Trial/Cutter Guide	8mm × 16mm
6971588	Trial/Cutter Guide	8mm × 18mm
6971448	Rail Punch	8mm × 14mm
6971468	Rail Punch	8mm × 16mm
6971488	Rail Punch	8mm × 18mm
6971108	Shim Distractor	8mm
6971158	Implant Inserter	8mm

All PRESTIGE® LP Implants are Sterile Packaged

Item Number	Description	Size
6971250	PRESTIGE® LP Cervical Disc	5mm × 12mm
6971450	PRESTIGE® LP Cervical Disc	5mm × 14mm
6971650	PRESTIGE® LP Cervical Disc	5mm × 16mm
6971260	PRESTIGE® LP Cervical Disc	6mm × 12mm
6971460	PRESTIGE® LP Cervical Disc	6mm × 14mm
6971660	PRESTIGE® LP Cervical Disc	6mm × 16mm
6971270	PRESTIGE® LP Cervical Disc	7mm × 12mm
6971470	PRESTIGE® LP Cervical Disc	7mm × 14mm
6971670	PRESTIGE® LP Cervical Disc	7mm × 16mm
6971870	PRESTIGE® LP Cervical Disc	7mm × 18mm
6971480	PRESTIGE® LP Cervical Disc	8mm × 14mm
6971680	PRESTIGE® LP Cervical Disc	8mm × 16mm
6971880	PRESTIGE® LP Cervical Disc	8mm × 18mm

Important Product Information for PRESTIGE® Cervical Disc System

THIS DEVICE IS NOT FOR DISTRIBUTION IN THE U.S. OR ITS TERRITORIES.

IMPORTANT PRODUCT INFORMATION FOR PRESTIGE® CERVICAL DISC SYSTEM

PURPOSE:

The purpose of the PRESTIGE® Cervical Disc System is to treat cervical disc disease while maintaining the motion of the treated level.

DESCRIPTION:

The PRESTIGE® Cervical Disc is available in various sizes and may consist of either two articulating components or two articulating components, four bone screws, and two locking screws.

The device can be made of titanium alloy/titanium carbide composite or stainless steel.

INDICATIONS:

The PRESTIGE® Cervical Disc is generally indicated for use at any level from C2/C3 to C7/T1:

- for cervical degenerative discopathy and instability
  - in patients with adjacent levels either congenitally or surgically fused
  - for primary surgery for degenerative discopathies or extensive anterior decompression
  - revision surgery for failed disc operation, stenosis, post-operative instability
- pseudarthrosis or failed arthrodesis.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness or incompetency.
7. Any other disease or surgical problem which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia , osteoporosis. Osteoporosis is relative since this condition may limit the degree of obtainable correction and the amount of mechanical fixation.
9. Suspected or documented metal allergy or intolerance.
10. Any patient having inadequate tissue coverage over the operative site.
11. Any case not described in the indications.
12. Any patient unwilling to cooperate with postoperative instructions.
13. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
14. These devices must not be used for pediatric cases, or where the patient still has general skeletal growth.
15. Has severe osteopenia, osteoporosis, osteomalacia, or metabolic bone disease.
16. Has overt or active spinal and/or systemic infection.
17. This spinal implant system is not designed, intended, or sold for uses other than those indicated.

POSSIBLE ADVERSE EFFECTS:

Risks associated with the use of the PRESTIGE® Cervical Disc include: 1) those commonly associated with any surgery; 2) those specifically associated with cervical spinal surgery using an anterior approach; and 3) those associated with a spinal implant, as well as those pertaining to the PRESTIGE® Cervical Disc. There is also the risk that this surgical procedure will not be effective, and may not relieve or may cause worsening of preoperative symptoms.

1. Risks associated with any surgical procedure are those such as adverse reactions to anesthesia; pulmonary complications such as pneumonia or atelectasis; infection of the wound; systemic infection; abscess; cellulitis; wound dehiscence; swelling; wound hematoma; thrombosis; ischemia pulmonary embolism; thromboembolism; hemorrhage; thrombophlebitis; organ, nerve or muscular damage and death.
2. Risks associated with anterior interbody replacements of the cervical spine include dysphagia; dysphasia; dysphonia; otitis media; recurring aspirations; fistula; nerve deficits or damage; malunion of the mandible; tracheal, esophageal, and pharyngeal perforation; airway obstruction; external chylorrhea; hoarseness; vocal cord paralysis; warmth or tingling in the extremities; neural damage; damage to the spinal cord or nerve root; or graft in the neural canal; dural tears or leaking; loss of disc height; loss of proper curvature, correction, height or reduction of the spine; vertebral slipping; nerve root trauma; scarring, herniation or degeneration of adjacent discs; nerve damage possibly resulting in paralysis or pain, and surrounding soft tissue damage, vascular damage; spinal stenosis; and spondylolysis.
3. Risks associated with any implants in the spine are early or late loosening of the components; disassembly; bending or breakage of any or all of the components; implant migration; loss of purchase; implant fracture; bone fracture; foreign body reactions to the implant including allergic reaction; infection; possible tissue reaction; bone absorption; tumor formation or graft rejection; bone resorption; development of new radiculopathy; myelopathy or pain; cessation of bone growth of the operated portion of the spine; decreased strength of extremities; decreased reflexes; appearance of cord or nerve root injury; pseudoarthrosis; fracture of the vertebral body. Additionally, there is the possibility of misdiagnosis or missed diagnosis with radiographic imaging of the spine when implants are present.
4. Early or late loosening or movement of the device.
5. Implant migration.
6. Breakage of any or all of the components or instruments.
7. Foreign body reaction to the implants including possible tumor formation, auto immune disease, metallosis, and/or scarring.
8. Pressure on the surrounding tissues or organs, possibly resulting in oesophagas or trachea breakdown from component parts where there is inadequate tissue coverage over the implant. Implant or graft extrusion can lead to fistular complications.
9. Loss of proper spinal curvature, correction, height, and/or reduction.
10. Infection.
11. Bone fracture or stress shielding at, above, or below the level of surgery.
12. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis or other types of serious injury. Cerebral spinal fluid leakage.
13. Haemorrhage and/or hematomas.
14. Discitis, arachnoiditis, and/or other types of inflammation.
15. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
16. Inability to resume activities of normal daily living.
17. Death.

NOTE: Additional surgery may be necessary to correct some of the adverse effects.

!USA For US Audiences Only

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

WARNINGS AND PRECAUTIONS:

A successful result is not always achieved in every surgical case. Preoperative symptoms may be unrelieved or worsened. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. Preoperative planning and operating procedures, including knowledge of surgical techniques, are important considerations for the successful utilization of the PRESTIGE® Cervical Disc by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results.

Important Product Information for PRESTIGE® Cervical Disc System *Continued*

This document is to be used for information regarding device use, data requirements, patient obligations, etc. The following highlights some of the preoperative, intraoperative, and postoperative requirements.

PREOPERATIVE:

1. Only patients meeting the indications described should be considered candidates for the PRESTIGE® Cervical Disc.
2. The implants are provided either non-sterile or packaged sterile and are for single use only and are not to be sterilized for secondary use.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Packaging should be intact. The implants and instruments should be protected during storage especially from corrosive environments.
4. An adequate inventory of implant sizes should be available at the time of surgery.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the device to verify that all parts and necessary instruments are present before the surgery begins. The PRESTIGE® Cervical Disc System components are not to be combined with components from another manufacturer. Different metal types should not be used together.
6. All instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

1. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
2. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
3. Bone cement should not be used. The heat generated from the curing process may 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. These conditions are described in the protocol.

1. Detailed instructions on the use and limitations of the device must be given to the patient. Postoperative rehabilitation and restrictions must be reviewed with the patient prior to discharge.
2. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible; and, if applicable, returned to Medtronic Sofamor Danek. As with all orthopaedic implants, the PRESTIGE® Cervical Disc should never be reused under any circumstances.

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 Sofamor Danek.

CLEANING AND DECONTAMINATION:

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

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

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

STERILIZATION:

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

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	40 Minutes
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.*For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Medtronic Sofamor Danek. Further, if any of the implanted 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 Sofamor Danek product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION:

If further information is needed or required, please contact Medtronic Sofamor Danek:

www.sofamordanek.com

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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 judgement 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 medical information.

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