# PRESTIGE® ST

## Cervical Disc System Surgical Technique

DRAFT

Version A

# TABLE OF CONTENTS


PREOPERATIVE MEASUREMENT 4

PATIENT POSITIONING 5

EXPOSURE 6

DISCECTOMY/DECOMPRESSION 7

ENDPLATE PREPARATION 8

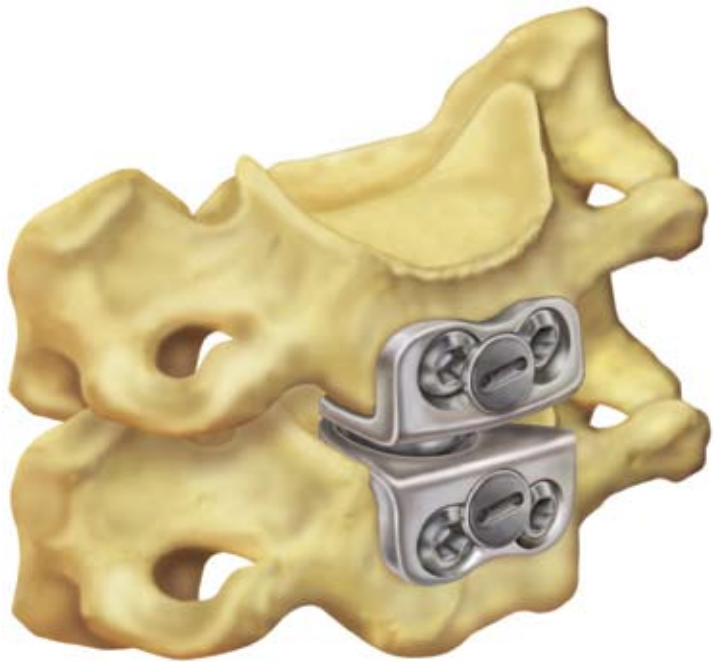
ANTERIOR PLANNING 10

IMPLANTATION 12

PLACEMENT VERIFICATION 14

PRODUCT ORDERING INFORMATION 15

IMPORTANT PRODUCT INFORMATION 17

# INTRODUCTION

The surgical benefits of an anterior approach to the cervical spine in the management of the intractable symptoms and signs associated with degenerative disc disease are widely appreciated. Usually, the symptomatic functional spinal unit (FSU) is mobile and mechanically stable preoperatively. Anterior cervical disc fusion, though providing symptomatic relief, has the disadvantage of converting the operated segment to a non-functional spinal unit. As a result, increased stress takes place at adjacent levels, which may, in turn, result in hypermobility and subsequent mechanical instability and/or accelerated degeneration.

Cervical disc arthroplasty is intended to preserve the motion segment, reduce return to work time, reduce reoperations due to pseudoarthrosis and potentially prevent degenerative changes in adjacent segments.

The PRESTIGE® ST Cervical Disc System offers proven biomechanics based on years of clinical experience, superior imaging and wear characteristics through a Stainless Steel material, and a simple, straightforward surgical technique consistent with a standard ACDF.

# SURGICAL TECHNIQUE

Using a computed tomography (CT) or magnetic resonance image (MRI) obtained so that the slices are parallel to the vertebral body endplates, determine the smaller of the two vertebral body endplates at the target disc space. The use of 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® ST 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 (*Figure 1c*).

*Note: Templating provides only approximate sizing. This initial assessment may vary due to 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.*

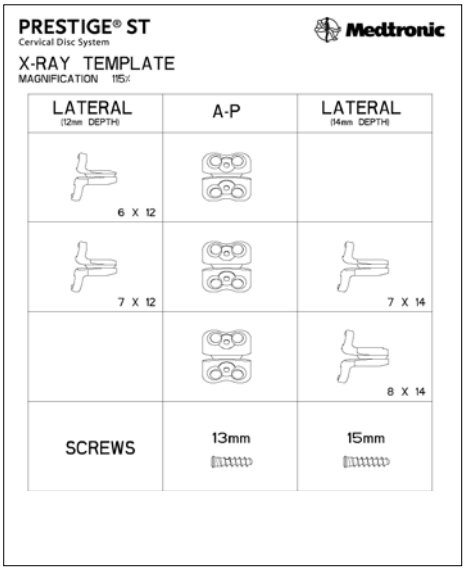



Figure 1a

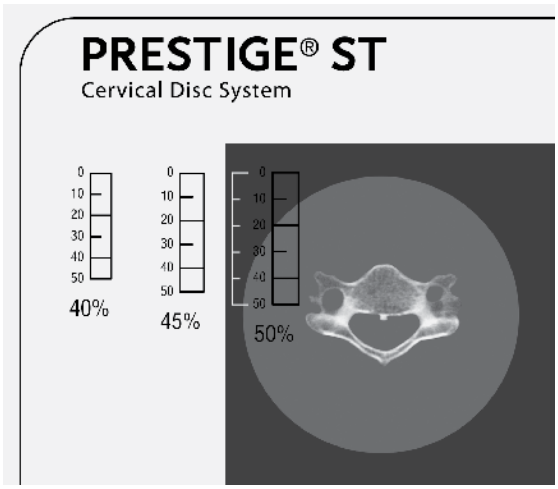



Figure 1b

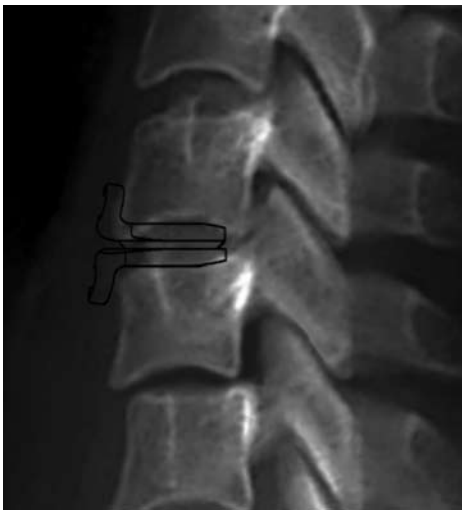


Figure 1c

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 pre-operative 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.*

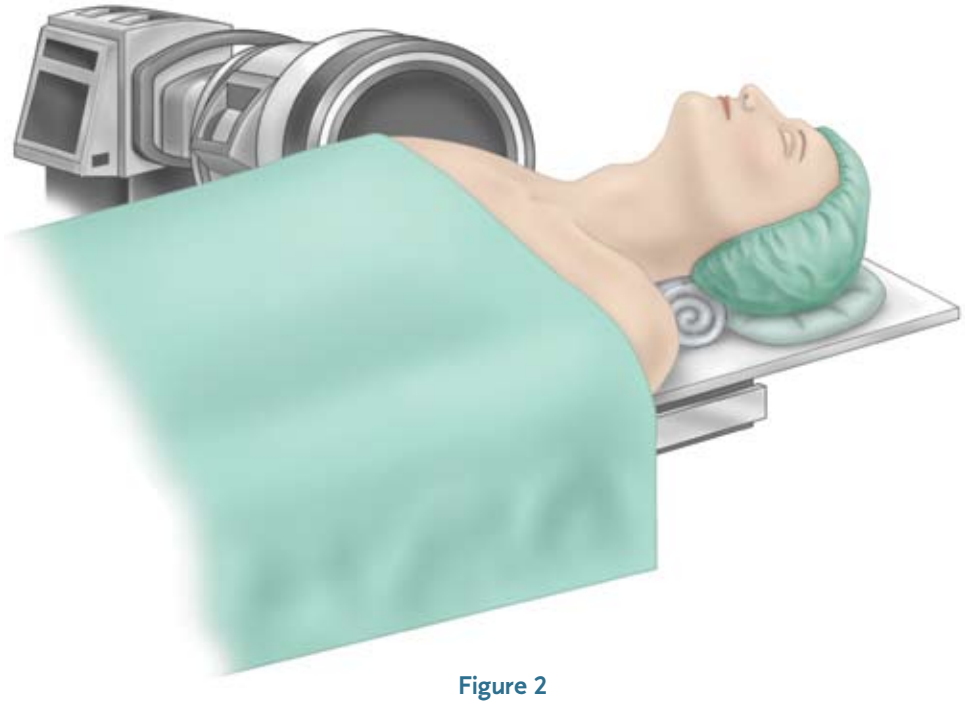


**Figure 2**

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.

*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.*

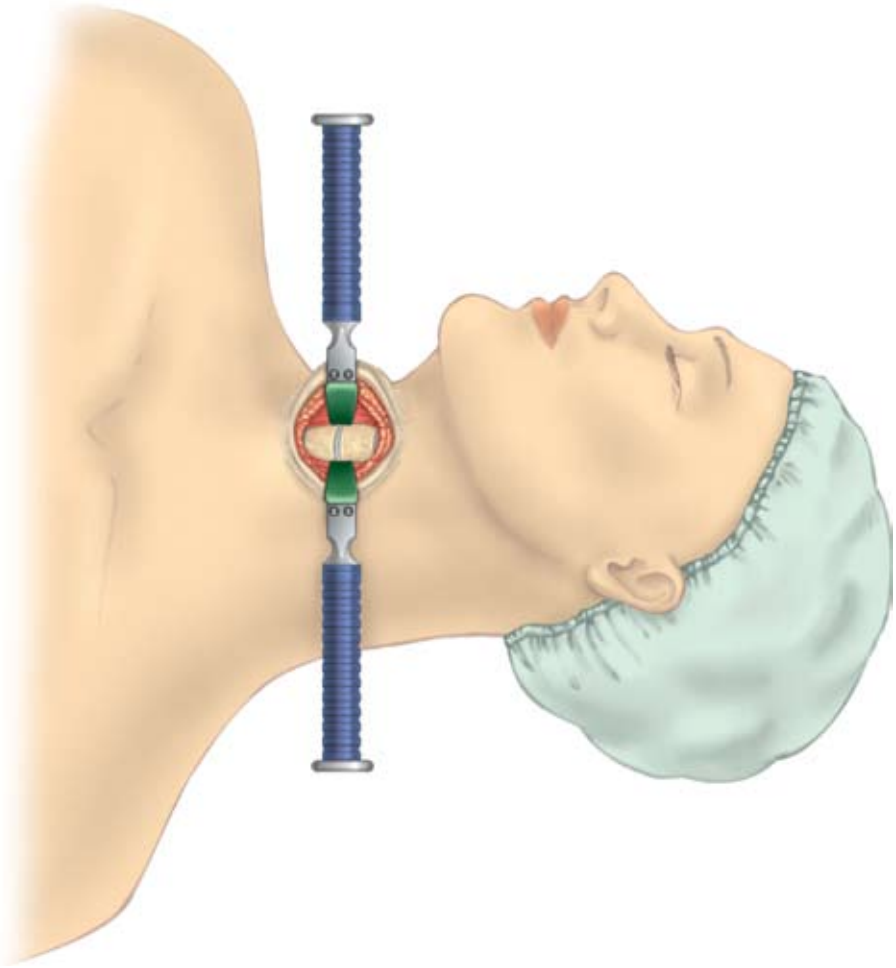


**Figure 3**

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 may be carefully removed if necessary. Lightly burr the anterior surface of the vertebral bodies to remove any soft tissue and bony protrusions to create a flat surface.

*Note: Take care to prevent excessive anterior bone removal.*

***NOTE: A complete and thorough discectomy and bilateral decompression are essential.***

**Figure 4**

After the discectomy and decompression is complete, relax or remove exterior distraction devices. Using either a round or cylindrical burr (surgeon preference), prepare the endplates 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 endplate preparation to the posterior aspects of the vertebral bodies to ensure maximum implant/endplate interface (*Figure 6*).

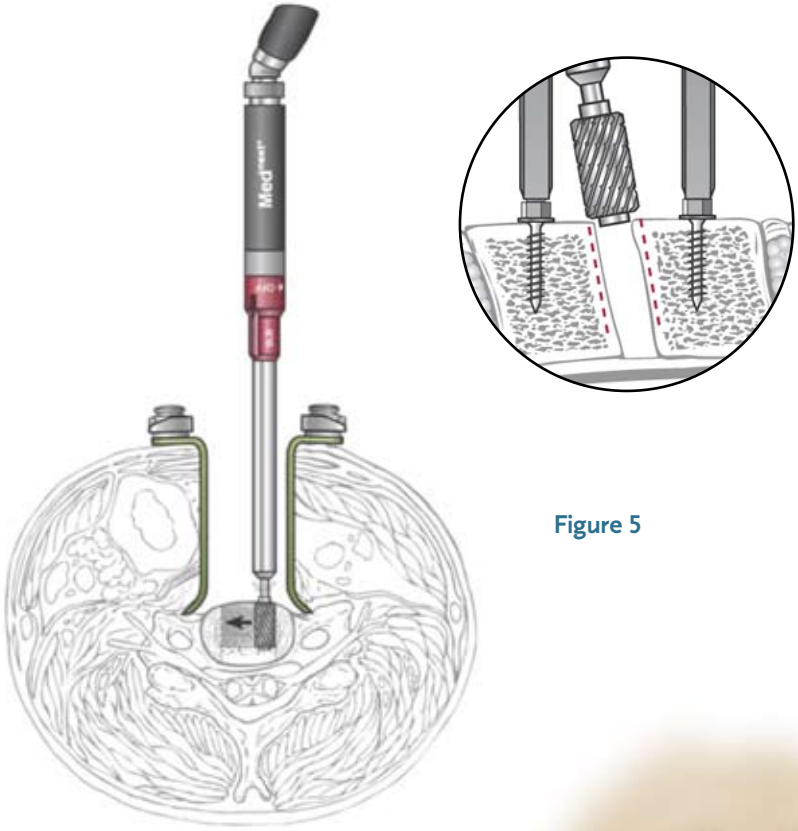


Figure 5

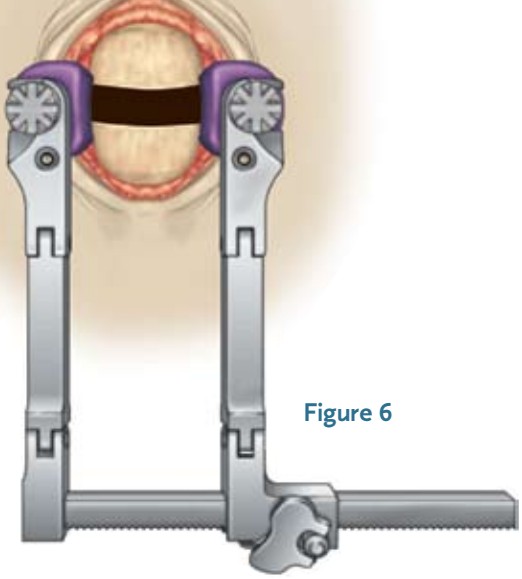


Figure 6

Utilize the Interbody Trial to ensure accuracy of the prepared disc space. The Implant Trial has the exact dimensions of the interbody portion of the Prestige Disc. After all distraction has been removed, it should slide into the prepared disc space with very little resistance. If the Trial does not completely fit into the disc space, or causes the vertebral bodies to splay, double check the end-plates for protruding bone that might interfere with placement of the Prestige Disc. Use a high-speed burr to remove any bony obstructions (*Figure 7*).

**Figure 7**

After final end-plate preparation is complete, the Interbody Trial serves as the guide for the cannulated Anterior Reamer (*Figure 8*). The cannulated Anterior Reamer is placed over the Interbody Trial handle and rotated to prepare the anterior surface to match the PRESTIGE® ST Disc angles (*Figure 9*).

**Figure 8**

**Figure 9**

*Note: Make sure Trial handle remains perfectly stationary during anterior reaming.*

Remove protruding bone from within the outer diameter of the planned surface that might interfere with a flush fit of the PRESTIGE® ST disc (*Figure 10*).

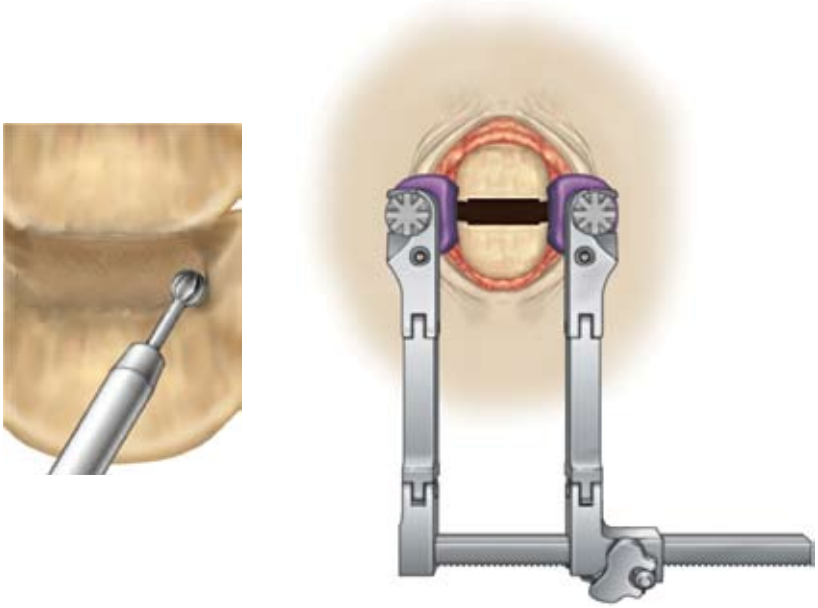


Figure 10

Utilize the corresponding Profile Trial to ensure accuracy of the anterior surface preparation and the angles relative to the disc space (*Figure 11*). Place the Profile Trial into the prepared disc space and 'sweep' it from side to side feeling for any resistance or obstructions that might interfere with proper fit of the PRESTIGE® ST disc. Use a high-speed burr to remove any bony obstructions.

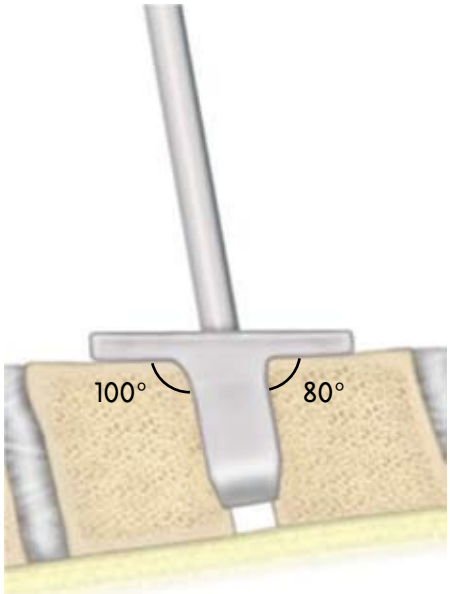



Figure 11

*Note: Corner (edge) must be removed with a burr to match radius of implant.*

Load appropriately sized PRESTIGE® ST disc onto Inserter from the Implant Loading Block by aligning tangs between Superior and Inferior components and tightening each pin by rotating in a clockwise manner. Inserter is marked for proper Superior/Inferior orientation.

Place PRESTIGE® ST disc into prepared disc space, ensuring the ball of the construct is placed cephalad (*Figure 13*). The Inserter is marked Superior/Inferior. The Disc should slide into the prepared disc space with very little resistance (*Figure 14*).

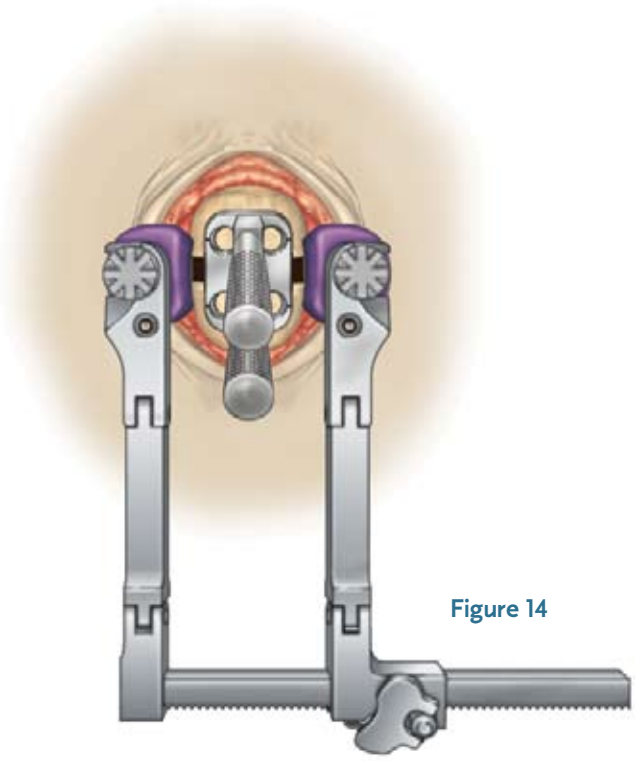


Figure 14

Figure 13

**Drill/Insert Bone Screws and Lock Screws**

With Inserter in place, drill all four bone screw holes using Drill Guide and 13mm drill (*Figure 15*).

Remove Drill Guide and place Bones Screws through Inserter (do not tighten). Bone Screws should be tightened sequentially until all four are completely tight (*Figure 16*).

After final tightening of bone screws, remove Inserter by rotating pins counterclockwise. Tilt the inserter cephalad/caudal to release from implant.

Place and tighten Lock Screws over heads of the bones screws (*Figure 17*).

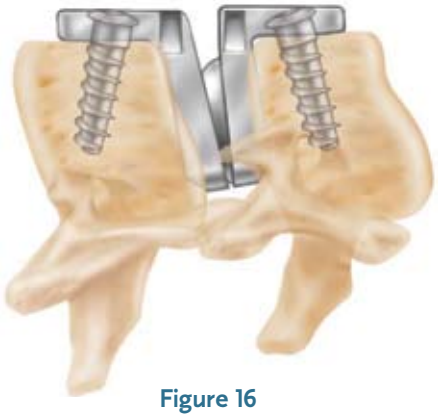


Figure 16

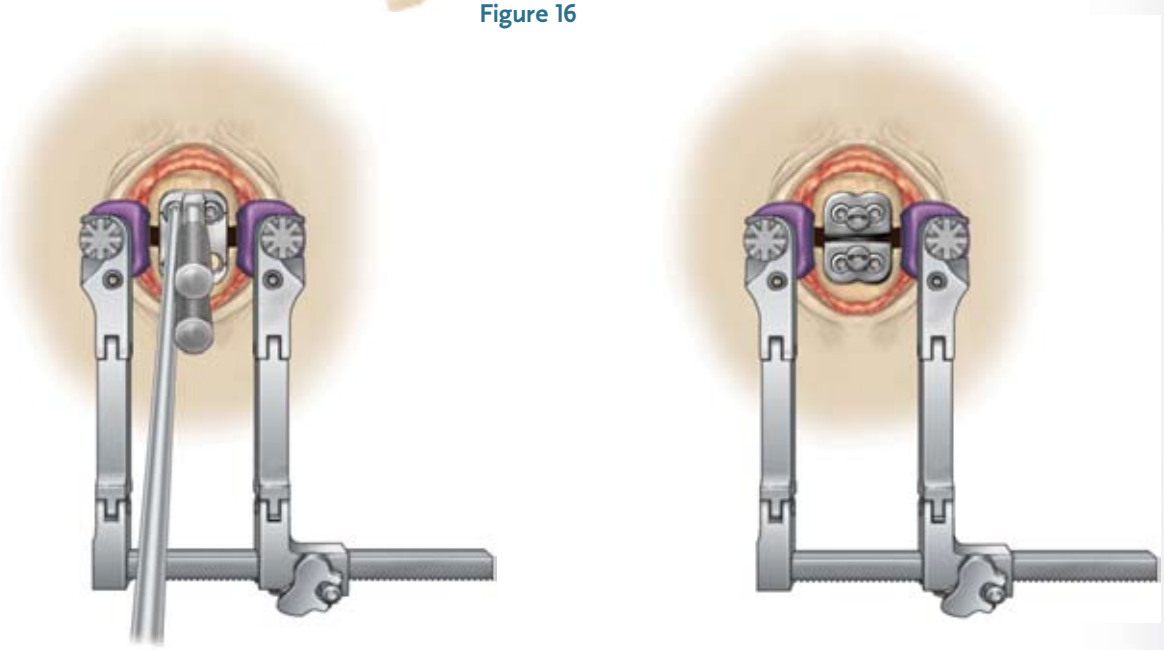


Figure 15

Figure 17

Following final Disc insertion (*Figure 18*), lateral and A/P radiographs may be taken to verify proper placement. Complete the surgery using standard anterior cervical disc closure procedures.

*Note: If explantation of the PRESTIGE® ST Cervical Disc is required, a separation of the implant from the endplate can be achieved using standard surgical instruments.*

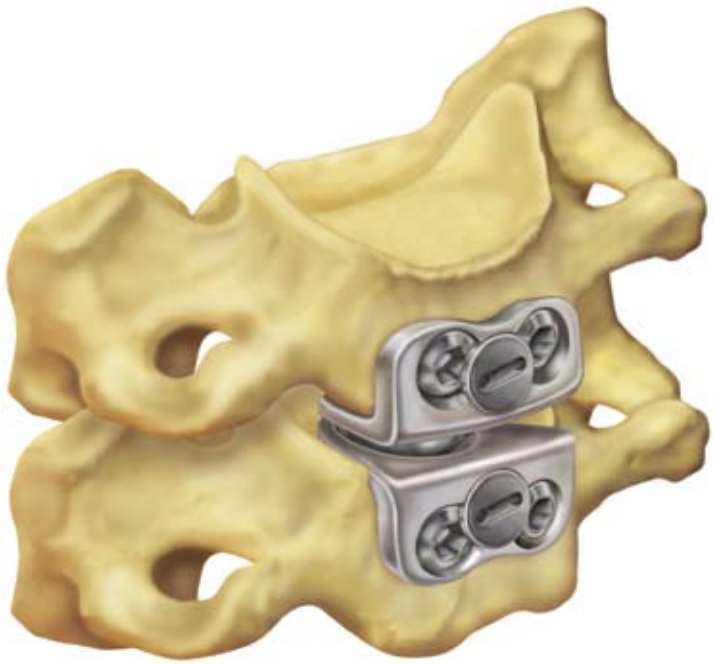


**Figure 18**

# PRODUCT ORDERING INFORMATION

Package insert will be placed here upon approval

# IMPORTANT PRODUCT INFORMATION

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# NOTES

listen. respond. deliver.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgement of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information..

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