SURGICAL
TECHNIQUE

Prestige LP™

Cervical Disc System with Streamlined Instruments

Medtronic

TABLE OF **CONTENTS**

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.

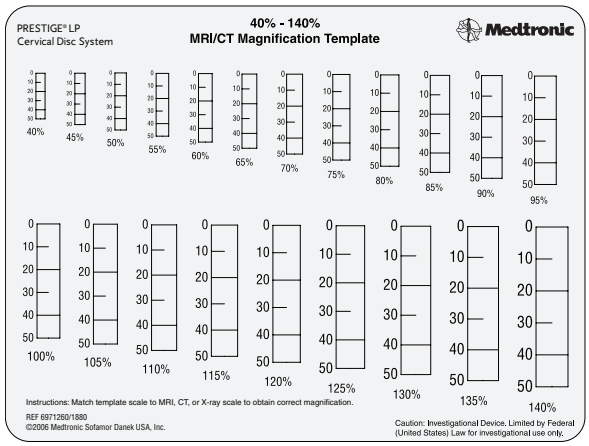


Figure 1a

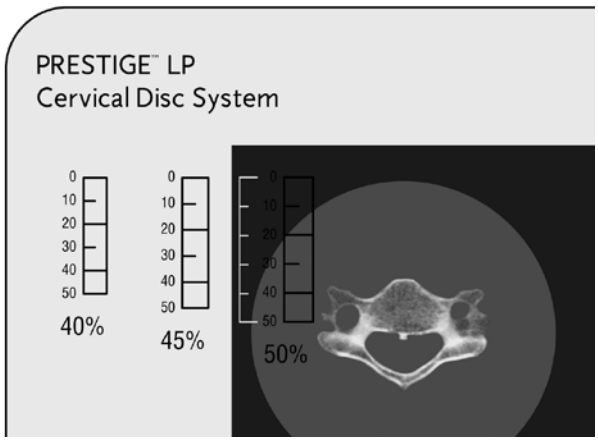


Figure 1b

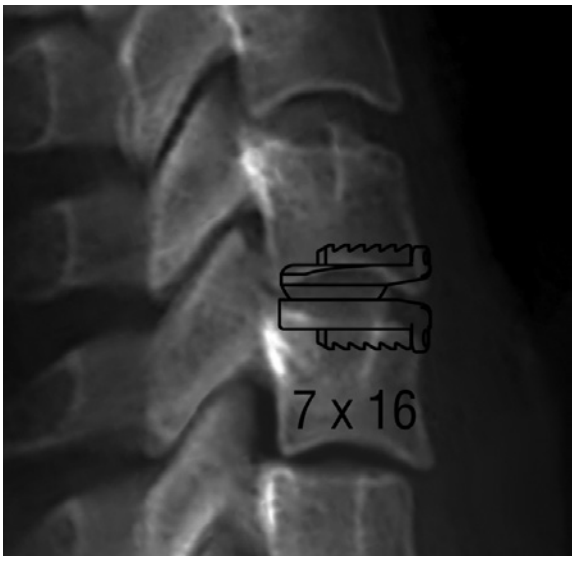


Figure 1c

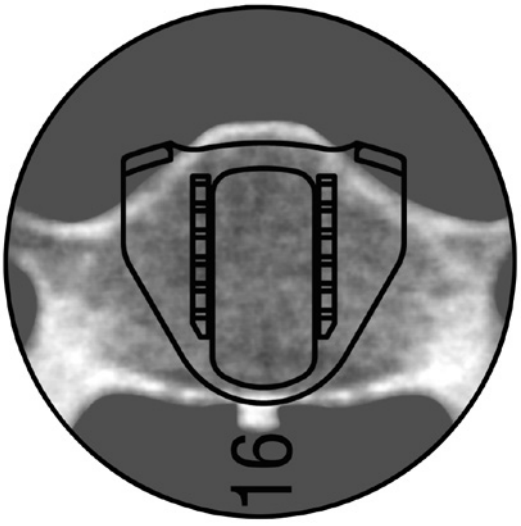


Figure 1d

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.

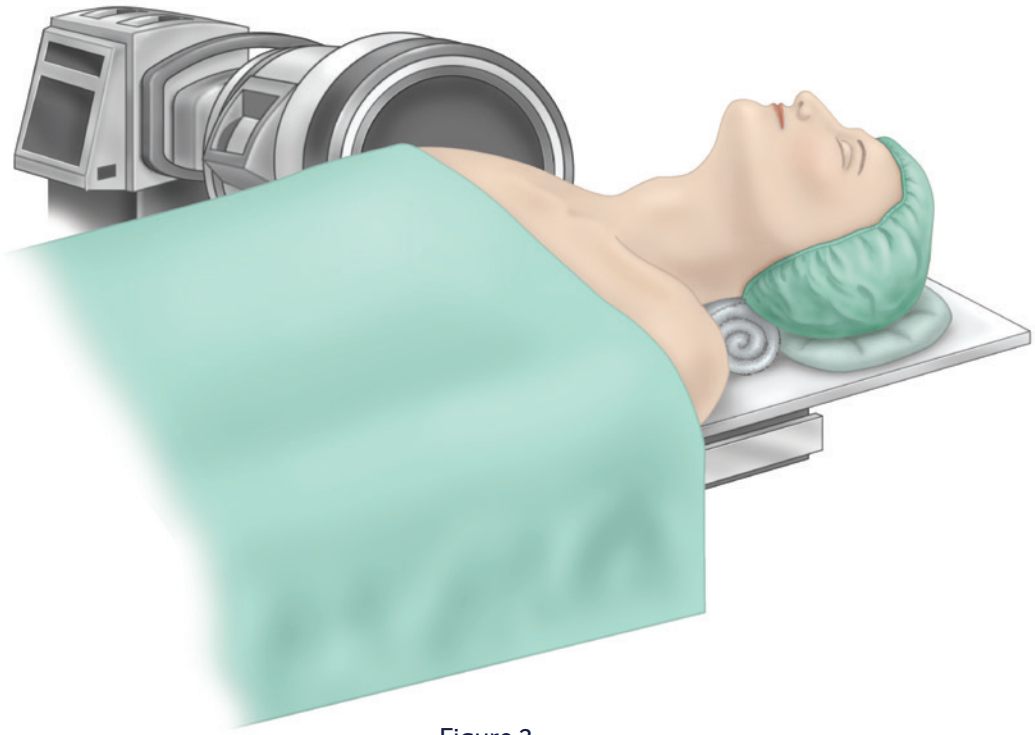


Figure 2

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 may be done with the help of distracting instruments such as the Medtronic Trimline™ Retractor Set.

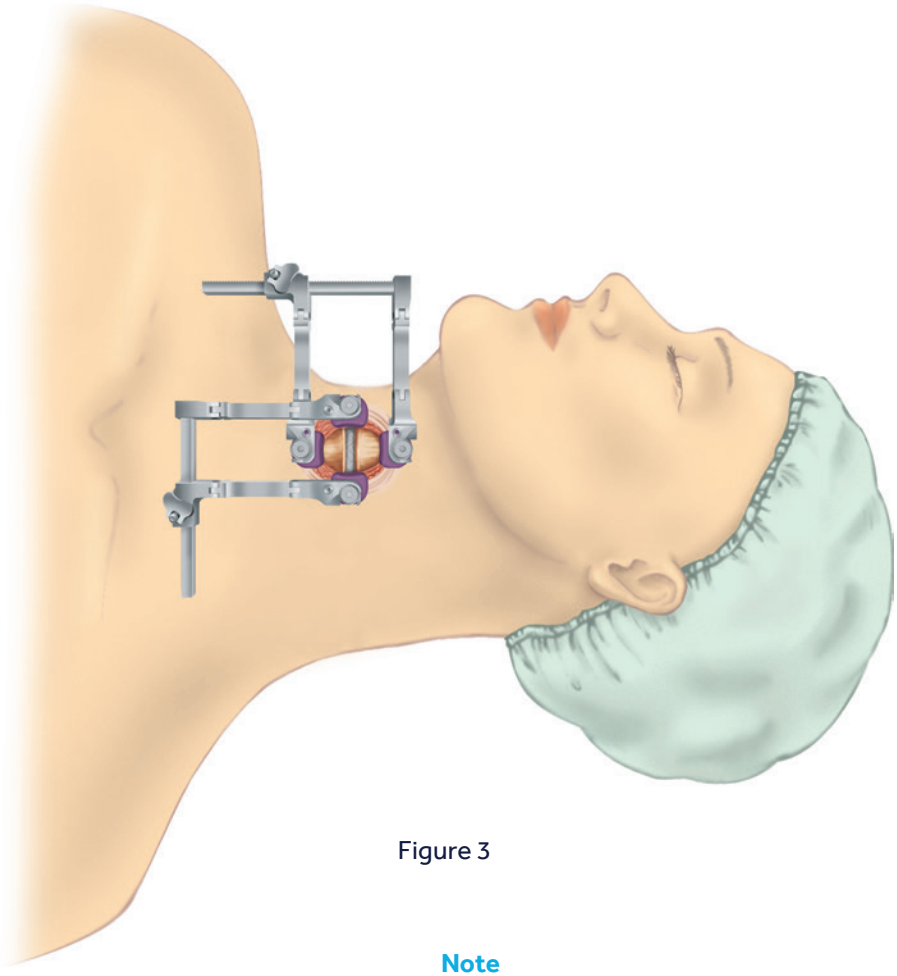


Figure 3

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.

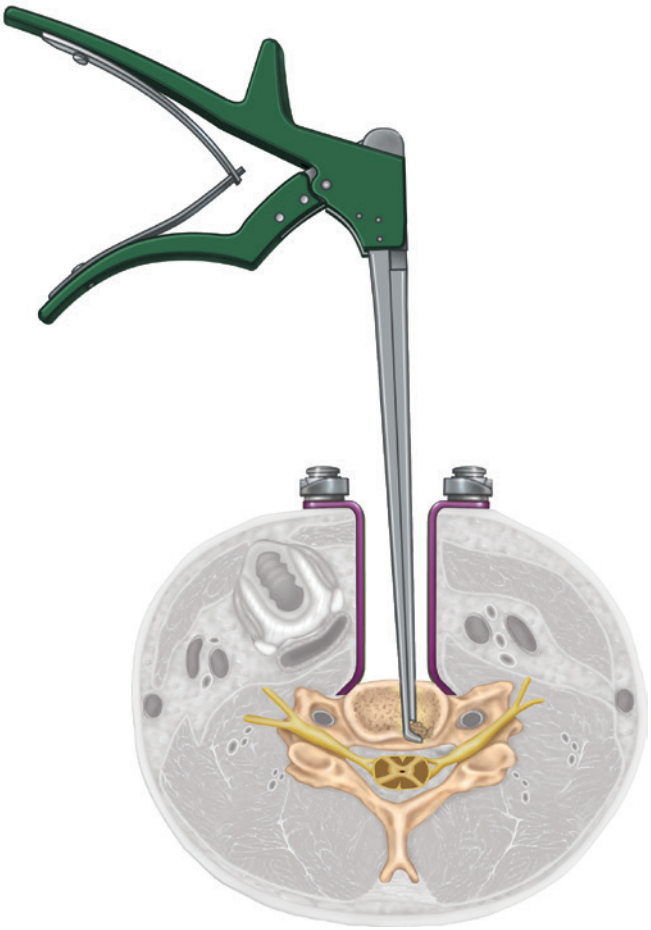


Figure 4

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, 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)**.

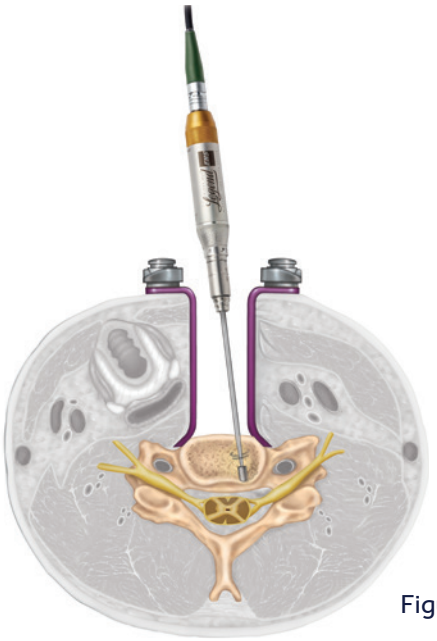


Figure 5

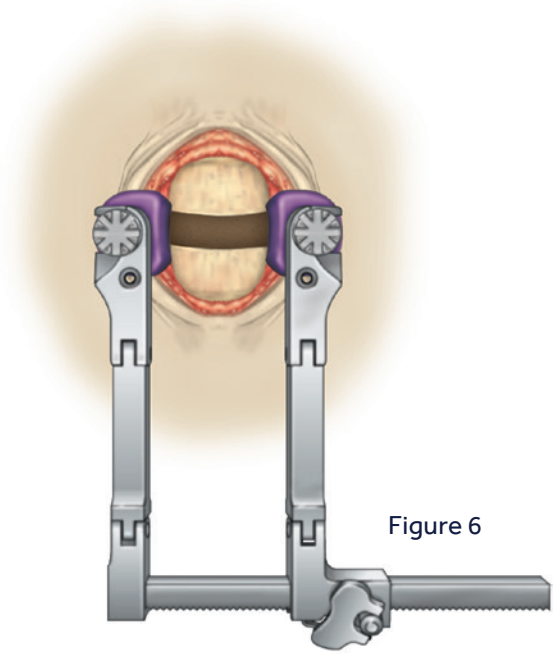


Figure 6

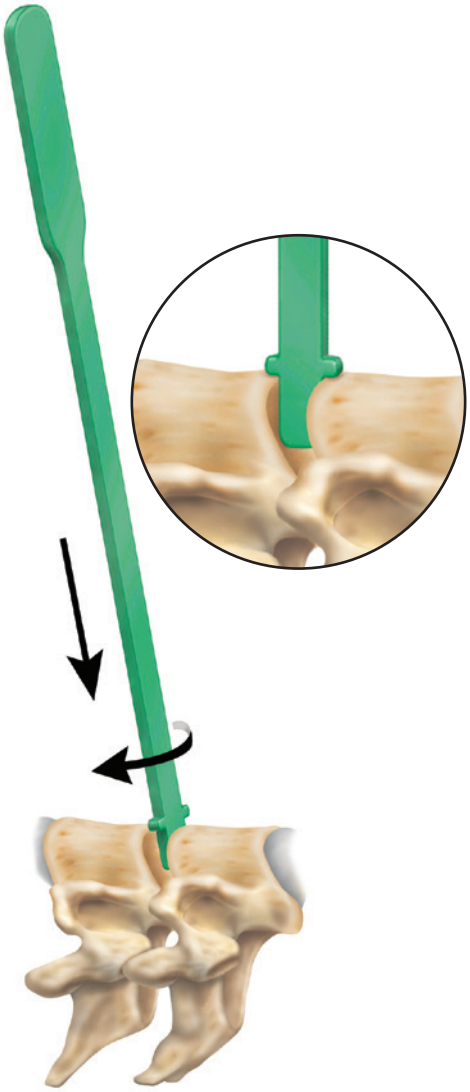


Figure 7

The appropriately sized Rasp can also be used, or used in conjunction with other end-plate preparation instruments (i.e. currettes), for completing this step. The appropriately sized Rasp should maximize end plate contact **(Figure 8)**. 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 9)**.

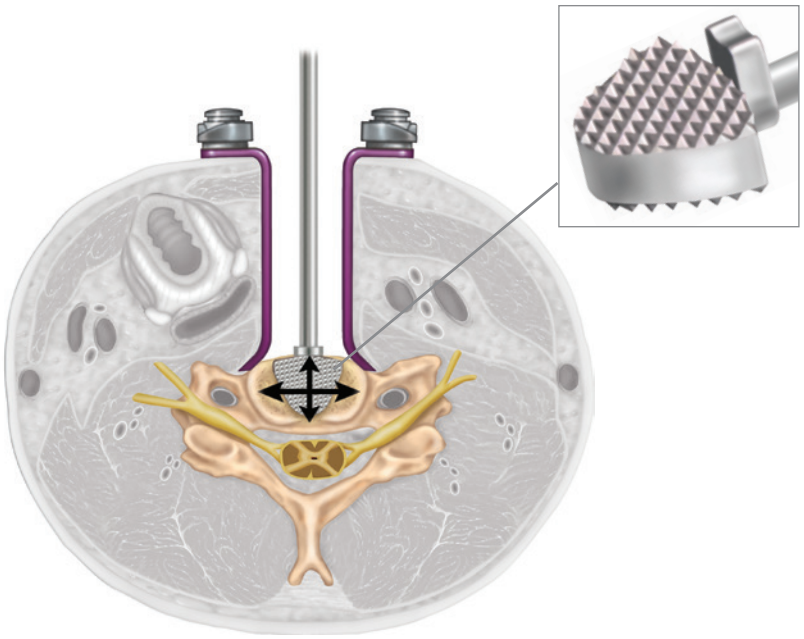


Figure 9

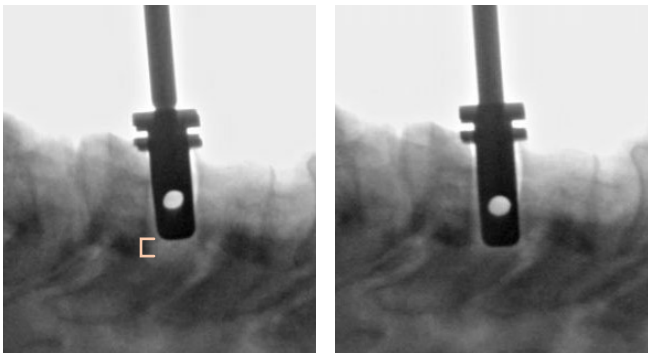
Figure 8

Note

Rasping will help remove any protrusions remaining after parallel burring.

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 **(Figure 10)**. 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. Once the appropriate Prestige LP™ Cervical Disc size is determined through the Implant Trial step, the Implant Trial will remain in the disc space (Figure 11).



Too short *Correct size*

Figure 11

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

With the appropriate Implant Trial in the disc space, select the corresponding Drill Guide to prepare the implant fixation channels in the end plates. Slide the corresponding Drill Guide over the Implant Trial shaft into the prepared disc space. There are spikes on the end of the Drill Guide that will hold the guide in place, centered on the midline of the vertebral bodies **(Figure 11a)**.

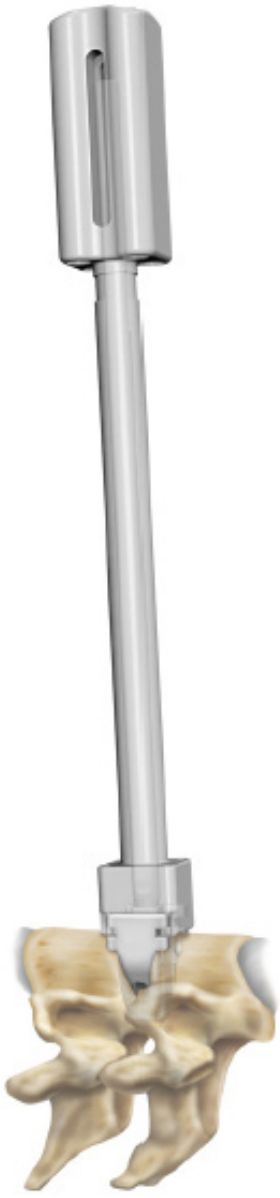


Figure 11a

Note

The Implant Trial includes a slot that indicates if the Drill Guide is fully seated. If the slot can be seen on fluoroscopy, the Drill Guide is not fully seated. The below image illustrates correct final placement **(Figure 11b)**.

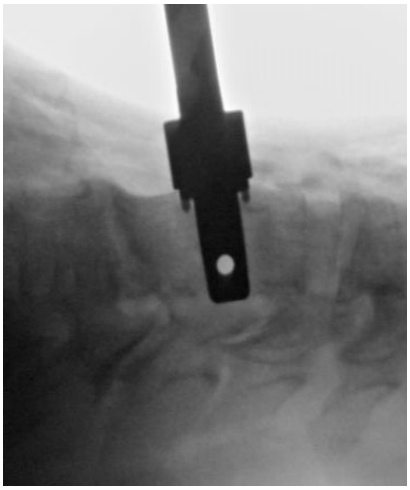


Figure 11b

Attach the Drill Bit (Rail Cutter Bit) to the Universal Handle. Insert the Drill Bit into one port on the Drill Guide. Drill the first fixation channel into the end plate. While holding the Drill Guide firmly in place, remove the Drill Bit. Drill the next channel in the contralateral port. Repeat the process for the third, and fourth channels **(Figure 12)**. Remove the Drill Guide while leaving the Implant Trial in the disc space.

Figure 12

STEP 8
RAIL CUTTING

Slide the corresponding Rail Punch over the Implant Trial shaft. The blades will engage the slots in the Implant Trial and align with the previously drilled holes. Gently tap the Rail Punch until the proximal end of both instruments are flush **(Figure 13)**. The extension handle and mallet are used to remove the rail punch **(Figure 14)**.

This should complete the preparation of the four channels into the end plates as shown **(Figure 15)**.

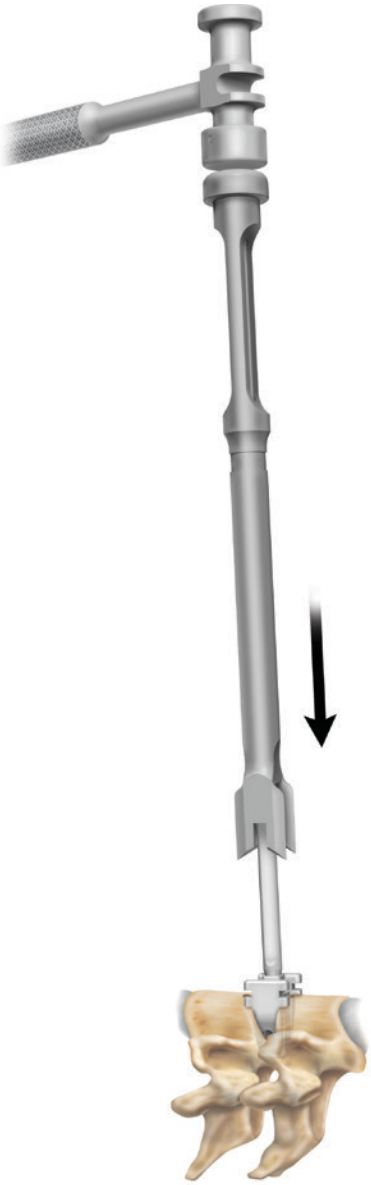


Figure 13

Figure 14

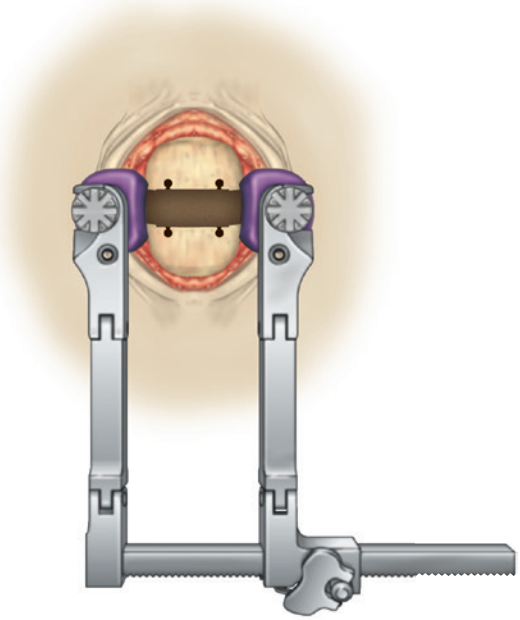


Figure 15

STEP 9
INSERTER ASSEMBLY/DISASSEMBLY

Slide the inner shaft into the Inserter Handle **(Figure 16)**. Turn the back handle clockwise to assemble and load the implant to the inserter **(Figure 17)**. Turn the back handle counterclockwise to release the implant and disassemble the instrument **(Figure 18)**. Once the inner shaft is no longer connected to the Inserter Handle pull the inner shaft out for cleaning and place it back in the tray **(Figure 19)**.

Assembly

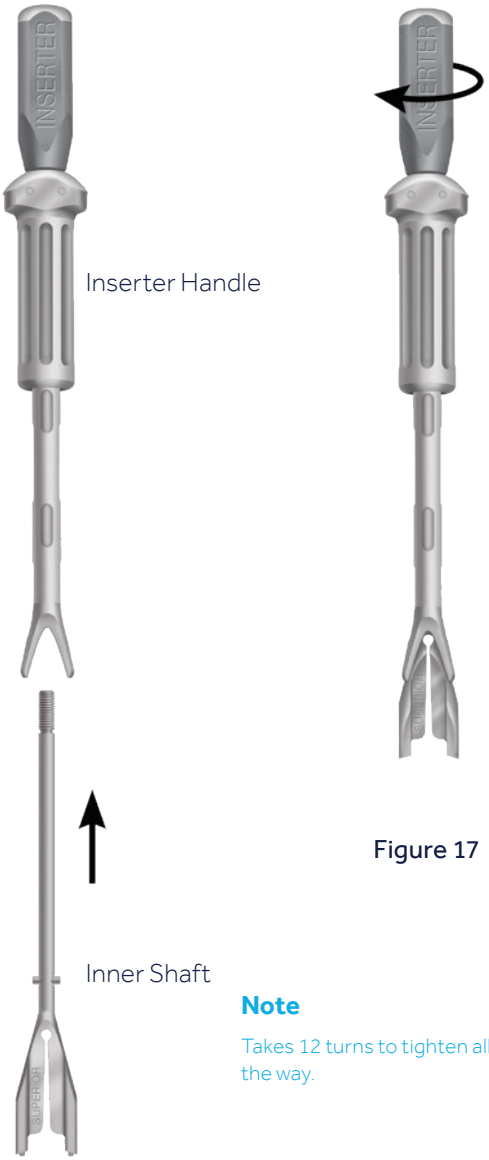


Figure 16

Figure 17

Note

Takes 12 turns to tighten all the way.

Disassembly

Figure 18

Note

Takes 12 turns to remove the inner shaft from the handle

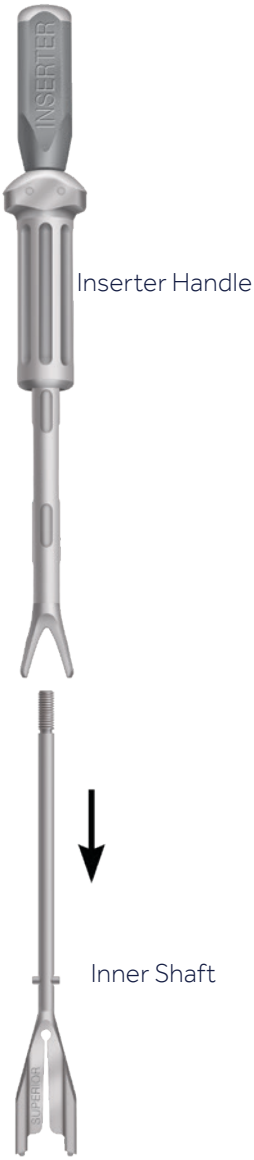


Figure 19

STEP 10
IMPLANTATION

When using the Loading Block, place the appropriately sized Prestige LP™ Cervical Disc in the corresponding slot **(Figure 20)**. 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 21)**. Advance the outer sheath toward the disc by rotating the back handle clockwise **(Figure 22)**. Remove from Loading Block. Implant Inserter and package are marked for proper superior/inferior orientation.

Note

The ball portion of the implant should be superior.

Note

Remove Tyvek separator.

Figure 20

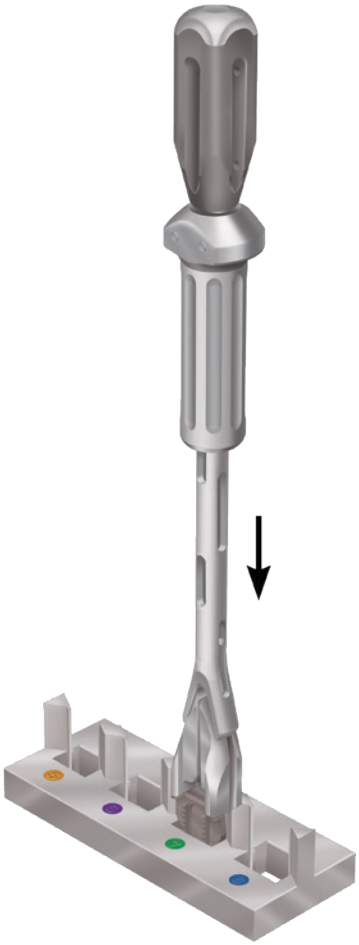


Figure 21

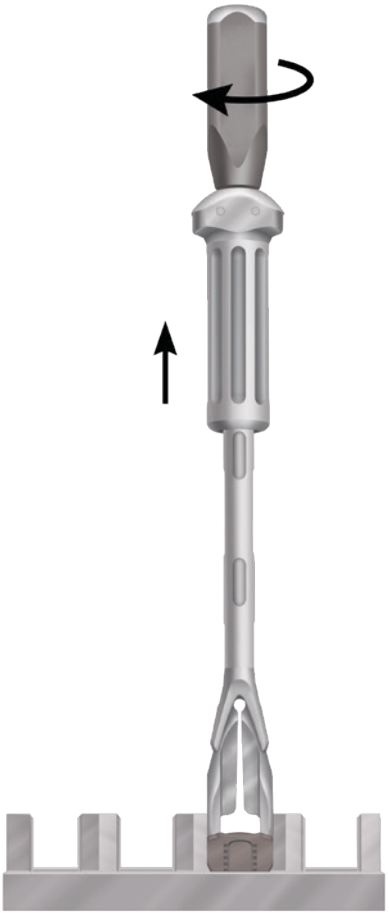


Figure 22

From the packaging **(Figure 23)**, load the appropriately sized Prestige LP™ Cervical Disc onto the bottom of the Implant Inserter by placing the four inserter prongs into the ports on the anterior disc tabs. Advance the outer sheath toward the disc by rotating the back handle clockwise. Remove from packaging **(Figure 24)**. The Implant Inserter and package are marked for proper superior/inferior orientation.

Note

Before placing the Prestige LP™ Cervical Disc into the prepared disc space, ensure the ball of the construct is placed cephalad. The disc should slide into the prepared disc space with only minor resistance.

Note

Remove Tyvek separator.

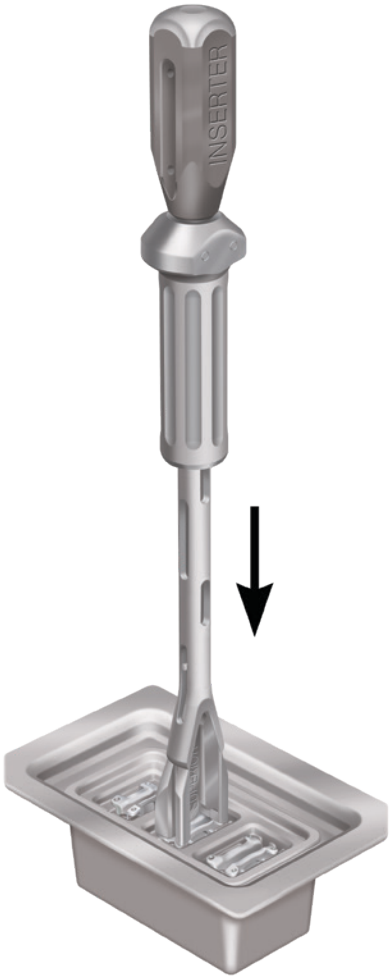


Figure 23

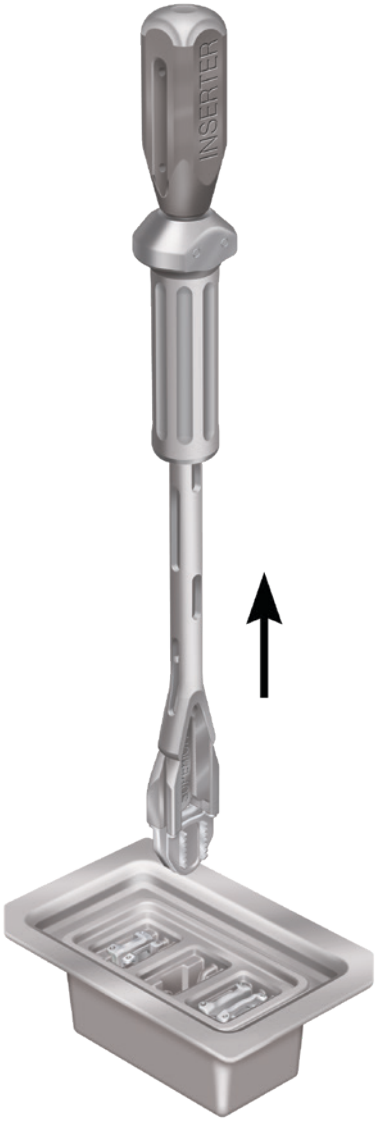


Figure 24

With the ball portion of the prosthesis positioned superiorly, align the Prestige LP™ Cervical 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 back handle counterclockwise to release **(Figure 25)** and remove the Inserter **(Figure 26)**.

Note

Utilize the Final Impactor to fully seat the Prestige LP™ Cervical Disc if necessary by aligning it with the anterior aspects of the implant and gently tapping with a mallet **(Figure 27)**.

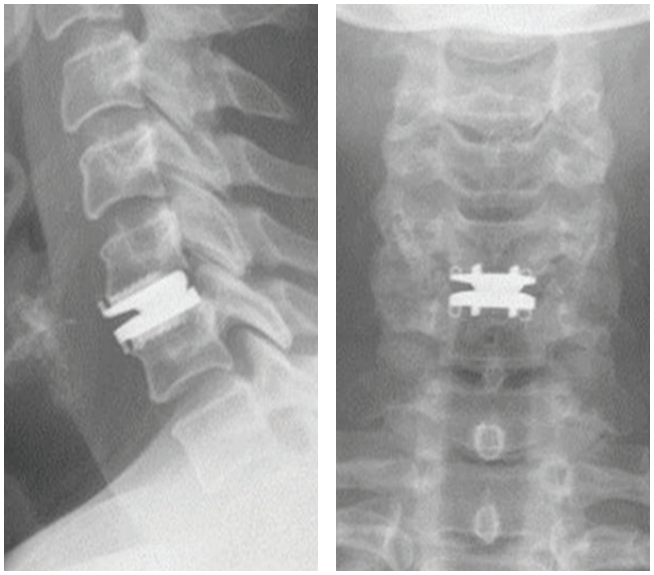
Figure 25

Figure 26

Figure 27

STEP 11
PLACEMENT VERIFICATION

Following implantation **(Figure 28)**, lateral and AP radiographs should be taken to verify proper placement. Complete the surgery using standard anterior cervical closure procedures.



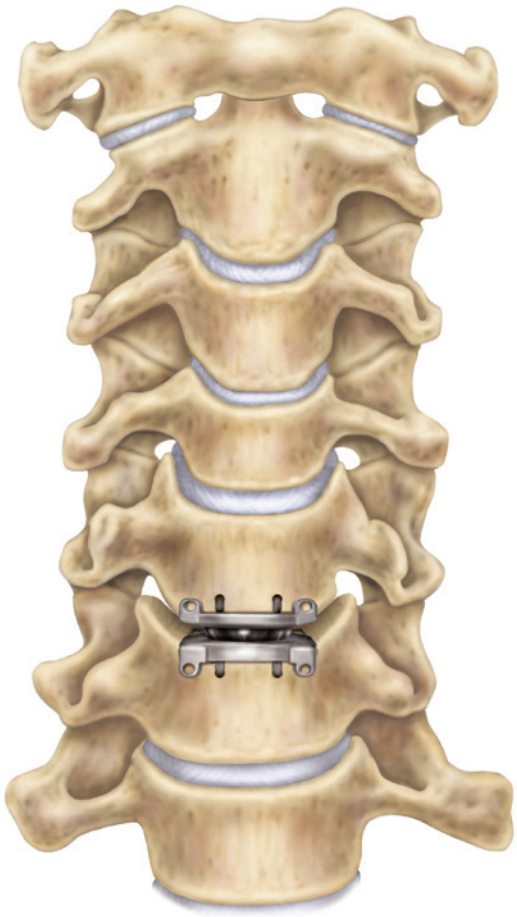


Figure 28

STEP 12
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 29)**.
- 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

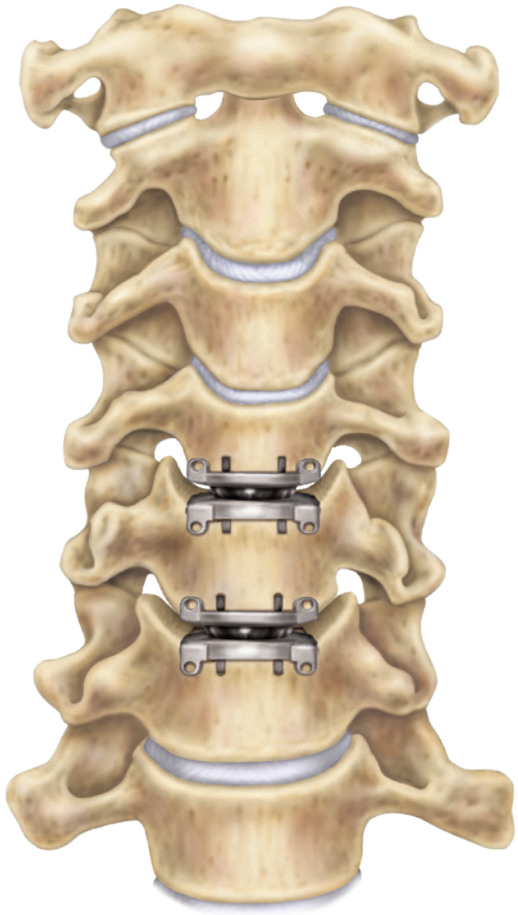
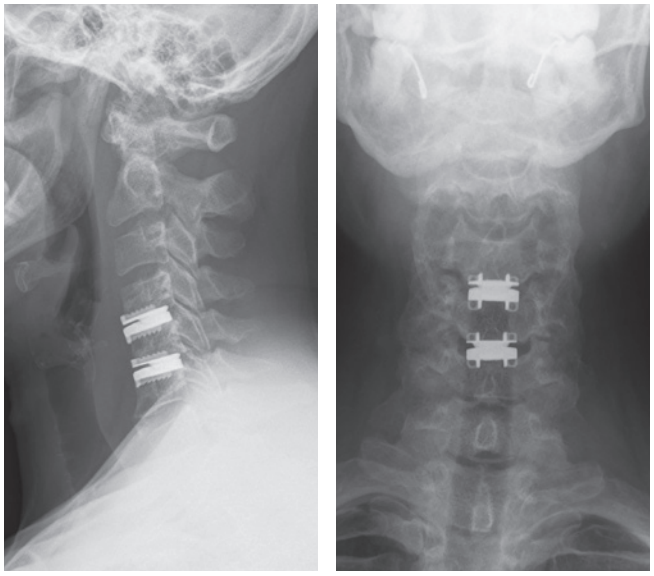


Figure 29



STEP 13
IMPLANT REMOVAL

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.

After applying distraction, a small osteotome may be used, along with an angled curette and forceps to disengage the fixation surface in between the device rails from the bone.

A Kocher or other general instruments may be used to remove the device components **(Figure 30)**.

Device Retrieval

Should it be necessary to explant a Prestige LP™ Cervical Artificial Disc, please contact Medtronic, Inc. immediately to receive instructions and request a copy of the explant protocol that will provide specifics on the return procedure, data collection, including histopathological, mechanical, patient, and adverse event information.

Please refer to the Prestige LP™ Cervical Artificial Disc Surgical Technique for step-by-step instructions on the required surgical technique for device retrieval. All explanted devices must be returned for analysis, in a leakproof container, with the date of explantation, explanting surgeon, and any known information regarding initial implantation, reasons for removal, and adverse event information.

Please note that the explanted Prestige LP™ device should be removed as carefully as possible in order to keep the implant and surrounding tissue intact. Also, please provide descriptive information about the gross appearance of the device in situ, as well as descriptions of the removal methods, i.e., intact or in pieces. Medtronic, Inc. will request additional information regarding the reason for removal, patient information, and associated clinical outcomes.

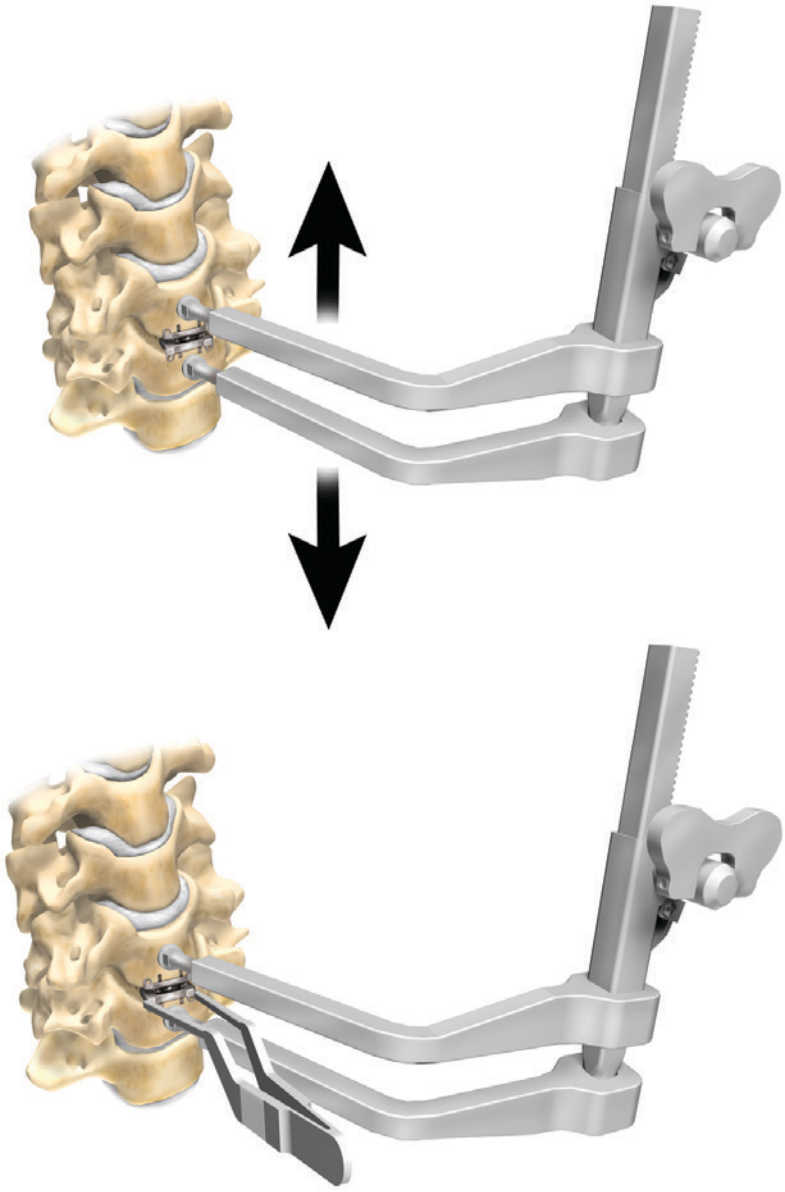


Figure 30

PRODUCT ORDERING **INFORMATION**

Instruments

Item Number	Item Description
6975205	Drill Guide 5mm
6975206	Drill Guide 6mm
6975207	Drill Guide 7mm
6975225	Implant Trial 5mm × 12mm
6975245	Implant Trial 5mm × 14mm
6975265	Implant Trial 5mm × 16mm
6975226	Implant Trial 6mm × 12mm
6975246	Implant Trial 6mm × 14mm
6975266	Implant Trial 6mm × 16mm
6975286	Implant Trial 6mm × 18mm
6975247	Implant Trial 7mm × 14mm
6975267	Implant Trial 7mm × 16mm
6975287	Implant Trial 7mm × 18mm
6975405	Rail Punch 5mm
6975406	Rail Punch 6mm
6975407	Rail Punch 7mm
6971105	Shim Distractor 5mm
6971106	Shim Distractor 6mm
6971107	Shim Distractor 7mm
G850000	Universal Handle
6973000	Inserter Handle
6973050	5mm Inserter Inner Shaft
6973060	6mm Inserter Inner Shaft
6973070	7mm Inserter Inner Shaft
6978999	Intervertebral Spreader
6971160	Final Impactor
6971115	Handle Extension
6975300	Impact Sleeve
6971114	Mallet
6971152	Loading Block
6975125	Rasp 5mm × 12mm
6975145	Rasp 5mm × 14mm

Item Number	Item Description
6975165	Rasp 5mm × 16mm
6975126	Rasp 6mm × 12mm
6975146	Rasp 6mm × 14mm
6975166	Rasp 6mm × 16mm
6975186	Rasp 6mm × 18mm
6975147	Rasp 7mm × 14mm
6975167	Rasp 7mm × 16mm
6975187	Rasp 7mm × 18mm
6971119	Rail Cutter Bit (Non sterile)

Implants

Item Number	Description
6972250	Prestige LP™ Disc 5mm × 12mm
6972450	Prestige LP™ Disc 5mm × 14mm
6972650	Prestige LP™ Disc 5mm × 16mm
6972260	Prestige LP™ Disc 6mm × 12mm
6972460	Prestige LP™ Disc 6mm × 14mm
6972660	Prestige LP™ Disc 6mm × 16mm
6972860	Prestige LP™ Disc 6mm × 18mm
6972470	Prestige LP™ Disc 7mm × 14mm
6972670	Prestige LP™ Disc 7mm × 16mm
6972870	Prestige LP™ Disc 7mm × 18mm

IMPORTANT
PRODUCT INFORMATION

Indications For Use

The PRESTIGE LP™ Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The PRESTIGE LP™ Cervical Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of non-operative treatment or have had the presence of progressive symptoms or signs of nerve root/spinal cord compression in the face of continued non-operative management prior to implantation of the PRESTIGE LP™ Cervical Disc.

Contraindications

The PRESTIGE LP™ Cervical Disc should not be implanted in patients with the following conditions:

- Active systemic infection or localized infection at the surgical site;
- Osteoporosis or osteopenia defined as a DEXA bone mineral density T-score ≤ -1.0;
- Allergy or sensitivity to titanium, aluminum or vanadium;
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation >3.5mm and/or >11° rotational difference from that of either level adjacent to the treated levels;
- Severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of disc height >50%, an absence of motion (<2°) as this may lead to a limited range of motion and may encourage bone formation (e.g. heterotopic ossification, fusion);
- Severe facet joint arthropathy;
- Significant cervical anatomical deformity or clinically compromised vertebral bodies at the affected level(s) due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion or nonunion) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis); or
- Significant kyphotic deformity or significant reversal of lordosis.

Warnings

The PRESTIGE LP™ Cervical Disc should only be used by surgeons who are experienced with anterior cervical spinal procedures and have undergone adequate hands-on training in the use of this specific device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the PRESTIGE LP™ Cervical Disc should use this device. Medtronic will offer hands-on training to physicians prior to their first use of the device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.

Correct sizing and placement of the device is essential to optimal performance. Information regarding proper implant size selection, implant site preparation, and the use of instrumentation before, during and after PRESTIGE LP™ surgery is provided in the PRESTIGE LP™ Cervical Disc Surgical Technique manual. Users are advised to read and understand the surgical technique manual and instructions for use prior to surgery.

Due to the proximity of vascular and neurological structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage with the use of this device. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants, or if pulsatile erosion of the vessels occurs because of close apposition of the implants. Care must be taken to identify and protect these structures.

Heterotopic Ossification (HO) is a potential complication associated with artificial cervical discs and could lead to reduced cervical motion.

Devices with metal-on-metal articulating surfaces (such as the Prestige LP™ Cervical Disc) may release wear debris, metallic particles or metal ions locally near the device and/or systemically. The short and long term effects of the wear debris, metallic particles and metal ions on the body are not known, but certain groups of patients may be at a higher risk including patients who are pregnant, patients who are planning to get pregnant, and patients who have renal disease.

Precautions

The safety and effectiveness of this device has not been established in patients with the following conditions:

- Axial neck pain as the solitary symptom;
- Skeletally immature patients, pediatric or adolescent children (<21 years old), or those over the age of 78;
- Prior cervical spine surgery, including prior surgery at the index level or adjacent levels;
- More than two cervical discs or two non-adjacent cervical discs that require surgical treatment;
- Facet joint pathology of involved vertebral bodies;
- Spinal metastases;
- An endocrine or metabolic disease that affects bones such as Paget's disease, osteomalacia, renal osteodystrophy, Ehlers-Danlos Syndrome, or osteogenesis imperfecta;
- Chronic or acute renal failure or history of renal disease;
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids);
- Diabetes mellitus requiring daily insulin management;
- Serious mental illness;
- Being treated for alcohol and/or drug abuse; and
- Pregnant.

Pre-operative

Patient selection is extremely important. In selecting patients for a total disc replacement, the following factors may negatively affect the success of the procedure: the patient's occupation or activity level; prior injury or ongoing illness (e.g., Alzheimer's disease, emphysema); alcoholism or drug abuse; and certain degenerative diseases (e.g., degenerative scoliosis, ankylosing spondylitis) that may be so advanced at the time of implantation that the expected useful life of the device is substantially diminished.

In order to minimize the risk of periprosthetic vertebral fractures, surgeons must consider all co-morbidities, past and present medications, previous treatments, etc. Surgeons should screen patients to determine if a DEXA bone mineral density measurement is necessary. If DEXA is performed, the patient should not receive the PRESTIGE LP™ Cervical Disc (per the contraindications listed above) if the DEXA bone mineral density T-score is ≤ -1.0, as the patient may be osteoporotic or osteopenic.

The patient should be informed of the potential adverse effects (risk/complications) contained in this insert (see POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH).

Preoperative planning may be used to estimate the required implant size and to assure that the appropriate range of sizes is available for surgery. Specific preoperative planning is necessary when performing a two-level procedure. The procedure should not take place if the appropriate range of sizes will not be available.

Inspect all instruments prior to surgery and replace any worn or damaged items. Instruments which have been used excessively may be more likely to break.

Intra-operative

Correct selection of the appropriate implant size is extremely important to ensure the placement and function of the disc. When performing a two-level procedure, 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. See the surgical technique manual for step-by-step instructions on the surgical technique, including determining the correct implant size.

Use aseptic technique when removing the PRESTIGE LP™ Cervical Disc components from the innermost packaging. Carefully inspect each component and its packaging for any signs of damage, including damage to the sterile barrier. Do not use PRESTIGE LP™ Cervical Disc components if the packaging is damaged or the implant shows signs of damage.

Use care when handling a PRESTIGE LP™ Cervical Disc component to ensure it does not come in contact with objects that could damage the implant. Exercise care to ensure implantation instruments do not contact the highly polished articulating surfaces of the endplates. Damaged implants are no longer functionally reliable. Visual inspection of the PRESTIGE LP™ Cervical Disc assembly is recommended prior to implantation. If any part of the assembly appears damaged, do not use the device.

When preparing the disc space, remove anterior or posterior osteophytes as needed, taking care to perform a complete discectomy while minimizing bone removal, as excessive bone removal may weaken the vertebral endplates or vertebral body.

Correct positioning of the rail punch is critical prior to performing the rail preparation step. Care should be taken to correctly position the rail punch during this step.

Ensure proper alignment and placement of the PRESTIGE LP™ Cervical Disc as misalignment may cause excessive wear and/or early failure of the device.

In a two-level procedure, 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, and comparing the facet and intradiscal heights in healthy adjacent levels. Implant Trials should fit snugly without distracting the disc spaces.

The PRESTIGE LP™ Cervical Disc components should not be used with components or instruments of spinal systems from other manufacturers. See the surgical technique manual for step-by-step instructions.

The PRESTIGE LP™ Cervical Disc implants are designed for single patient use only. Do not re-use, re-process, or re-sterilize the implants. Even if the device appears undamaged, re-use, re-processing, or re-sterilization may compromise the structural integrity of the implant and the intended function of the device which could result in patient injury.

Post-operative

Patients in the clinical study of the PRESTIGE LP™ Cervical Disc were instructed to use non-steroidal anti-inflammatory drugs (NSAIDs) for two weeks postoperatively. It has been reported in the literature that short-term postoperative use of NSAIDs may reduce the instance of heterotopic ossification (HO). To reduce the instance of HO, it is recommended that the PRESTIGE LP™ device be implanted in subjects able to tolerate the use of NSAIDs for two weeks post-operatively.

Patients should be instructed in postoperative care procedures and should be advised of the importance of adhering to these procedures for successful treatment with the device. Patients should be advised to avoid any activities that require repeated bending or twisting, heavy lifting, and challenging activities such as athletic activities. Gradual increase in physical activity will depend on individual patient progress.

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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.

Consult instructions for use at this website www.medtronic.com/manuals. Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.