

# BRYAN<sup>®</sup> CERVICAL DISC

Surgical Technique shown with BRYAN ACCEL<sup>™</sup> Instrumentation



Not for distribution in the U.S. or its territories.

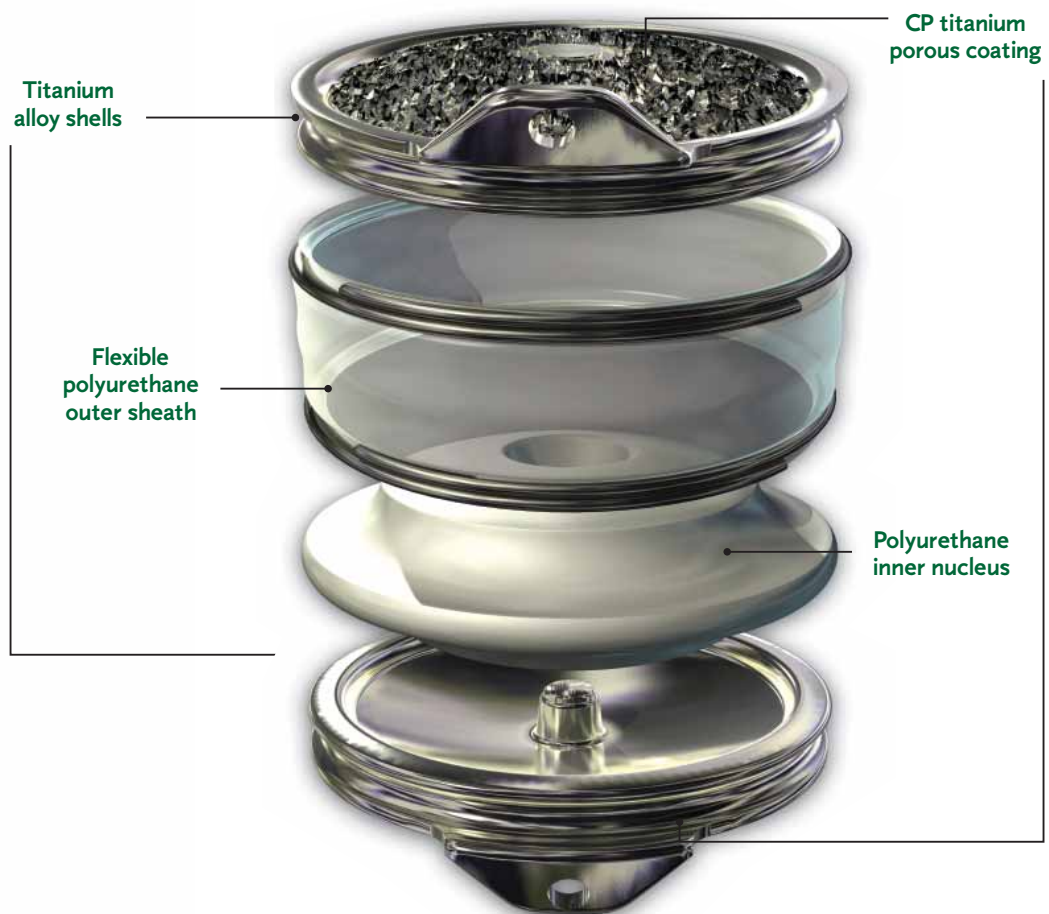
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# INTRODUCTION

The surgical benefits of an anterior approach to the cervical spine in the management of the intractable symptoms and signs associated with 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.

The BRYAN® Cervical Disc couples normal kinematics of the cervical spine with the surgical benefits of an anterior approach to the cervical spine and the symptomatic relief provided by decompression. Further, the BRYAN® Cervical Disc leverages significant clinical experience dating back to 2000.

In an effort to facilitate accurate and reproducible implantation of a BRYAN® Cervical Disc, this technique features surgical notes and pearls that will serve as valuable points of information. Surgical notes refer to various surgical steps that require emphasis throughout the procedure. Surgical pearls refer to helpful tips that will facilitate implantation of a BRYAN® Cervical Disc. Both should be consistently incorporated into the 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 a CT image is preferred. Do not include spurs or ridges that will be removed in the subsequent burring process. Determine the magnification factor of the image using the **BRYAN® Cervical Disc Template Set** (Figure 1a, 1b). Choose the prosthesis template corresponding to the measured magnification factor and follow the instructions on the template to estimate the prosthesis size (Figure 1c).

**NOTE** *Templating provides only approximate sizing. This initial assessment may vary due to magnification factors inherent in CT or MRI images. Exact device sizing is determined during the prosthesis sizing and disc space trialing steps.*

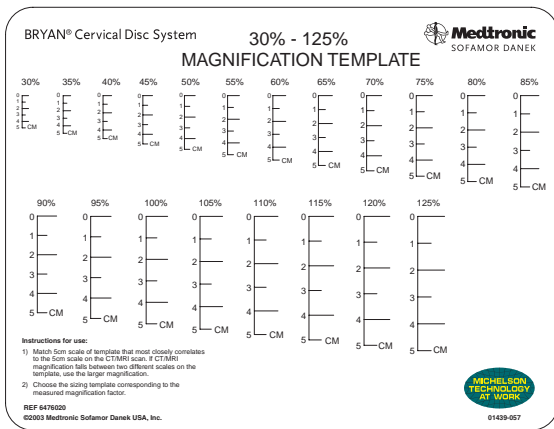


Figure 1a

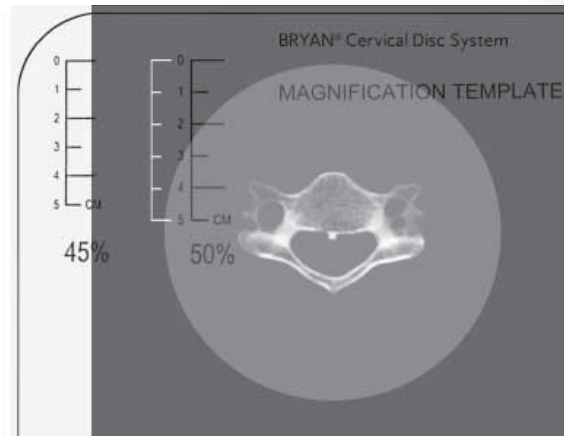


Figure 1b

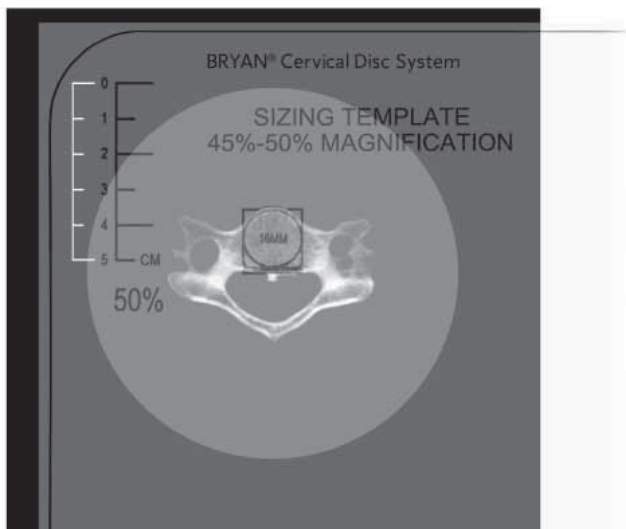


Figure 1c

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 to the cervical vertebral column 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.

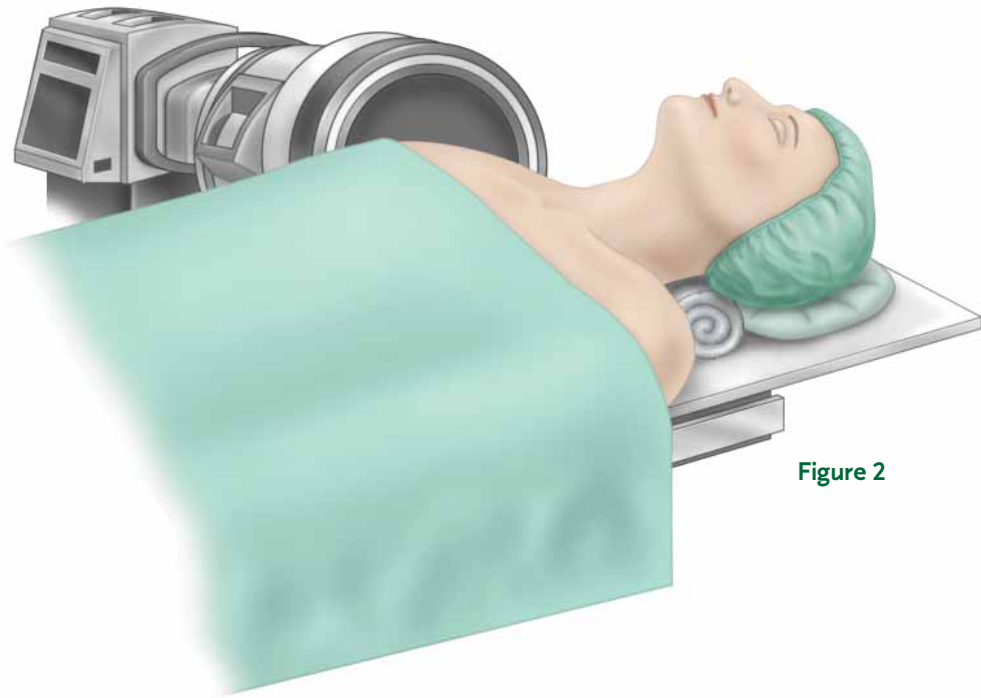


Figure 2

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 surgeon's ability to ensure proper placement of the instrumentation and/or prosthesis. Under such circumstances, it may be necessary to perform a fusion procedure.*

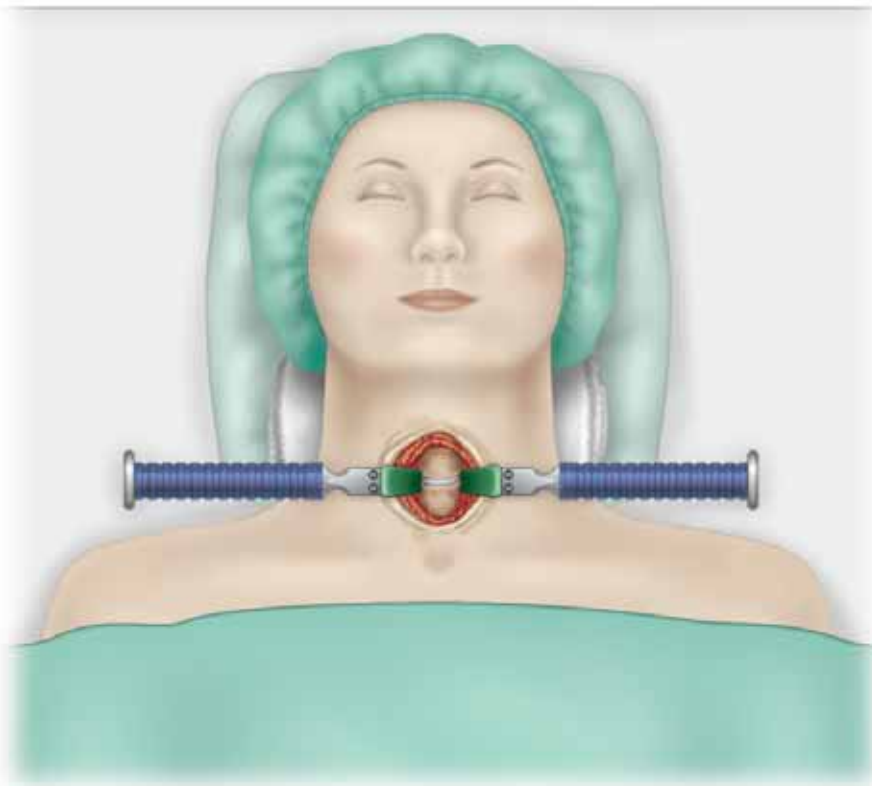


Figure 3

A standard anterior cervical discectomy is completed at the indicated level utilizing common retraction instrumentation (*Figure 4*). Pituitaries, curettes and kerrisons may be used to remove the disc material and endplate cartilage. Expose the bilateral unciniate processes as well as the posterior longitudinal ligament. Do not remove any part of the unciniate processes as they will serve as reference points for locating the center of the disc space.

Connect the **Drilling Handpiece** to the **MIDAS REX® System** or **Surgical Drive System**. Lightly burr the anterior surfaces of the vertebral bodies using the **4.8mm Fluted Ball Burr** to remove any soft tissue and bony protrusions to create a flat surface (*Figure 5*).

**NOTE** *The MIDAS REX® LEGEND®, MIDAS REX® III and MIDAS REX® CLASSIC Systems require adapters (See Drive System Options).*

Insert a Kerrison Rongeur into the disc space to remove the anterior lip of bone on the cephalad vertebral body. Keep the fixed shaft of the instrument parallel to the caudal endplate (*Figure 6*).



Figure 4

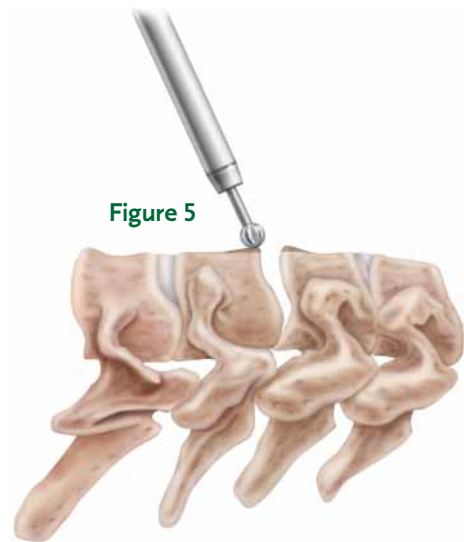


Figure 5

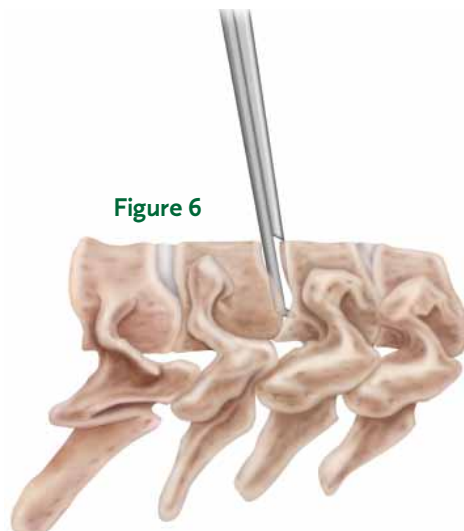
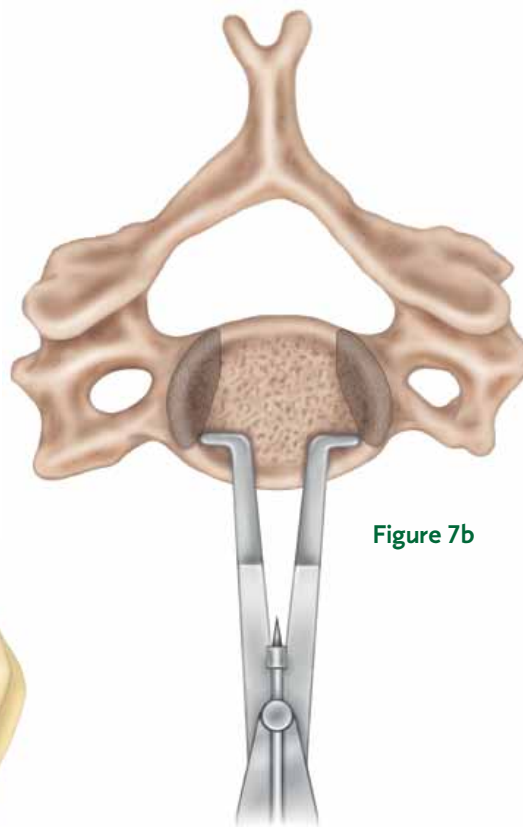
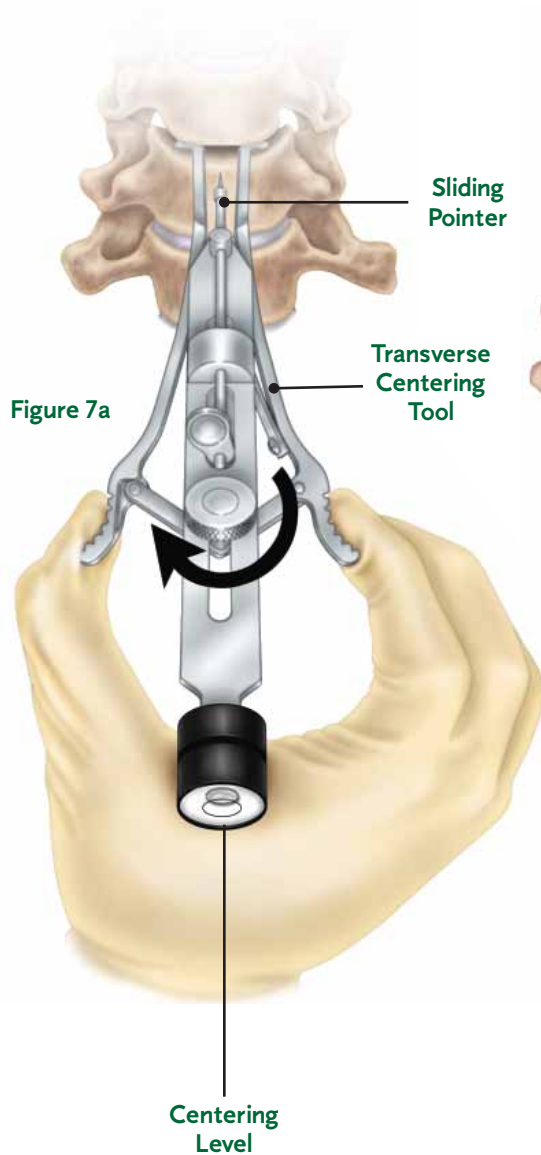


Figure 6

Place a **Centering Level** on the **Transverse Centering Tool** and insert into the target disc space (*Figure 7a*). Expand the tips of the tool until they contact the lateral soft margins (*Figure 7b*).





When the bubble is centered in the lateral direction (*Figure 8*), mark the center point of the superior vertebral body by advancing the sliding pointer (*Figure 9*). Extend the midline superiorly using a Bovie or sterile marker.

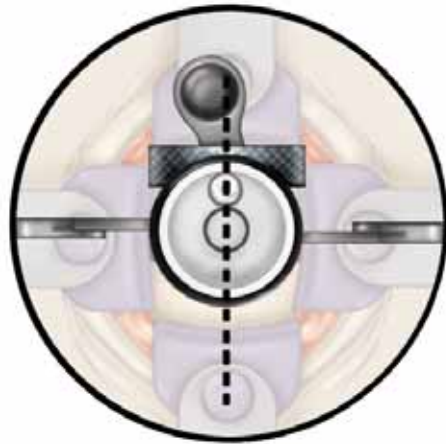


Figure 8

If the midline position is still in question an A/P radiograph should be obtained to confirm the midline position.

When using the Centering Level to position the Transverse Centering Tool, the bubble must be centered only in the transverse plane.

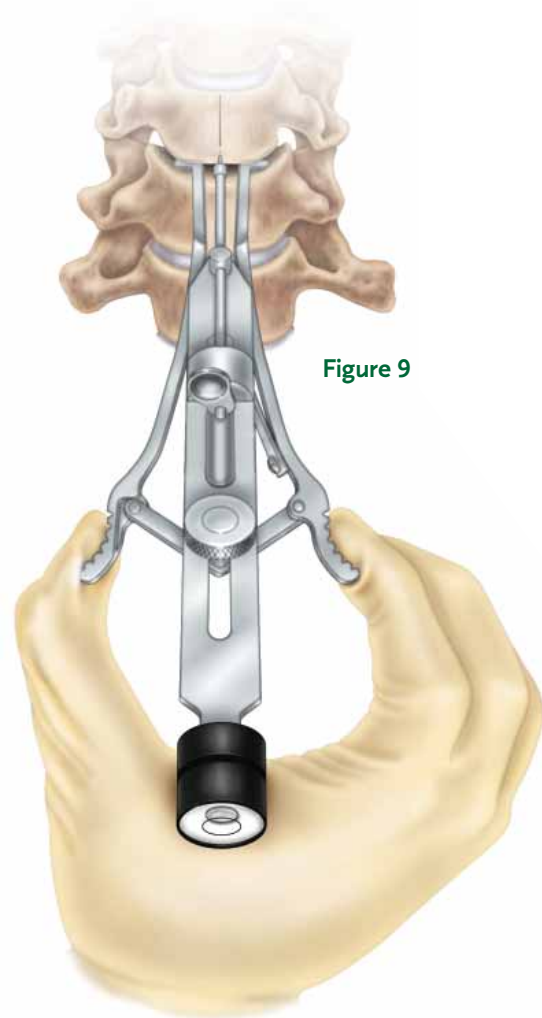
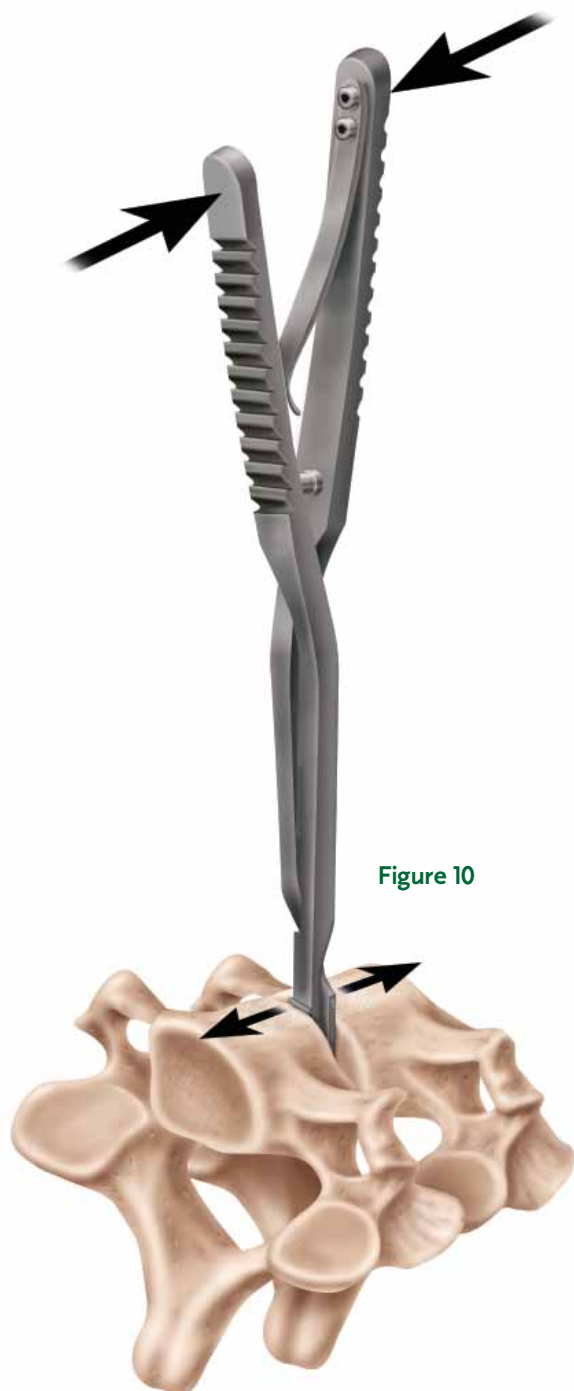


Figure 9

Insert the **Intradiscal Distractor** into the target disc space and carefully distract until reaching the 8.5mm hard stop (*Figure 10*). After achieving 8.5mm of distraction, maintain distraction for 60 seconds to adequately stretch the ligaments.

**NOTE** *An opening of the target disc space greater than 8.5mm may lead to improper fit of the prosthesis and is an indication for terminating the procedure and fusing the patient.*



## STEP 7 ANCHOR POST PLACEMENT

Select the **Alignment Guide** that will most closely match the neutral disc space height. Attach the **Milling Guides** (Figure 11) and place the construct in the target disc space (Figure 12). The construct should be relatively stable in the disc space with no vertebral distraction.

**NOTE** *The goal is not to distract the vertebral bodies.*

**NOTE** *If none of the Alignment Guides constructs are relatively stable in the disc space, an alternative treatment option should be considered.*

Insert a Steinmann Pin or similar instrument into the reference point made by the transverse centering tool. Slide the superior Milling Guide over the reference pin to maintain midline positioning.

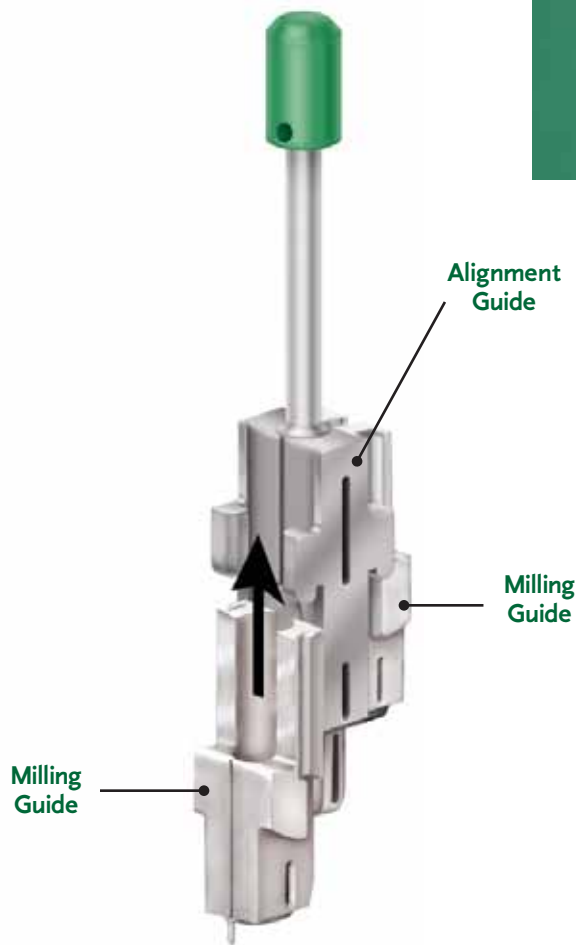


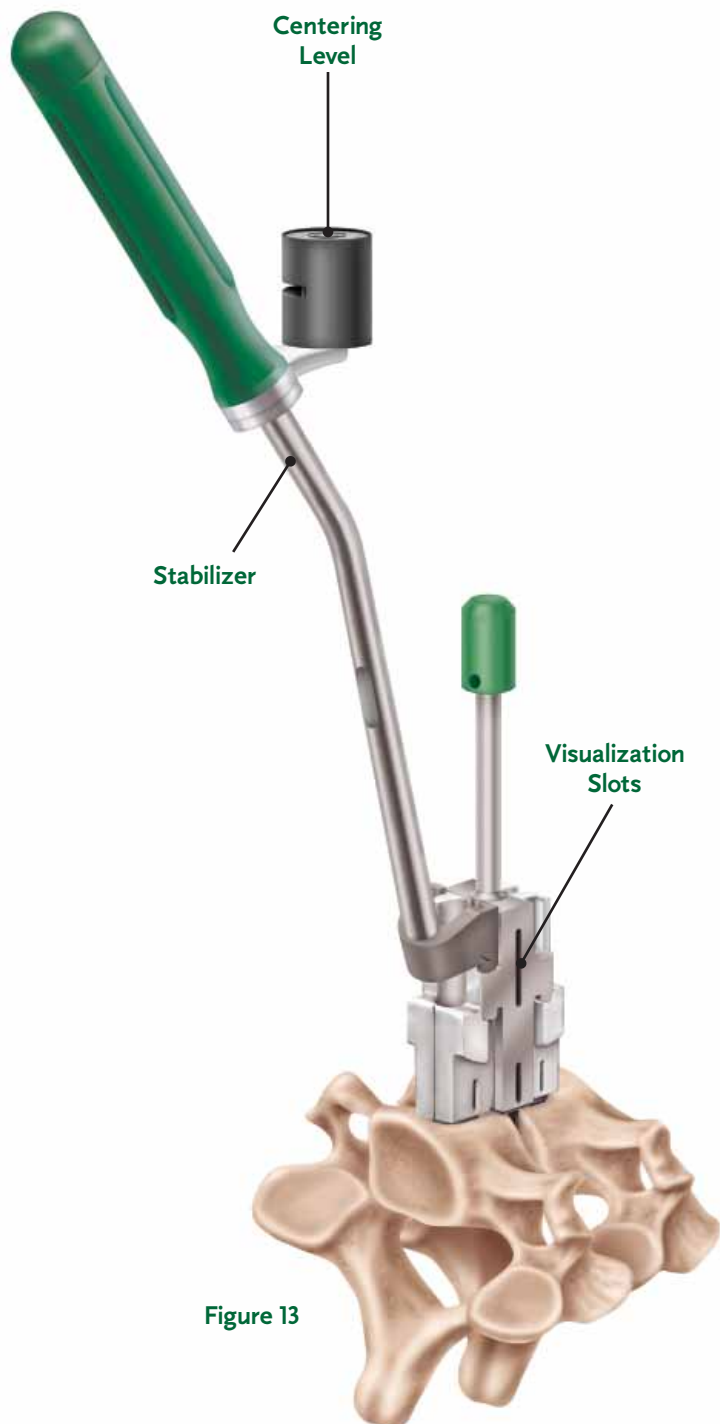
Figure 11



Figure 12

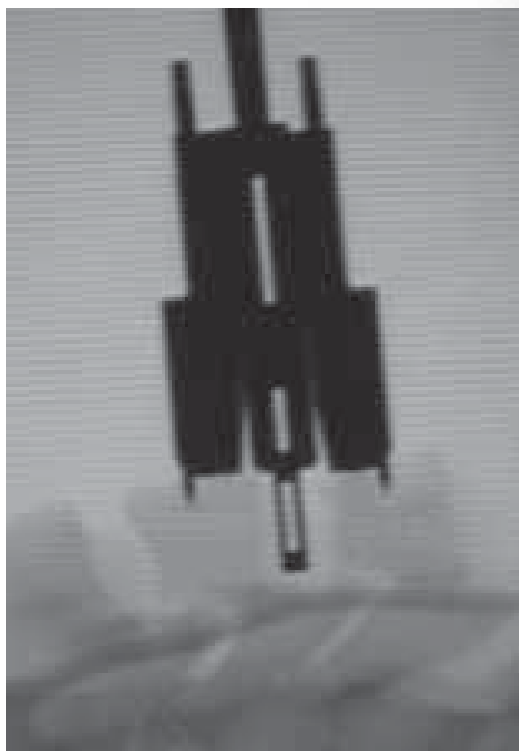
Place the Centering Level on the **Stabilizer** and attach it to the Alignment Guide construct (*Figure 13*). Using the bubble as a visual aid, center the assembly in the lateral direction.

Using a lateral fluoroscopy, verify that the Alignment Visualization Slots are parallel to the endplates and centered in the disc space (*Figure 14*).



**Figure 13**

The shaft of the Fluted Ball Burr can also be inserted through the Alignment Guide to verify sagittal alignment.



**Figure 14**

Attach the **Drill Bit** to the **Drilling Handpiece** and drill the superior Anchor Post Pilot Hole through the Milling Guide (*Figure 15*). Insert the appropriate **Anchor Post** into the **Anchor Post Driver** (*Figure 16*). Drive the Anchor Post through the Milling Guide until it is fully seated. Repeat for inferior Anchor Post Placement.

**NOTE** *The Stabilizer Handle should be used when securing the Milling Guides to the vertebral bodies.*

**NOTE** *Anchor Posts are available in 14mm or 16mm lengths and 3.5mm or 4.0mm diameter. The 4.0mm Anchor Post can be used if the 3.5mm Anchor Post becomes unstable.*

The appropriate sized Anchor Post is determined based on preoperative templating. Select the longest possible Anchor Post ensuring that its length does not exceed the diameter of the selected prosthesis.

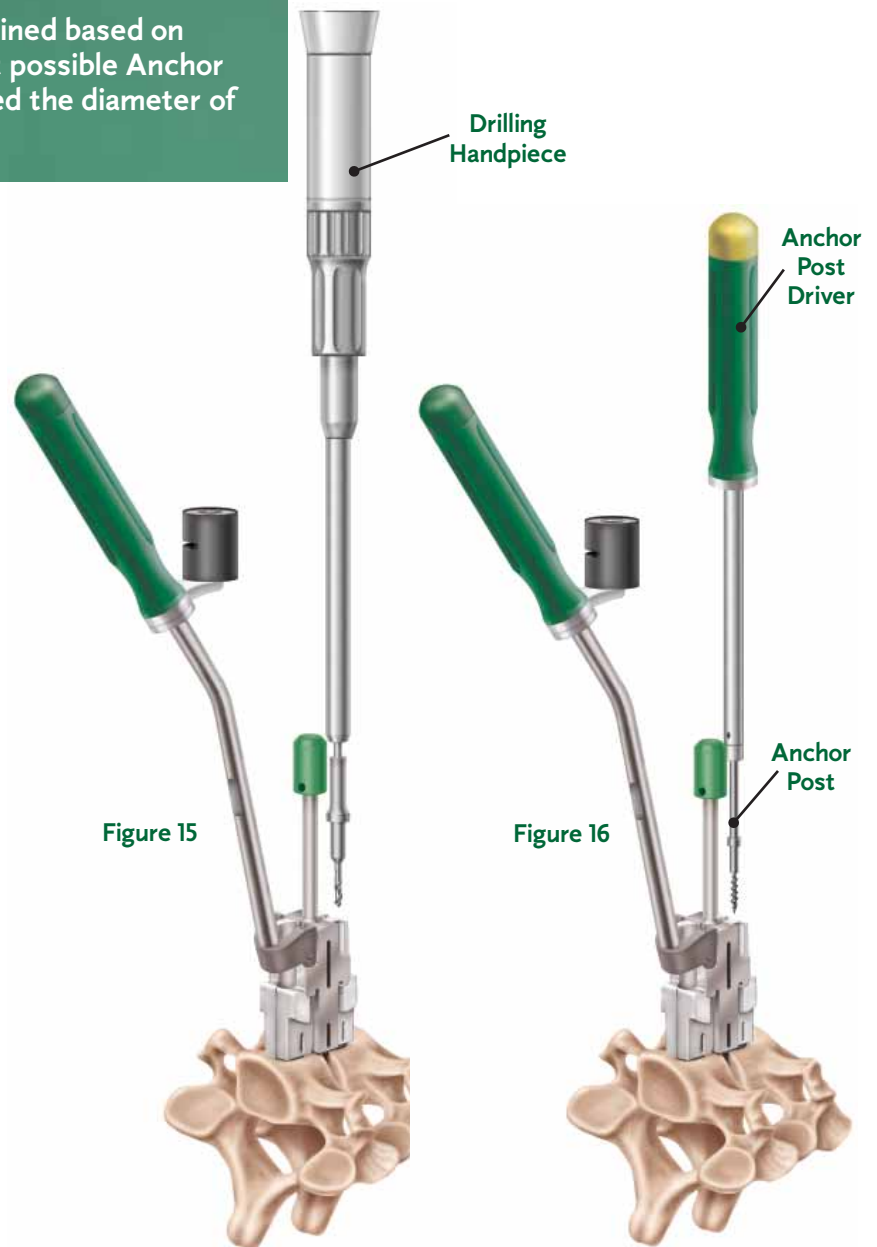


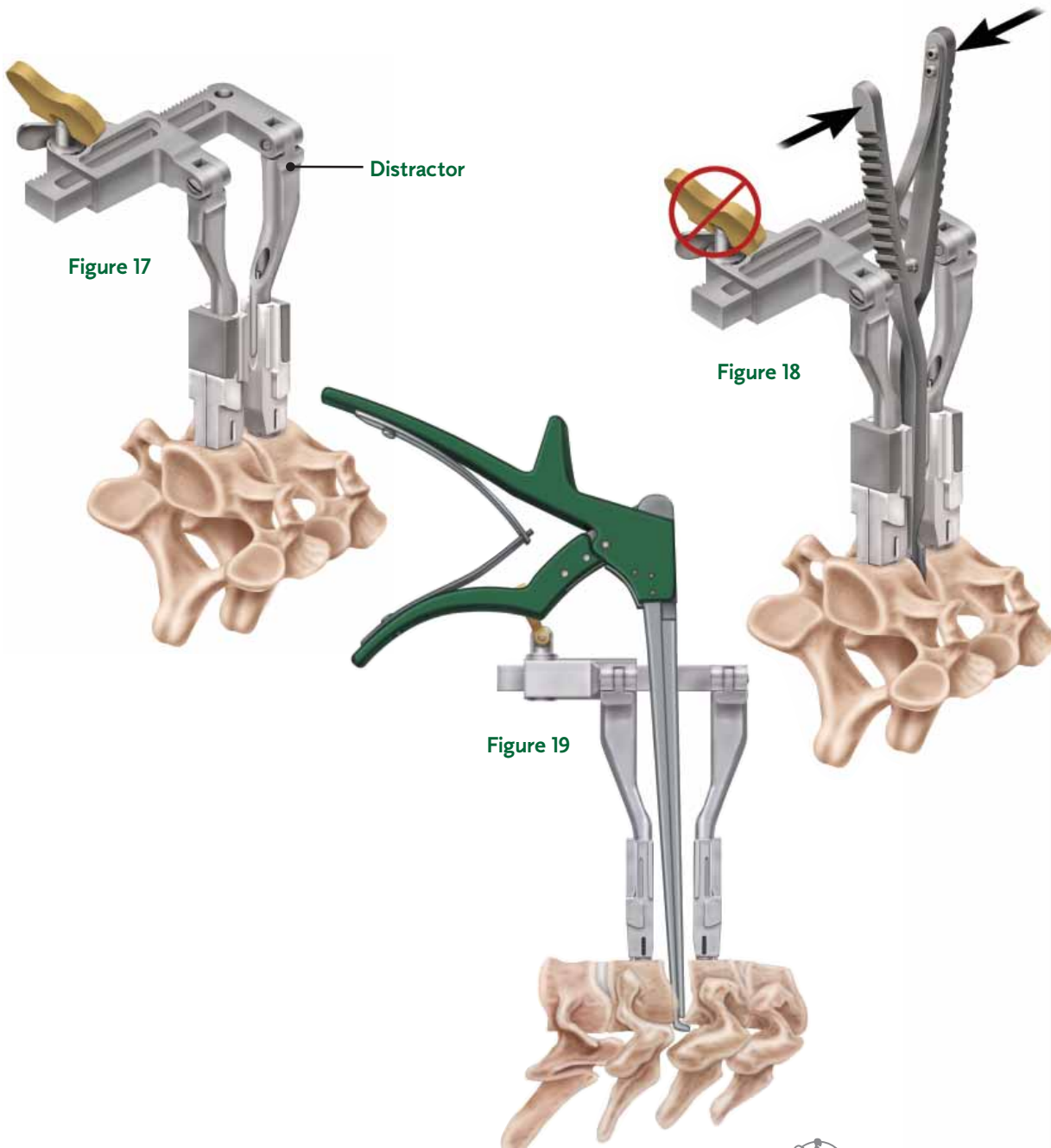
Figure 15

Figure 16

Attach the **Distractor** to the Anchor Posts and remove the Alignment Guide (*Figure 17*).

Re-insert the Intradiscal Distractor and carefully distract the disc space (*Figure 18*). Distraction should be performed using the Intradiscal Distractor in order to preserve the integrity of the screw-bone interface. The Distractor Key should only be used if additional distraction is required. Perform a thorough and complete decompression (*Figure 19*).

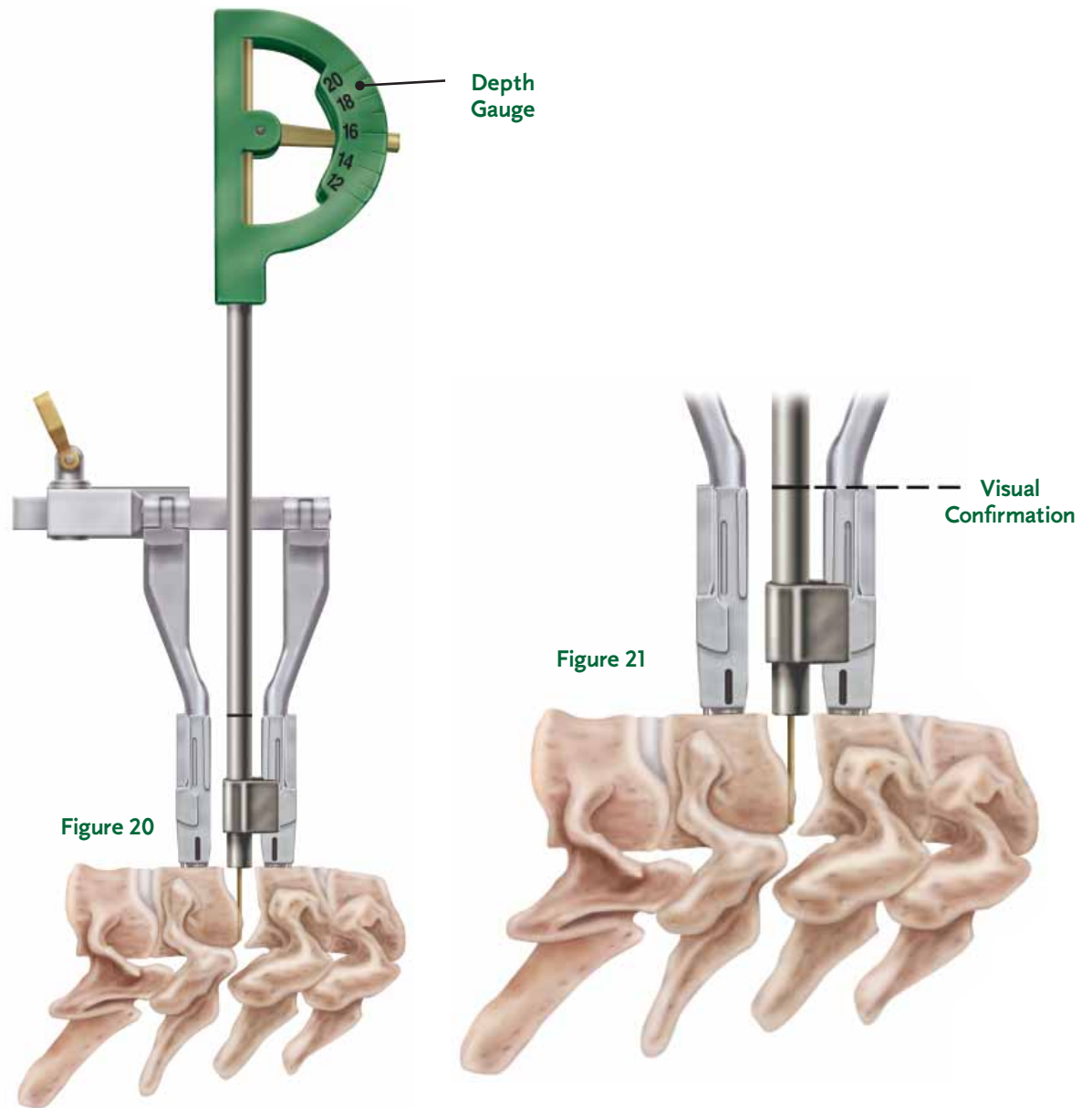
**NOTE** *Since the BRYAN® Cervical Disc prosthesis is a motion sparing device, a thorough bi-lateral decompression must be performed. Ensure all osteophytes and disc fragments are removed.*



Retract the **Depth Gauge** stylus and hold in the 12mm position. Carefully slide the Depth Gauge into the guide slot of superior Milling Guide. Make sure the Depth Gauge is fully seated and use the stylus to assess the posterior margin (*Figure 20*). Verify this position with fluoroscopy (*Figure 21*).

**NOTE** *The end of the Depth Gauge shaft must be even with the anterior surface of the vertebral body before measuring endplate depth. Lateral fluoroscopy should be used to verify proper Depth Gauge placement and position of the stylus.*

**NOTE** *The laser etched line on the Depth Gauge, when even with the top of the Milling Guide, visually confirms that the Depth Gauge is fully seated.*



Measure the endplate depth using the sizing scale (Figure 22). Repeat the process using the inferior Milling Guide (Figure 23). Choose the smaller of the two endplate sizes as indicated by the sizing scale.

**NOTE** *If the size indicated on the sizing scale falls between two sizes, choose the smaller size.*

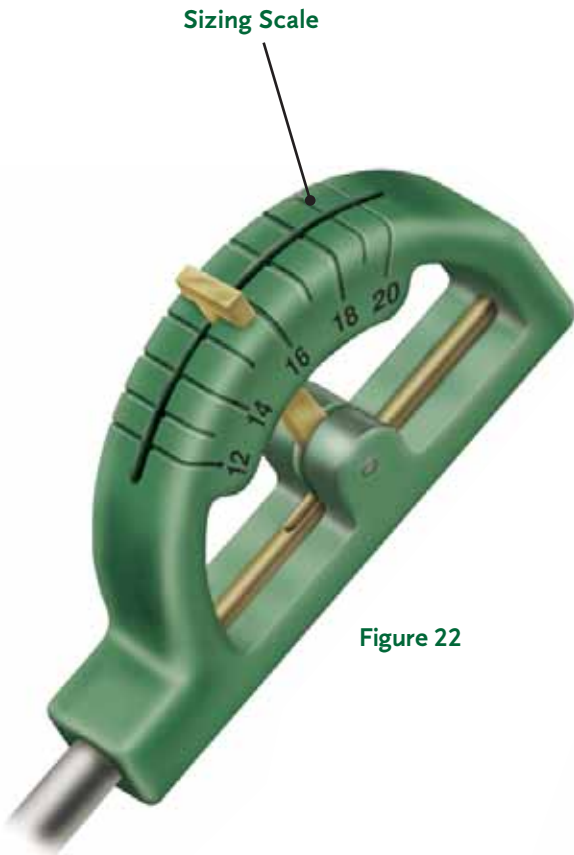


Figure 22



Figure 23



Use the appropriate size **Dual Headed Sequential Rasp** as indicated by the Depth Gauge to ensure endplate preparation and disc space height (*Figure 24*). If necessary, the Sequential Rasp may be used with the **Mallet** to remove additional bone (*Figure 25*).

**NOTE** *The 8.5mm Rasp must fit, fully seated, in the disc space to ensure enough clearance for the milling device.*

**NOTE** *Dual-headed Sequential Rasps are available in 14mm-18mm to mirror the implant offering.*

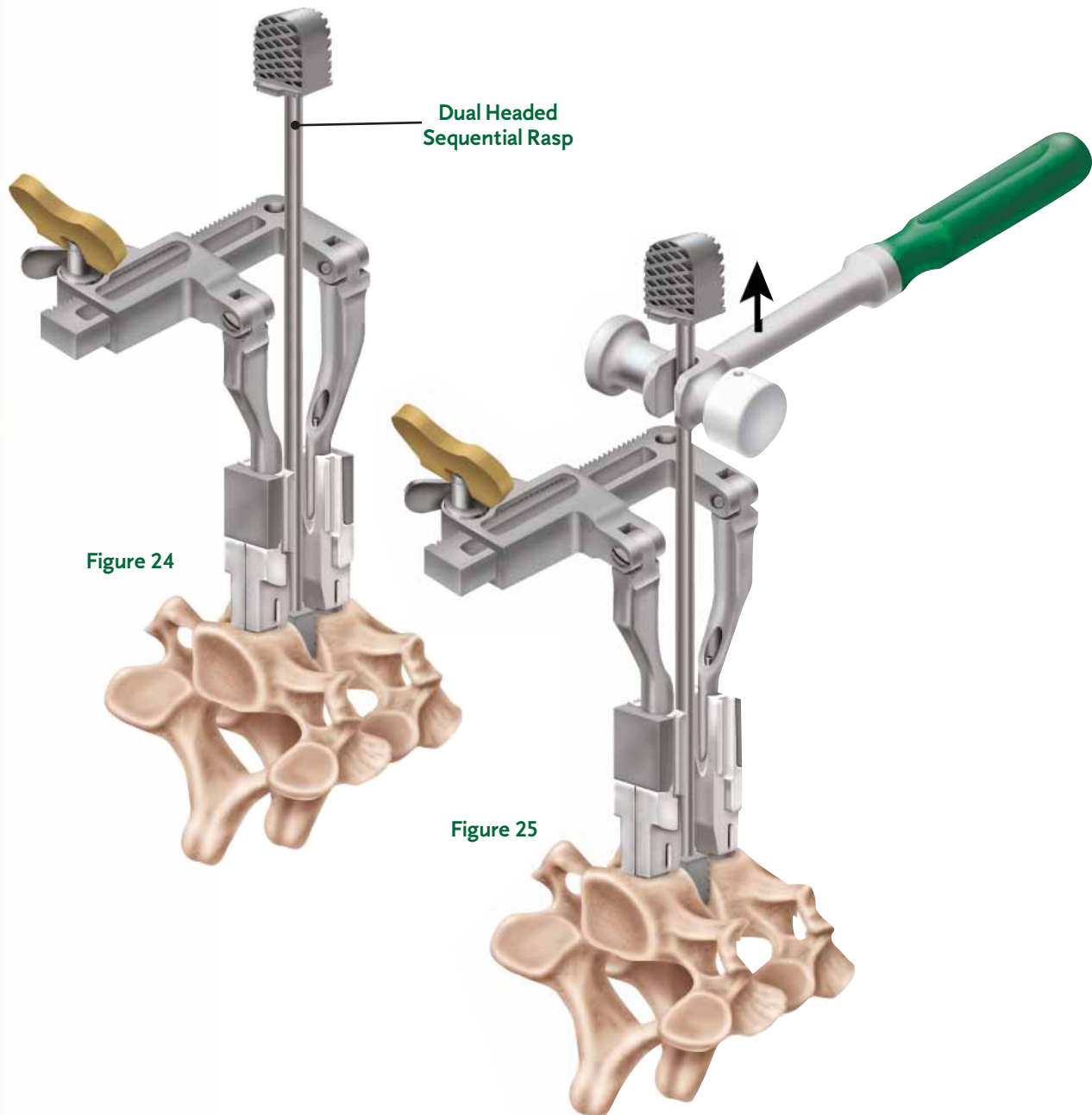


Figure 24

Figure 25

Select the appropriate **Disposable Milling Assembly** and insert through the **Milling Handpiece** (Figure 26), ensuring that the appropriate assembly aligns with the keyway of the Milling Handpiece. Place the construct on the **Milling Assembly Tool**, ensuring that the arrow on the Milling Handpiece lines up with the arrow on the Milling Assembly Tool (Figure 27). Squeeze the Milling Assembly Tool until the Disposable Milling Assembly fully engages the Milling Handpiece (Figure 28).

**NOTE** To ensure the Disposable Milling Assembly is fully seated in the Milling Handpiece, the red indicator should not be visible on the Disposable Milling Assembly.

**NOTE** Disposable Milling Assemblies are available in diameters of 14mm-18mm to mirror the implant offering.

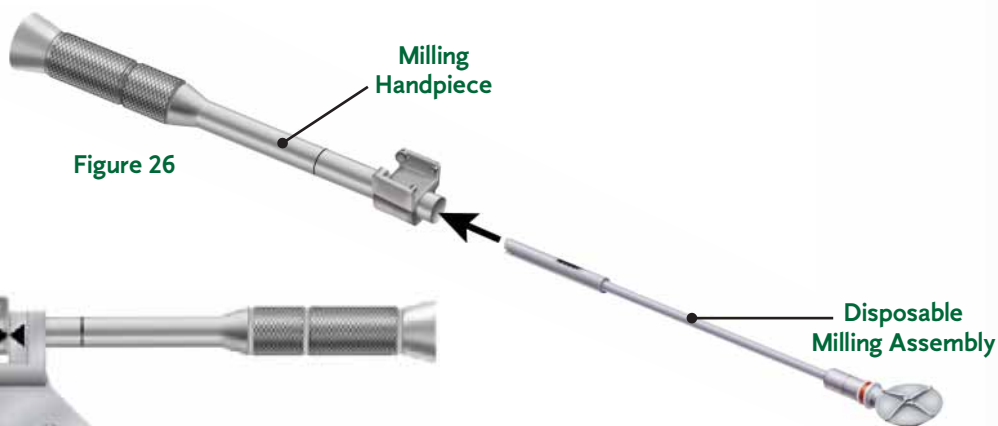


Figure 26

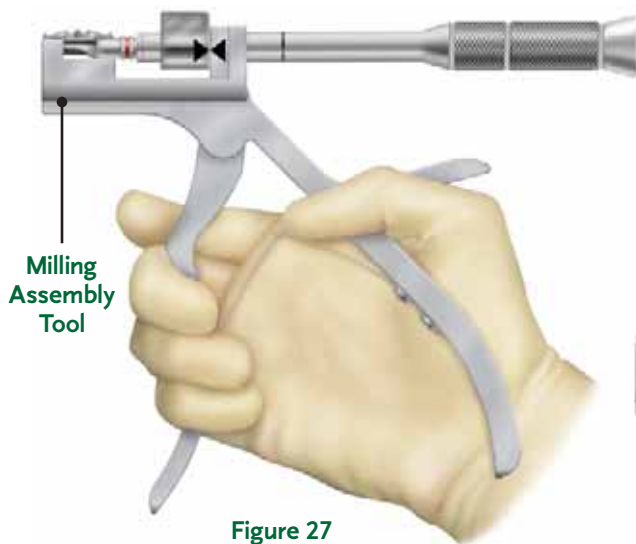


Figure 27



Figure 28

After the milling step is complete disengage the Disposable Milling Assembly from the Milling Handpiece by repositioning the Milling Handpiece so that the arrow on the Milling Handpiece points in the opposite direction as the arrow on the Milling Assembly Tool (*Figure 29*). Squeeze the Milling Assembly Tool to disengage the Disposable Milling Assembly (*Figure 30*).

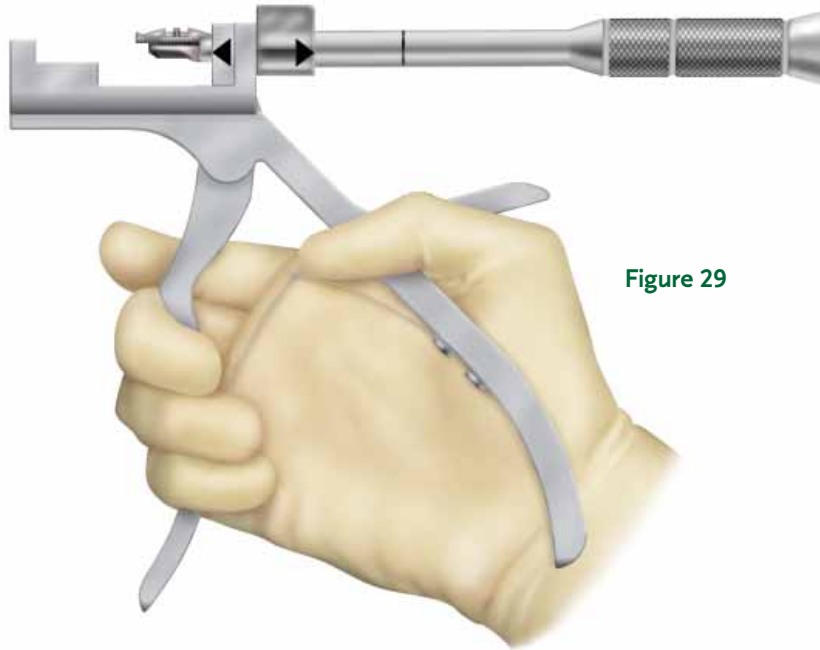


Figure 29

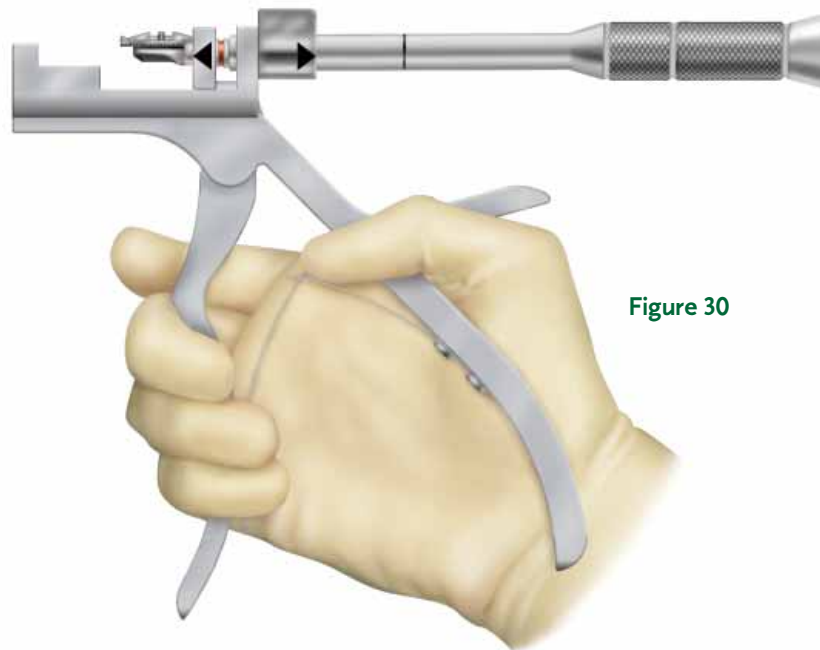


Figure 30

Insert the Milling Handpiece into the superior guide slot. **Prior to milling the endplates**, use fluoroscopy to ensure the milling construct is fully seated and the Milling Disc has not surpassed the posterior margin of the vertebral bodies. Activate the drive system and gently pivot the handpiece in a cephalad/caudal direction until engaging the hard stop (*Figure 31*). Irrigate throughout this step using sterile saline. Repeat the process using the inferior guide slot.

After endplate preparation, thoroughly irrigate the disc space to remove any debris. Also verify that a full and complete decompression has been performed. If necessary, gel foam may be applied to the endplates to reduce bleeding prior to implantation.

**NOTE** *The Stabilizer should be used during the milling process to counter any torque applied to the Distractor and Milling Guides.*

**NOTE** *Verify the presence of milled cavities on the endplate surfaces of both vertebral bodies.*

**NOTE** *The Milling Disc is fully seated when the Stabilizer lines up with the laser mark on the Milling Handpiece.*

**NOTE** *Disposable Milling Assemblies are for single patient use. Discard after the milling step has been completed.*



Figure 31

Screw the **Seal Plug** from the prosthesis package into one port of the BRYAN® Cervical Disc prosthesis. Turn the Seal Plug until the handle twists off (*Figure 32*). Care should be taken to thread the Seal Plug into the port and not bend the Seal Plug. Immerse the prosthesis into sterile saline. Without covering the open port, pump the prosthesis several times to allow the sterile saline to fill the device. While the implant is submerged, compress the prosthesis and thread a second Seal Plug into the remaining open port until it twists off, again being careful not to bend the Seal Plug.

Attach the prosthesis to the **Implant Inserter** and insert the prosthesis into the prepared disc space; gently tapping into place with a mallet if necessary (*Figure 33*). If the prosthesis does not fully seat into the prepared disc space, retract the locking arm sleeve on the Implant Inserter and rotate the sleeve 90 degrees. A slight tap on the tool can then be applied to fully seat the prosthesis (*Figure 34*).

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

**NOTE** Put bone wax in the anchor post holes after removing them to control any bleeding.

**NOTE** If explantation of the BRYAN® Cervical Disc is required, separation of the implant from the endplate can be achieved utilizing standard surgical instruments. A small osteotome may be used, along with an angled curette and forceps to separate the fixation surface from the bone.



Figure 32

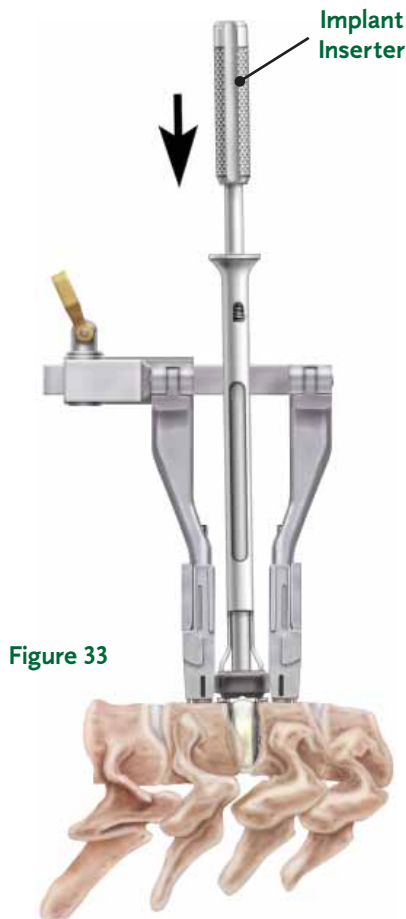


Figure 33

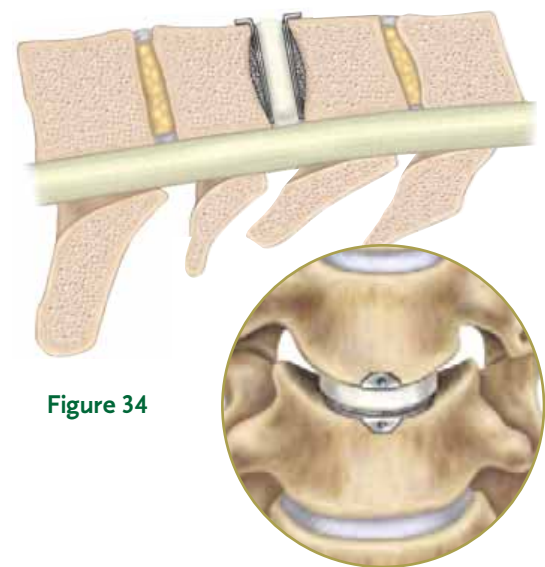


Figure 34

## BRYAN ACCEL™ CERVICAL DISC INSTRUMENTATION

Item Number	Description	Item Number	Description
6471350	Drilling Handpiece	6471610	Implant Inserter
6472015	Drill Bit with Collar*	6471351	MIDAS REX® LEGEND Adapter
6478210	Fluted Ball Burr 4.8mm*	6472095	BRYAN ACCEL™ Outer Case
6471360	Transverse Centering Tool	6472096	BRYAN ACCEL™ Inner Tray – Lower
6472003	Alignment Guide 3mm	6472097	BRYAN ACCEL™ Outer Lid
6472004	Alignment Guide 4mm	6472098	BRYAN ACCEL™ Inner Tray – Upper
6472005	Alignment Guide 5mm		
6472006	Alignment Guide 6mm		
6472007	Alignment Guide 7mm		
6472024	Anchor Post 3.5mm × 14mm*		
6472026	Anchor Post 3.5mm × 16mm*		
6472034	Anchor Post 4.0mm × 14mm*		
6472036	Anchor Post 4.0mm × 16mm*		
6472061	Mallet		
6472010	Milling Guide		
6472080	Stabilizer		
6472630	Anchor Post Driver		
6472045	Intradiscal Distractor		
6472040	Distractor		
6472050	Depth Gauge		
6472054	Dual Headed Sequential Rasp, 14mm		
6472055	Dual Headed Sequential Rasp, 15mm		
6472056	Dual Headed Sequential Rasp, 16mm		
6472057	Dual Headed Sequential Rasp, 17mm		
6472058	Dual Headed Sequential Rasp, 18mm		
6472511	Milling Handpiece		
6472515	Milling Assembly Tool		

ANCILLARY ITEMS – NOT IN SET	
6470114	14mm BRYAN® Cervical Disc Prosthesis
6470115	15mm BRYAN® Cervical Disc Prosthesis
6470116	16mm BRYAN® Cervical Disc Prosthesis
6470117	17mm BRYAN® Cervical Disc Prosthesis
6470118	18mm BRYAN® Cervical Disc Prosthesis
6472524	Disposable Milling Assembly, 14mm*†
6472525	Disposable Milling Assembly, 15mm*†
6472526	Disposable Milling Assembly, 16mm*†
6472527	Disposable Milling Assembly, 17mm*†
6472528	Disposable Milling Assembly, 18mm*†
6476020	BRYAN ACCEL™ Disc Template Set
6478600	Pouch Assembly Centering Level*
6471343	MIDAS REX® CLASSIC Adapter
6471344	MIDAS REX® MR III Adapter
6471700	Electric Drive System (115v)**
6471349	Electric Drive System (230v)**
6478831	Electric Drive System Case

\* Disposable Items

† Implant specific disposables required with each implant

\*\* Includes: Control Unit, Handheld Motor, Foot Pedal and Power Cord

## SURGICAL DRIVE SYSTEM

To use the Surgical Drive System, attach the BRYAN® Cervical Disc Handpiece to the handheld motor. The attachment will snap into position when fully seated. Firmly pull the handpiece to remove (Figure A).



Figure A

## MIDAS REX® DRIVE SYSTEMS

To use the MIDAS REX® LEGEND® Motor, attach the MIDAS REX® LEGEND® Adapter (6471351) to the motor and secure in place. If using the pneumatic system, supply pressure must be set to 80 psi. If using the electric system, reduce the speed to 27,000 RPM. Attach the BRYAN® Cervical Disc Handpiece to the MIDAS REX® LEGEND® Adapter. Pull the handpiece to remove (Figure B).



Figure B

To use the MIDAS REX® III Motor, screw the MIDAS REX® III Adapter (6471344) onto the motor and hand tighten by turning counter-clockwise. Supply pressure should be 80 psi. Attach the BRYAN® Cervical Disc Handpiece to the MIDAS REX® III Adapter. Pull the handpiece to remove (Figure C).



Figure C

To use the MIDAS REX® Classic Motor, install the MIDAS REX® Classic Regulator between the Universal Foot Control and the Motor Hose. Set the Regulator to 80 psi. Secure the 4-Pin Driver (included with 6471343) to the MIDAS Classic Motor. Tighten the collet nut with the MIDAS Rod and Wrench. Insert the motor into the MIDAS REX® Adapter (6471343) and turn counter-clockwise to tighten. Attach the BRYAN® Cervical Disc Handpiece to the MIDAS REX® Adapter. Pull the handpiece to remove (Figure D).



Figure D

**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 as applied to these devices. Some instruments are made in aluminum, 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 SOFAMOR DANEK 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 SOFAMOR DANEK 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 SOFAMOR DANEK or an authorized MEDTRONIC SOFAMOR DANEK repair representative.

Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

**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.

**CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.**

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

**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 SOFAMOR DANEK implants should only be implanted with MEDTRONIC SOFAMOR DANEK instruments.**

**Other complications 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.
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 SOFAMOR DANEK; 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 SOFAMOR DANEK 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 SOFAMOR DANEK.

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 SOFAMOR DANEK .

**Decontamination and Cleaning:**

Unless just removed from an unopened Medtronic Sofamor Danek 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 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.

**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.**

**Sterilization:**

Unless supplied sterile and clearly labeled as such, this instrument must be sterilized before use. 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 re-sterilized.

MEDTRONIC SOFAMOR DANEK instruments for use with internal spinal fixation implants must be steam sterilized according to the following process parameters:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Gravity	135 ± 1°C (273 ± 2° F)	25 min.

Use of this cycle meets the recommendations of the non-U.S. Health Care Authorities that suggest sterilization parameters which will minimize potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come onto contact with the central nervous system.

Or:

Steam	Pre-Vacuum	135 ± 1°C (273 ± 2° F)	6 min.
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**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.

**Further Information:**

In case of complaint, or for supplementary information, please see the address page of this information sheet.

**Product Complaint:**

Any Health Care Professionals (e.g., customer users of MEDTRONIC SOFAMOR DANEK 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 or MEDTRONIC SOFAMOR DANEK. 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 SOFAMOR DANEK 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 or MEDTRONIC SOFAMOR DANEK 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.

**Manufacturer**

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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. BRYAN ACCEL™ Cervical Disc Instrumentation is not available in the USA or its territories.

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