



**Medtronic**

# ACD™ Instrument Set

Surgical Technique Shown with the  
BRYAN® Cervical Disc System



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





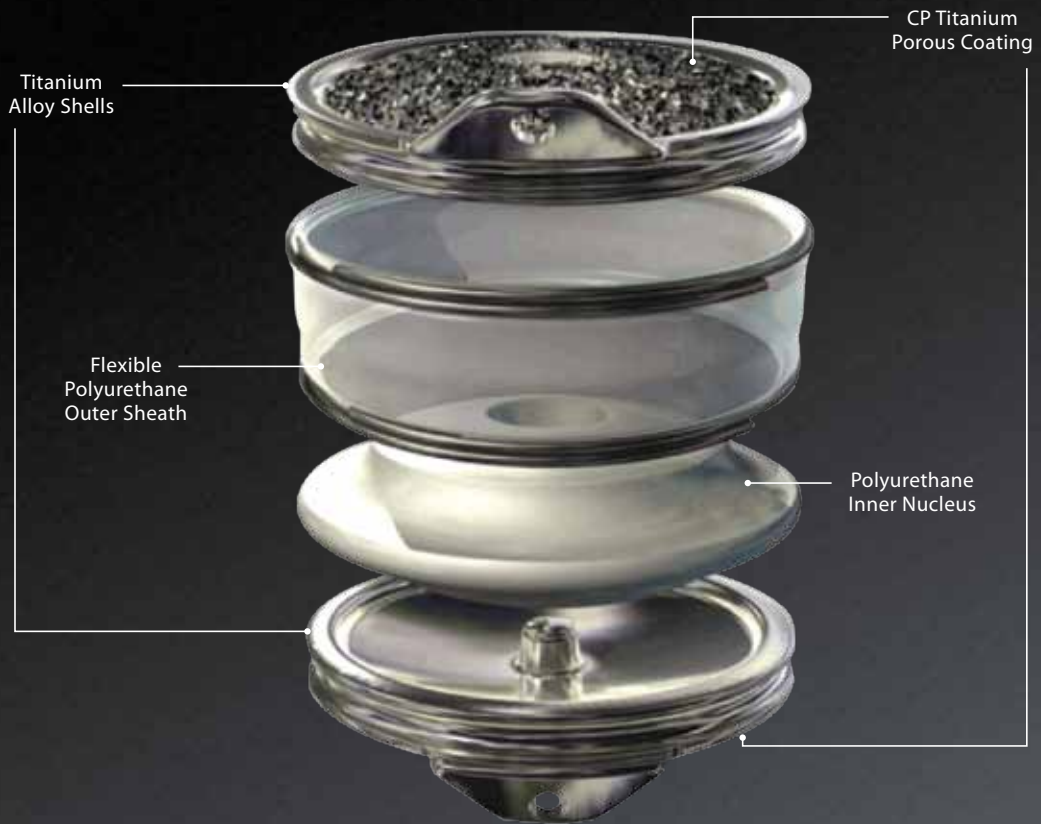


**Medtronic**

# ACD™ Instrument Set

## Surgical Technique Shown with the BRYAN® Cervical Disc System

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## Introduction

Dear Colleagues,

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 fusion, though providing symptomatic relief, has the disadvantage of converting the operated segment to a non-functional spinal unit. More favorable biomechanical conditions may be created by replacing the removed disc with a functional implant designed to allow motion at the index level. The goal of the BRYAN® Cervical Disc System is to preserve the physiologic motion of the cervical spine while maintaining the surgical benefits of an anterior approach and the symptomatic relief provided by decompression. To achieve optimal results, precision placement of the BRYAN® Cervical Disc is essential. The following pages describe and illustrate the placement of the BRYAN® Cervical Disc at C5–C6 in an effort to facilitate accurate and reproducible implantation.

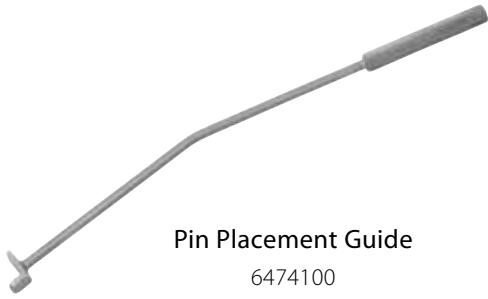
Extensive biomechanical, animal, and clinical investigations have been performed on the BRYAN® Cervical Disc System, and it is worthy of your evaluation. Please also see the package insert text that starts on page 19 of this document for the complete list of indications, contraindications, and warnings associated with the use of this device.

Sincerely,

Paul Anderson, MD  
Richard Assaker, MD  
Roberto Assietti, MD  
Richard Fessler, MD  
John Heller, MD

Stephen Papadopoulos, MD  
Vincent Pointillart, MD  
Rafael Sambale, MD  
Rick Sasso, MD

## Instrument Set



**Pin Placement Guide**  
6474100



**Universal Handle**  
6971117



**Pin Driver**  
6474630



**Distraction Pin**  
3.5mm x 14mm, 6474024  
4.0mm x 14mm, 6474034  
3.5mm x 16mm, 6474026  
4.0mm x 16mm, 6474036



**Non-sterile Drill Bit**  
6474276



**Pin Distractor**  
6474040



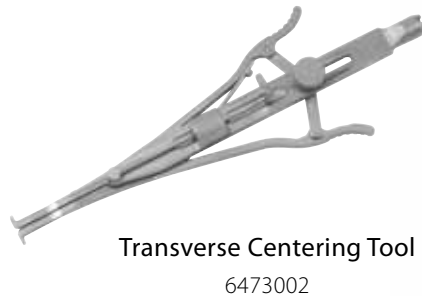
**Distraction Pin Cap**  
6474037



**Intravertebral Distractor**  
6478999



**Bubble Level**  
6473001



**Transverse Centering Tool**  
6473002



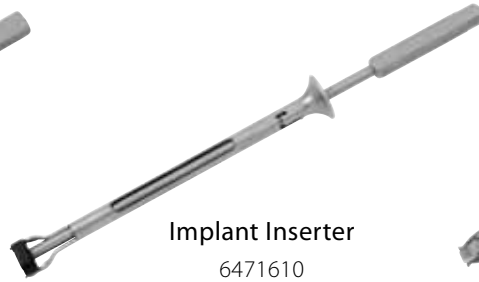
**Trial Sizer**  
14mm, 6475054  
15mm, 6475055  
16mm, 6475056  
17mm, 6475057  
18mm, 6475058

## Instrument Set *continued*



**Rasp**

14mm, 6474154  
15mm, 6474155  
16mm, 6474156  
17mm, 6474157  
18mm, 6474158



**Implant Inserter**

6471610



**Cutter**

14mm, 6474624  
15mm, 6474625  
16mm, 6474626  
17mm, 6474627  
18mm, 6474628



**MSB Power Adapter**

6475010



**Seal Plug\*\***



**BRYAN® Cervical Disc**

14mm, 6470514  
15mm, 6470515  
16mm, 6470516  
17mm, 6470517  
18mm, 6470518

\*\*Comes packaged with the implant.

## Power System Requirement

The Medtronic Electric Drive System and MSB Power Adapter are required to operate the Cutters in the ACD™ Instrument Set. Do not proceed without the following parts:

### Medtronic Electric Drive System

Cat. No.	Description	Qty/Set
6478835	Electric Drive System Case	1
6471341	Foot Pedal	1
6471342	Electric Drive Motor	1
6471704	Power Cord (US, 115V)	1
6472701	Electric Drive Console	1
6475010	MSB Power Adapter	1

## Preoperative Templating

Obtain a CT scan or an MRI so that the slices are parallel to the vertebral end plates. The smaller of the two end plates at the target disc space is used in estimating prosthesis size. The magnification factor of the image using the BRYAN® Cervical Disc Template Set is determined, and the Template corresponding to the measured magnification factor is used to estimate the prosthesis diameter (**Figure 1**).

#### Helpful Hint

*"Preoperative templates provide an estimate of the sizing, and the final implant size is determined intraoperatively. This step allows one to identify patients with vertebral end plates too small or large for the implant diameter range of 14mm to 18mm or with anomalous osseous morphology, vertebral arteries, etc."*

—**John Heller, MD**

#### Helpful Hint

*"Another option for preoperative templating is to use standard digital radiographic imaging software measurement tools to estimate the diameter of the end plates."*

—**Paul Anderson, MD**

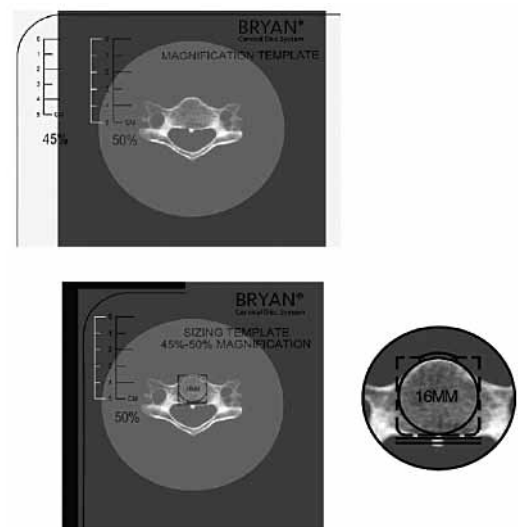


Figure 1



## Patient Positioning and Exposure

The patient is placed in the supine position with the neck supported posteriorly to achieve neutral sagittal alignment (**Figure 2**).

A standard transverse incision is used to access the cervical spine, and the longus colli muscles are elevated with medial/lateral retractor blades. Cranial/caudal retractors may also be used (**Figure 3**).

### ✓ Helpful Hint

*"In preoperative consultations with my arthroplasty patients, I have them sign consent forms for both arthroplasty and fusion procedures in case adequate fluoroscopic visualization of the target disc space is not possible. Both shoulders may be pulled down and secured for fluoroscopic visualization of the lower cervical spine. Use standard methods to identify the correct disc level."*

—**Paul Anderson, MD**



Figure 2

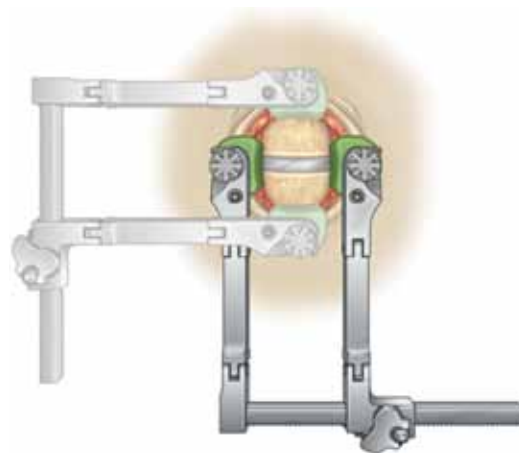


Figure 3

## Discectomy and Distraction Pin Placement

Before the Distraction Pins are inserted, an anterior discectomy is performed, thoroughly exposing the uncovertebral joints bilaterally. The osteophytes on the anterior surfaces of the vertebral bodies and the anterior cranial bony lip of the superior vertebral body should be resected with the goal of reestablishing the natural cortical margins (Figure 4).

The coronal midline positioning and sagittal angle of the Distraction Pins determine the final positioning of the BRYAN® Cervical Disc that will be implanted. The coronal midline of the vertebral bodies is identified by expanding the distal tips of the Transverse Centering Tool to the uncinates processes, centering the Bubble Level in the coronal plane, and advancing the pointer on the Transverse Centering Tool until it marks the anterior cortex of the vertebral body (Figures 5, 6, and 7).

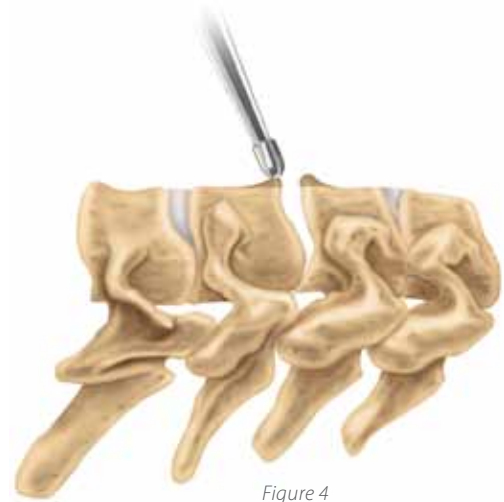


Figure 4

### ✓ Helpful Hint

*"AP fluoroscopy may be used to verify the midline before pin placement. The spinous processes are good reference points for locating the midline of each vertebral body."*

—Richard Assaker, MD

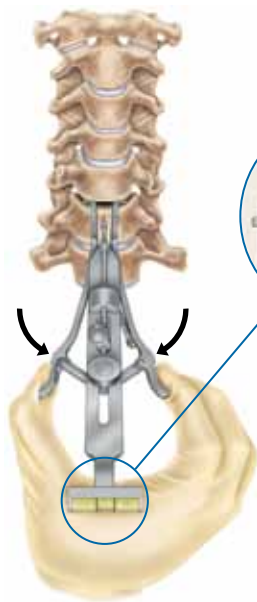


Figure 5

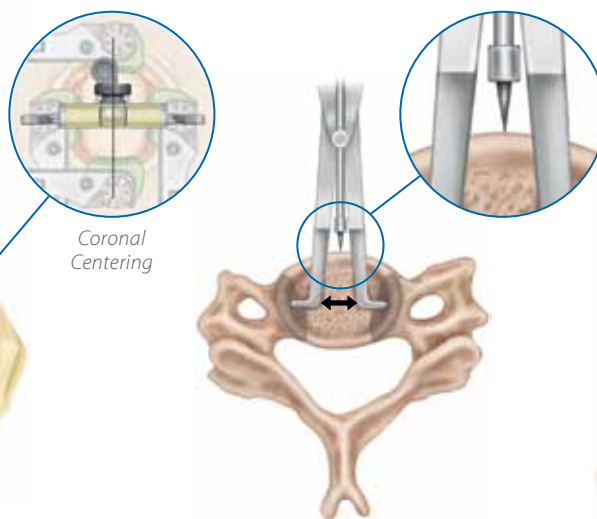


Figure 6

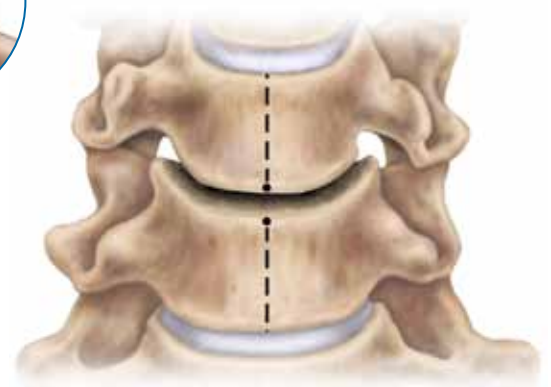


Figure 7

## Discectomy and Distraction Pin Placement *continued*

The Pin Placement Guide is placed on the coronal midline and used to adequately distance (7.5mm) the Distraction Pin from the vertebral end plates so it does not interfere with the depth stop on the Cutter during the milling step (**Figures 8 and 9**). The Drill Bit is attached to the Universal Handle and used to puncture the cortex of the vertebral bodies for easier insertion of the Distraction Pins (**Figure 10**).



Figure 8

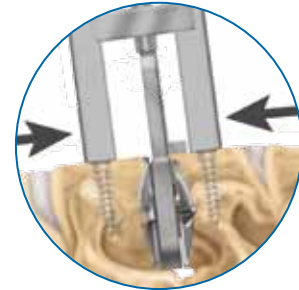


Figure 9



Figure 10

## Discectomy and Distraction Pin Placement *continued*

Using the Pin Driver, insert a Distraction Pin on the coronal midline of the caudal vertebral body and parallel to the caudal vertebral end plate. A second Distraction Pin is inserted on the coronal midline of the cranial vertebral body and parallel to the first Distraction Pin (Figure 11).



Figure 11

### Helpful Hint

*“For parallel insertion of the cranial pin, I like to place the Pin Distractor over the inserted caudal Distraction Pin and then use the cranial leg of the Pin Distractor as a reference for the angle of insertion for the cranial Distraction Pin” (Figures 12, 13, and 14).*

—Rafael Sambale, MD

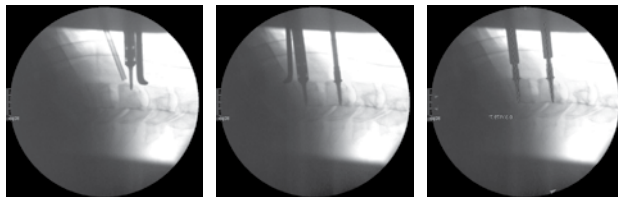


Figure 12

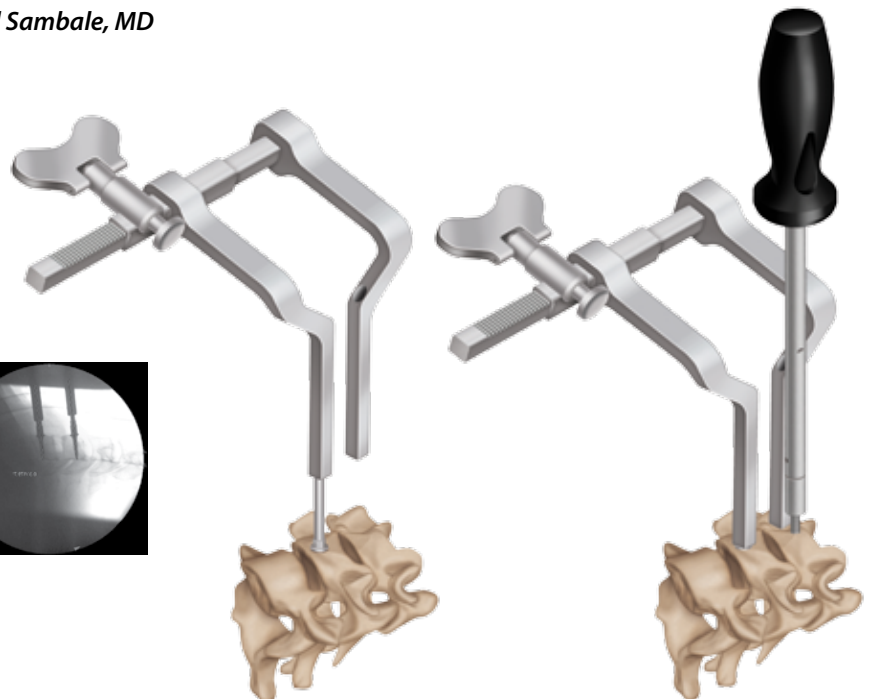


Figure 13

Figure 14

## Discectomy and Distraction Pin Placement *continued*

The Pin Distractor is placed over the Distraction Pins, and a Distraction Pin Cap is applied **only to the caudal Distraction Pin (Figure 15)**.

### ✓ Helpful Hint

*“Use care not to over-tighten the Distraction Pin Cap. One cap placed on the caudal pin is sufficient to anchor the Pin Distractor to the spine. If the bone quality is determined to be poor during the pin placement step, a fusion operation should be performed.”*

—**Vincent Pointillart, MD**

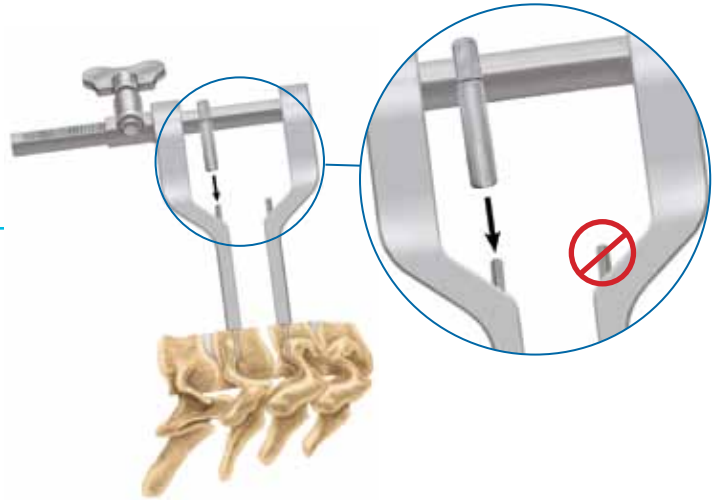


Figure 15

## Distraction

The Pin Distractor is only intended to maintain the parallel distraction achieved with the Intravertebral Distractor. With the Pin Distractor in the unlocked position, place the distal end of the Intravertebral Distractor on the posterior cortex of the disc space and expand the tips to achieve approximately 7.5mm of distraction; after holding this position for approximately 60 seconds with the Intravertebral Distractor, employ the lock on the Pin Distractor to maintain the distraction and remove the Intravertebral Distractor (Figure 16).

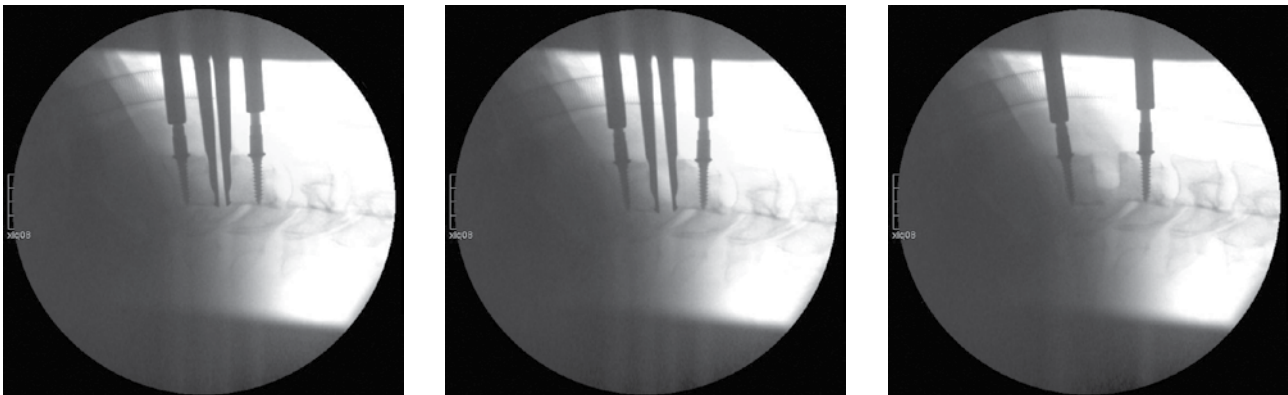
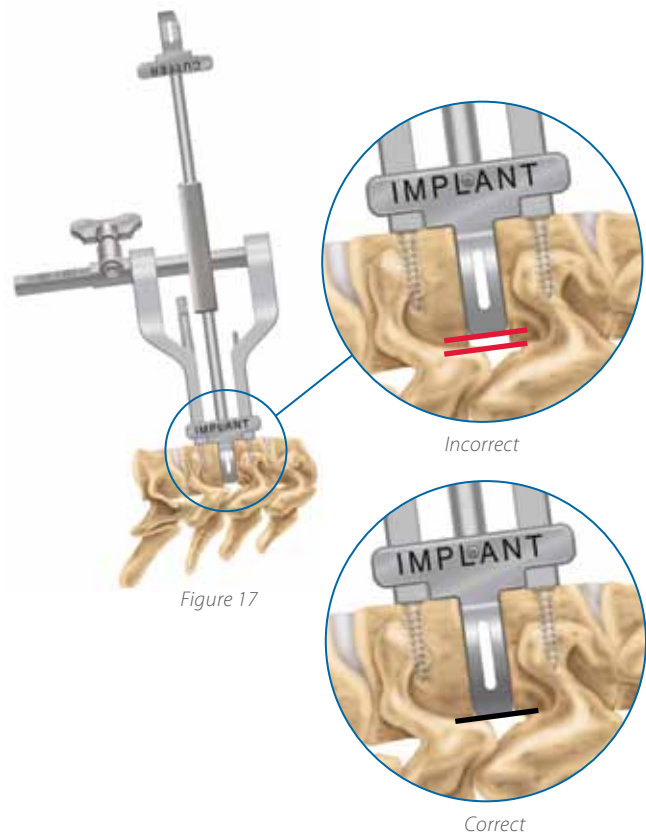


Figure 16

## Implant Size Selection

The appropriately sized BRYAN® Cervical Disc to be implanted is determined during implant size selection. The implant end of the Trial Sizer matches the height and depth of the corresponding BRYAN® Cervical Disc. When the appropriately sized trial is fully seated in the disc space, it should sit flat on the anterior vertebral bodies and flush on the vertebral end plates, and the distal end should rest within 1 mm of the posterior longitudinal ligament (**Figure 17**). On lateral fluoroscopy, there should be an unobstructed line of sight through the visualization slots on the distal end of the Trial Sizer.





## Decompression and End-plate Preparation

To perform a thorough bilateral foraminal decompression, the posterior uncovertebral joints are removed along with all osteophytes; the posterior longitudinal ligament may be removed, and the nerve roots decompressed as needed (Figures 18 and 19).

### Helpful Hint

*"To ensure a complete posterior decompression and to help mobilize the motion segment, I prefer to remove the posterior longitudinal ligament (PLL) in my arthroplasty procedures. The decompression may be thoroughly completed after the milling step, which will remove bone from both vertebral end plates and allow for better visualization and access to the posterior elements."*

—Rick Fessler, MD

Once the BRYAN® Cervical Disc size is chosen during implant size selection, the cutter end of the Trial Sizer is used to assess adequacy of the end-plate preparation for the milling step. The cutter end of the Trial Sizer matches the height and depth of the corresponding Cutter that is used during the milling step. Pay special attention to the medial and posterior-lateral uncus removal so that the full length and width of the Trial Sizer rests flat against the anterior vertebral bodies and flush against the vertebral end plates when fully seated (Figure 20). If the Trial Sizer does not fit readily into the disc space, use a burr to remove bone bilaterally from the posterolateral corners as needed.

The Rasp may be used to help flatten the end plates, but it is not intended to forcefully remove posterior bone.

### Helpful Hint

*"I like using a small-diameter barrel burr to prepare the end plates in my arthroplasty procedures as well as my ACDP procedures. It's an efficient and effective tool for flattening the end plates and resecting the uncovertebral joints."*

—Rick Sasso, MD

### Helpful Hint

*"At this stage of the procedure, it is important to assess whether adequate motion is present at the target disc space to warrant the use of the BRYAN® Cervical Disc. The cutter trial should fit snugly in the disc space without placing the disc space under too much tension. If you feel the 7.5mm distraction is excessive, it may be necessary to revert to a fusion."*

—John Heller, MD



Figure 18

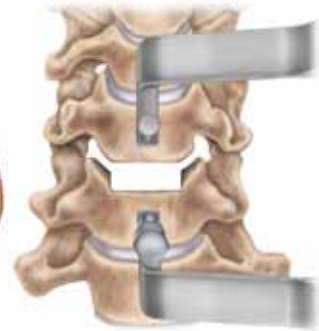


Figure 19

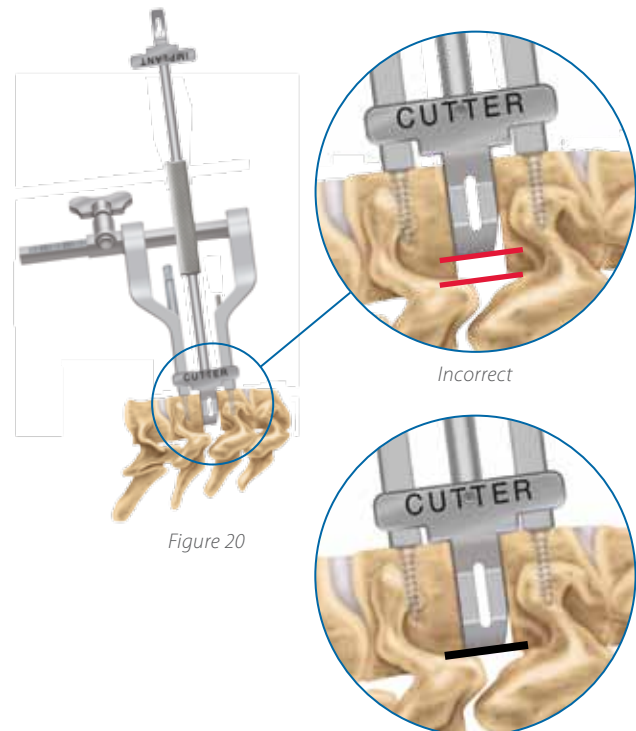


Figure 20

Incorrect

Correct

## Milling the End Plates

The appropriate-size Cutter is attached to the Power Adapter and inserted into the disc space (**Figure 21**). Fill the disc space with saline; then, as power is applied to the Cutter, the Pin Distractor is compressed by turning the key, and the end plates are milled until the hard stops on the Cutter prevent further compression (**Figure 22**). After the end plates are milled, the posterior third of each uncovertebral joint is fully resected and the nerve roots are fully decompressed. Confirm with fluoroscopy (**Figures 23 and 24**).

### ✓ Helpful Hint

*"Irrigation of the disc space is recommended during the milling step. If the pocket created by the Cutter is not fully completed, the milling step may be repeated."*

—**Roberto Assietti, MD**

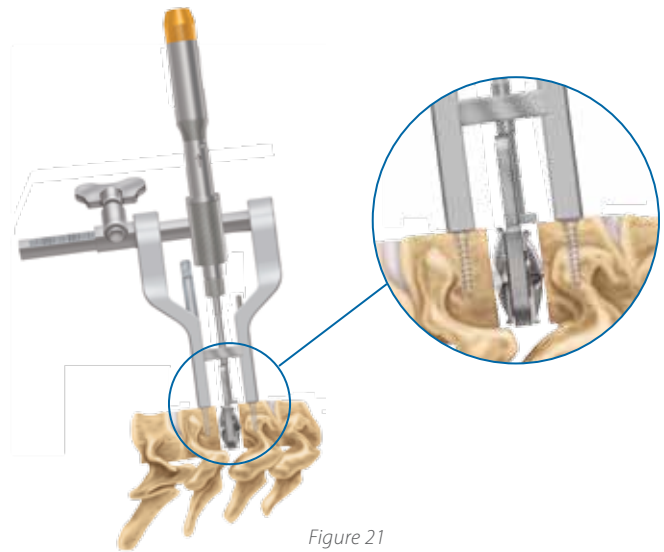


Figure 21

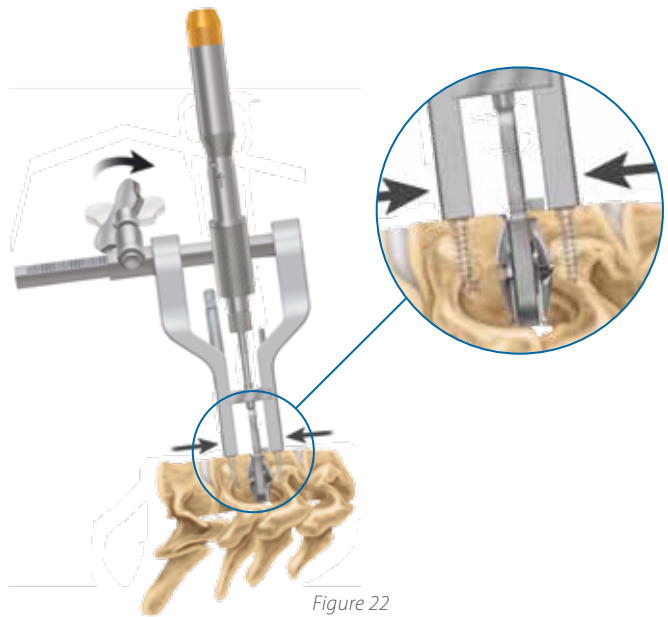


Figure 22

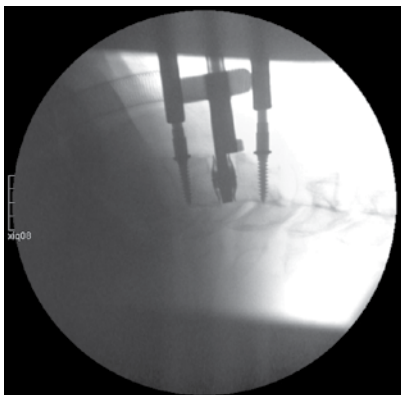


Figure 23

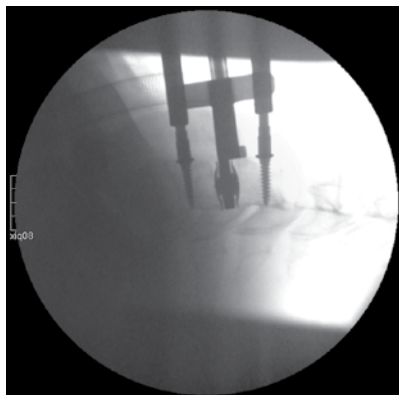


Figure 24



## Implant Insertion

Without bending the tip, screw a Seal Plug\* into one port of the implant and turn it until the handle twists off (Figure 25).



Figure 25

The implant is immersed into a sterile saline solution and, without covering the open port, is pumped until it is free of air bubbles and saline flows from the open port (Figure 26a).



Figure 26a

When the implant is filled with saline and held compressed, the second Seal Plug\* is screwed into the remaining open port, and the handle twisted off (Figure 26b).



Figure 26b

The BRYAN® Cervical Disc is attached to the Implant Inserter and introduced into the disc space (Figures 27, 28a, and 28b).

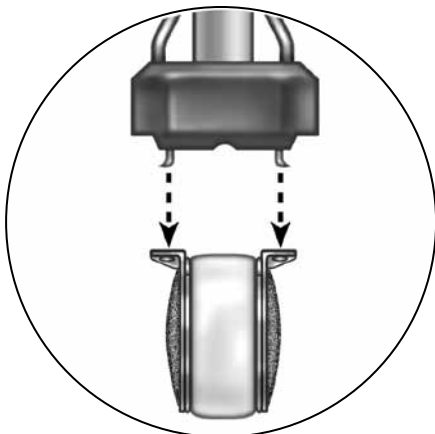


Figure 27



Figure 28a



Figure 28b

\*Comes packaged with the implant.

## Final Implant Placement

The Implant Inserter tip may be used as a positioner by pulling back on the adjustable shaft and rotating it into the open position (**Figures 29 and 30**). In the final position, one shell flange may rest 1mm to 2mm above the anterior surface of the vertebral body. Do not push it farther down. This condition is acceptable. The surgery is completed using standard anterior cervical closure procedures.



Figure 29



Figure 30

### ✓ Helpful Hint

*“Following final insertion of the implant, lateral and AP images (fluoroscopic or x-ray) are recommended to verify proper placement. Use bone wax or the hemostatic agent of choice to seal the Distraction Pin holes” (Figure 31).*

**—Stephen Papadopoulos, MD**

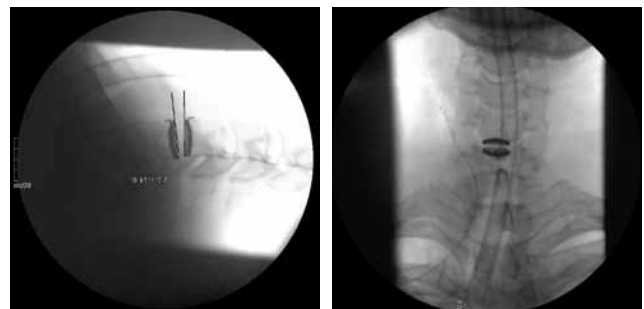


Figure 31

## Bi-level Implant Placement

The following surgical technique describes implantation of the BRYAN® Cervical Disc at two adjacent levels. For the bi-level technique, it is recommended to place the first BRYAN® Cervical Disc implant at the cranial motion segment using the steps described on pages 10–15 (Figure 32).

To insert the second BRYAN® Cervical Disc implant, remove the cranial Distraction Pin from the first (cranial) operated motion segment and insert it into the caudal vertebral body of the second (caudal) target motion segment, on the coronal midline and parallel to the caudal vertebral end plate. After placing the caudal Distraction Pin at the second target level, the Distraction Pin that is still in place from the first BRYAN® Cervical Disc operation is repositioned if it is not already parallel to the newly placed caudal Distraction Pin (Figure 33). Confirm placement using fluoroscopy (Figures 34 and 35).



Figure 32



Figure 33



Figure 34



Figure 35

## Implant Removal

If the BRYAN® Cervical Disc needs to be removed after implantation, the disc space is distracted, an osteotome or chisel is used to separate the implant from the vertebral body, and the implant is removed from the disc space. Please contact Medtronic for instructions on specimen retrieval and analysis.

## Power Assembly

To use the motor, attach the MSB Power Adaptor to the Medtronic Electric Drive System hand piece and secure in place. Attach the Cutter to the power adaptor. Pull the Cutter to remove (**Figure 36**).



Figure 36

## Product Ordering Information

Part Number	Description	Quantity In Set	Quantity Used	Price
6470514	BRYAN® 14mm Cervical Disc - OUS	2		
6470515	BRYAN® 15mm Cervical Disc - OUS	2		
6470516	BRYAN® 16mm Cervical Disc - OUS	2		
6470517	BRYAN® 17mm Cervical Disc - OUS	2		
6470518	BRYAN® 18mm Cervical Disc - OUS	2		
6474624	Cutter—14mm - OUS	1		
6474625	Cutter—15mm - OUS	1		
6474626	Cutter—16mm - OUS	1		
6474627	Cutter—17mm - OUS	1		
6474628	Cutter—18mm - OUS	1		
6474530	BRYAN® Cervical Disc System Suitcase	1		

### ACD™ Instrument Set

Part Number	Description	Quantity In Set	Quantity Used	Price
6473001	Bubble Level	2		
6473002	Transverse Centering Tool	1		
6474024	Distraction Pin 3.5 × 14mm	2		
6474034	Distraction Pin 4.0 × 14mm	2		
6474026	Distraction Pin 3.5 × 16mm	2		
6474036	Distraction Pin 4.0 × 16mm	2		
6474630	Pin Driver	1		
6474040	Pin Distractor	1		
6478999	Intravertebral Distractor	1		
6475054	Trial Sizer, 14mm	1		
6475055	Trial Sizer, 15mm	1		
6475056	Trial Sizer, 16mm	1		
6475057	Trial Sizer, 17mm	1		
6475058	Trial Sizer, 18mm	1		
6471610	Implant Inserter	1		
6474095	Instrument Case Label	2		
6474096	Instrument Case—Upper Tray	1		
6478909	Instrument Case—Bottom Tray	1		
6474276	Non-sterile Drill Bit	2		
6971117	Universal Handle	1		
6474154	Rasp, 14mm	1		
6474155	Rasp, 15mm	1		
6474156	Rasp, 16mm	1		
6474157	Rasp, 17mm	1		
6474158	Rasp, 18mm	1		
6478900	Distractor Pin Caddy	1		
6478901	Distractor Pin Caddy Lid	1		
1850077	Instrument Case	1		
1850079	Instrument Case Lid	1		
6476020	BRYAN® Template Set	1		
6475010	MSB Power Adapter	1		
6474100	Pin Placement Guide	1		
6474037	Distractor Pin Caps	3		
6471342	Motor Handpiece	1		

## Important Product Information for BRYAN® CERVICAL DISC PROSTHESIS AND STERILE SINGLE-USE ACCESSORIES

### BEFORE USING THE PRODUCT(S), READ THE FOLLOWING INFORMATION AND THE CURRENT REVISION OF THE BRYAN® CERVICAL DISC SYSTEM SURGICAL TECHNIQUE MANUAL.

#### SINGLE USE ONLY.

#### NOT TO BE RESTERILIZED.

Sterile unless package opened or damaged. Devices are double packaged in sealed pouches and sterilized to a 10<sup>-6</sup> Sterility Assurance Level.

#### DEVICE DESCRIPTION

The Medtronic Sofamor Danek BRYAN® Cervical Disc prosthesis is a cervical intervertebral disc prosthesis designed to permit motion similar to the normal cervical functional spinal unit. The prosthesis is intended to treat stable cervical degenerative disc disease without fusion, thereby providing the patient with the capability for motion at the treated level.

The device consists of a POLYURETHANE nucleus designed to fit between two TITANIUM alloy (Ti6Al4V) surfaces (shells).

The bone-contacting surface of each shell includes a TITANIUM (Ti) porous coating to encourage bony ingrowth and long-term stability. A POLYURETHANE sheath surrounds the nucleus and is attached to the shells with TITANIUM (Ti) wire, forming a closed compartment. TITANIUM alloy (Ti6Al4V) seal plugs provide for retention of a lubricant. Anterior stops on each shell help to prevent posterior migration of the device.

Sterile, single-use accessories that may be used in the surgical procedure are provided.

#### INDICATIONS

The device is indicated for use in skeletally mature patients undergoing primary surgery for treatment of mechanically stable, degenerative disc disease of the cervical spine at any one level or two adjacent levels between C3 and C7, as demonstrated by signs and/or symptoms of radiculopathy and/or myelopathy associated with spondylotic foraminal or canal stenosis and/or disc herniations.

#### CONTRAINDICATIONS

The device should not be implanted in patients with an active infection, osteoporosis, radiographic evidence of mechanical instability or the absence of demonstrated motion at the treatment level on preoperative flexion/extension radiographs.

#### WARNINGS

The safety and effectiveness of the device has not been established in patients requiring surgery at more than two levels, with a fusion at an adjacent level, or with advanced spondylosis at the treatment level.

Prior to use, the physician should be trained in the surgical procedure employed for the implantation of this device.

The device must be implanted in accordance with the Surgical Technique Manual for the BRYAN® Cervical Disc System.

The proper size device should be determined using the sizing guidelines described in the preoperative procedures section of the Surgical Technique Manual. This size will be verified intraoperatively. An oversized prosthesis may impinge upon the spinal cord. An undersized prosthesis may subside, producing subsequent disc space narrowing.

Improper burring or milling (including hand shaping of the end plates) may lead to inaccurate placement of the prosthesis, which may ultimately result in device migration. An improperly milled end plate requires termination of the device implant procedure.

Distracting the target disc space greater than 8.5mm may lead to improper fit of the prosthesis, and is an indication for terminating the procedure.

#### PRECAUTIONS

The presence of anatomical abnormalities and/or deformities may reduce the surgeon's ability to ensure proper placement of the prosthesis.

In some instances, there may be an interference that prevents implantation at C3-C4. In these instances, it will be necessary to perform a fusion procedure.

Prior to surgery, the operating table must be examined for compatibility with the instruments that interface with the table. Incompatibility may result in inaccurate placement of the prosthesis. The patient's position on the operating table must remain unchanged once the operation has begun. Lack of proper patient immobilization may result in inaccurate placement of the prosthesis.

The target disc space must be confirmed by fluoroscopy to assure proper placement of the prosthesis.

Failure to remove all anterior osteophytes may result in misalignment of the prosthesis shells.

A 4mm anchor post is available for use, and should be used under the conditions outlined in the SURGICAL TIPS section of the Surgical Technique Manual.

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

#### ADVERSE EFFECTS/COMPLICATIONS

In addition to the possible complications of anterior cervical spine surgery, the anticipated complications (adverse events), which may require additional surgery at the implant site include those mentioned below.

- Abnormal wear or fracture of implant
- Adverse reaction to the device
- Death
- Deep wound infection
- Device instability
- Device misplacement
- Device subsidence
- Dysphagia
- Dysphonia
- Epidural fibrosis
- Esophageal erosion
- Horner's Syndrome
- Incontinence
- Loss of range of motion at treated level
- Operative induced neurologic deficit
- Paralysis
- Recurrent laryngeal palsy
- Spinal fluid leakage
- Spondylotic bridging
- Stroke
- Unresolved pain

#### PATIENT INFORMATION

- Use of a cervical collar is at the discretion of the surgeon. The neck may be moved through a comfortable range of motion when the patient is fully awake and upright.
- Should preoperative symptoms fail to improve or worsen, or new symptoms develop, the surgeon should be promptly notified.
- Placement of the prosthesis does not prevent future surgical arthrodesis at the treated level should it become necessary.

#### PRODUCT COMPLAINTS

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U.S. Patent Nos: 5,674,296; 5,865,846; 6,001,130; 6,156,067; 6,562,045 – Other Patents Pending

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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.

