



AN EXPANDABLE
INTERBODY DEVICE
**THAT PROVIDES
CONTINUOUS
APPOSITION OF
BONE GRAFT-TO-ENDPLATE
DURING EXPANSION**

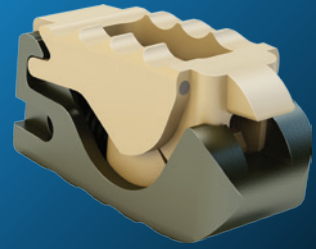
SURGICAL
TECHNIQUE

Elevate™ Spinal System
Expandable Interbody Device

Medtronic



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INTRODUCTION

The Elevate Expandable Interbody Device was developed as an implant for stabilization of the lumbar spinal column for PLIF, TLIF, and MAST® MIDLF® procedures. This surgical technique is designed to familiarize healthcare professionals with the surgical procedure.

Please carefully read this surgical technique and its appendix prior to the use of the implant.

The aim of this development was an implant which fits the anatomical shape of the vertebral endplates and combines the following essential features:

- Two implant options available:
 - **Standard implant** – offers posterior expansion and up to 8 degrees of lordosis when fully expanded (for more information, see chart on page 28)
 - **Extra-lordotic implant** – offers fixed posterior height with various degrees of lordosis when fully expanded (for more information, see chart on page 28)
- Bullet tip device with continuous lordotic expansion
- MAST® Procedure compatible
- Continuous apposition of bone graft-to-endplate during expansion
- Open volume design for appropriate bone graft material
- 10mm width
- Teeth on the surface to reduce the likelihood of expulsion
- Bullet-tip design allows for self-distraction and ease of insertion
- Tantalum markers allow radiographic visualization

Risks

Potential risks associated with the device include, but are not limited to:

- Implant migration
- Loss of spinal curvature, correction, height, and/or reduction
- Bone fracture or stress shielding at, above, or below the level of surgery
- Bone graft donor site complication
- Loss of spinal mobility
- Endplate disruption
- Neurological impairment

See IFU for a full list of risks, warnings, and contraindications.

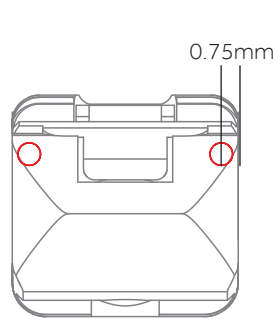
SIZE SPECIFICATIONS AND MARKER LOCATIONS

The diagrams on the left show the locations of the Tantalum x-ray markers as seen from a right-side TLIF approach as the view is rotated from a straight A/P to a lateral view. The diagrams on the right depict measurements for the available sizes.

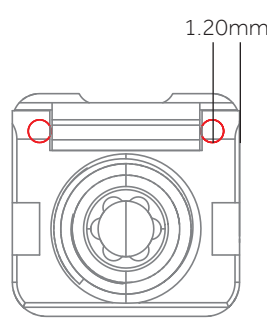
Straight A/P



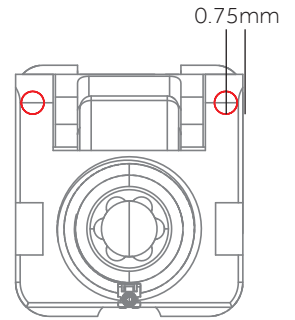
Anterior Markers



7mm and 8mm Implant Height Posterior Markers



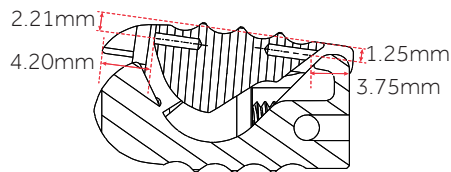
9, 10, and 11mm Implant Height Posterior Markers



Oblique-45° Angle

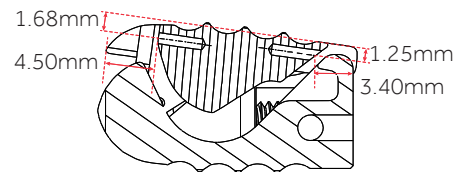


7mm Height Implant Measurements



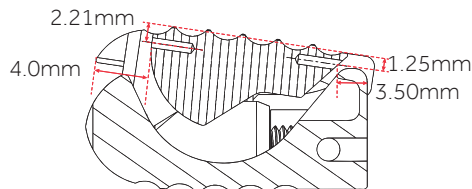
23mm length

8-11mm Height Implant Measurements

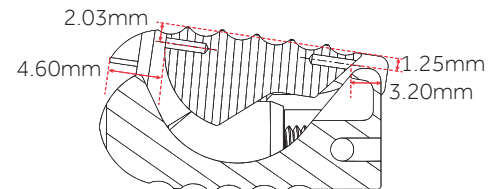


23mm length

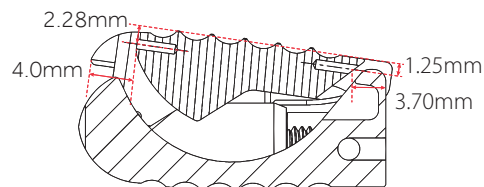
Lateral



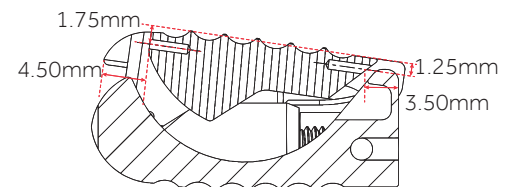
28mm length



28mm length



32mm length



32mm length

INSTRUMENT SET



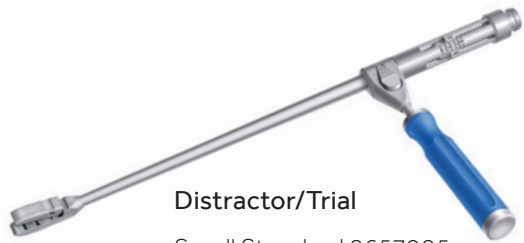
Distractor/Trial Driver

G851200



Torque Handle

G178101



Distractor/Trial

Small Standard 8657005
Large Standard 8657006
Small Extra Lordotic 8657007
Large Extra Lordotic 8657008



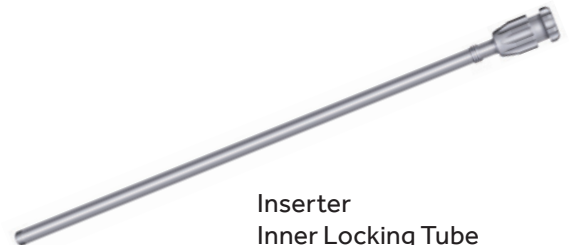
Inserter Drive Shaft

8657003



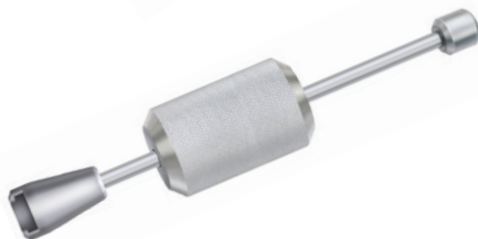
Extractor Forceps

8657012



**Inserter
Inner Locking Tube**

8657002



Slap Hammer

8657011



Inserter

8657001



Leverage Tool

8657013

TLIF APPROACH

OPEN AND MINIMALLY INVASIVE TECHNIQUES

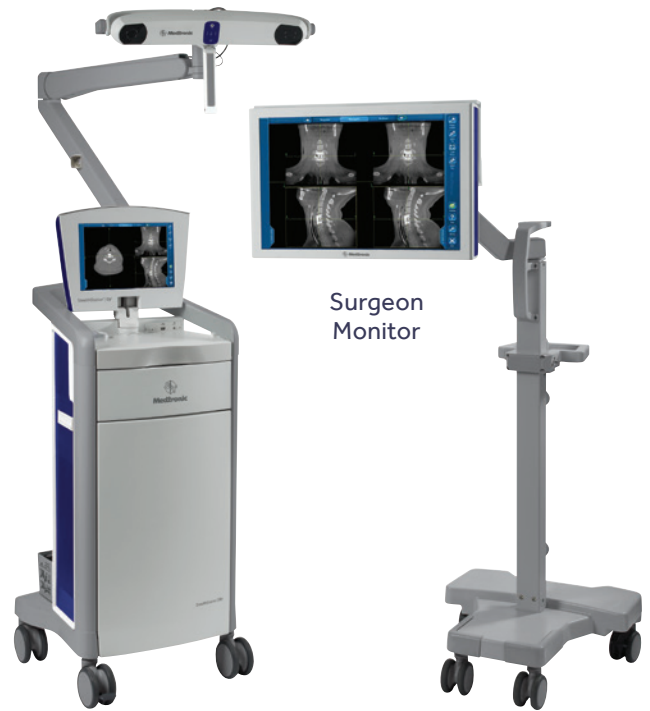
Positioning

Prone patient positioning in kyphosis facilitates the approach to the spinal canal as well as to the disc space. The kyphotic positioning should be taken into consideration when confirming implant sizing and angle in order to avoid hyperlordosis. Imaging guidance is only possible in the lateral view.

The prone position will allow a free abdomen to dismiss abdominal pressure on the stomach vessels. This can be achieved by using a positioning frame or padding. Use a well-padded prone support table that replicates physiological lordosis. This positioning may be tolerated by the patient for many hours and therefore may be suitable for extended spinal surgeries. Furthermore, it allows intraoperative imaging guidance in the A/P and lateral views. The O-Arm® Imaging System can be used to provide imaging assistance.



O-Arm Imaging System



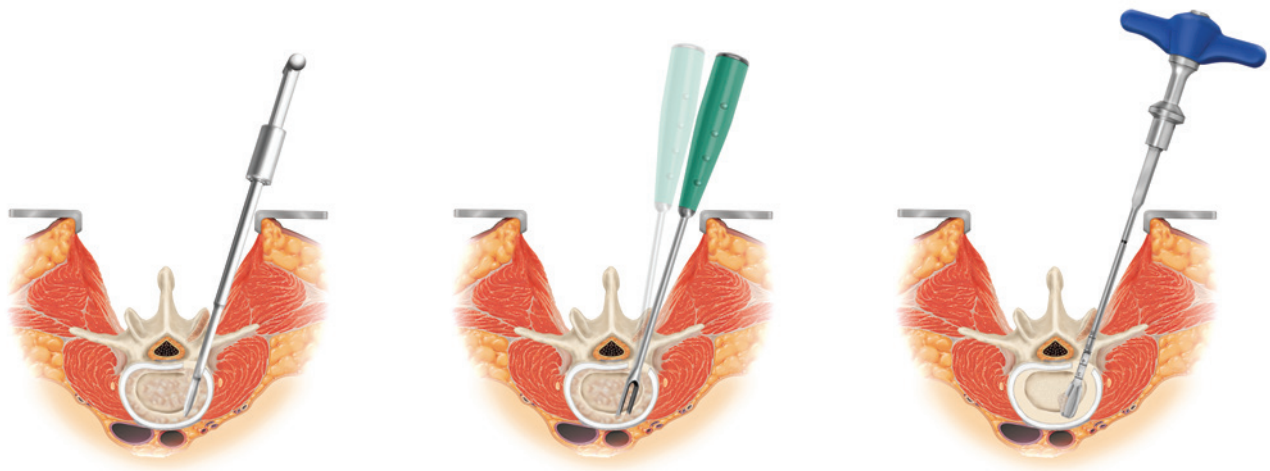
Staff Cart
with Camera

StealthStation S7 System

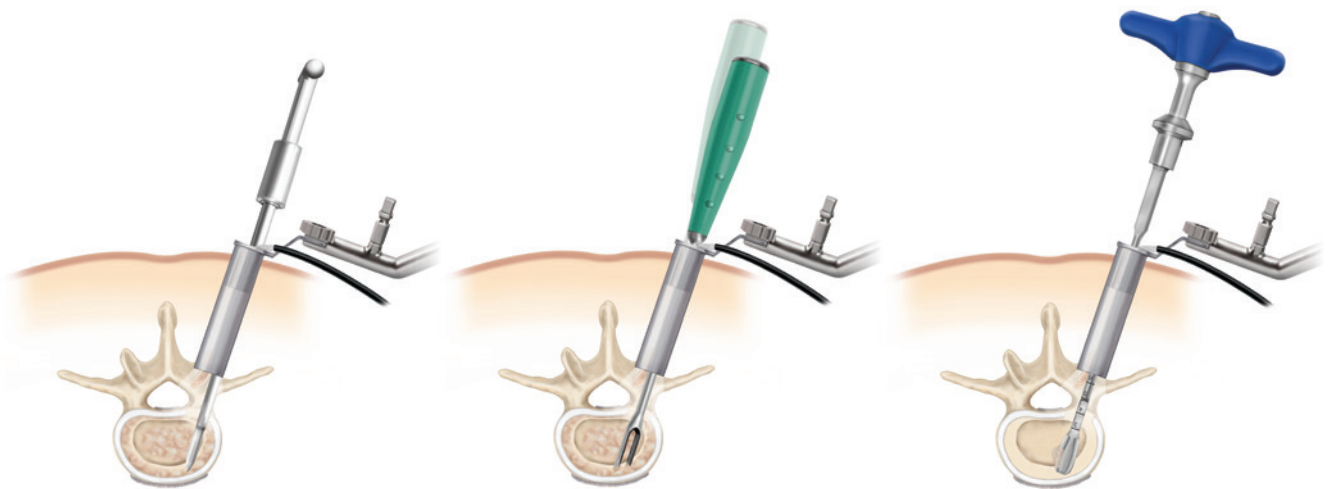
Decompression / Discectomy

Mark the affected segment in the midline after imaging guidance. Make a skin incision 4cm lateral to the midline at the level of the affected segment. Expose the interlaminar window and the medial aspect of the facet joint. In general, a bony resection towards cranial and lateral is required in the area of the facet joints. Due to the design of the implants, a partial medial facetectomy is necessary to insert the implants into the disc space. In most of the cases, a resection of the spinous process is not required. The maintenance of the superior lamina is suggested to keep the interlaminar, as well as the interspinous, stability of the superior adjacent level and motion segment.

Open the annulus and resect the nucleus and the inner annulus as completely as possible. After discectomy, remove the endplate cartilage. Ensure that the bony endplates stay intact. Injuring bony endplates may lead to implant subsidence into the vertebrae.



Open Technique



Minimally Invasive Technique

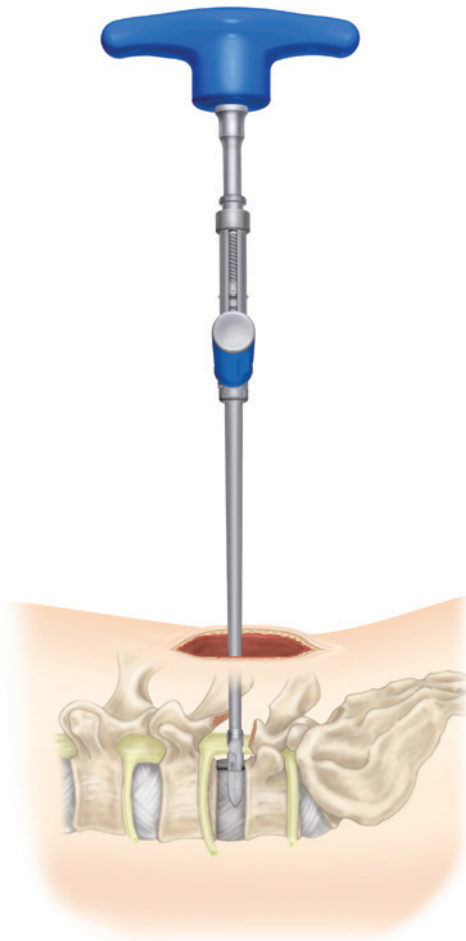
Distraction / Implant Size Determination

Instruments for use with the Elevate Spinal System:

Part Number	Description
8657005	Small Standard Distractor/Trial
8657006	Large Standard Distractor/Trial
8657007	Small Extra Lordotic Distractor/Trial
8657008	Large Extra Lordotic Distractor/Trial
G851200	Distractor Driver

For all following steps, please use caution during retraction of the dura mater and the offbranching nerve root(s).

In order to choose the appropriate type and size of the Distractor/Trial, use preoperative planning to determine the appropriate height and lordosis.



Open
Technique



Minimally Invasive
Technique

Distraction / Implant Size Determination Continued

Insert the Distractor/Trial into the disc space. A mallet may be used to facilitate placement. It is desirable to position the Distractor/Trial on the apophyseal ring. Attach the Distractor Driver onto the Distractor/Trial (**Figure 1**). Rotate the Distractor Driver in order to expand the tip of the Distractor/Trial (**Figure 2**).

Once a desired fit of the Distractor/Trial in the intervertebral disc space is achieved, determine the implant size. The window of the Distractor/Trial will show the intradiscal height of expansion. The head of the Distractor/Trial has length markings that are visible under fluoroscopy to help the surgeon determine the appropriate length implant to use (**Figure 2a**). Use chart on page 28 to choose the appropriate implant size.

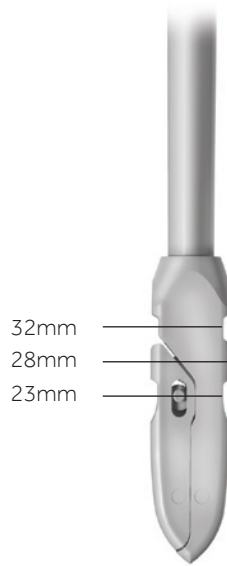


Figure 2a

Distractor/Trial markings

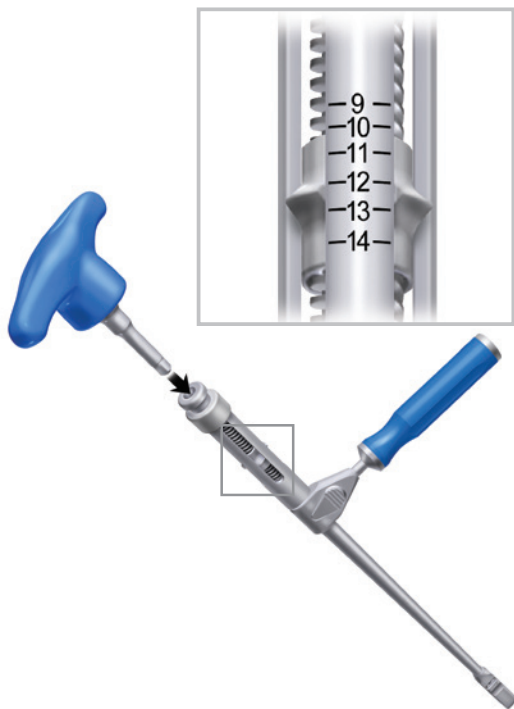


Figure 1

Attaching Distractor Driver onto the Distractor/Trial

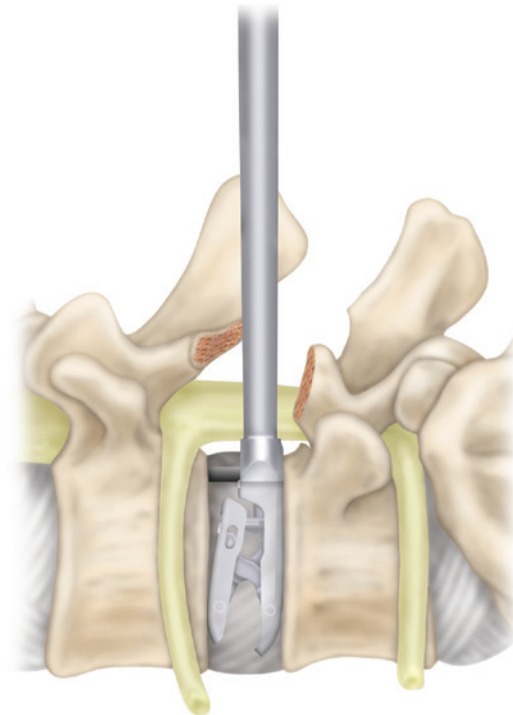


Figure 2

Expanded Distractor/Trial

This expandable interbody device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. In addition to filling the implant, the disc space may be filled with appropriate bone grafting material. Place anteriorly prior to implantation.

Expandable Interbody Device Implantation

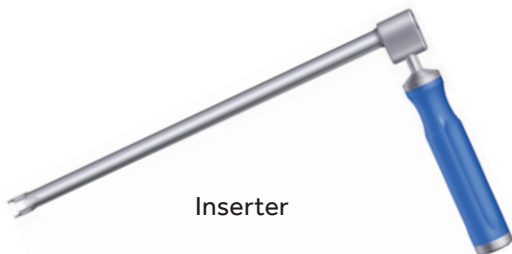
Instruments for use with the Elevate Spinal System:

Part Number	Description
8657001	Inserter
8657002	Inserter Inner Locking Tube
8657003	Inserter Drive Shaft
G178101	Torque Handle
8657013	Leverage Tool

Remove the correct size implant from the intact sterile packing. Pay attention to a correct implant size determination.

Thread the Inner Locking Tube into the Inserter in order to assemble the Inserter Assembly (Figure 3). Next attach the implant to the Inserter by turning the Inner Locking Tube clockwise (Figure 4).

It is recommended that the implant be attached to the Inserter so the PEEK portion of the implant with x-ray markers is superior during the insertion.



Inserter



Inserter Inner Locking Tube

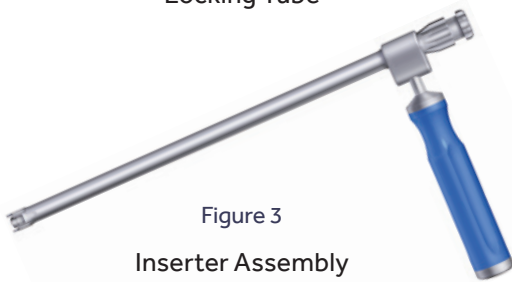


Figure 3

Inserter Assembly

Inserter - 8657001
 Inserter Inner Locking Tube - 8657002



Leverage Tool

8657013



Figure 4

Attaching Implant

Expandable Interbody Device Implantation Continued

Carefully insert the implant into the disc space (Figure 5). A mallet may be used to facilitate placement.

Advance the implant anteriorly so that the leading tip of the implant rests on the anterior apophyseal ring.

Note

Ensure the screw on the back of the implant is fully retracted and the PEEK nose is fully recessed within the Titanium Alloy bottom.

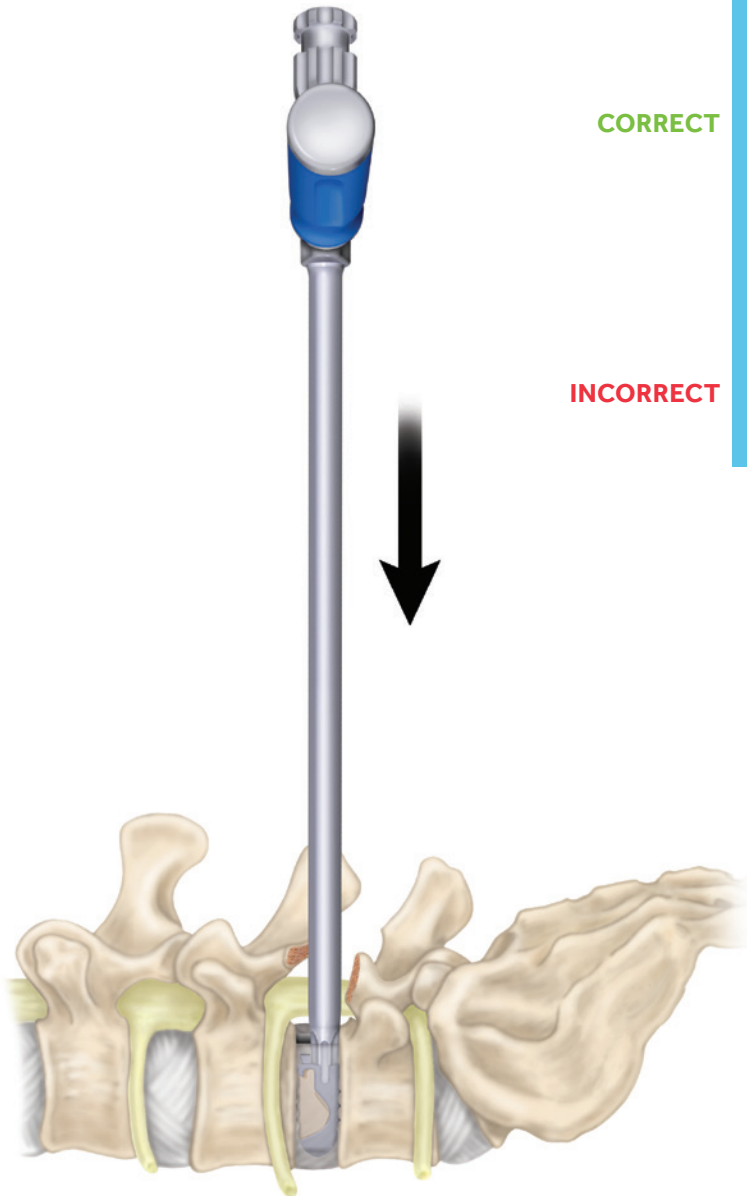
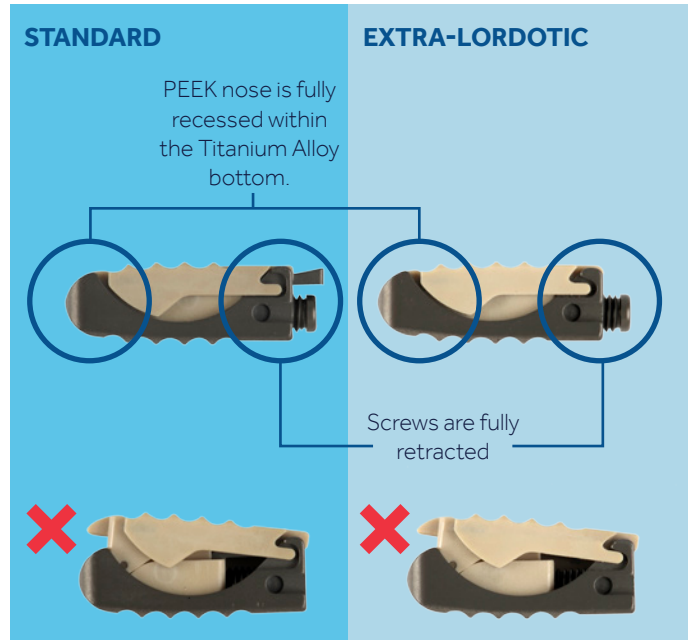


Figure 5

Expandable Interbody Device Implantation Continued

In order to expand the implant inside the disc space, insert the Inserter Drive Shaft along with the attached Torque Handle inside the Inserter Assembly (Figure 6). Next, turn the Torque Handle clockwise to expand the implant (Figure 7). Verify the correct position using imaging.

Important

The Torque Handle has a maximum torque of 2.5Nm to help mitigate the potential risk of endplate and implant damage.

Important

Do not strike the Torque Handle with a mallet or damage to the implant may result.

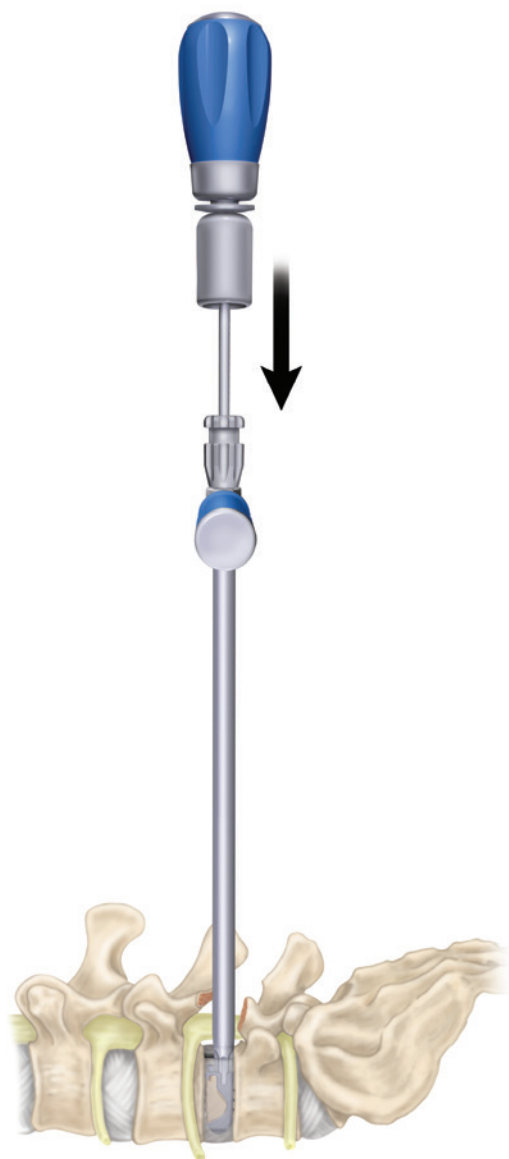


Figure 6

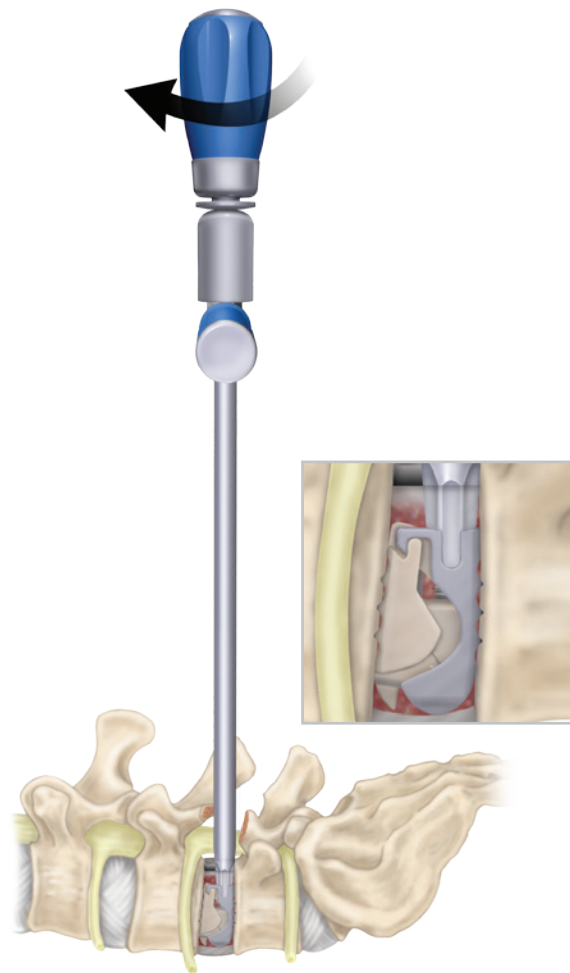


Figure 7

Expandable Interbody Device Implantation Continued

After implantation is completed, remove the Torque Handle and the Inserter Drive Shaft from the Inserter Assembly (Figure 8).

Next, disengage the Inner Locking Tube from the implant (Figure 9) and remove the Inner Locking Tube and Inserter from the disc space (Figure 10). Disassemble the Inner Locking Tube from the Inserter for cleaning.

Note

The Leverage Tool can be used to disengage the Inner Locking Tube from the implant.



Leverage Tool



Figure 8

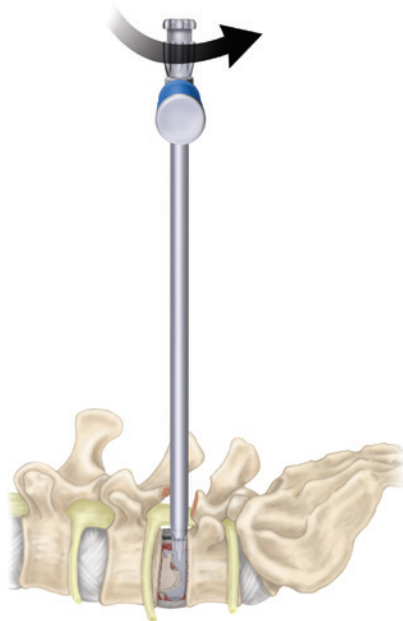


Figure 9



Figure 10

Expandable Interbody Device Implantation Continued

The implant can generate significant expansion forces. Care should be taken by the surgeon to avoid endplate damage caused by excessive expansion forces. If poor bone quality is suspected, the surgeon should limit the amount of torque that is delivered to the Torque Handle. Placement of the leading tip of the implant on the apophyseal ring is recommended.

The optimal position of the implant can be determined using the Tantalum x-ray markers in the implant (Figure 11).

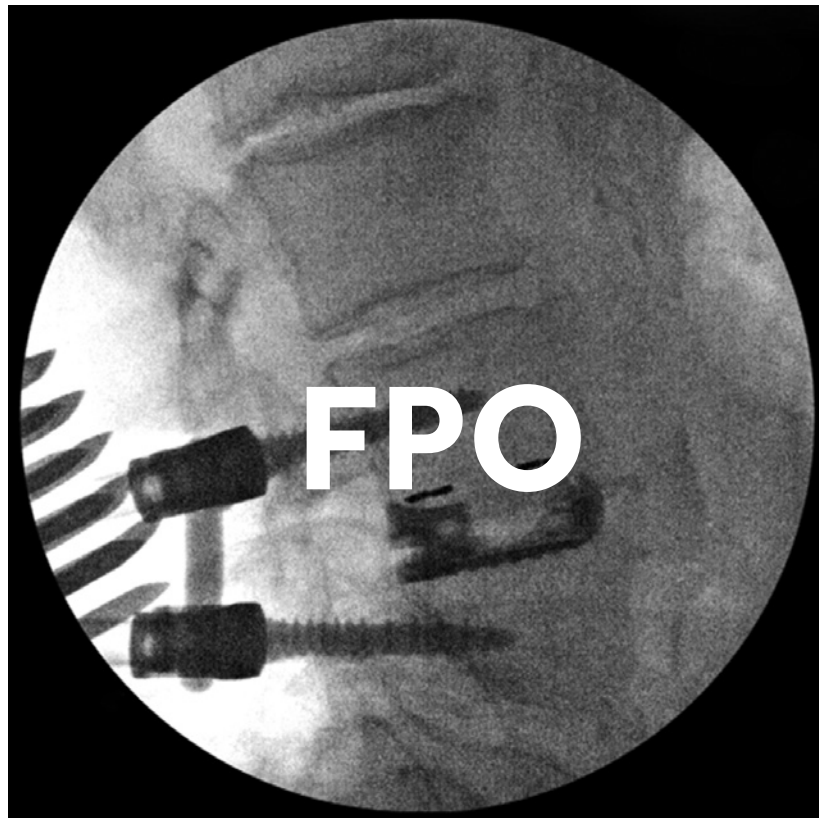


Figure 11

Elevate Expandable Interbody Device lateral view x-ray

Expandable Interbody Device Adjustment

If the implant must be repositioned or removed from the disc space, reattach the Inserter or use the Extraction Forceps. If the Inserter Assembly is used, collapse the implant by turning the Torque Handle counterclockwise (Figure 12). Attach a Slap Hammer to the Inserter Assembly to facilitate implant repositioning (Figure 13). If the implant will not collapse, the

Extractor Forceps may be used to help facilitate implant adjustment (Figure 14).

Please consider the increased risk to the neural elements during implant explantation.



Figure 12



Figure 13

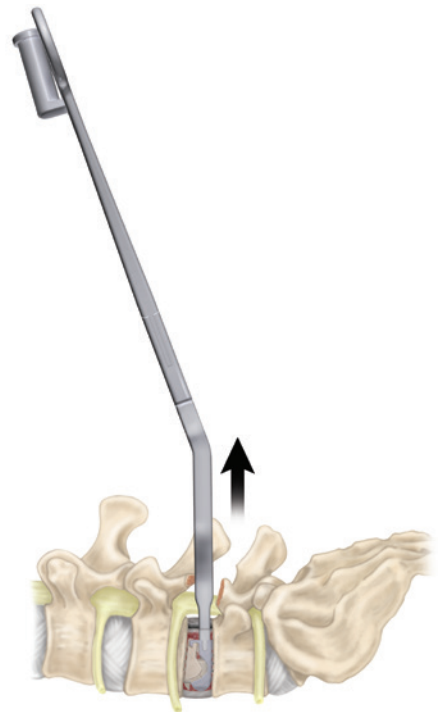
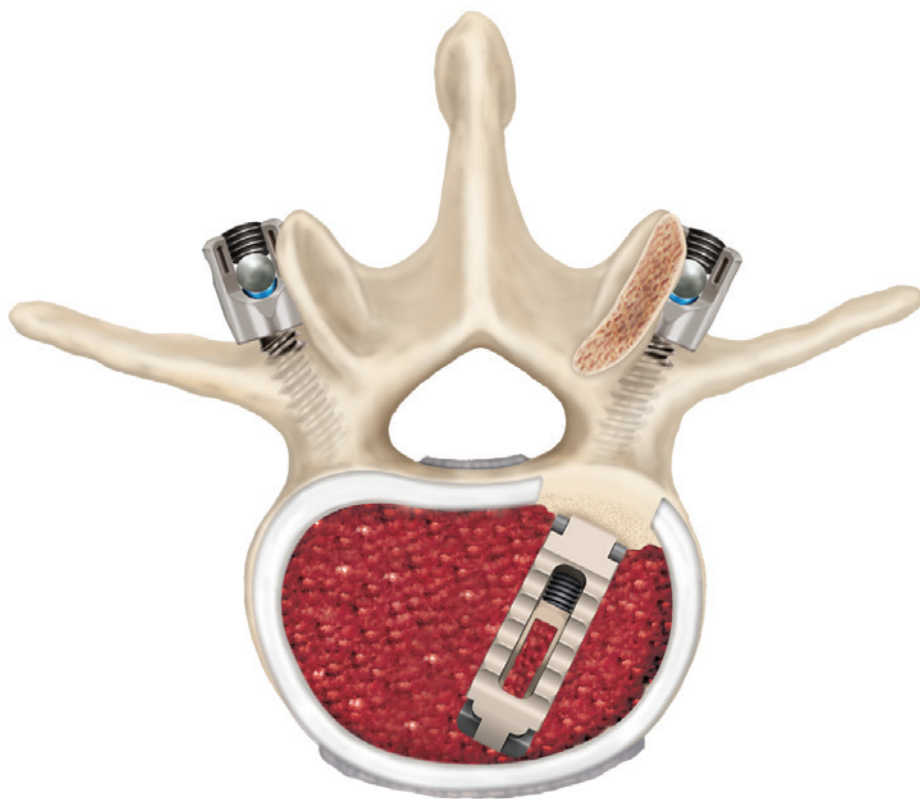


Figure 14

Supplemental Fixation / Postoperative Care

The Elevate Expandable Interbody Device is intended to be used with supplemental posterior fixation cleared for use in the lumbar spine.



Final position

PLIF APPROACH OPEN AND MINIMALLY INVASIVE TECHNIQUES

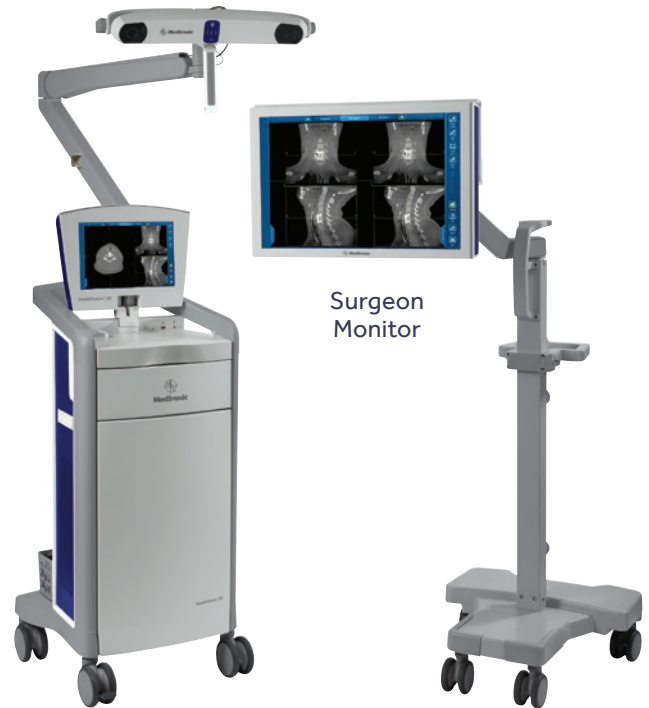
Positioning

Prone patient positioning in kyphosis facilitates the approach to the spinal canal as well as to the disc space. The kyphotic positioning should be taken into consideration when confirming implant sizing and angle in order to avoid hyperlordosis. Imaging guidance is only possible in the lateral view.

The prone position will allow a free abdomen to dismiss abdominal pressure on the stomach vessels. This can be achieved using a positioning frame or padding. Use a well padded prone support table that replicates physiological lordosis. This positioning may be tolerated by the patient for many hours and therefore may be suitable for extended spinal surgeries. Furthermore, it allows intraoperative imaging guidance in the A/P and lateral views. The O-Arm® Imaging System can be used to provide imaging assistance.



O-Arm Imaging System



Staff Cart with Camera

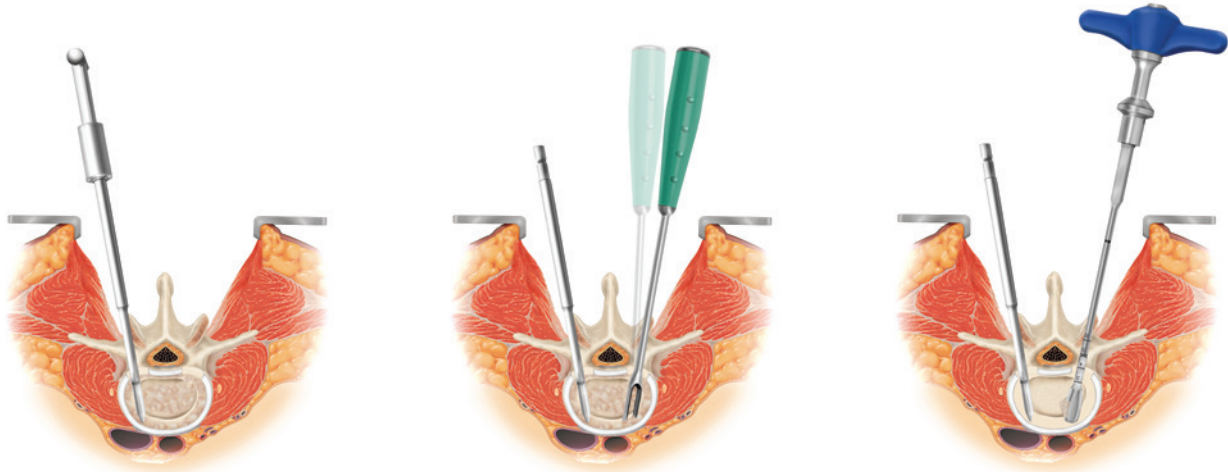
StealthStation S7 System

For complete labeling for the navigation products please contact Medtronic Navigation, General Business at 800-580-8860 or visit www.medtronic.com.

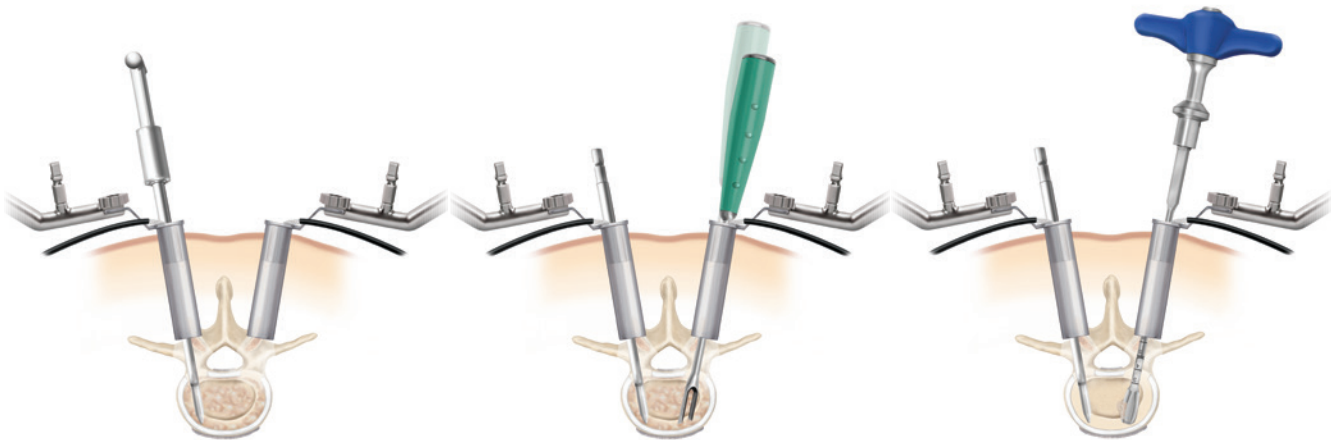
Decompression/Discectomy

Mark the affected segment in the midline after imaging guidance. Make a skin incision over midline or lateral to midline at the level of the affected segment. Expose the interlaminar window and the medial aspect of the facet joint. In general, a bony resection towards cranial and lateral is required in the area of the facet joints. Due to the design of the implants, a partial medial facetectomy is necessary to insert the implants into the disc space. In most of the cases, a resection of the spinous process is not required. The maintenance of the superior lamina is suggested to keep the interlaminar, as well as the interspinous, stability of the superior adjacent level and motion segment.

Open the annulus and resect the nucleus and the inner annulus as completely as possible. After discectomy, remove the endplate cartilage. Ensure that the bony endplates stay intact. Injuring bony endplates may lead to an implant subsidence into the vertebrae.



Open Technique



Minimally Invasive Technique

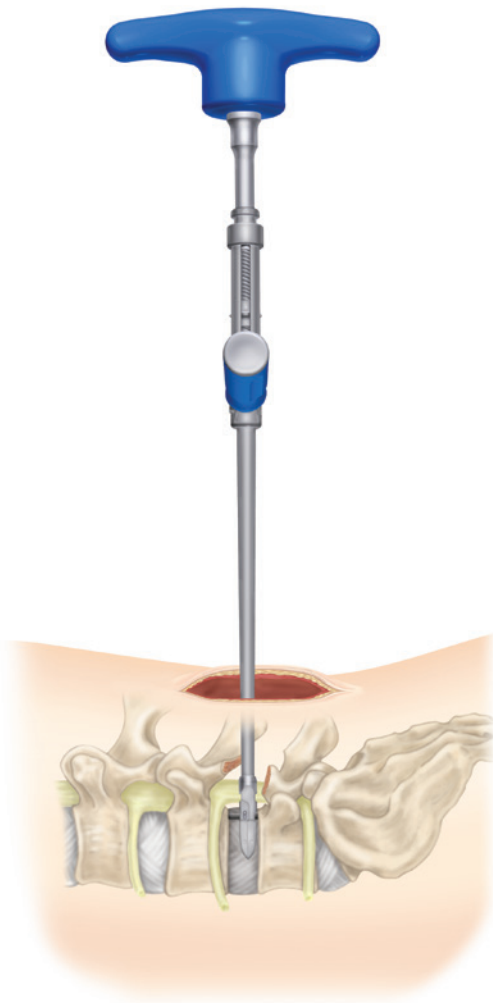
Distraction / Implant Size Determination

Instruments for use with the Elevate Spinal System:

Part Number	Description
8657005	Small Standard Distractor/Trial
8657006	Large Standard Distractor/Trial
8657007	Small Extra Lordotic Distractor/Trial
8657008	Large Extra Lordotic Distractor/Trial
G851200	Distractor Driver

For all following steps, please use caution during retraction of the dura mater and the offbranching nerve root(s).

In order to choose the appropriate type and size of the Distractor/Trial, use preoperative planning to determine the appropriate height and lordosis.



Open
Technique



Minimally Invasive
Technique

Distraction / Implant Size Determination Continued

Insert the Distractor/Trial into the disc space. A mallet may be used to facilitate placement. It is desirable to position the Distractor/Trial on the apophyseal ring. Attach the Distractor Driver onto the Distractor/Trial (Figure 15). Rotate the Distractor Driver in order to expand the tip of the Distractor/Trial (Figure 16).

Once a desired fit of the Distractor/Trial in the intervertebral disc space is achieved, determine the implant size. The window of the Distractor/Trial will show the intradiscal height of expansion. The head of the Distractor/Trial has length markings that are visible under fluoroscopy to help the surgeon determine the appropriate length implant to use (Figure 16a). Use chart on page 28 to choose the appropriate implant size.

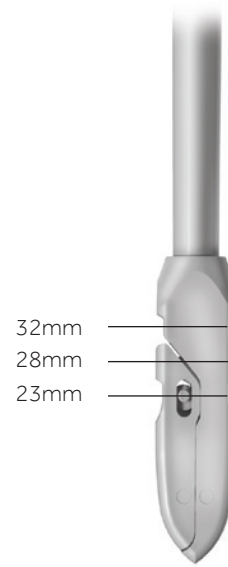


Figure 16a

Distractor/Trial markings



Figure 15

Attaching Distractor Driver onto the Distractor/Trial

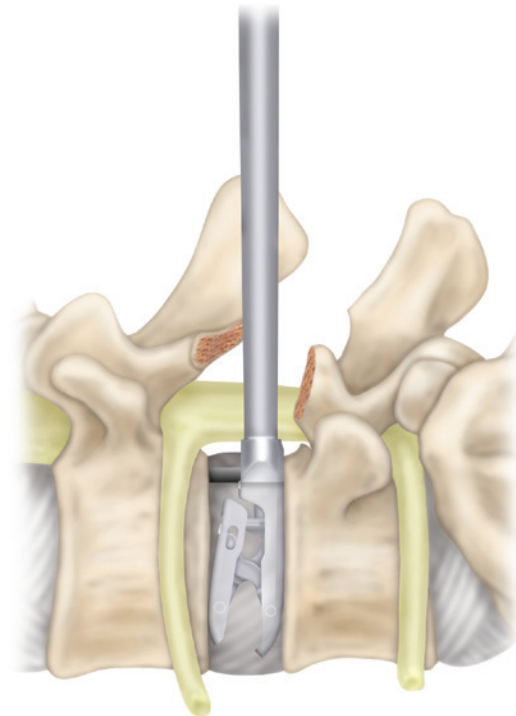


Figure 16

Expanded Distractor/Trial

This expandable interbody device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. In addition to the filling of the implant, the disc space may be filled with appropriate bone grafting material. Place anteriorly prior to implantation.

Expandable Interbody Device Implantation

Instruments for use with the Elevate Spinal System:

Part Number	Description
8657001	Insertor
8657002	Insertor Inner Locking Tube
8657003	Insertor Drive Shaft
G178101	Torque Handle
8657013	Leverage Tool

Remove the correct size implant from the intact sterile packing. Pay attention to a correct implant size determination.

Thread the Inner Locking Tube into the Insertor in order to assemble the Insertor Assembly (Figure 17). Next attach the implant to the Insertor by turning the Inner Locking Tube clockwise (Figure 18).

Ensure that the implant is attached to the Insertor so the PEEK portion of the implant with x-ray markers is superior during the insertion.



Expandable Interbody Device Implantation Continued

Carefully insert the implant into the disc space (Figure 19). A mallet may be used to facilitate placement.

Advance the implant anteriorly so that the leading tip of the implant rests on the anterior apophyseal ring.

Note

Ensure the screw on the back of the implant is fully retracted and the PEEK nose is fully recessed within the Titanium Alloy bottom.

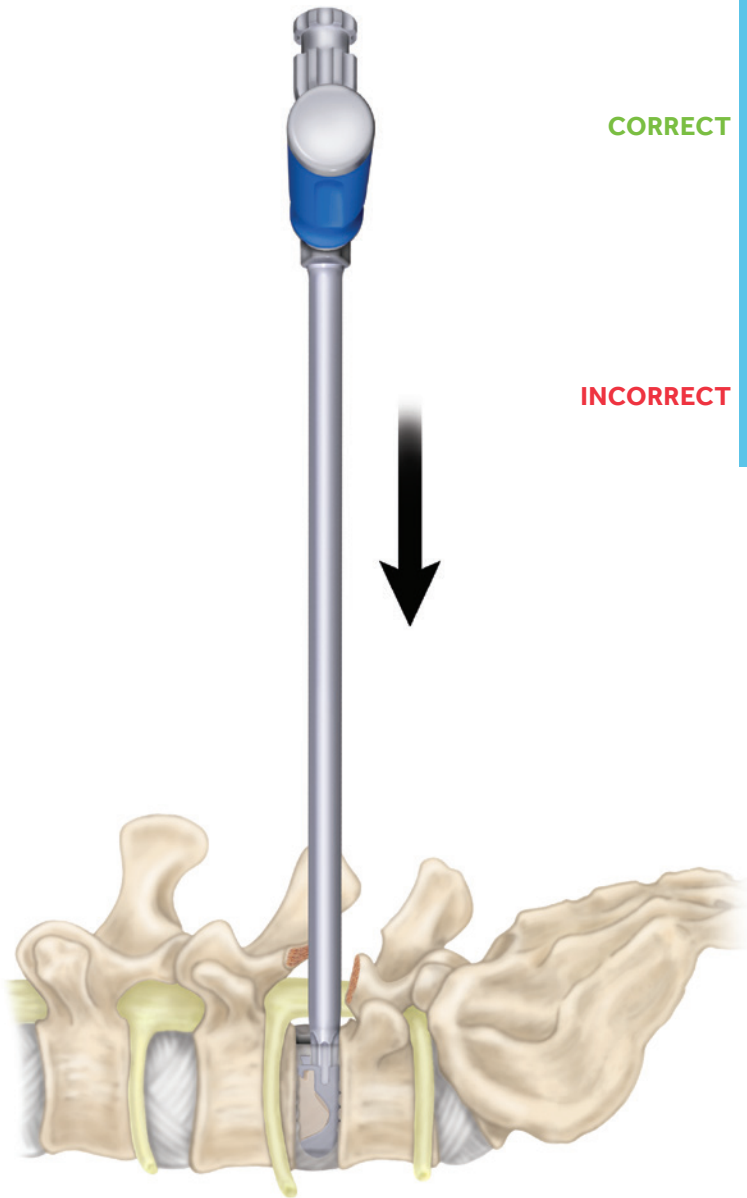
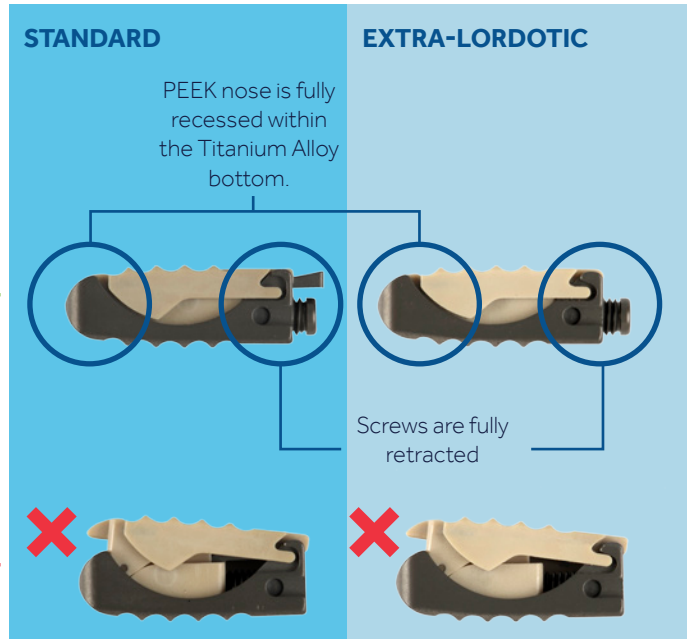


Figure 19



Expandable Interbody Device Implantation Continued

In order to expand the implant inside the disc space, insert the Inserter Drive Shaft along with the attached Torque Handle inside the Inserter Assembly (Figure 20). Next, turn the Torque Handle clockwise to expand the implant (Figure 21). Verify the correct position using imaging.

Important

The Torque Handle has a maximum torque of 2.5Nm to help mitigate the potential risk of endplate and implant damage.

Important

Do not strike the Torque Handle with a mallet or damage to the implant may result.

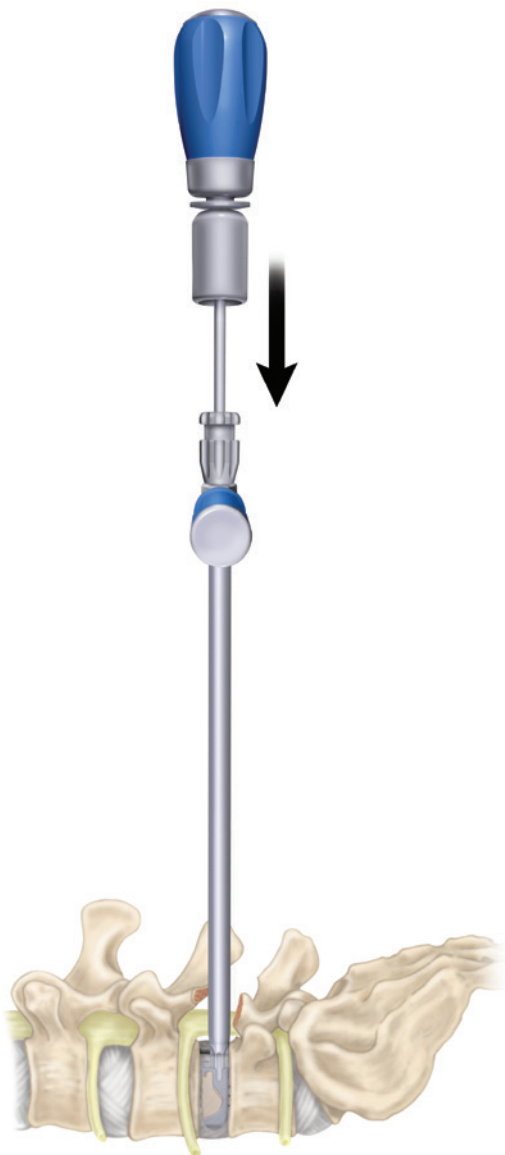


Figure 20

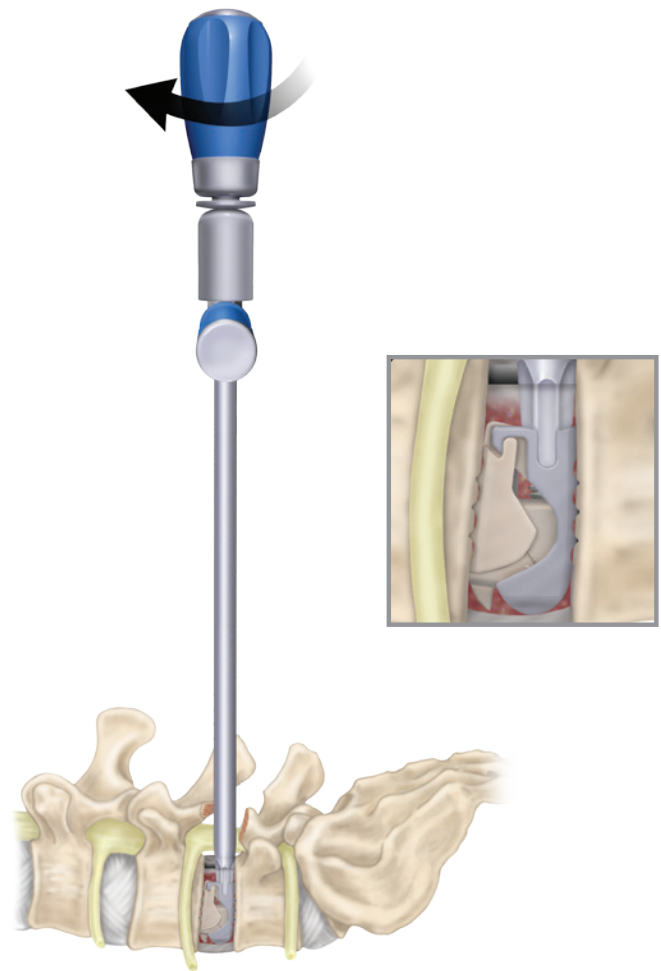


Figure 21

Expandable Interbody Device Implantation Continued

After implantation is completed, remove the Torque Handle and the Inserter Drive Shaft from the Inserter Assembly (Figure 22).

Next, disengage the Inner Locking Tube from the implant (Figure 23) and remove the Inner Locking Tube and Inserter from the disc space (Figure 24). Disassemble the Inner Locking Tube from the Inserter for cleaning.

Note

The Leverage Tool can be used to disengage the Inner Locking Tube from the implant.



Leverage Tool



Figure 22

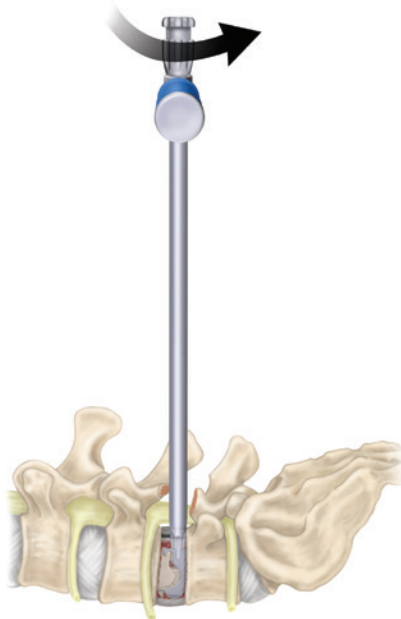


Figure 23



Figure 24

Expandable Interbody Device Implantation Continued

The implant can generate significant expansion forces. Care should be taken by the surgeon to avoid endplate damage caused by excessive expansion forces. If poor bone quality is suspected, the surgeon should limit the amount of torque that is delivered to the Torque Handle. Placement of the leading tip of the implant on the apophyseal ring is recommended.

The optimal position of the implant can be determined using the Tantalum x-ray markers in the implant (Figure 25).

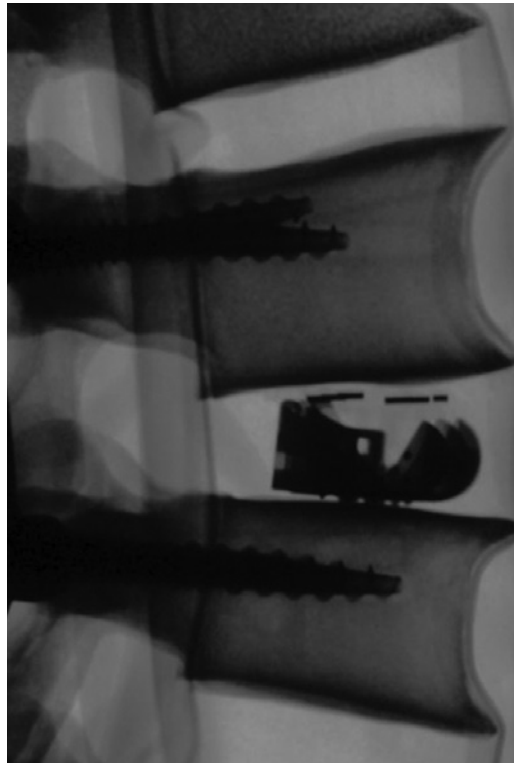


Figure 25

Elevate Expandable Interbody Device lateral view x-ray

Expandable Interbody Device Adjustment

If the implant must be repositioned or removed from the disc space, reattach the Inserter or use the Extraction Forceps. If the Inserter Assembly is used, collapse the implant by turning the Torque Handle counterclockwise (Figure 26). Then attach a Slap Hammer to the Inserter Assembly to facilitate implant repositioning (Figure 27). If the implant will not collapse, the

Extractor Forceps may be used to help facilitate implant adjustment (Figure 28).

Please consider the increased risk to the neural elements during implant explantation.

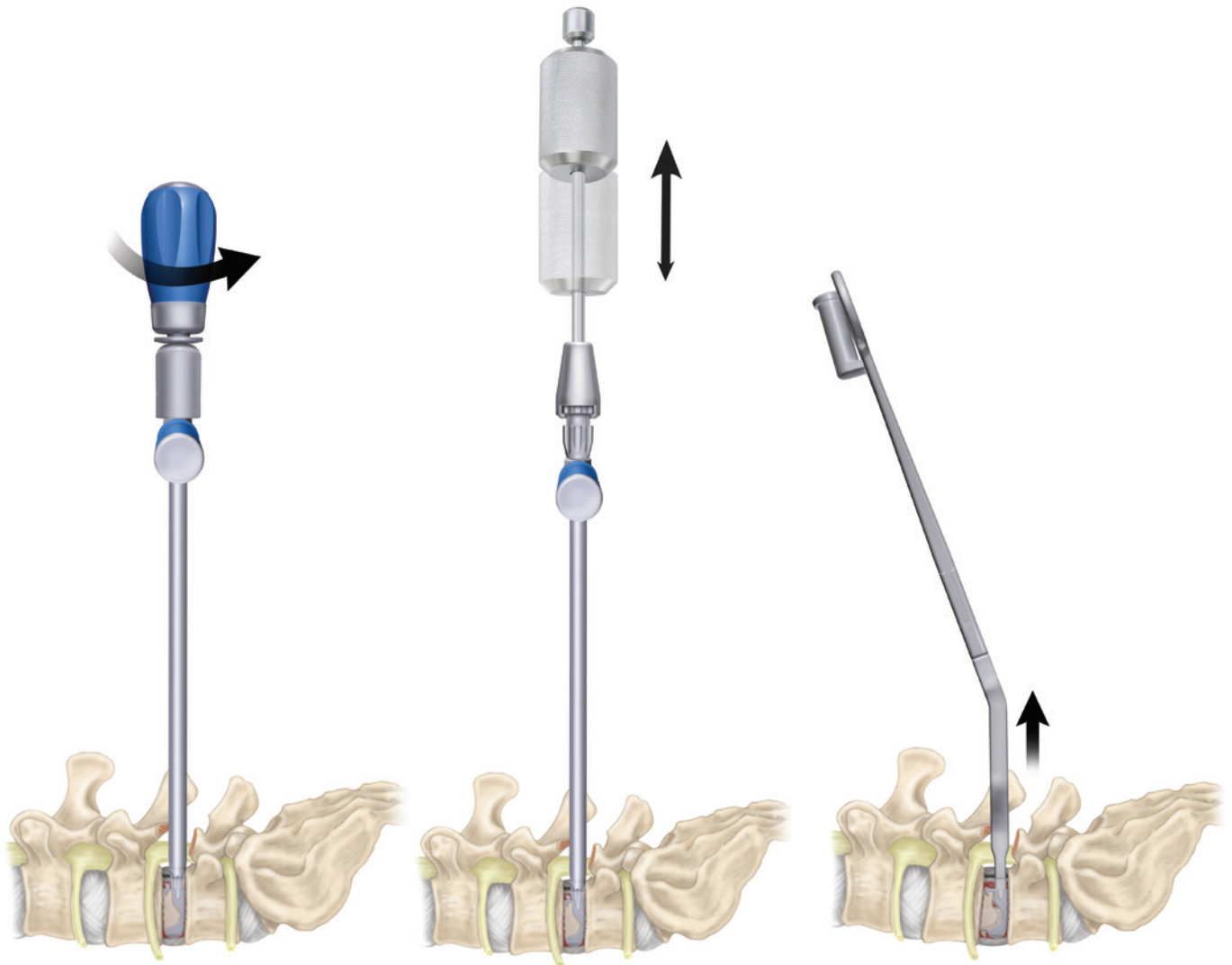


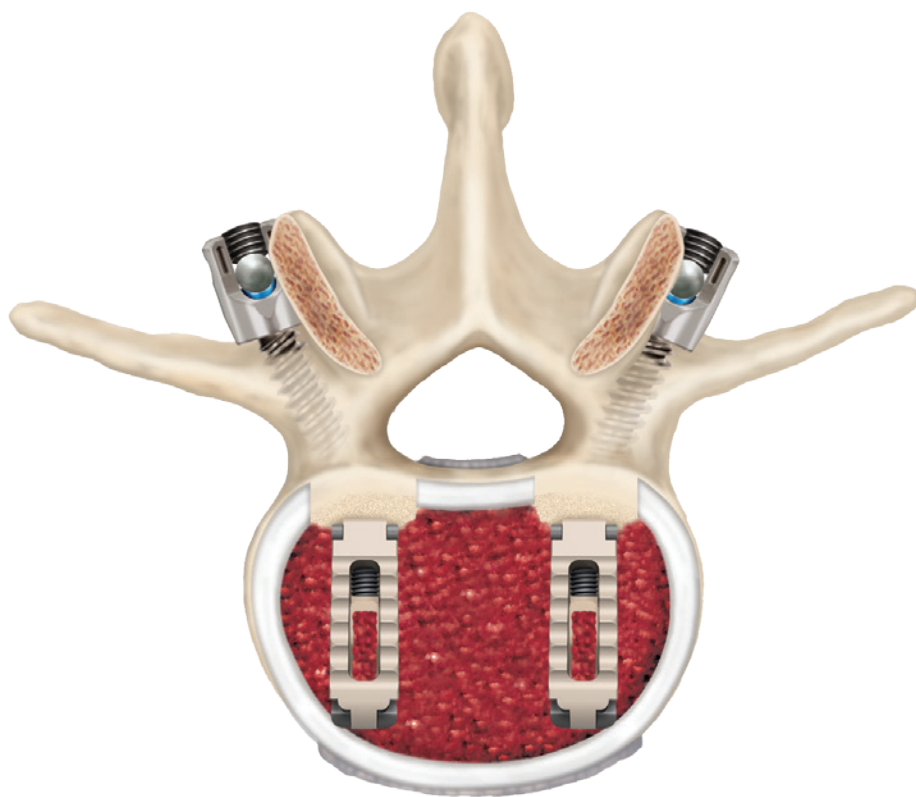
Figure 26

Figure 27

Figure 28

Supplemental Fixation / Postoperative Care

The Elevate Expandable Interbody Device is to be used with supplemental posterior fixation cleared for use in the lumbar spine.



Final position

MAST® MIDLF® PROCEDURE

A MAST MIDLF Procedure is an approach to the spine medial and deep to the segmental back muscles with the screw construct placed along the spinous process. For Exposure, Cortical Screw Starting Point and Trajectory Reference, Pilot Hole Starting Point and Drilling, Drill Positioning and Trajectory Reference, Fluoroscopic Trajectory Reference, Tapping, and Discectomy, please refer to the MAST MIDLF Procedure surgical technique.

IMPLANT EXPANSION MEASUREMENTS



Expanded



Collapsed

STANDARD IMPLANTS: Approximately 1mm of Posterior Expansion

Starting Height (mm) - Anterior	Length 23		Length 28		Length 32	
	Max Expanded Anterior Height (mm)	Max Lordosis (deg.)	Max Expanded Anterior Height (mm)	Max Lordosis (deg.)	Max Expanded Anterior Height (mm)	Max Lordosis (deg.)
Starting height 8mm	7770823 Elevate Standard 23 × 8mm		7770828 Elevate Standard 28 × 8mm		7770832 Elevate Standard 32 × 8mm	
	12	8	12	8	13	8
Starting height 9mm	7770923 Elevate Standard 23 × 9mm		7770928 Elevate Standard 28 × 9mm		7770932 Elevate Standard 32 × 9mm	
	13	8	13	8	14	8
Starting height 10mm	7771023 Elevate Standard 23 × 10mm		7771028 Elevate Standard 28 × 10mm		7771032 Elevate Standard 32 × 10mm	
	14	8	14	8	15	8
Starting height 11mm	7771123 Elevate Standard 23 × 11mm		7771128 Elevate Standard 28 × 11mm		7771132 Elevate Standard 32 × 11mm	
	15	8	16	8	16	8



Expanded



Collapsed

EXTRA-LORDOTIC IMPLANTS: No Posterior Expansion

Starting Height (mm) - Anterior	Length 23		Length 28		Length 32	
	Max Expanded Anterior Height (mm)	Max Lordosis (deg.)	Max Expanded Anterior Height (mm)	Max Lordosis (deg.)	Max Expanded Anterior Height (mm)	Max Lordosis (deg.)
Starting height 7mm	7770723 Elevate Extra Lordotic 23 × 7mm		7770728 Elevate Extra Lordotic 28 × 7mm		7770732 Elevate Extra Lordotic 32 × 7mm	
	11	13	12	11	12	10
Starting height 8mm	8880823 Elevate Extra Lordotic 23 × 8mm		8880828 Elevate Extra Lordotic 28 × 8mm		8880832 Elevate Extra Lordotic 32 × 8mm	
	12	13	13	11	13	10
Starting height 9mm	8880923 Elevate Extra Lordotic 23 × 9mm		8880928 Elevate Extra Lordotic 28 × 9mm		8880932 Elevate Extra Lordotic 32 × 9mm	
	13	13	14	11	14	10
Starting height 10mm	8881023 Elevate Extra Lordotic 23 × 10mm		8881028 Elevate Extra Lordotic 28 × 10mm		8881032 Elevate Extra Lordotic 32 × 10mm	
	14	13	15	11	15	10
Starting height 11mm	8881123 Elevate Extra Lordotic 23 × 11mm		8881128 Elevate Extra Lordotic 28 × 11mm		8881132 Elevate Extra Lordotic 32 × 11mm	
	15	13	16	13	16	12

Expansion numbers are meant to give close approximations of specific implant's expansion limitations taking into account an implant assembly at nominal geometry.

PRODUCT ORDERING INFORMATION

Elevate Instrument Set SPS02706

Part Number	Description
8657001	Inserter
8657002	Inserter Inner Locking Tube
8657003	Inserter Drive Shaft
G178101	Torque Handle
8657005	Small Standard Distractor/Trial
8657006	Large Standard Distractor/Trial
8657007	Small Extra Lordotic Distractor/Trial
8657008	Large Extra Lordotic Distractor/Trial
G851200	Distractor Driver
8657012	Extractor Forceps
8657011	Slap Hammer
8657013	Leverage Tool

ELEVATE SPINAL SYSTEM EXPANDABLE INTERBODY DEVICE
 PRODUCT ORDERING INFORMATION

Elevate Spinal System Implants Standard and Extra-Lordotic 23 and 28mm SPS02710					
Part Number	Starting Height	Expanded Anterior Height	Length	Description	Quantity
7770723	7mm	11mm	23mm	Elevate Extra-Lordotic 23 × 7mm	2
7770728	7mm	12mm	28mm	Elevate Extra-Lordotic 28 × 7mm	2
7770828	8mm	12mm	28mm	Elevate Standard 28 × 8mm	2
8880823	8mm	12mm	23mm	Elevate Extra-Lordotic 23 × 8mm	2
7770823	8mm	12mm	23mm	Elevate Standard 23 × 8mm	2
8880828	8mm	13mm	28mm	Elevate Extra-Lordotic 28 × 8mm	2
8880923	9mm	13mm	23mm	Elevate Extra-Lordotic 23 × 9mm	2
7770923	9mm	13mm	23mm	Elevate Standard 23 × 9mm	2
7770928	9mm	13mm	28mm	Elevate Standard 28 × 9mm	2
8880928	9mm	14mm	28mm	Elevate Extra-Lordotic 28 × 9mm	2

Elevate Spinal System Implants Standard and Extra-Lordotic 32mm SPS02711					
Part Number	Starting Height	Expanded Anterior Height	Length	Description	Quantity
7770732	7mm	12mm	32mm	Elevate Extra-Lordotic 32 × 7mm	1
8880832	8mm	13mm	32mm	Elevate Extra-Lordotic 32 × 8mm	1
7770832	8mm	13mm	32mm	Elevate Standard 32 × 8mm	1
8880932	9mm	14mm	32mm	Elevate Extra-Lordotic 32 × 9mm	1
7770932	9mm	14mm	32mm	Elevate Standard 32 × 9mm	1

Implants available for order as extra					
Part Number	Starting Height	Expanded Anterior Height	Length	Description	
8881023	10mm	14mm	23mm	Elevate Extra-Lordotic 23 × 10mm	
8881028	10mm	15mm	28mm	Elevate Extra-Lordotic 28 × 10mm	
8881032	10mm	15mm	32mm	Elevate Extra-Lordotic 32 × 10mm	
7771023	10mm	14mm	23mm	Elevate Standard 23 × 10mm	
7771028	10mm	14mm	28mm	Elevate Standard 28 × 10mm	
7771032	10mm	15mm	32mm	Elevate Standard 32 × 10mm	
8881123	11mm	15mm	23mm	Elevate Extra-Lordotic 23 × 11mm	
8881128	11mm	16mm	28mm	Elevate Extra-Lordotic 28 × 11mm	
8881132	11mm	16mm	32mm	Elevate Extra-Lordotic 32 × 11mm	
7771123	11mm	15mm	23mm	Elevate Standard 23 × 11mm	
7771128	11mm	16mm	28mm	Elevate Standard 28 × 11mm	
7771132	11mm	16mm	32mm	Elevate Standard 32 × 11mm	

IMPORTANT INFORMATION ON THE ELEVATE SPINAL SYSTEM

PURPOSE

This device is a fusion device intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician thoroughly knowledgeable in the implant's material and surgical aspects, and who has been instructed as to its mechanical and material applications and limitations.

DESCRIPTION

The ELEVATE™ Spinal System is an expandable PEEK, Tantalum, and Titanium alloy interbody device consisting of various lengths and starting heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The ELEVATE™ Spinal System expands for adjustable lordosis and height to match patient anatomy. The hollow geometry of the implants allows them to be packed with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. The implants may be implanted via a posterior or transforaminal approach and the procedure may be open or minimally invasive. The ELEVATE™ Spinal System can be implanted unilaterally and bilaterally. The ELEVATE™ Spinal System is intended to be inserted with ELEVATE™ Spinal System reusable instruments. ELEVATE™ Spinal System implants are for single use only. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS

The ELEVATE™ Spinal System Expandable Interbody Fusion Device is indicated for interbody fusion with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. These implants are to be used with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

CONTRAINDICATIONS

This device is not intended for cervical spine use.

Contraindications include, but are not limited to:

- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing a fusion.
- Any case not described in the Indications.
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

PLEASE NOTE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

Take into consideration that the segmental stability can be affected by a variety of factors.

POTENTIAL ADVERSE EVENTS

Adverse effects may occur when the device is used either with or without associated instrumentation. The risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include, but are not limited to:

- Implant migration.
- Breakage of the device(s).

- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis).
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain.
- Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury; and cerebral spinal fluid leakage.
- Hemorrhage of blood vessels and/or hematomas.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening or movement of the device(s).
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Change in mental status.
- Cessation of any potential growth of the operated portion of the spine.
- Death.

Note: Additional surgery might become necessary to correct adverse effects.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Trial distractors enable a simple and safe size destination. Over-distraction is to be avoided. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

When used in deformity procedures, undersizing the implant may limit endplate engagement and potentially lead to implant migration and/or expulsion.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

Document the used implants per patient with REF and LOT, so that the tracking, which is required by law, is guaranteed. The implants are only for single use. Do not re-process or re-use devices labeled as single use devices. Re-processing or re-use of single use devices may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

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

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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.

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