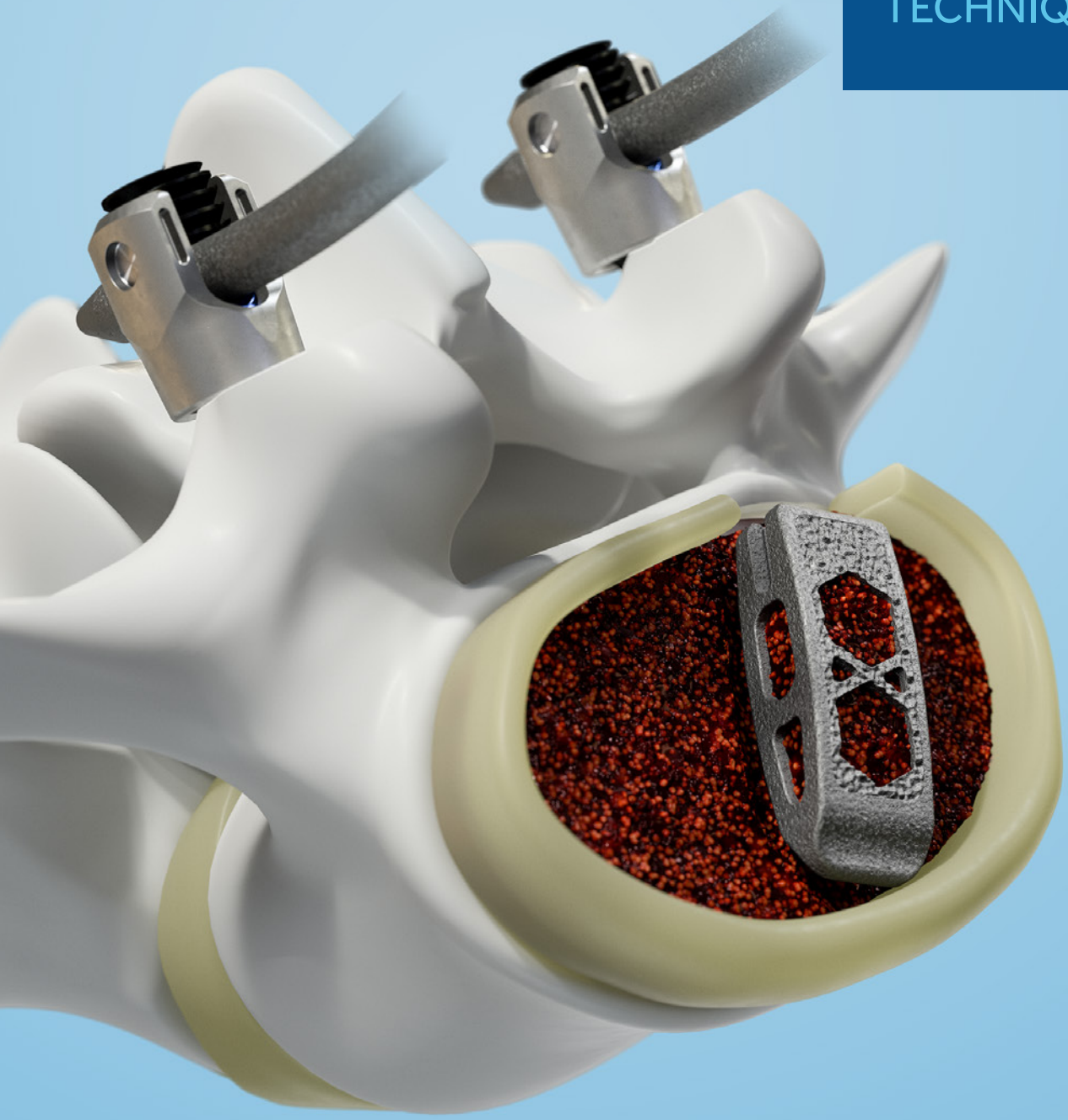
Adaptix™ Interbody System

with Titan nanoLOCK™ Surface Technology

SURGICAL TECHNIQUE



Medtronic

Further, Together

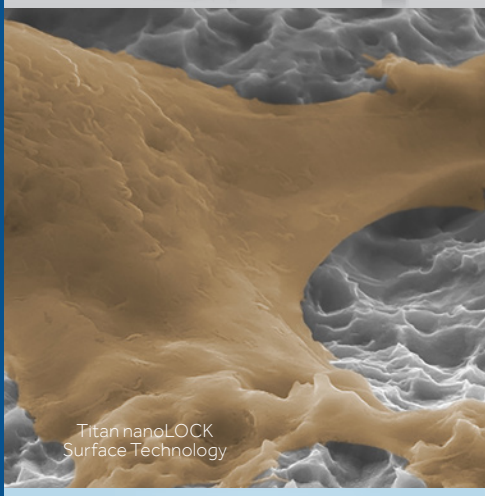
TABLE OF CONTENTS

INTRODUCTION

The Adaptix Interbody System was developed as an implant for stabilization of the lumbar spinal column via an open or minimally invasive transforaminal lumbar interbody fusion (TLIF) or posterior lumbar interbody fusion (PLIF) procedure. This surgical technique is designed to familiarize healthcare professionals with the surgical procedure. Please carefully read this surgical technique prior to the use of the implant.

The Adaptix Interbody System is a bullet-shaped titanium implant with a dolphin nose tip and Titan nanoLOCK Surface Technology that is designed for sagittal alignment restoration in the lumbar spine by offering multiple heights, and lengths.

StealthStation™ Navigation System



Titan nanoLOCK Surface Technology

Adaptix Implant

Risks

Risks/potential risks associated with the device include, but are not limited to:

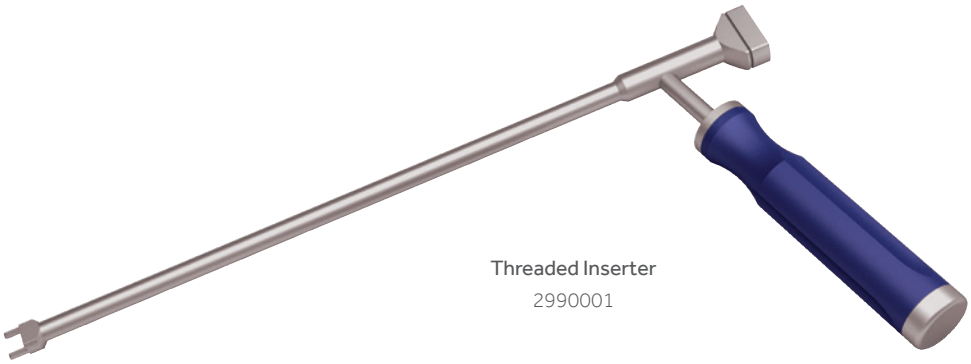
- Implant migration
- Loss of spinal curvature, correction, height, and/or reduction
- Bone fracture or stress shielding at, above, or below the level of surgery
- Bone graft donor site complication
- Loss of or increase in spine mobility or function
- Endplate disruption
- Neurological impairment

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

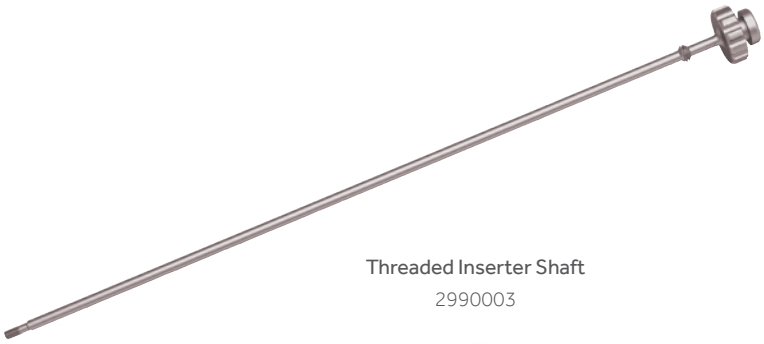
INSTRUMENT SET

IMPORTANT:
Please refer to "Trial Selection" section to ensure that the appropriate trial is used.

Distractor/Trial
2980822
See Product Ordering Information
for list of available trials.



Threaded Inserter
2990001



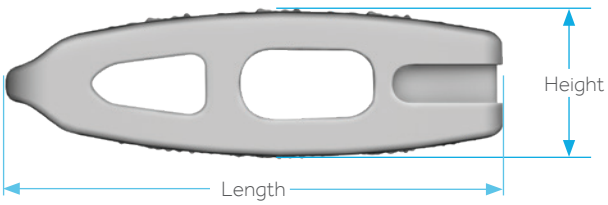
Threaded Inserter Shaft
2990003

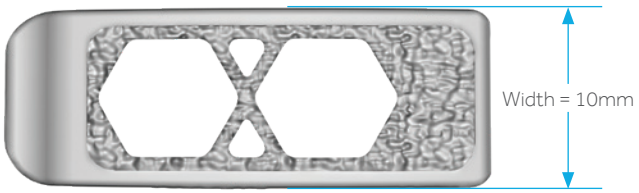
Slap Hammer
9074002

IMPLANT SIZE AND INTERNAL VOLUME

Part #	Length	Height	Internal Volume
84332406	24mm	6mm	0.33cc
84332407	24mm	7mm	0.35cc
84332408	24mm	8mm	0.40cc
84332409	24mm	9mm	0.45cc
84332410	24mm	10mm	0.51cc
84332411	24mm	11mm	0.56cc
84332412	24mm	12mm	0.61cc
84332413	24mm	13mm	0.67cc
84332414	24mm	14mm	0.72cc
84332415	24mm	15mm	0.77cc
84332416	24mm	16mm	0.82cc
84332806	28mm	6mm	0.40cc
84332807	28mm	7mm	0.48cc
84332808	28mm	8mm	0.58cc
84332809	28mm	9mm	0.66cc
84332810	28mm	10mm	0.74cc
84332811	28mm	11mm	0.82cc
84332812	28mm	12mm	0.89cc
84332813	28mm	13mm	0.97cc
84332814	28mm	14mm	1.05cc
84332815	28mm	15mm	1.12cc
84332816	28mm	16mm	1.20cc
84333407	34mm	7mm	0.61cc
84333408	34mm	8mm	0.70cc
84333409	34mm	9mm	0.80cc
84333410	34mm	10mm	0.89cc
84333411	34mm	11mm	0.98cc
84333412	34mm	12mm	1.08cc
84333413	34mm	13mm	1.17cc
84333414	34mm	14mm	1.27cc
84333415	34mm	15mm	1.36cc
84333416	34mm	16mm	1.45cc

Size Specifications





TLIF: Open and MAST Techniques

NAVIGATION AND NEUROMONITORING OPTIONS

Neuromonitoring Option

For neuromonitoring, a NIM™ PAK Needle or Navigated NIM™ PAK Needle may be used to access the pedicle. Triggered electromyograph (EMG) monitoring can be performed during advancement of the needle into the pedicle to ensure proper placement (**Figure 1**).

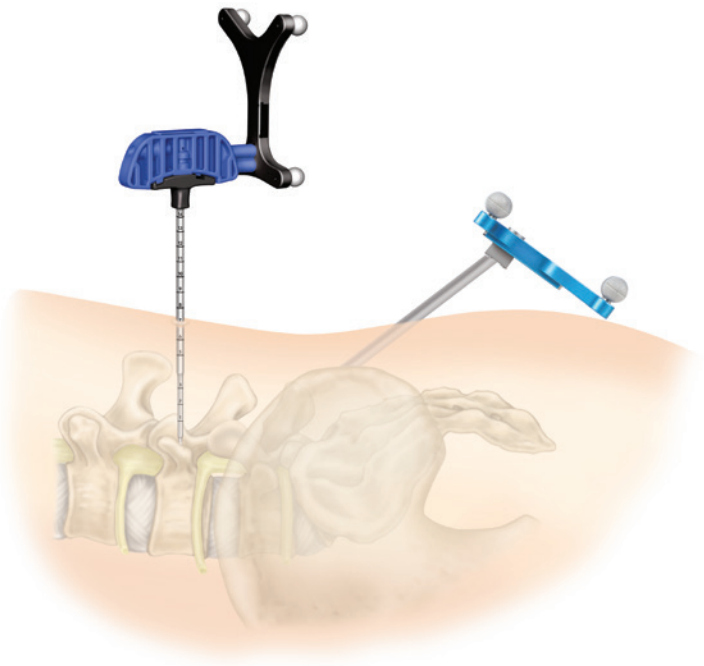


Figure 1

IMPORTANT

Please see the NIM-Eclipse™ Spinal System package insert and user's manual for complete instructions and a list of warnings, precautions, and other medical information.

The NIM-Eclipse System is intended for use to record, monitor, and stimulate/record biopotential signals including EMG, evoked response and nerve/muscle potentials, and for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. The system provides feedback to the surgeon and OR team to assist in the localization and assessment of spinal nerves and verification of placement of spinal instrumentation to avoid injury to at-risk nerve roots (**Figure 2**).

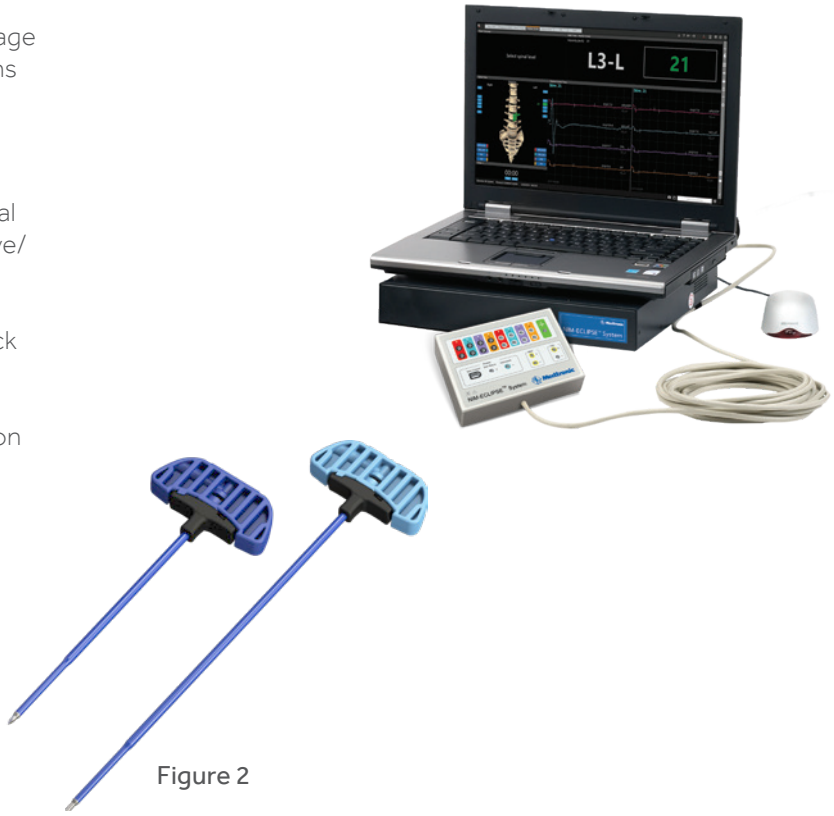


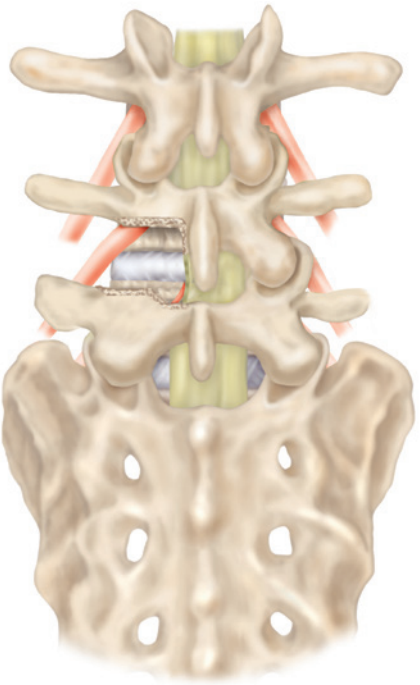
Figure 2

FACETECTOMY

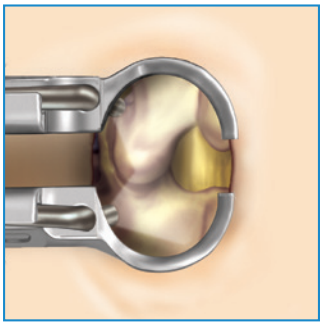
Expose the interlaminar window and the medial aspect of the facet joint. In general, a bony resection towards cranial and lateral is required in the area of the facet joints. Due to the design of the implants, a partial medial facetectomy is necessary to insert the implants into the disc space. In most 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.

Careful attention must be paid to removing a sufficient amount of the inferior portion of the inferior articulation facet and superior portion of the superior articulating facet to safely access the disc space **(Figures 3 and 4)**.

Use an Osteotome, Box Chisel, or Kerrison to remove the inferior end plate ridge adjacent to the pedicle.



Open Technique
Figure 3



MAST Technique
Figure 4

Aquamantys™ may be used to control bleeding from the paraspinous muscles during the exposure and to pretreat high risk vessels <1mm such as the parafacetal arteries. Aquamantys bipolar sealers can control and reduce blood loss leading to improved visibility and reduced surgical time.[1,2]

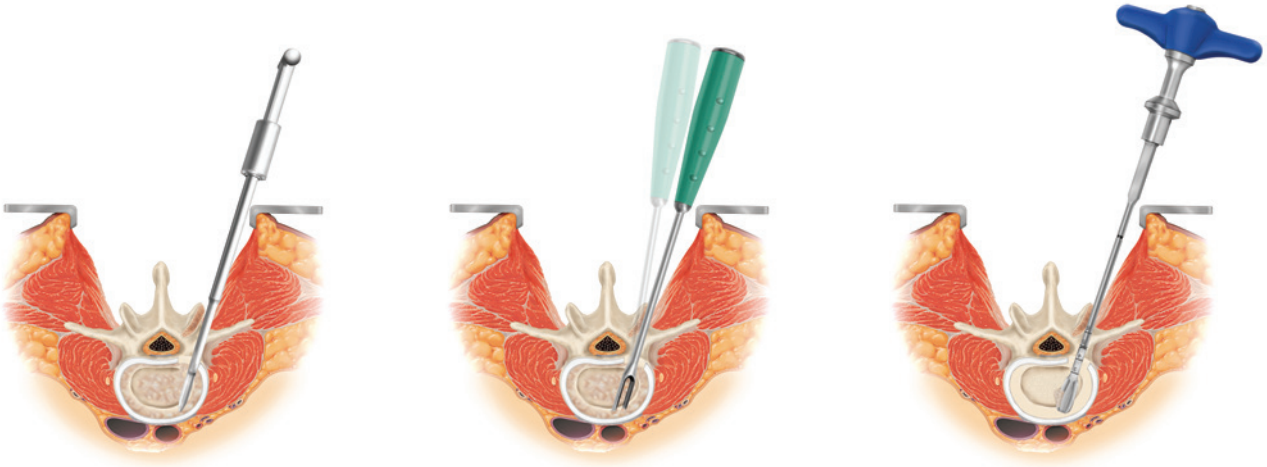
The Midas Rex™ high speed drilling system can be used to remove bone during spinal procedures.

1. Mankin KP, Moore CA, Miller LE, Block JE. Hemostasis with a bipolar sealer during surgical correction of adolescent idiopathic scoliosis. *J Spinal Disord Tech.* 2012;25(5):259-263.

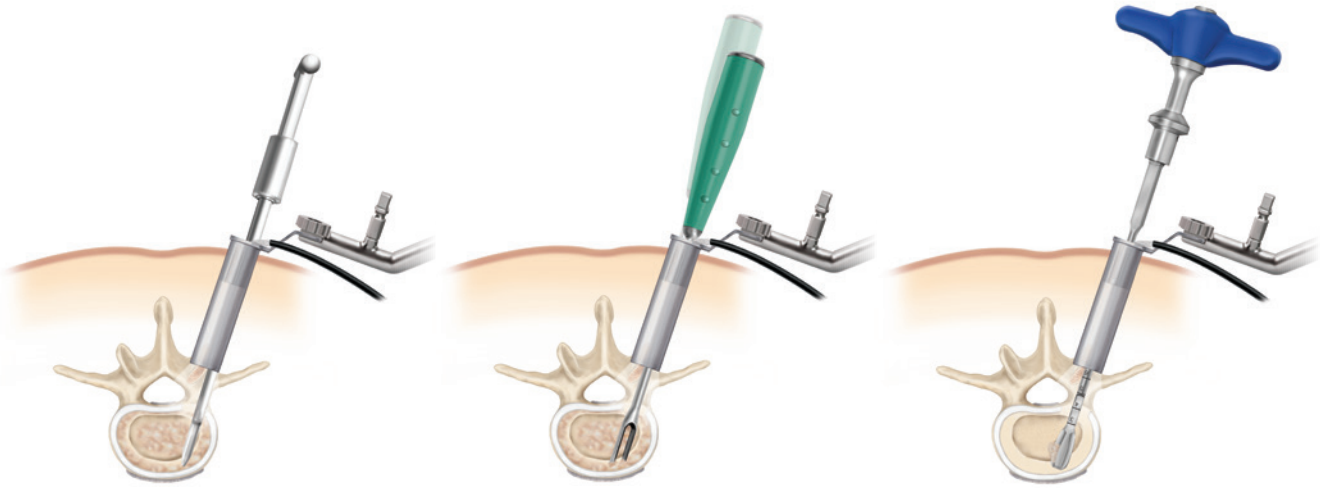
2. Snyder BD, Hedequist D, Shannon E. Hemostatic efficacy of bipolar wound sealer as adjunct to wound management in children with neuromuscular scoliosis. Poster presentation at Pediatric Orthopaedic Society of North America Annual Meeting 2007; Hollywood, FL.

DECOMPRESSION / DISCECTOMY

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.



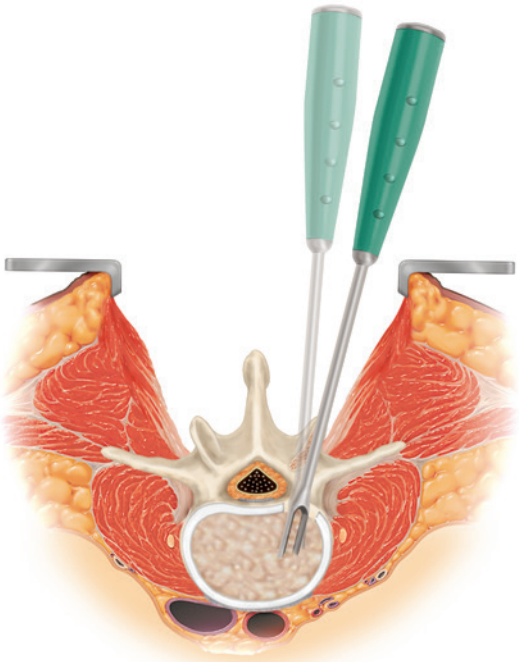
Open Technique

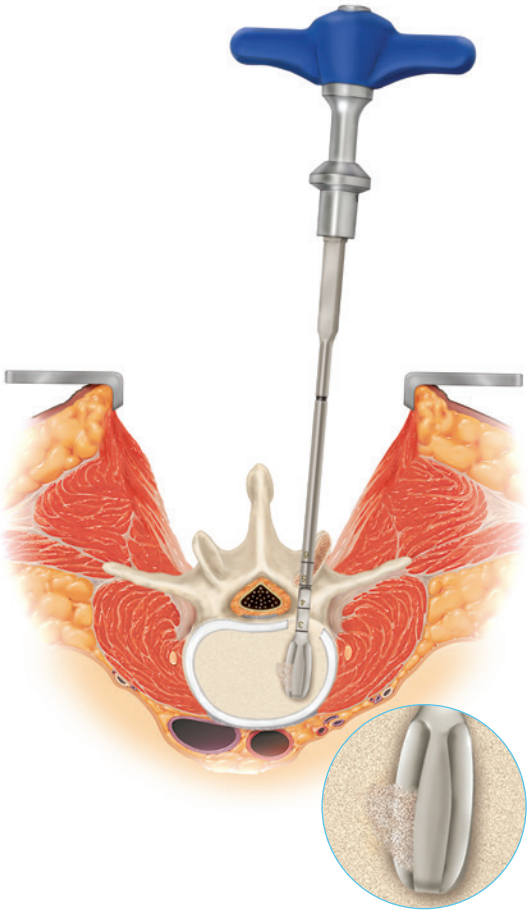


MAST Technique

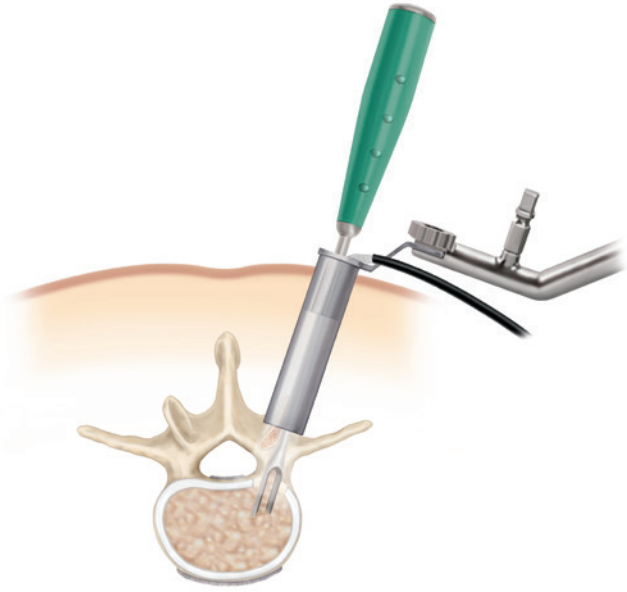
DISC SPACE **PREPARATION**

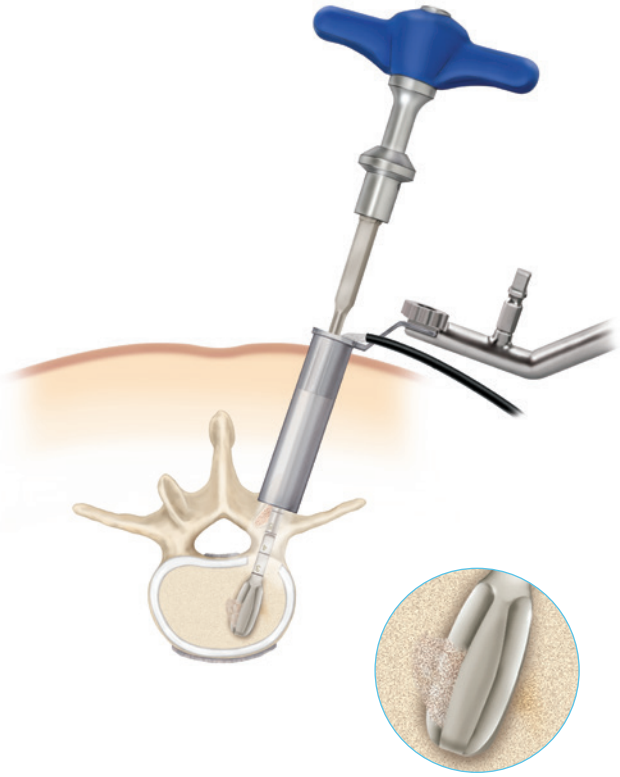
Open TLIF Technique





Remove disc using the blunt-tipped and side-cutting Rotate Cutters and/or the Disc Shavers.

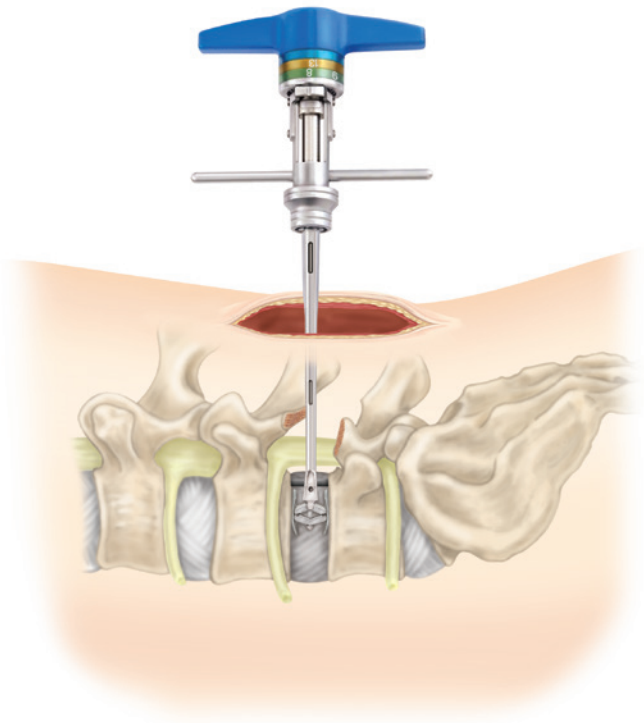




MAST TLIF Technique

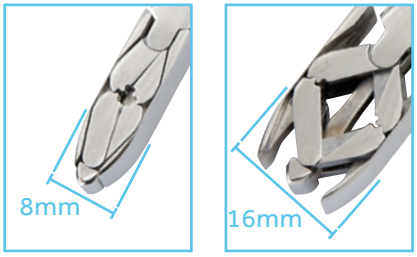
DISTRACTION

Open TLIF Technique

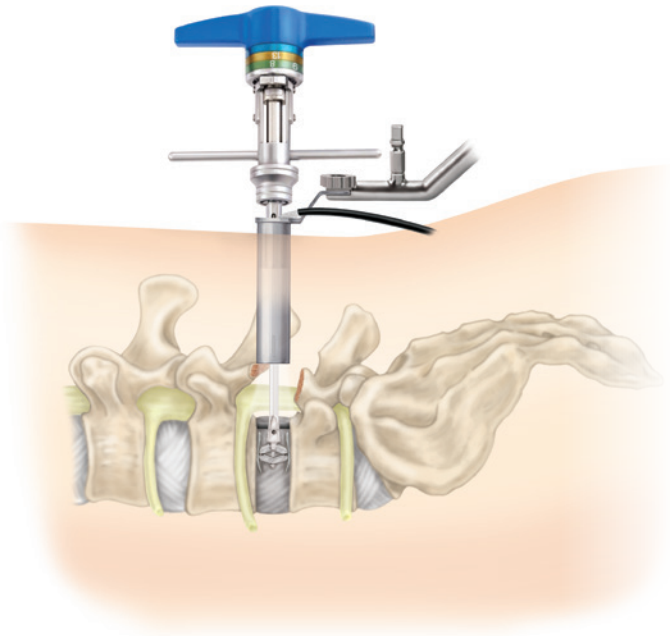


The disc space is sequentially distracted with a Distractor/Trial or the Scissor Jack™ Distractor until adequate disc space height is obtained and adequate foraminal size is restored.

If the Scissor Jack Distractor is used, insert the distractor with the curved sides touching the end plates and expand the distractor until the desired height is obtained.



Closed Open

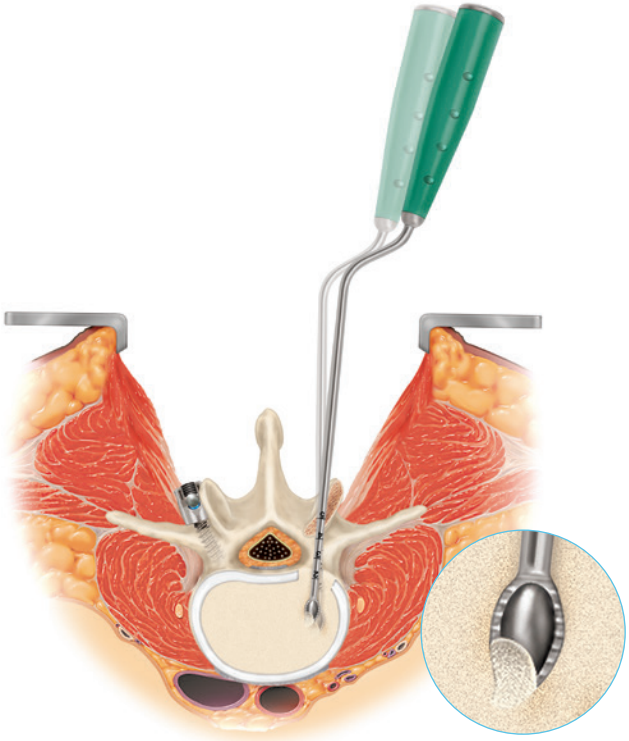


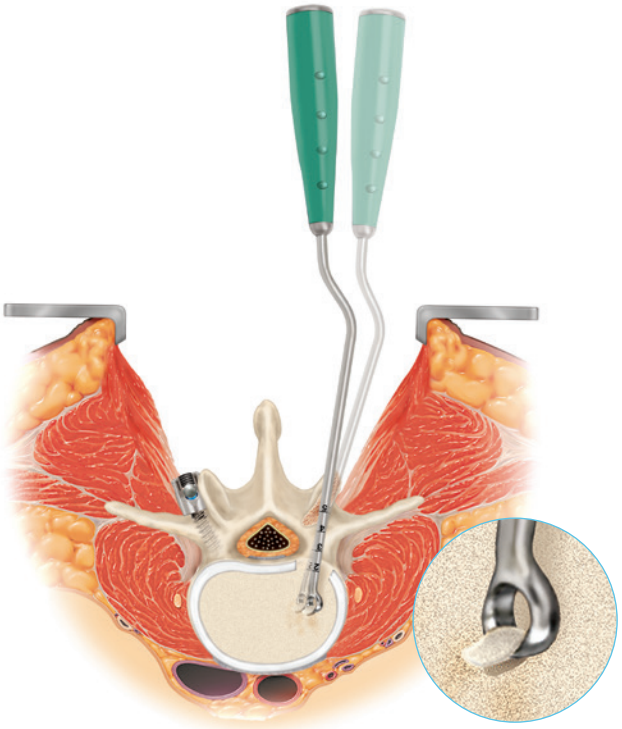
Insert supplemental screw and rod fixation and provisionally tighten the construct on the contralateral side to maintain distraction during disc space preparation.

MAST TLIF Technique

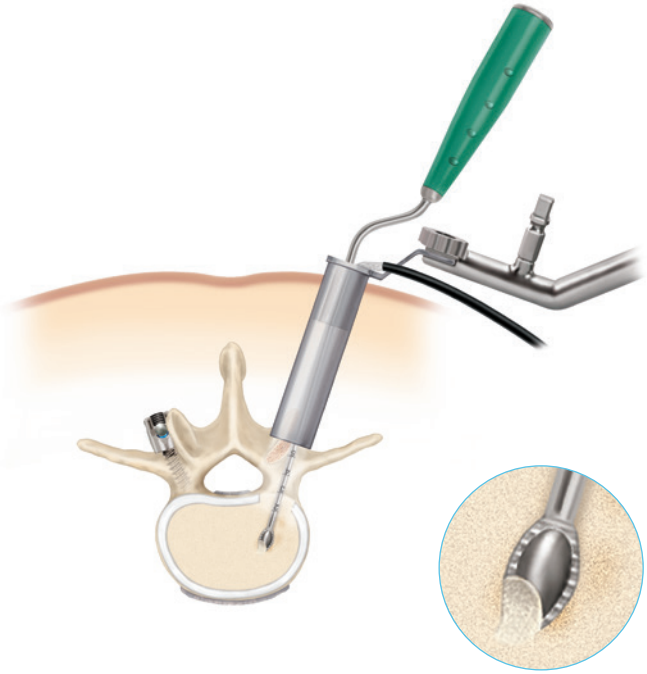
END PLATE **PREPARATION**

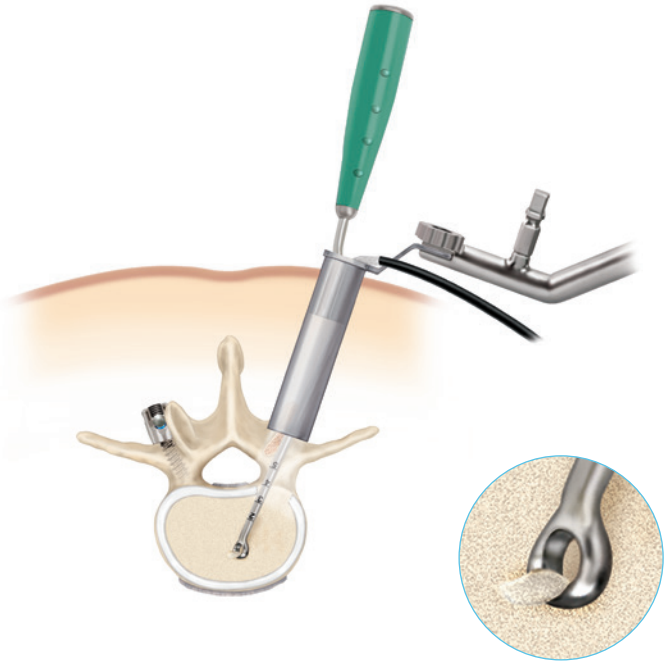
Open TLIF Technique





Specifically designed angled instruments allow disc resection and end plate preparation.

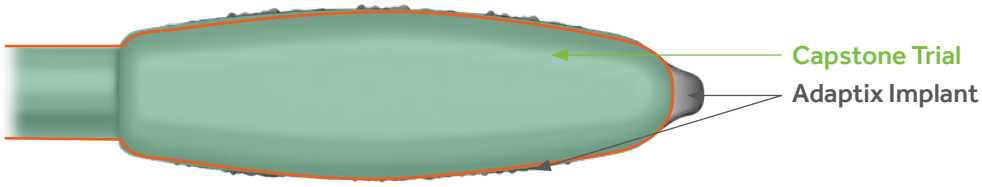




MAST TLIF Technique

IMPLANT
SIZE SELECTION

Medtronic Capstone Spinal System Trials can be used for sizing the Adaptix Implant. The below image is an overlay of the Capstone Trial and Adaptix Implant, illustrating their shared profiles.



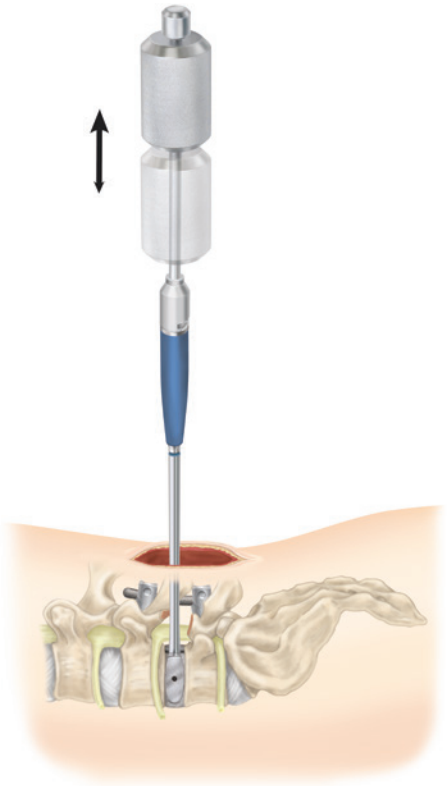
Trial Selection Guide

Refer to the below table for using Capstone Spinal System Trials with Adaptix Implants:

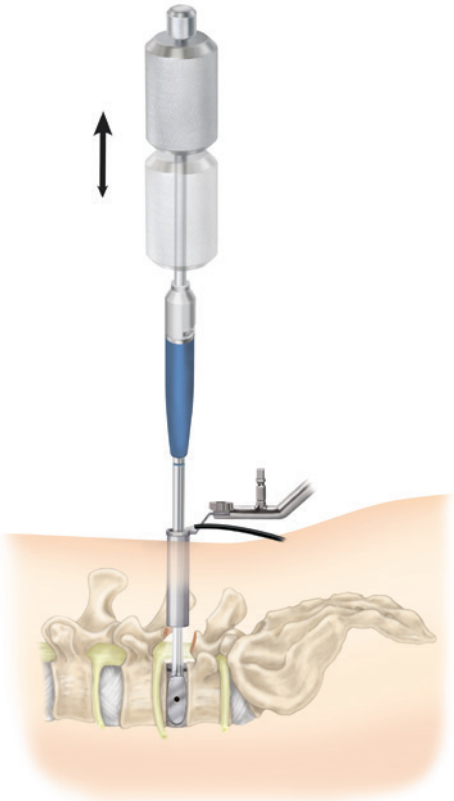
Capstone Trial Length	Adaptix Implant Length
22mm	24mm
26mm	28mm
32mm	34mm

TRIAL
INSERTION

Open TLIF Technique



Insert the Distractor/Trial until the desired disc space height is established. Use AP and lateral fluoroscopy to confirm proper placement and trajectory. A slap hammer can be used for removal.



AP View

MAST TLIF Technique

IMPLANT FILLING

The implant can be filled with either autograft bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate.

Autograft can be collected from the surgical site and morselized using the Midas Rex™ Electric Bone Mill System (**Figure 5**) or can be recovered from a secondary site using the Corex™ minimally invasive bone harvester **(Figure 6)**.

Allograft material such as cancellous and/or corticocancellous bone graft may be used. This can also be hydrated with CBMA using the Marrow Cellutions advanced bone marrow aspirate system.

The lateral and transverse openings can be used to fill the implant. **(Figures 7 and 8)**.

Figure 5

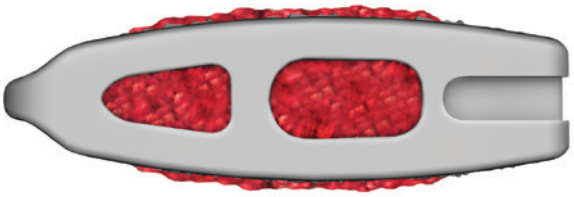


Figure 7

Figure 6

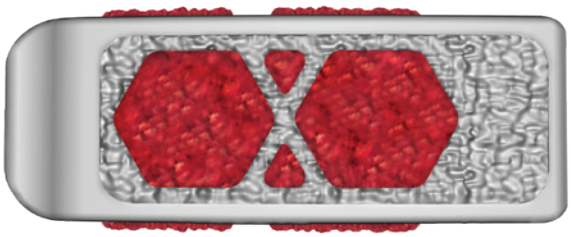


Figure 8

IMPLANT INSERTION

Open TLIF Technique

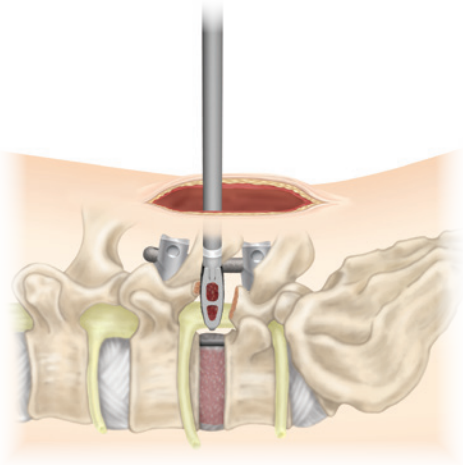


Figure 9

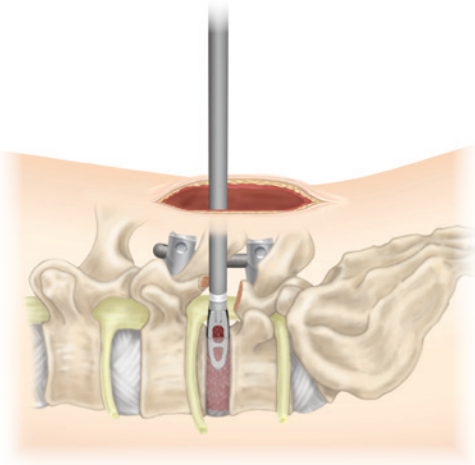


Figure 10

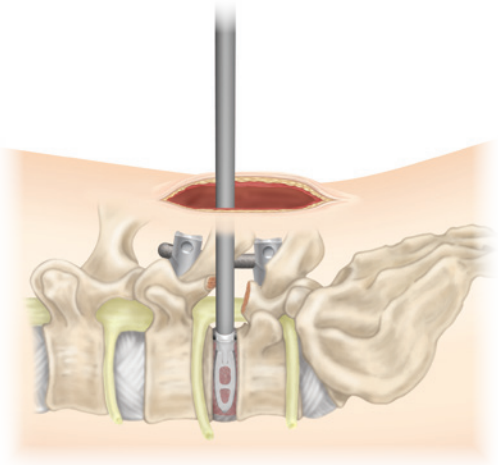


Figure 11

The appropriately sized Adaptix Implant is chosen during the trialing step and is firmly attached to the Inserter.

Before inserting the implant place appropriate bone graft material anteriorly and contralaterally, and in the implant's central cavity.

Gently impact the Adaptix implant until it is 3mm to 4mm below the posterior margin of the annulus.

Care should be taken to ensure the implant is aligned properly.

IMPORTANT

Ensure that the convex surfaces of the implant are aligned and in contact with the endplates during insertion as shown in Figures 9-11.

IMPORTANT

DO NOT insert the Adaptix implant sideways and rotate into final position.

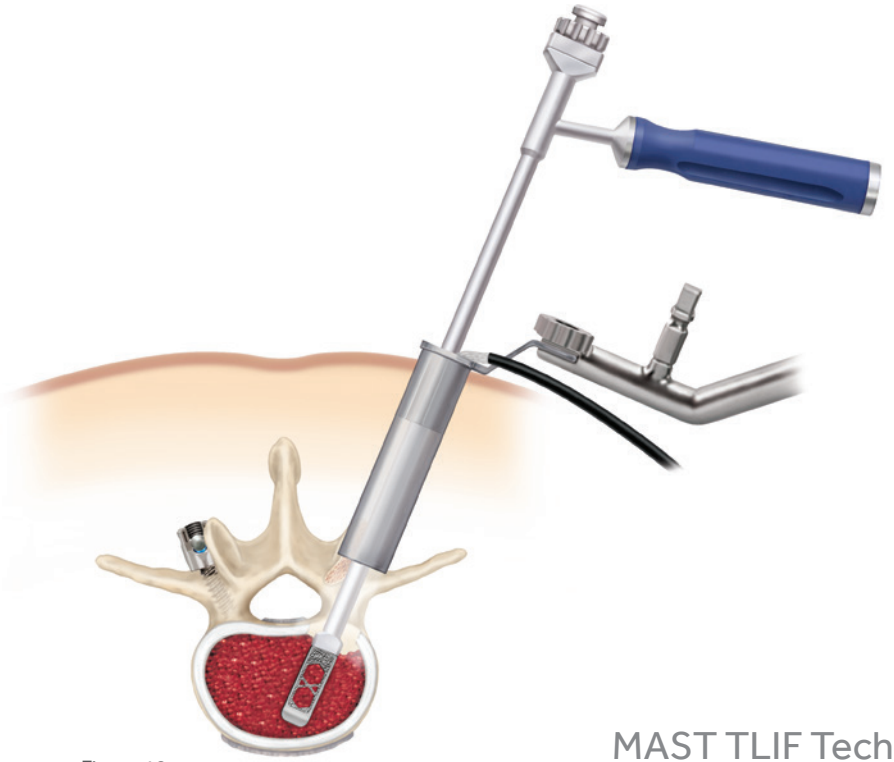
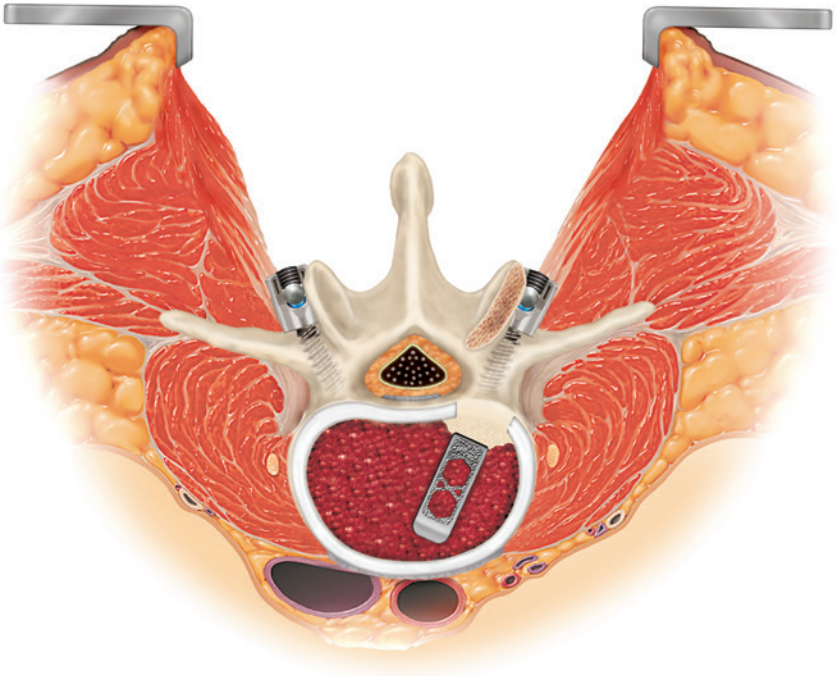


Figure 12

MAST TLIF Technique

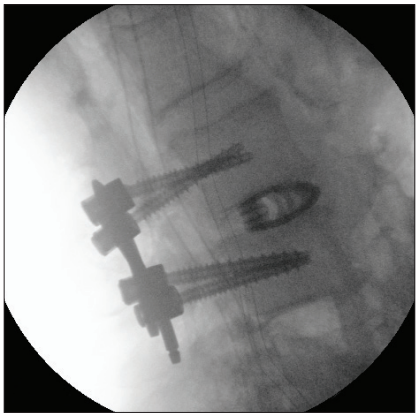
FINAL PLACEMENT

Open TLIF Technique



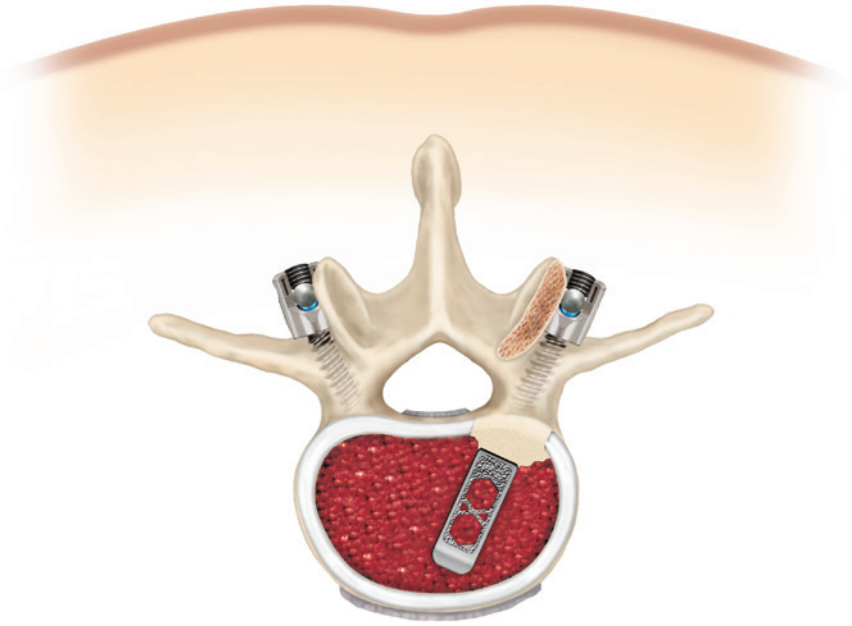
After the Adaptix implant is placed, the contralateral screw-rod construct is compressed to preload the interspace and restore lordosis. The extradural space and foramina are probed to ensure adequate decompression of the neural elements.

To facilitate satisfactory immobilization of the grafted interspace, segmental fixation is applied ipsilaterally using the standard technique.



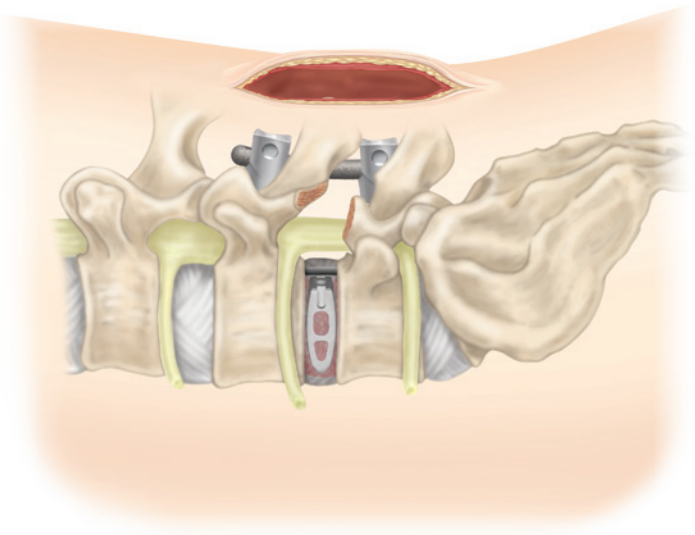
Lateral View

MAST TLIF Technique



ADDITIONAL FIXATION OPTIONS **AND EXPLANTATION**

The Adaptix Interbody system is intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.



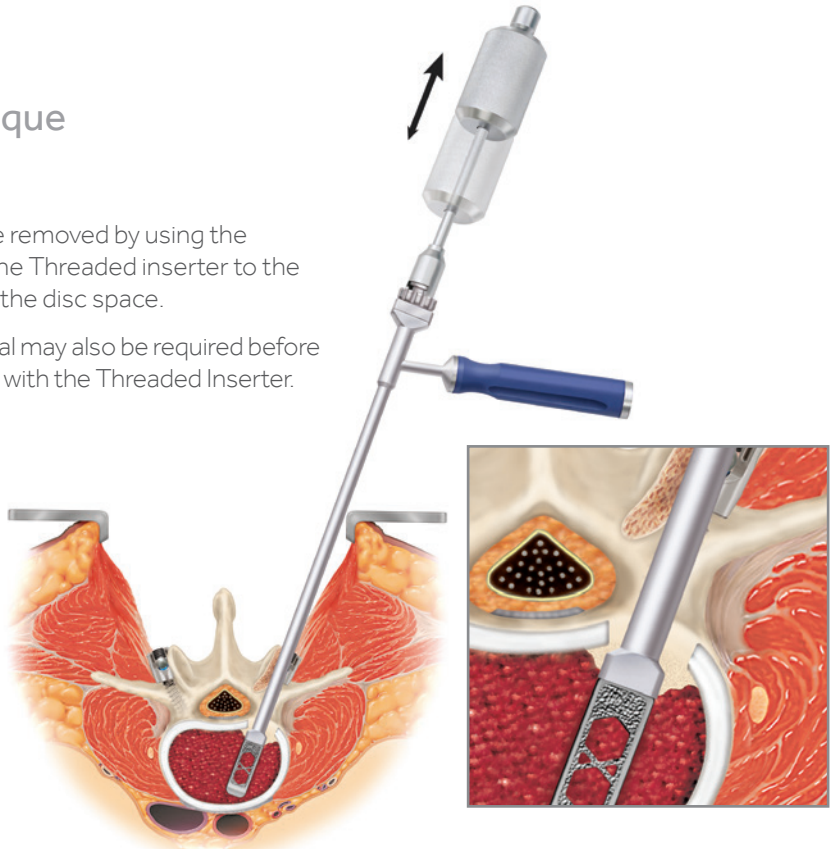
CD Horizon™ Solera™ Voyager™ Spinal System

EXTRACTION

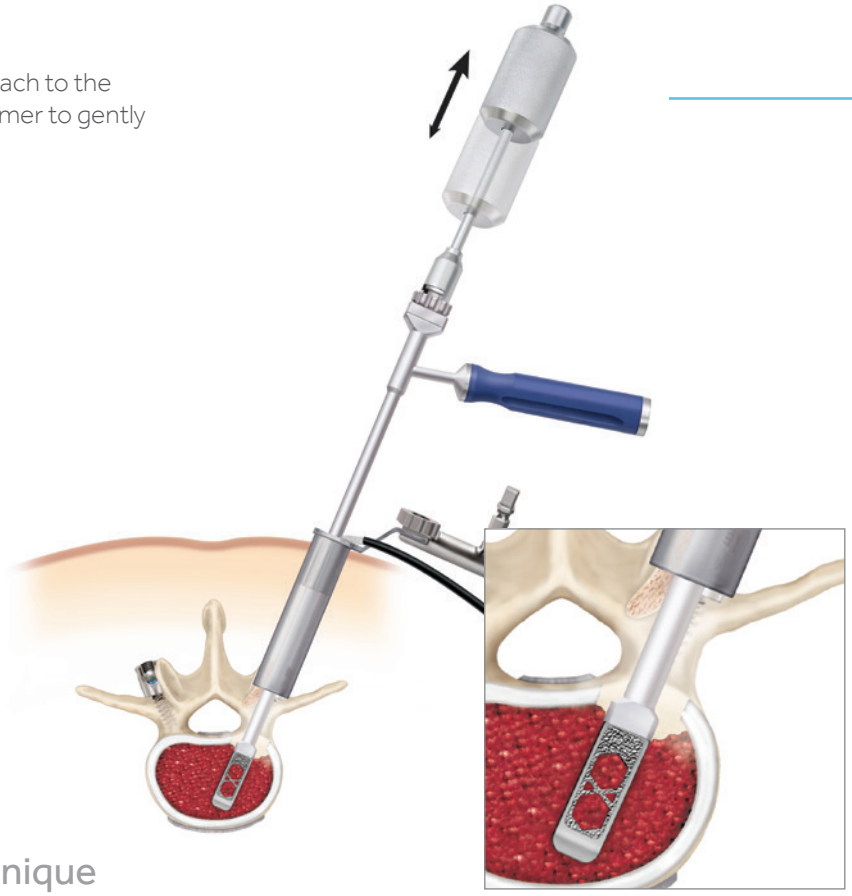
Open TLIF Technique

The Adaptix implant may be removed by using the Threaded Inserter. Attach the Threaded inserter to the implant and remove it from the disc space.

Distraction and bone removal may also be required before the implant can be removed with the Threaded Inserter.



Use the Inserter and reattach to the implant, using a Slap Hammer to gently remove the implant.



MAST TLIF Technique

PLIF: Open and MAST Techniques

NAVIGATION AND NEUROMONITORING OPTIONS

Neuromonitoring Option

For neuromonitoring, a NIM PAK Needle or Navigated NIM PAK Needle may be used to access the pedicle. Triggered electromyograph (EMG) monitoring can be performed during advancement of the needle into the pedicle to ensure proper placement (**Figure 13**).

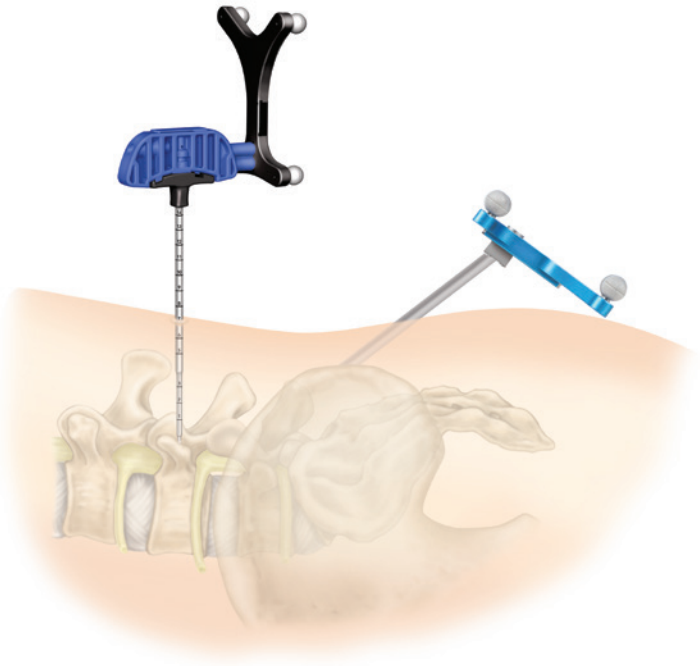


Figure 13

IMPORTANT

Please see the NIM-Eclipse Spinal System package insert and user's manual for complete instructions and a list of warnings, precautions, and other medical information.

The NIM-Eclipse System is intended for use to record, monitor, and stimulate/record biopotential signals including EMG, evoked response and nerve/muscle potentials, and for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. The system provides feedback to the surgeon and OR team to assist in the localization and assessment of spinal nerves and verification of placement of spinal instrumentation to avoid injury to at-risk nerve roots (**Figure 14**).

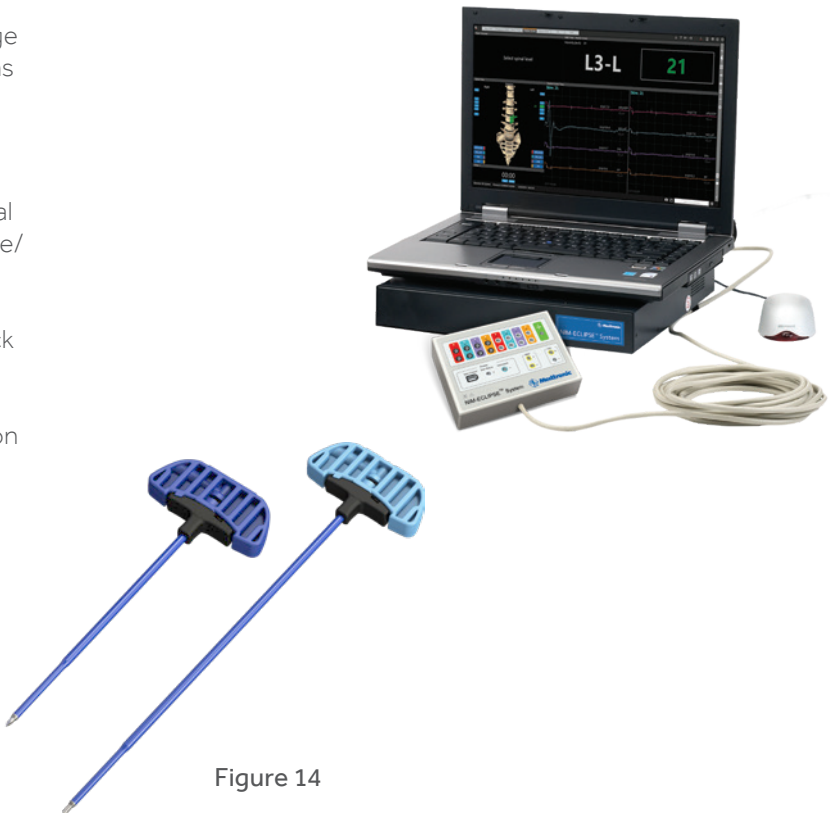
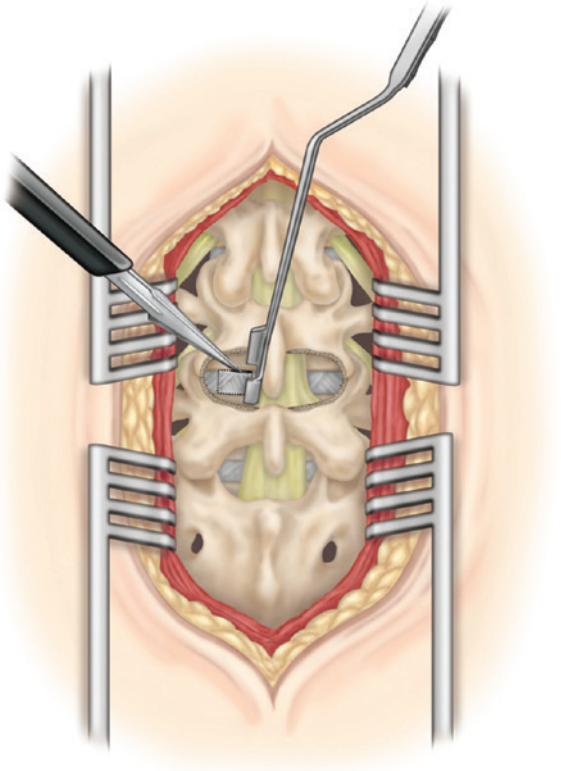


Figure 14

LAMINOTOMY AND **FACETECTOMY**

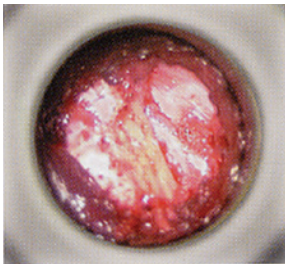
Open PLIF Technique



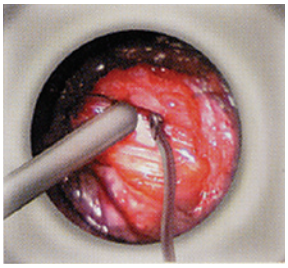
A conventional discectomy is performed by incising the annulus with a 15-scalpel blade lateral to the dural sac.

This is done bilaterally and soft fragments are then removed from the intradiscal space or extruded fragments are then removed with disc rongeurs in a conventional fashion.

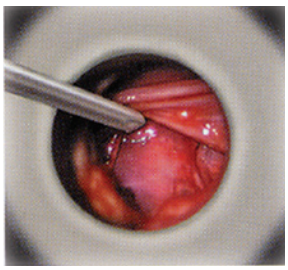
The main goal of this step is to remove extruded fragments, decompress neural elements and provide entry to the disc space for distraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.



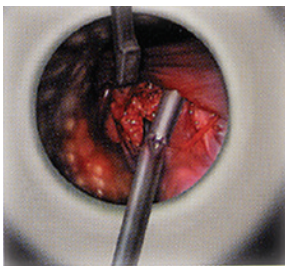
Soft Tissue Removal



Ligamentum Flavum Removal



Nerve Root Retraction

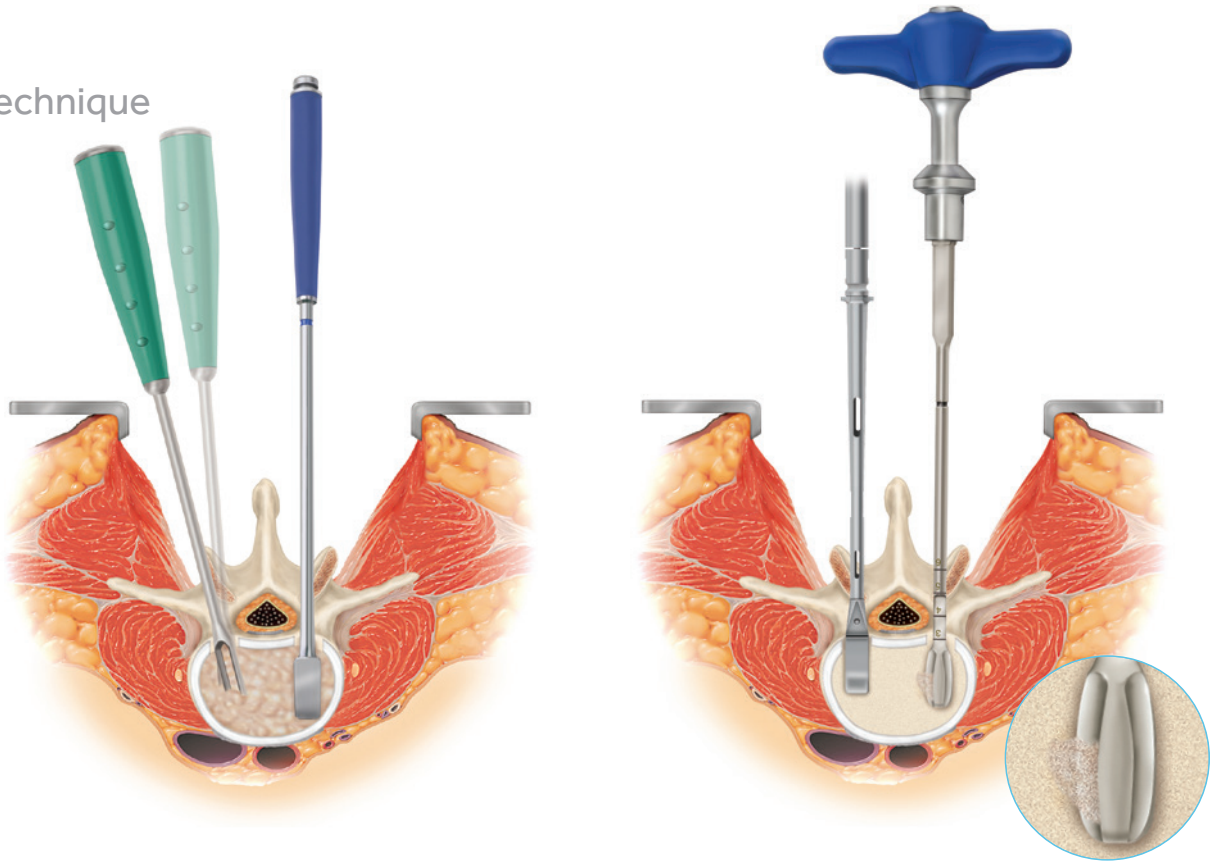


Discectomy

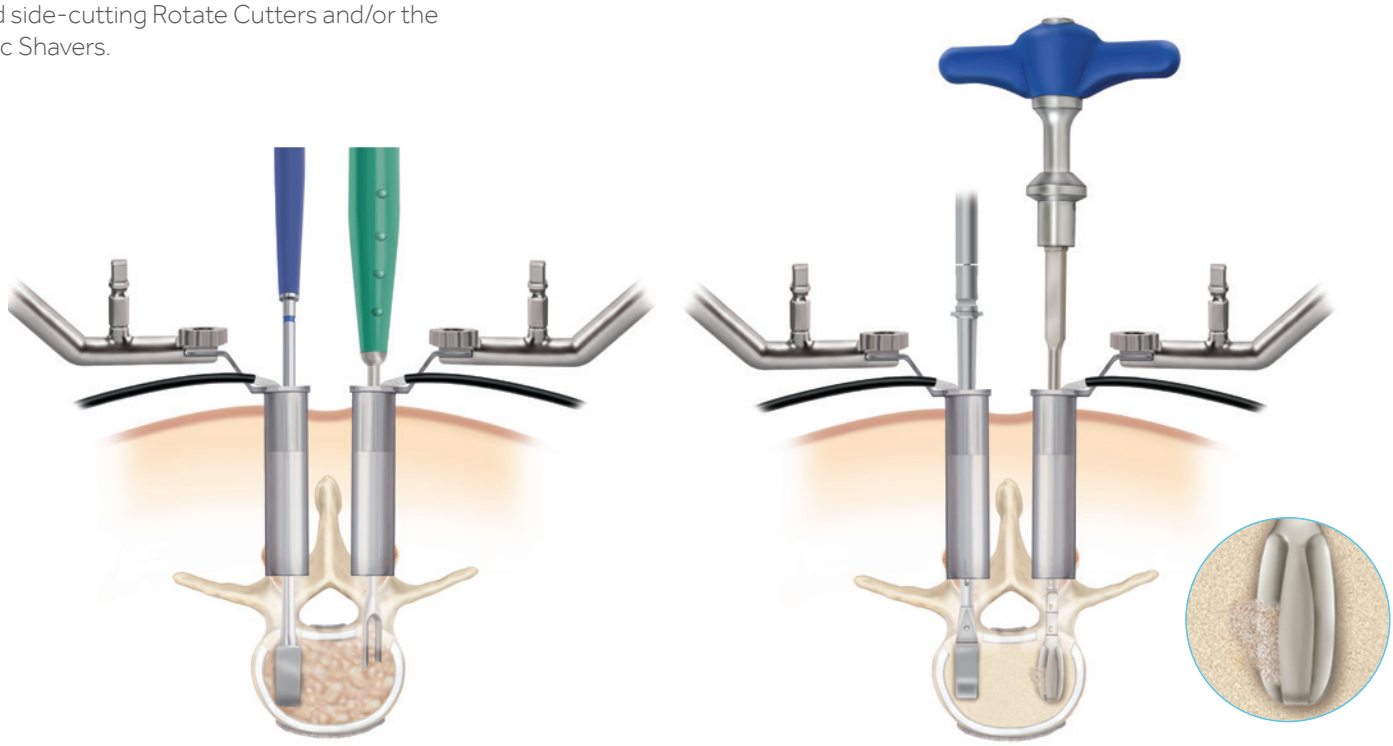
MAST PLIF Technique

DISC SPACE **PREPARATION**

Open PLIF Technique



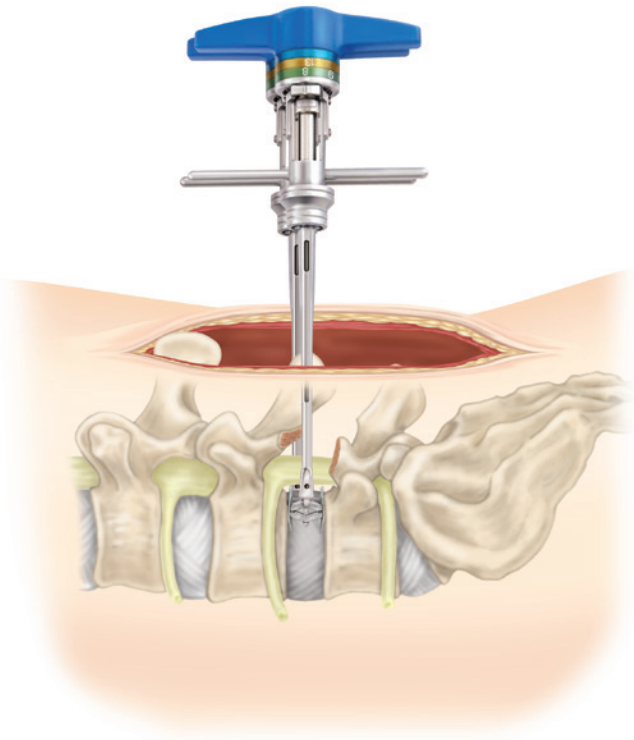
With the Distractor/Trial secured in the disc space, remove the disc using the blunt-tipped and side-cutting Rotate Cutters and/or the Disc Shavers.

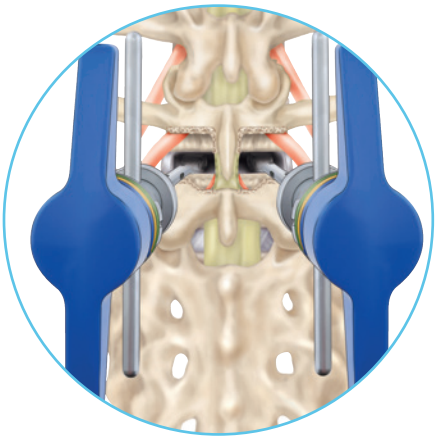


MAST PLIF Technique

DISTRACTION

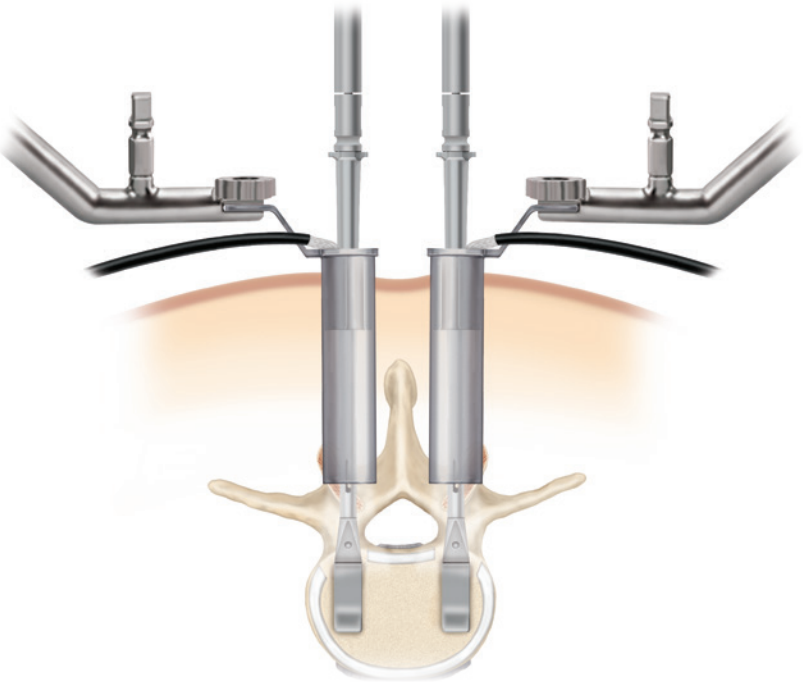
Open PLIF Technique



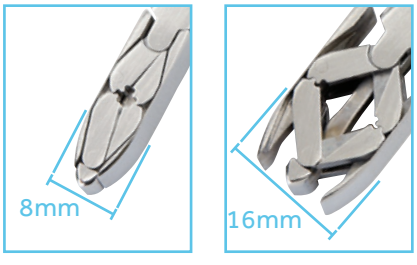


The disc space is sequentially distracted with the Distractor/Trial or the Scissor Jack Distractor until the original disc space height is obtained and the normal foraminal opening is restored.

If the Scissor Jack Distractor is used, insert the distractors with the curved sides touching the end plates and expand the distractors until the desired height is obtained.



Note
When two Scissor Jack Expandable Distractors are used in this approach, position the horizontal bars perpendicular to the disc space to ensure they do not interfere with one another.

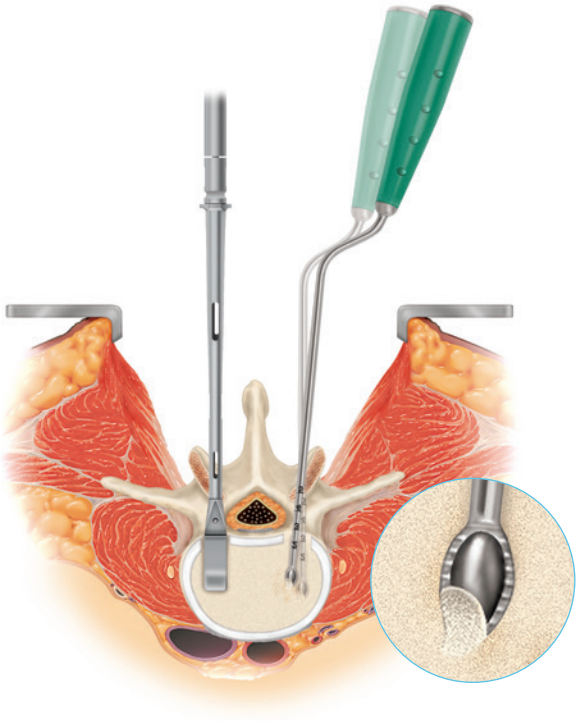


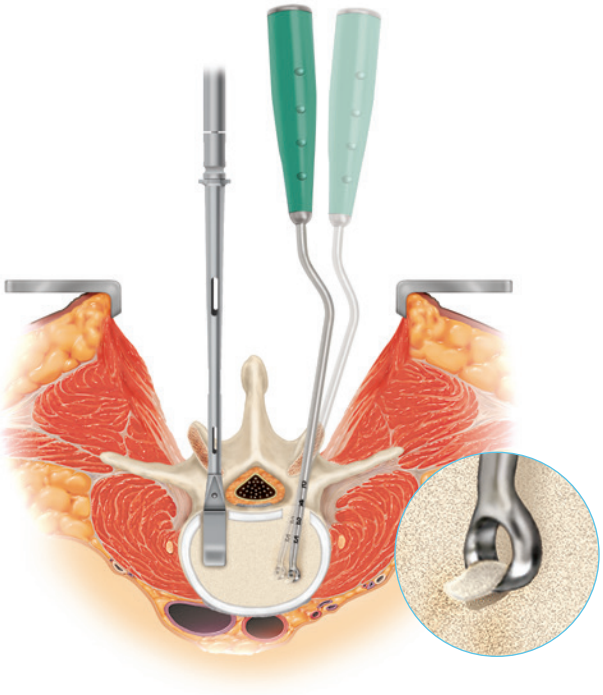
Closed Open

MAST PLIF Technique

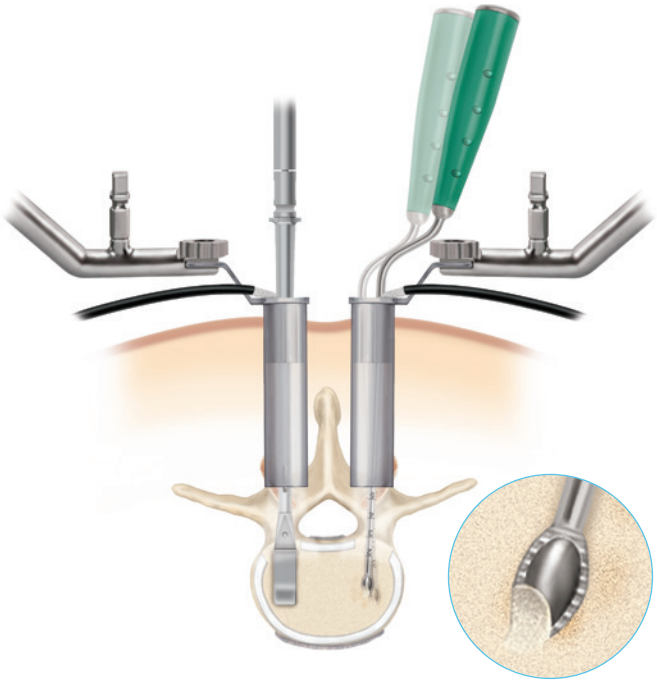
END PLATE **PREPARATION**

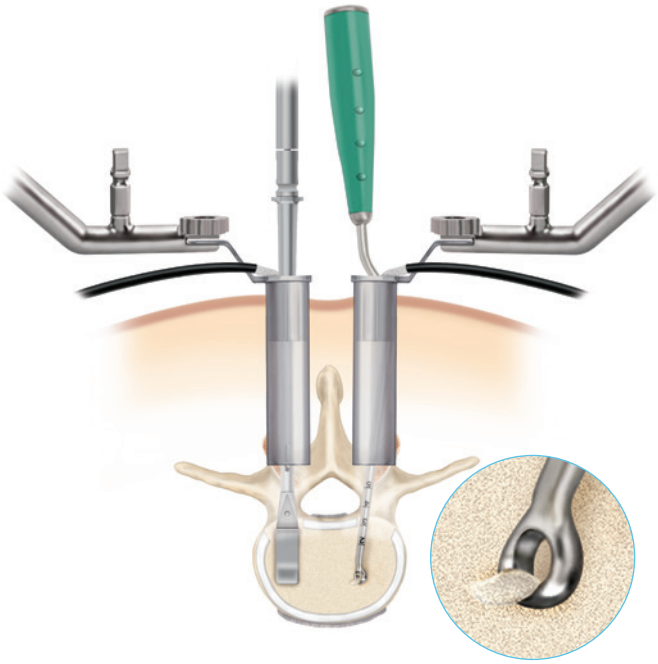
Open PLIF Technique





Specifically designed angled instruments allow disc resection and end plate preparation.

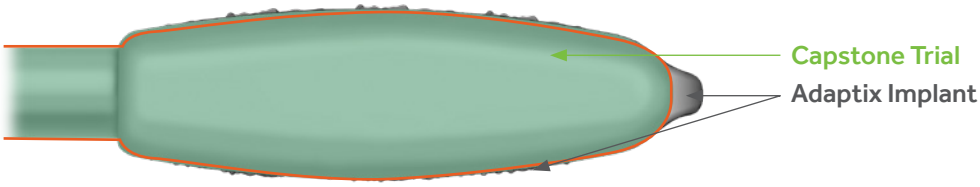




MAST PLIF Technique

IMPLANT
SIZE SELECTION

Medtronic Capstone™ Spinal System Trials can be used for sizing the Adaptix Implant. The below image is an overlay of the Capstone Trial and Adaptix Implant, illustrating their shared profiles.

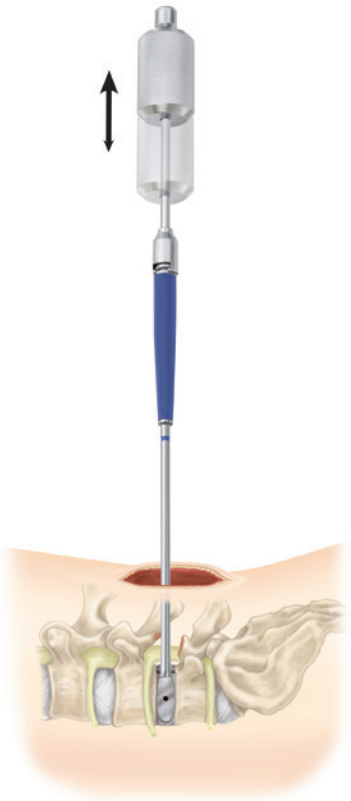


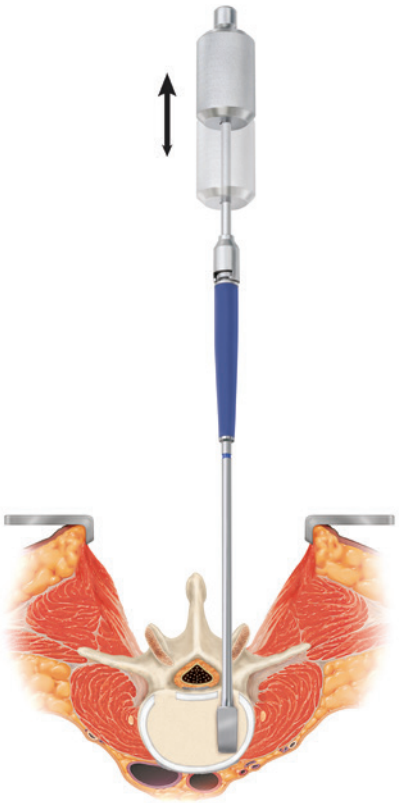
Trial Selection Guide

Refer to the below table for using Capstone Spinal System Trials with Adaptix Implants:

Capstone Trial Length	Adaptix Implant Length
22mm	24mm
26mm	28mm
32mm	34mm

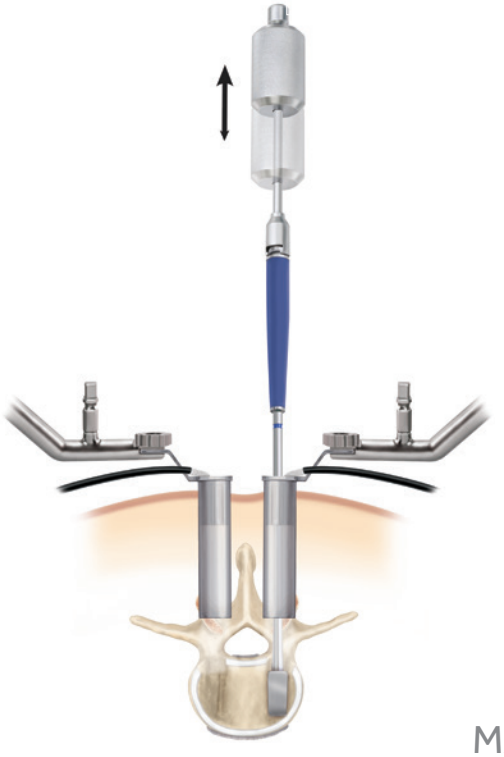
TRIAL
INSERTION





Open PLIF Technique

Insert the Distractor/Trial until the desired disc space height is established. Use AP and lateral fluoroscopy to confirm proper placement and trajectory. A slap hammer can be used for removal.



MAST PLIF Technique

IMPLANT INSERTION

Open PLIF Technique

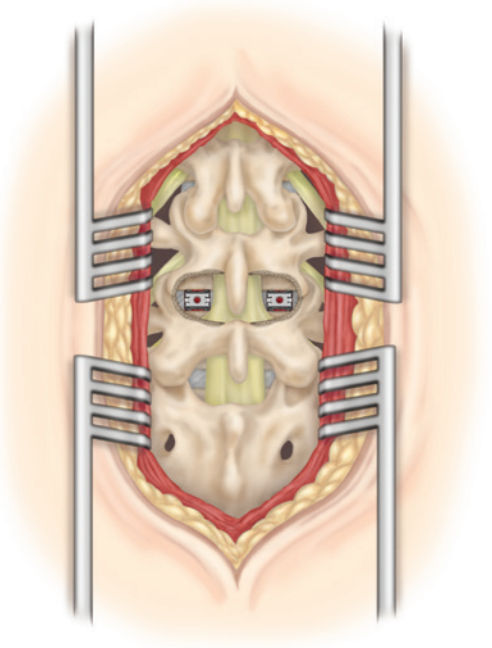


Figure 15

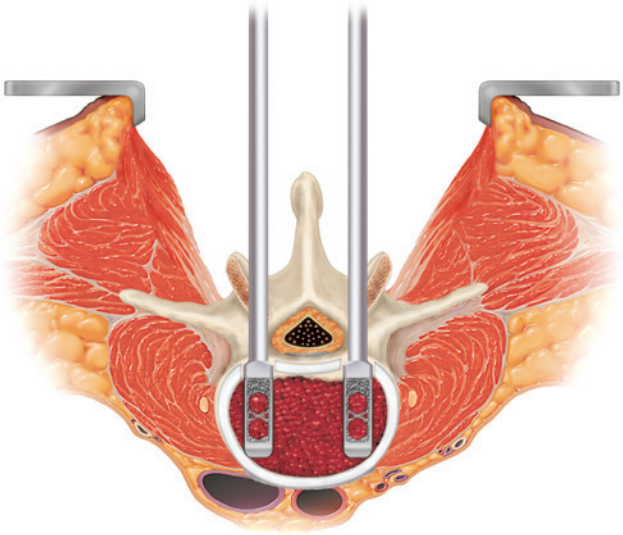


Figure 16

The appropriately sized Adaptix implant is chosen during the trialing step and is firmly attached to the Inserter.

Before inserting the implant, place appropriate bone graft material anteriorly and contralaterally, and in the implant central cavity.

Gently impact the Adaptix implant until it is 3mm to 4mm below the posterior margin of the annulus.

Care should be taken to ensure the implant is aligned properly.

IMPORTANT
Ensure that the convex surfaces of the implant are aligned and in contact with the endplates during insertion. See Figures 9 -11.

IMPORTANT
DO NOT insert the Adaptix implant sideways and rotate into final position.

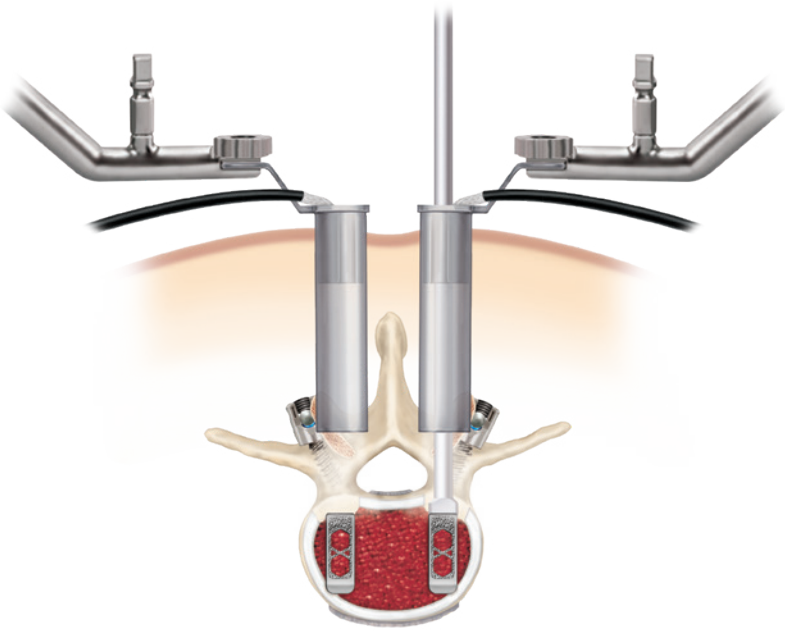
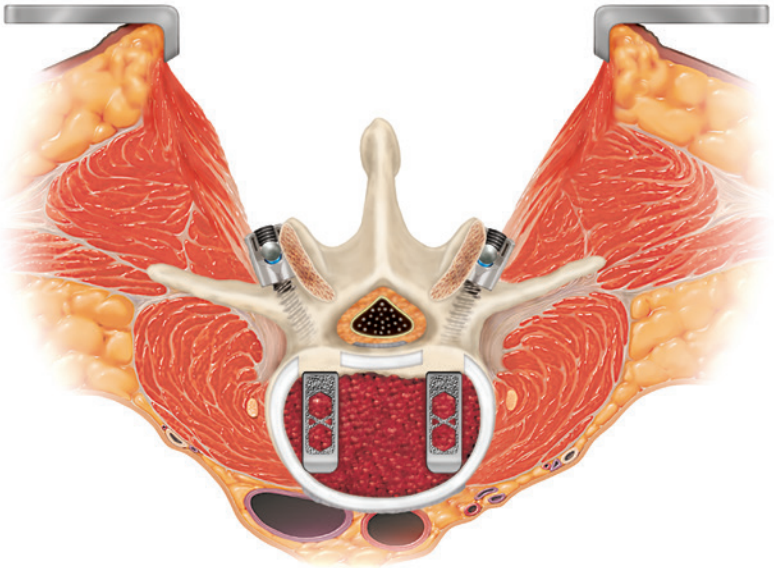


Figure 17

MAST PLIF Technique

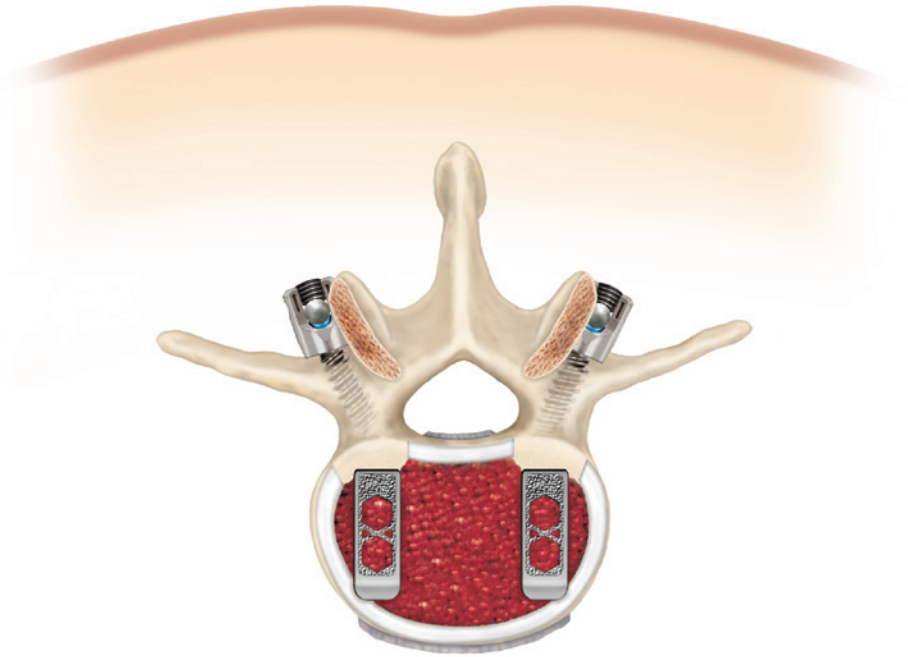
FINAL PLACEMENT

Open PLIF Technique



After the Adaptix implant is placed, the contralateral screw-rod construct is compressed to preload the interspace and restore lordosis. The extradural space and foramina are probed to ensure adequate decompression of the neural elements.

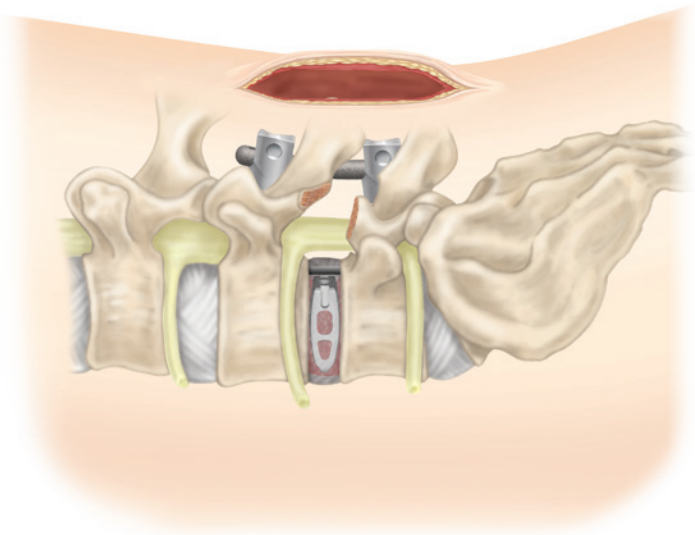
To facilitate satisfactory immobilization of the grafted interspace, segmental fixation is applied ipsilaterally using the standard technique.



MAST PLIF Technique

ADDITIONAL FIXATION OPTIONS **AND EXPLANTATION**

The Adaptix Interbody system is intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.



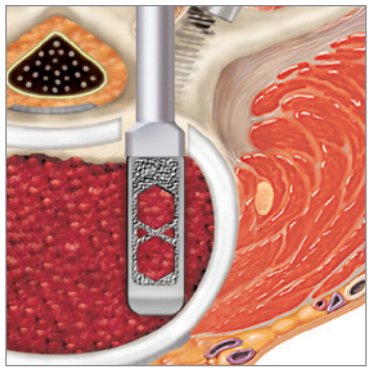
CD Horizon Solera Voyager Spinal System

EXTRACTION

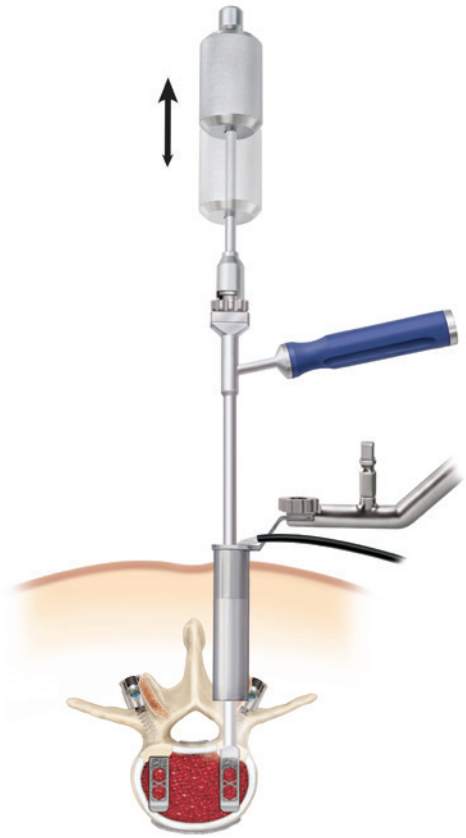
The Adaptix implant may be removed by using the Threaded Inserter. Attach the Threaded inserter to the implant and remove it from the disc space.

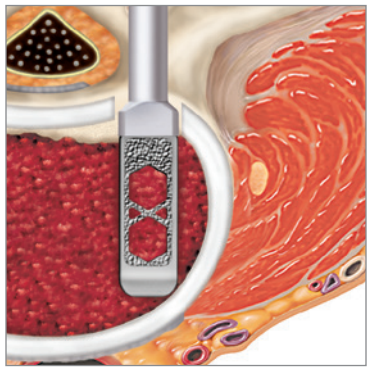
Distraction and bone removal may also be required before the implant can be removed with the Threaded Inserter.

Open PLIF Technique



Use the Threaded Inserter and Slap Hammer to gently remove the construct.





MAST PLIF Technique

Navigated MAST TLIF and PLIF Using Adaptix Spinal System and Disc Prep Instrument Set

TECHNOLOGY OVERVIEW

O-arm™ Image Acquisition System

O-arm Imaging System

Mobile Viewing Station

Main Cart

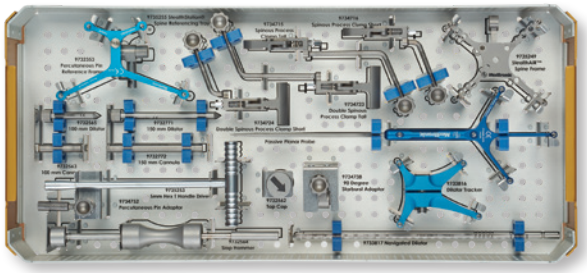
Camera Cart

StealthStation™ S8 Surgical Navigation

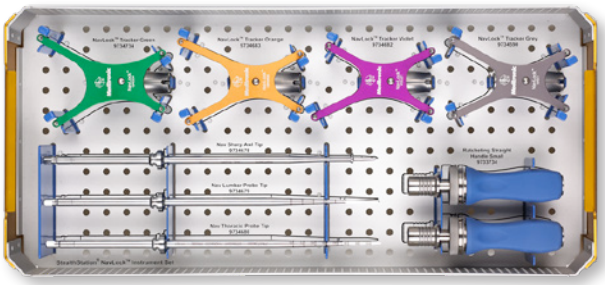
Navigated TLIF/DLIF Inserter shown with Adaptix implant

Navigated Stealth-Midas™ Powered Drilling System

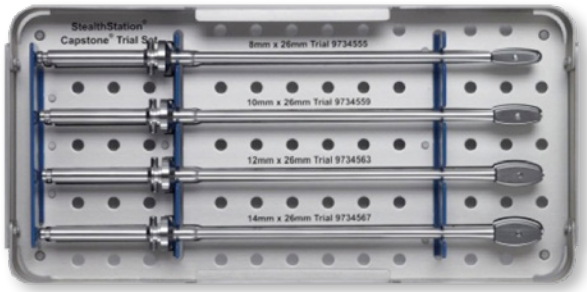
INSTRUMENTS AND EQUIPMENT



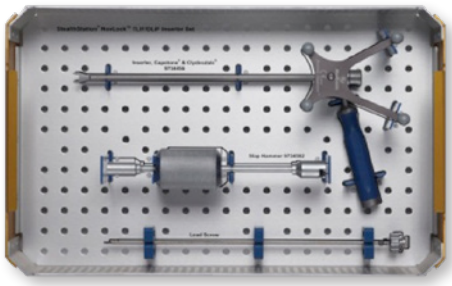
StealthStation Spine Referencing Set
(9735500)



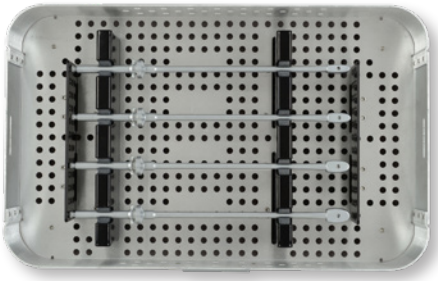
StealthStation NavLock Instrument Set
(9734833)



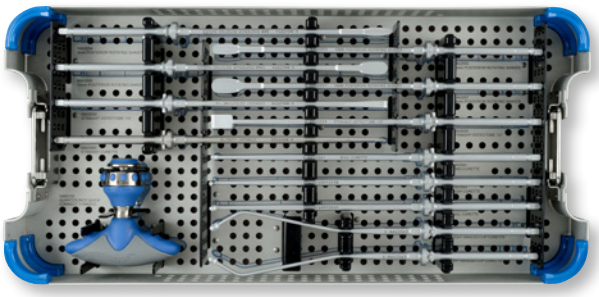
Navigated 26mmCapstone Trial Set
(SPS03127)
(9734834)



Navigated Inserter Set
(SPS03128)
(9734734)



Navigated 22mm Capstone Trial Set
(SPS02869)



Navigated Posterior Disc Prep Instrument Set
(SPS02937)

Spheres
(8801074)

Disposable Perc Pin
100mm (9733235)
150mm (9733236)

Navigated NIM PAK Needle
(PK1012)

O-arm Sterile
Tube Drape (optional)
(9732722)

Note

Adaptix Interbody System leverages the same instrument sets as Capstone Spinal System. See Trial Selection procedural step for Capstone Trial lengths and corresponding Adaptix implant lengths.

NAVIGATION EQUIPMENT AND ROOM SETUP

For a navigated surgery, the OR should be equipped with the O-arm Image Acquisition System, the Mobile Viewing Station (MVS), and the StealthStation S8 System **(Figure 18)**. Plug the MVS into a power source; connect the MVS to the O-arm System, and power on the system. Power on the StealthStation S8 System and start the Spine software. Connect the MVS to the StealthStation S8 System network port with a network cable or a crossover cable.

The equipment setup for Navigated Posterior Fixation Procedure has the StealthStation S8 Camera Cart positioned near the patient's feet.

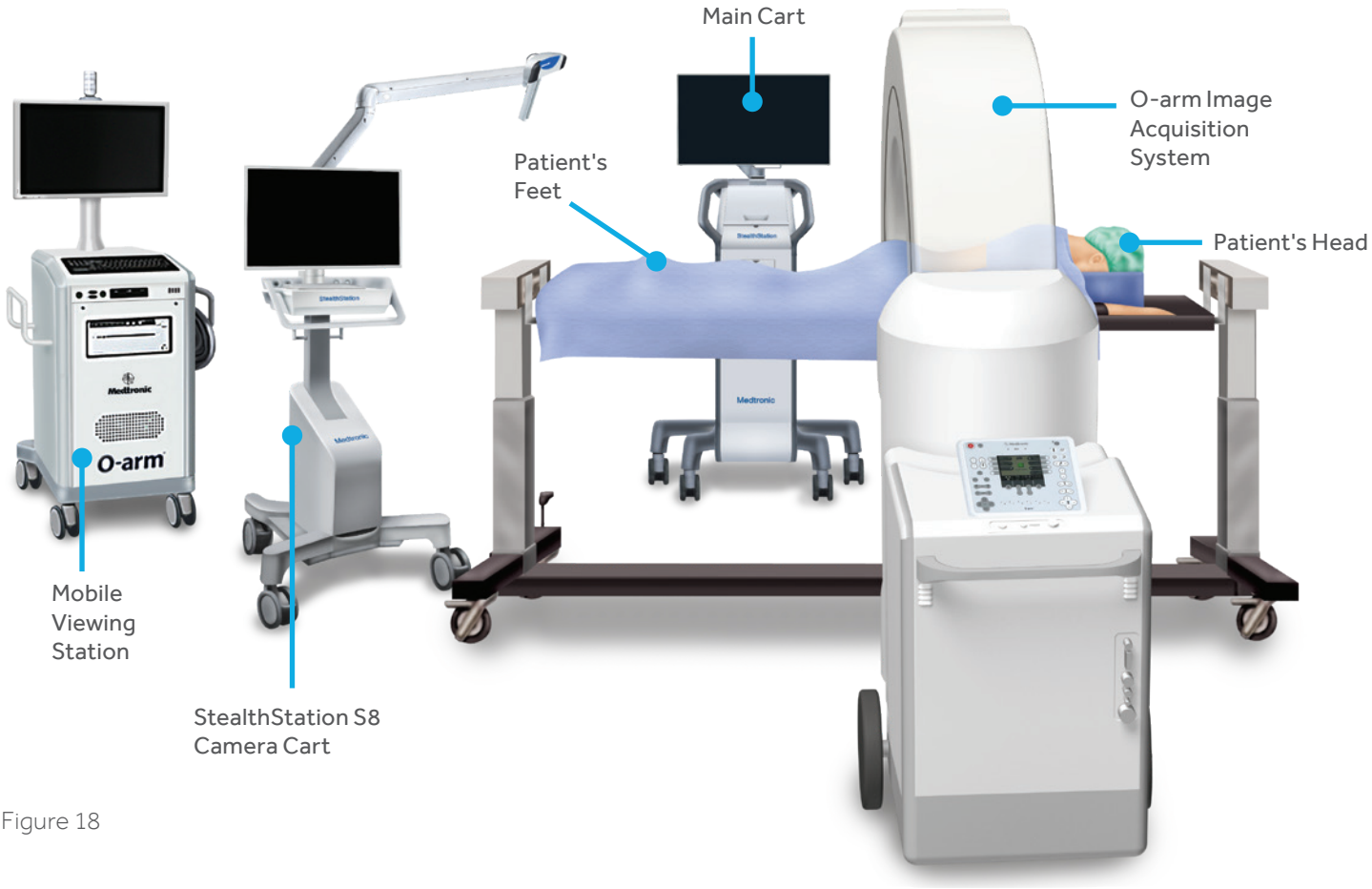


Figure 18

Note

During the OR set-up, consider the placement of the patient reference frame to ensure StealthStation Camera has direct line of sight to both the patient reference frame and instrument trackers. It's recommended to aim the instrument tracker towards the StealthStation Camera during use. Consider the best balance in camera position to view the patient reference frame and instrument trackers given the surgical procedure and set-up.

When positioning the O-arm System for the procedure, place it around the patient table approximately seven inches closer cephalad from the anatomy to be imaged **(Figure 19)**. The gantry should then be translated in the direction of the patient's feet for imaging. This will allow the gantry to be placed in a "park" position and remain in the sterile field throughout the procedure, if desired **(Figure 20)**.

The camera should be positioned at the foot end of the patient table so that the camera has an unobstructed line-of-sight to the Reference Frame which will be placed into the patient. Position the surgeon's monitor near the patient's side, opposite from the surgeon.

Place the patient in the prone position, lying flat on a Jackson spine top table or a Jackson table with the Wilson frame.

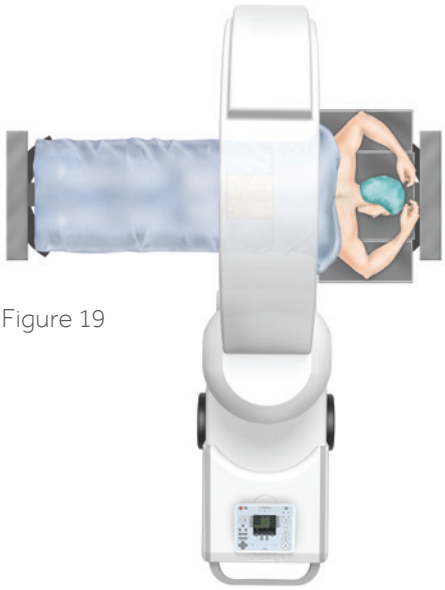


Figure 19

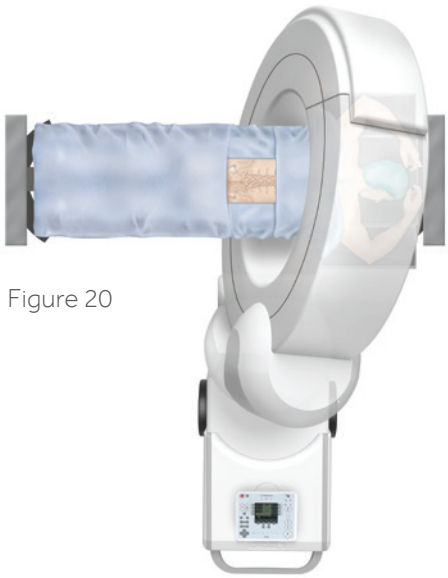
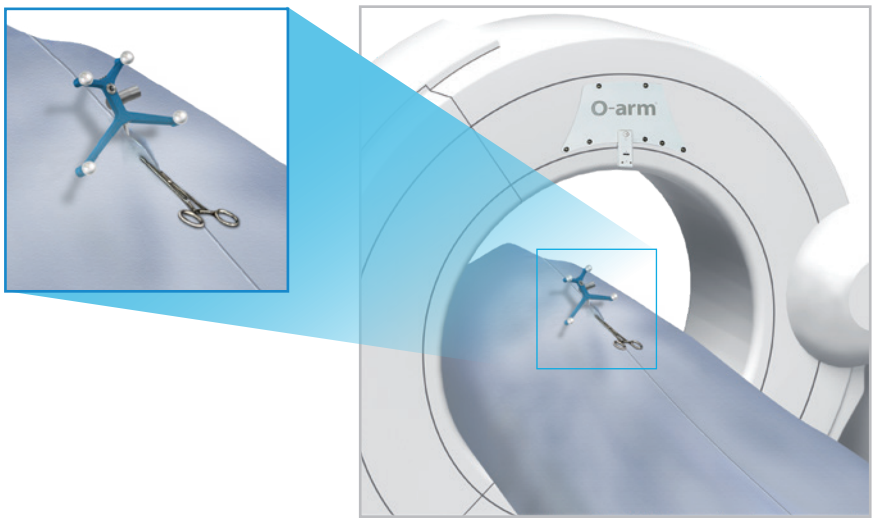


Figure 20

Helpful Information

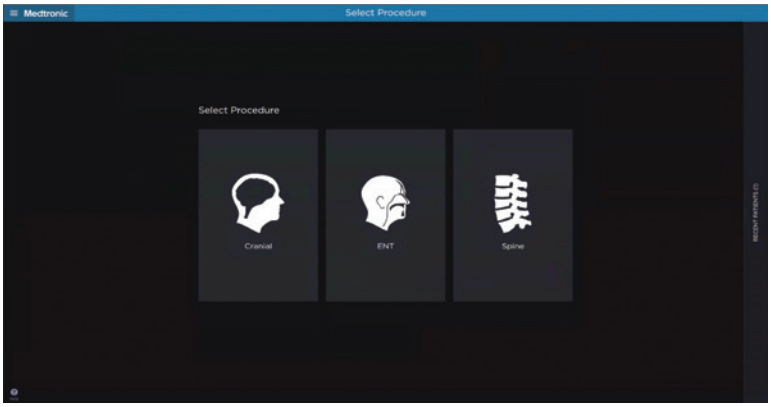
If the O-arm System will remain in the sterile field during the procedure, drape the O-arm System gantry using the O-arm IAS Sterile Tube Drape during the positioning of the system. If the O-arm System will be removed from the sterile field, place and clamp two half-drapes over the sides of the patient prior to positioning in the sterile field maintaining sterility around the patient while closing the gantry of the O-arm System.

Be sure that the reference frame is visible to the StealthStation camera after draping and be sure that any clamps placed on the drapes do not interfere with O-arm acquisition.



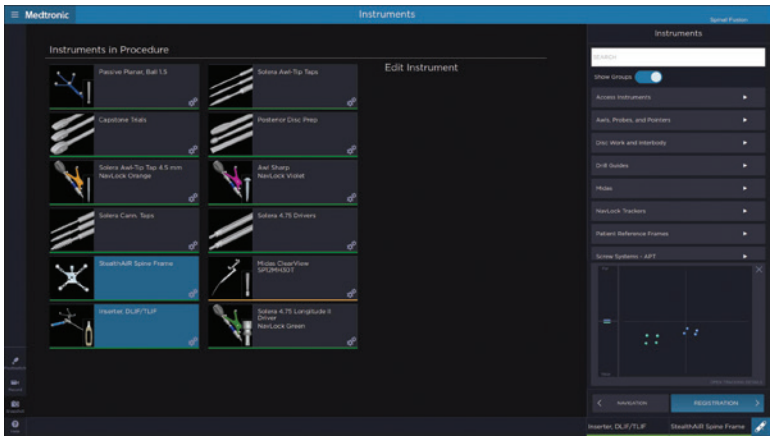
In the StealthStation S8 Spine Software, complete the "Select Surgeon" and then "Select Procedure" tasks. Continue through the software by completing the "Set-Up Equipment" and "Verify Instruments" tasks to reach the "Acquire Scan" screen.

StealthStation S8 Spine Software Workflow



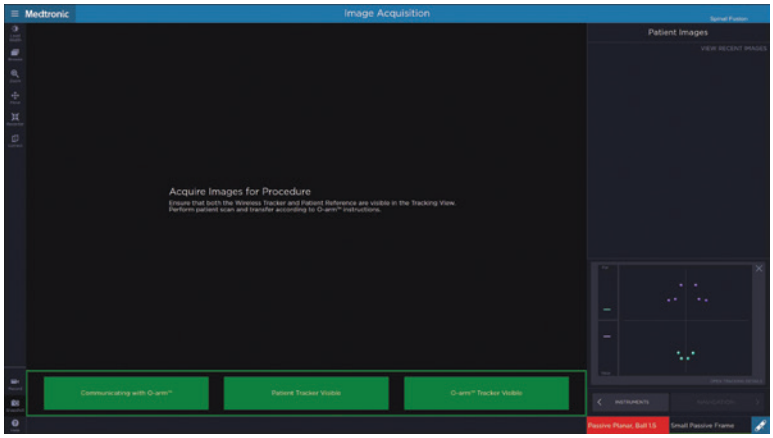
1. Select Procedure

Open the "Select Surgeon" menu and select the Primary Surgeon and the Surgical Procedure to be performed.



2. Verify Instruments

Check that the toolcards for all the navigated instruments needed for the procedure are shown on this screen. Instruments can be verified now or during a later step, but the toolcard for the instrument must appear on this screen to be verified and tracked.



3. Acquire Scan

The navigation system will remain on this screen until the O-arm System image acquisition step has been performed.

Note

It is recommended to verify navigational accuracy anytime changes are made to the navigation set-up (for example, the camera position is changed).

TLIF AND PLIF
PROCEDURAL WORKFLOW

VERIFY INSTRUMENTS	■ Navigated Shavers ■ Navigated Elevate Inserter ■ Navigated Dilator		■ NavLock Trackers ■ Passive Planer Probe
PLACE REFERENCE FRAME	■ Percutaneous Reference Pin with Percutaneous Reference Frame	– OR –	■ Spinous Process Clamp with Small Passive Reference Frame
ACQUIRE 3D IMAGE	■ Drape patient, bring O-arm System in field, and remove after image acquisition	– OR –	■ Drape O-arm System, bring in and leave in field after image acquisition
ACCESS	■ Determine entry points ■ Mark skin ■ Make skin incisions		
DECOMPRESS/ DISCECTOMY	■ Perform per the surgeon's usual manner		
INTERBODY PLACEMENT	■ Determine implant size using Rotating Shavers or Trials on surgeon monitor ■ Place bone graft anteriorly, contralaterally, and inside the interbody device		■ Insert the interbody device
ACQUIRE 3D CONFIRMATION IMAGE	■ Assess implant placement		

INSTRUMENT VERIFICATION

Attach the Sphere to a blue Reference Frame from the Spine Referencing Set and the NavLock Trackers from the NavLock Set. Check the Spheres to ensure they are secure. Next, attach the NavLock Trackers to the instruments.

Place each instrument tip into the divot in the blue Reference Frame and hold perpendicular **(Figure 21)** and visible to the camera until a confirmation color is seen. Use the tracking view in the lower right of the screen to ensure the camera is tracking the Reference Frame and instrument correctly **(Figure 22a)**.

To verify the Navigated TLIF/DLIF Inserter, place both prongs into the divot at once **(Figure 22b)**.

- Successful verification is indicated by a chime and a transition to green on the instrument toolcard.
- Failed verification is indicated by a "bonk" sound and indicates that the instrument may be positioned improperly in the divot or is bent/damaged. Inspect the instrument, if it is bent/damaged, do not use.
- If no sound is heard when the instrument is touched to the divot, this may indicate that the camera cannot see either the instrument or the frame.

Helpful Hint
Assigning an instrument to a specific colored NavLock Tracker will eliminate the need to switch the tracker from one instrument to the next instrument throughout the procedure. As an example, the grey tracker could be assigned to the tap and the orange tracker could be assigned to the driver.

Helpful Hint
OR staff can verify instruments before the surgeon enters prior to reference frame placement.

Important
Posterior Disc Prep instruments are verified with default instruments and not the actual tip.

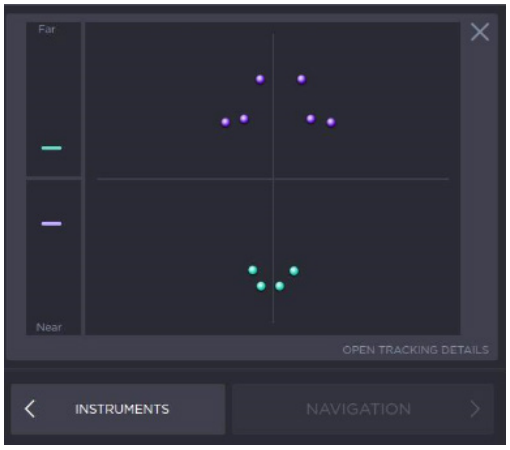


Figure 22a

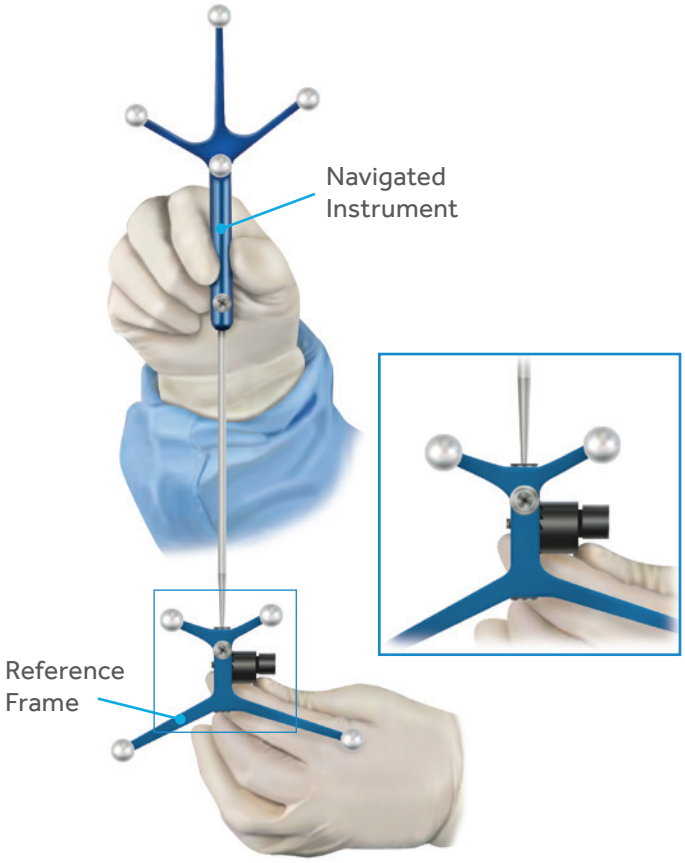


Figure 21

Figure 22b

REFERENCE FRAME **PLACEMENT**

When performing a navigated procedure with Adaptix, use of the Percutaneous Reference Pin with the Percutaneous Reference Frame is recommended. Pins are available in 100mm and 150mm lengths. For L5-S1 procedures, the surgeon should consider medializing the pin to avoid line-of-sight obstructions between the camera and the navigated instruments.

The preferred method places the pin down the posterior superior iliac spine (PSIS) much like the trajectory of an iliac screw, which drops the reference frame out of the way and does not pose potential line-of-sight obstacles between the camera and the screw placement **(Figure 23)**. This option is described below.

Upon palpation, locate the PSIS on the patient. Mark the skin a little medial and inferior to the PSIS to verify the appropriate location to place the pin.

Make a stab incision and locate the Cannula with the Dilator over the PSIS. Place the Dilator/Cannulas into the incision through the tissue until it contacts bone. Once docked, the Dilator/Cannula assembly is tapped with a mallet to make an indentation in the bone for the pin. While holding the Cannula in place, remove the Dilator and insert the pin through the Cannula. Place the Tap Cap on the pin and rotate the cap so the arrow on the Tap Cap points toward the camera. Orient the Pin/Tap Cap assembly approximately 30 degrees toward the midline of the patient and then angle it 30 degrees toward the foot of the patient.

Use an impactor to drive the pin into the bone until the Tap Cap contacts the top of the Cannula **(Figure 24)**. Remove the Tap Cap from the pin and attach the Percutaneous Reference Frame to the pin **(Figure 25)**.

Alternatively, the Spinous Process Clamp with the Small Passive Reference Frame can also be used. The clamp should be firmly attached to the spinous process inferior to the planned instrumented levels. With the camera positioned at the patient's feet, the clamp should be within an unobstructed view of the camera and the instruments.

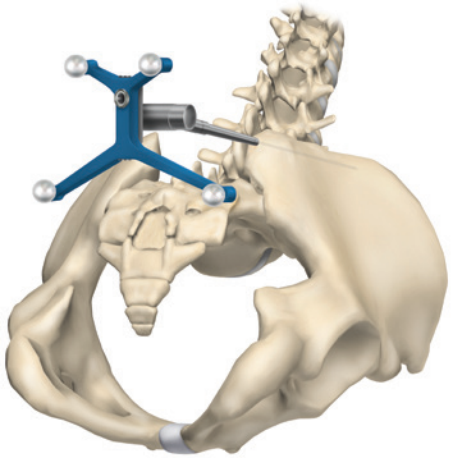


Figure 23

Helpful Hint
To keep the frame close to the patient and out of the way of surgical instruments, use the 100mm Percutaneous Reference Pin, if possible.

Important
Ensure the Reference Frame is properly secured to the anatomy. Neglecting to verify that the Reference Frame is secured could result in navigational inaccuracy if the hardware moves in relation to the anatomy after registration is complete.

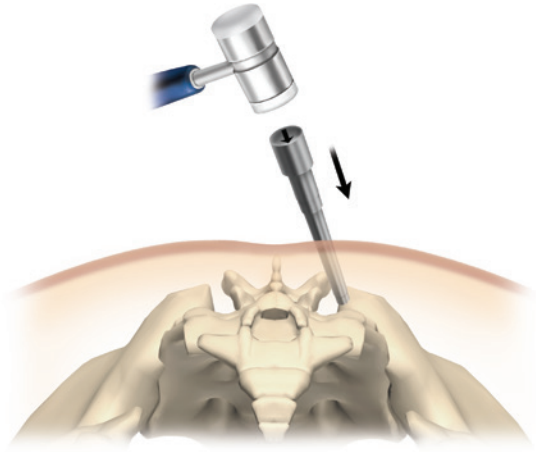


Figure 24

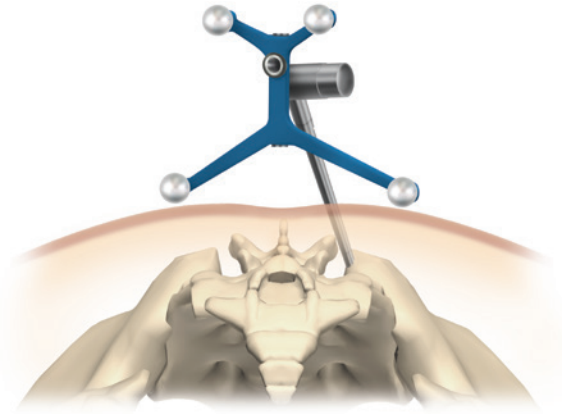


Figure 25

IMAGE ACQUISITION

At any time when fluoroscopy is used (2D or 3D acquisition) all personnel who are not wearing protective lead apparel should stand at least 15 feet (457.2cm) from the O-arm System with a certified moveable lead shield between themselves and the O-arm System to avoid unnecessary radiation exposure (**Figure 26**).

Establish the surgery site using 2D fluoroscopy scout images as needed. On the control panel, select the patient size, anatomy, and orientation. With the patient isocenter, position the O-arm System gantry to perform a 3D spin. Following the 3D spin, the images are transferred automatically to the StealthStation System. Should 2D images or a second 3D spin be desired, four preset O-arm System gantry positions may be set up and saved. Once the images are transferred, the O-arm System can be moved out of the way and into the park position.

O-arm System Isodose Curve

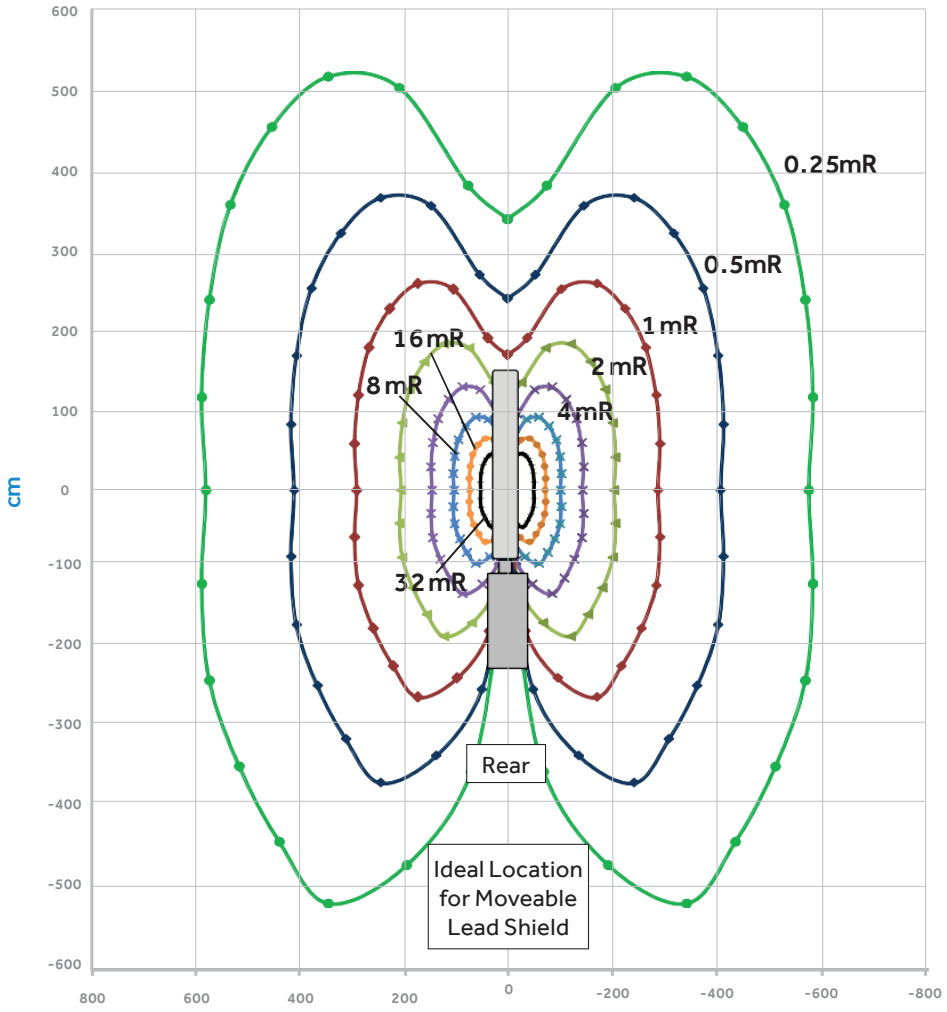


Figure 26

Scatter plot showing the shape of isodose curves for the maximum technique factors for the O-arm 02 Imaging System. Please refer to the end of this surgical technique for more information on the shape of isodose curves for the O-arm 1000.

- Protocol: Abdomen Standard Large
- Technique: 120 kVp, 330 mAs

Navigated MAST TLIF Procedure Steps

TLIF SITE ACCESS

Determine the surgical level and make the skin incision. Insert the Navigated Dilator into the incision and palpate the bony anatomy in both the coronal and sagittal planes to identify proper dilator positioning (**Figure 27a**). Access to the disc space can be performed with the METRx II System or the MAST Quadrant™ System. For ordering and assembly instructions for these systems, refer to the METRx™ II System or the MAST Quadrant System Surgical Techniques.

Once the Navigated Dilator is positioned, remove the Dilator Tracker from the Navigated Dilator and sequentially insert the dilators until the desired diameter is reached. Insert the corresponding METRx II System Tube or MAST Quadrant System Retractor. To confirm the access trajectory, reattach the Dilator Tracker to the Navigated Dilator (**Figures 27b and 27c**). Once the trajectory is confirmed, lock the retractor system and remove all dilators. With the Tube or Retractor in position, the TLIF may now be performed (**Figure 27d**).

Figure 27a

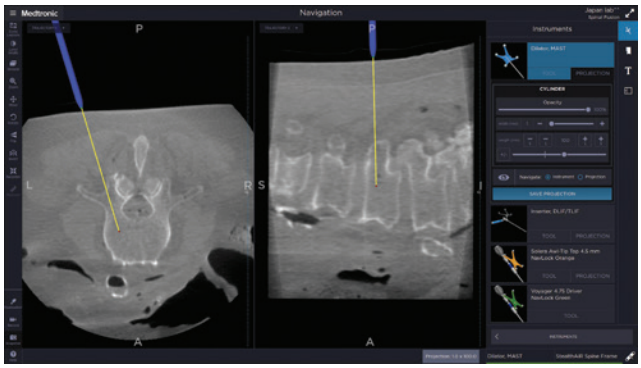


Figure 27b

Figure 27c

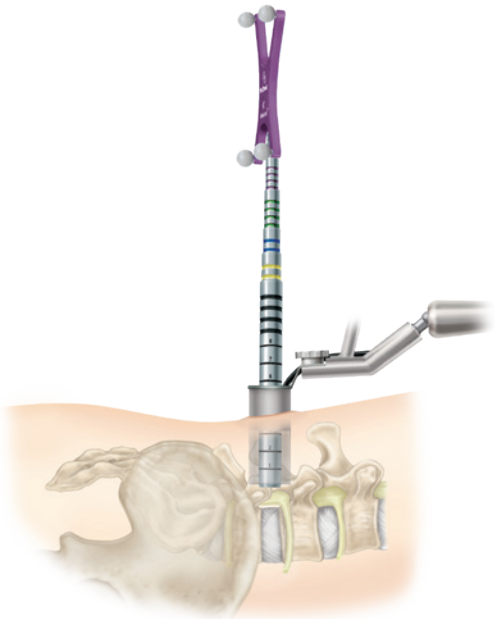


Figure 27d

A facetectomy and a laminotomy are performed using the navigated osteotome and other general instruments such as a Kerrison for bony removal (**Figure 28a and 28b**). The Midas Rex high speed drilling system can be used to remove bone during spinal procedures.

On the StealthStation System, choose the "Select Tip" tab to select the appropriate navigated instrument. Insert the navigated instruments into a NavLock Tracker, confirm accuracy by touching the tip of the instrument on a known anatomical point, and use the instrument in the disc space until the desired result is achieved. A 1cm-square annulotomy is made with a scalpel in Kambin's triangle. The disc is removed using a pituitary rongeur and navigated curettes.

The main goal of this step is to remove extruded fragments, decompress neural elements and provide entry into the disc space for distraction, with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is complete.

Remove disc using the navigated rotating shavers, curettes, or other general instruments (**Figure 28c**). Use the navigated cup or ring curettes to prepare the end-plates for trialing and implant placement.

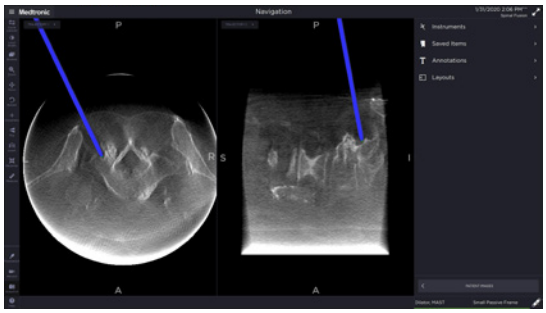
Important
Make sure the navigated disc prep instruments were verified with a default tip such as an awl or tap. Use "Select Tip" when choosing the applicable disc prep working end.

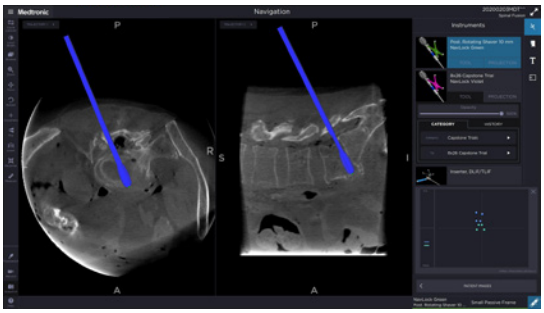
Important
During navigation, it is important to frequently confirm navigational accuracy by touching the tip of the navigated disc prep instrument on known anatomical points, including accuracy checkpoints, and comparing the position to the instrument tip in the image with its physical location.

Figure 28a

Figure 28b

Figure 28c





IMPLANT
SIZE SELECTION

Implant Size Selection with Rotating Shavers

On the StealthStation System, select the appropriate Rotating Shaver size from the "Tip" drop down list. In the "Projection" tab, click "Virtual Trial" and select Adaptix from the "Family" drop down list.

Helpful Hint
Ensure that the "Opacity" is set to 100% to see the projection.

The Navigated Rotating Shaver heights are available in 1mm increments from 7 to 14mm.

Insert the Navigated Rotating Shaver into the disc space in the direction parallel to the endplates, and progressively increase Shaver sizes from small to large using tactile feedback during rotation to approximate the starting height of the implant (**Figure 30a-30b**).

Use the Virtual Trial to confirm proper placement and alignment of the Shaver (**Figures 30c-30d**).

Navigated Rotating Shaver Trial Projection	Adaptix Implant
24mm	24mm
28mm	28mm
34mm	34mm

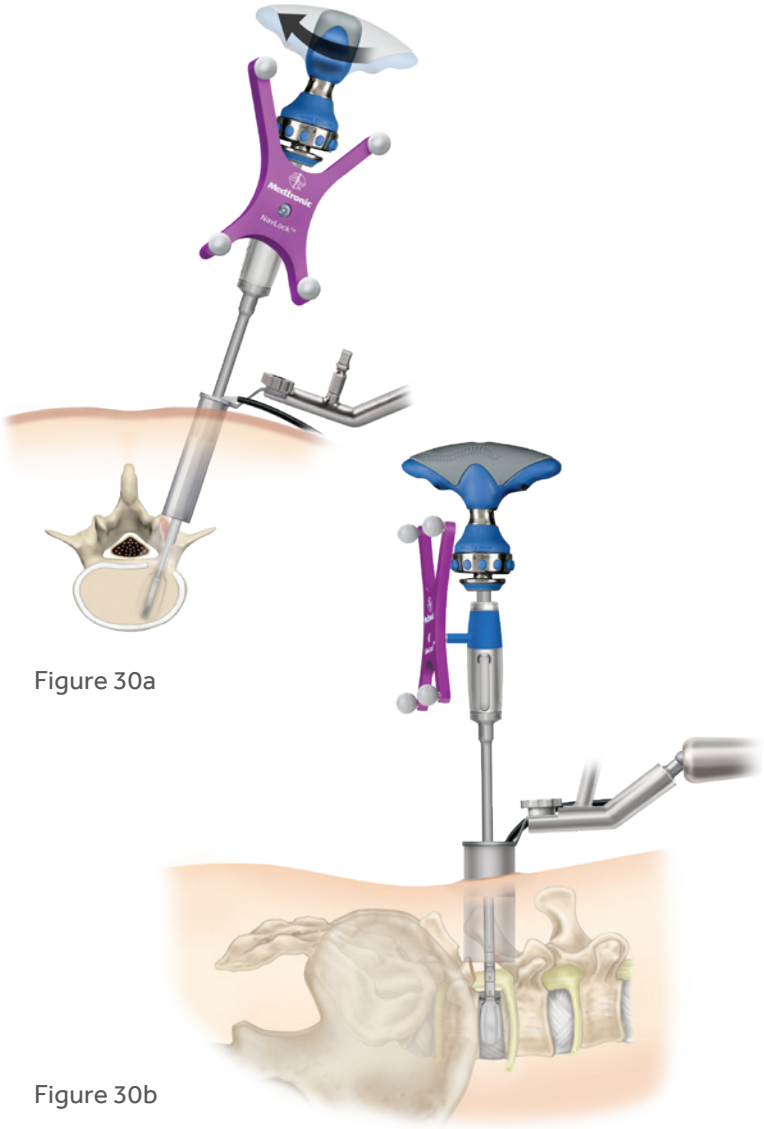


Figure 30a

Figure 30b

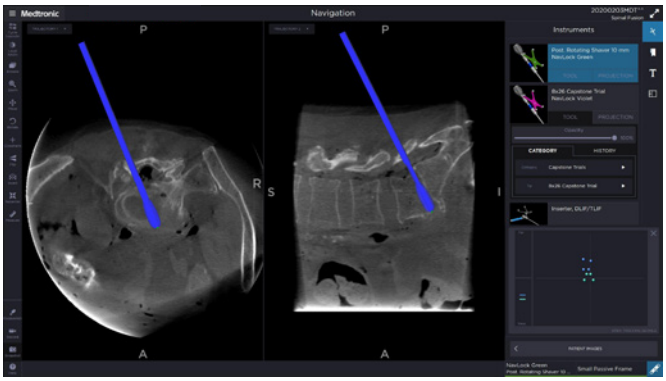


Figure 30c

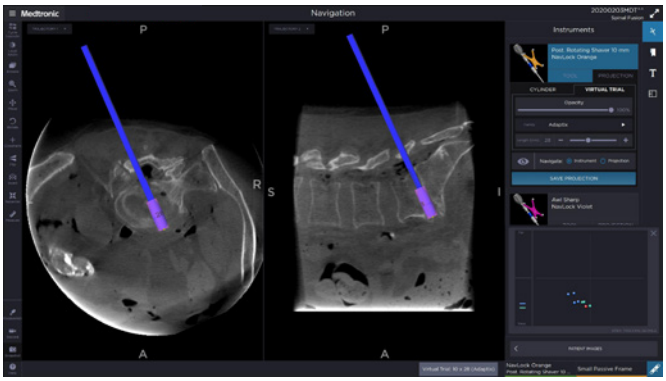


Figure 30d

Important
While trialing for the implant, ensure that bone endplates stay intact. Injuring bony endplates may lead to implant subsidence into the vertebrae.

Important
Use caution while trialing with Shavers if poor bone quality is suspected.

Implant Size Selection with Capstone Trials

Capstone Navigated Trials are available in 8mm, 10mm, 12mm, and 14mm heights in both 22mm and 26mm lengths. If other size options are desired, use standard TLIF procedure steps using non-navigated instruments for the trialing step.

Important

Adaptix™ is compatible with Capstone™ instruments. The Adaptix™ implant is 2mm longer than the Capstone™ trials, therefore, it's important to ensure that the appropriate implant is selectedown list to view the correct projection.

On the StealthStation System, select the appropriate trial size from the "Tip" drop down list. In the "Projection" tab, click "Virtual Trial" and select Adaptix from the "Family" drop down list. d from the "Family" drop

Helpful Hint

Ensure that the "Opacity" is set to 100% to see the projection.

Insert the CAPSTONE Spinal System Navigated Trials with a NavLock® tracker into the disc space until the desired disc space height is established.

Select the appropriate virtual projection length to match the desired length of the implant. Confirm proper placement and alignment of the trial from the projections shown matching the Adaptix implant. If needed, use a slap hammer to remove the trial (**Figure 31a-31c**).

Navigated Capstone Trial	Virtual Projection	Adaptix Implant
22mm	24mm	24mm
26mm	28mm	28mm
32mm	34mm	34mm

Helpful Hint

The Navigated Trials are not available for all size offerings for Adaptix Implant and Trials. Refer to the product ordering section in the back of the procedure guide for a list of the available sizes.

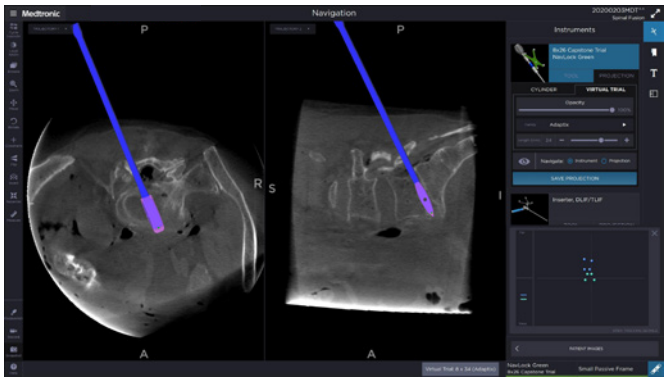


Figure 31c

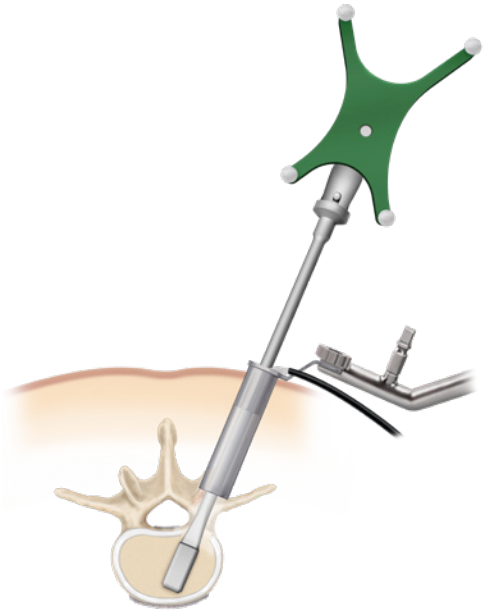


Figure 31a

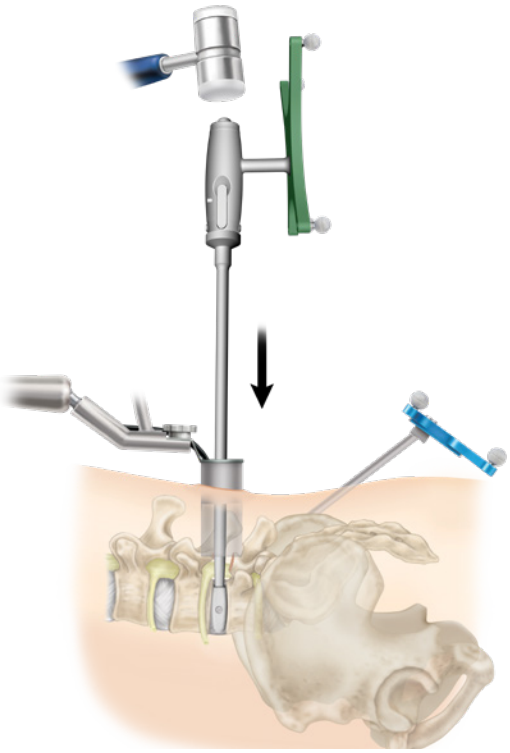


Figure 31b

IMPLANT **PLACEMENT**

On the StealthStation System, click the "Tool" tab and select Adaptix from the "Family" drop down list. Select the appropriately sized Adaptix implant as determined during the trialing step. Place appropriate bone graft material anteriorly and contralaterally in the disc space and in the implant's central cavity, and then firmly attach the implant to the Navigated Inserter. In the software, choose the "Select Projection" tab, then "Show as Implant" to adjust the implant size. Implant size must be adjusted to match selected implant. Use a mallet to gently insert the implant until it is 3mm to 4mm below the posterior margin of the annulus (**Figures 32a and 32b**).

To save an image of the implant in the software, leave the Inserter attached to the implant once placed and choose the "Select Projection" tab; then choose "Save Implant" (**Figure 33**).

Once the implant is positioned, unthread the Inserter from the implant and remove the Inserter. Place appropriate bone graft material into the disc space.

Important
Ensure that the convex surfaces of the implant are aligned and in contact with the endplates during insertion.

Important
DO NOT insert the Adaptix implant sideways and rotate into final position.

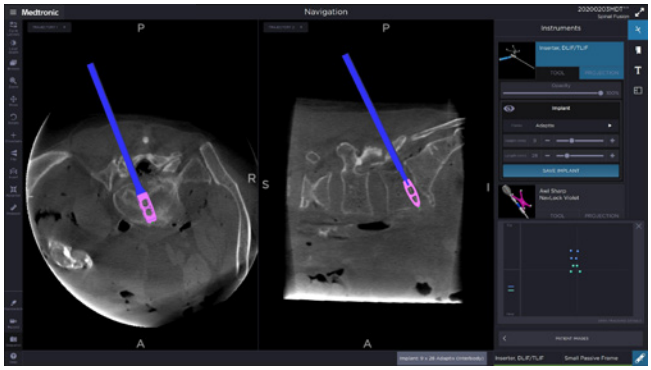


Figure 33

SUPPLEMENTAL **FIXATION**

Final position

The Adaptix interbody is intended to be used with supplemental posterior fixation cleared for use in the lumbar spine.

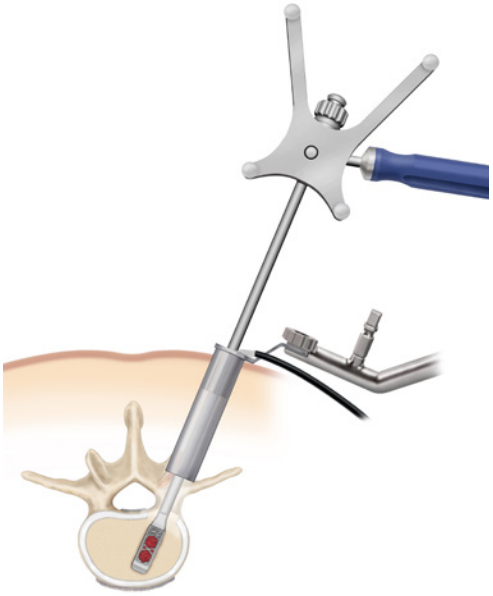


Figure 32a

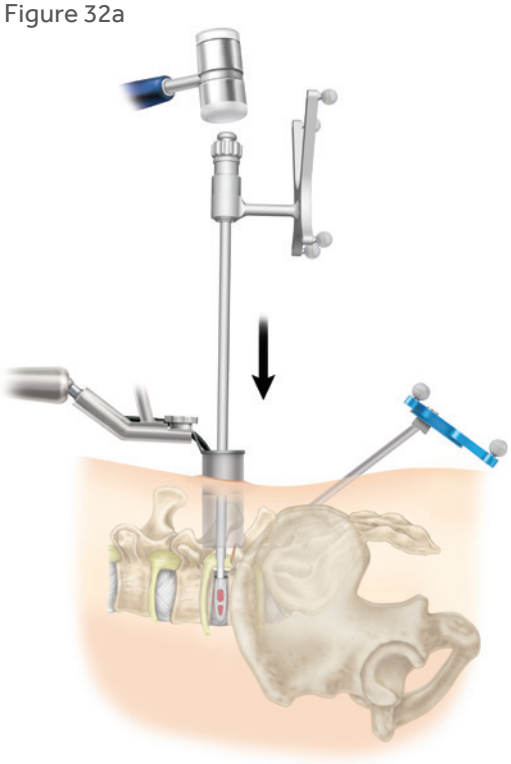
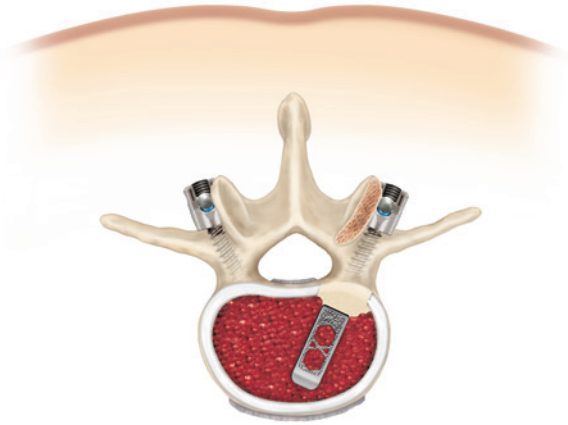


Figure 32b



Navigated MAST PLIF Procedure Steps

PLIF SITE ACCESS

Determine the surgical level and make the skin incision. Insert the retractor into the incision.

Once the retractor is in position, the PLIF may be performed (**Figures 34 and 35**). Laminotomy and facetectomy, disc space preparation, distraction, and end-plate preparation should be performed. Site access (laminotomy, facetectomy, disc space preparation, distraction, and end-plate preparation) should be performed following the steps outlined on pp. 42-43.

Important
Make sure the navigated disc prep instruments were verified with a default tip such as an awl or tap. Use "Select Tip" when choosing the applicable disc prep working end.

Important
During navigation, it is important to frequently confirm navigational accuracy by touching the tip of the navigated disc prep instrument on known anatomical points, including accuracy checkpoints, and comparing the position to the instrument tip in the image with its physical location.

Figure 34

Figure 35

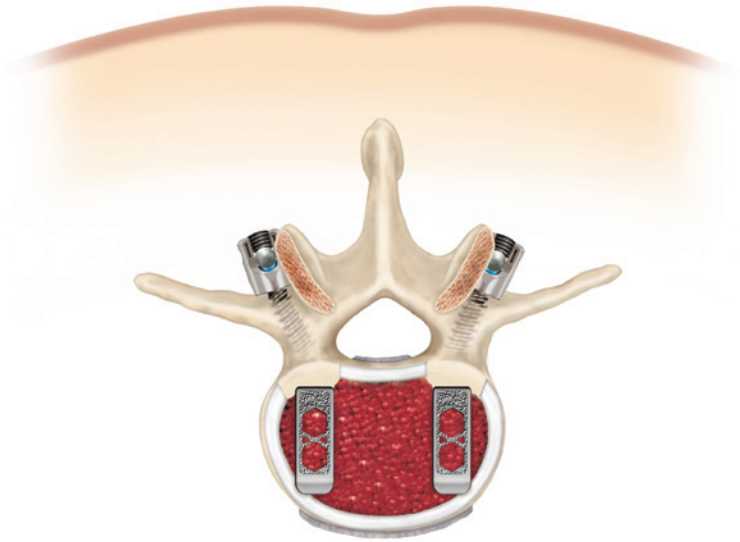
PLIF
PROCEDURE STEPS

For Implant Size Selection and Implant placement, please refer to the steps outlined on pp.44-46. This is done bilaterally.

SUPPLEMENTAL
FIXATION

Final Position

The Adaptix interbody is intended to be used with supplemental posterior fixation cleared for use in the lumbar spine.



Important
Ensure that you only have one navigated tracker in use at a time.

CONFIRMATION
IMAGE ACQUISITION

The Reference Frame should be left in place during the confirmation image acquisition to ensure that navigation can still be performed if any changes are required.

With the patient isocenter, position the O-arm System to perform a 3D image acquisition **(Figure 36)**.
During the acquisition process all personnel who are not wearing protective lead apparel should stand at least 15 feet from the O-arm System with a certified moveable lead shield between themselves and the O-arm System to avoid unnecessary radiation exposure. Perform the image acquisition to confirm screws, rods, and interbody placement **(Figure 37)**. Following confirmation, the Reference Frame should be removed.

Final 3D O-arm images may be obtained prior to final screw tab break-off to permit easier screw repositioning if needed.

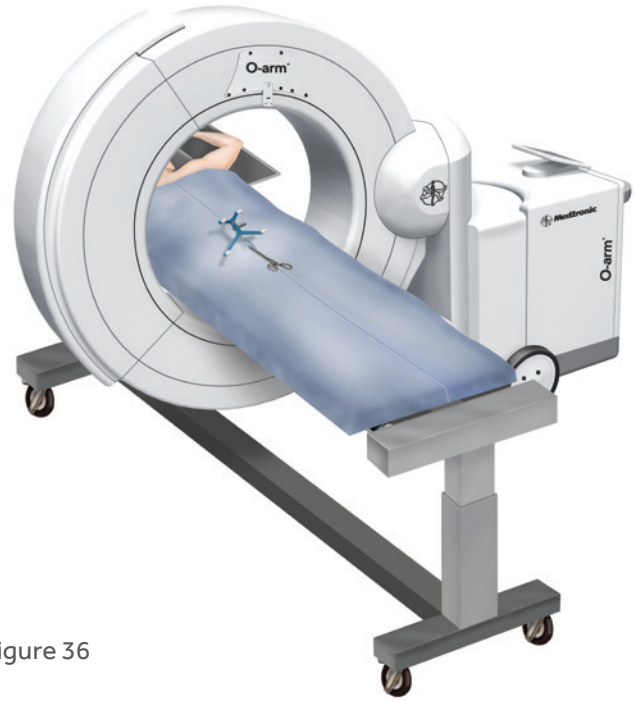


Figure 36

IMPLANT
EXPLANTATION

The Adaptix implant may be removed by using the Navigated Inserter. Attach the Inserter to the implant and remove it from the disc space. Distraction and bone removal may also be required before the implant can be removed with the Navigated Inserter.

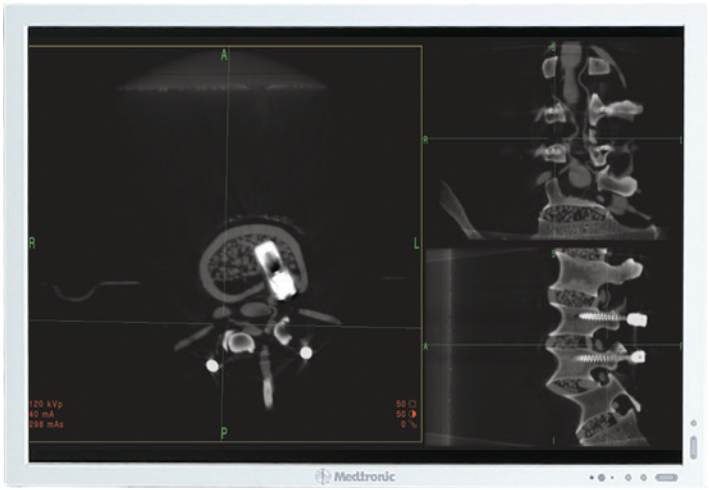


Figure 37

PRODUCT ORDERING INFORMATION

Adaptix 24 and 28mm Implants
SPS03132

Part Number	Description	Quantity
84332406	Adaptix 24mm × 6mm	2
84332407	Adaptix 24mm × 7mm	2
84332408	Adaptix 24mm × 8mm	4
84332409	Adaptix 24mm × 8mm	2
84332410	Adaptix 24mm × 10mm	4
84332411	Adaptix 24mm × 11mm	2
84332412	Adaptix 24mm × 12mm	4
84332413	Adaptix 24mm × 13mm	2
84332414	Adaptix 24mm × 14mm	2
84332806	Adaptix 28mm × 6mm	2
84332807	Adaptix 28mm × 7mm	2
84332808	Adaptix 28mm × 8mm	4
84332809	Adaptix 28mm × 9mm	2
84332810	Adaptix 28mm × 10mm	4
84332811	Adaptix 28mm × 11mm	2
84332812	Adaptix 28mm × 12mm	4
84332813	Adaptix 28mm × 13mm	2
84332814	Adaptix 28mm × 14mm	2
31000000	Generic Suitcase	1

Adaptix 34mm Implants
SPS03133

Part Number	Description	Quantity
84333407	Adaptix 34mm × 7mm	2
84333408	Adaptix 34mm × 8mm	2
84333409	Adaptix 34mm × 9mm	2
84333410	Adaptix 34mm × 10mm	2
84333411	Adaptix 34mm × 11mm	2
84333412	Adaptix 34mm × 12mm	2
84333413	Adaptix 34mm × 13mm	2
84333414	Adaptix 34mm × 14mm	2
8657021	Implant Suitcase	1

Capstone Instrument Set
Set Type 2351

Part Number	Description	Quantity
1850078	Triple Generic Outer Case	1
1850079	Generic Outer Lid	1
2980100	6mm Osteotome	1
2980622	6mm × 22mm Distractor/Trial	1
2980626	6mm × 26mm Distractor/Trial	1
2980722	7mm × 22mm Distractor/Trial	1
2980726	7mm × 26mm Distractor/Trial	1
2980822	8mm × 22mm Distractor/Trial	1
2980826	8mm × 26mm Distractor/Trial	1
2980922	9mm × 22mm Distractor/Trial	1
2980926	9mm × 26mm Distractor/Trial	1
2981022	10mm × 22mm Distractor/Trial	1
2981026	10mm × 26mm Distractor/Trial	1
2981122	11mm × 22mm Distractor/Trial	1
2981126	11mm × 26mm Distractor/Trial	1
2981222	12mm × 22mm Distractor/Trial	1
2981226	12mm × 26mm Distractor/Trial	1
2981322	13mm × 22mm Distractor/Trial	1
2981326	13mm × 26mm Distractor/Trial	1
2981422	14mm × 22mm Distractor/Trial	1
2981426	14mm × 26mm Distractor/Trial	1
2981522	15mm × 22mm Distractor/Trial	1
2981526	15mm × 26mm Distractor/Trial	1
2981622	16mm × 22mm Distractor/Trial	1
2981626	16mm × 26mm Distractor/Trial	1
2990001	Threaded Inserter	1
2990003	Threaded Inserter Shaft	1
2990005	Lower Tray	1
2990006	Upper Tray	1
9074002	Slap Hammer	1
2990002	Extractor	1

Scissor Jack™ Expandable Distractor
Set Type 565

Part Number	Description
9198990	Modular Opener
9198991	Variable Distractor Tip Assembly
9198992	SCISSOR JACK® Half Tray
9198993	SCISSOR JACK® Half Tray Lid

*Navigated interbody trials available

PRODUCT ORDERING INFORMATION

Posterior Microscope Instrument (PMI) Set
Set Type PMI

Part Number	Description
907340	8mm Small Rotate Cutter
907341	10mm Medium Rotate Cuter
907342	12 Large Rotate Cutter
907338	8mm Osteotome
907370	Mallet
907571	4mm Downbiting Pituitary
907610	8mm Pituitary Rongeur
9569536	4mm Pituitary, Ring Handle
9569570	4mm Upbiting Pituitary
907382	Graft Impactor
907380	Dural Retractor
907347	Small Forward Angle Curette
907348	Large Forward Angle Curette
907349	Small Reverse Angle Curette
907350	Large Reverse Angle Curette
907351	Left Angled Cup Curette
907352	Right Angled Cup Curette
907353	Right Straight Cup Curette
907354	Left Straight Cup Curette
907355	Ring Curette
907381	Bayoneted Forceps
2900164	Reamer T-handle
2940357	8mm Shaver
2940350	9mm Shaver
2940351	10mm Shaver
2940352	11mm Shaver
2940353	12mm Shaver
2940354	13mm Shaver
2940355	14mm Shaver
907406	Distracting Osteotome
907408	8mm Distractor
907409	9mm Distractor
907410	10mm Distractor
907411	11mm Distractor
907412	12mm Distractor
907413	13mm Distractor
907414	14mm Distractor
907391	Top Instrument Tray
907390	Middle Instrument Tray
907392	Bottom Instrument Tray
185-064	Generic Metal Case Lid
907393	Outer Case

Navigated 22mm Capstone Trials
SPS02869

CFN	Description	Qty
NAV2050	Capstone NAV Trial 8×22mm	1
NAV2051	Capstone NAV Trial 10×22mm	1
NAV2052	Capstone NAV Trial 12×22mm	1
NAV2053	Capstone NAV Trial 14×22mm	1
1850094	Lid, Base Generic	1
NAV2094	Capstone NAV 22mm Trial Tray	1

Navigated 26mm Capstone Trials
SPS03127

CFN	Description	Qty
9734555	Capstone NAV Trial 8×26mm	1
9734559	Capstone NAV Trial 10×26mm	1
9734563	Capstone NAV Trial 12×26mm	1
9734567	Capstone NAV Trial 14×26mm	1
1850097	Lid, Base Generic	1
3991003	Capstone NAV 26mm Trial Tray	1

Navigated TLIF/DLIF Inserter Set
SPS03128

CFN	Description	Qty
9734456	NAV Interbody Inserter	1
9734592	Slap Hammer	1
1850097	Lid, Base Generic	1
2968001	TLIF/DLIF NAV Inserter Tray	1

IMPORTANT PRODUCT INFORMATION
ON THE ADAPTIX INTERBODY SYSTEM WITH TITAN NANOLOCK™ SURFACE TECHNOLOGY

Note: not all parts may be available in each geography.

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 instructed as to its mechanical and material applications and limitations.

DESCRIPTION

The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology consists of additive manufactured titanium cages of various lengths and heights to accommodate patient anatomy. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The open geometry of the implants allows them to be packed with autograft bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate. The interbody device is treated with Titan Surface Technologies™, where nanoLOCK™ Surface Technology (MMN™) is designed to improve fixation to the adjacent bone. The nanoLOCK™ Surface Technology (MMN™) provides a microscopic-roughened surface with nano-scale features. The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Stainless steel and titanium implants are not compatible. They must not be used together in a construct. As with all orthopedic implants, in no case may the implants be re-used.

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS

The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. 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. The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

These patients should be skeletally mature and have had six months of nonoperative treatment. The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate. These implants may be implanted via an open or a minimally invasive posterior approach and/or transforaminal approach.

CONTRAINDICATIONS

This device is not intended for cervical spine use. Contraindications include:

- 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 use would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

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

POTENTIAL ADVERSE EVENTS

- 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, 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 and/or retropulsion 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.
- 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.

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 implants are important considerations in the successful use of the system. Further, proper selection and compliance of the patient will greatly affect results. Patients who smoke were 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.

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

A device that has been implanted should never be re-used or re-processed under any circumstances. Sterile packaged devices are never to be re-sterilized.

Reuse or reprocessing 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 in this document should be conveyed to the patient.

!USA For US audiences only

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

IMPLANT SELECTION

The selection of proper size, shape, and design of the implant for each patient is crucial to success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the human anatomy. Unless great care is taken in patient selection, placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage or loosening of the device before the fusion process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by Medtronic. In the interests of patient safety, it is therefore recommended that Medtronic implants are not used with devices from any other source.

Never, under any circumstances, reuse an Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology device. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

IMPORTANT PRODUCT INFORMATION
FOR THE ADAPTIX INTERBODY SYSTEM WITH TITAN NANOLOCK™ SURFACE TECHNOLOGY

PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the contraindications should be avoided.
- Care should be taken in the handling and storage of the device(s). They should not be scratched or damaged. Devices should be protected during storage especially from corrosive environments.
- The surgeon should be familiar with the various devices before use and should personally verify all devices are present before surgery.
- The size of device for the case should be determined prior to surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- Instruments will be cleaned and sterilized before use. Additional sterile implants and instruments should be available in case of an unexpected need.

INTRAOPERATIVE

- Instructions in any available Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology surgical technique manual should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the spinal cord and/or nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
- To ensure proper fusion below and around the location of the fusion, autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate must be used.
- Bone cement should not be used because this material may make removal of these components difficult or impossible.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as result of early or excessive weight- bearing, muscular activity, or sudden jolts or shock to the spine.
- The patient should be advised not to smoke or consume excess alcohol during period of the bone fusion process.
- The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices should be revised and/or removed immediately before serious injury occurs.
- Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology implants are interbody devices and are intended to stabilize the operative area during the fusion process.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING

Implants are supplied in a sterile form. Visually inspect all packaging before us. Packages should be intact upon receipt. Once the seal on the sterile package has been broken, the product should not be used or re-sterilized. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure there is no damage prior to use. Damaged packages or products should not be used and should be returned to Medtronic.

STERILIZATION

Implants are provided sterile and should only be used if they are marked sterile and clearly labeled as such in an unopened sterile package provided by the company. Only sterile products should be placed in the operative field.

CLEANING AND DECONTAMINATION

Instruments have reprocessing instructions enclosed within the product packaging. Refer to these detailed instructions for further information on the general considerations, cleaning, and sterilization procedures. These reprocessing instructions can also be found at http://manuals.medtronic.com/ according to the product part number.

PRODUCT COMPLAINTS

To report any product problems, contact Medtronic.

Patients in the European Union experiencing a serious incident in relation to the device should contact Medtronic and the competent authority of the Member State in which they are established.

MRI INFORMATION

MR Confidential

The Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology was determined to be MR Conditional based on non-clinical testing and engineering rationales. A patient with this device can be safely scanned immediately after device placement under the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla.
- Maximum spatial gradient magnetic field of 3000 Gauss/cm (30 T/m).
- Maximum whole-body average specific absorption rate (SAR) of 2.0-W/kg under normal operating mode for 15 minutes of scanning per pulse sequence.

Under the scan conditions defined, a worst-case interbody fusion device representative of the Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology produced a maximum temperature rise <5.0°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by a worst-case interbody fusion device representative of the Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology extends approximately 13mm for a spin echo sequence and 23mm for a gradient echo sequence in a 3 Tesla MR system.

Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

If the Adaptix™ Interbody System with Titan nanoLOCK™ Surface Technology is used in connection with any device which is not MR Conditional, be advised this combination was not tested in the MR environment and, therefore, higher heating and possible injury to the patient may occur. The presence of other implants or the health state of the patient may require a modification of the MR conditions.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is required, contact Medtronic.

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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