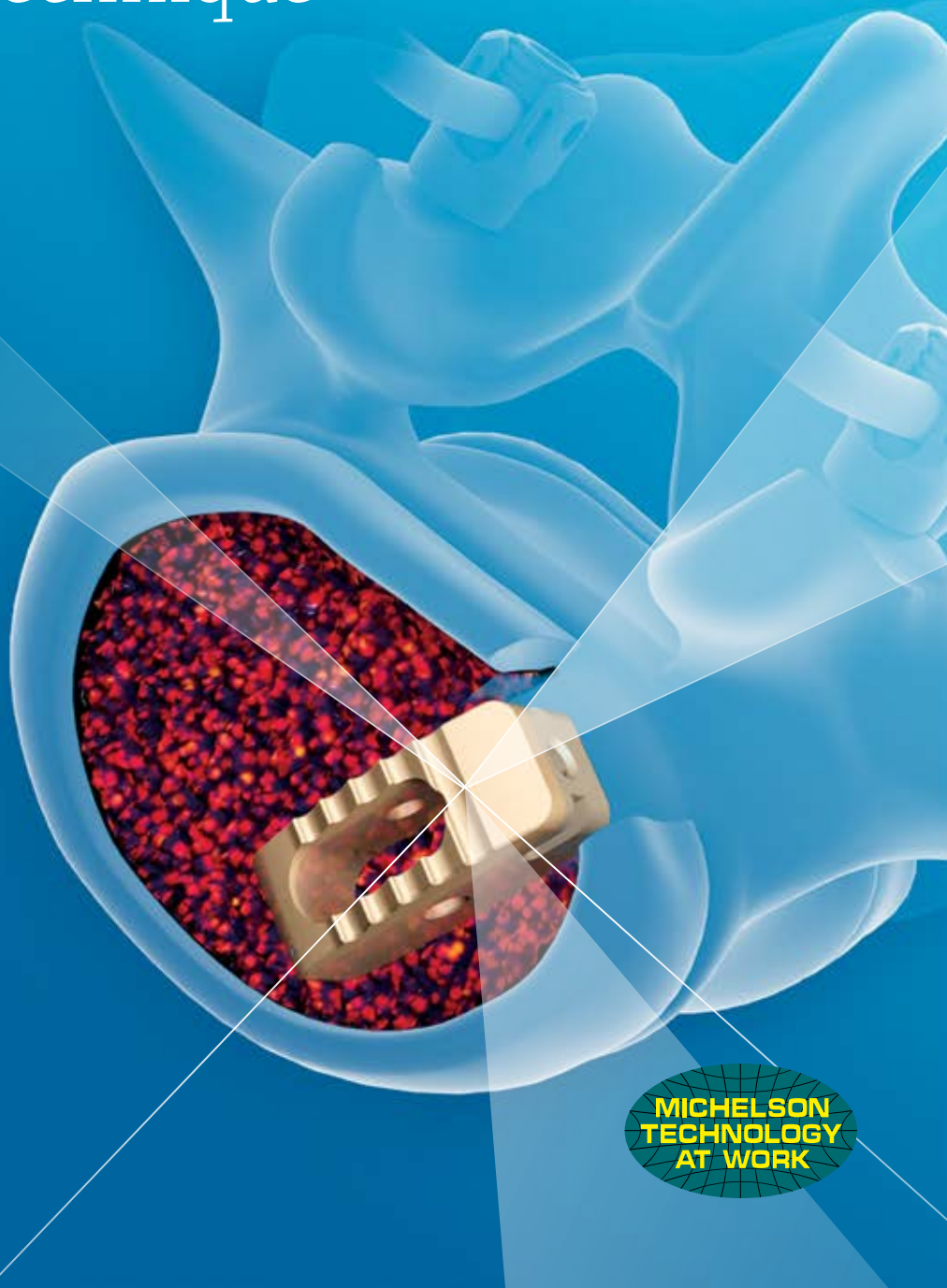
Medtronic

CAPSTONE® PEEK Spinal System

PLIF and TLIF

Surgical Technique



As described by:

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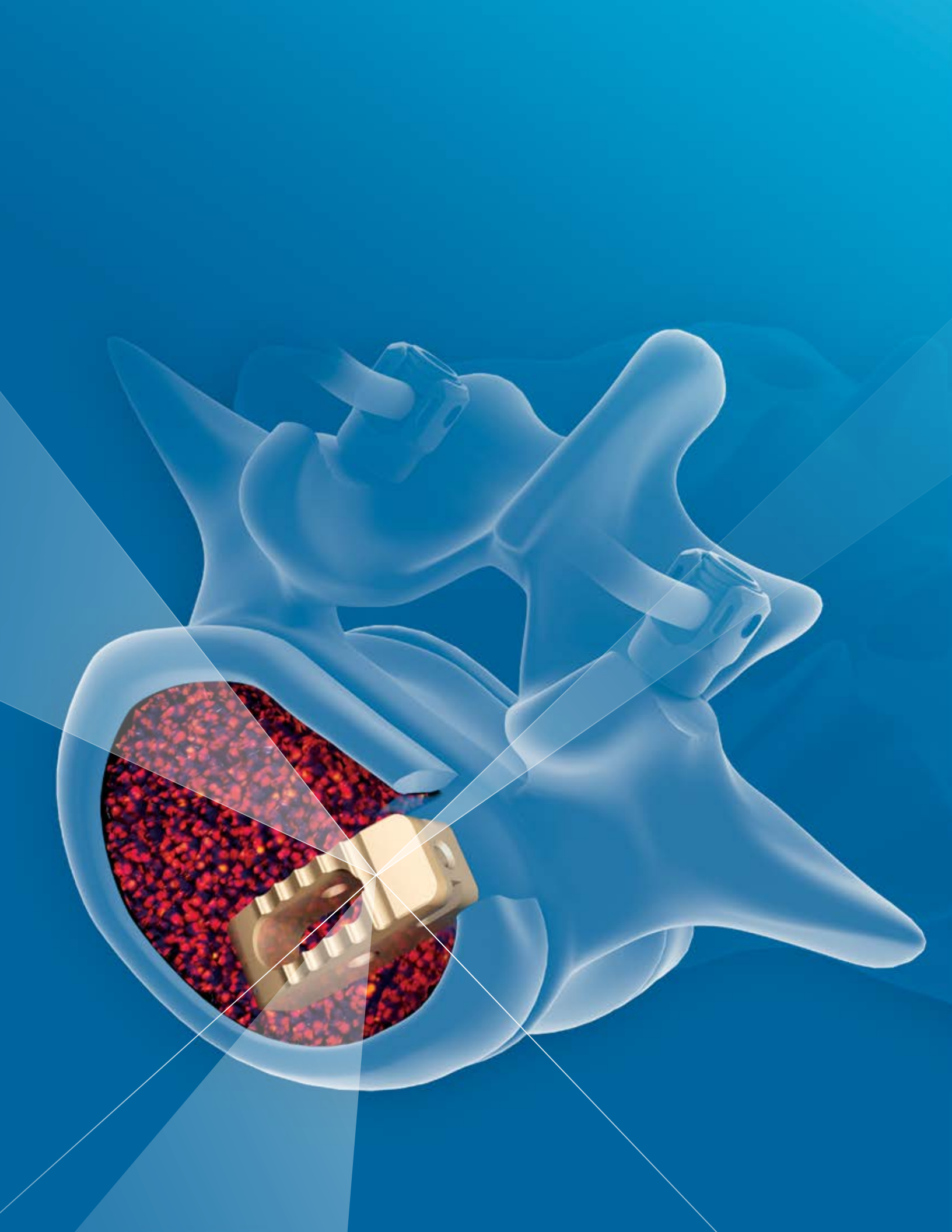
MICHELSON TECHNOLOGY AT WORK



Medtronic

CAPSTONE® PEEK Spinal System

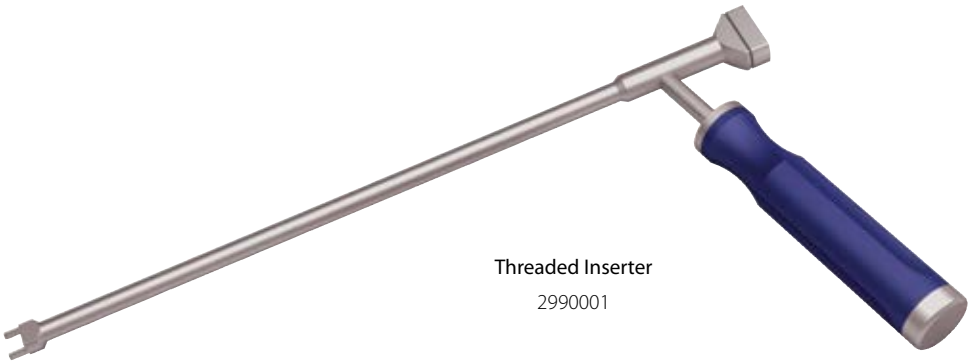
PLIF and TLIF

Surgical Technique

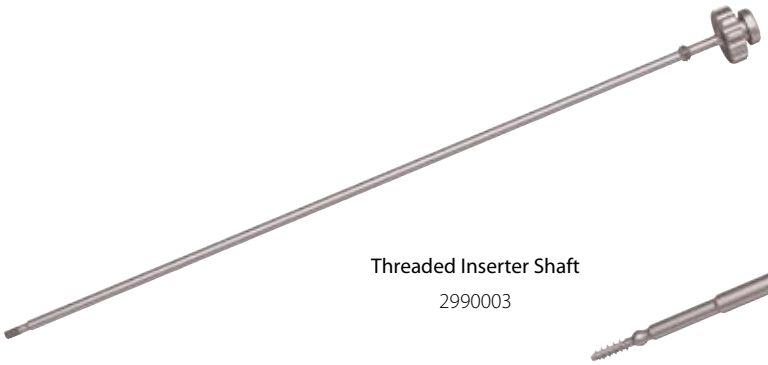
Instrument Set

Distractor/Trial
2980822

Distractor/Trial
2981032



Threaded Inserter
2990001



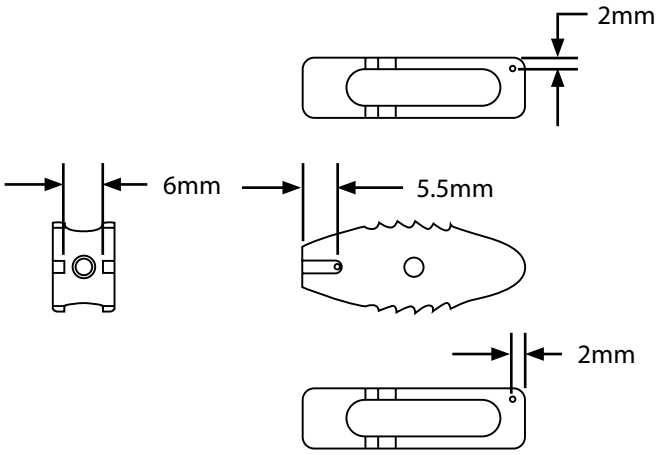
Threaded Inserter Shaft
2990003

Extractor
2990002

Slap Hammer
9074002

X-ray Marker Location

Below are diagrams demonstrating the location of the x-ray markers as the view is rotated from a lateral to a straight AP view.

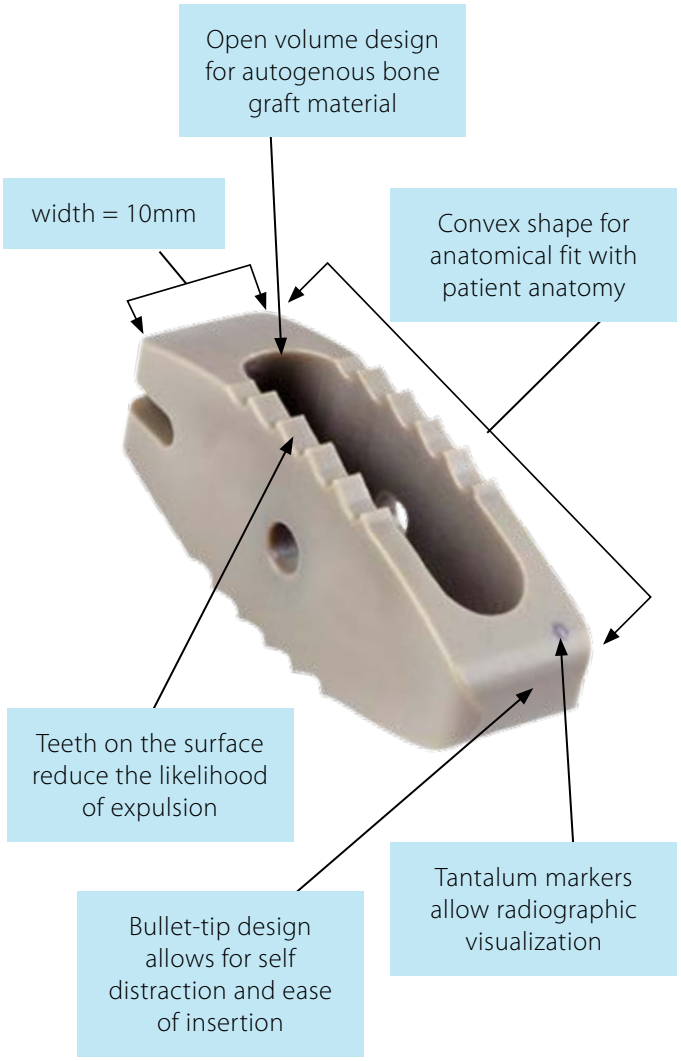


Marker Locations

Implant Sizing

Length	Height	Internal Volume
22mm	6mm	0.32cc
22mm	7mm	0.38cc
22mm	8mm	0.45cc
22mm	9mm	0.50cc
22mm	10mm	0.56cc
22mm	11mm	0.61cc
22mm	12mm	0.66cc
22mm	13mm	0.71cc
22mm	14mm	0.76cc
22mm	15mm	0.81cc
22mm	16mm	0.86cc
26mm	6mm	0.44cc
26mm	7mm	0.52cc
26mm	8mm	0.62cc
26mm	9mm	0.69cc
26mm	10mm	0.76cc
26mm	11mm	0.83cc
26mm	12mm	0.91cc
26mm	13mm	0.97cc
26mm	14mm	1.05cc
26mm	15mm	1.11cc
26mm	16mm	1.19cc
32mm	7mm	0.73cc
32mm	8mm	0.85cc
32mm	9mm	0.96cc
32mm	10mm	1.06cc
32mm	11mm	1.16cc
32mm	12mm	1.26cc
32mm	13mm	1.37cc
32mm	14mm	1.47cc
32mm	15mm	1.57cc
32mm	16mm	1.67cc
36mm	7mm	0.87cc
36mm	8mm	1.01cc
36mm	9mm	1.13cc
36mm	10mm	1.25cc
36mm	11mm	1.37cc
36mm	12mm	1.50cc
36mm	13mm	1.62cc
36mm	14mm	1.74cc
36mm	15mm	1.86cc
36mm	16mm	1.98cc

Benefits



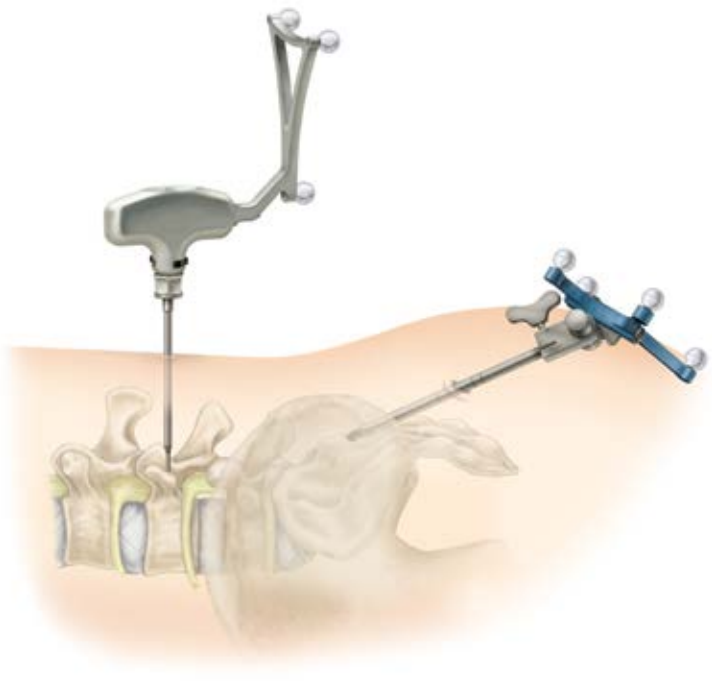
Risks

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 spinal mobility or function

TLIF: Open and MAST™ Techniques

Navigation and Neuromonitoring Options



Navigation Option

The FLUORONAV® MAST™ Spinal Procedural Solution can provide assistance with pedicle navigation. An additional module containing all of the necessary attachments is required for using the FLUORONAV® MAST™ Spinal Procedural Solution.

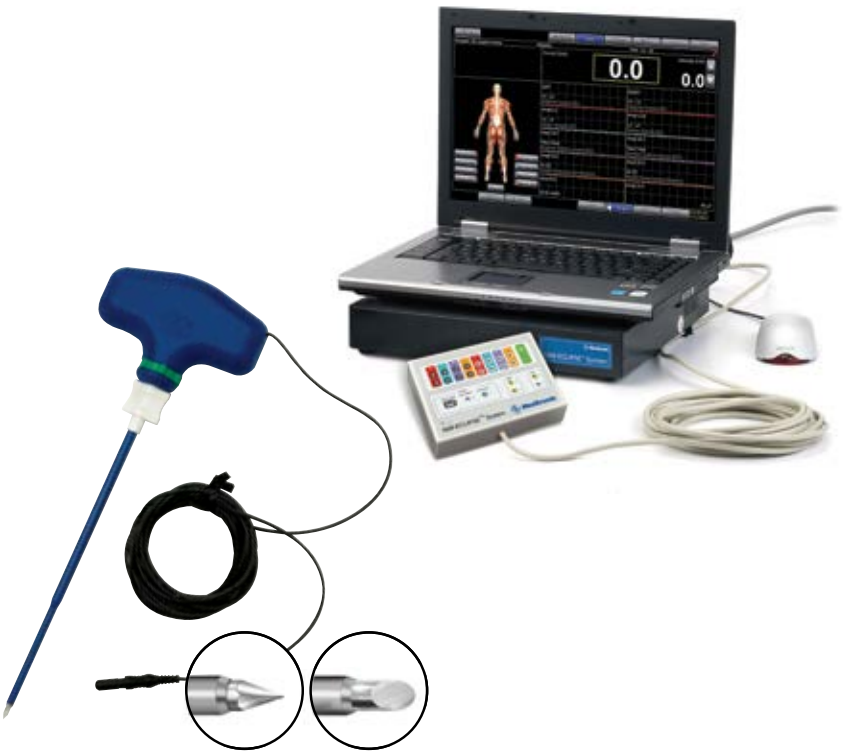
Neuromonitoring Option

For neuromonitoring, a NIM® PAK Needle or Pedicle Probe may be used to access the pedicle. Triggered EMG monitoring can be performed during advancement of the needle into the pedicle to ensure proper placement.

Important

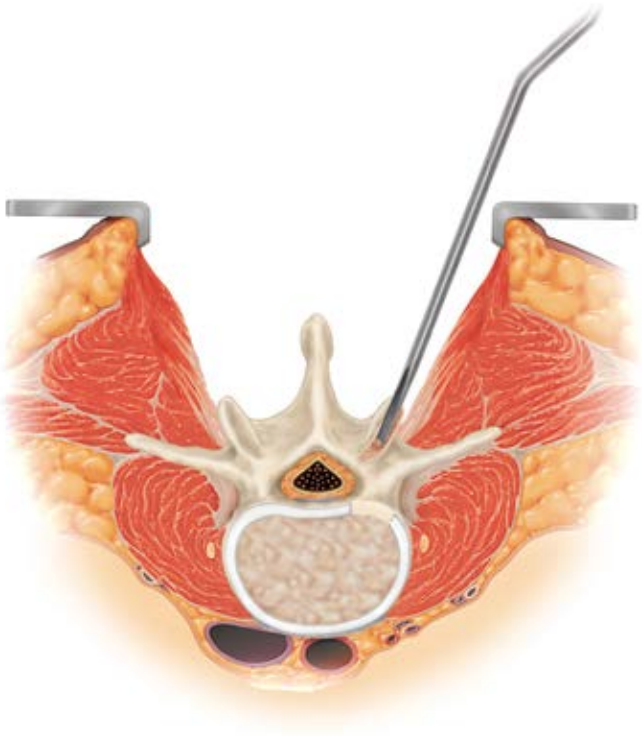
Please see the NIM-ECLIPSE® Spinal System package insert and user's manual for complete instructions and a list of warnings, precautions, and other medical information.

The NIM-ECLIPSE® Spinal System is intended for use to record, monitor, and stimulate/record biopotential signals including electromyograph (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.



Laminotomy and Facetectomy

Open TLIF Technique

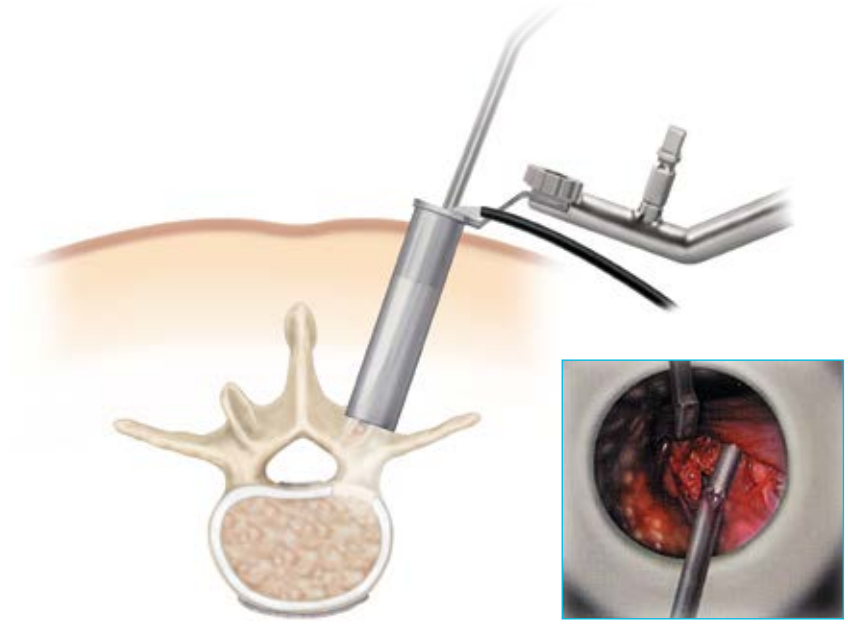


A facetectomy is performed on the ipsilateral side. Using an osteotome or drill, remove the ascending and descending articular processes.

Additional bony removal may be carried out using a Kerrison rongeur or drill.

A 1cm-square annulotomy is made with a scalpel in Kambin's triangle. The disc is removed using a pituitary rongeur and 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.

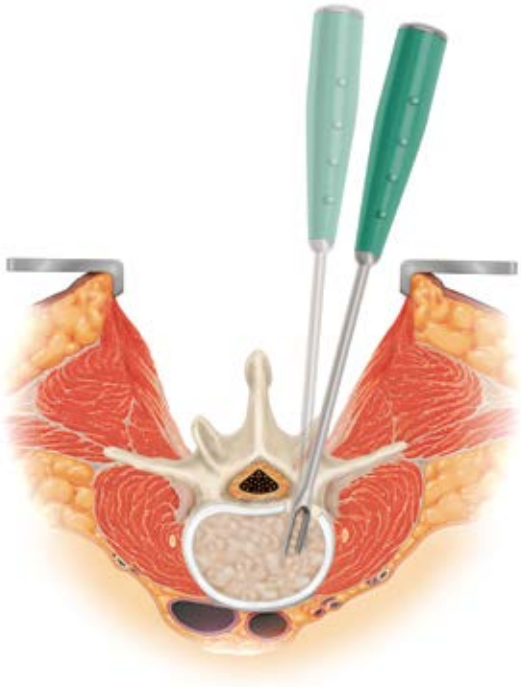


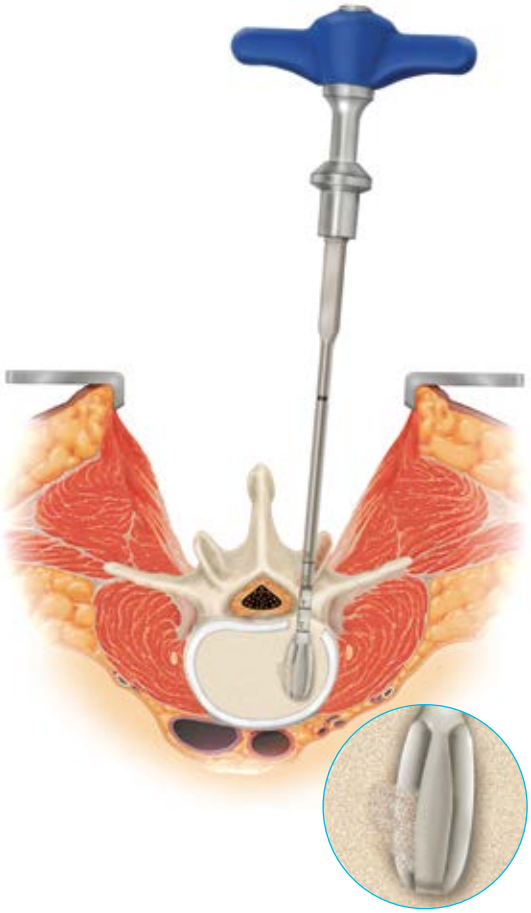
Discectomy

MAST™ TLIF Technique

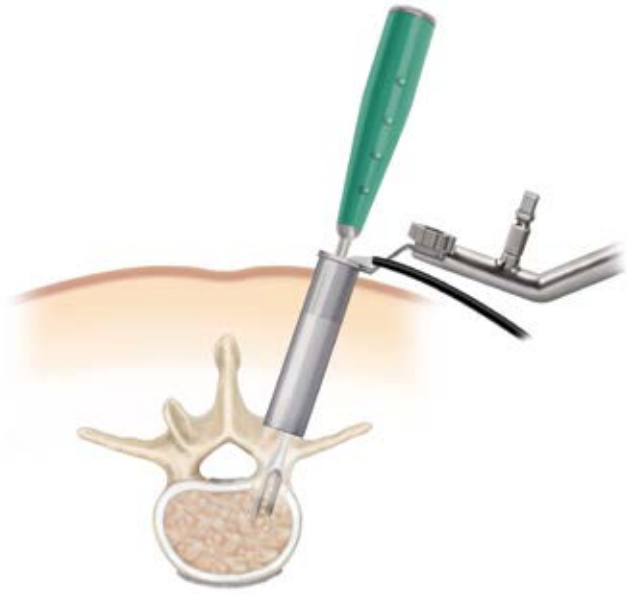
Disc Space Preparation

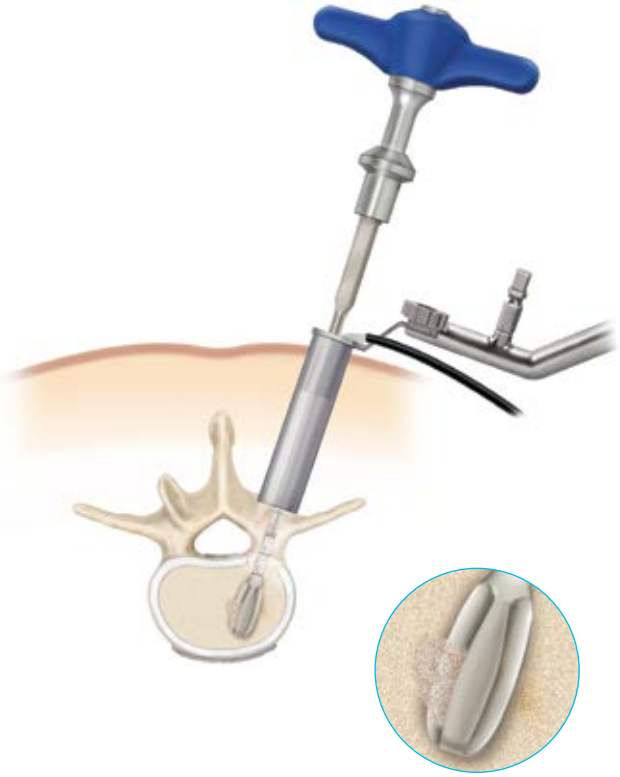
Open TLIF Technique





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

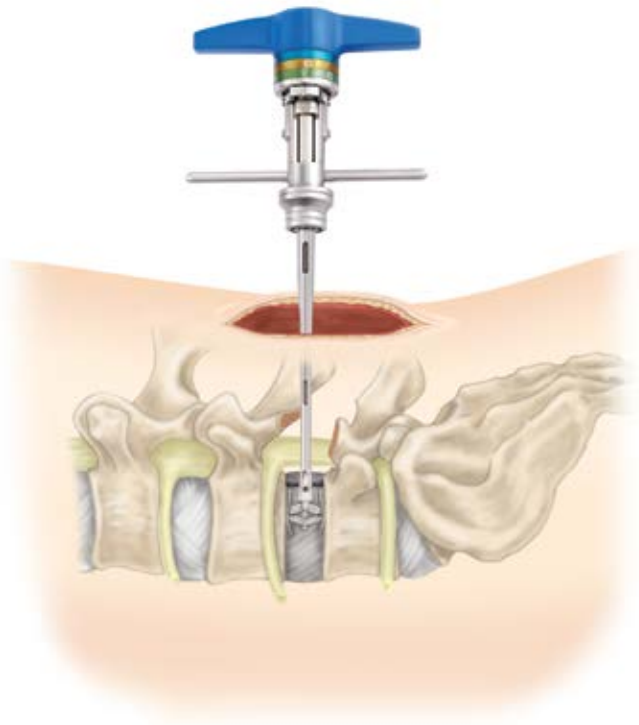




MAST™ TLIF Technique

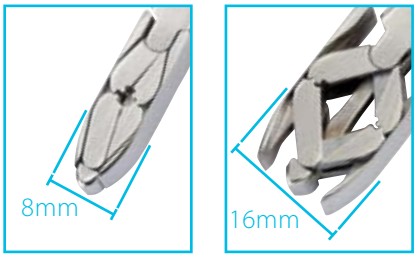
Distraction

Open TLIF Technique

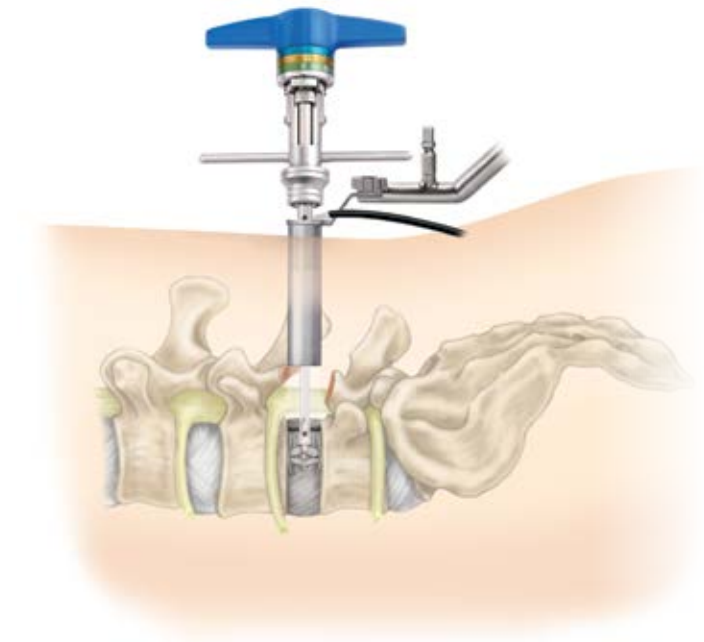


The disc space is sequentially distracted with a Distractor/Trial or the SCISSOR JACK® Distractor until adequate disc space height is obtained and adequate foraminal size is restored.

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**

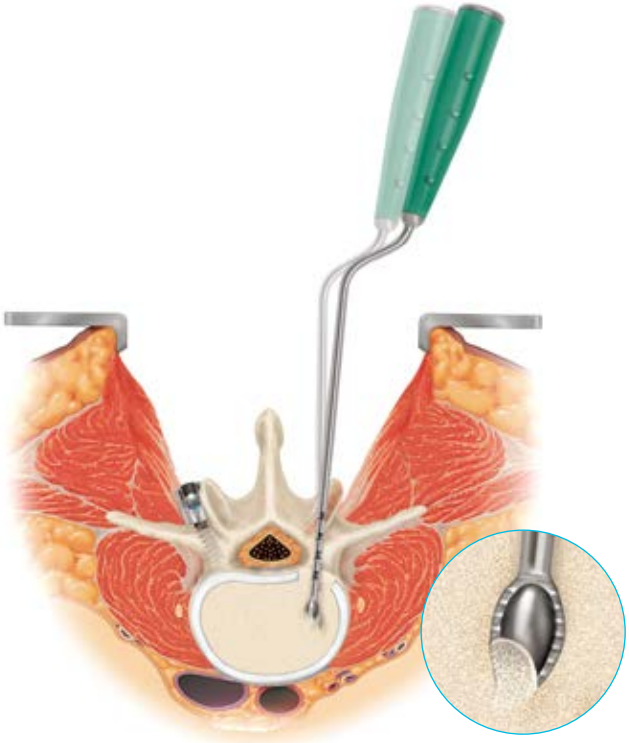


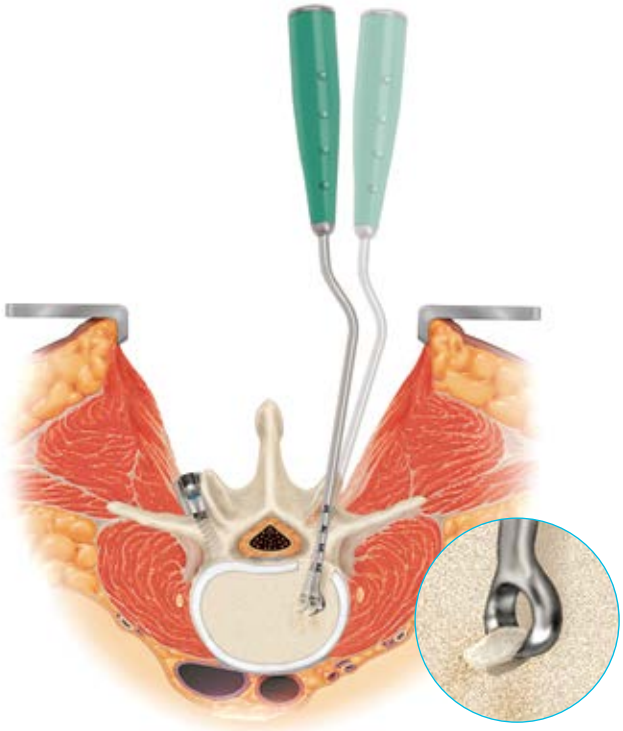
Insert supplemental screw and rod fixation and provisionally tighten the construct on the contralateral side to maintain distraction during disc space preparation.

MAST™ TLIF Technique

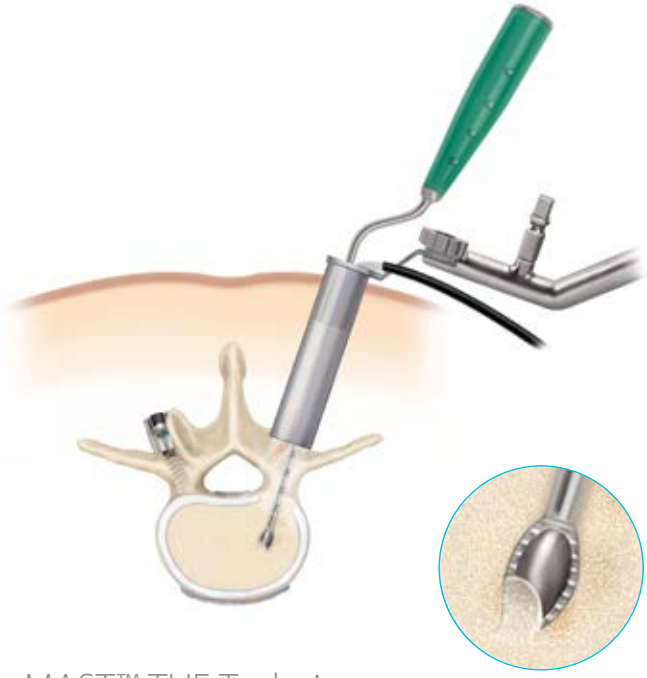
End Plate Preparation

Open TLIF Technique





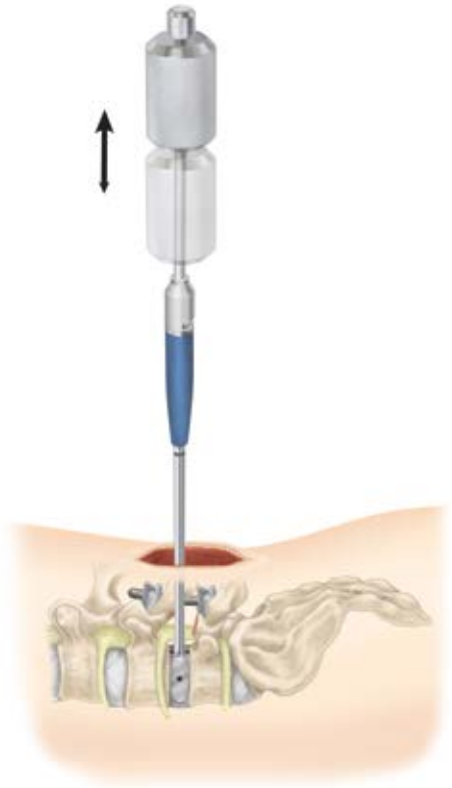
Specifically designed angled instruments allow disc resection and end plate preparation.



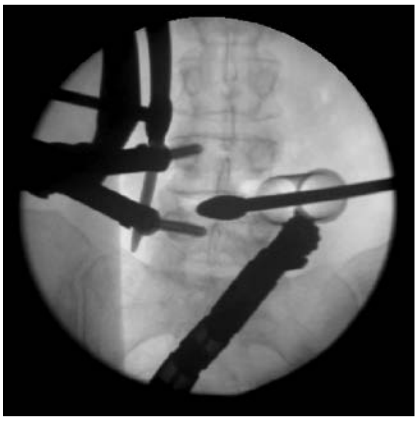
MAST™ TLIF Technique

Trial Insertion

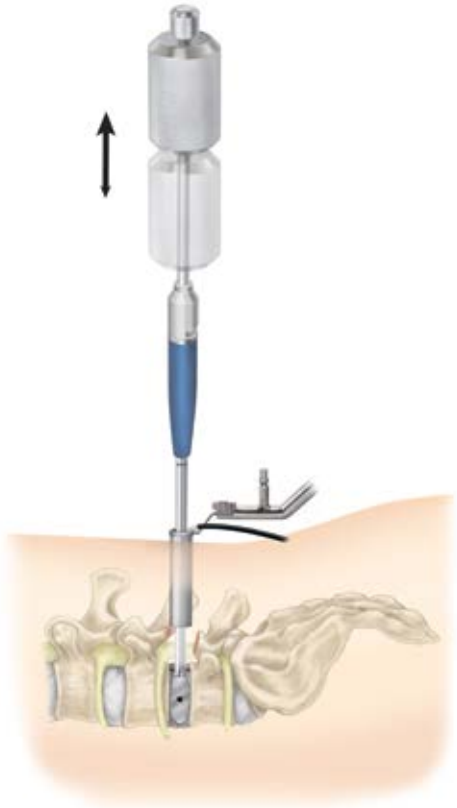
Open TLIF Technique



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.



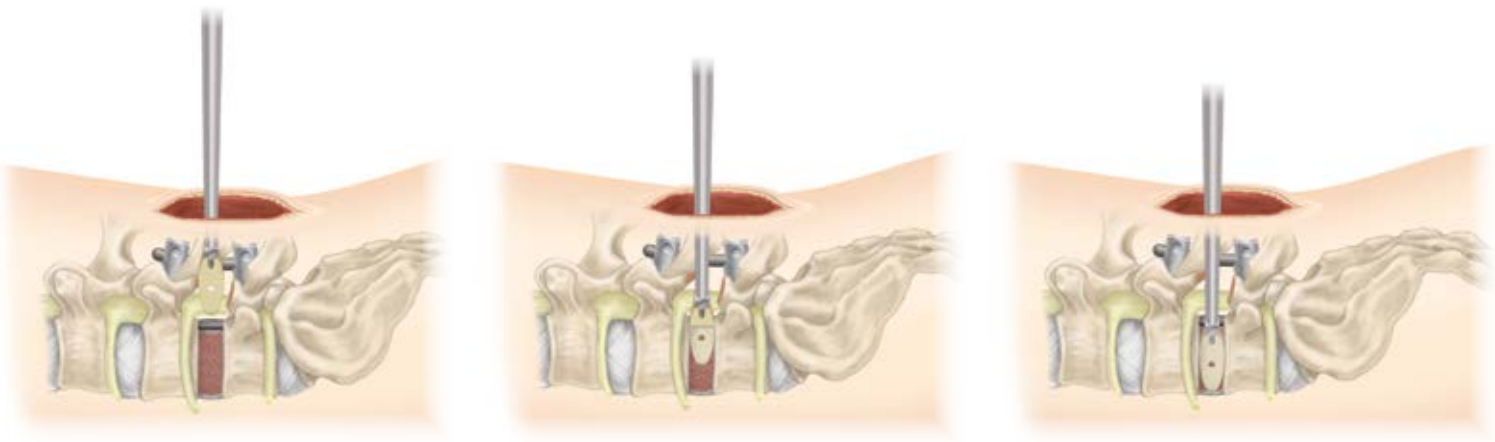
AP View



MAST™ TLIF Technique

CAPSTONE® PEEK Interbody Spacer Insertion

Open TLIF Technique

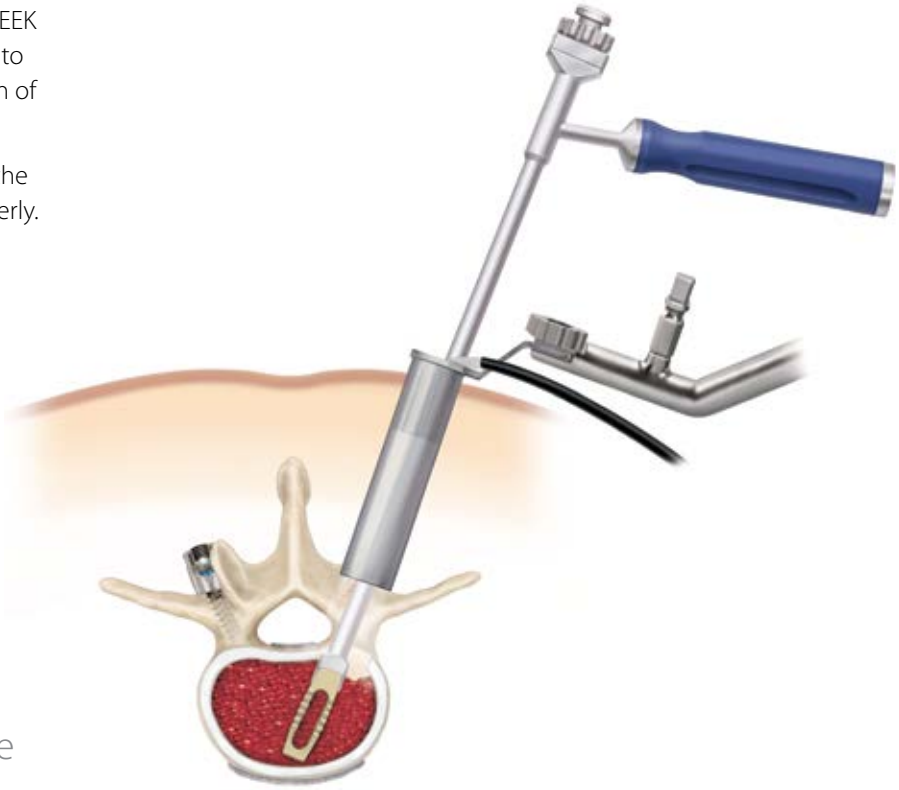


The appropriately sized CAPSTONE® PEEK Interbody Spacer is chosen during the trialing step and is firmly attached to the Inserter.

Before inserting the interbody spacer, place autograft anteriorly and contralaterally, and in the interbody spacer central cavity.

Gently impact the CAPSTONE® PEEK Interbody Spacer until it is 3mm to 4mm below the posterior margin of the annulus.

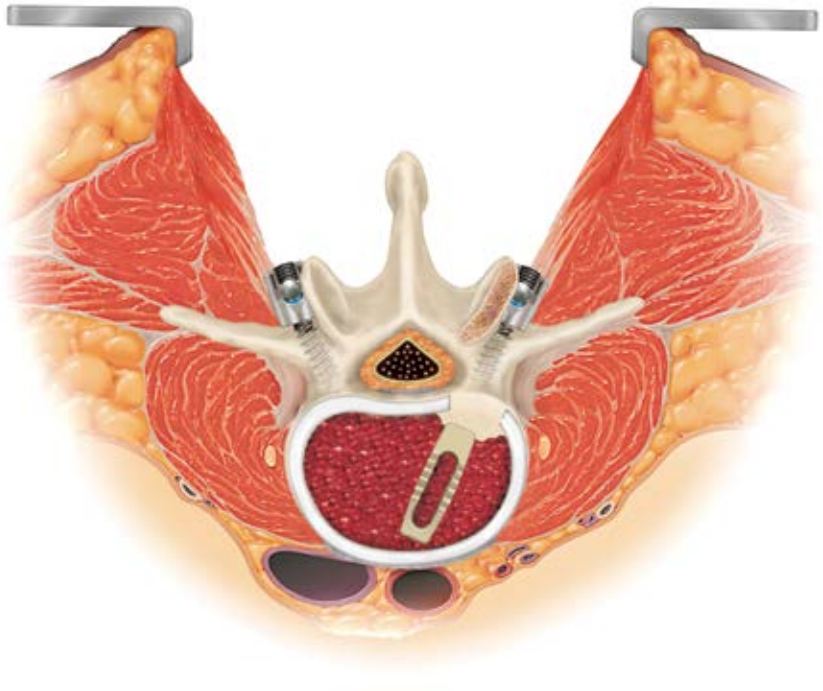
Care should be taken to ensure the interbody spacer is aligned properly.



MAST™ TLIF Technique

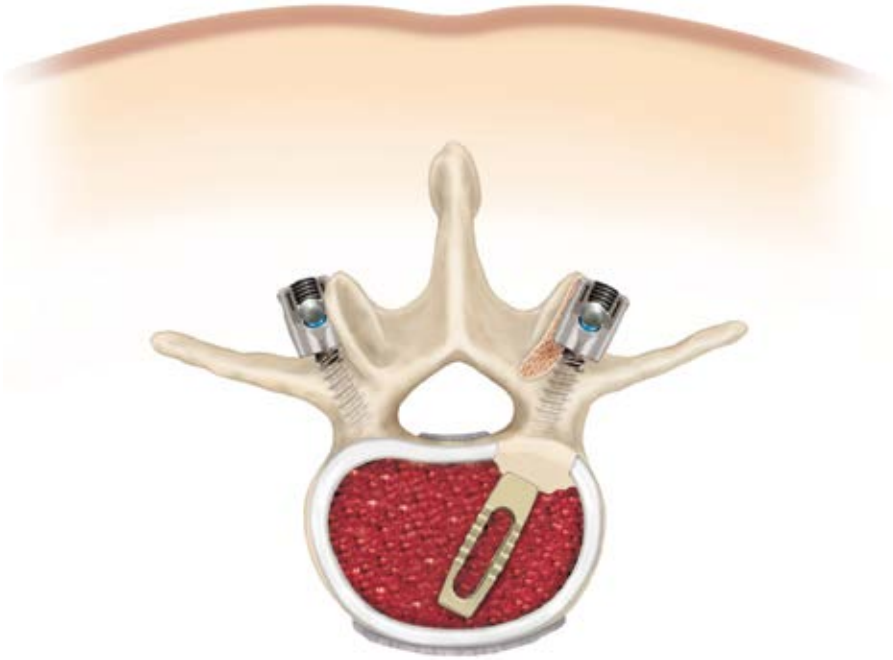
Final Placement

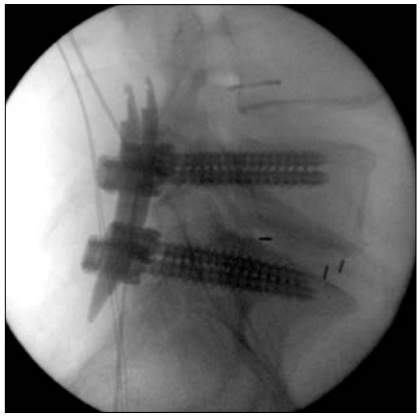
Open TLIF Technique



After the CAPSTONE® PEEK Interbody Spacer 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

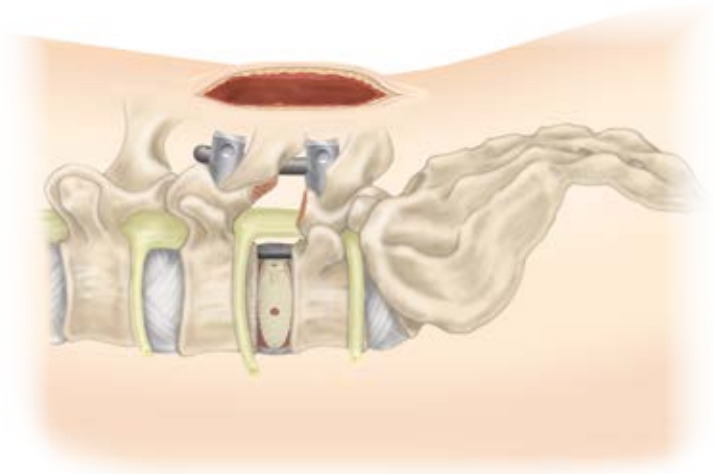
Additional Fixation Options and Explantation

The CD HORIZON® SOLERA™ System Set Screws (plugs) may be removed using the T27 Obturator and the Self-Retaining Breakoff Driver. The T27 Obturator is inserted into the working end of the Self-Retaining Breakoff Driver so that the knurled portion of the T27 Obturator is flush with the driver. Insert the T27 Obturator tip through the Counter Torque, which should be seated on the screw, and into the plug, turning counterclockwise until the plug has been removed. The pedicle screws may be removed using either the multi-axial Screwdriver or the Self-Retaining Screwdriver in connection with the Ratcheting Handle. First, attach the Ratcheting Handle to the modular end of the driver. Next, fully engage the hex end of the Screwdriver into the screw head, then, if using the multi-axial screwdriver, thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.

If removal of a CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is necessary, place the 7/32" torque-limiting set screwdriver over the midline nut and turn counterclockwise to loosen. Place the 3.0mm Hex Head Shaft Removal Driver into a standard Medtronic Quick Connect Handle. Place the tip of the 3.0mm Internal Hex Screwdriver into the set screw and confirm that the 3.0mm tip is completely inserted and seated in the set screw so that the tip does not strip the hex. Turn the screwdriver counterclockwise to loosen the set screw from the rod.

The CAPSTONE® PEEK Interbody Spacer may be removed by using the Threaded Inserter. Attach the Threaded Inserter to the interbody spacer and remove the spacer from the disc space.

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

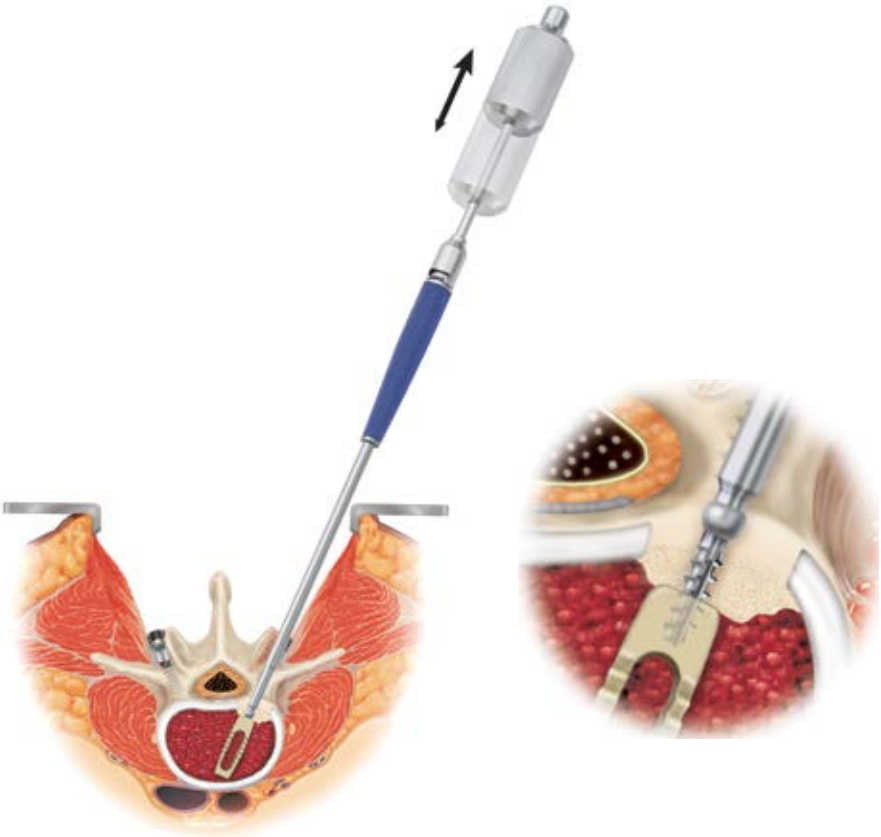


CD HORIZON® SOLERA™ 4.75mm Spinal System*

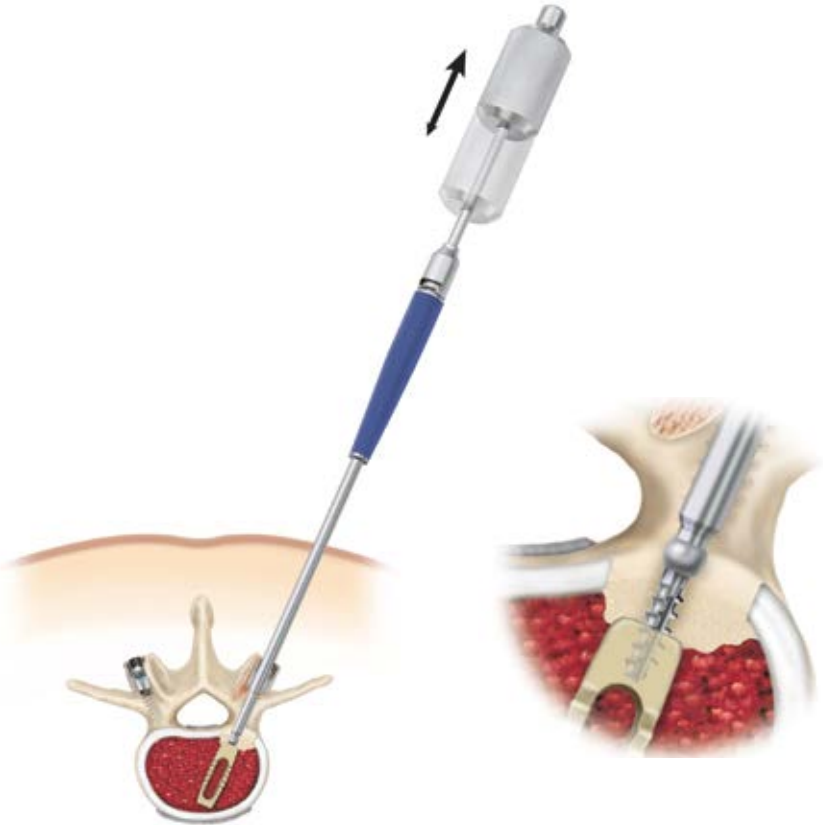
*Refer to the package insert for the fixation used.

Extraction

Open TLIF Technique



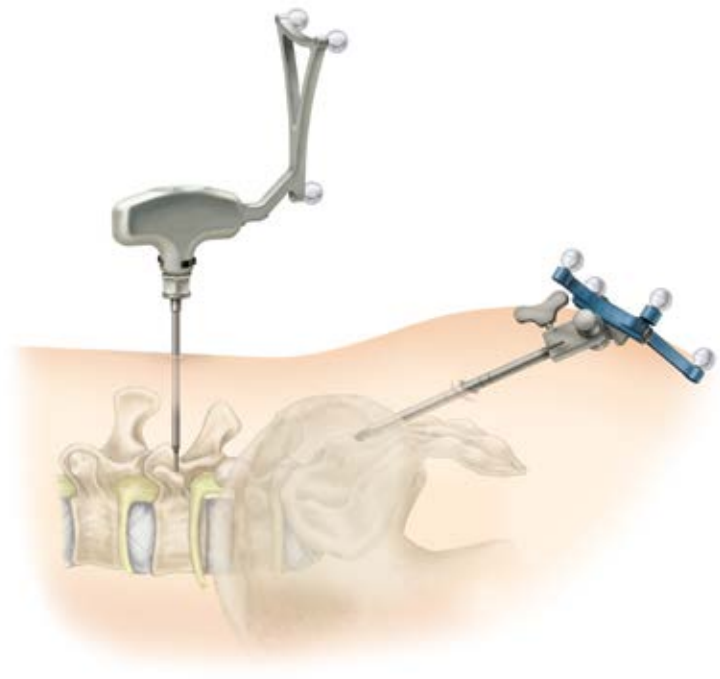
Use the Extractor and Slap Hammer to gently remove the construct.



MAST™ TLIF Technique

PLIF: Open and MAST™ Techniques

Navigation and Neuromonitoring Options



Navigation Option

The FLUORONAV® MAST™ Spinal Procedural Solution can provide assistance with pedicle navigation. An additional module containing all of the necessary attachments is required for using the FLUORONAV® MAST™ Spinal Procedural Solution.

Navigation Option

For neuromonitoring, a NIM® PAK Needle or Pedicle Probe may be used to access the pedicle. Triggered EMG monitoring can be performed during advancement of the needle into the pedicle to ensure proper placement.

Important

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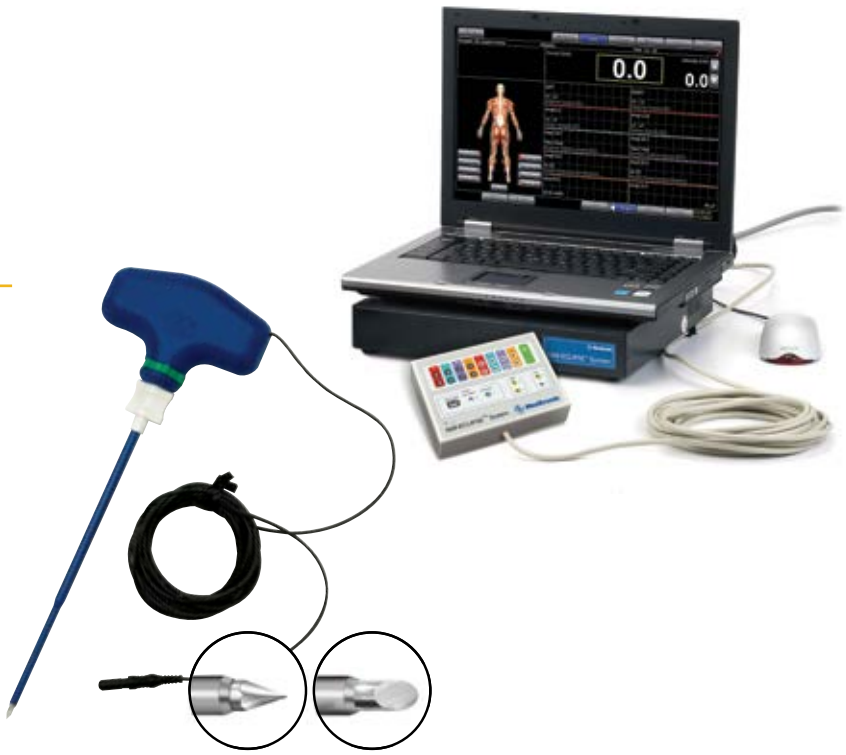
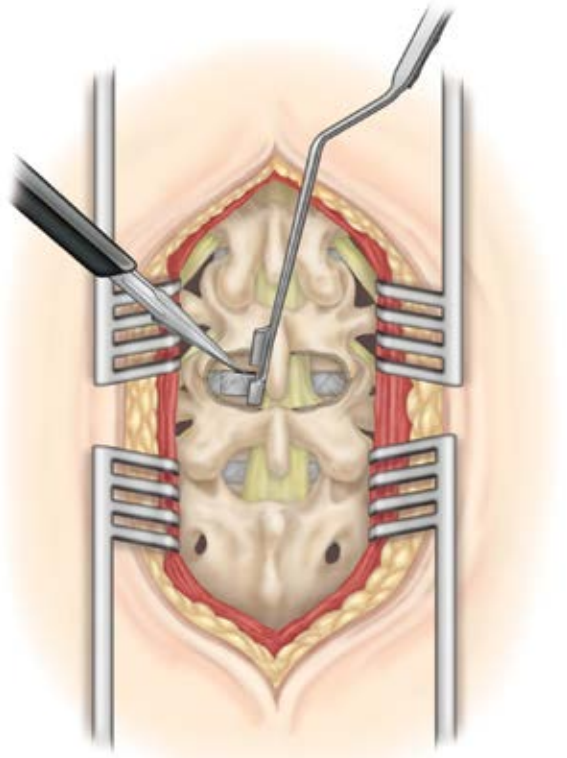


Laminotomy and Facetectomy

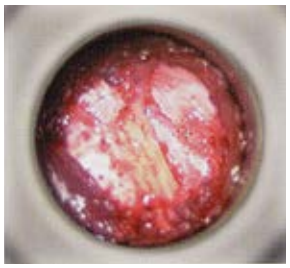
Open PLIF Technique



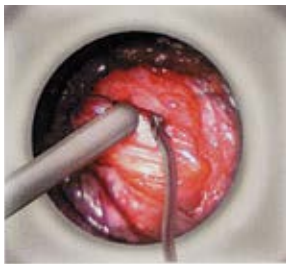
A conventional discectomy is performed by incising the annulus with a 15-scalpel blade lateral to the dural sac.

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.

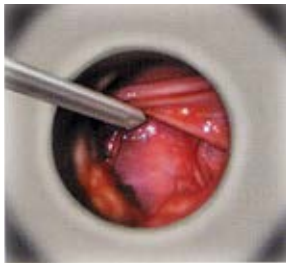
The main goal of this step is to remove extruded fragments, decompress neural elements and provide entry to the disc space for distraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.



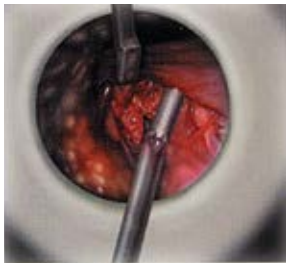
Soft Tissue Removal



Ligamentum Flavum Removal



Nerve Root Retraction

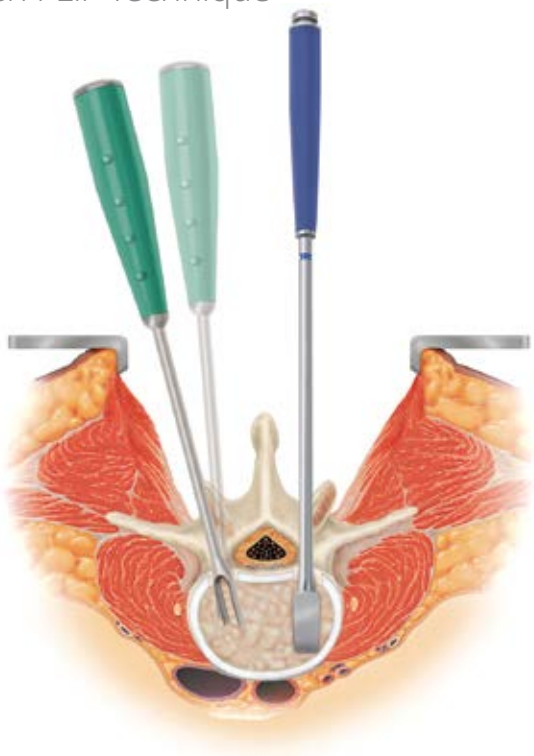


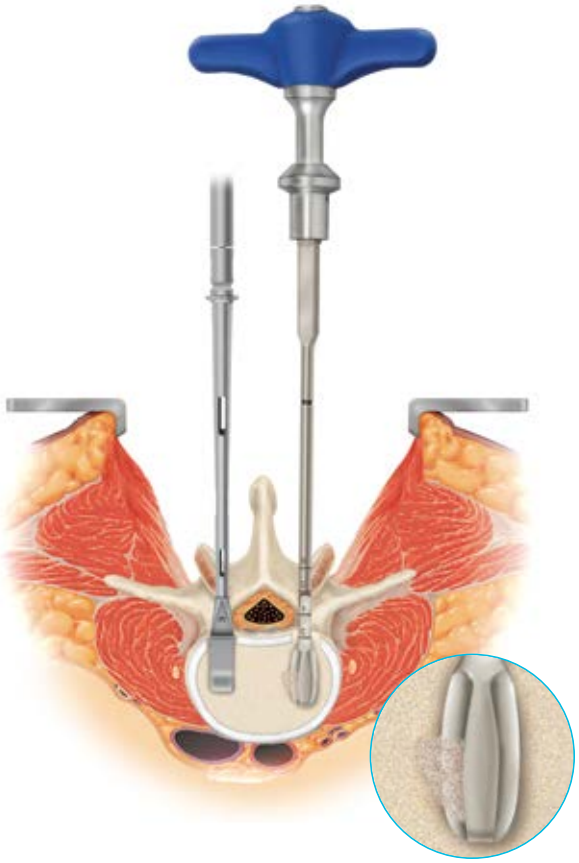
Discectomy

MAST™ PLIF Technique

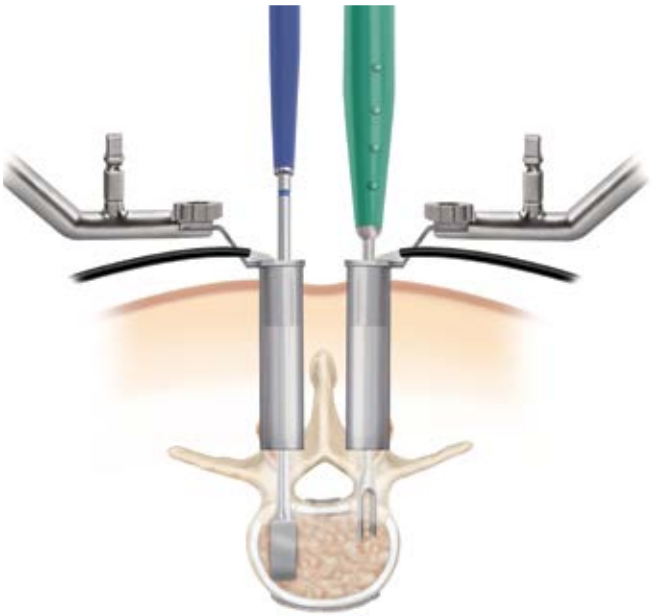
Disc Space Preparation

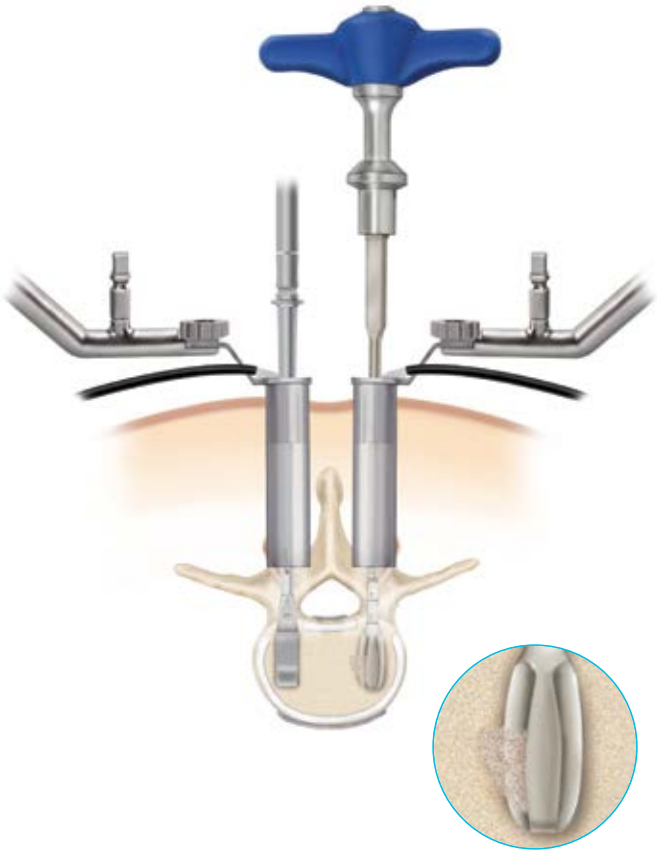
Open PLIF Technique





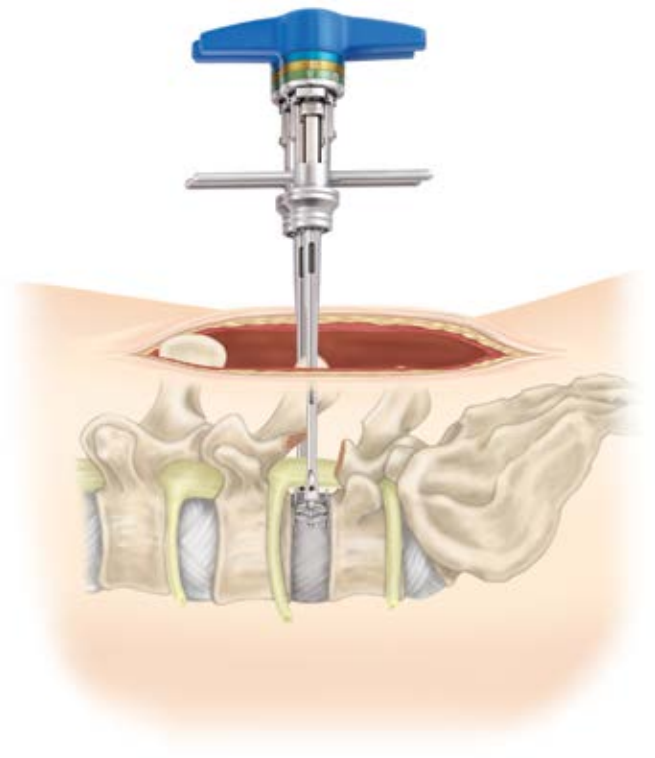
With the Distractor/Trial secured in the disc space, remove the disc using the blunt-tipped and side-cutting Rotate Cutters and/or the Disc Shavers.



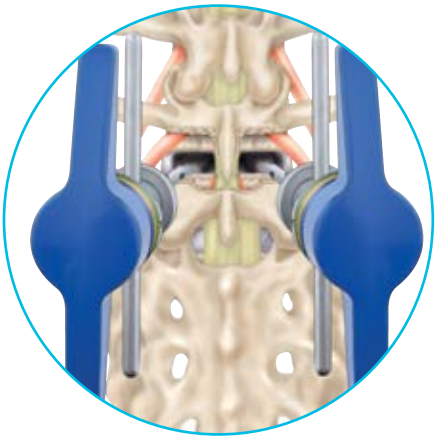


MAST™ PLIF Technique

Distraction

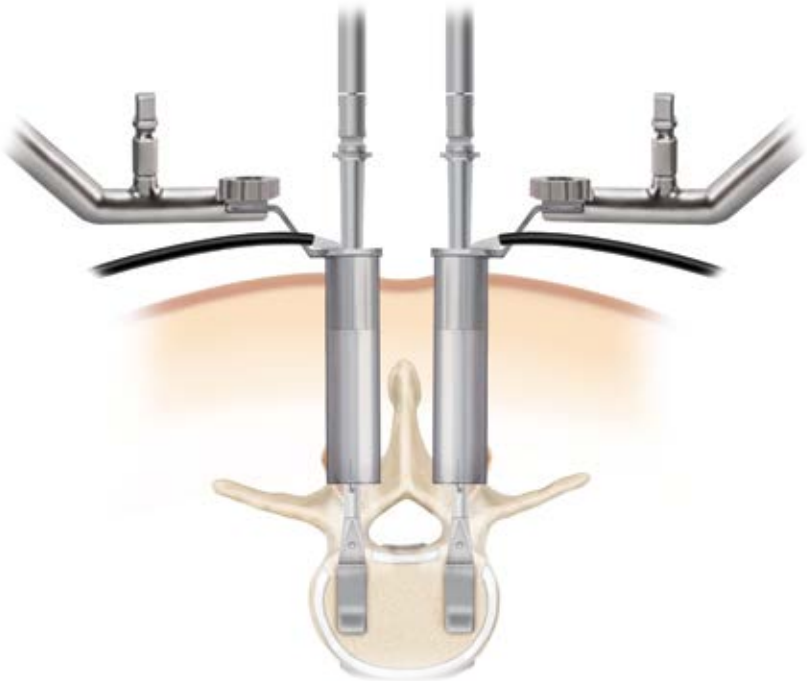


Open PLIF Technique



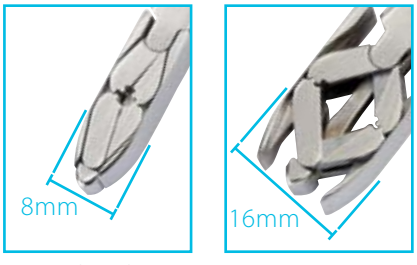
The disc space is sequentially distracted with the Distractor/Trial or the SCISSOR JACK® Distractor until the original disc space height is obtained and the normal foraminal opening is restored.

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.

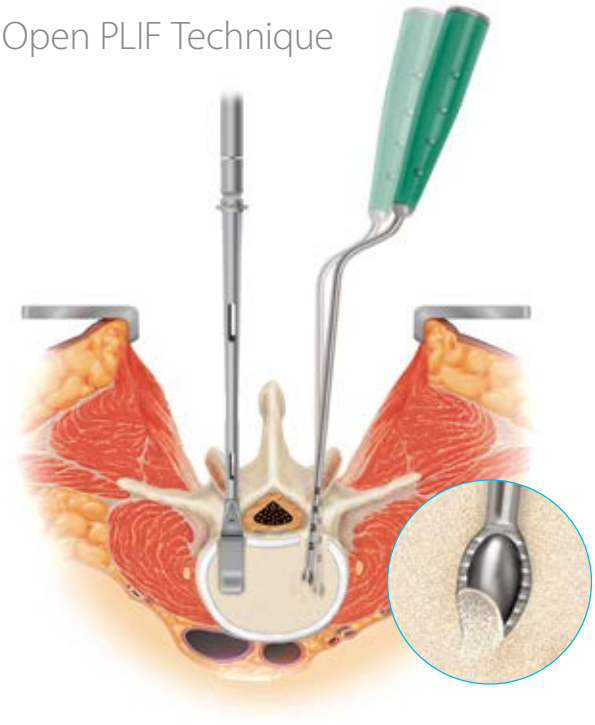


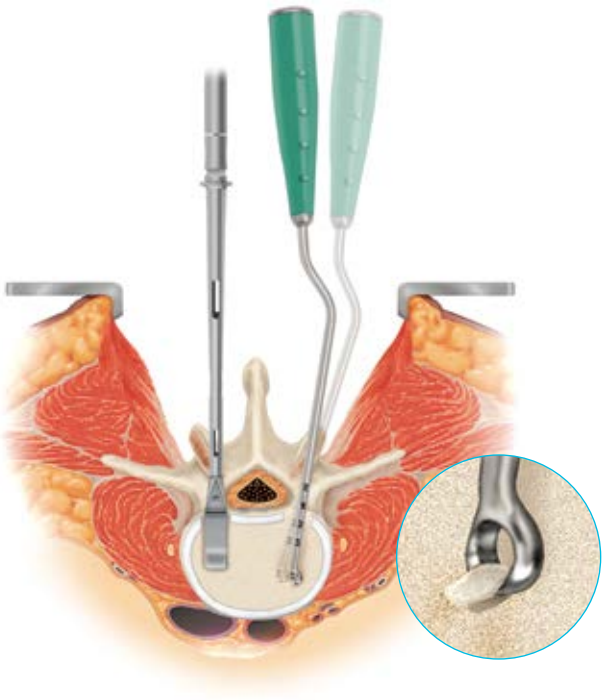
Closed Open

MAST™ PLIF Technique

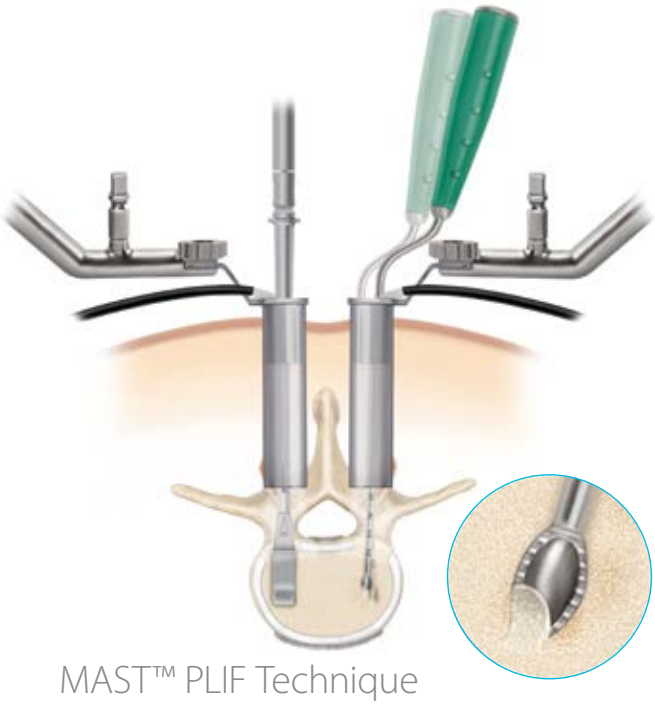
End Plate Preparation

Open PLIF Technique



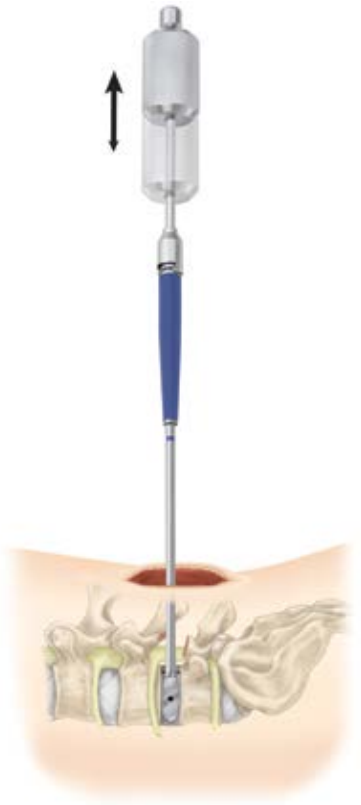


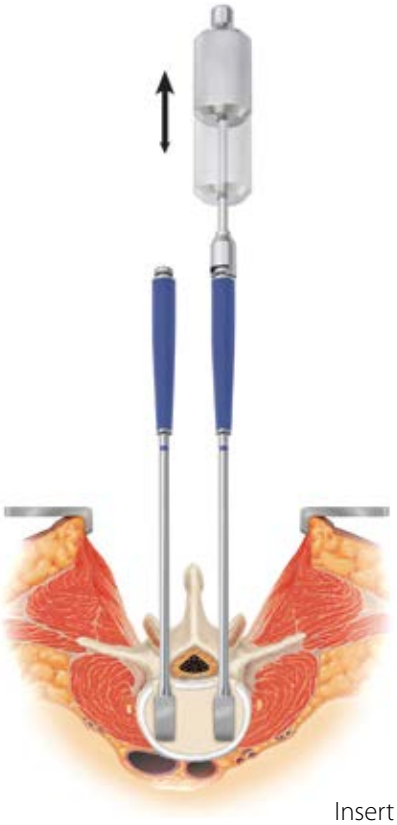
Specifically designed angled instruments allow disc resection and end plate preparation.



MAST™ PLIF Technique

Trial Insertion





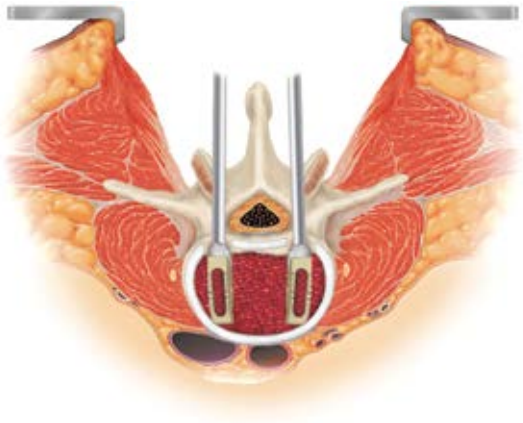
Open PLIF Technique

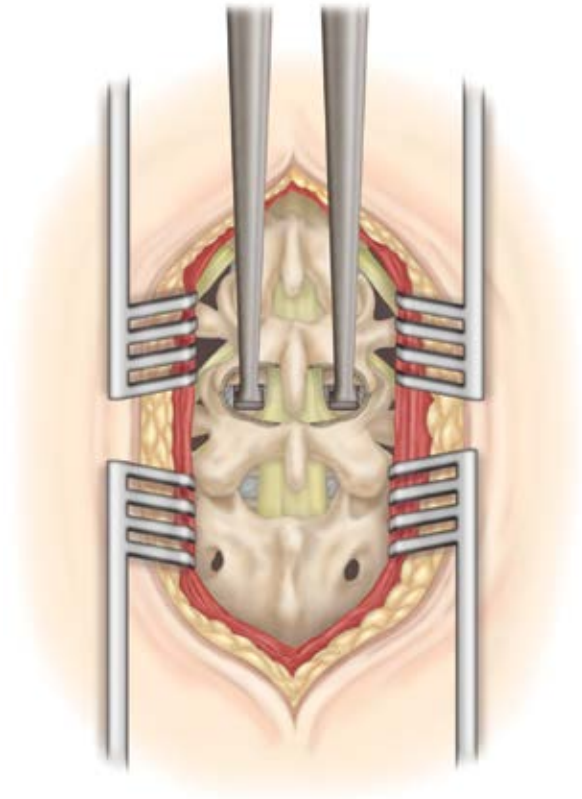
Insert the Distractor/Trial until the desired disc space height is established. Use AP and lateral fluoroscopy to confirm proper placement and trajectory. A slap hammer can be used for removal.

MAST™ PLIF Technique

CAPSTONE® PEEK Interbody Spacer Insertion

Open PLIF Technique



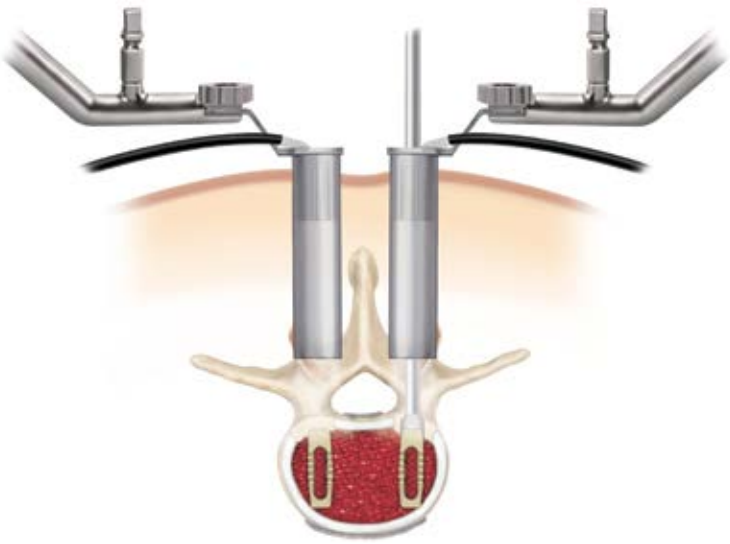


The appropriately sized CAPSTONE® PEEK Interbody Spacer is chosen during the trialing step and is firmly attached to the Inserter.

Before inserting the interbody spacer, place autograft anteriorly and contralaterally, and in the interbody spacer central cavity.

Gently impact the CAPSTONE® PEEK Interbody Spacer until it is 3mm to 4mm below the posterior margin of the annulus.

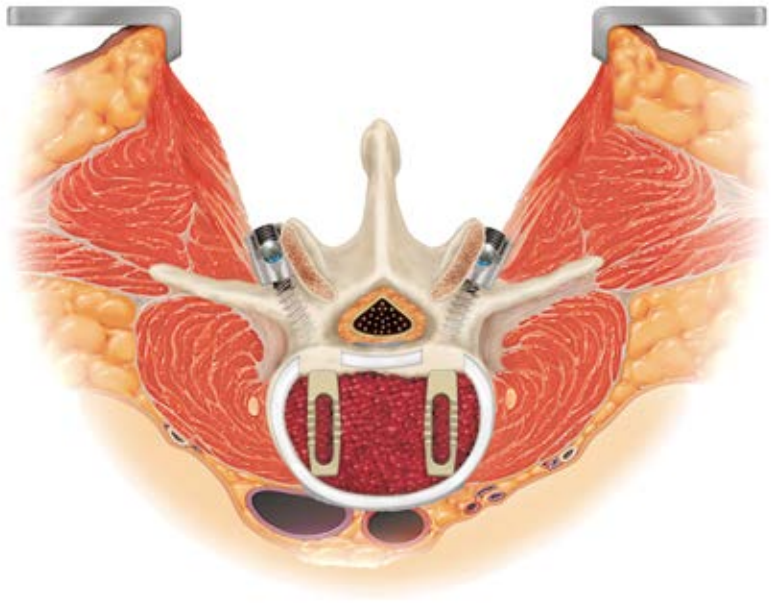
Care should be taken to ensure the interbody spacer is aligned properly.



MAST™ PLIF Technique

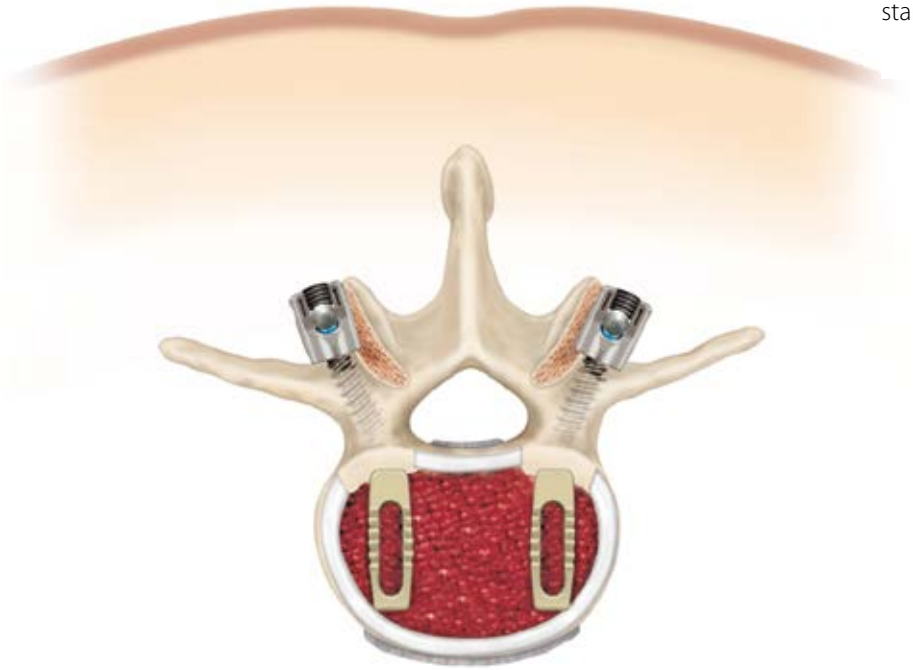
Final Placement

Open PLIF Technique



After the CAPSTONE® PEEK Interbody Spacer 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

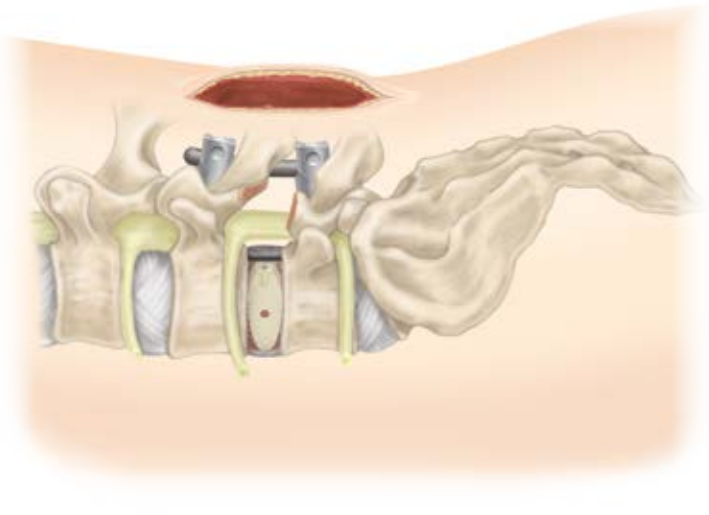
Additional Fixation Options and Explantation

The CD HORIZON® SOLERA™ System Set Screws (plugs) may be removed using the T27 Obturator and the Self-Retaining Breakoff Driver. The T27 Obturator is inserted into the working end of the Self-Retaining Breakoff Driver so that the knurled portion of the T27 Obturator is flush with the driver. Insert the T27 Obturator tip through the Counter Torque, which should be seated on the screw, and into the plug, turning counterclockwise until the plug has been removed. The pedicle screws may be removed using either the multi-axial Screwdriver or the Self-Retaining Screwdriver in connection with the Ratcheting Handle. First, attach the Ratcheting Handle to the modular end of the driver. Next, fully engage the hex end of the Screwdriver into the screw head, then, if using the multi-axial screwdriver, thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.

If removal of an CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is necessary, place the 7/32" Torque-Limiting Set Screwdriver over the midline nut and turn counterclockwise to loosen. Place the 3.0mm Hex Head Shaft Removal Driver into a standard Medtronic Quick Connect Handle. Place the tip of the 3.0mm Internal Hex Screwdriver into the set screw and confirm that the 3.0mm tip is completely inserted and seated in the set screw so that the tip does not strip the hex. Turn the screwdriver counterclockwise to loosen the set screw from the rod.

The CAPSTONE® PEEK Interbody Spacer may be removed by using the Threaded Inserter. Attach the Threaded Inserter to the interbody spacer and remove the spacer from the disc space.

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

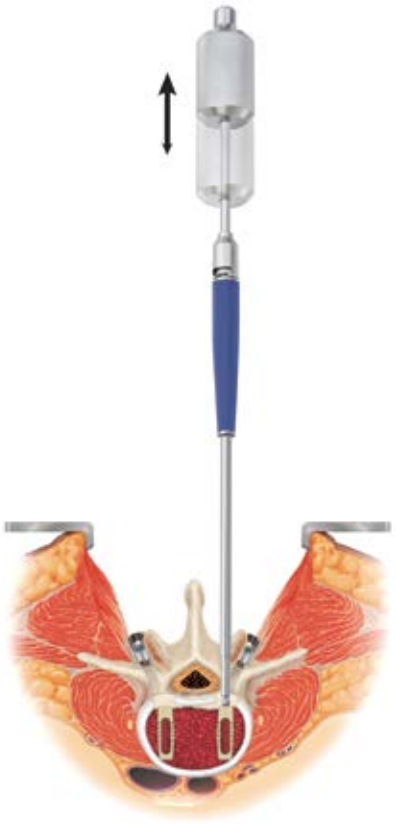


CD HORIZON® SOLERA™ 4.75mm Spinal System*

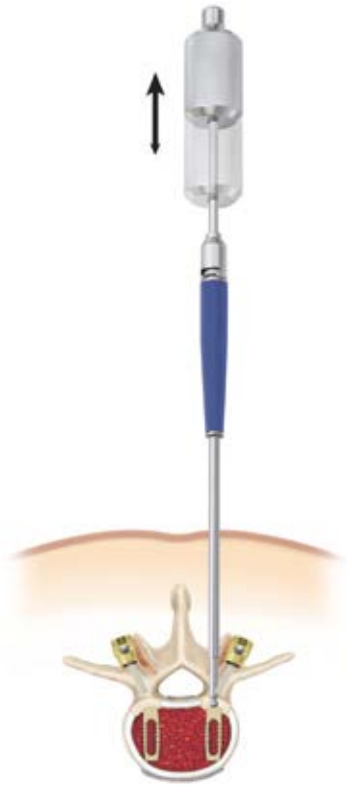
*Refer to the package insert for the fixation used.

Extraction

Use the Extractor and Slap Hammer to gently remove the construct.



Open PLIF Technique



MAST™ PLIF Technique

Product Ordering Information*

CAPSTONE® 22mm/26mm Even Height Implants Set Type 2134

Part Number	Description	Quantity
2990622	6mm × 22mm	2
2990626	6mm × 26mm	1
2990822	8mm × 22mm	4
2990826	8mm × 26mm	2
2991022	10mm × 22mm	4
2991026	10mm × 26mm	2
2991222	12mm × 22mm	4
2991226	12mm × 26mm	2
2991422	14mm × 22mm	2
2991426	14mm × 26mm	2
2991622	16mm × 22mm	2
2991626	16mm × 26mm	1
43000000	Large PEEK Suitcase	1

CAPSTONE® 22mm/26mm Odd Height Implants Set Type 2349

Part Number	Description	Quantity
2990722	7mm × 22mm	2
2990726	7mm × 26mm	2
2990922	9mm × 22mm	4
2990926	9mm × 26mm	2
2991122	11mm × 22mm	4
2991126	11mm × 26mm	2
2991322	13mm × 22mm	4
2991326	13mm × 26mm	2
2991522	15mm × 22mm	2
2991526	15mm × 26mm	2
43000000	Large PEEK 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

*Additional sizes of implants and trials are available, but are not provided standard in sets.

Product Ordering Information

CAPSTONE® 32mm Even Height Implants Set Type 2341

Part Number	Description	Quantity
2990832	8mm × 32mm	2
2991032	10mm × 32mm	2
2991232	12mm × 32mm	2
2991432	14mm × 32mm	2
2991632	16mm × 32mm	2
43000000	Large PEEK Suitcase	1

CAPSTONE® 32mm Odd Height Implants Set Type 2449

Part Number	Description	Quantity
2990732	7mm × 32mm	2
2990932	9mm × 32mm	2
2991132	11mm × 32mm	2
2991332	13mm × 32mm	2
2991532	15mm × 32mm	2
43000000	Large PEEK Suitcase	1

CAPSTONE® 32mm Trials Set Type SPS02389

Part Number	Description	Quantity
1850069	Full Size Lid	1
1850070	Full Size Case	1
1850073	Full Size Pin Mat	1
2980732	7mm × 32mm Distractor/Trial	1
2980832	8mm × 32mm Distractor/Trial	1
2980932	9mm × 32mm Distractor/Trial	1
2981032	10mm × 32mm Distractor/Trial	1
2981132	11mm × 32mm Distractor/Trial	1
2981232	12mm × 32mm Distractor/Trial	1
2981332	13mm × 32mm Distractor/Trial	1
2981432	14mm × 32mm Distractor/Trial	1
2981532	15mm × 32mm Distractor/Trial	1
2981632	16mm × 32mm Distractor/Trial	1

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

Important Product Information for the CAPSTONE® Spinal System

PURPOSE

This device is a fusion device intended for stabilization use 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 CAPSTONE® Spinal System consists of PEEK cages, titanium alloy cages and titanium cage of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

No warranties express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog or price list for further information about warranties and limitations of liability.

INDICATIONS

The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two 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. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. 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.

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

Adverse effects may occur when the device is used either with or without associated instrumentation. The potential 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 scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and 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 development of pain. Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury.
- Cerebral spinal fluid leakage.
- Haemorrhage of blood vessels and hematomas.
- Discitis, arachnoiditis, and or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and 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 pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and vertebral body) and bone graft or bone graft harvest site at, above, 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.

WARNINGS AND PRECAUTIONS

Do not re-use or re-process devices labeled as single use devices. Re-use or re-processing of single use devices may compromise the structural integrity and the intended function of the device which could result in patient injury.

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. 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, or alcohol/drug abuse patients, and those with poor muscle and bone quality and 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 with a previous surgery.

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.

!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 the proper size, shape, and design of the implant for each patient is crucial to the 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 a CAPSTONE® Spinal System device. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and predispositions such as those addressed in the aforementioned 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.
- Further information about this system will be provided upon request.
- The surgeon should be familiar with the various devices before use and should personally verify that all devices are present before the surgery begins.
- The size of device for the case should be determined prior to beginning the 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.
- Unless supplied sterile, all devices should be cleaned and sterilized before use. Additional sterile components should be available in case of any unexpected need.

Important Product Information for the CAPSTONE® Spinal System *continued*

INTRAOPERATIVE

- The instructions in any available CAPSTONE® Spinal System 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 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 must be used.
- When used via a posterior approach, supplemental posterior instrumentation is recommended. Posterior supplemental fixation is limited to Medtronic Sofamor Danek posterior instrumentation systems.
- Bone cement should not be used because this material may make removal of these components difficult or impossible. The heat generated from the curing process may damage or deform the PEEK devices.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient, as well as the corresponding patient's 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 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, or break, the devices should be revised and/or removed immediately before serious injury occurs.
- CAPSTONE® Spinal System 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

Devices may be supplied in a sterile or non-sterile form. Packages for each of the components should be intact upon receipt. Once the seal on the sterile package has been broken, the product should not be 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 that there is no damage prior to use. Damaged packages or products should not be used and should be returned to MEDTRONIC.

CLEANING AND DECONTAMINATION

Disassembly instructions as well as detailed cleaning instructions can be found at http://manuals.medtronic.com/. Refer to the Reprocessing Instructions for the Capstone Inserter– M708348B083 for disassembly, cleaning and sterilization instructions specific to the inserter instrument (part numbers 2990001 and 2990003).

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

Table 1: Sterilization cycle parameters for the United States and its territories

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	MINIMUM DRY TIME[1]
Steam	Gravity Displacement	250°F (121°C)	30 Minutes	30 Minutes
Steam	Gravity Displacement	270°F (132 °C)	15 Minutes	30 Minutes
Steam	Gravity Displacement	275°F (135°C)	10 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	270°F (132°C)	4 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	275°F (135°C)	3 Minutes	16 Minutes

For Medical Facilities Located Outside the United States and its territories: Some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

Table 2: Sterilization cycle parameters for medical facilities outside the United States and its territories

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	MINIMUM DRY TIME[1]
Steam	Gravity Displacement	273°F (134°C)	20 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	273°F (134°C)	4 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	273°F (134°C)	20 Minutes	30 Minutes

1 The minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer's recommendations.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment.

The sterilization cycles listed in Table 2 above are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Sterilization instructions can be found at http://manuals.medtronic.com/. Refer to the Reprocessing Instructions for the Capstone Inserter– M708348B083 for disassembly, cleaning and sterilization instructions specific to the inserter instrument (part numbers 2990001 and 2990003).

SERVICING

Inspect all instruments prior to use. Please return the instrument to Medtronic if any of the following are observed: corrosion, discoloring, pitting, or any other signs of wear.

Inspect the threaded shaft of the instrument. Please return the instrument to Medtronic if threads are damaged or distorted or if the shaft appears bent.

Inspect the silicone handle of the instrument. Please return the instrument to Medtronic if the silicone handle is discolored, cut, or damaged in any way.

PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, or performance should notify the distributor or MEDTRONIC. Further, if any of the implanted spinal system component(s) ever malfunctions (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax, or written correspondence. When filing a complaint, provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested.

MRI INFORMATION

The CAPSTONE® Spinal System has not been evaluated for safety, heating, migration, or compatibility in the magnetic resonance environment.

FURTHER INFORMATION

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

EC REP

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EXPLANATION OF SYMBOLS

SYMBOL	DEFINITION
EC REP	Authorized Representative in the European Community
Rx only	CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.
	Consult Instructions for Use
	Do not reuse.
LOT	Batch code
	Manufacturer
REF	Catalog Number
	Non-sterile
!USA	For U.S. audiences only.
CE 0123	The device complies with European Directive MDD 93/42/EEC
STERILE R	Sterilized by irradiation
	Use by date specified
CE	The device complies with European Directive MDD 93/42/EEC

Note

Note

www.medtronic.com

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For more information visit
www.myspinetools.com

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.

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