



Medtronic

CAPSTONE[®] PEEK Spinal System

PLIF and TLIF

Surgical Technique

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CAPSTONE® PEEK Spinal System

PLIF and TLIF

Surgical Technique

Implant and Instrument Set Features	2	PLIF: Open and MAST™ Techniques	
Instrument Set	3	Laminotomy and Facetectomy	17
X-ray Marker Location	4	Disc Space Preparation	18
Implant Sizing	5	Distraction	19
TLIF: Open and MAST™ Techniques		End-plate Preparation	20
Laminotomy and Facetectomy	7	Trial Insertion	21
Disc Space Preparation	8	CAPSTONE® PEEK Interbody Spacer Insertion	22
Distraction	9	Final Placement	23
End-plate Preparation	10	Navigation and Neuromonitoring Options	24
Trial Insertion	11	Additional Fixation Options	25
CAPSTONE® PEEK Interbody Spacer Insertion	12	Explantation	25
Final Placement	13	Product Ordering Information	26
Navigation and Neuromonitoring Options	14	Important Product Information	27
Additional Fixation Options	15		
Explantation	15		

Implant and Instrument Set Features

Implant Set Features

- » Self-distracting, bulleted tip
- » Convex-shaped Implants are designed to fit patient anatomy and to allow more accurate sizing
- » Teeth on the surface reduce likelihood of expulsion

Instrument Set Features

- » Posterior Lumbar Interbody Fusion (PLIF) or Transforaminal Lumbar Interbody Fusion (TLIF) procedural solutions combining CAPSTONE® Instrument Set, Posterior Microscope Instrument (PMI) Set, SCISSOR JACK™ Distractor, METRx® System, CD HORIZON® SEXTANT® II Rod Insertion System, PYRAMETRIX® Advance Instrument Set or the CD HORIZON® ENGAGE™ Spinal System
- » Distractor/Trials are designed with bullet-tip shape for self-distraction and ease of insertion
- » Convex-shaped Trials are designed to fit patient anatomy and to allow more accurate sizing
- » Compatible with open, mini-open, or MAST™ technique approaches

Instrument Set



Distractor/Trial
2980822



Distractor/Trial
2981032



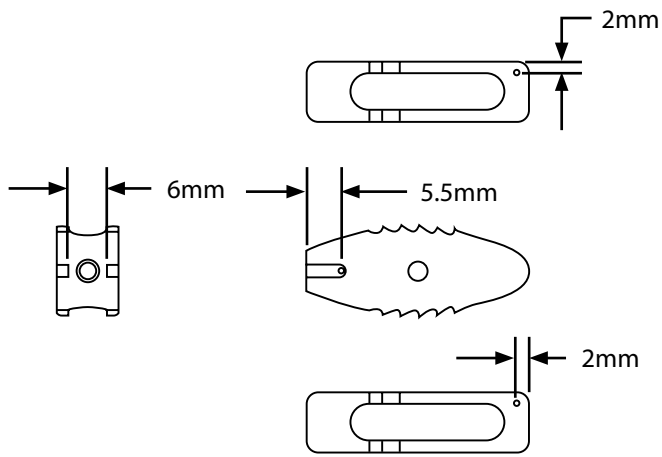
Threaded Inserter
2980001



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

Implant Sizing

Length	Height	Internal Volume
22mm	8mm	0.4cc
22mm	10mm	0.5cc
22mm	12mm	0.6cc
22mm	14mm	0.7cc
22mm	16mm	0.8cc
26mm	8mm	0.6cc
26mm	10mm	0.7cc
26mm	12mm	0.9cc
26mm	14mm	1.0cc
26mm	16mm	1.1cc
32mm	8mm	0.8cc
32mm	10mm	1.0cc
32mm	12mm	1.2cc
32mm	14mm	1.4cc
32mm	16mm	1.6cc
36mm	8mm	1.0cc
36mm	10mm	1.2cc
36mm	12mm	1.5cc
36mm	14mm	1.7cc
36mm	16mm	1.9cc

Width = 10mm

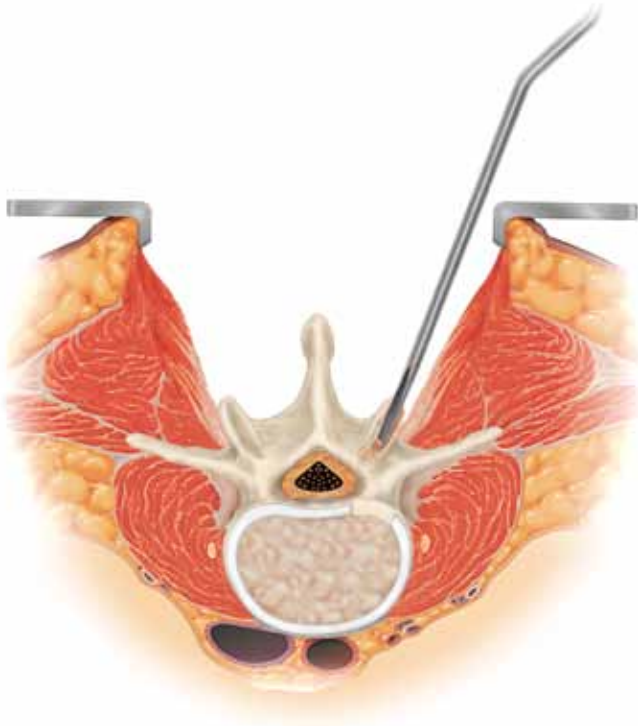




TLIF: Open and MAST™
Techniques

Laminotomy and Facetectomy

Open TLIF Technique

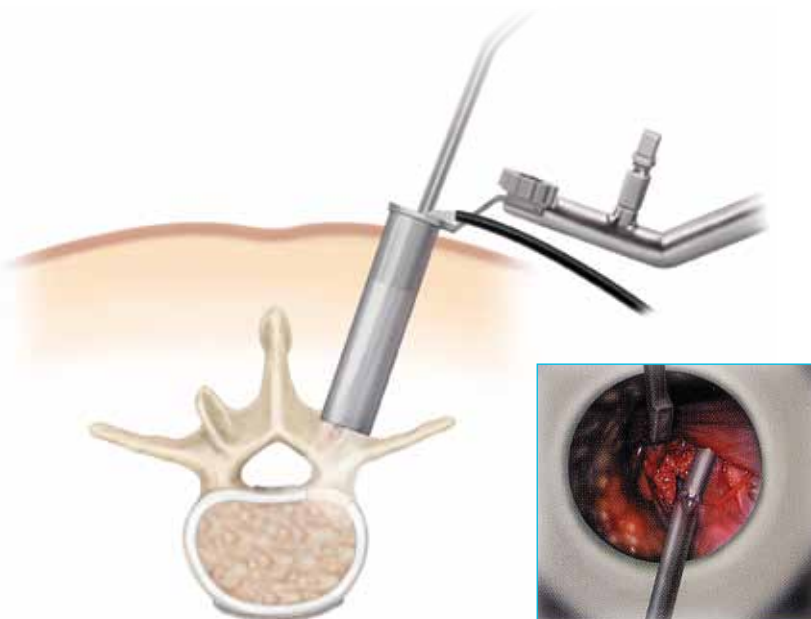


A facetectomy is performed on the ipsilateral side. Using an osteotome or drill, remove the ascending and descending articular processes.

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.

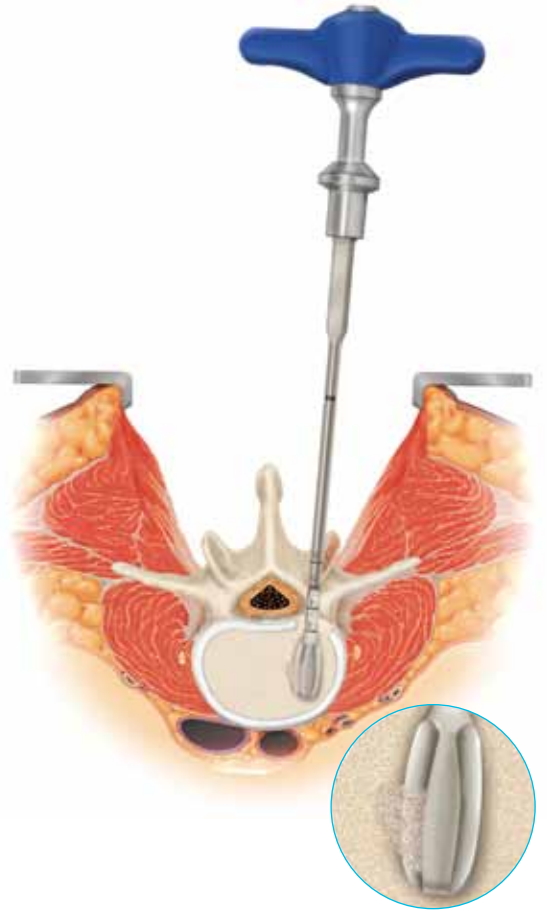
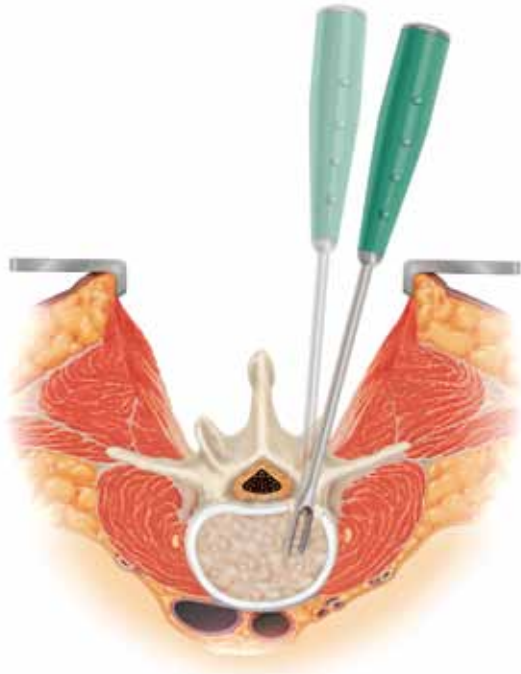


Discectomy

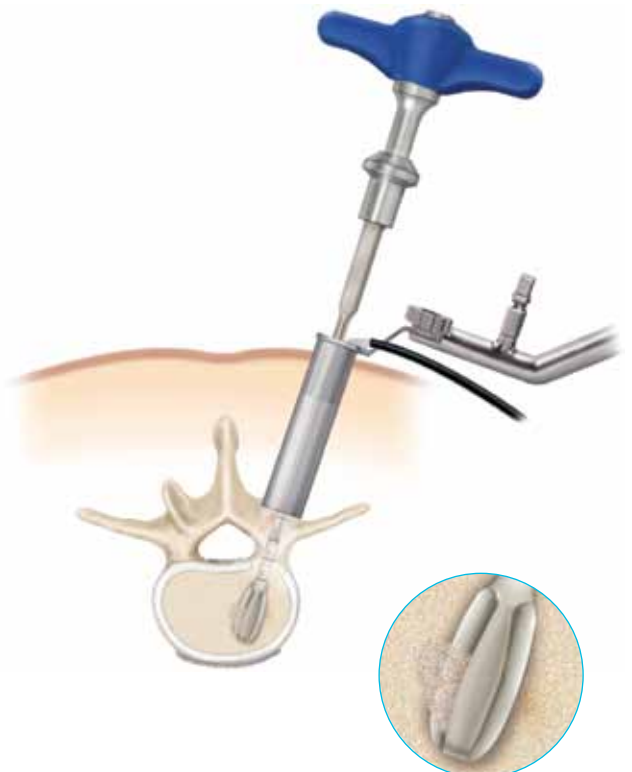
MAST™ TLIF Technique

Disc Space Preparation

Open TLIF Technique

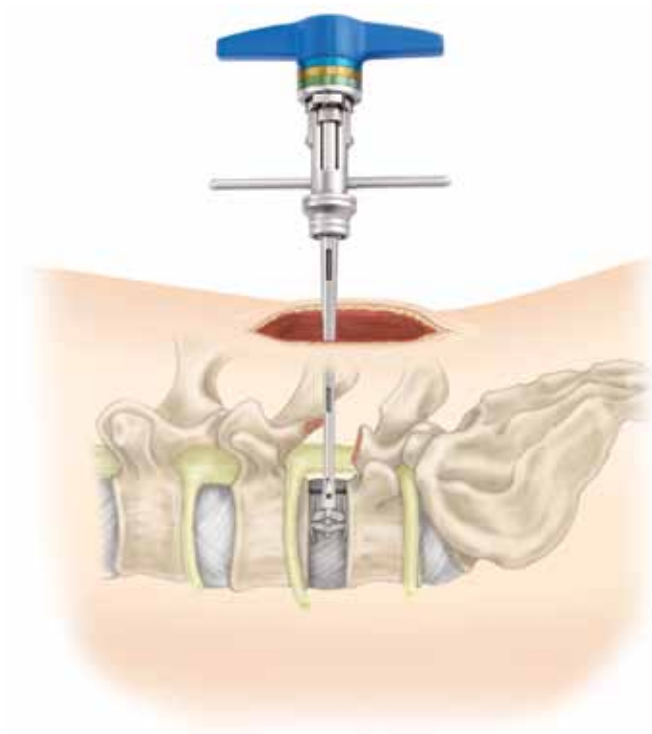


Remove disc using the Rotate Cutter. The instruments are blunt tipped and side cutting for safety.



MAST™ TLIF Technique

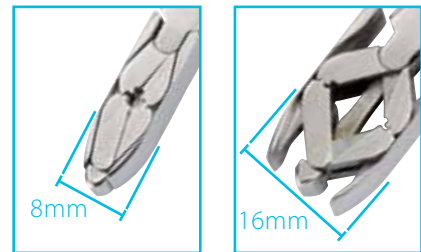
Distraction



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.

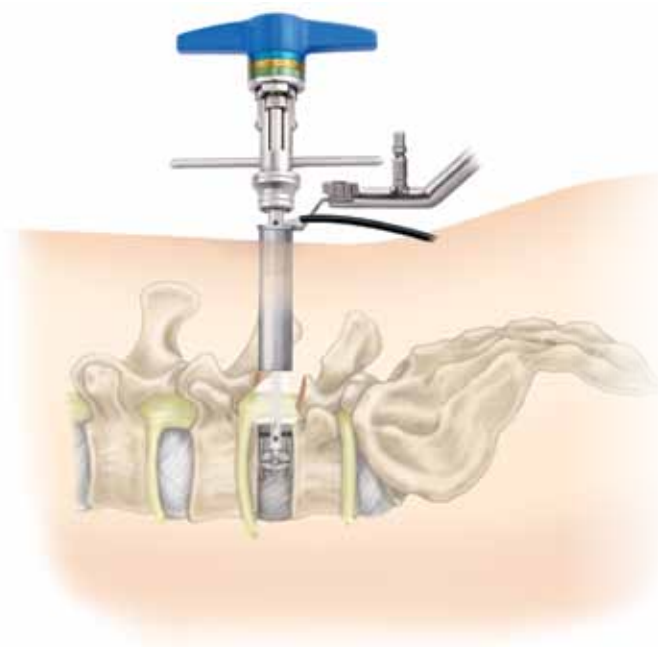
If the SCISSOR JACK™ Distractor is used, insert the distractor with the curved sides touching the end plates and expand the distractor until the desired height is obtained.



Close

Open

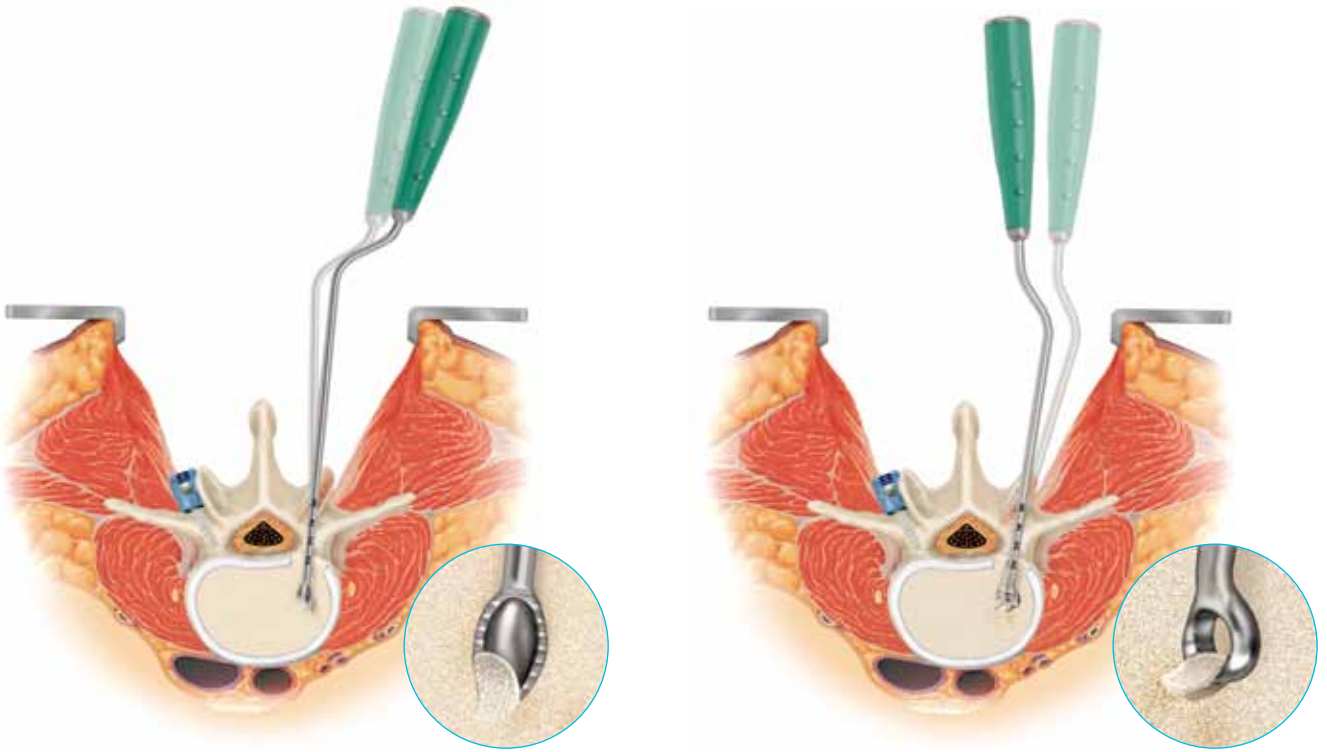
Insert supplemental screw and rod fixation on the contralateral side to maintain distraction during disc space preparation and provisionally tighten the construct.



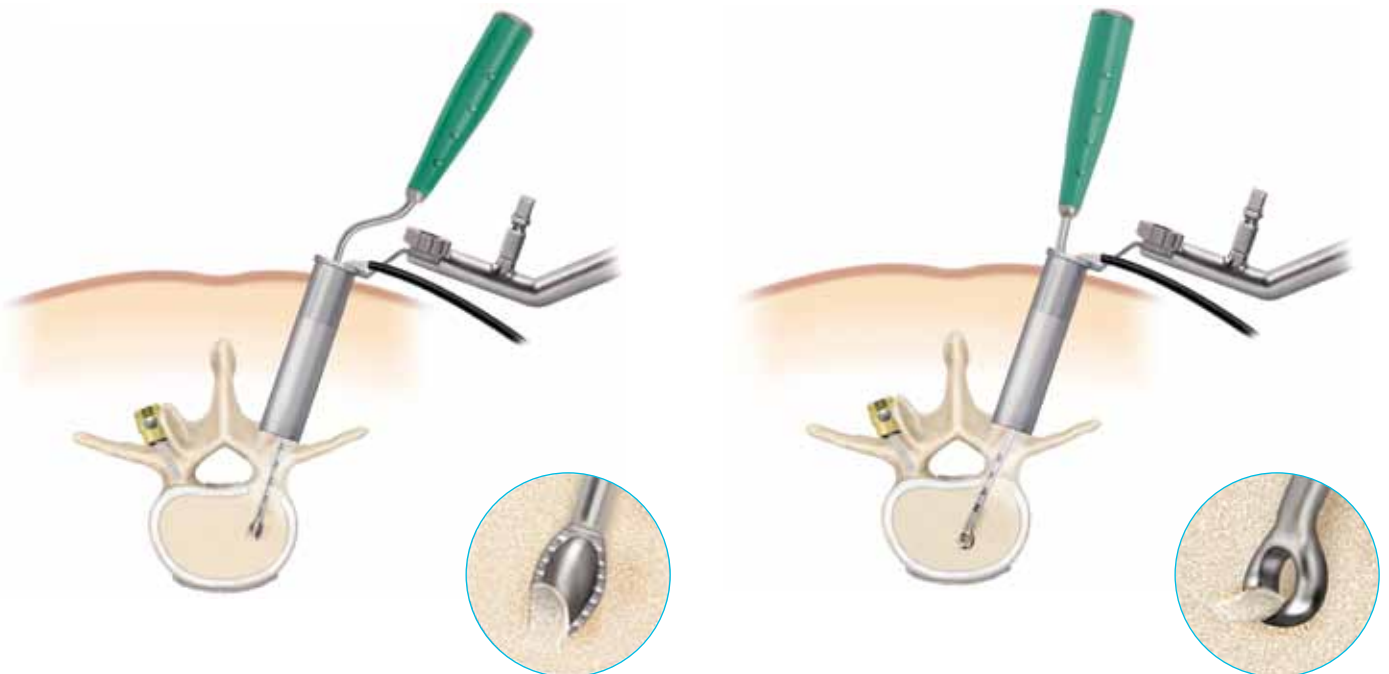
MAST™ TLIF Technique

End-plate Preparation

Open TLIF Technique

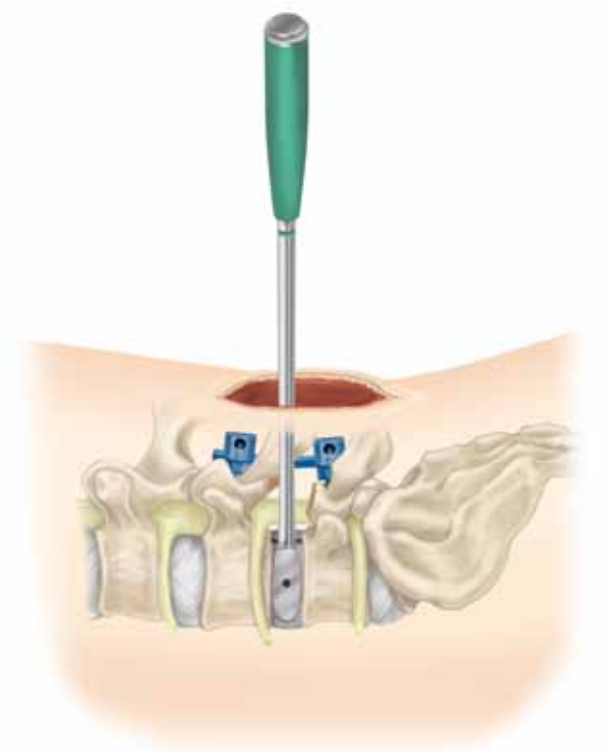


Specifically designed angled instruments allow disc resection and end-plate preparation.



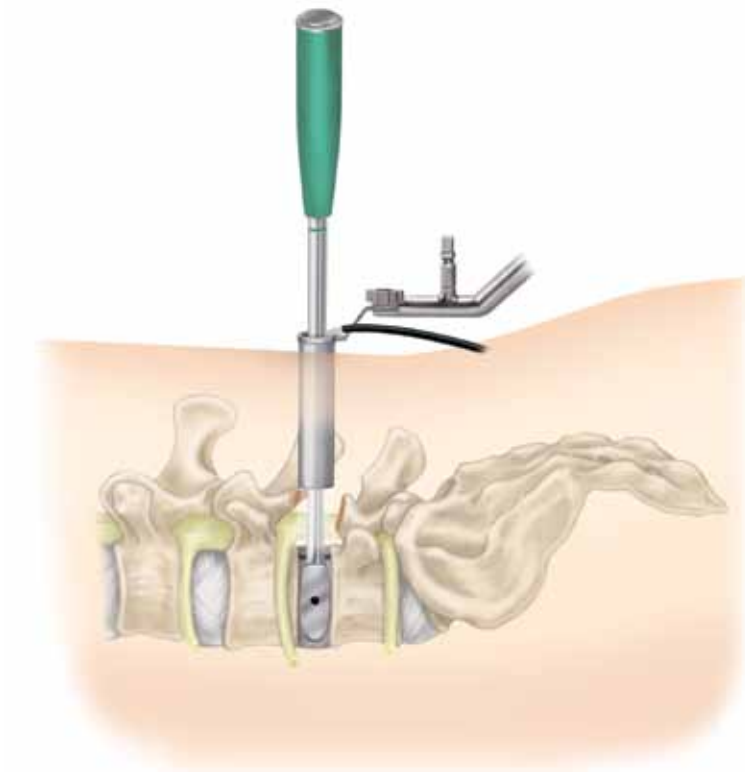
MAST™ TLIF Technique

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.

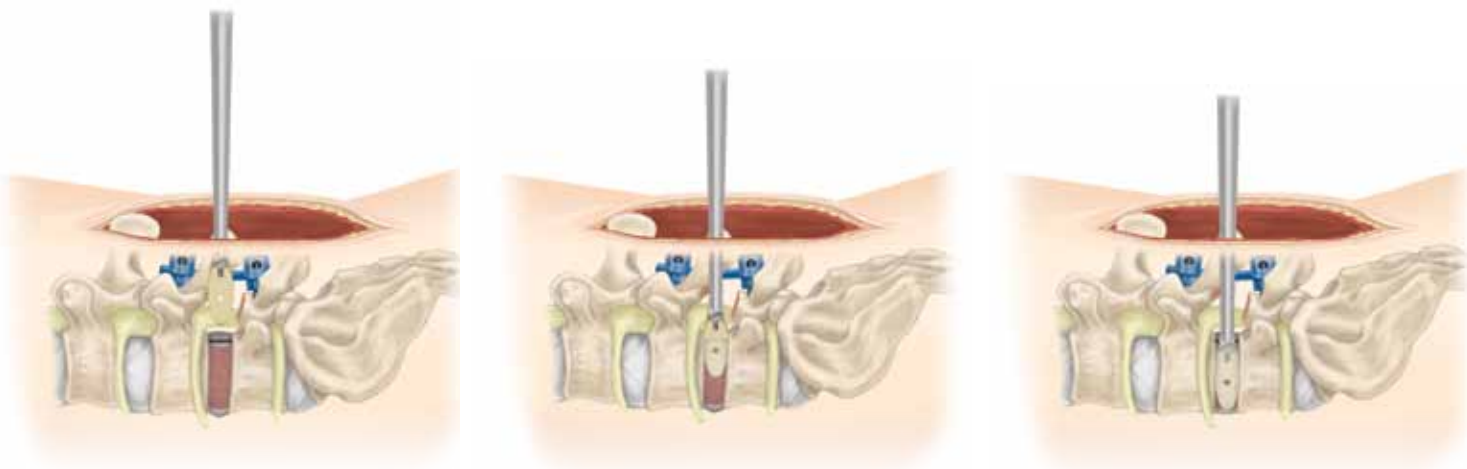


AP View

MAST™ TLIF Technique

CAPSTONE® PEEK Interbody Spacer Insertion

Open TLIF Technique

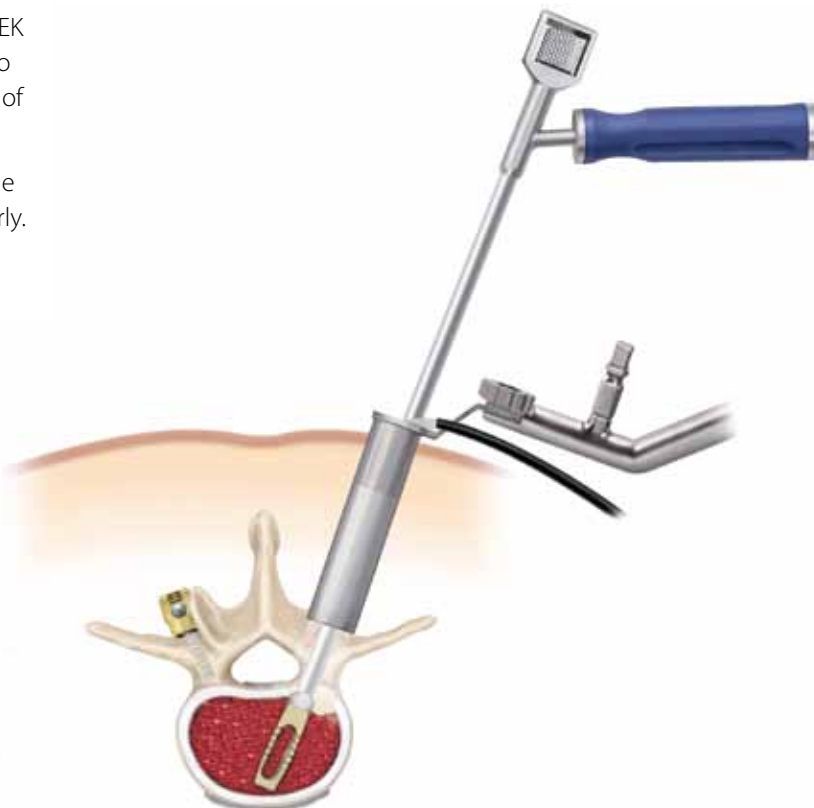


The appropriately sized CAPSTONE® PEEK Interbody Spacer is chosen during the trialing step and is firmly attached to the inserter.

Before inserting the interbody spacer, place autograft anteriorly and contralaterally, or 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.

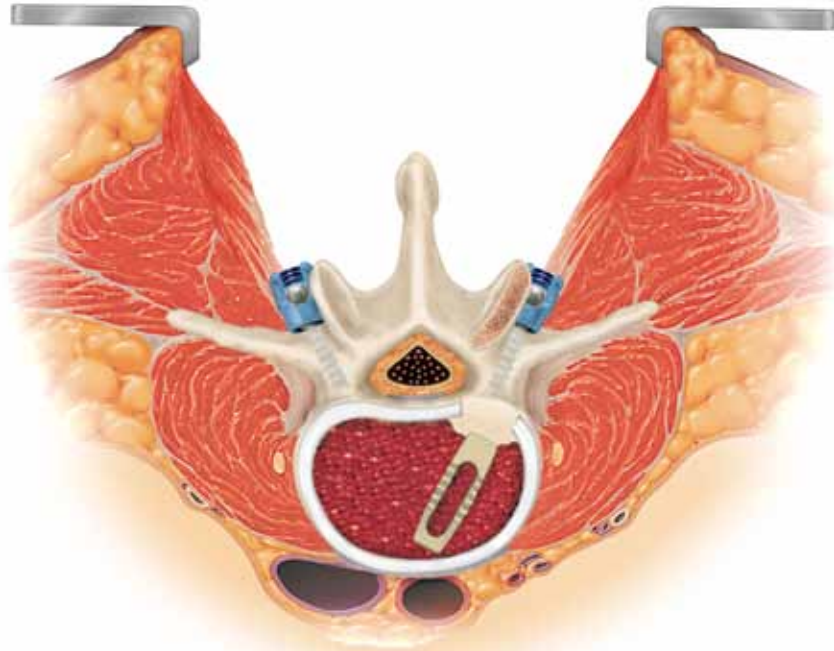
Care should be taken to ensure the interbody spacer is aligned properly.



MAST™ TLIF Technique

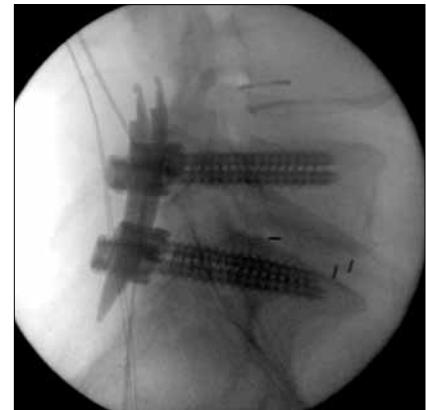
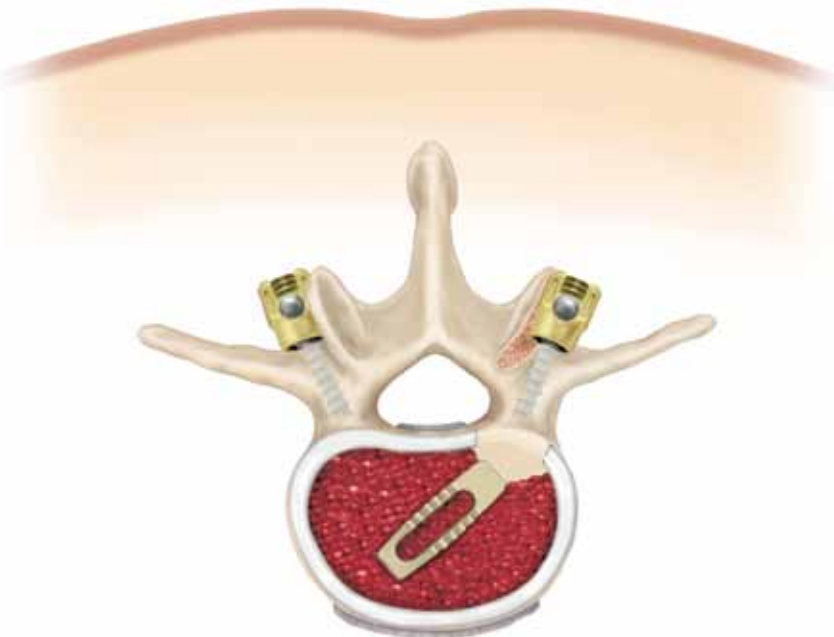
Final Placement

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.



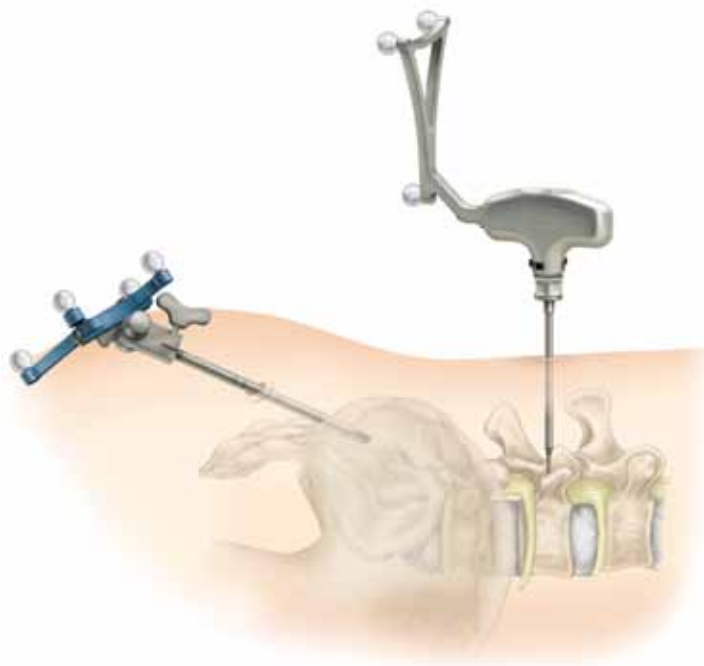
Lateral View

MAST™ TLIF Technique

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.



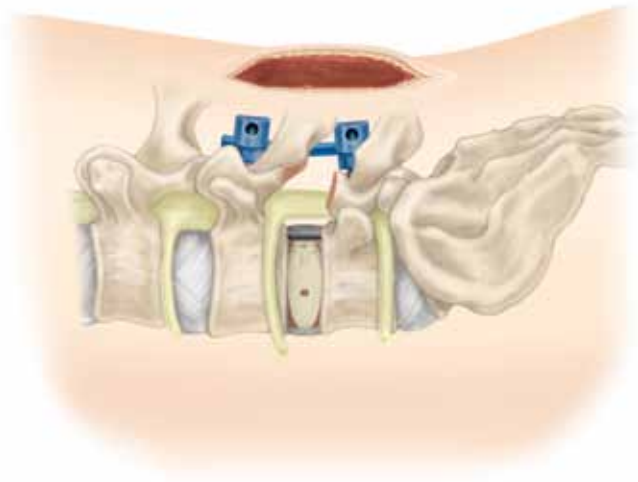
Additional Fixation Options and Explanations

The CD HORIZON® LEGACY™ 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 $\frac{7}{32}$ " 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 counter-clockwise 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. If greater force is needed, place the Slap Plate in the space between the impaction cap and the thumbwheel on the Inserter. Gently impact the slap plate to remove the implant.

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



CD HORIZON® LEGACY™ 5.5 SPINAL SYSTEM*

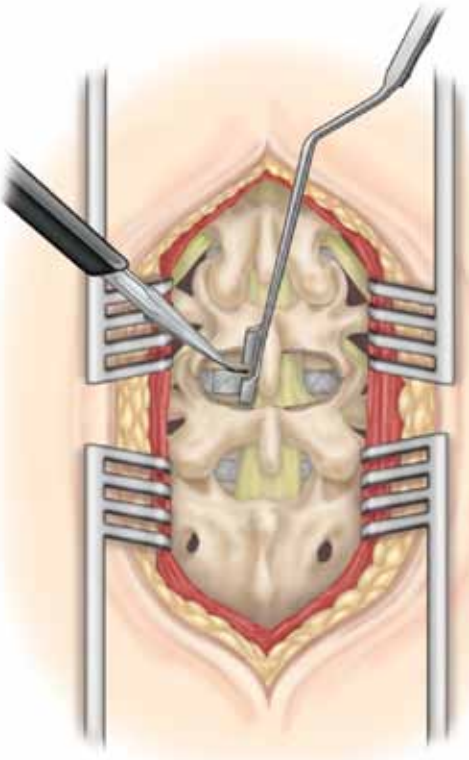
*Refer to the package insert for the fixation used.



PLIF: Open and MAST™
Techniques

Laminotomy and Facetectomy

Open PLIF Technique



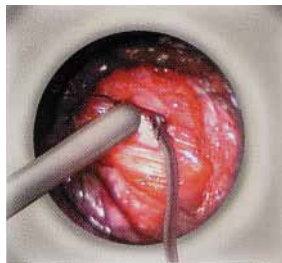
A conventional discectomy is performed by incising the annulus with a 15-scalpel blade lateral to the dural sac.

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.

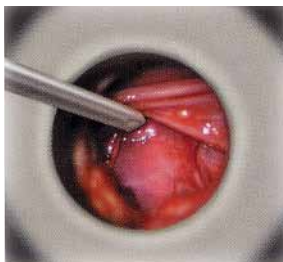
The main goal of this step is to remove extruded fragments, decompress neural elements and provide entry to the disc space for distraction with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.



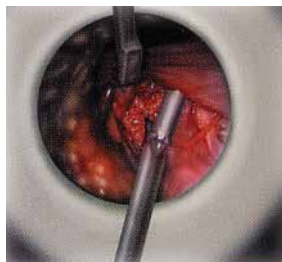
Soft Tissue Removal



Ligamentum Flavum Removal



Nerve Root Retraction

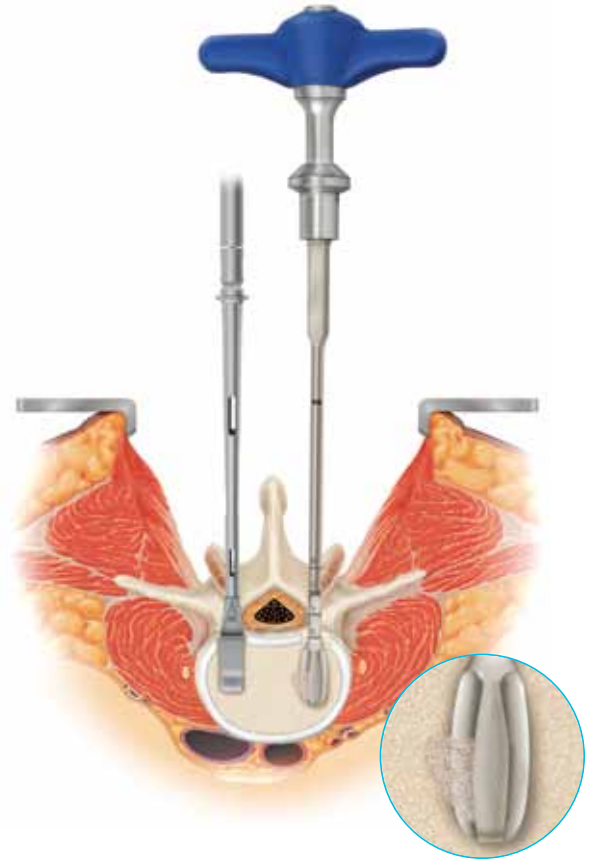
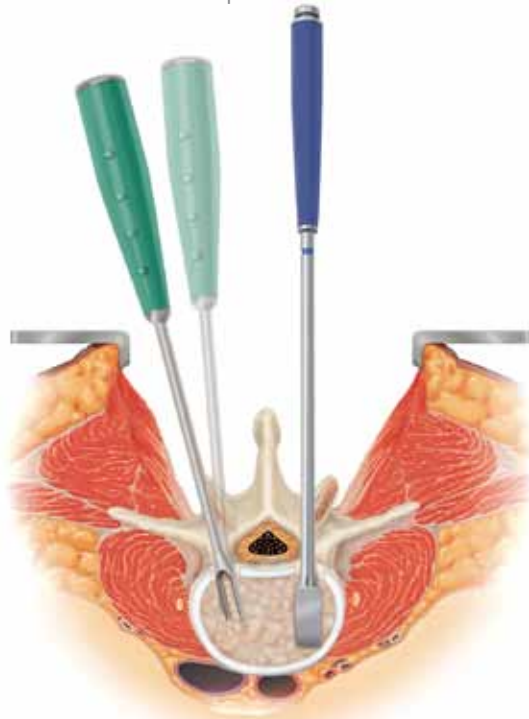


Discectomy

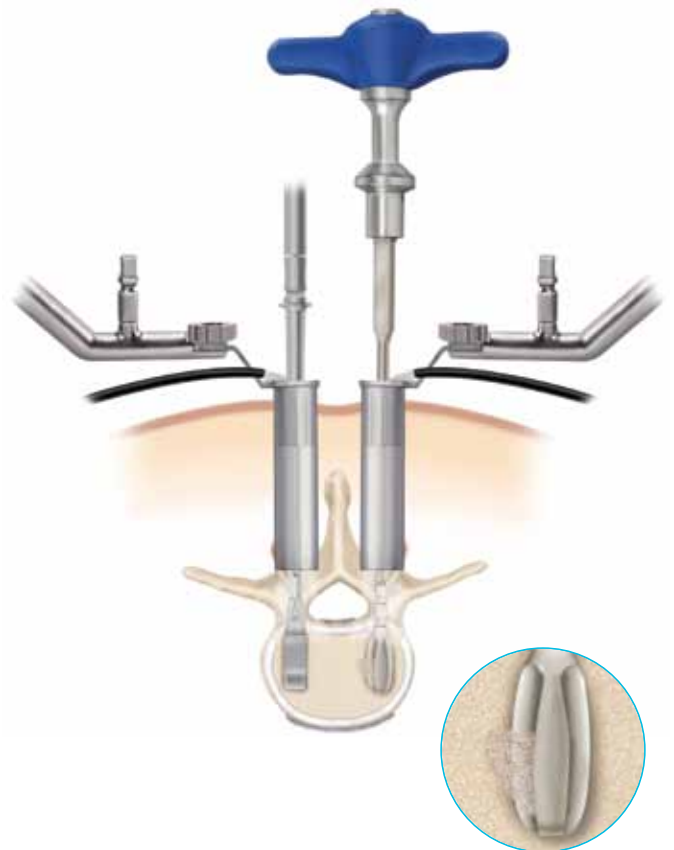
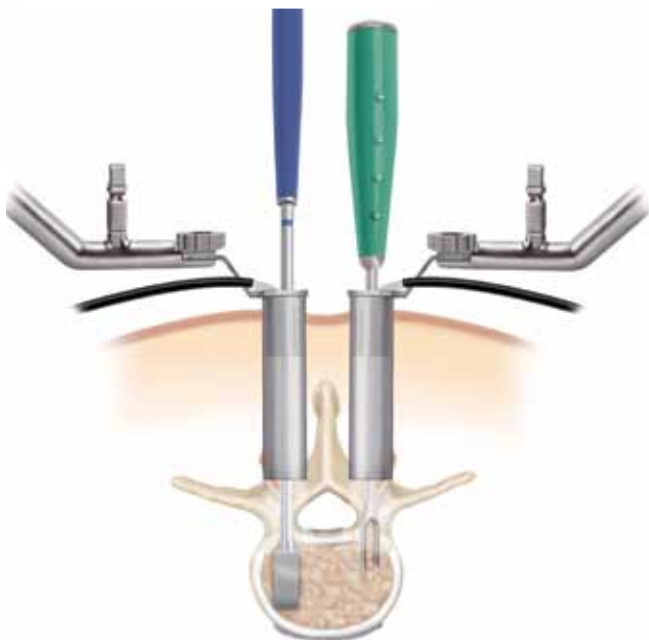
MAST™ PLIF Technique

Disc Space Preparation

Open PLIF Technique

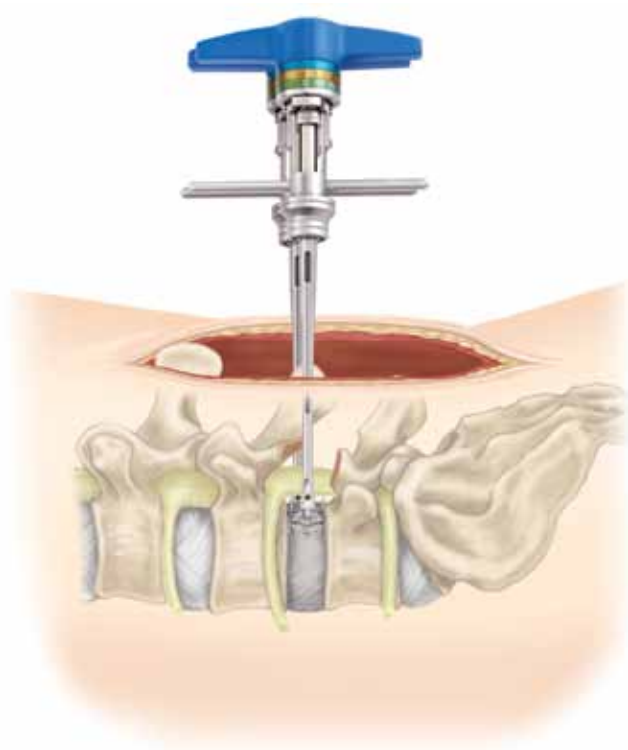


With the Distractor/Trial secured in the disc space, remove the disc using the Rotate Cutters and/or Shavers. The instruments are blunt tipped and side cutting for safety.

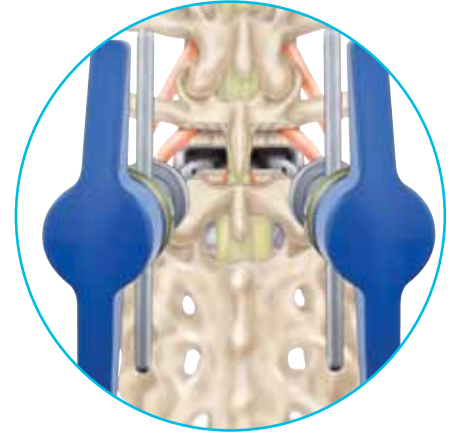


MAST™ PLIF Technique

Distraction



Open PLIF Technique

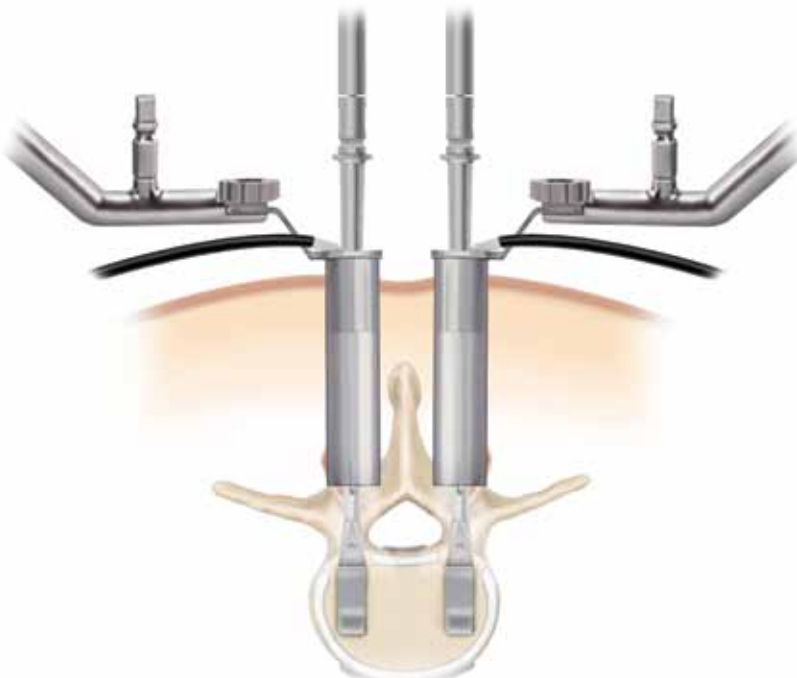


The disc space is sequentially distracted with the Distractor/Trial or the SCISSOR JACK™ Distractor until the original disc space height is obtained and the normal foraminal opening is restored.

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

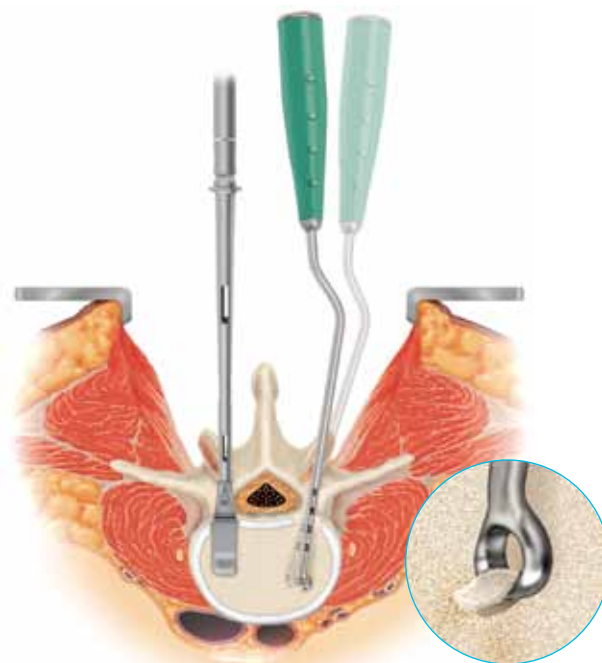
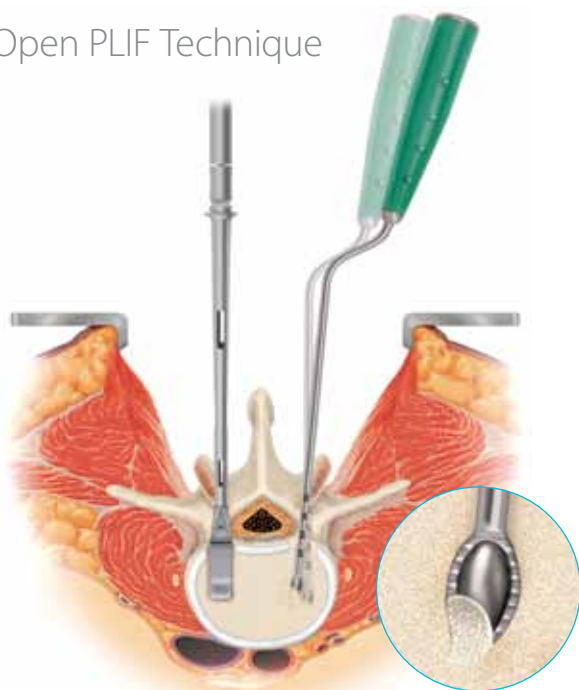


Open

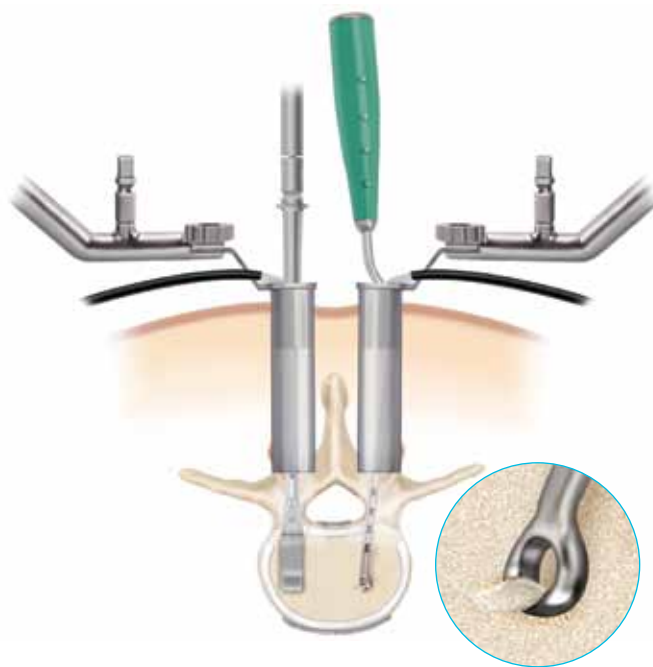
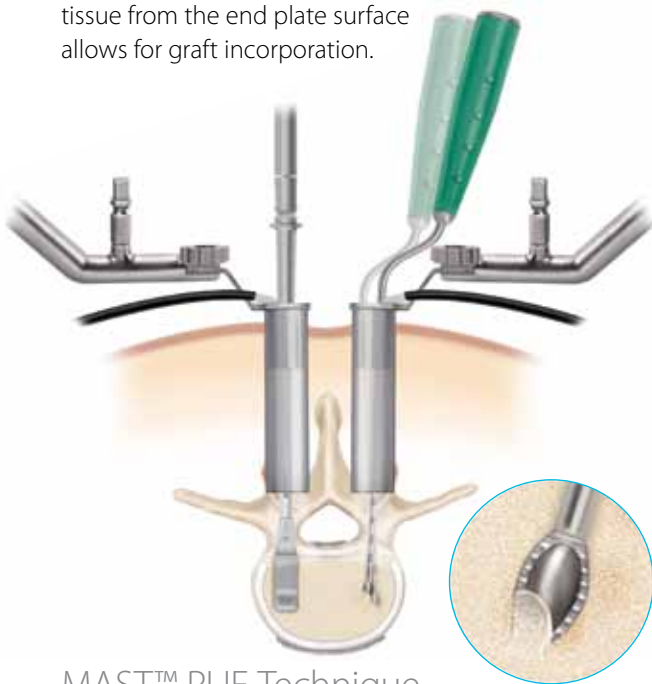
MAST™ PLIF Technique

End-plate Preparation

Open PLIF Technique



The remaining soft tissue or cartilaginous end plate is removed with vigorous scraping or curettage. Scrape medially under the midline and gradually work laterally in a sweeping motion until both caudal and cephalad end plates are cleared of soft tissue. The removal of the soft tissue from the end plate surface allows for graft incorporation.



MAST™ PLIF Technique

Trial Inserter



Open PLIF Technique

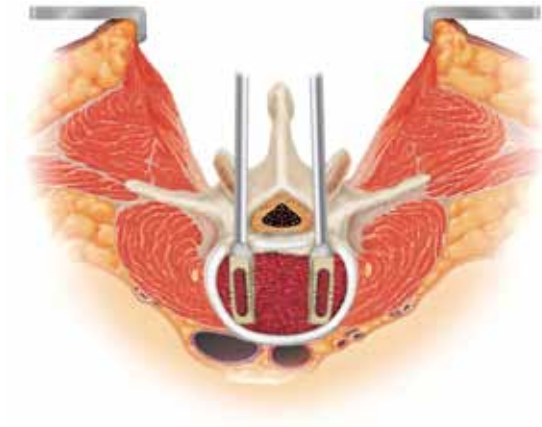
Insert the trials until the desired disc space height is established. A Slap Hammer can be used for trial removal.



MAST™ PLIF Technique

CAPSTONE® PEEK Interbody Spacer Insertion

Open PLIF Technique

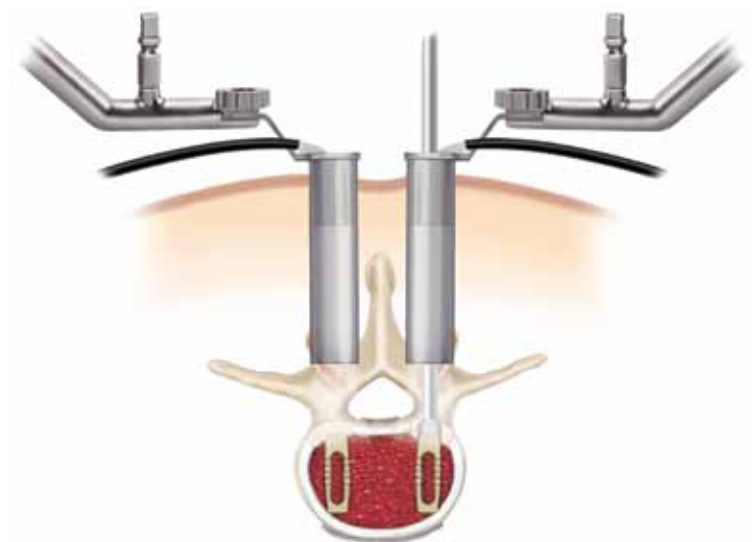
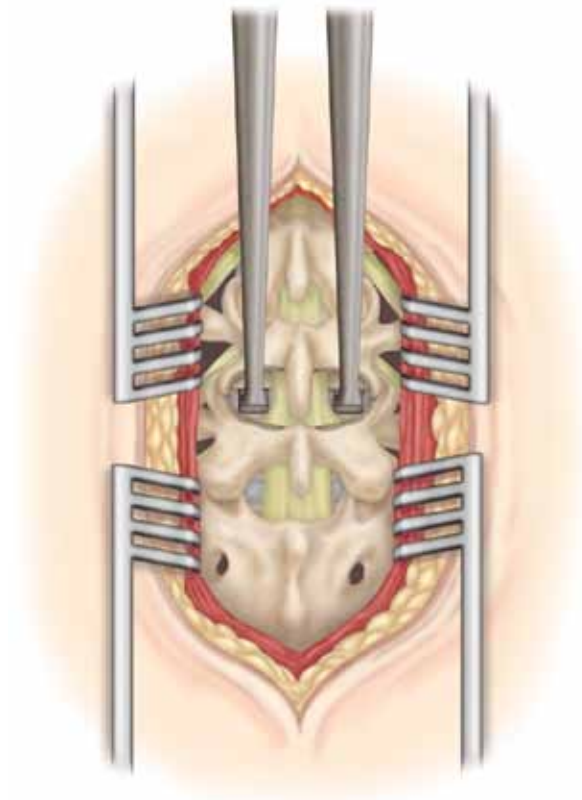


The appropriately sized CAPSTONE® PEEK Interbody Spacer is chosen during the trialing step and is firmly attached to the Inserter.

Before inserting the interbody spacer, place autograft anteriorly.

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

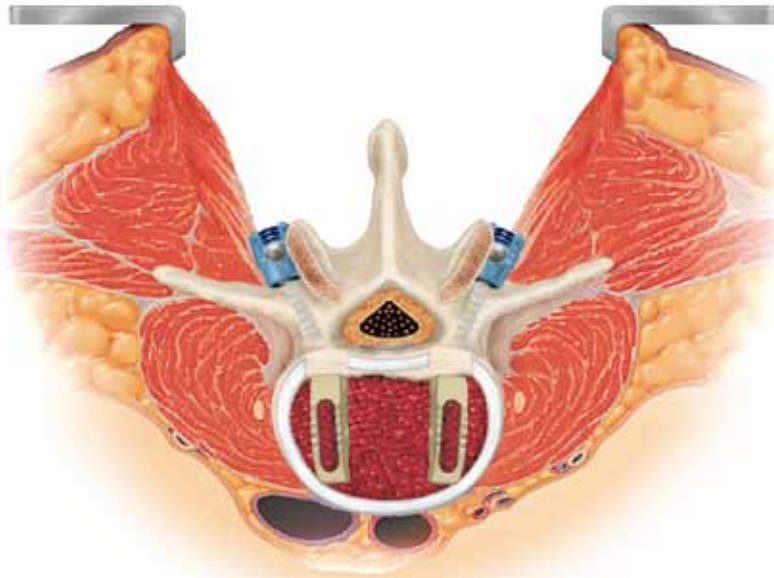
Care should be taken to ensure the interbody spacer is aligned properly.



MAST™ PLIF Technique

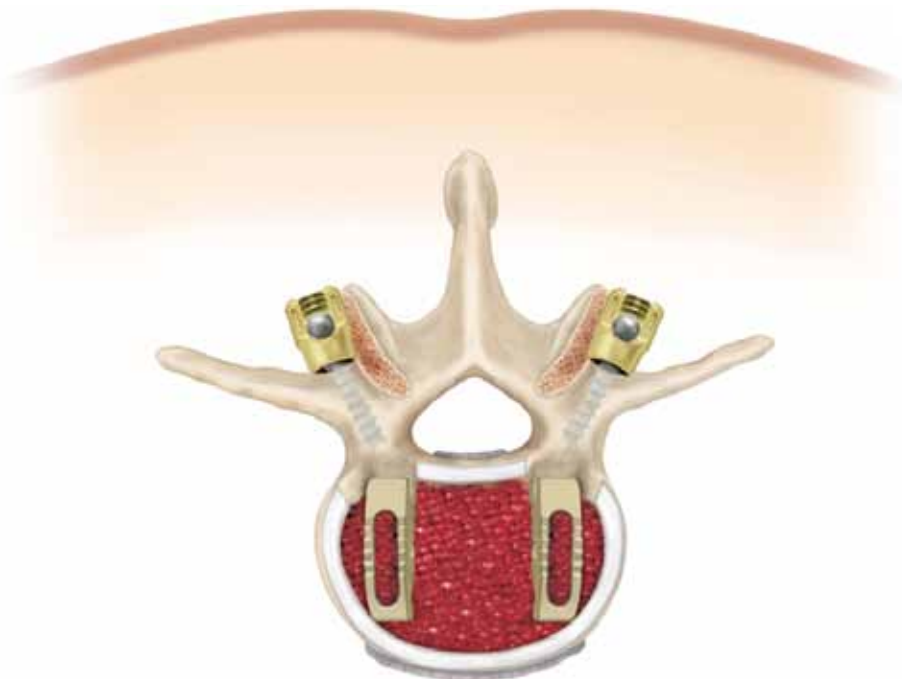
Final Placement

Open PLIF Technique



After the CAPSTONE® PEEK Interbody Spacer is placed, the 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 using the standard technique.

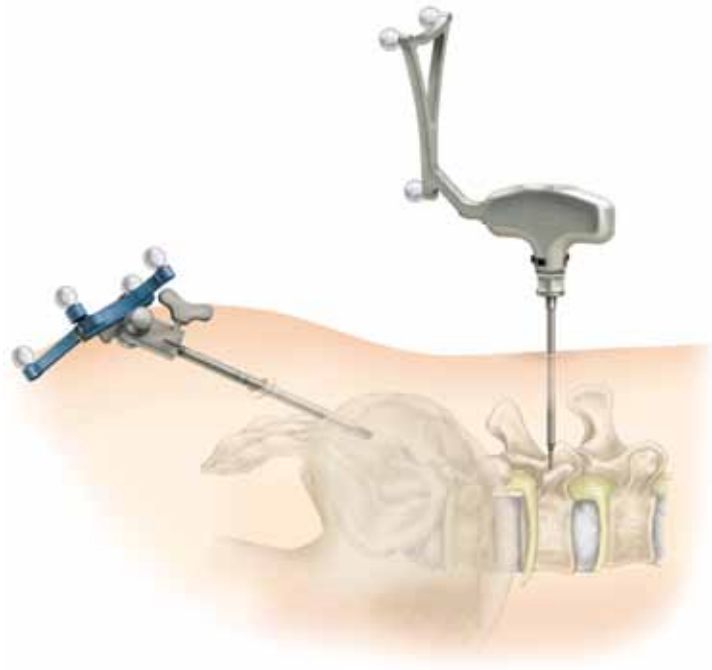


MAST™ PLIF Technique

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.



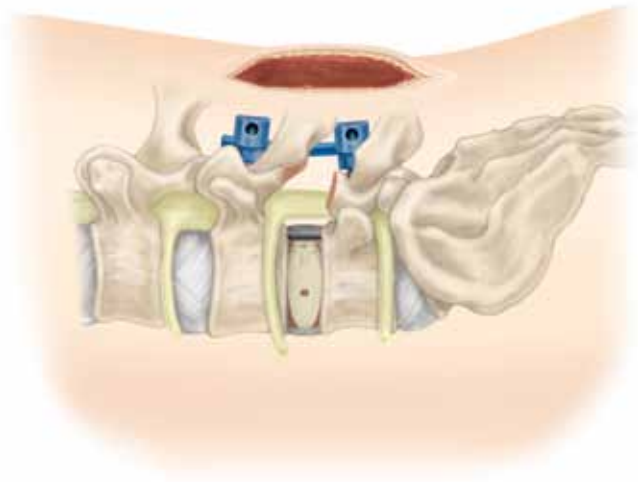
Additional Fixation Options and Explanations

The CD HORIZON® LEGACY™ 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 $\frac{7}{32}$ " 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 counter-clockwise 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. If greater force is needed, place the Slap Plate in the space between the impaction cap and the thumbwheel on the Inserter. Gently impact the slap plate to remove the implant.

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



CD HORIZON® LEGACY™ 5.5 SPINAL SYSTEM*

*Refer to the package insert for the fixation used.

Product Ordering Information

CAPSTONE® Instrument Set Set Type 335

Part Number	Description
2980001	Threaded Inserter
2980003	Slap Plate
2980100	6mm Osteotome
2980822	8mm × 22mm Distractor/Trial
2980826	8mm × 26mm Distractor/Trial
2980832	8mm × 32mm Distractor/Trial
2980836	8mm × 36mm Distractor/Trial
2981022	10mm × 22mm Distractor/Trial
2981026	10mm × 26mm Distractor/Trial
2981032	10mm × 32mm Distractor/Trial
2981036	10mm × 36mm Distractor/Trial
2981222	12mm × 22mm Distractor/Trial
2981226	12mm × 26mm Distractor/Trial
2981232	12mm × 32mm Distractor/Trial
2981236	12mm × 36mm Distractor/Trial
2981422	14mm X 22mm Distractor/Trial
2981426	14mm × 26mm Distractor/Trial
2981432	14mm × 32mm Distractor/Trial
2981436	14mm × 36mm Distractor/Trial
9074002	Slap Hammer

CAPSTONE® Implants Set Type 2134

Part Number	Description	Quantity
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
43000000	Large PEEK Suitcase	1

SCISSOR JACK™ Expandable Distractor Set Type 565

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

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

CD HORIZON® Spinal System

PURPOSE

The CD HORIZON® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION

The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other Medtronic spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® Rods, Hooks, Screws, Plates, CROSSLINK® Plates, Connectors, Staples and Washer, GDLH® Rods, Hooks, Connectors and CROSSLINK® Bar and connectors; LIBERTY® Rods and Screws; DYNALOK® PLUS and DYNALOK CLASSIC® Bolts along with rod/bolt connectors; and Medtronic Multi-Axial rods and screws. Please note that certain components are specifically designed to connect to 3.5mm, 4.5mm, 5.5mm rods or 6.35mm rods, while other components can connect to both 5.5mm rods and 6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

CD HORIZON® Hooks are intended for posterior use only. CD HORIZON® Staples and CD HORIZON® ECLIPSE® Rods and associated screws are intended for anterior use only. However, for patients of smaller stature, CD HORIZON® 4.5mm Rods and associated components may be used posteriorly.

The CD HORIZON® Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEK OPTIMA-LT1. Certain CD HORIZON® Spinal System components may be coated with hydroxyapatite. No warranties express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the Medtronic Catalog for further information about warranties and limitations of liability.

Never use stainless steel and titanium implant components in the same construct.

Medical grade titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct.

The CD HORIZON® Spinal System also includes anterior staples made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy and cobalt-chromium-molybdenum alloy. Do not use with stainless steel.

The CD HORIZON® AGILE™ Dynamic Stabilization device is comprised of four components and are comprised by a combination of materials. The proximal and distal rod components are manufactured from commercially pure titanium. The cable is fabricated from a 7x7 filament yarn made from titanium alloy, with a cylinder rotary-swaged to the end, made from the same material. The spacer portion of the device is manufactured from Polycarbonate-Urethane.

PEEK OPTIMA-LT1 implants may be used with stainless steel, titanium or cobalt-chromium-molybdenum alloy implants. **CD HORIZON® PEEK Rods are not to be used with CROSSLINK® Plates.**

To achieve best results, do not use any of the CD HORIZON® Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. As with all orthopaedic and neurosurgical implants, none of the CD HORIZON® Spinal System components should ever be reused under any circumstances.

INDICATIONS

The CD HORIZON® Spinal System with or without SEXTANT® instruments are intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylo-lysthesia; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm Rods and the CD HORIZON® Spinal System PEEK Rods and associated components may be used for the aforementioned indications in skeletally mature patients.

The CD HORIZON® SPIRE™ Plate is a posterior, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined); spondylolysthesia, trauma; and/or tumor.

When used as a pedicle screw fixation system in skeletally mature patients, the CD HORIZON® AGILE™ Dynamic Stabilization device is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the degenerative spondylolysthesia with objective evidence of neurologic impairment and/or failed previous fusion in the thoracic, lumbar and/or sacral spine. Additionally, when used as a pedicle screw fixation system, the CD HORIZON® AGILE™ Dynamic Stabilization device is indicated for use in patients who are receiving fusions with autogenous graft only; who are having the device fixed or attached to the lumbar or sacral spine; and/or are having the device removed after the development of a solid fusion mass.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System Rods may be connected to the VERTEX® Reconstruction System with the VERTEX® Rod Connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (immunocompromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
12. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.

13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
14. Any patient unwilling to follow postoperative instructions.
15. Any case not described in the indications.

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

1. Severe bone resorption.
2. Osteomalacia.
3. Severe osteoporosis.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without in–strumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Post operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss of or increase in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stresses shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolysthesia with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses.

In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend or fracture as a result of exposure to every day mechanical stresses.

PRECAUTION

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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

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

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

Important Product Information *continued*

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. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

In cases where a percutaneous posterior approach is used refer to the CD HORIZON® SEXTANT® surgical technique. MEDTRONIC CD HORIZON® Spinal System instrument set contains 3.5mm, 4.5 mm, 5.5mm and/or 6.35mm rods and implants, which are intended to be used with device specific instruments. For self breaking plugs, always hold the assembly with the Counter Torque device. Tighten and break-off the head of the plug to leave the assembly at optimum fixation security. After the upper part of the self breaking plug has been sheared off, further re-tightening is not necessary and not recommended. The head part should not remain in the patient. AFTER THE UPPER PART OF THE SELF BREAKING PLUG HAS BEEN SHEARED OFF, RE-ADJUSTMENT IS NOT POSSIBLE UNLESS THE PLUG IS REMOVED AND REPLACED WITH A NEW ONE.

When using DTT Transverse Links, the M6 plug should be tightened to between 8 and 9 Nm. (70 to 80 inch-lbs).

CD HORIZON® PEEK Rods are not to be used with CROSSLINK® Plates.

When using the CD HORIZON® AGILE™ Dynamic Stabilization device, refer to the surgical technique for the appropriate directions for use.

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 aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
- An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The CD HORIZON® Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

- 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 implant components may cause injury to the patient or operative personnel.
- The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
- Utilize an imaging system to facilitate surgery.
- To insert a screw properly, a guide wire should first be used, followed by a sharp tap. **Caution:** Be careful that the guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-wire does not advance during tapping or screw insertion. Remove the guide-wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.
- Caution:** Do not overlap or use a screw/bolt that is either too long or too large. Overlapping, using an incorrectly sized screw/bolt, or accidentally advancing the guidewire during tap or screw/bolt insertion, may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws/bolts are being inserted into spinal pedicles, use as large a screw/bolt diameter as will fit into each pedicle.
- Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
- To assure maximum stability, two or more CROSSLINK® Plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.
- Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws, especially screws or nuts that have a break-off feature. Once this is completed go back and firmly tighten all of the screws and nuts. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

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. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin during the bone graft healing process.
- The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
- The CD HORIZON® Spinal System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the CD HORIZON® Spinal System components should never be reused under any circumstances.

PACKAGING

Packages for each of the components should be intact upon receipt. 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

Unless just removed from an unopened Medtronic package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

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:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

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. *For outside the United States, 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.

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 and/or performance, should notify the distributor, 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, please 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.

FOR FURTHER INFORMATION:



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Contact Customer Service or your Sales Representative for the most up-to-date version of the package insert.

Important Product Information

General Instruments

PURPOSE

This instrument is intended for use in surgical procedures.

DESCRIPTION

Unless otherwise stated, instruments are made out of a variety of materials commonly used in orthopedic and neurological procedures including stainless steel and acetyl copolymer materials which meet available national or international standards specifications. Some instruments are made out of aluminum, and some with handles made of resin bonded composites, and while these can be steam autoclaved, certain cleaning fluids must not be employed. None of the instruments should be implanted.

Unless otherwise stated, instruments are made out of a variety of materials commonly used in orthopedic and neurological procedures including stainless steel and acetyl copolymer materials which meet available national or international standards specifications. Some instruments are made out of aluminum, and some with handles made of resin bonded composites, and while these can be steam autoclaved, certain cleaning fluids must not be employed. None of the instruments should be implanted.

INTENDED USE

This instrument is a precision device which may incorporate a measuring function and has uses as described on the label. Unless labeled for single use, this instrument may be re-used. If there is any doubt or uncertainty concerning the proper use of this instrument, please contact MEDTRONIC SOFAMOR DANEK Customer Service for instructions. Any available surgical techniques will be provided at no charge.

WARNINGS

The methods of use of instruments are to be determined by the user's experience and training in surgical procedures. Do not use this instrument for any action for which it was not intended such as hammering, prying, or lifting. This instrument should be treated as any precision instrument and should be carefully placed on trays, cleaned after each use, and stored in a dry environment. To avoid injury, the instrument should be carefully examined prior to use for functionality or damage. A damaged instrument should not be used. Additional back-up instruments should be available in case of an unexpected need. MEDTRONIC SOFAMOR DANEK does not and cannot warrant the use of this instrument nor any of the component parts upon which repairs have been made or attempted except as performed by MEDTRONIC SOFAMOR DANEK or an authorized MEDTRONIC SOFAMOR DANEK repair representative. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MEDTRONIC SOFAMOR DANEK catalog for further information about warranties and limitations of liability.

DO NOT IMPLANT THE INSTRUMENTS.

POSSIBLE ADVERSE EFFECTS

Breakage, slippage, misuse, or mishandling of instruments, such as on sharp edges, may cause injury to the patient or operative personnel.

Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose or even dangerous to the patient or surgical staff.

Proper patient selection and operative care are critical to the success of the device and avoidance of injury during surgery. Read and follow all other product information supplied by the manufacturer of the implants or the instruments.

Special precautions are needed during pediatric use. Care should be taken when using instruments in pediatric patients, since these patients can be more susceptible to the stresses involved in their use.

There are particular risks involved in the use of instruments used for bending and cutting rods. The use of these types of instruments can cause injury to the patient by virtue of the extremely high forces which are involved. Do not cut rods in situ. In addition, any breakage of an instrument or the implant in this situation could be extremely hazardous. The physical characteristics required for many instruments does not permit them to be manufactured from implantable materials, and if any broken fragments of instruments remain in the body of a patient, they could cause allergic or infectious consequences.

Over-bending, notching, striking and scratching of the implants with any instrument should be avoided to reduce the risk of breakage.


Under no circumstances should rods or plates be sharply or reverse bent, since this would reduce the fatigue life of the rod and increase the risk of breakage. When the configuration of the bone cannot be fitted with an available device and contouring of the device is absolutely necessary, contouring should be performed only with proper bending equipment, and should be performed gradually and with great care to avoid notching or scratching the device.

Extreme care should be taken to ensure that this instrument remains in good working order. Any surgical techniques applicable for use of this system should be carefully followed. During the procedure, successful utilization of this instrument is extremely important. Unless labeled for single use, this instrument may be reused. This instrument should not be bent or damaged in any way. Misuse of this instrument, causing corrosion, "freezing-up", scratching, loosening, bending and/or fracture of any or all sections of the instrument may inhibit or prevent proper function.

It is important that the surgeon exercise extreme caution when working in close proximity to vital organs, nerves or vessels, and that the forces applied while correcting the position of the instrumentation is not excessive, such that it might cause injury to the patient.

Excessive force applied by instruments to implants can dislodge devices, particularly hooks.

Never expose instruments to temperatures in excess of 134° C that may considerably modify the physical characteristics of the instruments.

 For US Audiences Only

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This device should be used only by physicians familiar with the device, its intended use, an additional instrumentation and any available surgical techniques.

For the best results MEDTRONIC SOFAMOR DANEK implants should only be implanted with MEDTRONIC SOFAMOR DANEK instruments.

Other complications to the patient and/or hospital staff may include, but are not limited to:

1. Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs or joints.
2. Breakage of the device, which could make necessary removal difficult or sometimes impossible, with possible consequences of late infection and migration. Breakage could cause injury to the patient or hospital staff.
3. Infection, if instruments are not properly cleaned and sterilized.
4. Pain, discomfort or abnormal sensations resulting from the presence of the device.
5. Nerve damage due to surgical trauma.

6. Dural leak in cases of excessive load application.
7. Impingement of close vessels, nerves and organs by slippage or misplacement of the instrument.
8. Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.
9. Cutting of skin or gloves of operating staff.
10. Bony fracture, in cases of deformed spine or weak bone.
11. Tissue damage to the patient, physical injury to operating staff and/or increased operating time that may result from the disassembly of multi-component instruments occurring during surgery.

OTHER PRECAUTIONS

1. Excessive forces when using bending or fixation instruments can be dangerous especially where bone friability is encountered during the operation.
2. Any form of distortion or excessive wear on instruments may cause a malfunction likely to lead to serious patient injury.
3. Regularly review the operational state of all instruments and if necessary make use of repair and replacement services.

DEVICE FIXATION

Some surgeries require the use of instruments which incorporate a measuring function. Ensure that these are not worn, that any surface engravings are clearly visible.

Where there is a need for a specified tightening torque, this may normally be achieved with torque setting instruments supplied by MEDTRONIC SOFAMOR DANEK; the pointer on these instruments must indicate ZERO before use. If not, return for recalibration.

With small instruments, excess force, beyond the design strength of the instrument, can be caused even by simple manual overloading. Do not exceed recommended parameters.

To determine the screw diameter with the screw gauge, start with the smallest test hole.

PACKAGING

MEDTRONIC SOFAMOR DANEK instruments may be supplied as sterile or non-sterile. Sterile instruments will be clearly labeled as such on the package label. The sterility of instruments supplied sterile can only be assured if the packaging is intact.

Packages for both sterile and non-sterile components should be intact upon receipt. All sets should be carefully checked for completeness and all components should be carefully checked for signs of damage, prior to use. Damaged packages or products should not be used and should be returned to MEDTRONIC SOFAMOR DANEK.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately re-sterilize all instruments used in surgery. Instruments should be thoroughly cleaned prior to re-sterilization. This process must be performed before handling, or before returning product to MEDTRONIC SOFAMOR DANEK.

EXAMINATION

Instruments must always be examined by the user prior to use in surgery.

Examination should be thorough, and in particular, should take into account a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, bruising or distortion, and that all components of the instrument are complete.

Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise unfunctional.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic Sofamor Danek. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

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:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

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. *For outside the United States, 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.

It is important to note that a sterilization wrap, package or sterilization container system should be used to enclose the case or tray in order to maintain sterility.

Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be re-sterilized.

OPERATIVE USE

The physician should take precautions against putting undue stress on the spinal area with instruments. Any surgical technique instruction manual should be carefully followed. If an instrument breaks in surgery and pieces go into the patient, these pieces should be removed prior to closure and should not be implanted.

Important Product Information *continued*

REMOVAL OF IMPLANTS

For the best results, the same type of MEDTRONIC SOFAMOR DANEK instruments as used for implantation should be used for implant removal purposes. Various sizes of screwdrivers are available to adapt to the removal drive sizes in auto break fixation screws.

It should be noted that where excessive bone or fibrous growth has occurred from the first surgery, there may be added stress on the removal instruments and the implants. Both instrument and implant may be prone to possible breakage. In this case it is necessary to first remove the bone and/or tissue from around the implants.

FURTHER INFORMATION

In case of complaint, or for supplementary information, please contact MEDTRONIC SOFAMOR DANEK.

PRODUCT COMPLAINTS

Any Health Care Professionals (e.g., customer users of MEDTRONIC SOFAMOR DANEK instruments), who have any complaint or who have experienced dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, MEDTRONIC SOFAMOR DANEK. Further, if any instrument "malfunctions", (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor or MEDTRONIC SOFAMOR DANEK should be notified immediately. If any MEDTRONIC SOFAMOR DANEK product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor or MEDTRONIC SOFAMOR DANEK should be notified as soon as possible by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, and the nature of the complaint.

FOR FURTHER INFORMATION:



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Contact Customer Service or your Sales Representative for the most up-to-date version of the package insert.

Important Product Information

CAPSTONE® Spinal System

PURPOSE

This device is a PEEK (POLYETHERETHERKETONE) 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 who is 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 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 use 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:

1. Infection, local to the operative site
2. Signs of local inflammation,
3. Fever or leukocytosis,
4. Morbid obesity,
5. Pregnancy,
6. Mental illness,
7. 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 segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Suspected or documented allergy or intolerance to composite materials,
9. Any case not needing a fusion,
10. Any case not described in the indications,
11. Any patient unwilling to cooperate with postoperative instructions.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
14. Spondylolisthesis unable to be reduced to Grade 1.
15. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
16. Any case that requires the mixing of metals from two different components or systems.
17. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
18. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
19. 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:

1. Severe bone resorption.
2. Osteomalacia.
3. 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:

1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or pseudoarthrosis).
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury. Cerebral spinal fluid leakage.
10. Haemorrhage of blood vessels and/or hematomas.
11. Discitis, arachnoiditis, and/or other types of inflammation.

12. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
13. Bone graft donor site complication.
14. Inability to resume activities of normal daily living.
15. Early or late loosening or movement of the device(s).
16. Urinary retention or loss of bladder control or other types of urological system compromise.
17. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
18. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
19. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
20. Loss of or increase in spinal mobility or function.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Cessation of any potential growth of the operated portion of the spine.
25. 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 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, 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 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

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and / or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. 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.
4. Further information about this system will be provided upon request.
5. The surgeon should be familiar with the various devices before use and should personally verify that all devices are present before the surgery begins.
6. 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.
7. Unless supplied sterile, all devices should be cleaned and sterilized before use. Additional sterile components should be available in case of any unexpected need.

INTRAOPERATIVE

1. The instructions in any available CAPSTONE® Spinal System surgical technique manual should be carefully followed.
2. 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.
3. Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the fusion, autogenous bone graft must be used.
5. When used via a posterior approach, supplemental posterior instrumentation is recommended. Posterior supplemental fixation is limited to Medtronic Sofamor Danek posterior instrumentation systems.
6. 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 and the corresponding patient compliance, are extremely important.

Important Product Information *continued*

1. 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.
2. The patient should be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
3. 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.
4. 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.
5. CAPSTONE® Spinal System implants are interbody devices and are intended to stabilize the operative area during the fusion process.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING

Devices are supplied in a sterile form. Packages for each of the components should be intact upon receipt. Once the seal on the 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

Unless just removed from an unopened MEDTRONIC package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to MEDTRONIC. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION

Devices are supplied in a sterile form. Once the seal on the package has been broken, the product should not be re-sterilized. When supplemental fixation is used, refer to the package insert of the supplemental instrumentation for sterilization information.

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 and/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, please 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.

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.

Covered by one or more of U.S. Pat. Nos. 5,772,661; 5,860,973 and other pending patent applications.



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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.

