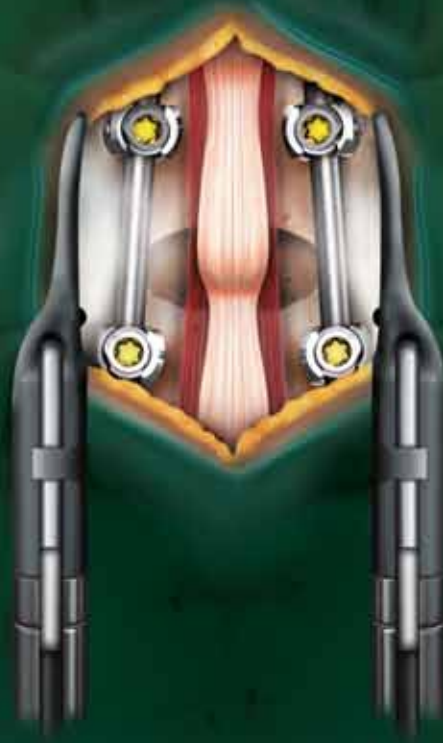




Medtronic

MAST[®] MIDLF[™] Procedure

Midline Lumbar Fusion Surgical Technique
Featuring the Gen 2.0 Retractor System



As described by:

Richard A. Hynes, MD, FACS
The B.A.C.K. Center
Melbourne, Florida

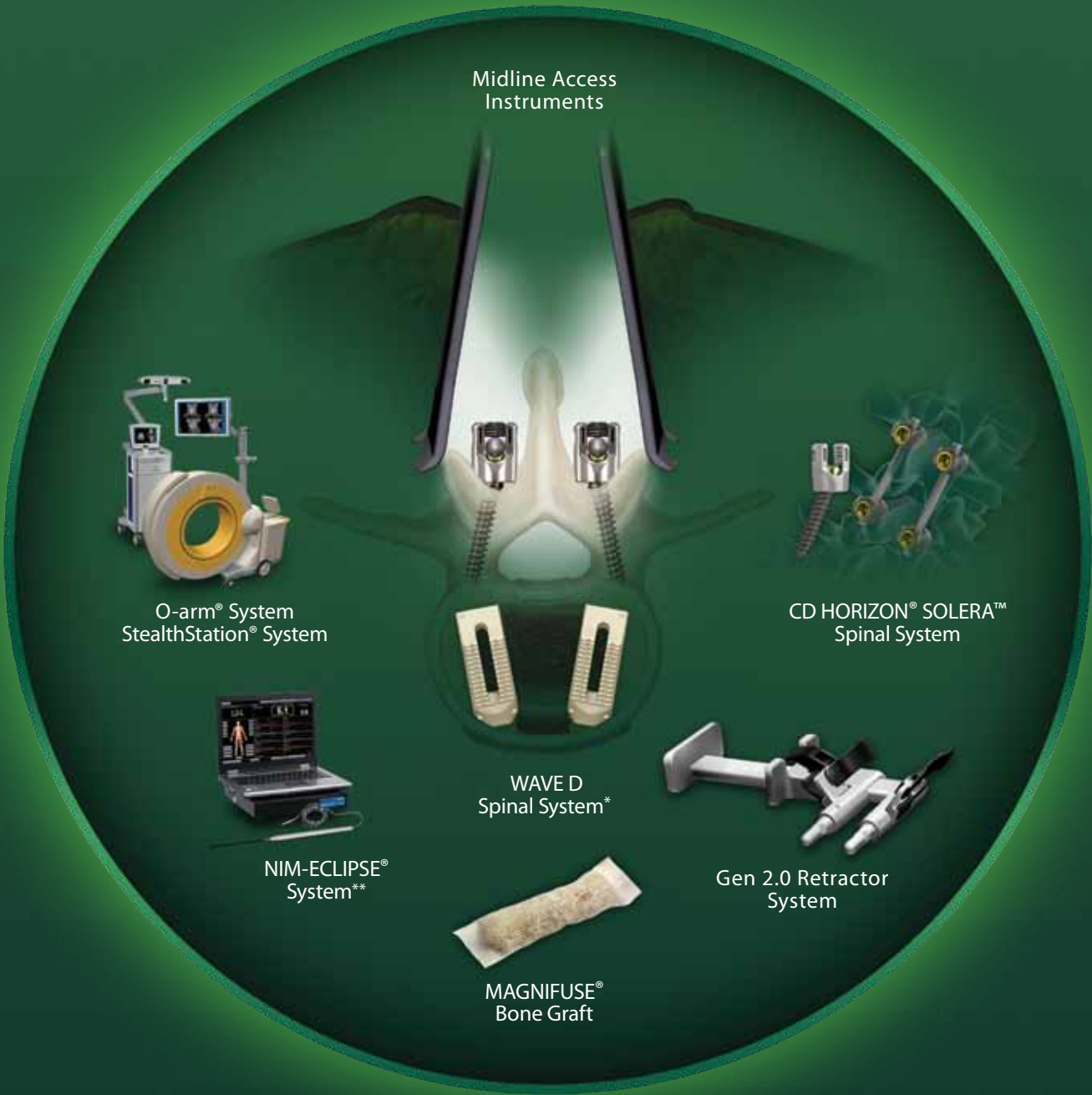
Stephen L. Ritland, MD
Flagstaff Medical Center
Flagstaff, Arizona

Charles L. Branch, Jr., MD
Wake Forest University
School of Medicine
Winston-Salem, North Carolina

Mladen Djurasovic, MD
Norton Leatherman
Spine Center
Louisville, Kentucky



MAST[®] MIDLF[™] Procedure utilizes a group of technologies that enable and facilitate a **midline** anatomic approach to lumbar **decompression** and fusion, **respecting** the muscle and neurovascular constraints along the superior articular process.



*Interbody implants are to be used with autogenous bone graft.

**The NIM-ECLIPSE[®] System is manufactured by Medtronic Xomed, Inc. Distributed by Medtronic Sofamor Danek USA, Inc.



MAST[®] MIDLF[™] Procedure

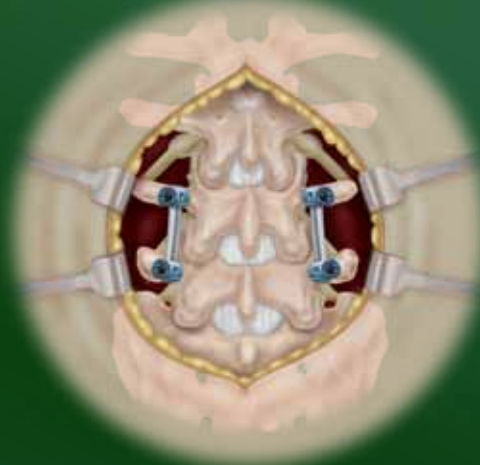
Midline Lumbar Fusion Surgical Technique Featuring the Gen 2.0 Retractor System

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A Familiar MAST® Approach



MAST® MIDLF™ Approach



Traditional Open Approach

Fixation, decompression, and interbody fusion through a laminectomy approach.

Surgical Considerations

A MAST® MIDLF™ procedure is an approach to the spine medial and deep to the segmental back muscles with the screw construct placed along the spinous process.

Medializing screw placement shifts screw entry to a point along the pars interarticularis or joint surface. This places the construct medial and deep to the segmental back muscles. It places the screw through potentially more cortical and stronger bone.

Retraction engages the segmental back muscles to provide an exposure over the lamina and articular processes. A dorsal approach to the lumbar spine has muscle constraints to the spinous process and to the superior articular process. The segmental neurovascular supply has relatively fixed constraints

along the line of the superior articular process including the medial branch of the dorsal ramus of the nerve in the mamilloaccessory notch and the artery of the pars interarticularis passing over the pars. Using an insertion which respects the muscle to the superior articular process lessens the risk of compromise to accompanying neurovascular elements. The Midline Retractor Blades engage the tendons and muscle to the superior articular process and provides exposure of the bony surface for screw placement. The medial-to-lateral trajectory used during placement of the CD HORIZON® SOLERA™ System Bone Screws allow placement of the construct which respects the integrity of the muscle and neurovascular constraints of the back.

Access and Illumination

- Integrated illumination technology is low profile and provides off-axis lighting to reduce glare.
- Attach the blades to the retractor and slide the light source onto the blades for easy assembly.

Gen 2.0 MIDLINE Retractor System with MIDLINE Blades



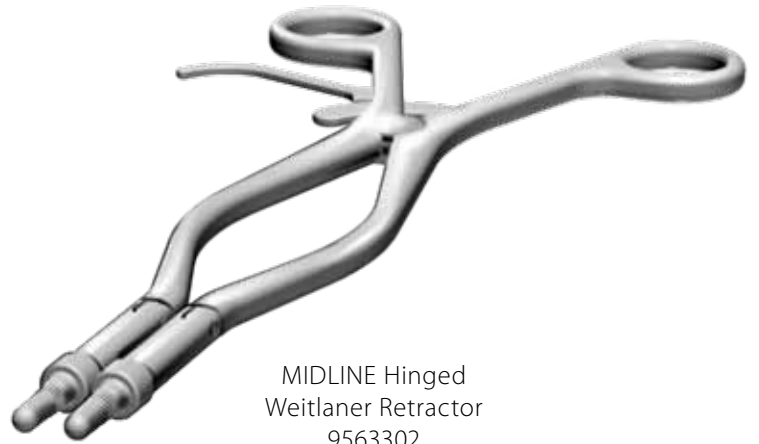
MIDLINE Hinged Weitlaner Retractor with MIDLINE Blades



Instrument Overview



Gen 2.0 MIDLINE Retractor System
9563303



MIDLINE Hinged
Weitlaner Retractor
9563302



Speculum
9563082



MIDLINE Blades
(4cm to 11cm)
See page 21 for detailed size
and ordering information.



MAST QUADRANT®
Illumination System
9560658



Blade Handle
9563002

Exposure

Localize the level and make a two inch incision using a midline laminectomy approach over the spinous process to the dorsolumbar fascia (**Figure 1**). The dorsolumbar fascia is opened exposing the erector spinae aponeurosis (ESA) (**Figure 2**). A paramedian opening between the tendons of the ESA preserves the integrity of the tendinous insertion to the spinous process for a minimal intervention with respect to the muscles (**Figure 3**). Gentle dissection along the process over the lamina elevates the multifidus arising on the process above, respecting the integrity of the muscle arising on the adjacent process and providing a bilateral window to the lamina and articular process (**Figure 4**).

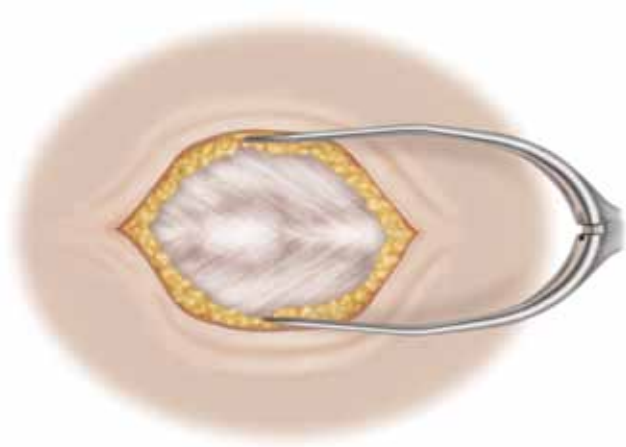


Figure 1

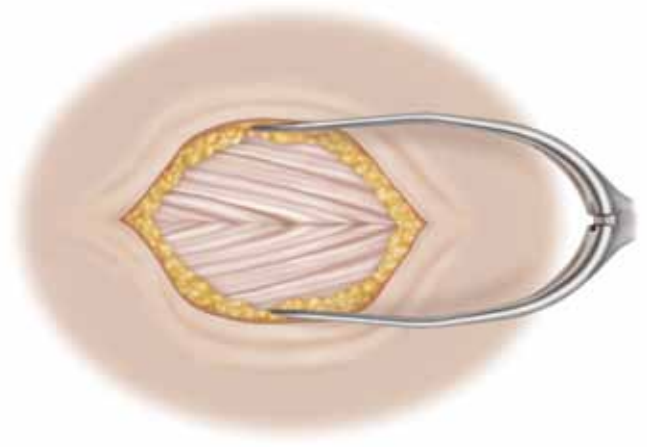


Figure 2

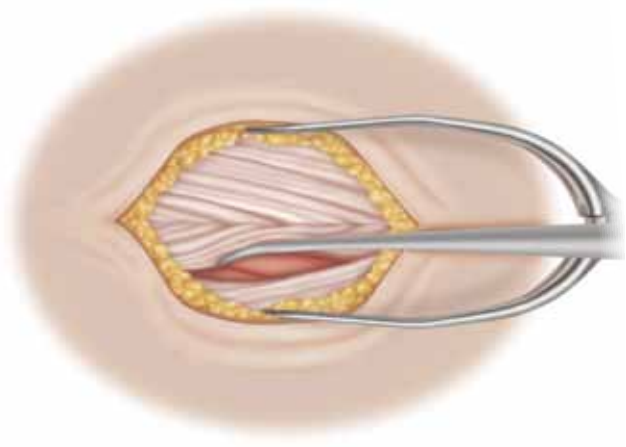


Figure 3

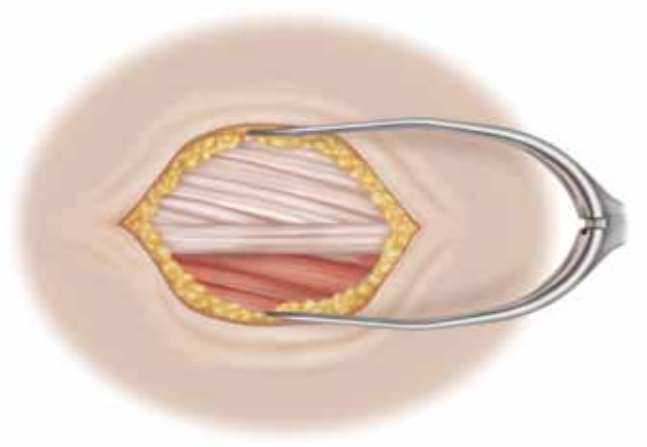


Figure 4

Exposure *continued*

Insert the Speculum by sliding the closed distal portion along the contralateral side of the spinous process and down the lamina to the facet (**Figures 5a and 5b**). Rotate the Speculum handle lateral to the incision and squeeze as to make a pathway and slide the blade down the speculum and into position (**Figure 6**). The blade is constrained by the tendons as it is inserted into the superior articular processes and traversing to the articular process.

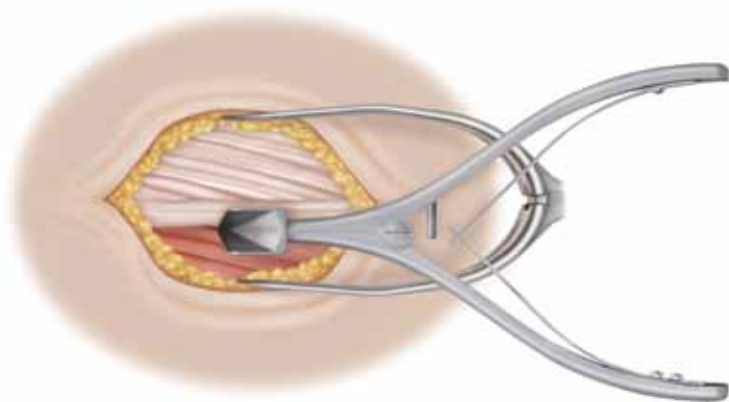


Figure 5a

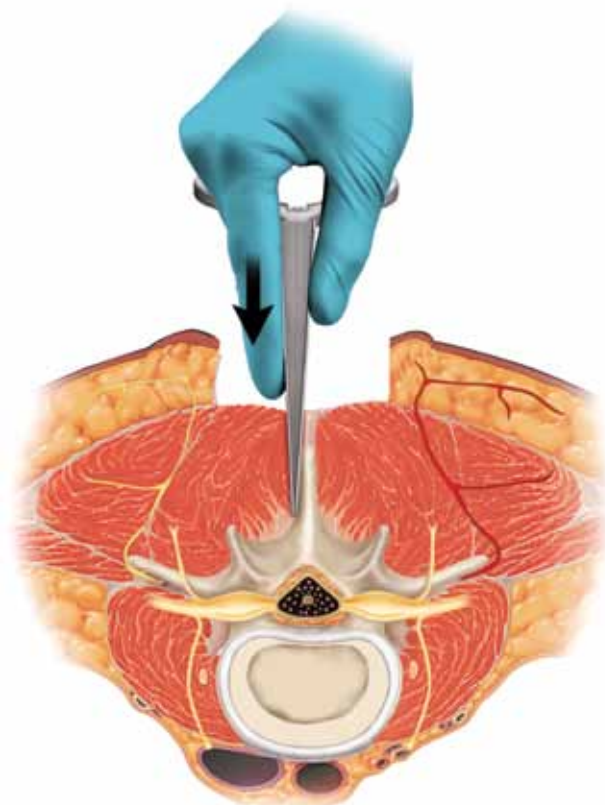


Figure 5b

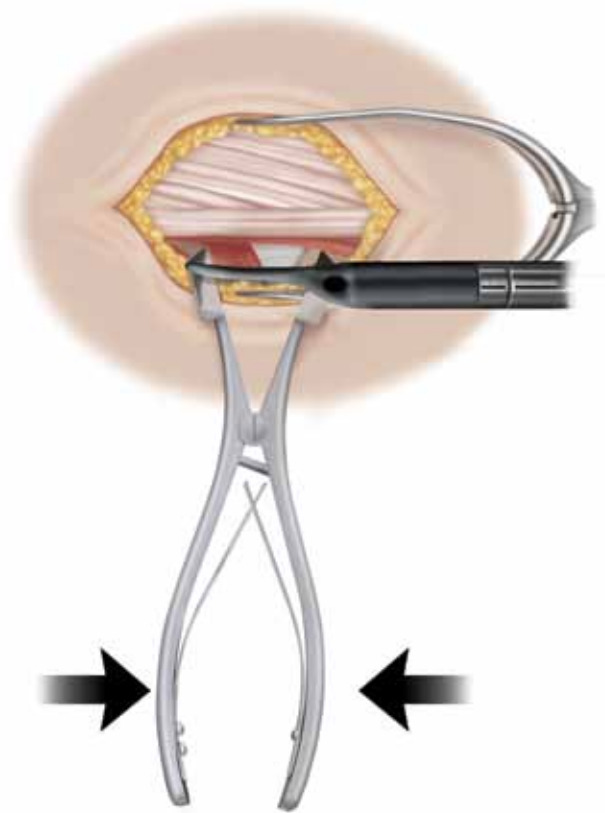


Figure 6

Exposure *continued*

The tip on the blade follows the contour over the articular process and engages under the tendon and under the margin of muscle and tendon traversing to the sacral articular process. Remove the Speculum and repeat the blade insertion step on the ipsilateral side (Figures 7a and 7b).

To aid with blade insertion or blade divergence, the Blade Handle instrument may be used. The handle is attached to the blade by sliding the tip of the handle into the light source slot of the blade (Figures 7c and 7d).

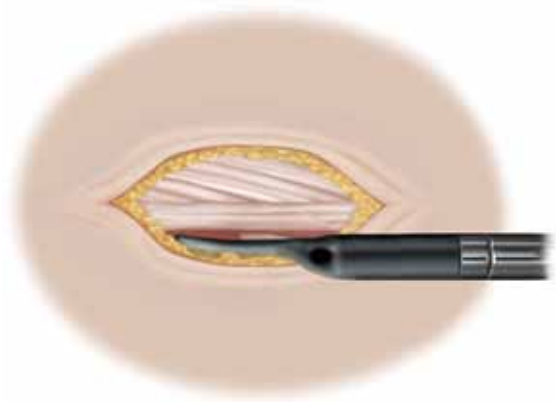


Figure 7a

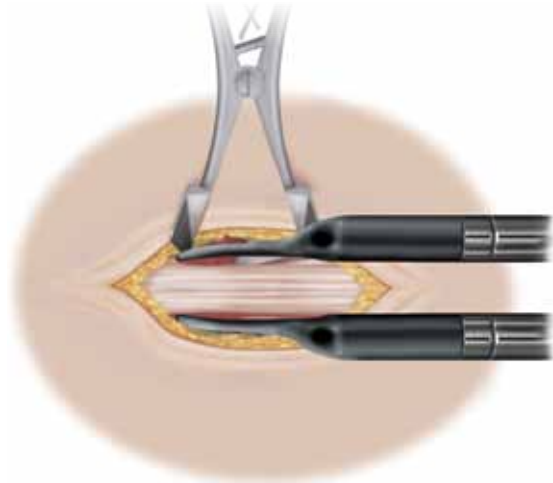


Figure 7b



Figure 7c



Figure 7d

Exposure *continued*

With the Gen 2.0 Retractor System or the MIDLINE Hinged Weitlaner Retractor in the closed position, attach the MIDLINE Blades. Use the blade handle if leverage is required for attachment. When using the MIDLINE Hinged Weitlaner Retractor, the lines on the blades and the lines on the retractor will align (Figure 8). This provides a 15° divergence to the blades which will make the retractor stable under the soft tissues. Rotate the blades one or two clicks before opening the retractor. Once the blades are in position, slide the light source over each blade (Figure 9).

A suture may be placed to secure the ESA and provide a more open visual window for screw placement. Skewing the retractor blades moves the operative window for cephalad and caudal screw prep on the left side (Figure 10). If the blades are causing excessive stretching of the skin, simply lengthen the incision.

✓ Note

The 15° divergent angle in the blade/retractor assembly prevents the natural tendency of the blades to be forced out of the incision.

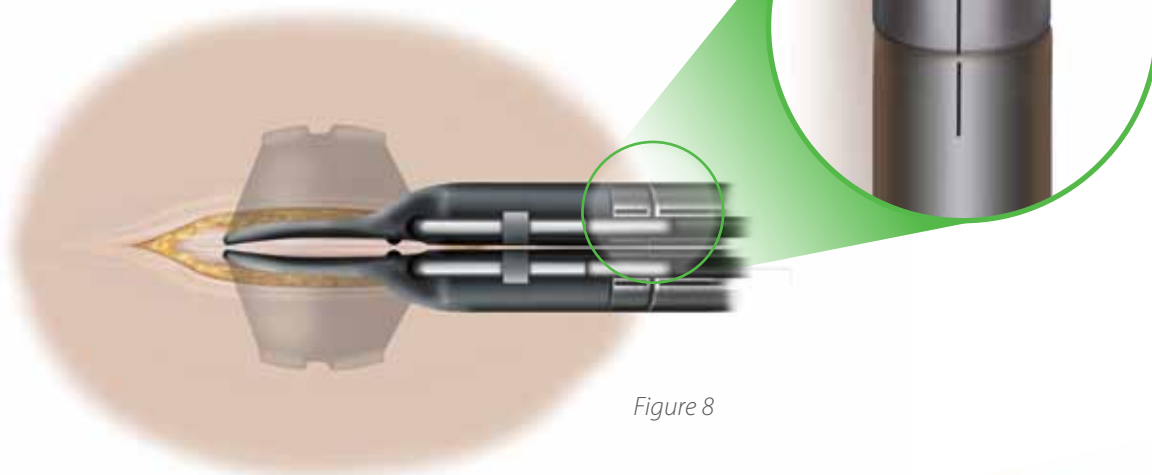


Figure 8

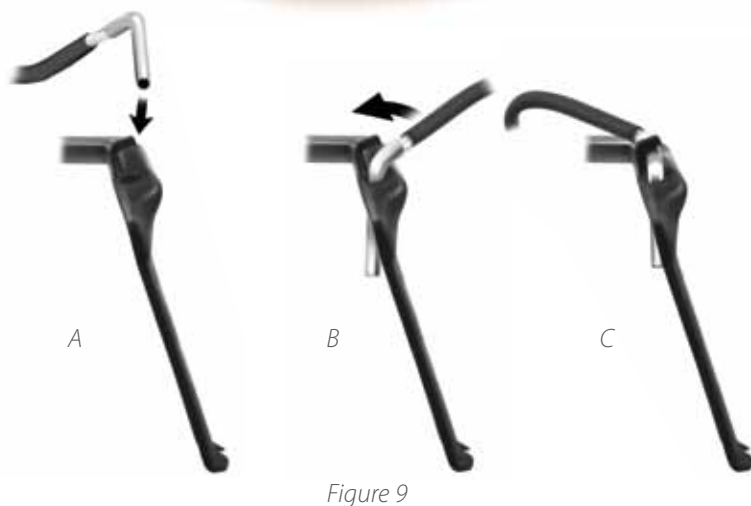


Figure 9

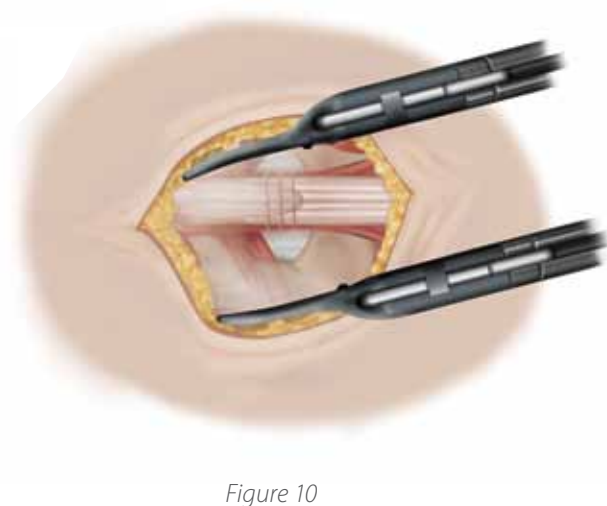


Figure 10

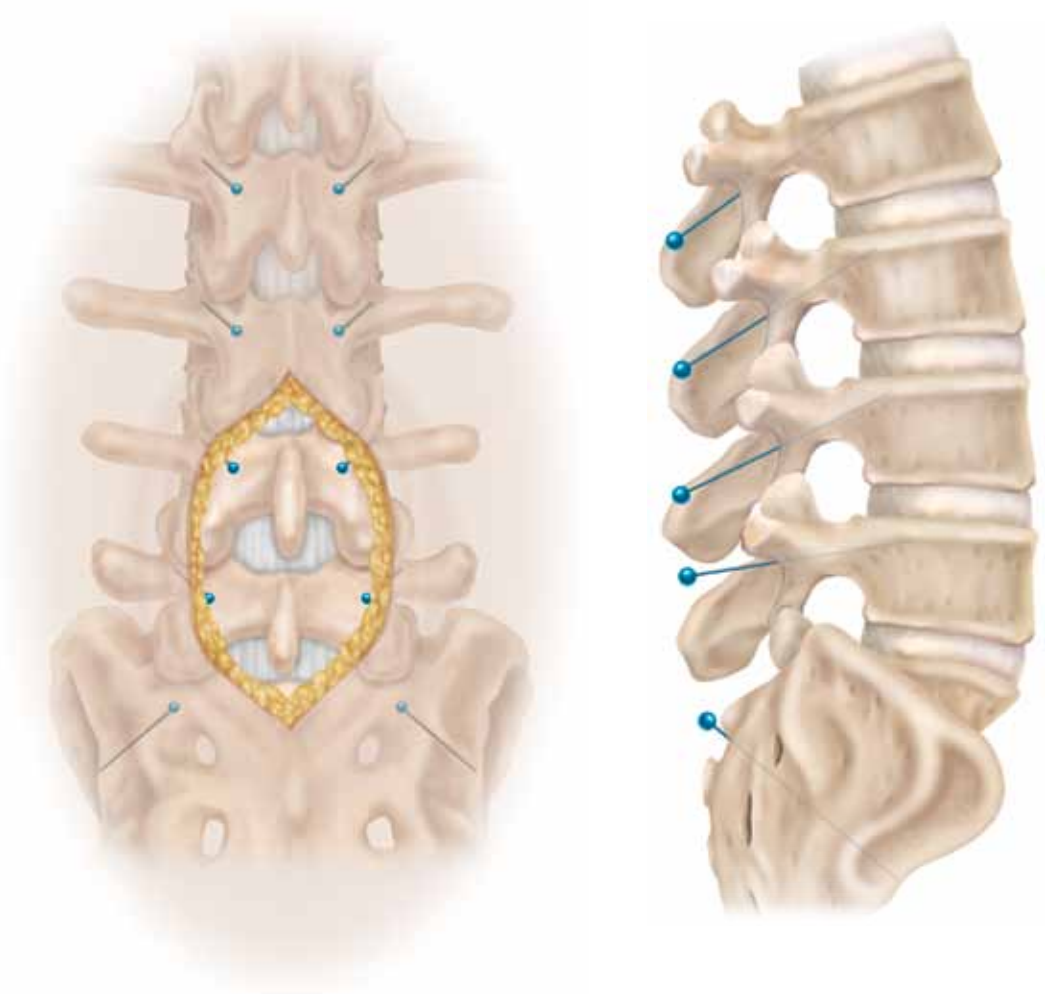
Cortical Screw Starting Point and Trajectory Reference

The starting point for a cortical screw is at the inferior aspect of the transverse process and about 3mm to 5mm medial to the lateral edge of the pars (approximate midpoint of the inferior facet of the level above). This allows the starting point to always be at the roof of the neuroforamen.

The trajectory for a cortical screw is approximately 20° medial-to-lateral and 30° to 45° caudal-to-cephalad. This trajectory allows implant placement up and away from the neural elements.

Note

The recommended entry point at the most cephalad instrumented level is 1mm to 2mm inferior, relative to the starting point for the caudal levels. This starting point and the resulting angle increases the distance from the adjoining facet.



Pilot Hole Starting Point and Drilling

Determine the starting point for each site based on the references on the previous pages. Using a Medtronic drill with a 2.2mm Match Head tip (10MH20), the pilot hole is made with the realization that this is pure cortical bone. Use of a two-hand technique on the drill facilitates oblique entry through the hard cortical bone and making a 2mm to 3mm pilot hole through the pars. The drill is aimed at the starting point to make a 2mm to 3mm starting hole (**Figure 11**).

Once the pilot hole is created, stop drilling. Re-orient the drill (leaving the tip in the pilot hole) in order to establish the final trajectory. This is generally done on lateral fluoroscopy. In the sagittal plane, attempt to create the greatest angle in the caudal to cephalad direction (**Figure 12**). This may at times have the shaft of the drill

approximate the same incline as the lamina itself. In the axial plane, move the handle of the drill 20° toward the spinous process (**Figure 13**). This results in a very acute drill trajectory over the top of the neuroforamen with a medial-to-lateral drilling direction away from the central canal (which is medial), and the exiting nerve root, which is caudal. The drill should be advanced slowly, with control, using irrigation to prevent bone injury. Slight tapping (i.e., gentle back and forth “pistoning” of the drill tip) during drilling is helpful to determine depth and when the maximum amount of bone has been traveled for the screw length. Use a ball-tipped probe to assess the depth, and confirm that there is no breach into the central spinal canal.



Figure 11

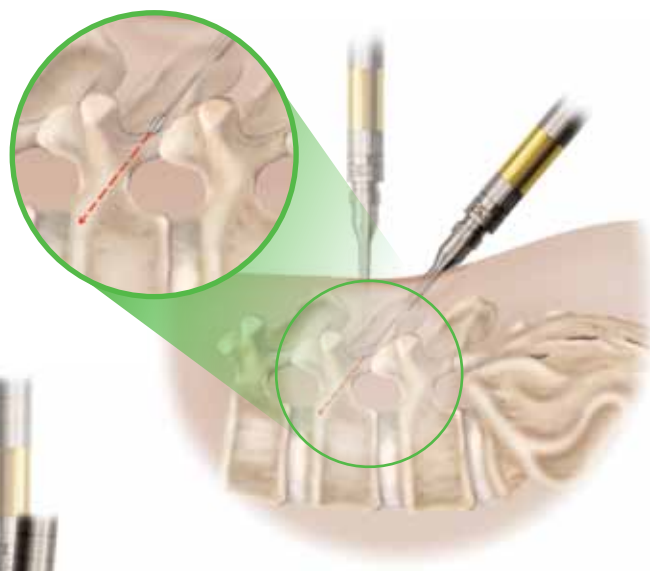


Figure 12

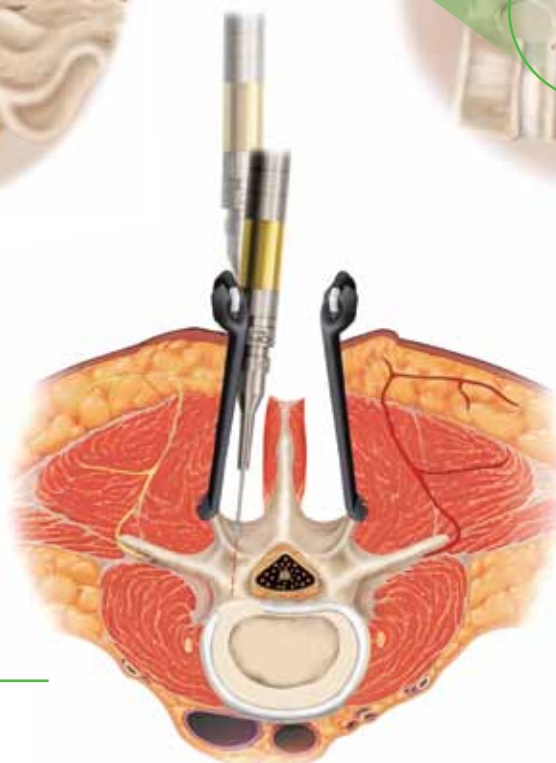


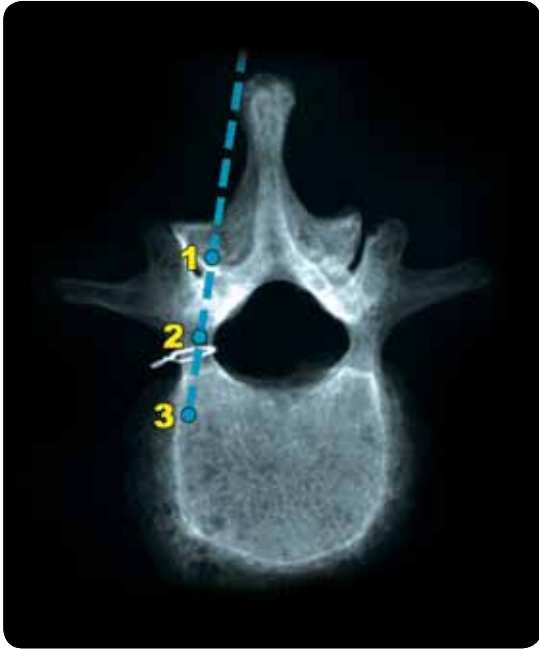
Figure 13

✓ Note

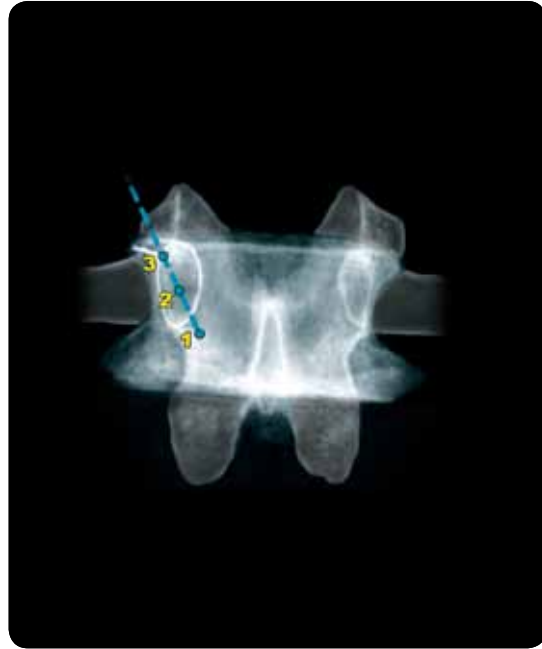
The drill can be stopped for verification as needed until it is completely through the dense cortical bone, typically 10mm to 15mm.

Drill Positioning and Trajectory Reference

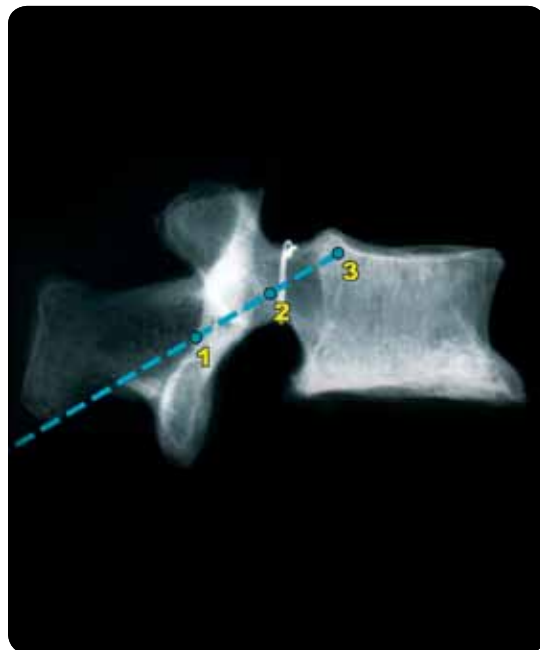
Fluoroscopic Trajectory Reference



Axial View



A/P View



Lateral View

Tapping

Line-to-line tapping is important for cortical thread screws (**Figure 14**). For example, a 5.0mm tap should be used in preparation for a 5.0mm diameter cortical screw. Reorienting the field of view visualizes the articular process and capsule for placement of the caudal screw entry at

the pole of the articular process (**Figure 15**). Do not under tap and be sure to tap the entire screw length due to the hardness of the bone. Note that the threaded portion of the tap in the CD HORIZON® SOLERA™ instrument set is 40mm in length (**Figure 16**).

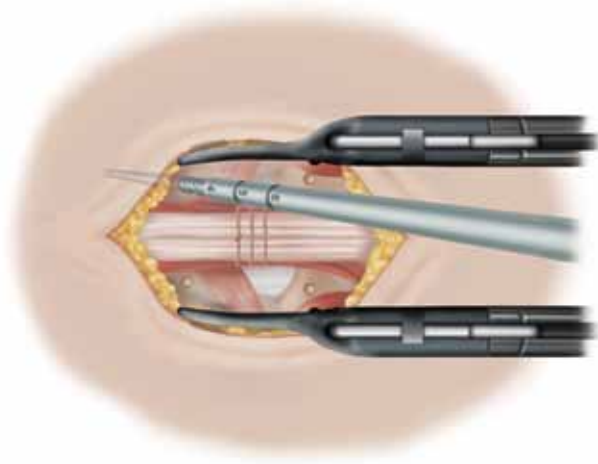


Figure 14

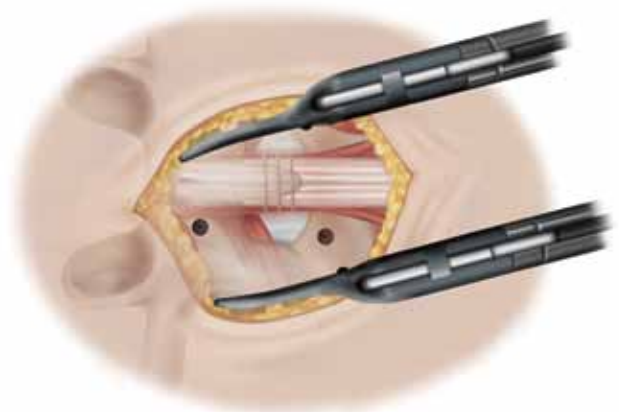


Figure 15



Figure 16

! Important

Screw placement is performed after the decompression and fusion to avoid compromising exposure and to preserve the landmarks and to protect the dura.

Discectomy

Remove the inferior articular process and laminar margin to expose the cartilage surface of the superior articular process of L5. Removing the medial superior articular process to the pedicle will expose the venous plexus and fat over the disc in the medial foramen allowing coagulation and division of small vessels to expose the disc (**Figure 17**). This same process should be repeated on the contralateral side when performing a bilateral fusion.

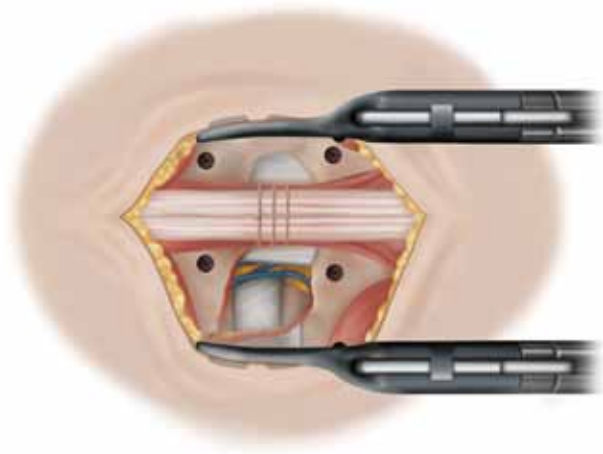


Figure 17

The disc space is prepared using general instruments such as rotating shavers, curettes, scrapers, and rasps as per the surgeon's routine. Following the decompression and disc space preparation, a TLIF or PLIF may be performed using interbody fusion devices in accordance with their respective surgical techniques.

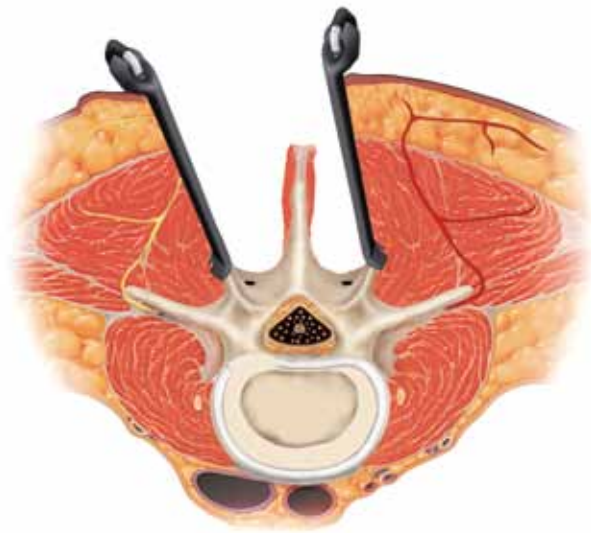


Figure 18

! Important

Decompression is performed such that a minimum of 3mm of bone remains between the tapped hole and the resection.

✓ Note

*Rotating the retractor frame/blades approximately 30° clockwise or counterclockwise will allow the surgeon to further drop their hand to obtain a more lateral-to-medial trajectory and aid contralateral disc space preparation and autogenous bone graft placement (**Figure 18**).*

Interbody Options

A variety of interbody options are available for fusion in patients with Degenerative Disc Disease at one or two levels from L2 to S1. Interbody implants are to be used with autogenous bone graft and supplemental fixation. For comprehensive instructions for implantation of these implants, refer to their respective surgical techniques.



CAPSTONE CONTROL™
Spinal System

Potential for less neural retraction when compared to the impacted technique*

- » May help minimize potential damage to the endplates
- » Insert and rotate delivery in the longitudinal plane
- » Potential for endplate disruption or implant migration
- » Possible neurological impairment



WAVE D
Spinal System

Provides 6 or 12 degrees of expandable segmental lordotic restoration

- » Allows for collapsibility *in situ*
- » Allows for packability of autograft post-expansion



FUSE™
Spinal System

Lordotic angles of 0, 4, and 8 degrees

- » Allows for insertion via an insert and rotate in the longitudinal plane or a standard impacted technique
- » Rectangular shape with a roughened honeycomb surface on the inferior and superior surfaces



LOOP®
Spinal System

Lordotic angle of 6 degrees

- » Offers 55 degrees of articulating range for insertion and final placement



CAPSTONE®
Spinal System

Anatomical convex shape for better fit with patient anatomy

- » Implant design allows for flexibility in surgical approach (TLIF or PLIF, Open or MAST)
- » Bullet nose aids in distraction during insertion



CRESCENT®
Spinal System

Implant design allows for positioning in the far anterior disc space

- » Is offered in a variety of materials
- » Incorporates 6 degrees of lordosis
- » Offers two attachment options

Interbody fusion devices are indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior 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.

* Mirkovic SR, Schwartz DG, Glazier KD. Anatomic considerations in lumbar posterolateral percutaneous procedures. 1995. *Spine* 20(18):1965-1971.

Enabling Technologies

Triggered intraoperative EMG monitoring, such as the NIM-ECLIPSE® Spinal System, may be used to verify the placement within the pedicle. The O-arm® Imaging System coupled with the StealthStation® Image Guidance System can also be used to navigate pedicle preparation and placement of CD HORIZON® SOLERA™ Spinal System screws.



NIM-ECLIPSE® Spinal System



Surgeon-controlled Ball-tip Probe



NavLock™ Navigated Instruments



O-arm® Imaging System



StealthStation® System



O-arm® and StealthStation® System Images

! 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 Surgeon Directed (SD) configuration 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.

NIM-ECLIPSE® System is manufactured by Medtronic Xomed, Inc. and distributed in the USA by Medtronic Sofamor Danek USA, Inc. For the complete labeling for the navigation products please contact Medtronic Navigation, General Business at 800-580-8860 or visit www.medtronic.com.

Cortical Screw Placement

Use a small probe to verify the depth and measure for the appropriate screw length; also palpate for a breach (**Figure 19**). Typical screw lengths are 25mm to 30mm. Insert the screw leaving enough of the head above the pars in order to capture the rod without abutting the facet capsule (**Figure 20**).

After the rod construct is secured the suture is released freeing the ESA tendons to fall back over underlying muscle.

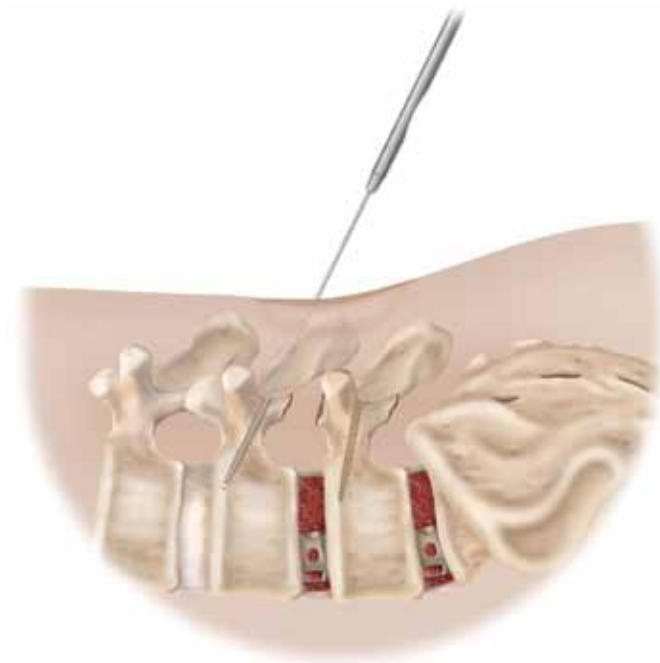


Figure 19

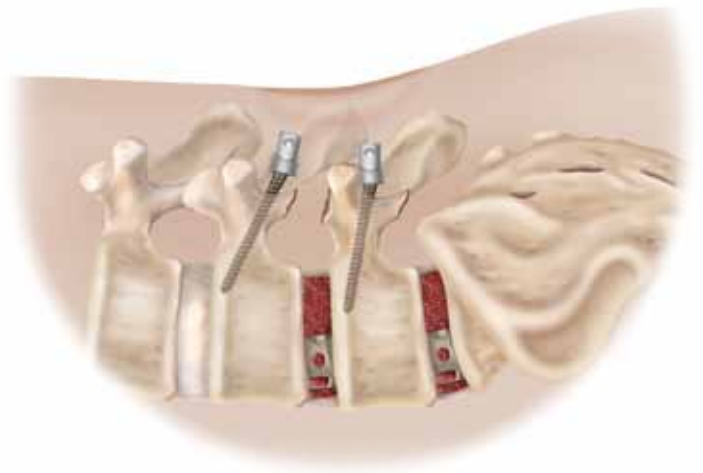


Figure 20

✓ Note

Leave the cephalad screw heads 2-3mm prouder than the caudal/distal screws to avoid abutment of the facet capsule.

Sacral Alar Screw Placement and Strategy

The starting point for a sacral alar screw is midway between the L5/S1 facet and the first dorsal foramen.

The trajectory for a sacral alar screw is flexible within the alar zone. This sacral strategy allows either a down-and-away or up-and-out trajectory. Both enable bicortical purchase (by selecting the appropriate length of screw) and construct alignment of the medially-placed cortical screws (Figures 21a, 21b, 21c, and 21d).

The key factors of sacral alar screw placement are:

- » Lateral to the medial wall of the foramen
- » 1mm to 2mm superior to the cephalad border of the foramen
- » Greater caudal to cephalad angulation



Figure 21a



Figure 21b



Figure 21c



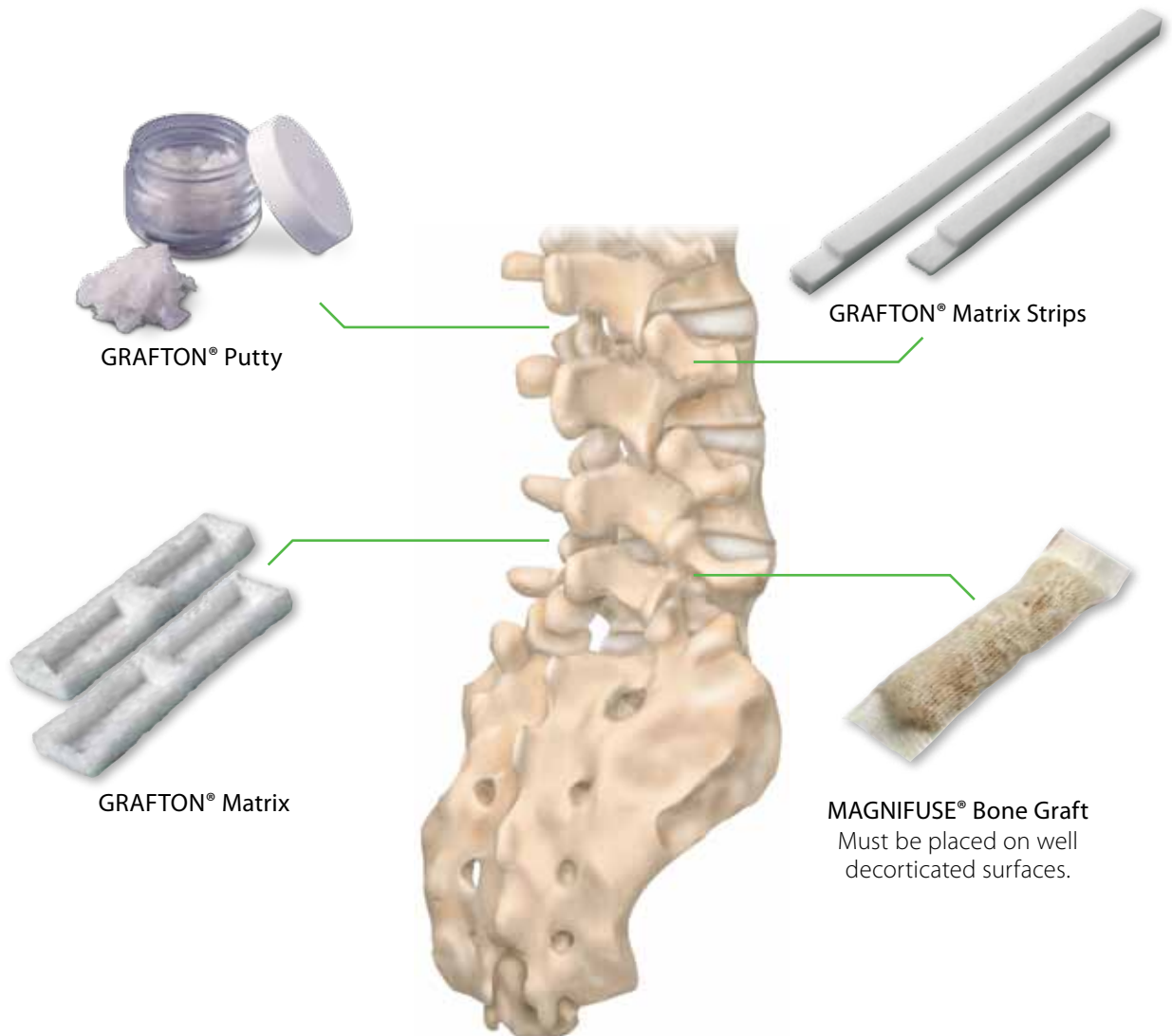
Figure 21d

✓ Note

A sacral alar fixation strategy involves placing a large diameter sacral pedicle screw into the ala.

Bone Graft Options

Precise placement of the bone graft (autograft or allograft bone) is essential to facilitate fusion. A number of Medtronic bone graft options are available as fillers for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure.



Final Construct

Once the rods are secured in the screws, compression is performed to place the implants in the final position (**Figures 22a and 22b**). For comprehensive instructions refer to the CD HORIZON® SOLERA™ Spinal System Surgical Technique or the CD HORIZON® LEGACY™ System Cortical Bone Screw Surgical Technique.

✓ Note

During compression, tighten the cephalad set screw so as to avoid the adjacent facet capsule.

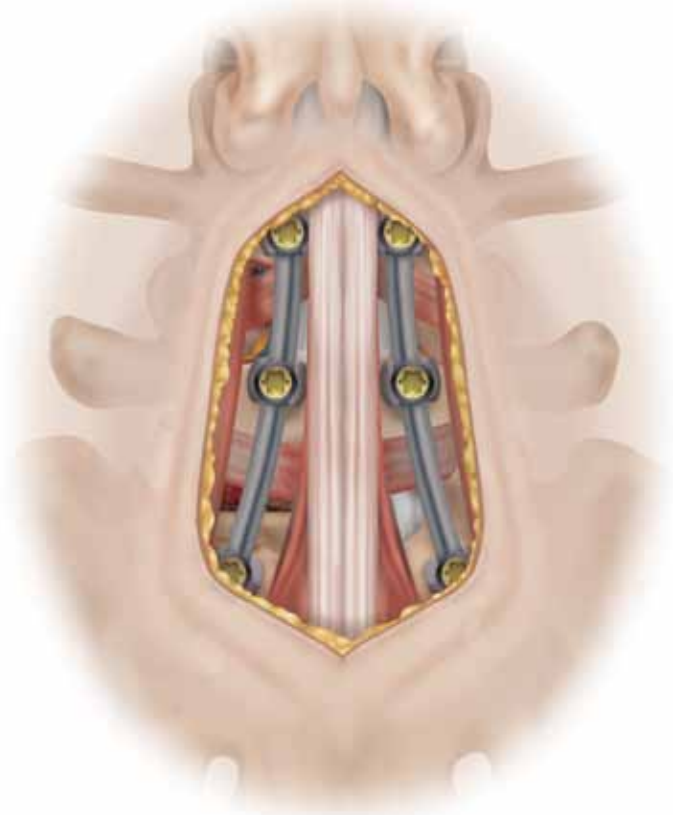


Figure 22a

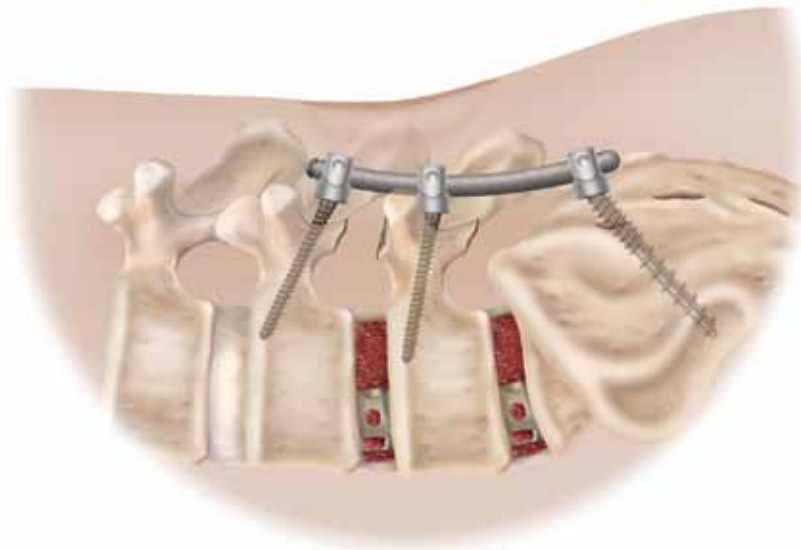


Figure 22b

Implant Explanation

The 4.75mm CD HORIZON® SOLERA™ set screws (plugs) may be removed using the T25 Obturator and the Self-retaining Breakoff Driver. The T25 Obturator is inserted into the working end of the Self-retaining Break-off Driver, so that the knurled portion of the T25 Obturator is flush with the driver. Insert the 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 Ball-ended T25 Bone Screw Removal Driver or the Self-retaining Screwdriver in conjunction with the Quick Connect Handle. First, attach the Quick Connect Handle to the modular end of the driver. Next, fully engage the T25 end of the driver into the screw head; then, if utilizing the Multi-Axial Screwdriver, thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.

The CD HORIZON® LEGACY™ Set Screws may be removed using the T27 Obturator and the Self-Retaining Break-Off Driver. The T27 Obturator is inserted into the working end of the Self-Retaining Break-Off Driver, so that the knurled portion of the T27 Obturator is flush with the driver. Insert the Obturator tip through the Counter Torque, which should be seated on the screw, and into the set screw, turning counterclockwise until the set screw 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 utilizing the Multi-Axial Screwdriver, thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.

Product Ordering Information

CD HORIZON® SOLERA™ Cortical Fixation Implant Set—SPS02557

Item Number	4.75mm CHROMALOY™ Pre-bent Rods	Qty/Set
1475501030	30mm	2
1475501035	35mm	2
1475501040	40mm	2
1475501045	45mm	2
1475501050	50mm	2
1475501060	60mm	2
1475501070	70mm	2
1475501080	80mm	2
1475501100	100mm	2

Item Number	4.75mm Cobalt Chrome/ Titanium Multi-Axial Screws	Qty/Set
54840004520	4.5mm × 20mm	6
54840004525	4.5mm × 25mm	6
54840004530	4.5mm × 30mm	8
54840004535	4.5mm × 35mm	6
54840005020	5.0mm × 20mm	6
54840005025	5.0mm × 25mm	8
54840005030	5.0mm × 30mm	8
54840005035	5.0mm × 35mm	6
54840006535	6.5mm × 35mm	4
54840006540	6.5mm × 40mm	4
54840006545	6.5mm × 45mm	4
54840007540	7.5mm × x 40mm	4
54840007545	7.5mm × 45mm	4

779170005	Standard 1/4-32 Titanium Set Screw	6
5440030	4.75mm Breakoff Set Screw	14
779145555	Side-Loading 5.5mm/Closed 5.5mm Connector	2
5480045	4.5mm Dual Lead Tap	1
5480050	5.0mm Dual Lead Tap	1
5480055	5.5mm Dual Lead Tap	1

6.5mm and 7.5mm screws are available upon request and are not included in the standard set configuration.

Midline Access Instrument Set—SPS02556

Item Number	Item Description
9563060	Blade, Left 4
9563061	Blade, Left 5
9563062	Blade, Left 6
9563063	Blade, Left 7
9563064	Blade, Left 8
9563065	Blade, Left 9
9563066	Blade, Left 10
9563067	Blade, Left 11
9563160	Blade, Right 4
9563161	Blade, Right 5
9563162	Blade, Right 6
9563163	Blade, Right 7
9563164	Blade, Right 8
9563165	Blade, Right 9
9563166	Blade, Right 10
9563167	Blade, Right 11
9563082	Speculum
9563303	MIDLINE Retractor
9563302	MIDLINE Hinged Weitlaner Retractor
9563002	Blade Handle

Drill Accessories

Item Number	Item Description
10MH22	Drill Bit
15TA23L	Drill Bit
AA15	Drill Attachment
AVA15DK	Drill Attachment

Accessories

Item Number	Item Description
9560658	MAST QUADRANT® Illumination System

For more information on any of the products shown in this technique, please contact your sales representative or customer service for the most up-to-date version of the package insert or visit <http://manuals.medtronic.com>.

Important Product Information

IMPORTANT INFORMATION FOR MEDTRONIC REUSABLE INSTRUMENTS

DESCRIPTION

Reusable instruments are made out of a variety of materials commonly used in orthopedic and neurological procedures which meet available national or international standards specifications.

INTENDED USE

These orthopedic manual surgical instruments are intended for use in surgical procedures to manipulate tissue, or for use with other devices in orthopedic surgery. An instrument may incorporate a measuring function which has uses as described on the label and the instrument.

DO NOT IMPLANT THE INSTRUMENTS.

If there is any doubt or uncertainty concerning the proper use of this instrument, please contact MEDTRONIC. Any available surgical techniques will be provided at no charge.

MEDTRONIC 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 or an authorized MEDTRONIC repair representative. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

WARNINGS

- 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.
- 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, patients could have allergic or infectious consequences.
- 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.

PRECAUTIONS

- Excessive force applied by instruments to implants can dislodge devices, particularly hooks.
- Never expose instruments to temperatures in excess of 135 °C that may considerably modify the physical characteristics.
- Extreme care should be taken to ensure that this instrument remains in good working order. During the procedure, successful utilization of this instrument is extremely important. Instruments should not be bent or damaged in any way. Misuse of instruments, resulting in corrosion, "freezing-up", scratching, loosening, bending, or fracture of any or all sections of an instrument, may inhibit or prevent proper function.
- These instruments should be carefully placed on trays, cleaned after each use, and stored in a dry environment.
- Do not use this instrument for any action for which it was not intended.
- Regularly review the operational state of all instruments and, if necessary, make use of repair and replacement services.
- To avoid injury, the instrument should be carefully examined for functionality or damage prior to use. A damaged instrument should not be used. Additional back-up instruments should be available.
- Preoperative and operating procedures, including knowledge of surgical techniques, 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.
- Proper patient selection and operative care are critical to the success of the surgery 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.
- Some surgeries require the use of instruments which incorporate a measuring function. Ensure that these are not worn and any surface engravings are clearly visible.

POSSIBLE ADVERSE EFFECTS

- Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs or joints.
- Infection, if instruments are not properly cleaned and sterilized.
- Pain, discomfort, or abnormal sensations resulting from the presence of the device.
- Nerve damage due to surgical trauma.
- Dural leak in cases of excessive load application.
- Impingement of close vessels, nerves, and organs by slippage or misplacement of the instrument.
- Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.

- Cutting of skin or gloves of operating staff.
- Bony fracture in cases of deformed spine or weak bone.
- 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.
- The methods of use of instruments are to be determined by the user's experience and training in surgical procedures. 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.

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

USA FOR US AUDIENCES ONLY

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

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

PACKAGING

Packages for components should be intact upon receipt. All sets should be checked for completeness and all components should be checked for signs of damage prior to use. Damaged packages or products should not be used and should be returned to MEDTRONIC.

Remove all packaging material prior to sterilization. Only sterile instruments should be used in surgery. Always immediately clean and 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.

EXAMINATION

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

Examination should be thorough and must include 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, deformation, or distortion, and that all components are complete.

NEVER USE INSTRUMENTS WITH OBVIOUS SIGNS OF EXCESSIVE WEAR, DAMAGE, OR THAT ARE INCOMPLETE OR OTHERWISE UNFUNCTIONAL.

VISUAL INSPECTION

Make certain of the following:

- Laser etchings, engravings, and other markings are legible.
- No cracks are present in instrument handles or any part of the instrument.
- Discoloration, corrosion, stains, or rust do not exist. If present, attempt to wipe clean in accordance with the instructions in the Manual Cleaning section of this document.
- There is no handle/shaft separation, and that the handle-to-shaft connection is secure.
- No cuts or gouges in silicone are present.
- There is no damage (cuts, tears, etc.) to the insulation.
- There is no damage to the working ends or tips. The working end should be free of cracks, sharp edged gouges, and other damage. When applicable, the working end should be sharp.
- There is no damage to threads.
- All parts are present and free of damage and deterioration. Examples of parts that may be missing, loose or damaged include set screws, springs, curved springs, pins, and prongs.
- Mating ends are free of damage (nicks, gouges, bends, etc.) that would interfere with the mating function.
- Cannulated instruments with a guide wire or other insertion tool are visually checked.

FUNCTIONAL INSPECTION

Make certain of the following:

- The parts intended to move will do so freely, without sticking, binding, or grinding.
- Springs return the handle of the instrument to its original position.
- Retention tabs hold appropriate mating parts and are not damaged.
- The instrument will function as intended with the appropriate mating parts.
- Ball detents will hold mating parts and are free from damage.
- Sharp edges are sharp to the touch and are not dull, have no nicks, or any other damage.
- Tips meet when appropriate.
- Ratcheting mechanisms are functional. This includes handles, latches, and other mechanisms. All teeth should be present and functional.
- Driver tips are not worn beyond functional use. If necessary, mate the instrument with the appropriate part.

Important Product Information *continued*

REPROCESSING – GENERAL CONSIDERATIONS

Cleaning is the removal of organic soil. Effective cleaning:

- minimizes the organic soil transfer from one patient to another
- prevents accumulation of residual soil throughout the product's use life
- allows for successful follow up sterilization. Adequate reprocessing is contingent upon the thoroughness of cleaning.

Cleaning is the initial step and sterilization occurs later in reprocessing and is intended to kill microorganisms to reduce the likelihood of transmission and possibilities of infection. To ensure acceptable reprocessing, there should be no delay between the steps in this document.

Bloodborne Pathogens

Universal precautions for handling this device after use should be observed by all hospital personnel according to OSHA Standard 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens.

Thorough Cleaning of Reusable Instruments

It is critical that reusable instruments are thoroughly cleaned after each use following the specific cleaning steps listed in this document. Ineffective or incomplete cleaning can hinder subsequent sterilization activities.

Automated Cleaning

A fully automated washer/disinfector cycle is not recommended as the sole cleaning method. Manual cleaning is required.

NOTE: Certain reusable instruments that should be disassembled prior to cleaning and sterilization are provided with specific reprocessing/disassembly/reassembly instructions. In regions where a copy of these instructions is required to be provided, the instructions may be found inside or attached to the packaging/container. Specific reprocessing/disassembly/reassembly instructions may also be found at <http://manuals.medtronic.com> by navigating to "Spinal & Biologics" and then "Instruments," where instructions are identified by system name and part number(s). Specific instructions also may be found for a particular instrument by searching on <http://manuals.medtronic.com> for instructions by the instrument part number.

Manual Cleaning

Disinfection agents such as sanitizing and chemical solutions act to reduce microbes on surfaces, but may not act as cleaners. Other types of soaps or detergents may not clean to an appropriate level of cleanliness. Enzymatic cleaning agents are recommended. This type of cleaner has been shown to effectively remove organic soils, such as blood, from instruments. The cleaning instructions have been validated by Medtronic using an enzymatic cleaner.

Cleaning Agents and Cleaning Tools

The following cleaning agents, solutions, or tools should NOT be used:

- Saline solution
- Alkaline cleaning agents
- Solutions containing chlorine (e.g., bleach) or aldehydes (e.g., glutaraldehyde)
- Formalin, mercury, chlorides, bromides, iodides, or ringers solution
- Metal brushes or scouring pads

The use of neutral pH enzymatic cleaners and soft bristled brushes and soft pipe cleaners are recommended.

Cleaning and Rinsing Water

If available, softened tap water should be used. De-ionized water should be used for the final rinse step to prevent mineral deposits on surfaces.

Use of Mineral Oil or Silicone-Based Lubricants

These types of lubricants should never be used as they may not be removed by these cleaning instructions. The lubricants may coat microorganisms, prevent direct contact of steam with instrument surfaces, and hinder sterilization.

MANUAL CLEANING INSTRUCTIONS

Proper Handling After Use

DO NOT allow instruments to dry after use and prior to cleaning. Cleaning and subsequent sterilization may be hindered when blood or bloody solutions are allowed to dry on instruments.

Cleaning Instructions – Point of Use

1. Remove all visible soil from instruments using non-shedding wipes.
2. Place instruments in a tray of water or cover with damp towels. Instrument should be cleaned within 30 minutes of use to minimize the potential for drying.

Cleaning Instructions – Dedicated Cleaning Area

1. Immediately transport the tray containing the covered instruments to a work area dedicated to further reprocessing.
2. Disassemble instruments if applicable*.

*NOTE: Certain reusable instruments that should be disassembled prior to cleaning and sterilization are provided with specific reprocessing/disassembly/reassembly instructions. In regions where a copy of these instructions is required to be provided, the instructions may be found inside or attached to the packaging/container. Specific reprocessing/disassembly/reassembly instructions may also be found at <http://manuals.medtronic.com> by navigating to "Spinal & Biologics" and then "Instruments," where instructions are identified by system name and part number(s). Specific instructions also may be found for a particular instrument by searching on <http://manuals.medtronic.com> for instructions by the instrument part number.

3. Rinse and flush instruments under warm running tap water for 2 – 3 minutes.
4. Scrub instruments with appropriately-sized, soft bristle brushes or pipe cleaners to aid in the removal of visible soil. Be sure to scrub inside any lumens or cavities.
5. Scrub until all visible soil is removed.
6. Using tap water, prepare an enzymatic cleaning solution according to the manufacturer's instructions, dilution recommendations, and temperatures.
7. Place instruments in the enzymatic cleaner, completely submerged, and soak for a minimum of 60 minutes.
8. Remove instruments from the enzymatic cleaner and flush under warm, running, tap water. Be sure that any lumens or cavities are flushed in the water stream. Rinse for 2 – 3 minutes.
9. Using tap water, prepare a second enzymatic cleaning solution according to the manufacturer's instructions, dilution recommendation and temperatures in an appropriately-sized sonicator.
10. Place the parts in the enzymatic cleaner, completely submerged, and sonicate for a minimum of 60 minutes.
11. Remove the parts from the sonicator and rinse using warm, running, tap water. Be sure that any lumens or cavities are flushed in the water stream. Rinse for 2 – 3 minutes.
12. Repeat rinsing as in step 11, this time with de-ionized water for an additional 2 – 3 minutes.
13. Dry the parts using clean, absorbent, non-shedding wipes.
14. Carefully inspect instruments, including any lumens and cavities, to ensure that all contamination has been removed. If any soil is still present, repeat the cleaning process or contact your Medtronic distributor immediately to arrange for disposal or replacement. Do not proceed with reprocessing of a soiled instrument.

SANITIZATION

MEDTRONIC reusable instruments are considered critical devices and must be sterilized prior to initial use, or in adherence to these reprocessing instructions before re-use. Sanitization with disinfectant solutions or chemicals is unnecessary and not recommended.

STERILIZATION INSTRUCTIONS

Ethylene oxide (EO), gas plasma, gamma irradiation, chemical vapor, or dry heat sterilization methods are NOT recommended for sterilization. Steam/moist heat is the recommended method of sterilization. Instruments must be sterilized prior to initial use, or as part of these reprocessing instructions, before re-use.

NOTE: Certain reusable instruments that should be disassembled prior to cleaning and sterilization are provided with specific reprocessing/disassembly/reassembly instructions. In regions where a copy of these instructions is required to be provided, the instructions may be found inside or attached to the packaging/container. Specific reprocessing/disassembly/reassembly instructions may also be found at <http://manuals.medtronic.com> by navigating to "Spinal & Biologics" and then "Instruments," where instructions are identified by system name and part number(s). Specific instructions also may be found for a particular instrument by searching on <http://manuals.medtronic.com> for instructions by the instrument part number.

Sterilization wraps, pouches, chemical indicators, biological indicators, and sterilization trays should be FDA-cleared for the selected sterilization cycle parameters.

The sterilization instructions below have been validated to a sterility assurance level of 10⁻⁶

1. Wrap or pouch the parts.
2. Inspect the packaging to ensure no rips, punctures, or seal failures are present in or on the packaging prior to loading into the sterilizer.
3. Load the parts into the sterilizer by following the sterilizer manufacturer's recommended loading procedures and load configurations.
4. Follow the sterilizer manufacturer's recommended procedures to program the sterilizer with any one of the sets of sterilization cycle parameters found in Tables 1 (for medical facilities in the US and its territories) and in Table 2 (for medical facilities outside the US and its territories).

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*	30 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.

Important Product Information *continued*

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	270°F (132°C)	4 Minutes*	30 Minutes
Steam	Dynamic-Air-Removal	275°F (135°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: Chamber size and chamber load differences may exist between industrial and health care facility sterilizer models. The sterilization parameters listed in Tables 1 and 2 can be achieved in both health care facility and larger, industrial sterilizer models. 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 are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the 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).

INSPECTION AND REASSEMBLY

- Carefully inspect the instrument for damage by performing a thorough examination as referred to the Examination section of this document.
- If the instrument is damaged, contact your Medtronic distributor immediately to arrange for disposal or replacement. Do not proceed with reprocessing of a damaged device.
- If the instrument was disassembled prior to cleaning and sterilization, reassemble.

NOTE: Certain reusable instruments that should be disassembled prior to cleaning and sterilization are provided with specific reprocessing/disassembly/reassembly instructions. In regions where a copy of these instructions is required to be provided, the instructions may be found inside or attached to the packaging/container. Specific reprocessing/disassembly/reassembly instructions may also be found at <http://manuals.medtronic.com> by navigating to "Spinal & Biologics" and then "Instruments," where instructions are identified by system name and part number(s). Specific instructions also may be found for a particular instrument by searching on <http://manuals.medtronic.com> for instructions by the instrument part number.

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 resterilized.

FURTHER INFORMATION

IN CASE OF COMPLAINT, OR FOR SUPPLEMENTARY INFORMATION, PLEASE CONTACT MEDTRONIC.

MRI INFORMATION

These instruments have not been evaluated for safety, heating, migration or compatibility in the magnetic resonance (MR) environment.

PRODUCT COMPLAINTS

Any health care professional (e.g., user of this system of products) having any complaints or having 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, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether or not a written report from the distributor is requested.



Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: + 31 45 566 80 00



Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone 800 933 2635 (In U.S.A.)
901 396 3133 (Outside of U.S.A.)
Fax 901 396 0356

EXPLANATION OF SYMBOLS

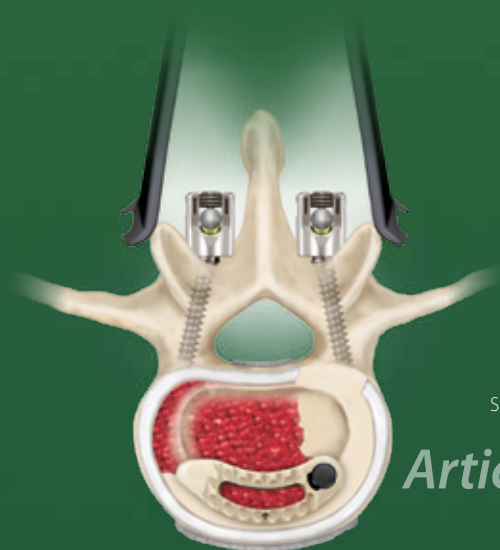
SYMBOL DEFINITION



Manufacturer

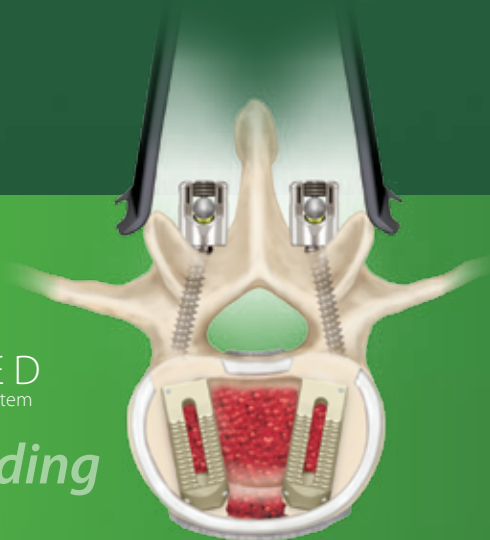


Caution: For U.S. audiences only.



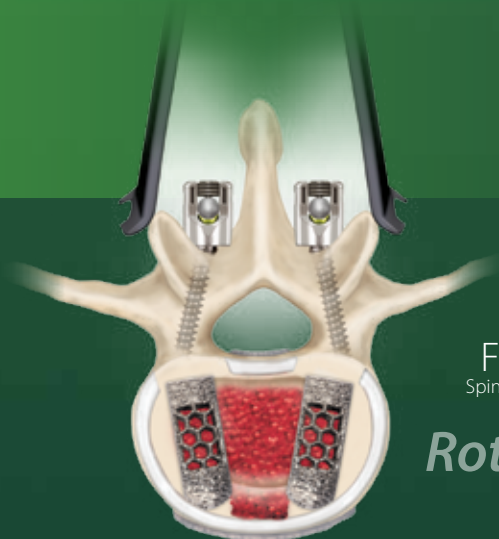
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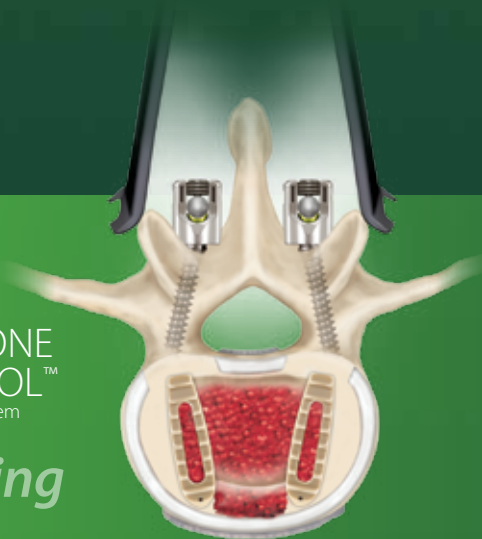
WAVE D
Spinal System

Expanding



FUSE[™]
Spinal System

Rotating



CAPSTONE
CONTROL[™]
Spinal System

Rotating

www.medtronic.com

Medtronic

Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

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.

