



**Medtronic**

**METRx<sup>®</sup>**

System

# Surgical Technique



The METRx<sup>®</sup> System allows access to the spine using a series of sequential muscle dilation tubes. This dilation approach causes less disruption to the surrounding muscles and also allows the paraspinal muscles to remain attached to the spinous process.

The minimally invasive implants and instruments require smaller incisions than traditional open surgery and are designed for muscle-sparing approaches.







# METRx<sup>®</sup>

System

## Surgical Technique

Instrument Set	2
Tubular Retraction	6
Spinal Fusion	8
Posterior Foraminotomy	10
Lumbar Stenosis	12
Discectomy	14
TLIF Procedure	16
PLIF Procedure	18
Product Ordering Information	20
Important Product Information	23

## Instrument Set



Instrument Set *continued*



40° and 90° Bayoneted Kerrison  
(1mm, 2mm, 3mm, 4mm, 5mm Available)



Flexible Arm  
Assembly



Assorted Bayoneted Instruments



Sucker (#6, #8, #10, and  
Suction Retractor Available)



Flexible Arm with  
Self-retaining Retractors



METRx® MED System  
Reusable Endoscope

## Instrument Set *continued*



Disposable Tube  
18mm, 22mm, and  
26mm Lengths



12.8mm Dilator



3cm to 9cm Length  
14mm Diameter



Tubular Retractor  
16mm and 18mm Lengths



14.8mm Dilator



3cm to 9cm Length  
16mm Diameter

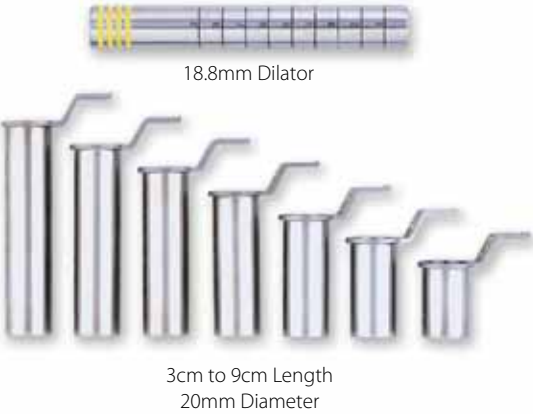
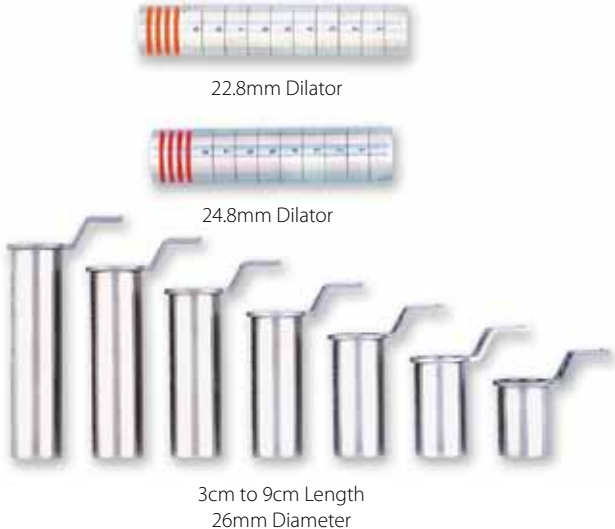
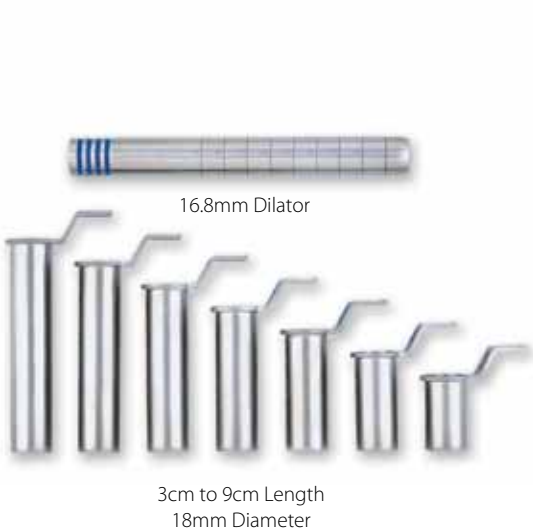


20.8mm Dilator



3cm to 9cm Length  
22mm Diameter

Instrument Set *continued*



## Tubular Retraction

### Targeting Using the METRx® System

A METRx® System procedure is initiated by inserting a spinal needle into the paraspinal musculature at the appropriate distance off the midline toward the bony anatomy (**Figure 1**). The placement is confirmed using lateral fluoroscopy.

METRx® System may be used for these procedures.

Procedure	Landmark Docking Point
Discectomy, Laminectomy, Stenosis	Inferior Aspect of the Superior Lamina
PLIF	Medial Aspect of the Facet
Pedicle Screws	Transverse Process/ Facet Junction
TLIF	Lateral Aspect of the Facet
Cervical Foraminotomy	Medial Facet/Laminar Junction
Far Lateral	Junction of TP and PARS of Superior Vertebra

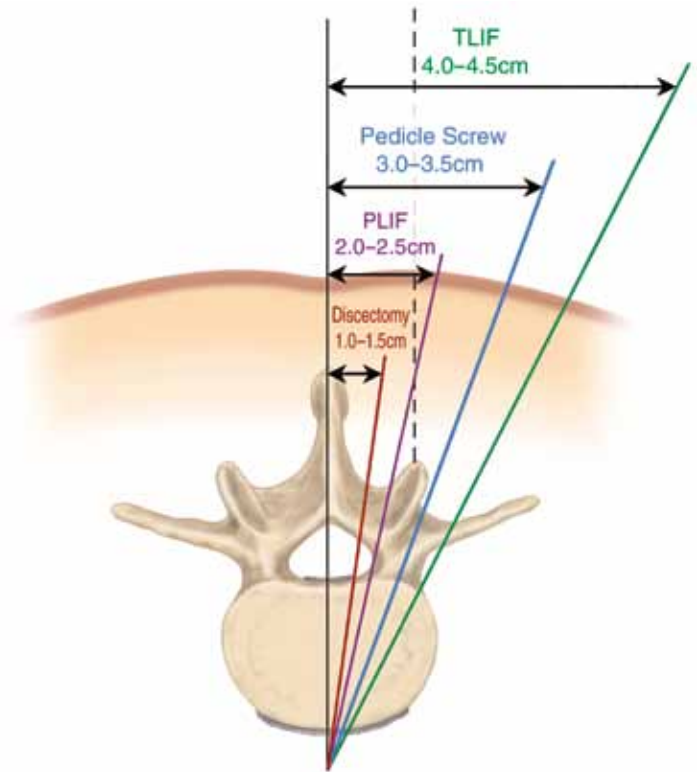


Figure 1

### Guidewire Insertion

The spinal needle is removed and a vertical incision is made at the puncture site. The incision length should match the diameter of the respective Tubular Retractor. For example, if a 14mm Tubular Retractor will be used, a 14mm incision should be made.

Some surgeons also incise the fascia to make tissue dilation easier. This is optional and can be performed later if tissue dilation is difficult.

The Guidewire is placed through the incision and directed toward the appropriate anatomy under lateral fluoroscopy (**Figures 2a, 2b, and 2c**). The Guidewire is advanced only through the lumbodorsal fascia. Great care must be taken to avoid penetration of the ligamentum flavum and inadvertent dural puncture with possible nerve injury or spinal fluid leak.

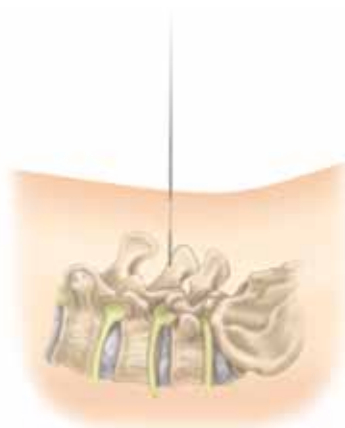


Figure 2a

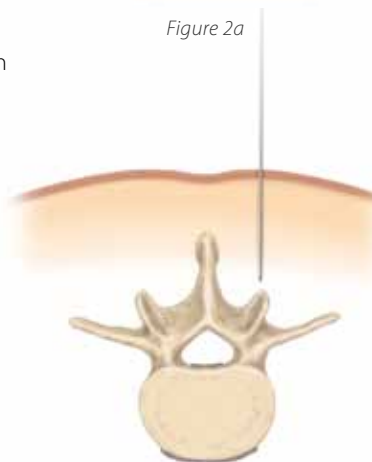


Figure 2b



Figure 2c



## Tubular Retraction *continued*

### First Dilator Insertion

Insert the cannulated soft tissue Dilator over the Guidewire using a twisting motion. Once the fascia is penetrated, remove the Guidewire and advance the Dilator down to the bony anatomy.

Use the initial Dilator to palpate the anatomy in both the coronal and sagittal planes (**Figure 3**). This maneuver confirms an appropriate approach laterally and helps expedite soft tissue removal (**Figure 4**).

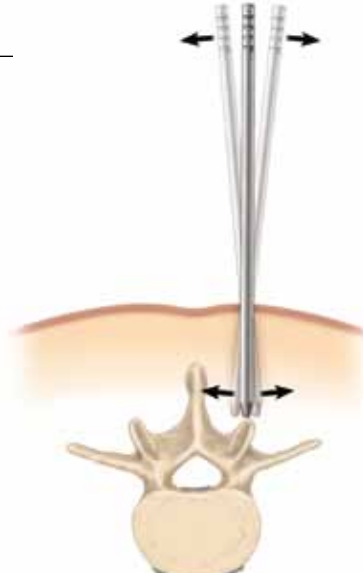


Figure 3

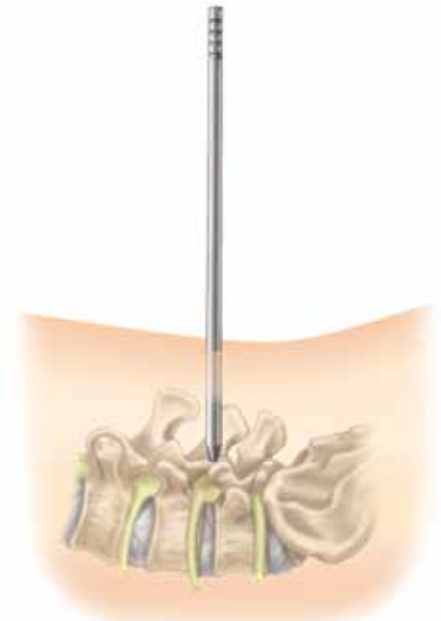


Figure 4

### Sequential Dilation and Tubular Retractor Insertion

The next series of Dilators are sequentially placed over each other (**Figure 5**). Only use the number of Dilators required to get to the preferred Tubular Retractor diameter. The depth markings on the Dilators are noted to indicate the Tubular Retractor length appropriate to the patient's anatomy.

The appropriate Tubular Retractor is placed over the sequential Dilators and seated firmly on the bony anatomy. The Flexible Arm is attached to the bed rail and the selected Tubular Retractor.

The Flexible Arm is secured and the sequential Dilators are removed, establishing a tubular operative corridor.



Figure 5

### Repositioning the Tubular Retractor

If repositioning of the Tubular Retractor is necessary, the Retractor can be moved or angled over the pathology by a process known as wandng (**Figure 6**). Insert the matching color Dilator into the tube. While downward pressure is placed on the Tubular Retractor, the Flexible Arm is unlocked, allowing the Tubular Retractor to be pivoted over the desired location.

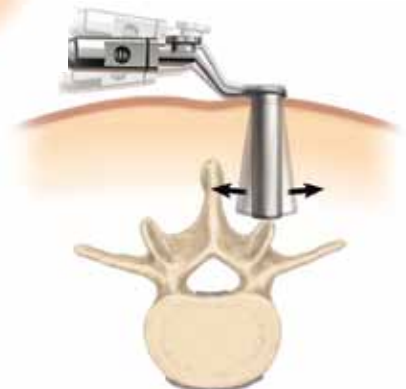


Figure 6

## Spinal Fusion Procedure utilizing METRx® X-TUBE® Retraction System

### Tube Introduction

The METRx® X-TUBE® Instrument is selected in accordance with exposed markings on the final Dilator (**Figure 7**). The Tube is then inserted over the Dilators and seated firmly flush with the bony anatomy and locked in place with the Flexible Arm. The Dilators are then removed establishing a tubular operative corridor.



Figure 7

### Tube Deployment

The METRx® X-TUBE® Instrument is expanded using the Opener instrument. Insert the Opener into the tube with the instrument stops facing medial/lateral and squeeze the handles (**Figure 8**). The tube will remain in the expanded position until the hinges are released.



Figure 8

### Pedicle Preparation

Inferior and superior pedicles may now be targeted (**Figure 9**).

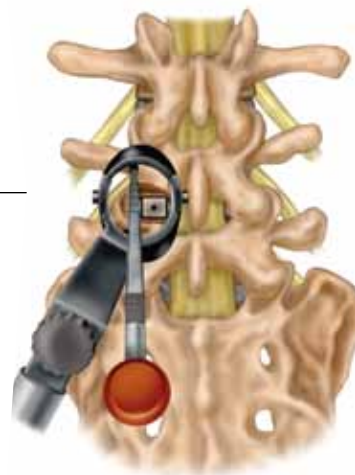


Figure 9

### Screw Insertion

Tap and insert the Pedicle Screw (**Figure 10**).



Figure 10

*For complete instructions of use for the implant system, please refer to the appropriate surgical technique and package insert.*

## Spinal Fusion Procedure utilizing METRx® X-TUBE® Retraction System *continued*

### Rod Insertion

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Using the MAST™ Rod Holder, the Rod may now be inserted (Figure 11).



Figure 11

### Compression

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Compression and/or distraction may be accomplished using the respective instruments from MAST™ Instrument Set (Figure 12).



Figure 12

### Tube Extraction

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The METRx® X-TUBE® Instrument is closed by turning the Opener instrument 90° so the stops are perpendicular to the hinges. The Opener is then compressed, causing the METRx® X-TUBE® Instrument to collapse (Figure 13).



Figure 13

*For complete instructions of use for the implant system, please refer to the appropriate surgical technique and package insert.*

## Posterior Cervical Foraminotomy utilizing METRx® System

### Patient Positioning and Room Set-up

METRx® System posterior cervical foraminal access is performed in a similar stepwise fashion as described in the previous posterior lumbar steps with the following exceptions:

### Patient Position

The patient is placed in a Mayfield pin holder with the frame extended as far as possible to allow adequate AP fluoroscopic visualization. The fluoroscope is rotated so the line of view is perpendicular to the spinal laminar line. Generally, the fluoroscope will come in from the surgeon's right, the surgeon being seated directly at the patient's head (**Figure 14**). When the Tubular Retractor is safely docked in operating position, the fluoroscope can be moved to allow room for the microscope.



Figure 14

### Guidewire Insertion

A 20-gauge Spinal Needle is inserted into the paraspinal musculature approximately 1cm to 2cm off midline at the appropriate level. The AP fluoro will allow the surgeon to safely access the lateral mass and stay clear of the canal. A stab wound is made over the needle puncture site, and the localizing Guidewire is passed down below the fascia. The Guidewire is advanced through the deep cervical fascia (**Figure 15**). It is not necessary to purchase the Guidewire on the bone of the lateral mass. If this is done, extreme care should be taken to make certain the Guidewire is safely docked well lateral on the lateral mass.

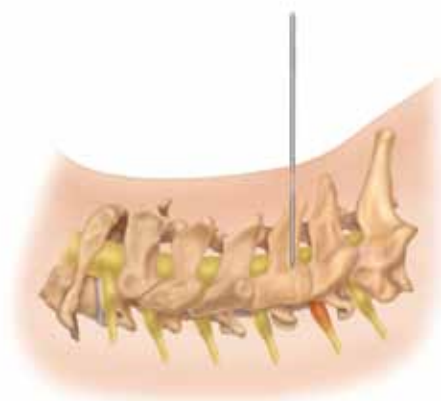


Figure 15

### Dilator Insertion

Posterior cervical soft tissue is slightly more dense and requires more care to be taken as Dilators are rotated incrementally down to the lateral mass until the desired Tubular Retractor is in place (**Figure 16**).

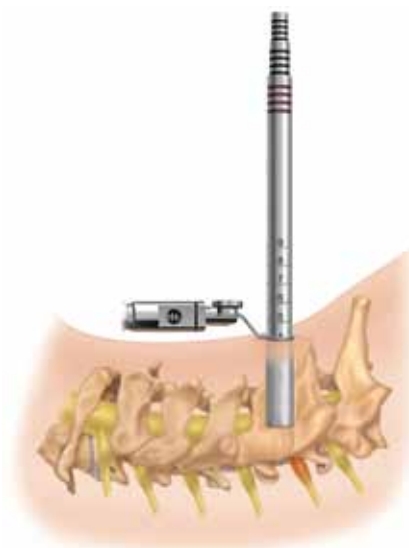


Figure 16

## Posterior Cervical Foraminotomy utilizing METRx® System *continued*

### Soft Tissue Removal and Lamina Identification

The soft tissue over the lamina and intralaminar space is removed with Bipolar Forceps and Pituitary Rongeurs (**Figure 17**). If the Tube is correctly positioned, the junction of the two laminae with the medial facet should be seen in the Tube (**Figure 18**). The initial laminar bites are taken in the caudal lamina in a caudal, then lateral, and then cranial direction, as the cranial laminar edge is addressed last (**Figure 19**). The bony work should continue until each pedicle is exposed.



Figure 17



Figure 18

### Cervical Root Identification and Disc Removal

With bipedal exposure, the axilla is generally explored first. Frequently a soft disc will be completely removed through the axilla. Occasionally, more cranially located fragments will have to be removed through the shoulder. The cervical Penfield and Hook can be used to gently retract the root in the axilla (**Figure 20**). The disc will frequently be seen in this location. The Curved Scissors may be used to incise the ligament as needed. The longer Hook may be used to explore the foramen after removal of the disc. Cotton patties may be used to obtain hemostasis along with Microbipolar Forceps.

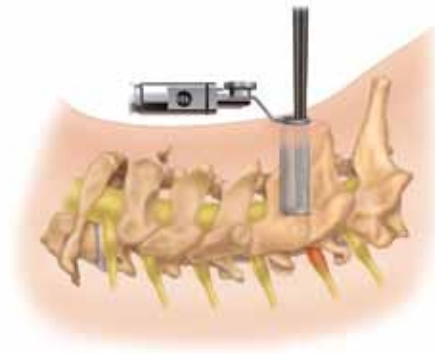


Figure 19

### Closure

After the root is decompressed, this site is irrigated thoroughly with saline. The Flexible Arm should then be loosened and the Retractor slowly removed incrementally. Bleeding should be progressively controlled with bipolar coagulation as the Retractor is withdrawn.

It is generally impossible to close the fascia. Subcuticular closures are done in an inverted manner and Steri-Strips or a Band-Aid may then be used as desired.



Figure 20

## Lumbar Stenosis utilizing METRx® System

### Decompression

In preparation for a spinal stenosis procedure, insert the appropriate-sized METRx® System Tube as previously described. Once the Tube is positioned, it is important to extend the laminotomy cephalad above the insertion of the ligamentum flavum. This is to ensure resection of all hypertrophied ligamentum. After the cephalad border of the ligamentum is exposed, it can be separated from the dura using Angled Currettes or a right or left Ball Tip Dissector (**Figure 27**). The ligamentum is then resected with a 90° or 40° Kerrison Punch (**Figure 28**). To ensure complete decompression of the lateral recess, the lateral exposure should allow palpation of the inferior pedicle. This often requires resection of the superior border of the lower lamina (**Figure 29**). It will also remove any caudal residual ligamentum, which often can compress the dura or nerve root. Foraminotomies are then performed, as necessary, to decompress both exposed foramina (**Figure 30**). The Ball Tip Probe should be able to pass freely into both the cephalad and caudal foramina.

After achieving the ipsilateral decompression, a separate contralateral exposure may be utilized to decompress the opposite lateral recess by following the aforesaid procedural steps (**Figure 31**).

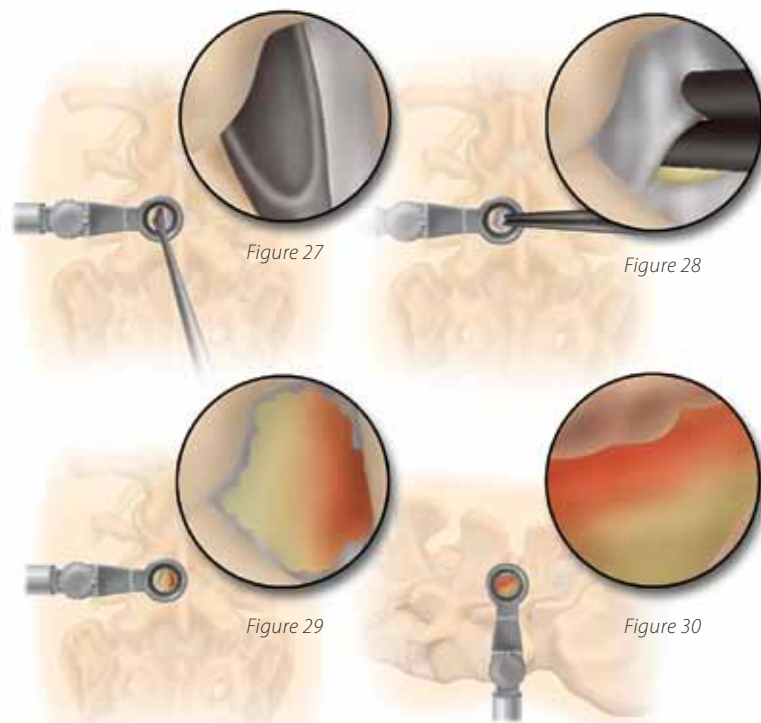


Figure 31

## Lumbar Stenosis utilizing METRx® System *continued*

### Contralateral Decompression from an Ipsilateral Approach

As an alternative to contralateral decompression from the contralateral side, an ipsilateral approach to contralateral decompression can be utilized. After completion of the ipsilateral decompression, the Tubular Retractor is angled medially to expose the anterior spinous process. An osteotome or a high speed drill can then be used to resect the anterior spinous process and the medial aspect of the contralateral lamina (**Figure 32**). This exposes the contralateral hypertrophied ligamentum flavum, which can then be resected using Kerrison Punches and Currettes (**Figures 33a, 33b, and 33c**). Care is taken to palpate the caudal pedicle and probe both the cephalad and caudal foramina to be certain that the decompression is complete (**Figure 34**).

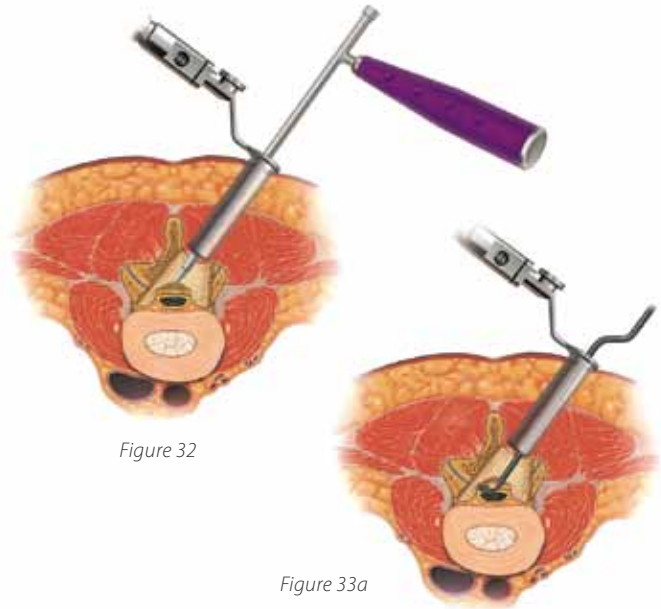


Figure 32

Figure 33a

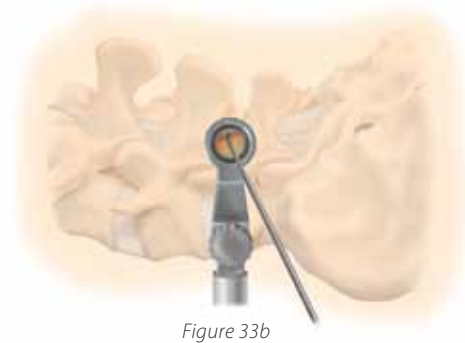


Figure 33b

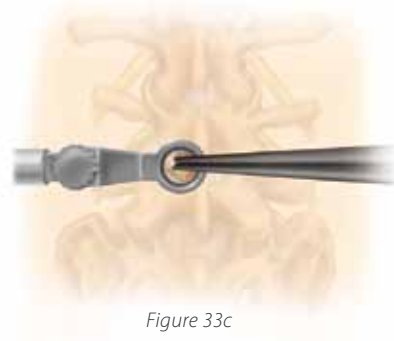


Figure 33c

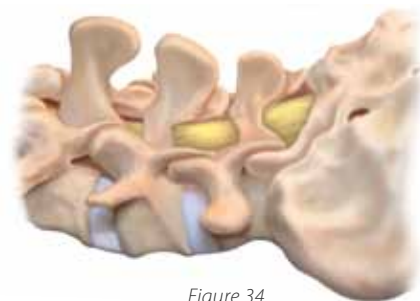


Figure 34

## Discectomy utilizing the METRx® System

### Soft Tissue Removal and Lamina Identification

It is essential to remove all soft tissue exposed in the operative corridor in order to maximize the working space within the Tubular Retractor. This can be accomplished with a Pituitary Rongeur and/or electrocautery.

The lamina edge is identified and the ligamentum flavum is detached from the undersurface of the lamina with a small Angled Curette (**Figure 35**).

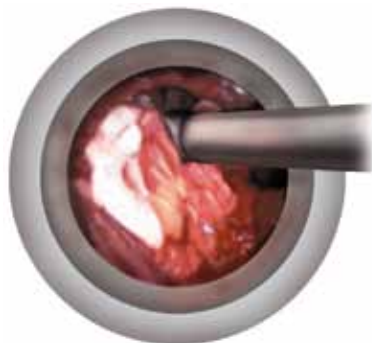


Figure 35

### Lamina and Interlaminar Space Identification

A hemilaminotomy/medial facetectomy is then performed with a Kerrison Punch or high speed drill (**Figure 36**). Lateral recess and/or foraminal stenosis can be addressed in this fashion. Effective utilization of lateral fluoroscopy will help tailor the dissection as necessary to access specific pathology. When the decompression is done mainly for lumbar stenosis and not a disc herniation, the laminotomy is carried just cephalad to the insertion of the ligamentum flavum onto the underside of the lamina. This assures that all hypertrophied ligamentum will be removed, adequately decompressing the canal. If the pathology is beyond the confines of the Tubular Retractor, wanding can be used to reposition the Tubular Retractor.



Figure 36



Figure 37

### Ligamentum Flavum Removal

The ligament is penetrated with the Curette or Ball Probe utilizing a twisting motion under the remaining superior lamina where the ligament is thin (**Figure 37**). It is peeled back caudally and dorsally, then resected with a Kerrison Punch (**Figure 38**).

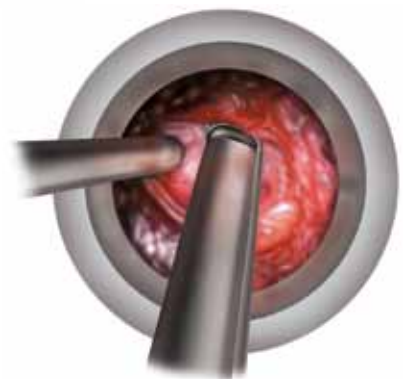


Figure 38



## Discectomy utilizing the METRx® System *continued*

### Nerve Root Exploration and Retraction

There is an initial tendency to “cone” the exposure down to the final target reducing the working space and visualization in the Tubular Retractor. In order to avoid this, it is important to complete soft tissue, bone, and ligament removal over the entire area of the exposure. Figure 39 shows appropriate exposure of the epidural space.

The dura and traversing nerve root are identified. The nerve root is retracted medially utilizing a Penfield Dissector, Love style, or Suction Retractor (**Figure 39**). The volar epidural space can then be explored. If necessary, epidural veins can be cauterized with bipolar forceps and divided with micro scissors (**Figure 40**). Cotton patties can also be used to obtain hemostasis.

### Discectomy and Closure

Identify the disc herniation. If an annulotomy is necessary, it can be accomplished with the Micro Scissors while protecting the nerve root with the Retractor. The herniated disc is then removed with a Pituitary Rongeur in a standard fashion (**Figure 41**). Intradiscal and extradiscal work can be carried out as one would normally perform during an open microdiscectomy. The nerve root is explored to ensure the decompression is complete.

Once the nerve root is decompressed, irrigate the disc space thoroughly. Epidural steroids may be injected if desired. Loosen the Flexible Arm assembly and slowly remove the Tubular Retractor. Any bleeding in the paraspinal musculature can be controlled with the bipolar forceps as the Tube is removed.



Figure 39



Figure 40

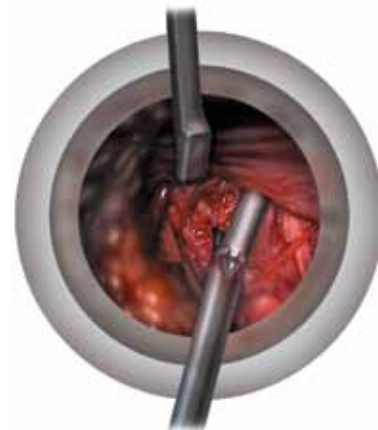


Figure 41

## TLIF Procedure Overview utilizing METRx® System and CD HORIZON® SEXTANT® II Percutaneous Rod System

### Soft Tissue Dilatation and Bony Exposure

In a TLIF procedure, a 22mm or 26mm diameter METRx® Tube or the METRx® X-TUBE® Retraction System is used to access the ipsilateral side following tissue dilatation. Once the Tube is positioned, remove the superior and inferior facet using an osteotome or drill. It is important to remove the entire facet in order to provide a better view and access to the disc space. Additional bony removal may be carried out at this time using a Kerrison Rongeur or drill. Use caution not to violate pedicle walls (Figures 42, 43, and 44).



Figure 42



Figure 43



Figure 44

### Disc Removal

Incise the disc space with a scalpel and begin disc removal using a Pituitary Rongeur. Continue disc removal using either the Straight or Curved Rotating Cutters. The Rotating Cutters are blunt tipped and side cutting for safety. A T-handle or a hand-held power drill may be used for more efficient removal of disc (Figures 45 and 46).



Figure 45



Figure 46

### Contralateral Screw Insertion

Insert CD HORIZON® LEGACY™ Cannulated Multi-Axial Screws using the CD HORIZON® SEXTANT® II Rod Insertion System on the contralateral side. The screws and instruments are used to maintain distraction during disc space preparation (Figure 47).

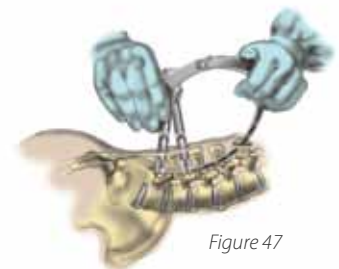


Figure 47

For complete instructions of use for the implant system, please refer to the appropriate surgical technique and package insert.

## TLIF Procedure Overview utilizing METRx® System and CD HORIZON® SEXTANT® II Percutaneous Rod System *continued*

### Restoration of Disc Space Height

Re-establish disc space height by using either the Impacted Distractors or the Expanding Distractor. Once adequate distraction has been obtained via the interbody space, provisionally tighten the contralateral Screws (**Figure 48**).

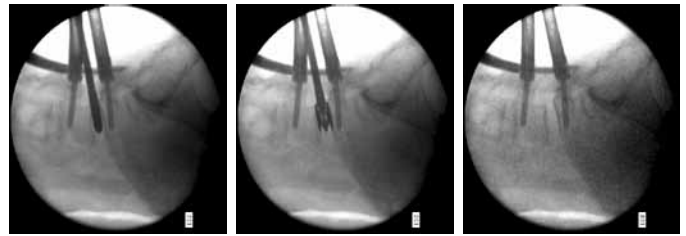


Figure 48

### End Plate Preparation

Using various Curettes and Scrapers, remove the cartilaginous material from the disc space and the end plates. Continue preparation of the bony end plates using Curettes, Scrapers, and Rasps. Specially designed angled instruments allow disc resection and end plate preparation on the contralateral side (**Figure 49**).



Figure 49

### Interbody Construct Insertion

Choose the appropriate size implant based on the use of the Trial Sizers and position the interbody implant (**Figure 50**).

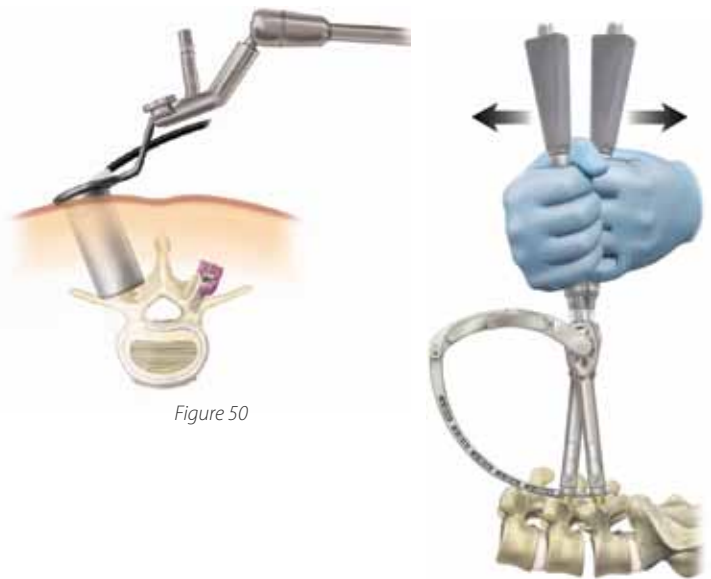


Figure 50

### Compression

Apply compression to the contralateral Screws. Break off the Set Screws to maintain compression on the interbody device (**Figure 51**).



Figure 51

### Ipsilateral Screw Insertion

Ipsilateral instrumentation may be inserted percutaneously using the CD HORIZON® SEXTANT® II instrumentation or via direct visualization through the METRx® Tube and METRx® X-TUBE® Retraction System (**Figure 52**).



Figure 52

*For complete instructions of use for the implant system, please refer to the appropriate surgical technique and package insert.*

## PLIF Procedure Overview utilizing METRx® System

### Preoperative Planning

The patient is placed on the operating table in the prone position with lateral C-arm fluoroscopy. Care should be used to maintain the patient in a lumbar lordotic position.

A Spinal needle is placed into paraspinous musculature 2–2.5cm off of midline at the appropriate level confirmed using lateral fluoroscopy (**Figure 53**).

The Guidewire is placed through the incision and directed toward the facet under lateral fluoroscopy.

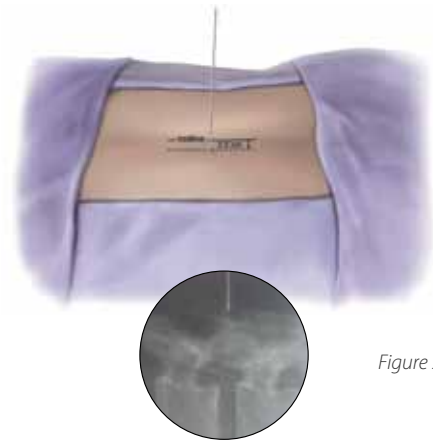


Figure 53

### Dilation/Tubular Retraction

Insert the initial cannulated soft tissue Dilator over the Guidewire. Once the fascia is penetrated, remove the Guidewire and advance the Dilator over the facet (**Figure 54**). Confirm the placement of the initial Dilator using lateral fluoroscopy.

Sequential Dilatation  
and Tubular Retractor Insertion

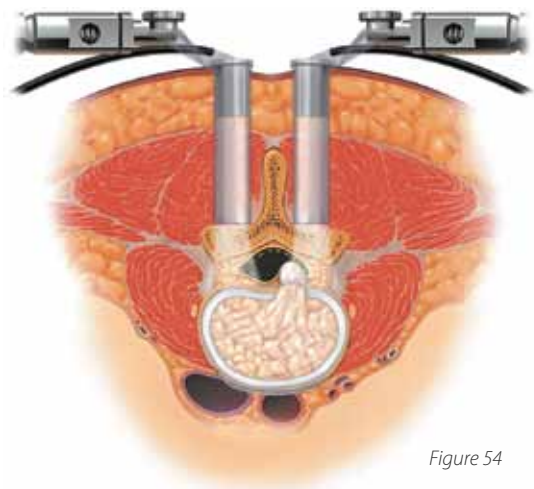


Figure 54

### Laminotomy, Facetectomy, and Discectomy

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

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

### Disc Space Distraction

The disc space is sequentially distracted until original disc space height is obtained and the normal foraminal opening is restored.

Insert the Distractor with the T-handle attached, with the flat surface parallel to the end plates. Rotate the Distractor 90 degrees to distract the space. Sequentially insert Distractors from side to side until the desired height is obtained.

The largest Distractor is left in the disc space in the distracted position while continued disc space preparation is performed (**Figure 55**).

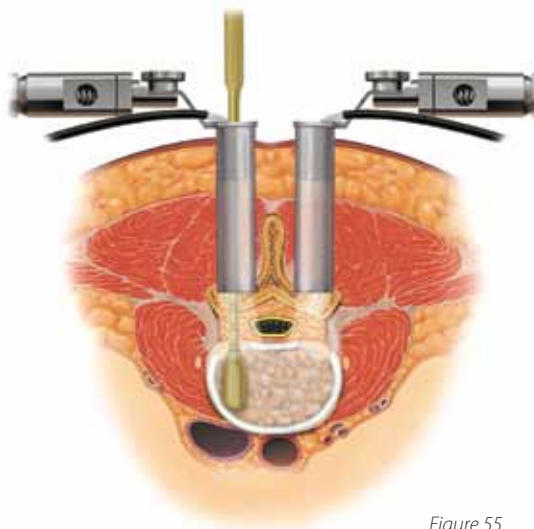


Figure 55

*For complete instructions of use for the implant system, please refer to the appropriate surgical technique and package insert.*

## PLIF Procedure Overview utilizing METRx® System *continued*

### Disc Space Preparation

Remove disc using the Rotate Cutters. The Rotate Cutters are bullet-nosed and side-cutting for safety (**Figure 56**). Disc Shavers are also available (**Figure 57**). A T-handle or a handheld power drill may be used for more efficient removal of the disc.

### End Plate Preparation

Remaining soft tissue or cartilaginous end plate covering is removed with vigorous scraping or curettage (**Figure 58**). 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 excellent graft incorporation.

### Interbody Construct Insertion

Select the appropriate sized construct as determined during the trialing step and attach it to the Inserter. Place autograft anteriorly in the prepared disc space and insert the construct (**Figure 59**). The Rotate Distractor is then removed and the preparation and insertion steps are repeated on the contralateral side.

### Screw Insertion

To facilitate satisfactory immobilization of the grafted interspace, segmental external fixation is applied using a standard technique (**Figure 60**).

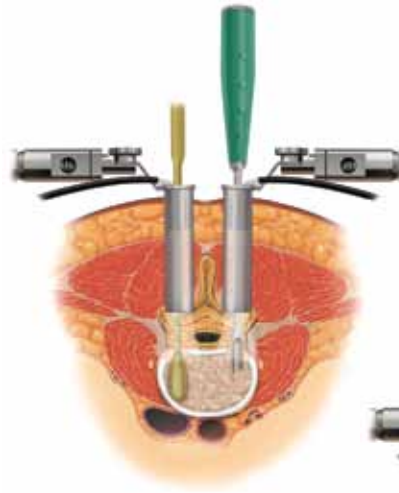


Figure 56

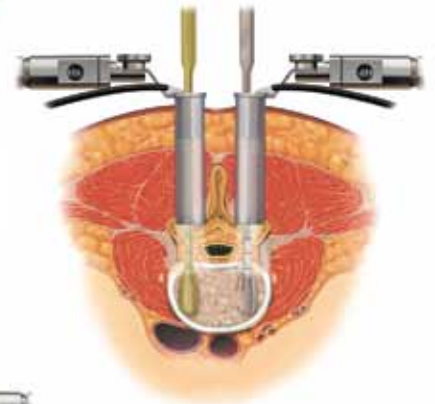


Figure 57

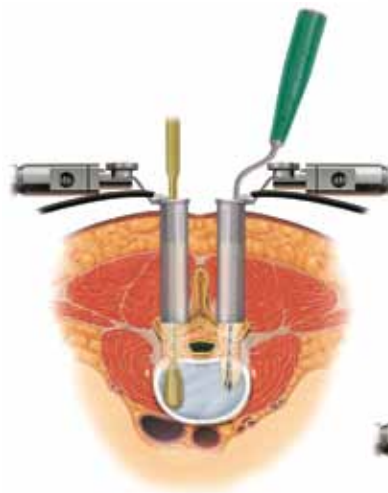


Figure 58

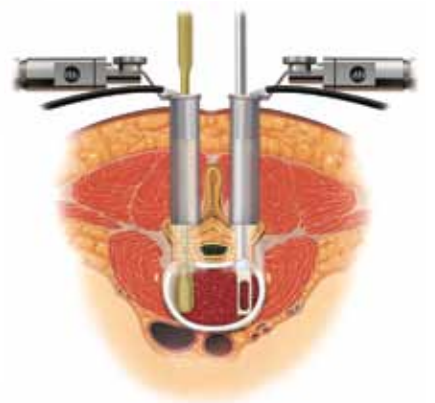


Figure 59

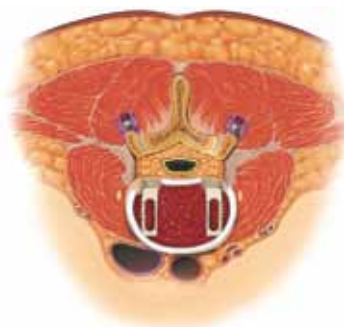


Figure 60

For complete instructions of use for the implant system, please refer to the appropriate surgical technique and package insert.

## Product Ordering Information

### KERRISONS

Part Number	Description
9560609	90° Bayoneted, 5mm
9560540	90°, 5mm
9560608	40° Bayoneted, 5mm
9560538	40°, 5mm
9560607	90° Bayoneted Kerrison, 4mm
9560606	40° Bayoneted, 4mm
9560605	90° Bayoneted, 3mm
9560539	90°, 3mm
9560604	40° Bayoneted, 3mm
9560537	40°, 3mm
9560603	90° Bayoneted, 2mm
9560602	40° Bayoneted, 2mm
9560601	90° Bayoneted, 1mm
9560600	40° Bayoneted, 1mm

### PITUITARY/SCISSORS

Part Number	Description
9560536	Straight Pituitary, 4mm
9560570	Upbiting Pituitary, 4mm
9560569	Downbiting Pituitary, 2mm
9560564	Upbiting Pituitary, 2mm
9560565	Straight MicroPituitary, 2mm
9560567	Upbiting MicroPituitary, 2mm
9560566	Pituitary with Tooth, 2mm
9560691	Micro Scissors
9560568	Curved Scissors

### DISSECTORS

Part Number	Description
9560562	90° MED Dissector
9560654	Bayoneted Dissector, Right
9560655	Bayoneted Dissector, Straight
9560656	Bayoneted Dissector, Left
9560687	Bayoneted Penfield #7 Push
9560639	Bayoneted Penfield #7 Pull
9560649	Bayoneted Penfield #4 Push
9560650	Bayoneted Penfield #4 Pull
9560558	Penfield #4
9560647	Bayoneted Penfield #2 Push
9560648	Bayoneted Penfield #2 Pull
9560559	Penfield #2

### BALL-PROBES

Part Number	Description
9560644	Bayoneted, Long, Right
9560645	Bayoneted, Long, Straight
9560646	Bayoneted, Long, Left
9560641	Bayoneted, Short, Right
9560642	Bayoneted, Short, Straight
9560643	Bayoneted, Short, Left
9560557	90°, Short
9560556	90°, Long
9560640	Woodson Probe
9560553	45° Woodson Probe

### CURETTES

Part Number	Description
9560620	Bayoneted Forward Straight CUP, 5.2mm
9560545	Bone, Straight, 5.2mm
9560624	Bayoneted Forward Angled CUP, 5.2mm
9560547	Bone, Angled, 5.2mm
9560628	Bayoneted Reverse Angled, 5.2mm
9560549	Bone, Reverse Angled, 5.2mm
9560621	Bayoneted Forward Straight CUP, 3.6mm
9560546	Bone, Straight, 3.6mm
9560625	Bayoneted Forward Angled CUP, 3.6mm
9560548	Bone, Angled, 3.6mm
9560629	Bayoneted Reverse Angled, 3.6mm
9560550	Bone, Reverse Angle, 3.6mm
9560623	Bayoneted Forward Straight CUP, 1.8mm
9560627	Bayoneted Forward Angled CUP, 1.8mm
9560631	Bayoneted Reverse Angled, 1.8mm

### HOOKS

Part Number	Description
9560560	Nerve
9560651	Bayoneted Nerve, Right
9560652	Bayoneted Nerve, Straight
9560653	Bayoneted Nerve, Left
9560689	MicroBayoneted Nerve, Right
9560638	MicroBayoneted Nerve, Straight
9560688	MicroBayoneted Nerve, Left

## Product Ordering Information *continued*

### RETRACTORS/FORCEPS

Part Number	Description
9560554	Wide Nerve Retractor
9560555	Nerve Root Retractor
9561525	Self Retaining Nerve Root Retractor
9561526	Self Retaining Retractor POST
9569571	Angled Bipolar Forceps
9569572	Straight Bipolar Forceps
9560573	Bipolar Cable
9560574	Angled Short/Finer Bipolar Forceps
9569690	Straight Short/Finer Bipolar Forceps

### SUCKERS

Part Number	Description
9560534	#10
9560535	#8
9560637	#6
9560561	Suction Retractor

### DILATORS/GUIDEWIRE

Part Number	Description
9560432	24.8mm
9560431	22.8mm
9560430	20.8mm
9560429	18.8mm
9561428	16.8mm
9561427	14.6mm
9561426	12.8mm
9560421	9.4mm
9560420	5.3mm
955-519	MED Guidewire

### TUBE RETRACTORS

Part Number	Description
9560756	26mm × 9cm
9560755	26mm × 8cm
9560754	26mm × 7cm
9560753	26mm × 6cm
9560752	26mm × 5cm
9560751	26mm × 4cm
9560750	26mm × 3cm
9560736	22mm × 9cm
9560735	22mm × 8cm
9560734	22mm × 7cm
9560733	22mm × 6cm
9560732	22mm × 5cm
9560731	22mm × 4cm
9560730	22mm × 3cm
9560726	20mm × 9cm
9560725	20mm × 8cm
9560724	20mm × 7cm
9560723	20mm × 6cm
9560722	20mm × 5cm
9560721	20mm × 4cm
9560720	20mm × 3cm
9561686	18mm × 9cm
9561685	18mm × 8cm
9561684	18mm × 7cm
9561683	18mm × 6cm
9561682	18mm × 5cm
9561681	18mm × 4cm
9561680	18mm × 3cm
9561676	16mm × 9cm
9561675	16mm × 8cm
9561674	16mm × 7cm
9561673	16mm × 6cm
9561672	16mm × 5cm
9561671	16mm × 4cm
9561670	16mm × 3cm
9561666	14mm × 9cm
9561665	14mm × 8cm
9561664	14mm × 7cm
9561663	14mm × 6cm
9561662	14mm × 5cm
9561661	14mm × 4cm
9561660	14mm × 3cm

## Product Ordering Information *continued*

### METRx® X-TUBE® RETRACTORS WITH INSTRUMENTS

Part Number	Description
9560768	25mm × 70mm Expanding Retractor
9560764	25mm × 80mm Expanding Retractor
9560762	25mm × 60mm Expanding Retractor
9560760	25mm × 40mm Expanding Retractor
9560758	25mm × 50mm Expanding Retractor
9560761	40mm Opener/Closer Instrument
9560763	60mm Opener/Closer Instrument
9560765	80mm Opener/Closer Instrument

### DISPOSABLE TUBE RETRACTORS

Part Number	Description
00721902836831	26mm × 9cm
00721902836824	26mm × 8cm
00721902836817	26mm × 7cm
00721902836794	26mm × 6cm
00721902836770	26mm × 5cm
00721902836756	26mm × 4cm
00721902836749	26mm × 3cm
00721902444517	22mm × 9cm
00721902444494	22mm × 8cm
00721902444487	22mm × 7cm
00721902444463	22mm × 6cm
00721902444418	22mm × 5cm
00721902444340	22mm × 4cm
00721902444319	22mm × 3cm
00721902836732	18mm × 9cm
00721902836725	18mm × 8cm
00721902836718	18mm × 7cm
00721902836701	18mm × 6cm
00721902836695	18mm × 5cm
00721902836688	18mm × 4cm
00721902836664	18mm × 3cm

### MICRO ENDOSCOPIC INSTRUMENTS

Part Number	Description
955-524	Micro Endoscopic Retractor, 16mm
9560118	Micro Endoscopic Retractor, 18mm
9560101	Reusable Endoscope
9560160	Disposable Endoscope Attachment, 16mm
9560180	Disposable Endoscope Attachment, 18mm
9560191	Adjustable Pinch Clamp
9560192	Tube Clamp POST

### ATTACHMENT INSTRUMENTS

Part Number	Description
9560524	METRx® Flexible ARM
9560523	Bed Rail Attachment
9561523	Bed Rail Clamp
9561524	Flexible ARM
9661525	
9561526	



## Important Product Information

### DESCRIPTION:

The METRx™ Microscope System is composed of a microscope, camera, an integrated video system, a video monitor and recorder, and various cannula, dilators, extension lenses, and associated instruments.

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

### A. INDICATIONS

The METRx™ Microscope is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervical, thoracic, or lumbar spine either from an anterior or posterior direction, for example, the METRx™ Microscope and accessories are intended to aid the surgeon's visualization of the surgical area and allow him/her to perform any type of surgical spinal procedure such as herniated disc repair, visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants. Other examples of generic surgical use of the METRx™ Microscope would be for use in the knee, ankle, shoulder, hand, wrist, and temporomandibular joint (TMJ).

### B. CONTRAINDICATIONS

The METRx™ Microscope and accessories have no known contraindications intrinsic to the device. No part of the microscope itself or its accessories should ever be used in a cutting or tearing action, i.e., never use the Microscope as an instrument. The optical device or its extension units should not be used to provide access to the surgical field. The device should not be inserted into body cavities, hollow organs, or natural body openings.

There are no other known risks associated with the use of the device outside of the normal and expected risks of surgery. The microscope should not be used non-sterile or in the presence of an infectious disease process.

### DIRECTIONS FOR USE:

Specific instructions for use depend on patient considerations. Therefore, Medtronic Sofamor Danek cannot provide a surgical procedure that will be applicable to all situations. Any available surgical procedure brochure or manual for the METRx™ System Microscope device and accessories should be reviewed prior to use. The only critical directions for use are to insert the cannula or dilators and position them in the surgical wound prior to insertion of the microscope extension rod lens and inner field visualization of the surgical site. Never use the microscope extension to provide access or as a surgical instrument in the surgical field. Once visualization assistance is obtained, the surgeon can then complete the planned surgical procedure.

### POTENTIAL ADVERSE EFFECTS:

Risks possibly associated with the use of the METRx™ Microscope and accessories are similar to those associated with any surgery to the planned area of instrument use. The most frequently stated risks are bleeding, neurological damage, damage to the surrounding soft tissue, and infection. Each of these risks has also been used to describe the risks associated with conventional surgical intervention. Additional risks associated with the use of METRx™ Microscope, other than those described for spinal surgery in general, may be instrument malfunction, such as bending, fragmentation, loosening, and/or breakage (whole or partial). Breakage of the tip in the patient may increase surgical time, since this instrument should not be implanted. Also, the surgery may not be effective. Similar risks are associated with the system use in other parts of the body.

Additional risks are attendant to surgery and the use of anesthesia, etc., and are not directly related to the use of the microscope and accessories. These include, but are not limited to, pneumonia, phlebitis, embolism, wound infection, blood loss with or without anemia.

### WARNINGS AND PRECAUTIONS:

A successful result is not always achieved in every surgical case. This fact is especially true in orthopaedic or neuro-surgery cases where many extenuating circumstances may compromise the results.

In the event of technical complications, the surgical technique can be converted to an open procedure and the surgery completed. 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 of the patient and the compliance of the patient will greatly affect the results.

In addition, the following should be considered:

1. This device is a delicate instrument. It should NOT be dropped, bent at a sharp angle, or exposed to any type of gamma radiation. Tip fracture fragmentation and optic damage may result if the microscope is not handled carefully.
2. Additional microscopes and accessories should be available at the time of surgery in case of possible contamination due to mishandling or removing the devices from the sterile field.
3. Components of the system should be thoroughly inspected during cleaning prior to surgery for possible damage.
4. Proper, secure component connections must be made to assure proper functioning of the optical, irrigation, and aspiration aspects of the device.

CAUTION – High Temperature

This light source is recommended for use with 100W light sources and 5mm fiber optic cables. Use of other cables and/or higher wattage light sources may result in high temperatures on the metal connection to the light cable which may result in injury to patient or staff and damage to product. Reduce intensity levels on high watt light sources and take precautions to protect patient and staff from injury.

**CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.**



FOR US AUDIENCES ONLY

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

### CLEANING PROCEDURE:

Exterior cleaning of the microscope and camera head is essential prior to any sterilization procedure. The camera head should be removed from the microscope prior to cleaning. To remove blood, organic matter, and irrigation solutions, all surfaces of the microscope and camera head should be cleaned with a mild detergent and water. Rinse with distilled, demineralized, or pyrogen-free water. Dry thoroughly. Without the removal of all contaminants from the surface, the sterilization medium will not contact the surfaces.

**WARNING: DO NOT USE ULTRASONIC CLEANER OR ABRASIVES DURING THE CLEANING PROCESS.**

### STERILIZATION:

The microscope, light cable, non-sterile instruments and instruments which are re-usable are recommended to be steam sterilized by the hospital using one of the following methods:

Some cameras (9560500, 9560501) are autoclavable following the same recommendations. If the products described in this document are sterilized by the hospital in a tray or case, it must be sterilized in a tray or case provided by Medtronic Sofamor Danek. Some accessories and instruments are supplied sterile and non-reusable. Sterile product will be clearly labeled as such on the package label. The sterility of the product supplied sterile can only be assured if the packaging is intact.

NOTE: The following note applies to the process parameter identified with the \* below: For use of this product and instruments 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.

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*

The microscope, camera and light cable can also be EtO sterilized. The following EtO cycle is recommended:

#### Preconditioning parameters:

Temperature: 55 ± 2° C

Relative Humidity: ≥ 35%

Vacuum: 21 ± 1 In Hg  
(508-559mm Hg)

Preconditioning time: 1 Hour

#### Sterilization parameters:

Ethylene Oxide Carrier: Oxyfume 2002

Temperature: 55 ± 2° C

Relative Humidity: ≥ 35%

Pressure: 19 ± 1 PSIG  
(2.25-2.39 bars)

Ethylene Oxide Concentration: 736 mg/L

Gas Exposure Time (Full Cycle): 4 Hours

Aeration: 11 Hours at 54°C minimum

The microscope and camera should be thoroughly cleaned prior to sterilization.

The integrated video system, video monitor, and recorder are also reusable and supplied non-sterile. These components should not be placed in the surgical field.

**CAUTION: SCOPES AND CAMERA CANNOT BE STEAM AUTOCLAVED UNLESS "AUTOCLAVABLE" IS ENGRAVED ON THE MICROSCOPE OR CAMERA BODY. THIS METHOD WOULD OTHERWISE PERMANENTLY DAMAGE THE OPTICAL COMPONENTS. CAUTION: DO NOT IMMERSE OR RINSE INSTRUMENTS IN COLD WATER OR ANY OTHER LIQUID TO ACCELERATE COOLING.**

### 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 Sofamor Danek. Further, if this system 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 Sofamor Danek 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:

If further information is needed or required, please contact:



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For the most up-to-date revision of the package insert, please contact Customer Service or your Sales Representative.

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## Important Product Information *continued*

### IMPORTANT INFORMATION ON THE 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  $\phi$ 3.5mm,  $\phi$ 4.5mm,  $\phi$ 5.5mm rods or  $\phi$ 6.35mm rods, while other components can connect to both  $\phi$ 5.5mm rods and  $\phi$ 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 MDT 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.

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® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion 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); spondylolisthesis; 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 as an adjunct to fusion.

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 as an adjunct to fusion.

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

In order to achieve additional levels of fixation as an adjunct to fusion, 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 instrumentation 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), dysesthesia, 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. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Bone loss or decrease in bone density, possibly caused by stresses shielding.
18. Graft donor site complications including pain, fracture, or wound healing problems.
19. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
20. 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.
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. 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 spondylolisthesis 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.

**USA** For US Audiences Only

**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:

#### 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.

## Important Product Information *continued*

### DEVICE FIXATION

In cases where a percutaneous posterior approach is used refer to the CD HORIZON® SEXTANT® surgical technique.

MEDTRONIC CD HORIZON® Spinal System instrumentation 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.**

### PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. 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.
4. 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.
5. 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.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

### INTRAOPERATIVE

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. 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.
4. Utilize an imaging system to facilitate surgery.
5. 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.
6. **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.
7. 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.
8. To assure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods should be used whenever possible.
9. 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.

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.

7. 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.

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For the most up-to-date revision of the package insert, please contact Customer Service or your Sales Representative.  
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## Notes

# Notes

## Notes



[www.sofamordanek.com](http://www.sofamordanek.com)

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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.

