Medtronic

Công ty TNHH Medtronic Việt Nam

Xác nhận tài liệu kỹ thuật trang thiết bị y tế

Tp. HCM, ngày 26 tháng 06 năm 2017

Đại diện pháp luật

Tổng Giám Đốc

PHILIP PHUOC DAO

Medtronic

METRx® II
System

The objectives and indications for surgery using the METRx® II System are the same as conventional open surgery. This is accomplished by applying traditional surgical techniques through a Tubular Retractor under loupes, microscopic or endoscopic visualization. Utilizing the specially-designed instrumentation in the METRx® II System, a laminotomy, medial facetectomy, foraminotomy, discectomy, PLIF, TLIF, posterior lateral fusion, and even pedicle screw insertion can be performed in a minimally invasive fashion.

Medtronic

METRx® II

System

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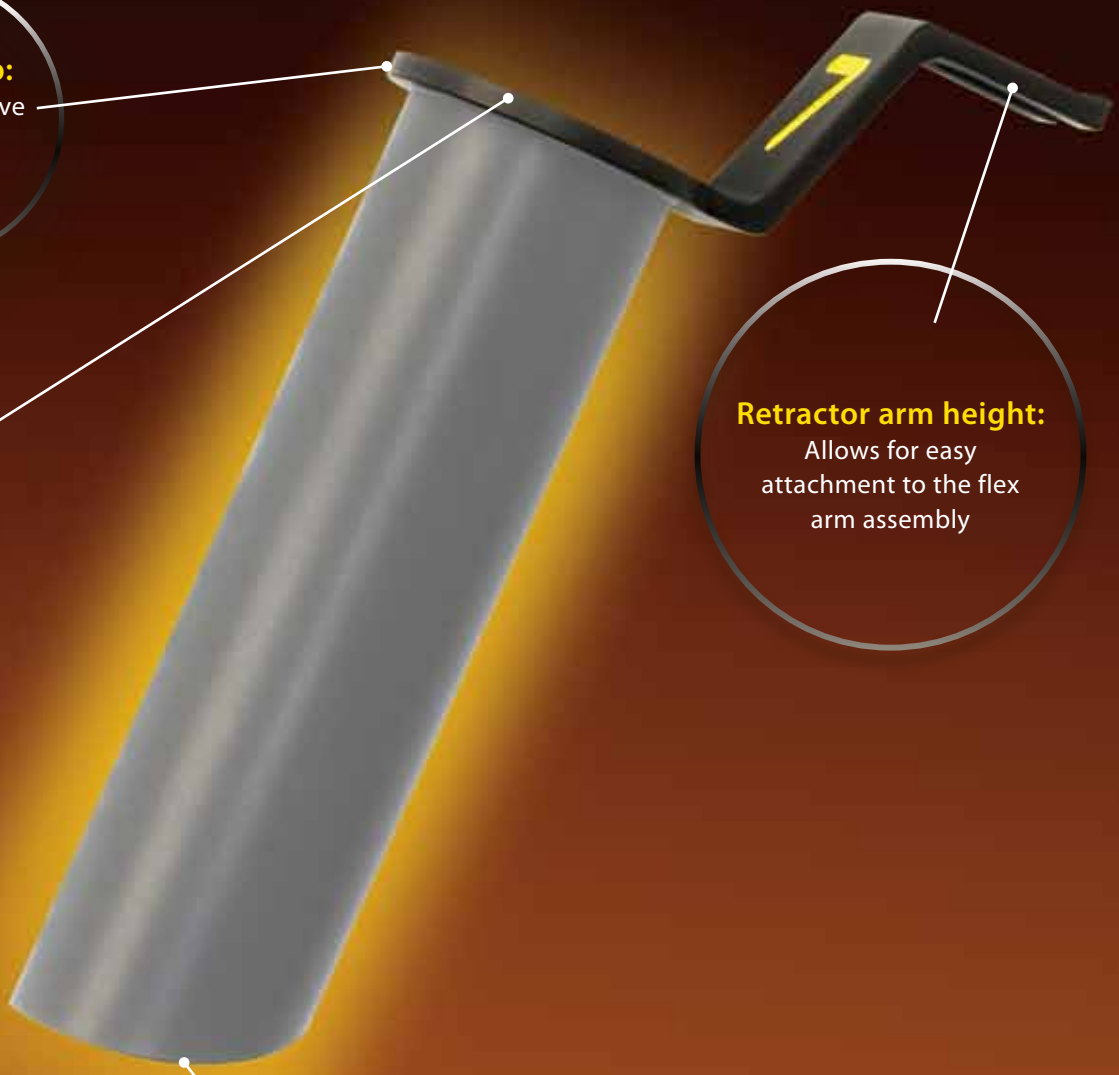
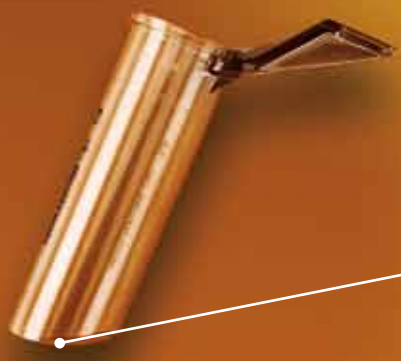


Rounded lip:
For intraoperative visualization

PVD coating:
Reduces glare from the light source

Retractor arm height:
Allows for easy attachment to the flex arm assembly



20 degree beveled tip:
Permits docking onto the lamina

Available in 14mm, 16mm, 18mm, 20mm stainless
Available in 18mm (only) disposable


Clear visibility of the labeling:
Helps reduce back table confusion
4/90
4/90
Ejector tip:
Engineered to remove bony tissue

Dual-Sided Penfields
Streamlined instrumentation
(push/pull feature)

Sucker #12
Large sucker diameter
for increased suction

4mm Pituitary Rongeur
Large rongeur for greater bone
biting capacity

Wide Suction Retractor
Large sucker diameter and
retracting feature

Cases

Streamlined packaging maximizes surgical flexibility, while minimizing the number of cases needed for surgery

Instrument Set
Includes standard and micro instruments

Tubular Retractor Set

Flex Arm and Dilator Set

Bipolars

Non-Stick Material:
Eliminates soft tissue sticking to instrumentation

Micropituitaries

Provide durability to meet the demanding needs of surgeons and complex procedures

Flex Arm

Innovative Design:
Provides increased rigidity and two independent working planes through new ball joint locking mechanism. In addition, allows the docking of additional instruments, including a self retaining nerve root retractor

Handles

Color Coded: Provides medical staff a visual reference to instrument size, helps reduce back table confusion
Available on all kerrisons, curettes, and pituitaries

Silicone: Provides for an ergonomic handling of the instruments
Available on all kerrisons, curettes, and pituitaries

Cases

Instrument Set

9569694 (Lid)

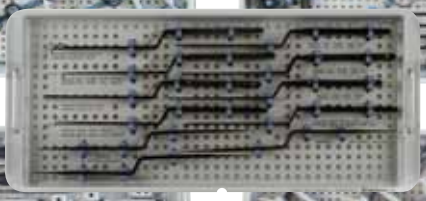
9569790 (Outer Case)

9569791

9569792

9569793

9569794



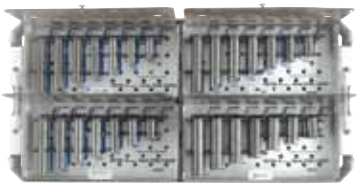
9569795

Tubes

9569694 (Lid)

9569796 (Outer Case)

9569797



Tube Caddies

9569667	14mm
9569677	16mm
9569687	18mm
9569727	20mm

9569798

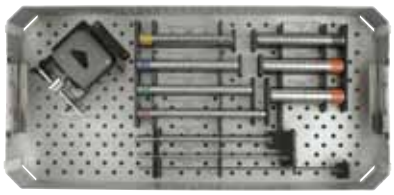
Tube Caddies

9569737	22mm
9569757	26mm

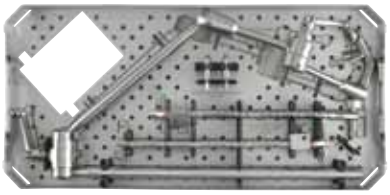
Flex Arm and Dilators

9569694 (Lid)

9569530 (Outer Case)



9569529



9569532

Beveled Disposable Retractors

18mm

Beveled Disposable Retractors

18mm width

Item #	Length
9569813	3cm
9569814	4cm
9569815	5cm
9569816	6cm
9569817	7cm
9569818	8cm
9569819	9cm

Straight Disposable Retractors

22mm

Straight Disposable Retractors

22mm width

Item #	Length
9560703	3cm
9560704	4cm
9560705	5cm
9560706	6cm
9560707	7cm
9560708	8cm
9560709	9cm

26mm

Straight Disposable Retractors

26mm width

Item #	Length
9562613	3cm
9562614	4cm
9562615	5cm
9562616	6cm
9562617	7cm
9562618	8cm
9562619	9cm

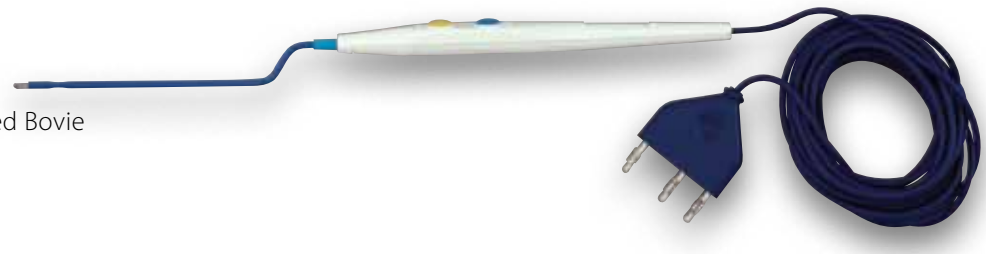
Disposable Light Sources

18mm RADIANCE Illumination
9560802

22mm RADIANCE Illumination
9560702

26mm RADIANCE Illumination
9560757

Disposable Bovies and Knives



Bayoneted Bovie
9569575

Sheathed Knife
1571-00

Bayoneted Discectomy Knife
1564-00

Beveled Stainless Retractors

14mm width

Item #	Length
9569660	3cm
9569661	4cm
9569662	5cm
9569663	6cm
9569664	7cm
9569665	8cm
9569666	9cm

16mm width

Item #	Length
9569670	3cm
9569671	4cm
9569672	5cm
9569673	6cm
9569674	7cm
9569675	8cm
9569676	9cm

18mm width

Item #	Length
9569680	3cm
9569681	4cm
9569682	5cm
9569683	6cm
9569684	7cm
9569685	8cm
9569686	9cm

20mm width

Item #	Length
9569720	3cm
9569721	4cm
9569722	5cm
9569723	6cm
9569724	7cm
9569725	8cm
9569726	9cm

Straight Stainless Retractors

22mm width

Item #	Length
9569730	3cm
9569731	4cm
9569732	5cm
9569733	6cm
9569734	7cm
9569735	8cm
9569736	9cm

26mm width

Item #	Length
9569750	3cm
9569751	4cm
9569752	5cm
9569753	6cm
9569754	7cm
9569755	8cm
9569756	9cm

Guidewire and Dilators

0.0625 × 12" Guidewire 955-519

5.3mm Dilator 9560420

9.4mm Dilator 9560421

12.8mm Dilator 9561426

14.6mm Dilator 9561427

16.8mm Dilator 9561428

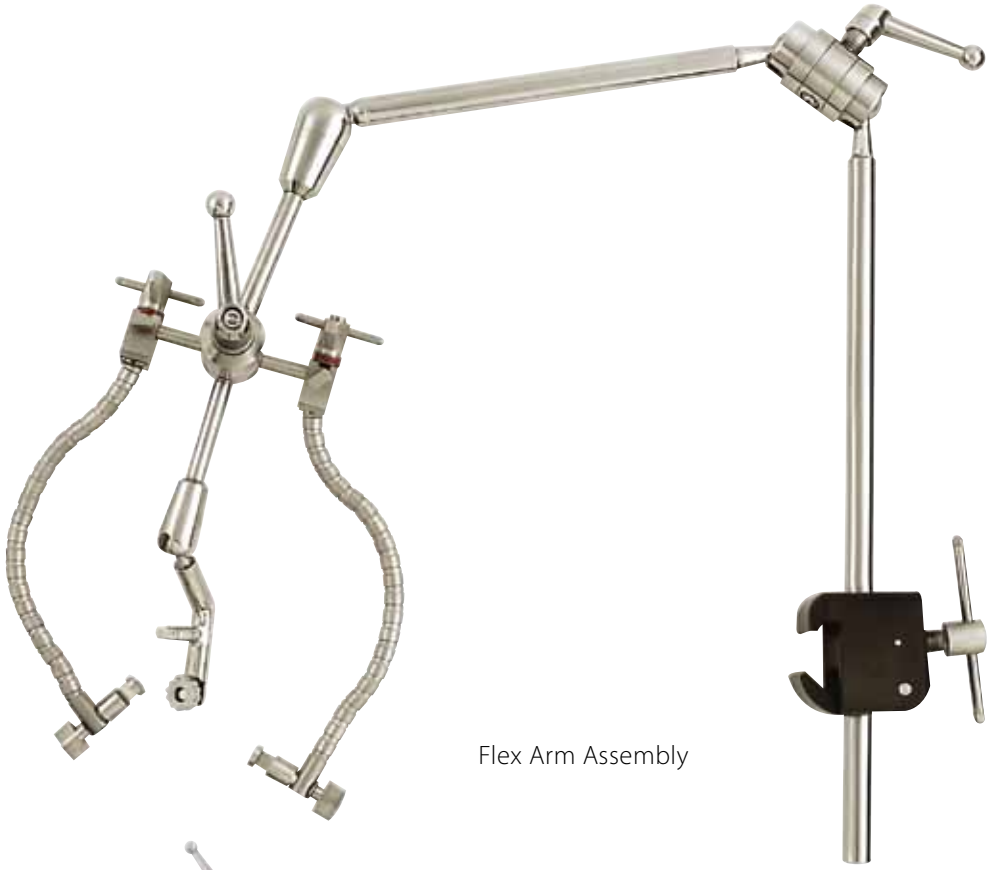
18.8mm Dilator 9560429

20.8mm Dilator 9560430

22.8mm Dilator 9560431

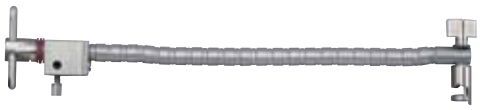
24.8mm Dilator 9560432

Flex Arm Assembly



Flex Arm Assembly

Rigid Flex Arm
9561524



Self Retaining
Nerve Root Retractor
9561525

Bed Rail Clamp
9561523

Self Retaining
Nerve Root Post
9561526

Bayoneted Kerrisons

Color Code (Handle)	
Black	*1mm and 2mm*
Gray	*3mm, 4mm, 5mm*

1mm 40° Kerrison
9569600

1mm 90° Kerrison
9569601

2mm 40° Kerrison
9569602

2mm 90° Kerrison
9569603

3mm 40° Kerrison
9569604

3mm 90° Kerrison
9569605

4mm 40° Kerrison
9569606

4mm 90° Kerrison
9569607

5mm 40° Kerrison
9569608

5mm 90° Kerrison
9569609

Bayoneted Curettes

Color Code (Handle)	
Black	*1.8mm*
Gray	*3.6mm and 5.2mm*

1.8mm Curette
Forward Straight Cup
9569623

1.8mm Curette
Forward Angled Cup
9569627

1.8mm Curette
Reverse Angled Cup
9569631

3.6mm Curette
Forward Straight Cup
9569621

3.6mm Curette
Forward Angled Cup
9569625

3.6mm Curette
Reverse Angled Cup
9569629

5.2mm Curette
Forward Straight Cup
9569620

5.2mm Curette
Forward Angled Cup
9569624

5.2mm Curette
Reverse Angled Cup
9569628

Suckers

Sucker #8
9560535

Sucker #10
9560534

Sucker #12
9569559

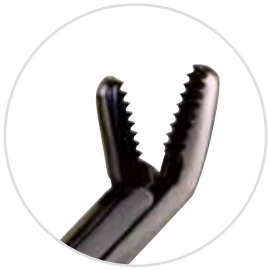
Suction Retractor
9560561

Wide Suction Retractor
9569560

Pituitaries

Color Code (Handle)	
Black	*Micro*
Gray	*All others*

2mm Micropituitary
9569565



2mm Upbiting Micropituitary
9569567

2mm Pituitary with Tooth
9569566

2mm Upbiting Pituitary
9569564

2mm Downbiting Pituitary
9569569

4mm Pituitary, Ring Handle
9569536

4mm Upbiting Pituitary
9569570

4mm Upbiting Rongeur
9569525

Scissors

Curved Scissors
9569568

Straight Micro Scissors
9560691

Bi-Polar Forceps

Straight Bi-Polar Forcep, Short Fine
9569690

Angled Bi-Polar Forcep, Short Fine
9569574

Straight Bi-Polar Forcep
9569572

Angled Bi-Polar Forcep
9569571

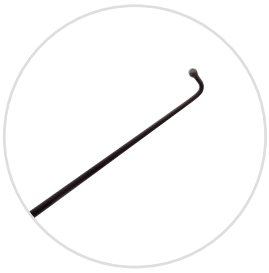
Bi-Polar Cable
9560573

Bi-Polar Spool
9560693

Bayoneted Probes

Woodson Probe
9569640

Short Ball Probes



Short Ball Probe, Left
9569643

Short Ball Probe, Straight
9569642

Short Ball Probe, Right
9569641

Long Ball Probes

Long Ball Probe, Left
9569646

Long Ball Probe, Straight
9569645

Long Ball Probe, Right
9569644

Bayoneted Penfields, Dual Sided

Penfield #2 Push/Pull
9569647

Push End | Pull End

Penfield #4 Push/Pull
9569649

Push End | Pull End

Penfield #7 Push/Pull
9569639

Push End | Pull End

Bayoneted Nerve Hooks and Dissectors

Nerve Hook, Left
9569653

Nerve Hook,
Straight
9569652

Nerve Hook, Right
9569651

Micro Nerve Hook, Left
9569688

Micro Nerve Hook, Straight
9569638

Micro Nerve Hook, Right
9569689

Dissector, Left
9569656

Dissector, Straight
9569655

Dissector, Right
9569654

Preliminary Steps: Targeting

Targeting Using the METRx® II System

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

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

(See Figure 1)

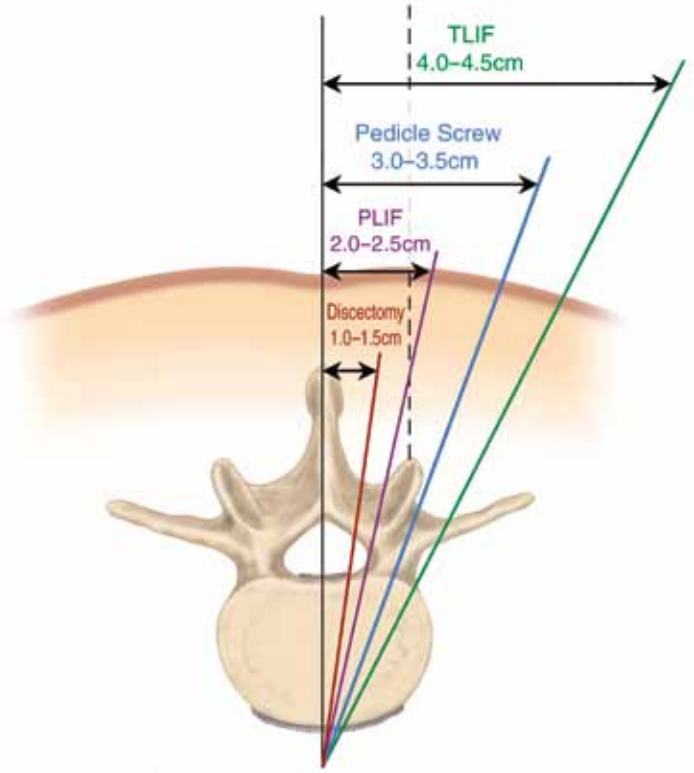


Figure 1

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—14mm Tubular Retractor, 14mm incision, and so on.

Some practitioners 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. 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 **(Figures 2a, 2b, and 2c)**.

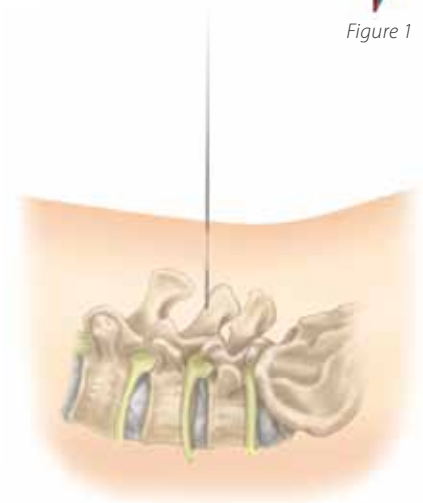


Figure 2a

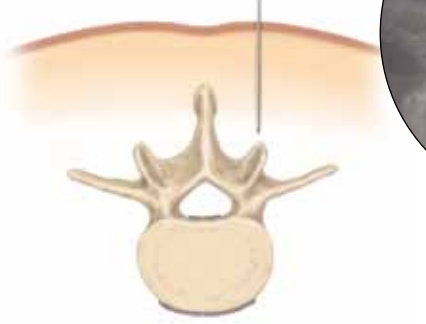


Figure 2b

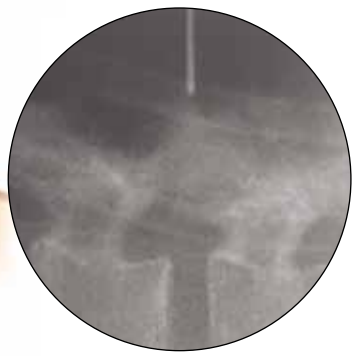


Figure 2c

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 **(Figure 3)**.

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

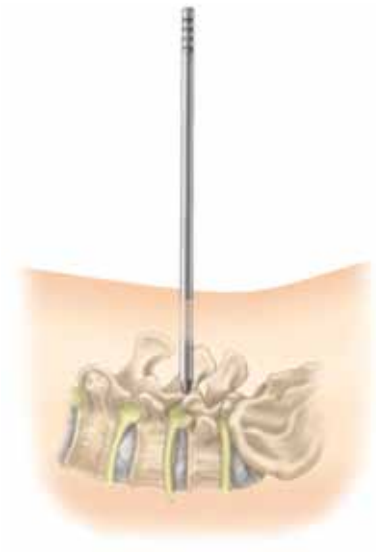


Figure 3

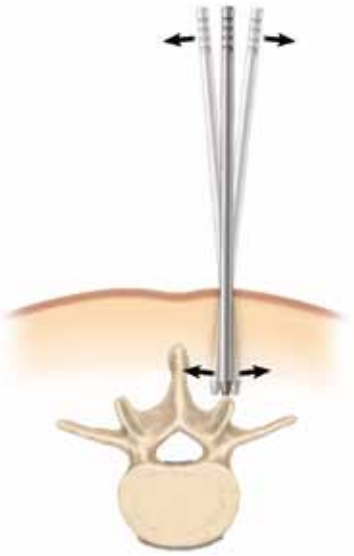


Figure 4

Sequential Dilation and Tubular Retractor Insertion

The next series of Dilators are sequentially placed over each other. 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 **(Figure 5)**.

The optimum 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 wanding. 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)**.

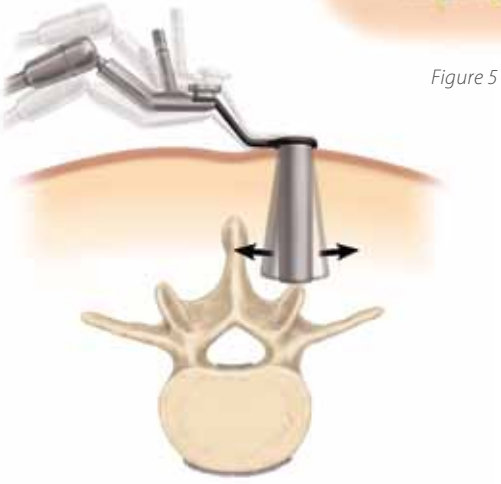


Figure 6

See Preliminary Steps: Targeting information on page 20 for steps that precede this technique.

Spinal Fusion Procedure using the METRx® II X-TUBE® Retraction System

METRx® II X-TUBE® System Introduction

A METRx® II X-TUBE® Retractor is selected in accordance with exposed markings on the final Dilator **(Figure 7)**. The METRx® II X-TUBE® System 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.

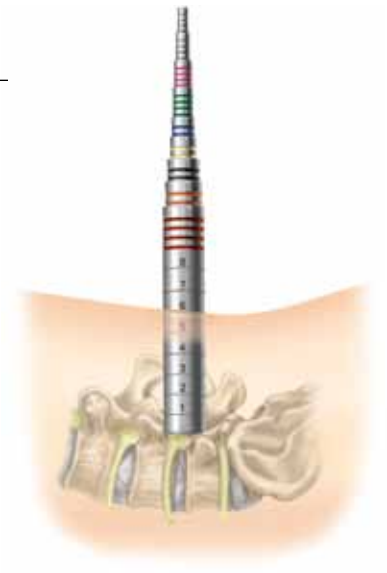


Figure 7

METRx® II X-TUBE® System Deployment

The METRx® II X-TUBE® Instrument is deployed by inserting the Opener Instrument in the tube and compressing the Opener Instrument handle **(Figure 8)**.

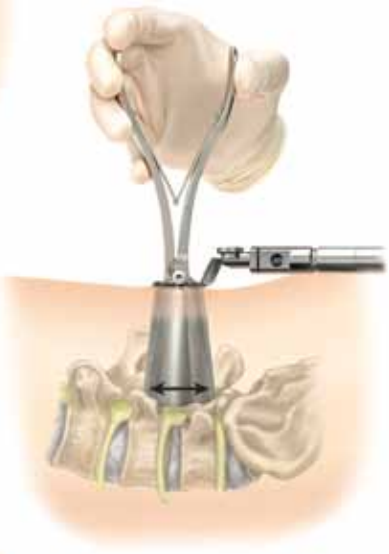


Figure 8

Pedicle Preparation

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

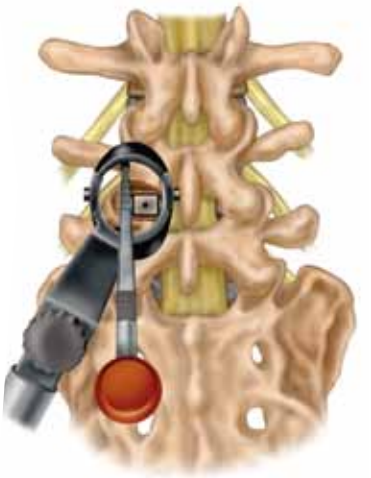


Figure 9

Screw and Rod Insertion

For screw and rod insertion and compression/distraction instructions, please refer to the CD HORIZON® LEGACY™ System surgical technique.

METRx® II X-TUBE® System Extraction

The METRx® II 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® II X-TUBE® instrument to collapse **(Figure 10)**.

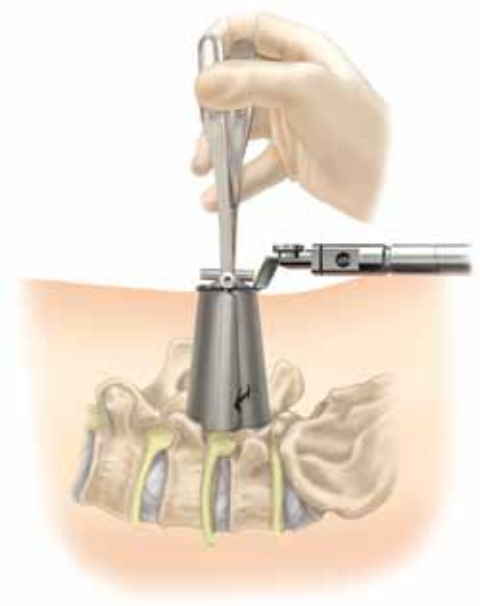


Figure 10

See Preliminary Steps: Targeting information on page 20 for steps that precede this technique.

Lumbar Stenosis using the METRx® II System

Decompression

In preparation for a spinal stenosis procedure, insert the appropriate size METRx® II System Tube as described in earlier steps of the technique. 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 Curettes or a right or left Ball Tip Dissector **(Figure 11)**. The ligamentum is then resected with a 90° or 40° Kerrison Punch **(Figure 12)**. 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 13)**. 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 14)**. 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 15)**.

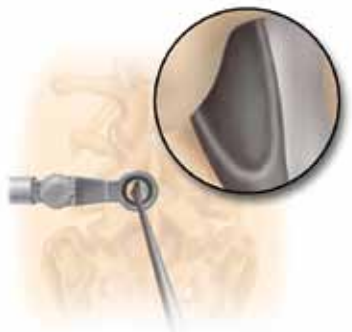


Figure 11

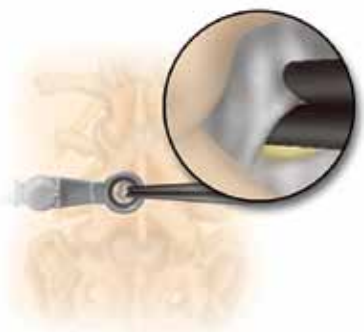


Figure 12

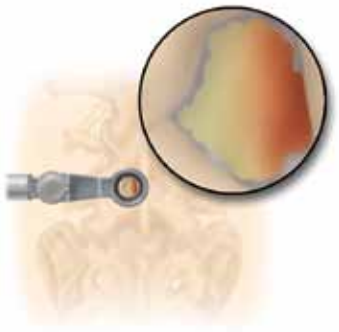


Figure 13

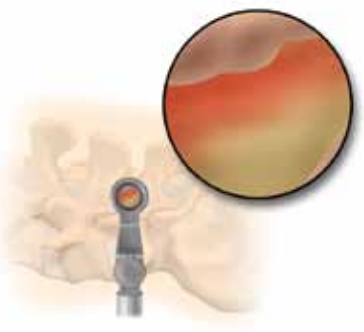


Figure 14

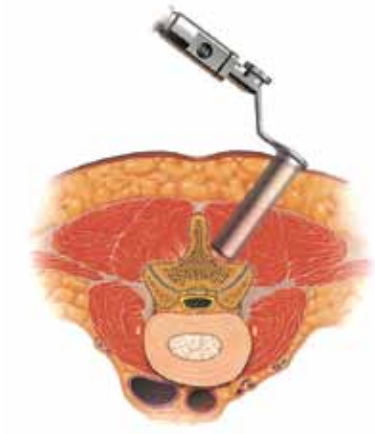


Figure 15

Contralateral Decompression from an Ipsilateral Approach

As an alternative to contralateral decompression from the contralateral side, an ipsilateral approach to contralateral decompression can be used. After completion of the ipsilateral decompression, the Tubular Retractor is angled medially to expose the anterior spinous process. A drill can then be used to resect the anterior spinous process and the medial aspect of the contralateral lamina **(Figure 16)**. This exposes the contralateral hypertrophied ligamentum flavum, which can then be resected using Kerrison Punches and Curettes **(Figures 17a, 17b and 17c)**. 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 18)**.

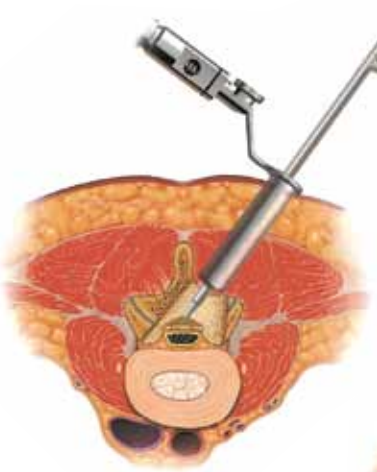


Figure 16

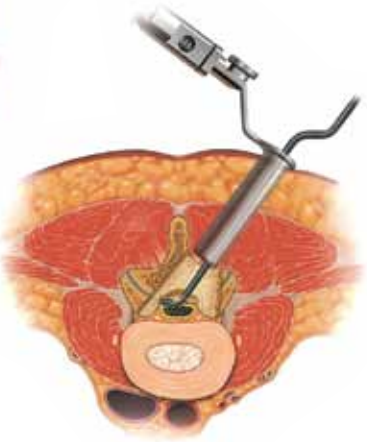


Figure 17a

Figure 17b

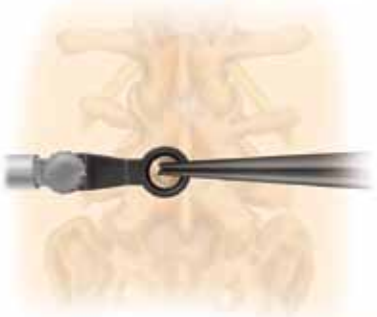


Figure 17c

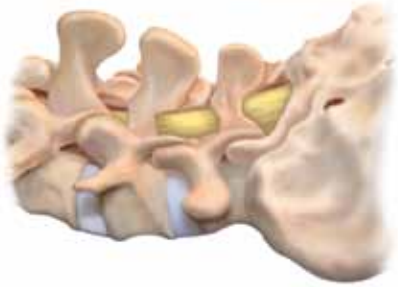


Figure 18

See Preliminary Steps: Targeting information on page 20 for steps that precede this technique.

Discectomy using the METRx® II System

Soft Tissue Removal and Laminar 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 laminar edge is identified and the ligmentum flavum is detached from the undersurface of the lamina with a small Angled Curette **(Figure 19)**.

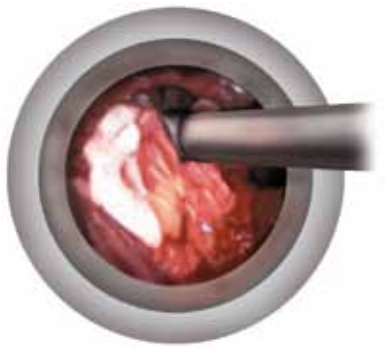


Figure 19

Laminar and Interlaminar Space Identification

A hemilaminotomy/medial facetectomy is then performed with a Kerrison Punch or high-speed drill **(Figure 20)**. 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.

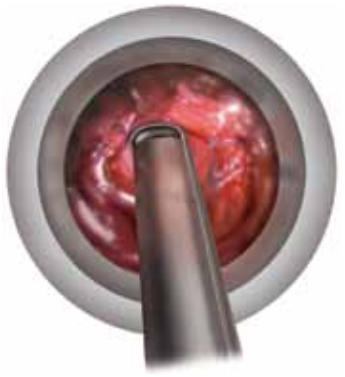


Figure 20

Figure 21

Ligamentum Flavum Removal

The ligament is penetrated with the Curette or Ball Probe using a twisting motion under the remaining superior lamina where the ligament is thin **(Figure 21)**. It is peeled back caudally and dorsally, then resected with a Kerrison Punch **(Figure 22)**.

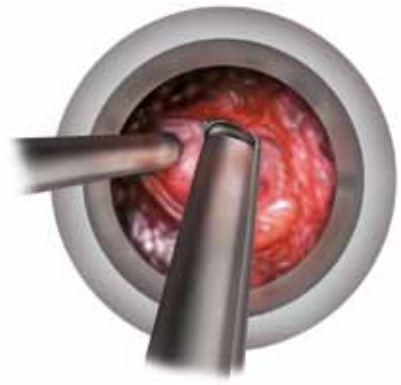


Figure 22

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 23 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 23)**. The volar epidural space can then be explored. If necessary, epidural veins can be cauterized with Bipolar Forceps and divided with micro scissors **(Figure 24)**. Cotton patties can also be used to obtain hemostasis.

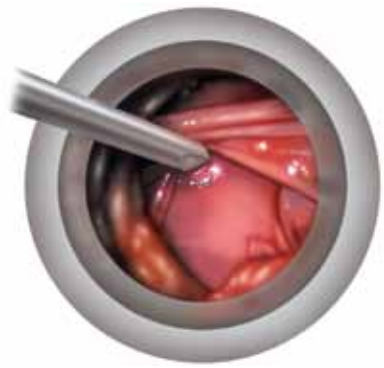


Figure 23

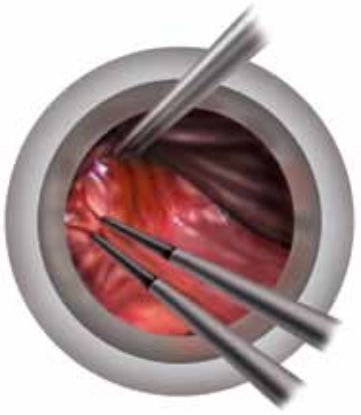


Figure 24

Discectomy and Closure

Identify the disc herniation. If an annulotomy is necessary, it can be accomplished with the Annulotomy Knife while protecting the nerve root with the Retractor. The herniated disc is then removed with a Pituitary Rongeur in a standard fashion **(Figure 25)**. 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.

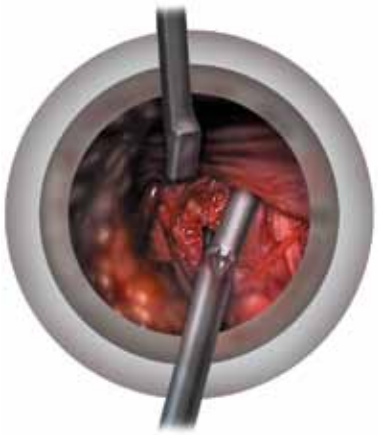


Figure 25

See Preliminary Steps: Targeting information on page 20 for steps that precede this technique.

TLIF using the METRx® II System

Soft Tissue Dilation and Bony Exposure

In a TLIF procedure, a 22mm or 26mm diameter METRx® II Tube is used to access the ipsilateral side following tissue dilation. Once the Tube is positioned, remove the superior and inferior facets 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 26, 27, and 28)**.

Figure 26

Figure 27

Disc Removal

Incise the disc space with a scalpel and begin disc removal using a Pituitary Rongeur **(Figure 29)**. Continue disc removal using either the Straight or Curved Rotating Cutters. The Rotating Cutters are blunt tipped and side cutting to ensure safety **(Figure 30)**. A T-handle or a handheld power drill may be used for more efficient removal of disc.

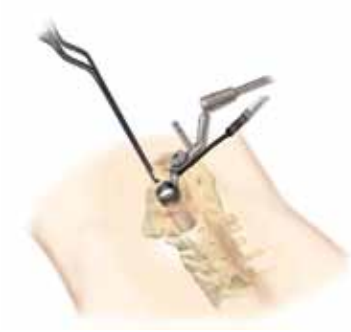


Figure 28

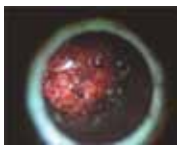


Figure 29

Implantation Steps

For Contralateral Screw Insertion, Restoration of Disc Height, Endplate Preparation, Interbody Construct Insertion, Compression and Ipsilateral Screw Insertion steps please refer to the CD HORIZON® SEXTANT® II PERCUTANEOUS PEEK Rod Insertion System surgical technique or the MAST QUADRANT™ Retractor System surgical technique. For end plate preparation and interbody construct insertion, please refer to one of our many interbody fusion device system surgical techniques.

Figure 30

See Preliminary Steps: Targeting information on page 20 for steps that precede this technique.

PLIF using the METRx® II 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 the paraspinous musculature 2cm – 2.5cm off of the midline at the appropriate level and confirmed using lateral fluoroscopy (Figure 31).

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

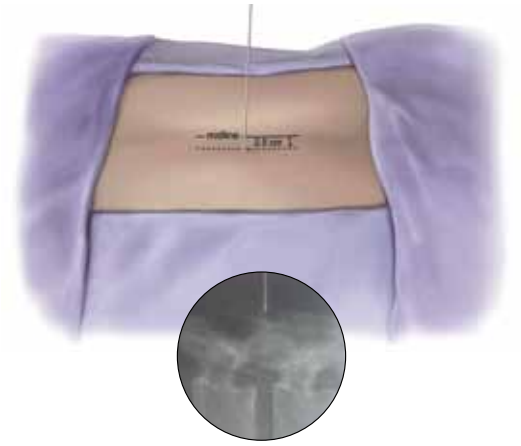


Figure 31

Dilation/Tubular Retraction

Insert initial cannulated soft tissue Dilator over the Guidewire. Once the fascia is penetrated, remove the Guidewire and advance the Dilator over the facet. Confirm the placement of the initial Dilator using lateral fluoroscopy. The next series of dilators are sequentially placed over each other. The optimum tubular retractor is placed over the sequential dilators and placed firmly on the bony anatomy.

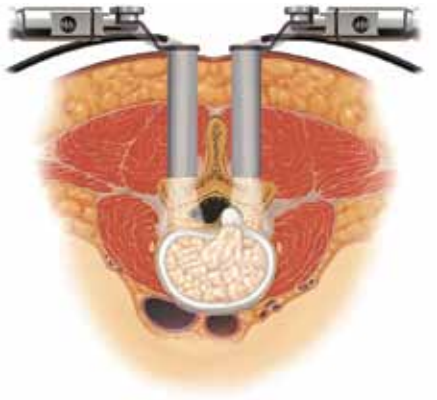


Figure 32

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 (Figure 32).

Implantation Steps

For Disc Space Distraction, Disc Space Preparation, Endplate Preparation, Wedge Insertion please refer to the CD HORIZON® SEXTANT® II PERCUTANEOUS PEEK Rod Insertion System surgical technique or the MAST QUADRANT™ Retractor System surgical technique. For end plate preparation and interbody construct insertion, please refer to one of our many interbody fusion device system surgical techniques.

See Preliminary Steps: Targeting information on page 20 for steps that precede this technique.

Posterior Cervical Foraminotomy using the METRx® II System

Patient Positioning and Room Set-up

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

Anatomic Location—Cervical Spine

Patient Position

The patient is placed in a Mayfield pin holder with 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 **(Figure 33)**. Generally, the fluoroscope will come in from the surgeon's right, the surgeon being seated directly at the patient's head. When the Tubular Retractor is safely docked in operating position, the fluoroscope can be moved to allow the microscope to be brought in.

Figure 33

Guidewire Insertion

A 20-gauge Spinal Needle is inserted into the paraspinous musculature approximately 1cm to 2cm off of the 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 34)**. 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.

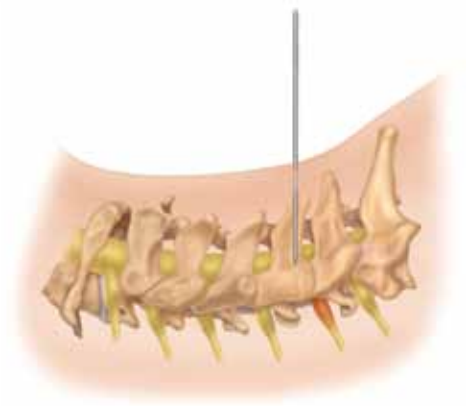


Figure 34

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 35)**.

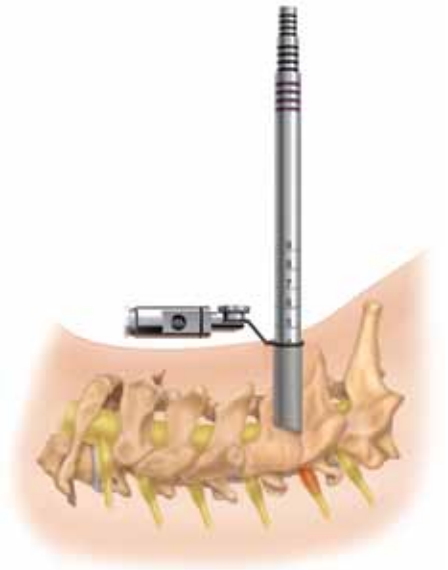


Figure 35

Soft Tissue Removal and Lamina Identification

The soft tissue over the lamina and intralaminar space is removed with an extended Bovie on low power and Pituitary Rongeurs **(Figure 36)**. If the Tube is correctly positioned, the junction of the two lamina with the medial facet should be seen in the Tube **(Figure 37)**. 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 38)**. The bony work should continue until each pedicle is exposed.

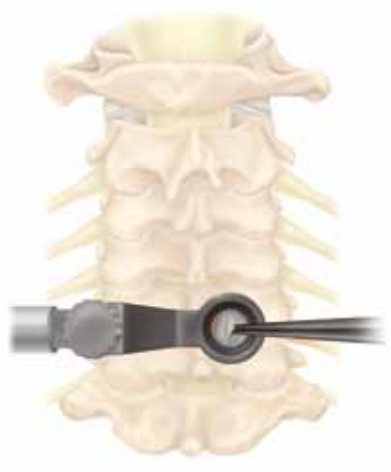


Figure 36

Figure 37

Cervical Root Identification and Disc Removal

With bipedicular 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 39)**. The disc will frequently be seen in this location. The Bayoneted Knife 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.

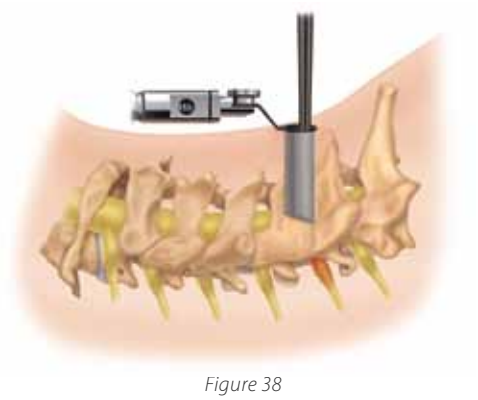


Figure 38

Closure

After the root is decompressed, the 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. Dermabond is also frequently used.

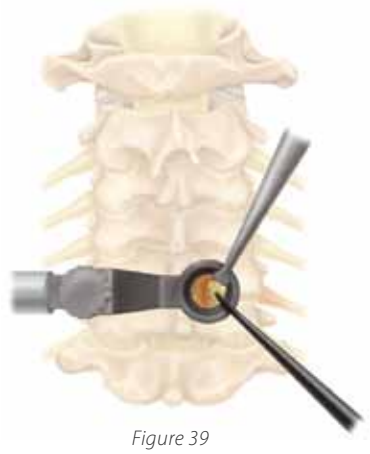


Figure 39

METRx® I and II System Part Number Cross Reference

METRx® II System Disposables

Item Number	Description	METRx® I System Item Number
9569813	Disposable 18mm × 3cm Angled Tube	9561813
9569814	Disposable 18mm × 4cm Angled Tube	9561814
9569815	Disposable 18mm × 5cm Angled Tube	9561815
9569816	Disposable 18mm × 6cm Angled Tube	9561816
9569817	Disposable 18mm × 7cm Angled Tube	9561817
9569818	Disposable 18mm × 8cm Angled Tube	9561818
9569819	Disposable 18mm × 9cm Angled Tube	9561819
9560703	Disposable 22mm × 3cm Tube	9560703
9560704	Disposable 22mm × 4cm Tube	9560704
9560705	Disposable 22mm × 5cm Tube	9560705
9560706	Disposable 22mm × 6cm Tube	9560706
9560707	Disposable 22mm × 7cm Tube	9560707
9560708	Disposable 22mm × 8cm Tube	9560708
9560709	Disposable 22mm × 9cm Tube	9560709
9562613	Disposable 26mm × 3cm Tube	9562613
9562614	Disposable 26mm × 4cm Tube	9562614
9562615	Disposable 26mm × 5cm Tube	9562615
9562616	Disposable 26mm × 6cm Tube	9562616
9562617	Disposable 26mm × 7cm Tube	9562617
9562618	Disposable 26mm × 8cm Tube	9562618
9562619	Disposable 26mm × 9cm Tube	9562619
9560802	METRx® Radiance Illumination System (18mm)	9560802
9560702	METRx® Radiance Illumination System (22mm)	9560702
9560757	METRx® Radiance Illumination System (26mm)	9560757
1571-00	Sheathed Knife Blade	9560551
9560575	Bayoneted Bovie	9569575
1564-00	Bayoneted Discectomy Knife	9560659

METRx® I and II System Part Number Cross Reference *Continued*

METRx® II System Non-Disposables

Item Number	Description	METRx® I System Item Number
9569530	Outer Case, Flex Arm	–
9569529	Dilators Tray	–
955-519	METRx® Guidewire	955-519
9560420	METRx® Dilator 5.3mm	9560420
9560421	METRx® Dilator 9.4mm	9560421
9561426	METRx® Dilator 12.8mm	9561426
9561427	METRx® Dilator 14.6mm	9561427
9561428	METRx® Dilator 16.8mm	9561428
9560429	METRx® Dilator 18.8mm	9560429
9560430	METRx® Dilator 20.8mm	9560430
9560431	METRx® Dilator 22.8mm	9560431
9560432	METRx® Dilator 24.8mm	9560432
9561523	Bed Rail Clamp	9561523
9569532	Flex Arm Tray	–
9561524	Flexible Arm	9560524
9561525	Self Retaining Nerve Root Retractor	9561525
9561526	Self Retaining Nerve Root Retractor Post	9561526
9569694	Outer Case, Lid	–
9569796	Outer Case, Non-Disposable Tubes	–
	Tube Tray 1	–
9569667	Tube Caddy, 14mm	–
9569660	14mm × 3cm Coated/Angled Tube	9561660
9569661	14mm × 4cm Coated/Angled Tube	9561661
9569662	14mm × 5cm Coated/Angled Tube	9561662
9569663	14mm × 6cm Coated/Angled Tube	9561663
9569664	14mm × 7cm Coated/Angled Tube	9561664
9569665	14mm × 8cm Coated/Angled Tube	9561665
9569666	14mm × 9cm Coated/Angled Tube	9561666
9569677	Tube Caddy, 16mm	–
9569670	16mm × 3cm Coated/Angled Tube	9561670
9569671	16mm × 4cm Coated/Angled Tube	9561671
9569672	16mm × 5cm Coated/Angled Tube	9561672
9569673	16mm × 6cm Coated/Angled Tube	9561673
9569674	16mm × 7cm Coated/Angled Tube	9561674
9569675	16mm × 8cm Coated/Angled Tube	9561675
9569676	16mm × 9cm Coated/Angled Tube	9561676
9569687	Tube Caddy, 18mm	–
9569680	18mm × 3cm Coated/Angled Tube	9561680
9569681	18mm × 4cm Coated/Angled Tube	9561681
9569682	18mm × 5cm Coated/Angled Tube	9561682
9569683	18mm × 6cm Coated/Angled Tube	9561683
9569684	18mm × 7cm Coated/Angled Tube	9561684
9569685	18mm × 8cm Coated/Angled Tube	9561685
9569686	18mm × 9cm Coated/Angled Tube	9561686

METRx® I and II System Part Number Cross Reference *Continued*

METRx® II System Non-Disposables *Continued*

Item Number	Description	METRx® I System Item Number
9569727	Tube Caddy, 20mm	–
9569720	20mm × 3cm Coated/Angled Tube	9560720
9569721	20mm × 4cm Coated/Angled Tube	9560721
9569722	20mm × 5cm Coated/Angled Tube	9560722
9569723	20mm × 6cm Coated/Angled Tube	9560723
9569724	20mm × 7cm Coated/Angled Tube	9560724
9569725	20mm × 8cm Coated/Angled Tube	9560725
9569726	20mm × 9cm Coated/Angled Tube	9560726
9569798	Tube Tray 2	–
9569737	Tube Caddy, 22mm	–
9569730	22mm × 3cm Coated Tube	9560730
9569731	22mm × 4cm Coated Tube	9560731
9569732	22mm × 5cm Coated Tube	9560732
9569733	22mm × 6cm Coated Tube	9560733
9569734	22mm × 7cm Coated Tube	9560734
9569735	22mm × 8cm Coated Tube	9560735
9569736	22mm × 9cm Coated Tube	9560736
9569757	Tube Caddy, 26mm	–
9569750	26mm × 3cm Coated Tube	9560750
9569751	26mm × 4cm Coated Tube	9560751
9569752	26mm × 5cm Coated Tube	9560752
9569753	26mm × 6cm Coated Tube	9560753
9569754	26mm × 7cm Coated Tube	9560754
9569755	26mm × 8cm Coated Tube	9560755
9569756	26mm × 9cm Coated Tube	9560756
9569694	Outer Case, Lid	–

METRx® I and II System Part Number Cross Reference *Continued*

METRx® II System Non-Disposables *Continued*

Item Number	Description	METRx® I System Item Number
9569790	Outer Case, Instruments	–
9569791	Instrument Tray 1	–
9560691	Micro Scissors	9560691
9569568	Curved Scissors	9560568
9569564	2mm Upbiting Pituitary	9560564
9569565	2mm Micropituitary	9560565
9569566	2mm Pituitary with Tooth	9560566
9569567	2mm Upbiting Micropituitary	9560567
9569569	2mm Downbiting Pituitary	9560569
9569570	4mm Upbiting Pituitary	9560570
9569536	4mm Pituitary, Ring Handle	9560536
9569525	4mm Pituitary Rongeur	New
9569792	Instrument Tray 2	–
9569623	Bayoneted Curette, 1.8mm, Straight	9560623
9569631	Bayoneted Curette, 1.8mm, Reverse	9560631
9569627	Bayoneted Curette, 1.8mm, Angled	9560627
9569621	Bayoneted Curette, 3.6mm, Straight	9560621
9569629	Bayoneted Curette, 3.6mm, Reverse	9560629
9569625	Bayoneted Curette, 3.6mm, Angled	9560625
9569620	Bayoneted Curette, 5.2mm, Straight	9560620
9569628	Bayoneted Curette, 5.2mm, Reverse	9560628
9569624	Bayoneted Curette, 5.2mm, Angled	9560624
9569793	Instrument Tray 3	–
9560535	Sucker #8	9560535
9560534	Sucker #10	9560534
9569559	Sucker #12	New
9560561	Suction Retractor	9560561
9569560	Wide Suction Retractor	New
9569954	Nerve Root Retractor	9560555
9569571	Angled Bipolar Forceps, U.S. Connection	9560571
9569572	Straight Bipolar Forceps, U.S. Connection	9560572
9569574	Angled Bipolar, U.S. Short/Fine	9560574
9569690	Short/Finer Straight Bipolar, Forceps	9560690
9569600	Bayoneted Kerrison, 1mm, 40°	9560600
9569601	Bayoneted Kerrison, 1mm, 90°	9560601
9569602	Bayoneted Kerrison, 2mm, 40°	9560602
9569603	Bayoneted Kerrison, 2mm, 90°	9560603
9569794	Instrument Tray 4	–
9560693	Straight Bipolar Forceps Spool	9560693
9560573	Bi Polar Cable, U.S. Connection	9560573
9569604	Bayoneted Kerrison, 3mm, 40°	9560604
9569605	Bayoneted Kerrison, 3mm, 90°	9560605
9569606	Bayoneted Kerrison, 4mm, 40°	9560606
9569607	Bayoneted Kerrison, 4mm, 90°	9560607
9569608	Bayoneted Kerrison, 5mm, 40°	9560608
9569609	Bayoneted Kerrison, 5mm, 90°	9560609

METRx® I and II System Part Number Cross Reference *Continued*

METRx® II System Non-Disposables *Continued*

Item Number	Description	METRx® I System Item Number
9569795	Instrument Tray 5	–
9569640	Bayoneted Woodsen, Probe	9560640
9569641	Bayoneted Ball Probe, Short Right	9560641
9569642	Bayoneted Ball Probe, Short Straight	9560642
9569643	Bayoneted Ball Probe, Short Left	9560643
9569644	Bayoneted Ball Probe, Long Right	9560644
9569645	Bayoneted Ball Probe, Long Straight	9560645
9569646	Bayoneted Ball Probe, Long Left	9560646
9569647	Bayoneted Penfield #2, Push/Pull	(Push 9560647) (Pull 9560648)
9569649	Bayoneted Penfield #4, Push/Pull	(Push 9560649) (Pull 9560650)
9569639	Bayoneted Penfield #7, Push/Pull	(Push 9560687) (Pull 9560639)
9569651	Bayoneted Nerve Hook, Right	9560651
9569652	Bayoneted Nerve Hook, Straight	9560652
9569653	Bayoneted Nerve Hook, Left	9560653
9569654	Bayoneted Dissector, Right	9560654
9569655	Bayoneted Dissector, Straight	9560655
9569656	Bayoneted Dissector, Left	9560656
9569689	Microbayoneted Nerve Hook, Right	9560689
9569638	Microbayoneted Nerve Hook, Straight	9560638
9569688	Microbayoneted Nerve Hook, Left	9560688
9569694	Outer Case, Lid	–

METRx™ MICROSCOPE 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.

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).

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.

!USA 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 onto 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		Sterilization parameters	
Temperature:	55 ± 2° C	**Ethylene Oxide Carrier:**	Oxyfume 2002
Relative Humidity:	≥ 35%	**Temperature:**	55 ± 2° C
Vacuum:	21 ± 1 In Hg (508-559mm Hg)	**Relative Humidity:**	≥ 35%
Preconditioning time:	1 Hour	**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 Medtronic or your Sales Representative.

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Important Information for Medtronic Instruments

PURPOSE:

This instrument is intended for use in surgical procedures.

DESCRIPTION:

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

Intended Use:

This instrument is a precision device which may incorporate a measuring function and has uses as described on the label.

Unless labeled for single use, this instrument may be re-used.

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

WARNINGS:

The methods of use of instruments are to be determined by the user's experience and training in surgical procedures.

Do not use this instrument for any action for which it was not intended such as hammering, prying, or lifting.

This instrument should be treated as any precision instrument and should be carefully placed on trays, cleaned after each use, and stored in a dry environment.

To avoid injury, the instrument should be carefully examined prior to use for functionality or damage. A damaged instrument should not be used. Additional back-up instruments should be available in case of an unexpected need.

MEDTRONIC 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. See the MSD catalog for further information about warranties and limitations of liability.

DO NOT IMPLANT THE INSTRUMENTS.

POSSIBLE ADVERSE EFFECTS:

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

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

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

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

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

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

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

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

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

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

!USA For US Audiences Only

CAUTION: FEDERAL (U.S.) LAW RESTRICTS THESE DEVICESTO 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.

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

OTHER COMPLICATIONS TO THE PATIENT AND/OR HOSPITAL STAFF MAY INCLUDE, BUT ARE NOT LIMITED TO:

1. Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs or joints.
2. Breakage of the device, which could make necessary removal difficult or sometimes impossible, with possible consequences of late infection and migration. Breakage could cause injury to the patient or hospital staff.
3. Infection, if instruments are not properly cleaned and sterilized.
4. Pain, discomfort, or abnormal sensations resulting from the presence of the device.
5. Nerve damage due to surgical trauma.
6. Dural leak in cases of excessive load application.
7. Impingement of close vessels, nerves and organs by slippage or misplacement of the instrument.
8. Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.
9. Cutting of skin or gloves of operating staff.
10. Bony fracture, in cases of deformed spine or weak bone.
11. Tissue damage to the patient, physical injury to operating staff and/or increased operating time that may result from the disassembly of multi-component instruments occurring during surgery.

OTHER PRECAUTIONS:

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

DEVICE FIXATION:

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

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

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

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

PACKAGING:

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

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

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

EXAMINATION:

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

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

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

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened Medtronic package, all instruments must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic. 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 the set 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.

Important Information for Medtronic Instruments *Continued*

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

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

OPERATIVE USE:

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

REMOVAL OF IMPLANTS:

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

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

FURTHER INFORMATION:

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

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PRODUCT COMPLAINT:

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

Notes

www.medtronic.com

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For more information visit
www.myspinetools.com

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

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

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