

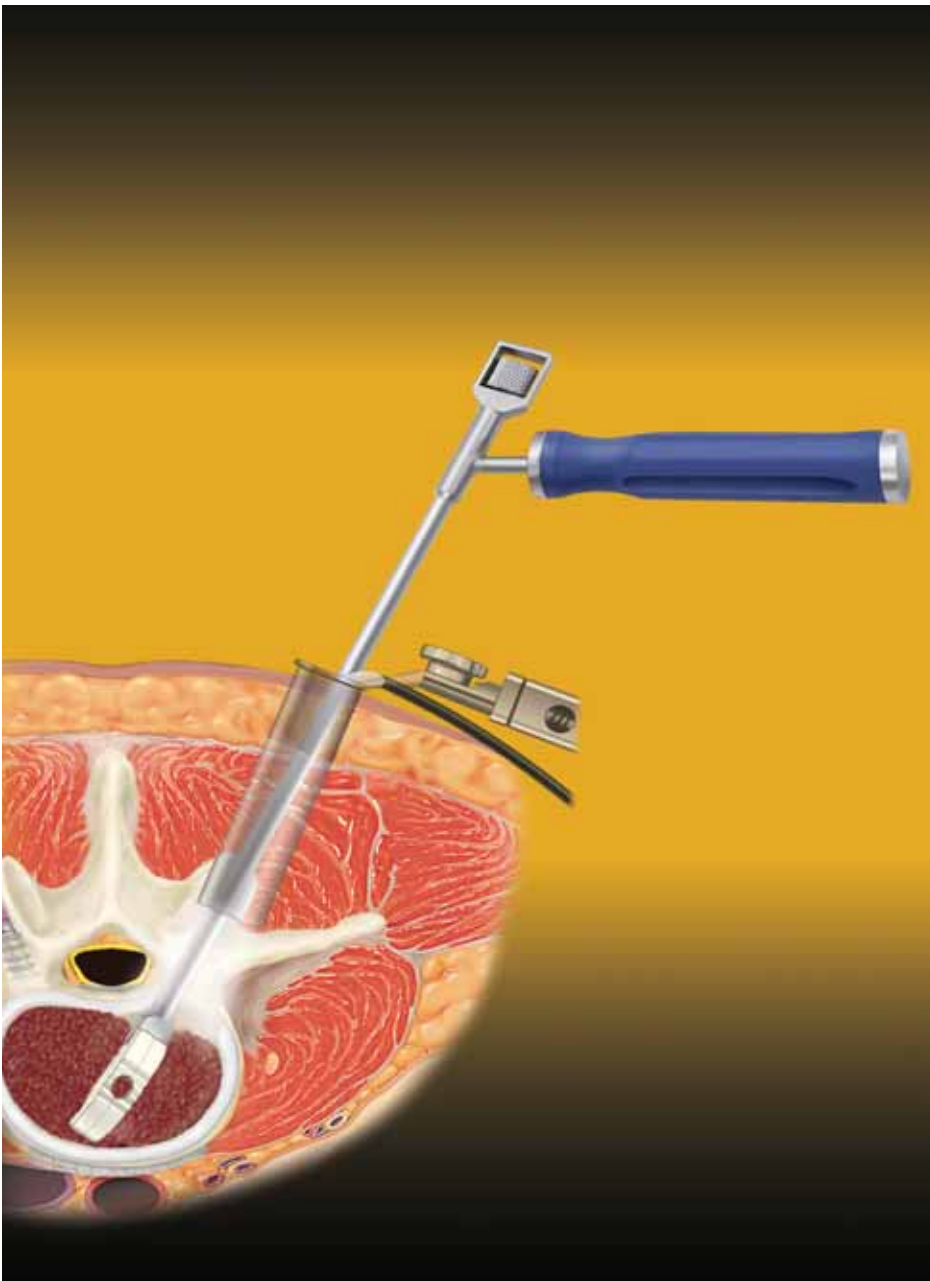


Medtronic

SOFAMOR DANEK

CAPSTONE[®]

Instrument Set Technique



as described by:

Charles Branch, Jr., M.D.
Wake Forest University
Baptist Medical Center
Winston-Salem,
North Carolina

Kevin Foley, M.D.
Semmes-Murphey Clinic
Neurologic & Spine Institute
Memphis, Tennessee

Anthony Salerni, M.D.
Neurosurgery
Lakes Regional Hospital
Laconia, New Hampshire



THE MOST VERSATILE INNOVATION IN INTERBODY INSTRUMENTATION

Versatile Design

- Bilateral or unilateral procedural solutions combining CAPSTONE® Instruments, METRx™ Tube, PYRAMETRIX® Advance Instruments, and CD HORIZON® SEXTANT® Rod Insertion System
- Open, mini-open or MAST™ approaches
- Bullet shape distractor/trials for self-distraction and easier insertion
- Convex shape trials better match patient anatomy and allow more accurate sizing
- Simple five-step procedure (bony resection, distraction, disc space prep, trial and insertion of construct)

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INSTRUMENTS



Distractor
2980822



Distractor
2981032



Inserter
2980001

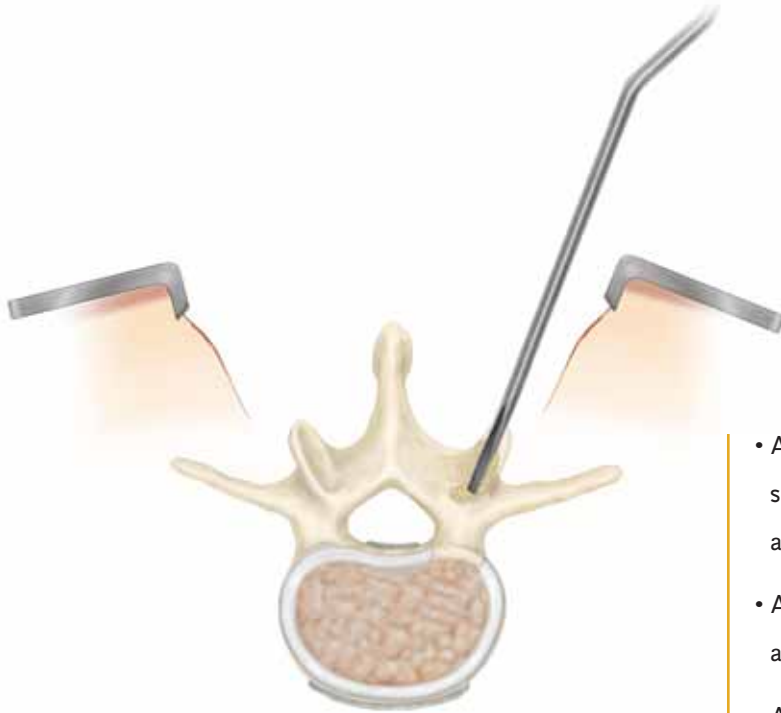


Slap Hammer
9074002

UNILATERAL TECHNIQUE

OPEN AND MAST™

Laminotomy, Facetectomy and Discectomy

UNILATERAL OPEN
TECHNIQUE

- A facetectomy is performed on the ipsilateral side. Using an Osteotome or drill, remove the ascending and descending articular processes.
- Additional bony removal may be carried out using a Kerrison Rongeur or drill.
- A 1cm square annulotomy is made with a scalpel in Kambin's triangle. Disc is removed using a Pituitary Rongeur and Curettes.



Discectomy

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

UNILATERAL MAST™
TECHNIQUE

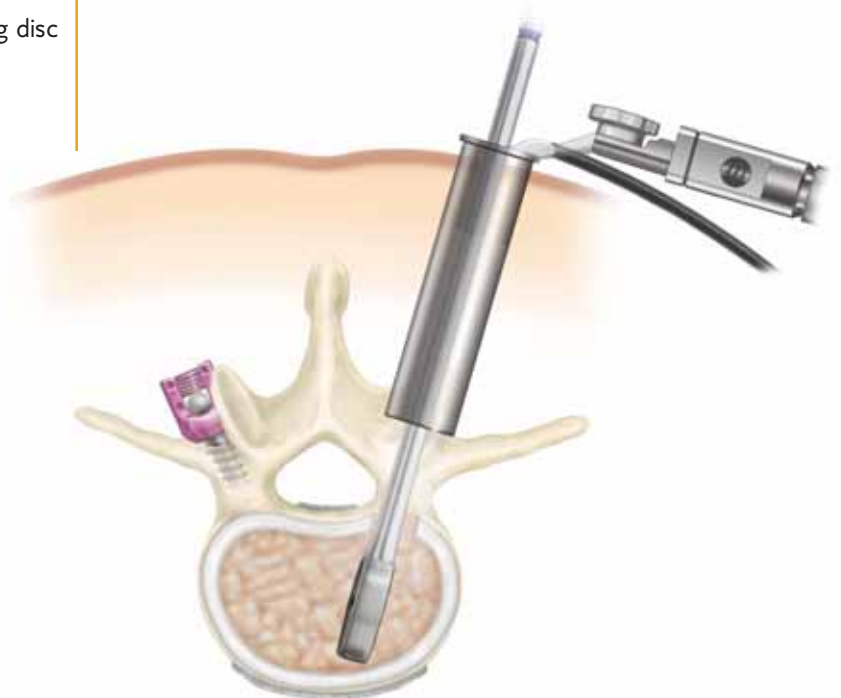
UNILATERAL OPEN TECHNIQUE



The disc space is sequentially distracted until adequate disc space height is obtained and adequate foraminal size is restored.

- Insert the Distractor with the curved sides touching the endplates.
- Sequentially insert Distractors until the desired height is obtained.
- Insert supplemental screw and rod fixation on contralateral side to maintain distraction during disc space preparation.
- Provisionally tighten construct.

Distraction



UNILATERAL MAST™ TECHNIQUE

Disc Space Preparation

UNILATERAL OPEN
TECHNIQUE

Remove disc using either the Straight or Curved Rotating Cutters. The Rotating Cutters are blunt tipped and side cutting to improve safety. A T-handle or a handheld power drill may be used for more efficient removal of disc.

UNILATERAL MAST™
TECHNIQUE

UNILATERAL OPEN TECHNIQUE

Endplate Preparation

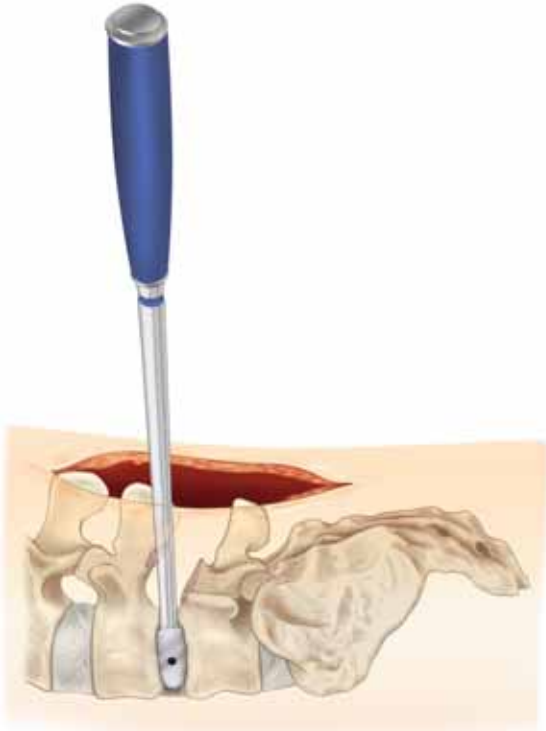


- Specifically designed angled instruments allow disc resection and endplate preparation.

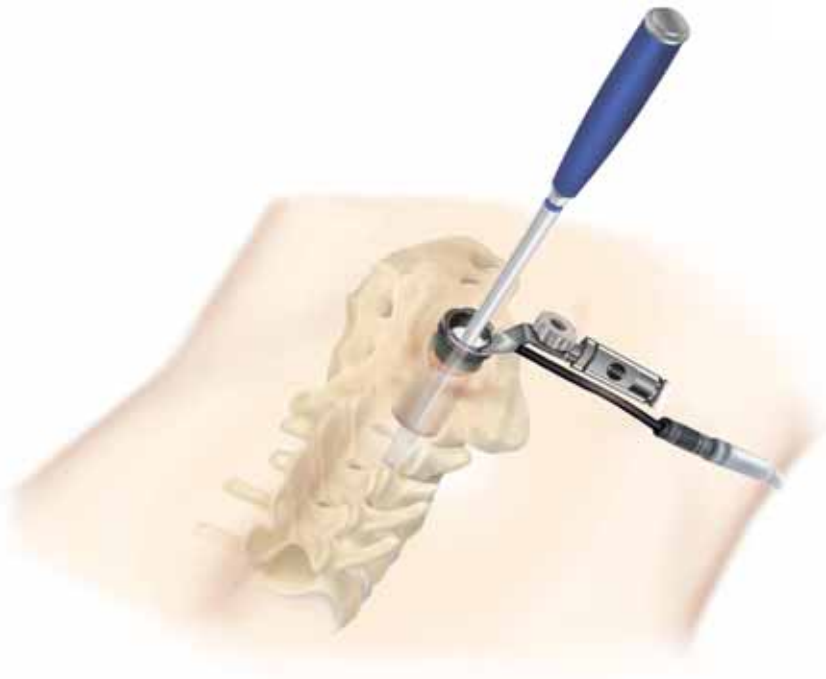


UNILATERAL MAST™ TECHNIQUE

Trial Insertion

UNILATERAL OPEN
TECHNIQUE

Insert trial until desired disc space height is established. Use A/P and lateral fluoroscopy to confirm proper placement and trajectory.

UNILATERAL MAST™
TECHNIQUE

UNILATERAL OPEN TECHNIQUE

Insert Construct



- The appropriate size construct is chosen from the trialing step.
- The appropriate size construct is firmly attached to the inserter.
- Before inserting the construct, place autograft anteriorly and contralaterally or in the bone construct central cavity.
- Gently impact the construct until it is 3 to 4mm below the posterior margin of annulus.
- Care should be taken to ensure the construct is aligned properly.

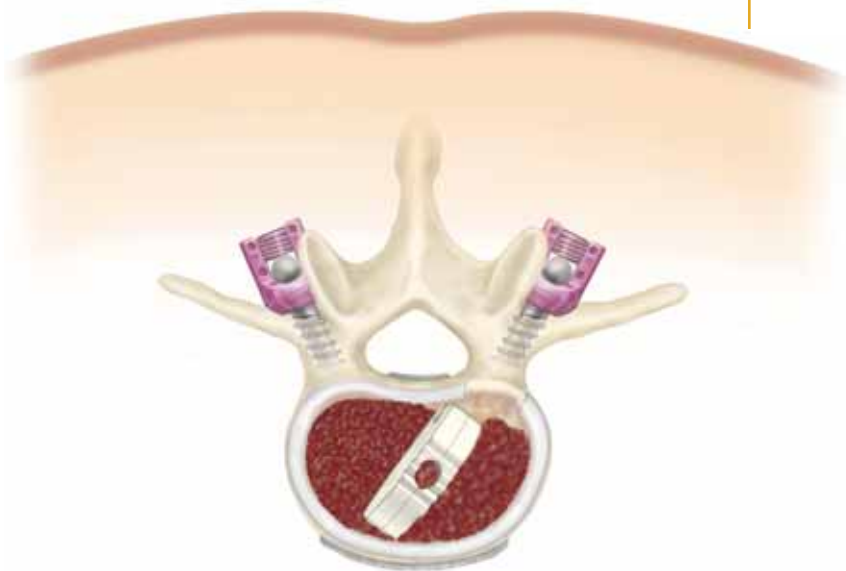


UNILATERAL MAST™ TECHNIQUE

Final Placement

UNILATERAL OPEN
TECHNIQUE

- After the final construct is placed, the contralateral screw-rod construct is compressed to preload interspace and restore lordosis. The extradural space and foramina are probed to ensure adequate decompression of the neural elements.
- To facilitate satisfactory immobilization of the grafted interspace, segmental internal fixation is applied ipsilaterally using standard technique.

UNILATERAL MAST™
TECHNIQUE

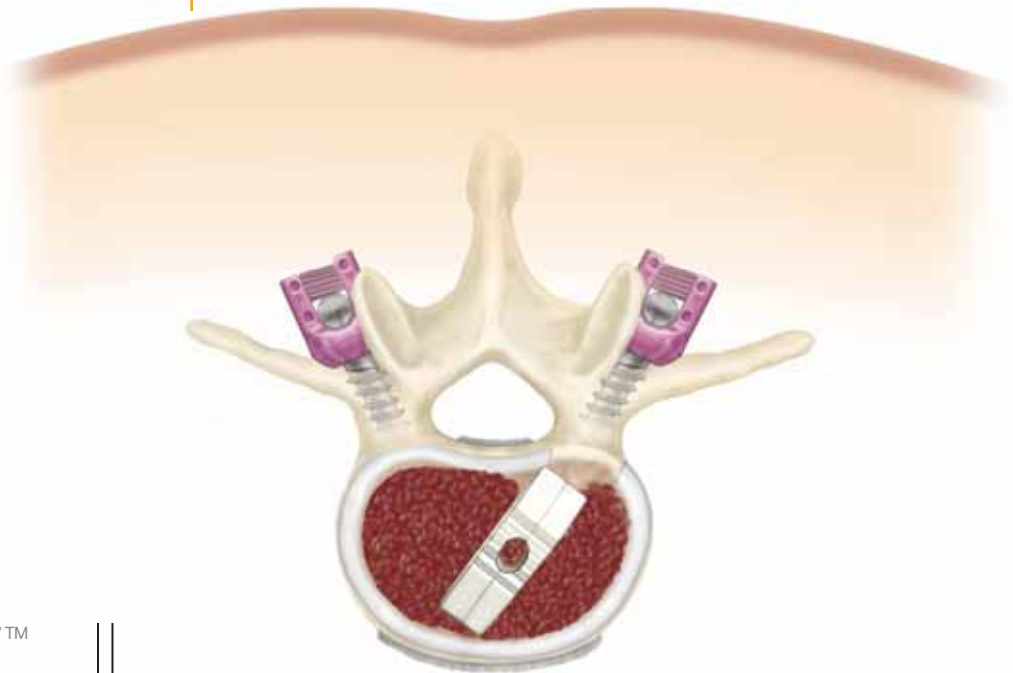
UNILATERAL OPEN TECHNIQUE

Additional Fixation Options



CD HORIZON® LEGACY™ 5.5
SPINAL SYSTEM

CD HORIZON® SEXTANT®
ROD INSERTION SYSTEM



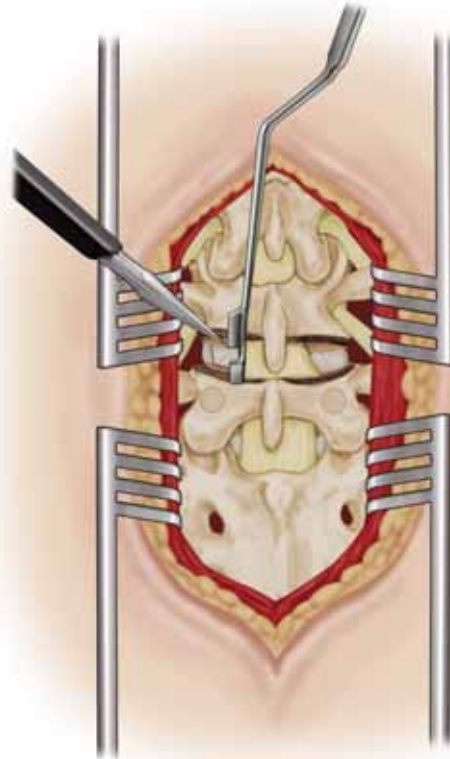
UNILATERAL MAST™ TECHNIQUE

BILATERAL TECHNIQUE

OPEN AND MAST™

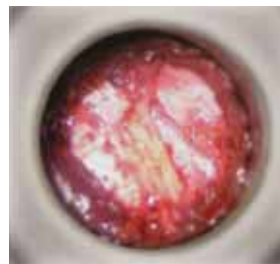
BILATERAL OPEN TECHNIQUE

Laminotomy, Facetectomy and Discectomy

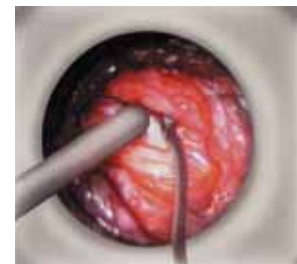


- A conventional discectomy is performed by incising the annulus with a 15-scalpel blade lateral to the dural sac.
- This is done bilaterally and then soft fragments from the intradiscal space or extruded fragments are removed with Disc Rongeurs in a conventional fashion.

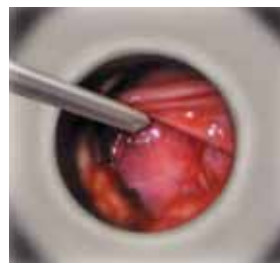
The main goal of this step is to remove extruded fragments, to decompress neural elements, and to provide entry to the disc space for distraction with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction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



Soft Tissue Removal



Ligamentum Flavum
Removal



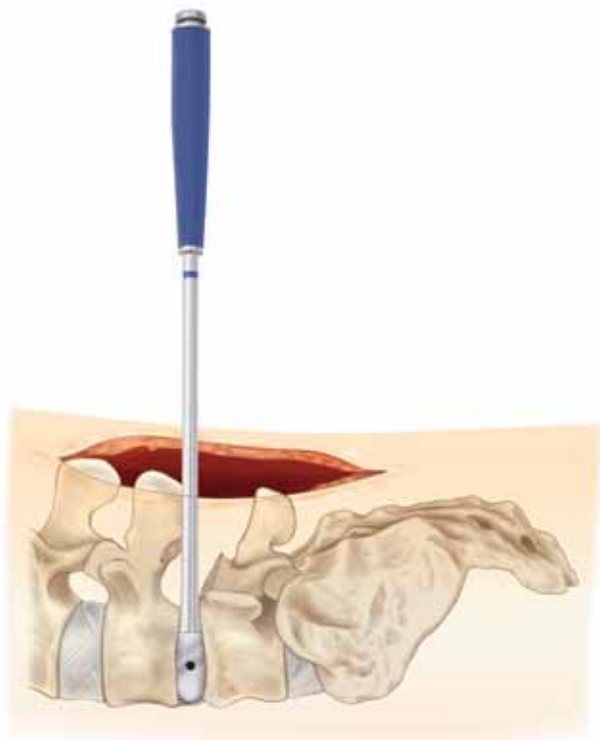
Nerve Root Retraction



Discectomy

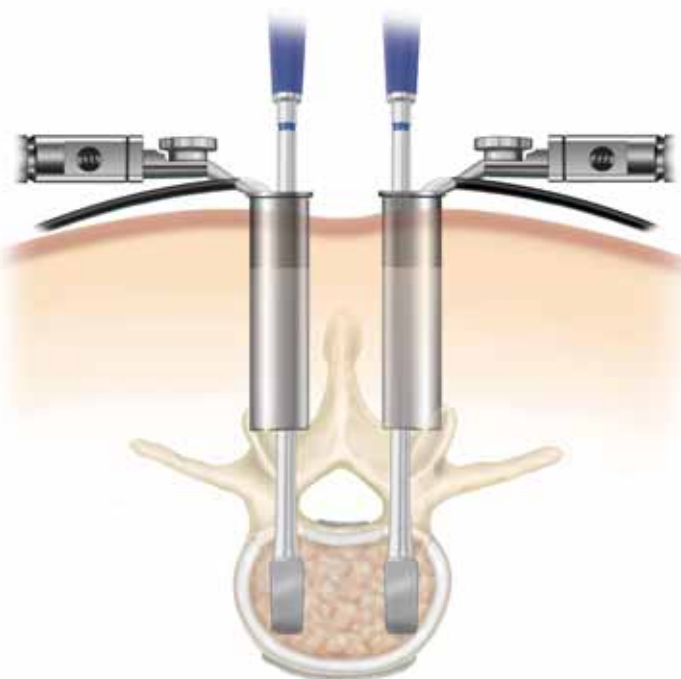
BILATERAL MAST™ TECHNIQUE

Distraction

BILATERAL OPEN
TECHNIQUE

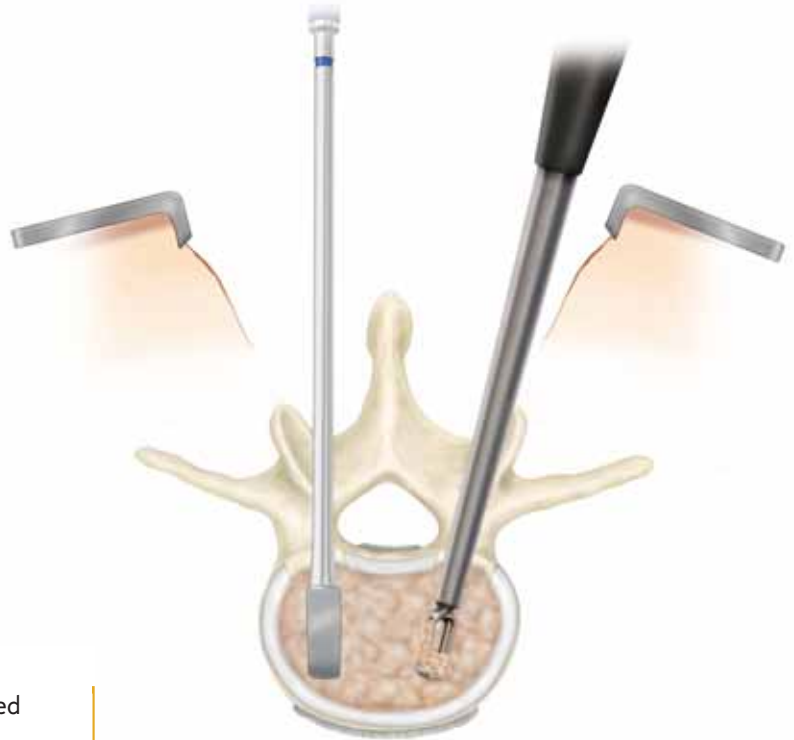
The disc space is sequentially distracted until original disc space height is obtained and normal foraminal opening is restored.

- Insert the Distractors with the curved sides touching the endplates.
- Sequentially insert Distractors until the desired height is obtained.

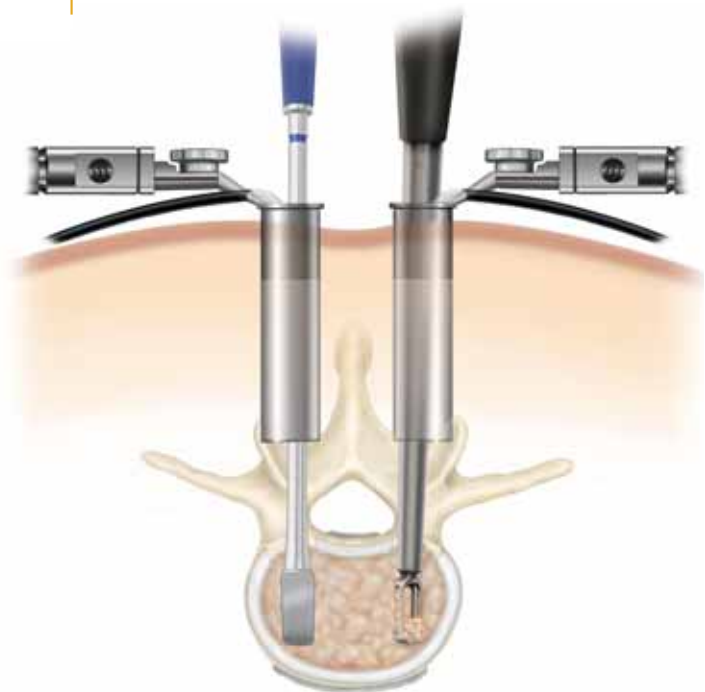
BILATERAL MAST™
TECHNIQUE

BILATERAL OPEN TECHNIQUE

Disc Space Preparation

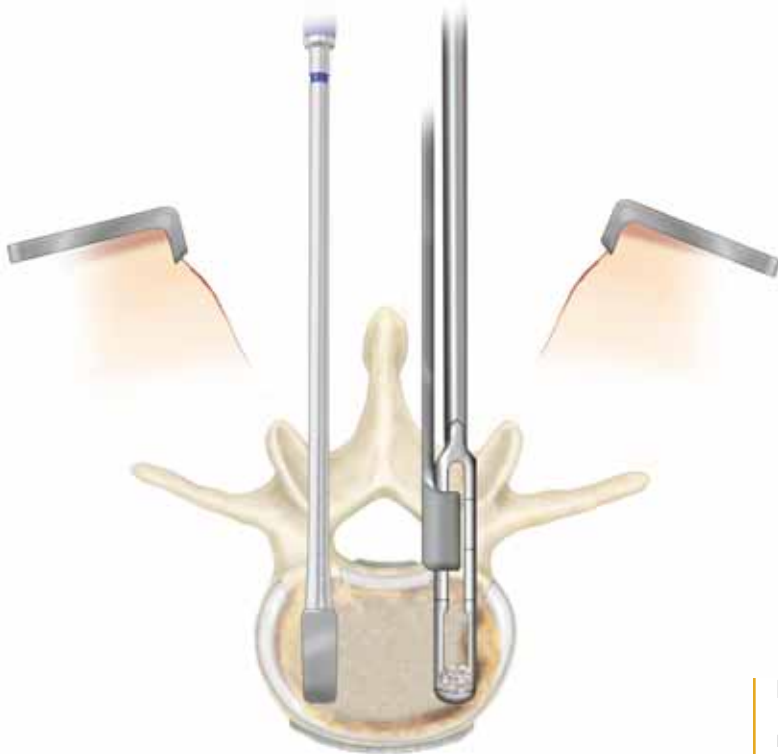


Remove disc using either the Straight or Curved Rotating Cutters. The Rotating Cutters are blunt tipped and side cutting to improve safety. A T-handle or a handheld power drill may be used for more efficient removal of disc.

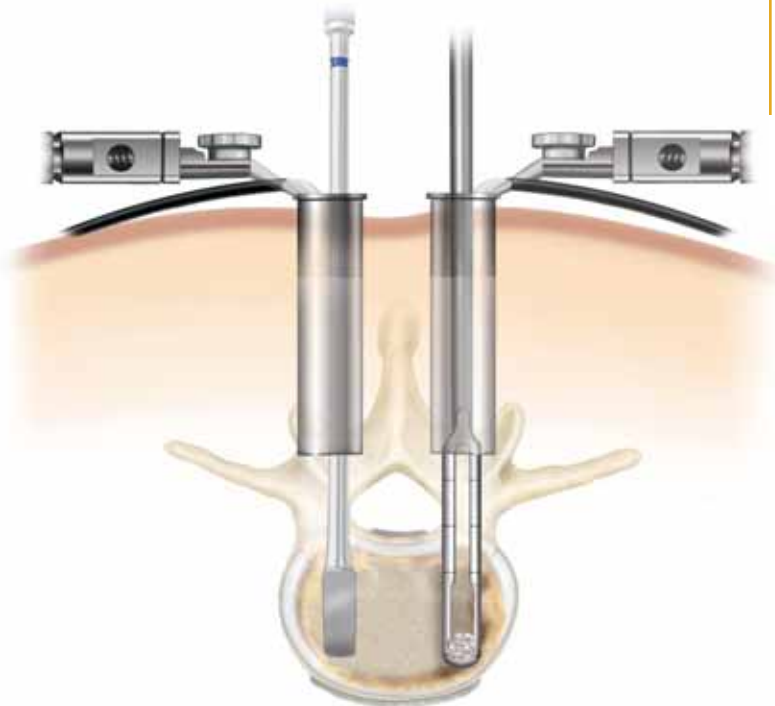


BILATERAL MAST™ TECHNIQUE

Endplate Preparation

BILATERAL OPEN
TECHNIQUE

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

BILATERAL MAST™
TECHNIQUE

BILATERAL OPEN TECHNIQUE

Trial Insertion

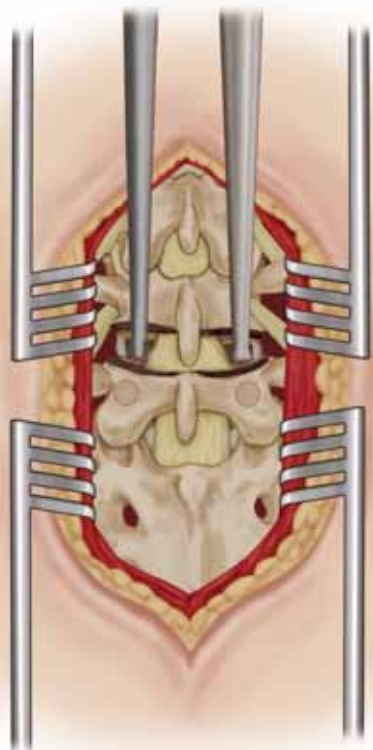
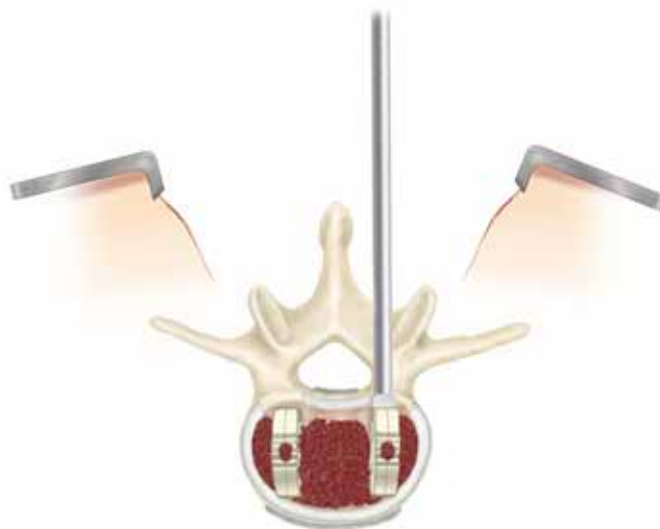


Insert trial until desired disc space height is established.

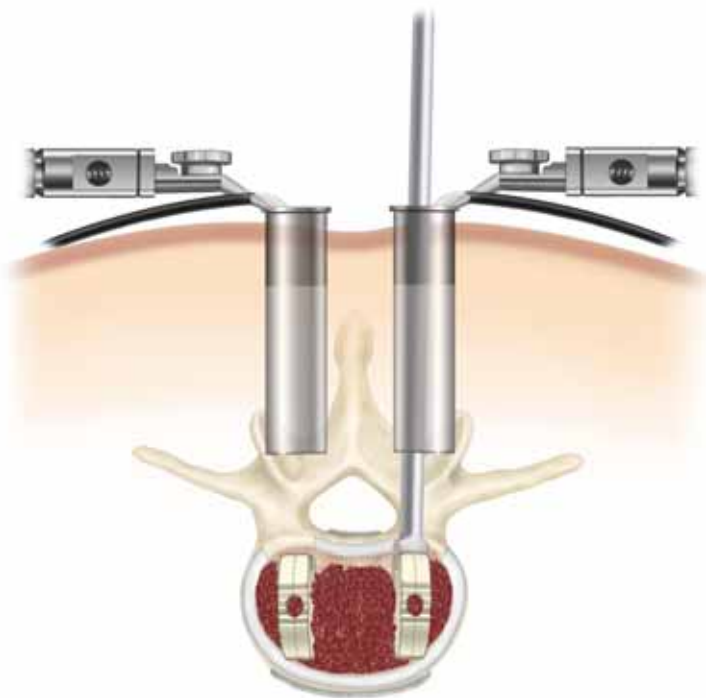


BILATERAL MAST™ TECHNIQUE

Insert Construct

BILATERAL OPEN
TECHNIQUE

- The appropriate size construct is chosen from the trialing step.
- The appropriate size construct is firmly attached to the inserter.
- Before inserting the construct, place autograft anteriorly.
- Gently impact it until it is 3 to 4mm below the posterior margin of the annulus.
- Care should be taken to ensure the construct is aligned properly.

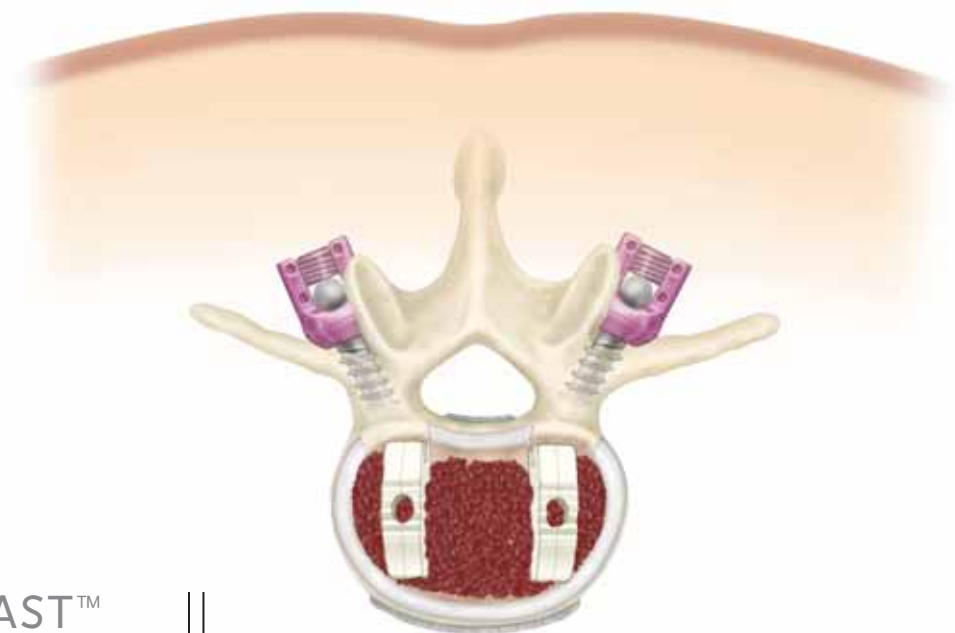
BILATERAL MAST™
TECHNIQUE

BILATERAL OPEN TECHNIQUE

Final Placement



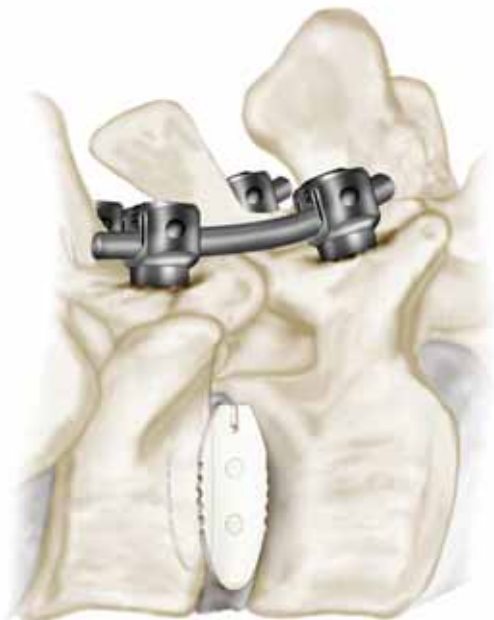
- After the final construct is placed, the extradural space and foramina are probed to ensure adequate decompression of the neural elements.
- To facilitate satisfactory immobilization of the grafted interspace, segmental internal fixation is applied using standard technique.



BILATERAL MAST™ TECHNIQUE

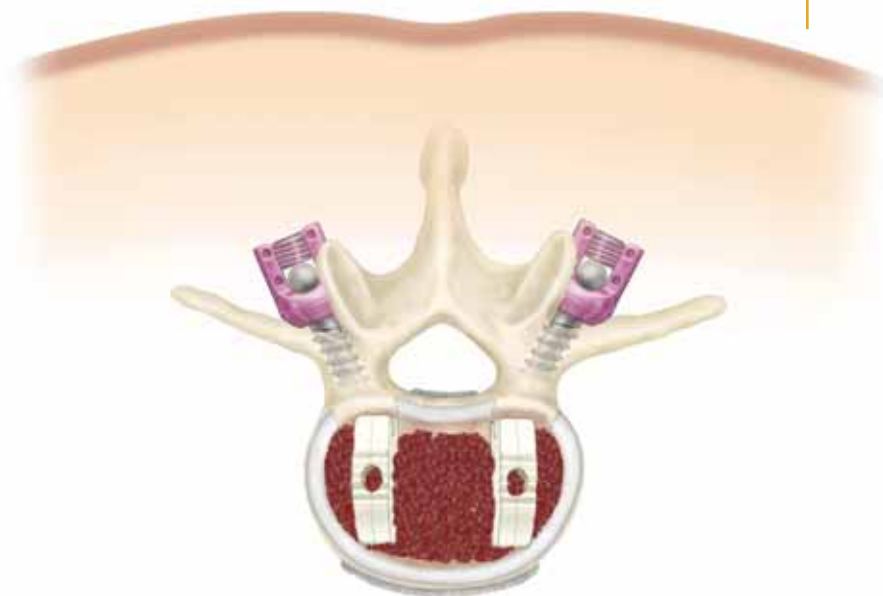
Additional Fixation Options

BILATERAL OPEN
TECHNIQUE



CD HORIZON® LEGACY™ 5.5
SPINAL SYSTEM

CD HORIZON® SEXTANT®
ROD INSERTION SYSTEM



BILATERAL MAST™
TECHNIQUE

Important Information for Medtronic Sofamor Danek 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 SOFAMOR DANEK Customer Service for instructions. Any available surgical techniques will be provided at no charge.

Warnings:

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

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

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

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

MEDTRONIC SOFAMOR DANEK does not and cannot warrant the use of this instrument nor any of the component parts upon which repairs have been made or attempted except as performed by MEDTRONIC SOFAMOR DANEK or an authorized MEDTRONIC SOFAMOR DANEK repair representative.

Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the 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 DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN ONLY.

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

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

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

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

Other Precautions:

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

Device Fixation:

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

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

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

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

Packaging:

MEDTRONIC SOFAMOR DANEK instruments may be supplied as 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 SOFAMOR DANEK.

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

Examination:

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

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

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

CLEANING AND DECONTAMINATION:

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

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

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

STERILIZATION:

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using 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*	Gravity*	273°F (134°C)*	20 Minutes*

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

*For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

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

Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be 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 SOFAMOR DANEK instruments as used for implantation should be used for implant removal purposes. Various sizes of screwdrivers are available to adapt to the removal drive sizes in auto break fixation screws.

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

Further Information:

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

Product Complaint:

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

listen. respond. deliver.

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

MEDTRONIC SOFAMOR DANEK USA, INC.

Spinal Division
Worldwide Headquarters
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133
(800) 876-3133

Customer Service: (800) 933-2635

www.sofamordanek.com

For more information go to www.myspinetools.com

MEDTRONIC SCHWEIZ AG

MEDTRONIC EUROPE
Route du Molliau, 31 - Case Postale
CH1131 TOLOCHENAZ - SWITZERLAND
Tel: +41 21 803 8000
Fax: +46 8 52 22 00 50

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