The global leader in today’s spine market, we combine our lifestyle friendly Minimal Access Spinal Technologies (MAST™), integrated image-guided products and neural monitoring tools to potentially help surgeons shorten surgical and recovery time and return patients more quickly to normal, active lives.

- MAST™ Capable
- Navigation Compatible
- NIM-SPINE™ Monitor Ready

The MAST QUADRANT® Retractor System provides surgeons with next-generation technology that will revolutionize the future of spine care.

As described by:
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The latest, most versatile and reproducible access system for fusion surgery

The new MAST QUADRANT™ Retractor System allows access, fusion, and fixation in one approach, and it provides the surgeon with more versatility and reproducibility to perform fusion surgery with confidence.

The MAST QUADRANT™ Retractor System features a familiar dilation technique for ease of use and no additional operating room time. The retraction capabilities provide the surgeon with the most options available today.

The Retractor provides user-friendly approaches to single- and multiple-level fusion procedures, with multiple modes of visualization—microscopes, loupes, and direct visualization.

This Retractor System is an extension of minimal access spinal technologies (MAST™). With the addition of interbody options and a CD HORIZON® Cannulated Screw, a complete, reproducible, minimally invasive procedural solution is achieved.

This MAST QUADRANT™ Retractor System may be used with all standard neuromonitoring systems including the NIM-SPINE™ System.

The MAST QUADRANT™ Retractor System and the medial lateral blades eliminate tissue creepage and provide the surgeon with better visibility.
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MAST QUADRANT™
Unilateral and Bilateral Technique

SURGICAL STEPS FOR

Access
Patient Positioning

The patient is positioned prone on an appropriate table for fluoroscopy. Two Flexible Arms may be required depending upon surgeon technique. The NIM-SPINE™ System may be utilized for nerve monitoring.
Incision Location and Tube Trajectory

*The location of the incision is dependent on the chosen procedure.*

For PLIF, the incision is made approximately 3.0 to 4.0cm off midline. After the tube insertion, the trajectory may be shifted medial to accommodate the interbody portion of the procedure and lateral to target the Pedicle Screws.

For TLIF, the incision is made approximately 4.0 to 4.5cm off midline. This trajectory allows direct access to both disc space and pedicles.
Guidewire and Initial Dilator Insertion

The Guidewire is inserted through the incision and directed toward the appropriate reference point. Slide Initial Dilator over Guidewire and place on the bony anatomy. Reference points may be either lamina or facet joint depending on preference and technique.
Palpate Anatomy with Initial Dilator

Use the Initial Dilator to palpate the bony anatomy in both coronal and sagittal planes to identify proper Dilator positioning.
Sequential Muscle Dilation

Use a Scalpel to ensure adequate skin incision and to incise fascia along the Dilator track. Dilators are sequentially placed over each other up to 22mm.

It may be beneficial to slide a knife along the side of the Dilators to release the fascia allowing for easier opening of the Retractor Blades.

The Retractor Blades are selected in accordance with exposed markings on the final Dilator.
**MAST QUADRANT™ Retractor Placement**

The MAST QUADRANT™ Retractor is inserted over the Dilators and placed over the bony anatomy and locked in place with the Flexible Arm. The Dilators are then removed establishing a tubular operative corridor. Again, ensure the skin incision is adequate, including incising of the fascia to allow for opening of MAST QUADRANT™ Retractor Blades.

The Flex Arm attachment may be attached to the Retractor before it is handed to the surgeon.

Ensure that blades are closed and perpendicular to the Retractor. Etched marks should be aligned.
Inserting the Light Source

The MAST QUADRANT™ RADIANCE™ Light Source may now be attached to the Retractor Blade. Place the metal tip of the light into the hole in the blades and then push the light under the built-in retaining sleeve.
Translating the MAST QUADRANT™ Retractor

Open the MAST QUADRANT™ Retractor by turning the base knob in a counter-clockwise direction. The Retractor will open up to 30mm allowing visualization of up to 52mm (surgeon should lengthen the skin incision to allow for the increase in Retractor opening).
Angling the MAST QUADRANT™ Blades

Articulation may now be achieved by moving the MAST QUADRANT™ Tabs to a vertical position. The Tabs can now be used as levers to articulate or angle the blades. If articulation requires excessive force, in spite of adequate skin and fascia incision, the Blade Openers may be used. The Blade Openers are placed on the outside lip of each blade and used as lever arms to help assist in articulation.
Closing the MAST QUADRANT™ Blades

To release the angle of the blades, press the buttons under the Tabs.

If needed, the MAST QUADRANT™ medial lateral blades may be added at this time. The blades slide onto the medial lateral rack and sit between the existing medial MAST QUADRANT™ Retractor.
Perform the same dilation steps on the contralateral side to gain bilateral access.
MAST QUADRANT™
Unilateral and Bilateral Technique

SURGICAL STEPS FOR

Interbody Implant Insertion
Bony Exposure

A facetectomy is performed ipsilaterally or bilaterally. Using a Bone Rongeur, Osteotome, or Drill remove the superior and inferior facets.

The extent of facetectomy is determined by the need for visualization of the disc space and decompression of the neural elements.
**Discectomy and Disc Removal**

A conventional discectomy is performed by incising the annulus with a 15-Scalpel Blade lateral to the dural sac. This is done unilaterally and/or bilaterally. 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.

Evaluate the status of adjacent nerve roots during this procedure with NIM-SPINE™ free-running EMG monitoring.

A 1cm annulotomy is made with a Scalpel starting from the lateral edge of the dura. Disc removal is initiated using a Disc Rongeur.
Discectomy and Disc Removal continued

Continue disc removal 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.
Endplate Preparation

Using various Curettes and Scrapers, remove the cartilaginous material from the disc space and the endplates. Thorough endplate preparation should be accomplished prior to insertion of the interbody construct.
Disc Space Distraction

The disc space is sequentially distracted until the original disc space height is obtained and normal foraminal opening is restored. Insert the CAPSTONE® Trial with the curved sides touching the endplates. Sequentially insert the CAPSTONE® Trial from side to side until the desired height is obtained.

Free-running EMG should be used to monitor the status of potentially affected nerve roots during this procedure.
CAPSTONE® Bone Insertion

Choose the appropriate size construct from the trialing step and attach the selected construct firmly to the Inserter. Before inserting the construct, place autograft anteriorly and contralaterally or in the bone construct central cavity. Taking care to ensure that the construct is aligned properly, gently impact the construct until it is 3 to 4mm below the posterior margin of the annulus.
SURGICAL STEPS FOR

Fixation
MAST QUADRANT™ Retractor Translation and Angling

The MAST QUADRANT™ Retractor is opened by turning the base knob in a counter-clockwise direction. Articulation may be achieved by using the MAST QUADRANT™ Tabs or the Blade Openers.
The MAST QUADRANT™ Retractor may now be translated to gain pedicle access.

Angulation may also be achieved.

AP Fluoro view using the NIM-PAK™ Needle with a radiolucent handle.
Accessing the Pedicle

Needle Insertion:

A NIM-SPINE™ Pedicle Access Needle (PAK) can be used to gain access to the pedicle. Place the NIM-PAK™ Needle at the intersection of the facet and the transverse process; the Needle may be advanced partially through the pedicle. EMG monitoring may now be performed to ensure proper placement of the Needle in the pedicle. An AP image should show the Needle tip at the lateral margin of the pedicle initially. As the NIM-PAK™ Needle advances towards the base of the pedicle, on the lateral image, it should approach the pedicle center on the AP image.
Triggere d EMG Monitoring

The NIM-SPINE™ System can be utilized to evaluate positioning within the pedicle through the use of free-running and triggered EMG nerve monitoring. The NIM-SPINE™ System Setup Guide and Electrode Placement Guide provides detailed instructions for system setup and implementation.

The NIM-SPINE™ Pedicle Access Needle includes an electrified Handle and insulated Cannula that enables electrification of the bone cutting portion of the device. The electrified Needle can then be utilized to generate triggered EMG feedback during initial entry into the pedicle. Prior to insertion into the pedicle, the NIM-SPINE™ Pedicle Access Needle should be electrified to 5–6mA. The surgeon should stop Needle insertion and investigate positioning within the pedicle if a triggered EMG response is generated during insertion.
Guidewire Insertion

The inner stylet of the NIM-SPINE™ Pedicle Access Needle is removed to allow the Guidewire to be inserted into the pedicle. Be extremely careful with regards to the position of the Guidewire. Unintentional advancement of the wire can potentially be very dangerous. Once the Guidewire is inserted, the NIM-SPINE™ Pedicle Access Needle may be removed.

In dense bone, where the Screw may be difficult to advance, ensure that the pedicle is fully prepared by using a Tap the same size as the inserted Screw to avoid possible Screwdriver damage. Fluoroscopy should be used to verify the position of the Guidewire and the Tap during this step. The threaded portion of the Tap is 45mm in length. This allows you to determine Screw length.
Screw Insertion

With the pedicles prepared and the proper Screw lengths determined, fully insert the hex end of the Multi Axial Screwdriver into the Screw head. Next thread the Screwdriver Sleeve into the Screw head. The combination of the hex head and the threaded sleeve provide a stable insertion instrument for inserting the Multi Axial Screws bilaterally. The Screw and Screwdriver are now placed over the Guidewire and inserted into the pedicle. Once your Screw has interfaced with bone you may now remove the Guidewire. After final Screw placement, Screw positioning can be verified with EMG monitoring by direct stimulation of the Screw.
Screw Position Evaluation

Triggered EMG monitoring should be used to verify positioning of the Screw within the pedicle.
**Rod Insertion**

To place the Rod into the MAST Rod Inserter, press the thumbswitch to the right and insert the Rod into the Inserter, then press the thumb-switch to the left to grip the Rod.

Lower the Rod Inserter into the Retractor and squeeze the Rod Inserter handles to rotate the Rod from the vertical to the horizontal position. Place the Rod into the Screw heads making sure lordosis will be achieved. Then, with the Rod seated in the Screw heads, move the thumbswitch to the right to release the Rod.
Rod Reduction

If the Rod is not fully seated into the bottom of the Screw head, the Beale Rod Reducer can be used to fully seat the Rod and simplify the Plug insertion process.

**NOTE:** Care should be taken with any Rod reduction maneuver. Improper instrument use may dislodge the implants or damage the bony or neurologic anatomy.

The Beale Rod Reducer is the preferred method for reduction when the Rod is lying even to the top of the implant head. To use the Rod Reducer, position the Reducer so that the handles are parallel to the Rod and grasp the Screw head from above. The Reducer handles are slowly compressed allowing the sleeve to slide down and seat the Rod. The Plug Starter or Provisional Driver is then inserted through the Rod Reducer to insert the Set Screw into the head of the Pedicle Screw.
Compression and Distraction

If either compression or distraction is needed, it should be performed at this time. In either maneuver, the Plug on one side of the motion segment should be provisionally tightened, with the Plug loose on the implant to be compressed or distracted. Compression or distraction will occur against the provisionally tightened implant.

The Provisional Driver may be used to temporarily lock and secure the Rod and implant construct. Usually, temporary fixation of the implant may be performed numerous times without damage to either the Plug or the implant threads. However, if the Plug has been cross-threaded, it must be replaced.

Care should be taken with all Plugs to ensure that the feet of either the Compressor or the Distractor are placed securely against the implant body and not against the Plug.

Failure to do this may result in slippage of the implant or premature breaking of the Plug. Once satisfactory compression or distraction has been achieved, final tightening may be performed.

It is preferred that compression be released just prior to the Plugs being broken off or final tightening. This technique will help ensure that the implant head and rod are normalized to one another and thus allow for the rod to be fully seated in the implant head during the final tightening step.

“It is highly recommended that the Plug not be broken off or final tightened under compression.”
Final Tightening

When all implants are securely in place, final tightening and breakoff of the Plug head are done. Insert the Self-Retaining Break-Off Driver into the cannulated portion of the Counter Torque which should be positioned over the implant and Rod. The T-handle on the Driver provides adequate leverage for the breakoff of the Plug head (between 88 – 106 in-lbs). The handle of the Counter Torque device should be held firmly to prevent torquing of the construct while the Plug is secured and sheared off.
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 acrylic copolymer materials which meet international or national standards specifications. Some instruments are made out of aluminum, and some with handles made of resin bonded composites, and while these can be steam autoclaved, certain cleaning fluids must not be employed. None of the instruments should be sterilized.

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 MSDL 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 further use. For this reason, it is 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 tissue.

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 the 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 surgery involving the 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 surgical technician exercise extreme caution when working in close proximity to vital organs, nerves or vessels, and that the force 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.

NOTE: For US Audiences Only

CAUTION: FEDERAL (U.S.) LAW RESTRICTIONS THIS 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. Bone fracture, in cases of deformed bone 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 leading 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, excessive 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.

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Packaging 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.

Do not use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise unfunctional.

CLEANING AND DECONTAMINATION:
When 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 disinfesting 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 disinfecting step.

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 never 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 instruments should be placed in the surgical field. Unless specified otherwise, these products are recommended to be steam sterilized by the hospital using the set of process parameters below:

<table>
<thead>
<tr>
<th>METHOD</th>
<th>CYCLE</th>
<th>TEMPERATURE</th>
<th>EXPOSURE TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam*</td>
<td>Pre-Vacuum*</td>
<td>270°F (132°C)</td>
<td>4 Minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>250°F (131°C)</td>
<td>60 Minutes</td>
</tr>
<tr>
<td>Steam*</td>
<td>Pre-Vacuum*</td>
<td>273°F (134°C)</td>
<td>20 Minutes</td>
</tr>
</tbody>
</table>

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 the outside the United States, and/or 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 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.

Note: 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.

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Purpose:
This instrument is intended for use in surgical procedures.

Description:
Monopolar Stimulator Instruments are available in a variety of designs. These instruments have a lead that ends with a connector that plugs into the NIM system.

Intended Use:
This device is intended for use as a stimulating accessory for the NIM system. The NIM system is intended for use in surgical procedures for patient-connected intravenous nerve monitoring, i.e. assisting the surgeon in locating and mapping motor nerves through the use of electromyographic (EMG) signals and electrical stimulus of nerves.

Indications:
This device is indicated for locating and identifying cranial and peripheral motor nerves during surgery, including spinal nerve roots.

Contraindications:
The use of paralyzing anesthetic agents will significantly reduce, if not completely eliminate, electromyography (EMG) responses to direct or passive neural stimulation. Whenever nerve paralysis is suspected, consult an anesthesiologist.

Warnings:
- MEDTRONIC SOFAMOR DANEK does not and cannot warrant the use of these instruments 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.
- The NIM does not prevent the surgical severing of nerves. If these devices are compromised, the surgical practitioner must rely on alternate methods, or surgical skill, experience and anatomical knowledge to prevent damage to nerves.
- To avoid patient burns:
  - Do not activate electrosurgical instruments while the stimulator is in contact with tissue.
  - Do not leave stimulating instruments in surgical field.
  - Do not store stimulating instruments in electrosurgical instrument holder.
  - Do not allow a second surgeon (i.e. fat harvesting) to use electrosurgical instrument while stimulator is in use.
  - If NIM accessories are used with stimulators other than the NIM System, do not exceed an energy level of 50 mJ per pulse (measured into a 1 kilo-ohm load).
- Do not use this accessory with other monitoring equipment than NIM Patient Interface STIM 1.
- Do not leave stimulating instruments in surgical field.
- If using this accessory with other monitoring equipment than NIM Patient Interface STIM 1, special operator attention may be required for current densities exceeding 2 mA RMS/cm². Current, mA RMS is generally lower than the stimulator current setting in mA. To calculate current, mA RMS, waveform morphology, pulse width, repetition rate, and the stimulator current delivered must be considered.
- High stimulator current may cause involuntary patient movement resulting in patient injury.
- Direct stimulator contact may disrupt the operation of active implanted devices.
- The surgical practitioner must choose the appropriate size instruments based on the procedure to be performed and the stimulating current necessary for the application.
- Avoid trans-thoracic stimulation; when possible, maintain anode and cathode stimulating sites in close proximity.
- False negative responses (failure to locate nerve) may result from:
  - Shorted EMS electrode or cabling (conductive parts of applied needle electrodes or cables contacting each other).
  - Patient Interface STIM 1 or STIM 2 fuse blown.
  - Patient Interface defective.
  - Inadequate stimulus current.
  - Inadequate current for stimulation of nerve through hardware, such as pedicle screws or stimulus dissection instruments, may vary based on the physical size, shape characteristics, and design of the hardware and proximity to the nerve.
  - Neuromuscular fatigue from prolonged or repeated exposure to electrical stimuli.
- While stimulating, it is recommended to use EMS monitor(s) equipped with active audio and/or visual current delivered feedback systems to ensure delivery of current to intended tissues.
- Proper handling, insertion, and placement of instruments is critical for safe and accurate EMG monitoring.
  - Improperly placed or bent needles increase the risk of needle breaking off in the patient.
  - Do not attempt to straighten bent needles because this may cause stress and weaken device, causing needle to break off in patient.
  - Extreme care must be taken when handling instruments with sharp points or edges.

Precautions:
- Inadequate stimulus current flow may be caused by non-flush contact between the stimulating instrument and the nerve, inadequate stimulator instrument electrical contact surface area, or high impedance.
- Electrode integrity should be checked (by pressing electrodes check on the NIM) after electrode insertion and before electrode removal to give additional assurance that electrode continuity was maintained throughout the entire procedure. If electrode impedance is very high, discontinue use and replace.
- Inability to deliver stimulus current flow may be caused by:
  - Stimulator return electrode not connected, or other incomplete electrical connection between the NIM, electrode and stimulator instrument.
  - Patient Interface STIM 1 or STIM 2 fuse blown.
  - Stimulus set to 0.00 mA.
- Defective instrument.
- Avoid accidental contact between connected but unapplied electrodes and other conductive parts.
- Reuse of single use instruments increase the risk of infection and may cause degraded or ineffective monitoring.
- Contaminated single use instruments must be disposed of in an appropriate sharps biohazard container in accordance with hospital or other user facility policy.

Instructions for Use:

1. Plug the connector end of the stimulating instrument into the cathode (+) connection on the NIM Patient Interface STIM 1.
2. Place a subdermal EMG needle electrode (included) in the desired location to serve as the ground, or anode (-) for the stimulator.

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The CAPSTONE® System incorporates technology developed by Gary K. Michelson, M.D.