Medtronic
SOFAMOR DANEK

CORNERSTONE-SR™ Instrumentation

Surgical Technique

as described by:

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Introduction

Dear Fellow Colleagues,

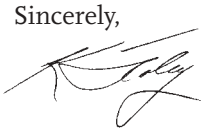
Anterior cervical discectomy utilizing the Smith-Robinson technique is a commonly performed procedure. The design goals of the CORNERSTONE-SR™ Instrumentation Set were to provide an expedient and reproducible means of preparing the cervical intervertebral space for receiving a Smith-Robinson-style graft. A series of cutters were designed to prepare parallel superior and inferior surfaces and create a posterior shelf in the endplates to prevent posterior migration of the graft after implantation.

A corresponding set of graft sizing trials allows the surgeon to quickly and conveniently measure the prepared intervertebral space and choose the proper graft size for a precise fit. A graft holder, tamps, and mallet are included in the instrument set for graft positioning and impaction.

Regeneration Technologies, Inc., of Alachua, Florida, offers pre-sized cortical allograft implants that can be used in conjunction with the CORNERSTONE-SR™Instrumentation Set. The grafts are precisely machined to specific dimensions, maximizing the surface area of contact between the recipient vertebrae and the implant.* The advantages of this graft are its biomechanical strength, consistent bone quality, and the elimination of complications associated with autologous graft harvesting.

The following monograph introduces the CORNERSTONE-SR™ Instrumentation Set, as well as many of our personal thoughts reflecting our current clinical practices and operative techniques.

Sincerely,



Kevin T. Foley, M.D.
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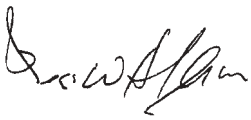
Stephen M. Papadopoulos, M.D.
Ann Arbor, MI



Regis W. Haid, Jr., M.D.
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Atlanta, GA

* Each sizing trial in the CORNERSTONE-SR™ Instrumentation set is keyed to a corresponding graft size.

STEP 1

Patient Positioning & Incision

The patient is placed in the supine position with the head in slight extension. The posterior cervical spine is supported to establish and maintain normal lordosis. The surgeon must then choose a right- or left-sided approach to the cervical vertebral column. After the approach is considered, the head may be rotated to allow for adequate exposure of the upper cervical spine *(Figure 1)*.

Typically a transverse skin incision is made. An avascular dissection plane is developed between the trachea and esophagus, medially, and the carotid sheath, laterally. Hand-held retractors are utilized to provide initial exposure of the anterior vertebral column and the adjacent longus colli muscles *(Figure 2)*.

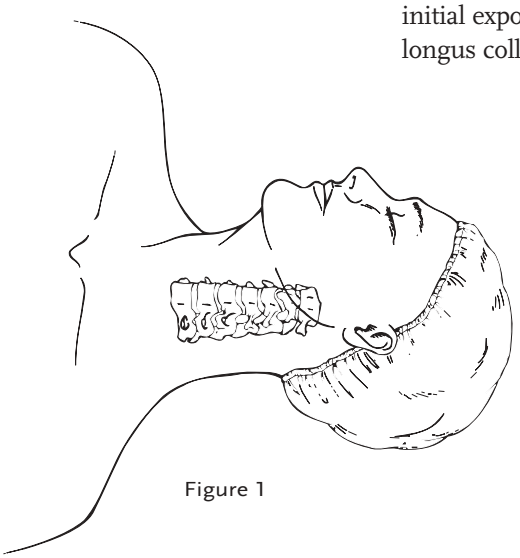

Figure 1

I prefer the left-sided approach due to the anatomic reliability of the recurrent laryngeal nerve. I typically use a transverse skin incision with a vertical, "muscle splitting" incision of the platysma. Adequate longitudinal exposure of this level is critical, particularly in multilevel procedures.
– S. Papadopoulos, M.D.

I typically approach from the right side and reserve the left-sided approach for redo surgery.
– K. Foley, M.D.

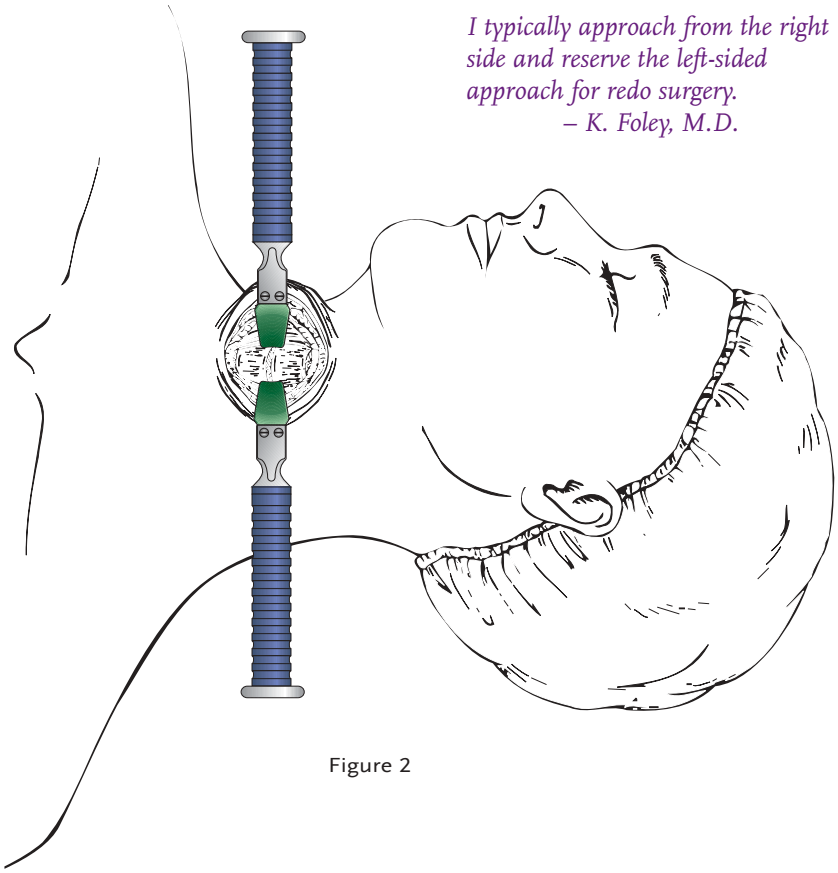

Figure 2

STEP 2

Exposure

After the anterior vertebral column has been exposed, the longus colli muscles are elevated and the medial/lateral self-retaining retractor blades are securely positioned beneath them *(Figure 3a)*. The slotted blade may be used if an anterior osteophyte prevents proper positioning *(Figure 3b)*. Then the longitudinal self-retaining retractor may be placed to provide optimal visualization *(Figure 4)*.

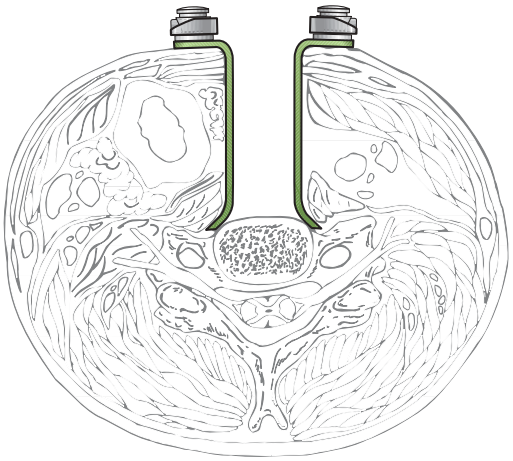

Figure 3a

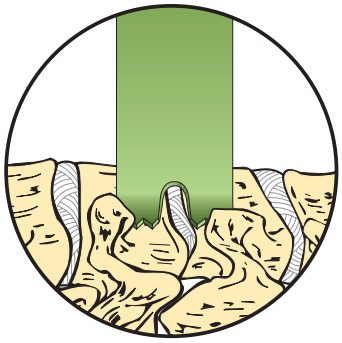

Figure 3b

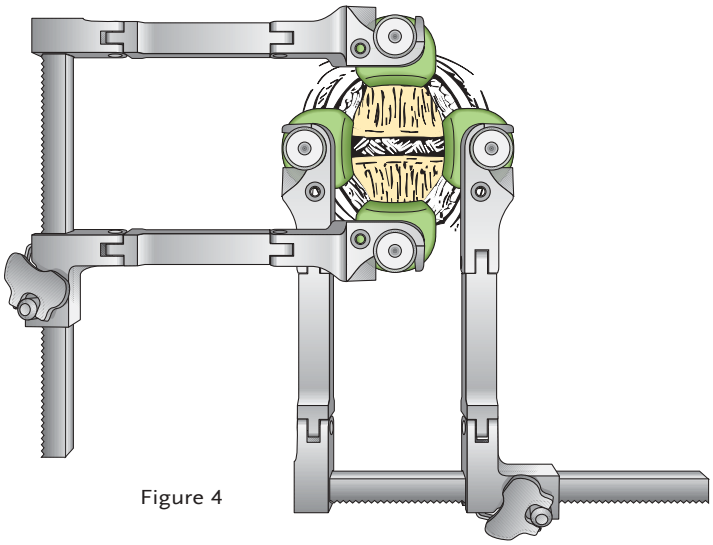

Figure 4

I usually perform an initial "anterior" discectomy widely to the uncovertebral joints, to allow proper "anterior release" prior to placement of the distraction pins. This is particularly important for the correction of cervical kyphosis.

– S. Papadopoulos, M.D.

STEP 2

Exposure

A vertebral body distractor may be used. The distraction pins are positioned midline in the vertebral bodies adjacent to the discectomy *(Figure 5)*. The distractor is placed over the pins and the appropriate amount of distraction is applied.

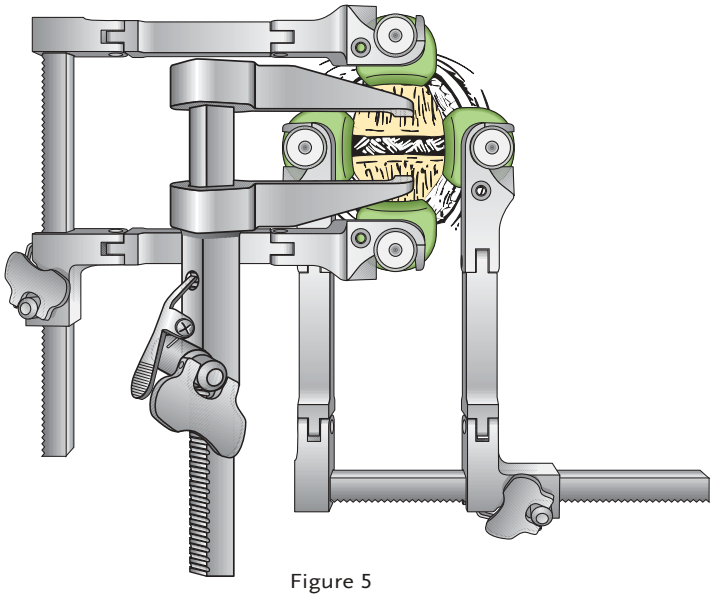

Figure 5

I prefer to use halter traction to distract the interspace. This reduces the "clutter" in the wound.

– K. Foley, M.D.

STEP 3

Discectomy

Discectomy is completed at the C5/C6 level. Pituitaries, curettes and kerrisons may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament *(Figures 6 and 7)*.

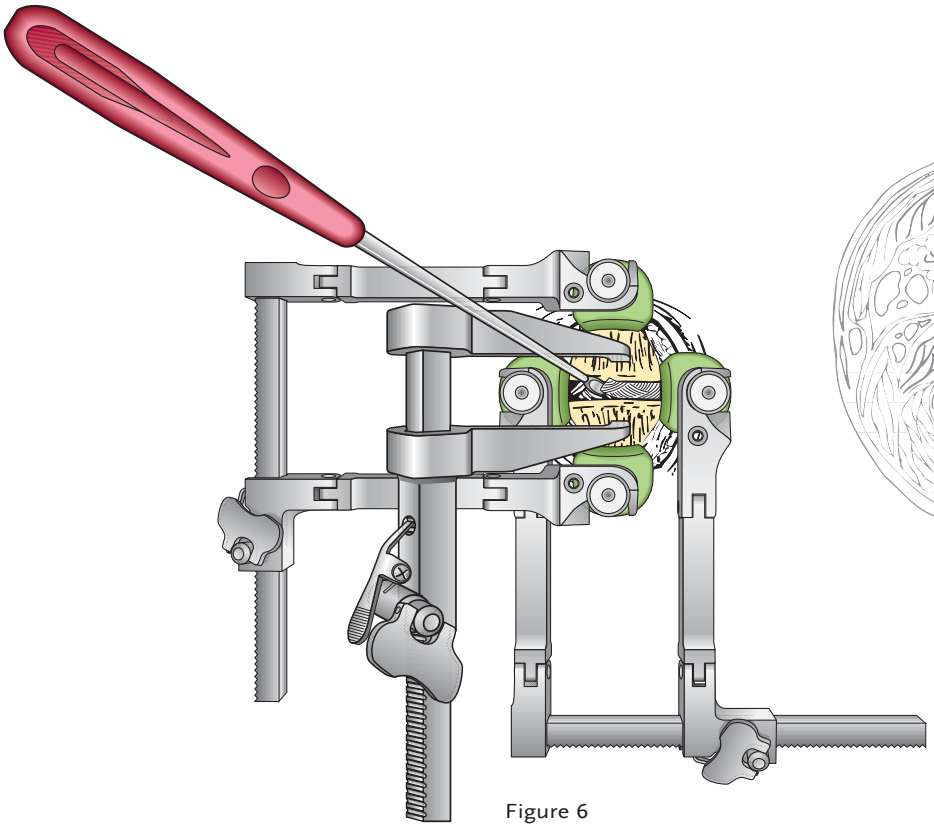

Figure 6

Figure 7

STEP 3

Discectomy

A high speed drill with a burr (match tip/round) may be utilized for removal of the posterior disc and osteophyte(s) to achieve neural decompression *(Figures 8a and 8b)*. The posterior longitudinal ligament and osteophytes are then carefully removed.

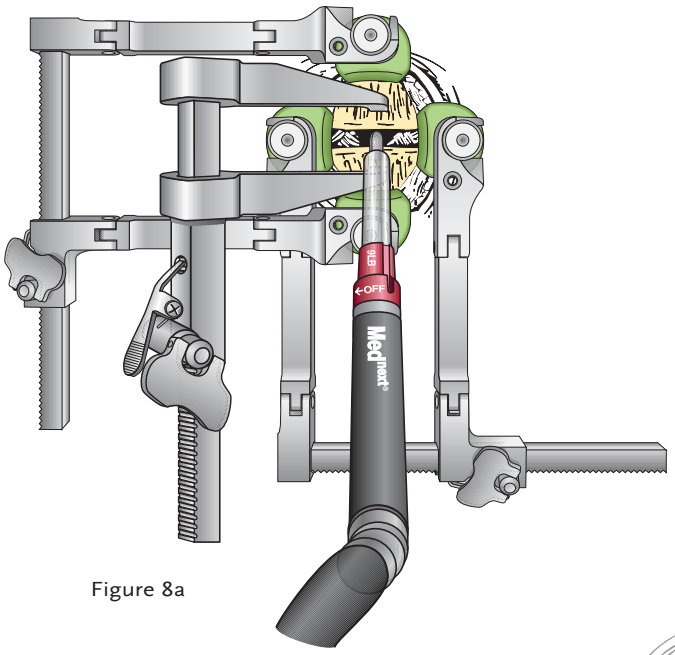

Figure 8a

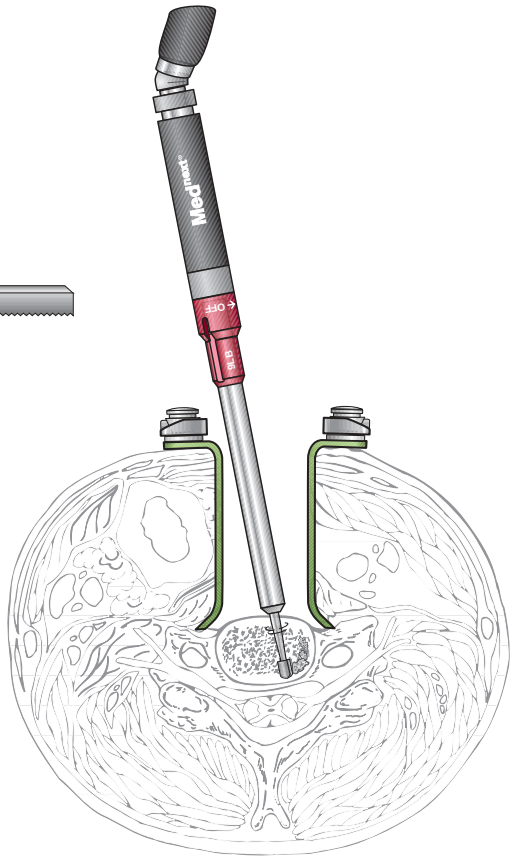

Figure 8b

STEP 4A

Graft Site Preparation

Once the decompression is completed, endplate preparation is carried out. This consists of creating a precisely matched mortise with the bone graft using a CORNERSTONE-SR™ cutter.

Select the CORNERSTONE-SR™ cutter that will decorticate the endplates with minimal bone removal, yet produce a "posterior lip" of bone to protect the spinal canal from posterior graft migration *(Figure 9e)*. This cutter helps ensure parallel endplate preparation.

The appropriate CORNERSTONE-SR™ cutter is determined by selecting the cutter whose distal tip just fits into the disc space *(Figure 9a)*. The cutter length should match the A/P depth of the desired pre-machined allograft (provided by Regeneration Technologies, Inc.). The distal tip adds approximately 1.5mm to the overall length of the cutter.

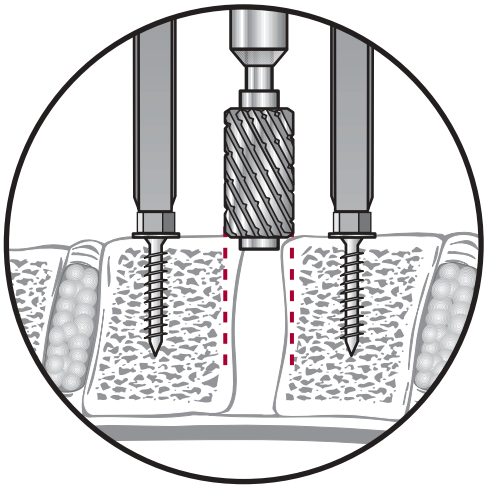

Figure 9a

A Midas Rex drill may be utilized to create parallel endplates.
– R. Haid, M.D.

STEP 4A

Graft Site Preparation

Generally, one pass of the cutter works best. Insert the cutter until the proximal cutter face aligns with the anterior cortex *(Figure 9b)*. Starting on the contralateral side, pull the cutter medially. This affords better control and visualization of the distal tip in the disc space *(Figures 9c and 9d)*.

Proper use of the CORNERSTONE-SR™ cutter is what affords the reproducibility of the "carpentry" and thus will dictate the outcomes compared to a free-hand technique.

– S. Papadopoulos, M.D.

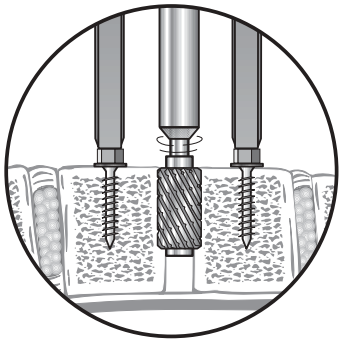

Figure 9b

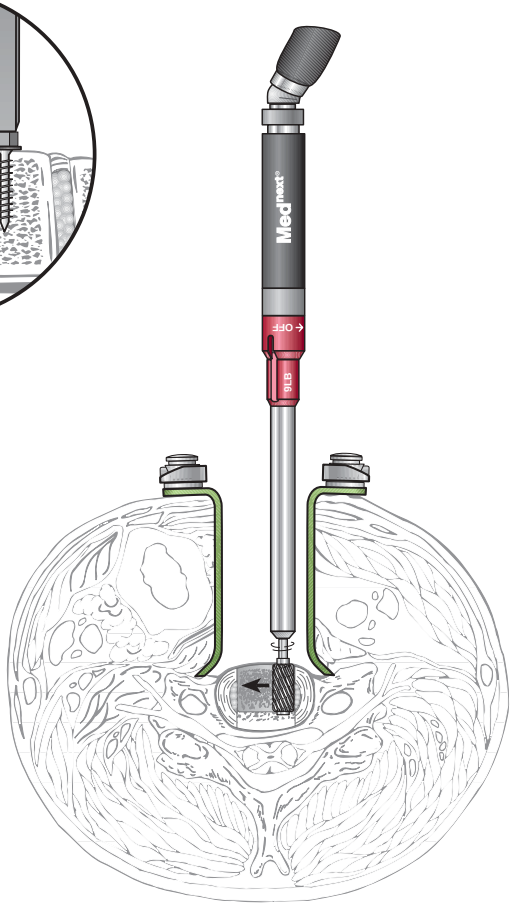

Figure 9c

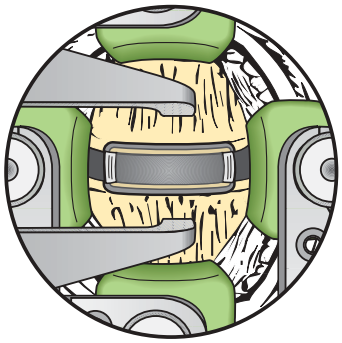

Figure 9d

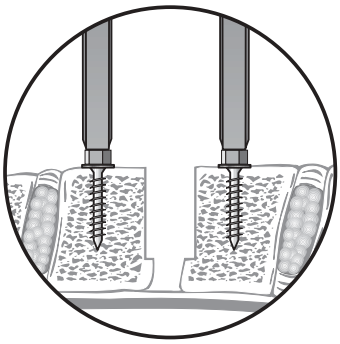

Figure 9e

STEP 4B

Graft Site Preparation– Free-hand Technique

When using a free-hand technique, while maintaining normal lordosis, remove the anterior inferior edge of the superior vertebral bone (C5) and remove the posterior superior edge of the inferior vertebral bone (C6) – (Figure 10a). This allows for better visualization and parallel endplates. Thus, in concept, there is both cortical bone for strength and to resist excessive subsidence and cancellous bone for bony ingrowth.

– R. Haid, M.D.

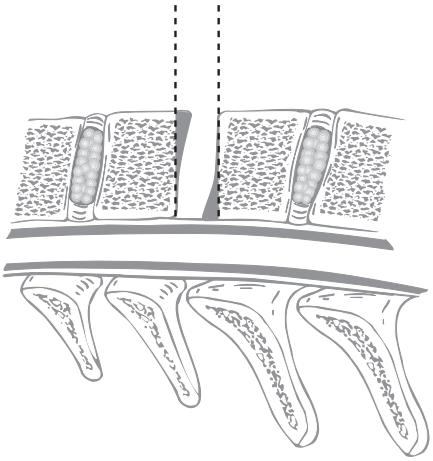

Figure 10a

When using a free-hand technique, I prefer to stay parallel to the endplates. This allows for better osteophyte removal at the uncovertebral joints, which are typically cephalad to the center of the disc space (Figures 10b and 10c).

– K. Foley, M.D.

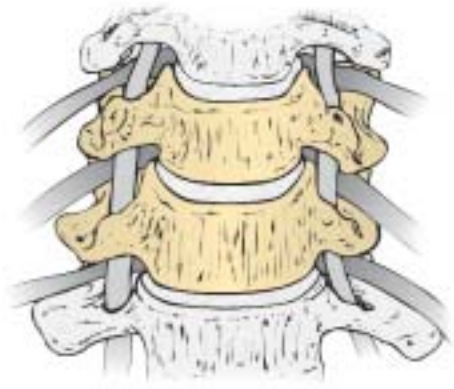

Figure 10b

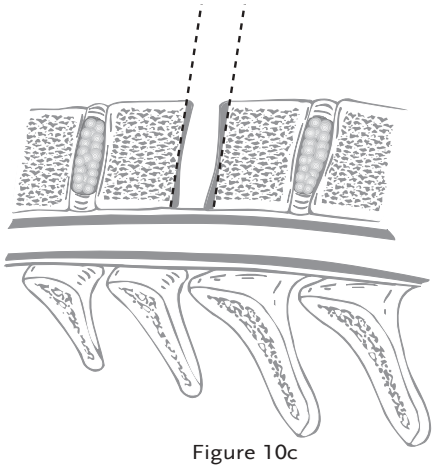

Figure 10c

STEP 5

Graft Sizing

Graft sizing is determined by selecting the trial that provides the most satisfactory fit in the prepared disc space *(Figure 11)*.

If you have used a free-hand technique, the trials will allow you to gauge how parallel you have made your endplates.

– K. Foley, M.D.

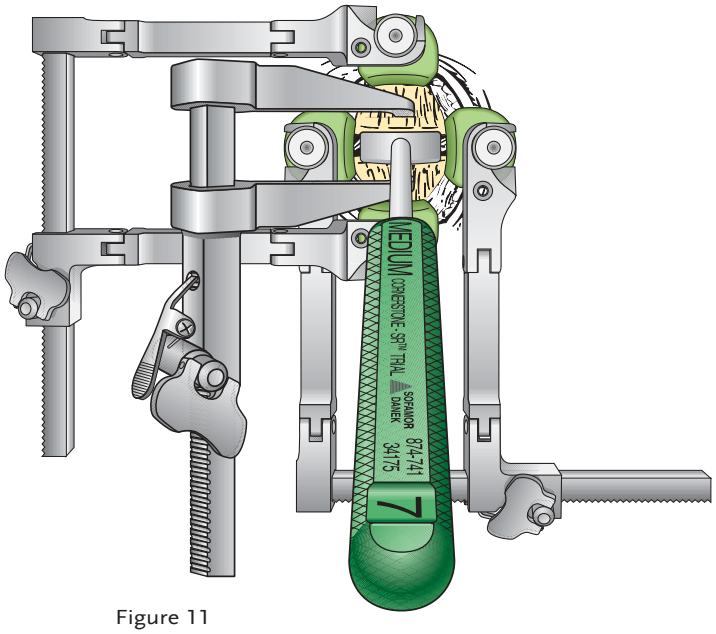

Figure 11

Tamp the trial completely into the interspace to ensure adequate fit of the graft.

– R. Haid, M.D.

STEP 5

Graft Sizing

The trial should fit flush and produce a tight interference fit *(Figures 12a and 12b)*. If it does not, choose a larger trial and/or re-evaluate your endplate preparation.

This is the significant advantage to using a trial before selecting a final allograft size.

– K. Foley, M.D.

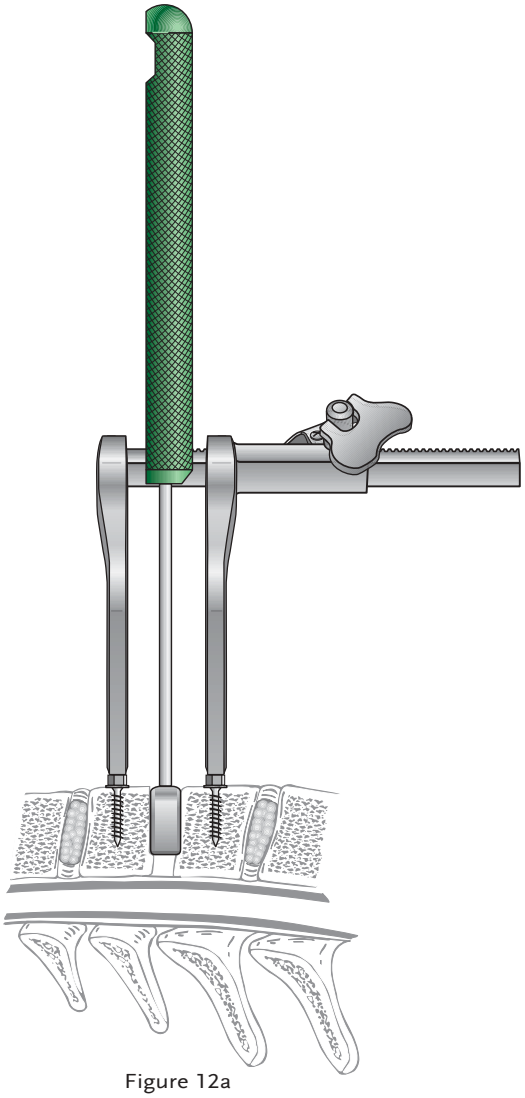

Figure 12a

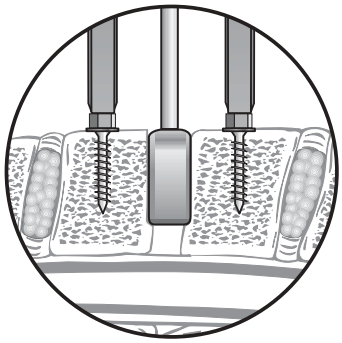

Figure 12b

If you choose a trial that is too large and over-force the trial, it may produce over distraction and cause the distraction pins to break out.

– R. Haid, M.D.

STEP 6

Graft Placement

Select the CORNERSTONE-SR™ allograft size that corresponds to the final trial *(Figures 13a and 13b)*.

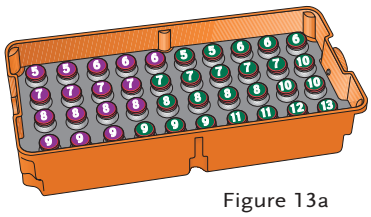

Figure 13a

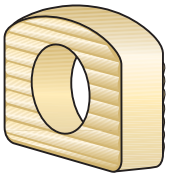

Figure 13b

Graft Holder/
Introducer
875-701

Figure 13c

The superior and inferior surfaces of the CORNERSTONE-SR™ allograft have pre-machined grooves to help prevent anterior migration.
– S. Papadopoulos, M.D.

I sometimes prefer to use the CORNERSTONE-SELECT™ allograft without grooves to increase graft-vertebral body interface.
– R. Haid, M.D.

The graft is held in place with the graft holder. The graft is oriented with the curved surface positioned anteriorly *(Figure 13c)*.

The center of the implant can be left empty or packed with any osteoinductive material the surgeon desires *(Figure 13d)*.

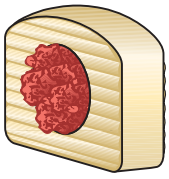

Figure 13d

I typically inject OSTEOFIL™ allograft paste (provided by Regeneration Technologies, Inc.) into the graft center.
– K. Foley, M.D.

STEP 6

Graft Placement

The implant is introduced into the prepared graft site *(Figures 13e and 13f)* then tapped into place using a tamp and mallet *(Figures 13g, 13h and 13i)*. If the surgeon so desires, an anterior cervical plate can then be applied *(Figure 13j)*.

Depending on the bone quality, I "pre-load" the graft by placing force on the intervertebral body pins. This allows for increased graft compression when the distraction pins are released.
– R. Haid, M.D.

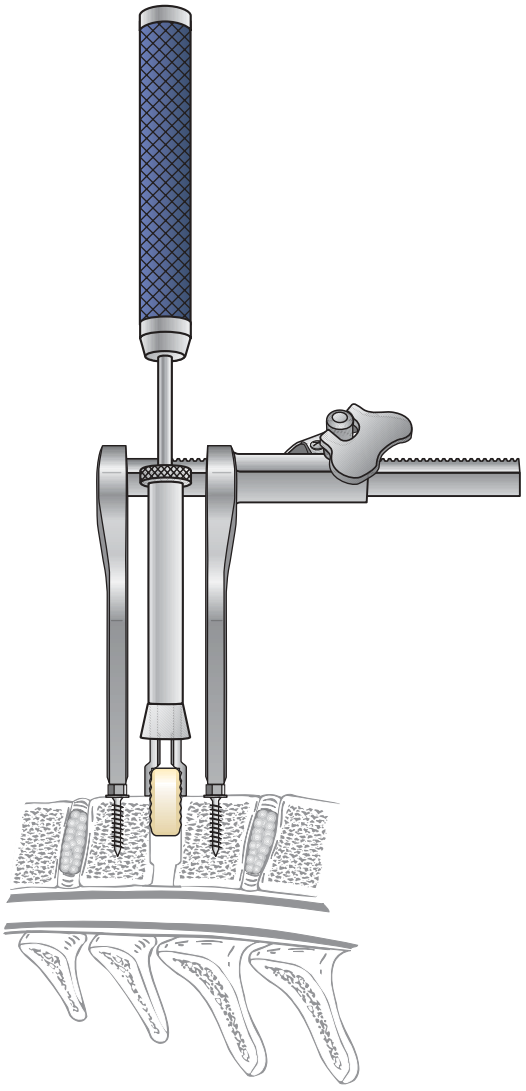

Figure 13e

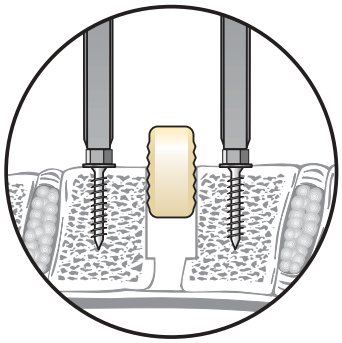

Figure 13f

I place the shavings from the endplate preparation within the center of the implant. If this is not of sufficient quantity, then I augment this with OSTEOFIL™ allograft paste (provided by Regeneration Technologies, Inc.).
– S. Papadopoulos, M.D.

STEP 6

Graft Placement

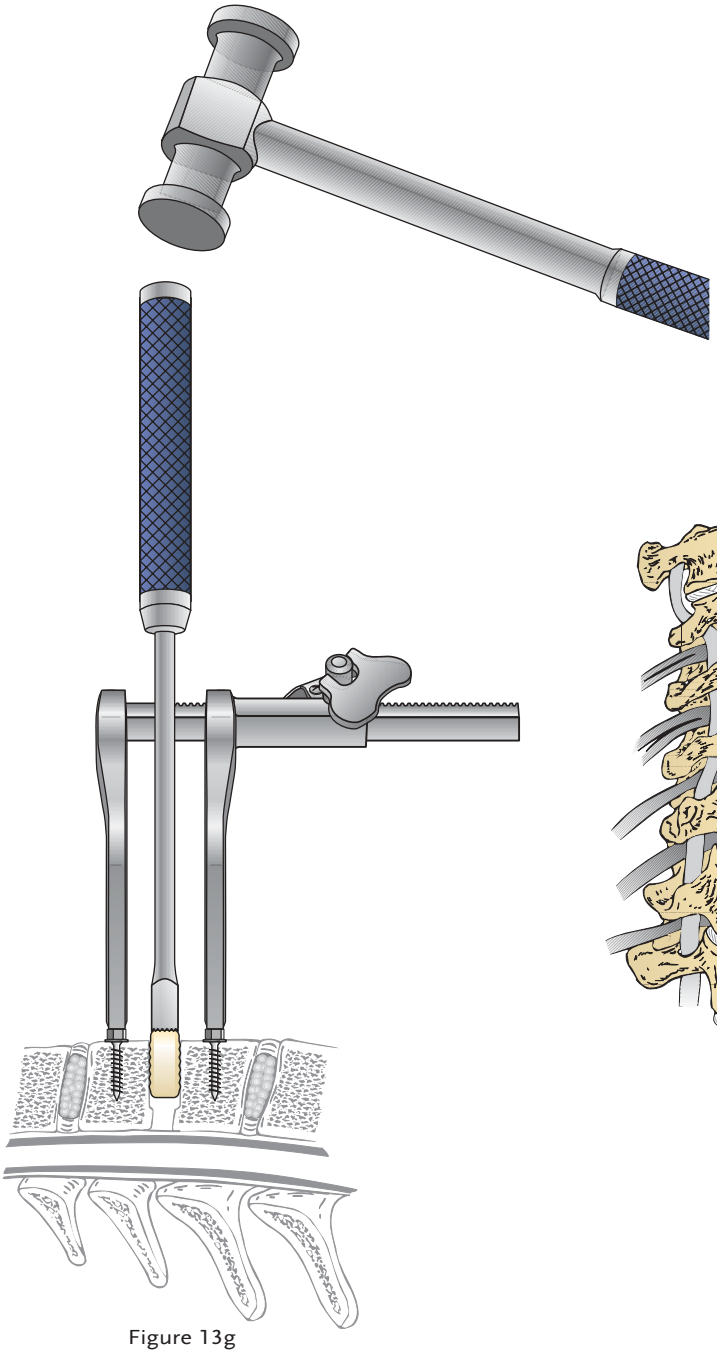

Figure 13g

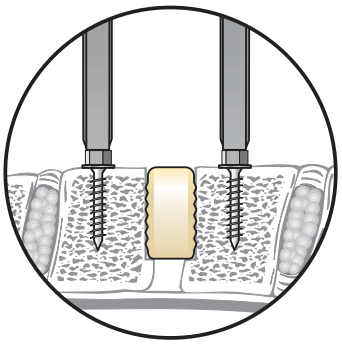

Figure 13h

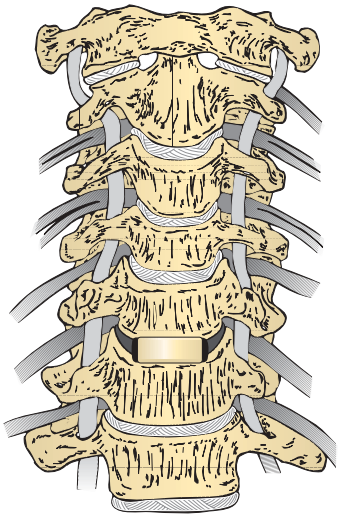

Figure 13i

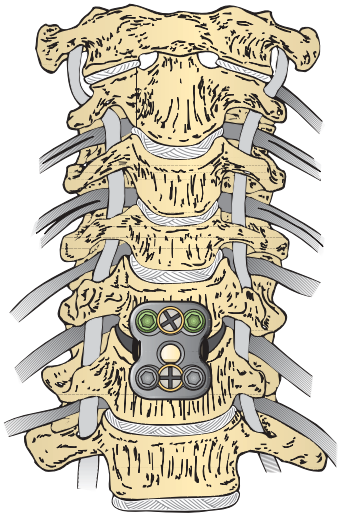

Figure 13j

I add a "hybrid" ATLANTIS™ plate construct, with fixed rigid screws typically below and non-fixed variable screws above to allow "controlled subsidence" during graft loading.

– R. Haid, M.D.

CORNERSTONE-SR™

INSTRUMENTS

TRIALS

ITEM	DESCRIPTION	ITEM	DESCRIPTION	ITEM	DESCRIPTION
874-511	5mm x 11mm x 11mm Trial	874-541	5mm x 14mm x 11mm Trial	874-041	10mm x 14mm x 11mm Trial
874-611	6mm x 11mm x 11mm Trial	874-641	6mm x 14mm x 11mm Trial	874-141	11mm x 14mm x 11mm Trial
874-711	7mm x 11mm x 11mm Trial	874-741	7mm x 14mm x 11mm Trial	874-241	12mm x 14mm x 11mm Trial
874-811	8mm x 11mm x 11mm Trial	874-841	8mm x 14mm x 11mm Trial	874-341	13mm x 14mm x 11mm Trial
874-911	9mm x 11mm x 11mm Trial	874-941	9mm x 14mm x 11mm Trial		

CORNERSTONE-SELECT™

INSTRUMENTS

TRIALS

ITEM	DESCRIPTION	ITEM	DESCRIPTION	ITEM	DESCRIPTION
6820050	5mm Trial	6820080	8mm Trial	6820120	12mm Trial
6820060	6mm Trial	6820090	9mm Trial	6820130	13mm Trial
6820070	7mm Trial	6820100	10mm Trial	6820140	14mm Trial

GENERAL INSTRUMENTS (Shared)

ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-701	Graft Holder/Introducer	875-712	6 x 12mm Tapper
875-708	8mm Tapper	875-715	Mallet

CASES

ITEM	DESCRIPTION	ITEM	DESCRIPTION
874990	Cornerstone-SR™ Case	8740995	Cornerstone-SELECT™ Case

CORNERSTONE-SR™

INSTRUMENTS

CUTTERS

ITEM	SIZE		ATTACHMENT
874-305	5mm Dia.	11mm Depth	Mednext® 9LB
874-306	6mm Dia.	11mm Depth	Mednext® 9LB
874-307	7mm Dia.	11mm Depth	Mednext® 9LB
874-308	8mm Dia.	11mm Depth	Mednext® 9LB
874-309	9mm Dia.	11mm Depth	Mednext® 9LB
874-310	10mm Dia.	11mm Depth	Mednext® 9LB
874-315	5mm Dia.	14mm Depth	Mednext® 9LB
874-316	6mm Dia.	14mm Depth	Mednext® 9LB
874-317	7mm Dia.	14mm Depth	Mednext® 9LB
874-318	8mm Dia.	14mm Depth	Mednext® 9LB
874-319	9mm Dia.	14mm Depth	Mednext® 9LB
874-320	10mm Dia.	14mm Depth	Mednext® 9LB
874-325	5mm Dia.	11mm Depth	Mednext® 12LB
874-326	6mm Dia.	11mm Depth	Mednext® 12LB
874-327	7mm Dia.	11mm Depth	Mednext® 12LB
874-328	8mm Dia.	11mm Depth	Mednext® 12LB
874-329	9mm Dia.	11mm Depth	Mednext® 12LB
874-330	10mm Dia.	11mm Depth	Mednext® 12LB
874-335	5mm Dia.	14mm Depth	Mednext® 12LB
874-336	6mm Dia.	14mm Depth	Mednext® 12LB
874-337	7mm Dia.	14mm Depth	Mednext® 12LB
874-338	8mm Dia.	14mm Depth	Mednext® 12LB
874-339	9mm Dia.	14mm Depth	Mednext® 12LB
874-340	10mm Dia.	14mm Depth	Mednext® 12LB

ITEM	SIZE		ATTACHMENT
874-345	5mm Dia.	11mm Depth	Stryker TPS
874-346	6mm Dia.	11mm Depth	Stryker TPS
874-347	7mm Dia.	11mm Depth	Stryker TPS
874-348	8mm Dia.	11mm Depth	Stryker TPS
874-349	9mm Dia.	11mm Depth	Stryker TPS
874-350	10mm Dia.	11mm Depth	Stryker TPS
874-385	5mm Dia.	11mm Depth	Midas “AM” Attachment
874-386	6mm Dia.	11mm Depth	Midas “AM” Attachment
874-387	7mm Dia.	11mm Depth	Midas “AM” Attachment
874-388	8mm Dia.	11mm Depth	Midas “AM” Attachment
874-389	9mm Dia.	11mm Depth	Midas “AM” Attachment
874-390	10mm Dia.	11mm Depth	Midas “AM” Attachment
874-391	5mm Dia.	11mm Depth	Midas “M” Attachment
874-392	6mm Dia.	11mm Depth	Midas “M” Attachment
874-393	7mm Dia.	11mm Depth	Midas “M” Attachment
874-394	8mm Dia.	11mm Depth	Midas “M” Attachment
874-395	9mm Dia.	11mm Depth	Midas “M” Attachment
874-396	10mm Dia.	11mm Depth	Midas “M” Attachment
874-405	5mm Dia.	11mm Depth	Midas “G8” Attachment
874-406	6mm Dia.	11mm Depth	Midas “G8” Attachment
874-407	7mm Dia.	11mm Depth	Midas “G8” Attachment
874-408	8mm Dia.	11mm Depth	Midas “G8” Attachment
874-409	9mm Dia.	11mm Depth	Midas “G8” Attachment
874-410	10mm Dia.	11mm Depth	Midas “G8” Attachment

TRIMLINE™ ACDF

INSTRUMENT SET

STANDARD DISTRACTOR SET

ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-080	Vertebral Body Distractor (Right)	875-089	16mm Distractor Pins, (10/Pkg) Sterile
875-087	12mm Distractor Pins, (10/Pkg) Sterile	875-090	Distractor Screwdriver
875-088	14mm Distractor Pins, (10/Pkg) Sterile	Note: Distractor pins are packaged sterile.	

STANDARD DISTRACTOR SET – AUXILIARY ITEMS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-084	Drill Guide (R)	875-950	Twist Drill

KERRISONS

ITEM	DESCRIPTION	ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-251	1mm Kerrison	875-252	2mm Kerrison	875-253	3mm Kerrison

HAND-HELD RETRACTORS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-050	Hand-Held Retractor, Straight, 18mm	875-052	Hand-Held Retractor, Back Lip, 20mm
875-051	Small Hand-Held Retractor, Straight, 18mm	875-053	Hand-Held Retractor, Curved, 23mm

SELF-RETAINING RETRACTORS AND BLADES

ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-110	Transverse Self-Retaining Retractor Frame	875-158	23x70mm Discectomy Blade
875-115	Longitudinal Self-Retaining Retractor Frame	875-160	20x30mm Longitudinal Blade
875-149	Retractor Blade Handle	875-162	20x40mm Longitudinal Blade
875-150	23x30mm Discectomy Blade	875-164	20x50mm Longitudinal Blade
875-152	23x40mm Discectomy Blade	875-166	20x60mm Longitudinal Blade
875-154	23x50mm Discectomy Blade	875-168	20x70mm Longitudinal Blade
875-156	23x60mm Discectomy Blade		

CURETTES

ITEM	DESCRIPTION	ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-300	Curette Straight 6-0	875-305	Curette Straight 1-0	875-313	Curette Angled 3-0
875-302	Curette Straight 4-0	875-307	Curette Straight 2-0	875-314	Curette Angled 2-0
875-303	Curette Straight 3-0	875-310	Curette Angled 6-0	875-315	Curette Angled 1-0
875-304	Curette Straight 2-0	875-312	Curette Angled 4-0		

MICRO CURETTES

ITEM	DESCRIPTION	ITEM	DESCRIPTION	ITEM	DESCRIPTION
875-370	Micro Curette Straight 6-0	875-374	Micro Curette Straight 2-0	875-383	Micro Curette Angled 3-00
875-372	Micro Curette Straight 4-0	875-380	Micro Curette Angled 6-0	875-384	Micro Curette Angled 2-0
875-373	Micro Curette Straight 3-0	875-382	Micro Curette Angled 4-0		

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 as applied to these devices. Some instruments are made in 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.

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.

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

Decontamination and Cleaning:
All instruments should be thoroughly cleaned before sterilization using established hospital methods. This includes the use of neutral cleaners followed by deionized water rinse.

Note:
Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

Also, certain instruments may require dismantling before cleaning.

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

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.

Sterilization:
Unless supplied sterile and clearly labeled as such, this instrument must be sterilized before use.

MEDTRONIC SOFAMOR DANEK instruments for use with internal spinal fixation implants must be steam sterilized according to the following process parameters :

METHOD: Steam	CYCLE:Gravity
TEMPERATURE: 121°C (250° F)	EXPOSURE TIME: 30 min.

Or :

METHOD: Steam	CYCLE:Pre-Vacuum
TEMPERATURE: 132°C (270° F)	EXPOSURE TIME: 4 min.

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: Steam	CYCLE: Gravity
TEMPERATURE: 134°C (273° F)	EXPOSURE TIME: 18 min.

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.

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 growth has occurred, 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 see the address page of this information sheet.

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.

Notes

For product availability, labeling limitations, and/or more information on any Medtronic Sofamor Danek products, contact your MEDTRONIC SOFAMOR DANEK USA Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA Customer Service toll free: 800-933-2635.

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See package insert for labeling limitations.

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