ATLAS® CABLE SYSTEM

Instructional Brochure

The Medtronic ATLAS® Cable System may simplify surgical procedures with accurate instrumentation and our integral crimp which eliminates intraoperative assembly.

ATLAS® Cable System

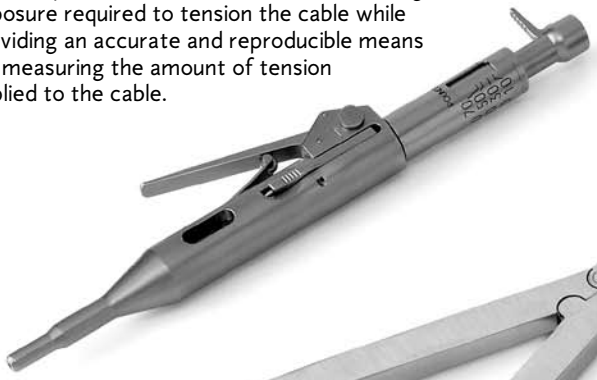
The ATLAS® Cable System may offer increased flexibility, strength and control over monofilament wire in the correction of spinal instability.

Sterilization Case
825-299

Used to sterilize and store the ATLAS® Cable instruments.

Cable Tensioner*
825-210

This low profile instrument minimizes the surgical exposure required to tension the cable while providing an accurate and reproducible means for measuring the amount of tension applied to the cable.



Provisional Crimp*
825-200

For use in sequential tightening of the cables. Allows for additional tensioning or loosening as required before the final lock of the cable.

Cable Crimper
825-220

Used in conjunction with the Cable Tensioner to lock the Integral Crimp.

Cutter
825-150

For use in cutting the cable after the Integral Crimp has been locked.

Integral Bar Crimp*
826-016 SS
826-216 Ti

Flat Bar (2 pack)
826-217 Ti

Double Leader Cable*
826-019 SS
826-219 Ti

Double Cable*
826-011 SS
826-012 SS (12 pack)
826-211 Ti
826-212 Ti (12 pack)

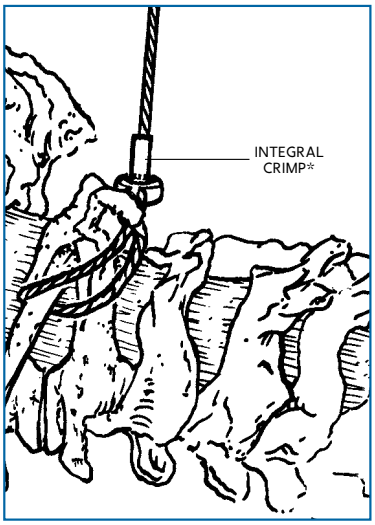
Single Cable*
826-013 SS
826-213 Ti

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

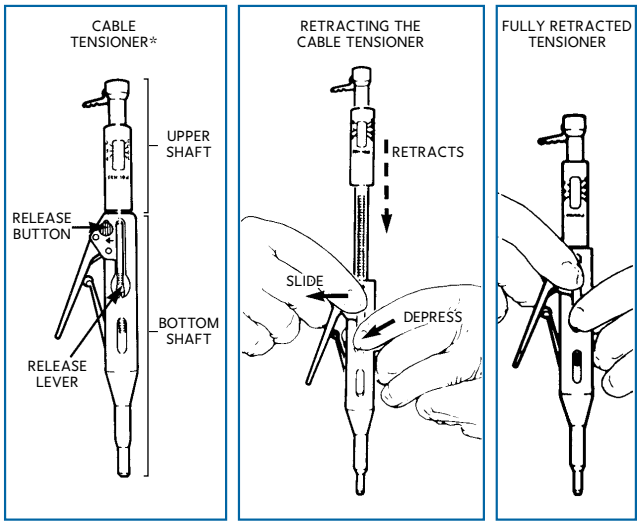
*U.S. Patent Nos. 5,395,374; 5,432,820; 5,569,253; 5,928,237; 6,077,268 and other patents pending.

CABLE TENSIONER INSTRUCTIONS

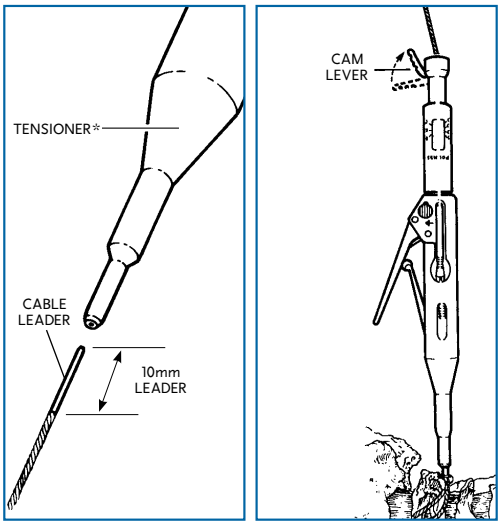
1 Slide cable through Integral Crimp*.



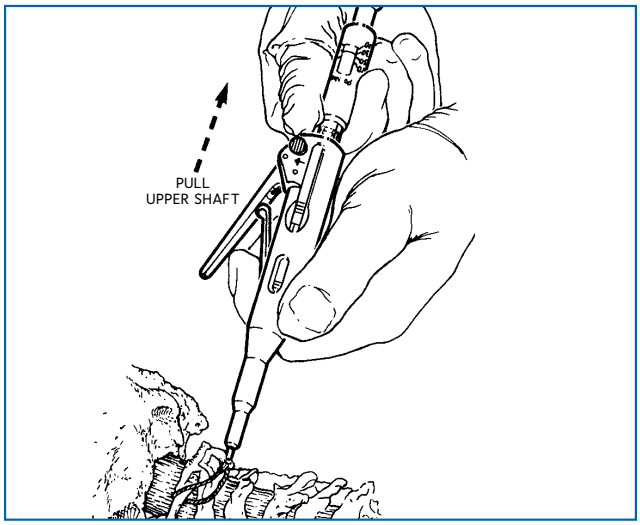
2 Prepare Cable Tensioner* by depressing the release lever and sliding the release button. This will fully retract the Cable Tensioner*.



3 To insert and lock cable, cable leader must be straight and short. Once cable has been threaded through Tensioner, lift cam lever and set firmly.

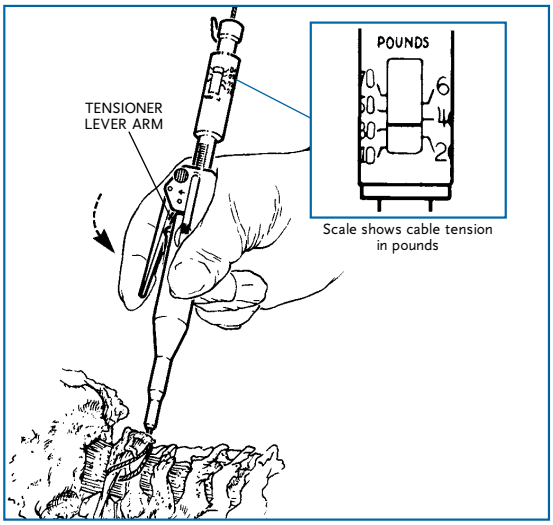


4 To remove cable slack, hold bottom shaft of Tensioner while extending upper shaft of Tensioner*.



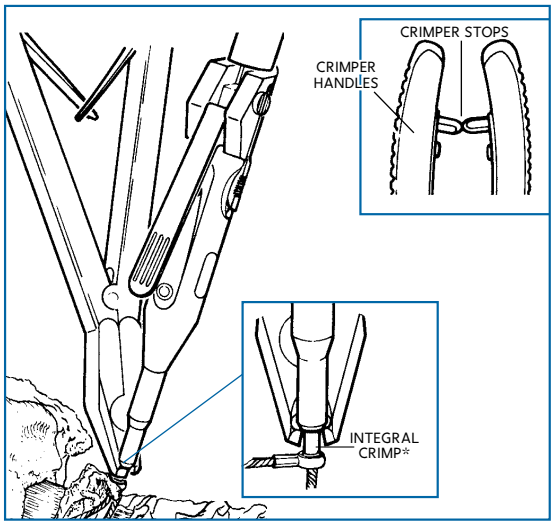
CABLE TENSIONER INSTRUCTIONS (CONTINUED)

5 To apply measured tension to Cable*, depress Tensioner* lever arm repeatedly until desired tension is achieved.

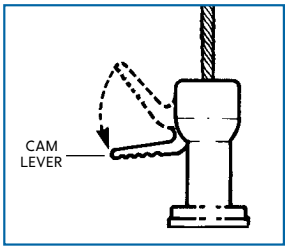


Maximum Cable Tension**:
Titanium Alloy Cables (30 lbs)
Stainless Steel Cables (60 lbs)

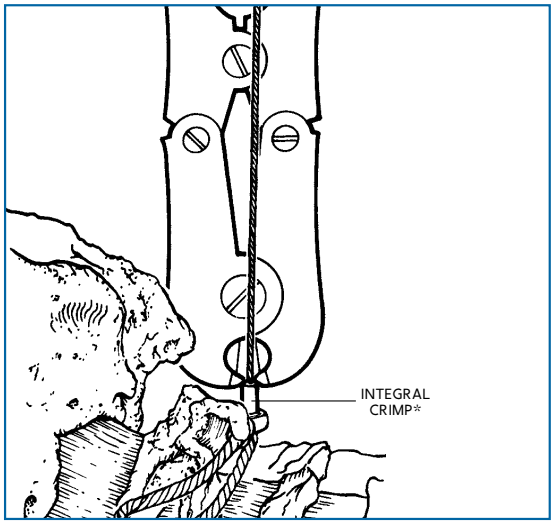
6 To secure Integral Crimp* onto cable, position Crimper* jaws around Integral Crimp* and squeeze Crimper Handles once until the Crimper Stops touch.



7 To release Cable* lower cam lever and remove Tensioner*.



8 Trim excess cable at end of Integral Crimp*.

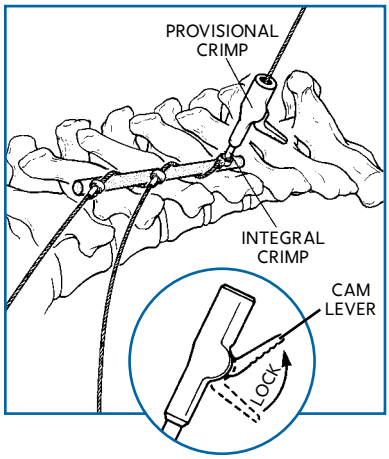


*U.S. PATENT NOS. 5, 312, 410; 5, 395, 374; 5, 423, 820; 5, 569, 253; and 5, 928, 237; and other patents pending apply to various aspects of the Integral Crimp and Cable Tension System.

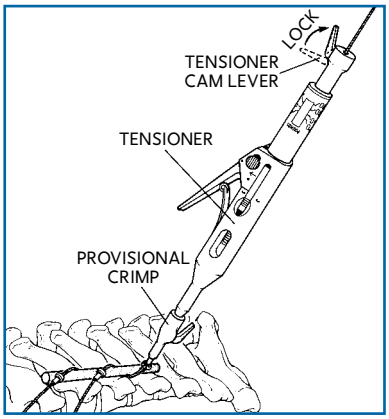
**The maximum cable tensions are not the required tensions, but the maximum tensions to which the cables can be tightened. The actual tension applied should be dependent on the quality of the bone and the medical judgment of the surgeon.

PROVISIONAL CRIMP INSTRUCTIONS

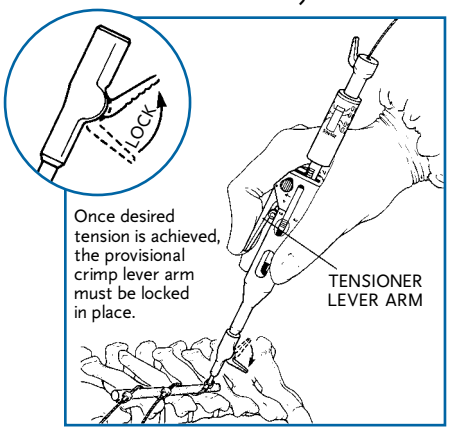
1 After cable has been inserted through Integral Crimp*, slide Provisional Crimp* onto cable and lock cam lever.



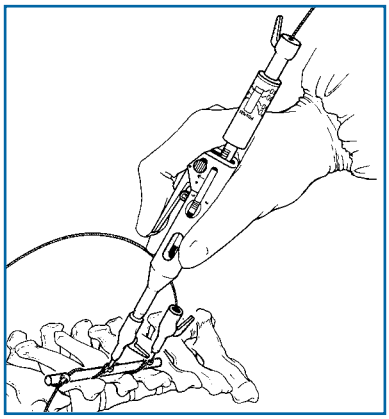
2 Thread cable through Tensioner* and lock Tensioner* cam lever.



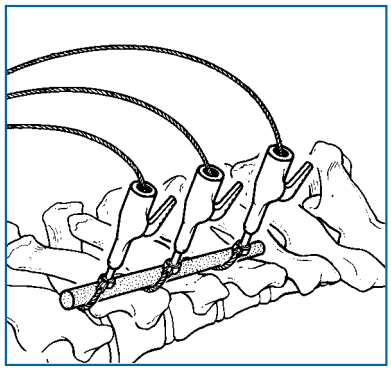
3 Depress Tensioner* lever arm repeatedly to desired tension. Provisional Crimp* lever arm will release automatically.



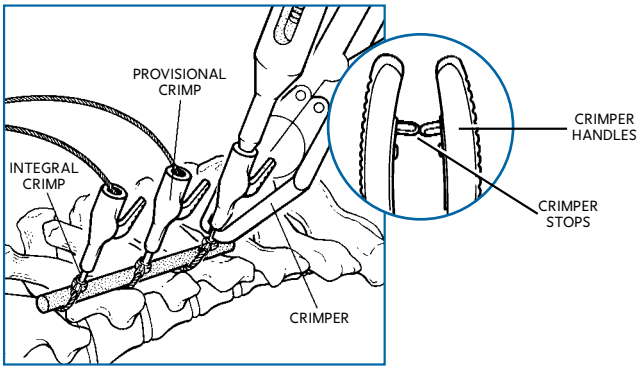
4 Repeat steps 1–3 on all remaining cables.



5 Tensioner* adjustments can be made at each location, by repeating steps 2 and 3.



6 To complete construct, position Crimper jaws around Integral Crimp*, and squeeze Crimper Handles once until the Crimper Stops touch.



7 Remove Tensioner* and Provisional Crimps*, trim excess cable at the end of Integral Crimp*.

*U.S. PATENT NOS. 5, 312, 410; 5, 395, 374; 5, 423, 820; 5, 569, 253; and 5, 928, 237; and other patents pending apply to various aspects of the Integral Crimp and Cable Tension System.

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*	Pre-Vacuum*	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment. *For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

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.

Contact Customer Service or your sales representative for the most up-to-date revision of the package insert.

Important Information on the ATLAS™ CABLE Instruments

INTRODUCTION

The ATLAS™ Cable System should be inserted using the specially designed ATLAS™ instruments. The following operation and maintenance applies to the ATLAS™ Cable Tensioner (Catalog Number 825-210). The design and/or use of the ATLAS™ Cable Tensioner may be covered in whole or in part by U.S. Patent No. 5,312,410 and other patents pending.

PROPER TENSIONING TECHNIQUE

TO TENSION AN ATLAS CABLE:

1. With the tip of the tensioner down, depress the Shaft Release Rocker and simultaneously press the Ratchet Release Button in the direction indicated by the engraved arrow. The shaft should drop into the most collapsed position.
2. Insert the cable leader into the tip of the tensioner and thread it through the instrument until it appears at the opposite end of the tensioner near the cam grip. Pull the cable through the instrument as far as practical.
3. Set the cam grip by flipping it up to tighten down on the cable, making sure the cam is set firmly.
4. To perform initial tensioning, grip the glider in the area of the cam grip and pull the shaft out while holding the housing. This action will pull the initial slack out of the cable.
5. To apply measured tension, operate the tensioning lever by depressing it with the finger or thumb. The tension scale indicator will read the cable tension directly in **pounds and Newtons.**

IMPORTANT NOTE:

The actual tension value should be decided by the surgeon taking into account the condition and quality of the patient's bone. However, the tension applied should never be in excess of 60 lbs. (267 Newtons) for stainless steel and 35 lbs. (156 Newtons) for titanium. Loads greater than this value may fracture the bone and/or damage the cable or instruments.

TO CRIMP:

1. Once the cable has been properly tensioned, the crimper can be positioned by coupling the tensioner tip with the mating groove in the crimper jaws.
2. The crimper (825-220) handles should be squeezed by hand to swage the crimp. To ensure complete crimping be sure that the crimper stops touch.

TO RELEASE THE CABLE:

1. Remove the crimper from its position at the tensioner tip.
2. Release the cam grip.
3. Slide the tensioner from the cable.

CUTTING OFF EXCESS CABLE:

Trim the excess cable at the end of the crimp using the Cable Cutter.

SUGGESTED TECHNIQUES:

1. More than one tensioner can be used at the apex of a severe curve to gain gradual correction.
2. Tensioner must be in fully collapsed position to allow for easy threading of cable.
3. Before inserting, the cable leader should be trimmed to approximately 5mm (.2 in.) and should be as straight as possible.
4. Cable can be rotated slightly to be threaded more easily.
5. If the cam is in the closed position, cable will not slide through the tensioner.
6. Tensioning handle should be allowed to return to initial position before depressing again. An audible click will be heard.
7. Never tension the stainless steel cable in excess of 60 lbs. (267 Newtons) or the titanium cable in excess of 35 lbs. (156 Newtons). Cable and/or instrument damage will occur.

STERILIZATION:

Unless marked sterile and clearly labeled as such, the products described are supplied non-sterile and must be sterilized prior to use. If the Medtronic Sofamor Danek components described in this insert are sterilized by the hospital in a tray or case, they should be sterilized in the tray or case provided by Medtronic Sofamor Danek. These may be steam sterilized by the hospital using the following process parameters:

NOTE: The following note applies to the process parameter identified with the ** below: For use of this product and instruments outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come onto contact with the central nervous system.

Method: Steam
Cycle: Gravity
Temperature: 250°F (121°C)
Exposure Time: 30 minutes

Or

Method: Steam
Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes

Or

Method: Steam**
Cycle: Gravity
Temperature: 273°F (134°C)
Exposure Time: 20minutes

Cleaning and Decontamination:

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and disinfecting of instruments can be performed with alkali aldehyde-free solvents at higher temperatures. Cleaning and decontamination can 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.

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

CARE AND MAINTENANCE:

The cable instruments are precision instruments. To ensure long life and proper operation, the following guidelines must be followed:

1. The ATLAS™ Cable Tensioner is provided non-sterile. The Tensioner sterilization should be performed by the hospital with the instrument in fully extended position to allow for proper venting and drainage.
2. Tensioner should be lubricated after each surgery and should never be stored wet.
3. Tensioner should never be used to pull a cable to a tension greater than 60 lbs. (267 Newtons). Instrument damage may occur.

NOTE: Carefully read and follow the important information contained in the ATLAS™ Cable System Package Insert.

CAUTION: If these instructions for care and maintenance are not followed, it would not be unusual for this instrument to jam, "freeze-up", disassemble, or otherwise not perform properly. Any of these anticipated consequences may prevent the use of the ATLAS Cable System and/or extend surgery time. Have sterile back-up instruments in case the need arises.

PHYSICIAN NOTE: Although the physician is the learned intermediary, the important medical information contained in this document should be conveyed to the patient.

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

!USA For US Audiences Only

CAUTION: Federal Law (U.S.A.) restricts these devices to sale by or on the order of a physician.

PACKAGING:

All ATLAS™ instruments should be checked for damage prior to use. Damaged packages or products should be returned to MEDTRONIC SOFAMOR DANEK. The ATLAS™ instruments are supplied non-sterile and must be sterilized prior to use.

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Medtronic Sofamor Danek. Further, if any of the implanted spinal system component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Medtronic Sofamor Danek product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Contact Customer Service or your sales representative for the most up-to-date revision of the package insert.

Important Information on the ATLAS™ CABLE Instruments

PURPOSE:

The ATLAS® Cable system is a temporary implant for the use in orthopaedic and cardiovascular surgery. The system is intended to help provide temporary stabilization, augment the development of solid bony fusion and/or aid in the repair of bone fractures.

DESCRIPTION:

The system consists of a multi-stranded cable in several configurations.

The ATLAS® Cable System implant components are made of medical grade stainless steel. Alternatively, the system may be made out of titanium alloy or titanium. The material type will be on the label. Stainless steel and titanium implant components must not be used together in a construct. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog or price list for further information about warranties and limitations of liability.

INDICATIONS, CONTRAINDICATIONS, AND POSSIBLE ADVERSE EFFECTS

INDICATIONS:

Properly used, this device will aid in the repair or attachment of bony structures. The indications and contraindications of this system should be well understood by the surgeon. The system is indicated for use whenever a conservative or a non-implant surgery is deemed insufficient to improve the medical condition of the patient.

The ATLAS® Cable System can be utilized anywhere monofilament wire has been previously found to be indicated. The indications are:

1. Spinal applications would include sublaminar and intraspinous process wiring for trauma applications. Another application would be the use of the ATLAS® Cable System for instrumentation involved in the correction of scoliotic, kyphotic, and lordotic deformities. The stainless steel system may also be used with other stainless steel spinal implants such as the Unit Rod or Luque Rod or wherever "wiring" may help secure the attachment of other implants. The titanium system may also be used with other titanium implants.
2. Trochanteric reattachment after trochanteric osteotomy following total hip arthroplasty.
3. Sternotomy indications would include the "re-wiring" of osteomizing sternums.
4. Trauma surgery indications would include olecranon, ankle, patella, and some shoulder fracture rewiring.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Presence of overt infection and/or localized inflammation.
2. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and the amount of mechanical fixation.
3. Suspected or documented metal allergy or intolerance.
4. Any patient having inadequate tissue coverage over the operative site.
5. Any time implant utilization would interfere with anatomical structures or expected physiological performance, such as impinging on vital structures.
6. Severe commuted fractures such that segments may not be maintained in satisfactory proximate reduction, i.e. "cannonball" fractures.
7. The presence of marked bone absorption or severe metabolic bone disease that could compromise the fixation achieved.
8. Any other medical or surgical condition which would preclude the potential benefit of surgery, such as elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), fever, leukocytosis, or a marked left shift in the WBC differential count.
9. If the stainless steel version is used, the physical contact of the ATLAS® Cable System with any metal implant made of anything other than implant grade stainless steel.
10. If the titanium or titanium alloy version is used, the physical contact of the ATLAS® Cable with any metal implant made of anything other than implant grade titanium.
11. The combination of the ATLAS® Cable with monofilament wire.
12. Any case not described in the indications.

POSSIBLE ANTICIPATED ADVERSE EFFECTS:

1. Early or late loosening of the components.
2. Disassembly, fraying, kinking, loosening, bending, or breaking of any or all of the components.
3. Foreign body reaction to the implants including possible tumor formation.
4. Pressure on the skin from component parts where there is inadequate tissue coverage over the implant causing skin irritation.
5. Loss of proper curvature, correction, height, and/or reduction.
6. Infection.
7. Cables cutting through soft osteoporotic, osteopenic, or cancellous bone.
8. Bone forming around the implant making removal difficult or impossible.
9. Non-union (or pseudarthrosis) or bone fracture.
10. Neurovascular compromise including radiculopathy, paralysis, or other types of serious injury causing pain.
11. Hemorrhage of blood vessels.
12. Cessation of growth of the operated portion of the bone.
13. Death.

NOTE: Additional surgery may be necessary to correct some of the anticipated adverse reactions.

IMPORTANT NOTE: The actual tension value should be decided by the surgeon taking into account the condition and quality of the patient's bone. However, the tension applied should never be in excess of 60 lbs. (27kg.) (267 Newtons) for stainless steel and 35 lbs. (16kg.) (156 Newtons) for titanium. Loads greater than this value may fracture the bone and/or damage the cable or instruments.

WARNINGS AND PRECAUTIONS:

A successful result is not always achieved in every surgical case. This fact is especially true in orthopaedic or cardiovascular surgery where many extenuating circumstances may compromise the results. The ATLAS® Cable System is only a temporary implant and should only be used to augment bony fusion or aid fracture healing. This device system is not intended to be the sole means of support. No implant can withstand body loads without the support of bone. In this event, bending, fraying, kinking, loosening, disassembly, and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the ATLAS® Cable System by the surgeon. Further, the proper selection of the patient and the compliance of the patient will greatly affect the results. For some spinal cases, patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for surgery. Patients with poor bone quality are also poor candidates for surgery.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

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CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Other preoperative, intraoperative, and postoperative warnings are as follows:

Implant Selection :

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and especially from corrosive environments.
4. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally check the devices to verify that all parts and necessary instruments are present before the surgery begins.
5. Read and carefully follow the package insert/directions for use of the cable tensioner devices.

INTRAOPERATIVE:

1. The instructions in the ATLAS® Cable and ATLAS® Cable instrument package inserts should be read and carefully followed. Use only ATLAS® Cable instruments during the procedure.
2. At all times, during spinal surgery, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Except for the final cutting action at the end of the procedure, do not cut or scratch or kink the cable or accessories with any sharp objects. Any such action may reduce the functional life of the construct.
4. Before closing the soft tissues, all of the crimps should be swaged firmly as described in the ATLAS® Cable instrument package insert. Recheck the tightness of all crimps after finishing to make sure that none have loosened during the swaging of the other crimps. Failure to do so may cause loosening.

POSTOPERATIVE:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, fraying, or breakage of the device are complications which can occur as a result of weight-bearing or muscular activity. The risk of device complications during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other weight-supporting devices. The patient should be warned to avoid falls or sudden jolts in position.
2. To allow the maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device assembly. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of athletic participation. If appropriate, the patient should be advised not to smoke or consume alcohol, non-steroidals, or aspirin during the bone graft healing process.
3. If appropriate, the patients should be advised of their inability to bend at the point of fusion and taught to compensate for this permanent physical restriction in body motion.
4. If a non-union develops or if the components, loosen, fray, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual bending, loosening, fraying, or breakage of the device. It is important that immobilization of the fracture or surgical site be maintained until firm bony union is established and confirmed by roentgenograph examination.
5. The ATLAS® Cable System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and must be removed. In most cases removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, any of the following complications may occur: (1) corrosion, with localized tissue reaction or pain, (2) migration of implant position resulting in injury, (3) risk of injury from postoperative trauma, (4) bending, loosening, and/or breakage, which could make removal impractical or difficult, (5) pain, discomfort, or abnormal sensations due to the presence of the device, (6) possible increased risk of infection, and (7) bone loss caused by stress shielding. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture or other complications.
6. Any retrieved devices should never be reused in another surgical procedure. The retrieved parts should be handled and disposed of in such a manner as to ensure that reuse is impossible.

PACKAGING:

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used and should be returned to MEDTRONIC SOFAMOR DANEK.

Cleaning and Decontamination:

Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic 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 one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment. *For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

Remove any packaging materials prior to sterilization. Use only sterile products in the operative field.

Important Information on the ATLAS™ CABLE Instruments (CONTINUED)

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance should notify the distributor, MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted ATLAS® Cable System component(s) ever “malfunctions” (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC SOFAMOR DANEK product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX, or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION:

Recommended directions of use of this system are available at no charge upon request. If further information is needed or required please contact MEDTRONIC SOFAMOR DANEK.

Contact Customer Service or your sales representative for the most up-to-date revision of the package insert.

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

MEDTRONIC
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

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

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