ATLAS® CABLE SYSTEM

User's Guide

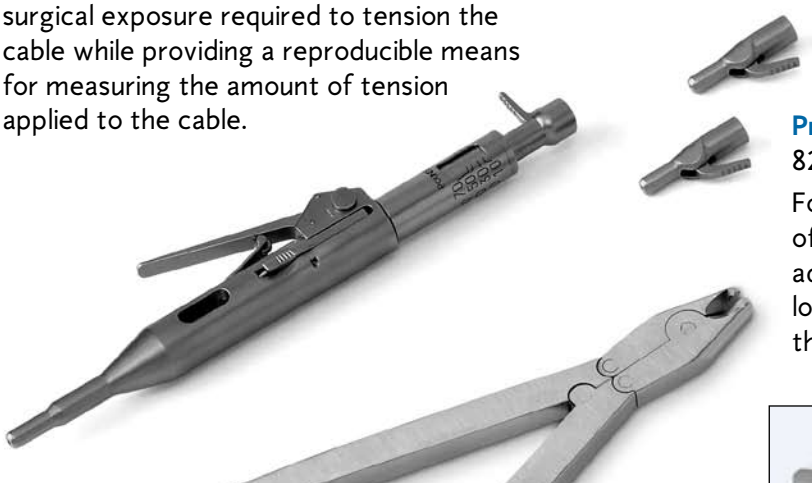
The ATLAS® Cable System may simplify surgical procedures by providing a cable tensioner with accurate measurements and an integral crimp that eliminates intraoperative assembly.

The ATLAS® Cable System may offer more advantages over monofilament wire to aid in the correction of spinal instability, including:

- Greater flexibility
- Increased strength in testing†

Cable Tensioner
825-210

This low-profile instrument minimizes the surgical exposure required to tension the cable while providing a 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.

Sterilization Case
825-299

Used to sterilize and store the ATLAS® Cable instruments.

Cable Crimper
825-220

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

Cutter
825-150

For use in cutting the cable after the Integral Bar 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

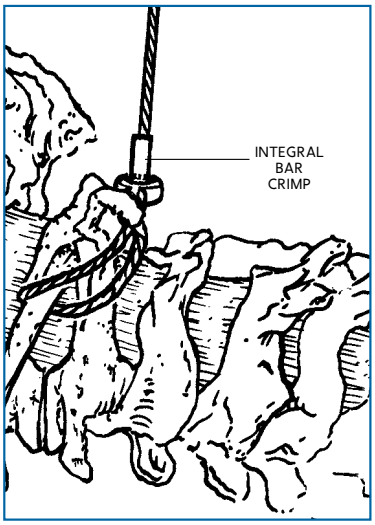
Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

*U.S. Patent Nos. 5,312,410; 5,395,374; 5,432,820; 5,569,253; 5,928,237; 6,077,268 and other patents pending apply to various aspects of the Integral Crimp and Cable Tension System.

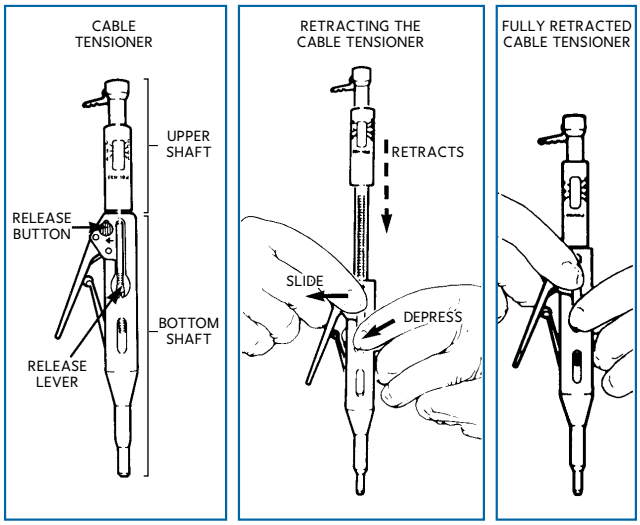
†Dickman CA, Papadopoulos SM, Crawford NR, Brantley AG, Gealer RL. Comparative mechanical properties of spinal cable and wire fixation systems. *Spine*. 1997 Mar 15;22(6):596-604.

Cable Tensioner Instructions

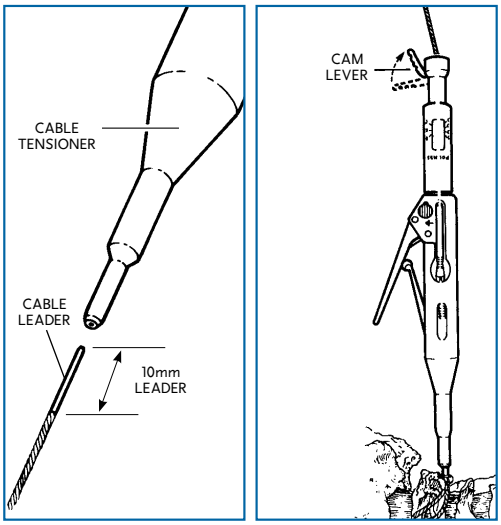
1 Slide cable through the Integral Bar Crimp.



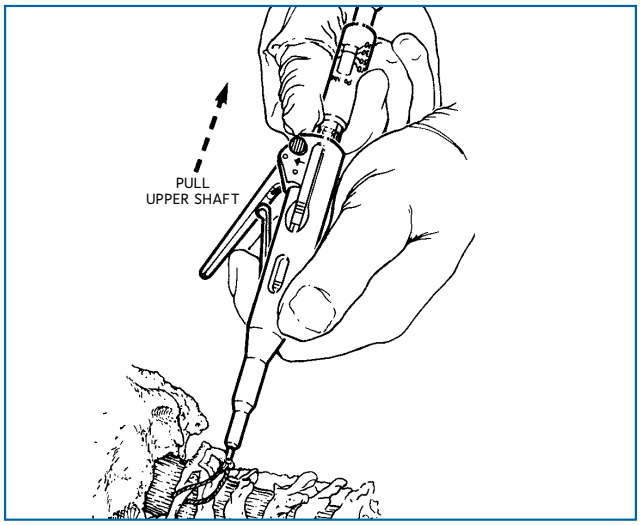
2 Prepare the Cable Tensioner by depressing the release lever and sliding the release button. This will fully retract the Cable Tensioner.



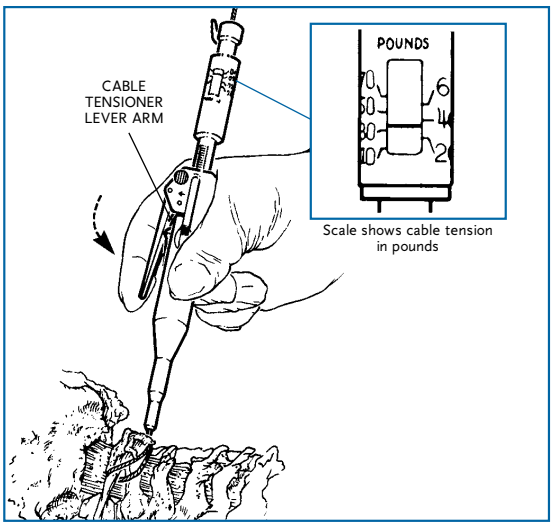
3 To insert and lock the cable, the cable leader must be straight and short. Once the cable has been threaded through the Cable Tensioner, lift the cam lever and set firmly.



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

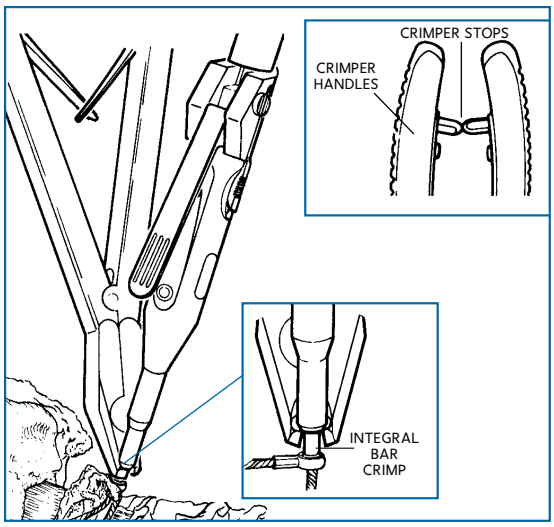


5 To apply measured tension to the cable, depress the Cable Tensioner lever arm repeatedly until the desired tension is achieved.*

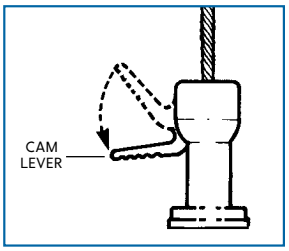


Maximum Cable Tension*:
Titanium Alloy Cables (35 lbs)
Stainless Steel Cables (60 lbs)

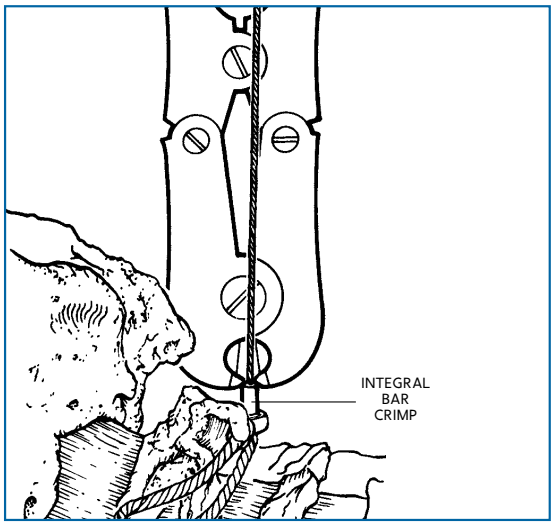
6 To secure the Integral Bar Crimp onto the cable, position the Cable Crimper jaws around the Integral Bar Crimp and squeeze the handles once until the Cable Crimper stops touch.



7 To release the cable, lower the cam lever and remove the Cable Tensioner.



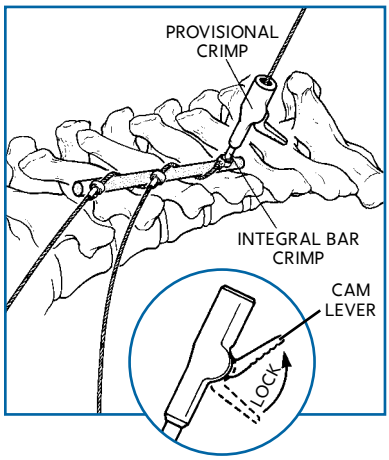
8 Trim the excess cable at the end of the Integral Bar Crimp.



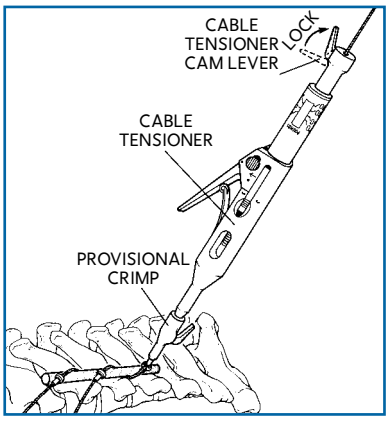
*The maximum cable tensions are not the required tensions, but the maximum tensions to which the cables can be tightened. The actual tension applied should be dependent on the quality of the bone and the medical judgment of the surgeon.

Provisional Crimp Instructions

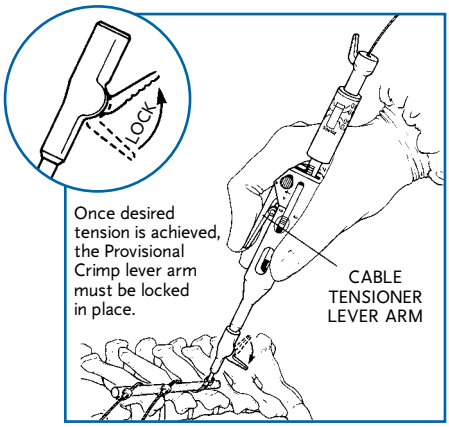
1 After the cable has been inserted through the Integral Bar Crimp, slide the Provisional Crimp onto the cable and lock the cam lever.



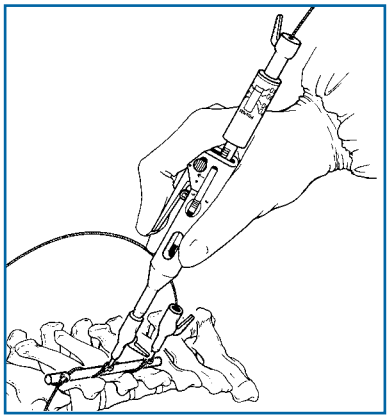
2 Thread the cable through the Cable Tensioner and lock the Cable Tensioner cam lever.



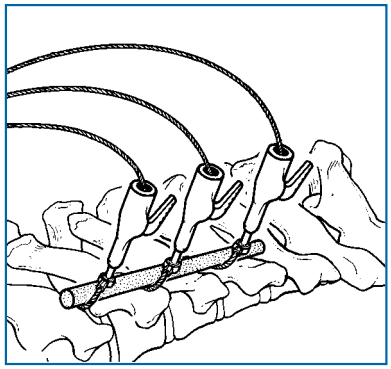
3 Depress the Cable Tensioner lever arm repeatedly until the desired tension is reached. The Provisional Crimp lever arm will release automatically.



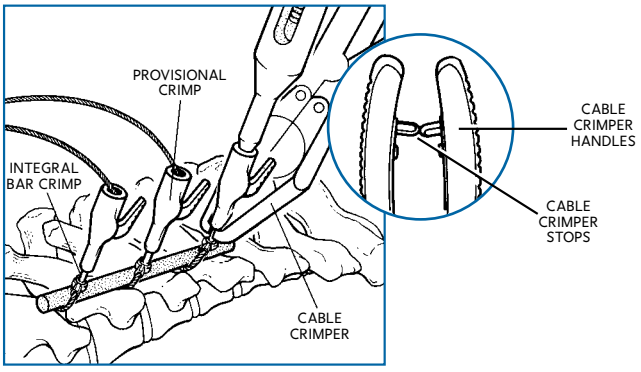
4 Repeat steps 1 to 3 on all remaining cables.



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



6 To complete the construct, position the Cable Crimper jaws around the Integral Bar Crimp and squeeze the handles once until the Cable Crimper stops touch.



7 Remove the Cable Tensioner and Provisional Crimps. Trim excess cable at the end of the Integral Bar Crimp.

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.

!USA For US Audiences Only

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.

Important Product Information (Continued)

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

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

EC REP

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

Insert 0380075 Rev A

Notes

Notes

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 judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.

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