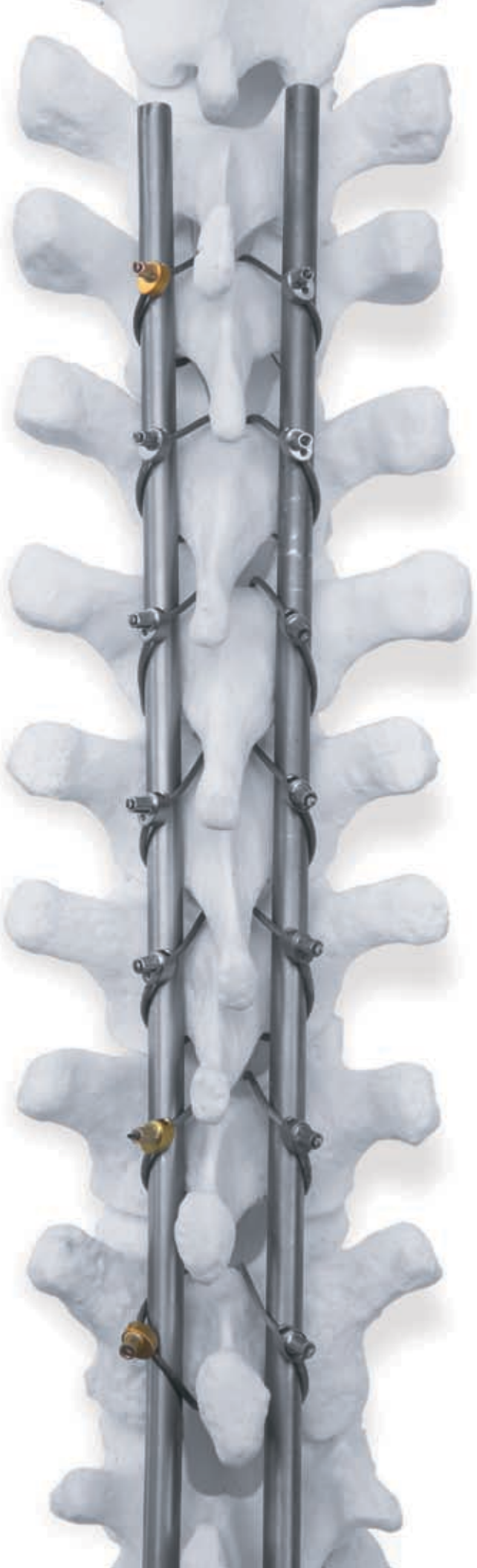


Surgical Technique

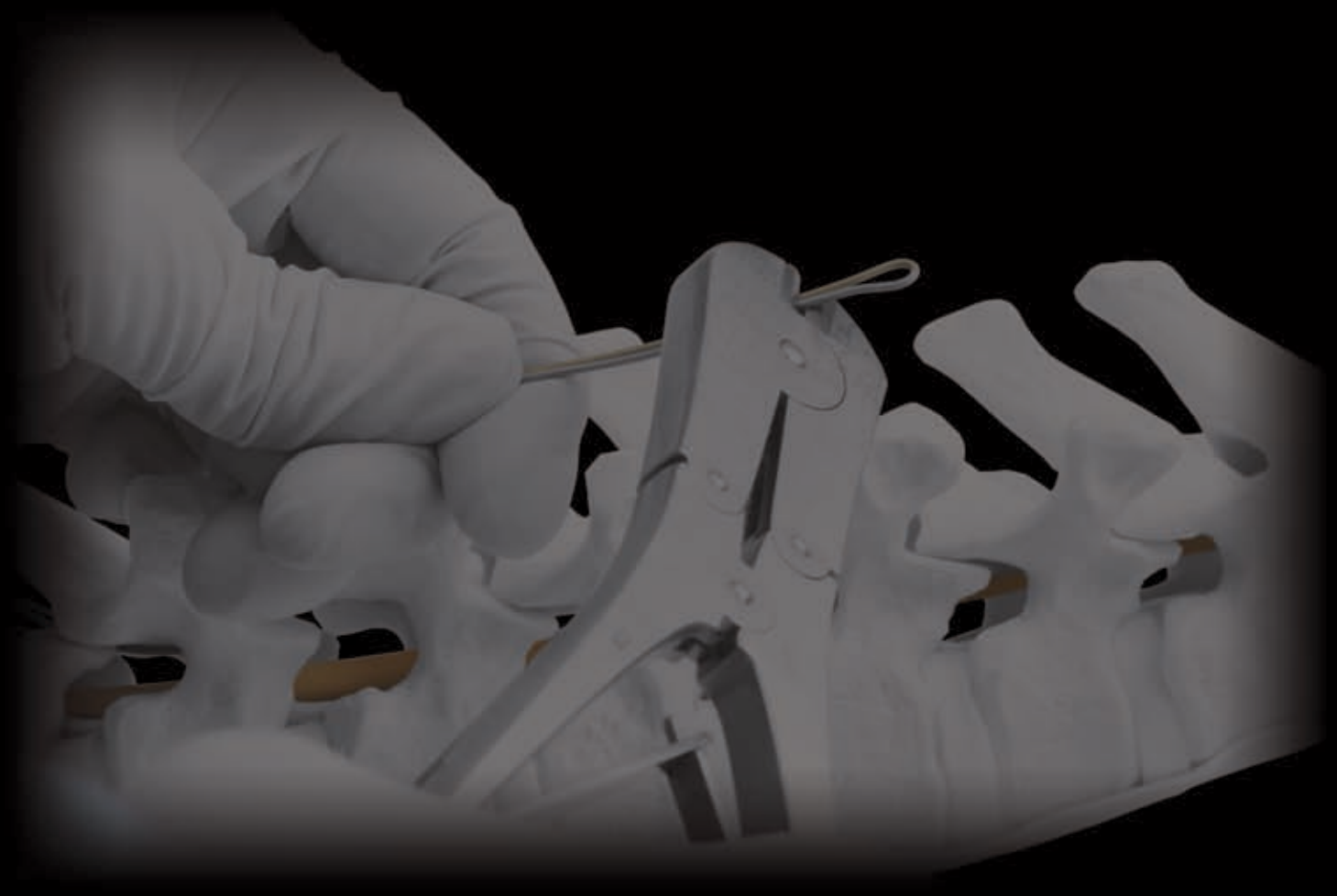
Lentur™ Cable System

Soft and Flexible Feel with Secure Stabilization

- Stronger alternative to monofilament fixation wires
- Designed to increase fatigue strength while maintaining flexibility

BIOMET® SPINE

Contents

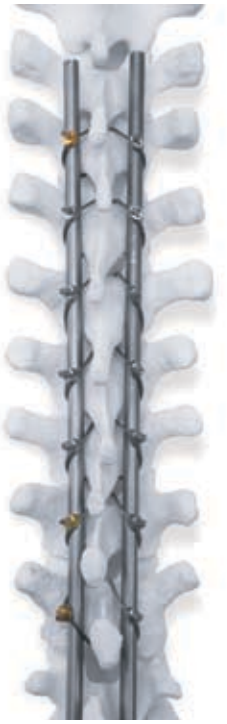


Introduction

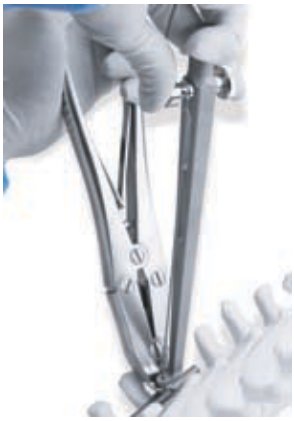
The Lentur™ Cable System is a stronger alternative to monofilament fixation wires with the design goal to increase fatigue strength while maintaining flexibility.

The smooth surface of the cable increases strength without increasing size and provides less risk of injury or abrasion during spinal fixation. The color coded Double Cables prevent inadvertent crossing of Cables under the lamina.

Cables are provided in individual sterile packs with the crimp attached to minimize the number of components needed in each procedure. The Lentur™ Cable System can be used in orthopedic trauma, spine reconstructive surgery, and cardiovascular surgery.



System Design Features and Benefits



Feature	**Benefit**
Lentur™ Cables	Crimp Already Attached Sterile Single Pack
Double Cable	Color Coded Leads With Matching Crimps
Instrumentation	Short Learning Curve Logical, Easy to Use
Versatile System	Use for Various Deformity Correction Techniques

Implants

Single Cables

The Single Cable allows the surgeon to pass the cable under one side of the lamina at a time. The crimp is attached to each cable for easy application.

The Single Cable With Attached Crimp is Offered in 55cm Length in 1.1mm Diameter

Double Cables

The Double Cable incorporates two cables connected with a malleable leader. The crimp is fastened to the other end of each cable. The double cable allows the surgeon to pass the cable under the left and right side of the lamina simultaneously. The crimp and leader are color-coded for easy application. This prevents inadvertent crossing under the lamina.

The Double Cable With Attached Crimps is Offered in 55cm Length in 1.1mm Diameter

Instrumentation

Cable Tensioner

Torque Driver

Crimper

Cutter

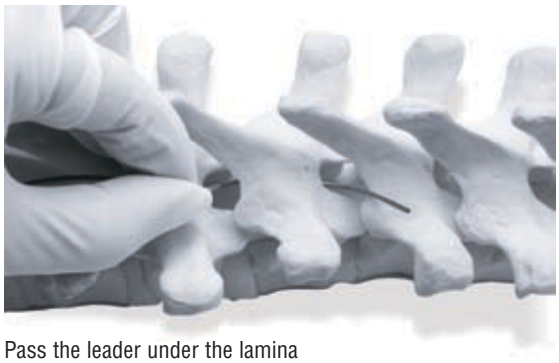
Single Cable

1) The Cable has a malleable leader and a crimp fastened at the end of the individual Cable. The leader can be formed (by hand) to ease passing the leader under the lamina. Gently pass the leader with only the Cable in contact with the lamina.

2) Next, thread the leader through the through hole of the crimp on the proximal tip of the Cable. The leader may require some straightening to ease passage through the crimp hole.

   Gently pull the Cable around the bone or the object to be secured, e.g. the rod, being sure to eliminate kinks or tight bends.

The leader can be formed by hand



Pass the leader under the lamina

Thread the leader through the attached crimp

3) Thread the leader through the hole located at the distal tip of the Tensioner.

   Press in the take-up spool, located at the proximal end of the Tensioner, and then thread the leader through the take-up spool. Pull the Cable through the take-up spool to eliminate any excess.

   Slowly turn the knurled knob opposite the spool to further provisionally tighten the Cable.

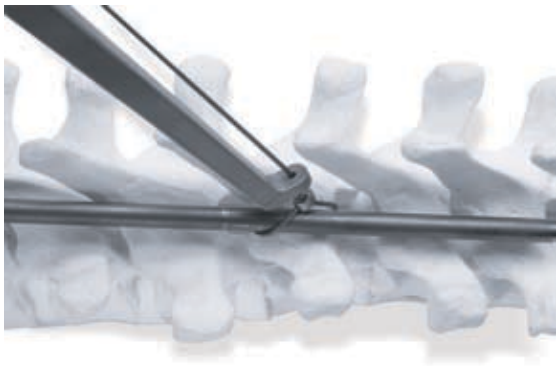
Thread the leader through the Tensioner

Press in the take-up spool and thread the leader through

Turn the knurled knob to tighten the Cable

Confirm the positioning and the appropriate tension applied to the Cable.

If the Cable requires loosening, pull the tab located at the top of the Tensioner to release the Cable.



Confirm position and tension

Pull tab to loosen the Cable

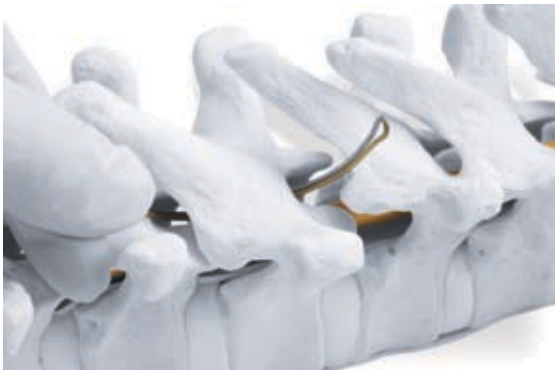
Double Cable

1) The Double Cable has an attached malleable leader and crimps fastened at the end of each individual Cable.

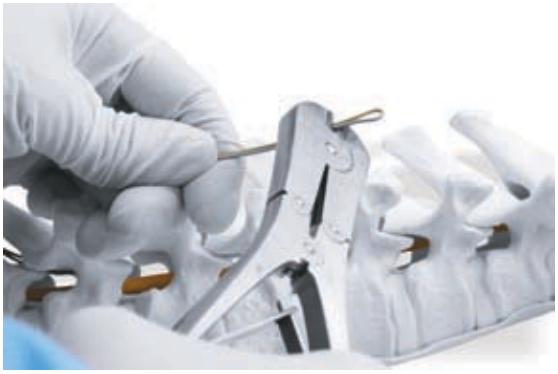
   Pass the leader portion underneath the lamina; a nerve hook may be used at the laminotomy site to catch the tip of the leader. The leader portion is then gently pulled through until only the Cable is in contact with the lamina.

2) Cut only the tip of the leader using the Cable Cutters to separate the two leaders. Each leader is color coded to match the crimp to ensure the Cables are not crossed. Do not cut off the entire leader to allow the surgeon to easily thread the Cable through the crimp.

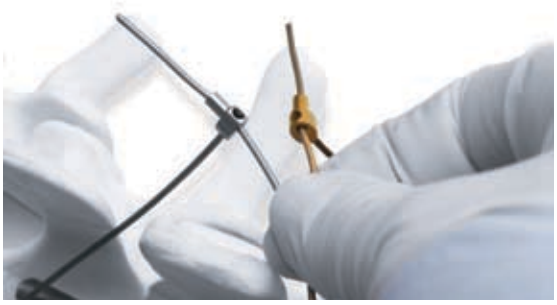
   The colored leader is then threaded through the corresponding colored crimp at the end of the Cable. The Cable is gently tightened down around the bone or objects to be secured.



Pass the double leader under the lamina



Cut the tip of the double leader to separate the Cables



Thread each leader through the corresponding crimp

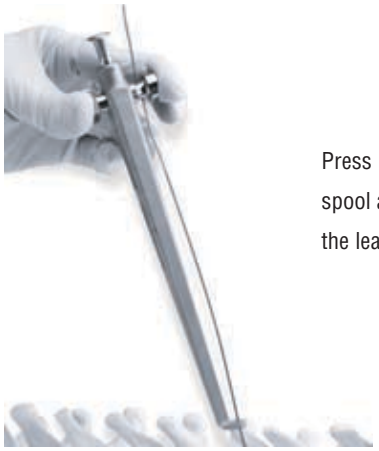
3) Thread the leader through the hole located at the distal tip of the Tensioner. Press in the take-up spool, located at the proximal end of the Tensioner, and then thread the leader through the take-up spool. Pull the Cable through the take-up spool to eliminate any excess.

   Slowly turn the knurled knob opposite the spool to further provisionally tighten the Cable.

   Confirm the positioning and the appropriate tension applied to the Cable.

   If the Cable requires loosening, pull the tab located on the top of the Tensioner to release the Cable.

Thread the leader through the Tensioner



Press in the take-up spool and thread the leader through

Turn the knurled knob to tighten the Cable

Torque

4) Set the torque limit on the Torque Driver by turning the setting to the recommended torque level based on the bone quality, location of the implant, and the application.

   Refer to page 12 for a guide to proper tensioning.

   Selecting the proper torque level is essential because it determines the Cable tension.

   Set the torque handle by pulling the knurled rounded portion located at the middle of the torque wrench.

   Attach the Torque Driver to the hex located in the knurled knob on the top of the Tensioner Instrument. Begin by turning until the appropriate tension is achieved as indicated by an audible click of the Torque Driver. The Surgeon should take proper care to watch the bone as the cable is tightened to detect cut out.

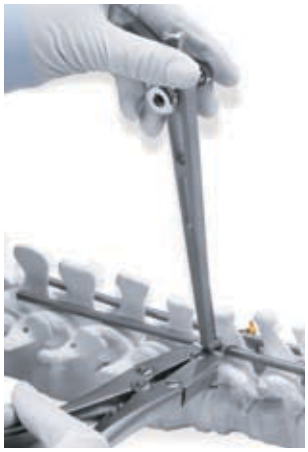
Set the appropriate torque level by turning the knurled ring

Attach the Torque Driver to the knurled knob on the Tensioner

Crimp

5) To secure the crimp, use the Crimper. Place the Crimper on the crimp and squeeze the handles until the indicator stop touches the opposite handle.

   Cut the excess Cable off flush at the tip of the crimp using the Cable Cutters.



Place the Crimper on the crimp and squeeze the handles together

Cut the remaining Cable with the cutter. It will be flush with the crimp.

Guide to Proper Tensioning

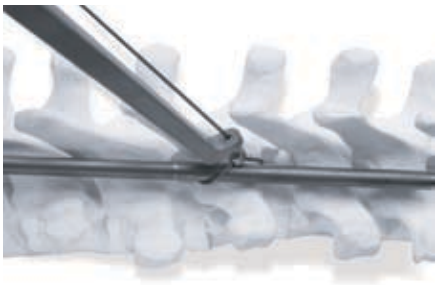
A) The proper tension is dependent upon the type of bone, quality of bone, and the loads applied to the specific implant location. In general, less tension should be applied to cancellous or osteoporotic bone. The Surgeon should be cautious to ensure bone cut out is limited.

B) Care should be taken to take all the slack out of the Cable and ensure the Cable is flush with the bone and/or rods.

C) When tensioning, avoid kinking the Cable. Resistance on the Cable may alter the force being applied to the object being fixed.

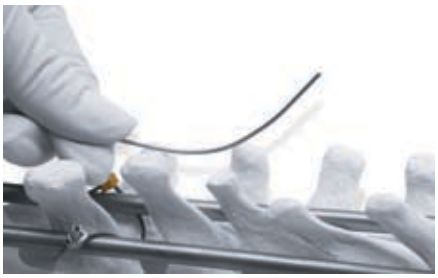
D) At NO time should a torque greater than 15in-lbs be applied to the Cable.

E) A MINIMUM of 5in-lbs of torque is usually necessary to obtain good fixation.



Ensure all the slack is pulled out of the Cable for secure fixation

Kinked leader may hinder the ability to pass through the instruments and crimp



A smooth curve will ease passing through instruments and implants

Set the torque to the appropriate level

The following are recommended torque ranges for a patient with good bone quality. Ranges may vary with the specific patient conditions:

Location	Range (in-lbs)
Occiput to C2 Sublaminar	10-12
C3-T1	10-12
C3-T1 Intraspinous or Facet	08-10
T1-T12 Sublaminar	10-12
L1-L5 Sublaminar	10-14
Cortical Long Bones	10-12
Greater Trochanter (Femur)	08-10
Olecranon	08-10
Patella	12-14
Patella – Tibial Tubercle	***

***Cannot set to any particular tension but must set at patella's proper position.

The table below indicates the corresponding Cable force to the torque value.

Applied Torque (in-lbs)	Cable Force on Bone (lb +/- 2lbs)
8	24
10	30
12	36
14	42

Implant Removal

Removal of the Biomet® Lentur™ Cable System can be performed by cutting the cable with the Cable Cutters. Pull the cables from under the lamina slowly and carefully.

Closure, Post-Operative Care

After implantation of the Biomet® Lentur™ Cable System is complete, wound closure is performed according to the standard protocol for the surgeon.

Indications for Use

The Lentur™ Cable System is indicated for use whenever a conservative or non-implant surgery is deemed insufficient to improve the medical condition of the patient. The System can be utilized anywhere monofilament wire has been previously indicated.

1. Spinal applications include spinal degenerative surgery, as an adjunct to spinal fusions and sublaminar and intraspinous process wiring for trauma applications. The Lentur™ Cable System may also be used with instrumentation involving the correction of scoliotic, kyphotic, and lordotic deformities. The titanium system is compatible with other titanium implants and the stainless steel system with stainless steel implants, wherever "wiring" may help secure the attachment of other implants.
2. Trochanteric reattachment after trochanteric osteotomy, following total hip arthroplasty.
3. Sternotomy indications include the "re-wiring" of sternums following osteotomy.
4. Trauma surgery indications include olecranon, ankle, patella, and some shoulder fracture rewiring. Properly used, the device will aid in the repair or attachment of bony structures. The surgeon should understand the indications and contraindications. The system in indicated for use whenever a conservative or non-implant surgery is deemed insufficient to improve the medical condition of the patient.

Contraindications

Contraindications include, but are not limited to:

1. Presence of infection and/or localized inflammation
2. Patient metal allergy or intolerance
3. Rapid joint disease, metabolic bone disease, cancer, tumor, or tumor like condition of the bone, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication because this condition may limit the degree of obtainable correction and the amount of mechanical fixation.
4. Inadequate tissue coverage of implant/operative site.
5. Interference with other critical 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. Undiagnosed infection, end stage malignant disease, or other unexplained disease that could compromise fixation achieved.
8. If the titanium or titanium alloy version is used, the physical contact of the Lentur™ Cable system with any metal not compatible with implant grade titanium.
9. If the Stainless Steel version is used, the physical contact of the Lentur™ Cable system with any metal not compatible with implant grade Stainless Steel.
10. The combination of the system with monofilament wire.
11. Any case not described in the indications.
12. Any patient unwilling to follow postoperative instructions.

Possible Anticipated Adverse Effects

1. Early or late loosening of the components.
2. Disassembly, fraying, kinking, loosening, bending, or breaking of any or all 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, and/or infection.
6. Cables cutting through soft osteopenic, osteoporotic, or cancellous bone.
7. Bone forming around the implant making removal difficult or impossible.
8. Nonunion or pseudoarthrosis or bone fracture.

9. Neurovascular compromise including radiculopathy, paralysis, or other types of serious injury causing pain.
10. Hemorrhage of blood vessels.
11. Cessation of growth of the operated portion of the bone.
12. 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 location and quality of the patients' bone. However, the torque applied should never be greater than 15in-lbs. 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. The fact is especially true in orthopedic or cardiovascular surgery where many extenuating circumstances may compromise the results. The Lentur™ Cable System is only a temporary implant and should only be used to augment bony fusion or aid fracture healing. The 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 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 Lentur™ Cable System by the surgeon. 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 an increased incidence of nonunions. 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.

- **Warning:** do not intermix implants with different non compatible metallic alloy types
- **Warning:** do not use if packaging is damaged/opened prior to use
- **Caution:** operating surgeon should have a good understanding of the cable system, surgical technique, and biomechanical principles of cable fixation
- **Caution:** federal law (USA) restricts the use of this device on the order of a physician only
- **Important:** avoid over tensioning cables as they may break or fray
- **Important:** cables may cut through soft bone that is not protected and immobilized
- **Single Use Only.** Never reimplant an explanted metal device, under any circumstances. Although the device appears undamaged, it may have small defects and internal stress patterns, which may lead to early breakage

Physician Note: Although the physician is the learned intermediary between the manufacturer and the patient, the important medical information given in this document should be conveyed to the patient.

Caution: For use on or by the order of a physician only.

Caution: Federal law restricts this devise to sale by or on the order of physician.

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

Implant Selection

This 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 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 surgical technique for use of the cable tensioner devices.

Intraoperative

1. The instructions in the Lentur™ Cable System and the Lentur™ Cable instrument package inserts should be read and carefully followed. Use only Lentur™ Cable instruments during the procedure.
2. Extreme caution during spinal surgery should be taken around the spinal cord and nerve roots. Any damage to the nerves may cause temporary or permanent loss of neurologic function.
3. Cut off excess cable flush with the crimp at completion of the procedure and after fully crimping the crimp. 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 crimped firmly as described in the surgical technique. The crimping should be complete before cutting cable.

Postoperative

1. The physician's postoperative directions and warning to the patient and the corresponding patient compliance are extremely important.
2. Detailed instruction on the use and limitation of the device should be given to the patient. Partial or non-weight bearing may be recommended or required to achieve firm bone 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.
3. 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.
4. The patient should be advised not to smoke or consume alcohol, non-steroidals, or aspirin during the bone graft healing process.
5. The patient or device should not be exposed to mechanical vibration that may loosen the device assembly. The patient should be warned of this possibility and instructed to limit and restrict their physical activities. If appropriate, restrict the patient's mobility at the fusion region.

6. If a nonunion occurs or if the components loosen, fray, bend and/or break, the device should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion 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.
7. The Lentur™ Cable System is a temporary internal fixation device to stabilize the operative site using the normal healing indicated because the implants are not intended to transfer or support localized tissue reaction or pain. Removal may be necessary due to migration of implant position, thus causing risk of injury from postoperative trauma, pain, discomfort, or abnormal sensations due to the presence of the device, possible increased risk of infection and bone loss caused by stress shielding. If bending loosening and /or breakage occur, removal may be difficult. Implant removal should be followed by adequate postoperative management to avoid fracture or other complications.

Care and Handling Instructions

Sterile packaged, single use components should be inspected prior to use for and damage or contamination. If components appear damaged, do not use.

Packaging

Packages for all of the implant components should be intact upon receipt. If a loner or consignment system is used, all the 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 Biomet Inc.

Cleaning and Decontamination

The Lentur™ Cable System includes components that are packaged sterile as single use devices. The Lentur™ Cable System sterile packaged components are sterilized by exposure to a minimum dose of 25-kGy gamma radiation. Do not use if package has been compromised.

Sterilization

The Lentur™ Cable System instruments are provided as nonsterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

Cycle: High Vacuum
Temperature: 270°F/132°C
Drying Time: 8 minutes

NOTE: Allow for cooling.

Individuals not using the recommended method, temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

Ordering Information

Titanium Cable Implant Case
(Catalog No. 14-500068)

Catalog #	Description	Qty/Kit
14-500052	Double Loop Ti Cable With 2 Crimps, 1.1mm Dia.	10
14-500051	Single Loop Ti Cable With 1 Crimp, 1.1mm Dia.	10

Implants are Individually Sterile Packaged.

Stainless Steel Cable Implant Case
(Catalog No. 14-500069)

Catalog #	Description	Qty/Kit
14-500056	Double Loop SST Cable With 2 Crimps, 1.1mm Dia.	10
14-500055	Single Loop SST Cable With 1 Crimp, 1.1mm Dia.	10

Implants are Individually Sterile Packaged.

Cable Instrument Case
(Catalog No. 14-500060)

Catalog #	Description	Qty/Kit
14-500061	Cable Cutter	1
14-500062	Torque Driver	1
14-500063	Crimper	1
14-500065	Cable Tensioner	4

Further Information

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

This brochure is presented to demonstrate the surgical technique utilized by Kenneth J. Noonan, M.D., Paul A. Glazer M.D., D. Raymond Knapp, Jr., M.D., Jonathan H. Phillips, M.D., and Charles T. Price, M.D. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient. Biomet and its surgical consultants are not responsible for the selection of the appropriate technique to be utilized for an individual patient.

For further information, please contact the Customer Service Department at:

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Parsippany, NJ 07054
973.299.9300 • 800.526.2579
www.biometspine.com

Notes:

At Biomet, engineering excellence is our heritage and our passion. For over 25 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

Lentur™ Cable System
Soft and Flexible Feel with Secure Stabilization

To learn more about this product,
contact your local Biomet Sales Representative today.

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