Surgical Technique

SuperCable®

Sternotomy Closure System

Written in conjunction with:
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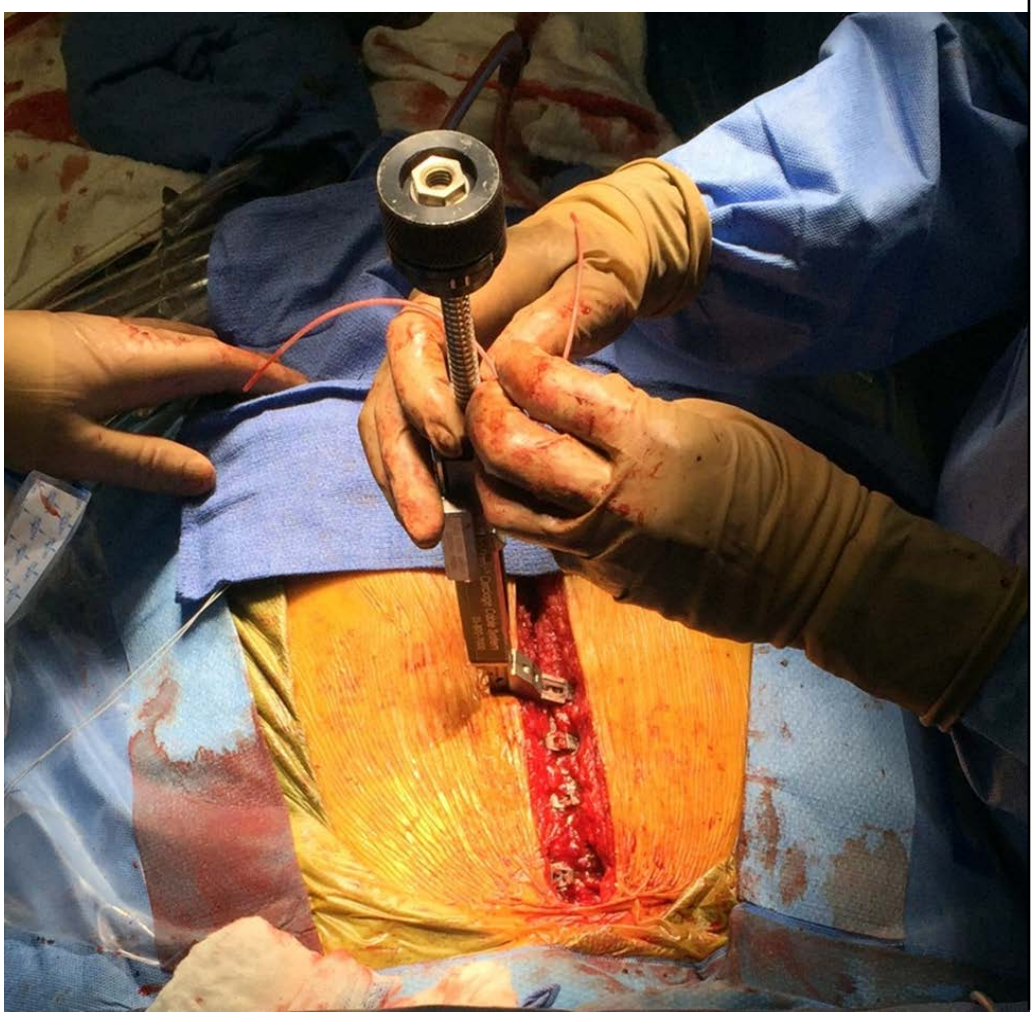
- **Iso-Elastic™ Polymer Cable**
- **Elastic property absorbs load and rebounds to stay tight**
- **Dual strand cable offers wide "footprint"**

These unique properties reduce the potential for "cut-through" and provide for dynamic compression across the healing sternotomy.

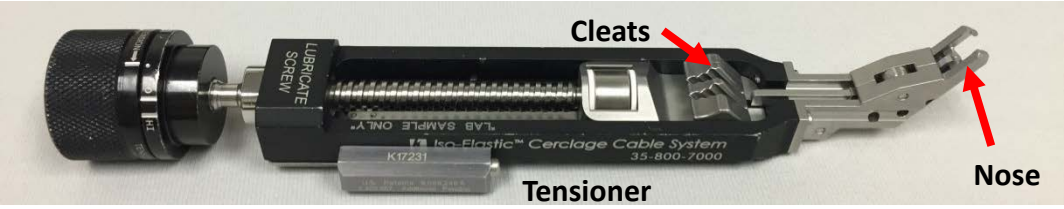


KINAMED®
INCORPORATED

SuperCable® Sternotomy Closure System - Surgical Technique

SuperCable items required to complete the sternotomy closure:

Consumables:	**Catalog No.**
SuperCable Iso-Elastic Sternotomy Closure Kit (4 Sternotomy Cables, 1 Curved Mini-Passer)	35-400-3010
SuperCable Iso-Elastic Sternotomy Closure Kit (2 Sternotomy Cables, 1 Curved Mini-Passer)	35-400-2005
Single Use Instruments:	
SuperCable Cerclage, Curved Mini-Passer (single-use, sterile-packed)	38-800-3400
Re-usable Instruments:	
SuperCable Cerclage, Tensioning Instrument, 60 Degree Angled	35-800-7000



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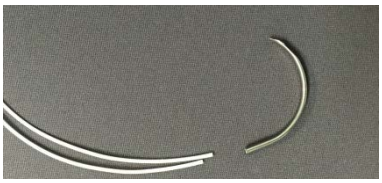
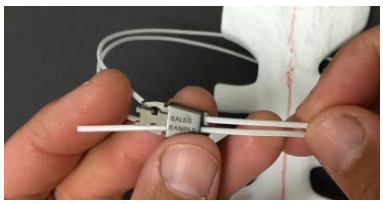
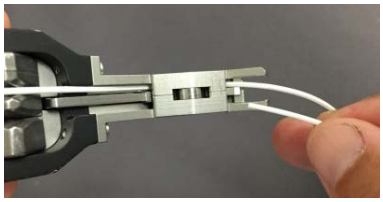


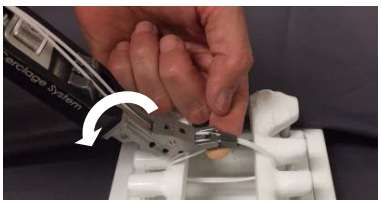
A. Fully Insert both cable ends into the passer.



B. Feed cable strands through locking clasp.



C. Insert both cable ends into nose of Tensioning Instrument.



D. Place finger under clasp, slide tensioner down to clasp and tip tensioning instrument back to engage clasp.

1. Open sterile packaged cable implant and deliver to the sterile field. The cable locking clasp comes preloaded on each cable.
2. Open the sterile, disposable, Curved Mini-Passer instrument and deliver to the sterile field. The Curved Mini-Passer can be re-used for multiple cables so only a quantity of one is required per surgical case. The Curved Mini-Passer cannot be re-cleaned and re-sterilized for use in subsequent surgical procedures.
3. Insert both free ends of a single cable unit into the open end of the passer with the natural curvature of the cable strands oriented to match the curvature of the passer. Push the cable ends into the passer until they reach a “stop” and can go no further. Fully inserting the cable ends into the passer in this way will provide adequate retention of the cables in the passer during subsequent use (Fig. A).
4. Before passing the cable, plan in advance which direction the Tensioning Instrument should face because this will define the direction the cable should be passed around the sternum. The instrument may “face” either towards or away from the user at the user’s discretion.
5. The 38-800-3400 Curved Mini Passer is provided with a blunt tip to help reduce the chance of soft tissue damage during passage around the sternum. Using this instrument, pass the cable down through the intercostal space on one side of the sternum, and then across the sternotomy and back up through the intercostal space on the opposite side. **CAUTION:** Take care not to damage or impinge upon the internal thoracic artery or other neurovasculature. Remove passer from cable after passing. Pass all of the cables that will be used to complete the closure. It is suggested that four SuperCables are used, one each in the 1st, 2nd, 4th and 5th intercostal spaces, along with a single standard monofilament wire placed in the manubrium.
6. If other hardware such as plates/screws or metal wires/cables are used, a minimum of two SuperCables may offer significant fixation benefits.
7. Thread the paired strands of each cable back through the clasp at the other end of the cable (Fig B). **Note:** The left and right cable strands may become reversed or twisted relative to one another during passage around the sternum. This does not affect performance of the cable and does not necessarily need to be addressed.
8. Apply the Tensioning Instrument to the first cable to be tensioned by feeding the free cable ends into the nose as shown in Fig. C. Take care not to cross the left and right cable strands as they enter the nose of the tensioner.

9. Once passed through the nose of the Tensioner, place a finger under the clasp as shown in Fig. D while pulling the free cable ends taut. Slide the Tensioning Instrument down to engage its nose with the notches on the sides of the cable clasp. Drop the back of the tensioner slightly as shown in Fig. D to facilitate this engagement with the clasp . Once the Tensioning Instrument is aligned over the clasp, raise the back of the instrument as shown in Fig. E so that the top of the nose engages down into the notches on the side of the clasp and sits coplanar with the top surface of the clasp (Fig. E).

10. Gain as much initial closure of the sternum as possible by vigorously pulling the free cable ends while maintaining counter-force through the clasp via the Tensioning Instrument (Fig. F). Using the Tensioning instrument as a handle, position the cable locking clasp so that the leading (distal) end of the clasp begins to enter into the intercostal space. This will minimize the profile of the clasp as it sits on the sternum and may allow easier access for the Tensioning Instrument.

11. Continue to manually pull the free cable ends to apply mild tension while directing the cable strands into the cleats on the Tensioning Instrument and then hold the strands against the cleats with a thumb or finger (Fig. G). Immediately rotate the knob on the Tensioning Instrument to begin to apply tension to the cable strands and capture them in the cleats. As initial tension is developed, the cable strands will engage into the cleats and approximation with a thumb or finger is no longer needed. **CAUTION:** Check to make sure both strands are captured in the cleats. Double-check the position of the clasp as described in Step 10 to ensure that the distal end of the clasp is positioned such that it sits into the anterior intercostal space. Keep the nose of the instrument aligned so that its top surface is coplanar with the top of the clasp and continue to turn the knob to increase cable tension while carefully monitoring the effect on the sternum.

12. The tensioning knob has indicator lines to provide feedback on the force that is being applied by the cable. The "LO" mark indicates approximately 80 pounds (360 Newtons) of compression. **Note:** It is important to observe the force reading while slowly turning the knob (Fig. H). Generally, it is recommended that the "LO" mark is not exceeded when tensioning cables for sternal closure. Exercise clinical judgement in determining the proper tension that achieves good fixation without causing damage to the sternum due to excessive force. Final tension depends on the surgeon's tactile and clinical assessment of bone quality and bone reduction. **CAUTION:** Over-tensioning could result in the cable damaging the bone.

13. Once desired tension is achieved, release the wedge insertion lever on the side of the Tensioning Instrument by depressing the button in the end of the lever. Pull back on the lever fully to insert the wedge to lock the cable and hold tension (Fig. I).

14. To release the Tensioning Instrument from the cable, first turn knob on Tensioning Instrument counter-clockwise to relieve tension. Then pull cable tails straight back towards knob to disengage them from the cleat. Disengage instrument from cable clasp and remove. Do not cut the free cable ends, as these will allow for subsequent re-tightening should additional tensioning be needed.

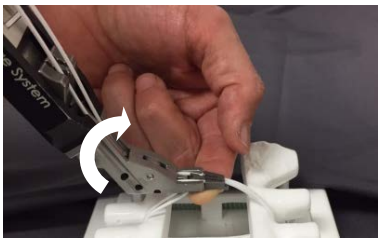
15. Repeat Steps 7-14 for additional cables as needed.

16. If desired, any cable may be re-tightened before wound closure by re-attaching the Tensioning Instrument to the clasp, re-tensioning the cable assembly, and fully re-seating the locking wedge (Steps 8-14).

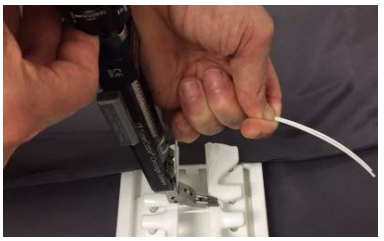
17. After all cables have been applied and appropriate closure has been confirmed, use scissors or a scalpel to trim the free cable ends as close to the clasp as possible.

18. The patient should be instructed to follow the standard post-sternotomy closure precautions to protect the healing sternum.

Note: Emergent re-entry may be accomplished by cutting the cable strands at the back edge of each locking clasp with a scalpel.



E. Rotate instrument forward until nose of instrument is coplanar with clasp.



F. Pull slack from cable loop to gain as much initial closure of the sternum as possible. Maintain alignment with clasp.

G. Hold cable strands over cleats with thumb or finger and begin to tension cable by turning knob clockwise.

H. Observe tension reading while slowly turning knob.

I. Pull back on lever until it stops to fully seat locking wedge.

DEVICE DESCRIPTION

The Kinamed SuperCable Iso-Elastic Cerclage System consists of a braided cerclage cable and attached metal clasp. The cable is flexible and possesses high fatigue and tensile strength. The cable is made from biocompatible materials, consisting of UHMWPE strands over a nylon core. The clasp components are made from titanium alloy. Refer to the device product label for identification of clasp material, cable diameter, and corresponding part number for the device enclosed. The general principles of patient selection and sound surgical judgment apply to the surgical procedure.

INDICATIONS for USE

- Sternotomy Closure

⚠ CAUTIONS

- When using the Curved Mini Passer, care should be taken to avoid puncture injuries and glove tears. Forceps or needle drivers should be used for holding and passing.
- Exercise care to avoid injury to or impingement upon the internal thoracic artery or other intercostal vessels and nerve bundles. Should vessel damage or suspected vessel damage occur, the device should be removed and the vessel repaired.
- Do not implant the Curved Mini Passer.
- Avoid wrapping the cables over sharp metal or bone surfaces.
- Care should be taken to control cable tension in patients with poor bone quality. Ideal tension may vary with bone quality or geometry. Reduced bone quality may warrant a lower tension.

CLEANING and MAINTENANCE of REUSABLE INSTRUMENTS

See SuperCable IFU (document B00109) for manual and automated cleaning instructions.

Maintenance of Reusable Instruments: Prior to autoclave sterilization, apply a surgical grade lubricant to the tensioner threads and the wedge insertion cam mechanism of the tensioning instrument. Be sure that the lubricant fully penetrates the mechanism. Wipe any excess lubricant that may have been deposited on the back of the instrument body. **Extreme care should be exercised lubricating this thread to prevent any excess lubricant from depositing in the cable holding grooves. Lubricant in cable holding grooves may cause cable slippage during tensioning.**
Do not disassemble any part of the tensioning instrument. Before each use, check calibration of tension gauge by confirming zero alignment of knob. The white line on outer portion of knob should align with white dot on inner portion when tension is first applied.

CARE and HANDLING

Use extreme care in handling and storage of implant components. Cable and clasp must be handled with care. Twisting, kinking, cutting, notching or scratching the braided cable surface may reduce the strength, fatigue resistance and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected during storage from corrosive environments, such as salt air, etc. Only instruments designed for use with this system should be used to ensure correct implantation. Damaged instruments may lead to improper cable tension or implant position, resulting in implant failure. Thorough familiarity with this surgical technique is essential to ascertain their proper working condition.

STERILITY

Cable and clasp are supplied sterile. The package should be examined prior to use for possible breaks in the sterile barrier. Cable contains polyethylene and nylon polymers. **Do not autoclave or re-sterilize cable implants.**
Instruments are provided as both single-use, sterile-packed and reusable, non-sterile. Reusable instruments must be steam sterilized prior to surgical use per the following validated procedure. Inspect instruments for dryness prior to sterilization.

Location of Use	Method	Cycle Type	Sterilization Temperature	Exposure Time[2]	Dry Time
Within the USA	Steam Autoclave Double Wrapped[1]	Pre-vacuum	132°C (270°F) Minimum	4 Minutes Minimum	60 Minutes Minimum
Outside the USA	Steam Autoclave Double Wrapped[1]	Pre-vacuum	134°C (273°F) Minimum	3 Minutes Minimum	60 Minutes Minimum

[1] Validated with KimGuard® KC600. (Validated to the following standards: ISO 17665-1:2006 and ANSI/AAMI ST79-2010)
[2] This is the exposure time only, it does not represent the total cycle time.

See SuperCable IFU (document B00109) for further details.

To view a video demonstration, click here or scan the QR code below.

KINAMED® INCORPORATED

Expect Innovation.

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bsi. ISO 13485 Medical Devices Quality Management
FM 75124

CE 0086

Caution: Federal law restricts this device to sale by or on the order of a physician. Prior to use of a Kinamed device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, and directions for use. US Patent Nos. 6,589,246, 7,207,090, 8,469,967, and 9,107,720. Europe Patent Nos. 1,389,940, 1,781,961 and 2,432,401. Japan Patent Nos. 4,829,236 and 5,938,095. Turkey Patent Nos. TR20130992T4 and TR201405440T4. Additional US and world patents pending.