Surgical Technique

SuperCable®

Sternal Closure System

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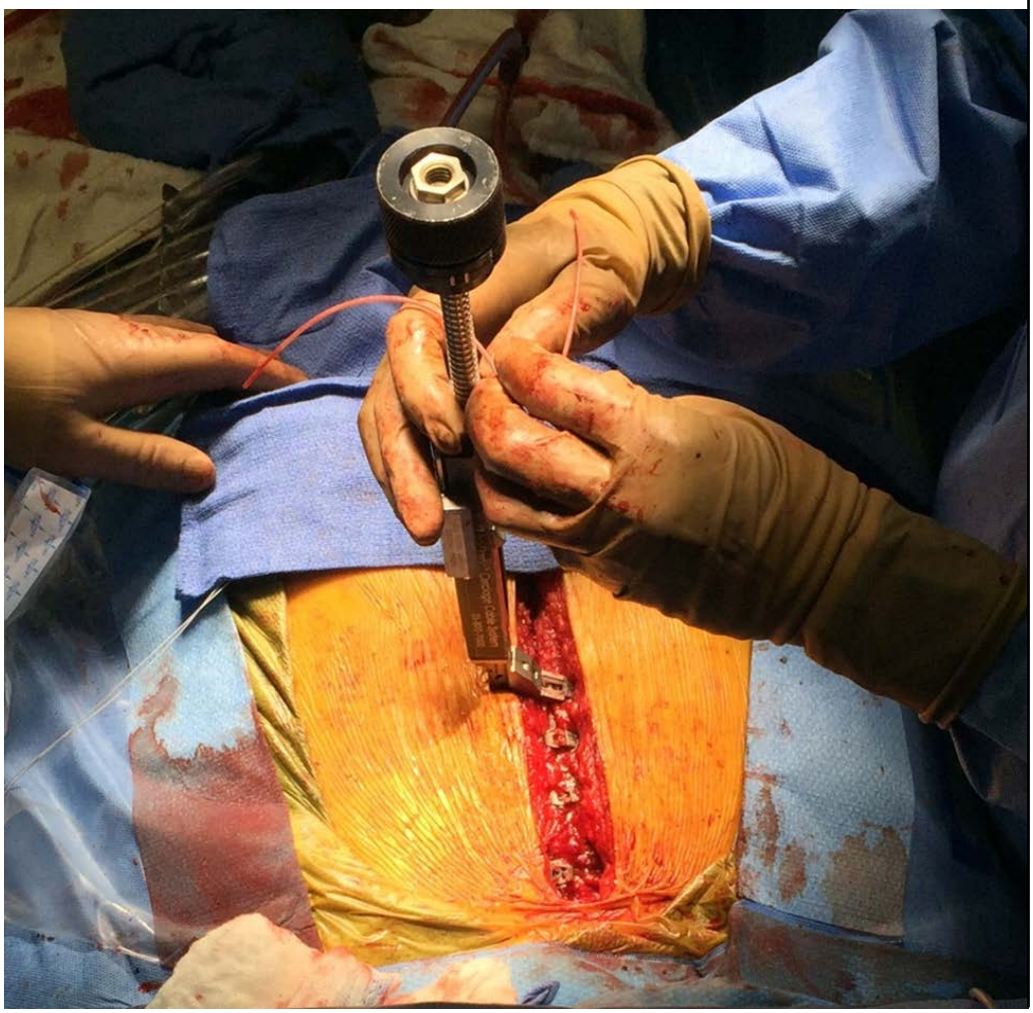
- Iso-Elastic™ Polymer Cable
- Elastic property absorbs load and rebounds to stay tight
- Dual strand cable offers wide "footprint"

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

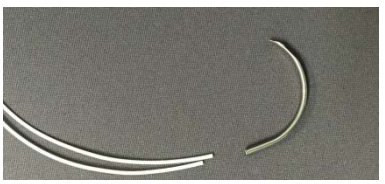


KINAMED® INCORPORATED

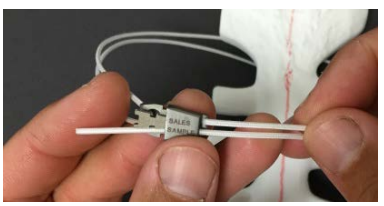
SuperCable® Sternal Closure System - Surgical Technique

SuperCable items required to complete the sternotomy closure:

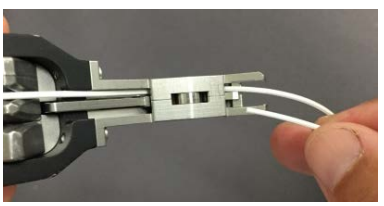
Consumables	Catalog No.	Quantity
SuperCable® Polymer Iso-Elastic™ Cerclage Cables, 1.5mm (implant)	35-100-1010	4 per procedure
Curved Mini Passer (sterile instrument)	38-800-3400	1 per procedure
Re-usable Instruments		
SuperCable® Tensioning Instrument, with 60° Angled Nose	35-800-7000	1 each



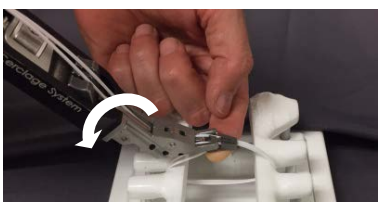
A. Fully Insert both cable ends into the passer.



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.

Surgical Technique

1. Open sterile packaged cable implant (35-100-1010) and deliver to the sterile field. The locking clasp comes preloaded on each cable.
2. Open the sterile, disposable, Curved Mini Passer instrument (38-800-3400) and deliver to the sterile field. **Note:** This item 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 through the intercostal space, plan in advance which direction the Tensioning Instrument (35-800-7000) 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. Using electrocautery to create a "pocket" in the dorsal intercostal space on the side where the cable clasp will sit may help to seat the clasp and minimize its profile (see Steps 9 and 10).
5. Using the Curved Mini Passer, 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. If no other sternal fixation hardware is to be used, it is suggested that four SuperCables are used, one each in the 1st, 2nd, 4th and 5th intercostal spaces. If other hardware such as plates/screws or metal wires/cables are used, a minimum of two SuperCables may offer significant fixation benefits.
6. 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 corrected.
7. 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.

8. 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).

9. 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.

10. 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. **Check to make sure both strands are captured in the cleats.** Double-check the position of the clasp as described in Step 9 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.

11. 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.

12. 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).

13. 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.

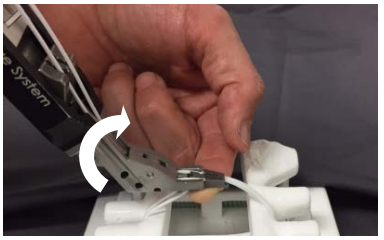
14. Repeat Steps 6-13 for additional cables as needed.

15. 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 6-13).

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

17. 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 braided 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

(1) Manual Soak: Completely submerge instruments in neutral pH endozime detergent for 5 minutes. Use a soft bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention should be given to hard to clean areas.
Manual Rinse: Remove instruments from enzymatic solution and rinse thoroughly under running tap water. Thoroughly and aggressively brush and flush through canulated areas using a water jet with the exit end submerged. Turn knob of tensioning instrument to fully expose remainder of threads on the lead screw. Flush instrument again to clear any debris.
(2) Combination Manual/Automated Soak and Rinse: Same as manual soak and rinse in section (1) above. **Washer/Dryer:** Place instruments in a suitable washer basket and load in an automatic washer/dryer. Cycle should be set for a Non Caustic wash for a duration of 70 minutes using neutral pH endozime detergent. The endozime detergent should be used at a specified concentration in a 14-minute cleaning cycle.

Maintenance of Tensioning Instruments: Prior to autoclave sterilization, apply a surgical grade lubricant to the threads and the wedge insertion mechanism. Be sure that the lubricant fully penetrates the mechanism. Wipe excess lubricant that may have 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.** See SuperCable IFU (document B00109) for full details.
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.**
The SuperCable Curved Mini Passer is provided sterile and is intended for single use only. Refer to the device package label for additional details including material information and expiration date. See IFU (document B00235) for further details.
Re-usable instruments are provided non-sterile and must be sterilized prior to surgical use per the following validated procedure:
Prevacuum/Pulsating: Double wrapped, 3 minutes at 134°C minimum or 4 minutes at 132°C minimum, dry time 60 minutes. Sterilization times represent exposure time only and not total cycle time. See SuperCable IFU (document B00109) for further details.

To view a video demonstration, click here or scan this code:

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SCC Accredited CB-MS
bsi. FM 75124 ISO 13485
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. TR201309922T4 and TR201405440T4. Additional US and world patents pending.