Surgical Technique

SuperCable®

Polymer Iso-Elastic™ Cerclage System*

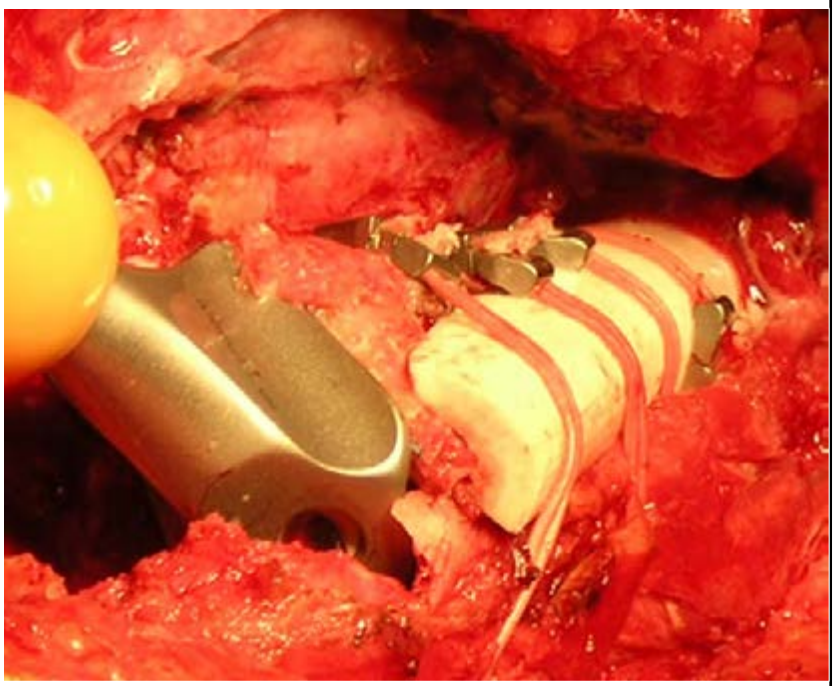
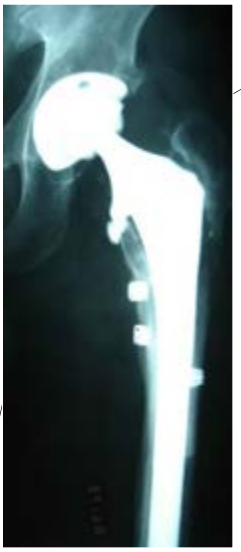


Photo and radiograph courtesy of Bradford Hack, MD, West Coast Orthopedics, Arcadia, CA



KINAMED INCORPORATED

*US Pat. Nos. 6,589,246; 7,207,090; 8,469,967. Japan Pat. No. 4,829,236. Turkey Pat. No. TR201309922T4. European Pat. No. 1,389,940; 1,781,961; 2,432,401. Additional US & World Patents Pending.

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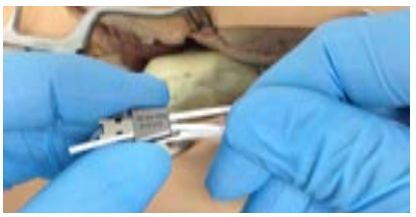
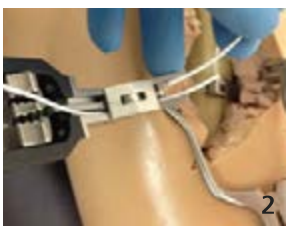
A. Position cable passer around bone.

B. Feed cable through distal passer hole.



C. Feed cable ends through metal clasp.

D. Pull both cable strands taut.



E1. Insert free cable ends under cross-bar, or **(E2)** into opening and through channel.

F. Slide along cables to engage with clasp.

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SURGICAL TECHNIQUE

1. Open sterile cable/clasp assembly and deliver to sterile field. Multiple cables may be delivered to the sterile field depending on the nature of the surgical procedure.

2. It is important to note the direction of introduction of the Cable Passer around the bone as this affects the orientation of the cable clasp and thus the orientation of the tensioning instrument relative to the user and the incision. Position the appropriate Cable Passer around the bone such that the distal end of the cannula emerges on the operating surgeon's side of the bone (Fig. A). Use care in passing the cable passer to avoid damage to neurovascular structures. Insert the free ends of both cables into the distal end of the passer cannula and feed through to the other side of the bone (Fig. B). Once the cable is looped around the bone, remove the passer.

3. Feed free cable ends through the metal clasp and pull the cable taut so that the metal clasp is as close to the bone as is practicable (Figs. C & D).

4. Turn the tensioning knob of the Tensioning Instrument counterclockwise until the moveable trolley at the end of the central screw is close to, but not in contact with, the distal end of the trough in which it travels. When using the standard or ACME thread tensioning instruments (part no. 35-800-2000 or 35-800-2020), thread the free cable under the small cross-bar that is on top of the nosepiece of the tensioner (Fig. E1). When using the Angled Tensioning instrument (35-800-7000), feed ends into openings and through channels (Fig. E2).

5. Attach the tensioning instrument to the metal clasp by holding cable ends taught and sliding nosepiece of tensioner down the cables until it engages in the slots in the base of the clasp (Fig. F). Hold the instrument so its nose is in alignment and coplanar with the flat surface of the clasp (Fig. G). Grasp and pull free cable tails equally taut to remove slack in the cables. Place the free cable tails into the slots of the cleat and hold with thumb (Fig. H).

⚠ Caution:

- **Avoid wrapping the cables over sharp metal or bone graft surfaces.**
- **The clasp should be placed in a region of bone that maximizes the conformity between the clasp and underlying surface (bone or allograft). The angle the cable makes with the clasp as it exits the clasp should be as small as is practicable.**
- **Cable tension should be equalized to the extent possible. When the two free cable ends are inserted into the tensioning instrument, the ends should be pulled taut so as to equalize their length.**

Surgical Technique

6. While holding cables in place on the cleat, use other hand to grasp only the knurled section of the knob on the tensioning instrument and turn knob clockwise until desired tension is achieved (Fig. I). Maintain engagement and proper coplanar alignment between the tensioning instrument and clasp. Compressive force applied by the cables is 80 lbs. (360N) when the white line on knob reaches first mark (LO), and 120 lbs. (530N) when the line reaches the second mark (HI) (Fig. J).

⚠ Caution:
Do not tension cable such that the line on the knob passes the second solid line (HI), exceeding 120 lbs. (530N) of compressive force. Grasp only the knurled portion of the knob and slowly turn while reading the tension level. The indicator marks should be read while turning the outer knob.

7. 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 (Fig. K). Pull back on the lever fully to insert the wedge to lock the cable and hold tension.

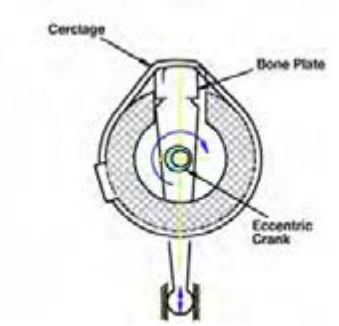
8. To release the Tensioning Instrument from the cable, first turn knob on tensioning instrument counter clockwise to relieve tension. Then pull cable tails straight back towards knob and then up to disengage them from the cleat (Fig. L) Disengage instrument from cable clasp and remove. **Do not cut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

9. Repeat steps 1-8 for additional cables as needed.

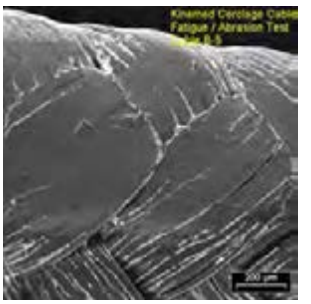
10. If desired, each cable may be re-tightened before wound closure by re-attaching the Tensioning Instrument to each clasp as described in steps 4-6, re-tensioning the cable assembly and fully re-seating the locking wedge as described in step 7.

11. After removal of the Tensioning instrument, use scissors or a blade to trim the free cable ends as close to the clasp as possible.

NOTE: The cable may be placed over smooth metal implants, such as bone plates, because the UHMWPE sheath is highly resistant to wear.

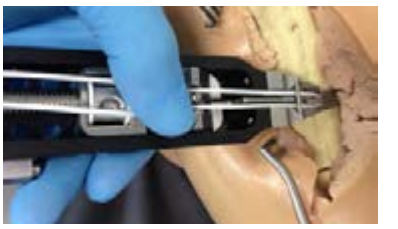


Test fixture with simulated bone plate.



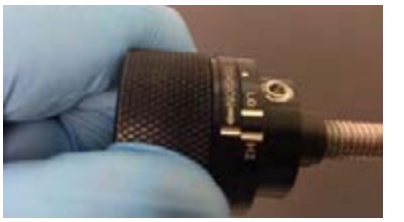
Test cable loaded at 445 N, with direct abrasive contact on a bone plate, after one million cycles. The cable exhibits fiber fusion but no fraying or breakage of fibers.

G. Engage nosepiece with clasp.

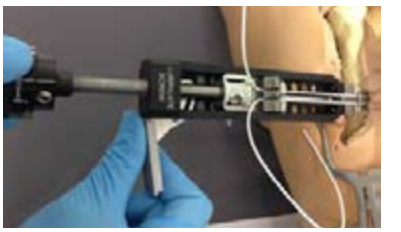


H. Push free cable ends into cleat.

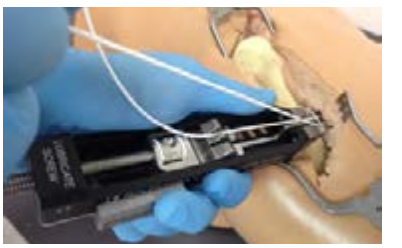
I. Confirm zero alignment of knob and turn knob clockwise to apply tension.



J. "HI" mark indicates 120 lbs.



K. Deploy cable locking wedge.



L. Pull back to remove cable from cleat.

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 cerclage procedure.

INDICATIONS for USE

- Repair of long bone fractures due to trauma or reconstruction.
- Reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy.

CLEANING and MAINTENANCE of INSTRUMENTS

- 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.
- Flush the instrument thoroughly with sufficient water and cleaning agent to remove blood and other material.
- Turn knob of tensioning instrument to fully expose remainder of threads on the lead screw. Flush instrument again to clear any debris.
- 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.
- 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 (Figure I).

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 assure 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 assure proper use of the instruments.

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 non-sterile and must be sterilized prior to surgical use per the following validated procedure: **Prevacuum/Pulsating:** Wrapped, 3 – 3.5 minutes, 134 °C – 137 °C . Sterilization times represent exposure time only and not total cycle time. Ref. B00109F SuperCable Product Insert/ IFU.

PART NUMBER INFORMATION

SuperCable® Polymer Iso-Elastic™ Cerclage Cables	Catalog No.
Polymer Iso-Elastic™ Cerclage Cable Assembly, 1.5mm (Ti Cable Lock)	35-100-1010
***SuperCable*® Polymer Iso-Elastic™ Cerclage Standard Instruments**	
SuperCable Cerclage Tensioning Instrument	35-800-2000
SuperCable Cerclage Cable Passer, 40 mm	35-800-3000
SuperCable Cerclage Cable Passer, 60 mm	35-800-3100
SuperCable Cerclage Autoclave Case	35-800-4000
***SuperCable*® Polymer Iso-Elastic™ Cerclage Optional Instruments**	
SuperCable Cerclage Tensioning Instrument, w/ ACME Thread	35-800-2020
SuperCable Cerclage Tensioning Instrument, w/ 60° Angle	35-800-7000
SuperCable Cerclage, Angled Cable Passer, 40 mm	35-800-3200
SuperCable Cerclage, Angled Cable Passer, 60 mm	35-800-3300
SuperCable Cerclage, Cable Passer, 1.5mm (Single-Use, Sterile-Packed)	35-400-1010*

KINAMED® INCORPORATED

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For more information:

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ISO 13485
FM 75124

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.

*CE mark does not apply to this item