

SuperCable[®]

Polymer Iso-Elastic™ Cerclage*

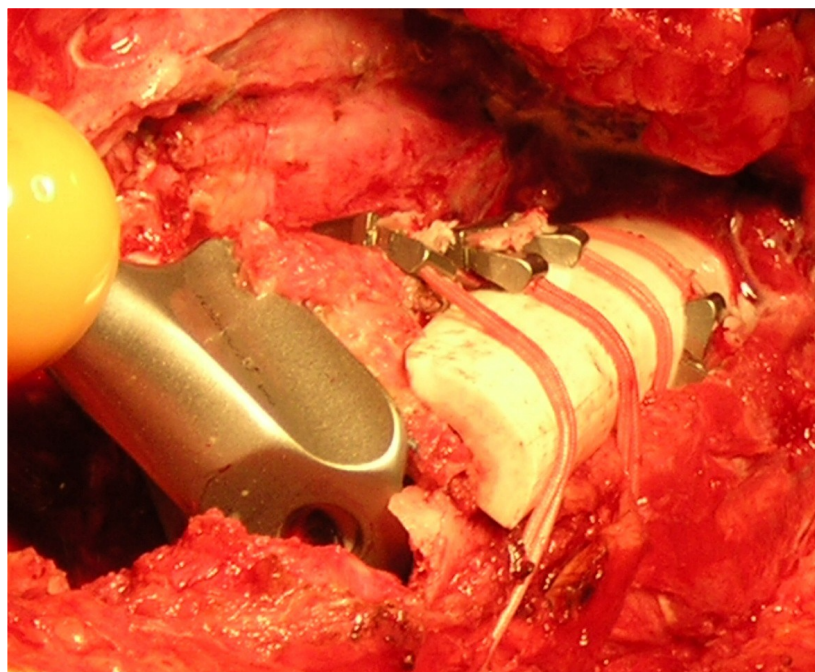


Photo and radiograph courtesy of Bradford Hack, MD, West Coast Orthopedics, Arcadia, CA



*US Pat. Nos. 6,589,246; 7,207,090; 8,469,967; 9,107,720.
Europe Pat. Nos. 1,389,940; 1,781,961; 2,432,401
Japan Pat. Nos. 4,829,236; 5,938,095.
Turkey Pat. Nos. TR201309922T4; TR201405440T4.
Additional US & World Patents Pending.

www.kinamed.com/patents



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Surgical Technique

SuperCable® Polymer Iso-Elastic™ Cerclage



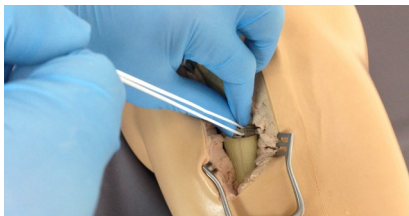
A. Position cable passer around bone.



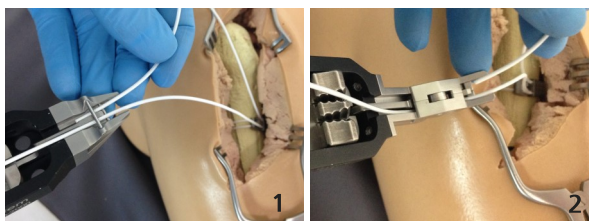
B. Feed cable through distal passer hole.



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.

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 reusable 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. Refer to document B00235 for details on usage of the single-use Curved Mini Passer (part no. 38-800-3400).
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 counter-clockwise 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 taut 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 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.

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. The tensioning knob has indicator lines to provide a feedback estimate on the force that is being applied by the cable. The "LO" mark indicates approximately 80 pounds (360 Newtons) of compression and the "HI" mark indicates approximately 120 pounds (530 Newtons) of compression. **Note:** It is important to observe the force reading while slowly turning the knob (Fig. J). Exercise clinical judgment in determining the proper tension that achieves good fixation without causing damage to the bone due to excessive force. Final tension depends on the surgeon's tactile and clinical assessment of bone quality and bone reduction.

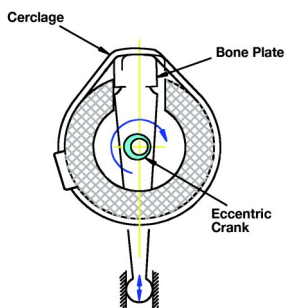


Caution:

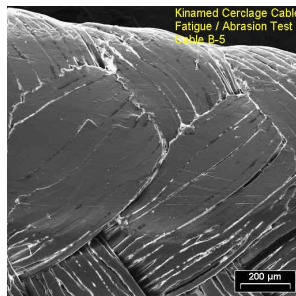
Over-tensioning could result in the cable damaging the bone.

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.

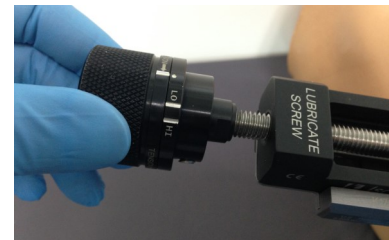
Surgical Technique



G. Engage nosepiece with clasp.



H. Push free cable ends into cleat.



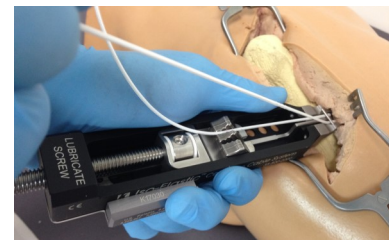
I. Confirm zero alignment of knob and turn knob clockwise to apply tension.



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 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. 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.

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 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 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

¹Validated with KimGuard® KC600. (Validated to the following standards: ISO 17665-1:2006 and ANSI/AAMI ST79-2010)

²This is exposure time only, it does not represent the total cycle time.

See SuperCable IFU (document B00109) for full details.

PART NUMBER INFORMATION

SuperCable® Polymer Iso-Elastic™ Cerclage Cables

Polymer Iso-Elastic™ Cerclage Cable Assembly, 1.5mm (Ti Cable Lock)

Polymer Iso-Elastic™ Cerclage Cable Assembly, 1.5mm (Ti Cable Lock)

SuperCable® Polymer Iso-Elastic™ Cerclage Standard Instruments

SuperCable Cerclage Tensioning Instrument w/ ACME Thread

SuperCable Cerclage Cable Passer, 40 mm

SuperCable Cerclage Cable Passer, 60 mm

SuperCable Cerclage Autoclave Case

SuperCable® Polymer Iso-Elastic™ Cerclage Optional Instruments

SuperCable Cerclage Tensioning Instrument, w/ 60° Angle

SuperCable Cerclage, Angled Cable Passer, 40 mm

SuperCable Cerclage, Angled Cable Passer, 60 mm

Catalog No.

35-100-1010

35-100-1040

35-800-2020

35-800-3000

35-800-3100

35-800-4000

35-800-7000

35-800-3200

35-800-3300



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FM 75124



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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.

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