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KINAMED®
SuperCable® Curved Mini Passer
Technique Supplement

This document supplements the SuperCable® Iso-Elastic™ Cerclage System Instructions for Use (document B00109) and Surgical Technique (document B00110).

CAUTION

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

Devices labeled for single use are intended to be used once only, for a single patient, because they may not perform as intended if they are reused. Reuse may lead to failure of the device to perform as intended.

Do not use if package is damaged.

As stated in the Instructions for Use (B00109), the **INDICATIONS FOR USE** for the SuperCable Iso-Elastic Cerclage System are as follows: (1) Repair of long bone fractures due to trauma or reconstruction; (2) Reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy; (3) Sternotomy closure; and (4) Sublaminar and intrafacet wiring of the spinal column.

As also stated in the Instructions for Use, the **CONTRAINDICATIONS** are as follows: (1) Active or suspected infection, either systemic or localized, in or around the implant site; (2) Patient conditions, mental or neurological, that would tend to impact the patient's ability to follow physician's instructions during the post-operative healing phase; (3) Skeletally immature patients; (4) Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site; (5) Insufficient quality or quantity of bone, which would inhibit rigid device fixation; (6) Any disease affecting the support and fixation of the prosthesis; (7) Distant foci of infection, such as genitourinary, pulmonary, skin or other sites which may spread to the implant site. The foci of infection should be treated prior to, during, and after implantation.

INSTRUCTIONS FOR USE

This Technique Supplement contains information on use of the SuperCable Curved Mini Passer, a manual surgical instrument that may be useful when using SuperCable under the labeled indications. Refer to Kinamed document B00109 for the SuperCable Iso-Elastic Cerclage System Instructions for Use. General surgical technique instructions are contained in Kinamed document B00110.

PASSER DESCRIPTION

SuperCable Curved Mini Passers (e.g. part number 38-800-3400) are single use manual instruments that facilitate passage of the SuperCable implant ends, such as for passage through rigid or semi-rigid structures like bone, cartilage, or tendon. The shape and cross-section of the Curved Mini Passer is designed to facilitate passage around or through such structures. Curved Mini Passers are designed for use with SuperCable implants only. Refer to the Surgical Technique (document B00110) for descriptions of the SuperCable implant and other associated instruments.

STERILITY

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. Refer to the Instructions for Use (document B00109) for sterility information on the SuperCable implant and other associated instruments.

USAGE

Refer to Kinamed document B00110 for instructions on use of the SuperCable implant and associated reusable instruments including the tensioning instrument.

To use the SuperCable Curved Mini Passer, remove the instrument from its package and deliver it to the sterile field. Gently insert both free ends of an unused SuperCable implant approximately 1.5 inches (38mm) into the bore of the Curved Mini Passer to create a temporary assembly. Using conventional suture or needle passing techniques, pass the leading end of the Passer / SuperCable assembly through or around the desired structures.

CAUTIONS

- *The tip of the Curved Mini Passer is sharp and care should be taken to avoid puncture injuries and glove tears. Forceps or needle drivers should be used for holding and passing.*
- *For sternotomy closure, exercise care to avoid injury to or impingement upon the internal mammary 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.*

After passage, remove the Curved Mini Passer by gently pulling out both cable ends. The cerclage procedure may then be continued as described in the Surgical Technique (document B00110). For sternotomy closure, the locking mechanism may be positioned toward the intercostal space to minimize the implant profile. The Curved Mini Passer should be discarded at the end of the procedure.

CAUTIONS

- *Do not implant the Curved Mini Passer.*
- *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.*
- *Recommended tensioner settings are meant to assist the surgeon in optimizing performance of the system, not to replace the surgeon's judgment. Care should be taken to control tension in patients with poor bone quality and ideal tension may vary with bone quality or geometry. Reduced bone quality may warrant a lower tension.*
- *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.*