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KINAMED® Incorporated
SuperCable® *TalonPasser*™ Technique Supplement

US Patent 11,020,161. www.Kinamed.com/patents

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

EXPLANATION OF SYMBOLS	
MD	**Medical device**
Rx Only	**Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.**
STERILE R	**Single use instruments are sterilized using gamma irradiation.**
	Do not resterilize
	Do not use if package is damaged and consult instructions for use.
	Do not re-use. 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.
REF	**Catalog number**
LOT	**Lot number**
	Caution
	Manufacturer
	Date of Manufacture
	Use-by date
UDI	**Unique Device Identifier**

MR SAFETY INFORMATION

Location of Use	MR Safety Information
Within the USA	The SuperCable® implant has not been tested for safety and compatibility in the MR environment (it has not been tested for heating, migration, or image artifact in the MR environment).

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; and (3) Sternotomy closure.

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 *TalonPasser* devices, which are manual surgical instruments 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 *TalonPasser* devices are single use manual instruments that facilitate passage of the SuperCable implant ends, such as for passage around rigid or semi-rigid structures like bone, cartilage, or tendon. The SuperCable *TalonPasser* attaches to the surgeon's finger and allows for tactile feedback during cable passage. SuperCable *TalonPasser* instruments 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 *TalonPasser* instruments are provided sterile and are intended for single use only. The package should be examined prior to use for possible breaks in the sterile barrier. 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 a SuperCable *TalonPasser*, remove the passer from its package, remove the tip protector, and deliver the passer to the sterile field. If desired, to ease retrieval after use, attach a suture to either or both of the small holes located near the large opening of the passer. Gently insert index or middle finger into the large opening of the passer until finger is firmly seated. Plan in advance the direction that the passer will be directed around the bone as this affects the orientation of the SuperCable locking clasp and thus the orientation of the tensioning instrument. Using the passer tip to provide tactile feedback, gently slide the curvature of the passer around the bone until its tip can be seen on the other side of the bone. Gently insert both free ends of an unused SuperCable cerclage cable implant into the distal tip of the passer until the ends can be felt by the operator. Remove finger from the passer and continue to feed the cable until its ends pass through the large opening of the passer.

CAUTIONS
- *As with any cable passer, exercise care to avoid injury to or impingement upon neurovascular structures. Should vessel damage or suspected vessel damage occur, the device should be removed and the vessel repaired.*

After cable passage and while maintaining hold of the clasp end of the cable, retract the passer along its path of insertion until the cable ends exit the passer tip and are free. The cerclage procedure may then be continued as described in the Surgical Technique (document B00110). The *TalonPasser* should be discarded at the end of each surgical procedure.

CAUTIONS
- *Do not implant a SuperCable TalonPasser.*
- *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.*