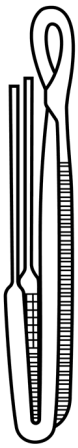

Infinity-Lock™

Instructions for use

CE 0086

GMDN 13906

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LAB 258 2.00

Infinity-Lock Ordering Information

Re-order Number	102-1097	102-1098
Nominal Size (USA)	1/8 x 16”	1/5 x 16”
Nominal Size (metric)	3 mm x 400 mm	5 mm x 400 mm
Minimum Tensile Strength	800N	1000N
Average Knot Strength (surgeon’s knot)	358N	453N

General Use

Infinity-Locks are non-absorbable, sterile, poly (ethylene terephthalate) sutures. They are prepared from fibers of high-molecular weight, long chain, linear polyesters having recurrent aromatic rings as an integral component. Infinity-Locks differ from USP Sutures in being in the form of woven tapes and in exceeding all USP sizes.

Infinity-Locks are available for the Indication listed below as tubular dense tapes, in widths of 1/8” & 1/5” (3 mm & 5 mm), and 16” (400 mm) long (See Ordering Information.) They are supplied without needles attached, and for single use only.

Sterility

Infinity-Locks are supplied sterile and double wrapped. They remain sterile unless the package is damaged or opened. Check the package is undamaged before using the Infinity-Lock. If its sterility is compromised it must not be resterilized.

Indication

These Infinity-Locks are single use devices intended to be used for soft tissue approximation, including Achilles tendon repair in patients with acute rupture of the Achilles tendon.

These oversize sutures are not suitable for use in cardiovascular, ophthalmic or neurological procedures.

Contraindication

Infinity-Locks integrate well with the patient’s tissue and consequently may not be suitable where eventual removal of the tape is anticipated.

Actions

Post-market surveillance data on Poly-Tapes have demonstrated that the risk of acute inflammatory reaction in tissues is minimal and the tensile strength remains satisfactory in vivo. The tapes are not absorbed but are gradually encapsulated by fibrous connective tissue.

Warnings and Precautions

- Do not resterilize. Discard open, unused Infinity-Locks.
- As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. If the patient is suspected of having any foreign body sensitivity, appropriate tests must be made prior to implantation.

- Surgeons must be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Infinity-Locks and care must be taken to select the correct size and strength of tape. Care must be taken with use in skeletally immature patients as it must not bridge, disturb or disrupt the growth plate.
- Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.
- In handling this or any other suture material, care must be taken to avoid damage from handling. Avoid crushing or crimping damage due to the application of surgical instruments such as forceps or needle holders.
- Adequate knot security requires the accepted surgical technique of flat, square ties with additional throws (i.e. a surgeon’s knot) as warranted by surgical circumstance and the experience of the surgeon.
- Do not use a reef knot as the tape may slip. Check that any knot is securely locked. To provide further stability a suture can be passed through the knot to secure the 2 ends of the tape. The corded sections are not intended for knotting and must be trimmed once the knot has been tied.
- Ensure that any knots remain well buried in tissue and take care to avoid anatomical hazards including soft tissue and nerves and to ensure they are not trapped by the tape.
- To trim excess length after knotting, cut straight across the Infinity-Lock at right angles to its edge to minimize generation of loose fiber fragments. After trimming it may be necessary to restrain the cut ends by stitching them back to the material.
- Any loose fibers formed when trimming the Infinity-Lock to length must be carefully removed from the incision wound.
- Failing to form the knot correctly and securely will have a significant effect on the strength of the repair (see table above for strength information.)
- When used with a fixation device, the strength of the combination may be less than that of the tape used alone and care must be taken that it does not damage or cut through the tape.
- If drilling bone tunnels to receive the Infinity-Lock, take care to leave an adequate bone thickness between the tunnel and the surface or between 2 parallel tunnels, to provide a sufficient bony bridge to resist expected forces that will be exerted on the bone by the reconstruction. Take into account the quality of the bone and round tunnels where possible, to avoid damage to the tape.
- It is recommended that wherever possible patients are placed on prophylactic antibiotics prior to surgery, including oral surgery, to minimize the risk of latent infections developing at the device site.
- The patient must be warned not to exceed the prescribed activity levels or to overload the repair before complete healing has occurred.

- Infinity-Locks must not be used if there is any evidence of infection.

Potential Adverse Effects

1. Possible adverse reactions associated with the use of this device include: wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infected wounds, minimal acute inflammatory tissue reaction, and transitory local irritation.
2. The tape could possibly break through the bone if bone tunnels are incorrectly positioned, the bone is of poor quality, or prescribed activity levels are exceeded.

Packaging and Labelling

1. The Infinity-Lock implants must be accepted only if the factory packaging and labelling arrive intact.
2. Contact the Sales Department if package has been opened or altered.

Storage

Products must be stored in the original unopened packaging away from moisture, dust, insects, vermin, and extremes of temperature and humidity.

Material Specifications

The Infinity-Lock is made from polyester. The green weft includes the colorant D&C Green #6 at levels of <0.01% by weight of the whole device.

Directions for use

Further information if required may be obtained from Xiros™ customer services enquiries@xiros.eu.com

Distributed in the USA by:

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Key to symbols that may be used on Xiros™ packaging


Do not use if package is damaged


Consult instructions for use


Do not re-sterilize


Do not reuse


Use by date


Manufacturer

Batch code

Catalogue number

Sterilized using irradiation


Caution

CAUTION: US Federal law restricts this device to sale by or on the order of a physician