neoligaments™

Poly-Tape with Fastlok™

High strength sterile polyester tape with titanium alloy Fastlok Fixation device

Instructions for use

CE 0086

STERILE R Rx only

GMDN 46242

neoligaments™

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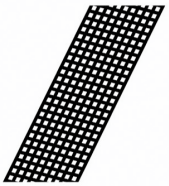
LAB 085 7.00

Ordering Information

Standard Poly-Tapes (supplied sterile) (Open Weave)

Ref	Nominal Size (Inches)	Nominal Size (mm)	Minimum Tensile Strength (N)	Average Fixation Strength (N)
102-1010 (doubled *)	0.4 x 20	10 x 500	480 (960*)	628 (898*)
102-1080 (doubled *)	0.4 x 30	10 x 800	480 (960*)	628 (898*)
102-1081	0.6 x 30	15 x 800	630	694
102-1082	0.8 x 30	20 x 800	950	967
102-1083	1.2 x 30	30 x 800	1380	1133

* Doubled (as per Warnings and Precautions 13)



Tube-Tapes (supplied sterile) (Open Weave)

Ref	Nominal Size (Inches)	Nominal Size (mm)	Minimum Tensile Strength (N)	Average Fixation Strength (N)
102-1040	dia. 0.2 x 20	dia. 5 x 500	1000	930

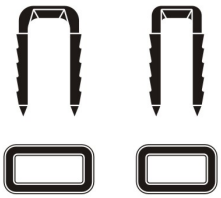
Multipack of 5 Ortho-Tapes (supplied sterile) (Dense Weave)

Ref	Nominal Size (Inches)	Nominal Size (mm)	Minimum Tensile Strength (N)	Average Fixation Strength (N)
102-1027	1/8 x 24	3 x 600	690	672

Fastlok (supplied sterile)

102-1380 6 mm x 23 mm Fastlok

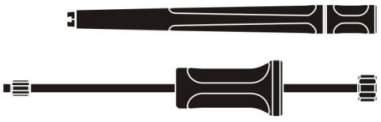
102-1381 8 mm x 23 mm Fastlok



Instruments (supplied separately)

202-1137 Impactor/Extractor

202-1118 Sliding Hammer



Description

Poly-Tapes are sterile non-absorbable implantable tapes made from polyester.

The Fastlok consists of a staple and buckle and is recommended for use with Poly-Tapes for soft tissue (tendon and ligament) fixation during orthopedic reconstruction procedures. The number and size of the Poly-Tapes used for this reconstruction, and the size and type of Fastlok, is according to the surgeon's preference, taking into account the patient's size and activity level.

This Instructions for Use leaflet applies only to the use of Poly-Tapes with a Fastlok fixation device. The Poly-Tape and Fastlok may be any of those listed above.

See Fastlok IFU (LAB 108) for information on the Fastlok including warnings, precautions, potential adverse events and directions for use.

Material specifications

The Poly-Tape is made from polyethylene terephthalate (polyester), which meets applicable specifications established by ISO 10993-1 for implantable medical devices.

Sterility

Poly-Tapes and Fastloks are supplied sterile and double wrapped. They remain sterile unless the package is damaged or opened. Check the package is undamaged before use.

Indications

Poly-Tapes are single use devices intended to be used for soft tissue (tendon and ligaments) fixation to bone with a Fastlok fixation device during orthopedic reconstruction procedures.

Contraindications

1. Any structural or pathologic condition of the bone or of the soft tissue being fixed which can be expected to impair secure fixation by the device.
2. Other physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing (blood supply limitation, infections, etc).
3. The patient's inability or lack of willingness to restrict activities to prescribed levels or follow the rehabilitation program during the healing period.
4. If the patient is suspected of having any foreign body sensitivity, appropriate tests should be made prior to material selection or implantation.
5. Poly-Tapes integrate well with the patient's tissue and consequently may not be suitable where eventual removal of the tape is anticipated.

Warnings and Precautions

1. The devices are provided sterile and remain so unless the packaging is damaged or opened. Store in standard conditions. DO NOT RESTERILIZE.
2. The devices are for single use only as they would be damaged by reprocessing. Do not use after the expiration date. Discard any open, unused product.
3. The general principles of patient selection and sound surgical judgement apply to the reconstruction procedure.
4. Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Poly-Tapes.
5. Take care to select a suitable Poly-Tape for the surgery to be undertaken.
6. The use of a Poly-Tape may not be suitable for patients who are skeletally immature. It will not elongate as the patient grows and so it must not bridge, disturb, or disrupt the growth plate. Bone quality should be assessed and surgery should not be performed on patients with insufficient or immature bone.
7. In handling Poly-Tapes, care should be taken to avoid damage from handling. Avoid crushing or crimping damage of the tape due to the application of surgical instruments such as forceps or needle holders.
8. 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.
9. If drilling bone tunnels to receive the Poly-Tape, take care to leave an adequate bone thickness between the tunnel and the surface or between two 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.
10. Check that any knot is securely locked. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.
11. Forming a knot in any tape or suture may reduce its overall strength by approximately 50%.
12. When used with a fixation device, the strength of the combination may be less than that of the tape used alone.
13. If using the 10 mm flat open weave Poly-Tape with a Fastlok, two loops (4 ends) are required to obtain adequate strength.
14 Be aware that the Poly-Tape might be damaged by sharp edges of bone tunnels and certain fixation devices. Wherever possible all bone edges should be rounded. The Fastlok supplied should be used for fixation.
15. Using excessive force to impact the Fastlok staple may cause damage to, or cut through, the Poly-Tape.
16. To trim excess length, cut straight across the Poly-Tape at right angles to its edge to minimize generation of loose fibre fragments. After trimming it may be necessary to restrain the cut ends by stitching them back to the material.
17. Any loose fibres formed when trimming the Poly-Tape to length must be carefully removed from the incision wound.
18. Ensure that any knots remain well buried in tissue.

19. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.
20. The patient should be warned not to exceed the prescribed activity levels or to overload the repair before complete healing has occurred.
21. Take care to avoid anatomical hazards including soft tissue and nerves. Ensure they are not trapped by the tape.

Potential Adverse Effects

Poly-Tapes:

1. Possible adverse reactions associated with the use of this device include: wound dehiscence, 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.

Directions for Use

Further information if required may be obtained from the Neoligaments Sales Department.

Distributed in the USA by:

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Key to symbols that may be used on Neoligaments™ packaging


Manufacturer


Consult instructions for use


Do not reuse


Do not use if package is damaged


Do not resterilize

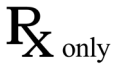

Caution


Use by date

Batch code

Catalogue number

Sterilized using irradiation



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