neoligaments™

Fastlok™

EN Instructions for use

LAB 108 10.00

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GMDN 45062

English

EN **Do not use if package is damaged**

EN **Do not reuse**

EN **Consult instructions for use**

LOT EN **Batch code**

REF EN **Catalogue number**

STERILE R EN **Sterilized using irradiation**

EN **Use by date**

EN **Manufacturer**

EN **Caution**

R_x only EN **Caution: US federal law restricts this device to sale by or on the order of a physician**

English

Implants
102-1380 6 mm x 23 mm Fastlok
102-1381 8 mm x 23 mm Fastlok

Instruments (supplied separately)
202-1137 Impactor Assembly
202-1118 Sliding Hammer

General Use
The Fastlok consists of a staple and buckle and is intended for the attachment of sutures or tapes to bone, for soft tissue and connective tissue repairs, tendon transfers, or autogenous and/or prosthetic ligament reconstruction, repair or replacement. Use the Neoligaments Impactor Assembly (see LAB 181) with the Fastlok, and vice versa, and follow the instructions given in this leaflet. Fastloks are suitable for USP 2 (Metric 5) sutures or larger.

Important
The Impactor Assembly 202-1137 can only be used with Fastlok products 102-1380, or 102-1381 and vice versa.

Sterility
The Fastlok is provided sterile, and remains so unless the package is damaged or opened.

Indications
Various soft tissue and connective tissue repairs including:
1. Tendon repairs, transplants or transfers in which the tendon is connected to bone via sutures or tapes.
2. Ligament repairs, reconstruction or replacement in which the ligament material is connected to bone via sutures or tapes.
3. Prosthetic ligament reconstructions and the attachment of other synthetic materials to bone.

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 programme during the healing period.

English

4. If the patient is suspected of having any foreign body sensitivity, appropriate tests should be made prior to material selection or implantation.

Warnings and Precautions
1. The general principles of patient selection and sound surgical judgement apply to the fixation procedure.
2. Use the device only for the listed Indications in patients whose conditions are not listed as Contraindications above.
3. The appropriate size implant should be preselected by the surgeon based on the bulk of the material to be attached.
4. Use care in storage and handling of implant components, and examine components for damage or defects prior to implanting. Care should be taken not to damage either the ligament, staple or buckle during surgery.
5. Postoperative activities should be controlled to ensure patient compliance with the prescribed rehabilitation programme.
6. The patient should be informed of the possibility that the Fastlok may need to be removed if the patient experiences persistent problems related to the device.
7. Removal of the Fastlok is optional but should normally be delayed for a minimum of one year to allow proper healing.
8. A removed Fastlok must never be reused and should either be discarded or returned to the manufacturer, within formalin, if an evaluation is required. The Fastlok is for single use as it will be subject to wear during the procedure which may affect performance on any subsequent use.
9. Take care not to over-impact the Fastlok to avoid damaging the sutures or tapes.

MRI Safety Information
MR Conditional

Non-clinical testing demonstrated that the Fastlok is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:
- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e. per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the Fastlok is expected to produce a maximum temperature rise of 1.5 °C after 15-minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact caused by the Fastlok extends approximately 15-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Potential Adverse Effects
1. Loosening, bending, or fracture of the staple and/or buckle plate may result in loosening of the material fixation to the bone.
2. Infections, both deep and superficial.
3. Patient foreign body sensitivity and adverse reaction to device materials.
4. Pain and inflammation at device location.

Packaging and Labelling
1. The Fastlok implants should be accepted only if the factory packaging and labelling arrive intact.
2. Contact the Neoligaments 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 Fastlok is made from titanium alloy Ti-6Al-4V (ISO 5832-3 or ASTM F136).

English

Directions for Use
Users of this device are encouraged to contact the Neoligaments Sales Department if, in their professional judgement, they require a more comprehensive surgical technique.

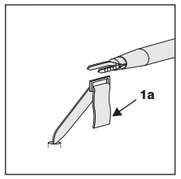
Impacting the Fastlok into Bone
See images at the end of this booklet.

Refer to the Impactor Assembly and Sliding Hammer Instructions for Use (LAB 181) prior to impacting the Fastlok into bone or removing the Fastlok from bone. This is available on the Neoligaments website.

Prior to starting the procedure unscrew the nut on the end of the Impactor to unlock the jaws. Position the bridge of the staple parallel to the inside of the jaws and re-tighten the nut. Ensure that the staple is held securely.
Figure 1
Thread the free end of the tape / suture (1a) through the buckle which must be held with forceps at the middle of its free long side (forceps not shown). Hold the Impactor above the buckle so that the legs of the staple are parallel with the buckle.
Figure 2
Bring the staple down past the side of the buckle over which the tape / suture is folded, so that the legs of the staple straddle the folded tape / suture. Turn the staple (Impactor) through 90° in the horizontal plane.
Figure 3
The buckle is then flipped down through 180° over the staple. Check that the staple legs still straddle both of the tape / suture layers. This last step must be performed carefully and it is vital that as the staple is turned it does not pierce or damage the tape / suture.
Figure 4
Ensure that the tape / suture is not trapped between the buckle and staple. Simultaneously pull on the end of the tape / suture (4a) while pushing the staple (Impactor) along the tape / suture (4b), forwards toward the chosen site for implanting the Fastlok. During this step do not straighten the tape / suture. Its two ends must be at the angle shown, otherwise it may be difficult to push the staple forward.
Figure 5
Stop moving the staple forward when the tips of its legs are within 10-15 mm from the bone tunnel (5a). Pinch the tape / suture using forceps to avoid damage to it from the sharp point on the staple ends. Keeping the tape / suture between the staple legs, adjust the Impactor so that its axis is perpendicular to the surface of the bone at the implantation site.
Figure 6
Pull on both the Impactor (6a) and free tape / suture end (6b) to ensure tension on the section of the material emerging from the bone tunnel (6c). During this step the staple ends should not be pressed against the bone until tension has been ensured.
Figure 7
While maintaining tension on the material (7a), hammer the Fastlok into the bone (7b). Ensure the Impactor remains perpendicular to the bone. Ensure that both staple legs engage on the bone and that they do not skid across the surface. This could cause the legs to splay and possibly fracture.
Figure 8
Release the staple and close the jaws of the Impactor. IMPORTANT: Rotate the Impactor through 90° and use it to finish driving the staple (8a) into the bone while maintaining tension on the tape / suture (8b). Ensure there is no visible gap between the underside of staple bridge and top surface of buckle and that the tape / suture is firmly held in place.

Removing the Fastlok from Bone
Figure 9
Clamp the staple in the jaws of the Impactor (9a).
Figure 10
Screw the end of the Sliding Hammer into the end of the Impactor.
Figure 11
Grip the handle (11a) on the Sliding Hammer and hammer it against the end cap (11b) on the instrument. Be careful not to trap fingers between the handle and end cap.

[1]



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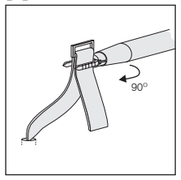

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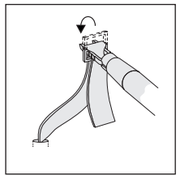

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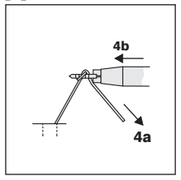

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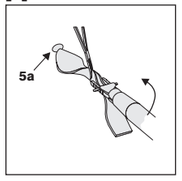

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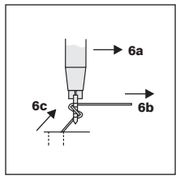

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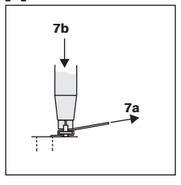

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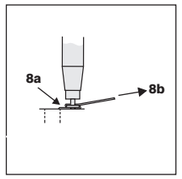

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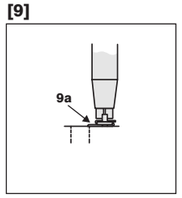

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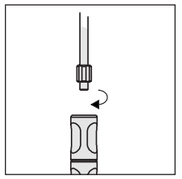

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