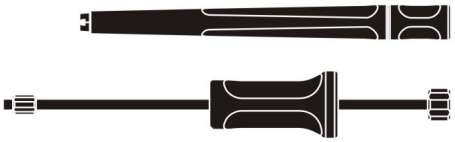

Impactor Assembly and Sliding Hammer

For fixation of sutures and tapes to cortical bone with the Fastlok™

Instructions for use

Xiros Limited, registered in England No. 1664824

CE

GMDN 12696

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

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LAB 181 3.00
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Ordering Information

Fastlok™ Instruments:
202-1137 Impactor Assembly
202-1118 Sliding Hammer

The Fastlok™ Instruments can only be used with the following products:
102-1380 6 mm x 23 mm Fastlok™
102-1381 8 mm x 23 mm Fastlok™

Patient Information

The following information is provided for use by clinicians, however as the learned intermediary between the company and the patient, the clinician must convey the aspects they consider relevant to the individual patient. The patient must be informed of the potential adverse effects (risks/complications) contained in this insert (see POTENTIAL ADVERSE EFFECTS).

Description

The Impactor Assembly and Sliding Hammer can only be used with the Fastlok products listed above.
The Impactor Assembly is required to impact Fastlok devices into the bone.
Both the Sliding Hammer and the Impactor Assembly are required to remove the Fastlok from bone.
This device is for use by orthopedic surgeons, familiar with the use of staples in 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.
These are reusable instruments. Repeated reprocessing has minimal effect on instruments.
End of life is normally determined by wear and damage due to use.
For further information contact the manufacturer.

Material Specifications

The instruments are made from stainless steel.

Intended Use

The instruments are intended for use with the Fastlok for fixation of sutures and tapes to cortical bone.

Indications for Use

Indicated for where the Fastlok is to be implanted or extracted. For Fastlok indications for use refer to the Fastlok (LAB 108) Instructions for Use.

Contraindications

For contraindications refer to the Fastlok (LAB 108) Instructions for Use.

Warnings

For warnings associated with the Fastlok, refer to the Fastlok (LAB 108) Instructions for Use.

Precautions

The instruments are supplied non-sterile and must be cleaned and sterilized before use.
Before initial use follow the steps for inspection, preparation for cleaning, manual cleaning, reassembly, user packaging, sterilization.

Packaging

- The instruments must be accepted only if the factory packaging and labelling arrive intact.
- Damaged packages or products should not be used and should be returned to the manufacturer.
- All instrument sets should be carefully checked for completeness and all components should be carefully checked to ensure there is no damage prior to use. See inspection instructions below.

Handling and Storage

- All devices should be treated with care, improper use or handling may lead to damage and/or possible malfunction. Devices should be checked to ensure that they are in working order prior to surgery (see inspection instructions below).
- Products must be stored away from moisture, dust, insects, vermin, and extremes of temperature and humidity.

Inspection

- The instruments must be checked for damage prior to every use.
- Devices should be checked to ensure that they are in working order prior to surgery as follows:
    - Twist the nut on the end of the Impactor Assembly, ensure the jaws open and close and can securely clamp the Fastlok.
    - Move the handle of the Sliding Hammer up and down the shaft, ensure that it moves freely along its length.
    - Screw the Sliding Hammer on to the end of the Impactor Assembly (Figure 1), ensuring that they fit together securely.
- Non-working or damaged devices should not be used and should be returned to the manufacturer after cleaning and sterilization according to the instructions below. The manufacturer will repair or replace the instruments.

Reprocessing Instructions for Instruments

Between uses or prior to returning to manufacturer, follow the steps for preparation for cleaning, point of use cleaning, pre-cleaning, manual cleaning, reassembly, user packaging, sterilization.

A manual cleaning method has been provided in these instructions. Due to the cannulated structure of the Impactor Assembly, an automated washing procedure is not recommended.

Before and after use, the instruments must be disassembled and thoroughly cleaned, until visually completely free of any adherent matter. The instruments must then be sterilized. Washing materials and chemicals must be suitable for stainless steel instruments. As not all cleaning agents may be available around the globe, the manufacturer does not recommend any specific cleaning agent. Cleaning agents should be used at the concentration level recommended by the detergent manufacturer.

Use of hard water should be avoided. Purified water should be used for final rinsing to eliminate mineral deposits on instruments.

Equipment and Accessories required for cleaning and sterilization

- Tray of water or damp towels
- Absorbent, non-shedding, cleaning wipes
- Cleaning bath or vessel large enough to allow complete immersion of the instruments
- Enzymatic cleaning agent (suitable for stainless steel instruments)
- Soft bristle brushes including a bottle brush of appropriate diameter and length to clean cannulation of Impactor Assembly
- Ultrasonic bath
- Purified water for final rinsing
- Surgical instrument lubricant suitable for use with stainless steel and steam sterilization

- Suitable packaging to sterilize the instruments in and maintain a sterile barrier
- Steam autoclave, it is recommended that the autoclave is validated/maintained in accordance with ISO 17665

Point of Use Cleaning
If attached, unscrew the end of the Sliding Hammer from the Impactor Assembly to disassemble (Figure 1).

- After use (maximum of 30 minutes post-operative) remove gross soil using absorbent paper wipes. Place instrument in a tray of distilled water or cover with damp towels to prevent drying of soil.
- Used instruments must be transported to the central cleaning facility in closed or covered containers to prevent unnecessary contamination risk.

Figure 1

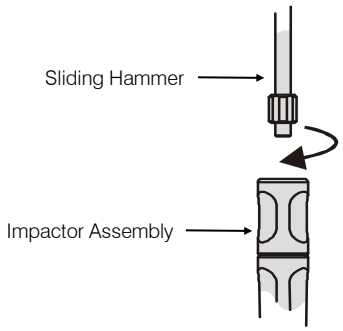

Figure 1: Sliding Hammer screws into the end of the Impactor. Screw together immediately before use and unscrew immediately after use.

Preparation for cleaning

- Disassemble the Impactor Assembly (Figure 2). Unscrew the nut from the threaded end of the shaft and pull out the shaft from the body of the Impactor Assembly.

Note, the Sliding Hammer cannot be disassembled.

Figure 2

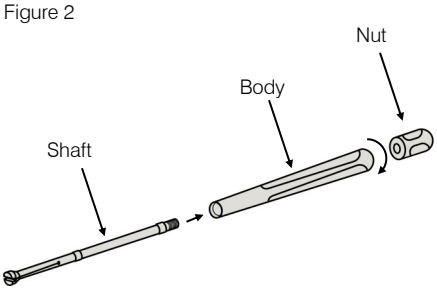

Figure 2: Assembly/ Disassembly of the Impactor Assembly

Pre-Cleaning

- Remove gross soil using wipes and solution of enzymatic cleaning agent.
- Immerse instrument in solution of enzymatic cleaning agent. Ensure that all surfaces are thoroughly wetted. Slide the Sliding Hammer along the shaft to ensure the whole shaft is wet.
- Soak for a minimum of 20 minutes.
- Using suitable soft bristle brushes clean the instrument thoroughly paying particular attention to bores, threads and any other difficult to clean areas.
- Use a bottle brush to clean the cannulation. Ensure that the brush passes the whole length of the cannulation.
- Rinse in running water until all traces of cleaning solution are removed.
- Allow to drain on absorbent paper or transfer immediately to cleaning step.

Manual cleaning

- Prepare an ultrasonic bath large enough to allow complete immersion of the instrument with a cleaning solution at the concentration and temperature specified by the detergent manufacturer.
- Immerse the instrument completely and activate the bath for a minimum of 15 minutes.
- Using suitable soft bristle brushes clean the instrument thoroughly paying particular attention to bores, threads and any other difficult to clean areas. Use a bottle brush to clean the cannulation. Ensure that the brush passes the whole length of the cannulation.
- Rinse for at least 1 minute in running water until all traces of cleaning solution are removed.
- If after completion of the cleaning soil remains visible on the instrument, the cleaning step above must be repeated. As the Sliding Hammer cannot be disassembled, slide the hammer along its shaft to ensure the whole shaft is clean.
- Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe and ensure device is completely dry after cleaning.

Reassembly

- After washing, carefully inspect each instrument for cleanliness and for damage or wear which may impair its function. If soil remains visible on the instrument, repeat the cleaning steps.
- A surgical instrument lubricant MUST be used on threads and moving parts before reassembling the instrument. The lubricant should be applied in accordance with manufacturers recommendation, for example in terms of amount and method of application.
- Reassemble the Impactor Assembly (Figure 2) ensuring the nut is not fully tightened, so that the shaft can move in the body and steam can fully penetrate.

1. Locate the shaft inside the body.
2. Twist the nut onto the threaded end of the shaft.

- Ensure the Impactor Assembly / Sliding Hammer is in working order (see inspection instructions).

User Packaging

- It is the responsibility of the user to choose suitable packaging that maintains a sterile barrier to sterilize and store the instruments in.

Sterilization
Steam autoclave the instruments using a sterilization cycle validated for stainless steel surgical instruments. It is recommended that the autoclave is validated/maintained in accordance with ISO 17665. The following sterilization cycles are recommended:

Cycle Type	Temperature Range	Minimum Exposure Time
Gravity Displacement	134-137^{O}C	10 Minutes
Porous Load	134-137^{O}C	3.5 Minutes

Ensure that instruments are dry before storage or use. Drying times can vary depending on the type of packaging, type of sterilizer and total load.

Potential Adverse Effects
Below is a list of the potential adverse effects (e.g. complications) associated with the use of the device including 1. risks associated with any surgical procedure; 2. risks associated with staple impactors and extractors, including the Fastlok Instruments.
1. Pertinent risks associated with any surgical procedure include: Infection.
2. Risks associated with staple impactors and extractors, including the Fastlok Instruments, include:

- If the Fastlok is not adequately impacted, this could lead to loosening of the suture or tape, or need for removal due to pain or irritation.
- If the Fastlok is over impacted, this could lead to damage of the suture or tape.

Additional surgery may be required to correct some of these events.

Refer to the Fastlok IFU (LAB 108) for risks associated with the Fastlok device.

Surgical Technique
Refer to the Fastlok (LAB 108) Instructions for Use, provided with the Fastlok device. Immediately prior to use, inspect the device according to inspection instructions above.

Disposal
No specific disposal requirements other than handling contaminated items as clinical waste.

Prior to returning to manufacturer, follow the steps for preparation for cleaning, point of use cleaning, pre-cleaning, manual cleaning, reassembly, user packaging, sterilization.

Complaints
Any health care professional who has any complaints or experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, usability, effectiveness, and/or performance, should notify the manufacturer and distributor immediately.
If the product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the manufacturer and relevant local regulatory authority should be notified immediately by telephone, email or written correspondence.
When filing a complaint, provide the component(s) name and number, lot number(s), your name and contact details and the nature of the complaint.

Key to symbols that may be used on Neoligaments packaging

	Date of manufacture (YYYY-MM-DD)
	Caution
NON STERILE	Non-sterile
	Manufacturer
LOT	Batch code
REF	Catalogue number
	Consult instructions for use
Rx only	CAUTION: US Federal law restricts this device to sale by or on the order of a physician