

Impactor Assembly and Sliding Hammer

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

Instructions for use

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GMDN 12696

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

Ordering Information

202-1137 Impactor Assembly
202-1118 Sliding Hammer



Material Specifications

The instruments are made from stainless steel, which meets applicable specifications established by ISO 10993-1.

Intended Use

The instruments are intended for use with the Fastlok for fixation of sutures and tapes to cortical bone (see LAB 108).

Indications

Indicated for where the Fastlok is to be implanted or extracted. See LAB 108, Fastlok Instructions for Use for details of the indications for the Fastlok.

Contraindications

For contraindications and potential adverse effects, see the instructions for use supplied with the Fastloks (LAB 108).

Warnings

- The instruments are supplied non-sterile and must be sterilized before use. See sterilization instructions below.
- The instruments must be accepted only if the factory packaging and labelling arrive intact.
- The instruments must be checked for damage prior to use and are not to be used if there are any signs of visible damage.
- Contact the Neoligaments Sales Department if the packaging has been opened or altered, or if any components are missing.
- The Impactor Assembly 202-1137 and Sliding Hammer 202-1118 can only be used with Fastlok products 102-1060, 102-1380, or 102-1381 and vice versa.

Precautions

- Products must be stored away from moisture, dust, insects, vermin, and extremes of temperature and humidity.

Reprocessing Instructions for Instruments

- Before and after use, the instruments must be dismantled 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.
- 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.
- For cleaning re-usable instruments, only specifically formulated cleaning agents suitable for stainless steel instruments should be used. However as not all cleaning agents may be available around the globe, Neoligaments 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. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments.
- Repeated reprocessing has minimal effect on instruments. End of life is normally determined by wear and damage due to use. Damaged instruments should be repaired or replaced by the manufacturer straight away.

Point of Use

- 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.

Preparation for cleaning

- Disassemble the Impactor Assembly. Refer to Figures 1 and 2 for assembly/disassembly instructions. Note, the Sliding Hammer cannot be disassembled.

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 of appropriate diameter and length 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 of appropriate diameter and length 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.

Inspection

- After washing, carefully inspect each instrument for cleanliness and for damage or wear which may impair its function. If such damage is found, return to the manufacturer for repair or replacement after sterilizing. 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.
- Reassemble the instruments, ensuring the nut on the Impactor Assembly is not fully tightened, so that the shaft can move in the body and steam can fully penetrate.

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. The following sterilization cycles are recommended:

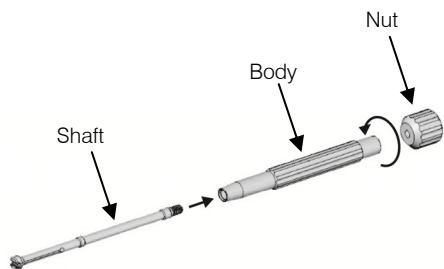
- 134-137°C for 10 minutes in a gravity displacement sterilizer, or
- 134-137°C for 3.5 minutes in a porous load sterilizer.

Impactor Assembly/Disassembly

Figure 1

Assembly:

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

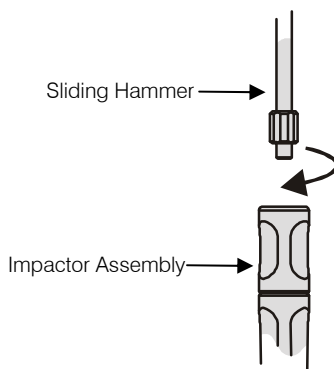


- Screw the end of the Sliding Hammer into the end of the Impactor Assembly if carrying out Fastlok removal.

Disassembly:

- If attached, unscrew the end of the Sliding Hammer from the Impactor Assembly to disassemble.
- Unscrew the nut from the threaded end of the shaft and pull out the shaft from the body of the Impactor Assembly.

Figure 2



Key to symbols that may be used on Neoligaments packaging



Date of manufacture (YYMM-DD)



Caution



Non-sterile



Manufacturer



Batch code



Catalogue number



Consult instructions for use



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