

NEWCLIP INSTRUMENTATION NON STERILE



INSTRUMENTS NON STERILES REUTILISABLES

NON-STERILE REUSEABLE INSTRUMENTS



Registered in sept. 2002
Obtenu en sept. 2002



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R_X only



Ref. NoticeAncillaires
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Lire les instructions avant utilisation / Read instructions before use
/ Leer las instrucciones antes de usar / Leggere le istruzioni prima
dell'uso / Ler as instruções antes da utilização / Vor Verwendung
die Anweisungen lesen / De instructies lezen vóór het gebruik /
Läs anvisningarna före användning / Kullanmadan önce talimatları
okuyunuz



N° lot / Batch n° / N° lote / N° di lotto / N° lote / Chargen-Nr / Batch
nr / Partijnummer / Seri no

Non-sterile reusable Newclip instruments



Product description

Newclip instruments are to be used only in trauma or orthopaedic surgery, when Newclip implants for osteosynthesis are fitted.

Indications and precautions

- These instruments must only be used by trained and qualified staff, recognized as being competent to carry out the operations described in the previous section, or to handle surgical instruments.
- The principles of use of specific Newclip instruments are laid out within the commercial brochures. There are also descriptions of operative techniques applicable to a given implant. These documents may be obtained from the company and its recognized distributors.
- The measurements marked on Newclip instruments which carry a measuring function are only accurate when the instruments are employed under the conditions prescribed in the relevant brochures.
- Furthermore, it is strictly forbidden to carry out any modification of Newclip instruments. Only the company, NEWCLIP TECHNICS, is allowed to do this and has the necessary technical ability.

Cleaning and sterilization

All non-sterile devices must be cleaned and sterilized prior to use by qualified professionals using the following guideline:

Warning	Before any use of these devices, check that none of the components has suffered deterioration, deformity or corrosion that may prejudice its correct functioning. Withdraw any blunt or damaged devices.
Reuse restrictions	Repeated sterilization procedures have little effect on these devices. The end of their useful life is normally determined by wear and damage resulting from use.
Conditions for use	These devices are sold non sterile. All devices must be cleaned, decontaminated and sterilized after removal of packaging material, before and after use.
Precaution	Any soiled instrument must be cleaned and decontaminated immediately.
Preparation for cleaning	Devices composed of several pieces must be dismantled prior to cleaning. Cannulated parts require special attention when cleaning. Solutions containing bleach or formaldehyde can damage the units and must not be used. These devices must not come into contact with fluorinated or chlorinated compounds, with fat-based detergents, and, in general, with any product which might modify their chemical component(s). Similarly the use of metallic brushes or other abrasive products is not allowed.

Cleaning	Cleaning may be carried out manually or mechanically according to the specifications provided by the supplier of the equipment to the hospital.															
Cleaning - manual	<u>Equipment: aldehyde-free detergent (alkaline or neutral) – brush with soft bristles – purified water</u> Rinse off excess soiling from the device. Apply the detergent according to the detergent manufacturer's instructions, with the brush on all surfaces, ensuring that devices with joints are cleaned in both the open and the closed positions. Particular attention must be applied to threaded areas and to areas which are hard to access. After cleaning, devices must be immediately rinsed carefully and thoroughly with purified water, during at least 1 minute. Ensure that water flows through cannula and difficult access areas.															
Cleaning - automated	<u>Equipment: washer/disinfector – alkaline or neutral detergent – purified water</u> Deposit the devices so as to leave joints open and to allow the water to flow through cannula and difficult access areas. Follow the instructions for concentration, temperature and contact time by the manufacturer of the cleaning agent. The minimum washing cycle is 5 minutes and rinsing 3 minutes.															
Disinfection	When washer/disinfector is employed, a final rinse at 95°C for 10 minutes can be performed in order to achieve thermal disinfection.															
Drying	The temperature in the drying phase must not exceed 134°C.															
Visual inspection	After cleaning (manual or mechanical), the device must be inspected. If the device is determined to not be visually clean at the end of the cleaning process, the user must repeat the previous cleaning steps, or alternatively, safely dispose of the device. Identify and discard any deteriorated or oxidised devices.															
Sterilization	<u>Recommended method: steam sterilization in autoclave:</u> Before sterilization, Newclip tray should be packaged in a legally marketed FDA-cleared sterilization wrap. They must be steam-sterilized using the following guideline:															
	<table border="1"> <thead> <tr> <th></th> <th>US Sterilization (only for United States)</th> <th>EU sterilization (only for Europe)</th> </tr> </thead> <tbody> <tr> <td>Sterilizer</td> <td colspan="2">Dynamic-air-removal steam sterilizer</td> </tr> <tr> <td>Temperature</td> <td>270°F / 132.2°C</td> <td>134°C / 273.2°F</td> </tr> <tr> <td>Exposure time</td> <td>4 min</td> <td>18 min</td> </tr> <tr> <td>Drying time</td> <td>20 min</td> <td>20 min</td> </tr> </tbody> </table>		US Sterilization (only for United States)	EU sterilization (only for Europe)	Sterilizer	Dynamic-air-removal steam sterilizer		Temperature	270°F / 132.2°C	134°C / 273.2°F	Exposure time	4 min	18 min	Drying time	20 min	20 min
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	The EU sterilization protocol (134°C - 18 min) is not validated for prion inactivation cycle in the <u>US sterilizers</u> . The devices can be sterilized repeatedly under these described conditions.															
Storage	These devices are subject to damage. We therefore advise that they are handled with care during transport and use and not stored in a damp environment.															

Since NEWCLIP is not familiar with individual hospital handling methods, and in particular cleaning, decontamination and sterilization, NEWCLIP cannot assume responsibility for sterility of implants, even though the guidelines have been followed.

Newclip has validated the instructions provided above as being capable of sterilizing its medical devices. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process.

IMPORTANT: For further information concerning the use of these products, please contact your supplier.

IMPORTANT: Those surgical products must be handled, and/or used by well-trained, knowledgeable surgeons aware of the present instructions.

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) or on the physician's prescription.

NEWCLIP TECHNICS cannot assume responsibility in case of non-respect of the above instructions.