Instructions for use of medical devices intended for re-sterilization

CHONDRECTOM™

Surgical instruments

CE

Before using surgical instruments, please read these handling instructions carefully.

Characteristics
Reusable and re-sterilizable surgical instruments are made of specialized corrosionresistant stainless steel in accordance with international standards.

Warnings
Surgical instruments must only be used for their intended purpose and in accordance with the information contained in the instructions for use. Damaged instruments must not be used. They must show no signs of wear and must be properly assembled. Only clean and disinfected instruments can be sterilized effectively. The instruments must be dry before the sterilization process. Service and repairs may only be carried out by an authorized service center. Repeated handling in accordance with the above instructions has a minimal effect on the instruments.

Reuse Restrictions
The product does not carry an expiration date and is independent of the number of processing cycles. The end of shelf life is determined by normal wear and tear and damage that occurs while using the tool.

Before the first use

THE INSTRUMENTS ARE DELIVERED NON-STERILE.

Brand new instruments should be washed in warm water with medical detergent (e.g., Cidezyme) before first sterilization.

Before each use
Be sure to inspect the tool before each use to confirm proper functionality. During the visual inspection, pay attention to cavities, cracks, or surface contamination.

Preparation for cleaning
Surgical instruments must be rinsed under running water for one minute immediately after use and contaminants must be removed with a plastic brush with synthetic bristles. Intense soiling must be removed immediately. Instruments should be cleaned immediately after use. Instruments that consist of several parts not integrally connected should be disassembled before washing and drying. Instruments with hinges should be opened before cleaning.

Manual cleaning
For manual cleaning, use cleaning and disinfecting agents (those approved for use in medicine and containing additional corrosion inhibitors, e.g., Sekusept, Neodisher), warm running water and a brush with synthetic bristles. Follow the instructions of the manufacturer of the cleaning and disinfecting agent with regard to dosage, concentration, temperature, compatibility of materials and time. Rinse under clean running water, for the final rinse use demineralised water. Visual control of instruments - washing should remove all postoperative biological contamination, there should be no spots or stains on the instruments.

Automatic cleaning
For automatic cleaning, use cleaning and disinfecting agents approved for use in medicine containing additional corrosion inhibitors, e.g., Sekusept, Neodisher. Load instruments, start the washing, rinsing and drying cycle. Follow the instructions, relevant procedures and programs indicated by the manufacturer of the used equipment. Depending on the type of used equipment, the cleaning cycle (wash, rinse, dry) at 90°C lasts at least 1 hour. Cleaning should remove all post-operative biological contaminants.

Disinfection
Disinfectant solution must be used according to the instructions on the packaging, e.g. Sekusept, Neodisher. Disinfection may be carried out simultaneously with instrument washing, using the same preparations, e.g., Chirosan. A final rinse in demineralized water optimizes the process. In the case of automatic cleaning, the final rinse can be regarded as thermal disinfection.

Drying
The instruments should be thoroughly dried by hand or in a dryer. If drying is used as a part of an automatic or disinfection cycle do not exceed 120°C.

Functionality review and testing
After the cleaning and disinfection process, visually check the cleanliness of the instruments. The instruments must be macroscopically clean. If any contamination is found, repeat the cleaning and disinfection process. All instruments should be visually inspected for damage and wear. It is recommended that cutting tips be free of damage and have continuous sharp edges. Where the instruments compose part of a kit, the assembly should be checked against the connected. The functionality of the tools should be checked before each sterilization. Damaged tools should be withdrawn from use.

Sterilization
Sterilization must be performed in accordance with the standard (PN-EN ISO 176650). The recommended sterilization procedure is steam sterilization at 121°C at 1 bar overpressure for a minimum of 20 minutes or at 134°C at 2 bar overpressures for a minimum of 10 minutes or steam sterilization using fractionated vacuum at 134°C, 2 bar overpressure, for 5 minutes.

Packaging
Individual packaging: standard medical packaging material may be used. Make sure that the packaging is large enough so that the packaged instrument will not cause weld tension. Sharp edges and tips should be protected.
Kit packaging: the instruments can be stacked on a pallet.

Storage
Tools after thorough washing and drying should be stored at a temperature of 5 - 30°C and a relative humidity not exceeding 70%. The room in which the tools are stored shall be clean, dry, darkened and provide a temperature within the above-mentioned range.

Storage and transportation
For transport, instruments must be protected from damage, moisture, and ensure complete traceability and sterility.

The instructions given above are appropriate for preparing surgical instruments for reuse. The handling unit is responsible for ensuring that the desired results are achieved. Validation and routine process control is required.

Additional information

Each time before use the instrument should be checked - it should be in working order, without postoperative biological contamination and residues after disinfection and sterilization, as well as without damage to the structure of the material, e.g. cracks, bends, splits, flakes.

Service
Service may be performed only by the Manufacturer.

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DANE TECHNICZNE WYROBU

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Produkt:	RA	GTIN:		Zatwierdzenie merytoryczne:	MARKETING	Weryfikacja techniczna:
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Wykonane przez:	Wymiary wyrobu (w mm): szer. x wys. x głęb.	Informacje dodatkowe:
Damian Syska	148 x 210 mm	
Kolory:	Wykończenie:	
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Numer zgłoszenia:
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