BHH MIKROMED

SURGICAL INSTRUMENTS – REGULATIONS FOR MEDICAL PRODUCTS FOR REPEATED STERILIZATION

Manufacturer: BHH MIKROMED Sp. z o.o.

Method: Moist heat sterilization – overpressure steam

Devices: Instruction applies to surgical instruments intended for repeated use, manufactured and supplied by BHH MIKROMED, made of corrosion proof stainless steel in accordance with international standards.

Warnings	Surgical instrument can be used only for its intended purpose. The instruments must be free from damages, signs of wearing out and properly assembled. Any instrument made of stainless steel may develop corrosion, stains or become damaged, if is handled without proper care or against guidelines recommended in the leaflet "Important information for instruments users". Leaving an instrument in a physiological salt solution can cause pitting corrosion. Only clean and disinfected surgical instruments can be effectively sterilised. Surgical instruments have to be dry before sterilisation process.
Limitations in repeated application	Repeated application confirming with this instruction has insignificant influence on the instruments. End of surgical instruments usability is defined by their normal wear out and damages resulting from their application.

INSTRUCTIONS	
Place of application	**Instruments are supplied non sterile.** Do not allow instruments to get significantly soiled. Intensive soiled have to be immediately removed. Surgical instruments should be made subject to the cleaning process immediately after use. Excess dirt should be removed with a single use tampon.
Storage and transport	For transport instruments should be protected from damage and moisture. It is recommended to carry out the procedure whenever it is justified by the next use.
Preparing for cleaning	When brand new instruments have been unpacked, prior to their first sterilisation they must be washed with warm water with preparations intended for medical application added /detergent e.g. Cidezyme/. Directly after the instruments have been used they should be placed in the water solution of disinfecting agents /concentration acc. to the manufacturer leaflet/. Multicomponent instruments must be disassembled before cleaning and drying. Instruments with connections and hinges should be opened before cleaning.
Cleaning automatic	Equipment: Washing station – disinfector (e.g. Miele G 7882 CD), ultrasonic washer. Detergent - preparations intended for washing, which have been approved for medical application, recommended by the manufacturer of the washing station – disinfector, containing corrosion inhibitors /e.g. Sekumatic, Secusept, Neodisher FLA/. Put the instruments inside, start cleaning, rinsing and drying cycle. Follow instructions, appropriate procedures and programs recommended by the device manufacturer. Depending on the applied device, the cleaning cycle /washing, rinsing, disinfection, drying/ in the temperature of 93°C lasts min. 1 hour. Cleaning must remove any blood, tissue, deposits and fluids. It should be noted that the components of the automatic cleaning process were phases in accordance with ISO 15883.
Cleaning manual	Equipment: detergent - preparations which have been approved for medical application, containing corrosion inhibitors /e.g. Sekusept, Neodisher/, warm running water, plastic brush. Should be applied indications from producer of cleaning and disinfection preparations regarding dosage, concentration, temperature, compatibility of materials and time. 1. Rinse contaminations from the instruments. 2. Use plastic brush /**no wire brushes or scrubs may be used**/, apply solution of the cleaning agent /e.g. Chirosan/. 3. Rinse with clean running water, last rinsing - with distilled water. 4. Visual control of the instruments - Cleaning must remove any blood, tissue, deposits and fluids, no stains or runs are acceptable
Disinfection	Apply disinfecting solution as prescribed on the preparation package /eg. Sekusept, Neodisher/. Disinfection may be carried out together with cleaning of the instruments and with application of the same preparations /e.g. Chirosan/. Final rinsing in demineralised water optimizes the process. In case of automatic cleaning, the final rinsing may be applied as an effect of thermal disinfection.
Drying	Dry the instruments thoroughly /manually or in a dryer/. If drying is an element of a cycle performed by a washing/disinfecting station do not exceed the temperature of 120°C.
Maintenance	Instrument hinges, after each cleaning and drying process, should be lubricated with paraffin based oil.
Revision and functionality control	After cleaning and disinfection process control visually surgical instruments cleanness. Instruments should be clean macroscopic. If there are any soils – cleaning and disinfection process have to be repeated. Visually control all instruments for damages and wear out. It is recommended that cutting tips reveal no scratches and have constant, sharp edges. Instruments with hinges: Control smooth movement of hinges. In case of instruments being a part of larger set, check connections between the components. Before every each sterilisation check functionality of instruments. Damaged instruments must not be used.
Packaging	Single: standard medical packaging material may be used. Make sure if the packaging is broad enough to avoid tension of welds. Protect sharp edges and tips. Sets: instruments may be placed on a pallet.
Sterilization	Autoclave - validated. For validation of the sterilization cycle, it is recommended to use biological indicators intended for the steam sterilization. Sterilisation must be carried out according to the steam sterilisation standard. It is recommend high pressure autoclaving at the temperature of 121°C and overpressure of 1 atm, for min. 20 minutes or, alternatively, sterilization at the temperature of 134°C and overpressure of 2 atm for min. 10 minutes. Instruments can be sterilized max. 20 times maintaining these rules.
Storage	After the instruments have been carefully cleaned and dried, they should be stored at the temperature of 5 – 30°C and relative humidity not exceeding 70%. Room, where sterilised instruments are stored should be clean, dry, dark and without temperature fluctuations.
Instructions given above are suitable for preparing products for reuse. **Organisation carrying out the process is responsible for ensuring that the desired results are achieved.** **Validation and routine process control is necessary.**	
Additional information	Every time before use the device must be controlled – it should be efficient, no toxic residues of disinfection or sterilization may be revealed, no damages of the material structure are acceptable /breaks, bends, fractures, peels off/
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REF	Nr kat. / Catalogue no.		Producent / Manufacturer		Użyć do / Used by
LOT	Nr serii / Serial no.		Data produkcji / Manufactured date	CE	Oznaczenie CE / CE Mark
	Zapoznaj się z instrukcją używania / Read the Instruction for use		Ostrzeżenie / Caution		
NON STERILE	Niesterylny / Nonsterile		Nie używać, jeśli opakowanie jest uszkodzone / Do not use package if damaged		

This instruction is based on the standard of PN-EN ISO 17664:2005 p.4 observing requirements of the p.3.