















SURGICAL IMPLANTS
- 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 implants** intended for single use, manufactured and supplied by BHH MIKROMED, made of corrosion proof stainless steel or titanium / titanium alloy in accordance with international standards.

Warnings	Leaflet "Information for implants users" should be used. Surgical implant can be used only for its intended purpose. Implants are intended for single use only .		
Limitations in repeated application	Repeated application confirming with this instruction has insignificant influence on the implants. None of implants can be used repeatedly.		
Instructions			
Place of application	Implants are supplied non sterile.		
Storage and transport	Products should be stored in the original packaging. Packaged products should be stored in a clean, dry place, in conditions that ensure protection against direct sunlight, pests, temperatures 15 -35°C and humidity 25% - 65%. For transport implants should be protected from damage.		
Preparing for cleaning	Packaged products should be stored in a clean, dry place, in conditions that ensure protection against direct sunlight, pests, extreme temperatures and humidity. Then they must be sterilized. they should be carefully cleaned with cleaners approved for medical use and in a manner preventing any disfigurement, damages and scratches of the surface, which damage the passivated coating of the implant.		
Cleaning automatic	<u>Equipment:</u> Washing station – disinfectant (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 – disinfectant, containing corrosion inhibitors /e.g. Sekumatic, Secusept, Neodisher FLA/. Indications of the cleaning and disinfection preparation manufacturer regarding dosage, concentration, temperature, compatibility of materials and time should be followed. Put the implants 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. It should be noted that the components of the automatic cleaning process were phases in accordance with ISO 15883.		
Cleaning: manual	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. <ol style="list-style-type: none"> 1. Rinse contaminations from implants. 2. Use plastic brush /no wire brushes or scrubs may be used/, clean in a manner preventing any disfigurement, damages and scratches of the surface, which damage the passivated coating of the implant. Apply solution of the cleaning agent /e.g. Chirozan/. 3. Rinse with clean running water, last rinsing - with distilled water. 		
Disinfection	Apply disinfecting solution as prescribed on the preparation package /eg. Sekusept, Neodisher/. Disinfection may be carried out together with cleaning and with application of the same preparations /e.g. Chirozan/. 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 implants 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.		
Packaging	Single: standard medical packaging material may be used.		
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 recommended high pressure autoclaving at the temperature of 121°C and overpressure of 0,1013MPa (1 atm.) for min. 20 minutes or sterilization at the temperature of 134°C and overpressure of 0,2026MPa (2 atm) for min. 10 minutes . Implants can be sterilized max. 20 times, observing these rules.		
Storage	Storage time of implants after the sterilisation depends on the type of the package and internal recommendation of the hospital, eg. hospital team dealing with infections, which determines storage conditions, temperature, humidity and permeability of the room. Standard storage conditions are: temperature of 15 – 35°C and relative humidity 25% - 65%. Room, where sterilised implants are stored should be clean, dry, dark, without temperature fluctuations and permeable to air..		
Drying	Dry the implants 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.		
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 REF	Catalogue no.	 Manufacturer	 Used by
 LOT	Serial no.	 Manufactured date	 Nonsterile
	Do not use package if damaged	 Do not reuse	 Caution
	Read the Instruction for use	 CE Mark	0197 Number of notified body
	Storage temperature limitation	 Storage humidity limitation	0044 Number of notified body for products manufactured before 01.10.2015

Instrukcja powstała na podstawie normy PN-EN ISO 17664:2005 pkt.4 w oparciu o wymagania punktu 3.