















**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.

<b>Warnings</b>	Leaflet "Information for implants users" should be used. Surgical implant can be used only for its intended purpose. Implants are intended for <b>single use only</b> .				
<b>Limitations in repeated application</b>	Repeated application confirming with this instruction has insignificant influence on the implants. <b>None of implants can be used repeatedly.</b>				
<b>Instructions</b>					
<b>Place of application</b>	<b>Implants are supplied non sterile.</b>				
<b>Storage and transport</b>	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.				
<b>Preparing for cleaning</b>	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.				
<b>Cleaning automatic</b>	<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, designed for cleaning metal implants /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.				
<b>Cleaning: manual</b>	Detergent - preparations which have been approved for medical application, designed for cleaning metal implants /e.g. Sekusept, Neodisher/, <b>warm running water</b> , 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 implants. 2. Use plastic brush <b>/no wire brushes or scrubs may be used/</b> , 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. Chirosan/. 3. Rinse with clean running water, last rinsing - with distilled water.				
<b>Disinfection</b>	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. 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.				
<b>Drying</b>	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.				
<b>Packaging</b>	Single: standard medical packaging material may be used.				
<b>Sterilization</b>	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 <b>at the temperature of 134°C and overpressure of 0,2026MPa (2 atm) for min. 10 minutes</b> . Implants can be sterilized max. 20 times, observing these rules.				
<b>Storage</b>	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..				
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 <b>BHH MIKROMED Sp. z o.o., ul. Porozumienia Dąbrowskiego 1980 no 11, 42-530 Dąbrowa Górnicza, Poland</b> <b>tel. +48 32 262-52-85, fax. +48 32 264-68-85</b> <a href="http://www.mikromed.pl">www.mikromed.pl</a> , e-mail: <a href="mailto:info@mikromed.pl">info@mikromed.pl</a>					
 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	<b>0197</b>	Number of notified body
	Storage temperature limitation		Storage humidity limitation	<b>0044</b>	Number of notified body for products manufactured before 01.10.2015

Instrukcja powstała na podstawie normy PN-EN ISO 17664:2022 pkt.4 w oparciu o wymagania punktu 3.