BIOVER AG Müliweg 2 · CH-6052 Hergiswil · www.biover.ch
Telefon +41/41/630 00 22 · Fax +41/41/630 00 53 · biover@biover.ch

Instructions for Cleaning and Sterilization of Titanium Microsurgical Instruments

Products:
Microsurgical Instruments Titanium flat handle
MI 8040.1 Titanium flat handle forceps for supermicrosurgery

Products by **Biover AG**, Müliweg 2, 6052 Hergiswil, Switzerland.

WARNING:
The instruments are supplied non-sterile and must be cleaned and sterilized prior to use.

Please note:
Due to the product's design and the materials used, a defined number of reprocessing cycles cannot be given. The number of reprocessing procedures is therefore determined by the function/wear of the device. In case of damage, the device should not be used.
The instrument must be reprocessed before sending back to the manufacturer for repair.

Symbol ISO 15223-1	Symbol Title	Symbol Meaning
	Consult Instructions for use	Consult Instructions for use
	Catalog Number	Catalog Number
	Batch Code	Lot Number
	Manufacturer	Manufacturer
	Non sterile	Medical device that has not been subjected to a sterilization process

Reprocessing Instructions:
Preparation before cleaning: Remove gross soiling immediately after use. Do not use detergent which may influence the result of the reprocessing process.

Transportation: Safe storage and transportation in a closed container to the reprocessing are to avoid any damage and contamination from the environment.

Manual Cleaning:
- Fully immerse all instruments in cold tap water for a minimum of 5 minutes.
- Brush all instruments separately with an appropriate brush. While brushing, mobilize all movable parts of the instruments.
- Treat all parts in an ultrasonic bath for a minimum of 10 minutes. Store instruments in the appropriate instrument racks.
- Rinse all instruments carefully with distilled water. While rinsing, mobilize all movable parts of the instruments.

Disinfection:
Chemical disinfection: Prepare a solution of the disinfectant according to the user instructions of the disinfectant manufacturer. Fully immerse all parts in the solution (for the interaction time, refer to the IFU of the manufacturer of the disinfectant). Only use disinfectants with proven effectiveness.

Drying: Manual drying can be performed using lint free towels and/or sterile compressed air.

Functional Testing, Maintenance: Visual inspection for cleanliness, no damage to the instrument and functional testing according to standard hospital processing instructions. If necessary, perform reprocessing process again until the instruments are visibly clean.

Packaging: Appropriate packaging for sterilization according to ISO 11607, ISO 17664 and EN 868.

Sterilization: Steam sterilization by applying a fractionated pre-vacuum process (according to ISO 13060 / ISO 17665) under consideration of the respective national requirements. Minimum parameters for the pre-vacuum cycle:

- 3 pre-vacuum phases
- Sterilisation temperature 132° C
- Exposure time 3 or 4 minutes
- Drying time 20 minutes

- 3 pre-vacuum phases
- Sterilisation temperature 134° C
- Exposure time 3 or 5 minutes
- Drying time 20 minutes

- 3 pre-vacuum phases
- Sterilisation temperature 135° C
- Exposure time 3 minutes
- Drying time 20 minutes

Storage: After sterilisation, reusable instruments must be kept in the sterile packaging in a dry and dust-free place at room temperature. Each clinical facility must set a maximum retention period for sterilized reusable instruments.

Reprocessing and Validation Information for the Cleaning and Sterilization Process
The following test devices, materials and machines have been used by SMP GmbH to validate the cleaning and sterilization processes:
- Detergent: Cidezyme (ASP)
- Ultrasonic bath: Elmasonic S 300 H; (Elma Hans Schmidbauer GmbH & Co. KG)
- Sterilizer: Selectomat HP 666-1HR, (Münchner Medizin Mechanik GmbH)

Details regarding cleaning, sterilization and drying can be found in the **Biover SMP Report Nos. 26714 and 26814**.

Accreditation of SMP GmbH according to DIN EN ISO/IEC17025 and the Council Directives 93/42/EWG and 90/385/EWG documented in certificate number D-PL-17769-01-01.

User Validation Process: It is recommended that each facility establish the efficacy of its cleaning and sterilization equipment and procedures.
It is the duty of the user to ensure that the correct methods and validation including resources, materials and personnel are deployed. Only then can the desired results be achieved. "State-of-the-art technology " and often national law require that these procedures and resources are validated and well-maintained.

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