Manufacturer
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EN INSTRUCTION FOR USE

Microvascular Clamps

This instruction for use is valid for following range of products:

REF Microvascular clamps Art. No: 5010-10 to 5915.
UMDNS-Code 15882

Warning

All instruments have been designed for surgical use only and may not be used for other purpose. Incorrect handling and care as well as misuse can result in premature wear of the instruments.
You are responsible for the sterility of the instruments. Therefore, please ensure that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (disinfector, sterilizer) were maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Additionally, please pay attention to the legal provisions valid for your country as well as to hygienic instructions of the doctor´s practice or of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions.

Important note

Carefully read these instructions before using Insto-Günter Stoffel Medizinprodukte GmbH. Keep them in a safe place for future reference and make them easily available.
The life cycle of the reusable product is not limited by the number of processing cycles, or by a time period. It is dependent on the number of applications, the type of use and the associated wear.

Defective products must go through the entire reprocessing process before being returned for repair.

Intended use

The surgery instruments have been designed for the application in the microsurgery. The products are provided for the temporary surgical invasive use.

Indication

Clamps are used to disconnect arteries or tissue. In addition, clamps are used to grasp or hold tissue safely.

Contraindication

The instruments may be used for its intended use by properly trained and qualified personnel (surgeons) only. The products should not be applied on the central nervous system or cardiovascular system.

The products are fine mechanical products. Please do not proceed violently. Negative adverse effects won't occur with proper handling.

NON STERILE **Implementing**

All instruments are to be cleaned, disinfected, and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile instruments (cleaning und disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments (see references and instructions for reprocessing).

Application instruction

The products may be used by trained personnel only. The products are fine mechanical products. Please do not proceed violently.

Place of use

Insert products in cold water (drinking water quality) immediately after each use (>40°C). Do not use cleaning agents or hot water (>40°C) as this may result in the fixation of residues and could reduce the cleaning success (risk of protein coagulation (denaturation)).
Remove surface contamination with single-use towel/paper towel.

Transport

Be aware of safe storage in a closed container and transport of instruments to the place of treatment to avoid damage of the instruments and contamination to the environment.

Preparation for decontamination

If possible, products have to be deconstructed respectively introduced in open state to further processing steps.

Pre-cleaning

The Vascular clamps were brushed under cold tap water and then put in an ultrasonic bath filled with water and cleaning detergent at 40°C. The Vascular clamps were treated with ultrasound for 15 min.

Cleaning

Basics

If possible, an automatic procedure (disinfector) should be used for cleaning und disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automatic procedure is not available; in this case, the significantly lower efficiency of a manual procedure has to be considered[1].

[1] In case of application of a manual cleaning and disinfection procedure a product and procedure specific validation under responsibility of the user is required

The pretreatment step is to be performed in both cases.

Automatic cleaning process

Place the instruments in open state to a sterilization tray on the insertion car and start the cleaning process.

Automatic cleaning process (Program No. 105; Washer - Disinfector G 7735 CD Miele):

1. 1 minute Pre-cleaning under cold tap water <40°C
2. Drain
3. 3 minutes Pre-cleaning under cold tap water <40°C
4. Drain
5. 5 minutes cleaning at 55°C under tap water with 0,5% alkaline detergent (Neodisher FA, Dr. Weigert)
6. Drain
7. 3 minutes Neutralization under cold tap water <40°C
8. Drain
9. 2 minutes Rinsing under cold tap water <40°C

Special manufacturer´s instructions of the cleaning machine have to be considered.

Disinfection

Pay attention to following points during selection of the disinfector:

- fundamentally approved efficiency of the disinfector (for example DGHM or FDA approval or CE marking)
- possibility for an approved program for thermal disinfection (at least 10 min at 93° C)(in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0,25 endotoxin units/ml), for example Aqua purificata
- only use of filtered air for drying
- regularly maintenance and check/calibration of the disinfector

The fundamental suitability of the instruments for an effective automatical cleaning and disinfection was demonstrated by an independent accredited test laboratory by application of the disinfector G 7736, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the cleaning detergent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg) considering the specified procedure.

Drying

Automatically drying in accordance to automatically drying process of the cleaning and disinfection 30 min at 60°C±5°C. If necessary, subsequent manual drying with lint free cloth und blowing out of lumen by sterile, oil free compressed air.

Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applicated.

Steam sterilization

- fractionated vacuum procedure[2] (with sufficient product drying)
- steam sterilizer according E EN 13060 bzw. EN 285
- validated according to EN ISO/ANSI AAMI ISO 17665
- maximum sterilization temperature 138 °C (280 °F; plus tolerance according to EN 554/ANSI AAMI ISO 1134)
- Sterilization time (exposure time at the sterilization time) at least 20 min (at 121 °C (250 °F)) or 5 min at 134 °C (273 °F)

[2] In case of application of the less effective gravity procedure a product, sterilizer, and procedure specific validation under responsibility of the user is required and possibly loger sterilization times.

The fundamental suitability of the instruments for an effective steam sterilization was demonstrated by an independent accredited test laboratory by application of the steam sterilizer EuroSelectomat (MMM Münchener Medizin Mechanik GmbH, Planegg), fractionated vacuum procedure, as well as of the specified procedure.

The flash sterilization procedure must not be used.

Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylenoxide sterilization, as well as plasma sterilization.

Check and functional test

It is important to examine the instruments before each use of damage and wear, especially of breaks, cracks, distortion or malfunction, screws have to be tightened. Especially important areas like cutting parts, grasping parts, closing parts, locking parts, latching parts, pins and all movable parts have to be examined carefully. If the instrument has been dismantled, a proper function must be ensured and screws have to be tightened after assembly.

Maintenance

Check all instruments after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, and impurities as well as on functionality. Do not further use damaged instruments (limitation of the re-use see chapter “reusability”). Still dirty instruments are to be cleaned and disinfected again.

Possibly required repairs may be performed by the manufacturer only. For the protection of our staff, only cleaned and sterilized instruments will be adopted. If repairs to insto- instruments will be performed by third parties, any kind of warranty claim expires.

Packing

We recommend the use of the intended sterilization trays und containers, but you can use single-use sterilization packaging’s (single or double packaging) and/or other sterilization containers as well, if the following requirements are fulfilled:

- according DIN EN ISO/ANSI AAMI ISO 11607 and DIN EN 868
- suitable for steam sterilization (temperature resistance up to least 141 °C (286 °F). sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packaging’s to mechanical damage
- regular maintenance according to the instructions of the manufacturer (sterilization container)

Storage

Please store the instruments after sterilization at a dry place. The instruments are to be stored horizontally in the closed package. Do not put any objects on the instruments or their packaging and do not store the instruments close by aggressive media.
Die Instrumente werden liegend in der geschlossenen Verpackung gelagert. Stellen Sie keine Gegenstände auf die Instrumente oder deren Verpackung und lagern Sie die Instrumente nicht in der Nähe von aggressiven Medien.

Handling

All instruments must be handled with great care during transport, cleaning, care and storage. Especially for cutting parts, grasping parts and other sensitive areas.

Special note

For the protection of our staff, only cleaned and sterilized instruments will be adopted. If repairs to insto- instruments will be performed by third parties, any kind of warranty claim expires.

Material resistance

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:

- strong acids (< pH 4) and alkalines (> pH 9)
- halogenated hydrocarbons
- organic solvents
- strong oxidizing agents/peroxides

Please do not clean any instruments, sterilization trays, and sterilization containers by use of metal brushes or steel wool.

Please do not expose any instruments, sterilization trays, and sterilization containers to temperatures higher than 141 °C (286 °F)!

Reusability

The instruments can be reused – in case of adequate care and if they are undamaged and clean as well as if they possess sufficient functionality -; the user is responsible for the use of damaged and dirty instruments (no liability in case of disregard).

Additional information

It is the obligation of the user to ensure that the reprocessing process, including resources, materials and personnel, is suitable to achieve the required results. The state of the art and national laws require the heed of validated processes.

Symbols for Instruction of Use

Symbol	Description	Symobl	Description
	“Manufacturer“		“Batch Code“
	“Caution, consult accompaying documents“		“Catalog Number“
	“Non-Sterile“		“Conformity to the Essential Requirements” – CE mark
	“Please note the Instruction for Use“	N/A	