Manufacturer
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EN INSTRUCTION FOR USE

Biopsy Forceps (rigid/ flexible)

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

REF Art. No: 48015 to 75026
UMDNS-Code 16-268 and 16-269

Attention

All instruments have been designed for surgical use only and may not be used for other purpose. Incorrect handling and maintenance as well as misuse can result in premature abrasive wear of these 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 Medizintechnik GmbH Biopsy Forceps. Keep them in a safe place for future reference and make them easily available for user or appropriate personnel.

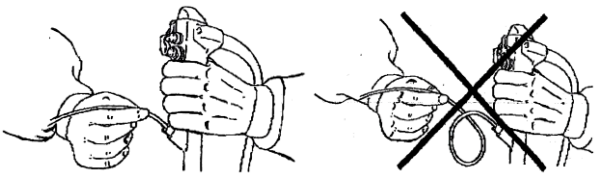
Intended use
A Biopsy Forceps is a medical instrument for the removal of tissue sample. They consists either of a scissor-like handle that closes the jaws which are fixed at the top while squeezing and thus sharply separating the tissue located between these. Or from a ring handle that closes the jaws fixed at the top by pulling the roll and thus sharply separating the tissue located between these.

Indication
A Biopsy Forceps is a medical instrument for the removal of tissue samples, for histological and pathological inspection in the field of surgery.

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 precision engineered 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).

The Biopsy Forceps has to be insert closed, slowly, carefully and without any use of force to the working channel and may not be cracked.



When opening the instrument, it is essential to make sure that at the handle the movement to open the mouth part is done only until the jaw part is completely open.
The attempt to open on the jaw part with increased effort can cause that the flexible inner tension of the Biopsy Forceps tear.

After using the endoscope, the instrument should be taken out immediately.

The winding diameter of the Biopsy Forceps may not be less than 20 cm.

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 Biopsy Forceps must be brushed with a soft brush until all dirt is removed under cold tap water and then put in an ultrasonic bath filled with water and cleaning detergent at 40°C. The Biopsy Forceps was treated with ultrasound for 15 min.

Cleaning
Basics
If possible, an automatical 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 automatical 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 ± 5°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 are not applicable.
Steam sterilization
- fractionated vacuum procedure[2] (with sufficient product drying)
- steam sterilizer according 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
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.
Be careful especially that the spiral has no irregularities and the jaw parts are accurate.
Check the function by placing the forceps in a 25 cm loop and gently press the coil of the handle: the jaw part must easily and smoothly open and close.

Maintenance
If possible do use instrument oil. In case of application use only instrument oils (white oil) admitted to steam sterilization considering the maximum possible sterilization temperature and with approved biocompatibility.
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.

Packaging
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.

Handling
All instruments must be handled with great care during transport, cleaning, maintenance and storage, especially 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 none use of damaged and dirty instruments (no liability in case of disregard).

Additional information
It is the responsibility 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
	“Manufacturer“
	“Caution, consult accompaying documents“
	“Non-Sterile“
	“Please note the Instruction for Use“
	“Batch Code“
	“Catalog number“
	“Conformity to the essential Requirements“ – CE mark