MANGESHIKAR
Uterine Manipulator

ENGLISH

Uterine Manipulator

INSTRUCTIONS FOR USE

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Uterine Manipulator

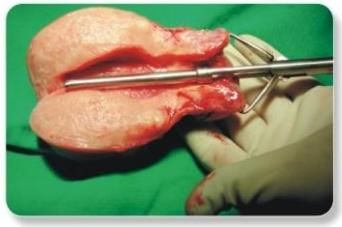
⚠ ***Please read all information contained in this insert.***
Incorrect handling and care as well as misuse can lead to premature wear of surgical instruments.

Intended Use
The Mangeshikar Uterus Manipulator by Bissinger was developed for the mobilisation and representation of the uterus in case of a complete laparoscopic hysterectomy, as well as for the protection of bladder, ureter, and rectum during the electrosurgical section of the uterus.

Contraindications
1. The uterine manipulator should not be used or only with special caution if one or more of the following points apply: Pregnancy: The use of a uterine manipulator is contraindicated in pregnant women as it can increase the risk of miscarriage or fetal damage.
2. Acute infections: In cases of acute pelvic or uterine infections, such as Pelvic Inflammatory Disease (PID), a uterine manipulator should not be used to avoid worsening the infection or spreading the pathogens.
3. Severe cervicitis: In cases of severe inflammation of the cervix, the use of a manipulator can exacerbate the inflammation or cause complications.
4. Malignancies of the cervix or uterus: Caution is advised in the presence of malignant tumors in the cervix or uterus, as manipulation could increase the risk of tumor cell spread.
5. Previous surgeries or injuries: Patients with a history of extensive pelvic surgeries or injuries may have an increased risk of complications due to scar tissue or anatomical changes that could make the safe placement of the manipulator difficult.
6. Suspected presence of any of the following diseases:
   - CJD - Creutzfeldt-Jakob Disease
   - vCJD - Variant Creutzfeldt-Jakob Disease
   - BSE - Bovine Spongiform Encephalopathy
   - TSE - Transmissible Spongiform Encephalopathy

Based on the patient's overall condition, the responsible physician must decide if the planned procedure can be performed. If the physician believes that the risks of the procedure outweigh the benefits for the patient, do not use the instrument.

Description
The instrument consists of a rotationally symmetrical handle which enables guiding of the instrument and the opening and closing of the integrated cervix claw forceps (tenaculum).



For representation and preparation purposes, the uterus may be moved to any position desired with your hands.
A sleeve with ceramic ring is slipped over the instrument shank in forward direction and thus allows the delineation of the vagina (vaginal delineating tube) and the protection of bladder, ureter and rectum. Depending on the uterus size, sleeves with different diameters are used.

Use and safety instructions
Non-observance of these use and safety instructions may lead to injuries, malfunctions or other unexpected incidents.
- Before initial use and any further use, all instruments must be completely cleaned, disinfected and sterilised and their function must be checked.
- It is very important to check every surgical instrument for visible damage and wear, such as cracks, breaks or insulation defects before each use. In particular areas such as blades, tips, notches, locking and blocking devices, as well as all movable parts, insulations and ceramic elements must be checked carefully.
- Never use any damaged instruments.

Assembly and Operation
For assembly and disassembly of the instrument follow the pictogram, which is available upon request, or can be downloaded on www.bissinger.com.
When assembled correctly, the instrument can be held in both the right and left hand.
Opening of the claw forceps: Press the back part of the handle to extend it and turn it clockwise.
Closing of the claw forceps: Turn anticlockwise and press the back part of the handle once again to retract it.

Preparation (Cleaning, Disinfection and Sterilization) of Products

General Principles
All products must be cleaned, disinfected and sterilized before each use; this particularly applies to the first use after delivery, as all products are delivered unsterilized (cleaning and disinfection after removing the transport protection packaging; sterilization after packaging). A thorough cleaning and disinfection is an indispensable requirement for effective sterilization.

Please note as part of your responsibility for the sterility of the products during use that
- generally, only suitable equipment and product-specific validated procedures are to be used for cleaning/disinfection and sterilization,
- the equipment used (WD, sterilizer, etc.) are to be regularly maintained and inspected, and
- the validated parameters are to be observed for each cycle.

Please ensure during use that contaminated instruments are collected separately and not placed back into the instrument tray in order to avoid further contamination of the loaded instrument tray. Clean/disinfect the contaminated instruments, then resort them back into the instrument tray and then sterilize the fully loaded instrument tray.

Please also adhere to the legal requirements applicable in your country as well as the hygienic requirements of the medical practice or hospital. This particularly applies to the various requirements (e.g. in Germany according to attachment 7 of KRINKO RKI BfArM recommendation for processing) regarding to an effective prion inactivation (not applicable for the USA).

Remark:
Application of the products is only admitted to qualified professionals.

Processing must performed only by qualified staff in the central sterilization service department of the hospital or in the processing room of the medical practice. Hospital or medical practice are responsible for selection and application of required of protective equipment and hygienic measures.

Cleaning and Disinfection
Principles
For cleaning and disinfection, if possible an automated procedure [WD (washer-disinfector)] should be used. A manual procedure – even using an ultrasound bath – should only be used according to country specific requirements (e.g. in Germany for critical B products automated procedure binding) and if an automated procedure is not available due to the significantly lower effectiveness and reproducibility.
Pretreatment must be carried out in both cases.

Pretreatment
Immediately after use (within maximum 2 h), large impurities must be removed from the products. If observation of this time is not possible in consequence of duration of application or of organizational reasons, it is the responsibility of the user to define and validate measures in order to avoid complete drying of contamination.

Procedure
1. Disassemble the products as possible.
2. Rinse the products for at least 1 min under running water (temperature < 35 °C/95 °F). Shift the movable parts back and forth at least three times during the prewash. If applicable: Rinse all lumina of the products at least three times (aids and minimum volume depend on the cavity to be rinsed).
3. Insert the disassembled products for the predefined soaking time in the pre-cleaning bath[1] (in an ultrasound bath that is not already activated), so that the products are completely submerged. Ensure that the products do not touch. Support the pre-cleaning by completely brushing all internal and external surfaces (at the beginning of the soaking time). The diameter of the brushes to be used for the channel is required to be slightly larger as the inner diameter of the corresponding channel. The length of shaft of the brush must not be shorter as the length of the channel. Shift the movable parts back and forth at least three times during the pre-cleaning. If applicable: Rinse all lumina of the products at least three times at the beginning and end of the soaking time (aids and minimum volume depending on the cavity to be rinsed).
4. Activate the ultrasound for an additional minimum soaking time (but not less than 5 min).
5. Then remove the products from the pre-cleaning bath and rinse them at least three times thoroughly (for at least 1 minute) with water. Shift the movable parts back and forth at least three times when rinsing. If applicable: Rinse all lumina of the products at least three times (aids and minimum volume depend on the cavity to be rinsed).

When selecting the cleaning agent[1], ensure that
- it is generally suitable for cleaning invasive medical devices made of metals and plastics,
- the cleaning agent is suitable for ultrasound cleaning (no foam formation),
- the cleaning agent is compatible with the products (see "Material Stability" section).

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning agent or the cleaning/disinfecting agent as well as the specifications for rinsing, must be adhered to. Only use freshly prepared solutions, sterile or low-germ (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water)[2] or only with a soft, clean, lint-free cloth (Attention: caution in case of products with rough surfaces, threads, sharp edges or comparable aspects with danger of attachment of particles from the cloth!) and/or filtered air to dry.

Automated Cleaning/Disinfecting [WD (Cleaning and Disinfection Device)]
When selecting the WD, ensure that
- the WD generally has verified effectiveness (e.g. DGHM or FDA approval/clearance/registration or CE marking in accordance with DIN EN ISO 15883),
- if possible, a tested program for thermal disinfection (A_0 value ≥ 3000 or – for older devices – at least 5 min at 90 °C/194 °F) is used (in chemical disinfection danger of disinfecting agent residues on the products),
- the program used is suitable for the products and contains sufficient rinsing steps (at least three degrading steps after cleaning (respectively neutralization, if applied) or conductance based rinsing control recommended in order to prevent effectively remnants of the detergents),
- for rinsing only sterile (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used,
- air used for drying is filtered (oil-free, low-bacteria and low-particle) and
- the WD is regularly maintained, inspected, and calibrated.

When selecting the cleaning system, ensure that
- it is generally suitable for cleaning medical instruments made of metals and plastics,
- providing no thermal disinfection is used – a suitable disinfecting agent with verified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is also used and that it is compatible with the cleaning agent used, and
- the chemicals used are compatible with the products (see "Material Stability" section).

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning agent and, if applicable, the disinfecting agent as well as specifications for rinsing must be adhered to.

Procedure
1. Disassemble the products as much as possible.
2. Place the disassembled products into the WD. Ensure that the products do not touch. If applicable: Enable active rinsing by connecting to the WD rinse port.
3. Start the program.
4. Disconnect the WD (at the appropriate time) and remove the products after the program has completed.
5. Inspect and pack the products as soon as possible after removal (see "Inspection," "Maintenance" and "Packaging" chapters, possibly after additional drying in a clean area).

The verification of products' general suitability for effective automated cleaning and disinfecting was provided by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory using the G 7836 CD washer-disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the Neodisher MediClean forte pre-cleaning and cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg). Here, the procedure described above was taken into consideration.

Manual cleaning and disinfection
When selecting the cleaning and disinfecting agent, ensure that
- it is generally suitable for cleaning and disinfecting medical instruments made of metals and plastics,
- the cleaning agent is suitable for ultrasound cleaning (no foam formation),
- a disinfecting agent with verified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is used and that this is compatible with the cleaning agent used, and
- the chemicals used are compatible with the products (see "Material resistance" chapter).

Combined cleaning/disinfecting agents should not be used if possible. Combined cleaning/disinfecting agents can be used only in cases of very low contamination (no visible impurities).

In case of manual cleaning and disinfection with a potential risk of injury and infection observation of measures of employment protection (e.g. protective clothing, protective glasses, gloves, air filtration) according to national requirements (e.g. in Germany TRBA 250) is required.

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning and disinfecting agent as well as specifications for rinsing, must be adhered to. Only use freshly prepared solutions, sterile or low-germ (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water)[3] or only with a soft, clean, lint-free cloth (Attention: caution in case of products with rough surfaces, threads, sharp edges or comparable aspects with danger of attachment of particles from the cloth!) and/or filtered air to dry.

Procedure
Cleaning
1. Disassemble the products as much as possible.
2. Place the disassemble products for the predefined soaking time in the cleaning bath (in an ultrasound bath that is not already activated), so that the products are completely submerged. Ensure that the products do not touch. Support the cleaning by completely brushing all internal and external surfaces with a soft brush. (Attention: Caution with products with narrow gaps, in which bristles of the brush can get stuck!) The diameter of the brushes to be used for the channel is required to be slightly larger as the inner diameter of the corresponding channel. The length of shaft of the brush must not be shorter as the length of the channel. Shift the movable parts back and forth several times during cleaning.
   If applicable: Rinse all lumina of the products at least five times at the beginning and end of the soaking time (aids and minimum volume depending on the cavity to be rinsed).
3. Activate the ultrasound for an additional minimum exposure time (but not less than 5 min).
4. Then remove the products from the pre-cleaning bath and rinse them at least three times thoroughly (for at least 1 minute) with water. Shift the movable parts back and forth several times when rinsing.
   If applicable: Rinse all lumina of the products at least five times (aids and minimum volume depend on the cavity to be rinsed).
5. Inspect the products (see "Inspection" and "Maintenance" chapters).

Disinfection
6. Place the disassembled and inspected products in the disinfection bath for the predefined soaking time so that the products are completely submerged. Ensure that the products do not touch. Shift the movable parts back and forth several times during the disinfection. If applicable: Rinse all lumina of the products at least five times at the beginning and end of the exposure time (aids and minimum volume depending on the cavity to be rinsed).
7. Then remove the products from the disinfection bath and rinse them at least five times thoroughly (for at least 1 minute) with water. Shift the moving parts back and forth several times during the rinse.
   If applicable: Rinse all lumina of the products at least five times (aids and minimum volume depend on the cavity to be rinsed).
8. Dry the products with filtered compressed air.
9. Pack the products as soon as possible after removal (see "Packaging" section, possibly after additional drying in a clean area).

The proof of the general suitability of the products for effective manual cleaning and disinfecting was provided by an independent, governmentally accredited and respected (§ 15 (5) German Law for Medical Devices) test laboratory using the Cidezyme/Enzol pre-cleaning and cleaning agent and the Cidex OPA disinfecting agent (Johnson & Johnson GmbH, Norderstedt). Here, the procedure described above was taken into consideration.

Inspections
Check all products after cleaning or cleaning/disinfecting for corrosion, damaged surfaces, chippings, contaminants and stains as well as remove damaged products (numerical restriction of reuse, see "Reusability" section). Any products that are still contaminated must be cleaned again and disinfected.

Maintenance
Reassemble disassembled products.
Instrument oiled or grease may not be used.
Exception: In the case of oiling joints, ensure that only instrument oils (white oil, without further additives) are used, which – taking into account the maximum applied sterilization temperature – are approved for steam sterilization and have a certified biocompatibility and that only a small amount is applied to the joints.

Packaging
Sort the cleaned and disinfected products into the corresponding sterilization tray.

Please pack the products or the sterilization trays in sterilization containers or very large products in single-use sterilization packaging (single or double packaging) in accordance with the following requirements (material/process):
- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature stability up to at least 138 °C (280 °F) sufficient steam permeability)
- sufficient to protect the products or sterilization packaging from mechanical damage
- undergo regular maintenance according to the manufacturer's specifications (sterilization containers)

do not exceed a maximum weight of 10 kg per package/contents of the sterilization container.

Sterilization
For sterilization, only the following sterilization methods may be used; other sterilization methods are not allowed.

Steam sterilization
- Fractionated vacuum procedure[4,5] (with sufficient product drying[6])
- Steam sterilizer in accordance with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- Validated in accordance with DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance in accordance with DIN EN ISO 17665)
- Sterilization time (exposure time at sterilization temperature):

Country	Fractionated vacuum procedure
Germany	at least 5 min[7] at 134 °C (273 °F)
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min[4]
France	at least 5 min at 134 °C (273 °F) if required for prion inactivation sterilization time 18 min
other countries	at least 5 min[7] at 132 °C (270 °F) / 134 °C (273 °F)
	Gravity displacement
Germany	not recommended[5]
USA	not recommended[5]
France	not recommended[5]
other countries	not recommended[5]

Verification of the general suitability of the products for effective steam sterilization was provided by an independent, governmentally accredited and respected (§ 15 (5) MPG) test laboratory using the HST 6x6x6 steam sterilizer (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum procedure, as well as the instrument oil LAWTON MEDOIL. Here, the typical conditions in the clinic and medical practice and the procedure described above were taken into consideration.

The flash sterilization procedure is generally not permitted.

Do not use dry head sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.

Storage
After sterilization, the products must be stored dry and free of dust in the sterilization packaging.

Material Stability
When selecting the cleaning and disinfection agents, please ensure that they do not contain the following components:
- Organic, mineral and oxidizing acids (minimum permitted pH value 5.5)
- Alkalis/strong alkalis (neutral/enzymatic (max. permitted pH 8.5, mandatory requirement for products made of aluminum or other alkali-sensitive materials, see “Special Instructions” section) or alkaline cleaner (max. permitted pH 11, mandatory requirement for products with intended application in prion-critical areas, e.g. in accordance with Annex 7 of KRINKO RKI BfArM recommendation for treatment) recommended)
- Organic solvents (e.g. alcohols, ethers, ketones, benzines)
- Oxidizing agents (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

Never clean products, sterilization trays or sterilization containers with metal brushes or steel wool.

All products, sterilization trays and sterilization containers can only be exposed to temperatures under 138 °C (280 °F).

Reusability
With proper care, the products can be reused if they are undamaged and uncontaminated. Each additional use or using damaged and/or contaminated products is the user’s responsibility.

If disregarded, any liability is excluded.

For details, see report.
Evaluation 193861-45

[1] If you – e.g. for occupational safety reasons – use a cleaning and disinfecting agent for this, please ensure that this is aldehyde-free (otherwise it would fixate blood contaminants) and has verified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), is suitable for disinfecting the products and is compatible with the products (see “Material Stability” section). Please keep in mind that the disinfecting agent used in pretreatment serves only for personal protection and cannot replace the disinfection step to be carried out later after cleaning.
[2] In case of consideration of a lower water quality as sufficient based on the background of national recommendations (e.g. in Germany KRINKO RKI BfArM recommendation for processing).
[3] In case of consideration of a lower water quality as sufficient based on the background of national recommendations (e.g. in Germany KRINKO RKI BfArM recommendation for processing).
[4] at least three vacuum steps
[5] The use of the less effective gravity displacement is only permitted if the fractionated vacuum procedure is not available. It requires significantly longer sterilization times and must be validated by the user for each specific product, device, procedure and parameter.
[6] The actual required drying time depends directly on the parameters, which are the sole responsibility of the user (loading configuration and density, sterilizer status) and must, therefore, be determined by the user. Nonetheless, drying time should not be under 20 min.
[7] or 18 min (prion inactivation, not relevant for the USA)

Repairs
Never attempt to perform repairs yourself. Service and repair work must only be performed by persons trained and qualified accordingly. If you have any question regarding these matters, contact either the manufacturer or your medico-technical department.
⚠ *Defective products must complete the entire reprocessing process before being returned for repair.*

Disposal
Disposal must be carried out in accordance with the respective applicable local and national laws and regulations.

Warranty
Günter Bissinger Medizintechnik GmbH exclusively supplies tested and faultless products to its customers. All products are designed and manufactured to comply with maximum quality requirements. We refuse any liability for products which have been modified as compared to the original product, misused or handled or used improperly.

Explanation of symbols

LOT Batch code

NON STERILE Unsterile

REF Reference number

Attention

Refer to instructions for use

CE 0297 CE-Mark and registration number of the Notified Body
DQS Medizinprodukte GmbH
August-Schanz-Straße 21
60433 Frankfurt, Germany

Manufacturer
Production date

℞ ONLY Attention:According to US-laws, this device must only be sold by a doctor or on the instruction of a doctor.