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Instructions for use

Handle for manual liposuction

Explanation of the safety symbols employed

Important information is accompanied by visual symbols in these instructions for use. These references are prerequisites for preventing hazards to patients and operating personnel, as well as for avoiding damage to or malfunctioning of the device. The instructions for use must be kept for the service life of the device.

Caution	LOT	Batch code	Keep dry	Refer to instruction manual/booklet	
Information	REF	Catalogue number	Rx ONLY	Attention: Under US Federal law, this device may be only sold to a physician or ordered by a physician.	
Manufacturer					

For further information about symbols used please refer to our homepage: www.moeller-medical.com/glossary-symbols.

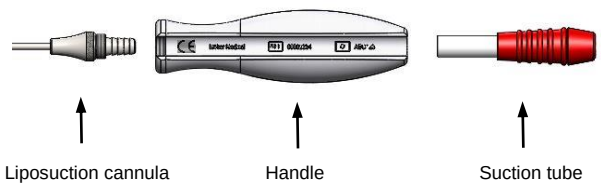
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and he competent authority of the Member State in which the user and/or the donor is established.

Intended use

The handpiece for manual liposuction is used for an ergonomic handling of the Vibrasat® liposuction cannulas.

The handle is not sterile upon delivery and must be cleaned and sterilised before each use in accordance with the reprocessing instructions.

Application



1. Screw the suction cannula into the thread of the handle.
2. Push the suction tube onto the connecting piece of the suction cannula.

This device may only be used by a doctor who is familiar with the indications, contraindications, limitations, typical findings and possible side effects of the device.

Reprocessing

General fundamentals and references

Clean, disinfect and sterilize the handle before use. The handle is delivered non-sterile. (Cleaning and disinfection after removal of transport packaging, sterilization after packaging). Effective cleaning and disinfection has to be regarded as crucial for a valid sterilization.

Referring to your responsibility regarding sterility of the handle in use ensure:

- Only validated and adequate procedures for cleaning/disinfection and sterilization of devices and products are to be used.
- Employed devices (RDG, sterilizer) have to be maintained and checked regularly.
- Validated parameters must be met each cycle.

Strictly keep to instructed concentration, temperature, operating times and guidelines for rinsing regarding cleaning and disinfection media. Freshly made solutions, only sterile or low-germ water (max. 10 germ/ml) as well as endotoxin (max. 0, 25 endotoxin-units/ml) water (e.g. purified water/highly purified water) have to be used. For drying soft, clean and lint-free tissue (cloths) or filtered air has to be used. Furthermore consider your country's legal regulations as well as hygienic rules for private clinics or hospitals. Especially this counts for different rules regarding an effective inactivation of prions (not applicable for the US).

Cleaning and Disinfection

Basics

For an optimal cleaning and disinfection result an automatic process (RDG (cleaning and disinfection device)) has to be in charge. A manual procedure – even though ultrasound treatment is applied - should only be an exceptional case because effectiveness and reproducibility is clearly lower.

Pretreatment is mandatory in both cases.

Because of danger of splashing it has to be taken care that pretreatment is not made under running water.

Pretreatment

Remove rough contamination from the handle immediately after indication (within max. 2 hours).

- Remove the liposuction cannulae or any other accessories from the handle (see specific instructions).
- Rinse the handle for at least 1 minute in waterbath (temperature < 35°C/95°F)

- Place the handle in the precleaning bath for the specified exposure time and ensure that it is sufficiently covered. Ensure that the handle does not touch any other devices that may also be in the bath.
- Support the cleaning process by moving the handle while submerged as well as brushing all inner and outer surfaces (from the start of the exposure time).
- Then activate the ultrasound (at least 5 minutes).
- Then take the handle out of the preclearance bath und rinse them at least 3 times properly (min. 1 minute) inside the waterbath.

When choosing the detergent[1] please check that:

- It is generally suitable for the cleaning of devices made from metal and plastic.
- The detergent is compatible with the ultrasound cleaning (no foaming).
- The detergent is compatible with the devices (see chapter “material resistance”).

Machine Cleaning/Disinfection (RDG (Cleaning and Disinfection Device))

When choosing the RDG’s Cleaning and Disinfection Devices please check that:

- RDG provides a proven effectiveness (for example DGHM- or FDA approval/Clearance/registration or CE sign acc. To DIN EN ISO 15883).
- Preferably a proven program for thermal disinfection (A_0-value > 3000 or – if devices are older - min. 5 min at 90°C/194°F) is in use (with chemical disinfection there is the risk of disinfection-agents residuals on the handle).
- The program is compatible with the handle and that is provides sufficient rinsing-cycles.
- Only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0, 25 endotoxin units/ml) water (for example purified water/highly purified water) will be used.
- filtered air (oil-free, low-germ- and low-particle) will be used for drying and
- RDG will be maintained and checked regularly.

When choosing the detergent-system please check that:

- It is generally suitable for the cleaning of devices made from metal and plastic,
- There is an additional suitable disinfection-agent with proven effectiveness in use (for example VAH/DGHM- or FDA/EPA registration/clearance resp. CE sign) when there is no thermal disinfection applied. Suitable disinfection-agent has to be compatible with the detergents and
- That applied chemicals are compatible with the handle (see chapter “material resistance”).

Procedure

- Remove the liposuction cannulae or any other accessories from the handle (see specific instructions).

[1] If you – e.g. because of industrial safety reasons – use detergents and disinfectants media please note that they are free from aldehyde (otherwise fixation of blood contamination), come with proven efficiency (for example VAH/DGHM- or FDA/EPA registration/clearance resp. CE sign), suitable for disinfection and compatible with the devices (see chapter “material resistance”). Please note that the disinfectants in use during preclearance serve personal security; it does not replace disinfections to be done later on after cleansing took place.

- Place the handle in the washer-disinfector with the opening pointing downwards. Ensure that the handle does not touch any other devices that may also be in the bath.
- Start the program.
- Remove the handle from RDG after program end.
- Check and pack the handle as soon as possible after removal (see chapter “Check” and “Packing”) after an additional drying session in a clean area as appropriate.

General proof of suitability for effective machine cleaning and disinfection of the handle has been provided by an independent, regulatory accredited and authorized (§15 (5) MPG) testing laboratory using RDG’s G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and pre-cleaning agent and detergent Neodisher MediZym (Dr. Weigert GmbH & Co. KG, Hamburg). The above described procedure was applied.

Manual Cleaning and Disinfection

When choosing the detergents and disinfection-agents please check that:

- They are generally suitable for the cleaning of devices made from metal and plastic.
- The detergent - if applicable - is compatible with the ultrasound cleaning (no foaming).
- There is a suitable disinfection-agent with proven effectiveness in use (for example VAH/DGHM- or FDA/EPA registration/clearance resp. CE sign) and that this disinfection-agent is compatible with the detergents in use.
- That applied chemicals are compatible with the handle (see chapter “material resistance”).

Preferably combined detergents/disinfection-agents should not be used. Only in cases of minor contamination (no soiling visible) combined detergents/disinfection-agents can be used.

Cleaning

- Remove the liposuction cannulae or any other accessories from the handle.
- Place the handle in the cleaning bath for the specified exposure time and ensure that it is sufficiently covered. Ensure that the handle does not touch any other devices that may also be in the bath. Support the cleaning process by moving the handle while submerged as well as brushing all inner and outer surfaces (from the start of the exposure time).
- Then activate the ultrasound (at least 5 minutes).
- Then take the handle out of the preclearance bath und rinse them at least 3 times properly (min. 1 minute) with water.
- Check the handle (see chapter “Check”).

Disinfection

- Place the handle in the disinfection bath for the specified exposure time and ensure that it is sufficiently covered. Ensure that the handle does not touch any other devices that may also be in the bath. Support the disinfection process by moving the handle while submerged.
- Then take the handle out of the disinfection bath und rinse them at least 5 times properly (min. 1 minute) with water.
- Dry the handle by blowing of and out with compressed (filtered) air.

- Pack the handle as soon as possible after removal (see chapter “Packing”) after an additional drying session in a clean area as appropriate.

General proof of suitability for effective manual cleaning and disinfection of the handle has been provided by an independent, regulatory accredited and authorized (§15 (5) MPG) testing laboratory using pre-cleaning agent and detergent Cidezyme/Enzol and disinfection-agent Cidex OPA (Johnson & Johnson GmbH, Norderstedt). The above described procedure was a pplied.

Check

After Cleansing resp. cleansing and disinfection check the handle for corrosion, damaged surfaces, split-offs, contamination and discoloration. Select damaged handles (limitation to re-use see chapter “Re-use”). Handles still contaminated have to undergo cleansing and disinfection again.

Packing

Please pack the handle resp. sterilization trays using only disposable sterilization packaging (single or double packaging) that comply with the following requirements (material/process):

- DIN EN ISO/AAMI ISO 11607 (for the US: FDA Clearance)
- Suitable for steam sterilization (temperature resistant to min. 142°C (288°F) sufficient steam permeability.
- Handles resp. sterilization packaging must have sufficient protection from mechanical damage.

Sterilization

For sterilization only the following sterilization procedures are to be used; other sterilization procedures must not be used.

Steam Sterilization

- Fractional vacuum procedure[2], [3] (with sufficient product drying[4])
- Steam sterilization according to DIN EN 13060/DIN EN 285 resp. ANSI AAMI ST79 (for the US: FDA Clearance)
- Validation according to DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance evaluation (PQ))
- Maximum sterilization temperature 138°C (285°F, plus tolerance according to DIN EN ISO 17665)
- Sterilization time (exposure time with sterilization temperature)

[2] min. three vacuum cycles

[3] The use of the less effective gravitation procedure is only permitted when fractional vacuum procedure is not available and it requires generally far longer sterilization time as well as a product-, device-, procedure- and parameter-specific validation to be made under the solely responsibility of the user

[4] The actual drying time needed is subject to the parameters that lie in the responsibility of the user (loading configuration and –density, sterilizer’s condition) and has therefore to be determined by the user. Nevertheless drying times should not fall below 20 minutes

country	fractional vacuum procedure	gravitation procedure
Europe, other countries	Min. 5 min[5] at 132°C (270°F) / 134°C (273°F)	non-recommended
USA	min. 4 min at 132°C (270°F), drying time min. 20 min	non-recommended

General proof of suitability for effective steam sterilization of the handle has been provided by an independent, regulatory accredited and authorized (§15 (5) MPG) testing laboratory using a steam sterilizer HST 6x6x6 (Zirbus technology GmhB, Bad Grund) and using a fractional vacuum procedure. Typical private clinic's and hospital's conditions were incorporated and the above described procedure was applied.

The "Flash sterilization" is forbidden

Please also do not apply hot-air sterilization, radio-sterilization, formaldehyde sterilization- or EO sterilization, as well as plasma sterilization.

Storage

After sterilization the handle have to be stored in the sterilization package in a dry and dust-free area.

Material resistance

When choosing detergents and disinfection-agents please make sure to refrain from the following ingredients:

- Organic, minerally and oxidizing acids (minimum ph-value allowed 5,5)
- Alkaline solution (maximum ph-value allowed 8,5, neutral/encymatic cleaner recommended)
- Organic solvents (for example alcohol, ether, ketone, benzene)
- Oxidizing agents (for example hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbon

Never clean the handle with a metallic brush or steel wool.

Rinse aid and acid neutralization agents must not be used.

The handle may only be exposed to temperatures below 142°C (288°F)!

Re-use

Frequent reprocessing has little impact to the handle. The end of the product's operational life span is typically determined from attrition and use.

Möller Medical recommends to clean the handle after each usage!

[5] Resp. 18 minutes (prions'-inactivation, not applicable for the US)

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