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Reprocessing of the handgrip Vibrasat® power

General fundamentals and references

Clean, disinfect and sterilize all devices before use. All devices are delivered non-sterile:

- Cleaning and disinfection after removal of transport packaging
- Sterilization after packaging

Referring to your responsibility regarding sterility of devices in use ensure:

- Only validated and adequate procedures for cleaning/disinfection and sterilization of devices and products are to be used
- 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).
Effective cleaning and disinfection are a prerequisite for effective sterilisation.

Pull the handle off the ***Vibrasat® power*** control device and remove the cannula and the tube. The cable remains on the handle during reprocessing. It is not possible to disassemble the handle itself.

Cleaning and disinfection

Basics

- **The handgrip is not suitable for automatic/mechanical cleaning.**
- **Reprocessing have to occur immediately after usage of the handgrip, to prevent any attached clumps from hardening.**
- **With regard to the cleaning, disinfection and drying of critical areas such as slots, bore holes, threads and the anti-kink spring, particular attention is required.**
- **In order to prevent cable breaks, please make sure that the cable of the handgrip is not wounded up too tightly. For thorough cleaning, the anti-king spring surrounding the cable has to be bent in opposite directions.**
- **The handgrip must not be immersed or placed in any liquids.**
- **When rinsing with water, the handgrip should be held at an angle of 45°, so that the cannula connection point faces downwards.**
- **After autoclaving, the device must cool completely to avoid fracture of the materials due to impact loading.**

Preparation for cleaning

Remove any coarse soiling from the instruments directly after use (within 0.5 h at the latest) using a lint-free disposable cloth which has been soaked in disinfectant.

Manual Cleaning

When choosing the detergents[1] and disinfection-agents please check that:

- They are generally suitable for the cleaning of devices made from metal and plastic.
- 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 devices (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.

[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.

Equipment

- Suitable gloves
- Safety goggles
- Apron
- Suitable brushes (metals brushes not to be used under any circumstances
- Lint-free cloths
- Running water, T < 45 °C (113 °F) (drinking water quality, at least)
- Demineralised water
- pH-neutral, enzymatic cleaning agent, e.g. 1% aqueous solution of Cleaner N (manufactured by B. Braun)

Application

1. Using a soft brush and running water, remove all visible impurities from the handgrip.
2. Wipe the entire handgrip using a lint-free, disposable cloth that has been soaked in a cleaning solution.
3. Clean the handgrip using a second (clean) brush. Use a suitable brush to clean slots and holes, ensuring that all places can be reached. To clean the anti-kink spring and the surrounded cable, bend the anti-kink spring completely in one direction (fig. 1) and clean it very carefully with a long bristles brush (fig. 2). Repeat in opposite direction (fig. 3). Repeat the procedures, rinsing in between each time, until the handgrip is completely clean.

fig. 1

fig. 2

fig. 3

4. Rinse the handgrip with running water for a sufficient length of time following cleaning (at least two minutes).
5. Rinse once more using demineralised water.
6. Dry the handgrip using clean, lint-free, disposable cloths

Manual disinfection

Equipment:

- Timer
- Running water, T < 45 °C (113 °F) (drinking water quality, at least)
- Demineralised water
- Aldehyde-free disinfectant that is effective against bacteria, fungi and viruses (Meliseptol® HBV Tissues from B. Braun)

Application

7. Wipe the handgrip completely using Meliseptol® HBV Tissues, and allow the detergent to take effect for at least one minute.
8. Rinse the handgrip with running water for a sufficient length of time (at least two minutes), to ensure that the disinfectant has been completely removed.
9. Rinse once more using demineralised water.

Drying

Use oil-free, filtered compressed air to dry the handgrip. Pay particular attention to critical areas such as slots, bore holes, threads and the anti-kink spring.

General proof of suitability for effective manual cleaning and disinfection of the devices 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 applied.

Maintenance, checking and testing

Visual inspection:

Check the handgrip for cleanliness, corrosion, cracking, deformation, fracture, loss of insulation and signs of wear. The handgrip must not have any macroscopic impurities. Pay particular attention to critical areas such as slots, bore holes, threads and the anti-kink spring. Separate out damaged instruments (for numeric restrictions for reuse, see “Reusability”). Instruments which are still soiled must be cleaned and disinfected again.

Performance check:

Connect the handgrip to the ***Vibrasat®*** ***power*** control device and check that it is functioning correctly.

Packing

Please pack devices 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
- Devices 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.

country	**fractional vacuum procedure** [2,3,4]	**Gravitation procedure**
Europe, other countries	mind. 5 min at 132 °C (270 °F) / 134 °C (273 °F)	non-recommended
USA	USA mind. 4 min at 132 °C (270 °F), Trocknungszeit mind. 20 min	non-recommended

General proof of suitability for effective steam sterilization of the devices 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.

[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.

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 all devices have to be stored in the sterilization package in a dry and dust-free area.
Following sterilisation, the instruments must be stored dry and dust-free in the sterilisation packaging at temperatures of ≥ +10 °C.

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 devices with a metallic brush or steel wool. Rinse aid and acid neutralization agents must not be used. All devices may only be exposed to temperatures below 142 °C (288 °F).

Re-use

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

Additional information

The procedure described above, which is to be performed prior to application, repair or maintenance, has been validated by the medical device manufacturer as suitable for preparing instruments to allow them to be reused as per DIN EN ISO 17664.
The person preparing the product is responsible for ensuring that the preparation measures actually performed, materials and personnel in the preparation facility achieve the desired results. It is recommended to observe the requirements for hygiene when reprocessing medical devices (Recommendations of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) of the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)).

Please note that the suction cannulae are disposable products which must not be reprocessed.

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