en **Reprocessing instruction *Vibrasat® Pro Wand***

Safety symbols used

	Caution		Keep away from sunlight
	Information		Batch code
	Follow instructions for use		Serial number
	Manufacturer		Use by YYYY-MM-DD
	Catalogue number		Do not re-use
	Not suitable for use with MRI		Do not resterilise
	Do not use if package is damaged		Non sterile
	Keep dry		Attention: Under US federal law, this device may be only sold to a physician or ordered by a physician.
	Humidity, limitation		
	Temperature limitation		

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

- The ***Vibrasat®* Pro Wand** must not be lubricated or oiled as lubrication may damage the inner mechanics of the motor.
- The ***Vibrasat®* Pro Wand** may only be reprocessed with cleaning solutions with a neutral pH value.
- To prevent the cable from breaking, make sure that the cable of the ***Vibrasat®* Pro Wand** handle is only wound up loosely. The connecting cable must be sealed using the enclosed cap prior to sterilisation.
- Bodily fluids and tissues must not be allowed to dry on the ***Vibrasat®* Pro Wand,** the **cannula holder** and the **sealing rings** before the instruments are cleaned. To prevent tissue and bodily fluids from drying on, the parts must be cleaned within one hour of use.

General principles and information

Clean, disinfect and sterilise all instruments prior to use. All instruments are not sterile upon delivery. (Cleaning and disinfection after removal of the protective transport packaging; sterilisation after packaging). Effective cleaning and disinfection are a prerequisite for effective sterilisation.

Within the scope of your responsibility, ensure that the instruments are sterile prior to use:

- Only cleaning/disinfection and sterilisation procedures which have been sufficiently validated for the device and product must be employed.
- The devices used (washer and disinfector, autoclave) must be maintained and tested regularly.
- The validated parameters must be observed during each cycle.

When selecting the washer/disinfector, it must be ensured that

- the effectiveness of the washer/disinfector has been tested (e.g. DGHM or FDA approval/clearance/registration or CE marking as per DIN EN ISO 15883),
- as far as possible a tested programme for thermal disinfection (A0 value > 3000 or – for older devices – at least 5 min. at 90°C/194°F) is used (with chemical disinfection there is a risk of disinfection residue on the instruments),
- the programme used is suitable for the instruments and contains sufficient rinsing cycles,
- only sterile or low-germ (max. 10 germs/ml) or low-endotoxin (max. 0.25 endotoxins/ml) water (e.g. purified water/highly purified water) is used for rinsing,
- the air used for drying is filtered (oil-free, low-germ, low-particle),
- the chemicals used are compatible with the instruments (see chapter *“Material resistance*”).

Observe the instructions issued by the manufacturer of the cleaning and disinfection agents in terms of concentration, temperature, exposure time and details on rinsing. Only freshly produced solutions, sterile or low-germ (max. 10 germs/ml) or low-endotoxin (max. 0.25 endotoxins/ml) water (e.g. purified water/highly purified water) may be used. Soft, clean and lint-free cloths or filtered air are to be used for drying.

Also observe the valid legal provisions in your country as well as the hygiene regulations of the doctor’s practice or hospital. This applies in particular to the various specification as regards effective prion inactivation.

Cleaning and disinfection

Basics

To clean and disinfect the ***Vibrasat® Pro***, machine cleaning with a washer/disinfector and manual cleaning are necessary. A solely manual procedure, even using an ultrasound bath, should only be used in exceptional cases as the effectiveness and reproducibility are significantly lower.

This pretreatment step must always be performed.

1. Disassembly of the handle *Vibrasat® Pro Wand*

Remove the cannula holder and any accessories (cannulas, tubes etc.) from the handle. Remove the sealing rings from the cannula holder. Check these *(Figure 1, Item 1 and 2*) for signs of wear. If necessary, the sealing rings must be replaced **before** machine cleaning and disinfection of the cannula holder.

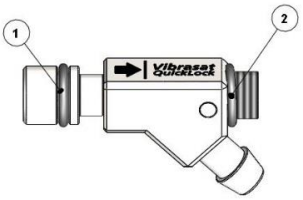


Figure 1

Disposable accessories must be disposed of after use as contaminated. Reusable accessories are designated as such and must be reprocessed separately.

2. Preparation of the cleaning agent

Prepare the cleaning bath with demineralised water as per the manufacturer's instructions. Please note that only neutral cleaning agents with a pH value of max. 8.5 may be used for reprocessing the ***Vibrasat® Pro Wand,*** the cannula holder and the sealing rings.

3. Pretreatment

a. Remove any coarse soiling from the ***Vibrasat® Pro Wand***, the cannula holder and the sealing rings directly after use (within 1 hour at most).
b. Rinse the handle thoroughly for at least 2 minutes under running water (< 40°C / 104°F). ⚠ **Risk of splashing!**
c. Clean the handle thoroughly with warm water (temperature < 40°C / 104°F), enzymatic cleaning agent with neutral pH value and a soft brush. Clean the gaps particularly carefully.
d. Clean the cannula holder and the sealing rings thoroughly from all sides with warm water (< 40°C / 104°F) and a soft brush. ⚠ **Risk of splashing!**

4. Cleaning

Manual precleaning of *Vibrasat® Pro Wand*

Clean the ***Vibrasat® Pro Wand***, the cannula holder and the sealing rings manually as per the following instructions prior to automatic cleaning.

a. Place the ***Vibrasat® Pro Wand*** in the precleaning bath for the stated exposure time, make sure that all the instruments are properly covered. The instruments must not touch each other.

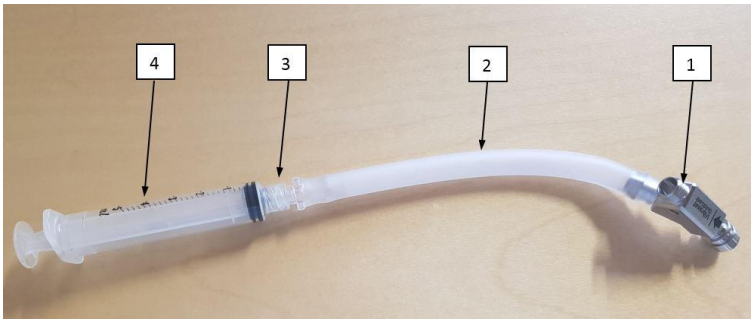
b. Then activate the ultrasound (for the minimum exposure time, but not less than 5 minutes).

c. Remove the handle from the precleaning bath and rinse it through and off at least three times (at least 1 minute).

Make sure that the cleaning agent used is fundamentally suitable for cleaning metal and plastic instruments, that it is suitable for ultrasound cleaning (does not foam) and that the agent is compatible with the instruments (see chapter "*Material resistance*").

Manual precleaning of cannula holder and sealing rings

- Place the cannula holder and sealing rings for 5 minutes in a cleaning bath prepared according to the manufacturer's instructions (temperature < 40°C / 104°F), make sure the parts are completely covered. The instruments must not touch each other.



1 Cannula holder

2 Tube

3 Tube nozzle adapter

4 Syringe body with Luer Lock connection

Figure 2

- Assemble items 1-4 (*Figure 2).*
- Using the syringe, rinse the cleaning solution through the inner bores of the cannula holder. Completely empty the syringe with the maximum possible hand pressure. When doing so, keep the outlet end of the cannula holder in the cleaning bath to avoid splashing the contaminated fluid. Repeat this process 3 times.
- Brush the outside surface for at least 30 seconds immediately after removal. Pay particular attention to the sealing groove, the tube nozzle and the thread. (Möller Medical recommends using the following brush: Interlock order no. 09488)
- Wipe down the outside surface with manual force for 30 s using a lint-free cloth.
- Clean the inside surfaces of the cannula holder using a suitable brush:
  - Material: Polyamide / stainless steel wire
  - Brush diameter 5.2 ±0.2 mm

- Length of area with bristles at least 7.5 cm

- Before use, place each brush in a cleaning bath for 5 minutes and then rinse off under running, demineralised water.
- ⚠ The brushes must be disposed of after each reprocessing!
- Bend the front of the brush by hand so that it can be guided fully through the cannula holder.
- To clean the inside surface, move the cannula holder over the brush area 5 times.
- Rinse through the cannula holder, especially the holes, under running, demineralised water (temperature < 40°C / 104°F) for 30 seconds.
- Wipe the sealing rings using a lint-free cloth.

Automatic cleaning

a. Place the medical devices, the cannula holders and the sealing rings in your washer/disinfector. Prevent the devices from touching each other (movements during washing can cause damage and the effectiveness of washing may be impaired). Examples for placement in the washer/disinfector: Cannula holders and sealing rings:



b. Start the programme.
c. Remove the instruments at the end of the programme.
d. As far as possible, check, assemble and pack the instruments immediately after removal from the washer/disinfector (see chapters "*Checking", "Maintenance" and "Packaging"*, if necessary after additional drying in a clean place).
e. The following cycle in the rinsing/disinfection machine is recommended as a minimum:

Proof of the fundamental suitability of instruments for effective manual cleaning and disinfection was provided by an independent, officially accredited and recognised (Section 15 (5) German Medical Devices Act) testing laboratory using the washer/disinfector G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and precleaning and cleaning agent Neodisher MediZym (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into consideration.

#	Designation	Cleaning agents	Minutes	Temp.
1	Precleaning	Cold water	4	< = 50°C (122°F)
2	Main cleaning	e.g. Neodisher Medizym	10	~ 55°C (131°F)
3	Neutralisation	e.g. Neodisher Z	6	< = 50°C (122°F)

4	Intermediate rinsing	Cold water	3	< = 50°C (122°F)
5	Thermal disinfection	Without	5	90 - 95°C (140°F)
6	Post rinsing	Cold water	5	< = 50°C (122°F)
7	Drying	Without	35	> = 99° C (210°F)

The rinsing/disinfection machine must satisfy the requirements of the standard ISO 15883. It must be properly installed and checked regularly as per ISO 15883.

5. Manual disinfection

Manual disinfection should only be performed if thermal disinfection was not performed in a washer/disinfector beforehand.

- Place the cleaned, assembled and checked instruments in the disinfection bath for the specified exposure time (note the manufacturer's specifications), making sure they are properly covered. The instruments must not touch each other.
- Remove the instruments from the disinfection bath and rinse these through and off with water at least five times (min. 1 minute). Dry the instruments by blowing out and through with filtered compressed air.
- As far as possible, pack the instruments immediately after removal (see chapter "*"Packaging"*, if necessary after additional drying in a clean place).

Proof of the fundamental suitability of instruments for effective manual cleaning and disinfection was provided by an independent, officially accredited and recognised (Section 15 (5) German Medical Devices Act) testing laboratory using the precleaning and cleaning agent Cidezyme/Enzol and the disinfection agent Cidex OPA (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into consideration.

Disinfection is only possible in connection with complete final sterilisation of reusable surgical instruments.

See section 9 **"Sterilisation"**.

6. Drying

Wipe any remaining water off the ***Vibrasat®* *Pro Wand*** with a lint-free cloth. The handle can also be dried with a compressed air gun.

7. Maintenance, inspection and functional test

a. Remove the sealing cap from the connecting cable.
b. Check each device to ensure that all remaining visible blood and dirt has been removed.
c. Inspect the devices visually for damage and/or wear.
d. If instruments form part of a larger system, check that the devices are connected to the additional components correctly.

If you are in any doubt as to the correct functioning of the device, please contact Möller Medical GmbH.

8. Packaging

Package the instruments or sterilisation trays in disposable sterilisation packaging (single or double packaging) which meets the following requirements (material/process):

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilisation (temperature resistance up to min. 142°C (288°F) sufficient steam permeability)
- sufficient protection of the instruments or sterilisation packaging from mechanical damage

9. Sterilisation

Only the sterilisation methods outlined below should be used; other sterilisation methods are not permitted.

Steam sterilisation

- Fractionated vacuum procedure [1], [2](with sufficient product drying [3])
- Steam steriliser according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- Validated according to DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance qualification (PQ))
- Maximum sterilisation temperature 138°C (280°F; plus tolerance as per DIN EN ISO 17665)
- Sterilisation time (exposure time at sterilisation temperature):

Country	Fractionated vacuum procedure	Gravitation procedure
Europe, other countries	at least 5 min[4] at 132°C (270°F) / 134°C (273°F)	not recommended
USA	at least 4 min at 132°C (270°F), drying time at least 20 min	not recommended

Proof of the fundamental suitability of instruments for effective steam sterilisation was provided by an independent, officially accredited and recognised (Section 15 (5) German Medical Devices Act) testing laboratory using the steam steriliser HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum procedure. The typical conditions in hospital and doctors' practices and the procedure described above were taken into consideration.

The flash sterilisation procedure is not permitted

Also do not use hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation or plasma sterilisation.

[1] at least three vacuum steps

[2] The use of the less effective gravitation procedure is only permitted if the fractionated vacuum procedure is not available and requires considerably longer sterilisation times as well as product-, device-, procedure- and parameter-specific validation under the sole responsibility of the user.

[3] The drying time actually required depends directly on the parameters which are the sole responsibility of the user (loading configuration and density, steriliser condition ...) and must therefore be determined by the user. Nevertheless, drying times of 20 minutes should not be undercut.

[4] or 18 min (prion inactivation, not relevant for USA)

10. Checking

Check all instruments after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chips, soiling and discolouration. Separate out damaged instruments (for numeric restrictions for reuse, see "*Reusability*"). Clean and disinfect instruments that are still soiled again.

11. Storage

Following sterilisation, the instruments must be stored dry and dust-free in the sterilisation packaging.

Material resistance

When selecting the cleaning and disinfection agents, make sure that they do not contain the following components:

- Alkalis (max. permitted pH value 8.5 neutral / enzymatic cleaner recommended)
- Organic solvents (e.g. alcohols, ethers, ketones, benzines)
- Oxidants (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

Never clean the instruments with metal brushes and steel wool.

Rinse aids and acidic neutralisers must never be used!

The instruments must not be exposed to temperatures in excess of 142°C (288°F)!

Reusability

Frequent reprocessing has little effect on these instruments. The end of the product life is normally determined by wear and damage due to use.

Troubleshooting

Problem	Possible cause	Remedy
Liquid residue inside the cable connector	No protective cap attached during the above cleaning, disinfection and sterilisation processes.	Remove the liquid as per Chapter 6 "*Drying"*.
Faulty device	Incorrect reprocessing	Contact the manufacturer
Soiling and/or residue on the device after reprocessing	Incorrect reprocessing	Repeat reprocessing as per the reprocessing instructions.

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