

## Processing (Cleaning, Disinfection and Sterilisation) of the Medijet<sup>®</sup> 1010/ 1020



## 1 General Principles

All instruments must be cleaned, disinfected and sterilised before each use; this also applies in particular to initial use after delivery, since all instruments are delivered non-sterile (cleaning and disinfection after removal from protective transport packaging; sterilisation after packaging). Effective cleaning and disinfection is an indispensable prerequisite for effective sterilisation.

Within the scope of your responsibility for sterility of the instruments during use, please ensure

- that in principle, only sufficiently device- and product-specific validated methods are used for the cleaning/disinfection and sterilisation,
- that the devices used (disinfector, steriliser) are regularly maintained and checked, and
- that the validated parameters are maintained during each cycle.

Please be aware of the additional legal regulations in effect in your country, as well as the hygiene regulations of the medical practice and/or of the hospital. This applies in particular for the various specifications with regard to effective prion inactivation.

## 2 Cleaning and Disinfection

### 2.1 Basic Principles

Only the manual method indicated should be used for cleaning and disinfection. It is not expected that a mechanical method is sufficiently suitable due to the specific geometry of the instruments<sup>1</sup>.

<sup>1</sup> If a mechanical method is nonetheless used, this takes place under the sole responsibility of the user and must be ensured through an additional product-, device- and method-specific validation under the responsibility of the user.

Pre-treatment is to be performed in both cases.

### 2.2 Pre-treatment

Directly after use (within a maximum of two hours), heavy contamination must be removed from the instruments. Do not disassemble the instruments to do so.

Use running water or a disinfectant solution for this purpose; the disinfectant solution should be aldehyde-free (otherwise contamination from blood will be set), have certified efficacy (e.g. VAH/DGHM or FDA/EPA approval or CE mark), be suitable for the disinfection of the instruments, and be compatible with the instruments (see "Material Resistance" chapter). To remove contamination manually, use only a soft brush or a clean, soft cloth which you only use for this purpose; never use metal brushes or steel wool.

Also rinse the thin instrument tube five times using a disposable syringe (minimum volume 50 mL) and rinse the thick tube for at least 1 min. under running water.

Subsequently disassemble the instruments only then (remove the two tubes from the connectors on both sides, the push ring and the extender as well as unscrew the bolt in the connector for the thicker tube (however the bolt should still be kept loose on the connector)).

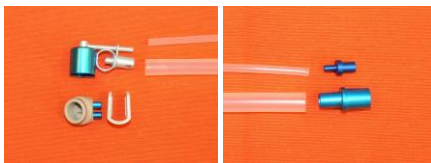


Figure 1: Medijet® disassembled



Figure 2: Detail view: Loosen bolt

## Operating, cleaning and maintenance instructions

Please be aware that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfection step to be performed later – after cleaning has taken place.

### 2.3 Manual Cleaning and Disinfection

When selecting the cleaning agent and disinfectant used, the following should be borne in mind:

- that these are fundamentally suitable for the cleaning and disinfection of instruments made of metals and plastics,
- that the cleaning agent – if applicable – is suitable for ultrasound cleaning (no development of foam)
- that a disinfectant whose efficacy has been certified (e.g. VAH/DGHH or FDA/EPA approval or CE mark) is used and that this disinfectant is compatible with the cleaning agent used, and
- that the chemicals used are compatible with the instruments (see "Material Resistance" chapter).

Combined cleaning agents/disinfectants should not be used, whenever possible. Combined cleaning agents/disinfectants can only be used in cases of very minor contamination (no visible contamination).

The concentrations, temperatures, and contact times indicated by the manufacturer of the cleaning agents and disinfectants as well as specifications regarding flushing should be strictly adhered to. Use only freshly prepared solutions, only sterile or low-germ (max. 10 microbes/mL) and low-endotoxin (max. 0.25 endotoxin units/mL) water (e.g. purified water/highly purified water) and only filtered air for drying.

### 2.4 Cleaning and Disinfection Process:

1. Disassemble the instruments as much as possible (see figure in "Pre-treatment" chapter)
2. Place the disassembled instruments for the specified contact time in the cleaning bath so that the instruments are sufficiently covered; facilitate the cleaning using ultrasound and careful brushing with a soft brush). Ensure that the instruments do not touch one another. Rinse the thin instrument tube at least five times at the start and at the end of the contact time using a disposable syringe (minimum volume 50 mL).
3. Then remove the instruments from the cleaning bath and flush them thoroughly at least three times with water. Rinse the thin instrument tube at least five times using a disposable syringe (minimum volume 50 mL) and rinse the thick tube for at least 1 min. under running water.
4. Inspect the instruments (see "Inspection and Maintenance" chapter).
5. Place the disassembled, cleaned and inspected instruments in the disinfection bath for the specified contact time such that the instruments are sufficiently covered. Ensure that the instruments do not touch one another. If applicable: Rinse the thin instrument tube at least five times at the start and at the end of the contact time using a disposable syringe (minimum volume 50 mL).
6. Then remove the instruments from the disinfection bath and flush them thoroughly at least five times with water. Rinse the thin instrument tube at least five times using a disposable syringe (minimum volume 50 mL) and rinse the thick tube for at least 1 min. under running water.
7. Dry the instruments by blowing them off/blowing them out with filtered compressed air.
8. Pack the instruments as promptly as possible after removal (see "Packaging" chapter; if necessary at a clean location after additional subsequent drying).

*Proof of fundamental suitability of the instruments for effective manual cleaning and disinfection was provided by an independent, accredited testing laboratory using the cleaning agent Cidezyme/Enzol and the disinfectant Cidex opa (Johnson & Johnson GmbH, Norderstedt). Here the procedure described above was taken into account.*

## 3 Inspection

Check all instruments after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipping and contamination and discard damaged instruments (for numerical limitation on re-use, see "Reusability" chapter). Instruments which are still contaminated must be cleaned and disinfected once again.

## 4 Maintenance

No instrument oils or greases should be used.

## 5 Packaging

Please package the disassembled instruments in disposable sterilisation packaging (single or double packaging) which meets the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607
- suitable for steam sterilisation (resistant to temperatures up to at least 138°C (280°F), sufficient steam permeability)
- sufficiently protect the instruments and sterilisation packaging from mechanical damage

## 6 Sterilisation

For sterilisation, only use the sterilisation methods listed below; other sterilisation methods are not permissible.

The instruments may only be sterilised when disassembled.

Steam sterilisation

- Fractionated vacuum method or gravity displacement method<sup>2</sup> (with sufficient product drying)
- Steam steriliser according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79
- Corresponding to DIN EN ISO 17665 (previously: DIN EN 554/ANSI AAMI ISO 11134) validated (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- Maximum sterilisation temperature 134°C (273°F; plus tolerance according to DIN EN ISO 17665 (previously: DIN EN 554/ANSI AAMI ISO 11134))
- Sterilisation time (exposure time at the sterilisation temperature) at least 3<sup>3</sup> min (fract. vacuum method) or 5<sup>3</sup> min (gravity displacement method) at 132°C (270°F)/134°C (273°F)

<sup>2</sup> The use of the less effective gravity displacement method is only permissible if the fractionated vacuum method is not available.

<sup>3</sup> or 18 min (prior inactivation)

*Proof of fundamental suitability of the instruments for effective steam sterilisation was provided by an independent, accredited testing laboratory using the steam steriliser Systec V-150 (Systec GmbH Labor-Systemtechnik, Wettenberg) and the fractionated vacuum method as well as the gravity displacement method. In doing so, typical conditions in the hospital and medical practice as well as the method described above were taken into account.*

The flash sterilisation method is fundamentally not permissible.

In addition, do not use any hot air sterilisation, no radiation sterilisation, no formaldehyde or ethylene oxide sterilisation and no plasma sterilisation.

## 7 Storage

After sterilisation, the instruments must be stored in the sterilisation packaging and kept dry and free of dust.

## 8 Assembly

Reassemble the disassembled instruments prior to use (in the reverse order as disassembly: Screw the bolt into the connecting piece for the thicker tube, insert both tubes, insert the extension).

## 9 Material Resistance

When selecting cleaning agents and disinfectants, ensure that they do not contain the following ingredients:

- organic, mineral and oxidising acids (minimum permissible pH 5.5)
- strong alkalis (maximum permissible pH 8.5, neutral/enzymatic cleaners recommended)
- organic solvents (e.g. alcohols, ethers, ketones, benzines)
- oxidising agents (e.g. hydrogen peroxide)
- halogens (chloride, iodine, bromine)
- aromatic/halogenated hydrocarbons

Never clean any instruments using metal brushes or steel wool.

No instruments should be exposed to temperatures above 138°C (280°F)!

## 10 Reusability

The instruments may – given appropriate care and provided that they are undamaged and uncontaminated – be reused up to 100 times; any re-use beyond this or use of damaged and/or contaminated instruments falls under the responsibility of the user.

No liability is accepted in case of non-compliance.