

General principles

All instruments have to be cleaned, disinfected and sterilised prior to each use; in particular this also applies to initial use after delivery as all instruments are supplied in a non-sterile state (cleaning and disinfection after removal of the protective transport packaging; sterilisation after packaging). Effective cleaning and disinfection is an imperative requirement for effective sterilisation.

As part of your responsibility for the sterility of the instruments in use please always ensure that only adequately device- and product-specific validated procedures are used for the cleaning/disinfection and sterilisation, that the devices used (ultrasonic bath, steriliser) are serviced and checked regularly and that the validated parameters are observed during each cycle. Owing to the intended purpose and the geometry/surface characteristics we recommend classification as B semi-critical or B critical (subject to the manner and site of the actual use).

Go to the address www.a-k-i.org (Working Group for Instrument Preparation) for general information on preparing instruments.

The disinfectant list of the German Association for Hygiene and Microbiology (DGHM www.dghm.org) of the Robert Koch Institute (www.rki.de) provides an overview of suitable disinfectants.

Cleaning and Disinfection

Principles

If possible a mechanical procedure (disinfector) should be used for the cleaning and disinfection. A manual process - also using an ultrasonic bath - should only be used in the absence of a mechanical method due to the significantly lower efficacy and reproducibility.

Pretreatment

Coarse contaminants have to be removed from the products immediately after use (within a maximum of 2 h). This involves using running water or a disinfectant solution; the disinfectant should be free of aldehyde (otherwise it would fix blood smears), exhibit proven efficacy (e.g. DGHM/VAH or FDA/EPA approval or CE symbol), be suitable for disinfecting instruments. Only use a dedicated soft brush to manually remove contamination, never use metal brushes or steel wool. With profiled instruments pay particular attention to cover all the surfaces and ensure that no further visible residue is recognizable, and afterwards rinse thoroughly (at least 1 min) under running water. Instruments, caked with water-insoluble contaminants, which cannot be removed manually, have to be segregated at this point.

Please take into account that the disinfectant used during pretreatment is only meant for your protection and cannot serve as a substitute for the subsequent disinfection step to be performed once cleaning has been completed.

Mechanical cleaning/disinfection -

(Disinfector/CDD (cleaning and disinfection device – e.g. Miele G7735CD))

In choosing the disinfector ensure that

- it always features certified efficacy (e.g. DGHM or FDA/EPA approval or CE symbol in accordance with DIN EN ISO 15883),
- if possible a tested program is used for thermal disinfection (A0-value > 3000) (with chemical disinfection risk of disinfectant residue on the instruments),
- the selected program is suitable for the instruments and includes enough rinsing cycles,
- only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used for rinsing,

- the air used for drying is filtered (oil-free, low in germs and particles) and that the disinfectant is serviced and checked regularly.

In choosing the detergent system to be used ensure that

- it is fundamentally suitable for cleaning instruments made of metals,
- if no thermal disinfection is used - an additional suitable disinfectant with proven efficacy (e.g. DGHM/VAH or FDA/EPA approval or CE symbol) is used and it is compatible with the detergent used.
- It is imperative to adhere to the concentrations, temperatures and action times, and requirements for rinsing, specified by the manufacturer of the detergent and any disinfectant

Procedure:

1. Place the instruments, using a basket for small items, into the disinfectant. Make sure that the instruments do not touch.
2. Start the program.
3. Remove the instruments from the disinfectant after the end of the programme.
4. After removal inspect and pack the instruments immediately, if possible (see the chapters "Inspection" and "Packaging").

Manual cleaning and disinfection

In choosing the detergent and disinfectant to be used ensure that

- they are fundamentally suitable for cleaning or disinfecting instruments,
- the detergent and disinfectant - if applicable - is suitable for ultrasonic cleaning (no foaming),
- a detergent and disinfectant with proven efficacy (e.g. DGHM/VAH or FDA/EPA approval or CE symbol) is used.

A requirement for using a combined detergent/disinfectant is a very low initial contamination level (no visible contamination) due to effectively performed pre-cleaning of instruments.

It is imperative to adhere to the concentrations and action times and requirements for rinsing, specified by the manufacturers of the detergent and disinfectant. Use only freshly made solutions, only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) or only filtered air for drying.

Procedure:

Cleaning and Disinfection

1. Place the instruments into the cleaning and disinfection bath for the specified action time, in such a way to sufficiently cover them (if necessary ultrasonic support (only using the stand/ sterilisation trays or careful brushing with a soft brush). Make sure that the instruments do not touch.
2. Then remove the instruments from the cleaning and disinfection bath, and rinse them thoroughly (at least 1 min) under running water.
3. Dry the instruments with compressed air.
4. Inspect the instruments (see the section "Inspection" and "Maintenance").
5. After removal pack the instruments as soon as possible (see the chapter "Packaging"), after additional subsequent drying in a clean location, if necessary.

Inspection

After cleaning or cleaning/disinfection check all the instruments for corrosion, damaged surfaces, chips, profile damage (e.g. bent instruments and those which no longer rotate true) and contamination, and segregate damaged instruments (see the section "Reusability" for limit on the number of re-uses). Instruments which are still dirty must be re-cleaned and disinfected.

Maintenance

Servicing is not required No instrument oils may be used.

Packaging

Pack the instruments in single-use sterilisation packs (single or double packaging) which meet the following specifications:

- in accordance with DIN EN 868-2ff/DIN EN ISO/ANSI AAMI ISO 11607
- suitable for steam sterilization (temperature resistant to at least 138°C (280°F), sufficient vapour permeability)
- adequate protection of the instruments or sterilisation packs against mechanical damage

Sterilisation

Use only the sterilisation methods listed below; other sterilisation methods are not permitted.

Steam sterilisation

4-fold fractionated vacuum process (with adequate product drying [the drying time mainly depends on aspects which the user is solely responsible for, and therefore has to be personally validated by the user.])

- Steam steriliser in accordance with DIN EN 13060 type B or DIN EN 285 (e.g. Lautenschläger 3119)
- validated in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (valid commissioning and product-specific performance assessment)
- max. sterilisation temperature 134°C (273°F; plus tolerance in accordance with DIN EN ISO/ANSI AAMI ISO 17665)
- Sterilisation time (exposure time at the sterilisation temperature) at least 5 min at 132°C (270°F)/134°C

Flash sterilization is prohibited.

Also do not use any hot air sterilisation, any radiation sterilisation, any formaldehyde or ethylene oxide sterilisation, any chemiclaves and any plasma sterilisation either.

Storage

After sterilisation store the instruments in the sterile pack in a dry and dust-free place. The instruments also require protection from the sun and heat.

Reusability

Frequent reprocessing does not have any effect or restriction on these instruments as the end of the product service life depends on wear and damage through use.

Disposable items (labelled as) are not certified for re-use. Safe use cannot be guaranteed if these products are re-used as there is an infection risk and/or the products are no longer safe.

The user is solely responsible for using damaged and dirty instruments.

We assume no liability if these recommendations are disregarded.