Devices

All re-usable general surgical instruments supplied by Kaisers.

**WARNING**

Improper sterilization and non-sterile handling of the instruments can lead to serious health hazards for patients. Please observe the national regulations and standards regarding the preparation of medical products. In case of patients suffering or suspected of having Creutzfeldt-Jakob-Disease (CJD) or possible variants thereof, the preparation of the instruments must be done in accordance with the respective national laws and regulations.

Using new instruments for the first time

Please check products for possible damage in transit. All instruments must be cleaned, disinfected and sterilised before use.

Field of application

The products must be used exclusively for the intended purpose by appropriately trained and qualified personnel. The doctor concerned is responsible for selecting the instrumentation for specific applications, for appropriate training and for adequately informing the operating personnel, as well as for operational use.

Checks

Instruments must be checked to ensure that they are in working order each time they are used. For reliable application, the functionality of the product must be particularly checked in the areas of the blades, points, locks, latches, safety catches and all moving parts with regard to cracks, breakages and other possible damage. Discard damaged products immediately.

Repair

The guarantee and warranty will become void if products are repaired by companies or persons not approved by Lifehealthcare Pty Ltd.

Disposal

Instruments that can no longer be repaired or re-conditioned should be sent to the usual hospital disposal facility.

Materials


**Limitations on Reprocessing**

Provided that appropriate care is taken and as long as the products are undamaged and not contaminated, the preparation process has little effect on the instruments. The end of the product's life is normally determined by the wear and usage of the instrument.

**Instructions**

Point of Use

Remove gross soil and minimize the risk of drying of contaminants.

Containment and Transportation

It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

**Preparation for Cleaning**

**Detergents, Disinfectants and Temperature Ranges**

Any liquid sterilants used must be registered with Therapeutic Goods Administration (TGA) and comply with AS/NZS 4187: 2014.

When selecting cleaning agents and disinfectants, ensure these do not contain the following constituents:

- Acids (< pH 5)/oxidising acids
- Alkalis (> pH 10)
- Organic solvents
- Benzene, phenol or ammonia
- Halogens, halogenated hydrocarbons, sodium chloride (in higher concentration),
- Oxidants / peroxides / hypochlorite

No instruments must be subjected to temperatures higher than 141 °C. All liability is excluded if this is disregarded!

**General Preparation Principles**

All instruments must be cleaned, disinfected and sterilised each time they are used; this applies particularly to the first time they are used after delivery, as all instruments are supplied unsterilised (cleaning and disinfection after removal of protective transit packaging; sterilisation after unpacking). Effective cleaning and disinfection is an indispensable prerequisite for effective sterilisation. When using instruments, ensure only methods for cleaning/disinfection and sterilisation, which have been adequately validated for the equipment and products are implemented, the equipment used (disinfector, steriliser) is regularly maintained and tested and that the validated parameters are maintained for each cycle.

Please also observe the legal regulations applicable in your country as well as the hygiene regulations of the medical practice or hospital. This applies particularly to the different requirements relating to effective prion inactivation.

**Cleaning and Disinfection – basic principles**

An automated process (disinfector) should be used wherever possible for cleaning and disinfecting instruments. Due to its significantly lower effectiveness and reproducibility, a manual process - even using an ultrasonic bath - should only be used if an automated process is not available.

The pre-treatment must be carried out in both cases.

**Pre-treatment**

Coarse contamination must be removed from the product directly after use (within a maximum of 2 hrs). For this purpose, use running water or a disinfectant solution; the disinfectant solution should be aldehyde-free (otherwise solidification of blood contamination may occur), have proven effectiveness (e.g. DGHM or CE marking), be suitable for the disinfection of instruments, and be compatible with the instruments (see section "Preparation for Cleaning").

For the manual removal of contamination, use only a soft brush or a clean soft cloth, which is used only for this purpose. Never use metal brushes or steel wool. Please note that disinfectants used for pre-treatment serve only to protect personnel and cannot replace the later disinfection steps, which are to be carried out when cleaning is complete.

If instruments can be taken apart, then take them apart before preparation.
The aspects listed below must also be taken into account with the following products/product groups:

- Instruments with joints (e.g. forceps, clamps, scissors, needle holders, abdominal retractors etc.):
  - Open and close the instrument several times during pre-treatment as well as during cleaning and disinfection.
  - Open and close the instrument several times during pre-treatment and place in the disinfector in the half-open position when carrying out automatic cleaning and disinfection.
  - If required, oil the joint (but not other surfaces of the product) using as little oil as possible.

- Instruments with teeth (e.g. saws, rasps, ...):
  - Ensure that residues are completely removed from the teeth.

### Cleaning - Automated (Machine Cleaning)

When selecting the cleaning/disinfection unit (WD, disinfector), it must be ensured:

- the WD has proven effectiveness (e.g. DGKH or CE marking according to DIN EN ISO 15883),
- that, if possible, a proven programme for thermal disinfection is used (As value > 3000 or - in the case of older units - at least 10 min at 93 °C, in the case of chemical disinfection there is a risk of disinfectant residue on the instruments),
- the programme used is suitable for the instruments and has sufficient rinsing cycles,
- only sterile water or water with low germ content (max. 10 germs/ml) or water with low endotoxin content (max. 0.25 endotoxin units/ml) (e.g. purified water (PW)/highly purified water (HPW)) is used.
- the air used for drying is filtered, and
- the WD is regularly maintained and tested.

When selecting the cleaning system to be used, it must be ensured:

- this is suitable for cleaning instruments,
- that - if thermal disinfection is not used – a suitable disinfectant with proven effectiveness is also used (e.g. VAH/DGHM or CE marking) and that this is compatible with the cleaning agent used, and
- that the chemicals used are compatible with the instruments (see section "Preparation for Cleaning").

It is essential that the concentrations specified by the manufacturer of the cleaning agents and disinfectants be observed. The procedure is as follows:

1. Place the instruments in the WD. When doing so, make sure that the instruments do not touch one another.
2. Start the programme.
3. When the programme has finished, remove the instruments from the disinfector.
4. Check and pack the instruments immediately after removal if possible (see section "Checking", "Maintenance" and "Packing", if necessary after further drying in a clean place).

### Cleaning - Manual

When selecting the cleaning agents and disinfectants to be used, it must be ensured:

- these are suitable for the cleaning and disinfection of instruments,
- the cleaning agent - if applicable – is suitable for ultrasonic cleaning (no foaming),
- a disinfectant with proven effectiveness is used (e.g. VAH/DGHM or CE marking) and that this is compatible with the cleaning agent used, and
- the chemicals used are compatible with the instruments (see section "Preparation for Cleaning").

Combined cleaning agents/disinfectants should only be used in the case of extremely low prior contamination (no visible contamination) of the instruments.

It is essential the concentrations and reaction times specified by the manufacturer of the cleaning agents and disinfectants be observed. Use only freshly prepared solutions, sterile water or water with low germ content (max. 10 germs/ml) or water with low endotoxin content (max. 0.25 endotoxin units/ml) (e.g. purified water (PW)/highly purified water (HPW)). For drying, use only clean, lint-free cloths, which are used only for this purpose, or oil-free, filtered air.

#### Cleaning

- Place the instruments in the cleaning bath for the specified reaction time so that the instruments are adequately covered (if necessary, ultrasonic assistance or careful brushing with a soft brush). Ensure the instruments do not touch one another.
- Remove the instruments from the cleaning bath and rinse them thoroughly for at least 1 minute using running water if possible.
- Check the instruments (see sections "Maintenance", "Inspection" and "Packaging").

#### Disinfection

- Place the cleaned and checked instruments in the disinfection bath for the specified reaction time so that the instruments are adequately covered. When doing so, make sure that the instruments do not touch one another.
- Then remove the instruments from the disinfection bath and rinse them thoroughly for at least 1 minute using running water if possible.
- Dry and pack the instruments immediately after removal if possible (see section "Packing", if necessary after further drying in a clean place).

### Cleaning - Ultrasonic

The following should be observed in Ultrasonic cleaning processes:

- Surgical instruments should be placed into suitable open sterilization trays or wire baskets.
- A suitable cleaning agent should be added, in accordance with the manufacturer’s instructions regarding concentration and water temperature.
- The cleaning solution must be replaced at regular intervals in accordance with the manufacturer’s instructions. Excessive dirt content of the cleaning solution will adversely affect cleaning results.
- Prescribed immersion or ultrasonic treatment times must be strictly observed.
- Check the instruments for loosened components after the ultrasonic bath.
- Ultrasonic cleaning must be followed by a rinsing cycle. To prevent water spots, fully demineralized or distilled water should be used for the final rinse.

### Disinfection

The solutions employed for chemical disinfection must always be used in accordance with the manufacturer’s instructions and be compatible with the instruments (see section "Preparation for Cleaning").

Pure water must be used for preparing the dilutions specified for the chemical disinfectants. The addition of detergents is not permitted. The manufacturer’s instructions regarding exposure time and concentration must be duly observed in each case.
**Sterilisation**

The sterilisation methods listed below must be used for sterilisation; other sterilisation methods are not allowed.

**Steam sterilisation**

- Fractionated vacuum method or gravity displacement method¹ (with adequate drying of the product)
- Steam steriliser in accordance with DIN EN 13060 or DIN EN 285
- Validation in accordance with DIN EN ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134) (valid IQ/OQ (commissioning) and product-specific performance qualification (PQ))
- Maximum sterilisation temperature 138 °C; plus tolerance according to DIN EN ISO 17665
- Sterilisation time (exposure time at sterilisation temperature) at least 15 min at 121°C or 5 min at 132°C or 3 min at 134°C

¹ The use of the less effective gravity displacement method is only permitted if the vacuum method is not available.

**Hot-air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation and plasma sterilisation must not be used.**

**Drying**

Ensure reliable drying. Reliable drying is an essential factor for successful sterilisation.

**Maintenance**

Reassemble instruments that have been taken apart.

Instrument oils should only be used when explicitly specified (see section “Preparation for Cleaning”). If oiling is desired, it should be ensured only instrument oils (white oil), which are approved for steam sterilisation, are used, taking into account the maximum sterilisation temperature applied, which have proven biocompatibility. Only moving parts must be oiled; instruments must not be given a complete coating of oil and, in particular, plastic components should not be oiled.

**Inspection**

After cleaning or cleaning/disinfection, check all instruments for corrosion, cracks, breakages, damaged surfaces, splitting, distortion, movability/operation and contamination. Discard damaged instruments immediately.

The areas of the blades, points, locks, latches, safety catches and all moving parts must be particularly carefully checked. Worn, corroded, distorted, porous and otherwise damaged instruments must be discarded immediately.

Instruments that are still contaminated must be cleaned and disinfected again.

Please sterilise instruments before returning them for repair.

**Packaging**

We recommend instruments be packed in single-use sterilised packaging (single or double packaging) and/or sterilisation containers which meet the following requirements:

- comply with DIN EN ISO 11607 (formerly: DIN EN 868-1) and DIN EN 868-2ff
- be suitable for steam sterilisation (temperature resistant to at least 141 °C, adequate vapour permeability)
- provide adequate protection against mechanical damage for the instruments and sterilisation packs
- be regularly maintained in accordance with the manufacturer's instructions (sterilisation containers)

**Storage**

Sterilised instruments must be stored in the sterilisation pack, dry and free from dust, in a closed cupboard.

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**Disinfecting solutions must be prepared afresh every day. Extended / multiple use can easily lead to the following problems:**

- Increased concentration due to evaporation (corrosion risk)
- Excessive dirt load (corrosion risk plus lower effectiveness)
- It is important to rinse all items sufficiently under clear running water. To prevent formation of water spots, the use of fully demineralized water is highly recommended.

Immediately after completion of cleaning and rinsing cycles, surgical instruments must be sufficiently dried.

The procedure is as follows:

1. Place the cleaned and checked instruments in the disinfection bath for the specified reaction time so that the instruments are adequately covered. When doing so, make sure that the instruments do not touch one another.
2. Remove the instruments from the disinfection bath and rinse them thoroughly for at least 1 minute using running water if possible.
3. Dry and pack the instruments immediately after removal if possible (see section "Packing", if necessary after further drying in a clean place).