



OHST

medical technology



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(Es gilt das jeweilige auf dem Produkt/Produktetikett abgedruckte CE-Zeichen)

(The CE mark printed on the product / product label applies in each case)

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Surgical Instruments and Instrument Trays

Before using the products the user is required to carefully study and comply with the following warnings, recommendations and product-specific instructions.

The manufacturer of these products does not accept any liability for direct or consequential damage caused by improper use or handling, in particular non-compliance with the following instructions for use, or due to improper care or maintenance. Detailed information on the compatibility with other medical devices, product-specific risks, indications or contraindications are shown in the instructions for use or surgical technique specific to the respective system.

These instructions for use apply to surgical instruments and instrument trays (hereafter referred to as "instrument") of OHST Medizintechnik AG which are used for the implantation of endoprostheses and surgical interventions. These instruments may be used only by medical specialists with appropriate experience and practice in the relevant specialist field. In case of questions please contact the manufacturer directly.

1. Instructions for Use

1.1. General Information

Instruments from OHST Medizintechnik AG are always part of a system. They may only be used with the original parts that belong to the respective system and only with the original implants that form part of these systems. Use of the instruments for other purposes is not permitted. Any manipulation of instruments is prohibited. If not used as intended, instruments can wear out faster, break or otherwise lose their function.

If a product of OHST Medizintechnik AG is passed on to others, anyone doing so must ensure that the product can be traced at any time (LOT tracking) and that these instructions are known.

Products undergoing clinical investigation

An instrument that is undergoing clinical investigation is marked as such on the packaging. These instruments do not carry a CE mark.

An instrument undergoing clinical investigation may only be used by doctors who are participants in the respective study group. The doctor must inform the patient in good time that the instrument is undergoing clinical investigation and is therefore associated with corresponding risks. In addition, the doctor is responsible for obtaining the written consent of the patient in good time.

Custom-made devices

If an instrument is a custom-made device, this is noted on the packaging. These instruments do not carry a CE mark.

A custom-made device may only be used by the doctor if there is no commercially available instrument that can be used instead. The doctor must inform the patient in good time that the instrument is a custom-made device and is associated with corresponding risks. In addition, the doctor is responsible for obtaining the written consent of the patient in good time.

Instruments connected to an active drive

In the case of drills and cutters which are intended for use with an active driving component, it must be ensured before use that the connections of the instrument and drive component match. The application is to be carried out in conjunction with irrigation with Ringer's solution in order to prevent overheating and avoid damage to the tissue. The information provided by the equipment manufacturer must be adhered to in order to ensure proper use.

1.2. Materials

The following materials are used:

- Metallic alloys and coatings
- Plastics such as PPSU, POM, HGW, silicone rubber

More information about the chemical and mechanical properties of the materials used is contained in DIN EN ISO 16061 and the additional material standards referred to therein, and is also obtainable from the manufacturer.

1.3. General Risk Factors

During the use of instruments, allergic reactions to the material used are possible, as is loosening, wear, corrosion, ageing and fracturing of the instrument or instrument parts.

During the use of milling cutters, drills and other cutting instruments, frictional heat may arise, which can lead to cell damage. Instruments may have sharp edges; when using plastic gloves there is a danger that the gloves will be destroyed – note the risk of infection! Rough, sharp or cutting surfaces of the instruments must not come into contact with clothing or other materials that shed fibres. Instruments with a large lever arm may transmit considerable forces and break if not handled properly. In this case it must be ensured that no fragments are left in the wound.

Impact plates may be deformed by blows with the hammer. There is a risk that parts may be split off. Any fragments that have fallen into the wound must be removed.

2. Preparation of Instruments

Caution: Only instruments that have been prepared in accordance with these Instructions for use may be used!

Brand-new instruments and instruments returned after being repaired must be removed from the transport packaging before being put into storage and/or introduced into the instrument cycle. Protective caps and films must be removed and disposed of properly.

The instruments are supplied unsterile. Before initial use, brand-new instruments and instruments returned after being repaired must undergo full preparation in the same manner as the instruments already in use.

All instruments must be cleaned, disinfected and sterilised after every use. Effective cleaning and disinfection is an essential prerequisite for effective sterilisation.

The operator is responsible for the cleaning/disinfection and sterilisation process, exclusively by trained personnel, and for the regular maintenance and care of the currently qualified cleaning and sterilisation equipment (e.g. according to DIN EN ISO 15883; DIN EN ISO 17665). This includes in particular ensuring compliance with validated parameters and processes.

As part of the responsibility for the sterility of the instruments during use, the operator must ensure in all cases that the prescribed procedure – appropriately validated for the specific device and product – for cleaning/disinfection and sterilisation is properly applied.

The user must also comply with the applicable laws in his country, as well as the hygiene regulations of the doctor's surgery or hospital. This applies in particular to the various requirements with respect to effective prion inactivation.

It should also be noted that, for some products, additional aspects are required, which are listed in separate product-specific Instructions for Use.

The recommendations listed under section 2 are for information purposes only. No liability is accepted with regard to the sterility of the instruments cleaned, disinfected or sterilised by the purchaser or user, nor with respect to re-sterilised instruments.

2.1. Cleaning and Disinfection

Basics

If possible, a validated automated procedure in the cleaning disinfection device (CDD) should be used for the cleaning and disinfection of the instruments. Owing to the significantly lower level of efficiency and reproducibility, a manual method – also involving use of an ultrasonic bath – should only be followed if an automated procedure is not available.

The use of ultrasound (applying the parameters specified by the manufacturer of the ultrasonic device) for pre-cleaning is permissible if the instruments have no joints / moveable parts / silicone handles or have been dismantled. In an ultrasound application, individual instruments or instrument parts must not touch one another in order to avoid secondary damage.

Pre-treatment of the instruments at the place of use and pre-cleaning can be carried out with regular tap water. For all other cleaning steps, deionised water (purified water) must be used.

For the manual removal of contamination on instruments and instrument trays, only soft brushes or clean, soft and lint-free cloths may be used which are used for this purpose only, but never metal brushes or steel wool.

If manual cleaning steps in Table 1 or Table 2 for instruments with multiple and varying construction features contradict one another, as a general rule the first construction feature and the corresponding cleaning workflow listed first in the table applies.

Pre-treatment of the instruments at the place of use

Immediately after surgery, coarse visible contaminations must be removed from the products using water and a cloth. The instruments and instrument trays must be brought to the cleaning department as soon as the internal workflows allow. If a delay in transport is to be expected, the instruments and instrument trays should be covered with a damp cloth to prevent drying of the contaminations. Metal instruments should never be stored in physiological saline solution (NaCl solution), as prolonged contact leads to pitting and stress corrosion.

Pre-cleaning

To achieve an optimal final result after manual or automated cleaning, effective pre-cleaning is indispensable, as this helps to keep the microbial and protein load low.

The following steps must be carried out for this:

1. Demountable instruments must be taken apart for the cleaning (note product-specific directions for use, assembly/disassembly instructions!).
2. The instruments must be placed in cold water with a temperature of $18\text{ °C} \pm 2\text{ °C}$ for at least 5 minutes.

Please ensure the following:

- All surfaces are wetted with water (if necessary, use a syringe to reach poorly accessible places).
- Drill-holes/internal contours are filled with water.
- Seals must be opened.
- Move movable parts while soaking.
- Instruments must not touch one another.

It should be noted that any disinfectants used are for personal safety only and cannot replace the subsequent disinfection step to be performed upon completion of the cleaning.

Pre-cleaning is followed by the manual or automated cleaning/disinfection procedure.

Mechanical cleaning / disinfection procedure

During manual cleaning, the following steps must be carried out in consideration of the construction features (see Table 1):

1. The instruments must be cleaned in a cold water bath with a soft brush or with a clean, soft and lint-free cloth until all visible contaminations have been removed. All parts that can be reached with a brush must also be scrubbed. If necessary, use of a bottle brush might be useful (see Table 1).
2. Rinse the instruments with a water pistol (static pressure at least 3 bar) with water at $18\text{ °C} \pm 2\text{ °C}$ for at least 15 seconds per instrument. The use of a bottle brush (see Table 1) may be expedient. Pay particular attention to poorly accessible areas (e. g. drill-holes, covered surfaces).
3. According to Table 1, the instruments must be placed in an alkaline solution heated to approx. 40 °C (e.g. neodisher® FA, Dr. Weigert) with or without ultrasound for at least 5 minutes. The instruments must be fully immersed. The use and dosage of the cleaning solution must be performed in accordance with the manufacturer's instructions.
4. After that, rinse the instruments with deionised (purified) water (see Table 1).
5. If contaminations are still visible after the cleaning procedure, repeat the entire cleaning procedure.

6. Fully immerse the instruments in a bath with a disinfectant solution (e.g. neodisher® Septo MED, Dr. Weigert) (see Table 1). The use and dosage of the disinfectant solution must be performed in accordance with the manufacturer's instructions.

Please ensure the following:

- All surfaces are wetted with the disinfectant solution.
 - Drill-holes/internal contours are filled with water.
 - Seals must be opened.
 - Instruments must not touch one another.
7. After the exposure time, the instruments are rinsed thoroughly with deionised (purified) water and then dried (see Table 1).

Upon conclusion of the manual cleaning, the instruments are inspected according to the point "Checks".

Table 1: Manual cleaning and disinfection instructions for instruments

Design features	Brushing	Rinsing (water pistol)	Place in cleaner (with ultrasound)	Place in cleaner (without ultrasound)	Rinsing	Disinfecting	Rinsing
<ul style="list-style-type: none"> - Joints - Movable parts that cannot be disassembled - Instruments with silicone handle 	Step 1	Step 2	not permissible	Step 3	Step 4	Step 5	Step 6
<ul style="list-style-type: none"> - Through-holes with inner workings (parts that protrude into the drill-hole) - Blind holes with and without a thread 	not permissible	Step 1	Step 2 (recommended)	Step 2 (permissible)	Step 3	Step 4	Step 5
<ul style="list-style-type: none"> - Through-holes without inner workings - Immovable parts that cannot be disassembled - Through-holes with a thread - permeable openings/lumens - Structured, rough surfaces 	Step 1 (bottle brush)	Step 2	Step 3 (recommended)	Step 3 (permissible)	Step 4	Step 5	Step 6
<ul style="list-style-type: none"> - Simple smooth surface (without internal contours) - All areas visible 	Step 1	Permissible	Step 2 (recommended)	Step 2 (permissible)	Step 3	Step 4	Step 5

Legend:

Step = Sequence of the cleaning procedure which must be followed

Not permissible = Cleaning step which must **not** be used for this construction feature

Permissible = Cleaning step which can be used for this construction feature, but which is not mandatory or should be replaced by the recommended step

Recommended = Cleaning step that should preferably be used, provided there are no opposing product features

Automated cleaning/disinfection procedure

In the selection of the CDD it must be ensured that:

- the CDD generally has a qualified state (e.g. according to DIN EN ISO 15883);
- a validated program for thermal disinfection (A_0 -value > 3000 or at least 5 minutes at 90 °C - 0 K/+3 K) is used (for chemical disinfection there is a risk of disinfectant residues on the instruments);
- the program used is suitable for the instruments and includes sufficient rinse cycles;
- only sterile water or water with a low germ count (max. 10 bacteria/ml) and low endotoxin count (max. 0.25 endotoxin units/ml) is used (e.g. purified water);
- the air used for drying is filtered accordingly;
- the CDD is maintained on a regular basis and kept in the qualified state.

In the selection of the process chemicals used it must be ensured that:

- these are fundamentally suitable for the cleaning of the instruments;
- if no thermal disinfection is used – a suitable disinfectant with proven efficacy (e.g. DGHM or FDA approval or CE mark) is also used and that this is compatible with the process chemicals used;
- the process chemicals used are compatible with the instruments (see section 2.3);
- all surfaces of the instruments are accessible to the process chemicals.

Prior to automated cleaning, the instruments must be pre-treated according to the applicable construction features (see Table 2).

1. The instruments must be cleaned in a cold water bath with a soft brush or with a clean, soft and lint-free cloth until all visible contaminations have been removed. All places that can be reached with a brush must be brushed; the use of a bottle brush (see Table 2) may be expedient.
2. Rinse the instruments with a water pistol (static pressure at least 3 bar) with water at 18 °C \pm 2 °C for at least 15 seconds per instrument. Pay particular attention to poorly accessible areas (e. g. drill-holes, covered surfaces).
3. According to Table 2, the instruments must be placed in an alkaline solution heated to approx. 40 °C (e.g. neodisher® FA, Dr. Weigert) with or without ultrasound for at least 5 minutes. The instruments must be fully immersed. The use and dilution of the cleaning solution must be performed in accordance with the manufacturer's instructions.
4. If contaminations are still visible after the cleaning procedure, repeat the entire cleaning procedure.
5. Rinsing with deionised water (purified water) is recommended before the instruments are then advanced to the automated cleaning and disinfection procedure (see Table 2).

Table 2: Pre-treatment for automated cleaning and disinfection

Design features Construction features	Brushing	Rinsing (water pistol)	Place in cleaner (with ultrasound)	Place in cleaner (without ultrasound)	Rinsing
<ul style="list-style-type: none"> - Joints - Movable parts that cannot be disassembled - Instruments with silicone handle 	Step 1	Step 2	not permissible	Step 3	Step 4 (recommended)
<ul style="list-style-type: none"> - Through-holes with inner workings (parts that protrude into the drill-hole) - Blind holes with and without a thread 	not permissible	Step 1	Step 2 (recommended)	Step 2 (permissible)	Step 3 (recommended)
<ul style="list-style-type: none"> - Through-holes without inner workings - Immovable parts that cannot be disassembled - Through-holes with a thread - permeable openings/lumens - Structured, rough surfaces 	Step 1 (bottle brush)	Step 2	Step 3 (recommended)	Step 3 (permissible)	Step 4 (recommended)
<ul style="list-style-type: none"> - Simple smooth surface (without internal contours) - All areas visible 	Permissible	Permissible	Permissible	Permissible	Permissible

Legend:

Step = Sequence of the cleaning procedure which must be followed

Not permissible = Cleaning step which must **not** be used for this construction feature

Permissible = Cleaning step which can be used for this construction feature, but which is not mandatory or should be replaced by the recommended step

Recommended = Cleaning step that should preferably be used, provided there are no opposing product features

The concentrations stated by the manufacturer of the process chemicals must be strictly adhered to. When immersing the instruments make sure that they do not touch one another. If applicable, the instruments must be connected to flexible rinsing tubes.

Position drill-holes and lumens in the CDD such that flushing is possible. A validated workflow for the automated cleaning program is shown in Table 3. A qualified CDD (e.g. Miele G7836 CD) is to be used for this.

Table 3: Validated workflow for automated cleaning and disinfection

Program block	Parameter
Pre-cleaning	Cold water inlet 2 min. exposure Emptying
Cleaning	Cold-warm water inlet Dosing of 0.5 % neodisher® FA at 40 °C Heating to 55 °C and 5 min. exposure at 55 °C Emptying
Neutralisation	Cold water inlet 3 min. exposure Emptying
Rinsing	Cold water inlet 2 min. exposure Emptying
Thermal disinfection	Purified water inlet Heating to 90 °C and 5 min. exposure at 90 °C Emptying
Drying	30 min. at 110 °C (please note the manufacturer's instructions for the machines used)

After the end of the program, the instruments are disconnected from the rinsing hoses and removed from the CDD under low-germ conditions.

Proof of general suitability of the instruments for effective automated cleaning and disinfection has been provided by independent accredited test laboratories using a CDD. Here, the method described above was applied.

Upon conclusion of the automated cleaning / disinfection procedure, the instruments are inspected according to the point "Checks".

Checks

Caution: Instruments must be checked for damage and function before every use!

After preparation, all instruments must be examined under sterile conditions with respect to corrosion, damaged surfaces, chips, dirt and function. Damaged instruments are to be rejected and replaced. Instruments which are still contaminated must be reprocessed.

Maintenance

Disassembled instruments are to be reassembled prior to sterilisation and their function checked (see product-specific instructions for use).

Wherever possible, no instrument oils should be used. If their use is nevertheless required, it must be ensured that only instrument oils (white oil) are used which – taking into account the maximum applied sterilisation temperature – are approved for steam sterilisation and have proven biocompatibility. Excess oil must be wiped off. After oiling, the instrument must be sterilised.

Packaging

After cleaning and before sterilisation, the instruments must be placed in the instrument tray and packaged together with the tray in disposable sterilisation packaging (single or double packaging) and/or sterilisation containers and/or sterile wipes that meet the following requirements:

- Compliance with DIN EN 868/ANSI AAMI ISO 11607
- Suitable for steam sterilisation (temperature stability up to at least 137 °C, sufficient steam permeability)
- Adequate protection of the instruments or sterilisation packagings against mechanical damage
- Regularly serviced according to the manufacturer's instructions (sterilisation containers)

2.2. Sterilisation

Caution: The instruments must not be sterilised in the protective packaging provided. New instruments are also to be cleaned prior to sterilisation! Storage of the instruments for sterilisation is done in the intended mounting brackets of the corresponding instrument tray. If no respective instrument tray is available, make sure that the instruments do not touch one another and position the instruments in such a way that residual moisture after drying is avoided.

Only steam sterilisation is permissible for the sterilisation. The points listed below must be observed for this. Other sterilisation methods are not permitted.

Steam sterilisation

- Fractionated vacuum procedure¹ at least three times (with sufficient product drying)
- Steam steriliser in accordance with DIN EN 13060 or DIN EN 285
- Validated according to DIN EN 554/ANSI AAMI ISO 17665 (valid commissioning and product-specific performance assessment)
- Sterilisation temperature of 134 °C (273 °F; plus tolerance according to DIN EN 554/ANSI AAMI ISO 17665). Apply the hold time for at least 3 min. Please note the nationally applicable instructions.
- Minimum drying time: 20 min
- Trays that require a longer drying time are marked with a symbol and the intended drying time in minutes.
- Depending on the load of the machine, a longer drying time may be required. If residual moisture is still available after drying, the drying procedure must be repeated.

¹ Use of the less effective gravitation process must be safeguarded by additional product, steriliser and process-specific validation (longer sterilisation times may be required).

All surfaces must be accessible to the water vapour. The instruments may be sterilised only loosely or in their original retainers and not one on top of the other in a sterilisation container that satisfies the above requirements (see section 2.1).

Proof of general suitability of the instruments for effective sterilisation has been provided by independent accredited test laboratories. Here, the sterilisation procedures described above were included and a sufficient sterilisation safety level ($SAL > 10^{-6}$) achieved.

2.3. Material Compatibility

Instruments must not come into contact with agents containing chlorine or fluorine. The process chemicals used must not contain the following ingredients:

- Mineral acid, with the exception of phosphoric acid
- Oxidizing acids
- Stronger lyes ($pH > 12.5$)
- Aromatic hydrocarbons, benzines
- Strong oxidizing agents
- Trichlorethylene/perchlorethylene

If in doubt, please contact the manufacturer of the process chemicals.

All instruments and instruments trays must not be exposed to temperatures higher than 137 °C (279 °F)!

2.4. Reusability

The instruments can – with appropriate care and provided that they are free from damage and contamination – be reused without restriction. However, they must be inspected for proper function and damage before each use!

Any further use or the use of damaged or contaminated instruments is the responsibility of the user. If this is ignored, all liability is excluded.

2.5. Storage and Handling

Instruments may only be stored in dust-proof dry areas/cabinets at room temperature. Under no circumstances may instruments be stored in the immediate vicinity of chemicals which, because of their ingredients, can give off corrosive vapours (e.g. active chlorine).

Instruments are sensitive to damage. They must therefore be treated carefully. Dents, scratches or other mechanical damage to the surfaces causes excessive wear and can cause corrosion and improper use. Instruments must be examined before use to ensure they are functioning properly. Any instruments that are no longer functioning correctly must be withdrawn from circulation.

Flexible shafts and drills may only be applied with a maximal torque of 0.2 Nm at a maximal inflexion of 45°. When using the instrument, the user must ensure that the bending radius of the flexible part is as uniform as possible. If the instrument is used with an uneven or S-shaped curve, the useful life may be shortened. The dimensional stability of the flexible coil is guaranteed up to a torque of 0.5 Nm.

When using flexible drills, the drilling gauge belonging to the system must be used.

3. Repair / Disposal

Damaged or improperly treated instruments or instruments altered without authorisation may no longer be used.

The packaging components and instruments are to be passed for waste recycling in accordance with their materials and the statutory provisions.

After consultation, these instruments can also be returned to the manufacturer for repair or replacement or for proper disposal free of charge cleaned and sterilised with a decontamination certificate or hygiene safety certificate.

4. Symbols



Attention, consult the accompanying documents



Manufacturing date (year - month)



Reference number



Lot number



Manufacturer



Non-sterile



Drying time after steam sterilisation in minutes