

ENT Navigation Optical and Electromagnetic

Reprocessing instructions for navigated instruments and trackers

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1 General information

1.1 Manufacturer



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1.2 Support & Feedback

If you cannot find the information you need in this guide, or if you have any questions, problems with our products, or suggestions for improvement, please contact our support team.

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1.3 Copyright

The content of this user manual is protected by copyright. Copying, publishing, or storing this user manual, either in whole or in part, is prohibited without the express written permission of the manufacturer.

2 Symbols

Please read these instructions carefully and follow them exactly. The terms Warning, Caution, and Note have specific meanings. Wherever they are used in the instructions, the following text should be read carefully to ensure safe and efficient use. For clear emphasis, these terms are preceded by a pictogram.



WARNING: Warning indicates a hazard to the patient or personnel. Failure to observe a warning may result in injury to the patient or personnel.



CAUTION: Caution indicates that certain measures must be taken to prevent damage to the instrument.



NOTE: Notes contain specific information on operation or explain important information.

3 General principles

This document applies to all reusable navigated instruments and trackers (hereinafter referred to as instruments) with electromagnetic or optical measurement technology.

All medical products used during surgical procedures in a sterile patient environment must be cleaned and sterilized before each surgical use. This applies in particular to the first use after delivery of non-sterile packaged products. Initial cleaning and disinfection is performed after removing the protective transport packaging.

Effective cleaning and disinfection are essential prerequisites for effective sterilization. Please ensure the sterility of the products as part of your responsibilities. Only product-specific validated procedures may be used for cleaning/disinfection and sterilization.



WARNING:

- The equipment used (disinfector, sterilizer) must be regularly maintained and checked.
- The validated parameters must always be adhered to.

Please also observe the country-specific legal and hygiene regulations of the medical practice or hospital. This applies in particular to the different requirements regarding effective prion inactivation.



WARNING: If the product has been used on a patient suspected of having Creutzfeldt-Jakob disease or a disease whose transmission route is unknown, it must not be reused. Dispose of it in accordance with the applicable legal regulations.

4 Cleaning and reprocessing

4.1 Basics

A mechanical process (disinfector) must be used for cleaning and disinfection. Manual cleaning is not permitted.

4.2 Pre-treatment

Immediately after use (within a maximum of 2 hours), coarse contamination must be removed from the instruments.

Use running water or a disinfectant solution for this purpose.

The disinfectant should:

- be aldehyde-free, as otherwise there is a possibility of blood contamination becoming fixed
- have proven efficacy (e.g., VAH/DGHM or FDA approval or CE marking)
- be suitable for the disinfection of surgical instruments
- be compatible with the materials of the instruments.

Only a soft brush or a clean soft cloth intended exclusively for this purpose may be used for manual removal of contaminants; metal brushes or steel wool must never be used. Moving parts must be moved back and forth several times during pre-cleaning.



WARNING: Please note that the disinfectant used during pre-treatment cannot replace the disinfection that must be carried out after cleaning.

4.3 Machine cleaning/disinfection

4.3.1 Selection of the disinfector

When selecting a disinfectant, ensure that:

- the disinfector has proven effectiveness (e.g., DGHM or FDA approval or CE marking in accordance with DIN EN ISO 15883)
- if possible, a tested program for thermal disinfection (A0 value > 3000 or – for older devices – at least 5 min at 90 °C) is used



WARNING: With chemical disinfection, there is a risk that disinfectant residues will remain on the instruments.

- the program used is suitable for the instruments
- and contains sufficient 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
- the disinfectant is regularly maintained and checked

4.3.2 Selection of the cleaning agent system

When selecting the cleaning agent system to be used, ensure that:

- it is suitable for cleaning medical devices made of metal and plastic
- if thermal disinfection is not used, a suitable disinfectant with proven effectiveness (e.g., VAH/DGHM or FDA approval or CE marking) is also used and that it is compatible with the cleaning agent used
- the chemicals used are compatible with the instruments.



WARNING: The concentrations specified by the manufacturer of the cleaning agent and, if applicable, the disinfectant must be strictly adhered to!

4.3.3 Procedure

1. Disassemble the instruments as far as possible (e.g., remove locking screws). The glass reflectors cannot be dismantled.
2. Place the dismantled instruments in the disinfectant. Make sure that the instruments do not touch each other. The glass reflectors must not come into contact with metal parts. Insert the cables loosely; they must not be kinked or crushed.
3. Start the program.
4. Remove the instruments from the disinfectant after the program has ended.
5. Check and pack the instruments immediately after removal, if necessary after additional drying, in a clean place.

5 Check

After cleaning or disinfection, check all instruments for corrosion, damaged surfaces, chips, or remaining dirt. If necessary, repeat the reprocessing steps.

In particular, check the glass reflectors for damage such as scratches, cracks, or clouding.

Damaged or corroded instruments must not be used again.

6 Packaging



WARNING: Do not reassemble the disassembled instruments before packaging!

Pack the instruments or the sterilization tray in single-use sterilization packaging (single or double packaging) and/or sterilization containers that meet the following requirements:

- DIN EN ISO / ANSI AAMI ISO 11607
- Suitable for steam sterilization (temperature resistance up to at least 141 °C (286 °F), sufficient steam permeability)
- Adequate protection of the instruments or sterilization packaging against mechanical damage
- Regular maintenance in accordance with the manufacturer's specifications (sterilization containers)

7 Sterilization

7.1 Sterilization procedure

Uncleaned instruments must not be sterilized, as the effectiveness of sterilization can only be guaranteed after prior cleaning and disinfection! Before sterilization, make sure that the instruments are clean.



WARNING: The user is responsible for carrying out the recommended sterilization procedures in order to achieve the desired or required sterilization effect.

7.2 Steam sterilization

Sterilization method	Temperature °C	Temperature °F	Temperature time	Holding	Drying time
Fractional pre-vacuum	121 °C	250 °F	>20 min		>20 min
	132 °C	270 °F	>3 min		>20 min
	134 °C	273 °F	>3 min		>20 min
	135 °C	275 °F	>3 min		>20 min
Gravity process	132 °C	270 °F	>60 min		>20 min
	134 °C	273 °F	>60 min		>20 min
	135 °C	275 °F	>60 min		>20 min
Prion program	134 °C	273 °F	>18 min		>20 min

Information on validation and ISO standards:

- Validated in accordance with DIN EN ISO 17665 (previously: DIN EN 554 / ANSI AAMI ISO 11134) (valid IQ / OQ (commissioning) and product-specific performance evaluation (PQ)).
- Maximum sterilization temperature 138 °C (280 °F; plus tolerance according to DIN EN ISO 17665 (previously: DIN EN 554 / ANSI AAMI ISO 11134)).
- Other autoclave settings and cycles may have a negative impact on the sterilization result and the function of the instruments.
- The instruments must be dry after cooling to room temperature. The specified drying times must be observed.
- Please note that overloading the sterilizer can reduce the sterilization result. Overloading also increases the possibility of unwanted condensation forming in the sterilizer, which increases the for-

mation of corrosion on instruments. Follow the manufacturer's instructions regarding the maximum load of the sterilizer.

- Applicable national legal regulations must be observed.
- The sterilizer manufacturer's operating instructions must be followed exactly.



CAUTION: The use of the gravity method and the prion program can reduce the service life of the instruments (see section "Reusability").

7.3 Other sterilization methods

The use of sterilization methods other than those specified here (such as flash sterilization, hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, plasma sterilization) is strongly discouraged.

8 Storage

After sterilization, the dry instruments must be stored in the sterilization packaging in a dry and dust-free place.

9 Reusability

The service life of functional, optically navigated instruments is not limited.

The service life of functional, electromagnetically navigated instruments is limited. For information on the limitation of the number of reprocessing cycles, please refer to the corresponding instructions for use of the instrument.

Improper handling, e.g., due to overloading, unsuitable cleaning agents, high sterilization temperatures, etc., reduces the service life of the instruments.

The instruments must be checked for integrity during the reprocessing process after disinfection and before sterilization. If a defect is found, the instrument must be discarded immediately and may not be used again.

Ergosurg accepts no liability for failure to comply with this instruction.

10 Material compatibility

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

- organic, mineral, and oxidizing acids (minimum permissible pH value 5.5)
- strong alkalis (maximum permissible pH value 11, neutral/enzymatic, slightly alkaline or alkaline cleaner recommended)
- organic solvents (e.g., alcohols, ethers, ketones, benzines)
- Oxidizing agents (e.g., hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons
- Heavy metal salts

11 Additional information

The instructions listed above have been validated by Ergosurg as suitable for the preparation of a medical device for reuse.

The reprocessor is responsible for ensuring that the actual reprocessing carried out with the equipment, materials, and personnel used in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process.

Similarly, any deviation from the instructions provided should be carefully reviewed by the reprocessor for its effectiveness and possible adverse consequences.

12 Customer service

If you have any questions or problems, please contact Ergosurg Customer Service. In order to ensure that your enquiry is processed quickly, please send us the product with the following information:

- Item number (REF)
- Serial number (SN) or (LOT)
- As detailed a description of the fault as possible



WARNING: To protect your staff and Ergosurg employees, the product (and any accessories) must be thoroughly cleaned and sterilized before shipping. If this is not possible due to urgency, the product must be prepared as far as possible and labeled accordingly.

Ergosurg GmbH may refuse to repair dirty or contaminated products for safety reasons.

13 Emergency number

In the event of an incident in accordance with Regulation (EU) 2017/745 Article 2 or the Medical Device User Reporting and Information Regulation (MPAMIV) § 2, please report it to us at the following telephone number:

+49 (0) 89 322094-63

Thank you for your support!