



REPROCESSING INSTRUCTION

for all GEUDER AG Products



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Reprocessing Instructions

for GEUDER AG Products

In accordance with paragraph 5 of the German Medical Devices Act (MPG), the responsibility for the publication of these instructions lies with:

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1. General Information

These reprocessing instructions apply to all GEUDER AG products. Insofar as special statements are made regarding individual products (e.g., instructions for dismantling or using cleaning adapters), these are enclosed with the respective product and are to be considered supplemental to these instructions.

Any deviations from these instructions (e.g., other sterilization processes or deviations from the manual or mechanical cleaning and disinfection methods) are the responsibility of the user. Geuder will accept no liability for damage to products resulting from deviations from the current instructions. For the rest, our General Terms and Conditions shall apply.

GEUDER AG reserves the right to amend these instructions in response to recent findings.

The current version of the instructions can be obtained from GEUDER AG, Heidelberg, or downloaded at www.geuder.de.

2. Background Information

Products are supplied in a non-sterile state and are not to be used without having previously been cleaned/disinfected and sterilized.

Effective cleaning/disinfection is an essential prerequisite for effective sterilization of the products. Sterilization in delivery packaging is not permissible.

Please ensure that only sufficiently validated devices and product-specific processes are used for cleaning/disinfection and sterilization and that the validated parameters are adhered to in each cycle.

In addition, please observe the statutory regulations in your country as well as the rules of hygiene of your facility, hospital or clinic. This especially applies to the different guidelines for effective prion inactivation.

Because of the intended use (contact with blood), we recommend categorizing instruments with complex geometries (e.g. lumen and hinge instruments) as "critical B" in accordance with RKI guidelines*. Instruments with simple geometries (e.g. knives, lances, forceps, etc) may be categorized either "critical A" or "critical B" (as long as there is no contact with blood).

* Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten, Bundesgesundheitsblatt. 44(2001), 1115-1126

3. Cleaning/Disinfection

Due to their distinctly greater effectiveness, mechanical processes (disinfectors) should be used for cleaning/disinfection.

For effective reprocessing, pre-treatment should begin as soon as possible, or, at the latest, 30 minutes after the operation has been performed. Make sure that lumen instruments (e.g. cannulas, handpieces) have unobstructed flow. Cleaning/disinfection should then follow within the next two (2) hours.

3.1 Pre-treatment

Regardless of the type of cleaning/disinfection process (manual or mechanical) subsequently used, the following pre-treatment steps must be performed:

Pre-treatment Sequence:

1. If at all possible, disconnect all detachable connections.
2. Paying special attention to uneven surfaces such as knurled handles, remove all macroscopic contaminants with a bristled toothbrush so soft that it will not damage delicate instruments. Be sure to take requirements for the protection of employees in regard to possible exposure to pathogens into account.
3. The adapters for any aspiration and/or irrigation lines must be flushed at least 5 times with 10 ml deionized or distilled water, whereby it must be ensured that no flushing liquid is drawn back into the aspiration or irrigation line.
4. If necessary, an aldehyde-free disinfectant (aldehyde causes blood residue to dry and become irremovable) can be added to the deionized or distilled water. The disinfectant must be compatible with the instruments (see Chapter 7).

Following the application of the disinfectant solution, the lines must then be flushed an additional 5 times with 10 ml of deionized or distilled water.

3.2 Ultrasonic Cleaning (optional)

Heavily dirty instruments may additionally be pre-cleaned in an ultrasonic bath. If ultrasonic cleaning is done, care must be taken that the exposure time and concentrations recommended by the manufacturer of the cleaning solution are observed and that the disinfectant is compatible with the instruments (see Chapter 7). At the same time, the liquid level specified by the manufacturer of the ultrasonic bath is to be adhered to (e.g., filled up to the mark).

Even when the bath has been correctly prepared, errors can be prevented by taking the following precautions:

- Products must be completely covered by the cleaning solution
- Instruments with hinges and/or joints, e.g., scissors, must be treated in an open state
- In order not to impair the effect of the ultrasound, products are to be placed in the bath on perforated instrument trays

Contamination of the ultrasonic bath impairs effective cleaning and increases the risk of corrosion. Therefore, the ultrasonic bath must be changed following each surgical procedure. The main criterion is visible contamination. In any case, frequent replacement of the bath - at least once a day - is necessary.

3.3 Mechanical Cleaning/Disinfection (Disinfector)

The following must be taken into account when selecting a disinfector:

- Only disinfectors that fulfil the requirements of DIN EN ISO 15883/AAMI ST15883 and having a verified effectiveness (e.g. CE marking, DGHM/VAH¹ listing or FDA² approval) are to be used.
- The disinfector must be equipped with flushing adaptors to allow the connection of lumen instruments (e.g. cannulas, handpieces), whose flushing pressures have been validated as being sufficient and reproducible in a specific setting.
- Because of the risk of disinfectant residues remaining on instruments when disinfecting with chemicals, products should be disinfected thermally with a proven disinfection program (A0 value > 3000, with old devices at least 10 minutes at 93°C (199°F)).
- The program used must be appropriate for the products and must include a sufficient number of flushing cycles.
- Only sterile or low-bacteria (max. 10 bacteria/ml) as well as low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. Aqua purificata / Aqua purificata valde (purified water (PW)/highly purified water (HPW) in accordance with the guidelines set in the European Pharmacopeia³ or the U.S. Pharmacopeia⁴) is to be used.
- The compressed air used for drying must be filtered and must meet your facility's requirements.
- The disinfector must be serviced regularly and checked according to the guidelines of the manufacturer and of your facility.

The following must be taken into account when selecting cleaning agents:

- The cleaning agents must be suitable for the cleaning of the products.
- If one chooses not to disinfect thermally (A0 value > 3000, with old devices at least 10 minutes at 93°C (199°F)), a suitable disinfectant whose effectiveness has been verified (e.g. CE marking, DGHM/VAH¹ listing or FDA² approval) and which is compatible with the detergent selected should be used.
- If an alkaline detergent is used, adequate neutralization in accordance with the manufacturer's instructions is to be performed.
- The chemicals used must be compatible with the products (see Chapter 7).
- The detergent and disinfectant concentrations specified by the manufacturer must be adhered to without fail.

Mechanical Cleaning Sequence:

1. Place the products in the protective perforated sterilizing tray. (When preparing the products for cleaning, ensure that they do not touch each other).
2. Place the perforated sterilizing tray containing the products in the disinfector (Attention: The manufacturer's instructions must be followed when stacking several disinfector baskets or perforated sterilization trays one on top of the other.).

^{1, 2, 3, 4} Please refer to chapter 10 "Abbreviations and Addresses"

3. Connect any lumen instruments (e.g., cannulas, handpieces) to the flushing adaptors of the disinfectant and, if possible, close any remaining unused flushing adaptors. The instruments, however, must first be checked beforehand for unobstructed flow or else the cleaning results may be called into question.
4. Start the program.
5. When the program is finished, remove the perforated sterilization tray from the disinfectant. Lumen instruments (e.g., cannulas, handpieces) may have to be dried using compressed air.
6. If possible, package the products or the perforated sterilization tray containing the products immediately following removal from the disinfectant (see Chapter 6).

3.4 Manual Cleaning/Disinfection

(Because of reduced effectiveness and reproducibility, only manually clean and disinfect when a mechanical process is not optional!)

The following must be taken into account when selecting detergents and disinfectants:

- The agents must be suitable for the cleaning and disinfecting of the products. Furthermore, they must be compatible with each other (due to the possibly heavy contamination, combining detergents/disinfectants is not recommended).
- The effectiveness of the disinfectant must have been verified (e.g. CE marking, DGHM/VAH¹ listing or FDA² approval).
- The chemicals used must be compatible with the products (see Chapter 7).

The concentrations and exposure times specified by the manufacturer of the detergent/disinfectant must be adhered to without fail. Only freshly produced solutions are to be used, and the disinfectant solution must not foam.

Use only sterile or low-bacteria (max. 10 bacteria/ml) as well as low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. Aqua purificata / Aqua purificata valde (purified water (PW)/highly purified water (HPW) in accordance with the guidelines set in the European Pharmacopeia³ or the U.S. Pharmacopeia⁴).

Manual Cleaning Sequence:

1. Place the products in the cleaning solution for at least the period of time specified by the manufacturer of the detergent/disinfectant.
2. If applicable, flush out all lumen instruments (e.g., cannulas, handpieces) at least 5 times each with a minimum of 10 ml cleaning solution at the beginning and end of the exposure time.
3. Contaminants adhering to the outside of the instruments are to be removed using the additional help of a soft bristled toothbrush.
4. Thoroughly rinse the products at least 5 times each with freshly distilled or deionized water (product lumina with at least 10 ml each). Repeat the cleaning process if the last rinsing solution is not clear or if impurities are still visible on the product.

^{1, 2, 3, 4} Please refer to chapter 10 "Abbreviations and Addresses"

Manual Disinfection Sequence:

1. Place the products in the disinfectant for at least the exposure time specified by the disinfectant manufacturer.
2. If applicable, flush out all lumen instruments (e.g., cannulas, handpieces) at least 5 times each with a minimum of 10 ml disinfectant at the beginning and end of the exposure time.
3. Thoroughly rinse the products at least 10 times each with freshly distilled or deionized water (product lumina with at least 10 ml each). Redo the entire cleaning/disinfecting process if the last rinsing solution is not clear or if impurities are still visible on the product.
4. Dry the products using filtered, compressed air.
5. If possible, package the products immediately (please refer to Chapter 6).

4. Testing

Following cleaning/disinfection, the products should be macroscopically clean, i.e., free from visible protein residues and other impurities. If this is not the case, the complete cleaning/disinfection process must be repeated. To avoid metal abrasion and corrosion, surgical instruments with movable parts must be cooled prior to the functional test. Hinged / joint instruments and products with threads must be oiled prior to the functional test (see Chapter 5).

Worn, damaged and porous products must be sorted out, as these no longer fulfill their function. Corroded products are also to be removed, since these can, as a result of the transfer of extraneous rust, trigger corrosion on products which are still intact.

Surgical products which are in a sound state must not be reprocessed together with products with damaged surfaces. Especially products from old stocks with flaking chromium or nickel coatings can cause discoloration or corrosion of high-grade stainless steel and titanium instruments. Therefore, it is recommendable to sort these products out or package them separately.

5. Care of Hinges and Locks

Hinged instruments or instruments with a lock (scissors, clamps, etc.) must be treated with a paraffin oil-based agent (e.g. Sterilit-Oil, Aesculap). This lessens metal-on-metal friction, helping prevent corrosion and keeps the instrument functioning smoothly. The paraffin agent should be applied manually and as thinly as possible. It is essential that such an agent always be applied to hard to reach threads, hinged joints, etc., each time the instruments are reprocessed. Taking the maximum applied sterilization temperature into account, it must also be ensured that only agents suitable for sterilization are used which have been approved for steam sterilization and have a tested biocompatibility.

6. Packaging and Sterilization

6.1 Packaging

Prior to sterilization, the perforated sterilization tray containing the products is to be placed in an appropriate sterilization tray container which, together with the filter material, must fulfil the following criteria:

- Be in accordance with the standards DIN EN (ANSI AAMI) ISO 11607 (DIN EN 868-8)
- Be suitable for steam sterilization (up to 141°C (285.8°F) and adequate steam permeability)
- Be serviced regularly

If disposable sterilization packages are used as an alternative, these must be in accordance with DIN EN (ANSI AAMI) ISO 11607 and suitable for steam sterilization (thermostable up to 141°C (285.8°F) and adequate steam permeability).

6.2 Steam Sterilization (Autoclave)

The times and temperatures specified are minimum requirements. If, for procedural reasons, the values have to be lowered, the user must validate these.

It is possible to exceed the time and temperatures specifications. However, longer sterilization times and higher temperatures stress the materials, causing them to age prematurely.

Only products which have been cleaned and disinfected can be sterilized.

Only the sterilization criteria listed below are to be used. Should the user select other forms of sterilization, then he must validate these (see below):

- Fractionated vacuum process (with adequate drying of the product)
The use of the less effective gravitation process must be approved by means of additional validation (longer sterilization times may be necessary). The gravitation process is unsuitable for lumen instruments (cannulas, handpieces).
- A steam sterilizer in accordance with DIN EN 13060 and DIN EN 285 and validated in accordance with DIN EN (ANSI AAMI) ISO 17665-1 (or when within the transition period – EN 554) (valid selection and product-specific performance qualification).
- Maximum sterilization temperature 137°C (279°F) (plus tolerance range in accordance with DIN EN (ANSI AAMI) ISO 17665-1 (or when within the transition period – EN 554)).
- Sterilization times:
 - **at least 20 minutes at 121°C (250°F), alternatively**
 - **at least 5 minutes at 132/134°C (270/273°F) ***

* The Robert Koch Institute⁵ recommends a sterilization time of 5 minutes at 134°C. This recommendation requires the use of an alkaline cleaning solution with a pH-value which is larger than 10. Should an alkaline cleaning solution not be used, then the sterilization time is to be increased to 18 minutes.

⁵ Please refer to chapter 10 "Abbreviations and Addresses"

The manufacturer will accept no liability for other sterilization processes (e.g., hot-air, ethylene oxide, formaldehyde, radiation or low-temperature plasma sterilization). Should these be selected, please refer to the corresponding valid standards (DIN EN (ANSI AAMI) ISO 14937 or process-specific standards such as DIN EN (ANSI AAMI) ISO 11135-1 (or when within the transition period – EN 550) for ethylene oxide sterilization) and be able to validate the suitability and effectiveness of the process (and if applicable, including analyses of the residue of the sterilizing agent) while taking the specific geometry of the product into consideration.

6.3 Storage

Sterilized products should be stored in a dry environment. Apart from this, no special conditions are necessary as far as storage is concerned.

The storage period is dependent on the type of packaging (please refer to Chapter 6.1).

7. Manufacturer Remarks

- Surgical instruments made from high-grade stainless steel and titanium can be reprocessed many times. It must, however, be taken into account that each chemical and thermal treatment stresses the materials, causing them to age.
- If the type of material limits the number of reprocessing cycles, this is indicated on the user instructions enclosed with the product.
- High-grade steels must not be permanently exposed to environments conducive to corrosion (e.g., chloride or iodine ions and their vapors) over long periods of time.
- Long delays before reprocessing must be avoided.
- When reprocessing manually, care must be taken that no damage is caused by the use of metal brushes, scouring agents or by the exertion of too much force.
- Products must be stored appropriately during sterilization (not on top of each other and fixed in place with sterilization strips or sterilization plates).
- Products should be sterilized in a "relaxed" state:
 - ⇒ hinges and joints open
 - ⇒ locks unlocked
 - ⇒ cannulas removed from handpieces
- Do not allow residues to dry on lumen instruments (e.g., cannula). Before they are to be laid aside, flush them out with sterile or low-bacteria (max. 10 bacteria/ml) distilled or deionized water.
- Only agents suitable for sterilization are to be used on the hinges and joints of instruments.
- The use of distilled or deionized water for all reprocessing cycles (including pre-cleaning) is recommended because tap water can cause the concentrations of ions on the surface of the steels to increase.
- Cleaning adapters accompany instruments insofar as these are needed for manual reprocessing or to connect lumen instruments to washing or disinfecting machines. Their use is explained in the cleaning instructions which accompany the product.
- It must be noted that when using alkaline cleaning solutions, certain materials such as aluminum may become corroded. In such cases, the manufacturer of the cleaning solution must be consulted.
- When using hydrogen peroxide H₂O₂ (for example in Miele's OXIVARIO[®] method), titanium instruments may become discolored. These discolorations can be attributed to changes in the thickness of the oxide layer and do not affect the quality of the instruments. This method is not suitable for products made from aluminum.

8. Manufacturer-Recommended Cleaning Solutions and Disinfectants

Geuder products should only be cleaned and disinfected with solutions and disinfectants which are appropriate for the material of the individual product. The following charts list the solutions and disinfectants of different manufacturers and the materials for which they are appropriate.

Solutions and disinfectants other than the ones listed below might also be appropriate, but in cases where they are to be used, the manufacturer should be consulted and asked if they are compatible with the materials in question.

8.1 Manuel Cleaning

Products	Stainless Steel	Adonized Aluminum	Adonized, Colored Aluminum	Titan	Silicone	PSU
Dr. Weigert, GmbH & Co. KG						
neodisher LM 2	X	X	X	X	X	X
neodisher medizym	X	X	X	X	X	X
neodisher mediclean	X	X	X	X	X	n.a.
neodisher Mediclean forte	X	X	X	X	X	X
Ecolab GmbH & Co. OHG						
Sekusept Cleaner	X	X	X	X	X	n.s.
Seku Zyme	X	X	X	X	X	n.s.
Bode Chemie GmbH & Co.						
Bodedex forte	X	X	X	X	X	X
Schülke & Mayr GmbH						
Gigazyme	X	X	X	X	X	X
S&M labor	X	n.a.	n.a.	n.a.	X	X
S&M labor flüssig	X	n.a.	n.a.	n.a.	X	X
Merz Consumer Care GmbH						
Mucadont ZYMAKTIV	X	X	X	X	X	X
Edisonite Super	X	X	X	X	X	X
Mucasol	X	n.a.	n.a.	n.s.	X	X
Edisonite	X	X	X	X	X	X

8.2 Manuel Disinfection

Products	Stainless Steel	Adonized Aluminum	Adonized, Colored Aluminum	Titan	Silicone	PSU
Dr. Weigert, GmbH & Co. KG						
neodisher Septo Med	X	X	X	X	X	X
neodisher Septo 3000	X	X	X	X	X	X
Ecolab GmbH & Co. OHG						
Sekusept aktiv	X	X	X	X	X	n.s.
Sekusept forte S	X	X	X	X	X	n.s.
Sekucid N	X	X	X	X	X	n.s.
Sekusept extra N	X	X	X	X	X	n.s.
Secucid konz.	X	X	X	X	X	n.s.

8.2 Manuel Dinfektion cont.

Products	Stainless Steel	Adonized Aluminum	Adonized, Colored Aluminum	Titan	Silicone	PSU
Bode Chemie GmbH & Co.						
Korsolex plus	X	X	X	X	X	X
Korsolex AF	X	X	X	X	n.a.	n.a.
Korsolex extra	X	X	X	X	X	n.s.
Korsolex FF	X	X	X	X	X	n.s.
Korsolex basic	X	X	X	X	X	X
Aseptisol	X	X	X	X	X	n.s.
Schülke & Mayr GmbH						
Gigasept Instru AF	X	n.a.	n.a.	X	n.a.	X
Gigasept AF	X	X	X	X	X	X
Gigasept FF	X	X	X	X	X	X
Lysetol FF	X	X	X	X	X	X
Merz Consumer Care GmbH						
Mucadont-IS	X	X	X	X	X	X
Mucocit-T	X	X	X	X	X	X
Mucocit-P	X	X	X	X	X	X

8.3 Mechanical Cleaning

Products	Stainless Steel	Adonized Aluminum	Adonized, Colored Aluminum	Titan	Silicone	PSU
Dr. Weigert, GmbH & Co. KG						
neodisher medizym	X	X	X	X	X	X
neodisher mediclean	X	X	X	X	X	X
neodisher mediclean forte	X	X	X	X	X	X
neodisher FA	X	X	n.a.	X	X	X
neodisher FA forte	X	X	n.a.	X	X	X
neodisher FM	X	n.a.	n.a.	X	X	X
neodisher MediKlar (Nachspülmittel)	X	X	X	X	X	n.a.
Ecolab GmbH & Co. OHG						
Sekumatic FR	X	n.a.	n.a.	X	X	n.s.
Sekumatic FRE	X	X	X	X	X	n.s.
Bode Chemie GmbH & Co.						
Dismoclean 24 vario	X	X	X	X	X	X
Dismoclean 21 pur	X	n.a.	n.a.	X	X	n.s.
Dismoclean 28 alka one	X	n.a.	n.a.	n.a.	X	n.s.
Schülke & Mayr GmbH						
Thermosept RKF	X	n.a.	n.a.	n.a.	X	X
Thermosept alka clean	X	n.a.	n.a.	n.a.	X	X
Thermosept RKN-zym	X	X	X	X	X	X
Thermosept RKI	X	n.a.	n.a.	n.a.	X	X
Thermosept RKA	X	n.a.	n.a.	n.a.	X	X
Merz Consumer Care GmbH						
Mucapur-AF	X	X	X	X	X	X
Mucapur-NF	X	X	X	X	X	X

8.4 Neutralisation

Products	Stainless Steel	Adonized Aluminum	Adonized, Colored Aluminum	Titan	Silicone	PSU
Dr. Weigert, GmbH & Co. KG						
neodisher Z	X	X	X	X	X	X
neodisher N	X	X	X	X	X	X
Ecolab GmbH & Co. OHG						
Sekumatic FNZ	X	X	X low concentration 0.1 %	X	X	n.s.
Sekumatic FNP	X	n.a.	n.a.	X	X	n.s.
Bode Chemie GmbH & Co.						
Dismoclean 25 acid	X	n.a.	n.a.	X	X	n.s.
Dismoclean 26 acid	X	n.a.	n.a.	X	X	n.s.
Dismoclean 64 neutra-dry	X	X	X	X	X	n.s.
Schülke & Mayr GmbH						
Thermosept NKZ	X	X	X	X	X	X
Merz Consumer Care GmbH						
Mucapur-N	X	n.a.	n.a.	n.s.	X	X
Mucapur-Z	X	X low concentration 0.1 %	X low concentration 0.1 %	n.s.	X	X

X appropriate
n.a. not appropriate
n.s. not specified

The information in these charts is the result of statements from the corresponding manufacturers and from our own experiences and tests we have conducted. Other solutions and disinfectants might also be appropriate, but in cases where these are to be used, the manufacturer should be consulted and asked if they are compatible with the materials in question.

9. Materials Used

9.1 Mechanical Cleaning/Disinfection

An independent accredited testing laboratory has verified that the products can effectively be cleaned and disinfected mechanically. In their tests they used the Disinfector *NEWAMATIC HO2-2T* of Belimed GmbH in Waldkraiburg (for thermal disinfection) and the detergent *Neodisher mediclean forte* of Dr. Weigert GmbH & Co. KG in Hamburg as a 0.7% solution. Desalinated water was used for the neutralisation, and the instructions given in Chapter 3.3 were followed.

9.2 Manual Cleaning/Disinfection

An independent accredited testing laboratory has verified that the products can effectively be cleaned and disinfected manually. In their tests they used the detergent *Bodedex forte* and the disinfectant *Korsolex plus* of Bode Chemie GmbH in Hamburg as 0.5% and 3% solutions respectively. The instructions given in Chapter 3.4 were followed.

9.3 Sterilization

An independent accredited testing laboratory has verified that the products can effectively be steam sterilized. In their tests they used the fractionated vacuum process *EuroSelectomat* of MMM Münchener Medizin Mechanik GmbH in Planegg. The instructions given in Chapter 6.2 were followed.

10. Abbreviations and Addresses

¹DGHM/VAH Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V. / Verbund für Angewandte Hygiene e.V.
(German Society for Hygiene und Microbiology) / (Association for Applied Hygiene)

www.dghm.org, www.vah-online.de

The list of disinfectants which the disinfectant commission of the VAH in cooperation with the DGHM has found to be effective can be obtained from:

mhp-Verlag
Marktplatz 13
65183 Wiesbaden

²FDA U.S. Food and Drug Administration
www.fda.gov

³Pharm. Eur. European Pharmacopeia

⁴USP U.S. Pharmacopeia
www.usp.org

⁵RKI Robert Koch Institute
Nordufer 20
13353 Berlin
www.rki.de