AGO MED

INSTRUCTION FOR USE

SURGICAL INSTRUMENTS

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VERSION 03

AGOMED MEDIZIN-TECHNIK GMBH

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PRODUCTS

The reprocessing instructions are valid for the following AGOMED product groups:

- Screwdrivers (blade and handle)
- Measuring instruments and gauges
- Tweezers
- Bending instruments
- Pliers / Rongeurs
- Spreader
- Scissors / Shears
- Levers
- Files
- Curettes
- Rasps
- Chisels
- Hammer
- Drill guides / aiming devices / drill guide handles / drill jig attachments
- Awls / Reamers / Drills / Positioning pins / Cutters
- Silicone hand and rings

IMPORTANT NOTES

Read these operating instructions carefully before use and keep them easily accessible for the user or operator.

Read the warnings marked with this symbol carefully. Improper use of the products may result in serious injuries to the patient, operators or third parties.

COMPLICATIONS AND UNDESIRABLE SIDE EFFECTS

None known.

SERIOUS EVENTS

Any serious incident occurring in relation to the medical device must be reported to the manufacturer and the competent authority in the Member State where the user and/or patient is located.

WARNINGS

AGOMED instruments are designed and manufactured so that their safe function is commensurate with the scope of their intended use. However, if a metallic instrument (e.g., steel, aluminum, titanium and its alloy, etc.) breaks during use, a medical imaging device (e.g., CT, X-ray, etc.) may be helpful in locating fragments and/or components of the instrument.

Surgically used instruments can pose a biohazard and facilities must ensure that transport and handling procedures comply with locally applicable regulations and guidelines.

Care must be taken when handling and cleaning sharp-edged instruments.

All products must be thoroughly cleaned and inspected prior to sterilization. Long, narrow cavities, blind holes, moving and complex parts require special attention during cleaning and inspection. Only cleaning agents labeled for use with medical devices may be used for cleaning. Follow the manufacturer's instructions. Cleaning agents with an applied dilution with a pH value between 7-9 are recommended. Strongly alkaline conditions (pH >10) can damage the components / products, e.g. made of aluminum. Do not use saline, environmental disinfectants (including chlorine solutions) or surgical antiseptics (such as products containing iodine or chlorhexidine). Do not use any cleaning agent that could damage the surface of the instruments.

MATERIAL AND MATERIAL RESISTANCE

The instruments are made of stainless steel. During sterilization, the instruments may be exposed to temperatures of 141°C maximum. The following warnings must be observed when selecting cleaning agents and disinfectants:

- Avoid high concentrations of chlorine
- Avoid use of oxalic acid
- Avoid use of hydrogen peroxide (H2O2)

SAFETY INSTRUCTIONS

The instruments are delivered exclusively UNSTERIL and must be cleaned, disinfected and sterilized before each use. This also applies to the first use after delivery (after removing the transport packaging).

REPROCESSING AND STERILIZATION

General:

Effective cleaning and disinfection is an indispensable prerequisite for effective sterilization. Agomed recommends only machine reprocessing. As part of your responsibility for the sterility of the individual components during use, please note as a matter of principle that

- Only sufficiently device- and product-specific validated procedures are used for cleaning/disinfection and sterilization,
- The devices used are regularly maintained and checked,
- The validated and/or manufacturer-recommended parameters are adhered to for each cycle.

In addition, please observe the legal regulations valid in your country as well as the hygiene regulations of the hospital. This applies in particular to the different specifications regarding effective prion activation. Agomed recommends in case of contact of products with elusive pathogens, such as variant Creutzfeld-Jakob disease (pathogen confirmed or suspected), to discard the products.

Cleaning agents, disinfectants and equipment:
When selecting the cleaning agents, disinfectants and equipment to be used, care must be taken at all steps to ensure that

- these are suitable for the intended application (e.g. cleaning, disinfection, ultrasonic cleaning of medical devices),
- the cleaning agents and disinfectants are aldehyde-free (otherwise fixation of blood contamination),
- these have a tested effectiveness (e.g. VAH/DGHM or CE marking),
- the cleaning and disinfection agents are suitable for the products and compatible with the products,
- the manufacturer's instructions, e.g. with regard to concentration, exposure time and temperature, are observed.

Auxiliaries:
Never clean the products with metal brushes or steel wool; failure to do so may damage the material. Use clean, lint-free cloths (e.g. Perform classic from Schülke & Mayr) and/or soft brushes (e.g. Justman Brush from VWR International) as aids. For drying, we recommend lint-free disposable cloths or medical compressed air.

Water:
With regard to water quality, we recommend using dematerialized and purified water (e.g. Aquapurificata) for the cleaning, disinfection as well as post-rinsing steps. High concentrations of minerals and/or contamination with microorganisms and the like can lead to stains on the products or even prevent effective cleaning and decontamination. For the following sections, the following definitions regarding water temperature must be observed:

- Cold water: temperature < 40°C
- Warm water: temperature > 40°C

LIMITS OF REPROCESSING

Repeated reprocessing cycles in accordance with these instructions will have minimal effect on the life or function of the product. Instruments do not have an unlimited functional life. The life of instruments depends on wear and possible damage resulting from surgical use and handling. Signs of damage and wear to a product may include, but are not limited to, corrosion (e.g., rust, pitting), discoloration, deep scratches, flaking, wear, and cracks. Equipment that is not functioning properly, equipment with unrecognizable markings, missing or removed (abraded) part numbers, and damaged and excessively worn equipment must not be used.

PREPARATION FOR CLEANING, DISINFECTION AND STERILIZATION

Laying down and preparing the instruments after the operation:
The first steps of proper reprocessing begin in the operating room. Coarse soiling, residues of hemostatic agents, skin disinfectants and lubricants as well as corrosive drugs should be removed, if possible, before the instruments are deposited. When discarding the instruments, the following must be observed: improper "dropping" of the instruments can damage them. Therefore, care must be taken to ensure that the instruments are deposited properly and that the instrument trays are not overfilled. If possible, dry disposal is preferred for transport to the cleaning/sterilization department. In the case of wet disposal, the instruments are placed in the appropriate cleaning solution immediately after the operation. The products should be reprocessed as quickly as possible to avoid drying of blood residues or similar and not to exceed the insertion time in the case of wet disposal (risk of material damage).

MECHANICAL CLEANING AND DISINFECTION

For machine reprocessing, the products are preferably taken from dry disposal. In the case of wet disposal, the products must be thoroughly rinsed after pretreatment, as foam can reduce the rinsing pressure during machine cleaning and impair the result. When selecting and using cleaning agents and disinfectants, the instructions in the previous chapter must be observed. Unless thermal disinfection is used in machine cleaning and disinfection, care must be taken to ensure that the disinfectant used is compatible with the cleaning agent.

When selecting the disinfector, it must be ensured that the following phases are part of a cleaning process in accordance with EN ISO 15883:

Phase	Temperature	Duration (min.)	Action
Pre-cleaning	Cold (T < 40 ° C / 104 ° F)	1	Rinsing with cold water
Cleaning	55 ° C (± 2 °C) 131 ° F (± 4 °F)	10*	Addition of the detergent
Neutralization	Cold (T < 40 ° C / 104 ° F)	2	Neutralize with deionized water
Rinsing	Cold (T < 40 ° C / 104 ° F)	1	Neutralize with deionized water
Thermal dis-infection (A0 value 3000)	≥ 90 ° C (194 ° F)	5	With dematerialized and purified water; do not add additional detergent
Dry	Device-specific (T< 141 ° C / 286 ° F) e.g. 100°C (program parameter)	Device-specific e.g. 30 min	Drying process

** The information given refers to the use of "Neodisher Medi Clean forte" from Dr. Weigert; the validation was carried out with a concentration of 0.2% at 50°C in a Miele PG 8535. If a different cleaner is used, exposure times, temperatures and concentrations may vary. The corresponding manufacturer's instructions must be observed.*

PROCEDURE FOR MACHINE CLEANING AND DISINFECTION

1. Place the products in the washer-disinfector (WD). The following must be observed
   - the loading patterns specified during validation are always observed,
   - the products are placed according to their sensitivity in such a way that damage is excluded.
2. Start the program
3. Remove the products from the washer-disinfector at the end of the program
4. Finally inspect the products (see chapter Inspection)
5. Pack the products in a clean place as soon as possible, if necessary after additional post-drying.

CHECK

Check AGOMED instruments after reprocessing and before sterilization for signs of end of product life:

- Cleanliness: If residues of contamination are detected during the visual inspection, repeat the cleaning steps for the affected medical devices until all visible contamination has been removed.
- Moisture: Carefully check the cavities and moving parts of the medical devices. If moisture is still present, the medical device must be dried manually.
- Damage, including signs of corrosion (e.g., rust, pitting), discoloration, deep scratches, peeling, cracks, and wear.
- Proper function, including, but not limited to, sharpness of cutting tools, pliability of flexible medical devices, mobility of hinges/joints/box locks and moving parts, such as handles, ratchets and couplings. Damaged or worn medical devices should not be used.

Lubricate instruments with moving components, e.g. hinges, articulated joints, spring-loaded ball bearings and threaded parts. It is recommended that only special oil (kerosene oil) be used for lubricating Agomed instruments during maintenance and care. Unless otherwise noted, disassembled instruments must be reassembled prior to sterilization, unless the case is not designed for the assembled instrument.

STERILIZATION

All UNSTERILE products can be sterilized with steam in an autoclave. The autoclave must comply with EN 285 or EN 13060 with regard to validation, maintenance and control. For the initial and subsequent sterilization, the parameters listed below have been validated in a Tuttnauer EHS 3870 according to the requirements of the current sterilization standards, EN ISO 17665 and ANSI AAMIST79.

Procedure	Parameters
Exposure duration	≥ 4 min.
Temperature	132 ° C / 134° C I 269,6 ° F – 273,2 ° F
Drying time	> 20 – 30 Min.

AGOMED recommends sterilization according to the validated procedures listed above. If other procedures are used by the user, they must be validated by the user. The ultimate responsibility for the validation of sterilization techniques and sterilization equipment lies with the user.

STORAGE CONDITIONS

After sterilization, the sterilized material must be stored in a dry and dust-free environment. Temperature fluctuations must be avoided to prevent corrosion damage. The maximum storage time depends on various factors such as packaging, storage methods, ambient conditions and handling. The user himself should define a maximum storage time for sterile products until use. Within this time, the products must be used or, if necessary, reprocessed (sterilized).

PACKAGING

Sterilization must be performed in single-use sterilization packaging and/or sterilization containers. These must comply with the applicable requirements (e.g. DINENISO/ ANSIAAMIISO11607/ISO11607/EN868), be suitable for the sterilization process and provide sufficient protection against mechanical damage. Regular maintenance in accordance with the manufacturer's specifications must be carried out.

DISPOSAL

The instruments must be disposed of in an environmentally friendly manner in accordance with valid hospital guidelines and taking into account applicable national laws and guidelines.

MATERIAL COMPATIBILITY OF AGOMED INSTRUMENTS

Knowledge of the materials used and their properties is essential to ensure expert preparation and maintenance of the instruments.

Steel:
AGOMED instruments are mainly made of corrosion-resistant steel, recognizable by its shiny or matte metallic color. Due to its high chromium and nickel content, corrosion-resistant steel forms a protective chromium oxide layer on the metal surface, also known as a passive layer. This passive layer protects the instrument from corrosion and rust. Incorrect or improper handling (e.g., damage to the surface) and chemical, electrochemical, or physical attack can affect corrosion resistance.

Two types of steel are used, distinguished by their composition and properties:

- Martensitic steel has high wear resistance and strong cutting ability, is corrosion resistant and its high hardness can be

influenced and adjusted by heat treatment. This steel is used for cutting and sharp pointed instruments, such as drills, drill heads, awls, milling cutters or cutting edges of pliers.

- Austenitic steel cannot be hardened by heat treatment and has high corrosion resistance, elasticity and robustness and is generally non-magnetic. This steel is used for non-cutting instruments, e.g. drill sleeves, measuring and aiming instruments.

AGOMED recommends disinfectant solutions or cleaning agents with a pH value of 7-11 for all types of steel.

Aluminum, titanium and its alloys:
Because aluminum is a lightweight material, it is used, for example, for cases, instrument handles and certain other instrument parts. An electrochemical surface treatment (anodizing) creates a resistant oxide layer on the aluminum, which can be colored.

Titanium or titanium alloys are widely used materials for implants. For instruments, titanium is used for only a few applications, mainly for color coding of instruments. The surface of titanium alloys is also electrochemically treated (anodizing), which creates a resistant oxide layer. With the help of this layer, different color shades can be applied.

Even though anodized aluminum, titanium and its alloys have good corrosion resistance, contact with strong alkaline cleaning or disinfecting agents and solutions containing iodine or certain metal salts, depending on the specific composition of the cleaning agent, can lead to chemical attack and dissolution of the surface.

For this reason, Agomed recommends disinfectants or cleaning agents with a pH of 6-9.5. Products with a higher pH, especially a pH higher than 11, should only be used subject to the material compatibility requirements listed on the data sheet and other information from the cleaning agent manufacturer.

Plastics:
Various types of plastic are used for specific instrument parts, such as handles. In addition to pure plastic, composite materials are also used in some cases, e.g. phenolic resin in wood look, reinforced with fabric for handles of screwdrivers, raspatories, chisels, etc., or plastics reinforced with carbon fiber.

All plastics used withstand correct reprocessing. Some plastics may soften during steam sterilization, but they do not experience permanent deformation at normal sterilization temperatures below 140 °C. However, the material can be damaged, for example, by repeated immersion in disinfectant with a pH outside the range of 4-9.5 and by overloading.
In addition, some rinsing aids can cause discoloration or embrittlement of plastics and composites with repeated use.

Recommended temperatures and pH values:

Material	Temperature	pH-Values
Steel	Up to 141 °C	7 - 11
Aluminium	Up to 150 °C	6 - 9,5
Titanium alloys	Up to 150 °C	6 - 9,5
Plastics	Up to 150 °C	4 - 9,5

Causes of corrosion and alteration or damage to the surface:
The surface of the instruments can be attacked and damaged by incorrect handling or contact with various substances. Knowledge of the following possible causes of corrosion and material damage can help prevent their occurrence.

Blood, pus, secretions, etc.:
Most human body fluids and residues contain chlorine ions that can cause corrosion if they remain attached to or dry on the instrument for extended periods of time. Therefore, the instruments should be cleaned and dried immediately after each use.

Salt solutions, iodine tinctures, water:
The chlorine and iodine ions in these solutions can cause pitting. Contact with these ions must be kept to a minimum. Rinse the instruments thoroughly with distilled water* to remove all residues. Normal tap water also often contains chlorides, as well as high concentrations of other minerals, which can form marks with strongly defined edges on the surface of the instrument. These can usually be removed using distilled water* and abrasion-resistant steel cleaners. Never leave the instruments in a wet state for a prolonged period of time. They should always be dried immediately. Condensation moisture generated during sterilization can be avoided by extending the drying phase.

** A conductivity of < 0.5 µS is recommended for distilled water.*

Detergents, disinfectants, rinsing aids and other additives:
Excessive concentrations of these products or highly acidic or alkaline cleaning agents may attack the protective oxide layer of steel, titanium and aluminum and cause corrosion, discoloration or other changes in materials, properties and surface conditions. When using such products, always follow the manufacturer's recommendations for concentrations, contact time, temperatures and material compatibility. Products with pH values between 7 and 9.5 are recommended. With repeated and prolonged use, some rinsing elements may attack certain plastics and cause discoloration or embrittlement. If the instruments are cleaned in an automatic washer/disinfector, the instructions of the respective manufacturers of the washer/disinfector, cleaning agents, rinsing elements and other additives must be observed.

Steel wool, steel brushes, files and other abrasive cleaning accessories:
Extra-fine or normal steel wool, steel brushes, files or other cleaning accessories with an abrasive effect on metals should never be used to clean surgical instruments, as this can lead to mechanical damage to the passive layer and thus to corrosion and malfunction.

Insufficient lubrication:
Moving instrument parts, such as joints, sliding elements, detachable threaded connections, etc., must be lubricated regularly. Constant metallic abrasion increases damage to the passive layer and thus significantly increases the risk of corrosion.

Residues of cleaning agents in packaging cloths:
Wipes used to wrap medical devices for sterilization must not contain residues of cleaning agents or other residues. Residues

of this type can be transferred to and interact with the surface of the medical device via steam.

Overloading of instruments:
Instruments are designed for a specific purpose only and must be used accordingly. Improper use can lead to mechanical overload, malfunction and permanent damage to the instrument, which in turn increases its susceptibility to corrosion.

Note on latex:
Since AGOMED instruments do not contain latex, they can be used safely in patients with a latex allergy.

REPAIRS AND SPARE PARTS

Faulty instruments can be sent to us for repair. Customer service will assess whether the instrument can be repaired or not. When returning the faulty instrument, please include a delivery bill with the following information:

- Clinic address, contact person and telephone number
- Item number of the returned faulty instrument
- Description of the problem

EXPLANATION OF THE SYMBOLS

HerstellerManufacturer

Production lot number, batch

Part number

Follow the instructions for use

Non-sterile

Medical device

Warning

Latex free

Protect from sunlight

Store dry

Caution: Federal law restricts this device to sale by or on the order of a physician.

Conformity with Medical Device Directive MDD 93/42/EEC