Instructions for Use
Reusable Surgical Instruments

These instructions for use fulfill the European Union's Medical Device Regulation 2017/745 for medical device instruction for use and reprocessing instructions.

To ensure hazards are as low as possible for patients and users, we request that you carefully observe these instructions for use. The application, disinfection, cleaning and sterilization of the medical device must only be performed by trained specialist personnel. As these devices are sold in a non-sterile state, they must be sterilized before each use.

Inspections
Before every use, the medical device must be checked for its functionality.

Damage on the surface, such as scratches, cracks, notches, grooves etc., as well as bent components, indicates the medical device must not be used. The medical device must then be repaired or disposed of by the medical facility. Do not use any damaged medical devices!

Application area
Our medical devices are standard, common-use instruments for surgical application in general surgery. However, the treating physician is responsible for the selection of instruments for certain surgical applications. The physician is also responsible for the appropriate training and sufficient briefing of the surgery personnel, proper handling during and following intended use, and for sufficient experience in the handling of the instruments.

Handling
The instruments must not be overstressed through twisting or levering, as this can lead to damage or to fracturing of instrument components.

Risks
If the instruments are not handled very carefully, then the following risks can occur:
- Damage of nerves, vessels and tissue
- Bleeding
- Infections

Application duration: Transient (< 60 minutes under normal conditions)

1. Indications

These instruments are to be used by medical professionals only for the intended use of general surgery or clinical use.

2. Contraindications

These devices cannot be used without the recommended reprocessing and sterilization settings and process outlined in this document. These devices cannot be used by individuals who are not medical professionals. These devices should not be used in non-clinical or non-surgical applications.

Combination with other products / instruments
Artemamed instruments should not be combined with products and components from other manufacturers.Combinations with products from other manufacturers can negatively influence the result of the intervention and are not permitted, as the used components are possibly not matched to each other.

During surgery it is recommended to exclusively use the instruments and accessories from Artemamed.

Correct disposal of the instruments

When the instruments are no longer able to be used due to wear, tear, or damage, they are to be subject to correct disposal. This means that the instruments are to be disassembled (as much as possible), the contaminations removed, and then the instruments are to be sterilized once more before the disposal. Take care to properly dispose of instruments with sharp or cutting edges.

3. Application

Attention! The instruments must not be overstressed through twisting or levering as this can lead to damage or to fracturing of instrument components.

4. Control

Perform checks before and after every application. Do not use instruments that are damaged, incomplete, or have loose components. Send damaged instruments with the loose components for repair. Do not undertake repair attempts on your own.

- Check instruments for damage, sharp edges, loose or missing components and rough surfaces.
- The opening and closing action must be a smooth movement without excessive play.

Instruction on reconditioning

Reconditioning cycles

Due to the product design and the materials used, no defined limit of the maximum reconditioning cycles to be performed can be specified. The end of the product life-cycle is normally determined by the wear, tear, and damage through use. If an instrument is displaying signs of material degradation, cracking, or breakage, the instrument cannot be reused and must be disposed of properly.

Preparation at the site of application

If possible the instruments should be disinfected with a non-adherent disinfectant and cleaned immediately after use. Remove coarse contaminants from the instruments directly after the application. The contaminants should not dry on the objects, so as to not impede the disinfection and cleaning processes. Do not use any adhesive agents as this leads to residue and can influence the success of the cleaning.

The instruments must under no circumstances be deposited in saline solution, as longer contact leads to pitting, corrosion, and rust.

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Preliminary Cleaning

Deposit instruments in cold deionized (DI) water for at least 5 minutes. Clean instruments under cold DI water with a soft brush until residues are no longer visible. Deposit instruments for 15 minutes in an ultrasonic bath in DI water at 40°C with 0.5% alkaline cleaning agent and start the treatment. Ultrasonic frequency of at least 35 kHz is recommended. Remove instruments and rinse with cold DI water.

After the completion of preliminary cleaning, the end-user has the option to perform either Manual Cleaning and Disinfection ***or*** Machine (Automatic) Cleaning and Thermal Disinfection.

Manual Cleaning and Disinfection

After the preliminary cleaning, the instructions for Manual Cleaning and Disinfection may be used as an alternative cleaning method to the Machine (Automatic) Cleaning and Thermal Disinfection.
CAUTION: Manual cleaning is not an appropriate method for cleaning hand instruments containing non-exposed actuating components, e.g. wishbone handle or standard handled graspers, punches, etc. The Machine (Automatic) Cleaning and Thermal Disinfection procedure should be followed for these instruments.

1. Immerse the instrument for 5 minutes in an 0.5% (v/v) enzymatic or alkaline cleaning detergent solution. Cleaning solutions may include, but are not limited to: ENZOL® enzymatic, neodisher® Mediclean forte, and Thermosept® alka clean. **CAUTION: Low acid or high alkaline solutions are not recommended, as they corrode metal parts and anodized aluminum and compromise polymer plastics, such as FEP (Fluorinatedethylenepropylene), ABS (Acrylonitrile Butadiene Styrene), Ultem™, Lexan™, and Cycolac™. If non-neutral pH cleaning chemistries are utilized, care should be taken to ensure appropriate rinsing, as validated by the end-user facility, and neutralization steps are taken so as to not negatively impact the fit, finish, or function of the device.** Cleaning solutions should always be mixed to the manufacturer's specification for concentration and cleaning should be conducted at ambient temperature unless otherwise stated in the cleaning solution manufacturer's instructions.

2. Scrub the instrument with a soft bristled brush, paying special attention to areas where debris might accumulate. Always avoid any harsh materials that can scratch or mar the surface of the instrument. Immerse the instrument in detergent, agitate and allow it to soak for one minute.

3. Rinse the instrument thoroughly with cold distilled water for at least 4 minutes after the cleaning process.

4. Immerse instruments in 1% v/v concentration disinfection solutions for a minimum of 20 minutes. Suitable disinfection solutions may include, but are not limited to: Bomix® plus, CIDEX®, WAVICIDE®-01, Gigasept®, Kohrsolin®, and equivalent products). Use the supplier's instructions for preparing the solution. **CAUTION: Low acid or high alkaline solutions are not recommended, as they corrode metal parts and anodized aluminum and compromise polymer plastics, such as FEP (Fluorinatedethylenepropylene), ABS (Acrylonitrile Butadiene Styrene), Ultem™, Lexan™, and Cycolac™. If non-neutral pH disinfection chemistries are utilized, care should be taken to ensure appropriate rinsing, as validated by the end-user facility, and neutralization steps are taken so as to not negatively impact the fit, finish, or function of the device.** Disinfection solutions should always be mixed to the manufacturer's specification for concentration.

5. After disinfection, the instruments should be rinsed for at least 4 minutes with cold distilled water or deionized sterile water. This procedure has been validated.

6. Dry instruments thoroughly clean utilizing compressed air, non-linting wipes, or an oven.

7. Check the instruments for visible soil. Repeat the cleaning if soil is visible, then re-inspect.

Machine (Automatic) Cleaning and Thermal Disinfection

After the preliminary cleaning, the instructions for Machine (Automatic) Cleaning and Thermal Disinfection may be used as an alternative cleaning method to the Manual Cleaning and Disinfection.

1. Load the instruments in the washer so that all design features of the device are accessible to cleaning and any that may retain liquid can drain (hinges should be open and cannulations/holes positioned to drain). Only use deionized water.
2. Run the automatic wash cycle. The minimum cycle parameters are listed below:

Minimum Washing Cycle Parameters			
Phase	**Recirculation Time**	**Temperature**	**Detergent**
Cold Pre-Wash	3 Minutes	20 °C (68 °F)	N/A
Cleaning Wash	10 Minutes	65.5 °C (150 °F)	Enzymatic or alkaline agent
Rinse 1	3 Minutes	50 °C (122 °F)	N/A
Rinse 2	3 Minutes	50 °C (122 °F)	N/A
Thermal Disinfection Rinse	5 Minutes	93 °C (194 °F)	N/A
Drying	20 Minutes	115°C (239°F)	N/A

3. Automatic wash cleaning solutions may include, but are not limited to: neodisher® Mediclean forte, Thermosept® alka clean, Prolystica® Ultra Concentrate Enzymatic Cleaner, and ProKlenz NpH Neutral Detegent. **CAUTION: Low acid or high alkaline solutions are not recommended, as they corrode metal parts and anodized aluminum and compromise polymer plastics, such as FEP (Fluorinat-edethylenepropylene), ABS (Acrylonitrile Butadiene Styrene), Ultem™, Lexan™, and Cycolac™. If non-neutral pH cleaning chemistries are utilized, care should be taken to ensure appropriate rinsing, as validated by the end-user facility, and neutralization steps are taken so as to not negatively impact the fit, finish, or function of the device.**

4. Check the instruments for visible soil. Repeat the cleaning if soil is visible, then re-inspect.

The above listed procedures have been validated.

Inspection and Maintenance

1. Artemamed non-sterile instruments are precision medical instruments and must be used and handled withcare.

2. Inspect the instruments for damage prior to use and at all stages of handling.

3. Devices with cutting functions or sharp points become dull with continuous use. This condition does not indicate a device defect. This condition indicates normal wear. Dull devices may require replacement if they no longer perform as designed. Inspection prior to use should include verifying the cutting ability and sharpness of these edges.

4. If damage is detected, do not use the device prior to consulting the manufacturer for guidance.

5. Dry the instruments thoroughly and lubricate all moving parts with a water-soluble instrument lubricant, prior to sterilization. Acceptable lubricants may include, but are not limited to: Steris Hinge-Free® Instrument Lubricant and neodisher® IP Spray. Apply lubricants in accordance with manufacturer's instructions. After drying, package the instruments in common hospital sterilization packaging (paper film), according to ISO 11607-1 and DIN EN 868-2, in preparation of the sterilization procedure.

Sterilization

Artemamed devices are provided non-sterile and must be adequately cleaned and sterilized prior to use orre-use. (See above instructions for cleaning).
Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

Follow your country-specific guidelines, standards, and requirements.

These sterilization settings have been validated.

Sterilization Parameters			
Method	**Exposure Temperature**	**Exposure Time**	**Drying Time**
Pre-Vacuum Cycle	134°C	5 Minutes	20 Minutes

Cooling – The instrument must be adequately cooled after being removed from the sterilizer. It should not be touched during the cooling process. Do not place the instrument on a cold surface or immerse it in a cold fluid.

Should the user deviate from the specified procedure, then the selected procedure must be validated by the user. Disinfection and cleaning solutions should be freshly prepared on a daily basis. With longer term use, the following problems can arise: hazard of corrosion through contamination, hazard of corrosion with increased concentration through evaporation, reduction of the disinfection effect through contamination. The residues from the cleaning process must be removed, as otherwise stains and/or discolorations occur on the instruments.
The application of other different cleaning and disinfection agents takes place outside of the responsibility of the manufacturer. The recommendations of the manufacturer of the cleaning and disinfection agents are to be observed.
The reconditioner undertakes the responsibility that the reconditioning is actually performed with the appropriate equipment, materials and personnel at the reconditioning facility in order to achieve the desired results. For this, validation and routine monitoring of the procedure is necessary.
Based upon the patient's general health condition, the responsible physician must decide whether the intended surgery can take place.

With suspected or diagnosed prion-based diseases, measures are to be undertaken that prevent a possible transmission to other patients, users and third parties. In the event of the application of the instruments to patients infected by prion-based diseases or HIV, we reject all responsibility for the reuse of those instruments.

If the instrument has been used on a patient with a confirmed or suspected transmissible spongiform encephalopathy, such as Creutzfeldt Jakob Disease (CJD), the instrument cannot be used again. Even with processing and sterilization, the risk of cross contamination cannot be eliminated, so the instrument must be destroyed.

Shipping for repair at Artemamed

Instruments for repair will only be accepted if these have been cleaned, disinfected and sterilized according to the above described reconditioning instructions. A certificate of sterilization is to be enclosed with the return shipment. For more useful information, please visit www.gSource.com.

Use as intended / misuse

The instruments must be exclusively used as intended in the specialized medical areas by trained and qualified personnel.
The treating physician, respectively the user, is responsible for the selection of the instruments for certain applications, respectively the surgical application, the appropriate training and information and the sufficient experience in the handling of the instruments.
Misuse, deficient care and reconditioning, incorrect handling, misappropriation and modifications to the instrument can severely impair its usability, cause damage and be the reason for serious injuries to the patient and user.

Avoid BA

Instruments with tungsten carbide (TC), such as wire cutters, needle holders, scissors, etc. should never be immersed in sterilizing solutions containing benzyl ammonium chloride (BAC). BAC can also be known under the abbreviations BZK, BKC, BAK, and ADBAC. BAC will soften and dissolve the tungsten carbide. Never use bleach as it will cause severe pitting.

Guarantee

This product is manufactured from high quality materials and is subject to quality control. If faults should occur, please contact customer service. For complete guarantee information, visit www.gSource.com.
We are, however, not able to undertake any guarantee that the product is suitable for the respective application. This must be ascertained by the user.
gSource does not accept any liability if these instructions for use have not been observed.

Serious Incidents

If any serious incident has occurred in relation to a Artema medical device, please report the serious incident to Artemamed, the proper authorities, and, if applicable, the competent authority of the Member State in which the user and/or patient is established.

Storage and transport

- Temperature: -20°C - +50°C

- Relative air humidity: 0 - 75%, non-condensing
- Air pressure: 500 - 1600 hPa

Meaning of the symbols

Product is Delivered Non-Sterile


Attention, Observe Notes


Observe Instructions for Use

Authorized European Representative Information

Catalog Number / Reference


Date of Manufacture


Manufacturer Information

Lot Number

Medical Device

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