SOS SURGICAL CO.

Mughal Pura, Gohadpur, Sialkot-Pakistan

Instructions for Use (IFU)	Revision 08: 05-Sep-2025	Copy # IFU-02
Reviewed and approved by Dr. Thomas Warnke		
Title: PRRC	Signature: (Verified when signed in black ink)	Thomas Warnke

11.0. Recommended Handling / Instructions for Use for Class I Medical Instruments

Introduction: These instructions comply with ISO 17664 and the applicable requirements of Annex I, Section 23.4 of Regulation (EU) 2017/745 on medical devices. They apply to:

Class I medical devices supplied by SOS Surgical Co. that consist of fixed assemblies, with the exception of those containing aluminum alloys. These instruments include specific design features such as hinges/box joints, threaded connections, lumens, forceps, and ratchets. A list of these Class I medical devices can be found in Section 11.15.

In countries where stricter requirements apply than those specified in this document, the user is responsible for compliance with the applicable laws and regulations. These instructions have been validated as suitable for Class I medical devices supplied by SOS Surgical Co. for medical use. It is the responsibility of the user/hospital/healthcare provider to ensure that cleaning is performed with appropriate equipment and materials, and that personnel are adequately trained to achieve the intended result. Any deviation by the user/hospital/healthcare provider from these instructions should be evaluated for its effectiveness in order to avoid potential adverse consequences.

11.1 WARNINGS	Unless otherwise specified, instruments supplied by SOS Surgical Company are delivered non-sterile and must be cleaned, lubricated (if required), and sterilized prior to use in accordance with hospital protocols and procedures described in this document. Reuse without sterilization poses a risk of infection to patients and/or users. Instruments must be sterilized before use. Refer to the sterilization instructions. To prevent the coagulation of mucus, blood, or other body fluids, do not immerse the instruments in hot water, alcohol, disinfectants, or antiseptics. Immersion in a solution should not exceed two hours. Do not use steel wool, wire brushes, pipe cleaners, or abrasive agents to remove biological contamination, as these may damage the instrument and cause corrosion. To protect the surface coating of black-finished instruments, store them separately from other instruments and avoid mechanical cleaning or abrasive agents, as these procedures may scratch the surface and remove the coating. Water quality may affect the outcome of instrument cleaning and disinfection. Therefore, only deionized water or purified/highly purified water should be used for all steps requiring water. Corrosion of instruments may be caused by high levels of chloride or other minerals in tap water. If stains or corrosion occur and other causes can be excluded, the quality of the tap water in your region may need to be evaluated. Most water quality issues can be avoided by using deionized water. Use of an instrument for purposes other than its intended use, as well as improper, ineffective, or insufficient maintenance, may significantly reduce the service life of the instrument and void the warranty. Specific instructions for the cleaning of medical devices can be found in the national infection control/prevention protocols. These medical devices must only be used by qualified personnel. Long, narrow cannulas and blind ends require special attention during cleaning.
11.2 Limitations	Repeated cleaning in accordance with these instructions has, unless otherwise specified, only minimal effects on the metal of Class I medical devices supplied by SOS Surgical Co. The end of the service life of medical devices made of stainless steel or other metals is generally determined by wear and damage arising during intended medical use. For replacement needs, please contact your responsible SOS Surgical Co. representative. For the reprocessing of Class I medical devices supplied by SOS Surgical Co., the use of non-foaming, alkaline, enzymatic cleaning agents is recommended (e.g., neodisher® Mediclean Forte from Dr. Weigert). Alkaline agents with a pH value of 12 or below may be used for cleaning stainless steel medical devices if required by law or local regulations, or where prion diseases such as transmissible spongiform encephalopathy (TSE) and Creutzfeldt-Jakob disease (CJD) present a risk. It is essential that alkaline cleaning agents are completely and thoroughly neutralized.
11.3 VALIDATED CLEANING INSTRUCTIONS	
Pre-Treatment at the Point of Use	• Pre-treatment should be carried out as soon as possible (within 2 hours) after use of the device. This timeframe is critical to prevent contaminants from adhering firmly to the device. • Rinse the device thoroughly with lukewarm water {not exceeding 43 °C (110 °F)} to remove visible residues. Cold or hot water should be avoided, as it may cause organic material to adhere more strongly to the device. • Remove visible biological contamination from the medical devices immediately after use with a disposable cloth or a lint-free wipe. • Perform a preliminary inspection to ensure that there are no visible signs of damage or contamination that could impair the use of the device. • Place the devices in a container with distilled water to loosen dried/encrusted soil. Carefully inspect the used medical devices and, if necessary, use enzymatic solutions (e.g., neodisher® Mediclean Forte from Dr. Weigert, or other compatible cleaning solutions commercially available) for pre-treatment. **Note:** Do not allow organic residues to dry on the instrument, as this may impede effective cleaning. Soaking in an enzymatic solution (according to the instructions of the enzymatic solution manufacturer) facilitates soil

	loosening/cleaning, particularly for medical devices with complex features such as hinges/box joints, threaded connections, lumens, blind ends, and ratchets.
Transportation	• Used medical devices must be transported to the decontamination area in closed or covered containers in order to avoid unnecessary contamination risks. • Likewise, reprocessed/sterilized instruments must be transported to the point of use in closed or covered sterile containers.
Preparation before cleaning	• Keep the working ends open for cleaning. Disassembly is not required, as the instruments described in this Instructions for Use cannot be disassembled. • All cleaning solutions should be prepared at the dilution and temperature recommended by the manufacturer of the cleaning solution. Softened tap water may be used for the preparation of cleaning solutions.
Automated Cleaning and Disinfection	**Equipment:** Uniclean PL II 10 washer-disinfector and/or any other washer-disinfector compliant with ISO 15883; process chemicals (e.g., neodisher® Mediclean Forte from Dr. Weigert or other compatible cleaning solutions commercially available) for pre-treatment. **Procedure:** 1. Connect flushing nozzle / system to washer disinfector. 2. Load the instruments such that hinges are open and cannulations and blind ends can drain. 3. Pre-wash with warm water for > 1 minute, temperature < 40 °C. 4. Drain. 5. Repeat pre-wash with warm water for 3 minutes, temperature < 40 °C. 6. Drain. 7. Clean with 0.5% alkaline detergent for > 5 minutes at 55 °C (e.g., neodisher® Mediclean Forte 0.5%). 8. Drain. 9. Neutralize with warm water at approx. 40 °C for 3 minutes, using neutralizing agent (e.g., neodisher® Z 0.1%). 10. Drain. 11. Rinse with deionized water for 3 minutes at approx. 40 °C. Instruments with hinges/joints, threaded connections, lumens, blind ends, serrations, ratchets, and other difficult-to-access areas must be rinsed using the spray arm/system available in the washer. 12. Drain. 13. Thermal disinfection at > 90 °C (minimum A_0 = 3000) for 5 minutes. 14. Drying in the washer-disinfector: 15–25 minutes at 90–110 °C. Adequate drying must be ensured by the washer-disinfector. If necessary, compressed air may additionally be used to achieve complete drying. 15. After completion of the entire cleaning, disinfection, and drying program, remove the products from the washer-disinfector and allow them to cool to room temperature.
Cleaning Instructions	We do not recommend manual cleaning of these medical devices.
Disinfection	Information on disinfection can be found above under Step 13 of the section ‘Automated Cleaning.
Visual Inspection of the Instruments	After completion of the cleaning and disinfection process, a thorough visual inspection of the instruments must be performed. No visible contamination may remain on any part of the medical device. A careful visual inspection for cleanliness is therefore a mandatory component of the reprocessing procedure.
Maintenance	Apply a small amount of surgical lubricant to hinges/joints. Dispose of dull or damaged instruments.
Inspection and Functional Check	**Foldable instruments:** Check the hinges for smooth movement without excessive play. Locking mechanisms (ratchets) should be tested for proper function. **All instruments:** Visually inspect instruments for damage and wear. Cutting edges must be free of nicks and exhibit a continuous edge. **Instruments with long, slender parts (particularly rotating instruments):** Inspect for deformation. If instruments are part of a larger assembly, verify the assembly together with the corresponding components.
Packaging	Individual devices may be packaged in a sterilization pouch or sterilization wrap intended for medical use. Care must be taken during packaging to ensure that the pouch or wrap does not tear. Devices should be packaged using pouches and/or wraps that comply with ISO 11607-1. Reusable wraps are not recommended. Medical devices may also be packaged/placed under the following conditions in perforated trays designed for sterilization: • Arrange all products so that all surfaces are exposed to steam. • The container or tray must be wrapped with sterilization packaging for medical use in accordance with ISO 11607, using the double-wrapping method or an equivalent method. Follow the container/tray manufacturer’s recommendations regarding loading and weight. The total weight of a packaged case or tray must not exceed 11.4 kg / 25 lbs. We recommend a bioburden test in accordance with ISO 11737-1 prior to sterilization.

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<table>
<tr><td>Sterilization</td><td>
Equipment: Complete autoclave unit (moist heat/steam sterilizer).
Moist heat/steam sterilization is the recommended method for Class I medical devices supplied by SOS Surgical Co. The use of an approved chemical integrator (Class 5) or a chemical emulator (Class 6) in each sterilization cycle is recommended.

The sterilizer manufacturer’s instructions for loading and operation must always be followed. Sterilization equipment must demonstrate effectiveness in accordance with EN 13060, EN 285, or ISO 17665. In addition, the manufacturer’s recommendations for installation, validation, and maintenance must be observed.

Based on process validation conducted by the organization, the following steam sterilization parameters are recommended for pre-vacuum steam sterilization.

<table>
<tr><td>Pre-Vacuum Cycle – Parameters</td><td>Temperature</td><td>Pressure</td><td>Exposure Time</td><td>Drying Time</td></tr>
<tr><td></td><td>℃</td><td>bar</td><td>Min</td><td>Min</td></tr>
<tr><td></td><td>134</td><td>2.2</td><td>4</td><td>10</td></tr>
</table>
Drying and Cooling
The recommended drying time for individually packaged medical devices is 10 minutes, unless otherwise specified in the product-specific instructions.

Drying times for medical devices processed in containers and packaged trays may vary depending on the type of packaging, the type of medical devices, the type of sterilizer, and the total load. A minimum drying time of 30 minutes is recommended; however, to prevent moist packaging, longer drying times than 30 minutes may be required under certain conditions or if otherwise recommended in the accompanying documentation. For large loads, verification of drying times by the healthcare provider is recommended.
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<tr><td>Storage</td><td>
Sterile-packaged medical devices should be stored in a designated, access-restricted area that is well ventilated and provides protection against dust, moisture, insects, vermin, and extreme temperatures/humidity. The recommended storage temperature is 18 to 25 °C.

Note: Before use, inspect each package to ensure that the sterile barrier (e.g., wrap, pouch, etc.) is not damaged, perforated, or moist, and does not show any signs of tampering. If any of these conditions are present, the contents shall be considered non-sterile and must be reprocessed by cleaning, packaging, and sterilization.
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<tr><td>11.4
Contraindications</td><td>The instruments must only be used for their intended purpose.</td></tr>
<tr><td>11.5
Usability / Lifetime</td><td>Class I medical devices have a limited service life. The typical service life of an instrument is 10 years. Considerations regarding usability refer to the maintenance of the product’s function and physical integrity. In general, the end of service life is determined by wear, damage, and performance impairment resulting from use.</td></tr>
<tr><td>11.6
Disposal</td><td>After the end of the service life of the products, or if the products are no longer functional, they should be scrapped by damaging the functionally relevant areas such as jaws, blades/edges, and tips using a hammer. Disposal must also comply with the applicable laws and regulations of the respective country.</td></tr>
<tr><td>11.7
Serious Incidents</td><td>A serious incident, as defined in Article 2(65) of MDR, is any event that results in or could lead to death, serious health deterioration, or a serious public health threat. In such cases, the incident must be reported to the manufacturer without delay, and the affected product must be returned without any modification for root cause analysis in accordance with Article 89 MDR. The incident must also be reported to the EU Authorized Representative and to the competent authority of the Member State in which the user or patient is established.</td></tr>
<tr><td>11.8
Intended Users</td><td>These medical devices are to be used by surgeons and physicians/medical professionals, but not by laypersons.</td></tr>
<tr><td>11.9
Intended Group Population</td><td>These medical devices are intended for use in all age groups.</td></tr>
<tr><td>11.10
Operating Instruction</td><td>
- Wear gloves when using the instruments.
- Use caution with sharp edges of the instruments, if present.
- Use caution with moving parts of the instruments, if present.
- Instruments must be stored in a dry place and handled carefully to avoid damage.
- These medical devices must only be used by qualified personnel. Use them only for their intended purpose to ensure maximum effectiveness.
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<tr><td>11.11
Manufacturer:
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SOS Surgical Co.
Mughal Pura, Gohad Pur, Sialkot-51360-Pakistan.
Tel: +92 321 7074949
E-Mail: sales@sossurgical.com
Web: www.sossurgical.com
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11.12 **EU Authorized Representative** EU REP	**KB International** Aurora utca ,13.al.1,1084-Budapest, Hungary Email: info@kb-intl.com SRN:HU-AR-000034102
11.13 **CE Marking** CE	The medical device (Class I) to which this document is accompanied are CE Marked
11.14 **Importer**	**SOS Surgical Germany e.K.** WittekindStr 25 32758 Detmold, Germany Tel: +49 05231 7099793 E-Mail: sales@sossurgical.de Web: www.sossurgical.de

The above instructions have been validated by the manufacturer of the medical device as suitable for the reprocessing of a medical device. It is the responsibility of the user to ensure that the described procedure, as actually performed with the available equipment, materials, and personnel, achieves the intended result. This requires verification and/or validation as well as routine monitoring of the process.

11.15. List of Class I Medical Instruments