

SKLAR LAPAROSCOPIC INSTRUMENTS RECOMMENDED CARE & CLEANING INSTRUCTIONS

CAUTION: The following instructions are for all Sklar Laparoscopic Instruments. Read instructions prior to use. Improper operation and care or use for purposes other than that intended can lead to premature wearing out of the surgical instruments. Always process new instruments prior to initial use.

GENERAL INSTRUCTIONS

Handling	Surgical Instrumentation should be handled and processed by qualified personnel who are specially trained & knowledgeable about hospital hygiene and sterilization technology. Always handle surgical instruments with great care during transportation, cleaning, maintenance, sterilization and storage. Surgical instruments corrode and their functionality is influenced when they come into contact with corrosive substances. Do not place instruments in acidic or strong detergents.
Inspection	It is important that every surgical instrument be inspected for damage, sharp edges, raw surfaces, ruptures, cracks, or malfunction prior to every application. Careful inspection should be given to areas such as cutting, sharpening, closing, locking and resting, as well as all moving components. Do not use damaged instruments. Do not carry out repairs yourself. Service and repairs should only be carried out by people with the relevant training and qualifications. Replace chapped and cracked O-rings.
Use	<p>Instruments are to be used exclusively for their stipulated purpose in the medical fields by correspondingly trained and qualified personnel. Only use shafts and instruments that agree in diameter. For instance, for instruments with a diameter of 5 mm, trocar sleeves with an inner diameter of at least 5.5 mm should be used. When trocar sleeves are introduced, trocar mandrels of a smaller diameter should never be used, i.e. 11 mm sleeve with 10 mm mandrel.</p> <p>Before every use, instruments should be examined for correct and functional mounting. Monopolar instruments may not be activated until at the appropriate location. Large vertical movements inside the trocar sleeve should not be carried out in the activated state. Before each use, insulated instruments should be examined separately again for any damage to the insulation, and in case of damage they should be exchanged. HF cables used must be completely compatible with the adapter plug. Too strong of power to the instruments can lead to damage and affect performance.</p>
Safety	In connection with use of instruments for electrosurgery, special safety precautions should be observed, since these can represent a significant hazard if used improperly, incorrectly or carelessly. Avoid touching these instruments with uninsulated instruments. People using the instruments for electrosurgery, should have the necessary specialized training. Do not use these instruments on patients with pacemakers. Do not use them in the presence of flammable liquids or anesthetics. HF generators for electrosurgery, which are used in connection with these instruments, were developed to destroy tissues and can be dangerous if handled improperly. Follow the safety precautions of the equipment manufacturer. Bipolar instruments are suitable, in connection with the relevant connection cables, for connection to the bipolar output of HF generators with an output maximum of 100 watts and an output voltage maximum of 600 V.

REPROCESSING INSTRUCTIONS

Warning	<p>The instruments must be prepared before their first use, before every further use and before sending them back to the manufacturer for repair in accordance with the general instructions for care, maintenance and cleaning. All instruments must be cleaned and sterilized before initial use. All instruments, especially bipolar tweezers, were developed for sterilization in the autoclave, and have been tested for this kind of sterilization. Remove connection cable(s) prior to cleaning and disinfecting instruments. Instruments have only limited stability. Exposures to excessive power can lead to damage and affect functioning.</p>
Preparation for Decontamination	<p>After every use, every surgical instrument should be immediately disinfected and thoroughly cleaned, paying close attention to slots, closings, pipes and other areas that are difficult to clean. If an instrument can be taken apart, it should be cleaned in a disassembled state. Adequate cleaning, inspection and maintenance help guarantee the operational capability of surgical instruments and extends the life of the instrument.</p>
Care & Cleaning	<p>Instruments must be thoroughly cleaned of foreign bodies. Cleaning and rinsing should take place immediately after every use because particles or dried secretions can adhere, whereby a later cleaning and sterilization could be made more difficult or impossible. All debris and foreign bodies must be thoroughly removed before sterilization of the instruments. Use warm water and commercial instrument cleaning detergent. For removing protein remains, enzymatic detergent should be used. Follow the relevant directions for use of such detergent(s).</p> <p>In order to avoid drying of operation residues and spreading of germs in the endoscopy areas, the instruments must be placed in a combined disinfecting and cleaning solution immediately after use. In connection with this:</p> <ul style="list-style-type: none"> • Store optical and mechanical components separately. • Dismantle instruments. • Take off rubber and sealing caps. • Clean thoroughly since blood, pus, protein residues etc. can call subsequent disinfection or sterilization into question. • Clean existing inner areas, such as guide channels etc., with the relevant cleaning brush and swab. • Rinse open valves and narrow channels with a cleaning gun. Carry out rinsing and brushing of the channels under the surface of water, to avoid spraying of germs in the environment. • Rinse all components first with cold and then with warm water. • Lay the used instruments carefully in the boxes. The detergent solution must be appropriate for the disinfectant. • Lay the instruments in a combined cleaning and disinfecting solution. • Subsequently rinse with distilled water and then dry inside and out with a cloth, swab or dry air.

Do not use corrosive or abrasive detergents. Detergents with a neutral pH value (7.0) are the most appropriate. Ultrasonic cleaning is appropriate, but be careful to refasten attachments that have been loosened by the vibrations. Washing machine cleaning is appropriate for disinfection up to 95° C. Carefully rinse with distilled water. Pipes must be blown out. **IMPORTANT:** After an instrument has been cleaned and rinsed, and before sterilization, treat all instruments with a naturally harmless oil (Paraffin Oil from DAB 8, or Ph. Eur. or USP XX); especially cuts, holes, locks, latches and all moving components. All instruments must be sterilized prior to use or storage.

Inspection & Functionality

Inspect instruments for functionality and for any damage that has occurred after each cleaning.

- Replace brittle and cracked sealing caps.
- Oil all moving components sparingly after cleaning with endoscope oil. Wipe off excess oil with a disposable towel.
- Sparingly grease rotating valves, valve pistons from trocar sleeves etc. after cleaning (before steam sterilization) with endoscope grease.
- Inspect the insulation of the cable and connections for cuts, holes, cracks, blowing, wear, etc. Do not use any damaged instruments.
- Send damaged instruments to the factory for repair.

Sterilization

Sterilize all instruments before every use. For preparation of surgical products various procedures can be used. For preparation of Sklar Laparoscopic products steam sterilization with the fractional process is recommended:

Temperature: 137° C
 Pressure: 3 bar
 Holding time: > 15 Minutes

Please follow the manufacturer’s recommendations for your sterilization apparatus regarding operation and loading. The instruments to be sterilized must be exposed carefully to the steam, including the interior surfaces. Allow instruments to cool to room temperature before use. Other times or temperatures can also be used, however, you should first validate deviations from the recommended values. (Instruction: Have the temperatures and/or sterilization times confirmed by your autoclave’s manufacturer.) The temperatures in the autoclave should not exceed 139°C, since otherwise handles, insulation and other non-metallic parts could be damaged. Do not sterilize with hot air or with a “flash” autoclave procedure. If only Pre-Vacuum Sterilization can be done, use the following parameters:

Sterilizer Type: Pre-Vacuum
 Preconditioning Pulses: 3
 Preconditioning Pressure: 2.5 psi
 Minimum Temperature: 132° C
 Half Cycle Time: 2 Minutes
 Minimum Dry Time: 0 Minutes
 Sample Configuration: Individually Wrapped

Storage

Instruments should be stored in a clean, dry environment. They should be stored individually in their packaging or in a protective container with separate compartments. Protect the points with fabric, gauze or tubes if you store the instruments in drawers. Instruments are, if not otherwise indicated, reusable and conform to ANSI/AAMI Sterilization Standards. We guarantee that our products can be sterilized at least twenty times, if the criteria cited above are observed. As a rule our products will exceed this standard, if an appropriate care and examination procedure is implemented for the instruments in your establishment.

Guarantee

Every surgical instrument bearing the Sklar brand name is guaranteed to be free of functional defects in workmanship and materials when used normally for its intended surgical purpose. Sklar accepts no responsibility for direct or consequential damage occurring as a result of improper use or operation or as a result of improper preparation, sterilization and maintenance, especially because of failure to observe the stipulated use or by improper use, operation, preparation and maintenance. Should unauthorized persons carry out modifications or repairs on the products, Sklar accepts no liability, and moreover the warranty is void. Components affecting safety may only be replaced with original components. After every repair or modification, the state of technical safety of the product must correspond to the applicable equipment standard.

Repair Service

For safe functioning of medical products, proper care and maintenance is necessary. Therefore we recommend careful examination for function and completeness after receipt and before any implementation, in order to protect against possible injury to patients and users. For every examination, repair or modification, a protocol should be created. Regardless of age, if any Sklar instrument needs service, return it to Sklar. All instruments must be cleaned and sterilized prior to return.

Note: It is the responsibility of the reprocessor to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the reprocessing facility, achieves the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the user from the instructions provided, must be properly evaluated for effectiveness and potential adverse consequences.