**INDICATIONS FOR USE**

Surgical Instruments are designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating or suturing. Surgical Instruments may also be used to facilitate the insertion of surgical implants.

**WARNING**

Instruments should not be used for anything other than their intended use.

- **Speedway Instruments** are supplied non-spillable, unless otherwise noted and must be cleaned, lubricated and sterilized prior to use according to hospital protocol and procedures as required by country specific norms.
- **Inappropriate use of instruments may result in patient injury, damaged or broken instruments.**
- **Proper cleaning, handling, sterilization and standard routine maintenance (such as sharpening, if applicable) will ensure that the instruments perform as intended and will extend their useful life.**
- **Delicate surgical instruments require special handling to prevent damaging the tips. Use caution during cleaning and sterilization.**
- **Use appropriate silicon tips for sterilization of instruments.**
- **Do not use dry heat sterilization or expose to phenols or any other chemicals.**
- **Do not apply excessive pressure or stress at joints; misuse will result in misalignment or cracks at the box locks or jaws.**
- **Bone Rongeurs and bone cutting forces should only be used to cut bone, never wire or pin. Do not twist or apply excessive stress during use.**
- **Appropriate protective gloves, eyewear and clothing should be worn while handling biologically contaminated instruments.**
- **Instruments manufactured from different metals or with special coating, should be processed separately to avoid electrolytic action between the different metals.**
- **Before use, inspect the instruments for possible damage, wear and tear or any non-functioning parts. Carefully inspect the critical, inaccessible areas, joints and all movable parts.**
- **Damaged or defective instruments should not be used or processed.**

**DECONTAMINATION AND STERILIZATION PROCEDURES**

- **Personnel should follow accepted guidelines as recommended in ANSI/AAMI ST79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities and ISO 17664.**
- **For Ethylene Oxide sterilization, follow the ANSI/AAMI ST41 Ethylene Oxide sterilization in health care facilities: safety and effectiveness, 4th edition. Sterilization of reusable medical devices is provided by the manufacturer for the processing of re-sterilizable medical devices.**
- **Instruction for reprocessing reusable surgical instruments is provided according to ISO 17664. The decontamination process does not sterilize the instruments. Refer to and process the instruments as outlined in the STERILIZATION section.**

**CARE AND HANDLING**

**1. PRECLEANING:**

- **Wash the instruments with distilled water and do not allow blood and/or bodily fluids to dry on the instruments.**
- **Remove gross contaminants with steady stream of lukewarm/cool water (below 110°F/43°C). Rinse each instrument thoroughly. Do not use soiled or contaminated solutions. Hard water should be avoided for rinsing.**
- **Open jaws of hinged instruments for cleaning. Give special attention to joints and serratations. Instruments having more than one part or piece must be disassembled to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly.**
- **Separate sharps and delicate surgical instruments. Avoid processing instruments of different metallic composition together.**

**2. RINSE:**

- **Rinse instruments thoroughly under warm distilled or demineralized water.**

**3. CLEANING:**

**CLEANING PRECAUTIONS:**

- **If appropriate, disassemble surgical instruments prior to cleaning and sterilization.**
- **Do not soak instruments in hot water, alcohol, disinfectants or antisepsics to avoid coagulation of mucus, blood or other body fluids.**
- **Do not exceed two hours soaking in any solution.**
- **Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents to remove soil as these will damage the instrument and lead to corrosion.**

**B. ULTRASONIC AND MECHANICAL CLEANING**

- **For ultrasonic cleaning, follow manufacturer's specifications for water level, concentration levels of cleaning agent and temperature.**
- **Use an ultrasonic cleaner to remove soil from hard-to-reach surfaces such as grooves, crevices and other parts after gross soil has been removed.**
- **Open or disassemble instruments as appropriate.**
- **When using mechanical washer, make sure all instruments stay properly in place and do not touch or overlap each other.**
- **Do not allow anodized instruments to come in contact with each other or other instruments.**
- **Always follow the manufacturer’s recommendations for cleaning and sterilization for automatic washer-sterilizers and use a free-rinsing, low-subsidizing detergent (pH 6.0 - 8.5). Due to variations in water quality, the type of detergent and its concentration may require adjustment for optimal cleaning.**

**4. RINSE AND DRY:**

- **Rinse all instruments thoroughly with distilled water to remove all traces of debridal cleansing agents. Make sure all internal lumens and ratchets are thoroughly rinsed. Instruments must be thoroughly dried and all residual moisture must be removed before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air may be used to aid the drying process.**

**2. LUBRICATE:**

- **The use of a water soluble instrument lubricant that is compatible with the method of sterilization to be used is recommended before instruments are sterilized.**

**6. STERILIZATION:**

**After following disinfection recommendations, reusable instruments are ready for sterilization.**

- **See ANSI/AAMI ST79.**
- **AAMI standards recommend that sterilizer manufacturer’s instructions for each sterilization cycle be followed.**

**PRODUCT INFORMATION DISCLOSURE**

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