KYOCERA Medical Technologies, Inc.

4001-001 Rev. J

Instructions For Use

Recommendations for the Care and Handling for Kyocera Medical Technologies, Inc. ("KMTI") Surgical Instruments and Instrument Cases

DESCRIPTION
KMTI instrumentation consists of devices and their accessories used in surgical procedures. Before using KMTI instrumentation for any surgical procedure, familiarity with, and attention to the appropriate, recommended surgical technique is imperative. KMTI instrumentation should only be used in combination with other KMTI products.

KMTI instruments and instrument cases are generally composed of titanium, stainless steel, aluminum, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and listed below. Instrument cases do not provide a sterile barrier and must be used in conjunction with sterilization wrap to maintain sterility. Instruments are provided nonsterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below.

DISCLAIMER
KMTI instrument cases are intended to protect instrumentation and facilitate the sterilization process by allowing steam penetration and drying. KMTI has verified through laboratory testing that our instrument cases are suitable for the specific sterilization cycles for which they have been tested. Health care personnel are ultimately responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in their particular health care facility. Testing should be conducted in health care facility to assure that conditions essential to sterilization can be achieved. KMTI and its distributors do not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical device supplied by KMTI that should have been cleaned and sterilized by the end user. All instruments are to be examined for wear and damage prior to surgery.

CLEANING AND DECONTAMINATION
All instruments must be thoroughly cleaned before each sterilization (including first use) and introduction into a sterile field.

Keep devices moist and do not allow blood and/or bodily fluids to dry on the devices. The decontamination process should begin immediately after completion of the surgical procedure.

KMTI rigid instrument cases may be washed and/or disinfected by using an automated washer-disinfection unit utilizing thermal disinfection. Temperatures, cycles, and disinfectant type used as instructed by manufacturer of washer-disinfection unit. Devices must be processed separately from trays and cases. All devices must be thoroughly cleaned before use.

1. **Pre-Cleaning:** Disassemble devices where applicable. The majority of the surgical instruments and trial devices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts.
2. **First Rinse:** Rinse devices under running tap water for a minimum of 2 minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris. Actuate devices with moving parts. Clear lumens/cannula/channels/holes of all debris using an appropriately sized bottle brush.
3. **Decontamination:** Soak the devices completely in an enzymatic cleaner or detergent solution* (e.g. ENZOL® Enzymatic Detergent). Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentration. Fully immerse the devices and allow them to soak for a minimum of 20 minutes. Following soak, use a soft-bristled brush to assist in the removal of gross soil, debris or contaminants, ensuring hard to reach areas are accessed and articulating devices with moving parts.
4. **Rinsing:** Remove the devices from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Use a syringe, pipette or water jet to flush lumens/cannula/channels/holes. Articulate devices with moving parts under running water in order to rinse thoroughly.
5. **Washing:** Immerse devices in the ultrasonic washer/cleaner with enzymatic cleaner or detergent solution* (e.g. ENZOL® Enzymatic Detergent) and sonicate for a minimum of 15 minutes. Follow the manufacturer's specifications for suggested water level, temperature, water quality and concentration of enzymatic cleaner or detergent.
6. **Rinsing:** Thoroughly rinse the devices with purified water for a minimum of 2 minutes. Use a syringe, pipette or water jet to flush lumens/cannula/channels/holes. Articulate devices with moving parts under running water in order to rinse thoroughly. Repeat rinsing a total of three (3) times.
7. **Inspection:** After cleaning/disinfection, devices should be visually inspected for contamination. If contamination is still visible, repeat steps 2, 3, 4, 5, 6 and 7. If devices continue to have visual contamination, do not use devices and contact KMTI Customer Service for further instructions.
8. **Drying:** Allow devices to air dry for a minimum of 20 minutes prior to inspection and sterilization preparation. Devices must be thoroughly dried to remove residual moisture before they are stored.
9. **Preparation and Assembly:** After cleaning/disinfection and inspection, any disassembled devices should be reassembled and visually inspected. Check for misalignment, burrs, bent, or fractured tips. Do not use if any of this damage is observed. Mechanically test the working parts to verify that each instrument functions correctly. Place devices into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines. FDA cleared sterilization wrap must be used.

* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. KMTI has validated the above manual cleaning method with the provided solution examples. Other cleaning/disinfection methods may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.

CARE AND HANDLING OF INSTRUMENTS
1. **General** – Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their performance. To minimize damage, conduct the following:
   - Inspect instrument cases and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair returned for servicing.
   - Only use an instrument for its intended purpose.
   - When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop safety procedures appropriate for all levels of direct instrument contact.
   - Instruments designated as "Single Use Only" are to be disposed of immediately after use. Reuse can cause small defects and internal stress patterns which may result in premature breakage.
2. **General Cleaning** – Clean instruments as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate enzymatic detergent to delay drying. Wash all instruments whether or not they were used or were inadvertently contacted with blood. Loosen and/or disassemble instruments with removable parts.
3. **Ultrasonic Cleaners** – can be used with hot water per the manufacturers' recommended temperature, however, room temperature was qualified. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of the equipment.

RESPONSIBILITIES OF THE USER
General – Health care personnel are ultimately responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in their particular health care facility.
Sterility – Users should conduct testing in health care facility to assure that conditions essential to sterilization can be achieved.

STORAGE AND SHELF LIFE
Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be taken in handling wrapped cases to prevent damage to the barrier. The health care facility should establish a shelf life for wrapped instruments cases, based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time and with handling.

Sterility: KMTI Instruments are provided non-sterile. Sterilization is recommended as follows:

Cycle	Dynamic-air-removal Steam
Minimum Temperature	132° C (270° F)
Exposure	4 Minutes
Drying Time	30 Minutes Minimum; 40 Minutes Maximum

This sterilization cycle (drying time) is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and a new cycle must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

The packaging in which non-sterile instruments are supplied should not be used for sterilization methods in the hospital. Repackaged and resterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

References: References to relevant literature may be obtained by calling Kyocera Medical Technologies, Inc. at +1 (909) 557-2360.

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

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