RECOMMENDATIONS FOR THE CARE AND HANDLING OF KYOCERA MEDICAL CORPORATION INSTRUMENTS AND INSTRUMENT CASES

DESCRIPTION
KYOCERA Medical Corporation instruments and instrument cases are generally composed of aluminum, stainless steel, and/or polymeric materials. The instrument cases are perforated to allow steam to penetrate these various materials and components. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing a sterilization and drying cycle that has been validated by the user for the equipment and procedures employed at the user facility. Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap to maintain sterility.
Surgical instruments are supplied non-sterile and must be cleaned and sterilized before use. After use, these instruments must be, at minimum, properly decontaminated, cleaned, and stored. The following information outlines the proper steps for reprocessing KYOCERA Medical Corporation instruments and instrument cases to help assure their long life.

MATERIALS
Aluminum
Stainless Steel
Polymeric Materials

WARNINGS AND PRECAUTIONS
- Surgical instruments and instrument cases are susceptible to damage for a variety of reasons including prolonged use, misuse, and/or rough or improper handling. Care must be taken to avoid compromising their exacting performance. To minimize damage and risk of injury, the following should be done: Inspect the instrument and instrument case for damage upon receipt and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned. Instruments in need of repair should be set aside for repair service or returned to KYOCERA MEDICAL TECHNOLOGIES, INC. (Instruments returned to KYOCERA MEDICAL TECHNOLOGIES, INC. or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST35 *Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings* provides guidelines for return, or contact KYOCERA MEDICAL TECHNOLOGIES, INC. or your distributor for further instruction).
- Unless otherwise indicated, instrument sets are NOT sterile and must be thoroughly cleaned and sterilized prior to use.
- When handling sharp instruments, use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.
- Do not open instrument sets outside the sterile field after sterilization.
- **Intra-Operative Precautions-** All trial, packaging and instrument components must be removed prior to closing the surgical site. Do not implant. After the surgical operation, it shall be confirmed that all the used instruments are returned and are in place.
  Instruments made of polymeric materials (e.g. trials) cannot be detected by diagnostic imaging; therefore the handling of polymeric instruments requires special attention. When a broken metal piece is found in the body, Magnetic Resonance Imaging (MRI) exams shall be avoided. If MRI is applied to the metal piece, it may cause serious injury.

LIMITATIONS AND RESTRICTIONS OF REPROCESSING
Surgical instruments and instrument cases are designed for their durability and ability for reuse. KYOCERA Medical Corporation's reusable instruments and instrument cases are typically manufactured from stainless steel, which permits a long life when handled and maintained properly. Repeated processing has minimal effect on these instruments and instrument cases. End of functional life is normally determined by wear and damage due to use.
Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

RESPONSIBILITIES OF THE USER
General- The following methods have been validated by KYOCERA Medical Corporation. Health care personnel should validate these procedures on their own equipment to ensure that these methods are effective in each health care setting.

Cleaning/Decontamination- The health care facility is responsible to insure that conditions essential to safe handling and decontamination can be achieved. ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* provides guidelines for design and personnel considerations, immediate handling of contaminated items and transportation, decontamination processes, servicing, repair, and process performance.

Sterility- ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* provides guidelines for cleaning and decontamination, preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

CLEANING AND DECONTAMINATION
General Cleaning- Clean instruments prior to initial sterilization and as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with an appropriate detergent or enzymatic solution (e.g. Enzol 1oz/gal) to delay drying. Wash all instruments whether or not they were used or inadvertently came into contact with blood or saline solution.

1. **Removal of Gross Contamination-** The effectiveness of subsequent decontamination processes depends on prior removal of gross soil as decontamination may be impaired by dried or coagulated protein. Gross soil should be removed under running water using a mechanical aid such as a brush with rigid nylon bristles. Care should be taken to avoid splashing and generating aerosols by holding instruments below the surface of the water in a sink into which water is running and continuously draining. Instruments should not be held under a running tap, as this is likely to result in splashing. Operators should wear protective equipment including gloves and goggles. Care should be taken to avoid penetrating or cutting injuries. Particular attention should be taken to remove all debris from all cannulations and obscure holes in the instruments.

2. **Washing/Disinfecting-** It is recommended that the instruments be decontaminated using an automatic washer-disinfection unit utilizing thermal disinfection. This should preferably be of the ultrasonic or continuous tunnel process type. The cabinet type is an acceptable alternative if a continuous process machine is not available. Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit. These detergents and/or rinse aids, however, should be of neutral or near neutral pH. Excessively acidic or alkaline solutions may corrode aluminum instruments or instrument cases. The following procedure provides a validated method for cleaning instruments including both manual and automatic washing/disinfection procedures. Other methods of cleaning may be suitable but must be validated by the user of the device.

Manual Cleaning for General Instruments
- Rinse instruments under cool running tap water to remove all gross soil while ensuring hard-to-clean areas were flushed.
- Completely immerse instruments in the enzymatic detergent (Enzol; 1 oz/gal) using lukewarm tap water and ensure that there are no bubbles on the instruments by actuating and using a syringe to flush hard-to-clean areas. Soak instruments for 1 minute.
- Brush the entirety of each instrument using a soft bristled brush (M16). Pay particular attention to hard-to-clean areas. Flush any crevices and hard-to-clean areas using a syringe. Remove instruments from the detergent and rinse in tap water.
- Dry instruments with a lint free cloth and filtered pressurized air. Visually inspect instruments for visual soil, paying close attention to hard-to-clean areas.

Manual/Mechanical Cleaning for Flexible Drill Shaft (Complex Instruments)
- Rinse instruments under cool running tap water to remove all gross soil while ensuring hard-to-clean areas were flushed.
- Completely immerse instruments in the enzymatic detergent (Enzol; 1 oz/gal.) using lukewarm tap water and ensure that there are no bubbles on the instruments by actuating and using a syringe to flush hard-to-clean areas. Soak instruments for 1 minute.
- Brush the entirety of each instrument using a soft bristled brush (M16). Pay particular attention to hard-to-clean areas. Flush any crevices and hard-to-clean areas using a syringe. Remove instruments from the detergent and rinse in tap water.
- If, after completion of above cleaning step, gross soil which had to be removed with the brush remains on the instruments, fully immerse instruments in the Enzol (1 oz/gal.) with lukewarm tap water in an ultrasonic unit and ensure that there are no bubbles on the instruments by actuating and using a syringe to flush hard-to-clean areas. Sonicate instruments for 10 minutes. Remove instruments from the detergent and rinse in tap water.
- Dry instruments with a lint free cloth and filtered pressurized air. Visually inspect instruments for visual soil, paying close attention to hard-to-clean areas.

Automated Cleaning for General Instruments
- Rinse instruments under cool running tap water to remove all gross soil.
- Using a syringe, flush all hard-to-clean areas using cool tap water.
- Transfer instruments into mesh baskets, load into the washer and run the following recommended automatic washer steps.

Phase	Time	Temperature & Water Quality	Detergent & Concentration
Pre-wash	2 min.	Cold Tap water	None
Enzyme Wash	1 min.	Hot Tap water	Enzol® 1 oz/gallon
Wash	2 min.	65.5°C(150°F) Tap water	Valsure® Neutral ¼ oz/gallon
Rinse	15 sec.	Hot Purified water	None
Drying	6 min.	98.8°C(210°F)	None

- Visually inspect instruments for visual soil, paying close attention to hard-to-clean areas.

Automated Cleaning for Flexible Drill Shaft (Complex Instruments)
- Rinse instruments under cool running tap water to remove all gross soil, while ensuring hard-to-clean areas were flushed.
- Fully immerse instruments in the enzymatic detergent (Enzol; 1 oz/gal.) using lukewarm tap water and ensure that there are no bubbles on the instruments by actuating and using a syringe to flush hard-to-clean areas. Sonicate instruments for 10 minutes. Remove instruments from the detergent and rinse in tap water.
- Transfer instruments into mesh baskets, load into the washer and run the above recommended automatic washer steps, the same as non-complex instruments.
- Visually inspect instruments for visual soil, paying close attention to hard-to-clean areas.

Ultrasonic Cleaners can be used with hot water per manufacturer's recommended temperature and specially formulated detergents. Follow manufacturers' recommendations for a proper cleaning solution formulated specifically for ultrasonic cleaners. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of the equipment.

Washer-Decontamination Equipment will wash and decontaminate instruments. Complete removal of soil from crevices and serrations depends on instrument construction, exposure time, pressure of delivered solution, and pH of the detergent solution, and thus may require prior brushing. Be familiar with equipment manufacturers' use and operation instructions. Be aware that loading, detergent, water temperature, and other external factors may change the effectiveness of the equipment.

3. **Preparation and assembly-** After cleaning/disinfecting, instruments should be prepared for sterilization and placed in their proper locations in the instrument cases.

STERILITY

KYOCERA Medical Corporation instruments can be steam autoclaved and repeated autoclaving will not adversely affect them, unless otherwise indicated in the labeling. If you have any problems when using KYOCERA Medical Corporation instruments, please bring this to KYOCERA MEDICAL TECHNOLOGIES, INC. or its distributor's attention when you return them. (Instruments returned to KYOCERA MEDICAL TECHNOLOGIES, INC. or its distributor's should be cleaned and sterilized prior to shipment. ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* provide guidelines for return, or contact KYOCERA MEDICAL TECHNOLOGIES, INC. or your distributor for further instruction).

Unless supplied sterile, instruments must be thoroughly cleaned and sterilized prior to surgical use. Set forth below is a recommended minimum cycle for steam sterilization that has been validated by KYOCERA Medical Corporation under laboratory conditions.

Instruments that have been used in a surgical environment should be thoroughly cleaned prior to autoclaving. Use of ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* is recommended. Wraps used during the steam sterilization process are to be FDA cleared wraps (e.g. Kimguard® Sterilization Wrap, K082554).

The following cycle parameters are recommended for instrument cases up to 25 lbs (11 kgs), as they have been validated for a Sterility Assurance Level (SAL) of 10^{-6}.

Steam autoclave cycle parameters;

Sterilizer type: Gravity
- Minimum temperature: 132ºC (270ºF)
- Exposure time: 15 minutes
- Minimum drying time: 45 minutes
- Cool-down time: 30 minutes outside of chamber on a wire rack.

Sterilizer type: Prevacuum
- Minimum temperature: 132ºC (270ºF)
- Exposure time: 4 minutes
- Minimum drying time: 45 minutes

* Validated by KYOCERA Medical Corporation under laboratory conditions.

STORAGE AND SHELF LIFE

Instruments and 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 exercised in handling of wrapped instruments and instrument cases to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped instruments and instrument 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, with handling, and whether woven or non-woven materials are used for the sterilization wrap.

DISCLAIMER

KYOCERA Medical Corporation instrument cases are intended to protect instrumentation and facilitate the sterilization process by allowing steam penetration and drying. KYOCERA Medical Corporation has verified through laboratory testing that its instrument cases are suitable for the specific sterilization methods and cycles recommended here. Health care personnel should ensure that any sterilization wrap method and material is suitable for use in sterilization processing and sterility maintenance in a particular health care facility.

COMMENTS REGARDING THE USE OF THIS DEVICE CAN BE DIRECTED TO ATTN:

Initial Importer:
KYOCERA Medical Technologies, Inc.
1289 Bryn Mawr Ave. Ste. A
Redlands, CA 92374

Manufacturer:
KYOCERA Medical Corporation
6 Takeda Tobadono-cho, Fushimi-ku, Kyoto
612-8450 Japan

SYMBOL GLOSSARY DEFINITIONS

ISO 15223-1, Medical Devices -- Symbols to be used with information to be supplied by the manufacturer -- Part 1: General requirements			
Symbol	Symbol Reference	Title of symbol	Description of symbol
	5.1.1	Manufacturer	Indicates the medical device manufacturer.
	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	5.4.3	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.
	5.4.4	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
Other standards or originally defined			
	21 CFR 801.109	Prescription Device	Indicates that the product is a medical device as defined in 21 CFR 820.3(l) and Federal Law (USA) restricts this device to sale by or on the order of a physician (21 CFR 801.109).