GUIDELINES FOR CLEANING, DISINFECTION AND STERILIZATION OF K2M SURGICAL INSTRUMENTS

These guidelines were established to promote safe and effective reprocessing practices for K2M surgical instruments in accordance with ANSI/ AAMI, AORN, and ISO recommended guidelines. These recommendations are intended to support prevailing hospital procedures for decontamination, cleaning and sterilization of surgical instruments. While it is recommended that the following steps are included in a decontamination/ reprocessing protocol the end-user bears the ultimate responsibility for the cleanliness and sterility of the surgical device.

WARNINGS	These guidelines are not intended for K2M implants or disposable instruments.
	Follow instructions provided by the manufacturer of cleaning solutions or equipment used in the processing of K2M instruments.
	Use care in handling and storage of the components. Prior to surgery components should be inspected for any evidence of damage or corrosion.
	Prolonged exposure to saline may result in corrosion of stainless steel instruments.
Limitations on Reprocessing	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.
Creutzfeldt-Jakob Disease (CJD)	Treat instruments that may have been exposed to CJD according to the health care facility's prion decontamination protocol. K2M recommends contacting the Center for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

INSTRUCTIONS	
Point of Use	Use flowing water and disposable wipes to remove excess soil.
Containment and Transportation	Reprocess instruments as soon as is reasonably practical according to the health care facility's infection control and hazardous waste management procedures.
Preparation for Cleaning	Some K2M surgical instruments may be disassembled or loosened to provide maximum exposure for cleaning. The method of release or disassembly is self-evident.
Manual Cleaning	Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not marr the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean K2M surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of 1 minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water.
Automated Cleaning/Disinfection	The use of ultrasonic cleaners for removal of small particles are acceptable for K2M surgical instruments, with the exception of torque-limiting handles. Washer-decontaminators may also be used in addition to manual cleaning. When utilizing an automated cleaner follow equipment manufacturer’s instructions for use, incorporating a low foaming, pH neutral detergent. Take care to place difficult-to-clean parts near the center of the rack, open side, down, minimizing touching between parts. Place small parts in baskets to prevent dislodging.

Cleaning Verification	Visually inspect all instruments for any remaining debris prior to sterilization. According to ANSI/AAMI standard ST79:2006, “the accepted standard for the degree of cleanliness is ‘visibly clean’”. To detect any residual blood or protein particulates that may be trapped in visually obstructed areas the instrument may be submerged in a 2% hydrogen peroxide solution. The appearance of bubbles confirms the presence of protein and the instrument should be recleaned. Rinse instruments following exposure to hydrogen peroxide.
Maintenance	Lubricate instruments with moving parts. Use of water soluble lubricants will allow steam penetration during sterilization.
Inspection and Functional Testing	Hinged instruments: Check for smooth movement of hinge without excessive "play". Locking (ratchet) mechanisms should be checked for action. All instruments: Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Check instruments with long, slender features (particularly rotating instruments) for distortion. Where instruments form part of a larger assembly, check assembly with mating components.
Packaging	Singly: A standard packaging material may be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In Sets: Load K2M instruments into the appropriate instrument trays. Ensure that cutting edges are protected.
Sterilization	The following steam autoclave cycles are recommended however sterilization should be in accordance with the sterilizer manufacturer's instructions and institution's procedures for ensuring sterility. **Autoclave Cycle** PREVACUUM Temperature: 270°F-275°F (132°C-135°C) Time: 20 minutes.
Storage	Packaged and sterilized instruments should be stored in an area that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.
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