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CLEANING AND HANDLING OF WRIGHT INSTRUMENTS
130561-8

The following languages are included in this packet:

English (en)

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL TECHNOLOGY, INC.

CLEANING AND HANDLING OF WRIGHT INSTRUMENTS

(130561-8)

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 Wright surgical instruments to help assure their long life.

Intra-Operative Precautions

Use medical devices in accordance with their labeled indications and Wright's instructions for use, especially during insertion and removal.

- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with Wright's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
  a. The material composition of the fragment (if known);
  b. The size of the fragment (if known);
  c. The location of the fragment;
  d. The potential mechanisms for injury, e.g. migration, infection;
  e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Cleaning Accessories	
Water	Cold deionized or reverse osmosis water should be used, as temperatures above 140°F (60°C) will coagulate proteins, rendering them difficult to remove from contaminated items.
Detergent	Prepare detergent (i.e. LIQUI-NOX®, Alconox, Inc. 8.5 pH) per manufacturer recommendations.
Enzymatic Cleaner	Prepare enzymatic cleaner (i.e. ENDOZIME®, Ruhof Corporation 6.0-7.5 pH) per manufacturer recommendations.
Manual Cleaning Accessories	Brushes and/or Pipe Cleaners, Syringes, Gloves, Absorbent Disposable Cloth (i.e. KIMWIPE®, Kimtech Science)
Ultrasonic Cleaner	Ultrasonic Cleaners should be monitored routinely to ensure they are working properly.

Limitations and Restrictions of Reprocessing

Surgical instruments are designed for their durability and ability for reuse. Wright's reusable instruments are typically manufactured from stainless steel, which permits a long life when handled and maintained properly. Repeated processing has minimal effect on these instruments. 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.

Cleaning/ Disinfection	
Warnings	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.
	Always double-wrap the components in an FDA-cleared CSR wrap or similar type non-woven, medical grade wrapping material. Flash-autoclaving of individual instruments should be avoided, whenever possible. Unwrapped components DO NOT maintain sterility.
Clean instruments 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 cold water or an appropriate detergent or enzymatic solution to delay drying. Clean all instruments whether or not they were used or inadvertently contacted with blood or saline solution.	
Preparation for Cleaning	• The cleaning process must be conducted so that all parts of the surgical instrument are exposed as permitted by instrument design. The cleaning process should include an individual properly gowned with appropriate glove and personal protective equipment. • This may require opening all hinged items or the disassembly of those items with multiple or removable parts. • Those items with mating surfaces, i.e. ratchets, hinges, serrations, lumens, blind holes, etc. must be carefully cleaned to remove all visible debris from the items. • Additional assembly/ disassembly instructions may be found in the product specific surgical technique.

Manual Cleaning	1. **Disassemble** all components as per manufacturer instructions (if appropriate). 2. **Rinse** with cold tap water to remove gross contamination. 3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes. 4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe. 5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens. 6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes. 7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe. 8. **Rinse** thoroughly/flush with deionized/reverse osmosis (RO/DI) water. 9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions. 10. **Rinse** thoroughly/flush with RO/DI water. 11. **Dry** with a clean, soft, absorbent, disposable cloth. 12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean. **Note:** Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Automated Cleaning/ Disinfection	An automatic cleaning process may involve a washer-sterilizer, a washer-sanitizer/disinfector, ultrasonic cleaner or other related type machines that clean and decontaminate items. There are many different types of automatic washer systems, each with their own unique instructions that must be followed. These machines typically perform an initial cold water rinse followed by a cleaning cycle using a low sudsing detergent (neutral to slightly basic pH, 7.0 to 10.0). The detergent is thoroughly rinsed off, followed by a final rinse in deionized or reverse osmosis water. The process cycle may also provide a drying function for the cleaned items. The automatic cleaning machine may also contain a decontamination cycle, which is discussed in the next section. • Ultrasonic cleaners can be used with hot water per manufacturer's recommended temperature (usually 90-140°F or 32-60°C) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners. Be aware that loading patterns, instrument cassettes, 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.

Inspection, Maintenance, and Testing

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 exacting performance. To minimize damage, the following should be done: • Inspect the instrument case and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair set aside for repair service or return to Wright. • After cleaning, the disassembled instruments should be reassembled and placed in their proper locations in the instrument cases where appropriate. • Only use an instrument for its intended purpose. • For devices with hinged/mating surfaces or moving components, a biocompatible, surgical-grade lubricant intended for heat sterilized medical instruments should be used per the manufacturer's guidelines.

Wright does not accept responsibility or liability of this instrument nor any of the component parts upon which repairs and/or modifications have been made or attempted except as performed by Wright.

Packaging

Wright instrument cases are intended to protect instrumentation during shipping. Health care personnel bear the ultimate responsibility 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 a particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Wright does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by Wright that should have been cleaned and sterilized by the end user.

Sterilization

Wright instruments manufactured of stainless steel may be steam sterilized with no detrimental effects. **Those instruments containing UHMWPE (Ultra high molecular weight polyethylene) cannot be steam sterilized, as heat is detrimental to the plastic.** These instruments should be sterilized by ethylene oxide (ETO) or other validated sterilization method. All items to be sterilized must be thoroughly cleaned and packaged appropriately for the type of sterilization. The package must permit contact of the sterilant with the item, while also serving as a barrier to microorganisms, during any storage period. Users should wear non-linting gloves, i.e. Latex or Nitrile, when handling reusable instruments, to minimize bioburden and particulates. Inspect the product packaging for tears, holes, moisture or other defects. If these concerns are present, segregate these items and reprocess them.

Steam Sterilization

The minimum recommended steam sterilization conditions for Wright reusable instruments are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Type	**Parameter**	**Minimum Set Point**
Prevacuum 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with AAMI ST79 Table 5 guidelines and have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

ETO Sterilization

Instrumentation to be ETO sterilized must be cleaned and packaged appropriately. The packaging for items ETO sterilized varies somewhat from steam sterilization, in that paper to paper, paper or polyethylene film to Tyvek®, synthetic nonwovens, textiles and rigid container systems suitable for ETO sterilization may be used. Use only a FDA-cleared sterilization wrap, pouch, or other device that is designed to allow sterilant penetration and to maintain sterility. The uniqueness of a hospital ETO sterilizer as compared to an industrial ETO sterilizer precludes Wright listing any processing parameters. The number of different variables involved in an ETO sterilization process, such as the ETO concentration and exposure time, relative humidity or temperature may vary significantly in a hospital unit as compared to an industrial sterilizer. The recommendations of the sterilizer manufacturer must be followed when sterilizing with ETO gas. Wright surgical instruments can be processed at temperatures of 55°C (131°F).

Storage

Surgical instruments that will not be utilized within a short time and will not be immediately returned to Wright, should be stored clean, decontaminated and completely dry. The packaging that items are sterilized in may offer an effective barrier to prevent contamination of the item. Those items in a sealed paper or polyethylene Tyvek® pouch may be stored in a sealed polyethylene bag, and sterilized at a later date. All instruments returned to Wright must be cleaned and decontaminated before shipping. The four main types of packaging for steam sterilization consist of textiles, nonwovens, pouch packaging and rigid container systems. These packaging types offer various levels of protection from contamination, which must be consistent with the final intent of the item.

References

ISO 17664:2004(E) Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices. ISO 17665 (2006) Sterilization of Health Care Product – Moist heat ANSI/AAMI ST79:2006 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for device manufacturers. AAMI TIR 30:2003 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

Adherence to ISO 17664, ISO 17665, AAMI TIR 12 and AAMI TIR 30 is noted within sterility validation procedure L114-0015. Validations are conducted to AAMI ST79 as applicable and are noted as such.