AEON Instrument Cleaning Instructions

Intended Use

Sheffield Medical Products instruments consist of manual surgical instruments and accessories intended for use in surgical procedures. The instruments offered are Class I reusable manual devices and Class IIa reusable devices.

Instrument utilization is determined by the user's experience and training in surgical procedures. Do not use this instrument for any purpose outside the intended use of the device, as it may seriously affect the safety and function of the product.

Caution - Handle devices with care to prevent cutting surgical gloves with sharp edged surgical instruments.

Recommendations for Care - Cleaning and Sterilization of Sheffield Medical Products Surgical Instruments

Thorough cleaning and rinsing are vital to reprocessing reusable medical devices. Effective cleaning must be carried out to achieve appropriate decontamination. All cleaning should be performed in a manner designed to minimize exposure to blood borne pathogens. Reusable medical devices should be kept moist immediately after use until cleaning. Devices capable of disassembly must be disassembled prior to cleaning. Thorough cleaning and rinsing should be carried out as soon as possible. Manual cleaning should be done while the instrument is immersed. The purpose of cleaning and rinsing is to remove all adherent visible soil and to reduce the number of particulates, microorganisms and pyrogens. Furthermore, thorough rinsing is necessary to remove any residual cleaning agents from the medical devices which could reduce the effectiveness of the sterilization process and protect microorganisms from destruction. Medical devices that will be stored between cleaning and decontamination should be dried with a low linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet instruments.

Cleaning Agents and Equipment

Detergents: Mild enzymatic detergent with a low pH should be used.

Water: The quality of water should be considered for use when preparing enzymatic detergents for rinsing and cleaning. Water hardness is a concern because deposits left on medical devices may result in ineffective cleaning and decontamination. Deionized water can help prevent discoloration and staining associated with mineral residues found in tap water.

Ultrasonic Cleaner: Ultrasonic cleaners are designed for fine cleaning of medical devices, not for disinfection or sterilization. They are used to remove soil from joints, crevices, cannulations and other difficult to access locations.

Cleaning Instruments: General purpose cleaning brushes, pipe cleaning, nonabrasive low linting cloths, ultrasonic cleaner.

NOTE: Brushes and pipe cleaners should have tight fit but be able to move back and forth in the area being cleaned.

Cleaning categories and instructions

Cleaning procedures are dependent on product features. Therefore, the following cleaning instructions are based on product features which present challenges to the cleaning process and not on specific products. Complex devices usually contain product features falling into more than one of the categories listed below. For such devices, a combination of cleaning procedures for the appropriate categories must be utilized. Products requiring more specific cleaning details are supplied with package inserts describing correct cleaning methods.

NON-METALS: Unless otherwise specified, all non-metallic instruments should be reprocessed following the same guidelines as metal products based on the design features applicable to the device.

Instruments WITHOUT hard to access cleaning locations (i.e. punches, screwdrivers, etc.)

Cleaning procedure:

1. Soak devices for a minimum of l minute in mild enzymatic detergent.
2. Use a brush and/or cloth to remove visible soil.
3. Rinse thoroughly with warm water
4. Inspect the devices for visible soil.
5. Repeat if soil is visible. Instruments with cannulations or holes (i.e. drill guides)

Instruments with cannulations and holes (i.e. drill guides)

Cleaning procedure:

1. Soak devices for a minimum of 10 minutes in mild enzymatic detergent.
2. Use a tight fitting brush/pipe cleaner to scrub the cannula/hole with a twisting motion to remove any additional soil.
3. Process devices for a minimum of 5 minutes in an ultrasonic cleaner containing warm enzymatic detergent.
4. Rinse thoroughly with warm water making sure to flush cannula/hole.
5. Inspect devices for visible soil.
6. Repeat if soil if visible

Hinged Instruments (i.e. pliers. cutters, etc.)

Cleaning procedure:

1. Soak devices for a minimum of 3 minutes in mild enzymatic detergent in fully open position.
2. Use a cleaning brush/pipe cleaner to remove additional soil from between the hinged areas.
3. Process devices for a minimum of 5 minutes in an ultrasonic cleaner containing warm enzymatic detergent.
4. Rinse thoroughly with warm water making sure to flush the hinged areas.
5. Inspect the devices for visible soil.
6. Repeat if soil is visible
7. Add lubricant to the hinged area while in the open position. Any validated and approved lubricant can be used.

Instruments with Interfaces (i.e. Slap Hammers, T-Handles)

Cleaning procedure:

1. Soak devices for a minimum of 5 minutes in mild enzymatic detergent.
2. Use a cleaning brush/pipe cleaner to remove additional soil from between the interfaces. Scrub interfaces several times using a twisting motion if possible.
   If components of the device can be retracted, it is necessary to retract or open the device in order to access and clean theses areas.
3. Process devices for a minimum of 1 5 minutes in an ultrasonic cleaner containing warm enzymatic detergent.

4. Rinse thoroughly with warm water making sure to flush the interface(s). If the components of the device can be retracted, it is necessary to retract or open the device for thorough rinsing at theses locations.
5, Inspect the devices for visible soil.
6. Repeat if soil is visible.

Instruments with Crevices (i.e. bolts, cutting blocks, broaches, etc.)

Cleaning procedure:

1. Soak devices for a minimum of 3 minutes in mild enzymatic detergent.
2. Use a cleaning brush to remove visible soil.
3. Rinse thoroughly in warm water
4. Inspect the devices for visible soil.
5. Repeat if soil is visible.

Special Instructions:

Even with proper handling, correct care and maintenance, surgical instruments should not be expected to last indefinitely. This is especially true for cutting instruments (e.g. drills. gouges, reamers, and chisels), driving instruments (e.g. impactors, extractors and mallets).These items are often subjected to high loads and/or impact forces. Before each use carefully inspect all instruments. Do not use a driving instrument that is severely marred and worn, or cutting instrument with dull edges.

NOTE: that at some point in time, instruments wear out and should be replaced. For guidelines related to care and handling of surgical instruments, see AORN recommended practices, AORN Journal 55(3):838, 1992

Materials used in Sheffield Medical Product's instruments have been used in nearly all modern sterilization methods with excellent results. For typical steam autoclave cycles, the following are recommended times and temperatures developed from outside testing using AORN/HIMA and AAMI established guidelines:

1. Gravity Displacement Sterilizer

   Wrapped cases, trays and instruments should be exposed to a minimum of 132°C (270°F) for 30 minutes or 121°C (250°F) for 55 minutes.

2. High Vacuum Sterilizer

   Wrapped cases, trays and instruments should be exposed to a minimum of 132°C (270°F) for a minimum of 4 minutes.

3. Flash Autoclave Cycle

   Sheffield Medical Product's recommends the strict adherence to both ANSI/AAMI AND AORN guidelines concerning flash autoclaving when considering this method of sterilisation.

4. Prevacuum Autoclave Cycle

   Prevacuum 134-137°C for a minimum exposure time of 3 minutes, which requires local validation and routine monitoring of the process.

5. Automated Washer-Disinfectors :

   Use only validated washer-disinfector machines with low-foaming, non-ionising cleaning agents and detergents, following the manufacturers instructions for use, warnings, concentrations and recommended cycles.

- Load instruments carefully with any joints in the open position.
- Place heavy instruments in the bottom of containers, taking care not to overload.
- Place instruments with concave surfaces facing down to prevent pooling of water

NOTE: Automated cleaning may not be suitable for all lumens and cannula, in which case clean manually. After manually cleaning, pass all devices through an automatic cleaning cycle to achieve disinfection.

Limitations on Reprocessing:

Repealed processing has minimal effect on stainless steel surgical instruments. End of life is normally determined by wear and damage in use. Any speci6c limitations on the number of reprocessing cycles shall be made available with the instrument.

It is the responsibility of the reprocessor to ensure that the reprocessing process is performed using equipment and materials which are validated. Personnel must be trained and competent in the re-processing facility processes, to fully achieve the desired result. This requires local validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

Sheffield Medical Product's recommendations for propel steam autoclave sterilization are based upon AORN/HIMA and AAMI guidelines. Proper load sizes, weights and mass should follow OSHA's and AAMI's recommended guidelines.

1. After the autoclave door is opened, all instruments must be allowed to cool thoroughly. The amount of dry time required is dependent upon the load size and its mass. Place instruments on a rack or shelf with linen cover until cooling is complete. The potential for condensation may increase if the case is not allowed to cool properly.
2. If condensation is observed check to insure that step 1 has been followed and verify that the steam that is being used for sterilization processing has a quality of more than 97%. Also confirm that the sterilizers have been inspected for routine maintenance in accordance with manufacturer's recommendations.

NOTE: Manual cleaning is NOT a disinfection process.

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