Sterilization Best Practices

Poster - 01

POINT OF USE – Instrument Preparation

Instruments should be kept free of gross soil during surgical procedures as blood, body fluids and saline can damage instruments and if allowed to dry, be difficult to remove during the decontamination process.

- Wipe instruments as needed during the surgical procedure with sterile surgical sponges moistened with sterile water. Do not use saline as saline can be corrosive to instruments.
- Irrigate instruments with lumens as needed with sterile water throughout the surgical procedure. Do not use saline as saline can be corrosive to instruments.
- Separate sharp instruments from other instruments to minimize risk of injury to decontamination personnel. Place disposable sharps into a receptacle that is proper for disposable. Extreme care must be taken in the management and disposal of sharps waste. Place reusable sharp instruments into a separate receptacle that is puncture-proof for transport.
- Multi-part instruments should be opened, disassembled, and arranged in an orderly fashion within their original set configuration to ensure return as a complete set after reprocessing.
- Hinged instruments should be fully open using stringers, racks, or instrument pegs designed to contain instruments.
- Protect delicate instruments from damage by placing light instruments on top of heavier instruments or segregate into separate containers. Microsurgical instruments should always be segregated into separate containers.
- If any delay in decontamination is expected, instruments should be moistened with a pre-soak solution or covered with a towel soaked with water to keep blood and debris from drying in or on instruments. Do not use saline as saline can be corrosive to instruments.

TRANSPORTATION – Contaminated Instruments

All instruments opened during a surgical procedure should be considered contaminated and properly contained for transport to prevent damage as well as exposure or injury to personnel and patients.

- Hand carried items may be contained using a plastic bag or container with a lid.
- Large quantities of instruments may be contained within a transport cart with doors or plastic cover. Items placed on top of a transport cart must be contained.
- Sharps must be contained in a puncture-resistant container and liquids must be contained in a spill-proof container.
- Transport containers (plastic bag, container or cart) must be labeled to indicate biohazard contents.
- Transport carts should be designed to prevent items from falling off or falling over during transport. Care should be taken to avoid contamination to the outside of the transport container (plastic bag, container with a lid or cart).
- Contaminated instruments should be transported to the decontamination area as soon as possible to prevent soiled items from drying.

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Poster - 02

DECONTAMINATION - Facility design and Personnel

Decontamination is the use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and are rendered safe for handling, use or disposal.

- The decontamination area should be separate from clean activities and accessible by a door and pass though window. The door and pass through windows should be kept closed when not in use.
- The floor, walls, ceiling and work areas should be made of non-porous materials able to withstand frequent cleaning and wet conditions.
- Negative air pressure and a minimum of 10 air exchanges per hour is recommended with air exhausted to the outdoors without recirculation.
- Temperature should be controlled between 60-65°F (16-19°C) and relative humidity between 30-60%. A daily record of temperature and humidity should be kept.
- An appropriate emergency eye wash station should be available.
- Three section sinks to soak, wash, and rinse should be approximately 36" from the floor, 8-10 inches deep and wide enough to accommodate instrument trays. Sinks should have medical grade air and faucets or manifold systems available for flushing instruments with lumens. Instruments should never be cleaned in a scrub or hand sink .
- Personnel must wear appropriate PPE (e.g. hair cover, fluid-resistant face mask, eye protection, liquid-resistant covering with sleeves, utility gloves and shoe covers). All head and facial hair should be completely covered. Jewelry, wristwatches and nail polish should not be worn.
- Before leaving the decontamination area, personnel should remove PPE and wash hands. Extreme care must be taken not to contaminate clothing or skin during removal of PPE.

DECONTAMINATON – Procedures

Decontamination should occur immediately after the surgical procedure to prevent soil from drying and the formation of biofilm. The instrument manufacturer's validated reprocessing instructions for use (IFU) should be available and followed.

- Upon arrival, instruments should be removed, sorted and prepared for cleaning. Extreme care should be taken to prevent loss of small parts.
- Pre-soaking, detergent type, detergent dilution, water quality, water temperature, cleaning implements (type, size, length) and cleaning should all comply with instrument manufacturer's IFU.
- When manually cleaning, always scrub below the water line surface to limit the creation of aerosols. After cleaning, thoroughly rinse all areas to remove debris and detergent residue. Some instruments may require rinsing with treated water (e.g. distilled, deionized, RO or sterile). Reusable brushes should be disinfected or sterilized at least daily.
- Ultrasonic cleaning should only be used for fine cleaning and not used to remove gross soil. Some ultrasonic and mechanical cleaners are designed to clean and disinfect specialized instruments, such as endoscopes. Specific sonication parameters (time and temperature) may be required for complex instruments, followed by rinsing and repeated sonication.
- Mechanical cleaning equipment should be tested upon installation, after major repairs and daily during routine use.

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Poster - 03

PREP & PACK – Inspection and Assembly

It is important to carefully inspect and assemble surgical instruments prior to packaging. A dirty or non-functioning instrument is a patient safety issue and should not be used.

- Visually inspect each instrument for cleanliness and function. Use a lighted-magnifying lens for detailed inspection of small or complex instruments.
- Return any dirty instrument to the decontamination area for re-cleaning. Document and report any non-functioning instrument to the appropriate person.
- Remove excess moisture from instruments using filtered, medical-grade, compressed air.
- Assemble instrument sets in an appropriate tray (e.g. perforated, wire-mesh-bottom, or containment device provided by the rigid container manufacturer). Be sure to inspect wire-mesh-bottom trays for any sharp edges or loose mesh-wire that could cause damage when wrapped.
- Arrange instruments in a manner that does not restrict air removal or sterilant penetration (e.g. assemble all hinged instruments in the open and unlocked position, disassembly multi-part instruments per the manufacturer's IFU and remove any stylets or plugs from instruments with lumens).
- Non-linting absorbent material (e.g. towel) may be placed in the tray to facilitate drying. For adequate drying, it may be necessary to wrap dense instruments with absorbent material. Plastic organizing trays and cassettes are known to require longer drying times.
- Some lumened instruments require flushing with treated water just prior to packaging.
- Instruments should not be held together with tape or rubber bands.

PREP & PACK – Packaging

Packaging systems must be validated for the intended sterilization process and used according to the manufacturer's instructions for use (IFU). Some instruments may require a specific packaging method.

- Paper-plastic peel pouches should only be used for small, light-weight instruments. Be sure to remove excess air before sealing pouch. Double pouching is not required, but may facilitate aseptic presentation to the sterile field. Paper-plastic peel pouches should not be used inside wrapped trays or rigid containers.
- Reusable wrappers should be laundered between uses and inspected prior to each use. Disposable wrappers should be inspected prior to each use and are for single-use only. Typically, two layers of wrap are required per the manufacturer's validated IFU. "Latex-free" indicator tape should be used where available for patient and staff safety.
- Rigid container systems should be decontaminated and inspected between each use. Filters, valves and other components must be used according to the manufacturer's validated IFU.
- Per AAMI and AORN, the maximum weight of instrument sets should not exceed 25 pounds (22 pounds per CSA and ISO). The maximum weight includes the packaging system.
- Prior to sterilization, all packaging should be labeled with a lot control label indicating load number, sterilizer number and date of processing.

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Sterilization Best Practices

Poster - 04

STERILIZATION – Steam under pressure

Steam sterilization is considered the process of choice over other sterilization processes. The instrument manufacturer's validated instructions for use (IFU) must be followed when selecting the method of steam sterilization and cycle parameters.

- Steam sterilization is possible using one of three methods – gravity displacement, pre-vacuum or steam flush pressure pulse (SFPP). Pre-vacuum and SFPP sterilizers are referred to as "dynamic air removal".
- Steam sterilizer parameters can be adjusted; however, standard cycles are recommended and should be used unless otherwise stated in the instrument manufacturer's IFU.
- Gravity displacement can sterilize routine instruments at 121°C/250°F with 30 minute exposure, plus drying time. At 132°C/270°F the exposure time is reduced to 15 minutes, plus drying time. Some complex instruments; however, require extended exposure times.
- Dynamic air removal sterilizers can sterilize routine instruments at 132°C/270°F with 4 minute exposure or 135°C/275°F with 3 minute exposure, plus drying time. Some complex instruments; however, require extended exposure times.
- Immediate-use steam sterilization (IUSS) can be accomplished for routine instruments using validated reduced cycle parameters. Some complex instruments; however, require extended sterilization cycles.
- Always load steam sterilizers with lighter items on top and heavier items below. Peel pouches, basins and instrument trays with solid bottoms should be placed on edge facing the same direction on the sterilizer shelf or cart. Rigid containers and wrapped instrument trays using perforated bottoms should be placed flat on the sterilizer shelf or cart. Never place items directly on or against the sterilizer chamber.
- After processing, all items should be allowed to cool to room temperature before handling.

STERILIZATION – Low Temperature

For heat and moisture sensitive instruments, a variety of low temperature sterilization processes are available. The instrument manufacturer's validated instructions for use (IFU) must be followed when selecting the method and cycle parameters.

- Ethylene oxide (EO) gas is available in 100% concentration or mixtures and takes hours to complete as additional aeration time is needed to remove the EO from the packaging and/or processed items. Many medical devices have been validated for use with EO; however, personnel monitoring is required along with maintaining health records for the duration of each healthcare worker's employment +30 years.
- Hydrogen peroxide (VH2O2) methods are available with sterilization cycles as low as 28 minutes for non-lumened instruments. No additional aeration is needed or personnel monitoring, according to the sterilizer manufacturers. Paper products are not compatible; therefore, synthetic packaging, labels, cards, etc.. must be used.
- Ozone is a sterilization process that takes around 4 hours to complete. This proprietary process is being reengineered to include H2O2 and is pending FDA clearance for a shorter cycle time.
- Peracetic acid is a liquid chemical sterilization process used primarily for endoscopes. It is important to verify proper selection of adapters and connect the device to the appropriate adapters as recommended by both the sterilizer and instrument manufacturer.

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Poster - 05

QUALITY ASSURANCE

Sterilization quality assurance is documented through the use of physical, chemical and biological indicators. Sterilization records should be maintained in compliance with local, state and federal regulations.

- Physical indicators (e.g. sterilizer print out) should be recorded and maintained for every cycle. The sterilizer operator should review and initial the print out after cycle completion before removing the load.
- For individual pack monitoring, an external and internal chemical indicator (CI) should be used. The external CI verifies the package was processed and the internal CI verifies sterilant penetrated inside the package. For steam processes, a Class 5 CI should be used to monitor critical loads (e.g. implants and immediate-use steam cycles). More than one CI should be used with a rigid sterilization container and/or wrapped multi-layered tray.
- For steam sterilizer load monitoring, a biological indicator (BI) should be used daily and all loads containing an implant. For low temperature processes, a BI should be used with every load. The BI is placed inside an approved PCD (process challenge device) and located as recommended by the sterilizer manufacturer. When processing steam loads containing an implant, the PCD should contain both a BI and a Class 5 CI. Routine items in the load can be released immediately based on the Class 5 results; however, implants should wait for the BI results. Release of implants before the BI incubation time for spore growth should be documented with an early release form. Steam loads not containing implants can be monitored with a Class 5 PCD for immediate load release. Pre-vacuum steam sterilizers should be tested daily for proper air removal. This test is called a Bowie-Dick test and is run by itself on the lowest shelf over the drain at 134°C for 3.5 or 4 minutes with dry time optional.
- Each day the sterilizer is BI tested, an unprocessed BI from the same lot should be incubated as a CONTROL in each incubator. BI spore growth verifies the incubator is working and the BI test was viable when used.

STERILIZER FAILURE

Sterilizers that fail any of the quality assurance tests should be reported immediately to a Supervisor and all test procedures reviewed. The load should be reprocessed and the sterilizer retested.

- If the sterilizer fails again, it is considered a malfunction and should be taken out of use. After servicing, retest with three (3) consecutive BI PCDs before using again. Steam pre-vacuum sterilizers should also pass three (3) consecutive Bowie-Dick tests following the BI tests.
- Positive BI test results should be sent to Microbiology Laboratory for confirmation of actual spore growth and not a false positive reported by the person viewing the BI or a malfunctioning auto-reader. Confirmation of a positive BI requires incubation for visible spore growth (not enzyme early-readout).
- Operator error is the leading cause of sterilizer failures, reported to be as high as 85% of failures. Examples include; incorrect use and/or interpretation of BI, incorrect cycle for load contents, use of inappropriate packaging materials or packaging technique, incorrect loading of sterilizer, etc. Proper in-servicing can eliminate sterilizer failure caused by operator error. For steam processes, using a Class 5 CI along with the BI, can effectively eliminate product recalls.
- Examples of sterilizer malfunction, include: poor steam quality or quantity, incomplete air removal, inadequate cycle temperature, insufficient time at required temperature.

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