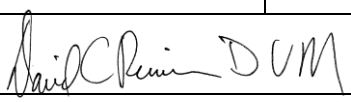
RUTGERS UNIVERSITY Office for Research

CMR STANDARD OPERATING PROCEDURE

TITLE: Sterile Processing		
SOP Category: Veterinary	**CMR SOP #: 7.21**	**Page: 1 of 20**
Effective Date: 09/27/2024	**Approval:** 	
Revisions: 9/10/2024		

SCOPE:

This SOP applies to all Animal Care Staff (ACS), ACS Supervisors (ACSS), Veterinary Staff (VS), and Research Staff (RS) at the Rutgers Newark, New Brunswick/Piscataway and Camden facilities.

OBJECTIVE:

This goal of this document is to provide an outline of proper cleaning, sterilization, and storage techniques for surgical instruments and other supplies used in sterile procedures. Proper sterile processing techniques are crucial in the prevention of infection and injury to animals.

DEFINITIONS

IFU – Instructions for Use. Accompany instruments, medical devices, and other items used in sterile processing. Provide instruction for the safe use of the product. If not provided with product, IFUs are available online or by request from the item manufacturer.

PPE – Personal Protective Equipment

PROCEDURES:

General Considerations

IFUs for instruments, devices, and cleaning supplies must be reviewed prior to reprocessing. Instructions in IFUs supersede guidelines provided in this document and must be followed to ensure proper care, particularly for complex instrumentation such as power equipment and endoscopic instrumentation.

A one-way workflow must be followed, separating the processes of decontamination, preparation and packaging, sterilization or disinfection, and storage. Items in different stages of reprocessing must not be mixed to prevent contamination.

Recommended PPE for staff should include bouffant hair coverings, shoe covers or dedicated footwear, and clean scrubs. Gloves must be worn at all stages of instrument reprocessing and should be changed between stages (for example, when working with clean instruments, replace gloves that were used to touch contaminated items). Staff with nail polish should not handle items without gloves at any stage of reprocessing.

The following solutions are damaging to instruments and should not be used for reprocessing. See Appendix 1 for examples of acceptable products.

Betadine	Peroxide	Dish soaps
Soaking in water	Saline	Bleach
Iodine	Hand soap	Chlorhexidine solutions
Porcelain cleaners	Household lubricants	Household cleansers
Surgeons' hand scrubs	Laundry detergent	Long-term soaking in stain or rust remover

Cleaning

Instruments must be cleaned as soon as possible after use. Cleaning refers to the removal of all soil, including organic matter and other materials, like drape residue.

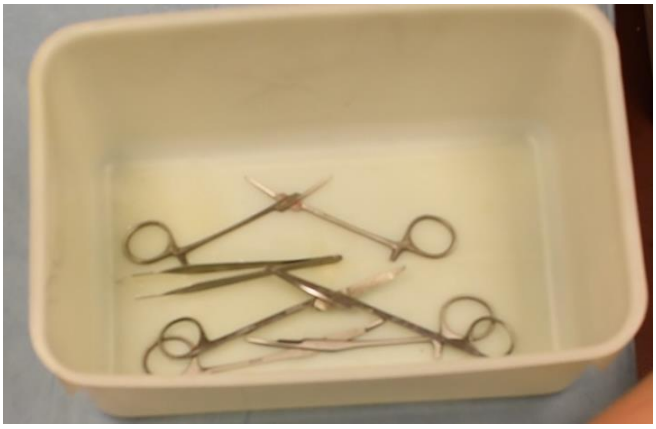
If instrument cleaning is delayed for any reason, such as transport to a different location for reprocessing, begin reprocessing at point of use.

Point of Use Reprocessing

1. Remove gross soil from instruments.

Wet gauze or other wettened non-abrasive materials can be used to remove gross soil from instruments.

2. Keep any remaining soil moist until instruments can be fully cleaned.
    a. Open and disassemble instruments so all surfaces are exposed to moistening agent.



    b. Keep moist by using commercial spray or foam products or covering instruments with a towel dampened with water. This step prevents soil from drying, which leads to the formation of biofilms.

3. Keep track of any instruments in need of repair and notify appropriate personnel. Instruments that are not in good repair should not be used on animals until they are functioning properly.

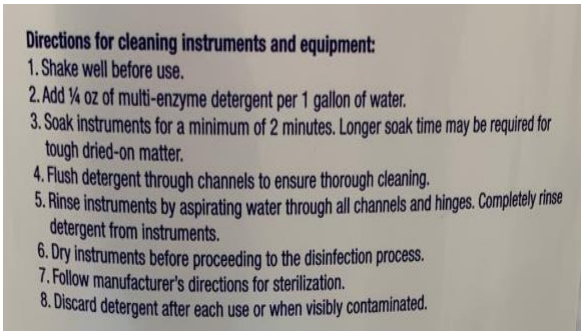
Cleaning

All instruments must be manually cleaned, regardless of whether they are further cleaned with an ultrasonic cleaner. Refer to IFU prior to cleaning and follow all instructions.

<u>Cleaning</u>

1. Fill soaking container with properly diluted instrument cleaning solution.

Detergent designed for instrument use. Dilution instructions can often be found on the cleaning solution container.

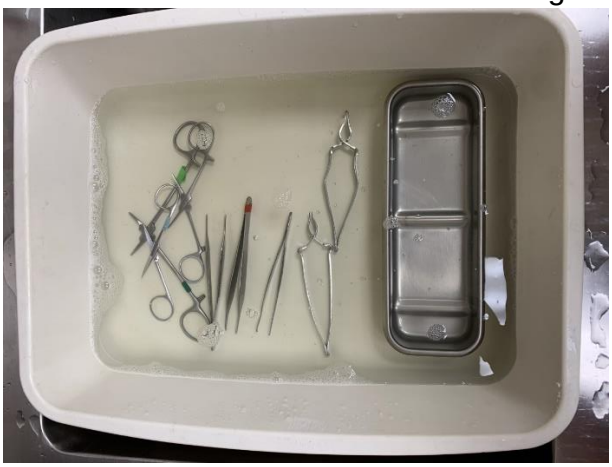


Directions for cleaning instruments and equipment:

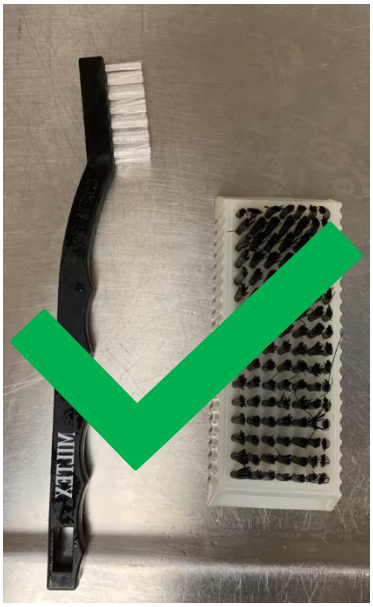
1. Shake well before use.
2. Add ¼ oz of multi-enzyme detergent per 1 gallon of water.
3. Soak instruments for a minimum of 2 minutes. Longer soak time may be required for tough dried-on matter.
4. Flush detergent through channels to ensure thorough cleaning.
5. Rinse instruments by aspirating water through all channels and hinges. Completely rinse detergent from instruments.
6. Dry instruments before proceeding to the disinfection process.
7. Follow manufacturer's directions for sterilization.
8. Discard detergent after each use or when visibly contaminated.

Container filled with properly diluted detergent.

2. Open and disassemble all instruments and completely submerge in solution. Take care to not stack delicate instruments to avoid damage.



3. Scrub instruments with nylon scrub brushes or non-abrasive sponges to remove all soil.



Never use stainless steel brushes to scrub items that will be sterilized.

4. Rinse instruments thoroughly with tap water. This can be done by submerging in a container filled with water.

Instruments should be submerged briefly and removed. Do not soak instruments in water.

5. If using ultrasonic cleaner, follow steps 6 to 9 below. If not, skip to step 10.
    a. **See Appendix 2 for additional instructions regarding the use of ultrasonic cleaners.**
6. Fill ultrasonic cleaner with properly diluted instrument cleaning solution.
7. If the solution is being used for the first time after filling, run one 10 minute cycle with no instruments to degas the solution.

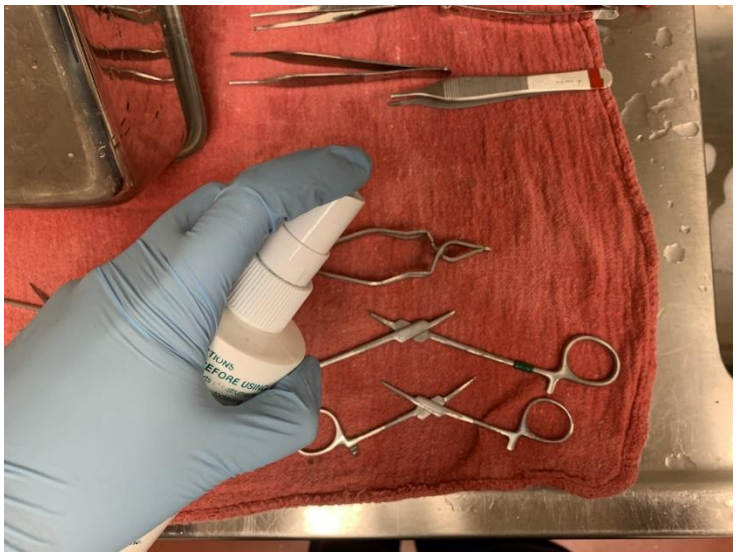
8. Load ultrasonic cleaner.

- Avoid stacking instruments excessively.
- Instruments should be opened and disassembled.
- Fill lumens or cannulas with diluted cleaning solution prior to placing in tray.
- Ensure all instruments are completely covered with diluted cleaning solution.

9. Place lid on ultrasonic cleaner. Set ultrasonic cleaner dial to 10 minutes and start cycle.

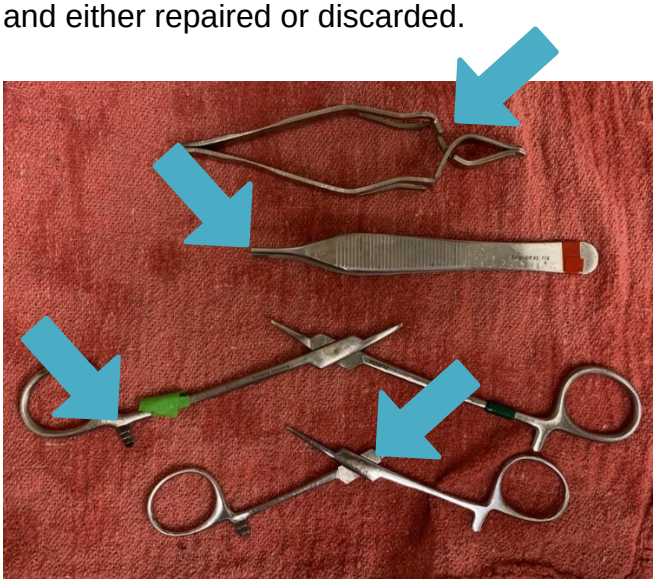
10. Remove instruments from tray and rinse instruments thoroughly with tap water. This can be done by submerging in a container filled with water (as in step 4).

11. If available, rinse instruments with final rinse of deionized, distilled, or reverse osmosis water.
12. Lubricate instruments as needed with lubricant designed for surgical instruments per the lubricant IFU.

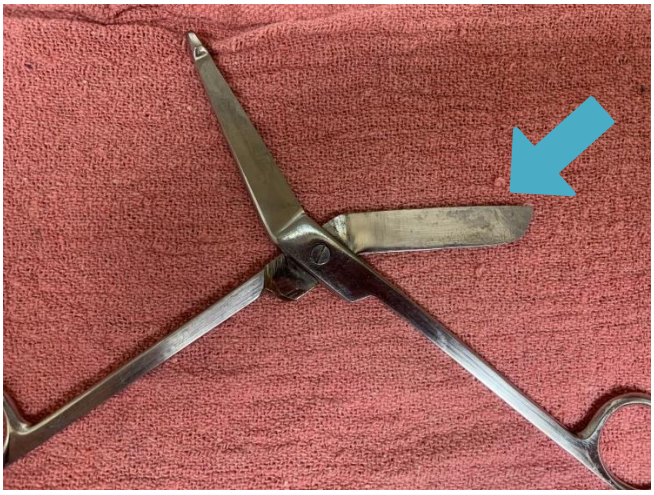


Inspection

After cleaning, inspect all instruments for cleanliness, functionality, and wear. Use test materials as appropriate to check sharpness of instruments with cutting edges. Any instrument that is worn, broken, damaged, or rusted should be taken out of circulation and either repaired or discarded.



Pay special attention to hard-to-clean areas when inspecting instruments for cleanliness.



Unclean instruments with debris that needs to be removed.

Hemostat with misaligned tip.

Needle holders with worn jaws.

Pitting (left) and rust (right).

Preparation and Packaging

Items must be appropriately packaged prior to sterilization.

Preparation Considerations

- Items to be sterilized should be fully dried.
- All parts of multi-part instruments must be accounted for. When possible, instruments with multiple pieces should be sterilized disassembled.
- All instruments with locks or ratchets should be unlocked for sterilization.
- If instruments belong to a set, ensure set is complete.
- Previously sterilized fabrics must be laundered prior to resterilization. Absorbent materials that cannot be laundered should be discarded and not be resterilized.

Packaging

1. Select appropriate packaging for sterilization method and item(s) to be sterilized.
    a. Heavy items or sets with many instruments should be wrapped in cloth or disposable sterilization wrap.
    b. Light items or small sets of instruments may be packaged in sterilization pouches.
2. Place item or set of items in packaging material.

If steam sterilizing, small items can be placed inside all-paper bags, then placed inside other packaging materials.

Items in pouches should have approximately ¼” to 1” of space surrounding them on all sides.

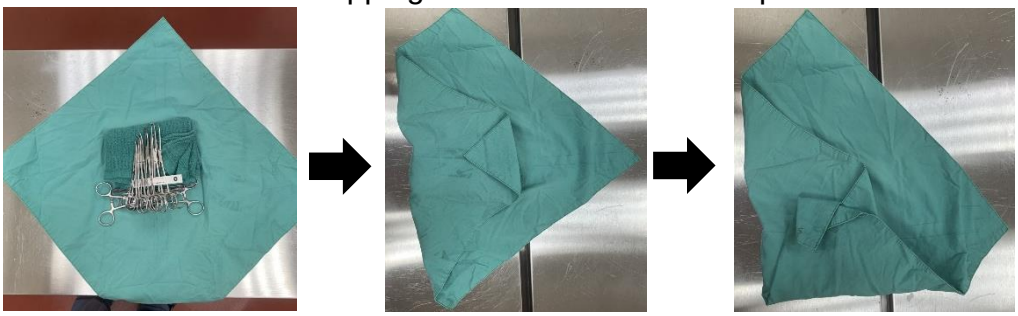
In a sterilization pouch, curved instruments should be placed so curve is pointing toward plastic side of pouch.

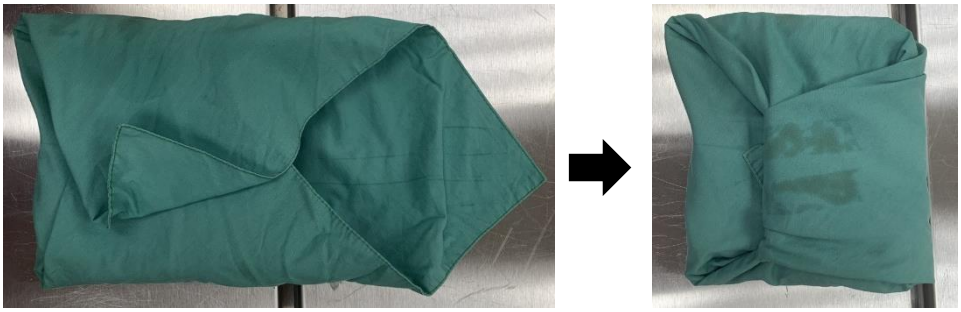
Delicate and/or sharp tips should be covered with instrument tip protectors to prevent instrument damage and packaging punctures.

A Type 4, 5, or 6 chemical indicator should be placed inside packaging. See Appendix 3 for an explanation of indicator types.

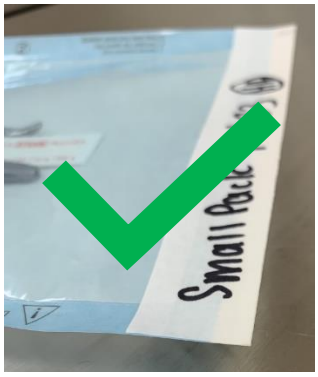
3. Package instruments.
    a. Items wrapped in sterilization wrap should be wrapped with two layers of material using the envelope method. Layers can be wrapped sequentially or simultaneously. Acceptable wrapping materials include reusable cloth wraps or disposable wraps such as SMS sterilization wrap.

Simultaneous wrapping with reusable cloth wrap

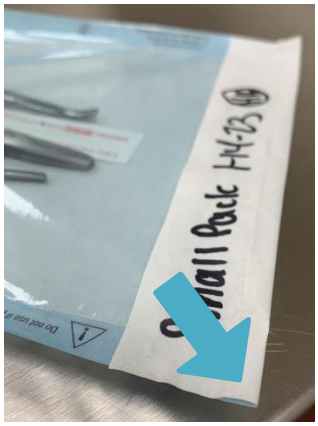




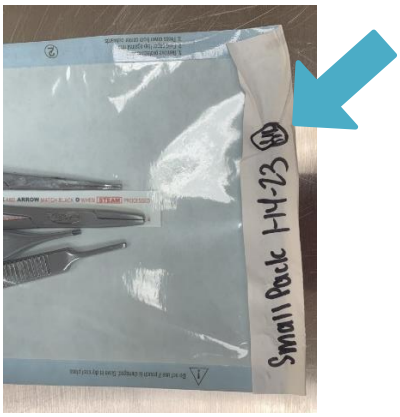
    b. If using sterilization pouches, ensure that an effective seal is formed. To achieve an effective seal on a self-seal pouch, keep the pouch flat while sealing, fold the package on perforations or pre-folds, and press the seal to the package starting in the middle and working to the edges.



Effective seal. Seals should not contain any gaps or crinkles.



Seal with gap. Package should rewrapped.

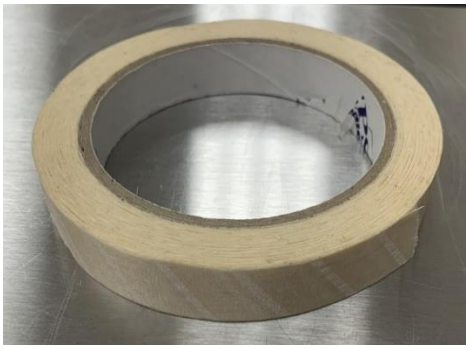


Seal with crinkle. Package should rewrapped.

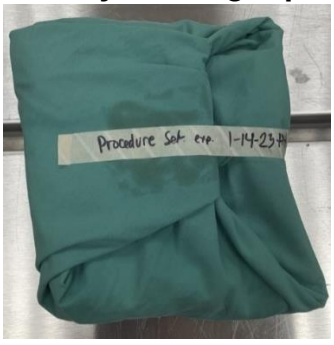
c. Single sterilization pouches may be placed inside an outer sterilization pouch as long as the pouches are not folded and pouches are oriented the same way (e.g. plastic touches plastic, paper touches paper).

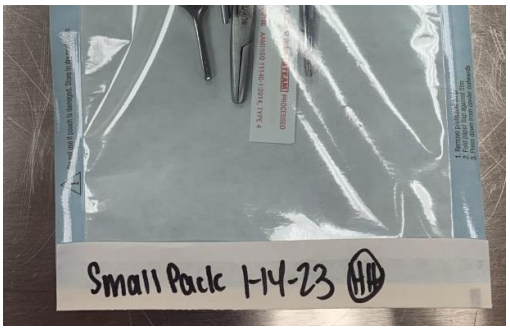
Ensure no part of inner pouch is sealed in the seal of the outer pouch.

4. Add an external indicator, such as sterilization tape, if the packaging does not have an external indicator.



5. Label packages with expiration date and contents. Expiration dates should be determined based on packaging IFU. **An expiration date of 6 months from the date of wrapping is recommended, however, packages may maintain sterility for longer periods if packaged, stored, and handled appropriately**.





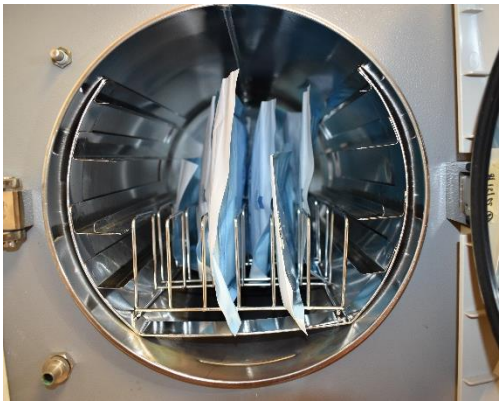
Steam Sterilization

Loading the Sterilizer

When loading the sterilizer, items must be placed to allow adequate steam and air flow. **DO NOT OVERLOAD the sterilization chamber.**

- Items must be placed so there is visible space between each item.
- Items must not touch the chamber walls.
- Large, heavy items should be placed toward the bottom of the sterilizer.
- Paper/plastic sterilization pouches must be placed on their edge in a rack. If multiple items are placed in the same rack, pouches must be arranged in the same way so that paper faces plastic. Only one item should be placed per row in a rack unless multiple items can be placed without overlapping.
- Items wrapped in sterilization wrap should be oriented to allow for draining. Trays without drainage holes should be tilted. Basins should be upside down and tilted on their edge.

Sterilization pouches should be placed in racks on their sides.

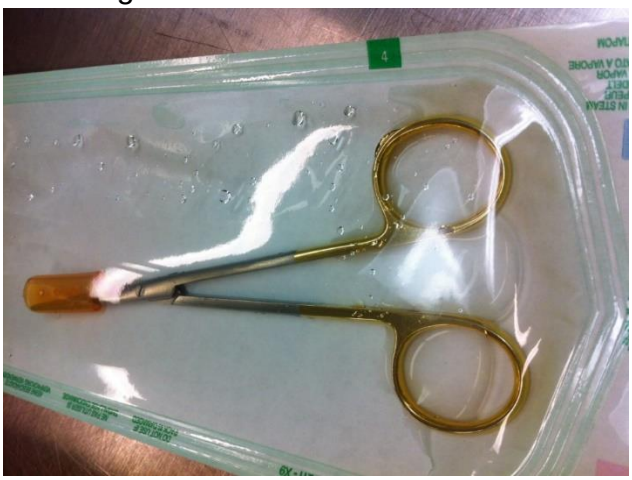


Properly loaded autoclaves.

After loading the sterilizer, select the appropriate cycle, press start, and allow the cycle to complete.

Unloading the Sterilizer

- Items must be cooled to room temperature before they can be handled.
- Any packs that are wet or contain residual moisture must be repackaged and resterilized. If single use wrap or pouches were used, discard the used packaging and use new packaging. Re-launder reusable wraps before sterilizing again.



This item is wet and should be repackaged and resterilized.

Low Temperature Sterilization

Low temperature sterilization methods can be used for items that are heat or moisture sensitive. Be sure to select the appropriate packaging material and be sure that the sterilization method is compatible with the items to be sterilized.

Storage and Transport of Sterile Items

- Sterile items should be stored in a clean, dry location.
- Sterile items should not be stored with non-sterile items.
- Packaged items should be handled with care and lifted, not dragged, when handled.
- Items wrapped in sterilization wrap should not be stacked.
- Sterile items should be rotated so that older items will be used first.

Sterilization pouches should be packed loosely in bins and containers to prevent damage to packaging.

A dedicated cabinet or shelf should be used to store sterile items separately from non-sterile items.

Event-based Sterility

When determining if a packaged item is still sterile, event-based sterility should be considered in addition to time-based expiration dates. If any of the following events occur, an item should no longer be considered sterile and must be resterilized before use.

- Past expiration date
- Wetness on or inside package
- Damage to packaging
- Package is dropped
- Package placed on unclean surface

Appendix 1. Examples of Acceptable Instrument Reprocessing Products

Prep Sprays to Keep Instruments Moist After Use

- Integra Miltex Instrument Prep Enzyme Foam
    - Supplier Number: Integra Miltex 3-760
    - Available from VWR, LabViva

Solutions for Manual and Ultrasonic Cleaning

- Endozime Enzymatic Instrument Detergent AW Triple Plus
    - Supplier Number: Ruhof 345APA
    - Available from Fisher Scientific, Henry Schein
- Roboz Enzymatic Instrument Cleaner
    - Supplier Number: Roboz EC-1000
    - Available from VWR, Fisher Scientific
- Enzol Enzymatic Instrument Detergent
    - Supplier Number: Advanced Sterilization Products 2252
    - Available from Henry Schein
- Integra Miltex Surgical Instrument Cleaner
    - Supplier Number: Integra Miltex 3-720
    - Available from VWR, Fisher Scientific, Henry Schein

Appendix 2. Ultrasonic Cleaner Use and Maintenance

Ultrasonic cleaners should be operated and maintained as per their IFU. Instructions in IFUs supersede guidelines provided in this appendix.

Preparation

- Ultrasonic cleaner solution should be prepared fresh on the same day that it will be used.
- Cleaning solutions should be low foaming and designed for use in an ultrasonic cleaner. Acceptable examples of cleaning solutions can be found in Appendix 1.

1. Fill chamber to fill line with appropriately diluted cleaning solution. Operating an ultrasonic cleaner that is not filled adequately can cause irreversible damage to the machine.
2. After filling, run one 10 minute cycle prior to running a cycle with instruments. This is called “degassing” and allows for the removal of dissolved gases and air bubbles that may interfere with the ultrasonic cleaner’s ability to effectively remove soil. This must be done every time solution is added.
3. Load instruments and proceed with ultrasonic cleaning as per instructions in SOP.

Maintenance

- Ultrasonic cleaners must be drained and cleaned at least daily. If any visible soil is present or if there is a change in solution appearance (e.g. cloudiness, color change), solution must be discarded and replaced. After draining, wipe chamber with disinfectant (such as Peroxigard) and rinse with water.
- Generally, ultrasonic cleaning solutions can be poured down the drain and do not require any special disposal. Contact REHS or refer to the cleaning solution Safety Data Sheet (SDS) for additional guidance.

Quality Assurance

- Efficacy of the ultrasonic cleaner should be tested regularly. This can be done with the use of test strips or foil. A piece of foil or a test strip should be placed in the ultrasonic cleaner basket for one cycle. Best results are obtained by placing the strip or foil vertically.

Appearance prior to cycle.

Fail result. Ultrasonic cleaner is not functioning effectively.

Pass result. Ultrasonic cleaner is functioning effectively.

Pass result for foil test. Foil should display holes or punctures after exposure to ultrasonic cleaner cycle. Use regular strength aluminum foil, not heavy-duty foil.

- If the test fails, try degassing the ultrasonic cleaner by running an empty cycle, then try test again. Repeated failures warrant further investigation, including machine servicing or repair.

Appendix 3. Explanation of Sterilization Indicators

Chemical Indicators

Note that Type and Class are used interchangeably to describe indicators. For example, a Type 4 and Class 4 indicator are equivalent.

Critical parameters are conditions that must be met for sterilization to occur. Critical parameters for steam sterilization are temperature, time, pressure, and steam.

While chemical indicators indicate that parameters have been met, it is important to remember that they do not guarantee that items are sterile. Proper reprocessing techniques are required to ensure instruments are prepared adequately so that sterilization processes can be effective.

1	Process indicator	Autoclave tape	Used to differentiate between items that have been processed and not processed. Do not indicate that cycle was effective.
2	Specific-use indicator	Air removal test	Test specific functionality of sterilizer; e.g. air removal of prevacuum autoclaves.
3	Single-variable indicator	Indicator that reacts to temperature	Indicates that a single critical parameter met or surpassed the threshold for sterilization to occur.
4	Multi-variable indicator	Indicator that reacts to temperature and time	Indicates that two or more critical parameters met or surpassed the threshold for sterilization to occur.
5	Integrating indicator or Integrator	Indicator that reacts to all critical parameters over a range of cycles	Indicates that all critical parameters met or surpassed the threshold for sterilization to occur.
6	Emulating indicator or Cycle Verification	Indicator that reacts to all critical parameters for a specific cycle	Can only be used for cycle they are designed for. Indicates that all critical parameters met or surpassed the threshold for sterilization to occur.

Biological Indicators

Biological indicators provide direct evidence that sterilizers are functioning appropriately by challenging the sterilizer with microorganisms that are resistant to the sterilization method in use. After sterilization, the indicators are typically incubated to allow for microbial growth. A negative result (no growth of microorganisms) indicates that the sterilizer is capable of sterilization.