QUAD
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Sterilization: What are surveyors looking for?

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Patients First. *Always.*

Survey Process Includes

- Reviewing Facility Documents
  - Policies & Procedures
  - Manufacturer's Instructions for Use (IFU)
  - Recordkeeping
- Interviews with Staff
  - Facility Leadership
  - Staff from the Operating Room and Sterile Processing
- Observation
  - Operating Room
  - Sterile Processing Areas
  - Storage Areas

Adoption of Current Infection Control Guidelines

- Evidence-based recommendations to prevent the transmission of infectious agents between patients and health care personnel
- Alignment with recognized guidelines
  - Centers for Disease Control and Prevention (CDC)
  - Association for Professionals in Infection Control & Epidemiology (APIC)
  - Association of periOperative Registered Nurses (AORN)
  - Association for the Advancement of Medical Instrumentation (AAMI)
- Reviewed annually
- Training provided to all staff (upon hire, annually, as needed)

Standard 7-A-6: The Infection Prevention and Control Program must include documentation that the facility has considered, selected, and implemented nationally recognized infection control guidelines.

Medicare
Ambulatory Surgery Center

Standard 7-A-8: The facility policy manual should include infection prevention and control policies and procedures that are consistent with current CDC guidelines.

Office-Based Surgical
Office-Based Procedural

Standard 7-C-1: The facility has a written protocol for the reprocessing of all surgical instruments and disinfection of all equipment used in patient care consistent with the manufacturer's instructions for use.

POLICY

Facility staff will handle and care for surgical instruments and powered equipment in accordance with the manufacturer's recommendations, evidence-based practices, and nationally recognized infection prevention guidelines.

Staff will practice standard and transmission-based precautions and wear appropriate personal protective equipment when handling and processing contaminated instruments and powered equipment. Decontamination of instruments and powered equipment will begin immediately after the completion of any invasive procedure and will be completed in a timely manner.

The Facility will follow the manufacturer's written instructions for detergent selection, cleaning methods, processing times, and the proper use, care, and maintenance of instruments and powered equipment.

Surgical instruments and powered equipment will be inspected and prepared for sterilization and/or storage after decontamination.

Manufacturer's Instructions for Use (IFU) Followed For Sterile Processing

Device-specific, validated cleaning instructions to ensure that, when followed precisely, sterilization is achieved.

- Point-of-use, manual/automated cleaning instructions
- Compatible chemical products
- Recommended cleaning implements (e.g., brushes, sponges)
- Approved packaging (e.g., pouches, wraps, rigid containers)
- Parameters for sterilization (i.e., time, temperature, pressure)
- The maximum number of times a device can be reprocessed
- Storage requirements (when applicable)

Standard 4-E-5: The manufacturer's specifications and requirements for all equipment are kept in an organized file and followed for each piece of equipment.

IFUs, are they?

- Available for all medical devices
- Easily accessible
- Consulted before/during reprocessing
- Followed precisely

4. Cleaning
a. **Manual**

1. Rinse Cannula under warm (≥49°C) running water (for a minimum of 2 minutes) to remove visible soil. Use a lint-free cloth wetted with water to aid in the removal of excess soil and contaminants.
2. Fully submerge the Cannula in the prepared cleaning solution. Use a syringe to flush the cleaning solution through the lumen, and then allow to soak for a minimum of 2 minutes.
3. After soaking the Cannula, while immersed in the cleaning solution, brush the outer surface for a minimum of 2 minutes using a bristled brush, (such as Sklar® 10-1650), to remove visible soil and contaminants from the distal fenestrations and the exterior of the Cannula.
4. After external cleaning, while still immersed in the cleaning solution, brush the interior (lumen) of the Cannula for a minimum of 2 minutes using an appropriately sized lumen brush, (such as Sklar® 10-1350 for 2.4mm Cannula), to remove soil and contaminants from the interior. Use a syringe to flush the interior (lumen) with the cleaning solution. Repeat this step until no visible soil or contaminants are observed exiting either end of the Cannula.

5. Prepare an ultrasonic bath with the cleaning solution. Immerse the Cannula in the ultrasonic bath and use a syringe to flush with the cleaning solution. Sonicate for a minimum of 10 minutes.
6. Remove the Cannula from the ultrasonic bath and thoroughly rinse under running tap water for a minimum of 1 minute.
7. Prepare an ultrasonic bath of filtered water. Immerse the Cannula in the ultrasonic bath and sonicate for a minimum of 10 minutes.
8. Remove the Cannula from the ultrasonic bath and use a syringe to flush the lumen of the Cannula with 60mL of filtered water a minimum of 3 times. Thoroughly rinse under warm running water for a minimum of 1 minute. Repeat this step at least 2 more times using filtered water for the final rinse.

WARNING: Inadequate rinsing or flushing may leave residual detergent on the Cannula. Read and review the hazards and precautions associated with the cleaning detergent.

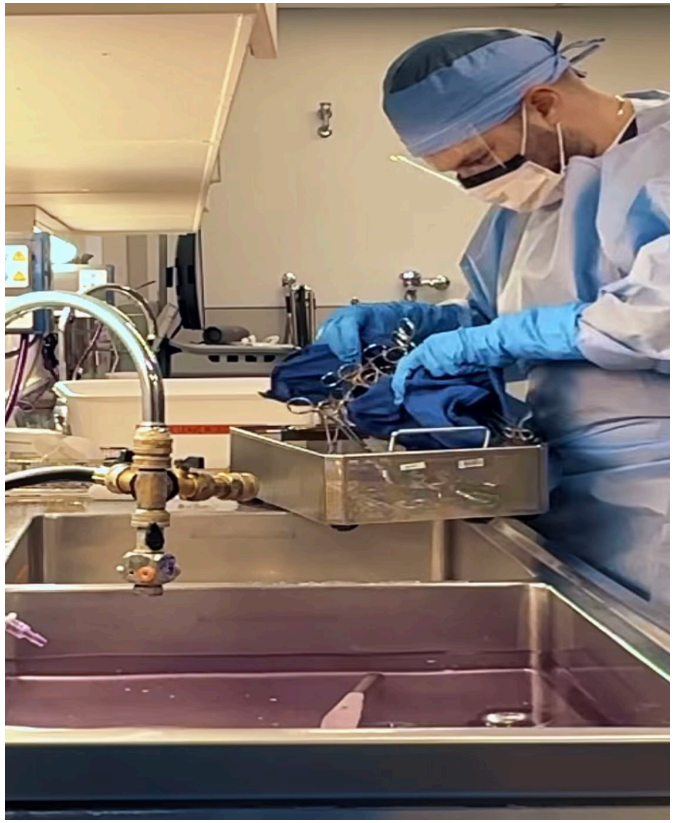
9. Upon completion of the manual cleaning visually inspect, using 10x - 15x magnification, Cannula shaft, hub and all recessed features to ensure that all visible soil and contaminants have been removed. If soil or contaminants remain, repeat the entire manual cleaning process.

Minimally: 32 minutes of cleaning and rinsing

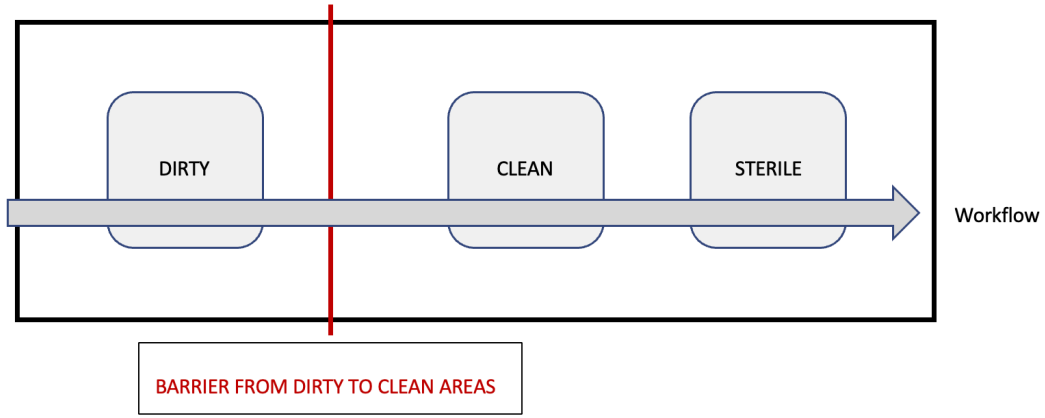
Observations & Interviews in Sterile Processing

- Prepare staff for engagement with surveyors
- Surveyor will observe reprocessing tasks
- Successful strategies include:
  - Having visual cues posted
  - Pull the IFU and follow step-by-step instructions
  - Use voice-activated timers or reference wall clocks for timed processes
  - Explain the steps (e.g., “I’m rinsing for 2 minutes”)
  - Describe rationales

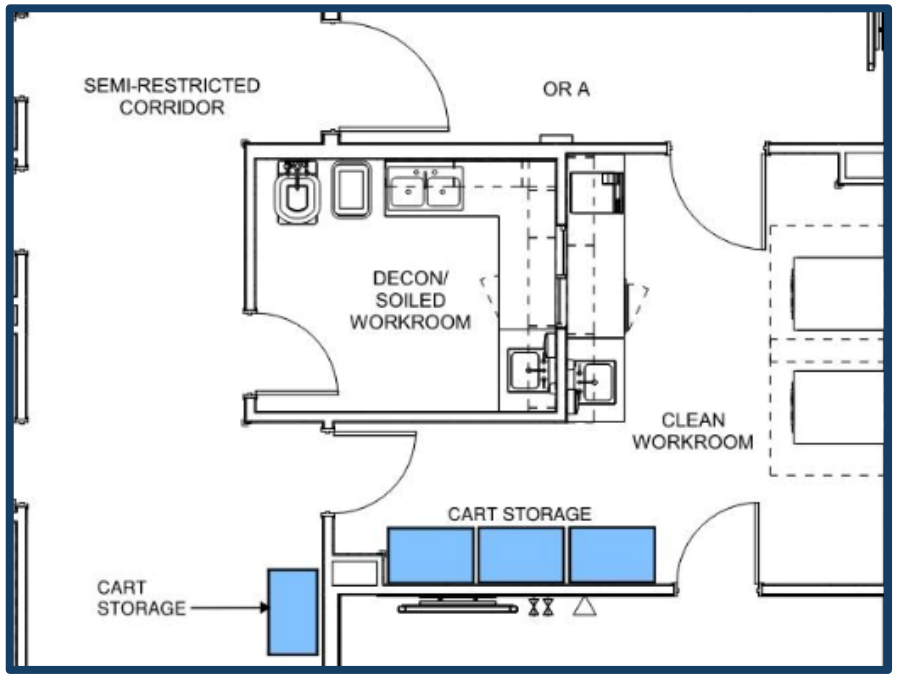
Standard 7-C-2: There is strict segregation of dirty surgical equipment and instruments that have been cleaned and are in the preparation and assembly area.

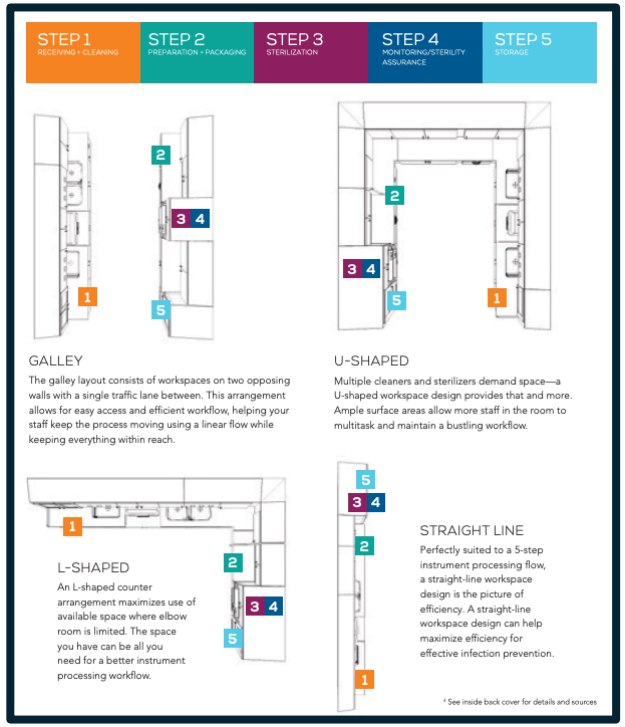


Unidirectional



Standard 7-C-3: The instrument preparation and assembly area (clean processing area) are separated by walls or space from the instrument cleaning and decontamination area (reprocessing area).





Standard 7-C-4: Single-use devices are not reprocessed unless they are approved by the FDA for reprocessing. Reprocessing of these devices is done by an FDA-approved reprocessor. NOTE: The FDA requirement does not apply to international facilities. International facilities must comply with local, state/provincial or federal/national requirements regarding reprocessing single-use devices.

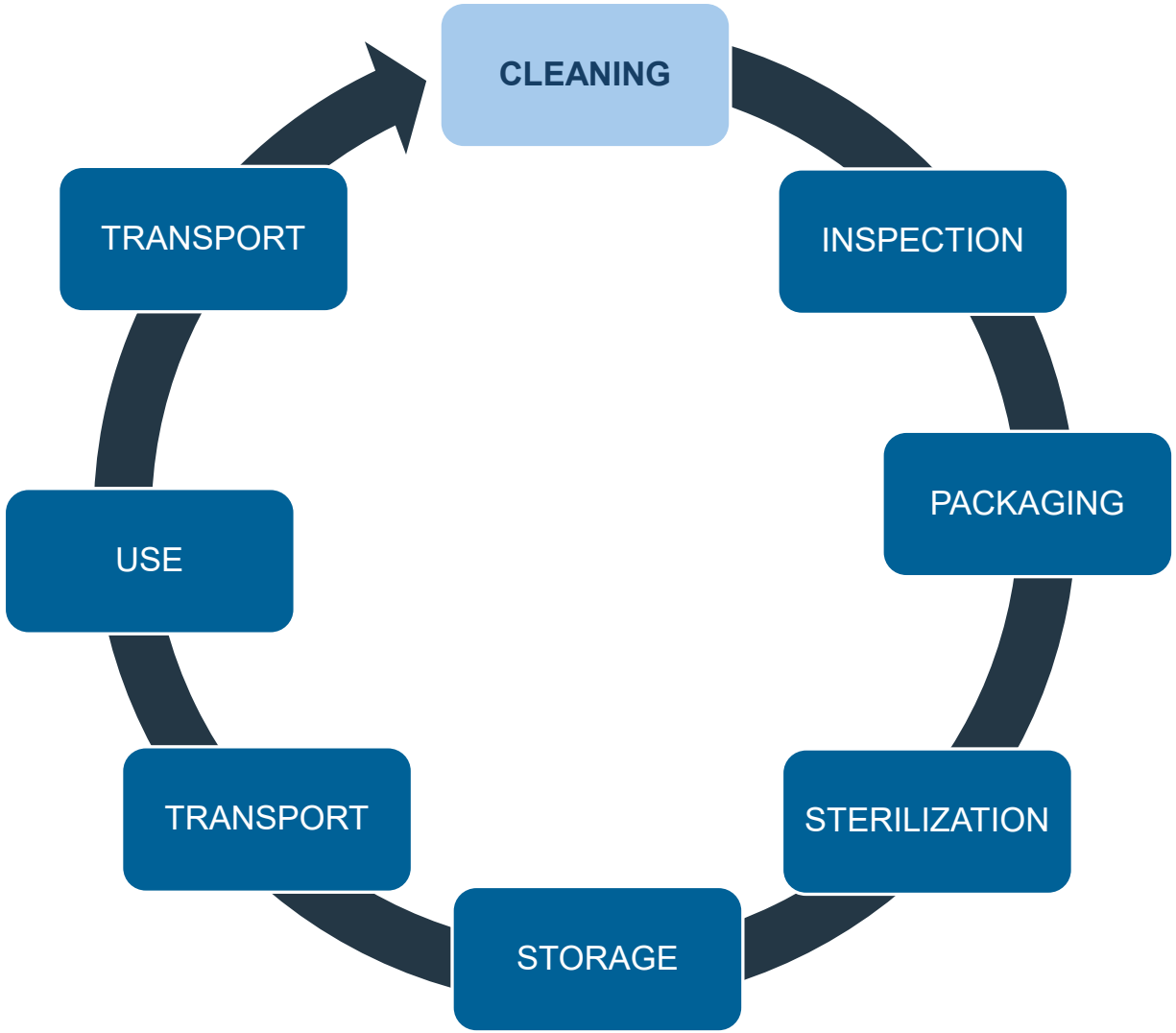
If the product does not have cleaning instructions, it should be discarded after use.

A reprocessed single-use device is an original device that has previously been used on a patient and is subjected to additional processing and manufacturing for a subsequent single use on a patient. It may not be processed onsite.

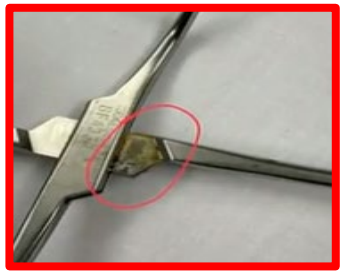
STERILIZATION CYCLE

If an instrument is not clean, it cannot be truly sterilized.

A breakdown at any stage puts the instruments at risk of not being sterilized during use in patient care.

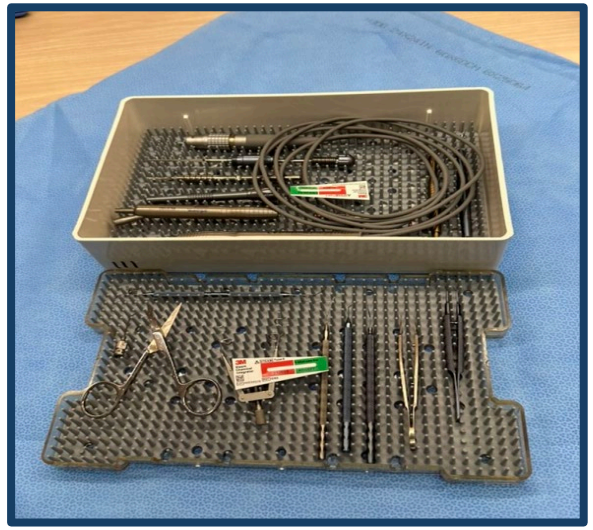


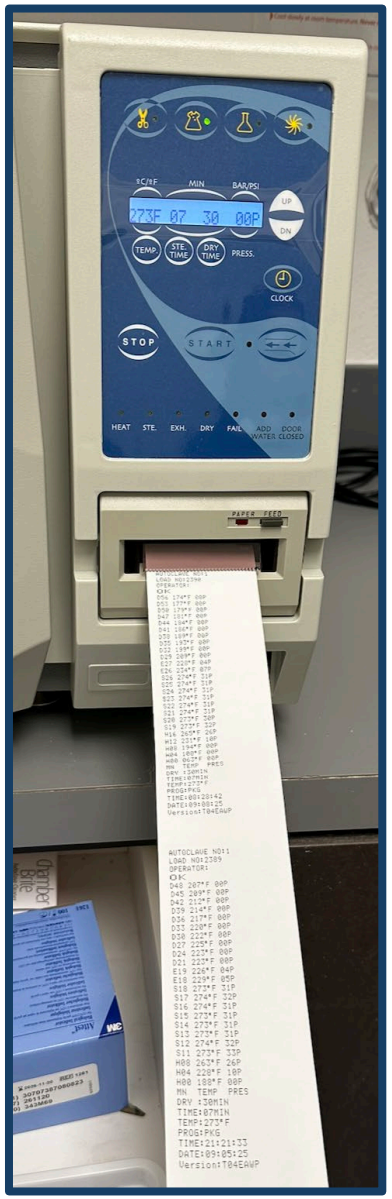
Ensuring the Device is Clean



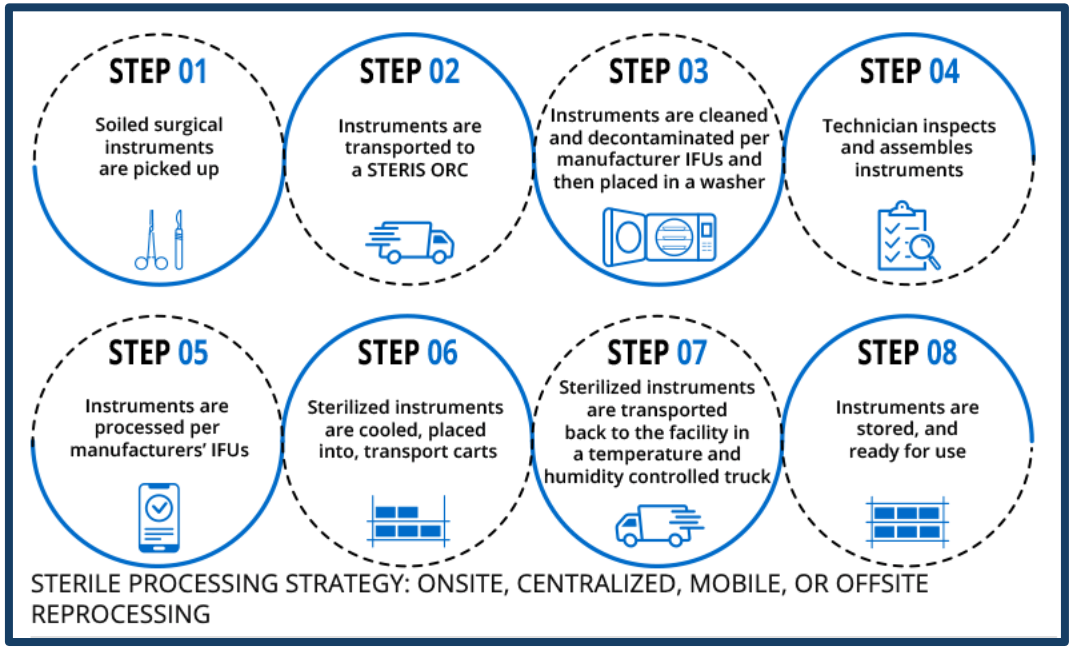
Standard 7-D-1: All instruments used in patient care are sterilized, where applicable.

- The required physical parameters for sterilization are achieved
  - According to the IFU
  - Correct packaging
  - Ensure the sterilant can reach all surface areas of the device
    - Disassembled (as recommended)
    - Hinged instruments – unlocked, opened





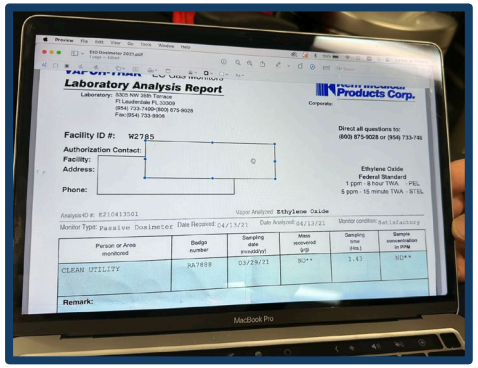
Standard 7-D-2: The facility has at least one (autoclave) that uses high-pressure steam and heat, or all sterile items are single-use disposable, or the facility has contracted with an outside vendor to process instruments, if applicable. Instrument reprocessing and sterilization must follow the manufacturer's instructions for use.



If the facility uses contracted services for reprocessing, confirm that a written contract holds the vendor accountable to meet all applicable standards (e.g., AAMI ST79), and that an annual contract review is part of the facility's QAPI program, with a defined process for validating the vendor's compliance, staff competence, and quality outcomes.

Standard 7-D-3: Additional methods in use can be chemical (Chemclave©) or gas (ethylene oxide/EO) sterilizer.

Standard 7-D-4: Gas sterilizers and automated endoscope re-processors (AER) must be vented and tested for occupational exposure in accordance with the manufacturer's specifications.



Engineering Controls: Ensure high-efficiency air-extraction fans and local exhaust ventilation are installed, particularly at cylinder connections.

Monitoring and Detection: Install, calibrate, and regularly check air monitoring systems to detect EO levels (EPA recommends, and some states require, detection capabilities below 10 parts per billion (ppb)).

Standard 7-D-5: The facility monitors the sterilization cycle's effectiveness in accordance with nationally and internationally recognized standards of practice and in conjunction with the manufacturer's instructions for use.

This includes but is not limited to:

- **Monitoring each sterilizer load for the appropriate mechanical indicators (e.g., time, temperature, and pressure);**

Cycle Type	Cycle Parameters			Drying Time[3]	Items to Be Sterilized (Always follow the instrument manufacturer's recommendations for sterilization.)
	Temperature Minimum	Time	Pressure Reference[2]		
Wrapped	270°F (132°C)	4 min	27.1 psi (186 kPa)	30 min	• Pouched or wrapped items manufacturers recommend for exposure at 270°F (132°C) for 4 minutes. • Wrapped cassettes
Wrapped	275°F (135°C)	3 min	31 psi (214 kPa)	30 min	• Pouched or wrapped items manufacturers recommend for exposure at 275°F (135°C) for 3 minutes • Wrapped cassettes
Delicate	250°F (121°C)	30 min	15 psi (104 kPa)	30 min	• Textiles and surgical packs wrapped for sterilization[4] • Items, except liquids, manufacturers recommend for exposure at 250°F (121°C) for 30 minutes
Unwrapped*	270°F (132°C)	3 min	27.1 psi (186 kPa)	30 min	• Instruments loose on a tray • Open glass or metal canisters • Tubing not used in surgical procedures (maximum length 40 in and minimum inside diameter 0.187 in) • Loose items manufacturers recommend for exposure at 270°F (132°C) for 3 minutes
5 Custom Cycles**	250°F (121°C) to 275°F (135°C)	3 min to 45 min	15 psi (104 kPa) to 31 psi (214 kPa)	0 min to 60 min	• Instruments with manufacturer instructions outside of Midmark Standard Cycle Parameters • Special applications requiring different programmed cycles

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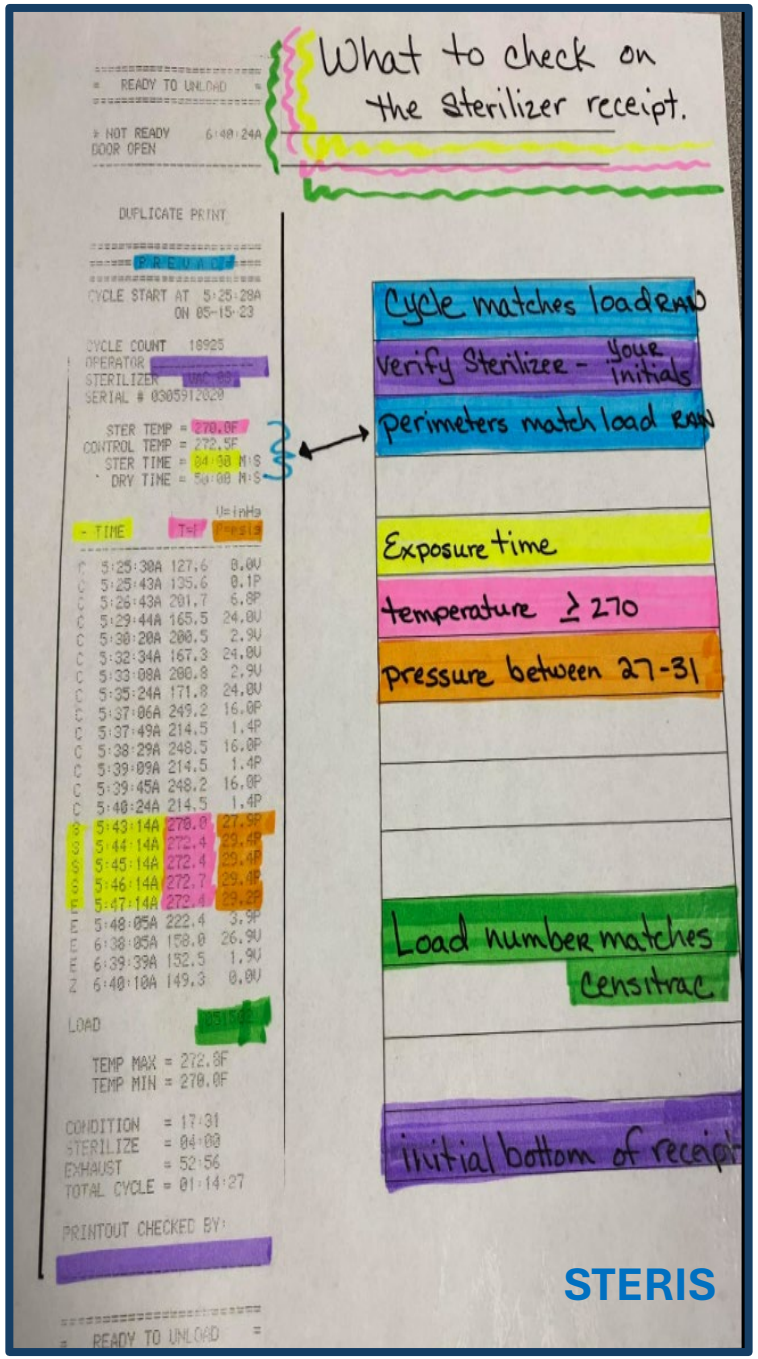
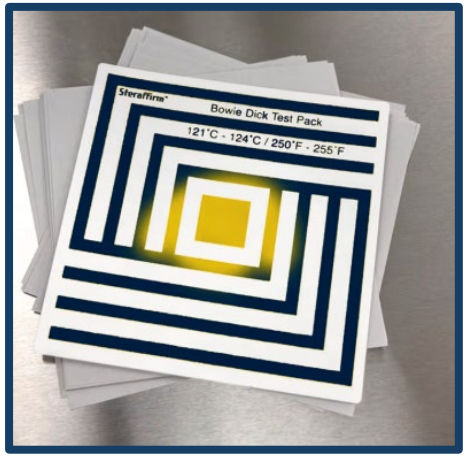
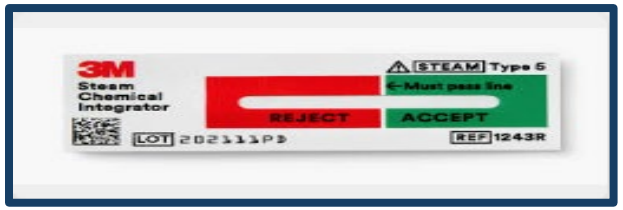


Standard 7-D-5: The facility monitors the sterilization cycle's effectiveness in accordance with nationally and internationally recognized standards of practice and in conjunction with the manufacturer's instructions for use.

This includes but is not limited to:

- **Using type 1 (external) and type 5 (internal) chemical indicators;**





CI Type	Title	Description	Use
1	Process Indicator	For use with every pack to distinguish processed from unprocessed load items.	Outside packs
2	Special Test Indicator	Intended for use in specific tests defined in relevant sterilizer/sterilization standards (e.g., Bowie and Dick Test)[6] described in ST79[7] and EN ISO 17665.[3]	Sterilizer tests
3	Single Variable Indicator	Reacts to one of the process variables of the sterilization process.	Inside packs
4	Multi-Variable Indicator	Reacts to two or more of the process variables of the sterilization process.	Inside packs
5	Integrating Indicator	Reacts to all the process variables of the sterilization process and mimics the response of a biological indicator.	Inside packs
6	Emulating Indicator	Reacts to all the process variables of the sterilization process giving a result related to the standard exposure conditions specified in a sterilization standard (e.g., 132°C for 4 minutes)[4]	Inside packs

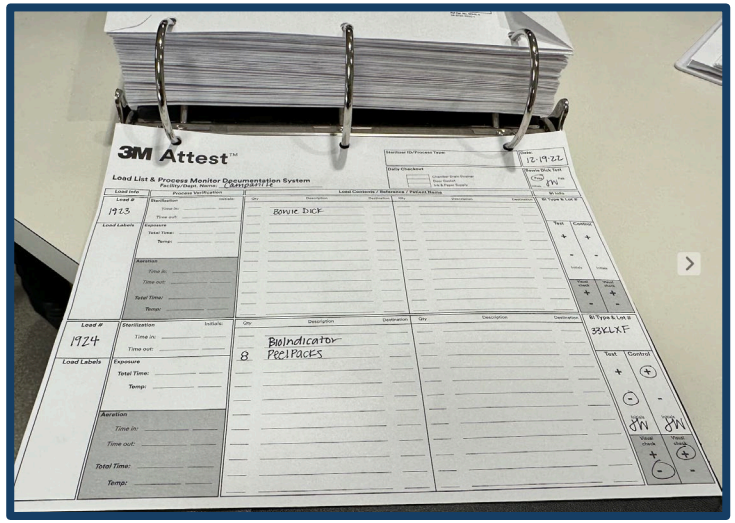
Standard 7-D-5 (Continued):
This includes but is not limited to:

- **Weekly biological indicator (spore test) for each sterilizer;**
- **Using a biological indicator for every load containing implantable items;**

<u>At a Minimum</u>:
Assess Lethality Weekly
& With Implants

Standard 7-D-5 (Continued): This includes but is not limited to:

- **Recording evidence of sterilization assurance monitoring for every load, and any corrective action is documented.**



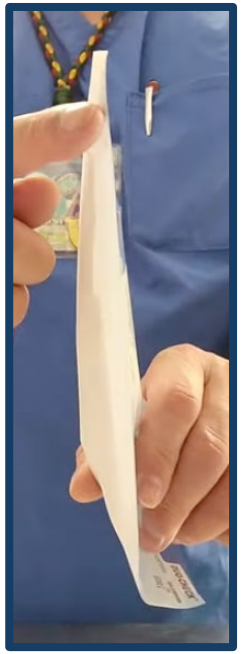
Sterilizer name: _____

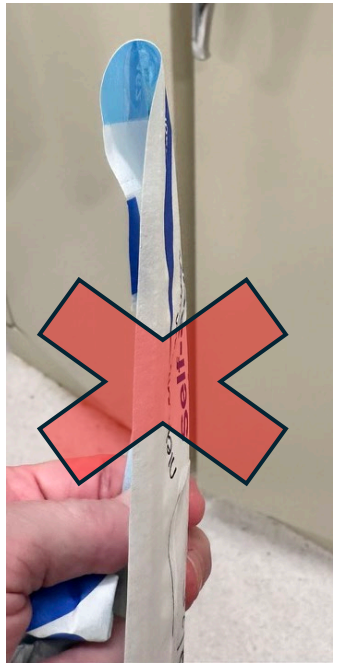
Load number	Equipment identification	Cycle start time	Cycle end time	Cycle parameters			Malfunction or failure codes	Chemical indicator		Spore test strip *test strip run	Date (mm/dd/yyyy)	Initials
				Duration (minutes)	Temperature (°C/°F)	Pressure		External Pass/fail	Internal Pass/fail			

Notes:

1. *For failed internal/external chemical or biological indicator, ensure to follow internal policies and procedures; notify Niagara Region Public Health and initiate back-up plans.*
2. *Manufacturer's instructions for sterilizing equipment are to be onsite and easily accessible.*
3. *Always follow the manufacturer's instructions when reprocessing equipment.*

Standard 7-D-6: Sterile instruments and supplies are packaged according to the manufacturer's instructions for use (IFU) and sealed effectively. Self-sealing peel pouches must be folded on the crease and may only be double-pouched when the process is validated by the manufacturer.





IFU - MENTOR Gel Implant Sizer
(3) PACKAGING:
Double wrap the Gel Sizer in surgical sterilization wrap intended for autoclave use. Note: it is imperative to use sterilization wrap and not a pouch to accommodate the flow of the steam during the sterilization process.

Peel Pouches – Review the IFU

Cardinal Health™ Sterilization Pouches and Tubing are to be used for medical products without lumens.

Directions for Use

Cardinal Health™ Sterilization Pouches and Tubing should be used in accordance with the preparation, packaging and sterilization chamber loading recommendations of the following standards:

- ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
- ANSI/AAMI ST41: Ethylene Oxide Sterilization in Health Care Facilities

Packaging

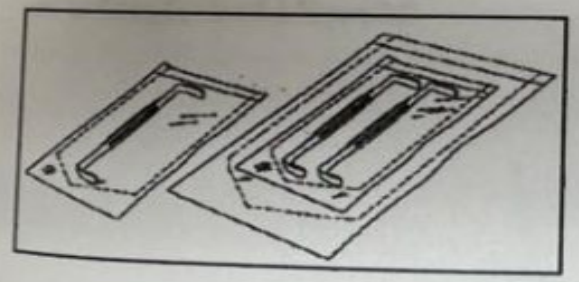
The pouch should only be filled 3/4 of the packing volume to allow proper air evacuation and sterilant penetration. Carefully press the excess air out of the pouch and ensure there is at least one (1) inch of area available around all four (4) sides of the enclosed items.

Sealing

Self-Seal Sterilization Pouch

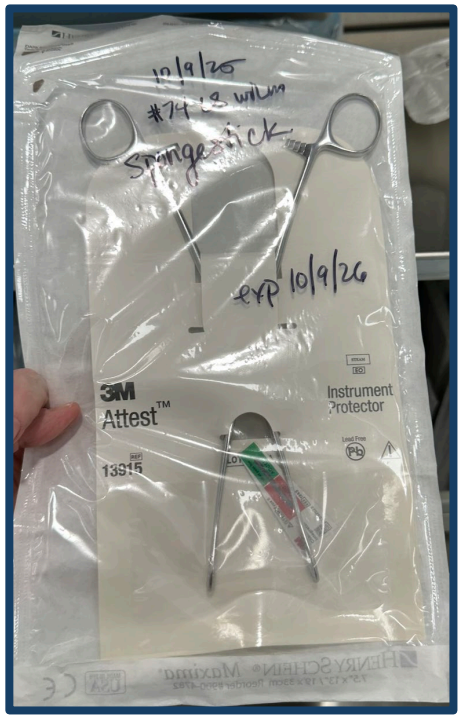
After removing the protective strip, seal the pouch by folding the adhesive strip onto the pouch. Apply pressure from the center of the adhesive, towards the edges. Repeat this motion an additional time for extra security.

If you are using a double pouching method, the pouch sizes should be selected so the inner pouch can be placed inside the outer pouch without folding. The inner pouch must also be sealed. The paper side of both pouches should face the same way. For example, paper towards paper and film towards film.



Example of single- and double-packaging with paper–plastic pouches. NOTE: Instruments should be oriented within pouches according to the health care facility's policies and procedures. (Source: ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities; Section 8.3.4/Figure 8)

Standard 7-D-7: Each sterilized pack is labeled with the date of sterilization and, when applicable, with the expiration date. When the facility has more than one sterilizer, labels must also identify the sterilizer used.



Following sterilization, does a peel pouch have an expiration date?

- No, event-related expiration only
- Yes, 9 months
- Yes, 12 months

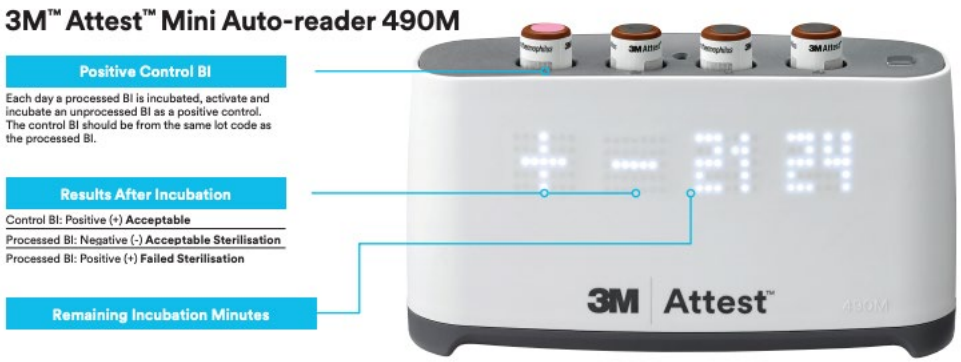
ANSWER: It depends on the IFU

Standard 7-D-9: Comprehensive monitoring records that include quality control are retained for the sterilization or other disinfection process and should be reviewed and stored for a minimum of three (3) years.

Each entry in the sterilization log must include:

- Date of Sterilization
- Type of sterilizer (such as steam, ethylene oxide, or dry heat) and cycle used
- Load identification number
- Load contents
- Exposure parameters (e.g., time and temperature)
- Operator's name or initials
- Results of the mechanical, chemical, and biological monitoring

Standard 7-D-10: There is a written policy and procedure for the management of a positive biological indicator.



Sample Policy

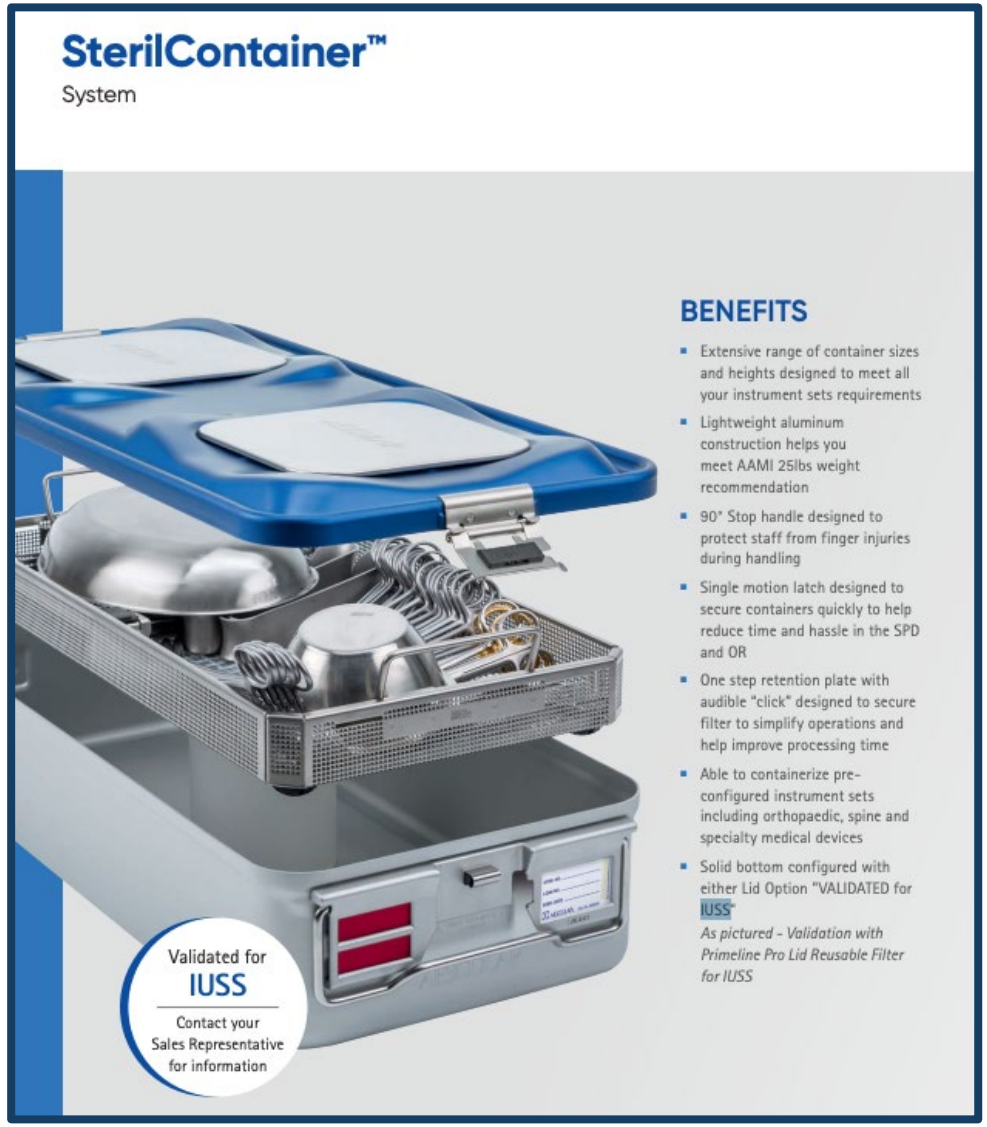
When a positive biological indicator (Attest® or Verify for VPro) is detected in a Surgical Services Department sterilizer, personnel responsible for that sterilizer will:

- Discontinue use of the sterilizer.
- Fill out and attach a Sterilizer Malfunction form on the sterilizer.
- Follow all instructions on the Sterilizer Malfunction Form.
- Notify the Infection Preventionist as soon as the positive biological indicator is discovered.
- Check whether the chemical indicator on the exterior of the Attest or Verify vial has changed appropriately.
- Have the sterilizer evaluated for proper use and function.
- Recall all items sterilized on all loads since the last negative biological indicator for the sterilizer with the positive BI.
- After the problem is corrected, and before the sterilizer is returned to service, run one Bowie-Dick test and three consecutive test runs, each with a biological and chemical indicator.
- If the test biological indicators are negative after the appropriate incubation time for the specific BI used, the sterilizer may be released for normal use.

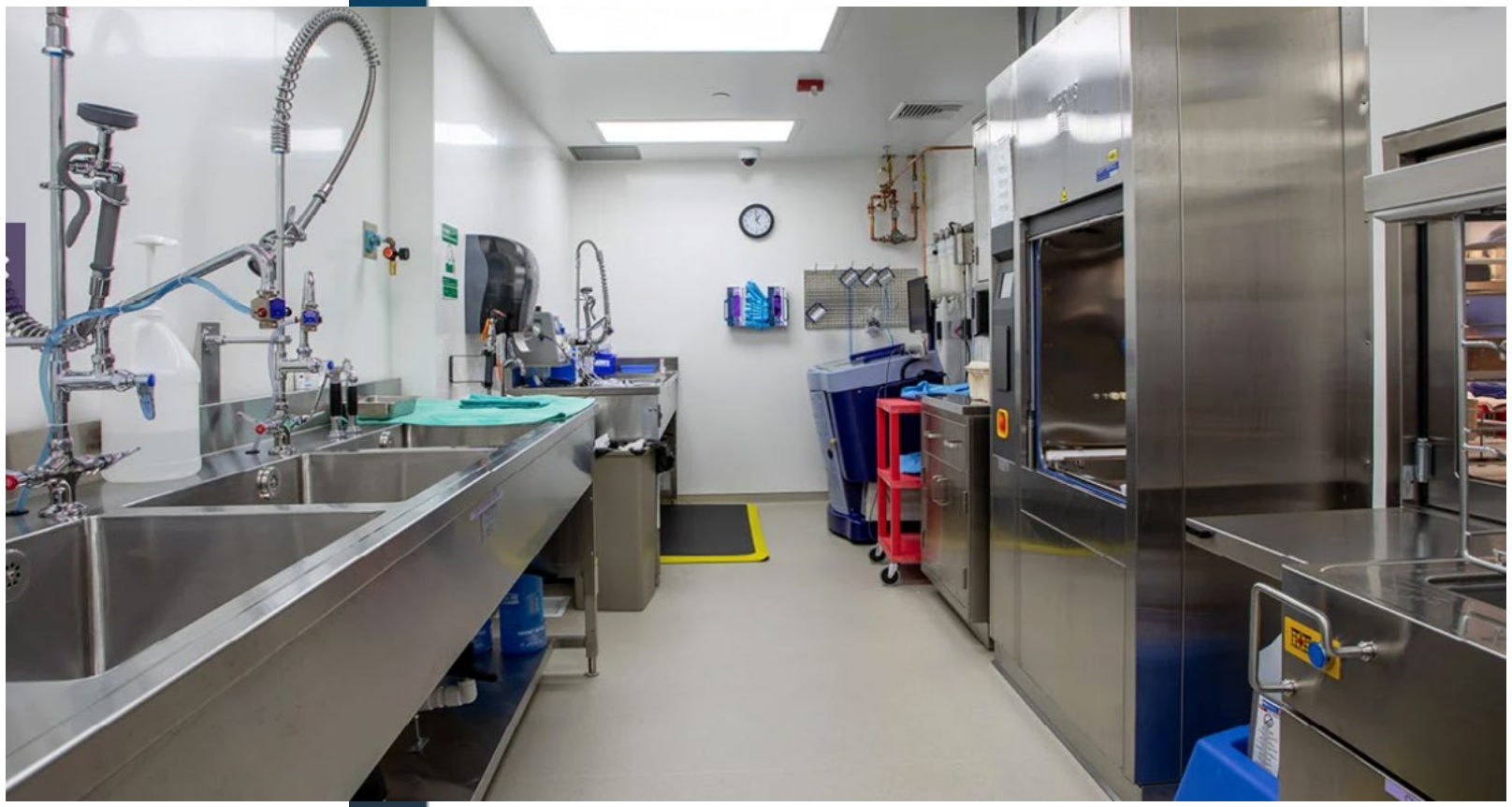
Standard 7-D-11: Immediate use steam sterilization (IUSS) is not done on a routine or frequent practice.

IUSS (formerly known as flash sterilization) can be performed safely when the device's manufacturer's instructions are strictly followed, including the protocols for cleaning, decontamination, sterilization, and transfer to the sterile field in a closed container.

Logging reasons for IUSS and tracing the item to the patient is crucial for surveillance.



Standard 7-F-6: Instrument handling and reprocessing areas are cleaned and maintained.



References by Standard

7-D-1	AAO Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments - 2018 https://www.aao.org/education/clinical-statement/guidelines-cleaning-sterilization-intraocular ANSI/AAMI ST79:2017/(R)2022; Comprehensive guide to steam sterilization and sterility assurance in health care facilities https://array.aami.org/doi/book/10.2345/9781570208027 CDC Sterilization Practices https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/sterilizing-practices.html CDC Recommendations for Disinfection and Sterilization Guidelines in Healthcare Facilities, 2023 https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html#tocBox

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