



Before Sterilization

Prior to sterilization, first consider:

- How does the manufacturer intend the device to be reprocessed?
- Is the sterilizer appropriate in meeting reprocessing parameters of your instruments?
- Is the sterilizer functioning properly?

Sterilization

Goal:

After thorough and meticulous cleaning has been performed,

"It is a process whereby all life forms are destroyed" (Reichert & Young, 1997) including bacteria, viruses, fungi, and spores

Sterilization

How does the goal of sterilization differ from other methodologies?

| Process | Goal |
|---------------------------------|--|
| Low-level disinfection | Capable of Killing most vegetative bacteria, some viruses, some fungi |
| Intermediate-level disinfection | Capable of killing vegetative bacteria (including TB), fungi, and enveloped and non-enveloped viruses |
| High-level disinfection | Capable of killing vegetative bacteria (including TB), fungi, enveloped and non-enveloped viruses, and possibly some spores (but not reliably) |

(CSA Z314.8-08, Decontamination of reusable medical devices)

Deciding what requires sterilization

TABLE 1: Spaulding's Classification of Medical Equipment/Devices and Required Level of Processing/Reprocessing

| Classification | Definition | Level of Processing/Reprocessing |
|-------------------------------|--|---|
| Critical Equipment/device | Equipment/device that enters sterile tissues, including the vascular system. | Cleaning followed by Sterilization |
| Semicritical Equipment/device | Equipment/device that comes in contact with nonintact skin or mucous membranes but do not penetrate them. | Cleaning followed by High Level Disinfection (as a minimum). Sterilization is preferred. |
| Noncritical Equipment/device | Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the client/patient/resident. | Cleaning followed by Low Level Disinfection (in some cases, cleaning alone is acceptable) |

(PIDAC Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings, 2006)

Types of Sterilization

There a number of recognized methods for sterilization, including:

- Steam (moist heat)
- Dry heat
- Ethylene Oxide
- Hydrogen Peroxide Plasma (*Sterrad*)
- Vaporized Hydrogen Peroxide (*VPRO*)
- Ozone (TSO_3)
- Chemosterilants (*various*)

There are also some methods **NOT acceptable** for sterilization:

- Boiling
- Microwave
- Bead sterilizers

Steam Sterilization

- First choice for heat tolerant critical devices (PIDAC, p.59, 2006)
- “Oldest, safest, cheapest, and most understood method of sterilization” (Reichert, Young, p.124, 1997)

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Manufacturers Recommendations

- Manufacturers have their medical devices validated.
- This will either be performed by the manufacturer, or privately through a contracted lab



Manufacturers Recommendations

- Alberta Health and Wellness "*Standards for Cleaning, Disinfection and Sterilization of Reusable Medical Devices for all Health Care Facilities and Settings; 2007*" requires:
 - **"4.4.1. The manufacturer must supply:**
 - **medical device-specific recommendations for cleaning and reprocessing of device;**
- (AH&W, 2008)

Manufacturers Recommendations

- **CAN/CSA-Z17664-06**, "Information to be provided by the medical device manufacturer":
 - "At least one validated method for reprocessing the medical device shall be specified."
 - The following information shall be stated where it is critical to the maintenance or the intended function of the medical device and the safety of the user(s) and the patient:
 - Details of process steps;
 - A description of special equipment and/or accessories;
 - Specification of process parameters and their tolerances." (CAN/CSA-Z17664-06, 3.1)

Manufacturers Recommendations

ANSI/AAMI

- "The reusable medical device manufacturer is responsible for ensuring that the device can be effectively cleaned, and sterilized."
- Sterilization qualification of a device requires microbiological, engineering, toxicological, and sometimes clinical evaluations of the device, **which are well beyond the capabilities of most health care facilities.**
- The device labeling should identify specific methods of **cleaning and sterilization that have been validated by the manufacturer.**" (ANSI/AAMI ST79:2006).

Why is device validation so important?

- There are no "default" or "routine" reprocessing parameters for devices based on composition (e.g. stainless steel, simple versus complex).
- Parameters are not arbitrary figures

Medical Device Validation

- Validated reprocessing instructions reflect complex testing.
- **Validation is scientific testing** performed to substantiate that the given reprocessing steps should yield a consistent logarithmic reduction in microbial count, repeatedly in practice.
- Known as sterility assurance level (SAL) of 10^{-6}
It is a determined probability that the device will be devoid of microbial life using a biological indicator overkill method

Medical Device Validation

- Performed in a controlled lab environment.
- Not a simple process, and this should not be discounted.
- AAMI :
Sterilization qualification of a device requires microbiological, engineering, toxicological, and sometimes clinical evaluations of the device, **which are well beyond the capabilities of most health care facilities.** (ANSI/AAMI ST79:2006).

How to obtain Validated instructions

Manufacturers provide users with a copy of the validated reprocessing instructions at purchase.

Talk to your supplier, or the manufacturer to obtain replacement instructions when lost.

There are private companies that supply reprocessing departments with databases of reprocessing instructions.

Validated Reprocessing Instructions

- Once obtained, manufacturer validated reprocessing instructions should be saved.
- Reprocessing procedures should be created incorporating these instructions.

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Appropriate Sterilizer?

What system for sterilization is in use?

- Chemosterilant?
- Dry heat?
- Gravity steam?
- Dynamic air removal?

Manufacturers instructions are for a specific, process, they are not interchangeable.

Appropriate Sterilizer?

Can the sterilizer meet the manufacturers instructions for reprocessing, the appropriate time and temperature?

At higher altitudes, some table top sterilizers may have difficulty meeting set temperatures, refer to the sterilizer manual.

Appropriate Sterilizer?

- Is the sterilizer validated to sterilize the types of items you intend to reprocess (e.g. lumens, wrapped instruments, etc.)
- *Is the sterilizer validated to sterilize medical devices?*

Before Sterilization

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- *Is the sterilizer appropriate in meeting the reprocessing parameters of your instruments?* ✓
- Is the sterilizer functioning properly?
(Sterilizer Quality Assurance and Maintenance)

Sterilizer Quality Assurance

Quality Assurance Testing

- Mechanical
- Chemical
- Biological

Maintenance

- Routine
- Repair

Sterilizer Quality Assurance

By monitoring mechanical, chemical, and biological indicators we are evaluating:

1. Time
2. Temperature
3. Pressure

Quality Assurance Testing

Mechanical, Chemical and Biological monitoring:

- All must be performed
- All must be documented
- Together these indicators provide reasonable confidence that the environment required for proper sterilization has occurred.

Quality Assurance Testing

Mechanical indicators refer to the gauges or digital readings displayed during a sterilization cycle.

- Temperature (how hot did the sterilizer get?)
- Pressure (if displayed)
- Time (how long was the cycle?)

IF not automatically printed, they must be manually recorded.

Quality Assurance Testing

Chemical indicators are classified as:

- Class 1 Process indicators
- Class 2 Indicators for specific tests
- Class 3 Single-parameter indicators
- Class 4 Multi-parameter indicators
- Class 5 Integrating indicators
- Class 6 Emulating indicators

Quality Assurance Testing

Class 1 Process indicators

- Typically, externally applied or visible from outside of package
- Examples include sterilization tape, peel pack process indicators.
- Typically only “fail” in gross malfunctions

(ISO 15882:2003(E), p.4, 2003)



Quality Assurance Testing

Class 2 Indicators for specific tests

- Designed for specific test procedures
- Bowie-Dick type tests
- Bowie-Dick type tests are specific to Dynamic Air Removal sterilizers.



(ISO 15882:2003(E), p.4, 2003)

Quality Assurance Testing

Class 3 Single-parameter indicators

- Intended to react with only one critical parameter of sterilization process
- Should be supplemented by other monitoring



(ISO 15882:2003(E), p.5-6, 2003)

Quality Assurance Testing

Class 4 Multi-parameter indicators

- 2 or more critical parameters of sterilization
- Common for temp, time, and saturated steam.

(ISO 15882:2003(E), p.4, 2003)



Quality Assurance Testing

Class 5 Integrating indicators

- Designed to “react to all critical parameters over a specified range of sterilization cycles”

(ISO 15882:2003(E), p.6, 2003)



Quality Assurance Testing

Class 6 Emulating indicators

- “Designed to react to all critical parameters over a specified range of sterilization cycles”

(ISO 15882:2003(E), p.6, 2003)



Quality Assurance Testing

Chemical indicators, *what's required:*

- “Each package shall have an externally visible chemical indicator” (CSA Z314.3-01 [7.5.1.1], P.14, 2001)
- “An internal chemical indicator shall be placed inside all packages. This indicator shall be placed in the area least accessible to steam.” (CSA Z314.3-01 [7.5.2.4], P.15, 2001)
- Dynamic Air Removal? ...*Daily BD*

Quality Assurance Testing

Biological Indicators

- “Represents a microbiological challenge to a sterilization process” (CAN/CSA-Z14161-06, p.4, 2006)
- “only with biological indicators can it be demonstrated directly that sterilization conditions adequate to inactivate micro-organisms resistant to the sterilization process were present” (CAN/CSA-Z14161-06, p.4, 2006)



Quality Assurance Testing

Biological Indicators

- *Bacillus stearothermophilus* spores are used for steam sterilization monitoring
- BI test packs used to verify that the conditions expected in the sterilizer have been met.
- “shall be conducted following installation, during requalification, and during routine testing of the sterilizer” (CSA Z314.3-0, [10.3.1.2], p.19, 2001)

Quality Assurance Testing

Biological Indicators

- “Routine testing shall be conducted every day the sterilizer is used. Testing should include every type of cycle that will be used that day” (CSA Z314.3-01 [10.5.1], p.21, 2001)
- Implantable devices? “Every load containing implantable devices shall be monitored” (CSA Z314.3-01 [10.5.1], p.21, 2001)

Quality Assurance Testing

Record your Mechanical, Chemical, and Biological parameter monitoring

- Save print-outs, *document mechanical parameters if necessary for each load.*
- Document daily testing of BI's (with results after incubation)
- Document requalification testing with BI's after repairs
- Document load contents

Routine and Preventative Maintenance

What responsibilities are expected of the users, and what are the responsibilities of the service technicians, and on what schedule.

- Refer to the sterilizer manual
- Talk to your service technician

Routine and Preventative Maintenance

User Responsibilities

- Cleaning
- De-scaling
- Filling water chamber as applicable
- Lubrication of hinges
- Filter cleaning

Service Technician

- Calibration
- Testing
- Repair
- Requalification

Routine or Preventative Maintenance

Identify a schedule for preventative maintenance

Documentation all routine or preventative maintenance (user and service technician)

- Keep a log book of all maintenance work and repair work.

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(Sterilizer Quality Assurance and Maintenance) ✓

Conclusion

- Obtain manufacturer instructions and incorporate into your policies and procedures
- Ensure that you have the proper sterilizer for the work intended.
- Monitor your process for quality assurance
- Perform routine maintenance
- Document everything.