STERIS UNIVERSITY

CLINICAL EDUCATION

VH2O2 Sterility Assurance with ANSI/AAMI ST90

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Disclosures

1. **Successful completion:** Participants must complete the entire program and submit required documentation. No partial credit will be given.
2. **Conflict of interest:** Employee of STERIS.
3. **Commercial company support:** Fees are underwritten by education funding provided by STERIS.
4. **Non-commercial company support:** None.
5. **Alternative/Complementary therapy:** None.

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Continuing Education

- STERIS Corporation is an approved provider of continuing nursing education by **CBRN** – provider # CEP 11681 and an approved Administrator Education Unit (AEU) and Infection Prevention Control (IPCH) provider by **BASC** – provider # 1417.
- This program is approved for:
  - **0** hour(s) of GI Specific content credit by **ABCGN** (American Board of Certification for Gastroenterology Nurses),
  - **1** AEU(s) & **0** IPCH(s) by **BASC** (Board of Ambulatory Surgery Certification), and
  - **1** contact hour(s) of continuing education credit
    - **ACI** (Association for Advancement of Medical Instrumentation (AAMI) Credentials Institute);
    - **CBRN** (California Board of Registered Nursing);
    - **CBSPD** (Certified Board for Sterile Processing and Distribution); and
    - **HSPA** (Healthcare Sterile Processing Association).

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Continuing Education

CCI® The Leader in Perioperative Certification

Through a partnership with CCI®, it also meets CNOR® and CSSM® recertification requirements for perioperative nurses.

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Learning Objectives

- Upon completion of this training, you will be able to:
- Identify how sterility assurance promotes a hospital's quality management system
- Create a sterility assurance process for vaporized hydrogen peroxide sterilization based on recommended practices

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Sterility Assurance

- Provides assurance that processed instruments and medical devices are safe for patient use.
- Confirms sterilant penetration to the items in the load
- Verifies sterilizer functionality and lethality

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Requirement of Doing Business

- Part of accreditation expectations
- Part of local or state requirements
- Part of a Quality Management System

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Quality Management System

"Collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is expressed as the organizational structure, policies, procedures, processes, and resources needed to implement quality management."

ANSI/AAMI ST90 (2017)

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Quality Management System Is Customizable

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Filling In The Details

- Risk Associated to a Process
- Standards and recommended practices, i.e. ANSI/AAMI ST58
- Risk Assessment
- Continued Quality Improvement

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Identifying The Customer And Customer Needs

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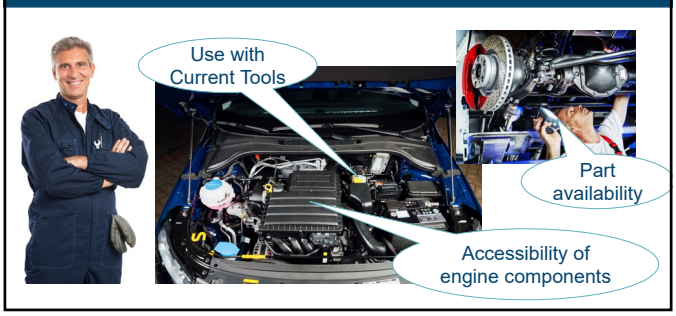
The Mechanic Is A Customer Too



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Customer Requirements

Patient

- Clean
- Does not cause a new or additional infection
- Safe
- Appropriate for the procedure

Doctor

- Functioning instruments
- Complete Sets
- On time
- Sterile

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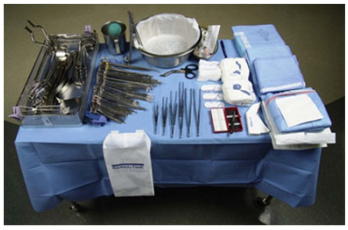
Inputs Dictate The Product

- Product
  - Complete Set
  - Functioning instruments
  - Clean
  - Sterile
  - Safe
  - On time



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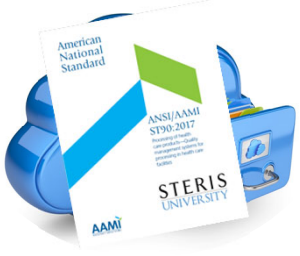
Quality Management System And Sterility Assurance

- Qualification of Equipment
- Verification of Processes
- Product Quality Assurance Testing
- Quality Control Inspections and Measurements



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Delivering A Sterile Device

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ANSI/AAMI ST58

American National Standard

ANSI/AAMI ST58:2013/(R)2018

Chemical sterilization and high-level disinfection in health care facilities

AAMI

- Includes Chemical Sterilization and high-level disinfection
- Specific sterility assurance recommendations
- Minimum requirements

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Important Terms

Validation: Documented procedure performed by the device manufacturer for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

ANSI/AAMI ST90 (2017)

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Important Terms, Cont'd

Verification: Documented procedure for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met within the user environment.

ANSI/AAMI ST90 (2017)

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Important Terms, Cont'd

Qualification: Process to demonstrate the ability to fulfill specified requirements.

ANSI/AAMI ST90 (2017)

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Quality Management Tests For Sterilization

Verification Testing

- Process performance
- Equipment performance
- Example: Qualification test

Quality Control Testing

- Individual batch, lot or cycle
- Example: Load release

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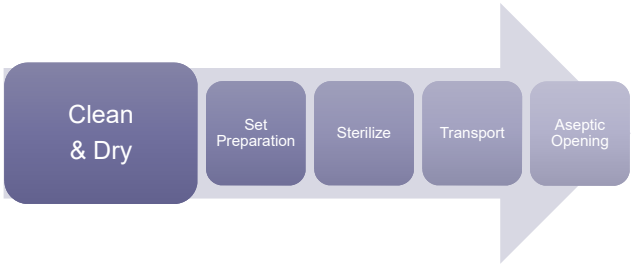
Quality Test For Decontamination



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Mechanical Cleaning Equipment

- Includes washer-disinfectors and ultrasonic cleaners
- Equipment Qualification
  - Installation
  - After major repairs
  - Changing cleaning chemistries
- Routine Monitoring
  - Daily

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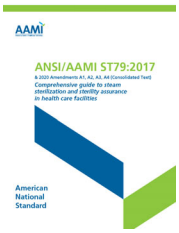

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Equipment Test Method

- Empty chamber
- Multiple locations for large ultrasonic equipment
- Each shelf of multi-tier racks

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Manual Cleaning Processes

- Visual Inspection

"The use of methods that are able to measure cleaning effectiveness that is not detectable using visual inspection may be considered in facility cleaning policy and procedures."

ANSI/AAMI ST58 (2018)

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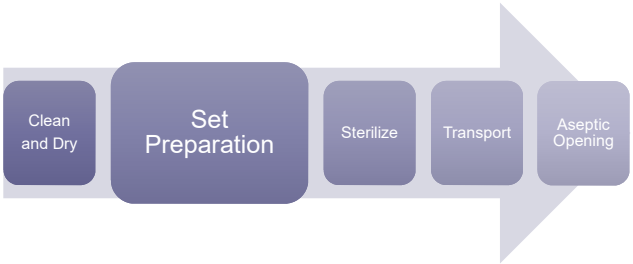
Delivering A Sterile Device



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Instrument Inspection

- Visual Inspection
- Test Equipment

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Ensuring Sterilant Reaches The Devices

- Product Testing
  - Initial set up
  - New or different types of packaging
  - Change in set content

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Quality Control Test With Chemical Indicators

- Every set and sterilization pouch
- Every layer of multi-level sets
- Placed in area least accessible to sterilant

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Poor Placement Of Chemical Indicators Causes False Failing Results

- Do not place directly beneath a device
- Do not place between the coils of cords or flexible devices

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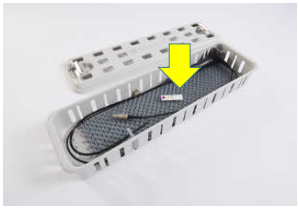
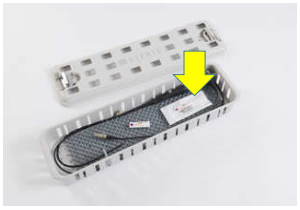
Pouched Trays And Pouches In Trays





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Evaluated In The Operating Room

- Proves sterilant penetration
- Last check before use

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Processing Status External Indicators

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Apply External Indicators To Pouches

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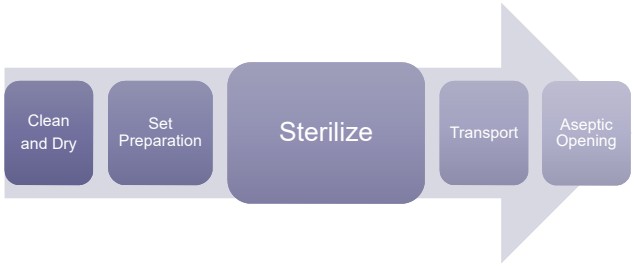
Delivering A Sterile Device



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Sterilizer Qualification

- Installation/relocation
- After major repairs
- After sterilization failures

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Product Testing

- Product Testing
  - Initial Sterilizer Set Up
- Periodic verification determined by each facility
- Performed anytime there is a major change in:
  - Types or material of packaging
  - Load configuration
  - Set weight

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Identification Of Product Families

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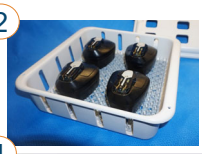

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Identify Product Families

- Design
- Materials of construction
- Weight
- Barrier Materials

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Identify Load Configurations

- Each cycle type
- Worst case load
- Consider:
  - Packaging
  - Mix Loads
  - Load Weights

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Test Protocol

- Representative set contents
- Set packaging selection
- Load configurations
- Sterilizer manufacturer and model number

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Routine Testing

- Routine Microbial Efficacy
  - Daily, preferably every sterilization cycle
- Leak test
- Calibration

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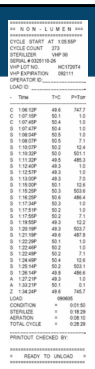
Load Release

- External Chemical Indicators
- Cycle Printout
  - Physical Monitors met parameter specification
  - Correct cycle
- Biological Indicator
  - Loads containing implantable devices
  - Loads are quarantined



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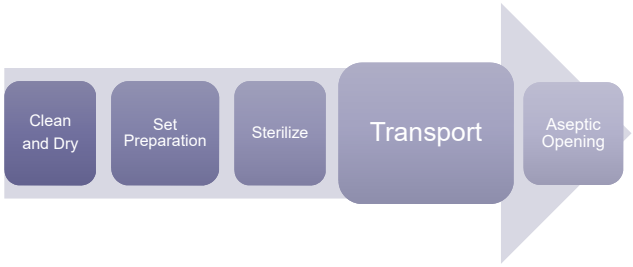
Delivering A Sterile Device



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Prevent Unprocessed Items From Being Used

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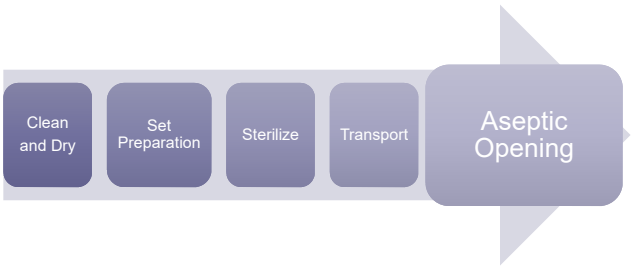
Delivering A Sterile Device



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Inspection

- Integrity of the packaging
- Interpret the external indicators

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Documentation

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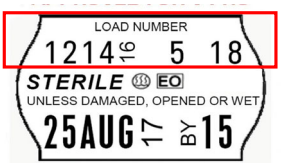
Lot Control

- Sterilizer identification
- Date of sterilization
- Cycle number



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Load Records

- Lot number
- Load contents
- Cycle printout
- Initials of operator
- Results of BI (if used)
- Inconclusive or failing chemical indicator results

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Equipment Verification Test Records

- Equipment qualification tests
- Product testing results
- Routine equipment test results

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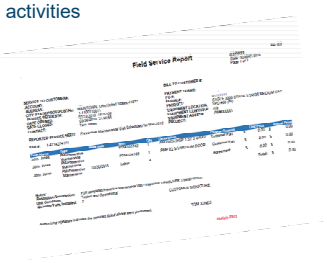
Equipment Service Records

- Preventative maintenance activities
- Repairs



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Record Retention

- Preserve legibility
- Based on local, state and federal guidelines
- Readily available
- Paper based or electronic

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Electronic Record Keeping

- Patient Electronic Health Records
- Mandatory reporting of infections
- Unannounced inspections
- Reduces documentation errors
- Process Improvement

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Action Items

- Refresh your sterility assurance programs for vaporized hydrogen peroxide sterilization
- Learn more about Quality Management Systems as defined by ST90
- Consider implementing electronic documentation where it is advantageous for your facility

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References

- Association for the Advancement of Medical Instrumentation. (2018). ANSI/AAMI ST58: 2013/(R)2018 Chemical sterilization and high-level disinfection in health care facilities. Arlington, VA: Author.
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Questions?

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