Reprocessing Validations: Disinfection and Sterilization

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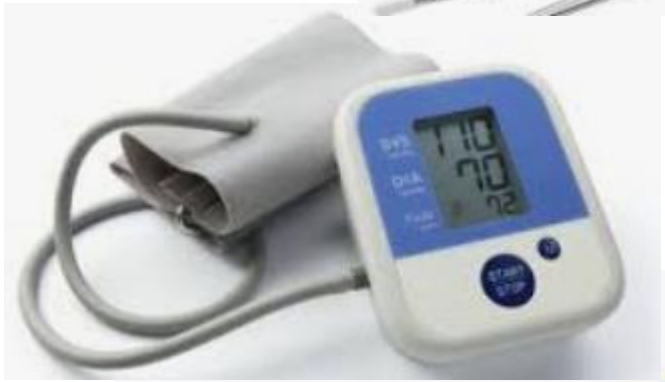
Reusable Medical Devices



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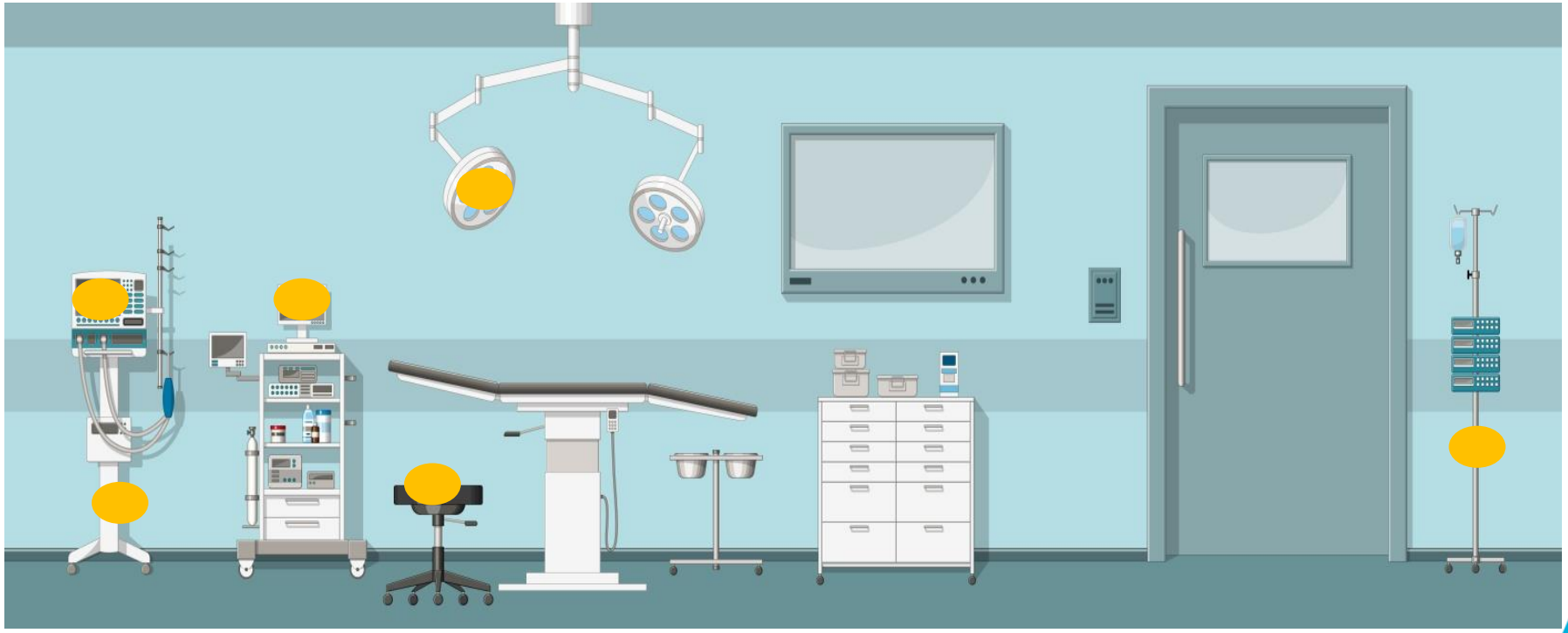

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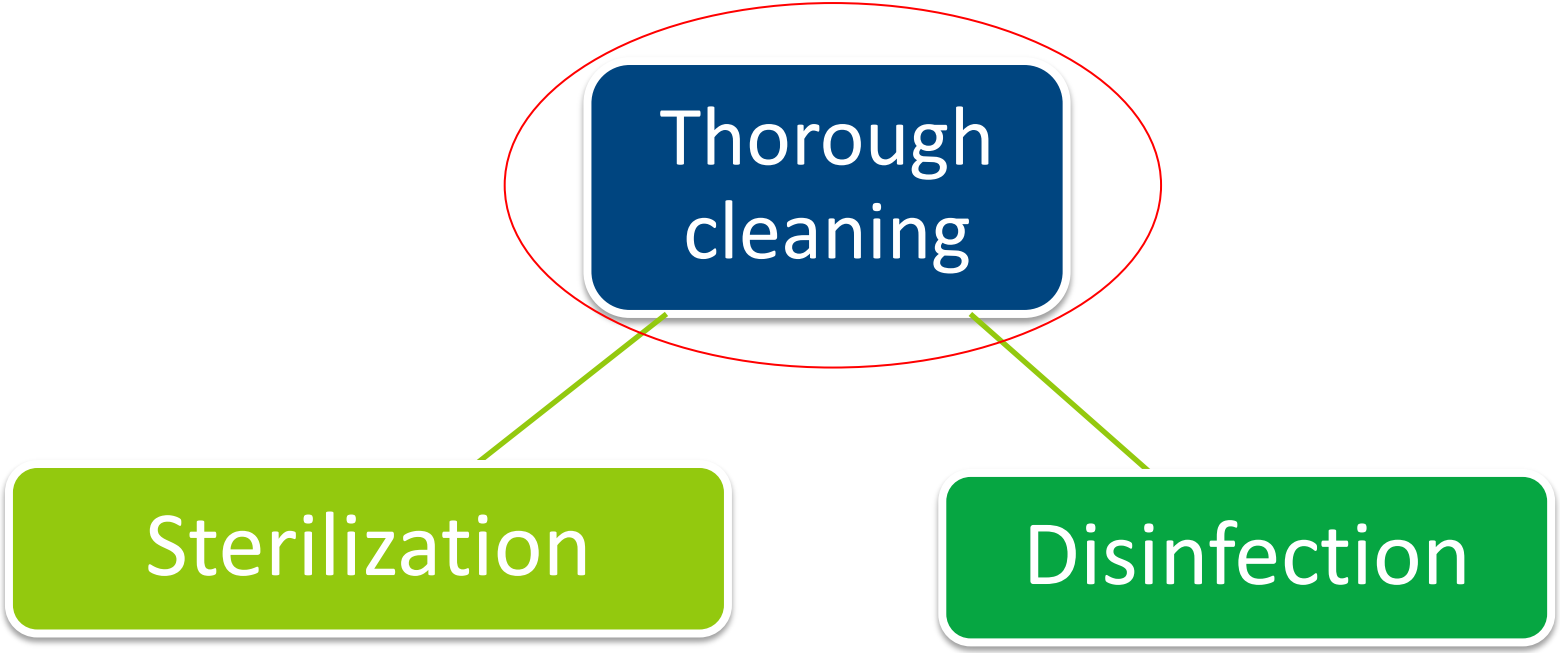
Process Overview – Reusable Devices



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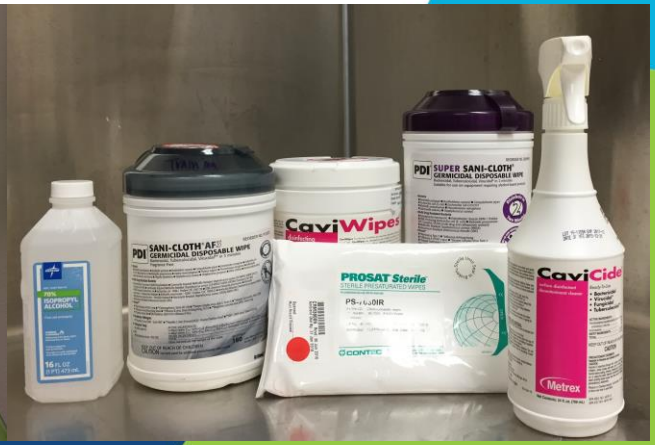
Disinfection Validations



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Why do Disinfection Validations?

Disinfection must be performed if the device is unable to be sterilized.

Disinfection maybe applicable for facilities where method of sterilization is not available.

Europe?

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Disinfection Validations

Manual

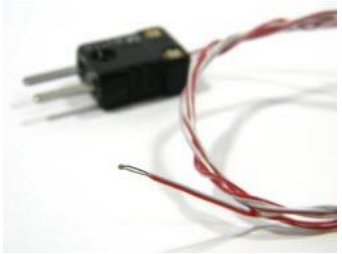
- Soaking
- Spraying/Wiping

Automated

- Endoscopes (AER)

Thermal

- Automated
  - Thermocouples (A_0)
  - Ampoules (Log reduction)
- Pasteurization



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Disinfection levels and acceptance criteria

Based on Spaulding Classification

Critical Devices =

Sterilization – SAL 10^{-6}

High Level Disinfection

- Mycobacterium – 6 Log reduction

Semi-Critical Devices =

High Level Disinfection

- Mycobacterium – 6 Log reduction

Non-Critical Devices =

Intermediate/Low Level Disinfection

- Mycobacterium – 3 Log reduction
- Four Vegetative Organisms – 6 log reduction separately

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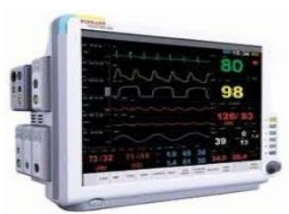
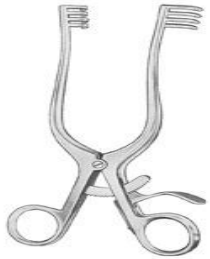
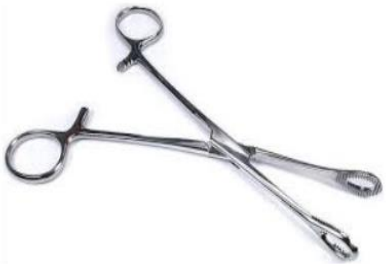
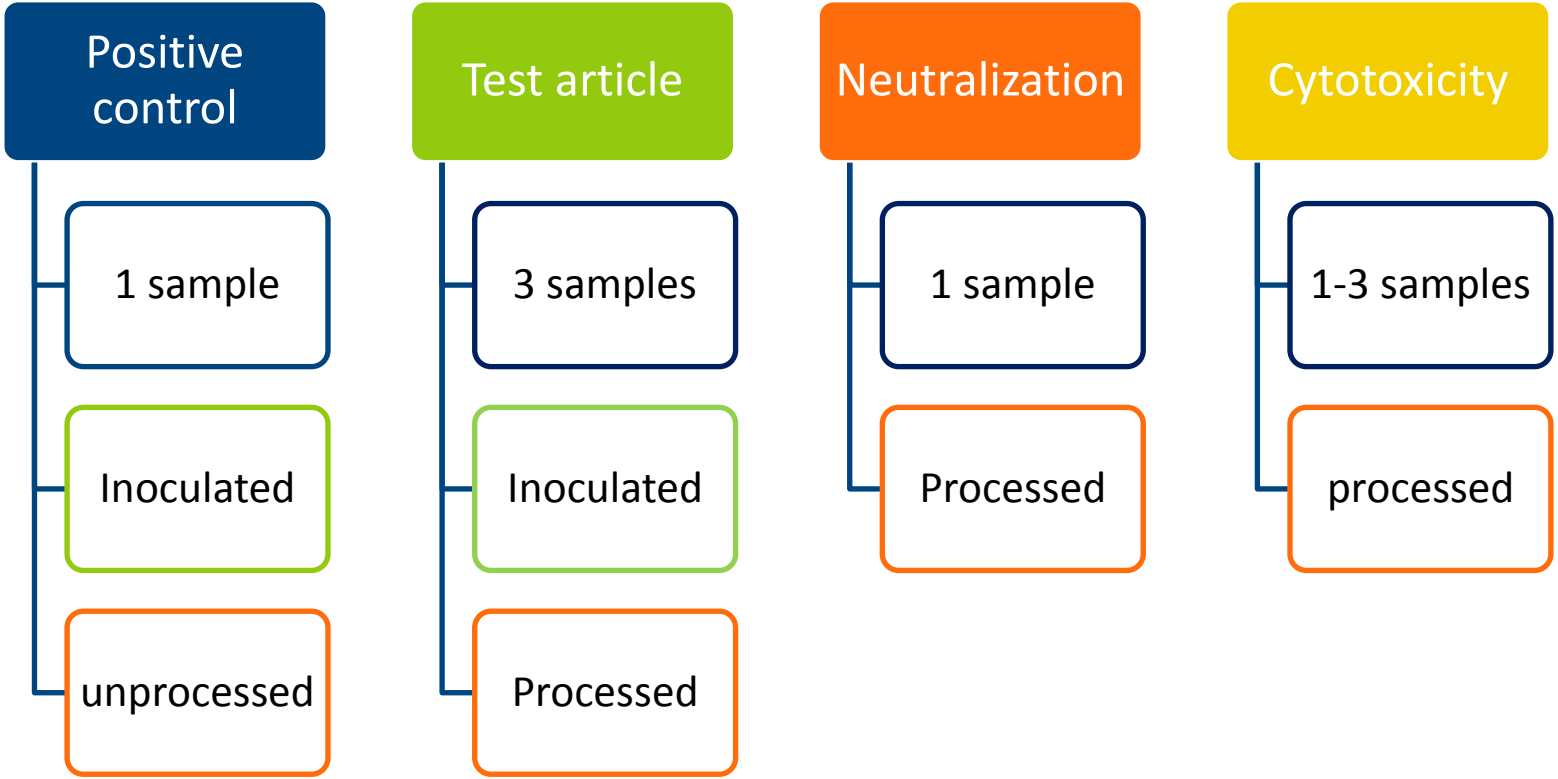
Spaulding Classification for Disinfection

Patient Contact	Examples	Device Classification	Disinfection Level
Intact skin	 	Non-critical	Low level or intermediate level disinfection
Mucous membranes or non-intact skin	 	Semi-Critical	High level disinfection
Sterile areas of the body including blood contact	 	Critical	Sterilization

Thermal Disinfection – Washer Disinfector (WD)

Category	A_0 value	Microbial (Ampoule)
Invasive – Semi-critical devices	> 3000 (90°C at 5 minutes)	**High level disinfection**
Non – Invasive (devices that will be sterilized after disinfection)	> 600 (90°C at 1 minutes)	**Intermediate level disinfection**
Intact skin	> 60 (70°C at 10 minutes)	**Low level disinfection**

Sample size and controls



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Inoculation Method

- Direct inoculation
- One test soil

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Phases of Disinfection Validation

- Neutralization Testing
- DISINFECTION VALIDATION
  - Cytotoxicity Testing
  - Bio Load Reduction Evaluation

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High Level Disinfection

High-Level Disinfection usually is performed through soaking the device for a specified time.

- Glutaraldehyde solutions (Cidex)
- Hydrogen peroxide based disinfectants
- Peracetic acid based disinfectants

https://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofreusablemedicaldevices/ucm437347.htm

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Intermediate-Low Level Disinfection

Intermediate and Low Level disinfections usually are performed by wiping or spraying the devices, occasionally by soaking

- Isopropyl alcohol (70% IPA)
- Quaternary ammonium compounds
- Sani-cloth, CaviCide Wipes/spray
- Hypochlorite (Chlorine)
  - Bleach (at different concentrations)

https://www.epa.gov/sites/production/files/2018-01/documents/2018.05.01.liste_.pdf

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Disinfection instructions – ISO 17664:2017

Required as part of the reprocessing in the EU

US	EU
Glutaraldehyde Solutions	Peracetic Acid/ Hydrogen Peroxide

Both types of disinfectants need to be validated if marketed in both EU and US

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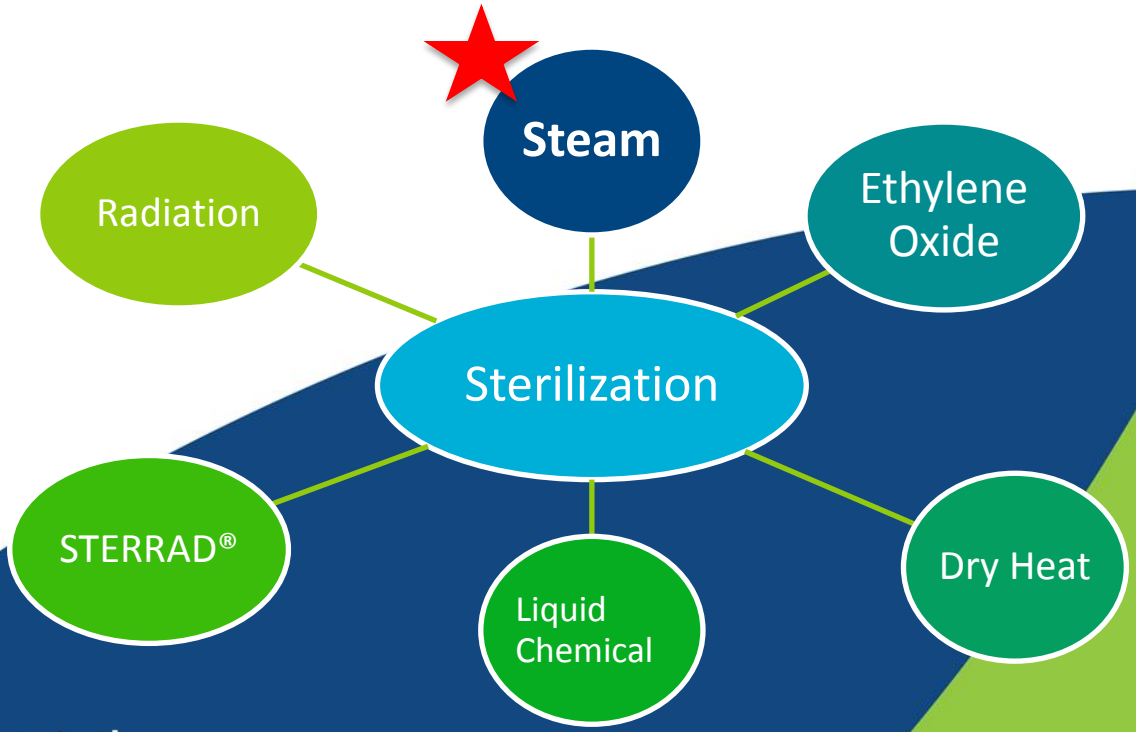
Methods of Sterilization



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Steam Sterilization

Benefits to steam under pressure:

- Most widely used method in health care setting
- Dependable
- Non-toxic
- Rapid killing action
- Relatively inexpensive

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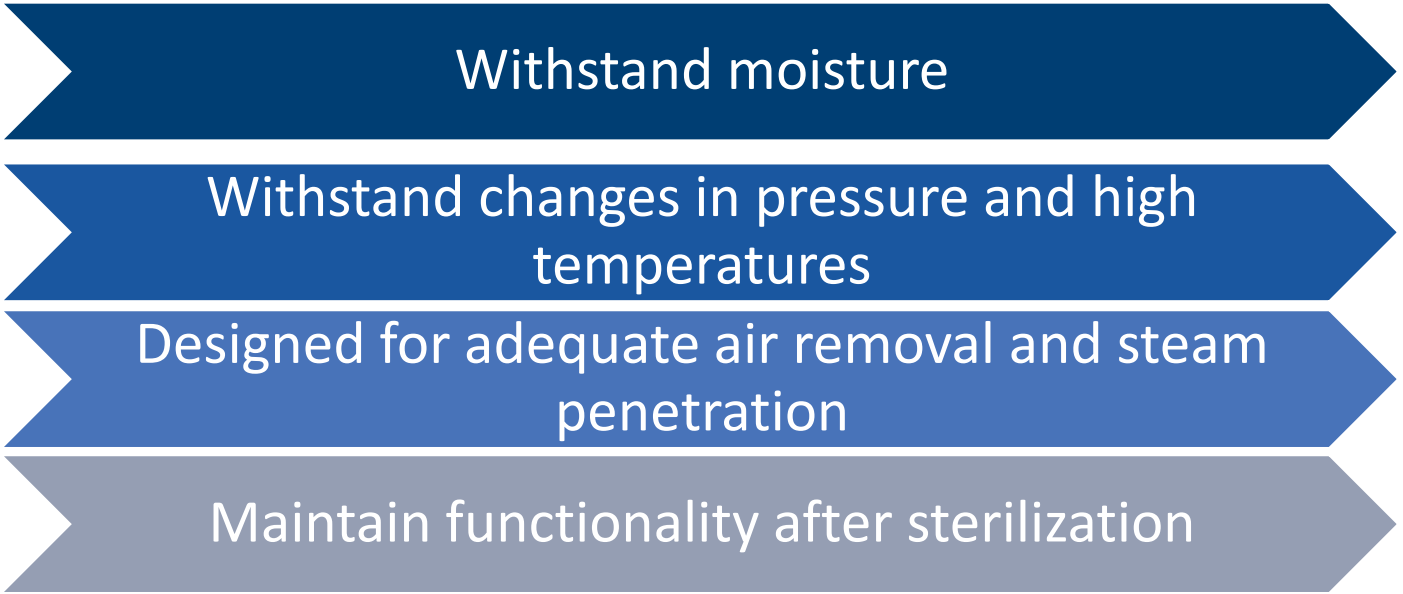
Product design considerations for steam sterilization



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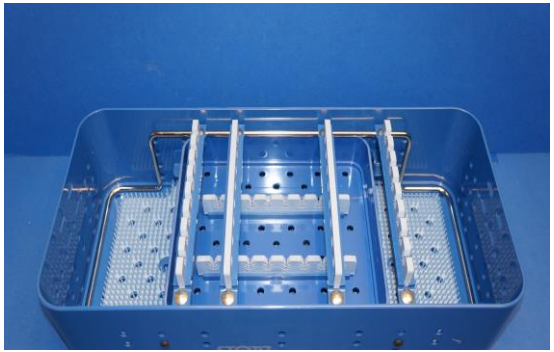
Sterilization Considerations

Device Design

- Material of device heats up quickly and remains hot
- Limit blind holes, dead-ended lumens, or insulated lumens
- Cannulas and entire device allows for air removal and steam penetration

Tray Design

- Reduce mass (<25 pounds)
- Proper steam flow throughout tray
- Holders have limited contact with device
- Holders do not block steam
- Holders allow devices to be in unlocked and open position
- Mass is distributed throughout tray
- Devices are not stacked on each other



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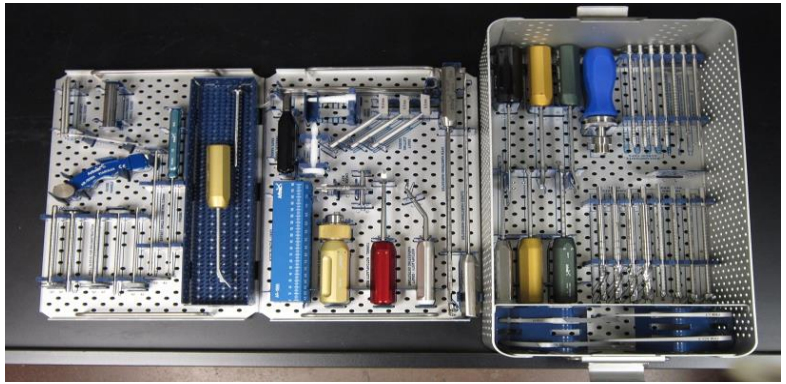
Samples size

Sterilization tray

1 tray



Device

3 devices

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Sterilization Validation Method

Most resistant organism: *Geobacillus stearothermophilus*

Overkill Method is used to determine the Sterility Assurance Level (SAL)assurance level of 10^{-6}.

BIs placed in the most difficult-to-sterilize areas:

- Lumens
- Mated surfaces
- Cannulas
- Heat Sink Areas

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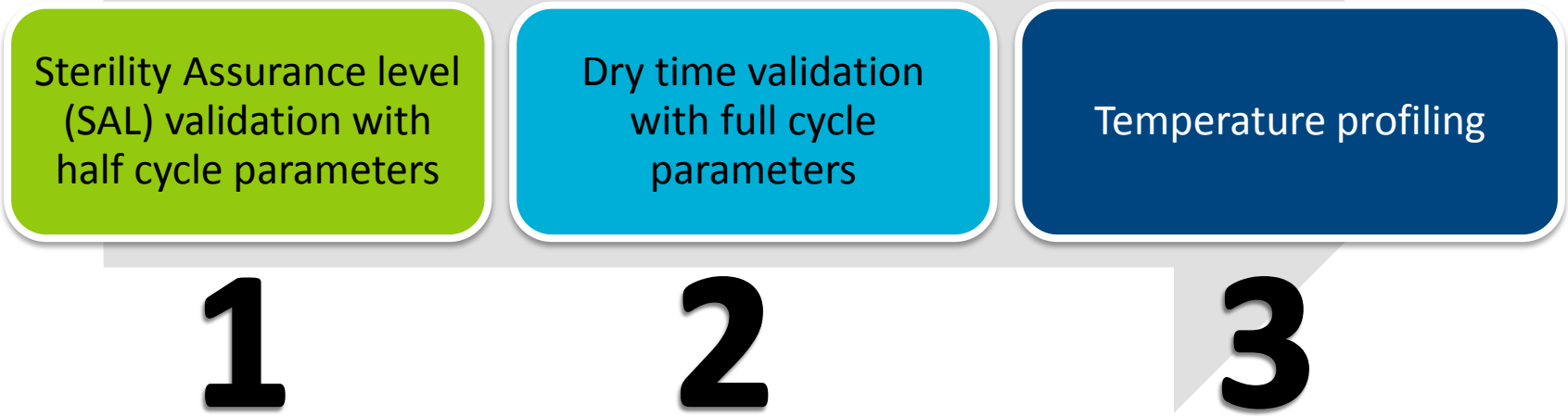
Steam sterilization validation steps



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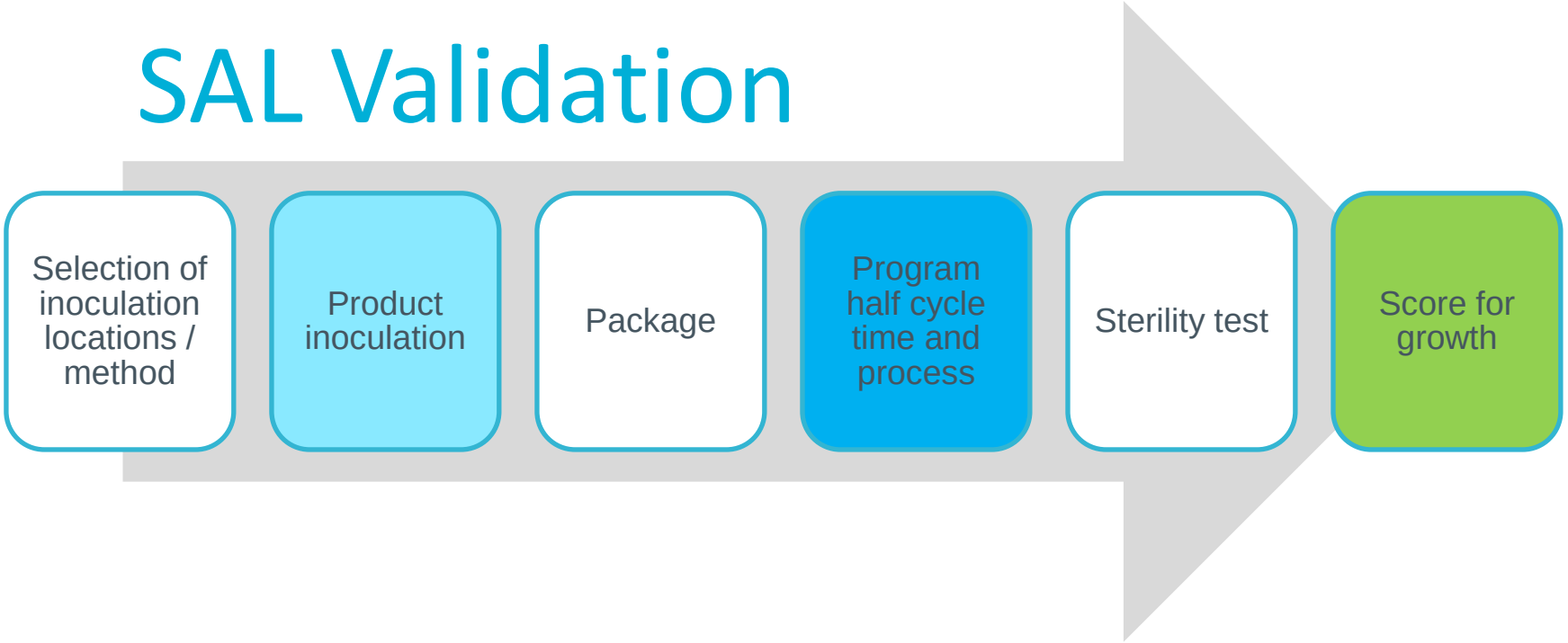
SAL Validation



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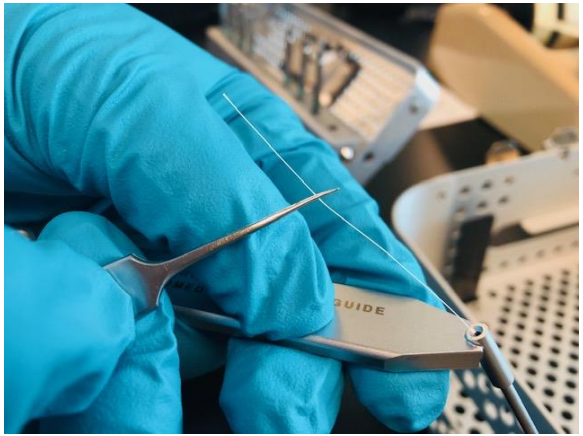
Product inoculation



- BI Strips
- Inoculated sutures and wires

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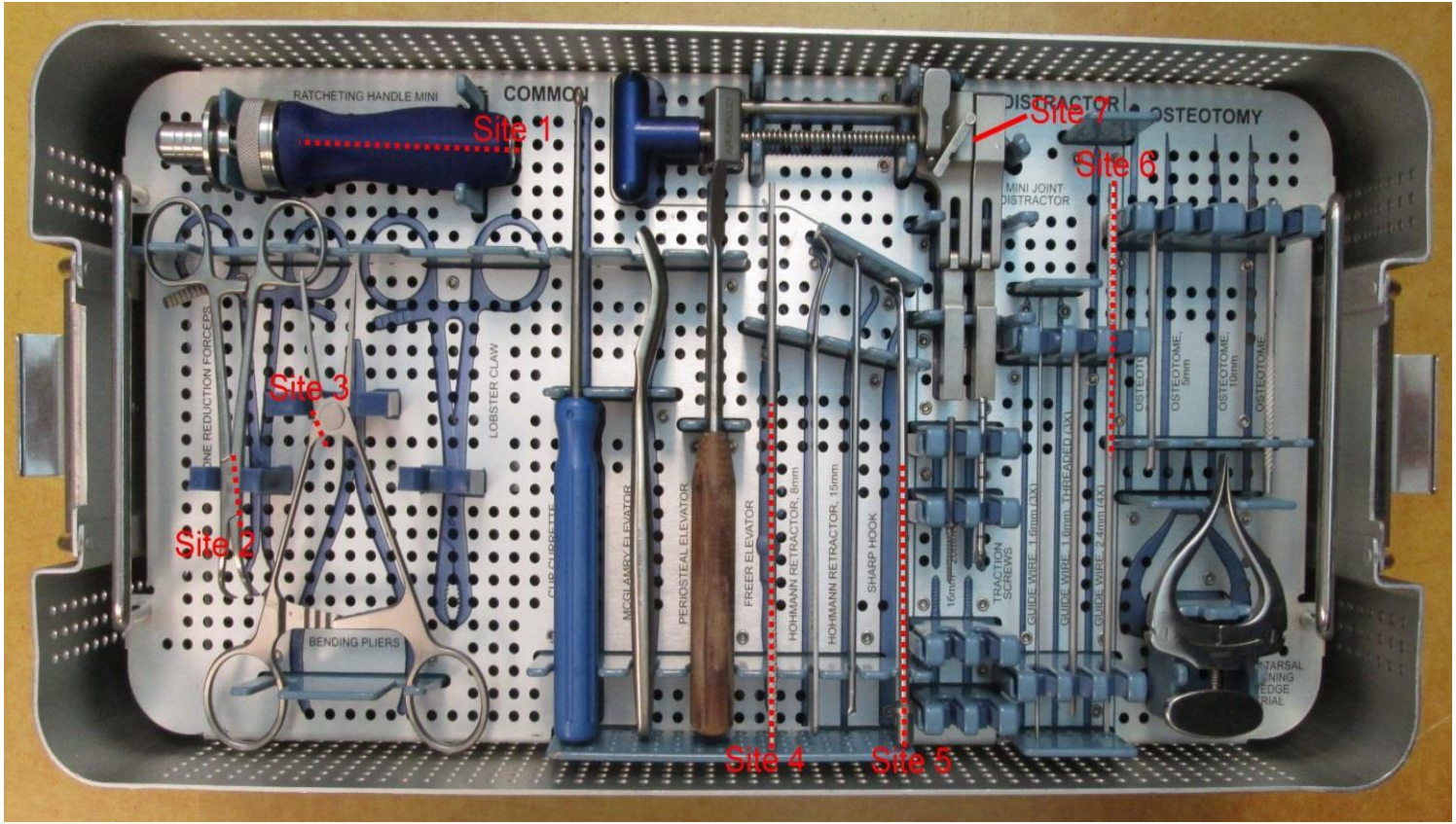

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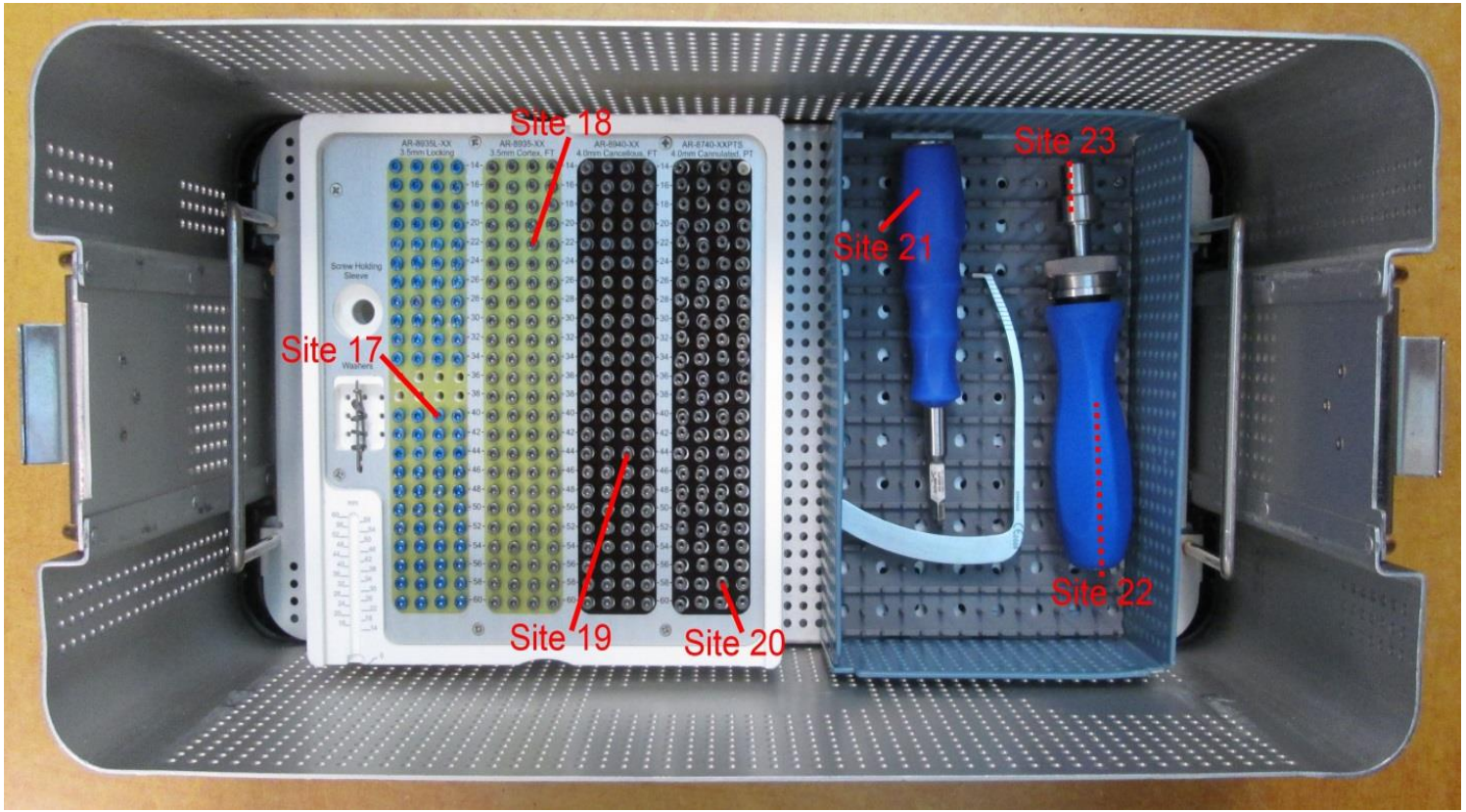

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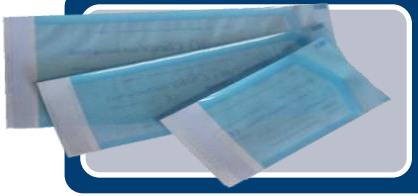
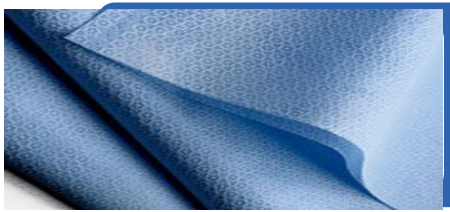
Types of packaging



Pouch

- Typically used for light weight medical devices



Sterilization wrap

- Must allow for steam penetration and adequate air removal and drying

Rigid container

- Come in many shapes, sizes, and materials
- May contain perforated openings for ease of sterilization
- Additional testing may be applicable

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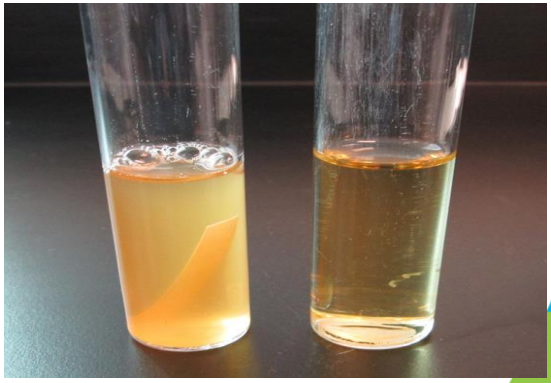
Sterilization Validation – Validation Method

Sterilization Cycle

Sterilizer Type:	Prevacuum	Prevacuum
Preconditioning Pulses:	4	4
Minimum Temperature:	132°C	135°C
Half Cycle Time:	2 minutes	1.5 minutes
Minimum Dry Time:	0 minutes	0 minutes

BI sterility testing



Incubation

- BIs and inoculated product are incubated at 55-60˚C for a minimum of 7 days
- BIs and inoculated product are scored for growth of the indicator organism

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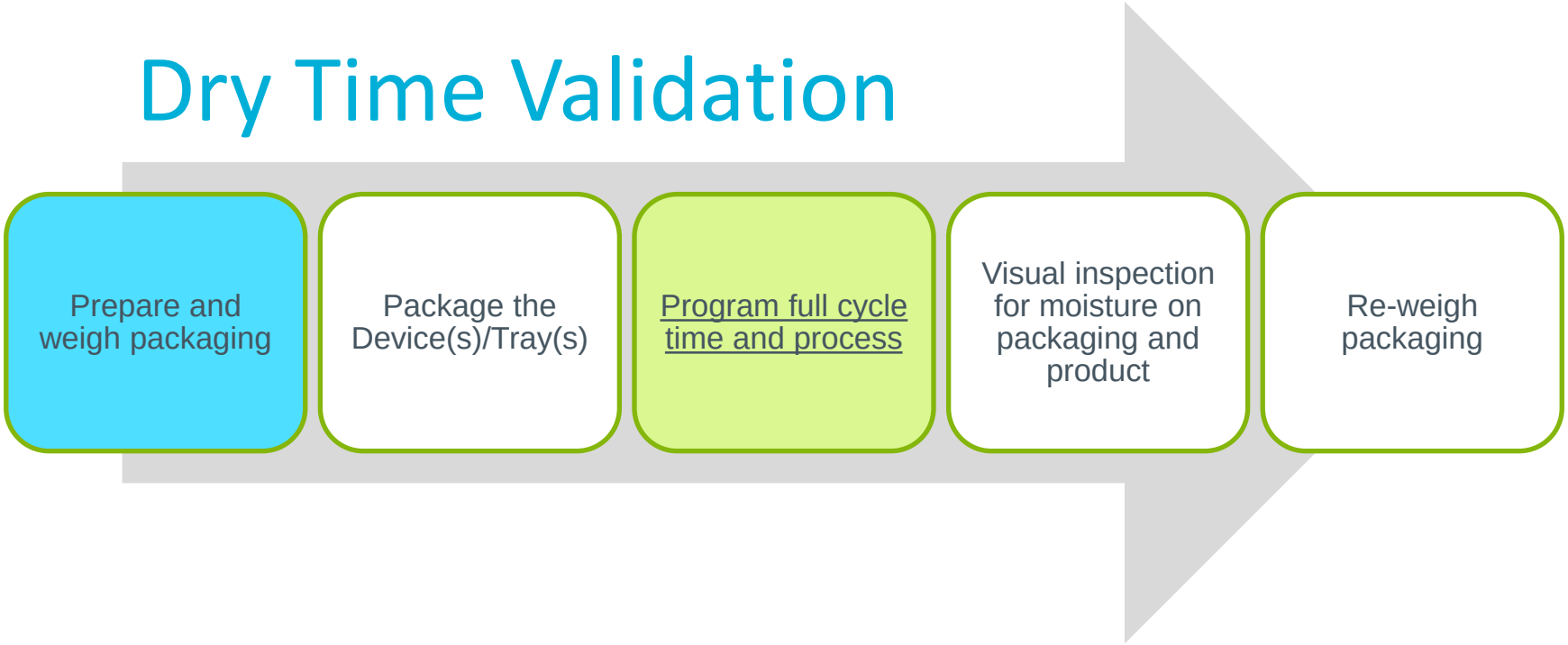
Prevacuum Half Cycle:
0 = No Growth
+ = Growth

Identification	Run #1	Run #2	Run #3
Site 1	0	0	0
Site 2	0	0	0
Site 3	0	0	0
Site 4	0	0	0
Site 5	0	0	0
Site 6	0	0	0
Site 7	0	0	0
Site 8	0	0	0
Site 9	0	0	0
Site 10	0	0	0
Site 11	0	0	0
Site 12	0	0	0
Site 13	0	0	0
Site 14	0	0	0
Site 15	0	0	0
Site 16	0	0	0
Site 17	0	0	0
Site 18	0	0	0
Site 19	0	0	0
Site 20	0	0	0
Site 21	0	0	0
Site 22	0	0	0
Site 23	0	0	0
Positive Controls	+, +	+, +	+, +
Negative Control	0	0	0
Environmental Control	**0**	**0**	**0**

Dry Time Validation



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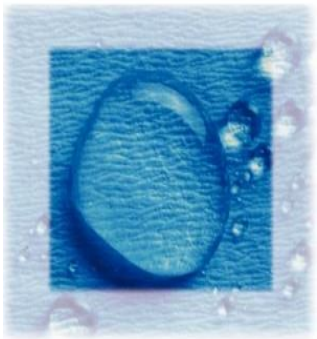
Dry Time Validation Acceptance Criteria

All validation cycles must be within specifications

Packaging and products must pass visual inspection with no moisture observed

Packaging weight gain cannot exceed 3%

[(Post weight – pre weight) / pre weight]
x 100 = weight gain percentage



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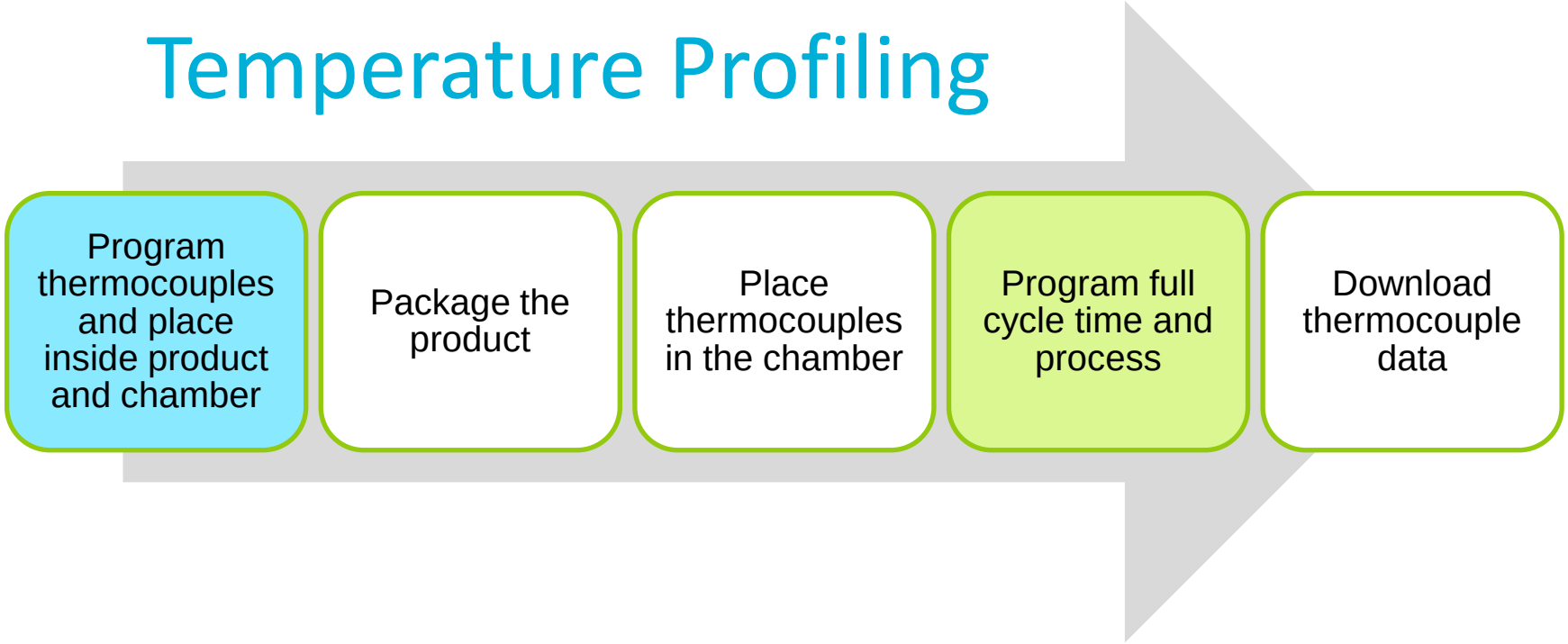
Temperature Profiling



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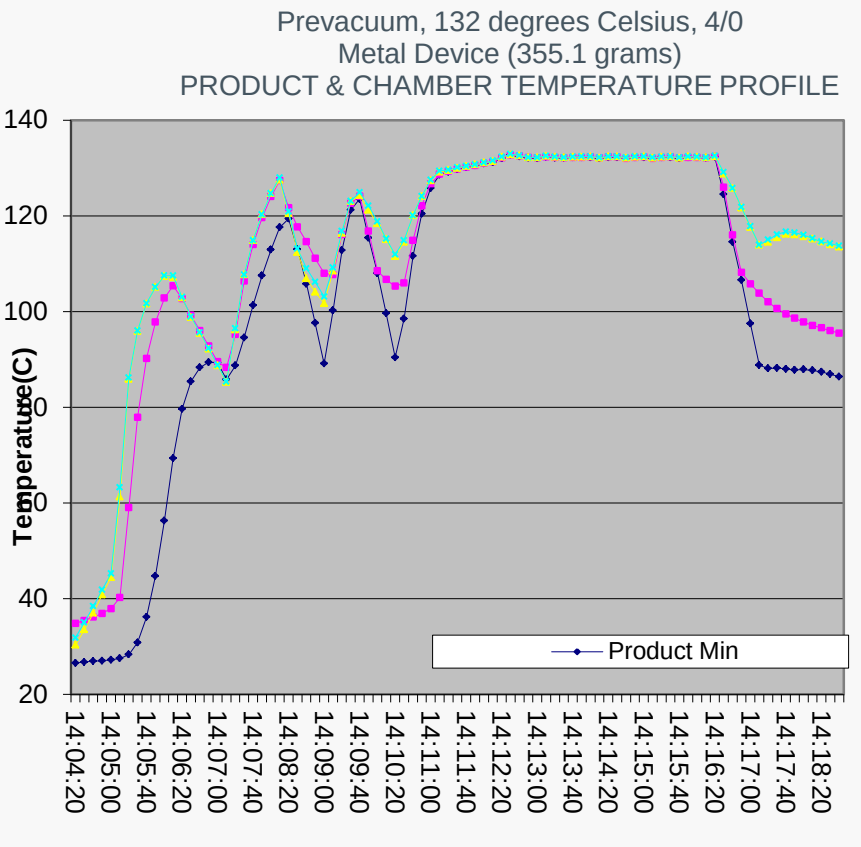
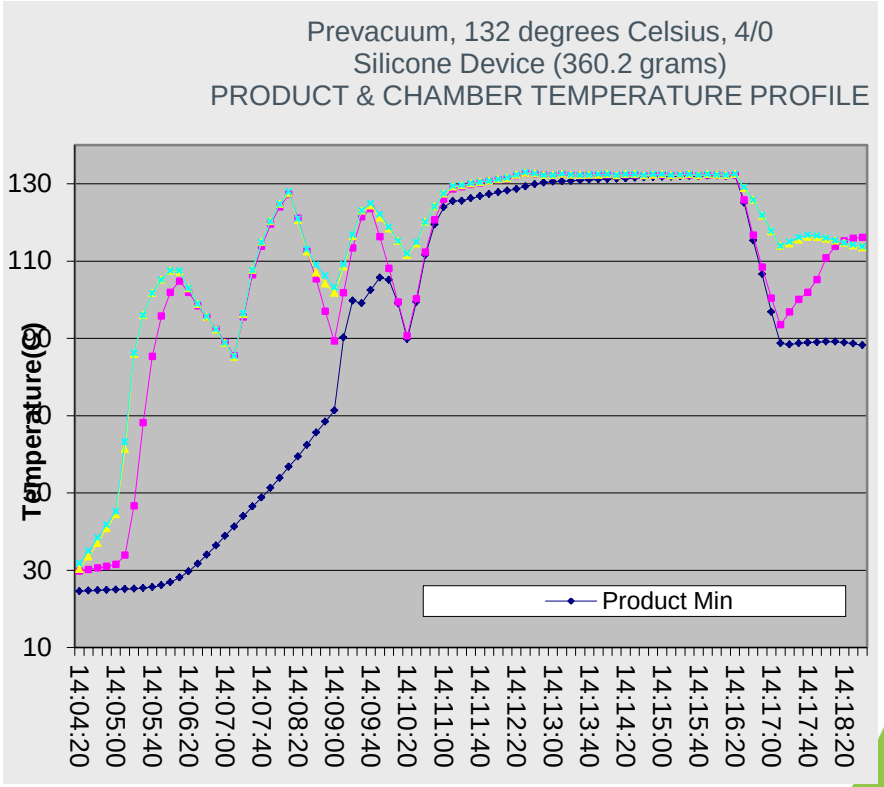
Metal vs. Silicon Device Temperature Profiling





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Gravity-Displacement – PHASING OUT

Steam enters chamber and air is displaced through a vent until the specified temperature and pressure is achieved

Used for products that allow effective air removal and steam contact

Sterilization Phases:

- Purge/ Charge
- Exposure
- Exhaust
- Drying
- Vacuum Relief

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Dynamic-Air Removal (Prevacuum)

Effectively removes the air from the chamber and replaces it with steam.

Air removal by using a series or pulsing of vacuums.

Used for products consisting of porous materials having cavities where air is difficult to remove.

Sterilization phases:

- Air removal/ conditioning
- Charge
- Exposure
- Exhaust
- Drying
- Vacuum relief

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Recent Sterilization Guidance

FDA-cleared

- Sterilizers
  - Steam, EO, STERRAD, Dry Heat
- Accessories
  - Biological Indicators, Chemical Indicators, Packaging

Parameters

- Parameters from AAMI TIR12
- No more extended cycles

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Cycle Parameters for Pre-vacuum Steam Sterilization Cycles

Item	132°C (270°F)	135°C (275°F)	Drying Times
Wrapped Instruments	4 min		20-30 min
		3 min	16 min
Textile Packs	4 min		5-20 min
		3 min	3 min
Wrapped Utensils	4 min		20 min
		3 min	16 min
Unwrapped Nonporous Items (e.g. instruments)	3 min	3 min	NA
Unwrapped Nonporous and Porous Items in a Mixed Load	4 min	3 min	NA

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Some current process parameters for reprocessing in CSSD in EU

COUNTRY	STEAM STERILIZATION	
Switzerland	134°C	18 minutes
Turkey		5 minutes
Belgium		5 minutes
Austria		5 minutes
France		18 minutes
Germany		5 minutes
England		3 minutes
Spain		5 minutes
Hungary		10 minutes
Portugal		4 minutes
Netherlands		3 minutes

Guidance from FDA

Reprocessing Medical Devices in Health care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff
Published 17 Mar 2015 (Revised in 2017)

http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015

This document supersedes: "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf) issued April 1996.

The draft of this document was issued on May 2, 2011.

For questions regarding devices regulated by the Center for Devices and Radiological Health, contact the Infection Control Devices Branch (INCB) at (301) 796-5580. For questions regarding devices regulated by the Center for Biologics Evaluation and Research (CBER), contact the Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Office of Device Evaluation

Center for Biologics Evaluation and Research

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References on NL Website

- Cleaning validations of reusable medical devices: https://www.nelsonlabs.com/Test/Cleaning-Validations-of-Reusable-Medical-Devices
- Disinfection Validation- High, Intermediate & Low Level: https://www.nelsonlabs.com/Test/Disinfection-Validation-High-Intermediate-and-Low-Level
- Sterilization validations of reusable medical devices: https://www.nelsonlabs.com/Test/Sterilization-Validations-Device-or-Trays
- Device Life-Cycle Testing: https://www.nelsonlabs.com/Test/Device-Life-Cycle-Testing

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Reference Standards

Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – March 17, 2015, Revised 2017

AAMI TIR12 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

AAMI TIR30 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

ANSI/AAMI TIR55 – Human Factors Engineering for processing medical devices

AAMI TIR34 – Water for Reprocessing of Medical Devices

AMSI/AAMI ST81– Sterilization of Medical Devices, Information to be provided by the manufacturer for the processing of resterilizable medical devices.

ANSI/AAMI ST79– Comprehensive guide to Steam Sterilization and sterility assurance in health care facilities

ANSI/AAMI ST58 Chemical Sterilization and high level disinfection in health care facilities

ANSI/AAMI ST9– Comprehensive guide to flexible and semi-rigid Endoscope Reprocessing in health care facilities

ANSI/AAMI ST77 Containment devices for reusable medical device sterilization

ANSI/AAMI ST67 Sterilization of health care products – Requirements for products labeled “STERILE”

ASTM F3208 – Standard test soils for validation of cleaning methods for reusable medical devices

Reference Standards

ISO 17664 Processing of health care products – information to be provided by the medical device manufacturer for the processing of medical devices

ISO 17665-1 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 17665-2 Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1

ISO 17665-3 Sterilization of health care products -- Moist heat -- Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization

ISO 15883: series – Washer-disinfectors

ANSI/AAMI/ISO 14160:2011 (WG10) – Sterilization of health care products - Liquid Chemical Sterilizing agents

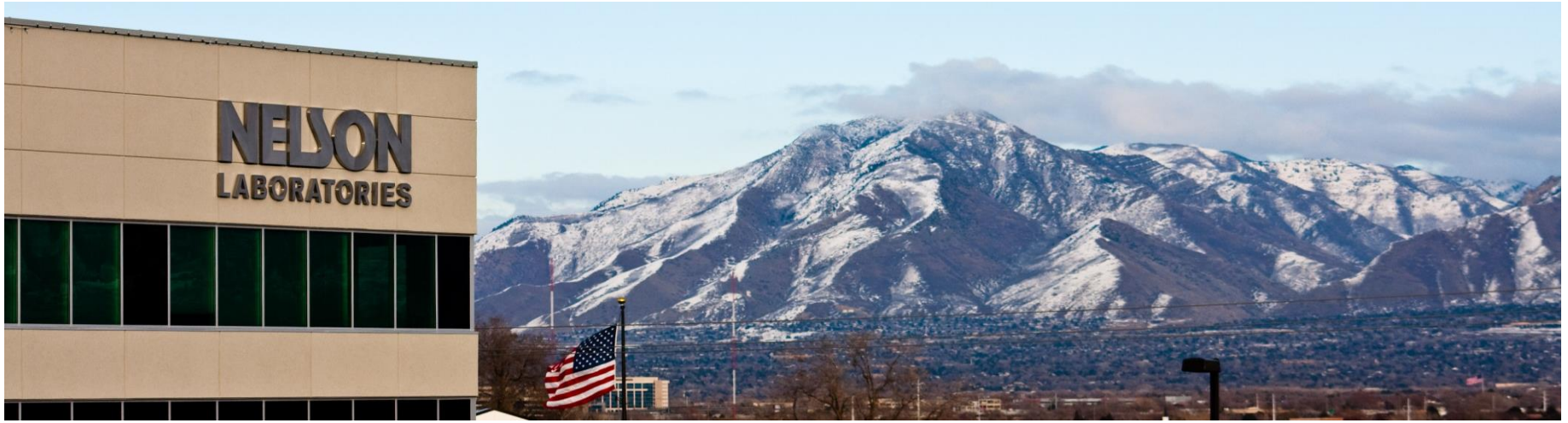
ISO 14937: Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices

EN 285: Sterilization - Steam sterilizers - Large sterilizers

EN 556-2: Sterilization or medical devices – Requirements for medical devices to be designated “STERILE” – Requirements for aseptically processed medical devices

PDA Technical Report No. 1: Validation of moist heat sterilization processes: Cycle design, development, qualification, and ongoing control

Thank You!



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