



Source: Microsoft Creative Commons

# A COVID-19 Update on Instrument Sterilization



Mary Govoni, MBA, CDA, RDH

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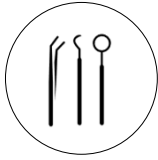


**Program provided with support from:**



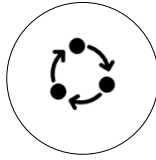
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## Program Objectives



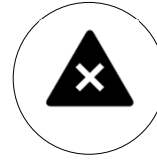
### Packaging Instruments

- Types of packing materials
- Selection of appropriate packaging
- Using pouches and wraps correctly



### Loading Instruments

- Placement in pouches/wraps
- Placement in sterilizers
- Use of indicators and integrators

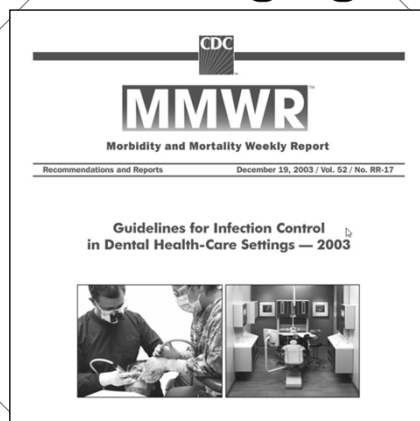


### Avoiding Processing Errors

- Failure label packs and monitor loads
- Removal of and storage of wet packs
- Lack of sterilizer maintenance

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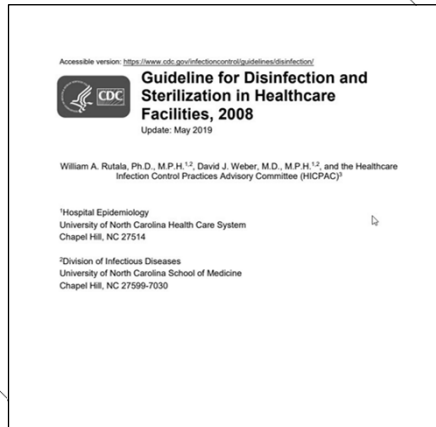
## Guidelines for Instrument Packaging



[RR5217 Dental Front.pmd \(cdc.gov\)](https://www.cdc.gov/mmwr/rr/rr5217.html)

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# Guidelines for Instrument Packaging



Disinfection & Sterilization Guidelines |  
Guidelines Library | Infection Control | CDC

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# Rules for use of sterilization packaging materials

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H - MEDICAL DEVICES

PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES  
Subpart G - General Hospital and Personal Use Miscellaneous Devices

Sec. 880.6850 Sterilization wrap.

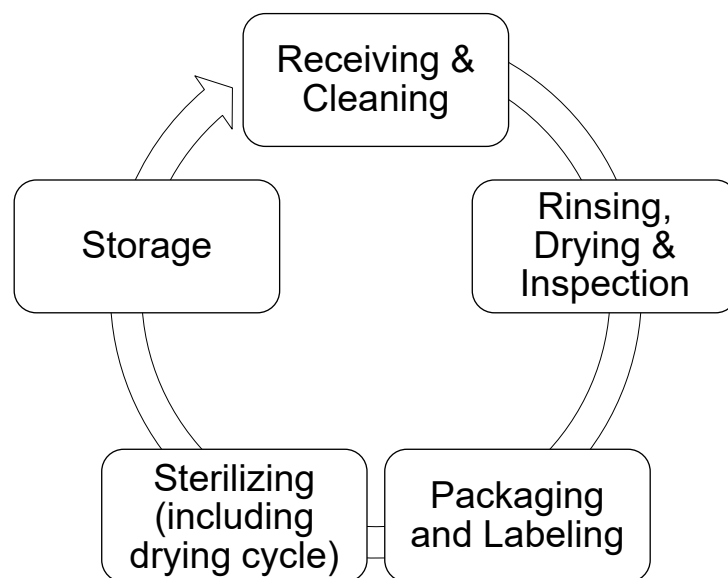
(a) Identification. A sterilization wrap (pack, sterilization wrapper, bag, or accessories, is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

(b) Classification. Class II (performance standards).

CFR - Code of Federal Regulations Title 21 (fda.gov)

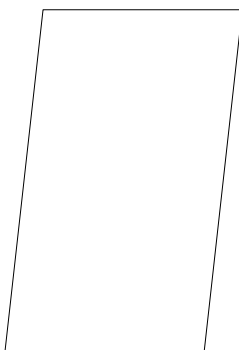
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## Instrument Processing Cycle



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## Why should instruments be dry before packaging?



- Excess moisture can compromise packaging material
  - Tears will compromise sterility in storage
- Excess moisture could prevent steam or chemical vapor from contacting instrument surfaces
- Rust, staining or pitting can occur on instrument surfaces



Source: elysiuminstruments.com

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## | Which packaging material to choose?

Dependent on:

Sterilization method (steam, dry heat or unsaturated chemical vapor)

Cost of materials

Instrument management system

Workspace available

Preference

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## | Sterilization Pouches

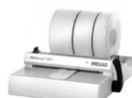
### Peel Pouches



Source: SkyDental Supply

Paper and plastic-type material

### Tubing



Source: Sterillu

Nylon or other material

### Reusable



Source: Enviro Pouch

Specialized fabric

Most common

Least common

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## Sterilization Pouches

### Disposable – single use

- Self sealing
- External & internal indicators
- Wide variety of sizes

### Reusable

- Finite use life – must track each use
- Difficult to seal
- Can become discolored

### Tubing

- Requires cutting to size
- Seal with autoclave tape or use heat sealer

Most efficient

Least efficient

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## Sterilization Pouches

- FDA cleared
- Appropriate for sterilization method
  - steam vs. dry heat
- Indicators incorporated into pouch
  - Internal and external
- Variety of sizes



Source: skydentalsupply.com



Source: omniahealth.com



Source: researchgate.net

Sterilization: Packaging & Storage  
| FAQs | Infection Control |  
Division of Oral Health | CDC

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## Sterilization Tubing

- FDA cleared
- Cut to size
- Heat sealed or seal with autoclave tape
  - No staples
- May need to place indicators in package



Source: Crosstex



Source: Defend



Source: Septodont

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## Sterilization Wrap

- FDA cleared
- Appropriate for sterilization method
- Two layers
  - Separate sheets
  - Two bonded together
- Two methods of wrapping
  - Envelope fold
  - Square fold



Source: Halyard Health



Source: HuFriedy Group



Source: Halyard Health

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## Sterilization Wrap

### Total Benefit

- Used primarily with cassettes and surgical instruments
- Sealed with autoclave tape
- Indicators placed inside wrapped cassette or instrument packs
- Wrap can serve as surface barrier in treatment areas



Source: HuFriedy Group

\$32,245

\$503,210,012

\$10,340

\$654,321



Source: Certol

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## Common Errors in Heat Sterilization

### • Skipping the dry cycle – putting wet packs into storage

- Subject to tearing
- Wicking effect
- <https://youtu.be/a6EnCVhl4BE>



Source: Crosstex/HuFriedy Group

### • Failure to validate that sterilizer

- Integrator in each load
- Weekly spore test
- Monitoring of mechanical function of sterilizer



Source: sowingo.com

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# Labeling packages for sterilization



Source: sterilizationproducts.com

**Before placing packaged instruments in the sterilizer, at a minimum, include the following information on the label:**

- Sterilizer used
- Cycle or load number
- Date of sterilization
- Expiration date, if applicable

Sterilization: Packaging & Storage | FAQs | Infection Control | Division of Oral Health | CDC

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## Labeling packages for sterilization

### • Labeling Systems:

- By hand – check with sterilizer mfr. about ink compatibility
  - ASTM standard 4236
- Autoclave-safe stickers that can be color-coded, date-stamped
- Labels printed from sterilizer
- Instrument sterilization tracking system/software
  - Tracks packages automatically when bar-coded and scanned



Source: sharpie.com



Source: Midmark



Source: 3M



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# Instrument Storage: Location

- **Central storage is most common**

- In or near sterilization area
- Must be in clean area
- Need to avoid moisture to keep packaging materials dry



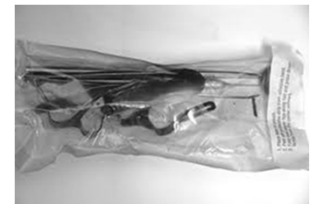
Source: HuFriedly Group



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## Common Errors with Sterilization Pouches

- Reuse – single use only!
- Overloading
  - Too many instruments
  - Pouch too small for items
- Placing wet instruments in pouches
- Improper seal and/or folding pouch
- Instruments protruding from the pouch



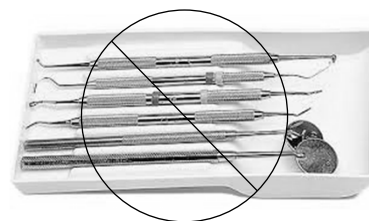
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## Common Errors with Sterilization Pouches

- Single instruments not packaged



Source: sdcep.org.uk



- Packaging single instruments in bulk in pouches does not maintain sterility once package has been opened

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## Indicators and integrators

- Instrument pouches have external and internal indicators that change color when instruments have been processed
  - Indicators may measure one – three of the parameters needed for sterilization
    - time, temperature, pressure
  - Integrating indicators measure all three parameters
- Some autoclave tapes contain lead, which may be regulated in some states for disposal



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## Sterilization Indicators

Type of Indicator	Description	Use in Dentistry
Type 1	Process	Autoclave tape – items have been processed
Type 2	Specific use	Bowie-Dick test packs (pre/post vacuum sterilizers)
Type 3	Single-variable	Temperature indicator Pouches - external
Type 4	Multi-variable	Pouches - internal
Type 5	Integrating indicator	Indicator strips Load validation
Type 6	Emulating indicator	Indicator strips Load validation

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## Common Errors in Heat Sterilization

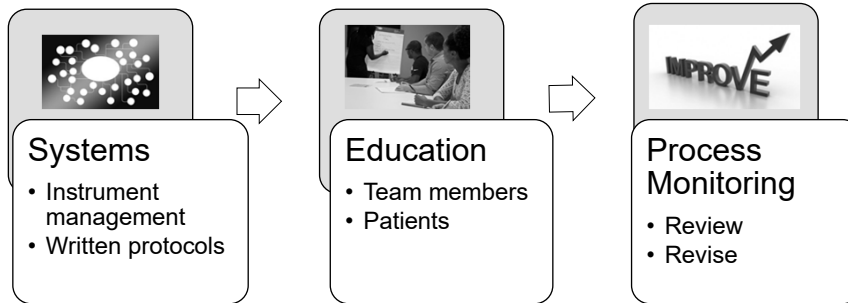
- Improper placement of pouches
  - Layering vs. Using separating racks
    - Only one layer on a tray
  - Paper up vs. Paper down
- Overloading the chamber
  - Consult manufacturer to determine load capacity
- Lack of maintenance - cleaning
  - Can cause staining or pitting of instruments



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## Key Take-Aways

Quality assurance for you and your patients



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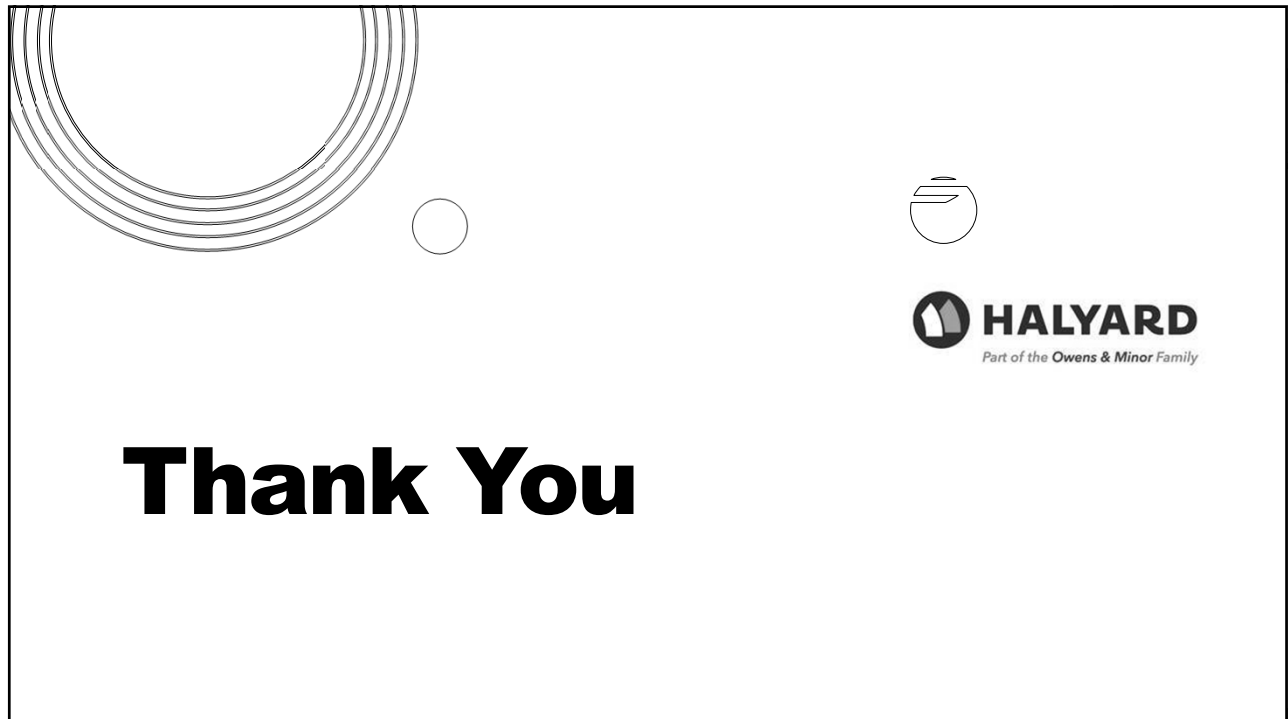
COMPLIANCE VIDEOS | MARY GOVONI & ASSC.

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