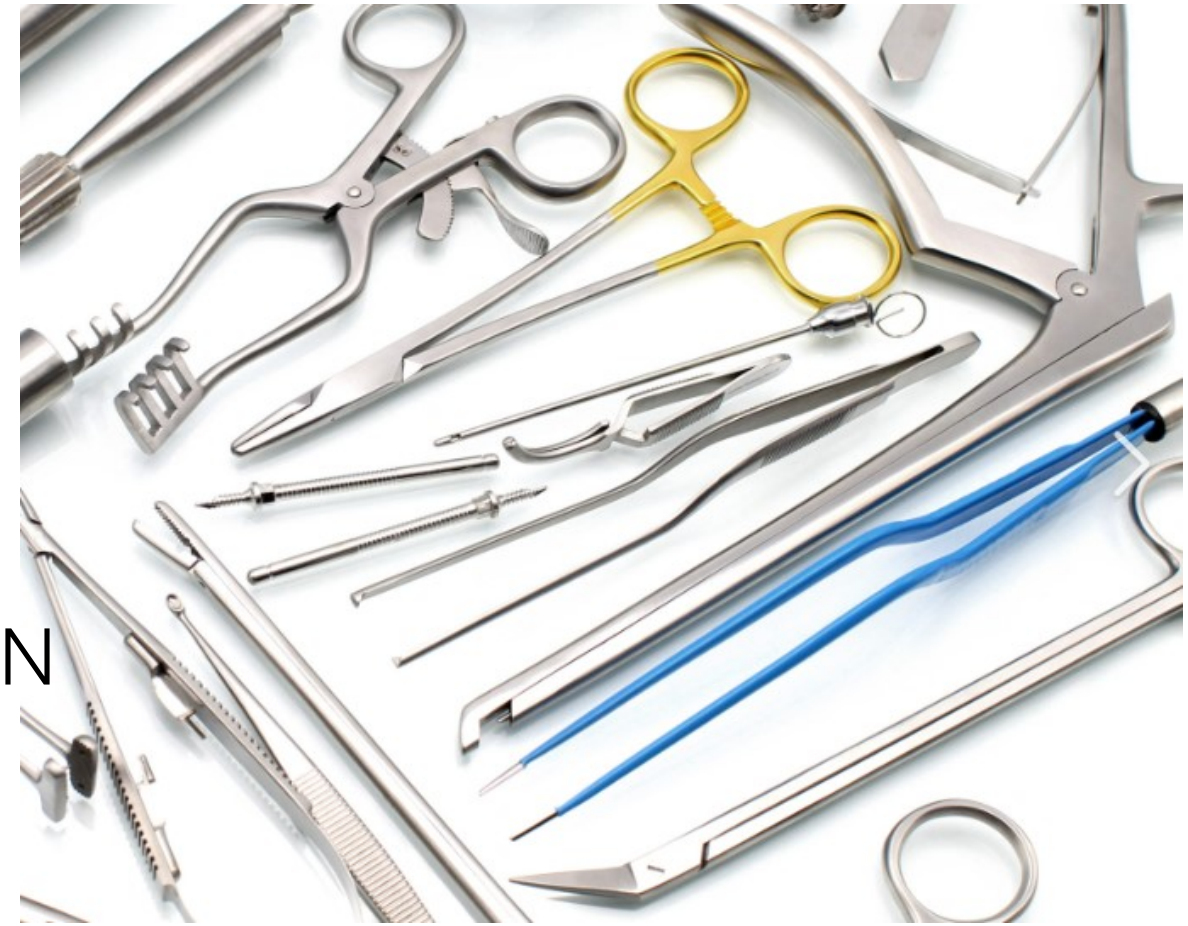
- AUTOCLAVE
- COLD CHEMICAL STERILIZATION
- HIGH LEVEL DISENFECTION

OVERVIEW



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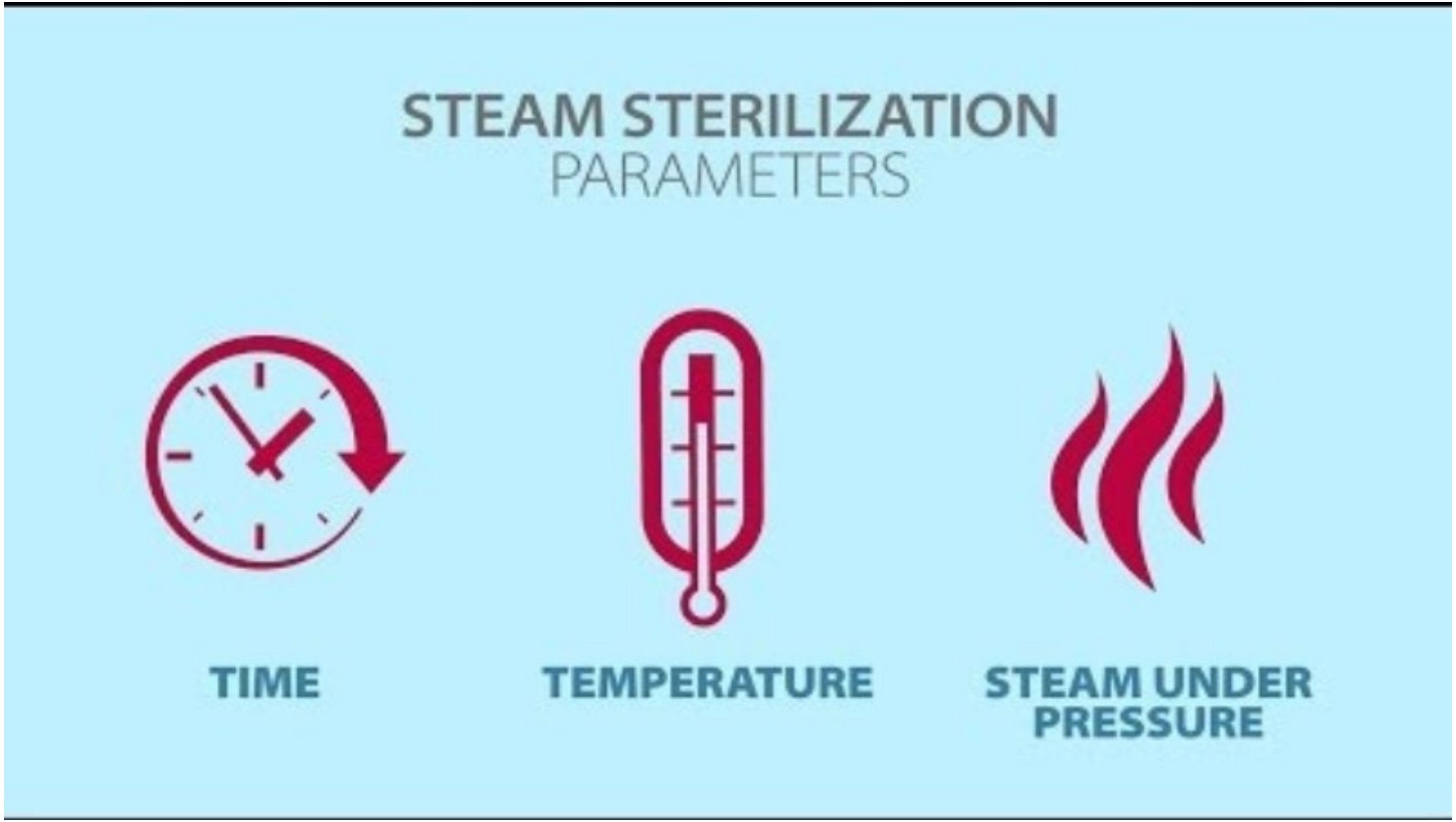
PURPOSE

AUTOCLAVE

A machine that uses steam under pressure to kill harmful bacteria, viruses, fungi, and spores on items that are placed inside a pressure vessel.

The process involves heating water to create steam, which is then pumped into a chamber (the autoclave) where the items to be sterilized are placed.

The combination of high temperature and pressure ensures thorough sterilization.



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TYPES OF AUTOCLAVES

TABLETOP

Tabletop autoclaves are compact and portable, making them ideal for small to medium-sized facilities.

They are designed to fit on countertops and are often used in dental offices, clinics, and other settings with limited space.

TYPES OF AUTOCLAVES

HOSPTIAL LARGE CAPACITY AUTOCLAVE

Industrial autoclaves, have capacities exceeding 200 liters and are built for high-volume, large-scale sterilization.

These units are essential for hospitals, pharmaceutical manufacturers, and industrial facilities where large quantities of materials or oversized equipment need to be processed regularly.

Large capacity autoclaves can accommodate large trays, bedpans, or bio waste containers, making them indispensable in high-demand environments.

AUTOCLAVE CATEGORIES

CLASS S - Vacuum-assisted autoclave

- A vacuum pump removes air from the chamber before steam is introduced
- Sterilizes wrapped packages and some hollow instruments
- *Commonly used in a doctor's office*

CLASS N - Gravity displacement autoclave

- Use gravity to displace air with steam
- Used for sterilizing solid, unwrapped instruments such as scissors and forceps

CLASS B - Vacuum pump removes air from the chamber before the sterilization process begins

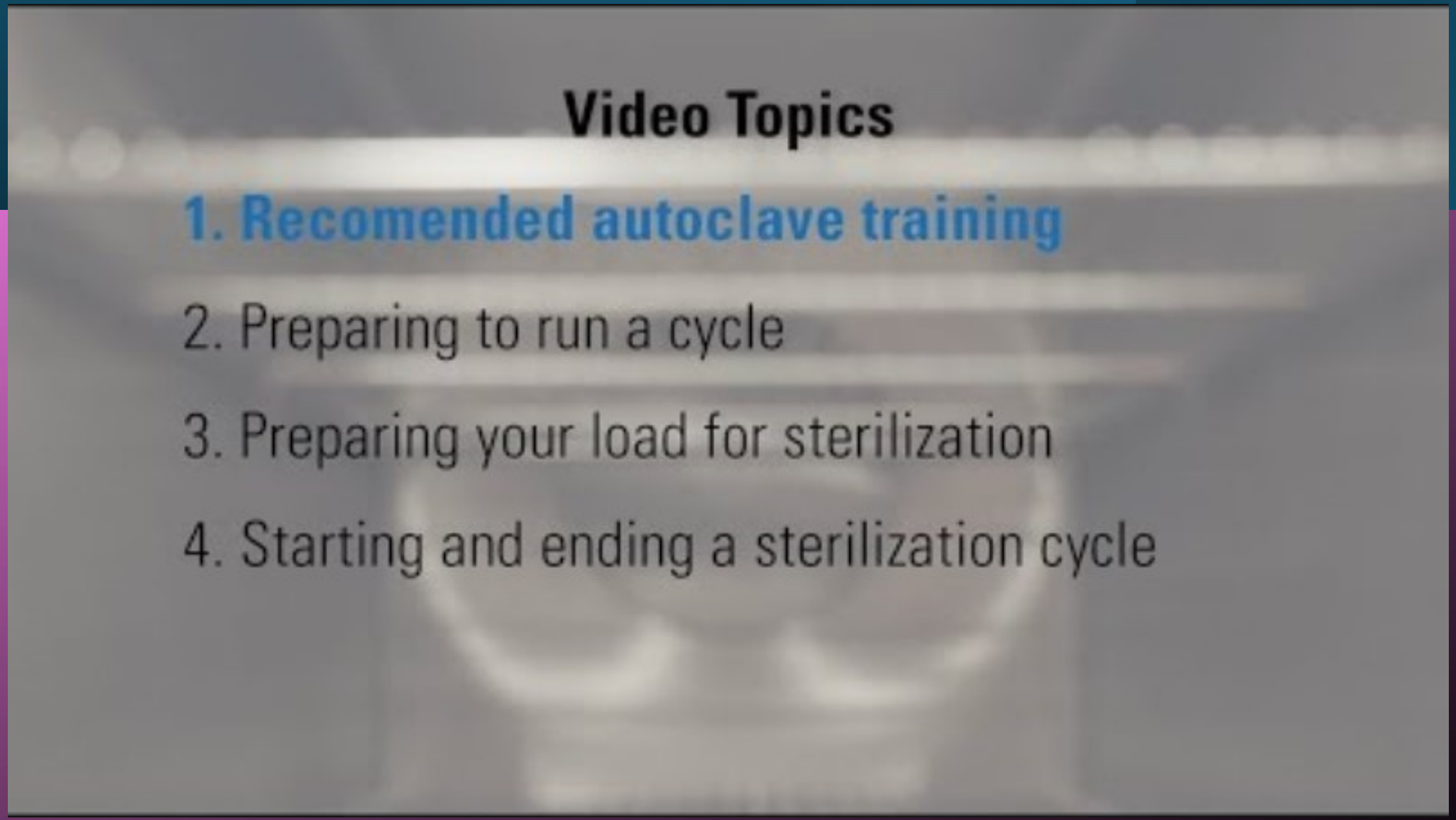
- Pre-vacuum stage ensures that steam penetrates porous and hollow items effectively, making Class B autoclaves suitable for a wide range of materials, including textiles, wrapped instruments, and hollow instruments
- The versatility makes it ideal for demanding applications, such as in dental practices and hospitals where instruments with complex structures require thorough sterilization

STANDARD OPERATING PROCEDURES (SOP)

KEY POINTS

The following key points should be included in any SOP

- ALWAYS READ AND FOLLOW MANUFACTURER INSTRUCTIONS PRIOR TO OPERATION
- PERSONAL PROTECTIVE EQUIPMENT
  Always wear appropriate PPE
- TRAINING - personnel must complete training on autoclave safety and operating procedures before using the autoclave
- INSPECTION - autoclaves must be inspected at least annually by a certified technician or per manufacturer's maintenance. A basic visual inspection should be done monthly.
- LOADING AND UNLOADING - load items carefully per manufacturer's instructions
- CYCLE PARAMETERS - set appropriate time and temperature according to instructions
- CYCLE COMPLETION - abort cycle is there are any issues detected such as open door or high-pressure failure
- DISPOSAL - dispose of autoclave waste correctly



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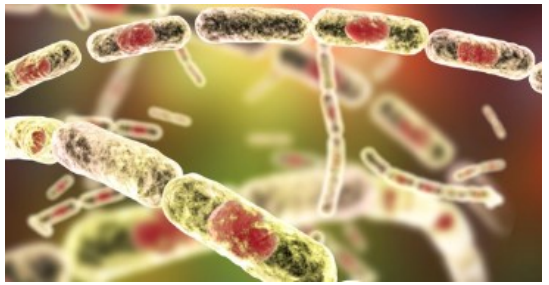
VALIDATING THE STERILITY OF A PACKAGE

Autoclave tape is a chemical indicator that changes color when exposed to certain temperatures

- They only confirm that the item has been through a heat cycle
- They **do not prove** that the conditions necessary for sterilization (the correct temperature, the required duration, proper steam penetration) were met.

The only way to confirm true sterilization is with a **biological indicator**



- This strip or self-contained vial contain spores of a highly resistant bacterium such as Geobacillus stearothermophilus

This spore is far more difficult to kill than common pathogens

- When an autoclave cycle can kill resilient spores, it provides a high degree of confidence that all other potential contaminants have been eliminated.
- As a best practice, this validation should be performed regularly (at least monthly) and for each type of load.

WHICH INSTRUMENTS TO *STEAM* PROCESS VS WHICH INSTRUMENTS TO *COLD* PROCESS

STEAM AND PRESSURE STERILIZATION

Instruments must be heat and pressure tolerant without degrading, deforming or breaking

- Reusable metal instruments
- Borosilicate types of glass
- Types of plastics
- Natural fibers

COLD CHEMICAL STERILIZATION

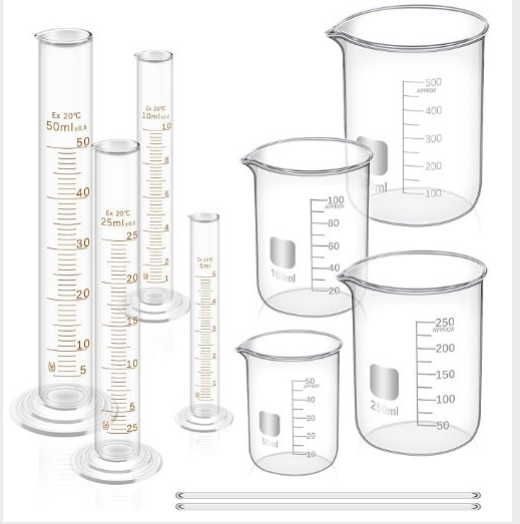
Instruments are smooth, moisture-sensitive, exposed on all sides and cannot withstand high temperatures

- Surgical instruments
- Medical devices
- Anesthetic equipment

TYPES OF INSTRUMENTS THAT CAN BE AUTOCLAVED

AUTOCLAVABLE INSTRUMENTS

- Surgical Instruments
- Glassware
- Stainless Steel & Aluminum Trays
- Autoclavable Plastic Ware
- Centrifuge Tubes
- Pipette Tips
- Chemical Solutions



TYPES OF INSTRUMENTS THAT CAN BE COLD CHEMICAL DISENFECTED

COLD STERILIZATION/HLD

- Instruments with lenses (endoscopes and arthroscopes)
- Dental instruments such as plastic impression trays, cheek extractors, Rinn kits, intraoral scanner tips
- Anesthetic equipment such as laryngoscopes, face mask, oral and nasal airways, endotracheal tubes

Critical vs. Non-Critical Instruments

"**Critical**" items such as surgical instruments and periodontal scalers, are used to penetrate soft tissue or bone.

These instruments have the greatest risk of transmitting infection and should always be sterilized using heat.

"**Non-Critical**" instruments are ones that do not penetrate soft tissue, or bone can be cold chemical sterilized.

- Endoscope and arthroscope lenses
- Plastic impression trays
- Cheek extractors
- Anesthetic equipment: endotracheal tubes, oral and nasal airways

PPE

Personal Protective Equipment

PPE acts as the first line of defense, protecting staff from potential hazards and ensuring the sterility of medical instruments remains uncompromised

- Household-cleaning-type rubber or plastic gloves
- Face mask
- Eye protection
- Gown

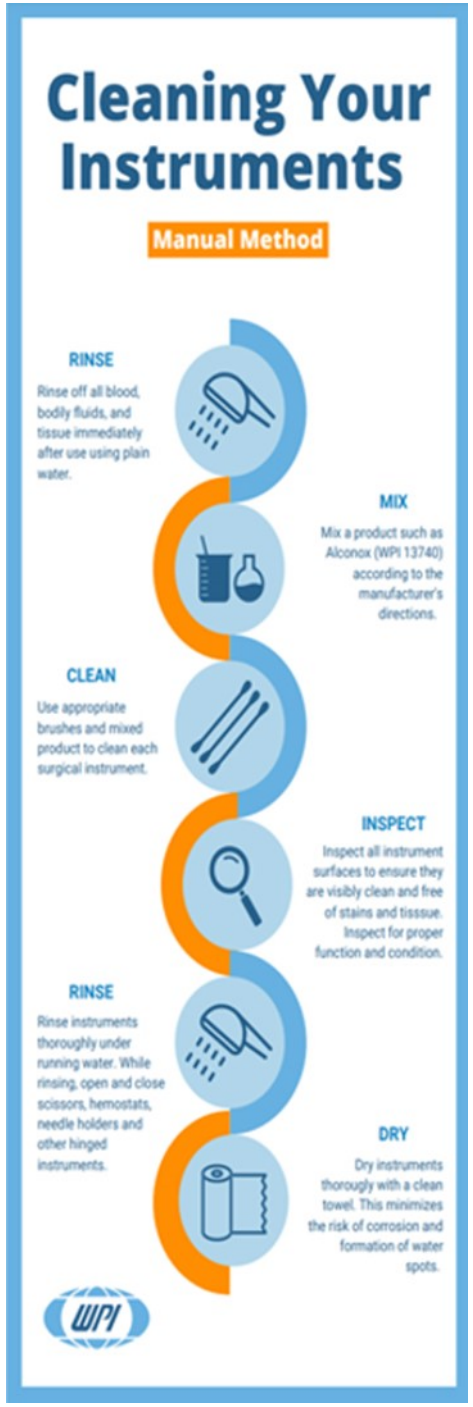
Always put on protective equipment prior to cleaning instruments

CLEANING AND PACKAGING MEDICAL INSTRUMENTS

CLEANING

Immediately after use, items must be cleaned to remove blood or debris that might interfere with the sterilization process

- Ultrasonic machines can be more effective than cleaning by hand
- After cleaning, rinse instruments to remove loose debris and detergents
- Inspect the instrument for any remaining debris
- Open hinged instruments and place all items on a pad and allow to sit until completely dry



CLEANING PROCESS

USE OF PPE – Always use appropriate PPE including eye protection, gloves and gown when sterilizing instruments

ENZYMATIC CLEANER - used for surgical instruments to effectively remove organic soils like blood, tissue, and other bioburden that can hinder the cleaning and sterilization process.

- Enzymes break down proteins, fats, and carbohydrates, making it easier to remove these substances from hard-to-reach areas like hinges and lumens.
- Enzyme cleaners helps prevent the formation of biofilms, which can harbor microorganisms and reduce the effectiveness of sterilization.
- Are PH neutral making them a compatible cleaner for surgical instruments

CLEANING AND PACKAGING MEDICAL INSTRUMENTS

PACKAGING

- Instrument packaging should be done in an area where there is low risk for contamination, using FDA approved materials.
- Sterilization Pouches - Used for packaging small, lightweight, single-use items
- Sterilization Wraps - Used for packaging instrument trays or cassettes
- Sterilization Containers - Used for packaging large items or sets of instruments

LABELING PACKAGES

Prior to sterilization, all packages must be labeled with the appropriate identifying information, such as:

- Date of sterilization
- Load run identification information
- Initials of staff processing packages
- General contents of package

This helps with identifying any packages related to a positive spore test or malfunction of equipment, that need to be removed from stock.

LABELING AND PROCESSING PACKAGES

LOADING PACKAGES

- Chemical indicators must be placed on the inside and outside of each package
- They visually indicate the parameters for proper sterilization have been met
- Biological indicators should be run at least monthly to verify proper function and sterility
- Package placement must allow for free circulation of sterilant (steam/chemical) to all surfaces;
    - ideally placed on their edge, in perforated or mesh racks.

LABELING AND PROCESSING PACKAGES

STORAGE AND MANAGEMENT OF STERILE INSTRUMENTS

STORAGE

Store sterile instruments in an area that reduces potential for contamination

The area should be:

- Clean and dry
- Protected from sunlight
- Separated from non-sterile items by a functional barrier

Although different sites utilize time-related expiration dates, data has shown sterile packages can be managed using “event related” factors.

Sterility is only considered to be “broken” under qualifying circumstances…

“Event Related” factors that compromise sterility

Package integrity - any tear, hole, puncture or broken seal renders the item non-sterile

Environmental Moisture - if a package becomes wet the protective barrier is broken and is considered contaminated

- Packages should be stored in a clean dry environment with controlled humidity

Handling and Storage - improper handling increases the risk of damage

- Items should be handled as little as possible
- Do not packed tightly packages may be crushed or damaged

STORAGE AND MANAGEMENT OF STERILE INSTRUMENTS

MANAGEMENT

- Handle sterile packages with extreme care and remove from stock if there is any doubt as to the item's sterility
- “Event related” factors (such as dropping, crushing, bending or puncturing packages) will compromise the sterility of its contents and require removal of the item from stock to be reprocessed
- Sites shall have a written process for routine evaluation of sterilized packages to ensure quality and safety
  - Double check integrity of packages prior to use
  - Evaluate packages at least monthly

MONITORING LOG AND MAINTENANCE

PURPOSE
of the Autoclave Log

- REGULATORY COMPLIANCE
Ensures required safety and regulatory standards are met
- DOCUMENTATION FOR REVIEW
Provides reliable records for audits, equipment issues, or investigation of concerns.
- CYCLE ACCOUNTABILITY
Tracks each sterilization run to maintain clear, traceable documentation.
- VERIFICATION OF STERILIZATION PARAMETERS
Confirms time, temperature, and pressure levels are reached for proper sterilization
- QUALITY CONTROL TRACKING
Logs results of chemical and biological indicators to verify autoclave performance
- PERFORMANCE MONITORING
Allows for easy identification of trends or recurring issues that may require maintenance or troubleshooting

REQUIRED MONTHLY DOCUMENTATION

MAINTENANCE AND DOCUMENTATION REQUIREMENTS

Monthly Cleaning:

- Write your initials in the box for the correct month after completing the required cleaning

Monthly Spore Testing:

- Circle the test result (+ / –) and add your initials for the month the biological indicator test was completed

- Document at least monthly

AUTOCLAVE LOG

	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov	Dec
Monthly Cleaning												
	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials
Monthly Spore Testing Results	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -
	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results

FOR EVERY AUTOCLAVE RUN complete one row

DATE - Record the date of the cycle

- ❖ Document date on sterilization pouch

TIME - Note the start time (or end time if that is your standard)

LOAD Number - Assign a sequential load number for tracking

- ❖ Document load number on sterilization pouch

LOAD DESCRIPTION - Briefly describe what is being sterilized (e.g., glassware, instruments, biohazard waste)

- ❖ Document load description on sterilization pouch

DURATION OF RUN CYCLE - Record the full cycle time

TEMPERATURE - Note the peak temperature reached during the run. Chemical indicators must be included in the packaging to ensure temperature thresholds are met. (Per type of pouch used)

STEAM PRESSURE - Record the pressure reading for the cycle

OPERATOR - Initials or name of the person who performed the run

- ❖ Document on the sterilization pouch

MAINTENANCE AND DOCUMENTATION REQUIREMENTS

Cycle-by-Cycle Documentation

Date	Time	Load #	Load Description	Duration of Run Cycle	Temperature	Steam Pressure	Operator of Each Run

AUTOCLAVE LOG

	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept	Oct	Nov	Dec
Monthly Cleaning												
	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials
Monthly Spore Testing Results	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -	+ / -
	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results	Circle results

Date	Time	Load #	Load Description	Duration of Run Cycle	Temperature	Steam Pressure	Operator of Each Run

TYPES OF INDICATORS

- MECHANICAL

Monitors the autoclave's physical parameters

- CHEMICAL

Uses physical indicators to show that items were exposed to the sterilization process

- BIOLOGICAL

Uses bacterial spores to prove the autoclave can kill microorganisms, providing the highest level of verification

MECHANICAL INDICATOR

STERILIZER	TEMPERATURE	PRESSURE	TIME
Steam Autoclave	121° C (250 ° F)	15 psi	15 min
• Unwrapped Items	121° C (270 ° F)	30 psi	3 min
• Lightly Wrapped Items	132° C (270 ° F)	30 psi	8 min
• Totally Wrapped Items	132° C (270 ° F)	30 psi	10 min
Dry Heat Wrapped	170° C (340 ° F)		60 min
Chemical Vapor	132° C (270 ° F)	20-40 psi	20 min
Ethylene Oxide	Ambient		8-10 hr

Types of Mechanical Indicators

- Built-in gauges, displays, or printouts in the autoclave

Measure

- Temperature – indicates a specific heat was met to kill the heat-resistant spores
- Pressure (PSI) - indicates the autoclave chamber has built enough pressure to allow steam to reach the temperatures needed for sterilization
- Time – indicates a specific duration was met for steam to penetrate the load

Purpose

- Verifies that required sterilization conditions were reached

Importance

- Provides the first visual assurance of proper sterilization

CHEMICAL INDICATOR

Types of Chemical Indicators

- Strips, tape, cards, or labels that change color when exposed to proper heat and steam

Measure

- Exposure of items to heat
- Exposure to steam
- Completion of the sterilization process

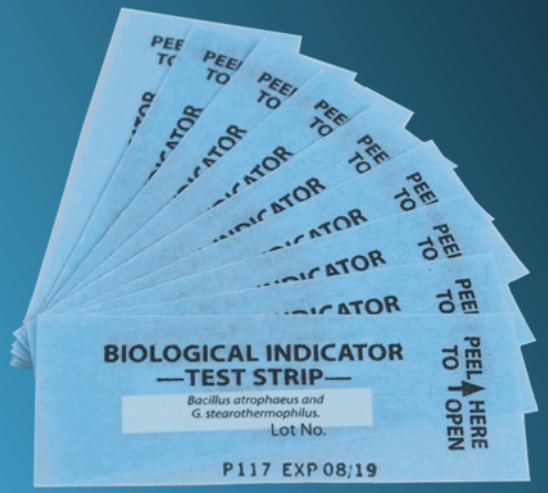
Purpose

- Show that packs were subjected to sterilization conditions

Importance

- Provides quick visual confirmation that items were processed, though it does not guarantee sterility

BIOLOGICAL INDICATOR



Types of Biological Indicators (Gold Standard)

- Vials or strips containing resistant bacterial spores to test sterilization effectiveness

Measure

- Ability of the autoclave to kill highly resistant microorganisms

Purpose

- Prove that the autoclave can achieve true sterilization

Importance

- Provides the highest level of verification, minimum monthly testing is required.
- Must be documented on the autoclave log

Common Types

- **Vial/Bottle Indicators** - Contains spores in a liquid medium; color changes after incubation shows growth or no growth.
- **Strip/Filter Paper Indicators** - Contains spores on a paper strip; incubated after the cycle to verify sterility.

Processing Options

- **In-Clinic Processing** - Some facilities incubate the indicators on-site to verify autoclave performance immediately.
- **External Laboratory Processing** - Indicators can be sent to a certified lab for incubation and confirmation, providing documented results for quality assurance.

**All lab supplies must have a process for checking expiration dates

POSITIVE SPORE MANAGEMENT

Purpose

Ensures patient safety and maintains sterilization quality by responding appropriately to a failed spore test

Utilize the “5 Rs”

1. **Report** - the result and notify a supervisor
2. **Remove** - and repair the sterilizer before further use
3. **Retrieve** - and recall all items processed since the last negative test, they’re considered non-sterile
4. **Retest** - the sterilizer after repairs, run three consecutive cycles with negative results
5. **Re-sterilize** - all recalled instruments using a properly functioning sterilizer

MAINTENANCE AND DOCUMENTATION REQUIREMENTS

Autoclave Maintenance

Purpose

Ensures safe, reliable operation, prolong autoclave lifespan, and supports accurate log documentation.

Maintenance Tasks & Responsibilities

<u>Daily / Before Use</u>

- Check door seals and chamber
- Clean trays and chamber surfaces
  - **Who** - Clinical staff

<u>Weekly</u>

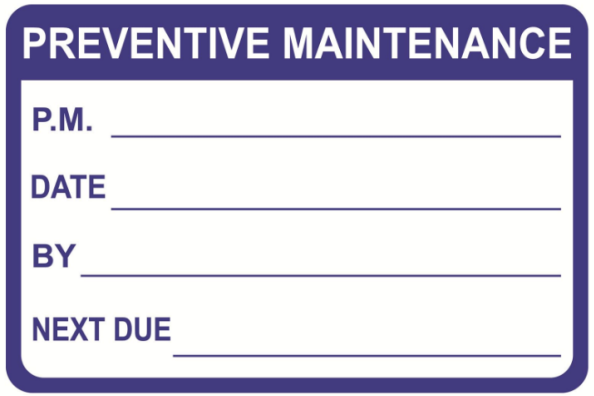
- Inspect gaskets and water levels
- Thorough chamber cleaning
  - **Who** - Clinical staff

<u>Monthly / Quarterly</u>

- Lubricate door and inspect valves
- Run test cycles
  - **Who** - Biomedical engineering / maintenance staff

<u>Annual / Preventive Maintenance</u>

- Full inspection, calibration, and parts replacement
  - **Who** - Manufacturer service technician / certified repair service



**Document weekly/monthly cleaning & maintenance on autoclave log to include date and initials of staff completing maintenance.

What is the Difference?

Cold Chemical Sterilization (CCS)

Uses liquid chemicals to eliminate all microorganisms from inanimate objects, including bacteria, viruses, and spores.

How it works - Instruments are submerged in a chemical solution (sterilant) for a specified duration, allowing the chemical to penetrate and destroy microorganisms.

High Level Disinfection (HLD)

A process that eliminates most microorganisms, including bacteria, viruses, and fungi, from medical instruments, but may **not** eliminate spores.

How it works - Instruments are submerged in a chemical solution (sterilant) for a specified duration, allowing the chemical to penetrate and destroy microorganisms.

COMMONLY USED SOLUTIONS

for CCS and HLD

GLUTARALDEHYDE

- A widely used, but older, high-level disinfectant and chemical sterilant
- Requires activation to become sporicidal (capable of killing spores)
- Solutions are typically acidic and need to be mixed or activated

HYDROGEN PEROXIDE BASED SOLUTIONS

- Can be used in various concentrations and formulations
- Some hydrogen peroxide solutions are ready-to-use and fast-acting
- May require a specific contact time and temperature for optimal efficacy.
- Some hydrogen peroxide solutions are compatible with automated endoscope reprocessors (AERs)

COMMONLY USED SOLUTIONS

for CCS and HLD

ORTHO-PHTHALALDEHYDE (OPA)

- A more modern high-level disinfectant that has gained popularity
- Offers superior mycobactericidal activity compared to glutaraldehyde
- Requires no mixing or activation
- Can be effective in a shorter time than glutaraldehyde
- May have better material compatibility than some other options

PERACETIC ACID

- Can be used in combination with hydrogen peroxide
- May be effective against a wide range of microorganisms
- May require specific temperature and contact time for optimal performance

SODIUM HYPOCHLORITE (BLEACH)

- Can be used for high-level disinfection at specific concentrations and contact times
- Not common

CCS/HDL SAFETY AND PREPARATION

- Ensure the CCS/HLD process is conducted in a well-ventilated area
- Ensure proper PPE to protect staff mucus membrane and skin (mask, gloves, eye protection, gown) are readily available for use
- Ensure solutions are mixed according to manufacturer guidelines

- Only trained personnel are tasked with CCS/ HLD instrument processing
- Use a chemical indicator to monitor solution effectiveness
- Follow manufacturers instructions when operating a reprocessing machine
- Confirm reprocessing outcome – sterile or high-level disinfection
- Chemical Disinfectants | Infection Control | CDC

VENTILATION REQUIREMENTS FOR COLD STERILIZATION

Chemical sterilants should be used in an area that is properly ventilated *

Rooms in which chemical disinfection and sterilization are performed should have a minimum of 10 air exchanges per hour (local regulations may require a higher minimum exchange rate)

When general room ventilation is not adequate, a self-contained, freestanding system or a local exhaust hood should be installed to capture chemical vapor during processing

When an outside exhaust system is not available, a ductless fume hood* can be used to deliver vapor to a filter system that chemically inactivates the vapor; then clean, filtered air is returned to the room.

Filters for these systems should be replaced at regular intervals

The engineering controls are virtually the same for OPA and glutaraldehyde: 10 air exchanges per hour

*Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

STERILE versus ASEPTIC versus CLEAN

STERILE ENVIRONMENT

- Space completely free from pathogens
- Sterile drapes, gowns, gloves
- Sterile instruments/equipment
- Controls of physical space

ASEPTIC TECHNIQUE

- Set of procedural guidelines to eliminate pathogens and reduce risk of infection
- Used to maintain a sterile environment
- Placing barriers

CLEAN ENVIRONMENT/TECHNIQUE

- Focus on reducing the overall number of germs, but don’t eliminate them
- Clean items that are not sterile
- High-level disinfected items
- Box of gloves, disinfect surfaces and non-critical medical equipment

COLD CHEMICAL STERILIZATION (CCS) & HIGH LEVEL DISINFECTION (HLD)

Immersion or “soak”

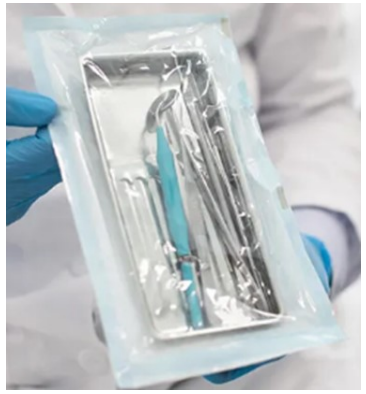
- Process/clean instruments and equipment as instructed in the previous slides
- Wear proper PPE according to sterilant manufacturer guidelines
- Submerge the cleaned and dried instruments/equipment in the cold sterilant solution, ensuring complete immersion - “soak”
- Allow the instruments to remain in the solution for the manufacturer's recommended contact time, which will vary depending on the solutions used
- Document time, date of each instrument submerged into sterilant solution

COLD CHEMICAL STERILIZATION

HANDLING & STORAGE

- Wear proper PPE
- Sterile technique is used following strict protocols to prevent contamination

- Thoroughly rinse the instruments using sterile water while wearing sterile gloves and/or using sterile tongs
- Ensure all sterilant is removed (toxic)
- Dry using a sterile cloth or place on a sterile drape and allow to air dry



- Proper drying after rinsing is crucial to prevent microbial growth.
  - Position instrument to avoid pooling
- Store the instruments in a sterile dry environment with a functional barrier separating from other supplies/equipment
- All instruments/equipment removed from the solution for immediate use must be rinsed and placed on a sterile field
- Sterile “Peel Packs” may be used

Sterilizing Practices | Infection Control | CDC

HIGH-LEVEL DISENFECTION

HANDLING & STORAGE

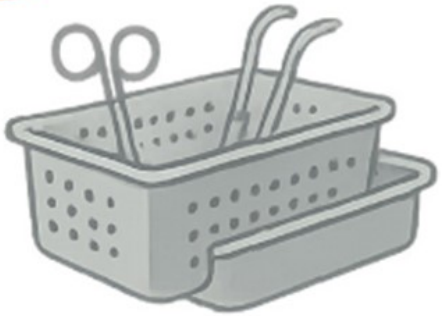
- Wear proper PPE
- Thoroughly rinse the instruments using clean water while ensuring all sterilant is removed (toxic)
- Dry by placing on a clean surface and allow to air dry
- Proper drying after rinsing is crucial to prevent microbial growth
    - Position instrument to avoid pooling
- Store the instruments in a dry environment with a functional barrier to preserve the HLD status

COLD STERILIZATION LIFECYCLE 2025

1 PRE-CLEANING

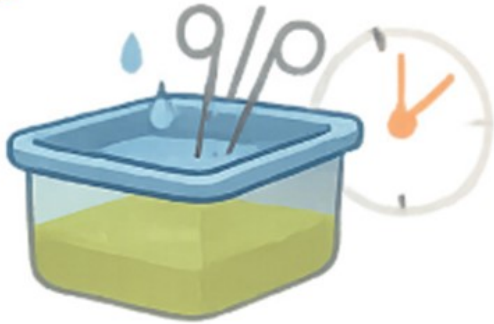
Precleaning instruments with enzymatic solution

2 LOADING



Loading instruments into perforated basket inside container

3 IMMERSING



Immersing completely in chemical sterilant for timed contact

4 TRIPLE RINSING

Triple rinsing with sterile water using drain basket

5 AIR.DRYING & STORAGE

Air drying and sterile until use

CCS/HDL DOCUMENTATION REQUIREMENTS

CCS/HLD DOCUMENTATION AND MONITORING

STRICT ADHERENCE
The cold chemical solution manufacturer's instructions are available to staff and must be meticulously followed

MATERIAL DATA SAFETY SHEETS
MSDS are readily available to staff in the event of a spill

SOLUTION MANAGEMENT

- The solution is changed according to manufacturer's instructions, not to exceed the expiration per activation date (usually not to exceed 30 days)
- A monitoring indicator is used daily and/or during each cycle to test the solution efficacy, and results are documented in the CCS/HDL log
- Solution must be changed if appearance is dirty/cloudy regardless of length of use
- Records are maintained for a minimum of 3 years

STAFF TRAINING
Staff training is completed to equip staff to follow established procedures related to the management of cold chemical solutions and documentation of instrument processing.

DOCUMENTATION
The following information will be documented in the CCS/HLD log:

- Date of soak
- Instruments
- Operator
- Patient information (if applicable)
- Solution Name
- Date solution put in use/expires
- Result of monitoring indicator

COLD CHEMICAL STERILIZATION SOLUTION LOG

NAME OF SOLUTION _____

Date Solution was Changed	Date of Solution Test (according to manufacturer's directions)	Test Results (+) Pass/ (-) Fail Circle one	Test By: Initials
		+ / -	
		+ / -	
		+ / -	
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		+ / -	
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Cold Sterilization Log

Follow Manufacture's recommended solution soaking time for sterilization, use of test strips to ensure solution efficiently destroys 100% of *Mycobacteriu Tuberculosis* and solution change.

Date	Name of Solution	Type of Instruments in Solution	Length of Time Items in Solution	Initials	Date Solution Tested	Solution Test Results	Date Solution Changed	Initials

CIDEX®

CIDEX® SOLUTION LOG SHEET

WARNING: DO NOT USE CIDEX® SOLUTION BEYOND ITS STATED USE & REUSE LIFE. USE TEST STRIPS WITHIN 90 DAYS OF OPENING BOTTLE.

Date Test Strip Bottle First Opened _____ Do Not Use After (Date)_____ Bottle Lot #:_____

QC Test Results _____ QC Test Date_____ Tested By (Initials) _____

Location/Dept _____

Date Solution Opened	Date Solution Expires	Date Solution Tested	Time Solution Tested	Solution MEC Test Results (circle one)	Tested By (Initials)	Temp in °F Before Use	Comments
				Pass Fail			
				Pass Fail			
				Pass Fail			
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				Pass Fail			

Notes:

ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.

a Johnson & Johnson company

888-783-7723

www.aspjj.com

AB-128003-01-US_A

DIRECTIONS

Prior to routine use, practice with control solutions (described in the QUALITY CONTROL section of this insert) to become familiar with proper testing technique and interpretation of results.

Test Procedure:

1. Immerse entire indicator pad of test strip into CIDEXPLUS solution for one (1) full second and remove.
2. Blot **firmly** for two (2) seconds by pressing the long edge of the strip on an absorbent paper towel to remove excess CIDEXPLUS solution. Lay strip, pad side up, on a paper towel.
3. **Sixty (60) seconds** after immersing the strip, compare indicator pad to the color blocks on the bottle label. Interpret and record results.
4. Discard the test strip according to OSHA, state and local regulations.

RESULTS

The color developed on the Serim DISINTEK GTA 2.1% Test Strip indicator pad indicates whether the concentration of glutaraldehyde in the CIDEXPLUS solution is above or below the MEC of 2.1%.

PASS - the color of the indicator pad is mostly purple; indicating the concentration of glutaraldehyde is **above** the 2.1% MEC.

FAIL - the color of the indicator pad is distinctly blotched yellow/ purple, similar to or having more yellow areas than the FAIL color blocks, indicating the concentration of glutaraldehyde is **at or below** the 2.1% MEC.

GLUTERALDEHYDE SOLUTION TEST STRIPS

monitor the minimum effective concentration (MEC) of gluteraldehyde solution

DIRECTIONS FOR USE

1 **Completely submerge** indicator pad of the test strip into the solution to be tested. Hold for one second and remove

2 Briefly rest the side of the strip on tissue paper to **remove** excess liquid

3 Wait **10 seconds** for the colour reaction to occur

4 Read the results at exactly 10 seconds after removal from solution by comparing to the colour chart provided.

COLOUR CHART

FAIL	FAIL	PASS
20-40%	50-70%	80-100%

DO NOT read results after 10 seconds

DISCONTINUE use of solution should a FAIL result occur

Medical Equipment Reprocessing – General Information & Resources

Equipment/Instrument Cleaning & Storage

Autoclave Usage, Management & Maintenance

Cold Chemical Usage & Management
- Sterilization and High-Level Disinfection

A presentation designed for:

- *PCP & Specialty Clinics*
- *Healthcare Personnel*
- *Quality Administrators*

January 2026

Remember:
Safe Equipment Protects Patients

Thank You!

This presentation has been developed in collaboration with the health plans listed