وزارة الصحة
Ministry of Health

Sterilization Area and Sterile Storage

objectives

- What is the different between Cleaning, disinfection, and Sterilization?
- Methods of sterilization
- Steam sterilizer testing
- The requirements for a safe sterile storage
- Sterile Storage Considerations
- Sterile Transportation
- CSSD Electronic Tracking Systems
- Environmental Cleaning Methods

Sterilization of Reusable Medical Devices

What is the different between Cleaning, Disinfection, and Sterilization?

Cleaning:
The removal of visible soil, organic and inorganic material from objects and surface. This is accomplished manually or mechanically using water with special detergent or enzymatic product.

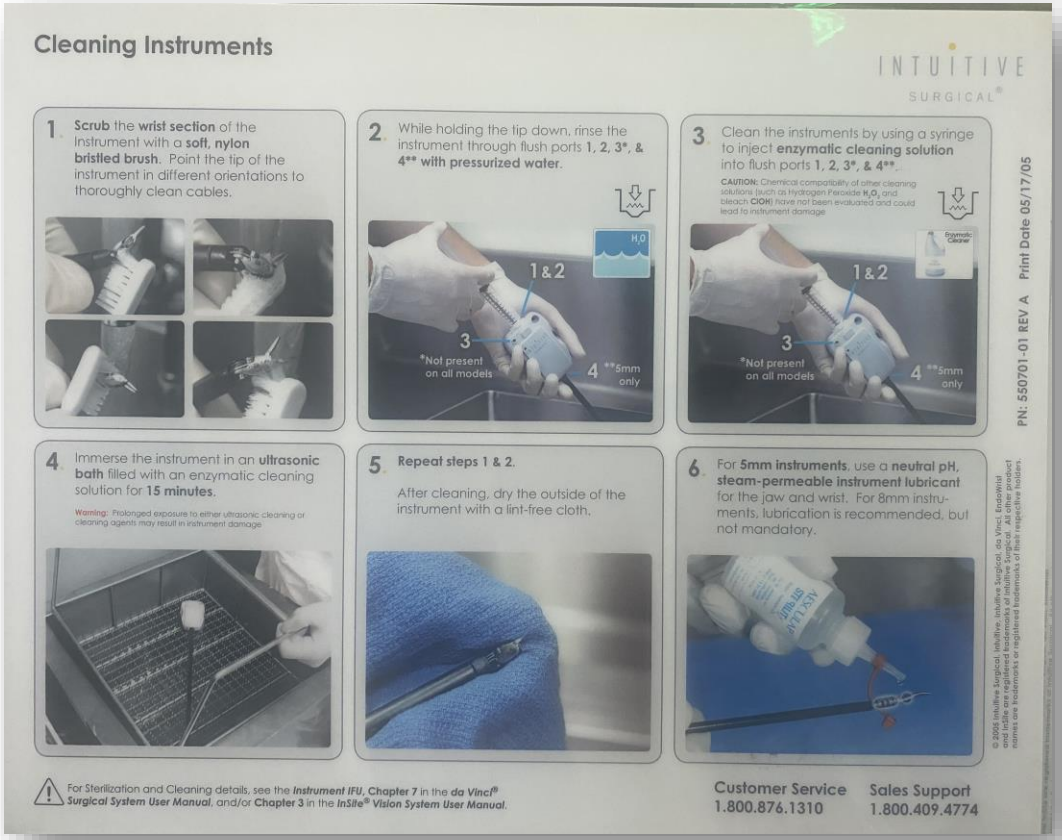
Disinfection:
The destruction of nearly all pathogenic microorganism except spores.

Sterilization:
Is the elimination of all disease-producing microorganisms, including bacterial spores.

Comment: Cleaning is the first and most essential step before any process of disinfection or sterilization can be carried out.

Manufacture’s Instruction For Use (IFU)

Manufacture’s instruction for use should contain detailed instructions on how to properly process and use the product, This includes disassembly, cleaning, assembly, disinfection and sterilization instructions.



Cleaning Instruments

INTUITIVE SURGICAL

1. **Scrub** the **wrist section** of the instrument with a **soft, nylon bristled brush**. Point the tip of the instrument in different orientations to thoroughly clean cables.

2. While holding the tip down, rinse the instrument through flush ports **1, 2, 3*, & 4** with pressurized water.**

3. Clean the instruments by using a syringe to inject **enzymatic cleaning solution** into flush ports **1, 2, 3*, & 4****.
CAUTION: Chemical compatibility of other cleaning solutions (such as Hydrogen Peroxide H_2O_2 and bleach **ClO(-)**) have not been evaluated and could lead to instrument damage.

4. Immerse the instrument in an **ultrasonic bath** filled with an enzymatic cleaning solution for **15 minutes**.
Warning: Prolonged exposure to either ultrasonic cleaning or cleaning agents may result in instrument damage.

5. **Repeat steps 1 & 2.**
After cleaning, dry the outside of the instrument with a lint-free cloth.

6. For **5mm instruments**, use a **neutral pH, steam-permeable instrument lubricant** for the jaw and wrist. For 8mm instruments, lubrication is recommended, but not mandatory.

For Sterilization and Cleaning details, see the ***Instrument IFU*, Chapter 7** in the ***da Vinci® Surgical System User Manual***, and/or **Chapter 3** in the ***InSite® Vision System User Manual***.

Customer Service 1.800.876.1310

Sales Support 1.800.409.4774

PN: 550701-01 REV A Print Date 05/17/05

Spaulding classification

Policy for the local decontamination of reusable equipment according to the Spaulding classification:

➢ RMDs shall be categorized as follows:

- Critical

Risk category: High.

Example: Surgical instruments, implants, rigid endoscope

Recommended level of decontamination: Sterilization.

- Semi-critical

Risk category: Intermediate.

Example: Respiratory equipment, non-invasive flexible endoscope.

Recommended level of decontamination: Disinfection (high level).

- Non-critical

Risk category: Low.

Example: blood pressure cuffs, stethoscopes

Recommended level of decontamination: Cleaning (visibly clean).

Sterilization Area

Sterilization Packaging Materials

Rigid container

Wrapping Material

Pouches

Methods of sterilization

High Temperature Sterilization

(steam sterilizer)

Low Temperature Sterilization

(Chemical sterilization)

We **must** use the method of sterilization according to what is recommended by the manufacture instruction **(IFU).**

Methods of sterilization

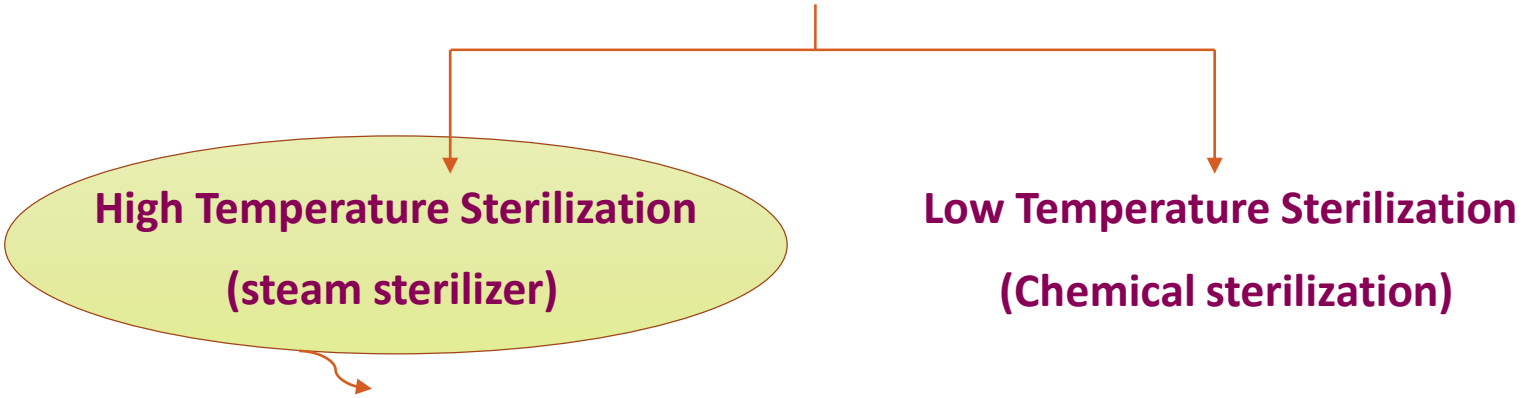
High Temperature Sterilization (steam sterilizer)

Low Temperature Sterilization (Chemical sterilization)

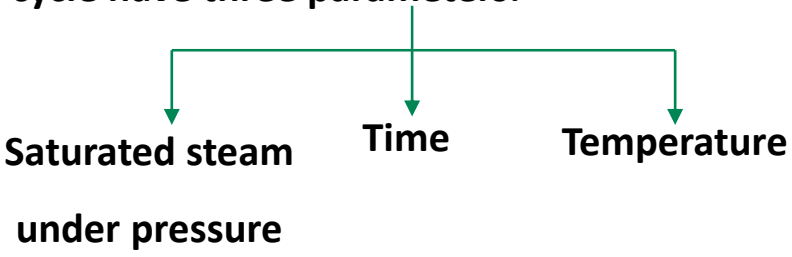
Sterilization standards worldwide recommend steam sterilization as the PROCESS of CHOICE, because it's:

- **Fast**
- **Efficient**
- **Relatively inexpensive**

Methods of sterilization



- **Steam under pressure devices are quickly and efficiently.**
- **Steam sterilization cycle have three parameters:**



Steam: Saturated steam that contains the maximum amount of water vapor.

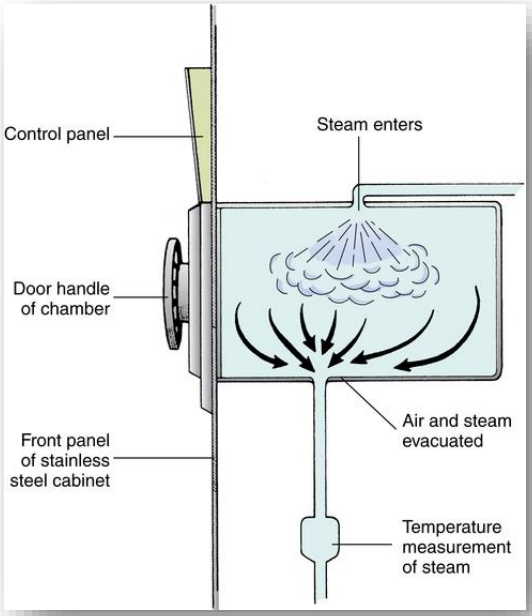
Methods of sterilization

High Temperature Sterilization (steam sterilizer)

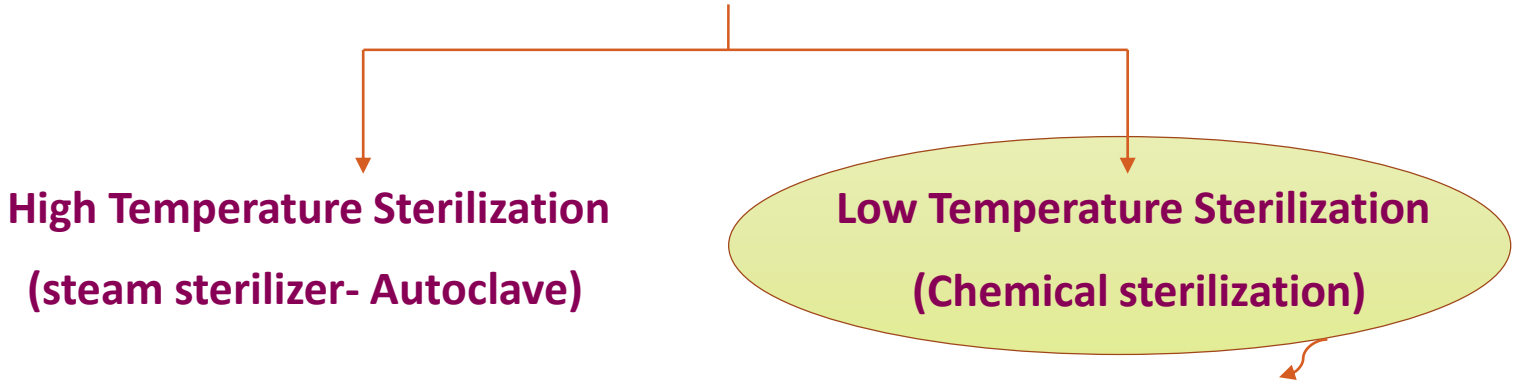
Two Basic Cycles

- **Prevacuum Cycle** — Dynamic-air removal
- **Gravity Cycle** — Gravity-displacement

Low Temperature Sterilization (Chemical sterilization)



Methods of sterilization



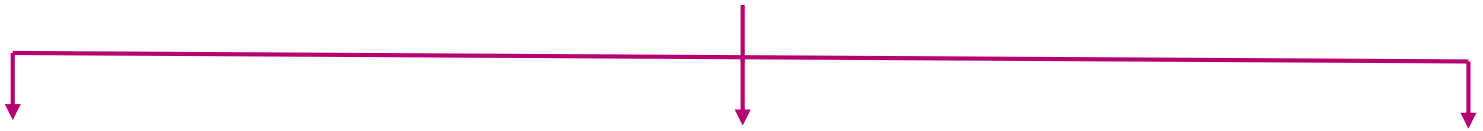
- Ethylene Oxide EtOH
- Hydrogen Peroxide Gas Plasma H_2O_2.
- Vaporized Hydrogen Peroxide VH_2O_2.
- Ozone sterilization O_3.

Principle of sterilization

- The level of quality assurance **0% of error**.
- So, how to make sure that each surgical instrument and set is safe for patient use??? **Monitoring**

- Tests **must be** performed in the machine daily or at least weekly. In addition, we check the external indicator (tape) and internal indicator (chemical integrator) of the sterilized packs.

Tests and Monitoring



Physical Monitoring

Biological Test

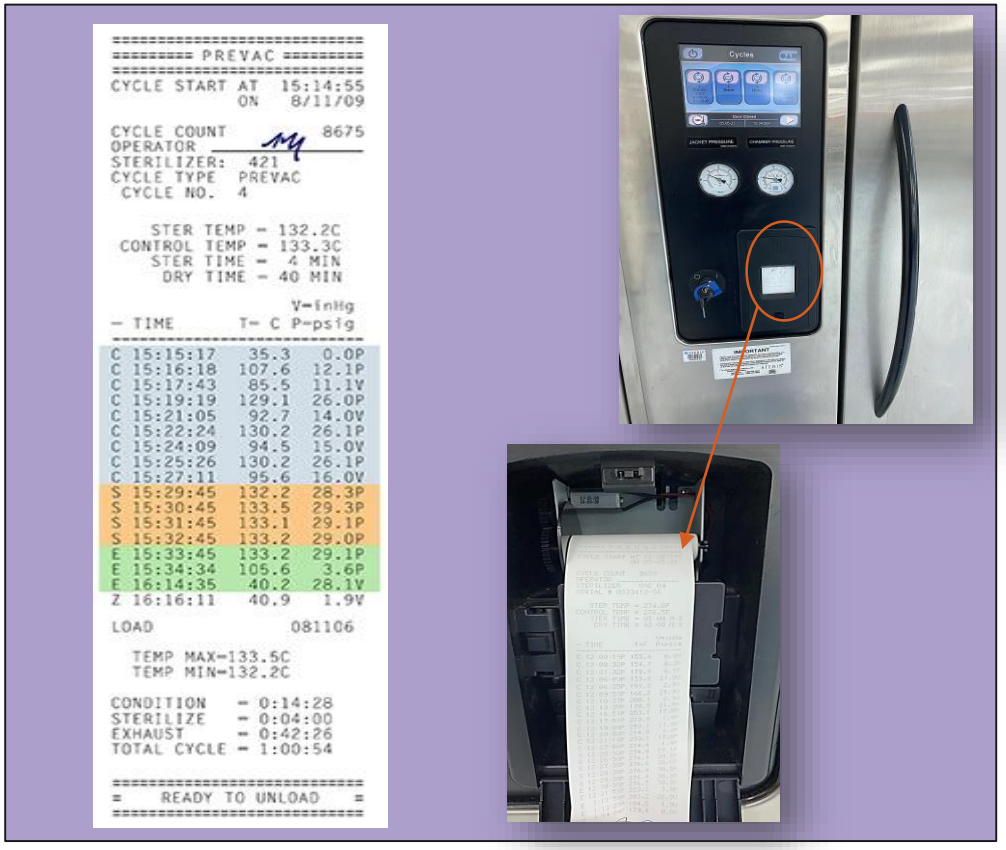
Chemical Test

Tests and Monitoring

Physical Monitoring

Printout

- Physical monitors are the visible monitors (time, temperature, and saturated steam pressure recorders, digital printouts, and gauges) on equipment that enable the operator to promptly determine whether the correct sterilizing parameters were met.
- They are the first monitoring tool used to detect a sterilization process failure and initiate a recall.



Print out

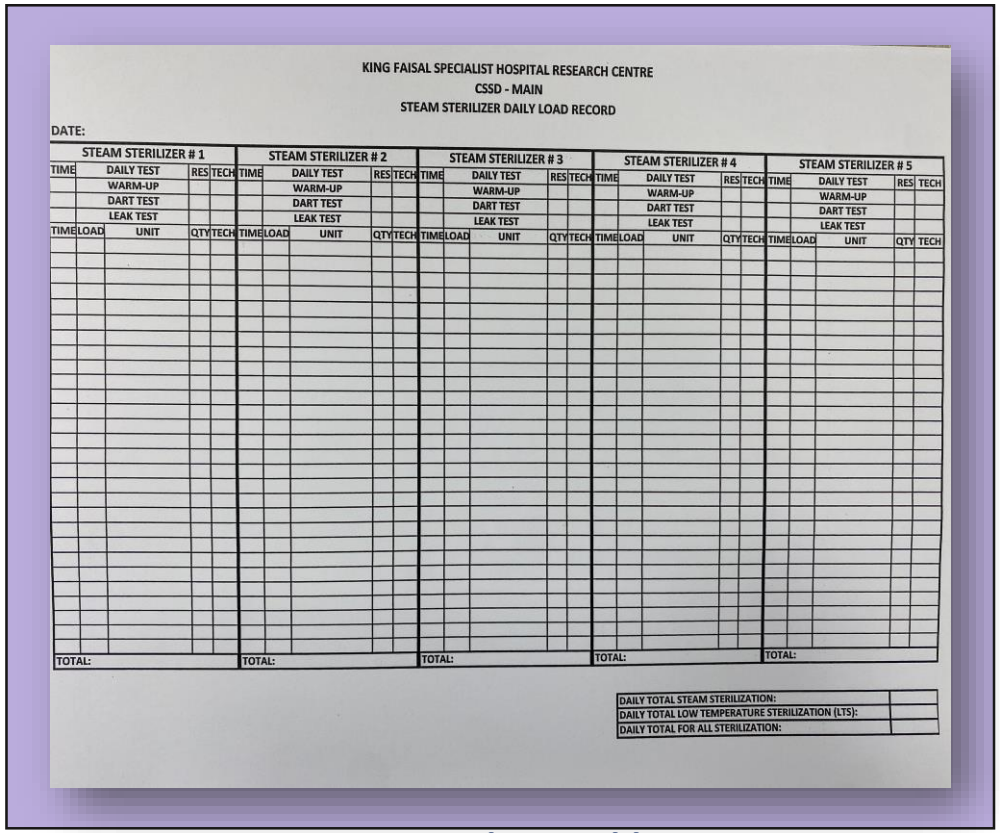
Tests and Monitoring

Physical Monitoring

Documentation and record keeping

- Documentation should be done manually or by printing an informative adhesive card out of the tracking system including:

  - Cycle parameters.
  - Tests results.
  - Loaded items and quantity.
  - Sterilizer cycle and load number.
  - Date of sterilization.



KING FAISAL SPECIALIST HOSPITAL RESEARCH CENTRE
CSSD - MAIN
STEAM STERILIZER DAILY LOAD RECORD

DATE:

STEAM STERILIZER # 1					STEAM STERILIZER # 2					STEAM STERILIZER # 3					STEAM STERILIZER # 4					STEAM STERILIZER # 5				
TIME	DAILY TEST		RES	TECH	TIME	DAILY TEST		RES	TECH	TIME	DAILY TEST		RES	TECH	TIME	DAILY TEST		RES	TECH	TIME	DAILY TEST		RES	TECH
	WARM-UP					WARM-UP					WARM-UP					WARM-UP					WARM-UP			
	DART TEST					DART TEST					DART TEST					DART TEST					DART TEST			
	LEAK TEST					LEAK TEST					LEAK TEST					LEAK TEST					LEAK TEST			
TIME	LOAD	UNIT	QTY	TECH	TIME	LOAD	UNIT	QTY	TECH	TIME	LOAD	UNIT	QTY	TECH	TIME	LOAD	UNIT	QTY	TECH	TIME	LOAD	UNIT	QTY	TECH
TOTAL:					TOTAL:					TOTAL:					TOTAL:					TOTAL:				

DAILY TOTAL STEAM STERILIZATION:	
DAILY TOTAL LOW TEMPERATURE STERILIZATION (LTS):	
DAILY TOTAL FOR ALL STERILIZATION:	

Documentation and record keeping

Tests and Monitoring

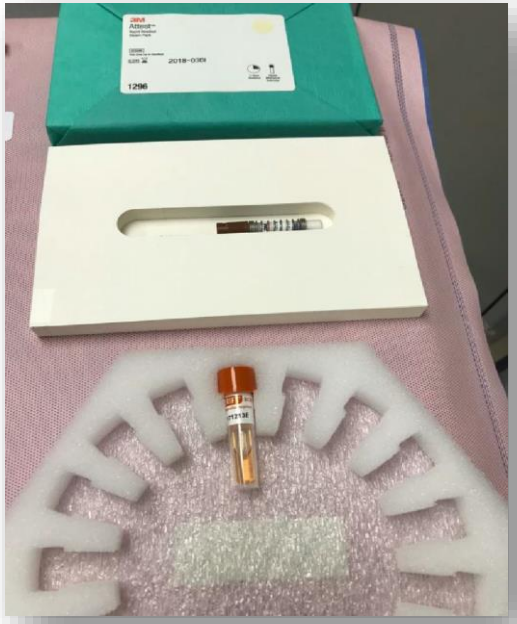
Biological Test

BIOLOGICAL INDICATORS

Control vial

Test vial

PCD
Process Challenge Device



PCD

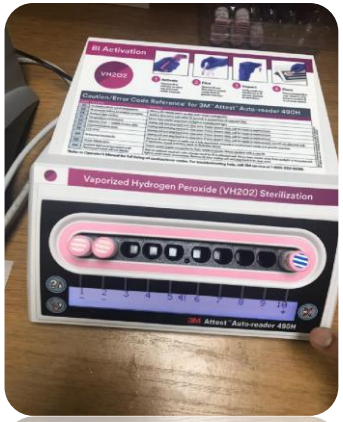
Bacterial Spores: Geobacillus stearothermophilus

Tests and Monitoring

Biological Test

For high and low temp sterilization

BIOLOGICAL INDICATORS



- ✓ **To indicate if spores present after sterilization process.**
- ✓ **It is important to follow the BI manufacturer**
- ✓ **Incubation result is very important for recall if positive.**
- ✓ **Control vial should have same lot of test vial.**
- ✓ **Documentation for one year is mandatory by MOH policies.**

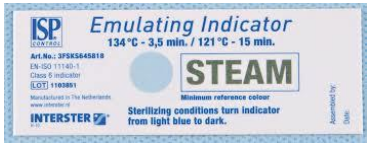
Tests and Monitoring

Chemical Test

Types	
Type1: process indicators	Use to show that the pack has been process 
Type2: indicators for use in specific test	
Type3: single variable indicators	React to one of the critical sterilization Time or temperature

Tests and Monitoring

Chemical Test

Type4: multivariable indicators Two or more of critical sterilization variable(time and temperature)	
Type5: integrating indicators; all critical sterilization variables (time, temperature and present of moisture)	
Type6: Emulating indicators All critical sterilization variables.	

Tests and Monitoring

Chemical Test

Type (1) External indicator

Tape: Help differentiate between processed and unprocessed loads

➢ External indicator tape for steam sterilization

Before:

After:

➢ External indicator tape for Hydrogen peroxide sterilization

Before:

After:

- Consult the manufacture instruction about the color changing

Tests and Monitoring

Chemical Test

Type (2) BOWIE-DICK test

- It's a **daily** **Pre**- sterilization test

Tests and Monitoring

ابوف ذا دراين

Chemical Test

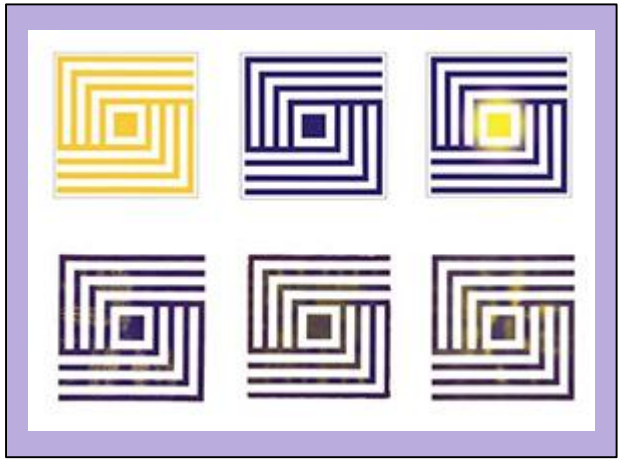
BOWIE-DICK TEST

- **A Bowie-Dick test is used to rapidly assess whether dynamic-air-removal steam sterilizers properly remove air from the chamber**

- **Test should be done every day that the sterilizer is used, "before the first processed load, and during sterilizer qualification testing.**

- **The Bowie-Dick test pack should be run in an empty chamber placed horizontally on a cart or shelf (not on the floor), over/near the drain.**

- **If sterilizer does not pass the Bowie-Dick test, personnel should determine whether it should be retested or call for service.**



Verify Bowie Dick Pack

Tests and Monitoring

Chemical Test

Internal indicator

Is an indicator strips and challenge packs capture sterilization or disinfection failures through immediate results

Loading Configuration

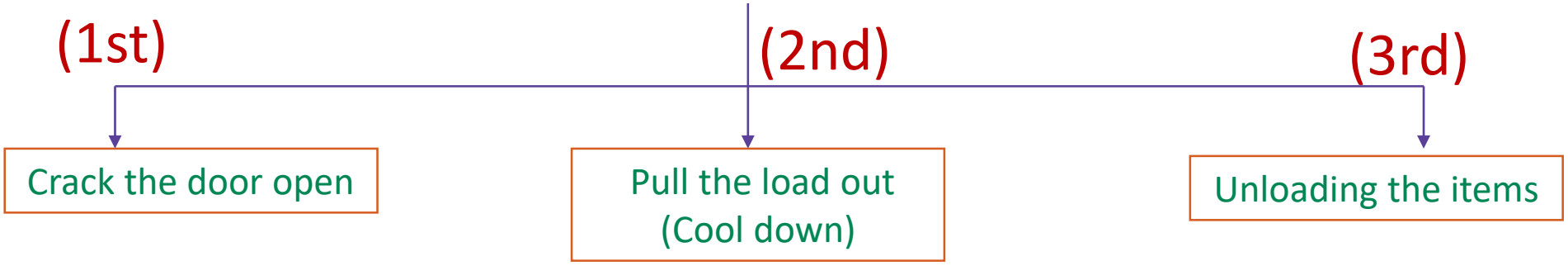
To ensure full steam contact and removal of air, the sterilization must be properly loaded to allow adequate air circulation and draining of the condensation.

Basic procedures for loading a sterilizer include:

- Allow for proper steam penetration and avoid overloading.
- Solid containers must be positioned so air can exit, and steam can enter.
- There should be visible space between packs to allow steam circulation and drying
- When combining loads, place hard goods on the bottom to prevent condensation from dripping onto lower packs.
- Packages must not touch the chamber walls.
- Basin sets should stand on an angle.

Unloading

Upon completion of the cycle, the operator is responsible to do unloading in the following manner:



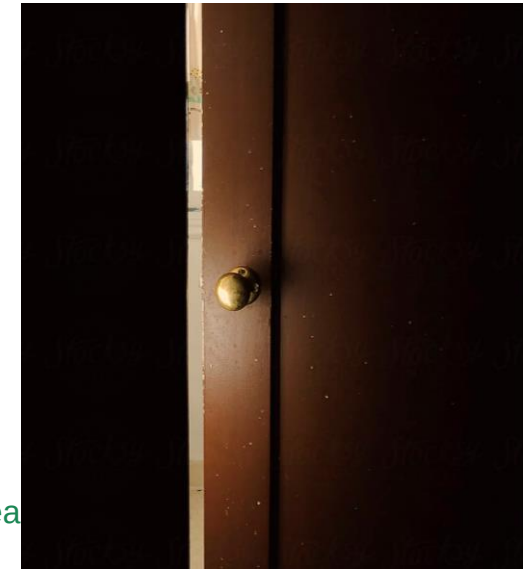
Unloading

Upon completion of the cycle, the operator is responsible for unloading complete ,unload the sterilizers in following manner:

(1st)

Crack the door open

- ✓ **Crack the door open to prevent wet packs**
- ✓ **Check the printout for (correct parameters/cycle time and date).**
- ✓ **Verify that the BI test vial number matches the lot number of the control vial.**



```
========================
========= PREVAC =========
========================
CYCLE START AT  15:14:55
            ON   8/11/09

CYCLE COUNT          8675
OPERATOR
STERILIZER:  421
CYCLE TYPE  PREVAC
 CYCLE NO.  4

   STER TEMP = 132.2C
CONTROL TEMP = 133.3C
   STER TIME =  4 MIN
    DRY TIME = 40 MIN

                    V=inHg
- TIME      T= C P=psig
------------------------
C 15:15:17   35.3   0.0P
C 15:16:18  107.6  12.1P
C 15:17:43   85.5  11.1V
C 15:19:19  129.1  26.0P
C 15:21:05   92.7  14.0V
C 15:22:24  130.2  26.1P
C 15:24:09   94.5  15.0V
C 15:25:26  130.2  26.1P
C 15:27:11   95.6  16.0V
S 15:29:45  132.2  28.3P
S 15:30:45  133.5  29.3P
S 15:31:45  133.1  29.1P
S 15:32:45  133.2  29.0P
E 15:33:45  133.2  29.1P
E 15:34:34  105.6   3.6P
E 16:14:35   40.2  28.1V
Z 16:16:11   40.9   1.9V

LOAD              081106

  TEMP MAX=133.5C
  TEMP MIN=132.2C

CONDITION    = 0:14:28
STERILIZE    = 0:04:00
EXHAUST      = 0:42:26
TOTAL CYCLE  = 1:00:54

========================
=    READY TO UNLOAD   =
========================
```

Unloading

Upon completion of the cycle, the operator is responsible for unloading complete ,unload the sterilizers in following manner:

After (some time)

(2nd)

Pull the load out
(Cool down)

Wet pack

- ✓ **Unload the rack**
- ✓ **Examine the load items in the load for:**

A. Any visible signs of moisture.

- A wet pack is considered contaminated (unsterile) and must be completely reprocessed.

B. Compromised packaging integrity .

C. Keep printed records of each cycle parameters (time, temp).

Unloading

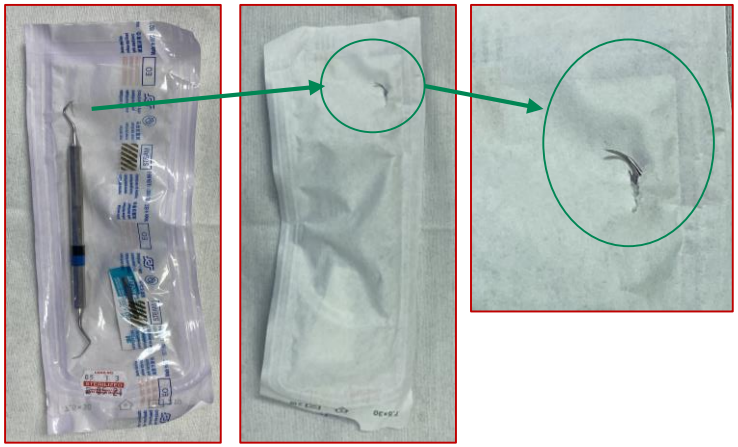
Upon completion of the cycle, the operator is responsible for unloading complete ,unload the sterilizers in following manner:

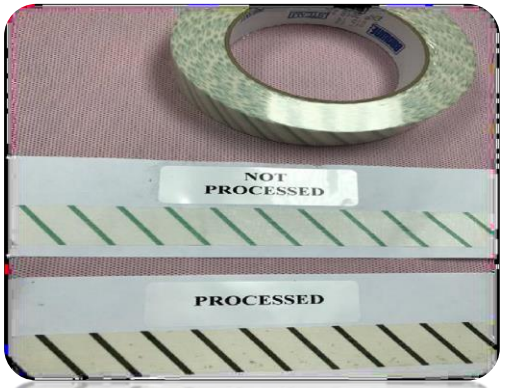
(3rd)

Pull the load out (Cool down)

Unloading the items

- ✓ Check the results of external chemical indicators.
- ✓ Allow the load to cool at room temperature.
- ✓ Ensure that cool down occurs in traffic free area.
- ✓ Every step is a check-point step even after sterilization.





Sterile Storage Area

During Transportation:

- ✓ Take care to follow correct hand hygiene to reduce the chance of contaminating items in the cart.
- ✓ Do not leave sterile transport carts unattended.
- ✓ When deliveries are complete, bring your cart back to CSSD

- **For decontamination**

- ✓ Empty carts should be processed through a cart washer if available or manually cleaned and disinfected if not, as per local policy.

Sterile Transportation

Closed Cart

Ideally closed or at minimum covered, to protect sterile items from contamination risk when travelling through public areas. Closed carts also reduce the chance of items falling out of the cart.

Correct Size and Weight

The cart should be an appropriate size with adequate shelves to hold the items being collected without stacking.

Washable

The cart needs to be cleaned effectively before returning to use in CSSD. compatible with a cart washer if available. facilitate effective manual cleaning and disinfection.

Servicing

constructed from robust materials to withstand the rigors of daily use. Doors, shelves and wheels must be maintained to ensure safety and ease of use to the users transporting items in the facility.

Handling

✓ Minimal handling to meet event related sterility

✓ Select the proper size of cart for the collection process and ensure it is functioning correctly.

✓ Bring any required documentation to log items being delivered.

✓ Perform hand hygiene before loading or unloading carts.

✓ Before transferring items, move the transport cart as close as possible to the instruments trays to reduce the risk of dropping them.

✓ Place heavier items on the middle or lower shelves.

Sterile Storage Area

- CSSD requires a safe storage zone for sterile and clean supplies used in production. Sterile reusable medical devices are packaged, and stored safely in an environmentally monitored (temperature, humidity and pressure) room using.

- Washable, round-edged shelving designed to avoid damage to packaging.

- Transport carts

The requirements for a safe sterile storage

Temperature and humidity controls : control the room temperature between **20-23C** and a relative humidity of **30–60%.** Humidity below 30% can reduce the barrier effectiveness of packaging materials while excess humidity and temperatures can allow moisture to condense on packages.

Positive air pressure: to prevent cross contamination, this room must be maintained under positive pressure to keep contaminants out.

Lighting :be adequate lighting to ensure items can be easily identified for use.

Shelves, transport carts and workstations : must be washable, designed to avoid damage to packaging , and allow for items to be stored without excess stacking.

Sterile Storage Considerations

Correct handling: do not drag or push items against surfaces causing friction or abrasion. This damages the packaging and compromises sterility.

Correct Shelving: shelving should be of correct size and design to hold items safely and ideally the **top and bottoms** shelves should be solid or covered to reduce or prevent dust accumulation.

Walls: packs must be at least **5cm** from walls and windows to reduce condensation risks.

Floors: packs should be kept at least **25-30cm** above the floor to prevent contamination from floor cleaning products, spills and inadvertent touching.

Ceilings: there should be at least 45cm between the highest package and the ceiling or fire sprinkler heads.

Sterile Storage Considerations

Removing items from a shelf:
Lift the front of the package underneath with one hand, place the other hand midway under the package and lift the whole item free from the shelf.

Minimal handling:
This is a critical element as each time a package is handled it is considered an event.

Food or drinks:
Never consume, store or transport food or drinks through a sterile supply room.

Corrugated boxes:
Harbor moisture, mold, mildews, insects and potentially contaminating micro-organisms. Do not use cardboard boxes

Don’t force or stack on shelves:

Items when forced , stacked, bent or compressed can force contaminated air inside or cause ruptures to closures and seams that me by difficult to detect

Dropped items: jarring and compression from landing, forces dust and airborne microorganisms into the package.
Dirt from the floor can also be carried onto the shelf and contaminate the next pack placed in that position. Dropped items must be considered contaminated and removed even if no damage is apparent.

Sunlight: items should not be exposed to direct sunlight and ideally not located near windows.

Moisture: packages must not be stored near or under sinks, pipes, sewage lines, drains or other items that could expose sets to moisture.
Ball pens :only validated markers should be used for writing on packages as ink from pens may seep into packages and also physically damage the surface

Rubber bands: force or compress packages so should never be used for sterile items .

Sterility Shelf Life

Shelf life refers to the period any disinfected or sterilized item is safe to use.

✓ The item will remain safe for use is more event-related than time-related.(Actual sterility may be indefinite depending on the package materials, the item itself and the handling and storage).

✓ Some manufactured items have a label claim of "Sterility guaranteed unless packaged is punctured or broken." This labeling claims indefinite shelf life under the condition of proper handling and storage.

FIFO

For reusable items processed in CSSD we have a fixed number of items and rely on a **'first in -first out'** method to ensure items are used on a rotational basis.

Recall

There is always a possibility that items have been released but later recognized as items that should have been rejected.

Some reasons for this include:

✓ Biological or chemical indicator wasn't used or didn't pass

✓ Documentation wasn't correctly completed

✓ Manufacturer recalled a defective item

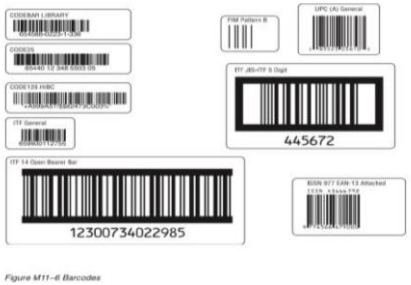
➢ When any of these things occur, Your facility should have a procedure for recall that includes at minimum: notifying all users

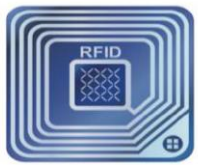
➢ impacted and documenting all actions in an adverse occurrence report.

CSSD Electronic Tracking Systems

Tracking System of Surgical Instrument

- The IT tracking system is an electronic documentation system they can be retrieved to show to an auditor.
- It is important to test the system internally to become familiar with how records can be accessed.
- As a minimum, the system records all items in circulation including surgical instruments and trays and contain information on tray contents supporting the printing of tray lists for assembly.
- All devices must be uniquely marked in some way to allow scanning. This may be achieved using several different options including bar codes, matrix marks, laser etching .





Thanks