

Steam Sterilization Cycles for Lab Applications

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STERIS
Life Sciences

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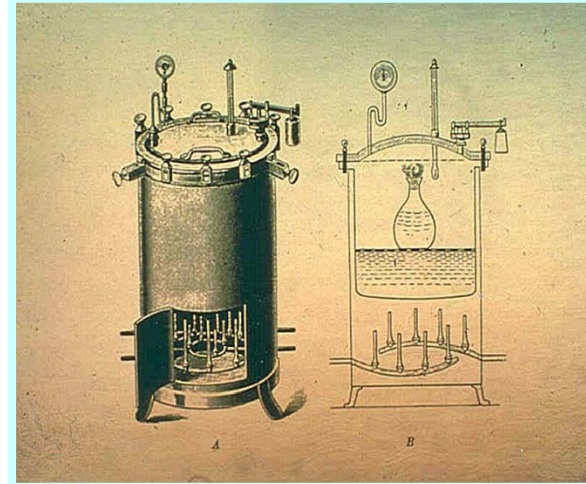


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Early Steam Sterilizers

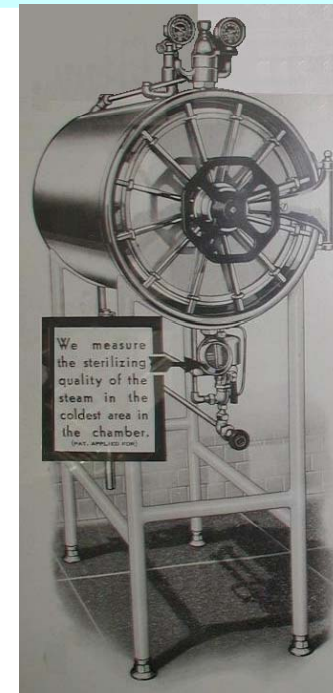
Koch Upright Sterilizer

- First Pressurized Sterilizer
- First built by Pasteur-Chamberlain
- Improved on by Koch in the 1880's



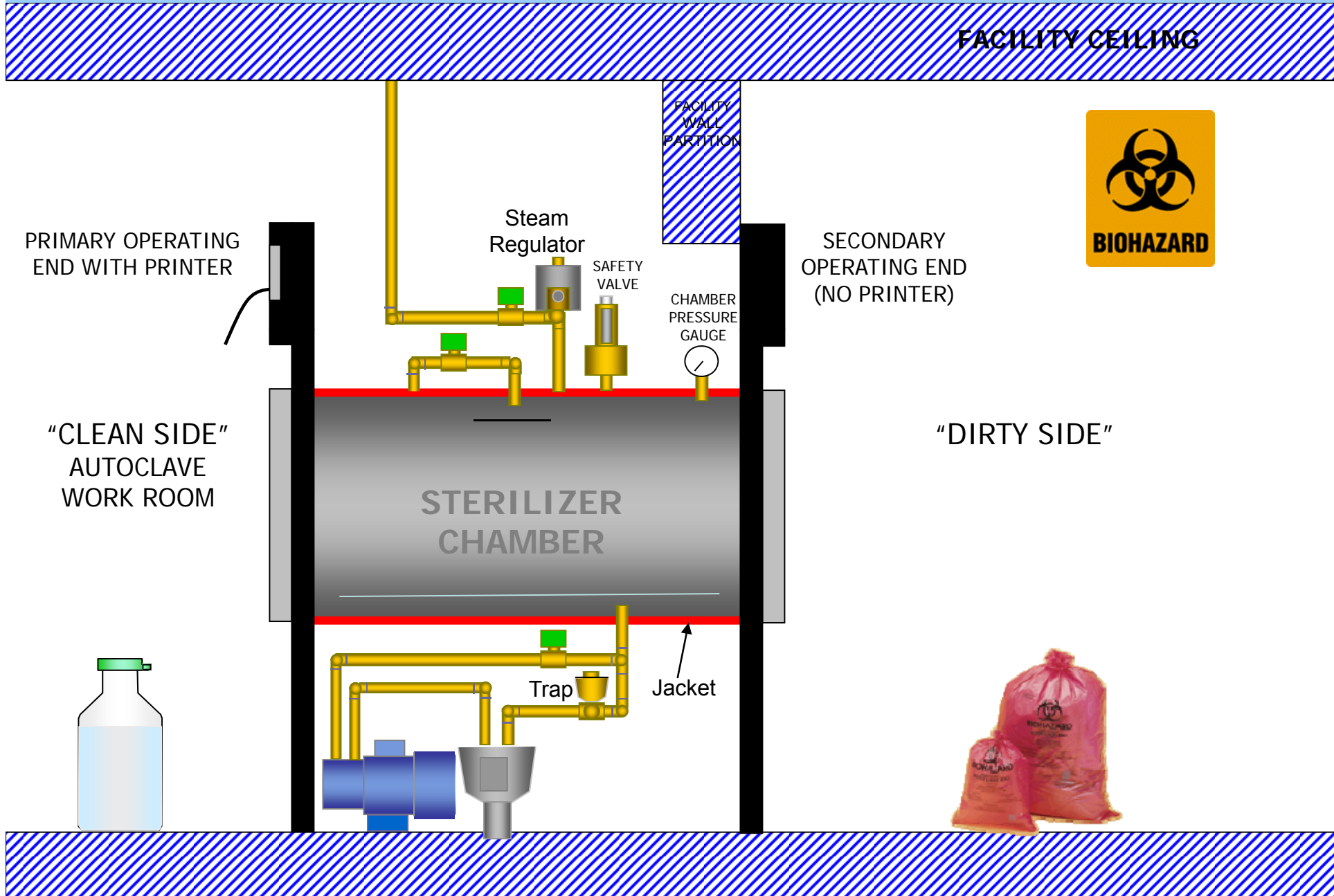
Amsco Sterilizer built in the early 1900's

- Several still operational Today



CENTURY PREVACUUM STERILIZER

SIDE VIEW OF BASIC COMPONENTS



Steam Sterilization

- **Advantages**

- Non-toxic
- Cycle easy to control and monitor
- Inexpensive
- Quick microbe kill times
- Least affected by various soils
- Rapid cycle time
- Penetrates medical packing, hollow tubing

- **Disadvantages**

- Not for materials that are sensitive to heat or moisture
- Potential for burns
- Steam generator system is needed

Steam Sterilization

- **Critical process parameters:**

- » **TIME**

- » **TEMPERATURE (115°-138°C)**

- » **SATURATED STEAM (Moisture)**

- **Where used:**

- » Non heat/moisture-sensitive products, components, supplies and equipment.

- » Decontamination of biohazardous or biological wastes.

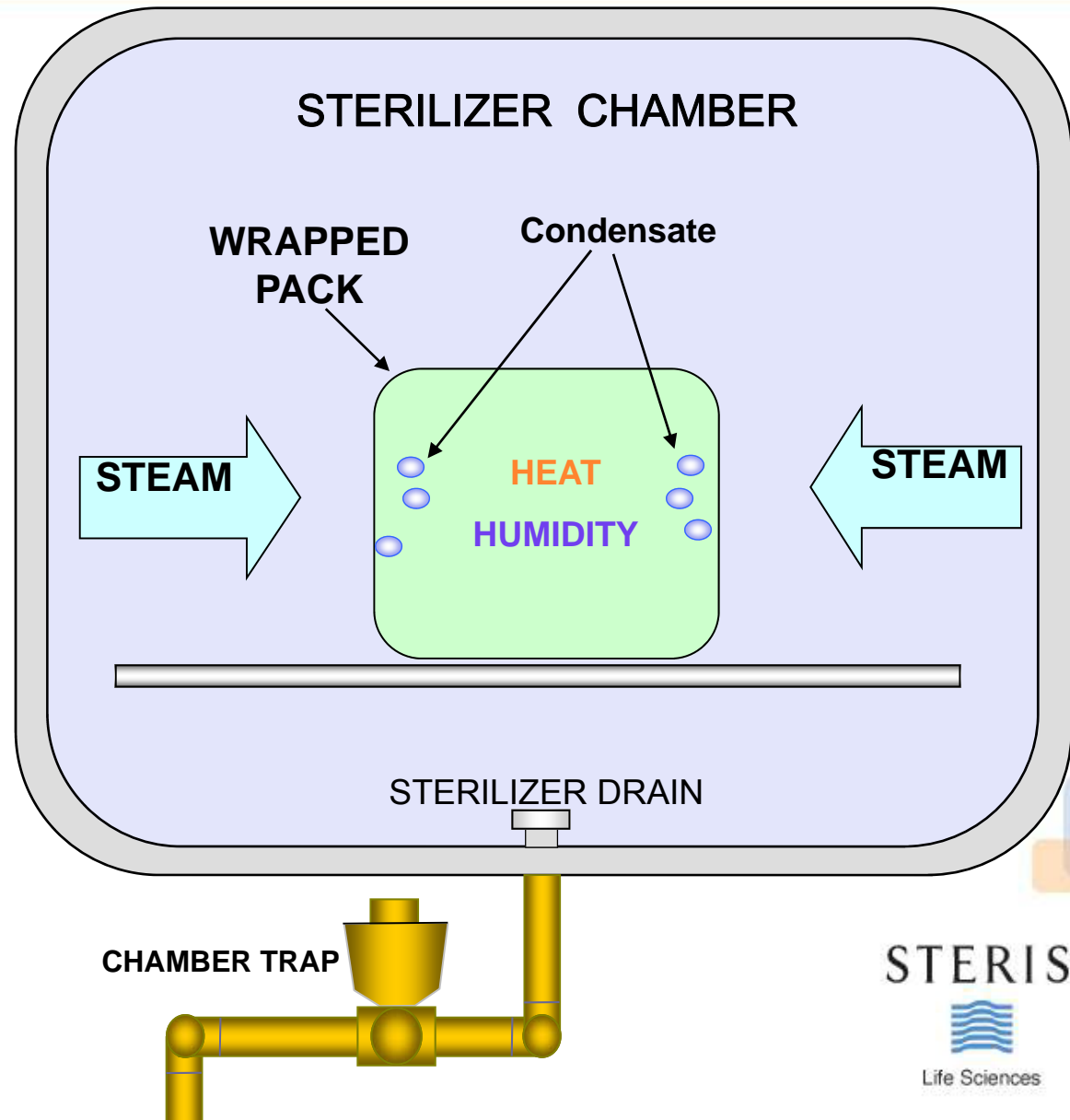


Steam Sterilization

The large transfer of heat and moisture to an object by steam accounts for the sterilizing activity steam.

Steam at very high temperature and pressure must come in contact with every surface or penetrate to the center of an item to achieve sterilization.

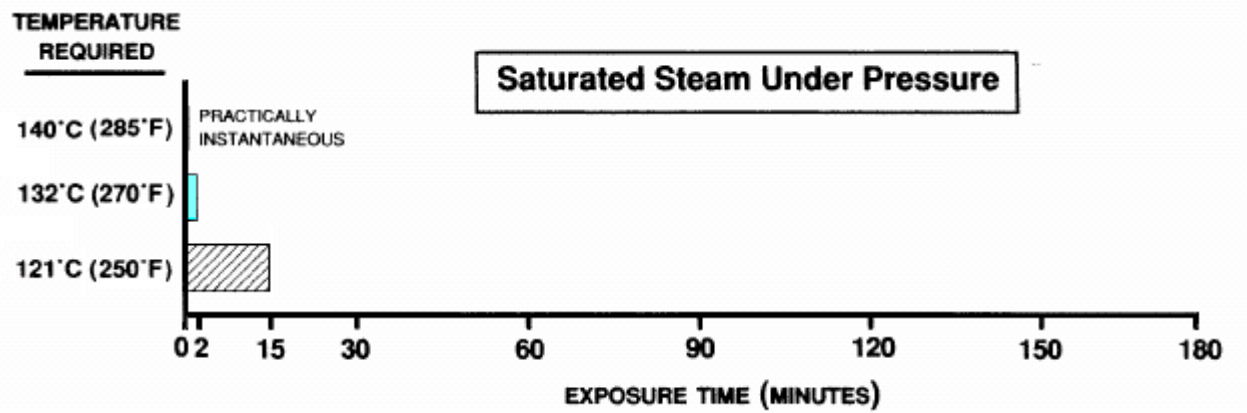
Steam must also remain in contact for enough time to sterilize



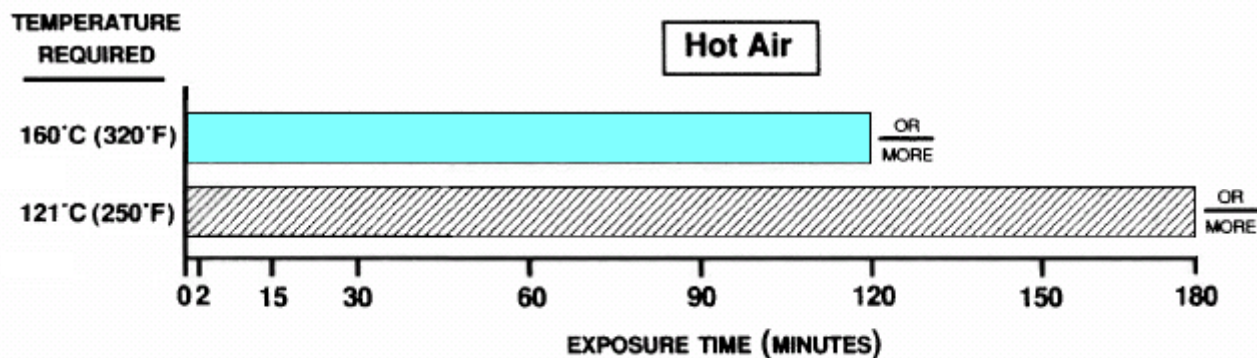
Heat Sterilization

Steam (Moist Heat)

- Steam sterilization of items in a steam sterilizer or retort



Dry Heat Oven Sterilizers



PRINCIPLES OF STERILIZATION

The Steam Sterilization Cycle

- A steam sterilization cycle consists of three basic phases:
 - » **Heating (come-up) phase** - steam enters the sterilizer jacket and air is removed from the sterilizer chamber, either by gravity displacement or mechanically (prevacuum). Objective: Remove air and replace with steam.
 - » **Sterilization (exposure) phase** - load is exposed to steam at a set temperature (measured and controlled by a temperature sensor in the drain line) for a set time. Objective: To sterilize the product.
 - » **Cool-down (drying) phase** - sterilizer chamber is exhausted to atmospheric pressure followed by circulating air through the chamber or by drawing a deep vacuum. Jacket heat is maintained during the drying phase. Objective: To return the product to atmospheric pressure and to help dry the product (prevacuum and gravity cycles)

CENTURY CYCLE DEFINITIONS

Purge

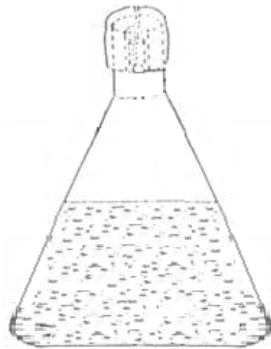
- Steam flows through the chamber for a programmed time to facilitate air removal.
- The steam-to-chamber valve and the chamber drain valve are open during purge.

Pulse

- One or more pressurization and vacuum phases to further remove air from the chamber as well as the product contained there-in.

Vented Closures

- Covers on bottles, tubes or flasks to relieve the excess internal pressure; allows the internal pressure to equalize and track the pressure change of the chamber during cooling, to minimize closure loss or container rupture. E.g. Cotton plugs, Morton closures, Autopour Closure (for Autopour Flasks), autoclave wrap.



Gravity Cycles



- > Operates on the downward air displacement air-removal principle.
- > Used for sterilizing nonporous heat and moisture stable goods at 250 or 270°F (121 or 132°C).
- > Place empty containers on side to let air flow out during cycle
- > Fast Exhaust following exposure phase
- > Dry phase is also normally used

Liquid Cycles



— Liquids



LIQUID CYCLE- Modified Gravity Cycle

>Used for sterilizing liquids, in flasks or test tubes with vented closures, at 250°F (121°C).

> Slow Exhaust following exposure phase

> No Dry phase following exhaust

> Follow the post cycle safety precautions recommended by the manufacturer

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Liquids Cycles

Loading and Safety Recommendations

- Only Type I borosilicate glass bottles or flasks should be used in autoclaves
 - Only vented closures should be used in a Century sterilizer liquids cycle.
 - Vented containers are typically filled approximately half full to avoid boil over and excessive solution loss.
 - Separate containers in the load so steam can circulate freely around each container.
 - Always use a liquid (slow exhaust) cycle when sterilizing liquids.
 - Do not mix loads which require different exposure time and exhaust.
 - Always wear protective gloves and apron (also face shield if processing liquids)
 - Sterilizer shelves/loading car will be hot after a cycle.
 - Do not move bottles if any boiling is present.
- **Follow the instructions and safety precautions in the sterilizer operator's manual**



Liquids Cycles

Preparation of culture media

Some general comments regarding preparation of culture media:

- Store media as directed on label. Check expiration date on the label.
- Directions for the preparation of commercial dehydrated culture media are provided on the label of each bottle. Follow these directions carefully.
- Most culture media require sterilization in an autoclave. Refer to label directions.
- The holding time of prepared culture media prior to sterilization should be minimized.
- Larger volumes of culture media may require longer sterilizer exposure times.
- Appropriate biological indicators may be used to verify the effectiveness of the cycle.
- **Follow the instructions and safety precautions in the sterilizer operator's manual**



Liquids Cycles Safety Recommendations

To prevent fall, keep floors dry by immediately wiping up any spilled liquids or condensation in the sterilizer loading and unloading area.

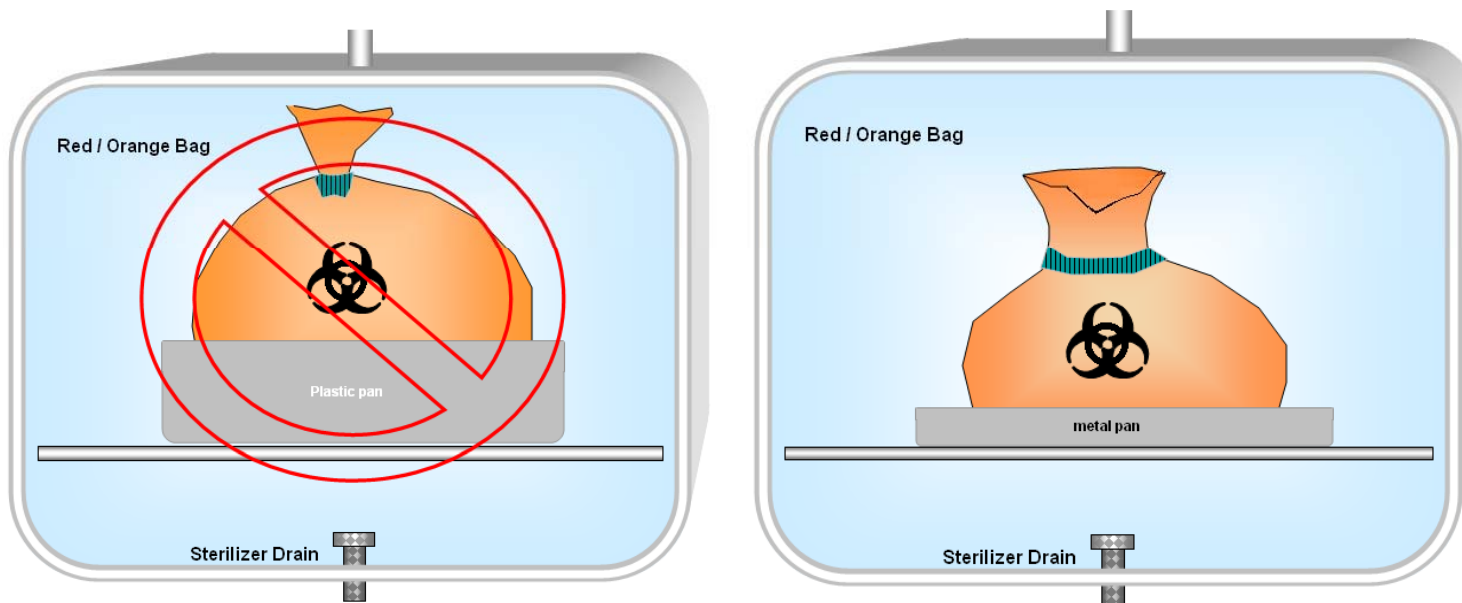


Bio-Hazard Bag Decontamination

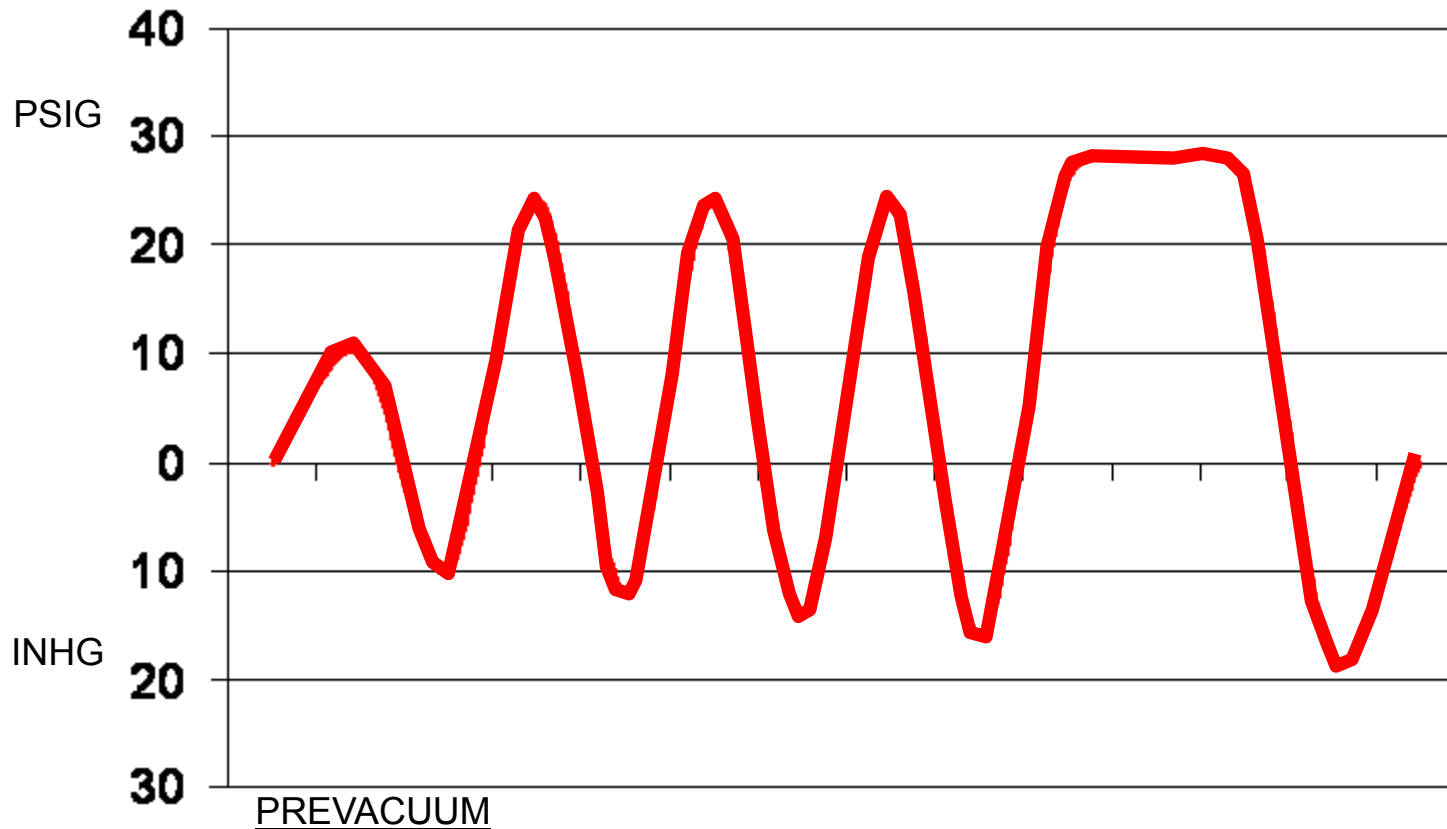
The transfer of heat into the bag was more efficient:

- > With smaller loads of microbiological waste
- > With stainless steel rather than polypropylene containers
- > With the sides of the bag rolled down to expose the top layer of Petri plates rather than with the top of the bag constricted by a twist-tie.

Use the recommended cycle and cycle precautions of the sterilizer manufacturer



Prevacuum Cycles



— Pre-Vac



- > Employs a mechanical air-removal system
- > For efficient, high-volume processing of porous heat and moisture stable materials, such as fabrics, wrapped hard goods, and container systems at 250 or 270°F (121°C or 132°C).
- > Fast Exhaust following exposure phase
- > Dry phase is also normally used

Prevac and Gravity Loading Recommendations

- Allow air space between packs, pouches, or other items
- Do not let items touch the walls of the sterilizer chamber
- Place pouches in wire basket to provide separation and proper orientation
- **Follow the loading recommendations of sterilizer manufacturer**



Cycle Parameters for Steam Sterilization



- ◆ Please refer to the operator manual.
- ◆ Be sure to select the right cycle for each item to be processed
 - > Liquids cycle for liquids
 - > Gravity or prevacuum cycles for dry goods (pouches or wrapped items)
- ◆ Larger volumes of liquids need more time to heat (see operator manual)
- ◆ Use chemical indicators with every cycle to confirm that the item has been processed.
- ◆ Look at the printout or recorder chart after the cycle to be sure the cycle operated normally.

Loading Recommendations for All Cycles

Items that **CAN NOT** be autoclaved are:

- **Flammable liquids**
- **Corrosive chemicals (such as: acids and strong bases)**
- **Radioactive material**
- **Some plastics or items that can not take higher temperatures**

The basic loading recommendations are in the sterilizer manual

Chamber Cleaning Recommendations


- Bleach or saline can cause corrosion if processed in a sterilizer with a stainless steel chamber
- A chamber cleaning is recommended after processing items that could leak bleach or saline on to a Century sterilizer chamber
- **Follow the loading recommendations of sterilizer manufacturer**



Clean the chamber drain strainer once a day

The diagram shows a cross-section of a sterilizer chamber. At the top center, a vertical pipe enters the chamber, with a red arrow pointing downwards into the chamber. At the bottom center, a vertical pipe exits the chamber, with an orange arrow pointing downwards. A horizontal pipe runs across the middle of the chamber. Below this horizontal pipe, a cylindrical component labeled 'Chamber drain strainer' is attached to the bottom pipe. The chamber is filled with a light blue liquid.

- Allow sterilizer to cool to room temperature
- Remove strainer
- Remove any debris from strainer
- Replace the strainer in the chamber drain
- Follow directions in the sterilizer manual

 **Steam in**

 **Air and Condensate out**

Basic Chamber Cleaning Recommendations

Basic Chamber Cleaning Recommendations:

- **Use appropriate personal protection equipment (gloves, protective apron, safety goggles or face shield)**
- **Make sure the autoclave is cool before cleaning**
- **Use soft brush or sponge mop to clean the inside of the autoclave**
- **Never use abrasive cleaning compounds, wire brushes or steel wool**

The basic cleaning recommendations are in the sterilizer manual

Biological Indicators

Why are Biological Indicators so important?

A Biological Indicator (BI) is a tool to determine if the sterilizer / sterilization process is working.

A BI works on the theoretical principle:

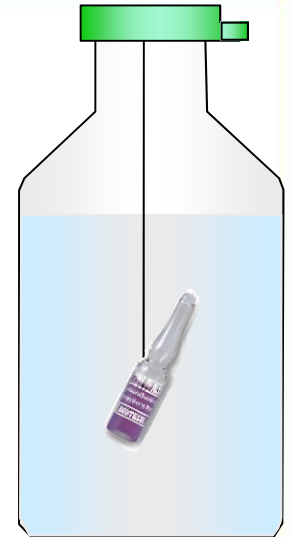
If a high population of the most resistant organisms to a particular sterilant can be inactivated (by sterilization) , there is a high PROBABILITY that all other organisms at that location in the sterilizer will also be inactivated.



Possible BI Uses:

- **Start-up testing of sterilization equipment.**
(Biomedical lab research, biosafety labs, lab animal facilities, etc.)
- **To validate* a sterilization cycle, or for periodic revalidation, in conjunction with thermocouples, recorders, etc.**
- **Routine monitoring of a sterilization cycle.**

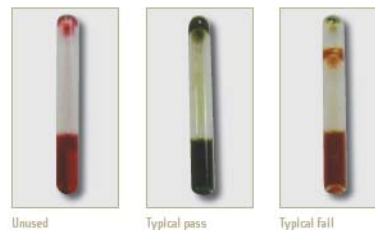
*Validation - DOCUMENTED evidence which provides assurance that a process will CONSISTENTLY produce a product meeting PRE-DETERMINED specifications and quality standards.



Chemical Indicators

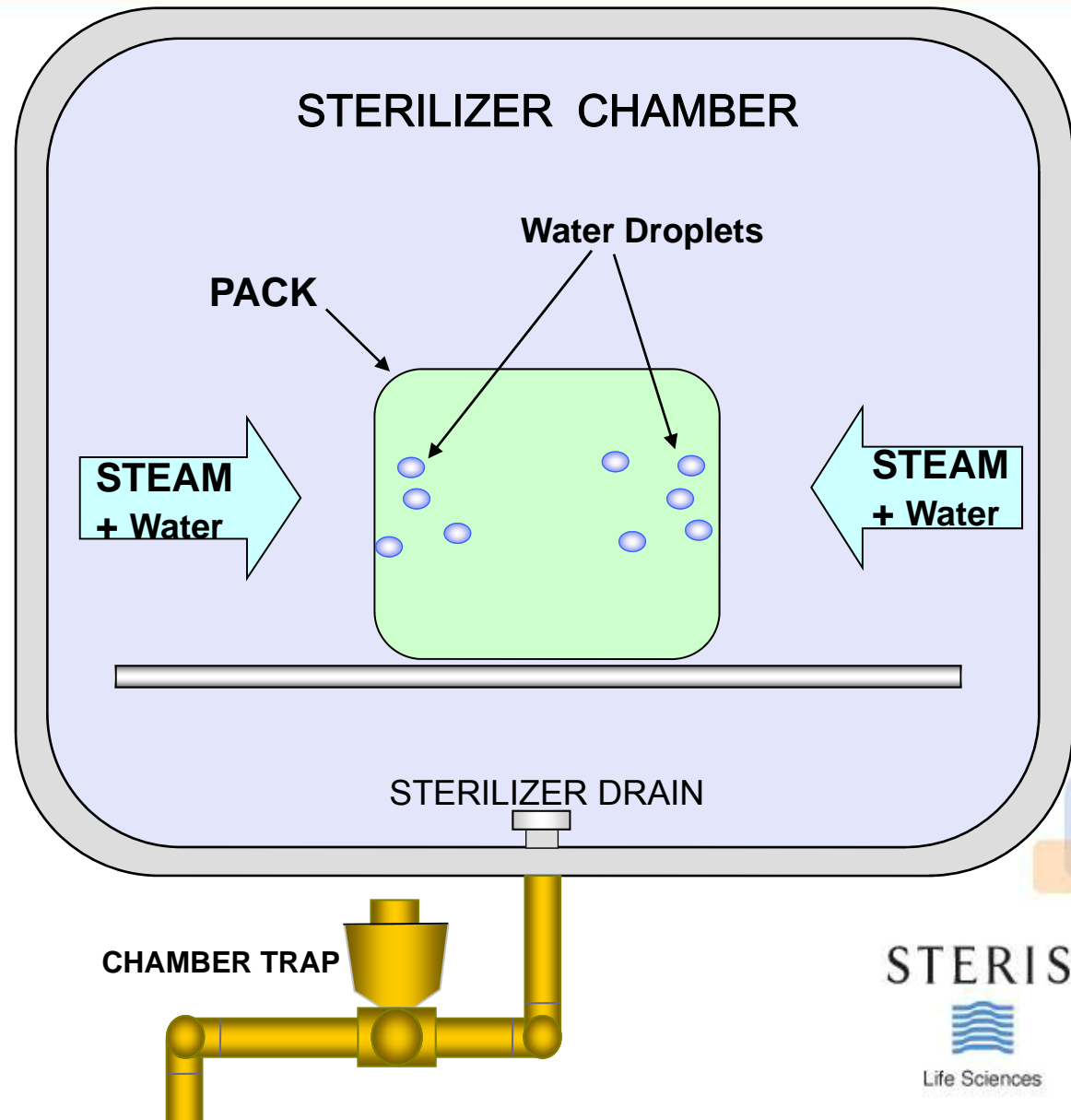
Device to monitor one or more critical parameters

- **Detects a variety of sterilizer malfunctions and procedure errors.**
- **Immediate visual results / may be kept as a record.**
- **Correct end point response does not prove sterility.**



Wet Steam

- Wet steam is undesirable as it has less energy than dry steam
- Wet steam can cause wet loads
- Wet loads can be considered to be non-sterile
- May be caused by:
Faulty traps on the sterilizer chamber or jacket, or faulty traps on the steam supply line.



Steam Sterilizer Maintenance

- ◆ Clean sterilizer strainer everyday the before the sterilizer is used.
- ◆ Clean the sterilizer chamber and loading equipment periodically (see the operator manual).
- ◆ Wipe up any spilled liquids or condensation in the sterilizer loading or unloading area to avoid slippery floor conditions.
- ◆ Report any sterilizer problems, alarms, or questions to your supervisor.
- ◆ Repairs should be made only by qualified service personnel

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