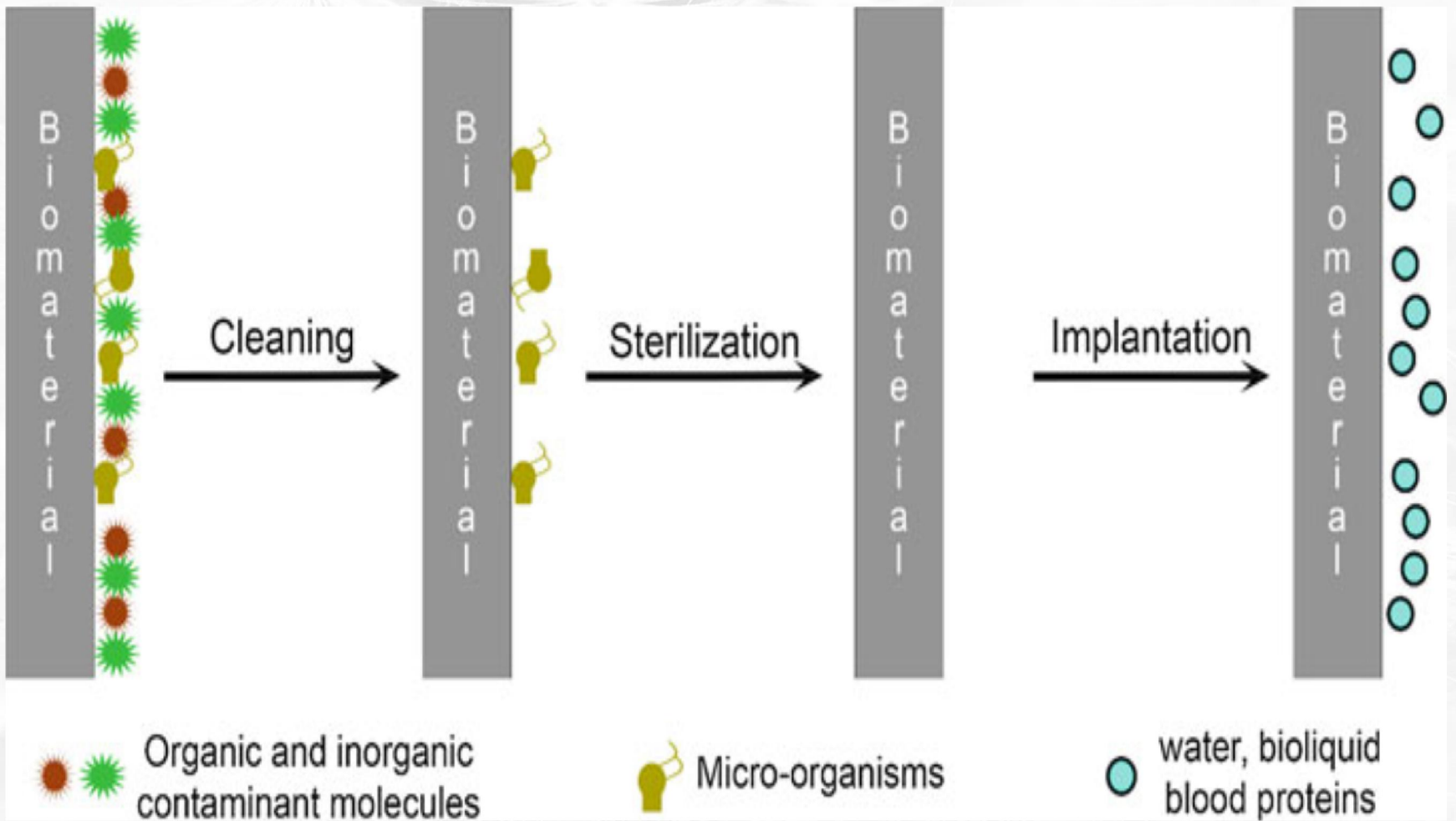




**Biomaterials  
Sterilization Methods**

# Introduction:

- Sterilization is a process in which all living and non-living organisms are removed
- Sterilization is the final step in the production of any biomaterials
- Sterilization is the best way to limit the risk of infection
- **The purpose** of sterilization is to deactivate the cellular processes involved in metabolism and ....



# Sterilization Methods:

## ➤ **physical:**

- Autoclave
- Irradiation Sterilization
- Dry heat sterilization

## ➤ **Chemical:**

- Ethylene Oxide
- Hydrogen Peroxide Plasma

# Ethylene Oxide:

- ✓ Ethylene oxide sterilization is a chemical process
- ✓ EO is an alkylating agent that disrupts the DNA of micro organisms
- ✓ consisting of four primary variables:
  - gas concentration → 450-1200 mg L<sup>-1</sup>
  - Humidity → 40-80%
  - temperature → 40-65 °C
  - Time → from a few hours up to a few days



# Ethylene Oxide:

- The sterilization process should ensure that all the parameters are placed inside the compartment
- Residual ethylene oxide after the sterilization process is toxic
- The ethylene oxide sterilization process consist of three processing phases:
  - Pre-conditioning
  - Sterilization
  - Aeration

# Advantages of EO sterilization:

- high diffusivity through solid matrixes
- Effectiveness and compatibility with most materials
- Flexibility, from the dependency on several factors
- It can sterilize heat-, moisture- and/or radiation-sensitive medical items
- For many MDs, elastomer polymeric materials and biomaterials, EO is the sterilant of choice

# Disadvantages of EO sterilization:

- lengthy cycle
- Cost
- potential hazards to patients, staff and environment
- the risks of handling a flammable and explosive gas.
- EO sterilization is not commonly recommended for liquid or powder products



# Hydrogen Peroxide Plasma:

- ✓ This process is fast and efficient and is carried out in a humid environment and low temperature.
- ✓ Gas plasmas are generated in an enclosed chamber under deep vacuum using RF or microwave energy
- ✓ The five stages of the process consist of:
  - I. Vacuum
  - II. injection
  - III. Diffusion
  - IV. Plasma
  - V. Vent
- ✓ The process operates in the temperature range of 37–44 °C and has a cycle time of 75 min



## Advantages

## Disadvantages

Safe for the environment

Cellulose, linens, and liquids cannot be processed

no toxic residuals

Some endoscopes or medical devices with long or narrow lumens cannot be processed

Cycle time is 28–75 min

Hydrogen peroxide may be toxic at levels greater than 1 ppm time-weighted average

Used for heat- and moisture-sensitive items since process temperature  $< 50\text{ }^{\circ}\text{C}$

Simple to operate

Compatible with most medical devices

# Autoclave:

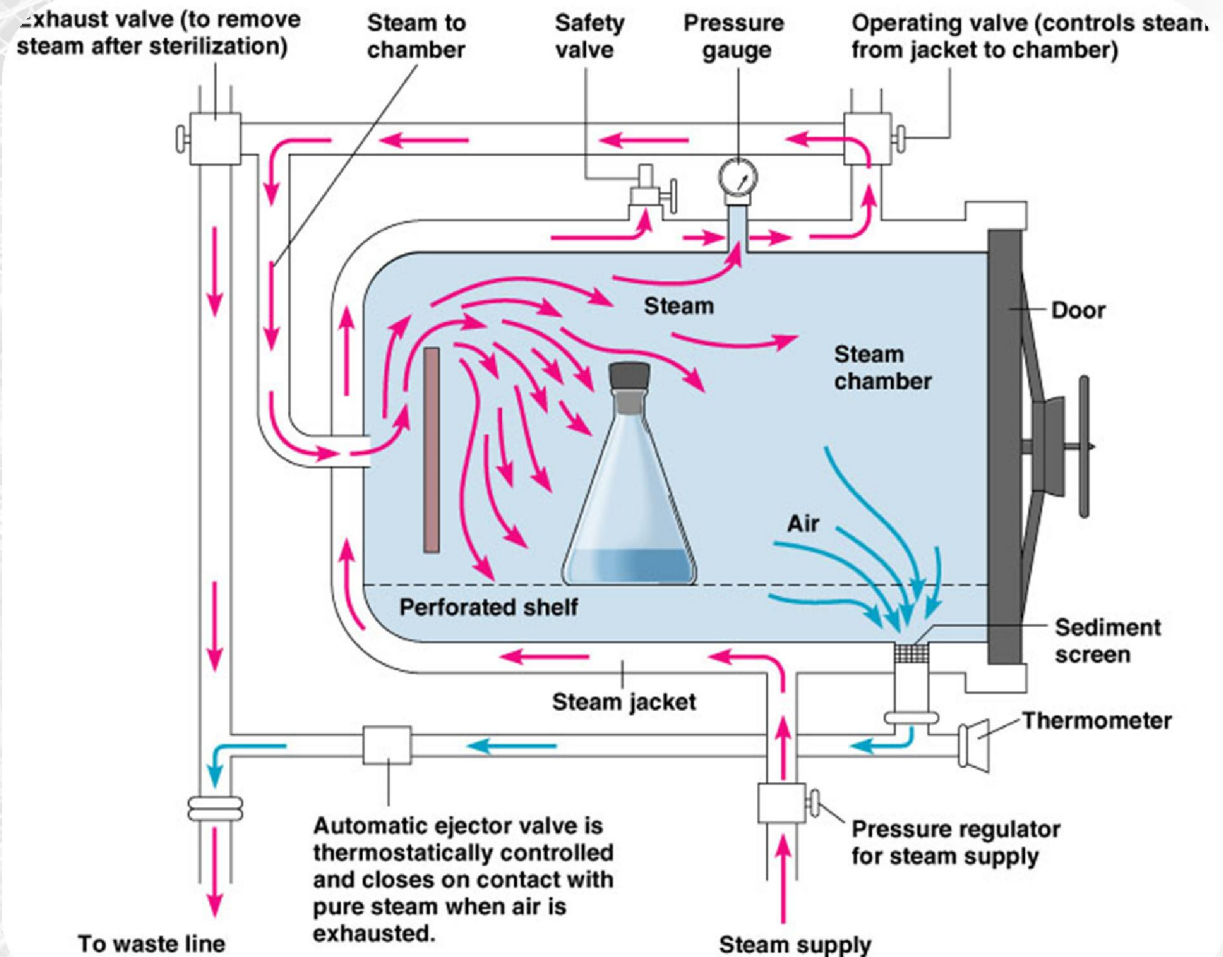
- The efficiency of the sterilization process depends on two major factors:
  - the thermal death time
  - the thermal death point or temperature
- Autoclaves use pressurized steam as their sterilization agent
- autoclaves need to have steam in direct contact with the material
- Moist heat destroys microorganisms by the irreversible coagulation and denaturation of enzymes and structural proteins



# Autoclave:

✓ Process steps include:

- preparation
- Loading
- air removal
- heating
- sterilization
- Exhaust
- drying



# types of Autoclave:

I. autoclave class N → temperature: 121 °C

II. autoclave class S

temperature: 121°C/pressur:1.1 bar

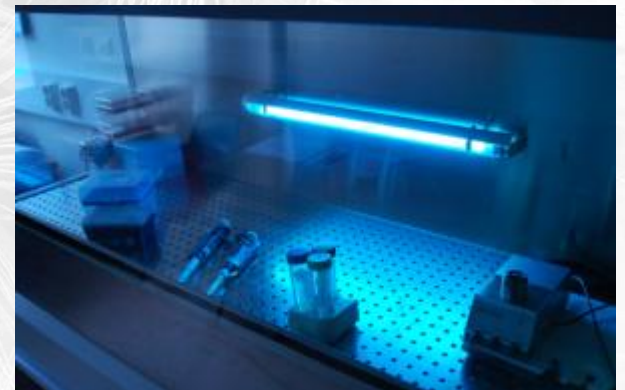
III. autoclave class B

temperature: 134°C/pressur:2.1 bar



# Irradiation Sterilization:

- ✓ It is a simple, rapid and efficacious method of sterilization
- ✓ Either gamma rays from a cobalt-60 (  $^{60}\text{Co}$  ) isotope source is used
- ✓ used when materials are sensitive to the high temperature
- ✓ The most commonly validated dose used to sterilize medical devices is 25 kGy
- ✓ The main disadvantage of this method is high cost



# Dry heat sterilization:

- ✓ It is not often used in the medical device
- ✓ Dry heat sterilization requires higher temperatures and longer exposure times than moist heat sterilization
- ✓ Dry heat sterilization occurs primarily by dehydration and oxidation
- ✓ This method occurs at 160-190 ° C sterilization
- ✓ Microorganisms are destroyed by coagulation of heat-induced protein

# Dry heat sterilization:

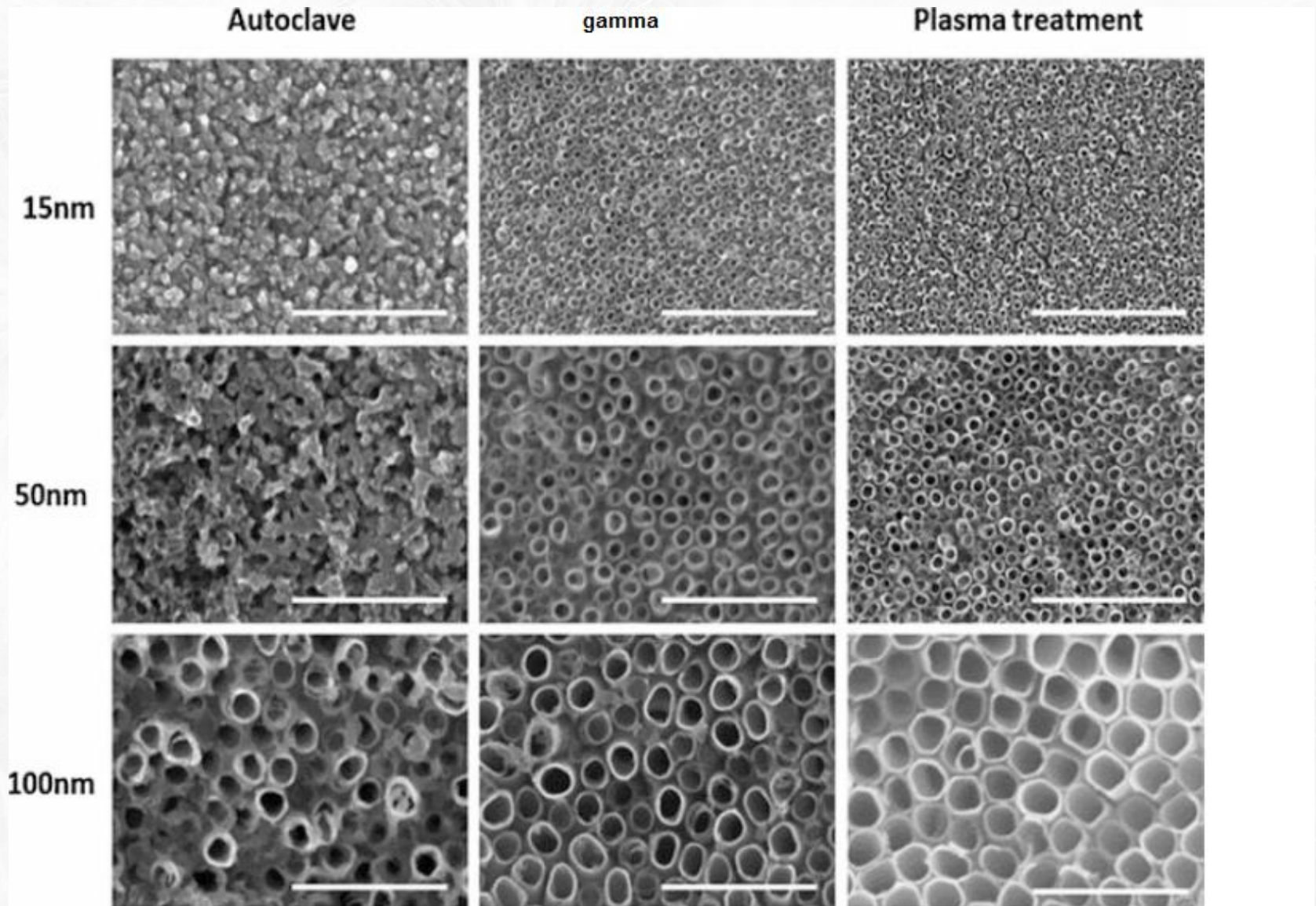
- ✓ The heat travels through the enclosure through conduction or transfer
- ✓ Based on this aspect, there are two methods that are used:
  - Sterilization according to tensile conduction
  - Sterilization in accordance with mechanical conduction





	polymer	ceramic	metal
EO	X	✓	✓
H2O2 gas	Elastomer, Silicon,PLA		✓
autoclave	Some		most
Gamma ray	Pla	✓	✓
Dry heat	Acetal,PTFE, Polysulfone , silicon,PLA		X

# Influence of various sterilization procedures on metals:



# Influence of various sterilization procedures on polymers:

