

STERILIZATION METHODS, TECHNIQUES AND CAPABILITIES

This techbit will detail the different sterilization methods and technologies currently available in today's medical market. We will focus on the more commonly used methods that can be found in the market today.

What is sterilization? Sterilization refers to any process that removes, kills, or deactivates all forms of life and other biological agents like prions present in a specific surface, object or fluid.

Choosing a sterilization method is one of the most important steps in developing a medical device. Using an insufficient or inappropriate sterilization method can prevent your medical device from receiving marketing clearance from regulatory bodies. Poor sterilization can lead to transmission of infectious diseases causing patient illness and even death. Medical device equipment is sterilized in a variety of ways. Both physical and chemical processes can be used to properly sterilize a me-

dical device. Some of the most common processes are steam sterilization, dry heat sterilization, chemical sterilization using gases like ethylene oxide, and radiation. The choice of sterilization technique will depend on the material composition of the medical device, its intended use, and how it's classified.

Sterilization can be classified under for the following categories:

- High Temperature/pressure sterilization
- Chemical sterilization
- Radiation sterilization

THE FOLLOWING IDENTIFIES THE VARIOUS STERILIZATION METHODS AVAILABLE, ITS COMMON METHODS AND APPLICATIONS THAT CAN BE APPLIED:

Methods	Most Common	Notes	Applications
High Temperature	Steam Autoclave	<ul style="list-style-type: none"> • High Pressure: 15-30 psi • Short sterilization time: 3-30min. cycle 	<ul style="list-style-type: none"> • Most surgical equipment: hand pieces, remotes, etc.
	Ethylene Oxide (EtO)	<ul style="list-style-type: none"> • Low temperature • Longer cycle time • Very hazardous to staff 	<ul style="list-style-type: none"> • Heat or moisture sensitive devices • Must be Tyvek packaged (or equivalent) • Disposable/plastic devices, single use instruments
Chemical	Sterrad	<ul style="list-style-type: none"> • Low temperature H2O2 plasma 	<ul style="list-style-type: none"> • Heat sensitive equipment: e.g. endoscopic instruments
	Steris	<ul style="list-style-type: none"> • Low temperature • Uses proprietary sterilant formulation • Process time: 12min. 	<ul style="list-style-type: none"> • Heat sensitive equipment: e.g. endoscopic instruments
	CidexOPA	<ul style="list-style-type: none"> • High-level disinfectant 	<ul style="list-style-type: none"> • Surgical Camera's (endoscopes)
Radiation	Gamma	<ul style="list-style-type: none"> • Low temperature • High sterilization time • Usually performed after packaging 	<ul style="list-style-type: none"> • Plastic or tubing products

MOST COMMONLY USED METHODS:

Steam Autoclave – Moist heat autoclaving is the fastest and most reliable form of sterilization in the medical equipment industry. Designed to use high pressure and high temperature steam to kill microorganisms. They are also used to render bio-hazardous materials inactive. To achieve the maximum effect of steam, it must be saturated. With moist heat sterilization procedures, the temperature and pressure can easily be monitored making it easy to determine if sterilization has occurred. There is no doubt that steam sterilization produces a high level of sterility and that's why it is the most often used form of sterilization in hospitals and laboratories.

Ethylene Oxide (EtO) - Ethylene oxide is a low temperature gaseous process widely used to sterilize a variety of healthcare products, such as single-use medical devices. Through the use of a vacuum-based process, EO sterilization can efficiently penetrate surfaces of most medical devices and its lower temperature makes it an ideal process for a wide variety of materials

Sterrad - The Sterrad system is a Hydrogen Peroxide Gas Plasma Sterilization system with an operating temperature range of 45-50°C. Operating cycle times range from 45-70 minutes, depending on size of system. This sterilization system uses a combination of hydrogen peroxide and low temperature gas plasma to quickly sterilize most medical instruments and materials without leaving any toxic residues.

The [ODU MEDI-SNAP®](#) connectors are highly reliable medical interconnect solutions ideal for a large variety of disposable applications including catheters, electro surgical pencils, endoscopes, laparoscopic and ablation devices.

The following sterilization process is available for ODU [MEDI-SNAP®](#): Steam sterilization with pre-vacuum or gravitation process. The connectors are tested with autoclave equipment in accordance with DIN EN 13060:2019-02 at 134 °C and 200 cycles (housing element made of PEI).



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