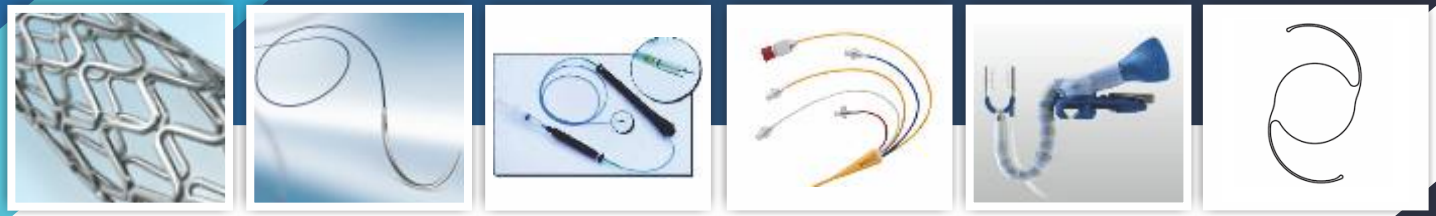
ETHYLENE OXIDE STERILIZERS

"Validatable" Sterilizers for the Medical Device Industry

ISO 9001:2015 ISO 13485:2016

IDEAS * INNOVATION * IMPLEMENTATION 25 YEARS 1991-2016

- *Easy "One Touch" Operation.*
- *With "In- Built" Aeration Facility*
- *Uses 100% E.O. Gas Cartridge*
- *Available In "Single Door" and "Double Door" Configuration*
- *Sterilization Cycle in Vacuum, hence much safer.*
- *Process Validatable as per EN-ISO 11135-2014*
- *Inhouse Quality Control of Sterilization Process.*
- *21 CFR Part - 11 Compliant Software and Recording (optional)*



These are **"Validatable"** Medical Sterilizers using Ethylene Oxide as the sterilant gas. They are capable of sterilizing medical devices even in packed form. With the increasing use of plastics, electronics and other heat sensitive or heat labile materials in the manufacturing of medical devices, used in modern day surgical procedures in hospitals, there is a need for a sterilization method which operates on low temperature that will not harm the plastic or polymer based devices and yet is extremely effective and offers a broad spectrum of applications. One such time tested method of sterilization which is both low temperature and yet very effective is "Ethylene Oxide Sterilization". It is one of the most accepted methods of sterilization used by Medical Device manufacturers worldwide who have in house sterilization facility. These sterilizers have been developed for specific applications involving long term invasive products like Cardiac Stents, Pacemakers and Intraocular lenses etc.

The sterilization process in our Validatable sterilizer is validatable as per EN-ISO 11135-2014

Our sterilizer has a digital printout and a graphical data recorder output . This helps the Quality controller to view each segment and parameter of the cycle and ensure that each process control limit as specified, has been met or not. The graphical format is multi colored representing the different sensors. The built in memory card has the capability to store more than three years of data which can be used as an immediate reckoner in case of product recall. The recorder has the facility of computer connectivity with a USB port and also the reliability of the standalone data recorder which is useful if the cycle were to be taken in manual mode. Our sterilizer has a separate steam generator to generate humidity in the sterilizer as well as a vaporizer for evaporating the gas ; as mentioned in the EN ISO 11135-2014 document . In our sterilizer , the steam supplied is of sterile grade and not high temperature water sprays. Requirement of temperature profile and humidity profile as stipulated in EN-ISO 11135 - 2014 are met in our sterilizer. Determination of leak test , rate of vacuuming , rate of injection of gas available in our sterilizer. Our Validatable sterilizer has a Performance Qualification Control program button which is used to automatically carry out the PQ by Half Cycle Method as described in EN ISO 11135-2014. During the gas puncturing stage the exact vacuuming process control limit is correctly defined in our sterilizer. The sterilizer has a Touch screen to select and view parameters , and insert numerical batch codes easily. 21 CFR Part 11 compliant software and record keeping available as an option. Already installed & used by most medical device manufacturers who manufacture long term invasive products like Cardiac stents, Intraocular lenses & Sutures etc...

SAFETY

- The cycle operates in vacuum and hence is safer to operate as there is minimum chance of leakage.
- The electronic design provides accuracy of operation, dependability and repeatability.
- As the doors are provided with a interlock, unless both the doors are closed , the cycle cannot be initiated.
- Once a cycle is started, the doors gets locked automatically and do not open till cycle is complete.
- Double Door Safety – interlocks prevent both doors from being opened simultaneously.
- The sterilizer aerates the load after sterilization and is continuous in one chamber and thereby eliminates gas exposure to operators during load transfers.
- Cycle Completion record is shown on the printout and display and only after successful completion of batch.
- Auto – Abort facility in case of any abnormal conditions.

Volume Appx.	Chamber Size H x W x D	100% E.O. Gas Qty.	Application
140 Ltrs.	16" x 16" x 34"	100gms	Suitable for Small Medical Device Manufacturers Manufacturing Miniature or Small Devices like Intraocular Lenses.
225 Ltrs.	16" x 16" x 54"	170gms	Suitable for Medium Size Medical Device Manufacturers Manufacturing Devices like Orthopedic Implants, Stents etc.
450 Ltrs.	24" x 24" x 48"	340gms	Suitable for Large Size Medical Device Manufacturers Manufacturing Devices like Implantable joint replacement, Peripheral Vascular grafts.
680 Ltrs.	24" x 24" x 72"	420gms	Suitable for Very Large Size Medical Device Manufacturers Manufacturing Devices like Implantable joint replacement, Peripheral Vascular grafts.

AKSA INDUSTRIAL PROCESS CONTROLS PVT. LTD.

(AN ISO 9001 : 2015 & ISO 13485 : 2016 CERTIFIED COMPANY)

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