Medical Device Sterilization
with Chlorine Dioxide Gas

ClorDiSys

CHLORINE DIOXIDE GAS STERILIZATION

Chlorine dioxide (CD) gas has been used as a sterilizing agent since the 1980's. It is a true gas at room temperature and has excellent distribution and penetration abilities. It is a registered sterilant with the US EPA, typically leaves no measurable residuals, and has been shown to reduce endotoxins.

CD gas is very similar to ethylene oxide (EtO) in how it is utilized and the SAL sterilization levels that can be achieved. CD gas holds advantages in the types of devices that can be sterilized, the overall processing time, and its environmental impact. CD is not explosive or carcinogenic and leaves no harsh residues. These properties allow for the sterilization of sensitive items, including those with embedded batteries. A simple carbon scrubber can remove chlorine dioxide gas, however it can also be exhausted to the environment in almost all locations, removing the need to scrub with hazardous solutions prior to removal. It is non-flammable and non-explosive at use concentrations, so it does not require expensive damage limiting construction. An integrated UV-VIS spectrophotometer measures and controls the gas concentration throughout the sterilization cycle ensuring the success of each cycle and allowing for parametric release. CD gas requires much shorter overall cycle times, allowing for products to get to the customer much faster. Devices can be packaged in Tyvek® pouches, display boxes, or final shipping containers. CD gas is safe on most materials and electronics, and ClorDiSys can assist with material compatibility testing to ensure your product is compatible. ClorDiSys has a draft Device Master Reference file available as a guide.

Chlorine dioxide is the optimal method for devices containing embedded batteries. This is true because unlike EtO, chlorine dioxide's non-explosive nature allows for the capability of sterilizing devices containing these materials. CD does not get absorbed into materials as EtO does, so aeration time is typically under 60 minutes. Chlorine dioxide is a true sterilant gas and works at ambient temperature. The boiling point of CD is low, at -40°C. CD gas will not condense on devices, which allows for even and consistent kill. Chlorine dioxide gas is a surface sterilant which provides an opportunity to sterilize pre-filled syringes while maintaining drug integrity. As with EtO, chlorine dioxide has the capability to successfully sterilize medical devices with complex geometries and small lumens.

STERILIZATION PROCESS COMPARISON

AGENT	ADVANTAGES	DISADVANTAGES
CHLORINE DIOXIDE GAS	- True gas sterilant - Compatible with embedded batteries - Short Cycles and Aeration - Ambient temperature - Concentration can be monitored and controlled -Can be used in-house	- Novel technology
ETHYLENE OXIDE	- True gas sterilant - Product compatibility - Low temp sterilization - Great penetration - Devices can be boxed	- Explosive - Carcinogenic - Supply chain shortages - Cannot safely sterilize batteries - Long cycle times
NITROGEN DIOXIDE	- True gas sterilant - Low temperature sterilization - Can be used in-house	- Items cannot be boxed - Smaller chamber sizes - Incompatible with cellulose materials such as boxes and traditional labels - Novel technology
E-BEAM	- Better product compatibility than Gamma and X-Ray - Rapid cycle time	- Limited penetration on dense products - Lower compatibility with polymers and semiconductors
X-RAY	- Great penetration	- Requires a more robust cycle when sterilizing items in cardboard boxes - Lower material compatibility
GAMMA IRRADIATION	- Great penetration - Dry sterilization process	- Lower compatibility with polymers and semiconductors - Higher cost - Typically only used by contract sterilizers
PERACETIC ACID	- Can be used in-house	- Not a true gas - Items cannot be boxed - Smaller chamber sizes - Incompatible with cellulose materials
HYDROGEN PEROXIDE VAPOR	- Common in hospitals - Can be used in-house	- Not a true gas - Items cannot be boxed - Smaller chamber sizes - Incompatible with cellulose materials

CONTRACT STERILIZATION

As an FDA registered Contract Sterilization facility (Registration #3013115071), we can sterilize your medical devices safely and efficiently at our facility. Our team provides world-class customer service to ensure that your products are processed quickly according to your product's specifications. Our leadership works with each client to carefully determine the proper cycle for each specific device and project that optimizes time, budget, and assured sterility. ClorDiSys then works with you through the validation process to simplify the process in creating a commercially viable solution.

Contract Sterilization Options

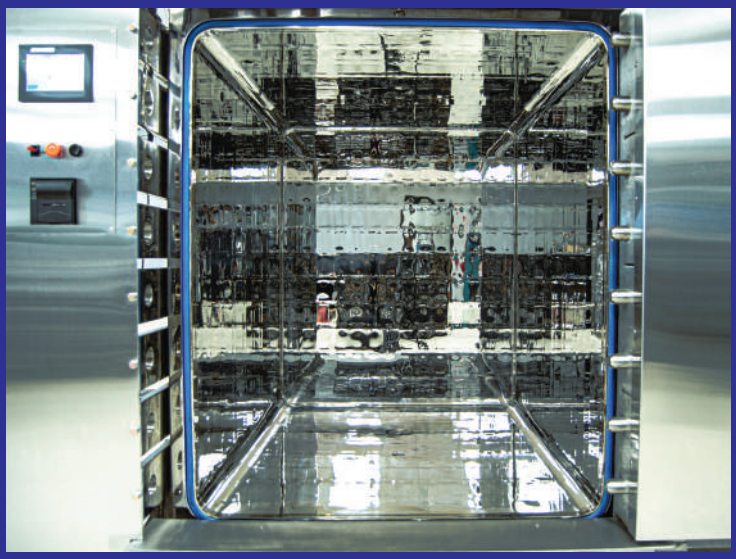
Chlorine dioxide gas is a microscopic molecule that is able to penetrate through shipping and display boxes as well as product packaging. However, many clients choose to sterilize devices without final packaging to avoid added sterilization time and consumable usage that sterilizing inside cardboard packaging creates.

ClorDiSys can work with you to evaluate which product format is best for you while undergoing the sterilization step in your product life cycle.

IN-HOUSE STERILIZATION

Currently, many facilities outsource the sterilization of products due to the challenges and concerns with conducting an ethylene oxide sterilization. However, ClorDiSys designs and manufactures chlorine dioxide gas vacuum sterilizers that can offer a simple and affordable way to perform sterilization within your facility. The transition to performing in-house sterilization can result in shorter turnaround times, and a reduction in costs for sterilization over time. Our Steridox line of sterilizers comes in multiple sizes to handle any quantity of items necessary. Easy to use, and less complex than EtO systems due to its non-explosive nature and simpler environmental controls, the Steridox line of sterilizers is a great fit for in-house sterilization.

Steridox
Chlorine Dioxide Gas Sterilizers



Chlorine Dioxide Sterilization chambers range in size to conform to capacity needs, currently up to four pallet loads. Due to the simplicity of the sterilization process, every step including; conditioning, exposure, and aeration, all occur within the chamber. Cycle times are also significantly lower in most scenarios.

Chambers can store multiple cycle recipes which allows for greater simplicity in sterilizing all product and packaging types.

Converting existing EtO sterilizers?

Facilities already performing sterilization on-site can easily transform existing ethylene oxide chambers can into chlorine dioxide sterilization chambers. We can work with you to determine the feasibility of conversion and provide a simple kit to convert your current sterilizer.

MATERIAL COMPATIBILITY

Chlorine dioxide gas is one of the most gentle sterilant agents available. Our proprietary generation method produces a pure chlorine dioxide gas which has been safely used on various medical devices including suture products, intraocular lenses, artificial joints, syringes, vials, pump systems, electronics, batteries powered devices, and more.

Chlorine dioxide is the method usually recommended when devices have embedded batteries, as they are not affected by chlorine dioxide. CD does not get absorbed into materials as EtO does, so aeration time is typically under 60 minutes. Chlorine dioxide is a true sterilant gas and works at ambient temperature. The boiling point of CD is low, at -40°C. CD gas will not condense on devices, which allows for even and consistent kill. Chlorine dioxide gas is a surface sterilant which provides an opportunity to sterilize pre-filled syringes while maintaining drug integrity. As with EtO, chlorine dioxide has the capability to successfully sterilize medical devices with complex geometries and small lumens.

RESIDUALS AND ENDOTOXINS

Chlorine dioxide's byproducts are chlorite, chlorate, and chloride which are non-carcinogenic, non-cytotoxic and non-teratogenic. Chlorine dioxide's properties, combined with the rapid aeration process results in residues typically being below detectable levels on product and packaging. This was confirmed in studies that showed no residuals after gas exposure by rinsing 304 stainless steel coupons with water for injection (WFI) and measuring using an HPLC method for detection of chlorite, chlorate, and chloride.

Endotoxins were tested using the LAL gel-clot test technique. In the sample composite extracts tested, < 0.03 EU/mL, or < I.2 EU/Device was found. This result is well under the maximum allowable limit of 20.0 EU/Device for general medical devices and under the 2.15 EU/Device limit for cerebrospinal contact devices. A separate study evaluated the ability of CD gas to reduce endotoxins showed a 2.4 log reduction on 316 stainless steel and a 4.1 log reduction on 304 stainless steel spiked with 4.1 log of e. Coli endotoxin.

STERILIZATION PROCESS VALIDATION

All sterilization methods for medical devices must be approved alongside the design and manufacture of the medical device itself. The chlorine dioxide gas sterilization validation process follows ISO 14937, which is also conducted in near identical fashion to EtO and ISO 11135.

- **Validated Sterilizer (IQ/OQ)-** *Same process as EtO*
- **Package Integrity Testing-** *Same process as EtO*
- **Product Functionality Testing-** *Same process as EtO*
- **Efficacy via Biological Indicators-** *Same process as EtO*
- **Overkill Methodology-** *Same process as EtO*
- **Process Characterization-** *Reference Device Master File available*
- **Residue/Toxicity Testing-** *Generic results available*
- **Endotoxin Testing-** *Same process as EtO*

ClorDiSys can assist with any or all of the above.

ClorDiSys Solutions, Inc of Branchburg, New Jersey (est. 2001) is a company providing years of experience in all aspects of chlorine dioxide technology with a strong background in the Medical Device and pharmaceutical industry operating under GxP.

Each project is approached by utilizing our strong sterilization and engineering skills while drawing on our background in Operations, Service, Validation, and Quality to provide solutions for all of your chlorine dioxide needs. We provide personal attention to ensure customer satisfaction in all services and equipment we supply.

Medical device sterilization has been performed with chlorine dioxide gas since the 1980's and is the leading solution for sterilization. Chlorine dioxide gas produced using our proprietary generation method is gentle on materials, non-carcinogenic, non-explosive, and is free of residuals.

ClorDiSys

www.clordisys.com

908-236-4100

Government Registrations and Approvals

US EPA Registered Sterilant per EPA OCSPP 810.2000

ClorDiSys EPA Registration# 80802-1

New Jersey headquarters is registered with the FDA as a Contract Sterilization facility (Registration #3013115071)

ClorDiSys Quality Management System Certified Under ISO 13485:2016

ClorDiSys sterilized Medical Devices on Market