



# Getinge Stericool H<sub>2</sub>O<sub>2</sub> Plasma Sterilizer

An innovative low-temperature solution

This document is intended to provide information to an international audience outside of the US.

GETINGE 



STERICOOOL

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# An intelligent solution for the CSSD

A trusted solution for sterilizing MIS instrumentation.

Hospital-acquired infections delay patient recovery and cost the healthcare system billions of dollars each year.<sup>1</sup> While there are many elements to an effective infection control policy, instrument sterilization plays an important role in minimizing the risk of cross-contamination.

Many components in advanced surgical tools cannot withstand the heat or pressure of traditional steam sterilizers. This has led to an increasing dependence on low-temperature sterilization technologies to maintain efficient infection control. Getinge's Stericool Low-Temperature Sterilizers are part of a wide portfolio for the central sterile services department (CSSD), providing the right solutions for hospitals embracing minimally invasive surgical (MIS) procedures as the standard of care.

Getinge Stericool H<sub>2</sub>O<sub>2</sub> Plasma Sterilizers offer a range of sizes and sterilization programs (fast, standard, and advanced) to suit a wide range of instruments. All related consumables are available from our global and well-trusted sales and service network, ensuring that Getinge is the complete source for your sterilization needs.



<sup>1</sup> <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1733452>

# Achieving accurate and consistent results

## – increasing hospital throughput

### **Extended life for delicate reusable instruments**

Optimized sterilization environment for delicate, heat-sensitive and moisture-sensitive medical instruments resulting in minimum instrument damage and lower repair costs.

### **Hydrogen peroxide sterilant (H<sub>2</sub>O<sub>2</sub>) 59% wt**

Stericool utilizes highly purified, high-efficacy 59% wt H<sub>2</sub>O<sub>2</sub> sterilant cartridges which are authenticated via the sterilizer's H<sub>2</sub>O<sub>2</sub> traceability system. The patented injector technology enables minimum use of sterilant at maximum efficiency.

### **User-friendly predefined sterilization programs**

The Stericool Sterilizers feature three fully automated programs to sterilize a wide range of sensitive medical instruments in less than an hour.

### **Multiple programs to meet specific needs**

The standard program is designed to sterilize general surgical instruments with single-channel flexible and moderate-length rigid lumens. The fast program provides shortened sterilization time for surface sterilization loads. The advanced program is designed to sterilize surgical instruments with long rigid lumens.

### **Highly intuitive user interface**

The Stericool Sterilizer features an innovative, user-friendly interface display. The intuitive design requires less training and can be easily operated by staff at all experience levels.

### **Optimized material compatibility and efficacy**

Patented dual-mode concentrator injector technology allows Stericool to offer both variable concentration and optimized cycle duration for a wide range of material compatibility.



**Peace of mind**

An optional independent monitoring system (IMS) monitors process data from independent sensors to give users additional verification of process parameters. Process data is also provided in printed reports for load release.

**Easy to learn and operate**

The intuitive design of the human-machine interface (HMI) screen simplifies use and provides clear graphical progress of the sterilization cycle.

**Minimized staff contact with sterilant**

The H<sub>2</sub>O<sub>2</sub> sterilant loading compartment locks electronically and automatically pierces containers.

**Improved safety for patients and operators**

State-of-the-art in-chamber RF plasma, created at the end of the cycle, prevents H<sub>2</sub>O<sub>2</sub> leakage to the environment and removes residue from instrument surfaces. In addition, a highly efficient in-line catalytic converter prevents release of H<sub>2</sub>O<sub>2</sub> from the sterilizer.

**Multiple volumes**

Meet the demanding requirements of your facility with a choice of 110 L and 160 L useable volumes.

**Automatically operated sliding door**

**High instrument throughput**

Two shelves and generous chamber sizes support high throughput.

**Zone separation**

Satisfy zone separation requirements with a double-door option for pass-through operation.

**Highly efficient**

An highly efficient in-line catalytic converter prevents release of H<sub>2</sub>O<sub>2</sub> from the sterilizer.

**Easy data management**

External interface for data logging (SD memory, USB and Ethernet), and optional T-DOC connectivity.

**Improved mobility**

Caster wheels offer smooth mobility. Rubber feet are provided.

# Reducing operating costs

## **Peace of mind with independent monitoring**

Independent monitoring system (IMS) is a documentation system that supports real-time monitoring of critical data from independent sensors to offer additional verification of process parameters. Process data from IMS is printed on a paper report and can be accessed electronically via the T-DOC Sterile Supply Management and Traceability Solution.

## **Data logging, interoperability**

Sterilization process validation logs may be transferred via SD memory card, USB connection or by Ethernet TCP/IP connections to any LAN or WAN network such as the Internet.



# Keeping medical staff safe and productive

## Ensuring staff and patient safety

Getinge's Stericool Low-Temperature Sterilizer range has an excellent environmental safety record. At the end of the sterilization cycle, in-chamber RF plasma ensures that there is no sterilant residue left on medical instruments and no residual H<sub>2</sub>O<sub>2</sub> leakage from the sterilizer, protecting both staff and patients.

## No residual toxic waste or harmful byproducts

The highly efficient in-line catalytic converter provides additional assurance against leakage of residual H<sub>2</sub>O<sub>2</sub> to the working environment.

## ISO 14937 compliant

Stericool has been validated by an independent, accredited third-party lab. SAL-6 compliant validation studies demonstrated a 10<sup>6</sup> reduction at the half-cycle using challenging lumens to match IFU claims.

## Cost-effective ownership

### Easy installation

Plug-and-play Stericool Sterilizers are designed to be mobile and can easily be integrated into healthcare facilities at any scale as they only require a standard power connection (three-phase connection is optional). No extra civil work, water source, drainage, waste management, ventilation, or mounting are required prior to installation.

## Ensuring quality reprocessing

### Double-door, pass-through operation

Single-door operation is standard. The pass-through double-door option perfectly satisfies zone separation requirements of modern CSSDs. If a cycle is aborted, sterilization loads are delivered back to the processing zone.

### Quality

Our products are manufactured under continuous quality control to appropriate medical and product quality standards.

## Reducing environmental impact

### Easy sterilant loading

Sterilant cartridges are simply inserted into the safe auto-locking compartment at the front. Cartridges feature a protective seal for safe handling.

### Intelligent system management

Stericool's intelligent system management software constantly monitors critical sterilization parameters, providing real-time information on the sterilization cycle progress. Its resident self-diagnostic programs provide guidance for easy preventive action and provide notice of imminent service expiration.

### State-of-the-art RF plasma technology

The RF plasma technology gently removes H<sub>2</sub>O<sub>2</sub> residuals from within the chamber and from the surface of sensitive medical instruments.

# Supporting your workflow

– with a full range of consumables

## Sterilant ST240 / ST030 cartridges



The H<sub>2</sub>O<sub>2</sub> sterilant cartridges have been designed with the operator's safety and ease of use in mind. When stored at room temperature, ST240 has a shelf life of 12 months from the date of manufacturing and ST030 has 45 days. Each cartridge has unique serial numbers for traceability tracking.

- ST240, 24 cycles for 110 L / 20 cycles for 160 L\*
- ST030, 2 cycles for 110 L and 160 L\*\*

\* Total cycles per cartridge will vary with program selection  
\*\* Sterilant ST030 has the same form factor of ST240 and is shipped via air freight

Tyvek® is a registered trademark of E.I. du Pont de Nemours and Company.

## Sterilization packaging in a wide range of standard sizes



Made of multilayer PET / PE film and high-grade Tyvek®, Tyvek® Sterilization Rolls and Pouches provide an effective microbial barrier for all your processed hospital instruments. A water-based and non-toxic Type I process indicator on the Tyvek® surface ensures an accurate visual confirmation by color change to differentiate between processed and unprocessed packages.

Getinge Pack Tyvek® Rolls are CE marked and in compliance with international standards ISO 11607-1, ISO 11140-1, and EN 868-5.

### Tyvek® Sterilization Roll

- 5 cm x 70 m
- 7.5 cm x 70 m
- 10 cm x 70 m
- 15 cm x 70 m
- 20 cm x 70 m
- 25 cm x 70 m
- 30 cm x 70 m
- 35 cm x 70 m
- 40 cm x 70 m

### Tyvek® Sterilization Pouch

- 7.5 cm x 20 cm
- 10 cm x 28 cm
- 15 cm x 30 cm
- 20 cm x 40 cm
- 25 cm x 45 cm

Getinge offers a comprehensive portfolio of consumables to support every step of your workflow in the CSSD. All Getinge brand consumables have been tested on Getinge equipment and conform to all relevant performance standards to ensure the quality of your results.

### Monitoring kits ensure peak performance



A process challenge device (PCD) in your sterilizer provides a snapshot of the conditions inside the sterilizer to ensure that the proper sterilization conditions have been achieved.

#### Getinge Routine Monitoring Kit

The Getinge Routine Monitoring Kit (VH<sub>2</sub>O<sub>2</sub>) is designed to be used in each sterilization cycle as an independent control device, ensuring that your sterilizer is continuously operating at peak performance. The kit is compliant with ISO 14937 routine monitoring guidelines.

The Getinge Process Challenge Kit (VH<sub>2</sub>O<sub>2</sub>) includes a reusable device (2 mm\* x 1,200 mm) and one box of single-use Getinge Assured Self-Contained Biological Indicators (VH<sub>2</sub>O<sub>2</sub>). A clear color change confirms exposure to appropriate sterilization conditions.

### Process indicators verify conditions



These products provide assurance that the pack was exposed to hydrogen peroxide. When a pack is opened, the OR staff can quickly verify that the conditions for sterilization were achieved and that the instruments and utensils are safe to use in surgical procedures.

#### Getinge Assured Self-Contained Biological Indicator

The Getinge Assured Self-Contained Biological Indicator (VH<sub>2</sub>O<sub>2</sub>) contains *Geobacillus stearothermophilus* spores (10<sup>6</sup> population) for biological testing of the sterilizer. After exposure to hydrogen peroxide and incubation for 24 hours at 55 °C, a clear color change will indicate growth or no growth.

#### Getinge Assured Plasma Indicator

The Getinge Assured Plasma Indicator gives visible confirmation that the pack has been exposed to hydrogen peroxide. Can be used as a permanent record.

#### Getinge Assured Record Label

The double self-adhesive Getinge Assured Record Label with process indicators for plasma sterilization allow easy printing of identical labels with minimal time and effort.

\* Internal dimension

# Take care

– of your investment

Optimizing your equipment's services is often an untapped opportunity to maximize productivity and reduce costs. A Getinge Care service offering will ensure that your equipment always performs at peak levels, allowing you to focus on saving lives.

## Prevent issues before they arise

Whether you're purchasing a low-temperature sterilizer or an entire CSSD, we'll be there to support you. By following a routine preventive maintenance schedule, Getinge Care keeps things running smoothly, with minimal interruption.

If something should need urgent attention, our certified field service representatives will be there to promptly support you and resolve the issue.

With a Getinge Care package, you can forecast your costs for the full life cycle of your equipment, minimizing unplanned costs. Our financial services team can analyze your needs and numbers to deliver a service package that gives you the best output for your investment. Ask your Getinge representative for more information.



### Getinge Care Standard

Supporting your internal technical service department



### Getinge Care Preventive

Scheduled maintenance intervals maximize uptime



### Getinge Care Plus

Uninterrupted protection with full cost control



### Getinge Care Premium

Full coverage for complete peace of mind





## Technical information

Dimensions	110 L	160 L
External dimensions (W x H x D)	1,910 x 680 x 864 mm	1,910 x 680 x 864 mm
Chamber dimensions single-door (W x H x D)	430 x 440 x 739 mm	492 x 532 x 739 mm
Chamber dimensions double-door (W x H x D)	430 x 440 x 745 mm	492 x 532 x 745 mm
Internal chamber dimensions (W x H x D)	400 x 405 x 710 mm	460 x 500 x 710 mm
Effective useable volume	110 L	160 L
Weight single-door	385 kg	395 kg
Weight double-door	415 kg	430 kg
Sterilization chamber	110 L	160 L
Sterilization cell	Rectangular, 316 L stainless steel	
Double-door pass-through operation	Supported	
Shelves (trays)	Two shelves with total load capacity 10 kg	Two shelves with total load capacity 12 kg
H <sub>2</sub> O <sub>2</sub> concentrator	Increases concentration to > 82% wt for improved efficacy	
Sterilization temperature	Average 55 °C	
Air intake	Through medical-grade HEPA filter	
Plasma type	Radio-frequency-excited plasma	
Plasma location	Inside the sterilization cell	
Plasma distribution	Homogenous within the sterilization cell	
Excess load alarm	Yes	
Excess humidity alarm	Yes	
Excess cellulose content alarm	Yes	
Catalytic converter	Yes	
Standards	EN ISO 13485, EN ISO 9001, ISO 14937 validated sterilization cycles and full CE (EMC EN 60601-1-2, LVD IEC 61010-2-040, and LVD IEC 61010-1) certification	



Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and for life science companies and institutions. Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the everyday life for people – today and tomorrow.

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