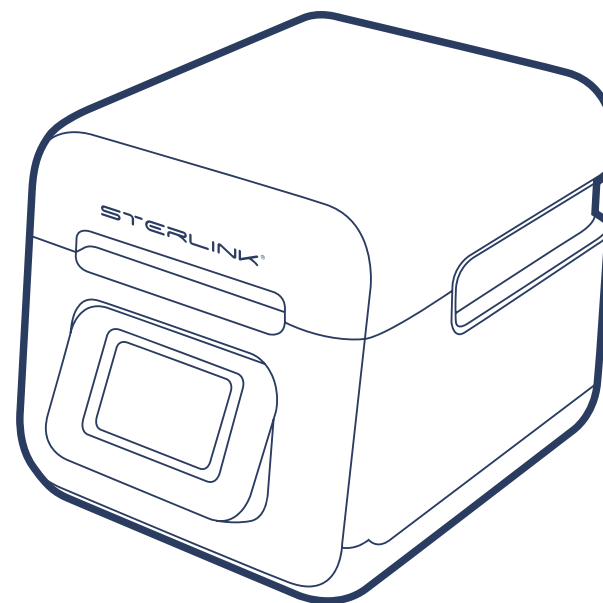


# Fast Low-Temperature Sterilization

Low Temperature Plasma Sterilizer



CE  
0068  
CE (MDD)

TÜV Rheinland  
EN ISO 13485:2016

KFDA  
KFDA Certificate

GMP  
GMP Certificate

Grand prize, SIIF 2016  
Gold prize, SIIF 2018

RoHS  
RoHS Compliance

UL US  
LISTED  
LABORATORY EQUIPMENT  
E502914



STERLINK®

STERLINK  
Plasma Sterilizer

# Introducing STERLINK®

## A low-temperature plasma sterilizer to sterilize a wide range of medical devices

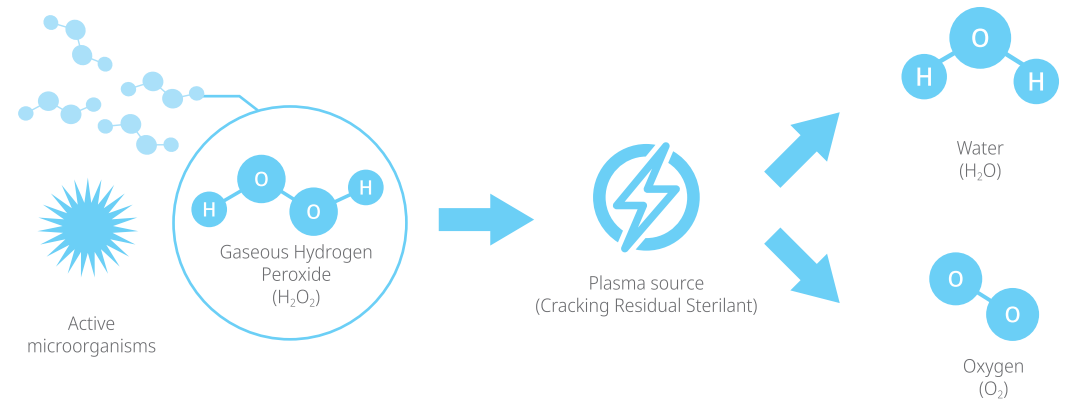
The STERLINK® FPS-15s Plus sterilization system is a low temperature plasma sterilizer to inactivate microorganisms for a broad range of metal and nonmetal medical devices and surgical instruments at low temperature. This product is reliable and provides a variety of methods of sterilization.

STERLINK® can sterilize medical devices by diffusing hydrogen peroxide vapor into the chamber or pouch. It rapidly sterilizes medical instruments and materials without leaving toxic residues. All stages of the sterilization cycle does not damage compatible instruments which are sensitive to heat and moisture.

This sterilizer can be used for metal and non-metal medical devices and can sterilize instruments with high lumen characteristics and micro sized equipments.

It consistently provides the Sterility Assurance Level (SAL) of  $10^{-6}$ , as defined by U.S. Food and Drug Administration (FDA) and international standards, only when used within the materials and geometric requirements given.

The devices have been pre-validated to the SAL of  $10^{-6}$  based upon high resistance conditions, including lumens within the claim lengths and mated surfaces.



### Hydrogen Peroxide Sterilization

After the sterilization process, the hydrogen peroxide gas is purified by plasma source to enable safe and environmental friendly sterilization.

ITS 10:40

INK®  
Sterilizer

History

# STERLINK® Overview

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## Fast Sterilization

- Smart Ready™ allows auto detection of moisture and pre-drying
- Just touch and start sterilization
- Automatic mode selection with individual barcode on pouch/cartridge



## Convenient POWER SAVING

- Sleep mode (Heater off)
- Screen saver for LCD display



## Eco-Friendly

- Decomposing residual  $H_2O_2$  into WATER and OXYGEN
- Equipped with  $O_3$  purifying filter



## Perfect DISINFECTION

- Improved sterile reliability with HEPA filter
- Easily replaceable

# Different Modes

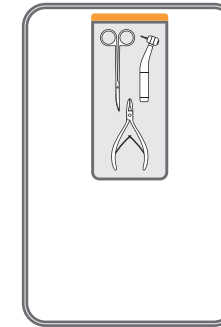
## STERPACK® (Pouch Mode)

World first pouch-type sterilization during 4 minutes is possible with the patented direct sterilant injection technology from Plasmapp.

- Vacuum sealed pouch can be stored up to 6 months in sealed sterile condition.
- STERPACK® sterilization does not require chamber cleaning as it leaves no residue in the chamber.
- Vacuum condition visualizes the sterile condition and prevents second contamination.
- Sterilant is stored safely inside the pouch which prevents any hazard from chemical exposure.

POUCH MODE  
 Sterilization Method: Pouch mode in FPS-15s Plus  
 Dimension: 135mm X 280mm  
 Sterilant: H<sub>2</sub>O<sub>2</sub> 58%

SR™ / SC™ Cycle: 3-6 min  
 Sterilization Cycle: 4 min  
 Overall: 7-10 min



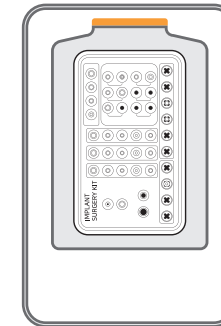
## STERPACK® Plus (Pouch Plus Mode)

Large capacity pouch reflecting market needs.

- Larger Volume
- Load Diversity
  - Implant kit
  - Clinical surgery kit
- Quick Cycle
  - 8 min sterilization process time
  - Perfect vacuum seal
  - 6 months preservation period

POUCH Plus MODE  
 Sterilization Method: Pouch mode in FPS-15s Plus  
 Dimension: 240mm X 410mm  
 Sterilant: H<sub>2</sub>O<sub>2</sub> 58%

SR™ / SC™ Cycle: 6-10 min  
 Sterilization Cycle: 8 min  
 Overall: 14-18 min



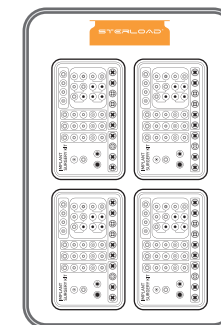
## STERLOAD® (Chamber Mode)

It is sterilized immediately in 15 minutes using a large chamber of 14 liters to increase user efficiency.

- Safe structure design contains sterilization agent inside cartridge to prevent exposure risk.
- Ergonomic design facilitates chamber mounting.
- No residue after sterilization to maintain clean chamber.
- Using 1 cartridge per cycle for economic usage.
- Using Tyvek® pouch protects sterilized medical tools from dust.

CHAMBER MODE  
 Sterilization Method: Chamber mode in FPS-15s Plus  
 Dimension: 264mm X 410mm (H: 125 mm)  
 Sterilant: H<sub>2</sub>O<sub>2</sub> 58%

SR™ / SC™ Cycle: 21 min  
 Sterilization Cycle: 15 min  
 Overall: 36 min





# Sterilization Cycle

## Flexible Sterilization modes depend on the capacity

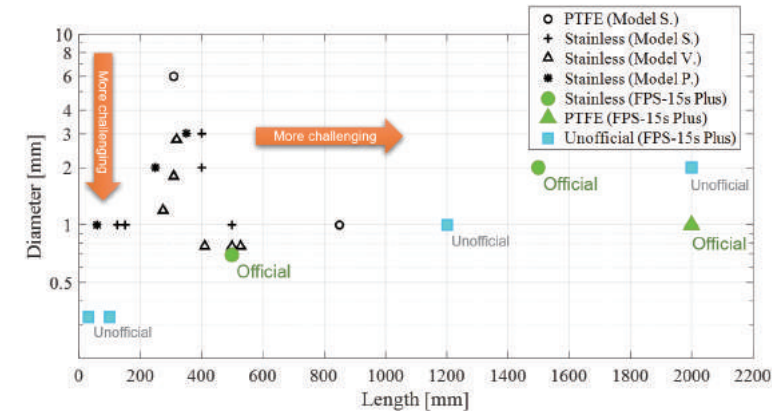
The STERLINK® FPS-15s Plus sterilizer provides a smart sterilization process that combines Smart Ready (SR™) and sterilization process and Smart Complete (SC™) to ensure sterilization efficiency, reliability and user safety. The sterilizer system is designed to operate only with the sterilant cassettes of STERPACK®, STERPACK® Plus and STERLOAD®. Each cassette has individual barcode which is scanned by the sterilizer to start the sterilization cycle automatically according to the barcode identifying the type of the cassettes.

The SR™ process is provided to measure residual moisture left on the medical devices and to perform optimized heating and drying process according to the analysis.

The sterilization process consists of the two consecutive and equal phases, and the critical process parameters in each phase are identical. The validation of the sterilization process is performed by using the half-cycle overkill method to demonstrate the 10<sup>-6</sup> SAL. The following table provides a brief description for each cycle.

Mode	Sterilant cassette	Process and overall cycle time (unit: min)		
		SR™ / SC™	Sterilization	Overall
POUCH	STERPACK®	3 — 6	4	7 — 10
POUCH Plus	STERPACK® Plus	6 — 10	8	14 — 18
CHAMBER	STERLOAD®	21	15	36

# Sterilization Performance



## Lumen claims for STERLINK®

Stainless #1: 0.7 x 500 in mm  
 Stainless #2: 2.0 x 1500 in mm  
 PTFE: 1.0 x 2000 in mm

## Unofficial test

Stainless #1: 0.33 x 20 in mm  
 Stainless #2: 0.33 x 100 in mm  
 Stainless #3: 1.0 x 1200 in mm  
 Stainless #4: 2.0 x 2000 in mm

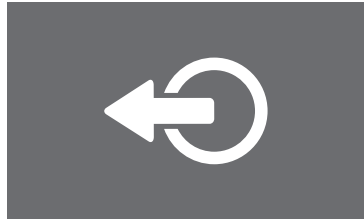
The lumen test is mandatory for invasive sterilization. The lumen structure consists of long tube connected with BI container. It is more difficult to be sterilized against the lumen with longer length and smaller diameter. The STERLINK® FPS-15s Plus has been tested with more challenging lumen structure.

# Sterilization Verification

We guarantee the best sterilization standard in reference to SAL of 10<sup>-6</sup>. After the test with BI inside the lumen, you can check whether the sterilization is reliable by cultivating the BI in the incubator. All the sterilization test report are certified by Korean MFDS and CE/MDD.

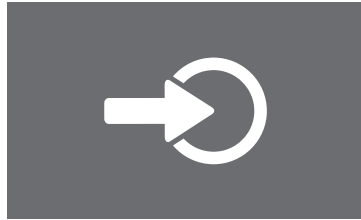


# STERLINK® Sterilization Process



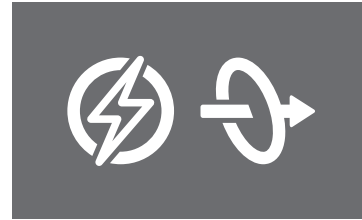
Base Pumping

For the invasive sterilization, ensure a sufficient degree of vacuum of 99% or more prior to injecting the sterilant. Using German PFEIFFER vacuum pumps provide long-term reliability.



Injection & Diffusion

The patented vaporizer technology increases the vaporization efficiency of the sterilant stored in the cassette and increases the pressure in the chamber or pouch to apply hydrogen peroxide to the surface and inside the medical device.



Plasma purification / Vacuuming

Remove residual sterilization using a high performance vacuum pump. Use plasma to purify residual hydrogen peroxide vapor.

# Patented Vaporizer Technology

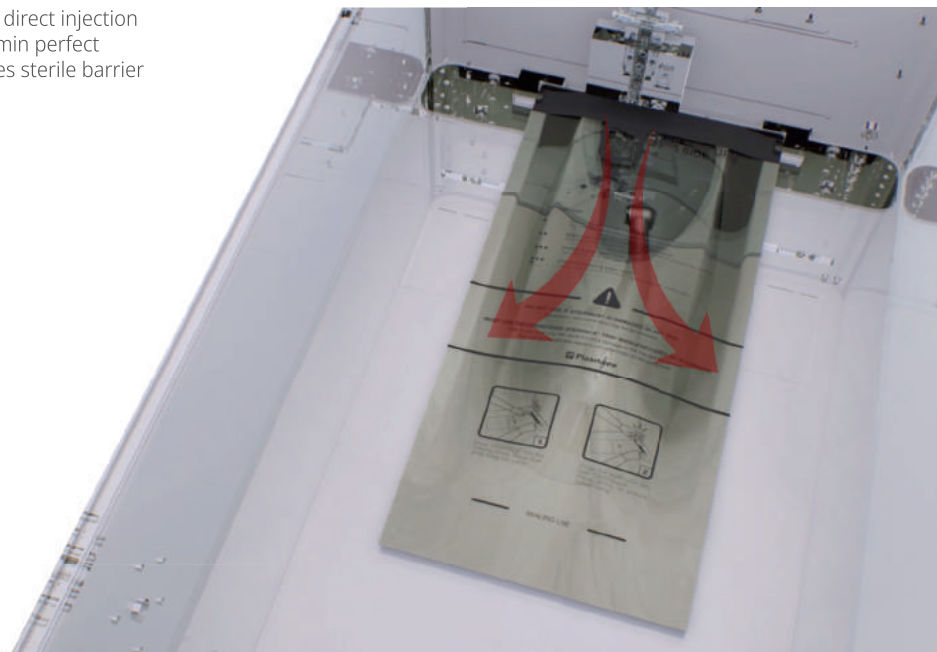
## Hydrogen Peroxide Gas Sterilization Requires 4 Key Elements

1. Sterilant - Secure retention reliability and user safety
2. Temperature Control - High speed temperature control using forced convection and thermal transfer
3. Vacuum Condition - Achieving 99% or more vacuum condition
4. Vaporizer - Patented Vaporizer specialized for direct injection

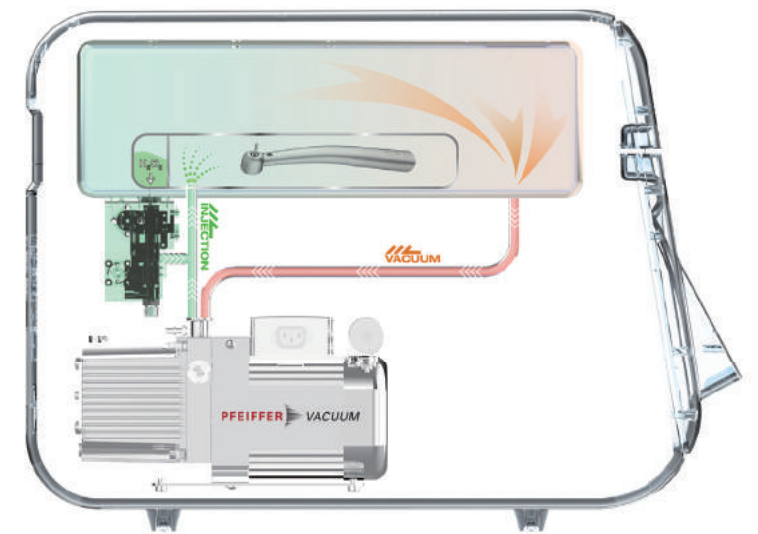
These 4 key elements are the core basis for achieving optimal Hydrogen Peroxide Gas Sterilization

# Direct Injection Technology

World first pouch-type direct injection technology enables 4 min perfect sterilization and secures sterile barrier condition.



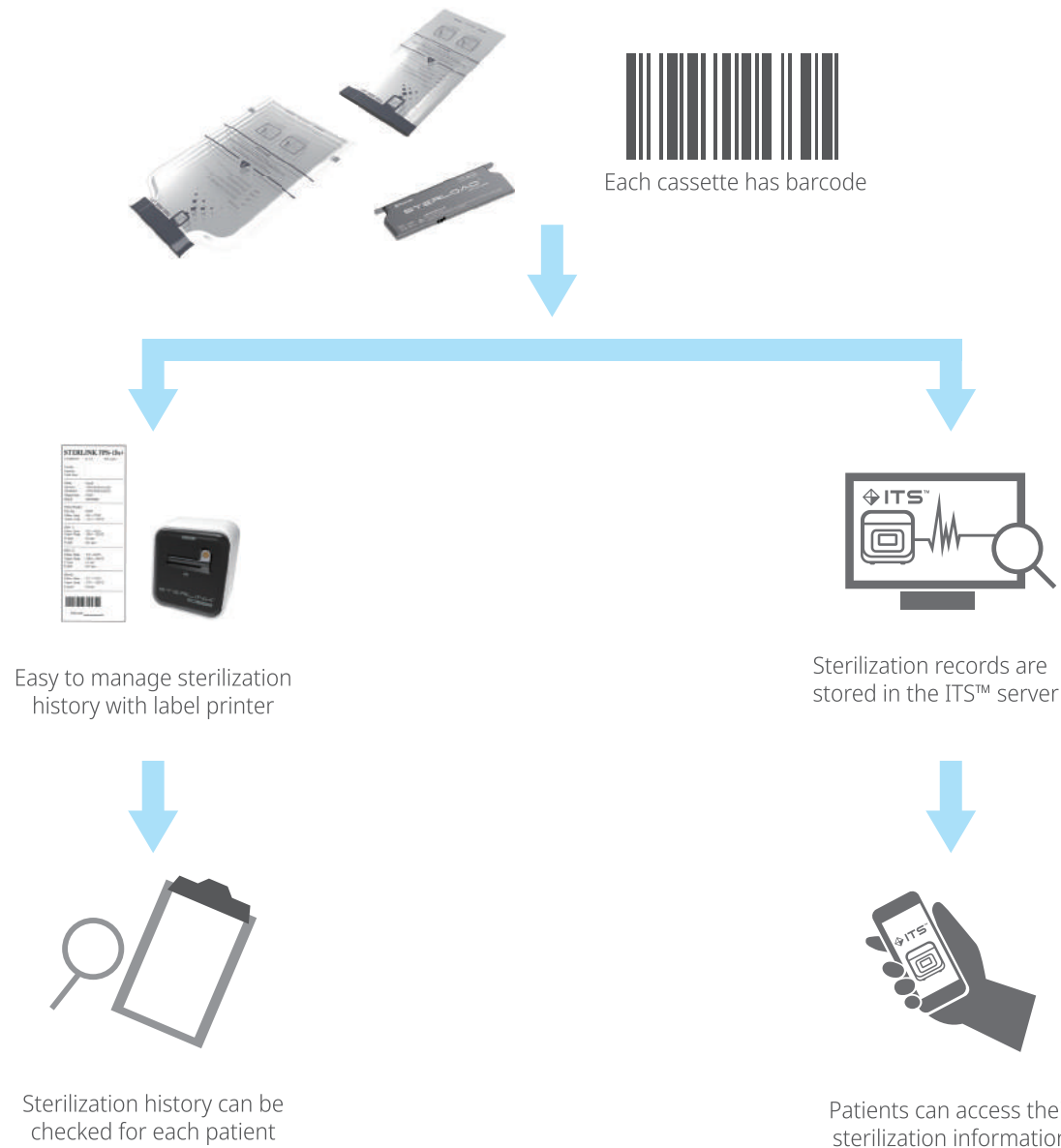
Plasmapp's low temperature plasma sterilizer (STERLINK®) guarantees a sufficient vacuum of more than 99% with German-made PFEIFFER Vacuum pump, and provides the patented vaporizer technology of Plasmapp.



# Sterilization Reliability

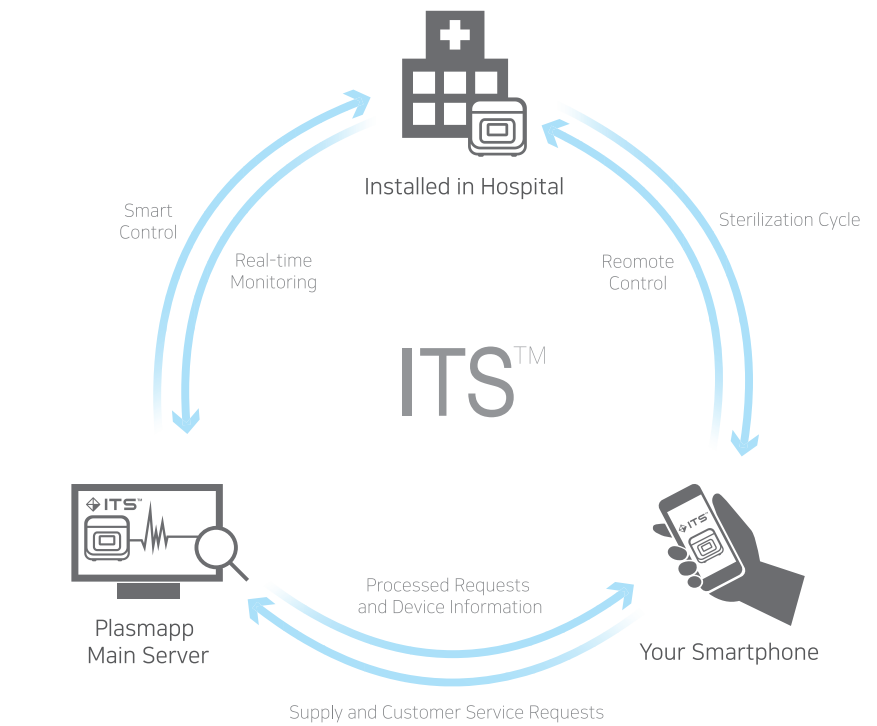
## Barcode Tracking

Each Barcode on STERPACK®, STERPACK® Plus and STERLOAD® allows for sterilization record tracking for individual patients. Barcode for STERPACK® & STERPACK® Plus & STERLOAD® Tracking Production Information included to assure STERPACK® & STERPACK® Plus & STERLOAD® validity. It helps prevent the use of expired cassettes. Also, barcode on cassettes find sterilization mode by itself.



## ITS™-Instrument Tracking System

Instrument Tracking System is a real-time sterilization monitoring system. Available as an analysis of actual usage data of STERPACK®, STERPACK® Plus and STERLOAD® as a remote device diagnostic tool. Provide advanced services that deliver accurate data analysis and immediate delivery to end users.



- ITS™ allows real-time monitoring which enables before service and worry-free usage because problems are tracked and resolved remotely.
- ITS™ securely records sterilization data in Plasmapp's main server.
- ITS™ monitors operation status of every sterilizer for on-time and accurate maintenance care.
- ITS™ provides remote software update to maintain STERLINK® with most updated software.
- Easy to use ITS™ mobile application allows direct access to sterilization records and sterilizer control.



# SMART READY™ / SMART COMPLETE™

## Starting sterilization cycle

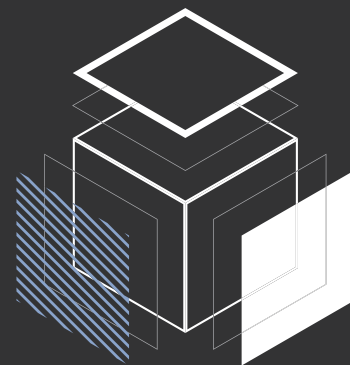
1. Check whether the door is closed when the load has been properly placed in the chamber.
2. Touch "Sterilize" icon to start sterilization cycle.
3. The sterilizer automatically scans the barcode printed on the cassette to check validity of the loaded cassette and determine the operation mode.
4. The sterilizer automatically check the door status and start the sterilization cycle.

## Cycle in progress and completed

The drying process and sterilization process will be initiated after measuring the load condition at the SR™ process.

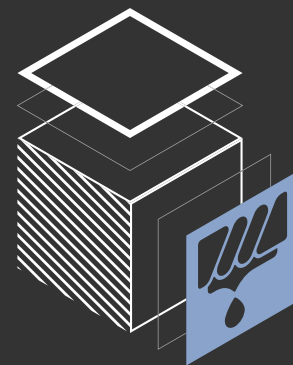
When the sterilization process is successfully completed, the smart complete (SC™) process is performed in order to ensure that there is no residual sterilant left on the sterilized instruments. After the relatively short SC™ process, the sterilization cycle is finished with summary of the cycle. Press the confirm switch to return to ready state.

## SMART READY™ Process



### 1. Smart Ready™

The volume of the sterilized object is measured at the same time as the preheating and find the optimal sterilization course.



### 2. Moisture Removal

Measure the residual moisture and dry the residual moisture.



### 3. Sterilizing

Sterilization cycle is in progress.



### 4. Smart Complete™

The sterilization is safely completed and comes out with vacuum sealed pouch.

# Comparison of sterilizers with STERLINK®



Auto Clave  
(Physical Sterilization)



Dry-heat Sterilizer  
(Physical Sterilization)



EO Gas Sterilizer  
(Chemical Sterilization)



Conventional  
Plasma Sterilizer



Plasmapp  
STERLINK®

	Auto Clave (Physical Sterilization)	Dry-heat Sterilizer (Physical Sterilization)	EO Gas Sterilizer (Chemical Sterilization)	Conventional Plasma Sterilizer	Plasmapp STERLINK®	
<b>Operating Temperature</b>	Up to 134°C	Up to 180°C	Up to 57°C	Up to 57°C	Up to 57°C	<b>Low Temperature</b> Sterilization of heat-sensitive medical instruments
<b>Cycle Time</b>	Up to 60 min. + 1 hour cooldown	Up to 120 min. + 1 hour cooldown	Up to 120 min. + 8 hour purification	Up to 70 min.	Up to 70 min.	<b>Sterilization Process Time</b> Pouch Mode : 4 min Pouch+ Mode : 8 min Chamber Mode : 15 min <b>Various Modes</b> Flexible environment for various situations
<b>Sterilant</b>	Hot Steam	Hot Air	E.O. Gas	H <sub>2</sub> O <sub>2</sub> (with plasma)	H <sub>2</sub> O <sub>2</sub> Direct Injection (with plasma)	<b>Definite Sterilization Method</b> Sterilization performance by direct sterilization to medical instruments
<b>Advantage</b>	<ul style="list-style-type: none"> <li>Cloth Sterilization Possible</li> <li>Large Volume</li> </ul>	<ul style="list-style-type: none"> <li>Cloth Sterilization Possible</li> <li>Large Volume</li> </ul>	<ul style="list-style-type: none"> <li>Low Temperature</li> </ul>	<ul style="list-style-type: none"> <li>Eco-Friendly</li> <li>Low Temperature</li> </ul>	<ul style="list-style-type: none"> <li>Economic Cost</li> <li>Small Size</li> <li>Ergonomic Design</li> </ul>	<ul style="list-style-type: none"> <li>Easy Maintenance</li> <li>Eco-friendly</li> </ul>
<b>Drawbacks</b>	<ul style="list-style-type: none"> <li>High Temperature</li> <li>Long Cycle Time</li> <li>Large Footprint</li> </ul>	<ul style="list-style-type: none"> <li>High Temperature</li> <li>Long Cycle Time</li> <li>Large Footprint</li> </ul>	<ul style="list-style-type: none"> <li>Highly Dangerous Toxic Gas</li> <li>Long Sterilization / Purification Time</li> <li>Very Low Efficiency (2 cycles / day)</li> </ul>	<ul style="list-style-type: none"> <li>No Cloth Sterilization</li> <li>High Cost</li> </ul>	<ul style="list-style-type: none"> <li>No Cloth Sterilization</li> </ul>	

## Specification

	Contents
Size	433 x 614 x 437 (W x D x H, unit: mm)
Chamber	264 x 410 x 125 (W x D x H, unit: mm)
Capacity	14 Liter
Weight	67 kg
Input	100-120/220-240 VAC, 50/60 Hz
Power	1 kVA
Class	Class IIb (Rule 15, Annex IX of MDD 93/42/EEC)
Temperature	Less than 57°C
Sterilant (58% H <sub>2</sub> O <sub>2</sub> )	Pouch Mode: STERPACK®
	Pouch Plus Mode: STERPACK® Plus
	Chamber Mode: STERLOAD®
Pouch Mode (STERPACK®)	SR™ / SC™ Cycle: 3-6min Sterilization Cycle: 4 min Overall: 7-10 min
Pouch Plus Mode (STERPACK® Plus)	SR™ / SC™ Cycle: 6-10 min Sterilization Cycle: 8 min Overall: 14-18 min
Chamber Mode (STERLOAD®)	SR™ / SC™ Cycle: 21 min Sterilization Cycle: 15 min Overall: 36 min
Display	7 inch TFT LCD Touch Screen

## Dimension (unit: mm)





# Plasmapp Worldwide

Plasmapp is leading the industry with excellence in technology and ethical practice. Welcome to be Plasmapp's Global Partner!

# Sterilant cassettes, Consumables and Accessories

## Sterilant cassettes



### STERPACK®

Impermeable pouch containing sterilant for POUCH mode

- Size: 135mm x 280mm
- Material: PP/NY
- Sterilant: Hydrogen peroxide (concentration: 58%)
- 1 cycle per pouch



### STERPACK® Plus

Impermeable pouch containing sterilant for POUCH Plus mode

- Size: 240mm x 410mm
- Material: PP/NY
- Sterilant: Hydrogen peroxide (concentration: 58%)
- 1 cycle per pouch



### STERLOAD®

Cassette containing sterilant for CHAMBER mode

- Size: 135mm x 42mm x 7mm
- Material: PC, PP
- Sterilant: Hydrogen peroxide (concentration: 58%)
- 1 cycle per cassette

## Consumables



### Tyvek® pouch (W 100)

Device sterile packaging pouch for CHAMBER mode

- Pouch width: 100mm
- Total length: 400mm
- Material: Tyvek® and Easy-Peel film
- 1 cycle per pouch



### Tyvek® pouch (W 200)

Device sterile packaging pouch for CHAMBER mode

- Pouch width: 200mm
- Total length: 400mm
- Material: Tyvek® and Easy-Peel film
- 1 cycle per pouch



### Tyvek® pouch (W 300)

Device sterile packaging pouch for CHAMBER mode

- Pouch width: 300mm
- Total length: 400mm
- Material: Tyvek® and Easy-Peel film
- 1 cycle per pouch

## Accessories



### Special Cart

Cart with locking wheel

- Size: 483mm x 660mm x 603mm
- Weight: 37kg



### Label-Printer

External thermal printer

- Size: 120mm x 102mm x 146mm
- Weight: 0.5kg
- Thermal paper width: 56mm



### STERSEAL®

Rotary sealer by HAWO

- Size: 505mm x 255mm x 145mm
- Weight: 12kg
- CE, ISO 11607
- Preset STERPACK® sealing mode



### Label Sticker Roll

Label sticker roll for label-printer

- Roll width: 56mm
- Roll length: 49 labels



### Chemical Indicator Tape

Chemical indicator for sterilization cycle monitor

- Tape width: 19mm
- Length: 55m
- Expiration date: 12 months after manufacturing date



### Chemical Indicator Strip

Chemical indicator for sterilization cycle monitor

- Size: 16mm x 100mm
- Expiration date: 12 months after manufacturing date



# Plasmapp Co.,Ltd.

Plasmapp is an innovative manufacturing company specializing in plasma technology. Based on the core technology of KAIST plasma physics laboratory, we are creating a market with differentiated products in the medical and industrial plasma device industries. Developed for medical markets, the world's first direct injection technology is certified and commercialized.

In the industrial plasma device market, we have developed and commercialized a plasma source (LJPS®) capable of stable surface treatment at atmospheric pressure, thus improving the productivity of the secondary battery manufacturing process.

Think Plasma, Think Plasmapp!

Plasmapp Co.,Ltd. Values innovation, diligence, creativeness and technical know-how to create smart plasma applications to satisfy every needs of plasma-tech industry. It is our mission to provide high quality and cutting-edge plasma solutions.

Best regards,  
CEO of Plasmapp  
Youbong Lim

## History

- 
- 2014**
    - Aug 01 Start-up as an individual business of Plasmapp (Gas Discharge Physics Lab. In KAIST)
  - 2015**
    - Mar 31 Incorporation of Plasmapp Co., Ltd.
    - Jul 22 Approval of venture company by SBC
    - Jul 23 Financial Investment (seed funding) from BPP
    - Sep 01 Dream Venture Star in Daejeon supported by SKT
    - Oct 01 TIPS Project supported by SMBA
    - Oct 27 Establishment of Plasmapp Research Lab
    - Dec 15 Financial Investment of Series-A from 3 VC's certified by SBC including Samsung
    - Dec 23 Selected as a KRIBB family company
    - Dec 30 Strategic Investment of Series-A from medical angel investors
  - 2016**
    - Jan 07 Establishment of Plasmapp SPP factory in Jukdong, Yuseong, Daejeon
    - Oct 10 Financial Investment of Series-A from 2 VC's
    - Oct 12 Laboratory construction investment agreement MOU with Daegu Metropolitan City
    - Dec 01 Establishment of Sales office in Seoul
  - 2017**
    - Jun 07 Exclusive distribution agreement with SaMT for South Korea market
    - Jul 07 Financial Investment of Series-B from SVC's including LB investment
    - Dec 01 Establishment of STERPACK factory in Osan
    - Dec 15 CE MDD Certification
  - 2018**
    - Jan 03 Selected as K-Global 300 company
    - Jan 31 Korean FDA certification (Model: STERLINK® FPS-15s Plus)
    - Mar 21 CE MDD certification (Model: STERLINK® FPS-15s Plus)
    - Jul 23 Certificate of Inno-Biz
    - Sep 10 Opening ceremony of Daegu branch