ON-DEMAND
Low-Temperature Plasma Sterilization

Plasmapp

Plasmapp

STERLINK
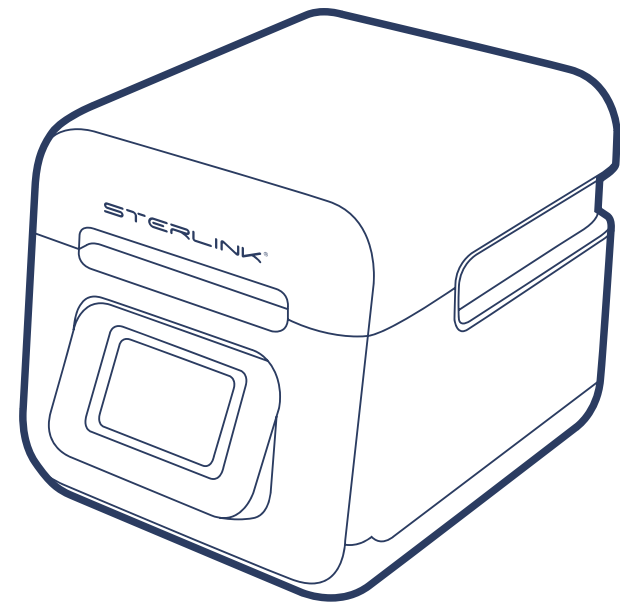Low Temperature Plasma Sterilizer

CE
0068
CE (MDD)

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM
MDSAP certificate

TÜV Rheinland
EN ISO 13485:2016

KFDA
KFDA certificate

GMP
GMP certificate

Grand prize, SIIF2016
Gold prize, SIIF 2018

RoHS
RoHS Compliance

c UL us
LISTED
LABORATORY EQUIPMENT
E502914

STERLINK®

Introducing

STERLINK ®

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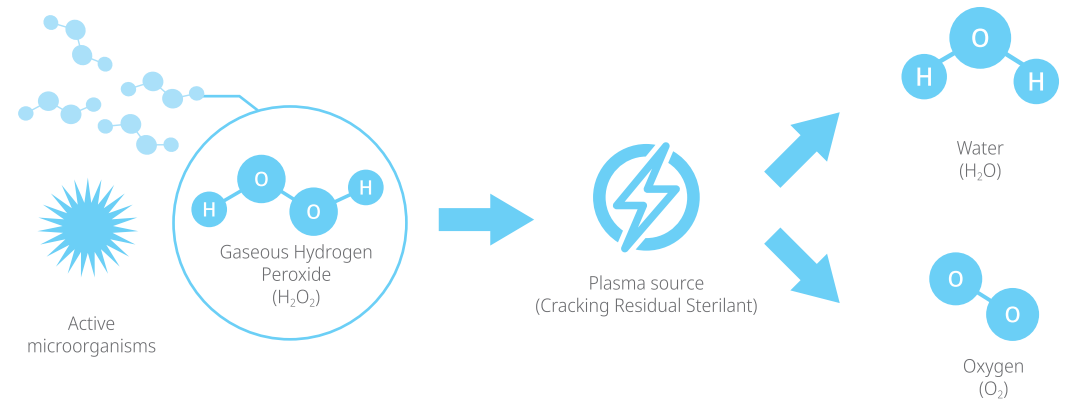## to sterilize a wide range of medical devices

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.

Active microorganisms

Gaseous Hydrogen Peroxide (H_2O_2)

Plasma source (Cracking Residual Sterilant)

Water (H_2O)

Oxygen (O_2)

Hydrogen Peroxide Sterilization

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

STERLINK® Overview

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 safety 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_2O_2 58%-59.5% (0.1 cc/cell)

SR™ / SC™ Cycle: 3-6 min
Sterilization Cycle: 4 min
Overall: 7-10 min
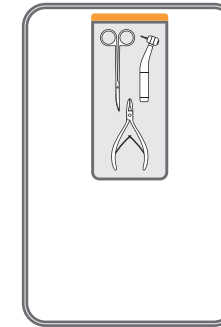
STERPACK® Plus (Pouch Plus Mode)

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_2O_2 58%-59.5% (0.3 cc/cell)

SR™ / SC™ Cycle: 6-10 min
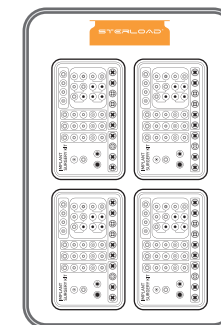Sterilization Cycle: 8 min
Overall: 14-18 min
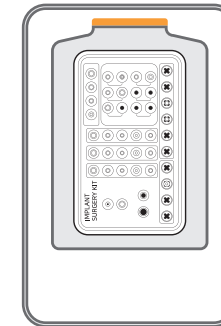
STERLOAD® (Chamber Mode)

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_2O_2 58%-59.5% (0.9 cc/cell)

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^{-6} 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
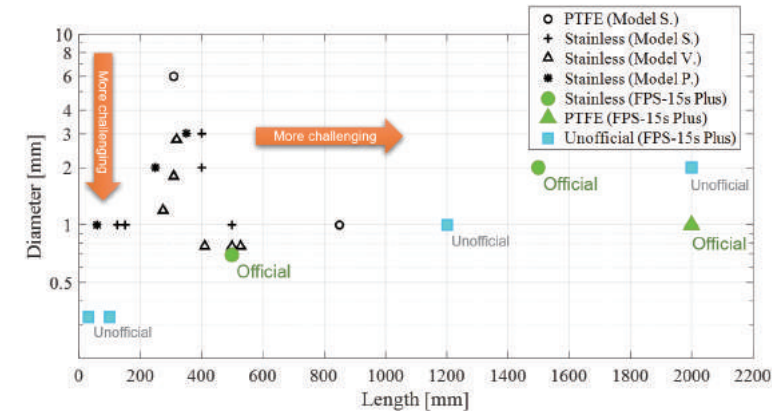
Lumen claims for STERLINK®

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^{-6}. 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.
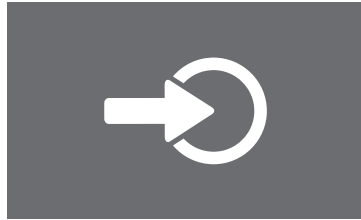

Before Sterilize   Success   Fail

STERLINK® Sterilization Process
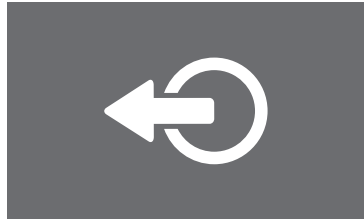
Base Pumping

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.
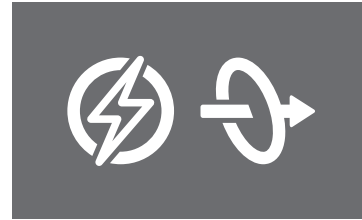
Plasma purification / Vacuuming

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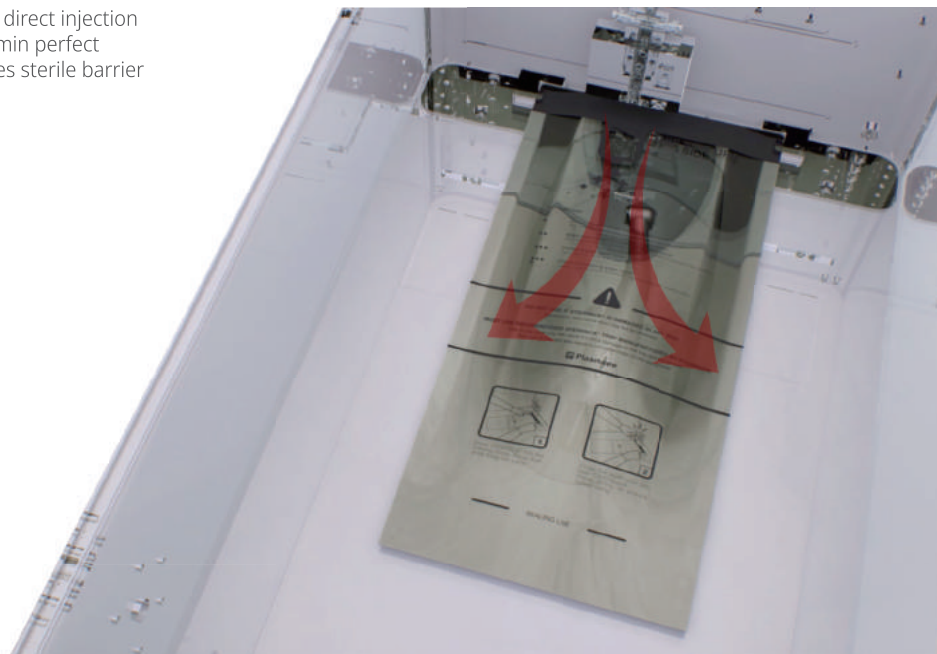
Patented Vaporizer Technology

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.
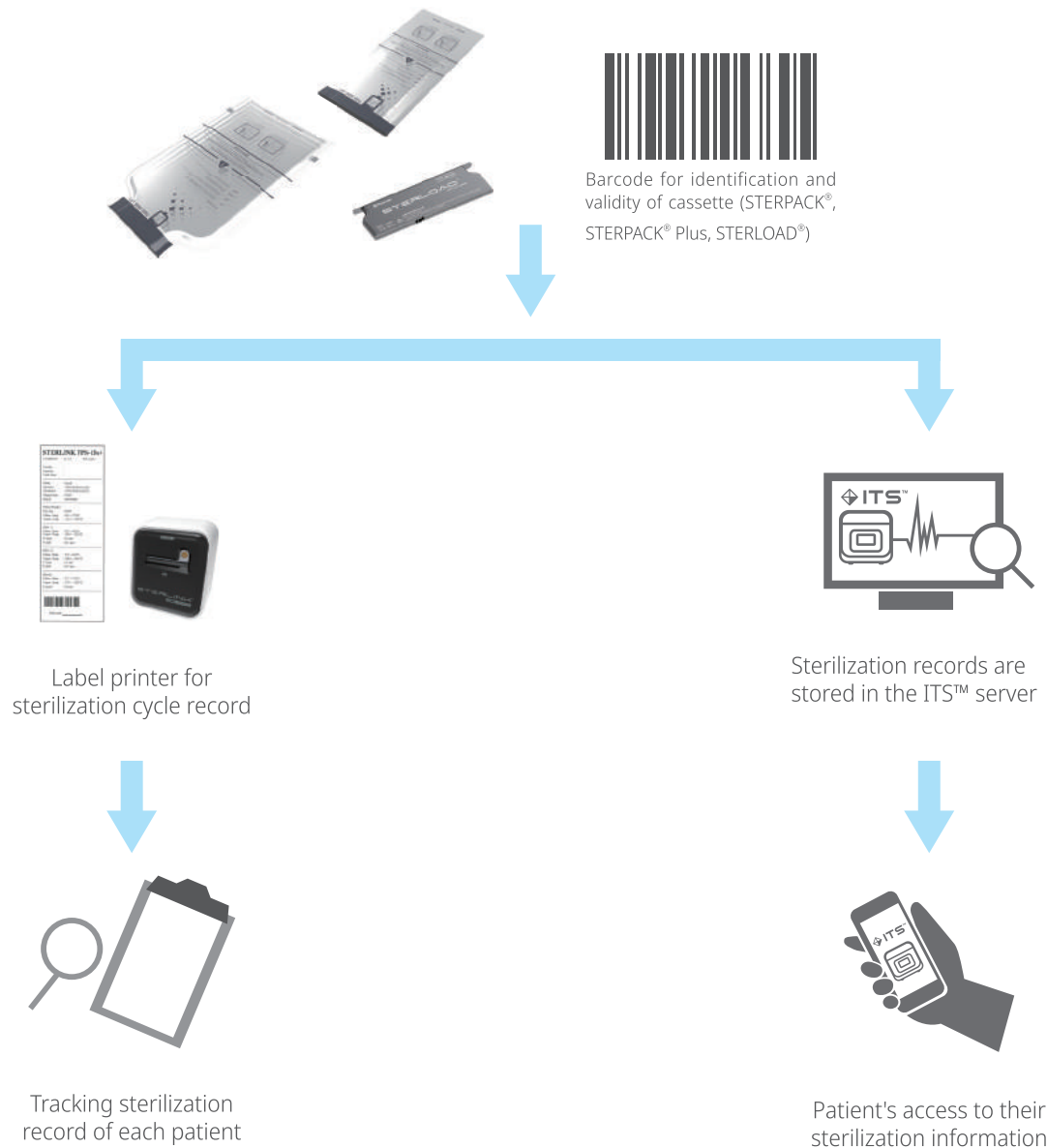

Plasmapp's low temperature plasma sterilizer (STERLINK®) guarantees a sufficient vacuum of more than 99% with German-made PFEIFFER Vacuum pump, and provides the patented vaporizer technology of Plasmapp.
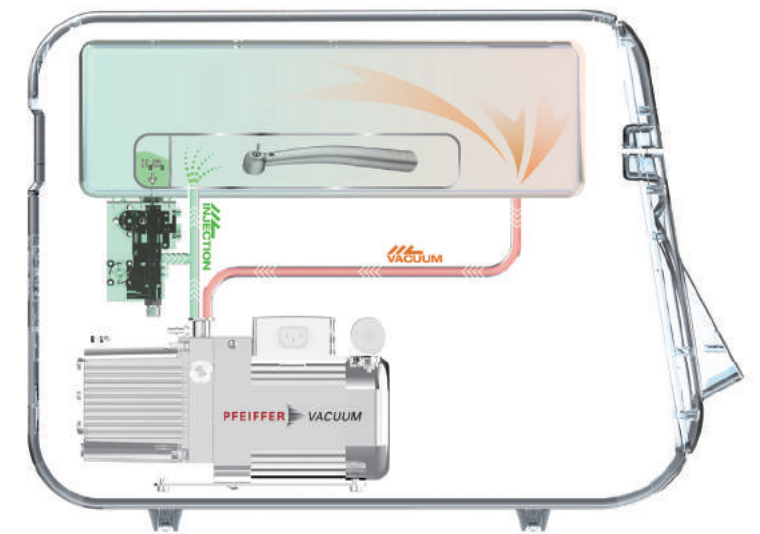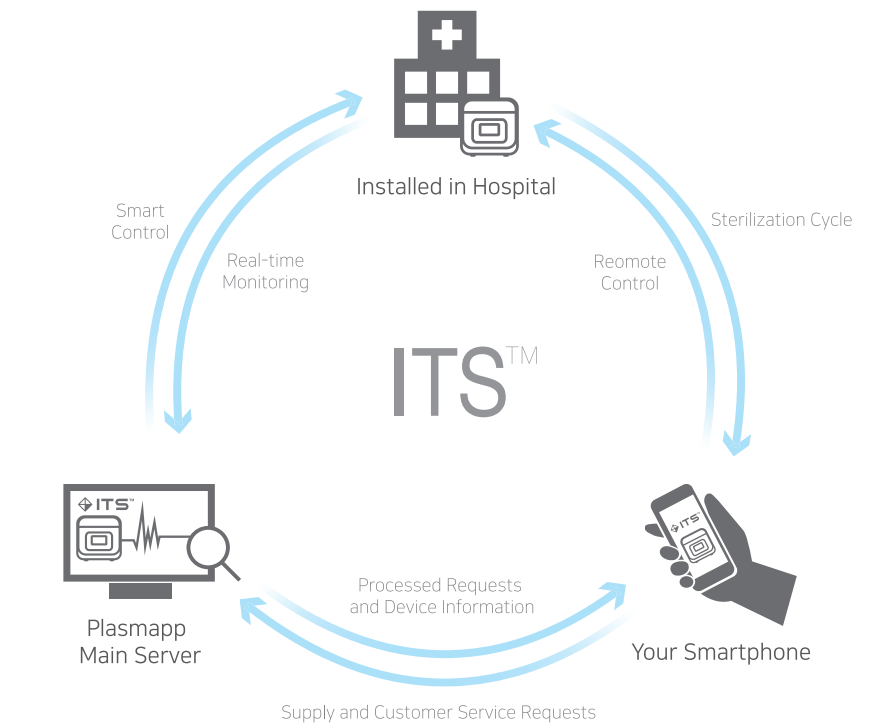
Sterilization Reliability

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.

Barcode for identification and validity of cassette (STERPACK®, STERPACK® Plus, STERLOAD®)

Label printer for sterilization cycle record

Sterilization records are stored in the ITS™ server

Tracking sterilization record of each patient

Patient's access to their sterilization information

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™

Installed in Hospital

Smart Control

Real-time Monitoring

Sterilization Cycle

Reomote Control

Plasmapp Main Server

Processed Requests and Device Information

Your Smartphone

Supply and Customer Service Requests

- 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™
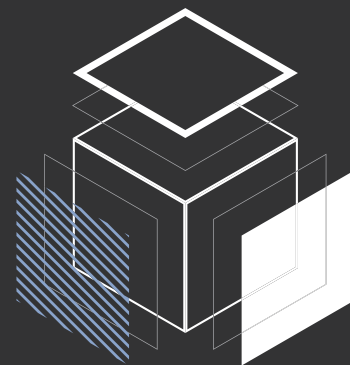
Starting sterilization cycle

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.
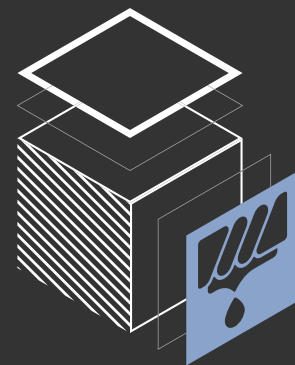
2. Moisture Removal

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®
Operating Temperature	Up to 134℃	Up to 180℃	Up to 57℃	Up to 57℃	Up to 57℃ — **Low Temperature** Sterilization of heat-sensitive medical instruments
Cycle Time	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.	Sterilization Process Time Pouch Mode : 4 min Pouch+ Mode : 8 min Chamber Mode : 15 min — **Various Modes** Flexible environment for various situations
Sterilant	Hot Steam	Hot Air	E.O. Gas	H_2O_2 (with plasma)	H_2O_2 Direct Injection (with plasma) — **Definite Sterilization Method** Sterilization performance by direct sterilization to medical instruments
Advantage	• Cloth Sterilization Possible • Large Volume	• Cloth Sterilization Possible • Large Volume	• Low Temperature	• Eco-Friendly • Low Temperature	Economic Cost Small Size Ergonomic Design — Easy Maintenance Eco-friendly
Drawbacks	• High Temperature • Long Cycle Time • Large Footprint	• High Temperature • Long Cycle Time • Large Footprint	• Highly Dangerous Toxic Gas Long Sterilization / Purification Time • Very Low Efficiency (2 cycles / day)	• No Cloth Sterilization • High Cost	No Cloth Sterilization

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℃
Sterilant (58% H_2O_2)	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%-59.5%)
- 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%-59.5%)
- 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%-59.5%)
- 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
- 250 strips per box

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 (KAIST Physics Laboratory Startups)

2015
Mar 31	Incorporation of Plasmapp Co., Ltd.
Jul 22	Approval of venture company by SBC
Jul 23	Seed Funding (TIPS Program Operation VC: BPP)
Oct 27	Establishment of R&D center
Dec 23	Series-A Funding (Including Samsung Venture Investment Cooperation)

2016
Jan 07	Establishment of Daejeon STERLINK® factory
Aug 04	GMP certificate for Daejeon STERLINK® factory
Aug 30	ISO 13485 certificate for Daejeon STERLINK® factory
Oct 12	Laboratory construction investment agreement MOU with Daegu city
Dec 01	Establishment of Sales office in Seoul
Dec 01	Commendation for Venture Company from Ministry of Trade, Industry and Energy
Dec 01	Grand Prize at Seoul International Invention Exhibition (Plasma Source)
Dec 01	Silver prize at Seoul International Invention Exhibition (Plasma Sterilization Packaging)

2017
Jun 07	Series-B funding (Including LB Investment)
Jul 24	Korean FDA certificate for STERLINK®
Dec 01	Establishment of Osan STERPACK® factory
Dec 15	CE MDD certificate for STERLINK®

2018
Jan 03	Selected as K-Global 300 company
Jul 23	Certificate of Inno-Biz Company from Ministry of SMEs and Startups
Sep 10	Opening ceremony of Daegu branch
Nov 20	cUL certificate for STERLINK®
Dec 08	Gold Prize at Seoul International Invention Exhibition (STERPACK® & STERLINK®)
Dec 24	ISO 13485 certificate for Osan STERPACK® factory

2019
Jan 09	Conversion of ISO 13485:2016 Certificate for Daejeon & Osan factory
Mar 26	GMP certificate in Daegu branch
Apr 12	CE MDD certificate for STERPACK®
Apr 25	Series-C Funding (Including Samsung Venture Investment Cooperation and LB Investment)
Apr 26	MDSAP certificate (STERLINK® factory in Daejeon & STERPACK® factory in Osan)
Apr 26	Korean FDA certificate for STERLINK® MINI