



## PL Series Low temperature Sterilizers

Vaporized H<sub>2</sub>O<sub>2</sub> sterilizers for hospitals, CSSDs and medical centers





## Customization. Innovation. Excellence.

### **Driven by customer needs**

Steelco is a leading infection control solution provider, supplying the healthcare, laboratory research and pharma sectors. Active in over 100 countries, Steelco has equipped numerous world renown hospitals and counts among its customers household names in the laboratory, pharmaceutical and industrial sectors.

Driven by customer feedback, Steelco develops, manufactures and supplies solutions that maximize infection control safety, optimize processes and minimize costs. Already a leader in innovation in areas such as automation, the integration within Miele organization has provided additional boost in technological development.

Steelco provides technical service and user training courses at the Steelco Academy as well as at customer sites. Our optional remote diagnostics capabilities and worldwide team of factory trained engineers ensure that you receive the service support you need to cost effectively maximize the uptime of your equipment.





## **Steelco PL Series**

## Low temperature Vaporized H<sub>2</sub>O<sub>2</sub> Sterilizers



**PL 40** 



Single hinged door, manual opening toward left

chamber volume 52 l option: on stand cabinet





Single or double hinged door manual opening towards left chamber volume up to 84 l



Single or double vertical sliding down door, automatic opening

chamber volume up to 148 l

# **Key Advantages** a winning combination

Innovative low-temperature vaporized hydrogen peroxide sterilization VH<sub>2</sub>O<sub>2</sub> technology that guarantees:

- Patient safety.
- · Ease of use.
- Delicate processing of instruments.
- · High safety for the operator.

The PL series guarantees the same levels of performance and safety regardless of chamber size.

#### Steelco sterilizers conform to:

European Directive for Medical Devices:

• 93/42/EEC and its revised versions

Technical norms and standards:

- EN ISO 14937 (ANSI/AAMI)
- EN ISO 14971
- UNI EN ISO 17665-1
- IEC EN 61010-1
- IEC EN 61010-2-040
- EN 62366-1
- IEC EN 61326-1



The ability to safely and effectively sterilize complex and delicate instruments, such as minimally invasive surgery instruments sensitive to heat and humidity, flexible, rigid endoscopes, or robotic surgery is increasingly required.

The PL Series guarantees a quality process without waste and interruptions.

The release of  $H_2O_2$  in the external environment is almost nil and much lower than all international guidelines. The  $H_2O_2$  concentration measured in independent tests is  $\leq 0.007$  ppm.



The dimensions of sterilization chambers and load combinations possible with removable shelves and accessories such as baskets and inserts meet diverse reprocessing needs.

All models in the series have 5 programs to be able to process a wide serie of instruments and loads.



Thanks to an accurate dosage of hydrogen peroxide and to advanced control of the exposure of the load to the sterilizing agent, the  $^{\prime\prime}H_2O_2$  total dose" guarantees the correct balance between sterilization effectiveness and material compatibility of the treated instruments.

The independent measurement of the process is assured with a range of indicators enabling the correct release of the processed load.



The PL Series maximize workflow optimization and ergonomy with process safety, guaranteed thanks to RFID technology.

Each different size of the sterilizer ensures the best ratio between machine size and usable load volume also for the benefit of easy integration into the barrier whilst providing good service access.

# Efficiency & Safety coming together



#### The sterilization process

Sterilization occurs by injecting vaporized hydrogen peroxide  $VH_2O_2$  into the sterilization chamber with the sterilizing agent being in contact with the outside and inner lumens of the load.

After the instruments have been exposed to the sterilization phase, the plasma phase is used to decompose hydrogen peroxide into safe elements of water vapor and oxygen to guarantee **the absence of hazardous residues**.



## Humidity level check performed at the beginning of each cycle

Removal of excess moisture from the load is done automatically before running each cycle. Control of the humidity level in the chamber in real-time at the beginning of the sterilization cycle prevents unwanted aborted cycles.

Processes with excessive humid loads are interrupted without the sterilizing agent cartridge being used, thus saving considerable of time and costs.



### **Continuous monitoring of the process**

Chamber pressure and temperature are monitored with redundant sensors. All process data are recorded and made available for traceability also in the paper printout. Each deviation from pre-established process parameters is notified by visual and audible alarms.



### Plasma generator outside the chamber

The external plasma generation system guarantees better protection of the reprocessed instruments and, at the same time, ensures high load capacity and reduction of alarms.



#### **Leak Test**

For best practice, a daily vacuum test in the Steelco PL sterilzer range can be programmed for automatic activation.



No dangerous release of H<sub>2</sub>O<sub>2</sub> at the end of the process!

Triple safety system for the reduction of hydrogen peroxide release:

- + Plasma generator outside the chamber
- + Platinum catalytic converter
- + Additional active carbon filter

	PL range	Reference	ppm	mg/m³
		OSHA PEL-TWA	1	1,4
	< 0.007 nnm	ACGIH TLV-TWA	1	1,4
PEL-TWA	≤ 0,007 ppm (≤ 0,010 mg/m³) OSHA method 1019	NIOSH REL-TWA	1	1,4
	OSHA Method 1019	ECHA OEL-TWA	1,4	
		MAK	0,5	0,7

OSHA, ACGIH, NIOSH, ECHA and MAK are bodies that establish universally recognized guidelines and maximum acceptable values.

# Safety & Performance coming together

The effectiveness of sterilization and the delicate handling of instruments are in perfect balance in the Steelco PL series



#### **Controlled exposure**

The process involves a sterilization temperature between 50 °C and 55 °C. Exposure to the sterilizing agent is split into 4 separate pulses. Thus, it avoids prolonged contact with high concentrations of hydrogen peroxide, which could damage instruments, ensuring that the load is exposed to a limited "H<sub>2</sub>O<sub>2</sub> total dose".

The plasma generation takes place without further heat in the chamber, avoiding the development of possible overheating, which is harmful to the most delicate instruments.

- + Safe one-shot cartridge: cycle cost guaranteed
- Ergonomic and fast front loading cartridge system with "poka-yoke" design
- + RFID identified sterilant cartridge to check expiry date, for traceability and to avoid misuse
- ◆ Zero risk of waste cartridge due to cycle interruption due to loading errors or excessive humidity
- Plastic cartridge without chemical residue at the end of the cycle even in the event of an interrupted cycle
- + Cartridges are suitable for sea and air shipment



#### The SteelcoPro PL sterilizing agent

The sterilizing agent is packaged in single-dose or double-dose sealed cartridges, depending on the model. The low volume of the cartridges considerably reduces the risks for the operator related to their handling compared to the handling of large bottles





### 5 high performance validated cycles

- Fast, dedicated to non lumened instruments with and without articulations
- Flex, for flexible endoscopes, including DaVinci® instruments
- Standard, for mixed loads: flexible, rigid, and semi-rigid lumens and nonlumened instruments
- Intensive, for mixed loads: flexible, rigid, and semi-rigid lumens and nonlumened instruments with more challenging dimensions
- Superfast, ultra-fast cycle for reduced loads that can be activated as an option on all models of the PL range.



### **Excellent penetration into hollow instruments**

Lumens:  $\emptyset \ge 0.5$  length  $\le 2200$  mm. (single, double, and triple channel)



### Quick recognition with RFID or Barcode readers

All the devices have the option of the Barcode or RFID scanner for rapid recognition of the operator, the load, and starting cycles.

Sterilizazion		PI	L 40			Р	L 70			PL	. 130	
programs*	Time min.	Kg max	Lumens	Iniziali- zation	Time min.	Kg max	Lumens	Iniziali- zation	Time min.	Kg max	Lumens	Iniziali- zation
Fast	24	11.8	No	+4 min	29	13.5	No	+3 min	27	19.5	No	+3 min
Flex	36	3.5	1 flex. endo	+4 min	39	5.5	1 flex. endo or 1 da Vinci	+3 min	37	10.5	2 flex. endo or 2 da Vinci	+3 min
Standard	51	5.5	12 max	+4 min	56	5.5	12 max	+4 min	48	10.3	22 max	+4 min
Intensive	58	3.5	3 max**	+4 min	62	4.5	3 max**	+4 min	60	6.5	3 max**	+4 min
Superfast	21	1.5	No	+4 min	22	2.2	No	+2 min	20	5.5	No	+2 min



<sup>\*\*</sup> Intensive cycle allows the sterilization of the most challenging hollow instruments.
\* In order to support validation procedures selected users are allowed to execute password protected half cycles. Additional sterilization programs can be added and validated by the customer.

# Safety & Performance coming together

In a safe sterilization process, the correct release of the load is a fundamental step.



### **Biological and chemical indicators**

Steelco PL sterilizers are complemented by a complete range of chemical and biological indicators, including quick reading solutions. The range also comprises packaging tape, incubators, and PCDs.



VH<sub>2</sub>O<sub>2</sub> **30 mins** self-contained biological indicators and **Rapid Read Incubator** (suitable also for steam, formaldehyde, and EO)



VH<sub>2</sub>O<sub>2</sub> **24 hours** self-contained biological indicators and **Incubator** (suitable also for steam, and EO)



VH<sub>2</sub>O<sub>2</sub> **Type 4** and **Type 1** indicators also available as adhesive label.







#### PCDs (process challenge devices)

The Steelco PCD range includes dedicated lumens, both rigid and flexible. When used in combination with biological and chemical indicators, they allow to verify the correct exposure to the sterilizing agent and ensure the proper release of the load.





# Ergonomics & Workflow coming together

Easy, quick, and safe loading and cycle start operations for a workflow without any interruption



#### **Compact design**

The "sliding door" solution that can also be operated by a pedal on the PL 130 model **reduces overall dimensions** and facilitates "hands-free" loading of the instruments.

The PL 70 and PL 40 models also offer **ease of operation** thanks to a small **hinged door**, making them the most compact in relation to the load capacity.

All the models have a rectangular sterilization chamber to accommodate the most frequently used accessories for packaging and loading.

Loading operations always take place at an ergonomic height.

### Immediately available

The models of the PL series are all **Plug & Play**, ready to be started quickly in any location.

They are equipped with **lockable pivoting wheels** for maximum ease of handling, even in confined spaces.





# Easy configuration & Productivity coming together

Being flexible in accepting different loads and, at the same time, preventing possible incorrect loading is the key for your productivity goals!



#### **Easy loading**

The design of semi-extractable shelves prevents incorrect positioning of the load for the benefit of process safety, reducing alarms or frequent interruptions in devices of this type.

All models are equipped with a **removable top shelf** to make the most of the height capacity.

Model	Chamber	Height	Shelves	Baskets	Inserts	Pouches capacity
DI 40			2	C1722	C1723	16
PL 40	PL 40,	230 mm	2	C1724*	C1725	6
DI 70	PL 70	220 mm	2	C1683	C1706	12
PL 70		220 111111		C1003	C1682	20
PL 130		175 mm	2	C1683	C1706	12
		175 mm		C1003	C1682	20

<sup>\*</sup> Half size loading basket

#### Perfect range of accessories

In addition to the removable shelves supplied, Steelco offers optional **baskets and inserts** for the correct arrangement of even the bulkiest loads.

These accessories guarantee excellent loading flexibility in relation to the choice of the cycle and an adequate diffusion and penetration of the hydrogen peroxide vapor.









### Reprocessing of \*da Vinci® optics

Validation of device compatibility and sterilization efficacy of the Steelco PL 130 and PL 70 using the FLEX cycle for "da Vinci" Si/X/Xi endoscopes. Load configuration: single tray on bottom shelf.

\* The "da Vinci" trademark and logo are registered trademarks of Intuitive Surgical, Inc.

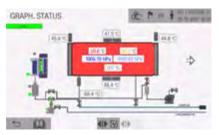


# Flexibility & Control coming together

The large 7" and 10" touchscreen control panel facilitates device control with bright, easy-to-read information even from a distance: an intuitive and practical aid for operators in their daily tasks.

In addition, the well-thought-out and userfriendly design and touch screen is consistent throughout the portfolio of Steelco devices, supporting intuitive operation and reliable processes.





#### A user friendly interface

Operators are supported in every step of their interaction with the device with clear and easy to understand operation tasks. Cycle programs can also be selected via barcode or RFID scanner.

The touch screen panel displays highly visible cycle status and alarm messages.

#### Cycle data storage

Cycle data are stored and available from the integrated printer and, if the device is connected to the network can be sent to a centralized traceability system.

#### **User access levels**

User access is split into 5 levels to ensure that only trained staff have access to specific functions: operator, department manager, service technician at the customer's site, authorized service technician, and manufacturer.

#### **Technical service mode**

The sterilizer is designed to simplify maintenance. Technical service interventions are speeded up by the availability of dedicated screens, including an easy-to-read synoptic that provides an overview of the active components and the values of the most critical parameters of the process.





## SteelcoData Live & Pro Management & traceability system



To ensure the availability of the right instruments in the right place at the right time, reprocessed to the correct standard in the minimum amount of time, and the lowest cost consistently.

#### **SteelcoData Live**

is a web based software allowing to see in real time machine performance, cycles data, and alarms with historic records. When available from the device, utility consumption are also stored. Information is traced and efficiently visualized for device monitoring and data management with different authorisation levels.

SteelcoData Live is also the link between Steelco machines and instrument traceability systems such as SteelcoData Pro

#### SteelcoData Pro

provides you the possibility to track sets as well as individual instruments from their point of use in the OR through each stage of and reprocessing, transportation and storage until they are ready to be used again.

#### Software features:

- Respects HL7 standard
- + Reliable information and data entirety



- + Traceability and backward traceability of user activities and material handling
- + Full coverage of activities in the CSSD
- Real-time analysis
- + Efficiency improvement tools
- + Procedure automation, no unnecessary steps
- Workstations can display only activities in the specific user's area of competence
- + Effective information sharing with customers
- Can be integrated with other client software systems

## **Capacity and Dimensions**

Layouts and configurations

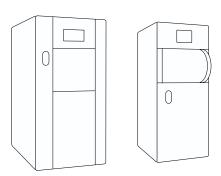


Model	Chamber (WxHxD) - mm			Litres	Overall (WxHxD) - mm		
Single door							
PL 40/1	350	230	640	51,5	535	930	777 (*)
PL 40/1 on stand cabinet						1630	` '

(\*) footprint (for outer dimensions add 53 mm of the door handle protrusion). Loading height: 1050 mm above finished floor when on stand closed cabinet.

#### standalone

PL 70 - PL 130



Model	Chamber (WxHxD) - mm			Litres	Overall (WxHxD) - mm		
Single door							
PL 70/1	450	220	825	81,7	642	1630	920 (*)
PL 130/1	450	400	795	143,1	770	1685	1040
Double door							
PL 70/2	450	220	850	84,1	642	1630	990 (*)
PL 130/2	450	400	820	147,6	770	1685	1070

(\*) footprint (for outer dimensions of PL 70 add 50 mm of the door handle protrusion). Loading height: PL 70, 1020 mm above finished floor - PL 130, 920 mm above finished floor

## **Technical Data**

### Components and versions

		Low Temperature Sterilizers					
	PL 40						
		Basic Advanced	Basic Advanced				
Sterilant							
SteelcoPro PL cartridge capacity	10 ml / 2 shots	7.5 ml / 1 shot	12 ml / 1 shot				
Chamber and doors							
Vertical sliding door	-	-	•				
Hinged door	•	•	-				
Chamber and door (s) material	AISI 316 L	AISI 316 L	AISI 316 L				
Frame, panels material	AISI 304	AISI 304	AISI 304				
Technical area							
Frontal access for service	•	•	•				
Frame on wheels for easy machine transport/positioning	0	•	•				
Built-in compressed air system	•	0	0				
Control system and traceability							
Touchscreen HMI	7"	7"	10"				
Barcode reader or RFID scanner	0	0	0				
Built-in thermal printer on loading side	•	0	0				
SD card for cycle and data backup	•	•	•				
USB port for machine data backup	0	0	0				
Ethernet port for digital traceability (SteelcoData software)	•	•	•				
Built in UPS - Uninterruptible power supply	-	0	0				
One additional free contact	0	0	0				
Supply							
Electrical connection (other connections available on request)	220/240V 1~ 50/60Hz	380/415V 3-+N 50/60Hz	380/415V 3~+N 50/60Hz				
Process monitoring							
Redundant sensors for chamber press./temp. monitoring	•	•	•				
Plasma generator	•	0	0				
Moisture detection sensor	•	0	0				
Futher options							
Floor anchoring	-	0 0	0 0				
• = Standard • = Not available							





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