



PLS Set

Permanent Life Support (PLS) System

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

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The PLS System

A therapy option for intensive care patients

Developed to support patients requiring respiratory and/or circulatory support with blood flows from 0.5l/min to 7.0l/min.

The PLS Set is a preconnected circuitry with the minimum number of essential components in order to achieve unobstructed blood flow with little blood damage, that may contribute to better patient outcomes.

The Permanent Life Support (PLS) System consists of the Rotaflow Console, a PLS Set including the PLS-i Oxygenator as well as a broad range of HLS Cannulae. It fulfills the demanding requirements for extended application time up to 14 days (tip-to-tip Bioline Coating).

We put patients first

Getinge and its well known Maquet brand has put patients first for over a century.

That's why we remain committed to real world healthcare challenges supported by a close relationship with our clinical partners.



Extracorporeal Heart-lung Support System

Areas of application

The PLS System is an adult respiratory and/or circulatory support system for use in the intensive care unit, cardiac catheterization laboratory as well as operating, trauma¹ and emergency rooms validated with the CE certification for 14 days continuous use.*

In the intensive care unit the PLS System can provide appropriate extracorporeal support to adult patients with a wide range of life threatening conditions. These may include:

- Acute Respiratory Distress Syndrome (ARDS)^{1,2,3,4}
- Pulmonary Embolism²
- Septic Shock Syndrome¹
- Multiple Organ System Failure¹

In the catheter laboratory and cardiology department the PLS System can be used to provide urgent circulatory support with oxygenation in the event of sudden heart failure thus preventing organ damage.

Emergency medical situations can benefit from the availability and mobility of the PLS System.

Certain patients can benefit from the rapid restoration and stabilisation of cardiopulmonary functions that ECLS can offer.

The following indications may be appropriate for using the PLS System:

- Anaphylactic shock¹
- Intoxication⁴
- Sever hypothermia¹
- Barotrauma^{3,4}

Areas of application may include:

- Cardiogenic shock^{1,4,5}
- Stand-by or prophylactic support during high-risk PCI
- Cardiopulmonary assist after right heart infarction⁴
- Bridge to recovery, bridge to bridge, bridge to decision, e.g. to treat myocarditis⁴

In the operating room patients who need post-surgery circulatory support can be transferred onto the PLS System and moved to the intensive care unit easily². Also patients from the emergency and trauma rooms who need treatment in other hospital departments, e.g. for revascularisation or PTCA (Percutaneous Transluminal Coronary Angioplasty), can be placed on the PLS System and then moved to the operating room, catheter laboratory or intensive care unit. Areas of application may include:

- Cardiogenic shock^{1,4,5}
- Low cardiac output syndrome (LCOS)⁴
- Bridge to recover, bridge to bridge, bridge to decision⁴

* In combination with HLS Cannulae, also with Bioline Coating.



The PLS System consists of:

Hardware

- Rotaflow Console with ICU Kit
- Rotaflow Drive Unit
- Rotaflow Emergency Drive
- Holder

Disposables

- PLS Set, PLS Set Plus or HIT Set PLS Plus
- HLS Cannuale

The preconnected PLS Set

Comprise the following components

- **PLS-i Oxygenator**
- **Rotaflow Centrifugal Pump RF-32**
- **Tube connections**
- **Bioline Coating or Softline Coating**
- **Priming set**
- **Accessories**

The PLS Set

- Tip-to-tip tubing set also available with Bioline Coating
- Ensures safe and effective patient support and user management
- The low resistance of the PLS-i Oxygenator and the efficiency of the Rotaflow Centrifugal Pump reduce blood damage to a minimum⁵

The PLS-i Oxygenator

- Highly plasma-resistance polymethylpentene (PMP) fibers and a modified housing
- PMP fibers eliminate plasma leaks
- With an approval for 14 days continuous use, the need for oxygenator replacement is significantly reduced⁵

The Rotaflow Centrifugal Pump

- Improved blood handling and lower levels of pump-induced hemolysis⁵
- Centrifugal blood pump without shaft or seals
- The one-point sapphire bearing and the low priming volume combined with the spiral formed chamber ensures gentle blood handling⁵, and optimised flood flow.

The PLS Set Plus

- Two additional connectors with luer lock for hemofiltration or dialysis
- The renal replacement therapy (CRRT) device can directly be connected to the extracorporeal circuit

HIT Set PLS Plus

- Specifically designed for use on patients who are susceptible to heparin-induced thrombocytopenia
- Combined with HLS Cannulae, the HIT Set PLS Plus can be used for up to 5 days, both with Softline Coating.



Technical data

PLS Set

Total priming volume	ca. 585 ml (PLS Set with 2 x 2.2 m tube length)
Blood flow rate	0.5 – 7 l/min

PLS-i Oxygenator

Gas exchange surface area	1.8 m ²
Heat exchange surface area	0.4 m ²
Water connectors	1/2" Hansen coupling
Housing material	Polycarbonate (PC)
Oxygenation fibers	Polymethylpentene (PMP)
Heat exchanger fibers	Polyurethane (TPU)

Rotaflow Centrifugal Pump

Surface area	190 cm ²
Housing material	Polycarbonate (PC)

Rotaflow Console + Rotaflow Drive

RPM speed	0 ... 5000 rpm
Resolution of display	0.01 lpm
Flow rates	0 ... 9.99 lpm
Dimensions (W × H × D)	179 × 243 × 385 mm
Weight	Approx. 14.4 kg

Product order details

Product	Article no.	Coating	Connectivity
PLS Set	BE-PLS 2050	Bioline Coating	-
PLS Set Plus	BE-PLS 2051	Bioline Coating	Hemofiltration or dialysis
HIT Set PLS Plus	BO-PLS 2051	Softline Coating	Hemofiltration or dialysis

References

- ^{1.} Arit M. et al. Extracorporeal membrane oxygenation in severe trauma patients with bleeding shock. Resuscitation 2010; 81 (7): 804 - 809
- ^{2.} Schmidt C. et al. Venovenous extracorporeal membrane oxygenation for acute lung failure in adults. The Journal of Heart and Lung Transplantation 2011; 21 (1): 9 - 15
- ^{3.} Thiara APS. et al. Extracorporeal membrane oxygenation support for 59 days without changing the ECMO circuit: a case of legionella pneumonia. Perfusion 2009; Vol. 24; (1): 45 - 47
- ^{4.} Puehler T. et al. Extracorporeal membrane oxygenation. Old instrument with a new look? Z Herz-ThoraxGefasschir (4) 2011; 25: 209 - 216
- ^{5.} Yu K. et al. Clinical Evaluation of Two Different Extracorporeal Membrane Oxygenation Systems: A Single Center Report. Artif. Organs 2011; Vol. 35; (7): 736



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