

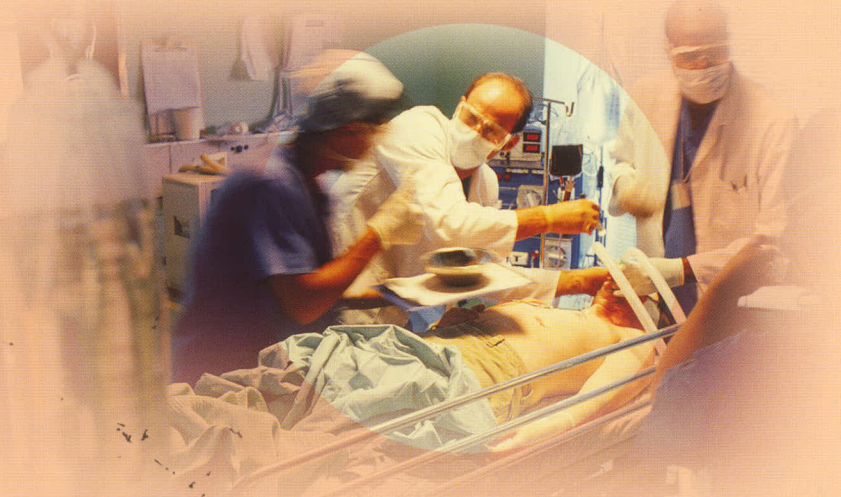
Endotoxin Removal Treatment

Sepsis is a serious clinical condition caused by infection. Sepsis can result in the cardiovascular dysfunction, leading to multiple organ dysfunction syndrome and death^{Ref.1)}. TORAYMYXIN™ is a direct hemoperfusion cartridge which is composed of polymyxin B covalently immobilized fibers^{Ref.2)}, removing blood endotoxin, and reduces the mortality due to severe sepsis and septic shock^{Ref.3)}.

Patients

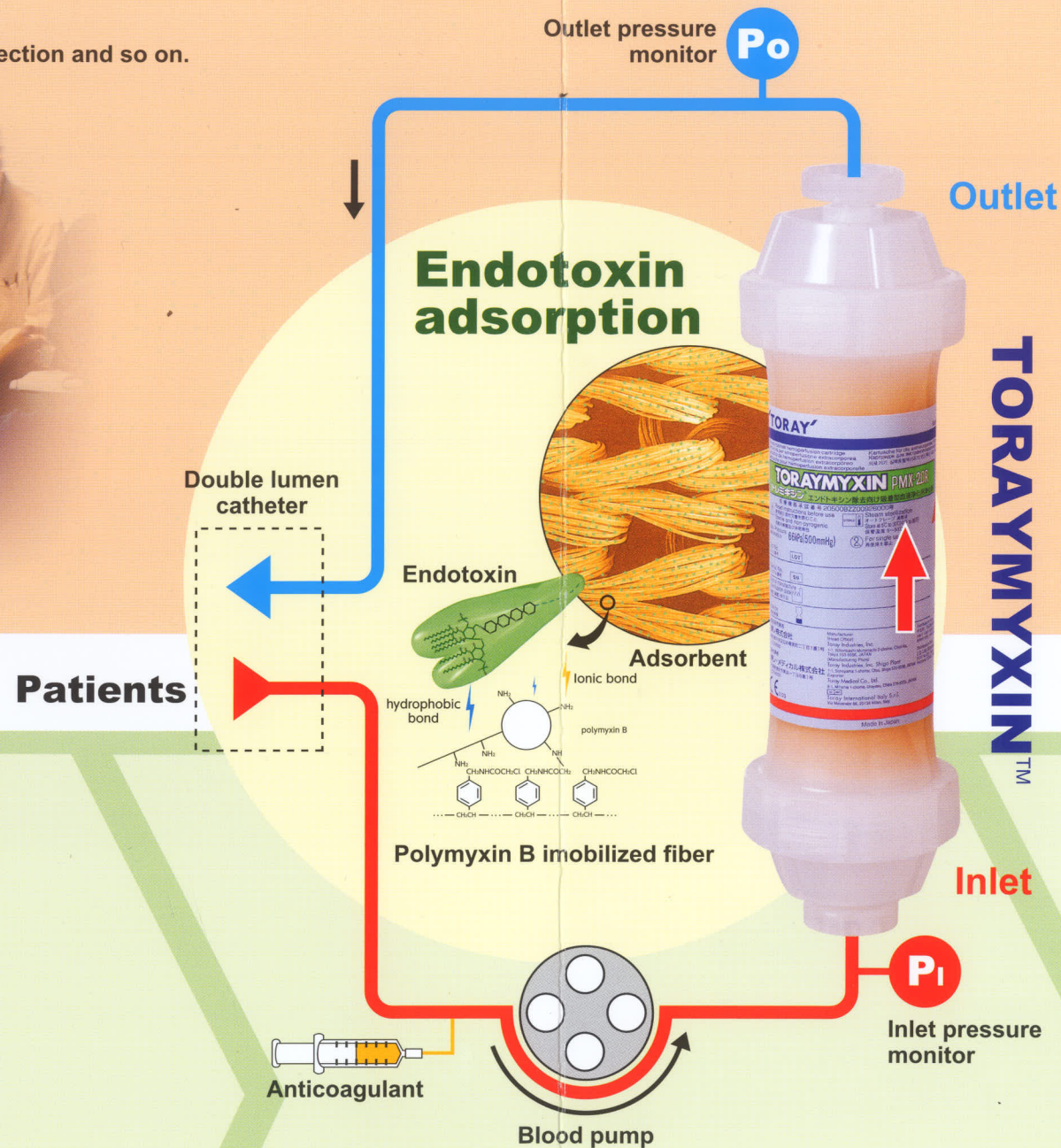
► Severe sepsis or Septic shock

- ◆ Due to peritonitis or severe pneumonia, urinary tract infection and so on.



*Sepsis is defined as systemic inflammatory response syndrome (SIRS) due to infection^{Ref.4)}.

Hemoperfusion procedure



Clinical Improvement^{Ref.5)}

- **Hemodynamics**
 - ◆ Blood pressure
 - ◆ Reduction of vasopressor requirement
- **Organ function**
 - ◆ Renal
 - ◆ Respiratory (Oxygenation)
- **Mortality**
 - ◆ 28 day-mortality
 - ◆ Hospital mortality

Procedure

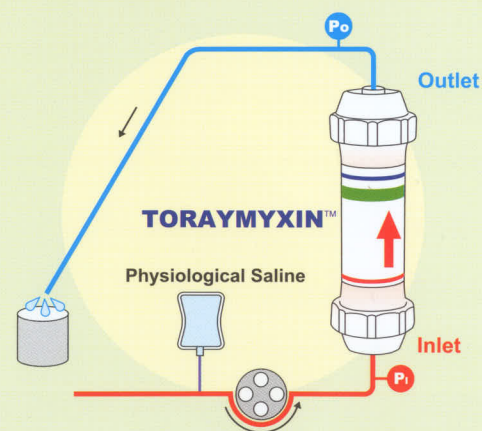
Rinsing and Priming

► Rinsing

- ◆ Physiological saline : at least 4 L

► Priming

- ◆ Heparinized saline (4 U/mL) : 500 mL

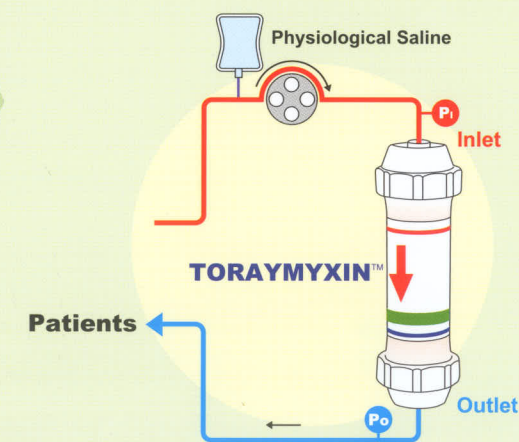


Note

- ◆ Flow the solution from bottom to top.
- ◆ At a flow rate of 100 mL/min.
- ◆ Not to enter air bubbles into the cartridge.
- ◆ Use 4 L or more of physiological saline solution for rinsing.
- ◆ Do not use the cartridge in case the presence of droplets on the inner surface of the pouch.

Ending

- Put the position of the cartridge upside down
- Flow physiological saline (100-200 mL)



Note

- ◆ At a low flow rate (approx. 50 mL/min)

Operating

- Blood flow rate : 100 (80-120) mL/min
- Duration : 2 hours
- Anticoagulant : Heparin
 - ◆ Bolus : 3,000 U
 - ◆ Continuous infusion : 20 U/kg body weight/hr

Note

- ◆ Closely monitor blood coagulation time.
- ◆ Maintain activated coagulation time (ACT) within 150-180 sec.
- ◆ Inlet pressure < 33 kPa (250 mmHg)
- ◆ Monitor the patient's symptom and vital signs (blood pressure, platelet counts, allergy).

TORAYMYXIN™ PMX-20R

Length	225 mm
Diameter (max)	63 mm
Priming volume	135 ± 5 mL
Fibers (dry weight)	56 ± 3 g
Inlet pressure	< 250 mmHg
Maximum pressure	500 mmHg
Sterilization	High-pressure steam sterilization
Expiration	2 years after sterilization

Operating procedure

Method	Direct Hemoperfusion (DHP)
Blood Flow Rate	100 (80-120) mL/min
Duration of DHP	2 hours
Rinsing	at least 4 L of physiological saline
Priming	500 mL of heparinized saline (4 U/mL)
Anticoagulant	Heparin 3,000 U as bolus, 20 U/kg body weight/hr as maintenance. The maximum maintenance dose allowed for any patient is 2,000 U/hr.

Equipment needed

A blood pump for extracorporeal circulation at a blood flow rate of 20-200 mL/min, monitors for inlet (Pi) and outlet (Po) pressures and an infusion pump for the administration of anticoagulants
Hemoperfusion blood tubing suitable for use with the hemoperfusion pump
12F or 14F double lumen catheter

Necessary components

Physiological saline: for rinsing (more than 4 L), for priming (500 mL), for ending (500 mL)
Anticoagulant (Heparin)

- Sterile •Single Use only •Do not re-use
- Do not use if the packaging is damaged or open
- Do not use if the sterilization indicator is whitish yellow
- **Read Instructions For Use carefully before use.**

Reference

1. Vincent JL et al.: Microvascular dysfunction as a cause of organ dysfunction in severe sepsis. Crit Care 9: S9-S12, 2005
2. Shoji H et al.: Extracorporeal endotoxin removal by polymyxin B immobilized fiber cartridge: designing and antiendotoxin efficacy in the clinical application. Ther Apher 2: 3-12, 1998
3. Cruz DN, et al.: Effectiveness of polymyxin B-immobilized fiber column in sepsis: a systematic review. Crit Care 11: 1-12, 2007
4. Bone RC et al.: Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. The Chest 101: 1644-1655, 1992
5. Cruz DN, Antonelli M, Fumagalli R. et al.: Early use of polymyxin B hemoperfusion in abdominal septic shock: the EUPHAS randomized controlled trial. JAMA 301: 2445-2452, 2009



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TORAY

Innovation by Chemistry

What's TORAYMYXIN™?

Endotoxin Removal for Patients with Severe Sepsis and Septic Shock



Extracorporeal Hemoperfusion Cartridge

TORAYMYXIN

PMX-20R