D2000 Cartridge
Operation Manual for Use of D2000 with the Terumo Spectra Optia™ Apheresis System

For use in the U.S. under FDA EUA200148: Authorization for Emergency Use in patients with COVID-19 admitted to the ICU with confirmed or imminent respiratory failure

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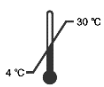
Explanation of Symbols

	Keep Dry		Sterilized by Steam
	Manufacturer Contact Information		Single Use Only
	Lot Number		Indicates Temperature Limits for Storage
	See instructions and warnings prior to use		Indicates Expiration Date

Manual Purpose

The purpose of the document is to provide instructions on the operation of the D2000 Cartridge with the Terumo Spectra Optia with Secondary Plasma Device (SPD) software. Clinicians should also refer to the Instructions for Use (IFU) for each respective device for full information on operation. The D2000 IFU is document number L.003.

Device Description

The Depuro D2000 Cartridge consists of a sterile, self-contained disposable Cartridge. The Cartridge is intended to assist in blood detoxification. It can be used in instances of drug overdose, hepatic encephalopathy, liver failure, in any condition which results in the release of endotoxin into the bloodstream, and in any condition which generates excess inflammatory response, such as sepsis, septic shock, or systemic inflammatory response syndrome (SIRS).

The Cartridge is integrated into the extracorporeal circuit, downstream from where the plasma is centrifuged. Treatment duration and indication for exchange of the cartridge depend on the clinical course. The maximum treatment time per single cartridge is 4 hours.

The instructions for use for the D2000 should be reference for detailed instructions on the operation of the D2000 Cartridge.

Indications

- The Depuro D2000 Cartridge is intended for adjunct use in the treatment of drug overdose and poisonings and in any condition that requires a reduction of metabolic waste products or inflammatory cytokines.
- The D2000 Cartridge filters plasma. It works with standard hospital equipment and blood lines and can be used when acute hemodialysis, apheresis, or therapeutic plasma exchange (TPE) is prescribed by a physician.

Contraindications

- The Depuro D2000 Cartridge should not be used in patients <18 years of age.
- The Depuro D2000 Cartridge should not be used in women who are pregnant or breastfeeding.
- The Depuro D2000 Cartridge should not be used in patients for whom treatment with an anticoagulant is inappropriate or are at increased risk for bleeding
- The Depuro D2000 Cartridge should not be used in patients with a known hypercoagulable condition manifesting in history of highly suspected deep venous thrombosis or pulmonary embolism.

Warnings

- Do not treat patients who are actively bleeding. If patients begin bleeding during a treatment, discontinue treatment.
- Due to the possibility of coagulation factor adsorption in the D2000 Cartridge, the use of this product in the treatment of patients who have a bleeding tendency must be approved by the responsible physician.
- Carefully read these Instructions for Use before performing filtration with the Depuro D2000 cartridge. Also consult and understand the plasma separator Instructions for Use.
- The D2000 Cartridge is for single use only. DO NOT REUSE due to risk of infection or contamination.
- The D2000 Cartridge is for use with plasma only and not for use with whole blood.
- Use proper aseptic technique during assembly and use to avoid contamination.
- The D2000 Cartridge must be fully primed before use by the procedure described in this manual.
- The D2000 Cartridge must be used only in accordance with the directions of a responsible physician who is familiar with the condition of the patient.
- During plasma purification, continuously monitor patient's condition and any possible reactions to the plasma purification process by observing physiologic parameters including body temperature, heart rate, respiratory rate, blood pressure, and coagulation time. In the event of any abnormality, suspend treatment in accordance with the directions of the responsible physician. D2000 Cartridge blood flow rate and anticoagulant flow rate must also be constantly monitored.

- If any problem occurs during treatment with the D2000 Cartridge, immediately ensure the safety of the patient and take appropriate measures, such as discontinuation of the treatment or replacement of the D2000 Cartridge or one or more of its individual components, in accordance with the directions of the responsible physician.
- Because of the possibility that some types of medication may be removed by adsorption during treatment, the type of medication, dosage, method and timing of administration must follow the instructions of the responsible physician. Before, during, or after treatment with the D2000 Cartridge, any medication must be administered only in accordance with the directions of the responsible physician and the precautions and instructions relevant to the medication.

Precautions

System Precautions: Before Use

- The D2000 Cartridge is not to be used after the expiration date has passed.
- The D2000 Cartridge must be stored in a clean, dry area, at 4-30°C (39-86°F).
- The D2000 Cartridge is comprised of plastic products and must not be exposed to excessive vibration or shock.
- The D2000 Cartridge is provided sterile and non-pyrogenic if its sterile barrier package and seal are intact.
- Do not re-sterilize.

- Examine each D2000 Cartridge paper peel pouch prior to use. Do not use any D2000 Cartridge device that appears to have been damaged or whose sterile-barrier seal has been broken.
- To avoid contamination, do not remove the D2000 Cartridge device from the sealed paper peel pouch until just before priming and assembly. Prime, assemble, and operate D2000 Cartridge using aseptic technique.
- Any D2000 Cartridge device showing signs of leakage or other abnormality during priming must be replaced, and the priming procedure restarted.
- The dosage of anticoagulant varies depending upon individual patients and should be determined by physician's instruction.

System Precautions: During Use

- Before and during treatment with the D2000 Cartridge, ensure there is no leakage in any extracorporeal circuit connection or component.
- The tolerance pressure of the D2000 Cartridge is 450 mmHg; however, inlet pressure must be maintained below 300 mmHg in order to prevent clogging and other abnormalities during operation. If pressure exceeds 300 mmHg at any time during operation, treatment is to be suspended and the cause of the high pressure is to be resolved before continuing treatment. In the event that a cause cannot be resolved, the D2000 can be changed out or the treatment can be discontinued at the order of the treating physician.

- The appropriate method and dosage of anticoagulant administration related to the extracorporeal circulation will depend on the patient's condition, and must be determined in accordance with the directions of the responsible physician.
- Ensure that no air enters the patient's blood vessels during the procedure or during rinse-back.
- The D2000 cartridge may reduce antibiotic levels during treatment. A higher dose of antibiotics may need to be considered during treatment with the D2000 cartridge.
- The D2000 Cartridge may adsorb blood glucose. During and after treatment, closely monitor patient’s blood glucose levels and adjust per hospital protocol.

System Precautions: Following Use

- Dispose of the used D2000 Cartridge device in accordance with official and institutional standards for biohazardous medical waste disposal.
- After treatment, monitor and adjust patient’s blood anticoagulation levels per hospital protocol.

Technical Specifications

Prime divert volume: 200mL
Notification pressure limit: 200mmHg
Maximum pressure limit: 300mmHg
Maximum plasma flow rate: 50mL/min

Prime the Plasma Separator

Prime the Spectra Optia per manufacturer's instructions.

Connect and Prime D2000

Aseptically insert the D2000 into the plasma circuit following on screen the instructions. With minimum agitation, rotate D2000 so red port (inlet) is on the bottom and blue port (outlet) is on the top (see Figure 1).

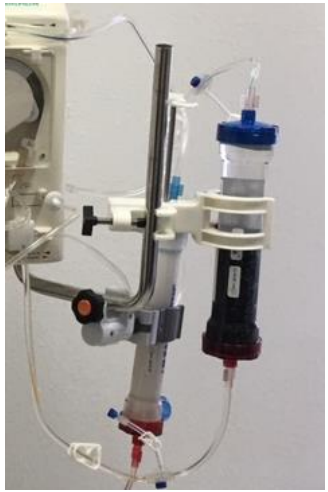


Figure 1 Image of D2000 in Fluid Circuit

Prime with 1L Normal Saline (NS). Once saline has entered column gently agitate column to ensure contents of column have not settled in device. The goal here is to have a uniform distribution of resin mix inside the column. Prime can be performed at up to 100 mL/min.

Initiate Treatment

Follow on screen instructions to initiate treatment. At start of treatment, adjust the plasma pump flow rate on plasma separation device to 25 ml/min for first 250 mL volume plasma processed. Increase the plasma flow rate up to 50mL as needed. This may be managed by the physician to operate between 15 and 50 ml/min.

Caution!	Anticoagulation must be effective at the beginning of the treatment. Anticoagulation regimen should be chosen at the discretion of the responsible physician.

NOTE: Check the circuit regularly to confirm there are no signs of blood clots, no air in the circuit, and the tubing lines are secure.

Follow standard operating procedures and suggestions for plasma separators for patient and blood level monitoring

Conclusion of Treatment

Follow on screen instructions to initiate rinse-back or end the run.

Dispose of used D2000 Cartridge according to your facility's procedure for biohazardous waste disposal.

Operation of the Plasma Separator

Refer to the Operator's Manual for all instructions related to the operation of the plasma separation device (e.g., Apheresis system with continuous plasma separation capabilities).

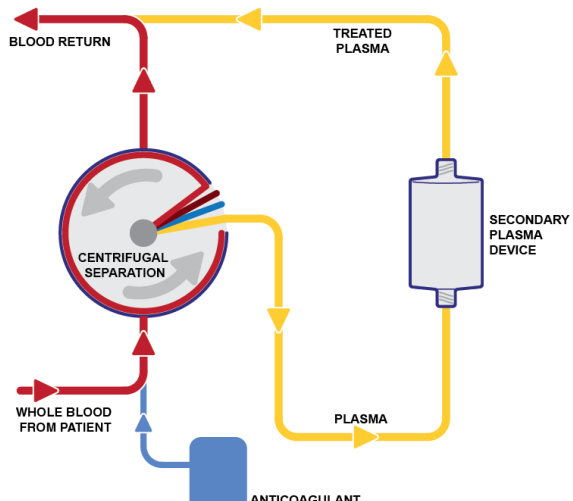


Figure 2 Fluid Schematic for Treatment with the D2000 Cartridge

Notes:

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Manufactured by:
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