PlasFree	Document Title **ClearPlasma Device – Instructions for Use**		
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Controlled document

Approval				
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Revision History		
Rev. #	**Date**	**Description**
01	14-Feb-2019	Original
02	05-Dec-2019	Labeling update, adding EU rep
03	25-May-2020	Amendments to sections 1.2, 1.3, 1.6, 1.5.4, 1.7 and section 9: as per DCC-005-2020.
04	20-Sep-2020	Amendments to section 1.3, "Contraindications": see DCC-014-2020.
05	17-Oct-2021	CCR-043-2021
06	24-Apr-2022	CCR-021-2022
07	06-Jun-2022	CCR-025-2022

DISTRIBUTION LIST		
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1. General Information

1.1. Device Description

ClearPlasma™ is an extracorporeal plasma absorber. The body of the absorber is a plastic housing with three principal compartments – inlet, resin compartment and outlet. The compartments are divided by two membranes, which define the resin compartment's limits (Figure 1).

Figure 1. ClearPlasma™ device (1) body, (2) cup, (3) membrane

1.1.1 Acceptable plasma flow rate: 5-10 mL/min
1.1.2 Optimum plasma flow rate: 6-12 mL/min
1.1.3 The device has no direct contact with the patient body (no contact with tissues or body fluids).
1.1.4 ClearPlasma™ medical device does not contain a medicinal product, is not produced by using animal tissue, does not incorporate human blood nor plasma derivative and is not manufactured utilising non-viable tissues nor cells of human origin nor their derivatives.

1.2. Intended Use

The ClearPlasma™ is a single-use medical device intended for removal of plasminogen from donor's plasma.

1.2.1 **Intended Users**

The ClearPlasma™ device is for professional use only and is intended to be used in blood banks, bedside of the patient and healthcare settings.

1.3. Indications

ClearPlasma™ is indicated for use in conditions where massive bleeding situations exist.

1.4. Contraindications

- with increased risk of blood clotting
- with fluid accumulation in the brain
- with retinal thrombosis
- experiencing a heart attack
- pregnant or breastfeeding women – safety has not been established
- under 18 years of age (safety has not been established)
- Caution should be exercised when using ClearPlasma™ in patients:

- with history of allergies to device components (polyethersyplone, polycarbonate) - careful monitoring for hypersensitivity reactions is required
- weighing less than 100 lb (45 kg). Blood flow rate should be adjusted to reduce the risk of an adverse effect.

1.5. **Warning**

a. Do not use if package is damaged or opened.
b. Keep away from sun or heat.

1.6. **Cautions**

1.6.1 ClearPlasma™ should only be administered by personnel who have been properly trained in administration of extracorporeal therapies.
1.6.2 The extracorporeal circuit should be monitored continuously during treatment for blood leaks. In the event of a blood leak during treatment, the health care provider should respond according to the facility's established protocols.
1.6.3 Air entering the extracorporeal circuit during treatment can result in serious injury or death. Check the integrity of all bloodlines and connections prior to the initiation of blood perfusion and periodically during the treatment. The venous return line or drip chamber should be continuously monitored with an air detector.
1.6.4 ClearPlasma™ should only be used as directed by a physician, exclusively for clinical investigation.
1.6.5 Pressure monitoring of the bloodline between the blood pump and the ClearPlasma™ device is recommended. If the pump system is not equipped with a pressure sensing device for this line, use of an accessory pressure monitoring device is recommended.
1.6.6 The fluid pathway in an intact device inside the protective pouch is sterile. Inspect the protective pouch for any sign of damage to the ClearPlasma™ device. Carefully remove ClearPlasma™ from the pouch and examine for defects.
1.6.7 For patients using medication that may interfere with coagulation, PDP should only be administered at the attending physician's discretion.

1.7. **Side Effects**

Allergic Reactions- Some people have allergic reactions to blood received during a transfusion, even when given the right blood type. In these cases, symptoms include hives and itching. Like most allergic reactions, this can be treated with antihistamines. However, if the reaction becomes serious, a doctor should be consulted. A fever can be another side effect happening after a transfusion and should be treated with conventional treatment.
For more details, please review current Investigator Brochure.

1.8. **Limitations**

This device is intended for use on persons above 18 old. The device is not recommended for women during pregnancy.
Note: Discretion should be used when treating a patient weighing less than 100 lb. (45 kg). Blood flow rate should be adjusted to reduce the risk of an adverse effect.
This device is not to be used for more than one treatment.
ClearPlasma™ is a single-use device.
ClearPlasma™ should be stored within the temperature range of 2-8°C and used within temperature range of 2 to 30°C.

1.9 **Foreseeable adverse events**

In event of wrong way using the device for e.g. wrong connection tubes and/or connection in the Opposite direction plasma will be halt in the device and accumulated, thus it will not be introduce into the patient or the new plasma collection bag. The device is engineered in a way that there is only one direction of use and only one connection tube can be used. All these modifications were made to prevent wrong use of ClearPlasma™.

2. Preparation for Treatment

ClearPlasma™ is intended for use with standard, commercially available bloodlines compatible with the pump system used. Female Luer connectors are required to connect with ClearPlasma™ blood ports. The roller blood pump should be capable of delivering up to 8 mL/min blood flow rate.

3. During Treatment

3.1. Monitor the pressure in the extracorporeal circuit, including the line between the Plasma bag and ClearPlasma™. Investigate any indication of abnormal pressure.

3.2. Visually inspect the ClearPlasma™ for any signs of clotting or plasma leaks from the circuit. Report all clotting or blood leaks to the responsible medical professional.

3.3. Periodically monitor the extracorporeal circuit for evidence of obstruction, security of fittings, and air within the circuit.

4. Termination of Treatment

4.1. When the treatment is completed, terminate the treatment as directed by the Instructions For Use.

4.2. Discard the ClearPlasma™ in an appropriate biohazard waste receptacle.

CAUTION: Reuse of ClearPlasma™ may result in secondary infection, device clotting and/or a biohazardous situation.

CAUTION: DO NOT USE ClearPlasma™ if it appears to be damaged. DO NOT USE ClearPlasma™ if beads appear to be free-floating within the endcaps.

CAUTION: Avoid the entry of air into ClearPlasma™.
Turn ClearPlasma™ so the inlet end is facing downward. Remove ClearPlasma™ outlet port plug and attach the venous line. Make sure that all air is removed before attaching back to the patients.

5. Performance Characteristics

Plasma filtering capacity Volume: 250 mL
Flow Resistance (Qb < 500 mL/min): 300 mmHg
5.1. Storage Fluid: Saline solution
Sterilization: Gamma Radiation

6. Device Contact Materials

Resin: 4% agarose beads
Plastic filter: Polyethersulfone membrane
Membranes: Polyetersyplone
Tubes: Polycarbonate and Polycarbonate

7. **Authorized Representative**
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8. **Manufacturer**
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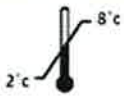
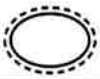
9. **List of symbols on the ClearPlasma™ labeling**

Symbol	Description
	Medical device
	Catalogue number
	Batch code
	Serial number
	Country of manufacture (Note: with a date of manufacture)
	Use-by date
	Do not re-use
	Non-pyrogenic
	Sterilized using irradiation (Note: By Gamma radiation)

Symbol	Description
	Consult instructions for use or consult electronic instructions for use
	Temperature limitation
	Manufacturer: Plas-Free Ltd Company# 515684009 At NGT3 Incubator,13 Wadi El Haj Nazareth, 17111 Israel ZIP 1603611 Ph: +972-46098615 Email: info@plas-free.com
	Authorized representative in the European community/European Union: MedNet EC-REP IIb GmbH Borkstrasse 10 48163Münster, Germany
	Keep away from sunlight and heat
	Keep package dry and keep away from rain
	Do not use if package is damaged (or opened) and consult instructions for use
	Single sterile barrier system with protective packaging outside
	Product quantity: one unit
Intended Use	Clinical use only: Exclusively for clinical investigation Or R&D use only Or Training use only
	Unique device identifier
	CE marking