



Extracorporeal Photopheresis (ECP)

Amicus Blue

Therapeutic Apheresis and Cell Collection

The Amicus Separator System for ECP includes the Phelix Photoactivation device to provide extracorporeal photopheresis, using a single-use disposable kit within an online, closed system. The ECP system is indicated for the palliative treatment of the skin manifestations of cutaneous T-Cell lymphoma (CTCL) that is unresponsive to other forms of treatment.

Online, closed photopheresis system

Single and double needle access options

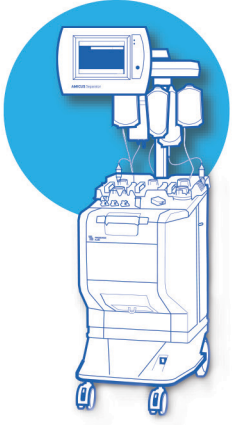
Low extracorporeal volume (163 mL)

Low minimum hematocrit (15%)

Process up to 8 liters of whole blood

Amicus Blue System with ECP

Versatility for Therapeutic Apheresis and Cell Collection



Amicus MNC Collection Technology

Utilizing the proven Amicus capabilities in separating and collecting mononuclear cells, the ECP protocol is an expanded indication for the Amicus Separator system.

Online Closed System

The Amicus Separator's single-use disposable kit combined with the Phelix Photoactivation Device create an online, closed system to perform photopheresis. The patient remains connected to the disposable kit throughout the procedure. After photoactivation, Amicus reinfuses the treated cells back to the patient.

Phelix Photoactivation Device

The Phelix Photoactivation Device is designed to operate with any Amicus Separator system that is enabled to perform ECP procedures:



- The device continuously monitors the intensity of UVA light, temperature of the collected MNCs, and agitation to ensure delivery of the target UVA light dose
- The device is designed to expose collected MNCs under constant agitation, with approximately 1.5 J/cm² of UVA light
- Bi-directional communication between the Amicus Separator and Phelix allows for easy control of the system from the Amicus device
- Photoactivation progress and results can be monitored and viewed from the Amicus Separator's touchscreen user interface

Procedure Flexibility

The Amicus Separator System offers the flexibility to perform additional procedures from a single device:

- ECP with Single/Double Needle Access*
- MNC Collections
- Therapeutic Plasma Exchange
- Red Blood Cell Exchange
- Platelet Collections



*The Amicus System for ECP has obtained CE mark approval for the indication of CTCL in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment.



Focused on Patient Safety and Comfort

- One kit for single needle or double needle access
- Low extracorporeal kit volume (163 mL)
- Low minimum patient hematocrit (15%)
- Process up to 8 liters of whole blood in 2 equal volume cycles
- Qualified with ACD-A
- Automated Custom Prime for patients having a lower total blood volume and/or lower hematocrit
- The needle-free 8-MOP injection site contains a 0.2-micron antimicrobial filter combined with a one-way valve, creating a functionally closed pathway in the disposable kit
- Patient saline option administers saline to keep access lines open
- Real-time fluid balance tracking
- Disposable kit irradiation sterilized to prevent the risk of reactions related to patient exposure to residual ethylene oxide

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Ordering Information

Code	Description
6R4580; 6R4590	AMICUS Separator Device
6R4590TH-M	AMICUS Separator Therapeutics MNC Device
6R4582	Phelix Photoactivation Device
X7R2345C	AMICUS Extracorporeal Photopheresis (ECP) Apheresis Kit - Single/Double Needle with Correct Connect
X7R2346	AMICUS Extracorporeal Photopheresis (ECP) Apheresis Kit - Single/Double Needle with Sampling Pouches
X7R2346C	AMICUS Extracorporeal Photopheresis (ECP) Apheresis Kit - Single/Double Needle with Correct Connect and Sampling Pouches
61126870375	AMICUS Mobility Wheel Assembly (Included with 6R4590TH-M device)



The Amicus ECP System is CE Marked in compliance with the applicable requirements of the Medical Device Regulation (EU) 2017/745 and includes:

- Amicus Separator
- Phelix Photoactivation Device
- Amicus ECP Apheresis Kits



Not all products listed or shown are available, or approved for sale in all countries. Contact your local Fresenius Kabi Representative for additional information and product availability.

Refer to the Instructions for Use and Operator's Manual for a complete list of warnings and precautions associated with the use of this products.



**FRESENIUS
KABI**

Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg
Germany

Phone: +49 (0) 6172 686 0

Corporate
www.fresenius-kabi.com

Amicus Blue Therapeutics
www.amicusblue-fresenius-kabi.com