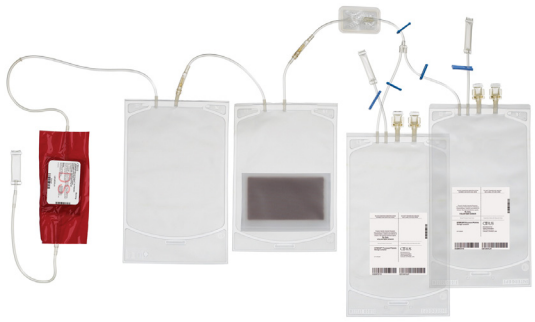
INTERCEPT® Blood System
pathogen reduction system
Process Specifications for Platelets and Plasma

SPECIFICATIONS

The INTERCEPT Blood System is comprised of separate disposable kits for platelets and plasma as well as a UVA Illuminator. The INTERCEPT treatment for platelets and plasma is performed on the same Illuminator platform for optimal efficiency.



INTERCEPT Blood System for Platelets

Compatible with Amicus apheresis platelet components suspended in PAS-3 or Trima apheresis platelet components suspended in 100% plasma. Sets are available in three configurations: Small Volume (SV), Large Volume (LV) and Dual Storage (DS).

INTERCEPT Blood System for Plasma

Compatible with apheresis or whole blood derived plasma.

INTERCEPT INT100 Illuminator

Compatible with all INTERCEPT processing sets for Platelets (SV, LV, DS) and Plasma.

INTERCEPT BLOOD SYSTEM

For CONTRAINDICATIONS, WARNINGS, and REFERENCES, see inside pages.
See package insert for full prescribing information.

INTERCEPT Blood System for Platelets

Collection and processing specifications:

Platelets in PAS-3

	Small Volume Set (SV)	Large Volume Set (LV)	Dual Storage Set (DS)	
Product Code	INT2110	INT2210	INT2510	
Platelet Source	Amicus Apheresis	Amicus Apheresis	Amicus Apheresis	
Suspension Medium	PAS-3 & Plasma (32-47%)	PAS-3 & Plasma (32-47%)	PAS-3 & Plasma (32-47%)	
Platelet Input Volume (mL)	255 - 325	300 - 390	300 - 390	375 - 420
Platelet Dose ($x10^{11}$)	2.9 - 5.0	3.0 - 6.0	3.0 - 6.0	4.0 - 8.0
Platelet Count ($x10^9$/mL)	0.9 - 2.0	0.8 - 2.0	0.8 - 2.0	0.95 - 2.1
RBC ($x10^6$/mL)	< 4	< 4	< 4	
CAD Time (hours)	4 -16	6 -16	6 -16	
Integrated Storage Containers	1	1	1 or 2	
Units per Carton	24 (Packaged as 4 foil pouches with 6 processing sets per pouch)			

Platelets must be exposed to UVA light within 24 hours after collection.

INTERCEPT Blood System for Platelets

Collection and processing specifications:

Platelets in 100% Plasma

	Small Volume Set (SV)	Large Volume Set (LV)	Dual Storage Set (DS)	
Product Code	INT2110	INT2210	INT2510	
Platelet Source	Trima Apheresis	Trima Apheresis	Trima Apheresis	
Suspension Medium	100% Plasma	100% Plasma	100% Plasma	
Platelet Input Volume (mL)	270 - 325	300 - 390	300 - 390	375 - 420
Platelet Dose ($x10^{11}$)	3.0 - 5.0	3.0 - 5.2	3.0 - 5.2	5.3 - 7.9
Platelet Count ($x10^9$/mL)	0.9 - 2.0	0.9 - 1.7	0.8 - 1.7	1.3 - 2.0
RBC ($x10^6$/mL)	< 4	< 4	< 4	< 4
CAD Time (hours)	12 - 24	12 - 24	12 - 24	12 - 24
Integrated Storage Containers	1	1	1	2
Units per Carton	24 (Packaged as 4 foil pouches with 6 processing sets per pouch)			

Platelets must be exposed to UVA light within 24 hours after collection.

INTERCEPT Blood System for Plasma

Collection and processing specifications:

Plasma

Product Code	INT3110
Plasma Input Volume (mL)	585 - 650
RBC (x10^6/mL)	<4
CAD	Flow through
Transfusion Units / Treatment	2 or 3 (user options)
Transfusion Unit Volume (mL)	~200 - 325
Type of Collection	Apheresis or whole blood*
Integrated Storage Containers	3
Units per Carton	24 (Packaged as 4 foil pouches with 6 processing sets per pouch)

*The use of whole blood derived plasma requires pooling of 2-3 units

INTERCEPT INT100 Illuminator

Hourly throughput

Platelet Units*	Plasma Units*
40	36

*Includes preparation, loading and unloading of UVA illuminator. Assumes 2-unit yield from each platelet treatment and 3-unit yield from each plasma treatment.

The UVA Illuminator is stackable by two, for maximum space efficiency.

Illuminator specifications

Order Code	INT100-60
Power Supply	120 VAC / 60 Hz / 5 A max
Measurements (feet)	H=1.21 / W=3.77 / D=2.42
Weight (lbs)	152
Stackable	by 2 instruments

Illuminator should be used in environmental conditions that meet the following:

- Temperature 18-30°C
- Humidity < 80%

INTERCEPT® Blood System for Platelets and Plasma
pathogen reduction system

CONTRAINDICATIONS

Contraindicated for preparation of plasma or platelet components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens. Contraindicated for preparation of plasma or platelet components intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interaction between ultraviolet light and amotosalen.

WARNINGS AND PRECAUTIONS

Only INTERCEPT Processing Sets for plasma or platelets are approved for use in the INTERCEPT Blood System. Use only the INT100 Illuminator for UVA illumination of amotosalen-treated plasma or platelet components. No other source of UVA light may be used. Please refer to the Operator's Manual for the INT100 Illuminator. Discard any plasma or platelet components not exposed to the complete INT100 illumination process.

Tubing components and container ports of the INTERCEPT Blood System for Plasma or Platelets contain polyvinyl chloride (PVC). Di(2-ethylhexyl)phthalate (DEHP) is known to be released from PVC medical devices, and increased leaching can occur with extended storage or increased surface area contact. Blood components will be in contact with PVC for a brief period of time (approx. 15 minutes) during processing. The risks associated with DEHP released to into the blood components must be weighed against the benefits of therapeutic transfusion.

PLATELETS Pulmonary events: Acute Respiratory Distress Syndrome (ARDS) INTERCEPT processed platelets may cause the following adverse reaction: *Acute Respiratory Distress Syndrome (ARDS)*. An increased incidence of ARDS was reported in a randomized trial for recipients of INTERCEPT processed platelets, 5/318 (1.6%), compared to recipients of conventional platelet components (0/327). Monitor patients for signs and symptoms of ARDS.

PLASMA Amotosalen-treated plasma may cause the following adverse reaction: *Cardiac Events*. In a randomized controlled trial of therapeutic plasma exchange (TPE) for TTP, five patients treated with INTERCEPT Blood System processed plasma and none with conventional plasma had adverse events in the cardiac system organ class (SOC) reported. These events included angina pectoris (n=3), cardiac arrest (n=1), bradycardia (n=1), tachycardia (n=1) and sinus arrhythmia (n=1). None of these events resulted in documented myocardial infarction or death. Monitor patients for signs and symptoms of cardiac events during TPE for TTP.

Amicus is a registered trademark of Fenwal Inc. Trima is a registered trademark of Terumo BCT, Inc.

Efficient platelet and plasma
pathogen reduction with
one device, one process

Contact a Cerus representative today.

CERUS

GLOBAL HEADQUARTERS | 2550 Stanwell Drive | Concord, CA US 94520 | 855.835.3523

www.cerus.com | www.intercept-usa.com

Rx only. For CONTRAINDICATIONS, WARNINGS, and REFERENCES, see inside pages.
See package insert for full prescribing information.

© 2016 Cerus Corporation. Cerus, INTERCEPT Blood System and INTERCEPT are registered trademarks of Cerus Corporation. MKTEN 00147 v3.0