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INTERCEPT® Blood System Pathogen Reduction System

Process Specifications for Platelets and Plasma

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

INTERCEPT Blood System for Platelets

Table 1.
Processing range requirements for platelets in PAS-3.

Platelets in PAS-3				
	Small Volume Set (SV)	Large Volume Set (LV)	Dual Storage Set (DS)	
Product Code	INT2140B	INT2240B	INT2540B	
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	< 4
CAD Time (hours)	4 -16	6 -16	6 -16	6 -16
Storage Containers	1	1	1	1 or 2
Units per Carton	24 (Packaged as 4 foil pouches with 6 processing sets per pouch)			

Platelets must be treated with the INTERCEPT Blood System within 24 hours after collection.

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INTERCEPT Blood System for Platelets

Table 2.
Processing range requirements for platelets in 100% plasma.

Platelets in 100% Plasma				
	Small Volume Set (SV)	**Large Volume Set (LV)**	**Dual Storage Set (DS)**	
Product Code	INT2140B	INT2240B	INT2540B	
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	0.8 - 1.7	0.8 - 1.7	1.3 - 2.1
RBC ($x10^{6}$/mL)	< 4	< 4	< 4	< 4
CAD Time (hours)	12 - 24	12 - 24	12 - 24	12 - 24
Storage Containers	1	1	1	2
Units per Carton	24 (Packaged as 4 foil pouches with 6 processing sets per pouch)			

Platelets must be treated with the INTERCEPT Blood System within 24 hours after collection.

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INTERCEPT Blood System for Plasma

Table 3.
Processing range requirements for plasma.

Plasma Processing Set	
Product Code	INT3140B
Plasma Input Volume (mL)	585 - 650
RBC (x10⁶/mL)	<4
CAD	Flow through
Transfusion Units / Treatment	2 or 3 (user options)
Type of Collection	Apheresis or whole blood*
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.

Plasma and Platelet processing sets:

- Do not freeze
- Do not store above 25°C

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INTERCEPT Blood System Illuminator

Table 4.
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. Platelet or plasma components may be illuminated in only one treatment cycle.

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

Table 5.
Illuminator specifications.

INT100 Specifications	
Order Code	INT100-60
Power Supply	120 VAC / 60 Hz / 5 A max
Measurements	H=14.5” / W=45” / D=29”
Weight	152 lbs

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

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

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CONTRAINDICATIONS

Contraindicated for preparation of platelets or plasma intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens. Contraindicated for preparation of platelets or plasma 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 platelets or plasma are approved for use in the INTERCEPT Blood System. Use only the INT100 Illuminator for UVA illumination of amotosalen-treated platelet or plasma components. No other source of UVA light may be used. Please refer to the Operator's Manual for the INT100 Illuminator. Discard any platelet or plasma components not exposed to the complete INT100 illumination process.

Tubing components and container ports of the INTERCEPT Blood System for Platelets and Plasma 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 (approximately 15 minutes) during processing. The risks associated with DEHP released into the blood components must be weighed against the benefits of therapeutic transfusion.

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.

Rx only. See package insert for full prescribing information.

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