

INTERCEPT® Blood System for Platelets - Processing Set (Semi-Integrated Set)

The INTERCEPT Blood System is comprised of disposable kits for platelets and a UVA Illuminator.







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 INT100 Illuminator

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

INTERCEPT® Blood System for Platelets - Processing Set (Semi-Integrated Set)

Input and Processing Specifications



| 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°/mL) | 0.9 - 2.0 | 0.8 - 2.0 | 0.8 - 2.0 | 0.95 - 2.1 |
| RBC (x10°/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 System within 24 hours after collection.



| 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°/mL) | 0.9 - 2.0 | 0.8 - 1.7 | 0.8 - 1.7 | 1.3 - 2.1 | |
| RBC (x10°/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 System within 24 hours after collection.

INTERCEPT® INT100 Illuminator

Input and Processing Specifications



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

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

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

INTERCEPT treatment using products INT2140B, INT2240B, or INT2540B requires an INT 100 with software version 6 or newer.

CONTRAINDICATIONS

Contraindicated for preparation of platelet components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens. Contraindicated for preparation of 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 interactions between ultraviolet light and amotosalen.

WARNINGS AND PRECAUTIONS

Only INTERCEPT Processing Sets for platelets are approved for use with the INTERCEPT Blood System. Use only the INTERCEPT INT100 Illuminator for UVA illumination for amotosalen-treated platelet components. No other source of UVA light may be used. Please refer to the Operator's Manual for the INT100 Illuminator. Discard any platelet components not exposed to the complete INT100 illumination process. Tubing components and container ports of the INTERCEPT Blood System contain polyvinyl chloride (PVC). Di(2-ethylhexyl)phtalate (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 into the blood components must be weighed against the benefits of therapeutic transfusion.

Rx Only. See package inserts for full prescribing information.



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