

INTERCEPT® Blood System for Platelets

Quick Start Guide

Pathogen reduced (PR) platelets can be used for ALL patients receiving platelet units^{1*}

- Reduces the transfusion transmission risk of a broad spectrum of pathogens, including emerging pathogens¹
- Replaces the need for bacterial testing (AABB standard 5.1.5.2; FDA Guidance)^{2,3}
- Eliminates the need for irradiation for prevention of transfusion-associated graft-versus-host disease (TA-GVHD) (AABB Standard 5.19.4.1)^{1,3}
- Meets requirements¹ to be a cytomegalovirus (CMV) risk mitigation strategy (AABB Standard 5.19.2)³
- Irradiation of pathogen reduced platelets is not required nor recommended (AABB Standard 5.19.4.1)³

Getting Started

1. NOTIFY lab and nursing staff of this new PR platelet product
2. ENTER needed product codes in your system, including:
 - a. ISBT code build
 - b. Error checking table
 - c. Hospital EMR and bed side scanning
 - d. Reimbursement
 - e. Process validation

NOTE:

A complete list of ISBT codes can be found here:

<http://bit.ly/ISBTcodes>

3. CONFIRM your system allows the use of either PR or irradiated platelets

NOTE:

Additional information here:

<http://bit.ly/HospitalStart>

or by emailing hospitalsupport@cerus.com

4. Billing and Reimbursement: Use P-code (P9073)

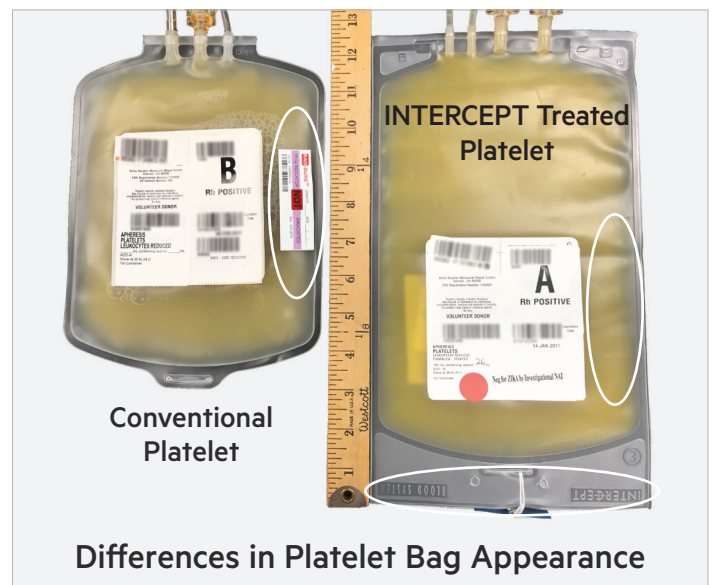
Key Characteristics of INTERCEPT® Blood System Treated Platelets

Commonly Referred To As:

- “Psoralen Treated” platelets (ISBT product codes)
- “Pathogen Reduced” (PR) platelets
- “Pathogen Reduction Treated” (PRT) platelets

Platelet Bags:

- 2.8” longer than conventional bags
- Volume and concentration are comparable



Differences in Platelet Bag Appearance

Hospital Staff Education

Specialized resources for nursing, blood bank/lab and medical staff education can be found here: <http://bit.ly/HospitalStart>

References

1. INTERCEPT Blood System for Platelets [Package Insert]. Concord, CA: Cerus Corporation; May 28, 2019.
2. FDA. Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion: Guidance for Industry. In: CBER, ed. Silver Spring, MD: US Food and Drug Administration; 2020.
3. AABB. Standards for Blood Banks and Transfusion Services 32nd Edition. Bethesda, MD: AABB; 2020.

*Warnings and Precautions

Only INTERCEPT Processing Sets for platelet components are approved for use in the INTERCEPT Blood System. Use only the INT100 Illuminator for UVA illumination of 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 for 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 into the blood components must be weighed against the benefits of therapeutic transfusion. PLATELETS: 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.

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 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.

Rx Only. See package inserts for full prescribing information.