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INTERCEPT® Blood System for Platelets Pathogen Reduction System

Case Study: Stanford Blood Center – The First Blood Center of its Size to Implement Pathogen Reduction for 100% of Platelet Components

Stanford Blood Center (SBC), a leader in the fields of transfusion and transplantation medicine, supplies >17,000 platelet products per year to Stanford and other area hospitals. Stanford is ranked as a top 20 hospital nationwide per the US News and World Report.[1]

The Challenge

In 2020, SBC maintained an inventory of 40% pathogen reduced (PR) platelets and 60% as tested platelets via primary, aerobic culture. With FDA's bacterial guidance[2] deadline quickly approaching, SBC needed to decide whether to adopt large volume delayed sampling (LVDS) for the remaining 60% platelet inventory, or to adopt a 100% pathogen reduced (PR) inventory.

The Solution

The Decision for a 100% PR Platelet Inventory: Simplified Blood Center Workflow and Hospital Demand

SBC analyzed all aspects of pursuing either a dual platelet inventory (PR and LVDS) versus a 100% PR platelet inventory, including impact to product loss/split rate, inventory management, equipment space and workflow, as well as hospital preference.

The following factors supported the decision for SBC to adopt 100% PR :

Hospitals Preferred PR Platelets	Hospitals supplied by SBC preferred PR platelets largely due to the safety and efficacy profile.	**Avoided False Positive Recalls**	Avoidance of false positive results and associated recalls, saving valuable time, resources and platelets for transfusion.
Reduced Volume Loss	Minimization of product loss that can occur with LVDS due to the increased sample size and the addition of the anaerobic bottle.	**Platelets Released Quickly**	The ability to release platelet products sooner after collection; delayed platelet release into inventory inherent with LVDS was not necessary.
Maintained Split Rate	Stanford was able to maintain its split rate with PR.	**Reduced Lab Space**	Increased laboratory space with the elimination of BacTAlert equipment.

"SBC is ensuring that the platelet units our donors generously provide are as safe as possible for any patient who may need them.... Having PR as another safeguard on top of the rigorous testing that we already do means maximizing safety for patients."

Harry Sussman

Operational Excellence (OpEx) Director, **Stanford Blood Center**

Attaining Clinician Acceptance of PR and Variable Dose Platelets at Stanford Hospital

Stanford Hospital underwent a process involving clinician and blood bank education and training to implement the use of PR platelets for all patients.

Clinician education included PR safety and efficacy data applicable to entire patient population as well as patient subgroups, and on the use of variable dose platelets.

- No effect on risk of clinically significant bleeding, adverse events, or all-cause mortality.[3]
- No adverse effects on blood use, mortality and length of stay for trauma, cardiac surgery and liver transplant patients.[4]
- Platelets with a count of ~ $2.2x10^{11}$/unit did not affect risk of significant bleeding when compared to standard and high doses in heme-onc patients.[5,6]
- Platelet dose standards used in other countries provided additional reassurance of safety and efficacy of variable dose platelets (i.e. 2.0-2.4 x 10^{11} in European countries).[7]

References: 1. U.S. News & World Report Hospital Rankings & Ratings," 2020-2021, https://health.usnews.com/besthospitals 2. Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion: Guidance for Industry. US FDA; December 2020. 3. Estcourt LJ et al. Cochrane Database Syst Rev. 2017;7:CD009072. 4. Nussbaumer W et al. Vox Sang. 2017 Apr;112(3):249-256. 5. Slichter SJ et al. N Engl J Med. 2010;362(7):600-613. 6. Estcourt LJ et al. Cochrane Database Syst Rev. 2015;10(10):CD010984. Published 2015 Oct 27. 7. Benjamin RJ et al, Transfusion. 2019 Apr;59(4):1404.

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. 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 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 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 : 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.

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Rx only. See package insert for full prescribing information.