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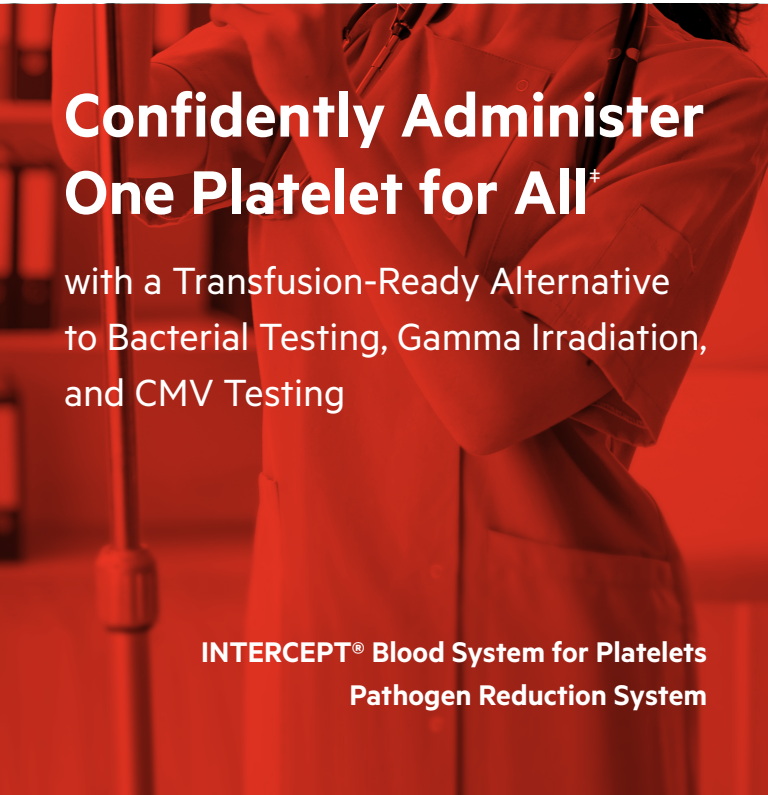

Confidently Administer One Platelet for All‡

with a Transfusion-Ready Alternative to Bacterial Testing, Gamma Irradiation, and CMV Testing

INTERCEPT® Blood System for Platelets
Pathogen Reduction System

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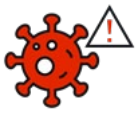
Risks and Challenges to the Blood Supply



Infectious Risk

Bacterial contamination in platelets is the largest transfusion-transmitted infection (TTI) risk.[1]

Non-Infectious Risk

Leukocytes may cause transfusion associated graft-vs-host disease (TA-GVHD)[2] and may increase risk of pulmonary injury.[3,4]

Insufficient Availability

Outbreaks and pandemics may impact blood safety and availability.[5,6]

Complex Inventory Management

Separate inventories for irradiated and CMV tested platelets may lead to inefficiencies and/or compliance issues related to transfusion errors.[7,8]

Is there something more you could be doing to help protect your vulnerable patients in need of supportive platelet therapy?

Elevate Patient Care with INTERCEPT Treated Platelets (INTERCEPT Platelets)

Help maximize sucess in patient treatment with reduced TTI risk.*[9]

Confidently administer one platelet for all‡ with a transfusion-ready approved alternative to bacterial testing, gamma irradiation, and CMV testing.[9]

Expand patient access to help ensure access to platelet products during outbreaks[5,6] and potentially receive platelets sooner.[10]

Demonstrated Safety & Efficacy

The INTERCEPT Blood System uses amotosalen, a psoralen, and UVA light to cross-link nucleic acids, blocking replication of pathogens and rendering them inactive.[11]

Learn more

*There is no pathogen inactivation process that has been shown to eliminate all pathogens. Certain non-enveloped viruses (e.g., HAV, HEV, B19, and poliovirus) and *Bacillus cereus* spores have demonstrated resistance to the INTERCEPT process.

INTERCEPT® Blood System for Platelets
Pathogen Reduction System

Help Maximize Sucess in Patient Treatment

Broad-Spectrum Pathogen Reduction

INTERCEPT Platelets help protect patients with broad-spectrum TTI risk reduction* through the inactivation of bacteria, viruses, parasites, and leukocytes.

Bacteria

Gram-negative, gram-positive, spirochetes

Viruses

Enveloped, non-enveloped

Leukocytes/ T-cells

Protozoan Parasites

Visit our website for a full list of pathogens inactivated with the INTERCEPT Blood System.

Demonstrated Safety & Efficacy

INTERCEPT Platelets have been evaluated in numerous clinical trials involving thousands of subjects. Primary endpoints were met, including corrected count increments (CCI) and bleeding criteria, both of which are measures of hemostatic efficacy.

Study Design	Patients	Endpoint	Met?
Phase IV study of INTERCEPT Platelets in routine use in thrombocytopenic patients[12]	2,291	Assisted mechanical ventilation	✓
Safety/efficacy of INTERCEPT Platelets, thrombocytopenic patients[13]	645	WHO Grade 2 bleeding	✓
Viability of INTERCEPT Platelets, clearance of amotosalen, healthy patients[14,15]	65	Recovery/ survival, clearance of amotosalen	✓
Safety/efficacy of INTERCEPT Platelets, thrombocytopenic patients[16]	43	1 hr CCI	✓
Safety/efficacy of INTERCEPT Platelets, thrombocytopenic patients[17]	32	Bleeding time	✓

"We have an obligation to our patients and their families to maximize the safety of the transfusions that they receive, which includes ensuring that all platelets are pathogen reduced."

Dr. Deva Sharma
Hematologist
Vanderbilt University Medical Center

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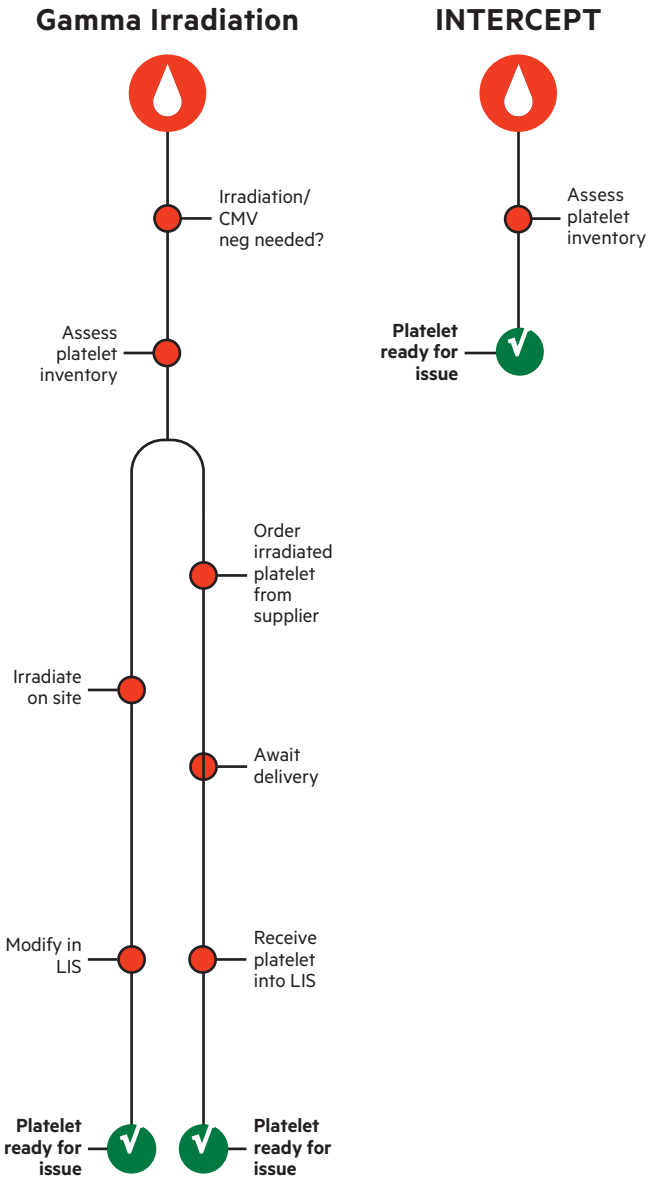
Confidently Administer One Platelet for All‡

Ready-to-Transfuse Solution

INTERCEPT Platelets may be used as an alternative to certain tests and procedures, including bacterial testing,[18] CMV testing,[9] and gamma irradiation.[9] This may help streamline inventory management and may reduce the risk of error due to the transfusion of non-irradiated components to patients for which TA-GVHD mitigation is indicated. The illustrative comparison on the right shows how workflow may be simplified.

"By implementing ...Pathogen Reduced Platelets we've been able to streamline our inventory and avoid costs associated with related TTIs, sepsis or TA-GVHD. We only need one inventory to treat all our patients, and no longer need to worry about CMV serology and irradiation. Overall, INTERCEPT® Platelets have driven efficiencies across our institution."

Dr. Jennifer Andrews
Medical Director Blood Bank
Vanderbilt University Medical Center



INTERCEPT® Blood System for Platelets
Pathogen Reduction System

Expand Patient Access

Blood Safety and Availability

Emerging infectious diseases can be unpredictable. INTERCEPT Platelets help ensure blood safety through the inactivation* of certain emerging pathogens,[9] helping to sustain blood availability during outbreaks.[5,6]

"Having pathogen reduced platelets not only minimizes TTI (transfusion transmitted infections), but you get the platelet products sooner. You don't need to wait for bacterial testing and there's no need to irradiate."

Dr. Maria de Los Angeles Muniz
Medical Director
University of Puerto Rico Medical Sciences

Earlier Platelet Availability

Release of platelets as early as day one provides flexibility in managing inventory and may enable hospitals to transfuse platelets earlier.[10]

INTERCEPT Platelets are potentially released sooner than LVDS (large volume delayed sampling) 48hr tested platelets.[10,19]

The usable shelf life for LVDS 48hr platelets is not 7 days, but ~5.5 days, only a half day more than INTERCEPT Platelets.[10,19]

Shifting from Reactive to Proactive Approach

Reactive Approach

- » Identify an emerging blood-borne pathogen
- » Develop an assay kit for identified pathogen
- » Manufacturers consider whether to commercialize the kit
- » Hospitals consider whether to use tested product if not mandated
- » Blood Centers consider whether to subsidize the cost of testing
- » FDA considers Draft Guidance
- » Accrediting agencies consider whether to require a Standard
- » CMS considers whether to reimburse when FDA requires the test
- » **While all this is occurring new pathogens likely have emerged – REPEAT**

VS.

Proactive Approach

- » Identify an emerging blood-borne pathogen
- » **Pathogen Reduction**[20**]

*There is no pathogen reduction process that has been shown to eliminate all pathogens. Certain non-enveloped viruses (e.g., HAV, HEV, B19, and poliovirus) and *Bacillus cereus* spores have demonstrated resistance to the INTERCEPT process.

**There is no pathogen reduction process that has been shown to eliminate all pathogens. Certain non-enveloped viruses (e.g., HAV, HEV, B19, and poliovirus) and *Bacillus cereus* spores have demonstrated resistance to the INTERCEPT process. For a full list of pathogens, including certain emerging pathogens, see Package Insert.

INTERCEPT® Blood System for Platelets
Pathogen Reduction System

INTERCEPT® Blood System for Platelets Pathogen Reduction System

INTENDED USE

The INTERCEPT Blood System for Platelets is intended to be used for ex vivo preparation of pathogen-reduced Amicus apheresis platelet components suspended in 65% PAS-3/35% plasma, and Trima apheresis platelet components suspended in 100% plasma in order to reduce the risk of transfusion-transmitted infection (TTI), including sepsis, and as an alternative to gamma irradiation for prevention of transfusion-associated graft versus host disease (TA-GVHD).

‡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 interaction between ultraviolet light and amotosalen.

WARNINGS AND PRECAUTIONS

Only INTERCEPT Processing Sets for platelets are approved for use in 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

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INTERCEPT® Blood System for Platelets
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>90% of leading US hospitals elevate patient care with INTERCEPT Platelets[21]

Join the Movement.

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