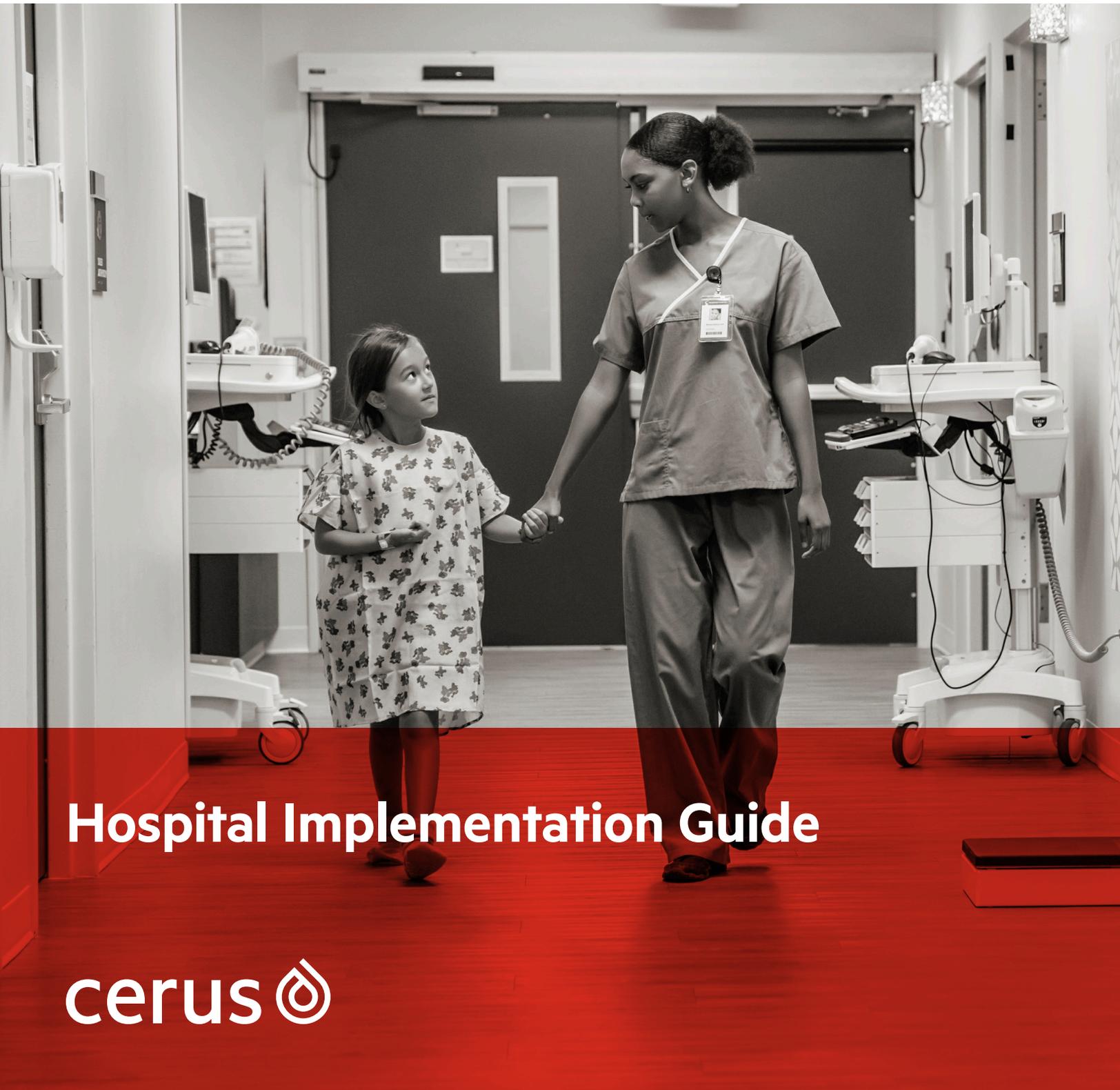




INTERCEPT® Blood System for Platelets Pathogen Reduction System



Hospital Implementation Guide



Welcome to the INTERCEPT® Blood System family

The following chapters will guide you through the implementation steps for receiving, distributing, and billing for platelets treated with the INTERCEPT® Blood System Pathogen Reduction System.

The chapters, and their objectives, are as follows:

1. Project Planning Overview	3
a. Review the roles and responsibilities of the potential project team members at your facility	
b. Review the unique benefits pathogen reduction of platelets provides and the recognition of pathogen reduction in Guidances and Standards	
c. ISBT nomenclature for INTERCEPT treated (psoralen treated) pathogen reduced platelets	
2. Platelet Logistics and Policy Updates	6
a. Setting hospital policy on use of pathogen reduction as an alternative to irradiation, and as a CMV mitigation strategy	
b. Inventory strategy and ramp up considerations for conversion to pathogen reduced platelets	
3. Getting Your IT Systems Ready	9
a. Key hospital/blood bank IT steps and topics:	
i. ISBT code build, error checking table, hospital EMR and bed side scanning considerations, reimbursement and process validation	
b. Concepts to consider if your system uses manual documentation	
4. Hospital Staff Education	13
a. Specialized resources for nursing, blood bank/lab and medical staff education	

Each chapter contains a checklist to help track your implementation progress. In addition, comprehensive, downloadable resources for each phase of implementation are available online at <http://hcp.INTERCEPT-USA.com>.

Upon completion of the implementation process for pathogen reduced platelets, these platelets will arrive from your blood supplier(s) transfusion-ready, with no additional bacterial testing necessary in your hospital blood bank.

If you have questions, please contact us at hospitalsupport@cerus.com.

1. Project Planning Overview

This chapter will suggest key members of your implementation team, guide you through background information about INTERCEPT treated (pathogen reduced) platelets, and provide a basic implementation checklist to assist in your project planning.

Key project personnel at your facility

As you read through this guide, you'll be able to identify the implementation team that will work best for your facility. Project teams often include some or all of the following roles or responsibilities:

- Director of Transfusion Medicine
- Transfusion Safety Officer (TSO) and/or Blood Bank Manager
- Laboratory Information System (LIS) staff
- Blood supplier / platelet provider representative
- Hospital Systems including personnel or representatives dedicated to the HIS/EMR updates
- Hospital Billing representative
- Nursing and General Hospital Education

The Director of Transfusion Medicine, Transfusion Safety Officer, and/or the Blood Bank Supervisor typically guide the distribution of information on pathogen reduced platelets, and lead communication to staff regarding changes to transfusion policy or blood bank operations. Key informational points include:

- INTERCEPT® Blood System for Platelets reduces transfusion transmitted infection (TTI) risk, including sepsis.^{1,2}
- Operational changes regarding potential hospital policy adjustments for the use of pathogen reduced platelets as an alternative to gamma irradiation and as a CMV mitigation strategy.
- Pathogen reduced platelets can be used for all patients receiving platelet units.^{2,3*}

The Blood Bank Manager, Blood Bank IT, and Hospital IT personnel may be responsible for the following pathogen reduced platelets implementation steps covered in the later chapters:

Chapter 2: Platelet Logistics and Policy Updates

Chapter 3: Getting Your IT Systems Ready

It is recommended to begin the work related to updating blood bank and hospital IT systems as early in the implementation process as possible in order to minimize any delays.

If you are not using a computerized system for your transfusion records, this chapter can help you plan for your documentation.

Chapter 4: Hospital Staff Education

Pathogen reduced platelets are recognized in multiple guidances and standards

Industry guidelines enable use of pathogen reduction as an option in place of certain tests and/or procedures. For more information regarding these guidances and standards, see the links at the end of this guide.



Bacteria

The FDA Guidance¹ and AABB Standard 5.1.5.2³ state that pathogen reduction (PR) can be used in place of bacterial testing.^{1,3}



T-cells

The INTERCEPT Blood System is approved by the FDA and meets requirement of AABB Standard 5.19.3.1³ as an alternative to gamma irradiation for the prevention of transfusion-associated graft-versus-host disease TA-GVHD^{+2,3}



CMV

PR provides cytomegalovirus (CMV) inactivation levels,² meeting AABB Standard 5.19.2³ requiring methods to reduce CMV transmission risk.



Protozoan Parasites

PR is an FDA recommended option to mitigate Babesia transfusion transmission for the states required to implement a strategy.⁴

PR is also FDA approved to reduce the risk of *T. Cruzi* and *Plasmodium* parasite transfusion transmission.²

For centers with approved FDA variance: PR can be used in place of deferral for otherwise-eligible donors who traveled to a malaria-endemic area⁵



Emerging Pathogens

WHO,⁶ European Centre for Disease Prevention and Control (ECDC)⁷ and FDA Guidance for Zika⁸ state that PR** can be used in place of Zika testing or importing from non-endemic areas.

+ Transfusion-Associated Graft vs. Host Disease

**Data for pathogen reduction of Zika virus by the INTERCEPT Blood System, pathogen reduction system, has been submitted for FDA review.

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.

ISBT nomenclature for INTERCEPT treated (pathogen reduced) platelets

INTERCEPT® Blood System treated platelets are known as “**Psoralen Treated**” platelets in the ISBT product codes. “**Psoralen Treated**” refers to the psoralen/UVA light used in the INTERCEPT Blood System process. The specific psoralen used is known as amotosalen. Platelet units are labeled “psoralen treated” indicating that they have undergone treatment with the INTERCEPT Blood System.

INTERCEPT Blood System treated platelets are also commonly referred to as “**Pathogen Reduced**” (PR) or “**Pathogen Reduction Treated**” (PRT) platelets.

The INTERCEPT Blood System is the only FDA approved pathogen reduction system for platelets.

Basic INTERCEPT Treated Platelets Implementation Checklist

Project Planning

- Assemble your project team and assign a project manager

INTERCEPT Platelet Logistics and Policy Updates (see Chapter 2)

- Confirm your start date with your blood provider
- Confirm your timeline to 100% (or desired inventory level) with your blood provider
- Design your education and communication plan to properly reflect your ordering processes, irradiation and CMV mitigation policies
- Update all relevant policies and procedures per your plan

Getting IT Systems Ready for INTERCEPT Treated Platelets (see Chapter 3)

- Build products with new ISBT codes as applicable into BBIS
- Program pathogen reduced platelets as an alternative to irradiated and CMV tested platelets according to hospital policy
- Update HIS to accept pathogen reduced platelets
- Update billing system with P-code and billing rate
- Confirm that key stakeholders have received education regarding ordering, policy, and procedure updates

Hospital Staff Education (See Chapter 4)

- Educate key hospital staff regarding the operational and clinical updates for pathogen reduced platelets

Resources available at hcp.INTERCEPT-USA.com



[Implementation Resources Webpage](#)



Recognizing a Septic
Transfusion Reaction Poster



Clinician Overview
Brochure

2. Platelet Logistics and Policy Updates

This chapter will assist you in updating a small number of key policies in your Blood Bank operations when using INTERCEPT treated (pathogen reduced) platelets.

Onboarding pathogen reduced platelets at your facility requires discussions with two key stakeholder groups:

1. Your platelet provider
2. Internal implementation team

Platelet Provider

It's a good idea to develop your implementation plan around a mutually agreed upon start date for receiving pathogen reduced platelets from your provider. Additionally, it is important to discuss the number of pathogen reduced platelet units your provider has available and a potential ramp-up plan.

- This discussion should clarify expectations for how both parties will manage ordering and inventory during the conversion to pathogen reduced platelets.
- Discuss a ramp-up plan to reach your target pathogen reduced platelet percentage that includes timelines and usage strategy for the products you'll be receiving.
 - If your Transfusion Committee has decided to use pathogen reduced platelets in specific patient populations, or a first-in-first-out basis across all patients, consider the number of pathogen reduced platelets needed.

Determine how your provider will label pathogen reduced platelet products before you receive them in your facility.

- Even though these tests are not required for pathogen reduced platelets, your provider's psoralen-treated label may still include text denoting tests like CMV, Zika or Babesia have been performed due to their manufacturing and labeling processes.

Internal Implementation Team

Blood Bank, Lab, Transfusion Medicine, and Nursing representatives are key to include on your implementation team to drive awareness of the planned change to INTERCEPT treated (pathogen reduced) platelets.

- Pathogen reduced platelets are clinically equivalent to the conventional platelets you receive. No changes in platelet administration are required.

Depending on the size of your facility, an educational plan may be helpful to inform key personnel about the benefits and any potential changes associated with pathogen reduced platelets.

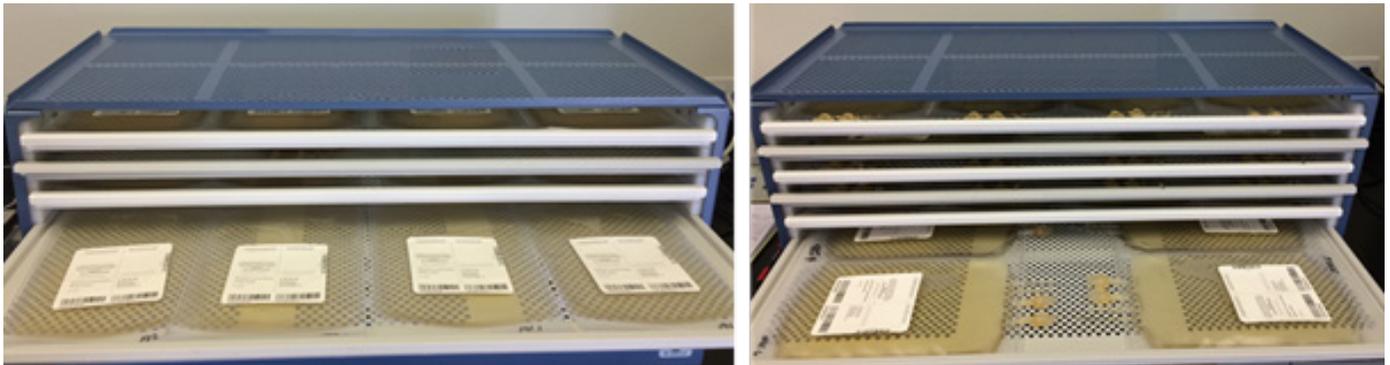
For example:

- A benefit of pathogen reduced platelet products is that they can be used for all patients regardless of disease state.* Pathogen reduction of platelets is an FDA approved alternative to gamma irradiation for the prevention of Transfusion-Associated Graft-Verus-Host Disease (TA-GVHD).² Education is needed to ensure that all staff who order and transfuse these products are aware of this change in these platelets.
 - Some hospital laboratories choose to attach a customized tie-tag to pathogen reduced products noting that irradiation isn't required as a visual reminder. For an example of this tie-tag please see the link at the end of this chapter.
- Pathogen reduced platelets meet AABB cytomegalovirus (CMV) mitigation standards for patients who require a risk reduction strategy for the transfusion transmission of CMV.³
 - For more information regarding CMV mitigation with pathogen reduction see the link at the end of this chapter.

Policies, procedures and order sets (if required) that reference "irradiated platelets" and/or "CMV-negative/safe platelets" should be updated to include how pathogen reduced platelets are an alternative to these attributes.

INTERCEPT platelet bags are 2.8 inches longer than conventional platelet bags. This allows for greater surface area for the platelet gas exchange and provides an easily recognizable visual cue that these are pathogen reduced INTERCEPT treated platelets, in addition to the "Psoralen-Treated" wording on the label.

It's important to make sure the bag is not rolled on top of itself and that the pigtailed aren't at risk of getting snagged in the shelf rollers. In either storage configuration pictured below, the platelet bags lay flat on the rotator shelf. The ports and pigtailed may be folded under the bag to accommodate the size of the rotator cabinet, however, the section of the bag containing the psoralen treated platelets should not be folded during storage.



The best communication pathway for your education plan is what works best for your hospital culture. An example SBAR (situation, background, assessment, recommendation) is available (see link at the end of this chapter). Additional resources, including electronic learning options, are available in the Hospital Staff Education chapter or by emailing hospitalsupport@cerus.com.

INTERCEPT Platelet Logistics and Policy Updates Checklist

- Confirm your start date with your blood provider

- Confirm your timeline to 100% (or desired inventory level) with your blood provider

- Design your education and communication plan to properly reflect your ordering processes, irradiation and CMV policies

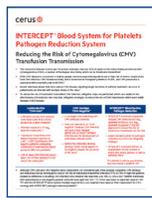
- Update all relevant policies and procedures per your plan

- Confirm that key personnel have received education regarding ordering, policy, and procedure updates

Resources available at hcp.INTERCEPT-USA.com



[Implementation Resources Webpage](#)



CMV Mitigation Sheet



Sample SBAR Sheet



Sample Tie Tags Sheet

3. Getting Your IT System Ready

This chapter will guide you through the necessary updates to your laboratory and hospital IT systems. If your facility uses a manual documentation system, this section provides considerations to keep in mind as you're updating the manual system.

When considering the scope of the IT changes required to effectively use INTERCEPT treated (pathogen reduced) platelets in your hospital, it is appropriate to segment the changes into 3 processes:

1. Inventory and Dispensing related IT
2. Transfusion related IT
3. Billing and Reimbursement related IT

Inventory and Dispensing related IT

The Inventory and Dispense process is mainly covered by the blood bank or transfusion service information system. The two technical tasks involved are:

1. Building the products in your system
2. Adjusting your system to identify pathogen reduced platelets as acceptable for patients requiring irradiated products, and as approved by your medical director or current transfusion policy as an alternative to CMV seronegative or CMV-Safe.

Listed below are the base product codes for pathogen reduced platelets you might receive from your blood supplier. The ISBT codes issued to INTERCEPT platelets identify them as psoralen-treated apheresis platelets. Depending upon what collection technology your blood provider uses to collect apheresis platelets, there are different groups of product codes. Apheresis platelets collected on Trima devices will be suspended in 100% plasma and platelets collected on Amicus devices will be suspended in platelet additive solution (PAS). ISBT codes have been assigned for other common platelet permutations, such as pediatric splits, aliquots, and washed platelets. For the current, complete list of INTERCEPT ISBT codes please see the link at the end of this chapter.

Apheresis in 100% Plasma

E8331 Apheresis PLATELETS | ACD-A/XX/20-24C | ResLeu:<5E6 | Psoralen-treated

E8332 Apheresis PLATELETS | ACD-A/XX/20-24C | ResLeu:<5E6 | 1st container | Psoralen-treated

E8333 Apheresis PLATELETS | ACD-A/XX/20-24C | ResLeu:<5E6 | 2nd container | Psoralen-treated

E8334 Apheresis PLATELETS | ACD-A/XX/20-24C | ResLeu:<5E6 | 3rd container | Psoralen-treated

E8335 Apheresis PLATELETS | ACD-A/XX/20-24C | ResLeu:<5E6 | < 3E11 plts | Psoralen-treated

(Continued on next page)

Apheresis in Platelet Additive Solution (PAS-C)

E8340 Apheresis PLATELETS | ACD-A>PAS-C/XX/20-24C | ResLeu:<5E6 | Psoralen-treated

E8341 Apheresis PLATELETS | ACD-A>PAS-C/XX/20-24C | ResLeu:<5E6 | 1st container | Psoralen-treated

E8342 Apheresis PLATELETS | ACD-A>PAS-C/XX/20-24C | ResLeu:<5E6 | 2nd container | Psoralen-treated

E8343 Apheresis PLATELETS | ACD-A>PAS-C/XX/20-24C | ResLeu:<5E6 | 3rd container | Psoralen-treated

E8344 Apheresis PLATELETS | ACD-A>PAS-C/XX/20-24C | ResLeu:<5E6 | <3E11 plts | Psoralen-treated

In the event you cannot find an ISBT code for a specific platelet configuration that is used in your facility, you can request a new ISBT code from the [ICCBBA website](https://www.iccbba.org/).

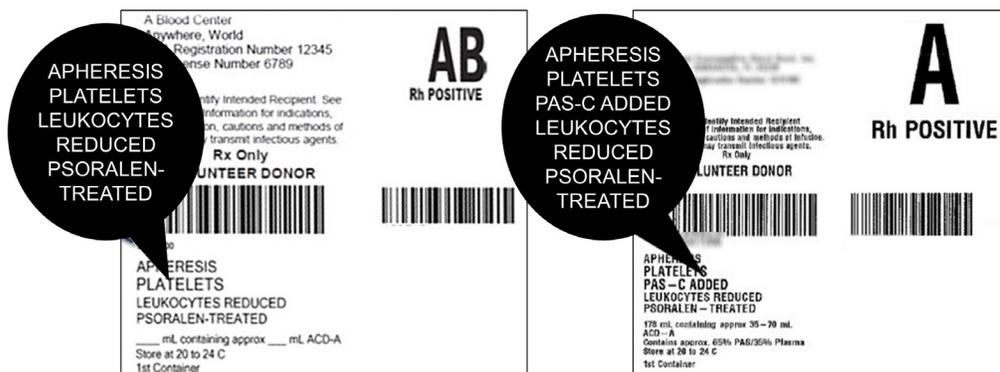


[ICCBBA Codes](https://www.iccbba.org/)
(website)

Transfusion related IT

While building and validating the products into your system, it may be helpful to check that:

1. Product label printers can print the product description as the character length is longer
2. Barcode readers are compatible
3. Transfusion tags print the accurate product/attribute description



The INTERCEPT Blood System Pathogen Reduction System for Platelets is recognized by the FDA and AABB as an alternative to gamma irradiation for the prevention of transfusion-associated graft-versus-host disease (TA-GVHD).^{2,3} Pathogen reduced platelets meet AABB Standards 5.19.2 cytomegalovirus (CMV) mitigation standards for patients who require a risk reduction strategy for the transfusion transmission of CMV.³ For more information regarding CMV mitigation by pathogen reduction see the link at the end of this chapter.

Please note, for the following sections, if your facility uses a manual documentation system, it's a good idea to review these considerations to keep in mind during your implementation process.

Blood Bank IT

Modern Blood Bank/Transfusion Service IT Systems include safeguards to prevent the transfusion of non-irradiated/non-CMV negative-tested products to patients at risk of TA-GVHD or the complications related to CMV. Hospitals that are currently using INTERCEPT treated (pathogen reduced) platelets have applied a variety of IT solutions to avoid the need to manually override these safeguards when assigning pathogen reduced platelets to patients, these include:

- If the system's algorithm allows for one permissible attribute, then change the attributes of pathogen reduced platelets and irradiated platelets to IRRPR and the attributes of pathogen reduced platelets and CMV-negative platelets to CMVPR.
- If the system's algorithm allows for multiple attributes, then the algorithm can be edited to where both IRR and PR attributes are acceptable. The same would apply for the CMV and PR attributes.
- If the system uses an error checking table where the algorithm references a table of acceptable product codes for irradiated products and CMV negative products, then pathogen reduced platelet products can be added to these tables for equivalency.

If you would like to be connected to other hospitals that use the same blood bank IT system as yours and have applied a working solution, email hospitalsupport@cerus.com.

Hospital IT

The hospital IT system may require updates to notify ordering clinicians that pathogen reduced platelets may be dispensed as an alternative to irradiated and/or CMV negative (or CMV safe) platelets. If your hospital IT system utilizes a bedside transfusion management system, updates must be applied so that the system can scan in the pathogen reduced platelet label.

- Update Computerized Physician Order Entry (CPOE) to include notification that psoralen-treated platelets may be dispensed as an alternative to irradiated/CMV-negative platelets
- If implemented, update bedside Hospital Information System (HIS) blood product administration system (i.e. eTAR, BPAM) to read new product barcode

Billing and Reimbursement related IT

There are a few key points to remember when setting up your billing for pathogen reduced platelets. CMS recognizes pathogen reduced platelets as a blood product, not as procedure, which is why pathogen reduced platelets should be billed using CMS' established P-code (P9073), not a CPT code.

- Centers for Medicare & Medicaid Services (CMS) granted a HCPCS Level II code for pathogen-reduced (PR) platelet components allowing hospitals to bill and secure reimbursement in the outpatient treatment setting
- CMS determines P-code payment rate annually, effective January 1st
- Use the appropriate P-code (P9073) – not CPT code – for third party payer billing of pathogen reduced platelets provided in the hospital outpatient setting.
- Hospital charge for pathogen reduced platelets should reflect the entire product cost, not just the blood supplier's incremental fee for the product.
- Ensure that hospital chargemaster entry for P9073 is accurate and up to date

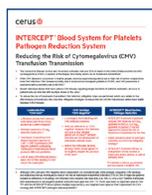
Getting your IT System Ready Checklist

- Build products with new ISBT codes as applicable into BBIS
- Program pathogen reduced platelets as an alternative to irradiated and CMV tested platelets according to hospital policy
- Update HIS to accept pathogen reduced platelets
- Update billing system with P-code and billing rate

Resources available at hcp.INTERCEPT-USA.com



[Implementation Resources Webpage](#)



CMV Mitigation Sheet



Sample Labels Sheet



Coding and Billing Guide



ISBT Codes Reference (xls)

4. Hospital Staff Education

We recommend that you consider an educational plan to facilitate your implementation of INTERCEPT® Blood System treated (pathogen reduced, psoralen treated) platelets. This chapter will walk you through the educational resources available for your nursing, blood bank / lab generalist, and physician staff. As nursing and lab staff typically handle the products more than any other departments, it is recommended to meet with their education leaders early in the implementation to notify them of the upcoming platelet product change.

In hospitals that have already implemented INTERCEPT platelets, nursing education has typically occurred two weeks before the first pathogen reduced platelets have been distributed from the blood bank. The main resources for this education are a nursing handout and an e-learning module that can be uploaded into your e-learning system.

The Nursing Handout Template

The handout can be used in live in-service sessions, as an email attachment, or posted in nursing stations, to announce the change in platelets. Some blood banks have also included the handout with each unit of pathogen reduced platelets distributed for the first few weeks of routine use in the hospital. For a fully editable version of this handout, please see the link at the end of this chapter.

The Nursing handout contains all the basic information that Hospital Nursing staff need to know about pathogen reduced platelets.

Key takeaways are:

- A picture of the physical differences in the bag size. The new platelet product bag is 2.8 inches longer than a conventional platelet bag.
- Sample product labels: The label contains two new words: “psoralen treated” which indicates that these products have undergone the pathogen reduction process.
- Sample tie tag (for use as an alternative to irradiation and CMV testing)
- There are no differences in the tubing used, transfusion time, or the ordering process for pathogen reduced platelets; these are the same as for conventional platelets.
- Conventional and pathogen reduced platelets may be transfused to the same patient, as needed.

Template: You will find that there are a few sections highlighted in yellow that you can customize to personalize it to your hospital’s transfusion service information and policies.



Optional E-Learning Module

If an e-learning module is preferred as your hospital's method of nursing education for new products, there is a comprehensive slide deck with slide notes for you to upload to your hospital's e-learning system at the end of this chapter. If it is required for Nursing staff to complete a post-test as part of the learning process, one is available to download at the link provided at the end of this chapter.

Additional optional CE accredited nursing modules on blood safety and transfusion medicine topics are available at www.bloodsafetyonline.com. These on-demand webinar courses are each worth 1 hour of credit provided by either the California Board of Nursing (CBRN) or Continuing Education Recognition Points (CERP), as approved by the American Association of Critical-Care Nurses (AACN). There is no charge to access these online learning modules.



In addition to the information included in the Nursing Education Handout previously described in this chapter, other materials are available to assist in the implementation process including:

- Frequently Asked Questions (FAQ) document: (See link at the end of this chapter)
 - Assists transfusion staff in answering questions regarding the INTERCEPT® treated (psoralen treated) platelets
 - Provides an extensive citation resource of peer reviewed publications on INTERCEPT treated platelets
- Sample psoralen treated platelet labels to use to test your LIS code build for base products only, your platelet provider can supply any additional needs

A comprehensive set of peer reviewed publications, case studies, white papers, safety data, package insert and educational presentations are available upon request, or at the links provided on the INTERCEPT health care professional website: <https://hcp.intercept-usa.com/>

- For assistance or in-person education on the INTERCEPT® Blood System and psoralen treated platelets please contact us at hospitalsupport@cerus.com.

Hospital Staff Education Checklist

- Educate key personnel regarding ordering, policy, and procedure updates

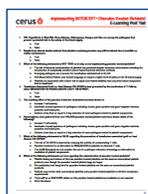
Resources available at hcp.INTERCEPT-USA.com



[Implementation Resources Webpage](#)



Nurse Template



eLearning Post Test



FAQ



Sample Labels



Nurse Training

Contact Cerus | **Email:** hospitalsupport@cerus.com **Phone:** 1-855-835-3523 **Web:** hcp.intercept-usa.com

*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 INT100 Illuminator for UVA illumination of amotosalen-treated plasma or 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 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: 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.

Resources available :

The following collection of documents that are referenced throughout this guide can be found online on the Implementation Resource page at hcp.INTERCEPT-USA.com



These include:

- Recognizing a Septic Transfusion Reaction Poster
- Clinician Overview Brochure
- CMV Mitigation Sheet
- Frequently Asked Questions (FAQs) Sheet
- Coding and Billing Sheet
- Sample Labels Sheet
- Sample SBAR Sheet
- Sample Tie Tags Sheet
- Nurse Training Deck
- eLearning Post-Test (and answer key)
- ISBT Codes Reference (.xls)

External Links

BloodSafetyOnline.com
(Free CE) website



ICCBBA - Request Codes (webpage)



References:

1. [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; 2019.



2. [INTERCEPT Blood System for Platelets \[Package Insert\].](#) Concord, CA: Cerus Corporation; July 17, 2018.



3. [AABB. Standards for Blood Banks and Transfusion Services 31st Edition.](#) Bethesda, MD: AABB; 2018.



4. [FDA. Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis: Guidance for Industry.](#) In: U.S. Department of Health and Human Services FDA, ed. Silver Spring, MD: Center for Biologics Evaluation and Research; May 2019.



5. [FDA. Exceptions and Alternative Procedures Approved Under 21 CFR 640.120," 21 CFR 630.10\(a\), 630.10\(h\), 630.30\(b\)\(1\)](#)



6. [WHO. Maintaining a safe and adequate blood supply during Zika virus outbreaks. Interim guidance.](#): World Health Organization; 2016.



7. [European Centre for Disease Prevention and Control. Zika virus and safety of substances of human origin – A guide for preparedness activities in Europe.](#) In: ECDC, ed. Stockholm 2016.



8. [FDA. Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components.](#) FDA Guidance for Industry July 2018.





Contact your Vitalant representative for more information.



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