cerus

INTERCEPT® Goes Beyond

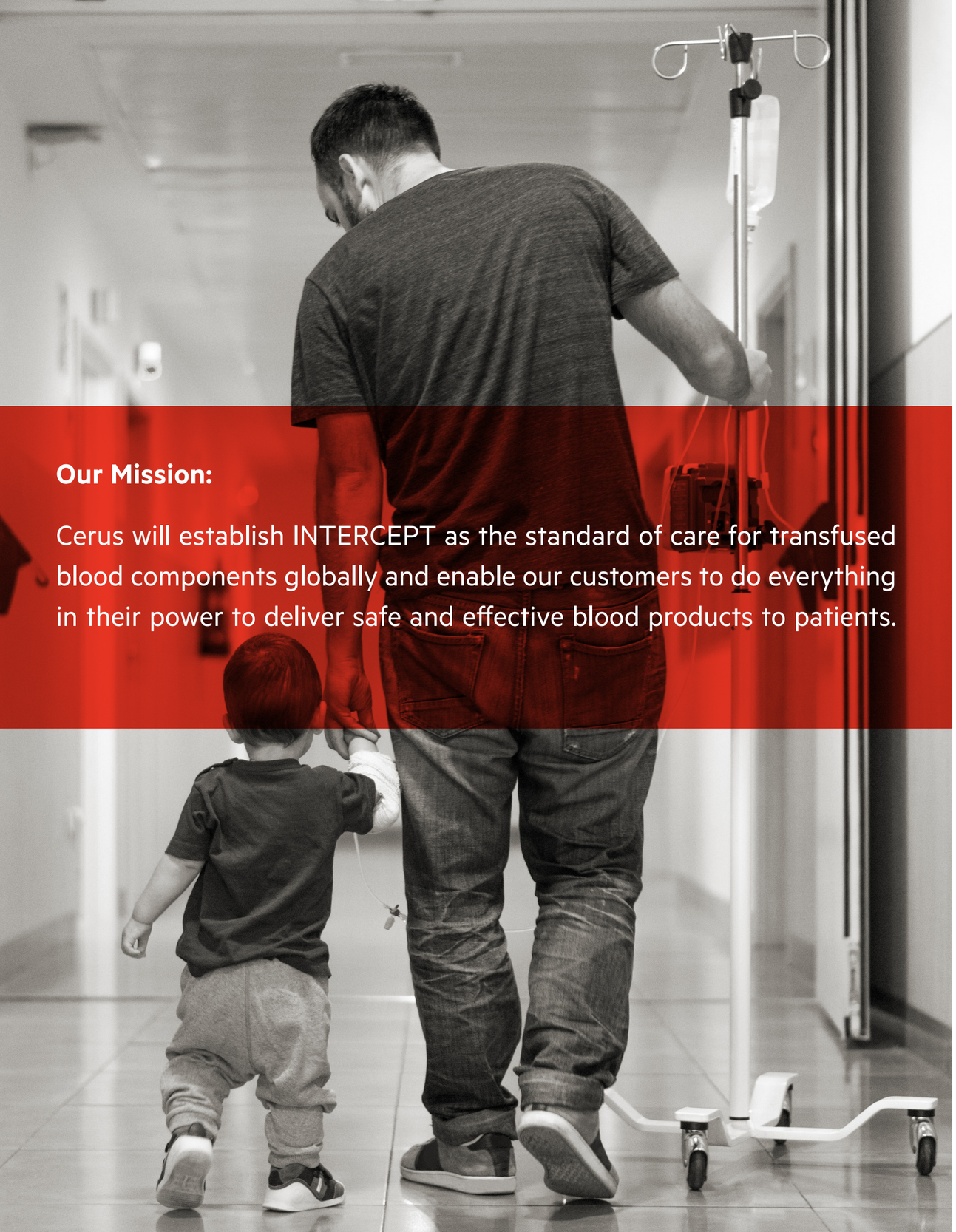
INTERCEPT® Blood System for Platelets Pathogen Reduction System

and

Pathogen Reduced Cryoprecipitated Fibrinogen Complex

(INTERCEPT® Fibrinogen Complex)

produced from the INTERCEPT® Blood System for Cryoprecipitation



Our Mission:

Cerus will establish INTERCEPT as the standard of care for transfused blood components globally and enable our customers to do everything in their power to deliver safe and effective blood products to patients.

INTERCEPT® Goes Beyond

Protect Patients

We protect patients by providing broad-spectrum transfusion transmitted infection risk reduction with the inactivation of bacteria, viruses, protozoans and leukocytes.

Improve Availability*

We ensure earlier availability, resulting in younger, fresher platelets and immediate availability of fibrinogen and other vital clotting factors when minutes matter.

Deliver Value

We deliver economic value and operational efficiencies by providing one transfusion-ready inventory, eliminating waste and reducing costs associated with testing and risks of TTIs, sepsis and TA-GvHD.

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. For a full list of pathogens, please refer to package inserts.

**INTERCEPT Fibrinogen Complex is available for immediate use for up to 5 days when stored thawed; when stored frozen, requires thawing prior to use.*

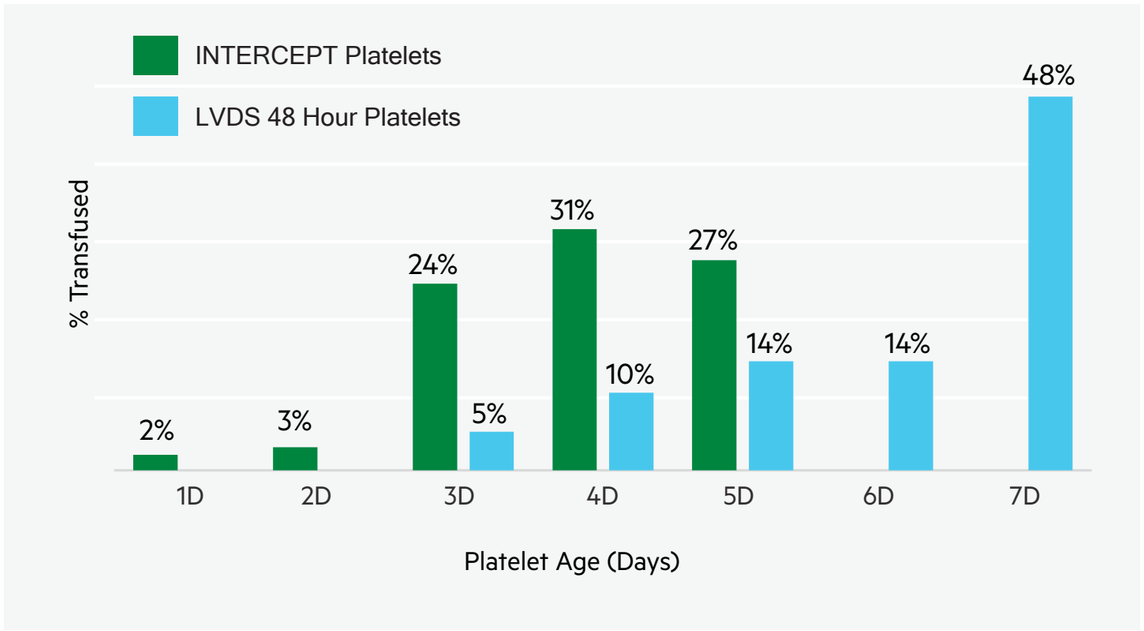
100% of Leading Hospitals Have Implemented Use of INTERCEPT® PLATELETS.[1]

INTERCEPT® Blood System for Platelets

Improve Availability

Release of product on day one provides flexibility for managing inventory and may enable hospitals to attain fresher platelets sooner.

Helps to ensure blood supply continuity with the ability to mitigate TTI risk due to emerging pathogens.

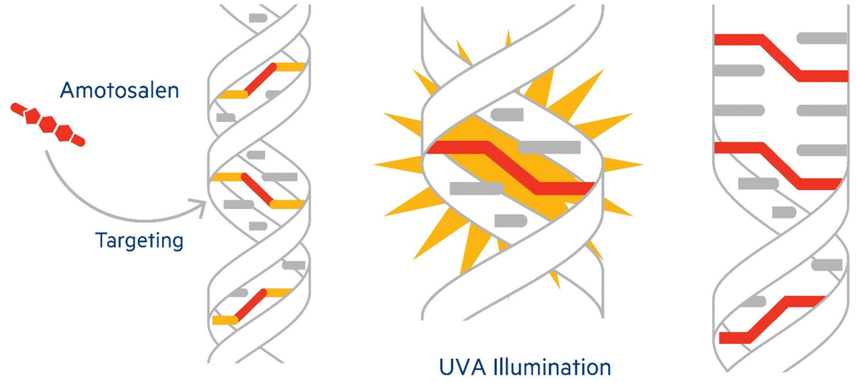


Early release enables hospitals to transfuse platelets earlier with INTERCEPT Platelets:[2]
Graph demonstrates ability to TRANSFUSE EARLIER at HOSPITAL with PR.

Protect Patients

Broad spectrum transfusion transmitted infection (TTI) risk reduction by inactivating viruses, bacteria, and protozoans, as well as prevention of transfusion-associated graft vs. host disease (TA-GvHD) via the inactivation of leukocytes.

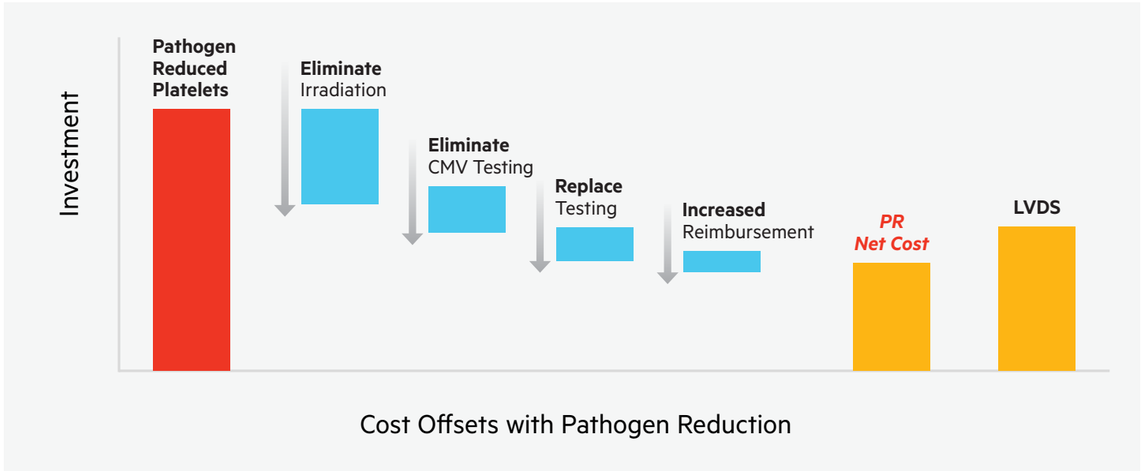
INTERCEPT Blood System
Mechanism of Action



Deliver Economic Value and Operational Efficiencies

Operational efficiencies with PR may translate into economic benefits. PR grants hospitals simplicity with a single, ready-to-transfuse solution that complies with FDA malaria,[3] Babesia[4] and bacterial contamination[5] guidances without the need for testing. This results in minimal operational disruption and reduced potential additive cost to hospitals.

Total Economic Value vs. Perceived (Acquisition) Cost
Cost-offsets may be attained with INTERCEPT Platelets including replacement of irradiation, as well as certain tests and deferrals (illustrative figure).



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. For a full list of pathogens, please refer to package inserts.

Be Ready. When Minutes Matter™

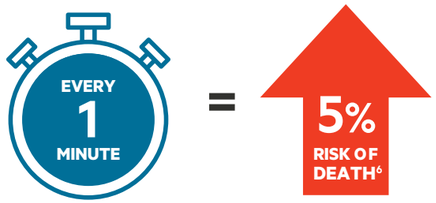
Pathogen Reduced Cryoprecipitated Fibrinogen Complex

(INTERCEPT® Fibrinogen Complex)

produced from the INTERCEPT® Blood System for Cryoprecipitation

Transfuse Immediately*[6]

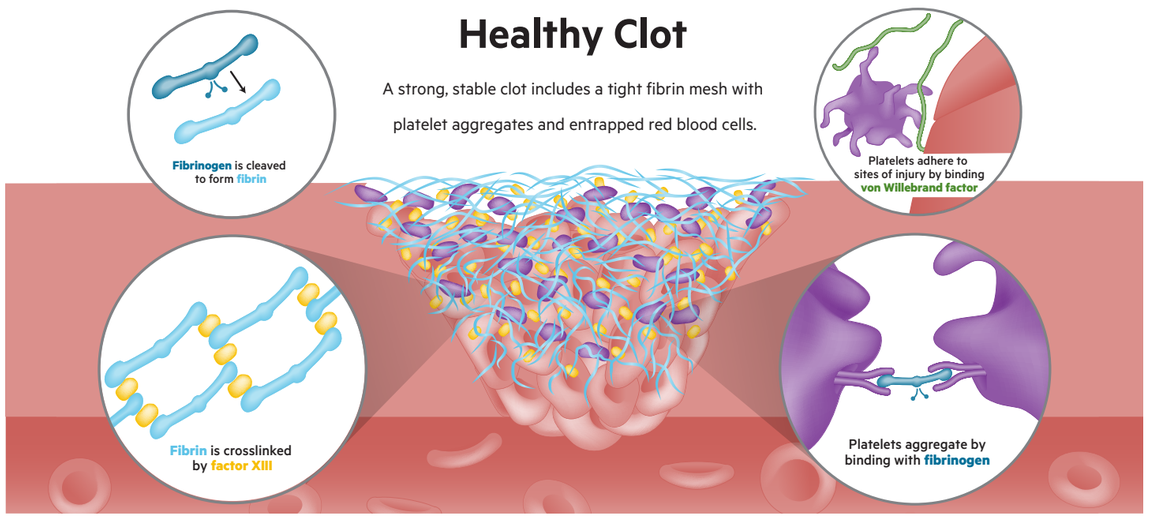
When controlling hemorrhage, faster is better. **5-day post-thaw shelf life** allows IFC to be **thawed in advance** and **available for immediate use**.



Faster is better.

Control Bleeding†

IFC is an enriched source of fibrinogen, factor XIII, von Willebrand factor, and other constituents, restoring clot strength and rapid hemostasis.[7-10]

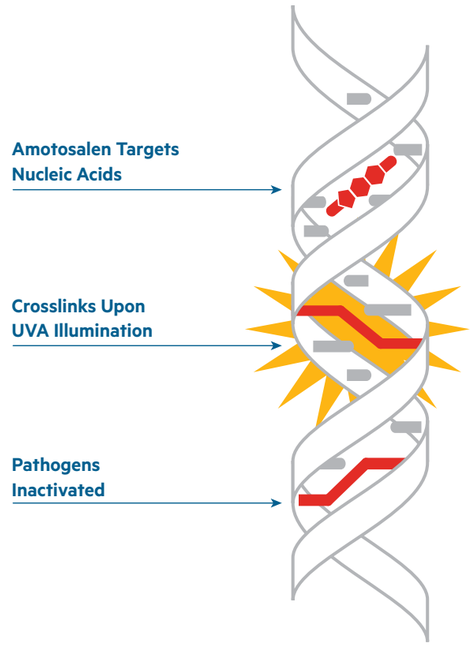


*INTERCEPT Fibrinogen Complex is available for immediate use for up to 5 days when stored thawed; when stored frozen, requires thawing prior to use.
†Bleeding associated with fibrinogen deficiency.

Protect Patients

Broad spectrum transfusion transmitted infection (TTI) risk reduction by inactivating viruses, bacteria, and protozoans, as well as prevention of transfusion-associated graft vs. host disease (TA-GvHD) via the inactivation of leukocytes.[11,12]

INTERCEPT® Blood System for Plasma Mechanism of Action

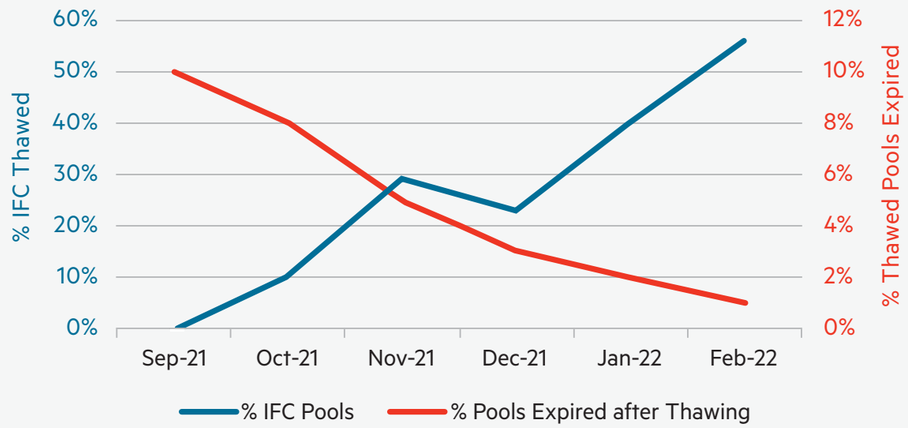


Upon UVA illumination, amotosalen cross-links nucleic acids to block replication and inactivates pathogens

Minimize Wastage

Transfusion-ready, room temperature IFC **minimizes wait times and wastage rates**, addressing common cryoprecipitated AHF inventory challenges.

If not immediately transfused, IFC can be returned to inventory and reallocated.



UF Health Case Study 2022
Blood product wastage after thawing decreased as the proportion of IFC thawed increased.[13]

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. For a full list of pathogens, please refer to package inserts.

INTERCEPT® Blood System for Platelets Pathogen Reduction System:

Rx only. See package insert for full prescribing information at hcp.intercept-usa.com/resources.

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. For a full list of pathogens, please refer to package insert.

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 platelets 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/or container ports of the INTERCEPT Blood System contain polyvinyl chloride (PVC). Di(2-ethlhexyl)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.

INTERCEPT® Blood System for Cryoprecipitation for the manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex:

Rx only. See package insert for full prescribing information at intercept-cryoprecipitation.com/resources.

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. For a full list of pathogens, please refer to package insert.

INDICATIONS FOR USE

- Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency.
- Control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or von Willebrand factor (vWF) are not available.
- Second-line therapy for von Willebrand disease (vWD).
- Control of uremic bleeding after other treatment modalities have failed.

Limitations of Use: Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used for replacement of factor VIII.

CONTRAINDICATIONS

Contraindicated for preparation of blood components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens.
Contraindicated for preparation of blood 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 the INTERCEPT Blood System for Cryoprecipitation is approved for use to produce Pathogen Reduced Cryoprecipitated Fibrinogen Complex.
For management of patients with vWD or factor XIII deficiency, Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used if recombinant or specific virally-inactivated factor preparations are available. In emergent situations, if recombinant or specific virally-inactivated factor preparations are not available, Pathogen Reduced Cryoprecipitated Fibrinogen Complex may be administered.

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11. INTERCEPT Blood System for Plasma Package Insert.
12. INTERCEPT Blood System for Cryoprecipitation for the manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Package Insert.
13. "Assessing Impact of INTERCEPT Fibrinogen Complex (IFC) on Wastage and Massive Transfusion Protocols (MTPs)." Cerus Corporation.

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