cerus

INTERCEPT® Goes Beyond

INTERCEPT® Blood System for Platelets Pathogen Reduction System

and

Pathogen Reduced Cryoprecipitated Fibrinogen Complex

(INTERCEPT® Fibrinogen Complex, IFC)

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 help protect patients by providing broad spectrum transfusion transmitted infection (TTI) risk reduction with the inactivation of bacteria, viruses, protozoans and leukocytes.[1-3]

Improve Availability

We allow for earlier blood component availability, providing younger, fresher platelets that may be transfused sooner,[4,5] and immediate availability† of fibrinogen and other vital clotting factors when minutes matter.[6]

Deliver Value

We deliver value and operational efficiencies by providing one transfusion-ready inventory, eliminating waste and reducing costs associated with testing and risks of TTIs, sepsis, and transfusion-associated graft vs. host disease (TA-GVHD).[7-10]

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

JOIN THE MOVEMENT.

INTERCEPT® Blood System for Platelets

The majority of the US platelet supply, over 1.4 million units each year, are treated with the INTERCEPT Blood System.[11]

Protect Patients*

The INTERCEPT Blood System provides **broad spectrum TTI risk reduction** by inactivating viruses, bacteria, and protozoans, as well as **prevention of TA-GVHD** via the inactivation of leukocytes.[1]

*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.

Improve Availability

Hospitals may receive **ready-to-transfuse platelets sooner,** providing flexibility in managing inventory.[4,5]

The INTERCEPT Blood System supports pandemic preparedness and **helps ensure blood supply continuity** by inactivating certain emerging pathogens.[12,13]

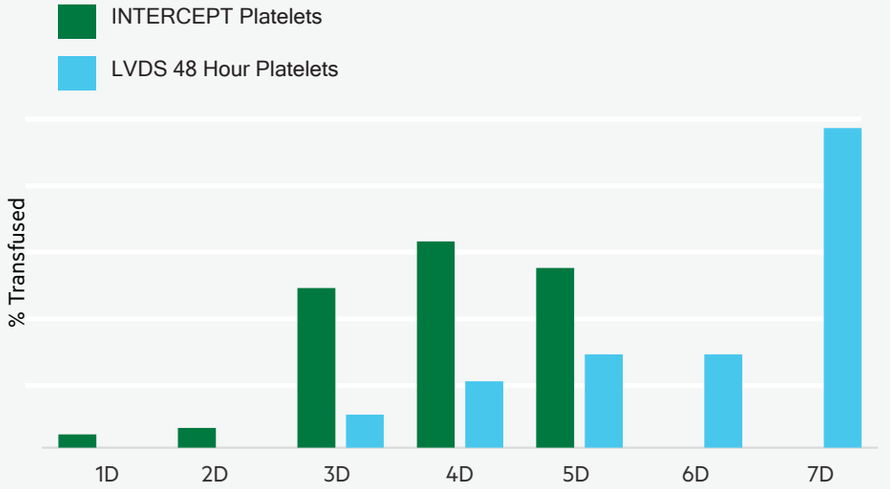
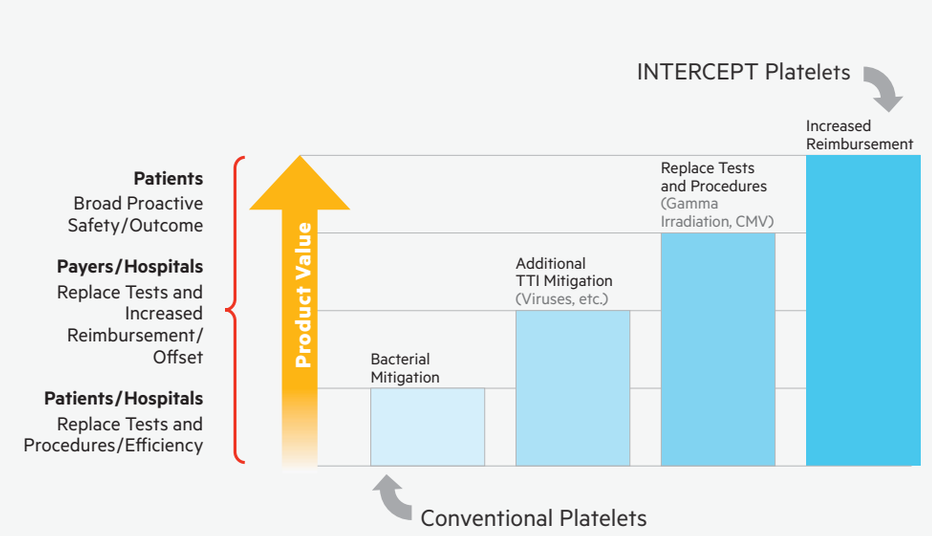


Figure demonstrates the ability for hospitals to transfuse INTERCEPT treated platelets sooner when compared with LVDS tested platelets.[4]

Deliver Value and Operational Efficiencies

With INTERCEPT treated platelets (INTERCEPT Platelets), hospitals receive a single, ready-to-transfuse solution that complies with FDA guidance on bacterial contamination,[14] malaria,[15] and Babesia,[16] without the need for testing. Replacement of tests and deferrals, including CMV serology and gamma irradiation, may provide operational efficiencies and cost savings.[7,8]



INTERCEPT Platelets provide hospital and patient value. (illustrative figure).

Be Ready. When Minutes Matter®

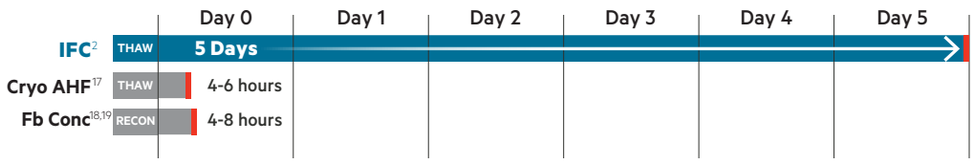
Pathogen Reduced Cryoprecipitated Fibrinogen Complex

(INTERCEPT® Fibrinogen Complex, IFC)

produced from the INTERCEPT® Blood System for Cryoprecipitation

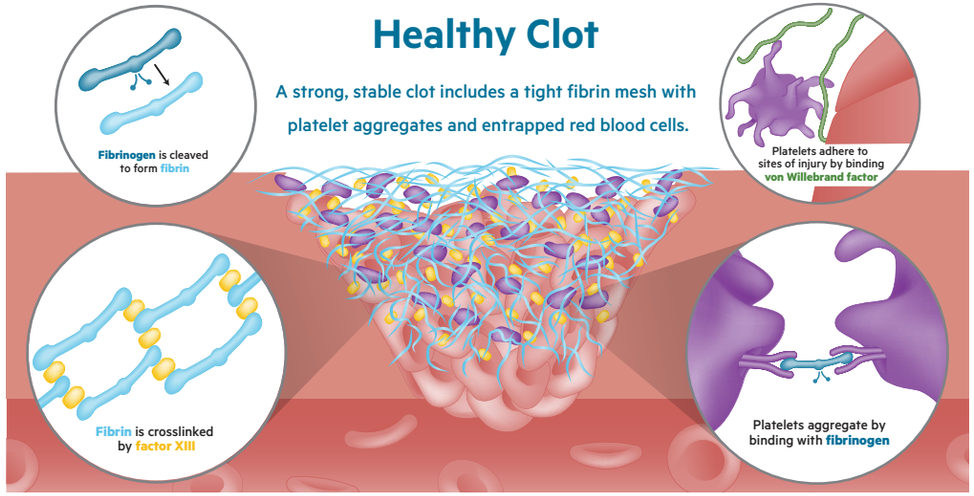
Transfuse Immediately*[6]

When controlling hemorrhage, faster is better.[6] **5-day post-thaw shelf life** allows IFC to be **thawed in advance** and **available for immediate use**.



Control Bleeding†

IFC is an enriched source of fibrinogen, factor XIII, von Willebrand factor, and other constituents, restoring clot strength and rapid hemostasis.[20-23]

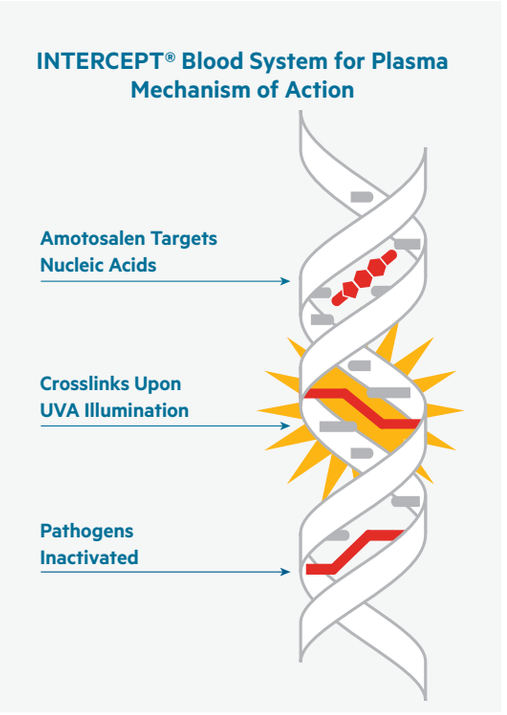


* INTERCEPT Fibrinogen Complex is available for immediate use for up to 5 days when stored thawed; when stored frozen, requires thawing prior to use.
† Bleeding associated with fibrinogen deficiency.

Protect Patients‡

IFC is produced from plasma treated by the INTERCEPT Blood System, which provides **broad spectrum TTI risk reduction** by inactivating viruses, bacteria, and protozoans, as well as prevention of TA-GVHD via the inactivation of leukocytes.[2,3]

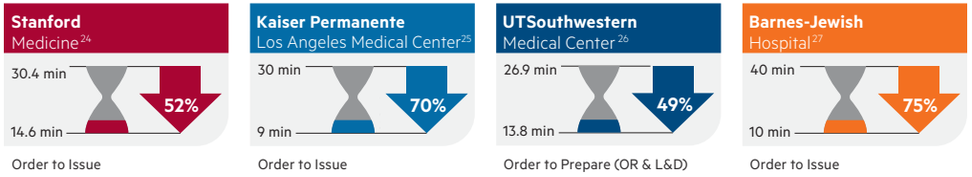
Upon UVA illumination, amotosalen cross-links nucleic acids to block replication and inactivates pathogens.



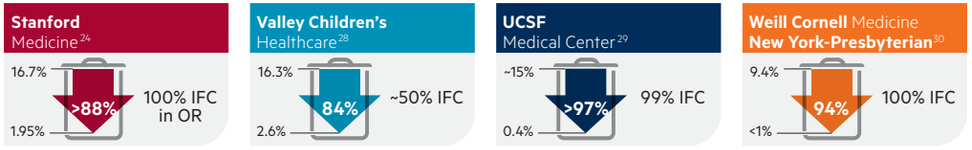
Improve Efficiencies

Transfusion-ready, room temperature IFC **improves turnaround times and wastage rates**.

IFC accelerates availability, minimizes wait times and increases reliability and predictability of blood component delivery.



IFC reduces blood component wastage, improving blood stewardship.



‡Broad spectrum transfusion transmitted infection risk reduction. 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.

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 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:

INTENDED USE

The INTERCEPT Blood System for Cryoprecipitation is intended to provide a functionally closed system for the production of Pathogen Reduced Cryoprecipitated Fibrinogen Complex.

Pathogen Reduced Cryoprecipitated Fibrinogen Complex is indicated for:

- 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: 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, 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.

REFERENCES

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Rx only. See package inserts for full prescribing information.

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