



Be Ready. When Minutes Matter[®]

**Pathogen Reduced Cryoprecipitated Fibrinogen Complex
(INTERCEPT[®] Fibrinogen Complex)**

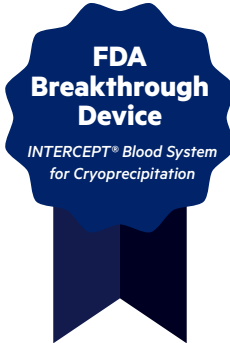
produced from the INTERCEPT[®] Blood System for Cryoprecipitation

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

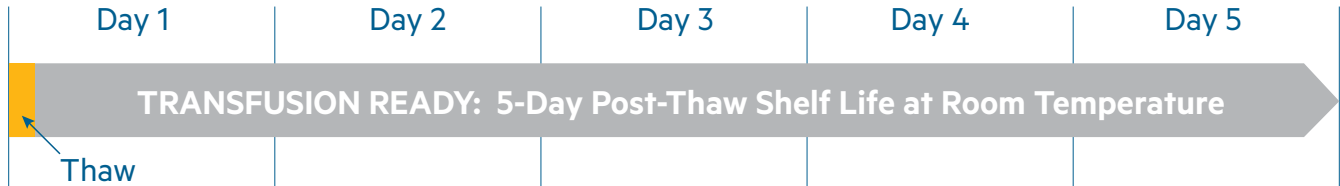
INTERCEPT® Fibrinogen Complex

Breakthrough Device to CONTROL BLEEDING

The ready-to-use INTERCEPT® Fibrinogen Complex (IFC)* is approved specifically for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency.



- Immediate, enriched source of key factors in effective hemostasis¹⁻³
 - » Fibrinogen
 - » Factor XIII
 - » von Willebrand Factor
 - » Other vital clotting proteins



TRANSFUSE IMMEDIATELY With the First Blood Components*

Thaw IFC in advance to minimize wait times and have available for immediate use.

PRODUCT	IMMEDIATE AVAILABILITY	MTP ⁴		
		ROUND 1	ROUND 2	ROUND 3
INTERCEPT® Fibrinogen Complex	Room Temp ≤ 5 Days*			
..... OR				
Cryoprecipitated AHF⁵	Room Temp ≤ 4-6 Hours Availability delayed due to time to thaw-on-demand, and establishment into later rounds of MTPs ⁴		

* INTERCEPT Fibrinogen Complex is available for immediate use for up to 5 days when stored thawed; and when stored frozen requires thawing prior to use.
 **There is no pathogen inactivation process that has been shown to eliminate all pathogens. Certain non-enveloped viruses (e.g., hepatitis A virus (HAV), hepatitis E virus (HEV), parvovirus B19 and poliovirus) and Bacillus cereus spores have demonstrated resistance to the INTERCEPT process.

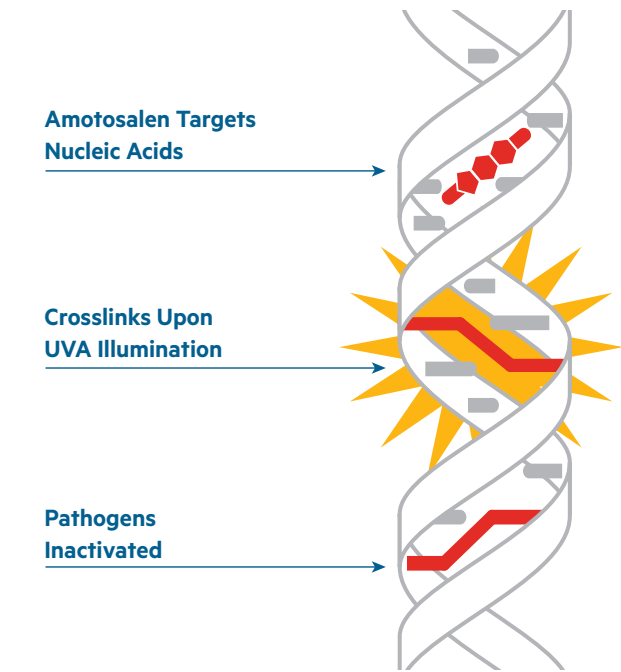
PROTECT PATIENTS: Pathogen Reduction

IFC provides broad spectrum transfusion transmitted infection (TTI) risk reduction, including viruses, bacteria, and emerging pathogens.^{6,7,**}

- Produced from plasma treated by the INTERCEPT Blood System.
- Pathogen reduction enables IFC's 5-day post-thaw shelf life.

The INTERCEPT® Blood System has 20 years of clinical and post-market surveillance experience.

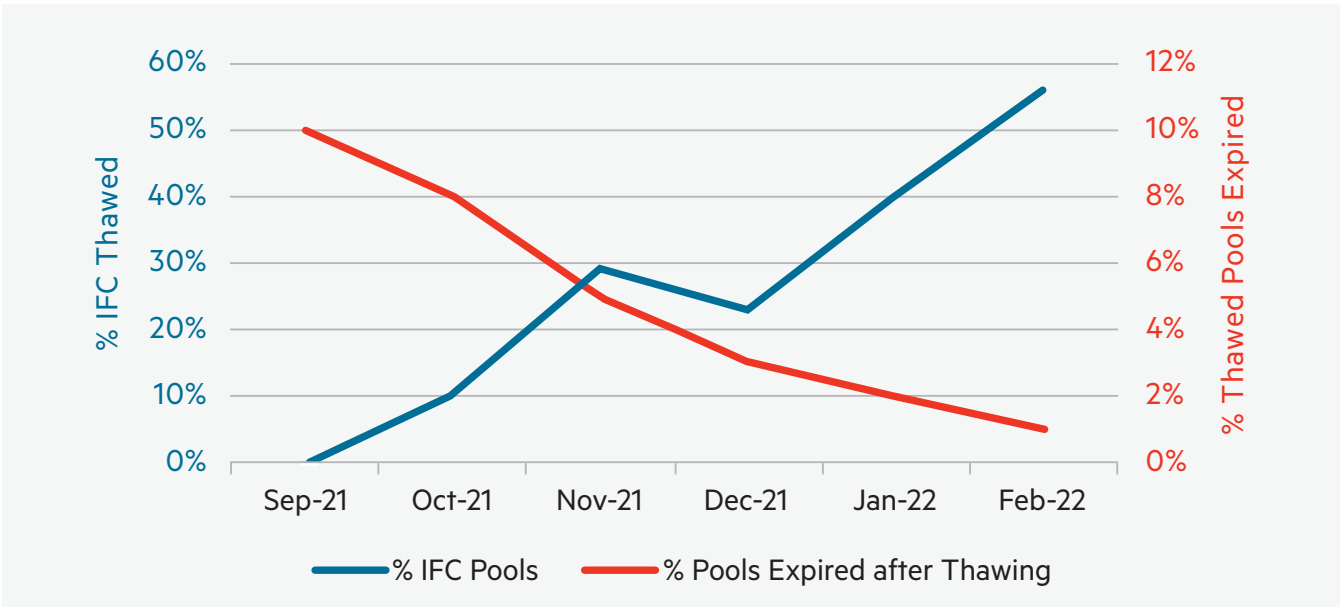
INTERCEPT® Blood System for Plasma Mechanism of Action



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

MINIMIZE WASTE

IFC's 5-day post-thaw shelf life enables product to be returned to inventory if not immediately transfused and reallocated to another patient.



UF Health Case Study 2022⁸
 Blood component wastage after thawing decreased as the proportion of IFC thawed increased.

The INTERCEPT® Fibrinogen Complex Advantage

TRANSFUSE IMMEDIATELY* 

CONTROL BLEEDING[†] 

MINIMIZE WASTE 

PROTECT PATIENTS[‡] 

*INTERCEPT Fibrinogen Complex is available for immediate use for up to 5 days when stored thawed; and when stored frozen requires thawing prior to use.
[†]Bleeding associated with fibrinogen deficiency.
[‡]Broad spectrum transfusion transmitted infection risk reduction.

Availability

Ready for Immediate Use!

Once thawed, may be stored at room temperature for up to 5 days.

- Provided in single-use containers
- Components may be purchased as single or pre-pooled units



Catalog #	Description	Average Fibrinogen (mg)*	# Donors [†]
FC10	Pooled Fibrinogen Complex 1.0, Cryoprecipitated, Psoralen Treated	740	2
FC15	Pooled Fibrinogen Complex 1.5, Cryoprecipitated, Psoralen Treated	1,457	4
FC20	Pooled Fibrinogen Complex 2.0, Cryoprecipitated, Psoralen Treated	2,220**	6
FC30	Pooled Fibrinogen Complex 3.0, Cryoprecipitated, Psoralen Treated	3,117	8
FC40	Pooled Fibrinogen Complex 4.0, Cryoprecipitated, Psoralen Treated	3,700**	10

* Mean fibrinogen content (per package insert). Fibrinogen content depends on donor plasma fibrinogen levels.
 ** Calculated based on pooling of FC10.
[†] Number of donors based on whole blood donors.

Hemorrhage Increases Mortality In



Hemorrhage is a Leading Cause of Preventable Death¹⁵

Trauma is the **#1** cause of death in adults <45 years old¹⁶

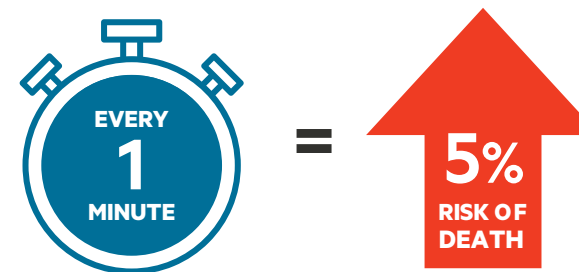
Of trauma deaths **~40%** from hemorrhage¹⁶

Hours until death **~1.6** from exsanguination¹⁷

Faster is Better in Hemorrhage Control¹⁸

Massive Transfusion Protocols (MTP) were developed to improve hemorrhage outcomes by delivering blood components quickly.

- Every minute of delay between the activation of an MTP and the arrival of the first blood components, results in a 5% increase in the odds of mortality.
- Timely delivery of blood components is an important metric, similar to “door-to-balloon” time.



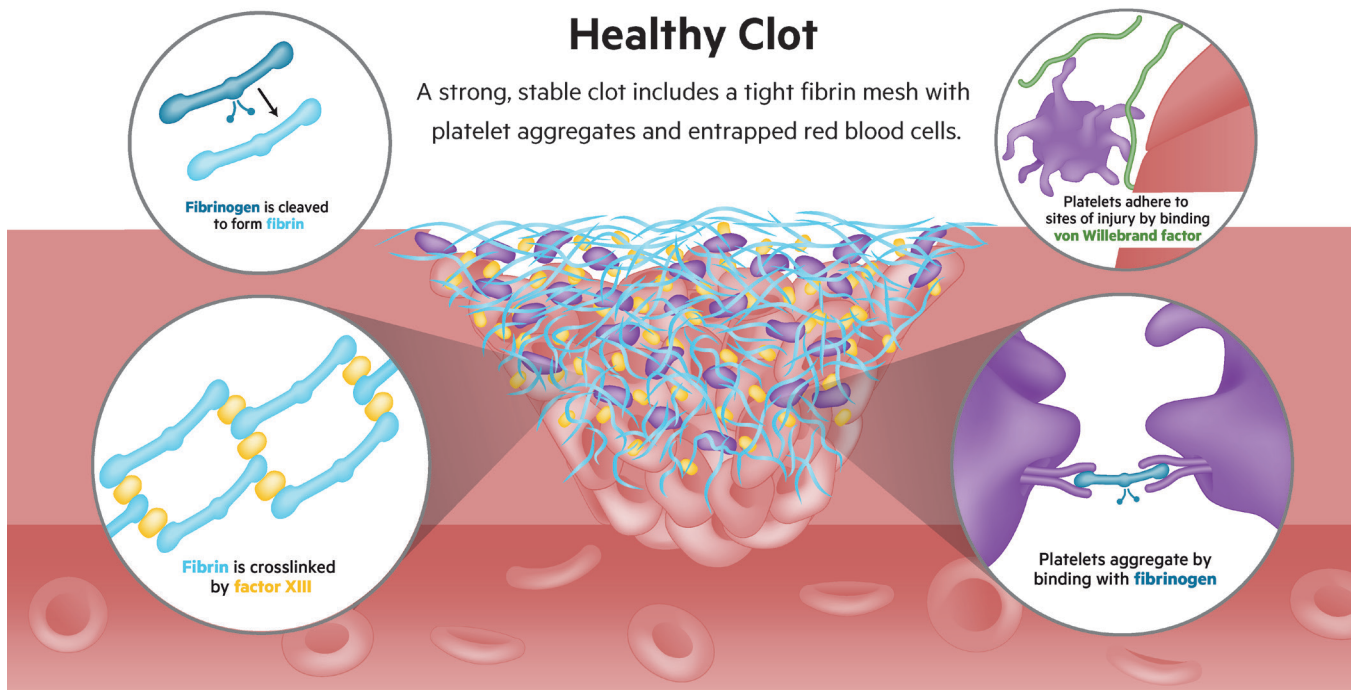
DELAY INCREASES MORTALITY¹⁸

¹⁸Severe loss of blood

Effective Treatment: Restoring Fibrinogen & Other Clotting Factors

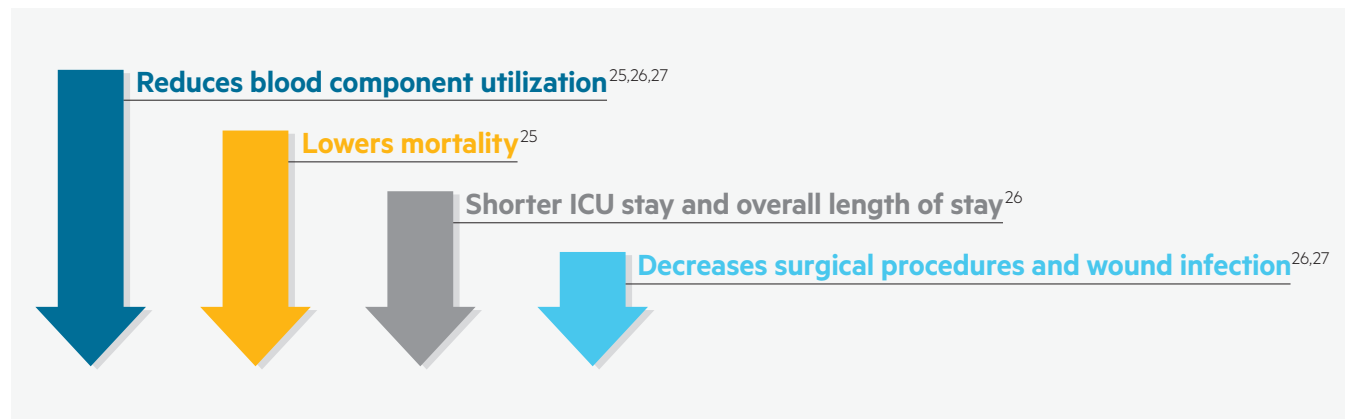
Early fibrinogen supplementation restores clot strength, reduces blood loss, and lowers mortality¹⁰

- Fibrinogen and other key clotting factors decrease rapidly and significantly in hemorrhage.^{10,19}
- Fibrinogen level is an independent risk factor for hemorrhage and mortality in trauma,²⁰ cardiac (CV) surgery²¹ and postpartum hemorrhage.²²



Early delivery of **Fibrinogen**, **factor XIII** and **von Willebrand factor** adds the clotting strength needed to achieve stable clot formation and restore hemostasis.^{10,23,24}

Early Fibrinogen Supplementation Improves Patient Outcomes*



*These results are based on studies evaluating cryo AHF. Results with IFC may vary.

MTPs Lack Critical Components from the Start

Cryoprecipitated AHF Inventory Challenges



LONG WAIT TIMES

15 min – 2.8 hours^{4,5}

Stored frozen and typically thawed in round 2 or 3 of MTP²⁹



SHORT SHELF LIFE

4 – 6 hours³⁰

Post thaw due in part to infectious risk



HIGH WASTAGE RATES

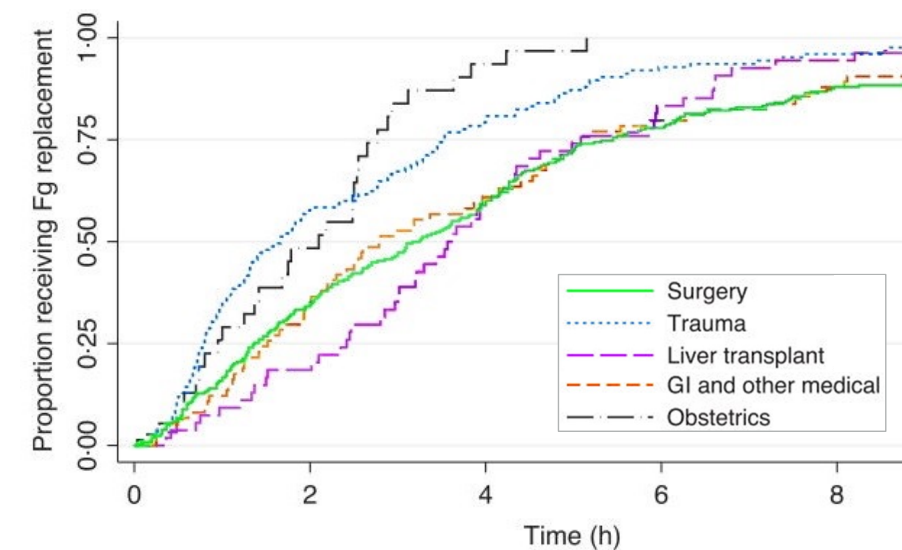
7 – 33%²⁹

Thawed cryo AHF is wasted

In >75% of U.S. exsanguination cases, cryo AHF arrives too late to be medically efficacious²⁸

Delays Impact Cryoprecipitated AHF Utility

Time to issue cryoprecipitated AHF by patient type³¹



- **2.5 hours:** Median time to receipt of cryo AHF after initiation of an MTP³¹
 - **Trauma and OB earliest: median of 1.7 hours**³¹
- **1.6 hours:** Median time to death from exsanguination¹⁷

Intended 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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Rx only.



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