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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

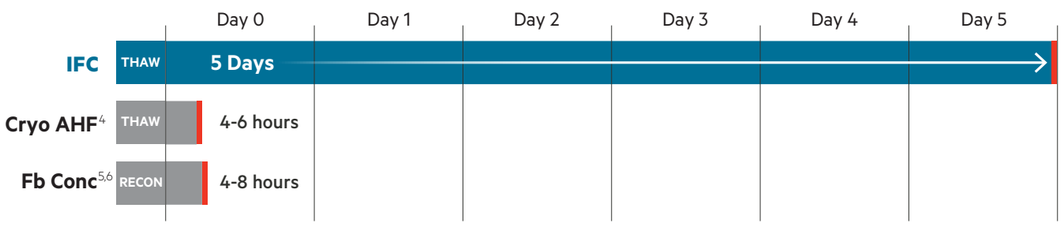
Breakthrough Device to CONTROL BLEEDING

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 hemostasis[1–3]
  - » Fibrinogen
  - » Factor XIII
  - » von Willebrand Factor
  - » Other vital clotting proteins

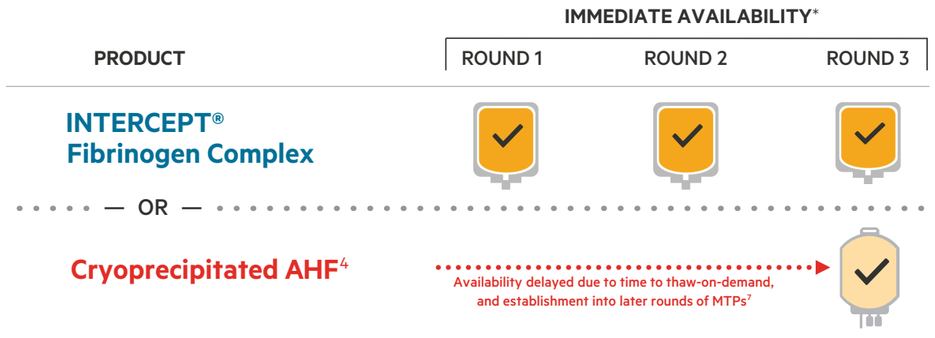
FDA Breakthrough Device
INTERCEPT® Blood System for Cryoprecipitation

5 Day Room Temperature Shelf Life



TRANSFUSE IMMEDIATELY With the First Blood Components*

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



* 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.

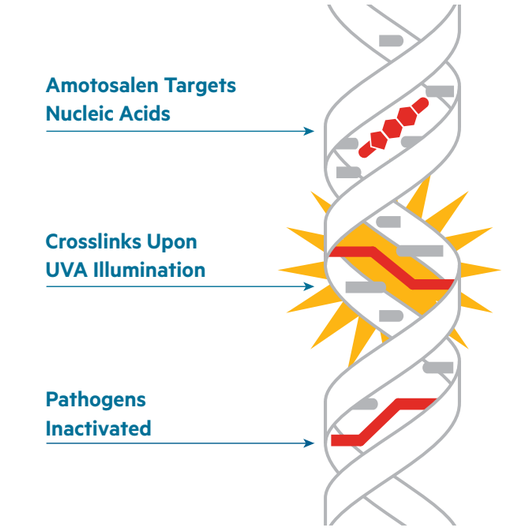
PROTECT PATIENTS: Pathogen Reduction

IFC provides broad spectrum transfusion transmitted infection (TTI) risk reduction, including viruses, bacteria, and emerging pathogens.[8,9,]**

- 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

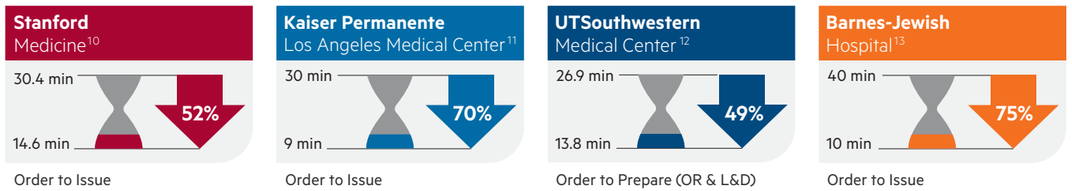


Upon UVA illumination, amotosalen cross-links nucleic acids to block replication and inactivates pathogens

IMPROVE EFFICIENCIES: Turnaround Times and Wastage

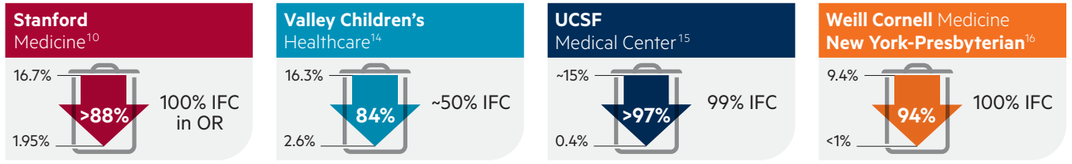
IFC accelerates availability, minimizes wait times and increases reliability and predictability of blood component delivery.

Improved Turnaround Times



IFC reduces blood component wastage, improving blood stewardship.

Significant Wastage Reduction



The INTERCEPT® Fibrinogen Complex Advantage

TRANSFUSE IMMEDIATELY*

CONTROL BLEEDING†

IMPROVE EFFICIENCIES

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.

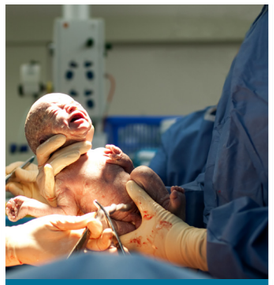
- Provided in single-use containers
- Components may be purchased as single or pre-pooled units

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	1,556	4
FC20	Pooled Fibrinogen Complex 2.0, Cryoprecipitated, Psoralen Treated	2,220**	6
FC30	Pooled Fibrinogen Complex 3.0, Cryoprecipitated, Psoralen Treated	2,845	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

Trauma[17,18]



Postpartum Hemorrhage[19]

Cardiac (CV) Surgery[20]

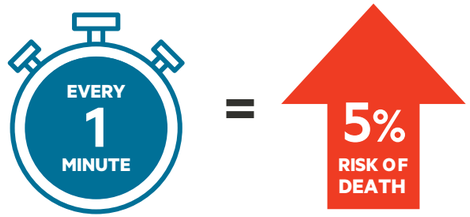
Combat[21,22]

Hemorrhage is a Leading Cause of Preventable Death[23]

Trauma is the **#1** cause of death in adults <45 years old[24]

Of trauma deaths **~40%** from hemorrhage[24]

Hours until death **~1.6** from exsanguination*[25]



DELAY INCREASES MORTALITY[26]

**Severe loss of blood*

Faster is Better in Hemorrhage Control[26]

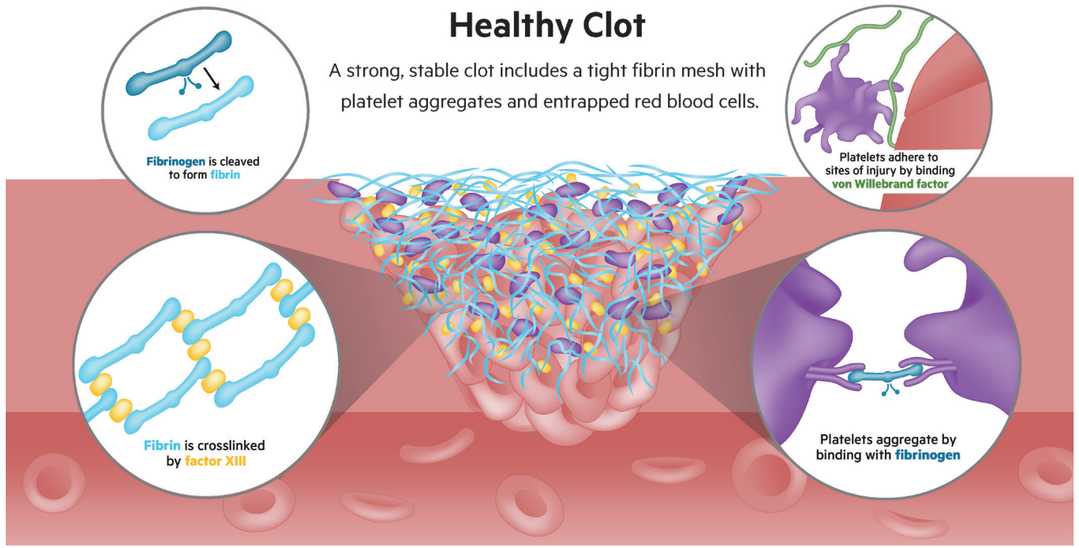
Massive Transfusion Protocols (MTP) were developed to improve hemorrhage outcomes by delivering blood components quickly.

- 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.

Effective Treatment: Restoring Fibrinogen & Other Clotting Factors

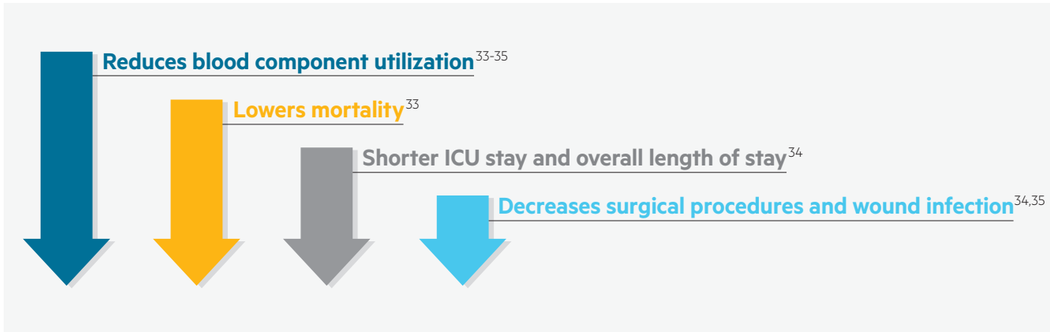
Early fibrinogen supplementation restores clot strength, reduces blood loss, and lowers mortality[18]

- Fibrinogen and other key clotting factors decrease rapidly and significantly in hemorrhage.[18,27]
- Fibrinogen level is an independent risk factor for hemorrhage and mortality in trauma,[28] cardiac (CV) surgery[29] and postpartum hemorrhage.[30]



Early delivery of **Fibrinogen**, **factor XIII** and **von Willebrand factor** adds the clotting strength needed to achieve stable clot formation and restore hemostasis.[18,31,32]

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[4,7]
Stored frozen and typically thawed in round 2 or 3 of MTP[36]

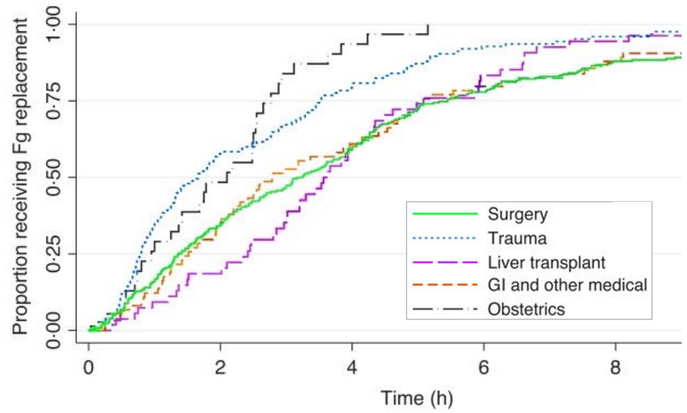
SHORT SHELF LIFE
4 – 6 hours[38]
Post thaw due in part to infectious risk

HIGH WASTAGE RATES
7 – 33%[37]
Thawed cryo AHF is wasted

In >75% of U.S. exsanguination cases, cryo AHF arrives too late to be medically efficacious[36]

Delays Impact Cryoprecipitated AHF Utility

Time to issue cryoprecipitated AHF by patient type[39]*



- **2.5 hours:** Median time to receipt of cryo AHF after initiation of an MTP[39]
  - **Trauma and OB earliest: median of 1.7 hours**[39]
- **1.6 hours**: Median time to death from exsanguination[25]

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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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