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Be Ready.
When Minutes Matter.

Pathogen Reduced Cryoprecipitated Fibrinogen Complex

prepared from the

INTERCEPT® Blood System for Cryoprecipitation

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

INTERCEPT®

Pathogen Reduced Cryoprecipitated Fibrinogen Complex

Breakthrough Device for Treating Uncontrolled Bleeding

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

- Pathogen Reduced Cryoprecipitated Fibrinogen Complex is prepared from the INTERCEPT Blood System for Cryoprecipitation
- Immediate, enriched source of key factors in effective hemostasis[1–3]
  - » Fibrinogen
  - » von Willebrand Factor
  - » Factor XIII
  - » Other vital clotting proteins

FDA Breakthrough Device
INTERCEPT® Blood System for Cryoprecipitation

Transfuse With the First Blood Products*

Approved for empirical use

PRODUCT	LONG-TERM STORAGE	IMMEDIATE AVAILABILITY	MTP[4] ROUND 1	MTP[4] ROUND 2	MTP[4] ROUND 3
INTERCEPT® Fibrinogen Complex	Frozen ≤ 12 Months	**Room Temp ≤ 5 Days***	✓	✓	✓
— OR —					
Cryoprecipitated AHF[5]	Frozen ≤ 12 Months	**Room Temp ≤ 4-6 Hours**	Availability delayed due to time to thaw-on-demand, and establishment into later rounds of MTPs[4]		✓
Platelets	Room Temp ≤ 5-7 Days	Room Temp ≤ 5-7 Days	✓	✓	✓
Plasma	Frozen ≤ 12 months	Refrigerated ≤ 5 Days	✓	✓	✓
RBC	Refrigerated ≤ 42 Days	Refrigerated ≤ 42 Days	✓	✓	✓

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

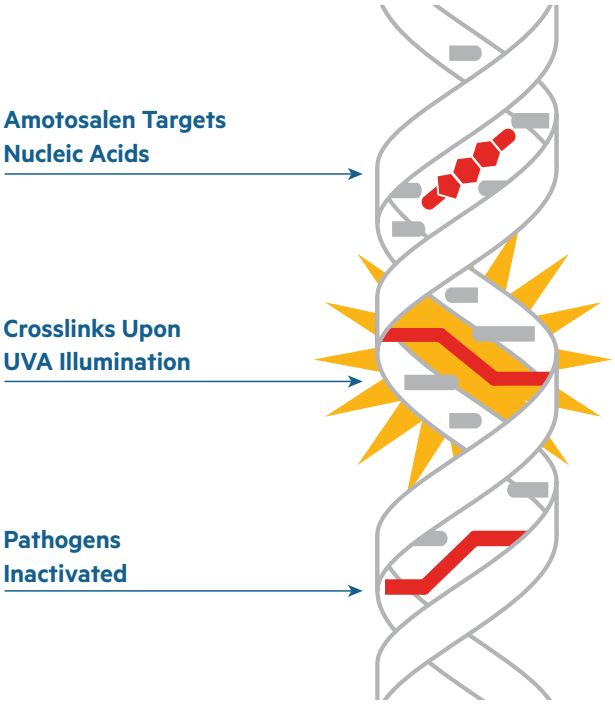
Pathogen Reduction

INTERCEPT® Fibrinogen Complex is produced from plasma treated by the INTERCEPT Blood System.

- Provides broad spectrum transfusion transmitted infection (TTI) risk reduction, including viruses, bacteria, and emerging pathogens[6,7]

INTERCEPT® treated plasma 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 Order-to-Transfusion Times

TRANSFUSION READY

- Thawed in advance
- Ready-to-deploy with first blood products
- No additional labelling or preparation required

CONVENIENT DOSING

- Single-use hemostatic doses
- Pre-pooled high doses available*

MINIMIZE WASTE

- 5-day post-thaw shelf life
- Return to inventory if not transfused
- Broad spectrum TTI risk reduction

**Pooling facilitates transfusion of high doses of fibrinogen from a single container.*
Fibrinogen content of Fibrinogen Complex depends on donor plasma fibrinogen levels.

INTERCEPT®

Pathogen Reduced Cryoprecipitated Fibrinogen Complex

Availability

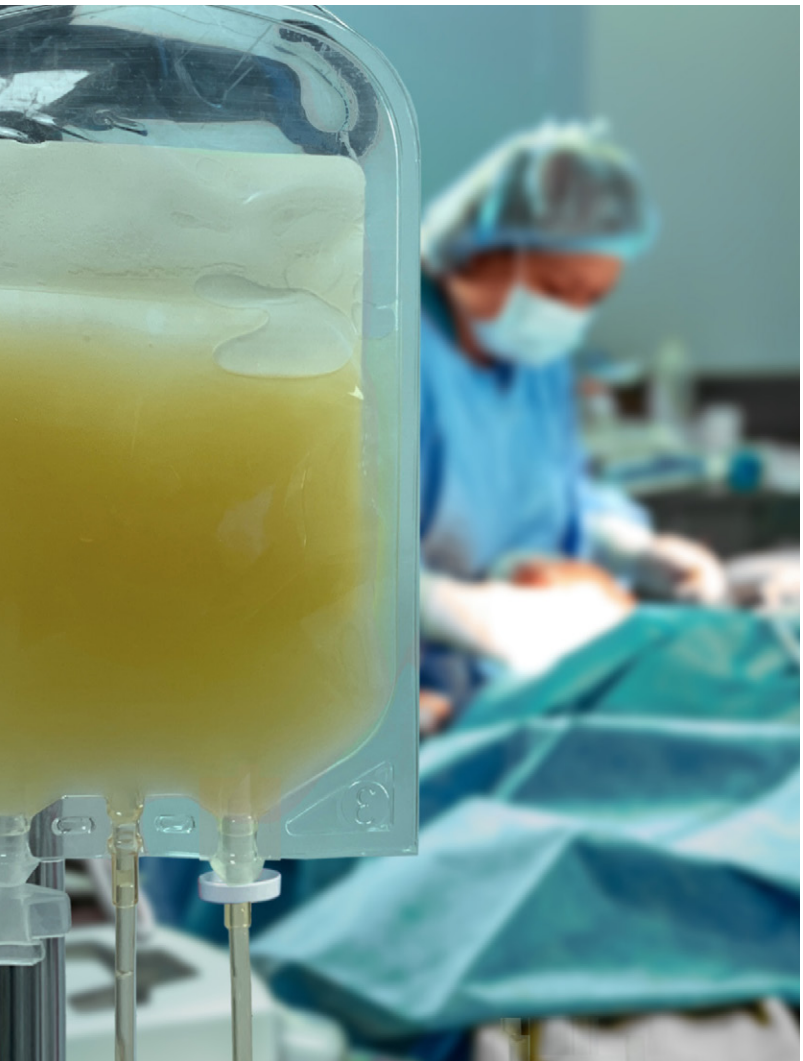
Ready for Immediate Use!

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)*
FC10	Pooled Fibrinogen Complex 1.0, Cryoprecipitated, Psoralen Treated	740
FC15	Pooled Fibrinogen Complex 1.5, Cryoprecipitated, Psoralen Treated	1,457
FC20	Pooled Fibrinogen Complex 2.0, Cryoprecipitated, Psoralen Treated	2,220**
FC30	Pooled Fibrinogen Complex 3.0, Cryoprecipitated, Psoralen Treated	3,117
FC40	Pooled Fibrinogen Complex 4.0, Cryoprecipitated, Psoralen Treated	3,700**

* Fibrinogen content depends on donor plasma fibrinogen levels
** Calculated based on pooling of FC10



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.

Hemorrhage is a Leading Cause of Preventable Death[8]

Trauma is the
#1
cause of death
in adults <45 years old[9]

Of trauma deaths
~40%
from hemorrhage[9]

Hours until death
~1.6
from exsanguination*[10]

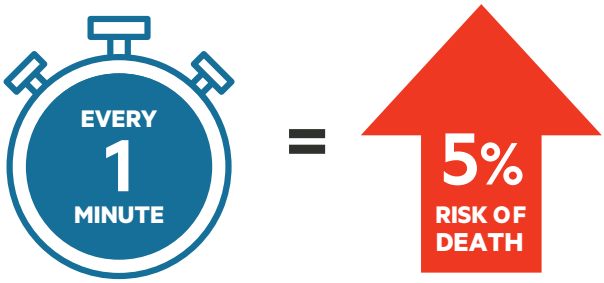
Hemorrhage increases mortality in:


Trauma[11,12]


Postpartum Hemorrhage[13]


Cardiac (CV) Surgery[14]


Combat[15,16]



DELAY INCREASES MORTALITY[17]

Faster is Better[17]

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

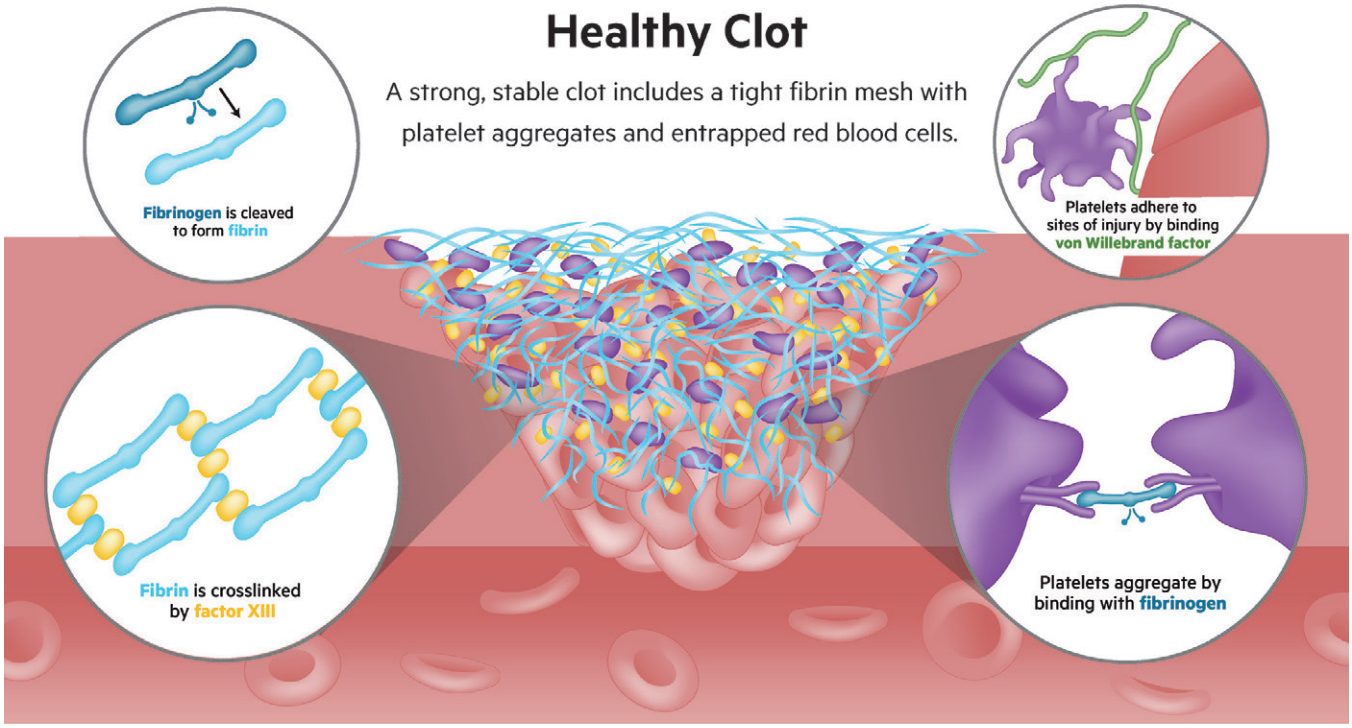
- Every minute of delay between the activation of an MTP and the arrival of the first blood products, results in a 5% increase in the odds of mortality.
- Timely delivery of blood products is an important metric, similar to “door-to-balloon” time.

**Severe loss of blood*

Effective Treatment:
Restoring Fibrinogen & Other Clotting Factors

Early fibrinogen supplementation restores clot strength, reduces blood loss, and lowers mortality[12]

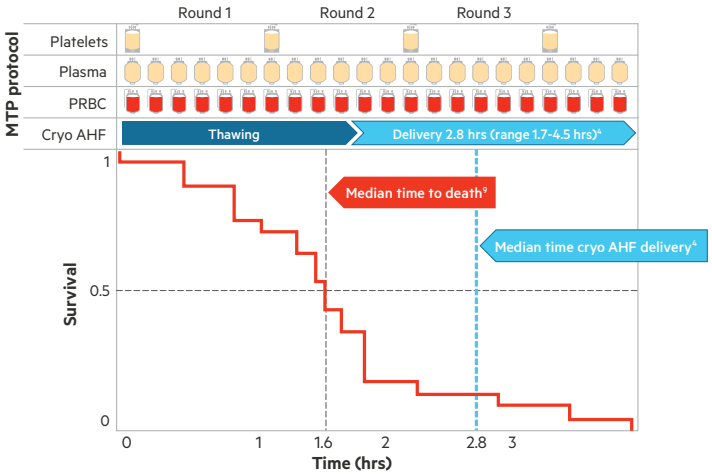
- Fibrinogen is the most critical protein needed for stable clot formation and hemostasis[12,18]
- Factor XIII adds strength and stability to clot formation[19,20]



Fibrinogen, **factor XIII** and **von Willebrand factor**
add the clotting strength needed to achieve stable clot formation and restore hemostasis.[21]

Early delivery of fibrinogen and other vital clotting factors add the clotting strength needed to achieve stable clot formation and restore hemostasis[12,18]

MTPs Lack Critical Components from the Start



Cryoprecipitated Antihemophilic Factor (cryo AHF): source of clotting factors for the treatment of coagulopathy in hemorrhage[5,19]

In >75% of U.S. exsanguination cases, cryo AHF arrives too late to be medically efficacious[22]

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 MTP[23]

SHORT SHELF LIFE

4 – 6 hours[24]

Post thaw due in part to infectious risk

HIGH WASTAGE RATES

7 – 33%[23]

Thawed cryo AHF is wasted

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. 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.