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 Fibrinogen Complex* 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

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Thaw</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TRANSFUSION READY: 5-Day Post-Thaw Shelf Life at Room Temperature**

**Transfuse With the First Blood Products***

Approved for empirical use

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>LONG-TERM STORAGE</th>
<th>IMMEDIATE AVAILABILITY</th>
<th>MTP$^4$</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERCEPT® Fibrinogen Complex</td>
<td>Frozen ≤ 12 Months</td>
<td>Room Temp ≤ 5 Days*</td>
<td>ROUND 1</td>
</tr>
<tr>
<td>Cryoprecipitated AHF$^5$</td>
<td>Frozen ≤ 12 Months</td>
<td>Room Temp ≤ 4-6 Hours</td>
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</table>

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>LONG-TERM STORAGE</th>
<th>IMMEDIATE AVAILABILITY</th>
<th>MTP$^4$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelets</td>
<td>Room Temp ≤ 5-7 Days</td>
<td>Room Temp ≤ 5-7 Days</td>
<td>✔</td>
</tr>
<tr>
<td>Plasma</td>
<td>Frozen ≤ 12 months</td>
<td>Refrigerated ≤ 5 Days</td>
<td>✔</td>
</tr>
<tr>
<td>RBC</td>
<td>Refrigerated ≤ 42 Days</td>
<td>Refrigerated ≤ 42 Days</td>
<td>✔</td>
</tr>
</tbody>
</table>

*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

INTERCEPT® treated plasma has 20 years of clinical and post-market surveillance experience

INTERCEPT® Blood System for Plasma

Mechanism of Action

**Amotosalen Targets Nucleic Acids**

**Crosslinks Upon UVA Illumination**

**Pathogens Inactivated**

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

**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.

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<table>
<thead>
<tr>
<th>Catalog #</th>
<th>Description</th>
<th>Average Fibrinogen (mg)</th>
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<tbody>
<tr>
<td>FC10</td>
<td>Pooled Fibrinogen Complex 1.0, Cryoprecipitated, Psoralen Treated</td>
<td>740</td>
</tr>
<tr>
<td>FC15</td>
<td>Pooled Fibrinogen Complex 1.5, Cryoprecipitated, Psoralen Treated</td>
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<td>FC20</td>
<td>Pooled Fibrinogen Complex 2.0, Cryoprecipitated, Psoralen Treated</td>
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<td>FC30</td>
<td>Pooled Fibrinogen Complex 3.0, Cryoprecipitated, Psoralen Treated</td>
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<tr>
<td>FC40</td>
<td>Pooled Fibrinogen Complex 4.0, Cryoprecipitated, Psoralen Treated</td>
<td>3,700**</td>
</tr>
</tbody>
</table>

* Fibrinogen content depends on donor plasma fibrinogen levels
** Calculated based on pooling of FC10
Hemorrhage is a Leading Cause of Preventable Death

Trauma is the #1 cause of death in adults <45 years old.

Of trauma deaths, ~40% from hemorrhage.

Hours until death, ~1.6 from exsanguination.

Faster is Better

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.
**Effective Treatment:**
Restoring Fibrinogen & Other Clotting Factors

Early fibrinogen supplementation restores clot strength, reduces blood loss, and lowers mortality\textsuperscript{12}

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

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**Healthy Clot**
A strong, stable clot includes a tight fibrin mesh with platelet aggregates and entrapped red blood cells.

Fibrinogen, factor XIII and von Willebrand factor add the clotting strength needed to achieve stable clot formation and restore hemostasis\textsuperscript{21}

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Early delivery of fibrinogen and other vital clotting factors add the clotting strength needed to achieve stable clot formation and restore hemostasis\textsuperscript{12,18}
MTPs Lack Critical Components from the Start

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

Cryoprecipitated Antihemophilic Factor (cryo AHF): source of clotting factors for the treatment of coagulopathy in hemorrhage.

Cryoprecipitated AHF Inventory Challenges

**LONG WAIT TIMES**
15 min – 2.8 hours
Stored frozen and typically thawed in round 2 or 3 of MTP.

**SHORT SHELF LIFE**
4 – 6 hours
Post thaw due in part to infectious risk.

**HIGH WASTAGE RATES**
7 – 33%
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 amotosalen 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.

References