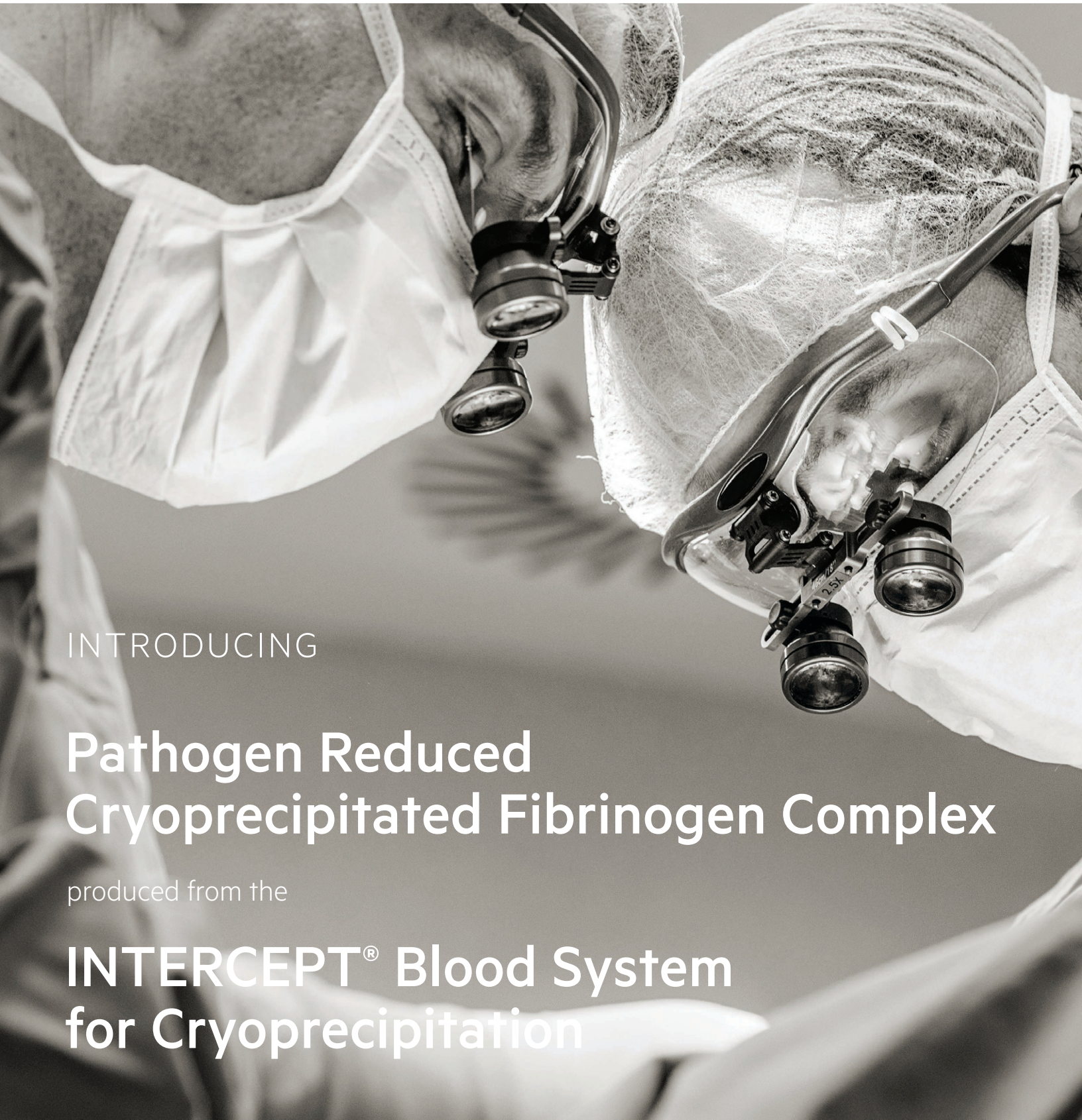
cerus



INTRODUCING

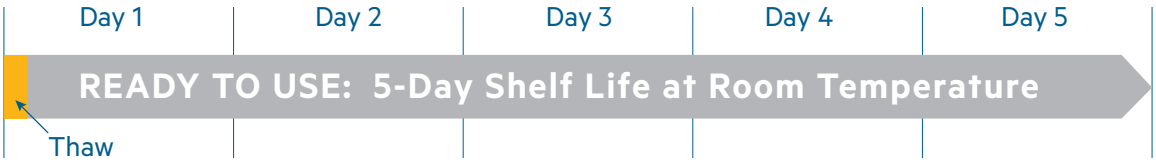
Pathogen Reduced Cryoprecipitated Fibrinogen Complex

produced from the

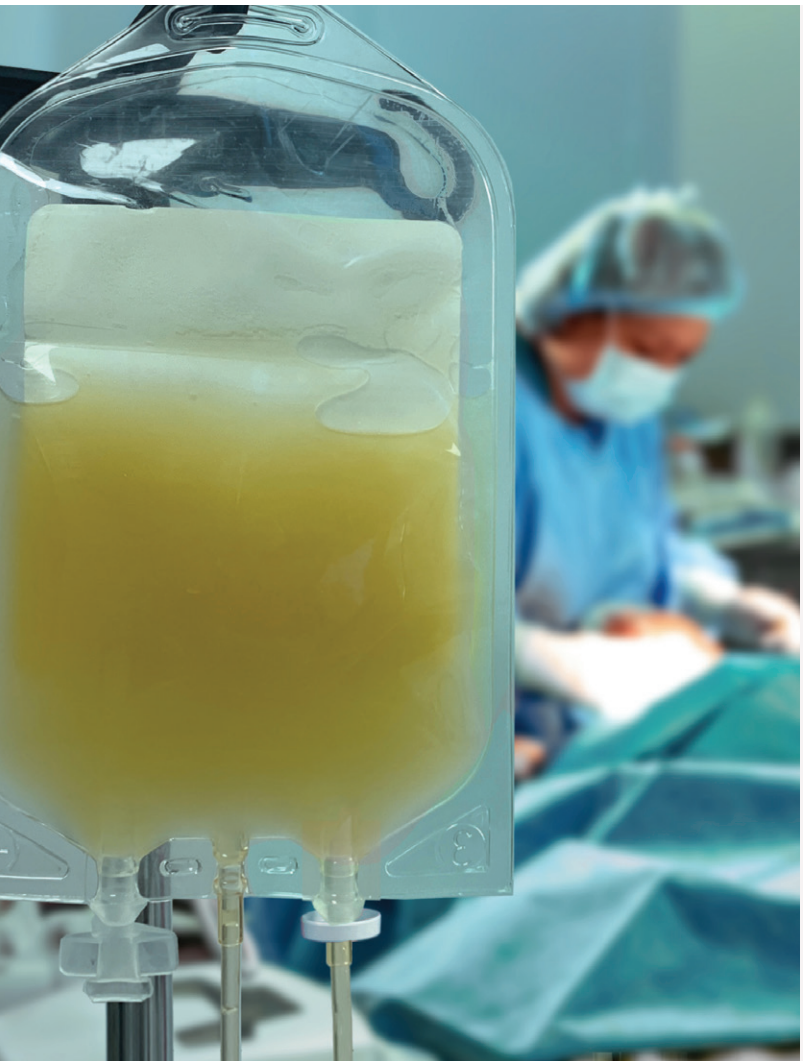
INTERCEPT® Blood System for Cryoprecipitation

Pathogen Reduced Cryoprecipitated Fibrinogen Complex

- For the **treatment and control of bleeding**, including massive hemorrhage, associated with fibrinogen deficiency[1]
- **Pathogen reduced, fibrinogen enriched, blood component**
- Serves as an **enriched source of fibrinogen**, factor XIII, vWF, and other constituents, based on in vitro studies
  - » Fibrinogen, vWF, and factor XIII are key **constituents in effective hemostasis** and functional levels correlate with risk of bleeding, morbidity and mortality[2,3,4,*]
- **5-day room-temperature shelf life** — Allows for immediate use when stored thawed



** Pathogen Reduced Cryoprecipitated Fibrinogen Complex has not been evaluated in a clinical setting*



Availability[1]

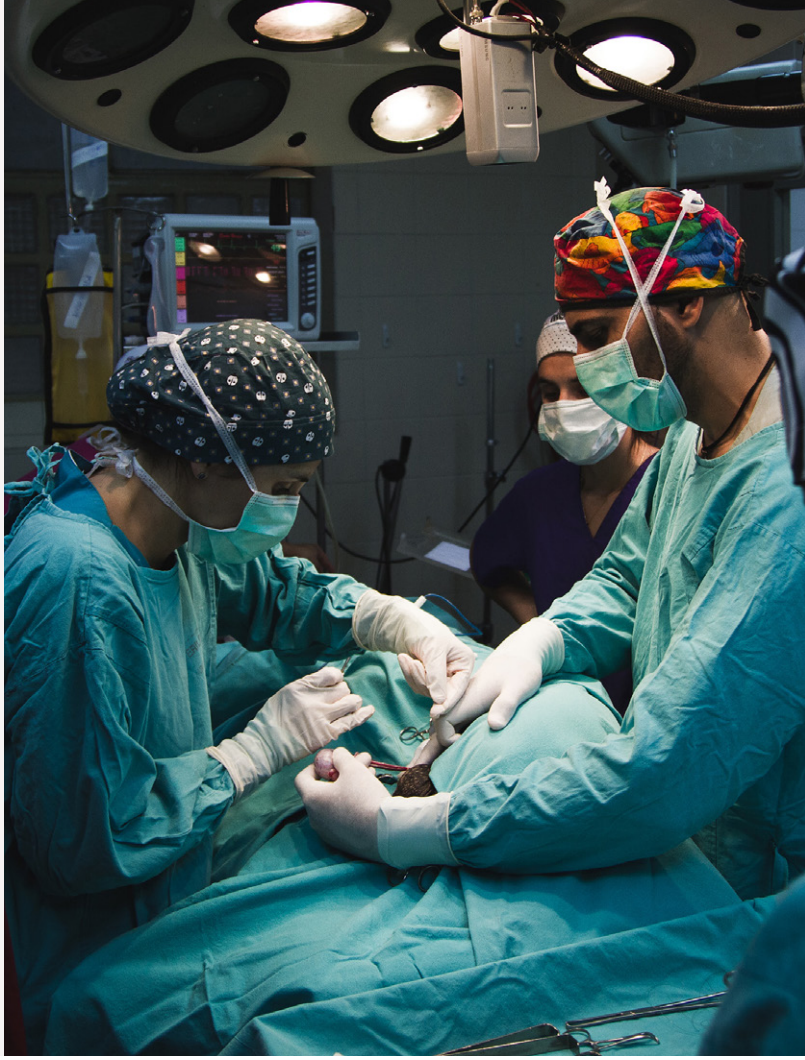
- Provided in single-use containers
- Received frozen with up to 12 months shelf life
- May be stored at room temperature for up to 5 days — allows for immediate use when stored thawed
- Components may be purchased as single or pre-pooled units

Catalog #	Description	Mean 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**

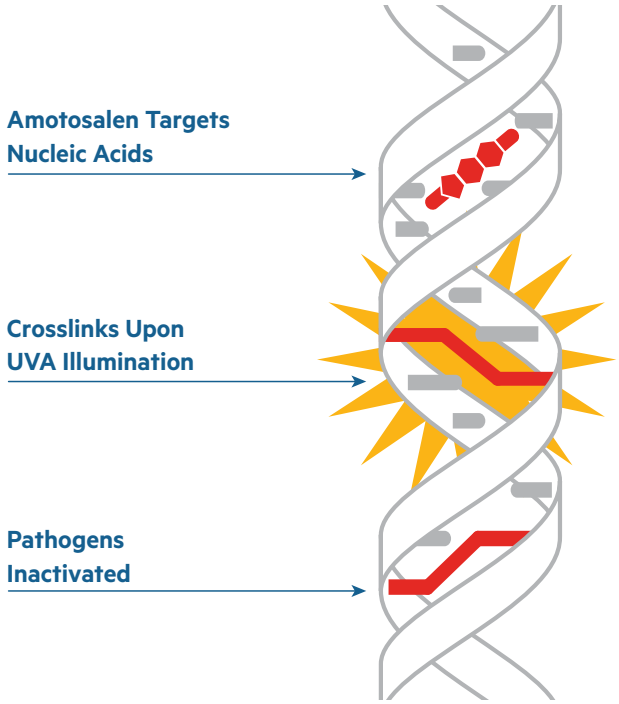
*** Calculated based on pooling of FC10*

Pathogen Reduced

- Pathogen Reduced Cryoprecipitated Fibrinogen Complex is produced from pathogen reduced plasma by the INTERCEPT® Blood System for Plasma Pathogen Reduction System
- Broad spectrum transfusion transmitted infection† risk reduction, including viruses, bacteria, and other pathogens[1,5]



INTERCEPT® Blood System for Plasma Mechanism of Action



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

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

†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.*

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 are not available
- Second-line therapy for von Willebrand disease
- 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 von Willebrand disease 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

1. INTERCEPT Blood System for Cryoprecipitation for the manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex [Package Insert]. Concord, CA. Cerus Corporation. November 24, 2020.
2. Levy, J. H., I. Welsby, et al. (2014). "Fibrinogen as a therapeutic target for bleeding: a review of critical levels and replacement therapy." Transfusion 54(5): 1389-1405; quiz 1388.
3. Schroeder, V. and H. P. Kohler (2016). "Factor XIII: Structure and Function." Semin Thromb Hemost 42(4): 422-428.
4. Peyvandi, F. (2018). "Diagnosis and management of patients with von Willebrand's disease in Italy: an Expert Meeting Report." Blood Transfus 16(4): 326-328.
5. INTERCEPT Blood System for Plasma [Package Insert]. Concord, CA, Cerus Corporation. May 1, 2020.

cerus

GLOBAL HEADQUARTERS | 1220 Concord Avenue | Concord, CA US 94520 | 855.835.3523

www.cerus.com | www.intercept-cryoprecipitation.com

Rx only.