

Pathogen Reduced Cryoprecipitated Fibrinogen Complex

(INTERCEPT® Fibrinogen Complex)

Implementation at a Large Level 1 Trauma Center

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Objectives

- Barnes Jewish Hospital
- BJH Blood Bank
- What is Intercept Fibrinogen Complex (IFC)?
- Why IFC over pooled Cryoprecipitate?
- Implementation Considerations – Solutions
- Where are we today?
- What more can we achieve?

Barnes Jewish Hospital St. Louis, Missouri



Barnes-Jewish Hospital

BJC HealthCare

2024

BY THE
NUMBERS

80,087

Emergency
Department visits



52,280

Inpatient
admissions



2,138

Attending
physicians



9,432

Employees
including

3,265

Registered
nurses

1,203

Residents
and fellows



26,730

Outpatient
surgeries



19,750

Inpatient
surgeries

1,409

Licensed beds
Includes Psych



1,284

Staffed beds



879

Allied health
professionals



15,000 Trauma patients

- **Comprehensive Cancer Center**
- **High Risk Women & Infants Center Service**
- **Level 1 Trauma Center**
- **Red Cell Exchange/Sickle Cell Program**
- **Consistently ranked among best in U.S.**
- **News & World Report**

Blood Bank Statistics

Annual Transfusions 2024 = 82,257

- RBCs 45,890
- Platelets 17,422
- Plasma 8,322
- Pooled Cryo AHF 919
- IFC 1,340
- LTWB 630
- 315 Massive Transfusion Protocols
- 572 Emergency Release Events

Services

- 56 staff (covering 24/7)
 - 16 days
 - 8 evenings
 - 7 nights
- 4 Quidel/Ortho Visions (~400 T&S/day)
- Advanced Reference Lab (~25 workups/day)
- Red Cell Exchange (~20/wk)
- Washed/Deglyced RBCs (~5/wk)
- Rare Frozen RBC Inventory (~35)
- Platelet Modification (~10/day)

Barnes Blood Bank



What is **INTERCEPT**[®] Fibrinogen Complex (**IFC**)?

- Approved to treat and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency¹
- Immediate*, enriched source of key factors in effective hemostasis²⁻⁴
- Pathogen reduced: produced from INTERCEPT treated plasma⁵



1. INTERCEPT Blood System for Cryoprecipitation for the Manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Package Insert.

2. Levy JH et al. Transfusion 2014;54:1389-405; quiz 1388. 3. Schroeder V et al. Seminars in Thrombosis and Hemostasis 2016;42(4):422-428.

4. Peyvandi, F. Blood Transfusion 2018; 16(4):326-328. 5. INTERCEPT Blood System for Plasma Package Insert. *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.

The INTERCEPT® Fibrinogen Complex Advantage

**TRANSFUSE
IMMEDIATELY***



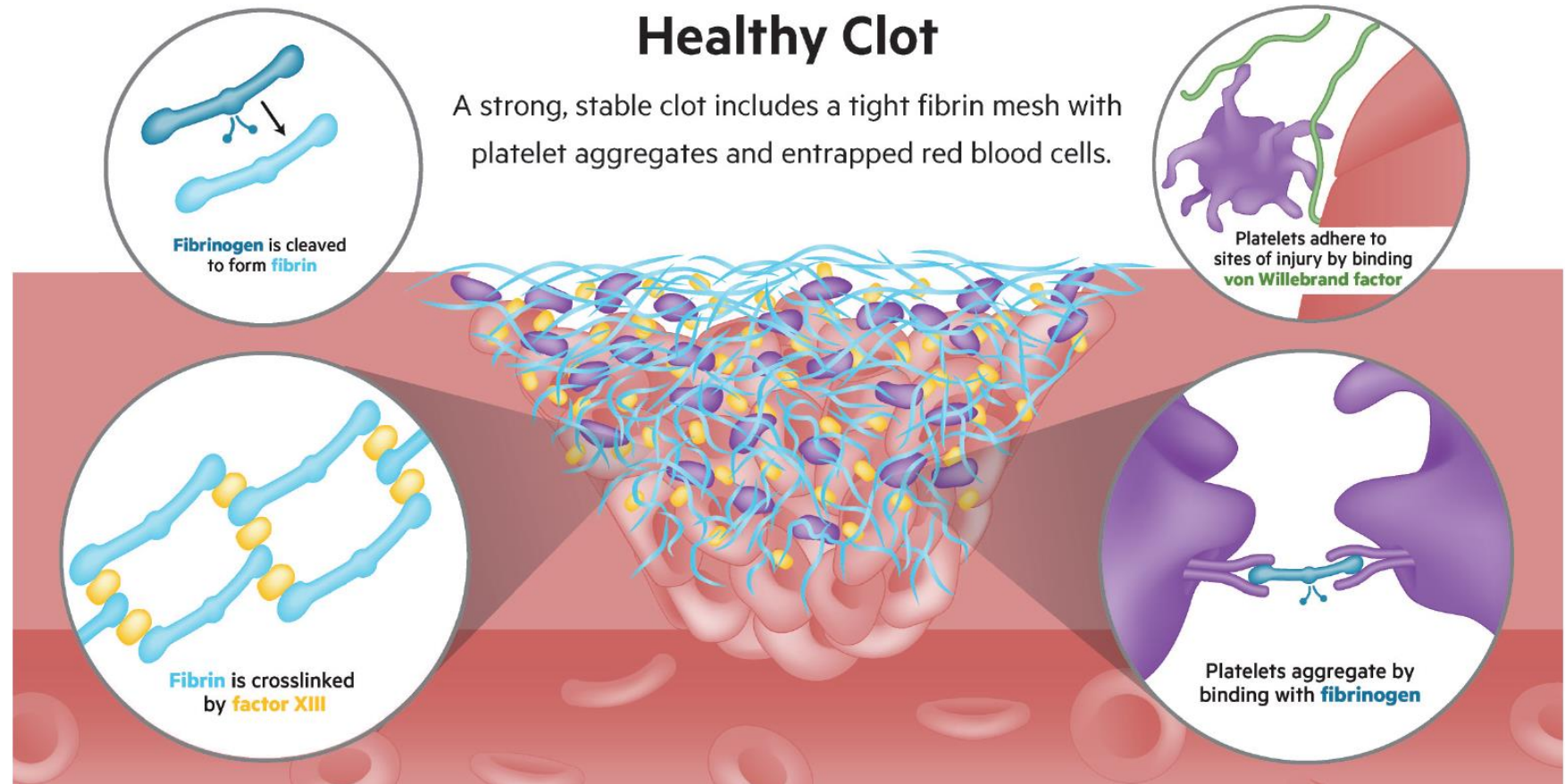
**CONTROL
BLEEDING[†]**

**MINIMIZE
WASTE**



**PROTECT
PATIENTS[‡]**

FDA Designated Breakthrough Device to CONTROL BLEEDING*



IFC is an enriched source of fibrinogen, factor XIII, von Willebrand factor, and other constituents, to restore clot strength and potentiate hemostasis.¹⁻⁴

Pathogen Reduced Cryoprecipitated Fibrinogen Complex¹

Indications, Contraindications, Warnings, Precautions

INDICATIONS

- 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: 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.

1. INTERCEPT Blood System for Cryoprecipitation for the Manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Package Insert.

Why use IFC¹ vs Cryo AHF² for fibrinogen supplementation at Barnes-Jewish?

- Requested by Providers
- Patient safety: Pathogen Reduced
- 5 Day vs 6 Hour post-thaw Expiration
- Ability to pre-thaw; ready to go
- Potential for improved Turn Around Time (TAT) for delivery to patient

1. INTERCEPT Blood System for Cryoprecipitation for the Manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Package Insert.

2. AABB. Circular of Information for the Use of Human Blood and Blood Components. Bethesda, MD: AABB; 2024.

Considerations for IFC Implementation

- Does our Blood Supplier have it?
- Cost – how to offset impact to budget?
- Dual inventory or solo inventory?
- How much inventory to keep on hand?
 - Cryo AHF usage ~10 units/day
- Staff triage of orders (IFC vs Cryo AHF) – Delays?
- Where to store pre-thawed IFC (20-24°C)?



Where we are today

- IFC Inventory built up over 6 months to offset cost
- IFC Implemented April 18, 2024
- IFC as primary; pooled cryo AHF as backup
- Inventory on hand ~100 IFC15
 - Shipment of 60 IFC/week
- Maintain 6 thawed IFC at all times
- Tabletop incubator to hold pre-thawed inventory
 - Helmer PC100-PRO; Rees Temperature Monitor
- Staff stress levels alleviated; no triage of orders
- Waste minimized to eliminated!



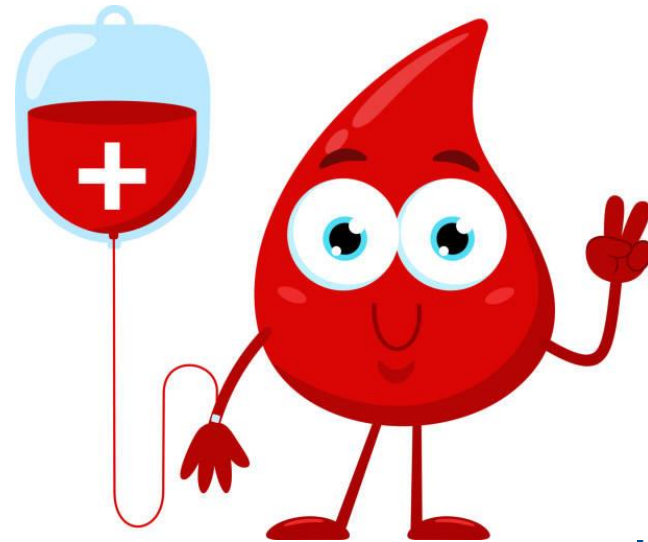
Wins

- Patient Safety: Pathogen Reduced¹
- Marked improvement in TAT:
 - Order to Issue
 - Order to Transfuse
- Cost Recovery as an institution

1. INTERCEPT Blood System for Cryoprecipitation for the Manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Package Insert.

TAT Improvement

- Order to Issue – 40 minutes to 10 minutes!
- Order to Transfuse – 90 minutes to 40 minutes!



Potential Cost Savings – OR (@ BJH)

- OR Time savings of 50 minutes
- OR room now open to support other cases sooner
- Average cost of one minute of OR = \$55/minute
- 50 minutes equates to ~**\$2,750** saved for each patient transfused with IFC
- Institutional savings achieved!

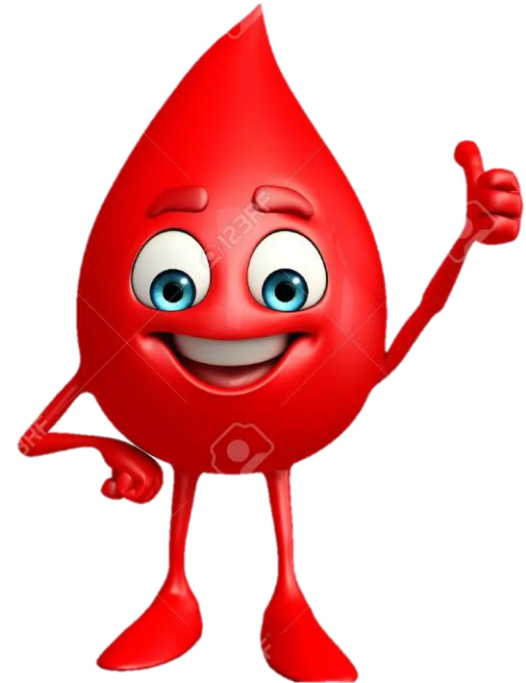


The future to explore....

- Replacing Fibrinogen Concentrate currently used by OB Services
- Use of IFC earlier in MTP Cycle
- Share IFC utilization across HSO consortium
 - Reduce waste for smaller HSOs/transfer to larger HSO
- Reduction in use of other blood products? (less donor exposure)

For Barnes-Jewish Hospital

- Great Decision Made! Worth the effort!
- Staff LOVE the process!
- Anesthesiologists LOVE the product!
 - “It’s a Gamechanger!”
- Trust gained with the surgical staff
 - High quality product
 - Patient safety
 - Received when needed for the patient



Thank you