



The Secrets of Cryoprecipitate: A Blood Banking Process Improvement

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Disclosures

- None

Objectives

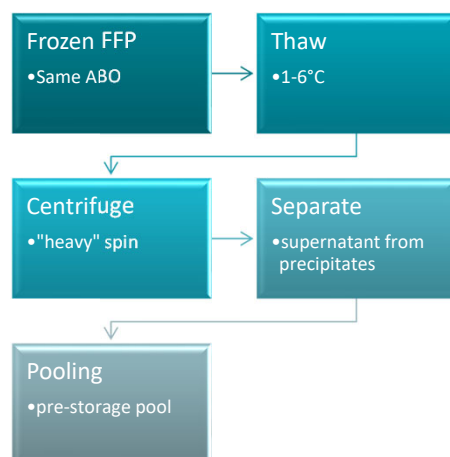
- What is cryoprecipitate?
- Product storage/requirements
- Indications for use
- Dosage
- Process improvement

What is Cryoprecipitate?

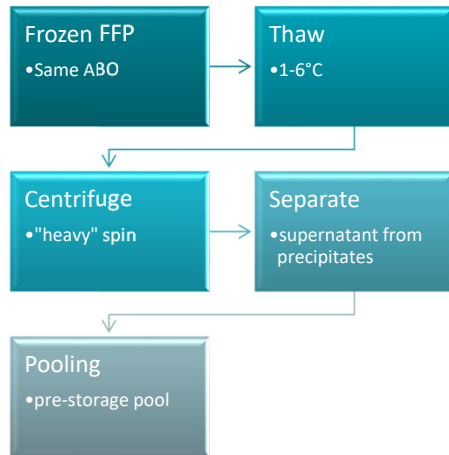
- Cryoprecipitate (cryo) is cold-insoluble proteins that precipitates when FFP is thawed.
- It is rich in plasma proteins:
 - Factor VIII
 - Fibrinogen
 - Factor XIII
 - von Willebrand factor
 - Fibronectin



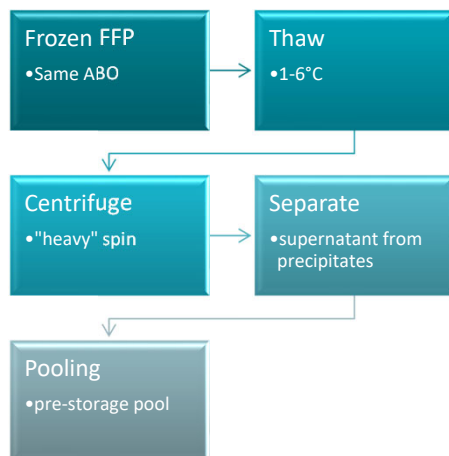
How is it Manufactured?



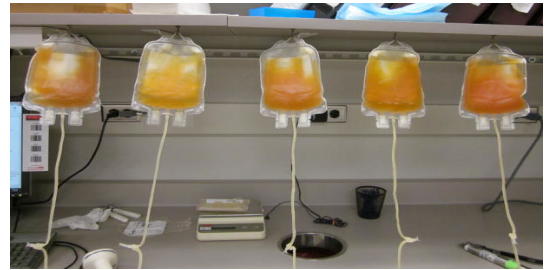
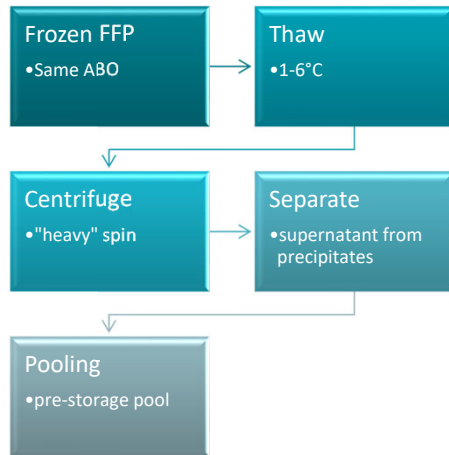
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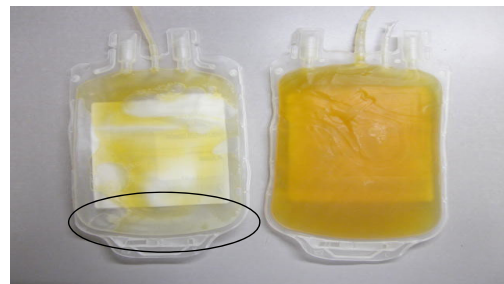
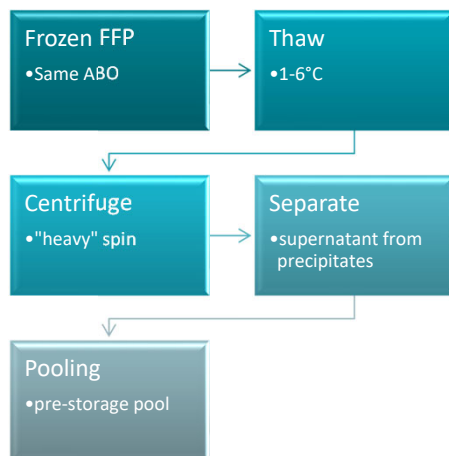
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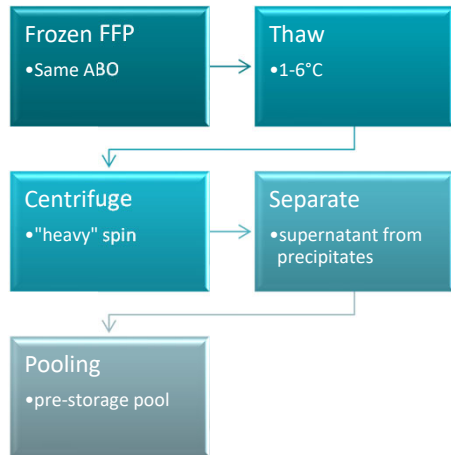
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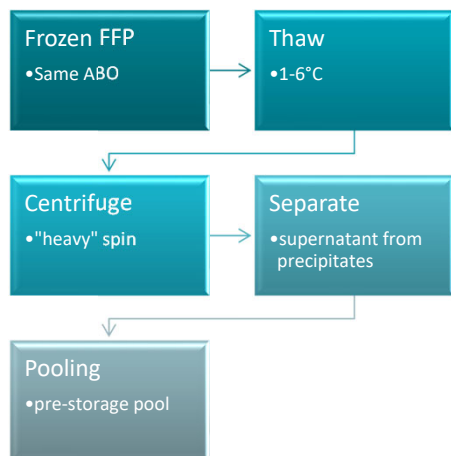
How is it Manufactured?



How is it Manufactured?



How is it Manufactured?



Product Storage

Storage and Shelf Life of Cryo

| Frozen | | Thaw | |
|-------------|---------|-------------|---------|
| Storage: | ≤ -18°C | Quick thaw: | 30-37°C |
| Shelf life: | 1 year | Storage: | 20-24°C |
| | | Shelf life: | 6 hours |

Product Requirements

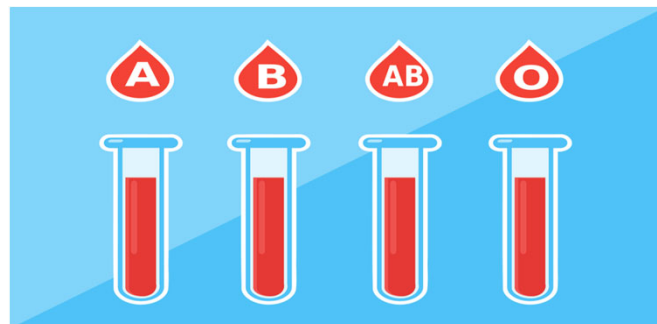
- FDA regulations: test 4 pools per month
- Each pool must contain a minimum of 80 International Units (IU) of Factor VIII and 150 mg of fibrinogen times the number of units in the pool.
- 5-pool:
 - Factor VIII ≥ 400 IU/pool
 - Fibrinogen ≥ 750 mg/pool

Indications for Use

- Patients that benefit from cryoprecipitate:
 - Fibrinogen deficiency
 - Disseminated Intravascular Coagulation (DIC)
 - Massive transfusion with bleeding
 - Inherited disorder of fibrinogen
 - Uremic bleeding

Selection and Administration

- ABO compatible
- Rh incompatible



Standard Dose

- The standard adult dose at Mayo Clinic Rochester is 10 units, 2 pools
- External blood suppliers provide blood products to other Mayo campuses
 - They produce pools of 5 units at higher dosages
 - Allowing other Mayo sites to drop their standard adult dose, from 10 to 5 units

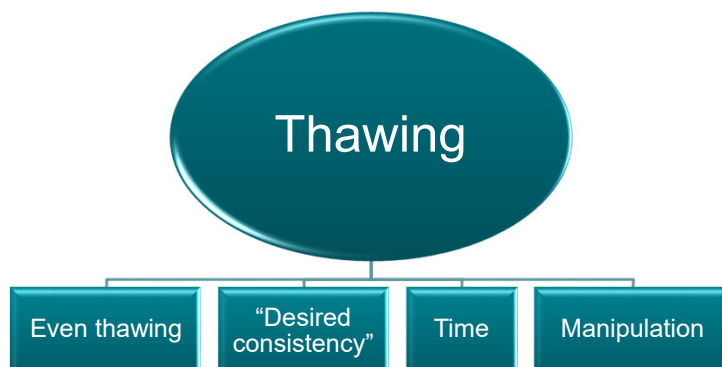
Standard Dose

- Benchmark with other Mayo sites and implement a method that produces higher fibrinogen levels

Case Study

- Middle aged man underwent a redo aorta operation
- Required a long cardiopulmonary bypass run and cooling to 18°C
- Patient started to bleed a lot
 - New graft caused fibrinogen depletion significantly
- Received 40 units of cryo

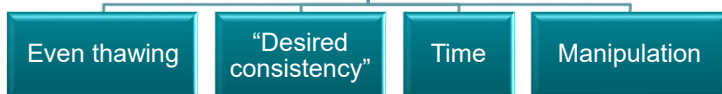
Process Improvement



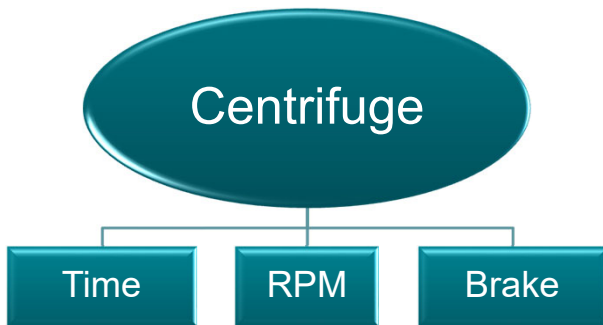
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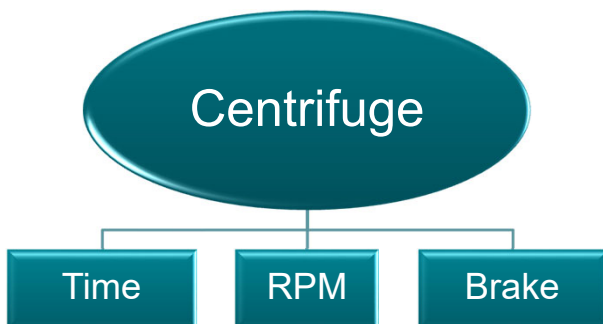
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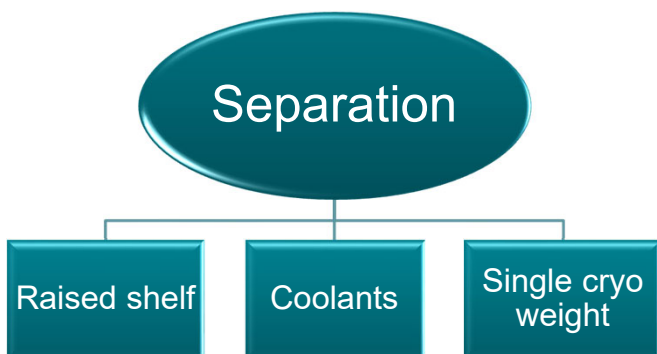
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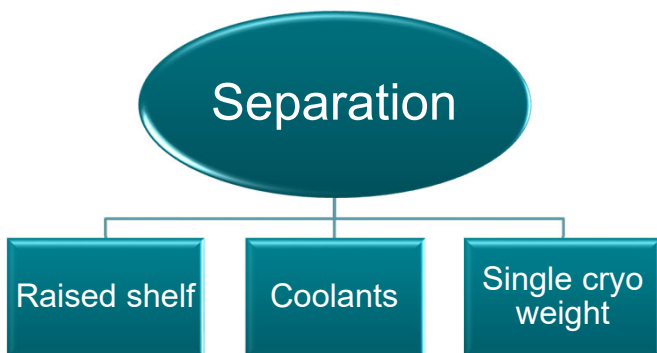
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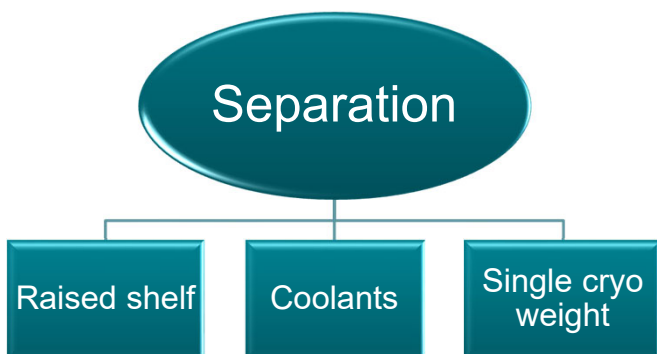
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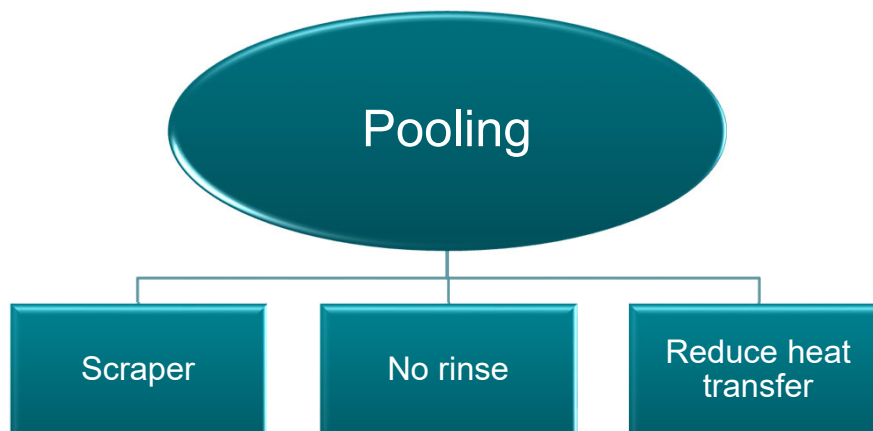
Process Improvement



Process Improvement



Process Improvement



Implementation

- Validated a process that had an average of $\geq 1,450$ mg/unit of fibrinogen
- Implemented new process 11/5/18



Implementation

| | Regulatory Requirements | Average Pre-Intervention Results | Average Post-Intervention Results | Goal Values |
|-----------------------|-------------------------|----------------------------------|-----------------------------------|-------------|
| Factor VIII (IU/pool) | ≥ 400 | 823 | 782* | NA |
| Fibrinogen (mg/pool) | ≥ 750 | 1389 | 1574* | ≥ 1450 |

*As of 6/3/19

Process Improvement Conclusion

- Help standardize the cryoprecipitate dosage and benefit the patient, as the needs of the patient come first.
 - Reduce donor exposure, increase inventory, and potentially cost saving for patients
- With continual monitoring and potential improvements the dosage change will become effective.

Summary

- Cryoprecipitate
- Storage
 - Frozen
 - Thawed
- Indications
- Standard Dose
- Process Improvement

References

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