

# KryoSure™ Blood Component Freezing Bag

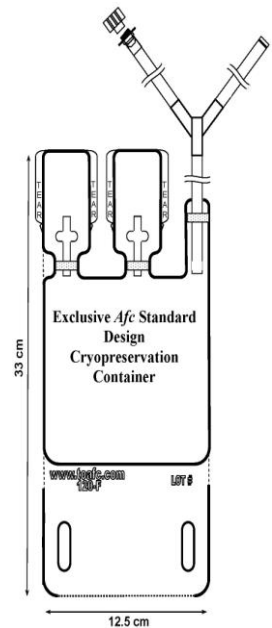
Volume Capacity 50ml - Usage Range 10ml. - 20 ml.

Flexible to Minus 208°C - Catalog Number: 20-F

- Volume = 20 ml at 1 cm thick
- Capacity = 50 ml
- 0.15 ml per segment
- Inside surface area = 149 cm<sup>2</sup>
- Outside Dimensions = 7.5 cm x 33 cm
- Tare Weight = 21 grams
- Tare Weight Minus Tubing Set = 14 grams
- Label Pocket size = 6.9 cm x 8.6 cm
- Working temperature = +20°C to *Minus 200°C*
- Length With Label Folded = 19 cm

**Description:** This Cryopreservation Bag is made from the highest quality USP Class VI materials available. The design and materials permit the bag to remain flexible in liquid nitrogen; thus greatly enhancing reliability during short or long term cryopreservation.

- The FEP material is non-reactive with all chemicals and biologicals including DMSO and DMF.
- Each bag has a unique number engraved into the label pocket and the same number is etched into the fill tube to provide three un-alterable segments for cross-identification to the bag. Each segment contains approximately 0.15ml.
- The segments may be stored in the large, integrally attached label pocket.
- Rounded corners provide for cold strength durability during cryopreservation and maximal product retrieval after cryopreservation.
- Enhanced retrieval of the contents is afforded by the hydrophobic nature of FEP material.
- The bag has two sterile Covered Spike Ports and a PVC Fill Tube for sterile docking.
- The ISBT 128 compliant label pocket and bag remain transparent while frozen.
- Each bag is individually tested and inspected.
- The bags are steam sterilized: Sterility Assurance Level (SAL) 10<sup>-6</sup>.



**Applications:** This bag is designed for normal to extreme cryopreservation temperatures.

- The bag contains and protects liquids and suspensions in mechanical freezers, vapor phase, or liquid nitrogen environments.
- The bag fits in standard metal freezer cassettes.
- With proper handling the bag may be used for cell culture or centrifugation.

**Bag Material:** The bag materials are selected for biocompatibility.

- The bag and all materials are (ADCF) animal-derived component free.
- All bag materials meet USP Class VI requirements.
- The bag is free from all extractable or leachable materials.
- The bag is non-immunogenic.
- The bag walls are .005" thick Fluoro-Ethylene-Propylene (FEP).
- The bag is optically clear.

**Inlet Tube:** The inlet tube consists of 4mm PVC (standard I.V.) tubing with a "Y" branch and a clamp. One side of the "Y" ends in a female luer fitting, the other side is sealed. Sterile docking to the inlet tube permits sterile filling of the bag. Another option is to fill through the female luer connector. The inlet tube and its fittings can be removed prior to cryopreservation.

**Exit (Spike) port:** The exit spike port is manufactured from FEP; this ISO compliant spike port with septum is protected from external contamination by an integral tear-open tamper-evident cover.

**510(k) cleared. Inquire regarding Device Master File**

**Reference number:** 349617

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