

KryoSure™ Vaccine Freezing Bag

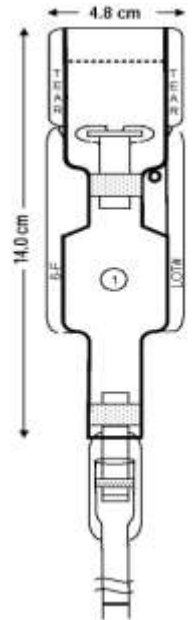
Volume Capacity 6ml - Usage Range 0.1ml. - 6 ml.

Flexible to Minus 208°C - Catalog Number: 6-F

- Volume = 6 ml at 1.0 cm thick
- Capacity = 6 ml
- Inside surface area = 20 cm²
- Outside Dimensions = (fill port removed, ready to freeze): 14.0 cm x 4.8 cm
- Tare Weight = 6 gms
- Tare Weight Minus Tubing = 4 gms
- Label Attachment Hole = 0.25 cm
- Working temperature = +200C to *minus 200C*

Description: This Cryopreservation Bag is made from the highest quality USP Class VI materials available. The unique design of this cryopreservation bag allows for closed system sterile transfer and aseptic recovery of sterile contents such as cellular vaccines, donor lymphocyte infusions (DLI), and other small volume clinical and industrial applications.

- The FEP material is non-reactive with all chemicals and biologicals including DMSO and DMF.
- Enhanced retrieval of the contents is afforded by the hydrophobic nature of FEP material.
- The bag is emptied by needle access through a conventional septum after removing the tamper-evident liquid nitrogen proof cover.
- The neck of the bag is designed to be heat sealed to isolate and encapsulate the contents in this fully closed and sealed bag.
- Rounded corners provide for cold strength durability during cryopreservation and maximal product retrieval after cryopreservation.
- Sealing and removing the inlet port requires a high temperature bar sealer.
- AFC offers two high temperature sealers: AFC model FEP-4; and Packworld model 7016.
- A label may be tied to the bag through the label attachment hole.
- Each bag is individually tested and inspected.
- The bags are steam sterilized: Sterility Assurance Level (SAL) 10⁻⁶.



Applications: This bag provides the ability to freeze, thaw, and dispense individual doses created from a common reservoir sterile transferred by use of an *Afc* TS-917 sterile transfer set (sold separately).

- The bag contains and protects liquids and suspensions in mechanical freezers, vapor phase, or liquid nitrogen environments.
- Multiple bags will fit in standard metal freezer cassettes.
- With proper handling the bag may be immersed in liquid nitrogen, or used for cell culture and 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 walls are .005" thick Fluoro-Ethylene-Propylene (FEP).
- The bag is optically clear so contents may be viewed, even microscopically.
- The FEP material is free from all extractable or leachable materials.
- The FEP material is non-immunogenic.

Inlet Tube Lead: The inlet tube consists of a single 4mm standard PVC tubing for sterile connection. The fill tube and the tube connector can be completely removed by sealing and severing the neck of the bag.

Exit port: The needle access septum is protected from potential contamination by an integral tear-open tamper-evident cover. The septum is made from USP Class VI latex-free polyisoprene.

510(k) cleared. Inquire regarding Device Master File

Reference number: 093807

April 29, 2010

