

CellSeal®

Closed-System Cryogenic Vial

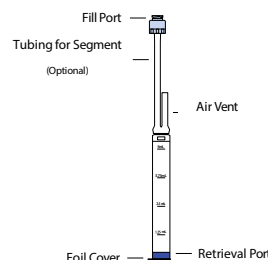
CELLSEAL® NEEDLELESS CLOSED-SYSTEM CRYOGENIC VIAL

NOTE: Handle the device using aseptic technique.

REQUIRED MATERIALS

- Standard Luer connector syringe (10 mL syringe for 5 mL vial, and 5 mL syringe for 2 mL vial recommended)
- Exam gloves
- Processing rack
- Compatible sealing device (Sexton RF Sealing System recommended)
- Clean scissors
- Alcohol swabs
- Water bath
- Compatible cryogenic storage accessory, such as a box, cane, or controlled rate freezing container (Sexton Cryogenic Box, Rack, and Freezing Container recommended)
- Cryogenic gloves

1. Use clean scissors to cut the packaging. Wearing exam gloves, remove the vial from the packaging. Place vial upright with tubing and needleless port at the top in the processing rack. Reclose the packaging. **Do not handle the vial by the fill port. Handling product by the fill port weakens the tubing and fill port joint.**

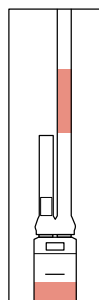


2. Working inside a biosafety hood or cleanroom, aseptically prepare the needleless port site by swabbing the top of the port with an alcohol wipe. Allow the port to air dry up to 1 minute before accessing. Be sure to remove any particulate on the needleless port surface. For loading the sample, use an appropriately sized syringe and needle to draw up the sample to be stored.

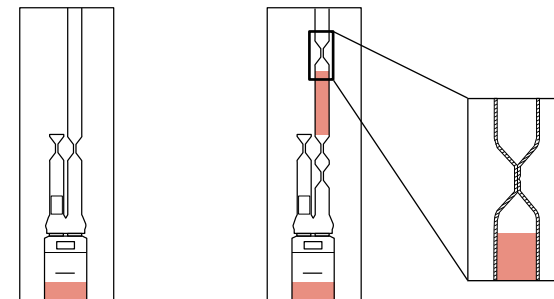
- a. If using a 5 mL vial, a 10 mL syringe is recommended.
- b. If using a 2 mL vial, a 5 mL syringe is recommended.

It is recommended to draw a small volume of air into the syringe first and then draw the sample. The air will be used to level the column of liquid in the tubing or to assist in pushing the entire sample into the vial. **Do not fill the vial with more than the stated maximum volume.**

3. Connect the needleless syringe containing your sample to the needleless port by pushing the syringe adapter into the needleless port septum and turning the syringe clockwise. Once connected, push the sample into the vial. **Do not use any non-standard Luer connectors; they may damage the needleless port. To avoid dislodging the air vent filter, be sure to fill the vial at a moderate speed using the recommended syringe size.**
4. If a segment is desired, pull back on the syringe plunger to create a clear space in the tubing column above and below the liquid for the segment. Push the air into the tubing to place the liquid column at the desired level, or push the entire sample into the vial.



5. Using a sealer designed for use with ethylene-vinyl acetate tubing, seal the tubing as described in 5a or 5b below. **NOTE:** It is recommended to use Sexton RF Sealing System for sealing of CellSeal vial's tubing.
 - a. If a segment is desired, place a seal above and below the liquid in the tubing. Place an additional seal below the bottom seal for optimal folding over of segment for storage.
 - b. If no segment is desired, place a seal near the vial body alone. **Placing a seal in the tubing may require a longer sealer dwell-time than a standard blood bag.**



Seal Configuration for No Segment Seal Configuration for Segment Seal Close-Up View

6. Seal the air vent tubing above the filter, making this a closed system. Once a closed system is created, use clean scissors to cut off any additional tubing. **NOTE:** The vial is intended to be frozen in the upright position only, and stored at cryogenic temperatures (as low as -196 degrees Celsius).
7. Place vial and folded integral segment into box, cane, or controlled rate freezing container for storage. **NOTE:** Sexton Cryogenic Storage Boxes, Racks, and Freezing Container are recommended.
8. When segment is needed, remove vial from cold storage and immediately cut off segment with clean scissors and thaw per user's validated sample thawing instructions.
9. When sample is needed, remove vial from cold storage and thaw per user's validated sample thawing instructions. **NOTE:** Sexton Thawing System is recommended. **NOTE:** Vial is for single use only.
10. Cut open the vent tube with clean scissors.
11. Remove the foil on the bottom of the retrieval port. Thoroughly swab the retrieval port septum with a sterile alcohol wipe. Allow to air dry up to 1 minute before accessing.
12. Use a non-coring needle and/or proper anti-coring technique (as described below) to puncture the retrieval port septum and extract the sample. It is recommended to use an 18G needle for this port.
Proper Anti-Coring Technique:
 - a. Hold the needle with the opening of the needle tip away from the retrieval port septum.
 - b. Insert the needle into the septum at a 45-60° angle.
 - c. Increase the angle of the needle gradually as the needle enters the vial.
13. If used with infectious or hazardous bodily fluids, dispose of vial according to institutional guidelines for medical waste.



MANUFACTURER
Sexton Biotechnologies

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MADE IN USA



X = Quantity per packaging configuration