Sexton Biotechnologies®
Part of Biolife Solutions

CellSeal® Connect
Closed-System Vial

1 Product Description

The CellSeal® Connect vial is designed for closed-system storage and retrieval of biological materials intended for cold or frozen storage (+25°C to -80°C). This product allows for sample filling and retrieval via sterile tube welding.

2 Precautions

- Handle the product using aseptic technique. If not using sterile welding, connection to product should be performed in a biosafety cabinet using aseptic technique.
- Single-use product. Attempts to reprocess, re-sterilize, and/or reuse may result in product failure and/or contamination of the sample.
- Discard product if mishandling occurs or product is expired.
- Product **may not** be used at cryogenic storage temperatures. Intended for storage temperatures equal to or warmer than -80°C.

3 Storage

This product is supplied sterile following gamma irradiation with a validated sterilization dose.
Product should be stored within the sterile packaging in a clean, dry location at room temperature until use.

4 Recommended materials

- Exam gloves
- Processing rack
- Radio Frequency Tube Sealing System (compatible with PVC tubing)
- Clean scissors
- Alcohol swabs
- Standard luer connector syringe (10 mL syringe for 5 mL vial; 5 mL syringe for 2 mL vial)
- Compatible thawing accessory such as water bath or thawing system
- Compatible storage accessory, such as a box, or controlled rate freezing container (Sexton Biotechnologies® Cryogenic Box, Rack, and Freezing Container recommended)
- Cryogenic gloves

5 User Instructions

1 Open pouch

In a biosafety cabinet (BSC) using aseptic technique, open the sterile pouch per standard operating procedures. Place vial upright with tubing and ports at the top in processing rack. **Do not remove the vial from the package by the fill port. Handling product by the fill port may weaken the tubing and fill port joint**.

2 Connect to vial fill tube

Vial filling may be accomplished via syringe using the swabable luer port or via sterile tube welding.

a. For syringe filling: Use an appropriately sized syringe to draw up the sample to be stored.
For the 5 mL vial, a 10 mL syringe is recommended.
For the 2 mL vial, a 5 mL syringe is recommended.

b. For filling via sterile tube welding: Use standard procedures to sterile weld the PVC fill tube line to a separate input line.

3 Fill vial

Advance the sample through the vial fill tubing at moderate speed to avoid residual sample in the tubing. If necessary, follow the sample with a small volume of air to fully empty the fill line. **Do not fill the vial with more than the stated maximum volume. Overfilling vials may result in the failure of the vial during freezing**.

a. Use the filling tool as the source of volume measurement.

b. Maximum allowable fill volume can be impacted by the expansion properties of the filled product.

c. Maximum allowable fill volume for the 5 mL vial is 4.9 mL.

d. Maximum allowable fill volume for the 2 mL vial is 1.9 mL.

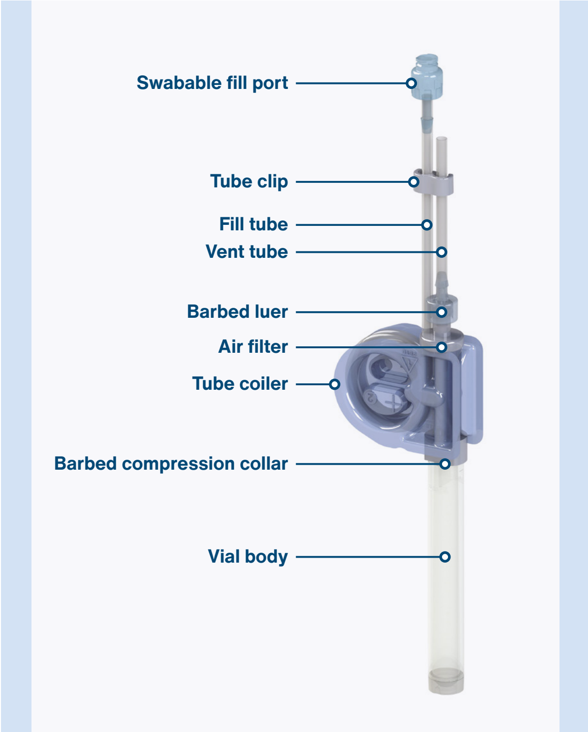

Figure 1: CellSeal Connect vial components.

Figure 2: CellSeal Connect vial filling.

5 User Instructions (cont.)

4 Seal vent tubing

Using a sealer designed for PVC tubing, seal the air vent tubing according to the sealer instructions. Place the tubing clip close to the barbed fitting and seal above the tubing clip as shown in Figure 3.

5 Seal fill tubing

Seal the fill tubing at a similar height to the prior seal, as shown in Figure 3, making this a closed system. Once the system is closed, use clean scissors to cut off additional tubing above the seals.

6 Vial storage

The vial is intended to be frozen in the upright position only. Vial is intended for storage at temperatures as low as –80°C.

7 Thawing

When sample is needed, remove vial from cold storage and thaw per user's validated sample thawing instructions. **NOTE: Vial is for single use only.**

8 Prepare for sample retrieval

Remove the tube coiler by gently prying apart, and discard both pieces. For closed-system retrieval, sterile weld the PVC fill tube line to a separate output line. Cut the air vent tube above the air filter with clean scissors.

9 Sample retrieval

Fold the air vent tube over and then invert the entire vial as shown in Figure 4. Provide gradual negative pressure to retrieve sample while ensuring minimal build-up of residual fluid in the tubing. **NOTE: It is important to keep the vent tube folded and upright while the vial is inverted to ensure sample material does not enter the vent tube.**

10 Disposal

Dispose of vial using standard procedures as medical or hazardous waste according to institutional guidelines.

Figure 3: Vent & fill tubing.

Figure 4: Sample retrieval.

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