

# CellSeal CryoCase™

## Cryogenic Protective Cassette



### 1 Product Description

CellSeal CryoCase™ is a rigid cassette container designed to encapsulate liquid samples, including biologic materials, for cold or frozen storage down to cryogenic temperatures (+25°C to -196°C).

The product is currently a pre-release version and is for **EVALUATION USE ONLY**.

### 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.

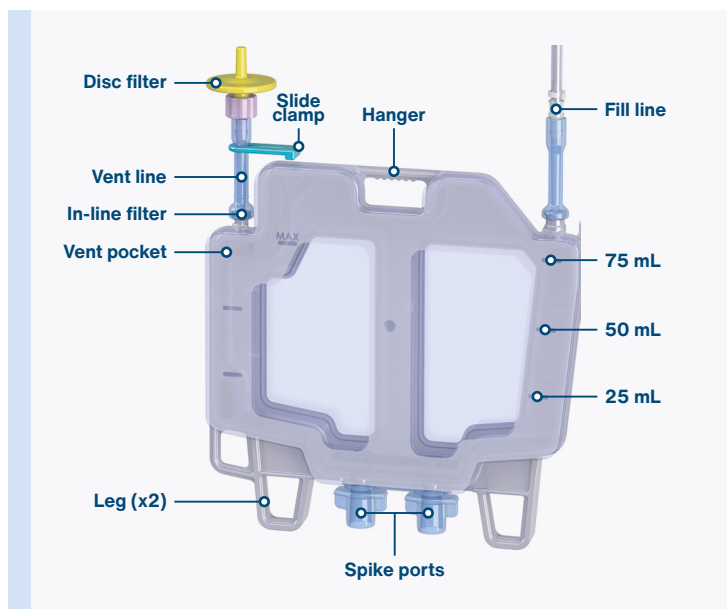


Figure 1: CellSeal CryoCase with labeled features.

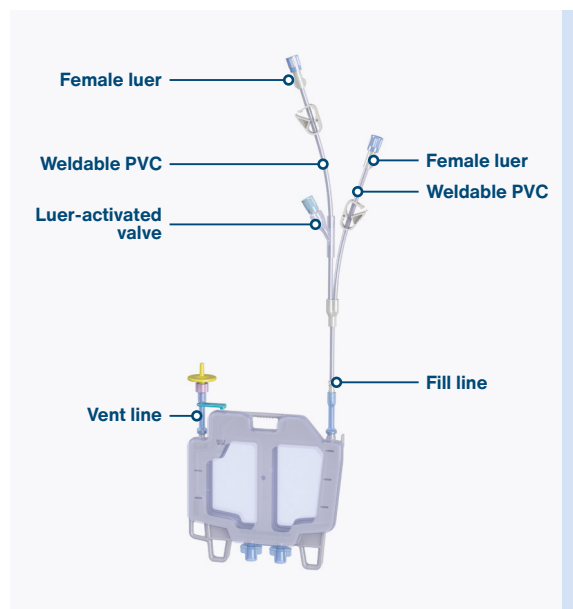


Figure 2: CellSeal CryoCase with labeled features and fill line connected.

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### 3 Storage

The CellSeal CryoCase is for **EVALUATION USE ONLY**.

This product is supplied following gamma irradiation with a non-validated 25-40 kGy sterilization dose. Product should be stored within the sterile packaging in a clean, dry location at room temperature until use.

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### 4 Recommended Materials

- ◉ Exam gloves
- ◉ Radio Frequency Tube Sealing System (compatible with EVA tubing 5.2 mm outer diameter)
- ◉ Clean scissors

#### For sterile welding connection:

- ◉ Sterile tubing welder
- ◉ PVC tubing, 4 mm outer diameter, connected to dispensing device (e.g. syringe or bag)

#### For luer connection:

- ◉ Biosafety cabinet
  - ◉ Syringe or other dispensing device with male luer lock connection
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### 5 Cryostorage User Instructions Fill, Seal, and Store for Cryostorage

**NOTE:** For ultra-low temperature storage, see Section 7.

#### ▶ 1 Open pouch

In a biosafety cabinet (BSC) using aseptic technique, open the sterile pouch per standard operating procedures. If sterile tube welding, a BSC is not required. Position cassette vertically, standing on legs, or rested flat on benchtop.

#### ▶ 2 Connect to CryoCase via fill line

##### a. Sterile welding:

Weld to one of the two PVC fill lines using standard tube welding technique. It is recommended to position and close the clamp on the container side of the weld prior to welding to maintain closure integrity in the event of a failed weld.

##### b. Luer connection:

Remove cap and attach syringe to desired luer lock fitting. If using the luer-activated valve connection, ensure the syringe is fully connected and the valve is opened. Luer connections must be performed in a BSC to maintain closure integrity.

#### ▶ 3 Fill container

Ensure all clamps are opened. Maintain cassette orientation (vertically standing on legs or rested flat on benchtop with hanger side up) while filling to avoid fluid ingress into venting pocket and vent line. It is recommended to use flow rates less than ~500 mL/min. The maximum recommended fill volume is 75 mL as indicated on the cassette lid (standing orientation only).

#### ▶ 4 Close vent and fill line clamps

Once filling is complete, close the fill line clamps and the slide clamp on the vent line.

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## 5 User Instructions Fill, Seal, and Store for Cryostorage (cont.)

### ▶ 5 Seal

Using standard radio frequency (RF) sealing techniques, seal the overmold portion of the fill line and the vent line as shown in **Figure 3**. Use scissors to carefully remove the excess vent and fill line components so that the filled cassette appears as shown in **Figure 3**. Dispose of the removed components according to standard procedures.

### ▶ 6 Freeze and store

Once sealed, the cassette is ready for freezing and cryostorage, according to standard procedures.

### ▶ 7 Post-use integrity testing of sterilizing filter

Once sealed, the sterilizing disc filter terminating the vent line (**Figure 1**) can be removed for a post-use integrity test by unscrewing the filter at the luer joint.

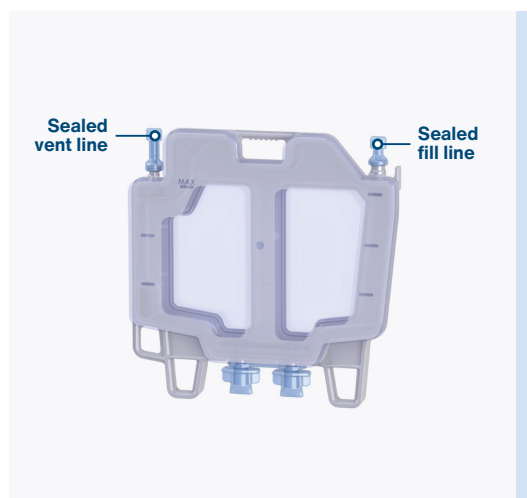


Figure 3: Sealed CellSeal CryoCase.

## 6 User Instructions Sample retrieval

### ▶ 1 Thaw

Remove product from frozen storage and thaw according to user's validated sample thawing instructions.

### ▶ 2 Prepare spike port

To access the spike port septum, tear away the bottom portion of the desired spike port by twisting by hand as shown in **Figure 4**.

### ▶ 3 Cut open vent line

Once ready for retrieval, vent the container through the vent line and in-line filter by making a small cut in one side of the vent line with scissors. The vent line has a circumferential marker line; cut above this line.

**NOTE: Ensure cut is made in the vent line and do not cut the sealed fill line.**

### ▶ 4 Spike adapter access

Using a standard spike adapter, insert the spike into the exposed spike port and apply firm, constant force until the spike port septum is pierced. **NOTE: Do not twist the spike adapter during septum puncture.**

### ▶ 5 Sample retrieval

Hang the cassette and open any clamps. Sample will drain via gravity.

## 6 User Instructions

### Sample retrieval (cont.)

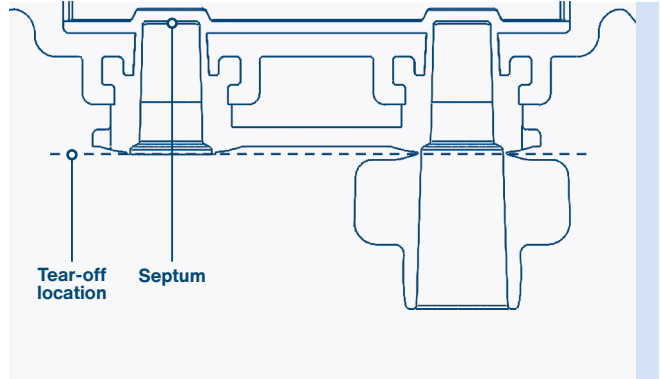
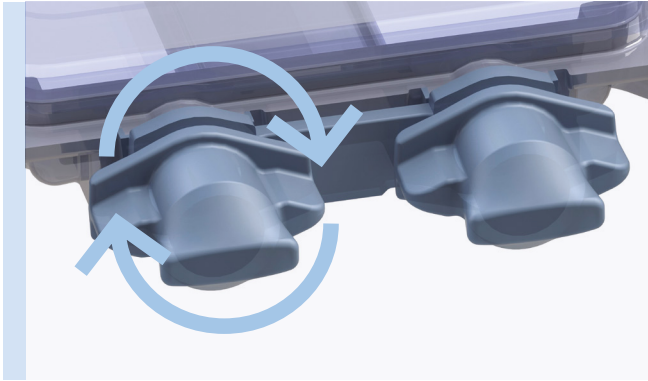


Figure 4: Spike port access and preparation.

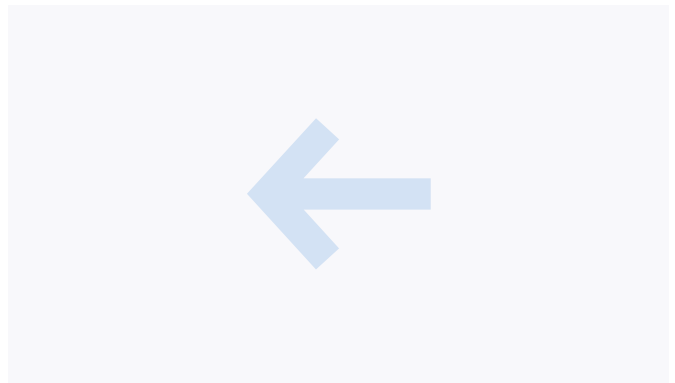
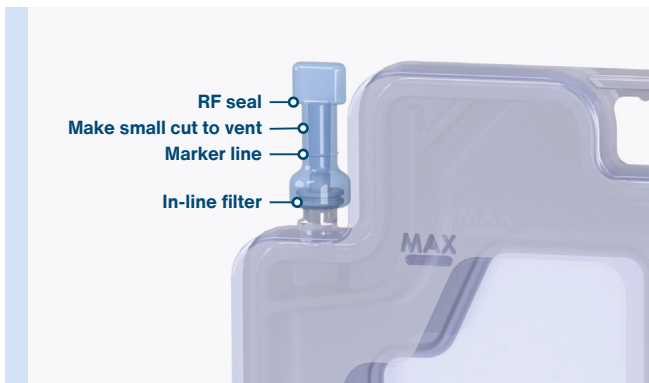


Figure 5: Cutting open vent line.

## 7 User Instructions

### Fill and Seal for Ultra-Low Temperature (ULT) Storage

CellSeal CryoCase can be used to store intermediate sample materials at ultra-low temperatures (ULT, which is approximately  $-80\text{ }^{\circ}\text{C}$ ). For such usage, the fill line may be retained during freezing and storage and used post-thaw for sample retrieval. In this case, complete Fill, Seal, and Store for Cryostorage steps 1 – 4 above.

**Do NOT seal and remove the fill line as described in step 5 of the cryostorage instructions.** For ULT storage, the vent line may be sealed and removed, or left unsealed and retained, depending on user preference.

Once frozen, care should be taken to avoid contact with or excessive motion of any retained fill and vent line components to avoid damage and potential loss of closure integrity.

Sample retrieval following ULT storage may be performed via spike ports or, in the case of a retained fill line, by using one of the connection methods in step 2 of the cryostorage instructions.