

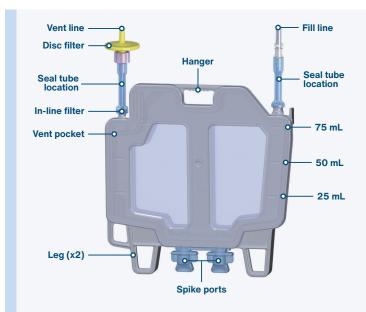
CellSeal[®] CryoCase[™] Cryogenic Storage Cassette

Product Description

CellSeal CryoCase is a rigid cassette designed to store samples down to cryogenic temperatures.

2 Precautions

- Single-use product. Attempts to reprocess, re-sterilize, and/or reuse may result in product failure and/or contamination of the sample.
- Standard aseptic processing techniques should be used during filling and retrieval.
- Maintain vertical orientation of the cassette when stored materials are in liquid phase. A CryoCase stand accessory is available.
- Discard product if mishandling occurs or product is expired.
- Standard laboratory personal protective equipment (PPE) should be used in conjunction with this product.



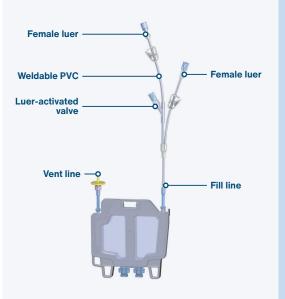


Figure 2: CellSeal CryoCase with labeled features and fill line connected.

Figure 1: CellSeal CryoCase with labeled features.

3 Storage

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

4 Recommended Materials

- Exam gloves
- Radio frequency (RF) tube sealing system (compatible with EVA tubing 5.2 mm, outer diameter)
- Clean clippers or 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 (BSC)
- Syringe or other dispensing device with male luer lock connection

5 Filling

1 Open pouch

Open the sterile pouch per standard operating procedures. Use in a BSC with aseptic technique unless making connection to the product fill line using sterile tube welding.

2 Connect via fill line

Connect to the CryoCase fill line using one of the below methods. Verify that the connection is intact and complete before proceeding to fill.

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 using aseptic technique in a BSC.

3 Fill

Ensure fill line tubing clamp is open. **Maintain vertical cassette orientation** using the CryoCase stand accessory (P/N CSCA-001) 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.

6 Sealing for Cryostorage

4 Seal

While maintaining the vertical orientation, use standard RF sealing technique to seal the seal tube portions of the fill line and the vent line as shown in **Figure 3**.

5 Prepare for storage

Verify seals are intact, then use clippers or scissors to carefully remove the excess vent and fill line components so that the filled cassette appears as shown in **Figure 3**.

6 Freeze and store

The sealed CryoCase cassette is ready for freezing and cryostorage according to standard procedures. Once frozen, the cassette may be stored in a vertical or horizontal orientation.

7 Post-use integrity testing of sterilizing filter

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. Dispose of all removed components according to standard procedures.





Z Sample Retrieval

8 Thaw

Remove product from frozen storage and thaw according to user's validated sample thawing instructions. It is recommended to maintain CryoCase in a vertical or tilted orientation during thaw to avoid fluid ingress into the vent line which may contribute to residual fluid loss. Gentle agitation may be used if desired to decrease thaw times.

9 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**.

> 10 Venting the cassette

CryoCase must vent for efficient sample retrieval. Use one of the methods below.

a. Spike adapter with built-in vent filter:

Many off-the-shelf spike adapters include a vent filter. CryoCase testing has been performed with a Qosina spike adapter that includes a vent filter (P/N 23203).

b. Cut open CryoCase vent line:

To vent the container through the vent line and in-line filter during retrieval, use clippers or scissors to make a small cut in one side of the vent line. 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.

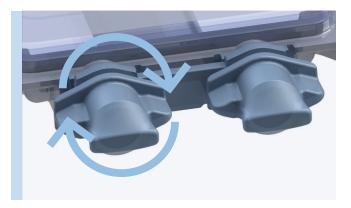
11 Spike adapter access

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. A slight twist of the spike (less than 90°) may be used during puncture, but avoid excessive twisting. Once the septum is punctured, use care to avoid accidentally dislodging the spike adapter.

7 Sample Retrieval (cont.)

12 Sample retrieval

CryoCase can be hung on a standard bag hanger to drain via gravity. Ensure any clamps are open.



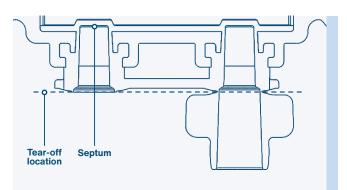


Figure 4: Spike port access and preparation.

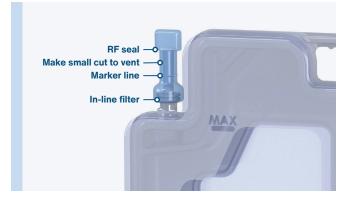




Figure 5: Cutting open vent line.

8 CryoCase Use in Ultra-Low Temperature Storage

CellSeal CryoCase can be used to store intermediate sample materials at ultra-low temperatures (ULT, which is approximately -80 °C). For such usage, the weldable PVC fill line may be retained during freezing and storage and used post-thaw for sample retrieval. In this case, fill CryoCase as normal and then RF seal the vent line tube and the PVC fill lines below the luer caps so that a weldable section of PVC remains. Once frozen, care should be taken to avoid contact with or excessive motion of any retained fill and vent line components.

Sample retrieval following ULT storage may be performed via spike ports or by sterile welding to the retained PVC fill line. Contact BioLife Solutions for more detailed instructions on the use of CryoCase in this application.

Biolife Solutions

3303 Monte Villa Parkway Suite 310 Bothell, WA 98021 USA T +1.866.424.6543 / +1.425.402.1400

F +1.425.402.1433E info@biolifesolutions.com

BioLifeSolutions.com

2024[®] BioLife Solutions. All Rights Reserved. Patents Pending.

Cell Processing Solutions

IG-SXB-240784_R02 CFD-24_2.0

4