

General Use Guidelines for VueLife® “C” Series Bags

VueLife® “C” Series Bags are the Saint-Gobain standard series FEP bags for *in vitro* bioprocessing applications. Applications include the culture of highly concentrated immune cells, such as T or NK cells, monocytes, dendritic cells, or macrophages.

The FEP material is transparent, withstands cryogenic temperatures, and provides permeability to oxygen and carbon dioxide whilst remaining impermeable to water. Each “C” series bag typically features a needleless injection site and “Y” connector with 7” PVC tubing leading to a female luer and a heat sealed sterile docking tube. The rounded corners provide strength, durability, and maximal product retrieval.

VUELIFE® “C” SERIES BAG PORT TYPES

VueLife® “C” Series Bags traditionally feature two types of ports; 1) a needleless valve and 2) a “Y” connector with a 7” PVC tube with a female luer end and a heat sealed sterile docking tube. Other types of ports, tubing and connections are available and can be customized to the needs of the user.



Fig. 1 Needleless Valve Port (Swabable; FLV)

This swabable needleless injection site allows for multiple use. The valve stem and body will mate securely with all standard luer syringes, luer connectors, and needle adapters. This port is made to be used multiple times (be sure to disinfect the port before and after use).

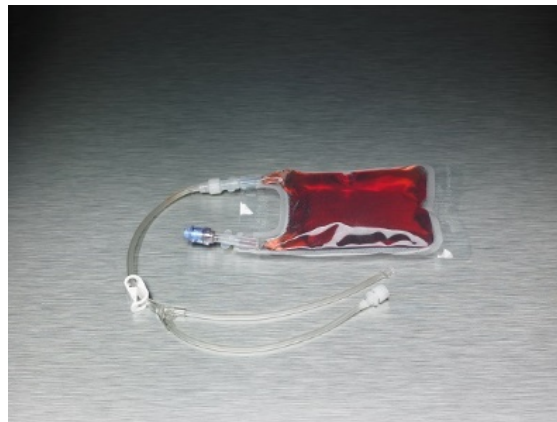


Fig. 2 FEP bag featuring a “Y” connector with 7” PVC tubing containing a female luer end and a heat sealed sterile docking tube

The PVC tubing with the “Y” connector and additional tubing allows for secure connection with standard luer syringes, luer connectors, and needle adapters at the female luer end or sterile docking to the PVC tubing via welding.

VUELIFE® “C” SERIES BAG FILLING

Manual Filling

Aseptic technique and procedures should be used at all times when filling the bag. Careful disinfection of connectors and ports both before and after use is recommended. The PVC tubing with the “Y” connector is typically used for filling and the needleless valve port for sampling or harvesting.

1. Attach the filled syringe to the female luer-lock, open the clamp, and inject the medium/cell suspension into the bag while holding the bag in an upright position.
2. To remove all residual medium from the tubing used to fill the bag, allow gravity to drain the tubing or push a small amount of air through the tubing.

3. Clamp off the tubing and remove the syringe from the luer-lock. Recap the end of the tubing.
4. If filling below the recommended fill volume is required, clamps can be used to restrict the volume in the VueLife® “C” Series Bag. Clamps are available in a variety of sizes and can be repositioned as needed to accommodate expanding cultures. *See below for catalog information for the VueLife “C” Series Standard Bags and the Clamps.*



Fig. 3 Various sized clamps for use with VueLife “C” Series Bags

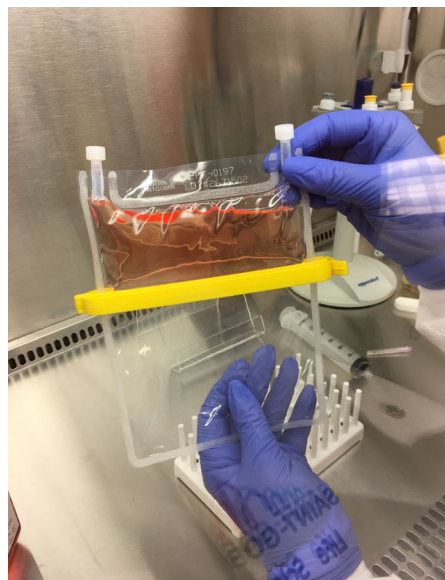


Fig. 4b The applied clamp showing that the liquid remains above the clamp

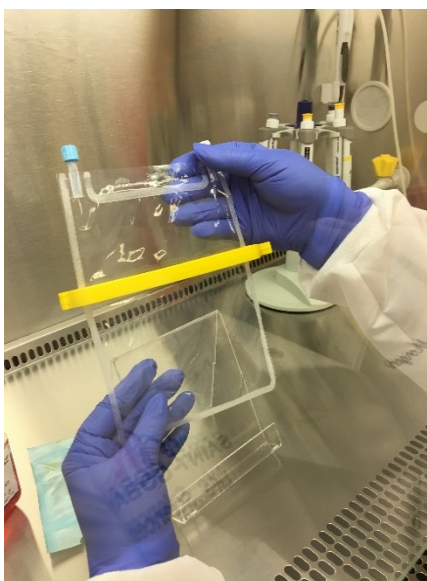


Fig. 4a Clamp applied for use with VueLife “C” Series Bags

5. These same steps are used for manually adding fresh medium during expansion of the culture.

Catalog Number	Product Description
1C-0005	Red Closure Clamp, 5 cm., Red, 1 cm. wide
1C-0007	Blue Closure Clamp, 7 cm., Blue, 1.2 cm. wide
1C-0010	White Closure Clamp, 10 cm., White, 1.2 cm. wide
1C-0014	Yellow Closure Clamp, 14 cm., Yellow, 1.2 cm. wide
1C-0022	White Closure Clamp, 22 cm., White, 1.2 cm. wide
1C-0032	White Closure Clamp, 32 cm., White, 1.2 cm. wide

Ordering Information on VueLife “C” Series Bags and Clamps

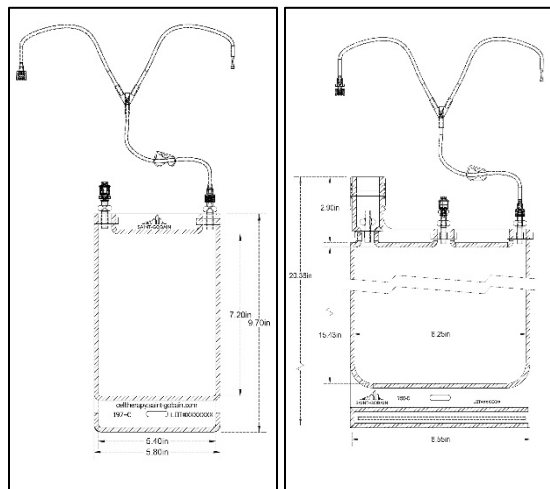
Product	Recommended Process Volume	Approx. Maximum Fill Volume	Approx. Interior Surface Area (2 x Bag Face)	Standard Ports & Tubing	Qty/Case
32-C	32 mL	40 mL	87 cm ²	1 FLV port; 7" length of PVC tubing that goes to "Y" with 2 more lengths of 7" tubing, one length sealed off, and one length with female luer port at end	10
72-C	72 mL	175 mL	193 cm ²		10
118-C	118 mL	275 mL	277 cm ²		10
119-C	119 mL	285 mL	286 cm ²		10
197-C	198 mL	500 mL	502 cm ²		10
290-C1	290 mL	900 mL	658 cm ²		10
750-C1	750 mL	2,500 mL	1,643 cm ²	1 FLV port; 1 spike port; 1 length of PVC tubing that goes to "Y" with 2 more lengths of tubing, one length sealed off, and one length with female luer port at end	10

1. Clamp the tubing of the VueLife® “C” Series Bag to contain any liquids inside the bag.
2. Connect the source bag to the VueLife® “C” Series Bag using your institution’s protocol for sterile tube welding.
3. Open the clamp on the tubing to facilitate the flow of liquids into the VueLife® “C” Series Bag.
4. Allow the contents of the source bag to drain into the recipient bag.
5. Close the clamp on the tubing of the VueLife® “C” Series Bag.
6. Using a sealer, seal and cut the used tubing according to your institution’s protocol. Ensure that an adequate length of tubing remains for future sterile docking needs.

CELL CULTURE SAMPLING

Disinfect the needleless valve port before and after usage with an appropriate disinfectant.

1. Attach a sterile syringe to the FLV port using the luer-lock.
2. Massage the bag gently to homogenize cell distribution for sampling.
3. Invert the VueLife® “C” Series Bag and gently fill and empty the syringe several times with the cell suspension by pushing and pulling the plunger of the syringe. This mixes the cell culture, breaks up any cell aggregates, and ensures a statistically valid sample of the culture.
4. Remove the required sample and process as intended using the syringe.



197-C

750-C

Filling Using a Sterile Connection Device (STCD)

A sterile connection device can be used to connect the tubing of the VueLife® “C” Series Bag to the tubing of a source bag containing medium and/or pre-selected cells.

CELL CULTURE SPLITTING OR TRANSFERRING CONTENTS INTO ADDITIONAL BAGS

Additional VueLife® “C” Series Bags can be used for transferring cell cultures for further processing, such as cell expansion.

Cell Culture Splitting Using a Sterile Connection Device (STCD)

1. Clamp the tubing of the VueLife® “C” Series Bag.
2. Utilizing your institutions’ protocol, connect the new VueLife® “C” Series Bag to the source VueLife® “C” Series Bag using the STCD.
3. Open the clamps on both bags and allow the culture to transfer into the new bag.
4. Stop the transfer by clamping the tubing.
5. Seal and disconnect the tubing between the two bags, making sure to leave a sufficient length of tubing for future sterile connections.
6. To transfer more medium, follow the procedure described in the “Filling” section.

HARVESTING CELLS FROM VUELIFE® “C” SERIES BAG

The following steps describe a manual procedure for cell harvest. Saint-Gobain typically uses the needleless valve port for manual harvest of cells from the VueLife® “C” Series Bags. The following procedure can also be done using the female luer end of the PVC tubing.

1. Clamp the tubing on the VueLife® “C” Series Bag.
2. Manually mix the contents of the bag by gently massaging the bag.
3. Disinfect and securely attach a sterile syringe to the FLV port.
4. Invert the bag. Remove the cell suspension by pulling the plunger of the syringe to fill the syringe.

5. Invert the bag to prevent accidental loss of liquids and disconnect the syringe.
6. Transfer the cell suspension to a suitable conical centrifugation tube or other container for further processing.
7. Repeat the above steps until the entire culture volume has been harvested.

ABOUT

SAINT-GOBAIN

Saint-Gobain Life Sciences is proud to take part in providing solutions for a multitude of cell therapy applications while collaborating with customers and industry partners to develop custom disposables, often for integration into automated systems. Through our material science expertise as well as our deep experience in bringing manufacturing technologies to scale, we are uniquely positioned to offer solutions to the numerous challenges faced by cell therapy manufacturers today.