



HANDLING GUIDELINES

for Optimum Use When Using Your
OriGen PermaLife Cell Culture Bag



OriGen **PermaLife Cell Culture Bags** provide a high-quality, scalable solution for your cell therapy needs, including the harvesting, expanding, concentrating, and freezing of critical cell cultures. PermaLife bags are made of a fluoroethyl polymer (FEP) film that is gas permeable, transparent, biocompatible, and chemically inert. The single-use disposable bags are provided sterile and a swabable needle-free port is attached to each bag.

PermaLife bags are used in cell culture applications which exposes the bags to numerous handling conditions and manipulations during routine use. As with all cell culture products, an abundance of caution should be taken to ensure handling does not affect product integrity. OriGen has validated that our bags and ports maintain integrity after numerous routine simulated use conditions as found in typical end-user environments. However, mishandling of the bag by the user can create leaks that occur on the circumference of the port and weld, on the weld near the port, or along the side seams.

OriGen has identified optimum handling guidelines to help prevent undesired outcomes from occurring during use. Please consider integrating these guidelines into your institutional protocols and training to keep your cell cultures safe.

1. DO NOT OVERFILL THE BAG

Working volumes for all PermaLife bags have been established as part of the validation activities and are defined as the maximum volume recommended for cell culture. We highly recommend that our customers adhere to these established working volumes. Determine your optimal cell culture volume, add 10%, and then select the appropriate bag size based on the specified working volume found in the table. If your optimal volume is between two bag sizes, use the larger bag size. Multiple bag sizes are available with scalable working volumes from 10ml to 3000ml to fit your needs (Figure 1).

PART CODE	WORKING VOLUME (ml)
PL07-2G	10
PL30-2G	40
PL70-2G	100
PL120-2G	150
PL240-2G	300
PL325-2G	450
PL500P-2G*	750
PL750-2G	1000
PL1000P-2G	1500
PL2000P2-2G	3000

Figure 1: PermaLife Working Volumes

2. HANDLE WITH CARE

It is highly recommended that bags be handled with care throughout the entire process. When performing manual mixing, ensure the bag is fully supported and gently mix the contents in the bag. You may rock the bag gently in a back-and-forth motion as long as the bag is fully supported. You may also apply gentle pressure to alternating sides of a fully supported bag as an aid in mixing (Figure 2A).

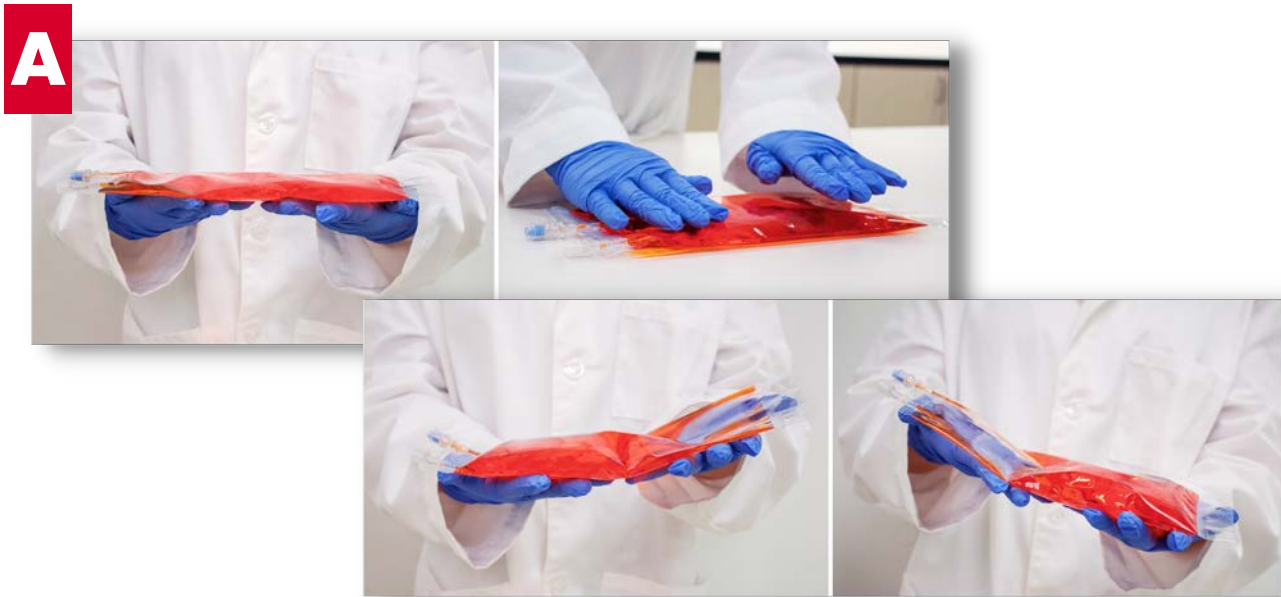


Figure 2: Correct (A) Handling and Mixing Methods

Take care to not crease, fold, squeeze, apply excessive pressure, or aggressively handle the bags during cell culturing (Figure 2B).



Figure 2: Incorrect (B) Handling and Mixing Methods – Squeezing (left), Folding/Creasing (right)

If you need to transport the bag, we advise that you carry smaller bags, one at a time, with both hands underhanded or use a sufficient size tray to support the transfer of larger bags. Do not grab and carry the bag by the ports when transporting the bag.

3. HANG THE BAG APPROPRIATELY WHEN NECESSARY

It is ideal to lay the bag on a flat surface when sampling to avoid stress on the ports, especially for larger bag sizes. If the bag needs to be inverted, it is advisable to hang the bag appropriately from a hook or stand using the bag's hanger hole or rod to allow for better stability and implementation of a two-handed technique when performing sampling.

A



Figure 3: Correct (A) Sampling Setup

B



Figure 3: Incorrect (B) Sampling Setup



Holding the bag with one hand and sampling using the other hand is not recommended due to the lack of control and movement that can occur with the syringe causing additional stresses at the ports.

4. TAKE CAUTION WHEN SAMPLING

When connecting a syringe and sampling the bag, it is possible for the user to twist or lever the syringe during use based on their technique. To avoid unnecessary twisting or levering of the syringe, we recommend using a two-handed technique using one hand to stabilize the port on the bag and one hand to connect the syringe (Figure 4A). When pulling fluid in and pushing fluid out of the syringe, we advise holding the upper part of the syringe barrel near the port with one hand and withdrawing or depressing the plunger using the other hand for better control (Figure 4B).

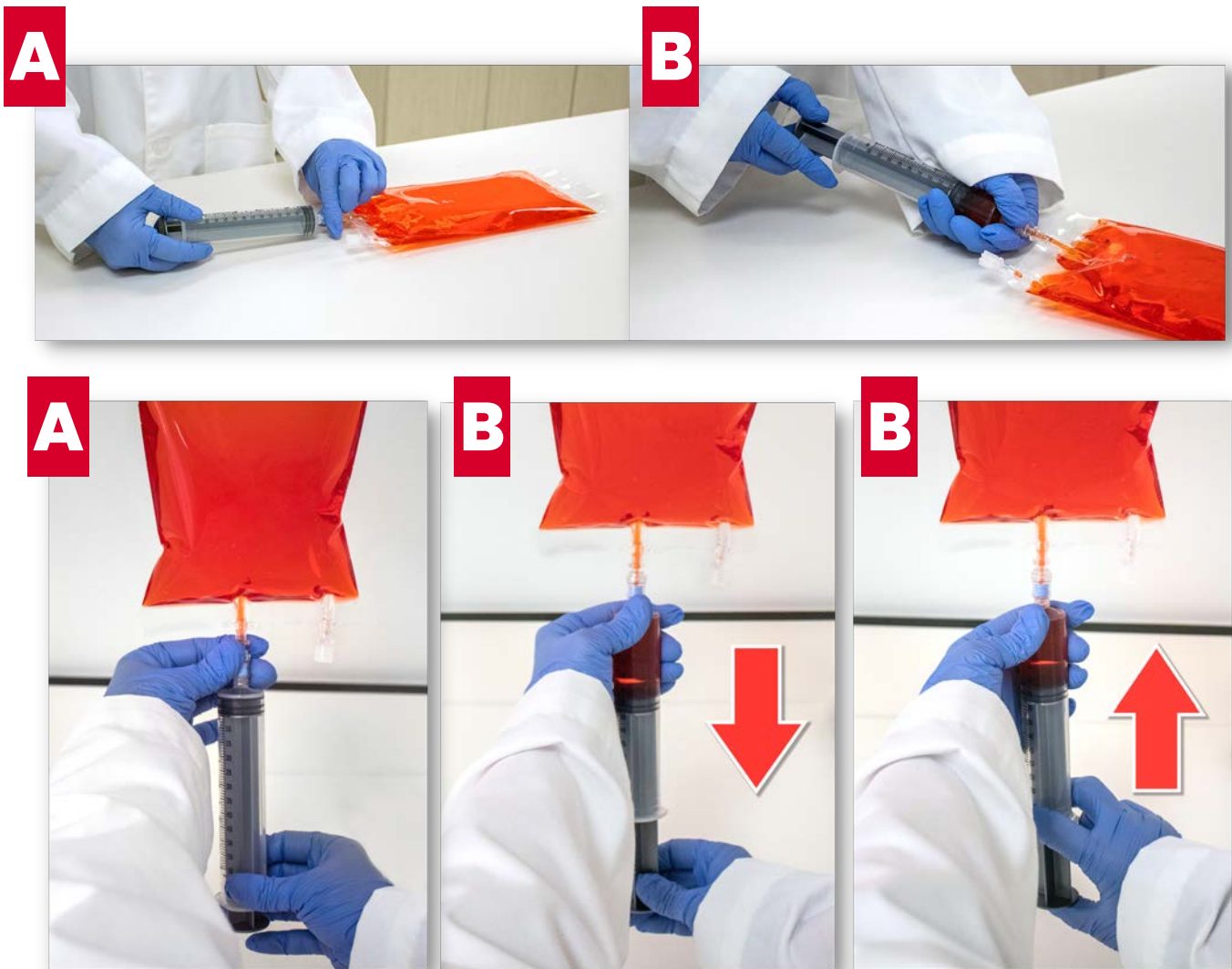


Figure 4: Correct (A, B) Two-Handed Sampling Methods

It is not advised to twist or lever the syringe more than 45 degrees when attached to the port (Figure 4C). The user should avoid pushing the syringe barrel up into the bag when connecting and sampling as this will cause the port and port seal to move into the bag body, stressing the port immensely (Figure 4D).



Figure 4: Incorrect (C) Sampling Methods – Excessive Levering and Twisting

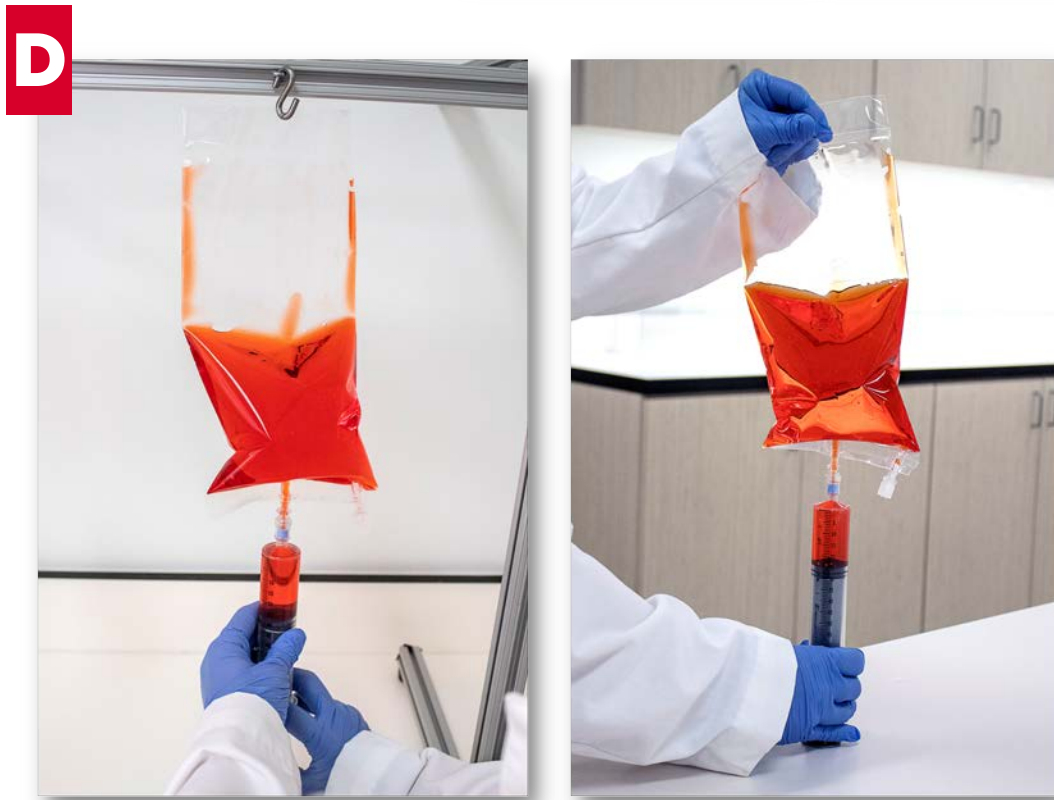


Figure 4: Incorrect (D) Sampling Methods – Pushing Syringe into Bag

5. NEVER STACK OR OVERLAP BAGS

Place the bags horizontally on a leveled incubator shelf. Ensure the bag is completely flat to prevent folding and creasing. Carefully place and remove bags from perforated incubator shelves as the bag and ports could get caught during placement and removal.

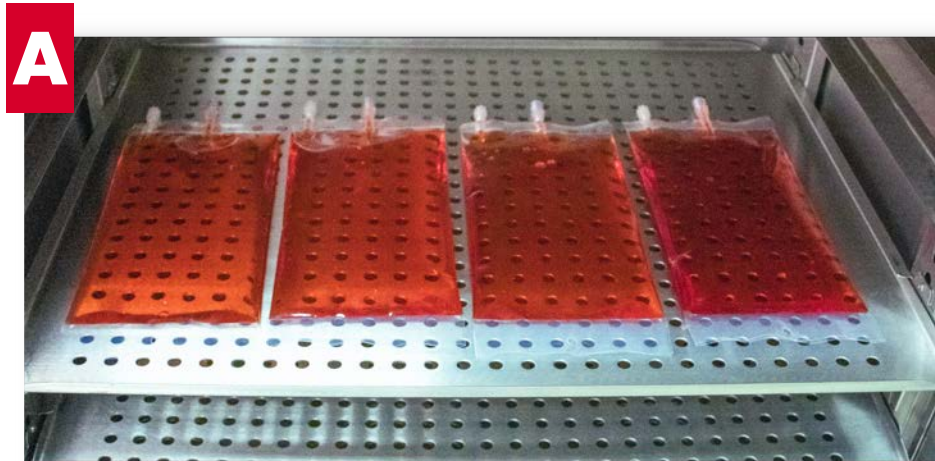


Figure 5: Correct (A) Placement of PermaLife Bags in Incubator

Never stack or overlap cell culture bags in the incubator.

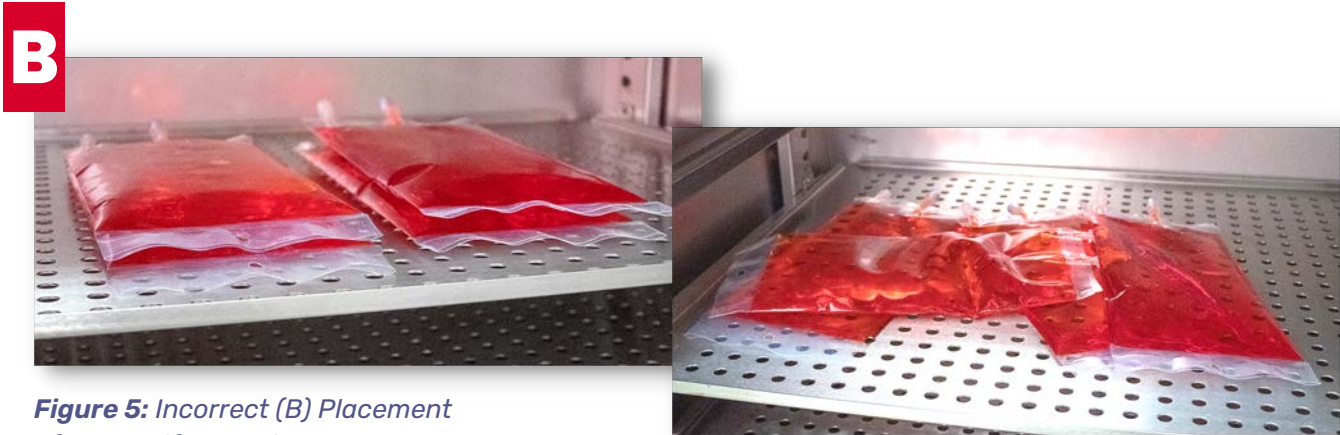


Figure 5: Incorrect (B) Placement of PermaLife Bags in Incubator

When removing the PermaLife bags, pick up the end closest to you and slide your hand under the bag to support it completely.

If you have further questions about the handling guidelines for optimum use of your OriGen PermaLife bags, please contact OriGen directly at info@origen.com or your local distributor. We thank you for your continued partnership with OriGen.