PALL Life Sciences

Instructions for Use USD 3055

Allegro™ 3D Biocontainers and Allegro Totes 1000 L, 2000 L and 3000 L

*Filtration. Separation. Solution.*_{SM}

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1. Introduction

The following procedure is provided for the installation of Pall single-use systems incorporating Allegro 3D biocontainers with capacities of 1000 L, 2000 L and 3000 L in the corresponding stainless steel Allegro totes. Pall Allegro 3D biocontainers must be used in accordance of this manual. The instructions contained in the biocontainer product documentation should be read thoroughly because they contain valuable information gained by extensive experience. It is very important that all instructions in this document are carefully followed and, where appropriate, they should be incorporated into the user's standard operating procedures. If some of the procedures do not suit your needs, please consult Pall or your local distributor before finalizing your system. Use of this product in a manner other than in accordance with Pall's current recommendations may lead to injury or product loss. Pall cannot accept liability for such injury or loss.

2. Considerations for Care and Use of Allegro Biocontainers

Warning: Operation outside the parameters defined in the product data sheet or with fluids incompatible with construction materials may cause personal injury and result in damage to the equipment. Incompatible fluids are fluids which chemically attack, soften, stress, attack or adversely affect the materials of construction. The system should never attempt to be transported or moved when filled. Please refer to Pall for exact limits and refer to USTR2527: Allegro 3D biocontainer validation guide. For more information please contact allegro@pall.com.

Warning: The use of solutions containing low molecular weight alcohol, especially isopropyl alcohol, to decontaminate the exterior of the Allegro biocontainers may, in circumstances where significant stress (repetitive bending and twisting) is applied during use, cause damage to the molded LDPE inlet and outlet ports. The flexible LDPE film of the Allegro biocontainers is not affected.

3. Receipt of Equipment

Allegro 3D biocontainers are usually provided as part of an Allegro system that has been sterilized by gamma irradiation by request.

1. Store the Allegro 3D biocontainer/system in clean, dry conditions between 0 and 30 °C without exposure to radiation sources like direct sunlight and, wherever practical, in the packaging as delivered.

2. Do not remove from packaging until just before use.

3. Check that the packaging is undamaged prior to use.

Caution: Avoid the use of sharp blades or pointed instruments that could damage the Allegro 3D biocontainers and other system components, and potentially damage the filter (if included). Do not open the bag by forcing any of the system components through the sealed end because this can generate particulate contaminants.

4. Ensure that the Allegro 3D biocontainer system selected is suitable for the application.

5. In addition to the part number, each biocontainer is identified by a unique lot number.

4. Installation and Operation

The hardware to support the 1000 L, 2000 L and 3000 L Allegro biocontainer systems are made of a stand, a base module that supports the 1000 L biocontainer, and available extension modules to accommodate the 2000 L and 3000 L Allegro biocontainer systems respectively, depending on the configuration (refer to Figure 1). Both the base module and the extension modules consist of passivated 304 SS. A hoist is necessary extend the top of the Allegro biocontainer for the 2000 L and 3000 L sizes. It is not needed with the 1000 L base module.

Note: A crane or fork lift should be onsite to stack the extension modules.
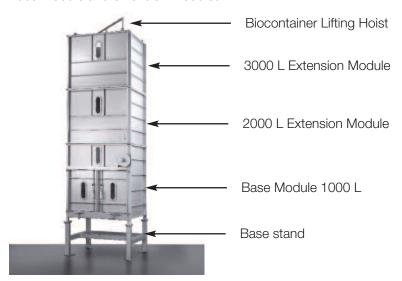
Figure 1
Base module and extension modules

- Biocontainer Lifting Hoist
- 3000 L Extension Module
- 2000 L Extension Module
- Base Module 1000 L
- Base stand

Table 1
General hardware assembly overview

Item	Part number	Dimensions	Weight
Base Stand	LGR3000STAND	1066 mm x 1260 mm x 600 mm high	70 Kg
Base Module	LGR3000BASE	1066 mm x 1260 mm x 1406 mm high	230 Kg
Extension Module	LGR3000EXT	1066 mm x 1260 mm x 1000 mm high	160 Kg
Lifting Hoist	LGR3000HOIST	405 mm x 225 mm high	10 Kg

4.1   Preparation and installation of the Allegro base and extension module

To prepare the tote for use:

1. Check that the area designated for use is clear and can accommodate the hardware system being installed. Ensure that the surface area is flat, level, and strong enough to bear the weight of the tote when full. If required, prepare studs for screwing the feet down. Please refer to Table 1 for clearance.

2. Using a forklift, position the stand on the level area intended for use (Figure 2).

Figure 2
Hardware stand

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3. Next using the forklift, lift the base module and position it over the stand (Figure 3).

Figure 3
Base module lifted directly over stand using a forklift

4. Ensure the base modules feet are completely aligned with the holes on the stand frame so the bolts can be inserted (Figure 4).

Figure 4
Stand frame alignment with base module

5. Once the bolts on the base module are aligned with the holes on the stand, slowly lower the fork lift to drop the bolts into place (Figure 5).
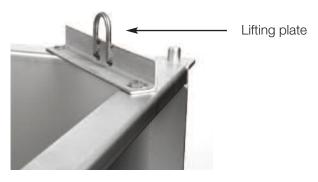
Figure 5
Bolts inserted into four holes

6. Secure nut and washer using an adjustable wrench to fasten the entire stand to the base module (Figure 6).

Figure 6
Secure bolts with nuts and washers

7. Attach an extension module(s) using a fork lift or hoist on the top of the base module as follows: **NOTE:** Extension module is not used for the 1000 L

   - Attach the two lifting plates to the top of the extension module by dropping one end over a position pin and aligning the other side with a bolt into the hole. Fasten down with a washer and nut and the adjustable wrench (Figure 7). (The lifting plates will be used to lift the extension module)

Figure 7
Lifting plate secured to top of extension module

Lifting plate

- Attach crane or hoist carabiner to the two locking plate eyes (Figure 8).

Figure 8
Crane secured to each lifting plate eye with a chain

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- Lift the extension module over the base module so that the four locating pins align with the four corner holes. Then lower the extension module on top of the base module so that the four corner locating pins insert into the holes on the base module (Figure 9).

Figure 9
Four corner locating pins aligned with four corner holes

Next fasten the ten bolts with nuts with top and bottom washers to secure the base module to the extension module (Figure 10).

Figure 10
Secure ten bolts with nuts and washers

4.2   **Preparation and installation of the hoist**

1. Attach the hoist bracket to the top of the extension module by placing each side of the bracket frame holes into the positioning pins. Fasten the other hole on the bracket feet using a bolt with nut and washer (Figure 11). This is installed in the same manner as the lifting plate mentioned above.

Figure 11
Bracket frame secured. **Note:** *Crossbar will not be attached at this step yet.*

2. Feed the stainless cable through the pulley on the top corner of the extension module and pull the cable toward the ground until the carabiner rests on the pulley (Figure 12).

Figure 12
Cable pulled through side pulley

3. Slide the other end of the stainless cable through the small hole located inside the friction wheel. Connect the cable lock to the cable by sliding it over the cable and fastening the two flat head screws secure it to the cable. This will prevent the cable from disconnecting from the friction wheel. (Figure 13)

Figure 13
Cable fastened by cable lock.

4. Using a ladder, pull the end of cable that has carabiner through large center pulley on hoist frame directly above extension module

5. Feed cable down from the center pulley until the stainless cable with carabiner attached is at the inside bottom of the base module. Open each of the doors on the base module by pulling the black locking pin toward you and turning the latch to the side (Figure 14).

Figure 14
Doors being opened

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6. Connect the carabiner on to the crossframe to the cable that has been lowered (Figure 15).

Figure 15
Carabiner attached to crossframe

7. To extend the cross frame arms, turn the knob on each arm and slide each arm to the four tote corners. The cross frame arms should be adjusted so they are 15 – 20 mm from the tote inner corners (Figure 16).

Figure 16
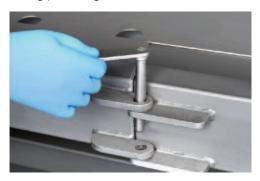*Knob turned to extend crossframe arm*

8. Using the friction wheel, raise the crossbar inside the tote to prepare for biocontainer installation (Figure 17).
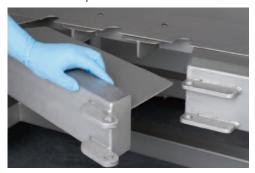
Figure 17
Operator raising crossframe

9. Prior to Allegro biocontainer installation, the lift pin needs to be released to unlock the port plate clamp (Figure 18).

Figure 18
Lifting pin being released

10. The swivel locking plate is used to secure and unsecure the ports of the Allegro biocontainer and needs to be opened to install the Allegro biocontainer. (Figure 19).

Figure 19
Swivel door opened

4.3 Installation of the Allegro biocontainer/system

1. Confirm that the selected Allegro 3D biocontainer/system is suited for the tote.

2. Inspect the Allegro biocontainer system packaging. Verify that it is free from damage that might compromise the integrity of the system.

3. Remove the system from its packaging. Do not unfold the Allegro biocontainer.

4. Hold the Allegro 3D biocontainer with the port plate facing down (at the bottom) and closest to the front (opening side) (Figure 20).

Figure 20
Unpackaged Allegro biocontainer inserted into tote

Note: Two operators are recommended to perform Allegro biocontainer installation

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5. Install the Allegro 3D biocontainer into the base of the tote and ensure biocontainer is as level as possible to the base of the tote. When laying flat, the ports of the biocontainer should align with the tote grooves (Figure 21).

Note: The Allegro biocontainer label is located on the top of the system and needs to be facing upward towards the user.

Figure 21
Ports aligned with grooves in base of the tote

6. Close all clamps on the outlet lines and ensure that the inlet lines are open on the biocontainer. Secure the lower swivel door and replace locking pin. Attach the four hoist clips to the holes four holes located at each corner of the top of the biocontainer. Ensure each clip fastens to the corresponding hole so that the crossbar is holding the four connection points (Figure 22).

Figure 22
Four hoist clips connected to biocontainer holes

4.4 Filling the Allegro biocontainer/system

Once the biocontainer is secured into the base of the tote and aligned with four hoist connection perform the following:

1. Check that the outlet lines are closed

2. Using the friction wheel, raise the biocontainer (Figure 23)

Figure 23
Raising the Allegro biocontainer using the friction wheel

3. The Allegro biocontainer should be raised so that the crossbar with the Allegro biocontainer connected is near the top of the extension module (Figure 24).

Figure 24
Allegro bicontainer raised inside the tote

4. Open the filling line supply and begin to fill the system through the biocontainer inlet.

5. After adding about 15 liters, stop and make sure the biocontainer base is flat and reaches into the corners of the tote.

6. Close the doors and monitor the filling process. Sight glasses are located on each module to view the filling. (Figure 25)

Figure 25
System filled with sight glasses covered

Warning: Do not fill the biocontainer above its maximum volume specifications

7. As the filling is in progress, the operator MUST regularly raise the hoist to avoid folds developing.

Warning: Failure to raise the hoist during the filling process may result in a fold in the biocontainer that can potentially cause uneven filling

Warning: Do not open the doors during filling operation.

Note: Allegro 1000 L 3D biocontainers can be filled from either the top or bottom ports. The 2000 L and 3000 L can only be filled from the bottom ports. The biocontainer will naturally move during filling. When filling through the top ports for the 1000 L, position the tubing in the center of the biocontainer, so it does not become snagged or pulled during the filling operation. Upon completion of filling, close the filling line. Disconnect the filling line in accordance with the requirements of the connection device and your own aseptic standard operating procedures

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4.5   Draining the Allegro biocontainer

4.5.1   From the bottom (1000 L, 2000 L, and 3000 L)

1. Connect the dispensing line in accordance with the requirements of the connection device and your own site aseptic procedures.

2. Open the clamp on the selected drain line.

3. Commence the draining operation. The biocontainer will collapse as the fluid is drained. Using the friction wheel, lower the crossbar to the base of the tote during the draining.

4. Once drainage is complete, close the clamp on the dispensing line.

5. Disconnect the dispensing line in accordance with the requirements of the connection device and your own site aseptic procedures.

4.5.2   From the top (1000 L only)

Draining from the biocontainer is usually performed via the bottom port. Fluid can be drained via the top ports if required. When emptying from the top, however, sufficient tubing length on the top ports must be allowed to compensate for the collapse of the biocontainer during emptying.

4.6   Removing Allegro 3D biocontainer from the Allegro tote

1. Drain the Allegro 3D biocontainer fully as noted above.

2. Close all clamps and disconnect the system completely.

3. Disconnect the crossbar from the biocontainer.

4. Open the locking port support plate and then slide the collapsed biocontainer directly towards you.

5. Remove the Allegro biocontainer/system.

5.   Allegro Biocontainer Replacement

Allegro 3D biocontainers/systems are designed for single-use and should be replaced in line with the cGMP requirements of the process. Discard the Allegro 3D biocontainer/system in accordance with local Health and Safety and Environmental procedures.

6.   Troubleshooting Guide

Problem: Allegro biocontainer is not filling/draining.

Cause: Fluid supply may be restricted or closed. Tubing may be crimped or twisted.

Solution: Check fluid supply. Confirm that all clamps on the appropriate line are open and that the tubing is not pinched or twisted. Ensure all connections on the appropriate line are fully activated.

Problem: The biocontainer does not open correctly during fill.

Cause: The biocontainer swivel door is not secure.

Solution: Ensure the swivel door is in position and secure. Check that the corners of the biocontainer are aligned with each of the corners of the tote. Ensure the side panels are folded over the top face of the biocontainer when installed. A 20 – 25 mm gap between the biocontainer and the edge of the tote is acceptable.

Problem: Excessive creasing and folds are observed during filling of the biocontainer and excessive pressure observed on the friction wheel.

Cause: The selected biocontainer may have been installed backwards with the label not above the center port.

Solution: The biocontainer will have to be drained and repositioned.

7. Scientific and Laboratory Services

Pall operates a technical service to assist in the application of all of its products. This service is readily available to you and we welcome your questions so that we can help. In addition, a full network of technical representatives is available throughout the world.

8. Warranty

Pall warrants that the Allegro systems manufactured by Pall, when properly stored and installed, and operated as per the specifications and design conditions stated in this document will be free from defects in material and workmanship during their shelf life.

Pall liability under any warranty is limited solely to replacing, or issuing credit for the Allegro systems that may become defective during the Warranty Period.

Appendix 1

Allegro biocontainer single-use standard systems

650-203T	1000 L cubic biocontainer for 3000 L tote, ½ in. ports (APST)
650-204A	1000 L cubic biocontainer for 3000 L tote, ½ in. ports (Advantaflex)
650-203U	2000 L cubic biocontainer for 3000 L tote, 1½ in. ports (APST)
650-203V	3000 L cubic biocontainer for 3000 L tote, 1½ in. ports (APST)

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