



Life Sciences

## Instructions For Use

USD 2868

# Allegro™ 3D Retrofit Biocontainers – 100, 200 and 500 L



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## 1. Introduction

The following procedures are provided for the installation of Pall single-use systems incorporating Allegro 3D retrofit biocontainers with capacities of 100, 200 and 500 L into suitable volume totes manufactured by suppliers other than Pall.

In addition to use in non-Pall manufactured totes, Allegro 3D retrofit biocontainers can also be used with the Pall range of Allegro plastic totes. They must not be used in association with Allegro stainless steel totes, which should be used with standard Allegro 3D biocontainers.

The instructions contained in the product documentation should be read thoroughly because they contain valuable information gained by extensive experience. It is very important that all instructions 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. Warning

Operation outside the specifications 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. Please refer to Pall for exact limits.



*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 retrofit biocontainers are usually provided as part of an Allegro system that has been sterilized by gamma irradiation.

1. Store the Allegro 3D retrofit biocontainer system in clean, dry conditions between 0 and 30 °C without exposure to radiation sources such as direct sunlight and, wherever practical, in the external packaging as delivered.
2. Do not remove from external packaging until just before use.
3. Check that the internal (usually double bag) packaging is undamaged prior to use.



*Caution: Avoid the use of sharp blades or pointed instruments that could damage the Allegro 3D retrofit biocontainers and other system components. Do not open the bag by forcing any of the system components through the sealed end because this can generate particulate contaminants and may damage or dislodge components.*

4. Ensure that the Allegro 3D retrofit biocontainer selected is suitable for the application.
5. In addition to the part number, each Allegro 3D retrofit biocontainer is identified by a unique identification batch number.

## 4. Preparation and Operation of the Tote with Allegro 3D Retrofit Biocontainer Systems

### 4.1 Prepare the Tote for Use

1. Follow the user instructions supplied by the tote manufacturer.
2. Ensure that the tote surfaces contacting the Allegro 3D retrofit biocontainer are clean, free of protruding objects and are dry.

### 4.2 Installation of Allegro 3D Retrofit Biocontainer/Systems

1. Confirm that the selected Allegro 3D retrofit system is suited for the tote.
2. Inspect the Allegro system packaging. Verify that it is free from visible damage that might compromise the integrity or sterility of the system.
3. Remove the system from its packaging by peeling open the protective bags as indicated on the package. Carefully remove by hand any ancillary packaging materials such as bubble wrap that might be present to protect system components. Do not unfold the biocontainer.
4. Hold the Allegro 3D retrofit biocontainer with the base port facing down and closest to you and the top multi-port system uppermost. Keep the side panels on the uppermost face of the Allegro 3D retrofit biocontainer.
5. Place the Allegro 3D retrofit biocontainer into the base of the tote from above or through doors or port if provided, and in accordance with general procedures provided by the tote manufacturer.



*NOTE: The side panels of the 100 and 200-liter biocontainer will be positioned at the front and rear of the tote when empty. The side panels of the 500 liter Allegro 3D retrofit biocontainer will be positioned at the left and right side of the tote when empty.*

6. Align the base port properly with the hole in the tote. Pass any tubing or system components attached to the bottom port through the hole in the tote and gently pull tubing while guiding the base port to the locating hole. Ensure that no tension is exerted on tube connections to the biocontainer ports, or any other tube connections to system components. Close locating/fixing device to secure port into the tote.
7. Align the corners of the Allegro 3D retrofit biocontainer with the corners of the tote. Avoid unfolding the biocontainer.
8. Position the tubing and hardware connected to the top ports in the center of the flattened bag, so the tubing and hardware do not snag or catch during filling.
9. Close all clamps on outlet lines.
10. Check that inlet lines are open.

### 4.3 Filling Allegro 3D Retrofit Biocontainers

Pall recommends using peristaltic pumps for the filling and emptying of the biocontainer.

1. Check that the outlet lines are closed.
2. Open the filling line(s).
3. Commence filling. The Allegro 3D retrofit biocontainer is self-aligning and will require no manipulation during filling.
4. Fill the Allegro 3D retrofit biocontainer to the desired level.



*Warning: Do not overfill the biocontainer above its maximum volume specification.*

Allegro 3D retrofit biocontainers can be filled from either the top or bottom ports. The biocontainer will naturally move during filling. No manipulation of the biocontainer is needed during filling. When filling through the top ports, position the tubing in the center of the biocontainer, so it does not become snagged or pulled during the filling operation.

5. Upon completion of filling, close the filling line. Disconnect the filling line in accordance with the requirements of the connection device and your own site aseptic procedures.

### 4.4 Dispensing from Allegro 3D Retrofit Biocontainers

#### 4.4.1 From the Bottom

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 dispensing line.
3. Commence the dispensing operation. The bag will collapse as the fluid is drained.
4. Position any additional tubing to prevent it from snagging or being pulled during dispensing operations.

The Allegro 3D retrofit biocontainer design maximizes fluid recovery, which can be further improved in totes with flat (non-sloped) bottoms by carefully lifting the biocontainer in the last few minutes of the dispensing stage. If manipulating the biocontainer, ensure that no strain is put on the bottom port.

5. Once drainage is complete, close the clamp on the dispensing line.
6. Disconnect the dispensing line in accordance with the requirements of the connection device and your own site aseptic procedures.

#### 4.4.2 From the Top

Dispensing from the biocontainer is usually performed via the bottom port.

Fluid can be dispensed 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. When dispensing from the top, the biocontainer must have been filled without allowing any air into the biocontainer so that the selected top outlet port remains in direct contact with the liquid at all times.

### 4.5 Removing Allegro 3D Retrofit Biocontainers from the Tote

1. Drain the Allegro 3D retrofit biocontainer fully.
2. Close all clamps and disconnect the system completely.
3. Disengage the bottom port according to the general instructions of the tote manufacturer.
4. Lift up the collapsed Allegro 3D retrofit biocontainer and remove from the tote.

## 5. Allegro 3D Retrofit Biocontainer Replacement

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

## 6. Troubleshooting Guide

Problem: 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: Biocontainer does not unfold to the walls of the tote.

Cause: (1) Biocontainer has not been installed in the correct orientation – side panels on 100 and 200 L biocontainers must be at the front and back of the tote. On 500 L biocontainers they should be at the sides.

(2) The biocontainer was unfolded during installation. Allegro biocontainers are designed to be self-aligning during filling and should not be unfolded, nor need any manipulation during filling.

Problem: Excessive creasing and folds are observed during filling of biocontainer.

Cause: The selected biocontainer is too large for the tote being used.

Solution: Ensure the correct biocontainer is used in the chosen tote.

Problem: The biocontainer does not form to the sides of the biocontainer.

Cause: The selected biocontainer is too small for the tote being used.

Solution: Ensure the correct biocontainer is used in the chosen tote.

## 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 Allegro systems manufactured by Pall, when properly stored and installed, and operated within recommended ratings, specifications and design conditions, 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.





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