PALL Life Sciences

USD 2519a

# Pall Allegro™ 3D Biocontainers and Totes

## For Integration into State-of-the-Art Single-use Systems


*Filtration. Separation. Solution.SM*

# State-of-the-Art Allegro Single-use Systems

## Description

Pall Allegro 3D biocontainers have been specially designed for large scale applications where 3D systems need to be both reliable and flexible, while providing great ease of use during their installation in the appropriate tote.

They are made from high quality film that meets the critical performance requirements expected for biotechnology and pharmaceutical manufacturing. As an extension to the Allegro 2D biocontainers product line, the Allegro 3D biocontainers incorporate state-of-the-art design features that not only improve the design and robustness of single-use systems, but bring considerable advantages in terms of ease of use and product recovery when dealing with large fluid volumes. The materials of construction for all of the Allegro biocontainer product range are kept the same, thus allowing for very easy scale-up as qualification is significantly reduced.

## Allegro 3D Systems Applications

- Cell culture media preparation and storage
- Buffer preparation and storage
- Product and cell harvesting
- Intermediate product storage
- Bulk product storage prior to filling

## Film Properties and Benefits

- Coextruded film, comprising inert polyethylene in the inner and outer layers and an EVOH[1] gas barrier interlayer
- Inert polyethylene fluid contact layer
- Excellent gas barrier properties
- Superior clarity and flexibility
- Compatible with a wide range of chemicals and pH
- Very low level of leachables
- No animal derived ingredients

### Film Typical Data

| Characteristics | Methods | Typical Values |
|---|---|---|
| Thickness | | 325 µm |
| Haze | ASTM D-1003 | 5 % |
| Water Vapor Transmission Rate | ASTM F-1249 | 0.32 g/m².day |
| Oxygen Permeability | ASTM D-3985 (23 °C, 0 % RH) | < 0.05 cm³/m².day.bar |
| Carbon Dioxide Permeability | Mocon Permatran C-IV (23 °C, 0% RH) | < 0.2 cm³/m².day.bar |

[1] *Ethylene Vinyl Alcohol*

# Unique Design for Ease of Use

Allegro 3D biocontainers are currently available in 100 L, 200 L, 500 L, 1000 L and 1500 L sizes. A sampling port is available for all options. All biocontainers have two inlet top ports for inclusion of sensors, allowing process monitoring or for use as an additional inlet port.


## Superior Design of the Allegro 3D Biocontainer

- New design to ensure fast and robust installation
- No operator involvement during biocontainer filling, reducing the risk of mishandling
- No tools or accessories needed during biocontainer filling
- Fill from top or bottom
- Combination of the biocontainer and tote allows for efficient drainage of the product (hold-up volume ≤ 0.5 % for all sizes of biocontainer)
- Choice of inlet and outlet connections: ⅜ in. to 1 in. to accommodate a wide range of flow rates
- Option to insert probes through a ½ in. port
- Ports designed to allow tubing attachments with cable ties or BarbLock® fittings
- Improved labeling for optimum traceability
  - Biocontainer part number and batch number visible on the top of the biocontainer
  - User area to input product batch information

## Allegro Systems Incorporating 3D Biocontainers: Easy and Quick to Install

1. Open and remove the packaging containing the Allegro single-use system
2. Fit the Allegro system in the tote using the unique locating plate
3. Position the bottom tubing conveniently below the tote
4. Position the top tubing and other components at the center of the folded biocontainer
5. Close and lock the doors
6. Configure clamps for filling
7. Start filling

# Integrated Design Features For Optimal Performance

The 100 L, 200 L, 500 L, 1000 L and 1500 L Allegro 3D biocontainers are designed to be installed in purpose-built 200 L, 500 L, 1000 L and 1500 L Allegro totes.
The combination of the Allegro 3D biocontainers and totes will ensure that your 3D systems get the maximum benefits from the improved design.

## Main Benefits of the Allegro Totes and Trolleys

- Alignment and locating mechanism between tote and biocontainer for perfect positioning
- Easy installation of the bottom tubing and other components
- Steady slope to the bottom port to maximize product recovery
- Slots on the left door to ensure full visibility of the fluid level
- Lockable doors to avoid accidental opening
- Bottom tubing and components protected by the trolley during operation
- Brakes of the trolley always in the front position for maximum security
- Passivated to ensure better corrosion resistance

## Characteristics

- 200 L tote can be used with both 100 L and 200 L Allegro 3D biocontainers
- 500 L, 1000L and 1500 L totes accommodate the 500 L, 1000 L and 1500 L Allegro 3D biocontainers respectively
- 200 L totes can be stacked full up to 3 high and 500 L, 1000 L and 1500 L totes can be stacked full up to 2 high to maximize floor space availability
- Adjustable feet to allow for uneven floors
- Trolleys are available on the 200 L and 500 L totes, and casters available on the 1000 L and 1500 L totes to enable easy movement of the totes in the manufacturing environment

# Validated to Ensure Regulatory Compliance

## Quality Standards

- The Allegro biocontainers are 100% leak tested
- The totes, trolley and biocontainers are manufactured under a Quality Management System Certified to ISO 9001
- Biocontainers are manufactured in a controlled environment (Class 10,000)
- The materials of construction of the Allegro biocontainers meet:
  - Biological reactivity *in vivo* for Class VI - 50 °C Plastics
  - ISO 10993 - USP 87
  - USP Physico-chemical testing for plastics
  - European Pharmacopeia (section 3.1.5)
  - Japanese Pharmacopeia (section 61 Part 1)
  - European Directive 85/572/EEC for food contact plastic materials

## An Extensive Validation Program has been Conducted to Include Testing for

- Oxygen permeability
- Carbon dioxide permeability
- Water vapor transmission rate
- Gamma stability and shelf life
- Endotoxin and particulate testing
- Extractables
- Handling of the totes with full biocontainers
- Stacking tests with full biocontainers
- Drainage test

# Allegro 3D Biocontainers Technical Specifications

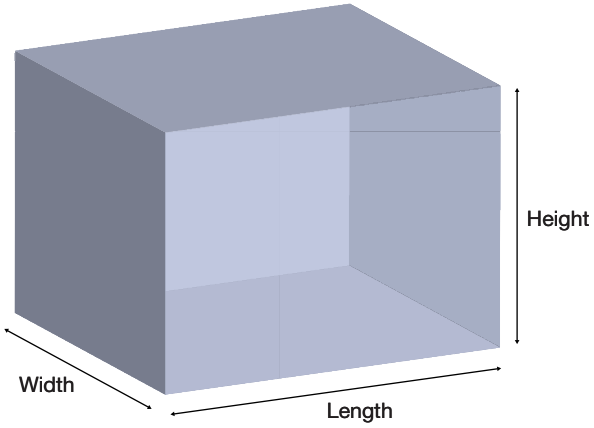
### Allegro 3D Biocontainer Characteristics

| Materials of Construction | | |
|---|---|---|
| Film: | Inner layer | Polyethylene |
| | Gas barrier layer | EVOH |
| | Outer layer | Polyethylene |
| Ports | | Polyethylene |

| Operating Parameters | |
|---|---|
| Temperature | 4 °C to 40 °C |

| Sterilization Method | |
|---|---|
| Gamma irradiation | Max dose : 50 KGy |

### Biocontainer Dimensions




### Nominal Dimensions

| Biocontainer Volume | Length (L) | Maximum Width (W) | Maximum Height (H) | Inlet Port | Outlet Port | Sample Port |
|---|---|---|---|---|---|---|
| 100 L | 725 mm (28.5 in.) | 525 mm (20.7 in.) | 290 mm (11.4 in.) | ⅜, ½, ¾ and 1 in. | ⅜, ½, ¾ and 1 in. | ¼ in. |
| 200 L | 725 mm (28.5 in.) | 525 mm (20.7 in.) | 570 mm (22.4 in.) | ⅜, ½, ¾ and 1 in. | ⅜, ½, ¾ and 1 in. | ¼ in. |
| 500 L | 1056 mm (41.6 in.) | 725 mm (28.5 in.) | 660 mm (26.0 in.) | ⅜, ½, ¾ and 1 in. | ⅜, ½, ¾ and 1 in. | ¼ in. |
| 1000 L | 1290 mm (50.8 in.) | 980 mm (38.6 in.) | 830 mm (32.7 in.) | ⅜, ½, ¾ and 1 in. | ⅜, ½, ¾ and 1 in. | ¼ in. |
| 1500 L | 1465 mm (57.7 in.) | 1110mm (43.7 in.) | 960 mm (37.8 in.) | ⅜, ½, ¾ and 1 in. | ⅜, ½, ¾ and 1 in. | ¼ in. |

## Ordering Information

**Product code**

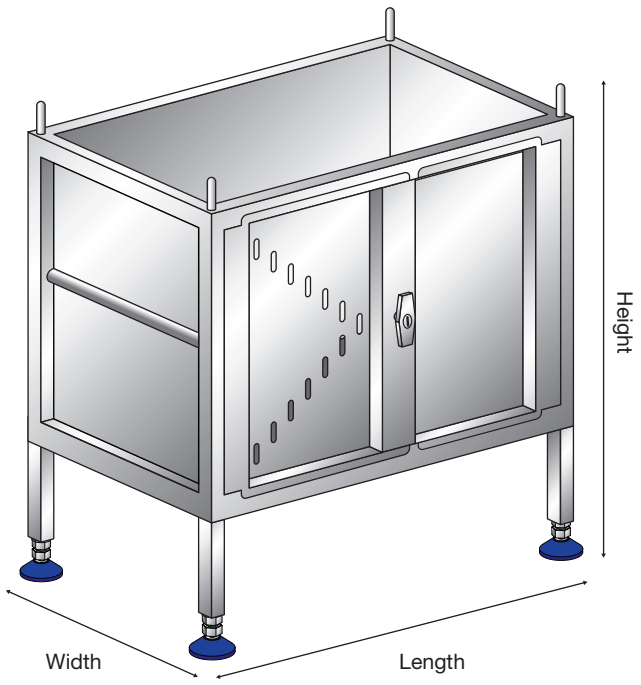
*Allegro biocontainers will not be sold as a stand-alone item, but rather integrated into Allegro single-use systems. In order to choose the right biocontainer for your system, please use the chart provided above and contact your local Pall representative for further assistance.*

# Allegro Totes and Trolleys Technical Specifications

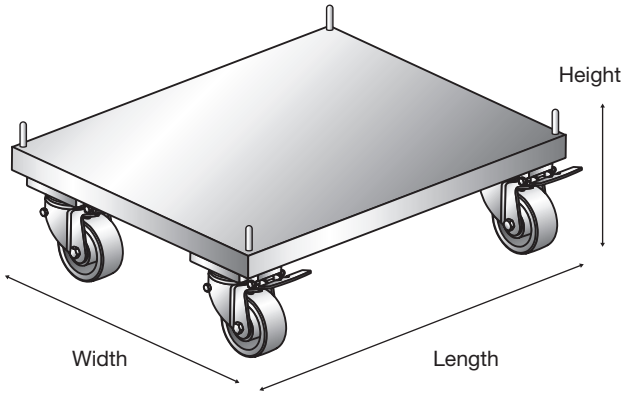
### Materials of Construction

| Item | |
|---|---|
| Totes | 304 stainless steel |
| Trolleys | 304 stainless steel |

### Tote Dimensions




### Trolley Dimensions




### Nominal Dimensions

| Item Description | Length (L) | Width (W) | Height (H) (without feet) | Stack Height: 2 High (min-max)[3] | Stack Height: 3 High (min-max)[3] | Door Clearance | Weight |
|---|---|---|---|---|---|---|---|
| 200 L Trolley | 815 mm (32.0 in.) | 703 mm (27.7 in.) | 285 mm (11.2 in.) | - | - | - | 28 kg |
| 200 L Tote[1] | 865 mm (34.1 in.) | 710 mm (28.0 in.) | 833 mm (32.8 in.)[2] | 1689 mm (66.5 in.)<br>1728 mm (68.0 in.) | 2473 mm (97.4 in.)<br>2518 mm (99.1 in.) | 450 mm (17.7 in.) | 52 kg |
| 500 L Trolley | 1200 mm (47.2 in.) | 845 mm (33.3 in.) | 285 mm (11.2 in.) | - | - | - | 34 kg |
| 500 L Tote | 1250 mm (49.2 in.) | 910 mm (35.8 in.) | 924 mm (36.4 in.)[2] | 1869 mm (73.6 in.)<br>1908 mm (75.1 in.) | Not applicable | 640 mm (25.2 in.) | 86 kg |
| 1000 L Tote | 1435 mm (56.5 in.) | 1181 mm (46.5 in.) | 1204 mm (47.4 in.)[2] | 2443 mm (96.2 in.)<br>2453 mm (96.6 in.) | Not applicable | 730 mm (28.7 in.) | 160 kg |
| 1500 L Tote | 1610 mm (63.4 in.) | 1311 mm (51.6 in.) | 1334 mm (52.5 in.)[2] | 2703 mm (106.4 in.)<br>2713 mm (106.8 in.) | Not applicable | 820 mm (32.3in.) | 200 kg |

*[1] Note: 200 L tote can be used with either 100 L or 200 L Allegro 3D biocontainers. [2] add 74 mm - 104 mm to height when using levelling feet.*
*[3] Totes must not be stacked on casters or trolleys.*

## Ordering Information

### Tote Ordering Information

| Item Description | Pall Part Number |
|---|---|
| 200 L Tote[1] | LGRTTE200L |
| 500 L Tote | LGRTTE500L |
| 1000 L Tote | LGRTTE1000L |
| 1500 L Tote | LGRTTE1500L |

*[1] Note: 200 L tote can be used with either 100 L or 200 L Allegro 3D biocontainers.*

# Accessories

## Accessories Matrix

| Tote Size | Feet | Trolley | Casters | Lid | Trays | |
|---|---|---|---|---|---|---|
| | | | | | Upper | Lower |
| 200 L | S | O | X | O | O | O |
| 500 L | S | O | X | O | O | O |
| 1000 L | S | X | O | O | O | O |
| 1500 L | S | X | O | O | O | O |

*S = Supplied as standard, O = Optional, available to order, X = Not currently available*

## Accessories Part Numbers

| Description | To Fit Tote Size(s) | Pall Part Number |
|---|---|---|
| Trollies | 200 L | LGRTRL200L |
| | 500 L | LGRTRL500L |
| Casters - Set of 4 | 1000 L | LGRCAST1000L |
| | 1500 L | LGRCAST1000L |
| Lids | 200 L | LGRTLD200L |
| | 500 L | LGRTLD500L |
| | 1000 L | LGRTLD1000L |
| | 1500 L | LGRTLD1500L |
| Lower Trays | 200 L | LGRTRAY200L |
| | 500 L | LGRTRAY500L |
| | 1000 L | LGRTRAY1000L |
| | 1500 L | LGRTRAY1500L |
| Upper Trays | 200 L | LGRADAPT200L |
| | 500 L | LGRADAPT200L |
| | 1000 L | LGRADAPT1000L |
| | 1500 L | LGRADAPT1500L |

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.



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