



Allegro™ 3D Biocontainers

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 extreme 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.



Film Properties and Benefits

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

Unique Design for Ease of Use

Allegro 3D biocontainers are currently available in 100 L, 200 L and 500 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 approximately 100 mL for all sizes of biocontainer)
- ▶ Choice of inlet and outlet connections: 3/8 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

Pall Allegro 3D Biocontainers and Totes - Unique Design for Ease of Use

The 100 L, 200 L and 500 L Allegro 3D biocontainers have been designed to be installed in purpose-built 200 L and 500 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 in order to ensure better corrosion resistance

Characteristics

- ▶ 200 L tote can be used with both 100 L and 200 L Allegro 3D biocontainers
- ▶ 500 L tote accommodates the 500 L Allegro 3D biocontainer
- 200 L totes can be stacked full up to 3 high and 500 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 to enable easy movement of the totes in the manufacturing environment

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

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

Further Information

Further information is available at BioPharmaceutical Single Use System Components

Application

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

Specifications

Allegro 3D Biocontainers

Typical Film Data:

Characteristics	Methods	Typical Values
Thickness		325 μm
Haze	ASTM D-1033	5 %
Water Vapor Transmission Rate	ASTM F-1249	0.4 g/m².day
Oxygen Permeability	ASTM D-3985 (23 °C, 0 % RH)	0.1 cm³/m².day.bar
Carbon Dioxide Permeability	Mocon Permatran C-IV (23 °C, 0 % RH)	0.2 cm³/m².day.bar

Materials of Construction

Film: Inner layer	Low Density Polyethylene		
Gas barrier layer	EVOH		
Outer layer	Low Density Polyethylene		
Ports	Polyethylene		

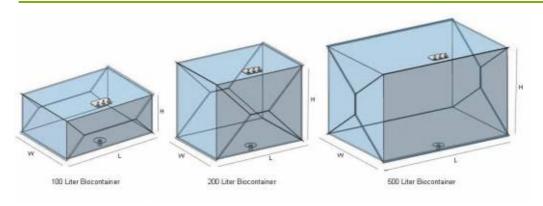
Operating Parameters

Temperature	4 °C to 40 °C	

Sterilization Method

Allegro 3D Biocontainer 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.)	3/8, ½, ¾ and 1 in.	3/8, ½, ¾ and 1 in.	⅓ in.
200 L	725 mm (28.5 in.)	525 mm (20.7 in.)	570 mm (22.4 in.)	3/8, ½, ¾ and 1 in.	3/8, ½, ¾ and 1 in.	¼ in.
500 L	1056 mm (41.6 in.)	725 mm (28.5 in.)	660 mm (26.0 in.)	3/8, ½, ¾ and 1 in.	3/8, ½, ¾ and 1 in.	¼ in.



Allegro Totes and Trolleys

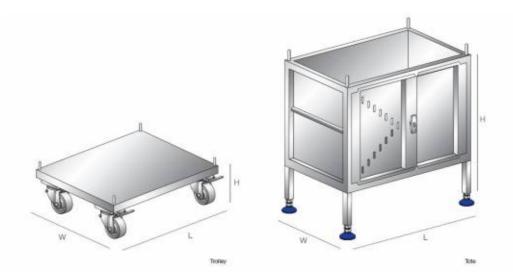
Materials of Construction

Trolleys 304 Stainless steel

Nominal Dimensions

Item Description	Length (L)	Width (W)	Height (H) without feet	Stack Height: 2 High (min-max)	Stack Height: 3 High (min-max)	Door Clearance	Weight
200 L Trolley	815 mm (32.0 in.)	665 mm (26.2 in.)	285 mm (11.2 in.)	-	-	-	28 kg
200 L Tote*	820 mm (32.3 in.)	650 mm (25.6 in.)	910 mm (35.8 in.)**	1689 mm (66.5 in.) 1728 mm (68.0 in.)	2473 mm (97.4 in.) 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	1205 mm (47.4 in.)	850 mm (33.5 in.)	1000 mm (37.2 in.)**	1869 mm (73.6 in.) 1908 mm (75.1 in.)	Not applicable	640 mm (25.2 in.)	86 kg

^{*} Note: 200 L tote can be used with either 100 L or 200 L Allegro 3D biocontainers. ** add 74 mm - 104 mm to height when using levelling feet.



Ordering Information

Allegro Biocontainers

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 in the specifications section and contact your local Pall representative or email Allegro@pall.com for further assistance.

Allegro Totes and Trolleys

Item Description	Pall Part Number
200 L Trolley*	LGRTRL200L
200 L Tote*	LGRTTE200L
500 L Trolley	LGRTRL500L
500 L Tote	LGRTTE500L

^{*} Note: 200 L tote can be used with either 100 L or 200 L Allegro 3D biocontainers

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