

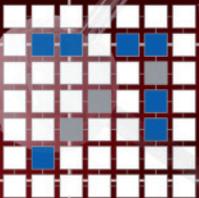


Life Sciences

USD 2471⁽¹⁾

Pall Allegro™ 2D Biocontainers

Integrated into Enhanced Single-use
Systems for Bioprocessing Applications



AllegroSystems
The Single-Use Solution

Filtration. Separation. Solution.SM

Enhanced Single-use 2D Biocontainers Systems for Bioprocessing Applications

Pall Allegro 2D biocontainers have been specially designed for applications where biocontainers must be both reliable and flexible. Single-use systems integrated with biocontainers are a proven and cost efficient alternative to manufacturing equipment containing glass, stainless steel and rigid plastic carboys. These systems are used in a large number of applications in the biopharmaceuticals industry from upstream and downstream processing to formulation and filling.

Pall Allegro 2D biocontainers are made from a high quality film that meets the critical performance and specifications required for biotechnology and pharmaceutical manufacturing. The 2D biocontainers are available from 50 mL up to 50 L and are part of the wider family of Allegro biocontainers. The Allegro 2D biocontainers integrate a number of features to enable the design of state-of-the-art single-use systems such as: sample ports available for all sizes, larger port option for sensor insertion,

high flexibility in tubing size options to meet the requested process flow rates. For applications where larger volumes need to be processed (> 50 L), Allegro 3D biocontainers are available. The materials of construction are identical throughout the whole product range, thus allowing for easy scale-up and qualification.

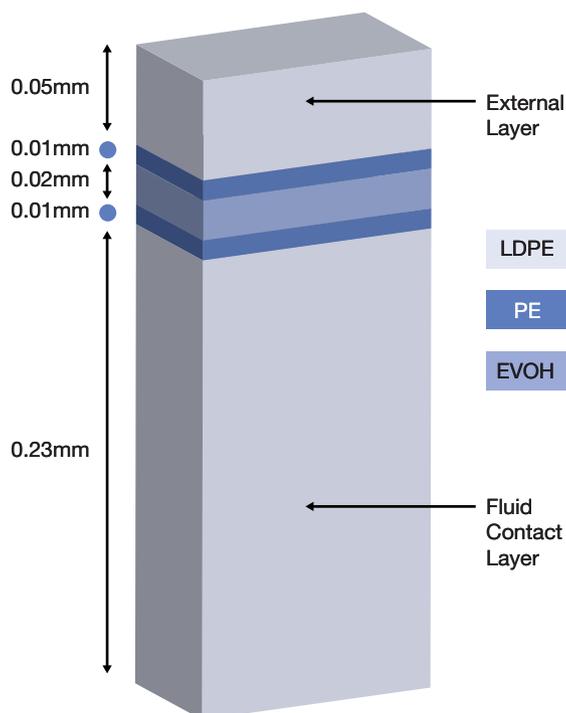
Applications

- ▶ Cell culture media preparation and storage
- ▶ Product harvesting
- ▶ Buffer preparation and storage
- ▶ Chromatography fraction collection
- ▶ Fraction pooling
- ▶ Intermediate product storage
- ▶ Bulk product storage prior to filling
- ▶ Filling Set
- ▶ Sampling



Manufactured with High Quality Film

Schematic Structure of Allegro Film



Allegro biocontainers incorporate state-of-the-art film structure. They are manufactured with a co-extruded film comprising an inert low density polyethylene in the inner and outer layers and a gas barrier film. The result of this very simple structure is a very low level of leachables associated to superior barrier properties. This is an advantage for the processing of oxygen-sensitive products.

Benefits

- ▶ Inert low density polyethylene fluid contact layer
- ▶ High clarity and flexibility
- ▶ Compatible with a wide range of chemicals
- ▶ Very low level of extractables and leachables
- ▶ No animal derived ingredients
- ▶ Excellent barrier properties

Film Typical Data

| Characteristics | Methods | Typical Values |
|-------------------------------|--------------------------------------|--|
| Thickness | | 325 µm |
| Haze | ASTM D-1003 | 5 % |
| Water Vapor Transmission Rate | ASTM F-1249 | 0.4 g/m ² .day |
| Oxygen Permeability | ASTM D-3985 (23 °C, 0 % RH) | 0.1 cm ³ /m ² .day.bar |
| Carbon Dioxide Permeability | Mocon Permatran C-IV (23 °C, 0 % RH) | 0.2 cm ³ /m ² .day.bar |

Compatibility Guideline for PE Based Materials¹

| Chemicals | Compatibility ² |
|---------------------------|----------------------------|
| Water pH 2.5 to 11 | ◆ - ◆◆ |
| Polar Solvents | |
| Alcohols | ◆ - ◆◆ |
| Acetone | ■ |
| Esters | ◆ - ◆◆ |
| Apolar Solvents | |
| Hydrocarbons | ■ - ● |
| Aromatic Fluid Substances | ■ - ● |
| Chlorinated Hydrocarbons | ■ ■ - ● |
| Alkalis | |
| Strong | ◆◆ |
| Weak | ◆◆ |
| Acids | |
| Strong | ◆◆ |
| Weak | ◆◆ |
| Oils | |
| Essential | ■ - ◆◆ |
| Vegetables | ◆◆ |
| Tween 80 | ◆ - ◆◆ |

¹ This information is not intended as a specification, it should only be used as guide for use of Allegro biocontainers. Because many factors can influence compatibility, pre-testing under process conditions is recommended. If any doubts exist about a specific application, please contact our Scientific & Laboratory Services.

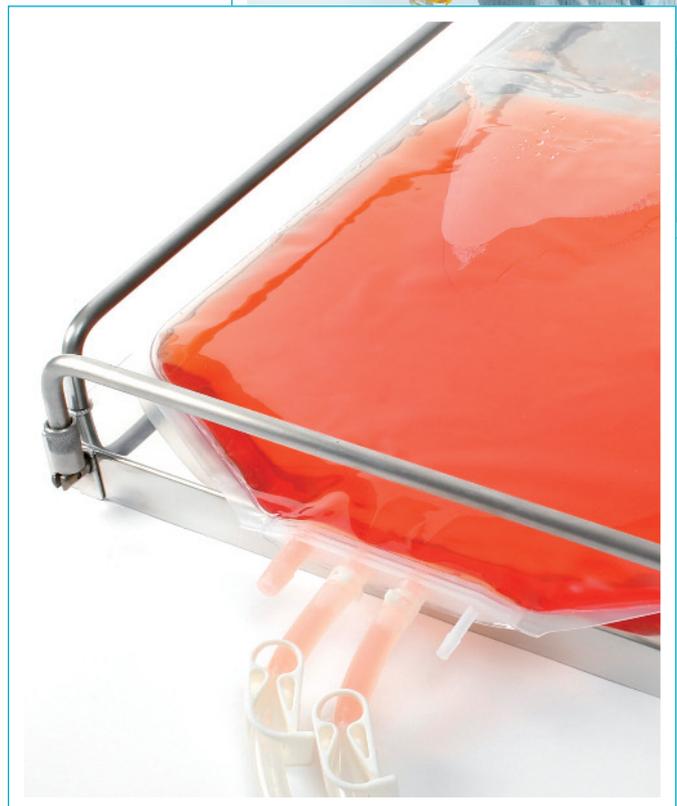
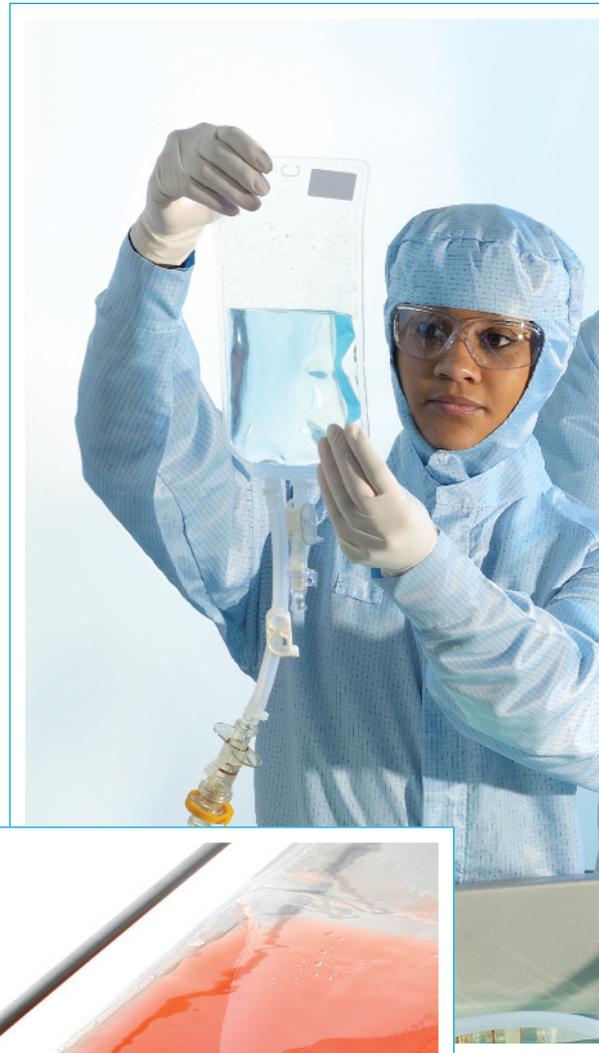
² Code: ◆◆ Excellent, no or negligible interactions expected
 ◆ Good, some interactions may be expected
 ● Interactions may occur
 ■ Interactions will occur
 ■ ■ Strong interactions expected

Superior Design for Integration into State-of-the-art Systems

The Allegro 2D biocontainers have been designed to cope with a wide range of operations from preparation, to storage and transportation of biopharmaceutical solutions. This is why maximum flexibility has been integrated into the design: a sample ports is available for all sizes, and for larger 2D biocontainer (> 5 L), there is the option to use an additional ½ in. port for the inclusion of sensors therefore allowing process monitoring.

Benefits

- ▶ Shape enables very efficient drainage of the fluid
- ▶ Sized to allow to be filled at nominal volume even in case of applications where freezing is required
- ▶ Choice of ¼ in. to ½ in. outlet and inlet connections. Option for ¼ in. port for all sizes
- ▶ Potential to insert probe through a ½ in. port
- ▶ Ports have been designed to allow tubing attachments with cable ties or BarbLock® fittings
- ▶ Improved labelling for optimum traceability
- ▶ Part number and batch number visible on the biocontainers
- ▶ Possibility for the end user to input product batch information
- ▶ Highly transparent biocontainers for easy visual inspection of the solutions



Technical Specifications



Materials of Construction

| | |
|----------------------|--------------|
| Inner Layer | Polyethylene |
| Oxygen Barrier Layer | EVOH |
| Outer Layer | Polyethylene |
| Ports | Polyethylene |

Operating Parameters

| | |
|-------------|-------------------|
| Temperature | - 80 °C* to 60 °C |
|-------------|-------------------|

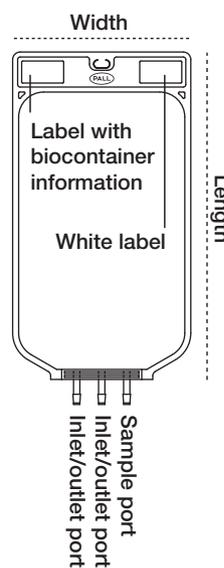
* Contact Pall for details

Sterilization Method

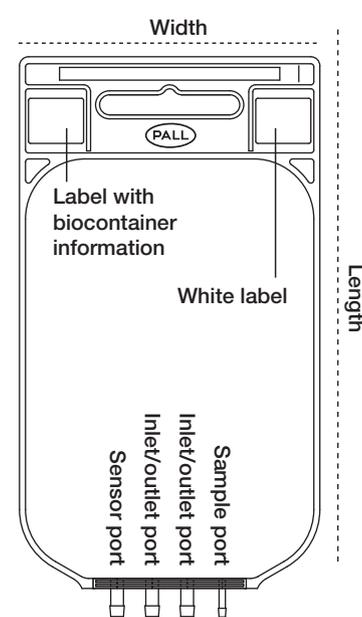
| | |
|-------------------|----------------------|
| Gamma Irradiation | Maximum dose: 50 KGy |
|-------------------|----------------------|

Allegro Biocontainers

≤ 1 L



≥ 5 L



Allegro 2D Biocontainers Nominal Dimensions

Nominal Dimensions

| Biocontainer Volume | Maximum Width | Maximum Length (Without Ports) | Inlet/outlet Ports | Sample Port | Sensor Port |
|---------------------|-------------------|--------------------------------|---------------------|-------------|-------------|
| 50 mL | 110 mm (4.3 in.) | 128 mm (5.04 in.) | ¼ in. | ¼ in. | No |
| 500 mL | 140 mm (5.5 in.) | 259 mm (10.2 in.) | ¼ in. | ¼ in. | No |
| 1 L | 178 mm (7.0 in.) | 327 mm (12.9 in.) | ¼ in. | ¼ in. | No |
| 5 L | 300 mm (11.8 in.) | 531 mm (20.9 in.) | ¼ in., ⅜ in., ½ in. | ¼ in. | ½ in. |
| 10 L | 430 mm (16.9 in.) | 633 mm (24.9 in.) | ¼ in., ⅜ in., ½ in. | ¼ in. | ½ in. |
| 20 L | 497 mm (19.5 in.) | 755 mm (29.7 in.) | ¼ in., ⅜ in., ½ in. | ¼ in. | ½ in. |
| 50 L | 690 mm (27.2 in.) | 926 mm (36.5 in.) | ¼ in., ⅜ in., ½ in. | ¼ in. | ½ in. |

Validated to Latest Regulatory Guidelines

Quality standards

- ▶ The Allegro biocontainers are 100 % leak tested
- ▶ The trolleys, trays and biocontainers are manufactured under a Quality management system certified to ISO 9001
- ▶ Biocontainers are manufactured in a controlled environment (Class 10,000, grade C)
- ▶ The materials of construction of the Allegro biocontainers meet:
 - Biological reactivity in vivo for Class VI - 50°C Plastics
 - USP 87 (cytotoxicity)
 - ISO 10993 (biological compatibility)
 - USP 661 Physicochemical tests for plastics
 - European Pharmacopoeia (Section 3.1.5)
 - Japanese Pharmacopoeia (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
- ▶ Freezing
- ▶ Sterility testing to AAMI/ANSI/ISO 11137
- ▶ Endotoxin and particulate testing
- ▶ Extractables

Speed of implementation and time to market

Pall Allegro systems can be developed and implemented in weeks rather than months. Because of the reduced requirements for validation (including cleaning and sterilization) and the ease of manufacturing, process steps can be developed very quickly.

Single-use technology will help you speed up your process development and installation of manufacturing process line, therefore reducing time to market.



Hardware for State-of-the-Art 2D Single-use Systems

Safe and reliable handling

Pall has designed hardware to ensure safe and reliable handling of our Allegro 2D biocontainers. The hardware has also been designed to provide maximum flexibility to the end user, and is based around a mobile base frame, where additional trays can be added.

Key features

- ▶ Designed to handle 5 L, 10 L, 20 L and 50 L biocontainers
- ▶ Manufactured from 304 Stainless Steel
- ▶ Designed to be handled in a clean-room environment
- ▶ Choice of trays to fit the biocontainer size
- ▶ Trays can be put at a 5° angle to maximize product recovery
- ▶ Options to be used in conjunction with Allegro 3D totes
- ▶ Filters and other components can be supported from the frame with standard laboratory clamps



Hardware Specifications

| Component | Length | Width | Height | Weight |
|-------------------------------|------------|------------|------------|---------|
| Trolley Base | 1092 mm | 821 mm | 628 mm | 30 Kg |
| Section | (43.0 in.) | (32.3 in.) | (24.7 in.) | |
| Trolley Stacking | 1092 mm | 821 mm | 550 mm | 13 Kg |
| Section | (43.0 in.) | (32.3 in.) | (21.6 in.) | |
| 10 and 20 L | 800 mm | 530 mm | 110 mm | 5.7 Kg |
| Tray | (31.5 in.) | (20.1 in.) | (4.3 in.) | |
| 50 L Tray | 1052 mm | 812 mm | 110 mm | 10.4 Kg |
| | (41.4 in.) | (31.2 in.) | (4.3 in.) | |
| Adapter for 200 & 500 L Totes | 826 mm | 541 mm | 183 mm | 3.6 Kg |
| | (32.5 in.) | (21.3 in.) | (7.2 in.) | |

Ordering Information

Description

| | |
|--------------------------------------|--------------|
| Trolley Frame Section | LGRBASE2D |
| Trolley Frame Base Section Mobile | LGRSTACK2D |
| Tray for 10 and 20 L Biocontainers | LGRTRAY020L |
| Tray for 50 L Biocontainers | LGRTRAY050L |
| Adapter Tray for 200 L & 500 L Totes | LGRADAPT020L |

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 contact your local Pall representative.



Life Sciences

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