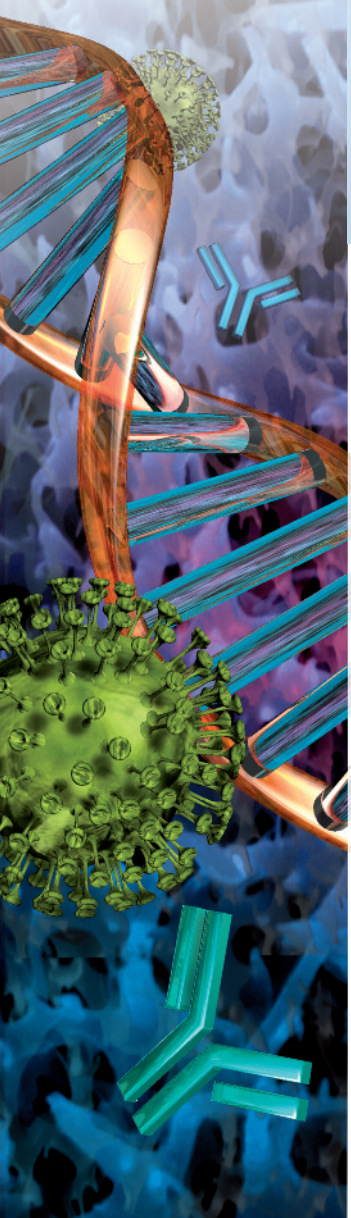
PALL Life Sciences

USD 2707

Allegro™ 2D and 3D Standard Systems



Faster Implementation of Validated Single-Use Systems

The Allegro 2D and 3D systems are state-of-the-art single-use systems designed and built by Pall Life Sciences in order to speed up the current biopharmaceutical production process. These best-in-class systems are available in standard configurations in order to facilitate faster qualification following customer evaluation. In addition, Pall Life Sciences also provides the supporting hardware for these systems in the form of totes and trolleys, which are essential best-fit solutions for transport, storage and handling.

Pall Life Sciences tests and delivers customized Allegro single-use system solutions to our customers to meet specific application requirements. These systems are employed throughout the Active Pharmaceutical Ingredient (API) production process to hold and process bulk product as well as to manage and supply peripheral fluids around unit operations, such as cell culture media, buffer and cleaning solutions. The systems are supplied as a single part number as a fully integrated and validated solution. Stringent quality control procedures are followed throughout the manufacturing and supply process including component selection and qualification, system validation, and manufacturing.

Where appropriate, these systems can be used immediately for holding various solutions during processing. All standard systems are gamma irradiated.

Typical activities these systems can be used for include:

- Long term stability studies/shelf life
- Compatibility studies
- Adsorption studies
- Freezing studies
- Holding process intermediates when no filtration is required
- Leachable studies

The Allegro systems are available with either platinum-cured silicone or C-Flex* tubing depending on the application requirements.

Filtration. Separation. Solution.SM

AllegroSystems
The Single-Use Solution

Quality Standards

- The Allegro systems and associated hardware are manufactured under a Quality Management System certified to ISO 9001
- The Allegro biocontainers are 100% leak tested during manufacture
- Allegro 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

The assembled systems undergo stringent qualification and validation as part of the manufacturing process. Additionally, all assembled systems are inspected for quality.

A summary of available configurations for the standard systems is shown in Table 1.

Figure 1

Standard Allegro 10 L System 619-30Z on an Allegro Tray System LGRTPE20L

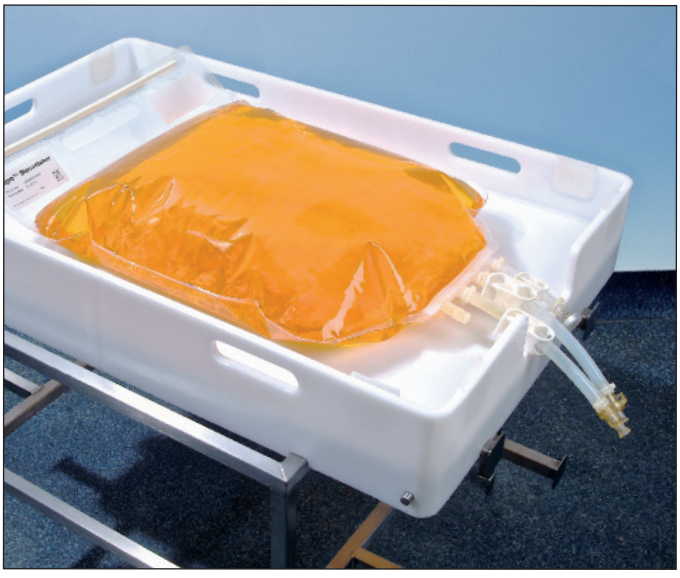


Table 1

Standard Irradiated Allegro System Part Numbers

Part Number	Quantity	Biocontainer Volume	Tubing	System Box Configuration Figure Ref. No.
619-30W	10	50 mL	PCS*	Figure 2
619-30Y	10	500 mL	PCS	Figure 2
619-31A	10	1 L	PCS	Figure 2
619-30X	10	5 L	PCS	Figure 4
619-30Z	10	10 L	PCS	Figure 4
619-31B	10	20 L	PCS	Figure 4
619-31C	10	50 L	PCS	Figure 4
619-31D	3	100 L	PCS	Figure 7
619-31E	3	200 L	PCS	Figure 7
619-31F	3	500 L	PCS	Figure 7
509-1225	10	50 mL	C-Flex	Figure 3
509-1226	10	500 mL	C-Flex	Figure 3
509-1227	10	1 L	C-Flex	Figure 3
509-1228	10	5 L	C-Flex	Figure 5
509-1229	10	10 L	C-Flex	Figure 5
509-1230	10	20 L	C-Flex	Figure 5
509-1231	5	50 L	C-Flex	Figure 5
509-1123	2	100 L	PCS	Figure 6
509-1124	2	200 L	PCS	Figure 6
509-1125	2	500 L	PCS	Figure 6

**PCS: Platinum-cured Silicone*

Figure 2

Allegro 2D Standard Sterile Systems – Platinum-cured Silicone and Septum Sample Port 50, 500 mL and 1 L: 619-30W, 30Y and 31A

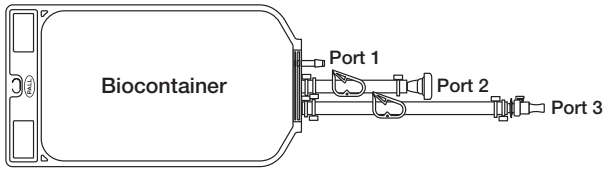


Figure 3

Allegro 2D Standard Sterile Systems – C-Flex Tubing and Needleless Luer Sample Port 50 mL, 500 mL and 1 L: 509-1225, 1226 and 1227

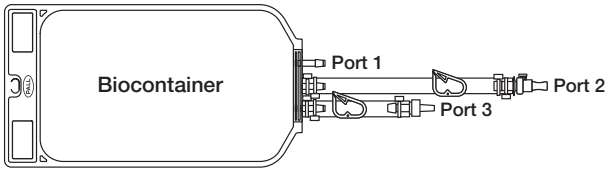


Figure 4

Allegro 2D Standard Sterile Systems – Platinum-cured Silicone and Septum Sample Port 5, 10, 20 & 50 L: 619-30X, 30Z, 31B and 31C

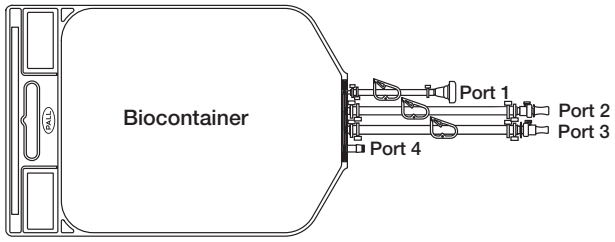
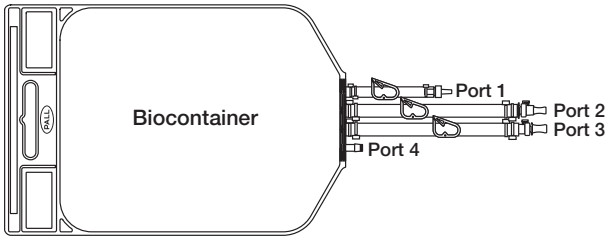


Figure 5

Allegro 2D Standard Sterile Systems – C-Flex Tubing and Needleless Luer Sample Port 5, 10, 20 and 50 L: 509-1228, 1229, 1230 & 1231



NOTE: Not drawn to scale. Actual systems may differ slightly in clamp positioning and tubing lengths.

Figure 6

Allegro 3D Standard Systems – Standard Sterile 100, 200 and 500 L Systems: 509-1123, 1124 and 1125

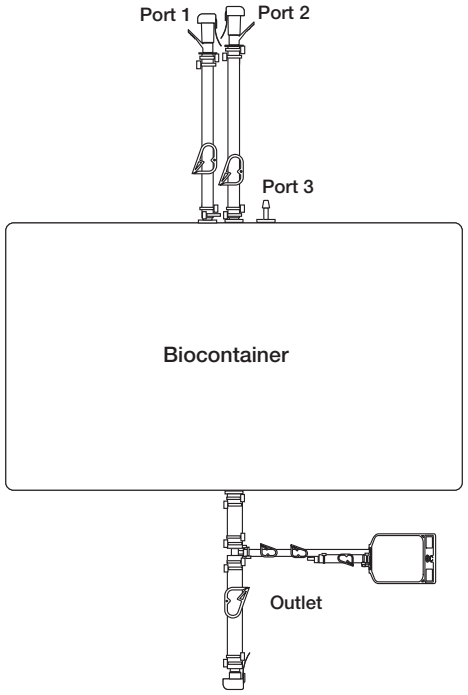
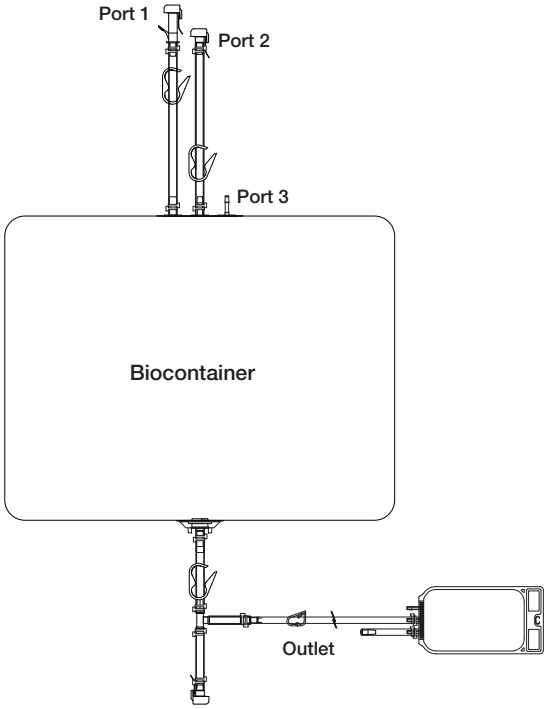


Figure 7

Allegro 3D Standard Systems – Standard Sterile 100, 200 and 500 L Systems: 619-31D, 31E and 31F



Standard Allegro 2D Systems

	50 mL – 1 L	
	Silicone/Septum 619-30W, 30Y & 31A (Figure 2)	**C-Flex/Luer 509-1225, 1226 & 1227 (Figure 3)**
Port 1	Closed	Closed
Port 2	10 cm (3.9 in.) platinum-cured silicone tubing with septum	30.5 cm (12 in.) C-flex tubing with male quick connect and cap
Port 3	20 cm (7.9 in.) platinum-cured silicone tubing with male quick connect and cap	10.2 cm (4 in.) C-flex tubing with needleless luer
	5 L – 50 L	
	Silicone/Septum 619-30X, 30Z, 31B and 31C (Figure 4)	**C-Flex/Luer 509-1228, 1229, 1230 and 1231 (Figure 5)**
Port 1	10 cm (3.9 in.) platinum-cured silicone tubing with septum	15.2 cm (6 in.) C-flex tubing with septumwith needleless luer
Port 2	20 cm (7.9 in.) platinum-cured silicone tubing with female quick connect and plug	30.5 cm (12 in.) C-flex tubing with male quick connect and cap
Port 3	20 cm (7.9 in.) platinum-cured silicone tubing with male quick connect and cap	30.5 cm (12 in.) C-flex tubing with female quick connect and plug
Port 4	Closed	Closed

Standard Sterile Allegro 3D Systems

	Global Designs: 100, 200 and 500 L (Figure 6 and 7)
Port 1	90 cm (3 ft) platinum-cured silicone tubing with male Kleenpak™ sterile connector
Port 2	180 cm (6 ft) C-flex tubing with male Kleenpak sterile connector
Port 3	Closed
Outlet	2 m (6.5 ft) platinum-cured silicone tubing to female Kleenpak sterile connector and t-off to 40 cm (1.3 ft) C-flex to 500 mL sample bag

** The fluid path of the irradiated Allegro 3D biocontainer systems is sterile and has been validated per ISO 11137 and AAMI TIR 33.*

Packaging

509-****

- Each unit placed is double bagged and heat sealed
- Supplied in box quantities as per Table 1
- Gamma irradiated

619-***

- Each unit placed is double bagged and heat sealed
- Supplied in box quantities as per Table 1
- Gamma irradiated

Documentation

The documentation supplied with these systems is as follows:

- System certificate

Ordering Information

To order these standard Allegro systems, please contact your local Pall representative and quote the desired part number (from Table 1). Box quantities are as defined in Table 1.

PALL Life Sciences

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5/11, 3k, GN10.3595 USD 2707