



Biotech

USD3191⁽²⁾

Allegro™ 3D Standard Systems



Faster Implementation of Validated Single-Use Systems

The Allegro 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.

Filtration. Separation. Solution.SM

Typical activities these systems can be used for include:

- ▶ Long term stability studies/shelf life
- ▶ Compatibility studies
- ▶ Holding process intermediates
- ▶ Bulk product hold

The Allegro 3D systems are available with AdvantaPure♦ platinum-cured silicone or AdvantaFlex♦ tubing depending on the application requirements.

Quality Standards

The Allegro 3D systems and associated hardware are manufactured under a Quality Management System certified to ISO 9001. The Allegro biocontainers are 100% leak tested during manufacturing. Allegro biocontainers are manufactured in a controlled environment (Class 10,000, grade C).

The materials of construction of the Allegro biocontainers meet:

- ▶ USP <88> Biological reactivity tests *in vivo* for Class VI - 50°C Plastics
- ▶ USP <87> Biological reactivity tests *in vitro* (cytotoxicity)
- ▶ ISO 10993 (biological compatibility)
- ▶ USP <661>, EP Section 3.1.5 and JP section 61 part 1 (physicochemical tests for plastics)
- ▶ USP <85> and EP Section 2.6.14 (endotoxins)
- ▶ USP <788> (particulates)
- ▶ 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 and system details are shown in Table 1 and Table 2.

Table 1

Standard Allegro 3D systems - ordering information

Part Number	Volume	Tubing	Box Quantity	Figure Number
6500-0374B	50 L	AdvantaPure platinum-cured silicone	3	Figure 2
6500-0374C	50 L	AdvantaFlex biopharmaceutical grade TPE	3	
6500-0374D	100 L	AdvantaPure platinum-cured silicone	3	Figure 3
6500-0373Z	100 L	AdvantaFlex biopharmaceutical grade TPE	3	
6500-0374E	200 L	AdvantaPure platinum-cured silicone	3	
6500-0374F	200 L	AdvantaFlex biopharmaceutical grade TPE	3	
6500-0374G	500 L	AdvantaPure platinum-cured silicone	2	
6500-0374H	500 L	AdvantaFlex biopharmaceutical grade TPE	2	
6500-0374J	1000 L	AdvantaPure platinum-cured silicone	1	Figure 4
6500-0374K	1500 L	AdvantaPure platinum-cured silicone	1	
650-203U	2000 L	AdvantaPure platinum-cured silicone	1	Figure 5
650-203V	3000 L	AdvantaPure platinum-cured silicone	1	

Figure 1

Standard Allegro 3000 L system installed in a 3000 L Allegro stainless steel modular tote



Table 2*Standard Allegro 3D systems - assembly details*

Part Number	Volume (L)	Description	Tube Type	System Details	Figure Number
6500-0374B	50	Standard system 50 L Allegro 3D biocontainer with silicone tubing	Silicone	Drain line: 50 cm tube ID $\frac{3}{8}$ in. with male MPC connector and clamp Inlet 1: 50 cm tube ID $\frac{3}{8}$ in. with male MPC connector and clamp Inlet 2: 50 cm tube ID $\frac{3}{8}$ in. with female MPC connector and clamp Sample lines: 20 cm tube ID $\frac{1}{4}$ in. with needle-free luer sampling	Figure 2
6500-0374C		Standard system 50 L Allegro 3D biocontainer with TPE tubing	TPE		
6500-0374D	100	Standard system 100 L Allegro 3D biocontainer with silicone tubing	Silicone	Drain line: 50 cm tube ID $\frac{1}{2}$ in. with male MPX connector and clamp Inlet 1: 50 cm tube ID $\frac{1}{2}$ in. with male MPX connector and clamp Inlet 2: 50 cm tube ID $\frac{1}{2}$ in. with female MPX connector and clamp Sample line: 20 cm tube ID $\frac{1}{4}$ in. with needle-free luer sampling	Figure 3
6500-0373Z		Standard system 100 L Allegro 3D biocontainer with TPE tubing	TPE		
6500-0374E	200	Standard system 200 L Allegro 3D biocontainer with silicone tubing	Silicone	Drain line: 50 cm tube ID $\frac{1}{2}$ in. with male MPX connector and clamp Inlet 1: 50 cm tube ID $\frac{1}{2}$ in. with male MPX connector and clamp Inlet 2: 50 cm tube ID $\frac{1}{2}$ in. with female MPX connector and clamp Sample line: 20 cm tube ID $\frac{1}{4}$ in. with needle-free luer sampling	
6500-0374F		Standard system 200 L Allegro 3D biocontainer with TPE tubing	TPE		
6500-0374G	500	Standard system 500 L Allegro 3D biocontainer with silicone tubing	Silicone	Drain line: 150 cm tube ID $\frac{1}{2}$ in. with male MPX connector and clamp Inlet 1: 150 cm tube ID $\frac{1}{2}$ in. with male MPX connector and clamp Inlet 2: 150 cm tube ID $\frac{1}{2}$ in. with female MPX connector and clamp Sample line: 20 cm tube ID $\frac{1}{4}$ in. with needle-free luer sampling	
6500-0374H		Standard system 500 L Allegro 3D biocontainer with TPE tubing	TPE		
6500-0374J	1000	Standard system 1000 L Allegro 3D biocontainer with silicone tubing	Silicone	Drain line: 150 cm tube ID $\frac{3}{4}$ in. with $1\frac{1}{2}$ in. sanitary connector and clamp Inlet 1: 150 cm tube ID $\frac{3}{4}$ in. with $1\frac{1}{2}$ in. sanitary connector and clamp Inlet 2: 150 cm tube ID $\frac{3}{4}$ in. with $1\frac{1}{2}$ in. sanitary connector and clamp Sample line: 20 cm tube ID $\frac{1}{4}$ in. with needle-free luer sampling	Figure 4
6500-0374K	1500	Standard system 1500 L Allegro 3D biocontainer with silicone tubing	Silicone		
650-203U	2000	Standard system 2000 L Allegro 3D biocontainer with silicone tubing	Silicone	Drain line: 400 cm tube ID $\frac{3}{4}$ in. with $1\frac{1}{2}$ in. sanitary connector and clamp Inlet 1: 400 cm tube ID $\frac{3}{4}$ in. with $1\frac{1}{2}$ in. sanitary connector and clamp Sample line: 30 cm tube ID $\frac{1}{4}$ in. with needle-free luer sampling	Figure 5
650-203V	3000	Standard system 3000 L Allegro 3D biocontainer with silicone tubing	Silicone		

Figure 2

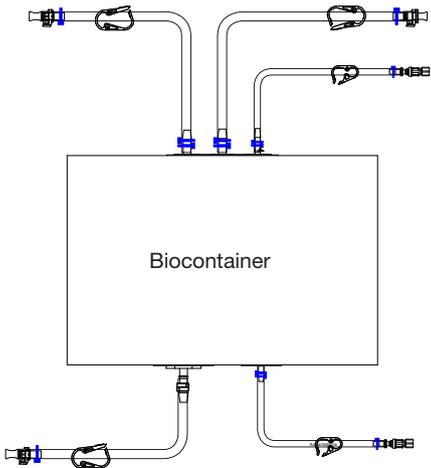


Figure 3

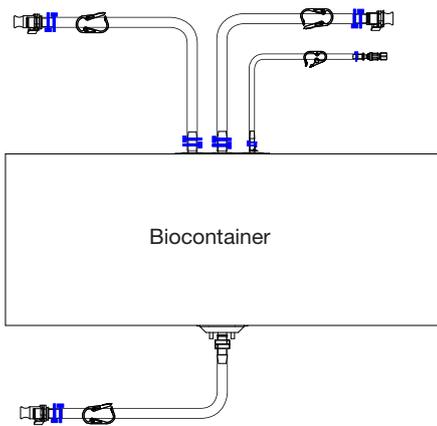


Figure 4

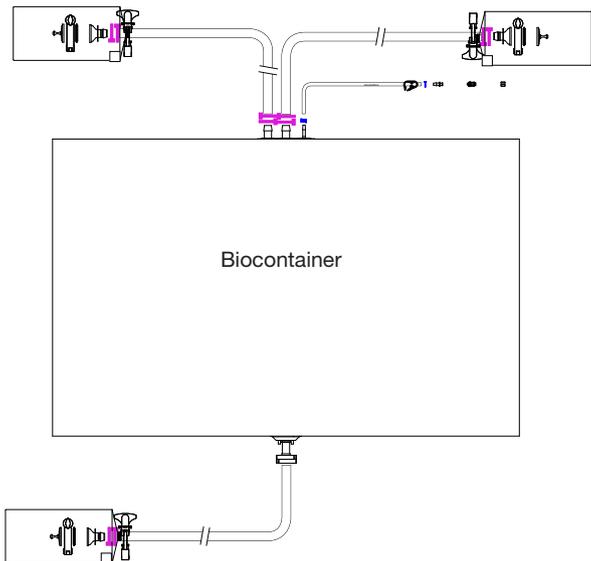
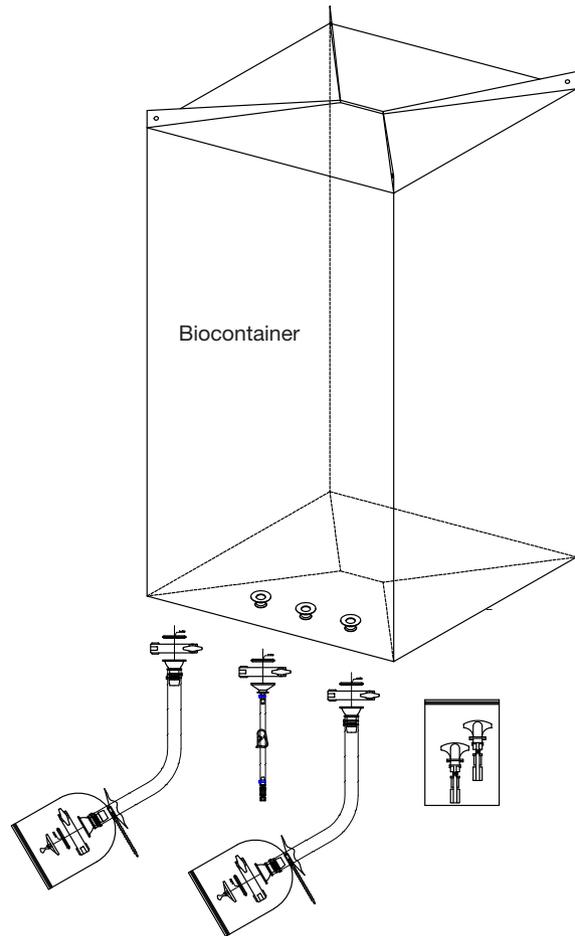


Figure 5



Packaging

650-****

Each unit placed is double bagged and heat sealed
Supplied in box quantities, gamma irradiated

6500-***

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Supplied in box quantities, gamma irradiated

Documentation

The documentation supplied with these systems is as follows:

- ▶ System certificate
- ▶ Irradiation 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.



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