



Allegro™ 2D Standard Systems



Faster Implementation of Validated Single-Use Systems

The Allegro 2D 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 trays used stand alone, or in conjunction with the bioprocess workstation, which are essential best-fit solutions for mobility, 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 product as well as to manage and supply peripheral fluids around unit operations, such as cell culture media, buffer, sampling operations, and cleaning solutions. The systems are supplied as a single standard part number as a fully integrated and validated solution.

Stringent quality control procedures are followed throughout manufacturing and supply process including component selection and qualification, system validation, and manufacturing. Where appropriate, these systems can be used immediately for holding various process 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 2D systems are available with AdvantaPure[◆] platinum-cured silicone or AdvantaFlex[◆] tubing depending on the application requirements.

Quality Standards

The Allegro 2D systems and associated hardware are manufactured under a Quality Management System certified to ISO 9001. The Allegro 2D biocontainers are 100% leak tested during manufacturing. Allegro 2D 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 Plastic
- ▶ 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 2D configurations for the standard systems and detailed design information are shown in Table 1 and Table 2.

Figure 1
Standard Allegro 2D 10 L system on an Allegro tray system LGRTPE20L



Table 1
Standard Allegro 2D systems - ordering information

Part Number	Volume	Tubing	Box Quantity	Figure Number	
650-202B	50 mL	AdvantaPure platinum-cured silicone	20	Figure 2	
650-202C	50 mL	AdvantaFlex biopharmaceutical grade TPE	20		
650-202D	100 mL	AdvantaPure platinum-cured silicone	20		
650-202E	100 mL	AdvantaFlex biopharmaceutical grade TPE	20		
650-202F	250 mL	AdvantaPure platinum-cured silicone	20		
650-202G	250 mL	AdvantaFlex biopharmaceutical grade TPE	20		
650-202H	500 mL	AdvantaPure platinum-cured silicone	20		
650-202J	500 mL	AdvantaFlex biopharmaceutical grade TPE	20		
650-202K	1 L	AdvantaPure platinum-cured silicone	20		
650-202L	1 L	AdvantaFlex biopharmaceutical grade TPE	20		
650-202M	2 L	AdvantaPure platinum-cured silicone	20		
650-202N	2 L	AdvantaFlex biopharmaceutical grade TPE	20		
650-202P	5 L	AdvantaPure platinum-cured silicone	10		Figure 3
650-202Q	5 L	AdvantaFlex biopharmaceutical grade TPE	10		
650-202R	10 L	AdvantaPure platinum-cured silicone	10		
650-202S	10 L	AdvantaFlex biopharmaceutical grade TPE	10		
650-202T	20 L	AdvantaPure platinum-cured silicone	10		
650-202U	20 L	AdvantaFlex biopharmaceutical grade TPE	10		
650-202V	50 L	AdvantaPure platinum-cured silicone	10		
650-202W	50 L	AdvantaFlex biopharmaceutical grade TPE	10		

Table 2

Standard Allegro 2D systems - assembly details

Part Number	Volume	Description	System Details	Figure Number
650-202B	50 mL	Standard system 50 mL Allegro 2D biocontainer	Line 1: 10 cm AdvantaPure internal diameter (ID) 1/4 in. outer diameter (OD) 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaPure ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	Figure 2
650-202C	50 mL	Standard system 50 mL Allegro 2D biocontainer	Line 1: 10 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	
650-202D	100 mL	Standard system 100 mL Allegro 2D biocontainer	Line 1: 10 cm AdvantaPure ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaPure ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	
650-202E	100 mL	Standard system 100 mL Allegro 2D biocontainer	Line 1: 10 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	
650-202F	250 mL	Standard system 250 mL Allegro 2D biocontainer	Line 1: 10 cm AdvantaPure ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaPure ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	
650-202G	250 mL	Standard system 250 mL Allegro 2D biocontainer	Line 1: 10 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	
650-202H	500 mL	Standard system 500 mL Allegro 2D biocontainer	Line 1: 10 cm AdvantaPure ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaPure ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	
650-202J	500 mL	Standard system 500 mL Allegro 2D biocontainer	Line 1: 10 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	
650-202K	1 L	Standard system 1 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaPure ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaPure ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	
650-202L	1 L	Standard system 1 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	
650-202M	2 L	Standard system 2 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaPure ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaPure ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	
650-202N	2 L	Standard system 2 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with pinch clamp, male MPC connector closed with MPC cap Line 3: Sealed-off port	

Part Number	Volume	Description	System Details	Figure Number
650-202P	5 L	Standard system 5 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaPure ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaPure ID 3/8 in. OD 5/8 in. with pinch clamp, female MPC connector closed with MPC plug Line 3: 20 cm AdvantaPure ID 3/8 in. OD 5/8 in. with pinch clamp, male MPC connector closed with MPC cap Line 4: Sealed-off port	Figure 3
650-202Q	5 L	Standard system 5 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaFlex ID 3/8 in. OD 5/8 in. with pinch clamp, female MPC connector closed with MPC plug Line 3: 20 cm AdvantaFlex ID 3/8 in. OD 5/8 in. with pinch clamp, male MPC connector closed with MPC cap Line 4: Sealed-off port	
650-202R	10 L	Standard system 10 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaPure ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaPure ID 3/8 in. OD 5/8 in. with pinch clamp, female MPC connector closed with MPC plug Line 3: 20 cm AdvantaPure ID 3/8 in. OD 5/8 in. with pinch clamp, male MPC connector closed with MPC cap Line 4: Sealed-off port	
650-202S	10 L	Standard system 10 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaFlex ID 3/8 in. OD 5/8 in. with pinch clamp, female MPC connector closed with MPC plug Line 3: 20 cm AdvantaFlex ID 3/8 in. OD 5/8 in. with pinch clamp, male MPC connector closed with MPC cap Line 4: Sealed-off port	
650-202T	20 L	Standard system 20 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaPure ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaPure ID 3/8 in. OD 5/8 in. with pinch clamp, female MPC connector closed with MPC plug Line 3: 20 cm AdvantaPure ID 3/8 in. OD 5/8 in. with pinch clamp, male MPC connector closed with MPC cap Line 4: Sealed-off port	
650-202U	20 L	Standard system 20 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaFlex ID 3/8 in. OD 5/8 in. with pinch clamp, female MPC connector closed with MPC plug Line 3: 20 cm AdvantaFlex ID 3/8 in. OD 5/8 in. with pinch clamp, male MPC connector closed with MPC cap Line 4: Sealed-off port	
650-202V	50 L	Standard system 50 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaPure ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaPure ID 3/8 in. OD 5/8 in. with pinch clamp, female MPC connector closed with MPC plug Line 3: 20 cm AdvantaPure ID 3/8 in. OD 5/8 in. with pinch clamp, male MPC connector closed with MPC cap Line 4: Sealed-off port	
650-202W	50 L	Standard system 50 L Allegro 2D biocontainer	Line 1: 10 cm AdvantaFlex ID 1/4 in. OD 7/16 in. with needle-free luer sampling valve and pinch clamp Line 2: 20 cm AdvantaFlex ID 3/8 in. OD 5/8 in. with pinch clamp, female MPC connector closed with MPC plug Line 3: 20 cm AdvantaFlex ID 3/8 in. OD 5/8 in. with pinch clamp, male MPC connector closed with MPC cap Line 4: Sealed-off port	

Figure 2

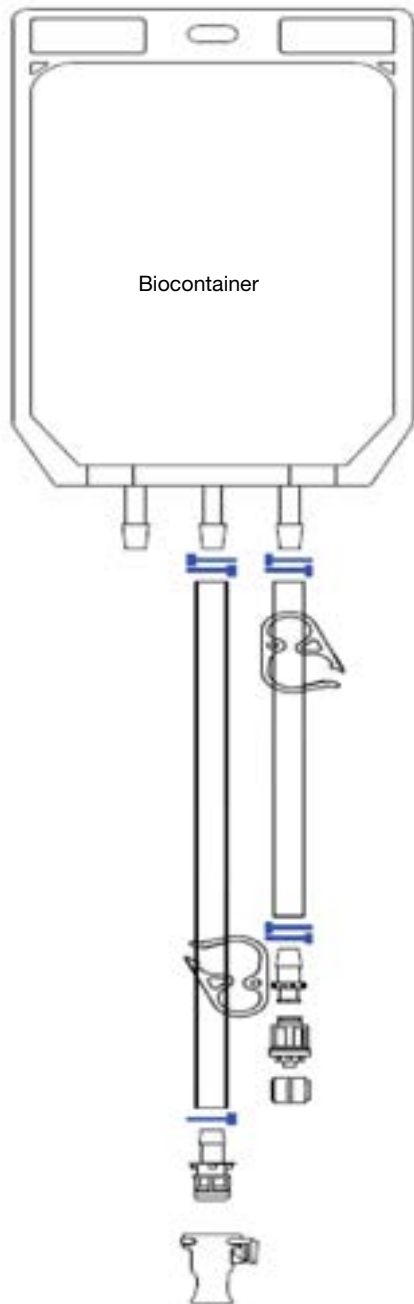
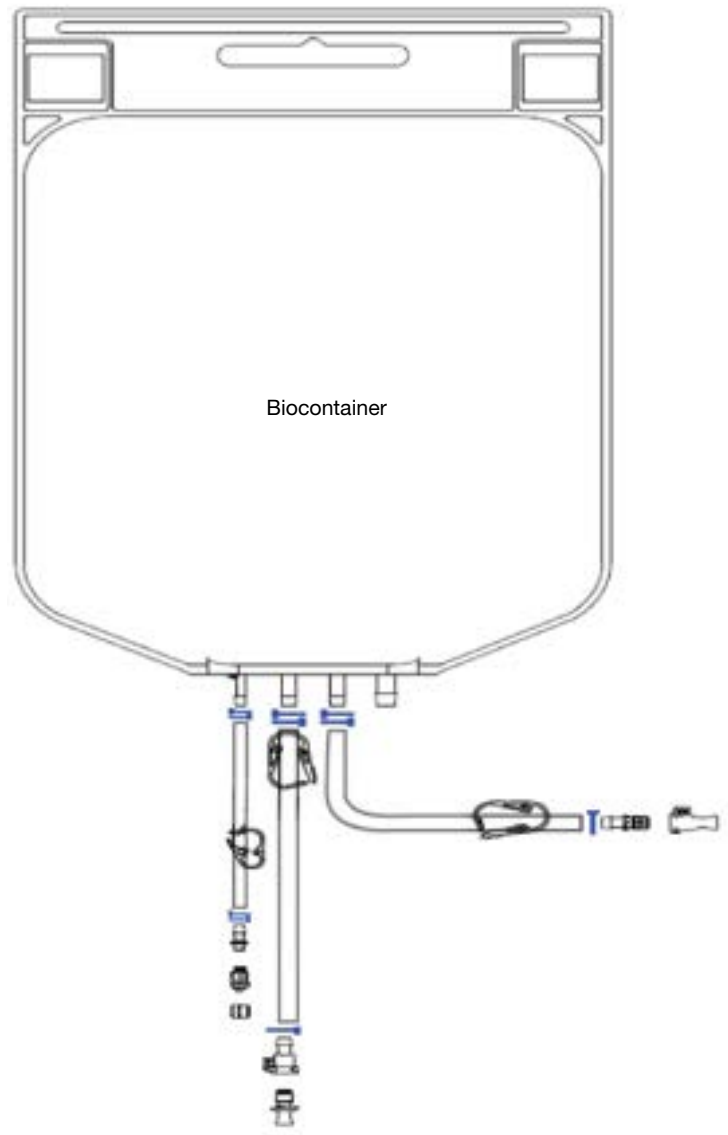


Figure 3



Packaging

650-****

Each unit placed is double bagged and heat sealed
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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