Labtainer Pro BioProcess Container

Providing improved performance, reliability, and higher quality assurance



As technology and innovation advances within the bioproduction industry, single-use technologies have also made considerable progress in the drug and vaccine manufacturing space. Some of the well-established and known advantages of SUT are lowered costs, reduced contamination risks, decreased facility footprint, increased flexibility, and production throughput efficiency with less clean-up, all resulting in quicker turnaround and increased production capabilities. The innovative concept of the new Thermo Scientific[™] Labtainer[™] Pro BioProcess Container (BPC) provides improved flexibility and assurance— without compromise.

Key advantages

Bioproduction requirements differ depending on the applications and processes used within a workflow. Products selected should complement workflow requirements. The Labtainer Pro BPC was developed in response to a variety of bioproduction workflow needs. The 2D style of the Labtainer Pro BPC provides improved ease of use, high reliability, and assured quality in sizes ranging from 50 mL to 20 L.

Applications

- Bioreactor feed and harvest
- Buffer and media storage; intermediate product hold and storage
- Bulk product storage prior to filling
- Chromatography feed
- Fraction collection
- Product sampling and transport

Key benefits

- Consistent contact materials in all BPCs of sizes from 50 mL to 2,000 L
- Film robustness for a reliable and durable product
- Improved handling for better ergonomics
- Optimized drainage
- Wider range of port sizing: 1/8–1/2 in. to eliminate the need for setup and step-down connections, resulting in fewer connections and better, less turbulent flow
- High level of assurance with 100% helium testing, automated manufacturing, and lot-based endotoxin and particulate testing
- No sharps or tools required for packaging removal, eliminating the risk of damage from unpacking tools.
- Reduction in packaging material, creating a more environmentally friendly product



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Product features

Reliability

- Enhanced port design and customization—2-, 3-, and 4-port configurations available without the need for excess ports in the chamber
- Improved sealing method—impulse heat sealing for port insertion utilizing Labtainer Automated Manufacturing (LAM) technology
- 100% helium integrity testing—helps ensure that our best product is delivered to the customer

Quality

- **Upgraded packaging**—easy-peel tape on the shipping box and an easy-open polyethylene (PE) outer bag
- Waste management—cardboard reduction up to 25%
- Improved outer polyethylene bag—manufactured in a controlled environment, resulting in cleaner packaging with less risk of particulates
- Lot-based testing—implementation of lot-based bacterial endotoxin (BET) testing and particulate testing of Labtainer Pro BPC products to USP <788> and USP <85> standards

Easy to use

- Enhanced ergonomics—improved handle features with the addition of a lower handle on the 2, 5, 10, and 20 L BPCs
- **Optimized drainage**—chamber design, port location, and low-profile port design minimizes liquid holdup

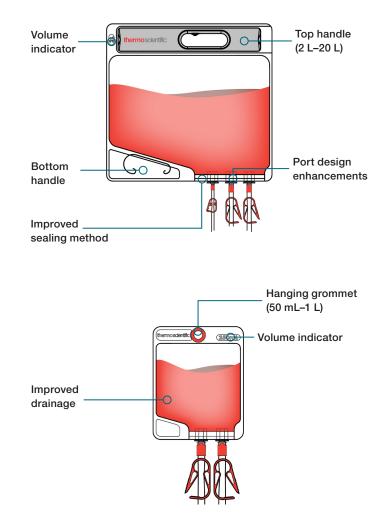


Table 1. Lablamer FTO DFO chamber specifications and options.				
Chamber size	Chamber dimensions (W x L)	Total surface area	Porting range options	Handling options
50 mL	15.0 x 11.7 cm (5.9 x 4.6 in.)	28.6 sq. in.	2-port	Hanging grommet
100mL	15.0 x 14.2 cm (5.9 x 5.6 in.)	40.1 sq. in.	2-port	Hanging grommet
250 mL	15.0 x 18.8 cm (5.9 x 7.4 in.)	59.9 sq. in.	2-port	Hanging grommet
500 mL	18.5 x 23.6 cm (7.3 x 9.3 in.)	102.3 sq. in.	2- or 3-port	Hanging grommet
1,000 mL	18.5 x 30.0 cm (7.3 x 11.8 in.)	136.8 sq. in.	2- or 3-port	Hanging grommet
2 L	34.3 x 32.5 cm (13.5 x 12.8 in.)	232.2 sq. in.	2-, 3-, or 4-port	Upper reinforced hanging handle
5 L	34.3 x 40.9 cm (13.5 x 16.1 in.)	318.7 sq. in.	2-, 3-, or 4-port	Upper reinforced hanging handle
10 L	34.3 x 64.3 cm (13.5 x 25.3 in.)	550.5 sq. in.	2-, 3-, or 4-port	Upper and lower reinforced hanging handles
20 L	45.0 x 69.3 cm (17.7 x 27.3 in.)	777.4 sq. in.	2-, 3-, or 4-port	Upper and lower reinforced hanging handles

Table 1. Labtainer Pro BPC chamber specifications and options.

In-process inspections and testing

In-process inspections and testing take place during the manufacturing process to ensure that each production run of the Labtainer Pro BPC system is being manufactured to the approved specifications.

Table 2. Product testing.

Test	Specification	Frequency
Irradiation dose	25–40 kGy	Each unit
100% visual inspection	Per build specification	Each unit
100% automated manufacturing inspection	Per build specification	Each unit
Endotoxin	USP <85>: Aqueous extracts contain <0.25 EU/mL as determined by the Limulus Amebocyte Lysate Test (LAL)	Lot
Particulate	USP <788> Particulate Matter in Injections— Light Obscuration Particulate Count Test	Lot
Sterility	ANSI/AAMI/ISO 11137 guidelines provide a minimum sterility assurance level (SAL) of 10 ⁻⁶	Routinely
Integrity	Helium integrity testing	Each unit

Table 3. Incoming component inspections.

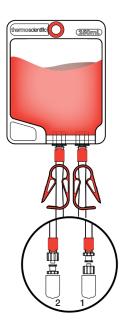
Component	Inspections
Film	Contamination
	Gels and carbons
	Width and gusset dimensions
	• Film thickness
	Tensile strength
	Chemical composition using FT-IR spectrometer
Ports, fittings, tubing,	Appearance and visual inspection
and end treatments	Dimensional analysis

Table 4. In-process inspections and testing.

Component	Inspections
Flexible container	Appearance
chambers	• 2 and port seal strength
	Dimensional analysis
	Leak and burst testing
Finished flexible	Correctness
containers	• Completeness
	Particulate debris
	Defects and damage
	Correct packaging

2 ports

2 ports



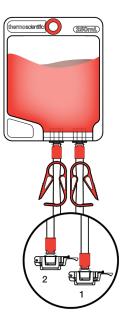
Line 1

Luer lock body with plug Tubing: thermoplastic elastomers (TPE), length: 30.5 cm (12 in.) ID x wall x OD: $0.32 \times 0.16 \times 0.64$ cm (1/8 x 1/16 x 1/4 in.)

Line 2

Luer lock insert with cap Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: $0.32 \times 0.16 \times 0.64$ cm $(1/8 \times 1/16 \times 1/4$ in.)

Size	Cat. No.	
	Aegis5-14	CX5-14
50 mL	17823936	<u>17863906</u>
100 mL	<u>17853936</u>	<u>17803916</u>
250 mL	<u>17873886</u>	<u>17883906</u>



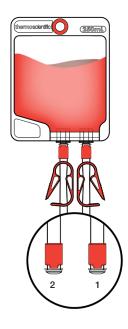
Line 1

CPC^{$^{\circ}$} AseptiQuik^{$^{\circ}$} G Connector Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.64 x 0.24 x 1.12 cm (1/4 x 3/32 x 7/16 in.)

Line 2

AseptiQuik G Connector Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.64 x 0.24 x 1.12 cm (1/4 x 3/32 x 7/16 in.)

Size	Cat. No.	
	Aegis5-14	CX5-14
50 mL	<u>17843936</u>	<u>17813916</u>
100 mL	<u>17883936</u>	17893906
250 mL	<u>17893886</u>	17883876



Line 1

Plug Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.32 x 0.16 x 0.64 cm (1/8 x 1/16 x 1/4 in.)

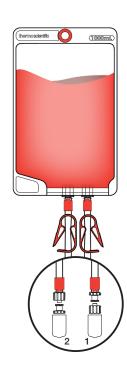
Line 2

Plug Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.32 x 0.16 x 0.64 cm (1/8 x 1/16 x 1/4 in.)

Size	Cat. No.	
	Aegis5-14	
50 mL	17883886	
100 mL	<u>17873936</u>	
250 mL	<u>17873906</u>	

2 ports

2 ports



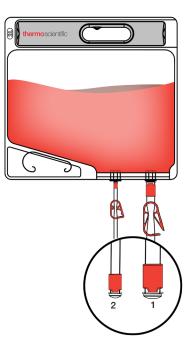
Line 1

Luer lock insert with cap Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.64 x 0.24 x 1.12 cm $(1/4 \times 3/32 \times 7/16 in.)$

Line 2

Luer lock body with plug Tubing: TPE, length: 46 cm (18 in.) ID x wall x OD: 0.64 x 0.24 x 1.12 cm $(1/4 \times 3/32 \times 7/16 \text{ in.})$

Size	Cat. No.	
	Aegis5-14	CX5-14
500 mL	<u>17813896</u>	<u>17843916</u>
1 L	17803896	<u>17833916</u>



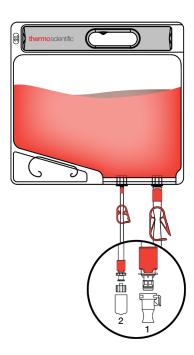
Line 1 Plug

Tubing: TPE, length: 45.7 cm (18 in.) ID x wall x OD: 0.95 x 0.32 x 1.59 cm (3/8 x 1/8 x 5/8 in.)

Line 2

Plug Tubing: TPE, length: 45.7 cm (18 in.) ID x wall x OD: 0.32 x 0.16 x 0.64 cm (1/8 x 1/16 x 1/4 in.)

Size	Cat. No.	
	Aegis5-14	CX5-14
500 mL	<u>17823896</u>	<u>17813886</u>
1 L	<u>17863936</u>	<u>17823916</u>
2 L	<u>17833896</u>	<u>17873956</u>
5 L	<u>17893876</u>	<u>17843886</u>
10 L	<u>17893956</u>	<u>17893916</u>
15 L	<u>17853956</u>	17893896
20 L	<u>17853896</u>	<u>17883916</u>



Line 1 MPC insert Tubing: TPE, length: 15.24 cm (6 in.) ID x wall x OD: 0.95x0.32x1.59cm (3/8 x 1/8 x 5/8 in.)

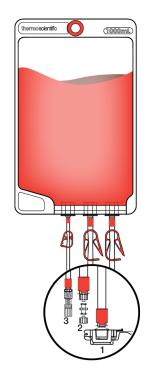
Line 2

Luer lock insert with cap Tubing: TPE, length: 15.24 cm (6 in.) ID x wall x OD: $0.32 \times 0.16 \times 0.64$ cm (1/8 x 1/16 x 1/4 in.)

Size	Cat. No.	
	Aegis5-14	CX5-14
2 L	<u>17893936</u>	<u>17873876</u>
5 L	<u>17823946</u>	<u>17813966</u>
10 L	<u>17833946</u>	17823926
15 L	<u>17813906</u>	
20 L	<u>17873896</u>	<u>17803926</u>

3 ports

3 ports



Line 1

AseptiQuik G Connector Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.64 x 0.24 x 1.12 cm (1/4 x 3/32 x 7/16 in.)

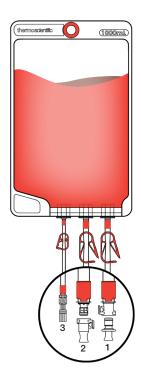
Line 2

Luer lock body and insert Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.64 x 0.24 x 1.12 cm $(1/4 \times 3/32 \times 7/16 in.)$

Line 3

Luer lock body with needleless Luer insert Tubing: TPE, length: 10.2 cm (4 in.) ID x wall x OD: $0.32 \times 0.16 \times 0.64$ cm (1/8 x 1/16 x 1/4 in.)

Size	Cat. No.	
	Aegis5-14	CX5-14
500 mL	<u>17843956</u>	<u>17803886</u>
1 L	<u>17803946</u>	<u>17853916</u>



Line 1

MPC body Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.95 x 0.32 x 1.59 cm (3/8 x 1/8 x 5/8 in.)

Line 2

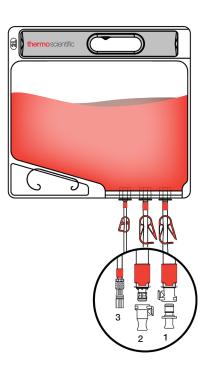
MPC insert

Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.95 x 0.32 x 1.59 cm (3/8 x 1/8 x 5/8 in.)

Line 3

Luer lock body with needleless Luer insert Tubing: TPE, length: 10.2 cm (4 in.) ID x wall x OD: $0.32 \times 0.16 \times 0.64$ cm (1/8 x 1/16 x 1/4 in.)

Size	Cat. No.	
	Aegis5-14	CX5-14
500 mL	<u>17843896</u>	<u>17873916</u>
1 L	<u>17803966</u>	<u>17863916</u>



Line 1

MPC body Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.95 x 0.32 x 1.59 cm (3/8 x 1/8 x 5/8 in.)

Line 2

MPC insert Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.95 x 0.32 x 1.59 cm (3/8 x 1/8 x 5/8 in.)

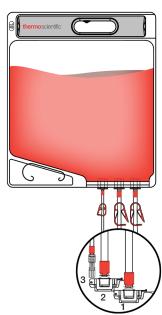
Line 3

Luer lock body with needleless Luer insert Tubing: TPE, length: 10.2 cm (4 in.) ID x wall x OD: $0.32 \times 0.16 \times 0.64$ cm (1/8 x 1/16 x 1/4 in.)

Size	Cat. No.	
	Aegis5-14	CX5-14
2 L	<u>17863896</u>	<u>17833886</u>
5 L	<u>17883896</u>	<u>17813926</u>
10 L	<u>17813946</u>	17883956
15 L	<u>17843906</u>	17843906
20 L	<u>17853946</u>	17853926

3 ports

4 ports



Line 1

AseptiQuik G Connector Tubing: TPE, length: 61 cm (24 in.) ID x wall x OD: 0.95 x 0.32 x 1.59 cm (3/8 x 1/8 x 5/8 in.)

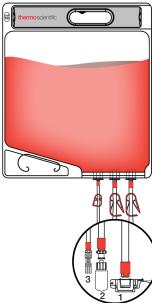
Line 2

AseptiQuik Connector G Tubing: TPE, length: 61 cm (24 in.) IDxwallxOD:0.95x0.32x1.59cm (3/8 x 1/8 x 5/8 in.)

Line 3

Luer lock body with needleless Luer insert Tubing: TPE, length: 10.2 cm (4 in.) ID x wall x OD: $0.32 \times 0.16 \times 0.64$ cm (1/8 x 1/16 x 1/4 in.)

Size	Cat. No.	
	Aegis5-14	CX5-14
2 L	<u>17863946</u>	<u>17823886</u>
5 L	<u>17843946</u>	<u>17863886</u>
10 L	<u>17883946</u>	<u>17843926</u>
15 L	<u>17833906</u>	<u>17823906</u>
20 L	<u>17813956</u>	<u>17813956</u>



Line 1

AseptiQuik G Connector Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.64 x 0.24 x 1.12 cm (1/4 x 3/32 x 7/16 in.)

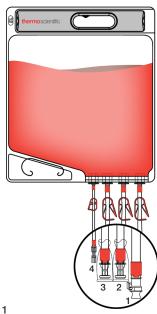
Line 2

Luer lock body with plug Tubing: TPE, length: 30.5 cm (12 in.) ID x wall x OD: 0.64 x 0.24 x 1.12 cm (1/4 x 3/32 x 7/16 in.)

Line 3

Luer lock body with needleless Luer insert Tubing: TPE, length: 10.2 cm (4 in.) ID x wall x OD: $0.32 \times 0.16 \times 0.64$ cm (1/8 x 1/16 x 1/4 in.)

Size	Cat. No.	
	CX5-14	
2 L	<u>17833926</u>	
5 L	<u>17873926</u>	
10 L	<u>17863926</u>	
15 L	<u>17863956</u>	
20 L	<u>17803936</u>	



Line 1 MPX body

Tubing: TPE, length: 61 cm (24 in.) ID x wall x OD: 1.27 x 0.32 x 1.91 cm (1/2 x 1/8 x 3/4 in.)

Line 2

3/4 in. triclamp with gasket, sterilized Tubing: TPE, length: 61 cm (24 in.) ID x wall x OD: $0.95 \times 0.32 \times 1.59$ cm ($3/8 \times 1/8 \times 5/8$ in.)

Line 3

3/4 in. triclamp with gasket, sterilized Tubing: TPE, length: 61 cm (24 in.) ID x wall x OD: $0.95 \times 0.32 \times 1.59$ cm ($3/8 \times 1/8 \times 5/8$ in.)

Line 4

Luer lock body with needleless Luer insert Tubing: TPE, length: 46 cm (18 in.) ID x wall x OD: $0.32 \times 0.16 \times 0.64$ cm (1/8 x 1/16 x 1/4 in.)

Size	Cat. No.	
	Aegis5-14	CX5-14
2 L	<u>17873946</u>	<u>17883926</u>
5 L	17803956	17893926
10 L	17893946	<u>17813936</u>
15 L	17853906	17823956
20 L	<u>17833956</u>	17833936

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