# Labtainer Pro BioProcess Container with BioTitan Retention Device

Next-generation Labtainer BPC providing improved performance, reliability, and higher quality assurance

As technology and innovation advances within the bioproduction industry, single-use technologies (SUTs) have also made considerable progress in the drug and vaccine manufacturing space. Some of the well-established and known advantages of SUTs are lowered cost, reduced contamination risk, decreased facility footprint, increased flexibility, and production throughput efficiency with less clean-up—all resulting in quicker turnaround and increased production capabilities. The innovative design of the 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. The selected 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 20 l
- Now manufactured with the Thermo Scientific<sup>™</sup> BioTitan<sup>™</sup>
  Retention Device—designed to provide superior universal
  retention that minimizes the risk of leakage and failure at
  the connection point
- Robust film for a reliable and durable product
- Improved handling for better ergonomics
- Optimized drainage
- Wide range of port sizes, from 1/8 to 1/2 in., eliminating the need for step-up 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 to remove packaging, thus eliminating the risk of damage from unpacking tools
- Reduction in packaging material, creating a more environmentally friendly product

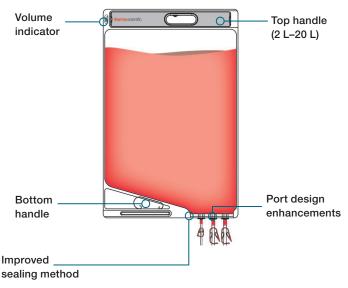
# **Product features**

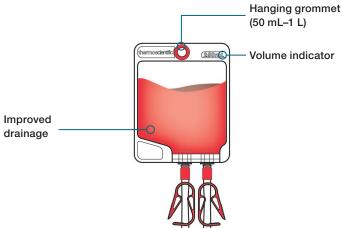
#### Reliability

- Enhanced port design and customization—2-, 3-, and 4-port configurations available without the need for excess ports in the chamber
- Higher performance, lower risk—the BioTitan Retention
   Device is designed to help eliminate the risk of leakage
   and failure at the connection point
- Improved sealing method—impulse heat sealing for port insertion utilizing Labtainer Automated Manufacturing (LAM) technology
- 100% helium integrity testing—helps ensure that our superior 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 performed according to USP <788> and USP <85> standards

#### Ease of 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 minimize liquid holdup

Table 1. Labtainer Pro BPC 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
100 mL	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

# 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 manufactured according to the approved specifications.

Table 2. Product testing.

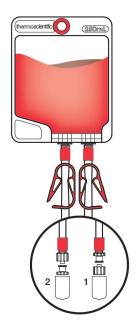
Test	Specification	Frequency
Irradiation dose	25-40 kGy	Each unit
100% visual inspection	Per build specification	Each unit
100% automated manufacturing inspection	Per build specification	Each unit
Endotoxin	USP <85>: aqueous extracts contain <0.25 EU/mL as determined by the limulus amebocyte lysate (LAL) test	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 <sup>-6</sup>	Routinely
Integrity	Helium integrity testing	Each unit

Table 3. Incoming component inspections.

Component	Inspections
Film	Contamination
	<ul> <li>Gels and carbons</li> </ul>
	<ul> <li>Width and gusset dimensions</li> </ul>
	• Film thickness
	Tensile strength
	<ul> <li>Chemical composition using FT-IR spectrometer</li> </ul>
BioTitan Retention	Appearance and visual inspection
Device, ports, fittings, tubing, and end treatments	Dimensional analysis

Table 4. In-process inspections and testing.

Component	Inspections
Flexible container	Appearance
chambers	<ul> <li>Seam and port seal strength</li> </ul>
	<ul> <li>Dimensional analysis</li> </ul>
	<ul> <li>Leak and burst testing</li> </ul>
Finished flexible	Correctness
containers	<ul> <li>Completeness</li> </ul>
	<ul> <li>Particulate debris</li> </ul>
	<ul> <li>Defects and damage</li> </ul>
	Correct packaging



# Line 1

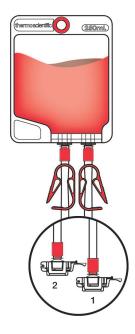
Luer lock body with plug Tubing: C-Flex<sup>TM</sup>, length: 30.5 cm (12 in.) ID x wall x OD:  $0.32 \times 0.16 \times 0.64$  cm ( $1/8 \times 1/16 \times 1/4$  in.)

#### Line 2

Luer lock insert with cap Tubing: C-Flex, 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.	
	Thermo Scientific™ Aegis™ 5-14 film	Thermo Scientific™ CX5-14 film
50 mL	PL30014.11	PL30001.11
100 mL	PL30014.12	PL30001.12
250 mL	PL30014.13	PL30001.13

# 2 ports



#### Line 1

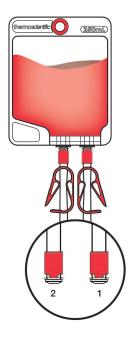
CPC<sup>™</sup> AseptiQuik<sup>™</sup> Connector G Tubing: C-Flex, length: 30.5 cm (12 in.) ID x wall x OD:  $0.64 \times 0.24 \times 1.12$  cm  $(1/4 \times 3/32 \times 7/16$  in.)

#### Line 2

AseptiQuik Connector G
Tubing: C-Flex, 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 film	CX5-14 film	
50 mL	PL30015.11	PL30002.11	
100 mL	PL30015.12	PL30002.12	
250 mL	PL30015.13	PL30002.13	

# 2 ports



#### Line 1

Plug

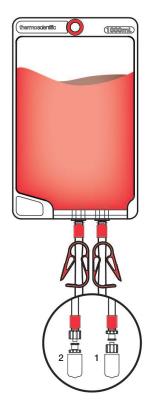
Tubing: C-Flex, length: 30.5 cm (12 in.) ID x wall x OD: 0.32 x 0.16 x 0.64 cm (1/8 x 1/16 x 1/4 in.)

#### Line 2

Plug

Tubing: C-Flex, 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 film	CX5-14 film
50 mL	PL30016.11	PL30003.11
100 mL	PL30016.12	PL30003.12
250 mL	PL30016.13	PL30003.13



# Line 1

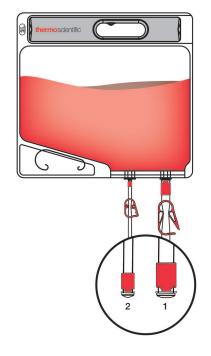
Luer lock insert with cap Tubing: C-Flex, length: 30.5 cm (12 in.) ID x wall x OD:  $0.64 \times 0.24 \times 1.12$  cm  $(1/4 \times 3/32 \times 7/16$  in.)

#### Line 2

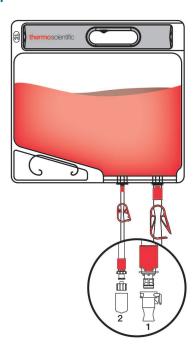
Luer lock body with plug Tubing: C-Flex, length: 30.5 cm (12 in.) ID x wall x OD:  $0.64 \times 0.24 \times 1.12$  cm ( $1/4 \times 3/32 \times 7/16$  in.)

Size	Cat. No.		
	Aegis5-14 film	CX5-14 film	
500 mL	PL30018.11	PL30005.11	
1 L	PL30018.12	PL30005.12	

# 2 ports



# 2 ports



# Line 1

Plug

Tubing: C-Flex, length: 45.7 cm (18 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 2

Plug

Tubing: C-Flex, 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 film	CX5-14 film
500 mL	PL30017.11	PL30004.11
1 L	PL30017.12	PL30004.12
2 L	PL30021.11	PL30008.11
5 L	PL30021.12	PL30008.12
10 L	PL30021.13	PL30008.13
20 L	PL30021.14	PL30008.14

#### Line 1

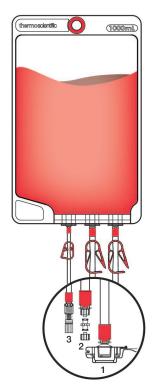
MPC insert

Tubing: C-Flex, length: 45.7 cm (18 in.) ID x wall x OD:  $0.95 \times 0.32 \times 1.59$  cm  $(3/8 \times 1/8 \times 5/8$  in.)

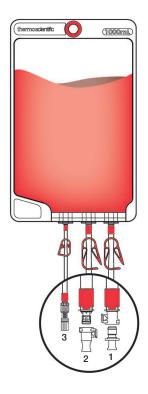
#### Line 2

Luer lock insert with cap
Tubing: C-Flex, 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.)

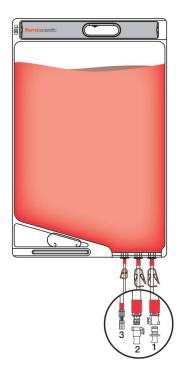
Size	Cat. No.	
	Aegis5-14 film	CX5-14 film
2 L	PL30022.11	PL30009.11
5 L	PL30022.12	PL30009.12
10 L	PL30022.13	PL30009.13
20 L	PL30022.14	PL30009.14



# 3 ports



# 3 ports



#### Line 1

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

#### Line 3

Luer lock body with needleless Luer insert Tubing: C-Flex, 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 film	CX5-14 film	
500 mL	PL30019.11	PL30006.11	
1 L	PL30019.12	PL30006.12	

#### Line 1

MPC body

Tubing: C-Flex, 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

MPC insert

Tubing: C-Flex, 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 3

Luer lock body with needleless Luer insert Tubing: C-Flex, 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 film	CX5-14 film
500 mL	PL30020.11	PL30007.11
1 L	PL30020.12	PL30007.12

#### Line 1

MPC body

Tubing: C-Flex, 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

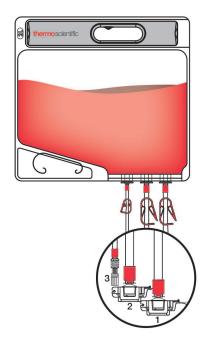
MPC insert

Tubing: C-Flex, length: 30.5 cm (12 in.) ID x wall x OD:  $0.95 \times 0.32 \times 1.59 \text{ cm}$  ( $3/8 \times 1/8 \times 5/8 \text{ in.}$ )

#### Line 3

Luer lock body with needleless Luer insert Tubing: C-Flex, 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 film	CX5-14 film
2 L	PL30023.11	PL30010.11
5 L	PL30023.12	PL30010.12
10 L	PL30023.13	PL30010.13
20 L	PL30023.14	PL30010.14



#### Line 1

AseptiQuik Connector G Tubing: C-Flex, 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

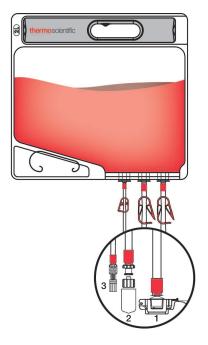
AseptiQuik Connector G Tubing: C-Flex, length: 61 cm (24 in.) ID x wall x OD: 0.95 x 0.32 x 1.59 cm (3/8 x 1/8 x 5/8 in.)

#### Line 3

Luer lock body with needleless Luer insert Tubing: C-Flex, 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 film	CX5-14 film
2 L	PL30024.11	PL30011.11
5 L	PL30024.12	PL30011.12
10 L	PL30024.13	PL30011.13
20 L	PL30024.14	PL30011.14

### 3 ports



#### Line 1

AseptiQuik Connector G
Tubing: C-Flex, 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

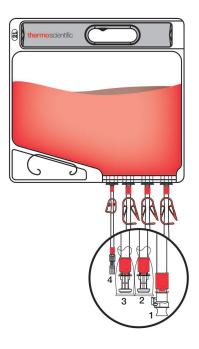
Luer lock body with plug Tubing: C-Flex, length: 30.5 cm (12 in.) ID x wall x OD:  $0.64 \times 0.24 \times 1.12$  cm  $(1/4 \times 3/32 \times 7/16$  in.)

#### Line 3

Luer lock body with needleless Luer insert Tubing: C-Flex, length: 10.2 cm (4 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 film	CX5-14 film
2 L	PL30025.11	PL30012.11
5 L	PL30025.12	PL30012.12
10 L	PL30025.13	PL30012.13
20 L	PL30025.14	PL30012.14

#### 4 ports



#### Line 1

MPX body

Tubing: C-Flex, 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. tri-clamp with gasket, sterilized Tubing: C-Flex, 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 3

3/4 in. tri-clamp with gasket, sterilized Tubing: C-Flex, 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: C-Flex, 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 film	CX5-14 film
2 L	PL30026.11	PL30013.11
5 L	PL30026.12	PL30013.12
10 L	PL30026.13	PL30013.13
20 L	PL30026.14	PL30013.14

# **thermo**scientific

#### **Accessories**

#### Labtainer BPC tote

Storage and handling are simplified with the Labtainer Pro tote. Designed to protect single-use BPCs, the tote can be used in a wide range of applications. The tote is designed with a sloped bottom for improved draining, and for the larger scale, a kickstand is included to aid in draining. There is also a window that allowings access to the tubing while stacked. For light-sensitive applications, the lid can remain on. The tote can be used with both the Labtainer Pro and Labtainer BPCs.

- Compatible with 2D BPCs up to 20 L in volume
- Made of durable high-grade High-density polyethylene (HDPE) material
- Nesting capability for easy storage
- Stackable for better utilization of space
- Provides light protection to BPCs

Table 5. Labtainer BPC tote specifications.

Description	Cat. No.
Small tote with lid (for 2D BPCs 5 L and under)	SV30200.01
Large tote with lid and kickstand (for 10 L and 20 L 2D BPCs)	SV30200.02

