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Thermo Scientific Labtainer Pro BioProcess Container (BPC) Unpacking Guide

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Warnings and safety information

WARNING: Read and understand this guide before unpacking the Labtainer Pro.
Failure to do so could result in personal injury or damage to the product. Always follow your company's approved safety procedures.

Use the following safety equipment while unpacking the Labtainer Pro:

- Gloves
- Lab coat, where appropriate or required

How to use this guide

Scope of this publication

This document covers the unpacking and inspection of the Thermo Scientific™ Labtainer Pro™ BioProcess Container (BPC).

Document change information

A summary of the changes that have been made to this document are listed below.

Revision	Date	Section	Change	Author
A	11/2018	--	Initial release	E. Hale
B	03/2021	--	Minor formating updates	T. Golightly
B	04/2021	1.3.2	Replaced “cable tie” with “BioTitan”	T. Golightly
B	04/2021	2.2.1	Updated Figure 2.1	T. Golightly
B	04/2021	2.2.6	Added a paragraph about the BioTitan	T. Golightly

Related publications

Other publications about the Labtainer Pro BPC are listed below.

Publication name	Doc. number
Thermo Scientific Labtainer Pro BPC Validation Guide	DOC0064
Thermo Scientific Labtainer Pro BPC Data Sheets	Various

Questions about this publication

If you have any questions or concerns about the content of this publication, please contact **technicaldocumentation@thermofisher.com** and your Thermo Fisher Scientific sales team.

1

Unpacking the Labtainer Pro BPC

1.1 Initial setup

Because of the implementation of new easy-peel tape and directional-tear openings on Labtainer Pro packaging, no tools are required for unpacking the outer polybags.

1.1.1 Document review

Review the following documents first in every shipment:

- Packing list
- Certificate of Analysis (COA) **Note:** Non-cGMP product will not include a COA
- Product label

If the shipment is missing a COA, visit the Thermo Fisher Scientific website and search for the part number and lot number. If no product label is found on the outside of the shipping box, standard and non-cGMP product labels are found on the product. If the shipment is missing the packing slip, check with the receiving department or contact your local sales representative to request a copy. If information does not match documentation, or required documents cannot be obtained, contact your local sales representative.

1.1.2 Appropriate workspace conditions

Acceptable carriers and surfaces have smooth edges and rounded corners. Unacceptable carriers and surfaces include carts and wire racks that have sharp edges.

- Ensure all workspaces are free of sharp objects
- Do not drag any part of the product across the floor
- Use acceptable trays, carts, or tables, or hold the product by hand
- Handle product carefully

1.1.3 Storage requirements

Store the Labtainer Pro in its original packaging, under ambient conditions (2–30°C) until ready to use.

If you are storing an unpacked product, avoid crushing, which can cause holes or other damage in the BPC film. Avoid this by stacking the product no higher than the quantity found in the original box. Avoid tearing or puncturing the bag by eliminating the use of sharp objects near the product.

1.2 Unboxing the Labtainer Pro

1.2.1 Acceptable and unacceptable box conditions

See Figures 1.1 and 1.2 for acceptable shipping box conditions. The Labtainer Pro is still usable if the box arrives in these conditions.

Figure 1.1. Worn box corner.

Figure 1.2. Minor perforation on box.

See Figures 1.3 and 1.4 for unacceptable shipping box conditions. If your box arrives in this condition, do not unbox the Labtainer Pro. Contact your sales representative.

Figure 1.3. Crushed box.

Figure 1.4. Puncture mark through the box.

1.2.2 Opening the box

The outer packaging has been developed to prevent damage due to unpacking with sharps or other tools. Position the box with the top side facing up. Then pull the easy-peel tape sealing the top flaps up and away from the box (Figure 1.5). **CAUTION:** Never use sharps to open the Labtainer Pro box. Never open from the bottom of the box or through any part of the cardboard.

Figure 1.5. Removing the easy-peel tape from the box.

1.2.3 Opening the outer polybag

After removing the Labtainer Pro from the box, locate the scored notches at the top of the outer polybag. Gripping the tear strip with one hand and the polybag with the other, pull the strip off the top of the bag (Figure 1.6). Then, remove the Labtainer Pro from the polybag.

Figure 1.6. Opening the outer polybag.

1.3 Inspecting the Labtainer Pro

1.3.1 Inspecting the chamber

Place the Labtainer Pro on a proper workspace surface. Unfold the chamber either all the way open or in segments to inspect for damage or abnormalities. Normal folding marks, light surface wrinkles, and/or light stress marks are acceptable (see Figures 1.7 and 1.8). Carbon or gel particulate on the surface (Figures 1.9) is also acceptable. See section 2.2 of this guide for more information.

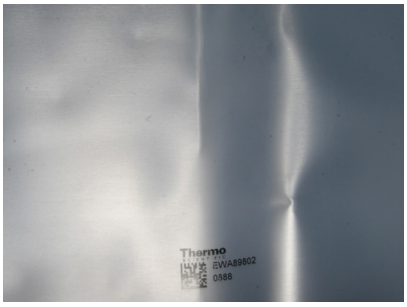

Figure 1.7. Folding marks on BPC chamber.

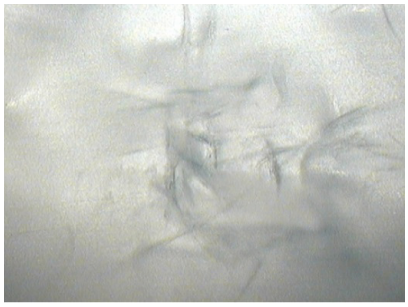

Figure 1.8. Light stress marks on BPC chamber.

Figure 1.9. Carbon or gel particulate on BPC surfaces.

1.3.2 Optional inspections

Inspecting tubing

Inspect the tubing for signs of damage or abnormalities. **Note:** After irradition, a tube may set in a slightly bent or kinked position as a result of the packaging operation. Packaging configurations are in place to reduce bent or kinked tubing. However, various tubing configurations can make bends or kinks difficult to eliminate. Most tubing kinks are cosmetic, and may be opened manually by pinching the wall of the tubing to release the kink without impact to product integrity.

Inspecting connection points and connectors

Inspect the connection points for the presence of a retainer type (such as BioTitan™ or BarbLock™ retainers), and proper fit.

Inspect connectors for missing caps or plugs on the ends. Connector inspection should also include the inspection of asptic, steam-through, and steam-to connectors to ensure that they are in the correct position, and have not been actuated. Connectors should be used in accordance with the manufacturer's current guidelines.

Inspecting filters

Verify the flow direction. **Note:** Vents on filters are fragile—handle with care. Filters should be used in accordance with the manufacturer's current guidelines.

2

BPC standards

2.1 Documentation

2.1.1 Manufacturing drawing

The manufacturing drawing (Figure 2.1) that accompanies a standard product is controlled by Thermo Scientific, and is available by request. The drawing includes:

- Detailed visualization of the product
- Product parts list

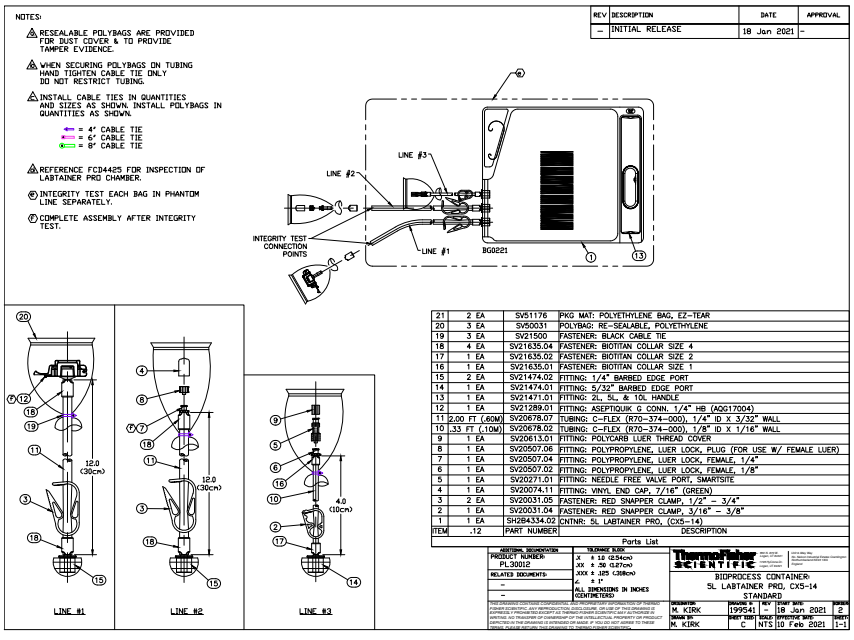

Figure 2.1. Manufacturing drawing for standard product.

The manufacturing drawing accompanying a custom product is controlled by the customer, and is part of the agreement with the customer. They include the same details as drawings for standard products. Customer approval is required for changes made to a manufacturing drawing for a custom product.

2.1.2 Certificates of Analysis

Certificates of Analysis (COAs) differ by product. They may have the following types of information:

- Lot number
- Description
- Expiration date
- Irradiation dosage
- Inspection
- Biological reactivity
- Cytotoxicity
- Physiochemical
- EP testing
- Endotoxin
- Particulate
- Certificate of Irradiation

Certificates of Processing for irradiated products provide the date of processing and dosage information. Filter certificates are available upon request. Non-cGMP products do not have a COA.

To attain the highest level of quality, Thermo Scientific has implemented lot-based bacterial endotoxin (BET) and particulate analysis testing for Labtainer Pro BPCs. The BET test is an *in vitro* assay for detection and quantitation of bacterial endotoxins to the USP 85 standard. Particulate analysis testing includes procedures for removing, counting, and sizing particulate contaminants on or in the BPC to the USP 788 standard.

2.1.3 Product specification (optional)

Product specification is not required for inspection. This may be used to cross-check customer specifications with vendor specifications.

2.2 Packaging standards

2.2.1 Inner packaging

Inner packaging varies by product type and size, and my vary on custom products. These may include the following:

- Protective plastic bags or polybags that cover the ends of each of the linesets on a BPC or tubing assemblies, and also over coils of tubing
- Bubble wrap surrounding filters, connectors, clamps, and BioTitan Retention Devices
- A layer of bubble wrap placed between coils of tubing and the chamber
- At least two outer polybags that cover the entire BPC assembly

2.2.2 Outer packaging

The outer packaging consists of a cardboard box and bubble wrap. The bubble wrap is used to cushion products, and is found on the bottom, between, and on top of the product.

2.2.3 Labeling

The product label (Figure 2.2) is found on each BPC chamber, or on the innermost polybag. It may also be found on the outside of the box. The product label includes the following information:

- Lot number
- Description
- Manufacturing date (custom products)
- Expiration date (standard products)

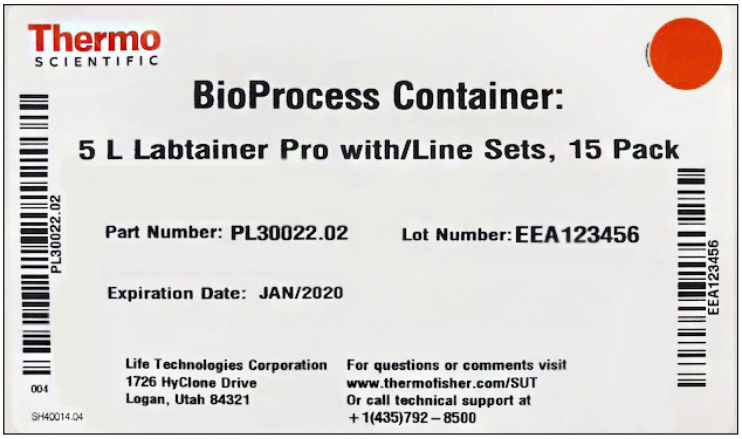

Figure 2.2. Example of product label.

The innermost section of the first polybag surrounding the product contains the following:

- Component labels for filters with our serial number
- Inspection record label, which contains the inspector's initials, the employee reference number, and the unit number
- May include the product label

The outermost polybag may include the user handling instructions for the BPC label. The box labels include:

- Product label
- User handling instructions for the BPC
- Filter labels
- Box inspection label

2.2.4 Film inspection

Each roll of film is inspected for gels/carbons and particulate, based on the criteria listed in Tables 2.1–2.3.

Table 2.1. Particulate product contact (fluid path). No particle density for any size shall exceed 4 per ft^2.

Size	Criteria
< 0.02 mm^2	Not counted
0.02–0.15 mm^2	≤ 3 per ft^2
0.20–2.00 mm^2	≤ 1 per ft^2
> 2.00 mm^2	0

Table 2.2. Particulate non-product contact. No particle density for any size shall exceed 5 per ft^2.

Size	Criteria
< 0.02 mm^2	Not counted
0.02–0.15 mm^2	≤ 5 per ft^2
0.20–2.00 mm^2	≤ 3 per ft^2
2.50–5.00 mm^2	≤ 1 per ft^2
> 5.00 mm^2	0

Table 2.3. Embedded carbons/gels.

Size	Criteria
< 0.60 mm^2	≤ 10 per ft^2
0.60–5.00 mm^2	≤ 3 per ft^2
> 5.00 mm^2	0

Particulate could be either a gel, carbon, or foreign material. Gel and carbon are formed during the resin-to-film conversion process. Carbons that are built up in the equipment can be released and embedded in BPC film. Gels are resin solids that pass through the extruder screens and can be extruded with the BPC film and embedded within the layers.

2.2.5 BPC chamber

All BPC chambers have an identification stamp (Figure 2.3). Found on the identification stamp is the lot number (shown as “EDX265913”), chamber part number (shown as SH2B2690.02), and a serial number (shown as “0001”).

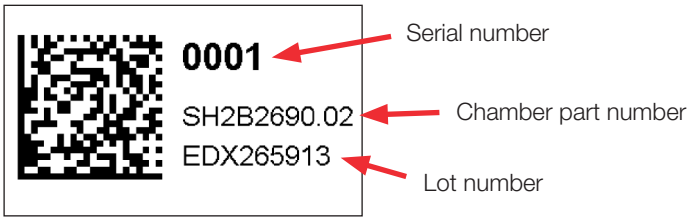

Figure 2.3. Example of an identification stamp.

The chamber inflation test includes the following:

- A representative sample is subject to an inflation test for leaks
- Each chamber is inflated, and then visually inspected for leaks

The chamber burst test includes the following:

- A representative sample is subject to burst testing, which slowly inflates a chamber until a total failure occurs
- This test is carried out to evaluate the risk factor of the fault

2.2.6 BPC components

Ports

Ports are the points where the linesets connect to the chamber. They are sealed into the film during the manufacturing of the chamber. The chamber lot number consists of the ports and the film used to create the chamber. The Labtainer Automated Manufacturing (LAM) system automatically tests components, such as ports. Individual product and lot numbers are digitally recorded during manufacturing, and are available for future quality checks or inquiries.

Tubing

Tubing is a flexible component that allows for the transfer of liquid from one location to another. Tubing materials and sizes vary greatly.

Fittings and connectors

Fittings are the T, Y, and X straight or elbow components that allow a lineset to:

- Change tubing sizes
- Allow for manifolding
- Direct flow path

Connectors are components that allow the lineset to connect to another BPC, tubing assembly, vessel, or other equipment. Various types of connectors exist, including aseptic, steam-through, small volume, and sampling. Depending on BPC design, many connectors can have liquid-tight terminations, such as caps and plugs. In other situations, only dust protection barriers are used in addition to polybags.

BioTitan Retention Device

The BioTitan Retention Device further enhances the overall reliability and integrity of the BioProcess Container (BPC). BioTitan is a universal tubing retention solution that helps eliminate the risk of leaks and failures of the tubing connection point. The device spans tubing ranges from 1/8 in. ID to 1 in. ID.

Filters

Filter flow direction is critical for processes. If the filter is fitted in the wrong direction, it will reduce the performance of the filter, and in some cases, will not provide the required filtration step. The flow direction is indicated on the product drawing or schematic. Filters should be used in accordance with the current manufacturer's guidelines.

3

Product support

3.1 Reporting an issue

If any issues are found during the inspection process, contact your Thermo Scientific product sales representative. You will be asked to describe the nature of the problem, and in some cases, the product will need to be sent to us for further inspection. Thermo Scientific sales and quality teams will reply to all product reports.

When reporting an issue, please include the following information:

- Product code
- Lot number
- Description of the problem
- Customer name
- Order name
- Quantity under complaint
- Color photographs of the product, if possible

3.2 Contact information

For general questions, contact our support team:

techsupport.bioprocessing@thermofisher.com
1 435 792 8500 option 2

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Find out more at **thermofisher.com/sut**

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