



Standard BioProcess Container (BPC) Unpacking and Inspection Guide

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Avertissements et consignes de sécurité



AVERTISSEMENT : veuillez lire et comprendre ce manuel avant de déballer les conteneurs BioProcess (BPC).

Si cette précaution n'est pas respectée, des blessures ou un endommagement du produit peuvent survenir. Respectez toujours les procédures de sécurité approuvées de votre entreprise.

Utilisez les équipements de sécurité suivants lors du déballage des BPC :

- gants ;
- blouse de laboratoire, le cas échéant ou si requis.

How to use this guide

Scope of this publication

This document covers the unpacking and inspection of Thermo Scientific™ BioProcess Containers (BPCs), including both 2D and 3D BPCs, manifolds, and tubing assemblies.

Document change information

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

Revision	Date	Section	Change Made	Author
A	05/2020	--	Initial release—corresponds to DOC0021 Rev. C	C. Jones

Related publications

Other publications about Thermo Scientific BPCs are listed below.

Publication name	Doc. number
Thermo Scientific BPC Validation Guide	DOC0017

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.



Introduction to the BPC

1.1 BPC packaging

1.1.1 Inner packaging

BPC inner packaging varies by product type and size, and may vary on custom products. These may include:

- 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 cable ties
- A layer of bubble wrap placed between coils of tubing and the chamber
- At least two outer polybags that cover the entire BPC assembly

1.1.2 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 inside the box.

1.1.3 Labeling

The product label (Figure 1.1) is found on each BPC chamber, or on the innermost polybag. It may also be found on the outside of the box.



Figure 1.1. Example of a product label.

The product label includes the following information:

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

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

1.2 BPC components

1.2.1 BPC chamber

All BPC chambers have an identification stamp. Found on the identification stamp is the lot number (represented by "ABC12345" in Figure 1.2), and a serial number (represented by "0004" in Figure 1.2).

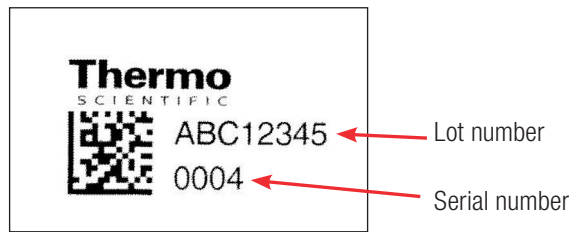


Figure 1.2. Example of an identification stamp.

There are two chamber tests performed on BPCs. 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

1.2.2 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.

1.2.3 Tubing

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

1.2.4 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 a flow path

Connectors allow a 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 circumstances, only dust protection barriers are used in addition to polybags.

1.2.5 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. The flow direction is indicated on the product drawing or schematic. Filters should be used in accordance with the current manufacturer's guidelines.

2

Unpacking the BPC

2.1 Initial setup

Before unpacking the BPC, ensure that a safety cutter or other similar tool is available. No other tools are required for unpacking BPCs.

2.1.1 Document review

Review the following documents first in every shipment:

- Packing list
- Certificate of Analysis (COA) **Note:** non-cGMP products 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 the documentation, or required documents cannot be obtained, contact your local sales representative.

2.1.2 Appropriate workspace conditions

Acceptable carriers and surfaces have smooth edges and rounded corners (Figures 2.1 and 2.2). Unacceptable carriers and surfaces include carts and wire racks that have sharp edges (Figure 2.3).



Figure 2.1. Smooth edges on an acceptable surface.

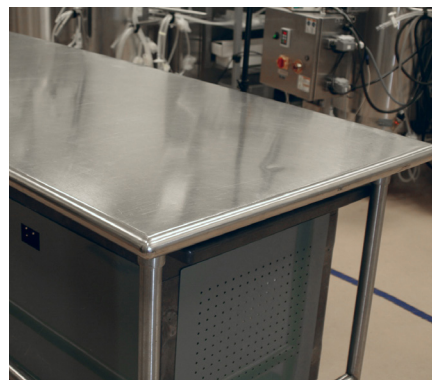


Figure 2.2. Rounded corners on an acceptable surface.



Figure 2.3. Wire rack as an unacceptable surface.

Use the following BPC handling guidelines:

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

2.1.3 Storage requirements

Store the BPC 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.

2.2 Unboxing the BPC

2.2.1 Acceptable and unacceptable box conditions

See Figures 2.4 and 2.5 for acceptable shipping box conditions. The BPC is still usable if the box arrives in these conditions.



Figure 2.4. Worn box corner.



Figure 2.5. Minor perforation on the box.

See Figures 2.6 and 2.7 for unacceptable shipping box conditions. If your box arrives in either of these conditions, do not unbox the BPC. Contact your sales representative.



Figure 2.6. Crushed box.



Figure 2.7. Puncture mark through the box.

2.2.2 Opening the box

Position the box with the top side facing up. Pull the sealed joint up and away from the box. Then, use a safety cutter or another similar tool along the taped seam (Figure 2.8). **CAUTION:** Never use straight blades to open the BPC box. Never open from the bottom of the box or through any part of the cardboard.



Figure 2.8. Using a safety cutter to open the box.

2.2.3 Removing the BPC restraint system

A BPC restraint system is added to all S.U.B., S.U.M., and S.U.F. BPC assemblies (except the 2,000 L S.U.B. and imPULSE mixers) with the intention of keeping the BPC assembly flat and preventing damage.

CAUTION: Never use sharps or other tools to cut the restraint system from its top, as damage may occur to the polybag or BPC. Use the following steps to remove the BPC from the restraint system.

1. Remove the inner packaging with the restraint system and BPC attached. There should be handles on the inner packaging to assist in removal (Figure 2.9).



Figure 2.9. Handles on the inner packaging.

2. Turn the inner packaging on its side (Figure 2.10).



Figure 2.10. Inner packaging on its side.

3. Either cut the restraint on the bottom or undo the cardboard inserts to remove the inner packaging (Figures 2.11 and 2.12).



Figure 2.11. Cutting the restraint on the bottom of the inner packaging.



Figure 2.12. Undoing and removing the cardboard inserts.

2.2.4 Opening the outer polybag

After removing the BPC from the restraint system inside the box, inspect the outer polybag for any damage. If there is no damage, use a finger to punch a hole through the end of the polybag and manually tear it open, using both hands (Figure 2.13). If necessary, run a safety cutter or another similar tool along the edge of the polybag to open, instead (Figure 2.14).



Figure 2.13. Opening the outer polybag by hand.



Figure 2.14. Opening the outer polybag with a safety cutter.

2.3 Inspecting the BPC

2.3.1 Inspecting the chamber

Place the BPC 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 light stress marks are acceptable (see Figures 2.15 and 2.16).

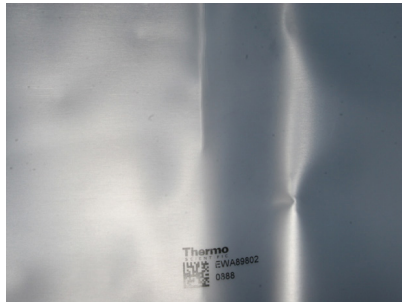


Figure 2.15. Folding marks on BPC chamber.

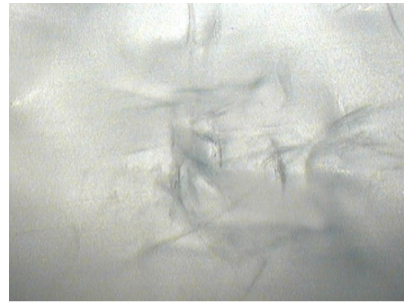


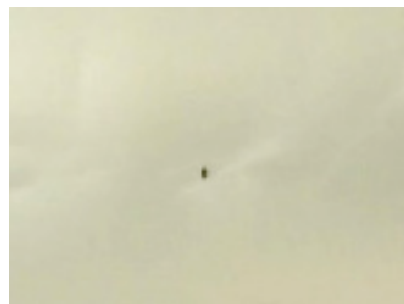
Figure 2.16. Light stress marks on BPC chamber.

Note: Cross-folding, however, involves folding the BPC in more than one direction, and is a main contributor to causing leaks in the chamber (Figure 2.17). Avoid cross-folding whenever possible.



Figure 2.17. Example of cross-folding.

Carbon or gel particulate on the surface (Figures 2.18 and 2.19) is also acceptable. See the film inspection criteria in section 2.3.3 for more information.



Figures 2.18 and 2.19. Carbon or gel particulate on BPC surface.

2.3.2 Optional inspections

Inspecting tubing

Inspect the tubing for signs of damage or abnormalities. **Note:** After irradiation, 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 cable ties or BarbLock™ retainers), and proper fit.

Inspect connectors for missing caps or plugs on the ends. Connector inspection should also include the inspection of aseptic, 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.

2.3.3 Film inspection criteria

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

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.

Table 2.1. Particulate product contact (fluid path).No particle density for any size shall exceed 4 per ft².

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 ft².

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

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 issue, 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 issue
- 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:

bpp.technicalsupport@thermofisher.com
1 800 792 8500 (option 2)

Appendix A—Manufacturing drawings and product specifications

Manufacturing drawings

The manufacturing drawing (Figure A.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

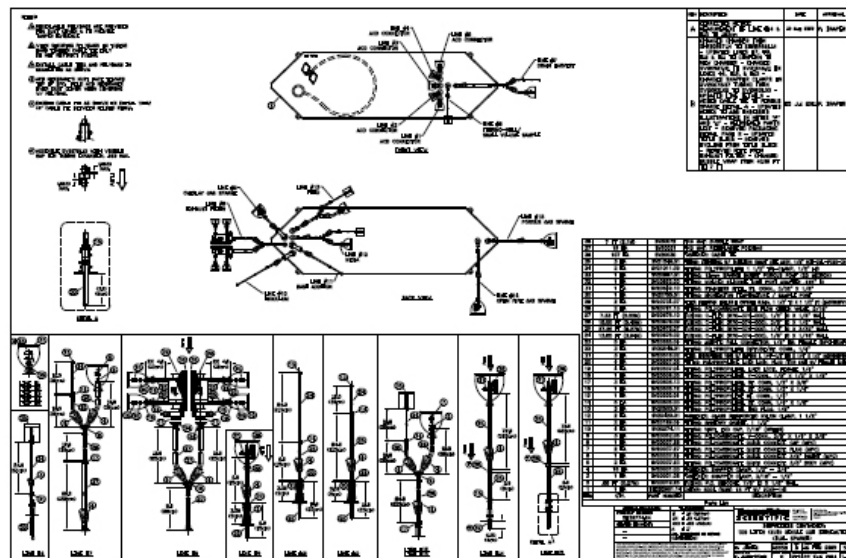


Figure A.1. Example of a manufacturing drawing for a standard product.

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.

Product specifications

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

Appendix B—Certificates of Analysis

Certificates of Analysis (COAs) differ by product. They may include 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.

Find out more at thermofisher.com/sut

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