
Cell culture media
High-quality, single-use
flexible packaging

Lonza

Pharma & Biotech

Platinum UltraPAK™ Bioprocess Containers

The benefits of disposable system use

As a leading supplier of flexible packaging for industrial and research applications, Lonza uses high quality proprietary film for the construction of its Platinum UltraPAK™ Products – a state-of-the-art packaging solution for cell culture media and related products.

In the rapidly developing cell therapy and bioprocessing fields, new processes and procedures are emerging that require the packaging of sterile liquid media and reagents in pre-made Flexible Bioprocess Containers. Lonza's Platinum UltraPAK™ Flexible Bioprocess Containers are single-use containers for liquid cell culture media, reagents, and buffers, as well as containment and storage vessels for intermediate and final products yielded from manufacturing processes.

Platinum UltraPAK™ Film consists of a two-web design, with both layers made entirely of non-animal origin (NAO) material. These layers consist of an inner contact and an outer support layer, with the inner product contact layer composed of high-quality, low density polyethylene to provide flexibility and a full NAO environment. The outer film layer is composed of nylon and polyethylene, which provides strength and acts as an excellent gas transmission barrier between the product and the environment.

Lonza Platinum UltraPAK™ Flexible Bioprocess Containers provide several distinct advantages over rigid wall packaging systems. In particular, Flexible Bioprocess Containers:

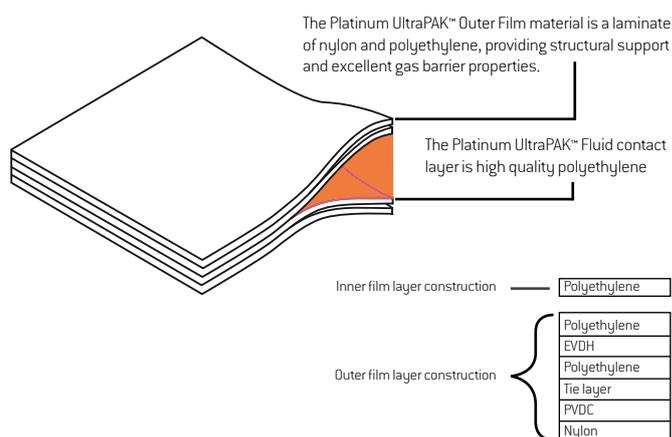
- Expand or collapse as liquid levels change, eliminating the need for sterilization of vent filters
- Provide a disposable primary product contact surface that, when emptied, can be compressed into a small size optimal for disposal
- Eliminate the need for validation of cleaning procedures common with multiple-use containers
- Provide true closed systems for the addition and removal of media and reagents, offering the highest level of confidence in sterility maintenance during use
- Are available in a wide variety of sizes with fill volumes between 50 mL and 10,000 L
- Feature fluid-handling tubing sets and connector systems that can be fully customized to support your specific applications
- Allow liquid packaging with minimal internal airspace, minimizing changes in reagent pH or oxidation.

Platinum UltraPAK™ Film structure and composition

An important component of our packaging is its proprietary polyethylene film formulation, specifically created by our engineers to provide durability and flexibility. Aside from having superior gas barrier properties, exhibiting undetectable endotoxin levels, and being certified as a USP Class VI material, our film is also entirely non-animal in origin. As a result, our film completely and reliably protects a wide variety of products that may come into contact with it, such as:

- Cell culture media
- Buffers
- Water for Injection (WFI)
- Final product yielded from downstream manufacturing processes

We chose a two-web polyethylene film design, providing more flexibility and less rigidity than single-web films – without sacrificing durability. Users can therefore avoid the cumbersome nature of more rigid films, as well as their tendency to generate pinhole leaks.



Platinum UltraPAK™ Product Contact Inner Web Film Structure

The inner product contact layer is constructed from 100% polyethylene (5mil LPDE)

Platinum UltraPAK™ High Barrier Outer Film Structure

The outer layer was chosen for its durability and superior gas barrier properties. The outer film composition, from outside to inside, is a laminate of the following:

- 1 mil Nylon: PVDC
- 2 mil PE
- 3 mil PE:EVOH: PE

Quality systems

Lonza's Flexible Bioprocess Containers are manufactured under strict quality standards to ensure product integrity. In addition, all of our packaging is manufactured in an FDA-registered ISO 7 cleanroom (class 10.000), adhering to cGMP, ISO 13485:2016 and ISO 9001:2015 standards, while the fitment and perimeter seals undergo 100% visual inspection on all bags. Furthermore, we routinely perform leak testing according to ASTM F2095-01. Platinum UltraPAK™ Flexible Bioprocess Containers and fluid paths are also supplied gamma-irradiated to ensure a SAL of 10⁶, substantiated according to ISO 11137 methodology.

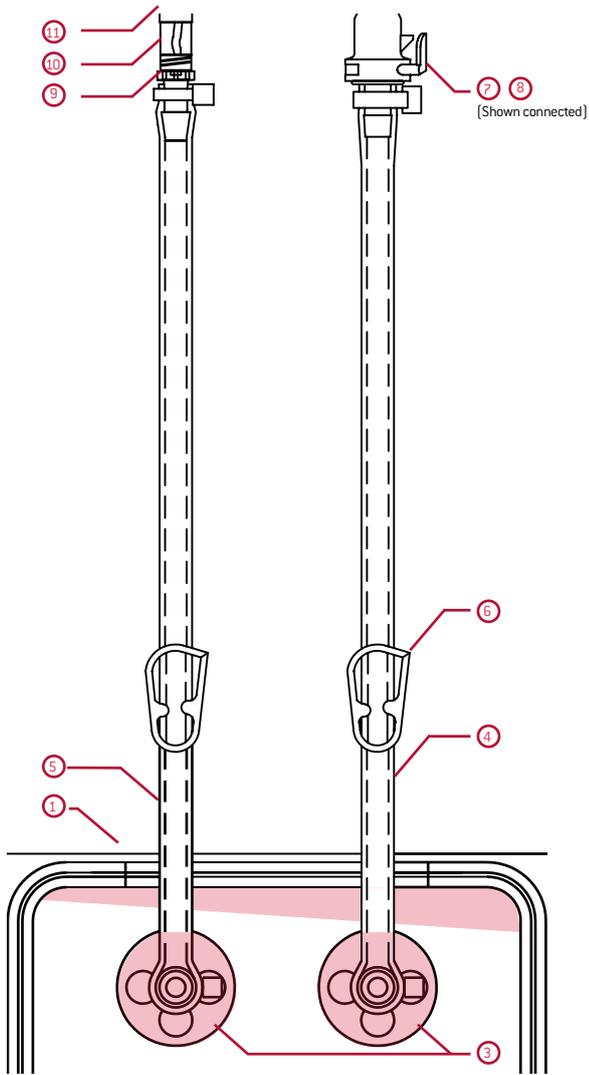
Validation testing methods

A comprehensive Qualification Guide supports our Platinum UltraPAK™ Flexible Bioprocess Containers and single-use assembly components.

The list below describes the validation testing methods that were performed on the inner and outer layers of the Platinum UltraPAK™ Polyethylene Film.

Assay	Test protocol
Endotoxin	USP <85>
Class VI plastic	USP class VI
Physiochemical testing	USP <661>
<i>In-vitro</i> biological reactivity	USP <87>
<i>In-vivo</i> biological reactivity	USP <88>
Water vapor transmission rate	ASTM F1249
Oxygen transmission Rate	ASTM D 3985
Carbon dioxide transmission rate	ASTM F2476
Seal and pull strength	ASTM F88 & ASTM D882
Brittleness temperature test	ASTM D1790-02
Freezing integrity study	SOP 1300.1618 & 1300.1019
Polyethylene with additives for containers for parenteral preparation	EP 3.1.5
Plastic containers for parenteral infusion	EP 3.2.2.1
Particulate testing	USP <788>
Shipping study	Meets ISTA procedure 1A & long distance shipping
Yellow index results	ASTM D 1925-70
Brittleness impact test	ASTM D 1790-14
Chemical resistance ratings	ASTM D 543-60T
Extractable	USP <1663>

A state-of-the-art
packaging solution

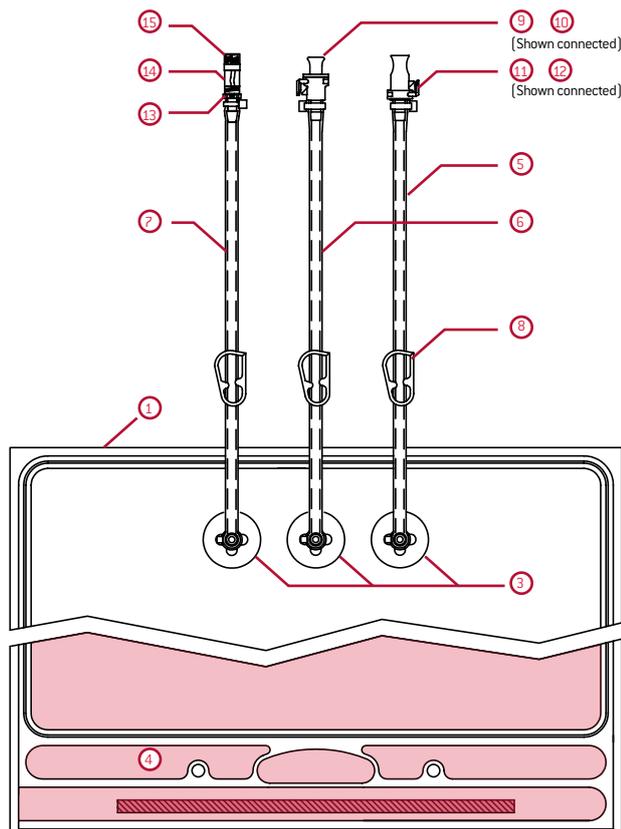


Flexible bioprocess containers schematics

To help you easily identify and visualize the Flexible Bioprocess Container Systems that best suit the needs of your applications, we have included sample schematics for several Flexible Bioprocess Containers in a variety of sizes. Please note that custom configurations can be created as needed.

Platinum UltraPAK™ 1 Liter Bag 08-E1322

Part	Q.P.A	Description
① S4111	1.00	1 liter bag
② BC-1001-I01	1.00	1 liter die (not shown)
③ TB-01062	2.00	Bag port with 1/4" barb
④ TB-01130	1.50 ft.	1/4" ID x 3/8" OD PVC tubing
⑤ TB-01254	1.50 ft.	1/4" ID x 3/8" OD C-FLEX NAO tubing
⑥ CL-01021	2.00	Pinch clamp
⑦ CN-01065	1.00	Male mpc with 1/4" barb
⑧ CP-01068	1.00	Female mpc cap
⑨ CN-01061	1.00	Female luer with 1/4" barb
⑩ CN-01225	1.00	Swabable valve
⑪ CP-01055	1.00	Male cover cap



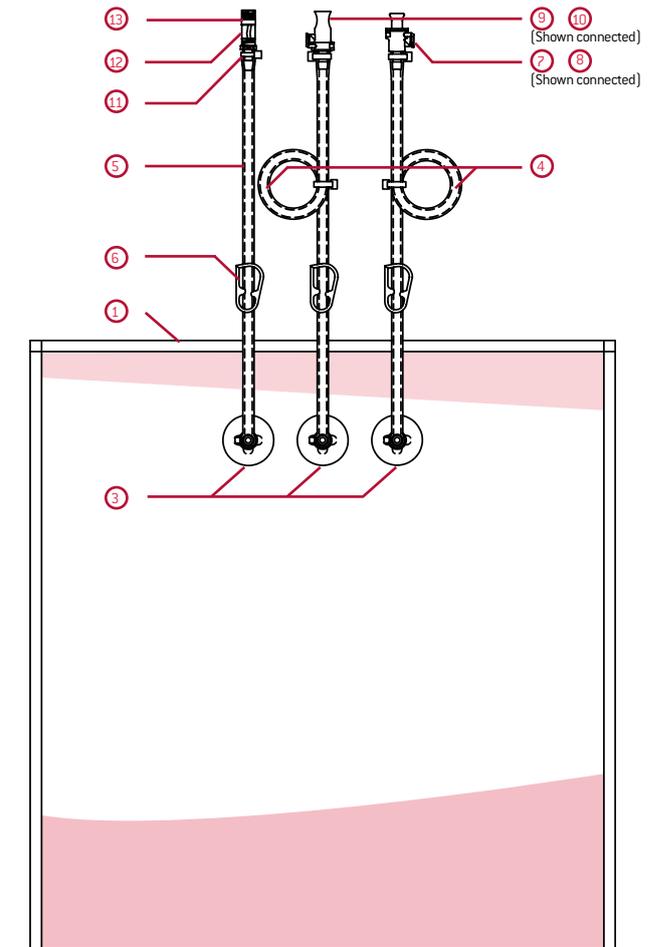
Platinum UltraPAK™ 20 Liter Bag 08-E1325

Part	Q.P.A	Description
① S4268	1.00	20 liter bag with fitments
② BC-0020-H20	1.00	20 liter die hanging style (not shown)
③ TB-01062	3.00	Bag port with 1/4" barb
④ PK-01098	1.00 ft.	0,325" DIA. hanging bar 12" long
⑤ TB-01130	1.50 ft.	1/4" ID x 3/8" OD PVC tubing
⑥ TB-01023	1.50 ft.	1/4" ID x 3/8" OD PCMGS tubing
⑦ TB-01254	1.50 ft.	1/4" ID x 3/8" OD C-FLEX NAO tubing
⑧ CL-01021	3.00	Small pinch clamp
⑨ CN-01055	1.00	Female mpc connector with 1/4" barb
⑩ CP-01020	1.00	Male mpc plug
⑪ CN-01065	1.00	Male mpc connector with 1/4" barb
⑫ CP-01068	1.00	Female mpc plug
⑬ CN-01061	1.00	Female luer with 1/4" barb Male cover cap
⑭ CN-01225	1.00	Swabable valve
⑮ CP-01055	1.00	Male cover cap

Platinum UltraPAK™ 100 Liter Bag 08-E314

Part	Q.P.A	Description
S4257	1.00	100 liter bag with fitments
BC-01000	1.00	100 liter die hanging style (not shown)
TB-01062	3.00	Bag port with 1/4" barb
TB-01023	12.00 ft.	1/4" ID x 3/8" OD PCMGS tubing
TB-01254	1.50 ft.	1/4" ID x 3/8" OD C-FLEX NAO tubing
CL-01021	3.00	Small pinch clamp
CN-01055	1.00	Female mpc connector with 1/4" barb
CP-01020	1.00	Male mpc plug
CN-01065	1.00	Male mpc connector with 1/4" barb
CP-01068	1.00	Female mpc cap
CN-01061	1.00	Female luer with 1/4" barb
CN-01225	1.00	Swabable valve
CP-01055	1.00	Male cover cap

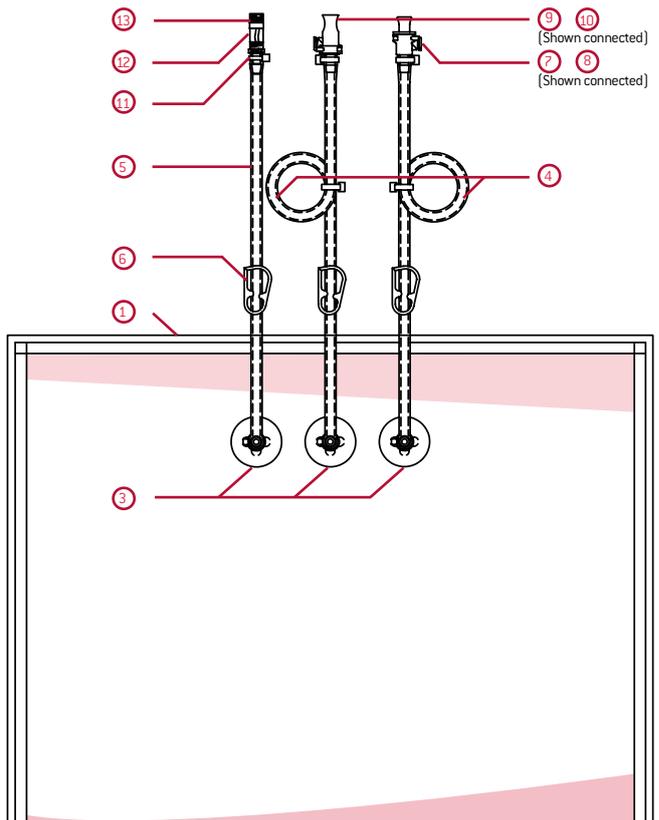
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Platinum UltraPAK™ 200 Liter Bag 08-E315

Part	Q.P.A	Description
S4258	1.00	200 liter bag with fitments
BC-01000	1.00	200 liter die hanging style (not shown)
TB-01062	3.00	Bag port with 1/4" barb
TB-01023	12.00 ft.	1/4" ID x 3/8" OD PCMGS tubing
TB-01254	1.50 ft.	1/4" ID x 3/8" OD C-FLEX NAO tubing
CL-01021	3.00	Small pinch clamp
CN-01055	1.00	Female mpc connector with 1/4" barb
CP-01020	1.00	Male mpc plug
CN-01065	1.00	Male mpc connector with 1/4" barb
CP-01068	1.00	Female mpc cap
CN-01061	1.00	Female luer with 1/4" barb
CN-01225	1.00	Swabable valve
CP-01055	1.00	Male cover cap

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Platinum UltraPAK™ Advantages

Aside from the superior properties of UltraPAK™ Film, our engineers have developed additional, unique designs and features to further enhance product performance. For example, the Platinum UltraPAK™ Containers offer:

- **Unmatched versatility in connectivity** – our standard systems offer MPC and Luer Connections, along with needle-less injection sites for sampling. Custom UltraPAK™ Containers offer additional connectivity devices, including (but not limited to) steam-in-place (SIP) and aseptic connections.
- **A continuous sealing process** – 250 mL–200 L bags have a continuous seal generated by an automated sealing process, eliminating seam leaks.
- **Convenient carrier handles** – available on 5 L, 10 L, and 20 L bags. The carrier handle is sealed separately and does not contact the inner product, eliminating areas for gas transmission.
- **Robust ports** – we have maximized the surface area where Platinum UltraPAK™ Film contacts the contained product. The surface area of our ports is therefore reduced, minimizing a key point of gas exchange, and at the same time, maintaining a robust connection between the barb and tubing.

Standard UltraPAK™ Flexible Bioprocess Container configurations

The list below describes the components on our premium pre-designed, made-to-order containers. All bags are individually wrapped and irradiated at 25-45 kGy.

Part code	Description	Qty/case
08-E1418	Platinum UltraPAK™ Bag 0.25 L <ul style="list-style-type: none"> • Port 1 : PVC Spike port • Port 2 : 0.118" ID x 0.164" OD PVC sealed end • Port 3 : 3/8" ID x 1/2" OD PVC with Male MPC and Female cap Individual wrapped, 10 bags per pack	30
08-E1322	Platinum UltraPAK™ Bag 1 L <ul style="list-style-type: none"> • Port 1: 18" ID of 1/4" OD C-flex tubing with female Luer needle-less injection site • Port 2: 18" ID of 1/4" OD PVC tubing with male MPC with female cap • Individually wrapped, 5 bags per pack 	25
08-E1323	Platinum UltraPAK™ Bag 5 L – side port	20
08-E1324	Platinum UltraPAK™ Bag 10 L – side port	20
08-E1325	Platinum UltraPAK™ Bag 20 L – side port <ul style="list-style-type: none"> • Port 1: 18" ID of 1/4" OD C-flex tubing with female Luer needle-less injection site • Port 2: 18" ID of 1/4" OD silicone tubing with female MPC with male cap • Port 3: 18" ID of 1/4" OD PVC tubing with male MPC with female cap • Hanging bar • Individually wrapped, 5 bags per pack 	20
08-E313	Platinum UltraPAK™ Bag 50 L	5
08-E314	Platinum UltraPAK™ Bag 100 L	5
08-E315	Platinum UltraPAK™ Bag 200 L <ul style="list-style-type: none"> • Port 1: 18" ID of 1/4" OD C-flex tubing with female Luer needle-less injection site • Port 2: 72" ID of 1/4" OD silicone tubing with male MPC with female cap • Port 3: 72" ID of 1/4" OD silicone tubing with female MPC with male cap • Individually wrapped 	5

Custom UltraPAK™ Flexible Bioprocess Container configuration

In addition to the standard designs of our catalog bags, Lonza also offers customized UltraPAK™ Flexible Bioprocess Containers to meet the needs of your specific application. With multiple tubing types and connectors at our disposal, creating a unique configuration tailored to your application is simple.

Filled UltraPAK™ Flexible Bioprocess Containers

In addition, Lonza offers Platinum UltraPAK™ Flexible Bioprocess Containers pre-filled with Lonza's or customers media, buffers and reagents.

Part code (US)	Part code (EU)	Description
08-199F	BE02-038P20	Bulk Packaged sterile filtered WFI-20L
08-199E	BE02-038P200	Bulk Packaged sterile filtered WFI-200L
08-003A	BE08-003A	HANKS' BSS, w/o CA, MG OR PR, 5L Bag (4L fill)
08-851J	BE08-851J	PBS-1X, w/o CA++ or MG ++ 15L
BP12-730P10	BE12-730P10	InsectXPRESS w/ L-Gln, 10L bag
BE12-771P10	BE12-771P10	PowerCHO-2 CD, w/o L-Gln w/o PR, 10L
BE12-771P20	BE12-771P20	PowerCHO-2 CD, w/o L-Gln w/o PR, 20L
08-879H	BE08-879H	X-Vivo 15 w/o gentamicin and pr, 5L
08-879P1	BE08-879P1	X-Vivo 15 w/o gentamicin and pr, 1L
BP02-054P1	BEBP02-054P1	X-Vivo15(04-744)contains rec tran 1L bag



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