



Lyoprotect®

The key to safe lyophilization

Product Catalog



Teclen® GmbH is a fully privately held company, founded by Rolf Lenhardt in 2017 with a unique vision: to design and manufacture containers for the lyophilization of active pharmaceutical ingredients (API).

“ Challenge what is in place and find a better solution. In dialog with customers, innovative solutions can be found. ”

Rolf Lenhardt

**Founder,
product development**

“ Engineers love technical challenges – so don’t hesitate to ask for individual solutions! ”



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Lyoprotect® Product Overview – Bulk

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Our key to safe lyophilization – the Lyoprotect® Membrane

The Lyoprotect® Membrane is a high-performance, bacteria-retentive membrane that ensures safe lyophilization by protecting both the product and personnel. It acts as a sterile barrier, preventing cross-contamination and fly-out, while allowing vapor to pass through freely.

Freeze-drying process parameters established with open containers can be directly applied – confirmed by test results with comparable drying performance.

Material & Structure

- » ePTFE (expanded polytetrafluoroethylene) laminated on non-woven PP
- » Naturally hydrophobic, chemically inert, and resistant
- » Product-contact side: ePTFE; PP backing faces outward

Function & Performance

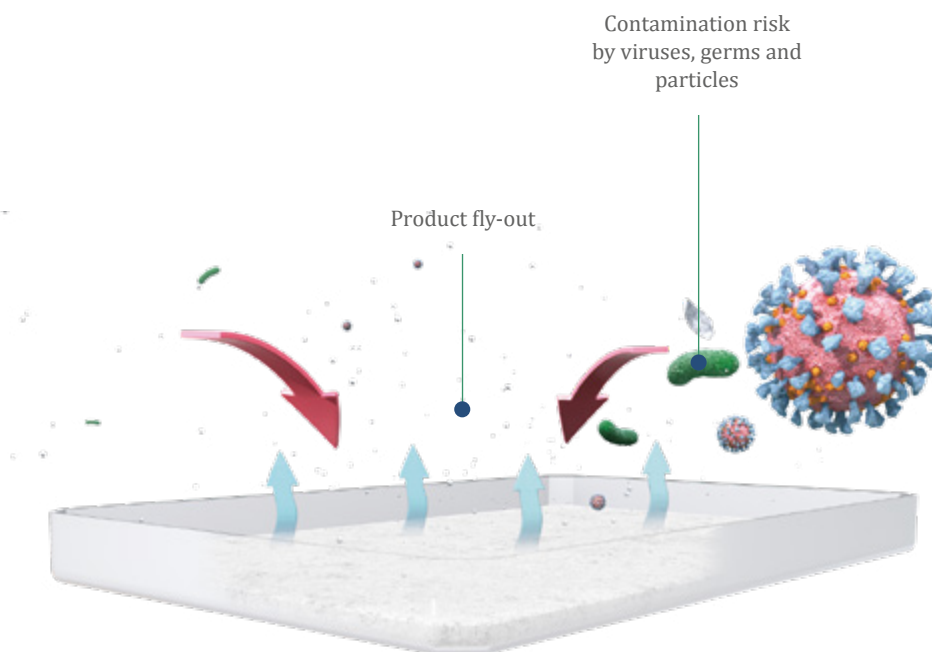
- » Bacteria-retentive and vapor-permeable
- » Microbial barrier validated to ASTM F1608 (LRV \geq 6)
- » High sublimation rate with negligible influence on the drying cycle
- » No contamination, no loss of product
- » Proven equivalence to open containers
- » Available non-sterile, ready-to-sterilize and sterilized
- » Autoclavable

“Our vision is to enable you to concentrate on API or formulation development while ensuring a more secure lyophilization cycle.”

Bulk API production

Our Lyoprotect® System will help you to produce safely and easily. Freeze-drying in an open container entails a few risks:

- » Fluffy dry powder flies out and generates product loss.
- » Risk of contamination of your product with particles or airborne germs.
- » When freeze-drying in open containers, your staff is under high risk to get contaminated with the API – please check your occupational exposure limit (OEL) for your specific API product.
- » Cleaning validation for your freeze dryer is required to handle different batches and to prevent cross contamination between different API products.

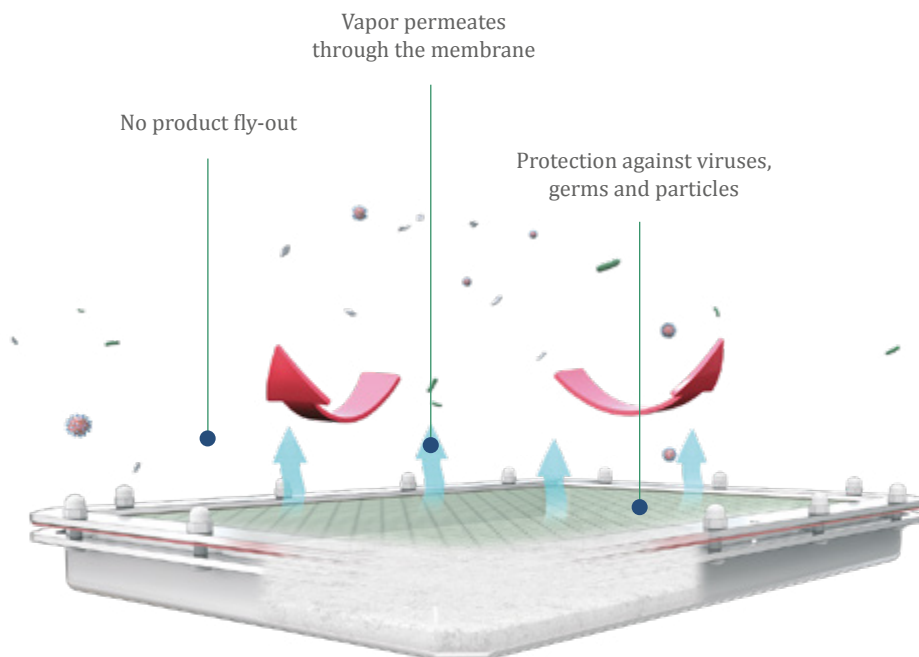


Problems with conventional methods

As each process is unique, we offer solutions for multiple use as well as single use. Very versatile and sustainable are our multiple-use stainless steel containers, which are available in several sizes and can even be customized in order to suit your freeze-drying shelf dimension and process.

If you wish to avoid the cleaning effort, our single-use trays can be the best choice. They are available as open tray in a bag solution or as closed trays with filler assembly.

All our products prevent fly-out and cross-contamination in your freeze dryer. The membrane acts as a sterile barrier and ensures optimum protection of your staff and product.



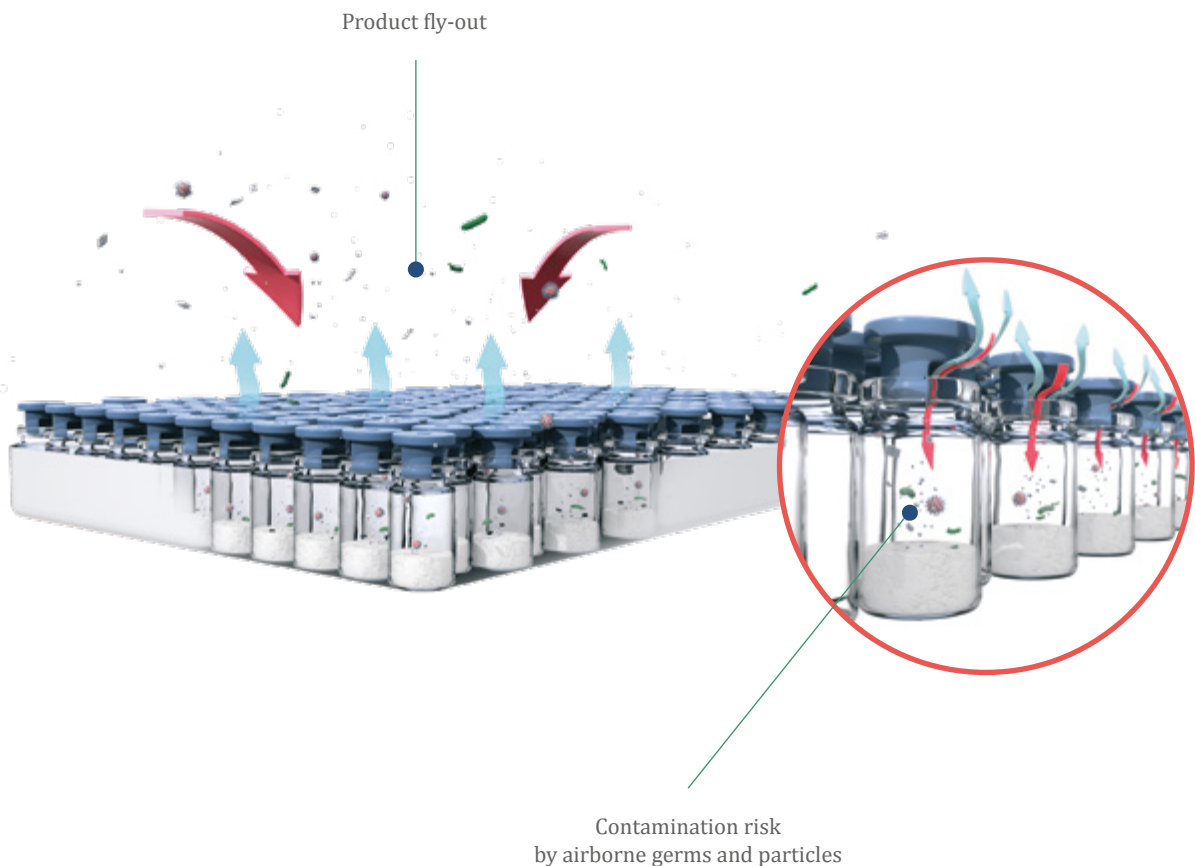
The Teclen® Lyoprotect® Solution

Freeze-drying in vials

During regular freeze-drying in vials, you still have the implication of product loss and fly-out. In addition, your staff and product are under contamination risk. Further, aseptic development and/or manufacturing for clinical studies is difficult and expensive to achieve.

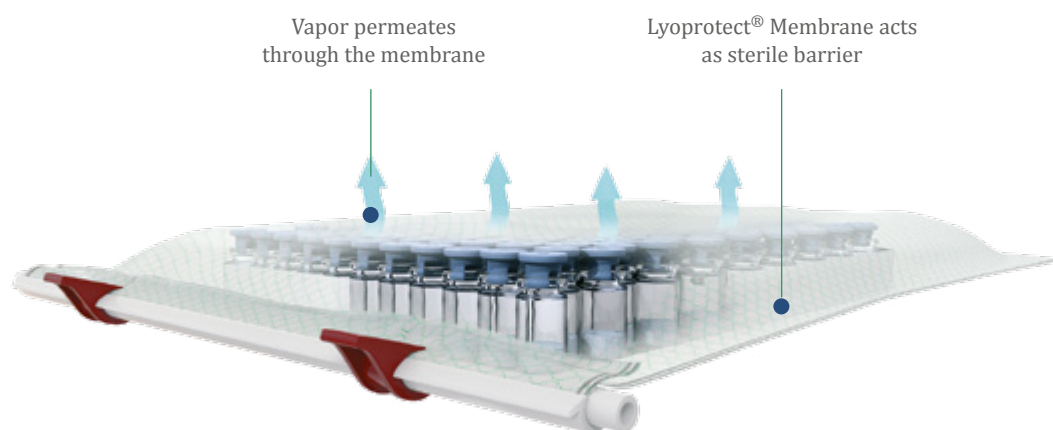
Our Lyoprotect® System will help you to produce safely and easily. Just place the vials into a tray and the tray into a Lyoprotect® Bag.

A tray (or frame) is used to accommodate the filled vials. Lyoprotect® Open Stainless Steel Trays OTS include a movable separation sheet that lets you adjust the usable area to suit different vial sizes and numbers. The vials are preferably arranged in a hexagonal or square layout, and the stoppers are in the drying position. The bag is closed and secured with the closing stick or via an integrated heat-sealing strip.



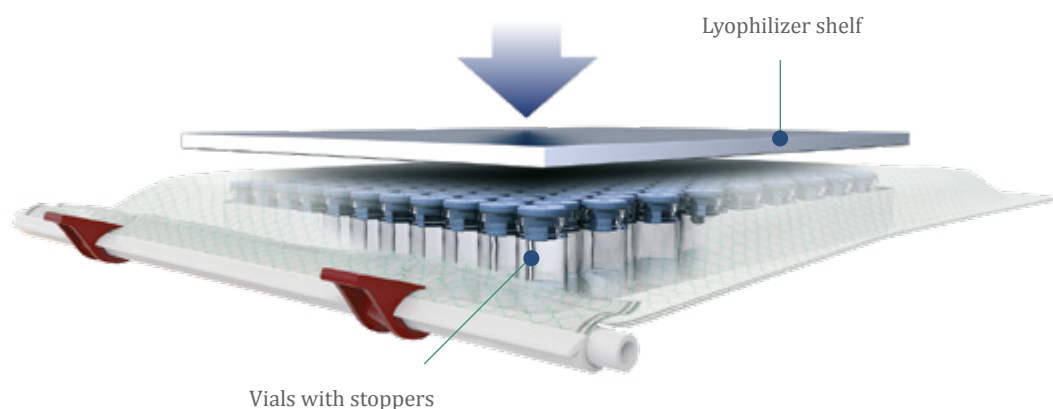
Problems with conventional methods

If aseptic criteria must be met, filling of vials, placement and closure of the bag needs to take place under a laminar flow/working bench – or even better, in an isolator or oRABS (check with your local authorities). And all required accessories (vials, stoppers, bag, closing stick etc.) need to be sterile.



But as soon as the bag is closed, you can move your assembly to any freeze dryer in your facility. Your product will be safe – the Lyoprotect® Membrane acts as a sterile barrier.

When the drying process is finished, the vials can be securely closed with the stoppers. This step is performed under high vacuum within the freeze dryer by lowering the shelves. The flexible materials of the Lyoprotect® Bag easily follow the movements and mechanical loads when the stoppers are pushed in. If decontamination of the outside of the vials is needed (e. g. H_2O_2), this can be done with the bag still in place. After decontamination you can remove the closed vials for crimping.



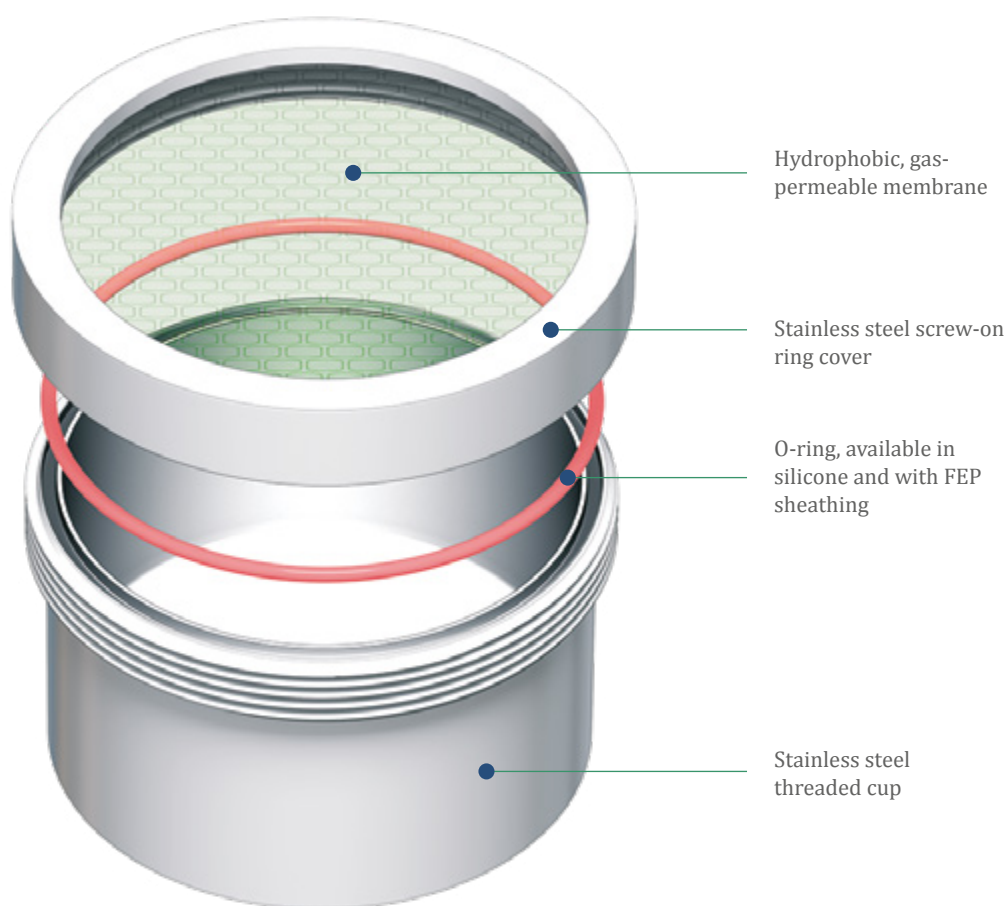
The Teclen® Lyoprotect® Solution



Multiple-use Cups

Teclen® Lyoprotect® Cups are designed for freeze-drying of pharmaceutical APIs (Active Pharmaceutical Ingredients). They are available in durable stainless steel (non-sensitive to shock and scratching, polished surface).

Stainless steel cups allow multiple use after cleaning. All components, including the Lyoprotect® Membrane, can be sterilized in an autoclave at up to 121°C (250°F) for 20 minutes. APIs can be produced aseptically in compliance with GMP.



Stainless Steel Cups

Each cup requires the Lyoprotect® Membrane and an o-ring to function properly as a barrier during lyophilization. Available in two sizes, for volumes from 10–150 ml.

Features

- » multiple-use
- » with screw-on ring cover
- » roughness: Ra < 0.4 µm
- » with inspection certificate 3.1
- » consecutive serial number
- » polished surface



Stainless Steel Cups, multiple-use

Product name	Article no.	Material	Volume	Dimensions	
1 Lyoprotect® Stainless Steel Cup VXS, polished	LPMU-VXS-BSmod	Stainless steel 1.4404 (316L)	10–50 ml	Diameter:	52 mm
				Ring cover:	58 mm
				Height:	34 mm
2 Lyoprotect® Stainless Steel Cup VS, polished	LPMU-VS-BS	Stainless steel 1.4404 (316L)	30–150 ml	Diameter:	93 mm
				Ring cover:	100 mm
				Height:	34 mm

Minimum order: 2 pcs

This product requires the following components:



Cup



Membrane



O-ring



O-ring FEP

Components

Membrane for Cup, single-use

Product name	Article no.	Material	Dimensions	Packaging unit
Lyoprotect® Membrane for Cup VXS ^①	LPMU-VXS-M	ePTFE on PP non-woven backing	Ø 56 mm	10 pcs
Lyoprotect® Membrane for Cup VS ^②	LPMU-VS-M	ePTFE on PP non-woven backing	Ø 97 mm	10 pcs

O-ring for Cup, multiple-use

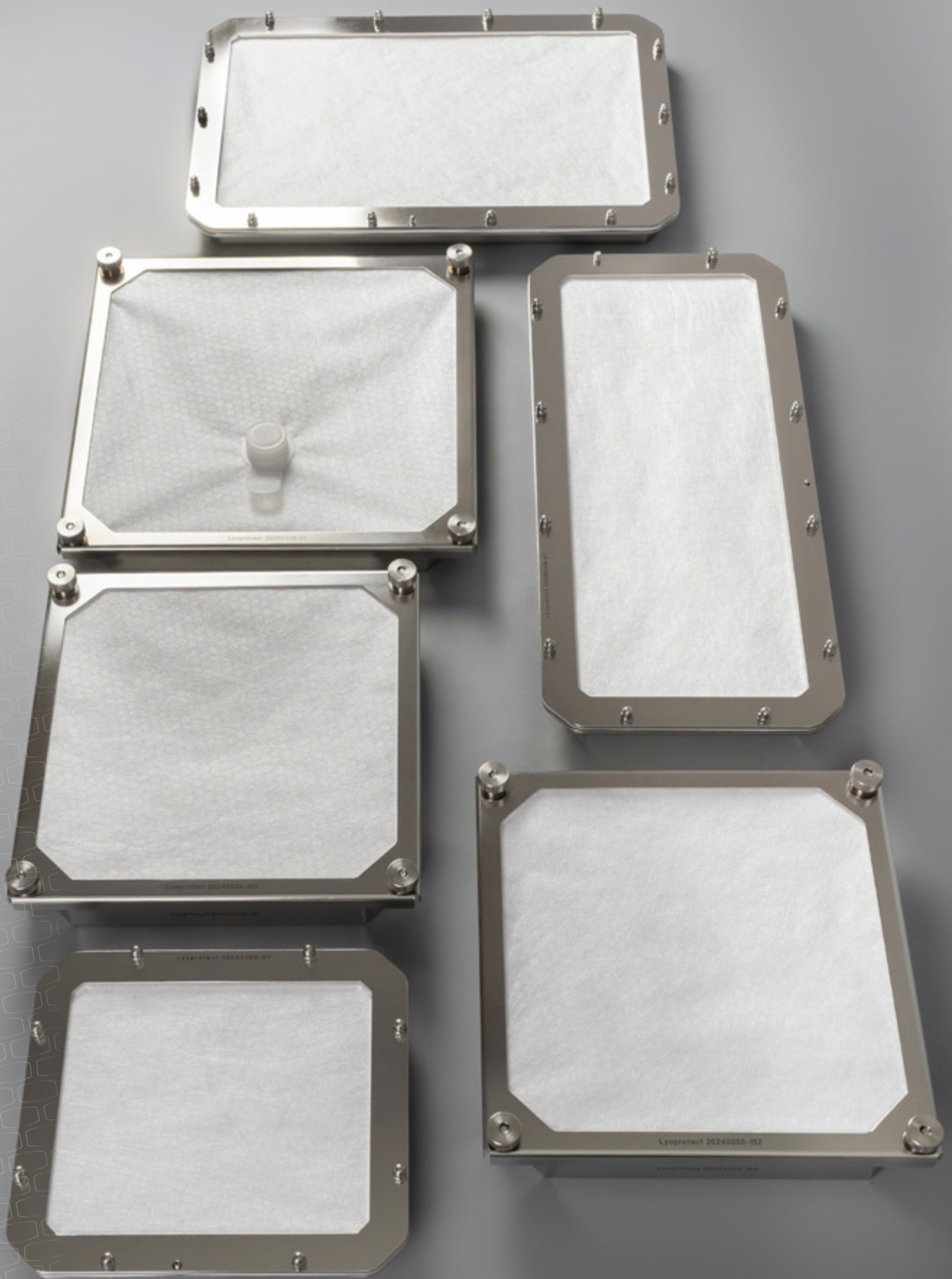
Product name	Article no.	Material	Dimensions	Packaging unit
Silicone o-ring VXS ^①	LPMU-VXS-OR	Silicone, 70 Shore A	Ø 50 x 1.5 mm	2 or 5 pcs
Silicone o-ring VS ^②	LPMU-VS-OR	Silicone, 70 Shore A	Ø 90 x 1.5 mm	2 or 5 pcs

O-ring FEP sheated for Cup, multiple-use

Product name	Article no.	Material	Dimensions	Packaging unit
O-ring VXS, FEP sheathed ^①	LPMU-VXS-ORFEP	Silicone o-ring with FEP sheathing, 70 Shore A	Ø 50 x 1.5 mm	2 or 5 pcs
O-ring VS, FEP sheathed ^②	LPMU-VS-ORFEP	Silicone o-ring with FEP sheathing, 70 Shore A	Ø 90 x 1.5 mm	2 or 5 pcs

^① Fits with LPMU-VXS-BSmod

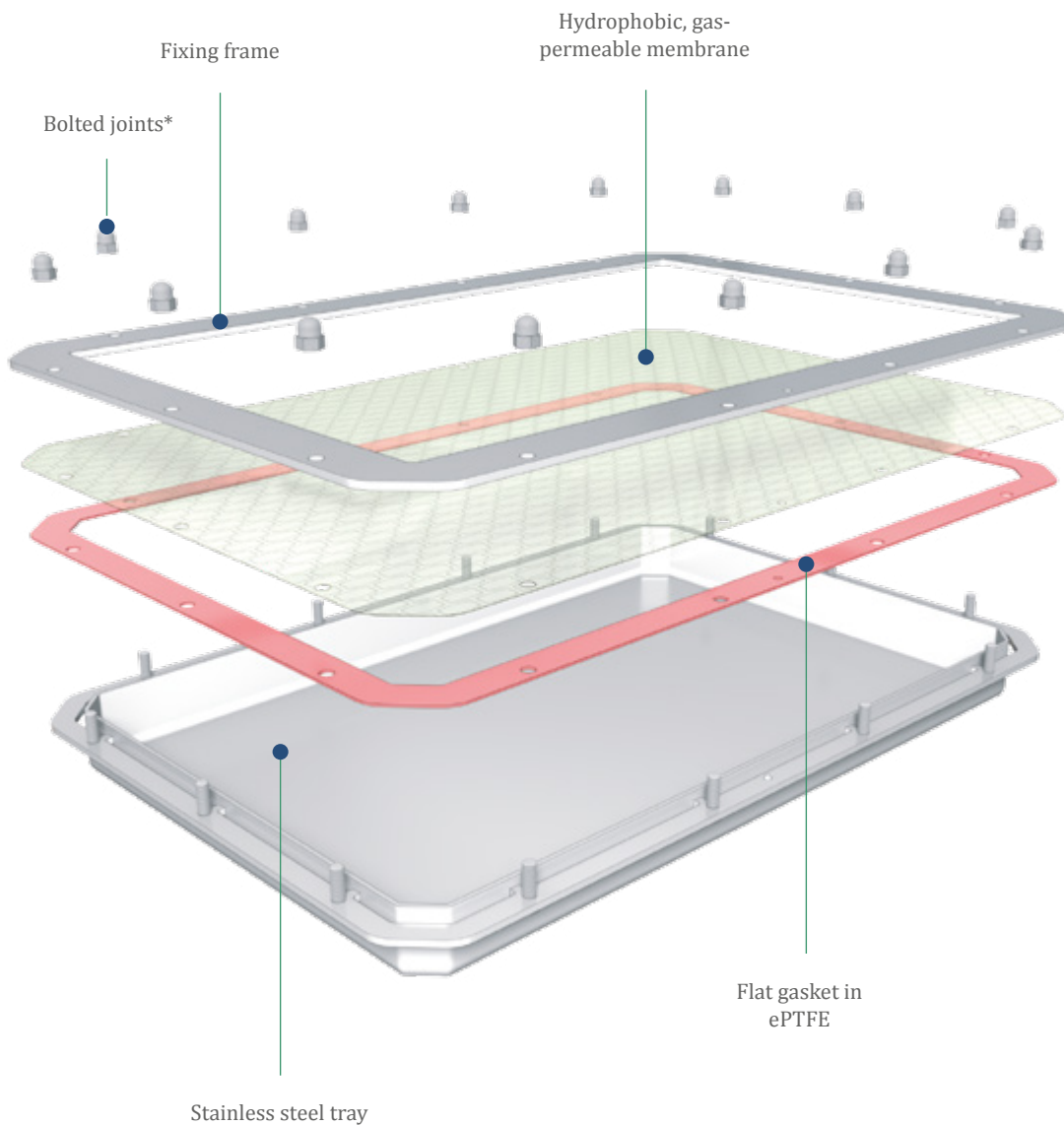
^② Fits with LPMU-VS-BS



Multiple-use Trays

Teclen® Lyoprotect® Trays are specifically designed for freeze-drying pharmaceutical APIs (Active Pharmaceutical Ingredients). Each tray requires the Lyoprotect® Membrane and Gasket to function properly as a barrier during lyophilization.

Lyoprotect® Stainless Steel Trays, Membranes and Gaskets can be sterilized in an autoclave at up to 121°C (250°F) for 20 minutes.



* Bolted joints or knurled nuts (quick-fix), depending on model

Stainless Steel Trays

Features

- » multiple-use
- » with fixing frame and bolted joints
- » roughness:
Ra < 0.4 µm
- » with inspection
certificate 3.1
- » consecutive serial
number
- » polished surface

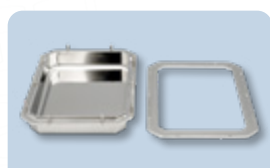
Quality made in Germany. Lyoprotect® Stainless Steel Trays are very robust, they don't warp and seat solidly on the footprint of your freeze-dryer – important assets for heat transfer rate and freeze-drying results. Thanks to the high-quality material, cleaning is easy. The serial number engraved on the frame of each tray facilitates the documentation e.g. of the filled-in substances.



Stainless Steel Trays, multiple-use

Product name	Article no.	Material	Volume	Dimensions	
1 Lyoprotect® Stainless Steel Tray V1622B	LPMU-V1622B-WS	Stainless steel 1.4404 (316L)	100–500 ml	Width: Length: Height:	155 mm 224 mm 43 mm
2 Lyoprotect® Stainless Steel Tray V2740B	LPMU-V2740B-WS	Stainless steel 1.4404 (316L)	400–2100 ml	Width: Length: Height:	270 mm 400 mm 43 mm
				Minimum order: 2 pc	
3 Lyoprotect® Stainless Steel Tray (customizable size)	LPMU-Vxxxx-WS	Stainless steel 1.4404 (316L)	up to 6000 ml	Width: Length: Height:	max. 500 mm max. 700 mm max. 53 mm
				Minimum order: 6 pc	

This product requires the following components:



Tray



Gasket



Membrane



Membrane with filler

Components

Gasket for Tray, multiple-use

Product name	Article no.	Material	Dimensions	Packaging unit
Lyoprotect® Gasket for Stainless Steel Tray V1622B ¹	LPMU-V1622B-FD	ePTFE	160 x 220 x 1 mm	2 or 5 pcs
Lyoprotect® Gasket for Stainless Steel Tray V2740B ²	LPMU-V2740B-FD	ePTFE	270 x 400 x 1 mm	2 or 5 pcs
Lyoprotect® Gasket for Stainless Steel Tray (customizable size) ³	LPMU-Vxxxx-FD	ePTFE	Custom	2 or 5 pcs

Membrane for Tray, single-use

Product name	Article no.	Material	Dimensions	Packaging unit
Lyoprotect® Membrane for Stainless Steel Tray V1622B ¹	LPMU-V1622B-M	ePTFE on PP non-woven backing	160 x 220 mm	10 pcs
Lyoprotect® Membrane for Stainless Steel Tray V2740B ²	LPMU-V2740B-M	ePTFE on PP non-woven backing	270 x 400 mm	10 pcs
Lyoprotect® Membrane for Stainless Steel Tray (customizable size) ³	LPMU-Vxxxx-M	ePTFE on PP non-woven backing	Custom	10 pcs

Membrane with Filler Assembly for Tray, single-use

Product name	Article no.	Material	Dimensions	Packaging unit
Lyoprotect® Membrane with Filler Assembly for Stainless Steel Tray V1622B ¹	LPMU-V1622B-MFA	ePTFE membrane on PP non-woven backing; PP filler assembly	160 x 220 mm; filler assembly: Ø 21.5 mm	10 pcs
Lyoprotect® Membrane with Filler Assembly for Stainless Steel Tray V2740B ²	LPMU-V2740B-MFA	ePTFE membrane on PP non-woven backing; PP filler assembly	270 x 400 mm; filler assembly: Ø 21.5 mm	10 pcs
Lyoprotect® Membrane with Filler Assembly for Stainless Steel Tray (customizable size) ³	LPMU-Vxxxx-MFA	ePTFE membrane on PP non-woven backing; PP filler assembly	Custom; filler assembly: Ø 21.5 mm	10 pcs

- ¹ Fits with LPMU-V1622B-WS
- ² Fits with LPMU-V2740B-WS
- ³ Fits with LPMU-Vxxxx-WS

Stainless Steel Trays Quick-Fix

The latest addition to the Lyoprotect® Stainless Steel Tray line offers the same high-quality features as our other models – with the added benefit of effort-less handling. Quick-Fix Trays are designed for fast, tool-free assembly. A specially engineered fixing frame ensures optimal surface pressure using just four knurled nuts. For traceability, the serial number is engraved both on the frame and on the side of each tray.

Features

- » multiple-use
- » with fixing frame and knurled nuts
- » roughness: Ra < 0.4 µm
- » with inspection certificate 3.1
- » consecutive serial number
- » polished surface

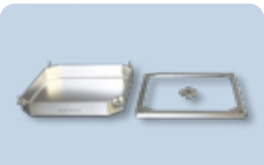


Stainless Steel Trays Quick-Fix, multiple-use

Product name	Article no.	Material	Volume*	Dimensions	
1 Lyoprotect® Stainless Steel Tray Quick-Fix 3030K	LPMU-QF3030K-WS	Stainless steel 1.4404 (316L)	400–2000 ml	Width:	300 mm
				Length:	300 mm
				Height:	45 mm
2 Lyoprotect® Stainless Steel Tray Quick-Fix 3040K	LPMU-QF3040K-WS	Stainless steel 1.4404 (316L)	550–2750 ml	Width:	300 mm
				Length:	400 mm
				Height:	45 mm
				Minimum order:	2 pc
3 Lyoprotect® Stainless Steel Tray Quick-Fix (customizable size)	LPMU-QFxxxxK-WS	Stainless steel 1.4404 (316L)	Custom	Width:	max. 300 mm
				Length:	max. 420 mm
				Height:	max. 55 mm
				Minimum order:	6 pc

* Filling height 5–25 mm, edge height of tray 30 mm

This product requires the following components:



Tray

+



Gasket

/



Membrane

+



Membrane with Filler

Components

Gasket for Tray, multiple-use

Product name	Article no.	Material	Dimensions	Packaging unit
Lyoprotect® Gasket for Stainless Steel Tray QF3030K ¹	LPMU-QF3030K-FD	ePTFE	300 x 300 x 1 mm	2 or 5 pcs
Lyoprotect® Gasket for Stainless Steel Tray QF3040K ²	LPMU-QF3040K-FD	ePTFE	300 x 400 x 1 mm	2 or 5 pcs
Lyoprotect® Gasket for Stainless Steel Tray QF (customizable size) ³	LPMU-QFxxxxK-FD	ePTFE	Custom	2 or 5 pcs

Membrane for Tray, single-use

Product name	Article no.	Material	Dimensions	Packaging unit
Lyoprotect® Membrane for Stainless Steel Tray QF3030K ¹	LPMU-QF3030K-M	ePTFE on PP non-woven backing	300 x 300 mm	10 pcs
Lyoprotect® Membrane for Stainless Steel Tray QF3040K ²	LPMU-QF3040K-M	ePTFE on PP non-woven backing	300 x 400 mm	10 pcs
Lyoprotect® Membrane for Stainless Steel Tray QF (customizable size) ³	LPMU-QFxxxxK-M	ePTFE on PP non-woven backing	Custom	10 pcs

Membrane with Filler Assembly for Tray, single-use

Product name	Article no.	Material	Dimensions	Packaging unit
Lyoprotect® Membrane with Filler Assembly for Stainless Steel Tray QF3030K ¹	LPMU-QF3030K-MFA	ePTFE membrane on PP non-woven backing; PP filler assembly	300 x 300 mm; filler assembly: Ø 21.5 mm	10 pcs
Lyoprotect® Membrane with Filler Assembly for Stainless Steel Tray QF3040K ²	LPMU-QF3040K-MFA	ePTFE membrane on PP non-woven backing; PP filler assembly	300 x 400 mm; filler assembly: Ø 21.5 mm	10 pcs
Lyoprotect® Membrane with Filler Assembly for Stainless Steel Tray QF (customizable) ³	LPMU-QFxxxxK-MFA	ePTFE membrane on PP non-woven backing; PP filler assembly	Custom; filler assembly: Ø 21.5 mm	10 pcs

¹ Fits with LPMU-QF3030K-WS

² Fits with LPMU-QF3040K-WS

³ Fits with LPMU-QFxxxxK-WS



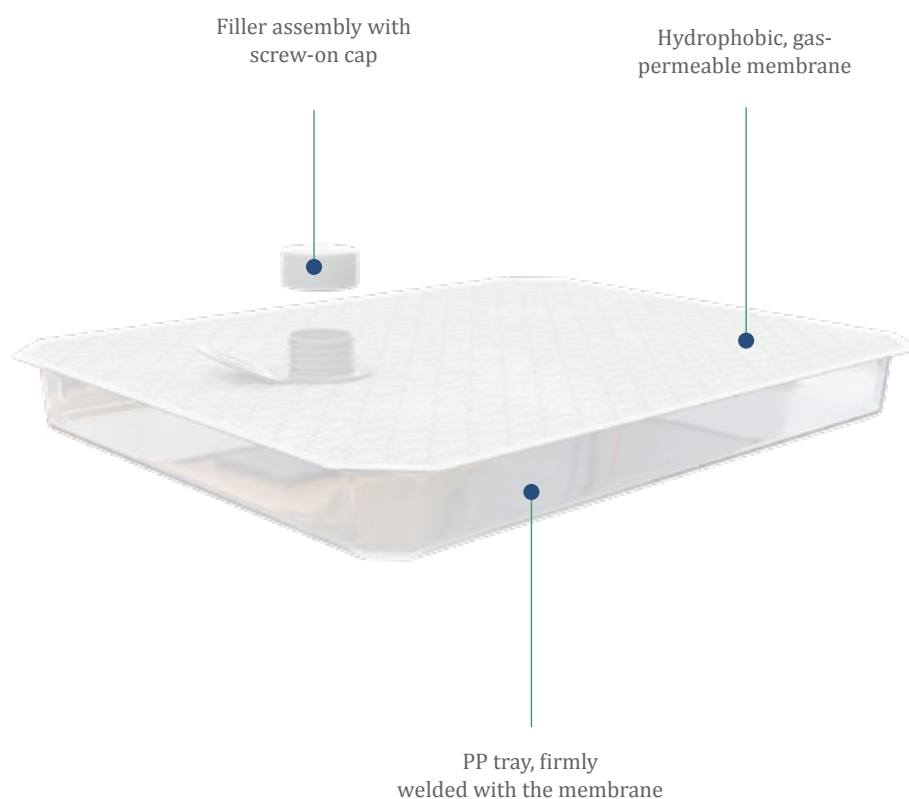
Single-use Trays

Lyoprotect® Single-use Trays with Filler Assembly combine simple handling with optimum protection of product and working environment. The Lyoprotect® Membrane acts as a sterile barrier and ensures zero fly-out. APIs can be produced under sterile conditions in compliance with GMP Annex 1.

Preliminary freezing in a conventional deep freezer is possible. The solid tray bottom facilitates safe transport and handling.

Alternatively, combine an open Tray PP with a Lyoprotect® Bag with Closing Stick or Heat Sealing.

Lyoprotect® Single-use Trays can be sterilized in an autoclave by up to 121°C (250°F) for 20 minutes.



Single-use Trays with Filler Assembly

The Lyoprotect® Single-use Trays with Filler Assembly are available in three sizes for filling volumes from 230 ml up to 2,800 ml (filling level 10–25 mm).

Features

- » single-use
- » easy filling via funnel or tube
- » filler opening:
Ø 21.5 mm, suitable for tubes with approx.
D_o ¾ inch or 20 mm



Trays with Filler Assembly, single-use*

Product name	Article no.	Material	Volume	Dimensions
1 Lyoprotect® Single-use Tray 1522 with Filler Assembly	LPSU-T1522-FA0909	ePTFE membrane, PP tray, PP filler assembly	230–570 ml	150 x 225 x 50 mm incl. cap, edge height of tray 30 mm
2 Lyoprotect® Single-use Tray 2230 with Filler Assembly	LPSU-T2230-FA0909	ePTFE membrane, PP tray, PP filler assembly	500–1,300 ml	225 x 300 x 50 mm incl. cap, edge height of tray 30 mm
3 Lyoprotect® Single-use Tray 3045 with Filler Assembly	LPSU-T3045-FA0909	ePTFE membrane, PP tray, PP filler assembly	1,100–2,800 ml	300 x 450 x 50 mm incl. cap, edge height of tray 30 mm

* Also available 'ready to sterilize' or 'sterilized' upon request.

Minimum order: 10 pcs

Optional accessories for this product:



Cutting Tool



Barrier pouch

Accessories

Cutting Tool

Product name	Article no.	Material	Dimensions	Packaging unit
Cutting Tool for Single-use Trays ① ② ③	LP-TCT-BG	Stainless steel 1.4305 (ASTM A314)	Outer: 230 x 340 mm Inner: 210 x 330 mm	10 pcs



The Lyoprotect® Cutting Tool is designed for cleanly opening Lyoprotect® Single-Use Trays and similar products. It ensures a precise cutting edge without generating particles.

Made of matte-finished, glass bead blasted stainless steel.

Barrier Pouch

Product name	Article no.	Material	Dimensions	Packaging unit
Barrier pouch 230x340 ①	BB2334-PETALPE	composite structure PET/AL/PE	Outer: 230 x 340 mm Inner: 210 x 330 mm	10 pcs
Barrier pouch 310x410 ②	BB3141-PETALPE	composite structure PET/AL/PE	Outer: 310 x 410 mm Inner: 290 x 400 mm	10 pcs
Barrier pouch 380x560 ③	BB3856-PETALPE	composite structure PET/AL/PE	Outer: 380 x 560 mm Inner: 360 x 550 mm	10 pcs

The aluminum barrier pouches are available in three sizes and are tailored to fit the Lyoprotect® Single-use Trays.

They protect the freeze-dried product from rehydration during storage when kept inside the tray. The open side of the barrier bag is joined with a heat-sealing device after the tray has been inserted into the bag.

- ① Fits with LPSU-T1522-FA0909
- ② Fits with LPSU-T2230-FA0909
- ③ Fits with LPSU-T3045-FA0909



Open Single-use Trays PP with Bag

T Lyoprotect® Single-use Trays are available in three sizes for filling volumes from 230 ml up to 2,800 ml (filling level 10–25 mm).

Combine with Lyoprotect® Bags for Bulk with Heat Sealing or Closing Stick for a closed barrier system.

Features

- » single-use
- » three sizes
- » combine with Lyoprotect® Bags



Open Trays PP, single-use

Product name	Article no.	Material	Volume	Dimensions	
1 Lyoprotect® Tray PP open 150 x 225 x 30 mm	LPSU-T15223	Polypropylene	230–570 ml	Width: Length: Height:	150 mm 225 mm 30 mm
2 Lyoprotect® Tray PP open 225 x 300 x 30 mm	LPSU-T22303	Polypropylene	500–1,300 ml	Width: Length: Height:	225 mm 300 mm 30 mm
3 Lyoprotect® Tray PP open 300 x 450 x 30 mm	LPSU-T30453	Polypropylene	1,100–2,800 ml	Width: Length: Height:	300 mm 450 mm 30 mm
				Minimum order: 10 pc	
Lyoprotect® Tray PP open (customizable size)	LPSU-Txxxxx	Polypropylene	Custom	Custom	
				Minimum order: 3.000 pc	

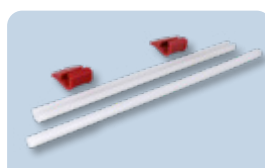
This product requires the following components:



Tray PP



Bag



Closing Stick



Bag with Heat Sealing

Components

Bag for Tray PP, single-use

Product name	Article no.	Material	Dimensions	Packaging unit
Lyoprotect® Bag 190 x 270 ^①	LPSU-Bag-19-27	ePTFE on PP non-woven backing, PP bottom film	190 x 270 mm	10 pcs
Lyoprotect® Bag 270 x 340 ^②	LPSU-Bag-27-34	ePTFE on PP non-woven backing, PP bottom film	270 x 340 mm	10 pcs
Lyoprotect® Bag 340 x 490 ^③	LPSU-Bag-34-49	ePTFE on PP non-woven backing, PP bottom film	340 x 490 mm	10 pcs

Closing Stick for Tray PP, multiple-use

Product name	Article no.	Material	Dimensions	Packaging unit
Lyoprotect® Closing Stick VS23 ^①	LPMU-Bag-VS23	HDPE	L profile: 230 mm L stick: 260 mm	2 pcs
Lyoprotect® Closing Stick VS31 ^②	LPMU-Bag-VS31	HDPE	L profile: 310 mm L stick: 340 mm	2 pcs
Lyoprotect® Closing Stick VS38 ^③	LPMU-Bag-VS38	HDPE	L profile: 380 mm L stick: 410 mm	2 pcs

Bag with Heat Sealing for Tray PP, single-use

Product name	Article no.	Material	Dimensions	Packaging unit
Lyoprotect® Bag 190 x 270 with Heat Sealing ^①	LPSU-Bag-19-27-HS6	ePTFE on PP non-woven backing, PP bottom film	190 x 270 mm + 60 mm heat seal	10 pcs
Lyoprotect® Bag 270 x 340 with Heat Sealing ^②	LPSU-Bag-27-34-HS6	ePTFE on PP non-woven backing, PP bottom film	270 x 340 mm +60 mm heat seal	10 pcs
Lyoprotect® Bag 340 x 490 with Heat Sealing ^③	LPSU-Bag-34-49-HS6	ePTFE on PP non-woven backing, PP bottom film	340 x 490 mm + 60 mm heat seal	10 pcs

^① Fits with LPSU-T15223

^② Fits with LPSU-T22303

^③ Fits with LPSU-T30453

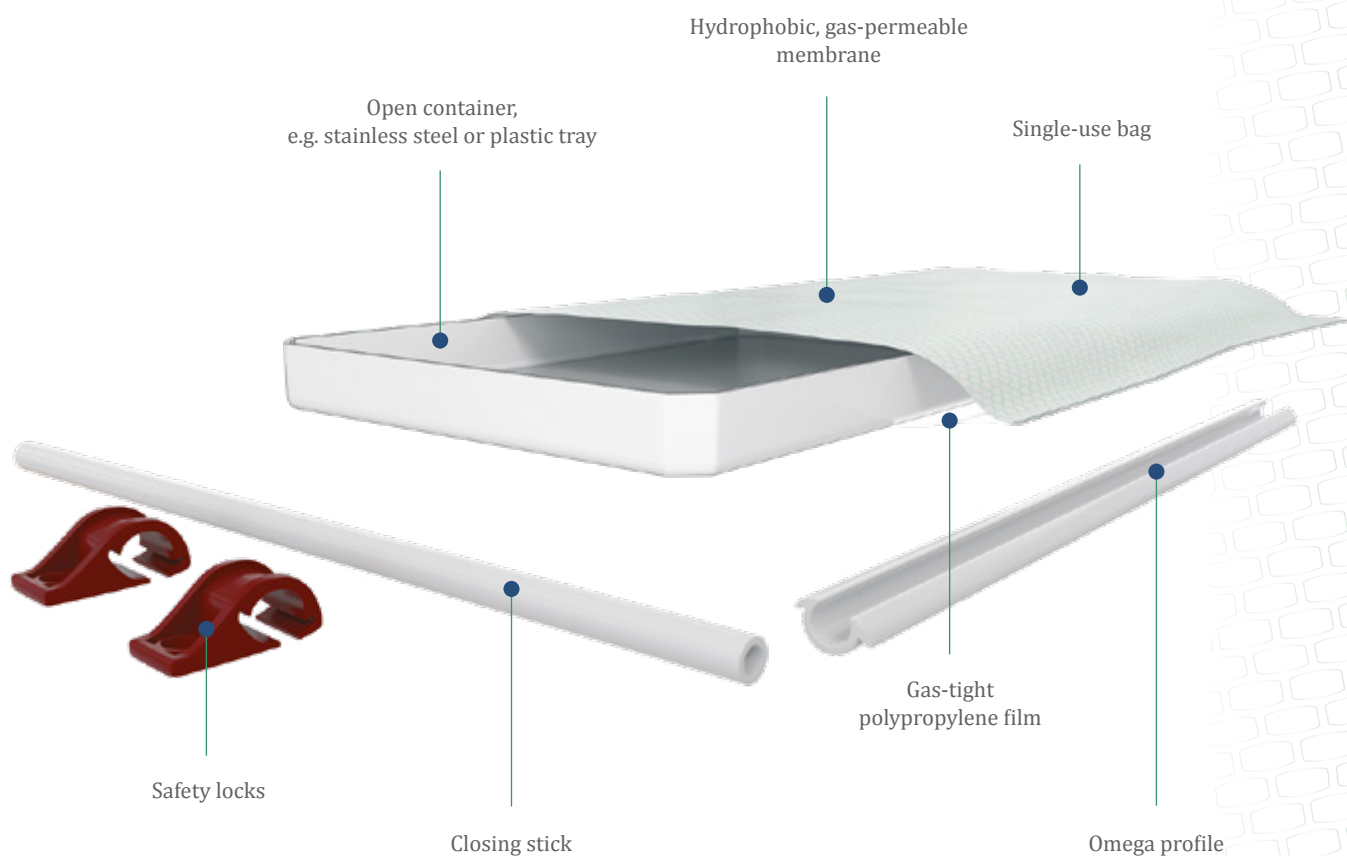


Single-use Bags for Bulk

Safely enclose any open container with a Lyoprotect® Bag for Bulk. The high-performance membrane ensures safe lyophilization without compromising the performance of the cycle.

Opt for a multiple-use closing system or choose a heat-sealing strip for flexible closure.

Lyoprotect® Bags and Closing Sticks can be sterilized in an autoclave at up to 121°C (250°F) for 20 minutes.



Bags for Bulk

The Lyoprotect® Bags for Bulk are a very flexible solution for bulk lyophilization without fly-out or contamination. They are customizable and can be combined with single-use or multiple-use trays.

Features

- » single-use
- » combine with single-use or multiple-use trays
- » closure with closing stick or heat-sealing strip
- » bespoke sizes
- » optional filler assembly



Bag for Bulk with Closing Stick, single-use

Product name	Article no.	Material	Dimensions
1 Lyoprotect® Single-use Bag (customizable size)	LPSU-Bag-xx-xx	ePTFE on PP non-woven backing, PP bottom film	Width: max. 660 mm Length: max. 900 mm Height: 1 mm
			Packaging unit: 10 pcs

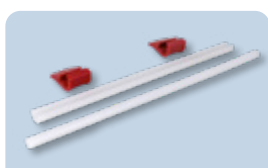
Bag for Bulk with Heat Sealing, single-use

Product name	Article no.	Material	Dimensions
2 Lyoprotect® Single-use Bag with Heat Sealing (customizable size)	LPSU-Bag-xx-xx-HS6	ePTFE on PP non-woven backing, PP bottom film and heat-sealing strip	Width: max. 660 mm Length: max. 900 mm Height: 1 mm heat-sealing strip length 60 mm as standard
			Packaging unit: 10 pcs

This product requires the following components:



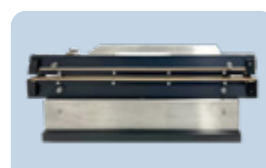
Bag



Closing Stick



Bag with Heat Sealing



Heat sealer (example)

Components

Closing Stick, multiple-use

Product name	Article no.	Material	Dimensions	Packaging unit
Closing Stick (customizable size) ^①	LPMU-Bag-VSxx	HDPE	max. 900 mm	2 pcs

Optional Filler Assembly

Product name	Article no.	Material	Dimensions	Packaging unit
Open Bag for Bulk with Filler Assembly* ^①	LPSU-BagFA-xx-xx-O (O= one side open)	PP	Opening: Ø 21.5 mm; suitable for tubes with approx. D _o ¾ inch or 20 mm	10 pcs
Open Bag for Bulk with heat sealing and Filler Assembly* ^②	LPSU-BagFA-xx-xx-HS6 (HS= heat-sealing strip on open side)	PP	Opening: Ø 21.5 mm; suitable for tubes with approx. D _o ¾ inch or 20 mm	10 pcs

* Height incl. filler assembly: 16 mm



Heat Sealer

Bags with a PP heat-sealing strip are joined with a heat-sealing device after the corresponding container has been inserted into the bag.

Example image for heat-sealing device (bar sealer)

- ^① Fits with LPSU-Bag-xx-xx
- ^② Fits with LPSU-Bag-xx-xx-HS6

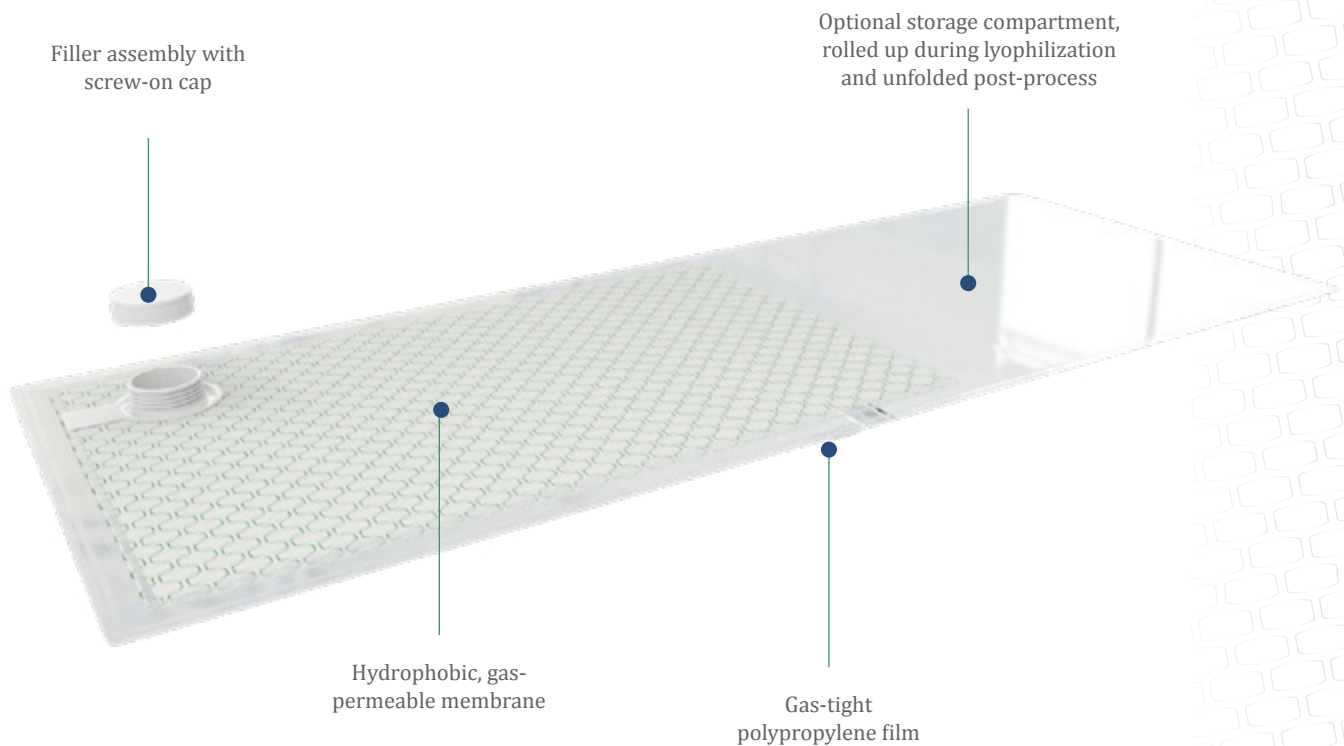


Single-use Bags for Direct Fill

Lyoprotect® Single-use Bags FA for Direct Fill are sealed on all sides and feature an integrated filler assembly on the upper side. They help maintain sterility throughout the process. Use the Bag FA with Storage to transfer the freeze-dried product directly into the designated compartment, and seal it for storage.

The small Bag DF is available in one size and does not include a filler assembly. It is ideal for handling small volumes in formulation and process development.

Lyoprotect® Bags can be sterilized in an autoclave at up to 121°C (250°F) for 20 minutes.



Bag FA for Direct Fill

Safely supported by the matching open tray, the Bag FA can be easily filled using a funnel or tube. Depending on the version, the freeze-dried product can either be poured directly into the integrated storage compartment or packed in a separate barrier pouch for storage or shipment.

Features

- » single-use
- » easy filling via funnel or tube
- » optional storage compartment
- » filler opening Ø 21.5 mm
- » only use with tray support

For more details about handling the Bag FA, please see the datasheet and operating instructions: <https://www.teclen.com/en/library/download>



Bag FA with Filler Assembly, single-use

Product name	Article no.	Material	Volume	Dimensions	
1 Bag FA	LPSU-BagFA-xx-xx	ePTFE on PP non-woven, PP bottom film	ca. 500–4,200 mm	Width:	max. 460 mm
				Length:	max. 900 mm
				Height:	16 mm
				Packaging unit: 10 pcs	

Bag FA with Filler Assembly and Storage Compartment, single-use

Product name	Article no.	Material	Volume	Dimensions	
2 Bag FA with Storage	LPSU-BagFA-xx-xx-Sx	ePTFE on PP non-woven, PP bottom film and storage compartment	ca. 500–2,530 mm	Width:	max. 460 mm
				Length:	max. 550 mm
				+ storage part	(max. 460 x 440 mm)
				Height:	16 mm
				Packaging unit: 10 pcs	

This product requires the following components:



Bag FA



Bag FA Storage



Tray



Barrier pouch (opt.)

Components

Open Tray, multiple-use

Product name	Article no.	Material	Dimensions	Minimum order
Open Tray Aluminum ¹ ²	LPMU-AX2740-AL	AlMg 4.5 Mn, black anodized	270 x 400 x 30 mm	2 pcs
Open Tray Stainless Steel ¹ ²	LPMU-OTxxxx-SS	Stainless steel 1.4404 (316L)	Custom	6 pcs



Optional Accessories

Barrier Pouch

Product name	Article no.	Material	Dimensions	Packaging unit
Barrier pouch ¹	BBxxxx-PETALPE	composite structure PET/AL/PE	Custom	10 pcs



- ¹ Fits with LPSU-BagFA-xx-xx
- ² Fits with LPSU-BagFA-xx-xx-Sx

Bag DF for Direct Fill

The small Bag DF, without a filler assembly, is ideal for formulation and process development. It is sealed with a closing stick and can hold volumes up to approximately 350 ml. If the freeze-dried product is to remain inside the bag for storage, it must be placed inside a barrier pouch to prevent rehumidification.

Features

» single-use

» direct fill

» for small volumes

» closing stick with omega profile and safety locks




Bag DF for Direct Fill, single-use

Product name	Article no.	Material	Dimensions	
1 Bag DF	LPSU-BagDF-13-25	ePTFE on PP non-woven backing material, PP bottom film	Width:	135 mm
			Length:	250 mm
			Thickness:	1 mm
			Packaging unit:	10 pcs




Lyoprotect® Bag DF in use in a laboratory freeze dryer, courtesy of Cilian AG

This product requires the following components:




Bag DF

+



Closing Stick

+



Barrier pouch (opt.)

Components

Closing Stick, multiple-use

Product name	Article no.	Material	Dimensions	Packaging unit
Closing Stick ¹	LPMU-Bag-VS17	HDPE	L profile: 170 mm L stick: 200 mm	2 pcs

Optional Accessories

Barrier Pouch

Product name	Article no.	Material	Dimensions	Packaging unit
Barrier pouch ¹	BBxxxx-PETALPE	composite structure PET/AL/PE	Custom	10 pcs



¹ Fits with LPSU-BagDF-13-25

Single-use Membranes

The Lyoprotect® Membrane is bacterial retentive, gas- and vapor-permeable and has excellent properties for lyophilization. The thin ePTFE (expanded polytetrafluoroethylene) membrane is laminated on a PP (polypropylene) non-woven backing material for stability. We can customize the Lyoprotect® Membrane to fit your specific requirements, in different sizes and with or without filler assembly.

Lyoprotect® Membranes, including the filler assembly, can be sterilized in an autoclave at up to 121°C (250°F) for 20 minutes.

Features

- » single-use
- » bespoke sizes for your application
- » optional filler assembly



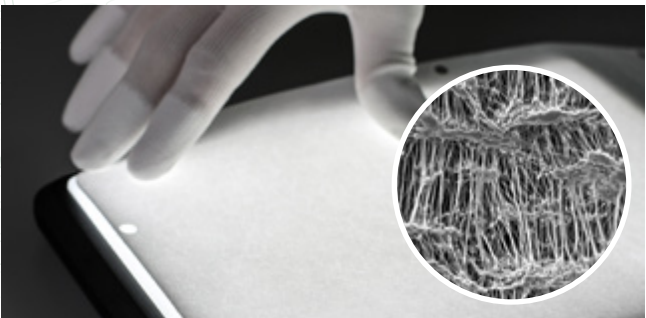
Customized Membrane*

Product name	Article no.	Material	Dimensions
Customized Membrane	LPCD-xxxx-M	ePTFE on PP non-woven backing material	Width: max. 600 mm Length: max. 1,000 mm
			Packaging unit: 10 pcs

Customized Membrane with Filler Assembly*

Product name	Article no.	Material	Dimensions
Customized Membrane with Filler Assembly	LPCD-xxxx-MFA	ePTFE on PP non-woven backing material, PP filler assembly	Width: max. 600 mm Length: max. 1,000 mm Height: 16 mm
			Filler opening: Ø 21.5 mm suitable for tubes with approx. D _o ¾ inch or 20 mm

* Membranes are also available 'ready to sterilize' or 'sterilized' upon request.



Lyoprotect® Membrane with 2000x magnification

Packaging unit: 10 pcs

Properties	Cup VXS	Cup VS	Stainless Steel Tray	Quick-Fix Tray	Open Tray	Single-use Tray	Bag FA	Bag FA-S	Membrane
	stainless steel	stainless steel	1622B	stainless steel	stainless steel*	T1522-FA	with filler assembly	with filler assembly	w/o filler assembly
			2740B		PP**	T2230-FA	with storage	with storage	with filler assembly
						T3045-FA	support required	support required	
Material	1.4404 (ANSI 316L)	1.4404 (ANSI 316L)	1.4404 (ANSI 316L)	1.4404 (ANSI 316L)	1.4404 (ANSI 316L)	ePTFE + PP	ePTFE + PP	ePTFE + PP	ePTFE
Filling volume	10–50 ml	30–150 ml	100–500 ml 400–2,100 ml max. 6,000 ml	400–2,750 ml	*indiv. sizes **see single-use tray	230–570 ml 500–1,300 ml 1,100–2,800 ml	indiv. sizes	indiv. sizes	
Customizable in size			✓	✓	✓	✓	✓	✓	✓
Multiple-use product	✓	✓	✓	✓	(✓)				
Sterilization methods									
Autoclaving	✓	✓	✓	✓	✓	✓	✓	✓	✓
Eto	✓	✓	✓	✓	✓	✓	✓	✓	✓
Handling									
Easy filling	●●	●●	●	●●●	●●	●●●	●●●	●●●	●●● ³⁾
Easy removal	●●	●●	●	●●	●●	●	●●	●●●	●●●
Robustness	●●●	●●●	●●●	●●●	●●	●●	●	●	●●
Functionality									
Sterile barrier	●●● ¹⁾	●●● ¹⁾	●●● ¹⁾	●●● ¹⁾	●●● ¹⁾	●●●	●●●	●●●	●●●
Preliminary freezing	●●●	●●●	●●●	●●●	●●	●●●	●●	●●	●●●
Storage	●	●	●	●	●	●	●●	●●●	●
Stackable (without rack)	●	●	●●●	●●●	●●●				
Performance									
Heat transfer shelf/container bottom	●●	●●	●●	●●	●●	●●	●●●	●●●	
Fast drying	●●●	●●●	●●●	●●●	●●	●●	●●●	●●●	●●●
Incoming goods inspection									
Endotoxine pre-sterilization					✓	✓	✓	✓	✓
Surface roughness	✓	✓	✓	✓	✓				
FTIR spectrometry						✓	✓	✓	✓
Lot release test									
Seam strength/tightness					✓	✓	✓	✓	
Tightness test			✓	✓		✓	✓	✓	
100 % control for visible particles	✓	✓	✓	✓	✓	✓	✓	✓	✓
Biocompatibility, food contact, pharmacopeia									
Food contact U.S. / EU	✓	✓	✓	✓	✓	✓	✓	✓	✓
TSE/BSE safe	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tests for sub-visible particles (SVP) acc. to USP 788; EP 2.9.19						✓	✓	✓	✓

● acceptable ● good ●● best ¹⁾ with bag/membrane ²⁾ with storage ³⁾ with filler assembly

All technical information and recommendations are based on our experiences and/or test results. They are given to the best of our knowledge, but do not state any liability by our company. Users are responsible for checking the suitability of the respective product for their specific application.



Lyoprotect 20260208-22

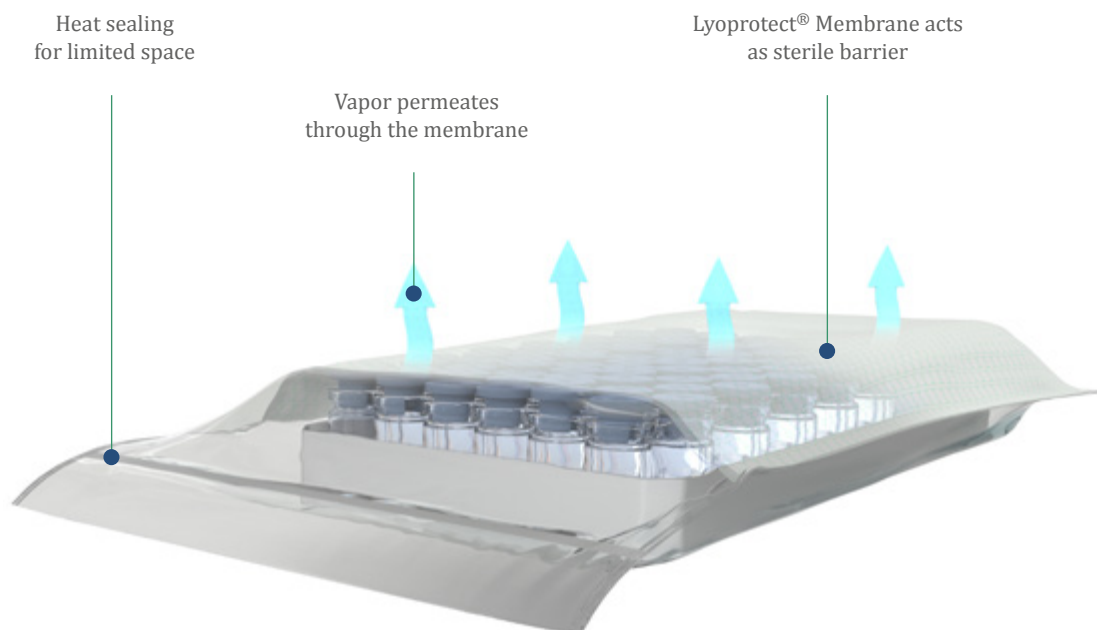
Lyoprotect 20260208-22

Single-use Bags for Vials

Lyoprotect® Single-use Bags for Vials are ideal for the lyophilization of sterile parenterals according to EU GMP Annex 1. Thanks to the sterile barrier function of the bag with its membrane upper side, freeze dryers without SIP (Sterilization In Place) can be used for lyophilization.

The Lyoprotect® Bag is a closed system, with the membrane upper side acting as a sterile barrier. After aseptic filling, the vials are placed inside the bag. The bag is then tightly closed, either via the heat-sealing strip or a closing stick. Afterwards, the enclosed vials can safely be moved.

Lyoprotect® Bags can be sterilized in an autoclave at up to 121°C (250°F) for 20 minutes. Bags for Vials are also available as “ready-to-sterilize” and sterilized versions.



Bags for Vials with Heat Sealing

Developed for sterile lyophilization processes, Lyoprotect® Bags for Vials feature an integrated PP heat-sealing strip for compact, secure closure. The ePTFE membrane upper side is vapor-permeable and acts as a sterile barrier, allowing safe sublimation while preventing contamination and fly-out.



Features

- » single-use
- » 60 mm heat-sealing strip
- » customizable size
- » max. 460 x 900 mm
- » CoA included

Bag with Heat Sealing, single-use

Product name	Article no.	Material	Dimensions	
1 Non-sterile Bag for Vials with Heat Sealing	LPGN-Bag-xx-xx-HS6	ePTFE on PP non-woven backing material, PP bottom film and heat-sealing PP film at the open side*	Width:	max. 460 mm
			Length:	max. 900 mm
			Height:	1 mm
2 Ready-to-sterilize Bag for Vials with Heat Sealing	LPGR-Bag-xx-xx-HS6	ePTFE on PP non-woven backing material, PP bottom film and heat-sealing PP film at the open side*	Width:	max. 460 mm
			Length:	max. 900 mm
			Height:	1 mm
3 Sterilized Bag for Vials with Heat Sealing	LPGS-Bag-xx-xx-HS6	ePTFE on PP non-woven backing material, PP bottom film and heat-sealing PP film at the open side*	Width:	max. 460 mm
			Length:	max. 900 mm
			Height:	1 mm

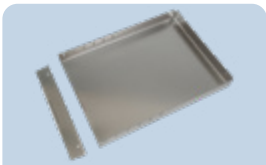
* Heat-sealing strip length 60 mm as standard

Packaging unit: 10 pcs

This product requires the following components:



Bag with Heat Sealing



Tray

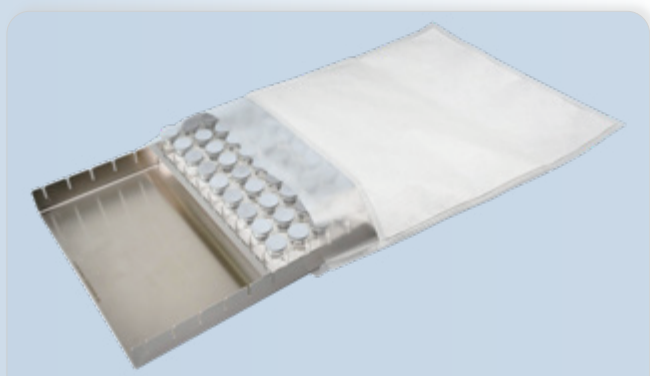


Heat sealer
(example)

Components

Open Stainless Steel Tray, slotted, multiple-use

Product name	Article no.	Material	Dimensions	Packaging unit
Open Stainless Steel Tray OTS2230, slotted ① ② ③	LPMU-OTS2230-SS	Stainless steel 1.4404 (316L)	220 x 300 x 30 mm	2 pcs
Open Stainless Steel Tray, slotted (customizable size) ① ② ③	LPMU-OTSxxxx-SS	Stainless steel 1.4404 (316L)	Custom	6 pcs



A Lyoprotect® Open Stainless Steel Tray OTS2230, slotted, is inserted into a Lyoprotect® Bag for Vials with Heat Sealing (LPGN-Bag-29-36-HS6).

Vials and stoppers shown in the image are not included in the scope of delivery.



Heat Sealer

Bags with a PP heat-sealing strip are joined with a heat-sealing device after the corresponding container has been inserted into the bag.

Example image for heat-sealing device (bar sealer)

- ① Fits with LPGN-Bag-xx-xx-HS6
- ② Fits with LPGR-Bag-xx-xx-HS6
- ③ Fits with LPGS-Bag-xx-xx-HS6

Bags for Vials with Closing Stick

Lyoprotect® Bags support sterile lyophilization processes by providing a closed, contamination-proof environment. Bags for Vials are also available with a reusable HDPE closing stick and safety clips, allowing fast and reliable closure. The ePTFE membrane upper side is vapor-permeable and acts as a sterile barrier, allowing safe sublimation while preventing contamination and fly-out.

Features

- » single-use
- » with closing stick
- » customizable size
- » max. 460 x 900 mm
- » CoA included



Bag with Closing Stick, single-use

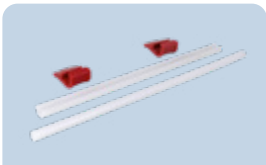
Product name	Article no.	Material	Dimensions	
1 Non-sterile Bag for Vials	LPGN-Bag-xx-xx	ePTFE on PP non-woven backing material, PP bottom film	Width:	max. 460 mm
			Length:	max. 900 mm
			Height:	1 mm
2 Ready-to-sterilize Bag for Vials	LPGR-Bag-xx-xx	ePTFE on PP non-woven backing material, PP bottom film	Width:	max. 460 mm
			Length:	max. 900 mm
			Height:	1 mm
3 Sterilized Bag for Vials	LPGS-Bag-xx-xx	ePTFE on PP non-woven backing material, PP bottom film	Width:	max. 460 mm
			Length:	max. 900 mm
			Height:	1 mm

Packaging unit: 10 pcs

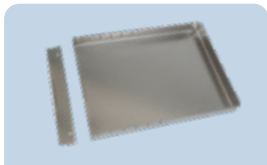
This product requires the following components:



Bag for Vials



Closing Stick



Tray

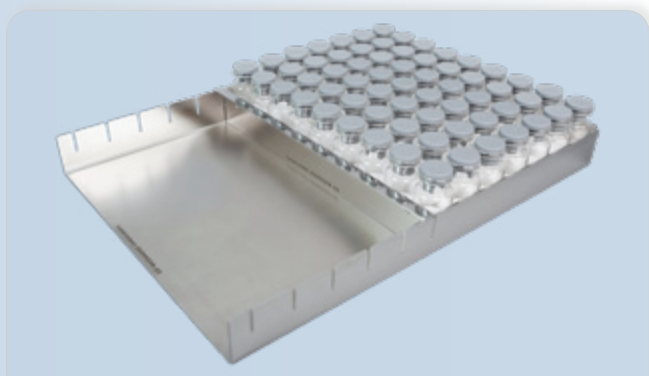
Components

Closing Stick, multiple-use

Product name	Article no.	Material	Dimensions	Packaging unit
Closing Stick (customizable size) ① ② ③	LPMU-Bag-VSxx	HDPE	max. 900 mm	2 pcs

Open Stainless Steel Tray, slotted, multiple-use

Product name	Article no.	Material	Dimensions	Packaging unit
Open Stainless Steel Tray OTS2230, slotted ① ② ③	LPMU-OTS2230-SS	Stainless steel 1.4404 (316L)	220 x 300 x 30 mm	2 pcs
Open Stainless Steel Tray, slotted (customizable size) ① ② ③	LPMU-OTSxxxx-SS	Stainless steel 1.4404 (316L)	Custom	6 pcs



Lyoprotect® Open Stainless Steel Tray OTS2230, slotted.

Vials and stoppers shown in the image are not included in the scope of delivery.

- ① Fits with LPGN-Bag-xx-xx
- ② Fits with LPGR-Bag-xx-xx
- ③ Fits with LPGS-Bag-xx-xx



Lyoprotect® Product Overview – Vials

Lyoprotect® – The key to safe lyophilization

Properties	Open Stainless Steel Tray, slotted	Open Aluminum Tray	Bag	Bag HS
Dimensions	electropolished 220 x 300 x 30 mm	black anodized 270 x 400 x 30 mm	max. 460 x 900 mm	max. 460 x 900 mm
Capacity (examples for vials acc. to ISO 8362)	e.g. 10R vials: 108–126 pcs	e.g. 10R vials: 176–209 pcs	2R–100R vials	2R–100R vials
Customizable in size	✓	✓	✓	✓
Multiple-use product	✓	✓		
Closing				
Closing system (multiple use)			✓	
Heat sealing				✓
Sterilization methods				
Autoclaving	✓	✓	✓	✓
Plasma sterilization	✓	✓	✓	✓
Sterile supply with SAL 10 ⁻⁶ (for bags with dimension 300 x 370 mm)			✓	✓
Handling				
Aseptic process in isolator / oRABS	✓	✓	✓	✓
Sterile bagging unit	✓			✓
Functionality				
Sterile barrier	✓ ¹⁾	✓ ¹⁾	✓	✓
Lyophilization cycle comparable to open vial	● ●	● ● ●	● ● ²⁾ / ● ● ● ³⁾	● ● ²⁾ / ● ● ● ³⁾
Performance				
Heat transfer shelf/container bottom	● ●	● ● ●	● ● ²⁾ / ● ● ● ³⁾	● ● ²⁾ / ● ● ● ³⁾
Fast drying	● ●	● ● ●	● ● ²⁾ / ● ● ● ³⁾	● ● ²⁾ / ● ● ● ³⁾
Incoming goods inspection				
Endotoxin pre-sterilization			✓	✓
FTIR spectrometry			✓	✓
Lot release test				
Seam strength/tightness			✓	✓
100 % control for visible particles	✓	✓	✓	✓
Biocompatibility, food contact, pharmacopeia				
Food contact U.S. / EU	✓	✓	✓	✓
TSE/BSE safe	✓	✓	✓	✓
Tests for sub-visible particles (SVP) acc. to USP 788; EP 2.9.19			✓	✓

● good ● ● best¹⁾ with bag/Bag HS²⁾ with stainless steel tray³⁾ with aluminum tray

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Quality is crucial and taken really seriously at Teclen®. Detailed information about Teclen's quality tests and measures can be found in the Validation Guide. The Teclen Quality Management System is ISO 9001 certified by TÜV Süd.



1. Visual & Material Inspections



100% visual inspection

- » We ensure that membrane and film are free of visual particles, nicks, pinholes or cuts.
- » For other components, we check e.g. for scratches and dimensional accuracy.



Receiving inspection of plastics with FTIR spectrometer

- » We use Fourier-transform infrared spectroscopy to verify the chemical composition of incoming plastic goods.



Full traceability

- » All articles can be traced by means of lot numbers or serial numbers with the help of our ERP system.

2. Material Safety & Compliance



BSE/TSE safe

- » We use materials that are free from the risk of contamination with agents associated with bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathies (TSE).



Compliance regarding food safety

- » Components comply with the regulations for materials and articles intended to come into contact with food according to (EC) No 1935/2004, (EU) No 10/2011 and (EC) No 2023/2006.



Receiving inspection of membrane with FTIR spectrometer

3. Particle & Microbial Load Testing



Single-use products fulfill requirements of USP 788 and EP 2.9.19

- » USP 788 and EP 2.9.19 are pharmacopeial standards related to particulate matter in injections. They define limits for particulate matter and particulate contamination. Even after cutting the membrane of a single-use tray, particles stay within the limits.



Abrasion resistance of membrane

- » A modified Gelbo-flex test proved that the Lyoprotect® Membrane does not emit any particulate matter through appropriate usage.



Endotoxin test

- » Test for bacterial endotoxins using Limulus-Amoebocyte-Lysate (LAL test) with Lyoprotect® Membrane.



Sterile Barrier functionality

- » "Microbial testing of Lyoprotect® with single-use membrane" by external laboratory acc. to test ASTM-F1608 (LRV \geq 6).



Seam strength test as part of lot release testing

4. Batch Control & Certificates



Lot release tests

- » Seam strength test and seam tightness test for bag integrity.



Serial number and inspection certificate 3.1 for stainless steel material

- » According to DIN EN 10204 3.1



Quality documentation with CoI, CoC and CoA

- » Certificate of Inspection, Certificate of Conformity and Certificate of Analysis available.



Simulating real conditions with our in-house freeze dryer

5. Validation & Origin



Validation Guide

- » Validation Guide Basic on request, free of charge.
- » Comprehensive Validation Guide Premium can be purchased (order no.: VAL-GUI-PR-xxx).



Extraction Study and Toxicological Assessment

- » This study analyzes extractables from the material used in Teclen Lyoprotect® Single-use Trays and Bags under conditions simulating their intended use. The results confirmed that all extractables were well below regulatory safety thresholds, verifying their safe use for pharmaceutical lyophilization.



Made in Germany

- » Products are manufactured in-house or at trusted partners within Germany.

The Teclen Team

Situated in the beautiful region of Bavaria, Germany, the Teclen Team takes immense pride in crafting most Lyoprotect® products in-house or, as needed, entrusting their creation to skilled partners within Germany.



Rolf Lenhardt

Director and founder
of Teclen GmbH



Carlos Amor

New Business Development &
Freeze-Drying Specialist



Carlos Castiblanco

Export Specialist &
Inside Sales



Marcelin Dränert

Inside Sales



Peggy Eisenhut

Quality Manager



Kerstin Lenhardt

Marketing & Documentation



Patrick Förster

Production, QA & Purchasing



Marion Weber

Accounting

“ We’re here to assist you in finding the optimal solution for your specific needs. ”

Contact:

Teclen GmbH

Münchener Str. 10
85667 Oberpframmern
Germany
www.teclen.com

Sales:

sales@teclen.com

Carlos Amor

Tel: +34 620 709 181
sales@teclen.com

Carlos Castiblanco

Tel: +49 8093 9048 894
sales@teclen.com

Marcelin Dränert

Tel: +49 170 1484 297
sales@teclen.com

Quality:

Peggy Eisenhut

Tel: +49 160 1473 506
quality@teclen.com

Imprint:

August 2025, V5.1

Publisher:

Teclen GmbH

Münchener Str. 10
85667 Oberpframmern
Germany

Design, layout, concept:

Britta Eriskat

Atelier für Gestaltung
www.eriskat.de

Technical illustrations:

Lorenz Mueller

default græy
www.defaultgrey.com

Photos:

Claudia Jungas Photography

Title page, pp. 8, 12, 18, 36, 46, 47, 48

All other photos:

Teclen GmbH



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