

Lyoprotect®

The key to safe lyophilization

» Product Catalog



Teclen® GmbH is a completely privately held company, which was founded by Rolf Lenhardt in 2016 with a very unique idea of designing and manufacturing containers for lyophilization of API (active pharmaceutical ingredients).

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



Anja Busch

Contact for sales
and any questions

» *Excellent consulting
is the essential thing.
Only if a product really
fits the customer's
requirements, I've done
a good job.* «

Phone: +49 170 1484 297
Email: sales@teclen.com

Rolf Lenhardt

Founder,
product development

» *Engineers love
technical challenges
– so don't hesitate to
ask for individual
solutions!* «

Email: info@teclen.com

Kerstin Lenhardt

Documentation and
marketing

» *Effective communica-
tion of the features and
benefits of our products
helps to make informed
decisions.* «

Content

About Teclen®	3
Lyoprotect® Membrane	5
Application	6
<i>Bulk API production</i>	6
<i>Freeze-drying in vials</i>	8
Lyoprotect® for Bulk	11
Multiple-use Cups	10
<i>Aluminum Cups</i>	12
<i>Stainless Steel Cups</i>	13
Multiple-use Trays	15
<i>Stainless Steel Trays</i>	17
<i>Aluminum Trays</i>	21
Single-use Trays	22
<i>Single-use Trays with Filler Assembly</i>	23
<i>Open Single-use Trays PP with Bag</i>	24
Single-use Bags	28
<i>Single-use Bags for Bulk</i>	29
<i>Single-use Bags FA for Direct Fill</i>	31
<i>Single-use Bag DF for Direct Fill</i>	33
Single-use Membranes	34
Lyoprotect® Product Overview – Bulk	35
Lyoprotect® for Vials	37
Single-use Bags	38
<i>Single-use Bags with Heat Sealing</i>	41
Lyoprotect® Product Overview – Vials	43
Lyoprotect® Quality Control	44
The Teclen Team	46
Contact, Imprint	47

Our key to safe lyophilization – the Lyoprotect® Membrane. During sublimation, the vapor can escape smoothly through the hydrophobic membrane.

Regular freeze-drying process parameters determined with an open container can be transferred and lead to the same drying results.

Material: *ePTFE – expanded polytetrafluoroethylene*

- » Naturally hydrophobic
- » Inert – low extractables

Membrane type: *bacterial retentive, gas- and vapor-permeable*

- » Freeze-drying tests showed the suitability for the application
- » Bacterial retentive in the application itself – Examination Report from SMP GmbH: „Microbial Barrier testing of Teclen® Lyoprotect® Cup with Lid equipped with Single-use Membrane“. Test report is available upon request.
- » Non-woven polypropylene backing
- » Ready to use with Lyoprotect® Cups and Trays
- » Upper side of the Lyoprotect® Single-use Trays
- » Top layer of the Lyoprotect® Bags
- » Available with filler assembly for trays and bags
- » Autoclavable

» *Our vision is to help you
concentrate on API or formulation
development and make the
lyophilization cycle more secure.* «

Application

Bulk API production

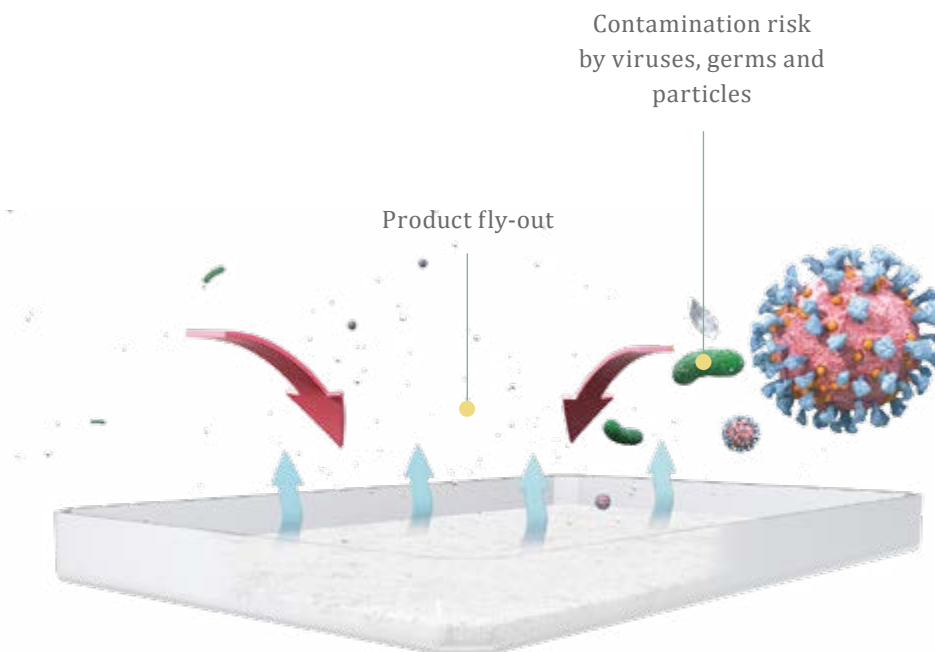
Our Lyoprotect® System will help you to produce safely and easily. Freeze-drying in an open container entails a few risks:

- » Fluffy dry powder flies out and generates product loss

- » Risk of contamination of your product with particles or airborne germs

- » During handling/removing the dry powder, 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-drier is required to handle different batches and to prevent cross contamination between different API products

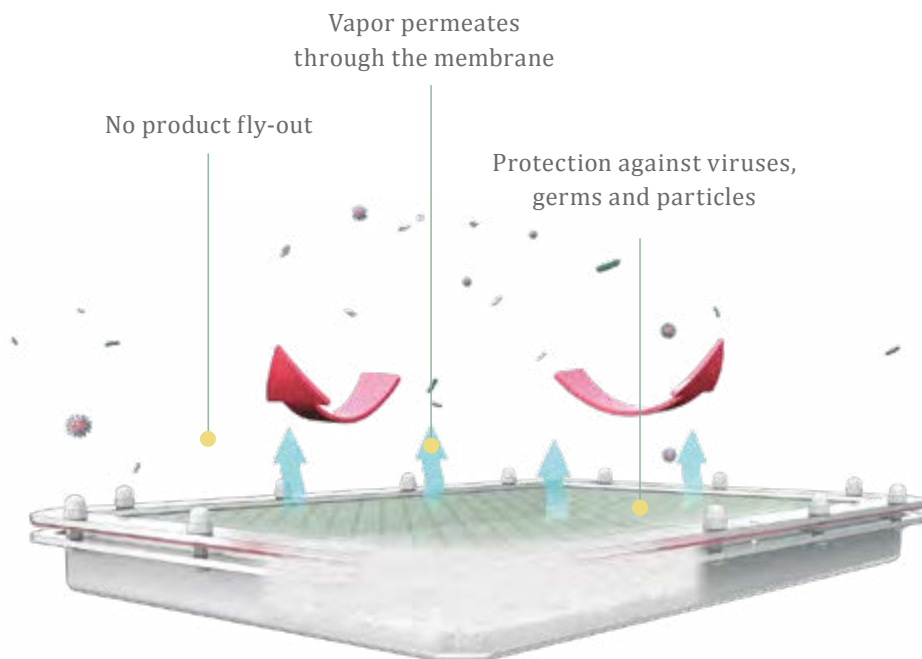


Problems with conventional methods

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-drier. The membrane acts as a sterile barrier and ensures optimum protection of your staff and product.



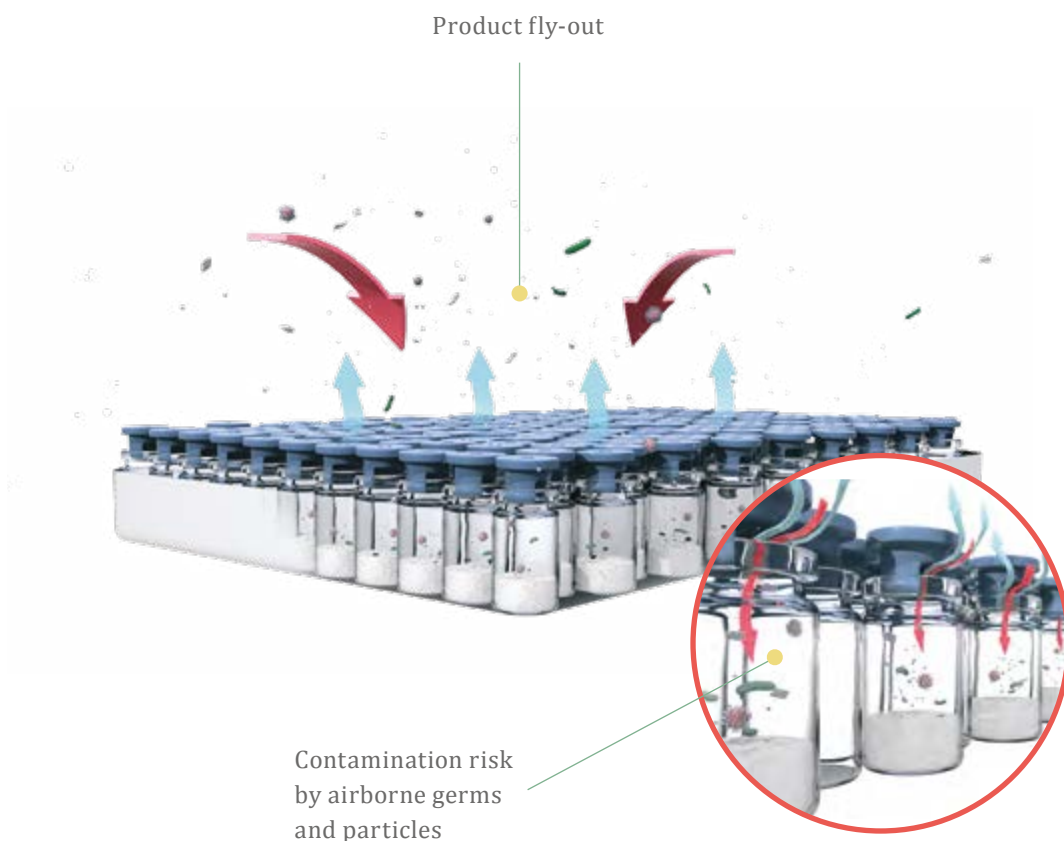
The Teclen® Lyoprotect® Solution

Application

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. These are preferably arranged in the middle of the frame, and the stoppers are in the drying position. Open space within the tray should be filled with empty vials. The bag is closed and secured with the closing stick or via an integrated heat-sealing strip.

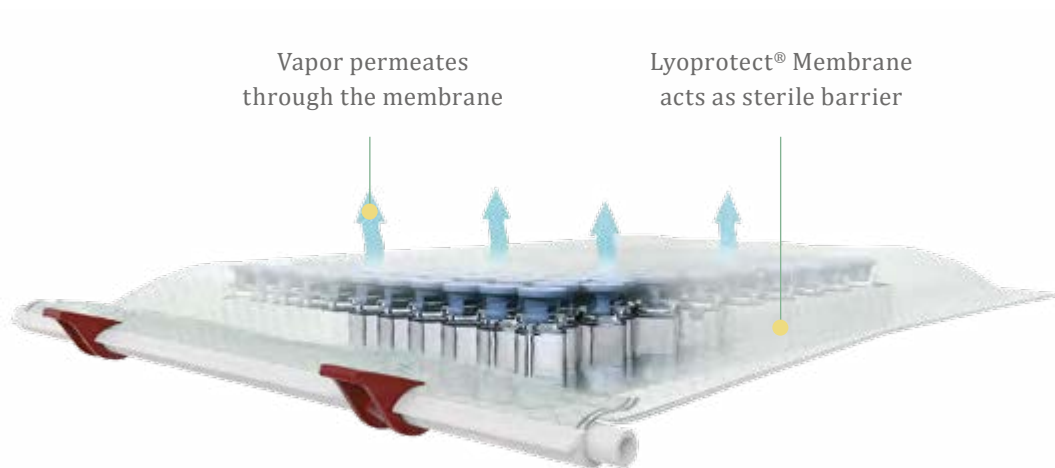


Problems with conventional methods

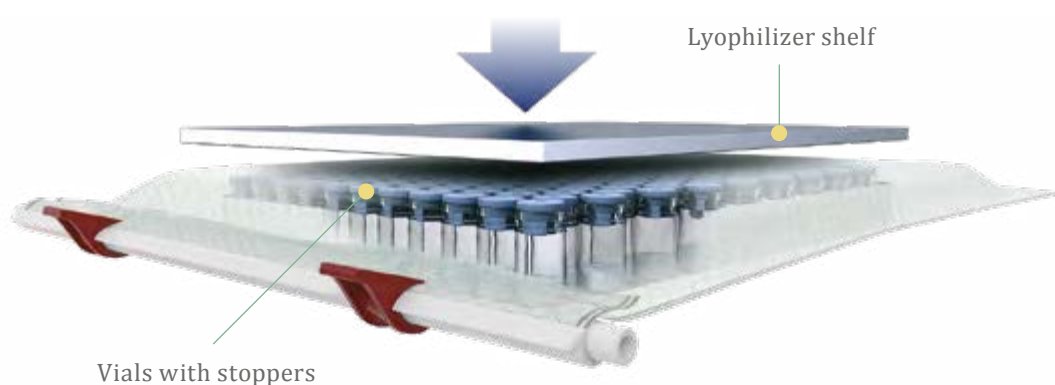
Application

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. 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-drier 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 is done within the freeze-drier 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

Stainless steel Cups S with engraved consecutive serial number. Perfect for an upscaling after Cups XS. More information about their application can be found in the Heraeus Case Study (Toxic Substances).

1201 - 07

20171201 - 08

20171201 - 09

- 12

20171201 - 13

20171201 - 14

17

20171201 - 18

20171201 - 19

20171201 - 22

20171201 - 23

Lyoprotect® for Bulk

The Teclen® Lyoprotect® Cups are designed for freeze-drying of pharmaceutical APIs (Active Pharmaceutical Ingredients). They are available in stainless steel or in aluminum (nonsensitive to shock and scratching, anodized surface).

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



Lyoprotect® for Bulk

Aluminum Cups

All cups require the Lyoprotect® Membrane and O-ring in order to work properly as barrier during lyophilization.

Cup XS Aluminum

LPMU-VXS-B

» multiple-use » with screw-on ring cover

Volume: 10–50 ml

Dimensions: Diameter: 52 mm
Ring cover: 58 mm
Height: 34 mm

Material: AlMg 4.5 Mn

Roughness: Ra ≤ 0.8 µm

Minimum order: 2 pcs



Membrane for Cup XS

LPMU-VXS-M

» single-use

Material: ePTFE on polypropylene non-woven backing material

Packaging unit: 10 pcs



O-ring for Cup XS

LPMU-VXS-OR

» multiple-use

Material: Silicone, 70 Shore A, 50 x 1.5 mm

Packaging unit: 2 and 5 pcs



O-ring FEP sheathed for Cup XS

LPMU-VXS-ORFEP

» multiple-use » FEP sheathing

Material: Silicone O-ring with FEP sheathing,
70 Shore A, 50 x 1.5 mm

Packaging unit: 2 pcs



Stainless Steel Cups

Cup XS Stainless Steel, polished

LPMU-VXS-BSmod

- » multiple-use » with screw-on ring cover
- » with inspection certificate 3.1
- » consecutive serial number » polished surface

Volume: 10–50 ml

Dimensions: Diameter: 52 mm
Ring cover: 58 mm
Height: 34 mm

Material: Stainless steel 1.4404 (316L)

Roughness: Ra < 0.4 µm

Minimum order: 2 pcs



Membrane for Cup XS

LPMU-VXS-M

- » single-use

Material: ePTFE on polypropylene non-woven backing material

Packaging unit: 10 pcs



O-ring for Cup XS

LPMU-VXS-OR

- » multiple-use

Material: Silicone, 70 Shore A, 50 x 1.5 mm

Packaging unit: 2 and 5 pcs



O-ring FEP sheathed for Cup XS

LPMU-VXS-ORFEP

- » multiple-use » FEP sheathing

Material: Silicone O-ring with FEP sheathing,
70 Shore A, 50 x 1.5 mm

Packaging unit: 2 pcs



Lyoprotect® for Bulk

Stainless Steel Cups

Cup S, polished

LPMU-VS-BS

- » multiple-use » with screw-on ring cover
- » with inspection certificate 3.1
- » consecutive serial number » polished surface

Volume: 30–150 ml

Dimensions: Diameter: 93 mm
Ring cover: 100 mm
Height: 34 mm

Material: Stainless steel 1.4404 (316L)

Roughness: Ra < 0.4 µm

Minimum order: 2 pcs



Membrane for Cup S

LPMU-VS-M

- » single-use

Material: ePTFE on polypropylene non-woven backing material

Packaging unit: 10 pcs



O-ring for Cup S

LPMU-VS-OR

- » multiple-use

Material: Silicone, 70 Shore A, 90 x 1.5 mm

Packaging unit: 2 and 5 pcs



O-ring FEP sheathed for Cup S

LPMU-VS-ORFEP

- » multiple-use
- » FEP sheathing

Material: Silicone O-ring with FEP sheathing,
70 Shore A, 90 x 1.5 mm

Packaging unit: 2 and 5 pcs



Multiple-use Trays

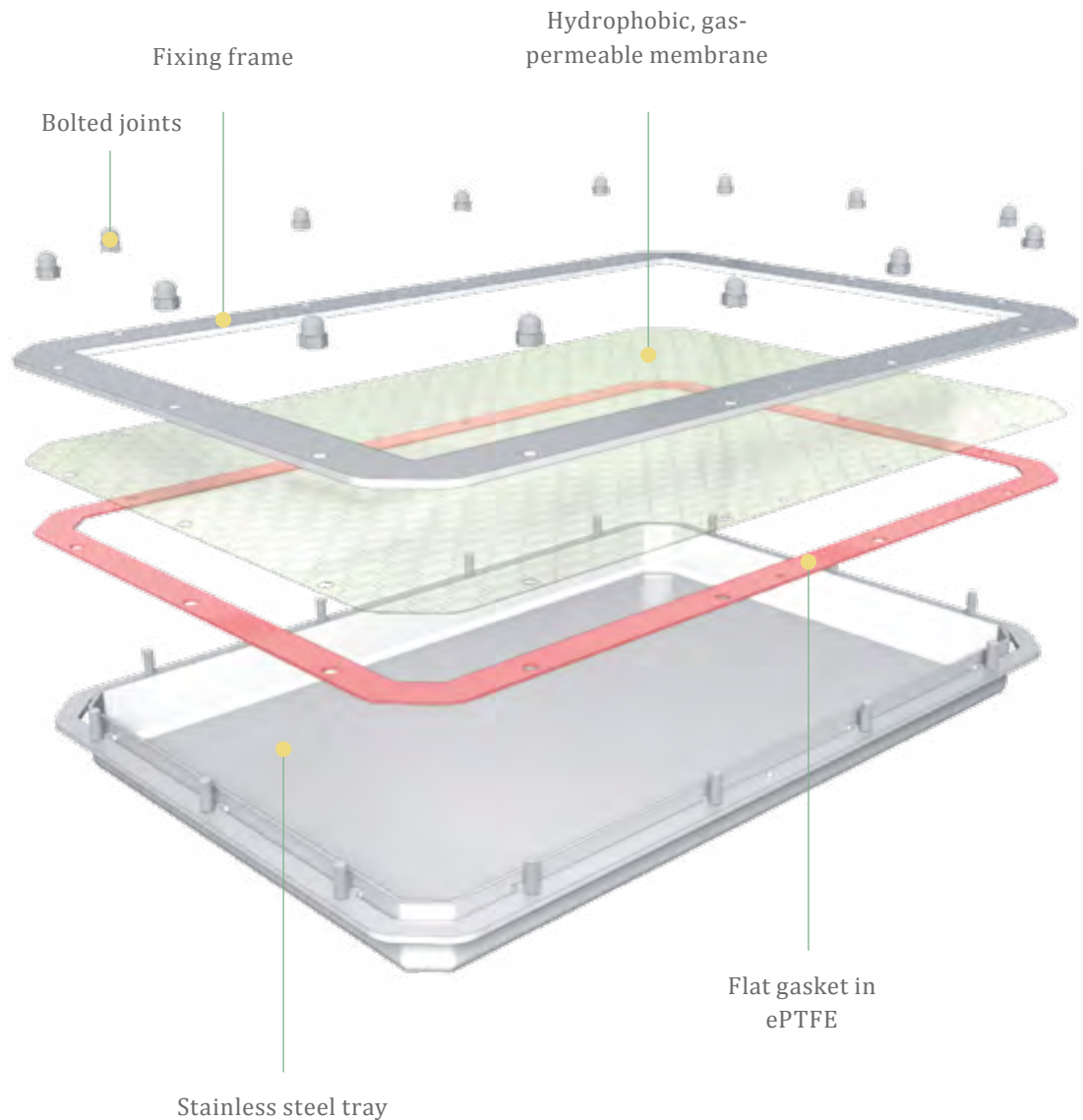
Stainless Steel Tray for bulk production of API. Laser-welded 45° corners facilitate residue-free cleaning.

Lyoprotect 20200403-03



Lyoprotect® for Bulk

The Teclen® Lyoprotect® Trays are designed for freeze-drying of pharmaceutical APIs (Active Pharmaceutical Ingredients). All trays require the Lyoprotect® Membrane and Gasket in order to work properly as barrier during lyophilization.



Stainless Steel Trays

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.

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

Stainless Steel Tray V1622B

LPMU-V1622B-WS

- » multiple-use » with fixing frame and bolted joints
- » with inspection certificate 3.1
- » consecutive serial number » polished surface

Volume: 100–500 ml

Dimensions: Width: 155 mm
Length: 224 mm
Height: 43 mm

Material: Stainless steel 1.4404 (316L)

Roughness: Ra < 0.4 µm

Minimum order: 2 pcs



Membrane for Stainless Steel Tray V1622B

LPMU-V1622B-M

- » single-use

Material: ePTFE on polypropylene non-woven backing material

Packaging unit: 10 pcs



Membrane with Filler Assembly for Tray V1622B

LPMU-V1622B-MFA

- » single-use

Membrane: ePTFE on polypropylene non-woven backing material

Filler assembly: PP (polypropylene), pharma grade, Ø 21.5 mm, with leakage-tight cap and non-slip retaining tab

Packaging unit: 2 pcs



Gasket for Stainless Steel Tray V1622B

LPMU-V1622B-FD

- » multiple-use

Material: ePTFE

Thickness: 1 mm

Packaging unit: 1, 2 and 5 pcs



Lyoprotect® for Bulk

Stainless Steel Trays

Stainless Steel Tray V2740B

LPMU-V2740B-WS

- » multiple-use » with fixing frame and bolted joints
- » with inspection certificate 3.1
- » consecutive serial number » polished surface

Volume: 400–1800 ml

Dimensions: Width: 270 mm
Length: 400 mm
Height: 43 mm

Material: Stainless steel 1.4404 (316L)

Roughness: Ra < 0.4 µm

Minimum order: 2 pcs



Membrane for Stainless Steel Tray V2740B

LPMU-V2740B-M

- » single-use

Material: ePTFE on polypropylene non-woven backing material

Packaging unit: 10 pcs



Membrane with Filler Assembly for Tray V2740B

LPMU-V2740B-MFA

- » single-use

Membrane: ePTFE on polypropylene non-woven backing material

Filler assembly: PP (polypropylene),
pharma grade, Ø 21.5 mm,
with leakage-tight cap and
non-slip retaining tab

Packaging unit: 2 pcs



Gasket for Stainless Steel Tray V2740B

LPMU-V2740B-FD

- » multiple-use

Material: ePTFE

Thickness: 1 mm

Packaging unit: 1, 2 and 5 pcs



Stainless Steel Trays

Stainless Steel Tray (customizable size)

LPMU-VXXXX-WS

- » multiple-use » with fixing frame and bolted joints
- » with inspection certificate 3.1
- » consecutive serial number » polished surface
- » customizable size

Volume: up to 6000 ml

Dimensions: Width: max. 500 mm
 Length: max. 700 mm
 Height: max. 53 mm

Material: Stainless steel 1.4404 (316L)

Roughness: Ra < 0.4 µm

Minimum order: 6 pcs



Membrane for Stainless Steel Tray (customizable size)

LPMU-VXXXX-M

- » single-use

Material: ePTFE on polypropylene non-woven backing material

Packaging unit: 10 pcs



Membrane with Filler Assembly for Stainless Steel Tray (customizable size)

LPMU-VXXXX-MFA

- » single-use

Membrane: ePTFE on polypropylene non-woven backing material

Filler assembly: PP (polypropylene),
 pharma grade, Ø 21.5 mm,
 with leakage-tight cap and
 non-slip retaining tab

Packaging unit: 2 pcs



Gasket for Stainless Steel Tray (customizable size)

LPMU-VXXXX-FD

- » multiple-use

Material: ePTFE

Thickness: 1 mm

Packaging unit: 1, 2 and 5 pcs



Multiple-use Trays

Aluminum Tray for bulk production of API. The excellent heat-transfer rate allows for fast drying.



Aluminum Trays

The Aluminum Tray is available in one size. In combination with the corresponding gasket and a Lyoprotect® Membrane you receive a closed container with a superior heat transfer performance.

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

Aluminum Tray Volume M

LPMU-VM-W

» multiple-use » with fixing frame and bolted joints

Volume: 100–500 ml

Dimensions: Width: 152 mm
Length: 216 mm
Height: 43 mm

Material: AlMg 4.5 Mn

Roughness: $Ra \leq 0.8 \mu m$

Minimum order: 2 pcs



Membrane for Aluminum Tray Volume M

LPMU-VM-M

» single-use

Material: ePTFE on polypropylene non-woven backing material

Packaging unit: 10 pcs



Membrane with Filler Assembly for Aluminum Tray Volume M

LPMU-VM-MFA

» single-use

Membrane: ePTFE on polypropylene non-woven backing material

Filler assembly: PP (polypropylene), pharma grade, Ø 21.5 mm, with leakage-tight cap and non-slip retaining tab

Packaging unit: 2 pcs



Gasket for Aluminum Tray Volume M

LPMU-VM-FDS

» multiple-use

Material: Silicone, 60 Shore A

Thickness: 1 mm

Packaging unit: 1, 2 and 5 pcs



Single-use Trays

Single-use Trays with Filler Assembly. Easy filling, no fly-out, no cross-contamination – ideal for bulk production of API.



Single-use Trays with Filler Assembly

The Lyoprotect® Single-use Trays with Filler Assembly combine simple handling with optimum protection of product and working environment.

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

Single-use Tray 1522 with Filler Assembly

LPSU-T1522-FA0909*

» single-use » easy filling via funnel or tube

Material: ePTFE membrane, PP tray, PP filler assembly

Volume: 230–570 ml

Dimensions: 150 x 225 x 50 mm incl. cap, edge height of tray 30 mm

Filler opening: Ø 21.5 mm,
suitable for tubes with approx. D_o ¾ inch or 20 mm

Packaging unit: 10 pcs

Also available: **Starter Kit Single-use Tray Small**, comprising 3 trays
LPSK-SUT-S



Single-use Tray 2230 with Filler Assembly

LPSU-T2230-FA0909*

» single-use » easy filling via funnel or tube

Material: ePTFE membrane, PP tray, PP filler assembly

Volume: 500–1,300 ml

Dimensions: 225 x 300 x 50 mm incl. cap, edge height of tray 30 mm

Filler opening: Ø 21.5 mm,
suitable for tubes with approx. D_o ¾ inch or 20 mm

Packaging unit: 10 pcs

Also available: **Starter Kit Single-use Tray Medium**, comprising 3 trays
LPSK-SUT-M



Single-use Tray 3045 with Filler Assembly

LPSU-T3045-FA0909*

» single-use » easy filling via funnel or tube

Material: ePTFE membrane, PP tray, PP filler assembly

Volume: 1,100–2,800 ml

Dimensions: 300 x 450 x 50 mm incl. cap, edge height of tray 30 mm

Filler opening: Ø 21.5 mm,
suitable for tubes with approx. D_o ¾ inch or 20 mm

Packaging unit: 10 pcs

Also available: **Starter Kit Single-use Tray Large**, comprising 3 trays
LPSK-SUT-L



Starter Kit Single-use Tray Mixed

LPSK-SUT-Mix

» comprises three trays, one of each type: Single-use Tray 1522, 2230, 3045

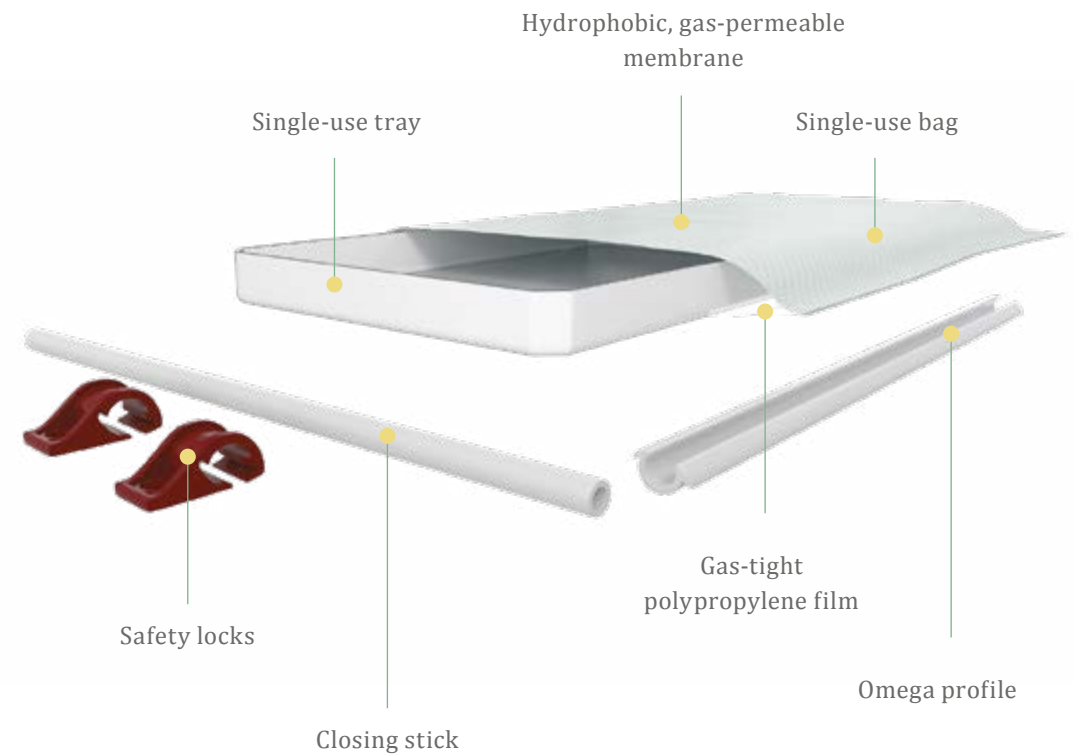
* The last 4 digits reflect the position of the filler assembly and the orientation of the retaining tab. Individual solutions possible upon request.

Lyoprotect® for Bulk

Open Single-use Trays PP with Bag

The open Lyoprotect® Tray PP for single use is ideal for freeze-drying of Active Pharmaceutical Ingredients (APIs) in bulk. The tray needs to be disposed after use and no cleaning costs arise.

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



Open Single-use Tray PP with Bag

Tray PP open 150 x 225 x 30 mm

LPSU-T15223

» single-use

Material: Polypropylene

Volume: 230–570 ml

Dimensions: Width: 150 mm
Length: 225 mm
Height: 30 mm

Packaging unit: 10 pcs



Bag 19 x 27

LPSU-Bag-19-27

» single-use » applicable tray dimensions 150 x 225 x 30 mm

Material: ePTFE on polypropylene non-woven backing material,
bottom film in polypropylene

Packaging unit: 10 pcs



Closing Stick VS23

LPMU-Bag-VS23

» multiple-use » with Omega profile and safety locks
» applicable for closing the Lyoprotect® Single-use Bag 19 x 27

Material: HDPE

Length: 230 mm

Packaging unit: 2 pcs

Also available: **Starter Kit**, comprising 3 Bags,
3 open Single-use Trays PP and 1 Closing Stick



Lyoprotect® for Bulk

Open Single-use Tray PP with Bag

Tray PP open 225 x 300 x 30 mm

LPSU-T22303

» single-use

Material: Polypropylene

Volume: 500–1,300 ml

Dimensions: Width: 225 mm

Length: 300 mm

Height: 30 mm

Packaging unit: 10 pcs



Bag 27 x 34

LPSU-Bag-27-34

» single-use

» applicable tray dimensions 225 x 300 x 30 mm

Material: ePTFE on polypropylene non-woven backing material,
bottom film in polypropylene

Packaging unit: 10 pcs



Closing Stick VS31

LPMU-Bag-VS31

» multiple-use » with Omega profile and safety locks

» applicable for closing the Lyoprotect® Single-use Bag 27 x 34

Material: HDPE

Length: 310 mm

Packaging unit: 2 pcs

Also available: **Starter Kit**, comprising 3 Bags,
3 open Single-use Trays PP and 1 Closing Stick



Open Single-use Tray PP with Bag

Tray PP open 300 x 450 x 30 mm

LPSU-T30453

» single-use

Material: Polypropylene

Volume: 1,100–2,800 ml

Dimensions: Width: 300 mm
Length: 450 mm
Height: 30 mm

Packaging unit: 10 pcs



Bag 34 x 49

LPSU-Bag-34-49

» single-use » applicable tray dimensions 300 x 450 x 30 mm

Material: ePTFE on polypropylene non-woven backing material,
bottom film in polypropylene

Packaging unit: 10 pcs



Closing Stick VS38

LPMU-Bag-VS38

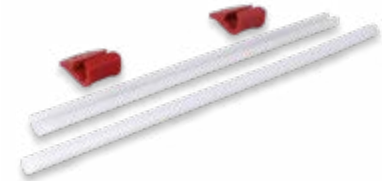
» multiple-use » with Omega profile and safety locks
» applicable for closing the Lyoprotect® Single-use Bag 34 x 49

Material: HDPE

Length: 310 mm

Packaging unit: 2 pcs

Also available: **Starter Kit**, comprising 3 Bags,
3 open Single-use Trays PP and 1 Closing Stick



Tray PP open (customizable size)

LPSU-Txxxxx

» single-use

Material: Polypropylene

Dimensions: customizable

Minimum order: 3000 pcs



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.



Single-use 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.

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

Bags for Bulk

LPSU-Bag-xx-xx

- » single-use » combine with single-use or multiple-use trays
- » closure with Closing Stick » bespoke sizes

Material: ePTFE on polypropylene
non-woven backing material,
PP bottom film

Filling volume*: ca. 500–5,000 ml

Dimensions: customizable

Packaging unit: 10 pcs



Closing Stick

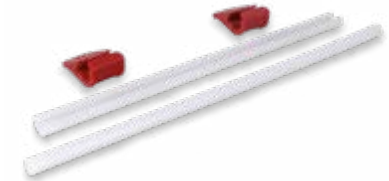
LPMU-Bag-VSxx

- » multiple-use » stick with omega counterpart and safety locks

Material: HDPE

Length: max. 900 mm

Packaging unit: 2 pcs



Bags for Bulk with Heat-sealing Strip

LPSU-Bag-xx-xx-HSx

- » single-use » combine with single-use or multiple-use trays
- » closure by heat sealing » bespoke sizes

Material: ePTFE on polypropylene
non-woven backing material,
PP bottom film and heat-sealing strip

Filling volume*: ca. 500–5,000 ml

Dimensions: max. 460 x 900 mm

Heat-sealing strip: length 60 mm as standard

Packaging unit: 10 pcs



* Height 1 cm, mean value
xx = width or length in cm

Bags FA for Direct Fill

Safely supported by the open tray, the Bag FA can easily be filled via the filler assembly by means of a funnel or tube. Available with or without storage compartment.



Single-use Bags FA for Direct Fill

Lyoprotect® Single-use Bags FA for Direct Fill help to 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.

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

Bag FA with Filler Assembly

LPSU-BagFA-xx-xx

» single-use » easy filling via funnel or tube

Material: ePTFE on polypropylene
non-woven backing material,
PP bottom film and filler assembly

Filling volume*: ca. 500–4,200 ml

Dimensions: max. 460 x 920 mm

Filler opening: Ø 21.5 mm, suitable for tubes with approx. D_o ¾ inch
or 20 mm

Packaging unit: 10 pcs



Bag FA with Filler Assembly and Storage

LPSU-BagFA-xx-xx-Sxx

» single-use » easy filling via funnel or tube » storage compartment

Material: ePTFE on polypropylene
non-woven backing material, PP bottom film,
storage compartment and filler assembly

Filling volume*: ca. 500–4,200 ml

Dimensions: max. 460 x 920 mm

Storage part: 30 cm length as standard

Filler opening: Ø 21.5 mm, suitable for tubes with approx. D_o ¾ inch
or 20 mm

Included: 1 PP clip band per bag to wind up storage compartment

Packaging unit: 10 pcs



Open Aluminum Tray AX2740

LPMU-AX2740-AL

» multiple-use » support for vials and bags, corners not welded
» perfect size to support bag with dimensions 250 x 380 mm

Material: AlMg 4.5 Mn, black anodized

Dimensions: 270 x 400 x 30 mm

Packaging unit: 2 pcs



* Height 1 cm, mean value
xx = width or length in cm

Lyoprotect® for Bulk

Single-use Bags FA for Direct Fill

Bag FA – Starter Kit

LPSK-BagFA-25-38

- » contains three Lyoprotect® Bags FA
- » plus one Open Aluminum Tray AX2740

Filling volume*: 950 ml

Bag dimensions: 250 x 380 mm

Tray dimensions: 270 x 400 x 30 mm

Packaging unit: 3 bags, 1 tray



Bag FA with Storage – Starter Kit

LPSK-BagFA-25-38-S30

- » contains three Lyoprotect® Bags FA with Storage and clip bands
- » plus one Open Aluminum Tray AX2740

Filling volume*: 950 ml

Bag dimensions: 250 x 380 mm plus 30 cm storage compartment

Tray dimensions: 270 x 400 x 30 mm

Packaging unit: 3 bags, 3 clip bands, 1 tray



* Height 1 cm, mean value

Single-use Bag DF for Direct Fill

Bag Direct Fill

LPSU-BagDF-13-25

» single-use » direct fill » dimension 135 x 250 mm

Material: ePTFE on polypropylene
non-woven backing material,
bottom film in polypropylene

Thickness: 1 mm

Packaging unit: 10 pcs



Closing Stick

LPMU-Bag-VS17

» multiple-use » with Omega profile and safety locks

Material: HDPE

Length: 170 mm

Packaging unit: 2 pcs



Bag Direct Fill – Starter Kit S

LPSK-Small-DF

» contains a set of three Lyoprotect® Single-use Bags for Direct Fill
» in max. dimensions 135 x 250 mm
» plus one corresponding closing stick (multiple-use)

Material: ePTFE on polypropylene
non-woven backing material,
bottom film in polypropylene

Packaging unit: 3 bags, 1 closing stick



Lyoprotect® for Bulk

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 by up to 121°C (250°F) for 20 minutes. EtO sterilization is also possible.

Customized Membrane

LPCD-xxxx-M

» single-use » bespoke sizes for your application

Material: ePTFE on PP non-woven backing material

Dimensions: max. 600 x 1,000 mm

Packaging unit: 10 pcs



Customized Membrane with Filler Assembly

LPCD-xxxx-MFA

» single-use » with filler assembly

» bespoke sizes for your application

Material: ePTFE on PP non-woven backing material,
PP filler assembly

Dimensions: max. 600 x 1,000 mm

Filler opening: Ø 21.5 mm, suitable for tubes with
approx. D_o ¾ inch or 20 mm

Packaging unit: 10 pcs



xx = width or length in cm

Lyoprotect® Product Overview – Bulk

Properties	Cup VXS	Cup VS	Stainless Steel Tray	Aluminum Tray	Open Tray	Single-use Tray	Bag FA	Bag FA-S	Membrane
	stainless steel	stainless steel	1622B	VM	stainless steel*	T1522-FA	with filler assembly	with filler assembly	w/o filler assembly
	aluminum		2740B		PP**	T2230-FA		with storage	with filler assembly
						T3045-FA	support required	support required	
Material	1.4404 (ANSI 316L) AlMg 4,5 MN	1.4404 (ANSI 316L)	1.4404 (ANSI 316L)	AlMg 4,5 MN	1.4404 (ANSI 316L) PP	ePTFE + PP	ePTFE + PP	ePTFE + PP	ePTFE
Filling volume	10–50 ml	30–150 ml	100–500 ml 400–1,800 ml max. 6,000 ml	100–500 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						on request	✓	✓	✓

● 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.

Single-use Bags

A tray containing vials is placed into the Lyoprotect® Bag.

After freeze-drying, the vials are securely closed by pushing in the stoppers within the bag.

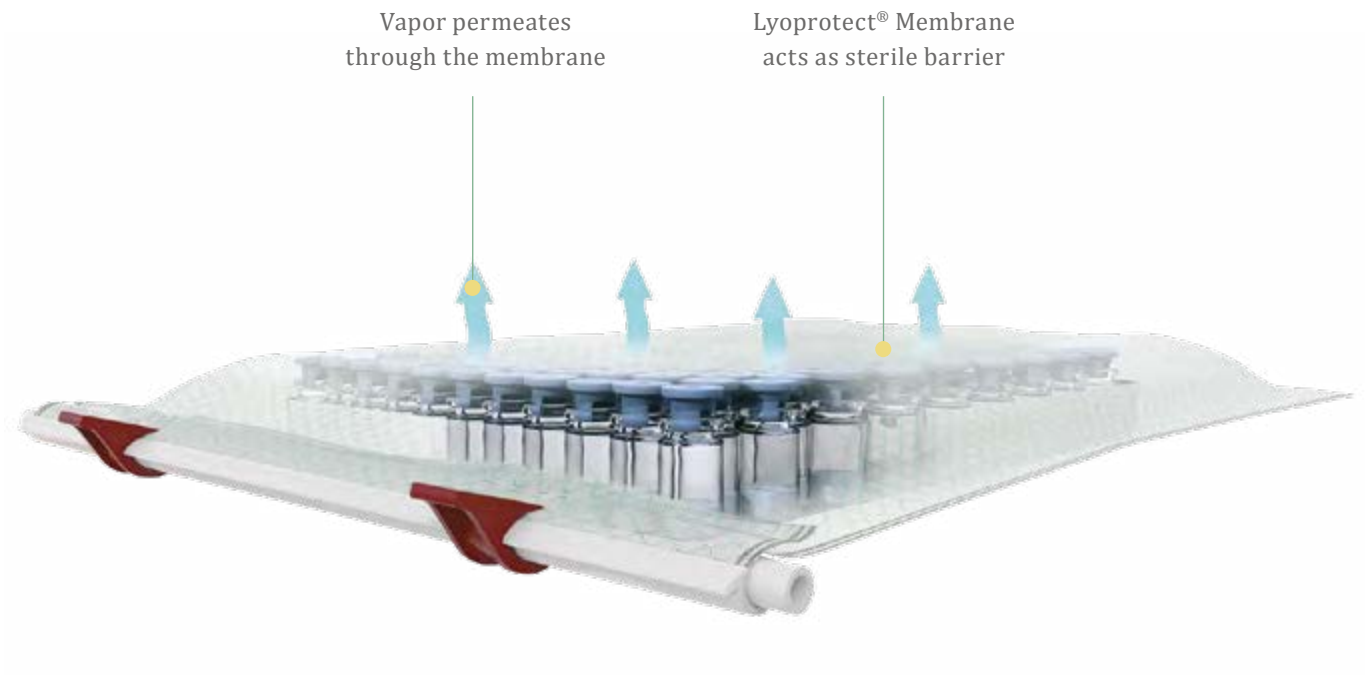


Lyoprotect® for Vials

L yoprotect® Single-use Bags consist of a smooth vapor-permeable ePTFE (expanded polytetrafluoroethylene) membrane facing the product, laminated with spunbonded polypropylene non-woven for strength. The bottom side of the bag is a gas-tight polypropylene film.

Both layers are welded together, and the open side is either locked with our Closing Stick (regular bags) or is heat-sealed (Bags HS). The bag dimensions are customizable and can be adjusted to a given tray size.

Lyoprotect® Bags and the Closing Sticks can be sterilized in an autoclave by up to 121°C (250°F) for 20 minutes. See Sterilization Recommendation for Lyoprotect® Bag and Closing Stick for more details.



Lyoprotect® for Vials

Single-use Bags

Bag 340 x 470

LPSU-Bag-34-47

- » single-use
- » applicable tray dimensions 270 x 400 x 30 mm
- » e.g. for 6R and 10R vials acc. to ISO 8362

Material: ePTFE on polypropylene
non-woven backing material,
bottom film in polypropylene

Packaging unit: 10 pcs



Closing Stick VS38

LPMU-Bag-VS38

- » multiple-use » with Omega profile and safety locks
- » applicable for closing the Lyoprotect® Single-use Bag 340 x 470

Material: HDPE

Length: 380 mm

Packaging unit: 2 pcs



Open Aluminum Tray AX2740

LPMU-AX2740-AL

- » multiple-use
- » support for vials and bags, corners not welded
- » perfect size to go inside bag with dimensions 340 x 470 mm

Material: AlMg 4.5 Mn, black anodized

Dimensions: 270 x 400 x 30 mm

Packaging unit: 2 pcs



Single-use Bags

Bag (customizable size)

LPSU-Bag-xx-xx

- » single-use » customizable size » max. 460 x 900 mm
- » applicable to customer's tray dimensions
- » e.g. for 6R and 10R vials acc. to ISO 8362

Material: ePTFE on polypropylene
non-woven backing material,
bottom film in polypropylene



Packaging unit: 10 pcs

Closing Stick (customizable size)

LPMU-Bag-VSxx

- » multiple-use » with Omega profile and safety locks
- » applicable for closing the Lyoprotect® Single-use Bag (dimension max. 900 mm)

Material: HDPE

Length: max. 900 mm

Packaging unit: 2 pcs



Open Aluminum Tray (customizable size)

LPMU-AXxxxx-AL

- » multiple-use
- » for vials and bags, not for bulk (corners not welded)
- » customizable size

Material: AlMg 4.5 Mn, black anodized

Dimensions: max. 350 x 450 x 50 mm

Packaging unit: 10 pcs



Lyoprotect® for Vials

Starter Kit S

LPSK-Small

- » contains a set of three Lyoprotect® Single-use Bags
- » in dimensions from 250 x 250 mm to 300 x 400 mm
- » plus one corresponding closing stick (multiple-use)

Material: ePTFE on polypropylene
non-woven backing material,
bottom film in polypropylene

Packaging unit: 3 bags, 1 closing stick



Starter Kit M

LPSK-Medium

- » contains a set of three Lyoprotect® Single-use Bags
- » in dimensions from 300 x 400 mm to 400 x 500 mm
- » plus one corresponding closing stick (multiple-use)

Material: ePTFE on polypropylene
non-woven backing material,
bottom film in polypropylene

Packaging unit: 3 bags, 1 closing stick



Starter Kit L

LPSK-Large

- » contains a set of three Lyoprotect® Single-use Bags
- » in dimensions from 400 x 500 mm to 800 x 800 mm
- » plus one corresponding closing stick (multiple-use)

Material: ePTFE on polypropylene
non-woven backing material,
bottom film in polypropylene

Packaging unit: 3 bags, 1 closing stick

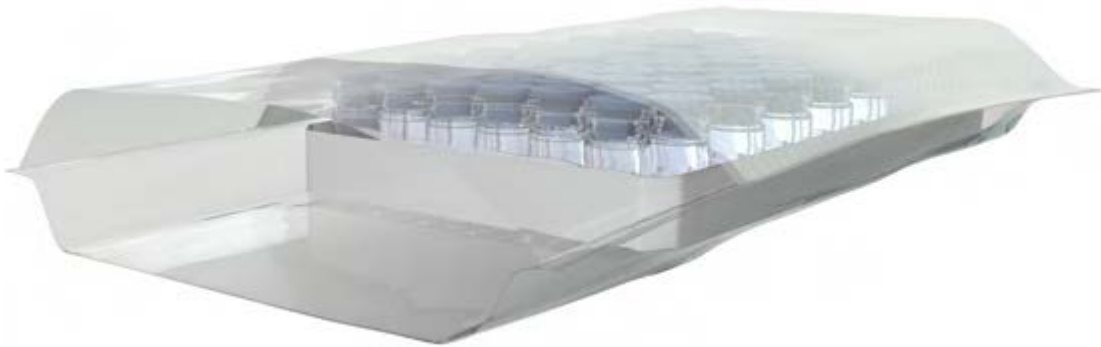


Single-use Bags with Heat Sealing

Lyoprotect® Single-use Bags with Heat Sealing differ from the regular Lyoprotect® Single-use Bags by their closing method. The open side of the bag is elongated by a 60 mm strip of PP (polypropylene) film, which has been welded to the ePTFE membrane and PP bottom of the bag.

Instead of using a closing stick, the PP film at the open side is heat-sealed by means of a heat sealer. This can be helpful if space is limited in the freeze-drier and you seek a more flexible solution.

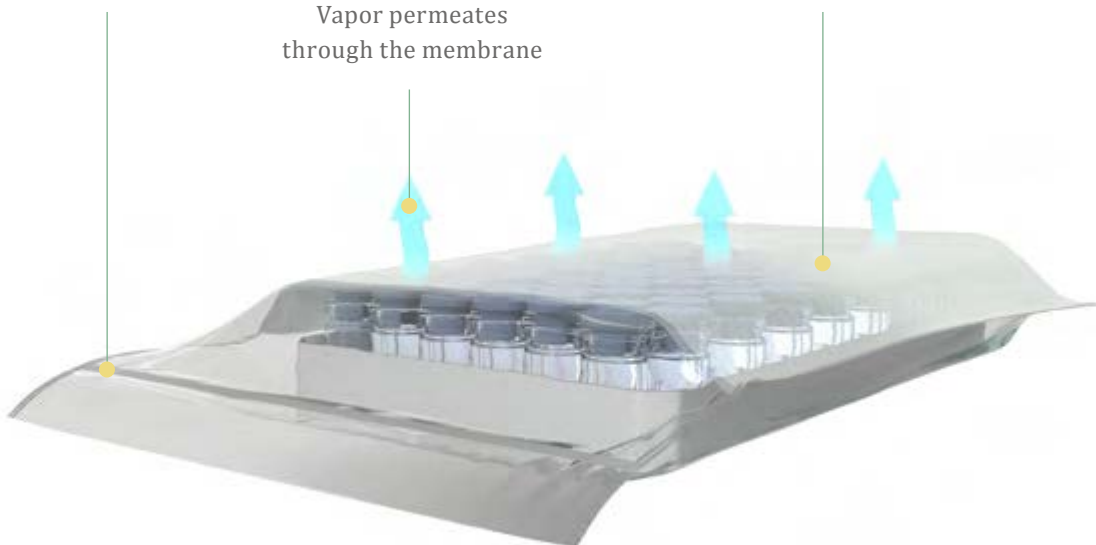
Lyoprotect® Bags can be sterilized in an autoclave by up to 121°C (250°F) for 20 minutes. See Sterilization Recommendation for Lyoprotect® Bag and Closing Stick for more details.



Heat sealing
for limited space

Lyoprotect® Membrane
acts as sterile barrier

Vapor permeates
through the membrane



Lyoprotect® for Vials

Bag with Heat Sealing (customizable size)

LPSU-Bag-xx-xx-HS6

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

Material: ePTFE on polypropylene non-woven backing material, PP bottom film and heat-sealing PP film at the open side

Packaging unit: 10 pcs



Bag with Heat Sealing – Starter Kit

LPSK-xx-xx-HS6

- » contains a set of three Lyoprotect® Single-use Bags with Heat Sealing
- » max. 460 x 900 mm » 60 mm heat-sealing strip

Material: ePTFE on polypropylene non-woven backing material, PP bottom film and heat-sealing PP film at the open side

Packaging unit: 3 pcs



Lyoprotect® Product Overview – Vials

Properties	Open Stainless Steel Tray	Open Aluminum Tray	Bag	Bag HS
	electropolished	black anodized		
Dimensions	225 x 300 x 30 mm	270 x 400 x 30 mm	max. 460 x 900 mm	max. 460 x 900 mm
Capacity (examples for vials acc. to ISO 8362)	10R vials: 108–126 pcs	10R vials: 176–209 pcs	for 6R and 10R vials	for 6R and 10R 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 under laminar flow	✓	✓	✓	✓
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			on request	on request

●● good ●●● best ¹⁾ with bag/Bag HS ²⁾ with stainless steel tray ³⁾ with aluminum tray

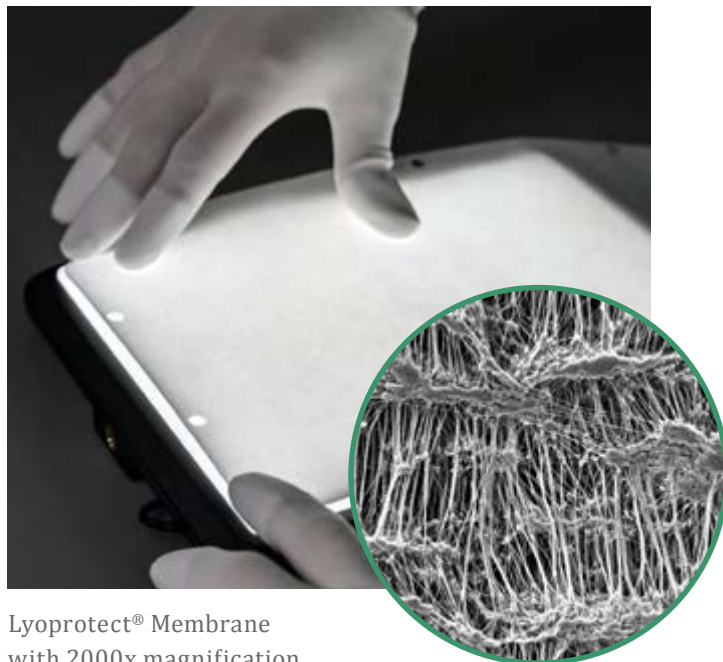
All technical information and recommendations are based on our experiences and / or test results. They are given to the best of our knowledge, but do not state any liability by our company. Users are responsible for checking the suitability of the respective product for their specific application.

Lyoprotect® Quality Control

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.



Receiving inspection of membrane with FTIR spectrometer



Lyoprotect® Membrane with 2000x magnification

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.

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.

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, particles stay within the limits.

Abrasion resistance of membrane

- » A modified Gelbo-flex test (DIN EN ISO 9073-10:2004) proved that the Lyoprotect® Membrane does not emit any particulate matter through appropriate usage.

Lot release tests

- » Seam strength test based on DIN 55529. Seam tightness test based on ASTM 1929 dye migration.

Endotoxin test

- » Test for bacterial endotoxins using Limulus-Amoebocyte-Lysate (LAL test) - Kinetic Turbidimetric Assay (KTA) with Lyoprotect® Membrane. LAL test acc. to EP 2.6.14.

Sterile Barrier functionality

- » “Microbial testing of Lyoprotect with single-use membrane” by external laboratory.

Serial number and inspection certificate 3.1 for stainless steel plates

- » 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.

Validation Guide

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

Made in Germany

- » Teclen is located in Bavaria, Germany, and takes pride in manufacturing most products in-house or entrusting their creation to skilled partners within Germany.

*The Teclen Quality Management System
is ISO 9001 certified by TÜV Süd.*



www.teclen.com



ISO 9001

Certified
Quality Management System

www.tuvsud.com/ms-cert

The Teclen Team

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



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



Contact, Imprint

Contact:

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

Sales:

Anja Busch
Tel: +49 (0)170 1484 297
sales@teclen.com

Carlos Castiblanco
Tel: +49 (0)8093 9048 894
sales@teclen.com

Quality:

Peggy Eisenhut
Tel: +49 (0)160 147 3506
peggy.eisenhut@teclen.com

Imprint:

March 2024

Publisher:

Teclen GmbH
Münchener Str. 10
85667 Oberpframmern
Germany

Design, layout, concept:

Britta Eriskat
www.eriskat.de

Technical illustrations:

Lorenz Mueller, default græy
www.defaultgrey.com

Photos:

Front page, page 3, 15, 20:
Christian Hartmann
www.christianhartmann.com

All other photos: Teclen GmbH



www.teclen.com