

Lyoprotect® – The key to safe lyophilization

Lyoprotect® Stainless Steel Tray for Lyophilization



Ideal for freeze-drying of bulk.
High quality made in Germany. Sustainable, robust, scalable.

✓ Sustainability

The combination of single-use and multiple-use components helps to reduce waste. The high-grade stainless steel tray is very resistant, only the membrane must be discarded.

✓ High quality

The stainless steel tray is manufactured in Germany. Thanks to the polished surface and laser-welded 45° corners, cleaning is easy. The engraved serial number facilitates the assignment and documentation.

✓ Safe sublimation

The membrane is designed for single use and is replaced before every new drying cycle. During sublimation, the vapor escapes via the hydrophobic membrane.

The membrane acts as sterile barrier and protects the product against contamination and the working environment and staff against fly-out.

✓ Sterilization

All components including the membrane can be sterilized in an autoclave at 121°C (250°F) for 20 minutes. APIs (Active Pharmaceutical Ingredients) can be aseptically produced in compliance with GMP.

✓ Process development

The dimensions of the Stainless Steel Trays permit individual upscaling. In combination with the Stainless Steel Cups* this allows for a continuous process development from a few milliliters in the laboratory up to a filling volume of

6 liters on a GMP production level. This way, you can achieve optimized footprint utilization of your freeze dryer shelves. Preliminary freezing in a deep freezer is possible.

Functional claims

- » Bacteria-proof container with vapor-permeable membrane
- » Very high sublimation rate
- » No fly-out
- » No cross-contamination
- » Preliminary freezing is possible
- » Safe compliance with occupational exposure limits (OEL 100 ng/m³) with flexible isolators

* Further information can be found in the data sheets of the Lyoprotect® Stainless Steel Cups for lyophilization.

Multiple-use Components

Tray with fixing frame

- » Stainless steel ANSI 316 L (1.4404) with polished surface (Ra < 0.4 µm)
- » Work's test certificate 3.1 for steel plates used
- » Engraved serial number
- » Plate thickness: fixing frame 3 mm, tray 2 mm

Sealing:

- » Expanded PTFE flat gasket, 1 mm

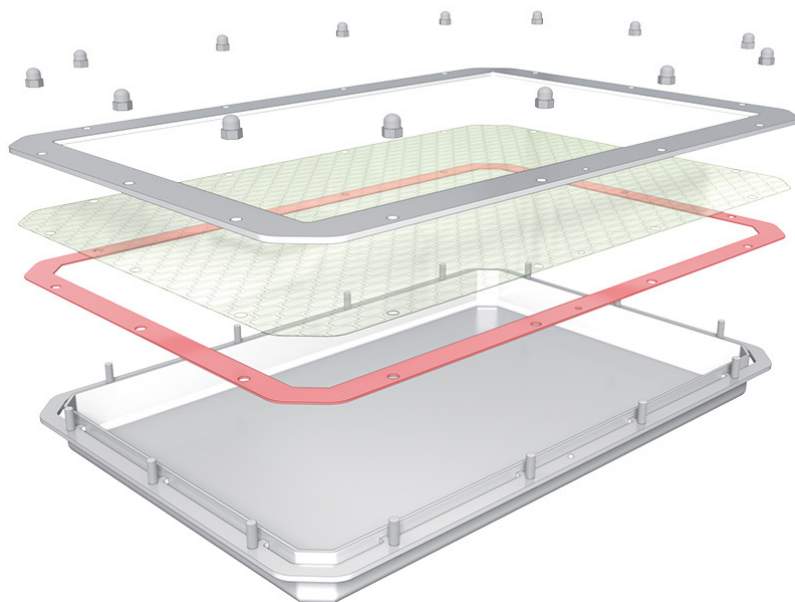
Single-use Component

Teclen® Lyoprotect® Membrane:

- » Expanded PTFE on non-woven polypropylene backing
- » Membrane faces the pharmaceutical product after assembly
- » Asymmetrical design serves as positioning aid

Quality claims

- » 100% visual inspection of membrane and components
- » Serial number and work's test certificate 3.1 for stainless steel plates
- » Lot release test (tightness test)
- » Full traceability and receiving inspection of the membrane with FTIR spectrometer
- » Membrane is BSE/TSE safe
- » Membrane Complies with (EU) No 10/2011 regarding food safety
- » On request: endotoxin test, extractables profile, toxicological evaluation of the membrane
- » Made in Germany



Lyoprotect® Stainless Steel Tray with fixing frame, flat gasket and single-use membrane



Laser-welded 45° corners facilitate residue-free cleaning



Lyoprotect® Stainless Steel Tray V2740B, membrane 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.



Contact
+49 170 148 4297 | sales@teclen.com
www.teclen.com

For detailed
order information
please see the
Teclen® Lyoprotect®
Product Catalog.

