



Instruction for Use TPP Triple Bagged 3-B SAL 10⁻⁶



The 3-B packaging system is specifically engineered for applications demanding aseptic or sterile product transfer. It is validated to achieve a sterility assurance level (SAL) of 10⁻⁶, ensuring maximum product sterility and compliance with stringent quality requirements.

Safety instructions

- **Handling and Safety**
Handling of biological materials shall be performed in full compliance with all applicable national and international regulations. Activities must conform to the laboratory's assigned biological safety level, the relevant Safety Data Sheets (SDS), and the manufacturer's Instructions for Use (IFU).
Appropriate personal protective equipment (PPE) shall be always worn during handling.
- **Risk of Contamination**
All operations shall be conducted in accordance with aseptic techniques and established Good Laboratory Practices (GLP). Packaging shall be opened immediately prior to use. Only products that are visually intact and free from defects shall be utilized. Products exhibiting visible damage, contamination, or any other irregularities shall be disposed of in accordance with applicable regulations.
- **Storage**
TPP products shall be stored under the following conditions:
 - Temperature: 10 °C to 30 °C (50 °F to 86 °F).
 - Light exposure: Products shall be protected from direct ultraviolet (UV) radiation.
 - Relative humidity: ≤ 60 %, with a recommended control range of 50 – 60 %.Storage conditions shall be monitored and recorded to ensure compliance with these requirements. Any deviations shall be documented, evaluated, and managed in accordance with the applicable quality.

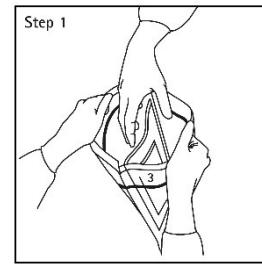
Instructions

- Verify the Expiration Date (EXP) marked on both the product label and the external packaging. Only use products with a valid EXP date.
- To guarantee compliance with the intended use, download the appropriate IFU for the 3-B product.
- Each product is protected by a triple sterile barrier system, individually sealed within three peel-open bags.
- Bag dimensions are specifically sized to prevent damage or perforation to the inner bag(s) during the opening of the outer bag, which ensures the maintenance of the sterile barrier and prevents product contamination.
- Each bag is clearly marked with a security number to guide the sequential removal process:
3: Outermost bag
2: Middle bag
1: Innermost bag
- Open the packaging sequentially. Bag 1 (the innermost bag) features the critical product data: Product Description, Lot Number, and EXP.
- Open the final barrier (Bag 1) and aseptically remove the product. The product is now ready for use according to the relevant application.



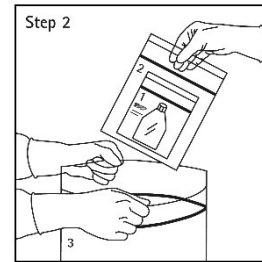
Step 1 – Bag 3, Entrance Area

- Open bag 3 (outermost bag) in the non-sterile environment



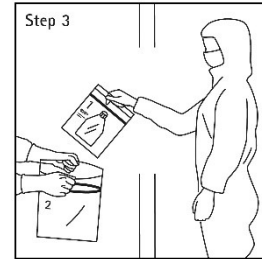
Step 2 – Bag 2, Transfer

- Remove bag 2 (middle bag)
- Transfer to cleanroom airlock or sterile environment



Step 3 – Bag 1, Cleanroom Airlock

- Open bag 2 inside the airlock or sterile environment and remove bag 1 (innermost bag)



Step 4 – Bag 1, Cleanroom

- Remove the product from bag 1 inside the biological safety cabinet (BSC)



Delivery Time

The product is partially manufactured-to-order; therefore, appropriate lead times must be accepted.

Additional Information

Instructions for use, chemical resistance lists, and quality certificates for individual products can be downloaded from the TPP website at www.tpp.ch.

Disclaimer

TPP products are intended for Research Use Only (RUO) and are not approved for clinical, diagnostic, or in vitro fertilization (IVF) applications. The full Terms & Conditions, including limitations of warranty and liability, intended use, and reseller obligations, are available at:

https://www.tpp.ch/page/qualitaets_sicherung/index.php

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