

STERILE DISPOSABLE SET

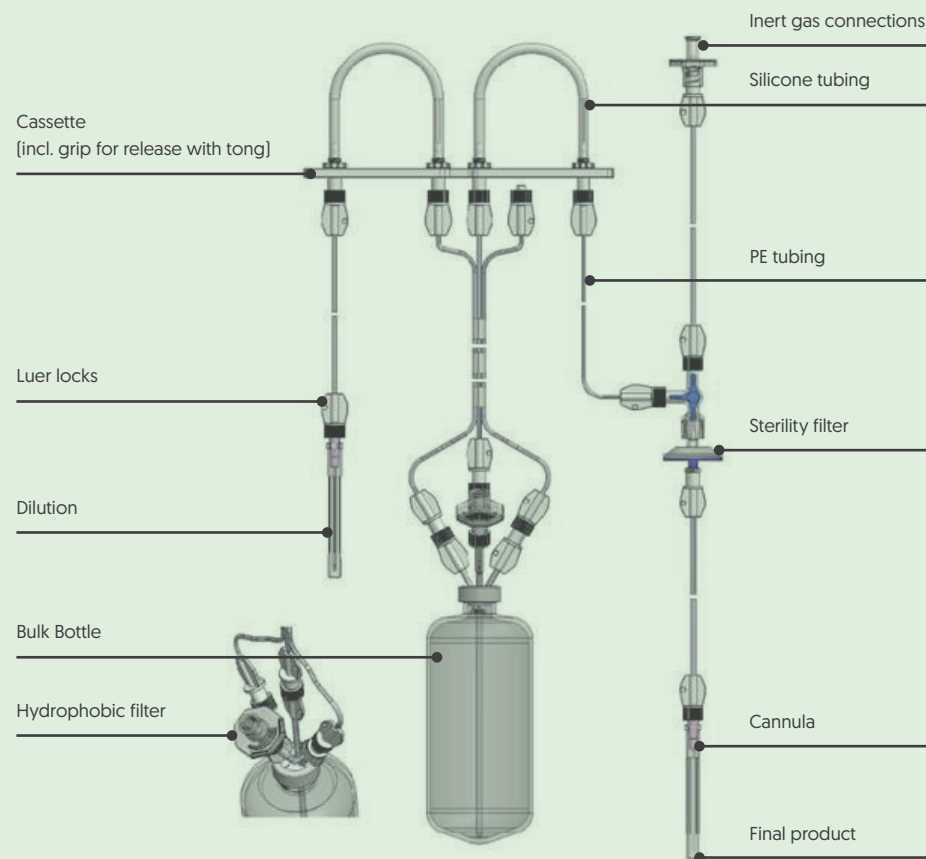
These sterile disposable sets are exclusively used for our dose dividers and are supplied and manufactured by Von Gahlen.

Disposable sets are designed for the safe, efficient, and contamination-free dispensing of radiopharmaceuticals using our OVDD and CVDD dose dividers. They ensure adherence to regulatory standards, enhance operator safety, and maintain the integrity of the radiopharmaceuticals being handled. The set includes all necessary components for handling and transferring radioactive solutions in clinical or laboratory settings.

Key features

- Sterility Assurance: ETO sterilized, ensuring a contamination-free environment.
- Single Use: Disposable to prevent cross-contamination and to meet radiation safety protocols.
- High-Quality Materials: Made from medical-grade, radiation-resistant materials to withstand radiopharmaceutical exposure.
- Ergonomic Design: Cassette-based design facilitates ease of use and reduces the time it takes technicians/operators to handle the equipment.

Variants	OVDD-STD	CVDD-STD	OVDD-BF
Dose Divider Model	OVDD	CVDD	OVDD
Filling method	Vial filtration	Vial filtration	Bulk filtration
Bulk vial capacity	150 mL	150 mL	150 mL
Sterility filter	Millex GS	Millex GS	Millex GS
Materials used for fluid path	98% PE, 2% silicone	95% PE, 5% silicone	98% PE, 2% silicone
Metal free	No	Yes	No



STANDARD FEATURES

General

- Standard disposable set based on PE/silicone material.
- Other disposable sets available upon request.
- Entirely manufactured in the EU.
- V-shaped bulk bottle bottom for minimum product loss.

Quality control

- ETO sterilized in accordance with ISO11135.
- Sterility is tested and approved according to 21 CFR 212 media fill test and ISO 13408-1 (2015).
- ETO residual tested [1 PPM].
- LAL-Endotoxins.
- Leachables and Extractables tested and approved according to ISO 10993-18.
- Components have no origins that could result in contamination by Transmissible Spongiform.
- Encephalitis (TSE), Bovine spongiform encefalopathie (BSE) or melamine.
- Every batch will be delivered with a Certificate Of Analysis [COA], which contains at least:
 - Lot or batch number.
 - Quality Release Testing Assay [Sterility, Bacterial Endotoxin test].
 - Product Expiration Date.
 - Product Release Date, including quality Assurance Approval.

Packaging

- Sets are individually packed in double pouch, each clearly labelled.
- Tamper-proof packaging Box of 6 sets.

Storage

- Store in a cool, dry place.
- Avoid direct sunlight.

Shelf Life

- Shelf-life 5 years (determined according to ISO 11607).

Manufacturer Information

- Von Gahlen Nederland B.V.
- Kelvinstraat 9
- 6902 PW Zevenaar
- The Netherlands
- Customer Support +31 316 528 275

Disclaimer

- This product is intended for professional use only. Proper radiation safety precautions must be followed in compliance with local regulatory guidelines.

OPTIONAL FEATURES

- 250 mL bulk bottle, separately packed.
- Millex 33 mm filter-vented.

