

TEVADAPTOR® Closed Drug Reconstitution and Transfer System

Vial Adaptor



ToxiGuard®

TECHNICAL DATASHEET

Intended use:

Tevadaptor® is a Closed System Drug Transfer Device (CSTD) that mechanically prohibits the release of the drug in vapor, aerosol or liquid form during preparation and administration, and prevents the introduction of microbial and airborne contaminants into the drug or fluid path, allowing the system to minimize exposure of individuals, healthcare personnel, and the environment to hazardous drugs.

Vial Adaptor:

The Tevadaptor® portfolio contains 3 different vial adaptors which firmly connect onto any standard vial, with a cap dimension of 13 & 20 mm (ref. 1MG245548), 28 mm (ref. 1MG245766) or 32 mm (ref. 1MG245769). Once connected to the Tevadaptor® Syringe Adaptor, it allows a safe drug transfer from the vial to another container (e.g. a semi-rigid bottle, an infusion bag, an elastomeric pump or a medication cassette reservoir for an ambulatory infusion pump). In case of multiple use vials, a protective cap can be used for safe and clean storage of the vial. Its intuitive design makes it easy to use: with minimal effort both components can be connected and a simple push on the wings of the Syringe Adaptor will disconnect them again. The ToxiGuard® mechanism in the vial adaptor ensures an immediate pressure equilibration, which makes air withdrawal in the syringe from the surrounding environment unnecessary. The ToxiGuard® double filter system contains a charcoal filter to prevent external contamination of the environment with hazardous drugs and a 0,2 micron membrane to ensure sterile air exchange. During manipulation the "click" sound indicates a safe and secure connection. The self-sealing elastomers prevent drug leakage and droplet formation on the outer septa surfaces.

TDPT-IL-00085

TECHNICAL DATASHEET VIAL ADAPTOR

Order information

	Vial Adaptor 20 mm with 13 mm Convertor	Vial Adaptor 28 mm	Vial Adaptor 32 mm
Article number / Reference	1MG245548	1MG245766	1MG245769
User box quantity	50 pcs	20 pcs	25 pcs
Transport box quantity	200 pcs	80 pcs	100 pcs

Product Characteristics

Product Technical data			
Cap dimension of fitting vial	13 & 20 mm	28 mm	32 mm
External fitting	Several wings assure a tight grip around the neck of the vial	Tight circular grip around the neck of the vial	Tight circular grip around the neck of the vial
Spike type	2-way spike with separate air and fluid path	2-way spike with separate air and fluid path	2-way spike with separate air and fluid path
Protective cap	Yes (white)	Yes (white)	Yes (blue)
Fluid path volume	0,15 ml	0,15 ml	0,15 ml
Membrane pore size	0,2 micron	0,2 micron	0,2 micron
Septum piercings	Up to ten times	Up to ten times	Up to ten times
Shelf life	3 years	3 years	3 years
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

Tolerates disinfection with alcohol 70% and chlorhexidine in alcohol (5 mg/70% alcohol)

Material Specifications

Component	Material	Material	Material
Spike	ABS	ABS	ABS
Injection Point Cover	Polyethylene	Polyethylene	Polyethylene
Elastomeric sealing	Polyisoprene	Polyisoprene	Polyisoprene
13 mm convertor	Polycarbonate		
Protective cap	ABS	ABS	ABS
0,2 micron Membrane	Acrylic co-polymer	Acrylic co-polymer	Acrylic co-polymer
Charcoal filter	Charcoal Zorflex®	Charcoal Zorflex®	Charcoal Zorflex®
Filter base	Polypropylene	Polypropylene	Polypropylene
Filter cover	Polycarbonate	Polycarbonate	Polycarbonate

Free of PVC, DEHP and Latex. Non-Pyrogenic. Free from lead, cadmium, arsenic and chrome. Meets standards and regulations with regards to the environment

Regulation

CE 0483
FDA 510(k) Cleared under ONB product code



STERILE EO



PVC-Free



Non-pyrogenic



Do not resterilize



Single use only, do not re-use



Not made with DEHP



Not made with natural rubber latex



Do not use if package is damaged



Keep dry



Keep away from sunlight

EC REP

CE 0483



TEVA Medical Ltd.
North Industrial Zone
P.O. Box 888 Kiryat Shmona,
Israel 1101801

Disposal of components should be according to local regulations and procedures for handling of hazardous drugs.

References:

1. https://www.accessdata.fda.gov/cdrh_docs/pdf14/K141448.pdf

TEVADAPTOR®

Keeps you safe in a click