

TEVADAPTOR® Closed Drug Reconstitution and Transfer System

Syringe Adaptor



Complies
with the
European
Sharps
Directive

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.

Syringe Adaptor:

The Tevadaptor® Syringe Adaptor fits any standard luer lock syringe. It allows, together with the other Tevadaptor® components, 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). Its intuitive design makes it easy to use: with minimal effort both components can be connected and a simple push on the wings will disconnect them again. The protective cap, included in the package, allows a clean delivery to the ward in case of bolus injections. The ToxiGuard® mechanism in the vial adaptor ensures an immediate pressure equilibration, which makes air withdrawal from the surrounding environment unnecessary at any stage of the procedure. 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. Additionally, the syringe adaptor is equipped with a self-retracting needle mechanism, protecting the manipulator from needle stick injuries. The needle only pierces the self-sealing elastomers and is never in contact with the rubber stopper of the vial.

TDPT-IL-00084

TECHNICAL DATASHEET SYRINGE ADAPTOR

Order information

Article number / Reference	1MG245567
User box quantity	50 pcs
Transport box quantity	300 pcs

Product Characteristics

Product Technical data

External fitting	Male luer lock connection
Needle bore size	16 G
Needle volume	0,04 mL
Protective cap	Delivered with every Syringe Adaptor
Septum piercings	Up to ten times
Shelf life	3 years
Sterilization	Ethylene oxide

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

Material Specifications

Component	Material
Syringe Adaptor cap	Polyethylene
Syringe Adaptor body and clamps	Polyacetal
Elastomer housing	ABS
Elastomeric sealing	Polyisoprene
Spring	Stainless steel
Needle	Stainless steel (aluminium free)
Hub	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

Tevadaptor® has been approved as a safety engineered device¹ that complies with the Sharps Directive² and the NIOSH Alert³ on the prevention of needle stick injuries in Health Care Settings.

CE 0483

FDA 510(k) Cleared under ONB product code



Consult instruction for use

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. Debra Adams, Council Directive 2010/32/EU: Impact on pharmacy team; HPE, issue 65, 2012 p23-26.
2. Council Directive 2010/32/EU of 10 May 2010, implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector conducted by HOSPEEM and EPSU, Official Journal of the European Union, 2010, L 134/66-72.
3. NIOSH Alert: Preventing Needle Stick Injuries in Health Care Settings, November 1999.
4. https://www.accessdata.fda.gov/cdrh_docs/pdf14/K141448.pdf

TEVADAPTOR®

Keeps you safe in a click