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.

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 device[1] that complies with the Sharps Directive[2] and the NIOSH Alert[3] on the prevention of needle stick injuries in Health Care Settings.

CE 0483

FDA 510(k) Cleared under ONB product code

PVC-Free


Non-pyrogenic

Do not resterelise

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

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Disposal of components should be according to localregulations 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