

TEVADAPTOR® Closed Drug Reconstitution and Transfer System

Syringe Adaptor Lock



Complies
with the
European
Sharps
Directive¹

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.

TECHNICAL DATASHEET

Syringe Adaptor Lock:

The Tevadaptor® Syringe Adaptor Lock (SAL) fits any standard luer lock connection. During drug preparation, 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).

The Tevadaptor® Syringe Adaptor Lock offers a wide array of essential safety features: a unique patented lock system for luer connections, that cannot be opened once locked; a linear safe connection to the Tevadaptor® Vial Adaptor with an audible “click” sound and an internal 16G needle that allows easy withdrawal of drugs, including viscous ones. The needle has a self-retracting mechanism, protecting the manipulator from needle stick injuries². Its intuitive design makes it easy to use: with minimal effort the SAL can be connected to another Tevadaptor® component and a simple push on the wings will disconnect it again. The self-sealing elastomers prevent drug leakage and droplet formation on the outer septa surfaces. The protective cap included in the package, allows a clean delivery to the ward, for example in case of bolus injections.

For closed administration, the SAL can be attached at the proximal end of the IV line (while a Luer Lock Adaptor is connected to the patient’s port). This will enable a safe disconnection at the end of the administration process.

TDPT-IL-00072

TECHNICAL DATASHEET SYRINGE ADAPTOR LOCK

Order Information

Article number / Reference	1MG245877
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 Lock
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

CE 0483

FDA 510(k) Cleared under ONB product code



Consult instruction for use

STERILE EO



PVC-Free



Non-pyrogenic



Do not re-sterilize



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



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

References:

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

TEVADAPTOR[®]

Keeps you safe in a click