

TEVADAPTOR® Closed Drug Reconstitution and Transfer System

Connecting set



Smart
"2-way spike"
for optimal
patient
safety

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.

Connecting set:

The Tevadaptor® Connecting Set firmly connects between a standard IV bag or a polyethylene container and any (gravity or pump) IV administration set with a proximal female luer lock connector. A safe drug transfer from the syringe into the IV bag or container is installed through the closed connection with the Tevadaptor® Syringe Adaptor. During manipulation the "click" sound indicates a safe and secure connection between the 2 components. The self-sealing elastomers prevent drug leakage and droplet formation on the outer septa surfaces. The smart "2-way spike" helps protect against admixture accidents which can be life-threatening for the patient. The separate "fluid-in path" ensures that the injected concentrated drug solution will flow into the bag or container for dilution and not into the tubing, in case the pinch clamp is left open after priming. After appropriate dilution, the drug can be safely administered through the "fluid-out path" and the IV administration set to the patient.

TDPT-IL-00082

TECHNICAL DATASHEET CONNECTING SET

Order information

Article number / Reference	1MG245549
User box quantity	100 pcs
Transport box quantity	100 pcs

Product Characteristics

Product Technical data	
Tubing length	40 cm
Volume of the tubing	2,80 ml
Spike type	Non-vented, 2-way spike with a "fluid-in path" and a "fluid-out path", preventing accidental administration of non-diluted drug solutions
Distal end of the tubing	Male luer lock connection with flow-stop protection cap
Clamp type	Pinch clamp
Septum piercings	Up to ten times
Shelf life	3 years
Sterilization	Ethylene Oxide

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

Material Specifications

Component	Material
Protective cap on spike	Polyethylene
2-way Spike	ABS
Elastomeric sealing	Polyisoprene
Soft tubing	DEHP-free PVC
Pinch clamp on tubing	Acetal
Male luer lock body and collar on distal end of tubing	ABS
FlowStop protection cap	Acrylic copolymer membrane (hydrophobic)

DEHP-free PVC. Non-pyrogenic. Free from latex, 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



Non-pyrogenic



Do not resterilise



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



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