

TEVADAPTOR® Closed Drug Reconstitution and Transfer System

Infusion Set 180cm



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.

Infusion Set 180cm:

The Tevadaptor® Infusion Set firmly connects between a standard IV bag or a polyethylene container and to any patient's IV catheter via a luer lock connection. A safe drug transfer from the syringe into the IV bag or container is enabled through the closed connection with the Tevadaptor® Syringe Adaptor/Syringe Adaptor Lock. During manipulation the "click" sound indicates a safe and secure connection between the two components. The self-sealing elastomers prevent drug leakage and droplet formation on the outer septa surfaces. The smart "2-way spike" helps protect against accidental entrance of concentrated drug into the patient's IV line. 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 is safely administered through the "fluid-out path" to the patient's infusion set.

TDPT-IL-00075

TECHNICAL DATASHEET INFUSION SET 180cm

Order Information

Article number / Reference	1MG245536
User box quantity	50 pcs
Transport box quantity	50 pcs

Product Characteristics

Product Technical data

Tubing length	180 cm
Volume of the tubing	17 ml
Spike type	Non-vented, 2-way spike with a "fluid-in path" and a "fluid-out path"
Drip chamber filter size	15 micron
Distal end of the tubing	Male luer lock connection with flow-stop protection cap
Clamp type	Pinch clamp and roller clamp
Septum piercings	Up to ten times
Shelf life	3 years
Sterilization	Ethylene Oxide
Drip chamber and drip tube	1ml=20 drops of distilled water

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)
Drip chamber	SBC and ABS
Roller clamp	ABS

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 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



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