

TEVADAPTOR® Closed Drug Reconstitution and Transfer System

# Spike Port Adaptor



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.

### Spike Port Adaptor:

The Tevadaptor® Spike Port Adaptor firmly connects between a standard IV bag or a polyethylene container and any (gravity or pump) IV administration set. 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 to the patient through the “fluid-out path” and the IV administration set.

TDPT-IL-00081

# TECHNICAL DATASHEET SPIKE PORT ADAPTOR

## Order information

Article number / Reference	1MG245551
User box quantity	100 pcs
Transport box quantity	100 pcs

## Product Characteristics

Product Technical data	
Tubing length	12 cm
Volume of the tubing	1,00 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	Standard spike port with twist-off connector
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
Distal twist-off and connector tubing	DEHP-free PVC
Pinch clamp on tubing	Acetal

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



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North Industrial Zone  
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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](https://www.accessdata.fda.gov/cdrh_docs/pdf14/K141448.pdf)

# TEVADAPTOR®

Keeps you safe in a click