

Closed System Transfer Device Reconstitution and Administration Components



Closed Secondary IV Set

TECHNICAL DATASHEET

- The Closed Secondary IV Set is connected to the Bag Adaptor CP, which is firmly connected to a standard IV bag or semi-rigid container.
- Its unique design presents a Chemfort® Syringe Adaptor (SA)
 component that connects to the Bag Adaptor CP allowing a safe
 drug transfer through a closed connection between Chemfort®
 components.
- It incorporates an internal 16G needle. The needle has a selfretracting mechanism that protects the operator from needlestick injuries.
- During manipulation a "click" sound indicates a safe and secure connection between two Chemfort® components.
- The self-sealing elastomers prevent drug leakage and droplet formation on the outer septa surfaces.
- A simple pinch on the SA wings will disconnect the SA from the Bag Adaptor CP. The system is still closed after the disconnection.
- The Closed Secondary IV Set can then be connected to a new Bag Adaptor CP attached to an IV bag with saline / new drug.

Indications for Use:

The Chemfort® Closed Administration components are a single use, sterile Closed System Transfer Device (CSTD) that mechanically prohibits the release of drugs, including antineoplastic and hazardous drugs, in vapor, aerosol or liquid form during administration, thus minimizing exposure of individuals, healthcare personnel, and the environment to hazardous drugs. Chemfort® Closed Administration prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 7 days.





Closed Secondary IV Set

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Order information

Article number / Reference	MG245255
User box quantity	70 pcs
Transport box quantity	70 pcs

Product Characteristics

Product technical data		
Length	102 cm	
Priming Volume	6 ml	
Insertion port	Syringe Adaptor	
Needle bore size	16G	
Clamp type	Pinch clamp and roller clamp	
Drip chamber filter size	15 micron	
Distal end of the tubing	Male luer lock connection with flow-stop protection cap	
Port connection disconnection	10	
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

Material Component Syringe Adaptor cap Polyethylene Syringe Adaptor body and clamps Polyacetal **Elastomer housing** Copolyester Elastomeric sealing Polyisoprene Stainless steel Spring Needle Stainless steel Hub Copolyester Soft tubing **PVC-DEHP** free Pinch clamp on tubing Acetal Drip chamber PVC DEHP Free body with ABS cup and Polyamid filter Roller clamp **ABS** Male luer lock body MABS Polypropylene and PVDF hydrophobic FlowStop protection cap

PVC-DEHP free. Non-pyrogenic. Free from latex, lead, cadmium, arsenic and Hexavalent chromium. Meets standards and regulations with regards to the environment.

Regulation

CE 0483

FDA 510(k) Cleared under ONB product code

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

Symbols taken from ISO 15223-1:2021





Medical device



and sterilized using ethylene oxide



pyrogenic



Do not re-sterilize



Do not re-use



Do not use if package is damaged





Keep away from sunlight



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