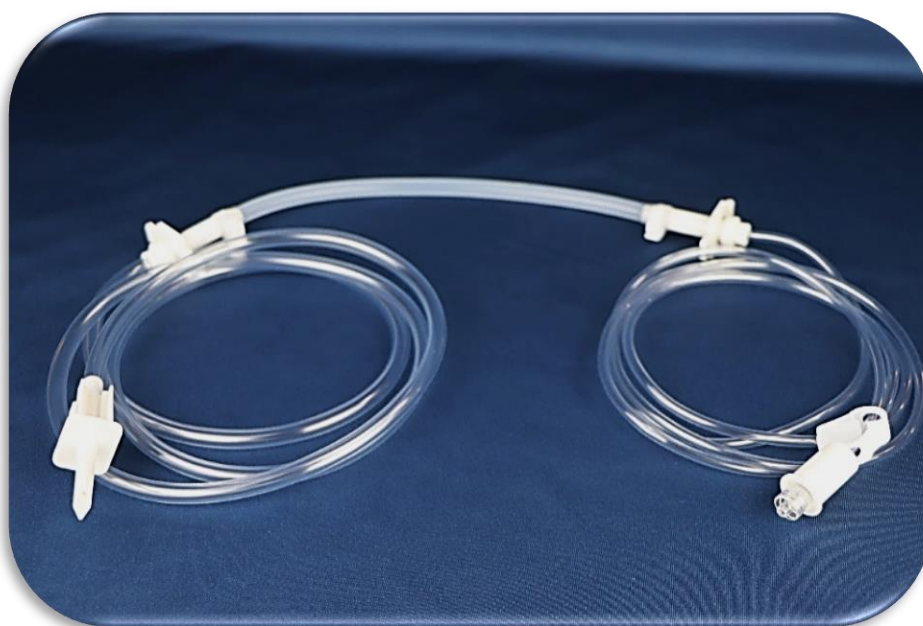




IFP-081-2326

Transfer Tube Set Sterile Spike to Male Luer Lock

IFP Medical sterile transfer tube sets are specifically designed to meet the critical demands of pharmaceutical compounding applications for sterile fluid processing. The transfer tube sets are designed to be installed efficiently into a Repeater pump. The features of the transfer tube sets provide an easy grip to install the universal spike into a sterile bag. The male luer lock hand grip provides an easy connection to a filter or sterile container. The material used in the construction of our tube sets is chemically compatible with a larger variety of chemical compounds. No adhesives are used in the tube joint connections. The transfer tube set is manufactured in accordance with GMP and complies with GMP guidelines. Our transfer tube sets are free from animal-derived components. The raw materials can be traced by Lot Number and are strictly regulated maintaining ISO 13485 & ISO 14001 quality standards.



Application

- Compatible with Repeater pump.
- Compatible with sterile compounding filters.
- Compatible with sterile medical bags.
- Sterile processing of liquid pharmaceutical compounds.
- Sterile transfer of pharmaceutical compounds.
- Dosing sterile pharmaceutical compounds into bags, vials, or syringes

Features and Benefits

- Universal Spike with vent for sterile bag connecting.
- High-strength silicone pump tubing.
- Male Luer lock with hand grip.
- All materials are DEHP-free.
- All formulas are Animal-Derived Component Free.
- The all-inclusive Validation Guide and the Regulatory Information Overview (RIO) are available for customers upon request.





Sterilization Methods:

Ethylene Oxide Sterilization (ETO)

Sterility: Each tubing in this lot undergoes validated ETO sterilization following ANSI/AAMI/ISO 11135, ensuring a minimum sterility assurance level (SAL) of 10⁻⁶ for the fluid path.

Refer to the condition described in the validation report. The EO residual volume ≤4mg, refers to ISO 10993-7 standard.

Regulatory Compliance (Biocompatibility, Physicochemical & Extractable Testing):

Summary of Results		
Method Description	Reference Standard	Result
Ames Genotoxicity	ISO 10993-3	Passed
Hemolysis – Indirect Contact	ISO 10993-4	Passed
<i>In Vitro</i> Cytotoxicity	ISO 10993-5	Passed
Systemic Toxicity - Rabbit Pyrogen (Material Mediated)	ISO 10993-11	Passed
Sterility Test: Bacteriostasis & Fungistasis	USP <71>	Passed
LAL Gel Clot Endotoxin	USP <85>	Passed
Biological Reactivity Tests, In-Vitro	USP <87>	Passed
Class VI Plastics - Biologic Reactivity Tests, In-Vivo:	USP <88>	Passed
Elastomeric Closures for Injection	USP<381>	Passed

Human and Veterinarian Use:

The product is safe for Human and Veterinarian use. CGMP CFR part 210 & 211, the additional requirements of 21 CFR part 600 and 21 CFR part 680 are applicable to the aseptic manufacturing process.

Animal-Derived Components & TSE/BSE Risk:

No animal-derived material is intentionally added or used during the manufacture of this product.

Shelf Life:

IFP Medical transfer tube sets have a shelf life of 3 years from the date of sterilization. Ethylene Oxide (ETO) Sterilized product packaging provides adequate protection to maintain a sterile barrier throughout the product's distribution, handling, and 3-year shelf life.

