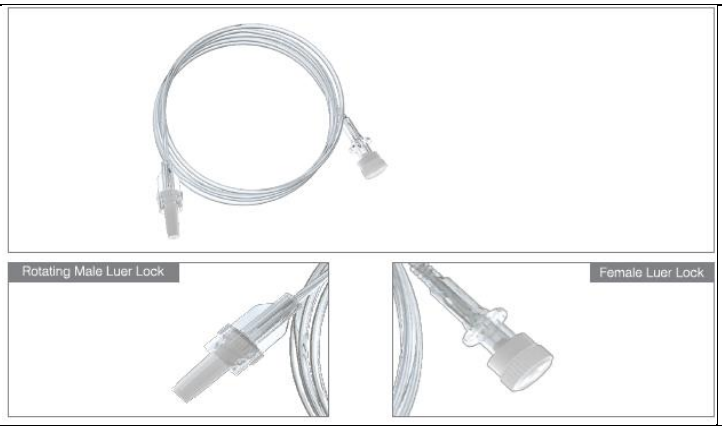
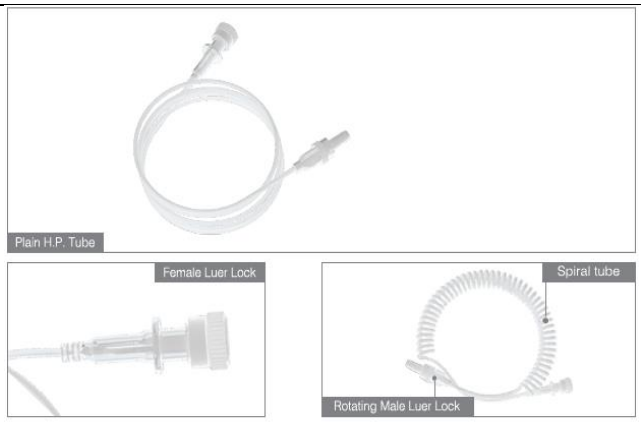
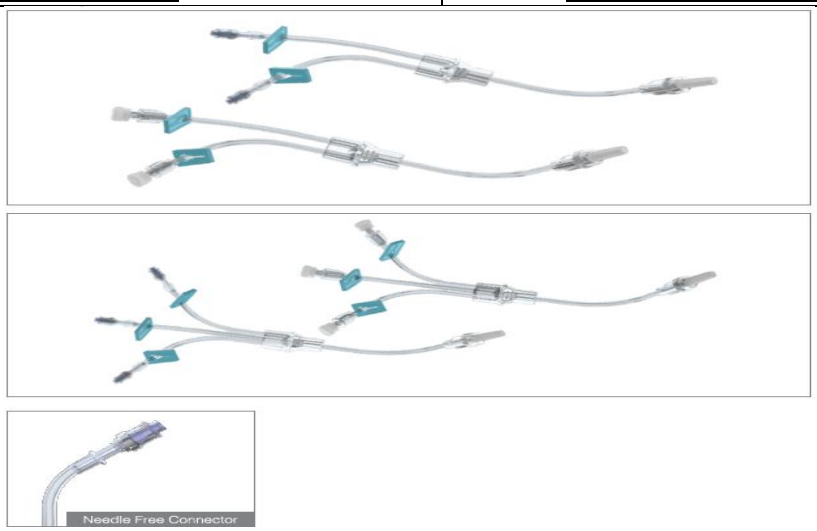


Extension tube



High Pressure Extension Tube



Multi-Lumen Extension tube

1. PRODUCT DESCRIPTION

- **Extension Tube:** The extension tube is a plastic tube which connects with medical devices that use standard luer lock or luer slip connector to deliver infused substances into patients. The Major components are PVC tube, male and female connector. Duration of Use: Short term. Material of Composition: PVC, PP, HDPE, PC.
- **High Pressure Extension Tube:** The extension tube is a plastic tube which connects with medical devices that use standard luer lock or luer slip connector to deliver infused substances into patients. The Major components are PVC tube, male and female connector. Duration of Use: Short term. Material of Composition: HDPE, PVC.
- **Multi-Lumen Extension Tube:** The extension tube is a plastic tube which connects with medical devices that use standard luer lock or luer slip connector to deliver infused substances into patients. The Major components are PVC tube, male and

female connector. Duration of Use: Short term. Material of Composition: HDPE, PVC, PC, PP.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa, Rule 2, medical device (classification as per MDR Annex II Section 1.1(f); Annex VIII).

3. PRODUCT CHARACTERISTICS & INTENDED USE

Extension line FLL - MLL standard-bore for pressure infusion/ mini-bore for pressure infusion:
Transfer of fluids, pharmaceuticals and parenteral nutrition solutions or blood and blood components by intravenous infusion. For use with compatible pressure infusion pumps with generated pressures up to 200 kPa (2 bar). The product can also be used under gravity and with a pressure cuff with generated pressures up to 50 kPa (0.5 bar).
Additional Feature: Male Luer-Lock protection cap with hydrophobic, bacteria-tight filter available, with on/off clamp.

- Latex free, DEHP free, BPA free
- Tubing: Non-PVC PE / PP also available.

INTENDED PURPOSE:

- **Extension Tube/Multi-Lumen Extension tube:** Extension Tube is used to extend the I.V. fluids pathway & for blood/blood derivatives/ nutritive or medicinal fluids transfusion & or infusion.
- **High Pressure Extension Tube:** Extension line provides an extension to the IV fluid pathway for blood, medication or transfusion & augment the IV liquid pathway and for blood/blood subsidiaries/nutritive or therapeutic liquids transfusion and implantation.

4. MATERIAL OF CONSTRUCTION

S. No.	Component/Parts	Material used
1.	Plain Stopper	PP (Poly-Propylene)
2.	Male Luer Lock	PC (Poly-carbonate)
3.	Extension Tube	PVC (Poly-vinyl Chloride)
4.	Female Luer Lock	PC (Poly-carbonate)
5.	Threaded Stopper	HDPE (High-Density Polyethylene)

Table No.-1 Components and their raw materials of Extension tube

S. No.	Component/Parts	Material used
1.	2-way Connector	PC (Poly-carbonate)
2.	3-way Connector	PC (Poly-carbonate)
3.	M.L. Rotator	PC (Poly-carbonate)
4.	Tube (OD-2.40)	PVC (Poly-vinyl Chloride)
5.	Pinch Clamp	POM (Polyoxymethylene)
6.	Plain Stopper	PP (Poly-Propylene)

Table No.-2 Components and their raw materials of Multi-Lumen extension tube

Phthalate free plasticizer *is used within the PVC material procured from the approved suppliers.*

5. TECHNICAL SPECIFICATION:

S. No.	Characteristics	Specified	Tolerance
1.	Visual and Leakage Check	Should be no Leakage and Free from Particle	-
2.	Tube Length	10 cm	± 10%
		20 cm	± 10%
		25 mm	± 10%
		50 mm	± 10%
		75 mm	± 10%
		100 mm	± 10%
		125 mm	± 10%
		150 mm	± 10%
		250 mm	± 10%
3.	OD. of Tube	As per assy. drawing	± 0.05 mm
4.	ID. of Tube	As per assy. drawing	± 0.05 mm
5.	Male Luer Connector	6% Taper	ISO 80369-7
6.	Female Luer Connector	6% Taper	ISO 80369-7
7.	Female Cap (Threaded Stopper)	6% Taper	ISO 80369-7
8.	Male Cap	Vented	---
9.	priming volume	As per finish goods standard	---

Table No.- 3 Technical Specification

6. REFERENCE COMPLIANCE STANDARD

S.No.	Name of Standard	ISO Std. No.
Standard for Extension Tube		
1.	Infusion equipment for medical use Part 10: Accessories for fluid lines for single use with pressure infusion equipment	ISO 8536-10:2015
2.	Small-bore connectors for liquids and gases in health care applications	EN ISO 80369-7:2021
3.	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	ISO 2859-1:1999/Amd 1:2011
4.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
5.	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness	EN ISO 14644-2:2015

	by particle concentration	
6.	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	EN ISO 15223-1:2021
7.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 11135:2014/Amd 1:2018
8.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	ISO 11607-1:2019/Amd 1:2023
9.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	ISO 11607-2:2019/Amd 1:2023
10.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
11.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
12.	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
13.	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	EN ISO 10993-6:2016
14.	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	ISO 10993-7:2008/Amd 1:2019
15.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
16.	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018
17.	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	ISO 10993-12:2021
18.	Biological evaluation of medical devices- Part 17 : Establishment of allowable limits for leachable substances	EN ISO 10993-17 :2023
19.	Medical devices -- Quality management systems -- Requirements for regulatory purposes	EN ISO 13485:2016
20.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
21.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
22.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
23.	Medical devices - Part - 1: Applications of Usability engineering to the medical devices.	IEC 62366: 2015
24.	Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018

25.	Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	EN ISO 11737-2:2020

Table No.- 4 Harmonized Standard

7. Packaging specifications

Packaging specifications		
S.no	**Type of Packaging**	**Packing material**
1.	Primary Packaging	Soft Blister Pack (PVC film) LD-70% PP-30%
2.	Inner (Duplex) Carton	3Ply
3.	Outer/Master Carton (Corrugated box)	5 Ply

Table No.- 5 Packaging specifications

8. COMPLIANCE INFORMATION

Manufacturing Site Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2,Sec-59, Phase-II, Ballabhgarh, Faridabad-121004, Haryana (INDIA)

Drug Manufacturing License No.: MFG/MD/2019/000106

QMS Certification: EN ISO 13485:2016

CE Marking: TUV-SUD Product Services GmbH

Prepared by:	Reviewed By:	Approved By:	Issued By:	
