

Fig.1: Closed IV Cannula

1. PRODUCT DESCRIPTION

Closed IV catheter systems are over-the-needle, intravascular catheters. These devices have a radiopaque catheter, needle, needle shield, septum, stabilization platform, integrated extension tubing, clamp, Luer adapter (single or dual port), vent plug, and pre-attached needleless connector. The needle and catheter are protected by a needle cover. The closed system is designed to keep blood contained within the device throughout the insertion process. The septum is designed to wipe visible blood from the needle surface as the needle is withdrawn from the catheter, further reducing the risk of blood exposure. The needle tip is passively protected when the needle is removed, reducing the risk of accidental needlestick injury. Continuous blood return is seen in the extension tubing. The vent plug prevents blood leakage from the extension tubing during insertion.

2. DEVICE CLASSIFICATION AND RULE

Closed IV Catheter falls under Class-IIa, Rule 7 device as per EU MDR 2017/745 Annexure VIII.

3. PRODUCT CHARACTERISTICS & INTENDED USE

INTENDED USE:

Closed IV catheter systems are intended to be inserted into a patient's vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy.

The 18-24 G devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.

Disposafe Closed I.V. Cannula is designed to provide safe, secure, and reliable intravenous access while minimizing the risk of blood exposure and infection. The closed system prevents backflow of blood, reduces the chance of needle-stick injury, and ensures maximum patient safety.

Features:

- Made from biocompatible, kink-resistant PTFE / FEP material.
- Integrated closed system prevents blood leakage.

- Needle with ultra-sharp bevel tip for smooth venipuncture.
- Safety mechanism reduces the risk of accidental needle-stick injuries.
- Transparent flashback chamber for instant venipuncture confirmation.
- Soft, flexible wings for easy fixation and patient comfort.
- Color-coded hub for quick identification of catheter size.
- Sterile, non-pyrogenic, and single-use.

Applications:

Closed I.V. Cannula is widely used in:

- Hospital and Critical Care Units – for safe and continuous IV therapy.
- Emergency Medicine & Trauma Care – for rapid fluid resuscitation and blood transfusion.
- Oncology – for chemotherapy administration.
- Pediatrics & Neonatology – for IV access in small and fragile veins.
- General Medicine & Surgery – for routine infusion of fluids, drugs, and nutrition.
- Blood Transfusion Units – for safe and efficient blood/blood product transfusion.
- ICU & Long-Term IV Therapy – reduces risk of infection and blood exposure.

4. PRODUCT VARIANTS

Following variants are available for the products

S.No.	Product	GMDN Code	Classification
1.	Closed IV Catheter	64574	Rule-7, Class-IIa

5. MATERIAL OF CONSTRUCTION

S. No.	Component Description	Material used
1.	Blood Control Body	PP
2.	Wing	PVC Soft
3.	Body Hub	PC
4.	Barrel	PC
5.	Needle Hub	PC
6.	Tube	PVC Soft
7.	Y Connector	PC
8.	Flow control Hub	PC
9.	NRV	PC
10.	Pinch Clamp	POM
11.	Plug	Latex
12.	Needle	SS
13.	SS Ball	SS
14.	Teflon Holder	POM
15.	Teflon	FEP
16.	PP Tube	PP
17.	Rubber Valve	Silicon
18.	Aligner	POM

19.	Threaded Stopper	HDPE

6. TECHNICAL SPECIFICATIONS:

	Gravity Flow Rate	Priming Volume	Isovue® 300 8.8 cP (mPa-s)	Optiray® 320 9.9 cP (mPa-s)	Omnipaque® 300 11.6 cP (mPa-s)	Optiray® 350 18.0 cP (mPa-s)	Isovue® 370| 20.9 cP (mPa-s)	Omnipaque® 350 20.4 cP (mPa-s)	Visipaque® 320 26.6 cP (mPa-s)	Maximum Power Injector Pressure Limit Setting
24 GA x 0.56 in (0.7 x 14 mm)	19 mL/min (1140 mL/hr)	0.4 mL	Not for use with power injectors							
24 GA x 0.75 in (0.7 x 19 mm)	18 mL/min (1080 mL/hr)	0.4 mL								
22 GA x 1.00 in (0.9 x 25 mm)	33 mL/min (1980 mL/hr)	0.4 mL	3.0 mL/sec	3.0 mL/sec	3.0 mL/sec	3.0 mL/sec	3.0 mL/sec	3.0 mL/sec	3.0 mL/sec	300 psi (2068 kPa)
20 GA x 1.00 in (1.1 x 25 mm)	61 mL/min (3660 mL/hr)	0.5 mL	5.5 mL/sec	5.5 mL/sec	5.5 mL/sec	4.5 mL/sec	4.5 mL/sec	4.0 mL/sec	4.0 mL/sec	
20 GA x 1.25 in (1.1 x 32 mm)	58 mL/min (3480 mL/hr)	0.5 mL	5.5 mL/sec	5.5 mL/sec	5.5 mL/sec	4.5 mL/sec	4.5 mL/sec	4.0 mL/sec	4.0 mL/sec	
20 GA x 1.75 in (1.1 x 45 mm)	51 mL/min (3060 mL/hr)	0.5 mL	5.5 mL/sec	5.5 mL/sec	5.5 mL/sec	4.5 mL/sec	4.5 mL/sec	4.0 mL/sec	4.0 mL/sec	
18 GA x 1.25 in (1.3 x 32 mm)	84 mL/min (5040 mL/hr)	0.5 mL	7.0 mL/sec	6.5 mL/sec	6.5 mL/sec	5.5 mL/sec	5.0 mL/sec	5.0 mL/sec	4.0 mL/sec	
18 GA x 1.75 in (1.3 x 45 mm)	79 mL/min (4740 mL/hr)	0.6 mL	7.0 mL/sec	6.0 mL/sec	6.0 mL/sec	5.0 mL/sec	5.0 mL/sec	4.5 mL/sec	4.0 mL/sec	

7. REFERENCE COMPLIANCE STANDARD

S No.	Name of Standard	Number
CLOSED IV CANNULA		
1.	Intravascular catheters — Sterile and single-use catheters Part 1: General requirements	ISO 10555-1:2023
2.	Intravascular catheters — Sterile and single-use catheters Part 5: Over-needle peripheral catheters	ISO 10555-5:2013
3.	Small-bore connectors for liquids and gases in healthcare applications	ISO 80369-7:2021

	Part 7: Connectors for intravascular or hypodermic applications	
General		
4.	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
5.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
6.	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015
7.	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
8.	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices Amendment 1: Revision of Annex E, Single batch release	ISO 11135:2014/Amd 1:2018
9.	Sterilization of health care products - Biological indicators - Part 1: General requirements	EN ISO 11138-1:2017
10.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
11.	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems Amendment 1: Application of risk management	ISO 11607-1:2019/Amd 1:2023
12.	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes Amendment 1: Application of risk management	ISO 11607-2:2019/Amd 1:2023
13.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1:2025
14.	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
15.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
16.	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
17.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/Amd 1:2019)	EN ISO 10993-7:2008/A1:2022
18.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2023
19.	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	EN ISO 10993-11:2018
20.	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12:2021
21.	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17:2023

22.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
23.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
24.	Medical devices -- Quality management systems -- Requirements for regulatory purposes	ISO 13485:2016
25.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
26.	European council directive concerning medical devices	MDR 2017/745

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	MATERIAL
Individual Sterile Packing (Blister)	Medical Grade Paper
Inner Carton	Kraft Pulp Paper
Master Carton	Kraft Pulp Paper

9. 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 0123
GMDN: 64574