1. PURPOSE: This document describes the product design and technical requirements of the Intravenous (IV) Cannula (or Catheter) range of products. As per Council Directive 93/42/EEC of 14th June 1993 as amended by 2007/47/EC concerning medical devices, Intravenous Cannula family is classified as Class IIa device. The Intravenous Cannula Family should comply with essential requirements of Medical Devices Directive 93/42/EEC as amended by 2007/47/EC and EN ISO 10555-1:2009/ ISO 10555-1:2013/Smd-1 & ISO 10555-5:2013 as product Standards.

2. INTENDED USE OF PRODUCT: IV Cannula with / without safety is inserted into the vein, mainly for the administration of intravenous fluids, withdrawal of blood samples and to deliver Intravenous fluid and medicines into human circulating system.

3. PRODUCT DESCRIPTION & FEATURES: The IV Cannula family is manufactured with high quality of raw material, ensuring optimal quality of the products.

Adva needle technology is designed to help clinicians improve first-stick proficiency by confirming immediate vessel entry at the point of insertion. Rapid flashback confirms vessel entry and may improve the chance of accessing difficult or compromised veins. *Closed IV Cannula can be used subcutaneously also.*

IV Cannula with integrated passive safety features to cover the needle after use to prevent the accidental needle prick injuries. Product is provided with blood control feature also.

Product is providing a passive safety tip clip to protect from the accidental needle stick injury after cannulations. When the needle and needle hub is withdrawn from the wing housing, the safety tip clip gets automatically activated inside the wing housing and locks on the needle tip. This ensures the needle tip is locked covered with safety tip clip before discarding, providing safety from accidental needle prick injury.

Based on the application and requirements, various features are incorporated in the IV Cannula designs as follows:

3.1 **IV Cannula with Injection Port and wings / IV Cannula with Injection Port, Snap fit cap & Saturable wings (With / Without Safety)**

3.1.1 Provided with injection port with non-return valve Silicon Valve for intermittent medication.

3.1.2 Smooth inner surface ensures free flow of blood.

3.1.3 Outer diameter of silicon tubing synchronizes with the inner diameter of the main body resulting in no leakage.

3.1.4 Ergonomically designed wings for proper fixation.

3.2 **IV Cannula without Injection Port & with wings / IV Cannula without Injection Port and with smaller wings (With / Without Safety)**

3.2.1 Prevent for infection from additional openings in the Cannula.

3.2.2 Safety needle guard automatically covers the needle's sharp bevel after withdrawal of needle from the hub, minimizing the risk of needle stick injuries.

3.2.3 Easy identification of needle guard after covering needle tip due to color coding.

3.2.4 Smooth edged safety needle guard with needle hub having rounded grip provides better support.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

3.2.5 Special tapered & kink resistant radiopaque catheter for easy insertion with optimal flow rates.

3.2.6 Ergonomically designed wings for proper fixation.

3.3 **IV Cannula with Integrated Three Way Stop Cock (With / Without Safety)**

3.3.1 Polycath can be used to administer two drugs fluids at the same time.

3.3.2 Rotating luer lock and threaded female ports facilitates safe and secure connection to luer of other systems.

3.3.3 Arrow indication marks on the handle to indicate the direction of flow.

3.4 **IV Cannula without Injection Port and without wings (With / Without Safety)**

3.4.1 Prevent for infection from additional openings in the Cannula.

3.4.2 Safety needle guard automatically covers the needle's sharp bevel after withdrawal of needle from the hub, minimizing the risk of needle stick injuries.

3.4.3 Easy identification of needle guard after covering needle tip due to color coding.

3.4.4 Smooth edged safety needle guard with needle hub having rounded grip provides better support.

3.4.5 Special tapered & kink resistant radiopaque catheter for easy insertion with optimal flow rates.

3.5 **IV Cannula for Quick flashback with ADVA needle (With / Without Safety)**

3.5.1 Quick flashback instantly confirms successful venipuncture.

3.5.2 Adva Needle technology enhances success in first prick of needle.

3.5.3 The overall insertion force of the needle is low, causing less pain during insertion.

3.5.4 Instant confirmation of blood flow along catheter body increases clinician's ability to successfully access the vein.

3.6 ***Closed IV Cannula with safety feature***

3.6.1 The pre-assembled system creates a closed single lumen fluid path, designed to minimize blood leakage from the catheter hub, and the potential for contamination and exposure to blood.

3.6.2 Instant confirmation of blood flow along catheter body increases clinician's ability to successfully access the vein. The IV Cannula with tubing is Latex-free, Non-DEHP & PVC-free as required.

3.6.3 The product is color coded and is available in the sizes from 18G to 24G.

3.7 **Common Features of IV Cannula family:**

3.7.1 Needle cover prevents accidental damage to needle or catheter.

3.7.2 Customized automated tipping technology for lower penetration forces.

3.7.3 Double tapered, kink resistant catheter with smooth surface offers painless cannulation.

3.7.4 Minimum clearance between catheter & needle to prevent peel back, less traumatic and convenient to use.

3.7.5 Highly chemical and kink resistant, catheter manufactured from tested bio-compatible materials offering longer indwelling time.

3.7.6 Back cut grinded beveled needle provides smooth vein puncture.

3.7.7 Transparent flash back chamber for easy visual confirmation of venipuncture (except Adva).

3.7.8 The product is color coded in accordance with ISO 10555-1:2013 & ISO 10555-5 for easy size identification and is available in the sizes from 14G to 27G.

3.7.9 Male or female fitting of device is provided with 6% luer taper for leak proof connection with other devices as per EN 20594-1, ISO 80369-7 & EN 1707.

3.7.10 The product is sterilized using EO (Ethylene Oxide) gas.

3.7.11 The product and packaging do not contain any constituents of animal origin.

3.7.12 Product classification as per EN ISO 10993 -1:2009/Ac:2010 / ISO 10993-1:2018.

3.7.12.1 **Device Connected with** - IV Set, Hypodermic Syringe without Needle, Three Way Stopcock & Extension Tube, etc.

3.7.12.2 **Contact duration** – B- Prolonged Exposure

3.7.12.3 **Categorization of Device** - External Communicating Device.

3.7.12.4 **Area of Contact** - Circulating Blood

3.7.12.5 **Applicable Biocompatibility Tests** - Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Sub-chronic Toxicity, Genotoxicity, Implantation, Hemocompatibility.

4. REFERENCE DOCUMENTS

S. No.	Document Code	Document Description
Applicable Regulatory standards		
4.1	EN ISO 13485:2016	Quality system - Medical Devices - Requirements for the Regulatory Purposes
4.2	MDD 93/42/EEC	European council directive for Medical Devices as amended by 2007/47/EC
4.3	EN ISO 14971:2012	Application of risk management to medical devices
4.4	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices — Amendment 1
4.5	ISO 11135:2014	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
4.6	ISO 11737-1:2018	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.
4.7	ISO 11737-2:2019	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
4.8	ISO 11607-1:2019	Packaging for terminally sterilized medical devices – requirements for materials, sterile barrier & packaging systems.
4.9	ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly process.
4.10	EN ISO 15223-1:2016	Symbols to be used with medical devices labels, labeling and information to be supplies

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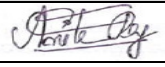
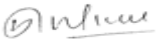
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

S. No.	Document Code	Document Description
4.11	EN 1041:2008+A1:2013	Terminology, Symbols and information provided with Medical Devices; Information supplied by the manufacturer with medical devices
4.12	ISO 10993-1:2018	Biological evaluation of medical devices – Evaluation and testing within a risk management process.
4.13	EN ISO 10993-3:2014	Biological evaluation of medical devices – Tests for genotoxicity, carcinogenicity and reproductive toxicity.
4.14	ISO 10993-4:2017	Biological evaluation of medical devices – Selection of tests for interaction with blood
4.15	EN ISO 10993-5:2009	Biological evaluation of medical devices – Tests for in vitro cytotoxicity
4.16	ISO 10993-6:2016	Biological evaluation of medical devices – Tests for local effects after implantation
4.17	EN ISO 10993-7:2008 / Amd 1:2019	Biological evaluation of medical devices – Ethylene oxide sterilization residuals
4.18	ISO 10993-10:2010	Biological evaluation of medical devices – Tests for irritation and delayed-type hypersensitivity
4.19	EN ISO 10993-11:2018	Biological evaluation of medical devices – Tests for systemic toxicity
4.20	EN ISO 10993-12:2012	Biological evaluation of medical devices – Sample preparation and reference materials
4.21	ISO 10555-1:2013 / Amd-1:2017	Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements.
4.22	ISO 10555-5:2013	Intravascular catheters -- Sterile and single-use catheters -- Part 5: Over-needle peripheral catheters.
4.23	EN 20594 – 1:1993 / AC:1997	Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - Part 1: General Requirements
4.24	EN 1707:1996	Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings
4.25	ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications.
4.26	ISO 9626:2016	Stainless steel needle tubing for manufacture of medical devices
4.27	EN 868-5:2018	Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods.
4.28	ISO 14644-1:2015	Clean rooms and associated controlled environments – Classification of air cleanliness
4.29	ASTM F 1980-2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
4.30	ISTA 2A	Partial Simulation Performance Tests for Packaged Products as per International Safe Transit Association
4.31	USP / IP	United States Pharmacopoeia / Indian Pharmacopoeia
Internal Standards / Documents		
4.32	QP/QPL/01	Quality Planning
4.33	QP/ECD/01	EC Vigilance
4.34	FP/QA/01	Finished product specification of IV Cannula
4.35	FP/QA/04	In process specifications for IV Cannula

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Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

S. No.	Document Code	Document Description
4.36	FP/QA/137	Finished Specification IV Cannula – 27G
4.37	FP/QA/138	Process control of IV Cannula - 27G
4.38	FP/QA/146	Process Control of Closed Safety –I.V. Cannula
4.39	FP/QA/149	Finished Product Testing of Closed Safety I.V. Cannula
4.40	PM/QA/2.01	Film for Blister Packing/ Pouch Packing
4.41	PM/QA/2.02	Medical Grade Printing Paper/ Tyvek Paper
4.42	PM/QA/2.03	Duplex Box Specification
4.43	PM/QA/2.04	Corrugated Box
4.44	PM/QA/2.06	Labels Specification
4.45	PM/QA/2.47	Instruction for Use
4.46	RM/QA/12	Specification of Needle
4.47	RM/QA/13	Specification of Catheter
4.48	RM/QA/09	Plastic raw materials
4.49	MF/IVC/01	Manufacturing of IV Cannula with wings & with injection port
4.50	MF/IVC/02	Manufacturing of IV Cannula with wings & without injection port
4.51	MF/IVC/03	Manufacturing of IV Cannula without injection port & without wings
4.52	MF/IVC/04	Manufacturing of IV Cannula with integrated 3 way stop Cock
4.53	MF/IVC/05	Manufacturing of IV Cannula without injection port & with small wings
4.54	MF/IVC/06	Manufacturing of Safety Intravenous Cannula without injection port
4.55	MF/IVC/07	Manufacturing of Safety Intravenous Cannula with injection port & with wings
4.56	MF/IVC/10	Manufacturing of IV Cannula with extension tube
4.57	WI/IVC/02	Maintenance of Clean Room
4.58	GTP/QC/09	Sterility Test
4.59	GTP/QC/10	BET Test
4.60	GTP/QC/12	Method for analysis of product Bioburden
4.61	GTP/QC/14	Monitoring of Bioburden of clean room manufacturing area
4.62	PML/MD/RA/01	Risk analysis of product
4.63	PML/MD/ER/01	Essential Requirements Checklist of the product
4.64	Drawing No.-ASSY-1001	Assembly Polyflon
4.65	Drawing No.-ASSY-1002	Assembly Polycan
4.66	Drawing No.-ASSY - 1003	Assembly Polycath
4.67	Drawing No.-ASSY - 1004	Assembly Polyneo
4.68	Drawing No.-ASSY - 1005	Assembly Polyon
4.69	Drawing No.-ASSY - 1018	Assembly Polywin
4.70	Drawing No.-ASSY - 1019	Assembly Polyflex
4.71	Drawing No.-ASSY – 1022	Assembly Polypen
4.72	Drawing No.-ASSY - 1101	Assembly Polysafety
4.73	Drawing No.-ASSY - 1007	Assembly Polyneo ADVA
4.74	Drawing No.-ASSY - 1010	Assembly Neonovo ADVA
4.75	Drawing No.-ASSY - 1039	Assembly Polyflex ADVA
4.76	Drawing No.-ASSY – 1040	Assembly Polyflon ADVA
4.77	Drawing No.-ASSY – 1041	Assembly Polycan ADVA
4.78	Drawing No.-ASSY – 1042	Assembly Polycath ADVA
4.79	Drawing No.-ASSY – 1044	Assembly Polypen ADVA
4.80	Drawing No.-ASSY - 1110	Assembly PolySafety Adva
4.81	Drawing No.-ASSY - 12085	Assembly Polywin Adva
4.82	Drawing No.-ASSY - 11285	Assembly Polywin Safety Adva

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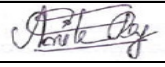
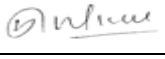
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

S. No.	Document Code	Document Description
4.83	Drawing No.-ASSY - 11523	Assembly Polycan Safety Adva
4.84	Drawing No.-ASSY - 1058	Assembly Polycath Safety Adva
4.85	Drawing No.-ASSY - 1102	Assembly Polypen Safety
4.86	Drawing No.-ASSY - 1103	Assembly Polywin Safety
4.87	Drawing No.-ASSY - 1104	Assembly Polycan Safety
4.80	Drg. No. ASSY. 13347	Needle Free connector (Safety with Wings)
4.81	Drg. No. ASSY. 1101.07	Safety Clip (Safety with Wings)
4.82	Drawing No.-ASSY - 13347	Needle Free connector
4.83	Drawing No.-ASSY - 10901	Assembly IV Cannula with tubing
4.84	Drawing No.-ASSY - 11840	Assembly Safety IV Cannula with tubing

5. SHELF LIFE

5.1 The Finished products shall conform to the specifications and functional requirements for a maximum of five years from the date of manufacturing.

6. STERILIZATION

6.1 **Paper and plastic film pouches/Blister packed product**: Product shall be sterilized with Ethylene Oxide (EO) gas as per standardized and validated sterilization cycle as per EN ISO 11135-1:2007 / ISO 11135:2014 and routine monitoring cycle is carried out as per WI/IVC/25. The medical grade paper is designed to allow maximum exchange of ethylene oxide, air and moisture. For detailed validation report refer to QA department. Based on validation result the routine cycle for sterilization is summarized as follows: -

S. No.	Particular	Limit
1	**Preconditioning**	
	(i) Time	60 minute ± 2 minutes
	(ii) Temperature of chamber	45°C (±5°C)
	(iii) Humidity	30% ~ 90%
2.	**Conditioning**	
	(i) Vacuum drawn and rate	-0.75Kg/cm2@30min.±15min.
	(ii) Vacuum holding time	10 minute ± 1 minutes
	(iii) Temperature of chamber	45°C (±5°C)
	(iv) Humidity of chamber	30% ~ 90%
3	**Sterilization**	
	(i) EO gas inlet temperature	Not less than 20°C
	(ii) Concentration of EO gas	550 mg/lit. ± 25 mg/lit.
	(iii) Temperature of chamber	45°C (±5°C)
	(iv) Exposure time	280 minutes±1min.
4.	**Aeration**	
	(i) Vacuum drawn and rate	-0.75kg/cm2@ 40min ± 25 min.
	(ii) Total number of aerations	2 nos.

The detailed record of routine monitoring is maintained with the QA as well as production department.

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Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
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Approved By	SS Rawat	AVP - Quality		05.01.2021

6.2 Product appearance and functional performance is not compromised by up to three EO sterilization cycles as the product is sterilized three times and the package of product remained intact. The ethylene oxide residue was also found within limit.

6.3 Revalidation is done once in a year. The calibration of instruments like pressure gauge, temperature gauge, temperature indicator and controller, PT 100 etc. are done time to time as per their due date of Re- calibration plan.

7. MATERIAL

7.1 All component materials should be such that components and product assemblies will pass material testing as specified in specifications.

S. No.	Parts where material is used	Base Material	Grade		CAS No.
1	Needle Cover	LDPE	24FS040		9002-88-4
			300YY		
			LDF201FG		
		Polypropylene	H-110MA		9003-07-0
			Titanpro 6331		
2	Needle Hub	Polypropylene	H110MA		9003-07-0
			H200MK		
		ABS	TR558A		9003-56-9
		PC	Lexan144R		25037-45-0
3	Catheter hub	Polypropylene	SM 498		9010-79-1
			Z433		
4	Port Cap (Snap fit type)	HDPE + LDPE	HDPE	50MA180	9002-88-4
				M200056	
				HI1600	
			LDPE	LDF201FG	9002-88-4
				24FS040	
5	Port Cap - Hinge Type	Polypropylene	Z433		9003-07-0
6	*Port Cap - Flon Type*	HDPE + LDPE	HDPE	HI1600	9002-88-4
			LDPE	LDF201FG	
				24FS040	
7	Flash Back Chamber	Polypropylene	H110MA		9003-07-0
			Titanpro 6331		
		K - Resin	KR 99HG		9003-55-8
		ABS	TR558A		9003-56-9
8	Silicon Tube	Silicon	-		7440-21-3
9	Luer Lock	HDPE	M200056		9002-88-4
			HI 1600		
10	Thumb Support	HDPE	M200056		9002-88-4
11	Slip Ring	Polyacetal	900P NC 010		9002-81-7
		Stainless Steel	SS 305		65997-19-5
12	Channel Housing	Polycarbonate	1201-15		25037-45-0
			Lexan 144R		

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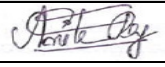
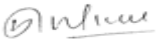
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

S. No.	Parts where material is used	Base Material	Grade	CAS No.
13	Handle	HDPE	50 MA 180 HI1600 M200056	9002-88-4
14	Butterfly	Polypropylene	SM 498	9010-79-1
15	Upper locking Half	Polypropylene	H110MA	9003-07-0
16	Lower locking half	Polypropylene	SM 498 H110MA	9003-07-0 9010-79-1
17	Needle / Cannula	Stainless steel	SS 304	65997-19-5
18	Catheters	PTFE FEP PUR	100-J 100-N -	9002-84-0 25067-11-2 550-33-4
19	Silicon ring	Silicon	N/A	7440-21-3
20	Porex Filter	Polyethylene	XM - 1347	9002-88-4
21	Plastic Part of Safety Clip-14G-17G	ABS	IFB-920	9003-56-9
22	Safety Steel Clip (14G - 17G)	Stainless Steel	SS 304	7439-89-6
23	Hydrophobic Plug (Self Seal Type)	Polyethylene	9089	9002-88-4
24	Valve	Silicon	-	7440-21-3
25	Wing	Thermo Plastic Elastomer	6FA70	308079-71-2
26	Safety clip	Polycarbonate	1201-15	25037-45-0
27	*Needle Hub*	ABS	IFB 700 / SHF 50+/ IFB920	9003-56-9
28	*Catheter hub*	CAP / PCB	350 Tenite + Propinat – 350A	25037-45-0
29	*Y-Site*	ABS / PCB	920555 / MX 711	25037-45-0
30	*C-Clamp*	Poly Acetal	1700P NC010	9002-81-7
31	*Tube clamp*	ABS	IFB 920	9003-56-9
32	*Tube*	PVC DEHP Free	IP 70 ND / IP 9T ND	9002-86-2
33	*Clip Housing*	Polypropylene	H110MA	9003-07-0
34	*Needle free Connector*	ABS / Poly Carbonate	IFB 920	9003-56-9
35	*Heparin cap*	ABS	SHF 50+ (M)	9003-56-9
36	*Rubber Port*	Synthetic Isoprene / Silicon Rubber	N/A	7440-21-3
37	*Straight Luer*	TPE	MX-711	308079-71-2
38	*Stopper*	Polyacetal	1700 P NC 010	9002-81-7
39	Unit Package Lid (Paper)	Medical Grade Grid Lacquered Paper	OCPSxxxx10x	N/A
40	Unit Package Lid (Tyvek)	Tyvek	2 FS / PA 5511	N/A
41	Unit Package Blister	PVC Film	Medical grade / Non-toxic	N/A
42	Unit Package Soft Blister	PP+PE Film	Medical grade / Non-	N/A

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Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

S. No.	Parts where material is used	Base Material	Grade	CAS No.
			toxic	
43	Duplex Box	Printed Paper board	N/A	N/A
44	Duplex Box Label	Adhesive Paper	N/A	N/A
45	Shipper Box (Big / Small)	Corrugated Paper board	N/A	N/A
46	EO Gas	30% EO & 70% CO2	N/A	EO - 75-21-8 CO_2 - 124-38-9

8. COMPONENT AND PROCEDURE FOR ASSEMBLY

8.1 Intravenous (IV) Cannula with Injection Port (with / without safety)

8.1.1 Components

(i)	Luer Lock Plug (36 Ribs)	-	Injection Molding
(ii)	Flash Back Chamber	-	Injection Molding
(iii)	Slip Ring	-	Injection Molding
(iv)	Body	-	Injection Molding
(v)	Needle Hub	-	Injection Molding
(vi)	Port cap	-	Injection Molding
(vii)	Needle Cover	-	Extrusion Molding
(viii)	Cannula	-	Injection Molding
(ix)	Catheter	-	Injection Molding
(x)	Silicon Tube	-	Extrusion Molding
(xi)	Safety tip clip	-	Injection Molding
(xii)	Safety plastic clip	-	Injection Molding
(xiii)	Luer Lock Plug (8 Ribs)	-	Injection Molding

8.1.2 Assembly

(i) Wing Housing Assembly - The assembly of slip ring, catheter and wing housing is done on automatic machine as per WI/IVC/39, WI/IVC/80 & WI/IVC/81.

(ii) Catheter tipping - The catheter tipping is carried out automatically as per WI/IVC/35.

(iii) Valve Assembly & Fitment - The Valve Assembly into the wing housing is done as per WI/IVC/06.

(iv) Needle Fixing - The assembly of needle with needle hub is done as per WI/IVC/38 and automatically as per WI/IVC/46 & WI/IVC/85.

(v) Needle Insertion and Cover Fixing - The Needle Insertion and needle cover Fixing is carried out as per WI/IVC/08.

(vi) Flash Back & Luer Lock Plug Assembly - The Flash Back chamber and Luer Lock Plug Assembly is done as per WI/IVC/41.

(vii) Assembly of Safety tip clip & Needle - The assembly of safety tip clip & needle is done as per WI/IVC/57.

(viii) Final Inspection - The final inspection of the product is done as per WI/IVC/15.

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Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

8.2 **Intravenous (IV) Cannula without Injection Port & with Wings (with / without safety)**

8.2.1 **Component**

(i)	Luer Lock Plug (36 Ribs)	-	Injection Molding
(ii)	Flash Back Chamber	-	Injection Molding
(iii)	Slip Ring	-	Injection Molding
(iv)	Body	-	Injection Molding
(v)	Needle Hub	-	Injection Molding
(vi)	Needle Cover	-	Extrusion Molding
(vii)	Cannula	-	Extrusion Molding
(viii)	Catheter	-	Extrusion Molding
(ix)	Luer Lock Plug (8 Ribs)	-	Injection Molding
(x)	Safety tip clip	-	Injection Molding
(xi)	Safety plastic clip	-	Injection Molding

8.2.2 **Assembly**

(i) Wing Housing Assembly - The assembly of slip ring, catheter and wing housing is done on automatic machine as per WI/IVC/39, WI/IVC/80 & WI/IVC/81.

(ii) Catheter tipping - The catheter tipping is carried out automatically as per WI/IVC/35.

(iii) Needle Fixing - The assembly of needle with needle hub is done as per WI/IVC/38 and automatically as per WI/IVC/46 & WI/IVC/85.

(iv) Needle Insertion and Cover Fixing - The Needle Insertion and needle cover Fixing is carried out as per WI/IVC/08.

(v) Flash Back & Luer Lock Plug Assembly - The Flash Back chamber and & Luer Lock Plug Assembly is done as per WI/IVC/09 & WI/IVC/41

(vi) Assembly of Safety tip clip & Needle - The assembly of safety tip clip & needle is done as per WI/IVC/57.

(vii) Final Inspection - The final inspection of the product is done as per WI/IVC/15.

8.3 **Intravenous (IV) Cannula without Injection Port & with Small Wings (with / without safety)**

8.3.1 Component

(i)	Luer Lock Plug (36 Ribs)	-	Injection Molding
(ii)	Flash Back Chamber	-	Injection Molding
(iii)	Slip Ring	-	Injection Molding
(iv)	Body	-	Injection Molding
(v)	Needle Hub	-	Injection Molding
(vi)	Needle Cover	-	Extrusion Molding
(vii)	Cannula	-	Extrusion Molding
(viii)	Catheter	-	Extrusion Molding
(ix)	Luer Lock Plug (8 Ribs)	-	Injection Molding

(x)	Safety tip clip	-	Injection Molding
(xi)	Safety plastic clip	-	Injection Molding

8.3.2 **Assembly**

(i) Wing Housing Assembly - The assembly of slip ring, catheter and wing housing is done on automatic machine as per WI/IVC/39, WI/IVC/80 & WI/IVC/81.

(ii) Catheter tipping - The catheter tipping is carried out automatically as per WI/IVC/35.

(iii) Needle Fixing - The assembly of needle with needle hub is done as per WI/IVC/38 and automatically as per WI/IVC/46.

(iv) Needle Insertion and Cover Fixing - The Needle Insertion and needle cover Fixing is carried out as per WI/IVC/08.

(v) Flash Back & Luer Lock Plug Assembly - The Flash Back chamber and & Luer Lock Plug Assembly is done as per WI/IVC/41.

(vi) Assembly of Safety tip clip & Needle - The assembly of safety tip clip & needle is done as per WI/IVC/57.

(vii) Final Inspection - The final inspection of the product is done as per WI/IVC/15.

8.4 Intravenous (IV) Cannula with Integrated Three Way Stop Cock (with / without safety)

8.4.1 **Component**

(i)	Luer Lock Plug (36 Ribs)	-	Injection Molding
(ii)	Flash Back Chamber	-	Injection Molding
(iii)	Needle Hub	-	Injection Molding
(iv)	Needle Cover	-	Extrusion Molding
(v)	Channel	-	Injection Molding
(vi)	Handle	-	Injection Molding
(vii)	Body	-	Injection Molding
(viii)	Cannula	-	Extrusion Molding
(ix)	Catheter	-	Extrusion Molding
(x)	Luer Lock Plug (8 Ribs)	-	Injection Molding
(xi)	Safety tip clip	-	Injection Molding
(xii)	Safety plastic clip	-	Injection Molding
(xiii)	Slip Ring	-	Injection Molding

8.4.2 **Assembly**

(i) Handle and Channel Assembly - The assembly of handle with channel is done as per WI/IVC/11.

(ii) Catheter tipping - The catheter tipping is carried out automatically as per WI/IVC/35.

(ii) Teflon & Butterfly Assembly - The Teflon (catheter) and butterfly assembly is carried out as per WI/IVC/13.

(iii) Needle Fixing - The assembly of needle with needle hub is done as per WI/IVC/38 and automatically as per WI/IVC/46.

(iv) Needle Insertion and Cover Fixing - The Needle Insertion and needle cover Fixing is carried out as per WI/IVC/08.

(v) Flash Back & Luer Lock Plug Assembly - The Flash Back Chamber & Luer Lock Plug assembly is done as per WI/IVC/41.

(vi) Assembly of Safety tip clip & Needle - The assembly of safety tip clip & needle is done as per WI/IVC/57.

(vii) Final Inspection - The final inspection of the product is done as per WI/IVC/15.

8.5 Intravenous (IV) Cannula without Injection Port & Wing (with / without safety)

8.5.1 Component

(i)	Luer Lock Plug (36 Ribs)	-	Injection Molding
(ii)	Flash Back Chamber	-	Injection Molding
(iii)	Slip Ring	-	Injection Molding
(iv)	Needle Hub	-	Injection Molding
(v)	Body	-	Injection Molding
(vi)	Needle Cover	-	Extrusion Molding
(vii)	Cannula	-	Extrusion Molding
(viii)	Catheter	-	Extrusion Molding
(ix)	Luer Lock Plug (8 Ribs)	-	Injection Molding
(x)	Safety tip clip	-	Injection Molding
(xi)	Safety plastic clip	-	Injection Molding

8.5.2 Assembly

(i) Body Assembly - The assembly of slip ring, catheter and wing housing (catheter hub) is done on automatic machine as per WI/IVC/3, WI/IVC/80 & WI/IVC/81.

(ii) Catheter tipping - The catheter tipping is carried out automatically as per WI/IVC/35.

(iii) Needle Fixing - The assembly of needle with needle hub is done as per WI/IVC/38 and automatically as per WI/IVC/46.

(iv) Needle Insertion and Cover Fixing - The Needle Insertion and needle cover Fixing is carried out as per WI/IVC/08.

(v) Flash Back & Luer Lock Plug Assembly - The Flash Back chamber and & Luer Lock Plug Assembly is done as per WI/IVC/41.

(vi) Assembly of Safety tip clip & Needle - The assembly of safety tip clip & needle is done as per WI/IVC/57.

(vii) Final Inspection - The final inspection of the product is done as per WI/IVC/15.

8.6 Intravenous (IV) Cannula with Injection Port, Snap Fit cap & Suturable Wing (with / without safety)

8.6.1 Components

(i)	Luer Lock Plug (36 Ribs)	-	Injection Molding
(ii)	Flash Back Chamber	-	Injection Molding
(iii)	Slip Ring	-	Injection Molding
(iv)	Body	-	Injection Molding

(v)	Needle Hub	-	Injection Molding
(vi)	Port cap	-	Injection Molding
(vii)	Needle Cover	-	Extrusion Molding
(viii)	Cannula	-	Extrusion Molding
(ix)	Catheter	-	Extrusion Molding
(x)	Silicon Tube	-	Extrusion Molding
(xi)	Luer Lock Plug (8 ribs)	-	Injection Molding
(xii)	Safety tip clip	-	Injection Molding
(xiii)	Safety plastic clip	-	Injection Molding

8.6.2 **Assembly**

(i) Wing Housing Assembly - The assembly of slip ring, catheter and wing housing (catheter hub) is done on automatic machine as per WI/IVC/39, WI/IVC/80 & WI/IVC/81.

(ii) Catheter tipping - The catheter tipping is carried out automatically as per WI/IVC/35.

(iii) Valve Assembly & Fitment - The Valve Assembly into the wing housing is done as per WI/IVC/06.

(iv) Needle Fixing - The assembly of needle with needle hub is done as per WI/IVC/38 and automatically as per WI/IVC/46 & WI/IVC/85.

(v) Needle Insertion and Cover Fixing - The Needle Insertion and needle cover Fixing is carried out as per WI/IVC/08.

(vi) Flash Back & Luer Lock Plug Assembly - The Flash Back chamber and & Luer Lock Plug Assembly is done as per WI/IVC/41.

(vii) Assembly of Safety tip clip & Needle - The assembly of safety tip clip & needle is done as per WI/IVC/57.

(viii) Final Inspection - The final inspection of the product is done as per WI/IVC/15.

8.7 Intravenous (IV) Cannula without Injection Port & without Wing (with / without safety)

8.7.1 **Component**

(i)	Luer Lock Plug (36 Ribs)	-	Injection Molding
(ii)	Flash Back Chamber	-	Injection Molding
(iii)	Slip Ring	-	Injection Molding
(iv)	Needle Hub	-	Injection Molding
(v)	Body	-	Injection Molding
(vi)	Needle Cover	-	Extrusion Molding
(vii)	Cannula	-	Extrusion Molding
(viii)	Catheter	-	Extrusion Molding
(ix)	Luer Lock Plug (8 Ribs)	-	Injection Molding
(x)	Safety tip clip	-	Injection Molding
(xi)	Safety plastic clip	-	Injection Molding

8.7.2 **Assembly**

(i) Body Assembly - The assembly of slip ring, catheter and body (wing housing/catheter hub) is done on automatic machine as per WI/IVC/39, WI/IVC/80 & WI/IVC/81.

(ii) Catheter tipping - The catheter tipping is carried out automatically as per WI/IVC/35.

(iii) Needle Fixing - The assembly of needle with needle hub is done as per WI/IVC/38 and automatically as per WI/IVC/46.

(iv) Needle Insertion and Cover Fixing - The Needle Insertion and needle cover Fixing is carried out as per WI/IVC/08.

(iv) Flash Back & Luer Lock Plug Assembly - The Flash Back chamber and & Luer Lock Plug Assembly is done as per WI/IVC/41.

(v) Assembly of Safety tip clip & Needle - The assembly of safety tip clip & needle is done as per WI/IVC/57.

(vi) Final Inspection - The final inspection of the product is done as per WI/IVC/15.

8.8 For Intravenous (IV) Cannula without Injection Port & without Wing (with / without safety)

8.8.1 Component for Polypen

(i)	Upper Locking	-	Injection Molding
(ii)	Lower Locking	-	Injection Molding
(iii)	Slip Ring	-	Import
(iv)	Needle Hub	-	Injection Molding
(v)	Body	-	Injection Molding
(vi)	Flash Back Chamber	-	Injection Molding
(vii)	Cannula	-	Extrusion Molding
(viii)	Catheter	-	Extrusion Molding
(ix)	Filter Plug	-	Injection Molding
(x)	Filter Membrane	-	Injection Molding
(xi)	Safety tip clip	-	Injection Molding
(xii)	Safety plastic clip	-	Injection Molding

8.8.2 Assembly

(i) Body Assembly - The assembly of slip ring, catheter and body (housing) is done on automatic machine as per WI/IVC/39, WI/IVC/80 & WI/IVC/81.

(ii) Catheter tipping - The catheter tipping is carried out automatically as per WI/IVC/35.

(iii) Needle Fixing - The assembly of needle with needle hub is done as per WI/IVC/38 and automatically as per WI/IVC/46.

(iii) Flash Back & Filter Plug Assembly - The Flash Back chamber and Filter Plug Assembly is done as per WI/IVC/64 & WI/IVC/75.

(iv) Assembly of Safety tip clip & Needle - The assembly of safety tip clip & needle is done as per WI/IVC/57.

(v) Final Inspection - The final inspection of the product is done as per WI/IVC/15.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

8.9 For Closed Intravenous (IV) Cannula (IV Cannula with Tubing- with / without safety)

8.9.1 Components

(i)	Catheter Hub	-	Injection Molding
(ii)	Y-Site	-	Injection Molding
(iii)	Needle-hub	-	Injection Molding
(iv)	Rubber Port	-	Import
(v)	Tubing	-	Extrusion Molding
(vi)	Needle	-	Import
(vii)	Slip Ring	-	Import
(viii)	Needle Cover	-	Extrusion Molding
(ix)	Luer Lock	-	Injection Molding
(x)	Heparin Cap	-	Import
(xi)	Tube Clamp	-	Injection Molding
(xii)	Wing	-	Injection Molding
(xiii)	Clip Housing	-	Injection Molding
(xiv)	C-Clamp	-	Injection Molding
(xv)	Needle free Connector	-	Import
(xvi)	Safety Clip	-	Insert Molding
(xvii)	Porex Filter	-	Import
(xviii)	Catheter	-	Extrusion Molding
(xix)	FB Chamber	-	Injection Molding
(xx)	Silicon Ring	-	Import
(xxi)	Straight Luer	-	Injection Molding
(xxii)	Silicon Rubber Stopper	-	Injection Molding

8.9.2 Assembly

(i) Body Assembly - The assembly of slip ring, catheter and catheter hub (housing) is done on automatic machine as per WI/IVC/39, WI/IVC/60, WI/IVC/80 & WI/IVC/81.

(ii) Catheter tipping - The catheter tipping is carried out as per WI/IVC/35.

(iii) Needle Assembly - The assembly of needle with needle hub is done as per WI/IVC/54.

(iv) Rubber Port Assembly - The assembly of rubber port into body is done as per WI/IVC/52 & automatically as per WI/IVC/53.

(v) Final Inspection - The final inspection of the product is done as per WI/IVC/15.

9. FUNCTIONAL SPECIFICATIONS

9.1 Needle Cover

9.1.1 Basic shape conical or a cylindrical tube as required.

9.1.2 Material should be clear to translucent for ease of visualization through the wall to the inside.

9.1.3 Interference fit of the bottom of the cover over the body with catheter adapter.

9.1.4 The fitting with the body should be such that it provides easy two hand removal for use but should also prevent accidental detachment during handling, shipping and storage.

9.2 **Flash Back Chamber**

9.2.1 Material clear to transparent to allow visualization through walls to inside. Functions as an extended blood flash back chamber.

9.2.2 Front nose to be a male luer in conformance with EN 20594-1:1993/A1:1997, ISO 80369-7:2016 & EN 1707:1996.

9.2.3 Should permit rapid air venting for immediate blood flash back but prevent blood leakage to outside.

9.2.4 Finished product shall demonstrate rapid flash back visualization when tested as per WI/QA/57.

9.2.5 When assembled into needle hub, it shall not accidentally detach from needle hub during handling, storage and shipping.

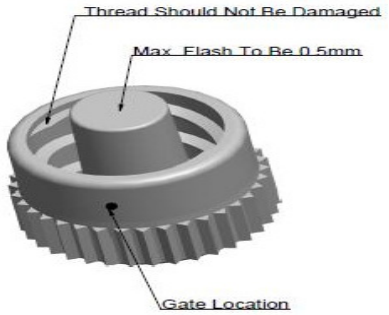
9.3 **Luer Lock Plug**

9.3.1 Also known as Luer Lock caps available in 36 ribs & 8 ribs, as per requirement.

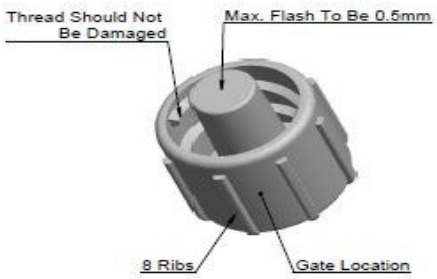
9.3.2 Male Luer Lock design to comply with EN 20594-1:1993/A1:1997, ISO 80369-7:2016 & EN 1707:1996.

9.3.3 External gripping features.

36 Ribs Luer Lock



8 Ribs Luer Lock



9.4 **Needle Hub and Cannula Assembly**

9.4.1 Needle material shall be stainless steel ground to a B-Bevel point.

9.4.2 Needle Hub material shall be clear for easy blood flash back visualization.

9.4.3 The needle having a notch near needle tip for rapid flashback along with catheter body (applicable for Adva) as given below-

9.4.4 The Cannula is press fit into the needle hub.

9.4.5 The joint strength shall be a minimum if 20N (2 Kg approx.) for all gauges from 14G to 20G and should be 10N (1 Kg approx.) for 22G to 26G. The tensile testing between needle and needle hub is done as per WI/QA/57.

Approvals	Name	Designation	Signature	Date
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Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

9.4.6 Needle hub shall provide a rear female luer taper as per EN 20594-1:1993/A1:1997, ISO 80369-7:2016 & EN 1707:1996.

9.5 **Body and Catheter Assembly**

9.5.1 Catheter tube should be translucent or transparent (except for fully radio opaque) and if required should have 2 or 3 radio opaque lines which are fully encapsulated.

9.5.2 Catheter tube should demonstrate inherent kink recovery.

9.5.3 Body should provide a female luer lock connector for the axial flow path and shall pass functional tests as per EN 20594-1:1993/A1:1997, ISO 80369-7:2016 & EN 1707:1996.

9.5.4 The body for IV Cannula with injection port should have a female luer connection at the side port as per EN 20594-1:1993/A1:1997, ISO 80369-7:2016 & EN 1707:1996. It shall also have a non-return valve made of silicone tube for injection of medicine or fluid with a syringe through the injection port.

9.5.5 The body material should be transparent or translucent for IV Cannula with Injection port. For IV Cannula without injection port, IV Cannula without injection port and small wings and IV Cannula without wings & without port, IV Cannula with Injection Port, Snap Fit Cap & Suturable wings. The body should be color coded as per international standard mentioned in Table – 1, 2 & 3.

9.5.6 The Joint Strength between body and catheter shall be as follows when tested as per WI/QA/57.

CATHETER GAUGE	*MINIMUM* JOINT STRENGTH
14G	15 N
16G	10 N
17G	10 N
18G	10 N
20G	5 N
22G	5 N
24G	3 N
26G	3 N
27G	*3 N*

9.5.7 The assembly shall not leak when tested as per WI/QA/57.

9.5.8 Water flow rate capacity through tipped catheter and body assembly shall be as follows when tested as per WI/QA/57. These average flow rate capacities shall be used in product labeling when required.

Table – 1 (Standard IV Cannula)

Catheter Gauge	Color Coding	Length of Catheter (± 1.0mm)	Outer Dimension of catheter as per ISO 10555-5		Average Flow Rate	
			Nominal Value (mm)	Range (mm)	Flow Rate (ml/min)	Limit (as per ISO 10555-5)
14G	Orange	45	1.9,2.0,2.1,2.2	1.85 to 2.25	305	90% to 115%
16G	Grey	45	1.6, 1.7, 1.8	1.55 to 1.85	200	90% to 115%
17G	White	45	1.4, 1.5	1.35 to 1.55	142	90% to 115%
18G	Deep Green	45	1.2, 1.3	1.15 to 1.35	95	90% to 115%

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Approved By	SS Rawat	AVP - Quality		05.01.2021

Catheter Gauge	Color Coding	Length of Catheter (± 1.0mm)	Outer Dimension of catheter as per ISO 10555-5		Average Flow Rate	
			Nominal Value (mm)	Range (mm)	Flow Rate (ml/min)	Limit (as per ISO 10555-5)
					90	
18G	Deep Green	38	1.2, 1.3	1.15 to 1.35	90	90% to 115%
18G	Deep Green	32	1.2, 1.3	1.15 to 1.35	95 90	90% to 115%
20G	Pink	38	1.0, 1.1	0.95 to 1.15	65	90% to 115%
20G	Pink	32	1.0, 1.1	0.95 to 1.15	65 56	90% to 115%
20G	Pink	25	1.0, 1.1	0.95 to 1.15	65 56	90% to 115%
22G	Deep Blue	25	0.8, 0.9	0.75 to 0.95	36	80% to 125%
24G	Yellow	19	0.7	0.65 to 0.75	23	80% to 125%
24G	Yellow	14	0.7	0.65 to 0.75	27	80% to 125%
26G	Violet	19	0.6	0.55 to 0.65	17	80% to 125%
27G	Light Orange	15 ± 1	0.6	0.55 to 0.65	12	80% to 125%

Table – 2 (Safety IV Cannula)

Catheter Gauge	Color Coding	Length of Catheter (± 1.0mm)	Outer Dimension of catheter as per ISO 10555-5		Average Flow Rate	
			Nominal Value (mm)	Range (mm)	Flow Rate (ml/min)	Limit (as per ISO 10555-5)
14G	Orange	45	1.9,2.0,2.1,2.2	1.85 to 2.25	305	90% to 115%
16G	Grey	45	1.6, 1.7, 1.8	1.55 to 1.85	200	90% to 115%
17G	White	45	1.4, 1.5	1.35 to 1.55	142	90% to 115%
18G	Deep Green	32	1.2, 1.3	1.15 to 1.35	105	90% to 115%
18G	Deep Green	45	1.2, 1.3	1.15 to 1.35	100	90% to 115%
18G	Deep Green	38	1.2, 1.3	1.15 to 1.35	100	90% to 115%
20G	Pink	25	1.0, 1.1	0.95 to 1.15	65	90% to 115%
20G	Pink	32	1.0, 1.1	0.95 to 1.15	61	90% to 115%
20G	Pink	38	1.0, 1.1	0.95 to 1.15	61	90% to 115%
22G	Deep Blue	25	0.8, 0.9	0.75 to 0.95	36	80% to 125%
24G	Yellow	14	0.7	0.65 to 0.75	27	80% to 125%
24G	Yellow	19	0.7	0.65 to 0.75	23	80% to 125%
26G	Violet	19	0.6	0.55 to 0.65	17	80% to 125%

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

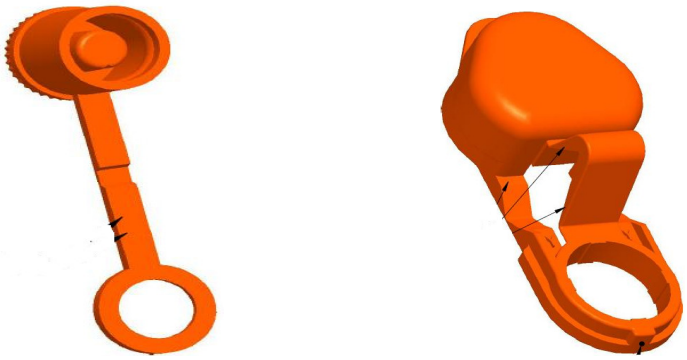
Table – 3 (Closed IV Cannula)

Catheter Gauge	Color Coding	Length of Catheter (± 1.0mm)	Outer Dimension of catheter as per ISO 10555-5		Average Flow Rate	
			Nominal Value (mm)	Range (mm)	Flow Rate (ml/min)	Limit (as per ISO 10555-5)
18G	Deep Green	32	1.2, 1.3	1.15 to 1.35	84	90% to 115%
18G	Deep Green	45	1.2, 1.3	1.15 to 1.35	79	90% to 115%
20G	Pink	32	1.0, 1.1	0.95 to 1.15	58	90% to 115%
20G	Pink	25	1.0, 1.1	0.95 to 1.15	61	90% to 115%
22G	Deep Blue	25	0.8, 0.9	0.75 to 0.95	33	80% to 125%
22G	Deep Blue	19	0.8, 0.9	0.75 to 0.95	36	80% to 125%
24G	Yellow	19	0.7	0.65 to 0.75	18	80% to 125%
24G	Yellow	14	0.7	0.65 to 0.75	19	80% to 125%

9.6 **Valve & Port Cap Assembly**

9.6.1 Port cap shall be securely held in position on the injection port so that the easy rotation by hand to any circumferential position is possible. The cover should not open during handling, storage & transportation.

9.6.2 The port cap shall allow two fingers opening and closing. The top of the port cap shall be lightly textured to provide a grip and minimize finger slippage during use.



Port Cap- Flon and Hinge type

9.6.3 The port cap design should be such that it shall remain open position and not accidentally close by itself while injection port is in use.

9.6.4 The one-way (non-return) port valve should be a piece of 8.0mm length of cylindrical tube shape of flexible material. It should be positioned in the axial flow path of the catheter adapter to occlude the opening to the injection port.

9.6.5 The valve shall remain in the closed position unless actuated via an increased liquid pressure in the port. Each valve is to be checked in process as per WI/IVC/06.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
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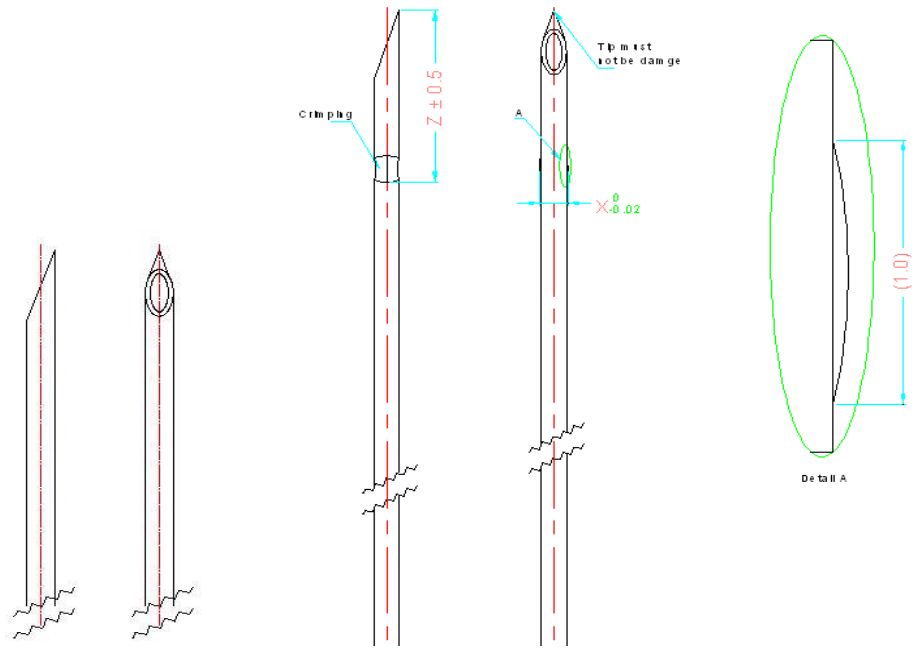
9.6.6 When in the closed position, the one-way valve shall not leak fluid from the inside flow path to the side port during administration of IV fluids through the catheter.

9.7 Crimping of Needle

9.7.1 Needle should not bend at crimped area. Dimension of the needle should comply with specification given below. The tip of the needle should not get damage during crimping.

S. No.	Gauge / Size	OD at crimped area (X+0/-0.02mm)	Distance of crimped area from Tip (Z±0.5mm)	
			Non – Adva Needle	Adva Needle
1	14	1.73 - 1.75mm	7.5 mm	7.5 mm
2	16	1.33 - 1.35mm	6.5 mm	6.5 mm
3	17	1.13 - 1.15mm		
4	18	0.98 - 1.00mm		
5	20	0.78 - 0.80mm		
6	22	0.63 - 0.65mm		8.1 mm
7	24	0.51 - 0.53mm		
8	26	0.46 - 0.48mm		N/A

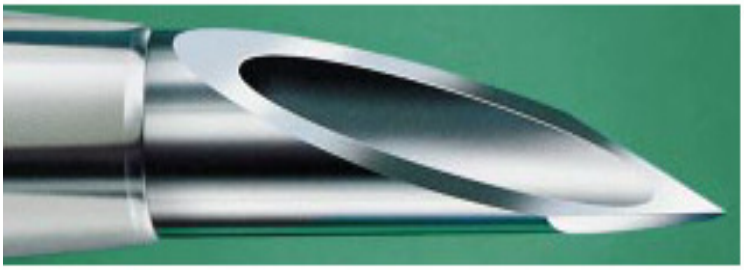


Needle before crimping Needle after crimping

9.8 Needle Tip / Catheter Tip

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

9.8.1 Finished product needle and catheter tip lubrication shall be such that no visible tip damage is evident to the naked eye.



9.9 **Needle Assembly / Catheter Assembly**

9.9.1 The catheter tip should fit slightly tight over the needle. The tightness should be just enough to hold the catheter & needle assemblies together. Also, the needle assembly should be easily removable with one hand from the catheter body assembly during normal use.

9.9.2 The trim distance between the catheter tip and heel of the needle bevel should be 0.0 mm ~ 1.0 mm as per ISO 10555-5:2013.

9.10 **Channel / Handle Assembly**

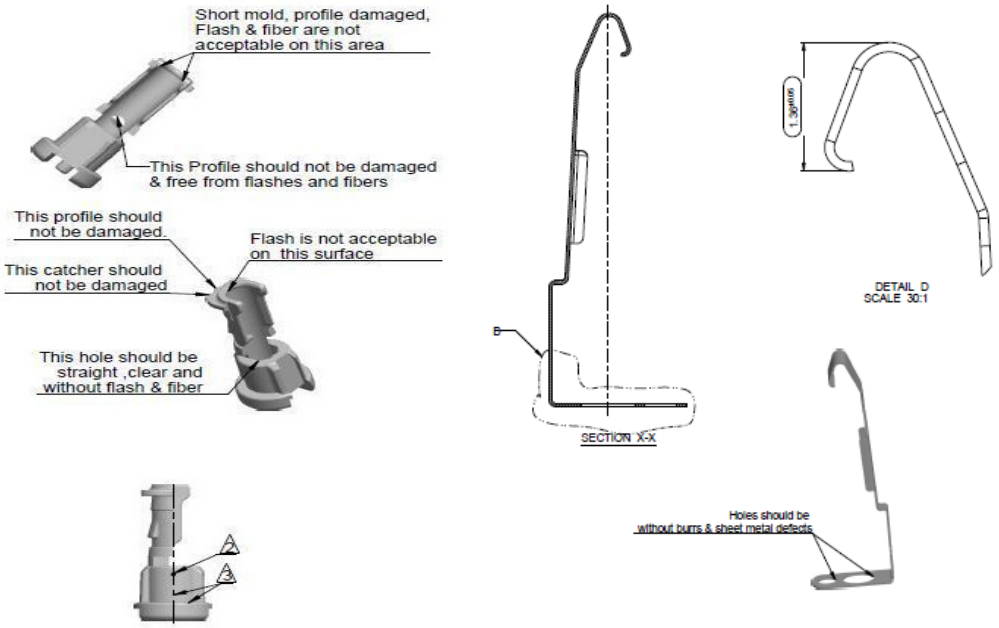
9.10.1 The channel and handle assembly done as per WI/IVC/11 should have a locking fit so that the handle does not come out of the channel after assembly and there is no leakage in the channel and handle assembly.

9.10.2 The channel should have female luer lock connection as per EN 20594-1:1993/A1:1997, ISO 80369-7:2016 & EN 1707:1996 at two ends.

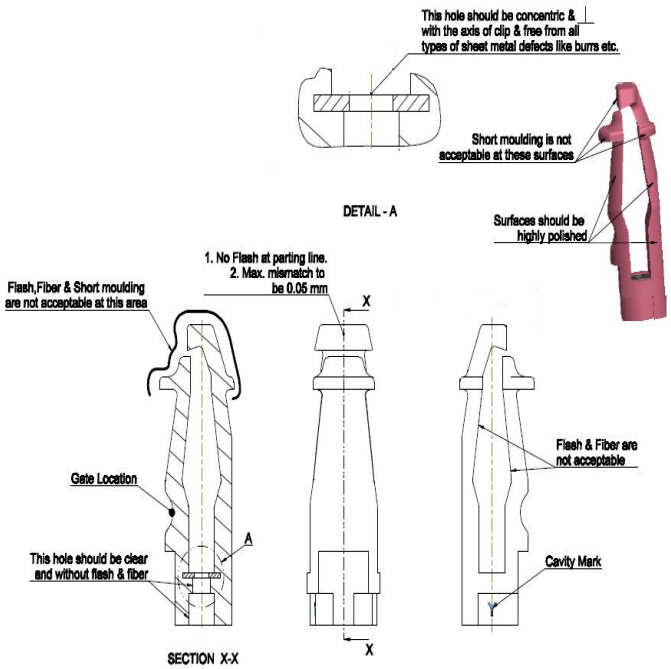
9.10.3 The channel and handle assembly shall be leak proof when tested in accordance with WI/QA/57.

9.11 **Safety tip clip**

9.11.1 Safety clip is as designed such that it can rest on needle in the body during normal & venipuncture stage & when needle pulls out from body, the safety clip also comes out from body. At final stage safety clip covers the needle tip. Safety clip & wing housing are the critical component. If safety clip doesn't work, then needle tip may cause of needle prick injury to the doctor or nurse. SS safety clip with plastic is used for 14G, 16G & 17G.



Safety Tip Clip used for 14G to 17G



Safety Tip Clip used for 18G to 26G

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

9.12 **Automated Assembly**

9.12.1 Component parts for automated assembly shall have features that accommodate handling feeding and assembly without resting & jamming.

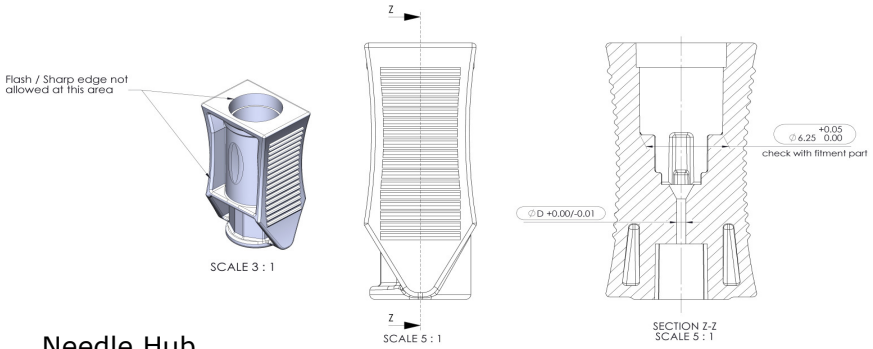
9.13 ***Needle Hub and Needle Assembly***

9.13.1 Needle material shall be stainless steel ground to a B-Bevel point.

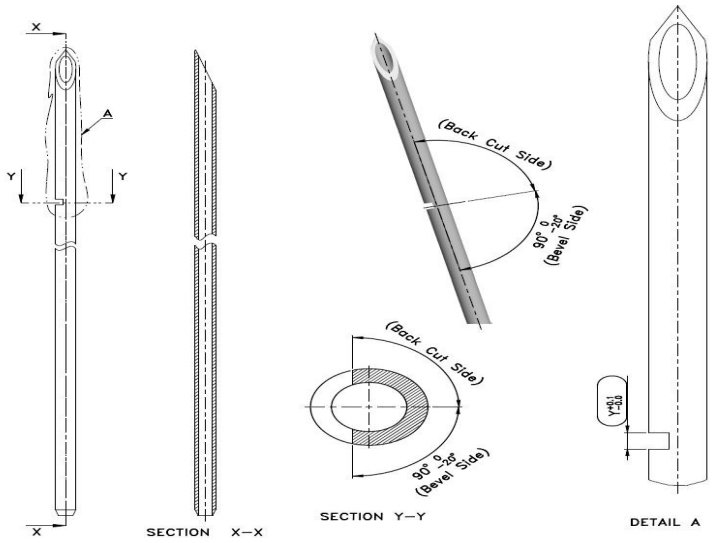
9.13.2 Needle Hub material shall be clear for easy blood flash back visualization.

9.13.3 The cannula is press fit into the needle hub.

9.13.4 The joint strength shall be a minimum of 20N (2 Kg approx.) for gauges 18G & 20G and should be 10N (1 Kg approx.) for 22G & 24G. The tensile testing between needle and needle hub is done as per WI/QA/57.



Needle Hub



Needle

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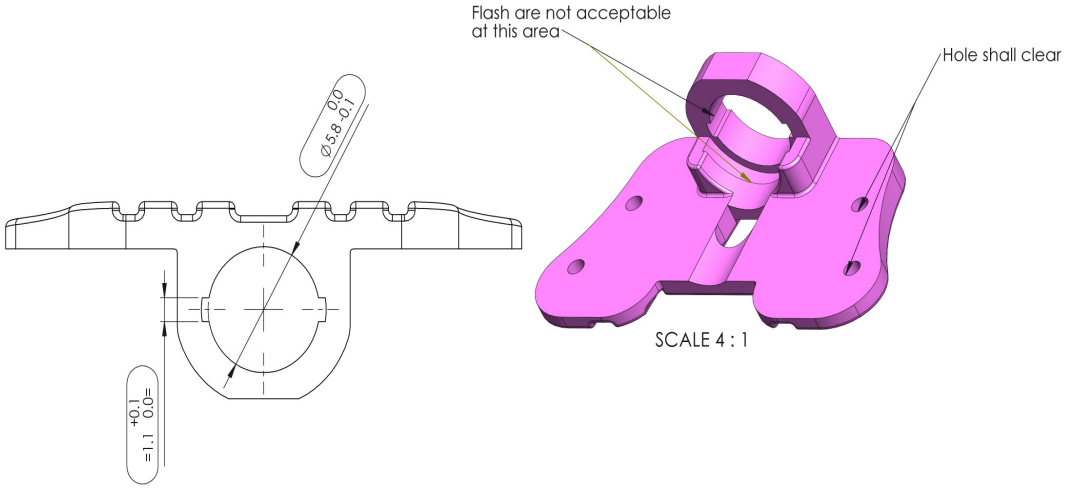
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

9.14 ***Wing***

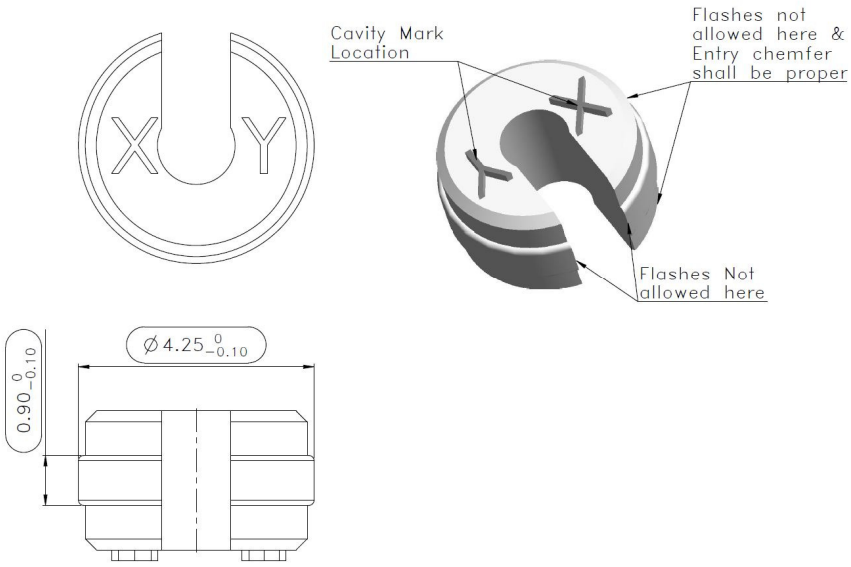
9.14.1 Component should be free from air bubble, flash, black particle & oil.

9.14.2 Color of component should be as per gauge sizes.



9.15 ***Silicon Rubber Stopper***

9.15.1 Component should be free from flash, black particle.



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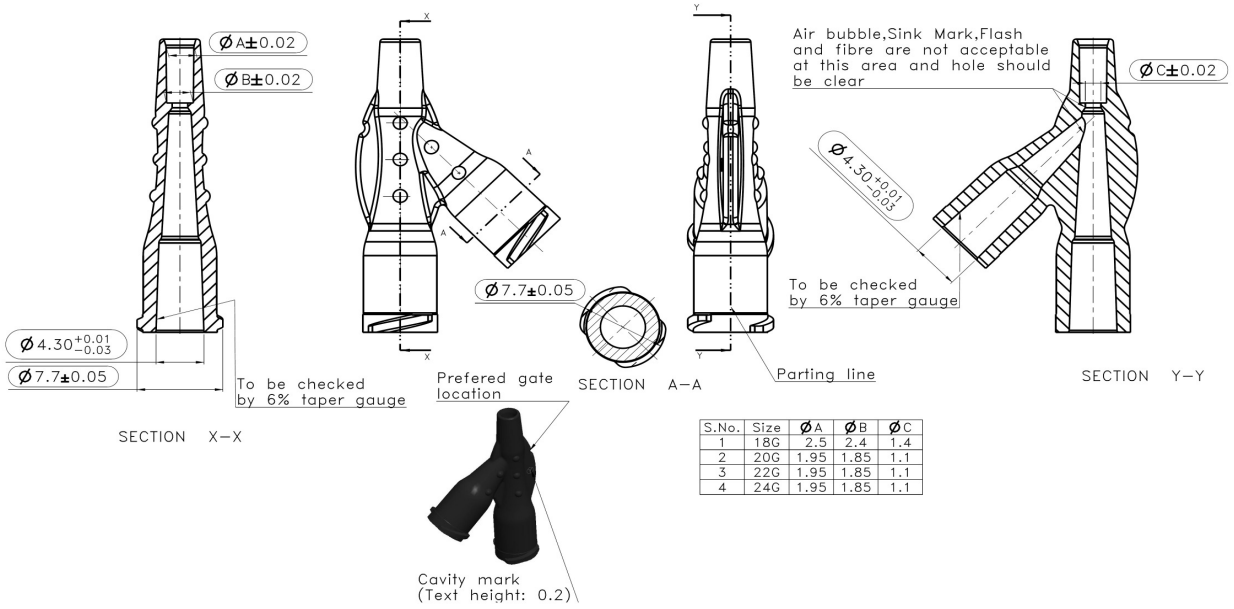
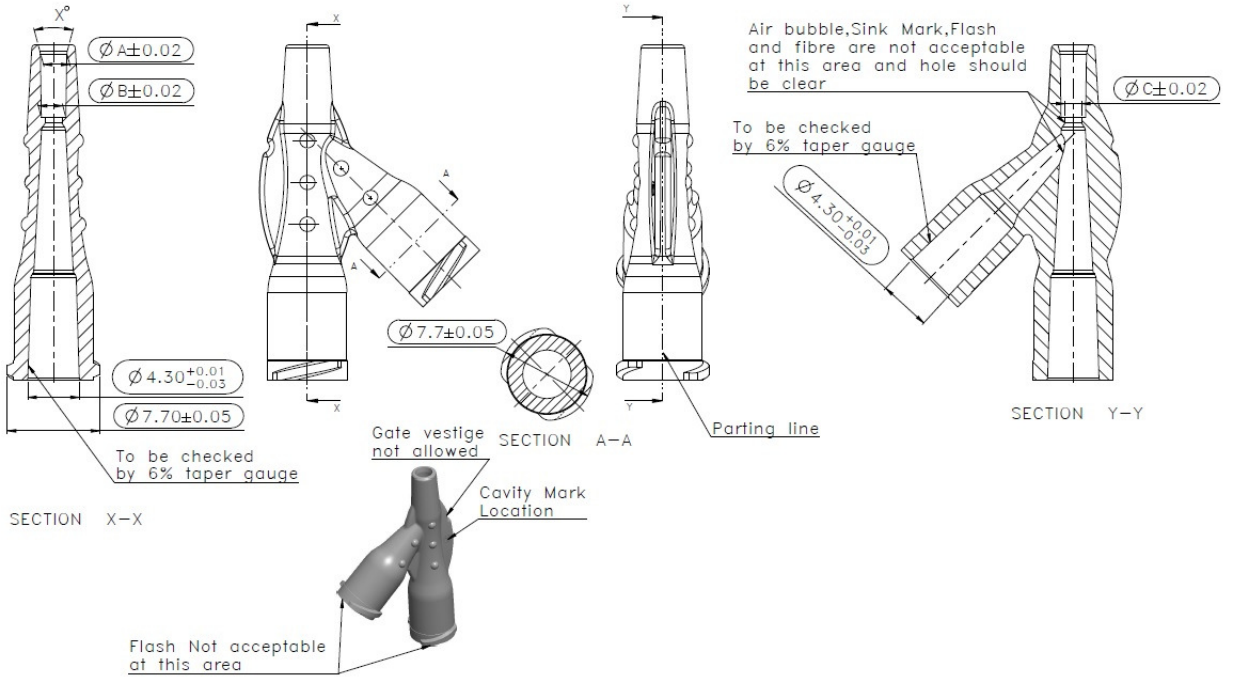
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

*9.16 **Catheter & Catheter Hub Assembly***

9.16.1 Catheter tube should be translucent or transparent (except for fully radiopaque) and if required should have 2 or 3 radiopaque lines which are fully encapsulated.



S.No.	Size	ØA	ØB	ØC
1	18G	2.5	2.4	1.4
2	20G	1.95	1.85	1.1
3	22G	1.95	1.85	1.1
4	24G	1.95	1.85	1.1



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Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021

9.17 **Luer Connections**

9.17.1 Male, female Luer and luer lock connections shall confirm to EN 20594-1:1993/A1:1997, ISO 80369-7:2016 and EN 1707:1996. The connections are tested frequently using calibrated male and female gauge.

9.18 ***Heparin Cap***

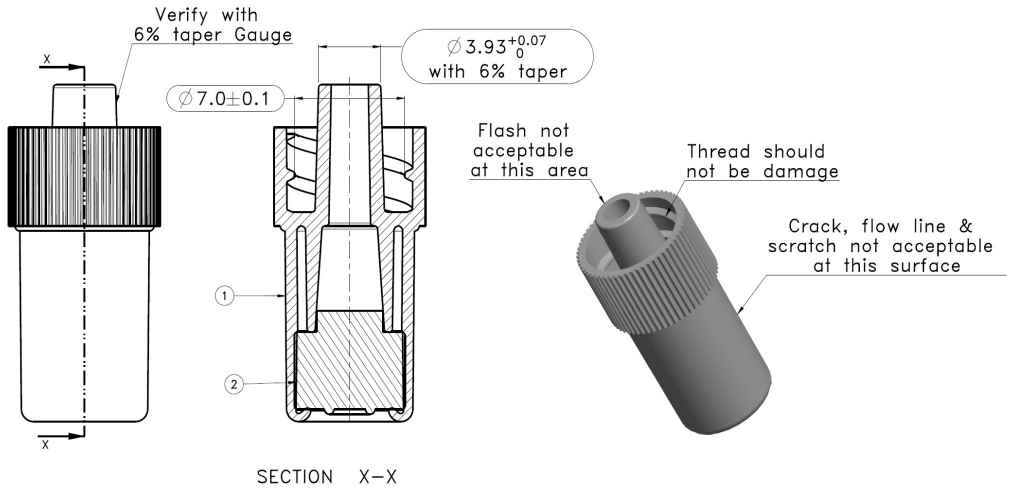
9.18.1 6% male Luer & thread profile shall be as per EN 20594-1 & ISO 80369-7/EN 1707.

9.18.2 Heparin Cap shall make a leak proof joint when tested with air pressure of 3bar.

9.18.3 Heparin Cap when perforated by a needle of 0.6mm diameter and keeping in this position for 15 second shall not show any sign of bubble formation when tested at 0.2bar air pressure under water (after withdrawing the needle).

9.18.4 Surface shall be smooth & free from black particle, oil, dirt or foreign particle.

9.18.5 Component shall be transparent and shiny. Any yellowish or material burning marks shall not be accepted.



9.19 ***Needle Free Connector***

9.19.1 Connector is designed for the injection and aspiration of fluids for IV Systems and features higher flow rates, low priming volumes, and a straight through design for unobstructed flow.

9.19.2 Connector shall have the leak Proof Connection with Y Site as per EN 20594-1 & ISO 80369-7/EN 1707.

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Approved By	SS Rawat	AVP - Quality		05.01.2021

9.20 ***Tubing***

9.20.1 The tubing shall be transparent or sufficiently translucent to monitor the passage of bubbles of air. Available without DEHP/TOTM plasticizer.

9.20.2 The tubing at the joints are leak proof when tested at 0.5 kg/cm2 air pressure and must withstand specified static tensile force for NLT 15N.

9.20.3 The dimension of tubing is as given below table- 4-

Table- 4

Size / Gauge	Inner Diameter		Outer Diameter		Tube Length (mm)
	Closed IVC (± 0.05 mm)	Closed Safety IVC (± 0.05 mm)	Closed IVC (± 0.05 mm)	Closed Safety IVC (± 0.04 mm)	
18 G	1.80 mm	1.68 mm	2.57 mm	2.60 mm	95 ± 5 mm
20 G	1.80 mm	1.68 mm	2.60 mm	2.60 mm	
22 G	1.80 mm	1.20 mm	2.00 mm	2.20 mm	
24 G	1.80 mm	1.20 mm	2.00 mm	2.20 mm	

9.21 **Packaging**

9.21.1 Unit package bottom shall be a blister formed of PVC or PP+PE film and should be clear. It should be sealed with a printed lid of medical grade paper or Tyvek.

9.21.2 Unit package shall maintain a sterility barrier with its seal. The integrity of package shall not get damaged during normal handling, storage, sterilization or transportation.

9.21.3 Fifty (50) / Hundred (100) unit packages shall be packed into one Duplex for safety and non-safety IV Cannula, as per requirement.

9.21.4 Ten Duplex boxes shall be packed into one corrugated shipper boxes, as per requirement.

10. ENVIRONMENT FOR MANUFACTURING OF PRODUCT

- The product is manufactured in clean room-controlled conditions. The clean room is class 7 (in Static condition) meeting requirements set by ISO 14644-1:2015 for Clean Room. Clean rooms are provided with high efficiency particulate air filter (HEPA) and controlled temperature and humidity. The area is maintained as per WI/IVC/02.
- The clean rooms are continuously monitored for environmental bio burden by using settling plate method. The bio burden method, frequency and limit of colony forming unit (CFU) are defined in GTP/QC/14.
- The bio burden on the equipment, fixture, dresses of workers etc is also frequently monitored. The bio burden method, frequency and limit of colony forming unit (CFU) are defined in GTP/QC/14.

11. CLASSIFICATION

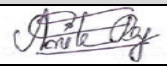
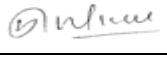
- As per "Classification Criteria" in Annexure IX of the Council Directive 93/42/EEC as amended by 2007/47/EC the family of IV Cannula is normally intended for continuous use for more than 60 minutes and less than 30 days. Hence these are for short-term use as per description in the 1.1 of Annexure IX.
- An IV Cannula penetrates inside the surface of body, hence is "Invasive device" as per 1.2 of Annexure IX. As per the Directive devices which penetrate the body through other than an establish body orifice are surgically invasive devices hence IV Cannula is "Surgically invasive device.
- As per Rule- 7 for Classification, all 'Surgically Invasive Devices' intended for short-term use are classified in **Class IIa**. Hence IV Cannula family is classified as Class IIa Medical device.

12. QUALITY PLAN

- A three tier Quality System is followed consisting of the Quality System Manual, the Standard Operating Procedures (SOPs) and Work Instructions and Formats.
- These take care of all the functional responsibilities of the management and company employees, production and quality control at various stages. It also takes care of the Quality Assurance needs and compliance with the various national and international standards and regulations. Quality planning is done as per QP/QPL/01.
- The Quality Plan covers all incoming, inprocess and finished products. The control and process are defined in the SOPs and Work Instructions and the observations are recorded in Formats and Registers.

REVISION SUMMARY

Supersedes	Effective Date	Reason for Review/Revision
Nil	Nil	New Issue
00	04.10.2019	• Section 3.0 has been updated. • Section 7.1 has process as per comments received from NB. • been updated to mention the contact and • Section 3.7.12.2 is updated to add contact duration. • Section 4.0, reference documents has been updated.
01	03.02.2020	• Section 4.0, reference standards has been updated.
02	*28.08.2020*	• Section 3.0, product description has been updated. • Section 4.0, reference documents has been updated. • Section 7.1, 8.9 & 9.0 updated to add information regarding Closed IV Cannula. • Catheter specification separately addressed for Standard, Safety and Closed IV Cannula in Table 1, 2 & 3.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		05.01.2021
Checked By	RD Sharma	DGM – QA & RA		05.01.2021
Approved By	SS Rawat	AVP - Quality		05.01.2021