1. PURPOSE

This document describes the product design and technical requirements of the Fistula Needle. As per Council Directive 93/42/EEC of 14th June 1993 as amended by 2007/47/EC concerning medical devices, Fistula Needle is classified as class IIa device and this device shall comply with essential requirements of Medical Devices Directive 93/42/EEC as amended by 2007/47/EC and related product standards.

2 INTENDED USE OF PRODUCT

The product is used to deliver blood into human circulating system during Haemodialysis. Fistula needle is used to connect blood lines to the blood vessel through needles when dialysis is carried out via an internal fistula. Safety features are provided to prevent the accidental needle prick injuries.

3 PRODUCT DESCRIPTION & FEATURES

3.1 It consists of a colored wing to identify the needle gauge and a stainless-steel cannula at one end and a long PVC tube with a closure on the other end.

3.2 The product is packed individually in blister or paper pouch and sterilized by using EO (Ethylene Oxide) gas.

3.3 Product is available in two types -

3.3.1 Fistula Needle with / without Safety (Rotating wings)

3.3.2 Fistula Needle without Safety (Fixed wings)

3.4 Color coded wing for easy identification of sizes from 15G to 17G.

3.5 Siliconised ultra thin walled & sharp beveled needle to minimize trauma to the patient.

3.6 30 cm long Soft, frosted and kink resistant PVC tubing.

3.7 Flexible butterfly wing for proper fixation.

3.8 Back eye needle to minimize interruption of blood flow.

3.9 Also available in Twin pack.

3.10 The product and packaging don't contain any constituent of animal origin.

3.11 Product classification as per EN ISO 10993-1:2009 / ISO 10993-1:2018

3.11.1 Device Connected with – Blood Line Set

3.11.2 Contact Duration – B- Prolonged

3.11.3 Categorization of Device - External Communicating Device.

3.11.4 Area of Contact - Circulating Blood

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

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager – QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head – QA		01.04.2020

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Reason: MoldSign Signature
Location: Moldova

4. REFERENCE DOCUMENTS

S. No.	Document Code	Document Description
Harmonized Standards		
4.1	EN ISO 13485:2016	Medical devices - Quality Management Systems - Requirements for Regulatory purposes
4.2	93/42/EEC as amended by 2007/47/EC	European council directive for medical devices
4.3	EN ISO 14971:2012	Application of risk management to medical devices
4.4	EN ISO 11135-1:2007	Validation & Routine Control of EO Sterilization.
4.5	EN ISO 15223 -1:2016	Symbols to be used with medical devices labels, labeling and information to be supplies
4.6	EN 1707:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings
4.7	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
4.8	EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices – requirements for materials, sterile barrier & packaging systems.
4.9	EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly process.
4.10	EN ISO 10993-1:2009 / AC:2010	Biological evaluation of medical devices – Evaluation and testing within a risk management process.
4.11	EN ISO 10993-3:2014	Biological evaluation of medical devices – Tests for genotoxicity, carcinogenicity and reproductive toxicity.
4.12	EN ISO 10993-4:2009	Biological evaluation of medical devices – Selection of tests for interaction with blood
4.13	EN ISO 10993-5:2009	Biological evaluation of medical devices – Tests for in vitro cytotoxicity
4.14	EN ISO 10993-6:2009	Biological evaluation of medical devices – Tests for local effects after implantation
4.15	EN ISO 10993-7:2008 / AC:2009	Biological evaluation of medical devices – Ethylene oxide sterilization residuals
4.16	EN ISO 10993-11:2018	Biological evaluation of medical devices – Tests for systemic toxicity
4.17	EN ISO 10993-12:2012	Biological evaluation of medical devices – Sample preparation and reference materials
4.19	EN 62366:2008	Medical Devices – Application of usability engineering to medical devices
4.20	EN 1041:2008	Terminology, Symbols and information provided with Medical Devices; Information supplied by the manufacturer with medical devices
4.21	EN ISO 11737-1:2006/ AC:2009	Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products.
4.22	EN ISO 11737-2:2009	Sterilization of medical devices — Microbiological methods —Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
Non-Harmonized Standards		
4.23	ISO 9001:2015	Quality Management Systems: Requirements

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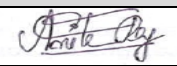
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head – QA		01.04.2020

S. No.	Document Code	Document Description
4.24	ISO 14971:2019	Application of Risk Management for Medical Devices
4.25	ISO 10993 -1:2018	Biological evaluation of medical devices – Evaluation and testing within a risk management process.
4.26	ISO 10993-10:2010	Biological evaluation of medical devices – Tests for irritation and delayed-type hypersensitivity
4.27	ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
4.28	ISO 11607-1:2019	Packaging for terminally sterilized medical devices – requirements for materials, sterile barrier & packaging systems.
4.29	ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly process.
4.30	ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, Validation and routine controls of a sterilization process for medical devices
4.31	EN 868-5:2018	Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods.
4.32	ISO 11737-1:2018	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.
4.33	ISO 11737-2:2019	Sterilization of medical devices — Microbiological methods —Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
4.34	ISO 14644-1:2015	Cleanroom and associated controlled environments - Classification of air cleanliness
4.35	USP / IP	United States Pharmacopoeia / Indian Pharmacopoeia
Internal Standards / Documents		
4.36	QP/ECD/01	EC Vigilance
4.37	QP/QPL/01	Quality Planning
4.38	RM/QA/09	Plastic Raw Material
4.39	FP/QA/12	Finished product testing for AV Fistula Needle
4.40	FP/QA/62	Process Control of Fistula Needle
4.41	WI/MDS/07	Assembly of Fistula Needle
4.42	WI/MDS/101	Manufacturing of Integrated A V Fistula Needle
4.43	PM/QA/01	Film for Blister Packing/ Pouch Packing
4.44	PM/QA/02	Medical Grade Printing Paper/ Tyvek Paper
4.45	PM/QA/03	Specification for duplex box
4.46	PM/QA/04	Specification for Transit container
4.47	PM/QA/06	Specification for labels
4.48	PM/QA/15	Pouch for Unit Packing of Product
4.49	PM/QA/47	Instruction for Use
4.50	TF/RA/30	Risk analysis of product
4.51	Drg. No. ASSY- 9003	Assembly Drawing for Fistula Needle with fixed wings
4.52	Drg. No. ASSY- 9023	Assembly Drawing for Fistula Needle with rotating wings

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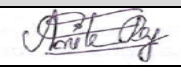
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
Checked By	RD Sharma	DGM – QA & RA		01.04.2020
Approved By	SS Rawat	Head – QA		01.04.2020

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/Soft Blister packed product**: Product shall be sterilized with Ethylene Oxide (EO) gas as per standardized and validated sterilization cycle in compliance with EN ISO 11135-1:2007 / ISO 11135:2014 and routine monitoring cycle is carried out as per WI/IVC/25. The unit pouch made of polypropylene & polyethylene film and medical grade paper. The medical grade paper allows maximum exchange of ethylene oxide, air and moisture but providing bacteria barrier properties. 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 (ii) Temperature of chamber (iii) Humidity	 60 minute ± 2 minutes 45°C (±5°C) 30% ~ 90%
2.	Conditioning (i) Vacuum drawn and rate (ii) Vacuum holding time (iii) Temperature of chamber (iv) Humidity of chamber	 -0.75Kg/cm2@30min.±15min. 10 minute ± 1 minutes 45°C (±5°C) 30% ~ 90%
3	Sterilization (i) EO gas inlet temperature (ii) Concentration of EO gas (iii) Temperature of chamber (iv) Exposure time	 Not less than 20°C 550 mg/lit. ± 25 mg/lit. 45°C (±5°C) 280 minutes±1min.
4.	Aeration (i) Vacuum drawn and rate (ii) Total number of aerations	 -0.65kg/cm2@ 30min ± 15 min. 2 nos.

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

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 calibration plan.

7. MATERIAL

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
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Approved By	SS Rawat	Head – QA		01.04.2020

7.1 All component materials selected comply with the specification. The product and packaging do not contain any constituents of animal origin.

S. No.	Part Where Material is used	Base Material	Grade	CAS No.
1	Needle cover	Low density polyethylene	24 FS 040 / M200056 / TITAN 201FG	25087-34-7
2	Tube	PVC	IP 65 / IP 65 ND / BT 31 / BT 31 ND	9002-86-2
3	Needle	Stainless Steel	SS 304	7439-89-6
4	Click Clamp	Poly Propylene	SM 498 / H110MA	9010-79-1
5	Needle hub	Rigid Poly Vinyl Chloride/PCB	MMP 20 B	9002-86-2
6	Rotating Wing	EVA	TAI 50X	24937-78-8
7	Fixed Wing	PVC	7350M / IP 9T / IP 31T	9002-86-2
8	Luer Lock	High density polyethylene	M200056 / HI 1600	25087-34-7
9	Female Luer	Rigid Poly Vinyl Chloride	MMP 20 B ND	9002-86-2
10	Safety Cover	Poly Propylene	SM 498	9010-79-1
11	Unit package Paper	Medical Grade Paper	OCPSxxxx10x	N/A
12	Unit package film	PE + PP	Medical grade / Non-toxic	N/A
13	Unit Package pouch	Paper / PE + PP	N/A	N/A
14	Duplex Box	Printed Cardboard paper	N/A	N/A
15	Transit Package	Semi craft paper	N/A	N/A
16	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 Fistula Needle (Fixed & Rotating Wings with/ without safety feature)

8.1.1 Components

(i) Needle Cover - Injection molding
(ii) Needle - Imported
(iii) Wings - Injection molding
(iv) Tubing - Extrusion
(v) Click Clamp - Injection molding (Imported)

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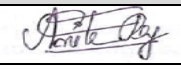
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
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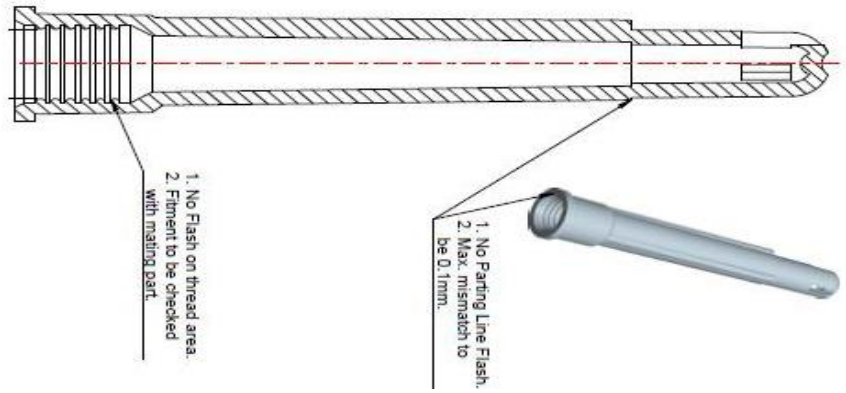
(vi)	Female luer	-	Injection molding
(vii)	Luer lock	-	Injection molding
(viii)	Needle Hub	-	Injection molding
(ix)	Safety Cover	-	Injection molding

8.1.2 Assembly - Assembly of Fistula Needle is done as per WI/MDS/07 in controlled environment conditions.

9. FUNCTIONAL SPECIFICATIONS

9.1 Needle Cover

- Cylindrical shape tube. Length to accommodate the needle fully.
- Material should be clear to translucent for ease of visualization through the wall to the inside.



- Interference fit of the bottom of the cover over the body. The fitting with the butterfly should be such that it provides easy two hand removal for use but should also prevent accidental detachment during handing, shipping and storage.

9.2 PVC Tubing

- The tubing shall be transparent or sufficiently translucent to monitor the passage of bubbles of air and the liquid.
- The tubing at the joint of female connector and Butterfly is leak proof and must withstand specified static tensile force.

Length of Tubing (in mm)	ID of Tubing (in mm)	OD of Tubing (in mm)
300 (± 10)	3.5 (±0.1)	5.5(±0.1/ -0.0)

9.3 Needle

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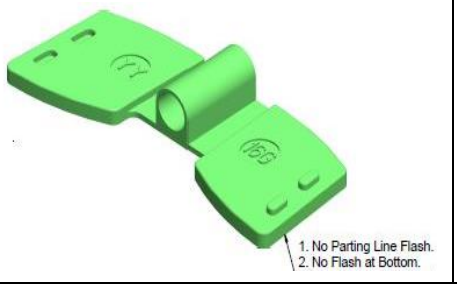
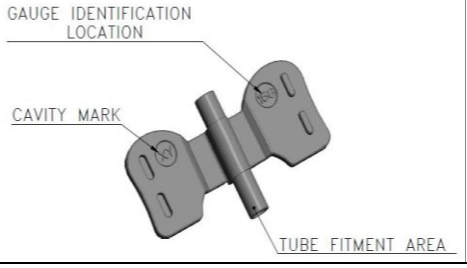
- Needle (material grade SS 304) is provided to access the vein with smooth & painless insertion.
- To provide required flow of transfusion of blood. Effective length of needle – 25mm ±1mm.

9.4 Wings (Butterfly)

- The Wings (rotating & fixed) are in butterfly shape for easy handling & attachment to the skin.
- The Wings are color coded to the specific size of needle for instant identification of needle size.

Fixed wing	Integrated wing with Housing
	

- The Wings are connected with distal end of PVC tube through a leak-proof joint.

Dimensions & Color Coding

F. G. Gauge	OD of Needle (in mm)	ID of Tubing (in mm)	OD of Tubing (in mm)	Color Coding (ISO 6009)
15	1.82 - 1.84	3.5 (±0.1)	5.5(±0.1/ -0.0)	Orange
16	1.64 - 1.66	3.5 (±0.1)	5.5(±0.1/ -0.0)	Green
17	1.46 - 1.48	3.5 (±0.1)	5.5(±0.1/ -0.0)	Yellow

9.5 Needle Hub

- Shall be free from Flashes & any prominent gate mark.
- Shall be free from Check for general molding defects like short filling, black particles, etc. Shall be free from any visual defects, short molding, and oily stains.

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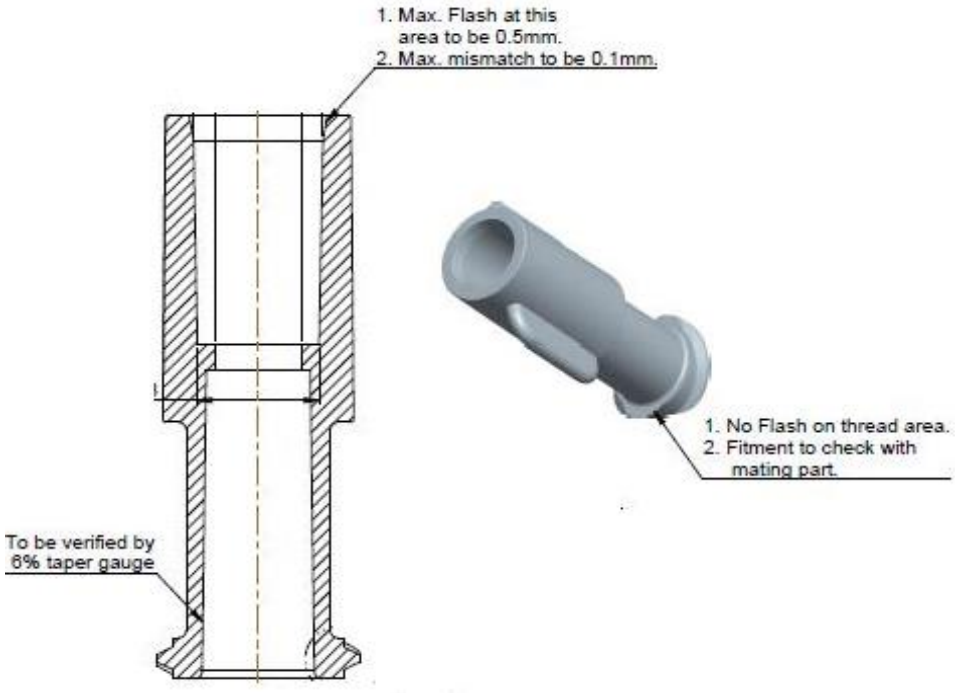
- Bore of the needle hub shall allow easy passage to the needle of appropriate size.

9.6 Female Luer Connector

- Female Luer connector design shall comply with EN 20594–1:1993, ISO 80369-7/ EN 1707 and it should be transparent.
- Shall have 6% taper for easy connection with luer lock.



9.7 Click Clamp

- Clamp when closed shall stop the flow of liquid.

9.8 Luer Lock

- Male Luer Lock design shall comply with EN 20594–1:1993, ISO 80369-7/ EN 1707:1996.
- Shall have external gripping features.

9.9 Packaging

9.9.1 Unit package shall be a clear PP+PE film, sealed with a printed lid of medical grade lacquered paper.

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9.9.2 Unit package shall maintain a sterility barrier through its seal. The integrity of the package shall not be compromised during normal handling, storage, sterilization or transportation.

9.9.3 Unit package shall open reliably without tearing and particulate matter generation.

9.9.4 Fifty (50) pcs of unit packages shall be packed into one Inner Duplex printed cardboard box.

9.9.5 Ten (10) Duplex boxes shall be packed into one corrugated shipper box, as per customer requirement.

9.9.6 The combination of shipper box/duplex box/unit packaging system shall provide adequate product protection during normal shipping, handling and storage, till the product reaches the end user.

10 ENVIRONMENT FOR MANUFACTURING OF PRODUCT

- The product is manufactured in controlled conditions. The area is class -7 (in static condition) meeting requirements set by ISO 14644-1:2015. The area is provided with High Efficiency Particulate Air filter (HEPA) and controlled temperature and humidity. Clean rooms are validated frequently for efficiency of HEPA filter. 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 the "Classification criteria" Annexure- IX of the Council Directive 93/42/EEC as amended by council directive 2007/47/EC the Fistula Needle is used for more than 60 minutes and less than 30 days. Hence these devices are for 'short term use' as per the description in the 1.1 of Annexure- IX.
- This device 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 Fistula needle 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 Fistula Needle is classified as **Class- IIa** Medical devices.

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Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
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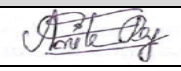
12. QUALITY PLAN

- 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, in process 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***
06	16.06.2015	Addition of revision summary & Change made in clause no. 2,4 & 7.
07	25.08.2016	• Updated the reference of relevant standards in section 4, 6.1 & 9.6. • Also, updated the table in section 9.4, 6.1 & 7.1 • Added section 9.2 & 9.5
08	*26.10.2018*	• *Product classification details as per EN ISO 10993-1:2009 added in Section 3.11.* • *Updated Section 4.0, reference documents to include latest version of applicable standards & segregated as harmonized and non-harmonized.* • *Packaging information added in Section 9.9.*

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.04.2020
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