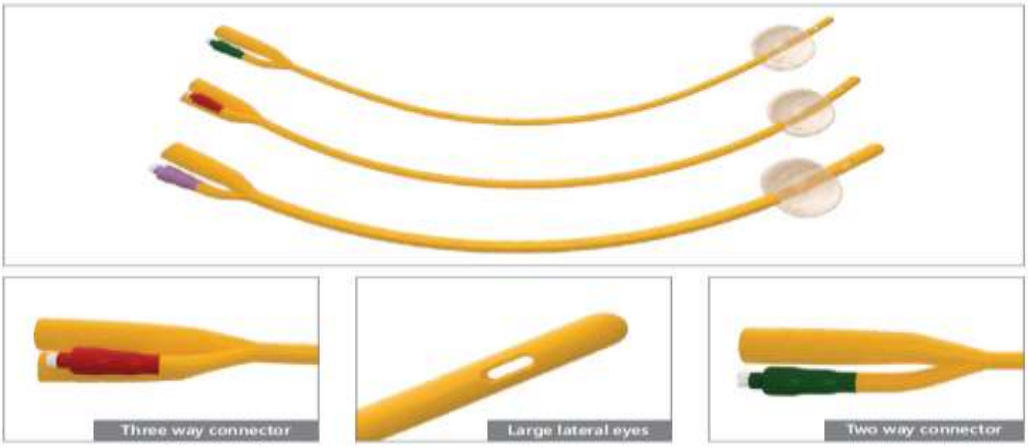


1. PRODUCT DESCRIPTION

A Foley's catheter is a sterile tube with a silicon balloon attached at the end. It has separate channels for urine drain and inflating the balloon. A non-return valve is also attached at the end of balloon channel through which the sterile water is injected to fill the balloon with it. Duration of Use: Short term. Material of Composition: PP, SS, POM, Silicon.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 5, device as per EU MDR 2017/745 Annexure VIII.

3. INTENDED USE

Foley balloon Catheter is used to drain retained urine from the bladder into a collection bag. It has a balloon attached to it which goes inside the bladder. This balloon is filled with sterile water to enable to hold the Foley's balloon catheter inside the bladder. Foley's balloon catheter is also used during the surgical operations where is patient is bedbound.

4. PRODUCT VARIANTS

Following variants are available for the products

Item Code	Two way		Three way	
	Size in FR	Balloon Capacity	Size in FR	Balloon Capacity
92310019	6	1.5cc-3cc	16,18,20,22,24,&16	30cc-50cc
92310020 to 92310021	8-10	3cc-5cc	14	15cc-30cc
92310022	12	5cc-15cc		
92310023	14	15cc-30cc		
9230024 to 92310029	16-26	30cc-50cc		
SIZE				
FR	**8**	**10**	**12**	**14**
Colour code	**black**	**grey**	**white**	**green**
FR	**16**	**18**	**20**	**22**
Colour code	**orange**	**red**	**yellow**	**violet**
FR	**24**		**26**	

Colour code	blue	pink

5. MATERIAL OF CONSTRUCTION

S. No.	Component Description	Material used
1	Foley Tube	Latex/Silicon
2	Non-return Valve	Polypropylene (PP)
3	Valve Cap	Polyvinyl chloride (PVC) Film

6. PRODUCT SPECIFICATION

S. No.	Characteristics	Specified value	Tolerance
1.	Visual	Should be free from any particle	
2.	Molding Defect	Should be free from any physical damage	
3.	Length of tube	±20%	400mm
4.	6% taper	Should be complies with ISO 80369-7	
5.	Strength between tube & connector	Tube should not detach at 20N	
6.	Leakage Between Tube and Balloon	Should be no leakage	
7.	Leakage Between tube and Funnel Connector	Should be no leakage	
7.	Eye cut	Should be free from burr and improper cutting	
8.	Funnel connector cap	Should be properly closed	
9.	Catheter tip	Should be smooth and free from defect	
10.	Surface of the tube	Should be smooth	
11.	Number of eye cut	Should be comply with standard	
12.	Color of the tube	Should be according to standard	
13.	Kink of tube	Should be no kink	
14.	Sealing peel open force	NLT-1.5N	
15.	Packing integrity	200mmHg	
16.	sterility	As per lab report for individual sterilization cycle	
17.	Bacterial endotoxin	As per lab test report	
18.	Physico-chemical test	As per lab test report	

- Safe, User friendly design
- Manufactured from latex rubber coated with silicone to eliminate the risk of encrustation.
- Coned distal end provided with burr eyes to prevent risk of injury.
- Hard plastic valve ensures inflation/deflation of balloon.
- Color coded for size identification.

- Soft rubber for best possible patient comfort blockage- free trauma-less de-catheterization.

TYPE	SIZE	PRODUCT LENGTH	DESIGNATED OPTIMAL BALLOON CAPACITY (ML/CC)	BALLOON CAPACITY RANGE ON CUSTOMER DEMAND (ML/CC)	PACKING INNER/OUTER UNIT
2 Way Infant	6FR	305±5	1.5	1.5	20/500
2 Way Peadiatric	8FR & 10FR	305±5	3	3,3-5,5	20/500
2 Way Standard	12FR	400±5	15	5-15,15	20/500
	14FR	400±5	15	5-15,15,15-30,30	20/500
	16FR-22FR	400±5	30	5-15,15,15-30,30	20/500
	24FR-30FR	400±5	30	15-30,30	20/500
2 Way Female	12FR - 24FR	400±5	15	5-15,15,15-30,30	20/500
3 Way Standard	16FR - 26FR	400±5	30	15-30,30	20/500

7. REFERENCE COMPLIANCE STANDARD

S.No.	Name Of Standard	Standards
1)	Sterile urethral catheters for single use	EN ISO 20696:2018
2)	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
3)	Medical Devices - Application for Risk Management to Medical Devices	EN ISO 14971:2019
4)	Biological evaluation of medical devices. Part 1: Evaluation and testing as part of the risk management process	EN ISO 10993-1:2020
5)	Biological evaluation of medical devices. Part 3: Genotoxicity, carcinogenicity and reproductive toxicity tests	ISO 10993-3:2015
6)	Biological Evaluation of Medical Devices - Part 4: Selection of Tests Relevant to Blood Interactions	EN ISO 10993-4:2017
7)	Evaluation of the biological effects of medical devices - Part 5: In vitro cytotoxicity tests.	ISO 10993-5:2009
8)	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residues.	EN ISO 10993-7:2008
9)	Evaluation of the biological effects of medical devices - Part 11: Systemic toxicity tests	EN ISO 10993-11:2018
10)	Biological evaluation of medical devices - Part 12: Sample preparation and control samples	EN ISO 10993-12:2021
11)	Symbols used on medical device labels in labeling and information provided.	EN ISO 15223-1:2021

12)	Sterilization of medical devices - Microbiological methods - Part 1: Determination of the microbial population on products	EN ISO 11737-1:2021
13)	European Union Medical Devices Regulation	MDR 2017/745
14)	Medical devices - Part - 1: Application of usability engineering to medical products.	IEC 62366: 2015
15)	Clinical Investigations of Medical Devices in Humans - Good Clinical Practice	ISO 14155:2020
16)	Medical Devices - Aftermarket Surveillance for Manufacturers	ISO 20416:2020
17)	Sterilization of medical devices - Chemical indicator - Part 1 General requirements	EN ISO 11140-1:2015
18)	Medical devices-Post market Surveillance for manufacturer	ISO/TR 20416:2020
19)	Sterilization of health care products-Biological indicator-Part 1 General requirement	EN ISO 11138-1:2017
20)	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	ASTM-F1980

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	MATERIAL
Individual Sterile Packing (Blister)	Soft Blister
Inner Carton	400 GSM
Master Carton	5 Ply corrugation

9. OTHER DETAILS

Storage: store in a cool and dry place and keep away from direct sunlight and extreme heat.

Method of Sterilization: sterilized using ethylene oxide.

Shelf life: 05 years from the month / date of sterilization.

Biocompatibility: the product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.

Disposal: Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

10. COMPLIANCE INFORMATION

Manufacturer 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**,** TUV SUD Product Service GmbH

CE Marking: TUV SUD Product Service GmbH, EC Notified body No. 0123

GMDN Code: 34917

ABBREVIATIONS

QMS – Quality Management System

GMDN – Global Medical Device Nomenclature