Product data sheet

All Silicone Foley Catheter, PVC-free

Pediatric, 2-Way



Area of application

Pediatric Silicone Foley Catheters are used for transurethral drainage of urine from the bladder. Pediatric sizes (Ch/Fr 6, 8, 10) can be retained for up to 30 days if using sterile aqueous glycerin solution for balloon inflation. If sterile water is used for balloon inflation a retention time of only 14 days is recommended. The products are for single use only.

Product range

Total Length, mm (±10)	Balloon Capacity, ml	CH/FG	Tip	Reference
All Silicone Foley Catheter, Pediatric, 2-Way, with Preloaded Nylon Guidewire				
310	1.5	6	Nelaton	43150601
310	3.0	8	Nelaton	43150803
310	5.0	10	Nelaton	43151005

Sterilization

Sterile, Sterilized by ethylene oxide, Shelf life: 5 years

Certifications

CE-marking	CE 2797
Product classification	Class IIB(EU)
Quality system certified to	ISO 13485 Medical Device Single Audit Program (MDSAP)
European Medical Device Nomenclature (EMDN)	U010201 URETHRAL PROSTATIC AND BLADDER CATHETERS, NELATON, WITH BALLOON
Global Medical Device Nomenclature (GMDN)	34917

Instructions for use

Included?	Yes

Material specifications

Contains latex?	No
Contains DEHP?	No
Contains PVC?	No
Contains cotton?	No
Contains paper?	Packaging only
Catheter shaft and funnel	Silicone
X-ray line	Silicone
Balloon	Silicone
Tip	Silicone, Barium Sulfate
Hard valve	Polypropylene, Polyester, Nitrile, Stainless steel
Valve sleeve	Polypropylene
Guidewire	Nylon
Catheter Sleeve	Ethylene-vinyl acetate

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Packaging information

Reference	Primary pack./Single peelpack		Secondary pack./Shelf box		Tertiary pack./Shipper			Gross weight kg	Pallet Qty. pcs
	Qty. pcs	Dimensions, mm (LxW)	Qty. pcs	Dimensions mm (LxWxD)	Qty. pcs	Dimensions mm (LxWxD)	Volume m^3		
43150601	1	500 x 66	5	510 x 80 x 35	250	520 x 430 x 375	0.084	7.0	2,500
43150803	1	500 x 66	5	510 x 80 x 35	250	520 x 430 x 375	0.084	7.0	2,500
43151005	1	500 x 66	5	510 x 80 x 35	250	520 x 430 x 375	0.084	7.0	2,500

GTIN codes

REF	Primary package	Secondary package	Tertiary package
43150601	06944932754553	16944932754550	26944932754557
43150803	06944932754560	16944932754567	26944932754564
43151005	06944932754621	16944932754628	26944932754625

Packaging material

Primary package	Coated paper, Film
Secondary package	Ivory Cardboard
Tertiary package	Double-wall corrugated fiberboard

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Pediatric, 2-Way

Storage and handling	
	This way up
	Keep dry
	Fragile, handle with care
	Keep away from sunlight
	Do not resterilize
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Temperature limit (-15° to 49°C)
	Consult instructions for use or consult electronic instructions for use

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