



GUANGDONG BAIHE MEDICAL TECHNOLOGY CO., LTD.
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Technical Data

(Disposable Silicone Foley Catheter)

1. Device Description

Disposable Silicone Foley Catheter is a kind of catheter, drainage catheter. Disposable Silicone Foley Catheters manufactured by Baihe are not with medicine and animal tissue.

2. Intended Use

The product is intended use for disposable catheterization for patients for Medical Therapy Units. The duration of use is not more than 30 days.

3. Expiration Date

Shelf life: 3 years.

4. Device Specification

Type	Size(Fr)	OD(mm)	Color code	Balloon capacity Min/Max, ml	L(mm) ±5%	S(mm) ±5%	Product code
Single lumen (without balloon)	6	2.0 ± 0.1	/	/	250 310 410	/	FX-1006
	8	2.7 ± 0.1	/				FX-1008
	10	3.3 ± 0.2	/				FX-1010
	12	4.0 ± 0.2	/				FX-1012
	14	4.7 ± 0.2	/				FX-1014
	16	5.3 ± 0.2	/				FX-1016
	18	6.0 ± 0.2	/				FX-1018
Double lumen (with balloon)	6	2.0 ± 0.1	Green	2/3	250 310	170 230	FX-2006
	8	2.7 ± 0.1	Blue	3/5			FX-2008
	10	3.3 ± 0.2	Black	3/5			FX-2010
	12	4.0 ± 0.2	White	5/10	280 400	170 290	FX-2012
	14	4.7 ± 0.2	Green	5/10			FX-2014
	16	5.3 ± 0.2	Orange	20/30			FX-2016
	18	6.0 ± 0.3	Red	20/30			FX-2018
	20	6.7 ± 0.3	Yellow	20/30			FX-2020
	22	7.3 ± 0.3	Violet	20/30			FX-2022
	24	8.0 ± 0.3	Blue	20/30			FX-2024
	26	8.7 ± 0.3	Pink	20/30			FX-2026



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Triple lumen (with balloon)	16	5.3 ± 0.2	Orange	20/30	280 400	170 290	FX-3016
	18	6.0 ± 0.3	Red	20/30			FX-3018
	20	6.7 ± 0.3	Yellow	20/30			FX-3020
	22	7.3 ± 0.3	Violet	20/30			FX-3022
	24	8.0 ± 0.3	Blue	20/30			FX-3024
	26	8.7 ± 0.3	Pink	20/30			FX-3026

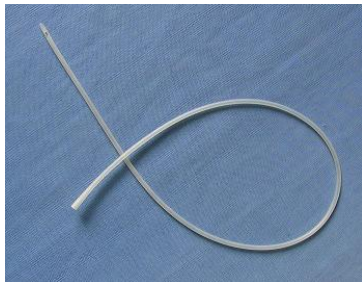
Marks:

1. L is the overall length. S is the effective length.
2. Do not contain medicine and animal tissue.

5. Classification

Disposable Silicone Foley Catheters are in Class II b, according to the Rule 5 in Annex X of MDD.

6. Picture



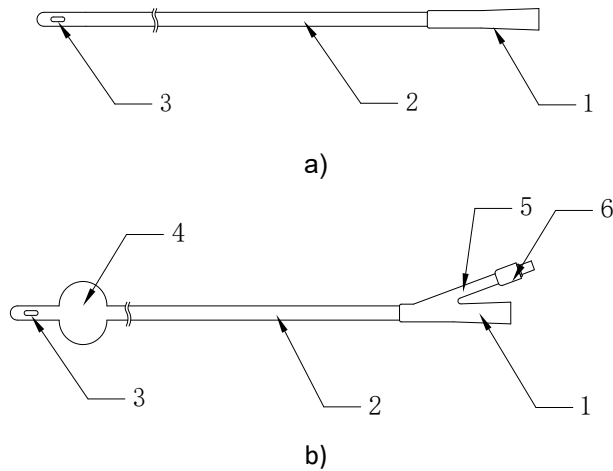
Single lumen



Double lumen



Triple lumen





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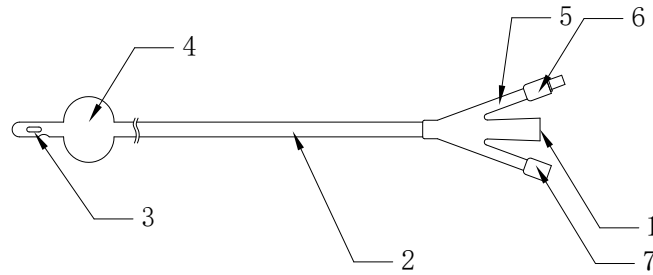
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c)

- | | | | |
|-------------------------|----------|--------------------|-----------|
| 1- Drainage lumen | 2-Shaft | 3-Eyelet | 4-Balloon |
| 5- Inflation lumen site | 6- Valve | 7-Flush lumen site | |

Drawings in attachment 2

7. Bill of Material

Parts	Materials	Blood-contacting
Shaft	Silicon rubber	No
Balloon	Silicon rubber	No
Drainage lumen, Inflation lumen site, Flush lumen site	Silicon rubber	No
Valve	ABS	No

8. Device package

Disposable Silicone Foley Catheters are packaged in primary package, secondary package, and tertiary package. Primary package: packed by EVA bag (350*45mm), and then sealed with coated medical paper and complex film (505mm*70mm).

Secondary package: Single layer corrugated paper. The size is 510mm*80mm*45mm. And contain 10 primary packages.

Tertiary package: Double walled corrugated board. The size is 525mm*340mm*250mm. And contain 20 secondary packages.

