



Instructions for Use of Dilation Balloon Catheter

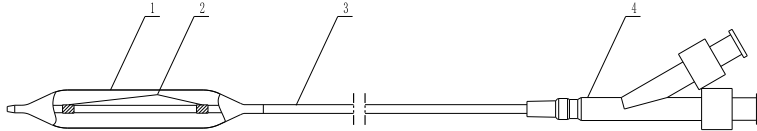
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Instructions for Use of Dilation Balloon Catheter

【Product name】

Dilation Balloon Catheter

【Structure】



1-Balloon 2-Radiopaque marker 3-Lumen tube 4-Three-way handle

【Models and Specification】

Models and Specification	Balloon diameter		Ball oon Wor king pres sure	Ballo on Withs tand press ure	Code/ Balloon length (mm)	Code/ Endosco pe channel (mm)	Code/ Catheter effective length (mm)
	Code	Diam eter	Mpa	Mpa			
BD-01 (02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14) 1 (2, 3, 4, 5, 6) 0 (1, 2, 3) B2 (B6, C2, C3, C5, D2, D4, E1, E2, E3, F3, F1)	01	04	1.0	1.6	0:15	0:N.A	B2:600
	02	05	1.0	1.6	1:20	1:2.8	B6:900
	03	06	0.8	1.2	2:30	2:3.2	C2:1050
	04	08	0.8	1.2	3:40	3:2.0	C3:1100
	05	10	0.6	1	4:60		C5:1200
	06	12	0.6	1	5:80		D2:1600
	07	14	0.5	0.8	6:100		D4:1800
	08	16	0.5	0.7			D5:1900
	09	18	0.5	0.7			E1:2000
	10	20	0.3	0.5			E2:2200
	11	25	0.3	0.5			E3:2300

	12	30	0.2	0.35			F3:2500
	13	35	0.2	0.35			F1:2600
	14	40	0.2	0.35			

【Packaging list】

Internal package: Paper-plastic bag, 1 pcs/bag

Middle package: Paper box, 1pcs/box

Outside package: Corrugated box

【Production license】

苏食药监械生产许 2014—0044 号.

【Certificate number】

苏食药监械（准）字****第*****号

【Product standard】

YZB/苏*****

【Intended use】

The Dilation balloon catheter is mainly used for dilating the digestive tract stricture and adjuvant therapy. Sterile, for single-use.

【Method of use】

(1) Preparation before use:

1. Check carefully if the instrument and the package are in good condition.
2. The plastic protective cover and protective steel wire in one end of the balloon should be removed.
3. Do not inflate with air or liquids before use, keeping the vacuum state of the balloon.

(2) Operation:

1. Insert 0.035” guide wire to the narrow distal end in the supervision of

endoscope or other auxiliary equipments and leave it there.

2. Select appropriate dilation balloon catheter and insert slowly and carefully along the guide wire end to the narrow section. Make sure that the balloon stretches out of the endoscope completely and is in the appropriate position, with two radiopaque points locating separately in both ends of narrow section.
3. Inflate the balloon with liquids by inflator with pressure gauge. At the working pressure the balloon is completely inflated as columnar, then stop inflating and keep for 3 minutes. Note that the inflation pressure cannot be larger than the specified burst pressure. Consider if it is necessary to dilate repeatedly according to the dilation effect.

Notice:

1. Do not use air or any other air material as the inflation material of the balloon.
2. The inflation pressure can not be larger than the specified burst pressure.
3. If being in the condition of balloon burst or sudden decrease of balloon pressure, the operation should be stopped immediately. And the balloon should be deflated and withdrawn from the human body together with the endoscope as a whole part. Then cut off the balloon from the front end of the endoscope, and change another new balloon to continue the operation.

4. Deflate the balloon by pumping liquids from the balloon after dilation operation is finished, then withdraw the balloon slowly.

(3) Dispose:

Dispose this device according to recognized hospital standard.

【Cautions】

1. The operators of this product should be trained physicians.
2. Please use the inflator with pressure gauge to inflate the balloon, so as to supervise the pressure exactly for the balloon may burst if the pressure is too high.
3. Do not use this equipment when the package is damaged.
4. It's a disposable product, thus re-use, re-treatment and re-sterilization are forbidden. Please destroy it after use.
5. Do not use this product when the valid period is exceeded.

【Contraindications】

It includes but is not limited to the following contraindications:

- Patients with serious cardiopulmonary insufficiency, coagulation disorders and is not suitable for endoscope surgery.
- Patients' esophagus or fundus of stomach is in Varices Bleeding period caused by portal hypertension.
- Patients with acute inflammation
- Patients are in ulcerative colitis bleeding period.
- Patients are in complex adhesive intestinal obstruction.

【Storage and transportation】










1. The single package is paper-plastic bag, middle is the box, and outer is the carton. When in transport, it should be kept clean, dry and sealed.

The transport condition should be of the temperature of $-20^{\circ}\text{C} \sim 70^{\circ}\text{C}$, and the humidity of $10\% \sim 90\%$. It could not be transported together with sand, metal fragments, glasses, or keen-edged stuff, nor with the poisonous, corrosive or flammable stuff. Slings of packages when loading and unloading, insulation under the sun or drenching in rain are all prohibited.

2. This instrument is sterilized product, for single use only. Store the sterile package at the temperature of $-20^{\circ}\text{C} \sim 60^{\circ}\text{C}$ and the humidity of $10\% \sim 90\%$. Store the instrument at the dry room of good ventilation. Do not store it in direct sunlight.

3. Do not store the sterile package containing the instrument in places where it will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised, which could cause risk of infection control or patient's affected part infection.

【Explanation for used symbols】

	CE certified by TUV SUD		Lot number
	Single use		Date of manufacture
	Sterilized by EO		Manufacturer
	Read the IFU		European union representative
	Validity of device		

【Validity Period】 3 years

【Manufacturer】 Jiangsu Changmei Medtech Co., Ltd.

【Registered Address】

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Jiangsu, China

【Manufacture Address】

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European union representative:

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