常美医疗
Changmei Medtech

Instruction for Use of 3-stage Dilation Balloon Catheter

JS-CE-SM-08-01, A/0

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Jiangsu Changmei Medtech Co., Ltd.

Instruction for Use of 3-stage Dilation Balloon Catheter

【Product name】

3-stage Dilation Balloon Catheter

【Product structure and components】

3-stage Dilation Balloon Catheter is made up of balloon (PA), catheter (PA), radiopaque markers (Tal), and handle component (PC). The product should be sterile.

【Specification and model】

<table>
<tr><th>Model</th><th>Balloon dia. code</th><th>Balloon dia.（D）(mm)</th><th>Balloon length L (mm)</th><th>Balloon working pressure (atm)</th><th>Endoscope channel ID code</th><th>Working length L1 (mm)</th></tr>
<tr><td rowspan="6">TB-
28(32,42)
SK(A, C, D, E, K, N, P, Q, T, U, V, W, LK）-A（B, C, D, E, F）
55（80）</td><td>A</td><td>6-7-8</td><td rowspan="6">55
80</td><td>3-6-10</td><td rowspan="6">28: Channel ID ≥2.8mm
32: Channel ID ≥3.2mm
42: Channel ID ≥4.2mm</td><td rowspan="6">SK:600
A:900
C:1050
D:1100
E:1200
K:1600
N:1800
P:1900
Q:2000
T:2200
U:2300
V:2400
W:2500
LK:2600</td></tr>
<tr><td>B</td><td>8-9-10</td><td>3-5.5-9</td></tr>
<tr><td>C</td><td>10-11-12</td><td>3-5-8</td></tr>
<tr><td>D</td><td>12-13.5-15</td><td>3-4.5-8</td></tr>
<tr><td>E</td><td>15-16.5-18</td><td>3-4.5-7</td></tr>
<tr><td>F</td><td>18-19-20</td><td>3-4.5-6</td></tr>
<tr><td colspan="7">Note: each size of the balloon diameter corresponds to a separate balloon pressure, for example, when the balloon diameter is 6-7-8mm, then the corresponding pressure is 3-6-10atm.</td></tr>
</table>

【Packaging list】

Inner package: Paper-plastic bag, 1 piece/bag

Middle package: Paper box, 5pcs/box

Outer package: Corrugated box

【Intended use】

It is suitable for adults and adolescents in the dilation operation of digestive tract stricture under endoscopes. Sterile, for single-use.

【Contraindication】

It includes but not limited to the following contraindications：

1. Patients with serious cardiopulmonary insufficiency, coagulation disorders and is not suitable for endoscope surgery.
2. Patients' esophagus or fundus of stomach is in Varices Bleeding period caused by portal hypertension.
3. Digestive tract acute corrosive damage is less than one week.
4. Acute inflammation or ulcerative colitis is in bleeding period.
5. Severe hemorrhoids or anal varicose veins is in bleeding period.
6. Aortic aneurysm or cardiopulmonary failure.
7. Extensive intestinal adhesion and multiple small bowel obstruction.
8. Known or suspected digestive tract perforation.

【Notice】

1. Do not use the instrument when the package is damaged.

2. Users should be trained doctors.

3. Do not use the instrument when the valid period is exceeded.

4. Single use only, discards after use. Do not reuse.

5. Please use the inflator with pressure gauge to fill the balloon, so that the pressure can be monitored accurately.

【Usage】

a) Preparation:

1. Check the equipment carefully before use, confirm the aseptic packaging and product are in good condition. If the packaging is damaged, the end of the catheter is worn, the catheter twists together or the balloon is damaged, do not use.

2. One end of the balloon has a protective sleeve, which should be removed first.

3. Do not inflate or inject the balloon, keep the balloon in vacuum state.

b) Catheter insertion

Choose appropriate endoscope channel according to the model and specification of the 3-stage dilation balloon catheter. Move

the 0.035 inch guide wire via endoscope channel to narrow distal end and left. Insert the 3-stage dilation balloon catheter along with the end of the guide wire, and the balloon is sent to the narrow part by moving 2-3cm each time. Make sure the radiopaque markers are in both end of the narrow part in order to dilate the balloon. (This method is suitable for the non-guidewire 3-stage dilation balloon catheter, if with a guide wire, this process can be omitted. Move the product directly to the narrow part via endoscope channel by 2-3cm each time, and make sure the radiopaque markers are in both end of the narrow part.

Note:

- **Move the 3-stage dilation balloon catheter to the narrow part slowly.**

c) Balloon dilation

1. There are three independent dimensions which can gradually increasing its diameter. Balloon size is printed on the label.

2. Dilate the balloon to the working pressure corresponding to the minimum diameter, and maintain the pressure until the predetermined effect of expansion. For greater balloon diameter, please continue to increase the pressure, but the pressure should not exceed the maximum value on the label.

Note:

- **Do not use air or other gaseous substances as filling medium of the balloon.**

- **Pressure shall not exceed the maximum working pressure on the label.**

- **If there is balloon rupture phenomenon, stop the operation immediately. Deflate the balloon and withdraw the balloon with endoscope as a whole carefully. Do not attempt to withdraw the ruptured balloon through the endoscope. After withdrawing the balloon, replace a new one to perform the operation.**

d) Catheter removal

1. After completing the operation, the liquid is pumped cleanly, and the balloon is contracted, then withdraw the balloon.

2. Please withdraw the catheter from the endoscope slowly. If the withdrawal resistance is too large, please take the endoscope and the catheter as a whole in order to prevent damage to the human tissue, the balloon and the endoscope.

3. In order to better withdraw the balloon, please put the endoscope end straight to reduce the resistance.

Note:

- **Before withdrawing, the balloon must be in the state of complete contraction and emptying all the filling medium.**

e) Postoperative disposal of the equipment

Dispose the equipment in accordance with generally accepted standards of hospital waste treatment.

【Storage & Transport】

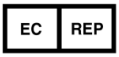
1. The instrument is sterile and disposable. It should be placed in the environment with relative humidity of less than 80% and without corrosive gas. Store the device at cool, dry, clean room of good ventilation.

2. Do not store the sterile instrument in places where it will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised, which could pose a risk of infection control or cause infection in affected part of patients.

3. The single package is paper-plastic bag, middle is the box, and outer is the corrugated carton. Transportation should maintain clean, dry and sealed.

4. Transportation conditions: It should prevent stress and could not be transported together with sand, metal fragments, glasses or keen-edged stuff, nor with the poisonous, corrosive or flammable stuff. Slinging of packages when loading and unloading, insulation under the sun or drenching in rain are all prohibited.

【Explanation for symbols】

	Disposable		Sterilized by EO
	Date of manufacture		Expiration date
	Do not use when the package is damaged		Read instructions before use
	Lot number		Note that see instruction for use
	EU representative		Manufacturer
	CE certified by TUV SUD		

Compile date: 2015.09.22

【**Validity Period**】3 years

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