Single Use Bougie Dilator

INSTRUCTIONS FOR USE

STERILE EO

2

CE 0123

【Product Name】Single Use Bougie Dilator

【Intended Use】

This device is used for the exploration and dilation of esophageal strictures, dilatation of upper esophageal webs, lower esophageal rings, caustic strictures, peptic esophageal strictures and temporary ease of esophageal carcinoma.

【Indications】

This device is designed to expand narrowed parts of the esophagus.

1. Those with inactive inflammatory stricture of the digestive tract caused by various causes.
2. Patients with anastomotic stenosis after gastrointestinal surgery.
3. Patients with achalasia and sphincter of Audi dysfunction.
4. Cicatricial stricture of the digestive tract.
5. Palliative expansion of unresectable advanced gastrointestinal tumors.
6. Abnormal development of the digestive tract, such as the esophageal ring.
7. Stenosis caused by foreign bodies or stones.

【Specifications】Specification definition method

<table>
<tr><th>No.</th><th>REF</th><th>Max insertion diameter OD±0.3mm</th><th>Guide wire lumen ID+0.3mm</th><th>Working Length L±10mm</th><th>Soft droop mm</th><th>Accept Guidewire</th></tr>
<tr><td>1</td><td>BD700-05</td><td>Φ5</td><td rowspan="5">Φ1.5</td><td rowspan="16">700</td><td rowspan="4">240-280</td><td rowspan="16">0.035</td></tr>
<tr><td>2</td><td>BD700-06</td><td>Φ6</td></tr>
<tr><td>3</td><td>BD700-07</td><td>Φ7</td></tr>
<tr><td>4</td><td>BD700-08</td><td>Φ8</td></tr>
<tr><td>5</td><td>BD700-09</td><td>Φ9</td><td rowspan="4">110-200</td></tr>
<tr><td>6</td><td>BD700-10</td><td>Φ10</td><td rowspan="5">Φ2.0</td></tr>
<tr><td>7</td><td>BD700-11</td><td>Φ11</td></tr>
<tr><td>8</td><td>BD700-12</td><td>Φ12</td></tr>
<tr><td>9</td><td>BD700-13</td><td>Φ13</td><td rowspan="7">60-100</td></tr>
<tr><td>10</td><td>BD700-14</td><td>Φ14</td></tr>
<tr><td>11</td><td>BD700-15</td><td>Φ15</td><td rowspan="6">Φ2.5</td></tr>
<tr><td>12</td><td>BD700-16</td><td>Φ16</td></tr>
<tr><td>13</td><td>BD700-17</td><td>Φ17</td></tr>
<tr><td>14</td><td>BD700-18</td><td>Φ18</td></tr>
<tr><td>15</td><td>BD700-19</td><td>Φ19</td></tr>
<tr><td>16</td><td>BD700-20</td><td>Φ20</td></tr>
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【Warnings】

Do not use this device for any purpose other than stated intended use.

If the package is opened or damaged when received, do not use. Visually inspect with particular attention to parts scattered, and sealing parts breaks. If any abnormality is detected that would prohibit proper working condition, do not use. Please notify the manufacturer for return authorization.

【Contraindications】

Contraindications to dilation include, but are not limited to:

1. Uncooperative patient;
2. Asymptomatic strictures;
3. Inability to advance the dilator through the strictured area
4. Coagulopathy;
5. Known or suspected perforation;
6. Severe inflammation or scarring near the dilation site;
7. Recent myocardial infarction;
8. Those who have fistulas, deep ulcers, and large diverticula in the stenosis.
9. Endoscopy can not reach the narrow part or the visual field is unclear.
10. The lumen is too narrow for the elderly.
11. The general condition of the patient is poor and the cardiopulmonary insufficiency cannot tolerate surgery.

【System Preparation】

1. Prior to use, check surfaces of the products for any abnormality such as cracks, burrs, or foreign materials trapped within the products. Do not use the product that shows any abnormality.
2. Prior to use, read the label of the product, choose the suitable Bougie Dilator.

【Direction for Use】

1. Perform a screening endoscopy to identify the stenotized area.
2. Insert a guide wire through the working channel of the endoscope. With the help of lubricant, the guide wire slides smoothly through. Advance the guide wire past the tip of the instrument and the stenotized area until the tip is clearly visible with endoscopy.

CAUTION: While placing the guidewire, do not continue to advance the wire if resistance is encountered.

3. When the guide wire is in a position well beyond the stenotized area, slowly withdraw the endoscope in increments of 5 - 10 cm while advancing the guide wire in increments of 5 - 10 cm.to ensure that the guide wire stays in place.

CAUTION: Continuous fluoroscopic monitoring of the guidewire is important to ensure that it remains in the correct position.

4. When the endoscope is completely removed, fluoroscopy confirmed that the guidewire was not dislodged.

NOTE: the position of the guide wire can be monitored externally through the use of marker tapes both before and during dilation with respect to the dental arch.

5. Generously lubricate the dilator and advance it over the pre-positioned guide wire to the stenotized area.

NOTE: The printed distance markings can be used as a guide to avoid excessive expansion into the gastric cavity.

NOTE: Bougies should be washed with sterile water before using in order to clean all particulates from the surface. Lubrication can be performed by wetting the surface with sterile water or lubricating with a standard medical grade water based lubricant.

6. Continue with the esophageal dilation. Based on the size of the stenosis, determine which bougie diameter to use, starting with a smaller bougie diameter and gradually increasing the diameter. Hold the bougier by the blunt, proximal end and hold the lumen against the distal, conical tip over the end of the guide wire.

7. Slide the bougie along the guide wire while continuing to monitor the position of the guide wire.

8. After the dilatation is complete, carefully remove the bougie and the guide wire from the patient.

NOTE: Successive dilations are performed by repeating steps 5 - 6.

9. Dispose of the bougie in accordance with internal hygiene regulations.

10. Must wear protective clothing (gloves, masks, goggles, overalls, etc.)!

【Patient population】

The patient population or patient target group is determined from the indication of the responsible doctor, who treats the patient diagnostically or therapeutically within the scope of an endoscopy (the leading intervention in itself) according to the intended use of the medical product. There are no known restrictions on the patient population or patient target group.

• Use of the product in minors:

The user makes the use of the product in minors dependent on whether the physiological and anatomical conditions of the patient allow the use of the product.

• Use of the product in pregnant or breastfeeding women:

The indication for the use of the product in pregnant or breastfeeding women

must be set closely by the user on the basis of the respective individual physiological and anatomical conditions.

【Attentions】

• Do not use if the package is open or damaged when received.

• Do not use if it is expired.

• The device is a single-use sterile product. Destroy after use. Do not reuse.

【Storage】

• The product can only be transported and stored in the packaging provided.

•The product must be stored dry and protected from direct sunlight at room temperature.

• Do not place anything on the storage packaging or sterile barrier system!

• Do not store near irritating chemicals.

【Packaging】

The equipment is put into the paper-plastic bag first, then into the middle box, and finally into the outer box.

【Date of Manufacture】

Please refer to the label on pouch.

【Symbol Instruction】

	Manufacturer		Do not re-use
	Date of manufacture		Use-by date
	Batch code		Catalogue number
	Sterilized using ethylene oxide		Do not use if package is damaged
	Consult instructions for use		Caution

【Shelf Life】3 years after sterilization.

【Manufacturer】Anrei Medical (HZ) Co., Ltd

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