Edwards Balloon Catheter

Instructions for Use

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Please verify that you have the latest version of the instructions for use prior to using the device by visiting http://THVIFU.edwards.com or by calling 1.800.822.9837. In order to access the instructions for use, an IFU Code will be required.

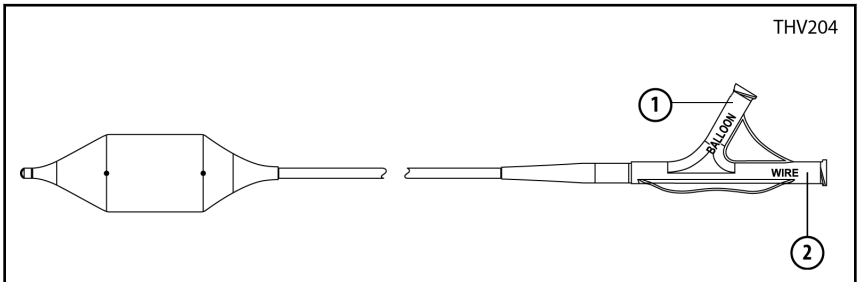
STERILE: The balloon catheter is supplied sterilized by ethylene oxide.

1.0 Device Description

The Edwards Balloon Catheter consists of a shaft and balloon with radiopaque markers indicating working length of the balloon. The proximal end of the device has a "Y-connector" with a balloon inflation port labeled as "BALLOON" and a guidewire lumen port labeled as "WIRE." The inflation parameters are as follows:

Table 1: Inflation Parameters

Model	Balloon Dimensions	Inflation Volume
9350BC16	16 mm x 4 cm	10 ml
9350BC20	20 mm x 4 cm	16 ml
9350BC23	23 mm x 4 cm	21 ml
9350BC25	25 mm x 4 cm	26 ml



Black dots indicate position of radiopaque markers.

1. Balloon Inflation Port
2. Guidewire Lumen Port

Figure 1: Edwards Balloon Catheter

Table 2: Device Compatibility

Model	Minimum Sheath Compatibility	Maximum Guidewire Diameter
9350BC16	14F (4.7 mm)	0.035 in (0.89 mm)
9350BC20		
9350BC23		
9350BC25	16F (5.3 mm)	

Note: For proper volume sizing, the balloon catheter should be used with the inflation device provided by Edwards Lifesciences.

2.0 Indications

- The Edwards balloon catheter is indicated for balloon aortic or pulmonic valvuloplasty.

3.0 Contraindications

- Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient's medical condition could affect successful use of this catheter.

4.0 Warnings

- The device is designed, intended, and distributed for single use only. **Do not resterilize or reuse the device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing.
- Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed.

5.0 Precautions

- For special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis Instructions for Use.
- Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon.
- The device is not intended for post-dilatation of deployed transcatheter heart valves.
- While exposed within the body, device advancement and retrieval should not be done without the aid of fluoroscopy. Do not advance or retract the device unless the balloon is fully deflated under vacuum.

6.0 Potential Adverse Events

Complications associated with standard catheterization, balloon valvuloplasty, and the use of angiography include, but are not limited to, the following potential device and procedural adverse events. Device related potential adverse events include, but are not limited to, balloon rupture and balloon separation following balloon rupture. Procedure related potential adverse events include, but are not limited to, allergic reaction to anesthesia or to contrast media, injury including perforation or dissection of vessels, thrombus formation, plaque dislodgement and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion and/or death (aortic only), pulmonary embolization (pulmonic only), arrhythmia development, cardiac perforation, cardiac tamponade, conduction system injury, pleural effusion (pulmonic only), hematoma, infundibulum injury, annular tear or rupture and/or valve leaflet dehiscence, severe valve insufficiency, valve restenosis, valve and/or conduit damage, valvular tearing or trauma, valvular regurgitation thromboembolic events, inflammation, bleeding and infection.

7.0 Directions for Use

1. Prepare access site for balloon catheter insertion and position guidewire using standard techniques.
2. Flush the balloon catheter with heparinized saline. Attach a high pressure 3-way stopcock to the balloon inflation port.
3. Prepare a 20 ml or larger syringe with 5 ml diluted contrast solution (15:85 contrast to heparinized saline) and attach to the stopcock.
4. Completely fill the inflation device provided by Edwards with diluted contrast solution and attach in the locked position to the stopcock; close the stopcock to the inflation device.
5. Slowly pull vacuum with the syringe repeatedly to remove air, leaving neutral pressure in the system.

6. Close the stopcock to the balloon catheter. Gradually remove contrast medium into the syringe to achieve the appropriate volume (as specified in Table 1: Inflation Parameters) by rotating the knob of the inflation device. Close the stopcock to the syringe and remove the syringe.
7. Remove the balloon cover and hydrate the length of the balloon catheter.
8. Advance the balloon catheter over the guidewire, through a sheath, to the target location, and position the balloon markers at the intended site.
9. Fully inflate the balloon with the inflation device.
10. Completely deflate the balloon, and gently withdraw the balloon catheter and remove from the sheath.

8.0 How Supplied

STERILE: The balloon catheter is supplied sterilized by ethylene oxide.

9.0 Storage

Store in a cool, dry place.

10.0 Device Disposal

Used devices may be handled and disposed of in the same manner as hospital waste and biohazardous materials. There are no special risks related to the disposal of these devices.

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