Edwards Lifesciences

Ascendra Balloon Aortic Valvuloplasty 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.

1.0 Device Description

The Ascendra Balloon Aortic Valvuloplasty Catheter (Figure 1 on page 3) consists of a shaft and balloon with radiopaque marker bands indicating working length of the balloon. At the proximal end of the device, there is a standard “Y-connector” for balloon inflation and the guidewire lumen. An extension tubing is supplied for use with the balloon valvuloplasty catheter during inflation. The inflation parameters are as follows:

Table 1. Inflation Parameters

Model	Nominal	
	Balloon Dimensions	**Inflation Volume w/extension tubing**
9100BAVC	20 mm x 3 cm	15 mL

Device Compatibility:

• Maximum guidewire diameter: 0.035" (0.89 mm)

• Minimum sheath compatibility: 14F (4.62 mm)

Note: For proper volume sizing, the balloon valvuloplasty catheter should be used with an appropriately sized inflation device.

2.0 Indications

The Ascendra Balloon Aortic Valvuloplasty Catheter is indicated for balloon aortic 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 (IFU).

• Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon.

• 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, allergic reaction to anesthesia or to contrast media, thrombus formation, plaque dislodgement and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion and/or death, arrhythmia development, cardiac perforation, conduction system injury, hematoma, infundibulum injury, annular tear or rupture and/or valve leaflet dehiscence, severe valve insufficiency, valve restenosis, valve damage, balloon rupture, balloon separation following balloon rupture, valvular tearing or trauma, thromboembolic events, and infection.

7.0 Directions for Use

Step	Procedure
1	Prepare access site for balloon valvuloplasty catheter insertion and position guidewire using standard techniques.
2	Flush the guidewire lumen with heparinized solution. Attach the extension tubing to the balloon inflation port.
3	Prepare the inflation device with diluted contrast solution (15:85 contrast to heparinized saline) and attach to the extension tubing.
4	Induce a negative pressure to remove any air from the balloon and inflation lumen. Repeat until all air is expelled. Close the stopcock to the balloon valvuloplasty catheter, ensuring the system is maintained at negative pressure.
5	Fill the inflation device with the appropriate volume of diluted contrast medium. Refer to Compliance Table for Pressure and/or Volume vs. Diameter.
6	Open the stopcock to the balloon valvuloplasty catheter. Allow the inflation lumen to fill with the diluted contrast medium. Maintain at neutral pressure.
7	Remove balloon cover.
8	Advance the balloon valvuloplasty catheter over the guidewire, through the introducer sheath, across the valve, and position the balloon at the intended site utilizing the radiopaque markers.
9	Fully inflate the balloon with the inflation device.
10	Completely deflate the balloon, and gently withdraw the balloon valvuloplasty catheter and remove from the sheath.

8.0 How Supplied

Supplied pouched and sterilized by ethylene oxide.

9.0 Storage

The Ascendra Balloon Aortic Valvuloplasty Catheter should be stored 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.

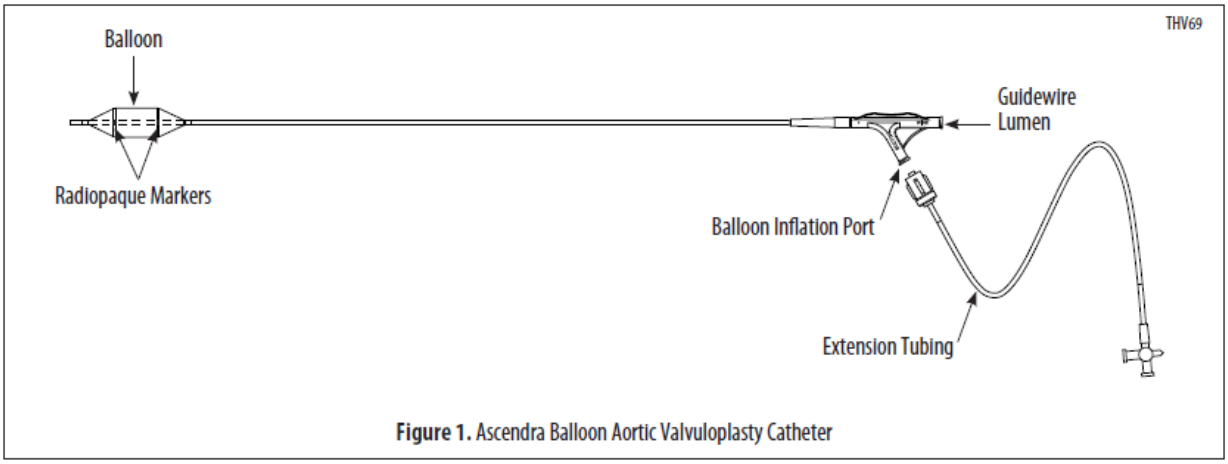

Figure 1. Ascendra Balloon Aortic Valvuloplasty Catheter

Compliance Table Pressure and/or Volume vs. Diameter

Volume (ml)	Volume w/ Balloon Extension (ml)	Applied Pressure ATM (kPa)	Diameter (mm) ø±10%
10.0	11.0	2.0 (202.7)	18.3
10.5	11.5	2.5 (253.3)	18.6
11.0	12.0	3.0 (304.0)	18.8
11.5	12.5	3.5 (354.6)	19.0
12.0	13.0	4.0 (405.3)	19.2
12.5	13.5	4.5 (456.0)	19.4
13.0	14.0	5.0 (506.6)	19.5
13.3	14.3	5.5 (557.3)	19.6
13.5	14.5	6.0 (608.0)	19.8
13.8	14.8	6.5 (658.6)	19.9
14.0	15.0	7.0 (709.3)	20.0
14.3	15.3	7.5 (759.9)	20.1
14.5	15.5	8.0 (810.6)	20.2

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