V8 and TAV8 Balloon Aortic Valvuloplasty Catheter

Instructions for Use

The V8 and TAV8 are identical in construction differing only in balloon bulb length. Both products are referred to in this document as V8.

Date Printed: April 2018

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℞ ONLY

Indications for Use/Intended Use

The V8 Balloon Aortic Valvuloplasty Catheter is indicated for Balloon Aortic Valvuloplasty.

Contraindications

The V8 Balloon Aortic Valvuloplasty Catheter is contraindicated for post-implant dilatation of balloon expandable transcatheter heart valves. The V8 is not contraindicated for post dilatation of self-expanding transcatheter heart valves.

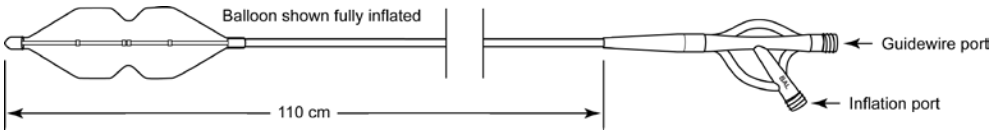
Unpacking and Inspecting the Product

Carefully inspect each item as it is unpacked for any signs of damage which may have occurred during shipment.

Check for any damage or defects. Do not attempt to use if items in package are loose, damaged or defective. Contact Customer Service immediately if anything is damaged or defective.

Device Description

The V8 Balloon Aortic Valvuloplasty catheter system features an anatomically configured dilatation balloon on the tip of a co-axial catheter. The balloon dilates stenotic valve leaflets and the surrounding native tissue in an effort to increase aortic valve area and systemic blood flow in stand-alone valvuloplasty procedures, and prior to and/or after transcatheter self-expanding heart valve implantation. The figure-8 shaped balloon limits undesirable balloon movement during inflation by locking into the patient's aortic valve structure, while the undersized waist segment is intended to limit excessive dilatation of the valve annulus.



The above figure is for reference only. The manifold port labeled "BAL" is for balloon inflation/deflation. The straight manifold port is unlabeled and used for passage of a guidewire.

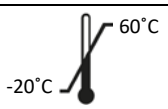
Device compatibility

Guidewire: 0.035" (0.89 mm) diameter, 260 cm (or other exchange) length.

Balloon Waist Size	17-23mm
Balloon Bulb Size	22-28mm
Minimum sheath compatibility	12F (4.0 mm)

Rated Burst Pressure (RBP): 3.0 Atm.

Symbols and Definitions

	Use by date		Caution, consult accompanying instruction for safety information
	Consult accompanying instructions		Not made with natural rubber latex
	Manufacturer		Single Use, Do not reuse
	Date of Manufacture		DEHP free
	Orderable/Catalogue part number		Do not re-sterilize
	Lot number/Batch code		Email Address
			Phone Number
	Indicates a medical device that can be broken or damaged if not handled carefully.		Keep Dry
	Inflation Volume		Rated Burst Pressure
	Introducer Sheath Size		
	Supplied sterilized by ethylene oxide gas and for single use only. The package is sterile and non-pyrogenic **only if** the package is not opened or damaged.		
	Caution: United States Federal law restricts this device to sale by or on the order of a physician.		
	Indicates a medical device that should not be used if the package has been damaged or opened.		
	Indicates the temperature limits to which the medical device can be safely exposed.		

Potential Complications/Outcomes/Adverse Events

- There is potential for balloon separation following balloon rupture or misuse and the subsequent need to use a snare or other medical interventional techniques to retrieve device fragments. Large diameter balloons are capable of bursting circumferentially creating device snag points that can inhibit catheter withdrawal.
- Moderate to severe subannular/left ventricular outflow tract (LVOT) calcification has been associated with increased risk of aortic root rupture during transcatheter aortic valve replacement (TAVR) procedures with balloon-expandable prostheses[1]. BAV procedures may be similarly cautioned.
- Cardiac or Vascular Perforation or Dissection
- Conduction System Injury Requiring a Temporary or Permanent Pacemaker
- Supraventricular or Ventricular Tachyarrhythmia Development
- Hematoma or Severe Vascular Injury Resulting in Transfusion, Surgical Repair or Loss of Limb
- Anaphylaxis or Other Contrast Reactions Including Acute Renal Failure following Balloon Rupture
- Restenosis Development
- Death
- Thromboembolic Events Including Stroke
- Cardiovascular Injury Requiring Emergent Surgery
- Valvular Tearing or Trauma Resulting in Severe Aortic Regurgitation
- Myocardial Infarction
- Hemodynamic Compromise or Shock Requiring Appropriate Intervention Including IAPB Support or Intubation
- Inflammation or Infection
- Tamponade and Need for Pericardiocentesis
- Lack of significant hemodynamic improvement despite dilatation of the aortic valve
- Trauma to the prosthetic valve and/or dislodgement of the valve prosthesis during post implantation dilatation

1: Barbanti et al; Circulation. 2013; 128:244-253

Warnings

- Do not exceed the rated burst pressure. Pressure in excess of the rated burst pressure can cause balloon rupture, embolization of balloon fragments, and potential inability to withdraw the catheter.
- If excessive resistance is felt upon removal, or the balloon bursts during inflation, the balloon and sheath should be removed together as a unit over the guidewire, maintaining vascular access. Continued guidewire access permits reintroduction of a new introducer sheath to preserve hemostasis.
- Multiple inflations of the balloon in excess of the rated burst pressure can cause irreversible enlargement of the waist diameter as a function of pressure.
- Use only appropriate balloon contrast inflation medium, in a 1:8 or higher dilution of contrast medium to saline. Do not use air or gaseous medium to inflate the balloon.
- This catheter is not intended for pressure measurement or fluid injection.
- The catheter should be used prior to the 'Use Before' date noted on the package label.
- During the procedure, an external defibrillator should always be on hand and ready to use.
- Temporary pacing, or permanent pacing, may be required due to intra-cardiac catheter or guidewire manipulation, or balloon-inflation-induced heart block.
- Prolonged inflation of the balloon can cause prolonged hypotension and hypoperfusion of critical vascular beds resulting in loss of conscious and acute cardiopulmonary arrest. Duration should be limited to a brisk inflation/deflation cycle. Limit the number of inflations and correctly size the balloon per the Balloon Sizing section.
- Do not reuse the V8 product as it compromises the intended function or performance or encourages the spread of infection. The V8 product should be used on one patient for a single procedure then discarded. It should not be reprocessed and used again, even on the same patient.

Precautions

- Avoid extended exposure to light and store at room temperature.
- Proper functioning of the catheter depends upon its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching, or forceful wiping of the catheter. Do not use product if contents of package are broken or loose.
- Dilatation procedure should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- Careful attention must be paid to the maintenance of tight catheter connections before proceeding to avoid air introduction into the system.
- Under no circumstances should any portion of the catheter system be advanced against significant resistance. The cause of the resistance should be identified with fluoroscopy and action taken to remedy the problem.

Prepping the Device

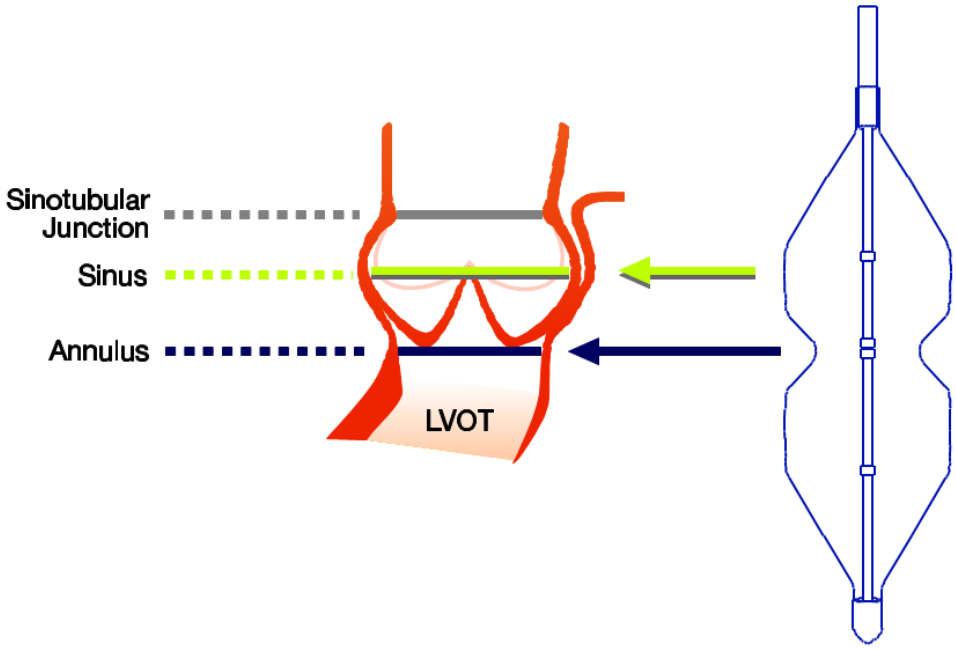
NOTE: DO NOT REMOVE THE BALLOON PROTECTOR UNTIL AFTER THE AIR PURGING PROCESS IS COMPLETED.

1. Attach a high pressure 3-way stopcock to the balloon inflation port. (BAL)
2. Attach a 50cc or 60cc syringe filled with approximately 6cc-10cc of sterile normal saline. Draw back on the syringe to apply full vacuum. Repeat this procedure 3 or 4 times until total air evacuation. Close the stopcock at pressure equilibrium (no vacuum).
3. Fill the inflation syringe with the desired volume (see Balloon Sizing Chart, provided separately) with a solution of 1:8, or lower concentration (higher dilution), contrast medium to saline and reattach the syringe and apply continuous vacuum.
4. Remove the balloon protector.

Performing the Procedure

For Stand-Alone Valvuloplasty and Dilatation Prior to Transcatheter Heart Valve Implantation

1. Apply continuous vacuum using the inflation syringe in order to maintain a minimum balloon wrap profile and advance the balloon over a 0.035" diameter wire, through the introducer sheath, and across the valve.
2. Align the balloon's central marker bands with the native valve annulus.

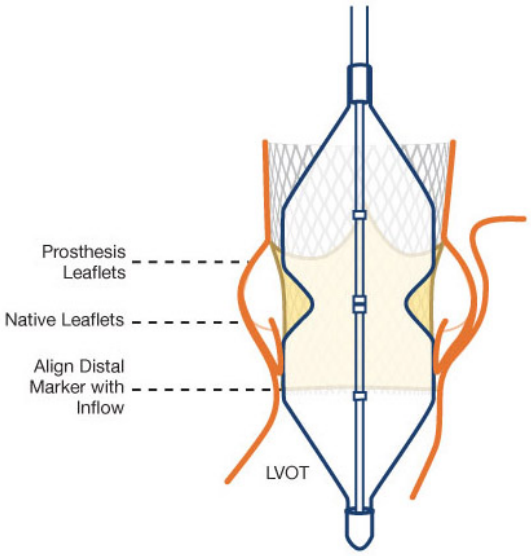


3. Release balloon vacuum. When releasing vacuum there may be 1-3cc's of saline/contrast drawn into the catheter. Confirm the intended inflation volume in the syringe, and if needed, adjust the intended inflation volume.
4. Rapid ventricular pacing can be used to aide in balloon fixation during inflation. If rapid pacing is not used, brace the catheter shaft along the outer curvature of the aortic arch before balloon inflation, and position the balloon center 1mm to 2mm further into the left ventricle from the annulus before inflation.
5. Rapidly inflate and deflate the balloon with the 50cc/60cc syringe. If pacing was elected to be used, terminate after balloon deflation. If the balloon bursts, withdraw the balloon by removing the balloon and sheath together as a unit, as described in the Warnings section.
6. Repeat steps 2-5, if needed, until desired results are achieved, allowing sufficient time for complete hemodynamic recovery between inflations. Maintain wire position throughout the procedure.
7. Antiplatelet and anticoagulant therapy is recommended throughout the procedure to avoid blood clot(s) which may result in embolization and vascular occlusion.
8. Remove the catheter while applying a continuous vacuum with the syringe and pulling back slowly on the catheter while holding the introducer sheath firmly in place.

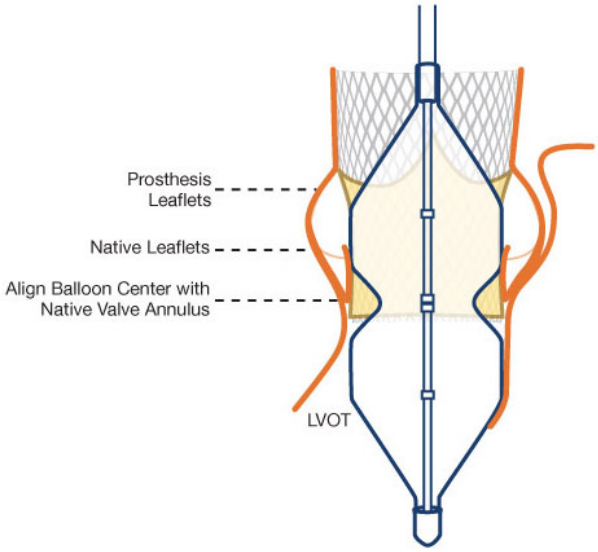
For Dilatation Post Implantation Self-Expanding Transcatheter Heart Valves

1. Perform steps 1 and 3 from the Stand-Alone procedure.
2. Align the balloon with the valve prosthesis in one of two ways:

Position #1



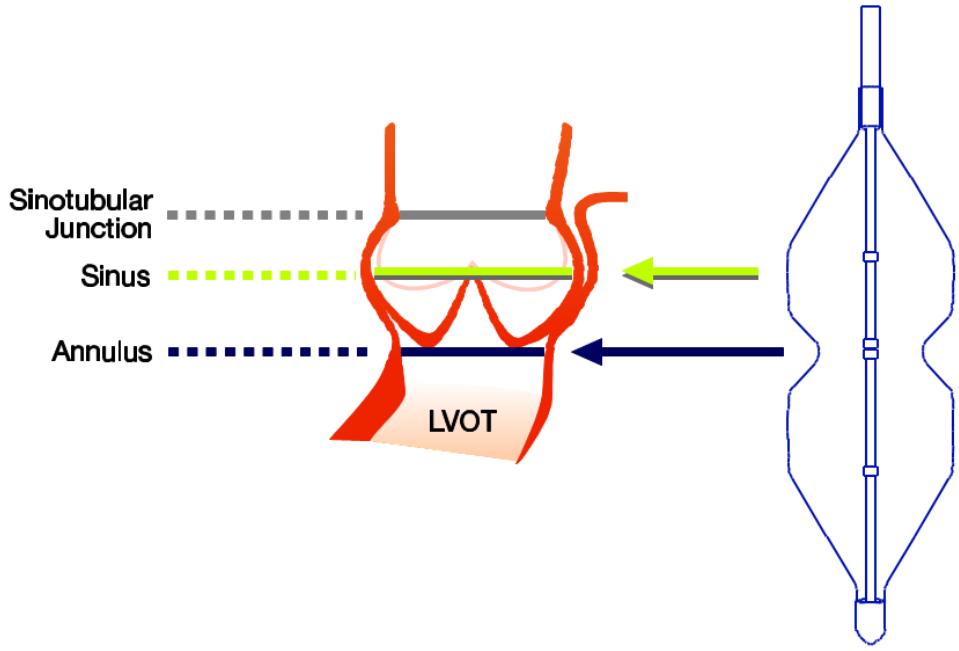
Position #2



3. **Position #1**: Align the distal marker of the V8 with the inflow edge of the valve prosthesis frame. This position minimizes balloon extension beyond the prosthetic valve frame into the LVOT region.
   Position #2: Center the V8 waist with the native annulus. This position permits flaring of the prosthesis frame above and possibly below the native annulus.
4. Rapid ventricular pacing should be used during balloon inflation to avoid dislodgement of the prosthesis.
5. Perform steps 5-8 from the Stand-Alone procedure.

Balloon Sizing

Bulbous balloon segments and waist segment inflation diameters must be carefully considered in selecting a particular catheter size for any patient. The following recommendations may not be appropriate for any given procedure and are intended for general guidance only. When used as a post dilatation balloon, refer to the specific valve manufacturer's instructions on proper sizing and use of the V8.



In all cases, the balloon bulbous segment should be at least 4mm smaller in diameter than the mean diameter of the native aortic sinus.

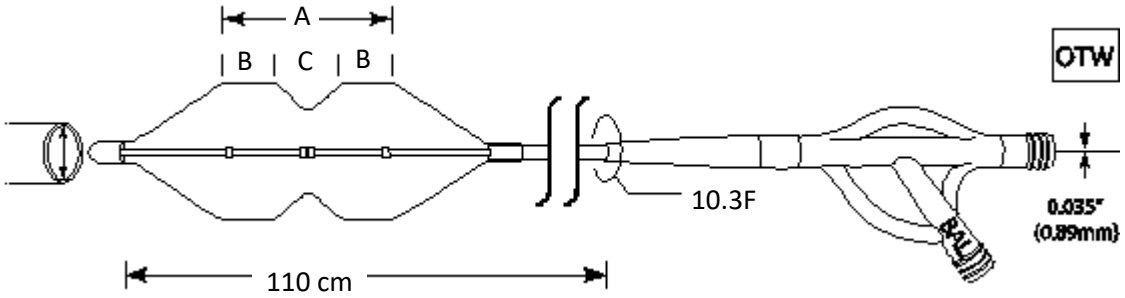
- **For Stand-Alone and Dilatation Prior to Transcatheter Heart Valve Implantation,** the nominal balloon bulb diameter is recommended to be 1mm to 2mm larger than the mean diameter of the native annulus.
- **For Position #1** of Dilatation Post Implantation Self-Expanding Transcather Heart Valves, the distal bulb diameter should be no greater than the mean diameter of the native annulus.
- **For Position #2** the bulb diameter is recommended to be 1mm to 2mm larger than the mean diameter of the native annulus.

If moderate to severe calcium is observed in the subannular/LVOT region, balloon undersizing or underfilling should be considered.

Increasing the inflation volume or exchanging for a larger balloon size may be considered if the initial balloon inflation does not produce desired results.

Balloon Dimensions

Per Chart below



REF Number	Distal to Proximal Length mm A	Bulbous Segment Length mm B	Waist Segment Length mm C	Nominal Proximal Bulb Diameter mm	Nominal Distal Bulb Diameter mm	Nominal Waist Diameter mm
172212C110	32	10	12	22	22	17
V8-1722	28	8	12	22	22	17
TAV8-1722	24	Distal – 4 Proximal - 8	12	22	22	17
192412C110	32	10	12	24	24	19
V8-1924	28	8	12	24	24	19
TAV8-1924	24	Distal – 4 Proximal - 8	12	24	24	19
212612C110	32	10	12	26	26	21
V8-2126	28	8	12	26	26	21
TAV8-2126	24	Distal – 4 Proximal - 8	12	26	26	21
232812C110	32	10	12	28	28	23
V8-2328	28	8	12	28	28	23
TAV8-2328	24	Distal – 4 Proximal - 8	12	28	27	23

Balloon Sizing Chart

Listed on each product label is a single inflation volume in cc's ("Inflation Volume"). A fully prepped catheter at pressure equilibrium (no vacuum) contains approximately 1 to 3 cc's of fluid dead space within the catheter shaft ("Catheter Volume"). The recommended Inflation Volume is in addition to this Catheter Volume.

Total amount of fluid used = Catheter Volume + Inflation Volume

Injecting a fully prepped catheter at pressure equilibrium with the desired Inflation Volume inflates the V8 to its nominal balloon dimensions.

In addition to the Inflation Volume shown on the product label, a Balloon Sizing Chart is packaged separately with each device showing a range of alternative Inflation Volumes with corresponding balloon dimensions.