INOUE BALLOON™ A

Balloon Aortic Valvuloplasty Catheter
Instruction for Use

Caution : Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Caution : This product contains natural rubber latex which may cause allergic reactions.

TORAY

I. INDICATION

INOUE BALLOON™ A is indicated for balloon aortic valvuloplasty (BAV) in patients with aortic stenosis.

II. DEVICE DESCRIPTION

1. Product summary

INOUE BALLOON™ A is intended for balloon aortic valvuloplasty (BAV) in patients with aortic stenosis (AS). The device is inserted over a guidewire and inflated with a predetermined amount of diluted contrast medium using the supplied syringe connected to the balloon inflation luer-lock hub (b). This results in the staged inflation of the balloon from hourglass to barrel shape. The balloon is stretched and made thinner by pushing the inner tube (a) in when passed through the introducer sheath. A radiopaque marker is provided to align the balloon center and the aortic valve using fluoroscopy **(See Figure 1,2 and 3)**.

2. Set contents

This product is composed of the catheter and two accessories (caliper & syringe with extension tube).

A. Catheter

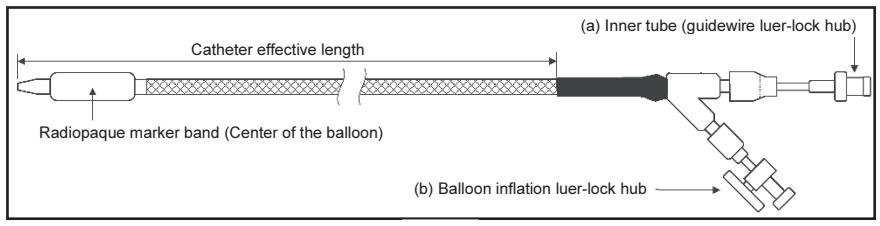

Figure 1

Balloon shape change

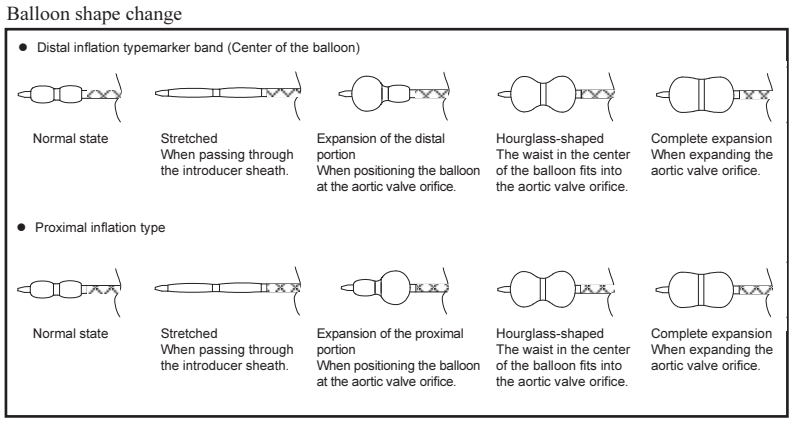

Figure 2

B. Accessories

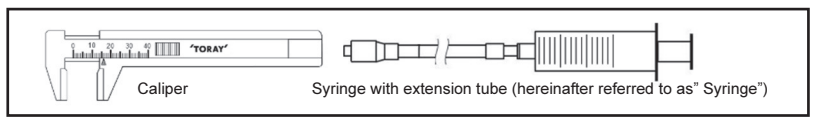

Figure 3

3. Additional items

The additional items listed below, not included in the package, are needed to perform the BAV.

Additional items	Conform conditions
Guidewire (commercially available)	Outer diameter: 0.89 mm (0.035 inch), Length: 260 cm or longer
Introducer sheath	10 Fr. - 14 Fr.
Angiography catheter	Compatible diameter of guidewires: 0.89 mm (0.035 inch) or 0.97 mm (0.038 inch)
Diluted contrast medium	Contrast medium diluted 5-fold with saline
Syringe for flushing (commercially available)	Syringes with a capacity of 10 to 20 mL
Heparinized saline solution for flushing	-

4. Specification (Size of catheters)

type	Cat. No.	Shaft length	Balloon maximum outer diameter	Balloon available range	Recommended sheath introducer size (Minimum size *)
Distal inflation type	PTAV-16R	105 cm	16 mm	14 - 16 mm	11 Fr. (10 Fr.)
	PTAV-18R		18 mm	16 - 18 mm	11 Fr. (10 Fr.)
	PTAV-20R		20 mm	18 - 20 mm	11 Fr. (10 Fr.)
	PTAV-22R		22 mm	20 - 22 mm	11 Fr. (10 Fr.)
	PTAV-24R		24 mm	20 - 24 mm	12 Fr. (11 Fr.)
	PTAV-26R		26 mm	22 - 26 mm	14 Fr. (12 Fr.)
Proximal inflation type	PTAV-16RP		16 mm	14 - 16 mm	11 Fr. (10 Fr.)
	PTAV-18RP		18 mm	16 - 18 mm	11 Fr. (10 Fr.)
	PTAV-20RP		20 mm	18 - 20 mm	11 Fr. (10 Fr.)
	PTAV-22RP		22 mm	20 - 22 mm	11 Fr. (10 Fr.)
	PTAV-24RP		24 mm	20 - 24 mm	12 Fr. (11 Fr.)
	PTAV-26RP		26 mm	22 - 26 mm	14 Fr. (12 Fr.)

*Minimum introducer size: Internal diameter varies by sheath manufacturer. Resistance may be felt if using smaller than the recommended size.

III. CONTRAINDICATIONS

1. Patients with aortic regurgitation degree of 3 or higher by Sellers classification as it may exacerbate aortic regurgitation and/or induce left heart failure.
2. Patients suspected of forming a fresh left atrial thrombus as it may result in embolism.
3. Patients with suspected thrombus on the valve as it may result in embolism.
4. Patients with bacterial endocarditis as it may exacerbate infection.

IV. WARNINGS

1. Do not use after the “use before” date shown on the label preceded by the following symbol: ⌛.
2. Do not reuse and do not resterilize. **INOUE BALLOON™ A** is intended for SINGLE USE ONLY. Discard the catheter and its accessories after procedure. Reuse may result in product damage and/or adverse events (i.e., infection, thrombosis, embolism, etc.)
3. The catheter should only be used by physicians proficient in BAV procedure. Independent use should not be attempted by anyone not completely trained, as it may result in severe patient injury or death.
4. This product contains natural rubber latex. Natural rubber latex may rarely cause allergic symptoms like itching, redness, urticaria, edema, fever, dyspnea, asthma-like symptoms, low blood pressure and shock. If those symptoms happen, stop using immediately and take appropriate actions.
5. Do not use a guidewire that is bent. Replace it with a new one as soon as possible. Continued use of a bent guidewire may impede catheter movement or cause guidewire breakage.
6. Balloon inflation diameter must be carefully considered in selecting a particular size for any patient, especially for patients with severe calcification, extensive calcification, narrowing of the sinus of valsalva or narrowing of the aorta. Ensure prior to use that the appropriate balloon size has been selected based on the patient’s specific condition such as height and echocardiography results. Dilating the aortic orifice with a large balloon diameter may cause injury to the valve, balloon damage, mesh break or other adverse events and/or device problems. If a mesh break or any other problem occurs, immediately deflate and remove the balloon, and replace it with a new catheter.

7. When expanding the balloon, begin with a smaller balloon diameter and increase the diameter if necessary. If the degree of valve stiffening, calcification, and subvalvular stenosis is significant, dilation can cause damage, resulting in regurgitation.
8. If aortic regurgitation occurs or worsens after valvular dilation, discontinue subsequent dilation. Otherwise, it may cause further aortic regurgitation.
9. Do not use guidewires made of nickel-titanium alloy. Breakage is difficult to predict and to visualize under fluoroscopy.
10. If you use this device to support transcatheter aortic valve replacement (TAVR), please refer to the TAVR IFU for the additional steps related to the selection and use of valvuloplasty balloons.

V. PRECAUTIONS

1. Before use

Do not use if the package has been opened or damaged. Confirm before opening the sterile pouches. Confirm that the catheter and its accessories are functioning properly. Always keep extra sets of the products so that replacement can be made if necessary.

2. During use

A. Do not tap or hit on the catheter and its accessories (such as with forceps). This could cause damage to the catheter shaft, balloon, etc.
B. Always perform advancement, manipulation and withdrawal of the **INOUE BALLOON™ A** and the guidewire under fluoroscopic guidance.
C. Administer an adequate amount of heparin according to its IFU and the latest guidelines.
D. Do not inflate the balloon beyond the maximum balloon inflation diameter **(See II. DEVICE DESCRIPTION 4. Specification “Balloon available range”)**. Otherwise, it may cause damage to the device or patient injury. If strong resistance is met during manipulation, discontinue the procedure and determine the cause of the resistance before taking further action. If the cause of the resistance cannot be determined, withdraw the balloon catheter and guidewire.
E. Ensure the guidewire is inserted in the catheter before pushing the inner tube of the catheter into the connector. If the guidewire is not in place, the balloon portion may bend at a sharp angle and make subsequent manipulation difficult.
F. Do not twist the inner tube while elongating the balloon. If the inner tube is twisted, it will occlude and/or damage the guidewire lumen and this could make it impossible to advance or withdraw the guidewire.

VI. HOW SUPPLIED / STORAGE

1. **INOUE BALLOON™ A** is sterilized with ethylene oxide gas prior to shipment. The catheter and accessories are sterile if the package is undamaged and unopened.
2. Store in a cool, dry, dark place.

VII. DIRECTION FOR USE

1. Opening the sterile package

Remove the catheter from package. Verify the balloon size is suitable for the procedure and the selected accessories accommodate the catheter as labeled.

2. Preoperative Preparation: Checking the balloon diameter and air removal from catheter

A. Flush the inner tube of the catheter with heparinized saline.
B. Ensure that the connector of the catheter bears the same alphabet letter as that printed on the **Syringe (See Figure 4)**.

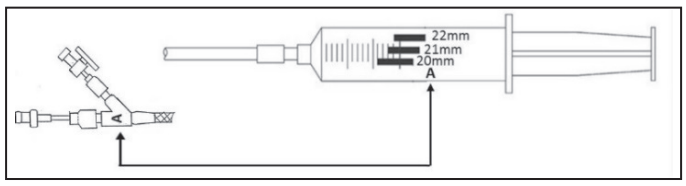

Figure 4

NOTE: Balloons can only be inflated to the correct diameter with the **Syringe** in the same package. Do not use the **Syringe** for a catheter from different packages or the syringe commercially available. Syringe for flushing should be used for flushing and air removal.

NOTE: The Extension tube and the supplied syringe are glued together by adhesive, so do not force them to twist.

C. Connect the syringe for flushing to the balloon inflation luer-lock hub and inject the contrast medium diluted 5-fold with physiological saline. The inflation and deflation of the balloon are repeated, and the air inside the balloon is discharged. Then lock the balloon inflation luer-lock hub. (The balloon lumen is filled with diluted contrast medium.) **(See II DEVICE DESCRIPTION 2. Set contents)**

NOTE: Remove air completely from the balloon lumen. Any air remaining inside the balloon lumen may prevent balloon inflation at the predefined diameter or cause air embolism following balloon rupture.

NOTE: Do not inject diluted contrast medium at more than the predetermined dose for inflating the balloon to the applicable maximum diameter. Otherwise, the balloon inflated beyond the applicable diameter may cause a break in the mesh between the inner and outer rubber layers of the balloon, resulting in an irregular balloon inflation. If the mesh has broken, stop using the device.

D. Fill the **Syringe** with diluted contrast medium to the predetermined level in the scale (the proximal end of the red indicator bar representing the minimum inflation diameter) **(See Figure 6)**.

E. Connect the **Syringe** to the balloon inflation luer-lock hub without letting in air **(See Figure 5)**.

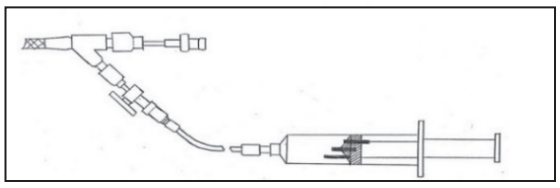

Figure 5

F. Open the stopcock for the balloon inflation luer-lock hub and slowly inject the predetermined dose (for the applicable minimum inflation diameter indicated as (a)) of diluted contrast medium by manually pushing the **Syringe** plunger to the end (indicated as (c)). Close the stopcock and measure the balloon diameter with the caliper to see if the balloon diameter matches the applicable minimum inflation diameter. Close the stopcock for the injection port and remove the **Syringe** from the port.

Repeat the above procedure to inflate the balloon with the predetermined dose for the applicable maximum inflation diameter (indicated as (d)). Close the stopcock and measure the balloon diameter with the caliper to see if the balloon diameter matches the applicable maximum inflation diameter. Meanwhile, check the dose required to inflate the balloon only in the proximal part (indicated as (b)) during the course of inflation. Open the stopcock for the injection port and draw the whole volume of diluted contrast medium into the **Syringe** to deflate the balloon. Then close the stopcock for the injection port and remove the **Syringe** from the port **(See Figure 6)**.

NOTE: Once the balloon is inflated, inspect the integrity of the mesh and symmetry of the balloon, and confirm that there is no balloon inflation failure or insufficient inflation. They can occur due to breakage of the inner balloon layer or the mesh, or inadequate injection volume.

<Example of the balloon diameter: 22 mm at maximum inflation>

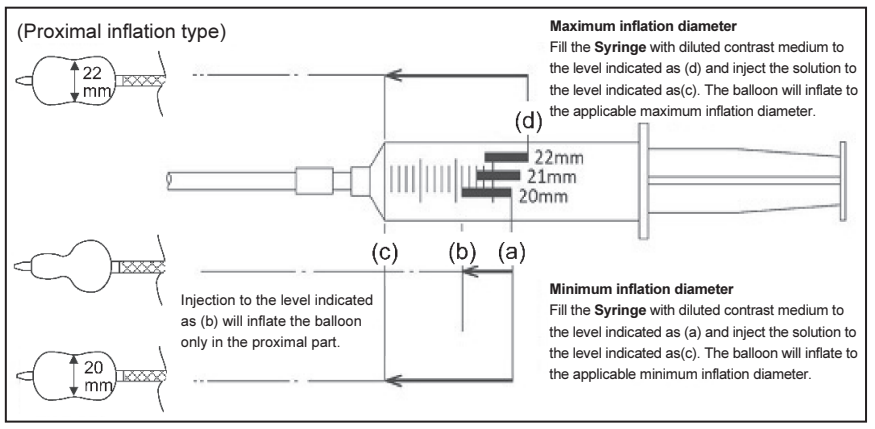

Figure 6

3. Instructions for Use

A. Prepare patient and place introducer sheath and guidewire into access site using standard percutaneous catheterization techniques.

B. Backload the distal tip of the catheter over the prepositioned guidewire and advance the catheter up to the introducer sheath.

C. Push the inner tube of the catheter into the Y-connecter and place the pin into the slot on the Y-connecter. This results in elongating the balloon. Then guide the catheter through the introducer sheath over the guidewire.

NOTE: Be particularly careful in the retrograde approach. The catheter may dislodge thrombus or debris potentially causing cerebral embolism. Careful attention must be paid while inserting the introducer sheath into the femoral artery due to the high risk of bleeding at the insertion site and arterial complications.

NOTE: Deflate the balloon further by withdrawing the dilute contrast medium into the **Syringe**, using the introducer set for insertion of the catheter. If the balloon is not further deflated in this manner it may be difficult to insert the catheter into the sheath. If insertion is still difficult, never force the catheter through the sheath, but replace the sheath with a larger size and try again.

D. After the balloon has completely passed through the introducer sheath, unlock the inner tube from the Y-connecter and pull the inner tube until resistance is felt. Thus return the balloon to its original length.

NOTE: In elongating the balloon, ensure that the guidewire is inserted inside the catheter before pushing the inner tube of the catheter into the connector. If the guidewire slips off, the balloon portion may bend at a sharp angle and lose function for the subsequent procedures.

E. Connect the **Syringe** filled with the predetermined dose of diluted contrast medium to the balloon inflation luer-lock hub. Meanwhile, check the scale on the Syringe to see if the dose of diluted contrast medium inside the **Syringe** matches the dose required for the desired balloon inflation diameter.

NOTE: In connecting the **Syringe** to the catheter, ensure the extension tube of the **Syringe** is securely locked to the connector so that they will not be disconnected during operation.

F. Advance the catheter over the guidewire and insert the balloon into the aortic orifice.

G. Inject the diluted contrast medium to inflate the distal half (or proximal half) of the balloon **(See Figure 6)**. Slightly pull back the balloon (if distal inflation type) or push forward (if proximal inflation type) to position it in the aortic orifice.

H. Maintaining the catheter compression directly against the valve port, inject the remaining contents of the diluent contrast medium to fully inflate the balloon.

I. Immediately retract the **Syringe** plunger strongly to apply negative pressure in order to minimize the time for balloon deflation.

J. Withdraw the catheter over the guidewire to the introducer sheath. Elongate the balloon portion by pushing the inner tube into the Y-connecter and placing the pin into the slot on the Y-connecter. Let the balloon elongate fully and remove the catheter and guidewire through the introducer sheath.

NOTE: Make sure that no diluted contrast medium remains in the balloon before the balloon elongation procedure.

NOTE: When removing the catheter, the balloon may not pass smoothly through the introducer sheath. In this case, negative pressure is applied to the balloon when the catheter is pulled out. Try pushing and pulling the catheter a couple of times. If it still does not pass, flush the inside of the sheath with saline. This also makes it easier to remove the catheter. If these are not effective, remove the catheter with the introducer sheath.

NOTE: If the balloon is subjected to twisting forces beyond those which it is designed to withstand, a small opening in the inner balloon layer may develop, thus allowing leakage of the radiopaque diluted contrast medium into the space between the two latex layers of the balloons. At this point, the outer wall of the balloon is the only layer which will expand (**See Figure 7**).

Should this occur, the clinician would observe that deflation of the balloon following valvuloplasty becomes impossible. This is due to the continued flow of diluted contrast medium from the center of the balloon into the space between the two layers. The opening between the layers acts as a one-way valve and obstructs the return flow of diluted contrast medium as the inner layer contracts, thus preventing the diluted contrast medium from being withdrawn when negative pressure is exerted on the syringe.

If the balloon cannot be deflated, it must immediately be withdrawn from the valve orifice. The unique design of the catheter features 4 small holes (small escape openings) through which the diluted contrast medium will gradually escape. They are located 180° from one another in the outer latex layer of the distal part and center (waist) of the balloon. After withdrawing the balloon to the aorta, the user should then elongate the balloon by pushing inner tube into the Y-connecter. The guidewire must extend beyond the catheter tip (**See Figure 7**). This action will facilitate and accelerate the flow of the diluted contrast medium from the balloon. If deflation is not complete within this time, wait several more minutes until the balloon has deflated spontaneously. At this time, ensure that the heparin has been administered in adequate amounts to prevent thrombus formation; an additional dose may be required. In this situation, do not use normal saline or any other fluid to inflate the balloon. Do not attempt to expand the balloon to the point of rupture, as several times the maximum inflation volume is required for rupture to occur.

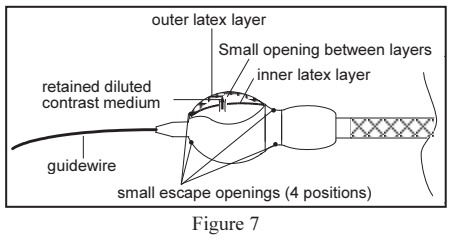

Figure 7

4. Disposal

Discard the **INOUE BALLOON™ A** in the manner approved by your institution for medical waste.

VIII. POTENTIAL COMPLICATIONS, ADVERSE EFFECTS

- Exacerbation of regurgitation
- Arrhythmias such as atrial fibrillation, heart block, bradycardia, and ventricular tachycardia or fibrillation.
- Blood vessel damage
- Congestive heart failure or pulmonary edema
- Myocardial damage, cardiac perforation, or cardiac tamponade
- Aortic valve damage
- Ruptured chordae tendineae
- Thrombosis, embolism, myocardial infarction, stroke, or transient ischemic attack
- Infection
- Allergic reaction to contrast medium or device components
- Hypotension
- Respiratory arrest
- Kidney failure
- Vasovagal reaction
- Bleeding or hematoma at the puncture site

IX. CLINICAL REFERENCES

1. Toshihiro Moriki, Tetsuya Tobaru et al.: The brand-new Inoue balloon for retrograde approach: first experience in Japan. Cardiovascular Intervention and Therapeutics. 34(3):293-294 (2019)
2. Mike Saji et al.: Transcatheter aortic valve replacement in patients with extremely severe aortic stenosis. International Journal of Cardiology 329 162–166 (2021)
3. Kenichi Ishizu et al.: Retrograde balloon aortic valvuloplasty with the newly invented Inoue balloon for aortic stenosis accompanied by severe heart failure: A case report. Clinical Case Reports. 9(4):2011-2015 (2021)
4. Ryo Ninomiya et al.: Safety and feasibility of retrograde INOUE-BALLOON for balloon aortic valvuloplasty without rapid ventricular pacing during transcatheter aortic valve replacement. Cardiovascular Intervention and Therapeutics. 37(2):372-380 (2022)

X. DISCLAIMER OF WARRANTY AND LIMITATIONS OF REMEDY

1. Toray will replace any defective the **INOUE BALLOON™ A** and set contents (e.g., damaged product), free of charge. In the event of a product complaint, the user is requested to return the **INOUE BALLOON™ A** and packaging materials so that the cause of the complaint may be fully investigated.
2. Toray is not responsible for any damage caused due to improper handling, operation and storage, including use after the expiry date given on the product label, preceded by the symbol: .
3. Toray is not responsible for any damage to the **INOUE BALLOON™ A** or its accessories caused by transportation, handling and storage at the health care facility, whether physical damage or human injury.
4. Toray is not responsible for any damage caused by reprocessing or reuse of the **INOUE BALLOON™ A** or its accessories, whether physical damage or human injury.
5. Toray is not responsible for any damage, whether physical damage or human injury, which may arise from the misuse of the **INOUE BALLOON™ A** (catheter, caliper and **Syringe**). Do not substitute with other manufacturers' products.

SYMBOLS USED IN MEDICAL DEVICE LABELING

STERILE EO	Sterilized using ethylene oxide		Keep dry
STERILE EO	Single sterile barrier system and sterilized using ethylene oxide		Keep away from sunlight
	Use by date		Refer to instruction manual
LATEX	Contains natural rubber latex		Manufacture
REF	Catalog number	LOT	Batch code
	Single use only	MD	Medical Device

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