



Edwards

AUTUS SIZE-ADJUSTABLE VALVE, MODEL AUT001

Final Draft



Instructions for Use

CAUTION: US law restricts this device to sale by or on the order of a physician.

1. DEVICE INFORMATION

1.1. DEVICE DESCRIPTION

The AUTUS Size-Adjustable Valve (AUTUS valve) is a stented bileaflet synthetic pulmonary valve comprised of 0.1 mm expanded polytetrafluoroethylene (ePTFE) leaflets mounted on a balloon-expandable 316L stainless-steel frame. The frame is encased by a sleeve of ePTFE that extends below the level of the stent frame to allow for suture placement and fixation of the device to the tissue. The sleeve is made of ePTFE stretch graft material to allow for frame expansion when subject to radial forces (i.e. balloon dilation).

The valve is available in a single size of 12.7 mm internal diameter (ID), see **Figure 1**. The balloon-expandable frame can be expanded in 2 mm increments pre- and post-implant within a functional diameter range from 12.7 mm ID to 22 mm ID, see **Table 1**. As the frame expands radially, the coaptation height of the leaflets decreases.

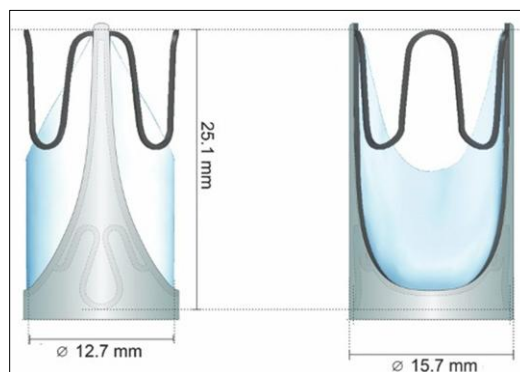


Figure 1: AUTUS Valve Nominal Dimensions

Table 1: AUTUS Valve - Key Dimensions (Functional Diameter Range)

Internal Diameter (mm)	Outer Diameter (mm)	Length (mm)
12.7	15.7	25.1
14	17	24.7
16	19	24.0
18	21	23.1
20	23	21.9
22	25	20.5

The valve is stored under dry packaging conditions and does not require rinsing prior to implantation.

2. INDICATIONS FOR USE

The AUTUS valve is indicated for the management of pediatric patients weighing ≥ 10 kg who require surgical pulmonary valve replacement for dysfunctional native or surgically-repaired right ventricular outflow tract (RVOT), as determined by echocardiography to meet the following criteria: (1) severe pulmonary stenosis (i.e., right ventricle (RV) to pulmonary artery (PA) peak instantaneous gradient ≥ 60 mmHg); (2) $\geq$ moderate pulmonary regurgitation; or (3) $\geq$ moderate pulmonary stenosis (i.e., RV to PA peak instantaneous gradient ≥ 40 mmHg) and $\geq$ moderate pulmonary regurgitation.

3. CONTRAINDICATIONS

The AUTUS valve is contraindicated in patients who have active bacterial endocarditis, any other active infection in the heart or body, or have a known intolerance to anticoagulant or antiplatelet drugs (including aspirin).

4. WARNINGS

FOR SINGLE USE ONLY. This device is designed, intended, and distributed for single use only. Do not resterilize or reuse this device. There are no data to support the sterility, non-pyrogenicity, and functionality of the device after sterile reprocessing.

DO NOT FREEZE OR EXPOSE THE VALVE TO EXTREME HEAT. Exposure of the valve to extreme temperatures will render the device unfit for use. (Refer to **Section 10.2** for recommended storage conditions).

DO NOT USE the AUTUS Valve:

- If the tray/Tyvek lid are opened, damaged, or stained
- If the expiration date has elapsed, or
- If it is dropped, damaged, or mishandled in any way. Should a valve be damaged during insertion, do not attempt repair.

5. PRECAUTIONS

- Safety and Effectiveness of the AUTUS valve in a non-pulmonary position, including aortic, mitral, or tricuspid valve replacement has not been established.
- Safety and effectiveness of deploying a transcatheter valve within the AUTUS valve has not been established. There is no non-clinical or clinical data on valve-in-valve procedures with the AUTUS valve.
- Safety and effectiveness of post-implant expansion of the AUTUS valve has not been established. There is currently limited clinical data on post-implant valve expansion procedures. The total number of expansion procedures that a patient can undergo in a lifetime is unknown. There is presently no clinical experience with more than one expansion procedure being performed for a patient.
- DO NOT EXPOSE the valve to any solutions, chemicals, antibiotics, etc., except for sterile physiological saline solution.
- DO NOT GRASP the leaflet material of the valve with instruments or use forceps to manipulate leaflet material. Even the most minor leaflet material abrasion or defect may over time lead to significant impairment of valve function.

- DO NOT OVERSIZE. Oversizing at the time of the implant procedure with or without pre-expansion may cause valve damage or localized mechanical stresses, which may in turn injure the heart or result in leaflet material failure, frame distortion or regurgitation.
- DO NOT TRIM the sleeve/sewing cuff to beyond the most inferior portion of the stent frame (as indicated by black line). Excessive trimming of sleeve could result in insufficient sleeve material for correct suture placement during implantation.
- DO NOT attempt balloon dilatation of the AUTUS valve after suturing the valve into the right ventricular outflow tract during the index procedure. This may cause damage to or failure of the AUTUS valve and may lead to patient injury.
- DO NOT attempt to crimp/compress an expanded valve down to a smaller diameter. This may cause damage to the frame and/or leaflet material.
- DO NOT deform frame when handling device. Deformation may occur due to:
 - Incorrect pre-implant balloon expansion (e.g. malignment of balloon, under inflation of balloon)
 - Crushing and/or manually compressing the valve during implantation
 - Incorrect post-implant balloon expansion (e.g. inappropriate balloon length, balloon malalignment with frame, incorrect wire placement)
 - Deformation of the frame could lead to valve dysfunction, leaflet material damage or frame fracture
- During pre-implant balloon expansion, DO NOT adjust position of valve with the balloon inflated. Movement of valve while the balloon is inflated could result in leaflet material abrasion or tearing.
- DO NOT position valve in right ventricular outflow tract during implantation such that distal valve is not coaxially aligned within the main pulmonary artery (See **Section 11.5** for proper positioning and alignment as indicated in the figures). This can result in the valve being placed under compressive forces from the overlying patch and/or native vessel. Failure to assure correct valve positioning could potentially lead to valve dysfunction, leaflet material damage, frame fracture, vessel/patch erosion or aneurysm formation.
- During post-implant balloon expansion, DO NOT position wire incorrectly, use an inappropriate balloon length or allow balloon malalignment with frame (specifically, working length of balloon must remain straight throughout full length of device during inflation). Failure to do so could damage leaflet material and result in possible valve dysfunction.
- DO NOT inflate balloon beyond nominal pressure during post-implant valve expansion procedure. Failure to do so could place excessive tension on the valve sleeve-tissue suture line. Excessive tension could result in suture hole elongation/tearing of sleeve material, potentially leading to paravalvular leak, valve dysfunction or device embolization.
- Clinical long-term durability has not been established for the AUTUS valve. Regular medical follow-up is advised to evaluate valve performance.
- Cases of valve frame fracture have been observed clinically. There may be limitations with x-ray imaging to confirm fracture events. If frame fracture is suspected, advanced imaging (e.g., fluoroscopy) to evaluate the presence of fractures is recommended when clinically indicated.
- There is presently no clinical experience with post-implant expansions of fractured valve frames. Limited engineering data suggests that valve frames with fractures at the base of the frame along the leaflet attachment feature (where fractures have been observed clinically) may maintain acceptable valve hydrodynamic performance when expanded.
- Cases of reduced leaflet mobility have been observed clinically. Patients experiencing impaired leaflet mobility should be followed closely. Advanced imaging to evaluate impaired leaflet mobility is recommended when clinically indicated.
- There is no clinical experience with post-implant expansions of valves with reduced leaflet mobility. The potential clinical impact of reduced leaflet mobility on the ability to perform post-implant valve expansion is unknown. If leaflet thrombus is suspected, additional imaging, including transesophageal echocardiography or CT imaging should be considered prior to performing a post-implant valve expansion procedure.
- As with any implanted medical device, there is a potential for patient immunological response. Some components of the AUTUS valve are a metal alloy that contains chromium, nickel, and molybdenum. Care should be exercised in patients with hypersensitivities to these materials.

6. POTENTIAL ADVERSE EVENTS

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

- Allergic reaction to valve materials or contrast media
- Annulus damage including dissection, perforation, or tear
- Atelectasis
- Aortic damage including dissection, perforation, or tear
- Bleeding, including peri- or post-procedural, anticoagulant-related, pericardial tamponade, or hematoma
- Blood related issues, including anemia, coagulopathy, or hemolysis
- Blood pressure alteration, including hypo- or hypertension
- Cardiac arrest (asystole)
- Cardiac arrhythmias or conduction disturbances
- Cardiogenic shock
- Coronary artery compression
- Death
- Deep vein thrombosis (DVT)
- Disseminated intravascular coagulation (DIC)
- Embolism
- Esophageal tear/rupture
- Fever
- Frame fracture or distortion with or without obstruction or loss of structural integrity
- Hemolysis
- Hypoxemia
- Infection, including endocarditis, local (wound) or systemic
- Multi-system organ failure (MOF)
- Myocardial infarction
- Neurologic events, including cerebrovascular accident (CVA) or transient ischemic attack (TIA)
- Pain, swelling, or bruising at the catheterization site
- Perforation of a major blood vessel or a heart chamber
- Pericardial effusion
- Pleural effusion
- Pneumonia
- Pneumothorax
- Prosthetic Insufficiency – regurgitation and/or stenosis
- Pulmonary artery damage, including dissection, perforation, or tear
- Pulmonary edema
- Radiation-induced erythema
- Reduced exercise tolerance
- Reduced leaflet mobility
- Renal failure (RF) or insufficiency, including acute RF and contrast induced nephropathy
- Respiratory failure
- Rupture of the RVOT
- Thrombocytopenia, including heparin-induced thrombocytopenia (HIT)
- Thromboembolism, including arterial, venous, peripheral, pulmonary, or central thromboembolism
- Transvalvular or valvular leaking
- Valve nonstructural dysfunction, including paravalvular leak, leaflet impingement, leaflet damage (caused by instruments or sutures), pannus, prosthesis mismatch (due to inappropriate sizing, distortion at implant)
- Valve structural dysfunction/deterioration (stenosis or regurgitation)
- Valvular thrombosis

For the specific adverse events that occurred in the clinical study, see **Section 8.5**.

7. INDIVIDUALIZATION OF TREATMENT

The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all the circumstances presented by that patient.

7.1. ANTI-PLATELET THERAPY

AUTUS valve recipients must be maintained on aspirin therapy indefinitely after valve implantation. The adequacy of platelet inhibition should be assessed post-implantation; if a patient is found to be non-responsive to aspirin, they should be commenced on alternative antiplatelet therapy (i.e., clopidogrel).

7.2. VALVE DIAMETER EXPANSION PRE-IMPLANT

To optimize the valve diameter to match the patient's body surface area at implant, the 12.7 mm ID AUTUS valve may be expanded pre-implant using a non-compliant percutaneous balloon dilation catheter.

Refer to procedural details in **Sections 11.3 and 11.4.**

7.3. VALVE DIAMETER EXPANSION POST-IMPLANT

To address prosthesis-patient mismatch due to expected patient somatic growth and / or improved ventricular function, the AUTUS valve may be expanded post-implant via percutaneous transcatheter balloon dilation using a non-compliant percutaneous balloon dilation catheter.

Refer to procedural details in **Section 11.6.**

8. CLINICAL STUDIES

8.1. STUDY DESIGN

The clinical safety and effectiveness of the AUTUS valve, model AUT001 was established based on the outcome data of an investigational study of the device. The study was a prospective, single-arm, multi-center study and included two phases: the Early Feasibility (EFS) and the pivotal study. The EFS enrolled 11 subjects December 6, 2021, and December 13, 2023, at 3 U.S. sites, and the pivotal study enrolled 51 subjects between February 5, 2024, and February 17, 2026, at 12 U.S. sites, for a total of N=62 subjects. Due to the limited size of the patient population, and because the same device and largely similar clinical protocols were used in the two phases clinical data from the EFS and the pivotal study phases were pooled.

The study utilized an independent Data Monitoring Committee (DMC), Clinical Events Committee (CEC), Eligibility Screening Committee (ESC), Echocardiography Core Laboratory (ECL), and an Independent Medical Assessment of Valve/Stent frame integrity.

Clinical Inclusion and Exclusion Criteria

Patients treated in the study were pediatric patients (18 months to 16 years) with clinically significant pulmonary valve disease requiring surgical pulmonary valve replacement and anatomy suitable for implantation of the study valve. Key exclusions included conditions associated with elevated procedural risk, significant comorbidities, active infection, contraindications to required medications, or other factors that could affect study participation or outcomes. Complete inclusion and exclusion criteria are available at <https://clinicaltrials.gov/study/NCT05006404>.

8.2. ACCOUNTABILITY OF PMA COHORT

At the time of database lock, 62 subjects were enrolled and implanted with the AUTUS valve. Of the 62 enrolled subjects, 100% (62) subjects have completed 1-month follow-up, 96.8% (60) subjects have completed 6-month follow-up, and 82.3% (51) subjects have completed 1-year follow-up.

8.3. STUDY POPULATION

The demographics and baseline characteristics of the study population are representative of pediatric patients with congenital pulmonary valve disease who require pulmonary valve replacement, as summarized in **Table 2**. Median (range) age and weight of subjects was 8.5 years (1.9 – 16.2 years) and 24.0 kg (10.2 – 71.7 kg), respectively.

Table 2: Demographic and Baseline Characteristics

Demographic or Characteristic	AUTUS Valve Subjects N=62
Age, years	
Mean (SD)	8.5 (3.7)
Median (Min, Max)	8.5 (1.9, 16.2)
Sex at birth, n (%)	
Male	42 (67.7%)
Female	20 (32.3%)
Ethnicity, n (%)	
Hispanic or Latino	15 (24.2%)
Not Hispanic or Latino	44 (71.0%)
Unknown or declined to answer	3 (4.8%)
Race, n (%)	
Caucasian	36 (58.1%)
Black or African-American	5 (8.1%)
Asian	4 (6.5%)
American Indian or Alaska Native	0
Native Hawaiian or Other Pacific Islander	0
Multiracial	8 (12.9%)
Other	6 (9.7%)
Unknown or declined to answer	3 (4.8%)
Height, cm	
Mean (SD)	123.9 (23.5)
Median (Min, Max)	127.1 (81.0, 174.5)
Weight, kg	
Mean (SD)	27.4 (13.5)
Median (Min, Max)	24.0 (10.2, 71.7)
BSA, m²	
Mean (SD)	0.96 (0.32)
Median (Min, Max)	0.91 (0.48, 1.73)

BSA = Body surface area, SD = Standard deviation.

The relevant medical and surgical history is presented in **Table 3**. The majority of subjects (48, 77.4%) presented with $\geq$ moderate pulmonary regurgitation alone. There were also 12 (19.4%) subjects with a combination of $\geq$ moderate pulmonary stenosis and $\geq$ moderate pulmonary regurgitation and 2 (3.2%) subjects with severe pulmonary stenosis alone.

Table 3: Medical and Surgical History

Medical History	AUTUS Valve Subjects N=62
Primary anatomic diagnosis, n (%)	
ToF / pulmonary stenosis	40 (64.5%)
ToF / pulmonary atresia	7 (11.3%)
ToF / absent pulmonary valve	1 (1.6%)
ToF / discontinuous pulmonary arteries	1 (1.6%)
Double outlet right ventricle	5 (8.1%)
Congenital pulmonary stenosis	6 (9.7%)
Pulmonary atresia / intact ventricular septum	1 (1.6%)
Transposition of the great arteries	1 (1.6%)
Other cardiac history, n (%)	7 (11.3%)
Anomalous coronary artery origin	2 (3.2%)
Bicuspid aortic valve	1 (1.6%)

Medical History	AUTUS Valve Subjects N=62
Systolic heart failure	1 (1.6%)
Tricuspid valve dysplasia	4 (6.5%)
Type of pulmonary valve dysfunction, n (%)	
Severe pulmonary stenosis*	2 (3.2%)
Moderate or greater pulmonary regurgitation	48 (77.4%)
Moderate or greater PS** and moderate or greater PR	12 (19.4%)
RVOT Type (at AUTUS valve Implant), n (%)	
Transannular patch repair	48 (77.4%)
Valve-sparing repair	8 (12.9%)
Native	4 (6.5%)
Prosthetic valve	1 (1.6%)
Other	1 (1.6%)
Prior valve repair (non-pulmonary valve), n (%)	1 (1.6%)
Aortic valve	0
Mitral valve	0
Tricuspid valve	1 (1.6%)
Prior cardiac surgeries, n (%)	
Yes	58 (93.5%)
No	4 (6.5%)
Number of prior cardiac surgeries, n (%)	
0	4 (6.5%)
1	39 (62.9%)
2	17 (27.4%)
3	2 (3.2%)
History of cardiac surgical procedures, n (%)	58 (93.5%)
Systemic to pulmonary artery shunt	10 (16.1%)
Tetralogy of Fallot repair	48 (77.4%)
Transannular patch	42 (67.7%)
Valve-sparing	7 (11.3%)
Transannular patch repair	6 (9.7%)
Valve-sparing repair	2 (3.2%)
Pulmonary valve replacement	1 (1.6%)
Atrial septal defect closure	7 (11.3%)
Patent ductus arteriosus closure	12 (19.4%)
Patent foramen ovale closure	6 (9.7%)
Main pulmonary arterioplasty	4 (6.5%)
Bilateral branch pulmonary arterioplasty	3 (4.8%)
Left pulmonary arterioplasty	7 (11.3%)
Right pulmonary arterioplasty	1 (1.6%)
Ventricular septal defect closure	5 (8.1%)
Other ²	5 (8.1%)
Prior cardiac catheterization, n (%)	33 (53.2%)
Diagnostic	15 (24.2%)
Interventional	23 (37.1%)
Balloon pulmonary valvuloplasty	6 (9.7%)
Left pulmonary artery angioplasty	5 (8.1%)
Left pulmonary artery stent insertion	11 (17.7%)
Left pulmonary artery stent dilation	6 (9.7%)
Other ³	3 (4.8%)
Unknown	1 (1.6%)
Prior non-cardiac surgical interventions, n (%)	23 (37.1%)

Medical History	AUTUS Valve Subjects N=62
Airway	3 (4.8%)
Tracheostomy	3 (4.8%)
Ear, nose, and throat	11 (17.7%)
Gastrointestinal	10 (16.1%)
Gastrostomy tube placement	4 (6.5%)
Genitourinary	6 (9.7%)
Musculoskeletal	5 (8.1%)
Neurological	2 (3.2%)
Other ⁴	3 (4.8%)

ASD = Atrial septal defect, ToF = Tetralogy of Fallot, PFO = Patent foramen ovale, PR = Pulmonary regurgitation, PS = Pulmonary stenosis, RVOT = Right ventricular outflow tract

*Peak transvalvular pressure gradient >60 mmHg.

**Peak transvalvular pressure gradient >40 mmHg to ≤60 mmHg.

¹RVOT type = arterial switch operation, LeCompte maneuver.

²Four subjects underwent 6 other prior cardiac surgical procedures, including left atrial appendage resection, RVOT plication, PFO enlargement, and partial ASD closure, anterior aortopexy, and anterior tracheopexy.

³Three subjects underwent other prior cardiac catheterization procedures, including closure of systemic to pulmonary artery shunt, stenting of distal transverse aortic arch, and ASD closure.

⁴Three subjects underwent other prior non-cardiac surgical interventions, including right diaphragm plication, tracheoesophageal fistula repair, and imperforate anus repair.

8.4. VALVE IMPLANT PROCEDURE

Table 4 below presents procedural data. Sizing of the valve prior to implantation was determined based on the body surface area of the patient, targeting a pulmonary valve annulus z-score of -1 to +1 (Ref. 5). All enrolled study subjects underwent pre-implant size-adjustment (via balloon expansion) of the AUTUS valve to match the valve diameter to the subject's body surface area. The smallest implanted diameter was 14 mm ID (N = 7, 11.3%) and the largest implanted diameter was 20 mm ID (N = 10, 16.1%). There were 32 (51.6%) subjects who had a new right ventricular outflow tract/transannular patch placed, while 26 (41.9%) subjects underwent primary closure of the main pulmonary artery after implanting the AUTUS valve.

Table 4: Valve Implant Procedure Details

Procedural Details	AUTUS Valve Subjects N=62
Pre-implant valve expansion, n (%)	
Yes	62 (100.0%)
No	0
Pre-implant valve expansion balloon catheter nominal diameter, n (%)	
14 mm	7 (11.3%)
16 mm	17 (27.4%)
18 mm	28 (45.2%)
20 mm	10 (16.1%)
22 mm	0
Implanted AUTUS Valve diameter, n (%)	
12.7 mm	0
14 mm	7 (11.3%)
16 mm	17 (27.4%)
18 mm	28 (45.2%)
20 mm	10 (16.1%)
22 mm	0

Procedural Details	AUTUS Valve Subjects N=62
New right ventricular outflow tract/transannular patch, n (%)	
Yes	32 (51.6%)
No	30 (48.4%)
New main pulmonary artery patch, n (%)	
Yes	33 (53.2%)
No	29 (46.8%)
Primary main pulmonary artery closure, n (%)	
Yes	26 (41.9%)
No	36 (58.1%)

As shown in **Table 5**, 100% (N = 62) of enrolled study subjects achieved acute procedural success, assessed intraoperatively.

Table 5: Valve Implant Procedure - Assessment of Acute Procedural Success

Assessment of Acute Procedural Success	AUTUS Valve Subjects N=62
Acute Procedural Success*, n (%)	62 (100.0%)
RV to PA systolic pressure gradient <40 mmHg	62 (100.0%)
None or trivial pulmonary regurgitation	62 (100.0%)
No paravalvular leak	62 (100.0%)

PA = Pulmonary artery, RV = Right ventricular, TEE = Transesophageal echocardiogram.

*Defined as RV to PA peak systolic pressure gradient <40 mmHg (assessed via direct pressure measurement), none or trivial pulmonary regurgitation (assessed via TEE), and no paravalvular leak (assessed via TEE).

8.5. SAFETY RESULTS

The analysis of safety was based on the available follow-up for all 62 enrolled subjects.

Primary Safety Endpoint

All 62 (100%) subjects met the primary safety endpoint. All subjects were free from a device-related complication through 30 days post-valve implantation, with zero cases of death, valve thrombosis requiring reintervention, or symptomatic thromboembolism, as summarized in **Table 6**.

Table 6: Primary Safety Endpoint (30 Days) – CEC Adjudicated

Primary Safety Endpoint*	AUTUS Valve Subjects N=62 n (%)
Primary Safety Endpoint*	62 (100%)
Death	0 (0%)
Valve thrombosis requiring intervention	0 (0%)
Symptomatic thromboembolism	0 (0%)

CEC = Clinical Events Committee

*Defined as freedom from device-related complication through 30 days, including death, valve thrombosis requiring intervention, and symptomatic thromboembolism, as adjudicated by the CEC.

Freedom from device-related complication through latest follow-up (CEC Adjudicated)

Through 1-year follow-up, all 62 (100%) subjects are free from a device-related complication, defined as death, valve thrombosis requiring reintervention, or symptomatic thromboembolism as adjudicated by the CEC.

All-Cause, cardiac, procedure-related and device-related mortality, surgical and transcatheter cardiac interventions, valve-related Adverse Events (CEC adjudicated)

Through 1-year follow-up, there were no cases of all-cause, cardiac, procedure-related, or device-related mortality. There were no CEC-adjudicated device-related adverse events, including no cases of valve thrombosis, thromboembolism, major hemorrhage, endocarditis, or hemolysis.

Two subjects underwent cardiac interventions (surgical or transcatheter) that were not related to the AUTUS valve or procedure, as adjudicated by the CEC. One subject underwent cardiac catheterization for placement of an atrial septal defect occlusion device. One subject underwent surgical reintervention to treat aortic valve endocarditis, with all intracardiac prosthetic materials explanted, including the study device. These results are summarized in **Table 7**.

Table 7: All-Cause, Cardiac, Procedure-related, Device-related Mortality, Surgical and Transcatheter Cardiac Interventions, Valve-related Adverse Events - CEC Adjudicated

Safety Event	AUTUS Valve Subjects			
	Discharge	30 Days	6 Months	1 Year
	N=62	N=62	N=60	N=51
	n (%)	n (%)	n (%)	n (%)
Mortality (all cause)	0	0	0	0
Cardiac-related	0	0	0	0
Procedure-related	0	0	0	0
Device-related	0	0	0	0
Valve thrombosis	0	0	0	0
Thromboembolism	0	0	0	0
Other cardiac or valve intervention (surgical or transcatheter)*	0	0	0	2 (3.8%)
Major hemorrhage	0	0	0	0
Endocarditis	0	0	0	0
Hemolysis	0	0	0	0
Device explantation*	0	0	0	1 (1.9%)

CEC = Clinical Events Committee.

*Non-AUTUS valve-related.

Frame Fracture Assessment

There were no cases of major frame fractures observed through 1-year follow-up, with major frame fracture defined as a frame fracture resulting in device embolization, hemodynamic compromise, or intervention. There were 3/62 (4.8%) subjects with minor frame fractures, as summarized in **Table 8** below. For all 3 subjects, the fractures were first observed at the 1-year follow-up visit. There were no clinical sequelae associated with the minor frame fractures and valve function was preserved through latest follow-up for all 3 subjects.

Table 8: Frame Fracture Assessment

Valve Frame Fracture	AUTUS Valve Subjects	
	Discharge	1 Year
	N=62	N=51
	n (%)	n (%)
All Frame Fracture (Major* and Minor), n (%)	0	3 (5.9%)
Major Frame Fracture*, n (%)	0	0
Hemodynamic compromise	0	0
Embolization	0	0

	AUTUS Valve Subjects	
	Discharge	1 Year
	N=62	N=51
Valve Frame Fracture	n (%)	n (%)
Intervention required	0	0
Minor Frame Fracture, n (%)	0	3 (5.9%)
X-ray Not Performed, n (%)	0	0

*Major frame fracture defined as fracture resulting in embolization, hemodynamic compromise (defined as the new onset of moderate or greater pulmonary regurgitation or mean trans-pulmonary valve gradient >40 mmHg as assessed by the Echocardiography Core Laboratory), or intervention.

Leaflet Mobility

There were 2 subjects with reduced mobility of one valve leaflet. Diagnosis was made by routine follow-up transthoracic echocardiogram (TTE) at 6 months for one subject and at 1 year for one subject. Available hemodynamic assessments demonstrated preserved valve function in both subjects with reduced leaflet mobility as shown below in **Table 9**. The subjects demonstrated no consistent trends in transvalvular mean gradient. Mild pulmonary regurgitation was present at 1 year in both subjects. Neither subject had any clinical symptoms, sequelae, or adverse events (including no evidence of leaflet thrombosis or pulmonary thromboembolism) related to the reduced mobility findings.

Table 9: Valve Hemodynamic Performance Through 1 Year

Subject	Valve Hemodynamics	Baseline	Discharge	30 Days	6 Months	1 Year
1*	Transvalvular Mean Gradient, (mmHg)	6	10	12	24	17
	Pulmonary Regurgitation Grade	Severe	None	None	None	Mild
2**	Transvalvular Mean Gradient, (mmHg)	5	5	3	9	14
	Pulmonary Regurgitation Grade	Severe	None	None	Mild	Mild

*Reduced leaflet mobility first observed on 6-month TTE and persisted on 1-year TTE

**Reduced leaflet mobility first observed on 1-year TTE

Adverse Effects That Occurred in the PMA Clinical Study

Table 10 documents the adverse effects related or probably related to the device or procedure that occurred in the clinical study, as well as other adverse events of clinical interest. Unless otherwise noted, the device or procedure relatedness was adjudicated by the CEC.

There was one site-reported device-related adverse event, which was increasing pulmonary stenosis (mild) and mild pulmonary regurgitation at the 1-year follow-up visit. The subject with this event also reported non-compliance with the required anticoagulation regimen prior to the 1-year follow-up visit. The event is considered ongoing, with CEC adjudication pending. There have been no adverse events that were CEC-adjudicated as related to the device. No unanticipated device-related adverse events were identified.

Table 10: Procedure- or Device-Related Adverse Effects in the Study

Event*	Event Rate (n, %) N=62
Device-related increased pulmonary stenosis (mild) and mild pulmonary regurgitation*	1 (1.6%)

Event*	Event Rate (n, %) N=62
Frame fracture (non-major)**	3 (4.8%)
Impaired leaflet mobility***	2 (3.2%)
Pleural effusion	6 (9.7%)
Pneumothorax	6 (9.7%)
Atelectasis with pleural effusion	1 (1.6%)
Arrhythmia	6 (9.7%)
Pericardial effusion	1 (1.6%)
Left pulmonary artery injury	1 (1.6%)
Right lung hematoma	1 (1.6%)
Right ventricular dysfunction	2 (3.2%)
Tricuspid valve regurgitation*	1 (1.6%)
Pneumomediastinum	1 (1.6%)
Acute post-operative fever	3 (4.8%)
Post-operative hypertension	1 (1.6%)
Post-operative hypotension	1 (1.6%)
Hypoxemia	1 (1.6%)
Mild erythema of sternotomy incision	1 (1.6%)
Acute post-operative thrombocytopenia	1 (1.6%)
Acute post-operative hyperglycemia	1 (1.6%)
Bleeding post chest tube removal	1 (1.6%)
Sternal wound drainage	2 (3.2%)
Chest/chest wall pain	1 (1.6%)
Nausea and/or vomiting	9 (14.5%)
Constipation	1 (1.6%)
Diarrhea with fever	1 (1.6%)
Omental hernia	1 (1.6%)
Left vocal cord paralysis	1 (1.6%)
Contact dermatitis	1 (1.6%)
Epistaxis	2 (3.2%)
Anaphylactoid reaction	1 (1.6%)
Rib pain	1 (1.6%)
Increased creatinine	1 (1.6%)

*Site-reported as related or probably related to the device or procedure. CEC adjudication is pending.

**Frame fractures were assessed by the Independent Medical Reviewers.

***Impaired leaflet mobility events were evaluated by the ECL.

8.6. EFFECTIVENESS RESULTS

The analysis of effectiveness was based on the available follow-up for all 62 enrolled subjects

Primary Effectiveness Endpoint

Of the 60 subjects who completed 6-month follow-up post-valve implantation, all 60 (100%) met the primary effectiveness endpoint as summarized in **Table 11**.

Table 11: Primary Effectiveness Endpoint (6 Months)
Echocardiographic Core Lab Assessed/CEC Adjudicated

	AUTUS Valve Subjects
	N=60
Primary Effectiveness Endpoint*	n (%)
Primary Effectiveness Endpoint*	60 (100.0%)
RVOT mean gradient ≤ 40 mmHg	60 (100.0%)
Less than moderate pulmonary regurgitation	60 (100.0%)
No AUTUS valve reinterventions, excluding valve expansion to address prosthesis-patient mismatch	60 (100.0%)

CEC = Clinical Events Committee

*Defined as acceptable hemodynamic function at 6 months, including mean RVOT gradient ≤ 40 mmHg and pulmonary regurgitation grade < moderate as assessed by the Echocardiographic Core Laboratory and no AUTUS valve reintervention except for valve expansion to address prosthesis-patient mismatch as assessed by the CEC.

Effectiveness Outcome at 1 Year

Of the 51 subjects who completed 1-year follow-up, all 51 (100%) had an RVOT mean gradient ≤ 40 mmHg and less than moderate pulmonary regurgitation, as shown in **Table 12**. There were no AUTUS valve reinterventions at 1-year follow-up, excluding valve expansions due to somatic growth.

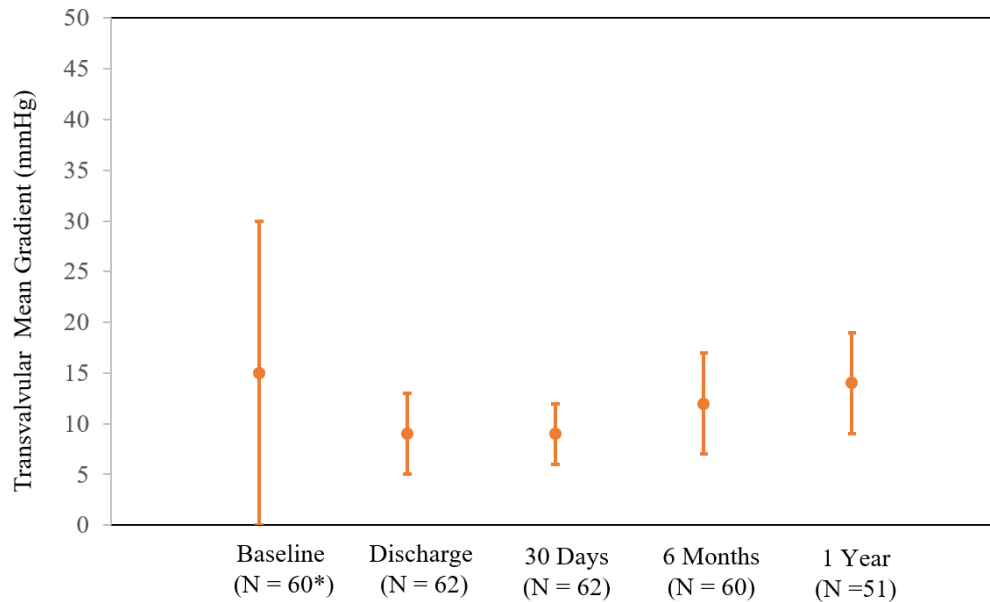
Table 12: Effectiveness Outcomes (1 Year)
Echocardiographic Core Lab Assessed/CEC Adjudicated Valve Implant Population

	AUTUS Valve Subjects
	N=51
Effectiveness Outcome*	n (%)
Effectiveness Outcome*	51 (100.0%)
RVOT mean gradient ≤ 40 mmHg	51 (100.0%)
Less than moderate pulmonary regurgitation	51 (100.0%)
No AUTUS valve reinterventions, excluding valve expansion to address prosthesis-patient mismatch	51 (100.0%)

CEC = Clinical Events Committee

*Defined as acceptable hemodynamic function at 1 year, including mean RVOT gradient ≤ 40 mmHg and pulmonary regurgitation grade < moderate as assessed by the Echocardiographic Core Laboratory and no AUTUS valve reintervention except for valve expansion to address prosthesis-patient mismatch as assessed by the CEC.

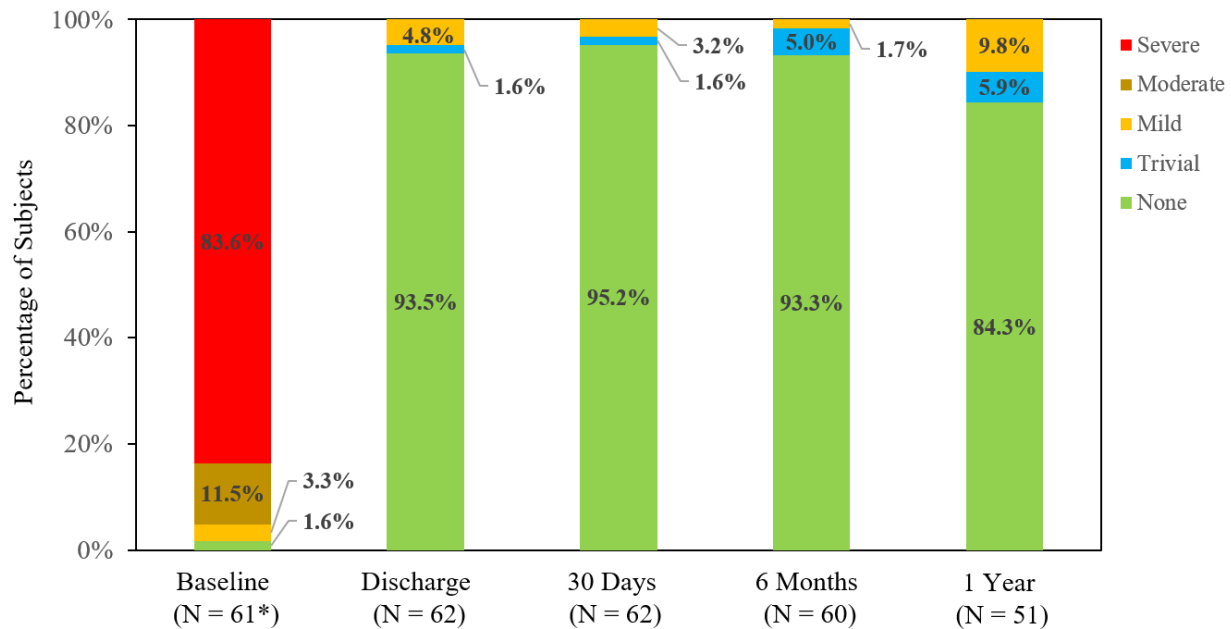
Figure 2 below presents the transvalvular mean pressure gradient (Continuous Wave Doppler) at each visit through 1-year follow-up. At discharge, the mean transvalvular pressure gradient was 9 ± 4 mmHg and remained low through 1-year post-valve implantation (14 ± 5 mmHg).



* Continuous Wave Doppler transvalvular pressure gradient could not be measured by the Echocardiography Core Laboratory on baseline transthoracic echocardiograms (TTE) in 2 Subjects.

Figure 2: Transvalvular Mean Pressure Gradient (mmHg) by Visit

Figure 3 below presents the pulmonary regurgitation grade assessed by transthoracic echocardiogram. At baseline, 83.6% of subjects had severe pulmonary regurgitation, and 11.5% had moderate pulmonary regurgitation. At 1-year post-valve implantation, 84.3% of subjects had no pulmonary regurgitation, 5.9% had trivial regurgitation and 9.8% had mild regurgitation. No subject had greater than mild pulmonary regurgitation.

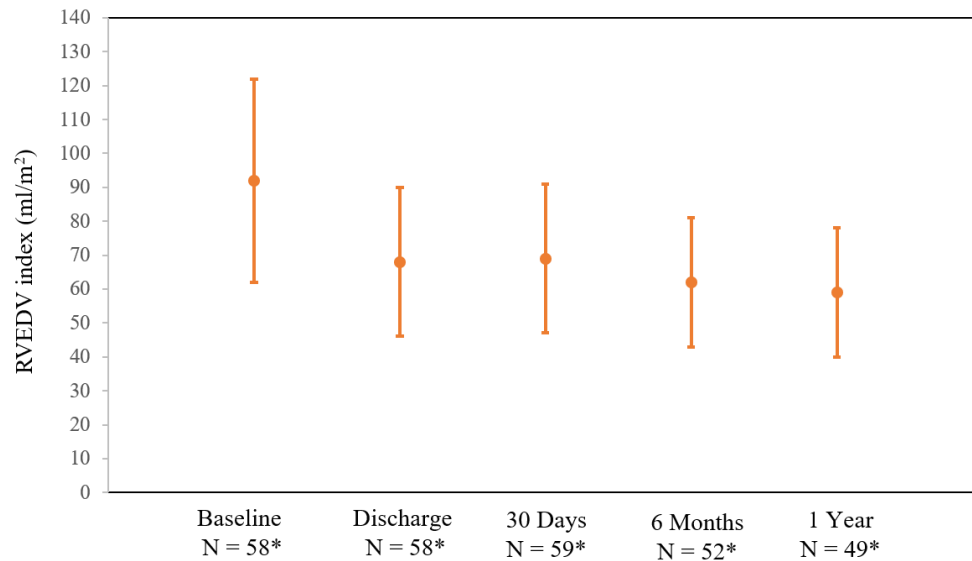


* Pulmonary regurgitation grade (assessed by measurement of vena contracta jet width) was not evaluable by the Echocardiography Core Laboratory in 1 subject.

Figure 3: Pulmonary Regurgitation Grade By Visit

Right Ventricular End Diastolic Volume (RVEDV) Indexed to Body Surface Area

Figure 4 below presents the right ventricular end diastolic volume (RVEDV) indexed to body surface area through 1-year follow-up. At baseline, the mean RVEDV index was 91.9 ± 30.2 ml/m² for the study population. At 6-month follow-up, the mean RVEDV index had decreased to 62.0 ± 19.3 ml/m² and was 58.5 ± 18.5 ml/m² at 1 year.



* Sample sizes < 62 at baseline, discharge, and 30 days, < 60 at 6 months, and < 51 at 1 year, reflect transthoracic echocardiogram studies where RVEDV index could not be assessed.

Figure 4: Right Ventricular End Diastolic Volume (RVEDV) Index(ml/m²) By Visit

Modified Ross Class for Pediatric Heart Failure

Figure 5 presents the Modified Ross Heart Failure Class through 1-year follow-up. At 1 year, 94.1% (N = 48) of subjects were asymptomatic (Class I), compared to 58.1% (N = 36) at baseline. There were no subjects who were Class III or Class IV.

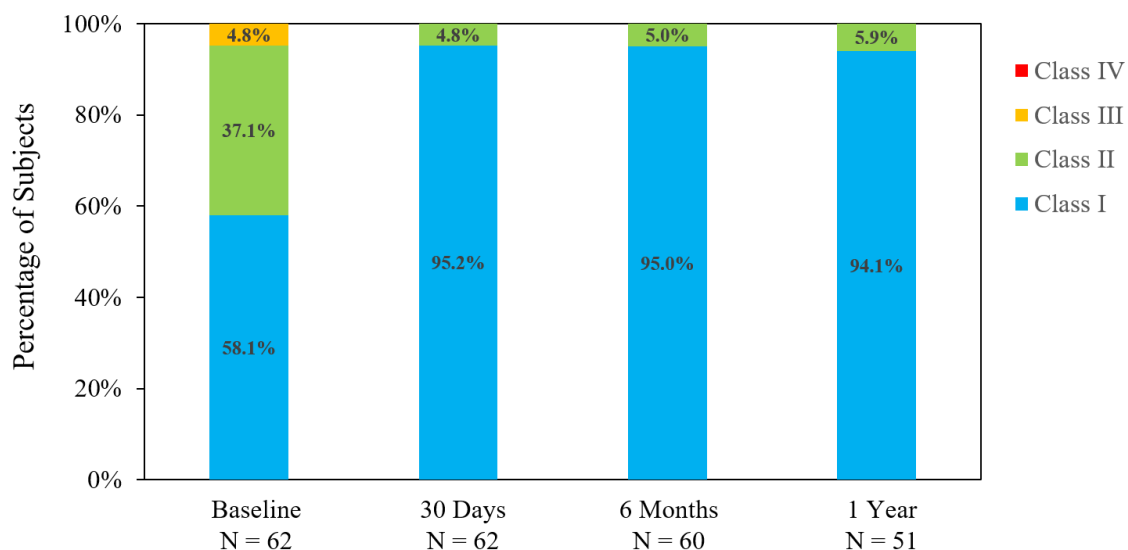


Figure 5: Modified Ross Pediatric Heart Failure Class

Post-Implant Valve Expansion Outcomes

To date, 2 subjects in the AUTUS valve clinical study underwent successful post-implant valve expansion without any device-related complications. Post-implant valve expansion was not mandated at predefined intervals. The study protocol included prespecified criteria to guide consideration of post-implant valve expansion, although the decision was ultimately left to the treating physician and based on clinical judgment. Post-implant expansion considerations included the following:

- Normal RV function: RV-to-PA peak gradient ≥ 40 mmHg (2-D echo Doppler)
- Pre-existing RV systolic dysfunction: RV-to-PA peak gradient ≥ 30 mmHg (2-D echo Doppler)
- New-onset RV systolic dysfunction: RV free wall strain $< -20\%$ (2-D echo) or ejection fraction $< 45\%$ (3-D echo), and RV-to-PA peak gradient ≥ 30 mmHg (2-D echo Doppler)
- New-onset symptoms: Modified Ross Class II or greater, and RV-to-PA peak gradient ≥ 30 mmHg (2-D echo Doppler)

One subject underwent post-implant valve expansion at 13 months post-implant following somatic growth (BSA increased from 1.20 to 1.48 m²) and an increase in mean gradient from 13 mmHg at discharge to 29 mmHg at 1 year, consistent with prosthesis-patient mismatch.

A second subject underwent post-implant valve expansion at 37 months post-implant following somatic growth (BSA increased from 1.01 m² to 1.41m²), new exertional shortness of breath, an increase in mean gradient from 23 to 44 mmHg, and elevated RV systolic pressure, consistent with prosthesis-patient mismatch. In both subjects, the valve was dilated from 18 to 20 mm, and both subjects met acute procedural success post-expansion. Outcomes are summarized below in **Table 13a** and **Table 13b**.

Table 13a: Post-Implant Valve Expansion - Subject 1

Variable	Baseline	Discharge	30 Days	1 Year	Post-Implant Valve Expansion Procedure*	Discharge Post- Valve Expansion*	30 Days Post- Valve Expansion
Height, cm	148.0	149.0	149.5	160.0		165.3	161.7
Weight, kg	37.2	35.1	34.7	44.8		46.0	49.3
BSA, m ²	1.23	1.20	1.19	1.40		1.42	1.48
PR Grade **	Moderate	None	None	None		Trivial	Trivial
Mean TPG, mmHg**	4	13	12	29		25	14
RV Systolic Function (qualitative)	normal	mildly diminished	normal	normal		normal	normal
RVEDV indexed to BSA**	121.8	105.0	67.5	44.9		73.3	77.1

BSA = Body surface area; RV = Right ventricular; PR: Pulmonary regurgitation; TPG: Transvalvular pressure gradient; RVEDV: Right ventricular end-diastolic volume

*Post-implant valve expansion procedure was performed at 13 months post-valve implantation.

**Echocardiography Core Laboratory assessed data

Table 13b: Post-Implant Valve Expansion - Subject 2

Variable	Baseline	Discharge	30 Days	1 Year	2 Years	3 Years	Post-Implant Valve Expansion Procedure*	Discharge Post- Valve Expansion*	30 Days Post- Valve Expansion
Height, cm	129.0	128.0	130.0	134.0	140.0	146.5		148.0	148.0
Weight, kg	29.4	28.9	29.3	35.7	41.8	46.0		46.8	47.9
BSA, m ²	1.01	1.01	1.03	1.16	1.28	1.38		1.39	1.41
PR Grade**	Severe	None	None	None	Trivial	Mild		Mild	Mild
Mean TPG, mmHg**	6	15	13	17	23	44		31	14
RV Systolic Function (qualitative)	borderline mildly diminished	mildly decreased	mildly decreased	mildly decreased	mildly decreased	mildly decreased		mildly decreased	mildly decreased
RVEDV indexed to BSA**	108.8	80.5	69.4	61.4	63.6	79.9		67.9	51.4

BSA = Body surface area; RV = Right ventricular; PR: Pulmonary regurgitation; TPG: Transvalvular pressure gradient; RVEDV: Right ventricular end-diastolic volume

*Post-implant valve expansion procedure was performed approximately 37 months post-valve implantation (1 month after the 3-year follow-up visit).

**Echocardiography Core Laboratory assessed data.

Sub-group Analyses

Subgroup analyses were performed on the primary safety and effectiveness endpoints. There was no gender, age, racial or ethnic differences observed for the primary safety or effectiveness endpoints. The study was not specifically powered for these subgroups.

9. PATIENT COUNSELING INFORMATION

Patients with prosthetic heart valves are at risk from bacteremia (e.g., undergoing dental procedures) and should be advised about prophylactic antibiotic therapy.

Patients should be encouraged to always carry their Patient Implant Card and to inform their healthcare providers that they have an implant when seeking care.

10. HOW SUPPLIED

10.1. PACKAGING

The AUTUS valve is provided sterile and nonpyrogenic. The device is packaged in a double sealed tray placed into an individual shelf carton. Upon receipt of the carton, inspect the exterior for signs of damage. Device and shelf carton are labeled with a single unique serial number for traceability.

WARNING: Carefully inspect the valve before implantation for any evidence of damage. Damage to the valve renders the device unfit for use.

10.2. STORAGE

The AUTUS valve should be stored dry, at room temperature, and away from direct sunlight, in the original unopened packaging.

10.3. ADDITIONAL EQUIPMENT

The pre-implantation and post-implantation valve expansion procedures require additional equipment that is not supplied with the AUTUS valve. Pre-implant valve expansion requires an appropriate diameter non-compliant balloon dilation catheter, with a minimum 4 cm working length balloon. Post-implant valve expansion requires an appropriate diameter non-compliant balloon dilation catheter, with a maximum 2 cm working length balloon. Both procedures require a hand insufflator to inflate the balloon to its specified nominal pressure.

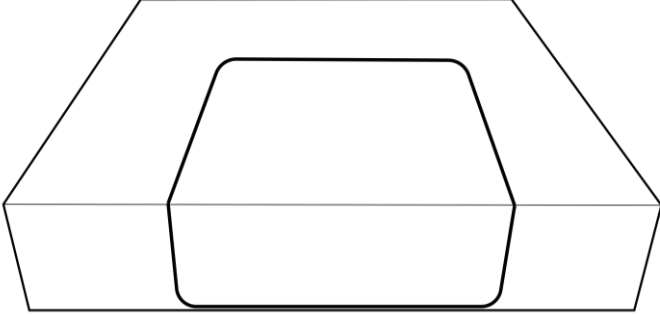
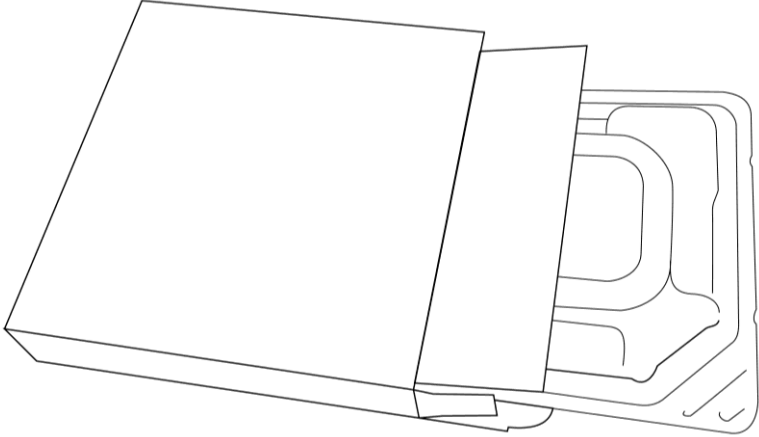
11. DIRECTIONS FOR USE

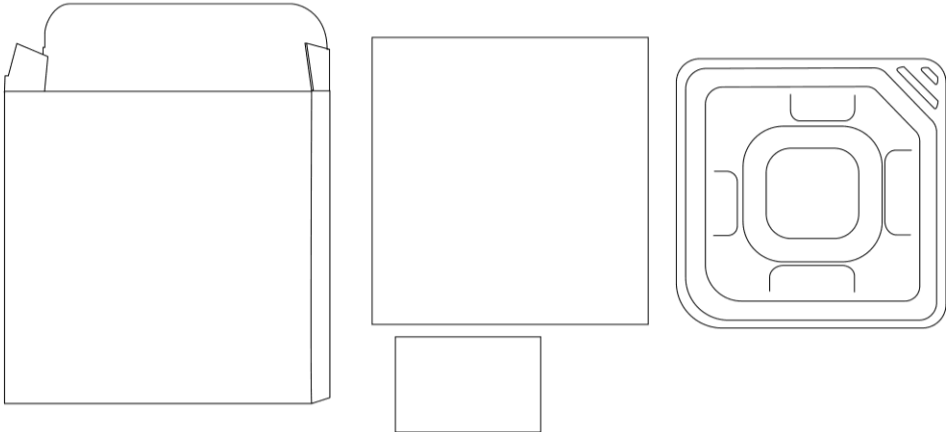
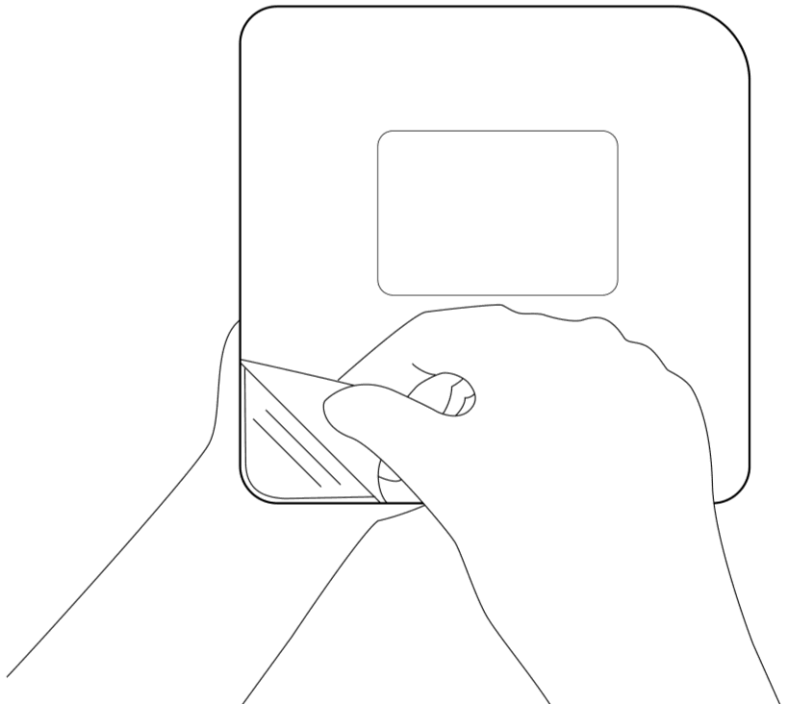
11.1. PHYSICIAN TRAINING

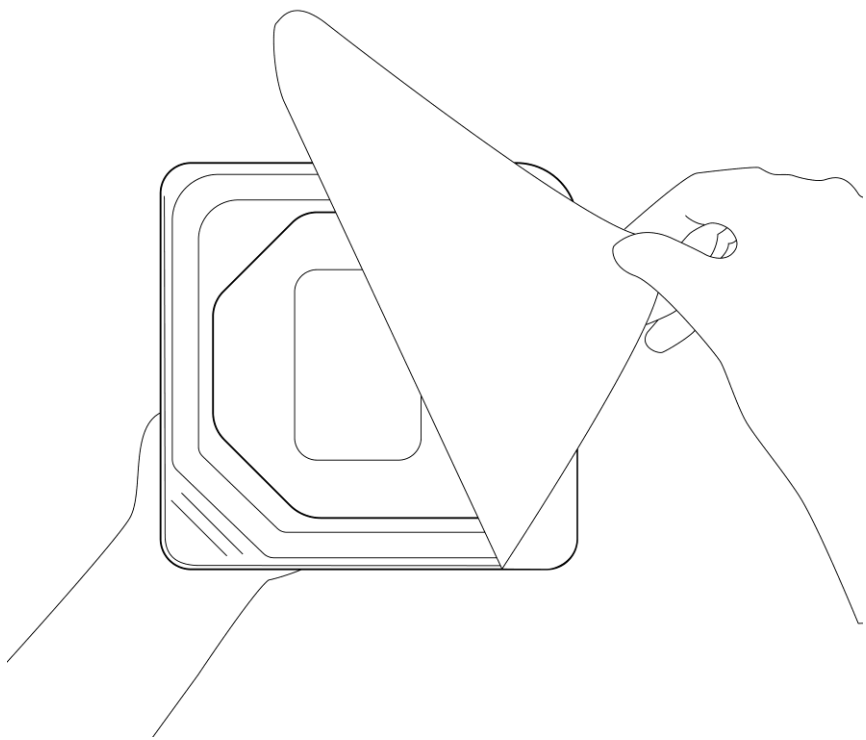
Physician training is required prior to use of the AUTUS valve.

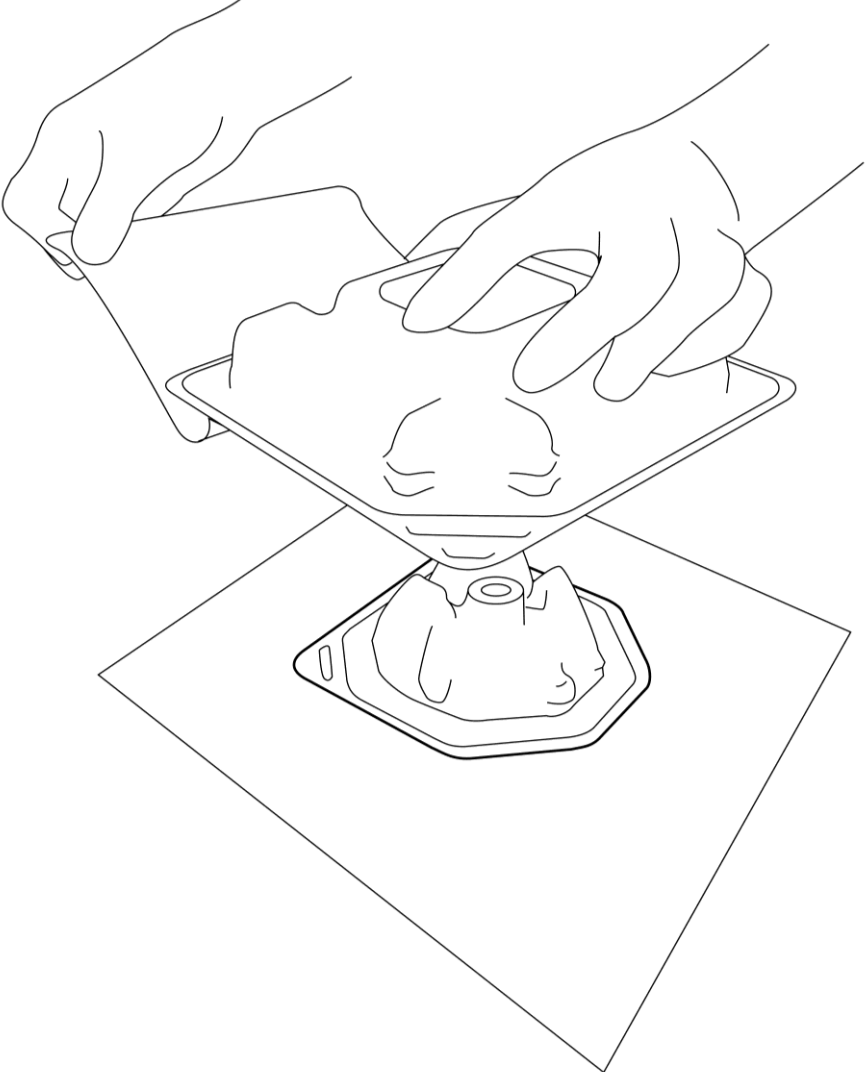
The primary intended users are cardiac surgeons who perform these valve replacements, interventional cardiologists who perform the post-implant valve expansion procedure, and the staff (operating room nurses and technicians) responsible for preparation and implant of surgical valves.

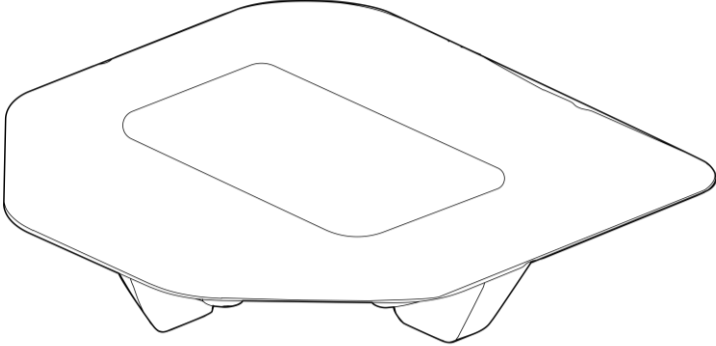
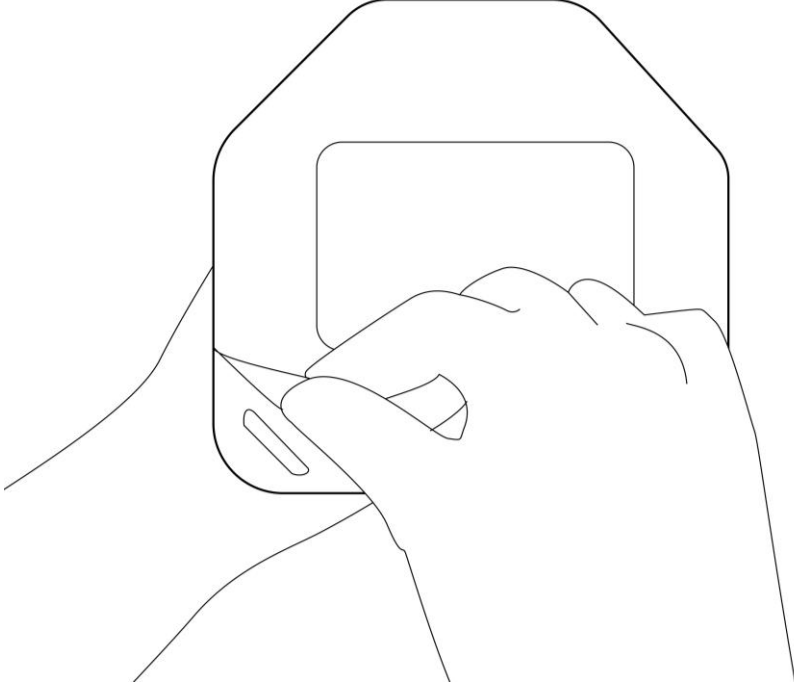
11.2. HANDLING AND PREPARATION INSTRUCTIONS

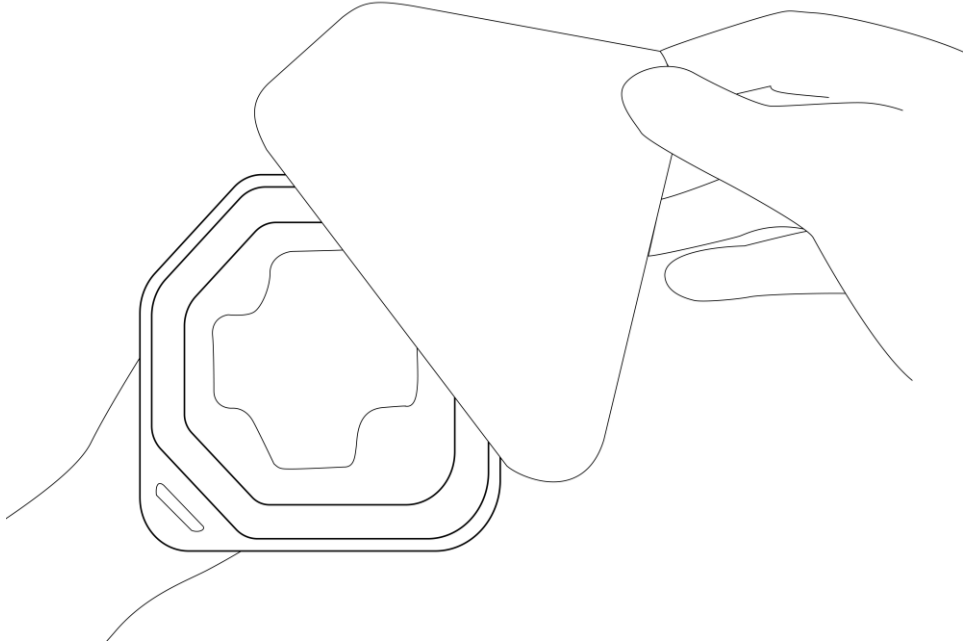
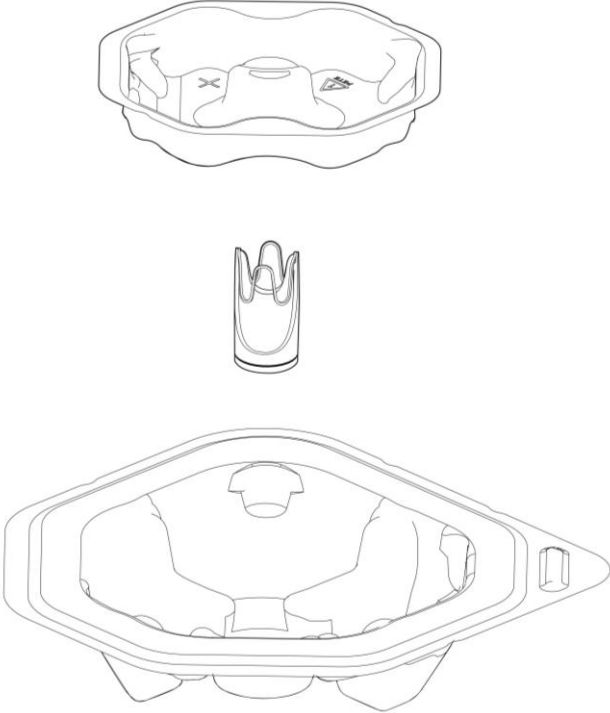
Step	Packaging
1	Examine the Shelf Carton Box: Verify the label content. Examine the package for evidence of damage and broken or missing seals (Figure 6). The packaged device and shelf carton are labeled with a single unique serial number for traceability. WARNING: Check expiration date on packaging before use. Do not use product if expiration date has elapsed.
	 Figure 6
2	Open Carton Box and Remove Contents: Once it is confirmed that valve implantation will proceed, open the carton and remove the contents onto the non-sterile field (Figure 7). Examine the Outer tray and lid for any evidence of damage and broken or missing seals.
	 Figure 7

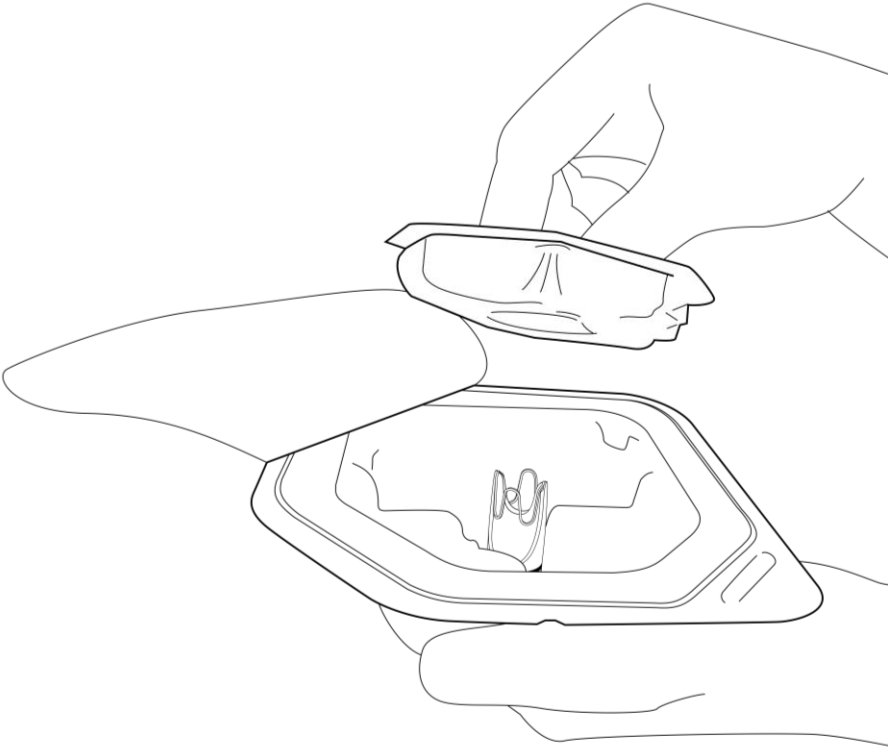
Step	Packaging
3	Content Description: IFU, Sealed Outer Tray, and Patient Implant Card, implant data card and peel off stickers. (Figure 8).
	 Figure 8
4a	Open the Outer Tray: Near the sterile field, hold the base of the outer tray and peel the lid from the outer tray (Figure 9).
	 Figure 9

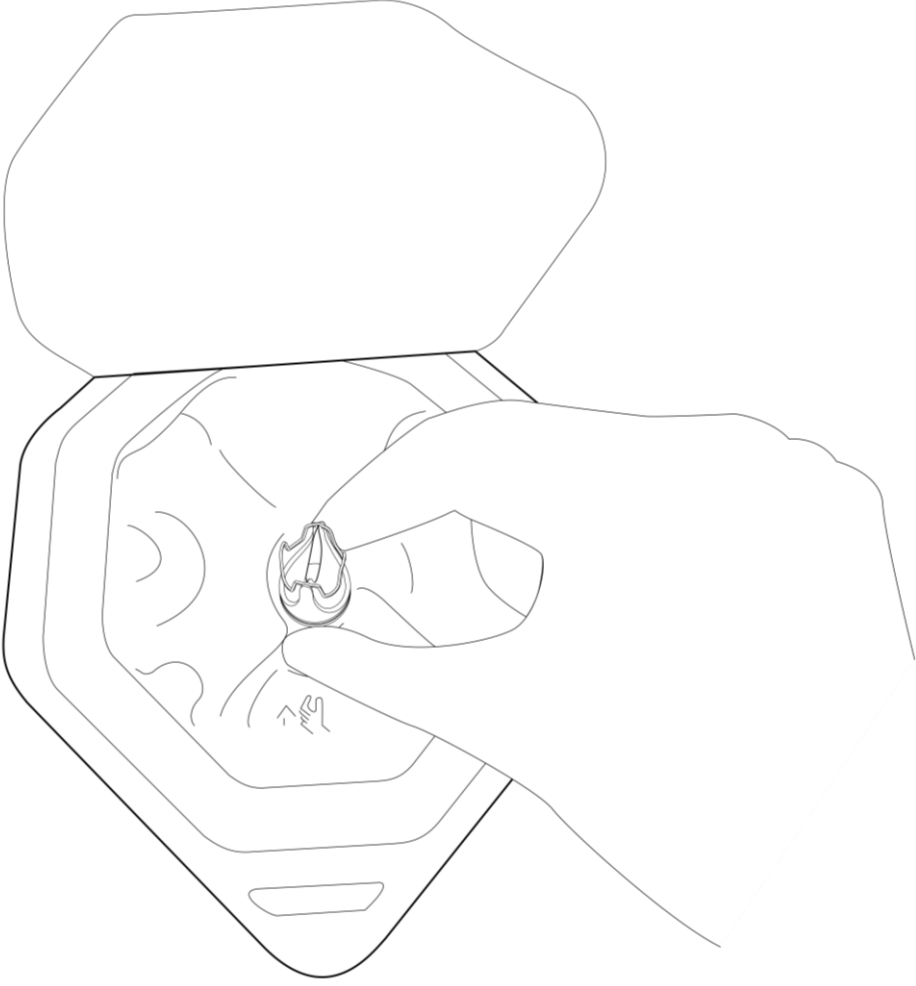
Step	Packaging
4b	Outer tray peeled back to show inner tray (Figure 10).
	 Figure 10

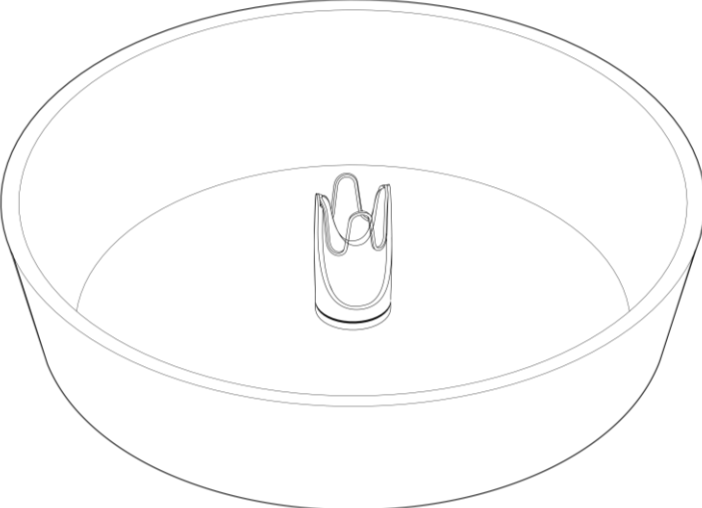
Step	Packaging
5	Aseptic Transfer: The inner tray and contents are sterile. Transfer the inner tray to the sterile field (Figure 11). The contents of the inner tray must be handled using a sterile surgical technique to prevent contamination.
	 Figure 11

Step	Packaging
6	Label Verification: Verify that the serial number on the Inner Tray label matches with the shelf carton and patient Implant Card (Figure 12). CAUTION: If any difference in serial number is noted, the valve should be returned unused.
	 Figure 12
7	Open the Inner Tray: Before opening, examine the inner tray and lid for evidence of damage, stains, and broken or missing seals. Hold the base of the inner tray and peel the lid from the inner tray (Figure 13). CAUTION: Do not open the inner package until implantation is certain and the surgeon is ready to place the valve.
	 Figure 13

Step	Packaging
8	Inner Tray Opened: (Figure 14) CAUTION: The valve is not secured to the inner tray. Care should be taken while peeling back the lid.
	 Figure 14
9	Inner Packaging Components: Plastic retainer, AUTUS valve, Inner Tray (Figure 15 and Figure 16).
	 Figure 15

Step	Packaging
10	Remove the plastic retainer from Inner Tray: CAUTION: The valve is not secured to the inner tray. Care should be taken while removing the retainer.
	 Figure 16

Step	Packaging
11	Remove AUTUS valve from Inner Tray: Pick up valve with thumb and forefinger, as indicated by the arrows. (Figure 17). CAUTION: Avoid contacting the frame or leaflet material.
	 Figure 17

Step	Packaging
12	Transfer valve to Open Sterile Container: Place valve upright in open sterile container (Figure 18). CAUTION: The valve does not require rinsing prior to implantation. CAUTION: Avoid contact of the valve with towels, linens, or other sources of particulate matter that may be transferred to the leaflet material.
	 Figure 18

11.3. VALVE SIZING PRE-IMPLANT

Sizing of the valve prior to implantation should be determined based on the body surface area of the patient, targeting a pulmonary valve annulus z-score of -1 to +1 (Ref. 2, 3, 4, 5). The chart below (**Figure 19**) is provided for reference to guide AUTUS valve sizing (Ref. 5).

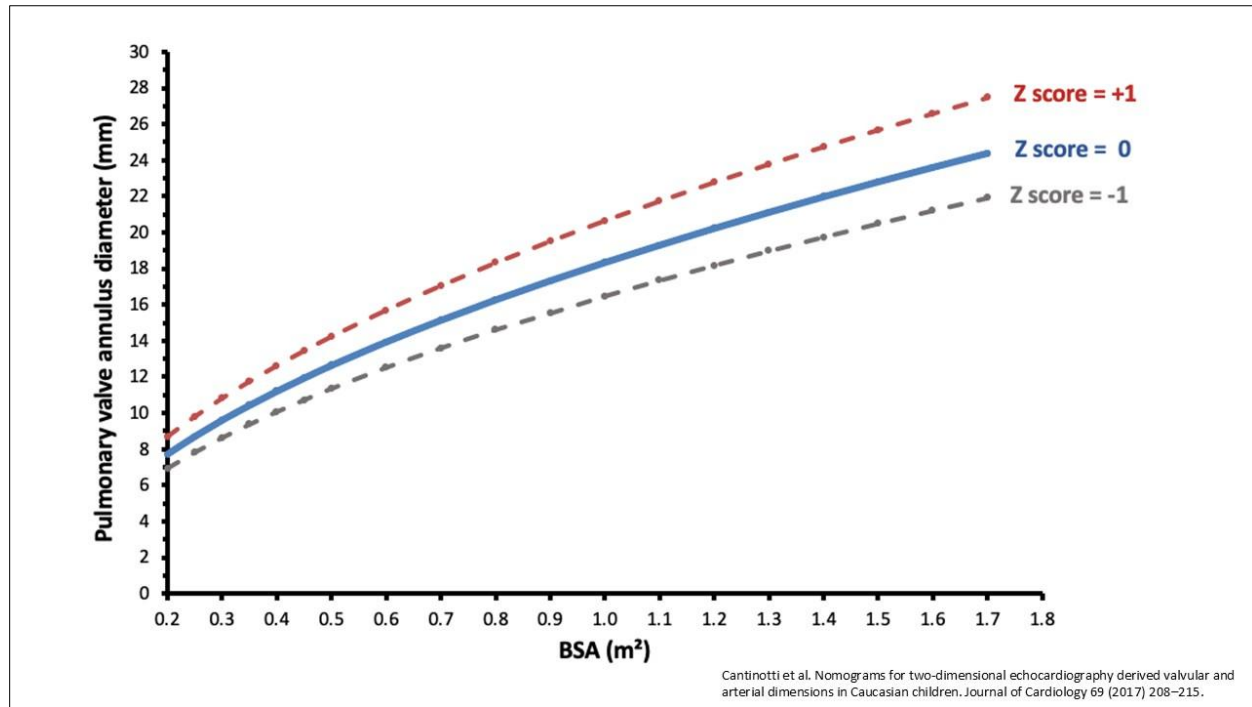


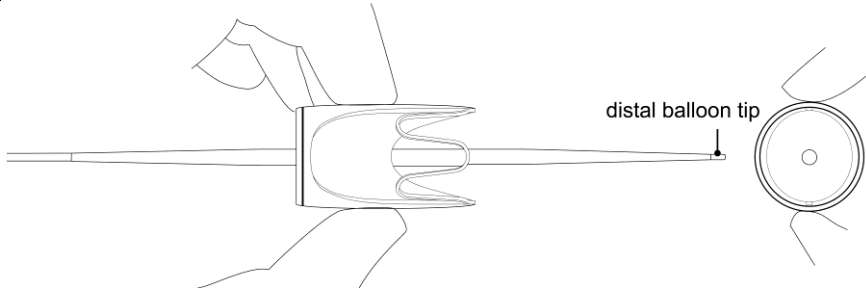
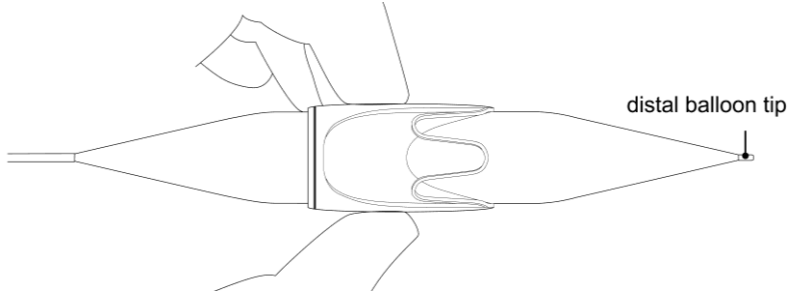
Figure 19: Guide for Sizing of AUTUS Valve

The decision-making surrounding valve sizing at implant, must ultimately be made by the physician on an individual basis after carefully weighing all the risks and benefits to the patient.

11.4. VALVE DIAMETER EXPANSION PRE-IMPLANT

The AUTUS valve (nominal internal diameter = 12.7 mm) may be balloon expanded prior to implant to customize the valve diameter to match the patient's body surface area.

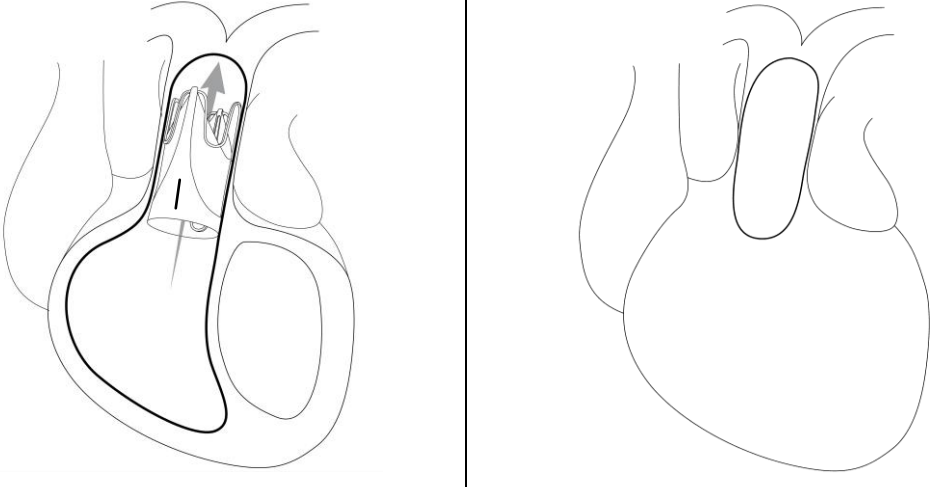
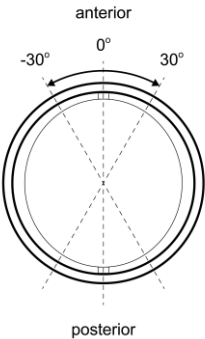
Step	Pre-Implant Valve Expansion
1	Set up a separate sterile field in the Operating Room. Select appropriate diameter non-compliant balloon dilation catheter, open onto sterile field. With the valve opening (annulus end) facing the distal tip of the balloon catheter, slide an uninflated minimum 4 cm length balloon through the valve opening (taking care to minimize contact with the leaflets) so that the device is positioned across the mid-portion of the uninflated balloon (full length of device must be positioned within working length of balloon) with the uninflated balloon in the center of the valve lumen (Figure 20).

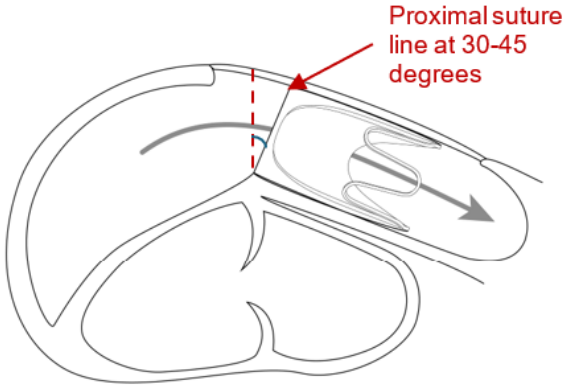
Step	Pre-Implant Valve Expansion
	 Figure 20
2	Using a hand insufflator, inflate the balloon to its specified nominal pressure, then deflate. Once the balloon is fully deflated, carefully slide the valve (holding the device gently at the outer sleeve, as shown, without compressing the frame) over the distal balloon tip, ensuring that the balloon tip does not make contact with the leaflets (Figure 21).  Figure 21 CAUTION: Avoid contacting leaflet material with balloon tip. Avoid contact with the leaflet material when manually handling device. WARNING: During pre-implant balloon expansion, DO NOT adjust position of valve with the balloon inflated. Movement of valve while the balloon is inflated could result in leaflet material abrasion or tearing. Avoid compression of valve frame. Compression of the frame could lead to valve dysfunction.

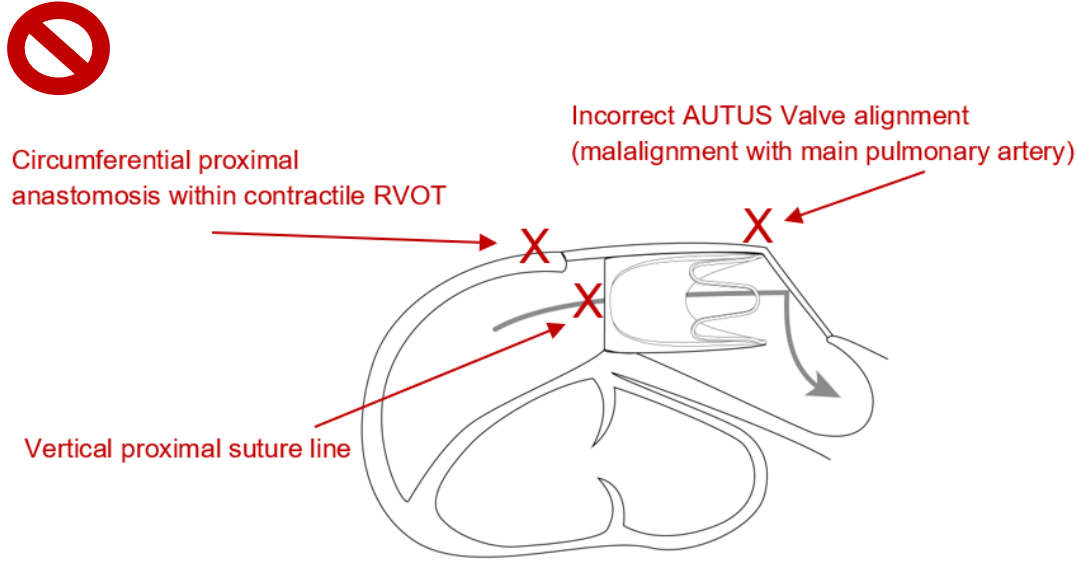
11.5. DEVICE IMPLANTATION

The AUTUS valve is compatible with implantation in the right ventricular outflow tract (pulmonary valve position).

Step	Implant Procedure
1	The surgeon should be familiar with the recommendations for proper sizing and placement in the pulmonary valve position (Section 11.3). The surgeon can implant the valve at the appropriate size and enlarge the right ventricular outflow tract with a patch. Because of the complexity and variation of cardiac valve replacement surgery, the choice of surgical technique, appropriately modified in accordance with the previously described WARNINGS and PRECAUTIONS, is left to the discretion of the individual surgeon. In general, the following steps are to be employed (See Steps 2, 3, 4, 5 outlined below):
2	Trim the ePTFE sleeve (sewing skirt) to the solid black line at base of sleeve, see Figure 18) prior to implantation; the sleeve should not be trimmed beyond the most inferior portion of the stent frame

Step	Implant Procedure
	(per solid line at base of sleeve, see Figure 18) as this could leave insufficient sleeve material for proper suturing. Inspect native pulmonary valve annulus region, excise any residual pulmonary valve leaflet tissue (native or prosthetic leaflet material). CAUTION: Failure to adequately resect residual leaflet tissue could result in excess pannus formation or impingement of the valve leaflet(s). When positioning the valve in the RVOT, the valve should be oriented anterior-posterior within the main pulmonary artery, with the suture line in proximity to the native pulmonary valve annulus (Figure 22).
	 Figure 22: Valve Positioning in RVOT
	Place the valve so that the valve orientation is anterior-posterior (no more than +/- 30 degrees) within the main pulmonary artery. (Figure 23).  Figure 23: Implanted Valve Orientation
3	Ensure the distance from the proximal suture line to the right pulmonary artery orifice is adequate to accommodate the full length of the valve. The distal end of the valve should not extend to the orifice of the right (or left) pulmonary artery. CAUTION: Failure to appropriately position the distal end of valve within the main pulmonary artery could lead to impaired blood flow into the branch pulmonary arteries (right and left pulmonary

Step	Implant Procedure
	artery) or obstruct the passage of instruments/wires into the branch pulmonary arteries during a subsequent transcatheter procedure. • Ensure correct valve alignment with main pulmonary artery The circumferential proximal valve suture line should be sewn in a non-vertical fashion, with the anterior suture line shifted in a cephalad direction by 30-45 degrees to provide a posterior tilt to the valve. This will ensure the valve is correctly aligned, coaxial with the main pulmonary artery (i.e. the valve should be coaxial with the main pulmonary artery with no anterior tilt of the distal end of the valve). (See Figure 24). This ensures that the posterior valve strut is parallel to the posterior pulmonary artery wall and the anterior valve strut does not protrude anteriorly into the native or reconstructed anterior pulmonary artery wall. Figure 24 shows correct valve alignment in RVOT. Figure 25 demonstrates implantation technique that should be avoided: A vertical proximal suture line (whether sewn to contractile RVOT muscle or an RVOT patch) results in AUTUS valve malalignment with the main pulmonary artery so that it is no longer coaxial with the centerline of the main pulmonary artery (i.e. results in anterior tilt of distal valve within main pulmonary artery). The valve malalignment is magnified by sewing a circumferential proximal anastomosis within contractile right ventricular outflow tract (RVOT) tissue. WARNING: A vertical proximal suture line may result in valve malalignment, with distal anterior tilt causing the valve to protrude into the anterior vessel/patch wall after closure of the main pulmonary artery. Excessive compressive forces across the anterior valve may result in increased risk of frame fracture. If anterior tilt of the distal valve is recognized or if anterior valve compression is noted after implantation, a redundant anterior main pulmonary artery patch should be utilized to minimize compressive forces on the anterior valve struts (See Figure 25). WARNING: Avoid sewing the anterior portion of the circumferential proximal suture line/anastomosis within contractile right ventricular outflow tract (RVOT) tissue as this could lead to worsening valve malalignment with the main pulmonary artery and could lead to compressive forces on the proximal valve and an increased risk of frame fracture (See Figure 25). WARNING: DO NOT sew contractile RVOT (right ventricular muscle or patch) tissue directly to anterior sleeve of the AUTUS valve. Failure to use anterior patch augmentation could result in compressive forces on the valve leading to risk of frame fracture (See Figure 25).
	 Proximal suture line at 30-45 degrees Figure 24: Correct Valve Alignment within Main Pulmonary Artery

Step	Implant Procedure
	 Circumferential proximal anastomosis within contractile RVOT Incorrect AUTUS Valve alignment (malalignment with main pulmonary artery) Vertical proximal suture line Figure 25: Incorrect Valve Alignment within Main Pulmonary Artery
4	The choice of suture technique to secure the valve into position is left to surgeon discretion. Use of a running or interrupted suture technique to assure correct valve positioning and alignment within the RVOT (non-vertical suture line – see Figure 24) should be used. Suturing of the ePTFE sleeve to the surrounding tissue should be performed using non-absorbable polypropylene suture (Size 4-0 or 5-0). The suture bite depth is recommended to be no less than 1.5 mm from the bottom edge of the sleeve. The distance between suture bites on the sleeve should be approximately 2 mm. CAUTION: Larger distance between suture bites may result in paravalvular leak. WARNING: Care must be exercised when passing the suture needle through the lower margin of the sleeve to avoid possible laceration of the leaflet material. If an anterior RVOT patch is required, this should be sized to match the AUTUS valve outer diameter. Use pericardium (native or bovine), homograft, or ePTFE cardiovascular patch (at least 0.6 mm thickness) to construct the anterior RVOT patch. CAUTION: In order to avoid placing tension on patch/native tissue suture line or anterior valve, the patch must be adequately sized. CAUTION: Avoid cutting or damaging the frame or leaflet material when placing and cutting the sutures.

11.6. POST-IMPLANT VALVE EXPANSION

Careful consideration should be given prior to proceeding with a post-implant valve expansion to address forward flow restriction / prosthesis-patient mismatch. The mean transvalvular gradient in combination with right ventricular function and right ventricular pressure, as assessed by transthoracic echocardiogram, should be the principal hemodynamic parameters used to determine whether intervention is indicated.

- Valve expansion must be performed using an appropriate 2 cm working length non-compliant percutaneous balloon catheter, which has a diameter 2 mm larger than the diameter (ID) of the implant.
- All valve expansions must be performed in 2 mm increments. Hemodynamic parameters and valve function must be assessed after each expansion.
- Coronary arteries must be visualized via angiography to assess spatial relationship to valve prior to balloon expansion.

- Rapid right ventricular pacing must be performed (following a standard pacing protocol) to stabilize balloon position when performing a post-implant valve expansion (i.e. perform rapid RV pacing to reduce systemic blood pressure by 50% during inflation and deflation of balloon catheter) procedure.
- Multiple expansions may be needed to achieve desired hemodynamic outcomes, defined as meeting at least one of the following hemodynamic parameters:
 1. RV pressure: Ao (aortic) pressure: $\leq 1/2$;
 2. Peak-to-peak RV to PA systolic pressure gradient: ≤ 15 mmHg;
 3. Peak-to-peak RV to PA systolic pressure gradient: $\geq 50\%$ reduction (pre vs post dilation).

WARNING: During post-implant balloon expansion, DO NOT position wire incorrectly, use an inappropriate balloon length or allow balloon malalignment with frame (specifically, working length of balloon must remain straight throughout full length of device during inflation). Failure to do so could damage leaflet material and result in possible valve dysfunction.

WARNING: DO NOT inflate balloon beyond nominal pressure during post-implant valve expansion procedure. Failure to do so could place excessive tension on the valve sleeve-tissue suture line. Excessive tension could result in suture hole elongation/tearing of sleeve material, potentially leading to paravalvular leak, valve dysfunction or device embolization.

PRECAUTION: There is presently no clinical experience with post-implant expansions of fractured valve frames. Limited engineering data suggests that valve frames with fractures at the base of the frame along the leaflet attachment feature (where fractures have been observed clinically) may maintain acceptable valve hydrodynamic performance when expanded.

12. RETURN OF VALVES

Edwards Lifesciences is interested in obtaining recovered clinical specimens of the AUTUS valve for analysis. Contact Edwards for return instructions. If you decide to return the device, please follow these instructions:

- Unopened Package with Sterile Barrier Intact: If the trays have not been opened, return the valve in its original packaging.
- Package Opened but Valve is Not Implanted: If the inner tray is opened, the valve is no longer sterile. Please return the device in its original packaging. Refrigeration is not necessary under these circumstances.
- Explanted Valve: The explanted valve should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde and returned to the manufacturer. Refrigeration is not necessary under these circumstances. Contact Edwards Lifesciences to request an Explant Kit for return to Edwards.

13. 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.

14. MAGNETIC RESONANCE (MR) SAFETY INFORMATION

 The AUTUS Size-Adjustable Valve is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:	
Static Magnetic Field	3.0 or 1.5 T
Maximum Magnetic Field Spatial Gradient	20 T/m (2,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil or Extremity RF transmit-receive coil
Maximum Whole Body SAR	2 W/kg (Normal Operating Mode)
Limits on Scan Duration	60 minutes

MR Image Artifact	The presence of this implant may produce an image artifact. In non-clinical testing, the image artifact caused by the device extends approximately 45 mm from the AUTUS Size-Adjustable Valve when imaged with a gradient echo pulse sequence and a 3.0 T MR system.
If information about a specific parameter is not included, there are no conditions associated with the parameter.	

15. PATIENT LABELING

A patient implant card request form is provided with each AUTUS valve. After implantation, all requested information should be completed on this form. The serial number may be found on the package. The original form should be returned to the Edwards Lifesciences address indicated on the form or completed on-line. Upon receipt, Edwards Lifesciences will provide an identification card to the patient.

16. REFERENCES

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5. Cantinotti M, Giordano R, Scalese M, et al. Nomograms for two-dimensional echocardiography derived valvular and arterial dimensions in Caucasian children. *J Cardiol*. 2017;69(1):208-215. doi:10.1016/j.jjcc.2016.03.010

17. SYMBOL LEGEND

Symbol	ISO Reg. No. ¹	English
	N/A	Model Number
	0434A	Caution
	1641	Consult Instructions for Use
	2501	Sterilized using Ethylene Oxide
	2498	Serial Number
	3082	Manufacturer
	2497	Date of manufacture
	2606	Do Not Use if Package is Damaged and consult Instructions for Use
	2607	Use by Date
	1051	Do Not Reuse
	2608	Do Not Resterilize

Symbol	ISO Reg. No. ¹	English
	N/A	Model Number
	2724	Non-pyrogenic
Rx only	N/A	CAUTION: US law restricts this device to sale by or on the order of a physician.
	N/A	MR Conditional
	N/A	Keep Dry
	N/A	Keep away from sunlight
	3704	Double sterile barrier system

Note: The labeling for this product may not contain every symbol depicted in this legend

¹ ISO 7000 Graphical symbols for use on medical equipment – Registered symbols



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