TRIFORMIS RESILIA Tricuspid Valve, Model 11300T

Instructions for Use

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

Figure 1: TRIFORMIS RESILIA Tricuspid Valve

1.0 Device and Accessories Description

1.1 Device Description

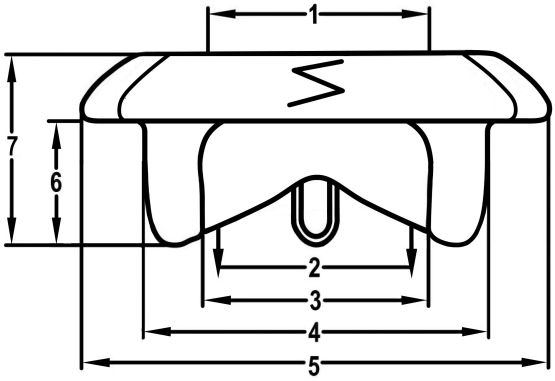
The TRIFORMIS RESILIA tricuspid valve, model 11300T, is a stented tri-leaflet prosthetic heart valve comprised of RESILIA bovine pericardial tissue. This low-profile valve is based on the Edwards PERIMOUNT valve design with a nitinol wireform. The valve is mounted on a retainer with a holder system attached to the valve. The holder system has a dial that is turned prior to implantation to allow the posts to be folded inward during implantation.

The valve is stored under dry packaging conditions and does not require rinsing prior to implantation. The valve is available in sizes 25, 27, 29, 31 and 33 mm. See Table 1 for nominal dimensions.

The TRIFORMIS RESILIA tricuspid valve can only be used with the handle model 1140M and model 1141M.

The TRIFORMIS RESILIA tricuspid valve is designed to be used with sizer model 1173B.

Table 1: Nominal Dimensions for TRIFORMIS RESILIA Tricuspid Valve, Model 11300T



Valve Size	25 mm	27 mm	29 mm	31 mm	33 mm
1: Inflow Orifice Diameter (mm)	23.0	25.0	27.0	29.0	29.0
2: Effective Orifice Diameter (mm)	19.5	21.0	23.0	25.0	25.0
3: Stent Diameter (Wireform, mm)	25.0	27.0	29.0	31.0	31.0
4: Valve Housing External Diameter (mm)	27.5	29.5	31.5	33.5	33.5
5: External Sewing Ring Diameter (mm)	37.5	40.0	42.5	44.5	46.0
6: Effective Profile Height (mm)	10.0	11.0	11.5	12.0	12.0
7: Total Profile Height (mm)	15.0	16.0	17.0	18.0	18.0
Note: For Sizing, Refer to Section 11.2					

RESILIA Tissue

RESILIA tissue is created with a technology called Edwards Integrity Preservation. The technology incorporates a stable-capping anticalcification process, which blocks residual aldehyde groups that are known to bind with calcium. The technology also incorporates tissue preservation with glycerol, which replaces the traditional storage in liquid- based solutions such as glutaraldehyde. The storage method eliminates tissue exposure to the residual unbound aldehyde groups commonly found in glutaraldehyde storage solutions.

Valve Structure

The lightweight wireform is made of a corrosion-resistant nickel-titanium alloy (nitinol), chosen because of its superelastic characteristics, allowing it to fold inward during implantation, and is covered with a polyester fabric.

A cobalt-chromium alloy band and polyester band surround the base of the valve below the wireform frame providing structural support for the orifice. Similar to other Edwards bioprosthetic valves, the nickel-titanium alloy wireform and cobalt-chromium alloy band in the model 11300T can be identified on fluoroscopy. This allows for identification of the valve's inflow and outflow edges to facilitate identifying the landing zone for potential future transcatheter interventions. A compliant silicone-rubber sewing ring that is covered with a porous, seamless polytetrafluoroethylene (PTFE) cloth is attached to the wireform frame and facilitates tissue ingrowth and encapsulation.

The sewing ring has an asymmetric region that is designed to align with the septal portion of the tricuspid annulus.

The valve has posteroseptal and anteroseptal commissure marks (single black lines), and an anterior septal segment mark ("S" mark). The black commissure markers and septal segment mark facilitate the orientation of the valve.

1.2 Sizers and Tray

Use only sizer model 1173B (Figure 2) with the model 11300T TRIFORMIS RESILIA tricuspid valve.

CAUTION: Do not use other manufacturers' valve sizers, or sizers not listed above to size the model 11300T TRIFORMIS RESILIA tricuspid valve.

Sizer model 1173B is used for sizing of the annulus. The barrel of the sizer model 1173B indicates the tissue annulus diameter at the base.

The sizer model 1173B is labeled with the valve size. The complete set of sizers is housed in a tray, model SET1173, which can be resterilized and reused.

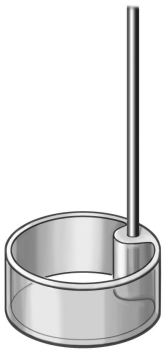


Figure 2: Model 1173B Barrel Sizer

1.3 Valve Holder System and Handle

A holder is attached to the valve by means of a blue polymer thread to facilitate handling and suturing the valve during implantation.

The holder/handle assembly consists of two components; the holder system (Figure 3 and Figure 4) that is mounted to the model 11300T TRIFORMIS RESILIA tricuspid valve, and a handle (model 1140M or 1141M) that is attached to the holder system at the time of surgery (Figure 5). The holder is detached by the surgeon. (Refer to **Section 11.4 Device Implantation**).

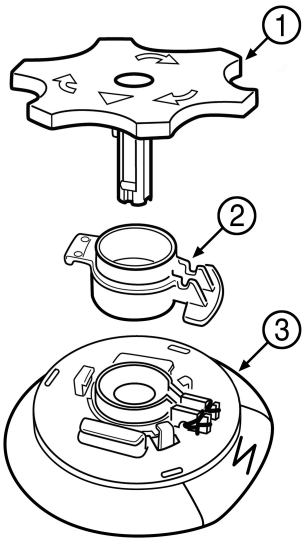


Figure 3: TRIFORMIS Holder System

1. Dial
2. Adapter
3. Holder

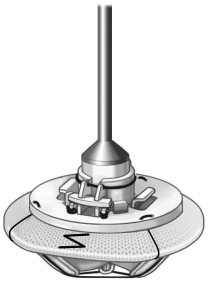


Figure 4: TRIFORMIS RESILIA Valve attached to Holder/ Handle assembly

Only the following handles (Table 2) may be used with the model 11300T TRIFORMIS RESILIA tricuspid valve.

Table 2: Accessory Handles

Model	Shaft Material	Overall Length		Reusable
		in	cm	
1140M	Nitinol	11.3	28.6	Yes
1141M	Stainless Steel	12.0	30.5	Yes

The model 1140M handle has a malleable nitinol shaft and the model 1141M handle has a stainless steel shaft. Both handles are supplied by Edwards non-sterile and must be sterilized prior to use. After sterilization, the nitinol shaft of the 1140M handle, returns to its original straight shape.

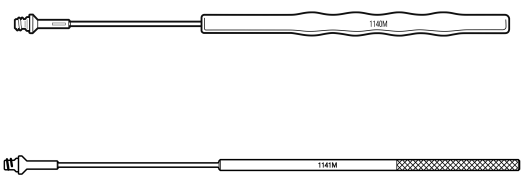


Figure 5: Model 1140M (top) and 1141M (bottom) Accessory Handles

2.0 Intended Use and Indications for Use

The TRIFORMIS RESILIA tricuspid valve, model 11300T, is intended for use as a heart valve replacement.

The TRIFORMIS RESILIA tricuspid valve, model 11300T, is indicated for the replacement of native or prosthetic tricuspid heart valves.

3.0 Contraindications

The TRIFORMIS RESILIA tricuspid valve, model 11300T, is contraindicated in patients who have untreatable hypersensitivity to nitinol alloys (nickel and titanium).

4.0 Warnings

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

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 Storage**, for recommended storage conditions).

DO NOT USE the valve if:

- **The foil pouch, sealed trays or lids are opened, damaged, or stained**
- **The expiration date has elapsed, or**
- **It is dropped, damaged, or mishandled in any way. Should a valve be damaged during insertion, do not attempt repair.**

The above may result in dehydration of the tissue, contamination, and / or compromised sterility.

DO NOT EXPOSE the valve to any solutions, chemicals, antibiotics, etc., except for sterile physiological saline solution. Irreparable damage to the leaflet tissue, which may not be apparent under visual inspection, may result.

DO NOT GRASP the leaflet tissue of the valve with instruments or cause any damage to the valve. Even the most minor leaflet tissue perforation may enlarge in time to produce significant impairment of valve function.

DO NOT OVERSIZE. Oversizing may cause valve damage or localized mechanical stresses, which may in turn injure the heart or result in leaflet tissue failure, stent distortion and regurgitation.

DO NOT PASS CATHETERS, transvenous pacing leads, or any surgical instrument across the valve with the exception of a surgical mirror used to examine struts and suture placement. Other surgical devices may cause leaflet tissue damage.

Inadequate air removal during or after surgery may lead to moderate to major pulmonary air embolism.

As with any implanted medical device, there is a potential for the patient to develop an immunological response. Some components of the model 11300T are a metal alloy that contains nitinol (an alloy of nickel and titanium), cobalt, chromium, nickel, molybdenum, manganese, carbon, beryllium and iron. Care should be exercised in patients with hypersensitivities to these materials. This device was not made with natural rubber latex but may have been produced in a latex- containing environment. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials. Safety of the TRIFORMIS RESILIA valve has not been tested in patients with nickel allergy.

5.0 Adverse Events

5.1 Observed Adverse Events

As with all prosthetic heart valves, serious adverse events, sometimes leading to death, may be associated with the use of tissue valves. In addition, adverse events due to individual patient reaction to an implanted device or to physical or chemical changes to the components, particularly those of biological origin, may occur at varying intervals (hours or days) necessitating reoperation and replacement of the prosthetic device.

The TRIFORMIS RESILIA tricuspid valve, model 11300T, is similar in design to the Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis, model 7300TFX.

Adverse events associated with the use of Carpentier-Edwards PERIMOUNT pericardial bioprostheses compiled from the literature and from reports received through the product surveillance system in accordance with the United States regulations establishing Good Manufacturing Practices, section 820.198, include stenosis, regurgitation through an incompetent valve, perivalvular leak, endocarditis, hemolysis, thromboembolism, thrombotic obstruction, bleeding diatheses related to the use of anticoagulation therapy, and malfunctions of the valve due to distortion at implant, fracture of the wireform, or physical or chemical deterioration of valve components. Types of tissue deterioration include infection, calcification, thickening, perforation, degeneration, suture abrasion, instrument trauma, and leaflet detachment from the valve stent posts. These complications may present clinically as abnormal heart murmur, shortness of breath, exercise intolerance, dyspnea, orthopnea, anemia, fever, arrhythmia, hemorrhage, transient ischemic attack, stroke, paralysis, low cardiac output, pulmonary edema, congestive heart failure, cardiac failure, and myocardial infarction.

5.2 Potential Adverse Events

Adverse events potentially associated with the use of valves and the surgical procedure include:

- Death
- Allergic reaction/immunological response
- Angina
- Annulus (damage, tear)
- Aortic incompetence
- Arterial dissection
- Asystole and/or cardiac arrest
- Bleeding
  - Peri- or post-procedural
  - Anticoagulant related
  - Pericardial tamponade
  - Hematoma
  - Hemorrhage
  - Cerebrovascular
- Blood – Coagulopathy
- Blood – Hemolysis/Hemolytic Anemia
- Blood – Anemia
- Blood Pressure alteration (hypotension, hypertension)
- Cardiac – Arrhythmias/Conduction Disturbances
- Cardiogenic shock
- Coronary artery (right) injury
- Deep vein thrombosis (DVT)
- Disseminated intravascular coagulation (DIC)
- Embolism
- Esophageal tear/rupture
- Endocarditis

- Hypoxemia
- Infection – local, wound or systemic
- Myocardial infarction
- Multi-system organ failure (MOF)
- Neurologic Events
  - Stroke (CVA)
  - Transient Ischemic Attack (TIA)
- Pericardial effusion
- Pleural effusion
- Pulmonary edema
- Pneumonia
- Prosthetic Insufficiency –Regurgitation/Stenosis
- Reduced exercise tolerance
- Renal failure, acute
- Renal insufficiency
- Respiratory failure
- Right Ventricular muscle injury
- Thrombocytopenia, (Non-HIT)
- Thrombocytopenia, heparin induced (HIT)
- Thromboembolism
  - Arterial, venous, peripheral, central
- Transvalvular or Valvular Leaking
- Valve dislodgement/instability
- Valve – Nonstructural dysfunction
  - Paravalvular Leak
  - Leaflet impingement
  - Leaflet tissue damage (instruments /sutures)
  - Pannus
  - Patient Prosthesis Mismatch (PPM) (due to inappropriate sizing)
  - Distortion at implant
- Valve – Structural dysfunction/deterioration
- Valve – Thrombosis

6.0 Clinical Studies

6.1 Clinical Studies - RESILIA tissue

The clinical safety and effectiveness of the TRIFORMIS RESILIA tricuspid valve, model 11300T was established based on the outcome data of the COMMENCE trial, which assessed the safety and effectiveness of the model 11000A (aortic) and model 11000M (mitral) valves. The COMMENCE trial devices and the TRIFORMIS RESILIA tricuspid valve are all comprised of the same RESILIA bovine pericardial tissue. The key differences between the tricuspid model 11300T and COMMENCE trial devices are the nitinol wireform material which allows for the valve posts to be folded inward during implantation, the valve holder system to fold the valve posts, softer sewing ring with asymmetric region to mimic the tricuspid annulus, and orientation marks. These changes were evaluated in non-clinical testing. The safety and effectiveness outcomes of the COMMENCE trial are applicable to model 11300T. The Instructions For Use supplied with MITRIS RESILIA mitral valve, model 11400M, provides information on the COMMENCE trial.

6.2 Clinical Studies - Tricuspid Valve Replacement

Edwards performed a real-world evidence (RWE) study (#2025-01) to establish a reasonable assurance of the safety and effectiveness of the TRIFORMIS RESILIA tricuspid valve, model 11300T for tricuspid valve replacement. The results of this study supported interpretability and served as the primary source of evidence.

This study was a retrospective, observational cohort study based on secondary use of real-world data of adults ≥18 years of age in the US undergoing surgical tricuspid valve replacement with a Magna Mitral (model 7000TFX), Magna Mitral Ease (model 7300TFX), or MITRIS RESILIA mitral valve (model 11400M) between January 1, 2016 and August 30, 2024. The data source contained de-identified electronic health record (EHR) and claims data sourced from 19 US integrated delivery networks, capturing approximately 18% of care delivered in the US. This data source was also linked with another third-party partner that provides open claims, social determinants of health data, and mortality data to augment the mortality data captured in the EHRs for mortality ascertainment. Safety outcomes included rates of device failure requiring non-surgical (transcatheter) reintervention (e.g., valve-in-valve implantation), device failure requiring medical intervention (e.g., thrombolytic therapy specifically for valve related thrombosis), valve thrombosis, major paravalvular leak, and endocarditis. Effectiveness outcomes included rates of heart failure hospitalization, surgical tricuspid valve reintervention, and all-cause mortality.

To be eligible for cohort entry patients had to be age ≥18 years as of the index date, have evidence of primary or secondary tricuspid valve disease (TVD) as of the index date, and an EHR encounter in the 365 days prior to and excluding the index date and in the day following the index date through day 365 (representing observability). Individuals in whom it could not be ascertained that the device of interest was implanted in the tricuspid position (vs. mitral position) were excluded.

The final study population included 204 patients who met the inclusion and exclusion criteria of the study, as shown in Table 3. Of these, 147 patients received a Magna Mitral Ease valve (model 7300TFX), and 57 patients received a MITRIS RESILIA valve (model 11400M) in the tricuspid position. No patients were excluded due to age, as all patients were ≥18 years of age at device (index) date. 167 patients underwent isolated TVR, 33 patients underwent TVR plus MVR, and 4 patients underwent TVR with two devices within 10 days. The median [IQR] follow up duration was 303 [82-1042] days (mean: 592). Person-years follow-up at 1 year were 131.1 and at 2 years were 208.8. The cumulative person-years accrued over the course of the entire study were 331.1.

The demographics and baseline medical history of the study population are typical for tricuspid heart valve replacement patient procedures performed in the US (Table 4 and Table 5). Baseline NYHA class was largely not available (93%) and thus not summarized. Nearly half of the patients (99/204; 48.5%) were undergoing TVR for active infective endocarditis, defined as an endocarditis diagnostic code within 6 weeks prior to the index date. This study population was found to be representative of real-world use of these devices in the tricuspid position in comparison to published literature including a contemporary report from the Society of Thoracic Surgeons Adult Cardiac Surgery database[4].

The primary safety and effectiveness endpoints are summarized in Table 6 and Table 7. The all-cause mortality rate was estimated using the Kaplan-Meier method; all the other event rates were estimated using the cumulative incidence function (CIF) method, which treated death as a competing risk. In addition, Kaplan-Meier curves were calculated for all the clinical endpoints where death was handled as a censoring event for all endpoints other than all-cause mortality. At 1 year follow-up (representing 131.1 person-years), there were no device failures requiring either transcatheter intervention, medical (i.e., thrombolytic) intervention, or surgical intervention. There were also no valve thrombosis events. There were two valves with major paravalvular leaks and 66 endocarditis events. The all-cause mortality rate at 1 year was 26.5%. The cumulative incidence of heart failure hospitalization was 21.4% at 1 year. The Kaplan-Meier curves of the primary safety and effectiveness endpoints

through 2-years are presented in Figures 6-10. Additional outcomes of interest at 1-year are presented in Table 8, with associated Kaplan Meier curves through 2-years presented in Figures 11-14.

As a sensitivity analysis, the Kaplan-Meier estimate for all-cause mortality at 30 days within the study was determined to be 6.9% with a 95% CI 3.3-10.3%, summarized in Table 9. This rate is in line with reported operative mortality rates from several contemporary series, including a recent report from the STS Registry (5.7%)[4] and a comprehensive meta-analysis reporting on 35 studies (5,316 patients) spanning the last 5 decades (overall operative mortality 12%; 95% CI: 9-15%)[5]. To assess the potential undercapture of the surgical tricuspid reintervention outcome, a less specific algorithm was applied, requiring only a code concept from the procedure table indicating tricuspid valve replacement surgery following index procedure, defined via either International Classification of Diseases (ICD)-10 or Current Procedural Terminology (CPT) codes (without requiring a diagnostic code for device failure). Utilizing this less specific definition for surgical tricuspid reintervention revealed 5 events occurring between 4- and 12-months post-procedure, yielding a cumulative incidence for surgical tricuspid reintervention of 3.5% (95% CI 0.5-6.5%) by 1 year, summarized in Table 10. Due to concerns that endocarditis rates may have been overcaptured due to carryover coding from the index hospitalization, a secondary definition of endocarditis requiring an inpatient encounter was explored in a post-hoc sensitivity analysis, which yielded significantly lower rates (24 events, 14.8%; 95% CI 9.2-20.3%) at one-year, as summarized in Table 11.

Subgroup analyses for key safety and effectiveness outcomes with sufficient events (i.e. endocarditis, heart failure hospitalization, and all-cause mortality) are presented in Tables 12-14. Endocarditis event rates were significantly higher among patients with a history of endocarditis or active endocarditis at baseline, as well as among patients with a history of intravenous (IV) drug use. A large fraction of the study population were IV drug users who underwent TVR because of tricuspid valve endocarditis—a population that has been shown to have high rates of recurrent endocarditis because of continued drug use.[6] In contrast to endocarditis events, heart failure hospitalizations were more frequent in older patients and those without a history of endocarditis or IV drug use, likely indicating a more complex, secondary etiology of TR in these subgroups. Mortality rates were higher in patients with history of endocarditis (31%) than in those without (20%).

The incidence rate of all-cause mortality was contextualized with estimates available in published literature. Several studies also report one-year all-cause mortality rates similar to those observed in the study. [7, 8, 9] The Kaplan-Meir curve of heart failure hospitalization demonstrates that the majority of these events occurred within 30 days of the index hospitalization. Thus, it is likely that many of these events reflected post-operative heart failure, which is common in patients undergoing atrioventricular valve replacement. The real world evidence demonstrated that the use of the TRIFORMIS RESILIA tricuspid valve did not raise major safety concerns and supports a reasonable assurance of safety and effectiveness of the TRIFORMIS RESILIA tricuspid valve in patients with a diseased or malfunctioning tricuspid valve that require surgical TVR.

Table 3: Patient Screening Attrition

Screening Criteria	Number of Patients
Patients with TVR procedure (01/01/1980 - 08/30/2024)	1761
Patients with eligible TVR procedure*	1525
Patients with eligible TVR and device after 01/01/2016	288
Patients with eligible TVR and device within 10 days of each other	273
Patients with eligible TVR and device within 10 days of each other PLUS device linkable to a TVR (primary analysis population)	**204**
Single device, single TVR	167
Two devices within 10 days, TVR plus MVR within 10 days†	33
Two devices within 10 days, only TVR mentioned‡	4

TVR: tricuspid valve replacement; MVR: mitral valve replacement
*TVR codes: CPT 33465; ICD10PCS 02RJ0KZ, 02RJ0JZ, 02RJ08Z
†MVR Codes: CPT: 33430; ICD10PCS 02RG08Z, 02RG0JZ, 02RG0KZ, 02RG07Z
‡Double-checked for any mitral procedure; negative
Note: No patients were excluded for age. All patients were ≥18 years old at device (index) date.

Table 4: Key Baseline Demographics

Demographic Characteristic	N = 204
Age (years, mean ± SD)	49.50 ± 18.05
Age categories (%)	
18-64	72.1
65-74	15.2
≥75	12.7
Sex (% female)*	53.9
Race (%)*	
American Indian or Alaska Native	0.5

Demographic Characteristic	N = 204
Asian	1.5
Black or African American	9.3
Native Hawaiian or Other Pacific Islander	2.0
Other Race	4.4
White	65.7
Ethnicity (%)*	
Hispanic or Latino	6.9
Not Hispanic or Latino	77.0

*Demographic information was not reported/missing in 9.3%, 16.7%, and 16.2% of eligible patient records for Sex, Race, and Ethnicity, respectively.

Table 5: Key Medical History

Characteristic	N = 204
Stroke (%)	5.9
Atrial fibrillation (%)	29.9
Congenital heart disease (%)	20.1
Peripheral artery disease (%)	1.0
Coronary artery disease (%)	29.9
Myocardial infarction (%)	8.3
Ventricular assist device (%)	0.5
Hypertension (%)	51.0
Diabetes (%)	14.7
Chronic kidney disease (%)	19.6
End-stage renal disease (%)	7.4
Liver disease (%)	23.5
Cirrhosis (%)	8.3
Obesity (%)	13.2
Body Mass Index (median [IQR])*	25.30 [21.66, 28.41]
Heart failure (%)	48.0
Heart failure hospitalization within 1 year prior to index (%)	39.7
Tricuspid stenosis (%)	10.8
Pulmonary heart disease (%)	23.0
Infections (e.g. HIV, hepatitis, other bacterial and viral infections) (%)	68.6
Endocarditis (%) Current: ≤6 weeks prior to index date Remote: >6 weeks prior to index date	 48.5 4.9
Cancer (%)	12.7
Chronic lung disease/COPD (%)	5.9
Home oxygen (%)	3.4
Esophageal varices (%)	0.5
Ascites (%)	7.4
GI bleed (%)	9.8
Smoking within the last year (%)	27.9
Substance use disorder (%)	33.3
IV drug use (%)	33.8
Other mental health disorders (%)	61.8
Remote use of temporary mechanical circulatory support (>10 days prior to index date) (%)	10.3
Prior Cardiovascular Surgery (>10 days prior to index date) Mitral valve replacement (%) Other mitral surgery (%) Aortic valve replacement (%) Non-valvular cardiac surgery with cardiopulmonary bypass (%) Heart transplant (%)	 1.0 1.0 0.0 0.5 0.5

*Body Mass Index (BMI) was not reported/missing in 10.8% of eligible patient records.
IV: intravenous

Table 6: Safety Outcomes at One Year

Endpoint	N Events	CIF Estimate*
Device Failure with transcatheter re-intervention	0	0.0% (0.0-0.0%)
Device Failure with medical intervention	0	0.0% (0.0-0.0%)
Surgical tricuspid reintervention	0	0.0% (0.0-0.0%)
Valve Thrombosis	0	0.0% (0.0-0.0%)
Major Paravalvular Leak	2	1.2% (0.0-2.9%)
Endocarditis[†]	66	37.8% (30.3-45.2%)

CIF: cumulative incidence function

*Probability (incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

[†]Endocarditis events may have been overcaptured due to carryover coding from the index hospitalization.

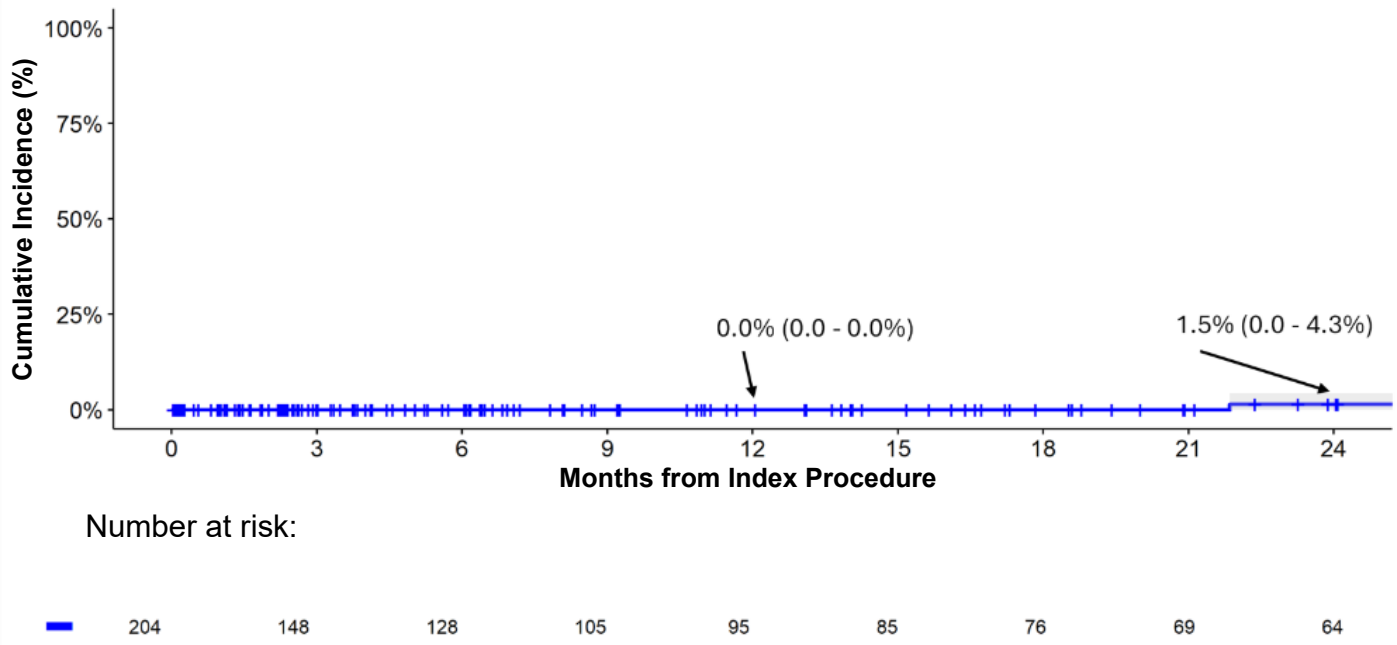


Figure 6: Kaplan-Meier Curve of Valve Thrombosis Through 2 Years

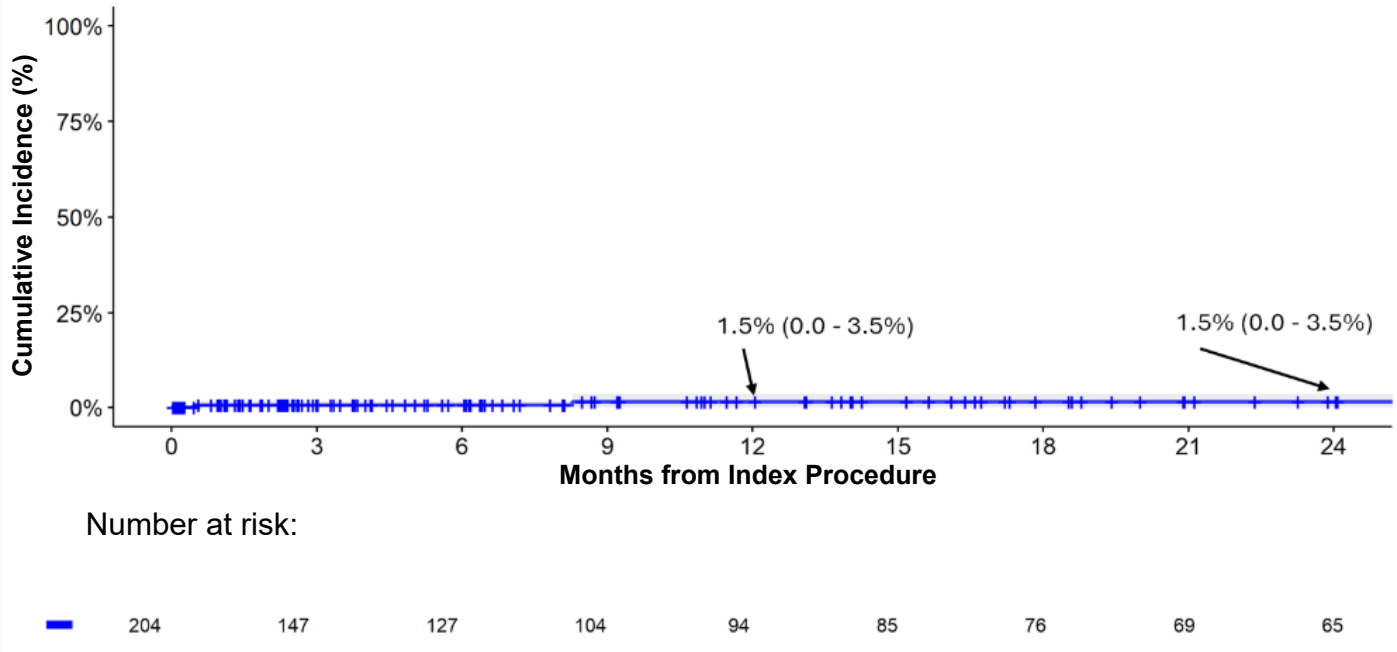


Figure 7: Kaplan-Meier Curve of Major Paravalvular Leak Through 2 Years

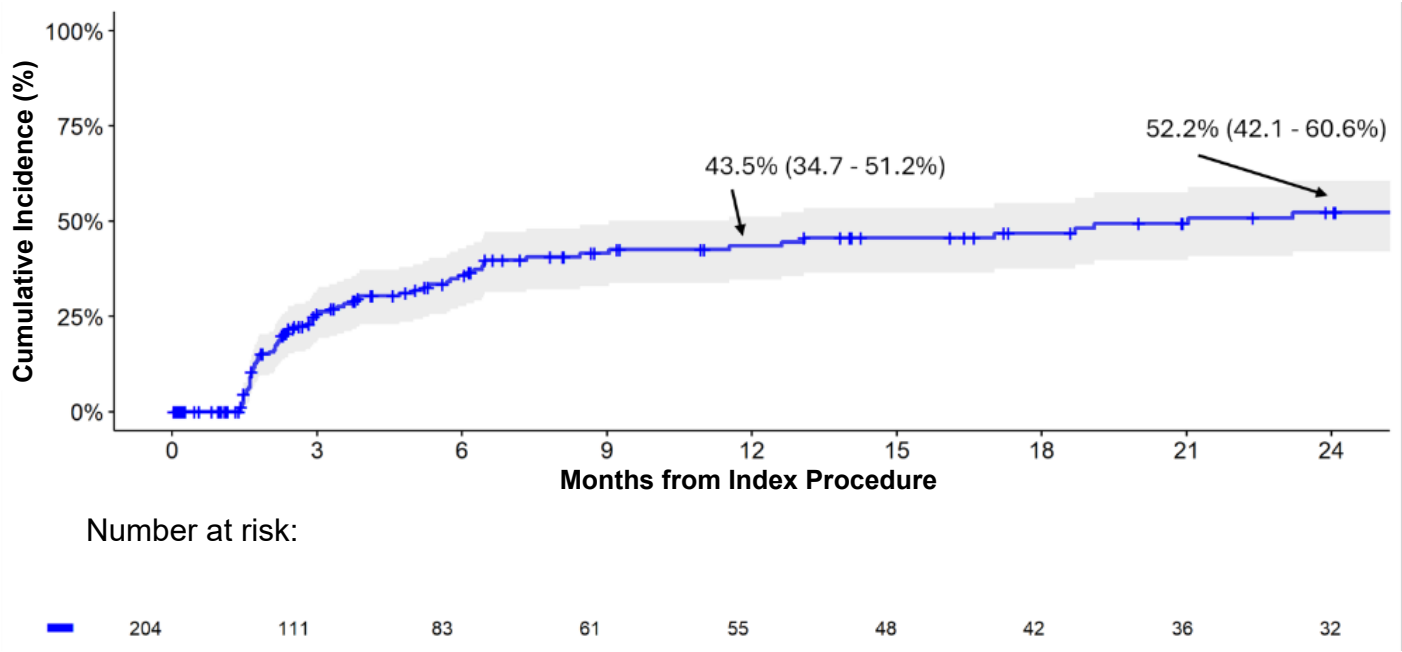


Figure 8: Kaplan-Meier Curve of Endocarditis Through 2 Years

Table 7: Effectiveness Outcomes at One Year

Endpoint	N Events	CIF Estimate*
All-cause mortality	45	26.5% (19.4-33.0%)
Heart failure hospitalization	32	21.4% (15.5-27.3%)

CIF: cumulative incidence function

*Probability (incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the Kaplan-Meier method for all-cause mortality and using the cumulative incidence function method which treated death as a competing risk for heart failure hospitalization. The CI for all-cause mortality was obtained using the log-log transformation method based on Greenwood's formula for variance estimation. The CI for heart failure hospitalization was obtained using standard normal approximation.

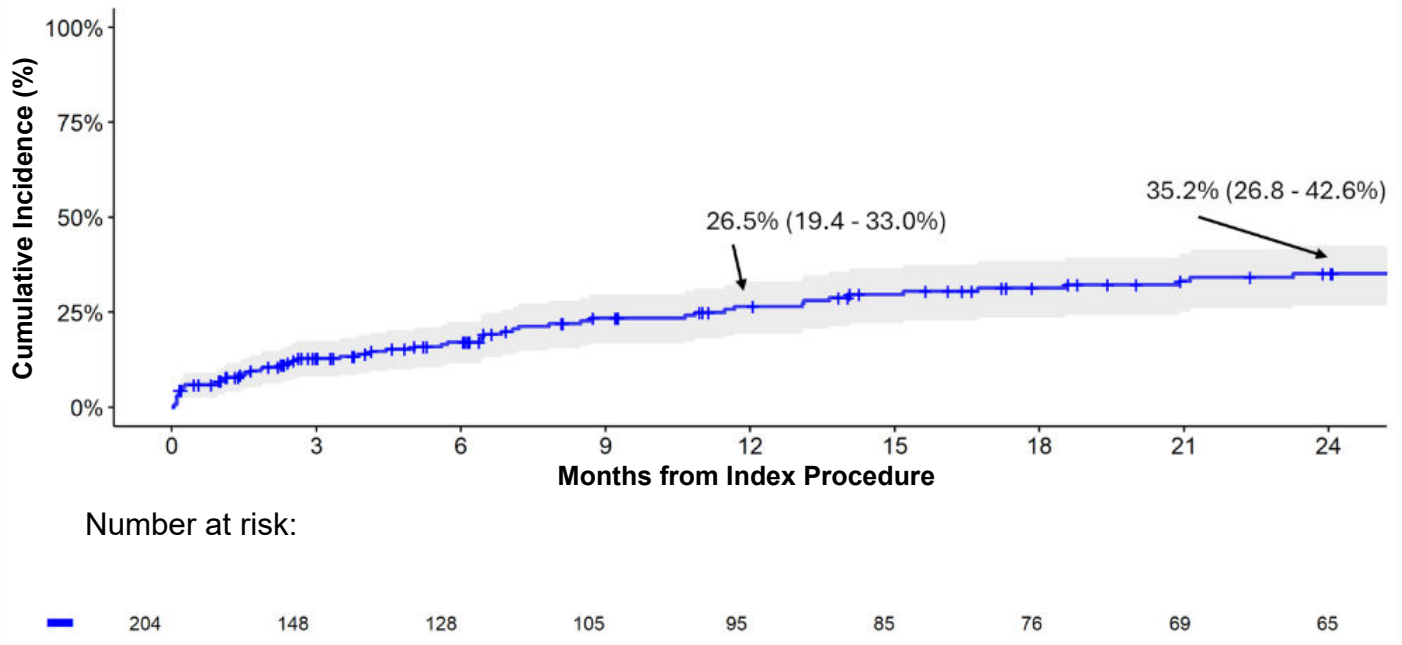
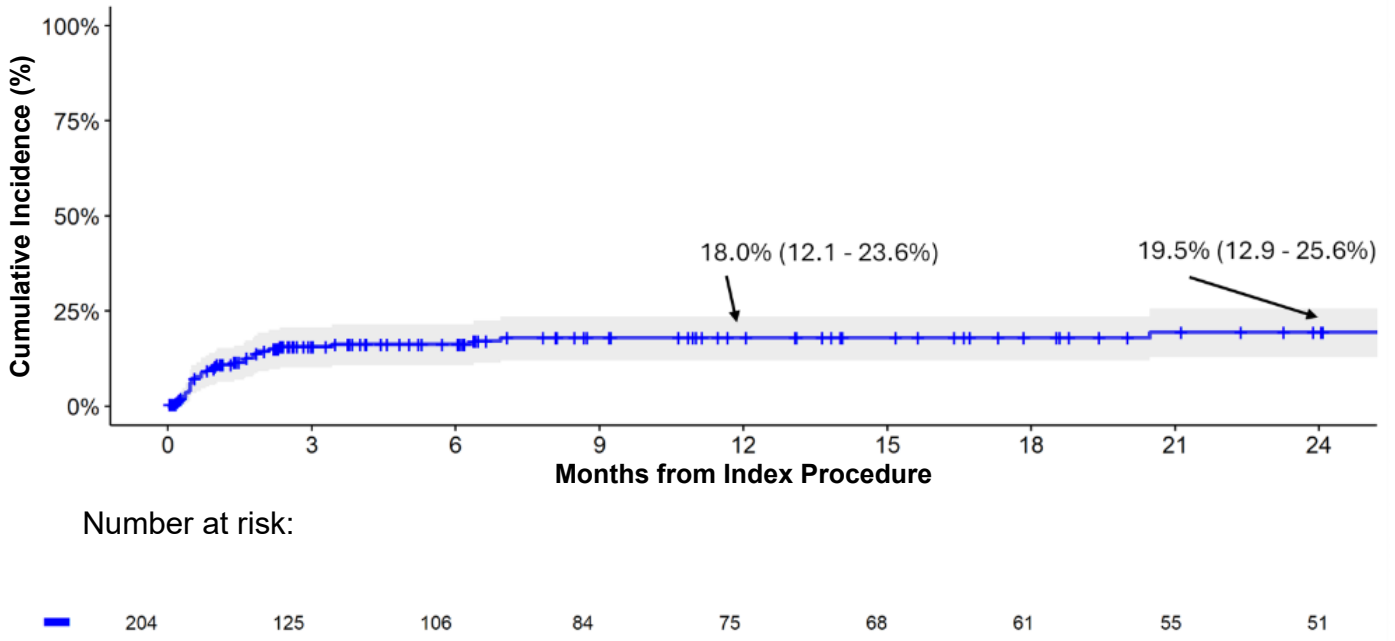


Figure 9: Kaplan-Meier Curve of All-Cause Mortality Through 2 Years



Number at risk:

	204	125	106	84	75	68	61	55	51

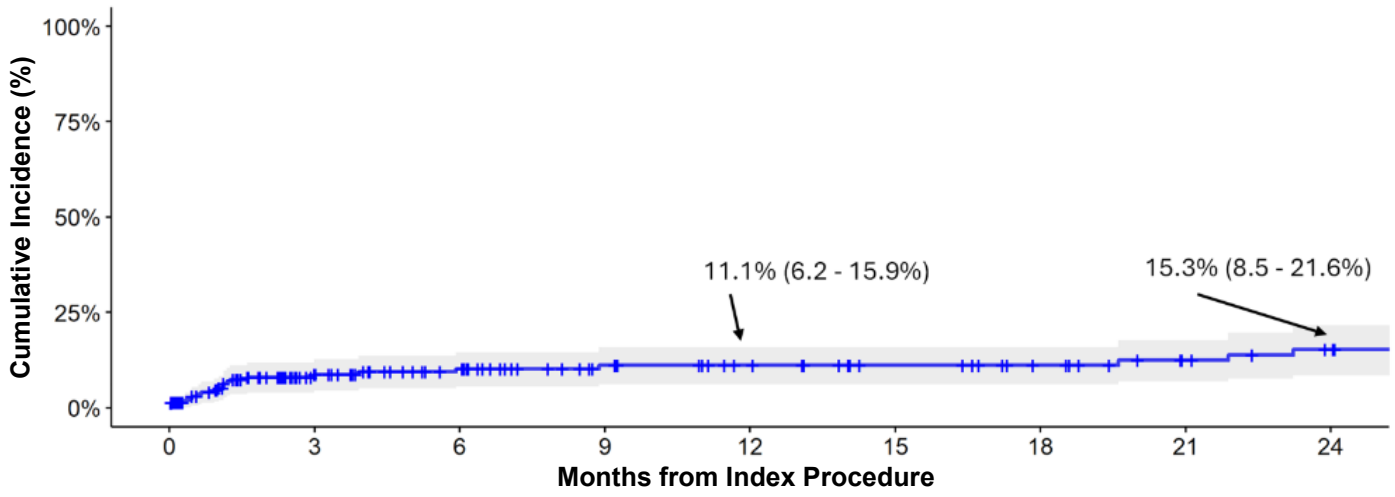
Figure 10: Kaplan-Meier Curve of Heart Failure Hospitalization Through 2 Years

Table 8: Additional Outcomes of Interest at 1 Year

Endpoint	N Events	CIF Estimates*
Pulmonary embolism	19	10.1% (5.8-14.5%)
Major hemorrhage	8	4.6% (1.4-7.8%)
Dialysis	15	7.8% (4.0-11.7%)
Ventricular assist device or transplant	1	0.5% (0.0-1.5%)

CIF: cumulative incidence function

*Probability (cumulative incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.



Number at risk:

	204	135	114	93	85	77	71	63	58

Figure 11: Kaplan-Meier Curve of Pulmonary Embolism Through 2 Years

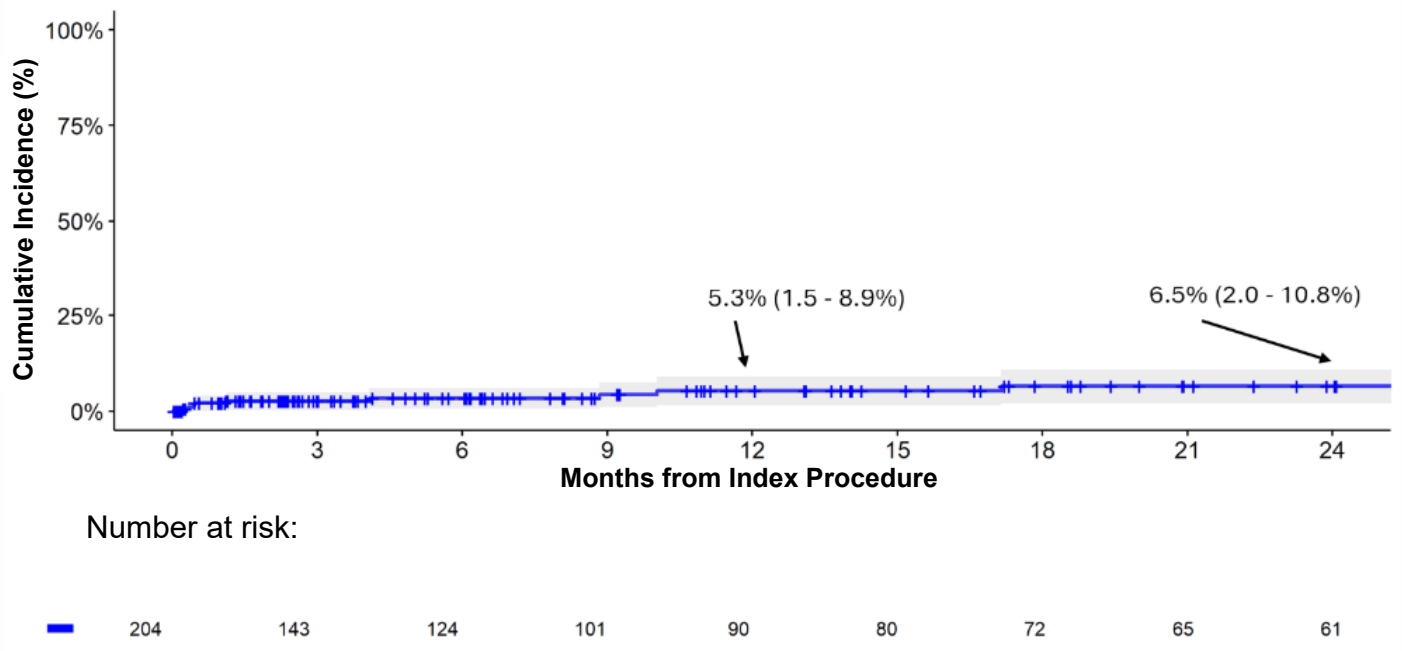


Figure 12: Kaplan-Meier Curve of Major Hemorrhage Through 2 Years

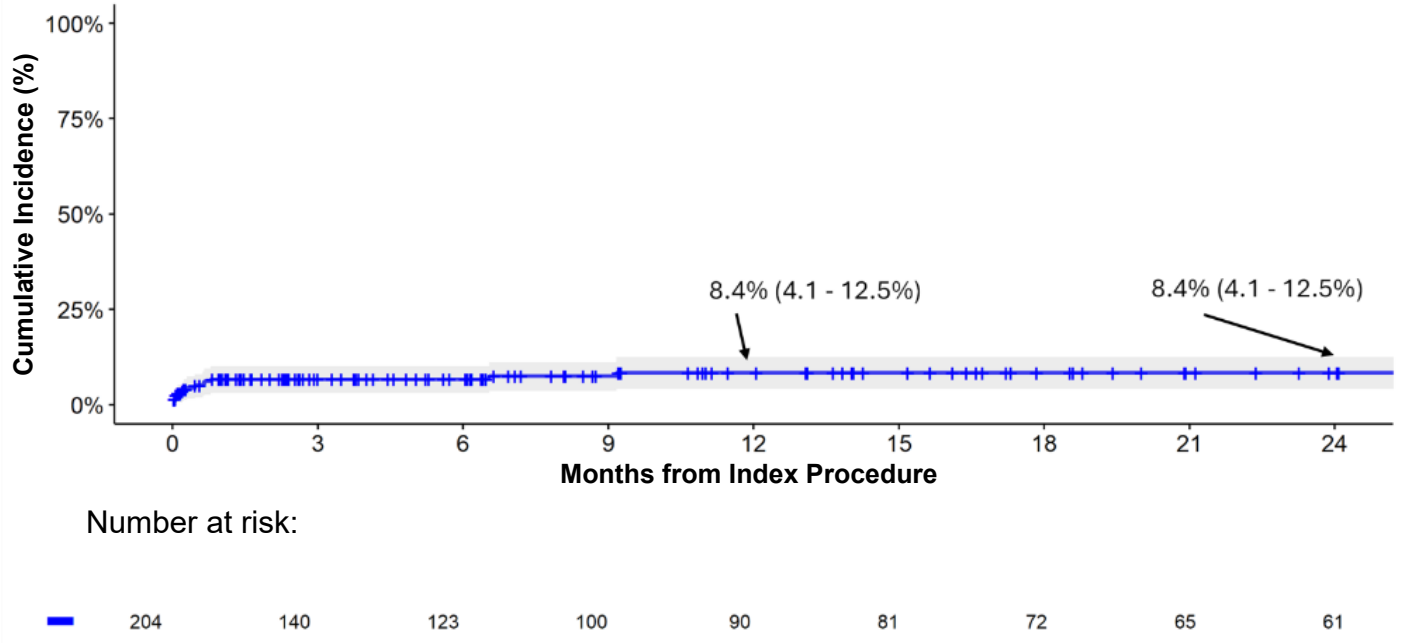


Figure 13: Kaplan-Meier Curve of Dialysis Through 2 Years

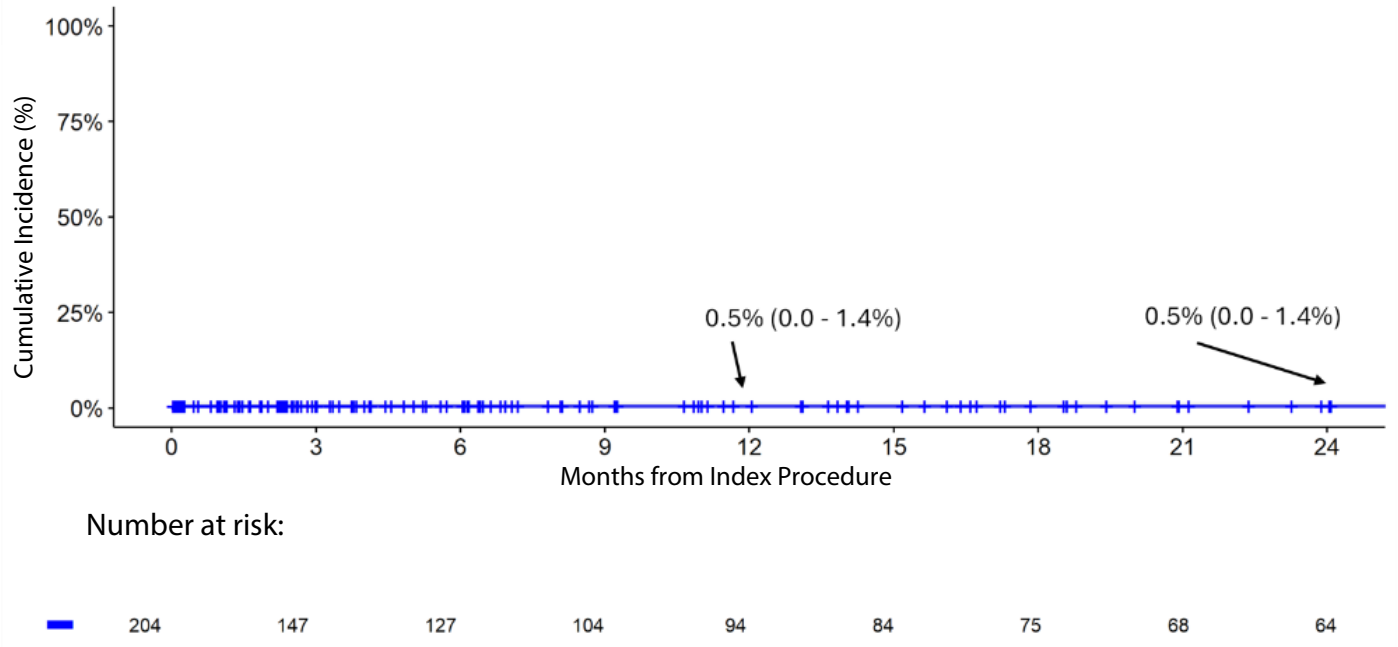


Figure 14: Kaplan-Meier Curve of Ventricular Assist Device Implantation or Heart Transplant Through 2 Years

Table 9: All-Cause Mortality Outcome at 30 Days

Endpoint	N Events	Kaplan-Meier Estimate*
All-cause mortality at 30 days	14	6.9% (3.3-10.3%)

*Kaplan-Meier estimate (95% confidence interval [CI]). The CIs were obtained using the log-log transformation method based on Greenwood's formula for variance estimation.

Table 10: Surgical Tricuspid Reintervention (Alternative Definition) Outcome at 1 Year

Endpoint	N Events	CIF Estimate*
Surgical tricuspid reintervention (alternative definition)	5	3.5% (0.5-6.5%)

CIF: cumulative incidence function
*Probability (cumulative incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

Table 11: Inpatient Endocarditis Outcome at 1 Year

Endpoint	No. of Events	CIF Estimate*
Inpatient endocarditis	24	14.8% (9.2-20.3%)

CIF: cumulative incidence function
*Probability (cumulative incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

Table 12: Endocarditis at 1 Year by Subgroup

Subgroup	No. of Events	CIF Estimate*
No MVR (n=171)	61	42.5% (34.1-50.9%)
MVR (n=33)	5	16.0% (2.8-29.2%)
Female (n=110)	37	39.9% (29.5-50.3%)
Male (n=75)	18	27.3% (16.4-38.3%)
Missing Sex (n=19)	11	57.9% (31.2-84.6%)
Age 18-64 (n=147)	57	44.3% (35.4-53.3%)
Age 65-74 (n=31)	2	7.5% (0.0-17.7%)
Age ≥75 (n=26)	7	33.8% (11.9-55.7%)
No Endocarditis (n=95)	12	15.6% (7.2-23.9%)
Endocarditis (n=109)	54	56.8% (46.5-67.2%)
No IV Drug Use (n=135)	33	30.1% (21.2-38.9%)
IV Drug Use (n=69)	33	52.0% (39.2-64.9%)
No Prior TVR (n=196)	63	37.4% (29.9-45.0%)
Prior TVR (n=8)	3	37.5% (1.1-73.9%)
MITRIS RESILIA (n=57)	9	20.3% (7.6-33.0%)
Magna Mitral Ease (n=147)	57	42.5% (33.9-51.0%)

CIF: cumulative incidence function; IV: intravenous; MVR: mitral valve replacement; TVR: tricuspid valve replacement
*Probability (cumulative incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

Table 13: Heart Failure Hospitalization at 1 Year by Subgroup

Subgroup	No. of Events	CIF Estimate*
No MVR (n=171)	23	13.1% (7.8-18.4%)
MVR (n=33)	9	28.5% (12.2-44.8%)
Female (n=110)	22	20.2% (12.3-28.0%)
Male (n=75)	8	10.4% (2.9-17.9%)
Missing Sex (n=19)	2	10.5% (0.0-24.9%)
Age 18 - 64 (n=147)	16	10.7% (5.5-15.8%)
Age 65 - 74 (n=31)	7	26.7% (8.8-44.5%)
Age ≥75 (n=26)	9	33.1% (13.1-53.1%)
No Endocarditis (n=95)	24	26.0% (16.6-35.5%)
Endocarditis (n=109)	8	6.9% (1.9-11.9%)
No IV Drug Use (n=135)	28	21.0% (13.6-28.3%)
IV Drug Use (n=69)	4	6.0% (0.2-11.7%)
No Prior TVR (n=196)	31	15.8% (10.5-21.2%)
Prior TVR (n=8)	1	12.5% (0.0-37.0%)
MITRIS RESILIA (n=57)	7	12.7% (3.8-21.6%)
Magna Mitral Ease (n=147)	25	16.6% (10.3-22.8%)

CIF: cumulative incidence function; IV: intravenous; MVR: mitral valve replacement; TVR: tricuspid valve replacement
*Probability (cumulative incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

Table 14: All-Cause Mortality at 1 Year by Subgroup

Subgroup	No. of Events	Kaplan-Meier Estimate*
No MVR (n=171)	35	25.5% (17.6-32.7%)
MVR (n=33)	10	31.9% (13.3-46.5%)
Female (n=110)	19	21.5% (12.2-29.8%)
Male (n=75)	13	20.2% (9.4-29.6%)
Missing Sex (n=19)	13	68.4% (38.8-83.7%)
Age 18-64 (n=147)	32	26.4% (17.9-34.0%)
Age 65-74 (n=31)	6	22.9% (4.5-37.5%)
Age ≥75 (n=26)	7	31.2% (8.0-48.6%)
No Endocarditis (n=95)	17	20.4% (11.1-28.8%)
Endocarditis (n=109)	28	31.0% (20.5-40.1%)
No IV Drug Use (n=135)	28	24.9% (16.2-32.8%)
IV Drug Use (n=69)	17	29.1% (16.3-40.0%)
No Prior TVR (n=196)	43	26.2% (19.0-32.8%)
Prior TVR (n=8)	2	24.4% (0.0-64.8%)
MITRIS RESILIA (n=57)	10	22.1% (8.3-33.8%)
Magna Mitral Ease (n=147)	35	27.0% (18.8-34.4%)

IV: intravenous; MVR: mitral valve replacement; TVR: tricuspid valve replacement
*Kaplan-Meier estimate (95% confidence interval [CI]). The CIs were obtained using the log-log transformation method based on Greenwood's formula for variance estimation.

7.0 Post-Operation Management

TRIFORMIS RESILIA tricuspid valve recipients should be maintained on anticoagulation therapy, except where contraindicated, during the initial stages after implantation as determined by the physician on an individual basis and as per guidelines [Ref 1]. Long-term anticoagulation and/or antiplatelet therapy should be considered for patients with risk factors for thromboembolism.

8.0 Patient Selection

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. A bioprosthesis is recommended for TVR in patients of any age for whom anticoagulant therapy is contraindicated, cannot be managed appropriately, or is not desired. Patient preference is a reasonable consideration in the selection of tricuspid valve operation and valve prosthesis. A bioprosthesis is reasonable for patients who elect to receive this valve for lifestyle considerations after detailed discussions of the risks of anticoagulation versus the likelihood that a second valve replacement may be necessary. The ACC / AHA Guidelines contain the complete recommendations for bioprosthetic valve selection [Ref 1].

8.1 Specific Patient Populations

The safety and effectiveness of the model 11300T valve has not been established for the following specific populations because it has not been studied in these populations:

- Patients who are pregnant;
- Nursing mothers;
- Patients with abnormal calcium metabolism (e.g., chronic renal failure, hyperparathyroidism);
- Patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis, Marfan's syndrome);
- Children, adolescents, and young adults;
- Patients with hypersensitivity to metal alloys that contain cobalt, chromium, nickel, molybdenum, manganese, carbon, beryllium and iron;
- Patients with hypersensitivity to latex;
- Patients with hypersensitivity to tissue with alpha-gal antigen.

9.0 Patient Counseling Information

Careful and continued medical follow up (at least by an annual visit to the physician) is advised so that valve-related complications, particularly those related to material failure, can be diagnosed and properly managed. Patients with valves are at risk from bacteremia (e.g., undergoing dental procedures) and should be advised about prophylactic antibiotic therapy. Patients should be encouraged to carry their Implant Data Card/Patient Identification Card at all times and to inform their healthcare providers that they have an implant when seeking care.

10.0 How Supplied

10.1 Packaging

The TRIFORMIS RESILIA tricuspid valve, model 11300T, is provided sterile and nonpyrogenic, in a double barrier tray package. The valve is sterilized by ethylene oxide. The double tray package is in a foil pouch which is in a carton. Upon receipt of the carton, inspect the exterior for signs of damage.

Each valve is contained in a carton with a temperature indicator displayed through a window on the side panel. The temperature indicator is intended to identify products that were exposed to transient temperature extremes. Upon receipt of the valve, immediately inspect the indicator and refer to the carton label to confirm a "Use" condition. If the "Use" condition is not apparent, do not use the valve and contact the local supplier or Edwards Lifesciences representative to make arrangements for return authorization and replacement.

WARNING: Carefully inspect the valve before implantation for evidence of extreme temperature exposure or other damage. Exposure of the valve to extreme temperatures will render the device unfit for use.

10.2 Storage

The TRIFORMIS RESILIA tricuspid valve, model 11300T, should be stored at 10 °C to 25 °C (50-77 °F), in the foil pouch and shelf carton.

11.0 Directions for Use

11.1 Physician Training

The techniques for implanting this valve are similar to those used for any stented surgical valve. No specific training or special facilities beyond that required for cardiac surgical procedures are required to implant the model 11300T.

The primary intended users are cardiac surgeons who perform these valve replacements and the staff (operating room nurses and technicians) responsible for preparation and implant of heart valves.

11.2 Sizing

WARNING: Valve holders and fragments of handles and sizers are not radiopaque and cannot be located by means of an external imaging device. Loose fragments in the vasculature have the potential to embolize.

CAUTION: Do not use other manufacturers' valve sizers, or sizers not listed above, to size the TRIFORMIS RESILIA tricuspid valve. Incorrect sizing may occur, which may result in valve damage, localized native tissue damage, and / or inadequate hemodynamic performance.

CAUTION: Examine sizers for signs of wear, such as dullness, cracking or crazing, prior to use. Replace sizer if any deterioration is observed. Continued use may result in fragmentation, embolization, and / or prolonged procedure.

Sizer model 1173B is used for sizing of the annulus for tricuspid procedures. The barrel of the sizer model 1173B indicates the external stent diameter at the base.

Sizer model 1173B is made of a transparent material to allow visualization of the subvalvular apparatus during sizing. Ensure no chord will be in the way of the struts.

CAUTION: Exercise special care when using sub-valvular apparatus preservation techniques to avoid chordae entrapment by a strut.

WARNING: Avoid oversizing the bioprosthesis. Oversizing may cause bioprosthesis damage or localized mechanical stresses, which may in turn injure the heart or result in leaflet tissue failure, stent distortion and regurgitation.

Sizing with barrel sizer model 1173B:

To size with barrel sizer model 1173B, pass the barrel portion of the sizer through the tricuspid annulus. Ensure the barrel portion is directly in plane of the tricuspid annulus and the sizer passes through the orifice without encroachment on the ventricular muscle to avoid oversizing of the bioprosthesis (Figure 15).

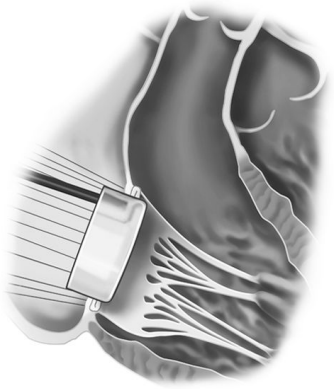


Figure 15

Consider valve dimensions, including external sewing ring diameter, when selecting appropriate valve size for patient annulus to ensure optimal fit.

Some techniques such as placement in an intra-annular position, use of pledgets, leaflet reefing, or tricuspid subvalvular apparatus preservation may further reduce the size of the tricuspid annulus which can result in the need for a smaller bioprosthesis to be implanted. When using these techniques, it is recommended to re-size the annulus to avoid oversizing of the bioprosthesis.

11.3 Handling and Preparation Instructions

WARNING: Check expiration date on packaging before use. Do not use product if expiration date has passed. This may result in compromised sterility.

WARNING: Do not open foil pouch into sterile field, the foil pouch is a protective cover only. The outer surface of the outer tray is not sterile and may compromise the sterile field. The innermost package tray is sterile and may be introduced into the sterile field.

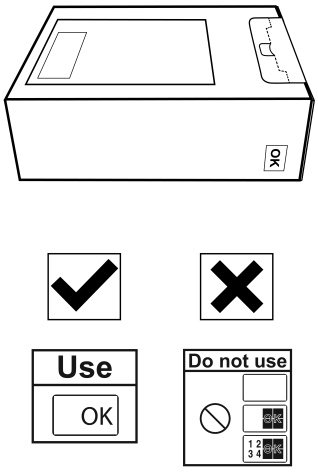
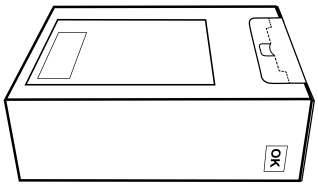
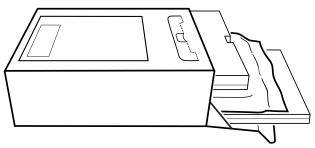
CAUTION: Do not open the TRIFORMIS RESILIA tricuspid valve, model 11300T package until implantation is certain.

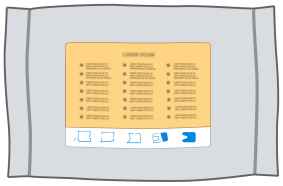
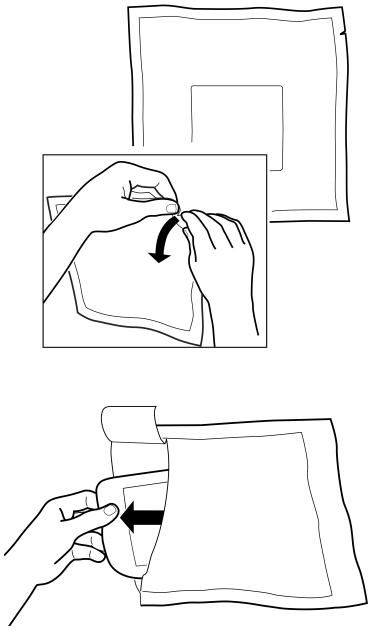
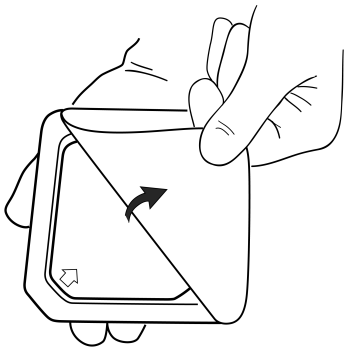
The model 11300T, DOES NOT REQUIRE RINSING prior to implantation.

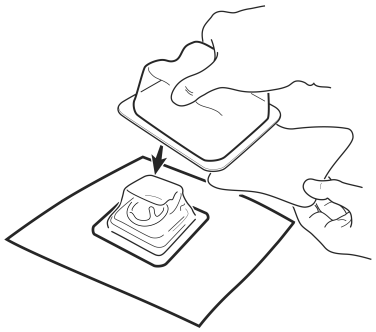
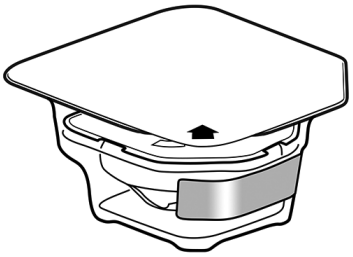
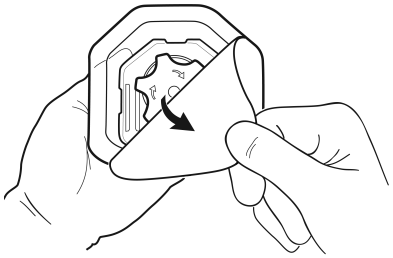
CAUTION: If the valve is rinsed prior to implantation, it must then be kept hydrated with sterile physiological saline irrigation on both sides of the leaflet tissue throughout the remainder of the surgical procedure. Rinsing every

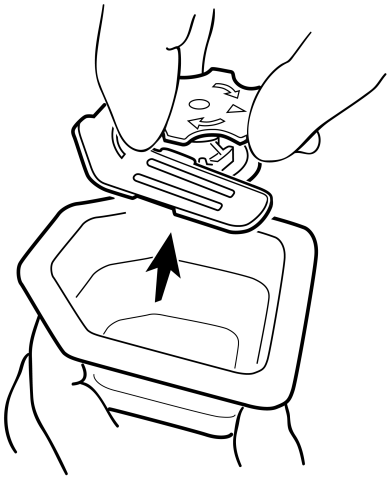
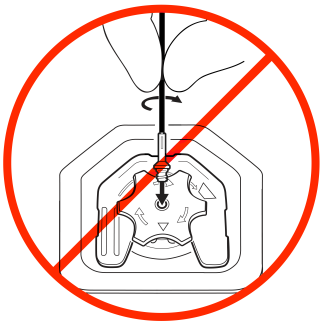
1 - 2 minutes is recommended, as tissue dehydration can lead to valve dysfunction.

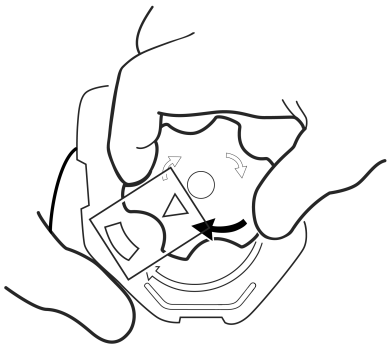
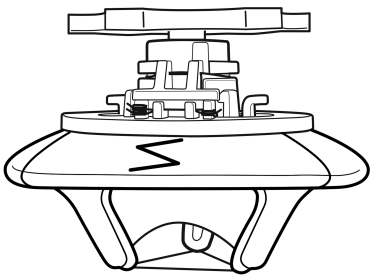
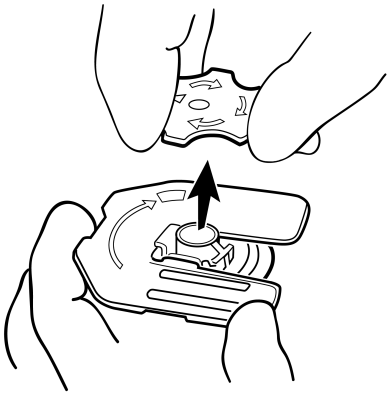
CAUTION: Avoid contact of the leaflet tissue with towels, linens, or other sources of particulate matter that may be transferred to the leaflet tissue.

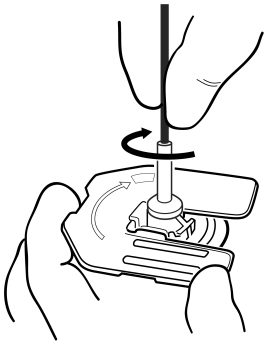
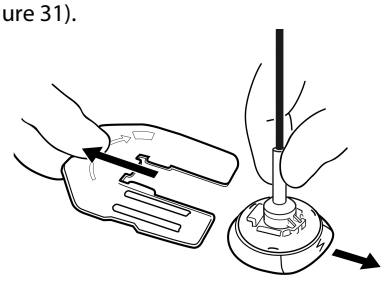
Step	Procedure
1	**Verify the TagAlert:** Verify that the TagAlert, visible through the shelf carton, indicates the valve is okay to use. Use the valve only if the TagAlert reads "OK" as shown in Figure 16.  **Figure 16**
2	**Examine the Shelf Carton Box:** Examine the package for evidence of damage and broken or missing seals (Figure 17).  **Figure 17**
3	**Open Carton Box and Remove Foil Pouch:** Once the appropriate size valve is chosen, open the carton and remove the foil pouch from the carton in the non-sterile field (Figure 18).  **Figure 18** Examine the foil pouch for evidence of damage and broken or missing seals. **Note: Review both sides of the foil pouch including the yellow label describing**

Step	Procedure
	aseptic transfer steps for the valve (Figure 19).  **Figure 19**
4	**Open Foil Pouch and Remove Outer Tray:** Open the foil pouch and remove the outer tray in non-sterile field. Examine the outer tray for evidence of damage and broken seals (Figure 20).  **Figure 20**
5	**Open the Outer Tray:** Near the sterile field, hold the base of the outer tray and peel the lid from the outer tray (Figure 21).  **Figure 21**

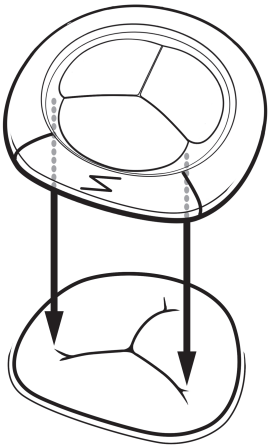
Step	Procedure
6	**Aseptic Transfer:** The inner tray and contents are sterile. Transfer the inner tray to the sterile field (Figure 22). The contents of the inner tray must be handled using a sterile surgical technique to prevent contamination.  **Figure 22**
7	**Silver Label Verification:** Verify that the serial number on the silver label matches with the shelf carton and Implant Data Card (Figure 23).  **Figure 23** **CAUTION: If any difference in serial number or size is noted, the valve should not be implanted. If the incorrect size valve is used, valve damage, localized native tissue damage, and/or inadequate hemodynamic performance may result.**
8	**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 24).  **Figure 24** **CAUTION: Do not open the inner package until implantation is certain and the surgeon is ready to place the valve.** **CAUTION: The valve is not secured to the inner tray. Care should be taken while peeling back the lid to prevent the valve from dislodging from the tray.**

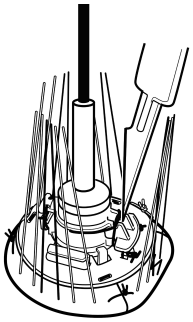
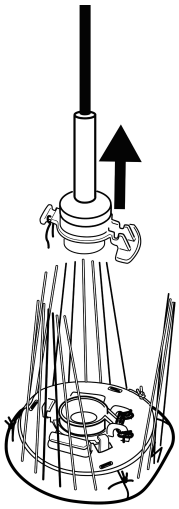
Step	Procedure
	Contamination, damage to the valve, and loss of sterility may result. **CAUTION: The valve does not require soaking. If the valve is rinsed prior to implantation, it must then be kept hydrated with sterile physiological saline irrigation on both sides of the leaflet tissue throughout the remainder of the surgical procedure. Rinsing every 1 – 2 minutes is recommended, as tissue dehydration can lead to valve dysfunction.**
9	**Remove valve from the inner tray (Figure 25).**  **Figure 25** **CAUTION: Do not try to insert the handle into the Dial (Figure 26).**  **Figure 26**
10	**Fold the Commissure Posts:** While holding the retainer, turn the dial clockwise (Figure 27) to fold the stent posts (Figure 28). The dial should be turned until the triangle on the dial is at the landing zone on the retainer and a hard stop is felt. **Note: It is normal to hear a clicking noise and feel some resistance when turning the dial.**

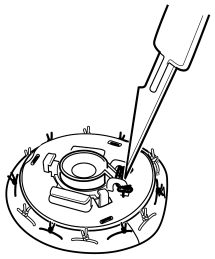
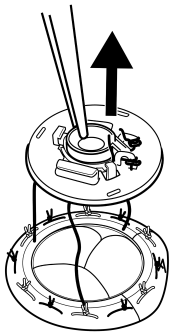
Step	Procedure
	 **Figure 27**  **Figure 28**
11	**Remove the Dial:** Remove the dial by pulling straight up on the dial (Figure 29). The dial will only be able to be removed when the triangle on the dial is within the landing zone on the retainer.  **Figure 29**

Step	Procedure
12	**Attach the Handle:** Attach the model 1140M or 1141M handle. To attach, align the handle with the adapter on the valve holder and turn clockwise until resistance is felt (Figure 30).  **Figure 30** **CAUTION: Do not grasp the valve with hands or surgical instruments.** **CAUTION: Use only Edwards model 1140M or 1141M handle. Use of non-Edwards handle may result in loose valve system attachment.** **CAUTION: Examine the handle for signs of wear, such as dullness, cracking or crazing, prior to use. Replace handle if any deterioration is observed. Continued use may result in fragmentation, embolization, or prolonged procedure.** **CAUTION: The handle/holder assembly is required for implantation and should not be removed until the valve is sutured to the annulus. This may result in improper seating of the valve.**
13	**Remove Retainer:** Hold the base of the model 1140M or 1141M handle and pull the retainer away by grasping the ridge on the narrow edge of the retainer (Figure 31).  **Figure 31**

11.4 Device Implantation

Step	Procedure
1	The surgeon should be familiar with the recommendations for proper sizing and placement (Refer to **Section 11.2 Sizing**). Because of the complexity and variation of tricuspid valve replacement surgery, the choice of surgical technique, appropriately modified in accordance with the previously described **Warnings**, is left to the discretion of the individual surgeon. In general, the following steps should be employed: a) Surgically remove the diseased or damaged valve leaflets and all associated structures deemed necessary. Alternatively, techniques of chordal preservation can be performed. **CAUTION: Exercise special care when using sub-valvular apparatus preservation techniques to avoid chordae entrapment by a strut.** b) Surgically remove any calcium from the annulus to ensure proper seating of the sewing ring of the valve. c) Measure the annulus using only the tricuspid sizer model 1173B (See Figure 2). Consider valve dimensions, including external sewing ring diameter, when selecting appropriate valve size for patient annulus to ensure optimal fit. d) Orient valve with "S" adjacent to septal annulus. e) Place sutures through the sewing cuff. Ensure proper seating of the TRIFORMIS RESILIA tricuspid valve. f) Tie sutures with the holder in place to minimize the potential for suture looping or chordal entrapment. **CAUTION: Do not remove the holder prior to seating the valve and tying the sutures to minimize the potential for suture looping or chordal entrapment.** g) Examine the bioprosthetic leaflets for distortion after removal of the holder. **CAUTION: Do not remove holder prior to parachuting valve for placement of valve.** **CAUTION: When choosing a valve for a given patient, the size, age, and physical condition of the patient in relation to the size of the valve must be taken into consideration to minimize the possibility of obtaining a suboptimal hemodynamic result. The size selection of a valve, however, must ultimately be made by the physician on an individual basis after carefully weighing all of the risks and benefits to the patient.** **CAUTION: Adequate removal of calcium deposits from the patient's annulus must be performed before implantation to avoid damage to the delicate bioprosthesis leaflet tissue as a result of contact with calcium deposits. Insert the sizer into the tricuspid annulus. The barrel of the sizer should always fit comfortably in the annulus (Refer to Section 11.2 Sizing).** **CAUTION: Use only sizer model 1173B during the selection of the valve size; other sizers may result in improper valve selection (Refer to Section 1.2 Sizers and Tray). Like other surgical valves, the TRIFORMIS RESILIA tricuspid valve, model 11300T is usually implanted using pledgeted mattress sutures. It is recommended to size the annulus after the sutures have been placed, as sutures may decrease the size of the bioprosthesis that can be implanted.**
2	**Proper orientation of the model 11300T for implantation in the tricuspid annulus:** The wireform frame of the model 11300T is symmetrical, and the three (3) commissure stent posts are equally spaced. The black commissure markers on the sewing ring are intended to aid in proper orientation as the sewing ring is designed for a specific orientation of the valve. Prior to suturing the valve, orient the valve such that the black "S" marking aligns with the septal portion of the tricuspid annulus (Figure 32). The black commissure markers approximate the posteroseptal and anteroseptal commissure.  **Figure 32** **Note: The intercommissural distance varies from patient to patient and the black commissure markers indicate approximate orientations.**
3	Place sutures through the sewing cuff. **CAUTION: Ensure suture placement is within the annulus to minimize injury to the right coronary artery.**
4	Use the handle to facilitate parachuting and positioning of the valve. Maintain tension on the sutures as the bioprosthesis is lowered; this minimizes the potential for the formation of suture loops that might entrap a leaflet.
5	Maintain the model 11300T tricuspid valve placement on the annulus by gently stabilizing the holder.

Step	Procedure
	Cut the retaining blue polymer thread on the septal side of the adapter with a scalpel (Figure 33). This enables removal of the handle and the adapter from the valve as one unit. Avoid cutting or damaging the stent or leaflet tissue when cutting the blue polymer thread.  **Figure 33**
6	Remove the handle and handle adapter by pulling handle away from the holder base (Figure 34).  **Figure 34** **CAUTION: The remaining part of the holder is required for implantation and should not be removed until the sutures are tied. Premature holder removal may result in prolonged procedure or suture looping.**
7	Tie the suture to secure the valve and cut the sutures above the knots. **CAUTION: Avoid looping or catching a suture around the commissure stent posts of the TRIFORMIS RESILIA tricuspid valve, model 11300T, which would interfere with proper valvular function. To minimize the potential for suture looping, it is essential to leave the deployed holder in place until all knots are tied.** **CAUTION: If the deployed holder attachment threads are cut before the sutures are tied down, the holder will no longer minimize the potential for suture looping around the commissure stent posts.**

Step	Procedure
	CAUTION: When using interrupted sutures, it is important to cut the sutures close to the knots and to ensure that exposed suture tails will not come into contact with the leaflet tissue. **CAUTION: Avoid placement of annular sutures deep into the adjacent tissue to avoid arrhythmias and conduction abnormalities. Avoid obstruction of right coronary artery when implanting in the tricuspid location.**
8	Cut the retaining blue polymer thread on the holder base at the single cut point at the septal side of the base. This unfolds the commissure stent posts (Figure 35).  **Figure 35** **CAUTION: The single cut point contains three (3) blue polymer threads. Ensure all three (3) blue polymer threads are cut to allow the holder to be removed from the valve. Do not cut blue polymer threads at any other location.**
9	Use forceps to grasp the blue component of the holder to remove the holder and retaining blue polymer thread from the valve (Figure 36).  **Figure 36**
10	After removing the holder, examine the leaflets for distortion and/or suture looped around a strut. It is recommended to place a surgical mirror through the leaflets after the holder removal in order to examine each strut and proper suture placement.

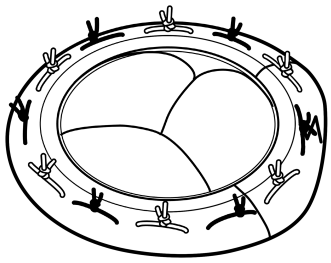


Figure 37

Figure 37 shows the TRIFORMIS RESILIA tricuspid valve implanted.

11.5 Accessory Cleaning and Sterilization

The accessories for the TRIFORMIS RESILIA tricuspid valve, model 11300T, are reusable and packaged separately. Handle models 1140M and 1141M and sizer model 1173B are supplied nonsterile and must be cleaned, disinfected, and sterilized in the tray base and lid before each use. Refer to the Instructions for Use supplied with the reusable accessories for cleaning and sterilization instructions.

11.6 Return of Valves

Edwards Lifesciences is interested in obtaining recovered clinical specimens of the TRIFORMIS RESILIA tricuspid valve, model 11300T, for analysis. Contact the local representative for return of recovered valves.

- Unopened Package with Sterile Barrier Intact: If the foil pouch or 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. If the valve is not implanted, it 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.
- 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.

11.7 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.

12.0 MRI Safety Information

MR Conditional

Non-clinical testing demonstrated that the model 11300T valve is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T only
- Maximum spatial gradient field of 3000 gauss/cm (30 T/m) or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg per 15 minutes of scanning (i.e. per pulse sequence)
- Normal mode operation of the MR system for both SAR and gradients.

Under the scan conditions above, the model 11300T valve is expected to produce a maximum temperature rise of 2 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the model 11300T valve when imaged with a gradient echo pulse sequence and a 3.0 tesla MRI system. Optimization of MR imaging parameters is recommended.

13.0 Patient Labeling

13.1 Patient Identification Card

A Patient Identification Card is provided to each patient implanted with the TRIFORMIS RESILIA tricuspid valve, model 11300T.

13.2 Patient Information

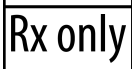
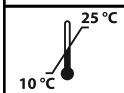
Patient information materials may be obtained from Edwards or an Edwards clinical sales specialist.

14.0 References

1. Otto CM, Nishimura RA, Bonow RO et al. 2020 ACC/AHA Guideline for the Management of Patients with Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines, Journal of the American College of Cardiology (2020), doi: 10.1161/ CIR. 0000000000000923
2. Candice Baldeo et al. Does chemo-radiation predispose to structural valve deterioration? International Journal of Cardiology 211 (2016) 53–54
3. Syed Wamique Yusuf, et al., Radiation-induced heart disease: a clinical update, Cardiol. Res. Pract. (2011), 317659, 9 pages
4. Thourani VH, Bonnell L, Wyler von Ballmoos MC, Mehaffey JH, Bowdish M, Kurlansky P, Jacobs JP, O'Brien S, Shahian DM, Badhwar V. Outcomes of Isolated Tricuspid Valve Surgery: A Society of Thoracic Surgeons Analysis and Risk Model. Ann Thorac Surg. 2024;118:873-881. doi: 10.1016/ j.athoracsur.2024.04.014
5. Hussain ST, Witten J, Shrestha NK, Blackstone EH, Pettersson GB. Tricuspid valve endocarditis. Ann Cardiothorac Surg. 2017;6:255-261. doi: 10.21037/acs.2017.03.09
6. Scotti A, Sturla M, Granada JF, Kodali SK, Coisne A, Mangieri A, Godino C, Ho E, Goldberg Y, Chau M, et al. Outcomes of isolated tricuspid valve replacement: a systematic review and meta-analysis of 5,316 patients from 35 studies. EuroIntervention. 2022;18:840-851. doi: 10.4244/ eij-d-22-00442
7. Kundi H, Popma JJ, Cohen DJ, Liu DC, Laham RJ, Pinto DS, Chu LM, Strom JB, Shen C, Yeh RW. Prevalence and Outcomes of Isolated Tricuspid Valve Surgery Among Medicare Beneficiaries. Am J Cardiol. 2019;123:132-138. doi: 10.1016/j.amjcard.2018.09.016
8. Moraca RJ, Moon MR, Lawton JS, Guthrie TJ, Aubuchon KA, Moazami N, Pasque MK, Damiano RJ, Jr. Outcomes of tricuspid valve repair and replacement: a propensity analysis. Ann Thorac Surg. 2009;87:83-88; discussion 88-89. doi: 10.1016/j.athoracsur.2008.10.003
9. Ejiofor JI, Neely RC, Yammine M, McGurk S, Kaneko T, Leacche M, Cohn LH, Shekar PS. Surgical outcomes of isolated tricuspid valve procedures: repair versus replacement. Ann Cardiothorac Surg. 2017;6:214-222. doi: 10.21037/ acs.2017.05.02

Symbol Legend

	ISO Reg. No.[1]	English
	N/A	Model Number
	0434A	Caution
	N/A	MR Conditional
	1051	Do not re-use
	N/A	Quantity
	2607	Use-by date
	2497	Date of manufacture
	2498	Serial Number
	2724	Non-pyrogenic
	N/A	Medical Device
	N/A	Unique device identifier
	N/A	Size

	ISO Reg. No.[1]	English
	2501	Sterilized using ethylene oxide
	2606	Do not use if package is damaged and consult instructions for use
	N/A	Caution: US law restricts this device to sale by or on the order of a physician.
	1641	Consult instructions for use on the website
	1641	Consult instructions for use
	3699	Contains biological material of animal origin
	3723	Contains hazardous substances
	3082	Manufacturer
	0632	Temperature limit
	N/A	Use product if indication is shown
	N/A	Do not use product if indication is shown
	3704	Double sterile barrier system
	N/A	Work Order

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

[1] ISO 7000 *Graphical symbols for use on medical equipment - Registered symbols*

2026-04
10060260001 A

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU