Lessons learned from 800+ patients treated with tricuspid TEER

The TRILUMINATE Pivotal trial

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Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Abbott, Edwards LifeSciences, W.L. Gore
Consultant Fees/Honoraria	Abbott, AngioDynamics, Biosense Webster, Boston Scientific, Edwards LifeSciences, Medtronic, Philips, Siemens, W.L. Gore
Individual Stock(s)/Stock Options	N/A
Royalties/Patent Beneficiary	N/A
Executive Role/Ownership Interest	N/A
Other Financial Benefit	N/A

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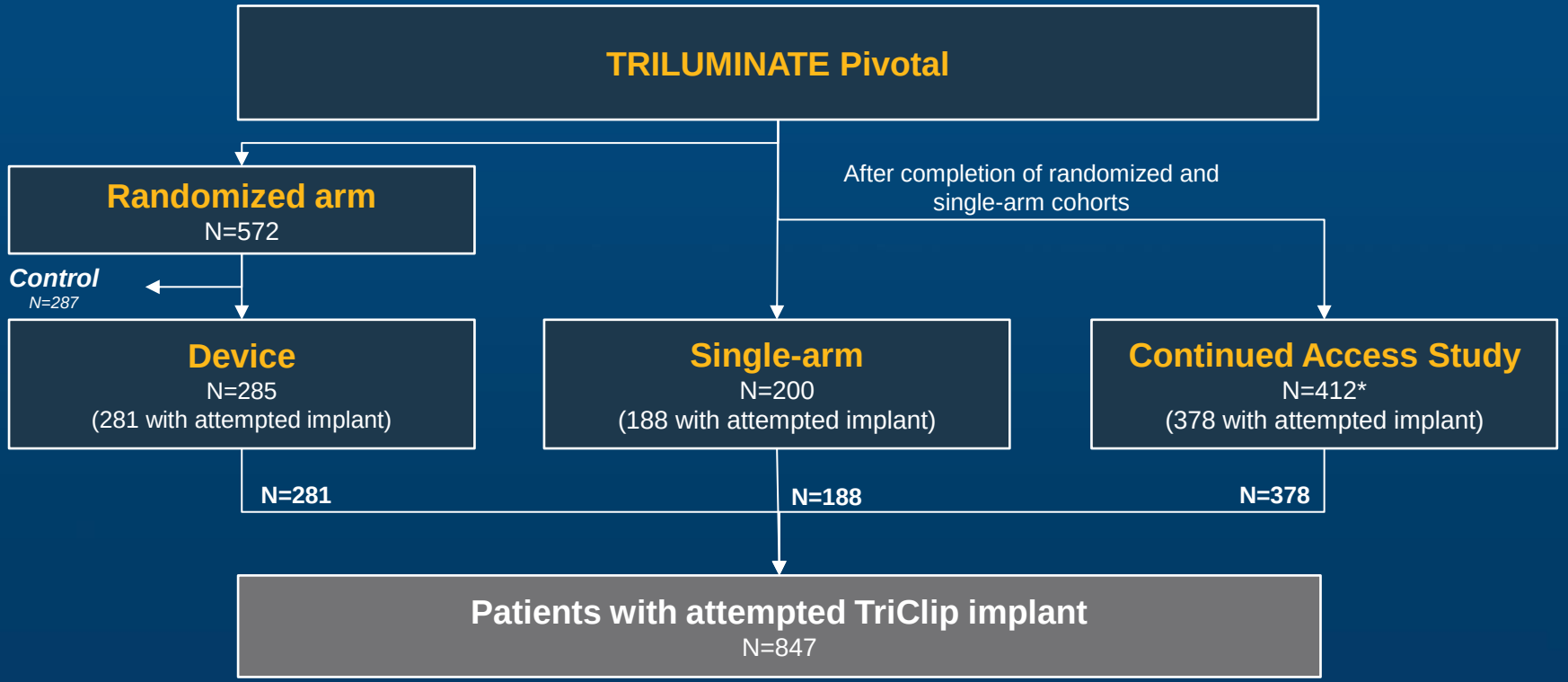
Background

- The TRILUMINATE Pivotal trial is a randomized, controlled trial of the treatment of symptomatic patients with severe TR with the TriClip device and includes a concurrent single-arm cohort.
  - Primary endpoint at 1 year was met, driven by improvements in quality of life.
  - At 2 years, a 28% relative risk reduction in heart failure hospitalizations was observed with TriClip compared to GDMT alone.
- Upon completion of the randomized trial, a continued access study was initiated, with 30-day follow-up now available.

Aim: To assess short-term outcomes in all patients with an attempted TriClip implant from the TRILUMINATE Pivotal trial.

The TRILUMINATE Pivotal trial was funded by Abbott; ClinicalTrials.gov number, NCT03904147.

Study Design



*Discrepancy between number enrolled and attempted in CAS due to study ending after TriClip approval.

Baseline Characteristics

Baseline Characteristic	Attempted Implant N=847
Age (years)	79 ± 8
Sex (female)	59%
Atrial fibrillation	85%
Hypertension	85%
HFH in previous 1 year	26%
CRT/CRT-D/ICD/Permanent pacemaker	27%
Prior mitral or aortic intervention	39%
Liver disease	8%
Renal disease	37%
NYHA III/IV	56%
KCCQ-OS Score	56 ± 22
6MWD (m)	240 ± 118

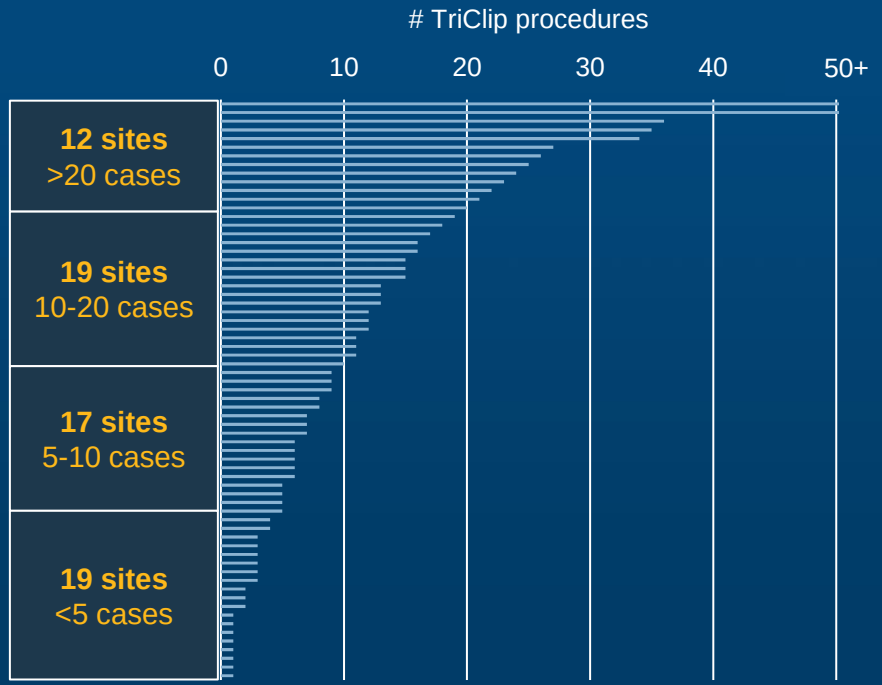
Baseline Characteristic	Attempted Implant N=847
TR etiology	
Functional	90%
Degenerative	3%
Mixed	4%
CIED lead-related	3%
Coaptation gap (mm)	6 ± 3
RVEDD, base (cm)	5.1 ± 0.8
RV TAPSE (cm)	1.5 ± 0.5
RV FAC (%)	36 ± 7
Right atrial volume (mL)	149 ± 85
Tricuspid annulus diameter (cm)	4.3 ± 0.7
LVEF (%)	58 ± 10

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Procedural Outcomes

Procedural Characteristic	Attempted Implant N=847
Implant success	98.7%
Number of clips implanted	2.0 ± 0.7
TriClip generation	
TriClip	18%
TriClip G4	82%
Procedure time (minutes)	146 ± 73
Device time (minutes)	82 ± 58
Length of hospital stay (days, median IQR)	1.0 (1.0, 1.0)
Discharge status	
Home	96.2%
Rehabilitation center	1.9%
Nursing home	1.4%
Death	0.2%
Other	0.2%

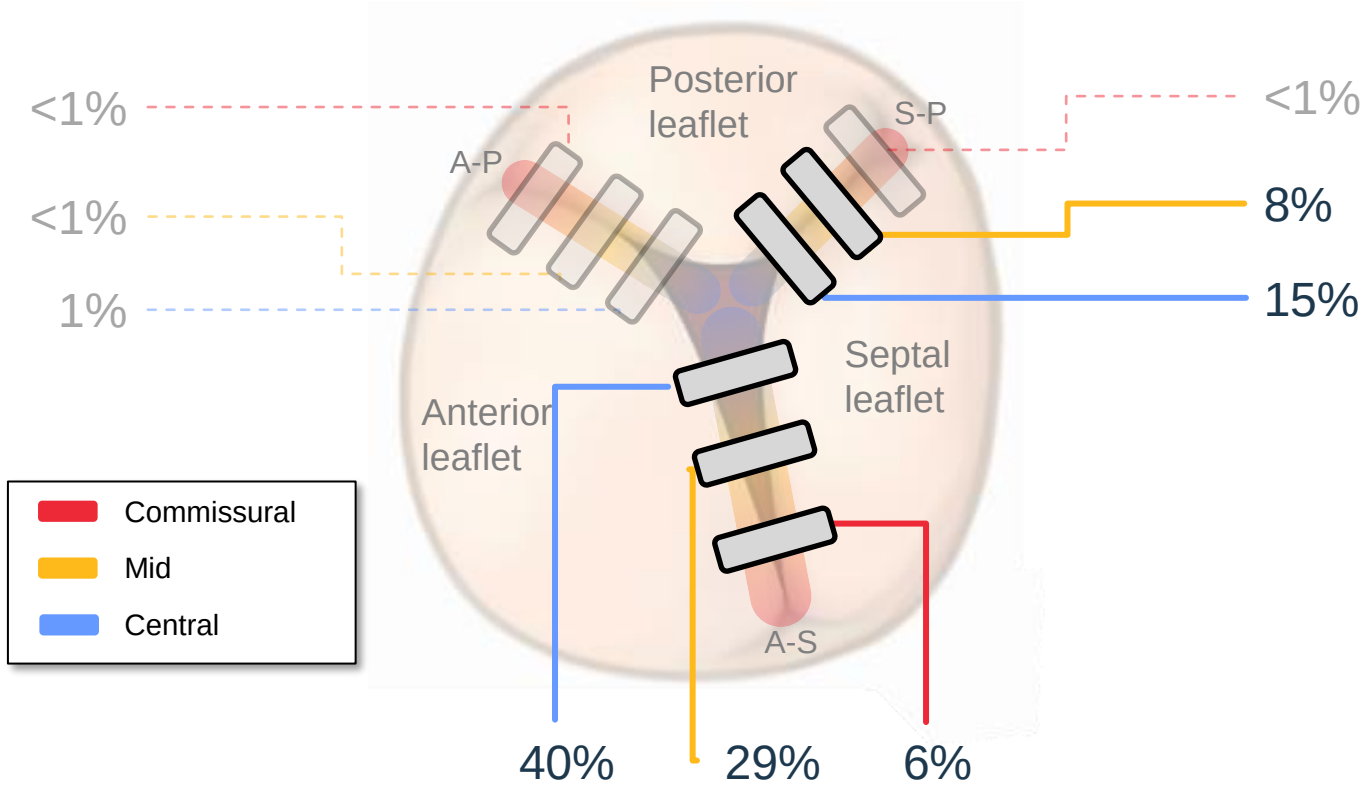


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TRILUMINATE™ PIVOTAL TRIAL

TriClip Frequently Placed Along A-S & P-S

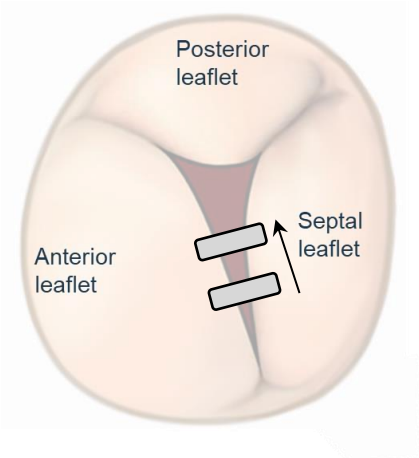


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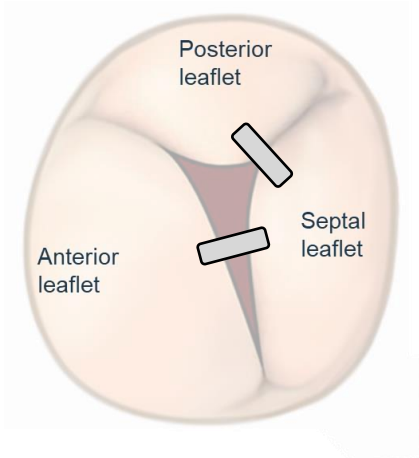
Most Common Clipping Strategies

Zipper
30% (252/847)



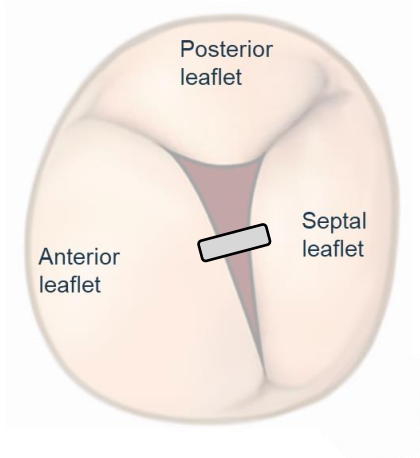
Multiple Clips along a single coaptation line, moving from a commissural location towards the center

Multi-Plane
24% (203/847)



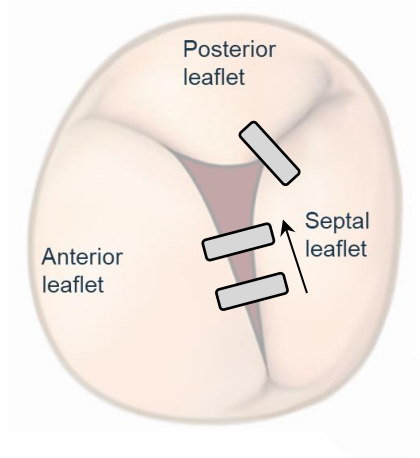
Single Clips along different coaptation lines

Single Clip
19% (163/847)



Single Clip along any coaptation line

Mixed
11% (94/847)



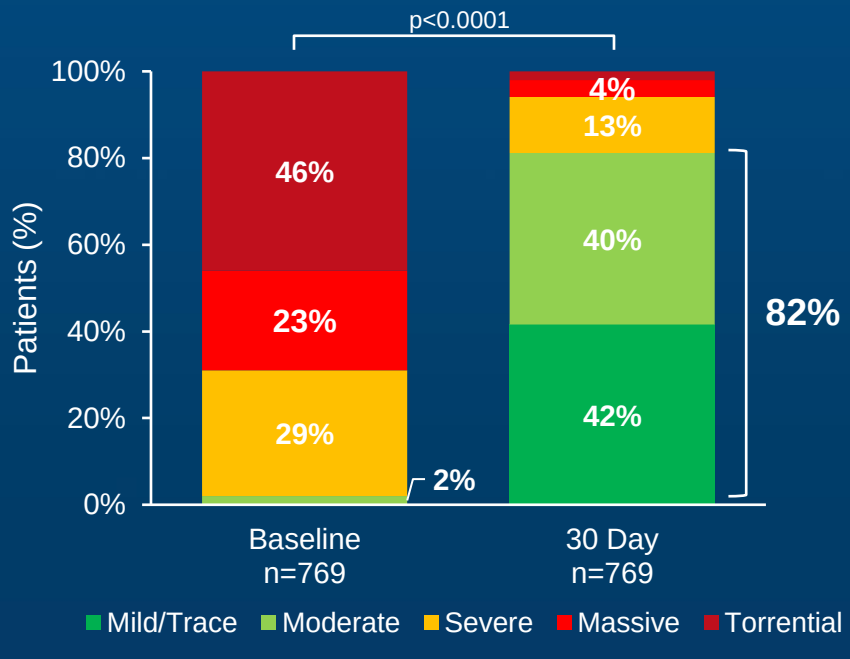
Zipper + Multi-Plane

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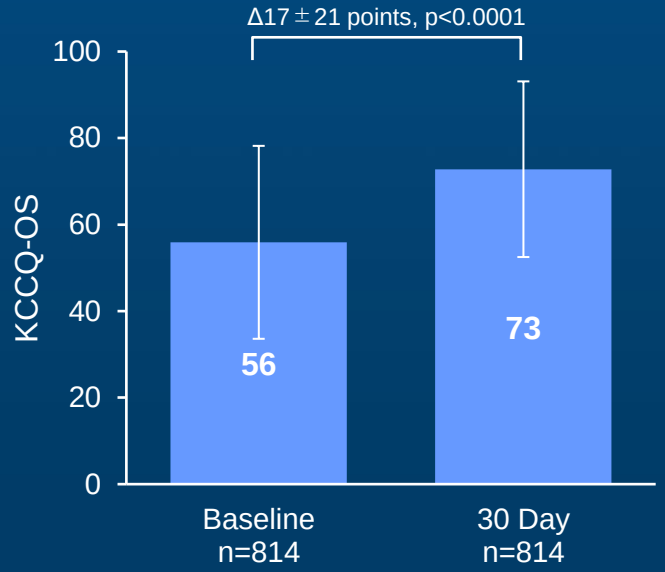
TR and KCCQ after T-TEER

TR Severity



1 grade reduction: 18% **≥2 grade reduction: 77%**

KCCQ



Paired data shown.

Adverse Events through 30 Days

Adverse Events through 30 Days	Attempted Implant N=847
Major adverse events through 30 days	0.6%
Cardiovascular mortality	0.4%
New-onset renal failure	0.2%
Non-elective cardiac surgery	0%
Endocarditis requiring surgery	0%
Major bleeding	3%
Device embolization	0.1%
Single leaflet device attachment	6.7%
Device thrombosis	0%
New conduction disturbance requiring PPM[1]	0.2%
Lead revision/replacement/removal[2]	0.4%

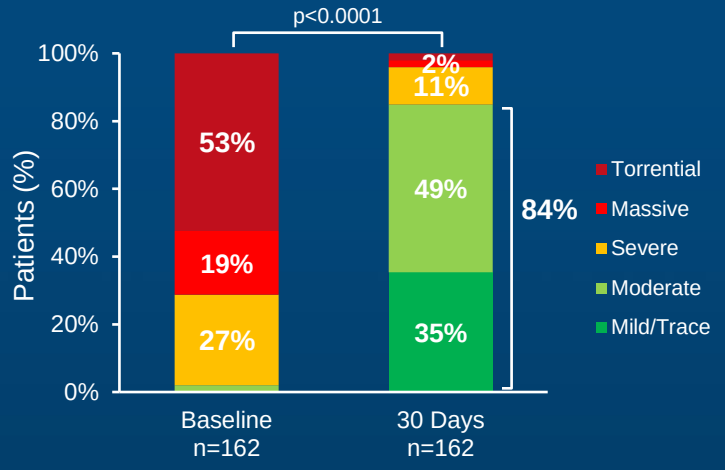
Adverse Events through 30 Days	Attempted Implant N=847
All-cause mortality	0.5%
Heart failure hospitalization	3.0%
Myocardial infarction	0%
Tricuspid valve surgery	0.2%
Tricuspid valve intervention	0.6%
Transient ischemic attack	0%
Stroke (VARC II)	0.2%
Cardiogenic shock	0.4%
Pericardial effusion	0%

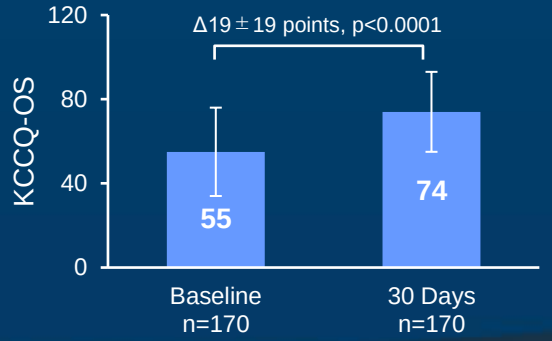
[1]In pacemaker naïve patients.
[2]In patients with pre-existing pacemaker (N=225)

Outcomes in Patients with Transvalvular CIED Leads

Characteristic	Patients with transvalvular CIED leads N=175
Major adverse events through 30 days	
Cardiovascular death	0.6%
Endocarditis requiring surgery	0%
New onset renal failure	0%
Non-elective CV surgery for TriClip-related AE	0%
Length of hospital stay (days, median, IQR)	1 (1,1)
Major bleeding (through 30 days)	3%
Tricuspid valve surgery	0.6%
Tricuspid valve re-intervention	1%
SLDA	5%
Embolization	0%
CIED lead revision/replacement/removal[1]	0.6%

[1]Right atrial lead displaced in one patient, required placement of a new ICD.





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Outcomes Across Experience

Outcome through 30 days	Cases 1-5 N=318	Cases 6-10 N=220	Cases ≥10 N=450
Procedural Outcomes			
Procedure time	177 ± 76	165 ± 89	127 ± 56
Device time	106 ± 74	92 ± 60	69 ± 45
Number of clips implanted	2.2 ± 0.8	2.1 ± 0.7	2.0 ± 0.7
ICU admission	15%	10%	6%
Safety Outcomes			
All-cause Mortality	0.6%	0.5%	0.4%
Major bleeding	6%	2%	2%
Tricuspid valve reintervention	2.2%	0.5%	0.2%
New pacemaker	0.3%	0%	0%
Major adverse events	1.3%	0.5%	0.4%
Effectiveness			
Moderate or less TR	74%	84%	83%
TR grade reduction	2.3 ± 1.1	2.6 ± 1.1	2.2 ± 1.1

Roll-in data included.

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Conclusion

In the largest analysis of early T-TEER to date, TriClip was safe and effective, with significant improvements in qualify of life at 30 days.

- Low rates of mortality, heart failure hospitalizations, bleeding, conduction disturbances and device thrombosis through 30 days
- Safe and effective in patients with transvalvular CIED leads, with similar TR reduction versus non-CIED patients
- Improved procedural and device time with experience

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Rx Only

Important Safety Information

TRICLIP™ G5 SYSTEM

Indications
The TriClip™ G5 System is indicated for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, who are at intermediate or greater risk for surgery and in whom transcatheter edge-to-edge valve repair is clinically appropriate and is expected to reduce tricuspid regurgitation severity to moderate or less, as determined by a multidisciplinary heart team.

Contraindications
The TriClip™ G5 System is contraindicated for use in patients with the following conditions: Intolerance, including allergy or untreatable hypersensitivity, to procedural anticoagulation; Untreatable hypersensitivity to Implant components (nickel-titanium alloy, cobalt-chromium alloy); Active endocarditis or other active infection of the tricuspid valve.

Potential Adverse Events
The following events have been identified as possible complications of the TriClip™ G5 Procedure. Allergic reactions or hypersensitivity to latex, contrast agent, anaesthesia, device materials and drug reactions to anticoagulation, or antiplatelet drugs; Additional treatment / surgery from device-related complications; Bleeding; Blood disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT)); Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias); Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, unstable angina, and stable angina); Cardiac perforation; Cardiac tamponade; Chest pain; Death; Dyspnea; Edema; Embolization (device or components of the device); Endocarditis; Fever or hyperthermia; Fluoroscopy and Transesophageal echocardiogram (TEE) -related complications: Skin injury or tissue changes due to exposure to ionizing radiation, Esophageal irritation, Esophageal perforation, Gastrointestinal bleeding; Hypotension / hypertension; Infection including: Septicemia; Nausea or vomiting; Pain; Pericardial effusion; Stroke / cerebrovascular accident (CVA) and transient ischemic attack (TIA); System organ failure: Cardio-respiratory arrest, Worsening heart failure, Pulmonary congestion, Respiratory dysfunction or failure or atelectasis, Renal insufficiency or failure, Shock (including cardiogenic and anaphylactic); Thrombosis; Tricuspid valve complications, which may complicate or prevent later surgical repair, including: Chordal entanglement / rupture, Single leaflet device attachment (SLDA), Dislodgement of previously implanted devices, Tissue damage, Tricuspid valve stenosis, Worsening, persistent or residual regurgitation; Vascular access complications which may require additional intervention, including: Wound dehiscence, Bleeding of the access site, Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation (rupture), vascular occlusion, Embolism (air, thrombus), Peripheral nerve injury; Venous thrombosis (including deep vein thrombosis) and thromboembolism (including pulmonary embolism).

CAUTION: Product(s) intended for use by or under the direction of a physician. Prior to use, reference to the Instructions for Use, inside the product carton (when available) or at www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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