

MitraClip™

Transcatheter Mitral Valve Repair

EVERY PATIENT IS UNIQUE

THE ONLY TAILORED THERAPY
MITRACLIP™ G4



NT

NTW

XT

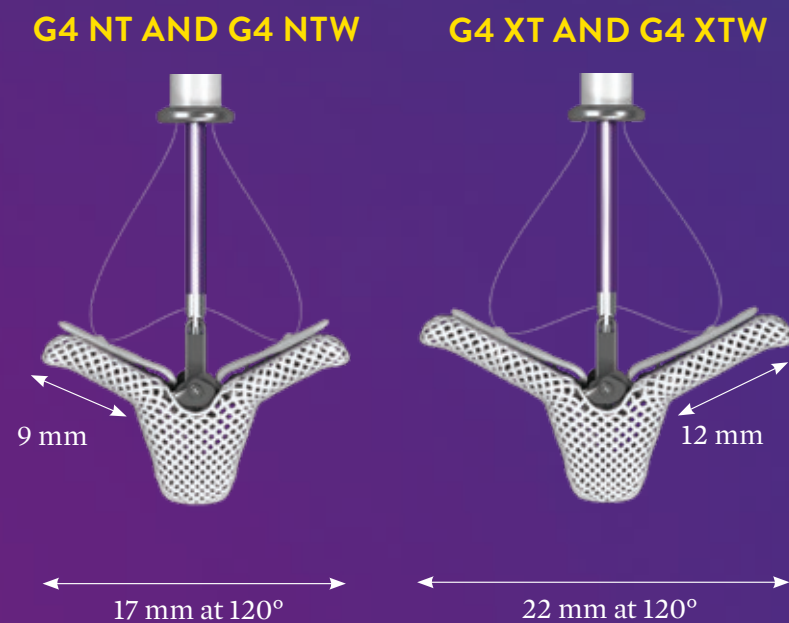
XTW

See Important Safety Information referenced within.



TAILOR YOUR TREATMENT. OPTIMIZE YOUR OUTCOMES.

EXPANDED PORTFOLIO OF CLIP SIZES

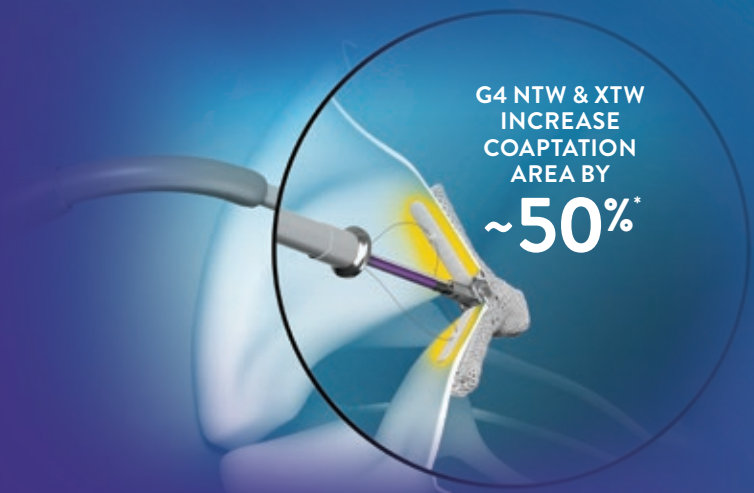


CHOOSE CLIP SIZE BASED ON EACH MITRAL VALVE ANATOMY

ANATOMICAL CONSIDERATIONS		FAVORS G4 NTW	FAVORS G4 NT	FAVORS G4 XTW	FAVORS G4 XT
LENGTH OF MOBILE LEAFLET IN GRASPING ZONE	Leaflet Length < 9 mm	+	+		
	Leaflet Length ≥ 9 mm			+	+
WIDTH OF JET	Broad jet	+		+	
VALVE AREA	Smaller Valve		+		
	Larger Valve	+		+	+

MitraClip G4 Clip Selection recommendations are based on the clinical experience of physicians. The EXPAND G4 observational study evaluates adherence to Clip Size Selection Recommendations and their associated outcomes.

DESIGNED TO FURTHER REDUCE MITRAL REGURGITATION WITH A SINGLE CLIP*



“ **ALLOWS US TO TREAT
PATIENTS WITH 1 CLIP
MORE OFTEN THAN BEFORE.**
Echocardiographer with 6 years of
MitraClip experience, commenting
on MitraClip G4

CONFIRM AND OPTIMIZE LEAFLET GRASPING

CONTROLLED GRIPPER ACTUATION (CGA)

INCREASED EFFICIENCY

STREAMLINED PROCEDURE

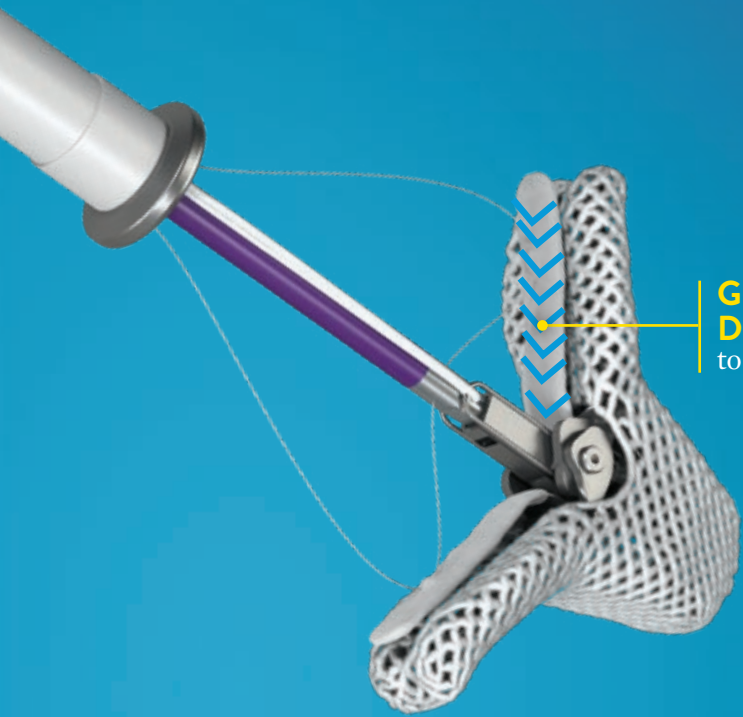
NEW GRIPPER LEVERS



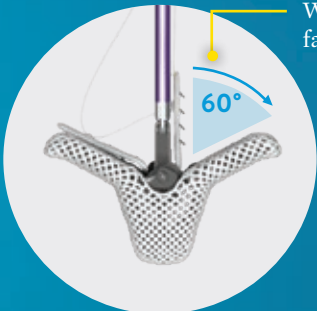
BOTH GRIPPERS LOWERED



ONE GRIPPER LOWERED



GRIPPERS DESIGNED TO DISTRIBUTE RETENTION FORCE
to grasp leaflet with confidence



Wide grasping opening to facilitate full leaflet insertion

60°

13% REDUCTION IN CLIPS IMPLANTED PER PROCEDURE*



1.4 IMPLANTED CLIP RATE

11% SHORTER PROCEDURAL TIME*



50 MIN. AVERAGE DEVICE TIME

“ IN OUR INSTITUTE, WE HAVE NOW REDUCED DEVICE TIME TO ~20 MIN.
Echocardiographer with 6 years of MitraClip experience, commenting on MitraClip G4

SIMPLIFIED PROCEDURAL STEPS¹

- 40% reduction in system preparation steps
- Simplified system deployment with reduced number of steps



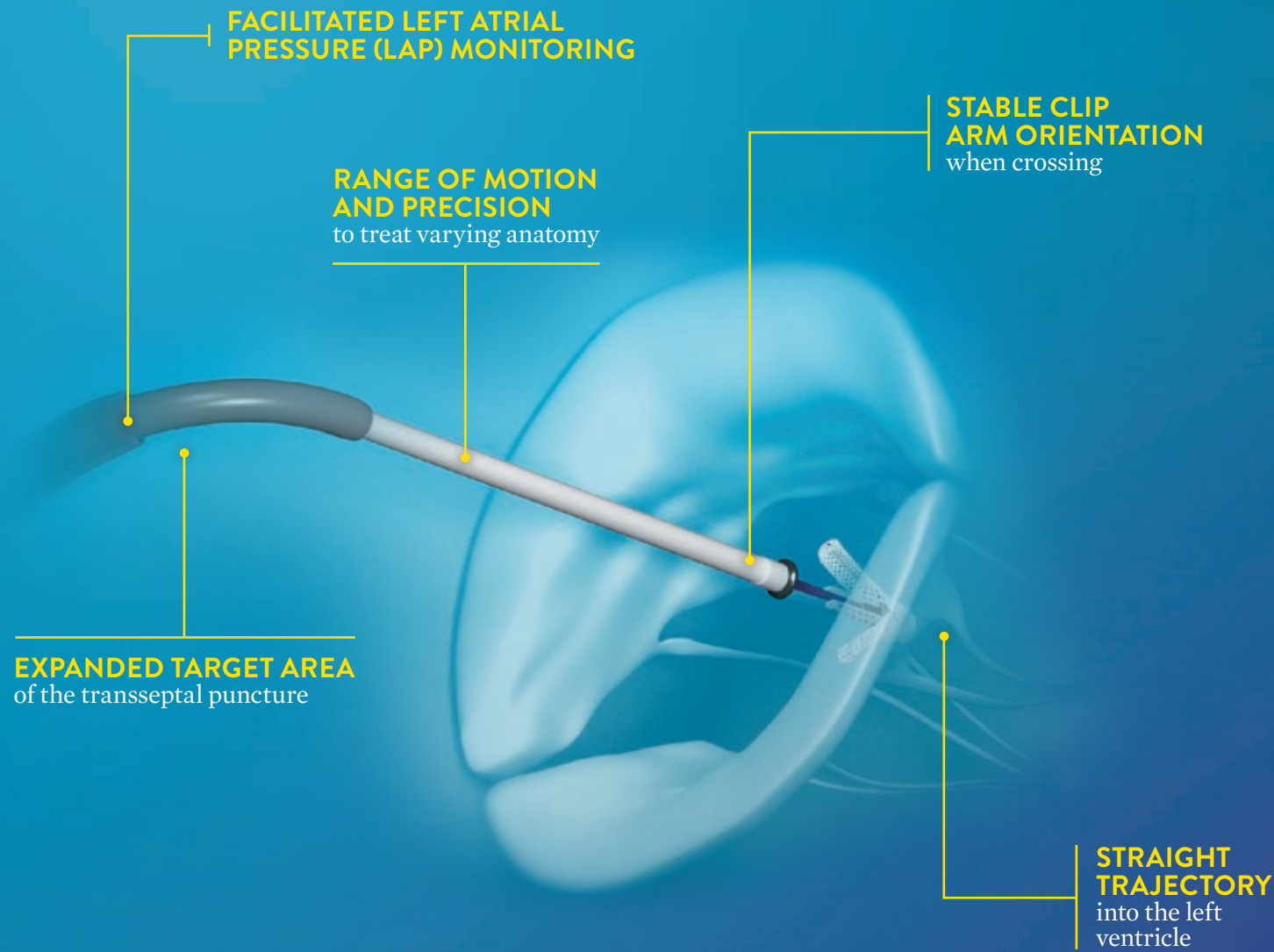
SIMULTANEOUS
Clip and Gripper Line detachment

4 See Important Safety Information referenced within.

The testimonial does not provide any indication, guide, warranty or guarantee as to the response patients may have to the treatment or effectiveness of the product or therapy in discussion. Opinions about the treatment discussed can and do vary and are specific to the individual's experience and might not be representative of others.

*Data on File at Abbott.

PRECISION AND CONTROL.
DELIVERY SYSTEM DESIGNED
SPECIFICALLY FOR MV REPAIR



FIRST AND FOREMOST.
EVERY TIME. OVER TIME.

OVER 16

YEARS OF CLINICAL EXPERIENCE*

OVER 100K

PATIENTS TREATED WORLDWIDE*

OVER 30K

PATIENTS STUDIED IN CLINICAL TRIALS*

MOST EXPERIENCED

FIELD & TRAINING TEAM

MITRACLIP™ IS THE ONLY PROVEN TMV** THERAPY THAT GIVES YOU CONFIDENCE IN:

SAFETY

96.6% freedom from device-related complications at 12 mths²

EFFICACY

- 87% MR ≤1+; 97% ≤2+ at 30 days in PMR patients³
- 99% MR ≤2+ at 24 mths in SMR patients²

DURABILTY

Only TMV device with proven durable outcomes to 5+ years⁴

SURVIVAL

- Lowest 30-day mortality reported to date in large scale studies⁵
- Only MV Device shown to improve survival in HF Patients with SMR²

QUALITY OF LIFE

2.5X more likely to experience a large improvement in health-related QOL^{6†}

*Data on File at Abbott.
**Transcatheter Mitral Valve.
†Large is defined as ≥20 pt difference in KCCQ-OS score.

MitraClip™
Transcatheter Mitral Valve Repair

MITRACLIP CLIP
DELIVERY SYSTEMS

INDICATIONS FOR USE

- The MitraClip™ G4 System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.
 - The MitraClip™ G4 System, when used with maximally tolerated guideline-directed medical therapy (GDMT), is indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (or functional) mitral regurgitation (MR; MR ≥ Grade III per American Society of Echocardiography criteria) in patients with a left ventricular ejection fraction (LVEF) ≥ 20% and ≤ 50%, and a left ventricular end systolic dimension (LVESD) ≤ 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a multidisciplinary heart team experienced in the evaluation and treatment of heart failure and mitral valve disease.
- Read all instructions carefully. Use universal precautions for biohazards and sharps while handling the MitraClip™ G4 System to avoid user injury. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury, including:
 - MitraClip™ G4 Implant erosion, migration or malposition
 - Failure to deliver MitraClip™ G4 Implant to the intended site
 - Difficulty or failure to retrieve MitraClip™ G4 system components
 - Use caution when treating patients with hemodynamic instability requiring inotropic support or mechanical heart assistance due to the increased risk of mortality in this patient population. The safety and effectiveness of MitraClip™ in these patients has not been evaluated.
 - Patients with a rotated heart due to prior cardiac surgery in whom the System is used may have a potential risk of experiencing adverse events such as atrial perforation, cardiac tamponade, tissue damage, and embolism which may be avoided with preoperative evaluation and proper device usage.
 - For the Steerable Guide Catheter and Delivery Catheter only:
 - The Guide Catheter: the distal 65 cm of the Steerable Guide Catheter with the exception of the distal soft tip, is coated with a hydrophilic coating.
 - The Delivery Catheter: coated with a hydrophilic coating for a length of approximately 131 cm.
 - Failure to prepare the device as stated in these instructions and failure to handle the device with care could lead to additional intervention or serious adverse event.
 - The Clip Delivery System is provided sterile and designed for single use only. Cleaning, re-sterilization and / or re-use may result in infections, malfunction of the device and other serious injury or death.
 - Note the product “Use by” date specified on the package.
 - Inspect all product prior to use. Do not use if the package is open or damaged, or if product is damaged.

CONTRAINDICATIONS

The MitraClip™ G4 System is contraindicated in patients with the following conditions:

- Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or post procedural anti-platelet regimen
- Patients with known hypersensitivity to clip components (nickel / titanium, cobalt, chromium, polyester), or with contrast sensitivity
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

WARNINGS

- DO NOT use MitraClip™ outside of the labeled indication.**
- The MitraClip™ G4 Implant should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g.,

IMPORTANT SAFETY
INFORMATION

transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.

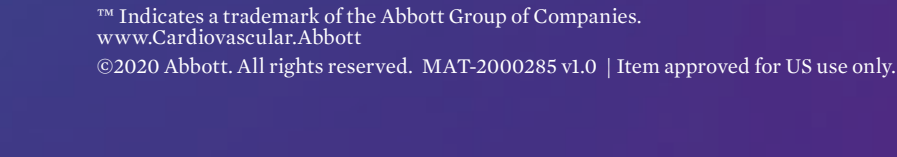
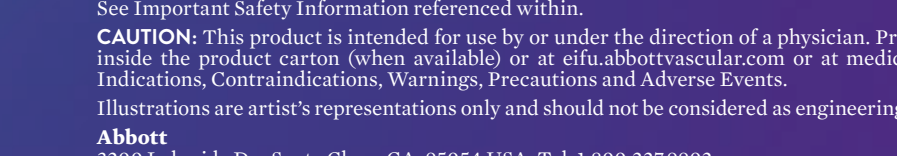
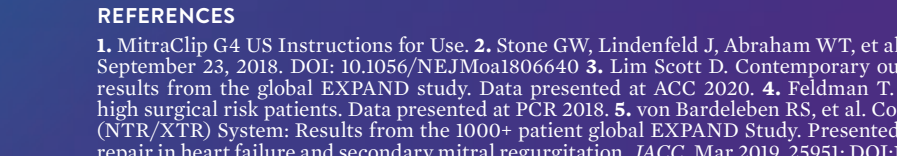
PRECAUTIONS

- Prohibitive Risk Primary (or degenerative) Mitral Regurgitation
 - Prohibitive risk is determined by the clinical judgment of a heart team, including a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, due to the presence of one or more of the following documented surgical risk factors:
 - 30-day STS predicted operative mortality risk score of
 - ≥8% for patients deemed likely to undergo mitral valve replacement or
 - ≥6% for patients deemed likely to undergo mitral valve repair
 - Porcelain aorta or extensively calcified ascending aorta.
 - Frailty (assessed by in-person cardiac surgeon consultation)
 - Hostile chest
 - Severe liver disease / cirrhosis (MELD Score > 12)
 - Severe pulmonary hypertension (systolic pulmonary artery pressure > 2/3 systemic pressure)
 - Unusual extenuating circumstance, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapy for malignancy, major bleeding diathesis, immobility, AIDS, severe dementia, high risk of aspiration, internal mammary artery (IMA) at high risk of injury, etc.
 - Evaluable data regarding safety or effectiveness is not available for prohibitive risk primary patients with an LVEF < 20% or an LVESD > 60 mm. MitraClip™ should be used only when criteria for clip suitability for primary have been met.
 - The heart team should include a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease and may also include appropriate physicians to assess the adequacy of heart failure treatment and valvular anatomy.
- Secondary Mitral Regurgitation
 - Evaluable data regarding safety or effectiveness is not available for secondary MR patients with an LVEF < 20% or an LVESD > 70 mm.
 - The multidisciplinary heart team should be experienced in the evaluation and treatment of heart failure and mitral valve disease and determine that symptoms and MR severity persist despite maximally tolerated GDMT.

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

The following ANTICIPATED EVENTS

have been identified as possible complications of the MitraClip™ G4 procedure. Death; Allergic reactions or hypersensitivity to latex, contrast agent, anaesthesia, device materials (nickel / titanium, cobalt, chromium, polyester), and drug reactions to anticoagulation, or antiplatelet drugs; Vascular access complications which may require transfusion or vessel repair including: wound dehiscence, catheter site reactions, Bleeding (including ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage), Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, vascular occlusion, Emboli (air thrombotic material, implant, device component), Peripheral Nerve Injury; Lymphatic complications; Pericardial complications which may require additional intervention, including: Pericardial effusion, Cardiac tamponade, Pericarditis; Cardiac complications which may require additional interventions or emergency cardiac surgery, including: Cardiac perforation, Atrial septal defect; Mitral valve complications, which may complicate or prevent later surgical repair, including: Chordal entanglement / rupture, Single Leaflet Device Attachment (SLDA), Thrombosis, Dislodgement of previously implanted devices, Tissue damage, Mitral valve stenosis, Persistent or residual mitral regurgitation, Endocarditis; Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias); Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, and unstable / stable angina); Venous thromboembolism (including deep vein thrombosis, pulmonary embolism, post procedure pulmonary embolism); Stroke / Cerebrovascular accident (CVA) and Transient Ischemic Attack (TIA); System organ failure: Cardio-respiratory arrest, Worsening heart failure, Pulmonary congestion, Respiratory dysfunction / failure / atelectasis, Renal insufficiency or failure, Shock (including cardiogenic and anaphylactic); Blood cell disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT)); Hypotension / hypertension; Infection including, Urinary Tract Infection (UTI), Pneumonia, Septicemia, Nausea / vomiting; Chest pain; Dyspnea; Edema; Fever or hyperthermia; Pain; Fluoroscopy, Transesophageal echocardiogram (TEE) and Transthoracic echocardiogram (TTE) –related complications: Skin injury or tissue changes due to exposure to ionizing radiation, Esophageal irritation, Esophageal perforation, Gastrointestinal bleeding.



For more information about MitraClip™ G4, please speak with your Abbott representative, or visit MitraClip.com.

REFERENCES

1. MitraClip G4 US Instructions for Use. **2.** Stone GW, Lindenfeld J, Abraham WT, et al. Transcatheter mitral valve repair in patients with heart failure. *N Engl J Med*. September 23, 2018. DOI: 10.1056/NEJMoal806640 **3.** Lim Scott D. Contemporary outcomes with MitraClip™ (NTR/XTR) System in primary mitral regurgitation: results from the global EXPAND study. Data presented at ACC 2020. **4.** Feldman T. The EVEREST II REALISM Continued Access Study: Five-year outcomes in high surgical risk patients. Data presented at PCR 2018. **5.** von Bardeleben RS, et al. Contemporary, real-world, clinical outcomes with the next generation MitraClip™ (NTR/XTR) System: Results from the 1000+ patient global EXPAND Study. Presented at ESC 2019. **6.** Arnold SV, et al. Health status after transcatheter mitral valve repair in heart failure and secondary mitral regurgitation. *JACC*. Mar 2019, 25951; DOI:10.1016/j.jacc.2019.02.010.

See Important Safety Information referenced within.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist’s representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Abbott
3200 Lakeside Dr., Santa Clara, CA. 95054 USA, Tel: 1.800.227.9902

™ Indicates a trademark of the Abbott Group of Companies.
www.Cardiovascular.Abbott

©2020 Abbott. All rights reserved. MAT-2000285 v1.0 | Item approved for US use only.

