MITRACLIP™ CODING AND PAYMENT GUIDE

MitraClip™ Transcatheter Mitral Valve Repair

MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

Medicare Information

Medicare Coverage

CMS provides coverage for TMVr under Coverage with Evidence Development[1]. Among the coverage criteria specified in this National Coverage Determination (NCD):

- Treatment of significant symptomatic degenerative mitral regurgitation when furnished according to an FDA-approved indication.
- Both a cardiothoracic surgeon and a cardiologist have independently examined the patient face-to-face and evaluated the patient's suitability for mitral valve surgery and determination of prohibitive risk.
- TMVr must be performed by an interventional cardiologist or cardiothoracic surgeon. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intraoperative technical aspects of TMVr as appropriate.
- All TMVr cases must be enrolled in the national transcatheter valve therapy (TVT) registry.

Other institutional and operator requirements apply based on multi-society guidelines. Refer to the NCD Decision Memo and MLN Matters® Number MM9002 for additional details and requirements.[1,2]

To stay up to date on Medicare policy updates that impact TMVr with the MitraClip™ therapy, visit: www.mitraclipmedicareupdates.com

Medicare covers TMVr under NCD 20.33 for patients with degenerative/primary mitral regurgitation who are at prohibitive risk for mitral valve surgery. On August 14, 2019 CMS reopened NCD 20.33 to consider expanding coverage to patients with secondary MR. There is no coverage for secondary MR during the coverage analysis process.

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Private Payer and Medicare Advantage Information

Private Payers

Private payer plans vary significantly in coverage and compliance requirements for TMVr with the MitraClip™ therapy.

- Commercial payers should be consulted in advance of the procedure to verify terms and conditions of coverage.
- Please check with your payer regarding appropriate coding and payment information.
- Commercial payer payment methods vary for reimbursing inpatient services including case rates, percent of billed charges, DRGs, and device carve outs.
- Commercial payer policies vary on details such as:
  - prior authorization requirements
  - co-surgeon requirements
  - covered disease etiology (primary/secondary MR).
- Individual case consideration / appeals process.

Please consult the commercial payer directly to ensure complete understanding of any relevant coverage policies and billing requirements.

Medicare Advantage

Medicare Advantage plans must cover TMVr with the MitraClip™ therapy consistent with the national coverage determination (NCD).

- Medicare Advantage plans **may not** impose more restrictive coverage criteria than detailed in the NCD
- Medicare Advantage plans **may** use prior authorization/pre-certification to ensure compliance with the NCD

Please reach out directly to Medicare Advantage plan administrators to understand any specific prior authorization/pre-certification requirements that may apply.

Contact Information

Abbott is committed to supporting appropriate patient access to the MitraClip™ therapy. And educating providers on the latest coverage, coding and payment policy.

For additional questions, please contact the Reimbursement Hotline:

800 354 9997

ReimbursementHelp@Abbott.com

MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

FY 2020 Hospital Inpatient Payment - Medicare

National Average Reimbursement Information

TMVr procedures are assigned to MS-DRG 266/267: Endovascular Cardiac Valve Replacement and Supplement Procedures. Proposed rates for FY2021 show a slight increase of approximately 3% for the DRG family. The rates in the table below are the national average payment rates for TVT registry participants.

	FY 2020[6, 9]	FY 2021[9, 10]	% CHANGE
MS-DRG	266/267	266/267	
With MCCs	$51,791	$53,349	+3.0%
Without MCCs	$41,394	$42,443	+2.5%
Weighted Average	$46,073	$47,351	+2.8%

Weighted average using MS-DRG breakdown of TMVr cases in 2018 MedPAR; 45% w/MCCs

FY2020 Payment Rates Effective October 1, 2019 – September 30, 2020

Inpatient Only Procedure

The TMVr procedure is designated by CMS as an Inpatient Only Procedure. Therefore, the two-midnight rule for Medicare does not apply. In addition, there is no designated APC payment for the TMVr procedure nor a C-Code for the TMVr device

MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

Procedure Codes

ICD-10-PCS PROCEDURE CODE	DESCRIPTOR
02UG3JZ	Supplement mitral valve with Synthetic Substitute, Percutaneous approach
B245ZZ4	Ultrasonography of Left Heart, Transesophageal

For other concomitant conditions, other TEE codes may apply.
Diagnostic cardiac catheterization may also be coded when it is performed for specific evaluation beyond the approach to the procedure. If the cardiac catheterization is part of the approach for the procedure, it may not be coded separately.[7]

Diagnosis Codes

Below are the ICD-10-CM codes currently included in the NCD for TMVr.[2] It is the responsibility of the hospital and physician to determine the appropriate diagnosis code(s) for each patient. As discussed above, participation in the TVT Registry is a requirement of TMVr coverage. Secondary ICD-10-CM Diagnosis Code Z00.6 should be used to denote clinical trial participation for these TMVr claims.[2]

ICD-10-CM DIAGNOSIS CODES [2, 5]	DESCRIPTOR
I34.0	Nonrheumatic mitral (valve) insufficiency
I34.1	Nonrheumatic mitral valve prolapse
Z00.6	Encounter for exam for normal comparison and control in clinical research program

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Documentation of Patient Comorbidities

Patient complications and comorbidities should be identified on admission. Ensure the documentation addresses the acuity, treatment of the comorbidity while in the hospital, and the status on discharge. Always use the most detailed and appropriate code available versus defaulting to an "unspecified" code. It is the responsibility of the hospital or physician to determine appropriate coding for a particular patient and/or procedure.

For reference, below are the common major complications and comorbidities on TMVr claims based on the FY2018 MedPAR data.

ICD-10-CM	DESCRIPTOR
A41.9	Sepsis, unspecified organism
G93.41	Metabolic encephalopathy
I21.4	Non-ST elevation (NSTEMI) myocardial infraction
I50.21	Acute systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic and diastolic heart failure
I51.1	Rupture of chordae tendineae, not elsewhere classified
J18.9	Pneumonia, unspecified organism

ICD-10-CM	DESCRIPTOR
J69.0	Pneumonitis due to inhalation of food or vomit
J96.00	Acute respiratory failure, unsp w/hypoxia or hypercapnia
J96.01	Acute respiratory failure with hypoxia
J96.02	Acute respiratory failure with hypercapnia
J96.21	Acute and chronic respiratory failure with hypoxia
K72.00	Acute and subacute hepatic failure without coma
N17.0	Acute kidney failure with tubular necrosis
N18.6	End stage renal disease
R57.0	Cardiogenic shock
R65.21	Severe sepsis with septic shock

Source: FY2018 MedPAR data

MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

Additional Requirements

Additional coding requirements are necessary for TMVr cases enrolled in the TVT Registry.

ADDITIONAL REQUIRED INFORMATION	NOTES
NCT 02245763	National Clinical Trial Number is required for cases enrolled in the TVT Registry.[2] For Form UB-04 paper claims, enter 02245763 in the value amount, value code D4. For 837I electronic claims, enter 02245763 in Loop 2300 REF02 (REF01 = P4).[8]
Condition Code 30	Condition Code is required for cases enrolled in the TVT Registry.[2]

For additional considerations for private payer and Medicare Advantage plans, please reference the Coverage section of this guide

MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

Hospital Claim Checklist:

This checklist is provided as a summary of the information used to process claims for TMVr procedures with the MitraClip™ System per CMS's NCD. It is the responsibility of the hospital and/or physician to determine appropriate coding for a particular patient and / or procedure. Any claim should be coded appropriately and supported with adequate documentation in the medical record.

CODES / MODIFIERS / OTHER	WHEN USED?	INCLUDED	NA
DIAGNOSIS CODES [2,5]			
I34.0/I34.1: Nonrheumatic mitral valve disorders	When appropriate	☐	☐
Z00.6: Examination of a participant in a clinical trial	All cases	☐	☐
Applicable Secondary Diagnosis Codes	When appropriate	☐	☐
PROCEDURE CODE			
02UG3JZ: Supplement mitral valve with Synthetic Substitute, Percutaneous approach	All cases	☐	☐
B245ZZ4: Ultrasonography of Left Heart, Transesophageal	All cases	☐	☐
CONDITION CODE			
Condition Code 30	All cases	☐	☐
NCT NUMBER			
02245763	All cases	☐	☐
D4: Value Code	All cases	☐	☐

MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

Procedure Codes and CY 2020 Payment - Medicare

CPT‡ CODE[3]	DESCRIPTOR	NATIONAL AVERAGE PAYMENT[4]	TOTAL FACILITY RVUs[4]	WORK RVUs[4]
TMVr PROCEDURE WITH IMPLANT				
33418	Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; initial prosthesis	$1,882	52.16	32.25
33419	Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; additional prosthesis (es) during same session (List separately in addition to code for primary procedure). (Use 33419 in conjunction with 33418)	$445	12.32	7.93

Angiography, radiological supervision, and interpretation performed to guide TMVr (eg, guiding device placement and documenting completion of the intervention) are included in these codes. Do not report diagnostic right and left heart catheterization procedure codes (93451, 93452, 93453, 93456, 93457, 93458, 93459, 93460, 93461, 93530, 93531, 93532, 93533) with 33418 or 33419 when done intrinsic to the valve repair procedure.

TRANSEOPHAGEAL ECHOCARDIOGRAPHY (TEE) (for intra-procedural monitoring)				
93355*	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg,TAVR, transcathether pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D	$238	6.58	4.66

*Note that 93355 is bundled and not separately payable when reported on the same physician claim as the TMVr with MitraClip™ procedure (33418) or with anesthesia services

CY2020 Payment Rates Effective January 1-December 31, 2020

MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

Coding Modifiers and Additional Requirements

MODIFIER	NOTES
-Q0	Use for physician claims for cases enrolled in the TVT Registry.[5]
-62	Use for physician claims for cases where two surgeons / co-surgeons perform TMVr. Note that in scenarios where co-surgeon participation is medically necessary, the submission of supporting documentation is required.[2]
-80/-82	Use for assistant surgeon claims for TMVr. Append modifier to assistant surgeon claims; do not append modifier to primary surgeon claims. Use -80 when TMVr is performed at non-teaching community hospitals without surgery residents. Use -82 for when TMVr is performed at teaching hospitals with surgery residents; -82 indicates qualified surgery resident unavailable. Documentation regarding medical necessity required.

ADDITIONAL REQUIRED INFORMATION	NOTES
NCT 02245763	National Clinical Trial Number is required for cases enrolled in the TVT Registry.[2] For Form CMS-1500 paper claims, enter 'CT' followed by 02245763 in Field 19. For 837P electronic claims, enter 02245763 (no 'CT') in Loop 2300 REF02 (REF01 = P4).[8]

For additional considerations for private payer and Medicare Advantage plans, please reference the Coverage section of this guide

MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

Coding for Co-surgeons

TMVr is covered by Medicare when performed by a single operator, or by co-surgeons as clinically appropriate. Per the TMVr NCD (20.33), "The heart team's interventional cardiologist or a cardiothoracic surgeon must perform the TMVr. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVr as appropriate." [2]

The Physician Final Rule 2019 states that the -62 modifier for TMVr has a status indicator of one (1) which signifies that co-surgeons may be paid.

- Both surgeons use the same CPT code and apply the -62 modifier. Each surgeon submits a separate claim for their professional services.
- CMS' general policy regarding co-surgeons, and medical necessity thereof, apply to TMVr procedures. At this time, there are no TMVr-specific criteria or guidance for co-surgeons, nor do we anticipate that CMS will develop such TMVr-specific direction regarding co-surgeons.
- Each surgeon's role must be clearly defined in the operative notes. See below table for considerations.
- Local Medicare Administrative Contractors (MAC) will determine the medical necessity of co-surgeons performing TMVr based on the documentation submitted. MACs would likely expect each co-surgeon to produce their own procedure / operative report detailing their role in the procedure and clinical decision-making, as well as the rationale for each surgeon participating in the procedure.
- While co-surgeons are typically expected to be from different specialties, co-surgeons from the same specialty may be paid at carrier discretion.

CONSIDERATIONS	EXAMPLE
Note which tasks you completed.	"I advanced a wire from the right femoral vein to the superior vena cava for placement of the transseptal sheath and needle."
Note which tasks your co-surgeon completed.	"Dr. Smith advanced the mitral valve repair device and delivery system through the guide to the left atrium."
Avoid using the term "we."	Instead of "We positioned the clip" consider, "I advanced the implant into the LV, by advancing the delivery catheter handle as Dr. Smith assisted in positioning the Clip below the valve by maintaining our anterior/posterior position with the guide."

MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

Diagnosis Codes

Below are the diagnosis codes currently included in the NCD for TMVr.[2] It is the responsibility of the physician to determine the appropriate diagnosis code(s) for each patient. As discussed above, participation in the TVT Registry is a requirement of TMVr coverage. Secondary diagnosis code Zoo.6 should be used to denote clinical trial participation for these TMVr claims.[2]

ICD-10-CM DIAGNOSIS CODE[2,5]	CODE DESCRIPTOR
I34.0	Nonrheumatic mitral (valve) insufficiency
I34.1	Nonrheumatic mitral valve prolapse
Zoo.6	Encounter for exam for normal comparison and control in clinical research program

For additional considerations for private payer and Medicare Advantage plans, please reference the Coverage section of this guide

MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

For Implanting Physician(s):

This checklist is provided as a summary of the information used to process claims for TMVr procedures with the MitraClip™ System per CMS's NCD. It is the responsibility of the hospital and/or physician to determine appropriate coding for a particular patient and / or procedure. Any claim should be coded appropriately and supported with adequate documentation in the medical record.

CODES / MODIFIERS / OTHER	WHEN USED?	INCLUDED	NA
DIAGNOSIS CODES[2,5]			
I34.0 / I34.1: Nonrheumatic mitral valve disorders	When appropriate	☐	☐
Z00.6: Examination of a participant in a clinical trial	All cases	☐	☐
Applicable secondary diagnosis codes	When appropriate	☐	☐
CPT‡ CODES			
33418: Transcatheter mitral valve repair; initial prosthesis	All cases	☐	☐
+33419: Transcatheter mitral valve repair; add'l prosthesis(es)	Cases where two or more clips are implanted	☐	☐
CPT‡ CODE MODIFIERS			
-Q0: Investigational / Routine clinical service provided in a clinical research study that is in an approved clinical research study.	All cases	☐	☐
-62: When two surgeons work together as primary surgeons preforming distinct part(s) of a procedure.	When two surgeons/ co-surgeons perform the procedure. Supporting documentation is required to show medical necessity for co-surgeons	☐	☐
-80/-82: Surgical assistant	When surgical assistant services are used during the procedure.	☐	☐
NCT NUMBER			
02245763	All cases	☐	☐

+ denotes an add-on code. List separately in addition to primary procedure.

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For Echocardiographer

This checklist is provided as a summary of the information used to process claims for TMVr procedures with the MitraClip™ System per CMS's NCD. It is the responsibility of the hospital and/or physician to determine appropriate coding for a particular patient and / or procedure. Any claim should be coded appropriately and supported with adequate documentation in the medical record.

CODES / MODIFIERS / OTHER	WHEN USED?	INCLUDED	NA
DIAGNOSIS CODES[2,5]			
I34.0 / I34.1: Nonrheumatic mitral valve disorders	When appropriate	☐	☐
Z00.6: Examination of a participant in a clinical trial	All cases	☐	☐
Applicable secondary diagnosis codes	When appropriate	☐	☐
CPT‡ CODES			
93355: TEE for intra procedural monitoring	All cases	☐	☐
CPT‡ CODE MODIFIERS			
-Q0: Investigational / Routine clinical service provided in a clinical research study that is in an approved clinical research study.	All cases	☐	☐
NCT NUMBER			
02245763	All cases	☐	☐

IMPORTANT SAFETY INFORMATION

MITRACLIP™ DELIVERY SYSTEMS

INDICATIONS FOR USE

℞ ONLY

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.

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 MitraClipTM G4 Implant should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- 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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

MITRACLIP™ CLIP DELIVERY SYSTEMS INDICATION FOR USE (CONTINUTED)

- 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.

PRECAUTIONS

- Prohibitive Risk Primary (or degenerative) Mitral Regurgitation
  - Prohibitive risk is determined by the clinical judgment of heart team, including a cardiac surgeon experienced in mitra 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, internal mammary artery (IMA) at high risk of injury, etc.
  - Evaluable data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LVEF < 20% or an LVESD > 60mm. MitraClip™ should be used only when criteria for clip suitability for DMR 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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

MITRACLIP™ CLIP DELIVERY SYSTEMS INDICATION FOR USE (CONTINUTED)

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.

IMPORTANT SAFETY INFORMATION

Rx ONLY

STEERABLE GUIDE CATHETER

INDICATION FOR USE

The Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum

CONTRAINDICATIONS

- Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or post procedural anti-platelet regimen
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

WARNINGS

- DO NOT use MitraClipTM outside of the labeled indication.
- Read all instructions carefully. Failure to follow these Instructions, warning and precautions may lead todevice damage, user injury or patient injury. Use universal precautions for biohazards and sharps to avoid user injury.
- Use the Steerable Guide Catheter with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with
- on-site cardiac surgery and immediate access to a cardiac operating room.
- The Steerable Guide Catheter is designed for single use only. Cleaning, re-sterilization and/or reuse may result in infections, malfunction of the device or other serious injury or death.
- Patients with the following considerations in whom the Steerable Guide Catheter is used may have an increased risk of having a serious adverse event which may be avoided with preoperative evaluation and proper device usage.
- The Previous interatrial septal patch or prosthetic atrial septal defect (ASD) closure device which could result in significant difficulty in visualization or technical challenges during transseptal puncture and/or introducing the SGC into the left atrium.
- Known or suspected unstable angina or myocardial infarction within the last 12 weeks could increase the procedural morbidity and mortality, due to increased hemodynamic stress secondary to general anesthesia.
- Patients with active infection have an increased risk of developing an intraoperative and/or postoperative infection, such as sepsis or soft tissue abscess.
- Known or suspected left atrial myxoma could result in thromboembolism and tissue injury due to difficulty with device positioning.
- Recent cerebrovascular event (CVA) may increase the procedural morbidity associated with a transcatheter intervention, such as recurrent stroke.

PRECAUTIONS

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.

Disclaimer

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References and Brief Summary

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