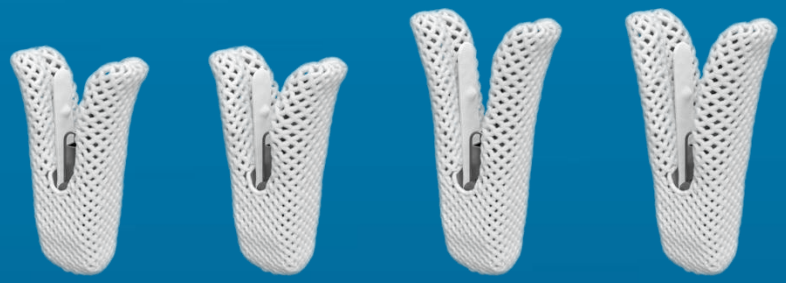
STRUCTURAL HEART

MitraClip™
Transcatheter Mitral Valve Repair

MitraClip™ G4

Therapy Training



GLOBAL STRUCTURAL HEART PRODUCT TRAINING CONTENT

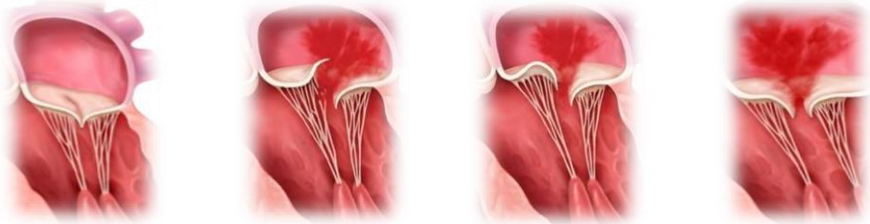
This content is for procedure and/or device training use. Content approved for product training in geographies with regulatory approval and/or commercial release.

Prior to use, reference the Instructions for Use (IFU) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. The IFU can be found inside the product carton (when available), on www.structuralheartsolutions.com or by calling Abbott Structural Heart Customer Service +1 (651) 756-5400.

INDICATION FOR USE

The MitraClip™ G4 Clip Delivery 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 Clip Delivery 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.



Normal Mitral Valve | PMR - Fail | PMR - Prolapse | Secondary MR

Images throughout this presentation are for illustrative purposes only, and for anatomical consideration to support device and procedural training

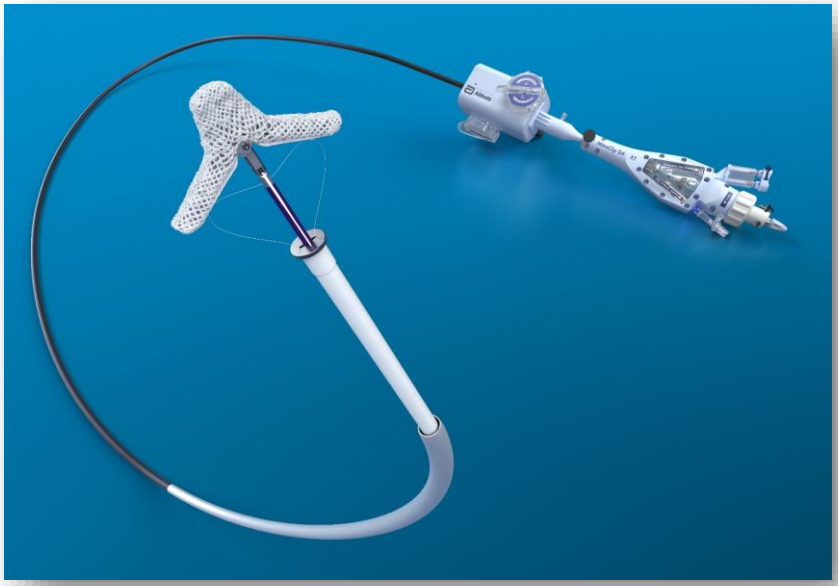
PRIMARY TRAINING OBJECTIVES

Procedural Success

- Establish a working knowledge of considerations for optimal patient outcome
- Establish a working knowledge of the MitraClip™ System functionality and proper usage
- Establish a working knowledge of procedural imaging

Procedural Efficiency

- Utilize systematic approach
  - Follow standard order of procedural steps with standard echo views
- Establish clear and consistent terminology

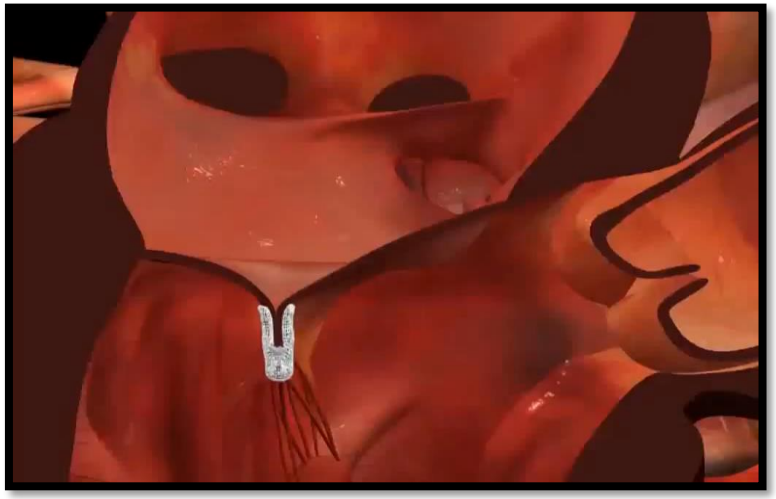


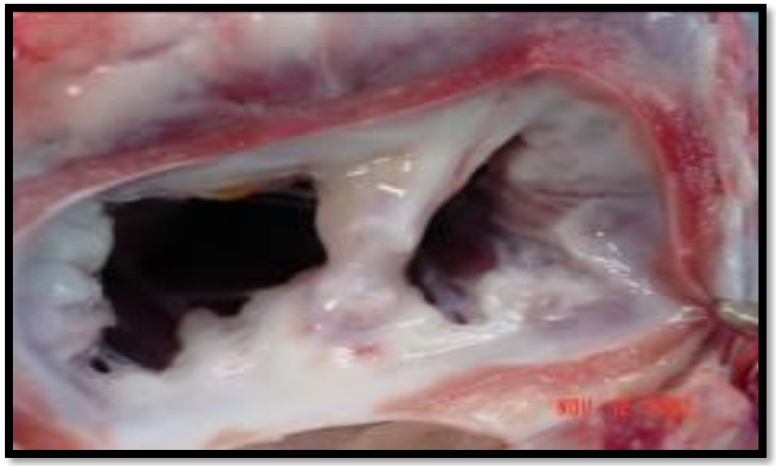
MITRACLIP™ CONCEPTS

MitraClip facilitates the reconstruction of an insufficient mitral valve through tissue approximation

- A mechanical solution to a mechanical problem

Repair creates a tissue bridge



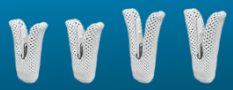


Porcine model, 6M

KEY DESIGN FEATURES

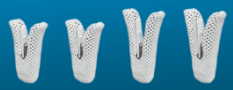
- Venous puncture
- Standard percutaneous left atrial access
- Integrated Left Atrial Pressure monitoring capability
- 4 Clip sizes providing versatile treatment options
  - Adaptability to varying patient anatomy

KEY DESIGN FEATURES



- Precise MitraClip™ placement control
  - Re-positioning capability
    - Allows multiple tissue grasps and releases
    - Facilitates optimal MR reduction
    - Provides option to not deploy Clip
- Real-time efficacy assessment
  - Normal hemodynamic loading conditions
  - Allows optimal MR reduction
- Each Leaflet is unilaterally engaged by a MitraClip™ Arm and Gripper
  - Simultaneous and independent Leaflet Grasping
  - Reduced risk of embolization
- Multi-step Clip deployment
  - Reduced risk of embolization
- MitraClip cover promotes tissue in-growth

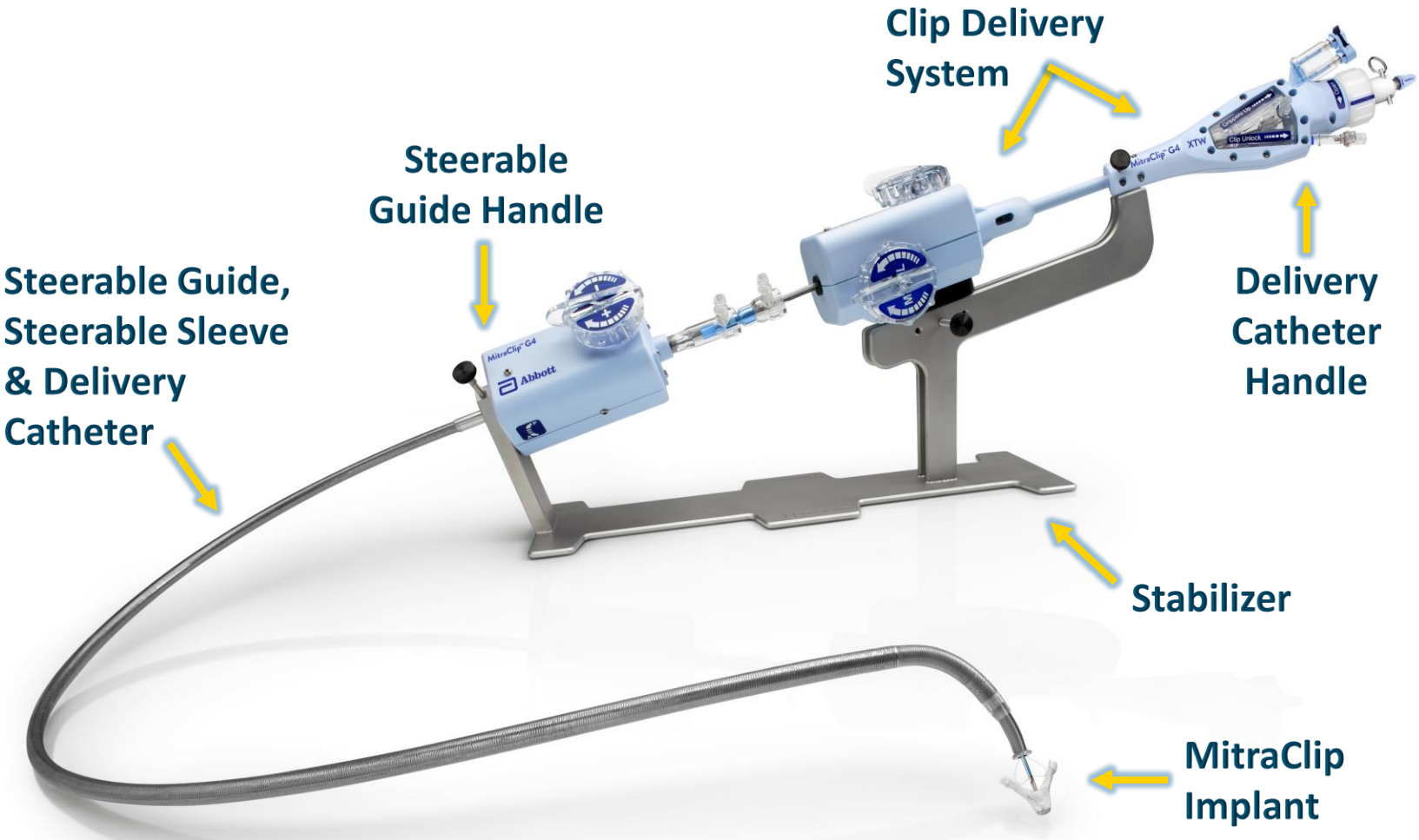
KEY DESIGN FEATURES



MRI Safety Information

- Non-clinical testing has demonstrated that the MitraClip™ G4 Implants are 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 Tesla (1.5 T) or 3 Tesla (3.0 T).
  - Maximum spatial field gradient of 4,000 Gauss/cm (40 T/m).
  - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).
- Under the scan conditions defined above, MitraClip G4 Implants are expected to produce a maximum temperature rise of less than or equal to 3.1°C after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by a pair of MitraClip Implants extends approximately 40 mm beyond MitraClip G4 Implants when imaged with a spin echo or gradient echo pulse sequence in a 3 T magnetic resonance imaging system. The presence of additional implants in a patient's valve may increase the image artifact size when imaged in an MRI system.

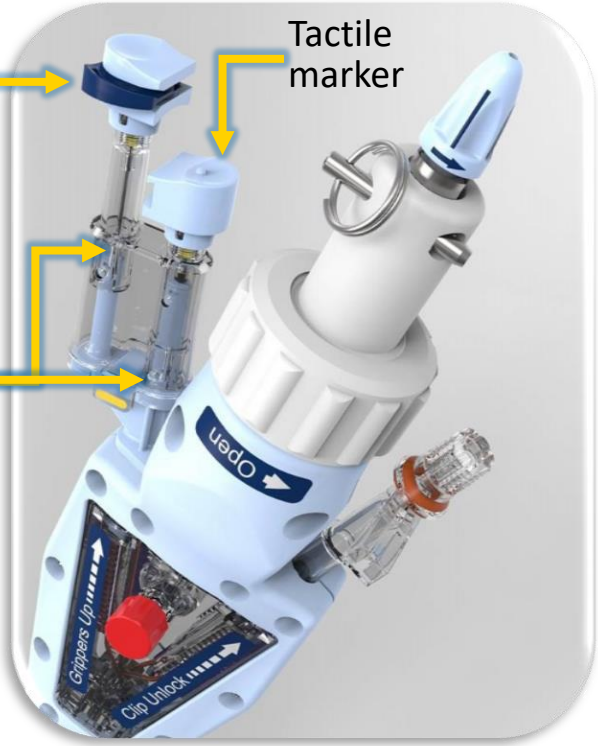
MITRACLIP™ G4 SYSTEM



MITRACLIP™ G4 SYSTEM

Latch allows users to switch between simultaneous & independent grasping.

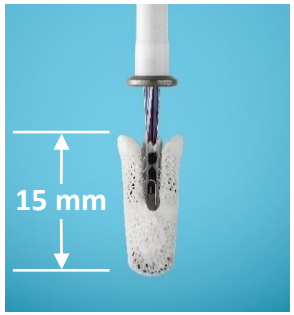
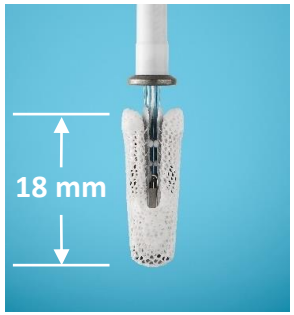
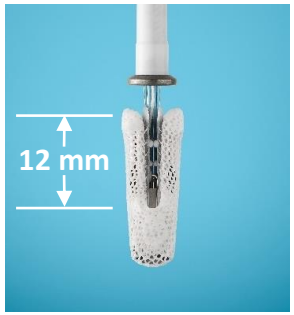
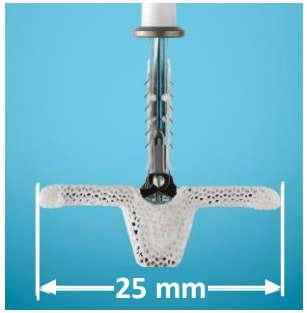
Independent Gripper Lines fixed to Gripper Levers.



CLIP ARMS OVERVIEW

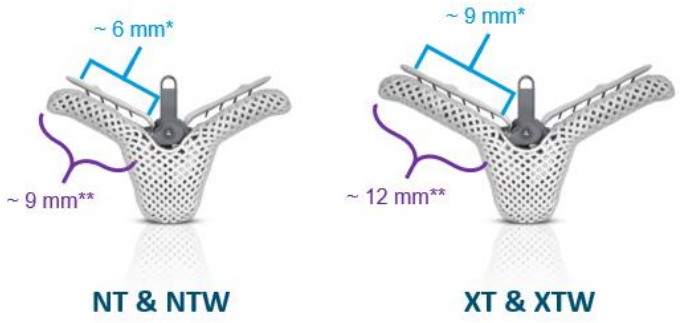
MitraClip Implant	G4 NT	G4 NTW	G4 XT	G4 XTW
Grasping width at 120°	17 mm minimum		22 mm minimum	
Clip width at 180°	20 mm nominal		25 mm nominal	
Arm width	4 mm max.	6 mm max.	4 mm max.	6 mm max.
Arm length (coaptation length)	9 mm maximum		12 mm maximum	

CLIP ARMS OVERVIEW

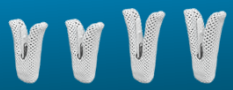
	Clip Length	Coaptation Length	Clip Arms at 120°	Clip Arms at 180°
G4 NT & G4 NTW				
G4 XT & G4 XTW				

* Leaflet insertion needed to engage all frictional elements

** Clip Arm length



MITRACLIP™ G4
CLIP SIZE CONSIDERATIONS



Key Anatomical Considerations to evaluate to ensure adequate MR reduction, Clip stability and preservation of MV area:

1. Length of the Leaflet
2. Width of the Jet
3. Mitral Valve Area (MVA)

	Anatomical Considerations		Favors G4 NTW	Favors G4 NT	Favors G4 XTW	Favors G4 XT
1. Leaflet insertion	**Length of mobile leaflet in grasping zone?**	Leaflet Length < 9 mm	+	+		
		Leaflet Length ≥ 9 mm			+	+
2. Jet Width	**Width of jet?**	Broad jet	+		+	
3. MVA	**Area of valve?**	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.

PRE-PROCEDURE PREPARATION

PRE PROCEDURE PREPARATION

KEY PATIENT CONSIDERATIONS

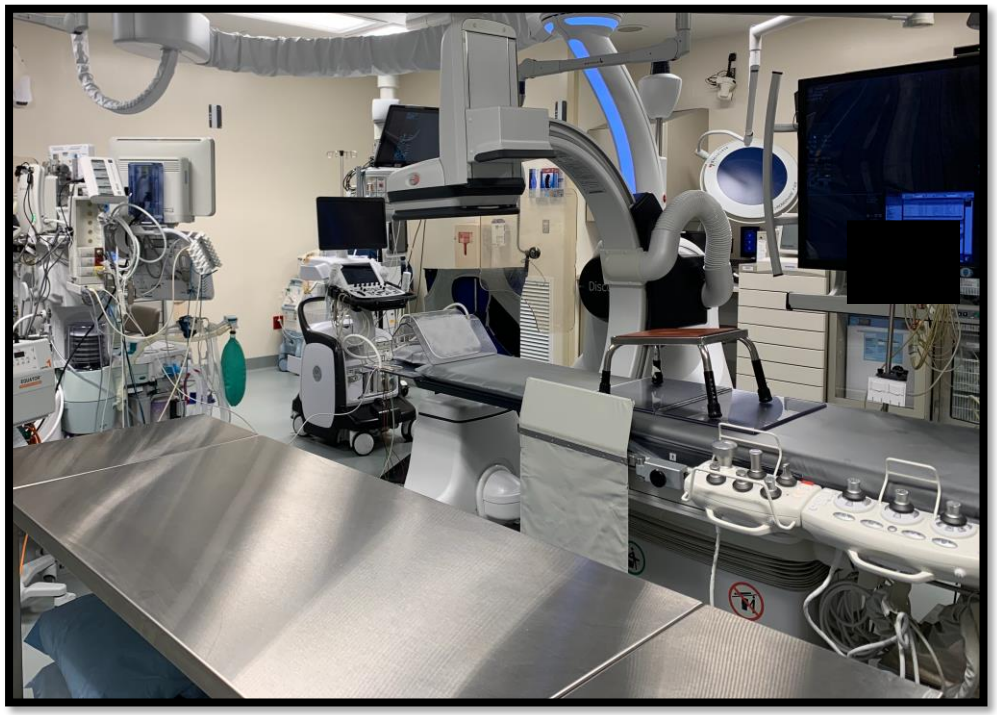
- Patient will be intubated, under general anesthesia
- Patient may have femoral or radial artery access
- Patient will have 25 Fr Steerable Guide in femoral vein
- Patient will be heparinized during procedure to ACT's greater than 250 seconds
- Patient will have TEE probe in place for extended period of time
- Patient may have bladder (Foley) catheter in place

PERIPROCEDURAL CARE

- Antibiotic Therapy
  - Administer prophylactic antibiotics per institutional guidelines for implanted devices
- Groin Access
  - Per institutional guidelines and similar to other catheterization procedures

ROOM EQUIPMENT

The MitraClip™ G4 System can be used in a standard cath-lab or hybrid room

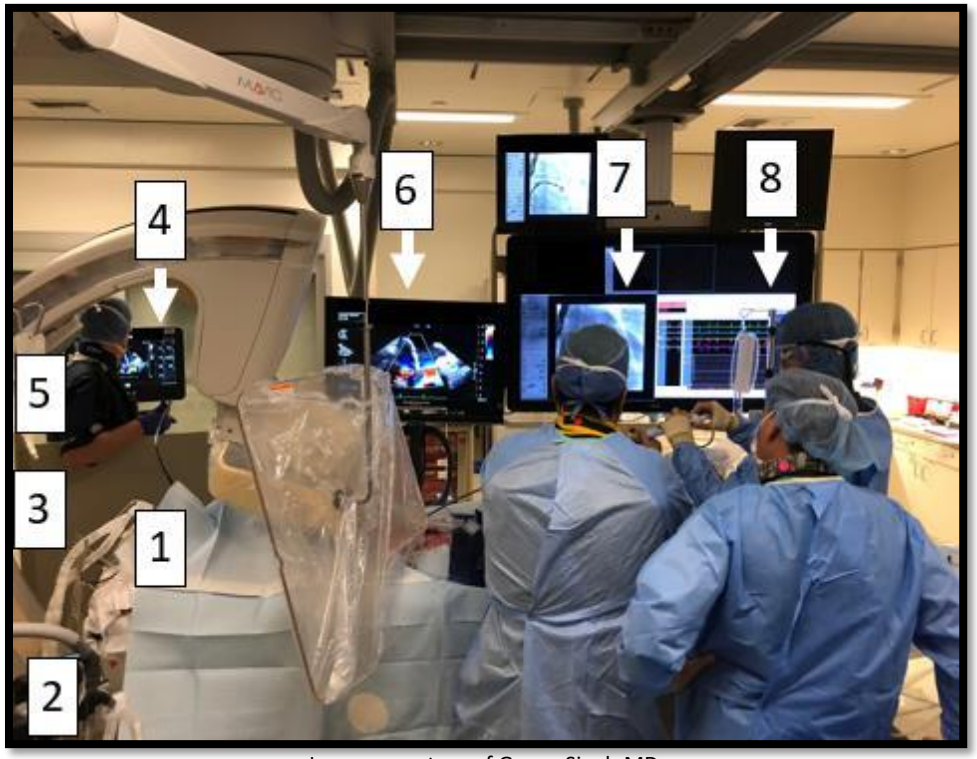


Images courtesy of Ruby Satpathy MD
Baptist Hospital Jacksonville, FL

Equipment required:

- Single plane fluoroscopy
- General anesthesia cart
- Two sterile tables
- Radiation protection
- Echocardiography machine
- 3D TEE probe
- Monitors: 1 echo slave for Implanter & 1 fluoro slave Monitor for Imager

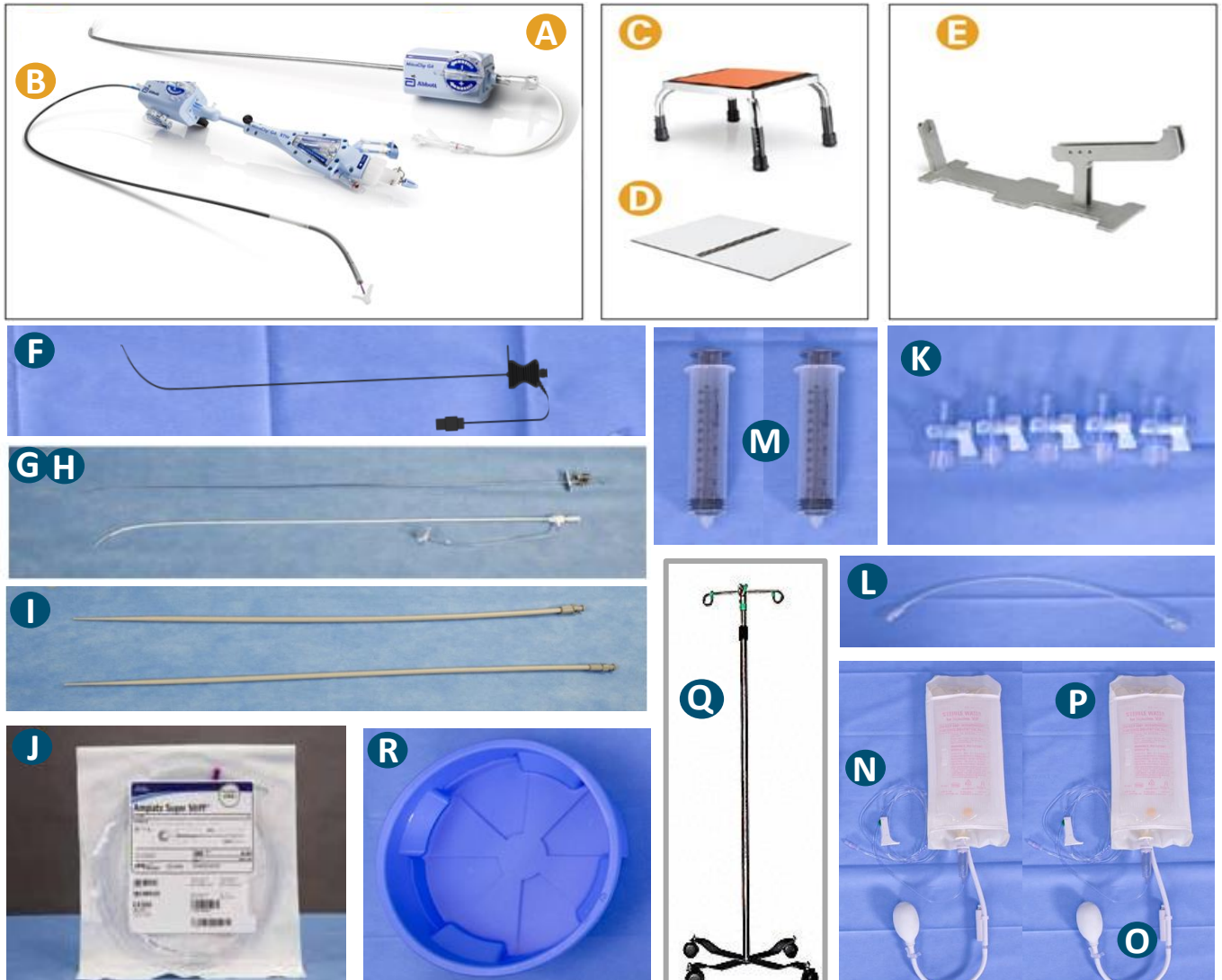
ROOM SETUP



Images courtesy of Gagan Singh MD
UC Davis Medical Center

1. Patient head
2. Anesthesia to right of patient
3. Lead shield for imager
4. TEE machine to left of patient
5. Lead shoulder apron for imager
6. Dedicated slave TEE screen in implanter's direct line of sight
7. Fluoroscopy screen
8. Hemodynamic screen

PROCEDURE ITEMS



	Product Name
A	Steerable Guide Catheter
B	Clip Delivery System
C	Lift
D	Support Plate
E	Stabilizer [Qty: 2 required]
F	Baylis RF transseptal needle ***or*** (G)
G	Transseptal Kit: Adult Transseptal needle (71 cm)
H	Transseptal Kit: Adult Transseptal sheath and dilator (60 cm/67 cm)
I	Femoral Dilators (12, 14, 18 Fr)
J	Exchange length support guidewire
K	High-pressure three-way stopcocks [Qty: 5 required]
L	High-pressure extension tubing [Qty: 3 required]
M	60 cc syringes with luer fitting [Qty: 2 required]
N	1000 ml pressure bags [Qty: 2 required]
O	Sterile IV tubing with thumbwheel Occluders [Qty: 2 required]
P	Heparinized Sterile saline solution (1 L bag) [Qty: 2 required]
Q	IV Pole
R	Large Basin with Heparinized saline

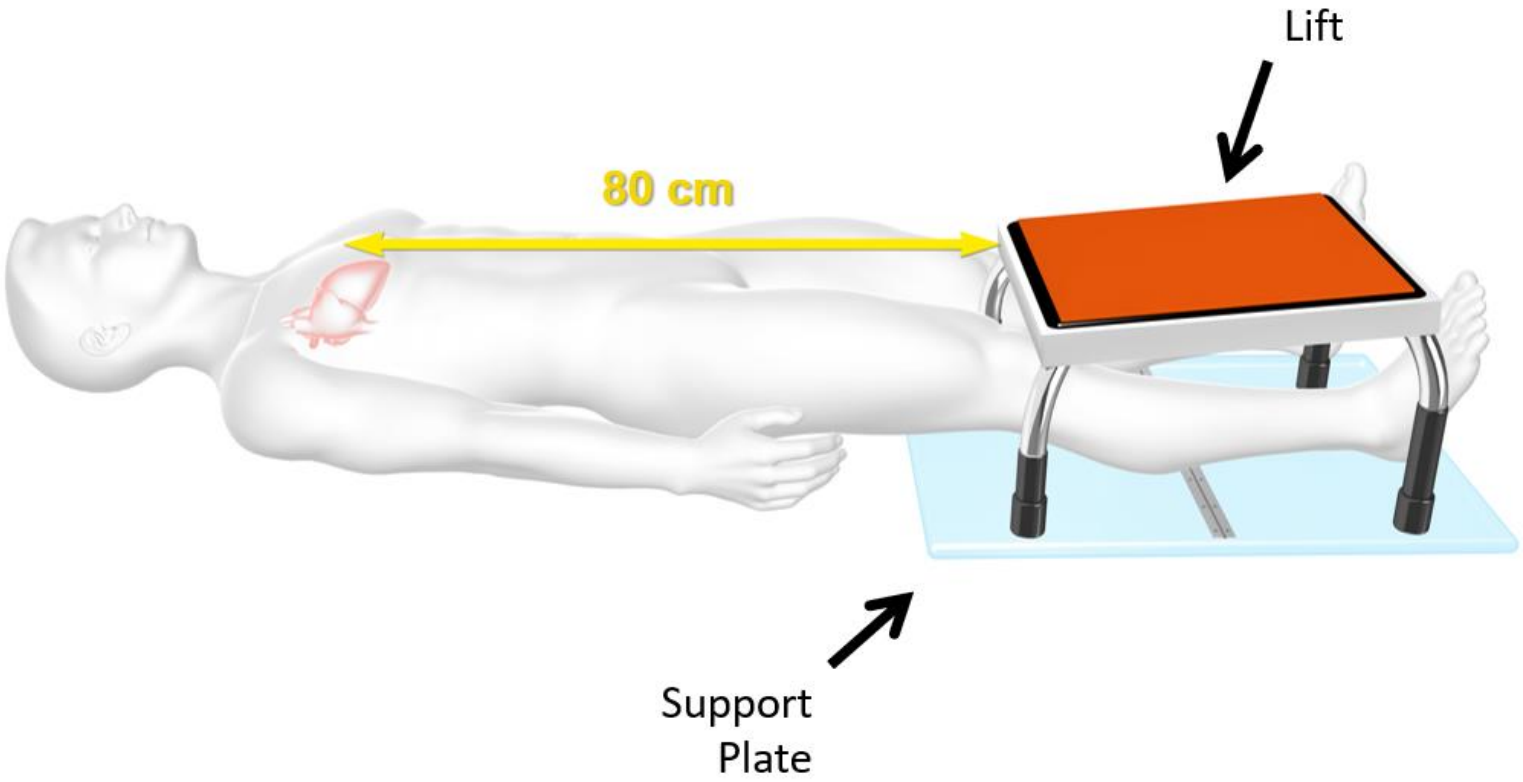
PATIENT POSITIONING

- Prepare the patient per institution's standard practice for transseptal catheterization.
- Place the support place under the patient's leg in the region between the area of the upper leg and the knee and place the Lift over the ipsilateral lower extremity prior to draping the patient.
- Place the Lift on the Support Plate such that the front edge (i.e. the edge that corresponds with the shorter legs of the Lift) is approximately 80 cm from the patient's mid sternum.
- Adjust the height of the Lift so that the front edge of the Lift is close to the patient's leg but is not impinging on it. Adjust the back legs to be 2 or 3 notches above the front legs (i.e., the back legs of the Lift are taller than the front legs).

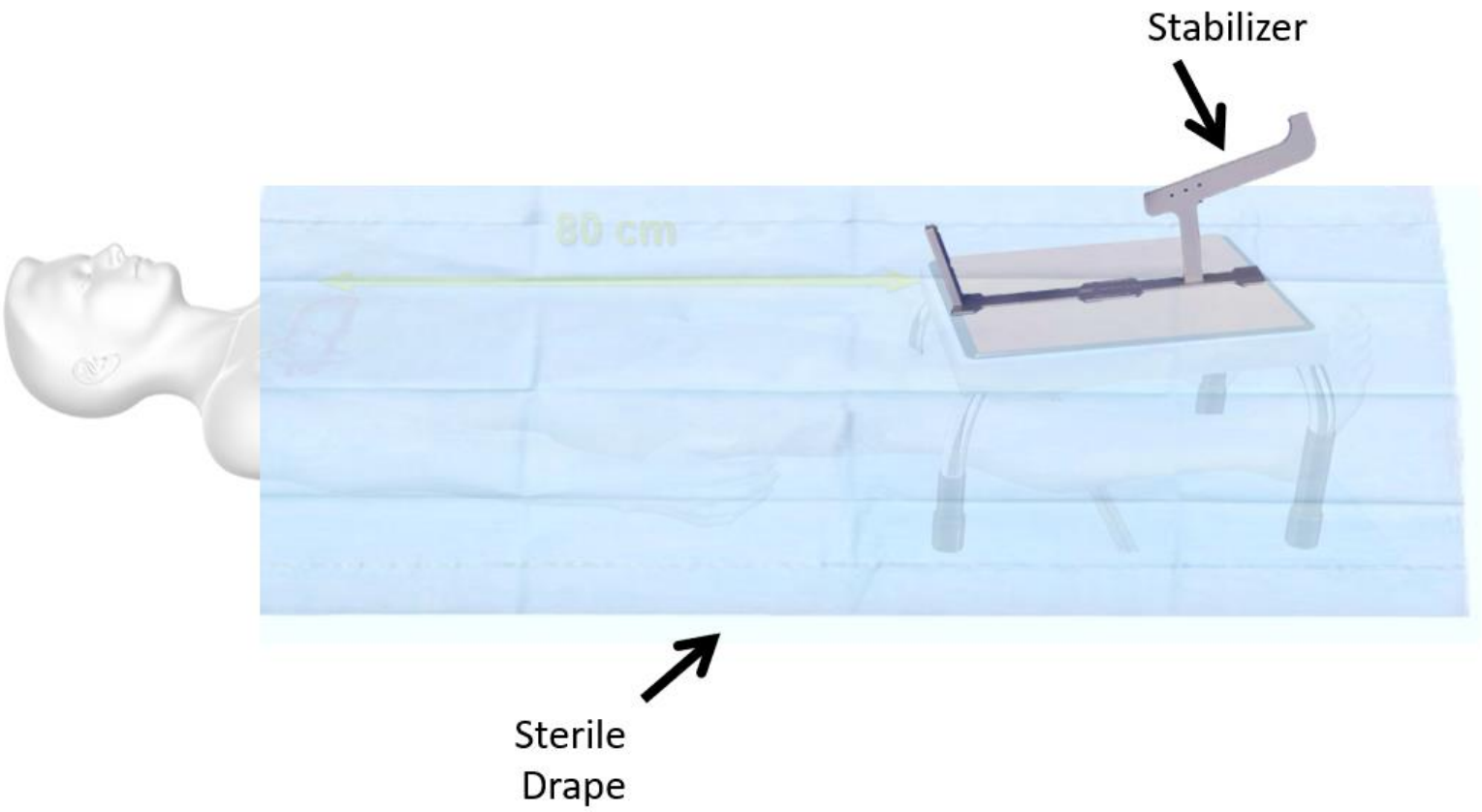
  CAUTION: *Ensure the Lift and Support Plate are covered completely by sterile drape during the procedure. Use towels as necessary to minimize direct contact between the patient and all surfaces of both the Lift and Support Plate.*

- Prepare the patient for invasive hemodynamic monitoring.

PATIENT POSITIONING

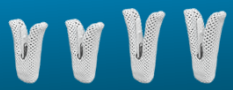


PATIENT POSITIONING



THE MITRACLIP™ PROCEDURE

PROCEDURAL OUTLINE



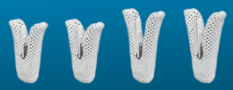
1. Definition of terms
2. Imaging
3. Transseptal
4. Steerable Guide Catheter Insertion
5. Clip Delivery System Insertion
6. Steering and positioning the MitraClip™ G4 System
7. Grasping the leaflets & verifying the grasp
8. MitraClip G4 Implant deployment
9. System removal
10. Additional Clip placement
11. Situational Steering
12. Post Procedure Considerations

DEFINITION OF TERMS

DEFINITION OF TERMS

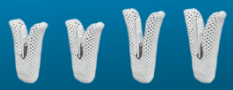
Term	Definition and Related Technique
Lock the Clip	1. Rotate the Lock Lever outward. 2. Fully advance the Lock Lever. 3. Rotate the Lock Lever inward to engage the lever.
Unlock the Clip	1. Rotate the Lock Lever outward and then retract the lever until the mark on the lever is fully exposed. 2. Rotate the Lock Lever inward to engage the lever.

DEFINITION OF TERMS



Term	Definition and Related Technique
Open the Clip Arms	1. Confirm the Clip is unlocked. 2. Turn the Arm Positioner at least ½ turn in the "Close" (clockwise) direction. 3. Turn the Arm Positioner in the "Open" (counter-clockwise) direction until the desired Clip Arm Angle is achieved. ***NOTE 1**: If Clip does not open smoothly, retract the Lock Lever farther, then repeat steps 2 – 3.* ***NOTE 2**: If the Clip Arms fail to open visibly (as observed under fluoroscopic guidance), use the following techniques in the order provided, as needed:* *A. Stop and return Arm Positioner to Neutral. Retract Lock Lever farther, then turn the Arm Positioner farther in the "Close" direction before turning in the "Open" direction. Advance the lock lever just enough so that the mark on the lever is still fully exposed.* *B. Turn the Arm Positioner to Neutral, then incrementally iterate the amount of Arm Positioner rotation in the "Close" direction followed by rotation in the "Open" direction. Iterate until Clip opens or until it is no longer possible to rotate the Arm Positioner in the "Close" direction. Advance the lock lever just enough so that the mark on the lever is still fully exposed.* *C. Turn the Arm Positioner to Neutral, iterate the amount of Lock Lever retraction past the mark in 5 mm increments, and rotate the Arm Positioner fully in the "Close" direction, before rotating in the "Open" direction, until Clip opens. Advance the lock lever just enough so that the mark on the lever is still fully exposed.* *D. Advance the Gripper Lever and repeat NOTE 2, Step C. Retract the Gripper Lever after Clip opens.* *E. If in the LA and free of tissue, release the DC Fastener, then release the Sleeve curves and repeat NOTE 2, Step C.* ***WARNING:** Do release the DC Fastener before releasing Sleeve curves, otherwise it may result in device damage and/or device or component embolization.* *F. If the Clip does not open after performing all steps in NOTE 2, DO NOT use the device.*

DEFINITION OF TERMS



Term	Definition and Related Technique
Arm Positioner to Neutral	Turn the Arm Positioner in the “Close” or “Open” direction until no resistance to turning is noted.
Invert the Clip Arms	1. Confirm the Clip is unlocked. 2. Turn the Arm Positioner at least ½ turn in the “Close” direction. 3. Turn the Arm Positioner in the “Open” direction until a Clip Arm Angle of 180° is observed under fluoroscopic guidance. Note the orientation of the blue line on the Arm Positioner. 4. Continue turning the Arm Positioner in the “Open” direction until the Clip Arms invert, no more than 1 full turn from 180°. **DO NOT** over-invert the Clip Arms. **DO NOT** turn Arm Positioner more than 1 full turn past a Clip Arm Angle of 180° or past when resistance is first noted. ***WARNING:*** *Turning the Arm Positioner in the “Open” direction more than 1 full turn past a Clip Arm Angle of 180° or turning past when resistance is first noted may result in device damage which could cause the Clip to become non-functional and lead to embolization, and/or conversion to surgical intervention.*

DEFINITION OF TERMS

Term	Definition and Related Technique
Raise the Grippers	a) Simultaneously – Confirm Gripper Levers are latched. Slowly retract the Gripper Levers until a hard stop is reached (under fluoroscopic and echocardiographic observation). **OR** b) Independently – Unlatch the Gripper Levers and slowly retract the desired Gripper Lever until a hard stop is reached (under fluoroscopic and echocardiographic observation). Re-latch the Gripper Levers.
Lower the Grippers	a) Simultaneously – Confirm the Gripper Levers are latched and fully advance the Gripper Levers. **OR** b) Independently – Unlatch the Gripper Levers and fully advance the desired Gripper Lever(s). Re-latch the Gripper Levers.

Note: Simultaneous leaflet capture with both Grippers should be attempted first. If unsuccessful, *Raise the Gripper(s)* to release leaflet capture and *Lower the Gripper(s)* to capture leaflets. Raising and lowering Gripper(s) can be done simultaneously or independently.

DEFINITION OF TERMS

Term	Definition and Related Technique
Identify Gripper Orientation	1. Unlatch the Gripper Levers. 2. Advance and retract the Gripper Lever with the tactile marker under imaging (echocardiography) to identify Gripper Lever to the corresponding leaflet. 3. Once Gripper(s) are identified, Raise the Gripper(s) until ready for leaflet capture.
Clip Arm Angle	• Angle between the inner edges of both Clip Arms. • All Clip Arm Angles are measured using fluoroscopy with optimal view allowing clear observation of the tip of the Clip and both arms in the same plane so they appear as a “V”.
Grasping Arm Angle	A Clip Arm Angle of approximately 120°.
Fully Close the Clip Arms	Turn the Arm Positioner in the “Close” direction until the Clip Arms contact the DC. • Under direct visualization, the Clip is fully closed when the Clip Covering contacts the DC. • Under fluoroscopic observation, the Clip is fully closed when the inner edges of the Clip Arms are parallel.

DEFINITION OF TERMS

Term	Definition and Related Technique
Establish Final Arm Angle	Verification step to confirm that the pre-deployment Clip Arm Angle will reflect the Clip Arm Angle post-deployment. 1. With the Lock Lever fully advanced, and the Arm Positioner to Neutral (note the orientation of the blue line on the Arm Positioner), turn the Arm Positioner 1 turn in the "Open" direction (confirm blue line has returned to the original orientation). The Clip Arms may open slightly (~5°) and then remain in a stable position. ***NOTE:*** *If continued opening of the Clip Arms is noted, reconfirm that the Lock Lever is completely advanced. Close the Clip Arms and Establish Final Arm Angle.* ***WARNING:*** *DO NOT turn the Arm Positioner more than 1 turn in the "Open" direction from neutral. Failure to stop turning the Arm Positioner at 1 turn in the "Open" direction past neutral may result in Clip opening or device damage which could cause the Clip to become non-functional and lead to embolization and/or conversion to surgical intervention.*

DEFINITION OF TERMS

Term	Definition and Related Technique
Left Atrial Pressure Capability	If using left atrial pressure capability, connect a fluid filled pressure monitoring system (not supplied) to the luer port of the Guide valve housing. Calibrate the pressure monitoring system and obtain measurements via the manufacturer's instructions for use. **Note:** Ensure no bubbles are present after inserting the CDS into the Guide. When measuring left atrial pressure, ensure the Clip is not obstructing the Guide Lumen, the Guide RO Tip Ring is between the RO Alignment Markers of the Sleeve, and the Sleeve is not deflected more than 90° as this may impair Guide lumen patency.

IMAGING

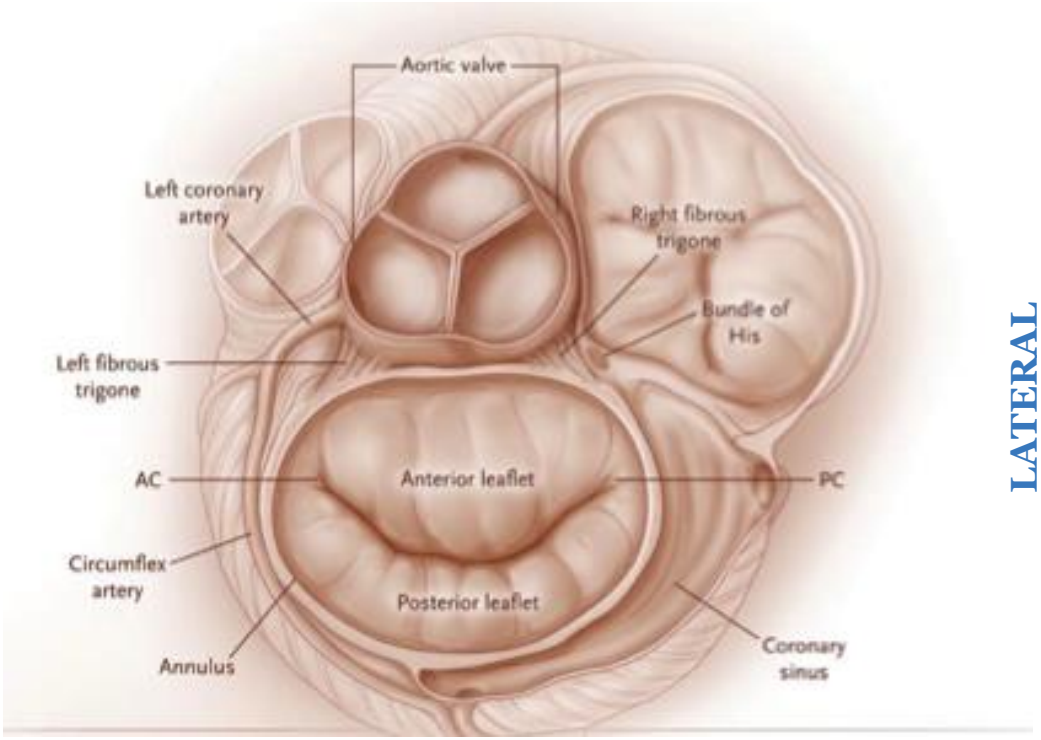
IMAGING

- Echocardiography
  - Always use Echocardiography for guidance and observation during use of the MitraClip™ G4 System.
  - Primary Imaging for anatomy and equipment
    - 2D transesophageal echocardiology
    - 3D live transesophageal echocardiology

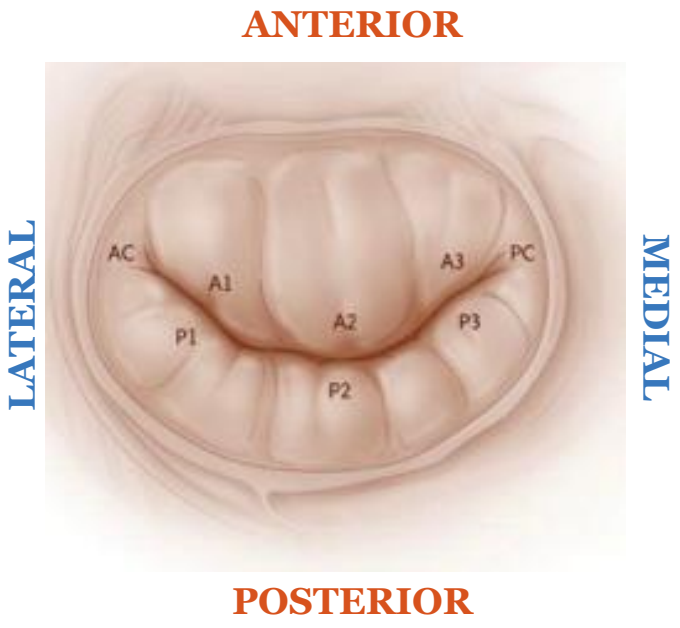
- Fluoroscopy
  - Always use fluoroscopy for guidance and observation during use of the MitraClip G4 System.
  - Secondary imaging for equipment and anatomical borders

IMAGING

Use of common anatomically based vocabulary reinforces clear communication.



N Engl J Med 2009; 361:2261-2269

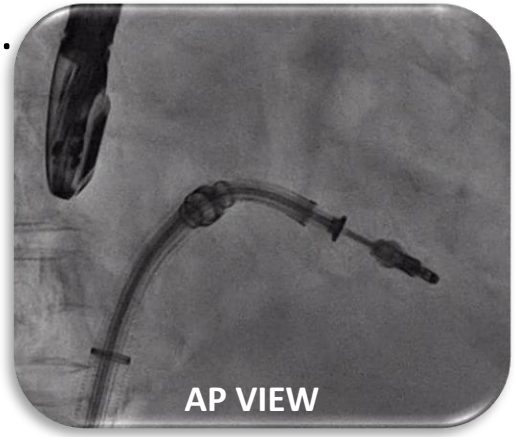


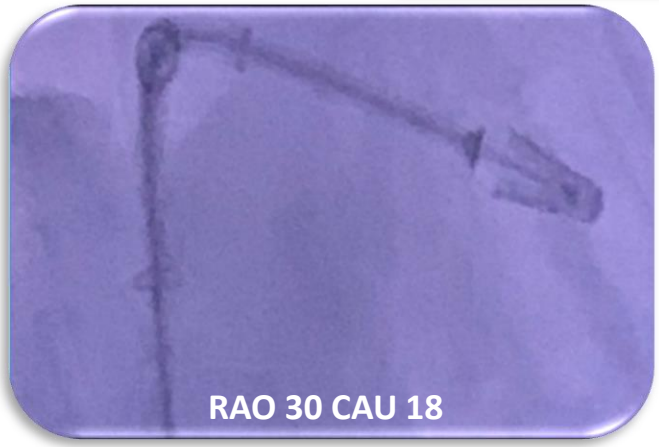
ECHO IMAGING

- Reliance on standard views for each procedural step.
  - Bi-caval
  - Short axis at base
  - Intercommissural or Bicom
  - 4 chamber
  - 5 chamber
  - Left Ventricular Outflow Track (LVOT)
  - 3D en face
  - X-Plane
  - Transgastric short axis
- Use each echo view efficiently to eliminate unnecessary device & TEE maneuvers.
- Teamwork between implanter and imager for procedural success & efficiency.

FLUOROSCOPY

- Fluoroscopic views used for MitraClip™ procedure.
  - AP
  - RAO (Cranial/Caudal)
  - LAO (Cranial/Caudal)
- Fluoroscopy is a tool that can assist in MitraClip positioning during the procedure:
  - Positioning Guide
  - Straddling
  - Positioning Clip in LA
  - Axial alignment
  - Opening Clip
  - Gripper position
  - Grasping
  - Establishing FAA
  - Deployment
- Fluoroscopy should not be used as a substitute for TEE.





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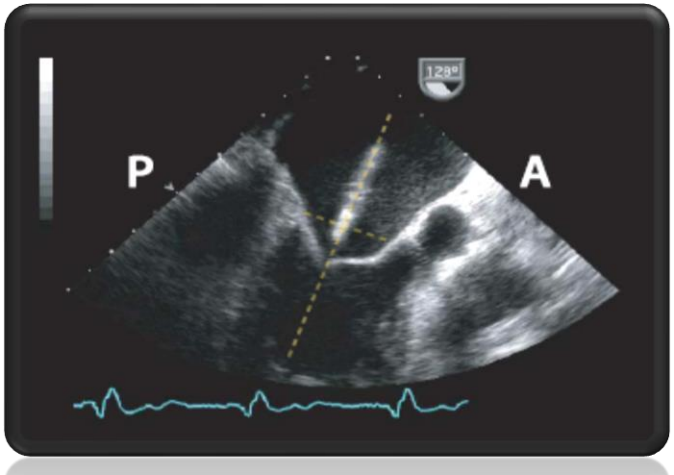
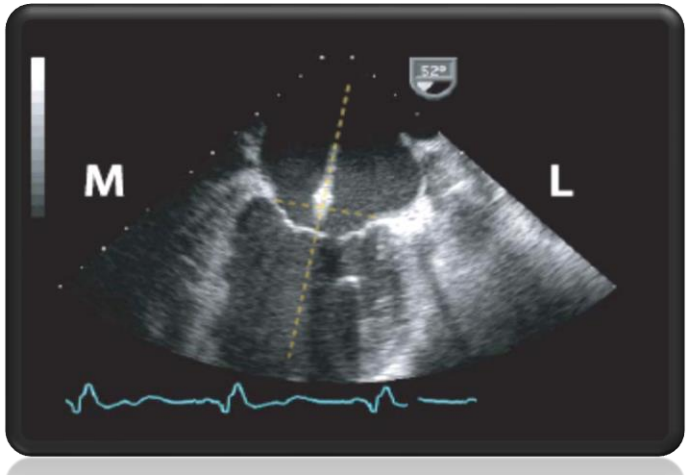
TRANSSEPTAL PUNCTURE

TRANSSEPTAL PUNCTURE GOALS

- Transseptal puncture is achieved through meticulous positioning of transseptal catheters on the fossa of the atrial septum.
- The goal of the transseptal puncture is to cross into the left atrium in a specific location to achieve:
  - Clip positioned perpendicular over the pathology with respect to the anterior-posterior and medial-lateral directions
  - Clip position of at least 1 cm above the leaflets
  - Achieve this position with the least amount of device manipulations as possible





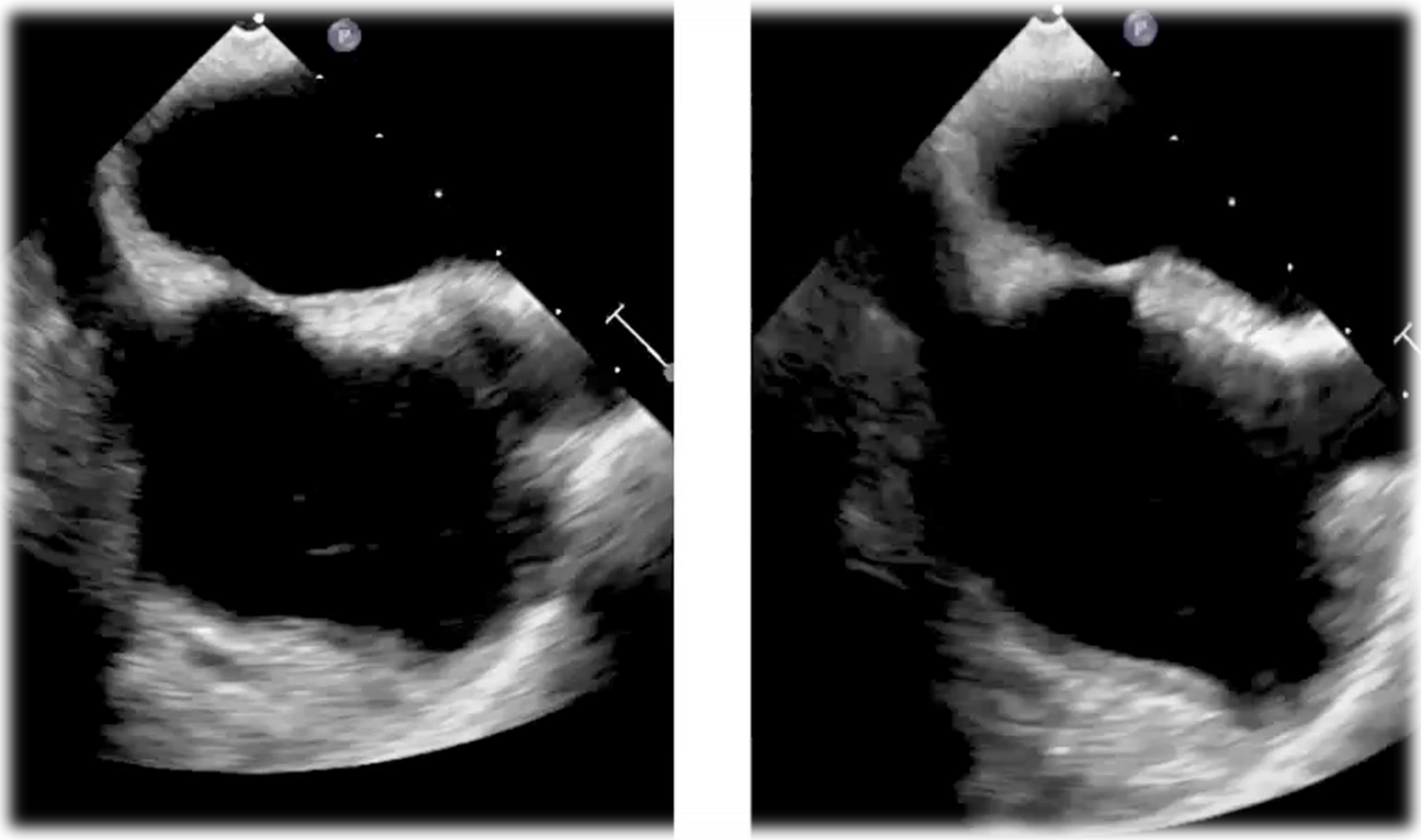
TRANSSEPTAL PUNCTURE

- Prepare the patient per institution's standard practice for transseptal catheterization

- Echo-guided puncture
  - Observe tenting in the bi-caval view (mid fossa)
  - Observe tenting in short axis at base view (posterior-mid fossa)
    - Consider use of X-plane to visualize SAX-B and bi-caval
  - Observe tenting in 4-chamber view (measure height)
  - Puncture and cross fossa in short axis at base view

TENTING: MID-FOSSA
IMAGING: BI-CAVAL, X-PLANE

Pull-back technique: retracting from the SVC to mid-fossa



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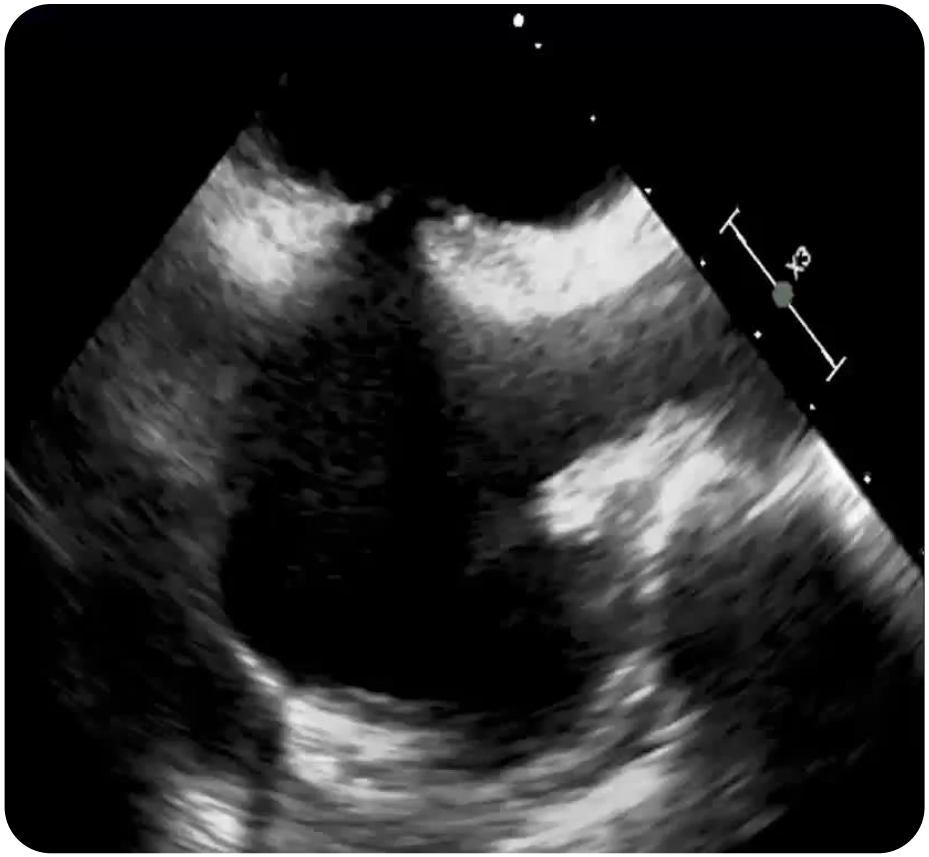
TENTING: MID-FOSSA
IMAGING: BI-CAVAL, X-PLANE

Tenting appropriately in mid-fossa:



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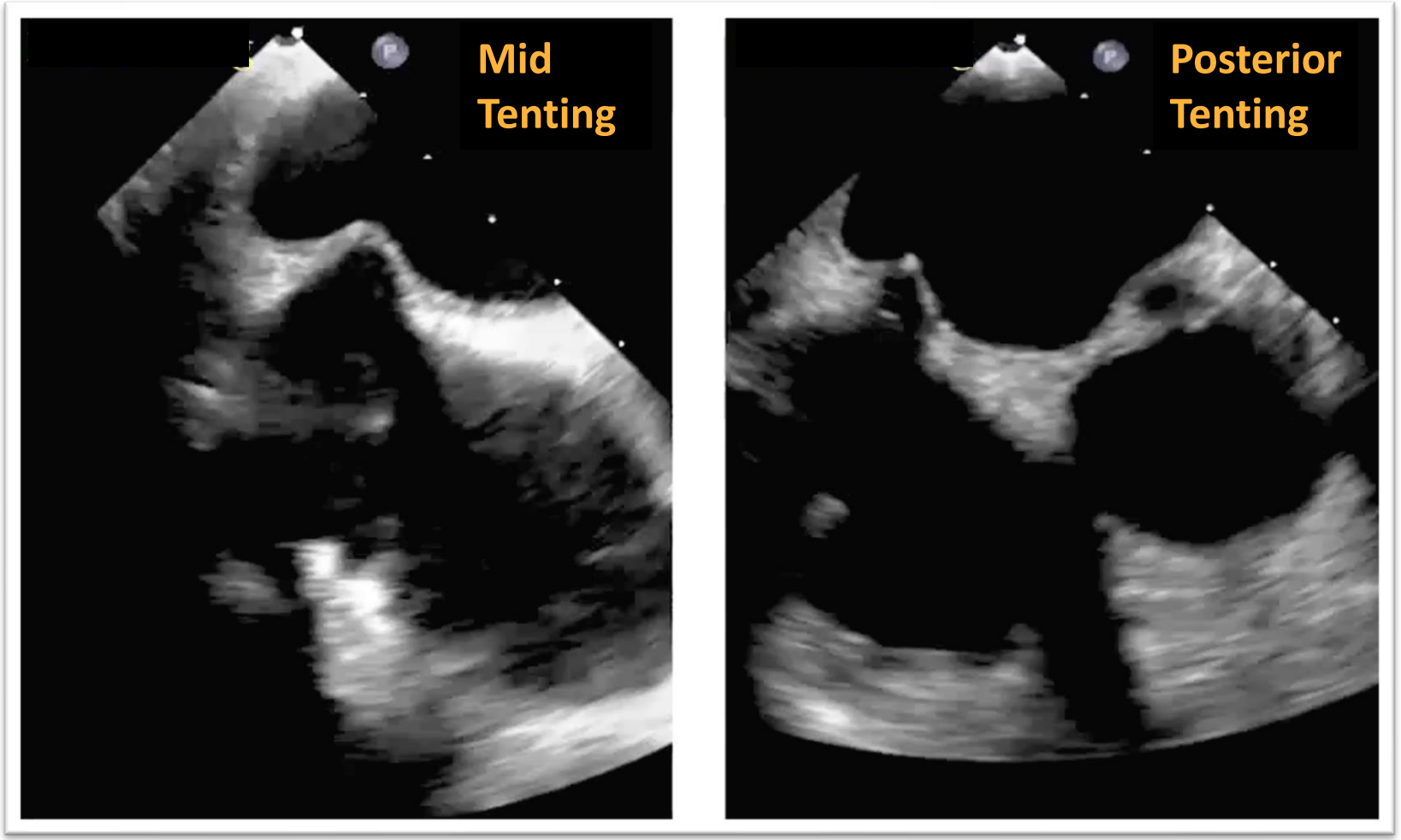
UC Davis Medical Center

TENTING: "POSTERIOR-MID" ASPECT OF FOSSA

IMAGING: SHORT AXIS AT THE BASE, X-PLANE



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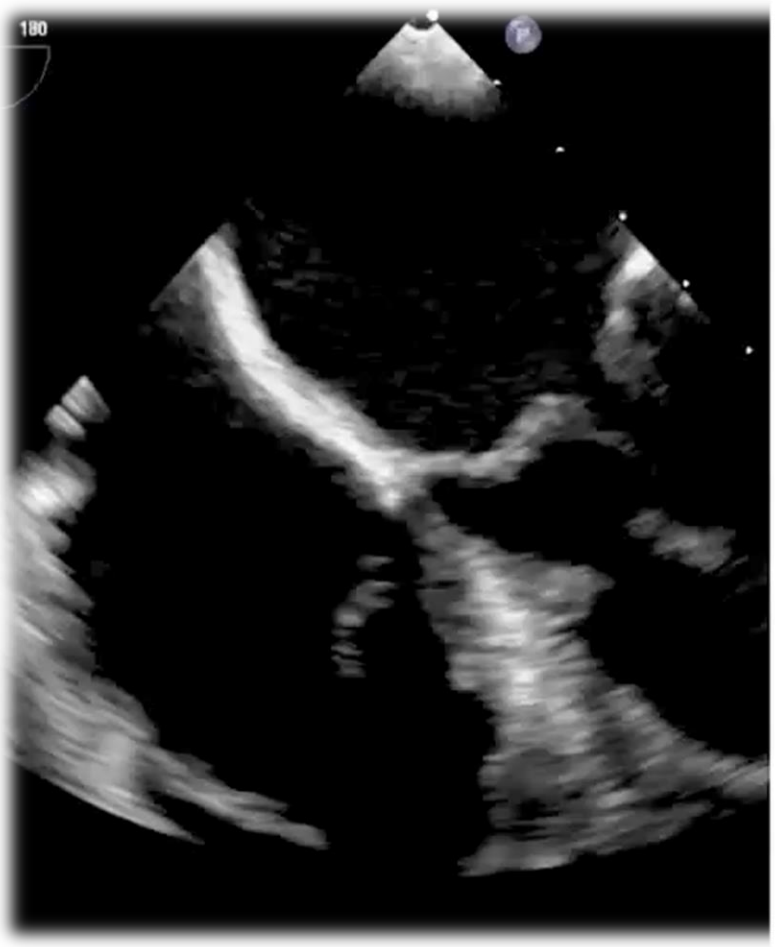
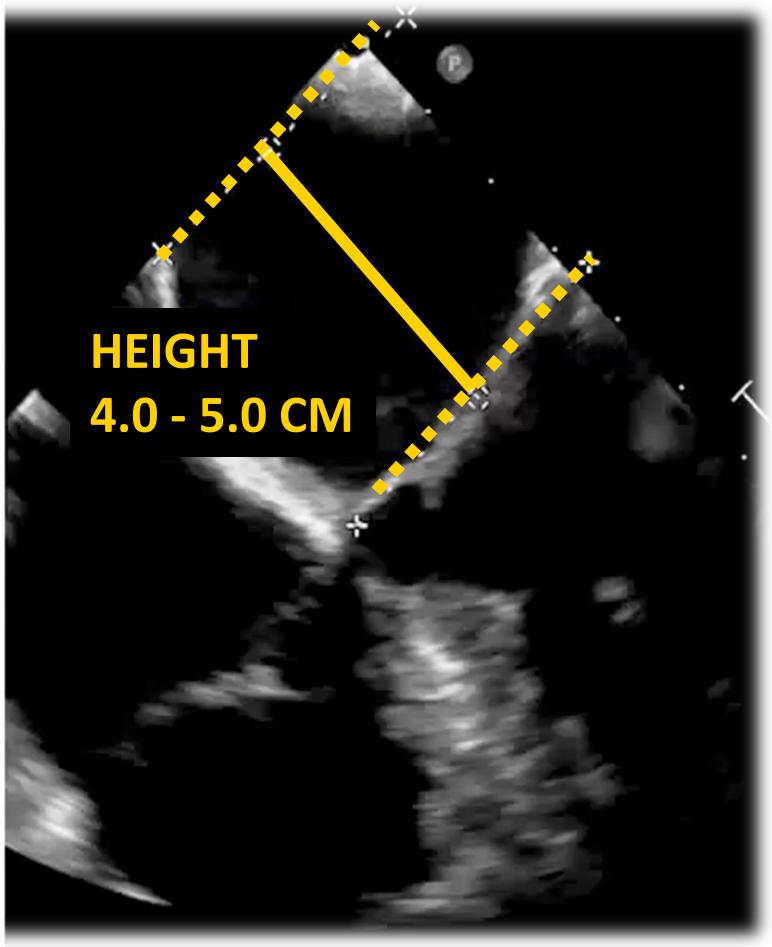
HOW TO OBTAIN HEIGHT MEASUREMENT

IMAGING: 4 CHAMBER OR 5 CHAMBER, HEIGHT 4.0-5.0 CM





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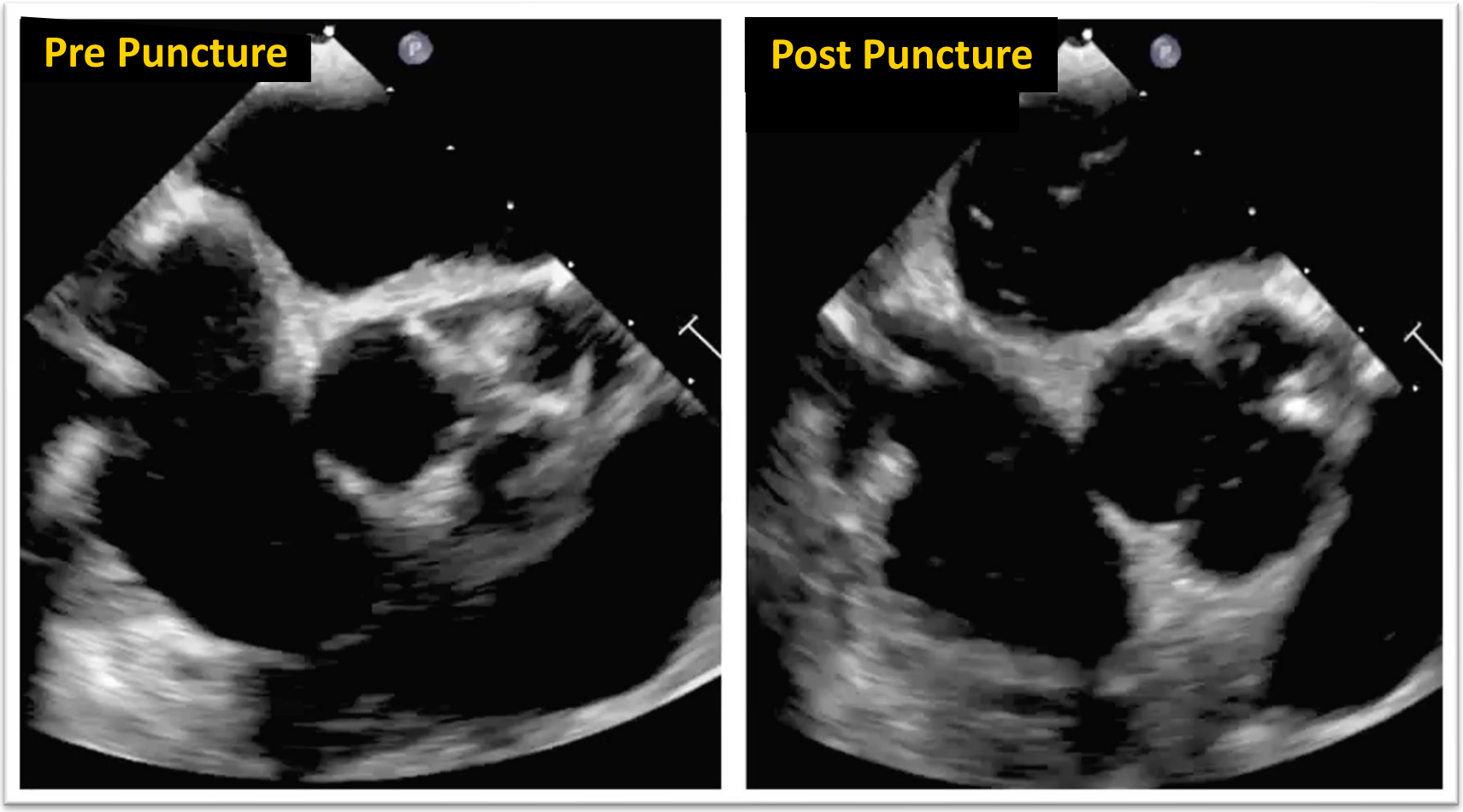
PUNCTURE AND CROSSING THE SEPTUM

IMAGING: SHORT AXIS AT THE BASE



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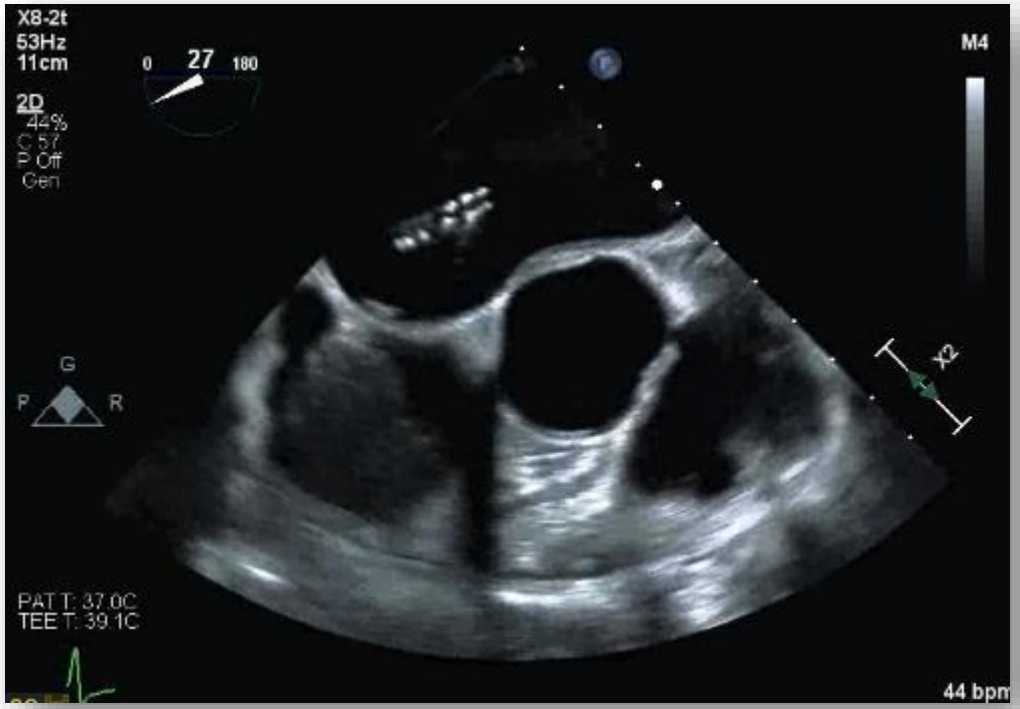
ACCESS TO THE MITRAL VALVE

- Access the LA to accommodate the Guide tip using transvenous, transseptal techniques and equipment.
- Advance Transseptal Sheath to mid LA.
- Flush Transseptal Sheath.
- Heparinize the patient.

WARNING: *Failure to administer heparin once transseptal access has been achieved may result in thrombus formation.*



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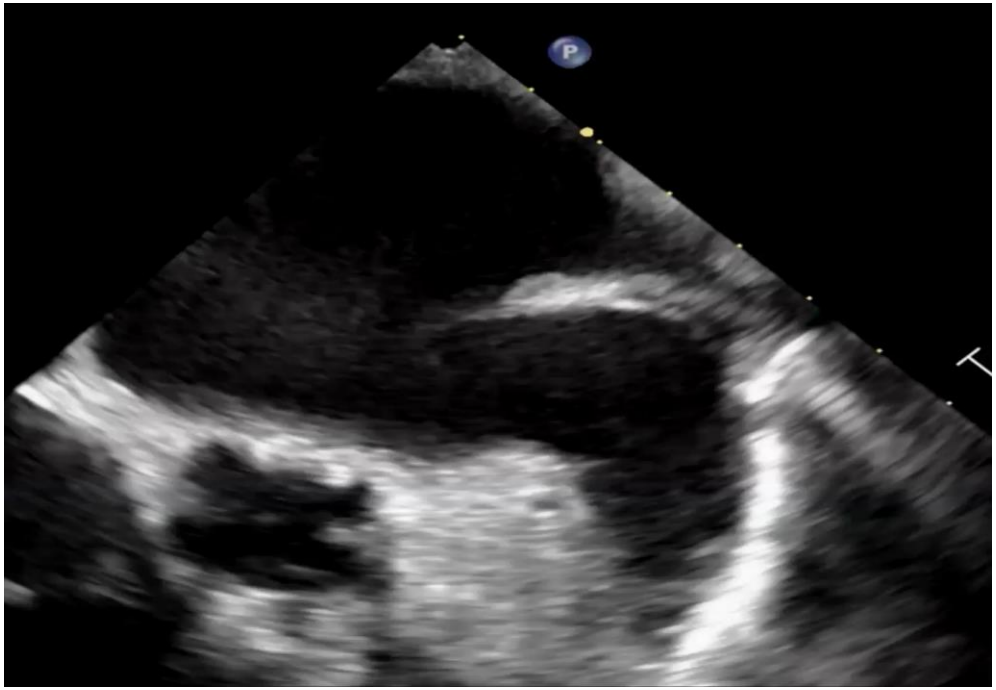
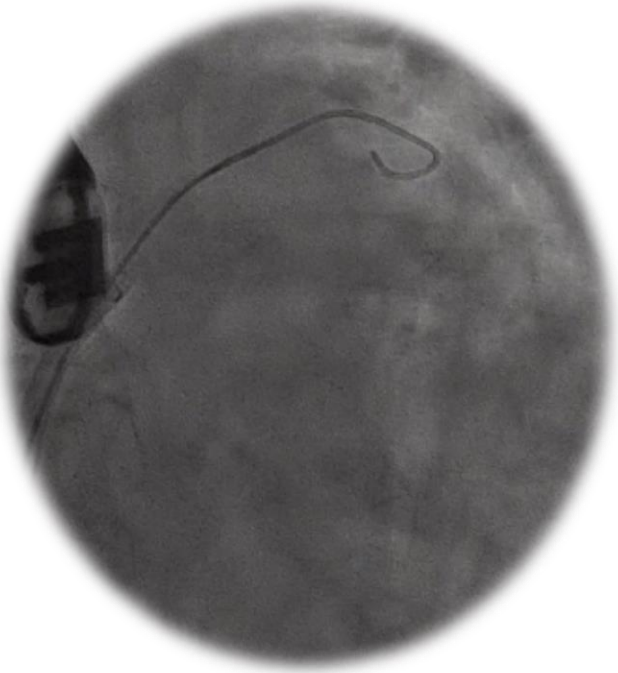
ACCESS TO THE MITRAL VALVE

- Carefully place an exchange length supportive guidewire in the left upper pulmonary vein or LA.





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STEERABLE GUIDE CATHETER INSERTION

STEERABLE GUIDE CATHETER INSERTION

- Dilate the subcutaneous tissue and femoral vein to accommodate the Guide shaft using standard dilation technique.

  WARNING: *Confirm a smooth transition between the Dilator and the tip of the Guide to minimize the risk of vascular and/or cardiac injury.*

  CAUTION: Always use pressure monitoring, echocardiography and fluoroscopy for guidance and observation during use of the MitraClip™ G4 System.

  WARNING: *Always use a careful, deliberate, and iterative approach to positioning the MitraClip G4 System. It is recommended to make multiple small adjustments rather than single large adjustments. Large adjustments may result in vascular and/or cardiac injury.*

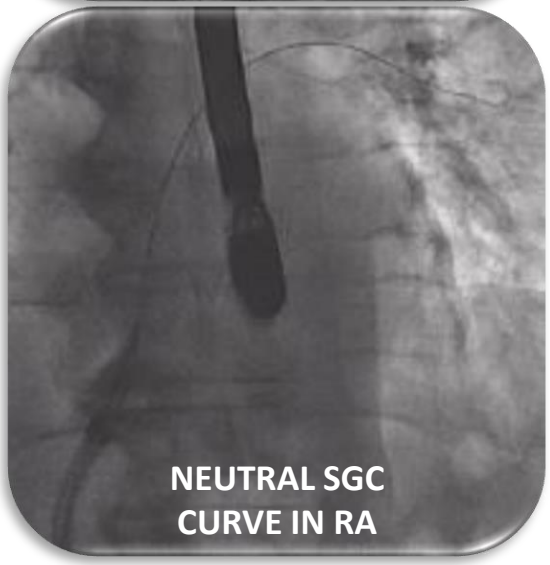
- Rotate +/- Knob in "-" direction until Guide curve is substantially straightened.
- Wet the surface of the Guide shaft with sterile saline.

STEERABLE GUIDE CATHETER INSERTION

- Insert the Guide-Dilator assembly over the stationary guidewire into the femoral vein.

  WARNING: *DO NOT use excessive force to advance or manipulate the Guide-Dilator assembly. If resistance is encountered, use echocardiography and/or fluoroscopy to assess before proceeding. Use of excessive force may result in arrhythmias, vascular and/or cardiac injury, including creation of a clinically significant atrial septal defect.*

- Advance the Guide-Dilator assembly to the RA. Rotate the +/- Knob to neutral, then place tip of the Dilator partially across the atrial septum.



Images courtesy of Gagan Singh MD
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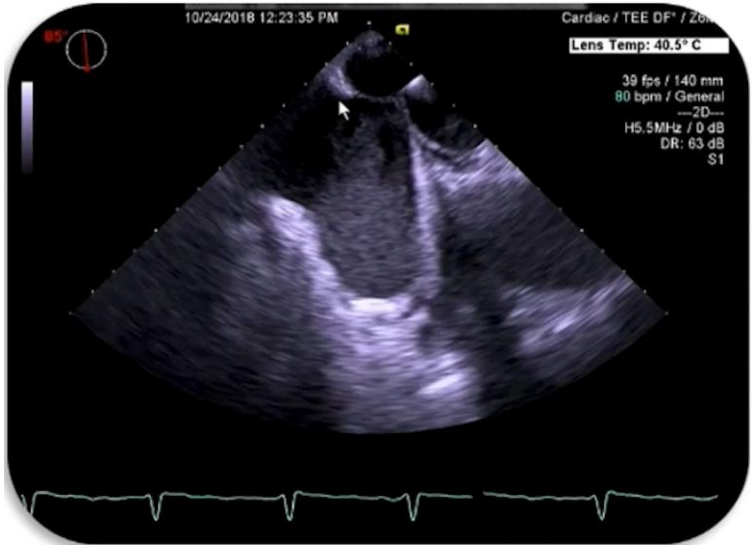
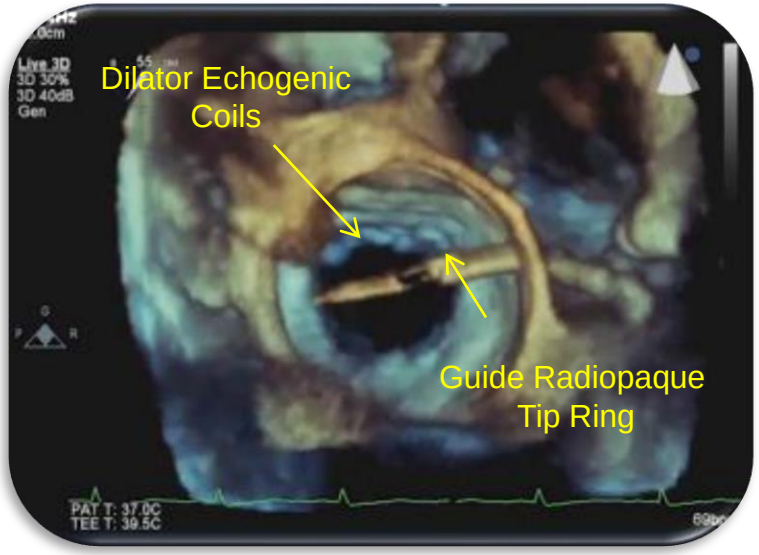
STEERABLE GUIDE CROSSING
IMAGING: SHORT AXIS AT BASE, BICAVAL, 3D

- Slowly dilate the atrial septum by gradually advancing the tip of the Guide-Dilator Assembly.

  ***WARNING**: DO NOT rapidly advance the Guide-Dilator assembly across the atrial septum. Rapid advancement may result in vascular and/or cardiac injury.*

- Advance the Guide-Dilator assembly until the tip of the Guide extends approximately 3 cm in the LA.
- Adjust Guide deflection and torque to position the tip away from adjacent tissues.





Images courtesy of Gagan Singh MD
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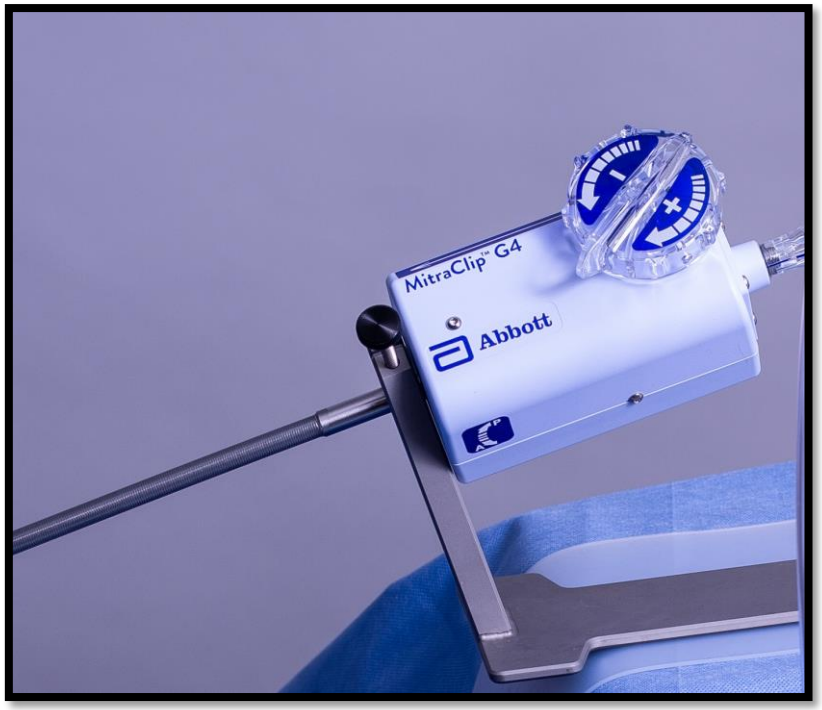
STEERABLE GUIDE CROSSING
IMAGING: SHORT AXIS AT BASE, BICAVAL, 3D

- Place the Silicone Pad on sterile drape over Lift. Place the Stabilizer onto the Silicone Pad.

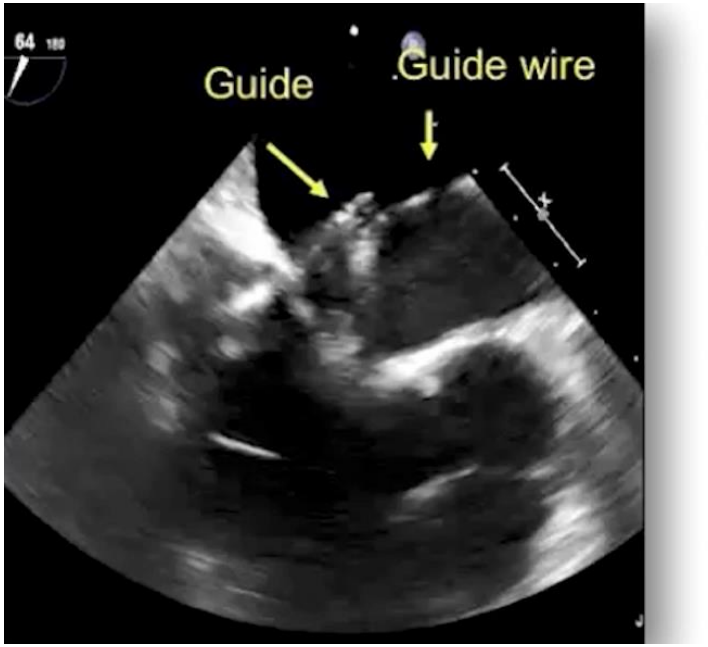
- Secure the Guide in the Stabilizer slot using the Fastener. Ensure the Fastener engages the metallic tube on the Guide shaft. The Guide handle should be immediately adjacent to the Stabilizer, such that they are in contact with each other.

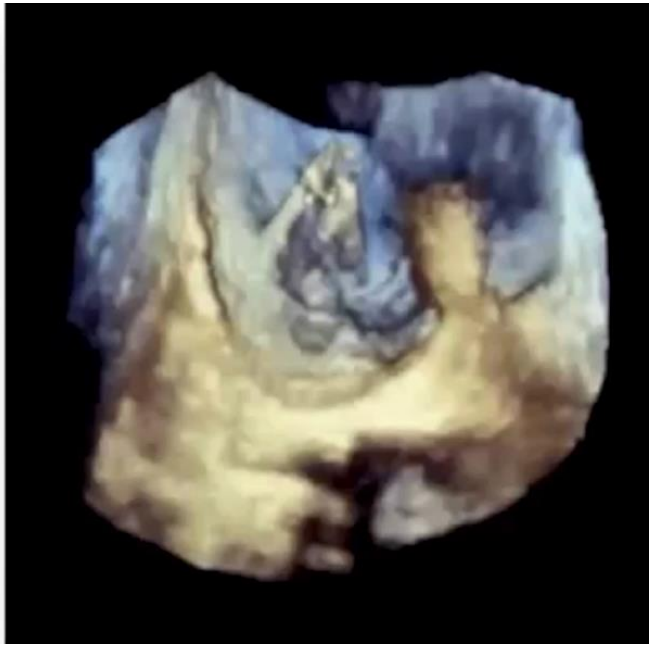


STEERABLE GUIDE CROSSING
IMAGING: SHORT AXIS AT THE BASE, 3D, FLUORO

- Retract the Dilator approximately 5 cm into the Guide, leaving the guidewire in the left upper pulmonary vein or LA.

  CAUTION: *Always loosen the Fastener before torquing the Guide to prevent stripping the screw.*





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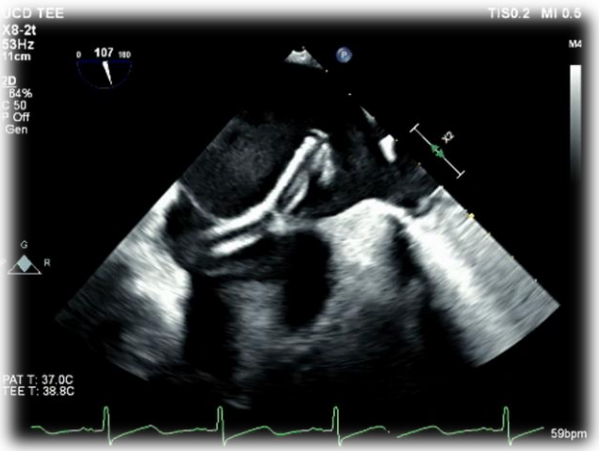
STEERABLE GUIDE CROSSING
IMAGING: SHORT AXIS AT THE BASE, 3D, FLUORO

- Retract the guidewire into the tip of the Dilator. Remove the Dilator and guidewire while gently aspirating the Guide (starting when the Dilator is approximately halfway retracted into the Guide, approximately 40 cm) using a 50-60 cc syringe. Cover Guide Hemostasis Valve with finger upon Dilator removal.

NOTE: *Avoid contacting tissue or creating a vacuum in the Guide lumen. If necessary, position the Guide handle below the level of the LA to allow blood to fill the Guide lumen.*



WARNING: *DO NOT create a vacuum while removing the dilator from the Guide; air may enter the lumen of the Guide, which may result in air embolism.*

WARNING: *Failure to fully retract guidewire into the Dilator may result in air embolism.*

Images courtesy of Gagan Singh MD
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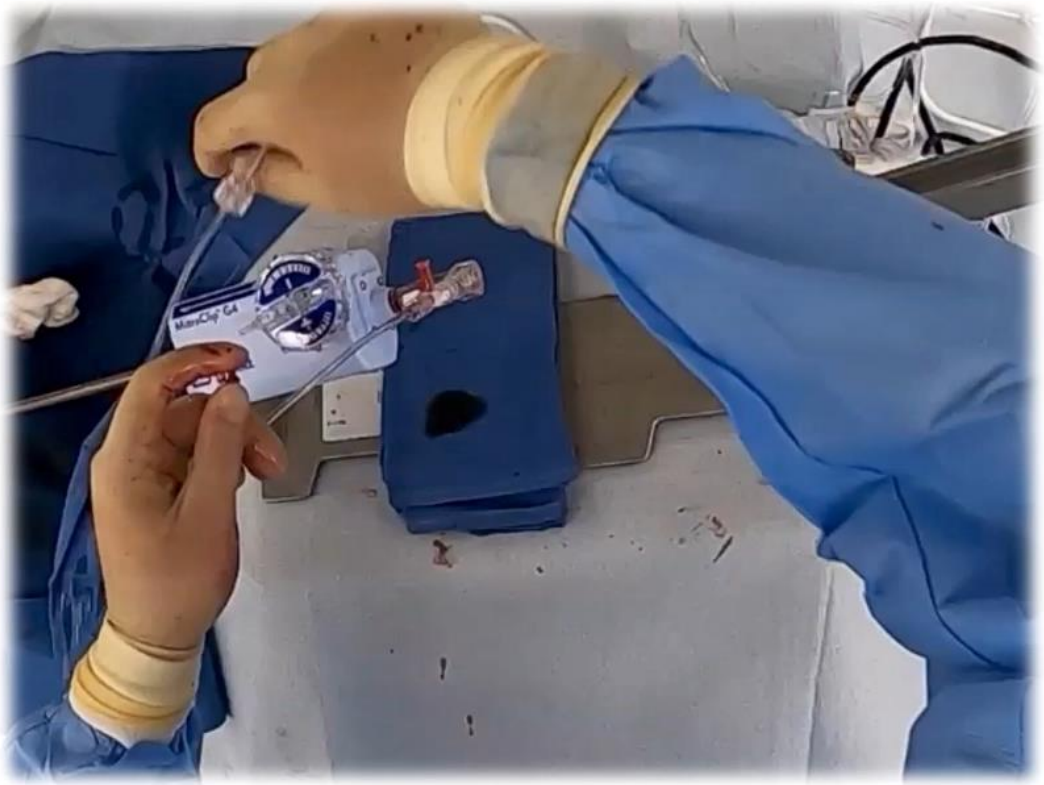
STEERABLE GUIDE CROSSING
LEFT ATRIAL PRESSURE CAPABILITY



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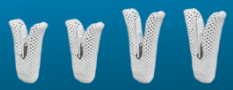
CLIP DELIVERY SYSTEM INSERTION

CLIP DELIVERY SYSTEM (CDS) INSERTION



- Confirm the Guide lumen is completely de-aired.

  WARNING: *To minimize the potential of air embolism, DO NOT introduce the CDS into the Guide until the Guide lumen has been completely de-aired.*

- Confirm there is a slow, continuous heparinized saline flush through both the Sleeve and the DC and that the tip of the Clip is just proximal to the tip of the Clip Introducer.

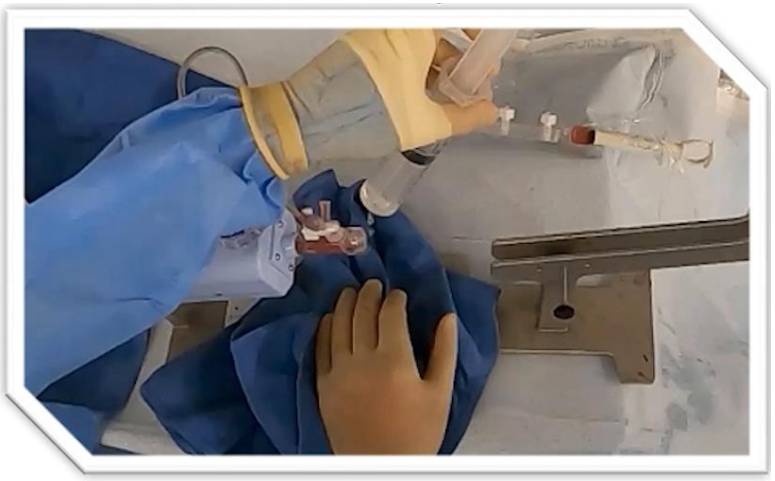
  CAUTION: *Failure to continuously flush the CDS with heparinized saline may reduce device performance.*

  WARNING: *Heparinized saline flush should be continuous throughout the procedure. Discontinuing flush may result in air embolism and/or thrombus formation. Ensure flow is visible through the drip chamber and that tubing is free from kinks and/or obstruction. Ensure pressure of 300 mm Hg is maintained.*

- Carefully remove the protective cover surrounding the Clip and Clip Introducer.
- Confirm that the stopcock on the Clip Introducer flush port is closed and that the Clip Introducer is de-aired.

CLIP DELIVERY SYSTEM (CDS) INSERTION

- While flushing heparinized saline on the Guide Hemostasis Valve, place the tip of the Clip Introducer against the Guide Hemostasis Valve and advance the Clip Introducer straight into the valve in a continuous motion while rotating the Clip Introducer in small clockwise and counterclockwise motions until the Clip can be observed distal to the valve.



WARNING: *DO NOT continue to advance the Clip Introducer if resistance is felt; the Guide Hemostasis Valve, Clip Introducer or the Clip may be damaged. Damage to these components may result in air embolism, vascular or cardiac injury.*

WARNING: *To minimize the potential of air embolization, ensure proper de-airing when inserting the Clip Introducer into the Guide Hemostasis Valve.*

Images courtesy of Gagan Singh MD,
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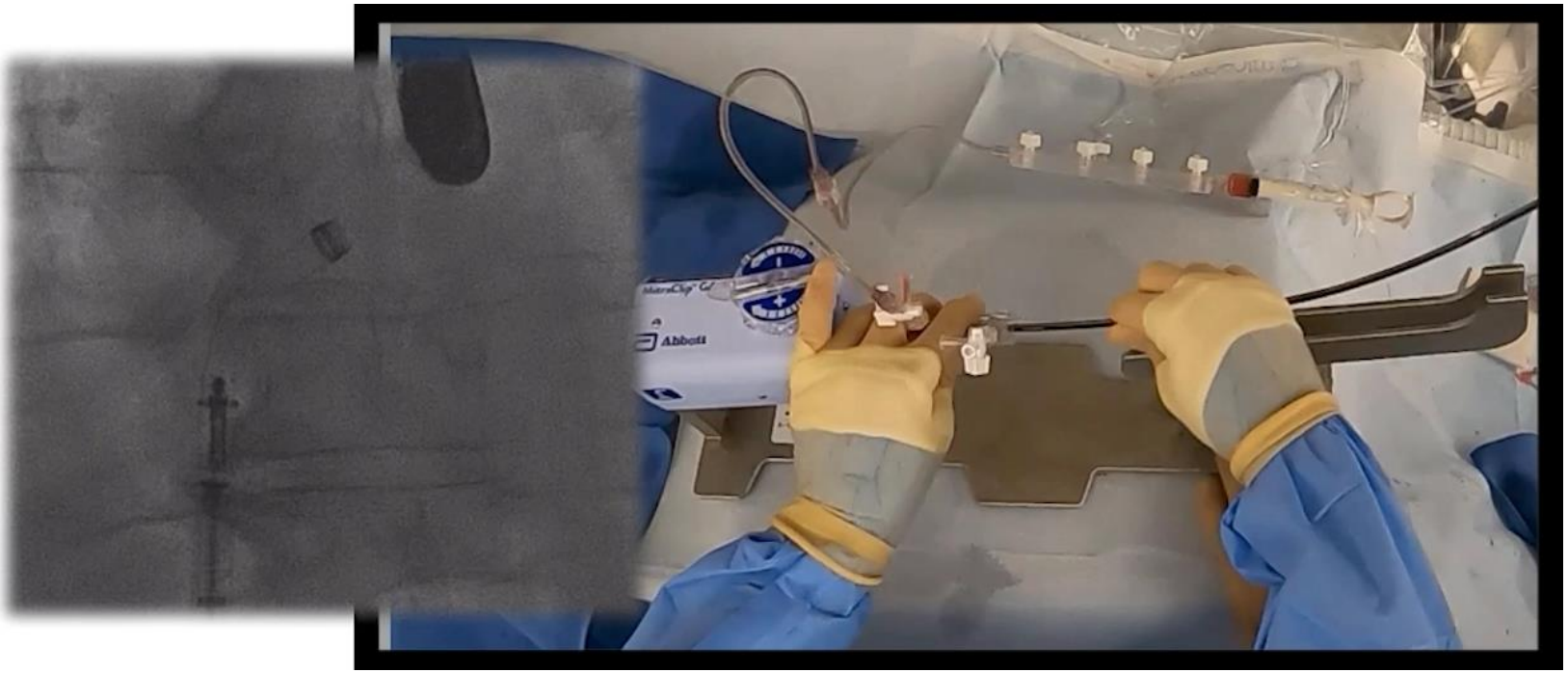
CLIP DELIVERY SYSTEM (CDS) INSERTION

- Leave the Clip Introducer fully inserted in the Guide Hemostasis Valve throughout the procedure.
- Align the Longitudinal Alignment Marker on the Sleeve shaft with the Alignment Marker on the Guide Hemostasis Valve.

CLIP DELIVERY SYSTEM (CDS) INSERTION

- Turn the +/- Knob to neutral then carefully advance the CDS through the Guide under fluoroscopic guidance. Stop when the tip of the Clip is even with the tip of the Guide.

  NOTE: *If resistance to CDS advancement is felt, reduce Guide deflection.*



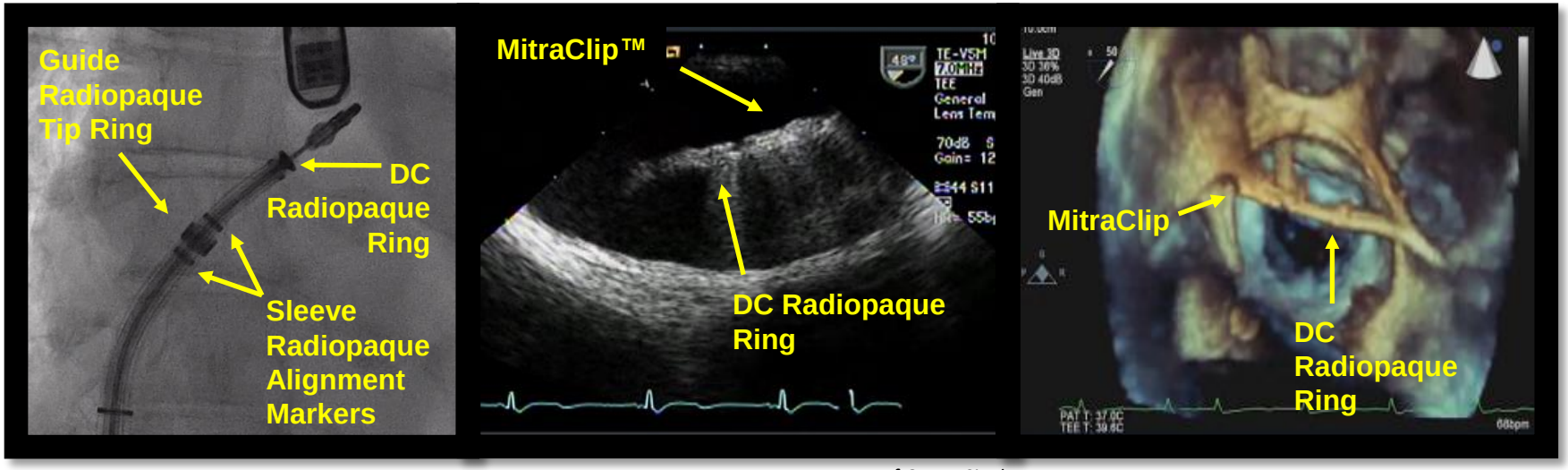
Images courtesy of Gagan Singh MD,
UC Davis Medical Center

ADVANCE CDS TO STRADDLING POSITION

IMAGING: SHORT AXIS AT THE BASE, 3D, FLUORO

- Under echocardiographic guidance, advance the CDS and retract the Guide iteratively as needed while maintaining the Guide in the LA. Stop when the Guide RO Tip Ring is between RO Alignment Markers of the Sleeve, as confirmed under fluoroscopic guidance.
- Position the Sleeve Handle in the Stabilizer slot.
- Confirm that the Clip is free from left atrial wall and valve tissue.

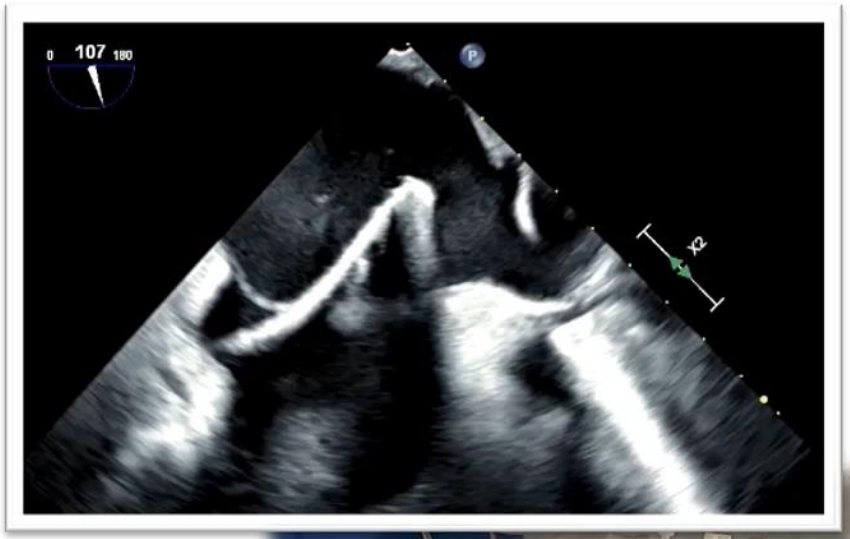
WARNING: *Failure to confirm that the Clip is free from the left atrial wall and valve tissue may result in cardiac injury.*



Images courtesy of Gagan Singh MD, UC Davis Medical Center

ADVANCE CDS TO STRADDLING POSITION

IMAGING: SHORT AXIS AT THE BASE, 3D, FLUORO



Images courtesy of Gagan Singh MD,
UC Davis Medical Center

STEERING FUNCTIONALITY OF THE MITRACLIP™ SYSTEM COMPONENTS

Guide Handle:	Anterior & Posterior
Sleeve Handle:	Medial, Lateral, Anterior & Posterior
Delivery Catheter Handle:	Clip Positioning, Grasping & Deployment
Stabilizer:	Medial & Lateral

STEERING AND POSITIONING THE MITRACLIP™ G4 SYSTEM

INITIAL MITRACLIP™ G4 SYSTEM POSITIONING IN THE LEFT ATRIUM

NOTE: Positioning is achieved with iterative adjustments of the Guide and CDS using torque, translation and knob adjustments.

The goals of positioning are:

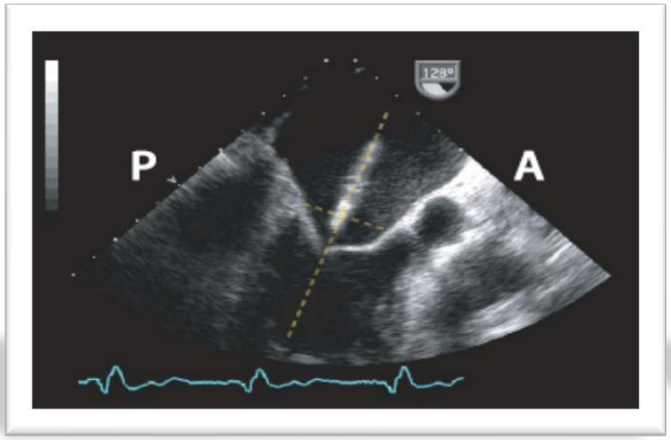
A. Positioning the Clip centrally over the valve with respect to anterior-posterior and medial-lateral directions.

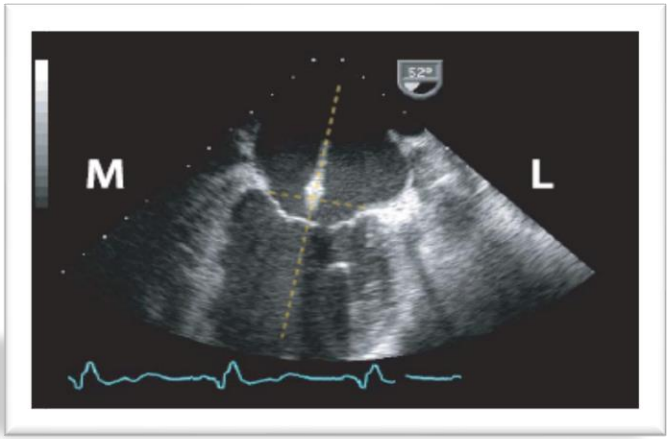
B. Aligning the Clip so the DC Shaft is perpendicular to the plane of the mitral valve.

C. Positioning the distal tip of the Clip at least 1 cm above the leaflets.

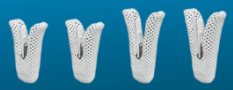
WARNING: *Excessive torque on the Guide and translation of the MitraClip G4 System may inadvertently displace the tip of the Guide from the LA, which may result in arrhythmias or cardiac injury.*

WARNING: *DO NOT continue to rotate or manipulate any of the handle knobs if significant resistance is noted; device damage may occur and result in cardiac injury.*





INITIAL MITRACLIP™ G4 SYSTEM POSITIONING IN THE LEFT ATRIUM

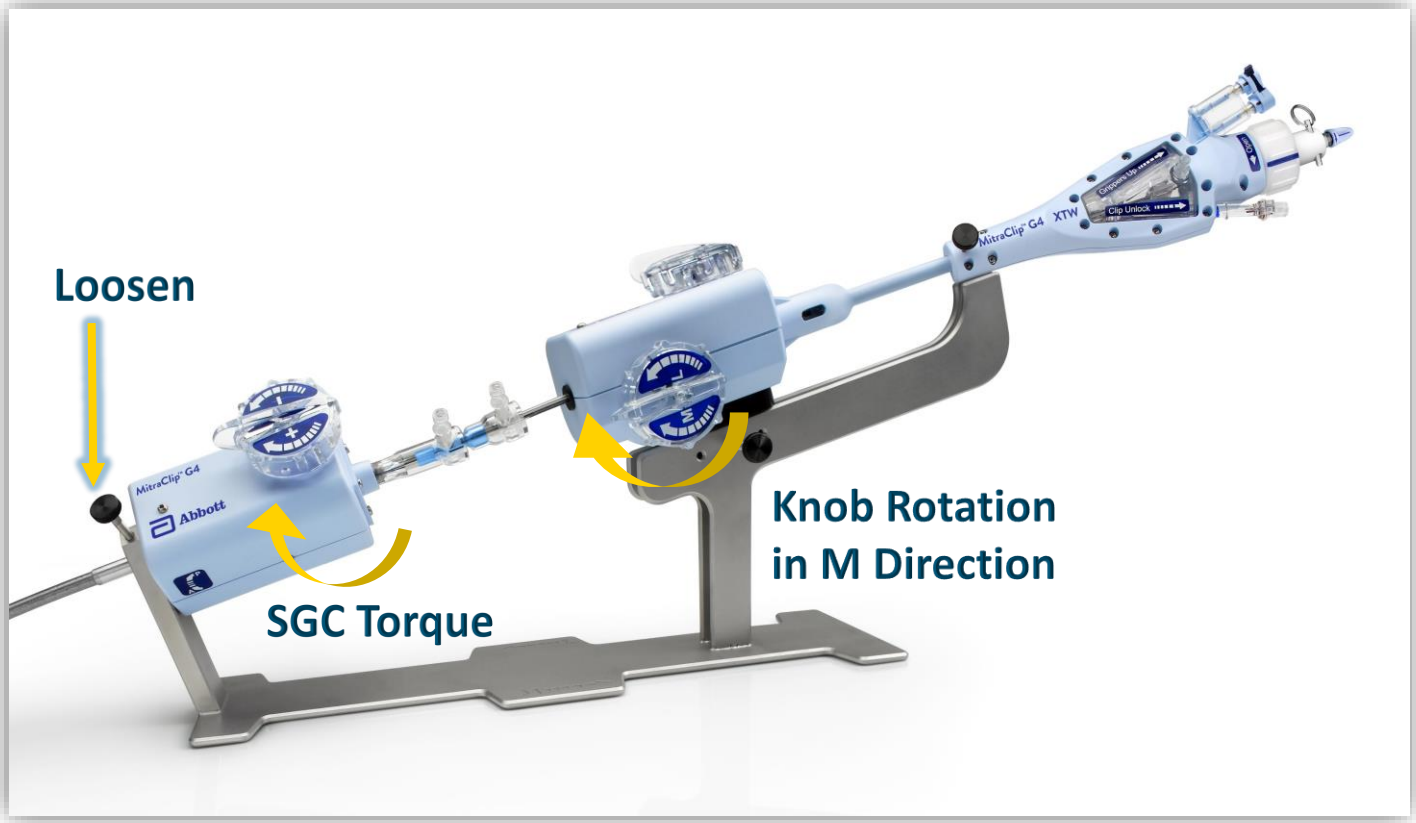


- Adjust the Guide position as necessary to maintain that the Clip is free from adjacent tissue.
- Adjust Sleeve deflection using the M/L Knob and/or the A/P Knob to deflect the Clip towards the apex. Retract the DC Radiopaque Ring against the Sleeve tip as necessary.
- During Sleeve deflections confirm that the Guide RO Tip Ring is between the RO Alignment Markers of the Sleeve prior to making maximum Sleeve deflections.

  ***WARNING**: DO NOT deflect the Sleeve tip more than 90° as device damage may occur. Use of damaged product may result in cardiac injury.*
- Secure the Sleeve handle in the Stabilizer using the Fastener.
- To reposition the MitraClip G4 System, move the Stabilizer with the system until positioning is adequate.

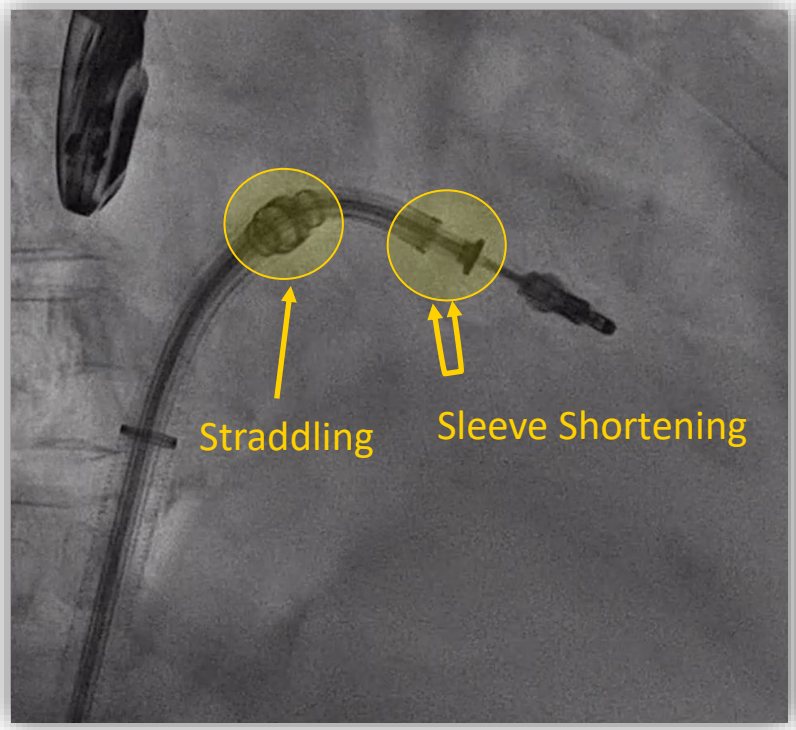
INITIAL MEDIAL DEFLECTION OF SLEEVE

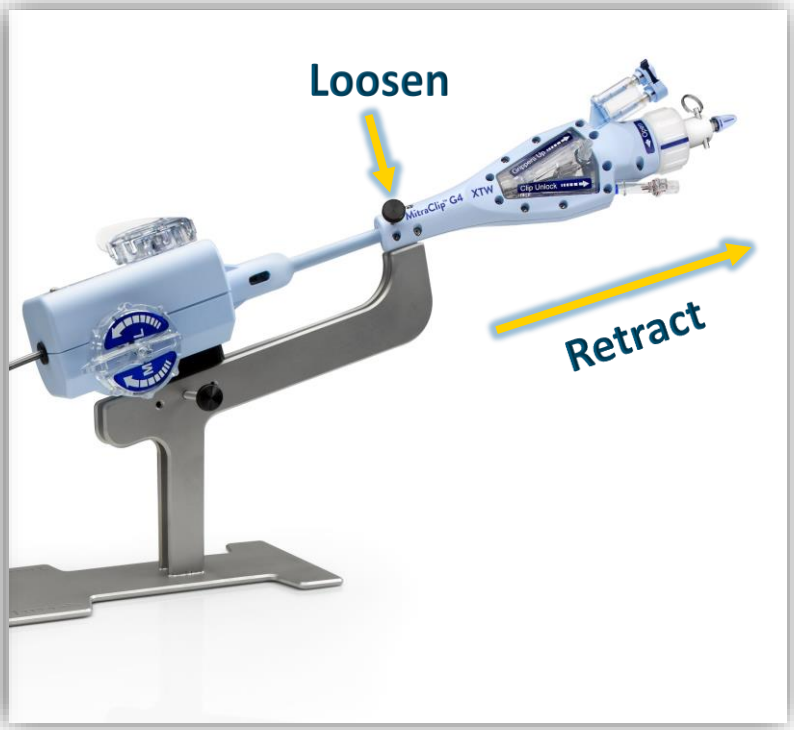
When you add (M) knob, the Clip will initially travel slightly anterior. Torque the Guide Posterior to move away from aorta.



INITIAL MEDIAL DEFLECTION OF SLEEVE

- Medial deflection will shorten the Sleeve.
- Loosen Delivery Catheter fastener, retract Clip, and re-secure fastener.





- After medial deflection, confirm that Guide RO Tip Ring has maintained its position, straddled between the RO Alignment Markers of the Sleeve.

Images courtesy of Gagan Singh MD,
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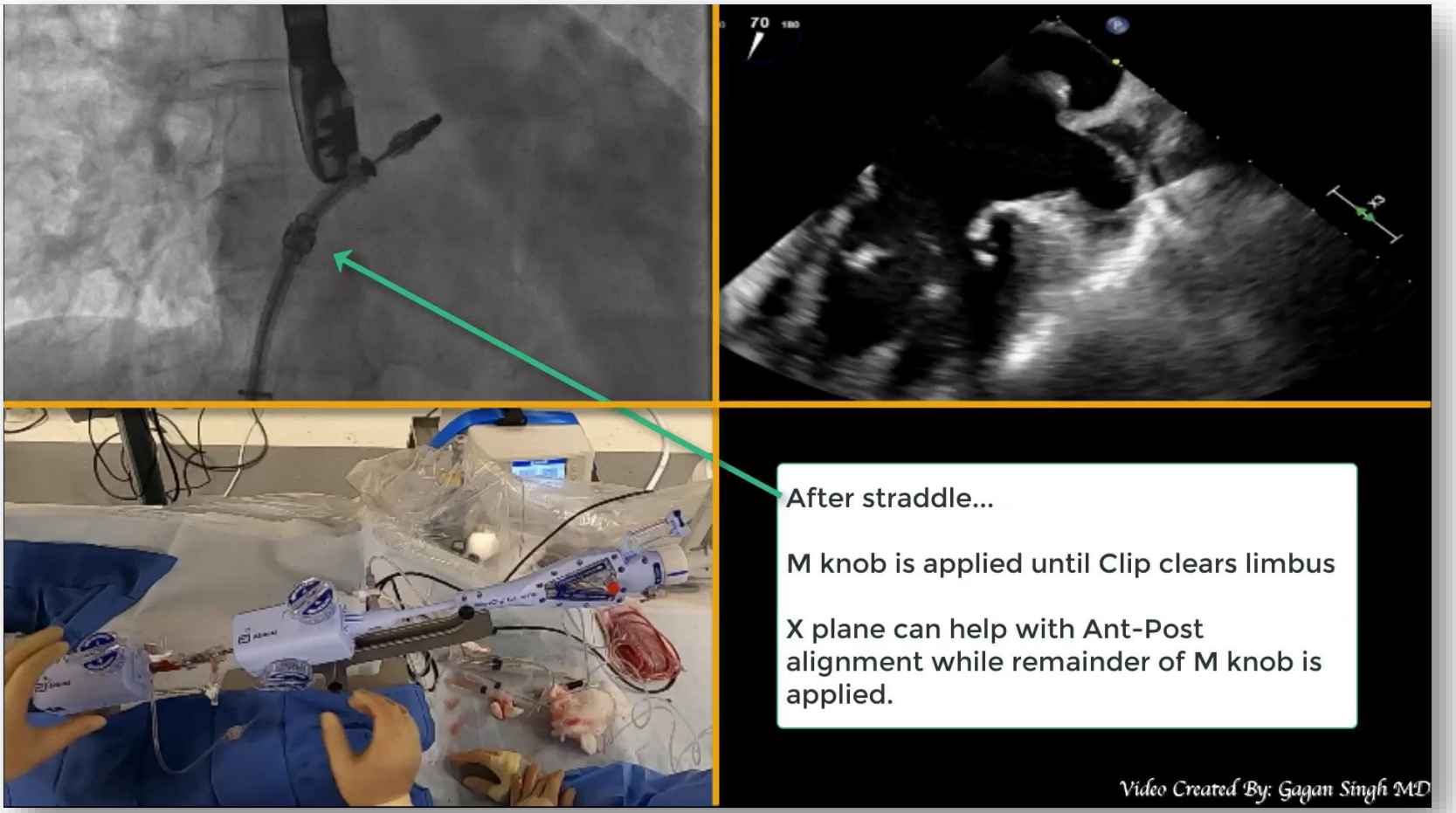
INITIAL MITRACLIP™ G4 SYSTEM POSITIONING IN THE LEFT ATRIUM



Images courtesy of Gagan Singh MD,
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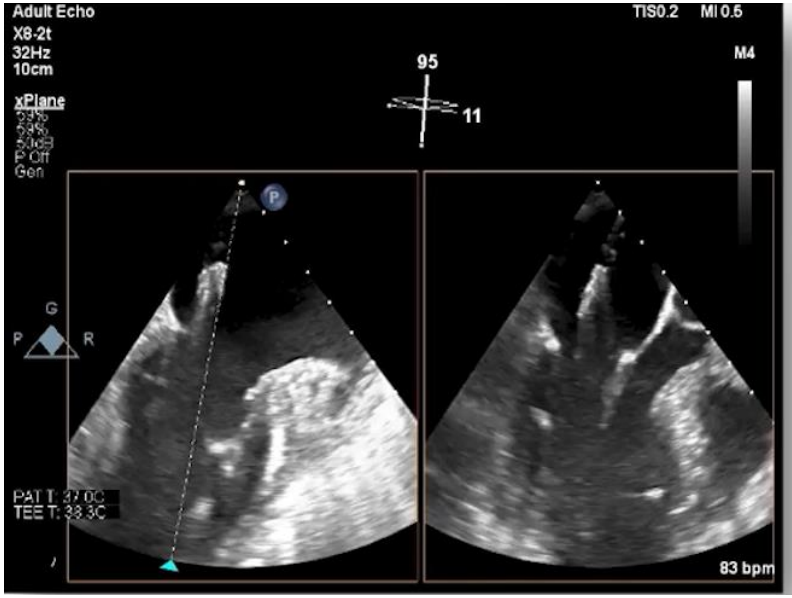
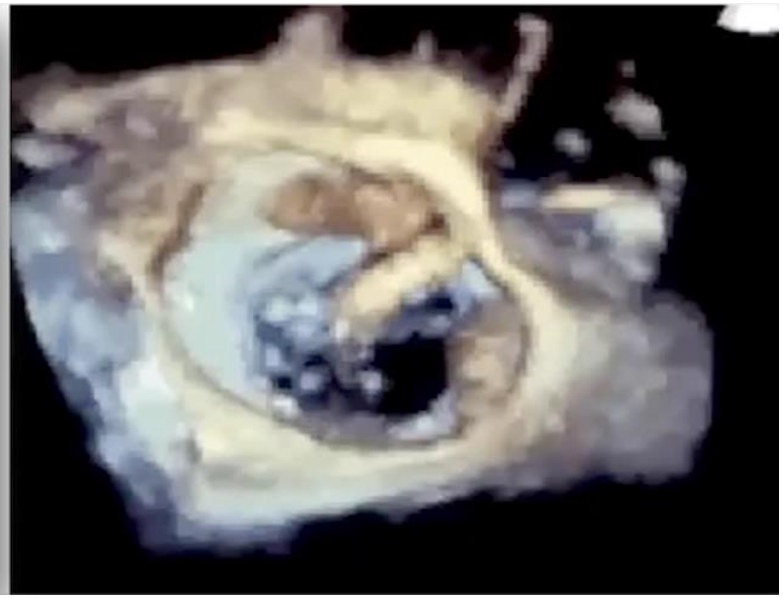
INITIAL MITRACLIP™ G4 SYSTEM POSITIONING IN THE LEFT ATRIUM

- Adjust the MitraClip G4 System position to maintain adequate height above the mitral valve in the LA.

WARNING: *Maintain the Clip above the leaflets until ready to grasp to minimize the risk of Clip entanglement in the chordal apparatus. Clip entanglement may result in cardiac injury, worsening mitral regurgitation, difficulty or inability to remove the Clip and conversion to surgical intervention.*



Images courtesy of Reddy Atmakuri MD
Banner Heart Hospital



Images courtesy of Gagan Singh MD
UC Davis Medical Center

FINAL MITRACLIP™ G4 SYSTEM POSITIONING

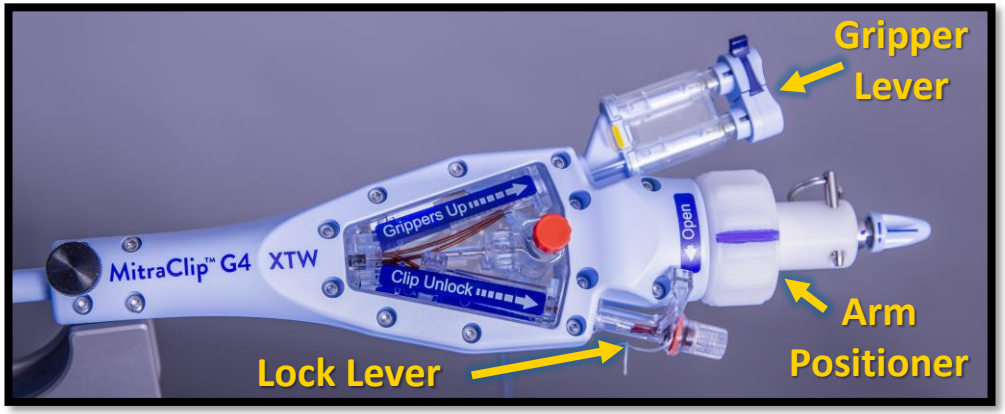
- Raise the Gripper(s).

  CAUTION: *Raising the Grippers more often than needed or retracting the Gripper Lever forcefully may damage the Gripper cover or Gripper line and impair CDS Performance.*

- Unlock the Clip and Open the Clip Arms to approximately 180°.

  WARNING: DO NOT RETRACT THE LOCK LEVER FORCEFULLY. *Retracting the Lock Lever forcefully may result in the inability to unlock Clip. Inability to open the Clip may result in valve injury or lead to deployment of the Clip in an unintended location.*

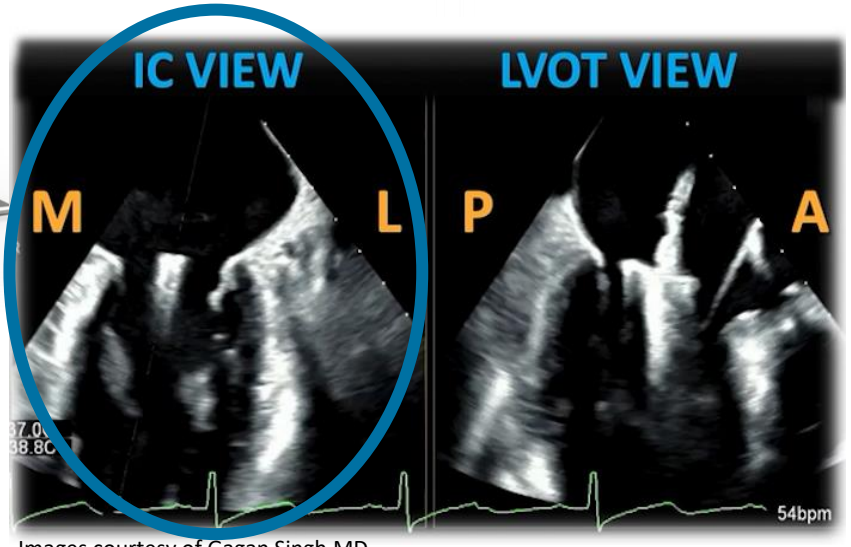
  - Rotate Lock Lever outward and then retract the lever until the mark on the lever is fully exposed.
  - Rotate Lock Lever inward to engage the lever.
  - Turn the Arm Positioner at least 1/2 turn in the “Close” (clockwise) direction.
  - Turn the Arm Positioner in the “Open” (counter-clockwise) direction until the desired Clip Arm Angle is achieved.



MEDIAL/LATERAL (M/L) ADJUSTMENTS
IMAGING: INTERCOMMISSURAL - BICOM, X-PLANE

- Adjust the MitraClip™ G4 System to reposition the Clip as necessary. Confirm that the distal tip of the Clip is at least 1 cm above the leaflets.

- M/L Knob
  - Clockwise (medial)
  - Counter Clockwise (lateral)

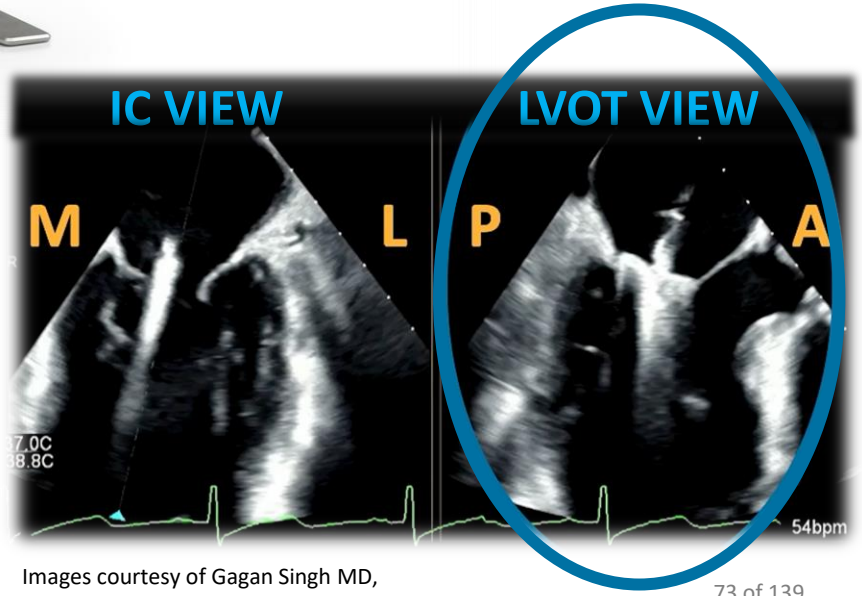


Images courtesy of Gagan Singh MD, UC Davis Medical Center

ANTERIOR/POSTERIOR (A/P) ADJUSTMENTS

IMAGING: LVOT , X-PLANE

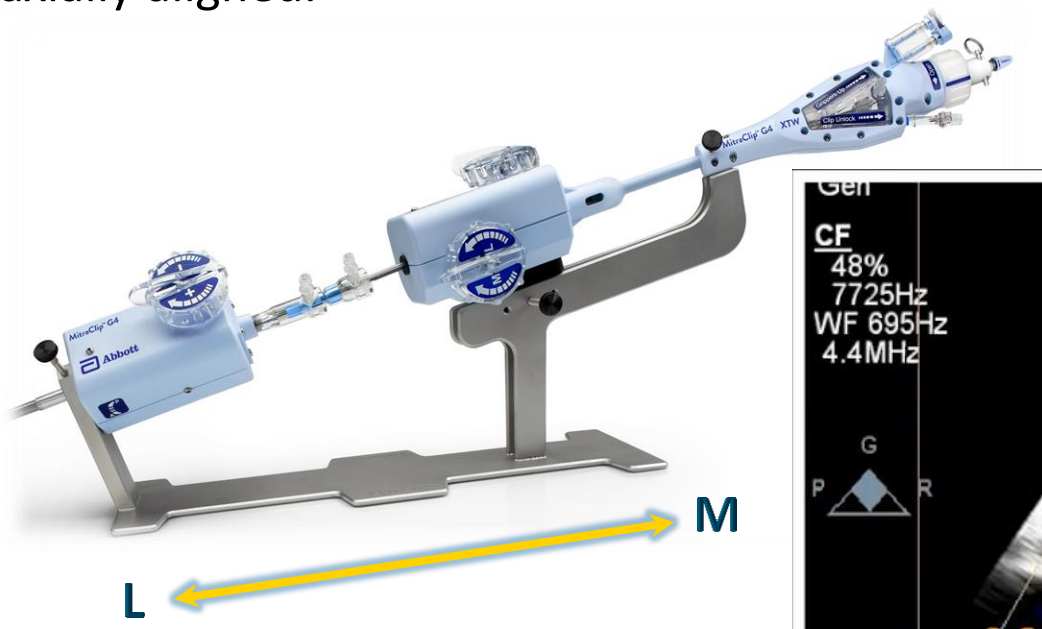
- Loosen Fastener
- Torque Guide
  - Clockwise (posterior)
  - Counter clockwise (anterior)

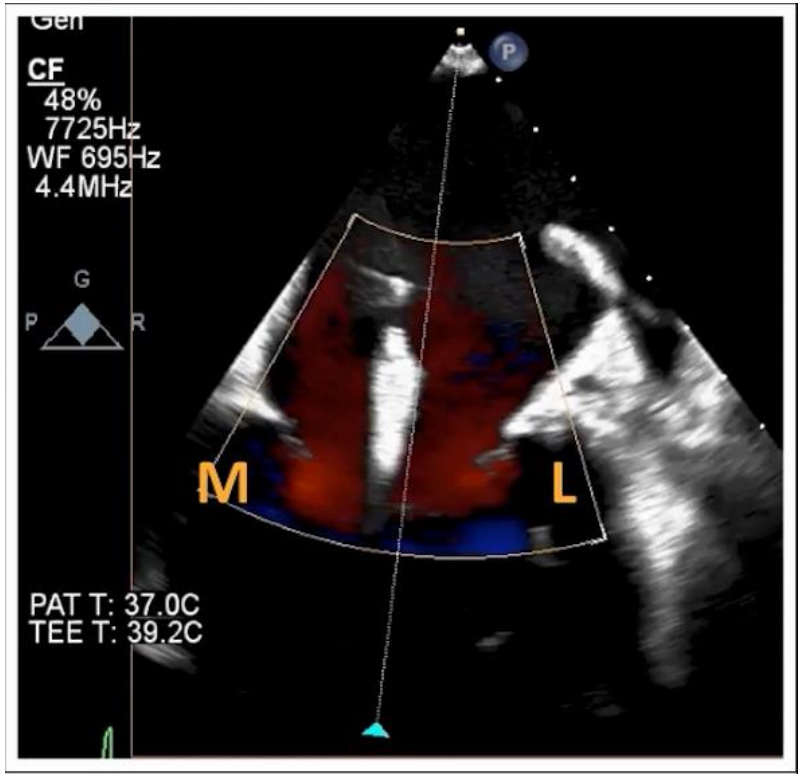


Images courtesy of Gagan Singh MD, UC Davis Medical Center

MEDIAL/LATERAL (M/L) ADJUSTMENTS
IMAGING: INTERCOMMISSURAL - BICOM, X-PLANE

This maneuver should only be used once the Sleeve & Clip have been axially aligned.





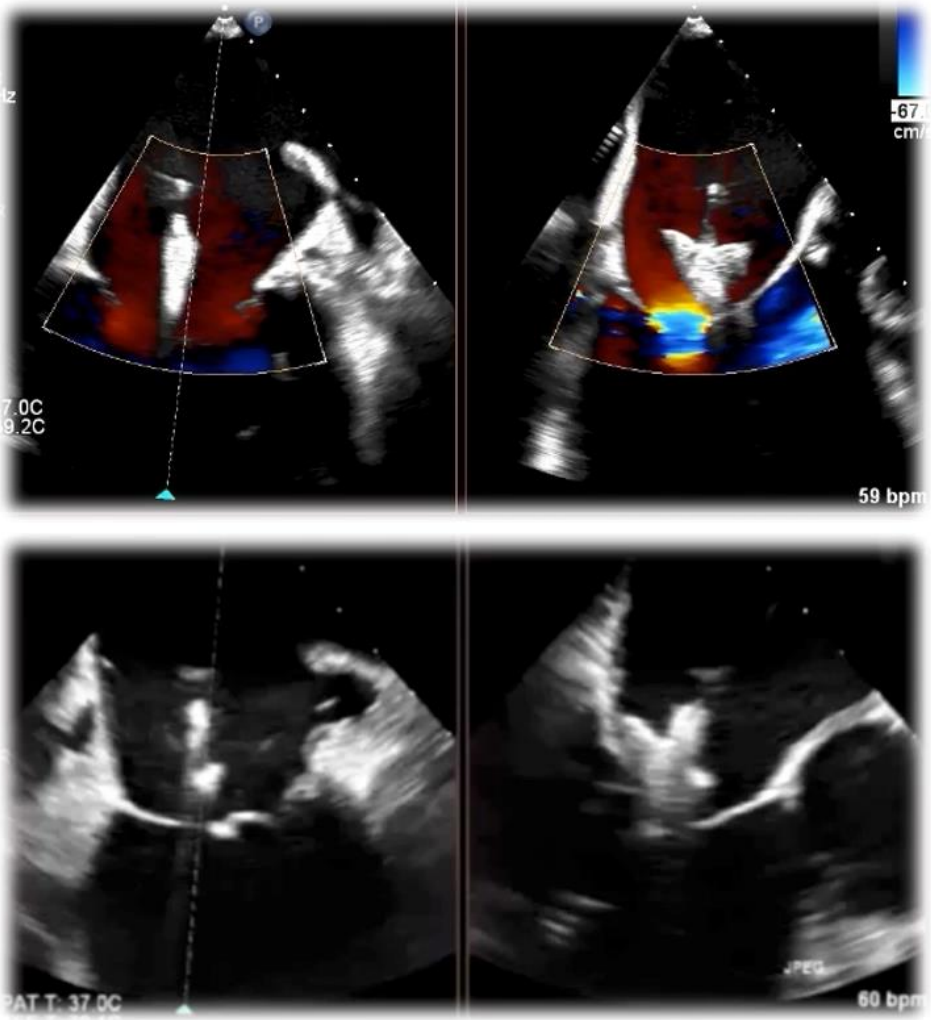
Images courtesy of Gagan Singh MD, UC Davis Medical Center

Move Stabilizer

- Retract (medial)
- Advance (lateral)

POSITION CLIP TO MR ORIGIN

- Split the MR jet in both LVOT & intercommissural (x-plane).
- Check Clip path observing anterior-posterior and medial-lateral position in both LVOT & intercommissural (x-plane).

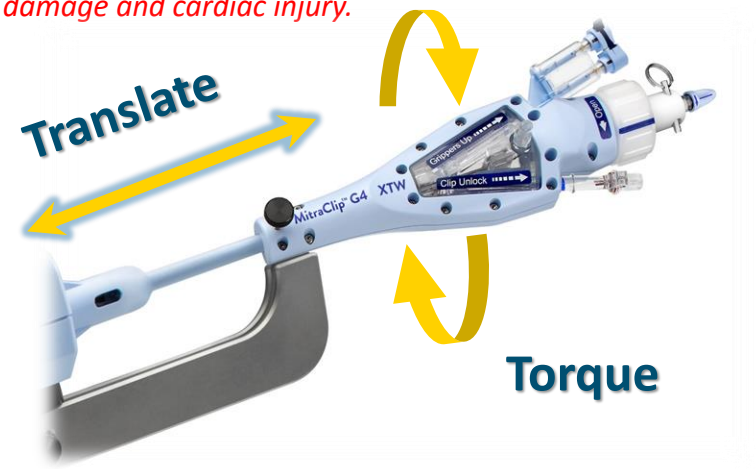


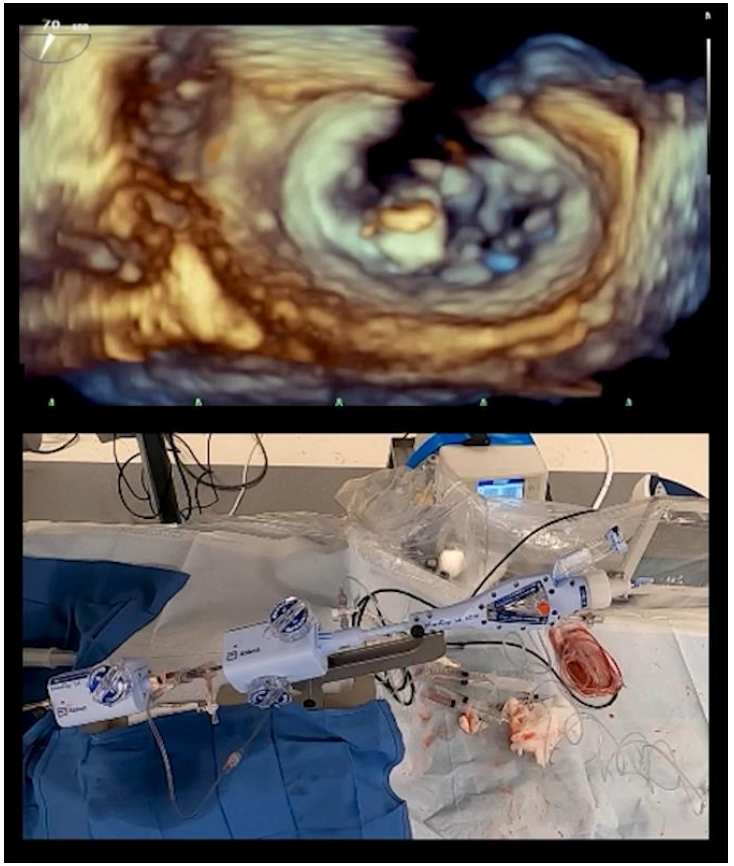
Images courtesy of Gagan Singh MD, UC Davis Medical Center & Moody Makar MD, Cedars Sinai Hospital

FINAL MITRACLIP™ G4 SYSTEM POSITIONING

- Rotate the DC handle to align the Clip Arms perpendicular to the line of coaptation. DO NOT rotate the Clip more than 90° in each direction.
- Carefully translate the DC shaft multiple times to release stored torque. Fully retract the DC.

WARNING: *Fully release stored torque. If not done, it may result in unwanted Clip Arm orientation changes during grasping. Torque of the DC Handle more than 180° may result in DC damage and cardiac injury.*

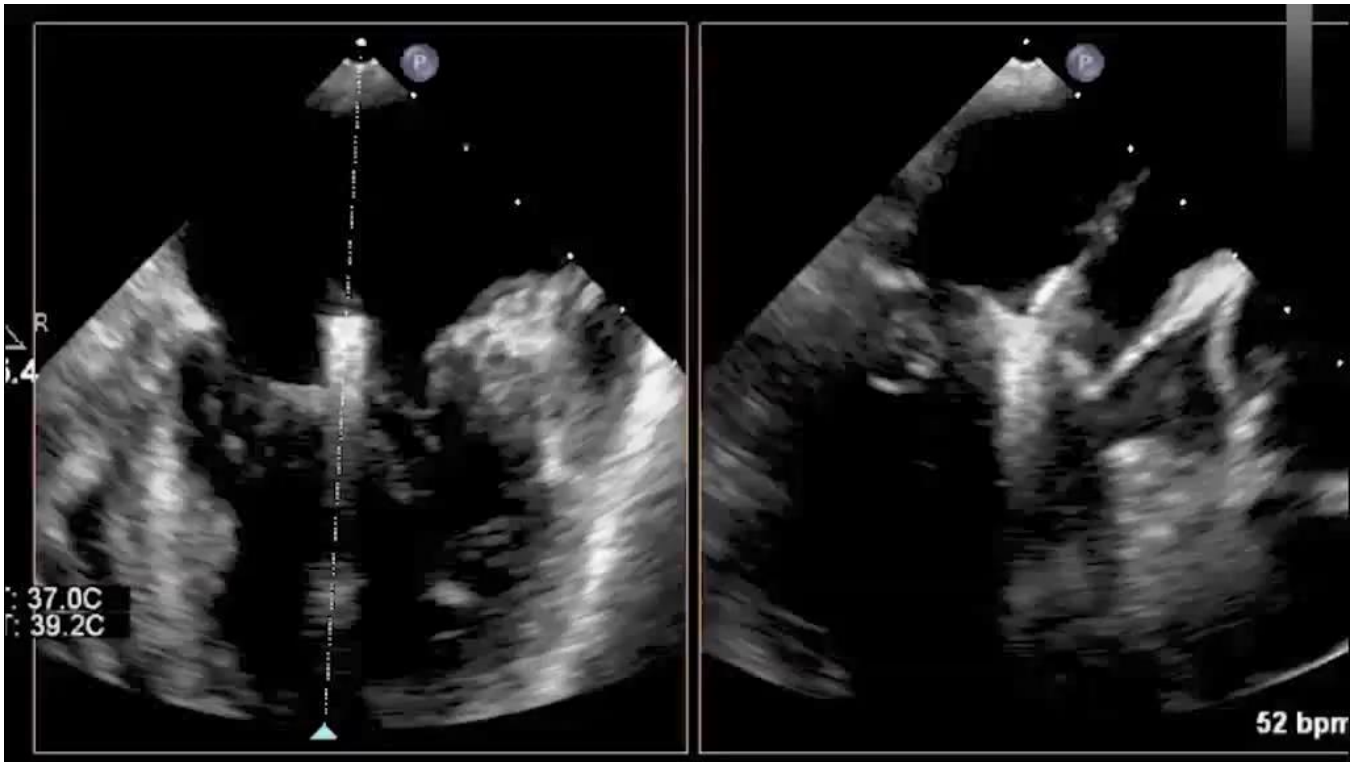




Images courtesy of Gagan Singh MD, UC Davis Medical Center

CLIP OPENED & PROPERLY ALIGNED

IMAGING: LVOT, INTERCOMMISSURAL - BICOM, X-PLANE

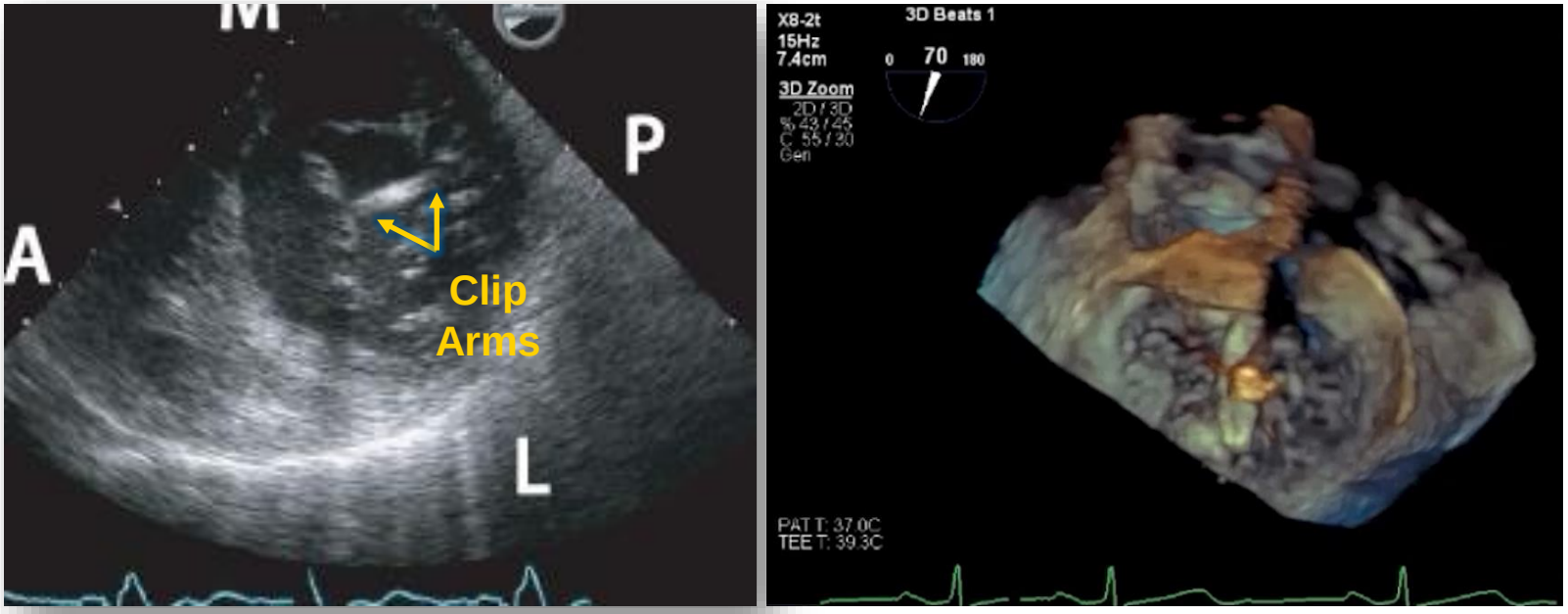


- Single Clip Arm seen.
- Shaft perpendicular to valve plane.
- Clip Arms of equal length.
- Grippers fully raised.

Images courtesy of Gagan Singh MD, UC Davis Medical Center

MITRACLIP™ ARMS OPEN & PROPERLY ALIGNED

IMAGING: 3D, TRANSGASTRIC SHORT AXIS



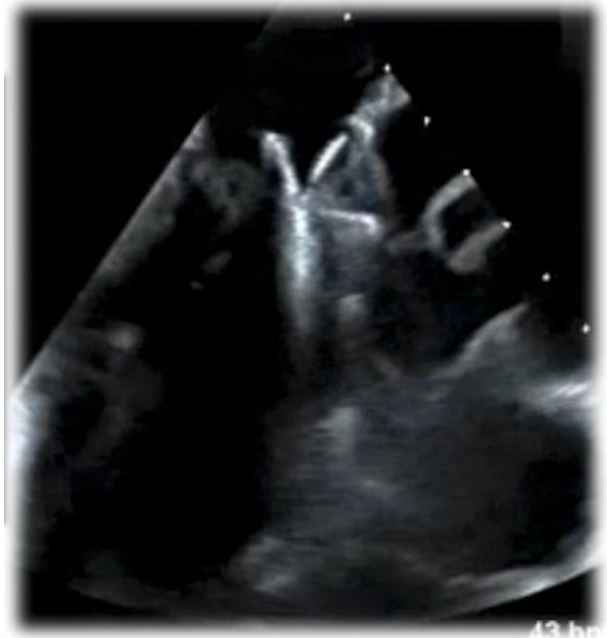
- Clip Arms are perpendicular to line of coaptation.
- Clip is not biased towards the anterior or posterior leaflet.

Images courtesy of Gagan Singh MD,
UC Davis Medical Center

IDENTIFY GRIPPER ORIENTATION

Identify Gripper Orientation is performed in the Left Atrium, after the Clip is opened and properly aligned.

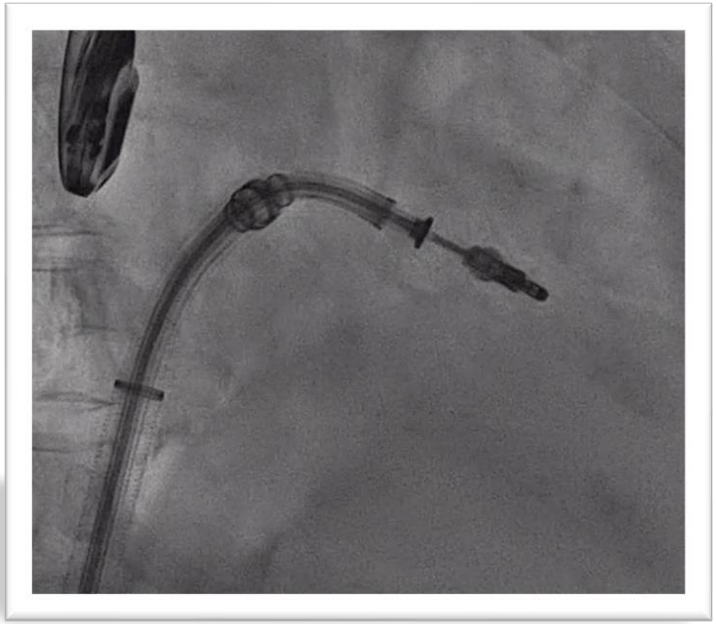
1. Unlatch the Gripper Levers.
2. Advance and retract the Gripper Lever with the tactile marker under imaging (echocardiography) to identify Gripper Lever to the corresponding leaflet.
3. Once Gripper(s) are identified, Raise the Gripper(s) until ready for leaflet capture.

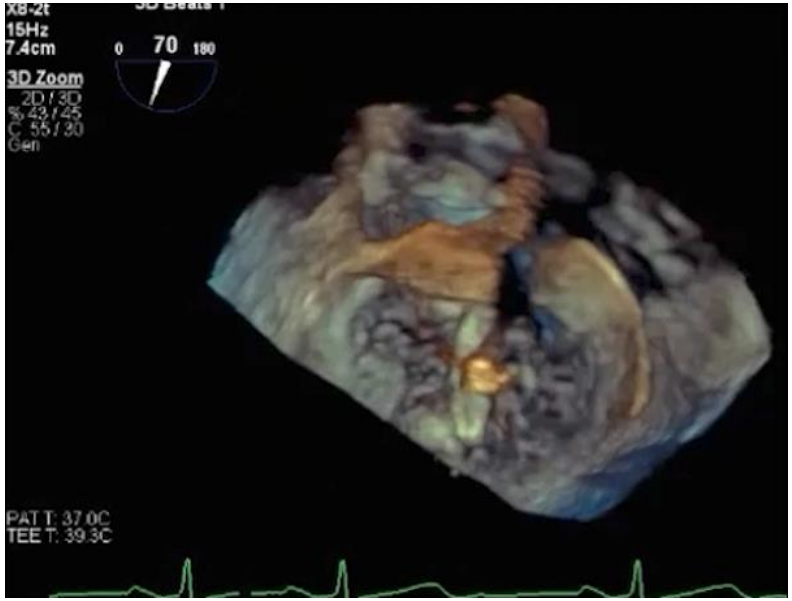


Images courtesy of Gagan Singh MD, UC Davis Medical Center

FINAL MITRACLIP™ G4 SYSTEM POSITIONING
IMAGING: INTERCOMMISSURAL, LVOT, X-PLANE AND FLUORO

- Close the Clip to a Clip Arm Angle of approximately 60°.
- Complete final MitraClip G4 System positioning in the LA using multiple imaging planes. Re-secure the Guide and Sleeve Fasteners as appropriate.





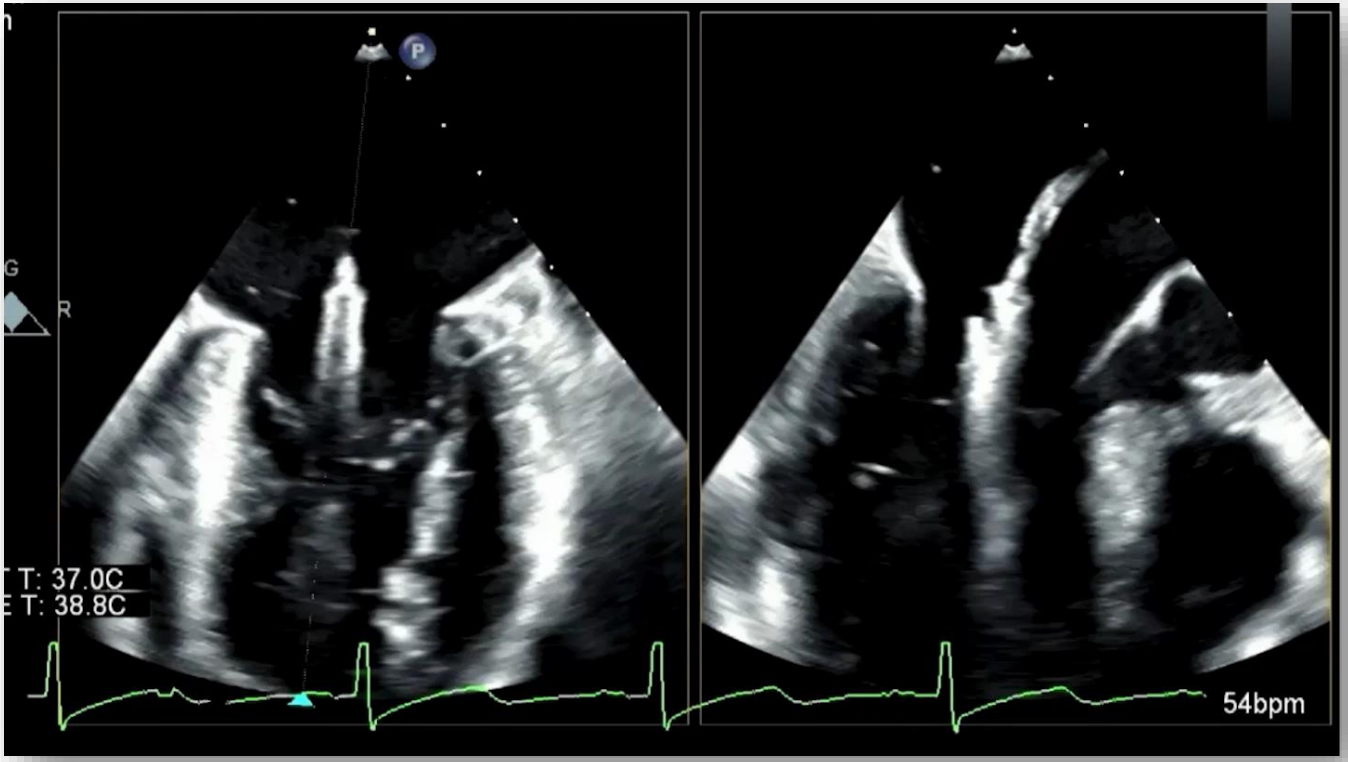
Images courtesy of Gagan Singh MD,
UC Davis Medical Center

GRASPING THE LEAFLETS AND VERIFYING THE GRASP

ADVANCE MITRACLIP™ INTO LEFT VENTRICLE

IMAGING: LVOT, X-PLANE, FLUORO

- Advance the DC distally to position the Clip approximately 2 cm below the valve. Ensure that the Clip Arms are oriented perpendicular to the line of coaptation.



Images courtesy of Gagan Singh MD,
UC Davis Medical Center

ADVANCE MITRACLIP™ INTO LEFT VENTRICLE

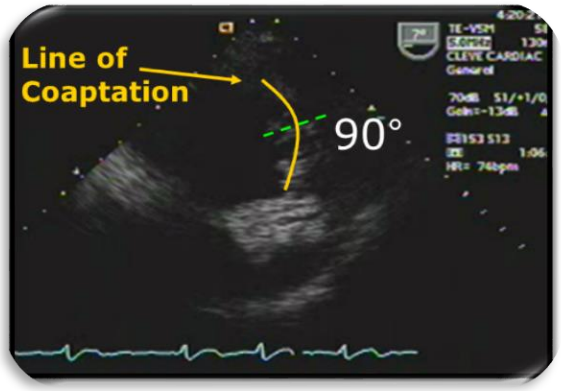
IMAGING: LVOT, X-PLANE, FLUORO

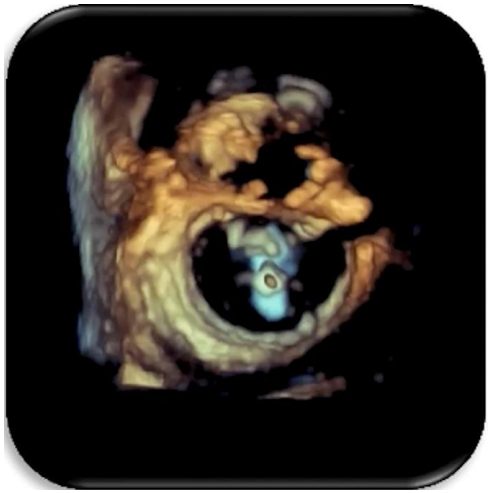
WARNING: *Do confirm Clip Arms are perpendicular to the line of coaptation. Failure to do so may result in loss of leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).*

WARNING: *DO NOT make substantial Clip Arm orientation adjustment in the LV. Clip entanglement in chordae may result in cardiac injury and worsening mitral regurgitation; and may result in difficulty or inability to remove the Clip and conversion to surgical intervention.*

WARNING: *Always ensure that either the Grippers are raised or that the Clip is closed while in the LV to avoid potential cardiac injury.*

- Open the Clip Arms to the Grasping Arm Angle.



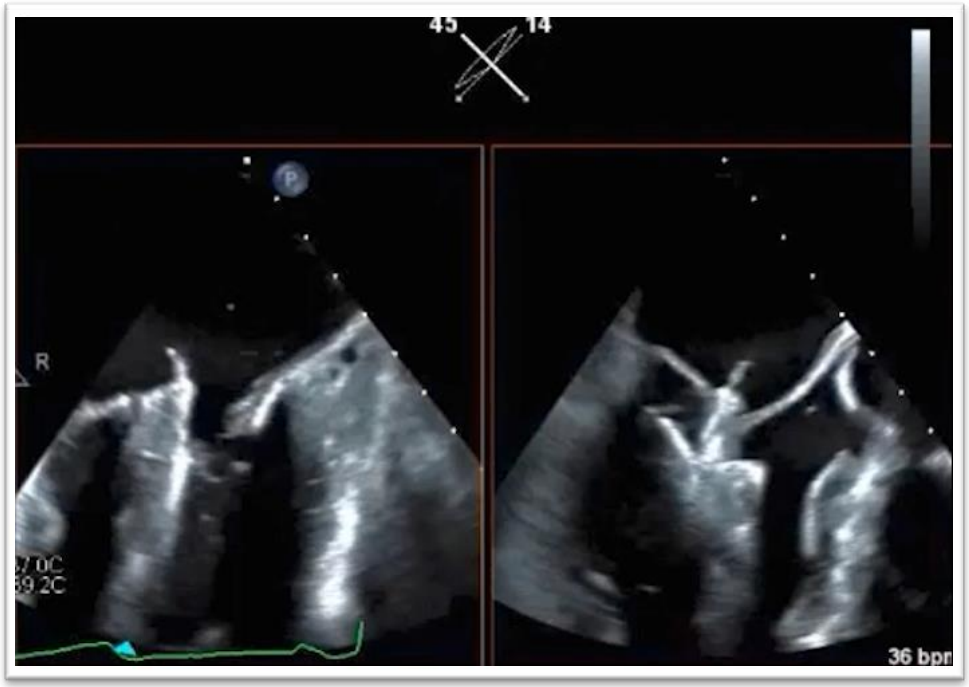


Images courtesy of Gagan Singh MD,
UC Davis Medical Center

PREPARATION FOR SUCCESSFUL GRASP

Keys:

- Optimal axial alignment, in all views
- Arms perpendicular to line of coaptation, in all views
- Leaflets freely moving above Clip Arms before grasp
- Grippers fully raised
- Clip Arms open to Grasping Arm Angle (~ 120^{o})
- Consider use of x-plane
- Use fluoroscopy to observe Clip Arm rotation

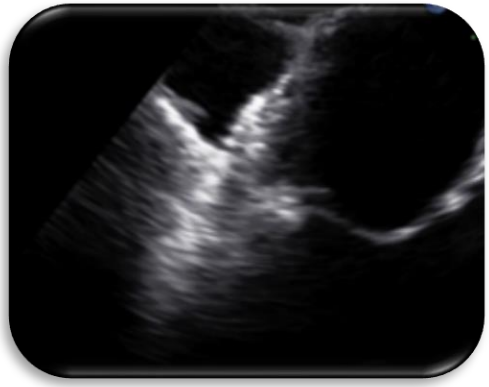


Images courtesy of Gagan Singh MD, UC Davis Medical Center

GRASPING TECHNIQUE

- Without using excessive force, retract the DC to grasp both anterior and posterior leaflets.

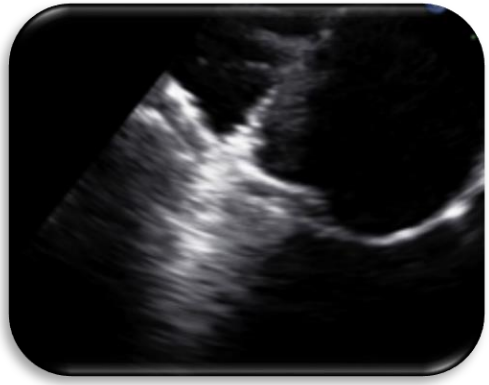
WARNING: *An improper grasp will allow one or both leaflets to move freely. Closing and deploying the Clip in this situation may result in loss of leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).*



Images courtesy of Richard Bae MD, Abbott Northwestern

- If the grasp appears satisfactory, Lower the Gripper(s) onto the leaflets.

NOTE: *Simultaneous leaflet capture with both Grippers should attempted first. If unsuccessful, Raise the Gripper(s) to release leaflet capture and Lower the Gripper(s) to capture leaflets. Raising and lowering Gripper(s) can be done simultaneously or independently.*



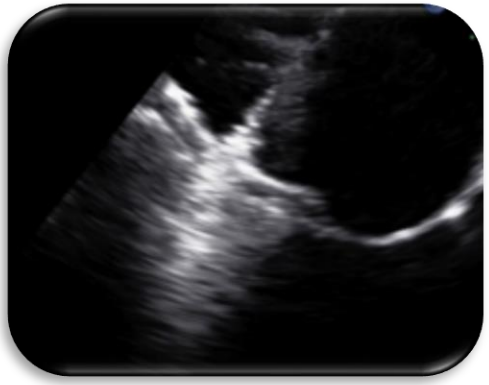
WARNING: *DO NOT advance the DC Handle or adjust the position of the MitraClip™ G4 System in a way that increases tension the leaflets after grasping the leaflets, as valve injury may occur.*

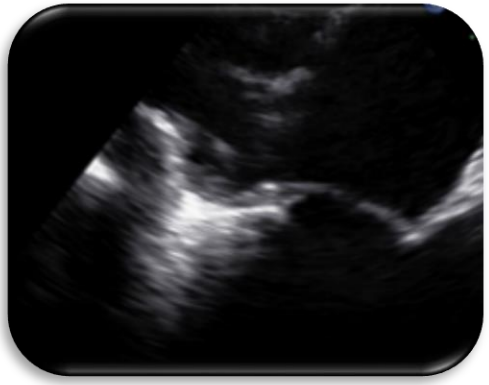
GRASPING TECHNIQUE

- If both Grippers have not lowered:
  - Lock the Clip
  - Confirm both Grippers have lowered
  - Unlock the Clip

WARNING: *Failure to confirm that both Grippers have been lowered onto the leaflets prior to closing the Clip may result in loss of leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).*

- Close the Clip until the Clip Arm Angle is approximately 60°. Release tension on the DC and secure the DC Fastener.

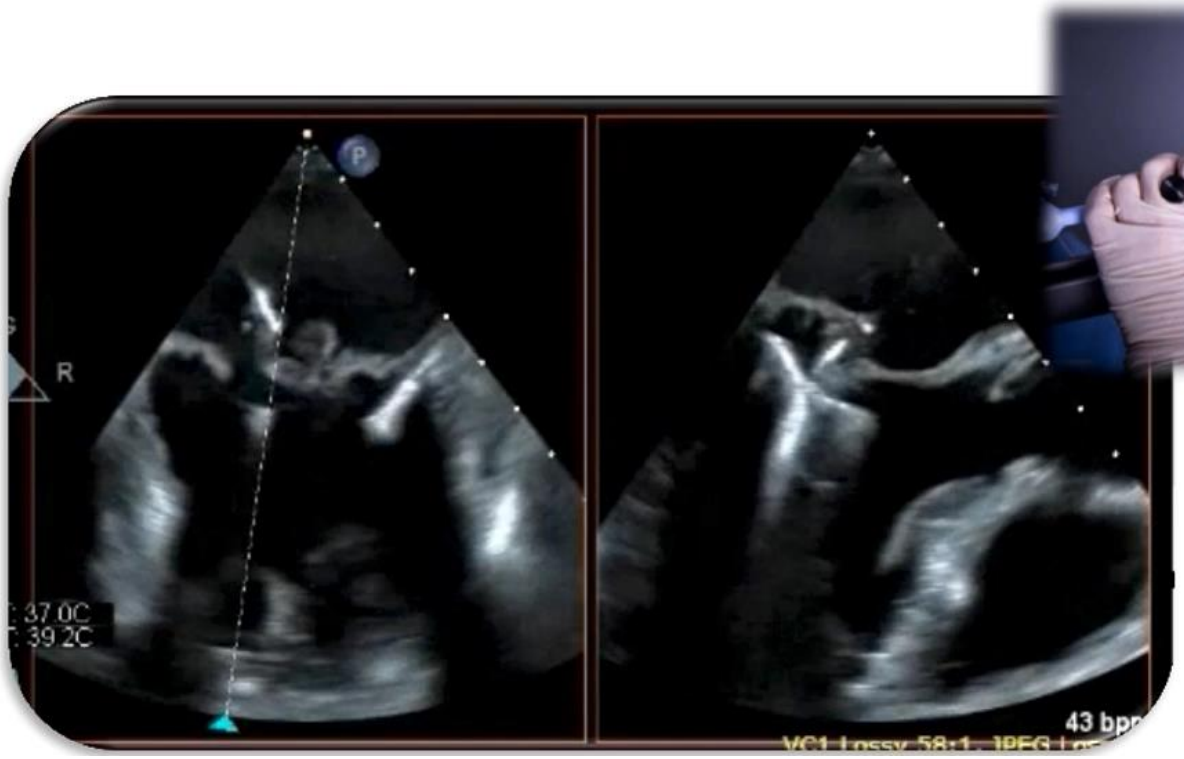


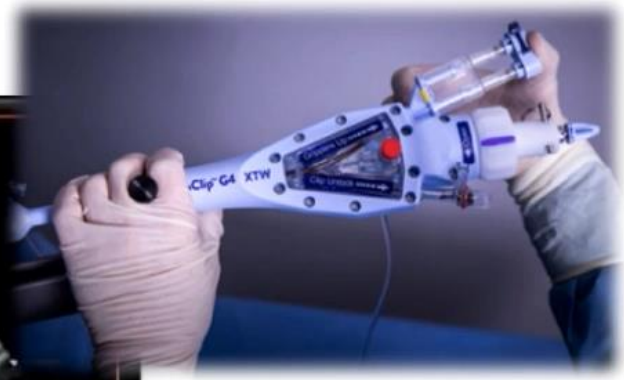


Images courtesy of Richard Bae MD, Abbott Northwestern

EXAMPLE OF PROPER GRASP
IMAGING: LVOT, X-PLANE

- Consider use of x-plane and Clip-store (echo) for grasp and leaflet insertion assessment.
- Consider suspending ventilation to reduce respiratory excursion.





Images courtesy of Gagan Singh MD, UC Davis Medical Center

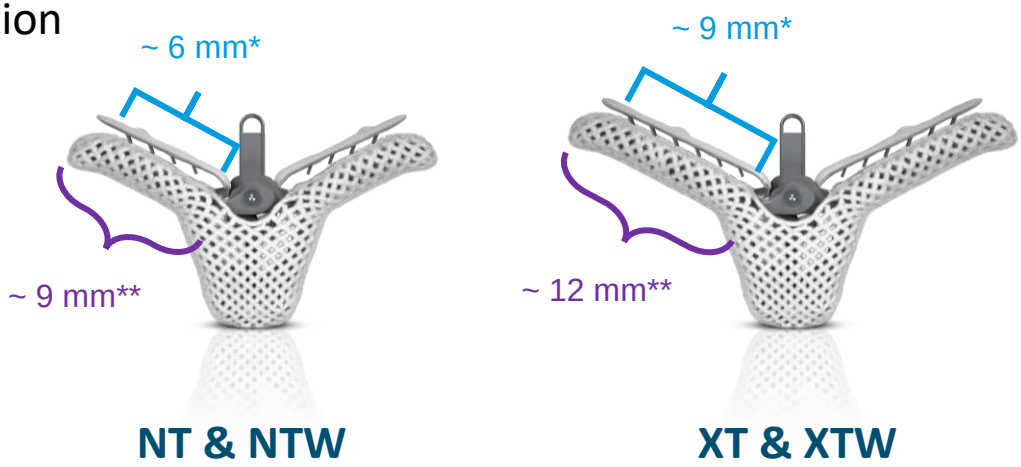
LEAFLET INSERTION

If Clip is in the proper position proceed to Leaflet Insertion Assessment:

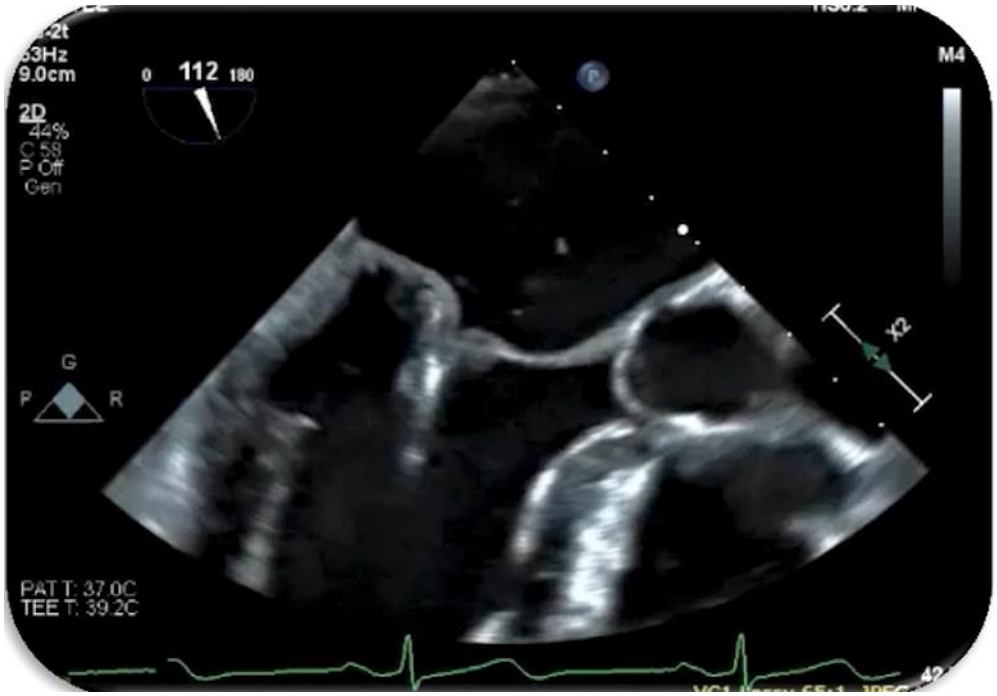
- Use Systematic Assessment with Clip at 60°.
- Consider use of x-plane and 3D to optimize leaflet insertion assessment.
- Use echocardiographic imaging to verify insertion of both leaflets and satisfactory grasp by observation of:
    - Leaflet immobilization
    - Single or multiple valve orifice(s)
    - Limited leaflet mobility relative to the tips of both Clip Arms
    - Adequate MR reduction

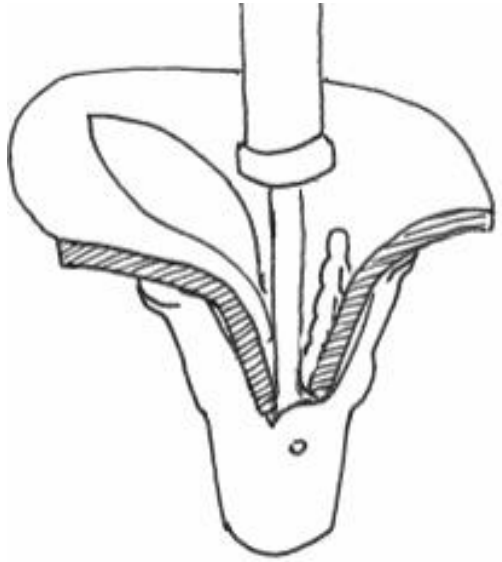
* Leaflet insertion needed to engage all frictional elements

** Clip Arm length



LEAFLET INSERTION ASSESSMENT:
IMAGING: LVOT, X-PLANE

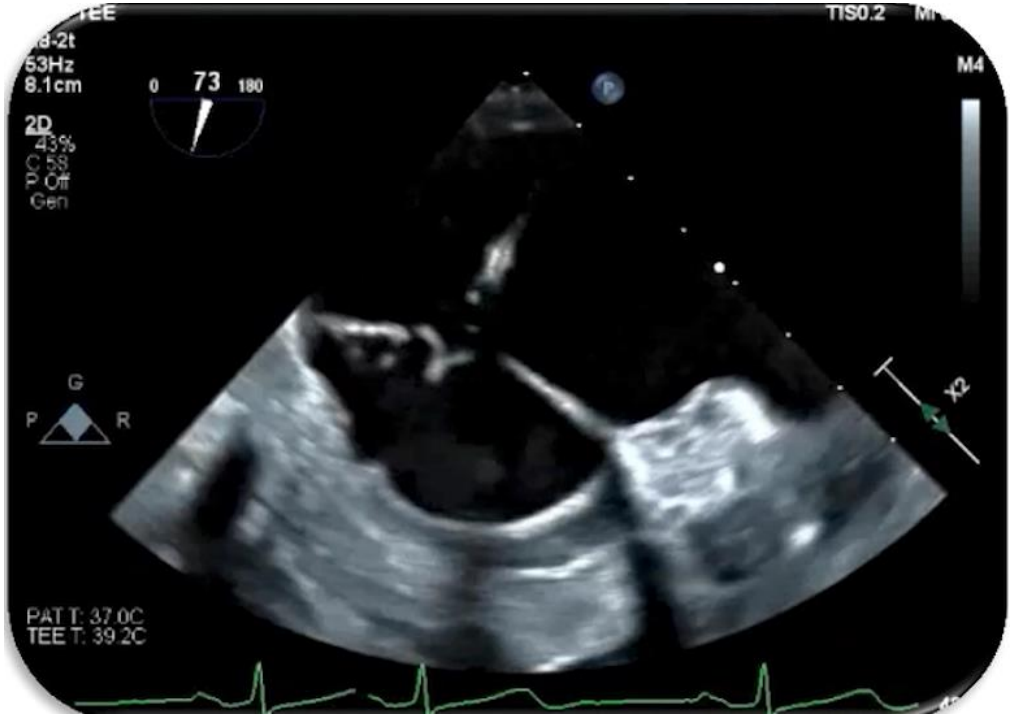


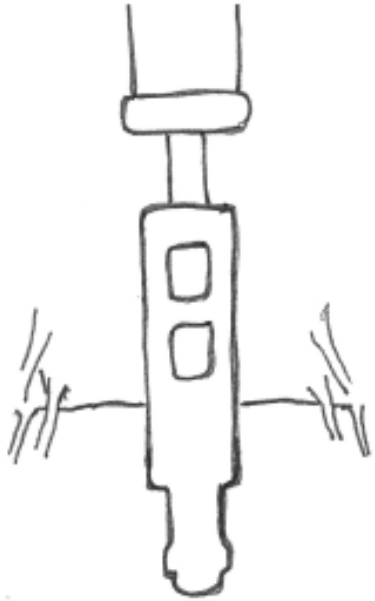


- Verify that both leaflets.
  - Go over the tip of the Clip Arms
  - Tips are fully inserted to base of ‘V’ between Gripper and Arms
- Confirm systolic & diastolic leaflet motion relative to tip of Arms is non-existent or limited.

Images courtesy of Gagan Singh MD,
UC Davis Medical Center

LEAFLET INSERTION ASSESSMENT:
IMAGING: INTERCOMMISSURAL – BICOM, X-PLANE

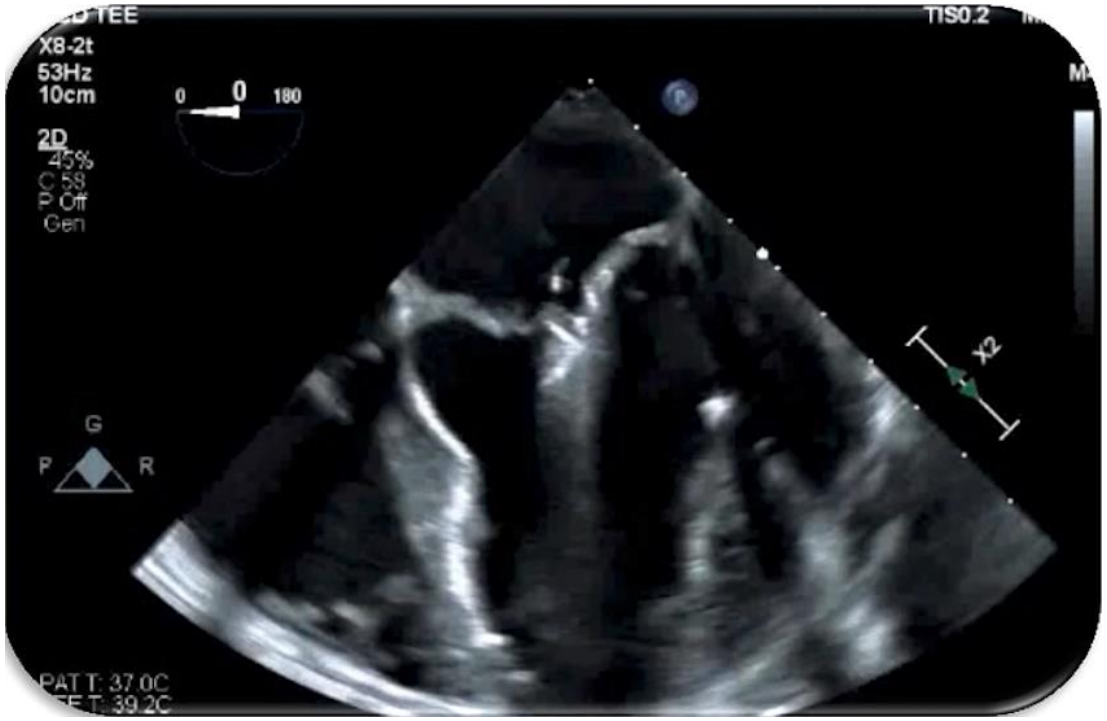


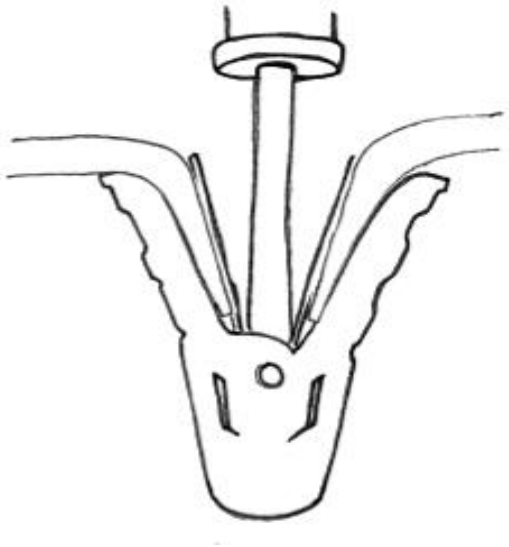


- On the medial and lateral sides of the Clip, the leaflets enter at the same level.
- Leaflet segments are stable, medial and lateral to the Clip.

Images courtesy of Gagan Singh MD,
UC Davis Medical Center

LEAFLET INSERTION ASSESSMENT:
IMAGING: 4 CHAMBER



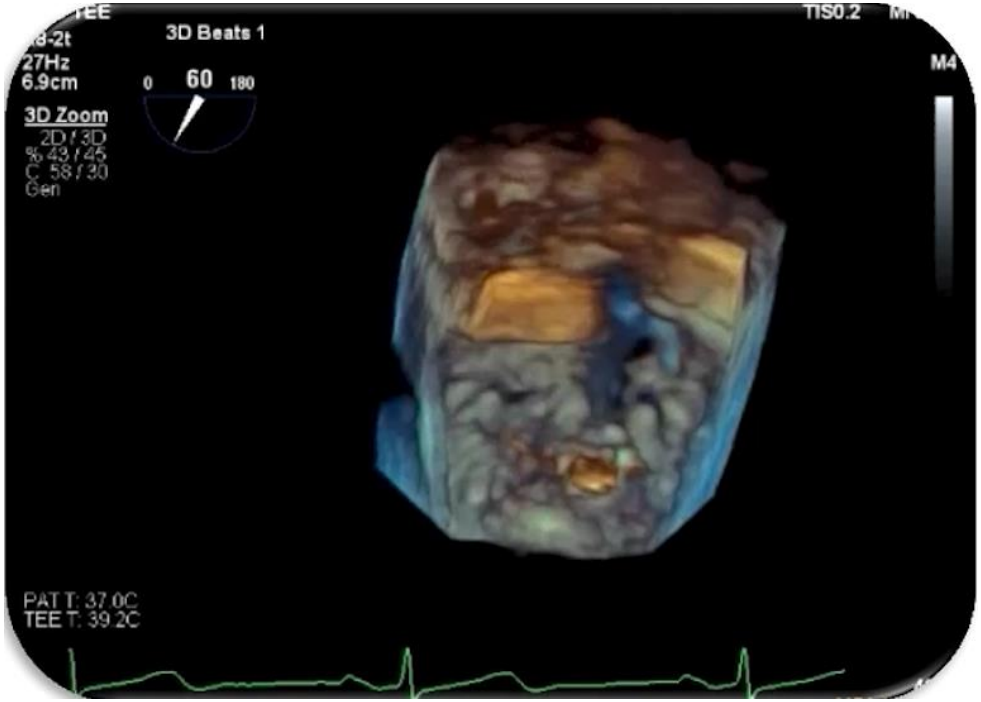


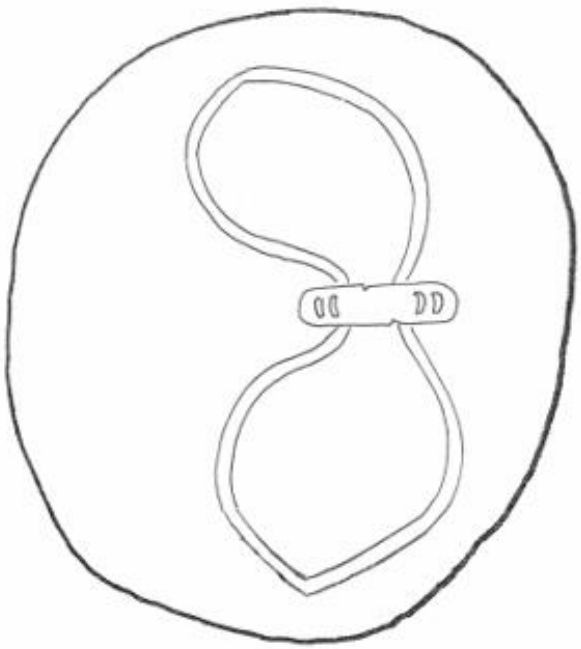
- Verify both leaflets.
  - Go over the tip of the Clip Arms
  - Tips are fully inserted to base of ‘V’ between Gripper and Arms

    NOTE: In this video example, the Anterior leaflet insertion cannot be verified.
- Confirm systolic & diastolic leaflet motion relative to tip of Arms is non-existent or limited.

Images courtesy of Gagan Singh MD,
UC Davis Medical Center

LEAFLET INSERTION ASSESSMENT:
IMAGING: 3D, TRANSGASTRIC SHORT AXIS





- Verify Clip Arms are perpendicular to Line of Coaptation.
- Confirm Clip is not biased towards the anterior or posterior leaflet.

Images courtesy of Gagan Singh MD,
UC Davis Medical Center

LEAFLET INSERTION ASSESSMENT:
CONTROLLED GRIPPER ACTUATION

CHECK AND CONFIRM

1. Imaging quality
2. Clip Arms perpendicular throughout grasping sequence
3. Perpendicular DC trajectory

SIMULTANEOUS GRASPING

If in doubt with leaflet insertion:

CONFIRM

1. Open to 120°, raise the Gripper where leaflet insertion is in doubt
2. Assess that leaflet insertion is adequate

If leaflet insertion is adequate:

RE-GRASP

1. Drop the Gripper
2. Slowly close the Clip to 60°, release tension on the DC, and secure the DC fastener
3. Verify leaflet insertion

*If leaflet insertion is **NOT** adequate:*

LEAFLET OPTIMIZATION

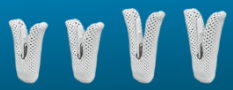
1. Subtle SGC/CDS adjustment and drop the Gripper
2. Slowly close the Clip to 60°, release tension on the DC, and secure the DC fastener
3. Verify leaflet insertion

*If leaflet optimization is **NOT** adequate:*

INDEPENDENT LEAFLET GRASPING

1. Open Clip Arms to 120° and raise both Grippers, position Clip near both leaflets
2. Engage mobile leaflet and drop the Gripper
3. Subtle SGC/CDS adjustment and drop the other Gripper
4. Slowly close the Clip to 60° and release tension on the DC, and secure the DC fastener
5. Verify leaflet insertion

CLOSING THE CLIP & EVALUATING CLIP POSITION



- Lock the Clip (with the Clip at 60^{o}).

  WARNING: *Failure to Lock the Clip may result in loss of leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).*

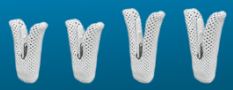
- Slowly close the Clip just until the leaflets are coapted and MR is sufficiently reduced. The Clip should maintain a distinct "V" shape.

  WARNING: *DO NOT use excessive force to close the Clip further than is necessary to adequately reduce MR. Leaflet injury may occur. DO NOT Close the Clip too tightly as it may result in leaflet injury or an inability to deploy the Clip. Inability to deploy the Clip may result in worsening mitral regurgitation, cardiac injury, a single leaflet device attachment (SLDA), and/or conversion to surgical intervention.*

  WARNING: *Failure to turn the Arm Positioner at least ½ turn in the "Close" direction after locking the Clip may result in loss of leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).*

- Use echocardiographic imaging to verify valve function, satisfactory coaptation, and insertion of both leaflets by observation of:
  - Leaflet immobilization
  - Single or multiple valve orifice(s)
  - Limited leaflet mobility relative to the tips of both Clip Arms
  - Adequate MR reduction
- Once leaflet insertion and MR reduction is satisfactory proceed to Clip deployment.

UNSATISFACTORY GRASP
LEAFLET INSERTION



- If the Clip position is not satisfactory, Raise the Gripper(s), Unlock the Clip and Invert the Clip Arms.

  WARNING: *Turning the Arm Positioner in the "Open" direction more than 1 full turn past a Clip Arm Angle of 180° or turning past when resistance is first noted may result in device damage which could cause the Clip to become non-functional and lead to embolization, and/or conversion to surgical intervention.*
- Retract the inverted Clip into the LA.
- Confirm both leaflets move freely.
- Repeat positioning steps, as necessary, then repeat grasping steps.
- If grasping fails to hold both leaflets and the Clip retracts to the LA, reposition the MitraClip™ G4 System.
  - Open the Clip Arms and reorient the Clip Arms in the LA, as needed, then repeat grasping steps.
  - If significant repositioning is necessary, fully close the Clip Arms and Lower the Grippers, then repeat positioning and grasping steps.
- If the Sleeve limits DC travel during grasping, an inadequate grasp may require repositioning of the MitraClip G4 System.
  - Raise the Grippers and open the Clip Arms to approximately 180° and advance the DC handle. Repeat positioning and grasping steps as necessary.

MITRACLIP™ G4 IMPLANT PRE-DEPLOYMENT CLIP ASSESSMENT

MITRACLIP™ IMPLANT
PRE-DEPLOYMENT CLIP ASSESSMENT

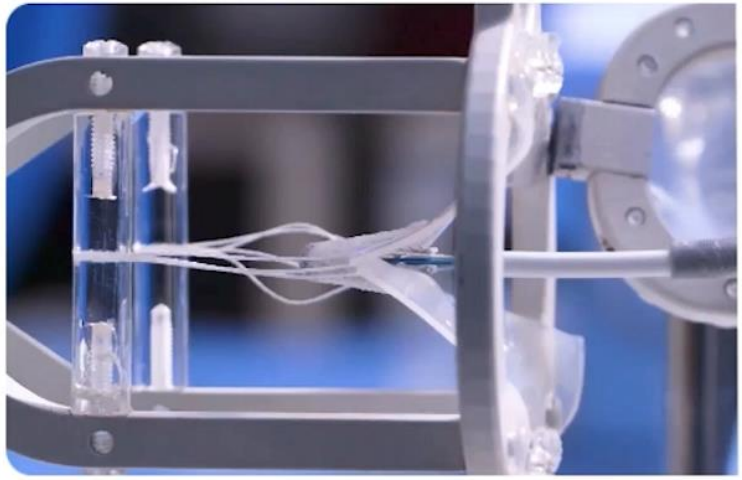
- Confirm DC Handle is secure.

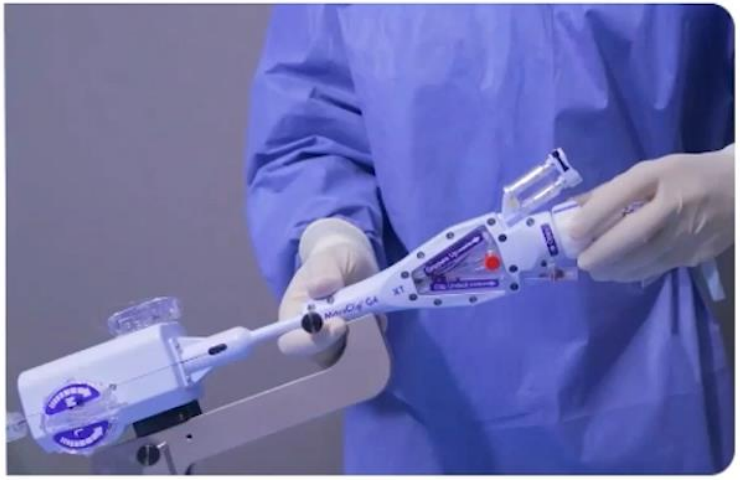
  WARNING: *Do secure DC Handle. If not done, it may result in leaflet injury or loss of leaflet insertion with resultant worsening mitral regurgitation, single leaflet device attachment (SLDA), and/or conversion to surgical intervention.*

- Establish Final Arm Angle.

  WARNING: *DO NOT turn the Arm Positioner more than 1 turn in the "Open" direction from neutral. Failure to stop turning the Arm Positioner at 1 turn in the "Open" direction past neutral may result in Clip opening or device damage which could cause the Clip to become non-functional and lead to embolization and/or conversion to surgical intervention.*

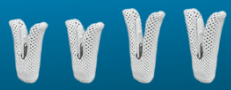
- Turn the Arm Positioner to the "closed" side of the neutral position.
- Perform mean pressure gradient assessment prior to proceeding to deployment.





CLIP DEPLOYMENT

DEPLOYMENT STEP 1:
LOCK LINE REMOVAL



- While holding the ends of the Lock Line remove the Lock Lever Cap and “O” ring. Unwrap the two ends of the Lock Line in a counterclockwise direction. Separate the ends of the Lock Line and remove the plastic cover from the lines so that no twists or knots are present.

  WARNING: *DO NOT let Line unravel freely. Do not remove Lock Line or plastic covers if line is bunched. Letting Line unravel freely may result in knots in the line. Removing Line if it is bunched may result in difficulty or inability to remove line due to knots or twists.*

- Grasp one of the free ends of the Lock Line, confirm the line moves freely, and slowly remove the Lock Line. Pull the Lock Line coaxial to the Lock Lever. If resistance is noted, stop and pull on the other free end to remove the Lock Line.
- Establish Final Arm Angle.

  NOTE: *The Clip Arms may open slightly (~5°) and then remain in a stable position. If Arms open more than slightly, close the Clip to the desired Arm position and re-Establish Final Arm Angle.*

  WARNING: *DO NOT turn the Arm Positioner more than 1 turn in the “Open” direction from neutral. Failure to stop turning the Arm Positioner at 1 turn in the “Open” direction past neutral may result in Clip opening or device damage which could cause the Clip to become non-functional and lead to embolization and/or conversion to surgical intervention.*

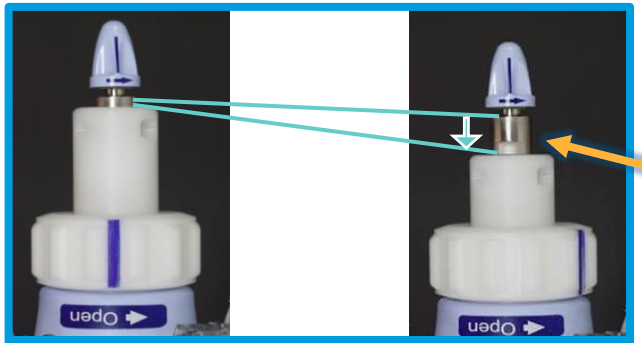
- Turn the Arm Positioner to neutral.

DEPLOYMENT STEP 2:
DELIVERY CATHETER SHAFT DETACHMENT

- Confirm that the Arm Positioner is neutral. Remove the Release Pin from the DC Handle.

- Turn the Arm Positioner in the “Open” direction until the Release Pin groove is fully exposed.

  NOTE: *After the Release Pin is removed, turning the Arm Positioner in the “Open” direction will not open the Clip Arms.*



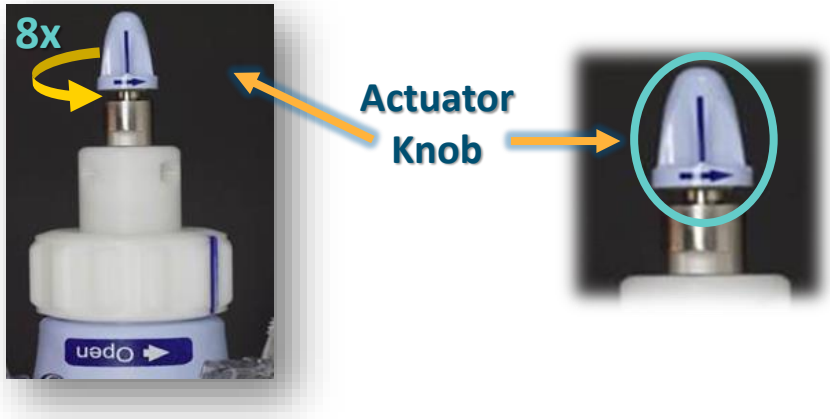
Turning the Arm Positioner in the Open direction moves the Slider away from the Actuator Knob, thus removing Actuator Mandrel tension.

Release Pin groove

DEPLOYMENT STEP 2:
DELIVERY CATHETER SHAFT DETACHMENT

- Turn the Actuator Knob of the DC approximately 8 turns in the direction of the arrow printed on the Actuator Knob. If it is difficult to turn the Actuator Knob, STOP and confirm that the Arm Positioner has been turned in the "Open" direction, such that the Release Pin groove is fully exposed.

WARNING: *Stop turning the Actuator Knob when resistance is felt, otherwise it may result in inability to deploy the Clip. Inability to deploy the Clip may result in worsening mitral regurgitation, cardiac injury, a single leaflet device attachment (SLDA), and/or conversion to surgical intervention.*



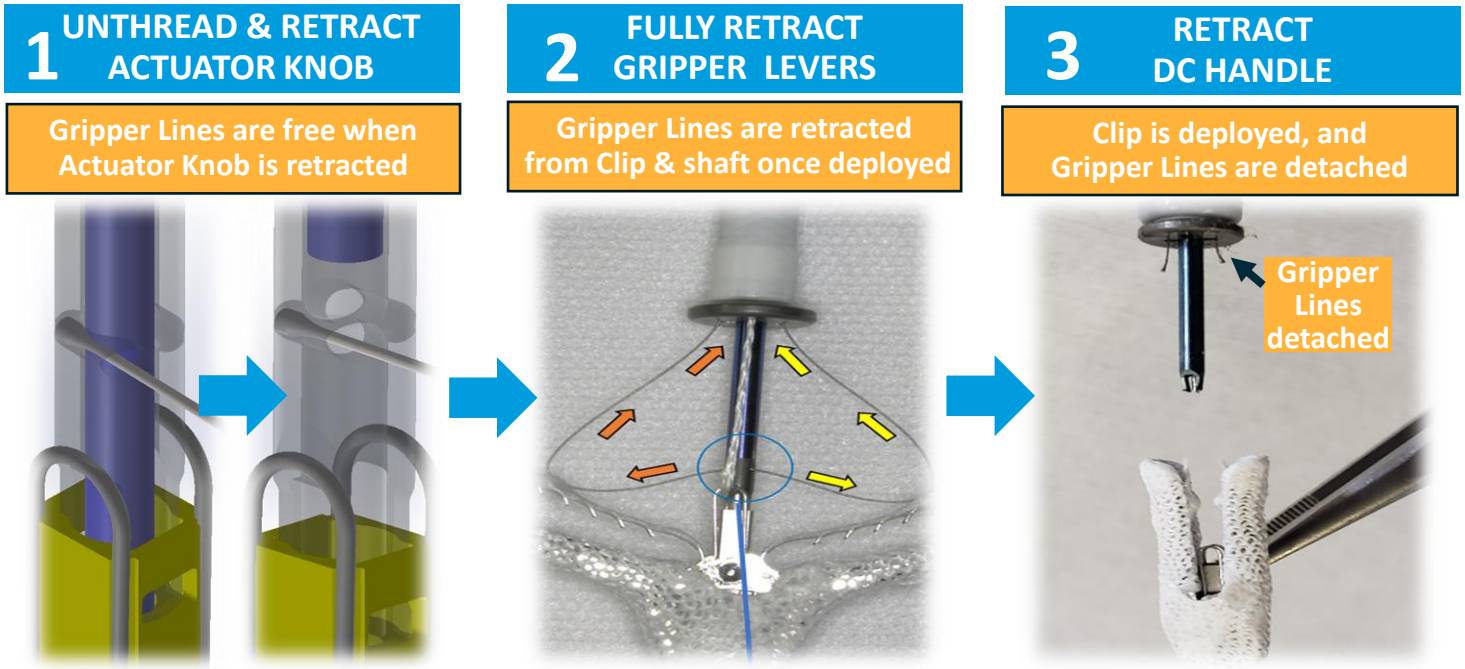
- Retract the Actuator Knob approximately 0.5 cm after it is fully unthreaded.

DEPLOYMENT STEP 2:
DELIVERY CATHETER SHAFT DETACHMENT

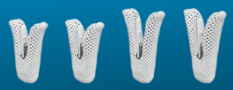
- Fully retract the Gripper Levers.

  WARNING: *Do retract the Gripper Levers fully prior to retracting the DC Handle. Failure to retract Gripper Levers may result in higher forces to deploy the Clip. This may result in worsening mitral regurgitation, cardiac injury or a single leaflet device detachment (SLDA).*

- Release the DC Fastener, and slowly retract the DC Handle until the DC Radiopaque Ring is against the tip of the Sleeve.

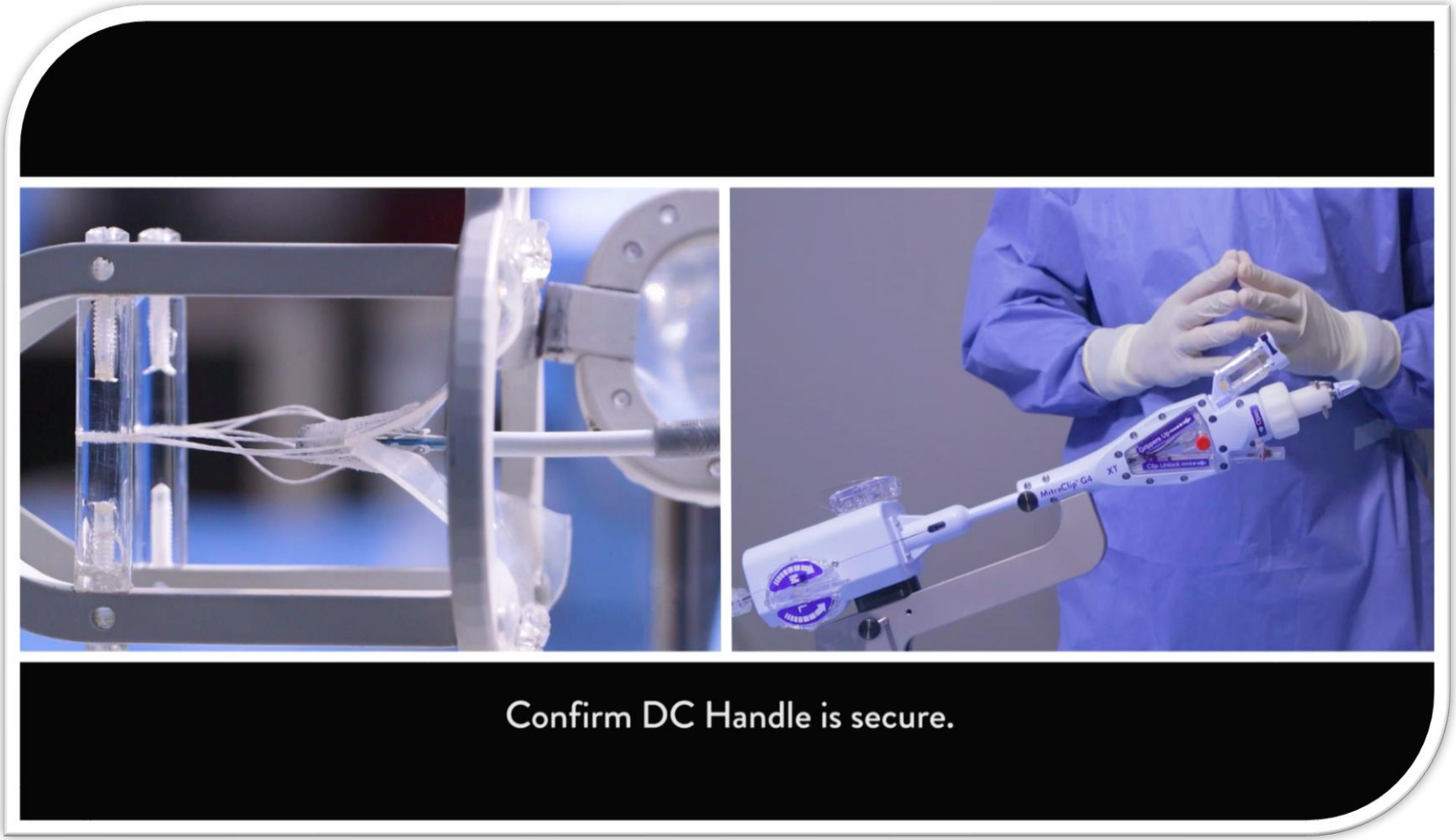


DEPLOYMENT STEP 2:
DELIVERY CATHETER SHAFT DETACHMENT



- Confirm the DC Fastener is secure.
- Confirm the Clip position is stable.
- Use echocardiographic imaging to verify valve function, satisfactory coaptation, and insertion of both leaflets by observation of:
    - Leaflet immobilization
    - Single or multiple valve orifice(s)
    - Limited leaflet mobility relative to the tips of both Clip Arms
    - Adequate MR reduction
- If placing an additional Clip proceed to next section. If not placing an additional Clip, proceed to MitraClip™ G4 System Removal.

DEPLOYMENT STEPS VIDEO



DEPLOYMENT SUMMARY

CLIP DEPLOYMENT:

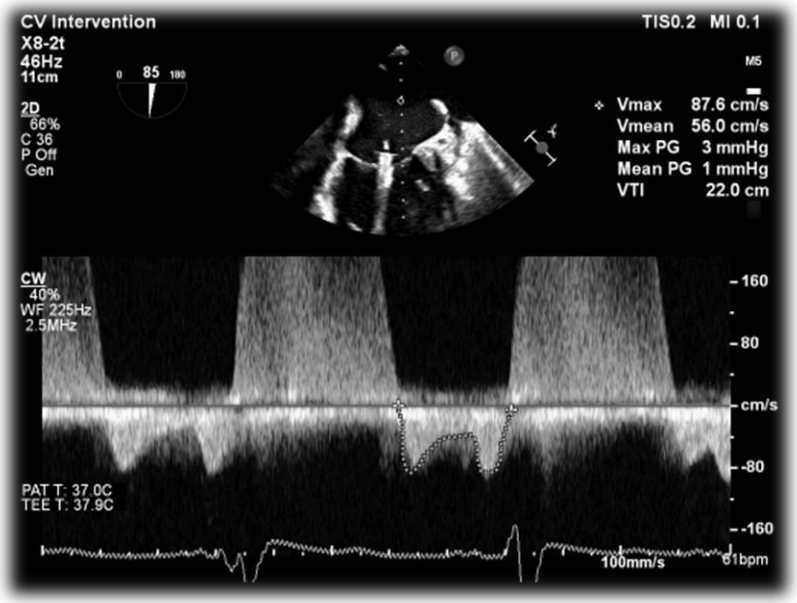
1. Lock Line Removal - EFAA
2. Remove release pin, Expose Release Pin groove
3. Unthread Actuator Knob, Retract Actuator Knob 0.5 cm
4. Fully Retract Gripper Levers
5. Release the DC Fastener and slowly retract the DC Handle

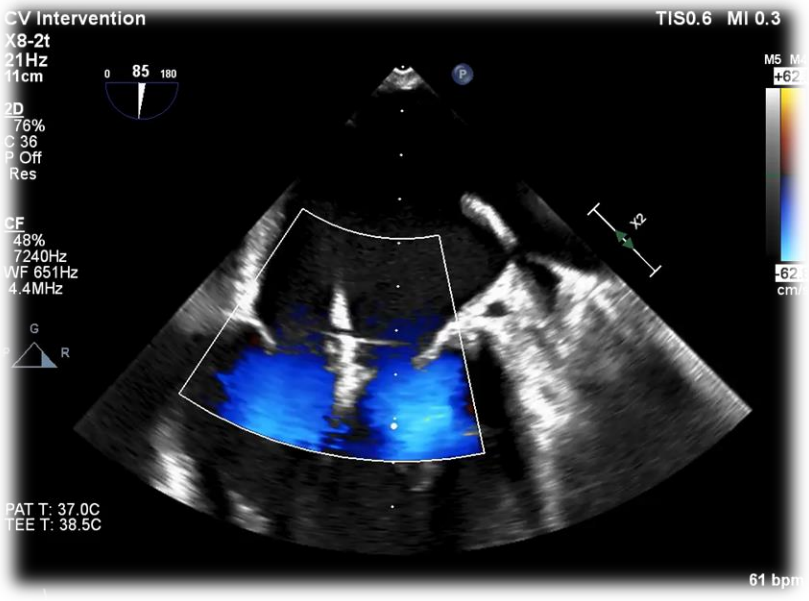
ADDITIONAL MITRACLIP™ G4 IMPLANT PLACEMENT

ADDITIONAL MITRACLIP™ CONSIDERATIONS

- Reduction in MR.
- Majority of residual MR isolated to one side of 1st Clip.
- Adequate MV area.

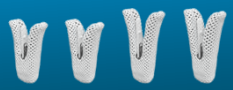
WARNING: *Use caution not to displace or dislodge an implanted Clip when placing an additional Clip; Clip detachment from leaflet(s) may occur which may result in a single leaflet device attachment (SLDA) or device embolization.*





Images courtesy of Moody Makar MD
Cedars Sinai Hospital

MITRACLIP™ PROCEDURAL STEPS

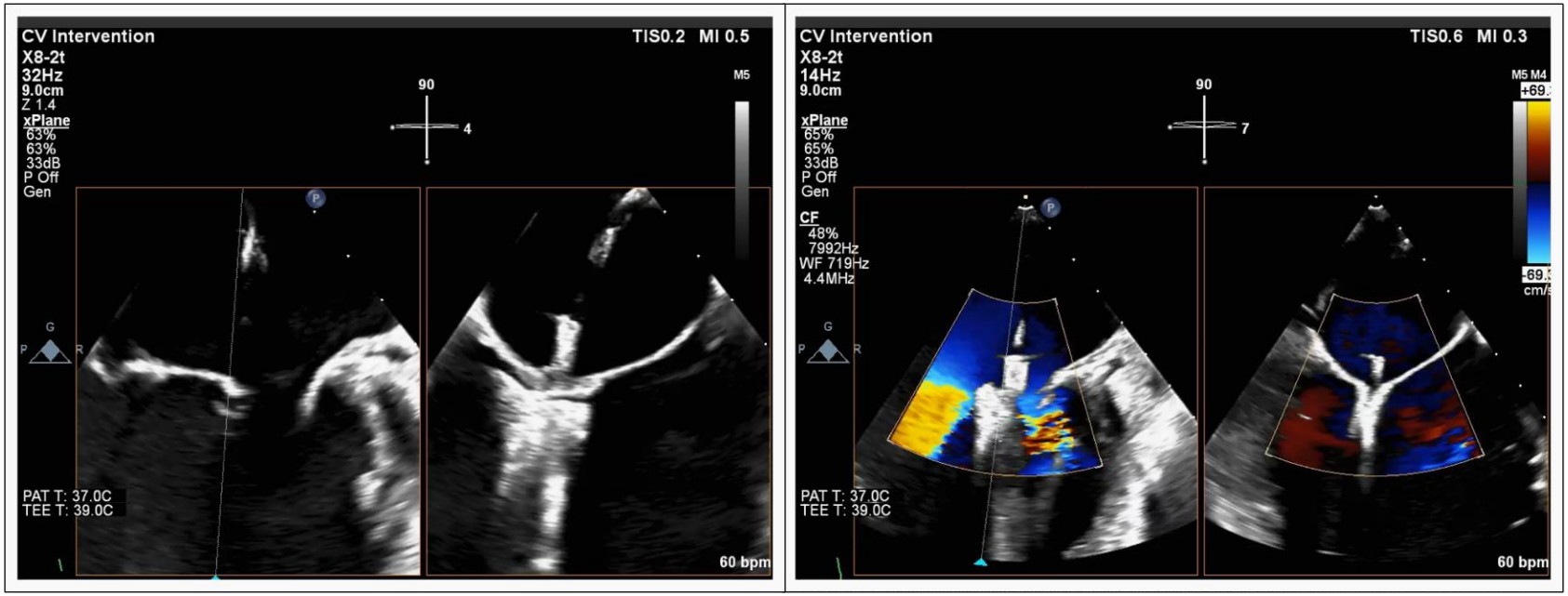


- When placing an additional Clip, the following are recommended:
  - In LA, ensure Clip Arms are oriented perpendicular to line of coaptation and Grippers are raised
  - Use both fluoroscopy and echocardiography when crossing into the LV and during grasping
  - Cross into LV with an Clip Arm Angle of < 60°

  ***WARNING**: DO NOT use excessive force or retraction distance during grasping. This may compromise leaflet capture and insertion. Loss of leaflet capture and insertion may result in inadequate reduction of mitral regurgitation and may result in a single leaflet device attachment (SLDA).*

- Consider holding respiration when crossing into LV and during grasping if significant movement is noted.
- Place additional Clip at a location to optimize MR reduction.
- Remaining steps are identical to Grasping the Leaflets and verifying the grasp.

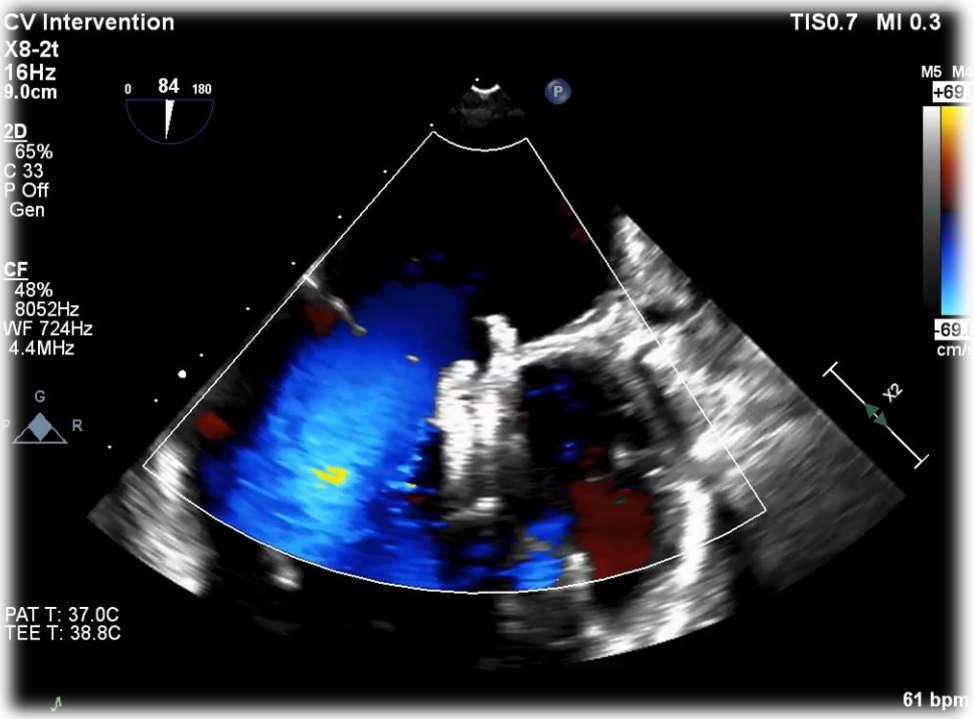
LEAFLET INSERTION ASSESSMENT:
IMAGING: LVOT, X-PLANE



- Verify both leaflets.
  - Go over the tip of the Clip Arms
  - Tips are fully inserted to base of ‘V’ between Gripper and Arms
- Confirm systolic & diastolic leaflet motion relative to tip of Arms is non-existent or limited.

Images courtesy of Moody Makar MD
Cedars Sinai Hospital

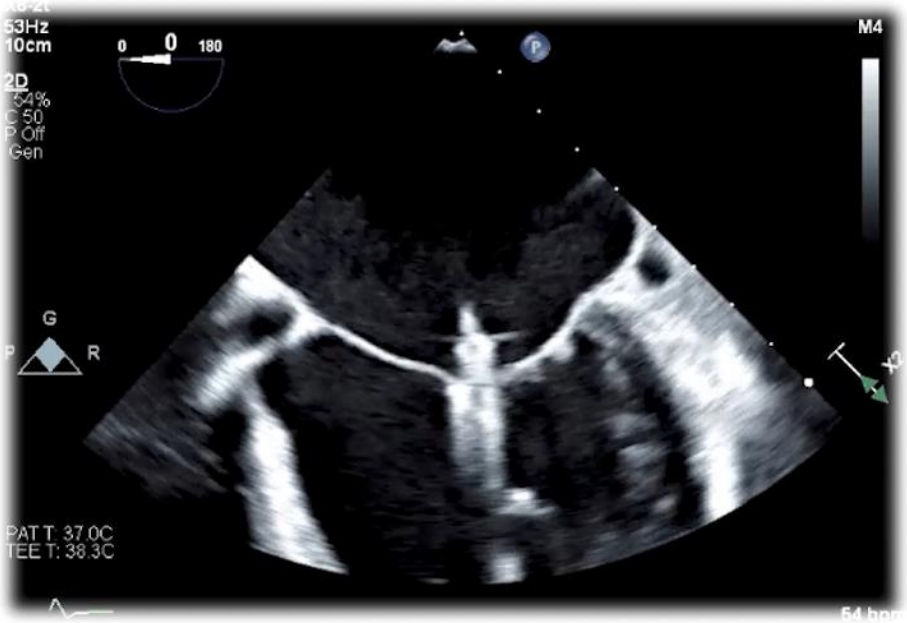
LEAFLET INSERTION ASSESSMENT:
IMAGING: INTERCOMMISSURAL – BICOM, X-PLANE



- On the medial and lateral sides of the Clip, the leaflets enter at the same level.
- Leaflet segments are stable, medial and lateral to the Clip.

Images courtesy of Moody Makar MD
Cedars Sinai Hospital

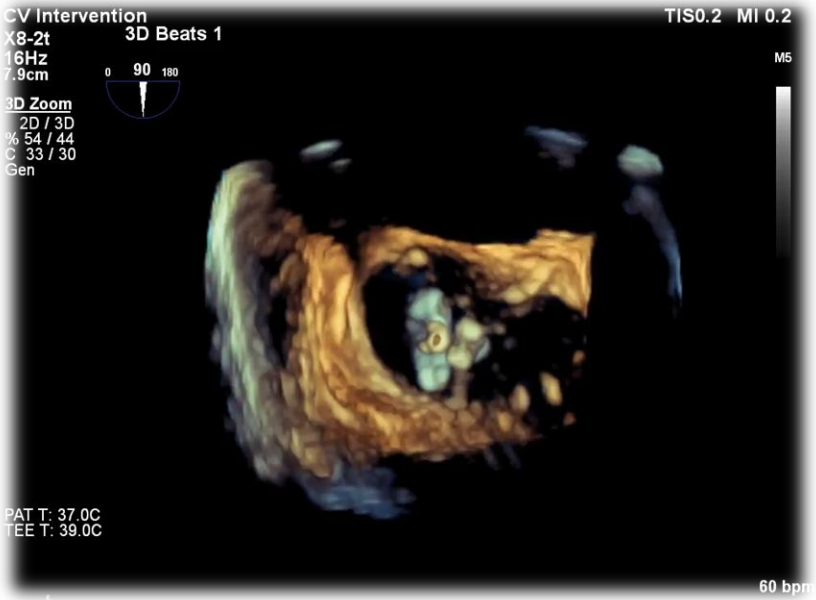
LEAFLET INSERTION ASSESSMENT:
IMAGING: 4 CHAMBER

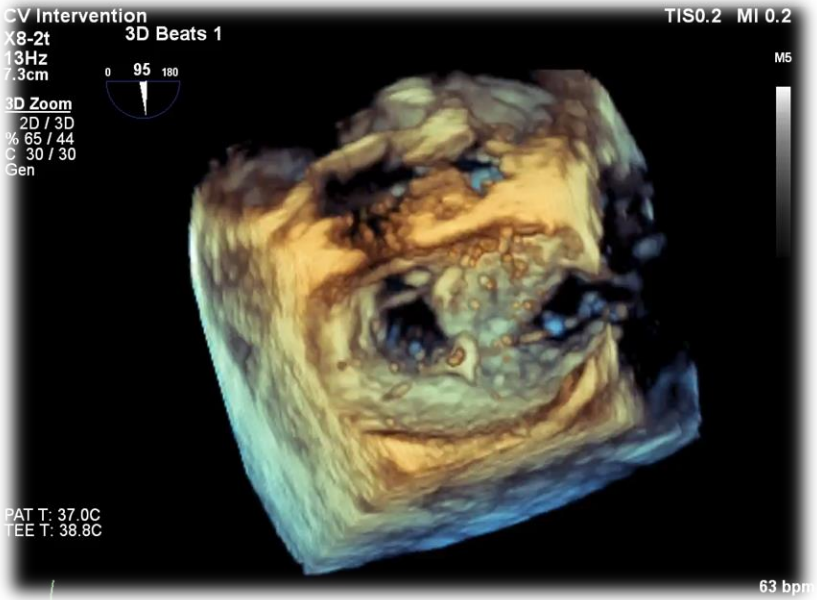


- Verify both leaflets
  - Go over the tip of the Clip Arms
  - Tips are fully inserted to base of ‘V’ between Gripper and Arms
- Confirm systolic & diastolic leaflet motion relative to tip of Arms is non-existent or limited

Images courtesy of Gagan Singh MD,
UC Davis Medical Center

LEAFLET INSERTION ASSESSMENT:
IMAGING: 3D, TRANSGASTRIC SHORT AXIS



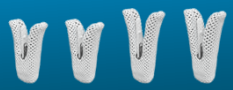


- Clip Arms are perpendicular to Line of Coaptation.
- Clip is not biased towards the anterior or posterior leaflet.

Images courtesy of Moody Makar MD
Cedars Sinai Hospital

MITRACLIP™ SYSTEM REMOVAL

MITRACLIP™ G4 SYSTEM REMOVAL



- MitraClip G4 SYSTEM REMOVAL AFTER CLIP DEPLOYMENT
  - Removal of the CDS while leaving the Guide in place
  - Removal of the CDS and Guide simultaneously
- MitraClip G4 SYSTEM REMOVAL WITH CLIP ATTACHED
  - Removal of the CDS while leaving the Guide in place
  - Removal of the CDS and Guide simultaneously

WARNING: *During MitraClip G4 System removal always retract the CDS by pulling only on the Sleeve Handle. Retracting the CDS by pulling on the DC Handle may result in device damage and/or device or component embolization, and may result in vascular and/or cardiac injury.*

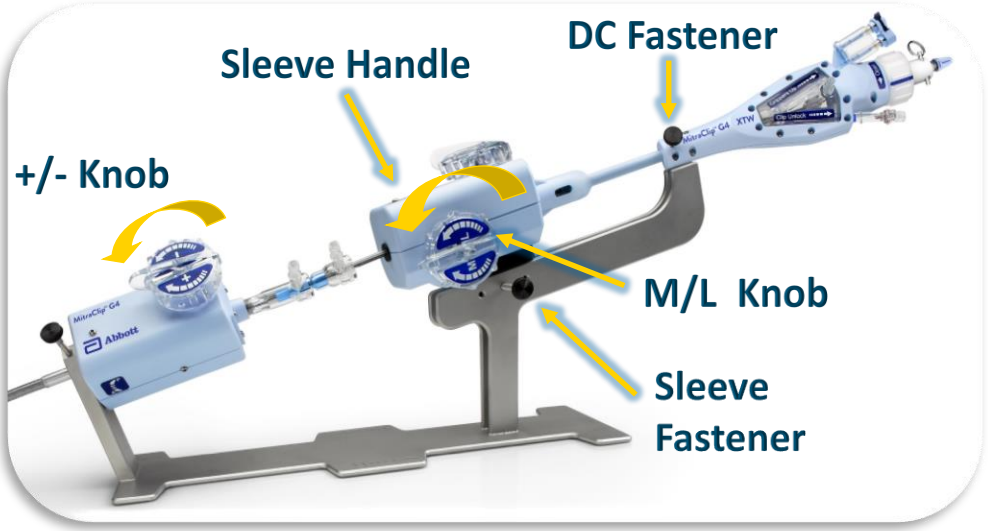
WARNING: *Do release the DC Fastener before releasing Sleeve curves otherwise it may result in device damage and/or device or component embolization.*

WARNING: *Use echocardiographic guidance while releasing Sleeve deflection. Failure to do so may result in cardiac injury.*

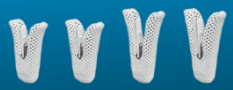
MITRACLIP™ G4 SYSTEM REMOVAL AFTER CLIP DEPLOYMENT

REMOVAL OF THE CDS WHILE LEAVING GUIDE IN PLACE

- Release DC Fastener.
- Slowly release Sleeve deflection by turning M/L Knob and A/P Knob to neutral.
- Secure DC Fastener once Sleeve curves are released.
- Straighten the Guide with the +/- Knob when the Delivery Catheter tip is free from the left atrial wall and the mitral valve.
- Release the Sleeve Fastener and retract CDS approximately 10 cm into Guide by pulling only on Sleeve Handle.



REMOVAL OF THE CDS WHILE LEAVING GUIDE IN PLACE

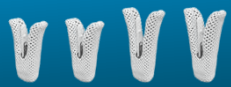


- Confirm that the Clip Introducer is still fully advanced in the Guide Hemostasis Valve.
- Retract the CDS by pulling only on the Sleeve Handle and position the Delivery Catheter tip inside the Clip Introducer. Begin gently aspirating the Guide (starting when the CDS is approximately halfway into the Guide, approximately 40 cm retracted) using a 50-60 cc syringe.
- Remove the CDS and the Clip Introducer simultaneously from the Guide by pulling on the Sleeve shaft and Clip Introducer. Ensure the Delivery Catheter tip is inside the Clip Introducer by visualizing the Proximal Sleeve alignment marker just outside the Clip Introducer. Aspirate the Guide during removal of the CDS and Clip Introducer. Cover Guide Hemostasis Valve with finger upon CDS removal. If necessary, position the Guide Handle below the level of the LA to allow blood to fill the Guide Lumen.

  WARNING: *DO NOT remove the tip of the CDS from the Guide without removing the Clip Introducer simultaneously. Failure to remove the Clip Introducer simultaneously may result in air embolization.*

  WARNING: *DO NOT create a vacuum while removing the CDS from the Guide; air may enter the lumen of the Guide which may result in air embolism.*
- Aspirate using a 50-60 cc syringe to remove any remaining air from the Guide.

REMOVAL OF THE CDS AND GUIDE SIMULTANEOUSLY



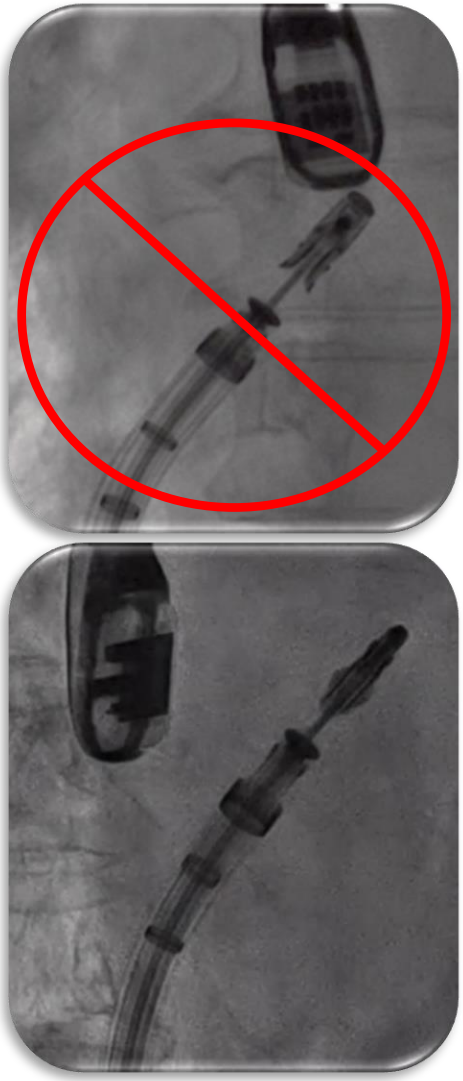
- Release the DC Fastener.
- Slowly release Sleeve curves by rotating the M/L Knob and the A/P Knob to neutral.
- Secure the DC Fastener once Sleeve curves are released.
- Straighten the Guide with the +/- Knob when the Delivery Catheter tip is free from the left atrial wall and the mitral valve.
- Release the Sleeve Fastener and retract the CDS approximately 10 cm into the Guide by pulling only on the Sleeve Handle.
- Carefully retract the Guide tip into the RA. The Guide may be straightened further with the +/- Knob if desired.
- Remove the MitraClip™ G4 System from the femoral vein, while providing hemostasis.

MITRACLIP™ SYSTEM REMOVAL WITH CLIP ATTACHED

REMOVAL OF THE CDS WHILE LEAVING GUIDE IN PLACE

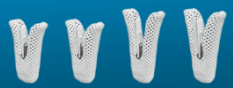
- Confirm Clip is locked.
- Fully Close the Clip Arms and continue to turn the Arm Positioner until it is no longer possible to rotate the Arm Positioner. Return the Arm Positioner to neutral.

  WARNING: *Failure to Fully Close the Clip Arms prior to retraction into the Guide may result in device damage, inability to remove the CDS and/or vascular and cardiac injury.*
- Lower the Grippers.
- Release the DC Fastener and retract the DC Handle until the DC Radiopaque Ring is fully against the tip of the Sleeve.
- Slowly release Sleeve deflection by rotating the M/L Knob and the A/P Knob to neutral.
- Rotate DC handle such that the Clip Arms are perpendicular to the Guide curve plane.
- Secure the DC Fastener once Sleeve curves are released.



Images courtesy of Gagan Singh MD, UC Davis Medical Center

REMOVAL OF THE CDS WHILE LEAVING GUIDE IN PLACE



- Straighten the Guide with the +/- Knob when the tip of the MitraClip™ G4 Implant is free from the left atrial wall and the mitral valve.

  WARNING: *Straighten the Guide prior to retracting the Clip into the Guide. If not done, it may result in device damage, inability to remove the CDS and/or vascular and cardiac injury.*

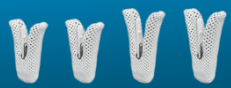
- Release the Sleeve Fastener and retract the CDS into the Guide by pulling only on the Sleeve Handle.

  NOTE: *If resistance is noted, advance and rotate the Clip by rotating the DC Handle then retract the CDS into the Guide. The Guide and/or Sleeve position may also be adjusted to facilitate Clip entry into the Guide. If necessary, retract the Sleeve or advance the Clip to create a 2-3 cm separation to facilitate Clip entry into the Guide.*

  WARNING: *Use fluoroscopic guidance while retracting the CDS into the Guide. Failure to do so may result in device damage, inability to remove the CDS and/or vascular and cardiac injury.*

- Confirm that the Clip Introducer is still fully advanced in the Guide Hemostasis Valve.
- Retract the CDS by pulling only on the Sleeve Handle and position the Clip inside the Clip Introducer. Begin gently aspirating the Guide (starting when the CDS is approximately halfway into the Guide, approximately 40 cm retracted) using a 50-60 cc syringe.

REMOVAL OF THE CDS WHILE LEAVING GUIDE IN PLACE



- Remove CDS and Clip Introducer simultaneously from the Guide by pulling on the Sleeve shaft and Clip Introducer. Ensure the Clip is inside the Clip Introducer by visualizing the Proximal Sleeve alignment marker just outside the Clip Introducer. Aspirate the Guide during removal of the CDS and Clip Introducer. If necessary, position the Guide Handle below the level of the LA to allow blood to fill the Guide lumen.

  WARNING: *DO NOT remove the tip of the CDS from the Guide without removing the Clip Introducer simultaneously and with the Clip inside the Clip Introducer. Failure to remove the Clip Introducer simultaneously may result in air embolism.*

  WARNING: *DO NOT create a vacuum while removing the CDS from the Guide; air may enter the lumen of the Guide which may result in air embolism.*

  WARNING: *DO NOT re-use the CDS after removal. Replace the CDS with a new device. Reinserting the CDS after removal may result in inability to open the Clip. Inability to open the Clip may result in valve injury or lead to deployment of the Clip in an unintended location.*

- Aspirate using a 50-60 cc syringe to remove any remaining air from the Guide.

REMOVAL OF THE CDS AND GUIDE SIMULTANEOUSLY

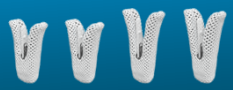
- Confirm Clip is locked.
- Fully Close the Clip Arms and continue to turn the Arm Positioner until it is no longer possible to rotate the Arm Positioner. Return the Arm Positioner to neutral.

  WARNING: *Failure to Fully Close the Clip Arms prior to retraction into the Guide may result in device damage, inability to remove the CDS and/or vascular and cardiac injury.*

- Lower the Gripper(s).
- Release the DC Fastener and retract the DC Handle until the DC Radiopaque Ring is fully against the tip of the Sleeve.
- Slowly release Sleeve deflection by rotating the M/L Knob and the A/P Knob to neutral.
- Rotate DC handle such that the Clip Arms are perpendicular to the Guide curve plane.
- Secure the DC Fastener once Sleeve curves are released.

Images courtesy of Gagan Singh MD, UC Davis Medical Center

REMOVAL OF THE CDS AND GUIDE SIMULTANEOUSLY



- Straighten the Guide with the +/- Knob when the tip of the MitraClip™ G4 Implant is free from the left atrial wall and the mitral valve.

  WARNING: *Straighten the Guide prior to retracting the Clip into the Guide. Failure to do so may result in device damage, inability to remove the CDS and/or vascular and cardiac injury.*

- Release the Sleeve Fastener and retract the CDS approximately 10 cm into the Guide by pulling only on the Sleeve Handle.

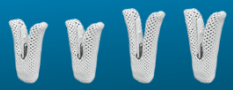
  NOTE: *If resistance is noted, advance and rotate the Clip by rotating the DC Handle then retract the CDS into the Guide. The Guide and/or Sleeve position may also be adjusted to facilitate Clip entry into the Guide. If necessary, retract the Sleeve or advance the Clip to create a 2-3 cm separation to facilitate Clip entry into the Guide.*

  WARNING: *Use fluoroscopic guidance while retracting the CDS into the Guide. Failure to do so may result in device damage, inability to remove the CDS and/or vascular and cardiac injury.*

- Carefully retract the Guide tip into the RA. The Guide may be straightened further with the +/- Knob if desired
- Remove the MitraClip G4 System from the femoral vein, while providing hemostasis

SITUATIONAL STEERING SCENARIOS

SCENARIOS



Excessive height

- Inadequate Delivery Catheter travel to advance Clip below leaflets

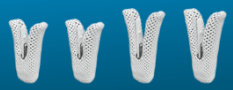
Inadequate height

- Inadequate Clip clearance when Delivery Catheter handle is fully retracted

Aorta hugger

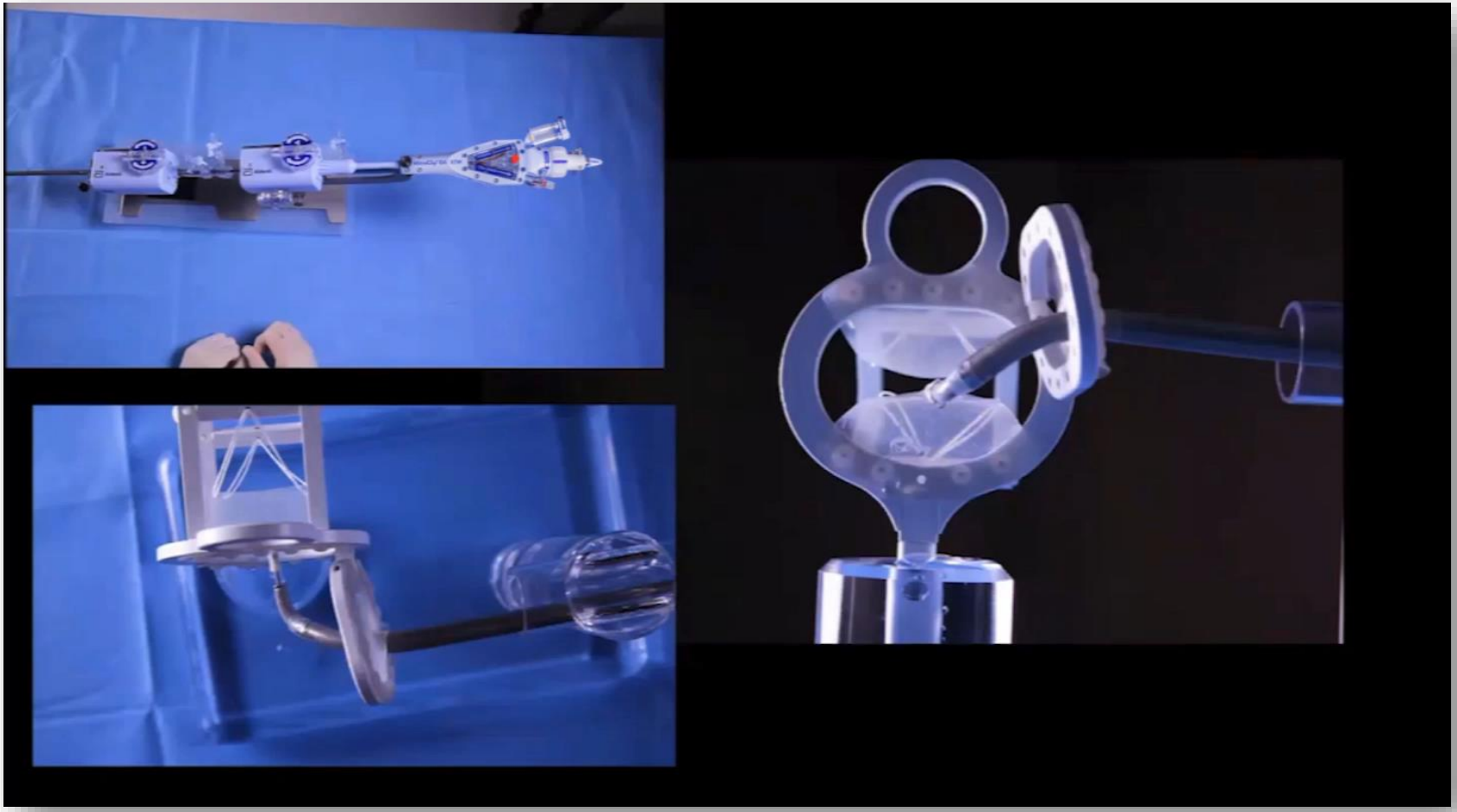
- Delivery Catheter biased toward aorta

EXCESSIVE HEIGHT

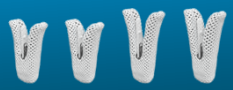


- Torque Guide Handle anterior until Clip is pointing at aorta
- Add (P) knob input (at least 180^{o} of knob input) until Clip is redirected to center of valve
- Adjust medial/lateral position (Intercommissural)
- Adjust anterior/posterior position (LVOT)

EXCESSIVE HEIGHT

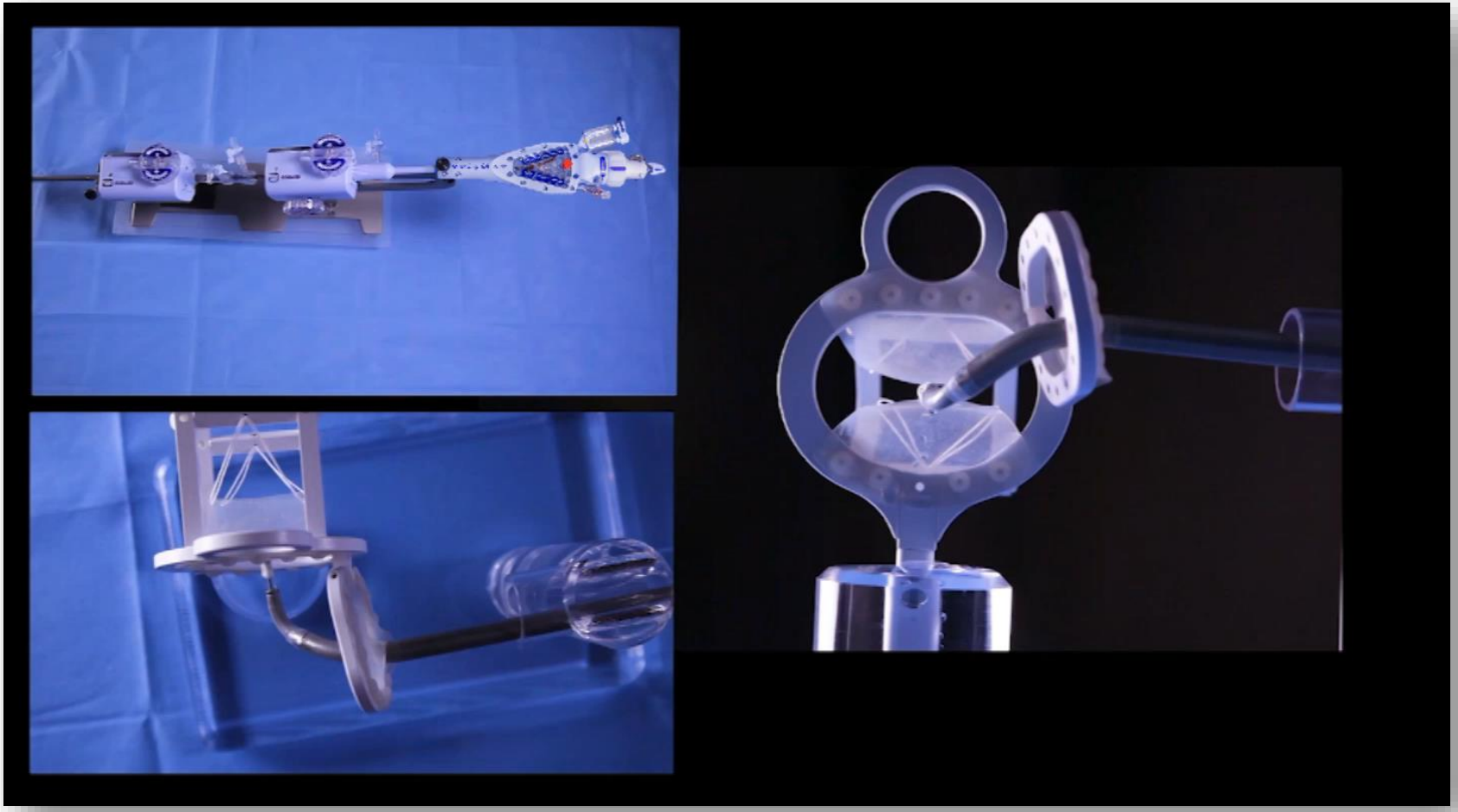


INADEQUATE HEIGHT



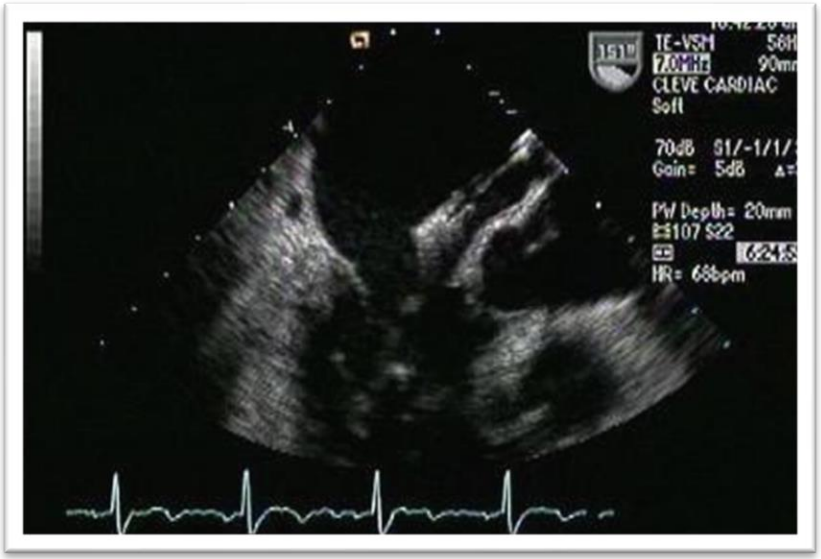
- Torque Guide Handle posterior until Clip is pointing at posterior annulus
- Add (A) knob input (at least 180^{o} of knob input) until Clip is redirected to center of valve
- Adjust medial/lateral position in (intercommissural)
- Adjust anterior/posterior position in (LVOT)

INADEQUATE HEIGHT



AORTA HUGGER

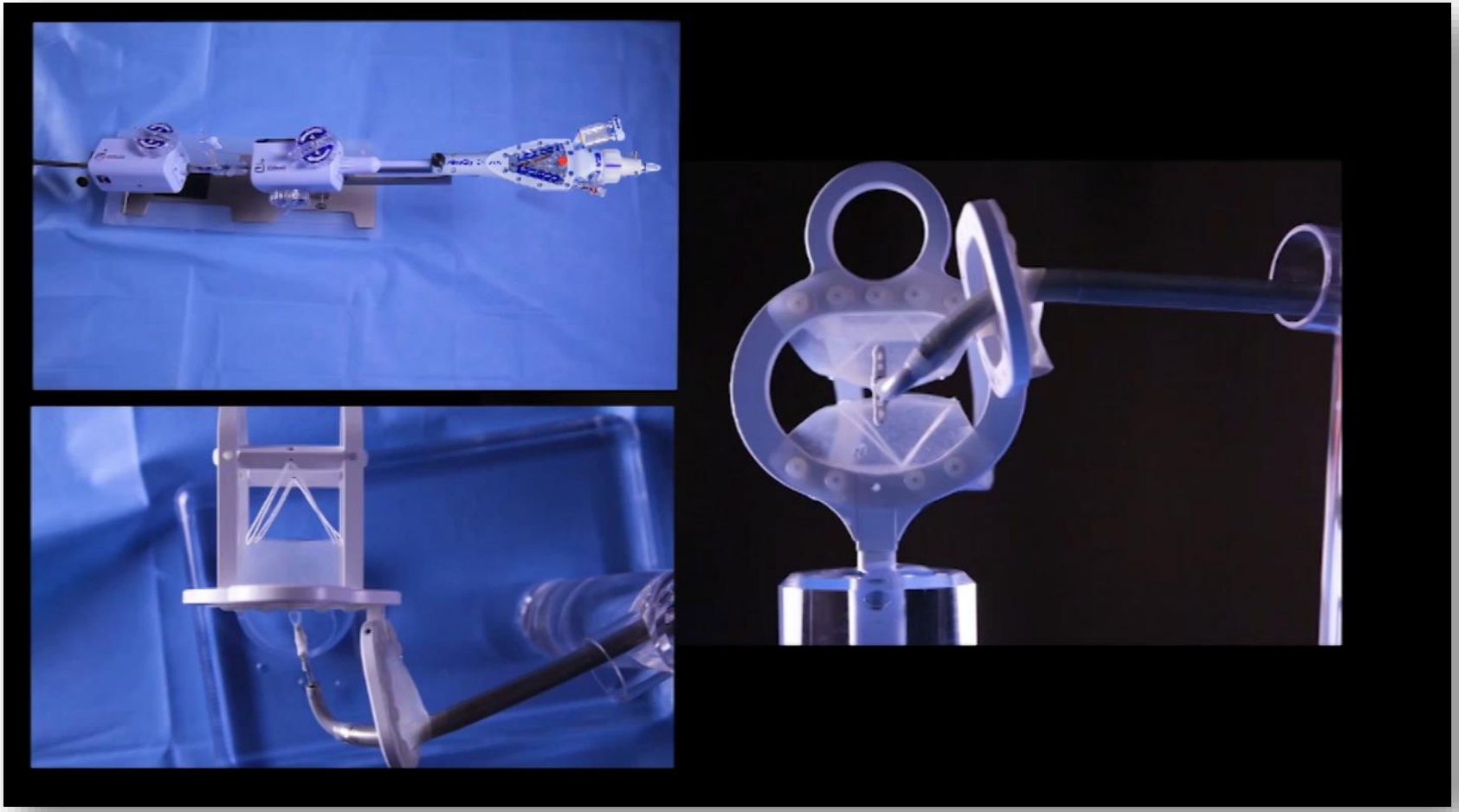
- Add (+) knob input to sweep posterior
- Adjust medial/lateral position (intercommissural)
- Adjust anterior/posterior position (LVOT)



Example of Aorta Hugger in LVOT echo view

NOTE: *Confirm Guide tip is appropriately positioned in LA*

AORTA HUGGER

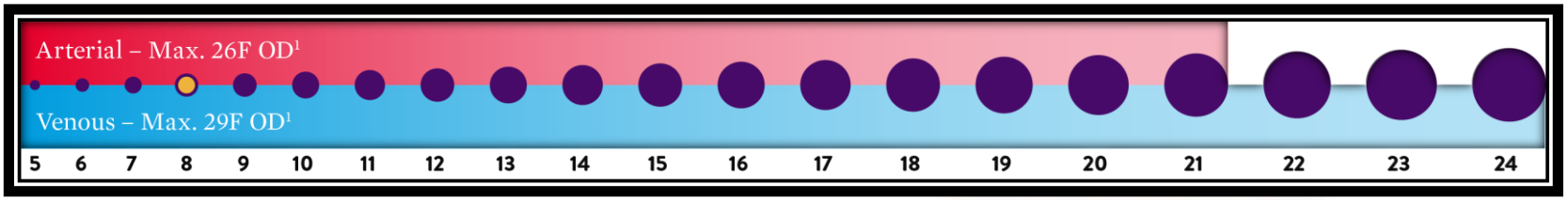


POST-PROCEDURE CONSIDERATIONS

Directly related to the MitraClip™ procedure and not intended to replace existing patient management per institutional guidelines

POST-PROCEDURE CARE

- Manage groin access per physician.
  - Perclose ProGlide™ (Venous Indication)
    - Suture-mediated closure device
    - Ability to close 29 Fr (OD) sheaths
    - Early ambulation for patients
    - Low 1.9% major complication rate in REALISM Trial[1].



  - Consider figure-of-8 stitch technique.

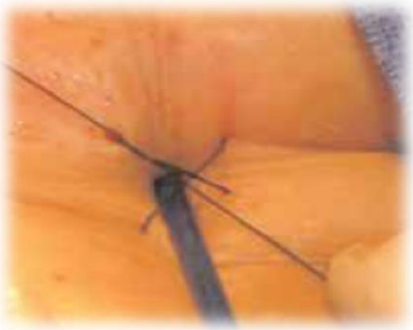
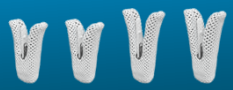


Image from CI Today, 7/8-2008,
J. Bagai, MD & D. Zhao, MD

[1]Kar, Saibal; Hermiller, James; et al. CRT 2018

POST-PROCEDURE CARE

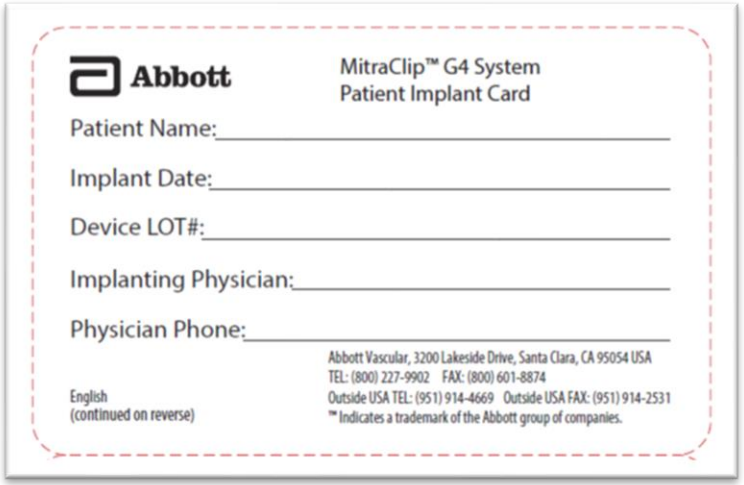


- Medical Therapy
  - Short-term anticoagulation therapy may be necessary after mitral valve repair with MitraClip™ Clip. Prescribe anticoagulation and other medical therapy per institutional guidelines.
- Endocarditis Prophylaxis
  - Patients undergoing any procedures known to potentially be associated with bacteremia after implantation of MitraClip should be prescribed prophylactic antibiotic therapy prior to such procedures.

POST-PROCEDURE CARE

- After placement of a MitraClip™ Clip, the Clip Identification Card should be filled out and the patient should be instructed to carry it with them at all times.

- All patients should be advised to limit strenuous physical activity for at least the first month post-procedure or longer if warranted.



Abbott

MitraClip™ G4 System
Patient Implant Card

Patient Name:_____

Implant Date:_____

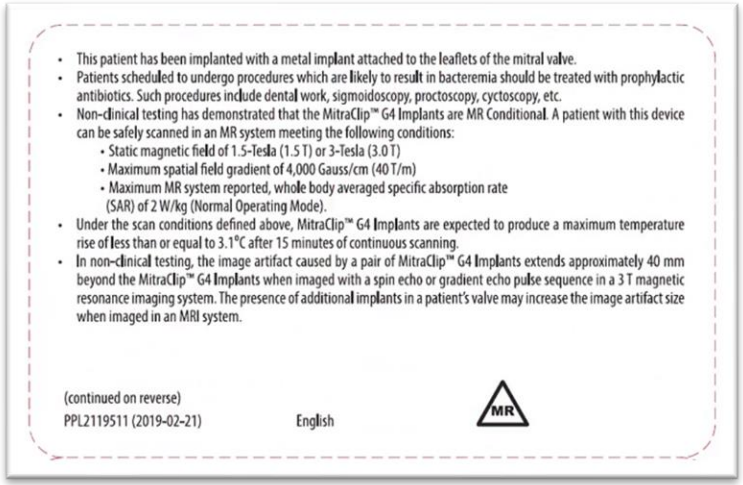
Device LOT#:_____

Implanting Physician:_____

Physician Phone:_____

Abbott Vascular, 3200 Lakeside Drive, Santa Clara, CA 95054 USA
TEL: (800) 227-9902 FAX: (800) 601-8874
Outside USA TEL: (951) 914-4669 Outside USA FAX: (951) 914-2531
™ Indicates a trademark of the Abbott group of companies.

English
(continued on reverse)



- This patient has been implanted with a metal implant attached to the leaflets of the mitral valve.
- Patients scheduled to undergo procedures which are likely to result in bacteremia should be treated with prophylactic antibiotics. Such procedures include dental work, sigmoidoscopy, proctoscopy, cystoscopy, etc.
- Non-clinical testing has demonstrated that the MitraClip™ G4 Implants are 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-Tesla (1.5 T) or 3-Tesla (3.0 T)
  - Maximum spatial field gradient of 4,000 Gauss/cm (40 T/m)
  - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).
- Under the scan conditions defined above, MitraClip™ G4 Implants are expected to produce a maximum temperature rise of less than or equal to 3.1°C after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by a pair of MitraClip™ G4 Implants extends approximately 40 mm beyond the MitraClip™ G4 Implants when imaged with a spin echo or gradient echo pulse sequence in a 3 T magnetic resonance imaging system. The presence of additional implants in a patient's valve may increase the image artifact size when imaged in an MRI system.

(continued on reverse)
PPL2119511 (2019-02-21)

English

MR

THANK YOU

IMPORTANT SAFETY INFORMATION

Rx ONLY

MITRACLIP CLIP DELIVERY SYSTEMS

INDICATION 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.

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., 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.
- 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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

MITRACLIP CLIP DELIVERY SYSTEMS INDICATION FOR USE (CONTINUED)

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, anesthesia, 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 MitraClip™ outside of the labeled indication.**
- Read all instructions carefully. Failure to follow these instructions, warning and precautions may lead to device 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.


Abbott