MitraClip
Percutaneous Mitral Valve Repair

Introduction to the MitraClip Therapy

Abbott
A Promise for Life

Agenda

- Mitral Regurgitation
- Concept & Device Overview
- MitraClip Procedure
- Clinical experience
- Patient profiles

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Mitral Regurgitation

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About Mitral Regurgitation

Mitral Regurgitation

Mitral regurgitation (MR) results from a lack of leaflet coaptation between the two leaflets of the mitral valve—the valve found between the left atrium and left ventricle of the heart. In a normally functioning mitral valve, blood flows in a single direction between the left atrium and left ventricle. MR is characterized by systolic retrograde flow from the left ventricle into the left atrium. Over time, MR may lead to heart failure.

Causes

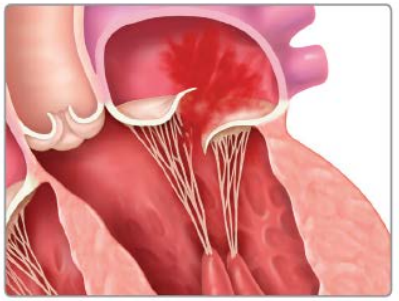
- Degenerative MR (also known as primary or organic MR) is usually due to an anatomic abnormality of the mitral valve itself, including the leaflets, and/or the subvalvular apparatus, such as the chordae or papillary muscles.
- Functional MR (also known as secondary MR) is the result of left ventricular dilation, which can be secondary to ischemic heart disease. Left ventricular dysfunction leads to annular dilation and incomplete coaptation of the mitral valve resulting in MR.

Consequences

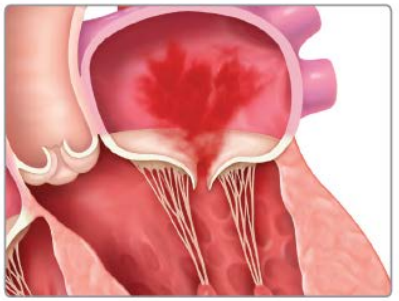
MR places an extra burden on the heart and lungs. In some cases, patients may never develop symptoms. In other cases, patients may develop an enlarged left ventricle as the heart works harder to maintain cardiac output. Patients with chronic MR may develop symptoms of heart failure, such as fatigue or inability to exercise, decrease in appetite, dry, hacking cough (often worse when lying down), shortness of breath especially at night, fainting, weight gain from fluid retention, or accumulation of fluid in feet, ankles, and lungs (edema).

Patients can also develop rhythm abnormalities that may require medical or interventional therapy. Overall patients with symptomatic severe MR have a worse quality of life, decreased functional capacity and increased rate of mortality.

Degenerative MR — Prolapse



Degenerative MR — Flail



Functional MR

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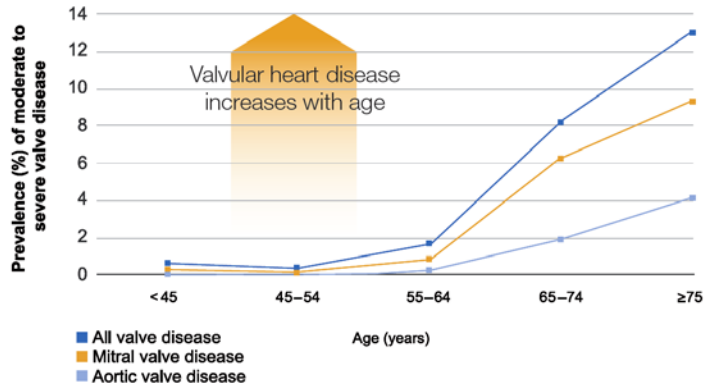
Prevalence and Unmet Need

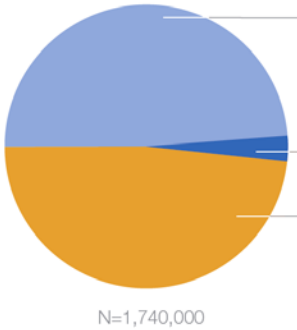
Epidemiological data show that MR in the range of moderate-to-severe to severe is the most frequent valve disease.[1,2] In fact, MR is the second most common form of valvular heart disease needing surgery in Europe.[3]

Although moderate-to-severe and severe MR are common, they continue to remain undertreated. In 2009, only approximately 2% of the estimated 1.7 million patients with MR ≥ 3+ were treated with surgical intervention.[1,7-10] Reasons for denying surgery include impaired left ventricular ejection fraction (LVEF), multiple comorbidities, and advanced age, all of which are determinants for high operative risk.[3,6]

Prevalance of Valvular Heart Disease by Age



U.S. MR Patient Population (2009) [1,7-11]



Surgical Candidates 49%

Of surgical candidates, up to 50% of patients are not referred to surgery, even if a surgical indication exists[3-5]

Surgical Patients 2%

High-Risk Patients* 49%

Factors prohibiting surgery include impaired LVEF, high operative risk, multiple comorbidities and advance age[4]

N=1,740,000

* High risk was defined as patients with EF <35% and/or age of 75+.

1 Heart Disease and Stroke Statistics 2010 Update: A Report from the American Heart Association. Circulation 2010;121:e46-e215.
2 Nkomo, VT et al. Lancet. 2006;368:1005-1011.
3 Iung, B et al. Eur Heart J. 2003;24:1231-1243
4 Mirabel, M et al. Eur Heart J. 2007;28:1358-1365.
5 Taramasso, M et al. Cardiol Res Pract. 2010;25:[Epub ahead of print].
7 Rankin, J et al. Determinants of Operative Mortality in Valvular Heart Surgery. J Thorac Cardiovasc Surgery, March 2006.
8 U.S. Census Bureau, Statistical Abstract of the U.S.
9 Patel et al. Mitral Regurgitation in Patients with Advanced Systolic Heart Failure, J of Cardiac Failure, 2004.
10 Gammie, J et al. Trends in Mitral Valve Surgery in the United States: Results from the STS Adult Cardiac Database, Annals of Thoracic Surgery 2009.
11 Data on file Abbott Vascular, March 2011.

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Treatment Options

Medical: There are no medications that are indicated to treat MR, but there are medications used to manage patient symptoms.

Surgical: For symptomatic patients diagnosed with moderate–severe or severe MR, surgery is generally recommended to repair or replace the mitral valve. Mitral valve repair or replacement typically involves open-heart surgery while on cardiopulmonary bypass. Patients recovering from mitral valve surgery may take several months to regain normal physical function and activity.

Percutaneous mitral valve repair: The MitraClip procedure is a minimally invasive catheter-based therapy. This new treatment increases the options for selected patients with MR. It has been shown to reduce MR, reverse left ventricular remodeling, improve NYHA functional class, and improve quality of life.[5]

5. Feldman T et al. EVEREST II RCT, TCT 2012, NPL03998-A

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Concept

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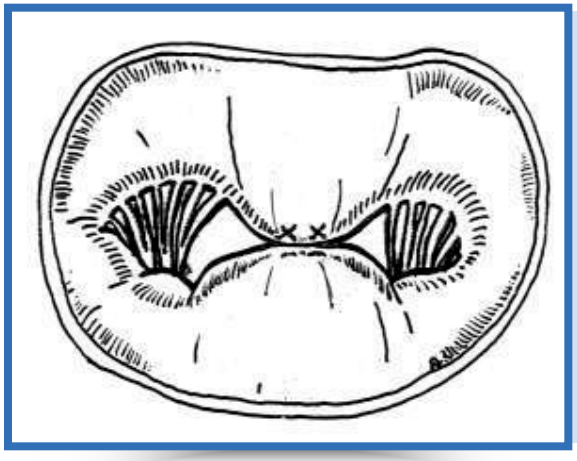
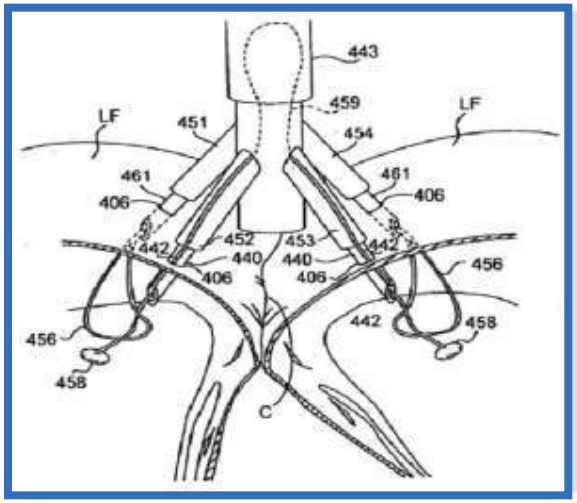
Concept: Percutaneous Mitral Valve Repair



- Double-orifice suture technique developed by Prof. Ottavio Alfieri
- First published results in 1998 illustrated proven benefit
- Suggested procedure best suited for minimally invasive approach



- Dr. Fred St. Goar, interventional cardiologist had patient successfully treated with edge-to-edge surgery
- Conceived several ideas for percutaneous valve repair
- Founded Evalve 1999 to develop devices to treat valvular disease

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Device Overview

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System

The MitraClip System performs **percutaneous mitral valve repair** by creating a vertical line of coaptation, forming a double-orifice valve.

- Beating heart procedure—no cardiopulmonary bypass
- Allows for real-time positioning and repositioning to optimize MR reduction
- Designed to preserve surgical options
- Femoral venous access
- Limited hospital length of stay compared to that after surgery[12]

The Clip Delivery System and Steerable Guide Catheter are designed to fit co-axially to accurately position and reposition multiple implants with the use of one guide.

12. Data on file Abbott Vascular. November 2011

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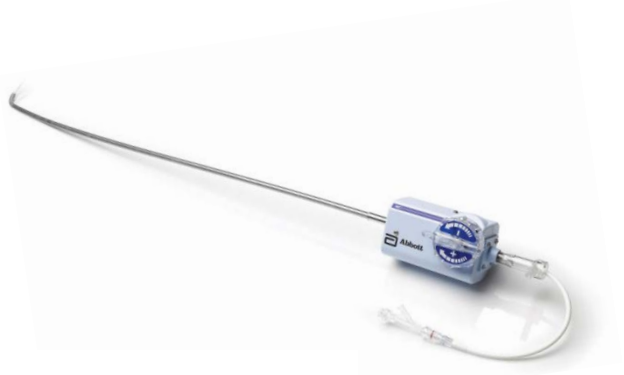
System Components

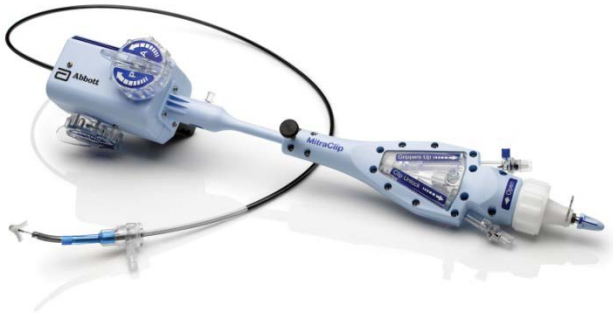
Steerable Guide Catheter

- 24 French steerable catheter
- Percutaneous venous access
- Requires successful transseptal puncture



Clip Delivery System

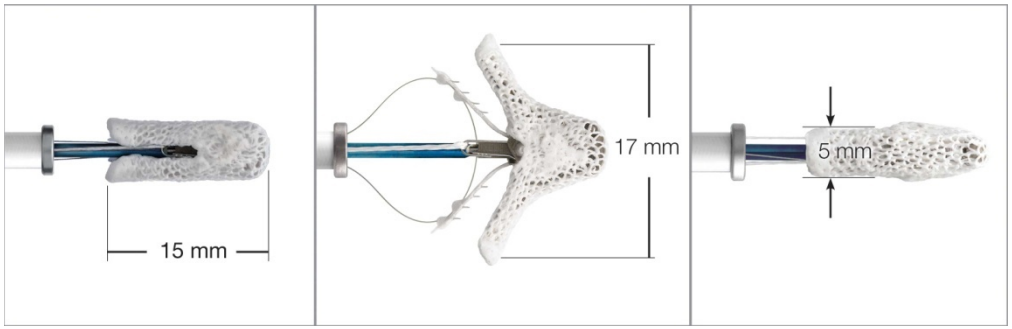
Contains the implant attached to a highly maneuverable delivery catheter with all controls at the proximal end.



MitraClip Device (Implant)

- Cobalt chromium construction
- Polyester cover designed to promote tissue growth
- Magnetic resonance conditional to 3 Tesla*

* Static magnetic field up to 3 Tesla; maximum spatial gradient in static field of 2500 gauss/cm or less; maximum whole-body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning.



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MitraClip Procedure

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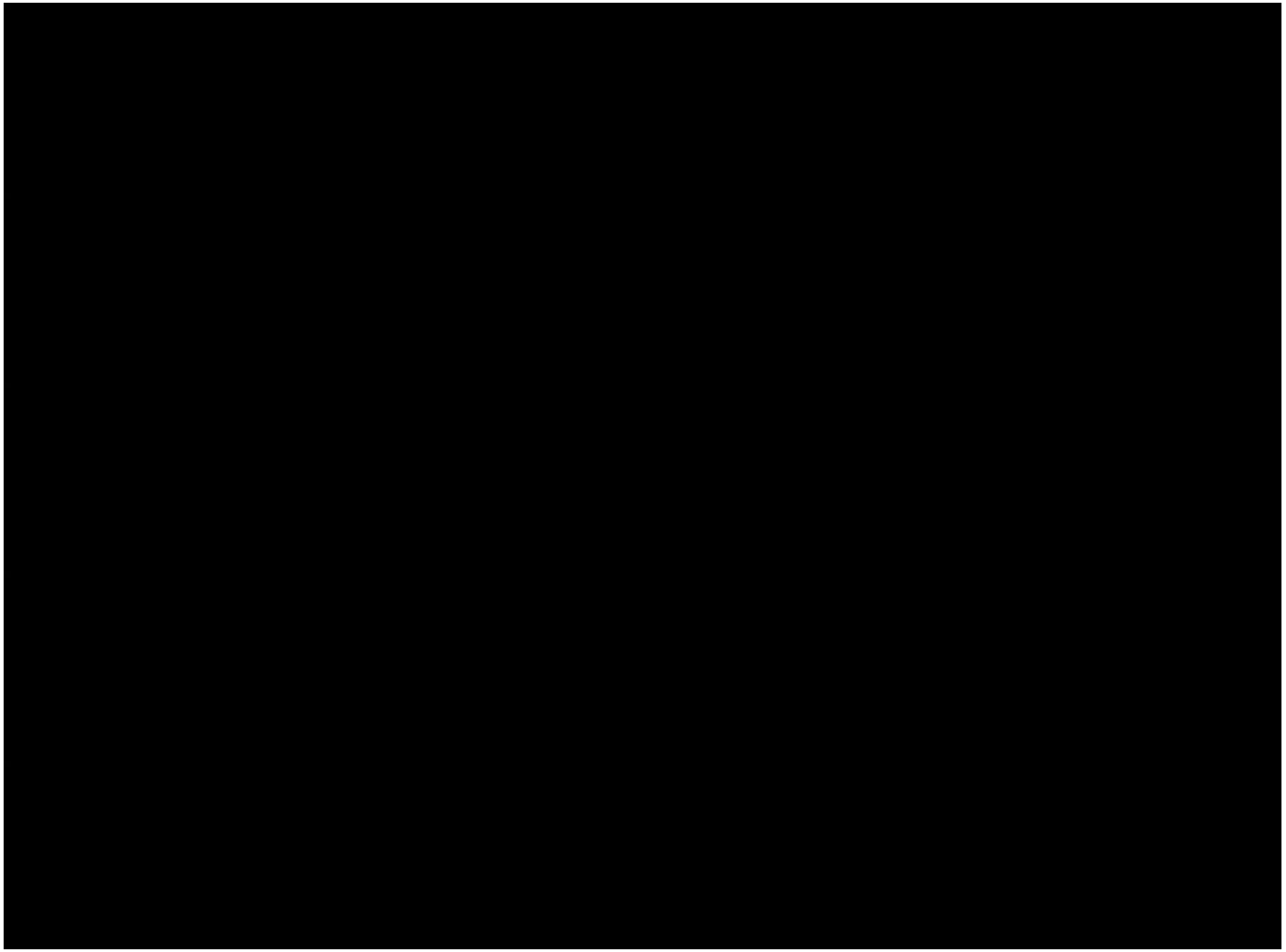
MitraClip Procedure Animation



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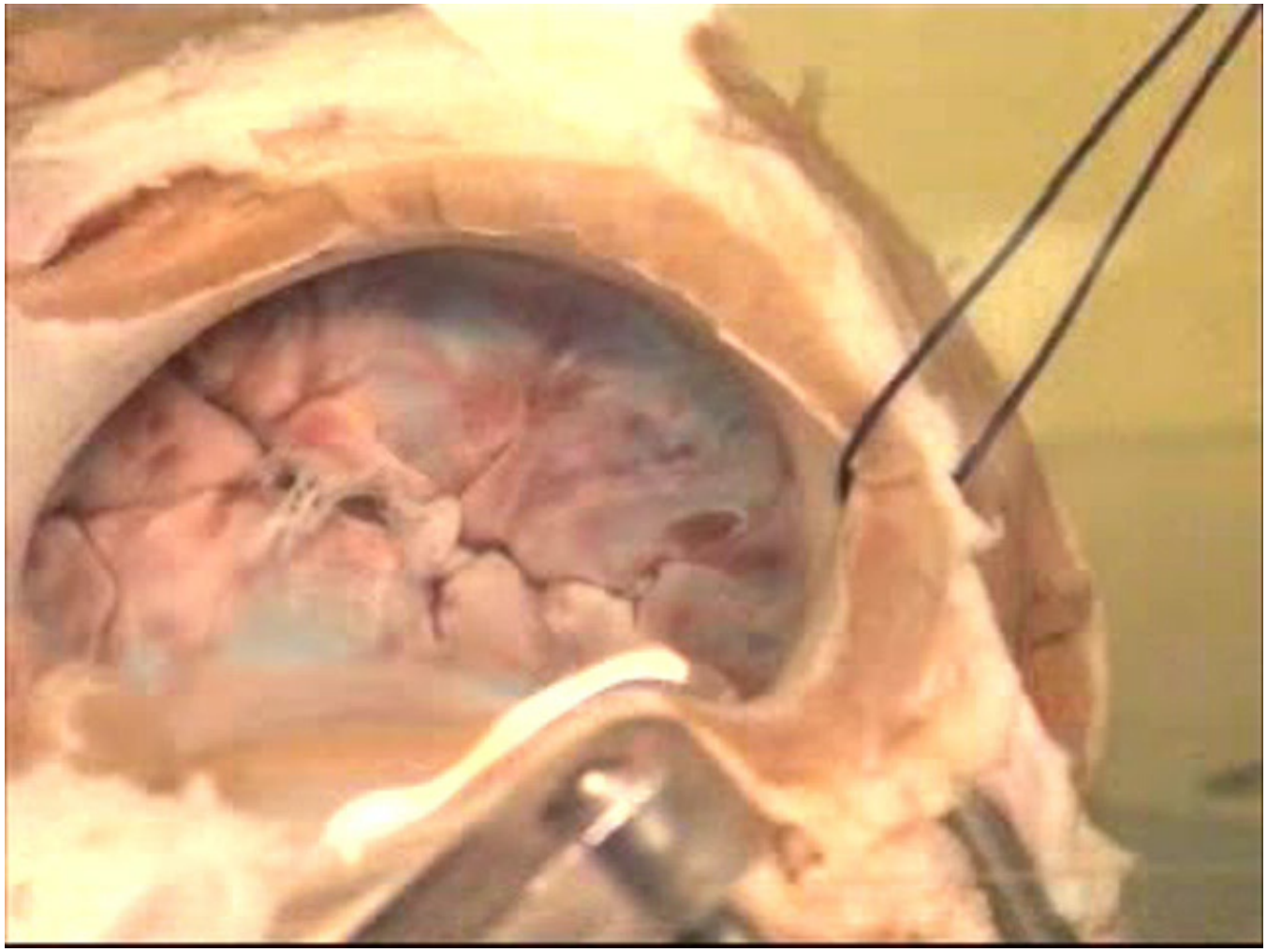
Cut Chord Model



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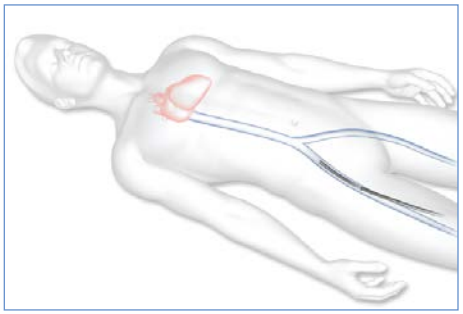
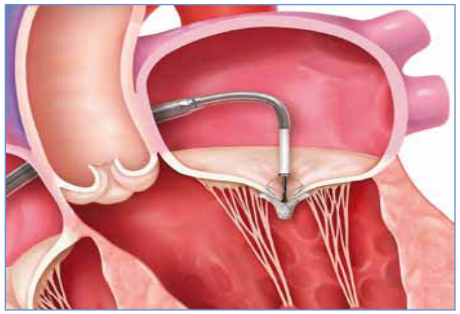
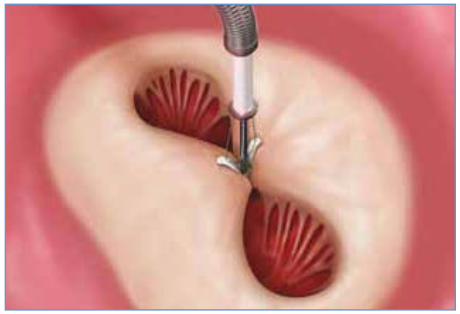
Procedural Overview



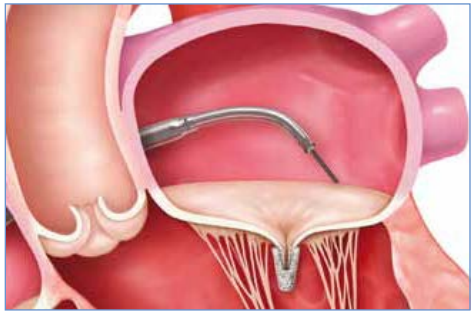
Venous access under general anesthesia



Clip is optimally positioned on MR jet



Creation of double-orifice valve



Clip implanted after validation of safe positioning

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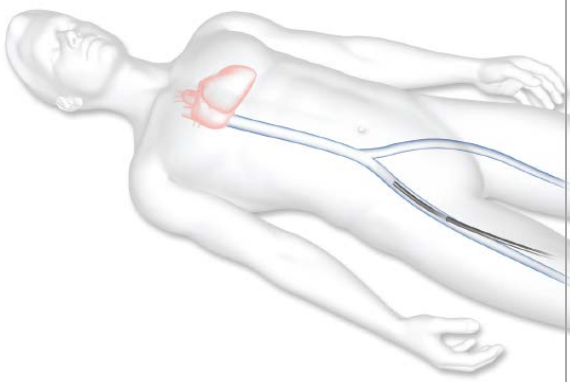
Procedural Overview

Patient and System Preparation



- The following considerations should be accounted for:
  - TEE probe will be in place for an extended period of time
  - Intubation under general anesthesia
  - 24 French sheath in femoral vein
  - Bladder/urinary catheter in place
  - Heparinization during procedure to ACT > 250
- System is prepared by removing all the air in the lumens of the Clip Delivery System and Steerable Guide Catheter
- System is functionally tested prior to use

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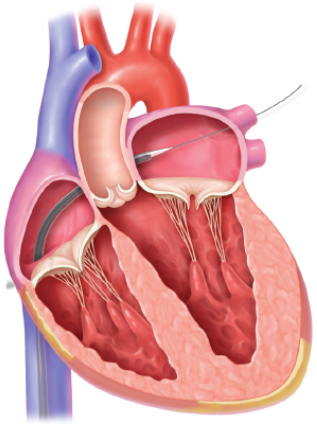
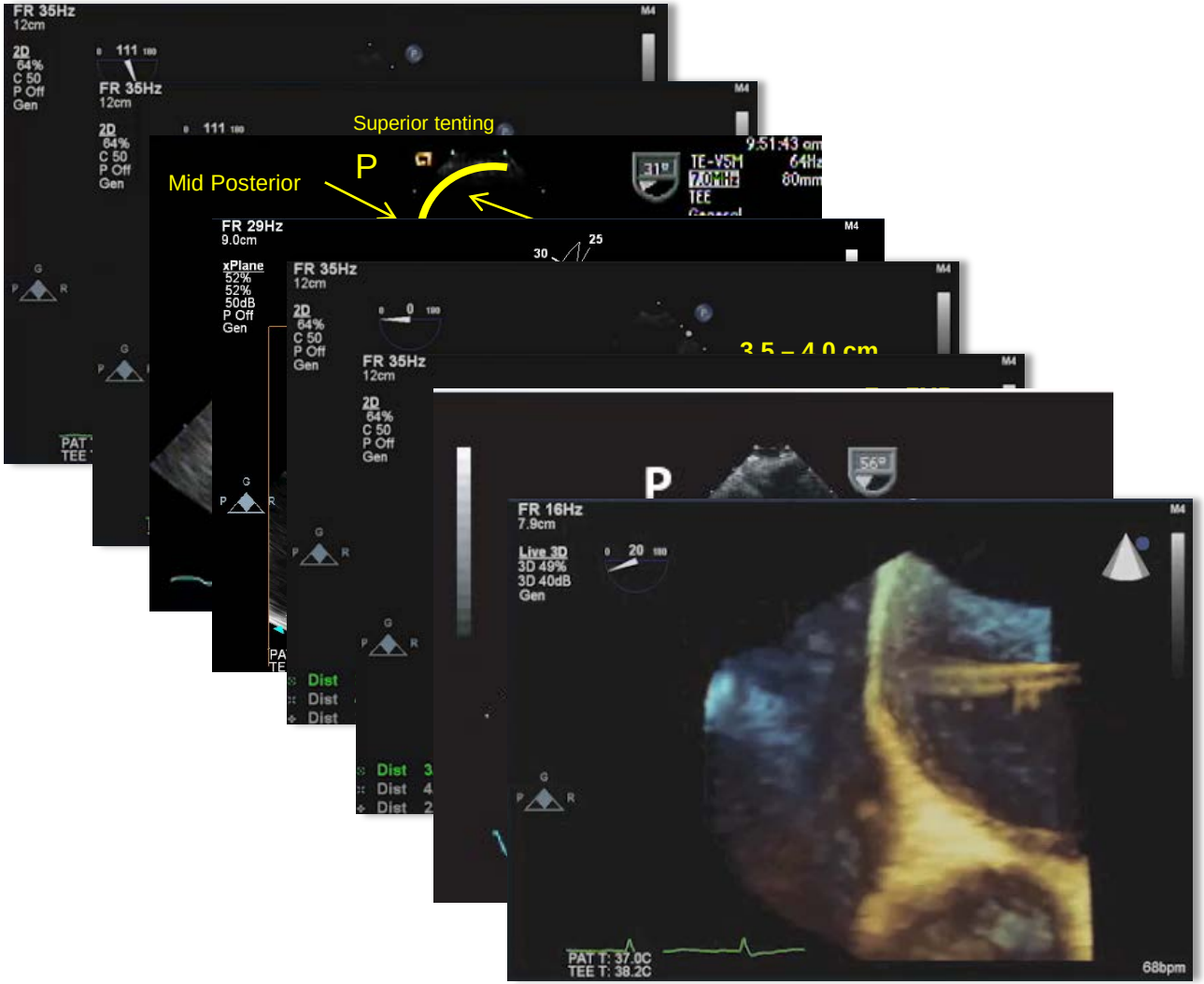
Procedural Overview

Transseptal Crossing and Guide Insertion



A transseptal procedure is performed to gain access from the right atrium to the left atrium. The Steerable Guide Catheter (Guide) and Dilator are then carefully advanced into the left atrium over a wire. Once the Guide is in place and secured, the wire and Dilator are removed leaving the Guide in the left atrium.



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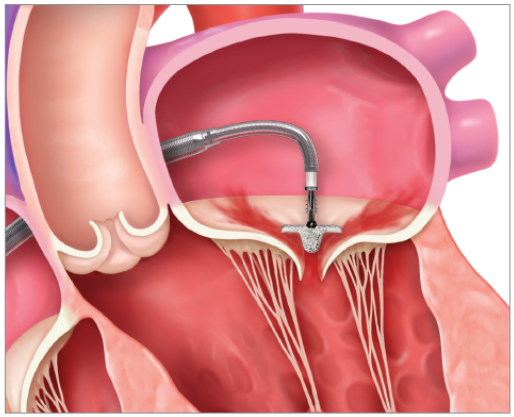
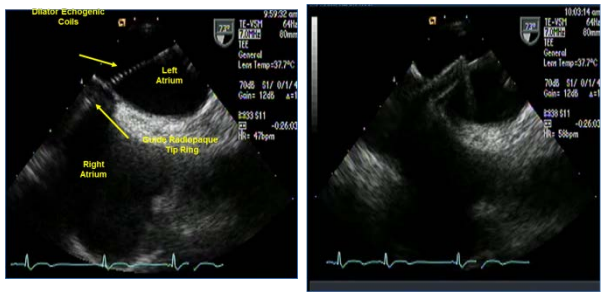
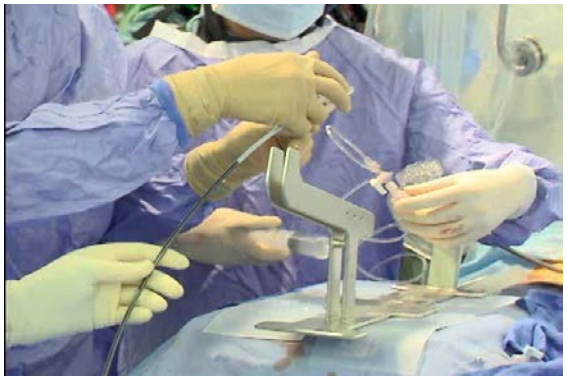
Procedural Overview

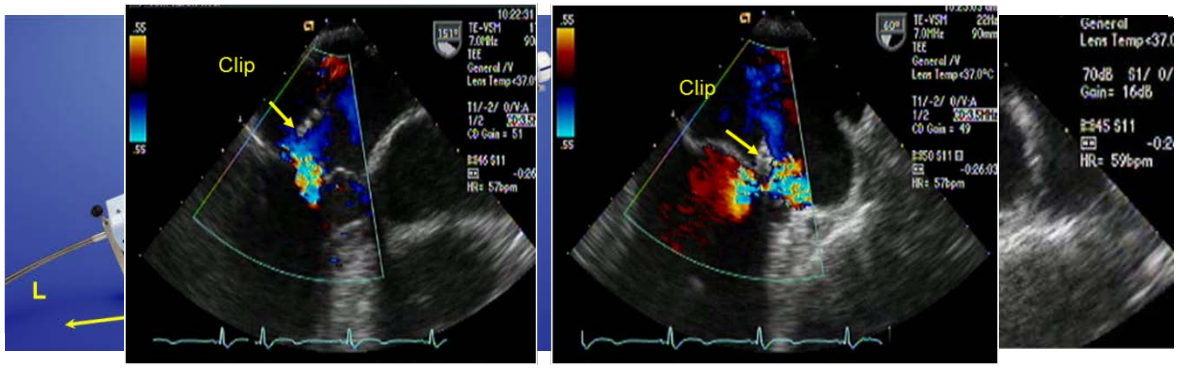
Clip Delivery System Insertion and Steering in the Left Atrium



To introduce the Clip, the Clip Delivery System (CDS) is advanced through the Guide into the left atrium. A series of steering maneuvers and manipulations with the Guide and CDS are required to align the Clip perpendicular to the mitral valve plane, and the Clip Arms perpendicular to the line of coaptation. These maneuvers are done under echocardiographic and fluoroscopic guidance.







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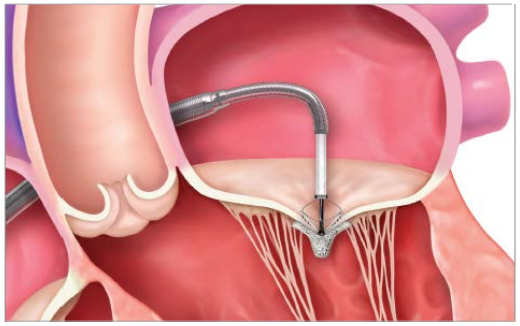
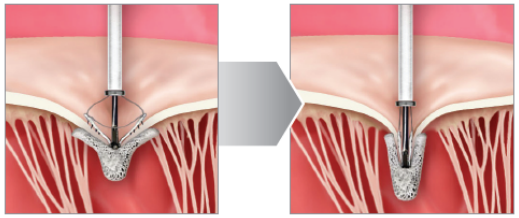
Procedural Overview

Advancing into Left Ventricle and Leaflet Grasping

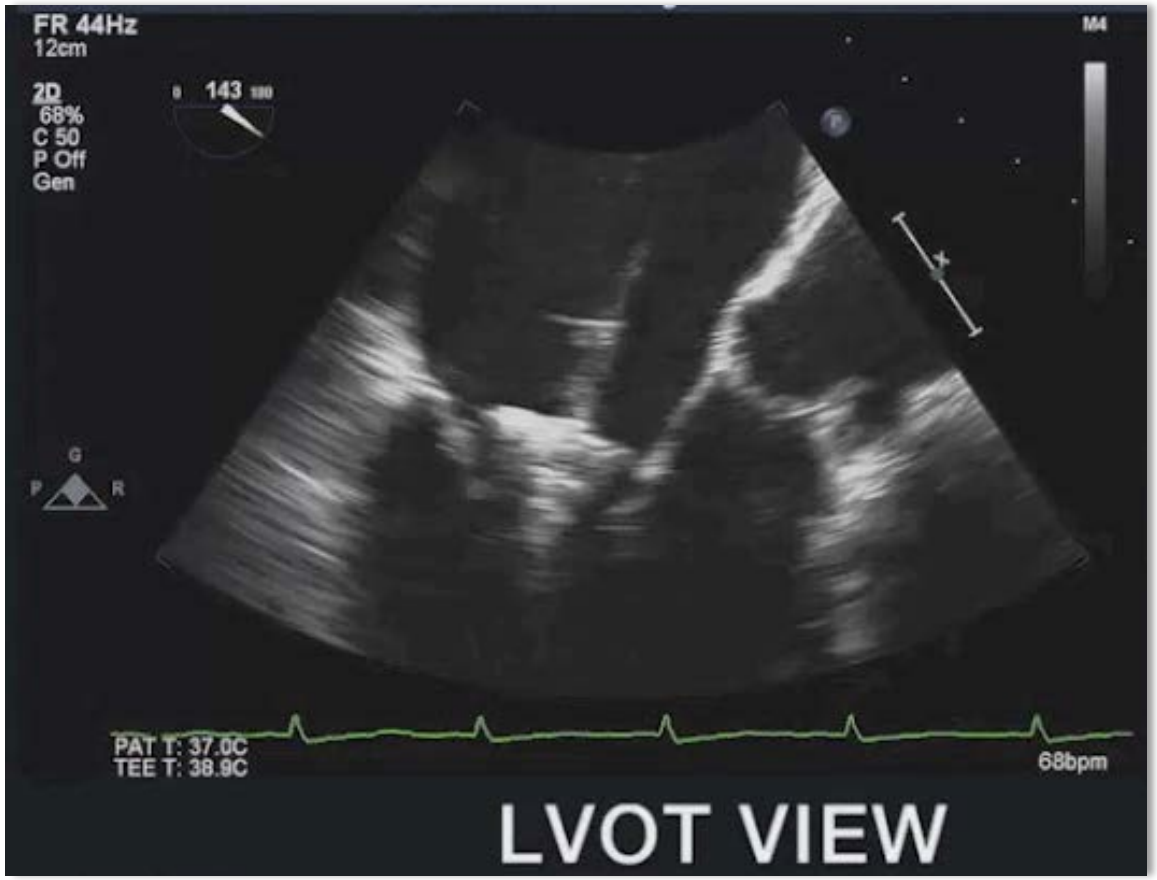


After the Clip is aligned over the regurgitant jet in the left atrium, the System is then advanced into the left ventricle to begin the grasping procedure. Leaflet grasping is done by slowly retracting the System back towards the left atrium to allow the leaflets to come to rest on the Clip Arms and then dropping the Grippers.



Clip Arms closed to 120º

Clip Arms closed to 20º



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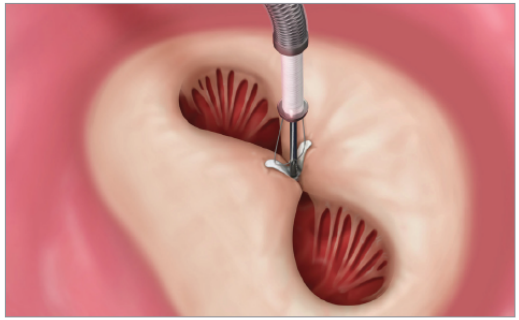
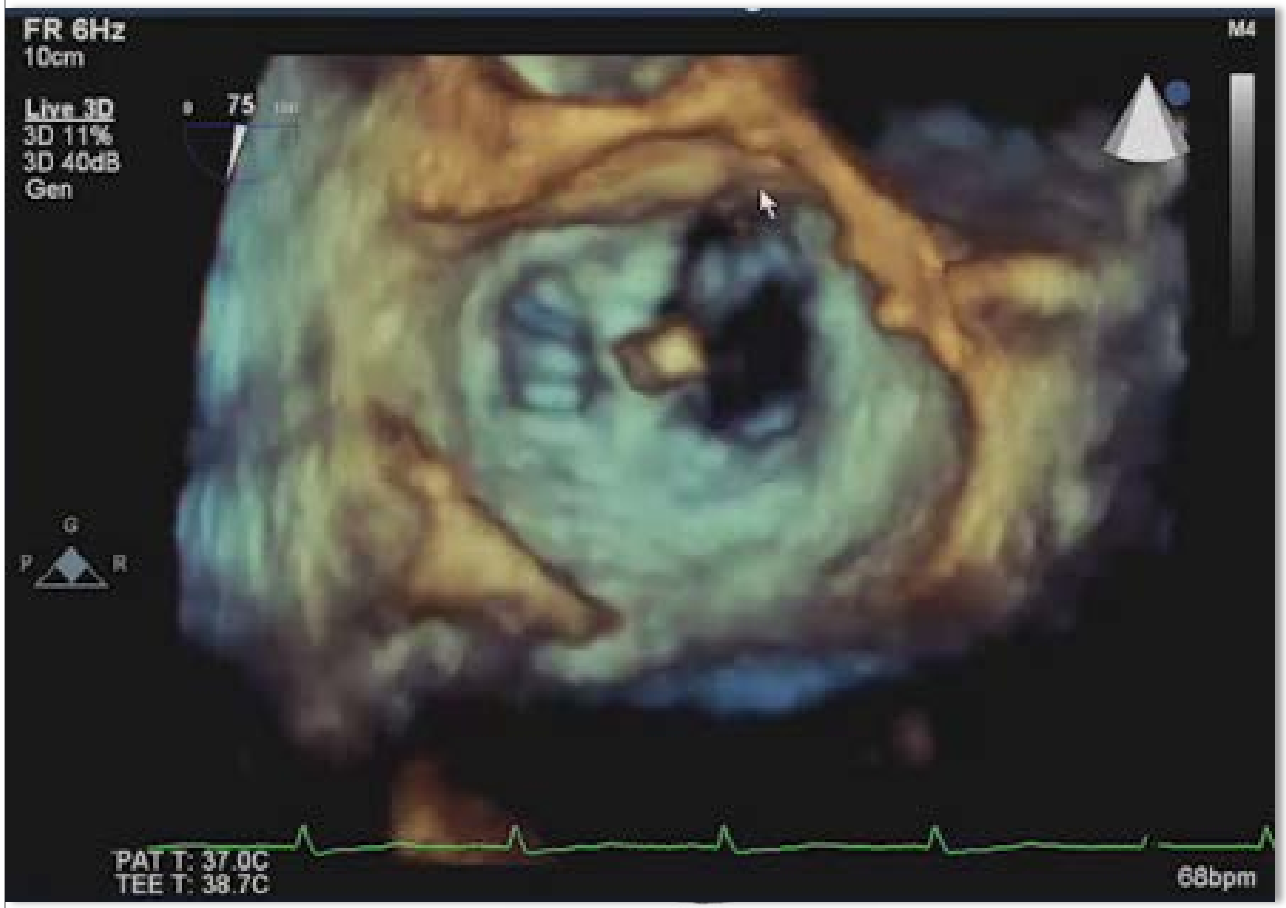
Procedural Overview

Leaflet Insertion Assessment and Hemodynamic Measurements



Prior to Clip closure and deployment, a leaflet insertion and hemodynamic assessment must be performed. The leaflet insertion assessment ensures both leaflets are fully inserted and secure into the Clip. In addition, the MR reduction and pressure gradients are assessed to ensure regurgitation reduction without stenosis.



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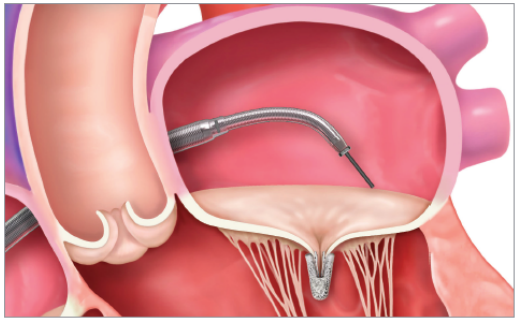
Procedural Overview

Deployment and System Removal



Once the assessments are positive, the Clip can be fully closed and deployed in a multistep process. The physician may also decide to place a second Clip to optimize MR reduction. The System is removed by releasing deflections on the catheter and slowly removing from the patient. Groin management and continued medical therapy are recommended per the institution's guidelines.

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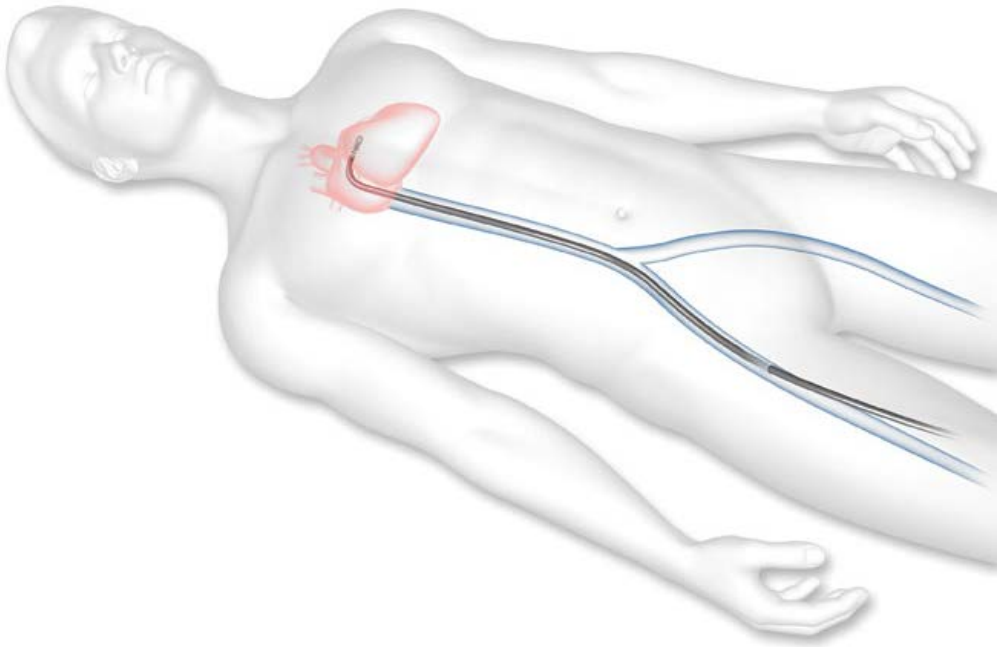
Post-procedure Considerations

Post-Procedure Recovery Instructions

- Patient might have to be intubated, procedure performed under general anesthesia
- Patient may have Femoral Arterial and/or Venous access
- Patient will have had 24 French sheath in Femoral Vein during procedure
- Patient will have foley catheter in place
- Patient will have had TEE probe in place for extended period of time
- Antibiotic Therapy
  - Administer prophylactic antibiotics per institutional guidelines for implanted devices
- Groin Access
  - Per institutional guidelines and similar to other catheterization procedures
- Anticoagulation Therapy
  - Short-term anticoagulation therapy may be necessary after cardiac valve repair with the MitraClip device. Prescribe anticoagulation and other medical therapies per institutional guidelines.



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Clinical Experience

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Worldwide Clinical Experience

- Over 13 000 patients have been treated with the MitraClip Therapy worldwide.[1]
  - 75% are considered high risk* for mitral valve surgery
  - 67% have functional mitral regurgitation (MR)

- The use of the MitraClip is supported by a rigorous clinical trial program.[1]
  - 50% are considered high risk* for mitral valve surgery

1. Data as of March 2014

*Determination of high surgical risk based on: logistic EuroSCORE ≥ 20%, or STS calculated mortality ≥ 12%, or pre-specified high surgical risk co-morbidities specified in EVEREST II High Risk Study protocol.

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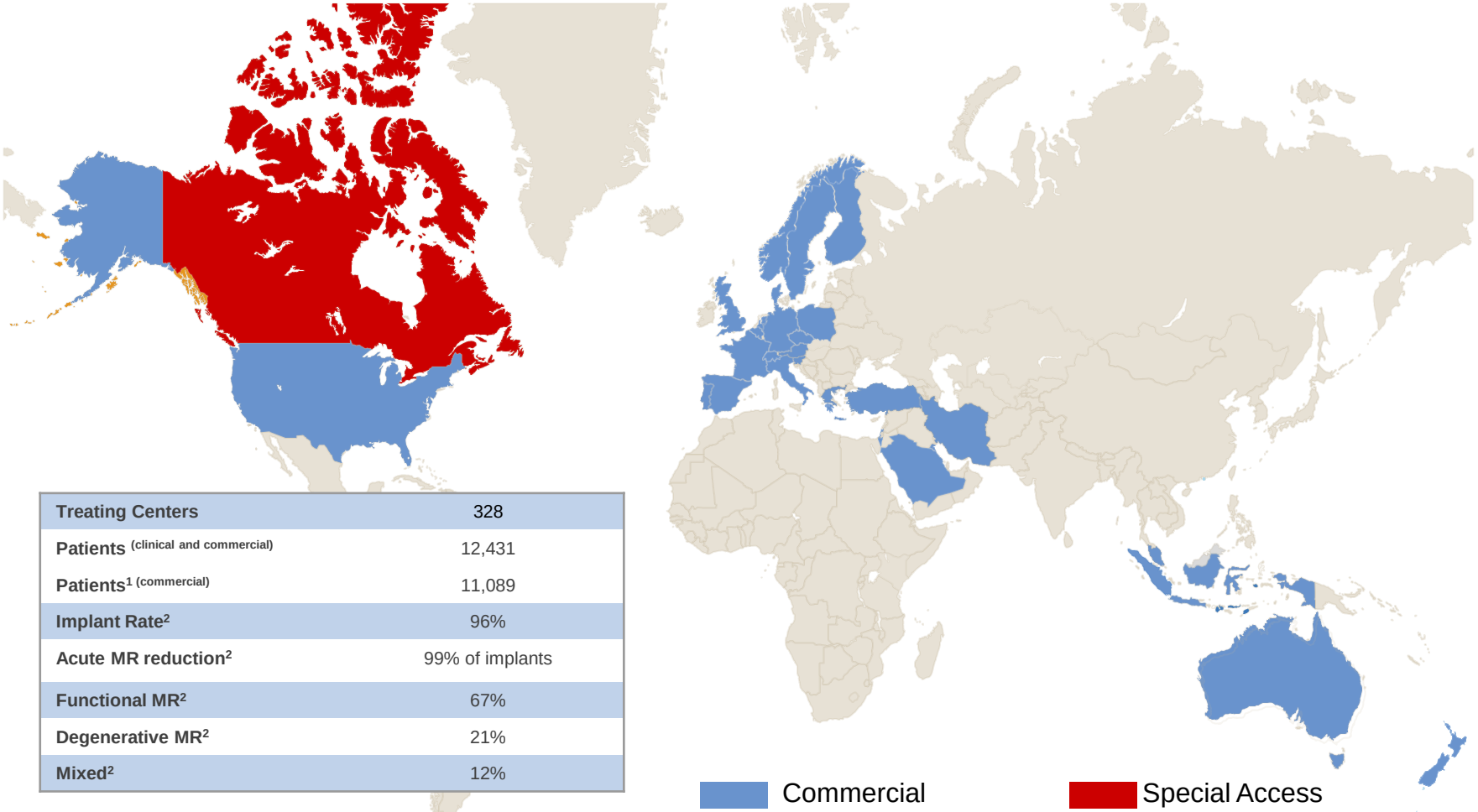
MitraClip Therapy
Current Global Adoption



Treating Centers	328
Patients (clinical and commercial)	12,431
Patients[1] (commercial)	11,089
Implant Rate[2]	96%
Acute MR reduction[2]	99% of implants
Functional MR[2]	67%
Degenerative MR[2]	21%
Mixed[2]	12%

1. First-time procedures only. Includes commercial patients, ACCESS I and ACCESS II patients.
2. Successful implants only.

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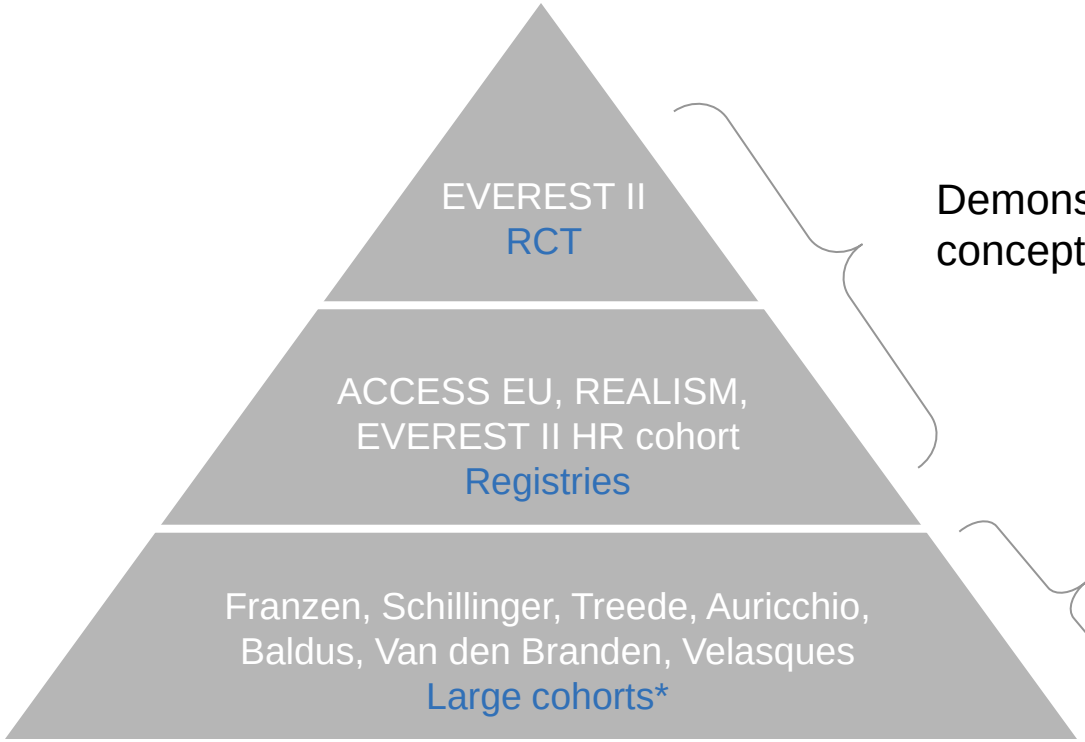
Growing body of clinical evidence



Demonstrated overall concept and clinical safety

Addressed specific patient populations

Randomized trials versus medical therapy

*large cohort is defined as >50 patients

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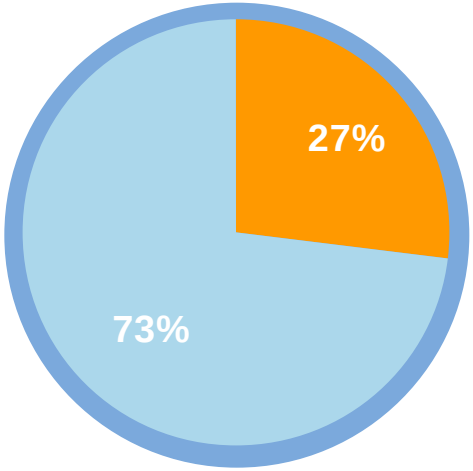
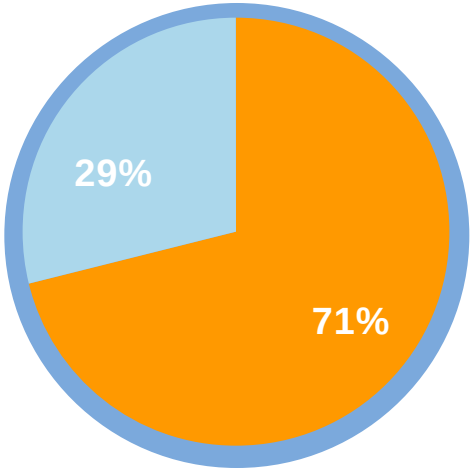
MitraClip Therapy
Broad Spectrum of Experience

EVEREST II
(Randomized Controlled Trial)



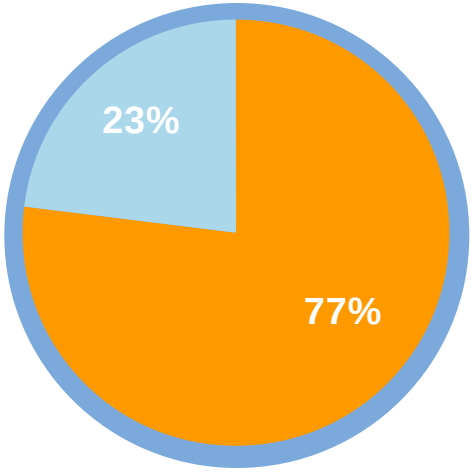
- 178 patients
- Device time – 156 minutes
- Implant rate – 89%

EVEREST
(High Risk Cohort^)



- 211 patients
- Device time – 128 minutes
- Implant rate – 95%

ACCESS EU
(Europe)



- 567 patients
- Device time – 118 minutes
- Implant rate – 99.6%

= DMR = FMR

^ Enrolled by February 28, 2010
Data on file Abbott Vascular, April 12, 2011
Schillinger, W. ESC 2012, ACCESS 1-year results

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Study Design

RESHAPE HF TRIAL

Prospective, randomized, parallel-controlled, multi-center clinical evaluation of the MitraClip device plus optimal standard of care therapy (Device group) compared to optimal standard of care therapy alone (Control group).

- Randomized 1:1 between MitraClip + standard of care therapy or standard of care therapy alone
- Approximately 800 patients to be enrolled in up to 75 sites across Europe
- Trial device: MitraClip system used within the IFU specifications
- 24mo follow up for all patients

Patient profile

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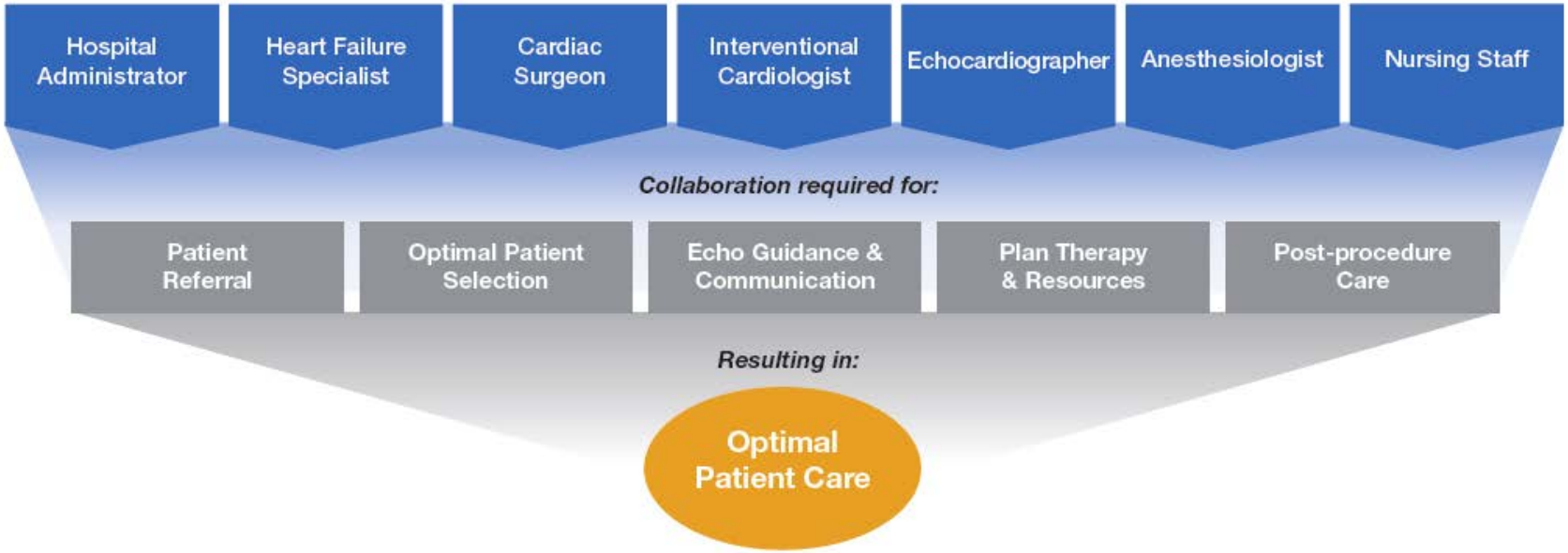
Multidisciplinary Team

A multidisciplinary approach and collaboration across specialties is critical to MitraClip Therapy success.



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MitraClip in Specific Patient Populations

Patient groups in which significant clinical benefits have been reported:

- Degenerative MR, declined for surgery[1]
- Severe LV dysfunction refractory to medical therapy[2]
- Severe Heart Failure, despite optimal medical therapy[3]
- CRT non-responders[4]
- Bivalvular Disease: Severe Aortic Stenosis and Mitral Regurgitation[5]

The following parameters should be taken into consideration by the Heart Team[6]:

- Moderate to severe or severe MR (Functional or Degenerative)
- Echocardiographic criteria for eligibility
- Level of surgical risk
- Greater than one year life expectancy

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The data is not from prospective studies and study results should be interpreted with caution

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Percutaneous edge-to-edge repair as treatment option for high risk surgical patients in 2012 ESC Guidelines on Acute and Chronic Heart Failure

ESC GUIDELINES

ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012

The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC

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Councils: Cardiovascular Imaging, Cardiovascular Nursing and Allied Professions, Cardiology Practice, Cardiovascular Primary Care.

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…"In patients with an indication for valve repair but judged inoperable or at unacceptably high surgical risk, percutaneous edge-to-edge repair may be considered in order to improve symptoms."…..

although its effect on survival is unknown. In this situation, the decision to operate should take account of response to medical therapy, co-morbidity, and the likelihood that the valve can be repaired (rather than replaced).

Secondary mitral regurgitation

This occurs because LV enlargement and remodelling lead to reduced leaflet closing. Effective medical therapy leading to reverse remodelling of the LV may reduce functional mitral regurgitation, and every effort should be made to optimize medical treatment in these patients.

Ischaemic mitral regurgitation is a particular type of secondary mitral regurgitation that may be more suitable for surgical repair. As it is often a dynamic condition, stress testing is important in its evaluation. An exercise-induced increase of effective regurgitant orifice ($\geq$13 mm^2) is associated with a worse prognosis. Combined valve and coronary surgery should be considered in symptomatic patients with LV systolic dysfunction, coronary arteries suitable for revascularization, and evidence of viability. Predictors of late failure of valve repair include large interpapillary muscle distance, severe posterior mitral leaflet tethering, and marked LV dilatation (LV end-diastolic diameter >65 mm). In these patients, mitral valve replacement, rather than repair, may be advisable. In the presence of AF, atrial ablation and left atrial appendage closure may be considered at the time of mitral valve surgery.

The role of isolated mitral valve surgery in patients with severe functional mitral regurgitation and severe LV systolic dysfunction who cannot be revascularized or have non-ischaemic cardiomyopathy is questionable, and in most patients conventional medical and device therapy are preferred. In selected cases, repair may be considered in order to avoid or postpone transplantation.

In patients with an indication for valve repair but judged inoperable or at unacceptably high surgical risk, percutaneous edge-to-edge repair may be considered in order to improve symptoms.[250]

13.4 Heart transplantation

Heart transplantation is an accepted treatment for end-stage HF.[251,252] Although controlled trials have never been conducted, there is consensus that transplantation—provided that proper selection criteria are applied—significantly increases survival, exercise capacity, quality of life, and return to work compared with conventional treatment.

Apart from the shortage of donor hearts, the main challenges in transplantation are the consequences of the limited effectiveness and complications of immunosuppressive therapy in the long term (i.e. antibody-mediated rejection, infection, hypertension, renal failure, malignancy, and coronary artery vasculopathy). The indications for and contraindications to heart transplantation are summarized in *Table 23*.

13.5 Mechanical circulatory support

MCS is an umbrella term describing a number of different technologies used to provide both short- and longer term assistance in patients with either chronic HF or AHF. A variety of terms have been used to describe the use of these technologies (*Table 24*).[211,253] The most experience is with MCS in end-stage

Table 23 Heart transplantation: indications and contraindications

Patients to consider	End-stage heart failure with severe symptoms, a poor prognosis, and no remaining alternative treatment options
	Motivated, well informed, and emotionally stable
	Capable of complying with the intensive treatment required post-operatively
Contraindications	Active infection
	Severe peripheral arterial or cerebrovascular disease
	Current alcohol or drug abuse
	Treated cancer in previous 5 years
	Unhealed peptic ulcer
	Recent thrombo-embolism
	Significant renal failure (e.g. creatinine clearance <50 mL/min)
	Significant liver disease
	Systemic disease with multiorgan involvement
	Other serious co-morbidity with poor prognosis
	Emotional instability or untreated mental illness
	High, fixed pulmonary vascular resistance (>4–5 Wood Units and mean transpulmonary gradient >15 mmHg)

HF = heart failure.

Table 24 Terms describing various uses of mechanical circulatory support (MCS)

Bridge to decision (BTD):	Use of MCS in patients with drug-refractory acute circulatory collapse and at immediate risk of death to sustain life until a full clinical evaluation can be completed and additional therapeutic options can be evaluated.
Bridge to candidacy (BTC):	Use of MCS to improve end-organ function in order to make an ineligible patient eligible for transplantation.
Bridge to transplantation (BTT):	Use of MCS to keep a patient at high risk of death before transplantation alive until a donor organ becomes available.
Bridge to recovery (BTR):	Use of MCS to keep patient alive until intrinsic cardiac function recovers sufficiently to remove MCS.
Destination therapy (DT):	Long-term use of MCS as an alternative to transplantation in patients with end-stage heart failure ineligible for transplantation.

MCS = mechanical circulatory support.

Source: J. Murray et al. - ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012 -European Heart Journal (2012) 33, 1787–1847

Abbott Vascular

Percutaneous edge-to-edge repair in ESC/EACTS 2012 Guidelines on the management of valvular heart disease

European Heart Journal
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ESC/EACTS GUIDELINES

Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

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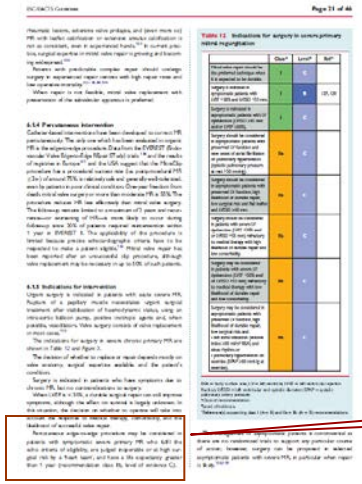

Indication for primary MR

"Percutaneous edge-to-edge procedure may be considered in patients with symptomatic severe primary MR who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a 'heart team', and have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C)."

Indication for secondary MR

"The percutaneous mitral clip procedure may be considered in patients with symptomatic severe secondary MR despite optimal medical therapy (including CRT if indicated), who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a team of cardiologists and cardiac surgeons, and who have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C)."

Source: A.Vahanian et al. - Guidelines on the management of valvular heart disease (version 2012) - European Heart Journal (2012) 33, 2451–2496

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MitraClip “beating porcine model” (for demonstration only)

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Porcine beating heart model / MitraClip procedure

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