

# MITRACLIP™

## 16+ YEARS OF MINIMALLY INVASIVE TECH AND INNOVATION

Abbott's MitraClip™ system is the world's first-of-its-kind transcatheter mitral valve repair (TMVr) therapy that provides select people living with a leaky mitral valve a viable treatment option. Explore 16+ years of landmark innovations that have helped more than 100,000 people in 75+ countries.<sup>1</sup>



### 2003

#### FIRST PATIENT

Octalina Mendoza from Caracas, Venezuela became the first patient to receive the MitraClip device in the EVEREST clinical trial<sup>2</sup> to treat her mitral regurgitation (MR) at age 55. MitraClip reduced her MR without open-heart surgery.

### 2009

#### ACQUISITION OF EVALVE INC.

Abbott acquired Evalve Inc. to expand its reach in the emerging market of minimally invasive heart repair.

### 2013

#### FDA APPROVAL

The U.S. Food and Drug Administration (FDA) approved MitraClip,<sup>1</sup> making the tech commercially available in the U.S. for treatment of primary MR.<sup>7</sup>

#### APRIL

##### REAL-WORLD STUDY

Abbott initiated the global EXPAND study to evaluate outcomes associated with MitraClip in a real-world setting.<sup>5</sup>

### 2019

#### MARCH

##### SECONDARY MR APPROVAL

Backed by COAPT™ trial data, the FDA approved MitraClip for treatment of secondary MR.<sup>7</sup>

#### SEPTEMBER

##### KEY DATA PRESENTED

Data presented at an interventional cardiovascular medicine meeting demonstrated that MitraClip was safe, reduced hospitalization rates, and improved survival and quality of life, compared to guideline-directed medical therapy alone over a three-year follow-up period.<sup>9,10</sup> Also, data published in *Circulation* showed that TMVr using MitraClip in heart failure patients with secondary MR<sup>7</sup> was intermediate-high economic value.<sup>11</sup>

#### JUNE

##### ASIA-PACIFIC MILESTONES

MitraClip received approval for first-ever commercial use in China and, separately, the fourth generation MitraClip received approval in Japan.<sup>1</sup>

##### HIGHEST MR REDUCTION TO DATE

Data presented at a virtual interventional cardiology event supported the positive, safe, and effective performance of MitraClip, and was backed by the highest reported MR reduction to date.<sup>13</sup>

### 1990s

#### THE EARLY YEARS

A team of cardiologists and engineers at medical device company Evalve Inc. initiated the development of a catheter-based technology to repair the heart's mitral valve.

### 2008

#### CE MARK

Supported by positive results in the EVEREST trial,<sup>2</sup> MitraClip is approved for use in the EU and other countries that recognize CE Mark, becoming the first commercially available device to provide a non-surgical treatment option for patients with MR.<sup>1</sup>

### 2012

#### COAPT™ TRIAL

Abbott began a seven-year landmark study investigating MitraClip for treatment of secondary MR,<sup>1</sup> called the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT™) trial.<sup>3</sup>

### 2018

#### MARCH

##### REIMBURSEMENT IN JAPAN

Japan's Ministry of Health Labour and Welfare granted national reimbursement for MitraClip to treat people with primary MR.<sup>1</sup>

#### SEPTEMBER

##### LANDMARK DATA PUBLISHED

COAPT™ trial findings published in the *New England Journal of Medicine* showed that patients who received MitraClip lived longer, were hospitalized less frequently for heart failure, and had a better quality of life compared to patients who received only medical therapy.<sup>6</sup>

#### JULY

##### MITRACLIP G4

The FDA approved the fourth-generation of MitraClip (MitraClip G4) to treat MR<sup>7</sup> in the U.S. with an expanded range of clip sizes, an alternative leaflet grasping feature and facilitation of procedure assessment in real-time that can be tailored to a patient's unique mitral valve anatomy.<sup>8</sup>

### 2020

#### JANUARY

##### 100,000 PATIENTS

Abbott proudly marked the 100,000th MR patient treated with MitraClip worldwide.<sup>1</sup>

##### REPAIR MR: NEW CLINICAL TRIAL

Abbott began a new trial to evaluate the impact of MitraClip for moderate-surgical-risk patients with severe primary MR<sup>7</sup> whose treatment options are often limited to open-heart surgery.<sup>12</sup>

#### SEPTEMBER

##### MITRACLIP G4 IN EUROPE

The fourth-generation of MitraClip was approved for use in the EU and other countries that recognize CE Mark as a treatment option for MR.<sup>1</sup>

##### EXPANDING ACCESS

The U.S. Centers for Medicare & Medicaid Services expanded coverage for TMVr to include patients with secondary MR.<sup>7</sup>

## ABBOTT'S COMMITMENT

Abbott creates life-changing technologies to help people with serious heart abnormalities, such as damaged heart valves or other heart defects. As a global healthcare leader that helps people live more fully at all stages of life, we have the most comprehensive structural heart portfolio in the industry. Through its cardiac devices and research, Abbott is addressing the critical unmet needs of people by providing life-saving therapies and offering a renewed chance at life.

For U.S. important safety information on MitraClip™ visit <http://abbott/MitraClipG4ISI>.

<sup>1</sup> PRIMARY MR is usually due to an abnormality of the mitral valve, which can be related to age, a birth defect or underlying heart disease. SECONDARY MR occurs in patients with coronary disease or heart failure.

#### REFERENCES

1. Data and documentation on file at Abbott. 2020.
2. ClinicalTrials.gov. Feasibility Study of a Percutaneous Mitral Valve Repair System. (EVEREST(I)). 2003. <https://www.clinicaltrials.gov/ct2/show/NCT00209339>.
3. Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation (The COAPT Trial) (COAPT). 2012. <https://clinicaltrials.gov/ct2/show/NCT01626079>.
4. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Approval of MitraClip Clip Delivery System (Primary Mitral Regurgitation). Abbott. October 2013. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100009>.
5. ClinicalTrials.gov. The MitraClip@ EXPAND Study of the Next Generation of MitraClip@ Devices. 2018. <https://clinicaltrials.gov/ct2/show/NCT03502811>.
6. G.W. Stone, J. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, et al., Transcatheter Mitral-Valve Repair in Patients with Heart Failure, *New England Journal of Medicine*. 379 (2018) 2307-2318. doi:10.1056/nejmoal806640.
7. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Approval of MitraClip Clip Delivery System (Secondary Mitral Regurgitation). Abbott. March 2019. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100009S028>.
8. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Approval of Expanded Indication for MitraClip G4. Abbott. July 2019. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100009S029>.
9. Sannino A, Smith II RL, Schiattarella GG, et al. Survival and cardiovascular outcomes of patients with secondary mitral regurgitation: a meta-analysis of 53 studies. *JAMA Cardiology* 2017; 2:1190-39.
10. Goliassch G, Bartko PE, Pavo N, et al. Refining the prognosis impact of functional mitral regurgitation in chronic heart failure. *Eur Heart J* 2018;39:39-46.
11. S.J. Baron, K. Wang, S.V. Arnold, E.A. Magnuson, B. Whisenant, A. Brieke, et al., Cost-Effectiveness of Transcatheter Mitral Valve Repair Versus Medical Therapy in Patients With Heart Failure and Secondary Mitral Regurgitation, *Circulation*. 140 (2019) 1881-1891. doi:10.1161/circulationaha.119.043275.
12. ClinicalTrials.gov. MitraClip REPAIR MR Study. 2020. <https://clinicaltrials.gov/ct2/show/NCT04198870>.
13. Rottbauer W. D. Contemporary Clinical Outcomes with MitraClip™ (NTR/XTR) System: Core-lab Echo Results from +1000 Patient the Global EXPAND Study. Data presented at PCR 2020.