HOW DOES THE TRIAL WORK?

- Approximately 800 trial participants at up to 80 medical centers located in the U.S., Canada, Japan, and Europe will participate in this trial.
- There are three arms or pathways to take part in this trial. Based on your heart's anatomy, a team of heart doctors will determine which arm of the trial is best for you.

1. Some trial participants will be randomly selected to receive either the Tendyne implant (the device being studied in this trial) or mitral valve repair therapy called MitraClip.
2. Those patients whose mitral valve is too hardened with calcification will receive the Tendyne implant.
3. Patients who don't have severe mitral calcification and also don't meet MitraClip indications will receive the Tendyne valve.

WHO CAN PARTICIPATE IN THE SUMMIT TRIAL?

Both men and women over the age of 18 can participate.

You may qualify if:

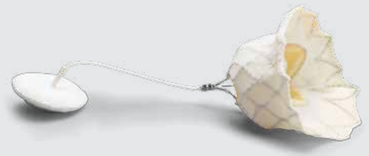
- You have been diagnosed with moderate to severe or severe mitral regurgitation, or severe mitral annular calcification, and are experiencing symptoms of heart failure.
- It has been determined by your heart team that transcatheter mitral valve replacement or repair is appropriate for you.

If you think you qualify and are interested in participating in this trial, please see the information on the back page of this brochure to contact your nearest participating site.

WHERE CAN I LEARN MORE ABOUT THE SUMMIT TRIAL?

Ask your doctor or contact the trial site below for more information about the trial goals, risks, and requirements for participation.

For more information on the SUMMIT Trial and a full list of trial sites, visit **www.clinicaltrials.gov** (keyword "NCT03433274").



THE TRIAL SITE IN YOUR AREA IS:

CAUTION: INVESTIGATIONAL DEVICE. LIMITED BY FEDERAL (U.S.) LAW TO INVESTIGATIONAL USE ONLY.

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Abbott 3200 Lakeside Drive, Santa Clara, CA 95054.

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SUMMIT TENDYNE™ TRIAL

PATIENT INFORMATION

INTRODUCING THE SUMMIT TRIAL

Clinical Trial to Evaluate the **S**afety and Effectiveness of **U**sing the Tendyne **M**itral Valve System for the Treatment of Symptomatic **Mit**ral Regurgitation

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WHAT IS MITRAL REGURGITATION?

Mitral regurgitation (MR) is a condition in which the heart's mitral valve doesn't close properly. When this happens, some blood flows backward through the valve. The heart must then work harder to push blood through the body, which can cause fatigue, shortness of breath, and worsening heart failure.

One type of MR is called Primary MR, also called degenerative MR (DMR). It can be related to age, a birth defect, or underlying heart disease. The other type of MR is called Secondary MR, also called functional MR (FMR). FMR is caused by a heart attack or other underlying heart diseases.

NORMAL

DMR

FMR

HOW IS MR TREATED?

There are two main treatments for mitral regurgitation: medical therapy and mitral valve open-heart surgery. There is also a transcatheter mitral valve repair option for select MR patients.

Medical therapy consists of prescription medicine taken to prevent symptoms associated with mitral regurgitation. Medicines include beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, and diuretics.

Surgery to repair or replace the mitral valve may be an option for patients with mitral regurgitation. While surgery is an effective treatment for some cases of mitral regurgitation, it is a major procedure with associated risks. Patients who are elderly, have advanced heart failure, or have other serious medical conditions may not be appropriate for surgery.

WHAT IS THE SUMMIT TRIAL?

The purpose of this trial is to evaluate a new investigational device called the **Tendyne™ Mitral Valve System**. The Tendyne Mitral Valve System is designed for the treatment of a diseased, damaged or malfunctioning mitral valve.

This trial will collect information on how safe and effective this device is in treating a leaking mitral valve as compared to MitraClip™, a transcatheter mitral valve repair system approved by the U.S. Food and Drug Administration.

A qualified team of physicians will monitor trial participants included in the SUMMIT Trial.

Trial participants will play an important role in helping physicians evaluate transcatheter mitral valve replacement as an option for patients with mitral regurgitation.

WHAT IS THE TENDYNE PROCEDURE?

The Tendyne procedure is an alternative to open-heart surgery to replace your mitral valve with a prosthetic valve. While under general anesthesia, a surgeon will make an incision in the left side of your chest. The surgeon will then guide the Tendyne Mitral Valve System, using a catheter to deliver the Tendyne replacement valve into your heart, without the need for heart-lung bypass, where the heart is stopped.

Ultrasound images of the heart are used to ensure the valve is correctly placed. A cord, (called the "valve tether") then connects the valve to a pad outside the bottom of the heart, which secures the valve in place.

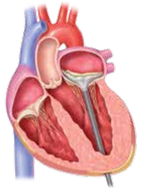
There are also risks with the Tendyne replacement valve procedure. Talk to your Doctor to determine if the Tendyne replacement valve procedure is right for you.

Potential benefits of the use of the Tendyne device include, but may not be limited to, the following:

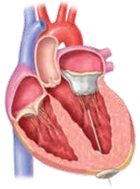
- Reduction in hospitalization rate due to complete elimination of MR
- Improvements in symptoms and quality of life
- Reduced mortality
- Reduced rates of recurrent MR
- Mitral valve replacement with avoidance of risks associated with cardiopulmonary bypass (CPB)

Refer to the informed consent form for a listing of potential adverse events associated with participation in the SUMMIT trial.

1 Access to the heart is gained through a small incision in the chest between the ribs.



2 The Tendyne valve is placed in the heart through the catheter.



3 The tether is secured to a pad at the bottom of the heart. The valve, tether and pad become a permanent implant, and may reduce mitral regugitation and improve blood flow.

WHAT IS INVOLVED IF I CHOOSE TO PARTICIPATE?

You will be screened to make sure you are a good candidate for treatment.

Your screening may include:

- An in-person visit with doctors: an interventional cardiologist and a cardiothoracic surgeon
- An echocardiogram (Echo) and Computed Tomography Angiogram (CTA, also called a cardiac CT), to determine if you have the appropriate valve anatomy
- A review of your medical history
- Blood tests

You can still see your personal cardiologist for regular check-ups and care. In addition, you will be monitored by regular follow-up exams at the medical center conducting the trial. Some travel expenses associated with these follow-up exams may be reimbursed.

WHAT HAPPENS IF I PASS THE SCREENING PROCESS?

1. You will be assessed in-person at the treatment center and then registered in the study.
2. You will receive your designated treatment.
3. You will also have follow-up exams at the following intervals:

**3 month visit is via phone*