SUMMIT
TENDYNE™ TRIAL

PATIENT INFORMATION GUIDE

A Clinical Trial for People with Mitral Regurgitation

This brochure describes a clinical trial evaluating the use of transcatheter mitral valve replacement (TMVR) for the treatment of mitral regurgitation and patients with severe mitral annular calcification. Please use this information, and consult your doctor to determine if participation in this clinical trial may be right for you.

The SUMMIT Clinical Trial

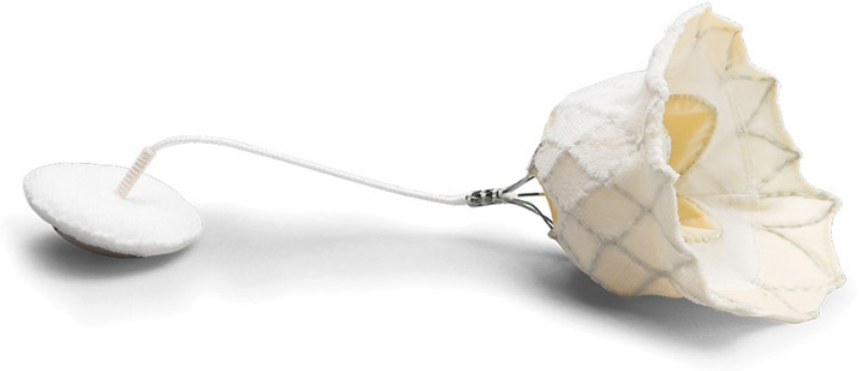
The purpose of the SUMMIT clinical trial is to evaluate the Tendyne™ Mitral Valve System for the treatment of patients with symptomatic, moderate-to-severe or severe mitral regurgitation or for patients with symptomatic mitral valve disease due to severe mitral annular calcification.

The Tendyne™ device is a minimally invasive alternative to open-heart surgery that replaces the patient's defective mitral valve without an incision to the patient's sternum. Importantly, the patient is not required to go on the heart-lung machine during a Tendyne™ procedure.

The SUMMIT Clinical Trial will help a team of medical experts evaluate the Tendyne™ device as a treatment for patients with severe mitral regurgitation who experience symptoms. Patients with mitral regurgitation may experience symptoms including shortness of breath, fatigue, chest pain or dizziness.

Patients will play an important role in helping doctors evaluate the Tendyne™ device as an option for patients with leaking mitral valves who are not candidates for surgery.

The doctors and hospitals that participate in the SUMMIT Clinical Trial specialize in mitral valve therapy.



The Tendyne™ Mitral Valve System

How Does the SUMMIT Trial Work?

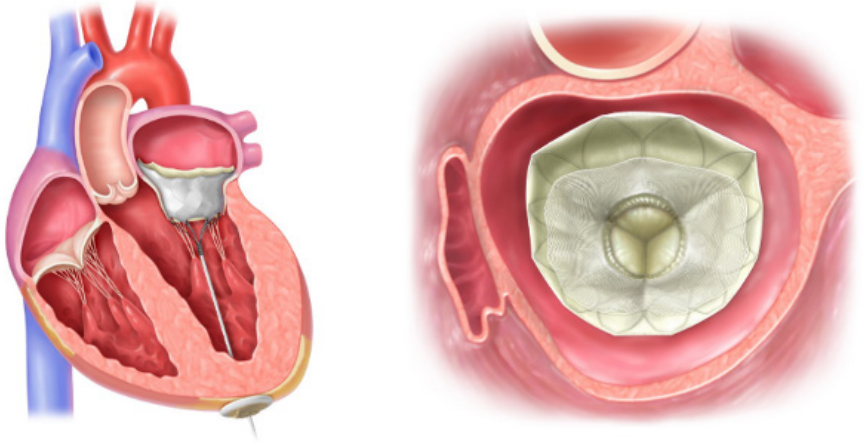
Approximately 800 patients will enroll in the SUMMIT Clinical Trial at up to 80 clinical sites in the United States, Canada, and Europe.

There are three ways that patients can participate in the SUMMIT Clinical Trial.

1. Patients may be will be randomly selected to receive either the minimally invasive Tendyne™ device, which is a new investigational treatment that completely replaces the mitral valve, or a MitraClip™ implant, which is an approved and minimally invasive mitral valve repair therapy that has been implanted in over 100,000 patients worldwide.

2. Patients with mitral valves that are too hardened due to calcification will receive the Tendyne™ procedure.

3. Patients who do not have severe mitral calcification and do not meet MitraClip™ indications will receive the Tendyne™ device.



The Tendyne™ Mitral Valve System Implanted

Are You a Candidate?

If you agree to participate in the SUMMIT Clinical Trial, you will be screened (evaluated). Your screening will include a physicial exam, an echocardiogram (Echo), blood tests and a review of your medical history. The results of these tests will determine if you are able to participate in the study. You may be eligible for this study if:

- You have been diagnosed with mitral regurgitation.
- You are willing and able to receive the clinical trial procedures and participate in follow-up monitoring.

Your research coordinator will discuss with you the full list of criteria for participating in the clinical trial.

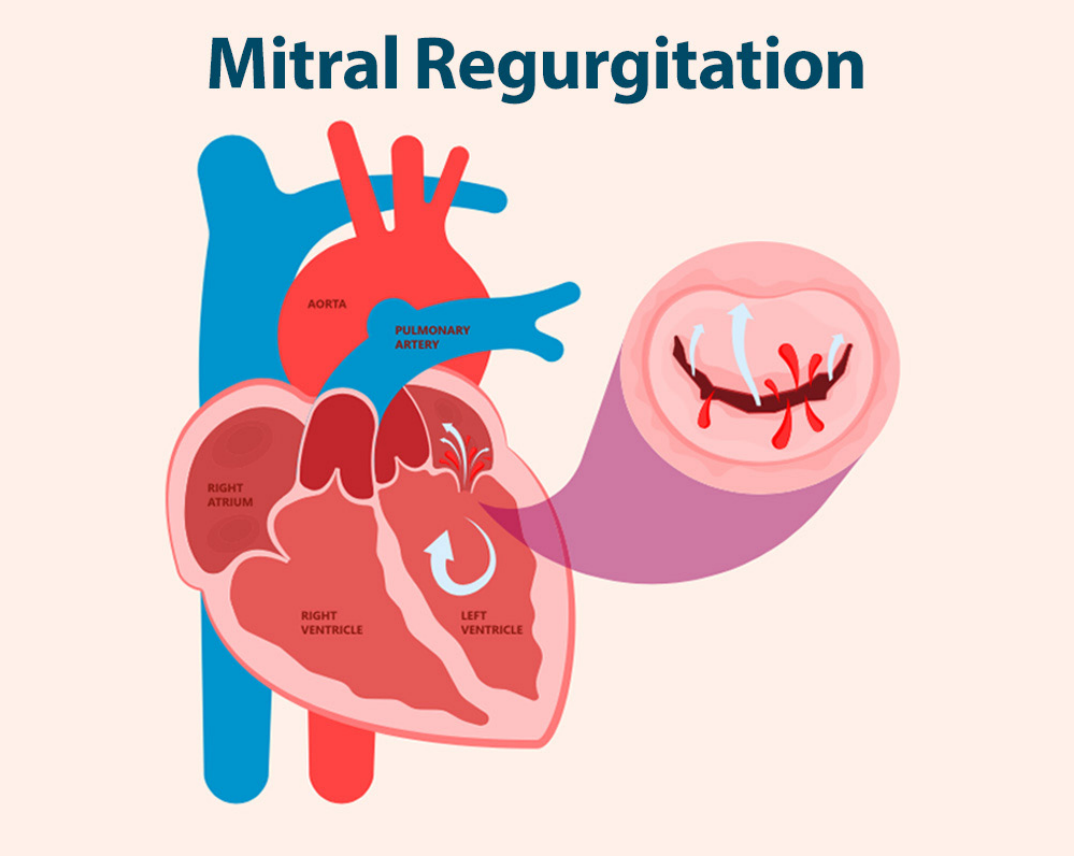
About Mitral Regurgitation

The mitral valve is one of four valves in your heart that opens to let blood flow forward and closes to prevent the backflow of blood.

Mitral regurgitation happens when blood leaks backward across the valve because your mitral valve does not close tightly.

Mitral regurgitation may cause symptoms including shortness of breath, chest pain, heart palpitations and fatigue. Patients with mitral regurgitation may also be asymptomatic (without symptoms).

Over time, mitral regurgitation can cause the heart to enlarge, weaken, and ultimately result in heart failure and death.



Potential Benefits Of The SUMMIT Clinical Trial

You may or may not experience any direct benefit from this clinical trial.

The potential benefit from undergoing screening tests and procedures is that you will have undergone a thorough examination of your medical condition and you may have a better understanding of available therapies.

Potential benefits of the clinical trial procedures may include improvement in the symptoms related to your mitral regurgitation. Replacing or repairing your mitral valve may provide both short- and long-term relief of your symptoms, improved mitral valve function, and improved cardiac function that could potentially increase your life expectancy and improve your quality of life.

Potential benefits of the Tendyne™ device include a less invasive procedure, shorter procedure time, less anesthesia, shorter hospital stays, and faster recovery compared to heart surgery for mitral regurgitation.

It is possible that you will receive no direct benefit from this clinical trial, but future patients may benefit from your participation.

Potential Risks Of The Clinical Trial

Risks of having your mitral valve replaced or repaired include death, stroke, and major bleeding. As the clinical trial progresses, you will be informed of new trial results that may affect your willingness to remain in the clinical trial. Your doctor and/or research team will speak to you about these risks and other potential complications and answer any questions you may have.

Questions To Ask Your Doctor

To help you learn more about this clinical trial, here are some questions you may want to ask your doctor:

- Am I a candidate for the SUMMIT Clinical Trial?
- What tests do I need?
- What are the possible risks, side effects, and benefits of participating in this clinical trial?
- How long will I be in the hospital?
- What will the recovery be like for the therapies in the SUMMIT Clinical Trial compared to open heart surgery?
- What restrictions and/or medications, if any, would I be on after the procedure?
- How frequently will I need to have follow-up visits?
- How long will the study last?

Where Can I Learn More About The SUMMIT Clinical Trial?

For more information on the SUMMIT Clinical Trial and to see a full list of clinical trial sites you can contact, please visit ClinicalTrials.gov.

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