EMPOWER TRIAL

A Minimally Invasive Investigational Treatment Opportunity for People with Heart Failure and Mild-to-Severe Functional Mitral Regurgitation (FMR)

A New Opportunity for Earlier Intervention

If your doctor has diagnosed your condition as heart failure with FMR, you may be eligible to participate in the **EMPOWER Trial** with the investigational the *Carillon Mitral Contour System*®—a new therapy designed to help people with any FMR. It is designed to address the underlying cause of FMR and the progression of your heart failure with the potential to improve your survival and quality of life.

The Challenge of Living with Heart Failure and Functional Mitral Regurgitation (FMR)

As someone with heart failure related to mitral valve regurgitation, you may worry about how this disease can progress and affect your quality of life. Simple daily activities like preparing meals, visiting with friends, or even moving from room to room can be difficult. You're not alone. More than 20 million people suffer from heart failure worldwide, and the number is growing rapidly.

This problem can make your heart's pumping less efficient because the left chamber of your heart becomes bigger. This might also cause the valve to leak more, which makes the pumping even weaker. This is called functional mitral regurgitation (FMR), and it can make your symptoms worse. You might experience:

- Shortness of breath or cough
- Fatigue (feeling tired and worn out)
- Abnormal sounds of the heart heard through a stethoscope
- Heart palpitations or fluttering heartbeat
- Swollen feet or ankles
- Lightheadedness

How the *Carillon Mitral Contour System* Works

The investigational *Carillon Mitral Contour System* is a minimally invasive therapy.

The permanent, investigational *Carillon*® device is placed using a non-surgical, catheter-based technique in the coronary sinus, a vein on the outside of the heart that is next to the mitral valve. During the procedure, the *Carillon* device is cinched around the mitral valve. This is designed to do two things: reduce your mitral valve regurgitation (leakage) and ultimately, reduce the size of your enlarged left ventricle. This approach is different from any other available treatment because it is intended to both reduce your FMR symptoms and improve the function of your heart over time.

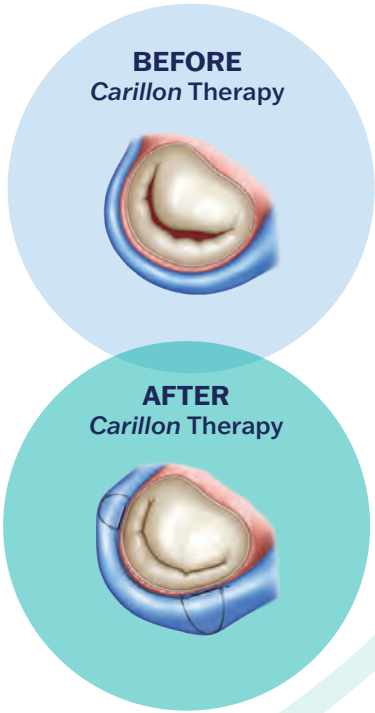
The investigational *Carillon* device has been evaluated in several safety studies and a blinded randomized, sham-controlled study that demonstrated that people treated with the *Carillon* therapy and heart failure medications may be more likely to have reduced mitral valve regurgitation and a reduction in left ventricle size than people taking medication alone. The *Carillon* therapy has been commercially available in Europe since 2012. However, it is an investigational device in the U.S. and Canada.

The procedure usually takes about an hour, and is performed in a catheterization lab.

What Other Treatment Options are Available?

People with heart failure and FMR typically have limited treatment options available. Existing options include medical management for earlier-stage patients and surgery for later-stage patients. You should discuss possible alternative treatments with your doctor prior to committing to participate in the **EMPOWER Trial**.

For more information about the **EMPOWER Trial** and the *Carillon* therapy, please scan this QR code or visit **www.cardiacdimensions.com/patients-empower-study/**



EMPOWER TRIAL

Who Can Participate in the EMPOWER Trial?

A study doctor will assess if you meet the eligibility criteria, such as:

- Have been diagnosed with heart failure and mild-to-severe FMR
- Have had symptoms of heart failure, such as difficulty walking up stairs, and require heart failure medications
- You should not have another device placed in your coronary sinus. However, if you have a CRT device with a lead in your coronary sinus, you may still be eligible for the study. Please speak with your doctor.
- Have not been hospitalized due to heart failure in the past 30 days
- Not participating in another heart failure trial
- If all of the above are generally applicable to you, you may be eligible to participate in the **EMPOWER Trial**

The EMPOWER Trial is a randomized, blinded, sham-controlled study, which means that people participating in the study will fall into one of two groups: those treated with the *Carillon* therapy, and those who do not receive the *Carillon* therapy but continue with their medications. You will not know what group you are in during the study.

If I Qualify, What Happens Next?

First, the study will be thoroughly explained to you, and you will have an opportunity to ask all your questions about the study, the therapy and follow-up requirements. When you have a good understanding of the study and are interested in taking part, you will be asked to provide consent to participate. At that point, additional assessments will be performed by your doctor and a final determination on your ability to participate will be made.

Participation in the trial still allows you to receive alternative therapies while remaining in the trial.

Clinical Follow-Up

If you provide consent to participate in this study, there will be up to 5 years of follow-up. After the procedure, you will return to see the study doctor for the follow-up visits in accordance with the study to undergo necessary assessments.

If you are in the control group, you may become eligible to receive *Carillon* therapy after your initial 24-month follow-up visit or once the study is unblinded for all participants, whichever occurs first.

Talk with your doctor to learn about the **EMPOWER Trial** and the *Carillon Mitral Contour System*, which has been designed to treat the symptoms and underlying causes of FMR.

For more information about the **EMPOWER Trial** and the *Carillon* therapy, please scan this QR code or visit **www.cardiacdimensions.com/patients-empower-study/**

Cardiac Dimensions®

5540 Lake Washington Blvd. NE | Kirkland, WA 98033
www.cardiacdimensions.com

©2026 Cardiac Dimensions. All rights reserved.

CAUTION: USA: Investigational device. Limited by Federal (or United States) law to investigational use. Canada: Investigational Device — To Be Used by Qualified Investigators Only. Cardiac Dimensions, Carillon, and Carillon Mitral Contour System are registered trademarks of Cardiac Dimensions Pty Ltd. The Carillon Mitral Contour System is CE Marked (0344) and is commercially available in Europe and other countries.
USCRB-23-033v3