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## **Functional Mitral Regurgitation (FMR) F.A.Q.**

### **1. What is Functional Mitral Regurgitation (FMR)?**

Functional Mitral Regurgitation (FMR) - also known as secondary mitral regurgitation - typically results from the dilation of the left ventricle, which is the main pumping chamber in the heart. The left ventricle increases in size as an adaptation to heart failure, but this also causes the mitral valve annulus to expand. This increase in annular dimension leads to mitral regurgitation, which is the backward flow of blood from the left ventricle into the left atrium of the heart, caused by incomplete closure of the leaflets of the mitral valve. This significantly compromises cardiac function and reduces the amount of oxygenated blood flow out of the left ventricle intended for the body and its organs.

### **2. How does FMR differ from Degenerative (primary) Mitral Regurgitation (DMR)?**

In degenerative - also known as primary Mitral Regurgitation, the valvular leakage is caused by diseased mitral valve leaflets themselves. In FMR, the mitral leaflets are normal, but the leaflets don't close properly due to a dilated mitral valve annulus.

### **3. Who is at risk of developing FMR?**

Patients who have been diagnosed with high blood pressure (hypertension), have experienced a myocardial infarction (heart attack) or have been diagnosed with heart failure are at risk for developing FMR.<sup>1</sup>

### **4. What are the symptoms of FMR and how does it impact patients' lives?**

Symptoms of FMR include shortness of breath, fatigue, weakness, and fluid build up. FMR is associated with high rates of mortality, poor quality of life and an increase in patient hospitalizations.

### **5. What is the prevalence of FMR?**

An estimated 26 million people worldwide have heart failure, most of whom also suffer from FMR.<sup>2</sup>

### **6. What are the current treatment options for FMR?**

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<sup>1</sup> Medscape. [http://www.medscape.com/viewarticle/716334\\_2](http://www.medscape.com/viewarticle/716334_2)

<sup>2</sup> Bui, AL., et al. (2011). Epidemiology and risk profile of heart failure. *Nat Rev Cardiol*, 8(1): 30-41.

Currently, there are very few therapies available for patients with FMR. The most common treatment for heart failure patients with FMR is medical management. ACE inhibitors, beta-blockers and diuretics can improve the condition of these patients, but many remain symptomatic with a prognosis that worsens as FMR progresses. Surgical repair with an annuloplasty ring has shown clinical benefits, but there is a risk of morbidity and mortality associated with surgery. Cardiac resynchronization therapy (CRT) has also been shown to occasionally reduce FMR and corresponding symptom improvement. However, it is only indicated for patients with concomitant electrical dyssynchrony, which accounts for less than a third of all heart failure patients.

## **7. How does the Carillon® Mitral Contour System® help patients with FMR?**

The **Carillon** Mitral Contour System is a minimally invasive treatment option for patients suffering from functional (secondary) mitral regurgitation (FMR). The **Carillon** system is specifically designed to treat FMR. Using a minimally invasive technique, the implant is placed in a vein outside of the heart, which lies adjacent to the mitral valve. During the procedure, this vein is used to reshape the heart valve (mitral annulus). The result is that the leaflets of the heart valve are brought closer to each other so that they can close more effectively and regurgitation (back-flow) of blood through the heart valve (mitral annulus) is reduced. Because the back-flow through the valve is reduced, more oxygen-rich blood flows forward, reducing heart failure symptoms and improving the overall function of the heart.<sup>3</sup>

Clinical data show that implanting the Carillon system is associated with significant reduction in FMR, and significant improvement in functional capacity and quality of life. Adverse events with the **Carillon** system have been limited.<sup>4</sup> The system's innovative catheter and device design allow for device re-capture and placement of another Carillon device, optimizing patient safety and device placement.

## **8. Can other devices be used with Carillon?**

The **Carillon** Mitral Contour System is compatible with other devices, which keeps all potential, future treatment options open for patients.

## **9. Does the device need to be removed or replaced after a certain length of time?**

The **Carillon** Mitral Contour device is a permanent implant and does not need to be removed once put into place. The device is designed to be incorporated into the tissue of the vein and remain there permanently.

## **10. Where can I find out more about the Carillon system?**

For more information visit <http://www.cardiacdimensions.com/PhysicianResources/index.html>

CAUTION: The Carillon Mitral Contour System has received CE Mark approval and is available for sale in the European Union.

CAUTION: The Carillon Mitral Contour System is not approved for use in the United States.

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<sup>3</sup> Siminiak, T., et al. (2012). Treatment of functional mitral regurgitation by percutaneous annuloplasty: results of the TITAN Trial. *European Journal of Heart Failure*, 14: 931–938.

<sup>4</sup> Ibid.