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The Carillon® Mitral Contour System® Fact Sheet

Product Overview:

The Carillon® Mitral Contour System® features a permanent implant developed for the treatment of heart failure patients who suffer from Functional (secondary) Mitral Regurgitation (FMR). The implant is placed in a vein outside of the heart, which lies adjacent to the mitral valve using a minimally invasive (catheter based) technique. The device consists of a distal anchor and a proximal anchor connected by a shaping ribbon and utilizes the heart's venous anatomy to reshape the mitral annulus. This approach allows for reduction of the dilated annulus, addressing a root cause of FMR. Through multiple clinical trials, Carillon has demonstrated compelling efficacy, significantly improving patients' symptoms, mitral regurgitation and quality of life.[1,2] Additional clinical trial data is currently being collected. The device is approved for use in Europe, after receiving CE Mark approval in 2011.

Features and Benefits:

Carillon has been shown in three prospective, controlled, multi-center clinical trials to be efficacious, significantly improving patients' heart failure symptoms, mitral regurgitation and quality of life.[3]

- Minimally invasive, percutaneous procedure – the device can be deployed rapidly and safely via a 9 French catheter.[4]
- Innovative catheter and device design allow for device re-capture and placement of another Carillon device, optimizing patient safety and device placement.
- All potential, adjunctive treatment options remain possible after Carillon placement (e.g., left ventricular lead, surgical mitral repair, mitral valve replacement).
- Device can be placed without general anesthesia.
- Patients do not need to be placed on long-term anticoagulation or anti-platelet therapy, unless otherwise indicated.
- Patients typically go home from the hospital the day after the procedure.
- Initial clinical data projects that the therapy will be shown to be cost effective.[5]

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[1] 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.
[2] Schofer J, et al. (2009) Percutaneous mitral annuloplasty for functional mitral regurgitation: results of the Carillon Mitral Annuloplasty Device European Union Study. *Circulation*. 120: 326-333.
[3] Siminiak, T., et al. (2012).
[4] Ibid.
[5] Borisenko, O., et.al. (2015). Cost-utility analysis of percutaneous mitral valve repair in inoperable patients with functional mitral regurgitation in German settings. *BMC Cardiovascular Disorders*. 15:43.

How It Works:

- With this minimally invasive procedure, a small catheter is introduced into the heart through a vein in the right side of the neck (jugular vein).
- The catheter is guided using standard interventional techniques to a vein that lies adjacent to the mitral valve.
- Carillon is placed, secured and released in a targeted location.
- During the procedure, this vein is used to reshape the heart valve (mitral annulus), so that the leaflets of the heart valve are brought closer to each other and can close more effectively.
- The result is a reduction in regurgitant (back-flow) volume through the mitral valve.
- 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.[6]

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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[6] Siminiak, T., et al. (2012).