



Carillon

Mitral Contour System[®]

Your First-line Interventional Therapy
for Functional Mitral Regurgitation

Reshaping the Course of Heart Failure™

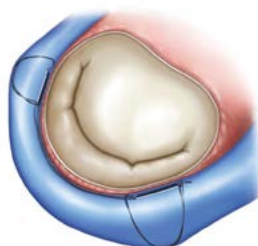
The Carillon Mitral Contour System® is a right heart transcatheter mitral valve repair (TMVr) device designed to treat the main cause of functional mitral regurgitation (MR) in patients with MR grades 2+ to 4+.

MR in the context of heart failure is strongly associated with adverse patient outcomes,¹ including one-year mortality rates up to 27% if left untreated.²

Designed to reshape the anatomy and function of the mitral apparatus from the coronary sinus, the Carillon® System reduces regurgitant volume and induces favorable left ventricular remodeling³⁻⁵ without compromising the valve or future treatment options.^{6,7}



Using familiar catheter techniques, the device can be recaptured and retrieved prior to release.



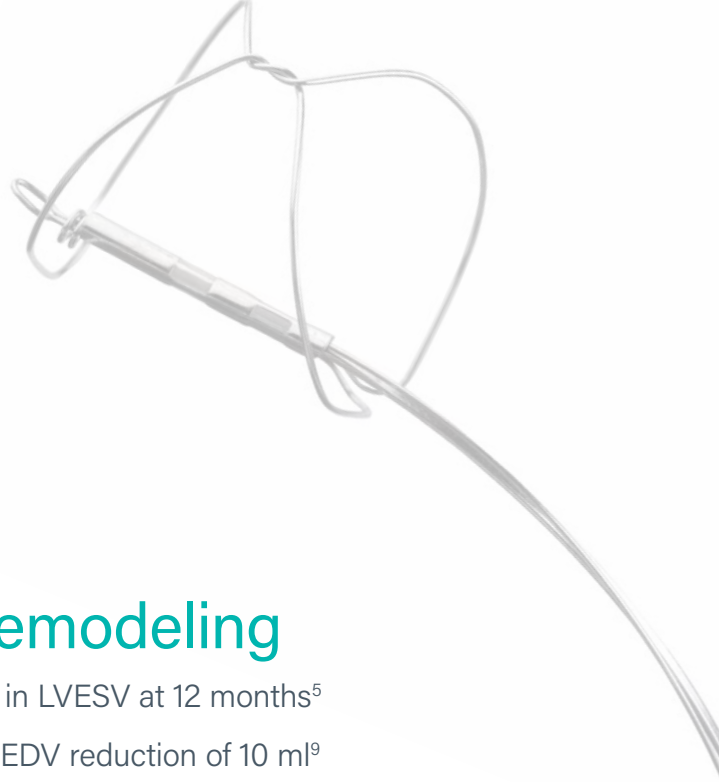
Distal and proximal anchors, connected by a shaping ribbon, utilize the heart's venous anatomy to cinch the mitral apparatus.

“

I don't have breathing
problems anymore.
I can do everything again.

→ **Gundula G.**
Carillon Patient





Significant favorable LV remodeling

- 10.4 ml reduction in LVEDV and 6.2 ml reduction in LVESV at 12 months⁵
- Significantly favorable effect on mortality with LVEDV reduction of 10 ml⁹

Improvement in MR and functional capacity

- 83% of patients realize an acute benefit⁸
- 32 m improvement in 6MWD at 12 months⁵

Broad clinical applicability

- Proven in patients with MR grade 2+ and greater⁵
- Designed to preserve future treatment options

Easy to use with a short learning curve

- No transseptal puncture, reducing the risk of cardiovascular complications
- Up to 60% average reduction in device procedure time when compared to other TMVr options^{3-5,10,11}

Clinically proven safety

- Multiple clinical trials have established a low rate of procedural complications³⁻⁵
- 48.2% fewer procedural events compared to other TMVr therapies^{5,10,11}

REDUCE FMR Clinical Trial

The Carillon System is the first TMVr therapy to demonstrate favorable left ventricular remodeling at one year and significant reduction in regurgitant volume in a blinded, randomized, sham-controlled trial (REDUCE FMR).⁵ The trial met its primary endpoint and results were consistent with the prior TITAN and TITAN II single-arm, multi-center studies.³⁻⁵

DESIGN

31 sites in EU, Australia and New Zealand **3:1** Randomization (vs. sham control)

120 Patients **87** Carillon System
33 Guideline-directed medical therapy

Key inclusion criteria:

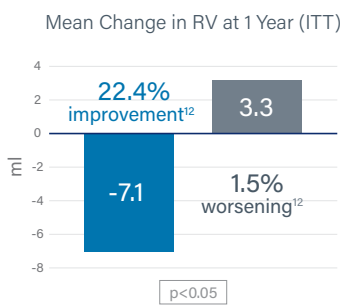
- MR grade 2+ to 4+
- NYHA class II-IV
- LVEF ≤50%

Primary endpoint:

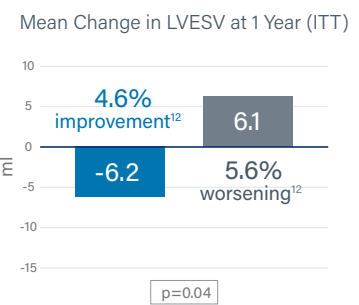
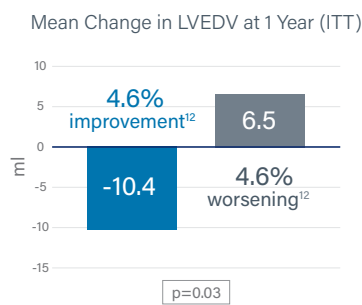
Change in regurgitant volume (RV) at 1 year, as assessed by blinded echo core lab

RESULTS

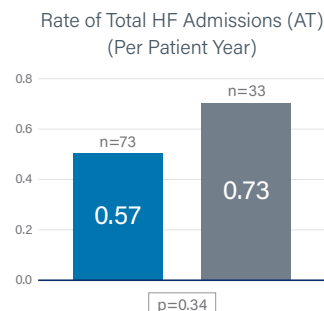
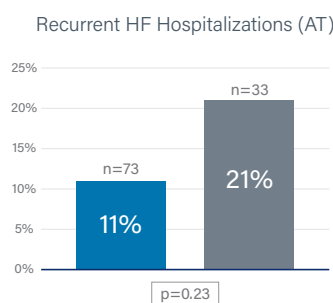
Significant Reduction in MR



Significant Favorable LV Remodeling



Recurrent HF Hospitalizations and Total HF Admissions



Positive Safety Profile

98.9% freedom from device-related MAE through 1 year*

Low MAE rate at 30 days and 12 months in treatment-only group



AT = As-Treated Population (n=106)
ITT = Intention-to-Treat Population (n=120)
*Events adjudicated by independent committee as related to device.

Ordering information

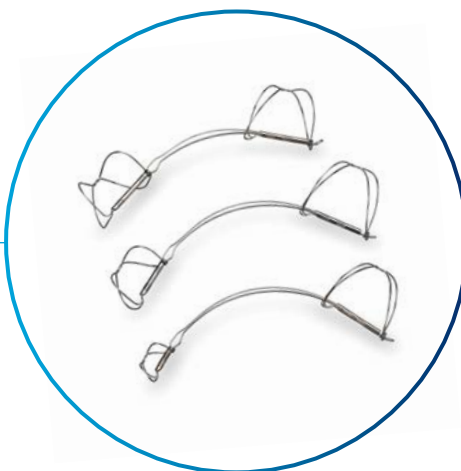
Product selection for various anatomical shapes and sizes:

Diameter 7mm to 20mm

Length 60mm to 80mm

For questions or to place an order, please contact:

sales@cardiacdimensions.com



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cardiacdimensions.com

1. Baskett RJF, Exner DV, Hirsch GM, Ghali WA. Mitral insufficiency and morbidity and mortality in left ventricular dysfunction. *Can J Cardiol.* 2007;23(10):797-800.
2. Trichon BH, Felker GM, Shaw LK, Cabell CH, O'Connor CM. Relation of frequency and severity of mitral regurgitation to survival among patients with left ventricular systolic dysfunction and heart failure. *Am J Cardiol.* 2003 Mar 1;91(5):538-43. [MR 3+ and 4+]
3. Lipiecki J, Siminiak T, Sievert H, et al. Coronary sinus-based percutaneous annuloplasty as treatment for functional mitral regurgitation: the TITAN II trial. *BMJ Open Heart.* 2016; 3: e000411.
4. Siminiak T, et. al. Treatment of functional mitral regurgitation by percutaneous annuloplasty: Results of the TITAN Trial. *Eur J Heart Fail.* 2012;14:931-38.
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6. Hoppe UC, Brandt MC, Degen H, et al. Percutaneous mitral annuloplasty device leaves free access to cardiac veins for resynchronization therapy. *Catheter Cardiovasc Interv.* 2009;74(3):506-11.
7. Latib, A. "Coronary Sinus Annuloplasty." New York, Montefiore Medical Center.
8. Kreyer K, Stobe S, Pfeiffer D, Laufs U, Hagendorff A. Treatment of functional mitral regurgitation by the Carillon Mitral Contour Device – an echocardiographic analysis of acute effects. Poster presentation. Universität Leipzig. 2019.
9. Kramer DG, Trikalinos TA, Kent DM, Antonopoulos GV, Konstam MA, Udelson JE. Quantitative evaluation of drug or device effects on ventricular remodeling as predictors of therapeutic effects on mortality in patients with heart failure and reduced ejection fraction: a meta-analytic approach. *J Am Coll Cardiol.* 2010 Jul 27;56(5):392-406.
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11. Messika-Zeitoun D, Nickenig G, Latib A, et al. Transcatheter mitral valve repair for functional mitral regurgitation using the Cardioband system: 1 year outcomes. *Eur Heart J.* 2019 Feb 1;40(5):466-472.
12. Data on file. Percent calculated by averaging individual patient percent changes.