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Customer Information

Systolic MDCT assessment avoids JenaValve prosthesis undersizing

We received notice that during a routine implantation in an AR patient using a size 27 JenaValve prosthesis, significant paravalvular leakage (PVL) occurred despite adequate positioning and deployment of the JenaValve prosthesis. As PVL did not resolve following repeat balloon valvuloplasty, a valve-in-valve procedure had to be performed.

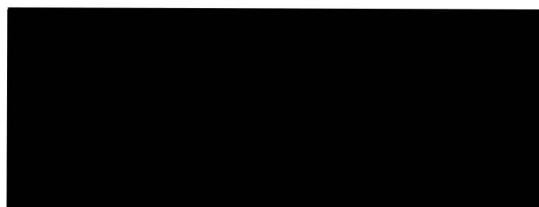
Prior to the procedure, a standardized MDCT scan and software-mediated three dimensional reconstructions were used to calculate the patient's native annular size and choose the corresponding JenaValve prosthesis. Annular dimensions in *diastolic* phase of the cardiac cycle were used.

During our investigation, repeat assessment of the MDCT data in both diastolic and systolic phase was performed. It became apparent that during *systolic* assessment, the patient's annular size was significantly *larger* if compared to diastolic assessment and, in this specific case, potentially lead to JenaValve prosthesis undersizing and PVL.

If not already implemented in routine practice in your respective center, we therefore strongly recommend to

- **Always use systolic MDCT data (10-20% of the cardiac cycle) to assess the largest annular dimension prior selecting the corresponding JenaValve prosthesis size to avoid potential undersizing and associated paravalvular leakage.**
- **Perform systolic assessment of annular dimensions in both AS and AR patients, as also in calcified AS, systolic annular dimensions are larger in systole if compared to diastole, thus impacting JenaValve prosthesis size selection.**

Thank you very much and best regards,



Medical Director/ Safety Officer

Select Literature:

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3. Bertaso AG, Wong DT, Liew GY, et al. Aortic annulus dimension assessment by computed tomography for transcatheter aortic valve implantation: differences between systole and diastole. *Int J Cardiovasc Imaging.* 2012 Dec; 28(8):2091-8