Background: Severe tricuspid regurgitation (TR) is associated with high morbidity and mortality rates with limited treatment options.

Objectives: We report the one-year outcomes of the Cardioband™ Tricuspid Valve Reconstruction System in the treatment of severe functional TR in 30 patients enrolled in the TRI-REPAIR study.

Methods: Between October 2016 and July 2017, 30 patients were enrolled in this single-arm, multicenter, prospective study. Patients were diagnosed with severe, symptomatic TR in the absence of untreated left-heart disease and deemed inoperable because of unacceptable risk for open-heart surgery by the local heart team. Clinical, functional, and echocardiographic data were prospectively collected before and up to one year post-procedure. An independent core lab assessed all echocardiographic data and an independent clinical event committee adjudicated the safety events.

Results: Mean patient age was 75 years, 73% were females, 23% had ischemic heart disease, and 93% had atrial fibrillation. At baseline, 83% were in NYHA Class III-IV, 63% had edema, and LVEF was 58%. Technical success was 100%. Through one year, one patient had a reintervention and exited the study. Five patients died of which one was device-related. Between baseline and one year (paired analyses), echocardiography showed average reductions of annular septolateral diameter of 16% (44mm vs. 37mm; p<0.0001), PISA EROA of 49% (0.73cm² vs. 0.37cm², p=0.0037), and mean vena contracta of 30% (1.2cm vs. 0.9cm, p=0.0046). Clinical assessment showed that at one year 78% of patients were in NYHA Class I-II (p=0.0003). Six minute walk distance improved by 42m (p=0.0525). Kansas City Cardiomyopathy Questionnaire score improved by 19 points (p=0.0009). Edema was absent in 70% of the patients.

Conclusions: These results show that the Cardioband tricuspid system performs as intended and appears to be safe in patients with symptomatic and severe functional TR. At one year significant reduction of TR through a sustained decrease of annular dimensions, improvements in heart failure symptoms, quality of life, and exercise capacity were observed. Further studies are warranted to validate these initial promising results.