



Mimicked Calcified Annulus Model for Preclinical Assessment of TAVR Devices

Technology No. 20170036

IP Status: Pending US Patent; **Application #:** 15/874,669

Mimicked Annular Calcification and Aortic Stenosis in Animal Models

An innovative annuloplasty ring, used in conjunction with an annuloplasty procedure in large animal models, creates consistent, reproducible models of aortic stenosis for long-term evaluation of transcatheter aortic valve replacement (TAVR) devices. The Calcified Annulus Model (CAM) annuloplasty ring is flexible, circular, planar in shape and covered with a fabric sheath secured to silicon and gold rings with sutures. During the annuloplasty procedure, the ring is cut into three sections, which are lowered into the aorta and secured with sutures. While the animal heals, the annuloplasty ring segments will scar and thicken into a fibrous pannus sheath within the native aortic annulus such that the protruding annuloplasty ring sections simulate calcific aggregations present in calcific aortic stenosis. This stenotic aortic annulus allows delivery and deployment of TAVR devices within the aorta of the large animal, effectively modeling proper TAVR use in human patients. The ring segments will be easily identified via echocardiography and x-ray fluoroscopy, which can also aid in the deployment of TAVR devices within the simulated calcified annulus model. Radial force of the TAVR stent opposing the healed annuloplasty ring sections within the aorta effectively secures the TAVR device within the aorta for long term evaluation of the TAVR device.

TAVR Device Testing

Annular calcification and aortic stenosis do not exist in healthy large animal models, so currently large animal models are limited in evaluating TAVR devices. This lack of disease poses a serious impediment to long-term preclinical evaluation of TAVR devices, as proper placement and anchoring of TAVR devices in humans depends on a disease state. This implanted aortic annuloplasty ring simulates calcific, stenotic, aortic annulus for TAVR implantation in large animal models, effectively creating and modeling the disease state necessary for anchoring TAVR devices in human patients and enabling other pre-clinical researchers with the technology and technique to improve the quality of TAVR product

development.

BENEFITS AND FEATURES:

- Improved pre-clinical models
- Consistent, reproducible large animal models of aortic stenosis
- Long-term evaluation of TAVR devices
- Scarring over implanted ring simulates calcific, stenotic, aortic annulus for TAVR implantation

APPLICATIONS:

- Medical device pre-clinical research
- Simulating annular calcification and aortic stenosis

Phase of Development - Device available on a low volume basis; method able to be shared.

Researchers

Richard Bianco

Professor, Department of Surgery

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