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SMT receives CE mark approval for Hydra TAVR device

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SMT (Sahajanand Medical Technology Pvt Ltd), the leading medical device company of India, focussed on innovative patient care in cardiovascular segment, has announced that Hydra TAVR device received European CE Mark approval for the treatment of patients diagnosed with aortic stenosis. This regulatory approval paves the path for SMT to tap into a fast growing $3.8 billion global market.

Hydra aortic valve is a self-expandable nitinol based supra annular aortic system with a mechanism for recapturing of the valve during deployment. This unique property of the device helps in precise placement of the valve and ensures orthotopic deployment. Hydra is available in three sizes; 22mm, 26mm & 30mm and is selected depending upon the diameter of the native annulus from 18mm to 27mm.

Clinical data from the Genesis trial conducted in India and presented at the India Valves Conference 2019 held in Chennai, confirm the system's ability to eliminate significant aortic regurgitation. In another CE clinical study conducted in Europe, the system also demonstrated a strong safety profile on 110 patients enrolled till February 2020.

The benefits of the Hydra Aortic Valve System are enabled by its frame design and repositionable and retrievable delivery system. The non-flared inflow section of the frame and supra-annular valve leaflet design ensures better aortic valvular area in smaller annuli and in valve-in-valve settings. The frame features 3 tentacles or antenna for better anchorage and larger cells (10mm) which give better access for the future coronary interventional procedures if required. The delivery cable is highly flexible and 18 French compatible, and the device can be recaptured, repositioned and retrieved even after 85%-90% of deployment of the valve thereby eliminating to almost zero complications of deployment of TAVR device. The precise orthotopic supra-annular placement, positioning and deployment is facilitated by this unique property of re-capturability of Hydra.

SMT has established a regional headquarter in Ireland to better serve its customers in Europe and Middle East. In addition to R&D and manufacturing center in Ireland, SMT has established direct presence and local offices in most of the large markets in Europe. SMT launched Supraflex Cruz DES last year in Europe and got critical success. Now with Hydra, SMT will be able to better serve its customers and patients across Europe.