



PRESS RELEASE

SMT Launches Hydra™ TAVI System in Russia, Offering Advanced Care for Aortic Stenosis Patients

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SMT (Sahajanand Medical Technologies), a global leader in innovative cardiovascular solutions, announces the launch of its **Hydra™ Transcatheter Aortic Valve Implantation (TAVI)** system in Russia. Hydra™ introduces a highly refined approach to managing severe aortic stenosis, providing physicians with a dependable and innovative option for high-risk patients who are not candidates for open-heart surgery.

Addressing the Growing Need for TAVI in Russia

TAVI procedures are increasingly gaining traction in Russia as an effective, minimally invasive solution for severe aortic stenosis. Hydra™ has been designed to meet the unique clinical needs of this growing patient population, reflecting SMT's ongoing commitment to advancing healthcare through technology.

“Russia’s medical community has shown significant interest in adopting TAVI technologies, and Hydra™ is a meaningful addition to the solutions available for treating complex cases,” said Mr. Sergey Antonov, Head of Commercial Operations for Russia. “Our entry into the market reinforces SMT’s dedication to supporting physicians with devices that combine precision, flexibility, and reliability.”

Key Features of Hydra™ TAVI System

Hydra™ is designed with features that address critical needs during aortic valve replacement procedures:

- **Adaptable Design for Precision:** Re-sheathable, re-positionable, and retrievable technology enables greater confidence during valve placement.
- **Supra-Annular Valve Configuration:** Allows for enhanced blood flow dynamics, helping to optimize post-procedure outcomes.
- **Frame Markers for Deployment Guidance:** Integrated markers aid physicians in achieving accurate valve placement during implantation.
- **Patient-Centric Safety Features:** A sealing skirt minimizes paravalvular leaks, while the stent frame design reduces interference with the conduction system, contributing to procedural safety.
- **Facilitated Future Coronary Access:** Open-cell design simplifies access to coronary arteries for future interventions, supporting long-term care.

Regulatory Approval by Roszdravnadzor



“In Russia, medical devices are regulated by **Roszdravnadzor** (The Federal Service for Surveillance in Healthcare). This agency oversees the registration, monitoring, and quality control of medical devices to ensure their safety and efficacy for use within the Russian Federation. We are very proud that Hydra is now approved in Russia which has its own strict regulatory requirements”, Added Mr. Ammad Shorbaji, Head of regulatory Affairs at SMT.

Hydra™ in the Russian Market

Hydra™ enters the Russian market at a pivotal time, with TAVI gaining widespread recognition for its ability to address complex cardiac cases. SMT’s presence in Russia, established through its successful **Supraflex Cruz™ drug-eluting stent system**, now expands to structural heart disease solutions with Hydra™. This aligns with SMT’s mission to bring advanced cardiovascular care to patients worldwide.

About SMT (Sahajanand Medical Technologies)

SMT is a global leader in cardiovascular medical devices, specializing in drug-eluting stents and structural heart disease solutions. Operating in over 80 countries, SMT is dedicated to advancing patient care through innovative medical technologies and clinical excellence, as demonstrated by the Multivessel TALENT trial. SMT has achieved recognitions from the Ministry of Health Sciences & Technologies for its tremendous contributions in the field of coronary healthcare. SMT also pioneered the introduction of biodegradable polymers in the cardiovascular segment.

About Hydra

Hydra is re-sheathable, re-positionable and retrievable self-expanding transcatheter aortic valve ensuring patient safety and good results during deployment. It has advanced features like markers on the frame for accurate guidance while deploying the frame. Hydra has a supra-annular design which helps in larger aortic valve area and best-in-class hemodynamic performance post procedure.

Hydra has less metal in the outflow portion which in turn helps in flexibility and ease of delivery of the frame reducing the chance of trauma to the aortic arch and sealing skirt mitigates paravalvular leak. Non-flared inflow part of stent frame reduces interference with the conduction system. Large open cells facilitate easy future coronary access.

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