



PRESS RELEASE

## **SMT Launches Hydra Transcatheter Aortic Valve Replacement (TAVR) System in Mexico, Expanding Global Reach**

Mumbai, Dec 17, 2024

**SMT** (Sahajanand Medical Technologies), a global leader in innovative cardiovascular solutions, announces the launch of its **Hydra Transcatheter Aortic Valve Replacement (TAVR)** system in Mexico. This marks a significant step in SMT's mission to bring cutting-edge, minimally invasive cardiac care to patients worldwide.

Mexico holds a pivotal position in the Latin American TAVR market, projected to reach **\$350 million in 2024** and expand at a **CAGR of over 20% through 2029**. The country's growing demand for advanced TAVR technologies is fuelled by a rising elderly population, increasing prevalence of aortic stenosis, and greater adoption of minimally invasive procedures. Hydra is uniquely positioned to address these needs, offering an innovative solution designed for precision, safety, and optimal patient outcomes.

### **Hydra TAVR: Precision and Innovation in Aortic Valve Replacement**

The **Hydra TAVR system** features advanced innovations, including:

- **Frame Markers:** Hydra is the first TAVR device to incorporate frame markers, ensuring precise implantation and ease of deployment.
- **Supra-Annular Design:** This enhances hemodynamic performance, delivering a larger effective valve area for improved patient recovery and quality of life.
- **Bovine Pericardium:** The valve is crafted with high-quality bovine pericardium for durability and reliability.
- **Reduced Trauma Design:** Hydra's flexible frame reduces trauma to the aortic arch, while its sealing skirt minimizes paravalvular leaks for improved safety.
- **Future-Proof Access:** Large open cells in the stent frame ensure easy coronary access for future interventions.

“With the approval of Hydra in Mexico, we are empowering physicians with an advanced TAVR system that combines precision, safety, and superior hemodynamics,” said **Joao Rodrigues**, Head of Latin America at SMT. “This milestone underscores our commitment to saving lives and transforming cardiac care in Latin America.”

**Approved by COFEPRIS: Meeting Mexico's High Regulatory Standards**



Hydra's approval by **COFEPRIS**, Mexico's Federal Commission for Protection Against Sanitary Risks, is a testament to SMT's dedication to meeting stringent regulatory requirements. COFEPRIS is recognized for its rigorous evaluation standards, ensuring the safety and efficacy of healthcare technologies introduced in the Mexican market.

"It is expected that COFEPRIS requires comprehensive technical and clinical data for product registration, which after several rounds of reviews SMT successfully addressed and provided the agency with all required technical and clinical studies We are incredibly proud of this achievement." added Ammad Shorbaji, Vice President of Regulatory Affairs at SMT.

### **A Global Expansion Strategy: Hydra TAVR in 20+ Countries**

The launch of Hydra in Mexico is part of SMT's broader strategy to expand access to high-quality cardiovascular solutions. Already available in more than **20 countries**, Hydra continues to revolutionize structural heart care by providing physicians with a reliable, re-sheathable, re-positionable, and retrievable TAVR system.

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### **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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