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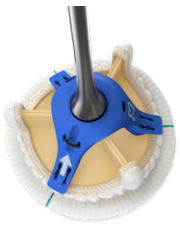
FACT SHEET

Avalus™ Pericardial Aortic Surgical Valve System

Disease Overview: **Aortic Stenosis**	Aortic stenosis is a common heart problem caused by a narrowing of the heart's aortic valve due to excessive calcium deposited on the valve leaflets. When the valve narrows, it does not open or close properly, making the heart work harder to pump blood throughout the body. Eventually, this causes the heart to weaken and function poorly, which may lead to heart failure and increased risk for sudden cardiac death. The standard treatment for patients with aortic valve disease is surgical aortic valve replacement (SAVR). During this procedure, a surgeon will make an incision in the sternum to open the chest and expose the heart. The diseased native valve is then removed and a new artificial valve is inserted. Once in place, the device is sewn into the aorta and takes over the original valve's function to enable oxygen-rich blood to flow efficiently out of the heart. For patients that are unable to undergo surgical aortic valve replacement, or prefer a minimally-invasive therapy option, an alternative procedure to treat severe aortic stenosis is called transcatheter aortic valve replacement (TAVR).
Avalus Surgical Valve Technology Overview	The Avalus Pericardial Aortic Surgical Valve System is a next-generation aortic surgical valve from Medtronic, offering advanced design concepts and unique features for the millions of patients with severe aortic stenosis who are candidates for open-heart surgery.  *The Avalus Surgical Valve* The Avalus valve, made of bovine tissue, is also the only stented surgical aortic valve on the market that is **MRI-safe (without restrictions)** enabling patients with severe aortic stenosis who have the Avalus valve to undergo screening procedures for potential co-morbidities.  *Single, One-Cut Release Valve Holder* **Provides Procedural Ease-of-Use** A soft and pliable sewing cuff on the Avalus valve facilitates needle penetration, suture placement, and valve seating for an improved implant experience. With its lower valve profile and narrow commissure posts that expands ostia clearance, these advancements give physicians more space for knot tying to secure it into place. A streamlined valve holder improves visibility in standard and minimally invasive approaches with a single, one-cut release once the Avalus valve is accurately positioned.

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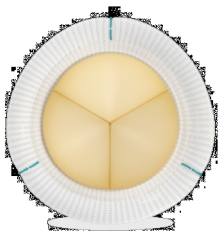
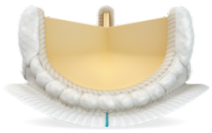
	Designed for Durability With interior mounted leaflets and frame design to enhance durability. In addition, AOA™ (alpha amino oleic acid) tissue treatment is used to help mitigate calcification.  *Leaflets Designed for Durability* **Optimizes Hemodynamic Performance** The Avalus valve features a supra-annular design with a flexible support frame and firm base to achieve coaptation to the native annulus and consistent hemodynamic performance. This advanced design is also intended to limit central regurgitation. **Supports Future Valve-in-Valve Procedures**  *Supra-Annular Valve Design* The unique dimensions and geometry of the Avalus valve enable future valve-in-valve replacements, if necessary. Its non-metallic polymer PEEK frame mitigates the risk of potential metal on metal corrosion with transcatheter stent materials. And the polymer frame filled with Barium Sulfate provides radiopacity and visibility.
Regulatory Status	The Avalus Pericardial Aortic Surgical Valve System is approved in sizes measuring 19, 21, 23, 25, 27mm throughout the U.S., Europe and other countries that recognize the CE (*Conformité Européene*) mark. The CE mark and FDA approval of the Avalus valve is based on clinical data from subsets of the PERIGON Pivotal Trial, a single arm, non-randomized, prospective study of more than 1,100 patients from 40 clinical sites across Europe, Canada and the United States.

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