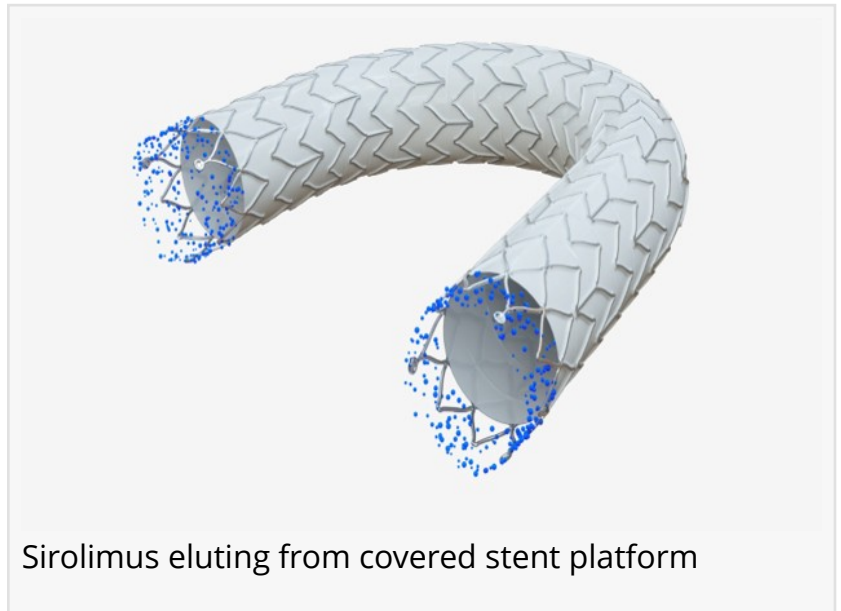


# Solaris Endovascular Receives FDA Breakthrough Device Designation for Solaris DE™, a new Drug-Eluting Covered Stent

DALLAS, TX, UNITED STATES, May 5, 2026 /EINPresswire.com/ -- Solaris Endovascular, Inc, a medical device company focused on next-generation endovascular therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for its first-in-class [Solaris DE™](#) drug-eluting covered stent indicated for use in hemodialysis patients for the treatment of stenosis within the dialysis outflow circuit at the venous anastomosis of a synthetic arteriovenous graft (AVG) in the veins of the arm.



The FDA's Breakthrough Device Designation is reserved for technologies that provide more effective treatment for life-threatening or irreversibly debilitating conditions and enables prioritized regulatory interaction and a more efficient path to approval.

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We are grateful for this Breakthrough Device Designation from the FDA, recognizing that the patients we serve cannot afford to wait.”

*Dr. Marco Costa*

For dialysis patients, maintaining access patency is a critical lifeline, yet failure remains a major clinical and economic burden that frequently requires multiple interventions per year and increases the risk of hospitalization, infection, and mortality. These failures are primarily driven by edge restenosis—the complex biological and mechanical processes occurring at and

beyond the stent margins that existing technologies do not adequately address.

Solaris DE is the first drug-eluting covered stent specifically designed to address edge restenosis,

one of the primary drivers of stent failures in dialysis access and other vascular beds. The device combines a self-expanding nitinol scaffold, an impermeable electrospun PTFE barrier, and a targeted sirolimus-eluting coating at the stent edges to inhibit neointimal hyperplasia and improve long-term vessel patency.

“We are grateful for this Breakthrough Device Designation from the FDA, recognizing that the patients we serve cannot afford to wait. Stent failure is not an engineering inconvenience, it is a fundamental biological problem, and Solaris DE was built to solve it. Beginning with the dialysis access and extending across the broader vascular continuum, this platform has the potential to transform care for millions of patients who have been underserved for far too long,” said Dr. Marco Costa, Chief Scientific & Medical Officer.

The FDA’s designation is anchored by the preliminary results of the DEScover Phase II multicenter clinical trial demonstrating 100% target lesion primary patency at six months in the AVG cohort. Full results from the DEScover multicenter trial will be presented at a forthcoming scientific forum.

Solaris DE is strategically positioned to leverage the newly announced CMS-FDA [RAPID](#) (Regulatory Alignment for Predictable and Immediate Device) coverage pathway. RAPID is designed to enable national Medicare coverage in as little as two months following FDA authorization—compared to approximately one year or more under previous processes.

“The RAPID pathway fundamentally changes the commercial equation for Breakthrough Devices,” said Randy Hubbell, CEO. “Predictable, immediate reimbursement significantly accelerates our path to establishing a new global standard of care.”

Solaris Endovascular continues to work closely with the FDA to initiate a pivotal U.S. study and advance toward Premarket Approval (PMA) as a first-in-class solution for dialysis access and peripheral vascular disease.

About Solaris Endovascular, Inc.:

Solaris Endovascular, Inc. is a growth-stage US-based medical device company dedicated to developing innovative endovascular solutions for patients with dialysis access challenges and Peripheral Artery Disease. With a proven stent platform and cutting-edge drug-eluting technology, Solaris Endovascular is committed to improving long-term patient outcomes and transforming vascular health.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding regulatory timelines, clinical development, reimbursement pathways, commercialization plans, and potential market impact. These statements are subject to risks and uncertainties, including

regulatory outcomes, CMS coverage finalization, clinical trial results, and market conditions, which may cause actual results to differ materially from those expressed or implied by such statements. Solaris Endovascular disclaims any obligation to update these forward-looking statements.

For further details, please visit our website at [www.solarisendovascular.com](http://www.solarisendovascular.com).

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