Solaris Endovascular Reports Positive Six-Month Interim Results for DEScover Trial

First Drug-Eluting Self-Expanding Covered Stent Demonstrates 95% Patency Through 6 Months; 100% Procedural Success and Zero 30-Day Device Related Adverse Events

Solaris DE Logo

SAN FRANCISCO, CA, UNITED STATES, October 27, 2025 /EINPresswire.com/ -- Solaris Endovascular, Inc., a U.S.-based, growth-stage medical device company pioneering next-generation endovascular stent-graft technology, today shared interim results from the DEScover Clinical Trial at the Transcatheter Cardiovascular Therapeutics (TCT) 2025 conference. The data mark a major advance in the treatment of dialysis access for the company's Solaris DE sirolimus-eluting electrospun PTFE covered stent device.

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>
> *Dr. Marco Costa*

The DEScover trial met its primary safety endpoint, and interim data showed an unprecedented 95% Target Lesion Primary Patency (TLPP) at six months and no device-related serious adverse events through 30 days. At six months, 100% of patients with prosthetic arteriovenous grafts (AVG) and 91% of patients with native arteriovenous fistulae (AVF) had patent target vessels.

"For the first time, we are seeing sirolimus successfully released from the metal edges of a covered stent—effectively addressing edge restenosis, the final frontier in this field," commented Dr. Leonardo Harduin, Principal Investigator of the DEScover study. "Achieving 95% patency with no safety concerns is incredible. If confirmed, these results may change medical practice in the future."

"Solaris DE validates the power of combining a modern stent design platform with advanced electrospun PTFE and controlled drug delivery," said Dr. Marco Costa, Chief Scientific & Medical Officer of Solaris Endovascular. "We believe these results position Solaris DE to become the new benchmark for sustained patency in dialysis access and peripheral artery disease."

About the DEScover Trial

The DEScover trial is a prospective, randomized, multicenter, Phase II feasibility study enrolling 120 patients with failing AVF and AVG access. Patients in the AVF cohort were randomized to receive balloon angioplasty (PTA) or the Solaris DE sirolimus-eluting electrospun PTFE covered stent, while the AVG group only received Solaris DE. The primary efficacy endpoint is Target Lesion Primary Patency (TLPP) at six months.

At the interim analysis, all patients completing six-month follow-up demonstrated safety and exceptional efficacy compared to historical benchmarks for PTA and non–drug-eluting covered stents, which report average TLPP rates between 51% and 89%.

The Solaris DE design uniquely integrates:
- Mechanical scaffold – self-expanding nitinol frame for precision and durability
- Structural barrier – next-generation electrospun PTFE membrane preventing neointimal cell migration
- Biological barrier – controlled sirolimus release from a biodegradable polymer coating at the stent edges to inhibit smooth-muscle proliferation

Building on the Solaris SX uncovered-edge design, Solaris DE enables sirolimus delivery directly to the vessel wall, sustaining patency beyond the stent edge.

Solaris Endovascular plans to submit an Investigational Device Exemption (IDE) for the base technology (without sirolimus), Solaris SX, to the U.S. FDA in December 2025, with first-in-human enrollment expected in Q1 2026.

About Solaris Endovascular
Solaris Endovascular, Inc. is a privately held, Delaware-based medical device company developing advanced self-expanding covered stent technologies to address restenosis in peripheral artery and dialysis access failures. The company's commercial product, Solaris SX, is approved in the European Union (MDR certified) and in 45 countries worldwide. The second-generation product, Solaris DE, integrates sirolimus-eluting technology to prevent edge restenosis—representing the first drug-eluting, self-expanding covered stent.
For more information, visit www.solarisendovascular.com

Randy Hubbell
Solaris Endovascular, Inc.
+1 215-688-6196
email us here
Visit us on social media:
LinkedIn

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