

Solaris Endovascular, Inc. Surpasses Key Enrollment Milestone in DEScover Randomized Clinical Trial

42 Patients Enrolled in Pioneering Drug-Eluting Covered Stent Graft Study

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-- [Solaris Endovascular, Inc.](#), a leading US-based medical device company specializing in advanced endovascular solutions, proudly announces a significant milestone in the DEScover clinical trial. This groundbreaking study, the first of its kind to focus on sirolimus-eluting covered stent grafts, is ahead of schedule and has successfully enrolled 42 patients out of the planned 120 patients.



The DEScover trial is being conducted as part of Solaris Endovascular's strategic initiative to gather comprehensive data supporting the global registration of the Solaris DE device. This device aims to revolutionize treatment for patients facing challenges with Dialysis Access Dysfunction and Peripheral Artery Disease.

Clinical Trial Overview:

- Objective: Evaluate the safety and efficacy of the Solaris DE (drug-eluting) endovascular stent graft in patients with arteriovenous fistulae (AVF) and arteriovenous grafts (AVG).
- Methodology: Participants with AVF (n=80) are randomized in a 1:1 ratio to receive either the Solaris DE device or standard balloon angioplasty, with a single arm design for AVG patients (n=40) treated with Solaris DE.
- Endpoints:
 - o Safety: Proportion of patients free from serious adverse events at 30 days.
 - o Efficacy: Target lesion primary patency at 6 months.

With healthcare costs for end-stage kidney disease surpassing \$59 billion in 2020, effective dialysis access management is more critical than ever. Vascular access failures, particularly restenosis, remain unresolved.

Solaris DE seeks to address this unmet clinical need by combining a mechanical barrier of the next-gen impermeable electrospinning PTFE with a biological barrier to block cell proliferation.

Industry Insights:

- Dr. Leonardo Harduin, DEScover Principal Investigator, and organizer of the [6th SAVE Symposium](#), one of the leading Scientific Conferences of Dialysis Access with approx. 600 attendees, highlighted: "The Solaris DE device, with its electrospinning PTFE coverage and sirolimus-eluting platform, is designed to effectively prevent restenosis and extend the functional duration of dialysis access for patients."
- Dr. Ziv J. Haskal, senior advisor and pioneer in covered stent research, added, "Addressing edge stenosis is the next frontier in dialysis access care. This trial has the potential to significantly advance our treatment strategies."
- Marco Costa, Chief Medical and Scientific Officer of Solaris Endovascular, remarked, "I remember vividly the excitement and anticipation as a physician-scientist 26 years ago, when we treated the first patients with sirolimus-eluting coronary stents (Cypher). Similarly, reducing restenosis will not only improve outcomes but also expand the covered stent market from \$1.4 billion to an anticipated \$3.0 billion by 2030."

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.

For further details, please visit our website at www.solarisendovascular.com.

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