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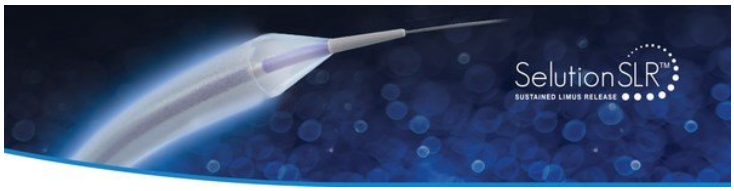
MedAlliance enrolls first two patients in PRISTINE study

October 12, 2020 | News

MedAlliance is the first DEB company in the world to receive USFDA Breakthrough Device Designation Status



MedAlliance a privately-owned medical technology company, headquartered in Nyon, Switzerland has announced the enrolment of the first two patients in the PRISTINE registry with SELUTION SLR™ 018 DEB (drug-eluting balloon) for the treatment of patients with Below the Knee disease (Chronic Limb Threatening Ischemia).

This is the first DEB accepted by the FDA for its "Breakthrough Program". SELUTION SLR (Sustained Limus Release) is a novel sirolimus-eluting balloon that provides a controlled sustained release of drug, similar to a drug-eluting stent (DES).

The PRISTINE registry is a follow up to the encouraging results seen in the PRESTIGE clinical trial (Below The Knee, Chronic Limb Threatening Ischemia) at 6 months.

PRISTINE is a Prospective Registry to Investigate the Safety and efficacy of Treatment with SELUTION SLR™ Sirolimus Drug-Coated Balloon in TASC C and D athero-occlusive Infra-iNguinal disease in patients with chronic limb-threatening ischemia from Singapore.

The objective of the registry is to evaluate over 12 months of safety and performance outcomes in 75 patients, with SELUTION SLR DEB in the treatment of infra-inguinal occlusive lesions (TASC C and D) in patients with chronic limb threatening ischemia (CLTI) at Singapore General Hospital.

The SELUTION Sustained Limus Release DEB offers an effective treatment for NIH in CLTI and has shown good target lesion patency, low target lesion revascularisation & relatively high amputation free survival as evidenced from the 6 months results of the completed PRESTIGE Trial.

MedAlliance is the first DEB company in the world to receive US Food and Drug Administration (FDA) Breakthrough Device Designation Status for a coronary DEB.