Paximus RCT-1 Study

A study to evaluate safety and performance of Paximus (Paclitaxel eluting percutaneous transluminal angioplasty balloon catheter) versus Mozec PTA balloon catheter for treatment of blocked or narrowed below the knee arteries

Study Design

- Prospective, multicentre, open label, randomised controlled study
- 280 subjects to be enrolled in 1:1 ratio

	Study Highlights
Reference No.:	MLS/Paximus™ RCT-1
Study Objective	To evaluate safety and performance of Paximus (Paclitaxel eluting percutaneous transluminal angioplasty balloon catheter) versus Mozec PTA balloon catheter for treatment of blocked or narrowed below the knee arteries
Primary Endpoint	• Major Adverse Events
Secondary Endpoints	• Primary Patency at 6 & 12 month • Late Lumen Loss (LLL) at post procedure and 6 month • All cause of death • Clinically driven target lesion revascularisation • Target limb amputation • Change of Ankle-Brachial index (ABI) at post procedure, 1,6,12 & 24 month • Walking Impairment Questionnaire (WIQ) at 1,6,12 & 24 month • Change in Rutherford Classification at baseline, post procedure, 1,6,12 & month • Device Success • Procedural Success • User Rating on Technical Properties
PK Endpoints	• Time taken to reach to maximum concentration in blood after deployment of the Paximus PEB PTA • Maximum concentration of the drug obtained in peripheral venous blood • Mean half life period of the drug in venous blood

	• Area under curve of the blood drug concentration • Time taken for drug to go below detectable levels in venous blood sample
Clinical Sites	20-25 sites
Sample Size	280 subjects
Follow-Up	Follow-up visits at 1 month, 6 months, 12 months and 24 months
Study Duration	24 months