# Promesa DES-1 Study

A study to evaluate safety and performance of Promesa™ DES sirolimus eluting self-expandable nitinol peripheral stent system for treating superficial femoral artery and iliac artery lesions

## Study Design

- Prospective, multicentre, single-arm, open label clinical study
- 30 subjects to be enrolled at 5 sites across India

| | Study Highlights |
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| **Reference No.:** | MLS/Promesa DES - 1 |
| **Study Objective** | To evaluate safety and performance of Promesa™ DES Sirolimus eluting self-expandable nitinol peripheral stent system for treating superficial femoral artery(SFA) and iliac artery lesions |
| **Primary Endpoints** | • Major Adverse Events at 6 months<br>• Primary Patency |
| **Secondary Endpoints** | • Major Adverse Events (MAE) at 1 month and 12 month<br>• All cause of death<br>• Clinically driven Target Lesion Revascularisation<br>• Target limb amputation<br>• Change in Rutherford Classification<br>• Hemodynamic Improvement<br>• Walking Impairment Questionnaire at 1,6,12 and 24 month<br>• User Rating on Technical Properties<br>• Technical Success<br>• Procedural Success |
| **Clinical Sites** | 5 sites across India |
| **Sample Size** | 30 subjects |
| **Follow-Up** | • Follow-up visits at 1 month, 6 months, 9 months, 12 months and 2 months |
| **Study Duration** | 24 months |