# CREDENCE BRS-1 STUDY

A clinical study to evaluate safety and performance of CREDENCE BRS Sirolimus Eluting BioResorbable Peripheral Scaffold System in subjects with de novo native peripheral artery lesions

## Study Design

- Prospective, open label and multicentric clinical study
- 30 subjects enrolled at 16 sites across India

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| **CTRI No.** | **CTRI/2017/01/007638** |
| **Study Objective** | **To evaluate safety and performance of the CREDENCE™ BRS Sirolimus Eluting BioResorbable Peripheral Scaffold System in subjects with *de novo* native peripheral artery lesions** |
| **Safety Endpoint** | • **Major Adverse Events** |
| **Performance Endpoints** | • **Technical success [During Procedure]**<br>• **Procedural success of the stenting procedure [Within 24 hours of scaffold implant procedure]**<br>• **Clinically-driven TLR Rate [1 Month, 6 Months, 12 Months, 2 years, 3 years, 4 years and 5 years]**<br>• **Clinically-driven TVR Rate [1 Month, 6 Months, 12 Months, 2 years, 3 years, 4 years and 5 years]**<br>• **Scaffold Fracture Rate [12 months]**<br>• **Distribution of Rutherford Classification [1 Month, 6 Months, 12 Months]**<br>• **Rate of primary sustained clinical improvement as assessed by changes in Rutherford Classification [1 Month, 6 Months, 12 Months]**<br>• **Rate of secondary sustained clinical improvement as assessed by changes in Rutherford Classification [1 Month, 6 Months, 12 Months]** |

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| | • **Walking improvement assessed by change in Six Minute Hall Walk from baseline [1 Month, 6 Months, 12 Months]**<br>• **Walking improvement assessed by change in Walking Impairment Questionnaire (WIQ) [1 Month, 6 Months, 12 Months]**<br>• **Patient utility values by change in EQ-5D [1 Month, 6 Months, 12 Months]** |
| **Angiographic Endpoints** | • **Late Lumen Loss [6 Months]**<br>• **Primary Patency [6 Months] as determined by Duplex Ultrasound / Colour Flow Doppler Ultrasound, PSVR ≤ 2.4 Analysed by: Stanford Core Laboratory, USA**<br>• **Patency by Duplex Ultrasound at 12 months** |
| **Clinical Sites** | **16 sites across India** |
| **Sample Size** | **30 subjects** |
| **Follow-Up** | **Clinically follow-up at 1 month, 6 months & 12 months**<br>**Telephonic follow-up at 2 years, 3 years, 4 years and 5 years.** |
| **Study Duration** | **Study start in July 2017**<br>**Estimated study completion April 2024** |

**Reference:**


1. Clinical Trial Registry- India (CTRI) http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=15326&EncHid=&userName=CTRI/2017/01/007638
2. Ferrone M, Melnick G, Isaza N, Cheng Y, Conditt G, Rousselle S, et al. TCT-526 Long-Term Biocompatibility of a Novel Bioresorbable Scaffold for Peripheral Arteries: A Preliminary Study in Yucatan Miniswine. Journal of the American College of Cardiology. 2018; 72(13 Supplement):B212.
3. Presented by Sahil Parikh. Extending the Role of BRS in PAD & clinical update. TCT-2018.