

CREDESCENCE BtK-1 Study

A clinical study to evaluate safety and performance of CREDESCENCE BtK Sirolimus Eluting BioResorbable Peripheral Scaffold System in subjects with Critical Limb Ischemia following percutaneous transluminal angioplasty of below the knee arteries

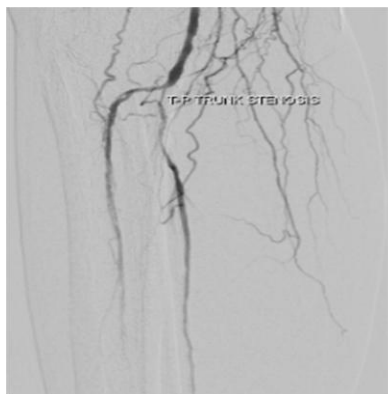
Study Design

- Prospective, multicenter and open label study
- 30 subjects enrolled at 12 sites across India

CTRI No.	CTRI/2016/11/007473
Study Objective	To evaluate safety and performance of the CREDESCENCE BtK Sirolimus Eluting BioResorbable Peripheral Scaffold System in subject with Critical Limb Ischemia disease due to de novo lesions (length ≤56mm) in below the knee arteries
Safety Endpoint	<ul style="list-style-type: none"> • Absence of clinical complications
Performance Endpoints	<ul style="list-style-type: none"> • Technical success [48 hours] • Limb salvage rates [6 month and 12 months] • Primary Patency Rate [1 Month, 12 Months, 2 years, 3 years, 4 years and 5 years] • TLR Rate [1 Month, 6 Months, 12 Months, 2 years, 3 years, 4 years and 5 years] • Clinical Success [1 day, 1 Month, 6 Months, 12 Months, 2 years, 3 years, 4 years and 5 years] • Improvement of Ankle-Brachial Index [1 day, 1 Month, 6 Months, 12 Months]
Angiographic Endpoints	<ul style="list-style-type: none"> • Late Lumen Loss [6 month] • Primary Patency [6 month] as determined by Duplex Ultrasound (DUS)/ Colour Flow Doppler Ultrasound (CFDU), PSVR ≤ 2.4 <p>Analysed by: Stanford Core Laboratory, USA</p>

Clinical Sites	12 sites across India
Sample Size	30 subjects
Follow-Up	Clinical follow-up at post-procedure 1 day, 1 month, 6 months, & 12 months, 2 Year, 3 Year, 4 Year, 5 Year.
Study Duration	Study start date: November 2016 Estimated study completion: July 2023

Angiographic Outcomes:



Pre-Procedure



Post-Procedure



6 Months FU

Reference:

1. Clinical Trial Registry- India (CTRI)
<http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=15321&EncHid=&userName=CTRI/2016/11/007473>
2. Presented by Girish Warawdekar. 30 Days clinical outcomes of novel thin strut (100 μ) BioResorbable Peripheral Vascular Scaffold System in the treatment of critical limb ischemia of below the knee arteries. At Euro PCR 2018.
3. Presented by Sanjeev Bhatt. Credence BtK-Sirolimus Eluting BRS Infra-Popliteal Artery. At Euro PCR 2018.
4. Presented as an interview by Vimal Someshwar. 30-day clinical outcomes of novel thin strut (100 μ) bioresorbable peripheral vascular scaffold system in the treatment of critical limb ischaemia of below-the-knee arteries. At Euro PCR 2018.
5. Presented as LBT by Gireesh Warawdekar. Clinical outcomes of sirolimus-eluting bioresorbable peripheral scaffold system in subjects with critical limb ischemia disease due to de novo lesions. At TCT-2018.