Morph India Study

A study to evaluate the safety and performance of BioMime Morph sirolimus-eluting stent system in very long (length ≤ 56 mm) coronary lesions in native coronary arteries with reference vessel diameter of 2.25 mm to 3.50 mm.

Study Design

- A Prospective, Single-Arm, Multi-Centre, Observational, Real World Study
- Sample size: 450 patients

CTRI Number	**CTRI/2016/12/007527**
Study Objective	**To evaluate the safety and performance of BioMime Morph Sirolimus-Eluting Stent System in very long (length ≤ 56 mm) coronary lesions in native coronary arteries with reference vessel diameter of 2.25 mm to 3.50 mm**
Primary Endpoint	• **Freedom of target lesion failure (TLF)** **TLF is defined as a composite of cardiac death, myocardial infarction attributed to the target vessel and target lesion revascularization**
Secondary Endpoints	• **Major adverse cardiac events at 1, 6, 12 and 24 months** **Composite of cardiac death, myocardial infarction attributed to the target vessel and ischemia driven target lesion revascularization** • **Stent thrombosis at 1 month, 6 months and 12 months follow-up**
Clinical Sites	**19 centers**
Sample Size	**450 subjects**
Follow-Up	**Clinical follow-up at 1 month, 6 months, 12 months and 24 months** **OCT at 6 months and QCA at 9 months**
Study Duration	**Study start date: 10th June, 2016** **Estimated study completion: December 2020**

Reference:

1. **Clinical Trial Registry- India CTRI/2016/12/007527**
   http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=15315&EncHid=&userName=CTRI/2016/12/007527