Morph-BGM Study

A study to evaluate safety and performance of the BioMime Morph Sirolimus Eluting Coronary Stent System in real world settings

Study Design

- Prospective, single-centre, observational, real world, post-marketing surveillance study
- Study Status: Recruitment ongoing

CTRI Number	CTRI/2017/03/008167
Study Objective	To evaluate safety and performance of the BioMime Morph Sirolimus Eluting Coronary 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 in real world settings
Safety Endpoint	• Major adverse cardiac events Composite of cardiac death, myocardial infarction and ischemia driven target lesion revascularization
Performance Endpoints	• 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 • Target vessel failure (TVF) TVF is defined as cardiac death, myocardial infarction attributed to the target vessel, or target vessel revascularization • Procedural success • Device success
Clinical Sites	Single center
Sample Size	A total of 100 subjects will be enrolled
Follow-Up	Follow-up visits at 1 month, 6 months, 12 months and 24 months
Study Duration	Study start date: 24th March 2017 Estimated study completion: January 2021

Reference:

1. **Clinical Trial Registry – India: CTRI/2017/03/008167**
   http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=17116&EncHid=&userName=CTRI/2017/03/008167