Morpheus Global Registry

A global registry 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.

Study Design

- A prospective, multi-center, single arm, observational, real-world registry
- Sample size: 400 patients globally (9 countries)

Clinical Trials.gov	**NCT02901353**
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**
Primary Endpoint	• **Freedom of target lesion failure (TLF)** **TLF is defined as a composite of cardiac death, myocardial infarction attributed to the target vessel (both Q-wave and non Q-wave) and ischemic-driven target lesion revascularization**
Secondary Endpoints	• **Major adverse cardiac events** **Composite of cardiac death, myocardial infarction attributed to the target vessel and ischemia driven target lesion revascularization** • **Stent thrombosis** • **Target Vessel Failure** **TVF as defined as cardiac death, myocardial infarction attributed to the target vessel, or target vessel revascularization.**
Clinical Sites	**15 sites globally (The Netherlands, Bulgaria, Slovakia, Hungary, Finland, Italy, South Africa, Malaysia, Jordan)**
Sample Size	**A total of 400 subjects will be enrolled**
Follow-Up	**Follow-up visits at 1 month, 6 months and 12 months**
Study Duration	**Study start date: 7th March 2017** **Estimated study completion: December 2020**

Reference:

1. **Clinical Trial Registration: NCT02901353**
   https://clinicaltrials.gov/ct2/results?cond=&term=NCT02901353&cntry=&state=&city=&dist=&Search=Search