MILES Global Registry

To evaluate the safety and efficacy of the BioMime sirolimus eluting coronary stent system in all comers real world population with coronary artery stenosis

Study Design

- Prospective, Multicenter, Single arm, Observational clinical registry
- The study will be enroll approximately 600 subjects (12 countries)

EU Clinical Trials Register	2013-005021-23
Study Objective	To determine the safety and efficacy of BioMime sirolimus eluting stent system in real world all comers population
Primary Endpoints	• Efficacy: Rate of Target Vessel Failure at 9 months • Safety: Rate of Stent Thrombosis (ARC "definite" or "probable") in presence of dual antiplatelet therapy
Secondary Endpoints	• Cumulative Target Vessel Failure at 1, 9, 12 and 24 months • Target Lesion Revascularization at 1, 9, 12 and 24 months • Major Adverse Cardiac Events at 1, 9, 12 and 24 months • Frequency of Stent Thrombosis a) Acute (0-24 hours after stent implant) b) Sub acute (24 hours to 1 month after stent implant) c) Late (1 month to 1 year after stent implant) d) Very Late (Beyond 1 year after stent Implant) e) By ARC definitions: Definite, Probable and Possible, at all follow up visits
Clinical Sites	20 sites globally (The Netherlands, Slovakia, Spain, Portugal, Bulgaria, Hungary, Korea, Ukraine, Saudi Arabia, Sri Lanka, Malaysia, Taiwan)
Sample Size	A total of 600 subjects will be enrolled
Follow-Up	Clinical follow-up at 30 days, 9 months, 1 year, and 2 years
Study Duration	Study start date: June 2013 Estimated study completion: December 2020