

# 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)

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|------------------------------------|---|
| <b>EU Clinical Trials Register</b> | 2013-005021-23  |
| <b>Study Objective</b>             | To determine the safety and efficacy of BioMime sirolimus eluting stent system in real world all comers population  |
| <b>Primary Endpoints</b>           | <ul style="list-style-type: none"> <li>• Efficacy: Rate of Target Vessel Failure at 9 months</li> <li>• Safety: Rate of Stent Thrombosis (ARC “definite” or “probable”) in presence of dual antiplatelet therapy</li> </ul>   |
| <b>Secondary Endpoints</b>         | <ul style="list-style-type: none"> <li>• Cumulative Target Vessel Failure at 1, 9, 12 and 24 months</li> <li>• Target Lesion Revascularization at 1, 9, 12 and 24 months</li> <li>• Major Adverse Cardiac Events at 1, 9, 12 and 24 months</li> <li>• Frequency of Stent Thrombosis               <ol style="list-style-type: none"> <li>a) Acute (0-24 hours after stent implant)</li> <li>b) Sub acute (24 hours to 1 month after stent implant)</li> <li>c) Late (1 month to 1 year after stent implant)</li> <li>d) Very Late (Beyond 1 year after stent Implant)</li> <li>e) By ARC definitions: Definite, Probable and Possible, at all follow up visits</li> </ol> </li> </ul> |
| <b>Clinical Sites</b>              | 20 sites globally (The Netherlands, Slovakia, Spain, Portugal, Bulgaria, Hungary, Korea, Ukraine, Saudi Arabia, Sri Lanka, Malaysia, Taiwan)  |
| <b>Sample Size</b>                 | A total of 600 subjects will be enrolled  |
| <b>Follow-Up</b>                   | Clinical follow-up at 30 days, 9 months, 1 year, and 2 years  |
| <b>Study Duration</b>              | Study start date: June 2013<br>Estimated study completion: December 2020  |