Bard LifeStent® Popliteal Artery Stent Project

The SVS PSO, M2S and Bard Peripheral Vascular are conducting a new quality improvement project to further evaluate the Bard LifeStent® for treatment of popliteal artery atherosclerosis. The Bard LifeStent® Vascular Stent Systems received FDA approval for treatment of popliteal artery atherosclerosis, with a requirement for post-approval surveillance. The current QI project is intended to confirm these findings in the real world practice of VQI centers. Non-identifiable data will be shared with Bard Peripheral Vascular from this project and a Steering Committee of the SVS PSO will analyze and publish the outcomes.

VQI centers that participate in the Bard LifeStent® project will be reimbursed for additional data entry and follow-up form completion. If you choose to participate in this project you will be required to participate in the PVI Registry and enter all consecutive PVI cases, regardless of device manufacturer.

Surveillance Project Details:

- VQI Peripheral Vascular Intervention (PVI) Registry™ captures all data
- Prospective, consecutively enrolling, nonrandomized multi-center
- 74 Patients
- Follow-up at 1 and 2 years
- Post-market surveillance through VQI does not require IRB review or patient consent
- Sites selected will be reimbursed for data collection efforts as follows:
  - $400 for completion of primary procedure record
  - $500 for completion of the 1 year follow-up record
  - $500 for completion of the 2 year follow-up record

Process:

Regulatory:

All data submitted for this project are part of the SVS PSO activity to improve the safety and effectiveness of vascular healthcare, and are covered under existing contracts with each site. As with all data submitted to a Patient Safety Organization concerning standard of care, specific patient consent and IRB approval is not required.

For more information, please contact BardLifeStent@M2S.com