

Bard LifeStent Popliteal Artery Stent Project

Quality improvement project to further evaluate the Bard LifeStent® for treatment of popliteal artery atherosclerosis.

VQI®

The Vascular Quality Initiative is a distributed network of regional groups that use a Patient Safety Organization and the M2S PATHWAYS cloud based system to collect and analyze data to improve the quality of vascular health care.

SVS PSO

The Society for Vascular Surgery Patient Safety Organizations houses the data registries used by VQI and collaborates with the FDA and medical device companies to evaluate the safety and effectiveness of vascular devices.

M2S, INC.

M2S is the technology partner for the SVS PSO, providing the M2S PATHWAYS cloud-based platform for the collection and analysis of clinical quality improvement data.

CONTACT US

For more information on this project, and to find out how your center can started, contact:

BardLifeStent@m2s.com

603-289-5509 (option 5)

www.vqi.org



The Bard LifeStent® Vascular Stent Systems received FDA approval for treatment of popliteal artery atherosclerosis, with a requirement for post-approval surveillance. This 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® Popliteal Artery Stent 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