SVS PSO Medtronic IN.PACT Admiral DCB ISR Project

The SVS PSO and M2S in collaboration with Medtronic, Inc. are conducting a new quality improvement project to confirm that IN.PACT Admiral DCBs are safe and effective for treatment of ISR lesions in the superficial femoral and popliteal arteries. The Medtronic IN.PACT Admiral DCB ISR Project received FDA approval for treatment of in-stent restenosis (ISR) lesions in the superficial femoral and popliteal arteries, with a requirement for post-approval surveillance. The current QI project is intended to confirm the safety and effectiveness of IN.PACT Admiral DCBs in the real world practice of VQI centers. Non-identifiable data will be shared with Medtronic, Inc. from this project and a Steering Committee of the SVS PSO will analyze and publish the outcomes.

VQI centers that participate in the Medtronic IN.PACT Admiral DCB ISR 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
- 50 Participating Sites
- 300 Patients
- Follow-up at 1 year, 2 year, 3 year
- Post-market surveillance through VQI does not require IRB review or patient consent
- Sites selected will be reimbursed for data collection efforts as follows:
  - $350 for completion of primary procedure record
  - $500 for completion of follow-up time points at 1 year and 2 years, respectively
  - $600 for completion of final 3 year follow-up time point

Process:
- Sites Complete Contract Addendum
- Web-Ex Training on Protocol and PVI Registry data collection
- Data entry of consecutive PVI cases
- Data collected from within VQI at follow up timepoints
- Payments for completed submissions - quarterly

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: MedtronicAdmiralDCB@m2s.com