

SVS PSO Medtronic IN.PACT Admiral DCB ISR Project

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.

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.

This project is intended to confirm the safety and effectiveness of IN.PACT Admiral DCBs in the real world practice of VQI centers.

SURVEILLANCE PROJECT DETAILS

- Data is captured in the Vascular Quality Initiative (VQI) Peripheral Vascular Intervention (PVI) Registry™
- Prospective, consecutively enrolling, nonrandomized multi-center
- 50 Participating Sites
- 300 Patients
- Standard PVI procedure form - no additional data elements need to be entered
- Follow-up at 1 year, 2 year, 3 year
- Post-market surveillance through VQI does not require IRB review or patient consent

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:

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