

SHORT TITLE: SAFE-DBC

RESEARCH PROTOCOL TITLE: A Prospective, Multicenter, Single Arm, Real-World Registry Assessing the Clinical Use of the Lutonix® 035 Drug Coated Balloon Catheter in Arteries of the Superficial Femoral Artery (SFA) and Popliteal Artery (PA)

PRINCIPAL INVESTIGATOR: David Lewis, MD

RESEARCH SPONSOR: Bard Peripheral Vascular, Inc.

Clinical Trials.Gov Listing at:

<https://clinicaltrials.gov/ct2/show/NCT02424383?term=Safe-DCB&rank=1>

STUDY PURPOSE

The purpose of this registry is to assess the clinical use, safety and outcomes of the Lutonix DCB Catheter. This catheter is used to restore blood flow by opening up blood vessels in the legs.

ELIGIBILITY CRITERIA FOR SUBJECTS

Age 21 years or older

Be able to give Informed Consent

Agree to comply with the follow-up requirements

Be treated with the Lutonix catheter

SUBJECT PAYMENT

Compensation will be \$25 for completed telephone visits at 30 days, 6 months, 24 months, 36 Months and \$50 for the one year in clinic follow up visit for a total of up to \$150. This payment will be made at the time of the visits.

RESEARCH LOCATION AND CONTACT PERSON

Lynn Skatrud, RN, CCRC

Meriter Wisconsin Heart

2601 West Beltline Hwy.

Suite 200

Madison, WI 53713

PHONE: 608-417-2168