MONARCH

POST-MARKET STUDY

CLINICAL STUDY PROTOCOL

Title: **A Prospective, Multi-Center, Single-Arm, Real World Study Assessing the Clinical Use of the Caterpillar™ Arterial Embolization Device for Arterial Embolization in the Peripheral Vasculature (MONARCH)**

Protocol Number: **BPV-18-001**

Study Type: **Post-Market**

Date: **December 17th, 2020**

Version: **2**

Study Device: **Caterpillar™ Arterial Embolization Device**

Sponsor: **Bard Peripheral Vascular, Inc.**
1625 West 3rd Street
Tempe, AZ 85281, USA

NCT Number: **NCT04244370**

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Sponsor – Ryan Melloy, Associate Director, Clinical Affairs — Date

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Lead Principal Investigator – Dr. William Rilling — Date

1. PROTOCOL SUMMARY

Title:	A Prospective, Multi-Center, Single-Arm, Real World Study Assessing the Clinical Use of the Caterpillar™ Arterial Embolization Device for Arterial Embolization in the Peripheral Vasculature
Sponsor:	Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, AZ 85281, USA
Objectives:	The primary objective of this study is to evaluate the performance and safety of the Caterpillar™ Arterial Embolization Device when used for arterial embolization in the peripheral vasculature in a real world, on-label application.
Design:	The post-market study is a prospective, multi-center, single-arm, real world study of the Caterpillar™ Arterial Embolization Device. Follow-up for all treated subjects will be performed at 30 days, as well as 6 and 12 months post-Index Procedure.
Study Device:	The Caterpillar™ Arterial Embolization Device (Caterpillar™ Micro and Caterpillar™) is a self-expanding arterial occlusion plug, intended for arterial embolization in the peripheral vasculature. The device is intended to be a permanent implant and consists of the following components: a cobalt-chrome stem, nickel-titanium fibers, platinum-iridium radiopaque marker bands and a polyurethane and polyethylene occlusion membrane. The Caterpillar™ Arterial Embolization Device is packaged as a single unit with the implant, loader, dispenser hoop, detachable delivery wire and torque tool. The device is intended for single-use only within a specific arterial vessel size range and does not require oversizing. The available sizes, product characteristics, intended arterial vessel diameter range and required delivery catheter size (inner diameter (ID)) are provided in the Instructions for Use (IFU).
Enrollment:	Enrollment will continue until up to fifty (50) subjects have been treated with the Caterpillar™ Arterial Embolization Device.
Study Sites:	Up to 20 investigational sites in the United States.
Study Population:	Male or non-pregnant female subjects ≥18 years of age who require arterial embolization in the peripheral vasculature.
Primary Endpoints:	**Primary Performance Endpoint:** **Technical Success** Successful occlusion of the target embolization site(s) as confirmed by the Investigator via angiographic assessment during the Index Procedure. Technical success will be reported for each target embolization site. **Primary Safety Endpoint:** **Freedom from Device-Related Serious Adverse Events (SAE)** Freedom from device-related serious adverse events (SAE) through 30-day follow-up.

Secondary Endpoints:	**Time Point of Occlusion** The percentage of target embolization site(s) with occlusion at ≤1, ≤2, ≤3, ≤4, ≤5, ≤10 and >10 minutes post-treatment. **Freedom from Recanalization** Freedom from clinically relevant recanalization of the target embolization site(s) through 30-days, 6 and 12-months follow-up as confirmed by the Investigator. Clinically relevant recanalization is defined as recanalization through the study device that requires a re-intervention. Freedom from recanalization will be reported for each target embolization site. **Freedom from Migration** Freedom from Migration will be reported for each study device as follows: • Freedom from clinically relevant acute migration of the study device(s) as confirmed by the Investigator via angiographic assessment during the Index Procedure. Clinically relevant migration is defined as migration of the study device from the target embolization site that requires intervention. • Freedom from clinically relevant migration of the study device(s) through 30-days, 6 and 12-months follow-up as confirmed by the Investigator. Clinically relevant migration is defined as migration of the study device from the target embolization site that requires a re-intervention. **Freedom from Device and/or Procedure-Related Adverse Events** Freedom from device and/or procedure-related adverse events (AE) through 30-days, 6 and 12-months follow-up. **Accuracy of Delivery** Accurate delivery of the study device to the target embolization site as assessed by the Investigator. **Ease of Trackability/Deliverability** Ease of study device trackability and deliverability as assessed by the Investigator. **Ease of Detachment** Ease of study device detachment as assessed by the Investigator. **Acceptability of Visibility** Acceptability of study device visibility under fluoroscopy as assessed by the Investigator.

Inclusion Criteria:	**Clinical Inclusion Criteria** 1. Subject or Legally Authorized Representative (LAR) must voluntarily sign and date the approved Informed Consent Form (ICF) prior to collection of study-specific data or performance of study-specific procedures. 2. Subject must be either male or non-pregnant female ≥18 years of age with an expected lifespan sufficient to allow for collection of primary endpoint data. 3. Subject must be willing and able to comply with protocol requirements, including all study visits and procedures. 4. Subject must require peripheral vascular occlusion at an arterial target embolization site(s) that can be treated with the Caterpillar™ Arterial Embolization Device according to the Instructions for Use (IFU). Note: Per Investigator discretion, up to five (5) Target Embolization Sites may be treated with up to ten (10) study devices per subject. **Angiographic Inclusion Criteria** 5. The target embolization site(s) must be located in a native arterial vessel(s) with the intended arterial vessel diameter ranges shown in the IFU, as assessed by the Investigator (via visual estimate). 6. The target embolization site(s) must have a landing zone sufficient to accommodate the device implant lengths shown in the IFU.
Exclusion Criteria:	**Clinical Exclusion Criteria** 1. The subject's access vessel(s) preclude safe insertion of the delivery catheter. 2. The subject's target embolization site(s) is located within a vein. 3. The subject's target embolization site(s) is located within the head, neck, heart or coronary vessels. 4. The subject's target embolization site(s) is located across highly locomotive joints or muscle beds (e.g. elbow, hip, knee, shoulder, thoracic inlet/outlet). 5. The subject's target embolization site(s) is located in a high-flow vessel where, in the opinion of the Investigator, there may be significant risk of migration and unintended (non-target site) occlusion. 6. The subject has a known allergy or hypersensitivity to contrast media that cannot be adequately pre-medicated. 7. The subject has a known allergy or hypersensitivity to any of the device materials including: cobalt, chromium, nickel, titanium, platinum, iridium, polyurethane or polyethylene. 8. The subject has planned use of anticoagulant (e.g. direct thrombin inhibitors, factor Xa inhibitors, vitamin K antagonists) or antiplatelet therapy before, during and/or after treatment with the study device,

	which, in the opinion of the Investigator, would clinically interfere with the study endpoints. 9. The subject has a known uncontrolled blood coagulation or bleeding disorder. 10. The subject has an unresolved systemic infection. 11. The subject's required pre-operative laboratory tests and/or physical examination indicate abnormal results, which, in the opinion of the Investigator, would clinically interfere with the study endpoints. 12. The subject has a connective tissue disorders (e.g. Ehlers-Danlos Syndrome), arteritis (e.g. Takayasu's Disease) or another circulatory disorder, which, in the opinion of the Investigator, would clinically interfere with the study endpoints. 13. The subject has another medical condition which, in the opinion of the Investigator, may cause him/her to be non-compliant with the protocol, may confound the data interpretation, or is associated with a life expectancy insufficient to allow for the collection of primary endpoint data. 14. The subject is currently participating in an investigational drug or another device study that has not completed the study treatment or that clinically interferes with the study endpoints. Note: Studies requiring extended follow-up visits for products that were investigational, but have since become commercially available, are not considered investigational studies.
Procedures:	All subjects will undergo an in-office clinical evaluation at the Screening Visit (prior to Index Procedure). Subjects that meet Eligibility Criteria will undergo additional in-office clinical evaluations and will be treated with the Caterpillar™ Arterial Embolization Device at the Index Procedure visit. An in-office follow-up visit or telephone contact will be performed at 30 days, as well as 6 and 12 months post-Index Procedure for all treated subjects.
Principal Investigator:	**William S. Rilling, MD, FSIR** Medical College of Wisconsin Division of Vascular and Interventional Radiology 9200 W Wisconsin Ave Milwaukee, WI 53226, USA
Medical Monitor:	**Daniel B. Brown, MD, FSIR** Vanderbilt University Medical Center Department of Radiology 1161 21st Avenue South Nashville, TN 37232, USA

2. STATISTICAL METHODS

This section describes the planned statistical analyses for the study. A detailed Statistical Analysis Plan (SAP) will be developed that outlines the methodology used in the statistical analyses described below.

2.1. Study Hypothesis

There is no formal statistical hypothesis for this study.

2.2. Sample Size Considerations

The sample size is based on potential adequacy of data to meet the study objectives; it is not based on any statistical consideration.

2.3. Data Analysis

The analysis population consists of all subjects who have been treated with the study device as defined in Section 5.2.3.

Data collected in this study will be summarized using descriptive statistics. Summary statistics will include frequency counts and percentages for categorical variables and mean, standard deviation, minimum, median, and maximum for continuous variables.

- educed number of embolization devices required per procedure, potentially resulting in reduced procedural time and fluoroscopy exposure