AVeNEW
CLINICAL STUDY

# CLINICAL STUDY PROTOCOL

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| **Title:** | **A Prospective, Multi-Center, Randomized, Concurrently-Controlled Clinical Study of the BARD® COVERA™ Arteriovenous (AV) Stent Graft in the Treatment of Stenosis in the Venous Outflow of AV Fistula Access Circuits (AVeNEW)** |
| **Protocol Number:** | **BPV-14-005** |
| **Study Type:** | **Investigational Device Exemption (IDE)** |
| **Date:** | **April 17, 2017** |
| **Version:** | **3.0** |
| **Study Device:** | **COVERA™ Vascular Covered Stent** |
| **Sponsor:** | **Bard Peripheral Vascular, Inc.**<br>1625 West 3rd Street<br>Tempe, AZ 85281 |

NCT Number: 02649946
*NCT Number added post-approval as per CT.gov requirement

[redacted]

BARD | PERIPHERAL VASCULAR

# 1 PROTOCOL SUMMARY

<table>
<tr><td>Title:</td><td>A Prospective, Multi-Center, Randomized, Concurrently-Controlled Clinical Study of the BARD® COVERA™ Arteriovenous (AV) Stent Graft in the Treatment of Stenosis in the Venous Outflow of AV Fistula Access Circuits</td></tr>
<tr><td>Sponsor:</td><td>Bard Peripheral Vascular, Inc.<br>1625 West 3rd Street<br>Tempe, AZ 85281</td></tr>
<tr><td>Objective :</td><td>The objective of this study is to assess the safety and effectiveness of the COVERA™ Vascular Covered Stent for the treatment of stenotic lesions in the upper extremity venous outflow of the AV access circuit.</td></tr>
<tr><td>Design & Overview:</td><td>This is a prospective, multi-center, randomized, concurrently-controlled clinical study designed to assess the safety and effectiveness of the COVERA™ Vascular Covered Stent for the treatment of stenotic lesions in the upper extremity venous outflow of the AV access circuit of hemodialysis subjects dialyzing with an AV fistula. This study will compare the use of the COVERA™ Vascular Covered Stent (following percutaneous transluminal angioplasty (PTA)) to PTA alone. This treatment is called the “Index Procedure.”<br><br>Follow-up for all treated subjects will be performed at hospital discharge, 30 and 90 days, as well as 6, 12, 18, and 24 months post-index procedure.</td></tr>
<tr><td>Study Device:</td><td>The COVERA™ Vascular Covered Stent is a highly flexible self-expanding endoprosthesis comprised of expanded polytetrafluoroethylene (ePTFE) encapsulating a nitinol (nickel-titanium alloy) stent framework. The inner lumen of the stent graft (blood contacting surface) is carbon impregnated.<br>The COVERA™ Vascular Covered Stent is available in a straight and a flared configuration. Devices will come on either an 8F or 9F system.<br>Table 1: COVERA™ Vascular Covered Stent Sizes
<table>
<tr><th colspan="2" rowspan="2"></th><th colspan="5">Covered Stent Length (mm)</th><th rowspan="2">Endovascular System Length (cm)</th></tr>
<tr><th>30*</th><th>40</th><th>60</th><th>80</th><th>100</th></tr>
<tr><td rowspan="5">Covered Stent Outer Diameter (mm)</td><td>6</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td rowspan="5">80 and 120</td></tr>
<tr><td>7</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>8</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>9</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td></tr>
<tr><td>10</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td></tr>
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* Note: only the straight configuration of the implant is available in 30mm length.</td></tr>
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| **Enrollment:** | A total of 280 subjects will be randomized to the study. The primary endpoint analysis will occur when 280 randomized subjects have completed or discontinued before their 6 month follow up. The key secondary endpoint analysis will occur when 280 randomized subjects have completed or discontinued before their 12 month follow up. All subjects will be followed for 24 months post index-procedure. |
| **Investigational Sites:** | Up to 35 investigational sites in the United States (US), Europe, and Australia/New Zealand will participate. Treated subjects will be distributed globally with 50-75% of the treated subjects in the U.S. |
| **Study Population:** | Male or non-pregnant female ≥ 21 years of age with an expected lifespan sufficient to allow for completion of all study procedures. Eligible subjects will have a hemodynamically significant stenosis. |
| **Inclusion Criteria** | **Clinical Inclusion Criteria**<br>1. Subject must voluntarily sign and date the Informed Consent Form (ICF) prior to collection of study data or performance of study procedures.<br>2. Subject must be either a male or non-pregnant female ≥ 21 years of age with an expected lifespan sufficient to allow for completion of all study procedures.<br>3. Subject must be willing to comply with the protocol requirements, including clinical and telephone follow-up.<br>4. Subject must have an upper extremity AV fistula that has undergone at least one successful dialysis session with two-needle cannulation, prior to the index procedure.<br>**Angiographic Inclusion Criteria**<br>5. Subject must have angiographic evidence of a stenosis ≥ 50% (by visual estimation) located in the venous outflow of the AV access circuit and present with clinical or hemodynamic evidence of AV fistula dysfunction.<br>6. The target lesion must be ≤ 9cm in length. Note: multiple stenoses may exist within the target lesion.<br>7. The reference vessel diameter of the adjacent non-stenotic vein must be between 5.0 and 9.0mm. |
| **Exclusion Criteria** | **Clinical Exclusion Criteria**<br>1. The subject is dialyzing with an AV graft.<br>2. The target lesion has had a corresponding thrombosis treated within 7 days prior to the index procedure.<br>3. The hemodialysis access is located in the lower extremity.<br>4. The subject has an infected AV fistula or uncontrolled systemic infection.<br>5. The subject has a known uncontrolled blood coagulation/bleeding disorder.<br>6. The subject has a known allergy or hypersensitivity to contrast media which cannot be adequately pre-medicated.<br>7. The subject has a known hypersensitivity to nickel-titanium (Nitinol) or tantalum.<br>8. The subject has another medical condition, which, in the opinion of the Investigator, may cause him/her to be non-compliant with the protocol, confound the data interpretation, or is associated with a life expectancy insufficient to allow for the completion of study procedures and follow-up.<br>9. 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 |

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| | 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.*<br>**Angiographic Exclusion Criteria**<br>10. Additional stenotic lesions (≥ 50%) in the venous outflow that are > 3cm from the edge of the target lesion and are **not** successfully treated (defined as ≤ 30% residual stenosis) prior to treating the target lesion.<br>11. An aneurysm or pseudoaneurysm is present within the target lesion.<br>12. The location of the target lesion would require the COVERA™ Vascular Covered Stent be deployed across the elbow joint.<br>13. The target lesion is located within a stent.<br>14. The location of the target lesion would require that the COVERA™ Vascular Covered Stent be deployed at or across the segment of fistula utilized for dialysis needle puncture (i.e., "cannulation zone").<br>15. The location of the target lesion would require that the COVERA™ Vascular Covered Stent be placed in the central veins (subclavian, brachiocephalic, Superior Vena Cava (SVC)) or under the clavicle at the thoracic outlet.<br>16. There is incomplete expansion of an appropriately sized angioplasty balloon to its expected profile, in the operator's judgment, during primary angioplasty at the target lesion prior to randomization. |
| **Procedures:** | All subjects will undergo a clinical evaluation at screening (prior to index procedure); treated subjects will also undergo a clinical evaluation prior to hospital discharge. A telephone screen to the subject and the dialysis center will be performed at all follow-up visits. The 6 month follow up should occur via an office visit to the investigational site in addition to the phone call to the dialysis center. |
| **Primary Endpoints** | **Primary Effectiveness Endpoints with Hypothesis Testing**<br>• Target Lesion Primary Patency (TLPP) through 6 months.<br>**Primary Safety Endpoint with Hypothesis Testing**<br>• Safety through 30 days. |
| **Secondary Endpoints:** | **Key Secondary Endpoint with Hypothesis Testing**<br>• TLPP through 12 months.<br>• Access Circuit Primary Patency (ACPP) through 6 months.<br>**Secondary Endpoints without Hypothesis Testing**<br>• TLPP through 30 days, 90 days, 18 months, and 24 months.<br>• ACPP through 30 days, 90 days, 12 months, 18 months, and 24 months.<br>• Rate of device and procedure related AEs involving the AV access circuit through 90 days, 6 months, 12 months, 18 months, and 24 months.<br>• Total Number of AV Access Circuit Reinterventions through 30 days, 90 days, 6 months, 12 months, 18 months, and 24 months.<br>• Total Number of Target Lesion Reinterventions through 30 days, 90 days, 6 months, 12 months, 18 months, and 24 months.<br>• Index of Patency Function (IPF) evaluated at 30 days, 90 days, 6 months, 12 months, 18 months, and 24 months.<br>• Index of Patency Function – Target Lesion (IPF-T) evaluated at 30 days, 90 days, 6 months, 12 months, 18 months, and 24 months.<br>• Secondary Patency evaluated through 30 days, 90 days, 6 months, 12 months, 18 |

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| | months, and 24 months.<br>• Acute Technical Success.<br>• Acute Procedure Success (Anatomic and Clinical Success). |
| **Lead Principal Investigator:** | [redacted] |
| **Angiographic Core Lab** | [redacted] |

STATISTICAL ANALYSIS PLAN

## 1.1 Overview of Study Design

The clinical study will be a prospective, multi-center, randomized safety and effectiveness study with the primary objective to demonstrate superior effectiveness and non-inferior safety of the COVERA™ Vascular Covered Stent by direct comparison to standard PTA alone for treatment of lesions of AV fistulas.

For the study to be considered successful, superiority of the COVERA™ Vascular Covered Stent must be demonstrated for the primary effectiveness endpoint, and non-inferiority of the COVERA™ Vascular Covered Stent must be demonstrated for the primary safety endpoint as compared to PTA alone.

## 1.2 Analysis populations

The analysis populations will be defined as follows for this study:

- The ITT population will consist of all enrolled subjects who have signed the ICF and have been randomized.

- The Modified ITT (MITT) population will consist of any subjects in the ITT population who are treated with the COVERA™ Vascular Covered Stent (following PTA) or PTA alone.

- A Per-Protocol (PP) population may be created if there are subjects who have any major protocol deviations. The PP population will consist of any subjects in the MITT population who do not have any major protocol deviation. The protocol deviations that are considered to have a "major" grade will be defined a priori in the analysis plan.

All analyses including the primary analyses will be primarily based on the MITT population. PP analyses may also be performed for the primary endpoints. They will only serve as sensitivity analyses for the primary analyses which are based on the MITT population. Additionally As-treated (AT) analysis may be performed in which subjects will be analyzed based on the actual treatment received instead of the randomized treatment, if there are subjects randomized but received the wrong treatment.

## 1.3 Randomization

The treatment randomization will be 1:1.

## 1.4 Assessment of the Comparability of Treatment Groups and Poolability of Investigational Sites

To demonstrate the comparability of the Control to Test subjects, the treatment groups will be compared with respect to demographics and baseline characteristics and other covariates using t-tests or Wilcoxon nonparametric tests for means and $X^2$-tests for proportions.

Demographics, baseline characteristics and other covariates will also be compared between the treatment groups by sites using descriptive statistics. Both primary endpoints will also be summarized by treatment group and by site. This can help identify any confounding covariates that can potentially explain the variability of the treatment effect across sites. Sites with fewer than 10 treated subjects may be combined for this purpose. The pooling will be restricted within country.

For the primary effectiveness endpoint, an analysis will be performed to examine the potential for interaction of site and treatment group. A Cox regression model will be fit that includes fixed effect for treatment group, site and the interaction of treatment group and site. If the p-value for the interaction term is <0.15, it will be considered evidence of a possible significant interaction effect, and additional analyses will be performed to explore the differences between sites to assess their potential causes and whether or not they are clinically meaningful.

For the primary safety endpoint, an analysis will be performed as well to examine the potential for interaction of site and treatment group. A logistic regression model will be fit that includes fixed effect for treatment group, site and the interaction of treatment group and site. If the p-value for the interaction term is <0.15, it will be considered evidence of a possible significant interaction effect, and additional analyses will be performed to explore the differences between sites to assess their potential causes and whether or not they are clinically meaningful.

Both primary endpoints will also be presented by geography (US versus OUS). Similar analyses will be performed to examine the potential for interaction of geography and treatment group for both endpoints. A Cox regression model for the primary effectiveness endpoint and a logistic regression model for the primary safety endpoint will be fit that includes fixed effect for treatment group, geography and the interaction of treatment group and geography. If the p-value for the interaction term is <0.15, it will be considered evidence of a possible significant interaction effect, and additional analyses will be performed to explore the differences between geographies to assess their potential causes and whether or not they are clinically meaningful.

## 1.5 Handling of Missing Data

Study endpoints may be missing due to withdrawal of consent, Investigator's decision, LTF and subject death. It is important to minimize missing data by all means and always record the reason for missing. Missing data will be handled as described subsequently.

The primary analysis of the primary effectiveness endpoint is a survival analysis. As a sensitivity analysis, the primary safety endpoint will also be analyzed using survival analysis techniques. In survival analyses, unobserved endpoints are a standard part of the analysis; they are known as "censored observations". As long as the censoring is unrelated to the treatment, this method of handling missing endpoints produces unbiased estimates of the freedom-from-event rates. In addition, as a sensitivity analysis, the primary effectiveness endpoint will be analyzed as a proportion-based binomial rate.

For both primary endpoints, the reason for the censoring of all subjects with missing endpoints will be reported. If there is any indication that the censoring is related to the treatment group, a worst-case analysis may be performed for each primary endpoint, in addition to the standard analysis. In a worst-case analysis, an event will be assumed to have occurred at the time the subject was censored for all such subjects in the Test group. In the Control group, all subjects with missing data will be assumed *not* to have had an event.

In addition, regardless of whether missing data are related to the study intervention, a tipping-point analysis will also be performed, in which assumptions about missing data are varied from worst-case to best-case to examine at what point the missing data would alter the results of the analysis.

## 1.6 Sample Size Estimation

The sample size is estimated to give adequate power on the two co-primary endpoints as well as for the key secondary endpoint. Sample size assumptions and determinations are summarized subsequently.

1) Key Secondary Endpoint – TLPP at 12 months:
   - Assumptions:
     - TLPP rate through 12 months for the study device treated subjects is 55%;
     - TLPP rate through 12 months for the PTA only treated subjects is 33%;
     - Allocation ratio: 1:1;
     - Attrition (drop-out) rate (by 12 months) = 15%
     - The Type 1 error, $\alpha = 0.025$ (one-sided); and
     - The Type 2 error, $\beta = 0.10$ (Power = $1 - \beta = 90\%$).
   - Sample Size:
     - 280 randomized subjects [238 evaluable] will give 90% power with one-sided type I error =0.025.

2) Primary Effectiveness Endpoint – TLPP at 6 months:
   - Assumptions:
     - TLPP rate through 6 months for the study device treated subjects is 73%;
     - TLPP rate through 6 months for the PTA only treated subjects is 50%;
     - Allocation ratio: 1:1;
     - Attrition (drop-out) rate (by 6 months) = 10%
     - The Type 1 error, $\alpha = 0.025$ (one-sided); and
     - The Type 2 error, $\beta = 0.10$ (Power = $1 - \beta = 95\%$).
   - Sample Size:
     - 280 randomized subjects [252 evaluable] will give 95% power with one-sided type I error =0.025.

3) Primary Safety Endpoint – Safety at 30 days:
   - Assumptions:
     - The primary safety rate through 30 days in the study device treated subjects is 95%;
     - The primary safety rate through 30 days in the PTA only treated subjects is 95%;
     - Non-inferiority margin $\delta = 10\%$;
     - Allocation ratio: 1:1;
     - Attrition rate (by day 30) = 5%; and
     - The Type 1 error, $\alpha = 0.025$ (one-sided).
   - Sample Size:
     - 280 randomized subjects [266 evaluable] will give 91% power with one-sided type I error =0.025.

Hence, the sample size of 280 randomized subjects, allocated 1:1, for 140 subjects in the COVERA™ Vascular Covered Stent arm and 140 subjects in the PTA alone arm, will provide approximately 86% power for the both primary effectiveness and primary safety endpoint. The sample size of 280 randomized subjects, allocated 1:1 for 140 subjects in the COVERA™ Vascular Covered Stent arm and 140 in the PTA alone arm, will provide approximately 90% power for the key secondary endpoint.

## 1.7 Primary Endpoints

### 1.7.1 Primary Effectiveness Endpoint

The Primary effectiveness endpoint is TLPP evaluated at 6 months (Refer to Section 4.1.1 for applicable definitions). In order to demonstrate clinically acceptable effectiveness, this randomized study will assess superiority of the rate of TLPP at 6 months of the COVERA™ Vascular Covered Stent as compared to standard PTA alone.

### 1.7.2 Primary Effectiveness Endpoint Hypothesis Test

The primary effectiveness endpoint is TLPP through 6-months. Objective: To assess if the 6 month TLPP for the COVERA™ Vascular Covered Stent is superior to that of PTA alone, by direct comparison.

The primary effectiveness endpoint will be evaluated by the following hypothesis:

**$H_0$**: The (survival) rate $S_1(t)$ of subjects in the study device treatment group with TLPP through $t \leq 6$ month post index procedure is less than or equal to that $S_2(t)$ of PTA treatment group.

**$H_1$**: The (survival) rate $S_1(t)$ of subjects in the study device treatment group with TLPP through $t \leq 6$ month post index procedure is greater than that $S_2(t)$ of PTA treatment group.

That is:

**$H_0$**: $S_1(t) \leq S_2(t)$, for $t \leq 6$ months

**$H_1$**: $S_1(t) > S_2(t)$, for $t \leq 6$ months

Rejection of the null hypothesis will signify that the 6 month TLPP of the COVERA™ Vascular Covered Stent is superior to the 6 month TLPP of PTA alone.

A Kaplan-Meier analysis will be used to estimate the survival rate of TLPP in the COVERA™ Vascular Covered Stent and PTA alone groups. A log-rank test will be used to test the primary effectiveness hypothesis to determine if COVERA™ Vascular Covered Stent is superior to PTA. The test is successful if the one-sided p-value is less than 0.025 and the result is in favor of the COVERA™ Vascular Covered Stent. In addition to the p-value of the test, the confidence intervals of the rate in each group will be provided.

### 1.7.3 Primary Safety Endpoint

The primary safety endpoint is proportion of subjects who are free from localized or systemic adverse events through 30 days that reasonably suggests the involvement of the AV access circuit (Refer to Section 4.1.2 for applicable definitions).

### 1.7.4 Primary Safety Endpoint Hypothesis Test

The primary safety endpoint is safety through 30 days. Objective: To assess if the 30-day primary safety rate for the study device is non-inferior to that of PTA alone, by direct comparison:

**$H_0$**: The primary safety rate $p_1$ in the Test group through 30 days post index procedure is inferior to that $p_2$ of the PTA treatment group.

**$H_1$**: The primary safety rate $p_1$ in the Test group through 30 days post index procedure is non-inferior to that $p_2$ of the PTA treatment group.

That is:

**$H_0$**: $p_1 \leq p_2 - \delta$

**$H_1$**: $p_1 > p_2 - \delta$

Where $\delta = 10\%$ is the non-inferiority margin, which is the range of difference that is considered not clinically important.

Non-inferiority Farrington and Manning Exact Test will be used to test the primary safety hypothesis. The test is successful if the one-sided p-value is less than 0.025. In addition to the p-value of the test, the confidence intervals of the rate in each group and the difference between the two groups will be provided.

## 1.8 Evaluation of Secondary Endpoints

All secondary endpoints will be tested as exploratory only unless both primary hypotheses are successful. The testing of the secondary objectives will be performed in a hierarchical fashion in the order in which they are listed below. This means that as soon as a null hypothesis is *not rejected*, all further hypotheses will be tested for exploratory purpose only. This hierarchical testing scheme ensures that the study-wide Type 1 error rate remains at 0.05 when all of the secondary endpoints are tested at $\alpha$=0.05.

### 1.8.1 Key Secondary Endpoint with Hypothesis Test: TLPP at 12 Months

The key secondary effectiveness endpoint is TLPP through 12-months. Objective: To assess if the 12 month TLPP for the COVERA™ Vascular Covered Stent is superior to that of PTA alone, by direct comparison.

The primary effectiveness endpoint will be evaluated by the following hypothesis:

**$H_0$**: The (survival) rate $S_1(t)$ of subjects in the study device treatment group with TLPP through $t \leq 12$ month post index procedure is less than or equal to that $S_2(t)$ of PTA treatment group.

**$H_1$**: The (survival) rate $S_1(t)$ of subjects in the study device treatment group with TLPP through $t \leq 12$ month post index procedure is greater than that $S_2(t)$ of PTA treatment group.

That is:

**$H_0$**: $S_1(t) \leq S_2(t)$, for $t \leq 12$ months

**$H_1$**: $S_1(t) > S_2(t)$, for $t \leq 12$ months

Rejection of the null hypothesis will signify that the 12 month TLPP of the COVERA™ Vascular Covered Stent is superior to the 12 month TLPP of PTA alone.

A Kaplan-Meier analysis will be used to estimate the survival rate of TLPP in the COVERA™ Vascular Covered Stent and PTA alone groups. A log-rank test will be used to test the key secondary effectiveness hypothesis to determine if the COVERA™ Vascular Covered Stent is superior to PTA. The test is successful if the one-sided p-value is less than 0.025 and the result is in favor of the COVERA™ Vascular Covered Stent. In addition to the p-value of the test, the confidence intervals of the rate in each group will be provided. Note that, unless both the primary endpoints are successful, hypothesis for the key secondary effectiveness will be tested for exploratory purpose only.

1.8.2 Key Secondary Endpoint with Hypothesis Test: ACPP at 6 Months

The key secondary endpoint is ACPP evaluated at 6 months (Refer to Section 4.2.1 for applicable definitions). Objective: To assess if the 6 months ACPP rates for the COVERA™ Vascular Covered Stent is superior to the primary patency rate for standard PTA, by direct comparison:

**$H_0$**: The (survival) rate $S_1(t)$ of subjects in the study device treatment group with ACPP through $t \leq 6$ month post index procedure is less than or equal to that $S_2(t)$ of PTA treatment group.

**$H_1$**: The (survival) rate $S_1(t)$ of subjects in the study device treatment group with ACPP through $t \leq 6$ month post index procedure is greater than that $S_2(t)$ of PTA treatment group.

That is:

**$H_0$**: $S_1(t) \leq S_2(t)$, for $t \leq 6$ months

**$H_1$**: $S_1(t) > S_2(t)$, for $t \leq 6$ months

Rejection of the null hypothesis will signify that the 6 month ACPP of the COVERA™ Vascular Covered Stent is superior to the 6 month ACPP of standard PTA alone.

A Kaplan-Meier analysis will be used to estimate the survival rate of ACPP in the COVERA™ Vascular Covered Stent and PTA alone groups. A log-rank test will be used to test this hypothesis to determine if the COVERA™ Vascular Covered Stent is superior to PTA alone. The test is successful if the two-sided p-value is less than 0.05 and the result is in favor of the COVERA™ Vascular Covered Stent. In addition to the p-value of the test, the confidence intervals of the rate in each group will be provided. Note that, unless both the primary endpoints, and the TLPP at 12-month endpoint are all successful, the hypothesis for the ACPP at 6-month will be tested for exploratory purpose only.

1.8.3 Secondary Endpoints with Descriptive Statistics

The following secondary endpoints will be summarized with descriptive statistics (without formal statistical hypothesis testing) using the MITT population. For categorical variables, summary statistics will include frequency counts and percentages. For continuous variables, summary statistics will include mean, standard deviation, minimum, median, and maximum. Refer to Section 4.2.2 for any applicable definitions.

- TLPP through 30 days, 90 days, 18 months, and 24 months.
- ACPP through 30 days, 90 days, 12 months, 18 months, and 24 months.
- Rate of device and procedure related AEs involving the AV access circuit through 90 days, 6 months, 12 months, 18 months, and 24 months.
- Total Number of AV Access Circuit Reinterventions through 30 days, 90 days, 6 months, 12 months, 18 months, and 24 months.
- Total Number of Target Lesion Reinterventions through 30 days, 90 days, 6 months, 12 months, 18 months, and 24 months.
- IPF evaluated at 30 days, 90 days, 6 months, 12 months, 18 months, and 24 months follow-up.
- IPF-T evaluated at 30 days, 90 days, 6 months, 12 months, 18 months, and 24 months.
- Secondary Patency evaluated through 30 days, 90 days, 6 months, 12 months, 18 months, and 24 months.
- Acute Technical Success.
- Acute Procedure Success (Anatomic and Clinical Success).