INTENDED USE / INDICATIONS FOR USE

The Innova Vascular Self-Expanding Stent System is indicated to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery (PPA) with reference vessel diameters from 4.0 mm to 7.0 mm and lesion lengths up to 180 mm.

CONTRAINDICATIONS

• Patients with contraindication to antithrombotic and/or antiplatelet therapy.

• Patients who exhibit angiographic evidence of severe thrombus in the target vessel or lesion site before/after undergoing Percutaneous Transluminal Angioplasty (PTA) procedure.

• A lesion through which a guide wire cannot pass.

WARNING

Do not use after the "Use By" date specified on the package. Ensure that the device has been properly stored in a cool, dark, dry place not to exceed 51 °C (124 °F).

Do not use if the temperature exposure indicator dot on the pouch label is red or missing.

Do not expose to organic solvents (e.g. alcohol).

Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures.

The stent is not designed for repositioning; once the stent is partially deployed, it cannot be "recaptured" or "reconstrained" using the stent delivery system.

PRECAUTIONS

• The delivery system is not designed for use with power injection systems.

• Do not use a kinked delivery system.

• Only advance the stent delivery system over a stiff 0.035 in guidewire.

• Always use an introducer or guide sheath for the implant procedure, to protect the access site.

• If strong resistance is met with the introduction of the delivery system, or if unable to initiate release of the stent, remove the entire system from the patient and introduce a new system.

• Never post-dilate the stent using a balloon that is larger in diameter than the nominal (labeled) diameter of the stent.

• When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.

• The stent delivery system is not intended for arterial blood monitoring.

• The minimally acceptable introducer or guide sheath size is printed on the package label. Do not attempt to pass the stent delivery system through a smaller size introducer or guide sheath than indicated on the label.

• Do not remove the thumbwheel lock prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent.

• Prior to deployment, ensure adequate distance between the proximal end of the stent and the introducer/guide sheath to prevent deployment within introducer/guide sheath.

• This device has not been tested in patients who are pregnant or patients who may be pregnant.

• Take caution when considering whether to use this device in patients with known allergy to nickel-titanium alloy or contrast media.

• Take caution when considering whether to use this device in patients with known allergy to nickel-titanium alloy or contrast media.

• In patients with poor kidney function, contrast agents may precipitate kidney failure.
A patient with this device can be scanned safely only under specific conditions. Failure to follow the conditions may result in severe injury. Non-clinical testing has demonstrated the Innovia™ Stents are MR Conditional for single and overlapping lengths ≤ 190 mm located at least 3 cm above the inferior edge of the femur. Subject follow-up occurred at 30 days, 6 months, 12 months, 2 years and 3 years (or 5 years in Japan only) in subjects successfully implanted with the Innova stent(s).

Eligible subjects were 18 years or older who consented to participate. These subjects had documented peripheral arterial disease defined as Rutherford categories 2, 3, or 4 and evidence of a stenotic, restenotic (from angioplasty only) or occlusive lesion(s) located in the native superficial femoral artery or proximal popliteal artery with degree of stenosis ≥ 70% by visual angiographic assessment. The vessel diameter was ≥ 4 mm and ≤ 7 mm and total lesion length was ≥ 30 mm and ≤ 190 mm located at least 3 cm above the inferior edge of the femur. Subject follow-up occurred at 30 days, 6 months, 12 months, 2 years and 3 years (or 5 years for subjects at Japan sites only). The first subject was enrolled April 1, 2011. Enrollment completed June 28, 2013. The database for this study reflects data collected through August 14, 2014.

The primary study endpoints were as follows:

- The primary safety endpoint was a composite of Major Adverse Events (MAE) defined as all causes of death through 1 month post-index procedure, target limb major amputation through 12 months post-index procedure and/or Target Lesion Revascularization (TLR) through 12 months post-index procedure. The primary safety endpoint assessed the composite MAE rate in order to demonstrate a 12 month MAE-free rate exceeds the performance goal (PG) of 59.6%.

- The co-primary effectiveness endpoints assessed primary stent patency rate at 12 months. Primary patency was defined as the percentage of lesions (target stented segments) that reach endpoint without a hemodynamically significant stenosis on DUS (Systolic Velocity (PSV) ratio < 2.4), and without TLR or bypass of the target lesion.

- The co-primary effectiveness endpoint (1) assessed stented segments intended to be treated with the core stent matrix (stent lengths from 20 mm to 150 mm) in stented segments intended to be treated with the entire stent matrix (stent lengths from 20 mm to 200 mm) in order to demonstrate that the 12 month vessel primary patency rate exceeds the PG of 66%.

- The co-primary effectiveness endpoint (2) assessed stented segments intended to be treated with the entire stent matrix (stent lengths from 20 mm to 200 mm) in order to demonstrate that the 12 month vessel primary patency rate exceeds the PG of 63%. In addition to rejecting the null hypothesis, a non-statistically driven goal needed to be observed, such that the rate of vessel primary patency at 12 months observed with the long stents must be ≥ 50%.

The SuperNOVA Study employed independent duplex ultrasonic, x-ray and angiographic core laboratories to review and analyze key study variables. An independent data reviewer was used to review study data on an ongoing basis and identify any potential safety trends. Adjudication of any potential major adverse events was conducted by an independent Clinical Events Committee (CEC).
## Patient Population

Table 1 provides a review of baseline demographics and clinical characteristics of the 299 subjects enrolled into the SuperNOVA study.

### Table 1: Baseline Demographics and Clinical Characteristics Overall (N=299)

<table>
<thead>
<tr>
<th>Age (Year)</th>
<th>67.4±9.7 (299) (45.0, 93.0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male Gender</td>
<td>74.2% (222/299)</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>1.3% (4/299)</td>
</tr>
<tr>
<td>Caucasian</td>
<td>79.6% (238/299)</td>
</tr>
<tr>
<td>Asian</td>
<td>14.0% (42/299)</td>
</tr>
<tr>
<td>Black, or African heritage</td>
<td>4.3% (13/299)</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>0.3% (1/299)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>0.3% (1/299)</td>
</tr>
<tr>
<td>Other</td>
<td>0.0% (0/299)</td>
</tr>
<tr>
<td>Not Disclosed</td>
<td>0.0% (0/299)</td>
</tr>
</tbody>
</table>

### General Medical History

- **History of Smoking**: 83.9% (251/299)
- **Current Diabetes Mellitus**: 40.5% (121/299)
  - Type 1: 2.3% (7/299)
  - Type 2: 36.8% (110/299)
  - Unknown: 1.3% (4/299)
- **Medically-Treated Diabetes**: 35.1% (105/299)
- **History of Hyperlipidemia requiring medication**: 74.9% (224/299)
- **History of Hypertension requiring medication**: 79.9% (238/299)
- **History of Chronic Obstructive Pulmonary Disease**: 4.3% (13/299)

### Cardiac History

- **History of Coronary Artery Disease**: 43.5% (130/299)
- **History of Myocardial Infarction (MI)**: 24.7% (74/299)
- **History of Congestive Heart Failure**: 8.4% (25/299)
- **New York Heart Assoc. (NYHA) Classification**:
  - I: 1.3% (4/299)
  - II: 2.7% (8/299)
  - III: 1.3% (4/299)
  - IV: 0.3% (1/299)
- **Unknown**: 2.7% (8/299)
- **History of Percutaneous Coronary Intervention (PCI)**: 28.4% (85/299)
- **History of Coronary Artery Bypass Graft (CABG) Surgery**: 18.1% (54/299)

### Current Angina Status

- **Stable Angina**: 14.7% (44/299)
- **Unstable Angina**: 0.3% (1/299)
- **None**: 81.9% (245/299)

### Neurologic/Renal History

- **History of Transient Ischemic Attacks (TIA)**: 7.0% (21/299)
- **History of Cerebrovascular Accident (CVA)**: 8.0% (24/299)
- **History of Renal Insufficiency**: 10.4% (31/299)
- **History of Renal Percutaneous Intervention**: 1.3% (4/299)

---

## Lesion Characteristics

Table 2 and Table 3 present the site-reported and angiographic core lab assessed lesion characteristics, respectively.

### Table 2: Baseline Site-Reported Lesion Characteristics (N=299 Lesions)

<table>
<thead>
<tr>
<th>Overall</th>
<th>Treated Limb</th>
<th>Right leg</th>
<th>Left leg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial Segments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal</td>
<td>11.0% (33/299)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mid</td>
<td>58.2% (174/299)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal</td>
<td>58.2% (174/299)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ostial</td>
<td>0.3% (1/299)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal Popliteal Artery</td>
<td>15.7% (47/299)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Lesion Reference Vessel Diameter (RVD, mm)</td>
<td>5.6±0.7 (299) (4.0, 7.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Lesion % Diameter Stenosis</td>
<td>91.7±8.2 (299) (70.0, 100.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Lesion Length (mm)</td>
<td>90.6±44.4 (299) (30.0, 190.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombus Seen</td>
<td>2.3% (7/299)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### TASC II Lesion Classification

- **A**: 40.5% (121/299)
- **B**: 42.1% (126/299)
- **C**: 13.7% (41/299)
- **D**: 3.7% (11/299)

### Predicted

- **Predilation Performed**: 81.9% (245/299)
  - If Yes, Number of Predilation Balloons Used: 1.1±0.4 (299) (1.0, 5.0)
- **Post-Deployment Dilation**
  - Post-Deployment Dilation Performed: 96.7% (289/299)
  - If Yes, Number of Post-deployment Balloons Used: 1.1±0.4 (289) (1.0, 3.0)
- **Target Lesion Final Outcome**
  - Final % Stenosis: 4.2±8.2 (299) (0.0, 50.0)
  - Thrombus seen in treated vessel at the end of the procedure: 0.7% (2/299)

---

*Values include the mean plus/minus standard deviation and range.

*Subjects under "Arterial Segments" may have checked more than one location present.
Table 3: Angiographic Core Lab Baseline Measurements (N=299 Lesions)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Leg</td>
<td>45.6% (136/298)</td>
</tr>
<tr>
<td>Left Leg</td>
<td>54.4% (162/298)</td>
</tr>
</tbody>
</table>

Arterial Segments:
- Proximal: 10.4% (31/298)
- Mid: 57.0% (170/298)
- Distal: 67.4% (201/298)
- Ostial: 1.7% (5/298)
- Proximal Popliteal Artery: 15.1% (45/298)

Distance from Ostium (mm): 100.1±54.2 (75) (0.0, 233.1)

Length (mm): 93.2±49.1 (293) (10.2, 284.7)

Reference Vessel Diameter (RVD) (mm): 5.0±0.9 (295) (2.9, 7.6)

Lesion Type:
- Eccentric Lesion: 46.6% (138/298)
- Concentric Lesion: 52.3% (156/298)

Bend (degrees):
- >45 degrees: 0.0% (0/298)
- >90 degrees: 0.0% (0/298)

Thrombus:
- Grade 0: 97.7% (291/298)
- Grade 1: 0.7% (2/298)
- Grade 2: 0.3% (1/298)
- Grade 3: 0.3% (1/298)
- Grade 4: 0.0% (0/298)
- Grade 5: 0.0% (0/298)

Calcification:
- None/Mild: 29.5% (88/298)
- Moderate: 34.6% (103/298)
- Severe: 35.6% (108/298)

Ulceration (Present): 13.4% (40/298)

Aneurysm (Present): 3.4% (10/298)

Patency to Foot:
- No Infrapopliteal Vessel Patent: 9.2% (23/250)
- 1 Infrapopliteal Vessel Patent: 30.0% (75/250)
- 2 Infrapopliteal Vessel Patent: 37.6% (94/250)
- 3 Infrapopliteal Vessel Patent: 23.2% (56/250)
- Anterior Tibial Artery Patent: 37.6% (112/298)
- Posterior Tibial Artery Patent: 54.0% (161/298)
- Peroneal Artery Patent: 56.7% (168/298)
- Profunda Femoris Artery Patent: 66.1% (197/298)

Study Results

Primary Safety Endpoint Results

Secondary Safety Endpoint Results

Table 4 summarizes the primary safety endpoint results for the SuperNOVA study. The 12 month MAE free rate was 85.6% with the lower 95% Confidence Interval (CI) exceeding the established PG of 59.6%.

Table 4: Primary Safety Endpoint and Components (N=299 Subjects)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Overall</th>
<th>95% CI</th>
<th>Lower 1-Sided</th>
<th>PG</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-Month Freedom from MAE</td>
<td>85.8% (230/286)</td>
<td>(81.1%, 89.8%)</td>
<td>81.1% (Met)</td>
<td>59.6%</td>
</tr>
<tr>
<td>12-Month MAE (Composite Endpoint)</td>
<td>14.2% (36/258)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Causes of Deaths at 1 Month</td>
<td>0.0% (0/289)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Limb Major Amputation</td>
<td>0.4% (1/285)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Lesion Revascularization (TLR)</td>
<td>14.2% (36/258)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Secondary Safety Endpoint Results

Table 5 summarizes the secondary safety endpoint results for the SuperNOVA study. The 1 month MAE free rate was 99.7%.

Table 5: Secondary Safety Endpoint and Components (N=299 Subjects)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Overall</th>
<th>95% CI</th>
<th>Lower 1-Sided</th>
<th>PG</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Month Freedom from MAE</td>
<td>99.7% (296/297)</td>
<td>(98.1%, 100.0%)</td>
<td>98.1% (Met)</td>
<td>88.0%</td>
</tr>
<tr>
<td>1-Month MAE (Composite Endpoint)</td>
<td>0.3% (1/297)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Causes of Deaths</td>
<td>0.0% (0/297)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Limb Major Amputation</td>
<td>0.0% (0/297)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Lesion Revascularization (TLR)</td>
<td>0.3% (1/297)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes:
- Values include the mean ± one standard deviation and range.
- Core lab reported "Treated Limb" may differ from the site reported "Treated Limb".
- Subjects under "Arterial Segments" may have checked more than one location present.
- Thrombus could have subjects with "N/A" response as allowed by CRF so percentages may not add up to 100%.
**Evaluation of Safety**

Table 6 displays the rates of Serious Adverse Events (SAEs) reported by MedDRA System/Organ Class (SOC). The sub-categories are Preferred Terms (PTs), and include only those SAEs that were reported by the treating physician as related to the device and/or the procedure.

Table 6: Serious Adverse Events by MedDRA System/Organ Class

<table>
<thead>
<tr>
<th>Event Category</th>
<th>PTs</th>
<th>Rate of Subjects With Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any serious adverse event</td>
<td>309</td>
<td>49.2% (147/299)</td>
</tr>
<tr>
<td>Not coded</td>
<td>4</td>
<td>0.7% (2/299)</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>36</td>
<td>8.4% (25/299)</td>
</tr>
<tr>
<td>Congenital, familial and genetic disorders</td>
<td>1</td>
<td>0.3% (1/299)</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>18</td>
<td>4.3% (12/299)</td>
</tr>
<tr>
<td>Retropertioneal hematoma</td>
<td>2</td>
<td>0.7% (2/299)</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>14</td>
<td>4.3% (13/299)</td>
</tr>
<tr>
<td>Catheter site hemorrhage</td>
<td>2</td>
<td>0.7% (2/299)</td>
</tr>
</tbody>
</table>

**Primary Effectiveness Results**

Table 7 presents primary patency results for the co-primary effectiveness endpoints incorporated into the SuperNIWA study. The performance goal of 60% was not met.

Table 7: Primary Patency in Core Stents Subjects through 12 Months

<table>
<thead>
<tr>
<th>Time from Index Procedure (months)</th>
<th>Number of Subjects</th>
<th>Entered</th>
<th>Censored</th>
<th>Events/Month</th>
<th>Events</th>
<th>Event Rate</th>
<th>At Risk</th>
<th>Std Error</th>
<th>SVS SE</th>
<th>SVS % CI</th>
<th>Event Free</th>
<th>Std Error</th>
<th>SVS % CI</th>
<th>Event Free</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-Month Primary Patency in Core Matrix Stents</td>
<td>259.5</td>
<td>259</td>
<td>254</td>
<td>244</td>
<td>243</td>
<td>243</td>
<td>236</td>
<td>220</td>
<td>95% CI</td>
<td>97.5% CI</td>
<td>66% (Not Met)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-Month Primary Patency in Entire Stent Matrix</td>
<td>298.5</td>
<td>298</td>
<td>293</td>
<td>283</td>
<td>282</td>
<td>280</td>
<td>269</td>
<td>246</td>
<td>95% CI</td>
<td>97.5% CI</td>
<td>66% (Not Met)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-Month Primary Patency in Long Stents</td>
<td>281.5</td>
<td>281</td>
<td>275</td>
<td>265</td>
<td>265</td>
<td>265</td>
<td>265</td>
<td>265</td>
<td>95% CI</td>
<td>97.5% CI</td>
<td>66% (Not Met)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As presented in Figure 1 and Table 9, the freedom from loss of primary patency at 12 months for the entire stent matrix was 73.7%.

**Figure 1. Primary Patency in Core Stents through 12 Months**

**Figure 2. Primary Patency in All Stents through 12 Months**

**Table 8: Primary Patency in All Stents through 12 Months**

<table>
<thead>
<tr>
<th>Time from Index Procedure (months)</th>
<th>Number of Subjects</th>
<th>Entered</th>
<th>Censored</th>
<th>Events/Month</th>
<th>Events</th>
<th>Event Rate</th>
<th>At Risk</th>
<th>Std Error</th>
<th>SVS SE</th>
<th>SVS % CI</th>
<th>Event Free</th>
<th>Std Error</th>
<th>SVS % CI</th>
<th>Event Free</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-Month Primary Patency in Long Stents</td>
<td>321.5</td>
<td>321</td>
<td>315</td>
<td>305</td>
<td>304</td>
<td>303</td>
<td>292</td>
<td>278</td>
<td>95% CI</td>
<td>97.5% CI</td>
<td>66% (Not Met)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-Month Primary Patency in Long Stents</td>
<td>315.5</td>
<td>315</td>
<td>309</td>
<td>300</td>
<td>299</td>
<td>298</td>
<td>290</td>
<td>276</td>
<td>95% CI</td>
<td>97.5% CI</td>
<td>66% (Not Met)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As presented in Figure 2 and Table 9, the freedom from loss of primary patency at 12 months for the entire stent matrix was 73.7%.

**Table 9: Primary Patency in All Stents through 12 Months**

<table>
<thead>
<tr>
<th>Time from Index Procedure (months)</th>
<th>Number of Subjects</th>
<th>Entered</th>
<th>Censored</th>
<th>Events/Month</th>
<th>Events</th>
<th>Event Rate</th>
<th>At Risk</th>
<th>Std Error</th>
<th>SVS SE</th>
<th>SVS % CI</th>
<th>Event Free</th>
<th>Std Error</th>
<th>SVS % CI</th>
<th>Event Free</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-Month Primary Patency in Long Stents</td>
<td>321.5</td>
<td>321</td>
<td>315</td>
<td>305</td>
<td>304</td>
<td>303</td>
<td>292</td>
<td>278</td>
<td>95% CI</td>
<td>97.5% CI</td>
<td>66% (Not Met)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-Month Primary Patency in Long Stents</td>
<td>315.5</td>
<td>315</td>
<td>309</td>
<td>300</td>
<td>299</td>
<td>298</td>
<td>290</td>
<td>276</td>
<td>95% CI</td>
<td>97.5% CI</td>
<td>66% (Not Met)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Secondary Effectiveness Endpoint Results
The secondary effectiveness endpoints are summarized in Table 10 and Table 11 below.

Table 10: Technical and Procedural Success (N=299)

<table>
<thead>
<tr>
<th>Overall</th>
<th>Technical Success</th>
<th>Procedure Success</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>99.0% (296/299)</td>
<td>99.0% (296/299)</td>
</tr>
</tbody>
</table>

\*Technical success was defined as the ability to cross and dilate the lesion to achieve residual angiographic stenosis no greater than 30%.

| Procedure Success was defined as technical success with no MAEs within 24 hours of the index procedure.

Table 11: Analysis of Secondary Effectiveness Endpoints (N= 299)

<table>
<thead>
<tr>
<th>Stent Nominal Diameter (mm)</th>
<th>Unconstrained Length (mm)</th>
<th>Reference Vessel Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>100</td>
<td>4.0</td>
</tr>
<tr>
<td>6</td>
<td>100</td>
<td>4.0 - 5.0</td>
</tr>
<tr>
<td>7</td>
<td>100</td>
<td>5.0 - 6.0</td>
</tr>
<tr>
<td>8</td>
<td>100</td>
<td>6.0 - 7.0</td>
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Subgroup Analyses
Gender: The female population had a higher overall TLR rate (22.4% vs. 11.4%) and a lower 12 month primary patency rate in the core stents matrix (50.6% vs 73.8%) than the male population. The female subgroup was slightly older with a greater prevalence of Rutherford classification 3 and 4 as well as hypertension compared to the male subgroup. The male subgroup had a higher prevalence of diabetes and coronary artery disease than the female subgroup. Despite these differences and the differences observed for patency in the core stent matrix, both female and male subgroups behaved similarly with respect to patency in the long stent matrix (44.4% and 48.1%, respectively). This subgroup analysis was not statistically powered.

Diabetic Patients: There was a slight trend towards higher patency in the non-diabetic population (44.4% and 48.1%, respectively). This subgroup analysis was not statistically powered.

Diabetic Patients: There was a slight trend towards higher patency in the non-diabetic population (44.4% and 48.1%, respectively). This subgroup analysis was not statistically powered.

Rutherford Classification: The subgroup analysis based on Rutherford classification (claudication vs. critical limb ischemia [CLI]) was not conclusive given the very small proportion of subjects with CLI (n=14). This analysis was not statistically powered.

Stent Matrix: The last subgroup analysis was based on stent matrix (core vs. long vs. entire matrix) and was not statistically powered either. The findings showed very similar patency rates between the entire matrix and the core matrix, both showing an advantage over the long matrix as it should be expected.

HOW SUPPLIED
The Innova™ Vascular Self-Expanding Stent System is supplied sterile inside a pouch. The device is sterilized via Ethylene Oxide. The device is non-pyrogenic.

Handling and Storage
Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible. The packaged device should be stored in a cool, dark place, and temperatures should not exceed 51 °C (124 °F).

RECOMMENDED MATERIALS
- 0.035 in (0.89 mm) stiff guidewire of appropriate length (300 cm length recommended for 130 cm length stent delivery systems)
- Introducer or guide sheath of appropriate size and length and equipped hemostatic valve
- Luer lock syringe 10 ml (10 cc) for flushing the stent delivery system

OPERATIONAL INSTRUCTIONS
Patient Preparation
The percutaneous placement of a self-expanding stent in a stenotic or obstructed artery should be done in an angiography procedure room with the appropriate imaging equipment. Patient preparation and sterile precautions should be the same as for any angioplasty procedure. Appropriate antiplatelet and anticoagulation therapy must be administered pre- and post-procedure in accordance with standard practices. Angiography should be performed to map out the extent of the lesion(s) and the collateral flow. Access vessels must be sufficiently patent to proceed with further intervention. If thrombus is present or suspected, thrombolysis should precede stent deployment using standard acceptable practice.

Inject Contrast Media
Perform angiogram using standard technique.

Evaluate and Mark the Stenosis
Observe fluoroscopically the most distal view of the stenotic or obstructed artery. Obtain a road map image of the lesion area if necessary.

Select Proper Stent System
1. Measure the diameter of the reference vessel (proximal and distal to the lesion or obstruction). Select a stent based on the table below to ensure a secure placement. Table 12 summarizes the total intended Innova Vascular Self-Expanding Stent sizes.

Table 12: Innova™ Vascular Self-Expanding Stent System Models and Sizes
3. Estimate the distance between the lesion and the entry site to select the proper stent delivery system length.

**Preparation of Stent Delivery System**

1. Open the outer box to reveal the pouch containing the stent delivery system.
2. Check the temperature exposure indicator on the pouch label to confirm that the product has not been compromised. See Warnings section.
3. After careful inspection of the pouch looking for damage to the sterile barrier, carefully peel open the pouch and extract the stent delivery system tray.
4. Carefully withdraw the stent delivery system from the tray by grasping the handle of the delivery system.

**Stent Deployment Procedure (Reference Figure 3)**

1. Remove slack from the system by advancing the system just beyond the target lesion, then, pulling the system back until stent radiopaque markers are still properly positioned across the target lesion.
2. Remove the thumbwheel lock \(\text{①}\) by compressing the tabs and pulling. Confirm that the radiopaque markers are still properly positioned across the target lesion.
3. Pre-dilate the lesion with a balloon dilatation catheter using conventional technique. After the lesion has been properly dilated, remove the dilatation catheter, leaving the guidewire with the tip distal to the lesion for stent system advancement.
4. Place the Innova™ Vascular Stent Delivery System over the guidewire. Advance the delivery system as a unit through the hemostatic valve of the introducer or guide sheath.
5. Examine the stent delivery system for any damage. If it is suspected that the sterility or integrity of the device has been compromised (i.e. kinking or missing component), the device should not be used. The device should not be used if the device is kinked, or if the thumbwheel lock is not attached.
6. Do not remove the thumbwheel lock prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent.
7. Attach a 10 ml (10 cc) syringe filled with saline to the flushing luer \(\text{⑥}\) on the handle. Apply positive pressure. Continue to flush until saline appears at the distal end of the guidewire lumen. Remove the flushing luer \(\text{⑥}\) by pulling the syringe or by pulling flushing luer \(\text{⑥}\) (Reference Figure 3).

**Notes:**

- **Precaution:** If strong resistance is met with the introduction of the delivery system or if unable to initiate release of the stent, remove the entire system from the patient and introduce a new system.
- **Notes:** For optimal performance, keep the entire length of the delivery system that is outside the body as straight and stable as possible. To do so, remove slack from the system, maintain slight backward tension on the delivery system, and anchor the handle on the patient or operating table during deployment. Alternatively, the operator may straighten and stabilize the distal end of the blue outer shaft during deployment.
- **Failure to eliminate slack (Reference Figure 4) and/or curvature of the delivery system catheter between the introducer/guide sheath and the delivery system handle during deployment may adversely affect deployment accuracy, especially in ipsilateral cases.**
- **If repositioning of the stent delivery system is required, reinserting the thumbwheel lock will prevent inadvertent deployment.**

**Recommended Method of Deployment**

1. While using fluoroscopy maintain position of the distal and proximal stent radiopaque markers \(\text{①}\) relative to the targeted site. Roll the thumbwheel lock \(\text{⑥}\) of the deployment handle in the direction of the arrow indicated on the handle. Continue to roll thumbwheel until the middle...
shaft radiopaque marker band ⑤ passes the distal stent radiopaque markers. Watch for the distal stent radiopaque markers to begin separating: separation of the distal stent radiopaque markers signals that the stent is deploying.

2. Continue to roll thumbwheel until the middle shaft radiopaque marker band ⑤ passes the proximal radiopaque markers of the stent resulting in full deployment, or until the white activation arrow is visible on the pull grip extension rod (for 150 mm to 200 mm length stents), which indicates that pull grip activation is required to complete stent deployment (Reference Figure 5). Long stents (150 mm to 200 mm length) will not be fully deployed by the thumbwheel alone.

Notes:
- When activating the pull grip, avoid rapid deployment.
- Do not restrict movement of the thumbwheel ④ otherwise deployment difficulties could be encountered.
- Do not attempt to pull a partially expanded stent back into introducer/guide sheath as dislodgement may occur.
- Do not push or pull the delivery system during deployment as this may compromise stent length.
- Long stents (150 mm to 200 mm length) require the pull grip to be retracted only after the white activation arrow is visible to complete deployment.

3. Long stents (150 mm to 200 mm length) require pull grip deployment after the white activation arrow becomes visible on the pull grip extension rod. Grasp the manual pull grip ③ and gently pull away from the handle in the direction of the arrow. Slowly pull back until the middle shaft radiopaque marker band ⑤ passes the proximal radiopaque markers of the stent resulting in full deployment.

4. View the delivery system under fluoroscopy, ensuring that the middle shaft radiopaque marker band ⑤ has crossed the proximal stent markers. The delivery system can now be withdrawn.

5. Grasp the guidewire a short distance from handle and repeatedly retract the system over the wire until fully removed. Use caution when withdrawing the stent delivery system and always manipulate under fluoroscopy. If unusual resistance is felt, carefully readvance and rotate the delivery system in an attempt to center the delivery system within the vessel, then carefully attempt to repeat withdrawal.

Note:
- Avoid bending the guidewire excessively near the handle when retracting device to aid removal and prevent guidewire kinking.

6. If incomplete expansion exists within the stent at any point along the lesion, balloon dilatation can be performed utilizing standard PTA technique.

Precaution:
- Never pre-dilate the stent using a balloon that is larger in diameter than the nominal (labeled) diameter of the stent.

7. Withdraw guidewire and sheath from patient and establish hemostasis per conventional technique.

Post Procedure
Assess patient for hematoma and/or other signs of bleeding at the puncture site.

REFERENCES
The physician should consult recent literature on current medical practice on stent implantation.

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