Real World Value Of The IN.PACT Admiral DCB (Medtronic) For Fem-Pop Lesions: From The IN.PACT Global Registry: What Else Does It Tell Us

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Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below:

- Consulting Fees/Honoraria: Medtronic, BARD, Spectranetics, Intact Vascular, Rexgenero, Bayer Healthcare, Daiichi Sankyo

Advances in endovascular procedures have markedly broadened options for treating symptomatic SFA disease.

Drug-coated balloons (DCBs) have demonstrated promising results at 1- and 2-years in randomized trials,1-7 with IN.PACT™ Admiral™ DCB showing sustained and durable benefit through 4 years.8,9

Evidence with DCBs has been greatly expanded in real-world registries10-13 but longer-term data remains limited.

Background

- Advances in endovascular procedures have markedly broadened options for treating symptomatic SFA disease
- Drug-coated balloons (DCBs) have demonstrated promising results at 1- and 2-years in randomized trials,1-7 with IN.PACT™ Admiral™ DCB showing sustained and durable benefit through 4 years.8,9
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IN.PACT Global Study

Overview
Real-world, prospective, multicenter, single arm independently-adjudicated femoropopliteal study

All-comers (RCC 2-4)

- 1535 patients enrolled
- 64 sites in EU, Mid-East, Latin America, Asia
- Independent adjudication by Clinical Events Committee
- Prospective subset analysis with core lab14 reported results (de novo ISR, long lesions ≥15 cm, CTOs ≥5 cm)
- Safety and effectiveness data on 150 mm DCB

Purpose: To expand the clinical evidence with the IN.PACT™Admiral™ DCB in the treatment of real-world patients with symptomatic femoropopliteal disease. This analysis reports longer-term outcomes through 2 years.

Primary Efficacy Endpoint

Defined as freedom from clinically-driven Target Lesion Revascularization1 within 12 months

Primary Safety Endpoint

Defined as freedom from device- and procedure-related death through 30 days, and freedom from target lesion major amputation or clinically-driven Target Vessel Revascularization within 12 months

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1. Day of re-intervention within the target lesion(s) due to symptoms or drop of ABI of ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI.
**IN.PACT Global Study**

**Key Eligibility Criteria**

Inclusion and exclusion criteria are intended to allow for evaluation of the IN.PACT™ Admiral™ DCB in a complex, real-world patient population.

**Inclusion Criteria**
- Rutherford Class 2, 3 and 4
- Lesion(s) in SFA and/or popliteal artery
- Single or multiple stenosis or occlusions of any lesion length ≥ 2 cm
- De novo or restenotic (including ISR)
- At least one infrapopliteal runoff vessel

**Exclusion Criteria**
- Rutherford Class 5 and 6
- Acute or sub-acute thrombus in the target vessel
- Previous surgical bypass to the target lesion
- Failure to successfully cross the target lesion with a guidewire

**Lesion Characteristics**

- **Lesion Type:**
  - Severe % (n)
  - Pre-dilatation % (n)
  - In-stent Restenosis % (n)
  - lesion Type:
  - De novo
  - Restenotic (non-stented)
  - Restenotic (stented)

- **Lesion Length (cm SD):**
  - 10.09 ± 0.54

- **Total Occlusions % (n):**
  - 33.5% (629/1872)

- **Certification % (n):**
  - 68.2% (1271/1872)

- **RVD (mm SD):**
  - 5.186 ± 0.681

- **Diameter Stenosis % (n):**
  - 88.8% ± 12.3

- **Dissections:**
  - 6
  - Presence of dissection

**Procedure Characteristics**

- **Device Success:** 68.4% (1271/1872)
- **Procedure Success:** 99.3% (1386/1397)
- **Clinical Success:** 98.6% (1379/1397)

**Baseline Characteristics**

- **N = 1406 Subjects**
- **RCC 2:** 83.4% (1169/1401)
- **RCC 3:** 45.4% (491/1075)
- **RCC 4:** 20.5% (285/1391)
- **RCC 5:** 11.2% (136/1217)

- **Previous Peripheral Revascularization (%):**
  - 68.6% (737/1075)

- **Concomitant BTK Disease (%):**
  - 45.3% (560/1269)

**Additional Effectiveness Outcomes**

- **Primary Sustained Clinical Improvement:** 68.6% (737/1075)

**Safety Outcomes through 2 Years**

- **Primary Safety Composite:** 81.7% (1037/1269)
- **Device or Procedure related Thrombosis:** 4.5% (57/1269)
- **Major Adverse Event:** 24.7% (314/1269)
- **All-cause Death:** 7.0% (89/1269)
- **CD-TLR:** 7.7% (95/1269)
- **Major Target Limb Amputation:** 0.7% (9/1269)

**Clinical Success**

- **Device success defined as successful delivery, inflation, deflation of the study balloon without complications (death, major target limb amputation, thrombosis of the target lesion, or rescue intervention).**
- **Procedure success defined as residual stenosis of ≤ 50% (non-in-stent restenosis, acute or sub-acute thrombus in the target vessel, failure to successfully cross the target lesion with a guidewire).**
- **Clinical success defined as procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or rescue intervention).**

**Primary Sustained Clinical Improvement**

- **Defined as freedom from target limb amputation, freedom from target vessel revascularization, and increase in Rutherford class at 24 months.**

**Safety Composite**

- **Defined as all-cause death, clinically-driven TVR, major target limb amputation, freedom from the target lesion site at 720 days and freedom from clinically-driven TLR within 24 months.**
### IN.PACT Global Study

#### Long Lesion Imaging Cohort

- **Characteristics**
  - **N=157 Subjects**
  - **N=164 Lesions**
  - **Age (Y, Mean ± SD)**: 69.5 ± 10.7 (155)
  - **Male (%)**: 66.2% (104/157)
  - **Diabetes (%)**: 41.0% (64/156)
  - **Hypertension (%)**: 87.9% (138/157)
  - **Hyperlipidemia (%)**: 76.7% (115/150)
  - **Lesion Length (cm ± SD)**: 26.4 ± 8.61
  - **Total Occlusions % (n)**: 60.4% (99/164)
  - **Calcification % (n)**: Severe % (n)
    - 71.8% (117/163)
    - 19.6% (32/163)
  - **Provisional Stent % (n)**: 39.4% (63/160)

#### In-Stent Restenosis Imaging Cohort

- **Characteristics**
  - **N=131 Subjects**
  - **Age (Y, Mean ± SD)**: 67.8 ± 10.1
  - **Male (%)**: 69.5% (91/131)
  - **Diabetes (%)**: 35.1% (46/131)
  - **Hypertension (%)**: 81.5% (106/130)
  - **Hyperlipidemia (%)**: 72.1% (93/129)
  - **Lesion Length (cm ± SD)**: 17.17 ± 10.47
  - **Total Occlusions % (n)**: 34.0% (48/141)
  - **Calcification % (n)**: Severe % (n)
    - 59.1% (78/132)
    - 8.3% (11/132)
  - **Provisional Stent % (n)**: 14.5% (19/131)

#### Chronic Total Occlusion Imaging Cohort

- **Characteristics**
  - **N=126 Subjects**
  - **N=127 Lesions**
  - **Age (Y, Mean ± SD)**: 67.5 ± 10.4
  - **Male (%)**: 69.0% (87/126)
  - **Diabetes (%)**: 29.6% (37/125)
  - **Hypertension (%)**: 82.3% (102/124)
  - **Hyperlipidemia (%)**: 64.5% (78/121)
  - **Lesion Length (cm ± SD)**: 22.83 ± 9.76
  - **Occluded Lesion Length (cm ± SD)**: 11.86 ± 8.05
  - **Calcification % (n)**: 71.0% (88/124)
  - **Provisional Stent % (n)**: 46.8% (59/126)

### IN.PACT Clinical Data

#### 12-month Outcomes Across IN.PACT Clinical Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Lesion Length (Mean ± SD, cm)</th>
<th>In-Stent Restenosis (ISR) %</th>
<th>Chronic Total Occlusion (CTO) %</th>
<th>Primary Patency (KM @ 360 days)</th>
<th>CD-TLR</th>
<th>Thrombosis</th>
<th>Major Amputation Target Limb</th>
</tr>
</thead>
<tbody>
<tr>
<td>IN.PACT SFA (DCB ARM) (N=220)</td>
<td>8.94 ± 4.09</td>
<td>0.0%</td>
<td>23.8%</td>
<td>87.0%</td>
<td>2.4%</td>
<td>1.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Long Lesion Imaging Cohort (N=157)</td>
<td>26.40 ± 8.61</td>
<td>0.0%</td>
<td>17.2 ± 10.5</td>
<td>88.7%</td>
<td>7.3%</td>
<td>3.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>BR Imaging Cohort (N=157)</td>
<td>17.17 ± 10.47</td>
<td>100%</td>
<td>60.4%</td>
<td>85.3%</td>
<td>7.3%</td>
<td>0.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td>CTO Imaging Cohort (N=157)</td>
<td>22.83 ± 9.76</td>
<td>18.0%</td>
<td>34.0%</td>
<td>83.5%</td>
<td>7.3%</td>
<td>4.3%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Clinical Cohort (N=1406)</td>
<td>12.09 ± 5.54</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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</tbody>
</table>

### IN.PACT Global Study

- **IN.PACT Global is the largest real-world study of DCB in patients with symptomatic femoropopliteal PAD, with independent clinical events committee and core-lab adjudication of outcomes in pre-specified imaging subgroups**
- **Results demonstrate unmatched performance of the IN.PACT DCB in difficult real-world lesion sets**
  - Long lesions averaging 26.40 ± 8.61 cm; 12-mo primary patency 91.1%
  - ISR lesions averaging 17.2 ± 10.5 cm; 12-mo primary patency rate of 88.7%
  - CTO lesions averaging 22.83 ± 9.76 cm; 12-mo primary patency rate of 85.3%
- **Durable long-term performance**
  - Low reintervention rate of 16.9% at 24 months
- **Robust data set that continues to confirm safety and effectiveness of the IN.PACT DCB in the treatment of complex real-world patients**

### Thank you!