Results from separate trials comparing drug-coated balloons to standard PTA alone for AV fistula maintenance.

Kaplan-Meier Analysis of Primary Effectiveness Endpoint

**END-POINT MET**

- IN.PACT AV Access Trial\(^1\)\(^{,\dagger}\)
  - IN.PACT™ AV DCB
  - STANDARD PTA
  - DELTA

**END-POINT NOT MET**

- Lutonix AV Clinical Trial\(^2\)\(^{,\dagger\dagger}\)
  - Lutonix™* DCB
  - STANDARD PTA
  - DELTA

Primary patency rates are defined differently; results are from different studies and may vary in a head-to-head comparison; chart is for illustration purposes only.

**Target Lesion Primary Patency Compared to PTA**

**180 days**

<table>
<thead>
<tr>
<th></th>
<th>IN.PACT™ AV DCB</th>
<th>PTA</th>
<th>DELTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lutonix™* DCB</td>
<td>71.4%</td>
<td>63.0%</td>
<td>14.7%</td>
</tr>
<tr>
<td>PTA</td>
<td>68.9%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**210 days**

<table>
<thead>
<tr>
<th></th>
<th>IN.PACT™ AV DCB</th>
<th>PTA</th>
<th>DELTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lutonix™* DCB</td>
<td>81.4%</td>
<td>59.0%</td>
<td>17.3%</td>
</tr>
<tr>
<td>PTA</td>
<td>59.0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Primary patency rates are defined differently; results are from different studies and may vary in a head-to-head comparison; chart is for illustration purposes only.

\(^1\) IN.PACT AV Access Trial: Target Lesion Primary Patency Rate was defined as freedom from clinically driven target lesion revascularization (CD-TLR) or access circuit thrombosis measured through 210 days post-procedure.

\(^2\) Lutonix AV Clinical Trial: Target Lesion Primary Patency was defined as freedom from clinically driven reintervention of the target lesion or access thrombosis at 180 days post-procedure.

Medtronic
REFERENCES
1. Results from the IN.PACT™ AV Access Clinical Trial found in the IN.PACT™ AV drug-coated balloon (DCB) Instructions For Use (IFU).

INDICATIONS FOR USE
The IN.PACT™ AV Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, for the treatment of obstructive lesions up to 100 mm in length in the native arterovenous dialysis fistulae with reference vessel diameters of 4 to 12 mm.

CONTRAINDICATIONS
The IN.PACT AV DCB is contraindicated for use in the following anatomy and patient types:
• Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
• Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
• Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
• Patients with known allergies or sensitivities to paclitaxel
• Women who are breastfeeding, pregnant, or are intending to become pregnant, or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure

WARNINGS
• A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-5 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Inadequate information is available to evaluate the potential mortality risk associated with the use of paclitaxel-coated devices for the treatment of other diseases/conditions, including this device indicated for use in arteriovenous dialysis fistulae.
• Physicians should discuss this late mortality signal and the benefits and risks of available treatment options for their specific disease/condition with their patients.
• Use the product prior to the Use-by date specified on the package.
• Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
• Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
• Do not move the guidewire during inflation of the IN.PACT AV DCB.
• Do not exceed the rated burst pressure (RBP). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
• The safety and effectiveness of the IN.PACT AV DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure has not been evaluated.
• The extent of the patient’s exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
• Appropriate vessel preparation, as determined by the physician to achieve residual stenosis of ≤ 30%, is required prior to use of the IN.PACT AV DCB. Vessel preparation of the target lesion using high-pressure PTA for pre-dilatation was studied in the IN.PACT AV Access clinical study. Other methods of vessel preparation, such as atherecotomy, have not been studied clinically with IN.PACT AV DCB.

POTENTIAL ADVERSE EFFECTS
Potential adverse effects which may be associated with balloon catheterization may include, but are not limited to, the following: abrupt vessel closure, allergic reaction, arrhythmias, arterial or venous aneurysm, arterial or venous thrombosis, death, dissection, embolization, hematoxia, hemorrhage, hypotension/hypertension, infection, ischemia or infarction of tissue/organ, loss of permanent access, pain, perforation or rupture of the artery or vein, pseudoscleromyxa, restenosis of the dilated vessel, shock, stroke, vessel spasm, or recoil.

Potential complications of peripheral balloon catheterization include, but are not limited to, the following: balloon rupture, detachment of a component of the balloon and/or catheter system, failure of the balloon to perform as intended, failure to cross the lesion. These complications may result in adverse effects.

Although systemic effects are not anticipated, potential adverse effects not captured above that may be unique to the paclitaxel drug coating include, but are not limited to, the following: allergic/immunologic reaction, alopecia, anemia, gastrointestinal symptoms, hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia), hepatic enzyme changes, histologic changes in vessel wall, including inflammation, cellular damage, or necrosis, myalgia/arthralgia, myelosuppression, peripheral neuropathy.

Refer to the Physician’s Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.

Please refer to appropriate product instructions for use for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.

CAUTION
Federal law (USA) restricts this device to sale by or on the order of a physician.