COMPARE THE RESULTS.

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\(^1,†\)

- LUTONIX™* DCB
  - 180 days: 86.1%
  - 210 days: 59.0%

- STANDARD PTA
  - 180 days: 68.9%
  - 210 days: 50.0%

- DELTA
  - 180 days: 22.4% vs. PTA
  - 210 days: 17.3% vs. PTA

Log-rank \(p < 0.001\) at 180-day and \(p = 0.02\) at 210-day

**END-POINT NOT MET**
Lutonix AV Clinical Trial\(^2,††\)

- LUTONIX™* DCB
  - 180 days: 71.4%
  - 210 days: 63.0%

- STANDARD PTA
  - 180 days: 64.1%
  - 210 days: 52.5%

- DELTA
  - 180 days: 8.4% vs. PTA

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

- **IN.PACT™ AV DCB**
  - 86.1%

- **PTA**
  - 68.9%

- **Lutonix™ DCB**
  - 71.4%

\(Δ\) **14.7% vs. PTA**

### 210 days

- **IN.PACT™ AV DCB**
  - 81.4%

- **PTA**
  - 59.0%

- **Lutonix™ DCB**
  - 64.1%

\(Δ\) **17.3% vs. PTA**

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.

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\(^1\) 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.
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 Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter is indicated for percutaneous transluminal angioplasty, following appropriate vessel preparation, for the treatment of obstructive lesions up to 100 mm in length in the native arteriovenous dialysis fistulae with reference vessel diameters of 4 to 12 mm.

CONTRAINDICATIONS
This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).

• Do not exceed the rated burst pressure (RBP). The RBP is based on the results of in vitro testing.
• Do not move the guidewire during inflation of the IN.PACT AV DCB.
• 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).
• Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
• 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.
• 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.

• Assess risks and benefits before treating patients with a history of severe reaction to contrast agents. Identify allergic reactions to contrast media and antipateplatelet therapy before treatment and consider alternatives for appropriate management prior to the procedure.
• This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
• The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events.

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 exposures.

• Patients who cannot receive recommended antipateplatelet and/or anticoagulant therapy
• Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries

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, arhythmias, arterial or venous aneurysm, arterial or venous thrombosis, death, dissection, embolization, hemotoma, hemorrhage, hypertension/hypertension, infection, ischemia or infarction of tissue/organ, loss of permanent access, pain, perforation or rupture of the artery or vein, pseudoaneurysm, 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.

Please 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.

PRECAUTIONS
• This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).

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