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\(^1,^t\)

- IN.PACT™ AV DCB: 86.1%
- Standard PTA: 68.9%

\(\Delta 22.4\%\) vs. PTA

Log-rank p < .001 at 180-day and at 210-day

END-POINT NOT MET

Lutonix AV Clinical Trial\(^2,^t\)

- Lutonix™ DCB: 71.4%
- Standard PTA: 63.0%

\(\Delta 8.4\%\) vs. PTA

Log-rank p = 0.06 at 180-day and p = 0.02 at 210-day

Target Lesion Primary Patency Compared to PTA

180 days

- IN.PACT™ AV DCB: 86.1%
- PTA: 68.9%
- Lutonix™ DCB: 71.4%

\(\Delta 14.7\%\)

210 days

- IN.PACT™ AV DCB: 81.4%
- PTA: 59.0%
- Lutonix™ DCB: 64.1%

\(\Delta 17.3\%\)

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.
PRECAUTIONS

• 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
• Contents are supplied sterile. Do not use the product if the inner packaging is damaged or
• Use the product prior to the Use-by date specified on the package.

WARNINGS

• Women who are breastfeeding, pregnant or are intending to become pregnant, or men
• Patients with known allergies or sensitivities to paclitaxel
• Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or
• Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
• Coronary arteries, renal arteries, and supra-aortic/ cerebrovascular arteries

The IN.PACT AV DCB is contraindicated for use in the following anatomy and patient types:

• The safety and effectiveness of the IN.PACT AV DCB used in conjunction with other drug-
• 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 athereceteromy, 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, hematoma, hemorrhage, hypotension/hypertension, infection, ischemia or infarction of tissue/organ, loss of permanent access, pain, perforation or rupture of the artery or vein, pseudoneuropathy, 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 leucopenia, neutropenia, thrombocytopenia), hepatic enzyme changes, histologic changes in vessel wall, including inflammation, cellular damage, or necrosis, 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 reference 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.

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).