RANGER™ Paclitaxel-Coated PTA Balloon Catheter

Exceptional Outcomes. Effortless Deliverability.
**RANGER™**
Drug-Coated Balloon

**Exceptional Outcomes:**
Ranger demonstrated consistent results with nearly 90% patency at 12-months in the RANGER II SFA and COMPARE Trials.

**Effortless Deliverability:**
Ranger is built on the .018” Sterling™ Balloon Platform with .018”/.014” guidewire compatibility and the lowest tip entry profile.

**Efficient Drug Transfer:**
TransPax™ is a next generation coating that efficiently transfers drug into the tissue, resulting in patency near 90% at 12-months while reducing downstream particulates and systemic drug exposure for the patient.
Exceptional Outcomes

Ranger™ DCB demonstrated consistent results with nearly 90% patency at 12-Months in the RANGER II SFA and COMPARE Trials

**COMPARE Clinical Trial**
World’s First Head-to-Head Prospective, RCT (1:1) comparing low dose Ranger Drug-Coated Balloon to higher dose IN.PACT™ Drug-Coated Balloon.

Ranger demonstrated similar primary patency as IN.PACT with half the total drug dose at 12-months

**RANGER™ II SFA Pivotal Trial**
Prospective, Multi-Center, Randomized Controlled Trial. Ranger Drug-Coated Balloon vs. Uncoated Balloon (3:1). Follow-up through 5 years.

12-MONTH PRIMARY PATENCY KAPLAN-MEIER ESTIMATE

Ranger demonstrated significantly lower CD-TLR and no difference in mortality vs. PTA at 12-months

Key Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Ranger</th>
<th>PTA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>70.6</td>
<td>69.1</td>
<td>0.189</td>
</tr>
<tr>
<td>Current/Former Smoker</td>
<td>85.3%</td>
<td>84.7%</td>
<td>0.019</td>
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<tr>
<td>Diabetic</td>
<td>42.4%</td>
<td>43.9%</td>
<td>0.806</td>
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<tr>
<td>Target Lesion Length (mm)*</td>
<td>82.5</td>
<td>79.9</td>
<td>0.655</td>
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<tr>
<td>Moderate/Severe Calcium**</td>
<td>47.8%</td>
<td>62.2%</td>
<td>0.73</td>
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</table>

Ranger n=278  PTA n=98

*Logrank p-value compares the entire K-M curves from time zero to full 1-year follow-up window.
** Core lab
***PACS Grade 3/4 may be considered similar to moderate/severe calcification. Grade 3: 36.3% Ranger, 52.0% PTA, p=0.006, Grade 4: 11.5% Ranger, 10.2% PTA, p=0.724

Ranger n=207  IN.PACT n=207

The average Target Lesion Length in the COMPARE Trial was ~126 mm

At 24 months, Ranger also had similar primary patency as IN.PACT with half the total drug dose

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1. COMPARE Clinical Trial 12-Month Results presented by Sabine Steiner, MD. LINC 2020. K-M Primary Patency = 88.4%. RANGER II SFA Pivotal Trial 12-Month Results presented by Marianne Brodmann. LINC 2020. K-M Primary Patency = 88.8%
2. COMPARE Clinical Trial 12-Month Results presented by Sabine Steiner, MD. LINC 2020. 12-Month Primary Endpoint: Binary Primary Patency = 83.0% for Ranger DCB and 81.5% for IN.PACT DCB [Pnon-inferiority<0.01]. Freedom from Major Adverse Events = 91.0% for Ranger DCB and 92.6% for IN.PACT DCB [Pnon-inferiority<0.05].
3. Based on total drug dose for 4mmx60mm or averages for full size matrix per the IN.PACT™ Admiral™ Drug-Coated Balloon Instructions for Use, www.medtronic.com and the Ranger™ Paclitaxel-Coated PTA Balloon Catheter Instructions for Use.
4. Results from the 150-patient COMPARE-1 Pilot phase. LINC 2019. 75% Ranger Patency (n=62) vs. 77% IN.PACT Patency (n=61) at 24 months. K-M estimate, p= 0.57 (logrank test).
5. RANGER II SFA Pivotal Trial 12-Month Results presented by Marianne Brodmann. LINC 2020. 12-Month Primary Endpoints: Binary Primary Patency = 82.9% for Ranger DCB and 66.3% for PTA (p=0.0017). Freedom from Major Adverse Events = 94.1% for Ranger DCB and 83.5% for PTA [Pnon-inferiority<0.0001].
Effortless Deliverability

Ranger™ DCB is built on the market-leading .018" Sterling™ Balloon Platform

Ranger has the lowest tip entry profile with .014"/.018" guidewire compatibility

Ranger DCB has a comprehensive matrix and is compatible with pedal access

<table>
<thead>
<tr>
<th>Ranger Matrix</th>
<th>40 mm</th>
<th>60 mm</th>
<th>80 mm</th>
<th>100 mm</th>
<th>120 mm</th>
<th>150 mm</th>
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<tr>
<td>4 mm</td>
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<tr>
<td>6 mm</td>
<td>5F</td>
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<td>7 mm</td>
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Over-the-wire catheter with working lengths of 80 cm, 90 cm, 135 cm and 150 cm

Ranger’s Proprietary Loading Tool serves as the balloon and drug protector to help prevent drug loss during insertion and limit a physician’s exposure to the drug.

6. DRG data, CY 2019, 0.018" PTA Balloons.
**Efficient Drug Transfer**

TransPax™ reduces downstream particulates⁹ and systemic drug exposure for the patient¹⁰

TransPax (Citrate Ester + Low Dose Paclitaxel)™ is a next generation coating that efficiently transfers drug into the tissue, resulting in patency near 90% at 12-months¹

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**TransPax is LIPOPHILIC**
(LOVES FATTY LESION TISSUE)
Enables targeted and efficient delivery of low dose paclitaxel into the lesion

**HIGH PATENCY¹**
Ranger demonstrated near 90% primary patency at 12-months in both COMPARE and RANGER II SFA

**TransPax is HYDROPHOBIC**
(REPELS WATER)
Protects the drug from dissolving in blood prior to deployment and limits drug waste

**REDUCED DOWNSTREAM PARTICULATES⁹**
As published in JACC CI, Ranger had the least amount of downstream particulates

**LOW SYSTEMIC DRUG EXPOSURE¹⁰**
In the Ranger II SFA PK Substudy, within one hour the majority of patients, 11 out of 12, had no measurable levels of paclitaxel in their bloodstream.

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¹Drug dose density = 2 µg/mm²
⁹ Gongora et al. Comparative Drug-Coated Balloon Study. JACC Cardiovasc Interv. 2015; doi.org/10.1016/j.jcin.2015.03.020
¹⁰ RANGER II SFA PK Substudy presented by Ravish Sachar, MD. VIVA 2019. At one hour 11 out of 12 patients had no measurable levels of paclitaxel in their bloodstream. At three hours the 12th patient had no measurable levels of paclitaxel in their bloodstream. The limit of quantification was defined as <1 ng/ml.
TWO DRUG-ELUTING SOLUTIONS. ONE TRUSTED PARTNER.

THE ONLY COMPANY WITH HEAD-TO-HEAD RCTs

Eluvia™ Drug-Eluting Stent and Ranger™ Drug-Coated Balloon are the only PAD devices backed by Level-1, Head-to-Head, Randomized Controlled Trials that demonstrate exceptional outcomes with differentiated technology — helping physicians make better, data-driven treatment decisions with a best-in-class drug-eluting portfolio.

RANGER DRUG-COATED BALLOON

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Prior to use, please see the complete “Instructions for Use” for more information on indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

WARNING: 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 3 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. Physicians should be aware of this late mortality signal and consider the benefits and risks of available treatment options for patients. See Section 8.1 (in the eIFU) for further information. INTERACTIONS/USE: The Ranger Drug-Coated Balloon (DCB) is indicated for percutaneous transluminal angioplasty (PTA) of the femoropopliteal arterial system and for the treatment of femoropopliteal arterial stenotic lesions (≤80% diameter stenosis) that have failed or are inadequately treated with standard PTCA, or when standard PTCA is contraindicated. CONTRAINDICATIONS: Use of the Ranger DCB is contraindicated in: • Patients with known hypersensitivity to paclitaxel (or structurally-related compounds). • Patients who cannot receive recommended antithrombotic and/or anticoagulation therapy. • Women who are breastfeeding, pregnant, or men intending to father children. • Patients judged by a doctor to possess complete confidence in an angiographic balloon or other primary placement of the delivery system. • Concomitant antithrombotic, and anticoagulant treatment. • Intra-arterial infusion of substances containing alcohol or detergents. • Patients with evidence of nonatherosclerotic vascular disease. • Patients receiving concomitant anticoagulation therapy. • Patients with ulcerative disease of the vessel wall. • Patients with severe vessel stenosis or occlusion. • History of allergy to taxanes. • Patients with a body mass index greater than 50 kg/m² or a weight greater than 250 lbs. • Patients with a history of impaired wound healing 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