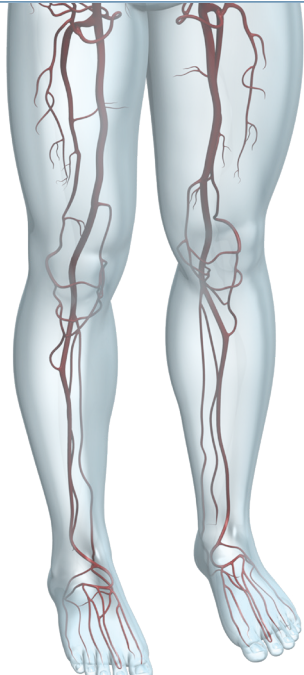


# COMPARE-1 CLINICAL TRIAL

## 12-MONTH RESULTS FROM PILOT PHASE PRESENTED AT LINC 2018<sup>1</sup>

### TRIAL DESIGN

**WORLD'S FIRST** Head-to-Head Prospective, **RANDOMIZED (1:1) CONTROLLED** Trial comparing the lower dose Paclitaxel RANGER DCB (2 µg/mm<sup>2</sup>) to the higher dose Paclitaxel IN.PACT DCB (3.5 µg/mm<sup>2</sup>)

BASELINE CHARACTERISTICS AND RESULTS	Ranger™ (n=74)		IN.PACT™ (n=76)	p-value
Total Occlusions	<b>39%</b>		<b>45%</b>	<b>0.5</b>
Total Occlusion Length	<b>111 mm</b>		<b>95 mm</b>	<b>0.5</b>
Target Lesion Length	<b>117 mm</b>		<b>122 mm</b>	<b>0.8</b>
Moderate to Severe Calcification	<b>58%</b>		<b>61%</b>	<b>0.7</b>
Diabetics	<b>34%</b>		<b>37%</b>	<b>0.7</b>
Patency*	<b>84%</b>		<b>89%</b>	<b>0.7</b>

**No statistically significant difference in patency between the higher dose Paclitaxel IN.PACT DCB and the lower dose Paclitaxel Ranger DCB.**

**The new generation Ranger uses approximately half the drug as IN.PACT.**

<sup>1</sup>Results from the 150 patients from the pilot phase. Overall trial will enroll up to 414 patients.  
\*KM Estimate

# COMPARE-1 CLINICAL TRIAL

## TRIAL DETAILS

### OBJECTIVE:

To compare two different Paclitaxel coated balloons (with different coatings and different Paclitaxel dose density) in the treatment of high grade stenotic or occluded lesions in SFA and/or PPA in PAD patients with Rutherford class 2-4.

### TRIAL DESIGN:

- Prospective, multicenter, randomized trial
- Randomization 1:1
- Phase 1: Pilot Study (150 patients)
- Phase 2: Extension (up to 414 patients) for testing of a formal non-inferiority hypothesis
- Stratification according to lesion length
- Follow-up clinical visits at 6, 12, 24 months

	Ranger™	IN.PACT™
Drug Dose	2.0 µg/mm <sup>2</sup>	3.5 µg/mm <sup>2</sup>
Longest Length Available	200 mm	150 mm
Platform	Sterling™	Admiral™ or Pacific™
Excipient	TransPax™	Urea

### KEY ENROLLMENT CRITERIA:

- Rutherford 2, 3 or 4
- Stenotic, restenotic or occlusive lesions ( $\geq 70\%$  stenosis) in the native non-stented SFA/PPA
- No prior treatment with drug coated balloons or drug-eluting stents in the treated limb
- Lesion  $\leq 300$  mm, RVD  $\geq 4$  mm and  $\leq 6.5$  mm

### DEFINITIONS:

#### Patency — Core lab adjudicated (12 months):

Efficacy: patency rate after one year defined as absence of clinically driven Target Lesion Revascularization (due to symptoms and drop of ABI of  $\geq 20\%$  or  $> 0.15$  when compared to post-procedure) or restenosis with Peak Velocity Ratio  $> 2.4$  evaluated by Duplex Ultrasound

**Ranger™** Paclitaxel Coated PTA Balloon Catheter is manufactured by Hemotek AG and distributed by Boston Scientific Corporation. All cited trademarks are the property of their respective owners. **CAUTION:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. This material is not for use or distribution in France.

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