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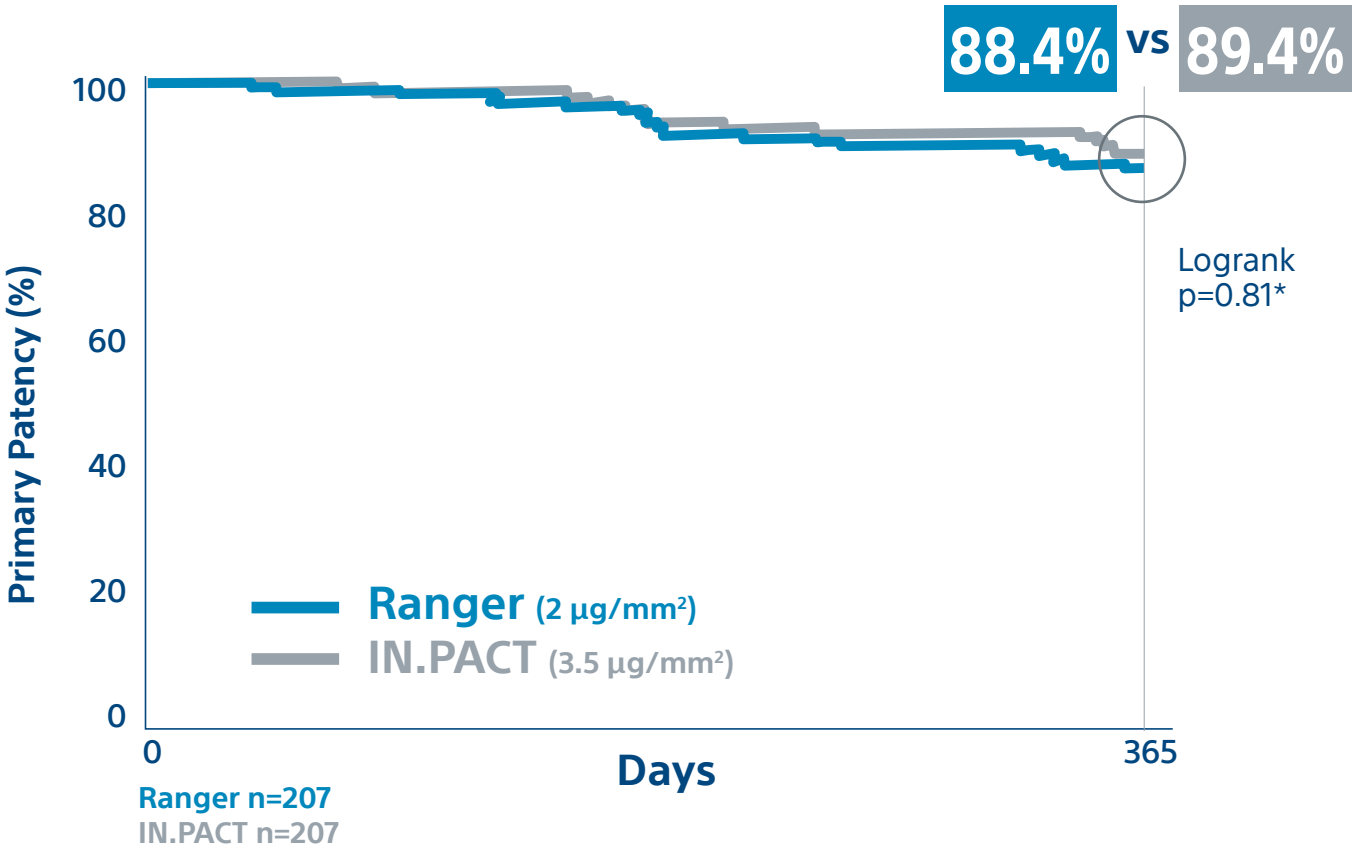
COMPARE CLINICAL TRIAL

12-MONTH FULL COHORT RESULTS PRESENTED AT LINC 2020[1]

WORLD'S FIRST HEAD-TO-HEAD, Prospective, Multi-Center
RANDOMIZED CONTROLLED TRIAL (1:1) comparing the lower dose Paclitaxel RANGER™ DCB (2 µg/mm²) to the higher dose Paclitaxel IN.PACT™ DCB (3.5 µg/mm²)

12 MONTH RESULTS:

PRIMARY PATENCY KAPLAN-MEIER ESTIMATE



PRIMARY ENDPOINTS	Ranger	IN.PACT	p-value
Binary Primary Patency	83.0% (156/188)	81.5% (141/173)	$P_{non\text{-}inferiority}$<0.01
Freedom from major adverse events	91.0% (182/200)	92.6 % (175/189)	$P_{non\text{-}inferiority}$<0.01

Both primary endpoints met

* Log-rank p-value compares the entire K-M curves from time zero to full one year follow-up window.

1. Presented by Sabine Steiner, MD.

COMPARE CLINICAL TRIAL

Ranger vs. IN.PACT Head-to-Head Randomized Controlled Trial

TRIAL DETAILS

	Ranger™ (n=207)	IN.PACT™ (n=207)	p-value
Paclitaxel dose density	2.0 µg/mm²	3.5 µg/mm²	
Average total paclitaxel dose per patient in trial	6,971 µg	13,035 µg	<0.0001
Excipient	TransPax™ citrate ester	Urea	

BASELINE CHARACTERISTICS

	Ranger (n=207)	IN.PACT (n=207)	p-value
Age	68.2	68.4	0.79
Female	38.2%	36.2%	0.68
Current/Former Smoker	77.3%	74.2%	0.63*
Total Occlusions	41%	43%	0.62
Total Occlusion Length	131 mm	113 mm	0.23
Target Lesion Length	124 mm	128 mm	0.65
Moderate to Severe Calcification**	50%	57%	***
Diabetics	31%	37%	0.18

* p-value based on entire distribution Never, Former or Current Smokers
** PACSS Grade 3/4 may be considered similar to moderate/severe calcification.
*** p-value for entire distribution of PACSS Calcium Grades 0, 1, 2, 3, 4 calcium for RANGER vs. INPACT. p- value was 0.20.

12 MONTH KEY RESULTS

	Ranger (n=207)	IN.PACT (n=207)	p-value
Mortality: All Cause	2.5%	1.6%	0.73
Mortality: Device or procedure related	0%	0%	N/A
CD-TLR	9.0%	7.4%	0.59

DEFINITIONS:

Primary safety endpoint — composite of freedom from device and procedure-related death through 30-days and freedom from major target limb amputation and CD-TLR through 12 months post index-procedure.

Primary efficacy endpoint — primary patency at 12 months defined as absence of clinically-driven target lesion revascularization (CD-TLR) or binary restenosis determined as a peak systolic velocity ratio > 2.4 evaluated by duplex ultrasound core laboratory analysis.

CD-TLR — a reintervention performed for ≥ 50% diameter stenosis (confirmed by angiography) within ± 5 mm proximal and/or distal to the target lesion after documentation of recurrent clinical symptoms of PAD (increase of 1 Rutherford class or more) and/or drop of ABI (≥20% or >0.15 when compared to maximum early postprocedural level).

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Ranger™ Paclitaxel-Coated PTA Balloon Catheter is distributed by Boston Scientific. The legal manufacturer is Hemoteq AG, Adenauerstrasse 15, 52146 Wurselen (Germany).

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 use only in countries with applicable health authority registrations. Material not intended for use in France.

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