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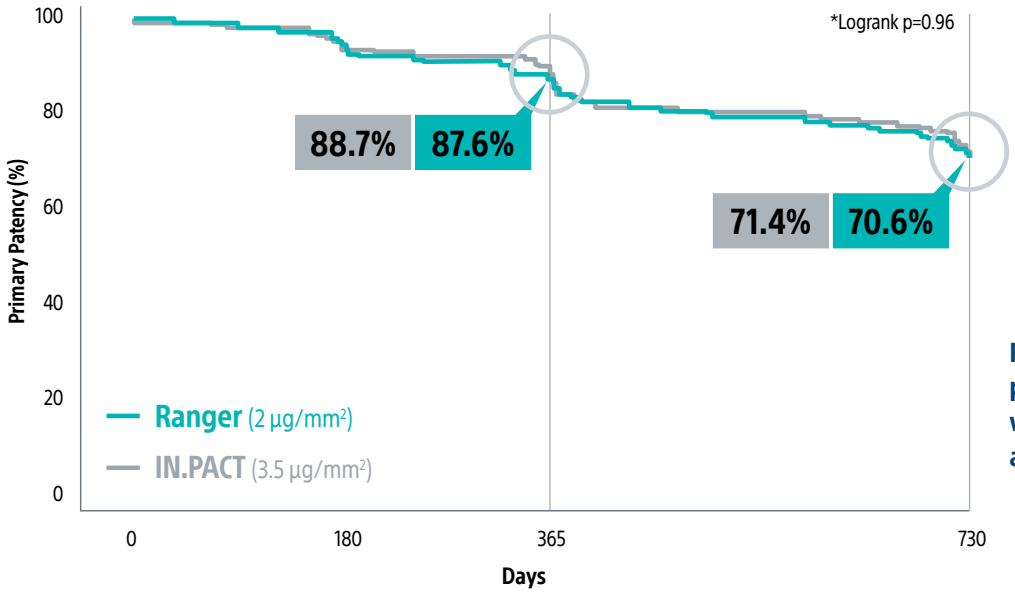
COMPARE CLINICAL TRIAL[1]

COMPARE is the world's first head-to-head prospective, RCT (1:1) comparing low dose Ranger™ DCB (2 µg/mm²) to higher dose IN.PACT™ DCB (3.5 µg/mm²)

PRIMARY PATENCY KAPLAN-MEIER ESTIMATE



Ranger demonstrated similar primary patency as IN.PACT with half the total drug dose[2] at 1 and 2 years.

At time point zero: **Ranger** n=207 **IN.PACT** n=207

*Log-rank p-value compares the entire K-M curves from time zero to day 790 (full 2-year follow-up window).

1. COMPARE Clinical Trial 2-Year Results presented by Sabine Steiner, MD. LINC 2021.
2. Based on total drug dose for 4mm x 60mm 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.

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%	75.3%	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**	51%	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. IN.PACT. p-value was 0.20.

COMPARE TRIAL DETAILS	RANGER (n=207)	IN.PACT (n=207)	p-value
Excipient	TransPax™ citrate ester	Urea	
Paclitaxel dose density	2.0 µg/mm^2	3.5 µg/mm^2	
Average total paclitaxel dose per patient in trial	6,971 µg	13,035 µg	**<0.0001**

3-YEAR KEY RESULTS[3]	RANGER (n=130)	IN.PACT (n=116)	p-value
K-M Primary Patency	long term primary patency data will not be collected		
K-M Freedom from All-Cause Mortality	92.8%	94.5%	0.51*
K-M Freedom from CD-TLR	74.4%	80.3%	0.18*

*Log-rank p-value compares the entire K-M curves from time point zero to day 1,095 (full 3 year follow-up window).

2-YEAR KEY RESULTS[1]	RANGER (n=207)	IN.PACT (n=207)	p-value
Mortality: All Cause	3.6% (7/196)	2.2% (4/181)	0.6
Mortality: Device or Procedure Related	0%	0%	1.0
CD-TLR	17.3%	13.0%	0.3
1-YEAR KEY RESULTS[4]			
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
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

* Primary Endpoint Met

1-Year Results Published in the European Heart Journal

COMPARE: prospective, randomised, non-inferiority trial of high vs. low dose paclitaxel drug-coated balloons for femoropopliteal interventions. doi.org/10.1093/eurheartj/ehaa049

3. COMPARE Clinical Trial 3-Year Results and TLR Characteristics presented by Sabine Steiner, MD. LINC 2022.
4. Sabine Steiner, et al. COMPARE: prospective, randomised, non-inferiority trial of high- vs. low-dose paclitaxel drug-coated balloons for femoropopliteal interventions, European Heart Journal, Volume 41, Issue 27, 14 July 2020, Pages 2541–2552, https://doi.org/10.1093/eurheartj/ehaa049.

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 post-procedural level).

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Peripheral Interventions
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