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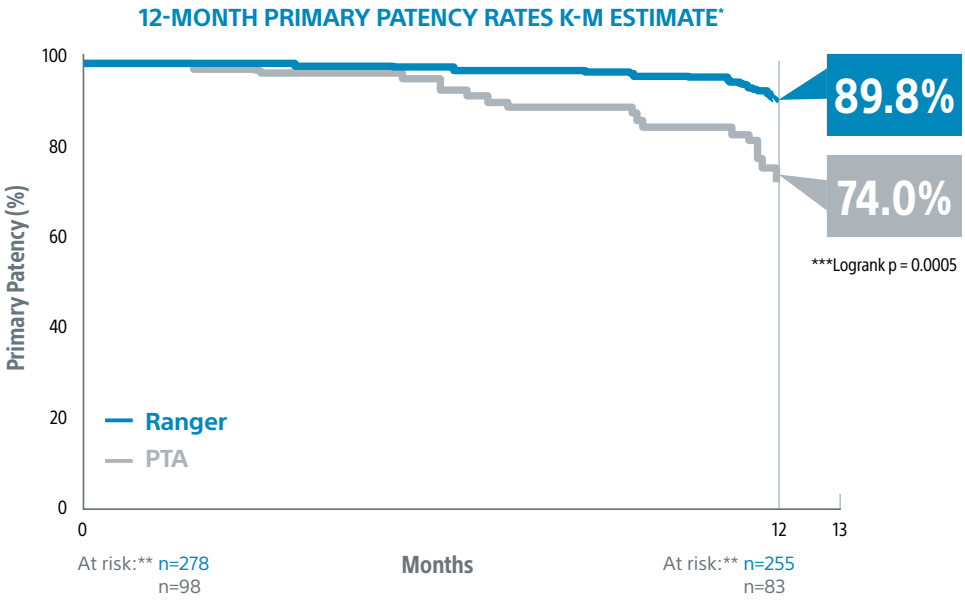
RANGER II SFA PIVOTAL TRIAL[1]

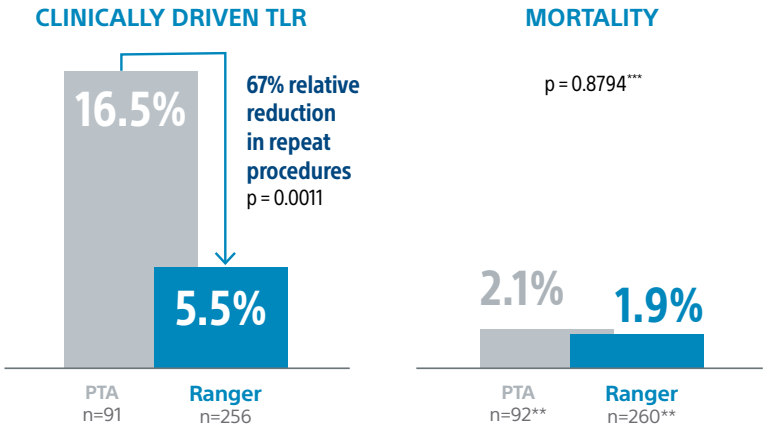
Prospective, Multi-Center, Randomized Controlled Trial
Ranger™ Drug-Coated Balloon vs. Uncoated Balloon (3:1). Follow-up through 5 years

Ranger™ demonstrated nearly 90% primary patency at 12 months



Clinically-Driven TLR (CD-TLR) & Mortality

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



* Kaplan-Meier Estimate: Primary patency as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) is ≤2.4 at the 12-month follow-up visit, in the absence of clinically driven TLR or bypass of the target lesion.
** At risk denotes the number of subjects entered in the calculation at the time interval.
*** Logrank p-value compares the entire K-M curves from time zero to full 1-year follow-up.

1. RANGER II SFA Pivotal Trial 12-Month Results presented by Marianne Brodmann. LINC 2020.

PRIMARY ENDPOINT RESULTS

	Ranger™ DCB (n=207)	PTA (n=98)	p-value
Primary Safety Endpoint (Freedom from MAE)	94.1% (241/256)	83.0% (75/91)	$P_{non\text{-}inferiority}<0.0001$
Primary Effectiveness Endpoint (Binary Primary Patency)	82.9% (194/234)	66.3% (57/86)	0.0017

KEY BASELINE CHARACTERISTICS

	Ranger DCB (n=207)	PTA (n=98)	p-value
Age (year)	70.6	69.1	0.189
Current/Former Smoker*	85.3%	84.7%	see footnote
Current Diabetes Mellitus	42.4%	43.9%	0.806
Target Lesion Length (mm)**	82.5	79.9	0.655
Calcium: PACSS Grade 3/4***	47.8%	62.2%	see footnote

* Current smokers: Ranger 31.3%, PTA 45.9%, p-value=0.009. Previous smokers: Ranger 54.0%, PTA 38.8%, p-value=0.010.
** Core lab.
*** PACSS 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 PK Substudy[2]

Study Method:

- Designed to evaluate the levels of paclitaxel in the systemic circulation of 12 subjects who were treated with Ranger DCB
- Protocol required blood draws: Baseline, 10 minutes, 30 minutes, 1, 3, 6, 24 or 48 hours, 7 days and 30 days after last Ranger DCB treatment and removal
- The limit of quantification was defined as < 1 ng/mL
- Average number of DCBs used per patient: 1.75

At one hour, 11 of 12 patients did not have measurable levels of paclitaxel in the bloodstream.

At three hours, the 12th patient did not have measurable levels of paclitaxel in their bloodstream

2. RANGER II SFA PK Substudy presented by Ravish Sachar, MD. VIVA 2019.

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