Zilver® PTX®: Consistent performance¹⁻⁵ proven through 5 years¹

PATIENT INFORMATION	Randomised controlled trial ¹	Single-arm study ²⁻³	Japan post-market surveillance ⁴	
Number of patients enrolled	479 (236 patients treated with Zilver PTX)	787	905	
Average lesion length (Zilver PTX arm)	66.4 mm	99.5 mm	147 mm	
Total occlusions (Zilver PTX arm)	32.8%	38.3%	41.6%	
Diabetics (Zilver PTX arm)	49.6%	36.2%	58.8%	
Rutherford classification	2-6	2-6	0-6	
Renal disease	10.2%	11.3%	43.8%**	
FRACTURE RATE	5 years: 1.9% (Zilver PTX and BMS combined)	1 year: 1.5%*	1 year: 1.5%	

- * Fracture-rate data were only collected at 1 year in the single-arm trial. (In the randomised controlled trial, fracturerate data were collected at 1, 3, and 5 years.)
- ** 81.1% (322/397) of the patients with chronic kidney disease were in renal failure (defined as eGFR <60 mL/min/1.73 m² and/or dialysis), and 35.5% (322/907) of the total patient population were in renal failure.4

CONSISTENT PERFORMANCE IN CLINICAL STUDIES¹⁻⁵ Zilver PTX freedom from TLR Zilver PTX primary patency 100% 100% 80% 80% Freedom from TLR Primary patency 60% 40% 20% 20% 2 5 Randomised trial: 72.4% at 5 years¹ (PSVR <2.0) Randomised trial: 84.9% at 5 years¹ Single-arm study: 80.5% at 2 years³ Single-arm study: 83.0% at 1 year* 2 (PSVR < 2.0) Japan PMS: 83.7% at 2 years⁵ Japan PMS: 70.3% at 2 years⁵ (PSVR \ge 2.4) *Patency data were not collected at 2-year follow-up.

COOK Zilver PTX

DRUG-ELUTING PERIPHERAL STENT

MEDICAL

PROVEN DRUG EFFECT AT 5 YEARS

Zilver PTX vs BMS (RCT)

84.9% 72.4%

FREEDOM FROM TLR at 5 years1

PRIMARY PATENCY at 5 years¹

Note: Numbers are for provisional Zilver PTX. See trial design on back.

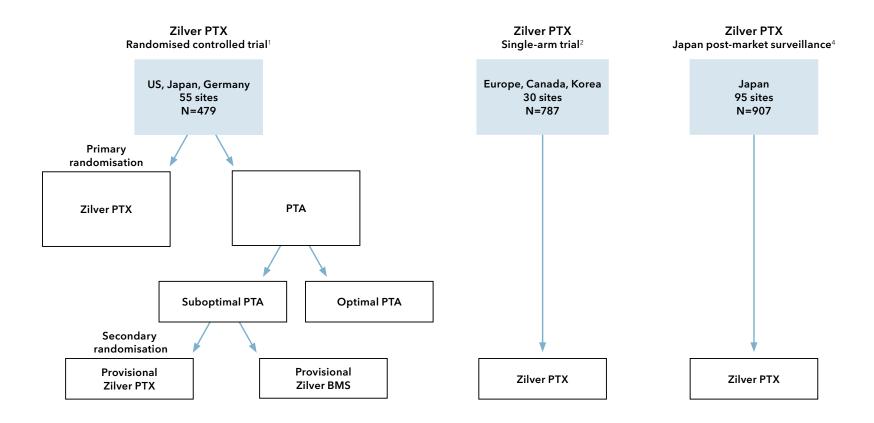
FREEDOM FROM TLR¹

Year	1	2	3	4	5
Provisional Zilver PTX	94.7%	89.1%	87.2%	84.9%	84.9%
Provisional Zilver BMS	82.8%	76.7%	74.1%	71.6%	71.6%

PRIMARY PATENCY (PSVR < 2.0)1

Year	1	2	3	4	5
Provisional Zilver PTX	90.3%	83.4%	81.6%	74.8%	72.4%
Provisional Zilver BMS	74.7%	65.8%	59.9%	57.9%	53.0%

Three major Zilver PTX trials



- 1. Dake MD, Ansel GM, Jaff MR, et al. Durable clinical effectiveness with paclitaxel-eluting stents in the femoropopliteal artery: 5-year results of the Zilver PTX randomized trial. Circulation. 2016;133(15):1472-1483.
- 2. Dake MD, Scheinert D, Tepe G, et al. Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: twelve-month safety and effectiveness results from the Zilver PTX single-arm clinical study. *J Endovasc Ther.* 2011;18(5):613-623.
- 3. Dake MD, Ansel GM, Jaff MR, et al. Sustained safety and effectiveness of paclitaxel-eluting stents for femoropopliteal lesions: 2-year follow-up from the Zilver PTX randomized and single-arm clinical studies. J Am Coll Cardiol. 2013;61(24):2417–2427.
- 4. Yokoi H, Ohki T, Kichikawa K, et al. Zilver PTX post-market surveillance study of paclitaxel-eluting stents for treating femoropopliteal artery disease in Japan: 12-month results. *JACC Cardiovasc Interv.* 2016;9(3):271-277.
- 5. Kichikawa K, Ichihashi S, Yokoi H, et al. Zilver PTX post-market surveillance study of paclitaxel-eluting stents for treating femoropopliteal artery disease in Japan: 2-year results. Cardiovasc Intervent Radiol. 2019;42(3):358-364.

