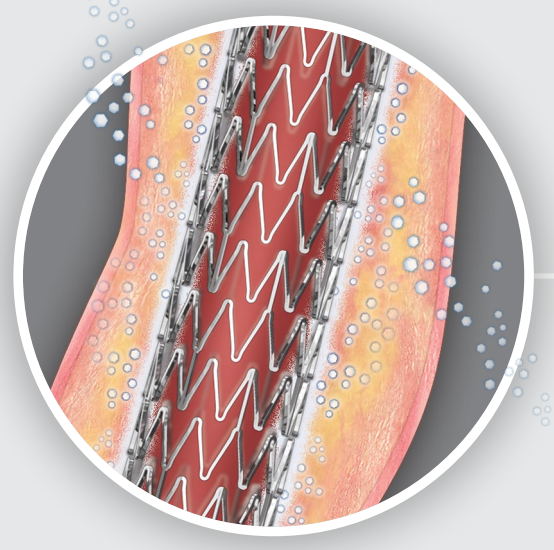
EXPECT TRANSPARENCY

Predictability and unmatched evidence through 5 years

Partnering with you to provide your patients with safe outcomes and unmatched results



Zilver® PTX®

DRUG-ELUTING PERIPHERAL STENT

5-Year Data

Only SFA DES trial to show superior 5-year results compared to standard of care.

Proven Safety

Zilver PTX has proven, long term-safety for your patients, and Cook is the only company to provide SFA patient-level data.

Prediction Model

Predict patients' freedom from TLR rates with our exclusive prediction model.

COOK® MEDICAL

EXPECT LONG-TERM EVIDENCE

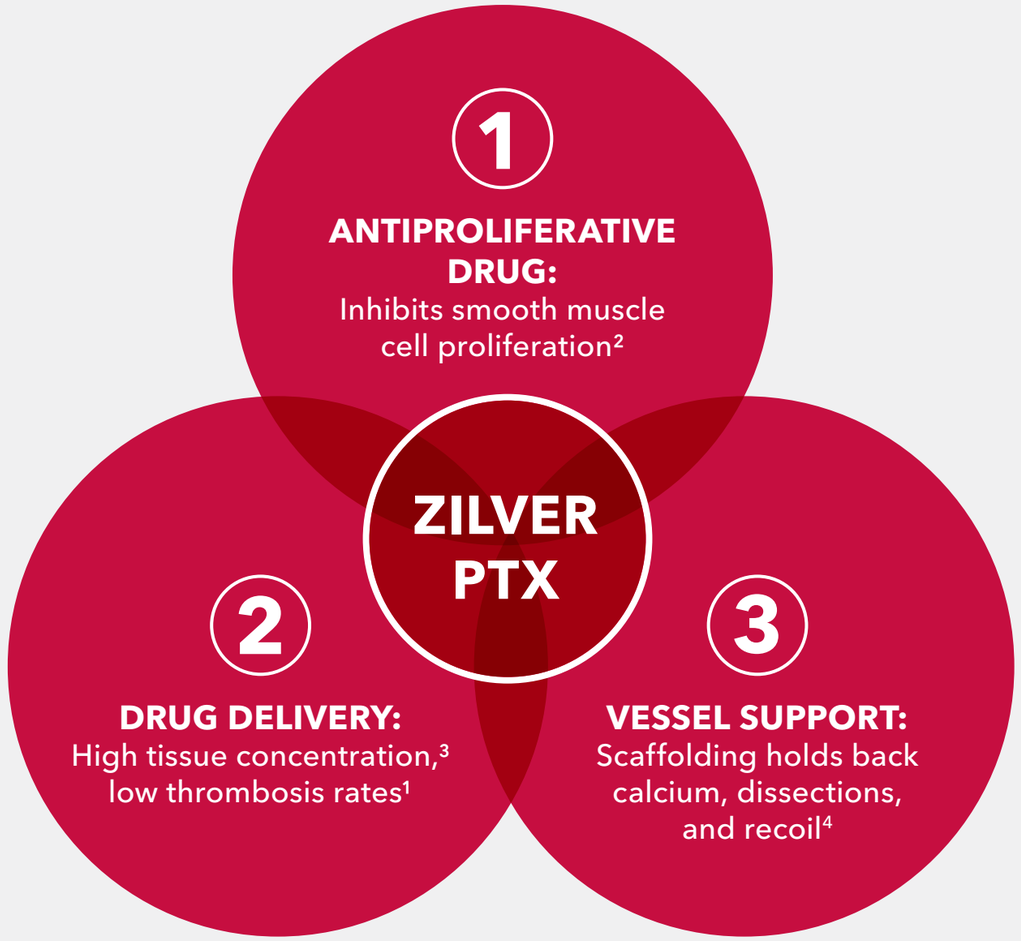
Proven results for your patients out to 5 years

72.4%
5-YEAR PATENCY[1]

84.9%
5-YEAR FF-TLR[1]

NOTE: Results are from the secondary randomization of Zilver PTX vs. Zilver bare-metal stent.

3 essentials for achieving 5-year results



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):1472-83.

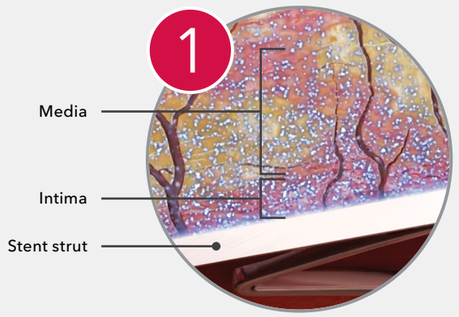
1. Dake MD, Ansel GM, Jaff MR, et al. Durable clinical effectiveness with paclitaxel-eluting stents in the femoropopliteal artery: 5-year results of the Zilver PTX randomized trial. *Circulation*. 2016;133(15):1472-83.
2. Axel D, Kunert W, Göggelmann C, et al. Paclitaxel inhibits arterial smooth muscle cell proliferation and migration in vitro and in vivo using local drug delivery. *Circulation*. 1997; Jul 15;96(2):636-45.
3. Dake MD, Van Alstine WG, Zhou Q, et al. Polymer-free paclitaxel-coated Zilver PTX Stents—evaluation of pharmacokinetics and comparative safety in porcine arteries. *J Vasc Interv Radiol*. 2011;22(5):603-610.
4. Litsky J, Chanda A, Stilp E, et al. Critical evaluation of stents in the peripheral arterial disease of the superficial femoral artery – focus on the paclitaxel eluting stent. *Med Devices (Auckl).* 2014;7:149-156.

Polymer-free technology[5]

Zilver PTX is the first drug-eluting stent approved for the SFA.[6]

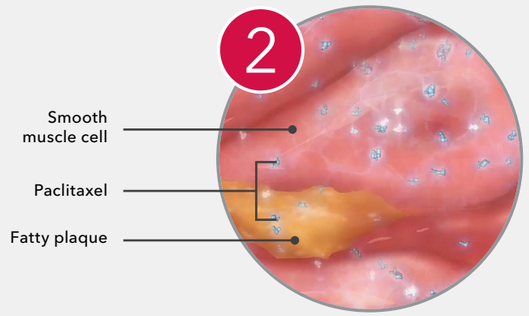
Paclitaxel inhibits neointimal hyperplasia[1] and has been proven over 5 years to reduce restenosis and reinterventions compared to bare-metal stents.[5]

HOW DRUG ELUTION WORKS



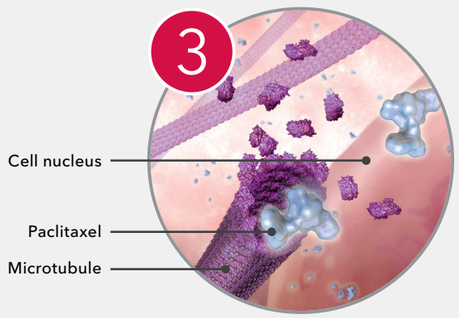
Release:

> 98% of the paclitaxel coating is released from the stent within 72 hours.*[7]
Cook Medical's proprietary, polymer-free coating process eliminates the potential risks associated with polymers.



Absorption:

Paclitaxel remains in the artery for **up to 56 days**.*[7]



Inhibiting:

Inside the cell, the drug binds to microtubules and inhibits mitosis.[7]

*Based on pharmacokinetic studies in porcine models.

5. 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):1472-83.
6. Orenstein B. Looking for a leg up—first drug-eluting stent for PAD approved. *Radiol Today*. 2013;14(3):14.
7. Dake MD, Van Alstine WG, Zhou Q, et al. Polymer-free paclitaxel-coated Zilver PTX Stents—evaluation of pharmacokinetics and comparative safety in porcine arteries. *J Vasc Interv Radiol*. 2011;22(5):603-610.

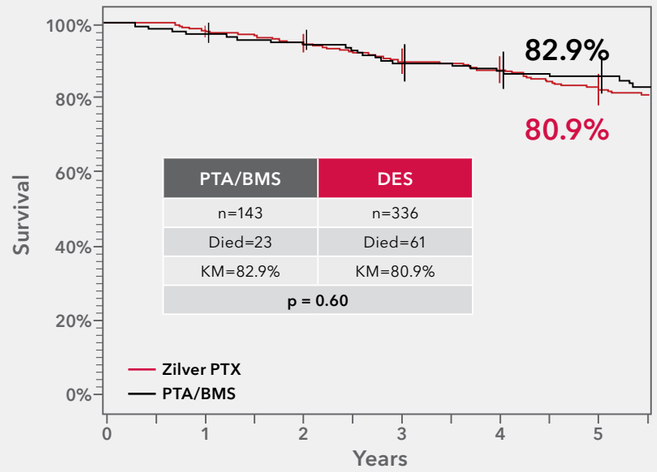
EXPECT SAFETY

No mortality signal is present in the actual treatment arm of the RCT, when compared to PTA/BMS.

In the aftermath of the Katsanos et al. meta-analysis, we were the only medical device company to make available extensive long-term data on our Zilver PTX drug-eluting stent. Zilver PTX is a paclitaxel-coated stent that obtained CE mark in 2009.

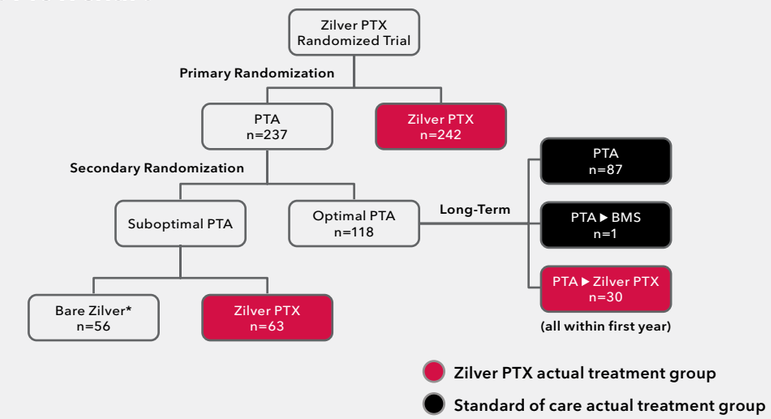
In a paper written by Dake et al.,[8] patient-level data were examined from two large studies comparing Zilver PTX stents with Zilver bare-metal stent (BMS) and percutaneous transluminal angioplasty (PTA) to determine if there was an increased mortality risk due to paclitaxel. The authors concluded there is no increase in long-term all-cause mortality for patients treated with Zilver PTX at 5 years compared to Zilver BMS.

Survival Rates at 5 Years Compared to Zilver BMS[8]



- Patients were analyzed based on actual treatment resulting in 336 Zilver PTX patients and 143 PTA/BMS patients.
- There is no difference in lost to follow-up and withdrawal rates between the Zilver PTX and control patients.
- Inflow tract stenoses and hypertension were more prevalent in the Zilver PTX group, other stenoses of the artery were more prevalent in the BMS group, no difference in other co-morbidities.

RCT Patient Flowchart[8]



*One BMS patient received Zilver PTX during reintervention within the first year.

8. Dake M, Ansel GM, Bosiers M, et al. Paclitaxel-coated Zilver PTX drug-eluting stent treatment does not result in increased long-term all cause mortality compared to uncoated devices. *Cardiovasc Intervent Radiol*. 2019;43:8–19.

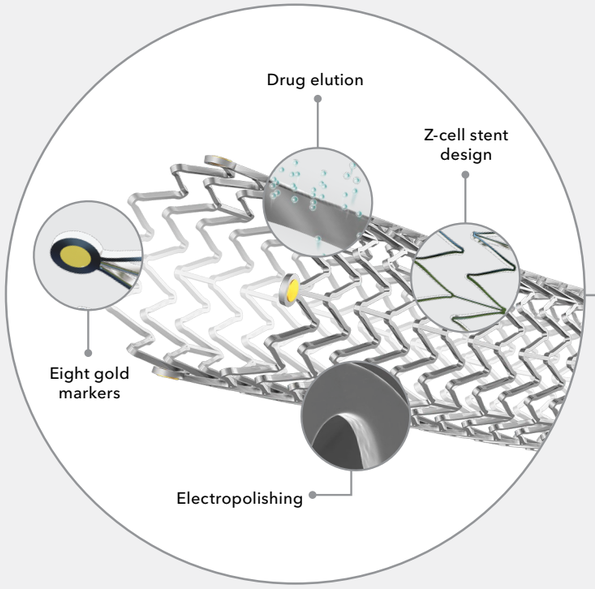
Warning: A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients. See further details in the section "Late Mortality Signal for Paclitaxel-Coated Devices" in IFU0117/IFU0122.

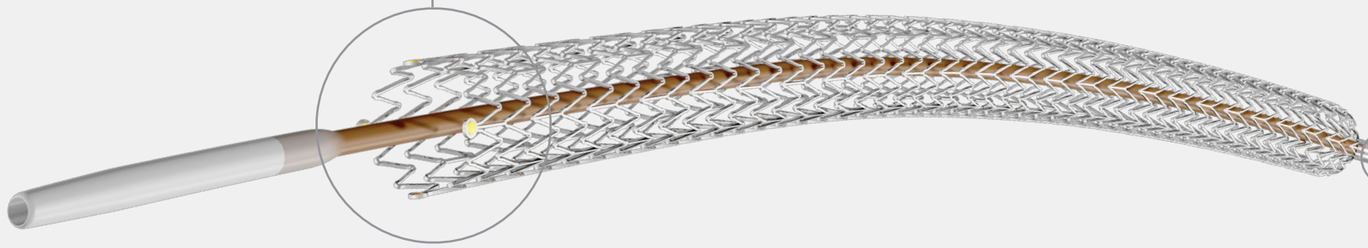
Simplified,* precise** deployment

- Single-handed thumbwheel provides simplified, precise stent deployment.
- Paclitaxel is coated onto the Zilver Flex® stent platform with polymer-free technology.
- Available in lengths up to 140 mm.

Stents AVAILABLE in up to 140 mm lengths***

AVAILABLE in 5, 6, 7, 8 mm diameters





*Simplified compared to previous Zilver PTX pin-and-pull delivery system

**Engineering verification testing (accuracy test of +/-3mm; criteria met)

***Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.

EXPECT LONG-TERM OUTCOMES

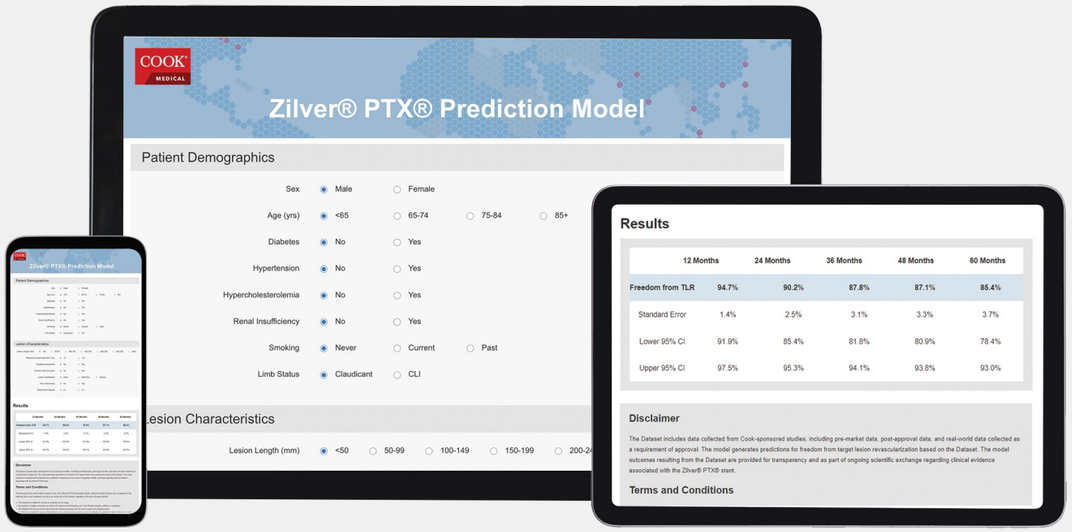
Zilver PTX prediction model

Only SFA dataset with a fully transparent, patient-level probability of SFA reintervention.

CardioVascular and Interventional Radiology recently published a peer-reviewed article written by Dake et al.[9] on our new prediction model for patients treated with a Zilver PTX drug-eluting stent. The model includes data generated from more than 2,200 patients in five global studies, including the randomized controlled trial.

This first-of-its kind tool for a drug-based endovascular device in the SFA allows you to input 15 different patient and lesion characteristics to predict your own patient's probability of freedom from TLR at 5 years if treated with a Zilver PTX stent.

Valuable evidence extracted from the prediction model will help you predict your patients' outcomes. Input your patient's data here.



EXPECT MORE.

To predict freedom from TLR outcomes, scan QR code for direct access to our prediction model.

9. Dake MD, Fanelli F, Lottes AE, et al. Prediction model for freedom from TLR from a multi-study analysis of long-term results with the Zilver PTX drug-eluting peripheral stent. *Cardiovasc Intervent Radiol*. 2020. https://doi.org/10.1007/s00270-020-02648-6

Ordering information

Order Number	Reference Part Number	Stent Diameter mm	Stent Length mm	Minimum Sheath Fr
.035 inch Wire Guide – 80 cm Shaft				
G35302	ZISV6-35-80-5.0-40-PTX	5	40	6
G35303	ZISV6-35-80-5.0-60-PTX	5	60	6
G35304	ZISV6-35-80-5.0-80-PTX	5	80	6
G35305	ZISV6-35-80-5.0-100-PTX	5	100	6
G35306	ZISV6-35-80-5.0-120-PTX	5	120	6
G35448	ZISV6-35-80-5.0-140-PTX	5	140	6
G35307	ZISV6-35-80-6.0-40-PTX	6	40	6
G35308	ZISV6-35-80-6.0-60-PTX	6	60	6
G35309	ZISV6-35-80-6.0-80-PTX	6	80	6
G35310	ZISV6-35-80-6.0-100-PTX	6	100	6
G35311	ZISV6-35-80-6.0-120-PTX	6	120	6
G35451	ZISV6-35-80-6.0-140-PTX	6	140	6
G35312	ZISV6-35-80-7.0-40-PTX	7	40	6
G35313	ZISV6-35-80-7.0-60-PTX	7	60	6
G35314	ZISV6-35-80-7.0-80-PTX	7	80	6
G35315	ZISV6-35-80-7.0-100-PTX	7	100	6
G35316	ZISV6-35-80-7.0-120-PTX	7	120	6
G35454	ZISV6-35-80-7.0-140-PTX	7	140	6
G35317	ZISV6-35-80-8.0-40-PTX	8	40	6
G35318	ZISV6-35-80-8.0-60-PTX	8	60	6
G35319	ZISV6-35-80-8.0-80-PTX	8	80	6
G35320	ZISV6-35-80-8.0-100-PTX	8	100	6
G35321	ZISV6-35-80-8.0-120-PTX	8	120	6

Order Number	Reference Part Number	Stent Diameter mm	Stent Length mm	Minimum Sheath Fr
.035 inch Wire Guide – 125 cm Shaft				
G35273	ZISV6-35-125-5.0-40-PTX	5	40	6
G35274	ZISV6-35-125-5.0-60-PTX	5	60	6
G35275	ZISV6-35-125-5.0-80-PTX	5	80	6
G35276	ZISV6-35-125-5.0-100-PTX	5	100	6
G35277	ZISV6-35-125-5.0-120-PTX	5	120	6
G35278	ZISV6-35-125-5.0-140-PTX	5	140	6
G35281	ZISV6-35-125-6.0-40-PTX	6	40	6
G35282	ZISV6-35-125-6.0-60-PTX	6	60	6
G35283	ZISV6-35-125-6.0-80-PTX	6	80	6
G35284	ZISV6-35-125-6.0-100-PTX	6	100	6
G35285	ZISV6-35-125-6.0-120-PTX	6	120	6
G35418	ZISV6-35-125-6.0-140-PTX	6	140	6
G35286	ZISV6-35-125-7.0-40-PTX	7	40	6
G35287	ZISV6-35-125-7.0-60-PTX	7	60	6
G35288	ZISV6-35-125-7.0-80-PTX	7	80	6
G35289	ZISV6-35-125-7.0-100-PTX	7	100	6
G35290	ZISV6-35-125-7.0-120-PTX	7	120	6
G35421	ZISV6-35-125-7.0-140-PTX	7	140	6
G35297	ZISV6-35-125-8.0-40-PTX	8	40	6
G35298	ZISV6-35-125-8.0-60-PTX	8	60	6
G35299	ZISV6-35-125-8.0-80-PTX	8	80	6
G35300	ZISV6-35-125-8.0-100-PTX	8	100	6
G35301	ZISV6-35-125-8.0-120-PTX	8	120	6

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.

Reference Part Number Key

ZISV6-35-80-5.0-40-PTX

- 40 = Stent Length (mm)
- 5.0 = Stent Diameter (mm)
- 80 = Introducer Length (cm)
- 35 = Wire Guide Diameter (.0XX inch)
- 6 = French Size

Caution: Use of this drug-eluting peripheral stent carries the risks associated with peripheral artery stenting, including vascular complications and/or bleeding events. Refer to the Instructions for Use (IFU) for full prescribing information including information on potential adverse events, contraindications, warnings, and precautions.

Please see product risk information in the IFU at cookmedical.eu

Notes

Notes

Customer Service

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AI-ESC-IR-OHNS-PI-RH-SUR-A4