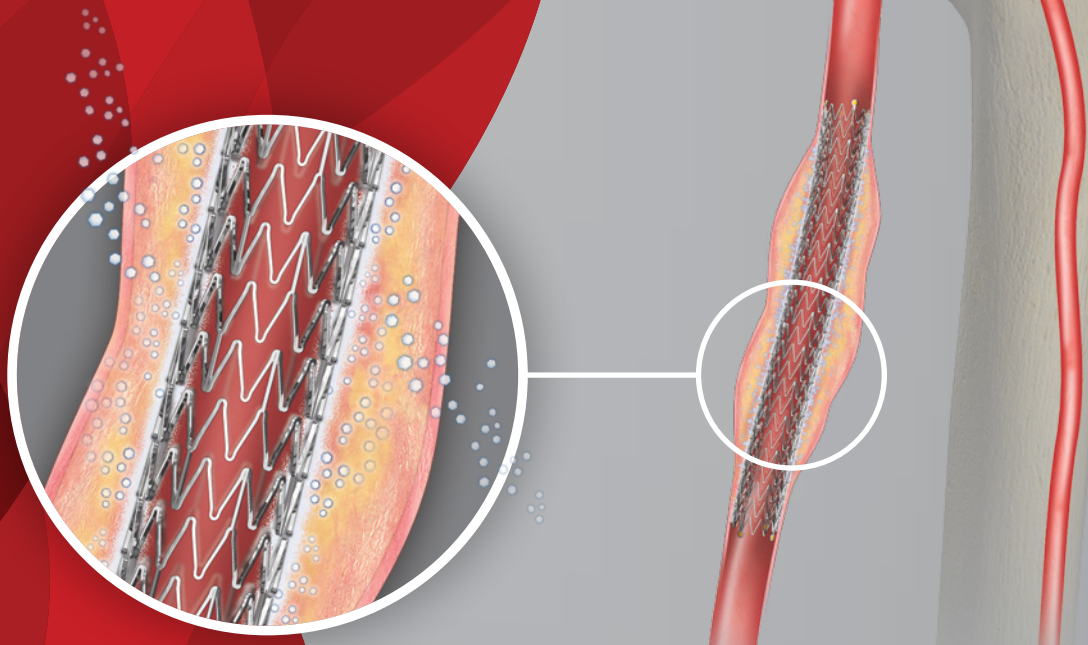
SEE WHY ZILVER PTX IS A GAME CHANGER.



Zilver® PTX®

DRUG-ELUTING PERIPHERAL STENT

COOK® MEDICAL

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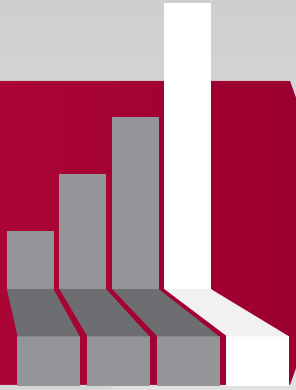
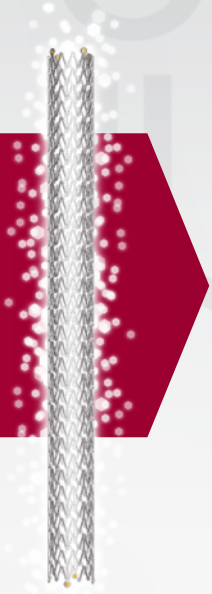
Game-changing
design

Game-changing
evidence



Game-changing
drug effect

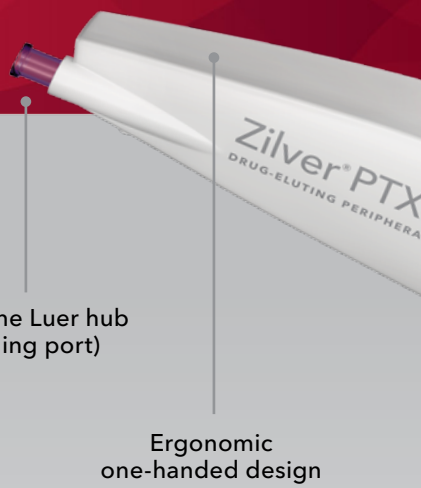


Zilver® PTX®

DRUG-ELUTING PERIPHERAL STENT

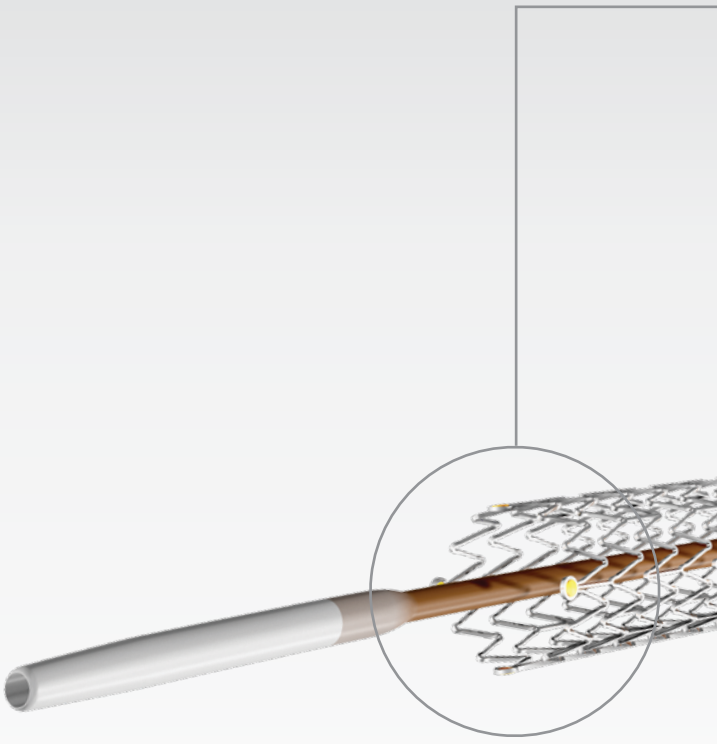
This is how the new Zilver PTX is raising the standard for treating SFA disease.

Game-changing
design



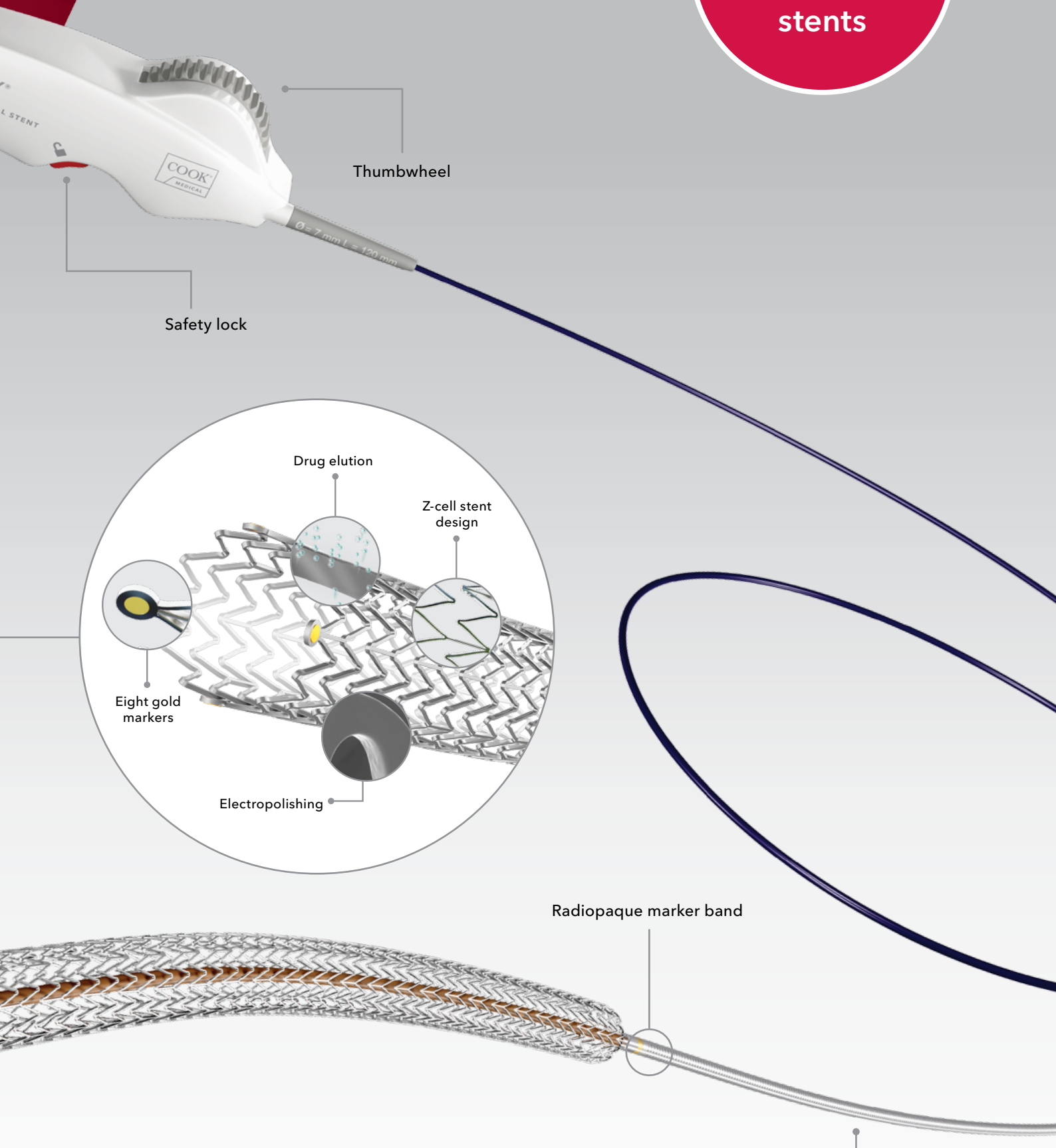
Zilver PTX has added several design elements for new, simple[1] deployment; greater efficiency; and even more options.

- New, single-handed thumbwheel delivers precise, accurate stent deployment[2]
- Based on Zilver Flex® stent platform that features fracture-resistance technology[3] (1.9% fracture rate through 5 years) along with balanced flexibility and radial force
- Reduced package size[4]
- Up to 120 mm stent lengths



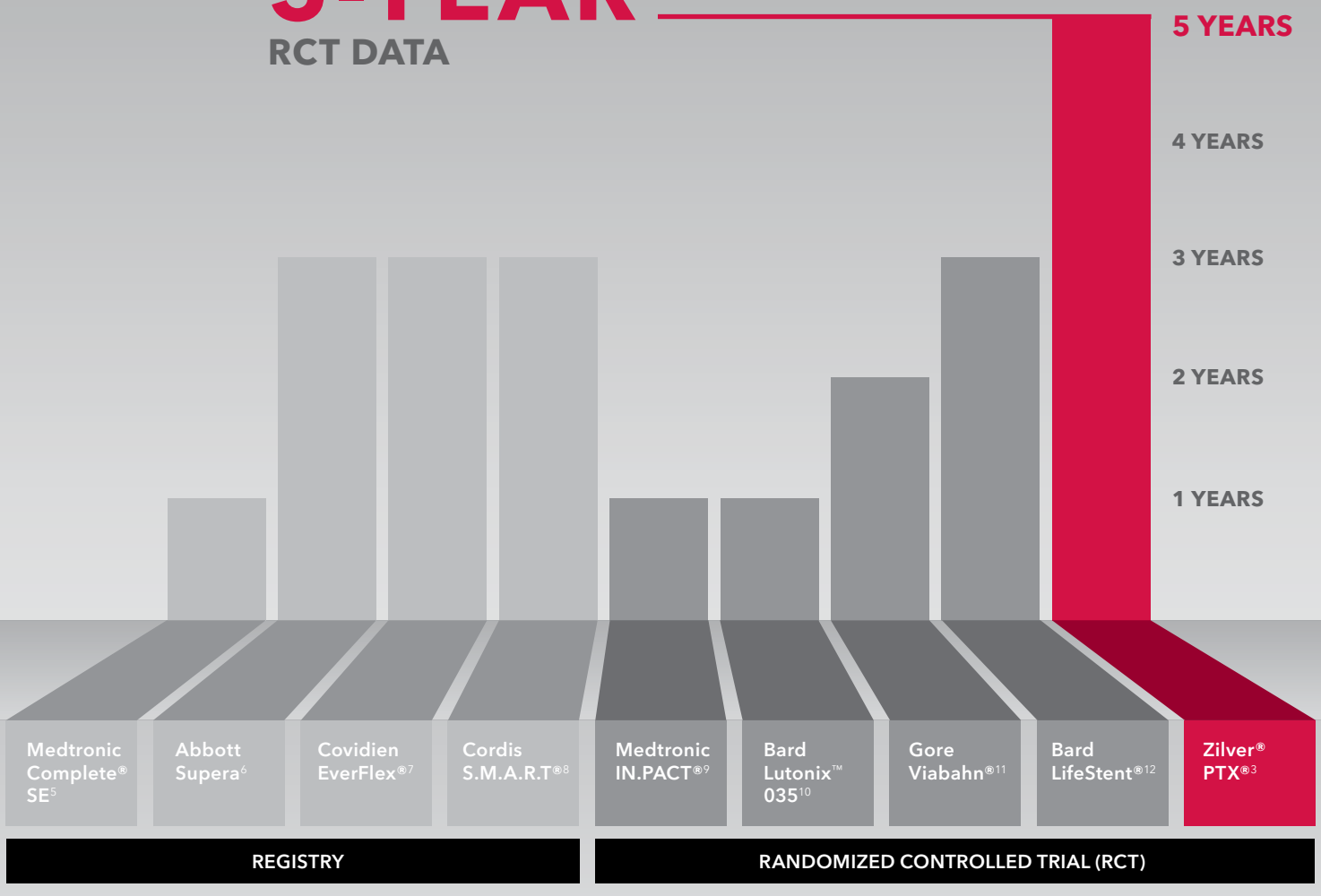
NEW, SIMPLE[1] DEPLOYMENT

AVAILABLE with 120 mm stents



Game-changing
evidence

FIRST AND ONLY
SFA STENT WITH 5-YEAR RCT DATA



Current pivotal trial data: Duration based on completed follow-up.

NOW WITH 5-YEAR DATA[3]

72%

PRIMARY PATENCY
AT 5 YEARS[3]

85%

FREEDOM FROM TARGET LESION REVASCULARIZATION (TLR)
AT 5 YEARS[3]

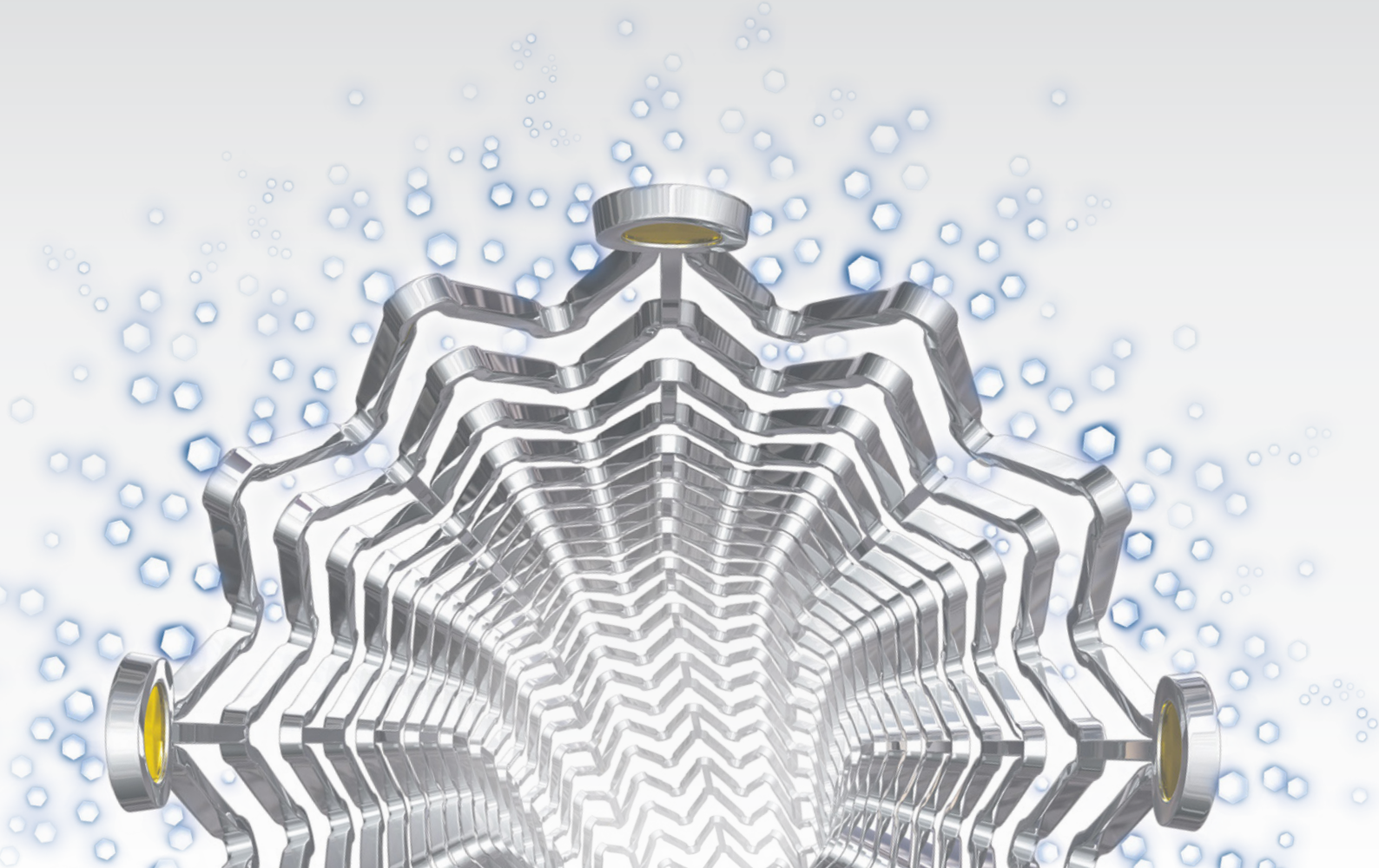
Note: Numbers are for provisional Zilver PTX.

Game-changing

drug effect

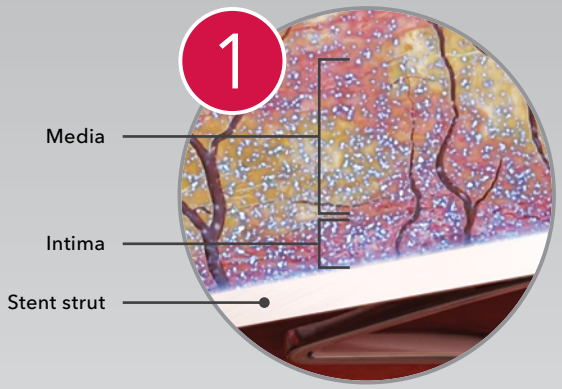
Zilver PTX is the first and only drug-eluting stent approved for the SFA.[13]

Paclitaxel inhibits neointimal hyperplasia[14] and has been proven over 5 years to reduce restenosis and reinterventions by nearly half compared to bare-metal stents.[3]



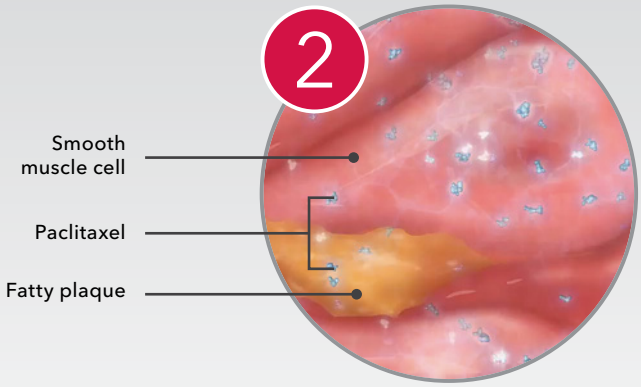
TIME-TESTED TECHNOLOGY[3]

How drug elution works



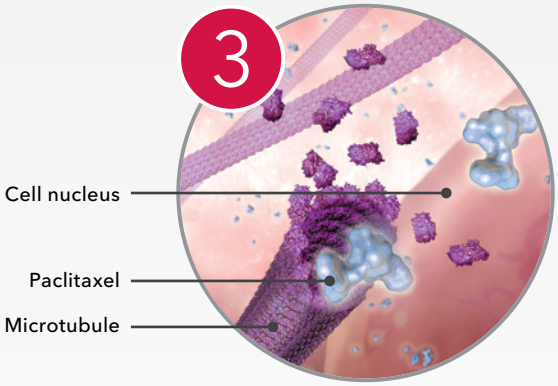
Release:

> 98% of the paclitaxel coating is released from the stent within 72 hours.*[14]
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**.*[14]



Inhibiting:

Inside the cell, the drug binds to microtubules and inhibits mitosis.[14]

*Based on pharmacokinetic studies in porcine models.

Zilver® PTX®

DRUG-ELUTING PERIPHERAL STENT

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	6.0
G35303	ZISV6-35-80-5.0-60-PTX	5	60	6.0
G35304	ZISV6-35-80-5.0-80-PTX	5	80	6.0
G35305	ZISV6-35-80-5.0-100-PTX	5	100	6.0
G35306	ZISV6-35-80-5.0-120-PTX	5	120	6.0
G35307	ZISV6-35-80-6.0-40-PTX	6	40	6.0
G35308	ZISV6-35-80-6.0-60-PTX	6	60	6.0
G35309	ZISV6-35-80-6.0-80-PTX	6	80	6.0
G35310	ZISV6-35-80-6.0-100-PTX	6	100	6.0
G35311	ZISV6-35-80-6.0-120-PTX	6	120	6.0
G35312	ZISV6-35-80-7.0-40-PTX	7	40	6.0
G35313	ZISV6-35-80-7.0-60-PTX	7	60	6.0
G35314	ZISV6-35-80-7.0-80-PTX	7	80	6.0
G35315	ZISV6-35-80-7.0-100-PTX	7	100	6.0
G35316	ZISV6-35-80-7.0-120-PTX	7	120	6.0
G35317	ZISV6-35-80-8.0-40-PTX	8	40	6.0
G35318	ZISV6-35-80-8.0-60-PTX	8	60	6.0
G35319	ZISV6-35-80-8.0-80-PTX	8	80	6.0
G35320	ZISV6-35-80-8.0-100-PTX	8	100	6.0
G35321	ZISV6-35-80-8.0-120-PTX	8	120	6.0

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	6.0
G35274	ZISV6-35-125-5.0-60-PTX	5	60	6.0
G35275	ZISV6-35-125-5.0-80-PTX	5	80	6.0
G35276	ZISV6-35-125-5.0-100-PTX	5	100	6.0
G35277	ZISV6-35-125-5.0-120-PTX	5	120	6.0
G35281	ZISV6-35-125-6.0-40-PTX	6	40	6.0
G35282	ZISV6-35-125-6.0-60-PTX	6	60	6.0
G35283	ZISV6-35-125-6.0-80-PTX	6	80	6.0
G35284	ZISV6-35-125-6.0-100-PTX	6	100	6.0
G35285	ZISV6-35-125-6.0-120-PTX	6	120	6.0
G35286	ZISV6-35-125-7.0-40-PTX	7	40	6.0
G35287	ZISV6-35-125-7.0-60-PTX	7	60	6.0
G35288	ZISV6-35-125-7.0-80-PTX	7	80	6.0
G35289	ZISV6-35-125-7.0-100-PTX	7	100	6.0
G35290	ZISV6-35-125-7.0-120-PTX	7	120	6.0
G35297	ZISV6-35-125-8.0-40-PTX	8	40	6.0
G35298	ZISV6-35-125-8.0-60-PTX	8	60	6.0
G35299	ZISV6-35-125-8.0-80-PTX	8	80	6.0
G35300	ZISV6-35-125-8.0-100-PTX	8	100	6.0
G35301	ZISV6-35-125-8.0-120-PTX	8	120	6.0

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

References

1. User testing feedback. Data on file.
2. See engineering verification testing (accuracy test of +/- 3 mm: criteria met).
3. Dake M. The Zilver PTX randomized trial of paclitaxel-eluting stents for femoropopliteal artery disease: 5-year results. Presented at: VIVA 2014: Vascular Interventional Advances Conference; November 4-7, 2014; Las Vegas, Nevada.
4. Data on file.
5. Summary of safety and effectiveness data (SSED): Complete® SE Vascular Stent System. Food and Drug Administration Web site. http://tinyurl.com/kllltmtk. Accessed Oct. 21, 2014.
6. Metzger DC. Technical tips and tricks to optimize the performance and outcomes with the Supera stent and probably all stents: Proper sizing, avoiding elongation and adequate predilation matter in producing good 3-year results. Presented at VEITHsymposium; November 2014; New York, NY.
7. Bosiers M. Durability II study: 3-year results. Paper presented at: the Annual Leipzig Interventional Course (LINC); January 2014; Leipzig, Germany.
8. Jaff MR. SMART nitinol self-expanding stent in the treatment of obstructive superficial femoral artery disease: Three-year clinical outcomes from the STROLL trial. Presented at: International Symposium on Endovascular Therapy; January 21, 2014; Miami Beach, FL.
9. Tepe G. Randomized trial of IN.PACT Admiral DCB vs. PTA for the treatment of atherosclerotic lesions in the SFA and/or PPA. Paper presented at: Charing Cross Symposium; April 5-8, 2014; London, UK.
10. LUTONIX® 035 Drug Coated Balloon PTA Catheter [package insert]. Tempe, AZ: C.R. Bard, Inc.; 2014.
11. Gore® Viabahn® Endoprosthesis with Heparin Bioactive Surface [package insert]. Flagstaff, AZ: W.L. Gore & Associates, Inc.; 2013.
12. Bard® LifeStent® XL Stent and Delivery System Vascular Application [package insert]. Tempe, AZ: Bard Peripheral Vascular, Inc.; 2010.
13. Orenstein B. Looking for a leg up—first drug-eluting stent for PAD approved. *Radiol Today*. 2013;14(3):14.
14. 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.

INTENDED USE: The Zilver PTX Drug-Eluting Peripheral Stent is intended for use in the treatment of symptomatic vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameter from 4 mm to 7 mm. To avoid involvement of the common femoral artery, the proximal end of the stent should be placed at least 1 cm below the origin of the superficial femoral artery. To avoid involvement of the below-the-knee popliteal artery, the distal end of the stent should be placed above the plane of the femoral epicondyles.

CONTRAINDICATIONS: Stenosis that cannot be dilated to permit passage of the introducer sheath • Stenting of an arterial vessel where leakage from the artery could be exacerbated by placement of a stent • Patients with bleeding disorders • Women who are pregnant, breastfeeding, or plan to become pregnant in the next 5 years should not receive a Zilver PTX Drug-Eluting Peripheral Stent. It is unknown whether paclitaxel will be excreted in human milk, and there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

WARNINGS: Persons with allergic reactions to nitinol may suffer an allergic reaction to this implant. • Persons allergic to paclitaxel may suffer an allergic reaction to this implant. • For adult use only. • Use of this device is restricted to a trained healthcare professional.

PRECAUTIONS: This product is intended for use by physicians trained and experienced in diagnostic and interventional vascular techniques. Standard techniques for interventional vascular procedures should be employed • Manipulation of the Zilver PTX Drug-Eluting Peripheral Stent requires fluoroscopic control • If resistance is met during advancement of the delivery system, do not force passage. Remove the delivery system and replace with a new device. • Do not try to remove the stent from the introducer system before use. • Ensure that the red safety lock is not inadvertently depressed before stent deployment is desired. • A 0.89 mm (0.035 inch) wire guide should be used during tracking, deployment, and removal to ensure adequate support of the system. If hydrophilic wire guides are used, they must be kept fully activated. • Do not use excessive force to deploy the stent. If excessive resistance is felt when beginning deployment, remove the delivery system without deploying the stent and replace with a new device. • Do not expose the delivery system to organic solvents (e.g., alcohol). • Do not use power injection systems with the delivery system. • Do not torque the delivery system during introduction or deployment. • The device is intended for single use only. Attempts to reprocess, re-sterilize and/or reuse may lead to device failure and/or transmission of disease. • The stent retraction sheath cannot be re-advanced nor can the stent be recaptured following the start of stent deployment. • Following stent deployment, if resistance is met during the withdrawal of the delivery system, carefully remove the delivery system and wire guide together as a unit.
If resistance is still encountered during removal of the delivery system and wire guide as a unit, remove the wire guide, delivery system and introducer sheath together as a unit.

POTENTIAL ADVERSE EVENTS: Potential adverse events that may occur include, but are not limited to: Allergic reaction to anticoagulant and/or antithrombotic therapy or contrast medium • Allergic reaction to nitinol • Atheroembolization (Blue Toe Syndrome) • Arterial aneurysm • Arterial rupture • Arterial thrombosis • Arteriovenous fistula • Death • Embolism • Hematoma/hemorrhage • Hypersensitivity reactions • Infection • Infection/abscess formation at access site • Ischemia requiring intervention (bypass or amputation of toe, foot or leg) • Pseudoaneurysm formation • Renal failure • Restenosis of the stented artery • Stent embolization • Stent malapposition • Stent migration • Stent strut fracture • Vessel perforation or rupture • Worsened claudication/rest pain.
Although systemic effects are not anticipated, refer to the Physicians' Desk Reference for more information on the potential adverse events observed with paclitaxel. Potential adverse events, not described in the above source, may be unique to the paclitaxel drug coating, including • Allergic/immunologic reaction to the drug coating • Alopecia • Anemia • Blood product transfusion • Gastrointestinal symptoms • Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis • Myalgia/Arthralgia • Myelosuppression • Peripheral neuropathy.

DRUG INTERACTIONS: Formal drug interaction studies have not been conducted with the Zilver PTX Drug-Eluting Peripheral Stent. In the absence of formal clinical drug interaction studies, caution should be exercised when administering paclitaxel concomitantly with known substrates or inhibitors of the cytochrome P450 isoenzymes CYP2C8 and CYP3A4.

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