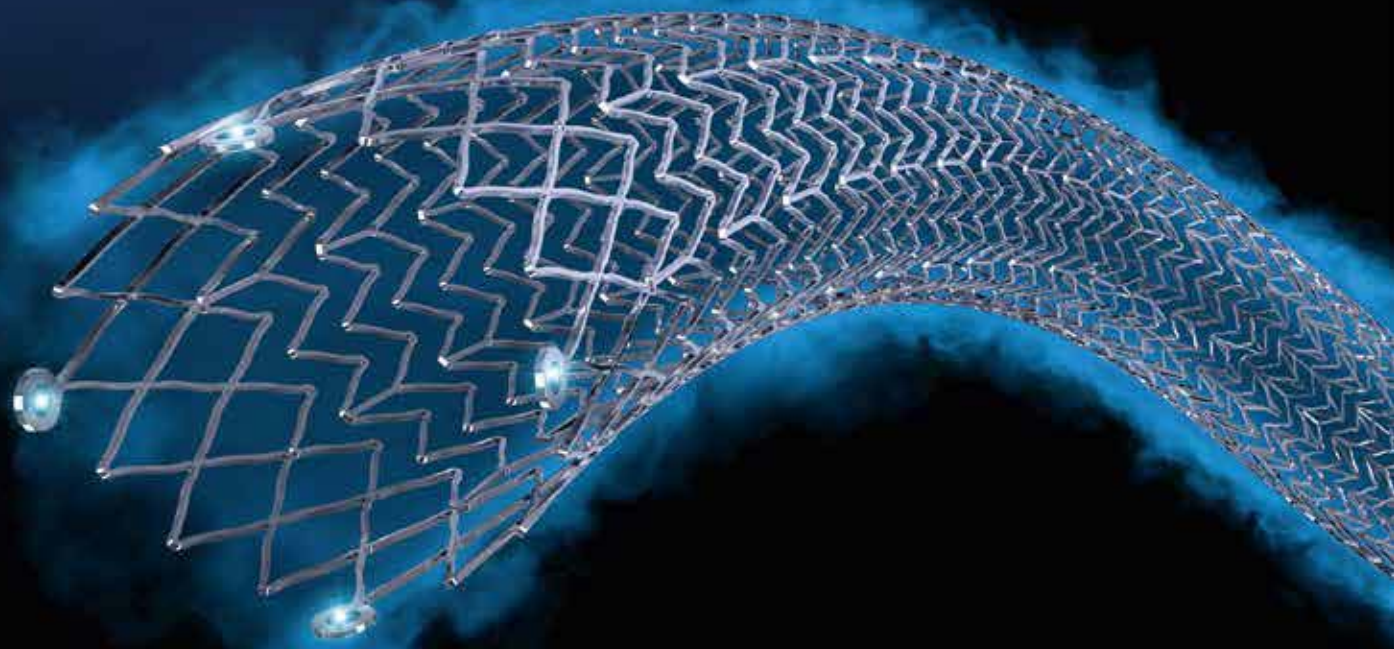
Boston Scientific

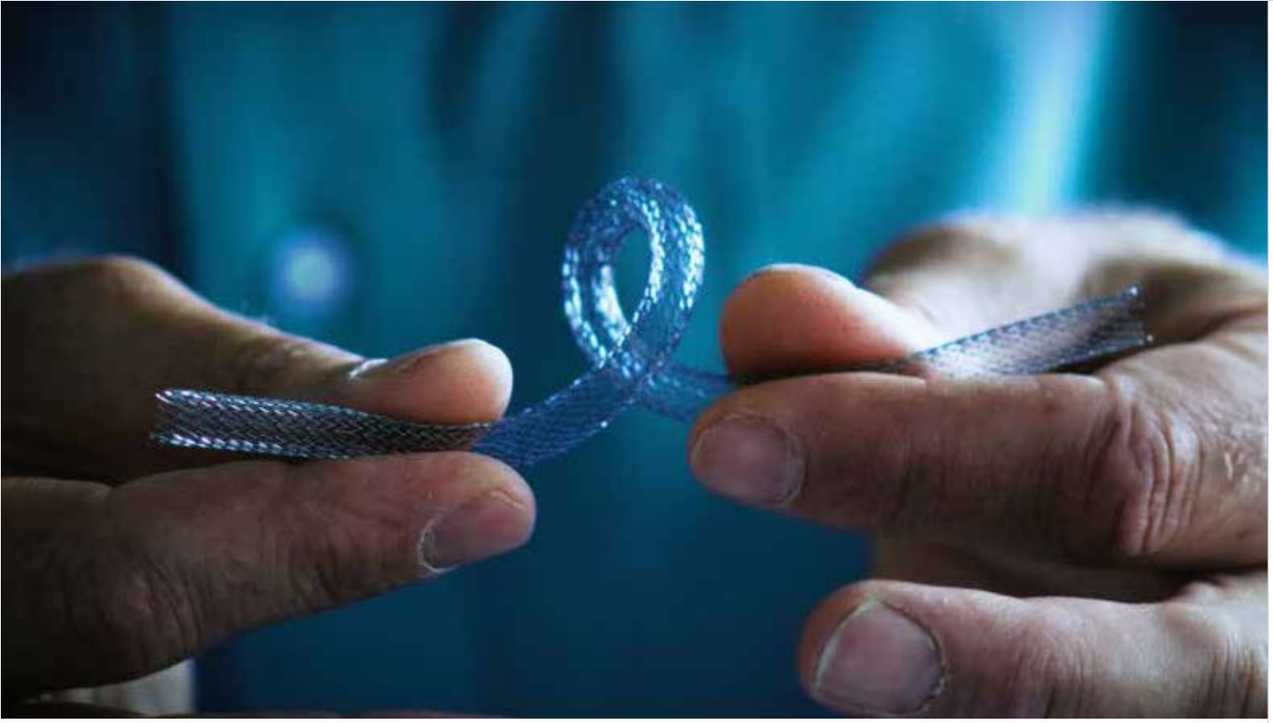
Advancing science for life™



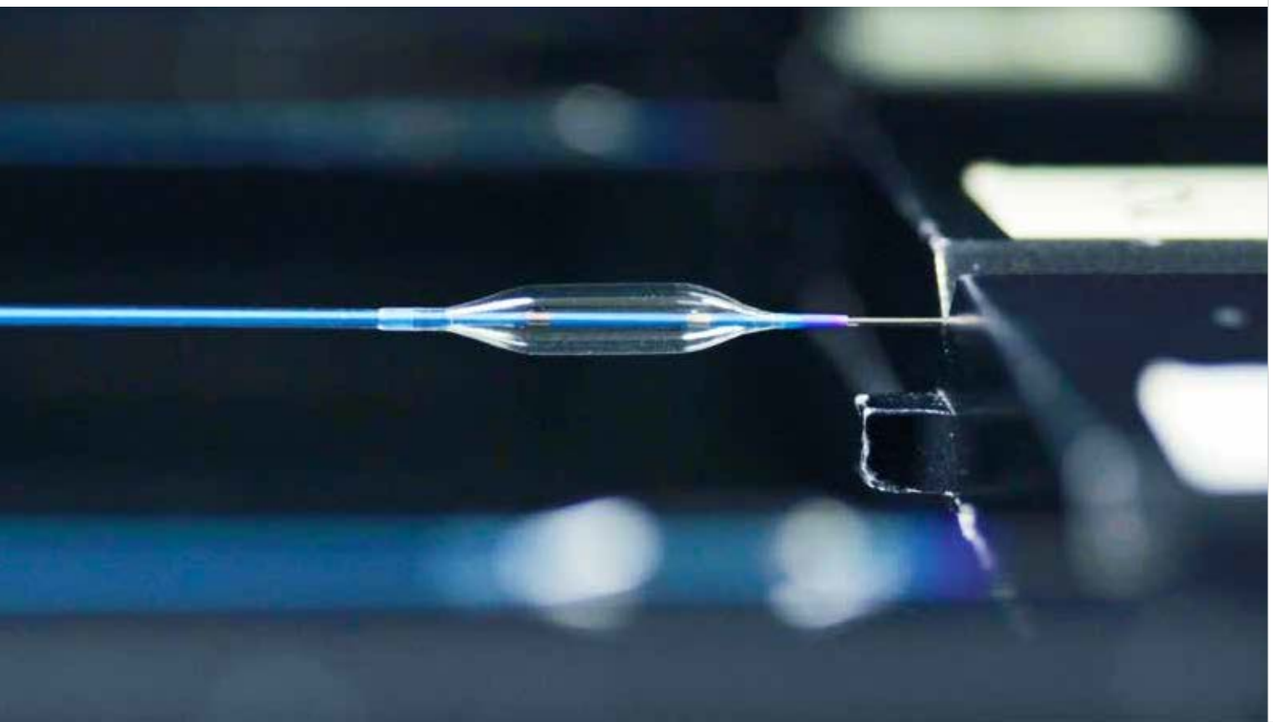
ELUVIA™ Drug-Eluting Stent | **RANGER™** Drug-Coated Balloon

TAKE THE FIGHT TO PAD

With bold evidence and superior choice.

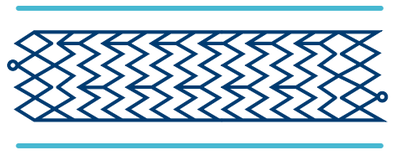


Every major advancement, decades in the making.



ELUVIA™ DES

Sustained release for the SFA.



Only the Eluvia Drug-Eluting Stent offers sustained drug release to match the restenotic process in the SFA,[1] with the lowest drug-dose delivered by the world's most proven polymer.[2]

WORLD'S MOST PROVEN PROMUS POLYMER
Tuned to intelligently deliver the lowest dose of drug (0.167 µg/mm²) of any drug-eluting SFA technology over 365 days.[2]

HYDROPHOBIC PROMUS POLYMER
Protects the drug from dissolving in the blood and offers highly controlled drug delivery to the target lesion.

REDUCED DOWNSTREAM PARTICULATES
Downstream particulates are minimal and comparable to a bare metal stent.[3]

LOW SYSTEMIC DRUG EXPOSURE
No measurable levels of paclitaxel in the bloodstream within 30 minutes.[4]

Two drug-eluting technologies developed with the robust engineering you've come to expect from the industry leader.

RANGER™ DCB

Delivers like nothing else.

Ranger DCB is built with TransPax™ next-generation coating on the physician preferred Sterling™ 0.014"/0.018" balloon platform[5], featuring the lowest tip entry profile of any SFA DCB.[6]

TransPax™ is LIPOPHILIC
Enables targeted and efficient delivery of low-dose paclitaxel (2 µg/mm²) into the lesion.

TransPax™ is HYDROPHOBIC
Protects the drug from dissolving in blood prior to deployment and limits drug waste.

REDUCED DOWNSTREAM PARTICULATES
Lowest amount of downstream particulates compared to other DCBs.[7]

LOW SYSTEMIC DRUG EXPOSURE
No measurable levels of paclitaxel in the bloodstream within an hour for the majority of patients.[8]

Defining a new standard.

The best outcomes for your patients begin with our investment in the quality and quantity of evidence you demand.

This is how we take the fight to PAD.

IMPERIAL RCT* - Eluvia DES vs. Zilver™ PTX™

The world's first head-to-head DES SFA Trial.[9]

EMINENT RCT* - Eluvia™ DES vs. BMS

The world's largest industry-sponsored RCT of DES for SFA.[10]

SAVAL RCT* - SAVAL DES vs. PTA

SAVAL DES receives the first ever Breakthrough Device Designation from the peripheral branch of the FDA.[11]

Enrollment Begins

1-Year Results

Superior primary patency vs. Zilver PTX.[12]

2-Year Results

Highest 2-Year primary patency ever reported for an SFA DES.[14] Statistically significant reduction in repeat procedures.[15]

1-Year Results

Superior primary patency vs. BMS.[16]

COMPARE RCT*† - RANGER DCB vs. IN.PACT DCB

The world's first head-to-head SFA DCB trial.[13]

RANGER II SFA RCT* - RANGER DCB vs. PTA

Pivotal, prospective RCT.

ELEGANCE‡ Registry

Capturing real world, global evidence in up to 5,000 patients treated with Ranger DCB or Eluvia DES over 5 years.

1-Year and 2-Year Results

Similar primary patency with HALF the total drug dose vs. IN.PACT.[13,18,19]

1-Year Results

Superior primary patency vs. PTA.[17]

2-Year Results

Highest 2-Year primary patency ever reported for an SFA DCB.[20]

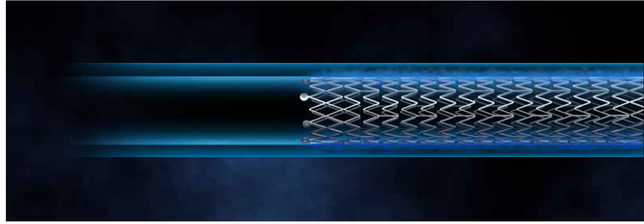
Enrollment Begins

BSC is committed to studying DE technologies in patient populations who have been historically underrepresented in clinical trials. Elegance will enroll no less than 40% women and 40% people of color.

* Randomized Controlled Clinical Trial † Investigator-Sponsored Research ‡ Registry

"Boston Scientific is the first company to design clinical trials to evaluate comparative effectiveness head-to-head against competitive technologies. Whether it's through independently adjudicated trials, investigator-sponsored research or real-world evidence from registries, we are committed to advancing science through best-in-class evidence generation."

- Michael R. Jaff, D.O., Vice President, Clinical Affairs, Innovation and Technology



ELUVIA DES

A new standard of care in SFA stenting.

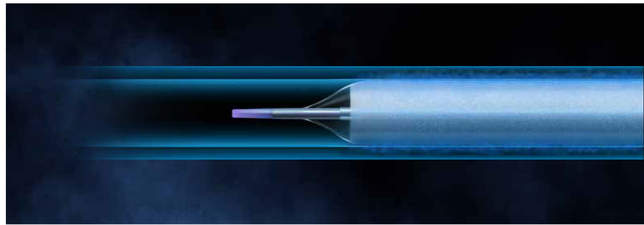
Designed to meet the challenges of the SFA with outstanding flexibility and precise stent placement, Eluvia DES demonstrates unparalleled clinical evidence and outcomes at 2-Years.[14]

Choose, then conquer.

RANGER DCB

Exceptional outcomes. Effortless deliverability.

Demonstrating exceptional outcomes at 2-Years,[21] Ranger DCB is built on the physician-preferred Sterling™ 0.014"/0.018" balloon platform[5] for ease and effectiveness.



Sources:

1. Iida, O. et al. Catheterization and Cardiovascular Interventions. 2011; 78:611-617. Kimura T, et al. N Engl J Med 1996,334-:561-567. Based on pre-clinical PK analysis for Zilver PTX. (Dake MD, et al. J Vasc Interv Radiol. 2011;22(5):603-610); IN.PACT Pacific, Lutonix and Ranger DCBs (Gongora CA, et al. JACC Cardiovasc Interv. 2015 Jul;9(8):1115-1123. doi: 10.1016/j.jcin.2015.03.020.); and Eluvia (Müller-Hülsbeck S. Expert Opin Drug Deliv. 2016 Oct 5:106.) Data on file at Boston Scientific.

2. Drug Dose Data from Eluvia DES, Zilver PTX, Lutonix 018 DCB, Lutonix 035 DCB, Stellarex 035 DCB and Ranger DCB Instructions for Use. Data on file at Boston Scientific. Represents total global sales of the PROMUS (Boston Scientific) and XIENCE (Abbott) stents since 2006.

3. Eluvia's drug dose density is 0.167µg/mm2. Total drug dose for 6x120mm stent is 409µg. Downstream particulates (≥ 10µm) collected with a polycarbonate filter showed Eluvia had 411 particulates vs. EverFlex BMS's 446, Zilver PTX's 10,523 and IN.PACT DCB's 977,333. Devices were tested in simulated-use conditions in a tortuous vessel model under clinically relevant flow conditions. Data on file at Boston Scientific.

4. Half-life = period of time required for concentration of drug in the bloodstream to be reduced by 50% Eluvia PK results from Boston Scientific data on file. Paclitaxel plasma concentrations measured at 10 and 30 minutes and 1, 2, 3, 4, 6, 12, 24 and 48 hours post-implant. Drug levels for Eluvia were too low to measure a plasma half-life. Presented by William Gray at LINC 2019. Data from Lutonix, Stellarex, Zilver PTX and IN.PACT Directions for Use. The limit of quantification was defined as < 1 ng/mL. IMPERIAL PK Substudy. Gray WA, et al; A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomized, non-inferiority trial. 1-Year Results. The Lancet. 2018 Oct 27;392(10157):1541-1551. doi: 10.1016/S0140-6736(18)32262-1. Epub 2018 Sep 24. PMID: 30262332.

5. DRG Data, CY 2021, 0.018" PTA Balloons.

6. Boston Scientific Data on File. Ranger Catheter Competitive Testing Report, 92517674. Measurements taken from 6 x 120 devices for Ranger DCB, Lutonix™ 035 DCB, IN.PACT Admiral DCB and Stellarex™ 035 DCB. Lutonix 018 DCB measurements taken from 6 x 150 devices.

7. Gongora et al. Comparative Drug-Coated Balloon Study. JACC Cardiovasc Interv. 2015 doi.org/10.1016/j.jcin.2015.03.020.

8. The limit of quantification was defined as < 1 ng/mL. At 1-hour 11 of 12 patients had no measurable levels of paclitaxel in their bloodstream. At 3-hours the 12th patient had no measurable levels of paclitaxel. RANGER II SFA PK Substudy. RANGER II SFA RCT 1-Year Results published in JACC:CI. doi.org/10.1016/j.jcin.2021.03.021.

9. Gray WA, et al; A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. 1-Year Results. The Lancet. 2018 Oct 27;392(10157):1541-1551. doi: 10.1016/S0140-6736(18)32262-1. Epub 2018 Sep 24. PMID: 30262332.

10. EMINENT RCT 1-Year Results presented by Yann Gouëffic, MD. VIVA 2021.

11. Caution: Investigational Device. Limited by Federal (or US) law to investigational use only. Not available for sale.

12. IMPERIAL Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against Cook Medical's Zilver™ PTX™ Stent, single-blind, non-inferiority design; independent core lab adjudication. Superiority determined in a post hoc analysis that was specified prior to unblinding. 1-Year Binary Primary Patency rate of 86.8% in the Eluvia arm vs. 77.5% in the Zilver PTX arm (p-value = 0.0144).

13. COMPARE 1-Year Results Published in the European Heart Journal. doi.org/10.1093/eurheartj/ehaa049

14. Kaplan-Meier Estimate. Intention to Treat. IMPERIAL head-to-head RCT. Highest 2-Year primary patency based on 2-Year Kaplan-Meier Primary Randomization for Zilver PTX RCT & EMINENT. Gray WA, LINC 2020 Müller-Hülsbeck S, et al. Cardiovasc Intervent Radiol. 2021;44(3):368-376.

15. Intention to treat. Adapted from Iida, O, VIVA 2019 Presentation. IMPERIAL Head-to-Head RCT 2-Year results. Clinically-Driven TLR data (Eluvia 12.7% vs. Zilver PTX 20.1%, p=0.0495).

16. EMINENT Trial: A global randomized controlled multi-center trial with 2:1 randomization of the Eluvia™ Drug-Eluting Stent against commercially-available Self-Expanding Bare Nitinol Stents, single-blind, superiority design; independent core lab adjudication. Primary Endpoint: 1-Year Binary Primary Patency rate of 83.2% in the Eluvia arm vs. 74.3% in the Bare-Metal Stenting arm (p-value = 0.0077).

17. RANGER II SFA RCT 2-Year Results presented by Ravish Sachar, MD. VIVA 2021. Sustained improvement was demonstrated for Ranger DCB vs. standard PTA through 2-Year follow-up in Kaplan-Meier analysis (log-rank p=0.0129). Superior primary patency was demonstrated at the 1-Year primary endpoint (Binary Primary Patency = 82.9% for Ranger DCB and 66.3% for PTA; p=0.0013) per Sachar R, et al. 1-Year Results From the RANGER II SFA Randomized Trial of the Ranger Drug-Coated Balloon. JACC Cardiovasc Interv. 2021;14(10):1123-1133. doi: 10.1016/j.jcin.2021.03.021.

18. COMPARE Head-to-Head RCT 2-Year Results presented by Sabine Steiner, MD. LINC 2021.

19. Based on total drug dose for (4mmx60mm) or (averages for full size matrix) per the Ranger™ Paclitaxel-Coated PTA Balloon Catheter and IN.PACT™ Admiral Instructions for Use.

20. Ranger II SFA 2-Year Results Presented at VIVA 2021 by Ravish Sachar. Highest 2-Year primary patency based on 2-Year Kaplan-Meier estimates reported for Ranger II SFA, IN.PACT SFA, ILLUMENATE and LEVANT II.

21. RANGER II SFA RCT 2-Year Results presented by Ravish Sachar, MD. VIVA 2021.

Eluvia™ Drug-Eluting Vascular Stent System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The ELUVIA Drug-Eluting Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters (RVD) ranging from 4.0-6.0 mm and total lesion lengths up to 190 mm. **CONTRAINDICATIONS:** Women who are pregnant, breastfeeding, or plan to become pregnant in the next 5 years should not receive an ELUVIA Drug-Eluting 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. • Patients who cannot receive recommended anti-platelet and/or anti-coagulant therapy. • Patients judged to have a lesion that prevents proper placement of the stent or stent delivery system. **WARNINGS:** 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 Section 8.1 of the DFU for further information. • The delivery system is not designed for use with power injection systems. • Only advance the stent delivery system over a guidewire. • The stent delivery system is not intended for arterial blood monitoring. • In the event of complications such as infection, pseudoaneurysm or fistula formation, surgical removal of the stent may be required. • Do not remove the thumbwheel lock prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent. • It is strongly advised that the treating physician follow the Inter-Society Consensus (TASC II) Guidelines recommendations (or other applicable country guidelines) for antiplatelet therapy pre-procedure to reduce the risk of thrombosis. Post-procedure dual antiplatelet therapy is required for a minimum of 60 days. **PRECAUTIONS:** Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures. • The stent is not designed for repositioning. • Once the stent is partially deployed, it cannot be "recaptured" or "reconstrained" using the stent delivery system. • The stent may cause embolization from the site of the implant down the arterial lumen. • This product should not be used in patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy. • Persons with a known hypersensitivity to paclitaxel (or structurally-related compounds), to the polymer or its individual components (see details in Primer Polymer and Drug Matrix Copolymer Carrier section), nickel, or titanium may suffer an allergic response to this implant. • Persons with poor kidney function may not be good candidates for stenting procedures.

PROBABLE ADVERSE EVENTS: Probable adverse events which may be associated with the use of a peripheral stent include but are not limited to: Allergic reaction (to drug/polymer, contrast, device or other) • Amputation • Arterial aneurysm • Arteriovenous fistula • Death • Embolization (air, plaque, thrombus, device, tissue, or other) • Hematoma • Hemorrhage (bleeding) • Infection/Sepsis • Ischemia • Need for urgent intervention or surgery • Pseudoaneurysm formation • Renal insufficiency or failure • Restenosis of stented artery • Thrombosis/thrombus • Transient hemodynamic instability (hypotensive/hypertensive episodes) • Vasospasm • Vessel injury, including perforation, trauma, rupture and dissection • Vessel occlusion. Probable adverse events not captured above that may be unique to the paclitaxel drug coating: Allergic/immunologic reaction to drug (paclitaxel or structurally-related compounds) or the polymer stent coating (or its individual components) • Alopecia • Anemia • Gastrointestinal symptoms • Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage or necrosis • Myalgia/Arthralgia • Peripheral neuropathy. There may be other potential adverse events that are unforeseen at this time.

Ranger™ Drug-Coated Balloon

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. 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 Section 8.1 (in the eIFU) for further information. INTENDED USE / INDICATIONS FOR USE: The Ranger Drug Coated Balloon (DCB) is indicated for percutaneous transluminal angioplasty (PTA) of de novo or restenotic lesions up to 180 mm in length located in native superficial femoral and proximal popliteal arteries (SFA/ PPA) with reference vessel diameters of 4 mm to 7 mm. **CONTRAINDICATIONS**: Use of the Ranger DCB is contraindicated in: • Patients with known hypersensitivity to paclitaxel (or structurally-related compounds). • Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy. • Women who are breastfeeding, pregnant, or men intending to father children. • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system. • Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries. **WARNINGS:** • To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel segment to be treated. The inflated length of the balloon (shoulder to shoulder) may exceed the length of the lesion/stenosis by approximately 10 mm on either side within the targeted artery. • The safety of using multiple Ranger DCBs with a total drug dosage exceeding 9266 µg of Paclitaxel in a patient has not been studied. • Using a drug-eluting stent in conjunction with Ranger DCB at the same treatment site has not been studied. **PRECAUTIONS:** • The balloon catheter should be used only by physicians trained in the performance of percutaneous transluminal angioplasty. • The balloon catheter should be used with caution for procedures involving calcified lesions due to the abrasive nature of these lesions. • The balloon catheter is not intended for injection of contrast medium. • Full arterial wall apposition of the Ranger DCB is necessary for proper drug transfer to the vessel. • Do not touch, wipe, bend, or squeeze the balloon. Do not allow it to contact any liquids including organic solvents such as alcohol or detergents prior to insertion. Damage to the balloon coating or premature release of the drug may occur. • This product should not be used in patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy. • If treating a long lesion (longer than the maximum balloon length available), each individual segment should be treated only once with a drug-coated balloon. Treat each segment with a new balloon and minimize overlapping of treated segments. Pregnancy / Lactation This product has not been tested in pregnant or breastfeeding women or in men intending to father children; effects on the developing fetus have not been studied and the risks and reproductive effects remain unknown. It is not recommended that the Ranger DCB be used in women attempting to conceive, or who are pregnant. Prior to use, careful consideration should be given to the continuation of breastfeeding, taking into account the importance of the procedure to the mother. It is not known whether paclitaxel is distributed in human milk. In lactating rats, milk concentrations appeared to be higher than maternal plasma levels and declined in parallel with the maternal levels. Mothers should be advised of the potential for serious adverse reactions to paclitaxel in nursing infants. Drug Information The mechanism of action by which paclitaxel reduces or reverses neointima formation and proliferation, leading to restenosis, as demonstrated in clinical studies has not been established. It is known that paclitaxel promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions. Drug Interaction Possible interactions of paclitaxel with concomitantly administered medications have not been formally investigated. Drug interactions of systemic chemotherapeutic levels of paclitaxel with possible concomitant medications are outlined in the labeling for finished pharmaceuticals containing paclitaxel, such as TAXOL™. Carcinogenicity, Genotoxicity, and Reproductive Toxicology No long-term studies in animals have been published in peer-reviewed literature to evaluate the carcinogenic potential of paclitaxel. Paclitaxel interacts with microtubules; this is the major mechanism by which it inhibits cell growth. One consequence is the loss of whole chromosomes via interactions with spindle microtubules during cell division. As such, paclitaxel is defined as an aneugen (agent causing an alteration in chromosome number). This indirect action is consistent with positive responses in in vitro and in vivo micronucleus genotoxicity assays, which detect DNA fragments. Positive results have also been reported for chromosomal aberrations in primary human lymphocytes. It is not known whether paclitaxel has a separate direct action on DNA in the generation of DNA strand breaks or fragments. It is negative in assays for gene mutation, including salmonella and CHO/HPRT. Paclitaxel administered via IV prior to and during mating produced impairment of fertility in male and female rats at doses > 1 mg/kg. Administration of paclitaxel during the period of organogenesis to rabbits at doses of 3 mg/kg/day caused embryo- and fetotoxicity. Maternal toxicity was also observed at this dose. No teratogenic effects were observed at 1 mg/kg/day; teratogenic potential could not be assessed at higher doses due to extensive fetal mortality. For comparison, the worst-case dose of paclitaxel delivered by the Ranger DCB (assuming maximum size and number of balloons used in a lesion) is 9266 µg, which is approximately 6 and 19 times less than the dose that saw effects in rats and rabbits, respectively, when normalizing to body weight. Pre and Post Procedure Antiplatelet Therapy It is strongly advised that the treating physician follow the Inter-Society Consensus (TASC II) Guidelines recommendations (or other applicable country guidelines) for antiplatelet therapy pre- and post procedure.

ADVERSE EVENTS: Potential adverse events include, but are not limited to, the following: • Allergic reaction (device, contrast medium, medications) • Arteriovenous fistula • Death • Hematoma • Hemorrhage/Bleeding • Hypotension/Hypertension • Infection/Sepsis • Pseudoaneurysm • Thromboembolic episodes • Vascular thrombosis • Vessel injury (e.g., dissection, perforation, rupture) • Vessel occlusion • Vessel spasm Potential adverse events not captured above that may be unique to the paclitaxel drug coating: • Allergic/immunologic reaction to drug (paclitaxel or structurally-related compounds) or coating or its individual components • 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 • Peripheral neuropathy Apart from hypersensitivity reactions (allergic/ immunologic reactions), the likelihood of paclitaxel related adverse events is low, due to the low exposure. There may be other potential adverse events that are unforeseen at this time.

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