Determine appropriate antiplatelet therapy based on the Inter-Society Consensus (TASC II) Guidelines recommendations (or other applicable country guidelines) for antiplatelet therapy post-procedure to reduce the risk of thrombosis. Patients who require premature discontinuation of antiplatelet therapy due to significant active bleeding or the expectation of significant active bleeding should be monitored carefully for cardiovascular and thromboembolic events and once stabilized have their antiplatelet therapy restarted without unnecessary delay.

BSC is committed to long-term follow-up of ongoing studies to further support safety and effectiveness of ELUVIA Drug-Eluting Stents.

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

Implantable Device Patient Information

Advise the patient that additional information may be available to them on the Boston Scientific website (www.bostonscientific.com/patientlabeling).

INFORMATION TO BRIEF THE PATIENT

The physician should consider the following points while counseling patients on the use of ELUVIA in association with the interventional procedure:

- Discuss the risks and benefits including review of potential adverse events listed in this document, both for ELUVIA and for other interventional treatments likely to be employed.
- Discuss patient allergies in particular the risk for patients who may be allergic to paclitaxel, polymer, nickel and/or titanium.
- Discuss the risks and benefits of antiplatelet therapy including risk of thromboembolism should the patient be allergic or discontinue use.
- Discuss post-procedure instructions, including any follow-up appointments, lifestyle changes, medications, and home-care or rehabilitation guidelines.
- Provide the patient with the completed implant card to carry and advise the patient that additional information, including MRI conditions, may be available to them on the Boston Scientific website (www.bostonscientific.com/patientlabeling).
- Instruct the patient to present the implant card to their Healthcare professionals (doctors, dentist, technicians) so they can take the necessary precautions.

Expected Lifetime

Inform the patient that the stent is a permanent implantable and has been tested for structural integrity (fracture resistance) for a minimum of 10 years; however, the materials of the device are nonbiodegradable and are intended to last for the lifetime of the patient.

REFERENCES

The physician should consult recent literature on current medical practice on stent implantation.

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

SYMBOL DEFINITIONS:

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

Table 3. Symbol Definitions

	Contents
IS R	Recommended Introducer Sheath
GW R	Recommended Guidewire
VS	Recommended Vessel Size
	Open Here
30 °C 15 °C 25°C R	Store at 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °F).

REF

H74939295600470	H74939295600810	H74939295701270
H74939295600670	H74939295601010	H74939295701570
H74939295600870	H74939295601210	H74939295700410
H74939295601070	H74939295601510	H74939295700610
H74939295601270	H74939295700470	H74939295700810
H74939295601570	H74939295700670	H74939295701010
H74939295600410	H74939295700870	H74939295701210
H74939295600610	H74939295701070	H74939295701510

EC REP

Boston Scientific Limited
Ballybrit Business Park
Galway IRELAND

AR REP

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link bostonscientific.com/arg

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www.bostonscientific.com

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ELUVIA™

OVER-THE-WIRE

Drug-Eluting Vascular Stent System

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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 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.

1. REUSE WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

STERILE – DO NOT RESTERILIZE – SINGLE USE ONLY

2. DEVICE DESCRIPTION

The ELUVIA Drug-Eluting Vascular Stent System is a device/drug combination product composed of: a device (stent system) and a drug coating (a formulation of paclitaxel contained in a polymer matrix). The characteristics of the ELUVIA Stent System are described in Table 1.

Table 1. ELUVIA Drug-Eluting Vascular Stent System Product Description

ELUVIA Drug-Eluting Vascular Stent System	
Available Stent Lengths (mm)	40, 60, 80, 100, 120, 150
Available Stent Diameters (mm)	6, 7
Stent Material	Nickel Titanium Alloy (NiTi)
Drug Product	A conformal coating of a polymer carrier consisting of paclitaxel (10% by weight) and PVDF (polyvinylidine difluoride 90% by weight) with a maximum nominal drug content of 517 ug on the largest stent (7.00 mm x 150 mm).
Average Stent Length Change At Vessel Diameter	The ELUVIA deployed stent length change from the delivery system is approximately 3% on average or less.
Delivery System Effective Length (cm)	75, 130

Contents

- One (1) ELUVIA Stent with Delivery System

Operating Principle

The ELUVIA Stent System is a device/drug combination product composed of an implantable endoprosthesis (stent), a dual layer drug coating and the stent delivery system.

ELUVIA consists of a bare metal stent coated with a dual layer system (a formulation of paclitaxel contained in a polymer matrix). The primer layer (PBMA) promotes the adhesion of the active layer to the stent. The active layer consists of the drug paclitaxel combined with the polymer PVDF-HFP. The drug/polymer combination allows the paclitaxel drug to be efficiently released over a period of time.

The material comprising the stent is a nickel-titanium (Nitinol) shape memory alloy. Shape memory alloys exhibit special properties including super elasticity and shape memory. Nitinol can exist in two phases: a martensite phase and an austenite phase. Changing from the martensite phase to the austenite phase, or the reverse, is referred to as a phase transformation. During a phase transformation, the atoms rearrange to a different structure, allowing the material to exhibit different behavior. Phase transformations can occur as a result of temperature or stress changes in the material.

The stent delivery system (SDS) is a triaxial design, which means that the design features an outer stationary sheath that aids in stent and delivery system stability during deployment. The stent delivery system consists of the inner sheath assembly comprised of two separate components, the inner liner provides the guide wire lumen for the delivery system and the proximal inner is the delivery system bumper which is a rigid surface to push against to keep the stent stationary during stent deployment as the middle sheath is retracted. The middle sheath protects and constrains the stent prior to stent deployment. The outer sheath provides system stability during stent deployment. The stent is deployed by retracting the middle sheath of the delivery system by pulling back on the pull grip and/or using the thumbwheel.

During manufacturing, the ELUVIA Stent undergoes heat treatments which impart "memory" in the nitinol, allowing it to expand to a specified diameter when exposed to certain conditions of stress and/or temperature. Then the stent is loaded into the delivery system, which transforms the stent into the martensite phase.

When the stent is exposed to body temperature and the middle sheath is retracted back to deploy the stent, the stent transforms from the martensite to austenite phase instantaneously. During the austenite phase, the stent will attempt to return to the diameter that was imparted on the stent during manufacturing. The vessel restricts expansion of the stent diameter.

Materials

2.1 Device Component Description

The stent system is comprised of: the implantable endoprosthesis and the stent delivery system. The stent is a laser cut self-expanding stent composed of a nickel titanium alloy (nitinol). On both the proximal and distal ends of the stent, radiopaque markers made of tantalum increase visibility of the stent to aid in placement. The stent is constrained within a 6F (2.1 mm maximum OD) delivery system. The delivery system is a triaxial design with an outer shaft to stabilize the stent delivery system, a middle shaft to protect and constrain the stent, and an inner shaft to provide a guidewire lumen. The delivery system contains a silicone lubricant on the inner surface of the middle sheath and outer sheath and on the outer surface of the inner shaft. The delivery system is compatible with 0.035 in (0.89 mm) guidewires.

The ELUVIA Drug-Eluting Stent is available in a variety of diameters and lengths. The delivery system is also offered in two working lengths (75 cm and 130 cm).

2.2 Drug Component Description

The ELUVIA Drug-Eluting Vascular Stent System is a self-expanding nitinol (nickel-titanium alloy) stent structure with tantalum radiopaque markers coated with a poly-butyl-methacrylate (PBMA) primar layer and polyvinylidene difluoride hexafluoropropylene (PVDF-HFD) with paclitaxel active layer. Below are the materials used in the ELUVIA Stent by percent weight.

Nitinol 99.999%

Paclitaxel <0.1%

PBMA <0.1%

PVDF-HFP <0.1%

Tantalum <0.1%

2.2.1 Paclitaxel Drug

The active pharmaceutical ingredient in the ELUVIA Drug-Eluting Vascular Stent System is semi-synthetic paclitaxel. Semi-synthetic Paclitaxel is synthesized from precursor compounds isolated from a spectrum of Taxus species and hybrids. The Chemical name of paclitaxel is: Benzenepropanoic acid, β-(benzoylamino)-α-hydroxy-, 6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,11-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, [2aR-[2aα,4β,4aβ,6β,9α(αR*,βS*),11α,12α,12aα,12bα]].

Paclitaxel is a diterpenoid with a characteristic taxane skeleton of 20 carbon atoms, a molecular weight of 853.91 g/mol and a molecular formula of C47H51NO14. It is highly lipophilic, insoluble in water, but freely soluble in methanol, ethanol, chloroform, ethyl acetate and dimethyl sulfoxide.

The chemical structure of Paclitaxel is shown in Figure 1.

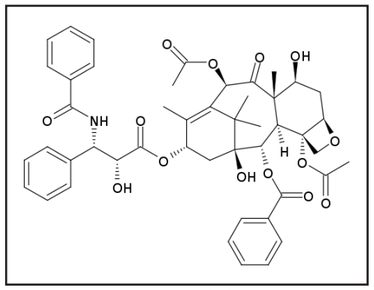

Figure 1. Chemical Structure of Paclitaxel (PTx)

2.2.2 Primer Polymer and Drug Matrix Copolymer Carrier

The stent contains a primer polymer layer PBMA - poly (n-butylmethacrylate) between the bare metal stent and drug matrix layer. The chemical structure of PBMA is provided below in Figure 2.

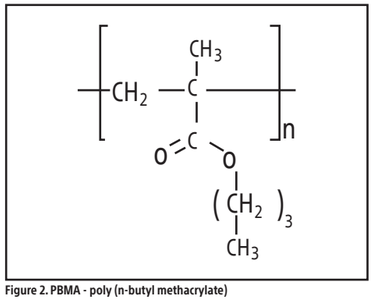

Figure 2. PBMA - poly (n-butyl methacrylate)

The drug matrix layer is comprised of a semi-crystalline random copolymer, PVDF – HFP - poly (vinylidene fluoride-co-hexafluoropropylene), blended with paclitaxel. The chemical structure of PVDF-HFP is provided below in Figure 3.

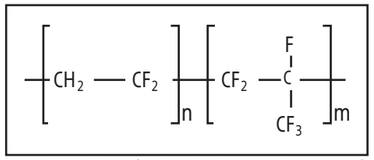

Figure 3. PVDF - HFP- poly (vinylidene fluoride-co-hexafluoropropylene)

2.3 Product Matrix and Paclitaxel Content

Table 2. ELUVIA Drug-Eluting Vascular Stent System Product Matrix and Paclitaxel Content

	Stent Nominal Diameter (mm)	Unconstrained Length (mm)	Working Length (cm)	Reference Vessel Diameter (mm)	Nominal Paclitaxel Content (µg)	Stent Length at Vessel Diameter (mm)
H74939295600470	6	40	75	4.0 - 5.0	135	40
H74939295600670	6	60	75		207	60
H74939295600870	6	80	75		272	79
H74939295601070	6	100	75		344	100
H74939295601270	6	120	75		409	119
H74939295601570	6	150	75		517	149
H74939295600410	6	40	130		135	40
H74939295600610	6	60	130		207	60
H74939295600810	6	80	130		272	79
H74939295601010	6	100	130		344	100
H74939295601210	6	120	130		409	119
H74939295601510	6	150	130		517	149
H74939295700470	7	40	75	5.0 - 6.0	135	41
H74939295700670	7	60	75		207	60
H74939295700870	7	80	75		272	77
H74939295701070	7	100	75		344	100
H74939295701270	7	120	75		409	118
H74939295701570	7	150	75		517	149

BSC (MB IFU Template 16.5354 x 11.6929 A3, 92310061M), IFU, MB, Eluvia, en, 51860297-01A

	Stent Nominal Diameter (mm)	Unconstrained Length (mm)	Working Length (cm)	Reference Vessel Diameter (mm)	Nominal Paclitaxel Content (µg)	Stent Length at Vessel Diameter (mm)
H74939295700410	7	40	130	5.0 - 6.0	135	41
H74939295700610	7	60	130		207	60
H74939295700810	7	80	130		272	77
H74939295701010	7	100	130		344	100
H74939295701210	7	120	130		409	118
H74939295701510	7	150	130		517	149

Non-Pyrogenic

ELUVIA Drug-Eluting Vascular Stent System meets pyrogen limit specifications.

User Information

Only physicians, technicians, and nurses experienced in preparing for and performing peripheral vascular procedures should use this device.

3. 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 mm - 6.0 mm.

Clinical Benefit Statement

The ELUVIA Drug-Eluting Vascular Stent System is designed 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 (PPA). Clinical Benefit can be measured by overall clinical outcomes as demonstrated by primary patency rates, freedom from amputation, freedom from TLR and overall survival with respect to other existing therapies.

Summary of Safety and Clinical Performance

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (EUDAMED) website: (https://ec.europa.eu/tools/eudamed).

4. CONTRAINDICATIONS

The ELUVIA Drug-Eluting Vascular Stent System is contraindicated for use in any situation in which percutaneous transluminal angioplasty (PTA) is contraindicated.

5. WARNINGS

5.1 General

- Do not use a kinked delivery system.
- Only advance the stent delivery system over a recommended guidewire. Use of other guidewires may lead to deployment difficulties resulting in adverse event or need for urgent intervention/surgery.
- When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.
- In the event of a bail out procedure (dissection or other complications requiring additional stent placement), stents used should be of similar composition.
- Should more than one stent be required, allow for at least 5 mm of stent overlap.
- Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the stent. If the lesion is not fully covered, use additional stents as necessary to adequately treat the lesion.
- The minimally acceptable introducer or guide sheath size is printed on the package label. Do not attempt to pass the stent delivery system through a smaller size introducer or guide sheath than indicated on the label.
- In the event of thrombosis of the expanded stent, thrombolysis and/or PTA should be considered.
- In the event of complications such as infection or vessel trauma, surgical removal of the stent may be required.
- Recrossing a partially or fully expanded deployed stent with adjunct devices must be performed with extreme caution to ensure that the adjunct device does not get caught within previously placed stent struts.
- Do not remove the thumbwheel lock prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent.
- In the event of stent deployment difficulties (e.g. partial deployment), manipulation of the device, removal/replacement of the delivery system, or urgent medical or surgical intervention may be required.
- 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 allergy to paclitaxel (or structurally-related compounds), to the polymer or its individual components (see details in these sections: Primer Polymer and Drug Matrix Copolymer Carrier sections), nickel, or titanium may suffer an allergic response to this implant.

5.2 Pre- and Post-Procedure Antiplatelet Therapy

The device carries an associated risk of acute, subacute, or late thrombosis, vascular complications, and/or bleeding events. 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 to reduce the risk of thrombosis.

6. PRECAUTIONS

6.1 General Precautions

- Do not use after the "Use By" date specified on the package. See How Supplied section prior to use.
- 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 an embolism from the site of the implant down the arterial lumen.
- Do not use if the temperature exposure indicator dot on the pouch label is red, indicating that stent expansion may have been compromised.
- Do not use if the temperature exposure indicator dot on the pouch label is missing.
- Do not expose to organic solvents (e.g. alcohol).

6.2 Pregnancy/Lactation

This product has not been tested in pregnant women or in men intending to father children; effects on the developing fetus have not been studied. The risks and reproductive effects remain unknown.

It is not recommended that the ELUVIA Drug-Eluting Vascular Stent System be used in women attempting to conceive, or who are pregnant.

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. Prior to implantation of an ELUVIA Stent, careful consideration should be given to the continuation of breast feeding,taking into account the importance of the stent to the mother.

6.3 Drug Information

The mechanism of action by which a Paclitaxel-Eluting Stent 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.

6.4 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. Given that the amount of paclitaxel loaded onto each ELUVIA Stent is at a minimum 400 times lower than that used in oncological applications of the drug and is released at considerably lower levels than this, drug interactions are unlikely to be detectable. This is reinforced since systemic levels of paclitaxel have not been detected post stent placement in clinical trials.

6.5 Magnetic Resonance Imaging (MRI)

Non-clinical testing has demonstrated the ELUVIA Drug-Eluting Vascular Stent is MRI Conditional. It can be scanned safely up to a total length of 150 mm and overlapping stents up to 200 mm under the following conditions:

- Static magnetic field of 3 Tesla and 1.5 Tesla.
- Static magnetic gradient field of ≤ 100 Tesla/meter (extrapolated).
- Normal operating mode only with a maximum whole body (WB) averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning for patient landmarks above the umbilicus (patient navel).
- Maximum whole body (WB)-SAR of 0.48 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.
- Use whole body transmit/receive coil only. Do not use local transmit coils. Local receive coils can be used.

MRI at 3 T or 1.5 T may be performed immediately following the implantation of the ELUVIA Drug-Eluting Vascular Stent. The ELUVIA Drug-Eluting Vascular Stent should not migrate in this MRI environment. This stent has not been evaluated to determine if it is MRI Conditional beyond these conditions.

3.0 Tesla Temperature Information

In non-clinical testing, the ELUVIA Drug-Eluting Vascular Stent at single lengths of 100 mm and overlapped lengths of 200 mm produced a maximum temperature rise of less than 3.6 °C at a maximum whole body averaged of 0.48 W/kg, that was determined by validated calculation for 15 minutes of MR scanning in a 3 Tesla GE Signa HDxt with software version: 24\LX\MR Software Release: HD16.0 v02 1131 MR scanner. In this model, the reported temperatures accounts for uncertainty and the cooling effects of perfusion.

- For landmarks above the umbilicus the calculated temperature rise was 1.94 °C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes with perfusion cooling and uncertainty.
- For landmarks below the umbilicus the calculated temperature rise was 3.63 °C for a whole body average SAR value of 0.48 W/kg and a continuous scan time of 15 minutes with perfusion cooling and uncertainty.

1.5 Tesla Temperature Information

In non-clinical testing, the ELUVIA Drug-Eluting Vascular Stent at single lengths of 150 mm and overlapped lengths of 200 mm produced a maximum temperature rise of less than 3.47 °C at a maximum whole body averaged specific absorption rate (SAR) of 0.41 W/kg, that was determined by validated calculation for 15 minutes of MR scanning in a GE 1.5 Tesla Coil, (Model 46-306600G2, General Electric Healthcare, Milwaukee, WI) MR scanner. In this model, the reported temperatures accounts for uncertainty and the cooling effects of perfusion.

- For landmarks above the umbilicus the calculated temperature rise was 0.9 °C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes with perfusion cooling and uncertainty.
- For landmarks below the umbilicus the calculated temperature rise was 3.47 °C for a whole body average SAR value of 0.41 W/kg and a continuous scan time of 15 minutes with perfusion cooling and uncertainty.

Image Artifact (Per ASTM F2119)

The image artifact extends approximately 5 mm from the perimeter of the device diameter and 1.5 mm beyond each end of the length of the uncoated ELUVIA Stent when scanned in non-clinical testing using the sequence, Spin Echo. With a Gradient Echo sequence the image artifact extends 12 mm from the perimeter of the device diameter and 1.8 mm beyond each end of the length of the stent with both sequences partially shielding the lumen in a 3.0 Tesla Achieva (Achieva Upgrade), Philips Medical Solutions, software version Release 2.5.3.0 2007-09-28 MR system with a Quadrature transmit/receive head coil. Image artifacts in a body birdcage coil are similar to the image artifacts in the transmit/receive CP head coil.

Recommendations

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

7. ADVERSE EVENTS

Potential 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)
- Bleeding/Hemorrhage
- Death
- Embolism (air, plaque, thrombus, device, tissue, or other)
- Hematoma
- Hypotension/hypertension
- Ischemia/necrosis
- Need for additional intervention or surgery
- Renal insufficiency or failure
- Restenosis of stented artery
- Sepsis/infection
- Thrombosis/thrombus
- Vasospasm
- Vessel occlusion
- Vessel trauma (perforation, pseudoaneurysm, injury, rupture, and dissection)

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 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

8. CLINICAL STUDIES

8.1 Summary of the Meta-Analysis: Late Mortality Signal for Paclitaxel-Coated Devices

A meta-analysis of randomized controlled trials published in December 2018 by Katsanos et. al. identified an increased risk of late mortality at 2 years and beyond for paclitaxel-coated balloons and paclitaxel-eluting stents used to treat femoropopliteal arterial disease. In response to these data, FDA performed a patient-level meta-analysis of long-term follow-up data from the pivotal premarket randomized trials of paclitaxel-coated devices used to treat femoropopliteal disease using available clinical data through May 2019. The meta-analysis also showed a late mortality signal in study subjects treated with paclitaxel-coated devices compared to patients treated with uncoated devices. Specifically, in the 3 randomized trials with a total of 1090 patients and available 5-year data, the crude mortality rate was 19.8% (range 15.9% - 23.4%) in patients treated with paclitaxel-coated devices compared to 12.7% (range 11.2% - 14.0%) in subjects treated with uncoated devices. The relative risk for increased mortality at 5 years was 1.57 (95% confidence interval 1.16 - 2.13), which corresponds to a 57% relative increase in mortality in patients treated with paclitaxel-coated devices.

As presented at the June 2019 FDA Advisory Committee Meeting, an independent meta-analysis of similar patient-level data provided by VIVA Physicians, a vascular medicine organization, reported similar findings with a hazard ratio of 1.38 (95% confidence interval 1.06 - 1.80). Additional analyses have been conducted and are underway that are specifically designed to assess the relationship of mortality to paclitaxel-coated devices.

The presence and magnitude of the late mortality risk should be interpreted with caution because of multiple limitations in the available data, including wide confidence intervals due to a small sample size, pooling of studies of different paclitaxel-coated devices that were not intended to be combined, substantial amounts of missing study data, no clear evidence of a paclitaxel dose effect on mortality, and no identified pathophysiologic mechanism for the late deaths.

Paclitaxel-coated balloons and stents improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices. The benefits of paclitaxel-coated devices (e.g., reduced reinterventions) should be considered in individual patients along with potential risks (e.g., late mortality).

In the IMPERIAL Trial such mortality signal has not been found at 2 years. Kaplan Meier mortality estimates at 2 years are 7.1% (95% CI: 4.1%, 10.0%) for the ELUVIA treatment device and 8.0% (95% CI: 3.7%, 12.4%) for the Zilver PTX paclitaxel-coated control device, which fall within the expected mortality rates for this patient population.

9. HOW SUPPLIED

The ELUVIA Drug-Eluting Vascular Stent System is supplied sterile inside a pouch. The device is sterilized via Ethylene Oxide.

Device Details

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Protect from light. Do not remove from carton until ready for use. Store at 25 °C (77 °F); excursions permitted to 15 °C - 30 °C (59 °F - 86 °F).

The ELUVIA Drug-Eluting Stent is a nitinol stent that has an upper temperature limit of 55 °C (131 °F).

Precaution: Do not use if the temperature indicator dot on the carton or pouch is red indicating that stent expansion may have been compromised.

10. OPERATIONAL INSTRUCTIONS

10.1 Inspection Prior To Use

Check the pouch for "Use By" date. Carefully inspect the sterile pouch before opening.

Do not use the product after the "Use By" date. If the integrity of the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package), contact your local Boston Scientific representative for return information. Do not use if any defects are noted.

Additional Items for Safe Use

10.2 Recommended Materials (not included in stent system package)

- 0.035 in (0.89 mm) stiff guidewire of appropriate length (300 cm length recommended for 130 cm length stent delivery systems)
- Introducer or guide sheath of appropriate size and length and equipped hemostatic valve
- Luer lock syringe 10 ml (10 cc) for flushing the stent delivery system

Preparation

10.3 Patient Preparation

The percutaneous placement of a self-expanding stent in a stenotic or obstructed artery should be done in an angiography procedure room with the appropriate imaging equipment. Patient preparation and sterile precautions should be the same as for any angioplasty procedure. Appropriate antiplatelet and anticoagulation therapy must be administered pre- and post-procedure in accordance with standard practices. Angiography should be performed to map out the extent of the lesion(s) and the collateral flow. Access vessels must be sufficiently patent to proceed with further intervention. If thrombus is present or suspected, thrombolysis should precede stent deployment using standard acceptable practice.

10.4 Inject Contrast Media

Perform angiogram using standard technique.

10.5 Evaluate and Mark the Stenosis

Observe fluoroscopically the most distal view of the stenotic or obstructed artery.

Obtain a road map image of the lesion area if necessary.

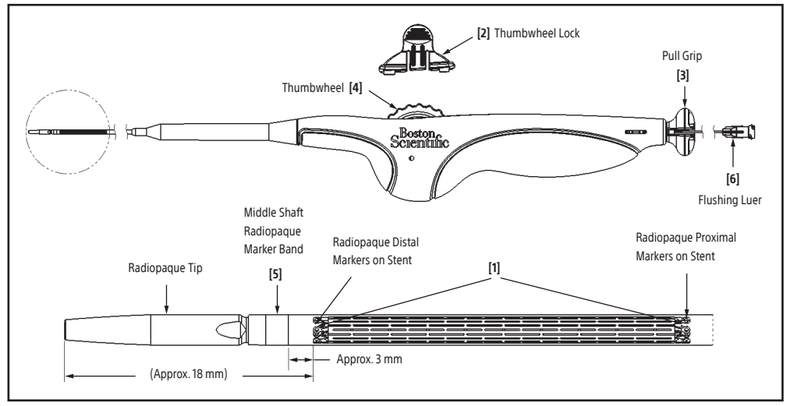

Figure 4. Stent Delivery System

Procedure

10.8 Delivery Procedures

1. Gain arterial access utilizing a 6F (2.1 mm) or larger sheath with a hemostatic valve.

   Precaution: Always use an introducer or guide sheath for the implant procedure, to protect the access site and prevent system damage.

   Precaution: Do not use a kinked delivery system. Kinking of the introducer/guide sheath at the access site can restrict the movement of the delivery system during deployment.

2. Pass a 0.035 in (0.89 mm) guidewire of appropriate length (300 cm length recommended for 130 cm stent delivery system length systems) across the lesion or obstruction.

   Note: A **stiff** 0.035 in (0.89 mm) guidewire is strongly recommended for deployment of the stent, especially for tortuous anatomy and contralateral approaches. Use of undersized guidewires may lead to insufficient support of the device which can compromise stent delivery.

   Note: If using a hydrophilic guidewire, ensure that it is hydrated at all times.

3. Pre-dilate the lesion with a balloon dilatation catheter using conventional technique. After the lesion has been properly dilated, remove the dilatation catheter, leaving the guidewire with the tip distal to the lesion for stent system advancement.

   Precaution: Physicians should use judgment based on experience in dilating arterial lesions and/or obstructions. Never force a balloon catheter to inflate to the point of risking dissection of the arterial wall.

4. Place the ELUVIA Drug-Eluting Stent Delivery System over the guidewire. Advance the delivery system as a unit through the hemostatic valve of the introducer or guide sheath.

   Note: Do not tighten toughy-borst such that it restricts the movement of the delivery system.

   Note: Do not remove the thumbwheel lock prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent.

10.9 Stent Deployment Procedure (Reference Figure 5)

1. Remove slack from the system by advancing the system just beyond the lesion, then, pulling the system back until stent radiopaque markers **[1]** are centered over the target lesion.

   Note: Prior to deployment, ensure adequate distance between the proximal end of the stent and the introducer/guide sheath to prevent deployment within the introducer/guide sheath.

2. Remove the thumbwheel lock **[2]** by compressing the tabs and pulling. Confirm that the radiopaque markers are still properly positioned across the lesion.

   Precaution: If strong resistance is met with the introduction of the delivery system or if unable to initiate release of the stent, remove the entire system from the patient and introduce a new system.

   Note: For optimal performance, keep the entire length of the delivery system that is outside the body as straight and stable as possible. To do so, remove slack from the system, maintain slight backward tension on the delivery system, and anchor the handle on the patient or operating table during deployment. Alternatively, the operator may straighten and stabilize the distal end of the blue outer shaft during deployment.

10.6 Select Proper Stent System

1. Measure the diameter of the reference vessel (proximal and distal to the lesion or obstruction). Select a stent based on Table 2.
2. Measure the entire length of the actual lesion and select the proper length of the stent(s) to be deployed. To help ensure adequate apposition, it is recommended that the length of the stent be chosen so that the ends of the stent extend at least 5 mm beyond both ends of the lesion into healthy tissue.

   Precaution: Should more than one stent be required to cover the lesion, allow for at least 5 mm of stent overlap. It is generally recommended that the distal stent be placed first.

   Precaution: When multiple stents are required, if placement results in metal to metal contact, stent materials should be of similar composition.

3. Estimate the distance between the lesion and the entry site to select the proper stent delivery system length.

10.7 Preparation of Stent Delivery System

1. Open the outer box to reveal the pouch containing the stent delivery system.
2. Check the temperature exposure indicator on the pouch label to confirm that the product has not been compromised. See Precautions section.
3. After careful inspection of the pouch looking for damage to the sterile barrier, carefully peel open the pouch and extract the stent delivery system tray.
4. Carefully withdraw the stent delivery system from the tray by grasping the handle of the delivery system.
5. Examine the stent delivery system for any damage. If it is suspected that the sterility or integrity of the device has been compromised (i.e. kinking or missing component), the device should not be used. The device should not be used if the device is kinked, or if the thumbwheel lock is not attached.
6. Do not remove the thumbwheel lock **[2]** prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent.
7. Attach a 10 ml (10 cc) syringe filled with saline to the flushing luer **[6]** on the handle. Apply positive pressure. Continue to flush until saline appears at the distal end of the guidewire lumen. Remove the flushing luer **[6]** (by pulling the syringe or by pulling flushing luer **[6]**) (Reference Figure 4).

   Note: Failure to eliminate slack (Reference Figure 5) and/or curvature of the delivery system catheter between the introducer/guide sheath and the delivery system handle during deployment may adversely affect deployment accuracy, especially in ipsilateral cases.

   Note: If repositioning of the stent delivery system is required, reinserting the thumbwheel lock will prevent inadvertent deployment.

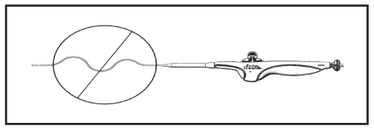

Figure 5. Eliminate slack

10.10 Recommended Method of Deployment

1. While using fluoroscopy maintain position of the distal and proximal stent radiopaque markers **[1]** relative to the targeted site. Roll the thumbwheel **[4]** of the deployment handle in the direction of the arrow indicated on the handle. Continue to roll thumbwheel until the middle shaft radiopaque marker band **[5]** passes the distal stent radiopaque markers. Watch for the distal stent radiopaque markers to begin separating: separation of the distal stent radiopaque markers signals that the stent is deploying.
2. Continue to roll thumbwheel until the middle shaft radiopaque marker band **[5]** passes the proximal radiopaque markers of the stent resulting in full deployment, or until the white activation arrow is visible on pull grip extension rod (for 150 mm length stents), which indicates that pull grip activation is required to complete stent deployment (Reference Figure 6). Long stents (150 mm) will not be fully deployed by the thumbwheel alone.

   Note: When activating the pull grip, avoid rapid deployment.

   Note: Do not restrict movement of the thumbwheel **[4]** otherwise deployment difficulties could be encountered. Do not attempt to pull a partially expanded stent back into introducer/guide sheath as dislodgement may occur.

   Note: Do not push or pull the delivery system during deployment as this may compromise stent length.

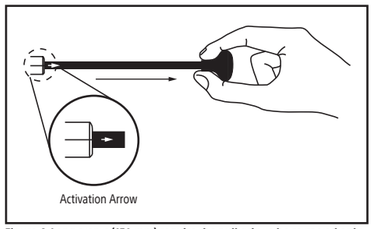

Figure 6. Long stents (150 mm) require the pull grip to be retracted only after the white activation arrow is visible to complete deployment.

3. Long stents (150 mm) require pull grip deployment after the white activation arrow becomes visible on the pull grip extension rod. Grasp the manual pull grip **[3]** and gently pull away from the handle in the direction of the arrow. Slowly pull back until the middle shaft radiopaque marker band **[5]** passes the proximal radiopaque markers of the stent resulting in full deployment.
4. View the delivery system under fluoroscopy, ensuring that the middle shaft radiopaque marker band **[5]** has crossed the proximal stent markers. The delivery system can now be withdrawn.
5. Grasp the guidewire a short distance from handle and repeatedly retract the system over the wire until fully removed. Use caution when withdrawing the stent delivery system and always manipulate under fluoroscopy. If unusual resistance is felt, carefully readvance and rotate the delivery system in an attempt to center the delivery system within the vessel, then carefully attempt to repeat withdrawal.

   Note: Avoid bending the guidewire excessively near handle when retracting device to aid removal and prevent guidewire kinking.

6. If incomplete expansion exists within the stent at any point along the lesion, balloon dilatation can be performed utilizing standard PTA technique.

   Precaution: Never post-dilate the stent using a balloon that is larger in diameter than the nominal (labeled) diameter of the stent.

7. Withdraw guidewire and sheath from patient and establish hemostasis per conventional technique.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose of device and packaging as follows:

After use, device may contain biohazardous substances. Devices that contain biohazardous substances are considered biohazardous waste and should be stored in a biohazard container that is labeled with the biological hazard symbol. Untreated biohazardous waste should not to be disposed of in the municipal waste system. Biohazardous substances should be removed via Incineration prior to disposal. Alternatively, biohazardous waste may be disposed of utilizing a certified facility for biohazardous waste for proper treatment in accordance with hospital, administrative, and/or local government policy.

10.11 Post-Procedure

Assess patient for hematoma and/or other signs of bleeding at the puncture site.

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