Rx ONLY

The XIENCE V®, XIENCE nano®, XIENCE PRIME®, XIENCE PRIME® LL, XIENCE Xpedition®, XIENCE Xpedition® SV and XIENCE Xpedition® LL , XIENCE Alpine™ (XIENCE Family) of Everolimus Eluting Coronary Stents on the MULTI-LINK VISION® or MULTI-LINK MINI VISION® Delivery Systems

INDICATIONS

The XIENCE Family of Everolimus Eluting Coronary Stent Systems are indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions for XIENCE V (length ≤ 28 mm), XIENCE PRIME, XIENCE Xpedition and XIENCE Alpine (lengths ≤ 32 mm) with reference vessel diameters of ≥2.25 mm to ≤ 4.25 mm. Additionally, the entire XIENCE Family is indicated for treating *de novo* chronic total coronary occlusions.

CONTRAINDICATIONS

The XIENCE Family of stents is contraindicated for use in patients:

- Who cannot receive antiplatelet and/or anti-coagulant therapy
- With lesions that prevent complete angioplasty balloon inflation or proper placement of the stent or stent delivery system
- With hypersensitivity or contraindication to everolimus or structurally-related compounds, cobalt, chromium, nickel, tungsten, acrylic, and/or fluoropolymers.

WARNINGS

- Ensure that the inner package sterile barrier has not been opened or damaged prior to use.
- Judicious patient selection is necessary because the use of this device carries the associated risk of stent thrombosis, vascular complications, and/or bleeding events.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

PRECAUTIONS

- Stent implantation should only be performed by physicians who have received appropriate training.
- Stent placement should be performed at hospitals where emergency coronary artery bypass graft surgery is accessible.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. Long-term outcomes following repeat dilatation of the stent are presently unknown.
- Risks and benefits should be considered in patients with severe contrast agent allergies.
- Care should be taken to control the guiding catheter tip during stent delivery, deployment and balloon withdrawal. Before withdrawing the stent delivery system, visually confirm complete balloon deflation by fluoroscopy to avoid guiding catheter movement into the vessel and subsequent arterial damage.
- Stent thrombosis is a low-frequency event that is frequently associated with myocardial infarction (MI) or death.
- When DES are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the SPIRIT family of trials.
- Compared to use within the specified Indications for Use, the use of DES in patients and lesions outside of the labeled indications may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death.
- Orally administered everolimus combined with cyclosporine is associated with increased serum cholesterol and triglycerides levels.
- A patient's exposure to drug and polymer is proportional to the number and total length of implanted stents. See Instructions for Use for current data on multiple stent implantation.
- Safety and effectiveness of the XIENCE Family of stents have not been established for subject populations with the following clinical settings:
  - Patients with prior target lesion or in-stent restenosis related brachytherapy, patients in whom mechanical atherectomy devices or laser angioplasty catheters are used in conjunction with XIENCE Family stents, women who are pregnant or lactating, men intending to father children, pediatric patients, unresolved vessel thrombus at the lesion site, coronary artery reference vessel diameters < 2.25 mm or > 4.25 mm or lesion length > 32 mm, lesions located in saphenous vein grafts, unprotected left main coronary artery, ostial lesions, lesions located at a bifurcation or previously stented lesions, diffuse disease or poor flow (TIMI < 1) distal to the identified lesions, excessive tortuosity proximal to or within the lesion, recent acute myocardial infarction (AMI) or evidence of thrombus in target vessel multivessel disease, and in-stent restenosis
- Everolimus has been shown to reduce the clearance of some prescription medications when administered orally along with cyclosporine (CsA). Formal drug interaction studies have not been performed with the XIENCE Family of stents because of limited systemic exposure to everolimus eluted from the stent.
- Everolimus is an immunosuppressive agent. Consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.
- Oral everolimus use in renal transplant patients and advanced renal cell carcinoma patients was associated with increased serum cholesterol and triglycerides, which in some cases required treatment.
- Nonclinical testing has demonstrated that the XIENCE Family of stents, in single and in overlapped configurations are MR conditional up to 68 mm in length for XIENCE V and XIENCE nano only and up to 71 mm in length for all other XIENCE Family stents. It can be scanned safely under the conditions in the *Instructions for Use*.
- The XIENCE Family of stents should be handled, placed, implanted, and removed according to the *Instructions for Use*.

POTENTIAL ADVERSE EVENTS

Adverse events (in alphabetical order) which may be associated with percutaneous coronary and treatment procedure including coronary stent use in native coronary arteries include, but are not limited to:

- Abrupt closure, Access site pain, hematoma, or hemorrhage, Acute myocardial infarction, Allergic reaction or hypersensitivity to contrast agent or cobalt, chromium, nickel, tungsten, acrylic and fluoropolymers; and drug reactions to antiplatelet drugs or contrast agent, Aneurysm, Arterial perforation and injury to the coronary artery, Arterial rupture, Arteriovenous fistula, Arrhythmias, atrial and ventricular, Bleeding complications, which may require transfusion, Cardiac tamponade, Coronary artery spasm, Coronary or stent embolism, Coronary or stent thrombosis, Death, Dissection of the coronary artery, Distal emboli (air, tissue or thrombotic), Emergent or non-emergent coronary surgery, Fever, Hypotension and / or hypertension, Infection and pain at insertion site, Injury to the coronary artery, Ischemia (myocardial), Myocardial infarction (MI), Nausea and vomiting, Palpitations, Peripheral ischemia (due to vascular injury), Pseudoaneurysm, Renal Failure, Restenosis of the stented segment of the artery, Shock/pulmonary edema, Stroke / cerebrovascular accident (CVA), Total occlusion of coronary artery, Unstable or stable angina pectoris, Vascular complications including at the entry site which may require vessel repair, Vessel dissection

Adverse events associated with daily oral administration of everolimus to organ transplant patients include but are not limited to:

- Abdominal pain (including upper abdominal pain); Anemia; Angioedema; Anorexia; Asthenia; Constipation; Cough; Delayed wound healing/ fluid accumulation; Diarrhea; Dyslipidemia (including hyperlipidemia and hypercholesterolemia); Dyspnea; Dysgeusia; Dyspepsia; Dysuria; Dry skin; Edema (peripheral); Epistaxis; Fatigue; Headache; Hematuria; Hyperglycemia (may include new onset of diabetes); Hyperlipidemia; Hyperkalemia; Hypertension; Hypokalemia; Hypomagnesemia; Hypophosphatemia; Increased serum creatinine; Infections and serious infections: bacterial, viral, fungal, and protozoal infections (may include herpes virus infection, polyoma virus infection which may be associated with BK virus associated nephropathy, and/or other opportunistic infections); Insomnia; Interaction with strong inhibitors and inducers of CY3PA4 or PgP; Leukopenia; Lymphoma and other malignancies (including skin cancer); Male infertility (azospermia and/or oligospermia); Mucosal inflammation (including oral ulceration and oral mucositis); Nausea; Neutropenia; Non-infectious pneumonitis; Pain: extremity, incision site and procedural, back, chest, and musculoskeletal; Proteinuria; Pruritus; Pyrexia; Rash; Stomatitis; Thrombocytopenia; Thrombotic microangiopathy (TMA)/Thrombotic thrombocytopenic purpura (TTP)/ Hemolytic uremic syndrome (HUS); Tremor; Urinary tract infection; Upper respiratory tract infection; Vomiting
- Live vaccines should be avoided and close contact with those that have had live vaccines should be avoided. Fetal harm can occur when administered to a pregnant woman. There may be other potential adverse events that are unforeseen at this time.

Prior to use, please reference the *Instructions for Use* at www.abbottvascular.com/ifu for more information on indications, contraindications, warnings, precautions, and adverse events.

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