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 ≤ 32 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 guidewinder movement into the vessel and subsequent arterial damage.
• Stent thrombosis is a rare, 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 of lesions and lesions outside of the labeled indications may have a higher exposure to drug and polymer.

POTENTIAL ADVERSE EVENTS
Adverse events may be associated with percutaneous coronary and treatment procedure including coronary stent use in native coronary arteries 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 hypolipidemia); Dysphagia; Dyspepsia; Dysuria; Dry skin; Edema (peripheral); Epistaxis; Fatigue; Headache; Hematuria; Hyperglycemia; Myocardial infarction (MI); Nausea and vomiting; Palpitations; Peripheral edema; 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
• Infections: bacterial, viral, fungal, and protozoal infections (may include pseudomonas aeruginosa, enterococcus faecalis, methicillin-resistant Staphylococcus aureus (MRSA), Candida, Pseudomonas aeruginosa, Serratia marcescens, Escherichia coli, Legionella pneumophila, Mycobacterium tuberculosis, and Mycobacterium avium intracellulare); Infections at the site of vessel puncture; Infections with implant device; Infections with medical device; Infections with implant device in the area of the vessel puncture; Infections with medical device in the area of the vessel puncture; Infections with implant device in the area of the vessel puncture; Infections with medical device in the area of the vessel puncture
• Acute myocardial infarction, Allergic reaction or hypersensitivity to contrast agent or cobalt, chromium, nickel, tungsten, acrylic, and/or fluoropolymers; and drug reactions to antiplatelet drugs or contrast agent, Aneurysm, Arterial perforation and injury to the coronary artery, Arterial rupture, Arteriovenous fistula, Arhythmias, 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 emboliz (air, tissue or thrombotic), Emergent or non-emergent coronary surgery, Fever, Hypertension and / or hypertension, Infection and pain at insertion site, Injury to the coronary artery, Ischemia (myocardial, Myocardial infarction (MI), Nausea and vomiting, Palpitations, Peripheral edema, 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
• Allergic reactions to drugs or chemicals that are used in conjunction with XIENCE Family stents, women who 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.
• Alpha-fetoprotein and/or other opportunistic infections; Insomnia; Interaction with strong inhibitors and inducers of CYP3A4 or PgP; Insomnia; Interaction with strong inhibitors and inducers of CYP3A4 or PgP; Lymphoma and other malignancies (including skin cancer); Male infertility (azospermia and/or oligospermia); Mucosal inflammation (including oral ulceration and oral mucositis); Mucosal inflammation (including oral ulceration and oral mucositis); Mucosal inflammation (including oral ulceration and oral mucositis); Mosquito bites and/or Other opportunistic infections; Mucosal inflammation (including oral ulceration and oral mucositis); Mucosal inflammation (including oral ulceration and oral mucositis)
• Acute myocardial infarction, Allergic reaction or hypersensitivity to contrast agent or cobalt, chromium, nickel, tungsten, acrylic, and/or fluoropolymers; and drug reactions to antiplatelet drugs or contrast agent, Aneurysm, Arterial perforation and injury to the coronary artery, Arterial rupture, Arteriovenous fistula, Arhythmias, 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 emboliz (air, tissue or thrombotic), Emergent or non-emergent coronary surgery, Fever, Hypertension and / or hypertension, Infection and pain at insertion site, Injury to the coronary artery, Ischemia (myocardial, Myocardial infarction (MI), Nausea and vomiting, Palpitations, Peripheral edema, 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

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