



Memo

TO: Medical Healthcare Professionals
FROM: Abbott Vascular
SUBJECT: **Metal Allergy Product Testing**

The Abbott Vascular MULTI-LINK® family of coronary stents are designed of biocompatible material that is well tolerated by the body's immune system. However, on rare occasions a patient may have a known sensitivity and require allergy testing.

Although a reaction to 316L stainless steel, or L-605 cobalt chromium alloy is considered to be extremely rare, Abbott Vascular will provide a sample of material for allergy testing. The material provided will be a stent manufactured from the same type of stock 316 L stainless steel or L-605 cobalt chromium alloy material, but may not be an identical stent pattern to the patients implant.

Abbott Vascular does not make specific recommendations regarding the use of these materials in allergy testing and assumes no responsibility in their use. Sample materials are provided non-sterile. The request for this material must come from the patient's allergist or dermatologist, who will conduct the specific testing.

The following warning statement is included in the Instructions for Use approved by the FDA and included with each stent.

“Persons allergic to 316L stainless steel (including the major elements iron, chromium, nickel, molybdenum) may suffer an allergic reaction to this implant.”

“Persons allergic to L-605 cobalt chromium alloy (including the major elements cobalt, chromium, tungsten, nickel) may suffer an allergic reaction to this implant”

If you require additional assistance or information, please contact Abbott Vascular Customer Service at 800-227-9902.

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ONLY The XIENCE™ V Everolimus Eluting Coronary Stent on the MULTI-LINK MINI-VISION® or MULTI-LINK VISION® Delivery System

INDICATIONS

The XIENCE V Everolimus Eluting Coronary Stent System (XIENCE V stent) is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (length \leq 28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm.

CONTRAINDICATIONS

The XIENCE V stent 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 fluoropolymers.

WARNINGS

- Ensure that the inner package sterile barrier has not been opened or damaged prior to use.
- Judicious patient selection is necessary because device use has been associated with 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 is 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. Use fluoroscopy to avoid arterial damage.
- Stent thrombosis is a low-frequency event that current drug-eluting stent (DES) clinical trials are not adequately powered to fully characterize. Stent thrombosis 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 XIENCE V 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, including more tortuous anatomy, 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 and total length of implanted stents. See *Instructions for Use* for current data on multiple stent implantation.
- Safety and effectiveness of the XIENCE V stent 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 devices are used simultaneously, 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 $<$ 2.5 mm or $>$ 4.25 mm or lesion lengths $>$ 28 mm, lesions located in saphenous vein grafts, unprotected left main coronary artery, ostial lesions, chronic total occlusions, 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, moderate or severe lesion calcification, multivessel disease, in-stent restenosis, and patients with longer than 24 months follow-up

- Everolimus has been shown to reduce the clearance of some prescription medications when it was administered orally along with cyclosporine (CsA). Formal drug interaction studies have not been performed with the XIENCE V stent because of limited systemic exposure to everolimus eluted from XIENCE V.
- 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 was associated with increased serum cholesterol and triglycerides that in some cases required treatment.
- Non-clinical testing has demonstrated that the XIENCE V stent, in single and in overlapped configurations up to 68 mm in length, is MR Conditional. It can be scanned safely under the conditions in the *Instructions for Use*.
- The XIENCE V stent 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 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 artery bypass graft 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, Acne, Anemia, Coagulopathy, Diarrhea, Edema, Hemolysis, Hypercholesterolemia, Hyperlipidemia, Hypertension, Hypertriglyceridemia, Hypogonadism male, Infections: wound infection, urinary tract infection, pneumonia, pyelonephritis, sepsis and other viral, bacterial and fungal infections, Leukopenia, Liver function test abnormality, Lymphocele, Myalgia, Nausea, Pain, Rash, Renal tubular necrosis, Surgical wound complication, Thrombocytopenia, Venous thromboembolism, Vomiting

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.