



XIENCE V[®] and Magnetic Resonance Imaging Examination

To Whom it May Concern:

Thank you for your inquiry regarding magnetic resonance imaging (MRI) examinations of patients implanted with the Abbott Vascular XIENCE V[®] and XIENCE nano[™] Everolimus Eluting Coronary Stent (hereafter referred to as XIENCE V[®] stent). The XIENCE V[®] Everolimus Eluting Coronary Stent is a device/drug combination product consisting of either the MULTI-LINK VISION[®] Coronary Stent or the MULTI-LINK MINI VISION[®] Coronary Stent coated with a formulation containing everolimus, the active ingredient, embedded in a non-erodible polymer. The MULTI-LINK VISION[®] stents are manufactured from medical grade L-605 cobalt chromium (CoCr) alloy.

The following post implant precaution statement is included in the Instructions for Use of the XIENCE V[®] Everolimus Eluting Coronary Stent System:

“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 following conditions:

- Static magnetic field of 1.5 or 3 Tesla
- Spatial gradient field of 2500 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) for each duration of a sequence

The XIENCE V[®] stent should not migrate in this MRI environment. Non-clinical testing at field strengths greater than 3 Tesla has not been performed to evaluate stent migration or heating. MRI at 1.5 or 3 Tesla may be performed immediately following the implantation of the XIENCE V[®] stent.

Stent heating was derived by using the measured non-clinical, *in vitro* temperature rises in a GE Excite 3 Tesla scanner and in a GE 1.5 Tesla coil in combination with the local specific absorption rates (SARs) in a digitized human heart model. The temperature rise was derived by validated calculation. At overlapped lengths up to 68 mm, the XIENCE V[®] stent produced a non-clinical maximum local temperature rise of 3°C at a maximum whole body averaged SAR of 2.0 W/kg (normal operating mode) for one sequence of 15 minutes. These calculations do not take into consideration the cooling effects of blood flow.

The effects of MRI on overlapped stents greater than 68 mm in length or stents with fractured struts are unknown.

As demonstrated in non-clinical testing, an image artifact can be present when scanning the XIENCE V[®] stent. MR image quality may be compromised if the area of interest is in the exact same area, or relatively close to, the position of the XIENCE V[®] stent. Therefore, it may be necessary to optimize the MR imaging parameters for the presence of XIENCE V[®] stents.”

Clinical Research
Abbott Vascular

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

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 2.25 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-polymers 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 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 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. Use fluoroscopy to avoid 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 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 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 $<$ 2.25 mm or $>$ 4.25 mm or lesion length $>$ 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, and in-stent restenosis
- 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 and in patients treated for advanced renal cell carcinoma 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 (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 CYP3A4; 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, and back; 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.



MULTI-LINK MINI VISION® Coronary Stent System

INDICATIONS

The MULTI-LINK MINI VISION RX and MULTI-LINK MINI VISION OTW Coronary Stent Systems are indicated for improving coronary luminal diameter in patients with abrupt or threatened abrupt closure with failed interventional therapy of de novo and restenotic native coronary artery lesions (length \leq 25 mm) with reference vessel diameters from 2.0 mm to 2.5 mm.

CONTRAINDICATIONS

The MULTI-LINK MINI VISION Coronary Stent Systems are contraindicated for use in:

- Patients in whom anti-platelet and / or anti-coagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.

WARNINGS AND PRECAUTIONS

WARNINGS

Long term outcome for this permanent implant is unknown at present.

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and / or bleeding events.
- Persons allergic to L-605 CoCr alloy (including the major elements cobalt, chromium, tungsten, nickel) may suffer an allergic reaction to this implant.
- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition. Placing multiple stents of different metals in contact with each other may increase the potential for corrosion. The risk of *in vivo* corrosion does not appear to increase based on *in vitro* corrosion tests using an L-605 CoCr alloy stent (MULTI-LINK VISION® Coronary Stent) in combination with a 316L stainless steel alloy stent (MULTI-LINK TETRA Coronary Stent).

Stent Handling – Precautions

- **For single use only.** Do not resterilize or reuse. Note the product “Use By” date.
- **Do not remove stent from its delivery system** as removal may damage the stent and / or lead to stent embolization. Stent system is intended to perform together as a system.
- Delivery system should not be used in conjunction with other stents.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during catheter removal from packaging, placement over guide wire and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Do not manipulate (e.g., “roll”) the stent with your fingers, as this action may loosen the stent from the delivery balloon.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon, as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement – Precautions

- **Do not prepare or pre-inflate delivery system prior to stent deployment** other than as directed. Use balloon purging technique described in **Delivery System Preparation**.
- Implanting a stent may lead to dissection of the vessel distal and / or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).

- When treating multiple lesions, stent the distal lesion prior to stenting the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent, and reduces the chance of dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel.
(See **Stent / System Removal – Precautions**)
- Placement of a stent has the potential to compromise side branch patency.
- **Do not exceed the Rated Burst Pressure as indicated on the product label.** Monitor balloon pressures during inflation. Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.
- An unexpanded stent may be retracted into the guiding catheter one time only. Subsequent movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undeployed stent back into the guiding catheter. Should **any resistance** be felt **at any time** during withdrawal of the Coronary Stent System, the entire system should be **removed as a single unit**.
- Stent retrieval methods (use of additional wires, snares and / or forceps) may result in additional trauma to the coronary vasculature and / or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

Stent / System Removal – Precautions

Should **any resistance** be felt **at any time** during either lesion access or removal of the delivery system post-stent implantation, the entire system should be **removed as a single unit**.

When removing the delivery system as a single unit:

- DO NOT retract the delivery system into the guiding catheter.
- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating hemostatic valve to secure the delivery system to the guiding catheter; then remove the guiding catheter and delivery system as a **single unit**.

Failure to follow these steps and / or applying excessive force to the delivery system can potentially result in loss or damage to the stent and / or delivery system components.

If it is necessary to retain guide wire position for subsequent artery / lesion access, leave the guide wire in place and remove all other system components.

Post Implant – Precautions

When **crossing a newly deployed stent** with a guide wire, balloon or delivery system, exercise care to avoid disrupting the stent geometry.

MRI (Magnetic Resonance Imaging) statement

The MULTI-LINK MINI VISION stent has been shown in non-clinical testing to be MRI safe immediately following implantation. **MRI test conditions used to evaluate this stent were: for magnetic field interactions, a static magnetic field strength of 3 tesla with a maximum spatial gradient magnetic field of 3.3 tesla/meter; for MRI-related heating, a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR imaging.** While a single stent produced a temperature rise of less than 0.6°C and should not migrate under these conditions, the response of overlapping stents or stents with fractured struts is unknown. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3 tesla. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

POTENTIAL ADVERSE EVENTS

Adverse events may be associated with the use of a coronary stent in native coronary arteries:

- Acute myocardial infarction • Allergic reaction to contrast • Arterial perforation • Arterial rupture • Arteriovenous fistula • Cardiac arrhythmias • Bleeding complications (including transfusions) • Coronary spasm • Death • Dissection of the coronary artery • Drug reaction to anti-platelet agent • Emergency or non-emergent coronary artery bypass graft surgery • Entry site complications • Hypotension / hypertension • Infection • Injury to the coronary artery • Ischemia • Pseudoaneurysm • Restenosis of the stented segment • Stent embolization • Stent thrombosis / emboli • Stroke / cerebrovascular accident • Total occlusion of the coronary artery • Unstable angina pectoris • Vascular complications



**MULTI-LINK VISION®
Coronary Stent System**

INDICATIONS

The MULTI-LINK VISION RX and MULTI-LINK MINI VISION OTW Coronary Stent Systems are indicated for improving coronary luminal diameter in the following (see **Individualization of Treatment**):

- Patients with symptomatic ischemic heart disease due to discrete de novo or restenotic native coronary artery lesions (length ≤ 25 mm) with reference vessel diameters ranging from 3.0 mm to 4.0 mm.
- Patients with symptomatic ischemic heart disease due to lesions in saphenous vein bypass grafts (length ≤ 25 mm) with reference vessel diameters ranging from 3.0 mm to 4.0 mm.

- Restoring coronary flow in patients experiencing acute myocardial infarction, as confirmed by ST segment elevation or angiographic findings, who present within 12 hours of symptom onset with native coronary artery lesions of length \leq 25 mm with a reference vessel diameter of 3.0 mm to 4.0 mm.
- Outcome (beyond 9 months) for this permanent implant is unknown at present.

CONTRAINDICATIONS

The MULTI-LINK VISION RX and MULTI-LINK VISION OTW Coronary Stent Systems are contraindicated for use in:

- Patients in whom anti-platelet and / or anti-coagulant therapy is contraindicated.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon.

WARNINGS AND PRECAUTIONS (see Individualization of Treatment):

WARNINGS

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and / or bleeding events.
- Persons allergic to L-605 cobalt chromium alloy (including the major elements cobalt, chromium, tungsten, nickel) may suffer an allergic reaction to this implant.
- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition. Placing multiple stents of different metals in contact with each other may increase the potential for corrosion. The risk of in vivo corrosion does not appear to increase based on in vitro corrosion tests using an L-605 CoCr alloy stent (MULTI-LINK VISION Coronary Stent) in combination with a 316L stainless steel alloy stent (MULTI-LINK TETRA Coronary Stent).

Stent Handling – Precautions

- **For single use only.** Do not resterilize or reuse. Note the product "Use By" date.
- **Do not remove stent from its delivery system** as removal may damage the stent and / or lead to stent embolization. Stent system is intended to perform as a system.
- Delivery system should not be used in conjunction with other stents.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during catheter removal from packaging, placement over guide wire and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Do not manipulate (e.g., "roll") the stent with your fingers, as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

Stent Placement – Precautions

- **Do not prepare or pre-inflate delivery system prior to stent deployment** other than as directed. Use balloon purging technique described in **Delivery System Preparation**.
- Implanting a stent may lead to dissection of the vessel distal and / or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel. (**See Stent / System Removal – Precautions**).
- Placement of a stent has the potential to compromise side branch patency.
- **Do not exceed Rated Burst Pressure (RBP) as indicated on product label.** Balloon pressures should be monitored during inflation. Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.
- An unexpanded stent may be retracted into the guiding catheter one time only. Subsequent movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undeployed stent back into the guiding catheter. Should **any resistance** be felt **at any time** during withdrawal of the coronary stent system, the entire system should be **removed as a single unit**.
- Stent retrieval methods (use of additional wires, snares and / or forceps) may result in additional trauma to the coronary vasculature and / or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

Stent / System Removal – Precautions

Should **any resistance** be felt **at any time** during either lesion access or removal of the delivery system post-stent implantation, the entire system should be **removed as a single unit**.

When removing the delivery system as a single unit:

- DO NOT retract the delivery system into the guiding catheter.

- Position the proximal balloon marker just distal to the tip of the guiding catheter.
- Advance the guide wire into the coronary anatomy as far distally as safely possible.
- Tighten the rotating hemostatic valve to secure the delivery system to the guiding catheter; then remove the guiding catheter and delivery system as a single unit.

Failure to follow these steps and / or applying excessive force to the delivery system can potentially result in loss or damage to the stent and / or delivery system components.

If it is necessary to retain guide wire position for subsequent artery / lesion access, leave the guide wire in place and remove all other system components.

Post Implant – Precautions

Care must be exercised when **crossing a newly deployed stent** with a coronary guide wire, balloon or delivery system to avoid disrupting the stent geometry.

MRI Statement

The MULTI-LINK VISION Coronary Stent has been shown in non-clinical testing to be MRI safe immediately following implantation. **MRI test conditions used to evaluate this stent were: for magnetic field interactions, a static magnetic field strength of 3 tesla with a maximum spatial gradient magnetic field of 3.3 tesla/meter; for MRI-related heating, a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR imaging.** While a single stent produced a temperature rise of less than 0.6°C and should not migrate under these conditions, the response of overlapping stents or stents with fractured struts is unknown. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3 tesla. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

POTENTIAL ADVERSE EVENTS

Adverse events may be associated with the use of a coronary stent in native coronary arteries:

- Acute myocardial infarction • Arrhythmias, including VF and VT • Death • Dissection • Drug reactions to anti-platelet agents / contrast medium • Emboli, distal (air, tissue or thrombotic emboli) • Emergent coronary artery bypass surgery • Hemorrhage, requiring transfusion • Hypotension / hypertension • Infection and / or pain at insertion site • Ischemia, myocardial • Perforation • Pseudoaneurysm, femoral • Restenosis of stented segment • Spasm • Stent embolization • Stent thrombosis / occlusion • Stroke / cerebrovascular accident • Total occlusion of coronary artery