XIENCE Family of Everolimus Eluting Coronary Stent Systems - P070015/S122 and P110019/S066

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

**Product Name:** XIENCE V and XIENCE nano Everolimus Eluting Coronary Stent System, XIENCE PRIME and XIENCE PRIME LL Everolimus Eluting Coronary Stent System, XIENCE Xpedition, XIENCE Xpedition SV, and XIENCE Xpedition LL Everolimus Eluting Coronary Stent System, and XIENCE Alpine Everolimus Eluting Coronary Stent System

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**Address:** 3200 Lakeside Drive, Santa Clara, CA 95054

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**Approval Letter:** [P070015/S122 and P110019/S066](http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070015s122a.pdf)

**What is it?** The XIENCE Family of Everolimus Eluting Coronary Stent Systems (EECSSs) consists of stent that is coated with the drug everolimus and a delivery catheter. The stent is made from a cobalt chromium alloy ([http://www.merriam-webster.com/medlineplus/alloy](http://www.merriam-webster.com/medlineplus/alloy)) and is used to

The design of the stent differs between the XIENCE V and the XIENCE PRIME; however, the XIENCE PRIME, XIENCE Xpedition and XIENC Alpine have an identical stent design.

There are no current design changes to the XIENCE Family of EECSSs. The only change is the expanded use to include chronic total occlusions (CTOs), which was determined during a clinical trial. However, the delivery catheters are different in design. The XIENCE Family of EECSSs is for single-use only.

How does it work? A XIENCE stent is placed on the end of a delivery catheter with a small balloon mounted on the end. The delivery catheter with the XIENCE stent is inserted into a blood vessel in the groin or arm and advanced, under fluoroscopy (http://www.fda.gov/Radiation EmittingProducts/Radiation EmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115354.htm), into the diseased/narrowed coronary artery which supplies oxygen-rich blood to the heart muscle.

With the help of a guidewire, the catheter is positioned across the diseased/narrowed portion of the coronary artery that needs to be widened. The balloon is then inflated, expanding the stent and the coronary artery. The stent is pressed against the coronary wall where it will remain permanently implanted to help keep the coronary artery open. The delivery of the stent may be followed by repeated balloon inflations within the stent to achieve the desired result. Over time, the coronary artery wall will heal around the stent as it continues to support the coronary artery.

When is it used? The XIENCE Family of EECSSs is used in patients who have a narrowing in their coronary artery, including chronic total occlusions (CTOs), caused by coronary artery disease – a condition that occurs when the arteries that supply oxygen-rich blood and nutrients to the heart become narrowed or blocked by a gradual build-up of “plaque.” Plaque is made of fatty deposits (cholesterol (http://www.nlm.nih.gov/medlineplus/cholesterol.html)), white blood cells, calcium, and scar tissue that collect over time in the coronary artery. If these arteries become blocked or narrowed, treatment may be required to improve blood flow.

What will it accomplish? A significantly narrowed or blocked (occluded) coronary artery limits blood and oxygen flow to the heart and can cause chest pain as well as damage to the heart muscle. Placement of the XIENCE drug-eluting stent (http://www.nlm.nih.gov/medlineplus/ency/article/007473.htm) within the narrowed coronary artery, including CTOs, improves blood flow. The stent remains in the artery to help maintain the improved blood flow.
**When should it not be used?** The XIENCE Family of EECSSs should not be used in patients:

- Who cannot take medicines that thin the blood and prevent blood clots;
- Who are not suitable candidates for balloon angioplasty or proper placement of the stent or stent delivery system; or
- With hypersensitivity or contraindication to the drug (everolimus), metals (such as, cobalt, chromium, nickel, tungsten), acrylic or fluoropolymers.

**Additional information:** The Summary of Safety and Effectiveness Data and labeling for both [P070015/S122](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=p070015s122) and [P110019/S066](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=p110019s066) are available online.

**Other Resources**