

## **SECTION 9.0 LABELING**

The following section presents the proposed commercial Instructions for Use (IFU) and patient labeling consisting of the stent implant card and patient information guide for the XIENCE™ V Everolimus Eluting Coronary Stent System.

### **9.1 Instructions for Use**

The Instructions for Use will be provided as an electronic IFU (eIFU) on [www.abbottvascular.com/ifu](http://www.abbottvascular.com/ifu), an Abbott Vascular website. The IFU content is provided on the following pages and is reflective of the clinical trial information available at time of PMA submission. The instructions for both the XIENCE V RX EECSS and the XIENCE V OTW EECSS platforms have been combined into a single IFU. The IFU is presented in Attachment 9A.

## 9.2 Patient Labeling

The stent implant card and patient information guide will be included in an envelope that will be placed inside the product carton. This information is intended to be supplied to the patient.

### Stent Implant Card

The XIENCE V EECSS stent implant card is applicable to both the XIENCE V RX EECSS and XIENCE V OTW EECSS and provides a reference for the patient regarding their XIENCE V stent implant. The stent implant card is shown in Figure 9-1 below.

**Please carry this card at all times.  
Show it to any medical personnel  
who may be treating you.**

Magnetic resonance imaging (MRI) test results indicate that single and overlapped XIENCE V stents of no more than 69 mm in length pose no known hazards under static magnetic fields of 3 Tesla or less, spatial gradients of 720 gauss/cm or less, and maximum whole body averaged specific absorption rates (SAR) of 3.0 W/kg for 15 minutes of imaging. When tested at the maximum of these parameters, the XIENCE V stent does not produce a temperature rise of more than 1 degree C.

The response of overlapped stents greater than 69 mm in length or with fractured struts is unknown. MRI image quality may be compromised near the XIENCE V Stent. Prior to undergoing a MRI scan, inform your doctor that you have a XIENCE V Everolimus Eluting Coronary Stent.

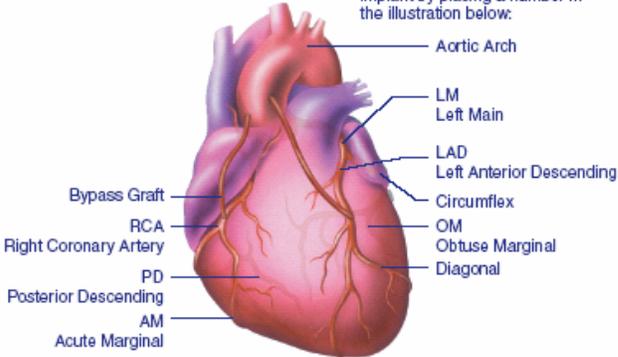


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### Stent Implant Location

Note the location of each stent implant by placing a number in the illustration below:



**Stent Identification Information**

Please Complete:	Please Complete:	Please Complete:	Please Complete:
Product Part # (REF)	Product Part # (REF)	Product Part # (REF)	Product Part # (REF)
Product Lot #	Product Lot #	Product Lot #	Product Lot #
Location of First Stent	Location of Second Stent	Location of Third Stent	Location of Fourth Stent

### Medication Reminder

\_\_\_\_\_ mg of \_\_\_\_\_ must be taken \_\_\_\_\_ times per day through \_\_\_\_\_.

\_\_\_\_\_ mg of \_\_\_\_\_ must be taken \_\_\_\_\_ times per day through \_\_\_\_\_.

**IMPORTANT:** Do not stop your medications before the above dates without contacting your cardiologist. If surgery, dental work, or any other procedure (e.g. colonoscopy) that would require you to stop taking the above medications early are recommended, you and your cardiologist should carefully consider the risks and benefits of this additional surgery versus possible risks from early discontinuation of these medications.

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**Figure 9-1 Stent Implant Card – Front and Back Sides**

**Patient Information Guide**

The XIENCE V EECSS patient information guide is a booklet provided as a service by Abbott Vascular to answer some of the questions patients may have regarding the treatment for their condition. The Patient Information Guide is presented in Attachment 9B.