

# SPIRIT IV

**Principal Investigator:**

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**Sponsor:**

Medtronic, Abbott Vascular

**Study Purpose:**

A Clinical Evaluation of the XIENCE™ V Everolimus Eluting Coronary Stent System (EECSS) in the Treatment of Subjects with *de novo* Native Coronary Artery Lesions.

**Objective:**

To see if a new drug-coated stent system is safe and effective in treating the narrowing of your heart artery. The new drug-coated stent is the XIENCE™ V Everolimus Eluting Coronary Stent System (the "**XIENCE V Stent**"). The XIENCE V Stent will be compared to a drug-coated stent that has been approved by the U.S. Food and Drug Administration ("**FDA**") for treating narrowed arteries. The approved stent is the TAXUS® EXPRESS<sup>2</sup>™ Paclitaxel-Eluting Coronary Stent (the "**TAXUS Stent**"). If the next generation TAXUS stent is approved by FDA during the Study, the newer TAXUS stent will be used for comparison.

**Inclusion Criteria:**

- Target lesion(s) must be located in a native coronary artery with visually estimated diameter of 2.5 mm to 4.25 mm and lesion length  $\leq$  28 mm
- The target lesion(s) must be in a major artery or branch with a visually estimated stenosis of  $\geq$  50% and  $<$  100% with a TIMI flow of  $\geq$  1
- Non-study percutaneous intervention for lesions in a non-target vessel allowed if per protocol and within protocol defined time frames

**Exclusion Criteria:**

- Lesion located within an arterial or saphenous vein graft or distal to a diseased (vessel irregularity per angiogram and any visually estimated diameter stenosis  $>$  20%) arterial or saphenous vein graft
- Lesion involves a bifurcation in which the side branch is  $\geq$  2 mm in diameter and the ostium of the side branch is  $>$  50% stenosed by visual estimation
- Located in a major epicardial vessel that has been previously treated with PCI  $<$  9 months prior to the index procedure
- Lesion involves a side branch requiring pre-dilatation
- Total occlusion (TIMI flow 0) prior to wire crossing

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- Restenotic from previous intervention
- The target vessel contains thrombus
- Subject has received brachytherapy in any epicardial vessel (including side branches)

**Status:**

Follow-up Only.

If you have any questions, please feel free to contact the coordinators, and they will be happy to answer any questions you have regarding this study.