

# Elite

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## Sponsor:

Cordis, a Johnson & Johnson Company

## Study Purpose:

A Prospective, Single-Blind, Randomized, Multi-Center Study comparing the CYPHER® ELITE™ to the CYPHER® Bx VELOCITY® Sirolimus-Eluting Stent Systems

## Objective:

The objective of this study is to show similar (non-inferior) safety and effectiveness between CYPHER® ELITE™ and CYPHER® Bx VELOCITY® Sirolimus-Eluting Stent Systems in a prospective, multi-center, randomized clinical study for the treatment of *de novo* native coronary lesions.

## Inclusion:

1. Subjects with *de novo* atherosclerotic CAD in 1 or 2 vessels
2. The subject must be  $\geq 18$  years of age
3. Female of childbearing potential must have a negative pregnancy test within 7 days prior to enrollment
4. Diagnosis of angina pectoris as defined by stable angina pectoris Canadian Cardiovascular Society Classification (Class I, II, III) OR non-ST segment elevation acute coronary syndrome (Braunwald Classification B&C) OR non-ST segment elevation myocardial infarction  $\geq 48$  hours from the time of study index procedure OR asymptomatic subjects with a positive stress test
5. Treatment of  $\leq$  two lesions in one or two major coronary arteries  
(1 target lesion in each of 2 vessels or 2 target lesions in 1 vessel)
6. Target vessel diameter must be  $\geq 2.25$ mm and  $\leq 4.0$  in diameter (visual estimate)
7. Target lesion stenosis is  $> 50\%$  and  $< 100\%$  (visual estimate)
8. Target lesion length  $\leq 30$  mm (for each target lesion(s)) with a total implanted stent length  $\leq 66$ mm. Additional stents can be used to treat dissections, etc.;

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however, these must be the same stent to which the subject has been randomized in the study.

9. Subject or Legally Authorized Representative must provide written informed consent prior to the procedure using a form that is approved by the Institutional Review Board/Independent Ethics Committee.

### Exclusion:

1. ST Segment Elevation Myocardial Infarction (STEMI) within 30 days of the study index procedure.
2. Unprotected left main coronary disease with  $\geq 50\%$  stenosis
3. Total coronary occlusion or TIMI grade 0 or 1 in the target vessel
4. Angiographic evidence of thrombus within target lesion(s)
5. Calcified target lesion(s) which cannot be, in the investigator's opinion, successfully pre-dilated
6. Bifurcation disease involving a side branch  $\geq 2$  mm in diameter
7. Prior stent within 5 mm of target lesion(s)
8. Ostial target lesion(s)
9. Target lesion(s) within a coronary bypass graft (e.g., saphenous vein or arterial graft)
10. Documented left ventricular ejection fraction  $\leq 25\%$
11. Impaired renal function (creatinine  $> 250$   $\mu\text{mol/L}$  or  $> 2.5$  mg/dl) at the time of treatment
12. Pretreatment with devices other than conventional balloon angioplasty
13. Significant angulation in the target vessel that, in the Investigator's opinion, may preclude stent delivery and deployment
14. Subject previously treated with brachytherapy
15. Recipient of heart transplant
16. Subject with a life expectancy less than 12 months
17. Known allergies to the following: aspirin, clopidogrel bisulfate (Plavix®) and ticlopidine (Ticlid®), heparin, stainless steel, contrast agent (that cannot be managed medically), or sirolimus that cannot be managed medically.
18. Any significant medical condition which, in the Investigator's opinion, may interfere with the subject's optimal participation in the study
19. Currently participating in an investigational drug or device study that has not completed the primary endpoint or that clinically interferes with the study endpoints
20. In the Investigator's opinion, the lesion is not suitable for stenting.
21. Known bleeding or hypercoagulable disorder
22. Known or suspected active infection at the time of the study procedures
23. Subject is known to be pregnant, a prisoner, mentally incompetent, and/or alcohol or drug abuser
24. Subject has had major surgical or interventional procedures unrelated to this study within 30 days prior to this study or planned surgical or interventional procedures within 30 days of entry into this study.

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**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.