Circulatory System Devices Panel
Questions for Discussion

IntraCoil Self-Expanding Peripheral Stent
P000033

April 23, 2001

Question #1

The U.S. clinical trial of the IntraCoil Stent System was based on primary stenting versus PTA in the treatment of atherosclerotic disease of the superficial femoral and/or popliteal artery. The sponsor has described why this primary stent study could not be completed. They have also described why they believe a re-analysis of the data supports the use of the IntraCoil Stent when the PTA results are suboptimal. Central to their justification is the suboptimal classification of 69 patients who had a $\geq$ 50 percent stenosis or a $\geq$ Grade C dissection following the pre-dilatation step, prior to receiving the IntraCoil Stent as the primary treatment method.

1a. Please discuss the use of the suboptimal pre-dilatation classification as a surrogate for suboptimal results with PTA.

1b. Please discuss any expected differences in terms of clinical outcomes between patients with suboptimal pre-dilatation and patients with suboptimal results from PTA.

1c. Given the IntraCoil Stent data shows improvement in acute safety, and no differences in safety and effectiveness at nine months, please discuss whether there is adequate data for a primary stent indication. If not, please discuss what additional information would be necessary to support a primary stent indication in the femoral and/or popliteal arteries.

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Question #2

The current labeling indicates the use of the IntraCoil Stent for the treatment of superficial femoral and/or popliteal artery occlusions or stenotic lesions in patients with suboptimal results following PTA. Stents placed in the popliteal artery location are subjected to significant deformations due to flexing of the knee. Bench testing demonstrated adequate kink resistance of the IntraCoil Stent. Based on the qualitative analysis of 149 lesions in the randomized study and 107 lesions in the roll-in patients, IntraCoil stents were placed in 48 popliteal arteries, of which 16 were placed in the suboptimal group.

2. **Please discuss whether the clinical data are adequate to determine the safety and effectiveness of the IntraCoil Stent in the popliteal artery.**

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Question #3

Product Labeling

One aspect of the pre-market evaluation of a new product is the review of its labeling. The labeling must indicate which patients are appropriate for treatment, identify potential adverse events with the use of the device, and explain how the product should be used to maximize benefits and minimize adverse effects. Please address the following questions regarding the product labeling (Section 2):

3a. Please comment on the INDICATIONS FOR USE section as to whether it identifies the appropriate patient population for treatment with this device.

3b. Please comment on the CONTRAINDICATIONS section as to whether there are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.

3c. Please comment on the WARNINGS/PRECAUTIONS section as to whether it identifies all potential hazards regarding device use.

3d. Please comment on the OPERATOR'S INSTRUCTIONS as to whether it adequately describes how the device should be used to maximize benefits and minimize adverse events.

3e. Do you have any other recommendations regarding the labeling of this device?

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Question #4

Training Program

4. Please identify and discuss the items that you believe should be contained in a physician's training program for this device.

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