

Product Name: NexStent Carotid Stent System

(Carotid Artery Therapeutics and Stroke Prevention)

P00171

Description:

- Nitinol self-expanding Carotid Artery Stent

Company:

- Endotex Interventional Systems, Inc. (Boston Scientific Corporation)
- Boston Scientific Corporation

General Modality:

- Medical Devices

Specific Modality:

- Stents

General Product Type:

- Bare Metal

Clinical Trials:

- CABERNET - Carotid Artery Revascularization Using the Boston Scientific EPI FilterWire EX and the Endotex NexStent
- SONOMA - Post-Market Approval Study of the NextStent Carotid Stent System and the FilterWire EZ Embolic Protection System

Commercial Approval:

- On Friday, November 3, 2006, Boston Scientific announced that NexStent received FDA approval for use patients with high risk carotid artery disease. The approval was issued October 27, 2006. The approval was based on results from the CABERNET trial.

- On April 13, 2005 EndoTex Interventional Systems, announced that the NexStent and Monorail Delivery System had been awarded a CE mark approving commercial distribution of the product(s) in Europe for the treatment of carotid artery disease. The approval was due to the results of the CABERNET trial.

Development Status - Commercial Events:

- On Thursday, August 14, 2008 Boston Scientific issued a recall for the NexStent. Initiated June 6, 2008, the recall was for any device manufactured between June 12, 2007 and May 2, 2008, distributed June 19, 2007 to May 5, 2008. The reason for the recall per the FDA is that "The tip of the stent delivery system may detach from the delivery system during the procedure. This could lead to increased procedure time, cause vessel wall injury, stroke and/or emergency surgery to remove the detached tip." Special note was made that any implanted device was safe and not affected by the recall with the problem occurring on the delivery catheter. The recall was effective for both Monorail and Over-the-Wire versions.
- On April 13, 2005 Boston Scientific announced that it would be the exclusive distributor in Europe and other international markets of the NexStent carotid stent and Monorail delivery system.
- In July 2001 Boston Scientific established an option to buy Endotex in exchange for an equity investment. (July 2001)
- Received IDE from FDA in January 2000

Development Status - Clinical Trials:

- The results of the CABERNET trial followed that the NexStent proved favorable and compared favorably to the standard of care as compared to carotid endarterectomy.
- Along with the NexStent the CABERNET trial also studied the FilterWire EZ Embolic Protection System.

Comments:

- This device is a coil shaped self-expanding carotid artery stent made of nitinol.
- Endotex is privately held firm located in Cupertino, CA.

Last Update: August 27, 2008

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