**FDA Regulation Of CAS Devices: What Is Happening And What Does The Future Hold**

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Mayo Clinic Florida  
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**Regulation of Carotid Artery Stents and Embolic Protection Devices in the United States**

A history of, and perspectives on, FDA regulation of carotid stents and associated embolic protection devices over the years.

BY SADAF A. TOOR, MS; KENNETH J. CAVANAUGH Jr, PhD; AND LISA M. LIM, PhD

EV TODAY. 2015 September

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**PREMARKET DEVICE REGULATION**

- Carotid stents are classified into the highest-risk category (Class III)
- FDA approval of a Premarket Approval (PMA) is required before that device can be marketed.
- PMA requires reasonable assurance that the device is both safe and effective

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**PREMARKET DEVICE REGULATION**

- EPDs are classified as moderate-risk (Class II)
- The 510(k) process is required before marketing.
- 510(k) clearance is given if the EPD is shown to be “substantially equivalent” to another currently marketed EPD.

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**PREMARKET DEVICE REGULATION**

- When a device involves first-of-a-kind technology or a novel indication for use, the FDA may solicit input from an Advisory Panel of external experts
- Advisory Panel recommendations are nonbinding
REGULATORY HISTORY

- The First Studies: high surgical risk
- The First FDA-Approved Carotid Stent 2004: use in high-surgical-risk Patients
- Approval for Standard-Risk Patients 2011

REGULATORY PERSPECTIVES ON MARKETING AND CLINICAL USE

- Manufacturers **cannot promote** a device for an unapproved use.
- The FDA cannot regulate the practice of medicine.
- So physicians may use marketed devices off-label, following what they believe is the best course of treatment for their individual patients.
- FDA does not require specific stents and EPDs to be used together.

FDA-approved carotid stents

- **Abbott Vascular**
  - Acculink/RX Acculink Carotid Stent System
  - Xact Carotid Stent System

- **Boston Scientific Corporation**
  - Carotid Wallstent Endoprosthesis
  - NexStent Carotid Stent System

- **Cordis Corporation**
  - Precise/Precise RX/Precise Pro RX Carotid Stent System

- **Covidien**
  - Protege GSP/Protege RX Carotid Stent System

- **Medtronic, Inc.**
  - Exponent Carotid Stent System

Embolic Protection Systems

- **Abbott Vascular**
  - Accunet/RX Accunet Embolic Protection System
  - Emboshield/Emboshield Nav6 Embolic Protection System

- **Boston Scientific Corporation**
  - FilterWire EZ Embolic Protection System

- **Cordis Corporation**
  - Angioguard XP/Angioguard RX Emboli Capture Guidewire

- **Covidien**
  - SpiderFX/SpiderFX Embolic Protection Device

- **Lumen Biomedical**
  - FiberNet Embolic Protection System

- **Medtronic, Inc.**
  - GuardWire Temporary Occlusion and Aspiration System

- **W.L. Gore & Associates**
  - Mo.Ma Ultra Proximal Cerebral Protection Device
  - Gore Embolic Filter
  - Gore Flow Reversal System

Future Directions: recent PMAs

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<tr>
<th>Device Name</th>
<th>Applicant</th>
<th>PMA Number</th>
<th>Date Approved</th>
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Searching the FDA Website

Future Directions: recent 510ks

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Searching the FDA Website

- For embolic protection devices, search the FDA 510(k) cleared devices database for product code NTE here: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Future Directions

[Graph showing Primary Endpoint (EFS analysis) over follow-up time years]

Stroke After Carotid Stenting and Endarterectomy in the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST)


Circulation. 2012;126:3054-3061; originally published online November 16, 2012. DOI: 10.1161/CIRCULATIONAHA.112.120830

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FUTURE DIRECTIONS

- The debate between the flexibility of the **open-cell** stent versus the wall apposition and plaque coverage of the **closed-cell** stent continues...
- Drug-coated stents?
  - “…could result in improved restenosis rates…”
  - “…new risks such as the “potential embolization of the drug coating could also result in increased complications.”