CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System - H060001

FDA approved this device under the Humanitarian Device Exemption (HDE) program. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System Manufacturer: Cordis Neurovascular, Inc.

Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf6/h060001a.pdf

Indicaciones

se utiliza con coils para el tratamiento de aneurismas intracraneales.

Compuesto por un stent auto-expandible y un sistema de entrega .

El stent sirve como un andamio para para prevenir la salida de los coils.

El stent es una malla metálica autoexpandible (nitinol) en forma de tubo.

El sistema de suministro se compone de un introductor y el alambre de entrega y son utilizados para entregar el stent al sitio de tratamiento.

How does it work?

Advance stent system through microcatheter. Position the stent by aligning the stent positioning marker of the delivery wire with the target site. Unsheath to deploy. Carefully retract the microcatheter, while maintaining the position of the delivery wire, to allow the stent to deploy across the neck of the aneurysm. The stent will expand as it exits the microcatheter. Maintain distal access. Exchange microcatheter for coiling procedure. Proceed with coiling procedure through stent cells. When is it used? The CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System is intended for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms.

What will it accomplish? The stent serves as a scaffold for embolic coils to prevent herniation of the coils into the parent vessel.

When should it not be used? The CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System should not be used in patients who:

the aneurysm size and/or parent vessel size does not fall within the indicated range cannot take blood-thinning (antiplatelet and/or anticoagulation) drugs to help prevent blood clots the angiography demonstrates the anatomy is not appropriate for endovascular treatment Additional information:

SSPB and Labeling will be available at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=h060001