Product Name: Complete® SE Stent System

(Product Peripheral Vascular Therapeutics - In Development, Lower Limb Advanced Arterial Therapeutics, Pathway Clinical Trial MarketTracks, Medtronic PV Lower Limb Advanced Arterial Therapeutics) P00866

Description:
A self-expanding nitinol stent and delivery system with a triaxial design including an inner shaft, a retractable sheath and a stabilizing sheath to reduce friction to help ensure accurate deployment.

Company/Sponsor:
Medtronic Vascular

Vessels:
- Femoral Arteries (SFA/Superficial)
- Common Iliac Arteries

General Modality:
Medical Devices

Specific Modality:
Stents

General Product Type:
Bare Metal

Clinical Trials:
- Efficacy of Balloon-Expandable Stent Versus Self-Expandable Stent for the Atherosclerotic Iliac Arterial Disease
- Medtronic Complete® Self-Expanding Stent and Stent Delivery System Registry
- SENS-FP Trial - Efficacy of Self-Expanding Nitinol S.M.A.R.T-CONTROL Stent Versus Complete SE Stent For The Atherosclerotic Femoro-Popliteal Arterial Disease : Prospective, Multicenter, Randomized, Controlled Trial
- The Complete® SE SFA Study - The Medtronic Complete Self-Expanding SFA Stent System for the Treatment of Atherosclerotic Lesions in the Superficial Femoral and/or Proximal Popliteal Arteries

Commercial Approval:
- Awarded a CE Mark September 2006 for use in iliac arteries
- Received FDA clearance on April 21, 2010 for the treatment of peripheral arterial disease (PAD) in the iliac arteries, major blood vessels within the pelvis that supply blood to the lower extremities
- Received FDA Clearance on November 15, 2007 for the Complete SE (self-expanding) Stent System for Biliary use

Development Status - Clinical Trials:
On January 5, 2009 Medtronic, Inc. announced the first patient’s enrollment in the FDA-approved clinical trial of the Complete SE stent for the treatment of peripheral arterial disease (PAD) in the superficial femoral artery (SFA);
- the study is a prospective, multicenter, single-arm trial planned to enroll 178 symptomatic PAD in the SFA patients at up to 30 sites globally with a Primary Endpoint of Major Adverse Events (MAEs) and Patency at 12 months
- On January 5, 2009 Medtronic, Inc. announced an update to the "The Complete SE Iliac Registry" which is an IDE-approved clinical trial for use in the treatment of iliac artery lesions in patients with symptomatic and asymptomatic PAD; the trial is a non-randomized, prospective study planned to enroll 60 patients; Primary Endpoints are Major Adverse Events (MAEs) at 30 days and nine months; As of January 5, 2009 enrollment is nearly complete with 12 U.S. sites participating

Comments:
- Complete SE offers an expanded size matrix, with diameters as small as 4 mm and lengths from 20-150 mm.
- All sizes are 6F sheath compatible.

Sources:


Trial of Stent for Peripheral Arterial Disease Growing Research Program Underscores Company Commitment to PAD™; Medtronic, Inc., January 5, 2009.


Last Update: May 19, 2010

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