**Product Name:** Absolute Pro Vascular Self-Expanding Stent System

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

**Description:**
Nitinol self-expanding stent with six proprietary radiopaque markers on the proximal and distal ends indicated to improve luminal diameter in patients with de novo or restenotic atherosclerotic lesions in the native common iliac artery and native external iliac artery with reference vessel diameters between 4.3 mm to 9.1 mm and lesion lengths up to 90 mm.

**Company/Sponsor:**
- Abbott Vascular/Guidant
- Abbott Vascular Devices

**Vessels:**
- Lower Limb Arteries
- Femoral-Popliteal Arteries (FemPop)

**General Modality:**
- Medical Devices

**Specific Modality:**
- Stents

**General Product Type:**
- Bare Metal

**Clinical Trials:**
- **ABSOLUTE** - Belgian Absolute Stent Trial: Self-Expanding Stent in Atherosclerotic Occlusive Disease of the Superficial Femoral Artery
- **ASSESS** - **ABSOLUTE™ .035 Peripheral Self-Expanding Stent System for Occluded or Stenotic Superficial Femoral or Proximal Popliteal Arteries**
- **BRAVISSIMO** - Physician Initiated Multi-Center Belgian-Italian-Dutch Trial Investigating Abbott Vascular Iliac Stents in the Treatment of TASC A, B, C & D Iliac Lesions
- **Fracture of self-expanding nitinol stents stressed in vitro under simulated intravascular conditions**
- **MOBILITY AP** - Trial to Evaluate the Safety & Efficacy of the Absolute Pro™ Peripheral Self-Expanding Stent System in Subjects With Atherosclerotic de Novo or Restenotic Lesions in the Native Common Iliac Artery and/or Native External Ili
- **Vienna Absolute Trial - Balloon Angioplasty**
- **Versus Stenting With Nitinol Stents in the Superficial Femoral Artery**

**Commercial Approval:**
- Received FDA clearance November 2003 for palliation of malignant strictures in the biliary tree
- Received FDA Approval in 2012 for the treatment of iliac artery disease
- On April 7, 2017 Abbott Vascular received PMA approval for Absolute Pro vascular for a change to the frequency of routine bacterial endotoxin testing

**Development Status - Commercial Events:**
Abbott Vascular completed the acquisition of Guidant’s vascular business in April 2006. The acquisition was made in connection with Boston Scientific's acquisition of Guidant Corporation.

**Development Status - Clinical Trials:**
The ASSESS Study (Evaluation of **ABSOLUTE** Stent System for Occluded Arteries) will investigate the performance of the **ABSOLUTE .035 peripheral self-expanding stent system in preventing restenosis of occluded or stenotic superficial femoral or proximal popliteal arteries.** The trial is a non-randomized, prospective, multi-center evaluation initiated in March 2005 with an expected completion in November 2008.

CONCLUSION: The treatment of TASC B and C femoro-popliteal lesions with use of the **ABSOLUTE** stent is safe and feasible. Short-term follow-up documents persistent improvement of hemodynamics. The 6- and 12-month data have to be awaited for further conclusions.

Vienna Absolute Study is being used to test the hypothesis that primary stenting with self expanding nitinol stents may improve patency after endovascular treatment of superficial femoral artery obstructions compared to balloon angioplasty with optional stenting; CONCLUSION: In the intermediate term, treatment of superficial-femoral-artery disease by primary implantation of a self-expanding nitinol stent yielded results that were superior to those with the currently recommended approach of balloon angioplasty with optional secondary stenting.

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exhibit a variable ability to withstand chronic deformation in vitro, and their response is highly dependent on the type of deformation applied.

The MOBILITY Trial will study the safety and efficacy of the Absolute Pro Peripheral Self-Expanding Stent System in patients with iliac artery disease.

The BRAVISSIMO trial investigates in a controlled setting, the long-term (up to 24 months) outcome of the self-expanding nitinol Absolute Pro (Abbott Vascular) and the balloon-expandable Omnilink Elite (Abbott Vascular) stent in TASC A&B and TASC C&D iliac lesions.

Sources:


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