**Product Name:** Protégé / Protege EverFlex 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, Lower Limb Critical Limb Ischemia - CLI)*

**Description:**

The EverFlex™ Self-Expanding Peripheral Stent System is a self-expanding Nitinol stent system intended for permanent implantation. The self-expanding stent is made of a nickel titanium alloy (Nitinol) and comes pre-mounted on a 6F, 0.035” over-the-wire delivery system. The stent is cut from a Nitinol tube in an open lattice design, and has tantalum radiopaque markers at the proximal and distal ends of the stent. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to establish patency.

**Company/Sponsor:**
- Covidien / Medtronic PLC
- FoxHollow Technologies (ev3)

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

**General Modality:**
- Medical Devices

**Specific Modality:**
- Stents

**General Product Type:**
- Bare Metal

**Clinical Trials:**

- DUR-POP (Durability Popliteal) - Physician Initiated Trial Investigating the Efficacy of the Implant of Protége EverFlex Nitinol Stents in Popliteal Lesions
- DURABILITY I - Nitinol stent implantation in long superficial femoral artery lesions
- DURABILITY II - The US StuDy for Evaluating Endovascular TreAtments of Lesions in the Superficial Femoral Artery and Proximal Popliteal By using the Protege EverFlex NitInol STent SYstem II
- DURABILITY ILIAC Study - Protege EverFlex and GPS Self-Expanding Iliac Study
- DURABILITY IIiAC PAS Study - The US StuDy for Evaluating Endovascular TreAtments of Lesions in the Superficial Femoral Artery and Proximal Popliteal By using the EverFlex NitInol STent System Post Approval Study
- DURABILITY+- - a Prospective, Multi-center, Controlled Study Measuring the Durability in Lesions of the Superficial Femoral Artery of the Protégé EverFlex+ Stent
- DURABILITY-200 - Physician Initiated Trial Investigating the Efficacy of the Implant of EverFlex 200mm Long Nitinol Stents in TASC C&D Femoropopliteal Lesions
- ENTRUST - EverFlex Self-expanding Peripheral Stent With Entrust™ Delivery System Clinical Study
- Fracture of self-expanding nitinol stents stressed evaluated in the DURABILITY trial, a long term efficacy and safety study...results of 128 Protg stents...by Schnefeld E, Schnefeld T, Osada N, Austermann M, Torsello G and published August 17, 2009 in Zentralbl Chir.

**Commercial Approval:**
- On December 14, 2016 Medtronic received PMA approval for Everflex self expanding peripheral stent system for its addition of electropolishing equipment to the manufacturing line.
- Received CE Mark for the PROTEGE EverFlex Self-Expanding Stent System for general use in the peripheral vasculature, including common and external iliac, subclavian and the superficial femoral artery on March 9, 2006
- Received FDA approval on March 18, 2008 for a 5mm PROTEGE EverFlex Stent
- Received FDA approval on March 9, 2006 for the PROTEGE EverFlex Self-Expanding Stent System for palliative treatment of malignant neoplasms in the biliary tree
- Received FDA approval in March 7, 2012 in the native Superficial Femoral Artery (SFA) and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 - 7.5mm.
- In April 2015, the Protege Everflex stent has received FDA approval for indication in the treatment of iliac artery stenosis
- On November 25, 2016 Medtronic received PMA approval for Everflex for updation on Process parameters.

**Development Status - Commercial Events:**
- On October 23, 2006 ev3 announced a worldwide fracture-free guarantee for its line of EverFlex stents within two years of stent implantation
- On July 22, 2007 ev3 and FoxHollow announced a company-wide merger to become a global leader in the endovascular device market
- July 12, 2010 - Covidien acquires ev3 for approximately 2.6 billion dollars

**Development Status - Clinical Trials:**

- Using 128 Protg stents in long femoropopliteal lesions in 103 patients, a first time occurrence; the authors concluded that "The Protg stent is a safe device with favourable short-term results. Restenosis and fracture rates are low, but long-term results still have to be evaluated in the future"
- Evaluated in the DURABILITY trial, a long term efficacy and safety study...
**Please Note:** All links will open in the current window - to open a link in a new window please right click the link and select "Open in New Window" or "Open in New Tab"
One-year follow-up after implantation of the EverFlex nitinol stent in long lesions of the superficial femoral artery.


