**Product Name:** PolarCath Peripheral Dilation System

*(Peripheral Vascular Therapeutics - In Development, Lower Limb Advanced Arterial Therapeutics, Pathway Clinical Trial MarketTracks, Medtronic PV Lower Limb Advanced Arterial Therapeutics, Lower Limb Chronic Total Occlusions - CTO, Lower Limb Critical Limb Ischemia - CLI)*

**Description:**
- Cryotherapeutic balloon angioplasty system utilizing liquid nitrous oxide

**Company/Sponsor:**
- NuCryo Vascular
- CryoVascular Systems, Inc. (Boston Scientific Corporation)
- Vascular Solutions, Inc.

**Vessels:**
- Femoral Arteries (SFA/Superficial)
- Lower Limb Arteries

**General Modality:**
- Medical Devices

**Specific Modality:**
- Other Medical Devices / Systems

**General Product Type:**
- Cryogenic Energy

**Clinical Trials:**
- Below-The-Knee (BTK) Chill - Quality of Life and Clinical Outcomes in Patients With Critical Limb Ischemia Receiving Cryoplasty Therapy
- CLASE - Prime Time for Superficial Femoral Artery (SFA) - The SFA Study
- CLIMB Registry - Critical Limb Ischemia
- Cryoplasty COBRA - Cryoplasty Therapy Or Conventional Balloon Post-Dilation of Nitinol Stents for Revascularization of Peripheral Arterial Segments (PolarCath Cryoplasty Versus Conventional Balloon Post-Dilation of Nitinol Stents in the Popliteal Artery
- Cryoballoon Angioplasty Broadens the Role of Primary Angioplasty and Reduces Adjuvant Stenting in Complex Superficial Femoral Artery Lesions
- Cryoballoon Trial
- Cryoplasty for Lower Extremity Arterial Occlusive Disease: Is the Outcome Worth the Price Tag?
- Cryoplasty for Peripheral Artery Disease in an Unselected Patient Population in a Tertiary Center
- Cryoplasty Versus Conventional Angioplasty in Femoropopliteal Arterial Recanalization: 3-Year Analysis of Reintervention-Free Survival by Treatment Received
- Cryoplasty versus conventional balloon angioplasty of the femoropopliteal artery in diabetic patients: Long-term results from a prospective single-center randomized trial
- CVSi Registry - CryoVascular Systems, Inc.
- Peripheral Balloon Catheter System Safety Registry
- FIX-IT Retro Registry - Clinical Outcomes of Cryoballoon Angioplasty

**Commercial Approval:**
- Received CE Mark in Europe in 2002
- Received marketing clearance from the FDA in September 2002
- On January 30, 2007 Boston Scientific announced that the FDA gave 510(k) clearance to add a new balloon length to their PolarCath Peripheral Dilation System product line. The new balloon is approved at 100-millimeters (mm).

**Development Status - Commercial Events:**
- On July 23, 2019 NuCryo Vascular has announced that the company has signed a commercialisation agreement with Lokai Medical, a specialty distributor of coronary/peripheral and interventional devices, to distribute the PolarCath Balloon Dilatation System in the USA.
- On April 18, 2005 Boston Scientific announced its decision to acquire CryoVascular Systems, the maker of the PolarCath Peripheral Dilation System
- On August 10, 2018 Nucryo Vascular has signed a commercialisation agreement with Lokai Medical, a specialty distributor of coronary/peripheral and interventional devices, to distribute the PolarCath balloon dilatation system in the USA.
- On November 2014, Vascular Solutions, Inc. entered into an agreement with NuCryo Vascular LLC under which Vascular Solutions will serve as exclusive distributor of the PolarCath Peripheral Dilatation System in the United States
- On April 2015, Vascular Solutions, Inc. has commenced sales of the PolarCath peripheral dilatation system in the United States in collaboration with NuCryo Vascular LLC, the manufacturer of the product.
- On May 2, 2019 NuCryo Vascular announced Series B financing and is launching its Extended PolarCath Balloon Dilatation Catheter. The Series B financing will provide the necessary working capital to support the expected rapid growth of the PolarCath Balloon Dilatation System while reaching corporate profitability in 2019.

**Development Status - Clinical Trials:**
- IDE Study Results
- Treatment Outcomes:
Three Different Percutaneous Revascularization Strategies for the Treatment of Lifestyle Limiting Claudication: A Retrospective Analysis

- Interventions Using Plain Balloon Angioplasty versus Cryoplasty with the PolarCath®: A Randomized Trial
- Treatment of Complex Superficial Femoral Artery Lesions With PolarCath Cryoplasty

**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”

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### Sources:


**November 5, 2014** --- "Commercial Events" field - New Distribution Activity --- "Sources" field - "Vascular Solutions, Inc. entered into an agreement with NuCryo Vascular LLC under which Vascular Solutions will serve as exclusive distributor of the PolarCath Peripheral Dilatation System in the United States." Vascular Solutions News Room.

**November 23, 2010** --- "Commercial Approval" field - Added FDA approval to dilate stenoses in the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal and subclavian arteries) and for the treatment of obstructive lesions of polytetrafluoroethylene (PTFE) access grafts or arteriovenous dialysis fistulae. The PolarCath Peripheral Dilatation System is also indicated for post-deployed stent expansion of self-expanding peripheral vascular stents. --- "Sources" field - <www.accessdata.fda.gov/cdrh_docs/pdf9/K092455.pdf> "501(k) NO: K092455"; FDA, September 4, 2009.

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**17.8% target lesion revascularization rate**

70% primary patency

82% clinical patency

80% of treated patients experienced ABI improvement

89% of treated patients experienced claudication improvement

Extended Follow-up — Up to 3.4 years

75% freedom from TLR

Below-the-Knee Chill Study Results

180 Day Outcomes Below-the-Knee Chill Study:

97% Acute technical success (N = 111)

- 2% >50% residual stenosis

- 1% Clinically significant dissections (due to guide wire Investigator Report)

- 6% Non-clinically significant dissections (Type A or B)

- 93% 180-day freedom from major amputation (N = 91)*

- 85% 365-day freedom from major amputation (N = 78)*

* N = total limbs reported.

Evaluated in an August 9, 2008 published study, titled "Pilot Study of Cryoplasty with Use of PolarCath Peripheral Balloon Catheter System for Dialysis Access" in which safety and feasibility of cryoplasty was observed in 20 patients with grafts (n=18) or arteriovenous fistulas (n=2) and in which the authors concluded that "Use of the PolarCath peripheral balloon catheter system as the initial balloon for dialysis access venous stenoses is safe but painful. Anatomic success rates after cryoplasty are low. Results of cryoplasty supplemented by PTA appear comparable to those of PTA alone"

Evaluated in a 27 patient trial with severely symptomatic (Rutherford Class >/3) Superficial Femoral Artery (SFA) disease that was presented at TCT 2008 by Subhash Banerjee, Emmanouil S. Brilakis, Jepsin Samuel, Cyril Varghese, and Tony S. Das as "Treatment of Complex Superficial Femoral Artery Lesions with PolarCath Cryoplasty" and took place between 8/2008 and 10/2007 in which Procedural Success was 100%, Primary Patency was 75% in the Cryoplasty only group (28 lesions) and 46% in the Cryostent group (11 lesions) and in which the authors concluded this treatment is effective in the SFA with a demonstrated improvement in intermediate term PAD symptoms


Last Update: August 1, 2019