

Cryoplasty Inflation Unit

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KEY FEATURES

- Reusable, nonsterile inflation device
- Developed for 100 inflations per device

NuCryo Vascular LLC has received 510(k) clearance for its next-generation, reusable Cryoplasty inflation device. The Cryoplasty inflation device, which will work in conjunction with the current PolarCath peripheral balloon dilatation system, will substantially lower the PolarCath per-case procedural cost. The system is used to perform balloon cryoplasty, a catheter-based

treatment that combines the inflation of a balloon with controlled cooling of the artery.

The PolarCath peripheral balloon dilatation system, available in the United States, has clearance from the US Food and Drug Administration to dilate stenoses in the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal, and subclavian arteries) and for the treatment of obstructive lesions of polytetrafluoroethylene access grafts or arteriovenous dialysis fistulas. The PolarCath system is also indicated for postdeployed stent expansion of self-expanding peripheral vascular stents. ■

