The Alucent NVS Vessel Restoration System with Photoactivated Linking
Product Fact Sheet

Overview

The Alucent Biomedical Natural Vascular Scaffolding (Alucent NVS) Vessel Restoration System with Photoactivated Linking is designed for the treatment of peripheral artery disease (PAD) of the lower extremities. The company recently announced that it will also seek to adapt the technology to assist maturation and preservation of arteriovenous fistula (AVF) for hemodialysis (HD).

Peripheral artery disease (PAD) is a debilitating, painful and highly prevalent condition in which arteries outside of the heart, frequently in the lower extremities, become narrowed or blocked due to a build-up of plaque, restricting blood flow to the limb or extremity. Affecting eight to 10 million people in the U.S., and 200 million people worldwide[i], PAD's primary risk factors include obesity, high cholesterol, hypertension, diabetes and tobacco use. The prevalence of PAD rises with age, from five percent at age 60 to 20 percent at age 80. The most commonly used treatments for PAD include angioplasty, stenting, and paclitaxel-coated devices. However, a significant unmet need still exists for the treatment of PAD, as a number of studies have shown that balloon angioplasty has a failure rate of more than 60 percent at twelve months[i]. This is especially true in the case of calcified or long lesions as well as those treatments complicated by arterial dissection. Many patients end up with limb amputations due to failures of current therapies.

Arteriovenous Fistula: The prevalence of end-stage renal disease continues to rise, and there is a growing need for hemodialysis. The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) guidelines and the Fistula First Breakthrough Initiative recommend AVFs as the preferred type of vascular access for HD, as they have superior patency rates, fewer complications, and lower health care costs. Early pre-clinical studies involving Alucent NVS therapy for AVF have been encouraging. Applying the treatment at fistula creation has facilitated maturation and promoted outward remodeling of the AVF.

About the Alucent NVS Vessel Restoration System with Photoactivated Linking

The Alucent NVS Vessel Restoration System with Photoactivated Linking is designed to use Natural Vascular Scaffolding (Alucent NVS) technology to open vessels and keep them open without the use of permanent implants in the treatment of PAD of the lower extremities. The system combines standard angioplasty with photoactivated linking of the structural proteins in the wall of a blood vessel. The intervention is designed to deliver immediate restoration of the vessel's lumen and sustained improvement of blood flow, without the introduction of a

	foreign implant, such as a metallic stent, into the patient's body. Because there is no rigid foreign material, the arterial wall has the potential to retain its natural functionality and flexibility and avoid the complications of permanent stents. Alucent NVS photoactivated linking is also designed to mitigate the well-known adverse effects of angioplasty, such as vessel recoil. Sustained, improved blood flow may result in pain relief, limb preservation, a reduction in reinterventions and an improved quality of life for patients.
How It Works	Alucent NVS is performed in concert with standard balloon angioplasty technique. First, standard predilatation angioplasty opens the vessel to its pre-stenotic size resulting in re-alignment of the native extracellular matrix proteins in the vessel wall. Then, during the Alucent NVS procedure, a novel light-activated, small molecule drug is delivered to the wall of the diseased artery, where it diffuses into the tissue near the proximity of the extracellular matrix proteins. An Alucent NVS light fiber is illuminated, activating the drug. The drug then flexibly re-links the native collagen and elastin, major structural components of the vessel wall, creating a natural scaffold, like a stent, that holds open the vessel, but without the need for a foreign implant.
Clinical Study Status	As of Q4 2020, a multicenter Phase 1 clinical trial called ACTIVATE I is underway to evaluate the safety and efficacy of the Alucent NVS in U.S. patients. Following ACTIVATE I completion, Alucent Vessel Restoration System with Photoactivated Linking will be studied in a larger cohort of patients in 2021. Prior to the U.S. Food and Drug Administration's approval to proceed with the ACTIVATE I study, pre-clinical testing in animal studies demonstrated acute and long-term safety and patency without the pro-inflammatory and mechanical risks of placing a rigid foreign implant into the blood vessel.
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[i] *Caradu, Caroline et al. Systematic review and updated meta-analysis of the use of drug-coated balloon angioplasty versus plain old balloon angioplasty for femoropopliteal arterial disease. Journal of Vascular Surgery. Volume 70, Issue 3, 981-995.e10.*