

Category

Best Medical Technology

Drug / Device Name

DETOUR System

Compound/ Tech Name

n/a

Trade Name

n/a

Date of Approval

N/A

Indications

At this time, the DETOUR System is currently an Investigational Device and is under review with the U.S. Food and Drug Administration

Proposed Indications for Use: The DETOUR System is indicated for use for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200 mm to 460 mm in length with chronic total occlusions (100 mm to 425 mm) or diffuse stenosis >70% who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The DETOUR System, or any of its components, is not for use in the coronary and cerebral vasculature.

Therapeutic Categories

complex peripheral arterial disease

Background information and need for drug/device

Peripheral arterial disease affects millions of lives worldwide, and that population is continuing to increase.

Patients with lifestyle limiting claudication or critical limb ischemia typically have lesions longer than 15cm which do not fare well with existing treatments, resulting in substantial financial burden for the health system. The more complex lesions are associated with costly index procedures. Procedure cost is driven by both the length of procedure time and the large volume of devices used treat these lesions.

Research shows that readmissions are associated with complications that contribute to a 30-day morbidity rate of 37% and 30-day readmission rate of 24%, the third highest rate of any diagnosis-related group, behind only congestive heart failure and psychoses¹. Existing endovascular approaches for complex lesions are associated with costly re-treatment procedures. A study reported that 30-day readmission rates for inpatient endovascular interventions in the US were 17.6%. Twenty one percent of

these patients underwent a subsequent peripheral arterial revascularisation or lower limb amputation and procedure costs were as high as \$386,428.

The easiest analogy is a traffic jam. Imagine there's gridlock traffic on the freeway due to an accident blocking southbound lanes. Authorities move the center barrier adding lanes from the less trafficked northbound side of the freeway to restore traffic flow. The flow of cars traveling north is largely uninterrupted but the cars traveling south now have a way around the blockage. That's DETOUR System in a nutshell – they apply this theory to the human superhighway – our arteries and veins.

Today, the gold standard for treating blocked arteries in the legs is surgical bypass. While it is a durable approach, it also presents a low risk of serious complications including cardiovascular events, wound complications, graft infections, and in rare cases even death. It also requires a multiple day hospital stay and a long recovery for patients, anywhere between 6-8 weeks. Endovascular procedures, while not as durable in most cases, can be performed in an outpatient setting so that patients are home same day.

Reference

1. Secemsky, E, Schermerhorn, M, Carroll, B, et al. Readmissions after revascularization procedures for peripheral arterial disease. *Ann Intern Med* 2018; 168 (2): 93–99.

History of the development of the drug/device

See image below for history of development. In addition to the image, after it was acquired by ENDOLOGIX we continued the development and preparation for FDA submission. We had a few relevant press releases of note which have also been attached.

Attached Files:

- EMBARGOED_Endologix completes PMA application for DETOUR System_Final 10922 1.docx
- Endologix_MedTech Breakthrough Awards_2023_Final 42823 1.docx
- Final clean_Endologix Announces 12Month Results of DETOUR2 IDE Trials 1.docx

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition

PTAB is performed using the DETOUR System, a unique innovative technology that allows the creation of a fully percutaneous femoropopliteal bypass that is routed through the femoral vein. Under fluoroscopic guidance the DETOUR system percutaneously creates a fem-pop bypass routed through the femoral vein. The system uses a proprietary spring-loaded crossing device to create the artery-vein-artery communication. Then proprietary stent grafts are deployed from the popliteal artery into the femoral vein, and from the femoral vein into the SFA through two anastomoses, resulting in a large lumen endograft bypass that delivers unobstructed flow from the SFA to the popliteal artery. The disruptive nature of PTAB therapy to transform the current standard of care makes it worthy of a world changing award. PTAB has the potential to change the paradigm for complex SFA treatment in the way EVAR and TAVR changed the paradigm for aortic repair. In many patients who may not be candidates for surgical or native endovascular revascularizations, PTAB will provide them with a new treatment modality.

From the patient's perspective, the possibility of avoiding prolonged hospital stays—as well as

complications such as wound infection, haemorrhage, or nerve injury—is compelling.

Attached Files:

- PQ Bypass Revisions 8 copy.jpg

Please provide appropriate references (ie Pubmed links)

[https://www.jvascsurg.org/article/S0741-5214\(22\)01274-5/fulltext](https://www.jvascsurg.org/article/S0741-5214(22)01274-5/fulltext)

<https://journals.sagepub.com/doi/full/10.1177/152666028211034862>