Navigate complex PAD with PTAB.

Introducing PTAB, the first-ever fully percutaneous transmural arterial bypass therapy using the DETOUR™ System

Endologix

Patients with long complex SFA disease face treatment tradeoffs

For patients with long complex superficial femoral artery (SFA) disease, minimally invasive endovascular treatments have limited efficacy. Open surgical bypass is the current standard of care, but patients face complication risks and prolonged recovery.

ENDOVASCULAR INTERVENTIONS

25.2%

will need reintervention at one year[1]

SURGICAL BYPASS

4.5% to 14%

infection rate post-surgery[1-3, 8]

5.7

days average hospital stay post-surgery[4]

PTAB with the DETOUR™ System

A percutaneous alternative to open lower limb bypass for patients with PAD who:

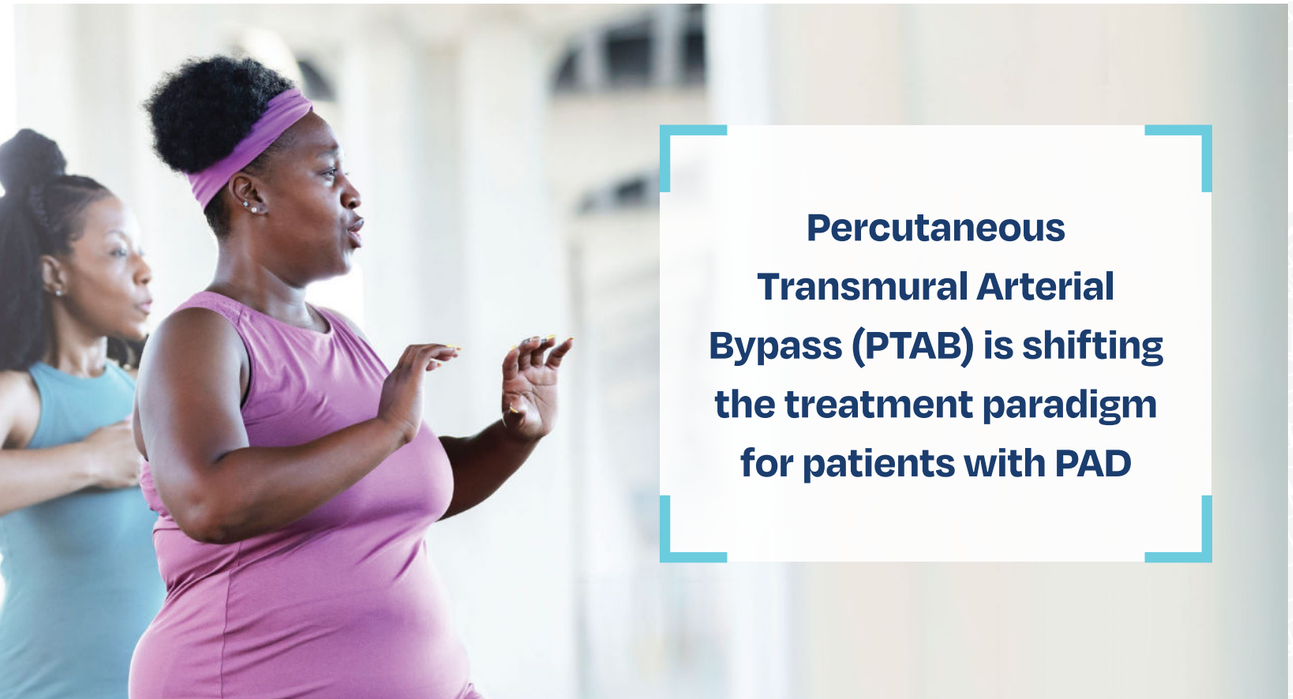
- Have long femoropopliteal lesions (20cm to 46cm in length)
- Have already undergone repeat endovascular procedures
- May not be good candidates for surgical bypass

PERCUTANEOUS TRANSMURAL ARTERIAL BYPASS (PTAB)

Long-term efficacy[5]

Minimal trauma to the body[5]

Minimal hospital stay[5]

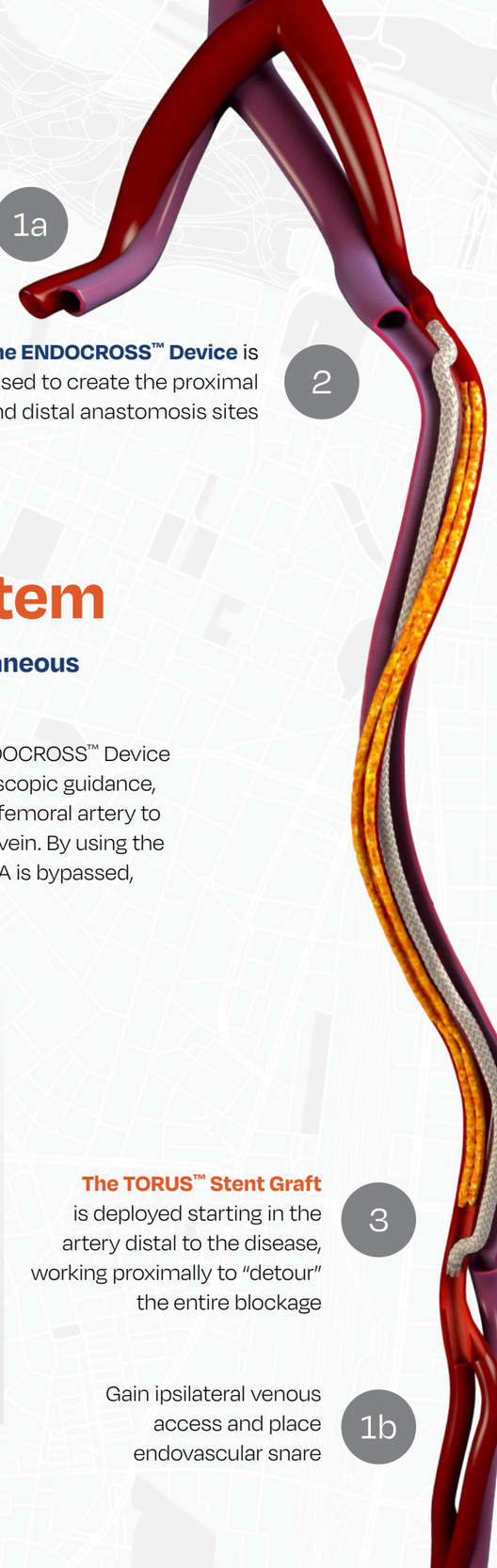


Percutaneous Transmural Arterial Bypass (PTAB) is shifting the treatment paradigm for patients with PAD

The DETOUR™ System bypasses lesions in the superficial femoral artery by using stents routed through the femoral vein to restore blood flow to the leg

Gain contralateral arterial access

1a



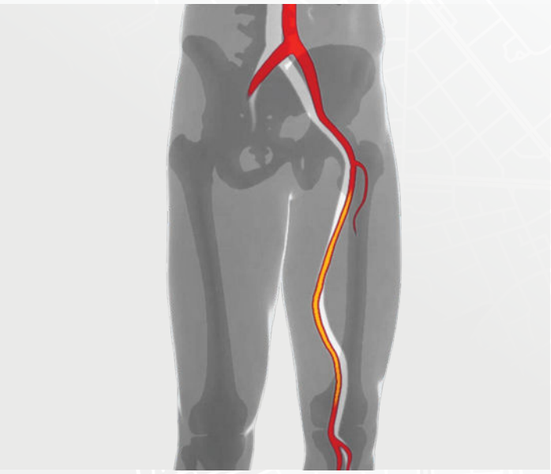
The ENDOCROSS™ Device is used to create the proximal and distal anastomosis sites

2

PTAB with the DETOUR™ System

Specifically designed for percutaneous treatment of long lesions

The DETOUR™ System consists of the ENDOCROSS™ Device and the TORUS™ Stent Graft. Under fluoroscopic guidance, TORUS™ Stent Grafts are placed from the femoral artery to the popliteal artery by way of the femoral vein. By using the femoral vein as a conduit, the diseased SFA is bypassed, allowing perfusion below the obstruction.



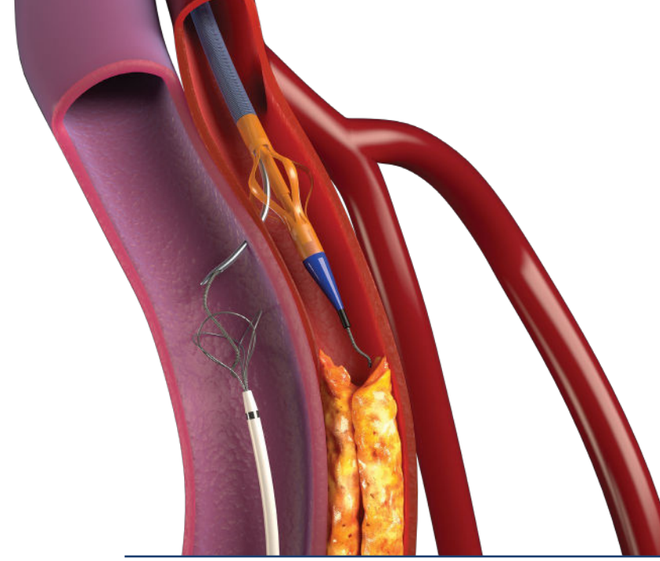
The TORUS™ Stent Graft is deployed starting in the artery distal to the disease, working proximally to "detour" the entire blockage

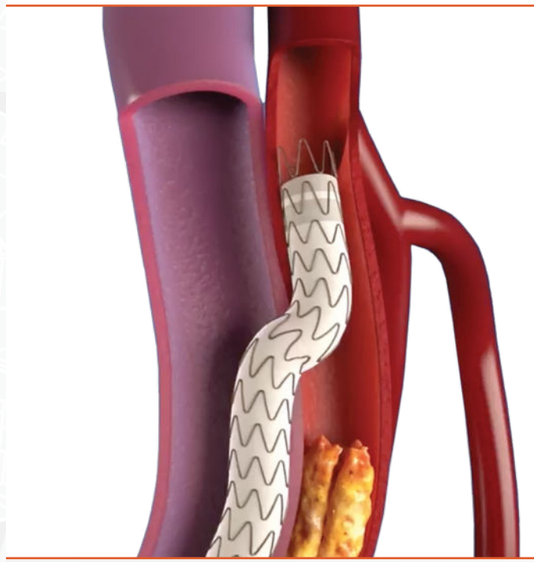
3

Gain ipsilateral venous access and place endovascular snare

1b

The ENDOCROSS™ Device enables guidewire delivery under fluoroscopic guidance





The TORUS™ Stent Graft is designed with radial strength to resist forces at the anastomoses sites

TORUS™ Stent Graft Sizes

length	diameter 5.5mm	6.0mm	6.7mm
100mm		✓	✓
150mm		✓	✓
200mm	✓	✓	✓

Embrace the Evidence

PTAB with the DETOUR™ System is clinically proven to be a safe and effective treatment for patients with long complex SFA disease.

CLINICALLY DEMONSTRATED IN PATIENTS WITH UNMET NEEDS:

32.7cm
mean lesion length[5]

96%
chronic total occlusion before the DETOUR™ System[5]

17%
of enrolled patients had in-stent-restenosis[5]

60%
had previous peripheral intervention[5]

DEMONSTRATED EFFICACY

87.7%
freedom from CD-TLR at 1 year[6]

92.4%
freedom from 100% occlusion[7]

97.2%
clinical success rate at 1 year[5]

DEMONSTRATED SAFETY

0.5%
infection rate at 30 days[7]

93%
freedom from major adverse events at 30 days[5]

2.5%
DVT rate at 30 days[5]

MINIMAL HOSPITAL STAY

1.1 DAY
average hospital stay[7]

Navigate complex PAD with PTAB
endologix.com/detour

*These are portrayals of typical PAD patients and not real patients

References

1. Kim et al. Outcomes of bypass and endovascular interventions for advanced femoropopliteal disease in patients with premature peripheral artery disease. J Vasc Surg 2021;74:1968-77
2. Shah, T, Tirziu, D, Ghare MI, Yang Y, Taoutel R, Gaston, S, Pietras C, Lansky AJ. Surgical Bypass of Femoral-Popliteal Arterial Disease: A Meta-analysis of Randomized and Prospective Trials. J CRIT LIMB ISCHEM 2022;2(4):E122-E130.
3. Voicu S, Trooboff SW, Goodney PP, Zwolak RM, Powell RJ. Medicare reimbursement of lower extremity bypass does not cover cost of care for most patients with critical limb ischemia. J Vasc Surg. 2020 Sep;72(3):1068-1074. doi: 10.1016/j.jvs.2020.01.062. PMID: 32829764.
4. Medicare open surgical bypass procedures based on 2021 data
5. Lyden. Percutaneous Bypass for Treatment of Long-Segment Femoropopliteal Disease: 12 Month Results from the DETOUR2 Trial. JVS 75, 6, E337-8
6. P220021 Summary of Safety and Effectiveness Data (SSED). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
7. Lyden. Durability of Percutaneous Bypass for Treatment of Femoropopliteal Disease: Two-year Outcomes of the DETOUR-2 Study. VAM 2023.
8. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JF, Fowkes FG, Gillepsie I, Ruckley CV, Raab G, Storkey H; BASIL trial participants. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. Lancet. 2005 Dec 3;366(9501):1925-34. doi: 10.1016/S0140-6736(05)67704-5. PMID: 16325694.

Indications for use

The DETOUR™ System is indicated for use for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200mm to 460mm in length with chronic total occlusions (100mm to 425mm) 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.

Contraindications

The DETOUR™ System is contraindicated in patients with:

- A distal common femoral artery (CFA) <7 mm in diameter.
- Increased risk of deep vein thrombosis (DVT), such as patients with a recent history of DVT, thrombophilia, and disseminated malignancy.
- Untreated flow-limiting aortoiliac occlusive disease.
- Lack of patent single vessel tibial runoff to ankle.
- Known coagulopathy, bleeding diathesis, or thrombocytopenia that cannot be medically managed.
- Known hypersensitivities, allergies or contraindications to: Nitinol; PTFE; aspirin; heparin; antiplatelet; anticoagulant or thrombolytic therapy; or contrast media that cannot otherwise be medically managed.

Refer to Instructions for Use for more information concerning Indications, Contraindications, Specific Anatomic Considerations, Warnings, Precautions, and Adverse Events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

NOTE: Not all product components are available in every country. Please consult with your Endologix representative to confirm product availability.

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