

Tack Endovascular System[®]

An innovative solution for dissection repair.



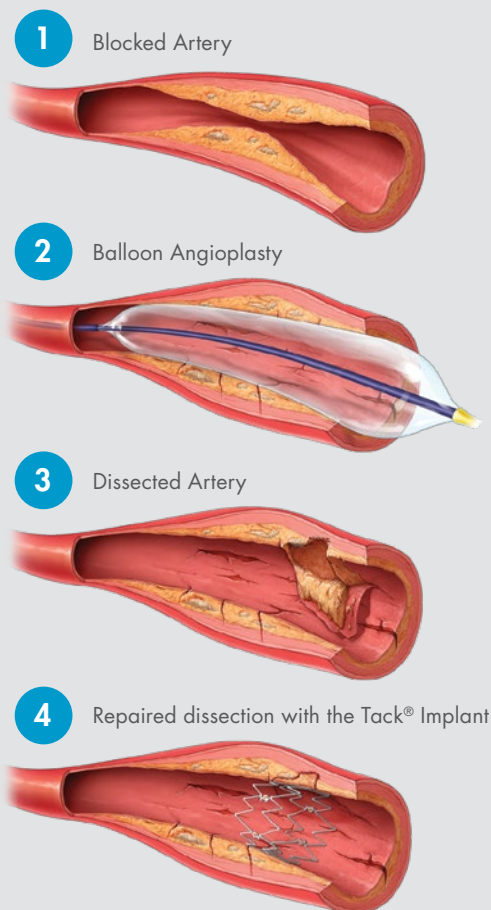
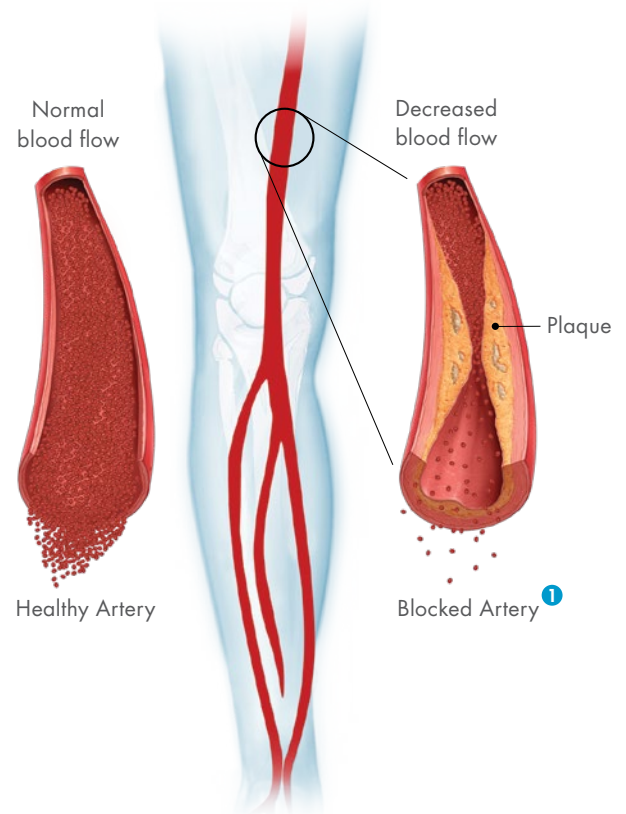
 **intact**[®]
vascular

Peripheral Artery Disease (PAD)

is a common condition, affecting more than 20 million people in the U.S. and over 202 million people globally.^{1,2}

PAD develops when arteries become clogged with plaque that limits blood flow to the leg.¹ This blockage can cause poor circulation, pain while walking, and changes in skin color.

The goals of treating PAD are to restore blood flow to manage symptoms (pain) and slow the advancement of atherosclerosis (plaque) to decrease risk of heart attack and stroke. Treating PAD is very important to slow or prevent progressing to the most severe form of the disease and/or losing limbs to amputation.



Balloon Angioplasty & Dissections

There are effective treatments for PAD, including balloon angioplasty. During this minimally invasive procedure, a small balloon is inserted into the diseased, narrowed section of the artery. The balloon is then inflated, expanding the artery to improve blood flow.²

There is a risk, however, that the arterial wall will become damaged—or torn—during the angioplasty procedure. These tears are called dissections.³

It's important to treat dissections quickly, so they don't further obstruct blood flow or result in the need for another procedure.

The Tack Endovascular System®

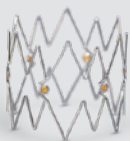
Today, there is an innovative solution specifically for repairing dissections.

The Tack Endovascular System is designed to repair the dissections created by balloon angioplasty.* The unique system has multiple independent Tack® implants made of a nickel-titanium alloy called Nitinol, deployed through a catheter or tube.

After examining the expanded artery for dissections, the physician can immediately address them by placing a single or multiple Tack implant(s) precisely where the vessel was damaged—repairing each tear by gently securing the tissue back against the arterial wall.⁴

The goal of your balloon angioplasty procedure is to restore healthy blood flow to the leg to manage symptoms and to prevent worsening of the disease. The Tack Endovascular System is a complementary therapy designed to repair dissections that may have occurred during angioplasty.

With the Tack Endovascular System, physicians can now safely and effectively repair dissections and prevent complications which may occur if left untreated.



Benefits and Risks

As with any medical procedure, endovascular repair with the Tack implant has potential benefits and risks. It is important that you talk with your doctor and understand all the potential benefits and risks associated with your peripheral arterial disease treatment.

Patient Implant Card

A patient implant card will be given to you by your doctor. It contains important information about the Tack implant. Be sure to show your implant card to any health care providers that treat you in the future.

Talk To Your Doctor

The information in this brochure should not be used as a substitute for talking with your doctor. If you have any questions about your Tack implant, or want more information about this innovative solution, please talk to your doctor.

***Tack Endovascular System (6F) FDA approved for SFA and proximal popliteal (3.5-6.0mm RVD) treatment of post-PTA dissections.**

REFERENCES

1. Yost M, The Sage Group 2016. [Press Release]
2. Fowkes GR, Rudan D, Rudan I, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet*. 2013;382(9901):1329-1340.

INTENDED USE: The Tack Endovascular System (6F) is intended for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 3.5mm to 6.0mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s).

CONTRAINDICATIONS FOR USE: The Tack Endovascular System is contraindicated for the following: 1. Patients with residual stenosis in the treated segment equal to or greater than 30% after PTA. 2. Tortuous vascular anatomy significant enough to prevent safe introduction and passage of the device. 3. Patients with a known hypersensitivity to nickel-titanium alloy (Nitinol). 4. Patients unable to receive standard medication used for interventional procedures such as anticoagulants, contrast agents and antiplatelet therapy.

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