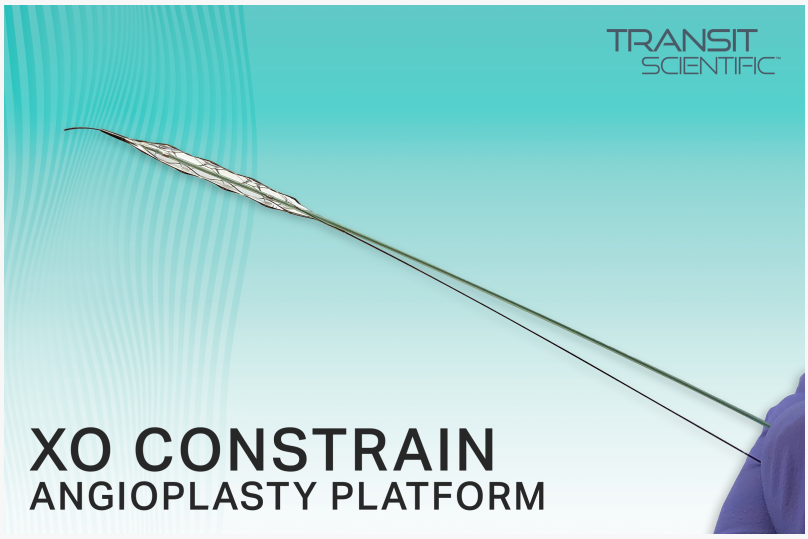
FDA Clears Balloon Dilation Scoring and Constraining Platform to Treat Small or Distal Peripheral Vasculature

Transformative Angioplasty Sheath Platform Compatible with a Broad Range of Off-the-Shelf PTA and PTCA Angioplasty Balloons Cleared by FDA



XO Constrain 20mm device preloaded with an off-the-shelf 4mm x 20mm PTCA balloon.

SALT LAKE CITY, UTAH, UNITED STATES OF AMERICA, June 26, 2024 /EINPresswire.com/ -- Transit Scientific, a pioneer in developing medical devices to treat calcified peripheral disease, dilate stenosed intimal hyperplasia, and access, cross, & deliver to distal vessels, announced today that its XO Constrain 2.2F Angioplasty Platform received FDA clearance to modify calcified plaque and fibrous lesions in the peripheral vasculature.

The XO Constrain Catheter is a low-profile balloon dilation scoring and constraining catheter that works with compliant and semi-compliant off-the-shelf Percutaneous Transluminal Angioplasty (PTA) and Percutaneous Transluminal Coronary Angioplasty (PTCA) balloons to expand the constraining structure and is designed to facilitate uniform, atraumatic balloon expansion, vessel scoring, and rewrap within small or distal vessels.

“The XO technology has shown effectiveness modifying, cracking, and dilating intimal and medial calcium using low pressures,” said Richard Saxon, MD, FSIR of Tri-City Medical, San Diego, California. “The new XO Constrain device brings added flexibility and a low profile, making it a good option for Peripheral Artery Disease (PAD) and Critical Limb Ischemia (CLI) disease below the knee and potentially below the ankle.”

The XO Constrain platform is compatible with a broad range of off-the-shelf PTA and PTCA balloons ranging in diameter from 1.5 to 4mm and 6 to 20mm in length. During balloon inflation, the struts rotate 90 degrees to prep and treat calcified stenotic atherosclerotic lesions, and

intimal hyperplastic lesions, and can be used for vessel prep for other treatment options. No consoles, new capital equipment, or complex learning curve are required.

Joseph Steele, MD, FSIR shared, “Often physicians pull PTCA balloons when treating the very small vessels in the distal peripheral vasculature and pedal vessels. The ability of XO Constrain to work with off-the-shelf PTCA balloons to facilitate controlled, concentric dilatation of stenosis in these small vessels provides a unique and exciting option for patients in need.”

Jennifer Arnold, President and Chief Executive Officer of Transit Scientific, remarked, “The FDA clearance of the XO Constrain platform marks a significant milestone for Transit Scientific. This achievement underscores our commitment to developing safe, innovative, and effective solutions for physicians. Building on this success, we plan to deliver a coronary version of the XO Constrain in the future.”

The XO Constrain System is intended to be used in conjunction with a PTA or PTCA balloon to facilitate dilation and apposition of the scoring surface to the stenotic material in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

This 510(k) clearance includes the XO Constrain 10mm, 15mm, and 20mm configurations. All three variations are offered with a working length of 145cm.

About Transit Scientific:
Transit Scientific is focused on establishing new standards of care with differentiated proprietary devices that (1) crack, break, and dilate calcified plaque, (2) dilate stenosed intimal hyperplasia, and (3) access, cross, and deliver to distal vessels. Transit’s XO Platforms are simple-to-use, are minimally invasive, use existing angioplasty balloons and guidewires, and preserve patient treatment options. The XO Platform does not require new consoles, capital equipment, or complex learning curves. Transit’s FDA-cleared devices include XO Constrain, XO Score OTW and XO Score Low Profile RX Angioplasty; XO Cross 014, 018, & 035 Microcatheters; XO Cath IO Embolic Delivery Microcatheter; and XO Cross Coronary systems. The company’s XO CS Coronary Angioplasty device is under development and not FDA-cleared or for sale at this time.

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