

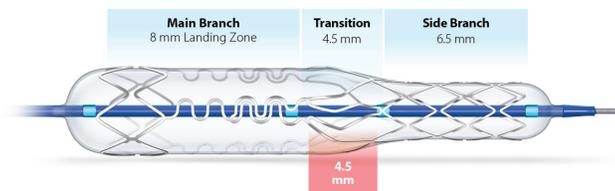
TRYTON Side Branch Stent Built For Bifurcation

Percutaneous coronary intervention (PCI) is a procedure used to open blocked coronary arteries caused by coronary artery disease (CAD). The procedure restores blood flow to the heart muscle without the need for open-heart surgery. Coronary stents are now used in nearly all angioplasty procedures to reduce the occurrence of re-occlusion of the treated lesion.

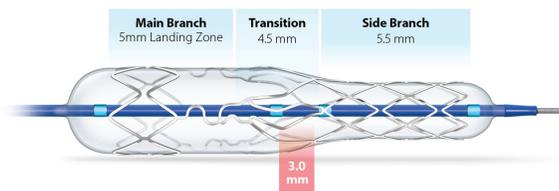
In many cases, CAD results in the buildup of plaque at the site where one artery branches from another, also known as a bifurcation. In patients undergoing PCI-stenting, approximately one-third have a bifurcation lesion.

Treatment with PCI at the site of a bifurcation can require additional time and be technically difficult. As a result, in many cases the side branch is not stented, leaving it vulnerable to higher rates of complications such as restenosis.

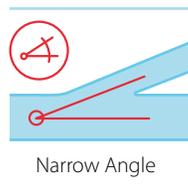
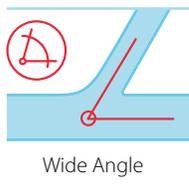
2.5 mm Side Branch (19 mm)



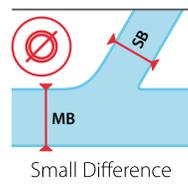
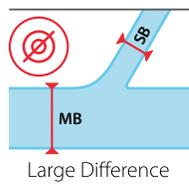
3.0 - 3.5 mm Side Branch (15 mm)



ANGLE



DIAMETER



Tryton Side Branch Stent

For interventionalists seeking to treat significant bifurcations predictably, the Tryton Side Branch Stent is designed to provide complete lesion coverage accommodating all vessel types with procedural control and superior outcomes.

The stent is made of cobalt chromium and is deployed in the side branch artery using a standard single-wire balloon-expandable stent delivery system.

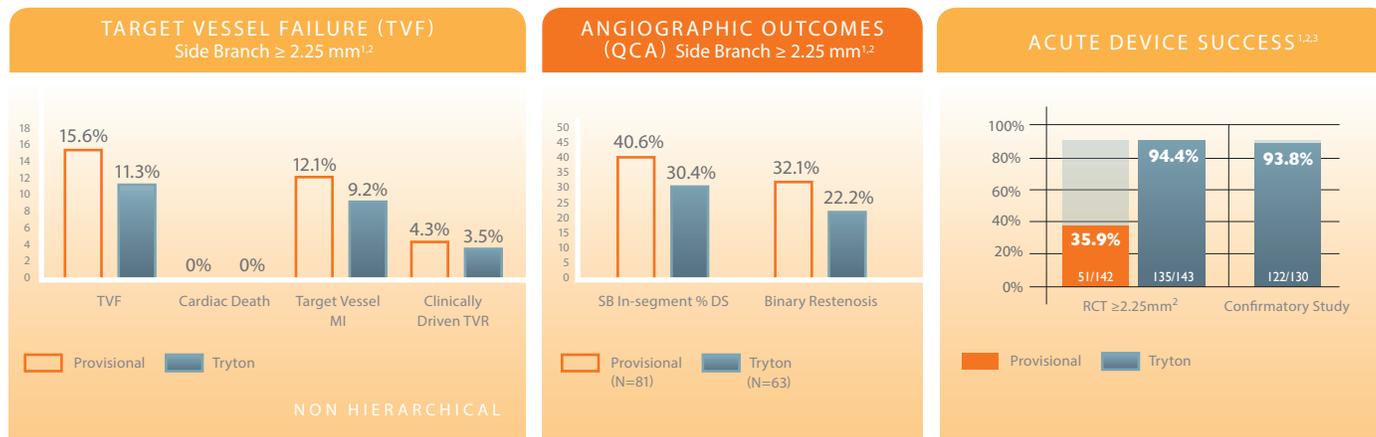
The Tryton Side Branch Stent is designed with Tri-ZONE® technology to match different anatomies of all significant bifurcation lesions and all main vessel stents.

1. Side branch zone provides scaffolding to secure the side branch with comparable performance to a traditional stent.
2. Transition zone is designed to provide radial strength and coverage to the ostium, accommodating the entire anatomy of a bifurcation.
3. Main branch zone provides a minimal metal to artery ratio to allow for integration with a drug-eluting stent.

Power in Numbers

More than 12,000 patients around the world have been treated with Tryton Side Branch Stent. The technology has been evaluated at over 100 research sites in more than 15 countries in order to match the unmet need for significant bifurcation lesions.

The pivotal Tryton Randomized Clinical Trial (RCT), the largest coronary bifurcation study ever conducted, compared the Tryton Side Branch Stent to conventional provisional treatment with balloon angioplasty in the side branch. The intended treatment population of patients with side branch vessels of 2.25 mm diameter or greater showed reductions in target vessel failure and side branch percent diameter stenosis with the Tryton stent. Both the Tryton and provisional treatment strategies were shown to have similarly low rates of stent thrombosis and no cardiac deaths reported at nine months. The Tryton Confirmatory Study, a single-arm study of the Tryton stent confirms the excellent results in significant bifurcations from the pivotal Tryton Randomized Clinical Trial.



1. Outcomes of a Dedicated Stent in Coronary Bifurcations with Large Side Branches: A Subanalysis of the Randomized TRYTON Bifurcation Study – CCI 2015, Génèreux et al. 2. RCT post-hoc intended cohort analysis (SB RVD 2.25mm QCA), Study was not designed to demonstrate statistical differences in secondary endpoints or endpoints in sub-populations. 3. Outcomes From the Tryton Confirmatory Study - JACC Interv. 2016 Génèreux et al.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. For healthcare professionals only. Prior to use, refer to the instruction for use supplied with this device for indications, contraindications, side effects, suggested procedure, warnings and precautions. **WARNINGS:** Use of the Tryton Side Branch Stent in appropriately sized main vessels and side branches is required for safe and effective performance of the device. Do not use the Tryton Stent in small side branches [$<$ 2.50 mm in diameter by visual assessment or $<$ 2.25 mm in diameter by quantitative coronary angiography (QCA)], as its use may lead to an increased risk of adverse cardiac events such as myocardial infarction and the need for repeat revascularization. To confirm appropriately-sized side branch diameters, the diameter of the pre-dilation balloon inflated to nominal pressure may be used as a reference. Alternatively, the use of quantitative imaging methods such as on-line quantitative coronary angiography, intravascular ultrasound or optimal coherence tomography should be considered. Use of the Tryton Side Branch Stent, as with percutaneous coronary stent implantation procedures in general, is known to be associated with the following risks: Vessel thrombosis. Increased length of hospital stay relative to those of coronary balloon angioplasty alone. Judicious selection of patients to receive this device rather than balloon angioplasty alone is strongly advised. Infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture. The stent may cause spasm, distal embolization, thrombus, or could migrate from the site of implantation. Excessive dilatation of the artery may cause vessel rupture and life-threatening bleeding. Stents may not be fully expanded during deployment, particularly in resistant lesions. Stent dislodgment from the balloon surface during deployment and/or dislodgment from the target site post-deployment can occur. Major bleeding.

Tryton is manufactured by Tryton Medical and distributed by Cordis.

Contact Information