TRYTON Side Branch Stent Built For Bifurcation

OVER 1800 PATIENTS IN 15 COUNTRIES AND 60 SITES¹.



¹Data on File With Tryton Medical Inc.

²RCT Dedicated Bifurcation Stent Vs. Provisional – Généreux, Et Al. JACC. 2015 ⁴RCT Post-Hoc intended Cohort analysis (SB RVD ≥2.25mm QCA); note that the RCT was not powered to show statistically significant differences in secondary endpoints or in primary endpoints in sub-populations

⁵Outcomes Tryton in Bifurcations Large Side Branches – RCT Subanalysis - Généreux Et Al - CCI 2016

⁶Device Success: Achievement of final in-stent residual stenosis <30% (by QCA) in SB using the assigned study device without malfunction

⁷Procedural Success: Achievement of a final in-stent diameter stenosis of <50% (by QCA) using the assigned device and with any adjunctive devices, without the occurrence of cardiac death, Q wave or non-Q wave MI, or repeat revascularization of the target lesion during the hospital stay

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.