

Tryton Side-Branch Stent

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Description

The Tryton Side-Branch Stent™ is a slotted tube balloon deployable stent with a modular design comprise of three zones: Distal (Side-Branch) Zone, Central (Transition) Zone and Proximal (Main Vessel) Zone (Figure 1). Tryton performs like a standard high-performance workhorse stent, i.e., balloon expandable, tracking over a single wire and axially oriented without the need for rotational orientation. The Tryton is simply tracked over a guidewire placed in the side-branch, such that the transition zone is at the side-branch origin. To insure precise delivery, the Tryton Side-Branch Stent is mounted on a balloon with four shaft markers, 2 standard proximal/distal stent markers, and 2 additional markers delineating the Transition Zone. The Tryton Stent is deployed after which the guidewire initially placed in the side-branch is repositioned into the distal main vessel. The Tryton stent is compatible with any standard workhorse stent

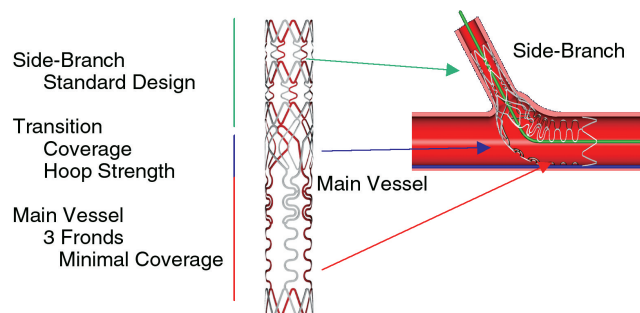


Figure 1. Schematic representing the Tryton Side-Branch Stent showing three zones: Distal (Side-Branch) Zone, Central (Transition) Zone and Proximal (Main Vessel) Zone. When positioned correctly within the vasculature the Side-Branch Zone resides in the side-branch, Transition Zone at the side-branch origin and the Main Vessel Zone in the main vessel proximal to the side-branch origin.

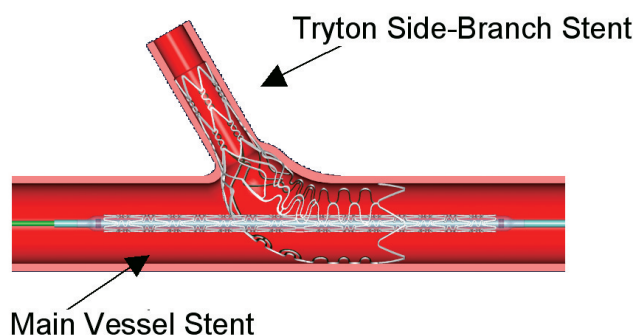


Figure 2. Schematic representing the spatial relationship between the Tryton Side-Branch Stent (deployed) with an undeployed main vessel stent. The distal end of the main vessel stent has been tracked through the proximal Main Vessel Zone of the Tryton Stent, between the specially designed fronds and into the distal main vessel.

(bare metal or DES), which is tracked into the Main Vessel Zone of the Tryton Stent and between specially designed fronds exiting into the distal main vessel stent (Figure 2). The main vessel stent is deployed after which a kissing balloon inflation is performed. Employing this strategy provides a means to definitively treat bifurcation lesions with similar coverage and hoop strength currently available with state of the art stents used in straight lesions (Figure 3).

History

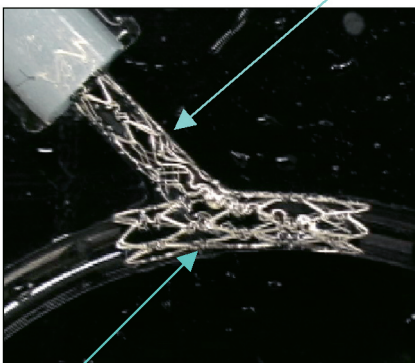
Tryton Medical, Inc. is a privately held company with offices in Newton, Massachusetts, USA founded to develop devices to treat bifurcation lesions within the coronary, cerebral and peripheral circulations.

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Tryton Side-Branch Stent



Main Vessel Stent

Figure 3. Photograph of a Tryton Side-Branch Stent deployed in a plexiglass model in combination with a Cypher Stent (Cordis/Johnson&Johnson, Miami, FL) using the protocol outlined within main text.

Technical specifications

Stent Characteristics

Deployment:	Balloon Expandable
Alloy:	Cobalt Chromium
Strut Thickness	0.003 inches
Angles:	All (15° to 90° leading angle)

Delivery System

Guide Compatibility:	5 French
Tracking:	Single Wire

Delivery Balloon:	Straight or Stepped
Marking System:	4 Balloon shaft markers

Stent Markers:
Shaft markers delineating the proximal & distal extent of the stent

Transition Zone Markers:
Shaft markers delineating the proximal and distal extent of the transition zone

Indications for use

The Tryton Side-Branch Stent is designed for the treatment of de novo bifurcation lesions with in the native coronary circulation. The Tryton Stent is used in conjunction with a standard balloon expandable coronary stent.

Tips and tricks for delivery (use)

The Tryton Side-Branch Stent is deployed according to the above protocol using standard techniques.

Clinical experience

Tryton First-In-Man Study, is a prospective single arm, multi-centre core lab study designed to evaluate the safety of the Tryton Side-Branch Stent.

Study P.I.:	Marie-Claude Morice
Angiographic Core Lab:	ICPS (Y. Louvard)
IVUS Core Lab:	CRF/Columbia (S. Carlier)
Clinical Sites:	Heart Center/Siegburg (E. Grube, P.I.) First Case: May 2006
	ICPS/Paris (M-C Morice, P.I.) First Case: Pending
	Thoraxcenter/Rotterdam (P.W. Serruys, P.I.) First Case: Pending