

# The Tryton Side Branch Stent

Maik J. Grundeken<sup>1</sup>, MD; Philippe Généreux<sup>2,3</sup>, MD; Joanna J. Wykrzykowska<sup>1</sup>, MD, PhD; Martin B. Leon<sup>2</sup>, MD; Patrick W. Serruys<sup>4\*</sup>, MD, PhD

1. Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands; 2. Columbia University Medical Center, New York Presbyterian Hospital/Cardiovascular Research Foundation, New York, NY, USA; 3. Hôpital du Sacré-Coeur de Montréal, Université de Montréal, Montréal, Québec, Canada; 4. International Centre for Circulatory Health, NHLI, Imperial College London, London, United Kingdom

The complete references and the accompanying supplementary data are published online at: [http://www.pcronline.com/eurointervention/V\\_issue/33](http://www.pcronline.com/eurointervention/V_issue/33)

## Device description

**Name and manufacturer:** The Tryton Side Branch Stent; Tryton Medical, Durham, NC, USA.

**Approval status:** CE mark in 2008 (including left main indication in 2014), not approved outside Europe, Russia and the Middle East.

**Platform:** Cobalt-chromium.

**Strut thickness:** 84 microns (0.0033”).

**Coating:** Not coated, available in bare metal only.

**Specific stent design:** The stent consists of three zones: 1) the distal side branch zone with conventional stent design; 2) the transition zone with three independently deformable panels providing ostial scaffolding and coverage; and 3) the proximal main branch zone with two “wedding bands” facilitating mounting of the stent on the delivery balloon and with three undulating fronds minimising the amount of metal (**Figure 1A**).

**Guiding:** 5 Fr or 6 Fr (depending on stent size).

**Classification according to MADS:** Inverted culotte in the “A (inverted)” category.

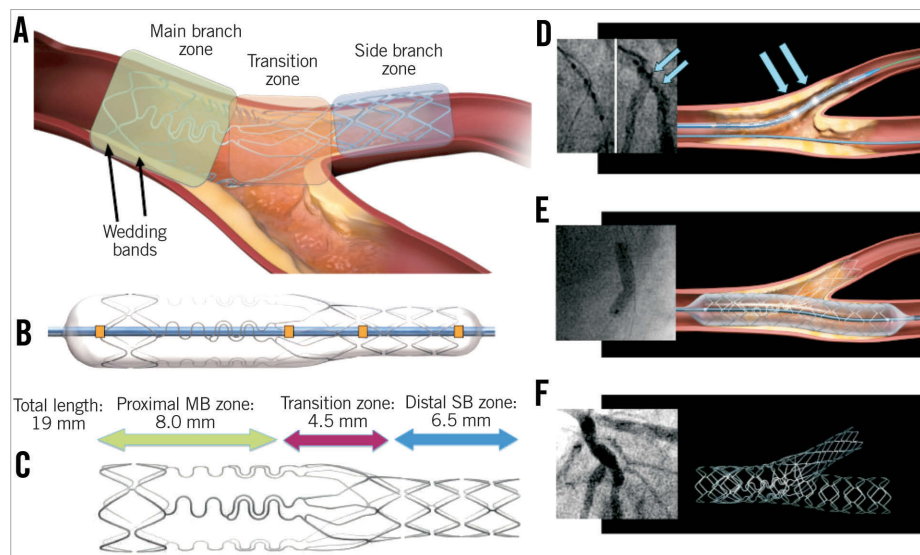
**Delivery system:** Single rapid exchange delivery system with four radiopaque markers to guide positioning. The stent is balloon-expandable and mounted either on a straight or on a stepped delivery balloon (**Figure 1B**).

**Stent sizes:** The straight version has a diameter of 2.5 mm. The stepped version has diameters ranging from 3.0-4.0 mm (proximal) and 2.5-3.5 mm (distal).

**Stent length:** The original Tryton is 19 mm (18 mm for larger-sized Tryton stents) and the more recent “Tryton short” is 15 mm (shortening the proximal main branch zone) (**Figure 1C**).

## Procedural details

After wiring both branches, predilatations of main and side branch are performed according to the operator’s preferences. Tryton positioning is performed using four radiopaque markers on the delivery system: two markers indicating the distal and proximal stent edges and two middle markers indicating the transition zone (orange squares, **Figure 1B**). The stent should be positioned in such a way



**Figure 1.** Tryton design and crucial procedural steps. Explanation of the panels can be found in the text.

\*Corresponding author: International Centre for Circulatory Health, NHLI, Imperial College London, London, SW7 2AZ, United Kingdom. E-mail: [patrick.w.j.c.serruys@gmail.com](mailto:patrick.w.j.c.serruys@gmail.com)

that the carina is positioned in-between the two middle markers (blue arrows, **Figure 1D**). After stent deployment, post-dilatation of the proximal main branch zone using the proximal optimisation technique (POT) is recommended to ensure adequate apposition of the wedding bands and the panels of the transition zone. Then, the side branch guidewire is retracted and advanced into the distal main branch. Dilatation of the main branch is performed, according to operator preference. After retracting the “trapped” main branch wire, a regular drug-eluting stent (DES), sized according to the distal main branch diameter as recommended by the European Bifurcation Club, is advanced and deployed in the main branch (**Figure 1E**). Finally, it is recommended to perform another POT before finalising the procedure with final kissing balloon dilatation using non-compliant balloons (**Figure 1F, Moving image 1, Moving image 2**).

## Clinical data

Multiple European registries, including the first-in-man study, consistently showed procedural success rates of 94-97.2% and encouraging clinical results<sup>1-6</sup>. Combined data from eight (published and unpublished) registries (n=925), pooled on a patient level, showed favourable outcomes at 1 year<sup>7</sup>. Target vessel failure (TVF) rate (composite of cardiac death, myocardial infarction [MI] and clinically indicated target vessel revascularisation [TVR]) was 6.5% at six months and 8.5% at nine months. One-year TVR rate was only 6.1%, and one-year stent thrombosis (ST) rate was low (0.5%)<sup>7</sup>.

Non-randomised intravascular imaging studies have shown less favourable healing patterns of the (bare metal Tryton-treated) side branch compared with the (DES-treated) main branch<sup>8-11</sup>. Although a single study suggested less favourable healing of the proximal main branch stent edge<sup>12</sup>, other studies have shown comparable healing between proximal and distal main branch, confirming that the Tryton with DES overlap does not negatively influence the healing of the proximal main branch<sup>8,10,11</sup>.

The Tryton stent was investigated further in the pivotal Tryton Investigational Device Exemption (IDE) randomised trial<sup>13</sup>. This was the first, and thus far only, randomised trial powered on clinical endpoints comparing a dedicated bifurcation stent with the provisional single-stent strategy. The primary non-inferiority endpoint of nine-month TVF, defined as the composite of cardiac death, target vessel MI and clinically driven TVR, was not met (17.4% in Tryton versus 12.8% in the provisional group,  $p_{\text{non-inferiority}}=0.42$ ), mainly due to a numerically higher rate of periprocedural MI (3x ULN of CK-MB) in the Tryton arm (13.6% versus 10.1%,  $p=0.19$ )<sup>13</sup>. The main secondary endpoint, powered for superiority, was percentage diameter stenosis (%DS) of the side branch, which was slightly lower in the Tryton group (31.6% vs. 38.6%,  $p=0.002$ ) when QCA was performed using the pre-specified per-protocol single-vessel QCA analysis. However, a *post hoc* QCA analysis using a bifurcation QCA algorithm did not show any difference between the two groups (34.8% vs. 32.0%,  $p=0.18$ )<sup>14</sup>. However, only ~40% met the inclusion criterion of side branch diameter >2.5 mm on visual estimate (~2.25 mm on QCA). It is

conceivable that only larger side branches will benefit from a two-stent approach and a *post hoc* analysis indeed suggested a beneficial effect of the Tryton stent over balloon angioplasty in patients with side branch diameters >2.5 mm. (TVF in Tryton 11.3% vs. provisional 15.6%,  $p=0.383$ ; Généreux, Washington, CRT 2014).

Data on the use of Tryton on left main bifurcation lesions are discussed elsewhere in this supplement<sup>15</sup>.

## Ongoing studies

Currently a single-arm registry is ongoing, representing an extension of the IDE trial, including 133 patients. The main inclusion criterion is side branch diameter >2.25 mm confirmed by QCA. The primary endpoint is the rate of periprocedural MI (3x ULN of CK-MB) which will be compared with a pre-specified performance goal of 17.9% (based on the periprocedural MI rate in the provisional group [11.9%] plus a non-inferiority margin of 6%).

The NORDIC V study is currently running to investigate the role of final kissing balloon dilatation (FKBD) in the Tryton strategy<sup>16</sup>. In this study, 150 patients will be randomised 1:1 between routine FKBD and a strategy in which FKBD is only performed when side branch %DS is >50% or TIMI flow <3. Patients will return for an angiographic follow-up with OCT at eight months.

An effort is currently being made to collect long-term clinical follow-up (five to seven years) of patients included in the previously published patient-level pooled analysis<sup>7</sup>.

## Unique features

- Only bifurcation stent specifically designed to facilitate an inverted culotte two-stent technique, offering potential advantages in scenarios where the side branch needs to be stented first.
- Special design with Tri-ZONE® Technology accommodating to a wide range of bifurcation anatomies and minimising the amount of metal in the main branch.
- Only device with a left main indication on its CE mark<sup>15</sup>.

## Potential improvements

Drug coating: currently only available as bare metal stent.

## Conflict of interest statement

P. Généreux received speaker fees from Abbott Vascular and consultancy fees from Cardiovascular Systems Inc. J. Wykrzykowska received speaker and consultancy fees from Abbott, Tryton Medical, Inc., and Stentys. M. Leon is on the scientific advisory boards of Abbott Vascular, Boston Scientific, and Medtronic; and is the principal investigator of the Tryton IDE trial. The other authors have no conflicts of interest to declare.

## References

The references can be found in the online version of the paper.

## Online data supplement

**Moving image 1.** Animation of the deployment sequence.

**Moving image 2.** Example of a Tryton case.

# Online data supplement

## References

1. Kaplan AV, Ramcharitar S, Louvard Y, Muller R, Davis HR, Morice MC, Serruys PW, Grube E. Tryton I, First-In-Man (FIM) Study: acute and 30 day outcome. A preliminary report. *EuroIntervention*. 2007;3:54-9.
2. Onuma Y, Muller R, Ramcharitar S, van Geuns RJ, Louvard Y, Morel MA, Morice MC, Davis R, Kaplan AV, Lefevre T, Grube E, Serruys PW. Tryton I, First-In-Man (FIM) study: six month clinical and angiographic outcome, analysis with new quantitative coronary angiography dedicated for bifurcation lesions. *EuroIntervention*. 2008;3:546-52.
3. Magro M, Wykrzykowska J, Serruys PW, Simsek C, Nauta S, Lesiak M, Stanislawska K, Onuma Y, Regar E, van Domburg RT, Grajek S, Geuns RJ. Six-month clinical follow-up of the Tryton side branch stent for the treatment of bifurcation lesions: a two center registry analysis. *Catheter Cardiovasc Interv*. 2011;77:798-806.
4. Grundeken MJ, Smits M, Harskamp RE, Damman P, Woudstra P, Hoorweg AJ, Baan J Jr, Arkenbout EK, Piek JJ, Vis MM, Henriques JP, Koch KT, Tijssen JG, de Winter RJ, Wykrzykowska JJ. Six-month clinical outcomes of the Tryton Side Branch Stent for the treatment of bifurcation lesions. *Neth Heart J*. 2012;20:439-46.
5. Agostoni P, Foley D, Lesiak M, Belkacemi A, Dens J, Kumsars I, Scott B, Oemrawsingh P, Dubois C, Garcia E, Lefevre T, Stella PR. A prospective multicentre registry, evaluating real-world usage of the Tryton side branch stent: results of the E-Tryton 150/ Benelux registry. *EuroIntervention*. 2012;7:1293-300.
6. Tarantini G, La Vecchia L, Galli M, Favero L, D'Amico G, Buja P, Russo F, Cabianca E, Napodano M, Musumeci G, Franceschini E, Grassi G, Pavei A, Bonmassari R, Cernetti C, Spedicato L, Caprioglio F, Reimers B, Isabella G. Clinical outcome of patients with de novo coronary bifurcation lesions treated with the Tryton Side Branch Stent. The SAFE-TRY prospective multicenter single arm study. *Int J Cardiol*. 2013;168:5323-8.
7. Grundeken MJ, Asgedom S, Damman P, Lesiak M, Norell MS, Garcia E, Bethencourt A, Woudstra P, Koch KT, Vis MM, Henriques JP, Onuma Y, Foley DP, Bartorelli AL, Stella PR, Tijssen JG, de Winter RJ, Wykrzykowska JJ. Six-month and one-year clinical outcomes after placement of a dedicated coronary bifurcation stent: a patient-level pooled analysis of eight registry studies. *EuroIntervention*. 2013;9:195-203.
8. Bartorelli AL, Trabattini D, Almonacid A, Fabbiochi F, Montorsi P, Galli S, Grancini L, Ravagnani P, Mintz GS, Kaplan AV, Popma JJ, Maehara A. Serial intravascular ultrasound analysis of complex bifurcation coronary lesions treated with the Tryton Bifurcation Stent in conjunction with an everolimus-eluting stent: IUVANT (Intravascular Ultrasound Evaluation of Tryton Stent) study. *Catheter Cardiovasc Interv*. 2015;85:544-53.
9. Ferrante G, Kaplan AV, Di Mario C. Assessment with optical coherence tomography of a new strategy for bifurcational lesion treatment: the Tryton Side-Branch Stent. *Catheter Cardiovasc Interv*. 2009;73:69-72.
10. Grundeken MJ, Garcia-Garcia HM, Kraak RP, Woudstra P, de Bruin DM, van Leeuwen TG, Koch KT, Tijssen JG, de Winter RJ, Wykrzykowska JJ. Side branch healing patterns of the Tryton dedicated bifurcation stent: a 1-year optical coherence tomography follow-up study. *Int J Cardiovasc Imaging*. 2014;30:1445-56.
11. Maehara A, van Geuns RJ, Louvard Y, Muller R, Grube E, Morice MC, Davis HR, Kaplan AV, Onuma Y, Serruys PW, Mintz GS. Serial intravascular ultrasound observations from the Tryton first-in-man study. *EuroIntervention*. 2014;10:475-83.
12. Dubois C, Adriaenssens T, Ughi G, Wiyono S, Bennett J, Coosemans M, Ferdinande B, Sinnaeve P, D'hooge J, Desmet W. Healing responses after bifurcation stenting with the dedicated TRYTON Side-Branch Stent in combination with XIENCE-V stents: a clinical, angiography, fractional flow reserve, and optical coherence tomography study: the PYTON (Prospective evaluation of the TRYTON Side-Branch Stent with an additional XIENCE-v everolimus-eluting stent in coronary bifurcation lesions) study. *Catheter Cardiovasc Interv*. 2013;81:E155-64.
13. Généreux P, Kumsars I, Lesiak M, Kini A, Fontos G, Slagboom T, Ungi I, Metzger C, Wykrzykowska JJ, Stella PR, Bartorelli AL, Fearon WF, Lefèvre T, Feldman RL, LaSalle L, Francese DP, Onuma Y, Grundeken MJ, Garcia-Garcia HM, Laak LL, Cutlip DE, Kaplan AV, Serruys PW, Leon MB. A randomized trial of a dedicated bifurcation stent versus provisional stenting in the treatment of coronary bifurcation lesions. *J Am Coll Cardiol*. 2015;65:533-43.
14. Grundeken MJ, Ishibashi Y, Généreux P, LaSalle L, Iqbal J, Wykrzykowska JJ, Morel MA, Tijssen JG, de Winter RJ, Girisic C, Garcia-Garcia HM, Onuma Y, Leon MB, Serruys PW. Inter-core lab variability in analyzing quantitative coronary angiography for bifurcation lesions: a post-hoc analysis of a randomized trial. *JACC Cardiovasc Interv*. 2015;8:305-14.
15. Grundeken MJ, Magro M, Gil R, Briguori C, Sardella G, Berland J, Wykrzykowska JJ, Serruys PW. Dedicated stents for distal left main stenting. *EuroIntervention*. 2015;11 Suppl V:V129-34.
16. Grundeken MJ, Lesiak M, Asgedom S, Garcia E, Bethencourt A, Norell MS, Damman P, Woudstra P, Koch KT, Vis MM, Henriques JP, Tijssen JG, Onuma Y, Foley DP, Bartorelli AL, Stella PR, de Winter RJ, Wykrzykowska JJ. Clinical outcomes after final kissing balloon inflation compared with no final kissing balloon inflation in bifurcation lesions treated with a dedicated coronary bifurcation stent. *Heart*. 2014;100:479-86.