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# The STENTYS® Self-Apposing Stent in bifurcation lesions

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*The authors have no conflict of interest to declare.*

## Introduction

Although there has been tremendous progress in our understanding of the complexity of bifurcations, the management of these lesions remains contentious[1]. A single stent strategy with provisional management of a "threatened" side branch either with ballooning or provisional stenting, followed by kissing balloon dilatation, remains the recommendation of the European Bifurcation Club[2]. This is not surprising as there is limited data available with dedicated bifurcation stents and the deployment of some of these devices can be technically challenging and requires a steep learning curve[3]. However, some of the best results in the treatment of bifurcation lesions have been obtained with self-expanding, drug-eluting stents,[4] and progress has been made so that the difficulty in achieving precise positioning is no longer their Achilles heel.

The STENTYS® stent (STENTYS SA, Paris, France) is a provisional, self-expanding nitinol stent (drug-eluting or bare metal) with small interconnections that can be disconnected by a balloon inflation between the struts to provide access to the side branch and, at the same time, cover the ostium[5] (Figure 1). It is designed to be effective in most commonly encountered bifurcation angulations regardless of the initial deployment position and with a learning curve comparable to current, cylindrical workhorse stent technology. The key advantage is the ability of the stent to conform to the anatomy of the bifurcation and to provide easy access to the side branch if necessary through its novel, disconnectable strut elements. The stent also offers the recommended provisional approach to bifurcation stenting in the choice between treatment strategies: i) main branch stenting only, ii) main branch stenting with disconnection or iii) main branch stenting with disconnection and T-stenting without a gap (Figure 2)

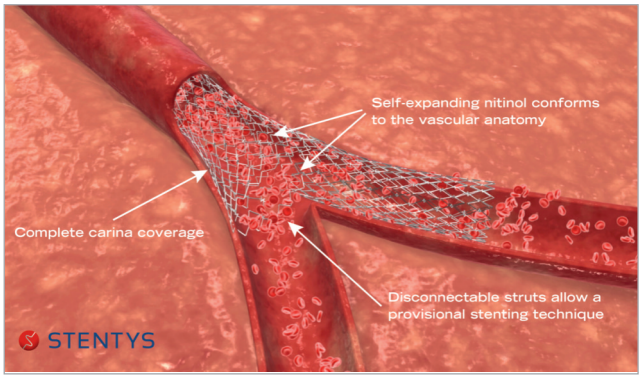


*Figure 1. Schematic diagram showing a provisionally opened STENTYS® Self-Apposing Stent Providing side branch access and full carina coverage.*

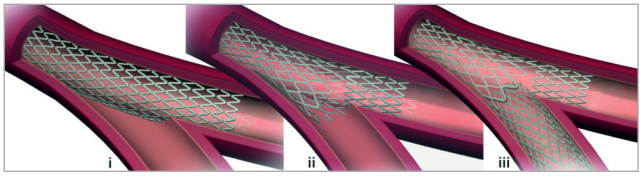


*Figure 2. Enhanced provisional technique; i) main branch stenting only; ii) main branch stenting + disconnection; iii) main branch stenting + disconnection + T-stenting without a gap.*

## Technical specifications

### The stent

The STENTYS® Self-Apposing Coronary Stent is designed to treat *de novo* coronary lesions that are in close proximity to a bifurcation with side branch angulations between 30° and 70°. The stent is

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available in three diameters (2.5-3.0 mm, 3.0-3.5 mm, and 3.5 mm-4.5 mm) and two lengths (22 mm and 27 mm) and can be used in the treatment of side branches as small as 2.25 mm. Manufactured from nitinol, a nickel-titanium alloy, the stent conforms to the shape of the artery and can expand to a maximum of 6.6 mm diameter at the carina (large size) (Figure 3). The unique Z-shape mesh cells are not welded together but are designed to allow for ease of disconnection. When fully expanded, the "step" height (strut and bridge) is about 1.2 mm in length. Although the strut width (68 µm) is narrower than most commercial stents, the stent's radial force is not compromised. In addition, the closed-cell design offers increased lesion coverage which may lessen or curtail the amount of distal thrombus embolisation during deployment.

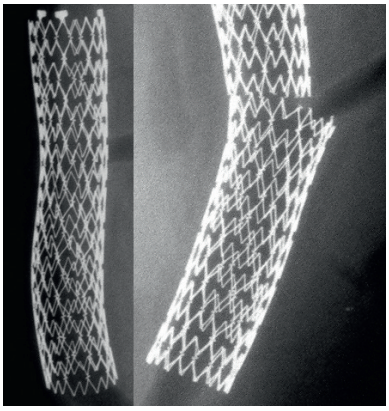

*Figure 3. Expandable nitinol: a nickel-titanium alloy showing conformability to the vessel anatomy and which allows the stent to expand to a maximum of 6.6 mm diameter at the carina (large size stent).*

The stent is available in two forms: bare metal and paclitaxel drug eluting (0.8 µg/mm$^2$ of stent) incorporated in a proprietary coating ProTeqtor®, a durable polymer matrix of polysulfone (PSU) and a soluble polyvinylpyrrolidone (PVP) that acts as an excipient. There are highly visible markers distally and proximally on the delivery system to facilitate accurate stent placement.

## The delivery system

A small, rapid-exchange delivery system allows the stent to be positioned and delivered in the main vessel by withdrawing a retractable sheath (Figure 4). The device is compatible with standard 6 Fr angioplasty guiding catheters and 0.014" guidewires. The same guidewire used in the main vessel can be used to cross the ostium if a provisional stenting strategy is required. There is a marker at the end of the sheath and at the stent stopper (located at the proximal edge of the stent) for accurate positioning and deployment. In addition, there is a distal marker on the outer sheath which moves proximally when the outer sheath is being retracted during stent deployment. Following deployment of the STENTYS® stent and disconnection at the side branch, any commercially available DES can be effectively deployed in the side branch to treat any residual disease without compromising the carina.

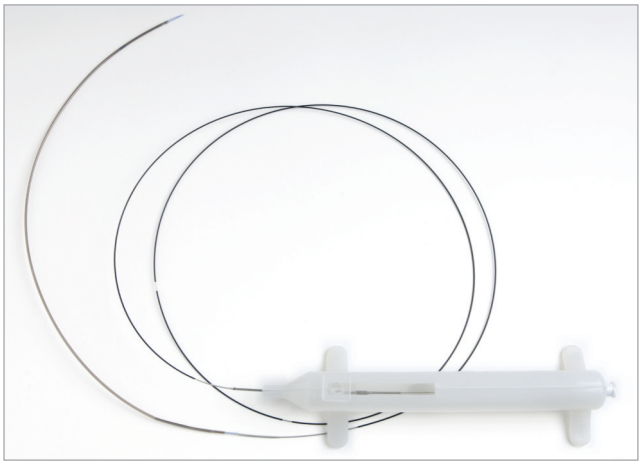

*Figure 4. A small 5 Fr rapid-exchange delivery system (6 Fr guide catheter compatible) allows the stent to be positioned and delivered in the main vessel by withdrawing a retractable sheath.*

## A brief summary of bench testing, animal and clinical data

Animal studies were performed in porcine coronary (n=13) and renal arteries (n=8)[5]. The average main branch (MB) diameter was 3.7 mm (2.5-5.5 mm) and the average side branch (SB) diameter was 2.2 mm (1.5-3.1 mm). Intravascular ultrasound (IVUS) confirmed optimal apposition of the stent in the main vessel and the side branch. Finite element analysis (FEA) imaging in a bifurcation model after stent deployment and disconnection confirmed that the disconnectors were not load-bearing elements and thus did not impact on the radial force of the stent, and that the stent exhibited acceptable mechanical strains (Figure 5).

Scanning electron microscope (SEM) demonstrated clean separation of the connector using a PTCA balloon inflated at low pressures in between the stent struts (Figure 6).

## Six month outcome analysis of the OPEN I study

This was a multicentre, prospective, non-randomised safety and feasibility study involving 63 patients[6]; 30-day results of the first 40 patients were previously reported[7]. Procedural success was

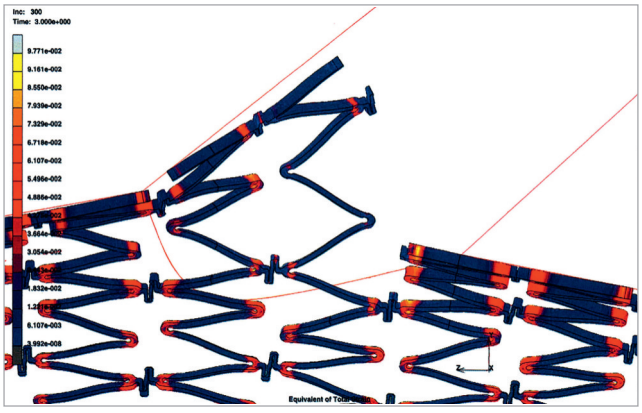

*Figure 5. Finite element analysis (FEA) image in a bifurcation model demonstrating that the disconnectors are not load-bearing elements and thus a disconnection does not affect the radial force of the stent.*

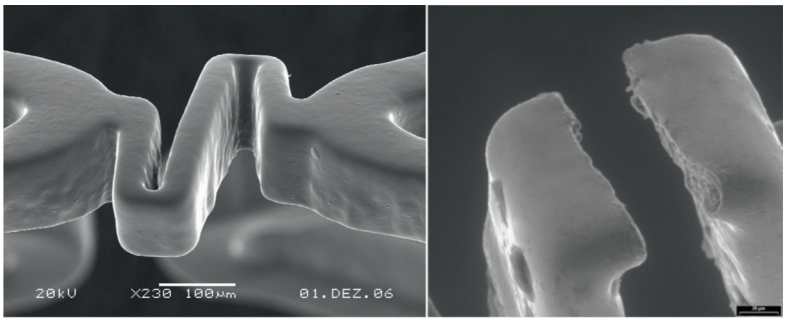


*Figure 6. Scanning electron microscope (SEM) image showing cleanly separated struts.*

achieved in 60/63 cases (95.2%). Disconnection of the stent mesh overlaying the SB ostium was achieved in 54/60 cases (90%); in some cases, disconnection was not attempted as the stents were placed too distally to allow for disconnection of the stent.

Following STENTYS® stent deployment in the MB, it was deemed necessary to stent the SB in five DES patients (19%) and 13 BMS cases (39%). Provisional stenting of the SB was performed in five (18.5%) DES and 13 (39%) BMS cases.

The cumulative MACE at six months is given in Table 1. The MACE rates were 3.7% and 27.3% for DES and BMS, respectively.

**Table 1. Cumulative MACE at six months in both BMS and DES groups.**

| | DES=27 n (%) | BMS=33 n (%) |
|---|---|---|
| Cardiac death | 0 | 0 |
| Q- wave MI | 0 | 0 |
| Non-Q-wave MI | 0 | 1 |
| Clinically driven TLR | 1 (3.7) | 8 (24.2) |
| Total MACE | 1 (3.7) | 9 (27.3) |

QCA results are summarised in Table 2. The LLL (mm) in the proximal and distal MB for BMS patients were notably higher than that observed in the DES group: in the proximal MB, 0.83 mm in BMS vs. 0.39 mm in DES; and in the distal MB, 0.85 mm in BMS vs. 0.40 mm in DES, comparable to LLL traditionally observed with other BMS[7] and paclitaxel-eluting stents. In the DES group, when taking into account both clinically and non-clinically driven TLR, only one in-segment restenosis (4%) was observed in the MB, which was proximal to the stent. In the BMS group, in-segment restenosis was observed in four (13%) patients proximal to the MB stent, and seven patients (23%) distal to the MB stent.

**Table 2. Summary of QCA data.**

| DES | RVD (mm) | LLL at 6 months (mm) |
|---|---|---|
| PMB | 2.89 | 0.39 |
| SD | 0.61 | 0.62 |
| DMB | 2.27 | 0.40 |
| SD | 0.39 | 0.50 |
| **BMS** | **RVD (mm)** | **LLL at 6 months (mm)** |
| PMB | 2.69 | 0.83 |
| SD | 0.50 | 0.65 |
| DMB | 2.40 | 0.85 |
| SD | 0.39 | 0.63 |

Fewer cases of in-segment restenosis were noted when the SB was stented. No in-segment restenosis in the SB was reported in the DES group when the SB was stented (0/5) compared with a restenosis rate of 4/21 (19%) in side branches which were not stented. In the BMS group, only 1/13 (8%) SB stents had restenosis as compared to 4/20 (20%) cases when the side branch was not stented. For all patients, when a SB stent was placed, the restenosis rate in the SB was 6%; when no SB stent was placed, the restenosis rate was 20% (Table 3).

**Table 3. Restenosis results in the side branch.**

| | DES (n=26) | BMS (n=33) |
|---|---|---|
| SB stent | 5 | 13 |
| Restenosis | 0 (0%) | 1 (8%) |
| Without SB stent | 21 | 20 |
| Restenosis | 4 (19%) | 4 (20%) |

This FIM study on the STENTYS® stent demonstrates that the device is safe and feasible, resulting in an excellent procedural success of 95.2%. There was a relatively low MACE in the DES version that also had a competitively low LLL in both the MB and the SB at six months. The precision-engineered disconnectable struts offered excellent "cross over" results for T-stenting and the increased gains in stent area over time are in line with the properties of a self-expanding stent that can limit the occurrence of late stent malapposition and so may potentially decrease stent thrombosis.

## A personal perspective of this device / why I like this device

This device is appealing to interventional cardiologists for several reasons. Most importantly, the expandable nature of nitinol enables the stent to easily adapt itself and conform to the various coronary architectures and the differing proximal and distal sizes often found in a bifurcation setting. This results in good apposition of the stent to the vessel wall and effective drug delivery. Good apposition of the STENTYS® stent was confirmed by the results of the APPOSITION II randomised trial; the stent showed a 10-fold reduction in stent strut malapposition compared to standard balloon-expandable stents[8]. The stent has also been shown to have a relatively low thrombotic profile which is desirable in patients with unstable angina. In addition, the simple, single, tubular stent design enables a provisional approach and is thus more similar to familiar workhorse stents than traditional dedicated bifurcation stents, and therefore

reduces the learning curve for the operator. In bifurcations, it is important that the operator is able to adapt to the procedural and anatomical needs that arise after stent implantation, with particular emphasis on preserving flow into the side branch. As such, this stent is ideally suited for such procedural needs, as due to its provisional approach, the operator can use the same wire to deploy the stent in the main branch and to subsequently gain access to the side branch. The disconnectable struts are located throughout the main body of the stent providing customised access to the side branch, and avoiding the need for cumbersome positioning around the carina prior to stent deployment thus ensuring the lesion is adequately covered. Moreover, the expansive property of the stent allows for full carinal coverage and the landing zone which covers the ostium of the side branch enables the implantation of a standard workhorse stent, if required, without a gap and with minimal overlap. Six month follow-up shows a competitive late luminal loss with the drug eluting version. The study also showed that other stents could be easily tracked through the stent once deployed to treat residual or tandem lesions.

In summary, this stent is desirable because its design is simple enough not to compromise the patient's safety and yet, at the same time, it can be easily adapted to treat the bifurcation and the side branch should the need arise.

## References

1. Hildick-Smith D, de Belder AJ, Cooter N, Curzen NP, Clayton TC, Oldroyd KG, Bennett L, Holmberg S, Cotton JM, Glennon PE, Thomas MR, Maccarthy PA, Baumbach A, Mulvihill NT, Henderson RA, Redwood SR, Starkey IR, Stables RH. Randomized trial of simple versus complex drug-eluting stenting for bifurcation lesions: the British Bifurcation Coronary Study: old, new, and evolving strategies. *Circulation*. 2010;121:1235-43. Epub 2010 Mar 1.

2. Hildick-Smith D, Lassen JF, Albiero R, Lefevre T, Darremont O, Pan M, Ferenc M, Stankovic G, Louvard Y; European Bifurcation Club. Consensus from the 5th European Bifurcation Club meeting *EuroIntervention*. 2010;6:34-8.

3. Rizik DG, Klassen KJ. Dedicated bifurcation devices. *Rev Cardiovasc Med*. 2010;11:S27-37

4. Doi H, Maehara A, Mintz GS, Dani L, Leon MB, Grube E. Serial intravascular ultrasound analysis of bifurcation lesions treated using the novel self-expanding sideguard side branch stent., *Am J Cardiol*. 2009;104:1216-21.

5. Laborde JC, Borenstein N, Behr L, Ramcharitar S. STENTYS coronary bifurcation stent. *EuroIntervention*. 2007;3:162-5.

6. Verheye S, Grube E, Ramcharitar S, Schofer JJ, Witzenbichler B, Kovac J, Hauptmann KE, Agostoni P, Wiemer M, Lefèvre T, Spaargaren R, Serruys PW, van Geuns RJ. Six month clinical and angiographic results of the STENTYS® dedicated coronary bifurcation stent with disconnectable struts. Submitted for publication *EuroIntervention* 2010.

7. Verheye S, Grube E, Ramcharitar S, Schofer JJ, Witzenbichler B, Kovac J, Hauptmann KE, Agostoni P, Wiemer M, Lefèvre T, Serruys PW, van Geuns RJ. First-in-man (FIM) study of the STENTYS bifurcation stent--30 days results. *EuroIntervention*. 2009;4:566-71.

8. van Geuns RJ, APPOSITION II Trans catheter and Therapeutics (TCT), Washington DC 29 Sep 2010.