EuroIntervention

The Cappella Sideguard™ stent

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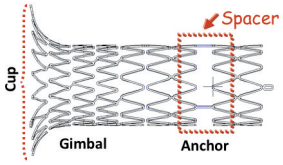
Introduction

The Cappella Sideguard™ (Cappella Medical Devices Ltd, Galway, Ireland) stent is one of three dedicated bifurcation stents designed specifically to treat the side branch (SB). The other two SB stents include the Tryton™ (Tryton Medical, Durham, NC, USA) and Biguard™ (Lepu Medical Technology Ltd., Beijing, China) stents.[1,2] These SB stents are designed to treat the SB first and thus commit the operator to stenting both branches of the bifurcation. They also require re-crossing into the SB after main branch (MB) stenting for final kissing inflation. The Tryton™ and Biguard™ stents facilitate the culotte technique, while the Sideguard™ facilitates T-stenting.

Device description

The Cappella Sideguard™ coronary SB stent (Figure 1) is a self-expanding trumpet shaped nitinol stent with a 3-segment design (cup, transition zone and anchor) that is deployed using a special balloon release sheath system. It is currently a bare-metal stent with a 64 µm strut thickness.[1,2] The Sideguard's™ trumpet shaped design and the memory properties of nitinol promote self-expansion and conformity to the anatomy and shape of the ostium and vessel wall upon deployment. These properties allow for complete wall apposition around the ostium, thus optimising scaffolding with minimum stress or shape deformation applied to the ostium in bifurcated lesions.[3,4] The Sideguard™ secures the SB for easy access after MB stenting, preventing closure of the SB from plaque or carina shaft and facilitating re-crossing into the SB for final kissing inflation. Post-procedurally, the nitinol will continue to apply pressure to the vessel wall producing positive remodelling.

The Sideguard™ is available in three sizes based on the diameter of the SB being treated: 2.5 for SB of 2.25-2.5 mm, 2.75 for SB of 2.50-2.75 mm, and 3.25 for SB of 2.75-3.25 mm. It is currently available only as a 10 mm long stent recommended for lesion lengths ≤7 mm but longer stents will be available in the future. Its short length, self-expandable nitinol system, low-profile (3.1 Fr) delivery system allows greater navigability even in very tortuous anatomy. Sideguard™ is ideal for bifurcation angles from 45°-135° prior to wiring. Radiopaque markers located at the distal and proximal ends of the Sideguard™ delivery system facilitate positioning of the stent at the SB ostium. Post-implantation, three radiopaque proximal and two distal markers are visible on fluoroscopy. If correctly implanted, the three proximal markers should be positioned at the ostium with a wide separation between the markers being very suggestive of optimal placement and scaffolding of the ostium. The proximal markers also aid accurate positioning of the stent at the SB ostium. One of the challenges of this device has been in its accurate placement at the SB ostium. Indeed given the design of the Sideguard™, it is essential that it be



Cup
- Excellent ostial coverage & protection
- Lowest radial force (easy to cross)

Gimbal
- Cylindrical portion with higher radial force (550 mmHg) to dilate ostial lesions
- Provides expanding force to open the side branch
- Transition zone between cup and anchor

Anchor
- Cylindrical portion with lower radial force (225 mmHg); 2 markers
- "Spacer" improves anchoring, keeping stent from migrating
- Enhances crossing flexibility

Figure 1. Design characteristics of the self-expanding Sideguard™ coronary side branch stent.

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accurately placed at the ostium for the device to be beneficial and optimally scaffold the ostium. Thus, the device has been perceived as having limited placement tolerance and has been one of the commonest criticisms about the stent. Thus, in order to facilitate and ease device positioning, the newest generation device has been designed with two proximal markers which are 2 mm apart (Figure 2). The most proximal marker is still to be placed at the ostium border line. The new second reference marker is 2 mm from the ostial marker and can be used as a reference to visualise the position of the SB under angiography and minimise foreshortening. Thus, the angiographic view which bests demonstrates the SB ostium and produces the least amount of foreshortening between the two markers would be the optimal angiographic view for Sideguard™ placement. The delivery system is composed of an exterior sheath that retains the device and an interior tube that supports the device and eliminates device movement during the deployment. The stent is deployed using a nominal pressure balloon, which splits the protective sheath thus releasing the Sideguard™ stent and allowing for precise deployment of the stent. Once released, the Sideguard™ gently self-expands into place in and around the ostial area of the vessel ensuring complete wall apposition around the ostium with minimum stress or shape deformation applied to the ostium. A conventional drug-eluting stent is then placed in the MB, the SB is re-accessed with a guidewire and the procedure is completed with a standard final kissing inflation.

The possible limitations of the Sideguard™ stent are that it requires accurate placement for an optimal result, it is not suitable for Y-shaped bifurcation lesions with an angle of <30-40, and it treats only the ostial lesion while more distal lesions will require another stent. The fact that the Sideguard™ is a bare-metal stent may be considered a limitation but the short length of the stent and continued positive remodelling provided by the self-expanding properties may be sufficient to compensate for this factor.

Sideguard™ procedure technique description

(Figure 3)

a) Wire both branches

b) Pre-dilate both branches, especially SB preferably with non-compliant balloons. Predilatation and adequate lesion preparation of the SB is crucial prior to Sideguard™ deployment

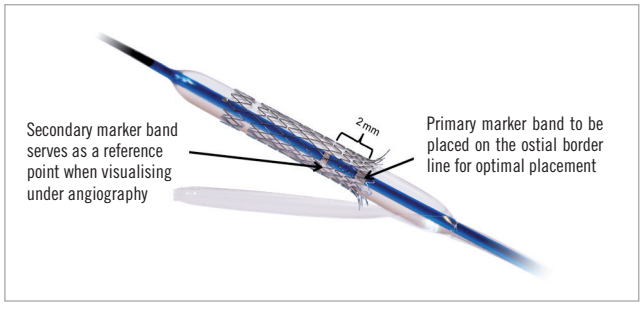

Figure 2. The delivery system has the lowest profile of any of the self-expanding stents and unlike other self-expanding stents has a unique balloon actuated splitable sheath that allows for accurate placement. The 3rd generation device has two proximal markers that facilitate accurate placement and help to reduce foreshortening.

c) Sideguard™ is advanced into the SB and positioned with proximal marker at ostium border line which is verified in at least two projections. A balloon is advanced in the MB over the bifurcation.

d) Sideguard™ in SB is deployed, the delivery system removed, an angiogram is performed, and if the result is adequate the wire is also removed.

e) MB balloon is then inflated (to ensure that if Sideguard™ inadvertently placed too proximally with struts protruding into MB, these struts will not obstruct MB stent placement) and removed.

f) A conventional drug-eluting stent is advanced in the MB and deployed.

g) The SB is re-wired and the procedure is completed with a gentle (<8 atm in SB) final kissing balloon inflation.

Clinical data

The 6-month results of the first 20 patients enrolled in the Sideguard™ first-in-human trial (SG-1) were first presented at TCT 2007.[5] Technical success was achieved in 16 (80%) patients. At 6-months, the target lesion revascularisation (TLR) rate was 12.5% (2/16) and there were no cases of stent thrombosis.[5] A second multicentre non-randomised trial was then performed with the next generation Sideguard™ device (SG-2). The 2nd generation Sideguard™ device had undergone minor changes to the stent delivery system and a major change to the stent design. The stent has a mixed open and closed cell design with a new mid-distal open cell that acts as a built-in anchoring system preventing the Sideguard™ from migrating following deployment. The technical success overall in the 93 patients enrolled in the Sideguard™ first-in-human (FIH) trials was 86%, however with design changes mentioned above, the device success increased to 97%. Results from the combined SG-1 and SG-2 FIH trials showed a major adverse cardiac event (MACE) rate of 4.8% at 30-day and 10.8% at 6-month.[6,1,4] Recently, the 12-month results became available demonstrating a MACE rate of 12%, accounted for predominantly by a target lesion revascularisation (TLR) of 9.6% (Table 1). However, if specifically looking at the SB, the TLR rate for the Sideguard™ stent was 4.8%. An interesting intravascular ultrasound (IVUS) sub-study performed on 11 patients suggests that further stent expansion occurs at the carina preserving ostial lumen dimensions.[7] The SB stent area (at the carina) increased from 3.9±1.2 to 4.6±1.1 mm^2 (p=0.04) resulting in no change in lumen area (3.9±1.3 vs. 4.0±1.3 mm^2, p=0.77) despite an intimal hyperplasia area of 0.6±0.7 mm^2. This data suggest that chronic stent expansion due to the self-expanding nitinol properties of the Sideguard™ may be sufficient to compensate for the late loss that occur with this bare-metal stent. The 3rd generation Sideguard™ stent with two proximal markers is currently undergoing evaluation in a multicentre European registry, with the objective of evaluating the efficacy and safety of this dedicated SB stent in a real world all-comer population.

Personal perspective

The Sideguard™ stent is ideal for SB protection in situations where the SB has modest or severe disease confined to the ostium or proximal 3-5 mm of the SB. It has become apparent from the

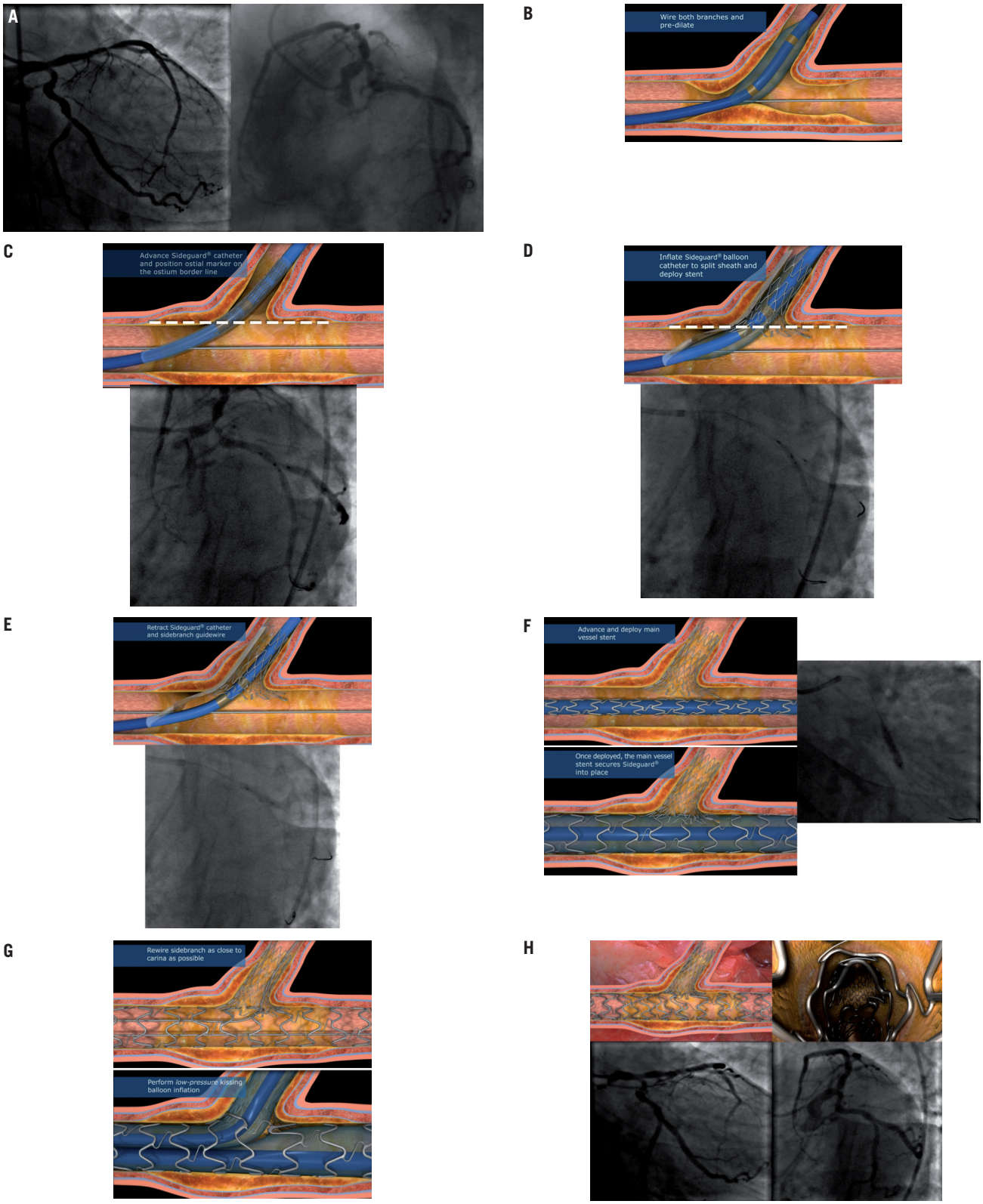

Figure 3. Step-by-step example of a Sideguard™ procedure. Baseline angiography showing a true bifurcation lesion of the circumflex artery and large obtuse marginal branch (Panels A). Both branches of the bifurcation were wired and pre-dilated (Panels B). The Sideguard™ stent was then advanced into the SB (Panel C) and a semi-compliant balloon into the MB to the level of the bifurcation. The Sideguard™ is then positioned with the proximal ostial marker on the ostium border line. The Sideguard™ catheter is then inflated to split the sheath and deploy the stent (Panel D). After waiting a few seconds for the Sideguard™ to fully expand, the delivery system and guidewire are removed from the SB and the MB balloon is then inflated to ensure that are no struts are protruding into the MB lumen (Panel E). A drug-eluting stent is then implanted on the MB across the ostium of the SB (Panel F); the SB is re-crossed with a guidewire; and final kissing inflation is performed (Panel G). Panel H demonstrates the final result graphically and angiographically.

Table 1. Clinical outcomes at 12-months of the Sideguard-1 and Sideguard-2 studies.

Major adverse cardiac event (MACE)	Sideguard' implants (N=83)
Up to 30 days	4.8% (4/83)
Up to 6-months	10.8% (9/83)
Up to 12-months	12% (10/83)
MACE at 12 months	
Cardiac death	1.2% (1/83)
Myocardial infarction	3.6% (3/83)
Target lesion revascularisation	9.6% (8/83)*
Other revascularisations at 12 months	
Ischaemia-driven target vessel revascularisation	3.6% (3/83)

Angiographic follow-up	Main vessel (N=73)	Side branch (N=73)
Late loss	0.21	0.58
% Diameter stenosis	12%	25%

Note: Unpublished data provided by Cappella Inc; *Includes two in hospital thrombosis events

recent publication of the BBC-ONE (British Bifurcation Coronary study: Old, New, and Evolving strategies) study that elective double stenting bifurcation with techniques such as the culotte and crush is not easily performed by all operators; and in inexpert hands may be associated with higher rates of periprocedural myocardial infarction, longer procedures, and higher X-ray doses.[8] Thus, we believe that SB protection with the Sideguard™ could facilitate and make the procedure more predictable and safe. Indeed, in the procedures we have performed with this device, we have never had acute closure of the SB, re-crossing into the SB after MB stenting has been easy with the use of a conventional floppy guidewire, and we have always been able to perform final kissing inflation. The self-expanding nature of the device, conformity to the anatomy and motion of the ostium, and continued positive remodelling are features that we find unique to the Sideguard™. We also believe that previous concerns about difficulty in placement are overcome after implantation of a few devices and with the development of the double proximal marker device. The availability of larger and longer sizes should also make the device applicable to a greater variety of lesions in the future. However, as with majority of the dedicated bifurcation stents, there is an as yet unmet need for published long-term clinical data on these devices.

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