Bifurcation coronary lesions account for 15–20% of all percutaneous coronary intervention (PCI) procedures and are often technically challenging with both lower procedural success rates and higher adverse event rates than those observed in non-bifurcation lesions. Conventional techniques used to treat bifurcation lesions, including provisional stenting and various two-stent approaches, have several shortcomings. Dedicated bifurcation stents such as the Cappella Sideguard® have been developed to overcome the problems associated with the current available techniques. This review focuses on the utility of the nitinol Sideguard stent in the treatment of bifurcation lesions and discusses the benefits of its trumpet-shaped design, self-expanding properties and low-profile delivery system. Treatment of bifurcation lesions using the Sideguard stent is straightforward and not subject to some of the limitations associated with conventional PCI techniques. Several trials are currently on the way to assess the safety and clinical efficacy of this very promising stent platform.

**Keywords**
Bifurcation coronary lesions, percutaneous coronary intervention, stenting, Cappella Sideguard, nitinol Sideguard stent, low-profile delivery system

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designed to satisfy the need for a dedicated SB device. The Cappella Sideguard stent was developed to overcome the limitations of both provisional and two-stent strategies, including the Cappella Sideguard® (Cappella Medical Ltd., Galway, Ireland). To date, the lack of head-to-head studies comparing a dedicated SB device with the provisional technique has hampered the ability of interventionalists to determine the optimal treatment strategy for bifurcation lesions. The Cappella Sideguard stent was designed to satisfy the need for a dedicated SB device.

Irrespective of the bifurcation stent strategy undertaken, there are a number of limitations common to all current techniques. These limitations include maintaining access to the SB throughout the procedure; jailing of the SB ostium by the MB stent struts, resulting in difficulty in either rewiring the SB or passing a balloon or stent into the SB; and inability to fully protect and scaffold the ostium of the SB. In the two-stent arm of the BBC-1 study, for example, there was a 15% failure rate in kissing balloons either due to failure to rewire the vessel or balloon delivery.3 Similarly, in the Nordic Bifurcation Study, a final kissing balloon (FKB) following a two-stent strategy was only performed in 74% of cases, despite its importance. The recent Nordic III study found that, while FKB did not impact clinical outcome, it was associated with a significant reduction of angiographic restenosis rates in the SB in true bifurcation lesions (7.9% for FKB versus 20% for non-FKB).8

Even drug-eluting stents (DES) appear to be less effective at reducing restenosis rates in the SB. High restenosis rates have been reported in Nordic-1, CACTUS and BBC-1 despite the use of DES. The higher restenosis rates may be due in part to decreased ostial coverage, which prohibits the antiproliferative drug coating from reaching the ostial wall.4 They may also be caused by significant coating damage on the ostial struts crossing into the MB, which occurs during the FKB pre-dilation.

To address shortcomings of both provisional and two-stent strategies, a number of dedicated bifurcation stents have been developed, including the Cappella Sideguard® (Cappella Medical Ltd., Galway, Ireland). To date, the lack of head-to-head studies comparing a dedicated SB device with the provisional technique has hampered the ability of interventionalists to determine the optimal treatment strategy for bifurcation lesions. The Cappella Sideguard stent was designed to satisfy the need for a dedicated SB device.

Technology Overview

The Sideguard is not a conventional stent platform. Instead, it represents a new approach to the treatment of bifurcation disease. The Sideguard stent is a Conformité Européenne-approved, self-expanding nitinol stent that flares proximally at the ostium of the SB into a trumpet shape (see Figure 1). Unlike conventional metal stents, the nitinol stent conforms to the shape of the lumen and produces positive remodelling.6 Self-expansion allows full apposition to the vessel wall and further luminal expansion, affording more room should intimal proliferation occur, without causing significant luminal narrowing and restenosis.

The Sideguard technology is comprised of two components: the implantable coronary sidebranch stent and a low-profile delivery system (3.2Fr). The thin-strut nitinol stent has a distal section that functions to anchor the device in the SB, while the proximal flared section achieves full ostial coverage. The stent is available in three diameters: Sideguard 2.5 for vessels between 2.25mm and 2.5mm; Sideguard 2.75 for vessels between 2.5mm and 2.75mm; and Sideguard 3.25 for vessels between 2.75mm and 3.25mm. Currently, the only length available is 10mm, for lesions of 7mm or less in length, but longer versions are expected in the future.

Unlike previous self-expanding stents, which were constrained on a catheter with a deployment sheath and ultimately delivered to the vessel upon retraction of the sheath,5 the Sideguard is delivered over a single, standard, rapid-exchange catheter identical to the standard technique for stent delivery. The stent is released when the protective sheath that keeps the Sideguard in place is split upon inflation of the balloon (see Figure 2). Once released, the Sideguard expands into place. The delivery system and the guidewire can then be removed from the SB and further stents can be delivered in the SB distal to the sideguard stent if required. If the main vessel is also to be treated, a conventional stent can be deployed as per usual practice. With this approach, Sideguard allows relatively easy treatment of SB lesions that would likely be ignored under provisional stenting.

Sideguard Placement Techniques

Before placement, both the MB and SB are wired and pre-dilated with non-compliant balloons. This pre-dilation step is crucial to proper placement. Next, the Sideguard is advanced into the SB and positioned under fluoroscopy. To help with correct placement, two proximal markers have been added to the third-generation delivery system that help the operator visualise position. When correctly placed, the most proximal of these two markers should be at the ostium border line, with the second marker 2mm from the ostial marker (see Figure 3). Placement should be verified by two projections.

After the Sideguard is advanced into position, it is then released by inflating the balloon to 12 BAR, which splits the sheath, thus releasing the stent (see Figure 4). The stent is then expanded. Once the correct placement is confirmed under angiogram, the wire is removed. The Sideguard has been designed so that the struts should not conflict with proper placement of the MB stent. A conventional stent of choice can now be deployed in the MB (see Figure 5). Finally, the MB and SB are rewired for the final kissing inflation.

Clinical Status

There are two possible primary causes of the high restenosis rates observed in the provisional T-stent technique and the two-stent
bifurcational strategy: stent underexpansion and inadequate SB stent coverage. Early data indicate that the Sideguard addresses both of these concerns. The self-expanding and positive remodelling properties of the Sideguard address the issue of stent underexpansion, and the trumpet-shaped design offers full coverage, thus protecting the ostial and SB anatomy. Doi et al. recently reported serial intravascular ultrasound (IVUS) examination (baseline and six-month follow-up) in 11 patients treated with Sideguard stents as part of the Sideguard I first-in-man study. In this series, the authors did not report any significant restenosis at six months, despite significant intimal hyperplasia due to the self-expansion of the nitinol stent. It was observed that the self-expansion properties of the nitinol stent resulted in significant increases in stent coverage at the SB carina, thereby compensating for any intimal hyperplasia observed over the six-month time period and no net change in luminal area.

The first-generation Sideguard clinical results were released at Transcatheter Cardiovascular Therapies (TCT) 2007, when results from 20 patients treated with Sideguard were published. The technical success rate of this first-in-human trial was 80%, with a revascularisation rate of 12.5% at six months. There were no cases of stent thrombosis. After this trial, the second-generation Sideguard was introduced, including the anchoring system that helped ensure more accurate placement and a more flexible, lower-profile sheath. The second generation represented a leap forward in clinical outcomes: with MACE rates of 12% at 12 months, as well as SB revascularisation rates of <5% and an M8 revascularisation rate of <2%. Two cases of thrombosis were observed, one peri-procedurally and a second in-hospital procedure-related event. In the Sideguard II trial, a high technical success rate was achieved in 94% (31/33) of the final cohort. Cappella is currently engaged in a large-scale registry (more than 250 patients) in Europe. This real-world study includes the latest-generation dual-marker system and should confirm the ease of use and hopes to confirm low TVF. This trial is under way and expected completion is mid 2011.

In summary, the Sideguard has been designed to confront the challenges unique to bifurcation disease that have hampered existing provisional and two-stent strategies. Studies have shown that restenosis rates remain significant with both provisional and two-stent techniques. The Sideguard represents a straightforward approach to the treatment of bifurcation lesions and minimises technical limitations associated with conventional PCI treatment methods. An ongoing registry and planned randomised study aim to further evaluate the clinical efficacy and safety of this stent platform.

**Figure 3: Sideguard Radiopaque Markers Assist with Placement Along the Ostial Border Line and Proper Visualisation Within the Side Branch Anatomy**

**Figure 4: Sideguard Balloon Inflates to Split Sheath and Release Stent**

**Figure 5: Sideguard’s Trumpet Shape Protects the Side Branch Ostium and Allows for Placement of any Main Branch Stent**