Dedicated Bifurcation Devices

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Coronary bifurcation lesions are a common challenge for interventional cardiologists, for which there is no clear consensus on optimal treatment. The side branch (SB) ostium has become the focus of new treatment strategies because it is a common site of restenosis. In comparison, restenosis and reintervention rates in the main branch are acceptably low, reflecting improved techniques and greater use of drug-eluting stents. Many different companies are evaluating dedicated bifurcation devices that are designed to offer easy access to the SB, but that differ in concept and in the degree of coverage provided to the SB ostium. Some are bare metal stents, whereas several are drug-eluting iterations based on platforms used in conventional stents. The promise of these dedicated bifurcation devices is illustrated by early results from single-arm clinical studies.

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Coronary bifurcation lesions, seen in approximately 10% to 15% of diagnostic catheterizations, remain a challenging lesion subset for percutaneous intervention.[1,2] Aside from the severity and distribution of atherosclerotic disease in the main branch (MB) and side branch (SB), several other factors contribute to the heterogeneity of these lesions, including absolute and relative vessel diameter, SB angulation, and extent of calcification and fibrous tissue buildup.[3] Given this added complexity, it is not surprising that bifurcation lesions have higher rates of procedural complications as well as higher rates of restenosis and target lesion revascularization (TLR) compared with nonbifurcated lesions, a finding seen consistently regardless of stent platform.[4,5] The optimal strategy for treating bifurcation lesions remains to be

determined, with meta-analyses showing that provisional T-stenting provides outcomes comparable to those with more complex 2-stent procedures.[6,7] Nevertheless, it is clear from angiographic and intravascular ultrasound studies that consistent coverage of the SB ostium, which prevents restenosis and need for TLR, is required to successfully treat bifurcation lesions and reduce major adverse cardiac event (MACE) rates.[4,8] In comparison, reintervention rates in the MB with available techniques are acceptably low.

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Currently under development are dedicated bifurcation devices that are designed to overcome limitations associated with use of conventional stents, such as guidewire entanglement ("wire wrap"), SB ostial gaps, MB stent overlap, and stent distortion and/or disruption.[3] These dedicated devices share a common goal of providing easy access to the SB, but differ in the degree of coverage provided to the SB ostium.[9] Based on our understanding of the procedural challenges, dedicated devices must conform to the heterogeneity of bifurcation lesions, and have a sufficiently low profile to consistently cross what can be a complex, tortuous, and calcified coronary pathway. Moreover, these devices must be integrated easily into the vessel carina regardless of SB angulation and extent of calcification. Given these procedural complexities, a dedicated device must be easy to use, particularly for intermediate-level operators, and allow passage of standard angioplasty wires through both MB and SB without wire wrap, which is a well-recognized cause for device deployment failure.[9] Finally, once the device is implanted, access should still be available to both limbs of the bifurcation to allow further stent expansion or additional stent placement, if necessary.

This article reviews 11 dedicated bifurcation devices currently under development, focusing on the therapeutic concept behind each device (ie, how and why it works) (Table 1). At the outset, it is important to distinguish between true bifurcation devices that extend past the carina to provide stent coverage in both MB and SB, and those that are primarily MB stents, which only provide access into the SB. The therapeutic concept of these so-called SB access devices is to provide coverage of the larger parent vessel but contain a port or wire offering access to the smaller daughter vessel. Finally, several stents have been recently developed that should be considered "side branch only" devices, some that are self-expanding, and others that rely on traditional balloon expandable platforms.

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Dedicated MB Devices

The Devax AXXESS™ system (Devax, Inc., Lake Forest, CA) is a self-expanding stent fabricated from nickel titanium (nitinol), which elutes the rapamycin analog Biolimus A9® from a biodegradable polymer coating.[9,10] The stent has a conical shape that is designed to encircle the carina, extending only a minimal amount into both limbs of the bifurcation (Figure 1). The conical shape matches the anatomy of most bifurcations $< 60°$. Accordingly, this system may provide some coverage of the SB ostium, but primarily offers full access to both limbs, thereby allowing further stenting of the MB and SB distal to the carina on a provisional basis. The stent is intended for deployment in a symmetrical manner, and therefore orientation of the stent within the vessel is not necessary. It has 3 radiopaque markers located at the distal tip at approximately 120° apart to facilitate placement and aid in accurate placement of additional stents in the bifurcation limbs. A fourth marker identifies the proximal portion of the stent. AXXESS is provided in 2 lengths (10 and 14 mm), with diameters intended to accommodate vessels from 2.75 to 4.25 mm in diameter. The distal flare can expand up to 8 mm in the largest-diameter stent.

In the Drug-Eluting Stent Intervention for Treating Side Branches Effectively (DIVERGE) study, the AXXESS stent was deployed at the level of the carina in 302 patients with de novo bifurcation lesions followed by provisional deployment of additional sirolimus-eluting stents in the MB and SB.[11] AXXESS was used with additional stenting of both MB and SB in 64.7% of patients, with an MB stent in 17.7%, and with an SB stent in 4.0%. The others did not undergo further stenting (12.3%) or did not have AXXESS deployed for anatomic

Table 1
Characteristics of Dedicated Bifurcation Devices

Stent	Stent Material	Drug-Eluting	GCS	Stent Delivery System	Mechanism of Stent Expansion
Devax AXXESS™	Nitinol	Biolimus A9	7F	Single wire rapid exchange system	Self expandable
Stentys bifurcation stent	Nitinol	No/Yes*	6F	Single wire rapid exchange system (second wire needed for SB access)	Self expandable; balloon to open access to SB
Tryton Side Branch Stent™	Cobalt chromium	No	6F	Single balloon, single wire rapid exchange system	Balloon expandable
Cappella Sideguard®	Nitinol	No	6F	Single balloon, single wire rapid exchange system	Balloon deployed; self-expandable
Medtronic coronary Y-stent	Cobalt alloy	No	6F	Double balloon, dual wire, single catheter	Balloon expandable (single inflation)
Taxus® bifurcation stent	Platinum alloy	Paclitaxel	7F	Double balloon, dual wire side-exchange catheter	Balloon expandable (single inflation)
Antares® coronary stent	Stainless steel	No	6F	Single balloon, rapid exchange system, with second wire in peel-away lumen	Balloon expandable (single inflation)
Abbott Vascular side branch access stent	Cobalt chromium	Everolimus	7F	Double balloon, dual wire, joined mandrel tip; MB rapid exchange and SB over-the-wire	Balloon expandable (single inflation)
Y-Med sideKicK™	Cobalt chromium	No	5F	MB fixed wire platform with rapid exchange steerable SB wire	Balloon expandable
Invatec Twin-Rail™	Stainless steel	No	6F	Double balloon, dual rapid exchange, single catheter	Balloon expandable (single inflation)
Minvasys Nile Croco®	Cobalt chromium	No/Yes*	6F	Double balloon, dual rapid exchange system with 2 independent catheters	Balloon expandable

GCS, guiding catheter size (French); MB, main branch; SB, side branch.
*Paclitaxel is eluted in newer stent iteration.
Devax Inc., Lake Forest, CA; Stentys, Inc., Princeton, NJ; Tryton Medical, Durham, NC; Cappella Medical Devices, Galway, Ireland; Medtronic, Minneapolis, MN; Boston Scientific, Natick, MA; TriReme Medical, Pleasanton, CA; Abbott Vascular, Redwood City, CA; Y-Med, San Diego, CA; Invatec, Italy; Minvasys, Gennevilliers, France.

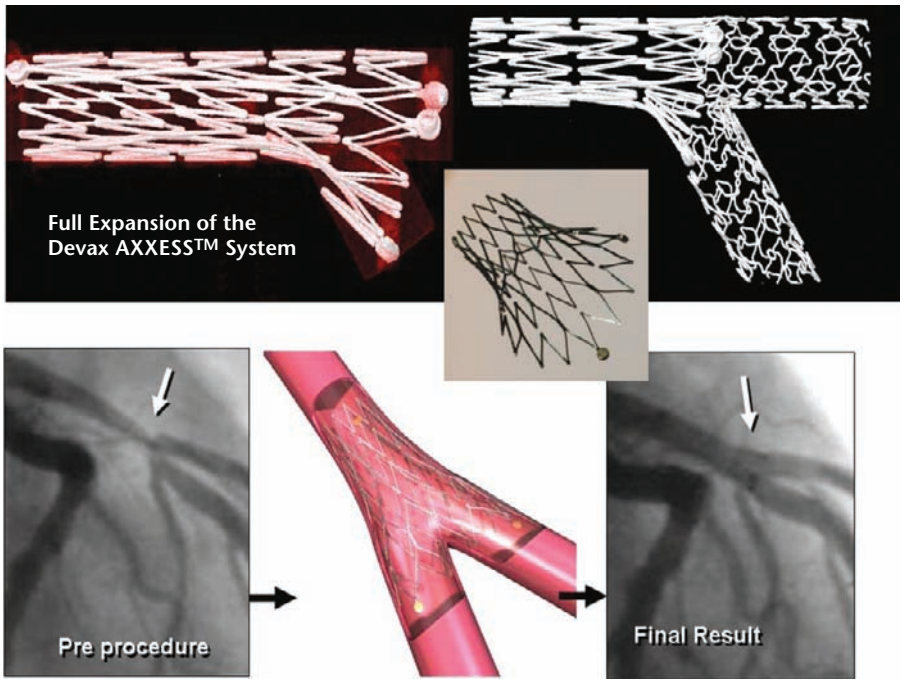
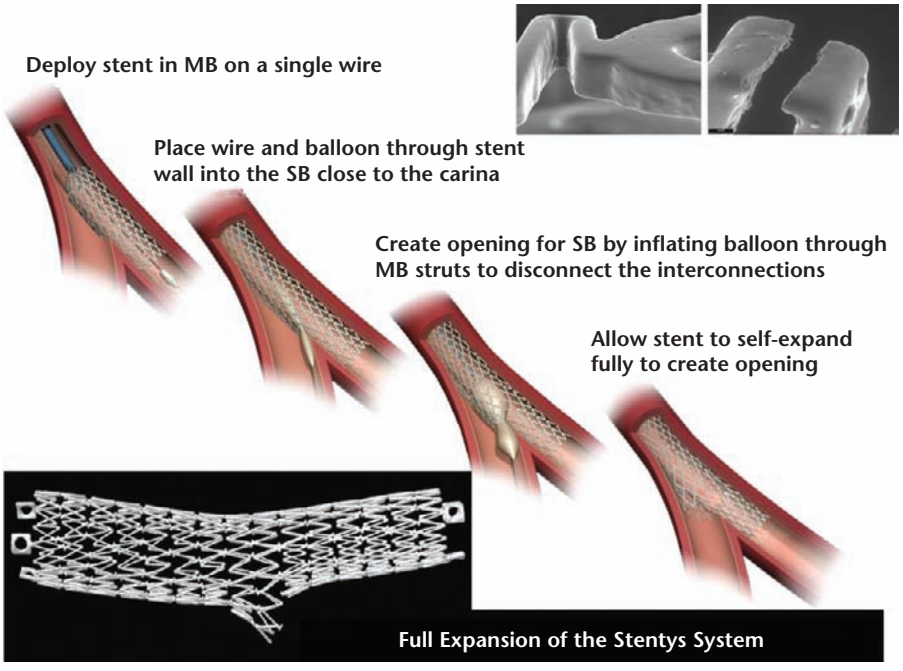


Figure 1. *Devax AXXESS™ self-expanding nitinol stent. The* right upper panel *shows the AXXESS stent after placement of additional stents in the main branch and side branch. The* right and left lower panels *show the angiographic appearance upon deployment (Devax Inc., Irvine, CA).*

reasons (1.0%). The 9-month cumulative MACE rate was 7.7%, consisting of death in 0.7%, non–Q-wave myocardial infarction (MI) in 3.3%, Q-wave MI in 1.0%, and TLR in 4.3%. Restenosis occurred in 6.4% of patients, including 3.6% and 4.3% with restenosis in the MB and SB, respectively. In the AXXESS stent, restenosis occurred in 0.7% of patients. These promising data may need to be confirmed using a more rigorous study design. Clearly, the main limitation of AXXESS is that most patients require additional stenting to fully treat the bifurcation lesion. This factor raises the question of whether it makes sense to convert the current provisional T-stenting strategy into a provisional MB-plus-SB technique, as may be frequently required with the AXXESS device.

The Stentys coronary bifurcation stent (Stentys, Inc., Princeton, NJ) is another self-expanding nitinol stent, which consists of Z-shaped mesh linked by small interconnections.[12] The drug-eluting version releases paclitaxel from a ProTeqtor® polymer matrix. It is unique in that the struts can be disconnected with an angioplasty balloon at any point along its 18-mm length except for the proximal and distal 2.5-mm segments. The stent is positioned in the MB over a single guidewire by withdrawing a retractable sheath; then the second wire with balloon is passed through the stent wall into the SB, and an opening created by balloon inflation (Figure 2). The SB opening can be created anywhere along the stent regardless of its initial positioning in the MB. Then, presumably a workhorse stent may be deployed in the SB without leaving an ostial gap. In theory, the self-expanding property of the stent allows it to fit each patient's unique bifurcation anatomy, with optimal ostial coverage achieved at bifurcation angles of 30° to 70°. The stent can expand to a maximum of 7 mm at the carina, making it suitable for bifurcations with diameters of 3.5 to 4.5 mm in the proximal MB and 2.5 to 3.0 mm in the SB.

Figure 2. *Deployment of the Stentys coronary stent. The* upper right panel *demonstrates the "disconnectable" struts for side branch (SB) access. The* lower left panel *shows the appearance after full stent expansion. MB, main branch (Stentys, Inc., Princeton, NJ).*



In the OPEN-I trial, the Stentys stent was evaluated prospectively in 40 patients with de novo bifurcation lesions who met the aforementioned vessel diameters and bifurcation angles.[12] The drug-eluting version was tested at 3 centers and the bare metal stent (BMS) at 6 centers. Simple disconnection of the stent mesh overlying the SB ostium was achieved in 37 patients, disconnection was not attempted in 2 patients after successful stent deployment, and the stent was not deployed in the remaining patient due to an extremely tortuous MB. The 30-day and 6-month MACE rates were 5% and 25%, respectively, which were largely driven by TLR. Moreover, procedural success of 100% and no MACE up to 30 days were recently reported with the Stentys stent in 20 patients with acute MI participating in the APPOSITION-I trial.[13] Despite these promising results, it is not yet certain whether the Stentys stent may be more prone to unintended fracture due to its disconnectable strut design; whether it will offer improved ostial coverage and ultimately better outcomes compared with current provisional T-stenting remains to be determined.

Dedicated SB Devices

There are 2 devices currently in development and testing, promoting a "save the side branch strategy" by focusing on definitive SB treatment before addressing the need for MB stenting. Although they may aid ultimately in the treatment of a bifurcation lesion, these devices are clearly intended for primary SB treatment, irrespective of the presence or absence of MB disease.

The Tryton Side Branch Stent™ (Tryton Medical Inc., Durham, NC) is a slotted-tube, cobalt-chromium, balloon-expandable stent.[14] It consists of 3 distinct but seamless zones: a distal SB region with a standard slotted-tube stent design, a central transition zone containing 3 independently deformable panels, and a proximal main vessel (MV) zone composed of 3 long filamentous fronds joined to a circumferential band at the proximal stent edge (Figure 3). It is delivered over a single wire, and is designed to avoid the need to rotate the catheter to achieve proper orientation. The stent is positioned based on transition zone markers, with the distal marker in the SB and proximal marker in the MV, and then deployed by balloon expansion. After deployment, the balloon may be withdrawn, maintaining guidewire position. If necessary, the wire can then be repositioned into the MB to allow tracking of a standard workhorse stent through the proximal and transition zones of the Tryton stent into the MB followed by final kissing balloon inflation. The Tryton stent is currently undergoing clinical evaluation.

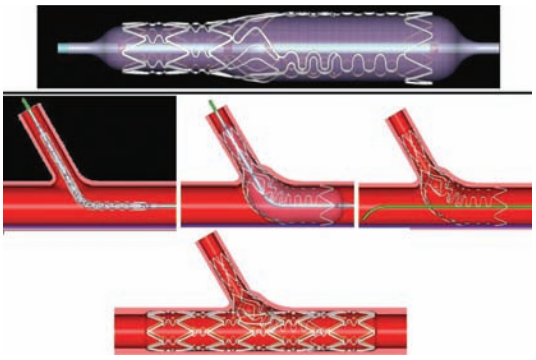


Figure 3. *Tryton Side Branch Stent™. The* middle panels *show deployment of the stent, and the* bottom panel *shows the stent after placement of a stent in the main branch (Tryton Medical, Durham, NC).*

The Cappella Sideguard® coronary stent (Cappella Medical Devices, Ltd., Galway, Ireland) is a trumpet-shaped, self-expanding nitinol stent that is deployed in the SB using a low-profile, single-catheter delivery system (Figure 4). The Sideguard is provided in 3 sizes allowing treatment of SB lumen diameters from 2.25 to 3.25 mm and lesion lengths < 7 mm. The flexible, low-profile delivery system allows easier navigation, even in tortuous and calcified vessels. Radiopaque markers located at the distal and proximal ends of the delivery system help to position the stent at the SB ostium. The stent is deployed by balloon, and then self-expands, with the trumpet shape helping it to conform to the SB ostium. After deployment, the delivery system and guidewire are removed, and then a standard workhorse stent can be deployed in the MB. After reaccessing the SB, the procedure is completed by kissing balloon inflation. The stent is currently a bare-metal version, but the next iteration is expected to be drug eluting. The first live cases with the Sideguard stent were recently performed.

Dedicated MB Plus SB Devices

Also in the bifurcation stent pipeline are those devices that offer significant stent coverage of both the MB and the SB (the so-called true bifurcation device). The Medtronic coronary Y-stent (Medtronic, Minneapolis, MN) is based on the Endeavor® platform, which offers a best-in-class crossing profile of approximately 0.044 inches. The stent is made from an advanced cobalt alloy, enabling the extremely thin stent struts to

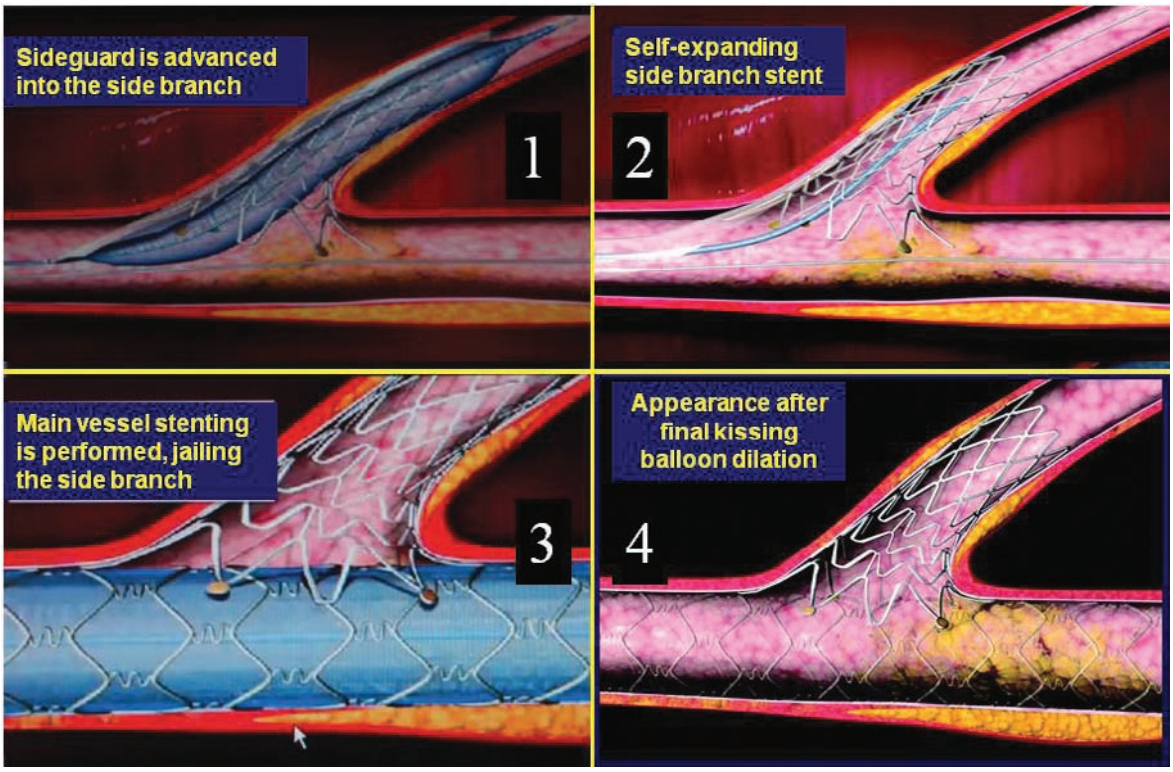


Figure 4. *Deployment sequence of the Cappella Sideguard® coronary stent (Cappella Medical Devices, Galway, Ireland).*

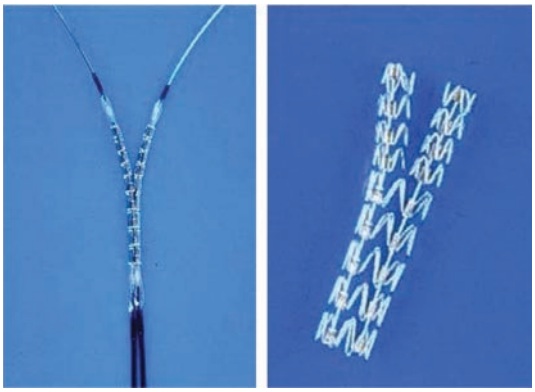


Figure 5. *Medtronic coronary Y-stent (Medtronic, Minneapolis, MN).*

provide sufficient strength to scaffold the artery (Figure 5). It is delivered over a dual-wire system through a single catheter, with the system's profile minimized through use of balloon-tapering and folding technology. The Y-stent is deployed by a single inflation of the dual-tapered balloon, thereby providing coverage of both MB and SB while respecting the bifurcation angle. It provides minimum coverage of the carina. The stent has the same modular architecture and fusion laser pattern used in the Driver® BMSs and Endeavor Resolute drug-eluting stents (DESs). Preliminary data from the first 33 patients enrolled in the BRANCH study revealed 1 primary endpoint event within 30 days (3.0%; a non–Q-wave MI). Acute success was achieved in 27 cases (82%). It is conceivable that some of the device delivery failures may have been due to under-rotation of the system. Given this early experience, it suggests aggressive predilatation is needed (though this may be said for any bifurcation device given an expected greater crossing profile than current workhorse stent platforms).

The Taxus® Bifurcation Stent System (Boston Scientific Corporation; Natick, MA), previously called the AST Petal Device, is designed to provide stenting of the MB with a 2-mm extension into the SB.[9] It is this short extension or "nipple" from which the device gets the name "petal" (Figure 6). The stent is made from a platinum-enhanced alloy and coated with paclitaxel in

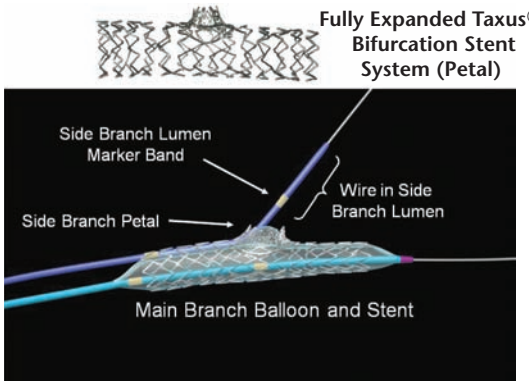


Figure 6. *Taxus® Bifurcation Stent System (Taxus; Boston Scientific, Natick, MA).*

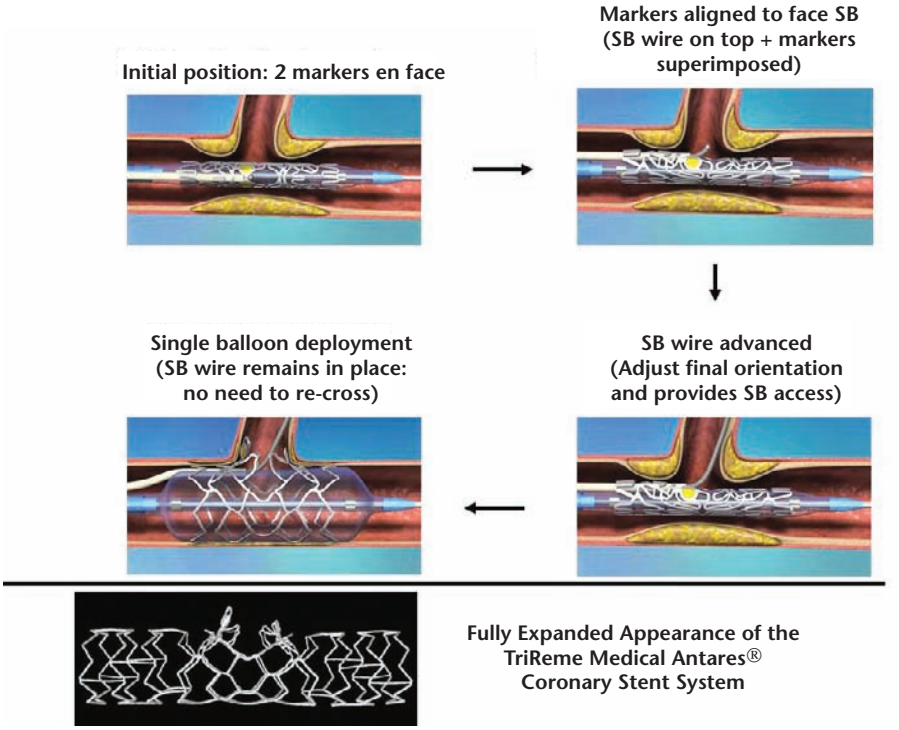
the Translute™ polymer carrier. It consists of the MB stent with a positional side petal that is positioned to provide SB access and support for the carina by outwardly deploying strut elements. The stent is delivered via a dual-side exchange catheter consisting of a main lumen and SB lumen. The main lumen guides the catheter to the lesion site, and the SB lumen supports proper alignment of the petal to the SB ostium. The distal ends of the main and SB lumens contain cylindrically and gumdrop-shaped balloons, respectively. Upon inflation, these balloons deploy the MB stent and the petal into the SB ostium. In other words, it is the distal placement of wires into the MB and SB that facilitates alignment and directs the petal into proper phase toward the SB. Following deployment, the operator has the option of performing additional SB stenting without removal or further manipulation of the SB wire. The intended consequence of extension of the petal into the daughter vessel is to ameliorate gaps in stent coverage of the SB ostium. This stent system is currently under evaluation in a 45-patient first-in-human trial.

MB Stent With SB Access Port

A number of devices are designed for primary stent coverage of the MB, preserving access into the SB; this may be ideal for employing a provisional T-stenting approach, while still maintaining the flexibility of choosing an upfront 2-stent strategy. These may also offer the advantage of simple wire preservation of the SB when bulky MB disease is present, even in the absence of SB involvement. These include the Antares® Coronary Stent System (TriReme Medical, Inc., Pleasanton, CA), Abbott Vascular Side Branch Access (more commonly referred to as Xience SBA) stent (Abbott Vascular, Redwood City, CA), Y-Med sideKicK™ (Y-Med, Inc., San Diego, CA), Invatec Twin-Rail™ (Invatec S.r.l., Italy), and Minvasys Nile Croco® (Minvasys, Gennevilliers, France).

The Antares stent consists of a single balloon-expandable 316L stainless steel stent with 0.0035-inch struts. The central part of the stent contains an SB preservation structure (ostial preservation structure) and 2 radiopaque markers that facilitate positioning of the stent. The stent is provided in 14- and 18-mm lengths, with sizes to accommodate MB diameters of 3.0 to 3.5 mm and SB diameters of 2.5 to 3.0 mm. The stent is delivered with a single, low-profile, rapid-exchange balloon catheter that also contains a preshaped, color-coded SB wire encased in a second peel-away lumen to minimize wire wrap (Figure 7). As the stent approaches the

Figure 7. *Deployment of the Antares® coronary stent system. SB, side branch (Antares; TriReme Medical, Pleasanton, CA).*



bifurcation, the catheter is torqued or rotated to align the markers with the SB ostium. Then the SB stabilizing wire is advanced to adjust final placement and allow SB access once the stent is deployed. In contradistinction to other devices that use distal placement of the SB wire to promote in phase alignment, proper placement of the Antares device is independent of wiring of the SB. In fact, the wire is only partially placed into the SB just prior to inflation. Upon balloon inflation, the stent expands in the MB, and the SB support automatically deploys, extending approximately 2 mm into the SB to provide ostial coverage. Access to the SB is maintained throughout the procedure, and allows provisional stenting of the SB.

The multicenter, single-arm TMI Ostial Preservation (TOP) trial is evaluating the Antares stent in up to 100 patients with de novo bifurcation lesions. Following deployment, SB treatment is at the discretion of the operator, but if stenting is chosen, then the protocol mandates use of the Taxus® Liberté® stent (Boston Scientific). Preliminary results from the first 39 patients are available. The device was successfully deployed with SB wire access in all patients. Provisional SB treatment included balloon dilatation only (61.5%), stenting (17.9%), and no further intervention (12.8%), with final thrombolysis in MI (TIMI) 3 flow in all patients. The 30-day MACE rate was 5.9% and included 1 patient with stent thrombosis, Q-wave MI, and TLR following hospital discharge, and 1 patient with a non–Q-wave MI while hospitalized.[15]

The Abbott Vascular Xience SBA stent is an everolimus-eluting stent that uses the drug, polymer, and scaffolding technology of the XIENCE™ V Everolimus-Eluting Coronary Stent System.[9] An earlier bare metal version was evaluated in the FRONTIER Registry,[5] which included 105 patients with bifurcation lesions. Although the device was deployed successfully at a high rate (91%) and with few acute procedural complications, the MACE rates were ultimately driven by long-term TLR. At 6 months, the MACE and TLR rates were 17.1% and 13.3%, respectively. The overall restenosis rate on coronary angiography was 44.8%, reflecting MB and SB restenosis rates of 29.9% and 29.1%, respectively. To address this issue, an everolimus-eluting version is under development.

The dual-wire SBA stent is composed of cobalt chromium with 0.0034-inch struts, and coated with a fluoropolymer containing everolimus.[9,16] The dual lumen delivery catheter contains a unique joining mandrel that holds the MB and SB tips together to avoid wire wrap while advancing the side-by-side wires (Figure 8). The joining mandrel is a pivotal feature of the device allowing for single-tip delivery and it may enhance a favorable crossing profile of Xience SBA. It is designed to self-rotate into proper alignment for the SB, and then deploy via a single kissing balloon inflation. Attached to the distal end of the catheter are 2 balloons—an MB balloon attached to the rapid-exchange lumen and an SB balloon attached to the over-the-wire lumen. The stent is crimped on both balloons to allow the SB balloon to exit through a portal in the center of the stent. Proximal to the balloons, the 2 inflation lumens are joined into a single common inflation lumen that can be pressurized with a single inflation device, a feature that may amplify the ease of use of Xience SBA. The system is advanced to a point just proximal to the target bifurcation, and then the joining mandrel is unlocked (retracted) at the proximal adapter hub allowing placement of the second wire in the SB (Figure 9). The system is then advanced into the bifurcation, and with a single inflation, both balloons are pressurized, deploying the MB stent and opening a portal into the SB. In a perfused synthetic coronary model, deployment of the Abbott Vascular SBA required less contrast and shorter fluoroscopy times than a provisional T-stenting approach, and also had a lower rate of wire wrap and less protrusion of the SB stent into the MB.[16] The results of this study suggest that Xience SBA may be particularly accommodating to additional SB stent deployment without gaps in ostial SB coverage (Figure 10). Further testing is needed to validate these bench-top results.

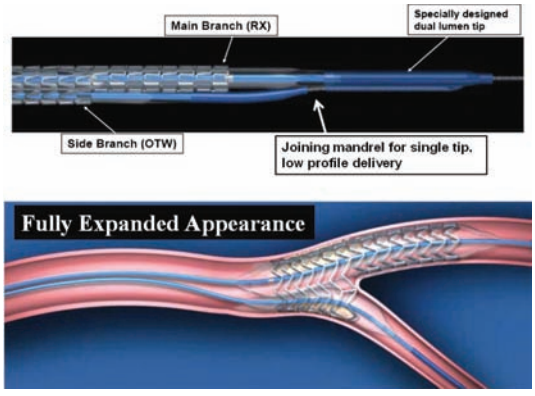


Figure 8. *Abbott Vascular side branch access stent (Xience SBA). The* upper panel *shows how the joining mandrel allows for a low profile, single-tip delivery. OTW, over the wire; RX, rapid exchange (Abbott Vascular, Redwood City, CA).*

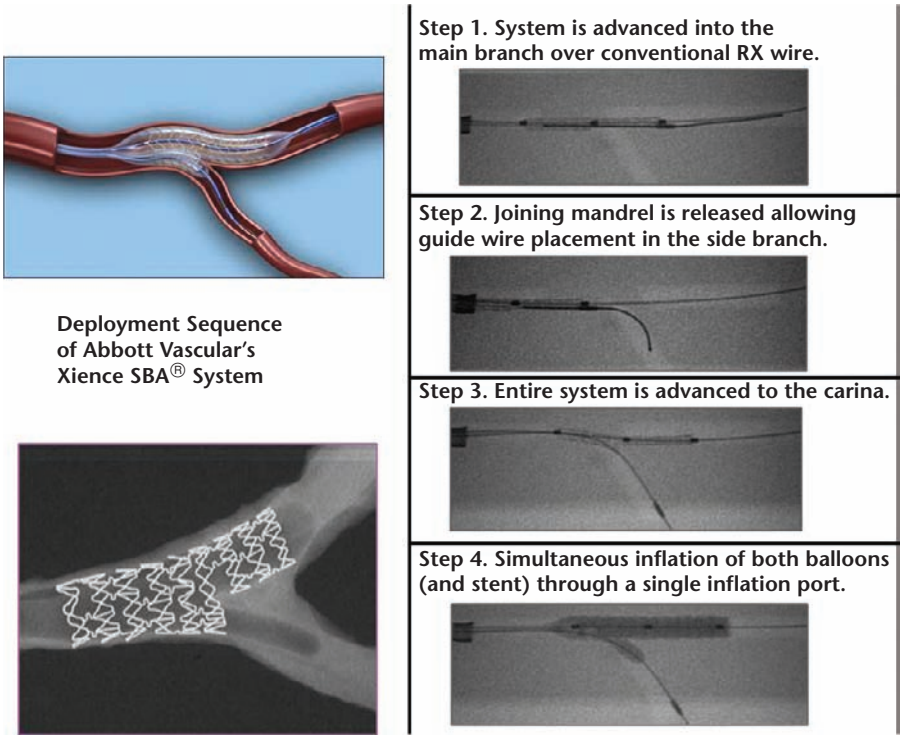


Figure 9. *Deployment sequence of the Abbott Vascular side branch access stent (Xience SBA). RX, rapid exchange (Abbott Vascular, Redwood City, CA).*

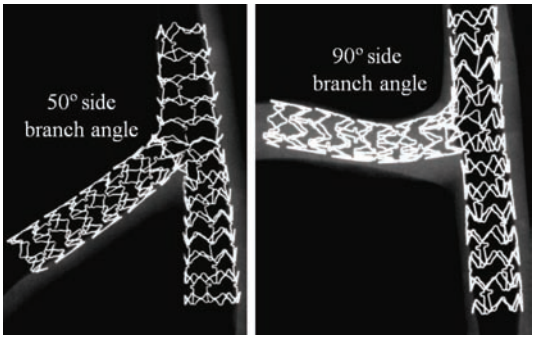


Figure 10. *High-intensity Faxitron radiographic images, demonstrating the potential for side branch (SB) ostial coverage of the Xience SBA system. Additional SB stent deployments are shown for SB angles of 50° and 90° (Abbott Vascular, Redwood City, CA).*

Although Xience SBA may be ideally suited for providing the operator the flexibility of choosing between a single versus 2-stent bifurcation strategy, it may be most suitable for providing simple SB preservation in the setting of isolated bulky MB disease.

The Y-Med sideKicK System combines an MB fixed-wire platform with a rapid-exchange steerable SB guidewire to provide SB access (Figure 11).[9] Three models with proximal, middle, or distal exit ports are available, and are selected on the basis of disease location in the bifurcation. Using 2 markers as a guide, the system can be easily rotated to align the port with the SB. The system deploys a stent in the MB with coverage extending from the proximal portion of the carina to a segment distal to the SB. The SB guidewire is passed through the exit port that runs parallel to the MB balloon, thereby providing access to the SB but without any ostial coverage. Additional SB stenting can be performed without need for wire removal. The design of the port through which the SB wire is passed helps to minimize wire wrap. The first-generation stainless steel stent was evaluated in 17 patients with 20 bifurcation lesions, yielding a device success rate of 80%.[17] A second-generation version made from cobalt chromium is under development.

The Invatec Twin-Rail system is a laser-slotted, stainless steel stent premounted on double balloons in its proximal portion and only on the MB balloon in its distal portion. The stent has a closed-cell design with variable stent geometry, which allows optimal adaptation to larger vessels and proper scaffolding for the SB ostium. The cells can expand to a maximum diameter of 5 mm in the proximal MB and carina region and 4 mm in the distal MB. The single catheter has a dual lumen that splits into 2 distal balloons with a central stopper that prevents further advancement once the carina is reached. The long tip of the SB balloon extends over the tip of the MB balloon to facilitate SB entry. The stent is deployed by a single simultaneous kissing inflation. The guidewire is maintained in the SB throughout the procedure, and the proper opening of the stent cell facing the SB is provided by the SB balloon.

Finally, the Minvasys Nile Croco consists of a cobalt chromium stent mounted on 2 independent, but jointed rapid-exchange catheters. The extra-thin stent (73 μm) is crimped on the MB balloon and tip of the SB balloon. Markers on the MB balloon indicate the position of the SB portal. The catheters are independently manipulated and inflated, first to deploy the stent in the MB,

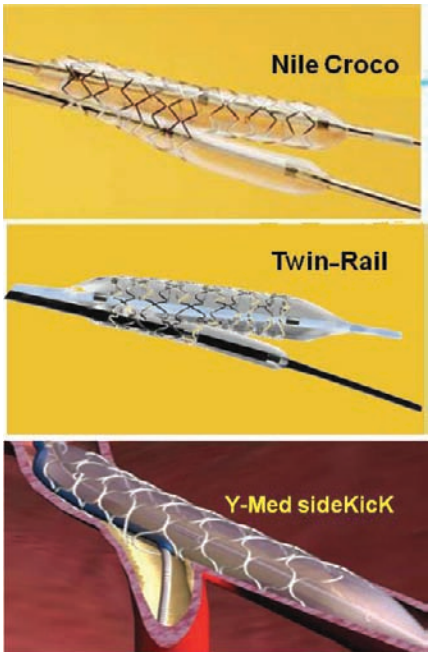


Figure 11. *Other main branch stents with side branch access ports: Minvasys Nile Croco® (top), Invatec Twin-Rail™ (middle), and Y-Med sideKicK™ (bottom) (Minvasys, Gennevilliers, France; Invatec, Italy; Y-Med, San Diego, CA).*

and then to advance the SB balloon into the SB to perform the final kissing inflation. The stent comes in a 24-mm length providing coverage 16 mm proximal and 8 mm distal to the carina. In the Nile Croco Registry device success was 96%, and the 6-month MACE and TLR rates were 12% and 9.4%, respectively.[18] A polymer-free paclitaxel-eluting version (Nile Pax®) providing drug release over 30 days has also been evaluated. Preliminary data from the BiPax study showed device success in 59 of 60 patients without any 30-day device-related MACE.[18]

Conclusions

The true incidence of bifurcation disease in everyday interventional practice needs to be better defined to estimate how often dedicated devices will be used and whether the frequency may differ for each proposed device. In addition, the regulatory requirements for bringing a dedicated device to market still need to be clarified. Which, if any, of these devices will require randomized, controlled trials versus registry trials has not been clearly defined. If the randomized, controlled trials are mandated by the US Food and Drug Administration (FDA), a "standard" treatment of comparison needs to be identified. Presumably, a comparative trial against provisional T-stenting would be required. However, how can the comparator in a pivotal approval trial be an off-label methodology? Consider the Abbott Vascular Xience SBA system, which seems profoundly similar to the company's current FDA-approved DESs, but offers SB access. Does the addition of a small SB port to the current XIENCE™ V Everolimus-Eluting Coronary Stent really necessitate a randomized, controlled trial (with an estimated cost of tens of millions of dollars) to bring this dedicated device to market?

Consider the Tryton Side Branch Stent™ as well as the Cappella Sideguard® coronary stent. Why would pivotal approval trials of either of these "side branch only" devices require a study design mandating randomization to MB and SB stenting (ie, provisional T-stenting), when this is not necessarily the intended therapeutic concept for which the device was developed?

The industry efforts to develop dedicated bifurcation devices are still ongoing, with design and regulatory hurdles yet to overcome. At this stage, there is no clear one-size-fits-all technology. Given the heterogeneity of bifurcation lesions, it is likely that several different devices may ultimately play a role in this treatment setting. However, it is equally important to point out that operator experience with current slotted-tube technology continues to increase. Unless ease of use is a primary focus for these dedicated bifurcation devices currently under development, device adoption by intermediate-level users may become an issue. Regardless, the key to treating bifurcation lesions remains how to best approach the SB. ■

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Main Points

- The side branch (SB) ostium is the focus of newer treatment strategies because it is a common site of restenosis.
- Angiographic and intravascular ultrasound studies have made it evident that consistent coverage of the SB ostium is required to successfully treat bifurcation lesions and reduce postprocedural adverse event rates.
- Dedicated bifurcation devices that are designed to surmount the limitations associated with conventional stents are currently under development.
- It is critical to distinguish between true bifurcation devices and those that are primarily main branch stents.

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