Svelte™ Acrobat Stent-On-A-Wire Coronary Stent System

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Coronary stenting is a percutaneous procedure intended to regain coronary artery patency overcoming the major limitations of balloon angioplasty: acute recoil and negative vessel remodelling. The first contemporary balloon-expandable stent was the Palmaz, immediately followed by an articulated variant known as the Palmaz-Schatz, the first stent to be tested in large multicentre trials (the Stent Restenosis Study [STRESS] and the Belgium–Netherlands Palmaz-schatz, the first stent to be tested in large multicentre trials (the stent restenosis study [sTress] and the Belgium–netherlands Palmaz-schatz, the first stent to be tested in large multicentre trials (the svelte™ Acrobat soAW coronary stent system consists of a balloon-expandable stent pre-mounted on svelte’s soAW delivery system with a 0.012-inch integrated guidewire tip (distance from the tip of the wire to the stent is 22mm). This is a balloon-expandable stent and the nylon balloon is also directly mounted onto the wire. The Acrobat SOAW may potentially facilitate percutaneous coronary intervention by reducing time/cost and minimising peri-procedural complications and therefore benefit a large number of patients in daily practice who are currently labelled as unfavourable for direct stenting.

Direct stenting may reduce local vessel trauma, minimise ‘geographical miss’, prevent distal embolisation and save time/money during percutaneous coronary interventions. However, direct stenting is currently performed in ≤50% of most catheter laboratories worldwide. Among the main reasons to pre-dilate, vessels anatomy (tortuosity and amount of calcification) play a central role in the operator’s decision. The recently developed Acrobat Stent-On-A-Wire (SOAW) coronary system combines a very thin (81µ) L605 CoCr stent mounted on a delivery system with a 0.012-inch integrated guidewire tip (distance from the tip of the wire to the stent is 22mm). This is a balloon-expandable stent and the nylon balloon is also directly mounted onto the wire. The Acrobat SOAW may potentially facilitate percutaneous coronary intervention by reducing time/cost and minimising peri-procedural complications and therefore benefit a large number of patients in daily practice who are currently labelled as unfavourable for direct stenting.

Key words
Percutaneous coronary intervention (PCI), direct stenting, Acrobat Stent-on-a-Wire, balloon-expandable stent

Description of the Device
The Svelte™ Acrobat SOAW coronary stent system consists of a balloon-expandable stent pre-mounted on Svelte’s SOAW single-lumen fixed-wire implantation catheter platform. The stent is made of cobalt–chromium alloy (L.605) and is available in diameters ranging from 2.5 to 4mm and lengths of 8 to 28mm. The Acrobat...
SOAW system is compatible with 5 French (Fr) guiding catheters (minimum internal diameter 0.056 inches).

The lesion entry profile of the formable radiopaque wire tip is 0.012 inches (see Figure 2). The SOAW implantation catheter’s operational extension is 145cm, and includes two proximal axis markers (90 and 100cm) to indicate the relative position of the implantation system up to the extremity of a radial or femoral guide catheter. Proximal and distal radiopaque markers are located under the balloon to indicate the operational extension of the balloon and the diameter of the expanded stent under fluoroscopy. There are balloon control bands on each end of the balloon to control expansion and deflation. An integral torquer device is located on the proximal axis (see Figure 3).

The basic steps to deploy the Acrobat SOAW coronary stent system are represented in Figure 4. This innovative stent system was recently evaluated in a first-in-man (FIM) study. The Svelte FIM trial was a multicentre (four sites), international (Brazil, The Netherlands and Colombia), prospective, non-randomised, single-arm registry of the novel Acrobat SOAW for the treatment of de novo coronary lesions. A total of 46 patients were enrolled with planned angiographic evaluation at six months. For a pre-specified cohort of 15 patients, serial intravascular ultrasound (IVUS) assessments right after stent implantation and at six months will be performed while for a cohort of 19 patients, optical coherence tomography (OCT) assessment at similar time points will be performed. The primary end-point of the study is the survival-free rate of combined major adverse cardiac events (MACE; cardiac death, myocardium infarction and target-lesion revascularisation) at 30 days. As secondary end-points it will analyse the following: device success rate; lesion success rate; procedure success rate; (individual) incidence of cardiac death, myocardium infarction and target-lesion revascularisation; binary restenosis and in-stent/in-segment late luminal loss at six months; stent thrombosis rate (according to ARC definition) up to six months. Figure 5 displays two examples of patients treated in the FIM series. The enrollment phase of this study
was recently completed. The Acrobat stent was deployed in 100% of the cases (89.1% of direct stenting) achieving a procedure success rate of 97.8%. Up to 30 days there were no deaths, Q-Wave Myocardial Infarction or complications. With improved access and a potential reduction in complications, the Acrobat allows for application in patients who are currently labelled as unfavourable for direct stenting.

**Future Perspectives**

CE Mark was granted to Svelte Medical for the BMS Acrobat soAW on 20 August 2010. With this approval, Svelte will now focus on the release of the drug-eluting stent (DES) version of the Svelte™ Acrobat, which is under development and will use a novel non-inflammatory carrier for the drug. The company also plans to initiate US clinical trials on the Svelte™ Acrobat SOAW technology in 2011.

**Conclusions**

The Svelte™ Acrobat SOAW has the potential to significantly improve PCI by reducing time and cost and minimising peri-procedural complications. With improved access and a potential reduction in complications, the Acrobat allows for application in patients who are currently labelled as unfavourable for direct stenting. Its innovative concept has completed enrollment in a FIM study, secured CE Mark for the BMS Acrobat product and the next-generation DES version is highly anticipated.

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