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AngioSculpt catheter still on a roll with latest FDA 510(k)

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In September 2004, **AngioScore** (Fremont, California) received the CE mark to launch its flagship product, the AngioSculpt, in Europe and has been on a regulatory roll with the angioplasty scoring balloon catheter ever since.

"Yes, we're actually doing quite well," President/CEO Thomas Trotter told *Medical Device Daily*.

On Thursday the company reported its latest achievement: FDA clearance to sell its AngioSculpt Percutaneous Transluminal Angioplasty (PTA) catheter for balloon dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal and infra-popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The PTA catheter is not labeled for use in the coronary or neuro vasculature.

Trotter said the latest FDA clearance to market the AngioSculpt PTA catheter opened up opportunities in what he termed the "largest and fastest-growing segments" of the U.S. peripheral artery disease (PAD) market, including the superficial femoral artery (SFA) and stenoses involving hemodialysis of synthetic or native arteriovenous (A/V) fistulae. He noted that in 2007 an estimated 275,000 SFA and 300,000 A/V fistula procedures were performed in the U.S.

The AngioSculpt PTA catheter received initial FDA 510(k) clearance for the treatment of infra-popliteal PAD in September 2005.

In January 2007, AngioScore's companion product, the AngioSculpt Percutaneous Transluminal Coronary Angioplasty (PTCA) scoring balloon catheter, received PMA approval from FDA for the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis and complex type C lesions, for the purpose of improving myocardial perfusion (*MDD*, Jan. 12, 2007).

Then, this past January, AngioScore reported obtaining import approval for the AngioSculpt in Japan for the interventional treatment of coronary artery disease (CAD). Gaining access to the Japanese market is something very few small device companies achieve, given Japan's high performance standards and stringent quality control requirements.

"You could probably put on one hand the number of small private companies that get it," Trotter said.

Designed to be an improved angioplasty catheter for complex lesions, the AngioSculpt is comprised of a semi-compliant angioplasty balloon surrounded by a scoring element, which is intended to work in tandem with the

balloon to deliver a scoring effect to the target lesion upon balloon inflation.

As the balloon inflates, the radial forces are concentrated along the surfaces of the nitinol-scoring element, which results in luminal expansion that is – according to AngioScore – "precise, predictable, and controlled." The catheters represent the "next generation" in angioplasty catheters, Trotter told *MDD*.

"It's got a lot of advantages in terms of helping the physicians do a better job of placing the stents or opening the arteries and it's a very safe device," Trotter said, adding that the AngioSculpt catheters have been used in more than 15,000 procedures worldwide.

With CE marks in Europe, FDA clearance and PMA approval in the U.S., and import approval in Japan for the CAD indication, Trotter said that completes "pretty much" all the regulatory approvals the company needs for the AngioSculpt catheter. The only thing that remains, he said, is approval for the peripheral indications in Japan, which is expected later this year.

In addition to gaining regulatory ground rather quickly, Trotter said AngioScore also has enjoyed success on the commercial side. Last year the company did just under \$10 million in sales, he said, and this year it anticipates "something a little more than \$20 million."

The company has doubled in size over the last 12 months in terms of its workforce, Trotter said, and has doubled its sales. AngioScore uses distributors in Europe and Japan and a direct sales force in the U.S., he added.

In October AngioScore reported raising \$30 million in private equity financing, which it said helped the company ramp-up its worldwide sales effort (*MDD*, Oct. 10, 2007).

On the product side, Trotter said the company has "a whole series of longer and larger AngioSculpts that will be released to the market over the next 12 months," for the peripheral indications, including those for which the company just received FDA clearance. Originally designed for smaller, below-the-knee vessels, the longer and larger catheters will be used in procedures involving larger, above-the-knee vessels.

He also mentioned a rapid-exchange version of the catheter for the coronary indications and – looking further into the future – a drug-coated version of the device that is in the works for the PAD market. ■

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