

# Product news

## Cook Medical

### Cook receives FDA approval to launch Zenith AAA Iliac Flex Legs

Cook Medical has announced approval from the FDA to market its improved Zenith abdominal aortic aneurysm (AAA) iliac Flex Legs and Z-Trak Introduction System, designed for use with the Zenith Flex AAA endovascular graft. The products have been developed specifically to provide increased flexibility and improved conformability in the aorta and iliac artery, a tortuous section of patient anatomy, for patients undergoing endovascular aneurysm repair (EVAR).

The Zenith AAA Flex Leg shorter external stents have increased gaps between them, leading to improved flexibility and conformability and reducing the potential of the leg to kink. The device, like the Zenith Flex main body, is constructed of polyester graft material supported by stainless steel Z-stent bodies.

Phil Nowell, global leader of Cook Medical's Aortic Intervention business unit explains that "As a modular device, the Zenith Flex endograft main body represents the highest order of engineering achievement in the pursuit of improved outcomes for patients undergoing EVAR. But until now, no company has addressed the issue of dramatically improving the other components – the ipsilateral and contralateral legs that seal the device below the aortic bifurcation. The development of the Zenith Flex AAA Legs is another step in Cook's ongoing journey to create innovative devices and technology that help physicians perform minimally invasive diagnostic and therapeutic procedures with the least possible trauma to the patient. In the near future, we expect to bring an even more advanced leg system to clinical trial that we expect may show even greater performance improvements."

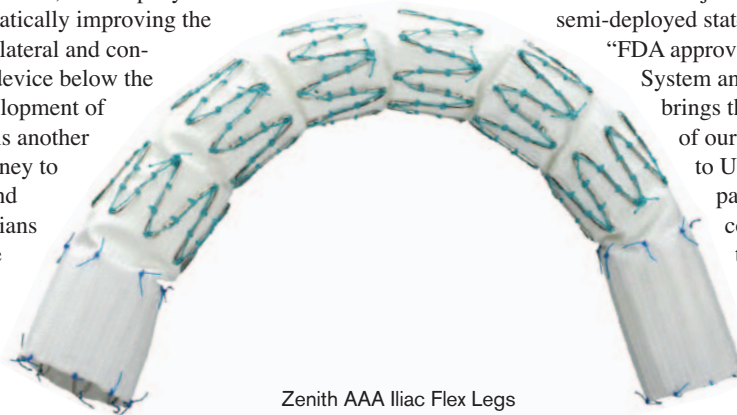
The Z-Trak Introduction System provides an integrated interface to the Zenith device, continuing its established maneuverability for precise, controllable device orientation and deployment of the

company's endovascular stent graft. Precision is key to this system, allowing the operator to make last-minute adjustments prior to deployment of the stent graft, affording physicians the ability to achieve highly accurate placement. The trigger-wire delivery mechanism allows adjustment of the endograft in a semi-deployed state for greater accuracy.

"FDA approval of the Z-Trak Introduction System and Zenith AAA Flex Leg brings the flexibility and deliverability of our market-leading AAA platform to US physicians and their patients," added Nowell. "Our commitment to creating innovative devices and technology to help physicians perform minimally invasive diagnostic and therapeutic procedures for aortic aneurysms that improve patient outcomes

and make the benefits of EVAR available to an ever-widening cohort of patients is revolutionizing the industry and creating a new gold standard for the treatment of this life-threatening disease."

The Cook Zenith AAA Flex Leg and Z-Trak Introduction System are available in the US, continental Europe and the UK.

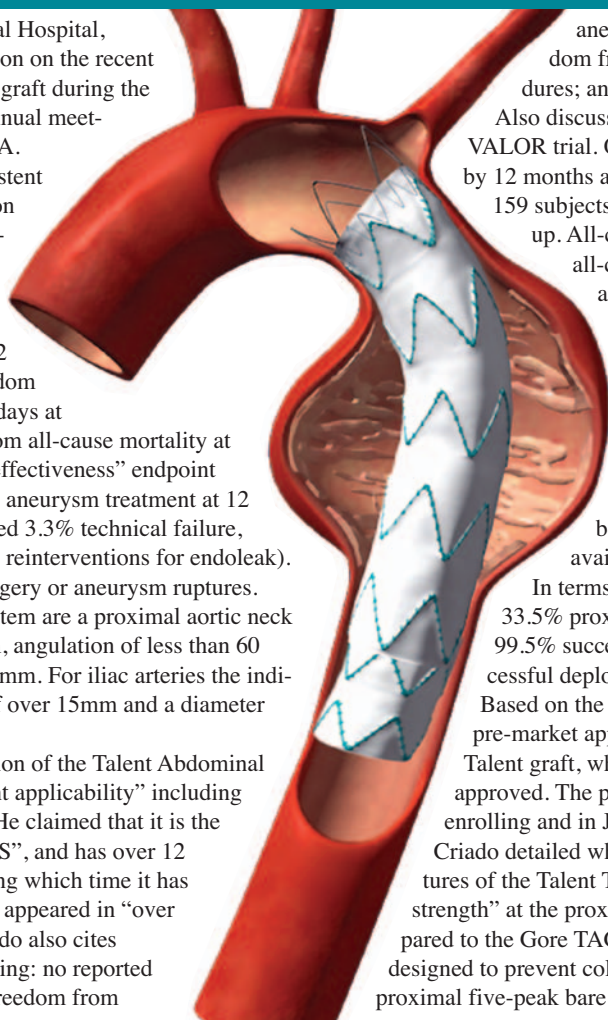


Zenith AAA Iliac Flex Legs

## Medtronic introduces new Talent stents

Dr Frank Criado, Union Memorial Hospital, Baltimore, MD, gave a presentation on the recent FDA approval of the Talent stent graft during the Society for Vascular Surgery's annual meeting, held June 5–8, San Diego, CA. Criado described how the Talent stent graft system, the fifth endograft on the US market for abdominal aortic aneurysms (AAAs) has been the subject of seven study arms, including the Enhanced Talent (eLPS) arm (n=166 between 2002 and 2003). The trial showed freedom from major adverse events at 30 days at 89.2% (148/166) and freedom from all-cause mortality at 98.2% (163/166). The "primary effectiveness" endpoint gave a result of 90.2% successful aneurysm treatment at 12 months (reason for failure included 3.3% technical failure, 2.5% aneurysm growth and 4.1% reinterventions for endoleak). There were no conversions to surgery or aneurysm ruptures. The indications for the Talent system are a proximal aortic neck with a length of more than 10mm, angulation of less than 60 degrees and a diameter of 20–32 mm. For iliac arteries the indications are for a fixation length if over 15mm and a diameter of 8–22mm.

Criado spoke about the introduction of the Talent Abdominal stent, describing its "broad patient applicability" including large neck sizes of up to 36mm. He claimed that it is the "leading stent graft outside the US", and has over 12 years of clinical experience, during which time it has been implanted 45,000 times and appeared in "over 150 peer-reviewed articles". Criado also cites "excellent clinical results" including: no reported ruptures or conversions; 98.2% freedom from



aneurysm-related mortality; 96.5% freedom from secondary endovascular procedures; and a 0.8% migration rate.

Also discussed were the conclusions of the VALOR trial. Of 195 enrolled patients, 31 had died by 12 months and five were not evaluable, leaving 159 subjects for evaluation at 12 months follow-up. All-cause mortality at 30 days was 2.1%; all-cause mortality at 12 months, 16.1%; and aneurysm-related mortality at 12 months was 3.1%. Criado described these as "highly favourable early and 12-month outcomes in low-risk subjects using the Talent stent graft." He notes that because of "the wide diameter treatment range, 25% of implanted subjects could not have been treated with current commercially available devices."

In terms of accuracy, VALOR showed a 33.5% proximal bare spring in Zones 1 or 2, 99.5% successful vessel access and a 99.5% successful deployment of the graft.

Based on the VALOR data, Medtronic submitted a pre-market approval application to the FDA for the Talent graft, which since the presentation has been approved. The pivotal trial VALOR II is currently enrolling and in June was at 90% completion.

Criado detailed what he considers to be the special features of the Talent Thoracic, such as its "superior radial strength" at the proximal and distal sealing zones (compared to the Gore TAG in competitive bench testing), designed to prevent collapse. Design elements include: a proximal five-peak bare spring providing trans-vessel fixation



Frank Criado presents the new Medtronic stents. Left: Talent Thoracic

and a mini support spring to enhance the seal and tissue incorporation.

To conclude, Criado talked about the new Talent Thoracic stent. It boasts the widest range of diameters currently available in the US (22–46mm) and Criado claims that it is used to treat 25% more thoracic patients than any other available device and has been the subject of more peer-reviewed publications than any other thoracic stent graft. It has been accumulating clinical experience for over 11 years and has been implanted more than 20,000 times, during which no graft collapses have been reported. It was proven effective and safe in a large, multi-centre clinical trial.

## EKOS

### EKOS introduces new EkoSonic endovascular system

EKOS Corporation announced today the launch of the EkoSonic Endovascular System (EkoSonic ES) with Rapid Pulse Modulation (RPM) for the dissolution of vascular blood clots. EkoSonic ES is the only endovascular system that can deliver microsonic energy and thrombolytic drugs simultaneously, providing a safer, faster and more complete way to remove clots by accelerating dissolution. The EkoSonic ES recently received FDA clearance.

"Unlike mechanical devices, EKOS technology does not fracture the thrombus or damage red blood cells. Faster clot dissolution means a lower lytic drug dosage, resulting in fewer complications. Physicians can treat patients in less time, with even greater clinical confidence," said Robert Hubert, EKOS president and CEO.

EkoSonic ES design features include an advanced control unit with an easier, more intuitive user interface, making set up and operation simple. EkoSonic ES is also compatible with a new line of endovascular devices, the Mach 4, which was specifically created to be compatible with the RPM technology.

## Kimberly-Clark

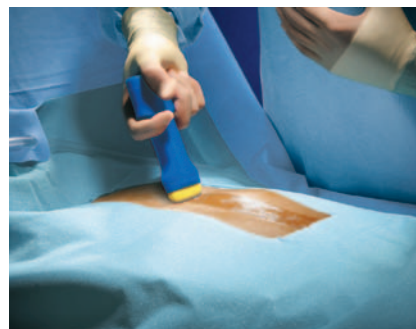
### Kimberly-Clark InteguSeal wins medical design award

InteguSeal, an innovative microbial sealant from Kimberly-Clark Health Care, has been awarded a prestigious medical design excellence award.

Designed to reduce the risk of skin flora contamination throughout a surgical procedure, InteguSeal Microbial Sealant uses a proprietary formulation to seal and immobilise pathogens to help protect against migration into an incision.

The US-based 2008 Medical Design Excellence Awards competition is organised and presented by Canon Communications LLC (Los Angeles) and recognises contributions and advances in the design of medical products. Entries are evaluated on the basis of their design and engineering features, including innovative use of materials, user-related functions that improve health care delivery and change traditional medical attitudes or practices, features that provide enhanced benefits to the patient and the ability of the product development team to overcome design and engineering challenges so the product meets its clinical objectives.

"We are honoured and delighted to be recognised by the MDEA judges for InteguSeal Microbial Sealant," said Kimberly-Clark Vice President of Global Sales and Marketing John Amat. "This award recognises the important work that medical device companies are doing to advance the design and functionality of products that contribute to improved patient outcomes and aid medical professionals on the front lines of delivering care."



## St Jude Medical

### St Jude announces CE Mark and launch of new guidewire

St Jude Medical has announced CE Mark approval and European launch of its line of HydroSteer hydrophilic-coated nitinol guidewires.

The HydroSteer line of guidewires features a lubricious hydrophilic coating which becomes slippery when wet, thereby reducing friction and enabling physicians to more easily manoeuvre the wires through the patient's vessels. Each wire in the HydroSteer line provides excellent steerability to help physicians navigate challenging vascular structures.

A radiopaque polymer jacket on the wire's nitinol core enhances the physician's ability to visualise the wire's location in the vessel. The core resists kinking while providing the flexibility physicians need to advance the wire through the vasculature. In addition, a torque device enhances steerability by aiding directional control. The torque device also has received CE Mark approval and is available for separate purchase.

"With the introduction of hydrosteer, physicians now may choose from a full complement of St Jude Medical guidewires used in interventional and diagnostic procedures," said Denis Gestin, president, International division.

