FDA Approves Covidien’s EverFlex Stent System for SFA/PPA Use

March 7, 2012—Covidien (Mansfield, MA) announced that the US Food and Drug Administration (FDA) has approved the EverFlex self-expanding peripheral stent system for use in the superficial femoral artery (SFA) and/or the proximal popliteal artery (PPA). The EverFlex system has been approved with a peripheral indication in international markets since 2006. It is now available in the United States, including a 200-mm stent length.

The clinical data supporting the FDA approval of the EverFlex system for use in the peripheral vasculature was obtained through the DURABILITY II trial that enrolled patients at clinical sites within the United States and Europe. DURABILITY II evaluated lesions up to 18 cm and tested the performance of a single long stent (up to 200 mm) in the SFA and PPA.

Covidien reported that the study results showed no major adverse events at 30 days and a 1-year stent fracture rate of 0.4%. Additionally, the primary patency rate at 1 year was 67.7% when analyzed by simple proportions of patients patent; using Kaplan-Meier time-to-event analysis, it was 77.2%.

“DURABILITY II is a landmark trial intended to study the patency and fracture resistance of placing a single nitinol stent in the superficial femoral artery,” commented Krishna Rocha-Singh, MD, National Coprincipal Investigator of DURABILITY II. “It provided the clinical evidence necessary to demonstrate that you can successfully treat long, complex lesions in the SFA with the EverFlex self-expanding peripheral stent.”

Abbott’s Absolute Pro Stent System Approved to Treat Iliac Artery Disease

March 7, 2012—Abbott Vascular (Santa Clara, CA) announced that the US Food and Drug Administration has approved the Absolute Pro vascular self-expanding stent system for the treatment of iliac artery disease. The Absolute Pro vascular stent system is indicated for the treatment of patients with de novo or atherosclerotic lesions in the native common iliac artery and native external iliac artery.

According to Abbott Vascular, Absolute Pro is a self-expanding nitinol stent system made with a flexible material to allow the stent to conform to challenging lesions. It also provides optimal stent visibility. The delivery system is designed to minimize friction during stent deployment and ensure precise stent placement at the lesion site.

Abbott Vascular stated that the approval is supported by results from the Absolute Pro arm of the MOBILITY trial, which demonstrated that the Absolute Pro device is safe and effective, even in patients with complex disease. MOBILITY is a prospective, nonrandomized, two-arm, multicenter study that evaluated the Absolute Pro (MOBILITY AP) and Abbott’s Omnilink Elite (MOBILITY OE) in patients with iliac artery disease.

In the Absolute Pro arm, 151 patients with iliac artery disease were enrolled at 33 centers in the United States. The company reported that the study met its primary endpoint, with a 9-month major adverse event rate of 6.1% ($P < .0001$). This result was found to be significantly lower than the performance goal of 19.5%, which was developed from published literature on previous iliac artery stenting studies. The major adverse event rate was defined as death due to any cause, myocardial infarction, clinically driven target lesion revascularization, and limb loss (major amputation only) on the treated side(s). The results of the Omnilink Elite arm of the study will be available later this year, advised the company.

“Iliac artery disease greatly impacts patients’ overall quality of life,” commented Tony S. Das, MD, Coprincipal Investigator of the MOBILITY trial. “The goal of treatment is to open narrowed iliac arteries to restore blood flow to the legs, thereby alleviating pain and improving the patient’s ability to walk farther and enjoy a more active lifestyle. With Absolute Pro, United States physicians now have an additional option that is proven safe and effective to treat many patients with this debilitating disease.”
FDA Announces Safety Label Changes for Statins

February 28, 2012—The US Food and Drug Administration (FDA) announced that it has approved important safety label changes for statins. Label revisions address adverse event information, drug interactions, and liver enzyme monitoring.

First, information about the potential for generally nonserious and reversible cognitive side effects (memory loss, confusion, etc.) and reports of increased blood sugar and glycosylated hemoglobin levels have been added to the statin labels. The FDA continues to believe that the cardiovascular benefits of statins outweigh these small increased risks.

Second, the lovastatin label has been extensively updated with new contraindications and dose limitations when it is taken with certain other medications that can increase the risk for muscle injury. The lovastatin dose limitation chart outlines the various interactions and dose limitation. The agency advised that health care professionals should refer to the drug labels for the latest recommendations when prescribing statins.

Finally, labels have been revised to remove the need for routine periodic monitoring of liver enzymes in patients taking statins. The labels now recommend that liver enzyme tests should be performed before starting statin therapy and as clinically indicated thereafter. The FDA has concluded that serious liver injury with statins is rare and unpredictable in individual patients and that routine periodic monitoring of liver enzymes does not appear to be effective in detecting or preventing serious liver injury.

The FDA Drug Safety Communication is posted on the agency’s website. It includes a summary of the data upon which the revisions are based, a chart outlining lovastatin dose limitations and drug interactions, and additional information for health care professionals and patients.

According to the FDA, these changes were made to provide the public with more information for the safe and effective use of statins and are based on the FDA’s comprehensive review of the statin class of drugs.

Single-ingredient products include Lipitor (atorvastatin, Pfizer Inc., New York, NY), Lescol (fluvastatin, Novartis Corporation, East Hanover, NJ), Mevacor (lovastatin, Merck & Co., Inc., Whitehouse Station, NJ), Altoprev (lovastatin extended-release, Schionogi Inc., Florham Park, NJ), Livalo (pitavastatin, Kowa Pharmaceuticals America, Inc., Montgomery, AL; marketed by Eli Lilly & Company, Indianapolis, IN), Pravachol (pravastatin, Bristol Myers Squibb Company, New York, NY), Crestor (rosuvastatin, AstraZeneca Pharmaceuticals LP, Wilmington, DE), and Zocor (simvastatin, Merck & Co., Inc.).

Combination products include Advicor (lovastatin/niacin extended-release, Abbott Laboratories, Abbott Park, IL), Simcor (simvastatin/niacin extended-release, Abbott Laboratories), and Vytorin (simvastatin/ezetimibe, Merck & Co., Inc.).

Covidien’s Solitaire FR Receives FDA Clearance

March 5, 2012—Covidien (Mansfield, MA) announced that the US Food and Drug Administration has granted 510(k) clearance for the company’s Solitaire FR revascularization device, intended for blood flow restoration to the brain in patients with acute ischemic stroke by mechanically removing blood clots from blocked vessels.

According to the company, the 510(k) application for the Solitaire FR device was based on the results of the SWIFT (Solitaire With the Intention for Thrombectomy) clinical study. In this comparison of two devices, the Solitaire FR device demonstrated superior performance to a commercially available mechanical clot retriever (Merci Retriever, Concentric Medical, Inc., recently acquired by Stryker Corporation, Kalamazoo, MI).

The SWIFT study randomly assigned 113 stroke patients at 18 hospitals to undergo clot removal with either the Solitaire FR or the Merci Retriever within 8 hours of stroke onset. The Solitaire FR showed a 2.5-times benefit in restoring blood flow to the brain, as determined by a blinded core lab; a 1.7-times improvement in poststroke neurological function; and a 55% reduction in mortality at 90 days, stated Covidien.

The SWIFT data were presented by Principal Investigator Jeffrey L. Saver, MD, at the International Stroke Conference in New Orleans, Louisiana, as previously reported in Endovascular Today.

“This new device heralds a new era in acute stroke care,” commented Dr. Saver. “We are going from our first generation of clot-removing procedures, which were only moderately good in reopening target arter-
ies, to now having a highly effective tool. This really is a game-changing result.”

Covidien advised that the Solitaire FR device will be available in the United States in April 2012. The device received CE Mark approval in Europe and has been commercialized internationally by Covidien since November 2009.

Control Medical’s Aspire Max Thrombus Aspiration System Cleared by FDA

February 28, 2012—Control Medical Technology (Park City, UT) announced that the US Food and Drug Administration has granted clearance for the company to market its Aspire Max thrombus aspiration system. The Aspire Max is described by Control Medical as a high-performance aspirator with integrated handles and valves that allow clinicians to instantly create, increase, decrease, slow, stop, or “pulse” aspiration force.

According to the company, the FDA clearance allows Control Medical to market the Aspire Max thrombus aspiration catheter system including an Aspire aspirator and a Max catheter in one package and/or Max aspiration catheters alone in multiple sizes with an indication to remove soft fresh thrombi, and emboli, from vessels in the peripheral vasculature.

The Max thrombus large-lumen catheters are available in multiple outer diameters and lengths and are designed to improve aspiration speed, force, and control.

AccessClosure’s MynxGrip Closure Device Approved

February 27, 2012—AccessClosure, Inc. (Mountain View, CA) announced the FDA approval and US launch of the MynxGrip vascular closure device (VCD).

According to AccessClosure, the MynxGrip VCD offers an active, extravascular, and patient-friendly vascular closure solution. The device incorporates the company’s Grip technology sealant to the distal end of the original Mynx sealant. The sealant actively grips and seals the arteriotomy while expanding and filling the tissue tract, providing a durable hemostasis.

The MynxGrip sealant consists of the same polyethylene glycol polymer used in the original Mynx sealant. Grip technology is a new configuration of PEG that adheres to the contours of the vessel wall, providing active closure of the arteriotomy. The MynxGrip sealant fully resorbs within 30 days. Grip technology has been used in international markets and is now commercially available in the United States, stated the company.

“There has been a long-standing perception that closure devices which ‘actively’ close the arteriotomy with sutures or clips provide greater security and have better results,” commented Stevan Himmelstein, MD. “Unfortunately, the tradeoff for these closure devices has been leaving foreign material permanently behind in the artery. MynxGrip is the first closure device that provides the benefits of an active, secure close while also being completely extravascular and bioabsorbable.”

Cook’s Zilver PTX Stent Approved in Japan

March 1, 2012—Cook Medical (Bloomington, IN) announced that it has received approval from Japan’s Pharmaceuticals and Medical Devices Agency to sell the Zilver PTX paclitaxel-eluting peripheral stent, which is indicated for treating peripheral arterial disease in the superficial femoral artery.

According to Cook, the Zilver PTX combines mechanical support via stenting with the drug paclitaxel to reduce the risk of restenosis. Data from the company’s multinational clinical trial conducted in Japan, the United States, and Germany were used to support regulatory submissions for the Zilver PTX in Japan, the United States, and Europe.

The device received CE Mark approval in August 2009 and is available in more than 45 countries. In the United States, it is under review by the Food and Drug Administration and is not available for sale, advised the company.

FDA Clears AngioDynamics’ NeverTouch Direct Kit

February 14, 2012—AngioDynamics, Inc. (Latham, NY) announced that the US Food and Drug Administration has granted 510(k) clearance for the NeverTouch Direct procedure kit for use with the company’s VenaCure EVLT (endovascular laser therapy) laser vein ablation system.

According to the company, the NeverTouch Direct kit allows a shorter procedure time for varicose vein
therapy by eliminating the need for a long guidewire or guiding sheath while continuing to treat patients with less pain and bruising compared to bare-tip fibers.

The NeverTouch Direct kit is indicated for endovascular coagulation of the great saphenous vein in patients with superficial vein reflux, treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremities. AngioDynamics expects to launch the kit in the summer of 2012.

ReCor Medical Receives CE Mark Approval for Paradise Renal Denervation System

February 20, 2012—ReCor Medical, Inc. (Ronkonkoma, NY) announced that its Paradise percutaneous renal denervation system has received CE Mark approval for the treatment of patients with resistant hypertension.

According to the company, the Paradise system includes a 6-F-compatible catheter with a cylindrical transducer that emits ultrasound energy circumferentially, allowing for a rapid and highly efficient renal denervation procedure. The device uniformly denervates all the way around the arterial wall while simultaneously cooling the endothelium to help enable a safe, consistent, and fast renal denervation procedure.

Thomas A. Mabin, MD, presented data from the first-in-man REDUCE clinical study at the TREND 2012 transcatheter renal denervation scientific meeting in Frankfurt, Germany. The data showed that systolic blood pressure was reduced by an average of 31 mm Hg in seven patients at 60-day follow-up after treatment with Paradise, stated the company.

“The initial results with Paradise are impressive,” commented Prof. Marc Sapoval, MD. “This degree of blood pressure reduction has significant health benefits for patients.”

ANCHOR Postmarket Registry Will Evaluate Aptus’ HeliFX

February 14, 2012—Aptus Endosystems, Inc. (Sunnyvale, CA) announced the start of the ANCHOR postmarket registry, which will evaluate the use of the company’s HeliFX aortic securement system. The company announced in November 2011 that it received 510(k) clearance from the US Food and Drug Administration for the HeliFX system for use during endovascular aneurysm repair (EVAR).

According to the company, the device’s EndoAnchor helical anchor technology enables independent endograft fixation to the aorta and mimics the suturing performed during open surgical repair of abdominal aortic aneurysms.

The global, multicenter, prospective ANCHOR registry will collect data on the treatment of abdominal aortic aneurysms and provide clinical knowledge for the optimal use of the HeliFX system. The registry will consist of two arms, “Primary” and “Revision,” which support the indications for use of the HeliFX system with commercially available endografts manufactured by Cook Medical (Bloomington, IN), Gore & Associates (Flagstaff, AZ), and Medtronic, Inc. (Minneapolis, MN).

The Primary group will characterize the HeliFX system placed at the time of endograft implantation for the prevention of graft migration and type 1 endoleak. The Revision group will characterize the HeliFX system in patients with previously implanted endografts that require treatment for graft migration and type 1 endoleaks.

The registry will enroll up to 1,000 patients at up to 75 sites in the United States and Europe in each arm of the registry. Patient data will be followed for up to 5 years. William Jordan, MD, and Jean Paul de Vries, MD, are the registry’s Principal Investigators in the United States and Europe, respectively, stated the company.

“The ANCHOR registry will prioritize the incremental value of the use of EndoAnchors in de novo EVAR patients with challenging proximal aortic neck anatomies that can lead to migration and type 1 endoleaks,” commented Dr. de Vries. “Moreover, EndoAnchors have been shown to be safe and feasible in revision surgery post-EVAR to solve inadequate proximal fixation and seal of
endografts. The ANCHOR registry will provide us with valuable longer-term data concerning improvement of endograft adaptation to the aortic wall.”

**Boston Scientific Launches TruePath CTO Crossing Device**

February 8, 2012—Boston Scientific Corporation (Natick, MA) announced the launch of the TruePath chronic total occlusion (CTO) device in the United States. The TruePath device is designed to facilitate the crossing of CTOs in the peripheral vasculature.

The company will begin marketing the product immediately in the United States and expects to launch the product in Europe and other international markets in the first half of 2012. Boston Scientific acquired the TruePath technology through its acquisition of ReVascular Therapeutics, Inc. (Sunnyvale, CA) in February 2011. The TruePath CTO device has received US Food and Drug Administration 510(k) clearance and CE Mark approval.

According to Boston Scientific, the TruePath CTO device features a rotating diamond-coated tip that is designed to break through occluded peripheral arteries and facilitate the placement of conventional guide-wires for treatment of peripheral lesions. The device is designed with an ultra-low 0.018-inch profile for optimal crossing. Once positioned, the distal tip rotates at 13,000 rpm to facilitate drilling through calcified lesions and other fibrous blockages. The company advised that the TruePath device requires no capital equipment and is available with an optional extension wire to facilitate catheter exchange and increase the working length beyond 300 cm.

The TruePath device was evaluated in the ReOpen clinical study, which was composed of 85 patients with peripheral artery lesions. Study results demonstrated that the device is safe and effective in facilitating the crossing of intraluminal CTOs after resistance or previous failed attempts with a conventional guidewire. In the study, technical success (defined as facilitation of CTO crossing) was achieved in 80% of patients, and improved postprocedure blood flow was observed in 82.4% of patients. Safety was demonstrated with a 98.8% rate of freedom from clinical perforation at the time of the procedure, stated Boston Scientific.

“CTOs are very challenging, requiring additional time, resources, and patient exposure to imaging contrast and radiation,” commented Jihad A. Mustapha, MD. “The TruePath device is an exciting new technology that allows me to effectively penetrate these difficult blockages with greater speed and ease, allowing access to untreated lesions and helping to improve overall patient outcomes.”

**AngioDynamics Launches DuraFlow 2 Chronic Hemodialysis Catheter**


According to AngioDynamics, the next-generation DuraFlow 2 is designed to provide higher blood flow over a longer time frame with lower recirculation rates. The 48-cm DuraFlow 2 allows for femoral catheter placement in patients of varying sizes. The catheter provides ease of insertion and sustained high-flow rates. A new rigid thermoplastic polyurethane luer provides increased durability, allowing for more secure fastening to dialysis machines. The device’s redesigned kit provides more convenience for hospitals’ inventory control and expands the product’s appeal to vascular access centers.

The new streamlined VP kit will be launched in the fiscal 2012 third quarter. The VP kit is designed to meet the needs of outpatient vascular access centers. Tray sizes for both the VP and basic kits have been reduced by approximately 30% for easier handling and storage within automated medical supply stations, the company stated.

**Cook’s Central Venous Catheters to Be Marketed With Cardinal Health’s Presource Procedural Kits**

January 30, 2012—Cardinal Health (Dublin, OH) and Cook Medical (Bloomington, IN) announced a 2-year, exclusive agreement for the North American distribution of Cook Medical’s central venous catheter (CVC) sets with Cardinal Health’s Presource customizable procedural kit.

Under the agreement, Cardinal Health and Cook
Medical will provide CVC procedural kits with either uncoated or Cook Spectrum CVC sets, which feature high flow rates and a comprehensive product line including power-injectable catheters. The companies stated that the partnership enables a cost-effective means to decrease the number of supplies needed to supplement standard CVC procedural kits.

Cook Medical’s Spectrum catheters are impregnated with the antibiotics minocycline and rifampin and meet the newly released 1A recommendation from the US Centers for Disease Control for reducing catheter-related bloodstream infections if maximal sterile barrier precautions have not helped a facility reach its infection prevention goal. Spectrum catheters have been shown to be five times less likely to produce infection than nonimpregnated catheters, stated the companies.

**Spectranetics to Market Thermopeutix’s Tapas Peripheral Infusion Catheter**

January 24, 2012—Spectranetics Corporation (Colorado Springs, CO) announced an agreement with Thermopeutix, Inc. (San Diego, CA) to commercialize the Thermopeutix Tapas catheter. The Tapas system is intended for targeted infusion of therapeutic and diagnostic agents in the peripheral vasculature.

According to Spectranetics, the Tapas catheter recently received 510(k) clearance from the US Food and Drug Administration. The device had been submitted for CE Mark approval for marketing in Europe. It will be launched in a limited number of hospitals in the United States and Europe during the first quarter of 2012.

The Tapas catheter features two compliant occlusion balloons that enable targeted local delivery of any physician-specified agent. It has the ability to adjust the treatment zone up to 300 mm, allowing for the treatment of long vessels with only one device and, in certain cases, multiple lesions with one device. The medication can be aspirated out of the catheter after treatment, providing localized intravascular treatment without systemic runoff.

The company noted that the Tapas catheter can be used in conjunction with Spectranetics’ laser atherectomy or other interventional devices. Clinical studies are currently underway to investigate whether debulking with laser or other atherectomy devices before drug delivery improves patient outcomes, stated Spectranetics.

“I am very excited to begin working with the new Tapas catheter,” commented Lawrence Garcia, MD. “Endovascular treatment is becoming an increasingly targeted therapy approach for our patients. We currently do not have a device that can provide local drug delivery while minimizing systemic effects and be adaptable to a wide variety of patients and anatomies. Although we are years away from the availability of other targeted therapeutic and diagnostic delivery systems in the United States, the Tapas catheter provides an opportunity for local drug delivery for our patient needs now.”

**US Pivotal Trial of PLC’s RenalGuard Begins Enrollment**

January 23, 2012—PLC Medical Systems, Inc. (Milford, MA) announced the start of enrollment in the CIN-RG trial, the company’s pivotal trial in the United States to study the efficacy of its RenalGuard Therapy and RenalGuard System in the prevention of contrast-induced nephropathy (CIN).

According to PLC, CIN-RG is designed as an adaptive, randomized controlled trial at up to 30 sites in the United States. Enrollment in the trial will include at least 326 patients and potentially up to 652 patients, depending on the outcome of a sample size re-estimation after 163 patients, which will ensure that the trial is sufficiently powered so that the final results are statistically meaningful. The United States study builds on two clinical trials by independent clinical investigators in Europe, both of which showed significant reductions in incident rates of CIN in at-risk patients through the use of RenalGuard compared to the current standard of care, stated the company.

The study’s Principal Investigators are Charles Davidson, MD; Richard J. Solomon, MD; and Roxana Mehran, MD. Michael Kim, MD, enrolled the trial’s first patient at Mount Sinai Hospital in New York City.

Dr. Mehran, who is Director of Interventional Cardiovascular Research at Mount Sinai, commented, “I am very excited to have this trial underway and overjoyed that Mount Sinai could enroll the first patient. CIN remains a real problem for patients undergoing cardiac catheterizations. RenalGuard trials give us the opportunity to examine a tool that could significantly reduce the incidence of CIN in our at-risk patients.”

Dr. Kim added, “RenalGuard offers us the potential for a method to reduce the incidence of CIN while allowing me as an interventional cardiologist to focus on the catheterization without having to worry that the contrast may be damaging the patient’s kidney.”
Covidien’s Solitaire FR Device Studied for Clot Retrieval in Stroke Patients

February 3, 2012—The American Stroke Association (ASA) announced data from the SWIFT study, which compared outcomes of treatment with the Solitaire flow restoration (FR) device (Covidien, Mansfield, MA) with the Merci Retriever device (Concentric Medical, Inc., which was recently acquired by Stryker Corporation, Kalamazoo, MI). Jeffrey L. Saver, MD, who is Principal Investigator of the SWIFT study, presented the data at the ASA’s International Stroke Conference in New Orleans, Louisiana. Covidien sponsored the SWIFT trial.

According to the ASA, the Solitaire FR device is a self-expanding, stent-based device that mechanically removes blood clots from blocked vessels after a stroke. After insertion into the clot via catheter, the device traps the clot and then both the device and clot are removed, restoring blood flow. The Merci Retriever uses a tiny corkscrew guided by a balloon-tipped wire to snare and remove the blood clot. Covidien’s Solitaire FR device is not yet approved in the United States, but it is available in Europe. The first-generation Merci Retriever received US Food and Drug Administration clearance in 2004.

The SWIFT trial was ended at the suggestion of a safety monitoring committee approximately 1 year earlier than planned due to significantly better outcomes with the new device, stated the ASA.

The trial enrolled 113 stroke patients at 18 hospitals in the United States between February 2010 and February 2011. The patients were randomly assigned to undergo clot removal with either device within 8 hours of stroke onset.

The average patient age was 67 years, and 68% of patients were men; 40% of patients had not improved with standard clot-busting medication before the study, whereas the remainder did not receive the medication at all. The time from the start of symptoms to the start of clot retriever treatment was 4.9 hours for Solitaire and 5.3 hours for Merci, on average. The study results account for this time difference.

“The experimental Solitaire FR device opened blocked vessels without causing symptomatic intracranial hemorrhage in 61% of patients compared with 24% of patients treated with the Merci retriever, a statistically significant difference,” commented Dr. Saver. “The use of the new device also led to better survival 3 months after stroke. There was a 17.2% mortality rate with the new device versus 38.2% with the older one.”

Additional statistically significant results showed that 2% of Solitaire patients had symptoms of bleeding in the brain compared to 11% of Merci patients. At 90-day follow-up, overall adverse event rates, including bleeding in the brain, were similar for the two devices. Also at 90 days, 58% of Solitaire patients had good mental/motor functioning compared to 33% of Merci patients. The Solitaire device also opened more vessels when used as the first treatment approach, necessitating fewer subsequent attempts with other devices or drugs.

“This heralds a new era in acute stroke care,” stated Dr. Saver. “We’re going from our first generation of recanalization procedures, which were only moderately good in reopening target arteries, to now having a highly effective recanalization device. This really is a game-changing result.”

Roll-In Data From Lombard Medical’s PYTHAGORAS AAA Trial Presented

February 24, 2012—Data from the roll-in phase of the PYTHAGORAS trial evaluating abdominal aortic aneurysm (AAA) repair using the Aorfix endovascular stent graft (Lombard Medical Technologies, Inc., Tempe, AZ) were presented at the VEITH Symposium in New York City in November and at the International Symposium on Endovascular Therapy in Miami Beach in January.

Thirty-day and 1-year follow-up data from the roll-in phase demonstrated no cases of the graft failing to seal against the artery wall; no cases of graft leakage, migration, or fracture; and, in all cases, the aneurysm sac decreased in diameter or remained stable after implantation of the Aorfix. The data were presented by Mark Fillinger, MD, at VEITH and William Gray, MD, at ISET.

According to Lombard Medical, PYTHAGORAS is the largest prospective, controlled study to include patients with highly tortuous aortic and iliac anatomies. The trial was designed to show the potential of Aorfix to treat both standard and difficult-to-treat AAA cases and consisted of two
groups. The roll-in group included 62 patients with aortic neck angles < 60°, and the study group consisted of 150 cases with aortic neck angles ≥ 60°.

Dr. Fillinger, who served as Principal Investigator of PYTHAGORAS, commented, “The Aorfix device has given excellent results in patients with typical anatomy, based on prospective independent monitoring. Although neck angles were < 60° in all ‘roll-in’ patients, 65% were > 45°, which is already at a challenging level.”

Dr. Gray added, “Clinical practice is increasingly moving toward endovascular aneurysm repair and away from surgery, and devices that both perform well and are flexible, such as Aorfix, will play an important role as a highly effective option for patients with more complex anatomy and increase the number of patients for whom a nonoperative AAA repair is possible.”

**Initial Data Presented on Eurocor’s Freeway Drug-Eluting Balloon**

February 2, 2012—Eurocor GmbH (Bonn, Germany) announced that data from its ongoing FREEWAY study were presented at a company-sponsored symposium during the 2012 Leipzig Interventional Course in Leipzig, Germany. On January 25, the company announced that the first patients were enrolled in the FREERIDE study. Both studies are evaluating Eurocor’s Freeway drug-eluting balloon (DEB).

According to Eurocor, FREEWAY is a multicenter, open, prospective randomized trial investigating the prevention of restenosis with a nitinol stent followed by treatment with the Freeway DEB versus stenting with a nitinol stent followed by uncoated balloon angioplasty postdilatation for the treatment of superficial femoral artery (SFA) or popliteal artery (PI segment) lesions. Prof. Josef Tacke, MD, is the Lead Manager of the study, which is being conducted at 15 European sites.

The study is investigating the rate of clinically driven target lesion revascularization (TLR) in 200 patients with de novo lesions that require stenting. All patients will receive treatment with nitinol stent implantation, and then they will be randomized in a 1:1 ratio to postdilatation with the Freeway DEB or an uncoated balloon. At 6 and 12 months, the patients will undergo duplex follow-up, as well as an angiographic follow-up in a subgroup at 6 months. An independent core lab will perform the analysis.

Currently, 82 patients have been enrolled. Six-month follow-up is available for 23 patients, 13 of whom have been treated with a nitinol stent and DEB. The trend shows a very low TLR rate of 7.7%. The second group of 10 patients, which was treated with a nitinol stent and uncoated balloon angioplasty, has shown a TLR rate of 20%.

Prof. Tacke commented, “In-stent restenosis is a serious problem in the SFA and PI segment. Drug-eluting balloons might be an option to prevent restenosis at an early stage for patients that need to be stented. The first insights are very promising, and we are looking forward to the final results of the study.”

According to Eurocor, the FREERIDE study is lead managed by Prof. Karl-Ludwig Schulte, MD. The first patients were successfully treated with the Freeway DEB in this randomized, prospective, multicenter clinical study that will enroll a total of 280 patients at 25 sites worldwide. The aim of the FREERIDE trial is to investigate the rate of clinically driven TLR using the paclitaxel-eluting Freeway balloon in comparison to an uncoated balloon in de novo or restenotic lesions in the SFA or PI segment.

Patients with occluded, stenotic, reoccluded, or restenotic lesions 4 to 15 cm in length will be treated with the Freeway DEB or with an uncoated balloon. Six- and 12-month duplex follow-up will be carried out, as well as angiographic follow-up in a subgroup at 6 months. This is an ongoing study, and the first angiographic analysis and results are expected in spring 2013, stated the company.

**Conformable GORE® TAG® Thoracic Endoprosthesis**

**INDICATIONS FOR USE:** The GORE® TAG® Thoracic Endoprosthesis is intended for endovascular repair of isolated lesions (not including dissections) of the descending thoracic aorta, in patients who have appropriate anatomy including: Adequate iliac/femoral access; Aortic inner diameter in the range of 16 - 42 mm; ≥20 mm non-aneurysmal aorta proximal and distal to the lesion. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials; Patients who have a condition that threatens to infect the graft. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and adverse events.