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Gore kicks off Thoracic Branch Endoprosthesis feasibility study

By Omar Ford, Staff Writer

W.L. Gore & Associates (Flagstaff, Arizona) is vying for a device approval that could potentially address off label thoracic branch procedures. On Tuesday, the company spoke with *Medical Device Daily* regarding the news that the first patient in the Gore Tag Thoracic Branch Endoprosthesis LSA Feasibility Study, a U.S.-based, multi-center feasibility trial, has been enrolled.

"We are planning to build toward pivotal, to show safety and efficacy globally with this device," Ryan Takeuchi, Aortic Business Unit Leader Gore Medical, told *Medical Device Daily*. "The benefit of the Gore Tag Thoracic Branch Device is for the left subclavian right now physicians would have to cover the left subclavian for some patients or have to surgically go in and cut the patient and

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New improved CT scanners lower dose, expand indications

By John Brosky, European Editor

NANCY, France — Someone should compile a case study. In the annals of medical technologies, the comeback of computer tomography (CT) in the face of crippling criticism is extraordinary.

The response of manufacturers of CT scanners to societal concerns over an alarming increase in the exposure of patients to radiation was both rapid and sweeping. In just three years the dose for routine exams has been cut in half.

Much was accomplished by software with the iterative reconstruction of low-dose images that some clinicians call the magic button.

Yet radiation is also being reduced significantly by ongoing changes to hardware. For example, against common sense,

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FDA clears Kiva VCF Treatment System for spinal fractures

By Amanda Pedersen, Senior Staff Writer

The first new approach to treating vertebral compression fractures (VCFs) in more than a decade has received FDA 510(k) clearance. **Benvenue Medical** (Santa Clara, California) says its Kiva VCF Treatment System, recently FDA-cleared, is an implant-based solution for vertebral augmentation and a departure from balloon kyphoplasty (BKP).

"We are excited to bring the Kiva System and its clinical benefits to the large and growing population of VCF patients in the U.S. market," said Robert Weigle, CEO of Benvenue Medical. "The VCF segment has little Level 1 clinical data, and we are proud to have sponsored one of the largest randomized studies in this space to date."

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WASHINGTON ROUNDUP

Warning letter hits Mercy IRB for procedures, record-keeping lapses

By Mark McCarty, Washington Editor

A college English professor, Mason Cooley, PhD, is credited with having said that documents "create a paper reality we call proof." The same might be said of electronic records, but the lesson was apparently lost on **Mercy Hospital IRB** (Chicago) which found itself in possession of a Jan. 10 FDA warning letter citing the IRB for procedural and record-keeping lapses in its review of device clinical trials. The IRB responded to the inspectional findings, but the agency found them all lacking, and requested documentation that staff had been trained in the revised procedures.

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INSIDE

Kiva

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Weigle told *Medical Device Daily* that the company plans to launch the Kiva VCF Treatment System at the **Society of Interventional Radiology** (SIR; Fairfax, Virginia) meeting in San Diego in March. That's also when the data will be presented for the first time, he said. The device will be sold in the U.S. through a direct sales force, he added.

VCFs are most often caused by osteoporosis, and there are 700,000 osteoporosis-related vertebral compression fractures annually in the U.S. alone, representing a large patient population which is only expected to continue growing as the population ages. Other causes of VCFs include trauma and malignant bone tumors that cause the spine to collapse.

BKP, the current standard of care for treating VCFs, was introduced to the market in the 1990s, Weigle noted, and there has been "little innovation in the space since then." Not only is the Kiva System the first new approach to treating VCFs, but it is also the first truly structural support device that offers support within the vertebrae rather than using a lot of bone cement, Weigle said.

While the specifics of the data will not be released until the SIR meeting in March, the company did note that in clinical studies the Kiva System met or exceeded the performance of BKP.

"Physicians and patients both benefit by having Kiva as a new, minimally invasive treatment option for painful VCFs. I'm excited to have been a part of KAST, an FDA-approved pivotal trial of the Kiva System, and I look forward to presenting the results at the Society for Interventional Radiology meeting in March," said Sean Tutton, MD, co-principal investigator in the KAST Study (Kiva System as a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial) and professor of radiology and surgery at the **Medical College of Wisconsin** (Milwaukee). KAST compared Kiva to the **Medtronic** (Minneapolis) KyphX System for balloon kyphoplasty.

VCFs occur when a vertebra (bone in the spine) cracks, fractures or collapses. Over the last 10 years, the approaches to treating VCFs have included conservative therapies or vertebral augmentation, traditionally performed with balloon kyphoplasty or vertebroplasty. The Kiva System features a cylindrical implant made from PEEK-OPTIMA, representing a new approach to vertebral augmentation. The traditional approaches rely solely on a bolus of bone cement, the company noted.

The Kiva System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit.

The Kiva implant is designed to provide structural support to the vertebral body and a reservoir to direct and contain bone cement during vertebral augmentation. The implant is delivered percutaneously over a removable guidewire in a continuous loop into the vertebral body through a small diameter, single incision. The amount of the Kiva implant delivered is physician-customized during the procedure.

The Kiva System received CE Mark in 2008 and it is distributed by Zimmer Spine in Europe.

"The feedback has been excellent, we're partnering with Zimmer over there . . . with FDA clearance now in hand, along with the data soon to be announced, enthusiasm will continue to grow," Weigle said.

Founded in 2004, Benvenue Medical is privately held and funded by Versant Ventures, DeNovo Ventures, Domain Associates and Technology Partners. Its first products are designed for the treatment of VCFs and degenerative disc disease, which have combined revenues of $1.6 billion globally. //

COURT REPORT

St. Joseph Health to pay $16.5M to settle whistleblower claims

Staff Report

Stein Mitchell Muse & Cipollone said that St. Joseph Health System/ St. Joseph London has agreed to pay $16.5 million to the U.S. and the Commonwealth of Kentucky to settle allegations by the law firm's clients that St. Joseph London performed unnecessary heart procedures on patients to maximize reimbursement from Medicare and Medicaid.

The settlement today was the result of the efforts of three whistleblowers: Michael Jones, MD, Paula Hollingsworth, MD, and Michael Rukavina, MD. As board certified cardiologists practicing in Kentucky, they uncovered the healthcare fraud involving patients who unknowingly received false diagnoses and unnecessary procedures at St. Joseph London. The unnecessary procedures performed on patients include invasive open-heart bypass surgeries, diagnostic cardiac tests and catheterizations, and implanting pacemakers and coronary stents.

The U.S. joined their lawsuit on Jan. 17, 2014. As part of the settlement with St. Joseph London said, the United States alleges a facility-wide scheme to perform medically unnecessary procedures on patients and pay kickbacks to the St. Joseph London cardiologists and their interrelated businesses under the pretext of professional service agreements. The Department of Justice also joined in the lawsuit to litigate claims against the non-settling defendant cardiologists and their related entities.

The settlement partially resolves a multi-year investigation by numerous government agencies, including the Department of Justice, the United States Attorney's Office for the Eastern District of Kentucky, the Department of Health and Human Services, and the Federal Bureau of Investigation in a continuing commitment to patient safety and quality of care. //

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