



Behind-the-scenes devices key in transplant surgery

By AMANDA PEDERSEN

Medical Device Daily Senior Staff Writer

Nearly 11 months ago to the day, Jeff Kepner made history as surgeons performed the first U.S. double-hand transplant surgery on him at the **University of Pittsburgh**. With the one year anniversary of Kepner's surgery approaching, *Medical Device Daily* spoke last week with the surgeon whose invention helped assure Kepner's doctors last May that the surgery was a success.

The Cook-Swartz Implantable Doppler Flow Probe is such a simple device, yet it performs a very important job, especially during complex transplant procedures – monitoring blood flow. William Swartz, MD, a plastic and hand surgeon with 38 years experience, told *MDD* he helped develop the device from his basement in the early '80s. The device is now sold through **Cook Vascular** (Vandergrift, *See Transplant, Page 5*

Needle stick incidents still prevalent despite reforms

By OMAR FORD

Medical Device Daily Staff Writer

Despite the development of safer devices, and tighter rules surrounding sharp medical applications, the rate of "needle stick" hasn't decreased but instead has seen an increase, according to a report published in the most recent issue of the *Journal of the American College of Surgeons*.

According to data from the report, operating rooms (OR) saw an increase of 6.5% of needle stick incidents stretching from 1993 to 2006. The study analyzed percutaneous injury surveillance from 87 hospitals in the U.S., comparing injury in surgical and nonsurgical settings before and after the Needlestick Safety and Prevention Act standards were adopted in 2000.

"I think the main message behind this study is that there has been no decrease in the occurrences of needle *See Needle, Page 3*

Washington roundup

PTO may double the term for provisional patent applications

By MARK McCARTY

Medical Device Daily Washington Editor

The U.S. Patent and Trademark Office has watched as provisional patent applications have died on the vine at an increasing rate over the past few years and is proposing to extend the window for provisionals from 12 to 24 months as a way of not only encouraging higher quality patent filings, but also to cut some of the clutter out of the agency's operations.

According to a notice in Friday's edition of the *Federal Register*, the percentage of provisional patent applications that make it all the way to full-blown applications dropped from 61.7% in 2004 to 50.8% four years later, even as total provisionals rose from a bit more than 102,000 to more than *See Washington, Page 7*

Urovalve's Surinate bladder device aims to improve quality of life

By LYNN YOFFEE

Medical Device Daily Staff Writer

It has been more than a half a century since the Foley catheter was invented and patients with bladder management problems haven't seen an improvement in devices to help drain their bladders in all of that time. Enter **Urovalve** (Newark, New Jersey), a company that's developed a bladder management system which is poised to dramatically improve the quality of life for people with urinary retention.

Urinary retention – the inability to empty the bladder – is caused by a number of temporary and chronic conditions. Men who suffer from this must insert a Foley several times a day to drain their bladders.

Urovalve was just granted an investigational device *See Urovalve, Page 8*

Don't miss today's MDD Extra: Neurology



MEDTRONIC'S COREVALVE FACES A \$74M INFRINGEMENT VERDICT	2
TRINTECH WRAPS UP \$34.5 MILLION SALE OF HEALTHCARE DIVISION.....	3



*Financings roundup***CleveX receives second half of \$1.7M commitment from investors****A Medical Device Daily Staff Report**

CleveX (Columbus; Ohio) reported that it has received the second half of the \$1.7 million promised late last year by investors during the company's Series B funding round.

Investors wanted to break their commitment into two equal tranches "to make sure the company continued its progress toward full commercialization," said Sam Finkelstein, who became chief executive of CleveX in July 2009.

CleveX makes ExiClip — a device that uses a hook to raise the skin, then quickly snips off a lesion for a biopsy and seals the wound with a metal clip, which is removed in about two weeks.

CleveX began to market its device last year to dermatologists who could use it to take skin biopsies. But dermatologists were slow to adopt the device, which was cleared for sale by the FDA in May 2007.

The company changed its target market focus after Finkelstein arrived. "We shifted our focus to primary care

physicians, and OB/GYN and internal medicine physicians," he said. "It's been very successful for us."

For primary care physicians, "we can eliminate suturing for them," Finkelstein said. "This is a suture-less product that dramatically reduces the amount of time for the procedures."

Finkelstein described the target market change as one of two pivotal events for CleveX in the last year. The other was signing **Physician Sales & Service** (PSS; Jacksonville, Florida) a publicly traded company as its exclusive distributor in the U.S. At the time, PSS had more than 700 field sales representatives, 41 sales regions and 29 distribution centers.

In July 2008, the company completed its Series A financing round with a \$14 million raise from investors like Plymouth Venture Partners (Ann Arbor, Michigan), and Ohio TechAngel Funds (Columbus).

The company that employs 12 people, including consultants, will use the second tranche of its Series B funding to continue its sales growth. By the end of February, it had trained 85 percent of the PSS sales force. "We've made good progress," Finkelstein said. "We have about 800 new using customers now. We will continue to build inventories." ■

Transplant*Continued from Page 1*

Pennsylvania), part of the **Cook Group** (Bloomington, Indiana).

The Doppler was developed to assess vascular patency. An implantable 20 MHz ultrasonic probe properly aligned in a suturable cuff, provides direct vessel monitoring of microvascular anastomoses at a specific site along a designated vessel. According to the company, a 1 mm piezoelectric crystal placed directly on the blood vessel provides an effective means of monitoring flow with improved specificity of vessel origin. A troubleshooting protocol including cable and channel verifiers, along with an internal self test circuit in monitor, allows for patient assessment with increased confidence, Cook says.

"For 10 years I made the cuffs for this Doppler device in my basement," Swartz told *MDD*. He then wrote papers about that experience and eventually Cook became interested in it through word of mouth, he says, and was able to take the device through FDA approval and then to market.

Behind the name

Swartz said the Doppler is named after Austrian physicist Christian Doppler who described the Doppler shift. As Swartz puts it, the Doppler shift explains "why a train whistle changes its sound when it's approaching and when it's leaving." In other words, the received frequency is higher compared to the emitted frequency during the approach, it is the same at the instant of passing by, and it is lower when it is leaving.

So this little tiny 1 mm crystal sits on the blood vessel and listens to the blood flow go by, Swartz explained. "And when there's no blood flow, there's no sound."

The Cook-Swartz Implantable Doppler Flow Probe is different than the Doppler ultrasound devices that are used above the skin, usually to detect blood clots in the legs, Swartz said. The latter device picks up blood vessels within a longer range, whereas the implanted crystal device only listens to blood flow in the immediate proximity to the crystal and thus eliminates confusion, he explained.

A man with new hands

Kepner's story was featured last year in *People Magazine* in the July 27, 2009 issue. The story tells of a man who woke up in a hospital bed in 1999 with his wife leaning over him, telling him he had been asleep for three weeks. Then 47, he had come down with an infection – Strep A bacteria – that destroyed his hands and feet. Last May 4, Kepner went through a nine-hour operation during which a team of 10 surgeons attached the wrists and hands of Jeff Keen to what was left of Kepner's forearms, according to *People*. Keen was a 23-year-old organ donor from Pennsylvania who died unexpectedly. Kepner became the first double-hand transplant recipient in the U.S. and the 12th worldwide, the magazine reported.

Being able to immediately identify a blood flow problem after a transplant surgery is important, Swartz said, because there is a critical window of about 4 hours during which the surgeon can go back in and fix the problem before the

See Transplant, Page 6

Transplant

Continued from Page 5

tissue dies. He added that it's not just important to monitor blood flow when doing transplants between people – such as in Kepner's case – but also when transplanting tissue on the same person. For example, Swartz said, a common transplant is to take a person's big toe off to make a thumb. "There's only two chances to do that . . . there's only two big toes," he said. "That makes it a high value [procedure], something we want to make sure to do everything we can to ensure the safety of that operation."

Compared to other methods

Other methods of monitoring blood flow post-op include looking at the skin and measuring the temperature of the skin, Swartz noted. These techniques are helpful, he said, but not quite as specific as using the Doppler. Another advantage to using the Doppler is that the device is so easy to use, the blood flow can be monitored by staff on a routine nursing floor, he said.

Prior to the Doppler being used, patients would be taken to an ICU where nursing personnel could monitor them around the clock – looking at the skin, measuring its temperature, maybe pricking it with a pin to see if it bleeds, or pressing on the skin to see if it blanches. "That's an expensive way to monitor a patient," Swartz said, noting the high cost of an ICU stay.

"Since the use of this technology, patients are monitored with this device on a routine nursing floor and nurses don't have to make any subjective decisions about what color the skin is or what temperature the skin is," he said. "Instead, they rely on the all or no sound of the Doppler."

Andy Cron, VP of Cook's surgery strategic business unit, told *MDD* that in many cases where the Doppler is used to monitor blood flow after a transplant procedure, the surgery is very complex and time-consuming; for instance, in head and neck plastic surgeries (to remove a tumor) where the surgeon is bringing free tissue flap up from another part of the body. "After a long surgery like that you wouldn't want that tissue to die on you," Cron said, emphasizing the importance of being able to accurately monitor blood flow after the procedure.

When Swartz is using the Doppler to monitor a post-op transplant patient, he typically monitors the blood flow once every 15 minutes for the first couple of hours, he told *MDD*. Then, he monitors the flow every hour for the first two or three days. That way, if a blood flow problem is detected, he would still have time to go in and fix it – which would actually mean taking the patient back to the operating room, opening up the blood vessel, and taking out the clot or unkinking the vessel to restore blood flow – before the four-hour window closes.

Swartz noted that the Doppler also is useful in small organ transplants, and transplants in children where the blood vessels are small and there isn't any good way to

monitor the tissues.

According to Swartz, one in 10 patients that have a microvascular transplant surgery will experience a blood clot or loss of blood flow. Prior to the availability of the Doppler device, only 50% of those flaps could be saved, he said. Since the use of this device, more than 75% of the clots or blood flow problems are corrected.

"There are some other devices out there that measure blood flow as well as this device," Swartz said. "They are typically placed on top of the skin to measure changes in the capillaries . . . but they have other drawbacks that make them somewhat less reliable and more costly than this device."

Cook's Biodesign graft

Another device transplant surgeons are finding useful, especially in complex cases like Kepner's double-hand transplant last year, is the Biodesign 8-Layer Tissue from **Cook Biotech** (West Lafayette, Indiana), which is designed to signal surrounding tissue to promote remodeling.

Cook says the Biodesign product line offers a new alternative in which the graft communicates with surrounding cells to encourage tissue growth across the scaffold, allowing the body to restore itself. Biodesign remodels into fully vascularized tissue that becomes stronger over time, providing a permanent repair without a permanent material, the company said. The Biodesign technology combines the best attributes of a biological graft – resistance to infection and complete remodeling – with the added benefits of moderate price, ease of use and widespread availability, Cook says.

In the past, plastics were often used in these types of procedures, Cron said, and those materials stay with the body for long periods of time. With the Biodesign, all that is left behind is natural tissue, he said.

One type of surgery where the Biodesign is particularly useful, he noted, is breast reconstruction surgery in women who have lost a breast due to cancer. "During the reconstruction phase, they essentially need to recreate or put these expanders in and expand the tissue there and create breast there," Cron said. "And a lot of times they are deficient of some tissue there . . . they will use a Biodesign material . . . it gives them more tissue to deal with."

The Biodesign material is also proving to be useful in pediatric patients who require chest-wall reconstruction because they are born with a small hole in their diaphragm. If surgeons use a plastic material it won't grow with the patient, Cron said. "What they used to do is treat that with a mesh – more of a plastic type mesh – and they would go back procedure after procedure because the kid grows."

While Kepner surely still has a long recovery road ahead of him, he can now do things most of us take for granted – cooking, playing catch, playing video games, and going bowling with his teenage daughter. Swartz told *MDD* he doesn't know whether or not the Doppler Flow Probe was

See Transplant, Page 8

Urovalve

Continued from Page 1

exemption (IDE) approval for its Surinate Bladder Management System, a device that's inserted just once a month and allows men to urinate at will, with no urine retention bags or other external devices.

"We describe the three functional benefits of the Surinate Bladder Management System as freedom, function and control," Harvey Homan, PhD, president/CEO of Urovalve, told *Medical Device Daily*. "They become free of external tubes and bags, free from having to insert a catheter to empty the bladder as with intermittent catheters. They have function of the bladder because it's allowed to fill and be emptied normally. And that's important for maintaining bladder health. Compared to the Foley, there are no external tubes and the bladder doesn't drain continuously as with the Foley. Once inserted it stays in place for up to 30 days."

Homan, who was recently appointed to the National Institutes of Health's Center for Scientific Review special emphasis panel for Urology and Small Business, said this is the first trial to test Surinate in humans. It will include up to 25 men with urinary retention problems that are either chronic, due to conditions such as spinal cord injuries, or acute, due to problems such as benign prostatic hyperplasia. He said that the company has already received word that this trial, assuming positive results, will be sufficient to achieve CE mark.

"It's a critical study for us," he said. "We're enthusiastic about generating data and seeing outcomes. We've have very favorable reactions to the concept of the device and we've done significant work in the lab to assess function."

Subbarao Yalla, MD, a professor of surgery (urology) at **Harvard Medical School** (Boston), and a member of Urovalve's board, told Homan that "If the device gets FDA clearance it will be the biggest advance in urinary catheters in more than 60 years."

The Surinate is a relatively simple device made of silicone. At the bladder end, the Surinate catheter expands into a diamond-shaped cage with an opening that allows urine to enter and travel through the bladder neck sphincter and external sphincter to the valve. The valve is operated by a hand held switching magnet that is about the size of the small finger. The patient will hold that external magnet within 3 cm-4 cm of the check valve magnet to open the valve and allow urine to flow out through the urethra. When the magnet is moved away, the valve closes.

"The bladder is allowed to fill and empty normally, which doesn't happen with a Foley in place," Homan said.

The Surinate can be inserted in the doctor's office in much the same way as a Foley with aid of a water soluble lubricant that can include a local anesthetic. Sedation is not required.

"There is a dire need in healthcare for Surinate. The fact is that, today, men who have a urinary retention condition have to rely on a 50-year-old product called the Foley catheter, or they must suffer through intermittent catheterization

four to six times a day. Surinate is designed to have several critically important advantages not only compared to the half-century-old product but also compared to the inconvenient products on the market today," said Homan.

When asked if the Surinate could be considered as a permanent implant, Homan said it's being assessed as a disposable not to be used longer than 30 days.

One of the biggest problems with catheterization is the risk of urinary tract infections. Homan said the company intends to conduct a future study to assess the frequency of UTIs with Surinate compared with Foley catheters.

The first study site is the **Shepherd Center** (Atlanta), a hospital that specializes in treatment, research and rehabilitation for people with spinal cord injury and brain injury.

The study, which starts this month, will assess patients 30 days after implantation and again at 30 after removal. ■

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Transplant

Continued from Page 6

a factor in the success of Kepner's procedure, but it likely provided assurance to the surgical team that the tissue was receiving proper blood flow. ■

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People in the News

- **CAS Medical Systems** (Branford, Connecticut) said that Kenneth Weisshaar was named to the board and will also serve as a member of its audit committee. Weisshaar is currently a director of Orthofix International. CAS Medical Systems makes devices for non-invasive patient monitoring.

- **MedSynergies** (Dallas) has named Joe Boyd, former VP of North American Sales and Operations at Perot Systems, and the recent chairman of Healthlink, to non-executive chairman of the MedSynergies board of directors. MedSynergies makes hospital-physician alignment solutions that leverage relationships, revenue cycle services and technology for healthcare organizations.

- Thomas D'Amico, MD, has been elected to the position of chairman of the **National Comprehensive Cancer Network** (NCCN; Fort Washington, Pennsylvania) board of directors. D'Amico, who was previously vice-chairman of the board, is director of clinical oncology program director of thoracic surgery, and professor in the department of surgery at Duke Comprehensive Cancer Center. The NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers.