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Ablation Catheter Treats Cardiac Arrhythmias

A new ablation catheter with an irrigated flexible tip is designed to reduce risk factors associated with the delivery of cardiac ablation therapy.

The FlexAbility ablation catheter is based on flexible catheter tip technology that reduces the rate of complications associated with ablation procedures through its ability to

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New Technology Could Revolutionize Treatment of Sepsis

A small microchannel device for processing blood could be used to remove problematic endotoxins, helping to prevent sepsis. Under development by researchers at Oregon State University (OSU; Corvallis, USA; www.oregonstate.edu), the prototype device is a processor, about the size of a coffee mug, constructed of thousands of microchannels the width of a human hair that provide accelerated heat and mass transfer as fluids move through them. The microchannels are coated with what the researchers called "pendant polymer brushes," repeating chains of carbon and oxygen atoms anchored to microchannel inner surface that

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MRI Brain Scans Detect Early Parkinson's

British researchers have developed a simple and fast magnetic resonance imaging (MRI) technique that has potential for diagnosing Parkinson's disease in the early stages.

The researchers demonstrated that their new MRI approach can identify individuals who have early-stage Parkinson's disease with 85%

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Imaging Capsule Can Replace Prepping for Colonoscopy

A new X-ray imaging capsule has the potential to safely produce high-resolution 3D images of the colon without requiring patients to go through a bowel cleansing process beforehand. The low-dose X-ray scans produced by the Check-Cap system are generated when movement in the colon is detected and are transmitted to an external recorder unit worn by the patient.

See article on page 4

Image: The Check-Cap imaging system safely reconstructs high-resolution 3-D images of the colon using an ingestible capsule and ultra-low-dose X-ray-based imaging technology.

Image: Courtesy of Check-Cap

"Black Box" Recorder Monitors Operating Rooms

A "black box," similar to that used in the airline industry, could improve patient safety and outcomes by identifying where errors occur in the operating room (OR) and teaching surgeons how to prevent them. Developed at St. Michael's Hospital (Toronto, ON, Canada; www.stmichaelshospital.com), in collaboration with

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Finger Sensor Warns of Impending Respiratory Distress

Photoplethysmogram (pleth) technology allows clinicians to monitor SpO_2, pulse rate, and respiration rate through a single integrated finger sensor. The Nellcor Respiration Rate System is a continuous, noninvasive

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Ultrasound Technology Helps Dissolve Blood Clots

A new system allows controlled and selective infusion of physician-specified fluids, including thrombolytics, for the treatment of pulmonary embolism (PE).

The EkoSonic Endovascular System is an ultrasound-facilitated catheter-directed low-dose fibrinolysis device

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Novel Cardiac Pacemaker Needs No Battery

A prototype self-powered cardiac pacemaker stimulated a living rat's heart using electrical energy converted from its body movements.

Developed by researchers at the Korea Advanced Institute of Science and Technology (KAIST; Daejeon, South Korea; www.kaist.ac.kr) and

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INSIDE

PRODUCT NEWS

To receive prompt and free information on products, log on to www.LinkXpress.com or fill out reader service form located on last page

OPERATING ROOM LAMP
ACEM

The STARLED7 NX features a CRI of 95, clear luminosity at 160,000 lux, and a color temperature of 4,500 K. The lamp can produce a perfect illumination under every condition, generating shadowless, clear and IR-free light with low consumption for enhanced working conditions.

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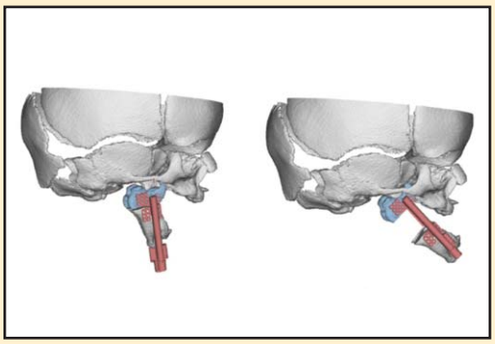

SURGICAL PLANNING SOFTWARE
3D Systems

The Medical Modeling Virtual Surgical Planning (VSP) software tools combine production-grade 3-D printing with personalized surgery tools. The result is a virtual-to-actual operating room in which surgeries can be planned, tested, refined, and delivered economically.

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FOOT/ANKLE OSTOMY IMPLANTS
4WEB Medical

The Osteotomy Truss System includes the largest offering of 3-D-printed foot and ankle osteotomy implants available. The system features 74 size options for internal bone fixation and osteotomies, opening wedge osteotomies of Hallux Valgus, and Cotton opening wedge osteotomies.

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Findings of Canadian Mammography Study Disputed By American Radiology and Breast Imaging Societies

A new study reveals that annual mammography failed to reduce breast cancer mortality in women compared with physical examination or routine care.

Researchers at the University of Toronto School of Public Health (Canada; www.dlsph.utoronto.ca) reviewed 25-year follow-up data of the Canadian National Breast Screening Study (CNBSS), and compared breast cancer incidence in women who did or did not undergo mammography screening. Study participants included 89,835 women (aged 40–59), randomly assigned to mammography (five annual mammography screens) or control (no mammography). Women in their 40's in the mammography arm and all women in their 50's in both arms received annual physical breast examinations.

The results showed that during the entire study, 3,250 women in the mammography group developed breast cancer, compared with 3,133 in the control group; 500 deaths due to breast cancer occurred in the screened patients versus 505 in the control group, resulting in a hazard ratio (HR) of 0.99. After 15 years of follow-up, a residual excess of 106 cancers was observed in the mammography arm, attributable to over-diagnosis. The study was published on February 11, 2014, in *BMJ*.

"Although the difference in survival after a diagnosis of breast cancer was significant between those cancers diagnosed by mammography alone and those diagnosed by physical examination screening, this is due to lead time, length of time bias, and overdiagnosis," concluded lead author Anthony Miller, MD, and colleagues. "Overall, 22% of screen detected invasive breast cancers were over-diagnosed, representing one over-diagnosed breast cancer for every 424 women who received mammography screening in the trial."

The study drew a quick response from the American College of Radiology (ACR; Reston, VA, USA; www.acr.org) and the Society of Breast Imaging (SBI; Reston, VA, USA; www.sbi-online.org). In a joint statement, the two organizations characterized the results as an "Incredibly misleading analysis based on the deeply flawed and widely discredited CNBSS." According to the ACR/SBI statement, the 32% rate of cancer detection by mammography is an extremely low number consistent with poor-quality mammography, and that mammography alone should detect twice that many cancers.

The organizations also noted that a prior outside review of the CNBSS confirmed the poor quality of mammography in the study. The ACR/SBI statement also questioned the randomization process used by CNBSS, pointing out that all women had a clinical breast examination prior to allocation, providing investigators with advance knowledge about which patients had breast lumps or enlarged lymph nodes.

Pelvic Organ Prolapse Surgeries Equally Effective

A new study has found that popular transvaginal surgeries for treating pelvic organ prolapse deliver comparable rates of success, while pelvic floor muscle training (BPMT) did not alter outcomes.

Researchers at the Cleveland Clinic (OH, USA; my.clevelandclinic.org), Duke University (Durham, NC, USA; www.duke.edu), and other institutions conducted a study to compare sacrospinous ligament fixation (SSLF) and uterosacral ligament suspension (ULS), the two most commonly performed transvaginal surgeries to correct apical vaginal prolapse and stress urinary incontinence. The multicenter study randomized 186 women with vaginal prolapse in stage 2, 3, or 4, to SSLF and 188 to ULS between 2008 and 2013 at nine US medical centers. The behavioral intervention was randomization to receive perioperative BPMT (186 patients), or usual care (188 patients). The two-year follow-up rate was 84.5%.

The results showed that two years after surgery, women who underwent SSLF and ULS had similar rates of success (60.5% and 59.2%, respectively), and similar rates of adverse events (16.7% and 16.5%). In addition, BPMT did not improve urinary symptoms at six months or prolapse outcomes at two years. The authors cautioned that their findings may not apply to women who do not undergo concomitant midurethral sling for treatment of stress incontinence, or to women undergoing transvaginal mesh or abdominal mesh augmented prolapse repairs. The study was published on March 11, 2014, in *JAMA*.

"Most pelvic surgeons have a personal preference for SSLF or ULS," said lead author Matthew Barber, MD. "The study results suggest that surgeons can stick with the procedure they are most comfortable with or tailor one of the two surgeries to the individual patient, and expect similar results."

Female pelvic floor disorders are a spectrum of conditions including pelvic organ prolapse and urinary incontinence. Approximately 300,000 surgeries for prolapse are performed annually in the United States alone, with SSLF and ULS being the two most widely used vaginal procedures. The SSLF procedure suspends the vaginal apex to the sacrospinous ligament using an extraperitoneal approach, whereas the ULS suspends the vaginal apex bilaterally to the proximal remnants of the uterosacral ligaments using an intraperitoneal approach. As a stand-alone therapy, BPMT is an effective treatment for pelvic floor symptoms with incontinence cure rates as high as 78% and improved prolapse stage in up to 17%.

Thoracic Stent Graft Treats Aortic Dissections

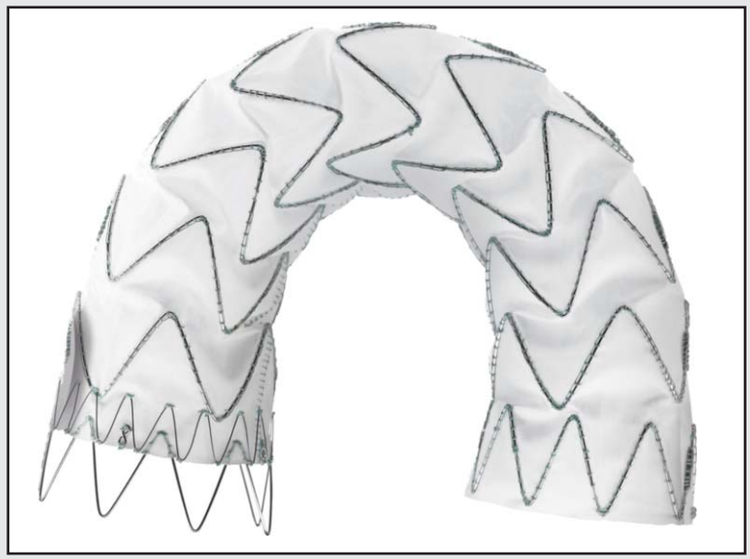
An innovative stent graft system has been expanded to treat dangerous tears in the upper segment of the body's main artery.

The Valiant Captivia Thoracic Stent Graft System can now be used for the treatment of type B aortic dissections, a serious cardiovascular condition associated with high morbidity and mortality in which the upper segment of the aorta has become torn along the innermost layer of the vessel wall. The system features a unique proximal tip-capture mechanism, which enables controlled deployment and accurate placement of the stent graft, as well as complete apposition to the vessel wall, regardless of angulations or over-sizing.

The size matrix of the Valiant Captivia Thoracic Stent Graft System has been expanded, with 11 new proximal FreeFlo tapered pieces, increasing configuration possibilities by 30% to address a wider range of patient anatomies. The line extension enables physicians to use the system in tapered aortas, which account for approximately 20% of all thoracic aortic aneurysm cases. The new pieces all taper by 4 mm along their approximately 150-mm length, and have proximal diameters that range from 26–46 mm.

The Valiant Captivia Thoracic Stent Graft System is a product of Medtronic (Minneapolis, MN, USA; www.medtronic.com), and has been implanted in over 50,000 patients world-wide since its initial 2005 launch in Europe. The additional system components for the treatment of aortic dissection have recently been approved by the US Food and Drug Administration (FDA) as well as receiving the Conformité Européene (CE) marking of approval, following several important studies.

"Acute type B aortic dissection is a potentially life-threatening condition that historically has been treated with either medical therapy or, when necessary, through invasive surgical techniques," said Joseph Bavaria, MD, professor of surgery, director of the thoracic aortic surgery program at the University of Pennsylvania (Philadelphia, USA; www.upenn.edu), and principal investigator of the DISSECTION study. "The trial we conducted shows that endovascular repair with the Valiant Captivia System provides a safe, effective and potentially life-saving treatment option for acute dissection patients."



"The anatomy of the thoracic aorta is complex and unique to every individual," said Matt Thompson, MD, professor of vascular surgery at St. George's Hospital (London, United Kingdom; www.stgeorges.nhs.uk) and primary investigator for the MOTHER registry study. "For patients with tapered aortas, thoracic endovascular aortic repair is not always straightforward and requires careful device sizing to ensure treatment success. The addition of tapered pieces to the Valiant Captivia System provides physicians with more options to confidently and effectively accommodate both straightforward and challenging anatomies."

Image: The Valiant Captivia thoracic stent graft system (Photo courtesy of Medtronic).

Robotic-Assisted Hysterectomy Reduces Hospital Readmission

Women undergoing robotic-assisted hysterectomy are significantly less likely to be readmitted to a hospital than women receiving laparoscopic, open, or vaginal hysterectomy, according to a new study.

Researchers at Lehigh Valley Health Network (Allentown, PA, USA; www.lvhn.org) identified 2,554 women with benign disease who had undergone a hysterectomy between January 2008 and December 2012. The 2,554 women were grouped by route: robotic-assisted laparoscopic hysterectomy (601 women), laparoscopic hysterectomy (427), vaginal hysterectomy (332) and abdominal (1,194) hysterectomy. Based on clinical records, the 30-day readmission rates, estimated blood loss (EBL), overall lengths stay (LOS) in the hospital, and total readmission costs were determined for each of the four surgical methods.

The results showed that the readmission rates for robotic, vaginal, laparoscopic, and open were 1.0%, 2.4%, 2.5%, and 3.5%, respectively. EBL, LOS, and sum of cost were less in the robotic cohort compared to the other three cohorts. The reasons for readmission identified included fever or infection, wound complications, comorbidities, vaginal bleeding, uncontrolled pain, and bowel issues. The study was published online on October 21, 2013, in the *Journal of Minimally Invasive Gynecology*.

"Recently published comparative effective research in robotic surgery has compared the learned curve of laparoscopy to the learning curve of robotic-assisted surgery," said lead author Martin Martino, MD. "Much of the benefit is due to the availability of 3-dimensional vision with improved dexterity. The purpose of our study was to remove that bias and evaluate quality outcomes after the learning curve for all patients having a hysterectomy for benign disease."

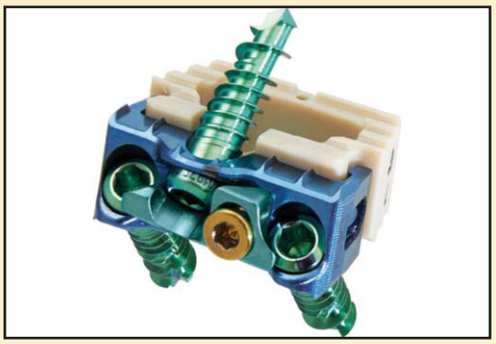
Hysterectomy, or surgical removal of the uterus, is one of the most common surgical procedures for women in the United States. Approximately 600,000 hysterectomies are performed each year, primarily to address benign conditions such as noncancerous tumors, pelvic pain, and abnormal uterine bleeding.

DRUG-RELEASING BALLOON
Biotronik

The Passeo-18 Lux features a highly flexible, low chronic outward force design and low-profile 4F delivery system. The device combines an uncoated balloon catheter with a balloon coating that enables optimal drug transfer to the target de novo and restenotic lesion tissue.

ENDOVASCULAR SYSTEM
EKOS

The EcoSonic system allows low-dose thrombolytic treatment in PE patients using a mini-ultrasound device in a catheter designed to deliver drugs. The device speeds up dissolving of clots by accelerating therapeutics into thrombus, allowing for reduced dose compared with standard care.



ANTERIOR CERVICAL DEVICE
Zimmer Spine

The Optio-C system consists of one PEEK IBF spacer, one anterior cervical plate, and three bone screws. The system maximizes fusion with a load-sharing interface and multiple implant footprints, and because it has no profile, soft tissue irritation is reduced for less invasive ACDF procedures.

Neurological Status Monitor Supports Surgical Patient Safety

A novel device monitors anesthetized patients neurological status in a wide array of surgical procedures where full monitoring may not be indicated, cost effective, or feasible.

The Evoked Potential Assessment Device (EPAD) assesses the neuromuscular junction (NMJ) by recording somatosensory evoked potentials (SSEPs), which are particularly effective in revealing damage to peripheral nerves during surgery caused by the way the patient is positioned on the surgical table. Involuntary compressing or stretching of peripheral nerves, or compromised blood supply to the nerves, can all lead to damage if the patient's position remains uncorrected. The condition is known as positioning effect.

By flagging SSEP changes that are consistent with positioning effect, the system allows caregivers to examine waveforms and adjust the patient's position to avoid nerve injury during anesthesia. The EPAD displays real time waveform data and graphical displays gathered via surface electrode packages that allow selective monitoring of integrated NMJ testing, including train of four, single simulation, and post-tetanic count. Bluetooth wireless technology allows easy set-up, control, and integration of the system into current operating room practices. The EPAD is a product of SafeOp Surgical (Hunt Valley MD, USA; www.safeopsurgical.com), and has been approved by the US Food and Drug Administration (FDA).

"We are excited to bring neurological monitoring to a greater population of surgical patients in the US market," said Curt LaBelle, MD, MBA, president of SafeOp. "Just as cardiac function and respiratory function are monitored in surgical procedures, we believe that nerve function monitoring will become standard of care in the future, resulting in fewer adverse events for patients."

Positioning effect occurs when the body is in certain positions for an extended period of time with the body's weight compressing or stretching nerves or blood vessels; an example of PE is when you wake from sleep with a numb arm. When sleeping, the brain monitors nerve function and wakes you up before permanent damage occurs. When under anesthesia, however, the brain cannot wake you up, and damage can continue and become permanent. As surgeries become longer and more complex, and utilize sophisticated technologies such as robotic assistance, a greater potential for positioning effect exists.

Image: A tablet display showing the EPAD status of the patient (Photo courtesy of SafeOp Surgical).

LED Lamp Lights Up Operating Field

A new light emitting diode (LED) operating room (OR) light produces perfect infrared free light, with excellent color temperature and low power consumption.

The STARLED7 NX LED is composed of 49 next-generation LEDs circularly placed and split into seven reflectors (with 7 LEDs in each one), and other 8 LEDs positioned radially around the handle. Light field dimensions are controlled via an optoelectronic management system that has no mechanical parts, adjusting field diameter to assure excellent sharpness of details in the operating area. Another important innovation is the microprocessor-controlled ACRIS system, which regulates the STARLED7 NX electrical output curves so that the power remains unaltered over time, ensuring that the LEDs maintain a longer life cycle of around 50,000 hours.

The high illumination level reaches 160,000 lux, with a color-rendering index of 95 and a color temperature of 4,500 K, allowing it to reproduce the exact chromatic scale of the colors of the human body. An ambient light-up ENDO system situated on the upper part of the lamp provides adjustable illumination levels according to the different use, and is particularly suitable during minimal invasive surgery (MIS) by visualizing the microscopic operating field as well as the surrounding environment clearly.

All functions are managed via the digital I–SENSE control panel positioned on the Cardanic shaft structure, controlling power, light intensity, light spot diameter dimension (focusing), the ENDO light, and depth of field for full visualization of the operating field and deep cavities. An optional SYNC mode is available to synchronize controls among combined lamps, such as a STARLED7 NX twin dome configuration, and STARLED7 NX with STARLED5 NX or STARLED3 NX lights. An optional remote control is useful for managing all the functions from a distant position.

Lamp position is ergonomically adjustable via both a central and lateral handles, assuring stability and constant illumination even during movement. The removable and sterilizable central handle can also house a video camera; thanks to ACEM-Video-System-Management (AVSM), the STARLED7 NX is compatible with all the cameras and monitors offered by ACEM. The lamp has been designed taking in consideration laminar flow and IS manufactured with a smooth and resistant material that makes cleaning quick, easy, and complete. The STARLED7 NX LED is a product of ACEM Medical Company (Bologna, Italy; www.acem.it).