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Novel SLN Tracer Maps Breast Cancer Metastasis

A new study describes how a novel sentinel lymph node (SLN) radiotracer helps determine breast cancer spread by targeting a specific antigen. Researchers at Beijing Cancer Hospital (BJC; Beijing, China; www.bjcancer.org) and Peking University Cancer Hospital & Institute (Beijing, China) conducted a retrospective

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Innovative Magnetic Platform Expedites Gallbladder Removal

A novel magnetic surgery system grasps and retracts tissue and organs in laparoscopic cholecystectomy procedures, facilitating access and visualization of the surgical site.

The Levita Magnetic Surgical System is comprised of a magnetic grasper device with a detachable tip and a magnetic controller. The grasper is inserted into the abdominal cavity via a small incision; once the magnetic tip reaches the gallbladder, the surgeon deploys it, attaching it to the body and the fundus of the gallbladder, and removes the grasper. The surgeon then uses the magnetic controller to maneuver and lift the gallbladder via a magnetic field, without

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Ultrasonic Shears Help Complex Procedures

Next generation ultrasonic shears provide optimal efficiency for easier dissection, faster transection, and more secure sealing. The Harmonic HD 1000i shears offer a seamless combination of precision, strength, and efficiency in numerous surgical specialties, including hepato-pancreato-biliary, thoracic, colorectal, gynecologic oncology, and other complex laparoscopic and open procedures. The device hand piece is integrated into the

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Intraventricular Assist Device Measures Blood Flow Directly

A new left ventricular assist device (LVAD) provides direct flow measurement, which may give clinicians the ability to detect potential patient problems earlier. The aVAD is surgically implanted in proximity to the heart, with one end attached to the left ventricle, while the other end is attached to the aorta.

See article on page 3

Image: The aVAD intraventricular axial flow LVAD

Image: Courtesy of PulseCath

Hand & Wrist MRI System Gets Market Approval

A novel hand and wrist imaging system has received CE Mark (Conformité Européenne) approval for the European market, and is now on sale in the European Economic Area (EEA).

The novel hand and wrist Magnetic Resonance Imaging (MRI) imaging system was developed by a life-science startup company, and previously received U.S. Food and Drug Administration (FDA) approval.

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Focused Ultrasound Device Helps Treat Essential Tremor

An innovative device uses magnetic resonance imaging (MRI) guidance to deliver focused ultrasound into the thalamus, the area of the brain thought to be responsible for tremor.

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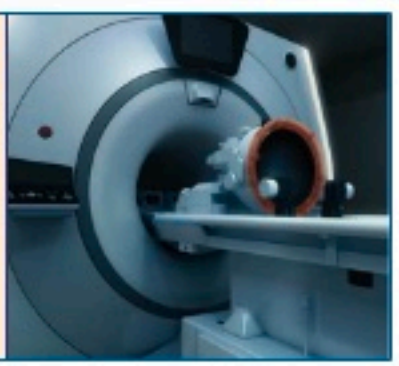

New Standards Released for Digital Projection Radiography

The US NEMA standards organization has published a new standard for medical imaging device manufacturers designing and manufacturing X-Ray equipment for projection radiography.

This new standard presents the minimum equipment requirements to facilitate quality control of Computed Tomography (CR) and Digital Tomography (DR) equipment at the facility level.

The new US National Electrical Manufacturers Association (NEMA; Arlington, VA, USA; www.nema.org) NEMA/MITA XR 30-2016 standard is intended for medical digital radiography, and medical X-Ray diagnostic imaging radiography. The standard was

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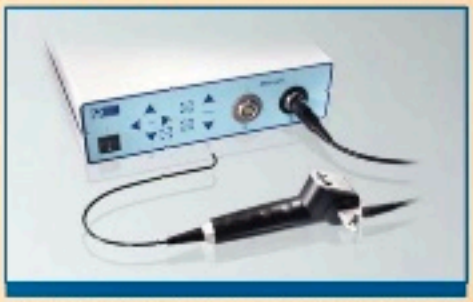
INSIDE

GLOBETECH MEDIA

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

VIDEO NASOLARYNGOSCOPE
Henke Sass Wolf



The HSW video nasolaryngoscope is based on CMOS chip-on-the-tip technology, and features integrated LED for optimal illumination. Its ultra-slim ergonomic design allows for gentle insertion, easy handling, and perfect control, making it suitable for all ENT applications.

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OR SYSTEMS INTEGRATION
Olympus

The ENDOALPHA increases efficiency and improves the ergonomics, communication, and information systems for medical teams in endoscopy suites and ORs. The SmartGuide navigation is designed to revolutionize the way surgeons and nurses interact with technology in the OR.

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SURGICAL LIGHT
Trumpf

The iLED 7 uses 3D sensor technology to ensure its light field size and intensity remain consistent regardless of the distance between it and the surgical site. It can be operated using a touch screen wall panel, wireless tablet, or from the sterile light handle, including acoustic feedback.

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LED Surgical Lamp Illuminates Operating Field

An innovative surgical lamp grants a homogeneous and shadowless light thanks to next generation light emitting diode (LED) technology.

The STARLED3 NX surgical lamp is composed of three reflectors that produce a well-blended and intense cone of light that can be focused through automatic adjustment of the light spot diameter. The resulting visual area is perfectly illuminated with a well-blended and intense (130.000 lux) cone of light with a color temperature (CCT) of 4.500 °K and a color rendering index (CRI) of 95. Despite the intensity, the lamp maintains a low energy consumption of just 69W, and is thus suitable for countless applications, including dentistry, gynecology, dermatology, general medicine, and surgery. The LED's maintain a life cycle of about 50,000 hours.

All functions are managed via the digital I-SENSE control panel, including power, light intensity, light spot diameter dimension (focus), and depth of field (DoF) adjustment for a full visualization of the operating field and deep cavities. The I-SENSE panel can also be used to synchronize the controls of combined lamps, such as a double STARLED3 NX (twin dome) configuration, or the STARLED3 NX combined together with a STARLED5 NX or a STARLED7 NX surgical lamp. An ENDO function gives the possibility to use the STARLED3 NX for minimal-invasive endoscopic surgery.

The slim, practical, and compact design provides ergonomic handling, making it easy to move and position. The lamp has also been designed taking in consideration laminar air flow in the operating room, resulting in a smooth and resistant material composition that makes cleaning quick, easy, and complete. The STARLED3 NX is a product of ACEM Medical Company (Bologna, Italy; www.acem.it), and is available in a ceiling mounted version (single, double, or together with other STARLED NX lamps); a wall mounted version; and a trolley mounted version powered by the proprietary rechargeable ACEM battery powered system (ABPS).

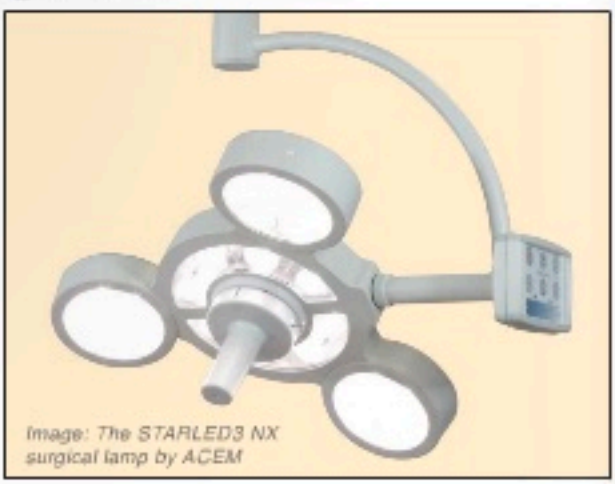

Image: The STARLED3 NX surgical lamp by ACEM

The ABPS battery system is wholly contained within the trolley base, with a control panel on the structure that allows management of all fundamental parameters, including residual charge, type of power supply, recharge status, and electrical power supply presence. The battery is recharged by an automatic charger with a maximum charging time of about 8 hours. An electronic control allows for automatic switching from electric power supply to battery power supply, so that STARLED3 NX can be used as a high performance mobile unit.

Nasoalveolar Molding Reduces Need for Cleft Lip Surgery

Researchers at the Loyola University Health System (Chicago, IL, USA; www.loyolamedicine.org) conducted a retrospective cohort study of 276 patients with complete unilateral and bilateral cleft lip and palate (U/BCLP) to compare the risk of early secondary nasal revision surgery following NAM and surgery – which consisted of cleft lip repair and primary surgical nasal reconstruction – versus surgery alone. The NAM treatment group consisted of 172 patients with UCLP and 71 patients with BCLP, whereas the non-NAM-prepared group consisted of 28 patients with UCLP and 5 with BCLP.

The results showed that the risk of secondary nasal revision for patients with UCLP was 3% in the NAM group and 21% in the non-NAM group. The risk of secondary nasal revision for patients with BCLP was 7% in the NAM group compared with 40% in the non-NAM group. Using multicenter averages, the researchers found that overall non-NAM revision rates were 37.8% for UCLP and 48.5% for BCLP. The study was published in the June 2016 issue of *The Journal of Craniofacial Surgery*.

"NAM is a technique that molds the patient's lip, nose and gums, decreasing the width of the cleft and contouring the nose before surgery is performed. This makes the surgery easier to perform and now has been shown to improve outcomes and reduce cost," said lead author plastic and reconstructive surgeon Parit Patel, MD. "Surgery always has a certain element of risk and the use of NAM reduces complications and the overall number of surgeries. This results in a potentially healthier child, which is really the ultimate goal."

Cleft lip and palate are two of the most common major birth defects, resulting from incomplete closure of tissues of the face during development; the cause is unknown in most cases. NAM is based on an oral plate similar to a dental retainer that is typically implanted in a baby's mouth four to five weeks after delivery, helping to correct the deformity by reducing the size of the cleft before surgery is performed.

Vaginal Insert Offers Alternative Treatment for Fecal Incontinence

A novel vaginal insert for bowel control eliminates the need for surgery or an in-office procedure for the treatment of female fecal incontinence (FI). The second-generation Eclipse System is comprised of a vaginal insert in the form of an inflatable balloon that is placed in the same location as a tampon or a diaphragm. The insert is composed of a base portion, an inflatable balloon portion, an inflation tube, and a self-closing Luer valve connection. The base portion positions the balloon and helps maintain the placement of the insert in the vagina. The balloon itself is made of thin walled silicone, with an enclosed, non-body contacting polyurethane liner to minimize air loss. The silicone inflation tube terminates in the self-closing Luer valve that connects to the patient pump.

The pump itself is fitted with a removable regulating valve that controls the amount of air introduced to the inflatable balloon. During inflation, the pump is squeezed seven to ten times to adequately fill the balloon, with any excess air vented out by the regulator. When inflated, the balloon exerts pressure through the vaginal wall, occluding the rectal area and providing immediate bowel control. The patient can inflate and deflate the device at home when needed, thus reducing the number of FI episodes and protecting from unwanted stool passage. The device is removed periodically for cleaning.

The insert is initially fitted using a sizing tool to assist with customizing insert size, and is inflated to the correct volume by a clinician to determine the correct regulator valve. A trial insert is available to allow patients to evaluate the therapy before deciding whether it works for them. The system is available in three base sizes and two balloon sizes, and is intended for women 18–75 years old who have had four or more FI episodes during a two-week period. The Eclipse System is a product of Pelvalon (Sunnyvale, CA, USA; www.pelvalon.com), and has been approved by the US Food and Drug Administration (FDA).

"With this FDA clearance for our next-generation Eclipse, we are excited to initiate the first phase of our commercial launch in select centers of excellence," said Miles Rosen, CEO and co-founder of Pelvalon. "We believe that this early phase of partnership with thought and practice leaders in the field of pelvic floor disorders will ensure a smooth expansion down the road."

"Eclipse is a nonsurgical therapy offering immediate bowel control that can be used early in the treatment pathway," said Holly Richter, MD, director of the division of urogynecology and pelvic reconstructive surgery at the University of Alabama (Birmingham, USA).

FI is the inability to control bowel movements and is a common problem, especially among older adults. It affects women about twice as often as men, most probably due to childbirth, nerve or muscle damage in the pelvic region, or gastrointestinal disorders such as irritable bowel syndrome (IBS). First-line treatments include dietary changes, exercise, and medication; if the issue persists, patients may need to move on to more invasive and costly treatments, such as surgery, surgical implants or injections.

Next-Generation Cervical Disc Treats Degenerative Disease

A new artificial disc system is designed to provide a long term, flexible alternative for cervical disk replacement procedures. The Rhine cervical disc system features a one-piece compressible elastomeric polymer core with dome-shaped, plasma-coated endplates and a central-split keel that are intended to minimize wear and tear between the polymer core and metal endplates. Fabricated using a proprietary molding technology, the monolithic compressible polymer core design was shown to be comparable to the natural cervical disc when subjected to biomechanical testing.

The system also feature a streamlined instrumentation kit that simplifies the surgical technique by integrating both disc trialing and keel cutting into a single instrument, and also includes a built-in adjustable stop that allows for customized anterior or posterior positioning of the disc, based on surgeon preference. The Rhine cervical disc system is a product of K2M (Leesburg, VA, USA; www.k2m.com), and has received the European Community CE marking of approval.

"We are excited to receive a CE mark for our Rhine cervical disc technology, as it represents an important regulatory milestone event for K2M as we continue to build our product portfolio and penetrate the global spine market with innovative techniques and technologies," said Eric Major, President and CEO of K2M. "We look forward to further expanding our international product offering, and will remain focused on the complex spine category across all of our international markets."

"The Rhine cervical disc system is manufactured through a proprietary over-molding process of elastomeric polymer that differentiates the system from the competitive offering," said principal inventor of the Rhine, orthopedic surgeon Casey Lee, MD. "The first single and multi-level surgical procedures using the Rhine system were recently completed in Belgium and Germany. We are committed to showing successful clinical results and are initiating a prospective observational clinical study in multiple sites throughout Europe."

Heart Disease Etiology Impacts Catheter Ablation Outcomes

A new study reveals that cardiomyopathy etiology impacts the long-term outcomes of catheter ablation procedures. Researchers at Alfred Hospital (Melbourne, Australia; www.alfred.org.au), St Bartholomew's Hospital (London, United Kingdom; www.bartshealth.nhs.uk), and other institutions conducted a study to examine the impact of cardiomyopathy etiology on long-term outcomes of catheter ablation in 101 patients between 2002 and 2014. The patients suffered from known heart disease (KHD; 77 patients) and idiopathic dilated cardiomyopathy (IDCM; 24 patients). All patients had a left ventricular ejection fraction (LVEF) lower than 45%.

The results showed that at three-year follow-up, the IDCM group showed less functional impairment and improved LVEF than the KHD group. Super responders, with an ejection fraction improvement of more than 15%, were overwhelmingly found in the IDCM group, and demonstrated greater AF control. The IDCM group also had significantly less all-cause mortality (1.3%) than the KHD group (17%). The study was published online on December 28, 2015, in the *Journal of Cardiovascular Electrophysiology*.

"Idiopathic dilated cardiomyopathy was associated with greater AF control and improvement in symptoms and LVEF, compared to patients with known heart disease post AF ablation," concluded lead author Sandeep Prabhu, MD, MBBS, of the Alfred Hospital, and colleagues.

AF is a medical condition that can lead to serious adverse events, such as thrombi travelling from the heart to obstruct arteries supplying the brain, causing stroke, or other parts of the body causing tissue damage. AF affects an estimated one percent of the population, with nearly three million AF patients in the United States and six million AF patients in Europe.