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I N T E R N A T I O N A L

Implant Enables Stem Cells to Grow Cartilage

A novel off-the-shelf cartilage regeneration solution helps the body to regenerate true hyaline cartilage and bone.

The CartiHeal Agili-C implant is intended for the treatment of focal articular cartilage and osteochondral defects. The implant scaffold, made of coral, reproducibly regenerates

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Real-Time Tracking Device for Soft Tissue Radiotherapy Receives Approval

New US clearance expands the indications for which clinicians will be able to use a real-time tracking device for monitoring motion during radiotherapy treatments for cancer. Varian Medical Systems (Palo Alto, CA, USA; www.varian.com) has received 510(k) clearance from the US Food and Drug Administra-

tion (FDA) for a Calypso soft tissue Beacon transponder that can help enhance the precision of radiotherapy and radiosurgery treatments for cancer. The new transponders, which are the size of a grain of rice, can be implanted within soft tissue throughout the body, with the exception of the lung. The Calypso

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New Laparoscopic Bowel Resection Procedure

A novel laparoscopic bowel lifting technique method could help introduce single-incision laparoscopic surgery (SILS) for low anterior resection of rectal cancer. Developed by researchers at Yokohama City University Medical Center (Japan; www.yokohama-cu.ac.jp), the laparoscopic bowel-lifting (LBL) technique

Cont'd on page 6

Snake-Like Endoscope Extends Surgeons' Reach

A new surgical endoscope offers snake-like abilities that allow surgeons to reach sites in the anatomy that were previously inaccessible by straight instruments. The highly articulate and multilinked endoscope is projected to expand minimally-invasive surgery (MIS) techniques into many types of surgical procedures.

See article on page 4



Image: The Flex System is the first surgical endoscopy device with snake-like abilities that allow it to reach places that straight instruments simply cannot

Algorithm Reduces CT For Pediatric Appendicitis

Implementation of an algorithm designed to diagnose pediatric patients with suspected appendicitis reduces the utilization of computed tomography (CT) imaging scans, without affecting diagnostic accuracy. The Mayo Clinic Children's Center (Rochester, MN, USA) researchers published their study's

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Predictive Monitoring Safeguards Chronically Ill Patients

A newly-introduced remote vital signs monitor uses a sophisticated predictive algorithm for cardiac interpretations on the fly. The OSTAR A300 remote telehealth system provides cloud-based monitoring powered by a predictive algorithm of BP readings to determine cardiac arrhythmia, valve function disease, and coronary artery disease (CAD).

Cont'd on page 4



Novel Implant Preserves Knee Ligaments

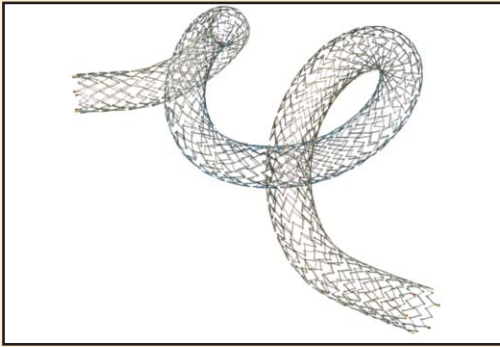
A new total knee replacement (TKR) system enables the natural function of the ligaments of the knee to be preserved. The Vanguard XP TKR system consists of a femoral component made of Co-Cr-Mo, two styles of tibial trays/plates with a locking bar, and dual bearings machined from polyethylene

Cont'd on page 4

Innovative Wound Dressing Wraps Burn Wounds

A new nanometric biomaterial coating hugs body contours like cling-wrap, preventing bacteria from colonizing wounds. Researchers at Tokai University (Tokyo, Japan; www.u-tokai.ac.jp) developed the nanosheets from poly-L lactic acid (PLLA), a biodegradable polyester that when centrifuged

Cont'd on page 3



SELF-EXPANDING STENT Biotronik

The Pulsar-18 offers 4F introducer sheath compatibility for stent diameters of up to 7 mm and lengths of up to 200 mm. The Pulsar-18 is designed to have high bending and axial flexibility, as well as a low crossing profile that allows use in tight lesions of the SFA.

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SMOKE EVACUATION SYSTEM Bovie Medical

The Smoke Shark II features a modern design, and minimizes exposure to smoke plume during electrosurgical procedures, increasing safety and reducing hazard. The cost-effective system is designed for maximized filter life, as well as reliable, surgical efficiency.

LINKXPRESS.COM HMI-11-14 241



SURGICAL LIGHTING Bowin Medical

The LEDtech features a minimally invasive surgery lighting mode, as well as low energy consumption. The flexible system offers true white light, pure light, and cool light, easy and flexible configurations, remote controller, and a long life of over 30,000 hours for the bulbs.

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Slim Surgical Lamp Provides Full-Size Illumination

A new surgical lamp utilizes next generation light emitting diode (LED) technology to provide excellent visual comfort and working conditions.

The STARLED3 NX surgical lamp is suitable for a range of diagnostic and surgical applications, including in the dental sector, gynecology and obstetrics, dermatology, and general medicine. Three reflectors produce a well-blended and intense (130,000 lux) cone of light with a color temperature of 4,500 K and a color-rendering index (CRI) of 95. Despite the intensity, the STARLED3 NX maintains a low energy consumption of just 69 W, even as 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 (focusing), and depth of field (DoF) adjustment for a full visualization of the operating field as well as deep cavities; an ENDO function is available

for endoscopy. The I-SENSE panel can also be used to synchronize 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.

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 airflow in the operating room, resulting in a smooth and resistant material composition that also makes cleaning quick and easy. 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 that can also be battery operated.

Image: The STARLED3 NX surgical lamp (Photo courtesy of ACEM)



Surgical System Enhances Partial Knee Replacement Options

A patellofemoral joint (PFJ) robotics-assisted surgery application provides a full suite of partial knee replacement options.

The Navio surgical system is intended for patients who may be suffering from early to mid-stage osteoarthritis (OA) and choose partial knee replacement as an alternative to total knee replacement (TKR). The addition of the PFJ application further expands the system's indications. The system uses a computerized tomography (CT)-free, robotics-assisted approach. An open implant architecture design allows users to select a number of different manufacturers' implants.

The system provides precise robotic control via an intelligent, handheld, computer-assisted bone cutting tool that offers increased safety and improved accuracy, while performing bone-shaping tasks through minimal incisions. The Navio surgical system

is a product of Blue Belt Technologies (Plymouth, MN, USA; www.bluebelttech.com), and has been approved by the US Food and Drug Administration (FDA). The Smith & Nephew (London, United Kingdom; www.smith-nephew.com) Journey system will be the first implant system available for use with the PFJ system application.

"We focus our technology development efforts on clinically relevant applications that can benefit from reproducible precision. Adding patellofemoral replacement was the logical next step for us," said Eric Timko, president and CEO of Blue Belt Technologies.

The PFJ is where the patella and the femur meet, in a groove within the femur called the patella-femoral groove. Within this groove, the patella moves largely lengthwise, but it has some side-to-side movement and can tilt and rotate as well.

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Radiotherapy After Mastectomy Helpful For Women Whose Breast Cancer Metastasized to Only a Few Lymph Nodes

Women whose breast cancer has metastasized to only a few lymph nodes under their arm are less likely to have a recurrence of their disease or to die from it if they have radiotherapy after mastectomy, according to new findings.

Paul McGale, PhD, a senior statistician in the Early Breast Cancer Trialists' Collaborative Group at the Clinical Trial Service Unit (CTSU) at Oxford University (UK; www.ctsu.ox.ac.uk), presented his findings March 19, 2014, at the European Breast Cancer Conference (EBCC-9), held in Glasgow (UK), and published March 19, 2014, in the *Lancet*, that, until now, there has been uncertainty over whether women with early breast cancer that has spread to just one, two, or three lymph nodes under the arm gain any benefit from radiotherapy after surgery. However, his findings revealed that radiotherapy improves their risks of remaining disease-free and slashes their chance of dying from breast cancer.

"Another result from our study is that the proportional benefits of radiotherapy were similar in women regardless of whether or not they had also received chemotherapy or hormonal therapy. This is important because most women today receive these therapies. Our results suggest that

women being treated today are likely also to benefit from radiotherapy if they have any positive lymph nodes," Dr. McGale stated.

Dr. McGale analyzed results from 3,786 women in 14 randomized trials starting between 1964–1982, who had been given mastectomies along with the surgical removal of lymph nodes under the arm (axillary dissection) and who were then randomized to receive either radiotherapy to the chest wall and surrounding regions or to no radiotherapy. The women fell into three categories: those with no cancer in the lymph nodes, those with cancer in one, two or three lymph nodes, and those with cancer in four or more lymph nodes. The women were followed up for an average of just over 11 years, and data on the number of recurrences and deaths were available up to 2009.

Dr. McGale discovered that the percentage declines in the recurrence and death rates in the 405 women who had only one positive node were similar to those for the women who had two or three positive nodes.

The benefit occurred regardless of whether the women were in trials where hormonal therapy or chemotherapy was given to all women. Sixty-five percent of women with one, two, or three posi-



tive nodes received chemotherapy, and an additional 21% with hormone-sensitive tumors received hormonal therapy.

To study this and further follow-up on their findings, Dr. McGale, Dr. Taylor and their colleagues are inviting investigators of more recent trials comparing different radiotherapy regimens to contribute data to the Early Breast Cancer Trialists' Group. The 3,786 women were part of a larger group of 8,135 women in 22 randomized trials starting before 2000. During the follow-up period, 5,424 (67%) were known to have died, and the extent of surgery was known for all but 183 (2%) of the women.

Image: A new study by Oxford scientists has found that thousands more women with breast cancer should be given radiotherapy as part of their treatment for the disease (Photo courtesy of GlowImages / Corbis).

Surgical Hypothermia Affects Even Warmed Patients

Despite forced-air warming, hypothermia is common and often prolonged in patients undergoing non-cardiac surgery, according to a new study.

Researchers at the Cleveland Clinic (CC; OH, USA; my.clevelandclinic.org) extracted data from the most recent visit of 143,157 patients who underwent non-cardiac inpatient surgery between April 1, 2005, and February 15, 2013. Patient records were only included if the anesthetic lasted at least one hour, forced-air warming was used, and time-weighted measurement of core temperature was taken in the esophagus. Estimates were obtained for one-degree temperature bands ranging from 34 °C to 37 °C.

The results showed that approximately one-third of the patients had a core temperature of 34 °C or lower for at least one hour; 8% were below 34 °C for more than three hours. The researcher found that esophageal temperatures below 35 °C as manifest in 5% of the patients significantly increased hospital length of stay and transfusion requirements, with the incidence of hypothermia greatest one hour after induction, and then progressively improving. The study was

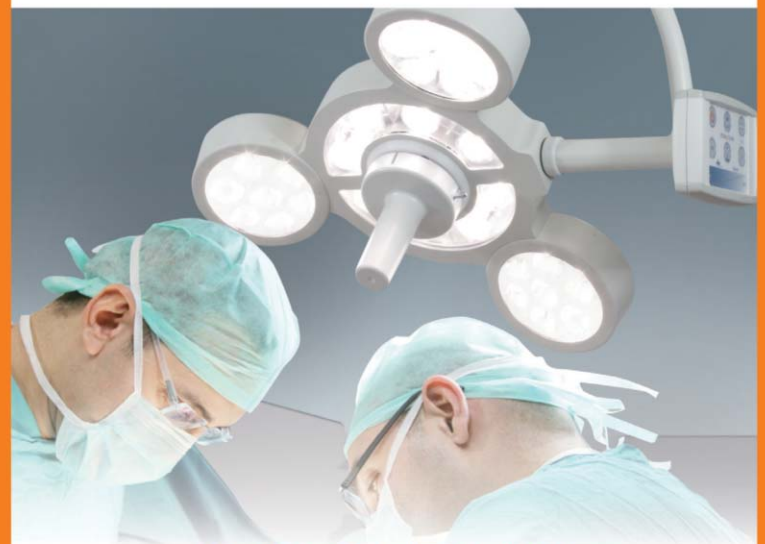
published online in the May 2014 issue of *Clinical Anesthesiology*.

"Hypothermia-related complications depend more on time-weighted core temperature than final intraoperative temperature. Even with forced-air warming, our results indicate that a fair fraction of patients still become hypothermic," said lead author Prof. Daniel Sessler, MD. "In fact, almost 10% of patients were distinctly hypothermic and remained near 35 °C at the end of surgery. This is a degree of hypothermia that has been shown to cause major complications in randomized trials."

Approximately 72,000 surgical patients around the world are warmed each day using forced-air warming convection and radiation to transfer heat from the movement of warm air across the surface of the patient's skin. For more than 20 years, forced-air warming has been regarded as the standard of care to help prevent surgical site infections (SSIs) and other serious complications of unintended hypothermia, including increased blood loss, morbid myocardial events, and reduced resistance to surgical wound infections.



Medical Lighting System



STARLED3 NX

Surgical LED lamp

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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 en-



vironment 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).

Image: The STARLED7 NX LED operating room lamp, designed with enhanced color temperature and low power consumption (Photo courtesy of ACEM Medical Company).

Combining Liver and Pancreatic Resections Is Safe

Combined liver and pancreatic resection (CLPR) is safe and can be performed with fairly low morbidity and mortality rates, according to a new study.

Researchers at the University of Strasbourg (France; www.unistra.fr) conducted a review of two prospectively maintained databases for pancreatic and liver resections to identify patients who underwent CLPR between January 1994 and January 2012. The researchers then examined the clinical, pathological, and surgical outcomes and analyzed postoperative morbidity results. In all, 50 consecutive patients with a median age of 58 years underwent CLPR. Indications for surgery included neuroendocrine carcinoma (16 patients), biliary cancer (15), colonic cancer (5), duodenal cancer (1), and others (13).

The type of pancreatic resection included pancreaticoduodenectomy (30), distal pancreatectomy (17), spleen-preserving distal pancreatectomy (2) and total pancreatectomy (1). Twenty-three patients had associated major hepatectomies, 27 underwent minor liver resections, and 11 had associated vascular resections. The

analysis showed no differences in postoperative morbidity in relation to extent of liver resection or type of pancreatic resection. The use of preoperative chemotherapy was the only independent risk factor associated with postoperative morbidity. The study was published on April 4, 2014, in the *British Journal of Surgery*.

“In Western countries, combined liver and pancreatic resections are performed rarely because of the perceived high morbidity and mortality rates,” said lead author Pietro Addeo, MD, of the University of Strasbourg Hôpital de Hautepierre-Hôpitaux, adding that the new study showed that “CLPR can be performed with fairly low morbidity and mortality rates. Patients receiving chemotherapy should be evaluated carefully before surgery is considered.”

Combined resection of both the liver and pancreas remains a controversial procedure. For many, the need for such an extended procedure implies a scope of disease spread that is usually not amenable to surgical control, and the extent of the procedure exposes the patients to substantial operative risks.

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