**MI-EYE 2 (TRICE MEDICAL, INC.) FOR DIAGNOSING JOINT INJURIES**

The mi-eye 2 is a battery-operated, single-use handheld arthroscope used to visualize and diagnose joint injuries in a doctor's office. The device consists of a needle with an integrated camera and light. Images are displayed on a Trice Microsoft Tablet with high-definition screen display.

**BIBLIOGRAPHY: TISSUE AND IMPLANT TRACKING INFORMATION SYSTEMS**

This report provides results of a mediated search conducted by a master's-level medical librarian in ECRI Institute’s Information Center. We searched PubMed, EMBASE, and selected web-based resources for studies and reviews published between January 1, 2012, and June 14, 2017.

**ZIP SURGICAL SKIN CLOSURE DEVICES (ZIPLINE MEDICAL, INC.) FOR CLOSING SURGICAL INCISIONS**

Zip® Surgical Skin Closure Devices are plastic, adjustable adhesive scaffolds applied on each side of a surgical incision to hold together the edges of the wound until it heals. Zip devices are intended as an alternative to sutures, staples, and tissue adhesives for superficial skin closure. Full-thickness wounds still require tissue approximation with deep dermal sutures before superficial closing with Zip devices.

**SYNVISC-ONE INJECTION (SANOFI-AVENTIS U.S. LLC) FOR TREATING OSTEOARTHRITIC KNEE PAIN**

Synvisc-One (hylan G-F 20) is an injectable treatment for pain due to knee osteoarthritis (OA) in patients whose pain has not responded adequately to conservative nonpharmacologic therapy and analgesics. Hylan G-F 20 is a unique chemically cross-linked hyaluronan, a physical property designed to help mimic healthy, young synovial fluid involved in lubrication and nutrition.

**IFUSE IMPLANT SYSTEM (SI-BONE, INC.) FOR MINIMALLY INVASIVE SACROILIAC JOINT FUSION**

The iFuse Implant System® is a sacroiliac joint (SIJ) implant that comes with surgical instruments intended for treating low-back pain associated with SIJ dysfunction. Minimally invasive surgery is performed through a 2 to 3 cm incision, and three titanium implants are placed in the SIJ using a cannulated delivery system intended to protect soft tissue. The implants are 30 to 70 mm in length and 4 and 7 mm in diameter.

**COOLIEF SINERGY COOLED RADIOFREQUENCY SYSTEM (HALYARD HEALTH, INC.) FOR TREATING SACROILIAC JOINT PAIN**

The Coolief Sinergy cooled radiofrequency (RF) system is intended to treat sacroiliac (SI) joint pain through denervation of the L4 and L5 primary dorsal rami and S1-S3 lateral branches. The RF generator and probe produce a thermal lesion with an average maximum tissue temperature >80°C. The system uses closed-loop circulation of sterile water to cool the probe and reduce adjacent tissue damage. The procedure is called cooled RF neurotomy.

**DEMINERALIZED BONE MATRIX FOR ORTHOPEDIC AND SPINE PROCEDURES**
Demineralized bone matrix (DBM) is well-established osteoinductive bone allograft material derived from pulverized cortical bone specimens. Osteoinduction refers to the stimulation of bone-forming osteoblasts from the patient's own mesenchymal stem cells already present at the site under repair. DBM is processed from human bone tissue using a demineralizing agent.

May 1, 2017 - Custom Product Briefs

SUPERION INTERSPINOUS SPACER (VERTIFLEX INC.) FOR TREATING LUMBAR SPINAL STENOSIS

The Superion® InterSpinous Spacer is an orthopedic implant intended to relieve lower back and limb pain and neurologic symptoms caused by age-related degenerative changes of the lumbar spine. Surgeons place the spacer between the affected vertebrae through a small incision to keep vertebrae apart and prevent spinal cord and nerve compression when the patient is upright. The Superion spacer is meant as an alternative to invasive decompressive surgery (i.e., laminectomy with or without fusion) for patients with moderately severe spinal changes.

Apr 25, 2017 - Custom Rapid Responses

ANTIBIOTIC-ELUTING CEMENT SPACERS FOR TREATING INFECTION FOLLOWING TOTAL JOINT REPLACEMENT SURGERY

Antibiotic-eluting cement spaces provide an intra-articular concentration of antibiotics that, together with systemic antibiotics, are designed to eliminate joint infection before implanting a new joint replacement. Spacers are typically used in 2-stage revision surgery involving implant removal and placement of temporary antibiotic-impregnated cement spacers, followed by reimplantation of a new prosthesis.

Apr 24, 2017 - Custom Product Briefs

DIGITEX SUTURE DELIVERY SYSTEM (COLOPLAST CORP.) FOR PLACING SUTURES DURING PELVIC SURGERY

The Digitex® Suture Delivery System (SDS) includes a single-use delivery device and suture cartridge intended to facilitate suture placement. The delivery device shaft's design allows the surgeon to adjust the angle of the needle housing. Digitex suture cartridges, used with the Digitex delivery device, are preloaded with precut suture lengths and are available in permanent and absorbable suture in sizes 0-0 or 2-0.

Apr 24, 2017 - Custom Product Briefs

ANCHORSURE FIXATION SYSTEM (NEOMEDIC INTERNATIONAL) FOR PLACING SUTURES DURING PELVIC SURGERY

The Anchorsure Fixation System is a disposable suture kit that surgeons use to attach suture to ligaments of the pelvic floor during transvaginal sacrospinous fixation for pelvic organ prolapse (POP) repair. The kit consists of monofilament polypropylene suture, an anchor, an anchoring handle, and a surgical needle.

Apr 21, 2017 - Custom Product Briefs

OVERVIEW OF TWO PELVIC SUTURE DELIVERY SYSTEMS

This overview compares features of the following two pelvic suture delivery systems intended to facilitate suture placement during pelvic organ prolapse (POP) surgery (Anchorsure® Fixation System and Digitex® Suture Delivery System).

Apr 20, 2017 - Custom Product Briefs

MYOPRO ARM ORTHOSIS (MYOMO, INC.) FOR STROKE REHABILITATION

The MyoPro® Motion-G is a powered arm brace intended to support and move a weak hand and arm in adults with moderate to severe upper extremity paralysis caused by stroke, brachial plexus injury, or other neuromuscular disorders. The device provides elbow flexion/extension and grasping function and may help individuals improve activities of daily living.

Apr 17, 2017 - Custom Product Briefs
TFN-ADVANCED PROXIMAL FEMORAL NAILING SYSTEM (DEPUY SYNTHESES) FOR PERFORMING HIP FRACTURE FIXATION

TFN-Advanced (TFNA) Proximal Femoral Nailing System is intended to surgically treat intracapsular, intertrochanteric, and subtrochanteric hip fractures. TFN stands for Trochanteric Fixation Nail, which is an earlier version of the nailing system. The TFNA system consists of a cannulated intermedullary nail, a cannulated helical blade, and a cannulated nail end cap; each is made of titanium alloy.

Apr 10, 2017 - Custom Product Briefs

TRIGEN INTERTAN NAIL SYSTEM (SMITH & NEPHEW, INC.) FOR PERFORMING HIP FRACTURE FIXATION

The TriGen InterTAN nail system is intended to surgically treat intracapsular, intertrochanteric, and subtrochanteric hip fractures. The nail system consists of an intramedullary nail and a lag screw. The nail has a trapezoidal shape to provide rotational stability, and it is press-fit into the medullary canal. The nail's distal tip has a clothespin shape designed to decrease stress and reduce anterior thigh pain.

Apr 1, 2017 - Custom Product Briefs

OVERVIEW OF TWO HIP FRACTURE FIXATION SYSTEMS

This overview compares features of the following two fixation systems intended to surgically treat intracapsular, intertrochanteric, and subtrochanteric hip fractures.

Feb 28, 2017 - Custom Product Briefs

TRUELOK HEX SYSTEM (ORTHOFIX, INC.) FOR LIMB LENGTHENING AND DEFORMITY CORRECTION

The TrueLok™ Hexapod (TL-Hex™) system is a three-dimensional (3-D) circular external fixation device designed to augment the previously developed TrueLok frame for treating lower-extremity bone fractures and deformities. The system uses circular and semi-circular external supports held to the bones by wires and half pins and interconnected by six struts.

Feb 9, 2017 - Custom Product Briefs

TENEX HEALTH TX SYSTEM (TENEX HEALTH, INC.) FOR TREATMENT-REFRACTORY TENDINOPATHIES

The Tenex Health TX® System combines use of ultrasound imaging with a minimally invasive pen-like surgical instrument that uses ultrasonic energy to visualize, cut, and remove diseased and damaged tissue in patients with treatment-refractory tendinopathies (e.g., lateral and medial epicondylitis, shoulder tendonitis, plantar tendonitis). The system has four components: console, TX MicroTip ultrasonic cutting instrument, inflation cuff, and foot pedal.

Feb 6, 2017 - Custom Product Briefs

RENAISSANCE X SYSTEM (MAZOR ROBOTICS, LTD.) FOR PRECISELY POSITIONING SURGICAL INSTRUMENTS OR IMPLANTS DURING SPINAL SUR...

The Renaissance X robotic spine surgery system is intended to assist surgeons in precisely placing surgical instruments or implants during spine surgery. The six-inch-tall robot guides insertion of surgical tools using a positioning arm; the surgeon directly controls the tools. Procedure planning and virtual placement of instruments and implants can be accomplished through preoperative planning based on computed tomography (CT) images, intraoperative planning based on a Renaissance X three-dimensional (3-D) scan image, or a 3D image uploaded from an external imaging system.

Jan 24, 2017 - Custom Product Briefs

SUPERCAPSULAR PERCUTANEOUSLY ASSISTED TOTAL HIP (SUPERPATH) SURGICAL TECHNIQUE FOR TOTAL HIP REPLACEMENT

The Supercapsular Percutaneously Assisted Total Hip (SuperPATH®) micro-posterior approach for total hip arthroplasty (THA) is intended to avoid cutting muscles or tendons during the procedure. It is an alternative to the conventional posterior approach and competes with other minimally invasive approaches for THA such as...
percutaneously assisted total hip (PATH) procedure. The procedure is performed with the SuperPATH Hip Technique instrument package developed specifically for this procedure.

Nov 8, 2016 - Custom Rapid Responses

THREAD CARPAL TUNNEL RELEASE FOR TREATING CARPAL TUNNEL SYNDROME

Thread carpal tunnel release (TCTR) is a minimally invasive surgery that uses ultrasound to guide the transection of the transverse carpal ligament with a piece of thread looped around the ligament. This technique is designed to cut only the ligament while not damaging adjacent tissue.

Nov 7, 2016 - Custom Product Briefs

REVERSE SHOULDER PROSTHESIS (DJO GLOBAL) FOR TOTAL SHOULDER ARTHROPLASTY

The Reverse® Shoulder Prosthesis (RSP) is intended to replace components of the shoulder joint damaged most often because of severe arthritis. RSP reverses the natural position of the ball (humeral head) and socket (glenoid fossa) of the shoulder joint to prevent subluxation (partial separation) of the joint.

Oct 27, 2016 - Technology Forecasts

ENHANCED-DEXTERITY PROSTHETIC ARM (LUKE ARM) TO RESTORE NATURAL ARM FUNCTIONS AFTER AMPUTATION

The enhanced movement and functionality of the LUKE (Life Under Kinetic Evolution) Arm (formerly DEKA Arm System) might improve quality of life for individuals with an upper-arm amputation, but high cost and complex training could limit utilization and patient access.

Oct 26, 2016 - Custom Product Briefs

BENCOX HIP SYSTEM (CORENTEC CO., LTD.) FOR TOTAL OR PARTIAL HIP REPLACEMENT

The Bencox® hip system is a set of components (femoral stem, acetabular cup, femoral head) intended to replace a damaged hip joint.

Oct 14, 2016 - Custom Product Briefs

LOSPA KNEE SYSTEM (CORENTEC CO., LTD.) FOR TOTAL KNEE REPLACEMENT

The Lospa® Knee System is intended for the primary replacement of a painful and disabled knee joint. The system consists of a femoral component, a tibial insert and baseplate, and a patellar component that can be configured to fit two design types posterior-stabilized (PS) and cruciate-retained (CR).

Sep 30, 2016 - Custom Product Briefs

AQUAMANTYS SYSTEM (MEDTRONIC PLC.) FOR HEMOSTATIC SEALING OF SOFT TISSUE AND BONE DURING SURGERY

The Aquamantys® system consists of a pump and bipolar sealer that uses a combination of radiofrequency (RF) energy delivered through a proprietary RF generator and saline to hemostatically seal soft tissue and bone in patients undergoing any of a variety of surgical procedures, including joint replacement.

Sep 20, 2016 - Custom Product Briefs

IFUSE IMPLANT SYSTEM (SI-BONE, INC.) FOR MINIMALLY INVASIVE SACROILIAC JOINT FUSION

The iFuse Implant System® is a sacroiliac (SI) joint implant and surgical instruments intended for treating low-back pain associated with SI joint dysfunction through minimally invasive surgery performed through a 2 to 3 cm incision. Three titanium implants are placed in the SI joint using a cannulated delivery system intended to protect soft tissue. The implants are 30 to 70 mm in length and 4 and 7 mm in diameter.

Sep 19, 2016 - Custom Product Briefs

MOBI-C ARTIFICIAL CERVICAL DISC (ZIMMER BIOMET) FOR TREATING TWO LEVEL DEGENERATIVE CERVICAL DISC DISEASE
The Mobi-C® Cervical Disc Prosthesis is an implant intended for intervertebral disc replacement at two contiguous levels from C3 to C7. Components include superior and inferior spinal plates made of a cobalt, chromium, and molybdenum alloy and an ultra-high-molecular-weight polyethylene mobile insert.

Sep 12, 2016 - Custom Product Briefs

MINTEMANG3 FIXATION DEVICE (SPINAL SIMPLICITY) FOR SPINAL FUSION PROCEDURES

The Minuteman®G3 fixation device is a minimally invasive, interspinous-interlaminar fusion device intended for temporal fixation of the thoracic, lumbar, and sacral spine in patients with degenerative disc disease, spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor.

Aug 31, 2016 - Custom Rapid Responses

PERCUTANEOUS LASER DISC DECOMPRESSION FOR TREATING HERNIATED LUMBAR DISCS

Percutaneous laser disc decompression (PLDD) is a minimally invasive surgical procedure intended to provide symptomatic relief of pain caused by a contained herniated intervertebral disc. The procedure uses laser light energy to vaporize a portion of the nucleus pulposus, diminishing intradiscal pressure. The pressure change is believed to be sufficient to alter the disc protrusion and relieve compression of the spinal nerve root and thereby provide pain relief.

Aug 25, 2016 - Custom Product Briefs

ODYSSEY 30 HOLMIUM LASER SYSTEM (CONVERGENT LASER TECHNOLOGIES) FOR TREATING URINARY STONES AND SOFT-TISSUE DISEASE

The Odyssey™ 30 Holmium Laser System can be used for multiple clinical indications, including kidney stone fragmentation and tissue ablation. The system has a 2100 nm infrared laser output that purportedly disintegrates stones and ablates tissue with little to no lateral tissue damage. The system comes with a range of fiber sizes.

Aug 10, 2016 - Custom Product Briefs

SIMPPLICITI SHOULDER SYSTEM (TORNIER, INC.) FOR TOTAL SHOULDER ARTHROPLASTY

The Simpliciti™ Shoulder System is a stemless press-fit, porous-coated, total shoulder arthroplasty system designed to treat patients who have shoulder joint pain, compromised range of motion, and loss of strength and functionality due to glenohumeral osteoarthritis.

Aug 10, 2016 - Custom Rapid Responses

CEMENTED VERSUS CEMENTLESS IMPLANTS FOR TOTAL KNEE REPLACEMENT

Bone cement has been used for many years to anchor knee implants to the femur and tibia during knee replacement surgery. Newer knee implants are now available that do not require bone cement to anchor the implant. Critical to the longevity of knee implants is the rate of implant loosening, which can lead to revision surgery. This Hotline Response compares cemented and cementless knee implants for differences in implant survival and complications.

Aug 2, 2016 - Custom Product Briefs

BENDINI SPINAL ROD BENDING SYSTEM (NUVASIVE, INC.) FOR MANIPULATING SPINAL ROD IMPLANTS

During minimally invasive spinal fusion surgery, rods can be attached to implanted screw heads and hooks to help align the patient's spine. The Bendini® Spinal Rod Bending System is made of a stylus, mechanical rod bender, and software that calculates the appropriate rod-bend location and angle. It is used instead of surgeon estimation of angles needed for rods to fit precisely to a patient's spine and manual bending with a french bender.

Jul 29, 2016 - Custom Rapid Responses

INTRAOPERATIVE COMPUTED TOMOGRAPHY FOR IMPROVING CLINICAL OUTCOMES IN NEUROSURGICAL AND SPINAL PROCEDURES
Intraoperative computed tomography is an example of an image-guided surgery system that provides preoperative and intraoperative information to surgeons by displaying the position of the system's probe in relation to patient anatomy in real time.

Jul 25, 2016 - Custom Product Briefs

**GRAFTJACKET MATRICES (WRIGHT MEDICAL TECHNOLOGY AND ACELITY) FOR TENDON AND LIGAMENT REPAIR AND WOUND CARE**

GraftJacket® matrices are immunologically inert acellular scaffolds derived from donated human skin tissue that has been processed to remove the epidermis and epidermal and dermal cells and freeze-dried to prevent ice-crystal formation and preserve the intact matrix. They are intended for use during surgical tendon and ligament repair and to promote wound healing.

Jul 20, 2016 - Custom Product Briefs

**CARTIFORM VIALBE OSTEOCHONDRAL ALLOGRAFT (OSIRIS THERAPEUTICS, INC.) FOR REPAIRING CARTILAGE**

Cartiform® viable osteochondral allograft is a cartilage graft of fresh biologic matrix (from a cadaver) and is intended to promote articular cartilage repair in patients with focal chondral defects.

Jul 18, 2016 - Custom Product Briefs

**DTRAX PLATFORM (PROVIDENCE MEDICAL TECHNOLOGY, INC.) FOR TREATING CERVICAL DEGENERATIVE DISC DISEASE**

The DTRAX® Platform is a family of products, including implants, grafts, bone screws, and surgical instruments, intended for use in cervical fusion surgery in patients with cervical radiculopathy and neck pain due to degenerative disc disease and facet arthropathy.

Jul 15, 2016 - Custom Product Briefs

**DENOVO NT NATURAL TISSUE GRAFT (ZIMMER BIOMET) FOR REPAIRING CARTILAGE**

DeNovo® NT Graft is a cartilage implant used to repair articular cartilage damage in knees, hips, ankles, and shoulders. It consists of "scaffold-free living articular cartilage" obtained from human infantile/juvenile donors and minced into small particles. The small particles are surgically implanted into the cartilage defect and secured with fibrin glue.

Jul 15, 2016 - Emerging Technology Reports

**WEARABLE POWERED EXOSKELETON USE AFTER SPINAL CORD INJURY**

Wearable powered exoskeletons are lower-extremity devices equipped with computer-controlled motors or actuators intended for use by individuals with impaired motor or sensory function of the lower extremities after spinal cord injury.

Jul 5, 2016 - Custom Product Briefs

**LUNA 360 SYSTEM (BENVENUE MEDICAL, INC.) FOR LUMBAR INTERBODY FUSION**

The Luna® 360 system is intended for interbody fusion in skeletally mature patients with degenerative disc disease (DDD). The system consists of a circular, expandable Luna implant and accessories used during the spinal fusion procedure. The device is intended for use in patients who have had at least six months of nonsurgical treatment.

Jul 1, 2016 - Custom Rapid Responses

**HYDRODISSECTION FOR TREATING NEUROLOGIC AND MUSCULOSKELETAL CONDITIONS**

Hydrodissection is the injection of fluids, typically normal saline, to help dissect entrapped nerves, or move tendons or fascia surrounding a nerve to treat neurologic and musculoskeletal conditions, such as carpal tunnel syndrome. Ultrasound is often used to guide the injection. The movement may disrupt adhesion and alleviate inflammation.

Jun 23, 2016 - Custom Product Briefs
ATTUNE KNEE SYSTEM (DEPUY SYNTHES, INC.) FOR TOTAL KNEE REPLACEMENT

Attune® Knee System is intended for total knee replacement in patients with a painful and disabled knee joint. The system is designed to reduce knee pain and improve knee stability and mobility. The Attune system consists of multiple implants and instruments.

Jun 23, 2016 - Custom Product Briefs

OSTEOAMP BONE GRAFT (BIOVENTUS, LLC.) FOR USE IN SPINAL FUSION AND TIBIA REPAIR PROCEDURES

OsteoAMP® is an allogeneic bone graft substitute intended for use as a bone graft during orthopedic procedures in which an autograft might be needed such as spinal fusion and tibia repair procedures. It purportedly contains endogenous growth factors rich in osteoinductive, angiogenic, and mitogenic proteins.

Jun 20, 2016 - Custom Product Briefs

STABILIT VERTEBRAL AUGMENTATION SYSTEM (DFINE, INC.) FOR TREATING VERTEBRAL FRACTURES

The StabiliT® Vertebral Augmentation System is a motorized, microprocessor controlled system intended to deliver bone cement during radiofrequency targeted vertebral augmentation (vertebroplasty or kyphoplasty) procedures in patients with vertebral fractures. The system is available in three configurations.

Jun 3, 2016 - Custom Product Briefs

SUBCHONDROPLASTY (ZIMMER KNEE CREATIONS, INC.) FOR MINIMALLY INVASIVE REPAIR OF KNEE BONE MARROW LESIONS

Subchondroplasty® is a proprietary, minimally invasive fluoroscopic procedure for guiding treatment of chronic bone marrow lesions to enable filling of the lesions with nanocrystalline calcium phosphate, a bone void filler. The procedure is intended to relieve knee osteoarthritis symptoms and provide an alternative to total knee replacement.

May 11, 2016 - Custom Rapid Responses

SACROILIAC JOINT FUSION FOR TREATING CHRONIC LOW-BACK PAIN

Chronic low-back pain (LBP) is a common cause of disability, and it is the second most common basis for physician visits for chronic conditions. In some patients, LBP's underlying cause is injury of the sacroiliac joint. One option for such patients is sacroiliac joint fusion, in which instrumentation (e.g., screws) and/or infused bone graft are intended to fixate the joint, which is intended to minimize motion and reduce pain.

May 6, 2016 - Technology Forecasts

JOINT-SPARING KNEE IMPLANT (ATLAS SYSTEM) FOR TREATING KNEE OSTEOARTHRITIS

The Atlas Knee System™ (Moximed, Inc.) is an investigational device implanted outside the medial side of the knee joint to reduce load and osteoarthritis symptoms. Younger, or more active patients with mild to moderate knee osteoarthritis might choose this option to delay arthroplasty.

Apr 28, 2016 - Custom Rapid Responses

SYSTEMS FOR CONCENTRATING BONE MARROW ASPIRATE

Bone marrow aspiration is a technique used to obtain bone marrow aspirate for regenerative therapy. Bone marrow–derived mesenchymal stem cells promote healing of bone, cartilage, and tendons. A bone marrow aspiration system/device is used at the point of care or in a laboratory setting to aspirate, concentrate, and deliver a mixture of whole blood and bone marrow aspirate.

Apr 20, 2016 - Custom Product Briefs

OSTEOCOOL RF TUMOR ABLATION SYSTEM (MEDTRONIC, PLC) FOR TREATING SPINAL METASTASIS

The OsteoCoolTM Radiofrequency Ablation (RFA) System is an electrosurgical cutting and coagulation system intended for palliative treatment of spinal metastases. Unlike monopolar RFA systems, the OsteoCool RFA system was designed to target localized spinal tumors using two separate probes and to provide active cooling.
of the targeted region, causing destruction of the tumor in bony tissues while preserving adjacent healthy normal neurologic tissues.

Apr 18, 2016 - Custom Product Briefs
NAVIO SURGICAL SYSTEM (BLUE BELT TECHNOLOGIES, INC.) FOR PERFORMING KNEE ARTHROPLASTY
The Navio® Surgical System is used to assist surgeons performing partial knee replacement. The technology includes software that is used to create a virtual surgical plan that obviates the need for standard mechanical cutting guides and jigs and preoperative computed tomography imaging. The handpiece allows real-time adjustments regarding bone cutting. Virtual navigation images show the progression of the cutting toward the final plan.

Apr 12, 2016 - Custom Rapid Responses
RADIOFREQUENCY ABLATION FOR TREATING KNEE OSTEOARTHRITIS
Osteoarthritis (OA) is the most common form of arthritis, occurring when the protective articular cartilage on the ends of the bones wears down and gradually worsens over time. This degeneration of tissue eventually leads to pain and joint stiffness and most commonly affects the joints in the knees, hips, hands, and spine. RF ablation for treating pain due to knee OA involves applying electrical heat to small sections of nerve tissue to prevent transmission of pain stimuli.

Apr 12, 2016 - Custom Product Briefs
MAKOPLASTY USING THE MAKO ROBOTIC ARM (MAKO SURGICAL CORP.) FOR PERFORMING TOTAL HIP ARTHROPLASTY, TOTAL KNEE ARTHROPLASTY ...
MAKOplasty® uses the Mako Robotic Arm of the Robotic Arm Interactive Orthopedic (RIO®) System to assist surgeons in performing partial knee resurfacing of one or two knee compartments in patients with early- to mid-stage knee osteoarthritis, total knee arthroplasty, or total hip arthroplasty. The RIO uses computed tomography (CT)- derived, patient-specific, three-dimensional modeling and software to plan surgery and align implants.

Apr 12, 2016 - Custom Product Briefs
DISCOGEL (GELSCOM SAS) FOR TREATING HERNIATED LUMBAR DISCS AND LUMBOSCIATICA
Discogel® is a gelified ethanol (a cellulose derivative product) and tungsten (a metallic contrast substance) medical implant intended to treat herniated discs and relieve back pain or sciatica.

Mar 3, 2016 - Custom Product Briefs
OMNIPAQUE (IOHLEXOL) INJECTION (GE HEALTHCARE) FOR CONTRAST-ENHANCED IMAGING
Omnipaque™ (iohexol) injection is a nonionic contrast agent used in patients during certain imaging exams (e.g., myelography, cisternography, head and body computed tomography, coronary or cerebral angiography, cystography) in an effort to improve test accuracy. Omnipaque is available as a “sterile, pyrogen-free, colorless to pale-yellow solution, in the following iodine concentrations 140, 180, 240, 300, and 350 mgI/mL.” The 140 and 350 mgI/mL solutions are not labeled for intrathecal administration for safety reasons; the other dosages are labeled for intrathecal administration.

Mar 3, 2016 - Custom Product Briefs
VISIPAQUE (IODIXANOL) INJECTION (GE HEALTHCARE) FOR CONTRAST-ENHANCED IMAGING
Visipaque is a dimeric, isosmolar, nonionic, water-soluble, radiographic contrast medium made with iodixanol. It is a solution available in concentrations of 270 and 320 mg of organically bound iodine per mL (550 and 652 mg of Iodixanol per mL, respectively). It can be used in numerous clinical radiology and imaging settings and is approved for use in children one year or older.

Mar 3, 2016 - Custom Product Briefs
ISOVUE (IOPAMIDOL) INJECTION (BRACCO DIAGNOSTICS, INC.) FOR CONTRAST-ENHANCED RADIOLOGY
Isovue® (iopamidol) is a nonionic low-osmolar monomer iodinated contrast agent (ICA) intended for use with computed tomography (CT) or angiography to help diagnose or assess various medical conditions. It is intended
for use only with an automated contrast injection system or contrast management system approved or cleared for use with this contrast agent. Injection for angiography is intra-arterial; injection for CT is intravenous.

Feb 22, 2016 - Custom Product Briefs
KNEEALIGN 2 SYSTEM (ORTHALIGN, INC.) FOR COMPUTER-ASSISTED ALIGNMENT DURING ORTHOPEDIC SURGERY
KneeAlign® 2 is a handheld device intended to provide computer-assisted femoral and tibial alignment during knee arthroplasty. The system comprises the KneeAlign 2 Surgical Navigation Unit and KneeAlign 2 Distal Femoral and Tibial instruments. The device is intended to enable surgeons to easily determine alignment axes and adjust orientation of the distant femoral and tibial cutting blocks to meet preoperative goals.

Feb 10, 2016 - Custom Rapid Responses
ELECTRIC BONE GROWTH STIMULATING DEVICES FOR TREATING ACUTE AND NONUNION BONE FRACTURES
Electric bone growth stimulators are used to treat several types of fractures. Typically, they are used when satisfactory fracture healing has not occurred naturally or the pace of healing is too slow—a condition called nonunion—as well as in acute conditions, such as spinal fusion procedures, in which the application of electrical stimulation is believed to enhance the fusion process.

Jan 18, 2016 - Custom Product Briefs
OVERVIEW OF FOUR STERNAL CLOSURE SYSTEMS
This overview compares the various features of four sternal closure systems intended for use after sternotomy or sternal reconstructive procedures as an alternative to wire fixation. Sternal Cable System™ (RTI Surgical, Inc.), SternaLock® Blu Primary Closure System (Zimmer Biomet, Inc.), Sternal Talon® (KLS Martin LP), and Tritium® Sternal Cable Plate System (RTI Surgical).

Jan 18, 2016 - Custom Product Briefs
STERNAL CABLE SYSTEM (RTI SURGICAL, INC.) FOR STERNAL FIXATION FOLLOWING STERNOTOMY AND STERNAL RECONSTRUCTIVE SURGERY
The Sternal Cable System™ is intended for use after sternotomy or sternal reconstructive procedures as an alternative to wire fixation. The system consists of a multistrand stainless-steel and titanium cable under tension and secured using the company's device-specific tensioner/crimper instrument to apply the appropriate amount of tension.

Jan 18, 2016 - Custom Product Briefs
TRITIUM STERNAL CABLE PLATE SYSTEM (RTI SURGICAL, INC.) FOR STERNAL FIXATION FOLLOWING STERNOTOMY AND STERNAL RECONSTRUCTIVE SURGERY
The Tritium® Sternal Cable Plate System is intended for use after sternotomy or sternal reconstructive procedures as an alternative to wire fixation. The Tritium system uses cables, plates, and screws to form a rigid closure across the median sternotomy.

Jan 1, 2016 - Custom Product Briefs
PEAK PLASMA BLADE DEVICES (MEDTRONIC PLC) FOR SURGICAL CUTTING AND COAGULATION OF SOFT TISSUE
Peak PlasmaBlade® cutting and coagulation devices are intended for use during general surgery procedures and are available in several models designed for specific applications. The Peak PlasmaBlade is an electrosurgical device that uses brief, high-frequency pulses of radiofrequency (RF) energy to induce the formation of electrical plasma along the edge of a thin, flat, highly insulated electrode.

Dec 31, 2015 - Custom Product Briefs
STERNAL TALON (KLS MARTIN, INC.) FOR STERNAL FIXATION AFTER STERNOTOMY AND STERNAL RECONSTRUCTIVE SURGERY
The Sternal Talon is a rigid sternal fixation two-piece clamping device intended for use after sternotomy or sternal reconstructive procedures as an alternative to wire fixation. The device has one or two projections resembling talons on each side of a plate.

Dec 28, 2015 - Custom Rapid Responses

**BONE SUBSTITUTION WITH BIOACTIVE GLASS DURING ORTHOPEDIC SURGERY PROCEDURES**

Living bone grafts taken from the patient's pelvis, femur, or tibia (autologous bone grafts or autografts) are the current standard material used to correct bone defects caused by trauma or disease. Due to the likelihood of complications and morbidities associated with harvesting the autograft, bone substitutes have been developed and studied as possible replacements for autologous bone grafts. Bioactive glass is composed of synthetic calcium phosphosilicate, which provides a scaffold for new bone growth.

Dec 28, 2015 - Custom Rapid Responses

**SYNTHETIC BONE GRAFT SUBSTITUTES FOR ORTHOPEDIC PROCEDURES**

During many orthopedic surgeries, bone graft material is needed to aid fusion and to fill bone voids. This is especially true for spinal fusion procedures and treatments for nonunion bone fractures. An autograft, obtained from the patient's own bone, provides viable osteogenic cells, which produce new bone-forming cells called osteoblasts.

Dec 28, 2015 - Custom Rapid Responses

**RADIOFREQUENCY DENERVATION FOR TREATING LOW-BACK PAIN**

Low-back pain affects up to 20% of the adult population at any given time, and 80% of the population will be affected at some point in their lives. Radiofrequency denervation is a procedure in which nerves are destroyed using heat generated by an electric current. Destroyed nerves can no longer transmit pain signals.

Dec 14, 2015 - Custom Product Briefs

**AUGMENT BONE GRAFT (BIOMIMETIC THERAPEUTICS, LLC) FOR ORTHOPEDIC PROCEDURES**

Augment® is intended to act as a substitute for autologous bone graft during ankle and foot surgeries requiring bone grafts. It is a synthetic substance that contains recombinant human platelet-derived growth factor B homodimer and a bioresorbable bone-like matrix (beta-tricalcium phosphate or β-TCP).

Dec 7, 2015 - Custom Rapid Responses

**OPEN VERSUS ENDOSCOPIC CARPAL TUNNEL RELEASE FOR TREATING CARPAL TUNNEL SYNDROME**

Carpal tunnel syndrome (CTS) is caused by compression of the median nerve as it enters the palm of the hand. Surgery for CTS involves cutting the transverse carpal ligament, which relieves pressure on the median nerve, which in turn reduces symptoms. The conventional surgical approach is open surgery, during which an incision is made at the base of the palm, and the surgeon has direct visual access to the ligament. By contrast, endoscopic surgery involves the use of a small flexible tube with a camera attached, and the surgeon views the ligament through the camera.

Nov 24, 2015 - Custom Rapid Responses

**CONTINUOUS COLD THERAPY DEVICES FOR TREATING ORTHOPEDIC TRAUMA**

Cryotherapy, or cold therapy, is commonly used in the early stages of orthopedic trauma or in the early postoperative period following orthopedic procedures such as hip or knee arthroscopy. Continuous cold therapy devices are used to better control the treatment temperature as alternatives to simple ice packs.

Nov 23, 2015 - Custom Product Briefs

**KIVA VCF SYSTEM (BENVENUE MEDICAL, INC.) FOR TREATING VERTEBRAL COMPRESSION FRACTURES**

The Kiva® Vertebral Compression Fracture (VCF) Treatment System consists of a group of single-use medical devices intended for treating spinal fractures in the thoracic and/or lumbar spine from T6-L5. The system enables percutaneous delivery of a small implant device into the body of the fractured vertebrae to provide
structural support and a reservoir for controlled delivery and containment of bone cement during vertebral augmentation.

Nov 22, 2015 - Custom Rapid Responses

CHANGES TO MECHANICAL PROPERTIES OF BONE CEMENT WHEN ANTIBIOTICS ARE ADDED

Bone cement is used in bone surgery to attach prosthetics to bone. Some surgeons use antimicrobial-impregnated bone cements to prevent infections, and others use them to treat orthopedic infections after they have developed. Concern exists over whether the addition of antibiotics alters the mechanical properties of bone cement and influences implant failure rates.

Nov 22, 2015 - Custom Product Briefs

ALTERA MINIMALLY INVASIVE ARTICULATING EXPANDABLE SPACER (GLOBUS MEDICAL, INC.) FOR LUMBAR INTERBODY FUSION

The Altera Spacer is an expandable lumbar interbody fusion device intended to provide structural stability after discectomy in skeletally mature individuals with degenerative disc disease (DDD). The device is designed to permit various surgical approaches to the lumbar spine (posterior or transforaminal) and to allow for articulation when inserted. Its several height ranges enable continuous expansion within a range to address patients' individual anatomical needs.

Nov 11, 2015 - Custom Rapid Responses

GUIDELINES FOR USING PLATELET-RICH PLASMA IN SURGICAL PROCEDURES

Platelets contain an array of substances that help in blood clot formation and tissue repair. These substances may be useful in treating acute injuries particularly in areas with limited blood supply such as articulating cartilage, ligament, and tendons.

Nov 9, 2015 - Custom Product Briefs

AVAMAX ADVANCED VERTEBRAL AUGMENTATION SYSTEM (CAREFUSION CORP.) FOR TREATING VERTEBRAL FRACTURES

The AVAmax® Advanced Vertebral Augmentation system is intended for use in vertebroplasty and balloon kyphoplasty to treat vertebral compression fractures. The device is an all-in-one system with components that include the AVAflex® curved vertebral augmentation needle, AVAmax vertebral balloon, AVAtex® bone cement, AVAmax vertebral augmentation drill, and AVAprep® patient preparation kit.

Nov 5, 2015 - Custom Rapid Responses

DEMINERALIZED BONE MATRIX FOR ORTHOPEDIC PROCEDURES

Demineralized bone matrix (DBM) is well-established osteoinductive bone allograft material derived from pulverized cortical bone specimens. DBM is commonly used as a bone graft extender for posterolateral spinal fusion surgery where it is mixed with autologous bone. Numerous DBM products are commercially available for use in spinal surgery and other orthopedic procedures, each with different amounts of osteoinductive proteins and may be combined with other materials to form the final product.

Nov 4, 2015 - Custom Rapid Responses

METAL-ON-METAL TOTAL HIP RESURFACING FOR DEGENERATIVE HIP DISEASE

Metal-on-metal (MOM) total hip resurfacing, designed as an alternative to total hip replacement (THR) for patients with severe chronic hip pain from arthritis, is primarily intended for active patients younger than 60 years of age who would be expected to need more than one THR during their lifetime.

Nov 1, 2015 - Custom Product Briefs

OVERVIEW OF SELECTED BALLOON KYPHOPLASTY AND VERTEBRAL AUGMENTATION SYSTEMS

This overview compares the various features of these three devices used to treat vertebral compression fractures (VCF) Kyphon® Balloon Kyphoplasty (Medtronic), the iVAS® Inflatable Vertebral Augmentation System
Stryker Corp), AVAmax® Advanced Vertebral Augmentation System (CareFusion), and the Kiva® CVF Treatment System (Benvenue Medical, Inc).

Oct 30, 2015 - Custom Product Briefs

**IVAS INFLATABLE VERTEBRAL AUGMENTATION SYSTEM (STRYKER CORP.) FOR TREATING VERTEBRAL FRACTURES**

The iVAS® Inflatable Vertebral Augmentation System is intended for treating vertebral compression fractures. The iVAS kits, which come in three sizes, include a balloon catheter, access cannula with diamond-tip stylet, locking syringe, inflator, and stopcock.

Oct 28, 2015 - Custom Product Briefs

**AXIALIF (TRANS1, INC.) FOR AXIAL LUMBAR INTERBODY FUSION**

The AxiaLIF® (Lumber Interbody Fusion) System is a minimally invasive fusion device intended to provide anterior spine stabilization (as an adjunct to spinal fusion) for patients with degenerative disc disease, low-grade spondylolisthesis, spinal stenosis, or with previously unsuccessful fusion.

Oct 28, 2015 - Custom Product Briefs

**KYPHON BALLOON KYPHOPLASTY (MEDTRONIC) FOR TREATING VERTEBRAL FRACTURES**

Kyphon® Balloon Kyphoplasty is a minimally invasive procedure that uses orthopedic balloons called tamps inserted into a patient’s vertebral fracture and inflated. The device is intended to restore a vertebra to its original height and to correct angular deformities. The void left by the balloon inflation is filled with Kyphon® bone cement intended to stabilize the vertebra.

Oct 20, 2015 - Custom Rapid Responses

**USE OF INTERBODY IMPLANTS IN LUMBAR FUSION IN PATIENTS AGE 65 OR OLDER**

Interbody implants have been studied for lumbar fusion in individuals 65 years of age and older and whether the use of spacers/cages during interbody fusion enhances the fusion process and improves patient outcomes compared to not using a spacer/cage.

Oct 20, 2015 - Custom Rapid Responses

**SHOULDER ARTHROSCOPY FOR TREATING SUBACROMIAL IMPINGEMENT SYNDROME AND ARTHRITIS OF THE ACROMIAL-CLAVICULAR JOINT**

Subacromial impingement is the trapping of the rotator cuff tendons beneath the anteroinferior portion of the acromion. The acromion is a projection of the scapula and articulates with the calvicle. Shoulder arthroscopy involves use of an arthroscope as a minimally invasive approach to examining and repairing tissue in and around the shoulder joint.

Oct 12, 2015 - Custom Rapid Responses

**FIXATION DEVICES AND JOINT REPLACEMENT IMPLANTS FOR TREATING HAMMERTOE**

Surgery to correct hammertoe can be accomplished using fixation devices or joint replacement implants. Kirschner wires (k-wires) were the gold standard fixation devices until recently when newer methods of bone fixation became available, including absorbable pins, cannulated screws, memory-based nitinol implants, two-piece interlocking titanium intramedullary implants, and completely buried implants. Joint replacement implants have also become options and are intended to act as joint spacers for improved joint stability and cosmetic results.

Oct 9, 2015 - Custom Product Briefs

**INTREPID DYNAMIC EXOSKELETAL ORTHOSIS FOR REHABILITATION OF SEVERE LOWER-LIMB INJURIES**

The Intrepid Dynamic Exoskeletal Orthosis (IDEO) is a “floor-reactive” support brace an individual wears on the lower extremity and is intended to support and protect various types of lower-extremity limb injuries to enable
the individual to return to high levels of activity, such as running. The U.S. Army developed the IDEO for use by active military members who experienced high-energy, lower-extremity trauma limb salvage injuries.

Sep 22, 2015 - Custom Rapid Responses

OXINIUM IMPLANTS FOR TOTAL JOINT ARTHROPLASTY

Total knee and hip replacement are usually considered when chronic pain and disability in the joint greatly interfere with an individual's activities of daily living. Oxinium (or oxidized zirconium) was developed to reduce surface wear and potentially extend the life span of hip and knee prostheses compared to metal prostheses that are typically constructed of cobalt-chrome alloy.

Sep 15, 2015 - Custom Product Briefs

NUCEL HUMAN AMNIOTIC ALLOGRAFT (NUTECH MEDICAL) FOR USE IN SURGICAL WOUNDS AND ORTHOPEDIC PROCEDURES

NuCel® is a minimally processed human tissue allograft derived from human amnion and amniotic fluid intended for use in surgical wounds and orthopedic procedures to purportedly provide an enhanced environment for tissue growth, repair, and healing. The allograft is available in four sizes.

Sep 15, 2015 - Custom Rapid Responses

SURGICAL DEVICES FOR REPAIRING ANNULUS FIBROSUS AFTER DISCECTOMY

The annulus fibrosus is a specialized dense connective tissue that surrounds the nucleus pulposus of the intervertebral disc. In a traditional discectomy, the hole created in the annulus fibrosus during surgery is not repaired. Leaving these holes open may predispose the disc to repeated herniation and cause persisting postoperative low-back pain in some patients.

Sep 15, 2015 - Custom Product Briefs

AFFINITY HUMAN AMNIOTIC ALLOGRAFT (NUTECH MEDICAL) FOR USE IN CHRONIC AND SURGICAL WOUNDS

Affinity® is a minimally processed human tissue allograft derived from human amniotic membranes that may be used in chronic and surgical wounds to purportedly provide an enhanced environment for tissue growth, repair, and healing.

Sep 15, 2015 - Custom Product Briefs

NUSHIELD PLACENTAL ALLOGRAFT (NUTECH MEDICAL) FOR USE IN CHRONIC AND SURGICAL WOUNDS

NuShield™ is a sterilized dehydrated placental allograft derived from human amnion and amniotic fluid intended for use in surgical wounds and orthopedic procedures to purportedly provide an enhanced environment for tissue growth, repair, and healing. The allograft is available in four sizes.

Sep 15, 2015 - Custom Rapid Responses

CLINICAL APPLICATIONS FOR THREE-DIMENSIONAL PRINTING TECHNOLOGY

Three-dimensional (3-D) printing, also called additive manufacturing, creates 3-D objects from plastic, metal, nylon, or other source material by building the object layer upon successive layer, until the entire object is complete. 3-printing has been used in musculoskeletal procedures, cardiovascular surgery, oncology, and drug delivery, among other clinical areas.

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