**CRITERIA FOR STANDARD AND REVERSE SHOULDER REPLACEMENT**

Standard shoulder replacement or anatomic total shoulder arthroplasty (aTSA) involves maintaining the relative locations of the ball-and-socket portions of the joint. Reverse total shoulder arthroplasty (rTSA) involves switching the relative locations of the ball and socket. The prosthetic ball is attached to the scapula, and the socket is installed at the end of the humerus. rTSA is commonly used for patients with damaged rotator cuff tendons.

**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.

**CALCIUM PHOSPHATE-BASED SYNTHETIC BONE GRAFT SUBSTITUTES FOR SPINAL SURGERY**

During spinal surgery, bone graft material is used to aid fusion and fill bone voids. An autologous graft (autograft), obtained from the patient's own bone, provides viable osteogenic cells that produce new bone-forming cells, called osteoblasts. The autograft also actively promotes new bone formation by producing growth factors (osteoinduction) and acting as a structural framework or scaffold to form new bone (osteococonduction). However, harvesting autologous iliac crest bone graft has limits, including pain and blood loss. Bone-graft substitutes based on calcium phosphate are extensively used in spinal surgery.

**DEXTROSE PROLOTHERAPY FOR KNEE OSTEOARTHRITIS**

Osteoarthritis (OA) is a disease of synovial joint cartilage that leads to considerable pain and loss of function. OA is a critical concern for veterans and current service members because the injuries and physical stress from military service increases the risk of developing OA. Dextrose prolotherapy involves the injection of hypertonic dextrose solutions in a joint capsule affected by OA to relieve pain and restore function. The mechanism of action may involve the release of growth factors and tissue growth stimulation.

**TISSUEMEND SOFT-TISSUE REPAIR MATRIX (stryker) FOR TENDON AND LIGAMENT REPAIR**

TissueMend Soft-tissue Repair Matrix is an acellular collagen membrane derived from bovine skin that is indicated for reinforcement of the rotator cuff, patella, Achilles, biceps, quadriceps, or other tendons during open or arthroscopic tendon repair surgery. Stryker states the matrix “serves as a scaffold for cellular ingrowth that is gradually remodeled by the body’s own tissues.”

**GRAFTJACKET REGENERATIVE TISSUE MATRIX (WRIGHT MEDICAL TECHNOLOGY) TO AUGMENT TENDON AND LIGAMENT REPAIR**

GraftJacket Regenerative Tissue Matrix (RTM) consists of 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 matrix architecture. The product is intended to augment various tendon and ligament surgical repairs.

**I-FACTOR BONE GRAFT (CERAPEDICS, INC.) FOR LUMBAR FUSION PROCEDURES**

I-Factor Bone Graft products are intended to replace or augment the use of autologous bone commonly used in spinal fusion incorporating interbody fusion devices by providing "a bone graft substitute that is remodeled into new bone during..."
the natural healing process," according to the company. Substitutes for autograft bone are used to avoid pain and risk of infection in the patient from whom it is harvested.

Jan 30, 2018 - Custom Product Briefs

**IJS-ELBOW (SKELETAL DYNAMICS, LLC) FOR STABILIZING THE ELBOW JOINT**

The Internal Joint Stabilizer (IJS)-Elbow stabilization system is intended for use in adults to enable early motion after elbow injury by providing temporary subcutaneous stability between the distal humerus and proximal ulna in patients with elbow instability resulting from injury, such as fracture or dislocation. The device is surgically implanted rather than externally fixated like a standard external fixation device used for elbow instability.

Jan 29, 2018 - Custom Product Briefs

**IBALANCE HTO SYSTEM (ARTHREX, INC.) FOR OSTEOTOMY OF THE FEMUR OR TIBIA**

The iBalance High Tibial Osteotomy (HTO) System is a surgical tool and orthopedic implant kit for correcting knee misalignment (varus deformity) in patients with degenerative joint disease. Clinicians perform HTO as an alternative to knee replacement or as bridge therapy in patients with moderate deformity and symptoms. iBalance is intended as an alternative to standard surgery with metal fixation braces (e.g., Puddu or TomoFix plates) to improve the procedure's safety and reproducibility.

Jan 25, 2018 - Custom Product Briefs

**RIBFIX BLU (ZIMMER BIOMET) FOR RIB FIXATION AFTER FLAIL CHEST INJURY**

RibFix Blu thoracic fixation system is intended to provide stabilization and rigid fixation of fractures in the chest wall caused by blunt force trauma and for sternal reconstruction procedures and planned osteotomies. The system comprises metallic locking bone plates and locking screws that provide fracture fixation. The implants are available in multiple sizes and manufactured from commercially pure titanium and titanium alloy.

Jan 25, 2018 - Custom Product Briefs

**LEVEL ONE THORACIC PLATING SYSTEM (KLS MARTIN GROUP) FOR RIB FIXATION AFTER FLAIL CHEST INJURY**

The KLS Martin Thoracic Plating System (also called Level One and L1 Rib) is intended to provide rigid fixation to fractures, osteotomies, and reconstruction procedures in the thoracic anatomy. The system consists of titanium plates and screws and the necessary instruments to facilitate placement of the implants.

Jan 18, 2018 - Custom Product Briefs

**RIBLOC U PLUS CHEST WALL PLATING SYSTEM (ACUTE INNOVATIONS, LLC) FOR RIB FIXATION FOLLOWING FLAIL CHEST INJURY**

The RibLoc U Plus Plating System is intended to stabilize rib fractures, fusions, and osteotomies to aid in bone healing. The system consists of titanium plates, titanium alloy screws, and accessory components intended to facilitate proper implantation of the plates and screws. The plates are implanted over the center of rib fracture lines and fixed to the bone to stabilize and hold the broken segments together.

Jan 18, 2018 - Custom Product Briefs

**MATRIXRIB FIXATION SYSTEM (DEPUY SYNTHES) FOR RIB FIXATION AFTER FLAIL CHEST INJURY**

The MatrixRIB Fixation system is intended for fixing, stabilizing, and reconstructing rib and sternum fractures, fusions, osteotomies, and resections. The MatrixRIB system consists of titanium, precontoured, shaped, and straight locking plates, locking screws, and splints intended to hold broken rib segments together.

Jan 18, 2018 - Custom Product Briefs

**LAPIPLASTY (TREACE MEDICAL CONCEPTS, INC.) FOR TREATING HALLUX VALGUS DEFORMITY (BUNIONS)**

Lapiplasty is a proprietary surgical procedure using the TMC (Treace Medical Concepts) Plating System to treat bunion deformity. Lapiplasty is intended to correct a misaligned metatarsal bone at the first tarsometatarsal joint by properly aligning the first metatarsal in the transverse, sagittal, and coronal planes. The plating system consists of plates and screws intended to hold together the fused bones and accessory instrumentation intended to facilitate and maintain proper bone alignment during the procedure. The instrumentation is also intended to reduce bunion size while removing minimal bone to prevent bone shortening and enable patients to bear weight during the six-week recovery period.

Jan 15, 2018 - Custom Product Briefs
OSTEOAMP BONE GRAFT (BIOVENTUS, LLC.) TO AID SPINAL FUSION

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. The manufacturer states that OsteoAMP contains endogenous growth factors rich in osteoinductive, angiogenic, and mitogenic proteins. OsteoAMP is processed from human cadaver bone and undergoes novel tissue processing techniques believed to preserve bone morphogenetic proteins (BMPs) and other growth factors.

Jan 2, 2018 - Custom Rapid Responses

CONTINUOUS PASSIVE MOTION DEVICES FOR AIDING RECOVERY FOLLOWING CARTILAGE REPAIR SURGERY

Several disease processes or acute trauma can damage articular cartilage. Any of several cartilage repair surgical procedures can be used to treat cartilage lesions. After cartilage lesion repair, continuous passive motion (CPM) devices are sometimes prescribed and are intended to aid recovery of cartilage and/or joint range of motion.

Dec 21, 2017 - Custom Rapid Responses

OSTEOCHONDRAL ALLOGRAFTS AND AUTOGRRAFTS FOR REPAIRING CARTILAGE IN THE KNEE

Allografts are tissue obtained from a cadaver donor; autografts are tissue obtained from the patient in whom it will be used. Osteochondral refers to articulating cartilage and the bone under it. Autograft cartilage is taken from a non-weight-bearing area in the form of a cylindrical plug containing healthy cartilage and underlying bone. The plug is then matched to the defect and impacted into place to provide a smooth cartilage surface. A single plug or multiple plugs may be used, and autografts are intended for only small cartilage defects; allografts are used for larger defects.

Dec 4, 2017 - Custom Product Briefs

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

The OsteoCool Radiofrequency (RF) Tumor Ablation System is an electrosurgical platform for percutaneous RF ablation (RFA) of bone tissue. RFA with OsteoCool is intended as palliative treatment for relieving pain and preventing bone failure in patients with cancer that has spread to the bones. RFA is used as an alternative or adjunct to pharmacotherapy, external beam radiation therapy, bone cement injection (cementoplasty), high-frequency focused ultrasound ablation, and surgical bone stabilization.

Dec 1, 2017 - 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.

Oct 31, 2017 - Custom Rapid Responses

NEXT-GENERATION SEQUENCING FOR DIAGNOSING PROSTHETIC JOINT INFECTION

Prosthetic joint infections (PJsIs) are devastating occurrences typically leading to implant removal and long-term antibiotic therapy. PJ diagnosis relies on clinical signs and symptoms and culturing of the infectious organism. Next-generation sequencing (NGS) of DNA is a molecular technique using polymerase chain reaction (PCR) to identify multiple bacterial populations from samples taken from the infection site and an implant's surface.

Oct 30, 2017 - Custom Product Briefs

MAKoplasty refers to orthopedic surgical procedures using the Mako® Robotic Arm system to perform joint arthroplasty of the hip or knee. The device has been alternately referred to throughout FDA documentation under the tradenames Mako, Makoplasty, Restoris, and Rio. The system uses computed tomography (CT)-derived, patient-specific, three-dimensional modeling and software to plan surgery and the robotic arm's stereotactic guidance and haptic feedback to help align an implant to improve joint implant positioning compared with conventional manual surgery.

Oct 25, 2017 - Custom Product Briefs

MAKoplasty refers to orthopedic surgical procedures using the Mako® Robotic Arm system to perform joint arthroplasty of the hip or knee. The device has been alternately referred to throughout FDA documentation under the tradenames Mako, Makoplasty, Restoris, and Rio. The system uses computed tomography (CT)-derived, patient-specific, three-dimensional modeling and software to plan surgery and the robotic arm's stereotactic guidance and haptic feedback to help align an implant to improve joint implant positioning compared with conventional manual surgery.

Oct 25, 2017 - Custom Product Briefs
Makoplasty refers to orthopedic surgical procedures using the Mako Robotic Arm to perform joint arthroplasty of the knee or hip. The Mako system uses computed tomography (CT)-derived, patient-specific, three-dimensional modeling and software to plan surgery and the robotic arm’s stereotactic guidance and haptic feedback to help align an implant and improve joint implant positioning accuracy compared with conventional surgery.

Oct 23, 2017 - Custom Product Briefs

ARThROfLEX DECELLULARIZED DERMAL ALLOGRAFT (ARTHREX, INC.) FOR REPAIRING ROTATOR CUFF TEARS

Arthroflex® decellularized dermal allograft is described by the manufacturer as “an acellular dermal extracellular matrix intended for supplemental support and covering for soft-tissue repair.” LifeNet Health® patented and validated a process (i.e., Matracell® technology) to make Arthroflex acellular purportedly without compromising biomechanical or biochemical properties. Arthroflex is available in a variety of sizes. Human dermal allografts have been used as scaffolding devices to augment surgical repair of rotator cuff tears.

Oct 23, 2017 - Custom Product Briefs

ALLOPATCH HD ACELLULAR DERMAL MATRIX (MUSCULOSKELETAL TRANSPLANT FOUNDATION) FOR REPAIRING ROTATOR CUFF TEARS

AlloPatch HD is a human acellular dermal matrix (ADM) used to replace damaged or “inadequate integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects,” according to the manufacturer. This allograft skin is minimally processed to remove epidermal and dermal cells and is available in hydrated and dehydrated forms in a variety of sizes and thicknesses. Clinicians can trim the allograft to the dimensions needed to cover a surgical site. Human dermal allografts have been used as scaffolding devices to augment surgical repair of rotator cuff tears.

Oct 23, 2017 - Custom Product Briefs

LIPOGEMS SYSTEM (LIPOGEMS INTERNATIONAL) FOR PROCESSING LIPOASPIRATED ADIPOSE TISSUE

The Lipogems System is a sterile, closed-loop, single-use adipose tissue-processing device intended for autologous adipose tissue transfer during surgery. The system consists of a tissue-processing cylinder containing five stainless-steel spheres, an input and output filter sieve, and a waste bag. The Lipogems System is intended to microfragment adipose tissue and separate adipose cells from proinflammatory blood and oil residue.

Oct 23, 2017 - Custom Product Briefs

I-FACTOR PEPTIDE-ENHANCED BONE GRAFT (CERAPEDICS, INC.) FOR TREATING CERVICAL DEGENERATIVE DISC DISEASE

The i-Factor Peptide-enhanced Bone Graft is intended to help reconstruct a degenerated cervical disc after single-level discectomy to treat herniated nucleus pulposus, spondylosis, or visible loss of disc height. It consists of a synthetic small peptide (P-15) bound to calcium phosphate particles that are suspended in a hydrogel carrier. The P-15 peptide is believed to enhance bone growth and cervical fusion by stimulating the proliferation of osteogenic cells within bone tissue.

Oct 23, 2017 - Custom Product Briefs

INFUSE BONE GRAFT SUBSTITUTE (MEDTRONIC PLC.) FOR TRANSFORAMINAL LUMBAR INTERBODY FUSION

Infuse Bone Graft substitute is intended to aid in fusing lumbar vertebrae using an anterior lumbar approach to treat degenerative disc disease. The primary reason for using Infuse is to avoid the adverse events (AEs) associated with harvesting autologous bone graft material from the patient. Transforaminal lumbar interbody fusion (TLIF) is not among the labeled indications for use of Infuse.

Oct 6, 2017 - Custom Product Briefs

INFUSE BONE GRAFT (MEDTRONIC PLC.) FOR ANTERIOR LUMBAR INTERBODY FUSION

Infuse Bone Graft (recombinant human bone morphogenetic protein-2 [rhBMP-2] applied to an absorbable collagen sponge) is a bone graft substitute intended to aid in fusing lumbar vertebrae using an anterior lumbar approach to treat degenerative disc disease. The primary reason for using Infuse is to avoid adverse events (AEs) associated with harvesting autologous bone graft material from the patient.

Oct 1, 2017 - Special HTA Reports

OSTEINDUCTIVE POTENTIAL OF COMMERCIAL DEMINERALIZED BONE MATRIX PRODUCTS

Demineralized bone matrix (DBM) is well-established osteoinductive bone allograft material derived from pulverized cortical bone specimens. Osteoinduction refers to the induction of osteoblast formation from the patient’s own osteogenic stem
cells already present at the repair site. DBM osteoinductive properties are attributable to DBM's composition and claimed mechanisms of action.

Sep 29, 2017 - Custom Product Briefs

HEMACLEAR TOURNIQUET (OHK MEDICAL DEVICES, INC.) FOR RESTRICTING BLOOD FLOW DURING ORTHOPEDIC SURGERY

HemaClear Tourniquet is a sterile, single-use exsanguinating device used during surgical limb procedures to provide a bloodless surgical field. HemaClear is intended to provide up to 95% exsanguination (blood removal), reduce risk of infection, shorten surgery times, and reduce postsurgical complications.

Sep 28, 2017 - Custom Product Briefs

BONESCALPEL (MISONIX, INC.) FOR ULTRASONIC BONE-CUTTING PROCEDURES

The BoneScalpel ultrasonic bone-cutting device is intended to assist surgeons performing orthopedic, reconstructive, and neurosurgical procedures. The BoneScalpel System consists of an ultrasonic generator and irrigation console that connects to a handpiece bearing a blunt blade that oscillates in a linear, piston-like motion. The BoneScalpel is intended to efficiently cut bone with reduced blood loss and damage to surrounding soft tissue.

Sep 20, 2017 - Special HTA Reports

PREOPERATIVE SKIN PREPARATION WITH CHLORHEXIDINE GLUCONATE PRODUCTS FOR REDUCING SURGICAL SITE INFECTIONS

Chlorhexidine gluconate (CHG) is a chemical with broad-spectrum antimicrobial properties that is available in over-the-counter products that reduce bacteria on skin before surgery. Many CHG products also contain alcohol intended to increase the product's effectiveness. These products are available as solutions, washes, sponges, and swabs. Preoperative skin preparation with CHG products is intended to reduce surgical site infection (SSI) risk.

Sep 20, 2017 - Custom Rapid Responses

OUTPATIENT PARTIAL AND TOTAL HIP REPLACEMENT SURGERY

Hip replacement may be necessary when joint damage is severe enough to limit daily activities and pain cannot be controlled with conservative treatments of physical therapy, medication, or other noninvasive treatments. Surgery may involve partial or total joint replacement. When performed on an inpatient basis, patients typically remain in the hospital for 1 to 3 days depending on physical condition and comorbidities.

Sep 15, 2017 - Special HTA Reports

PATIENT SAFETY ISSUES WHEN USING BONE ALLOGRAFTS IN SPINAL SURGERY

Bone allografts are commonly used in orthopedic procedures, and the demand for allografts has steadily increased in the last decade. Allograft bone obtained from live donors or cadavers offer a potential substitute for autologous bone grafts obtained from the iliac crest but have their own set of problems. Allografts may transmit infectious disease and have decreased mechanical strength and poor osteogenic properties. This Special Report is intended to examine the regulations as well as the measures taken by individual tissue banks to ensure patient safety. We also examine publications reporting on allograft-associated infections and efficacy of allografts in spinal fusion surgery.

Sep 15, 2017 - Technology Forecasts

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

The enhanced movement and functionality of the LUKK (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.

Aug 31, 2017 - Custom Product Briefs

INFUSE BONE GRAFT (MEDTRONIC PLC) FOR EXTREME LATERAL INTERBODY LUMBAR FUSION

Infuse Bone Graft is a bone graft substitute intended to aid in fusing lumbar vertebrae using an anterior lumbar approach to treat degenerative disc disease. The primary reason for using Infuse is to avoid the adverse events associated with harvesting autologous bone graft material from the patient. This Product Brief examines the clinical literature on the use of Infuse in extreme lateral interbody lumbar fusion surgery, which is an off-label use of Infuse.

Aug 28, 2017 - 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.

Aug 25, 2017 - Custom Product Briefs

**INFUSE BONE GRAFT (MEDTRONIC PLC) FOR LUMBAR POSTEROLATERAL FUSION**

Infuse Bone Graft is a bone graft substitute intended to aid in fusing lumbar vertebrae using an anterior lumbar approach to treat degenerative disc disease. The primary reason for using Infuse is to avoid the adverse events (AEs) associated with harvesting autologous bone graft material from the patient. This Product Brief examines the clinical literature on the use of Infuse in posterolateral lumbar fusion (PLF) surgery, an off-label use of Infuse.

Aug 18, 2017 - Custom Rapid Responses

**OUTPATIENT TOTAL AND PARTIAL KNEE REPLACEMENT SURGERY**

Knee replacement may be necessary if joint damage is severe enough to limit daily activities and pain cannot be controlled with conservative treatments of physical therapy, medication, or other noninvasive treatments. Surgery may involve partial or total joint replacement. When performed on an inpatient basis, patients typically remain in the hospital for 1 to 3 days depending on the patient’s physical condition and comorbidities.

Aug 14, 2017 - Custom Product Briefs

**ACP DOUBLE SYRINGE SYSTEM (ARTHREX, INC.) FOR PREPARING PLATELET-RICH PLASMA**

The ACP® Dual Syringe System is a blood centrifugation toolkit intended for concurrently preparing and delivering autologous platelet-rich plasma (PRP) to injured tissues. PRP contains high concentrations of platelet-derived growth factors proposed to promote connective tissue healing. Clinicians apply or inject PRP to stimulate healing of the skin, muscles, bones, and joints.

Aug 1, 2017 - Custom Product Briefs

**PRECICE SYSTEM (NUVASIVE, INC.) FOR LOWER-LIMB LENGTHENING AND DEFORMITY CORRECTION**

The Precice System is an adjustable intramedullary (IM) device intended for limb lengthening of the femur and tibia. The system is most commonly used to treat lower-limb length discrepancies due to acute and chronic fractures. A key feature of the system is the magnetic interaction between the IM nail and the handheld External Remote Controller (ERC) to noninvasively adjust the implant.

Jul 31, 2017 - Custom Product Briefs

**GPS III PLATELET CONCENTRATION KIT (ZIMMER BIOMET, INC.) FOR PREPARING PLATELET-RICH PLASMA**

The GPS III Platelet Concentration Kit is a blood centrifugation toolkit intended for concurrent preparation and delivering autologous platelet-rich plasma (PRP) to injured tissues. PRP contains high concentrations of platelet-derived growth factors proposed to promote connective tissue healing. Clinicians apply or inject PRP to stimulate healing of traumatic or surgical wounds of the skin, muscles, bones, and joints.

Jul 19, 2017 - Custom Product Briefs

**CARTIVA SYNTHETIC CARTILAGE (CARTIVA, INC.) FOR TREATING ARTHRITIS OF THE FIRST METATARSOPHALANGEAL JOINT**

Cartiva® Synthetic Cartilage Implant (SCI) is a small implantable hydrogel cylinder intended to treat osteoarthritis (OA) of the first metatarsophalangeal (MTP) joint of the foot. The device is surgically implanted within the joint perpendicular to the metatarsal head after drilling a small cavity in the head of the metatarsal bone. Cartiva is an alternative to joint fusion and, unlike fusion, offers the potential advantage of maintaining joint movement.

Jul 14, 2017 - Custom Product Briefs

**BIOCUE SYSTEM (ZIMMER BIOMET, INC.) FOR CONCENTRATING BONE MARROW ASPIRATE**

The BioCUE System is a blood and bone marrow aspirate concentration system designed for use in a clinical laboratory or intraoperatively at the point of care. Clinicians use the system to process a small sample of autologous whole blood and bone marrow mixture for rapid preparation of platelet-poor plasma and platelet-rich plasma (PRP). PRP mixed with autograft and/or allograft bone before application to an orthopedic surgical site may promote tissue healing and regeneration.

Jun 22, 2017 - Custom Product Briefs

**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.

**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 (hyaluronic acid) 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. Hyaluronic acid 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.

**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.

**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.

**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.
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 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 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 SYNTHES) 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.

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.
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.

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.

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.

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.

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).

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.

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.

MINUTEMANG3 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.

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 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 10, 2016 - Custom Product Briefs

SIMPLICITI 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 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 Viable 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 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 carpel 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.

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 18, 2016 - Custom Product Briefs

NAVIO SURGICAL SYSTEM (BLUE BELL 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

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 (IOHEXOL) 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

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.

Mar 3, 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 22, 2016 - Custom Product Briefs

ECRI Institute

The Discipline of Science. The Integrity of Independence.
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

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 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 1, 2016 - Custom Product Briefs

PEAK PLASMABLADE 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

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 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.
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 biodegradable bone-like matrix (beta-tricalcium phosphate or β-TCP).

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.

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.

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.

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.

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.

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.

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.
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.

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.

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.

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.

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.

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 clavicle. Shoulder arthroscopy involves use of an arthroscope as a minimally invasive approach to examining and repairing tissue in and around the shoulder joint.

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.

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.
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

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

NUSHEILD 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.

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

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.

Aug 26, 2015 - Custom Product Briefs

SYNTHECEL (DEPUY SYNTHES) FOR REPAIRING DURAL TEARS

Synthecel® Dura Repair is a dura substitute made from biosynthesized cellulose and water. Neurosurgeons use it to repair dural tears caused by intentional incisions or inadvertent surgical injury to the dura mater. Two forms are available Onlay or Substitute. Substitute contains about twice as much cellulose thickness and can be secured with sutures. Onlay is highly conformable and can be placed without sutures.

Aug 26, 2015 - Custom Product Briefs

DURAGEN PLUS (INTEGRALIFESCIENCESCORP.) FOR REPAIRING DURAL TEARS

DuraGen® Plus® Dural Regeneration Matrix is a dura substitute made of processed bovine collagen that neurosurgeons use to repair dural tears caused by intentional incisions or inadvertent surgical injury to the dura mater. DuraGen Plus is described as an ultra-pure type I collagen obtained from bovine Achilles tendon with no reported foreign body reactions or graft rejections. It may be used as an onlay or with tensionless sutures.

Aug 26, 2015 - Custom Product Briefs

DUREPAIR DURAL REGENERATION MATRIX (MEDTRONIC, INC.) FOR REPAIRING DURAL TEARS

Aug 26, 2015 - Custom Product Briefs
Durepair® Dural Regeneration Matrix is a dura substitute made of processed bovine collagen that neurosurgeons use to repair dural tears caused by intentional incisions or inadvertent surgical injury to the dura mater. Durepair may be used as an onlay or suturable graft.

Aug 26, 2015 - Custom Rapid Responses

DURA SUBSTITUTE PRODUCTS FOR DURAL TEAR REPAIR DURING NEUROSURGERY

The dura mater is the outermost of the three connective tissue membranes (meninges) that cover the brain and spinal cord and is composed of thick, dense, irregular tissue that is much stronger than the two inner membranes. Dura substitutes are made of animal or synthetic materials used to repair dura mater tears that occur from trauma or as a matter of course during neurosurgery.

Aug 22, 2015 - Custom Rapid Responses

PERCUTANEOUS DISCECTOMY FOR TREATING HERNIATED LUMBAR DISC

This Hotline Response focuses on percutaneous discectomy procedures, including percutaneous endoscopic discectomy and other related minimally invasive procedures, for treating herniated lumbar discs.

Aug 13, 2015 - Custom Product Briefs

ORTHOsoft® Systems are intended to aid orthopedic surgeons in performing knee and hip replacement surgery by providing intraoperative surgical navigation and positional guidance.

Aug 5, 2015 - Custom Product Briefs

The Galileo™ Positioning System, when used with Surgeon's Checklist software, is a digital radiography system intended to provide surgeons with both preoperative and intraoperative imaging, particularly during orthopedic procedures, to assist in proper implant placement. The intraoperative images are obtained using x-rays.

Updated: 3/20/2018