NVISIONVLE IMAGING SYSTEM (NINEPOINT MEDICAL, INC.) FOR IDENTIFYING SUSPICIOUS ESOPHAGEAL LESIONS DURING ENDOSCOPY

The NvisionVLE Imaging System is a high-resolution volumetric imaging system intended to identify suspicious esophageal lesions during endoscopic procedures. The system uses an advanced form of optical coherence tomography (OCT) and a scanning optical probe to obtain high-resolution, cross-sectional, real-time tissue imagery called volumetric laser endomicroscopy (VLE).

LYMPHOSHEEK (TECHNETIUM-99M TILMANOCEPT) (CARDINAL HEALTH, INC.) FOR SENTINEL LYMPH NODE ...

Lymphoseek (technetium-99m tilmanocept) is a radioimaging drug intended to help clinicians identify sentinel lymph nodes (SNLs) (i.e., lymph nodes that receive direct drainage from malignant tumors). Clinicians harvest SLNs to identify lymphatic metastasis, a major cancer prognostic factor. Lymphoseek is intended to improve the accuracy of standard SLN mapping with vital dyes and/or technetium-99m sulfur colloid (TcSC).

MOBILE UNITS FOR TREATING STROKE

A mobile stroke unit (MSU) is an ambulance specially equipped and staffed to diagnose and start stroke treatment in the field. The MSU team collaborates via telemedicine with a vascular neurologist, emergency dispatch, and stroke centers to reduce time to thrombolytic treatment, potentially improving health outcomes from ischemic stroke.

ACOUSTIC RADIATION FORCE IMPULSE FOR EVALUATING LIVER FIBROSIS

Acoustic radiation force impulse (ARFI) is an ultrasound-based elastography modality that can provide information on tissue stiffness. ARFI may help clinicians assess the severity of liver fibrosis in patients with chronic liver diseases without having to perform a liver biopsy. ARFI is available on some general-purpose ultrasound scanners.

DYEVERT PLUS CONTRAST REDUCTION SYSTEM (OSPREY MEDICAL, INC.) FOR REDUCING CONTRAST MEDIA DOSE

DyeVert Plus Contrast Reduction System is intended to reduce and monitor the amount of radiopaque contrast media volume during angiographic or computed tomography (CT) procedures. This system diverts excess contrast media to help protect the kidneys of patients with kidney risk factors, including moderate and severe chronic kidney disease, diabetes, older age, and hypertension. The system may reduce contrast volume as much as 40% in patients without compromising image quality.

IODINE-124 (124I)-POSITRON EMISSION TOMOGRAPHY FOR THYROID CANCER TREATMENT PLANNING

124I-positron emission tomography (PET) is a functional radioimaging technique that uses the positron-emitting 124I isotope to label and visualize thyroid gland tissue. 124I-PET is intended as an alternative to functional imaging with gamma-emitting iodine-131 (131I) to help oncologists plan treatment and follow-up care of patients with thyroid cancer.

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.
NMR LIPOPROFILE TEST (LABCORP) FOR PREDICTING CARDIOVASCULAR DISEASE RISK

NMR (Nuclear Magnetic Resonance) LipoProfile Test is a biochemical assay that uses magnetic resonance spectroscopy to measure levels of blood plasma lipids (total cholesterol, high-/low-density lipoprotein-bound cholesterol (HDL-C/LDL-C), and total triglycerides [TG]) routinely used to evaluate risks of future cardiovascular disease onset and progression.

Jun 8, 2017 - Custom Product Briefs

MIRDIAN COBALT-60 SYSTEM (VIEWRAY, INC.) FOR ADVANCED RADIOTHERAPY DELIVERY

The MRIdian Cobalt-60 System is an integrated magnetic resonance imaging and cobalt-60 radiotherapy delivery system intended to provide advanced radiation therapy, such as image-guided radiation therapy and stereotactic body radiation therapy. Incorporating MRI into the treatment delivery process may improve pretreatment planning and provide better positioning and tracking of tumors during treatment.

Jun 1, 2017 - Technology Forecasts

INTEGRATED POSITRON EMISSION TOMOGRAPHY/MAGNETIC RESONANCE IMAGING

Integrated imaging systems that combine positron emission tomography (PET) with magnetic resonance imaging (MRI) purportedly offer enhanced soft-tissue imaging detail without the ionizing radiation of computed tomography. However, high costs and uncertain reimbursement have slowed diffusion of integrated PET/MRI systems.

Apr 27, 2017 - Technology Forecasts

SPY ELITE SYSTEM (NOVADAQ TECHNOLOGIES, INC.) FOR ASSESSING TISSUE PERFUSION DURING PLASTIC AND RECONSTRUCTIVE SURGERY

The Spy Elite® Fluorescence Imaging System is a stand-alone fluorescence imaging system intended as an adjunctive method of assessing tissue perfusion intraoperatively using laser-assisted indocyanine green fluorescence angiography (LACGA) to visualize blood flow. System components include a multidirectional imaging arm, maneuverable fluorescence imaging head, dual LCD monitors, high-definition color printer, mobile cart with wheel locks, and software package. This report focuses on the system's use for plastic and reconstructive surgery.

Apr 3, 2017 - Technology Forecasts

HANDHELD ULTRASOUND DEVICES FOR EMERGENCY APPLICATIONS AND FIELD USE

Handheld ultrasound devices used in the field outside traditional healthcare settings have potential to augment patient triage and improve care. However, high-quality data demonstrating a definitive clinical benefit are lacking, potentially slowing broader diffusion of the technology.

Nov 4, 2016 - Custom Product Briefs

RADPAD SHIELDS (WORLDWIDE INNOVATIONS & TECHNOLOGIES, INC.) FOR PROTECTING PATIENTS AND CLINICIANS FROM SCATTER RADIATION

RadPad® shields are lightweight, disposable x-ray shields that are not made of lead and are intended to protect healthcare personnel and patients from x-ray scatter radiation during medical procedures, such as angiography, interventional radiology, and fluoroscopy. They are available in nonabsorbent and absorbent fabric coverings.

Oct 18, 2016 - Custom Product Briefs

GADAVIST (BAYER HEALTHCARE PHARMACEUTICALS, INC.) FOR CONTRAST-ENHANCED MAGNETIC RESONANCE IMAGING

Gadavist® (gadobutrol) is an injectable contrast agent intended for intravenous use in diagnostic magnetic resonance imaging (MRI) of brain or breast lesions and diagnostic magnetic resonance angiography (MRA) of supra-aortic or renal artery disease. The recommended dose for term neonates, children, and adults is 0.1 mL/kg body weight (0.1 mmol/kg).

Oct 18, 2016 - Custom Product Briefs

MAGNEVIST INJECTION (BAYER HEALTHCARE PHARMACEUTICALS, INC.) FOR CONTRAST-ENHANCED MAGNETIC RESONANCE IMAGING

Magnevist® (gadopentetate dimeglumine) is an injectable gadolinium-based contrast agent (GBCA) intended for intravenous use in diagnostic magnetic resonance imaging (MRI) of abnormal vascularities in the brain, spine, head, neck, and body. The recommended dose of Magnevist injection for children (2 years of age or older) and adults is 0.2 mL/kg (0.1 mmol/kg) administered intravenously at a rate not to exceed 10 mL per 15 seconds.
MULTIHANCE INJECTION (BRACCO DIAGNOSTICS, INC.) FOR CONTRAST-ENHANCED MAGNETIC RESONANCE IMAGING

MultiHance® (gadobenate dimeglumine) is an injectable gadolinium-based contrast agent (GBCA) intended for intravenous use for diagnostic magnetic resonance imaging (MRI) of the central nervous system in adults and children two years of age or older to visualize lesions in an abnormal blood-brain barrier or abnormal vascularity of the brain, spine, and associated tissues and for magnetic resonance angiography (MRA) to evaluate adults with known or suspected renal or aorto-iliac-femoral occlusive vascular disease.

DIGITAL BREAST TOMOSYNTHESIS FOR BREAST CANCER SCREENING

Digital breast tomosynthesis is an imaging technique that uses x-rays to capture images that are digitally manipulated to create tomograms (i.e., slices). The ability to examine the breast in slices reduces tissue overlap, which could reveal a suspicious lesion or resolve normal tissue overlap that mimics a suspicious lesion.

USE OF GONAD SHIELDING FOR PEDIATRIC IMAGING

Overexposure of the gonads to ionizing radiation can cause gonadal dysfunction (infertility or sterility), greatly reducing reproductive potential. Strategies for improving reproductive potential in patients exposed to radiation include cryopreservation of sperm/ova, radiation dose optimization, ovarian transposition, and gonadal shielding.

RADIATION EXPOSURE FROM BIPLANE RADIOGRAPHY/FLUOROSCOPY IN CHILDREN WITH CONGENITAL HEART DEFECTS

Radiographic/fluoroscopic (R/F) biplane imaging systems are designed to perform vascular imaging (angiography) during diagnostic and interventional procedures.

DEFINITY INJECTABLE SUSPENSION (LANTHEUS MEDICAL IMAGING, INC.) FOR CONTRAST-ENHANCED ECHOCARDIOGRAPHY

Definity® Injectable Suspension is an ultrasound contrast agent intended to opacify the left ventricular chamber of the heart in patients with suboptimal echocardiograms to enhance images of the ventricular endocardial border. Definity may be used as an intravenous bolus or by infusion and requires activation with the Vialmix® device before administration.

LUMASON INJECTABLE SUSPENSION (BRACCO DIAGNOSTICS, INC.) FOR CONTRAST-ENHANCED ECHOCARDIOGRAPHY

Lumason® injectable suspension (sulfur hexafluoride lipid-type A microspheres) is an ultrasound contrast agent intended to opacify the left ventricular chamber of the heart in patients with suboptimal echocardiograms to enhance images of the ventricular endocardial border. Sulfur hexafluoride lipid-type A microspheres supplied by the manufacturer have been marketed in the European Union as SonoVue® since 2001.

OPTISON INJECTABLE SUSPENSION (GE HEALTHCARE) FOR CONTRAST-ENHANCED ECHOCARDIOGRAPHY

Optison™ Injectable Suspension (perflutren protein-type A microspheres USP) is an ultrasound contrast agent intended to opacify the left ventricular chamber of the heart in patients with suboptimal echocardiograms, to enhance images of the ventricular endocardial border. The clinician injects Optison suspension into a patient's peripheral vein during echocardiography.

GI-BRONCH MENTOR PLATFORM (SIMBIONIX USA, CORP.) FOR SURGEON TRAINING TO PERFORM BRONCHOSCOPY AND GASTROINTESTINAL ENDOS ...

The GI-Bronch Mentor™ platform is a surgery simulation system intended to provide hands-on and didactic training to surgeons in gastrointestinal endoscopy and upper respiratory endoscopy (e.g., flexible bronchoscopy, bronchoscopy ultrasound) procedures. The GI and Bronch systems also come as smaller portable options.

MAGNETIC RESONANCE/ ULTRASOUND FUSION BIOPSIES FOR DIAGNOSING PROSTATE CANCER
Early diagnosis of prostate cancer is critical in reducing morbidity and mortality. Definitive pathologic diagnosis is established through a biopsy performed under transrectal ultrasound (TRUS) guidance. However, this procedure has been associated with high intraoperative variability, low predictive values, sepsis, and bleeding.

May 11, 2016 - Custom Rapid Responses

AUTOMATED DUAL-HEAD CONTRAST MEDIA INJECTORS FOR IMPROVING CLINICAL OUTCOMES AND SAFETY IN COMPUTED TOMOGRAPHY

Computed tomography (CT) is a noninvasive radiographic technique used to produce thin cross-sectional images or slices of the human body. Automatic contrast media injectors use electromechanically driven syringes to inject contrast media into catheters inserted in arteries or veins, which potentially decrease the amount of potentially harmful contrast media needed during CT exams. In dual-head injectors, one syringe is used for administering contrast medium and the other is used for administering saline solution before and after the contrast injection.

May 2, 2016 - Custom Product Briefs

SILHOUETTE WOUND SURVEILLANCE SYSTEM (ARANZ MEDICAL) FOR WOUND MEASUREMENT AND DOCUMENTATION

The Silhouette® Wound Surveillance System is a noninvasive three-dimensional measurement, imaging, and documentation system intended to provide accurate wound measurement, healing trends, and wound surveillance support. Clinicians use this noncontact system to measure and document the progression of external wounds over time.

Apr 28, 2016 - Custom Product Briefs

TRINITY SYSTEM (KOELIS) FOR TRANSRECTAL ULTRASONOGRAPHY FUSING MAGNETIC RESONANCE IMAGES TO GUIDE PROSTATE BIOPSY

The Trinity® system combines use of real-time, three-dimensional (3-D) transrectal ultrasound (TRUS) guidance with previously acquired magnetic resonance imaging (MRI) scans to target areas of the prostate for biopsy that are suspected to be cancerous.

Mar 3, 2016 - Custom Rapid Responses

VIRTUAL ENDOSCOPY FOR IMAGING THE UPPER GASTROINTESTINAL TRACT

The upper gastrointestinal (GI) tract from the esophagus to the duodenum can be examined using an endoscope to locate various problems such as ulcers, precancerous growths, or obstructions. Virtual endoscopy is a noninvasive alternative to endoscopy that uses three-dimensional imaging and computed tomography (CT) to capture detailed pictures of the inside surfaces of organs.

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

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.
RENALGUARD THERAPY (RENALGUARD SOLUTIONS, INC.) FOR PREVENTING CONTRAST-INDUCED NEPHROPATHY AFTER IMAGING EXAMS

RenalGuard Therapy™ is intended to help prevent contrast-induced nephropathy (CIN) and reduce the toxic effects of contrast media on kidney function. The RenalGuard uses a prescribed loop diuretic to induce the required level of high urine output. The system synchronizes intravenous (IV) infusion of sterile saline with urine output.

SYMPHION TISSUE REMOVAL SYSTEM (BOSTON SCIENTIFIC CORP.) FOR DIAGNOSTIC AND OPERATIVE HYSTEROSCOPY

The Symphion™ Tissue Removal System is a hysteroscopic visualization and resection system intended to remove submucosal uterine fibroids and polyps, assisted by a recirculating and filtering fluid management system that distends the uterus. Components include a controller with integrated fluid management (infusion and aspiration pumps), fluid management accessories, hysteroscope, bladeless resecting device, saline pole, and footswitch.

INTRAOPERATIVE IMAGING USING FLUOROSCOPY WITH COMPUTED TOMOGRAPHY

Computed tomography (CT) fluoroscopy or "real-time CT" combines the advantages of CT’s quality cross-sectional images with the speed of fluoroscopic guidance; these are CT systems that are capable of fluoroscopy. Advantages of CT fluoroscopy include reconstruction and display of CT images in real time; ability to image air, soft tissue, and bone; it does not superimpose anatomical structures as does conventional fluoroscopy; and patient breathing and motion do not affect image quality greatly.

REAL-TIME RADIATION EXPOSURE MONITORING IN HEALTHCARE WORKERS

Real-time electronic badges do not replace traditional badges because they do not record a permanent radiation exposure record; however, they can be used to help clinicians immediately adjust their behavior (e.g., repositioning themselves) to comply with occupational radiation safety procedures and reduce their exposure.

AXILLARY ULTRASOUND FOR STAGING AND MANAGING THE AXILLA IN WOMEN WITH BREAST CANCER

One of the first sites of breast cancer spread is to the lymph nodes located in the armpit (axilla). The presence or absence of axillary lymph node involvement is one of the most important factors in determining the long-term outcome of the cancer (prognosis), and it often guides treatment decisions.

DISCOVERY NM 530C (GE HEALTHCARE) FOR CARDIAC IMAGING

The Discovery™ NM 530c is a nuclear imaging system using single-photon emission computed tomography to perform myocardial perfusion imaging for diagnosing coronary artery disease.

DISCOVERY NM 750B (GE HEALTHCARE) FOR MOLECULAR BREAST IMAGING

The Discovery NM 750b system is a molecular imaging machine intended for diagnostic imaging of the breast and other small body parts. The device images and measures the distribution of selected single-photon emission radiotracers injected into the patient’s body through a vein.

D-SPECT CARDIAC SCANNER (SPECTRUM DYNAMICS MEDICAL) FOR CARDIAC IMAGING

The D-SPECT™ Cardiac Scanner is a single-photon emission computed tomography (SPECT) system intended to perform myocardial perfusion imaging. The system is intended to streamline imaging by personalizing data acquisition through use of a proprietary wristband worn by patients that uses advanced radiofrequency identification technology and is encrypted with patient and radiopharmaceutical agent information.

WHOLE BREAST ULTRASOUND FOR BREAST CANCER SCREENING IN WOMEN WITH DENSE BREAST TISSUE
Breast density is associated with an increased risk of developing breast cancer. Women with dense breasts may elect to have additional screening with ultrasound and magnetic resonance imaging in addition to mammography. Automated breast ultrasound systems, in which a scanner examines the whole breast, are now available. These systems use a completely automated linear transducer to scan the breasts and collect three-dimensional images.

**KONING BREAST CT (KONING CORP.) FOR THREE-DIMENSIONAL DIAGNOSTIC IMAGING**

The Koning Breast Computed Tomography (KBCT) is a breast-imaging system intended to provide three-dimensional (3-D) images of the breast to aid diagnosis of breast cancer or abnormal imaging findings. The role of a 3-D x-ray breast imaging technique, such as breast CT, is to improve visibility of breast regions in which a cancer could be obscured by overlapping tissue.

**WHOLE-BODY COMPUTERIZED TOMOGRAPHY VERSUS X-RAY FOR DIAGNOSING, STAGING, AND MONITORING MULTIPLE MYELOMA**

Multiple myeloma is a systemic cancer of plasma cells, a type of white blood cell present in bone marrow. Clinicians use whole-body computerized tomography or x-ray to diagnose, stage, and monitor the condition. Each has purported advantages and disadvantages.

**RADLINK GALILEO POSITIONING SYSTEM (RADLINK, INC.) FOR INTRAOPERATIVE GUIDANCE DURING ORTHOPEDIC SURGERY**

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.

**MAMMOMAT INSPIRATION WITH TOMOSYNTHESIS OPTION (SIEMENS CORP.) FOR SCREENING AND DIAGNOSIS OF BREAST CANCER**

The Mammatom® Inspiration with tomosynthesis option is the third imaging system to become available in the United States for performing digital breast tomosynthesis, a three-dimensional imaging technique for screening and diagnosis of breast cancer. The technology has been promoted, in particular, for screening women with dense breasts.

**SELENIA DIMENSIONS (HOLOGIC, INC.) AND SENOCLAIRE (GE HEALTHCARE) FOR 3-D BREAST TOMOSYNTHESIS**

Two digital breast tomosynthesis imaging systems are commercially available in the United States Selenia Dimensions System and the SenoClaire. Both systems provide digital two- and three-dimensional images for breast cancer screening and diagnosis.

**LESSRAY (SAFERAY SPIRANE, LLC) FOR LOW-RADIATION FLUOROSCOPIC IMAGING**

Lessray® is intended to increase the safety of fluoroscopy for the treatment planning and procedural guidance of medical conditions. Lessray involves the use of computer software to improve the quality of images from low-dose fluoroscopy.

Updated: 3/20/2018