NEW DRUGS

Asclera for Varicose Veins

The FDA has approved polidocanol injection (Asclera, BioForm Medical/Chemische Fabrik Kreussler) for the treatment of varicose veins. Polidocanol is suitable for small types of varicose veins when the aim is to improve appearance. The drug damages the cell lining of the blood vessels, causing them to close. Eventually, the vessels are replaced by other types of tissue. The product is intended to close “spider” veins (smaller than 1 mm in diameter) and reticular veins (1 to 3 mm in diameter). Adverse reactions may include leakage and hematoma, bruising, irritation, discoloration, and pain at the injection site.

Source: FDA, March 30, 2010

Pancreaze, a Pancreatic Enzyme

A pancreatic enzyme product (Pancreaze Delayed Release Capsules, J&J) has been approved to improve the digestion of food in patients with a pancreatic enzyme insufficiency. Patients with cystic fibrosis, chronic pancreatitis, pancreatic tumors, or total or partial pancreas removal are expected to benefit.

Before this approval, Creon (Abbott, formerly Solvay) and Zenpep (Eurand) were the only FDA-approved pancreatic enzymes on the market. In October 2007, the FDA established a deadline of April 28, 2010, for companies to stop making and distributing unapproved versions of these products.

Source: FDA, April 12, 2010

Generic Cozaar and Hyzaar For Hypertension

Teva’s generic versions of two hypertension drugs have been approved: losartan potassium tablets (Cozaar) and losartan potassium with hydrochlorothiazide (HCT) tablets (Hyzaar). Both generic losartan products carry the same safety warnings as their brand counterparts, including a boxed warning against their use during the second and third trimesters of pregnancy.

Losartan potassium is available in strengths of 25, 50, and 100 mg. Losartan potassium/HCT is approved in strengths of 50 mg/12.5 mg, 100 mg/12.5 mg, and 100 mg/25 mg.

The FDA also approved applications for losartan potassium and HCT 100-mg/12.5-mg tablets from Mylan, Roxane, and Torrent.

Source: FDA, April 6, 2010

NEW INDICATIONS

Xifaxan for Liver Disease

Rifaximin 550-mg tablets (Xifaxan, Salix) have been approved for reducing the risk of recurrence of overt hepatic encephalopathy in patients with advanced liver disease.

Hepatic encephalopathy is characterized by deteriorating brain function that can occur with liver impairment. Increased levels of ammonia in the blood are thought to play a role in the development of this serious condition.

Previously approved for the treatment of traveler’s diarrhea caused by Escherichia coli, rifaximin, a semisynthetic antibiotic, was granted orphan drug status in 1998.

Source: FDA, March 24, 2010

Tarceva for Maintenance Therapy in Lung Cancer

The FDA has approved daily erlotinib (Tarceva, OSI/Roche) as a maintenance treatment for patients with locally advanced or metastatic non–small-cell lung cancer (NSCLC) that has not progressed after four cycles of platinum-based, first-line chemotherapy. The FDA’s decision comes despite an earlier negative opinion from its advisory panel, which voted 12–1 against recommending approval for this expanded use.

The new approval was based on data from the phase 3 SATURN study. Erlotinib is already approved for treating advanced NSCLC that has spread after at least one course of chemotherapy.

Maintenance therapy is a relatively new paradigm in NSCLC treatment. Erlotinib is not intended to be used at the same time as certain types of chemotherapy for NSCLC.

Sources: OSI, April 16, 2010; Data-monitor, April 20, 2010

NEW FORMULATION

OxyContin Formula Might Reduce Opioid Abuse

A new version of controlled-release oxycodone (OxyContin, Purdue Pharma), is designed to discourage the misuse and abuse of this potent opioid. Oxycodone provides continuous, around-the-clock opioid analgesia for managing moderate-to-severe pain.

Because the drug is slowly released over time, each tablet contains a large quantity of medication, allowing for less frequent dosing. However, some people who have abused the previous formulation were at risk of high levels of oxycodone being released all at once, which can result in a fatal overdose.

The new formulation is intended to prevent the medication from being cut, broken, chewed, crushed, or dissolved; the goal is to decrease the risk of an overdose attributable to tampering. The new formulation is also less likely to be snorted or injected. However, the drug can still be abused or misused if a larger-than-recommended dose is ingested.

Source: FDA, April 6, 2010

DRUG NEWS

Avodart and Heart Problems

Dutasteride (Avodart, GlaxoSmithKline), a medication for treating an enlarged prostate gland, has shown a tendency to increase the risk of heart failure.
A new study was initially designed to examine the drug’s effectiveness in preventing prostate cancer. Approximately 6,700 men with high prostate-specific antigen (PSA) values but with no sign of cancer at biopsy received dutasteride or placebo. Four years later, prostate cancer was found in 25% of those receiving placebo and in 20% of those receiving dutasteride. However, heart failure occurred in twice as many treated men as in placebo patients. Several men who developed heart failure while taking dutasteride were also taking other drugs.

Dutasteride is already indicated for urinary problems, and heart failure risk has not been seen when the drug is used for that purpose. Merck’s finasteride (Proscar), which is prescribed for male-pattern baldness, shows the same cancer risk reduction without the additional side effects of dutasteride. Last year, before results of the new study were available, experts had recommended both drugs to decrease prostate cancer risk. However, the two drugs work in different ways and might not have the same safety profile.

Sources: N Engl J Med, April 1, 2010; Drug Watch, April 1, 2010; Associated Press, March 31, 2010

**FDA Temporarily Bans Rotarix Vaccine**

As a precaution, the FDA has recommended that pediatricians in the U.S. temporarily stop using GlaxoSmithKline’s Rotarix vaccine after a benign pig virus was found in the product. There was no evidence of a safety risk associated with the vaccine.

Rotavirus usually affects children younger than five years of age, and it is the leading cause of severe childhood diarrhea. Approved in the U.S. in 2008, the oral vaccine is typically given to babies at two and four months of age to protect against a gastrointestinal illness caused by rotavirus. Researchers found DNA from porcine circovirus 1 (PCV-1) in Rotarix. Follow-up testing revealed that DNA from the virus had been present in the vaccine since its early development. PCV-1 is found in everyday meat products but seldom results in disease in humans or animals.

Rotarix offers protection for two years. After that point, most children are old enough to withstand rotavirus illnesses with few complications. Patients are being advised to switch to Merck’s rotavirus vaccine, RotaTeq; three doses are needed instead of the two with Rotarix.


**ACCORD Trial Update**

In a multicenter study, lowering blood pressure (BP) to levels below those currently recommended did not decrease the risk of fatal or nonfatal cardiovascular disease (CVD) events in adults with type-2 diabetes at high risk for CVD events. Furthermore, lowering lipid levels with a fibrate and a statin did not reduce the risk of CVD events more than using a statin alone. The latest results from the landmark Action to Control Cardiovascular Risk in Diabetes (ACCORD) clinical trial are detailed in the Meeting Highlights feature on page 291.

Sources: N Engl J Med April 29, 2010; NIH, March 15, 2010

**More Tysabri, More Problems**

The risk of progressive multifocal leukoencephalopathy (PML) appears to increase with the number of natalizumab (Tysabri, Elan) infusions received. Natalizumab is indicated for the treatment of multiple sclerosis. New safety information is included in the drug’s label and patient Medication Guide. Information about the occurrence of immune reconstitution inflammatory syndrome (IRIS) in patients who have developed PML and who have subsequently stopped taking natalizumab has also been added to the label.

Source: FDA, February 5, 2010

**Warning: High-Dose Zocor Harms Muscles**

The FDA has alerted patients and health care professionals about the potential for an increased risk of myopathy from simvastatin (Zocor, Merck) at the 80-mg dose. Although muscle injury is a known adverse effect with all statins, the new warning addresses the risk with higher doses of simvastatin. Rhabdomyolysis, the most serious form of myopathy, can lead to severe kidney damage, kidney failure, and death.

Source: FDA, March 19, 2010

**Boxed Warning: Hepatic Injury and Propylthiouracil**

A boxed warning has been added to the prescribing label for propylthiouracil because of reports of severe liver injury, acute liver failure, and sometimes death in adult and pediatric patients.

In June 2009, the FDA notified health care professionals about the risk of serious liver injury. More recent reports have suggested an increased risk of hepatotoxicity with propylthiouracil when compared with methimazole (Tapazole, Jones Pharma/King). Although both drugs are indicated for the treatment of hyperthyroidism caused by Graves’ disease, health care professionals should carefully consider which drug to prescribe for patients with recently diagnosed Graves’ disease.

Patients should be monitored for signs and symptoms of liver injury, especially during the first six months of therapy. Propylthiouracil should not be used in pediatric patients unless they are allergic to or intolerant of methimazole and unless no other treatments are available.

Source: FDA, April 21, 2010
Osteoporosis Drugs May Cause Unusual Fractures

Long-term use of oral bisphosphonates for preventing and treating osteoporosis may be associated with femur fractures, according to two studies.

In the first study of postmenopausal women with osteoporosis, some patients took bisphosphonates for four years or more; others took calcium and vitamin D supplements only. When used for at least four years, bisphosphonates were linked to an increase in the buckling ratio, reflecting a higher risk of fracture.

In another study, researchers compared bone quality in biopsies from patients who had taken the drugs for several years with that of patients who did not take them. Of 21 women experiencing thigh bone fractures, 12 had taken the drugs for an average of 8.5 years; nine women had not taken them. The bisphosphonate group had “old” bone. Normally, bone is 20% old. The rate of 90% for old bone suggested that the body was not turning over bone; too much old bone lacks the ability to repair microdamage. As a result, the thigh bone can break with simple activity, such as climbing stairs.

Source: *HealthDay News*, March 11, 2010

Analgesics and Hearing Loss

The regular use of aspirin, acetaminophen, and nonsteroidal anti-inflammatory drugs (NSAIDs) may increase the risk of hearing impairment in men. Researchers surveyed almost 27,000 men 40 to 74 years of age in 1986 and every two years afterward. During 369,079 person-years of follow-up, 3,488 cases of impaired hearing were reported as follows:

- Men who used aspirin regularly for one to four years were 28% more likely to experience hearing loss than those who did not use it regularly, but the risk did not increase with a longer duration of use.
- Men who used NSAIDs or acetaminophen regularly for four or more years were 33% more likely to have impaired hearing than those not using these agents regularly.
- For NSAIDs and acetaminophen, the risk of hearing loss increased with longer durations of regular use.

For each class of analgesics, the magnitude of the association shrank with age. Although high-dose salicylates and NSAIDs have ototoxic effects, the relationship between acetaminophen and hearing loss has not been studied. The various classes of analgesics may impair hearing through different mechanisms.


Ranolazine (Ranexa) Could Be a Clue to Dyspnea

A 77-year-old man with chronic renal insufficiency was evaluated for moderate but progressive shortness of breath on exertion. Ranolazine (Ranexa, Gilead/CVTherapeutics), prescribed for angina, was determined to be the cause.

The patient had been taking medications for a variety of heart and renal conditions, including ranolazine, for the previous two months. Although he had reported some mild fatigue during the previous two years, his breathing problems had worsened within the previous two months. Pulse oximetry was 95% while he was sitting but dropped to 88% after he had walked 80 feet. After he was sitting again, it returned to 95%.

A cardiologist had prescribed ranolazine for a nonrevascularized left anterior descending arterial lesion and the initial symptoms of fatigue. A piperazine derivative, ranolazine is the first of a new class of drugs approved to treat chronic stable angina pectoris; it also improves exercise tolerance. Because the onset of symptoms appeared to coincide with ranolazine therapy, the drug was discontinued. One month later, symptoms had resolved.

Adverse events include dizziness, constipation, peripheral edema, and cardiac complications. The authors believe that this is the first published case of dyspnea on exertion to be possibly associated with ranolazine that required withdrawal from therapy.

Source: *Am J Geriatr Pharmacother* 2010;8:73–76

Hormones Might Not Help the Heart in Early Menopause

Women who start short-term estrogen plus progestin hormonal therapy have a greater risk of coronary heart disease during the first few years of menopause. Does that risk ever disappear?

Analyzing data for 16,608 postmenopausal women in the Women’s Health Initiative (WHI), investigators found no reduced risk in the first two years, including women who began therapy within 10 years after menopause. A possible cardioprotective effect in women who began therapy closer to menopause was apparent only after six years of use. Their results are similar to those of the Nurses’ Health Study, which found no protective effect in the first three years of hormone therapy that began within 10 years after menopause. Thus, these findings from the WHI and the National Health Service in Great Britain suggest a 29% increased risk in coronary heart disease risk during the first two years of use in women within 10 years of menopause. However, the result did not attain statistical significance.


Diabetic ICU Patients Benefit From Fewer Carbohydrates

One way to manage blood glucose levels in critically ill diabetic patients is to...
restrict their carbohydrate intake. This method worked just as well as prescribing insulin to reduce the possibility of hypoglycemia.

Researchers randomly assigned 337 patients to receive either an insulin infusion or a limited carbohydrate strategy consisting of glucose-free venous hydration, a hypoglycemic nutritional formula, and subcutaneous (SQ) insulin if blood glucose levels exceeded 180 mg/dL. The carbohydrate-restricted group received regular insulin 2 units/day, and the insulin group received 52 units/day. The median blood glucose levels were 144 mg/dL in the carbohydrate-restricted group of patients and 133.6 mg/dL in the insulin group.

More than four times as many insulin patients developed hypoglycemia compared with the carbohydrate-restricted group. Morbidity and mortality were comparable in the two groups. One quarter of the patients in each group died while they were in the intensive-care unit (ICU)—42 in the carbohydrate-restricted arm and 38 in the insulin arm. No difference was seen in the incidence of infectious complications or organ dysfunction.

The study was not intended to compare insulin therapy with no glycemic control at all; the goal was to compare two approaches for glycemic control in ICU patients. However, the findings do suggest that the strategy might be extended to other patients.

Source: J Crit Care 2010;25:84–89

**Five-Day Regimen for Dacogen**

A five-day dosing regimen has been approved for decitabine injection (Dacogen Eisai/MGI Pharma) for patients with myelodysplastic syndromes (MDS), a group of bone marrow diseases that alter the production of blood cells. Decitabine was first approved to treat MDS in 2006.

The new dosing option provides a more flexible regimen with a reduced infusion time. A 20-mg/m² continuous intravenous (IV) infusion is given over one hour and repeated daily for five days per cycle. The cycle is repeated every four weeks. The original three-day regimen is administered in an in-patient setting at a dose of 15 mg/m² in a continuous IV infusion over three hours, repeated every eight hours for three days per cycle and repeated every six weeks.

Source: Eisai, March 11, 2010

**Better Options Needed In Pulmonary Arterial Hypertension**

Although seven therapies have been approved to treat pulmonary arterial hypertension (PAH), they do not seem to reduce mortality, say researchers from Italy and the University of Chicago. These provocative and unexpected findings from a previous review showed no reduction in mortality rates, and the endpoints of all but one study that they analyzed were short-term ones. Thus, the changes were statistically significant, but they were not clinically meaningful.

Since that review, 10 new clinical trials have provided data for 1,500 patients. The pooled effect of all treatments thus revealed a striking mortality reduction of 39%. Having more than 3,500 patients in the meta-analysis enabled researchers to explore which types of patients or therapies were largely responsible for those findings. For example, in trials of patients with severe symptoms or advanced disease, treatment with a vasodilator did reduce mortality rates. However, the mechanism by which mortality rates were lowered was unclear, because it was unrelated to a specific class of drug, the dose, or the medication’s effects on a six-minute walk or hemodynamics.

This suggests a need for a change in thinking about the long-term use of vasodilators for patients with PAH that is non-vasoreactive, although the researchers admit that this view might be considered counterintuitive. They also question the ethics of conducting more clinical trials that use similar designs and endpoints and suggest lengthening trials to at least one year, especially because PAH is a fatal disease. New surrogate endpoints, such as imaging studies and biomarkers, are also recommended so that future trials can better reflect the mechanisms by which treatments affect the underlying disease.

Source: Am Heart J 2010;159:245–257

**PPIs plus Clopidogrel (Plavix) May Prevent Bleeding Ulcers**

Proton pump inhibitors (PPIs) and the anticoagulant clopidogrel (Plavix, Bristol-Myers Squibb/Sanofi-Aventis) are frequently prescribed together, but the risks and benefits of this strategy are unclear. In one study, heart patients who took a stomach acid-suppressing PPI with clopidogrel were only half as likely to be hospitalized for upper digestive tract bleeding as those using clopidogrel alone.

The trial also suggested that combining the drugs did not increase the risk of heart problems. Clopidogrel is usually prescribed for heart patients to reduce the risk of a heart attack or stroke, but it can also cause bleeding ulcers. PPIs, which are used to prevent or treat ulcers and acid reflux disease, may be prescribed with clopidogrel to reduce the risk of upper digestive tract bleeding. However, this practice may decrease the antiplatelet drug’s ability to prevent blood clots. Research is limited in terms of the impact of PPIs on the effectiveness of clopidogrel or on the ability of PPIs to reduce digestive tract bleeding.

The study was based on data from the Tennessee Medicaid program between 1999 and 2005. One group of patients took clopidogrel alone, and the other group took clopidogrel in combination...
with a PPI. Researchers then determined how many patients in each group had been hospitalized for gastroduodenal ulcers. They found that the concurrent use of a PPI and clopidogrel did not increase the risk of a heart attack, sudden cardiac death, stroke, or other cardiovascular problems. This was also true for patients undergoing angioplasty with stents. However, even though no elevated cardiovascular risk was found, it could not be ruled out. More data are needed to determine how combining clopidogrel and PPIs affects cardiovascular health.


Dobutamine Affects Blood Pressure Measurements

Dobutamine, which is used to increase cardiac output in patients with heart failure or cardiogenic shock, is also a substitute for exercise during blood pressure (BP) measurements; however, it isn’t known how the medication affects pulse amplification.

Researchers sought to determine how well brachial artery cuff pressures represented central aortic pressures during dobutamine infusions. They evaluated 25 patients undergoing coronary angiography to diagnose and evaluate coronary heart disease. A cuff oscillometer was used to measure brachial arterial pressures simultaneously with directly recorded aortic pressures at rest and during increasing rates of dobutamine infusion. In 15 patients, applanated radial pulses were fed into a SphygmoCor device and were calibrated to predict aortic pressures.

The oscillometric cuff systolic BP regularly overestimated the directly measured aortic systolic BP during the dobutamine infusion, but the SphygmoCor-derived aortic systolic BP underestimated it. At the peak of the infusion, systolic BP amplification averaged 14.9 mm Hg, with a maximum difference of 43 mm Hg.

When cuff pressures were used to calibrate radial artery pulses, the SphygmoCor device underestimated the aortic systolic BP at all dobutamine doses. However, when the more accurate aortic mean and diastolic BPs were used to calibrate radial artery pulses, the SphygmoCor accurately predicted the aortic systolic BP at baseline but not at the higher doses.

The increased pulse amplification during dobutamine infusion might have resulted from reduced amplitude and a change in timing of reflected waves. Although differences in systolic BP might not influence the conduct of routine stress tests to detect heart disease, they can lead to falsely elevated values in calculating the rate–pressure product and left ventricular wall stress.

The findings underscore the overall need for better noninvasive methods for measuring aortic pressure. Source: Am Heart J 2010;159:399–405

Triple-Strength Antiplatelet Therapy Benefits Patients With Stents

The use of drug-eluting stents has raised concern about stent thrombosis after the first month. Yet according to a study of 3,100 patients in South Korea, inhibiting platelet activation may be vital. Apparently, the more antiplatelet therapy, the better. Tripling the strength, rather than doubling it, reduced the long-term risks of complications after stenting and did not raise the risk of bleeding.

After stents were implanted, patients received a combination of aspirin and clopidogrel (Plavix) or aspirin, clopidogrel, and cilostazol (Pletal, Otsuka). During 12 months of follow-up, 47 patients died (21 in the triple-therapy group and 26 in the dual-therapy group). Myocardial infarction (MI) developed in five patients in the triple-therapy group and in 15 patients receiving dual therapy. Three triple-therapy patients had stent thrombosis (two subacute, one late), compared with 12 dual-therapy patients (two acute, three subacute, seven late).

It isn’t clear why triple therapy is beneficial, but its long-term success may be a result of continuing cilostazol. In addition to the enhanced platelet inhibition when used with dual antiplatelet therapy, cilostazol may have favorable effects on the vascular bed, such as blocking the formation of atheromatous plaque. It also improves endothelial cell function, which may partially explain the minimal risk of bleeding in the triple-therapy patients.

Although bleeding complications were not statistically significant, patients receiving the triple therapy were more likely to have rashes, gastrointestinal disturbance, and headache. Adverse effects resolved after cilostazol was discontinued.

Source: Am Heart J 2010;159(2):284–291 online

RESEARCH NEWS

Reovirus and Prostate Cancer

Using the reovirus, researchers in Canada have detected a therapy for localized prostate cancer. This respiratory, enteric, attenuated environmental virus previously showed potential against lymphoid, ovarian, breast, pancreatic, and high-grade glioma cancers. This is the first time that this orphan virus has been studied to treat prostate cancer.

Most people have been exposed to this common, widespread virus. It doesn’t cause significant illness in humans, but it can bring about a mild respiratory infection or mild diarrhea upon exposure to it.

Researchers examined the efficacy of the reovirus as an experimental therapy for prostate cancer in vitro and in vivo. Six patients in the study had confined,
early-stage cancer. Each patient received a single intracranial virus injection into a suitable prostate cancer nodule via transrectal ultrasound guidance. Three weeks later, the prostate gland was removed as part of the standard treatment.

Findings showed safety and efficacy with minimal toxicity and no viral replication in the normal parts of the prostate, and cancer cell death was evident. Studies to date have suggested that the side effects of the virus are relatively modest, consisting of mild, self-limiting flu-like symptoms.

Source: Cancer Res, March 9, 2010

**DEVICE BRIEFS**

**Recall: Introducer Kit**

The FDA and Thomas Medical Products have announced a class I recall of the Transseptal Sheath Introducer Kit (HeartSpan, Channel FX, Torflex, Braided Guiding Introducer Kit). These devices are used to pass heart catheters from the right side to the left side of the heart. If the sheath tip breaks off and separates during surgery, the fragment could move through the heart and arteries to vital organs, causing a blockage. This could lead to unplanned open-heart surgery, permanent injury, a stroke, a heart attack, or death. These devices were made and distributed from October 1, 2006, through December 27, 2009.

Source: FDA, March 5, 2010

**Inhalers with CFCs To Be Phased Out**

Seven metered-dose inhalers (MDIs), used to treat asthma and chronic obstructive pulmonary disease (COPD), will gradually be removed from the U.S. market. These inhalers contain chlorofluorocarbons (CFCs), which are said to deplete the ozone layer. The last dates on which these devices can be made, sold, or dispensed in the U.S. are as follows:

- June 14, 2010: Tilade (nedocromil, King); Alupent (metaproterenol, Boehringer Ingelheim)
- December 31, 2010: Azmacort (triamcinolone, Abbott); Intal (cromolyn, King)
- June 30, 2011: Aerobid (flunisolide, Forest)
- December 31, 2013: Combivent (albuterol/ipratropium, Boehringer Ingelheim); Maxair (pirbuterol, Graceway)

Until patients switch to an alternative, they should continue using their current inhaler medication. The government ordered the removal of CFCs in the U.S. as of January 1, 1996, except for certain limited uses, such as in MDIs.

Source: FDA, April 13, 2010

**Device Makers Must Mention Pediatric Data**

Manufacturers of medical devices will be required to provide information in certain premarket applications on pediatric patients whom the device is intended to treat, diagnose, or cure, even if the device is intended primarily for adults. Few devices are developed specifically for use in patients 21 years of age or younger at the time of their treatment or diagnosis.

The requirements are contained in the FDA Amendments Act of 2007.

Source: FDA, March 31, 2010

**Cardiovascular Patch (TachoSil) Controls Bleeding**

Nycomed’s TachoSil, an absorbable fibrin sealant patch, is now approved for use in cardiovascular surgery to prevent mild or moderate bleeding from small blood vessels when standard surgical techniques are ineffective or impractical. The patch is composed of a dry collagen sponge made from horse tendons and is coated with fibrinogen and thrombin. It is biodegradable, breaking down in the body within four to six months.

The plasma used to manufacture the patch is collected from U.S. donors who have been screened and tested for blood-transmitted diseases. The fibrinogen, thrombin, and collagen used in the patch undergo manufacturing processes to remove impurities and equine viruses.

Source: FDA, April 6, 2010

**NEW MEDICAL DEVICES**

**Marvin M. Goldenberg, PhD, RPh, MS**

**Name:** Esteem Fully Implantable Prosthetic Hearing Restoration System

**Manufacturer:** Envoy Medical Corp., St. Paul, Minn.

**Approval Date:** March 18, 2010

**Purpose:** The implanted device is used to treat moderate-to-severe sensorineural hearing loss in patients 18 years of age and older. In contrast to conductive hearing loss, sensorineural loss is permanent. Reductions in sound perception and in the ability to understand speech are often caused by genetic factors or inner-ear damage from noise, viral infections, or aging.

**Description:** Traditional hearing aids rely on microphones for amplification. Esteem used the body’s own eardrum as a natural microphone.

Similar to pacemaker technology, two transducers are included: a sensor and a driver that extend into the middle ear from the sound processor. The hearing aid is implanted just behind the ear. The sensor converts mechanical eardrum vibrations into electrical signals that are amplified by the sound processor and then filtered to compensate for the hearing loss. A driver then converts the enhanced electrical signal back to vibrations that are transmitted to the inner ear and perceived as sound. Sound waves travel into the ear canal and set the eardrum into motion, causing the bones of the middle ear to vibrate. The device senses these movements and delivers a
A small remote-control device allows patients to turn the system on or off and to adjust the volume. Older hearing aids do not filter out background noise, but Esteem seems to subvert the problem.

The implant is restricted to patients with stable bilateral hearing deficits, a normally functioning Eustachian tube, and normal middle-ear anatomy.

**Benefit:** After the device is implanted, external components are not readily visible, and patients are unaware of its presence. In one study, most patients had equal or improved speech reception and word recognition scores compared with using pre-implantation hearing aids. The new system may restore some hearing, an advantage over cochlear implants (the first devices to replace a human sense). The battery may last for up to nine years and never needs to be recharged.

**Precaution:** Taste disturbance and facial paralysis were related primarily to the surgery but resolved within one year.

**Sources:** www.envoymedical.com; www.medicaldevicedaily.com

**Name:** MiniMed Paradigm Real-Time Revel System

**Manufacturer:** Medtronics, Inc., St. Paul, Minn.

**Approval Date:** March 23, 2010

**Purpose:** An insulin pump is combined with a glucose-monitoring system for adults and children 18 years of age or older with type-1 or type-2 diabetes. A separate pediatric model is indicated for patients 7 to 17 years of age.

**Description:** Smart insulin pump therapy and continuous glucose monitoring include warnings of impending hypoglycemia or hyperglycemia. By sounding an alarm or vibrating, these alerts enable patients to intervene. Updated glucose values are displayed every 5 minutes, and glucose graphs are displayed at 3 hours and at 24 hours. Online software helps patients and physicians make needed adjustments based on easy-to-read reports, charts, and graphs.

Patients can confirm any changes with a fingerstick measurement. These predictive alerts can be set to go off during exercise or during sleep. Compared with a standard low-glucose alert, the new device improved detection of hypoglycemia by 36%.

**Benefit:** Features are easy to use, and eight thresholds can be set. Compared with fingerstick measurements, MiniMed offers a more comprehensive picture of glucose activity.

**Sources:** www.minimed.com; www.medtronic.com

**Name:** C-MOR Visualization Device

**Manufacturer:** Axis Surgical Technologies, Inc., Mountainview, Calif.

**Approval Date:** March 10, 2010

**Purpose:** This ergonomic lightweight device is used to confirm the diagnosis of structural problems, such as ligament tears during diagnostic, arthroscopic and endoscopic procedures.

**Description:** The self-contained, direct-imaging tool illuminates a patient's interior cavity through either a natural or a surgical opening. This portable device can be used to remove the apical vertebrae at T11 and T12 from a posterior approach.

**Benefit:** Endoscopic images, shown by an on-board liquid crystal diode (LCD) display, improve the surgeon's field of view and range of motion. The device can be operated with one hand. Rapid diagnosis of injuries saves time so that physicians do not have to wait for imaging results. The device can be used in hospital outpatient departments, office surgery suites, and ambulatory surgery centers.

**Sources:** www.medicalnewstoday.com; www.newedge.com