NEW DRUGS

Eyedrops for Bacterial Conjunctivitis

The FDA has approved besifloxacin ophthalmic suspension 0.6% (Besivance, Bausch & Lomb), a topical eyedrop for patients with nonviral bacterial conjunctivitis.

Bacterial forms of conjunctivitis are common in childhood, but they can occur in people of any age. Symptoms can include reddened eyes, swelling, eyelids sticking together, itching, watering, and a sticky discharge from the eyes. The course usually lasts for 7 to 14 days.

In clinical trials, the infection resolved more quickly for patients using besifloxacin eyedrops than for those using a solution containing only a preservative. The drug was effective in patients one year of age and older. Adverse events included redness of the eyes, blurred vision, eye pain, and headache.

Source: FDA, May 28, 2009

Orphan Designations

Ilaris for Cryopyrin-Associated Periodic Syndrome

Canakinumab (Ilaris, Novartis) is now approved for children and adults with cryopyrin-associated periodic syndrome (CAPS). CAPS comprises several rare but lifelong autoinflammatory disorders with debilitating symptoms and limited treatment options. Ilaris is the first approved treatment for patients as young as four years old with two types of CAPS: familial cold auto-inflammatory syndrome and Muckle–Wells syndrome.

CAPS is caused by a single gene mutation that leads to overproduction of interleukin-1 beta (IL-1β), which causes sustained inflammation and tissue damage. This fully human monoclonal antibody rapidly and selectively blocks IL-1β.

Ilaris is given once every eight weeks. Fewer than 10% of patients have experienced injection-site reactions.

The drug's approval was based on a three-part, one-year phase 3 study involving 35 patients. Ilaris has an orphan drug designation for CAPS in the U.S., as well as in the European Union, Switzerland, and Australia.

Sources: *N Engl J Med*, June 4, 2009; Novartis, June 18, 2009

Qutenza Patch For Postherpetic Neuralgia

NeurogesX, Inc., has announced the approval of an orphan drug designation for Qutenza (formerly NGX-4010), a high-concentration capsaicin dermal patch, to manage neuropathic pain in patients with postherpetic neuralgia (PHN). PHN is a chronic condition that develops following a herpes zoster (shingles) outbreak. Current therapies for PHN include antidepressants, anticonvulsant agents, topical anesthetics, and opioid analgesics.

The FDA is reviewing the company's New Drug Application (NDA) for Qutenza in PHN. If approved, Qutenza would benefit from seven years of market exclusivity for PHN as a result of this orphan designation.

Source: NeurogesX, June 2, 2009

NEW INDICATION

Single-Dose Reclast For Preventing Osteoporosis

Zoledronic acid injection (Reclast, Novartis) has been approved as the first therapy to prevent postmenopausal osteoporosis for two years with a single dose.

In a study involving more than 500 postmenopausal women with osteopenia, a single infusion significantly increased bone mineral density at two years compared with placebo.

Reclast is already approved as a once-yearly infusion to treat postmenopausal osteoporosis, increase bone mass in men with osteoporosis, and treat and prevent osteoporosis caused by glucocorticoids. Reclast is also approved for men and women with Paget's disease of bone.

Patients should not take Reclast if they are also taking Zometa, which contains the same active ingredient. Reclast can be given in a physician's office or at an infusion center.

Source: Novartis, June 1, 2009

NEW FORMULATION

Lamictal XR As Add-on Therapy in Epilepsy

The FDA has approved GlaxoSmithKline's extended-release lamotrigine tablets (Lamictal XR) as once-daily, add-on therapy for epilepsy patients 13 years of age or older with partial-onset seizures.

During a 19-week study, more patients who took this agent had a significant reduction in seizure frequency compared with patients receiving placebo. The patients in the study had been having seizures that were inadequately controlled with one or two antiepileptic drugs.

Partial seizures sometimes spread to affect the entire brain (secondary generalization). Lamictal XR is approved as add-on therapy for adults and adolescents who have partial seizures with or without secondary generalization. Patients who are currently taking immediate-release Lamictal twice daily can switch directly to once-a-day Lamictal XR and can use the same total daily dose.

Source: GlaxoSmithKline, June 1, 2009

DRUG NEWS

Do Drugs for ADHD Cause Sudden Death?

In a new study, children and teenagers who took stimulants such as methylphenidate for attention-deficit hyperactivity disorder (AHD) appeared to be at an increased risk of sudden cardiac death. However, the FDA says the study

has limitations and should not change the way the drugs such as Ritalin (Novartis) are used. Although the risk of sudden death is small, the study raises concerns about children with undiagnosed heart conditions.

Researchers collected data on stimulant use among 564 children and teenagers who died unexpectedly of unknown causes and an equal number who died in auto accidents. Many of the unexplained deaths were later attributed to previously undiagnosed cardiac arrhythmias. The odds of using stimulant medication were six to seven times greater among the children who died suddenly of unexplained causes than among those who died in car crashes. Ten children who died of unknown causes (fewer than 2%) took stimulants, compared with two children (0.4%) who died in auto accidents.

The results emphasize the importance of carefully screening and monitoring pediatric patients for heart conditions when medications for ADHD are prescribed.

Drugs such as methylphenidate (Concerta, Ritalin) and amphetamines (Adderall, Dexedrine) increase heart rates and raise blood pressure, but the risk has not been considered significant in healthy children. ADHD drugs must include a warning of the risk of sudden cardiac death in patients with heart problems.

Sources: *Am J Psychiatry* online and WebMD, June 15, 2009

Label Updates

Vyvanse in ADHD

The FDA has approved a label change for a once-daily therapy for attention-deficit hyperactivity disorder (ADHD). The label for lisdexamfetamine dimesylate (Vyvanse) will now include data showing significant symptom control in children six to 12 years of age from the first time point measured (1.5 hours) through 13 hours after the dose is taken.

With this approval, Vyvanse becomes the first oral ADHD stimulant to have 13-hour post-dose efficacy data for pediatric patients included in its labeling.

Source: Shire, June 1, 2009

Asthma Drugs

The FDA plans to update the label of montelukast sodium (Singulair, Merck) zafirlukast (Accolate, AstraZeneca), and zileuton (Zyflo, Cornerstone) with a precaution concerning neuropsychiatric events such as agitation, depression, insomnia, and suicidal thinking.

Montelukast is indicated for use in children and adults as an asthma and allergy treatment; zafirlukast and zileuton are approved as asthma treatments. All three products are leukotriene modifiers.

Neuropsychiatric events also included agitation, aggression, anxiousness, restlessness, dream abnormalities, hallucinations, irritability, suicides, and tremor.

Sources: FDA and *The Wall Street Journal,* June 12, 2009

Liver Injury with an Antithyroid Drug

The FDA is warning health care professionals of liver injury associated with the use of the antithyroid drug propylthiouracil (PTU) for the treatment of Graves' disease. An increased risk of liver damage was identified with this drug when compared with methimazole, an alternative therapy for Graves' disease.

PTU was approved in 1947. From 1969 to 2002, 32 cases of serious liver injury associated with the use of PTU were reported.

In patients with Graves' disease, the thyroid gland becomes overactive. PTU is considered a second-line therapy, except in certain patients who are allergic to or intolerant of methimazole. Because a rare birth defect has been reported with methimazole and not with PTU, PTU may be more appropriate for women with Graves' disease who are in the first trimester of pregnancy.

Patients taking PTU should be closely monitored for symptoms and signs of liver problems, especially during the first six months of therapy.

Source: FDA, June 4, 2009

Pharmaceutical Companies Agree To Reduce Costs Of Medicare Part D Drugs

The pharmaceutical industry has agreed to cut costs of brand-name drugs by almost 50% for many elderly Americans receiving Medicare benefits. These patients often face high out-of-pocket expenses when their benefits reach the gap in coverage that is known as the "donut hole." Beneficiaries currently must pay the entire cost of prescriptions after their initial coverage is exhausted but before catastrophic coverage begins. The gap costs senior citizens from $2,700 to $6,100 per year for medications that are not covered by Medicare Part D.

The deal will be part of an $80 billion reduction over the next 10 years, but according to the drug companies, it is valid only if Congress passes a comprehensive health care overhaul. The agreement was one of a number of pieces of health care reform that President Obama expected Congress to enact this year.

Senate Finance Committee Chairman Max Baucus (D-Mont.) helped to negotiate the agreement with the drug companies. Senator Chris Dodd (D-Conn.) and Barry Rand, from the American Association of Retired People (AARP), also participated. AARP, which represents 40 million older Americans, has been lobbying to eliminate the coverage gap completely.

The President says that drug companies will benefit when more Americans

can afford prescription drugs. The discount would apply to brand-name and biologic drugs but not generic drugs, and it is likely take effect in July 2010.

Under Medicare Part D, recipients pay about 25% of the cost of their drugs until they and the government have paid $2,700. At that point, beneficiaries must cover the full cost of drugs until they have spent $4,350 from their own pockets. When they reach that amount, Medicare's catastrophic drug benefit takes effect, and recipients pay only 5% of the cost of their drugs until the end of the year.

Sources: CNN, *The Washington Post*, Associated Press, June 22, 2009

Advisory for Levemir Insulin

Some vials of the long-acting insulin detemir (Levemir, Novo Nordisk) that had been stolen have reappeared and are being sold in the U.S. market. Three lots (a total of 129,000 vials) of this product were stolen. It's possible that these vials were not stored or handled properly and that they might be dangerous for patients to use. The FDA received one report of an adverse event caused by poor control of glucose levels after a patient used a vial from one of these three lots.

Patients should not use the product if their personal supply of insulin is from Lot XZF0036, XZF0037, or XZF0038. If patients switch to another brand of insulin, they should first contact their physician to see whether dosage adjustments are needed.

Levemir is a clear and colorless solution. Patients should always inspect their insulin visually before using it.

Source: FDA, June 13, 2009

Reglan without Akathisia

Although metoclopramide (Reglan, Schwarz) is often used as an antiemetic and an antimigraine therapy, acute akathisia has been linked to the drug. Researchers from Johns Hopkins University, New York University Medical Center, and Bellevue Hospital Center, however, have found that reducing the infusion rate can eliminate this adverse effect.

Researchers gave 36 patients a bolus and 32 patients an infusion. Akathisia developed in six patients in the bolus group (11%) but in none of the 32 patients in the infusion group.

Slowing down the infusion is a simple intervention that may improve patient comfort and satisfaction without a reduction in drug efficacy. The researchers found no difference between the groups in the effectiveness of treatment.

Source: *Am J Emerg Med* 2009;27:475–480

Ultrasound-Guided Anticoagulation

Deciding which patients can safely discontinue anticoagulation therapy is an unresolved problem in managing venous thromboembolism (VTE), according to researchers for the AESOPUS group.

In an earlier study, the authors had demonstrated that persistent residual vein thrombi, as shown by ultrasonography, are a powerful and independent risk factor for recurrent VTE. In this study, they wanted to assess whether ultrasonographic findings could guide treatment. They compared ultrasonography-guided (flexible) anticoagulation with fixed-duration anticoagulation in 538 patients who had finished three months of anticoagulation treatment. Patients with unprovoked deep-vein thrombosis (DVT) in the fixed-duration group received warfarin for three additional months. If the sonogram showed recanalized veins, the flexible-duration group was given no further therapy. If the sonogram showed persistent thrombi, the patients continued to receive anticoagulants for up to 21 months more.

Of the 268 patients in the fixed-duration group, 46 (17%) developed recurrent VTE, compared with 32 (12%) of 270 patients in the flexible-duration group. However, those findings indicated that a number of patients experienced a recurrence despite vein recanalization. Two patients in the fixed-duration group and four in the flexible-duration group experienced major bleeding.

Ultrasonography improved the ability to identify patients who were at the highest risk for recurrence, the researchers say. Tailoring the duration of oral anticoagulant therapy reduced the risk of recurrent VTE by 35% without an appreciable increase in hemorrhagic risk.

The findings suggest that the benefit was greatest in patients with unprovoked DVT. In these patients, 12 thromboembolic events were prevented at the cost of 65 person-years of extra treatment and no additional major bleeding events. In patients with secondary DVT, only two thromboembolic events were prevented at the cost of 36 person-years of extra treatment and two additional major bleeding events.

Source: *Ann Intern Med* 2009;150:577–585

Support for Bezalip In Dyslipidemia

Bezafibrate (Bezalip, Boehringer Ingelheim), which is used widely in the United Kingdom for dyslipidemia, has not been approved in the U.S. But that may change: researchers from University of Pennsylvania noted that bezafibrate prevented or delayed the onset of type-2 diabetes—an effect unique among the fibrates.

In their retrospective cohort study, patients using bezafibrate on a regular basis had a lower hazard ratio for incident diabetes compared with those using other fibrates. The longer the duration of treatment, the stronger the effect. Beza-

fibrate was used far more often (by 12,261 patients) than any other fibrate. Among bezafibrate patients, 272 developed diabetes (8.5 cases per 1,000 patients). Among patients using other fibrates, 131 developed diabetes (14.4 cases per 1,000 patients).

The authors repeated their analysis with patients who used oral antidiabetic drugs at the baseline examination, with progression to insulin therapy as the outcome. Bezafibrate was associated with a nonsignificant trend toward a lower risk of progression to insulin therapy.

In light of the increasing risk of diabetes, the researchers advocate a trial that can establish the effectiveness of an inexpensive and safe agent for both prophylaxis and treatment.

Source: *Diabetes Care* 2009;32:547–551

Better Adherence To Glaucoma Therapy Needed

Adherence to glaucoma medications could be improved, say researchers who surveyed patients at a Baltimore Veterans Affairs hospital. Of the 141 patients, 20% said they had missed or skipped doses in the previous week. Two-thirds of the patients said that they had at least one problem using their medication, and 17 patients said they had four or more problems, including eyedrops falling on the cheek, eyedrops leaking from the eyes, and hard-to-read print on the instructions, and difficulty paying for refills.

African-American patients were much more likely than Caucasian patients to be noncompliant with their glaucoma therapy. That finding is significant because the rates of glaucoma and blindness from glaucoma are higher in the African-American population, and the disease is often more advanced in these patients at the time of diagnosis.

Source: *Am J Geriatr Pharmacother* 2009;7:67–73

Aspirin May Help Fight Infective Endocarditis

Despite appropriate antibiotic therapy and modern echocardiographic and cardiac surgical approaches, mortality rates remain high (at 20%) for patients with *Staphylococcus aureus*–infective endocarditis (SA-IE). The ICE Investigators, an international group of researchers, suggest that it might be time to bring aspirin to the front line. They found that the recent use of acetylsalicylic acid was associated with a significantly lower overall rate of acute valve replacement surgery, particularly when valvular regurgitation, congestive heart failure, or periannular abscess was the indication for surgery.

In this study, the researchers analyzed data for 670 patients; 132 of the patients were taking aspirin at the time of the SA-IE diagnosis. Among the entire cohort, aspirin use was linked to reduced new-onset, moderate-to-severe valvular regurgitation. Although there was no difference in the occurrence of all-cause strokes, the researchers found a negative association between aspirin use and hemorrhagic stroke that approached significance.

Aspirin does not have potent growth inhibitory or bactericidal activity, and it is unlikely that *S. aureus* will develop resistance to the drug. The benefit of aspirin use in the study was independent of *S. aureus* antibiotic susceptibility.

Aspirin use at the time of the SA-IE diagnosis appeared to be safe, and there was no increase in hemorrhagic stroke or deaths in hospitalized patients. Aspirin also seems to improve infectious endocarditis outcomes through a reduced need for surgery. However, at the one-year follow-up visit, overall reported mortality in aspirin users (54 of 99 deaths) was significantly higher than in non-aspirin users (171 of 406 deaths). This association was also observed in patients who underwent surgery for SA-IE: nine of 36 aspirin patients died during the infectious carditis episode, compared with 35 of 221 non-aspirin patients who had valve-replacement surgery.

Source: *J Infect* 2009;58:332–338

Updated Guidelines For Psoriasis Care

The American Academy of Dermatology has released new guidelines for treating psoriasis with traditional systemic therapies consisting of three commonly used FDA-approved systemic agents: methotrexate, cyclosporine and acitretin. These drugs are easily administered orally and are less expensive than biologics.

This is the Academy's fourth of six sections of the guidelines of care for psoriasis. Three previously published sections focused on general recommendations for treating psoriasis and psoriatic arthritis and for using biologics and topical therapies.

Methotrexate is often effective even in severe cases, although it can cause nausea, fatigue, anorexia, and inflammation of the oral mucous membranes. White blood cell and platelet deficiency, liver damage, and lung scarring, birth defects, and miscarriage are also associated with this agent.

When cyclosporine is used for three to five years, scarring of the kidney's blood vessels may develop. In the U.S., the new guidelines limit the use of cyclosporine to one year.

Acitretin, an oral retinoid, is derived from vitamin A. Retinoids inhibit excessive cell growth and stimulate differentiation of the epidermis. Etretinate, the first retinoid introduced for the treatment of severe psoriasis, was replaced in 1988 by acitretin, the active metabolite of etretinate. Used alone, acitretin is the least effective of the traditional systemic therapies; it is often used along with ultra-

violet light. Potential effects include alopecia, nausea, abdominal pain, and joint and muscle pain. It can also cause birth defects; therefore, its use is limited to men and women of non-childbearing age.

The decision to prescribe these treatments or any other traditional therapy must be tailored to each patient.

Source: *J Am Acad Dermatol* online, June 4, 2009

New FDA Comissioner Plans To Strengthen Enforcement

Unanimously confirmed by the Senate in May, Margaret Hamburg, MD, the FDA's new commissioner, has promised to toughen enforcement and restore confidence in the agency. Her goals are to protect the public's health by ensuring safe, high-quality foods, drugs, and medical equipment. Dr. Hamburg says that in order to oversee the increase in imported foods, medical devices, and drugs, the FDA will need to develop more partnerships with foreign regulators.

In recent years, the FDA has been criticized for the occurrence of a series of food-borne illnesses. The most recent of these was a *Salmonella* outbreak that sickened 700 people, killed nine, and prompted the largest recall in U.S. history.

The FDA has also been criticized by its own scientists for approving medical devices without proper vetting.

Having trained at Harvard, Dr. Hamburg maintains wide support among industry, consumer, and patient advocacy groups.

Sources: *The New York Times* and *The Washington Post*, June 17, 2009; Reuters, June 22, 2009

RESEARCH NEWS

Stem-Like Immune Cells Destroy Tumors in Mice

A new approach to stimulating immune cells enhances their anticancer activity, resulting in a powerful antitumor response in mice. This study, reported from the National Cancer Institute, represents an important advance in the development of immunotherapy for cancer.

A subset of immune cells—T lymphocytes, or CD8+ memory stem cells—mediates strong antitumor immune responses. The investigators generated these potent cells in the laboratory by stimulating antitumor T cells in the presence of drugs designed to mimic an important signaling pathway called Wnt. Under the influence of Wnt, T lymphocytes acquired stem cell-like properties of multipotency and self-renewal, generating differentiating daughter cells while regenerating themselves when they were transferred back to mice from the laboratory. These stem cell-like qualities enabled about 40,000 T cells to trigger the destruction of large melanoma tumors (containing about 1 billion malignant cells).

This therapy improved the survival of treated mice compared with similar treatment using other types of memory T cells. If the results can be confirmed in humans, the use of tumor-reactive CD8+ memory stem cells might be able to reduce the numbers of tumor-specific T cells needed for successful immunotherapy.

Sources: *Nature Med* online and *NIH News*, June 14, 2009

HIV Patients Do Better With Early Therapy

Adults with HIV infection and few resources are more likely to survive if they start antiretroviral therapy (ART) before their immune systems are severely compromised.

In an ongoing clinical study (CIPRA HT 001), starting ART when the patient's CD4+ T-cell counts are between 200 and 350 cells/mm^3 improves survival compared with deferring treatment until the count falls below 200 cells/mm^3. In light of these results, the safety board recommended that the trial be ended prematurely. All study participants who have fewer than 350 CD4+ T cells/mm^3 will be offered ART.

The trial, which began in 2005, enrolled 816 adults ages 18 and older with early HIV disease and CD4+ T cell counts between 200 and 350 cells/mm^3.

This new finding has the potential to change the standard of care for HIV infection in many countries where ART is begun only when CD4+ T cell counts drop below 200 cells/mm^3. The results underscore the importance of identifying people with HIV infection earlier in the course of disease and of starting therapy earlier. It has been recommended that the study team continue to follow all patients for another year and to ensure that those receiving ART continue their therapy.

Source: *NIH News*, June 8, 2009

DEVICE RECALL

Medtronic, Sigma Pacemakers

The FDA is alerting patients to the Class I recall of Medtronic Kappa Series 600/700/900 and Sigma Series 100/200/300 pacemakers. These devices might fail because of a separation of wires that connect the electronic circuit to other pacemaker components, such as the battery.

Patients with malfunctioning pacemakers may experience a return of symptoms associated with an abnormal heart rate, such as fainting or lightheadedness. In rare cases, patients may experience serious injury or even death.

More than 1.7 million Kappa or Sigma pacemakers have been implanted throughout the world. Of those, only about 21,000 are affected by this recall.

Sources: FDA, June 11, 2009; Medtronic, www.KappaSigmaSNList.medtronic.com

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Cervista HPV HR and Genfind DNA Extraction Kit

Manufacturer: Third Wave Technologies, Inc., Madison, Wisc.

Premarket Approval Date: March 12, 2009

Use Classification: The *in vitro* diagnostic test is used to screen patients with atypical squamous cells of the cervix to determine whether colposcopy is needed. The reagents are used with Invader Call Reporter software to identify human papillomavirus (HPV) DNA from 14 high-risk genital HPV types that are commonly associated with cervical cancer. If test results are positive, HPV infection is likely to be present.

Description: DNA is isolated from a scraping of cells from the patient's cervix and is then mixed in reaction wells with probes that recognize HPV DNA. This reaction is detected by another substance that produces light, which is then measured to determine the presence of HPV in the cervical sample. Invader chemistry is used as a signal-amplification method of detecting specific nucleic acid sequences. Two types of isothermal reactions are used: a primary reaction occurs on the targeted DNA sequence, and a secondary reaction produces a fluorescent signal.

Purpose: The test provides information about the risk of developing cervical cancer. HPV infection is common and usually resolves on its own; however, if HPV DNA is present, the risk for developing cervical cancer is higher than if HPV is not detected. The test cannot determine the specific HPV type present.

Benefit: Test results may be used in women 30 years of age and older or in women of any age with borderline cytologic results to determine the need for additional follow-up and diagnostic procedures. Test results should be used together with the physician's assessment of the patient's cytology, history, and other risk factors.

Source: www.fda.gov

Name: Gore Bio-A Fistula Plug

Manufacturer: W. L. Gore & Associates, Flagstaff, Ariz.

Approval Date: May 6, 2009

Use Classification: Representing the next generation of anal fistula repair, this new sphincter-preserving device combines a synthetic, 100% bioabsorbable material with a patented design.

Description: The fistula plug is constructed with a synthetic material, polyglycolic acid/trimethylene carbonate. Bundled hollow tubes are attached to a circular disk, which helps the plug stay in place. This design helps to reduce the chance of a leading cause of fistula plug failure (i.e., extrusion of the plug through the distal opening of the fistula tract) and facilitates reproducible anchoring for dependable performance. The three-dimensional structure of the tubes expands to fill the defect and helps to hold the device in place within the fistula.

Purpose: Surgeons can customize the fistula plug for most defects. Each tube can be trimmed or removed entirely so that the device conforms for a precise fit. In the past, dislodgment of the device and degradation of the plug by bacterial enzymes accounted for some failures in the treatment of anal fistula. The tube's configuration, combined with the material, represents an improvement in the plug's design and may lead to more successful treatment outcomes.

Benefit: This synthetic material has been used successfully to treat thousands of patients. It provides a scaffold on which to build new tissue. Over time, when the patient begins to heal, the material is gradually absorbed by the body, leaving no permanent residue behind.

Source: www.medicalnewstoday.com

Name: Bryan Cervical Disc System

Manufacturer: Medtronic Sofamor Danek, Memphis, Tenn.

Approval Date: June 11, 2009

Use Classification: This titanium and polyurethane device is used to replace a diseased or bulging cervical disc that is causing neck or arm pain. A 10-year post-approval study is planned to evaluate the longer-term safety and effectiveness of the disc.

Description: An open anterior approach is used. After the diseased disc is removed, the Bryan disc is placed in milled pockets in the adjacent vertebral bodies (the neck bones). The device consists of two main metal pieces separated by a polyurethane part.

Purpose: The disc is used to replace a cervical disc from the C3 to C7 level in patients with intractable radiculopathy or myelopathy. Conservative therapy should be tried for at least six weeks before patients receive this device.

Benefit: The Bryan disc helps to stabilize the spinal level that has undergone surgery. Unlike a fusion procedure, the use of this disc allows motion at the operated spinal level. After the new disc is implanted, pain relief and improved function can be expected.

Contraindication: The Bryan disc should not be implanted in patients with infection at the operative site; osteoporosis; moderate-to-severe spondylosis; marked cervical instability; a significant cervical anatomical deformity or compromised vertebral bodies at the index level; significant kyphotic deformity or reversal of lordosis; a need for surgery at more than one cervical level; or allergies to titanium, polyurethane, or ethylene oxide.

Sources: www.fda.gov; www.medtronic.com ■