STRYKER CORP Form 10-K February 28, 2007

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

# Washington, D.C. 20549

# FORM 10-K

#### [X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

#### For the fiscal year ended December 31, 2006

Commission file number: 000-09165

## STRYKER CORPORATION

(Exact name of registrant as specified in its charter)

Michigan (State or other jurisdiction of incorporation or organization) **38-1239739** (I.R.S. Employer Identification No.)

2825 Airview Boulevard, Kalamazoo, Michigan49002(Address of principal executive offices)(Zip Code)Registrant's telephone number, including area code: (269) 385-2600

Securities registered pursuant to Section 12(b) of the Act:

Title of Each ClassName of Each Exchange on Which RegisteredCommon Stock, \$.10 par valueNew York Stock ExchangeSecurities registered pursuant to Section 12(g) of the Act:None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

YES [X] NO [ ]

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

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Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

YES [ ] NO [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES [X] NO [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

[]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer [X] Accelerated filer [] Non-accelerated filer []

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

YES [ ] NO [X]

Based on the closing sales price of June 30, 2006, the aggregate market value of the voting stock held by nonaffiliates of the registrant was approximately \$12,637,735,017.

The number of shares outstanding of the registrant's Common Stock, \$.10 par value, was 408,450,841 at January 31, 2007.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the Securities and Exchange Commission relating to the 2007 Annual Meeting of Shareholders (the "2007 proxy statement") are incorporated by reference into Part III.

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## FORWARD-LOOKING STATEMENTS

This report contains information that includes or is based on forward-looking statements within the meaning of the federal securities law that are subject to various risks and uncertainties that could cause the Company's actual results to differ materially from those expressed or implied in such statements. Such factors include, but are not limited to:

pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for the Company's products; regulatory actions; unanticipated issues arising in connection with clinical studies and eventual United States Food and Drug Administration (FDA) approval of additional OP-1 applications, the FlexiCore and CerviCore spinal implant products, the PlasmaSol sterilization products or other new product introductions; integration and other issues that could delay the introduction of the Sightline product line; changes in reimbursement levels from third-party payors; a significant increase in product liability claims; changes in economic conditions that adversely affect the level of demand for the Company's products; changes in foreign exchange markets; changes in financial markets; and changes in the competitive environment.

While the Company believes that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements contained in this report are qualified in their entirety by this cautionary statement.

#### **REGISTERED TRADEMARKS, TRADEMARKS AND SERVICE MARK**

Stryker Corporation or its subsidiaries own the registered trademarks ABG, Accolade, Apex, AVS, BoneSave, BoneSource, CentPillar, Chaperone, Crossfire, DEKOMPRESSOR, Duracon, eTrauma, FlexiCore, Formula, Gamma, GMRS, Grosse & Kempf, Hansson, Hoffman, Howmedica, i-Suite, Monotube, MX-PRO, Neptune, NRG, Omnifit, OP-1, Opus, Osteonics, PainPump, Partnership, Passport, PlasmaSol, Reflex, Restoration, Scorpio, SIDNE, Silverglide, Simplex P, Solar, SpineCore, SpinePlex, STAIR-PRO, Sterishield, Stryker, Stryker Leibinger, T2, TissueMend, TPS U2 ELITE, Triathlon, Trident, VLIFT, X3, Xia and Zoom; the trademarks 3-chip, Asnis, Avon, CerviCore, ConstaVac, Dall-Miles, Discmonitor, EIUS, Exeter, Gamma, Glideaway, Hydroset, Kinemax, Lock-Rite, OASYS, Omega, OrthoLock, OrthoPad, POWER-PRO, PureFix, Revolution, S2, Secur-Fit, Sightline, TenXor, Triax and Tritanium; and the service mark Physiotherapy Associates.

Not all products referenced in this report are approved or cleared for sale, distribution or use in the United States.

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# <u>PART I</u>

#### ITEM 1. BUSINESS

#### GENERAL

Stryker Corporation (the Company or Stryker) is one of the world's leading medical technology companies with the most broadly based range of products in orthopaedics and a significant presence in other medical specialties. Stryker works with respected medical professionals to help people lead more active and more satisfying lives. The Company's products include implants used in joint replacement, trauma, craniomaxillofacial and spinal surgeries; biologics; surgical, neurologic, ear, nose & throat (ENT) and interventional pain equipment; endoscopic, surgical navigation, communications and digital imaging systems; as well as patient handling and emergency medical equipment. Stryker also provides outpatient physical therapy services in the United States. Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a leading orthopaedic surgeon and the inventor of several orthopaedic products.

Stryker's filings with the United States Securities and Exchange Commission, including its annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, are accessible free of charge at www.stryker.com within the "For Investors" link.

In the first quarter of 2006, the Company acquired all of the outstanding stock of Sightline Technologies Ltd. (Sightline), a private, development-stage company. The acquisition of Sightline, a developer of flexible endoscopes, is expected to enhance the Company's presence in the gastrointestinal and other markets within its MedSurg Equipment segment.

In the fourth quarter of 2005, the Company completed the repatriation of \$722 million of foreign earnings under the provisions of the American Jobs Creation Act (the Act). The Act provided a temporary incentive for United States companies to repatriate accumulated income earned in foreign jurisdictions at a reduced income tax cost. The repatriated funds were invested pursuant to an approved Domestic Reinvestment Plan that conformed to the Act.

In the fourth quarter of 2005, the Company acquired, by merger, all of the outstanding stock of PlasmaSol Corp. (PlasmaSol). PlasmaSol has developed a technology that should allow Stryker to provide sterilization equipment for use with certain of its MedSurg Equipment products.

In the first quarter of 2005, the Company acquired eTrauma.com Corp. (eTrauma). The acquisition expanded the Company's endoscopic and digital imaging equipment product offerings within its MedSurg Equipment segment by adding eTrauma's proprietary Picture Archive and Communications Systems (PACS) image management and viewing software.

In the third quarter of 2004, the Company completed its acquisition, by merger, of SpineCore, Inc. (SpineCore), a developer of artificial lumbar and cervical discs. This acquisition is expected to enhance the Company's presence in the spinal implant market, an important growth area within its Orthopaedic Implants segment.

## PRODUCT SALES

The Company segregates its operations into two reportable business segments: Orthopaedic Implants and MedSurg Equipment. The Orthopaedic Implants segment sells orthopaedic reconstructive (hip, knee and shoulder), trauma, spinal and craniomaxillofacial implant systems; bone cement; and the bone growth factor OP-1. The MedSurg Equipment segment sells surgical equipment; surgical navigation systems; endoscopic, communications and digital imaging systems; as well as patient handling and emergency medical equipment. The Other category includes Physical Therapy Services and corporate administration, interest expense and interest and

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marketable securities income. The following amounts (in millions) and percentages represent business segment and domestic/international net sales during each of the three years ended December 31:

	2006		2005		2004	
	\$	%	\$	%	\$	%
Business segment sales:						
Orthopaedic Implants	\$3,110.1	57%	\$2,849.5	59%	\$2,556.2	60%

MedSurg Equipment	2,037.1	38	1,759.4	36	1,461.2	34		
Other	258.4	5	262.6	5	244.9	6		
Total net sales	\$5,405.6	100%	\$4,871.5	100%	\$4,262.3	100%		
Domestic/international sales:								
Domestic	\$3,556.8	66%	\$3,165.6	65%	\$2,753.0	65%		
International	1,848.8	34	1,705.9	35	1,509.3	35		
Total net sales	\$5,405.6	100%	\$4,871.5	100%	\$4,262.3	100%		
Additional financial information regarding the Company's operating segments and geographic areas can be found								
under the captions "Results of Operations" on pages 28 through 35 and "Note 11 - Segment and Geographic Data" on								

pages 62 through 64 of this report.

Approximately 75% of the Company's sales in 2006, 76% in 2005 and 78% in 2004 consisted of products with short lives, such as reconstructive, trauma, spinal and craniomaxillofacial implant systems (while implants have a long useful life to the patient, they have a one-time use to the hospital); disposables and expendable tools; parts and service revenues, including service and repair charges; and physical therapy revenues. The balance of sales in each of the years came from products that could be considered capital equipment, having useful lives in excess of one year.

The Company's backlog of firm orders is not considered material to an understanding of its business.

# **Orthopaedic Implants**

Orthopaedic Implants are designed and manufactured by Stryker Orthopaedics, Stryker Osteosynthesis, Stryker Spine and Stryker Biotech and consist of such products as implants used in joint replacement, trauma, craniomaxillofacial and spinal surgeries; bone cement; and the bone growth factor OP-1. Artificial joints are made of cobalt chromium, titanium alloys, ceramics or ultrahigh molecular weight polyethylene and are implanted in patients whose natural joints have been damaged by arthritis, osteoporosis, other diseases or injury. The Company's OP-1 bone growth factor, which induces the formation of new bone when implanted into bone, is composed of recombinant human OP-1 and a bioresorbable collagen matrix.

## Minimally Invasive Surgery

Many of Stryker's technologically advanced reconstructive implants are suited to minimally invasive surgery (MIS) procedures that are intended to reduce soft-tissue damage and pain while hastening return to function. The Company supports surgeons with technology, procedural development and specialized instrumentation as they develop new MIS techniques.

In 2006, the Company began the initial launch of a hip resurfacing product in certain international markets. This product represents a less invasive option for younger patients with the potential for enhanced stability and range of motion. In hip resurfacing procedures, very little bone is removed from the femoral head, the femoral neck is preserved and the femoral canal is spared.

In order to facilitate emerging procedural approaches, the Company has also developed instrumentation for MIS total hip arthroplasty. The Company's surgical navigation systems are frequently used in MIS procedures to improve the accuracy of measurements and to position the implant.

Stryker Osteosynthesis has a market leadership position in the Intramedullary (IM) Hip Screw market due to the minimally invasive nature of the Gamma Nail. In 2004, Stryker launched a new version of the Gamma Nail that can be implanted through an even smaller incision. In addition, surgeons are testing the use of the Company's surgical navigation systems for this procedure as well as in surgery for pelvic fractures.

The Company's Scorpio Total Knee Minimally Invasive Instrumentation is designed to complement the unique, minimally invasive total knee procedure pioneered by a leading orthopaedic surgeon. This technique can reduce the length of the incision by approximately 70%. Because of the Company's commitment to responsible science, a multicenter study was conducted to validate the technique's reproducibility and potential benefits, such as reduced pain and earlier return to function.

The EIUS Unicondylar Knee and the Avon Patellofemoral Joint are resurfacing, bone-conserving designs that are used to treat disease isolated to one compartment of the knee. These pre-total knee treatment options can also be implanted using minimally invasive techniques.

## Orthobiologics

Stryker strives to be an innovator and leader in the fast-growing field of orthobiologics with products that combine both natural and synthetic technologies. The Company's innovative product portfolio includes such products as OP-1, a proprietary, recombinant version of a signaling protein with multiple tissue regeneration properties; TissueMend, a single-layer acellular collagen matrix that is easy to handle and delivers both unrivaled strength and documented remodeling capability; Hydroset, the next generation in bone substitute technology which is injectible, sculptable and fast setting; BoneSource BVF, an effective osteoconductive bone substitute with excellent biocompatibility and mechanical stability; and BoneSave, a granules-based alternative to conventional bone grafting.

#### Hip Implant Systems

Through Stryker Orthopaedics, the Company offers a variety of hip implant systems for the global reconstructive market. The ABG Hip System, Partnership Hip System, Secur-Fit Hip System, Omnifit Hip System, Accolade Hip System and Restoration Hip System are all comprehensive systems of hip implants and associated instrumentation designed to provide physicians and patients with reliable results and to reduce operating time for primary and revision procedures. The Exeter Total Hip System is based on a collarless, highly polished, double-tapered femoral design that reduces shear stresses and increases compression at the cement/bone interface. During 2004, the Company began transitioning to its new Restoration Modular Revision Hip System in the United States, Europe, Australia and Canada. This system offers surgeons performing revision surgeries flexibility in treating complex hip stem revisions and restoring patient biomechanics. The Restoration Modular Revision Hip System also takes advantage of Stryker's long clinical history with hydroxylapatite (HA), a naturally occurring calcium phosphate material that demonstrates a high level of biocompatibility due to its resemblance to bone, by incorporating PureFix HA coating on many components. The Restoration Modular Revision Hip System complements the Company's existing Restoration HA and Restoration plasma spray (PS) monolithic revision systems.

In 2006, the Company announced that it received clearance from the FDA for its advanced bearing system, LFIT Anatomic Femoral Heads with X3 polyethylene liners. This represents a significant advancement in hip bearing technology with the combination of Stryker's Low Friction Ion Treatment (LFIT) technology and X3 advanced bearing technology. The femoral heads are anatomically sized for more natural hip performance.

Following the clinical success of its Crossfire technology, a highly crosslinked polyethylene designed to reduce wear, Stryker launched X3 polyethylene in 2005. X3 polyethylene is the Company's next-generation highly crosslinked polyethylene and features a higher level of strength and wear reduction in both hip and knee replacements.

Stryker was the first company to receive clearance from the FDA to commercially release for sale in the United States a hip implant with HA surface treatment. The Company's global clinical experience with HA-

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coated hip stems now extends over 20 years and reported clinical performance continues to equal or exceed that of comparable hip stems reported in the scientific literature.

The Company began a limited launch of its CentPillar Hip System in the Japanese market in 2003, with a full rollout in 2004. The Taro Hip System and CentPillar Hip System provide lines of products that offer an increased range of motion and a minimally invasive technique preferred by Japanese surgeons for their patients.

The Company received premarket approval (PMA) from the FDA in 2003 for its ceramic-on-ceramic hip replacement system, the Trident Ceramic Acetabular Insert, for patients in the United States. Stryker Orthopaedics has successfully launched the Trident ceramic insert in the United States, Europe, Australia and Canada. The Trident insert is wear resistant, and it is protected and strengthened by a patented titanium sleeve. In 2006, the Company launched the Trident Tritanium Acetabular Shell which contains a highly porous surface that closely resembles the structure of trabecular bone. This shell is designed for revision surgery and contains multiple screw holes to achieve bone fixation and initial stability. Other technologies used for total hip replacement include metal-on-conventional polyethylene and metal-on-highly crosslinked polyethylene articulations.

The Company entered 2007 with more than 30 years of clinical history with the Exeter Hip System, more than 20 years of clinical history with the Omnifit cemented stem and more than 20 years of clinical history with the Omnifit HA stem. Long-term clinical results are an important factor in the Company's ability to market hip implants.

#### Knee Implant Systems

The Company offers five major knee implant systems under the Stryker brand name: the Duracon, EIUS, Global Modular Replacement System (GMRS), Scorpio and Triathlon systems. Utilized in more than 500,000 procedures worldwide, the Duracon System combines high levels of joint conformity throughout the range of motion and consistent anatomic tracking. The DuraconTS and ScorpioTS Revision systems and Modular Rotating Hinge completed the product line offerings with implants for complex revision procedures.

Launched on a limited basis in the United States and Europe in 2004, the Triathlon Knee System represents the Company's evolutionary design that has been developed to more closely reproduce natural knee motion and is designed to provide mobility with stability through more than 150 degrees of flexion. In 2006, Stryker introduced anterior referencing instruments for use with this knee system. In 2005, the Company launched a posteriorly-stabilized (PS) version of the Triathlon knee following the launch of the cruciate-retaining (CR) version in 2004. During 2005, the Company continued its launch of the Triathlon Knee System on a worldwide basis throughout the United States and Europe and into Canada and the Pacific region. The state-of-the-art Triathlon Knee instrumentation is designed to improve operating room efficiency through a streamlined, integrated system providing options and flexibility to meet surgeons' varying preferences and multiple surgical techniques.

The GMRS is a global product that offers a comprehensive solution for severe bone loss in oncology, trauma and revision surgery patients. GMRS has tibial and femoral components, including a total femur, and a modular rotating hinge knee. The system employs both titanium and cobalt chrome alloys for strength and lightness of weight, together with the superior flexibility of the hinge. The MRS, the predecessor to the GMRS, was the first modular segmental replacement system when it was introduced in 1988. These systems' components have maintained a leadership position in this market segment since their introduction.

The Scorpio knee implant design is based on the epicondylar axis of the knee. This patented approach addresses significant clinical issues, such as improved patient rehabilitation and midflexion stability, through an increase in the patella-femoral moment arm and a single anterior-posterior radius. In 2006, the Scorpio HA CR and Scorpio HA PS versions were launched. The Scorpio HA CR product is designed to minimize polyethylene wear and the Scorpio HA PS product features a minimally invasive open box design and maximized stability. The Scorpio Plus Mobile Bearing tibial component was launched in markets outside the United States in 2001, and a clinical trial is in progress in the United States. This addition to the Scorpio line provides a competitive

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entry into the growing, mobile-bearing market segment. The Scorpio NRG, originally launched in Japan, was introduced in Europe and the Pacific region in 2005 and in the United States in 2006. Scorpio NRG provides additional kinematic benefits over ScorpioFlex, including increased rotational allowance, an articulating design for deeper flexion and greater extension allowance without impingement. The ScorpioFlex, which is available for both posterior cruciate-retaining and cruciate-substituting indications, is specifically designed for patients who have the ability and motivation to return to high-flexion activities such as gardening and golfing. ScorpioFlex has also enjoyed success in Japan, where it is sold under the trade name Scorpio SuperFlex. The Scorpio System is supported by the Passport instrumentation system, which was designed to provide intraoperative flexibility and precision as well as a simple, cost-effective approach to total knee replacement surgery.

The EIUS Unicondylar Knee replacement system is designed for the minimally invasive knee surgery market segment. This system marries bone-sparing femoral and tibial implants with sophisticated instrumentation and a surgical technique aimed at reducing rehabilitation time for patients.

#### Other Joint Replacement Products

The Company markets other joint replacement products, principally shoulder and elbow implants and related instruments, under the Stryker brand name. The Solar Total Shoulder System provides a unique design for the humeral head that allows surgeons to adjust tension of the supporting tissues while maximizing range of motion. The shoulder instruments offer surgeons increased visibility and access to this tightly confined joint space. The Solar BiPolar Shoulder provides surgeons with additional options for addressing rotator cuff arthropathy arthritis of the shoulder and incorporates the patented bipolar locking mechanism that is also used in the Company's hip implants. The Solar Shoulder product line gives surgeons increased intraoperative flexibility to restore the patient's shoulder kinematics. The Solar Total Elbow complements products offered for upper extremity procedures. The semiconstrained design and modular components address varying types of patient anatomy.

#### Bone Cement

Simplex bone cement, a material used to secure cemented implants to bone, was first approved for orthopaedic use in the United States in 1971 and is the most widely used bone cement in the world. The Company manufactures and provides several variations of Simplex bone cement to meet specific patient needs. Simplex has more than 45 years of clinical history, the longest of any bone cement, with more than 400 published clinical papers.

#### Trauma Implant Systems

Through Stryker Osteosynthesis, the Company develops, manufactures and markets its trauma extremities and deformities systems. These systems, including nailing, plating, hip fracture, external fixation systems and bone substitutes are used primarily in deformity corrections and in the fixation of fractures resulting from sudden injury. These products consist of internal fixation devices marketed under such names as Gamma, Grosse & Kempf, Omega, Dall-Miles, Asnis, AxSOS, Hydroset, T2 and S2, along with external fixation devices marketed under the Apex, Hoffmann II and Monotube Triax names.

The Company's internal fixation product portfolio includes a full array of IM nails, hip fracture devices and plates and screws in both titanium and stainless steel. These products complement the total hip and knee replacement offerings mentioned above by offering a restorative option in addition to total replacement.

To address the hip trauma and fracture segment, the Company markets several products, including the IM nail portfolio, led by the T2 Nailing System; the Gamma Nail, a unique IM nail for trochanteric fractures; the Omega hip screw system; the Asnis Cannulated Screw System; and the Hansson pin system, providing a complete offering of surgical solutions for the hip trauma patient. These hip fracture systems offer orthopaedic surgeons multiple options depending on their preferences and patient needs.

The T2 Nailing System includes femoral, tibial and humeral components with a common instrument platform for accuracy and ease of use. The Company has also recently introduced the T2 Ankle Arthrodesis Nail to provide the option for tibiotalocalcaneal fusion with a retrograde IM nail that provides for limited soft tissue

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damage in the ankle area, early weight bearing and compression of the subtalar and tibiotalar joints. Building on the success of this titanium nail, the Company introduced the stainless steel S2 tibial and femoral nails. The S2 nails are designed to meet the needs of Level 1 trauma centers in the United States and to broaden the Stryker product line in the rest of the world. Following an initial release in selected markets during 2003, the Gamma3 IM hip fracture nail was fully launched during 2004 in the United States, Japan and Europe. The Gamma3 is based on more than 15 years of Gamma Nail experience and is the third generation of IM short and long Gamma fixation nails. The Gamma3 System is designed to facilitate minimally invasive surgery and reduce surgery time through the use of newly designed implants and instrumentation. The Asnis Cannulated Screw System can help simplify the operative procedure through features that allow surgeons to place, insert and remove locking screws easily.

To address the knee trauma segment, Stryker offers the Hoffman II Modular Fixation System, the T2 SCN Nailing System and the SPS and AxSOS plating solutions. The Hoffman II knee-bridging frame is used to stabilize injuries to the knee until definitive treatment with a plate or nail, or reconstruction takes place. In addition, Stryker offers the T2 SCN Nail, which can be used for definitive treatment of supracondylar femur fractures just above the knee joint. This nail can also be used for periprosthetic fracture fixation for traumatic fractures in patients who have already had a joint replacement.

Stryker has several product lines for upper extremity trauma. The Numelock II Polyaxial Locked Plating System is the only comprehensive, upper extremity, polyaxial periarticular fracture fixation system on the market. The T2 Proximal Humeral Nail has been very well received and offers a minimally invasive option for fractures of the humerus. The Universal Distal Radius System complements the stainless steel Numelock II with a titanium option in distal radius plates and screws. The Universal Distal Radius System offers a wide array of precontoured, variable-sized plates for volar, distal and column approaches and both open reduction and internal fixation techniques. In 2006, the Company launched, on a limited basis, the second generation VariAx Universal Distal Radius System that is thinner than the original and features polyaxial locking. The AxSOS Locking Plate System, also introduced in 2006, is designed to treat metaphyseal and diaphyseal fractures with low profile anatomically contoured plates, a unique screw design and a simple instrument platform.

The Company's external fixation products also include the Hoffmann II Compact and MicroFix, the Monotube Triax monolateral system, the TenXor circular fixation system for complex fractures and a complete range of pins and wires for attaching the devices to fractured bones. The Hoffmann II Compact for upper extremity fractures includes a patented snap-fit mechanism that makes it easy for surgeons to construct the fixation device to fit the patient and align the fractured bones. It also has a full selection of lightweight radiolucent connection bars that allow for quick intraoperative fracture repair. The Monotube Triax System is available in three sizes and includes an adjustable feature that enables surgeons not only to stabilize fractures but also to lengthen the bone in cases where bone has been

removed due to damage. The TenXor hybrid frame enables surgeons to treat complex fractures around the joints with both pins and long transfixing wires. This attribute is especially useful for patients with multipart fractures near the ankle and knee. The system features advanced composite materials and is compatible with the Hoffman II snap-fit connection devices.

#### Craniomaxillofacial Implant Systems

Through Stryker Osteosynthesis, the Company develops, manufactures and markets plating systems and related implants and products for craniomaxillofacial surgery. In 2006, Stryker introduced HydroSet, a self-setting calcium phosphate bone substitute that is indicated to fill certain bone voids or gaps of the skeletal system. Also in 2006, the Company launched DuraMatrix, a second generation dura substitute technology, which is a conformable and resorbable membrane matrix engineered from highly purified type I collagen. In 2005, the Company extended its Universal Fixation System for craniomaxillofacial surgery with the addition of a facial trauma module.

#### Spinal Implant Systems

Through Stryker Spine, the Company develops, manufactures and markets spinal implant products including cervical, thoracolumbar and interbody systems used in spine injury, deformity and degenerative

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therapies. Spinal implant products include plates, rods, screws, connectors, spacers and cages, along with proprietary implant instrumentation. In 2006, the Company introduced the VLIFT vertebral body replacement system consisting of a preassembled, cylindrically shaped titanium cage with a distractible or retractable center. The hollow core of the cage allows for packing bone graft. Also in 2006, Stryker launched the AVS AS and AL Spacers which are used as vertebral body support devices in anterior procedures.

In 2004, Stryker introduced the OASYS fixation system developed to serve posterior cervical fusion, which is an emerging area of spinal surgery. The product was introduced in the United States following a successful launch in the European market during 2003. Also in 2004, Stryker introduced the Reflex Hybrid anterior cervical plate and the AVS PL vertebral spacer system. The Reflex Hybrid features the ability to utilize both fixed and variable angle screws. The AVS PL spacer system represents Stryker's initial product offering in the vertebral spacer category.

## OP-1 Implant/BMP-7

More than two decades ago, Stryker saw the potential that orthobiologic products held for orthopaedics in an aging world and began a long-term investment in OP-1, initially focused on the bone growth properties of OP-1. OP-1 was originally discovered by Creative BioMolecules, Inc. (a company that subsequently merged into Curis, Inc.) with which Stryker funded a long-term development collaboration with a vision to develop the first molecules to stimulate tissue regeneration. Stryker's first therapeutic product, OP-1 Implant, is composed of recombinant human OP-1 and a bioresorbable collagen matrix. OP-1 is a natural protein that the human body makes to induce bone formation. In preclinical studies, OP-1 induced the formation of new bone when implanted into bony defect sites. Stryker was the first company to enter clinical studies with a bone morphogenic protein, BMP-7 (or OP-1). Studies have been performed in two challenging clinical indications: first, in nonunion fractures of long bones, and second, in posterolateral spine fusions.

Stryker has received approval for a Humanitarian Device Exemption (HDE) from the FDA. This approval in the United States is for the use of OP-1 Implant as an alternative to autograft in recalcitrant long-bone nonunions where use of autograft is not feasible and alternative treatments have failed. An HDE, as defined by the FDA, is for a product intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals per year in the United States. As of December 31, 2006, Stryker had more than 800 hospital Institutional

Review Board (IRB) approvals for OP-1 Implant in patients in the United States under this HDE.

The Company has received market approvals from regulators in Europe, Australia and Canada for the indication of nonunion fractures of the tibia that failed prior autograft treatment or when autograft treatment is not feasible; for the treatment of long-bone nonunions secondary to trauma for the purpose of initiating new bone formation; or for the clinical indication of long-bone nonunions. The Company filed a Marketing Authorization Application (MAA) with the European Medicines Evaluation Agency (EMEA) for certain OP-1 uses, and the MAA was accepted for filing in July 1999. On December 14, 2000, the Committee for Proprietary Medicinal Products (CPMP) in Europe voted unanimously to recommend market authorization for OP-1 Implant (marketed in Europe under the name Osigraft) for the indication of nonunions of the tibia that failed prior autograft treatment or when autograft is not feasible. Final European approval was obtained for this indication in May 2001. A New Drug Application with the Therapeutic Goods Administration (TGA) in Australia was filed in December 1999, and in February 2001 the Australian Drug Evaluation Committee (ADEC) recommended the granting of marketing authorization for OP-1 Implant for treatment of long-bone nonunions secondary to trauma for the purpose of initiating new bone formation. Approval from the TGA was received in April 2001. In February 2002, the Company received approval to market OP-1 Implant in Canada for the clinical indication of long-bone nonunions.

In the United States, Stryker received a further HDE in May 2004 for revision posterolateral spine fusion following the completion of a pilot clinical study that indicated possible benefit of a new formulation of OP-1, known as OP-1 Putty, for this application. As of December 31, 2006, Stryker had more than 600 hospital IRB approvals for OP-1 Putty in the United States under this HDE.

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Demand for OP-1 Implant and OP-1 Putty continued to increase during each quarter of 2006. Stryker is committed to the further development of OP-1 as an alternative to iliac crest bone graft for patients requiring spinal fusion using a variety of surgical techniques. Spinal fusion is used to stabilize the spine and improve patient outcomes postoperatively. The Company conducted a multicenter pivotal trial in the United States and Canada using OP-1 Putty in posterolateral lumbar spine fusion in the setting of degenerative spondylolisthesis. In 2003, the Company completed enrollment in this trial and the final 2-year follow-up evaluation of the 297 enrolled patients was completed at the end of 2005. The results were analyzed and submitted to the FDA in June 2006 as part of a PMA application for the use of OP-1 Putty in posterolateral lumbar spine fusion surgeries. The PMA is currently under review by the FDA. Stryker has scheduled a meeting with the FDA for the first quarter of 2007 to optimize the clinical data package of the posterolateral lumbar spine fusion PMA submission. The Company continues to believe in the eventual approval of OP-1 for spinal fusion in the United States, though nearer term timing cannot be predicted. In December 2006, Stryker filed a MAA with the EMEA for a posterolateral lumbar spine fusion indication.

During 2006, Stryker filed an investigational device exemption (IDE) application with the FDA to start a clinical study in transforaminal lumbar interbody fusions using OP-1 Putty. The IDE was approved and patient recruitment will begin in 2007.

Stryker is also interested in exploiting the cartilage regeneration properties of OP-1 and has successfully completed preclinical studies showing that OP-1 can stimulate new cartilage formation and increase disc height in animal models of degenerative disc disease. In 2005, Stryker filed its first Investigational New Drug (IND) application with the FDA to treat degenerative disc disease with a new injectable form of OP-1 in a dose-ranging study in humans. During 2006, Stryker initiated the dose-ranging clinical study for the first time use of BMP-7 to regenerate cartilage tissue and patient enrollment has commenced. In December 2006, Stryker filed an IND application with the FDA to treat osteoarthritis in the knee with the injectable form of OP-1 and received FDA concurrence, in January 2007, to proceed with a clinical study.

# **MedSurg Equipment**

MedSurg Equipment products include surgical equipment; surgical navigation systems; endoscopic, communications and digital imaging systems; and patient handling and emergency medical equipment. These products are designed and manufactured by Stryker Instruments, Stryker Endoscopy and Stryker Medical.

The Stryker Instruments and Stryker Endoscopy product portfolios include micro powered tools and instruments that are used in orthopaedics, functional endoscopic sinus surgery, neurosurgery, spinal surgery and plastic surgery. The Total Performance System (TPS) is a universal surgical system that can be utilized in several medical specialties. The TPS U2 Drill and TPS Burs are designed for use by spine surgeons and neurosurgeons, while the TPS MicroDriver and TPS Sagittal Saw are designed for use by sports physicians and plastic surgeons. The Elite attachment line with a proprietary extendable bar system and Saber Drill for ENT surgery further extend the TPS System into spine, neurosurgery and ENT applications. The TPS System also powers Stryker Endoscopy Shaver Systems.

# Surgical Equipment

Through Stryker Instruments, the Company offers a broad line of surgical, neurologic, ENT and interventional pain equipment that is used in surgical specialties for drilling, burring, rasping or cutting bone in small-bone orthopaedics, neurologic, spine and ENT procedures; wiring or pinning bone fractures; and preparing hip or knee surfaces for the placement of artificial implants. Stryker Instruments also manufactures an array of different attachments and cutting accessories for use by orthopaedic, neurologic and small-bone specialists.

In 2006, the Company introduced the Stryker Precision Oscillating Tip Saw. In contrast to standard surgical saws with oscillating blades, this innovative saw has a stationary blade shaft with an oscillating tip. This feature gives surgeons the opportunity for greater accuracy while simplifying cuts and reducing the potential for

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soft tissue damage. This saw represents an advance in procedural simplification, offering customers the potential for time and cost savings by reducing the number of steps in the surgical process.

In 2006, the System 6 heavy duty power system was released. This next-generation system includes several new attachments, is more powerful and has a longer battery life. The System 6 Rotary Handpieces provide more options to surgeons by allowing both high-speed drilling and high-torque reaming in one handpiece. System 6 Heavy Duty Saws provide increased torque for a faster and more efficient cut.

In 2006, the Company launched the Silverglide Non-Stick bipolar forceps. These forceps rapidly diffuse heat, eliminating localized sticking of tissue to the instrument, thus reducing bleeding in neurosurgery procedures.

The introduction of the Maestro drill in 2005 expanded Stryker's line of micro powered instruments for spine, neurology and ENT applications. Employing the pneumatic technology that is the preference of many surgeons in these specialties, the Maestro drill leverages the Company's TPS and Consolidated Operating Room Equipment (CORE) platforms by using the same cutting attachments.

In 2004, Stryker launched the CORE electric console for use with its line of CORE powered instruments. The CORE platform console is a technological advancement on the precision and versatility offered by the TPS console platform and offers integrated irrigation, multi-handpiece functionality and a standardized user interface.

Stryker Instruments also produces products that are utilized in conjunction with joint replacement surgery. In 2004, Stryker introduced the Revolution Cement Mixing System, representing an improved design over its existing Advanced Cement Mixing System. The Revolution System is designed to provide one solution for mixing all surgical cements, in addition to offering mixing efficacy, safety and ease of use. Interpulse is a disposable, self-contained pulsed lavage system that is used by physicians to cleanse the surgical site during total joint arthroplasty. The

ConstaVac CBC II Blood Conservation System is a postoperative wound drainage and blood reinfusion device that enables joint replacement patients to receive their own blood rather than donor blood.

In 2005, the Company advanced its postsurgical technology with the introduction of the Block Aid PainPump System. This device enables one product to meet the needs of both site-specific pain management and a reprogrammable pump that is ideal for continuous nerve blocks. The Company also markets the PainPump2, a disposable system that offers electronically controlled flow rates of pain medication directly to the surgical site to help manage a patient's postoperative discomfort. This innovative design allows the physician to program the pump and provides a patient-controlled analgesia (PCA) option, previously unavailable to the market in a disposable pump.

To promote safety for patients and medical staff, Stryker works closely with hospitals and other health-care organizations to develop a broad product portfolio. In 2005, Stryker introduced its next-generation Sterishield T5 Personal Protection System, which advances its market-leading helmet, hood and gown to help provide protection for operating room personnel from infection, cross-contamination and harmful microorganisms. This system employs advanced user-cooling features and provides the option for integrated communication and lighting systems. The Neptune Waste Management System represents Stryker's leading product for waste management in the operating room. The self-contained device, first introduced in 2000 and consistently improved, collects and disposes of fluid and smoke waste from surgical procedures, minimizing the need for operator intervention and, therefore, the risk of exposure to these waste products. In 2004, the Company introduced the Neptune Bronze platform, which provides a low-cost alternative to its operating room waste management solution.

Through Stryker Instruments, the Company offers SpinePlex, a variation of its surgical Simplex bone cement for applications in the treatment of vertebral compression fractures. In 2006, the Company introduced the Disconnitor Discography System, a disposable device used to inject fluid into the intervertebral disc nucleus during discography procedures. This system features a digital display and allows physicians to save key data points for each disc. Stryker's radiofrequency generator system for chronic pain management, originally introduced in 2004, was enhanced in 2006 with improved user interfaces, a simplified operating system and the expansion of the cannula and electrode offerings including the industry's first monopolar nitinol electrode.

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Stryker also offers the Dekompressor, a single-use disposable device indicated for the percutaneous removal of disc nucleus material, which offers an early, less invasive approach to mitigating back and leg pain associated with contained lumbar herniations. This product, along with Stryker's offerings in percutaneous cement delivery, discography and radiofrequency denervation, allows Stryker to focus on the interventional pain management marketplace.

# Surgical Navigation Systems

Through Stryker Instruments, the Company offers a broad line of surgical navigation systems that give surgeons in several specialties the ability to use electronic imaging to see more clearly, align instruments better and accurately track where the instruments are relative to a patient's anatomy during surgical procedures. In 2006, Stryker released two groundbreaking navigation applications for the joint replacement and craniomaxillofacial implant markets. The eNdtrac ASM software and instrumentation give orthopaedic surgeons the option of navigating their cuts while eliminating the need to place additional pins in the femur and tibia outside of the surgical incision. The iNtellect software packages provide neurologic and ENT surgeons with enhanced graphics, a significantly simplified image import process, customizable procedure-specific workflows and user-friendly advanced tools for comprehensive planning and navigation.

During 2005, the Company launched a number of new products across multiple surgical specialties to better serve the surgical navigation marketplace. For the knee implant market, eNact Knee 3.1 software was introduced, further

simplifying the procedure via reactive workflow by leveraging Stryker's Smart Instrumentation and Camera technology. This unique technology promotes greater surgical efficiency because the software automatically reacts to a surgeon's individualized procedural workflow. To serve the implant instrumentation market, the Company introduced the OrthoLock Anchoring System, which allows for less invasive procedures and provides surgeons a choice between two and three pin tracker anchoring. Also introduced was the Ortho Grip Knee Pointer, which allows surgeons to utilize an ergonomically designed pistol grip instrument during the implant registration process. Stryker also released two major advancements in its Neuro portfolio with Neuro 2.0 software and the Shunt Placement Tool. Neuro 2.0 provides surgeons with the option of utilizing the Company's Mask technology to register the patient without traditional fiducial markers and increases surgical efficiency by significantly reducing intraoperative patient registration time. The Shunt Placement Tool provides a higher degree of accuracy for one of the most common neurosurgical procedures by utilizing a dedicated instrument and corresponding software designed specifically for the procedure. In spine navigation, Spine 1.2 software was released for support of complex spine procedures, such as multiple-level scoliosis repair, requiring intraoperative 3D CT data. Also in 2005, a portable laptop navigation system was introduced; it has a smaller footprint in the surgical suite, is easily portable, is cost efficient and offers the functionality and technological advantages of Stryker's System II Cart.

The Company launched the Navigation System II Cart and Camera as well as Hip 2.0, Uni-knee, and Knee 3.0 for use with the Stryker Navigation System in 2004. All of these new product offerings are imageless platforms incorporating more intuitive hardware and software functions that result in greater ease of use, less invasive procedures and reduced surgical time.

## Endoscopic, Communications and Digital Imaging Systems

Stryker Endoscopy produces and markets medical video-imaging and communications equipment and instruments for arthroscopy, general surgery and urology. Stryker Endoscopy has established a position of leadership in the production of medical video-imaging technology and accessories for minimally invasive surgery, as well as communications equipment to facilitate local and worldwide sharing of medical information among operating rooms, doctors' offices and teaching institutions. Products include medical video cameras, digital documentation equipment, digital image and viewing software, arthroscopes, laparoscopes, powered surgical instruments, sports medicine instrumentation, radio frequency ablation systems, irrigation fluid management systems, i-Suite operating room solutions and state-of-the-art equipment for telemedicine and enterprise-wide connectivity. Stryker's line of rigid scopes, which range in diameter from 1.9 millimeters to 10 millimeters, contains a series of precision lenses as well as fiber optics that, when combined with Stryker's high-definition (HD) camera systems, allow the physician to view internal anatomy with a high degree of clarity.

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In 2006, the Company introduced the 1188 HD Camera, the next generation of Stryker 3-Chip HD Cameras. The 1188 HD offers superior picture quality, enhanced clarity and more intuitive user controls. This product provides surgical teams with improved visibility during endoscopic procedures, which can improve overall surgical and patient outcomes. In conjunction with the launch of the 1188 HD Camera, the Company also introduced complementary products such as the X8000 Lightsource and Vision Elect Monitor, that feature improvements over earlier offerings. In 2004, Stryker introduced the first HD medical video 3-chip camera, the 1088 HD. To accommodate the recording of HD images, the Company introduced the Stryker Digital Capture (SDC) HD digital documentation system. Another milestone was the introduction of best-in-class scope technology with the U-500 FlexVision flexible ureteroscope. Also in 2004, Stryker launched its Formula shaver system, which is small, light and equipped with radio frequency identification (RFID), facilitating communication between the blade and console.

In 2006, Stryker launched the Infinity II Communication Platform featuring an intuitive customer interface and an open architecture. This second-generation model allows customers to run multiple PC applications from a single touch screen and to route HD Digital signals through the industry's first digital video-imaging (DVI) board.

In 2005, the Company acquired eTrauma which expanded the Company's endoscopic and medical video imaging equipment product offerings by adding eTrauma's proprietary PACS image management and viewing software. The PACS software was complemented by the 2005 launch of OrthoPad, Stryker's electronic medical records software. In 2006, Stryker launched Office PACS 3.4, which provides seamless integration between the clinic and the operating room.

## Patient Handling and Emergency Medical Equipment

Stryker Medical is a leader in the stretcher products segment, offering a wide variety of stretchers customized to fit the needs of acute care and specialty surgical care facilities. Early in 2006, Stryker Medical introduced the ACS Stretcher, a value offering for the basic ambulatory surgery center market. In 2004, the Company launched a completely new concept in stretcher design, the M-Series Stretcher. With a focus on patient safety and product mobility, the M-Series features Stryker's Glideaway siderails, which provide maximum coverage when raised and a zero-transfer-gap when lowered; a 700-pound weight capacity; an integrated transfer board; and four-wheel, steel-ring brakes for stability. The M-Series provides customers with three different mobility options to suit their transportation needs: a fifth wheel for enhanced steering, Big Wheel technology for increased maneuverability and the self-propelled Zoom technology. All three mobility options provide a safe and comfortable surface for patients while reducing the risk of back injury for hospital staff.

Stryker also produces beds and accessories that are designed to meet the unique needs of specialty departments within the acute care environment. In 2005, Stryker introduced the XPRT nonintegrated sleep surface with low air loss, percussion and rotational functions to aid in the prevention and treatment of certain ulcers and pulmonary care. In 2004, Stryker introduced the LD304 birthing bed, which features a removable foot section with the unique Lock-Rite System. Also introduced in 2004 was the Go Bed II medical/surgical bed that features low bed-height for safe patient ingress and exit. The Go Bed II also offers the optional Chaperone center-of-gravity bed-exit system with Zone Control to help prevent patient falls. Zone Control is a feature that enables the caregiver to adjust the sensitivity of the bed-exit system to accommodate different patient needs. Stryker has a complete line of intensive care unit (ICU) beds for critical care and step-down units. The beds incorporate advanced features that facilitate patient care, such as in-bed scales that accurately weigh the patient regardless of bed position and a radiolucent surface that facilitates chest x-rays without moving the patient from the bed.

The Company's legacy of innovation in the prehospital market continued in 2004 with the launch of the MX-PRO BT ambulance cot with a weight capacity of 850 pounds for use in the emergency medical services transport market. To facilitate patient transport up and down stairs, Stryker offers the STAIR-PRO series of stair chairs. To better serve the emergency medical market, in 2006 Stryker introduced a customized version of the POWER-PRO ambulance cot, which was originally introduced in 2005. This new version extends the original design to carry transport incubators on both inter-facility and intra-facility transports. The POWER-PRO ambulance cot is a revolutionary design with an advanced electronic/hydraulic lift system that enables emergency

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medical professionals to effortlessly raise and lower the cot with the press of a button, which helps mitigate caregiver back injuries.

#### Other

The Other category includes Physical Therapy Services. Physiotherapy Associates provides physical, occupational and speech therapy services to patients recovering from orthopaedic or neurologic illness and injury through a network of 487 outpatient physical therapy centers in 31 states and the District of Columbia. Physiotherapy Associates works closely with referring physicians to design and execute rehabilitation protocols with the goal of quick recoveries for injured workers, athletes and other patients.

#### PRODUCT DEVELOPMENT

Most of the Company's products and product improvements have been developed internally. The Company maintains close working relationships with physicians and medical personnel in hospitals and universities who assist in product research and development. New and improved products play a critical role in the Company's sales growth. The Company continues to place emphasis on the development of proprietary products and product improvements to complement and expand its existing product lines. The Company has a decentralized research and development focus, with manufacturing locations responsible for new product development and product improvements. Research, development and engineering personnel at the various manufacturing locations maintain relationships with staff at distribution locations and with customers to understand changes in the market and product needs.

Total expenditures for product research, development and engineering were \$324.6 million in 2006, \$284.7 million in 2005 and \$214.9 million in 2004. Research, development and engineering expenses represented 6.0% of sales in 2006, compared with 5.8% in 2005 and 5.0% in 2004. The higher spending level is the result of the Company's continued focus on new product development for anticipated future product launches and continued investments in new technologies. Recent new product introductions in the Orthopaedic Implants and MedSurg Equipment segments are more fully described under the caption "Product Sales" on pages 5 through 16 of this report.

In addition to internally developed products, the Company invests in technologies developed by third parties that have the potential to expand the markets in which the Company operates. Certain of these investments result in charges for purchased in-process research and development. The purchased in-process research and development charges of \$52.7 million recorded in the first quarter of 2006, \$15.9 million recorded in the fourth quarter of 2005 and \$120.8 million recorded in the third quarter of 2004 relate to the acquisitions of Sightline, PlasmaSol and SpineCore, respectively.

In 2006 and 2005, the Company acquired Sightline, a developer of flexible endoscopes, and PlasmaSol, a developer of sterilization equipment, respectively. At the date of the acquisitions, the technologies acquired had not yet reached technological feasibility. The Company is currently working to advance the technologies toward commercial applications prior to obtaining necessary approvals from the FDA for sale of the final products.

In 2004, the Company acquired SpineCore, a developer of artificial lumbar and cervical discs. Current products under development include the FlexiCore lumbar artificial disc and the CerviCore cervical artificial disc. FlexiCore is currently involved in a U.S. clinical study under an approved IDE granted by the FDA. Following completion of enrollment in the clinical study during 2005, a 2-year patient follow-up is ongoing prior to submission of a PMA application to the FDA. Submission of a PMA application for the FlexiCore disc is currently expected to occur in 2007. During 2005, the Company received clearance in Australia and CE Marking approval in Europe for the FlexiCore implant. Also in 2005, Stryker received conditional approval for a U.S. trial of the CerviCore cervical disc replacement. Enrollment in the IDE clinical study is expected to be completed in 2007. Submission of a PMA application utilizing the resulting data from this study is anticipated in 2009.

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The Company believes that the technologies acquired in the Sightline, PlasmaSol and SpineCore acquisitions will result in the introduction of new products and additional future sales. However, factors including regulatory delays, safety concerns or patent disputes could delay the introduction or marketing of these potential new products. Additionally, unanticipated issues may arise during current and future clinical trials that could delay or terminate a product's development prior to regulatory approval. The Company may experience an unfavorable impact on its

operating results if it is unable to capitalize on those efforts by attaining the proper FDA approval. As of December 31, 2006, the Company has not encountered significant issues and expects completion of the development and initial commercialization of the flexible endoscope technologies in 2007 and both the sterilization technologies and spinal disc implant technologies beginning in 2008.

In the fourth quarter of 2006, the Company opened a new facility to support product development activities across its manufacturing divisions. Located near Dehli, India, the facility will provide software and mechanical engineering resources for divisional R&D teams to accelerate new product innovation and it will facilitate the development and testing of Stryker's internal systems. Over time, the facility will also support local markets in Asia to expand the Company's presence in that region.

## MARKETING

Domestic sales accounted for 66% of total revenues in 2006. Most of the Company's products are marketed directly to doctors, hospitals and other health-care facilities by approximately 3,200 sales and marketing personnel in the United States. Stryker primarily maintains separate and dedicated sales forces for each of its principal product lines to provide focus and a high level of expertise to each medical specialty served.

International sales accounted for 34% of total revenues in 2006. The Company's products are sold in more than 100 countries through more than 1,350 local dealers and direct sales efforts. Local dealer support and direct sales are coordinated by approximately 2,400 sales and marketing personnel. Stryker distributes its products through sales subsidiaries and branches with offices located in Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, Denmark, Egypt, Finland, France, Germany, Greece, Hong Kong, India, Italy, Japan, Korea, Malaysia, Mexico, The Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Russia, Serbia and Montenegro, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Ukraine, the United Arab Emirates and the United Kingdom. Stryker exports products to dealers and to customers in Africa, Bangladesh, the Balkens, China, the CIS (former Soviet Union), Cyprus, Czech Republic, Hungary, Iceland, Indonesia, Ireland, Israel, Latin America, the Middle East, Paraguay, the Philippines, Slovakia, Thailand, Turkey, Uruguay and Vietnam. Additional information regarding the Company's international and domestic operations and sales appears in "<u>Note 11 - Segment and Geographic Data</u>" on pages 62 through 64 of this report.

The Company's business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is lower during the summer months.

#### COMPETITION

The Company is one of five leading competitors in the United States for orthopaedic reconstructive products. The four other leading competitors are DePuy Orthopaedics, Inc. (a subsidiary of Johnson & Johnson), Zimmer Holdings, Inc., Biomet, Inc., and Smith & Nephew plc. While competition abroad varies from area to area, the Company believes it is also a leading player in the international markets with these same companies as its principal competitors.

In the trauma implant segment, Stryker is one of five leaders competing principally with Synthes, Inc., Smith & Nephew Orthopaedics (a division of Smith & Nephew plc), Zimmer Holdings, Inc., and DePuy Orthopaedics, Inc.

In the craniomaxillofacial implant segment, Stryker is one of four leaders, together with the principal competitors Synthes, Inc., Walter Lorenz Surgical, Inc. (a subsidiary of Biomet, Inc.), and KLS Martin L.P.

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In the spinal implant segment, the Company is one of five leaders, including the principal competitors Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic, Inc.), DePuy Spine, Inc. (a subsidiary of Johnson & Johnson), Synthes, Inc., and Zimmer Holdings, Inc.

Several companies are engaged in the research and development of products for the repair of hard and soft tissues that, if approved, would compete with the Company's OP-1 product. Medtronic Sofamor Danek has received FDA approval for its recombinant bone morphogenetic protein ("rhBMP-2") for certain spine, trauma and orthopaedic indications including the treatment of acute, open fractures of the tibial shaft and spinal fusion surgeries. A number of companies currently provide various other therapies, including allografts, bone fillers and electrical stimulation devices for the treatment, repair or replacement of bone and joint tissue. The Company believes that its OP-1 product, which is approved for limited trauma and spine indications in certain markets and is currently in clinical trials for other indications, will ultimately compete with these products and with traditional therapies, such as autograft and allograft.

In the surgical equipment segment, Stryker is one of three leaders, together with the principal domestic competitors Medtronic Midas Rex, Inc. (a subsidiary of Medtronic, Inc.), and Linvatec, Inc. (a subsidiary of Conmed Corporation). These companies are also competitors in the international segments, along with Aesculap-Werke AG (a division of B. Braun Melsungen AG), a large European manufacturer.

In the surgical navigation segment, Stryker is one of six principal competitors including Medtronic Surgical Navigation Technologies (a division of Medtronic, Inc.), BrainLAB Inc. (a subsidiary of BrainLAB AG), Aesculap AG & Co. KG (a division of B. Braun Melsungen AG), Radionics, Inc. (a subsidiary of Tyco International Ltd.), and GE Medical Systems Navigation and Visualization, Inc. (a subsidiary of General Electric Company).

In the arthroscopy segment, the Company is one of four leaders, together with the principal competitors Smith & Nephew Endoscopy (a division of Smith & Nephew plc), Linvatec, Inc., and Arthrex, Inc. In the laparoscopic imaging products segment, the Company is one of four leaders, together with the principal competitors Karl Storz GmbH & Co. (a German company), Gyrus ACMI Corporation and Olympus Optical Co. Ltd. (a Japanese company).

The Company's primary competitor in the patient handling segment is Hill-Rom Company, Inc. (a division of Hillenbrand Industries, Inc.). In the specialty stretcher segment, the primary competitors are Hausted, Inc. (a subsidiary of Steris Corporation), Hill-Rom Company, Inc., and Midmark Hospital Products Group (a subsidiary of Ohio Medical Instrument Company, Inc.). In the emergency medical services segment, Ferno-Washington, Inc., is the Company's principal competitor.

In the United States outpatient physical and occupational rehabilitation market, the Company's primary competitors are independent, therapist-owned practices and hospital-based services, in addition to other national rehabilitation companies, including Healthsouth Corporation, NovaCare Rehabilitation (a division of Select Medical Corporation), Benchmark Physical Therapy and U.S. Physical Therapy, Inc.

The principal factors that the Company believes differentiate it in the highly competitive market segments in which it operates and enable it to compete effectively are innovation, reliability, service and reputation. The

Company believes that its competitive position in the future will depend to a large degree on its ability to develop new products and make improvements to existing products. While the Company does not consider patents a major factor in its overall competitive success, patents and trademarks are significant to the extent that a product or attribute of a product represents a unique design or process. Patent or trademark protection of such products restricts competitors from duplicating these unique designs and features. Stryker seeks to obtain patent protection on its products whenever possible. The Company currently owns approximately 820 United States patents and 1,330 international patents.

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## MANUFACTURING AND SOURCES OF SUPPLY

The Company's manufacturing processes consist primarily of precision machining, metal fabrication and assembly operations; the forging and investment casting of cobalt chrome; and the finishing of cobalt chrome and titanium. In addition, the Company is the sole manufacturer of its OP-1 product. Approximately 9% of the Company's cost of sales in 2006 represented finished products that were purchased complete from outside suppliers. The Company also purchases parts and components, such as forgings, castings, gears, bearings, casters and electrical components, and uses outside sources for certain finishing operations, such as plating, hardening and coating of machined components and sterilization of certain products. The principal raw materials used by the Company are stainless steel, aluminum, cobalt chrome and titanium alloys. In all, purchased parts and components from outside sources were approximately 44% of the total cost of sales in 2006.

While the Company relies on single sources for certain purchased materials and services, it believes alternate sources are available if needed. The Company has not experienced any significant difficulty in the past in obtaining the materials necessary to meet its production schedules.

Substantially all products manufactured by the Company are stocked in inventory, while certain products manufactured within the Company's MedSurg Equipment segment are assembled to order.

## REGULATION AND PRODUCT QUALITY

The Medical Device Amendments of 1976 to the federal Food, Drug and Cosmetic Act and the Safe Medical Devices Act of 1990 together with regulations issued or proposed thereunder provide for regulation by the FDA of the design, manufacture and marketing of medical devices, including most of the Company's products.

The FDA's Quality System regulations set forth standards for the Company's product design and manufacturing processes, require the maintenance of certain records and provide for inspections of the Company's facilities by the FDA. There are also certain requirements of state, local and foreign governments that must be complied with in the manufacturing and marketing of the Company's products. The Company believes that the manufacturing and quality control procedures it employs meet the requirements of these regulations.

Most of the Company's new products fall into FDA classifications that require notification of and review by the FDA before marketing, submitted as a 510(k). The Company's FlexiCore and CerviCore artificial disc products and OP-1 products require extensive clinical testing, consisting of safety and efficacy studies, followed by PMA applications for

specific surgical indications.

Stryker also is subject to the laws that govern the manufacture and distribution of medical devices of each country in which the Company manufactures or sells products. The member states of the European Union (EU) have adopted the European Medical Device Directives, which create a single set of medical device regulations for all EU member countries. These regulations require companies that wish to manufacture and distribute medical devices in EU member countries to obtain CE Marking for their products. Stryker has authorization to apply the CE Marking to substantially all of its products. The Company's OP-1 product has been considered a drug under the regulations for Europe, Australia and Japan.

The Company's Physiotherapy Associates, Inc., subsidiary is subject to various federal and state regulations regarding the provision of physical therapy services. The primary entities administering these regulations are the Centers for Medicare & Medicaid Services, CHAMPUS, state workers compensation agencies, state insurance commissioners and state licensing agencies.

Initiatives sponsored by government agencies, legislative bodies and the private sector to limit the growth of health-care expenses generally and hospital costs in particular, including price regulation and competitive pricing, are ongoing in markets where the Company does business. It is not possible to predict at this time the long-term impact of such cost-containment measures on the Company's future business.

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#### **EMPLOYEES**

At December 31, 2006, the Company had 18,806 employees worldwide, including 6,393 involved in manufacturing, warehousing and distribution operations; 5,632 in sales and marketing; 1,262 in research, development and engineering; 3,582 providing physical, occupational and speech therapy; and the balance in general management and administration. Certain international employees are covered by collective bargaining agreements that are updated annually. The Company believes that its employee relations are satisfactory.

#### EXECUTIVE OFFICERS OF THE REGISTRANT

Information regarding the executive officers of the Company appears under the caption "Item 10. Directors, Executive Officers and Corporate Governance" on pages 69 through 70 of this report.

#### ITEM 1A. RISK FACTORS

The following information contains specific risks that could potentially impact the Company's business, financial condition or operating results. The Company may be subject to additional risks that are not currently known to the Company or those which the Company deems immaterial that may also impact its business operations.

# The Company's inability to maintain adequate working relationships with healthcare professionals could have a negative impact on the Company's future operating results.

The Company maintains close working relationships with respected physicians and medical personnel in hospitals and universities who assist in product research and development. The Company continues to place emphasis on the development of proprietary products and product improvements to complement and expand its existing product lines. If the Company is unable to maintain these good relationships, its ability to market and sell new and improved products could decrease and future operating results could be unfavorably affec