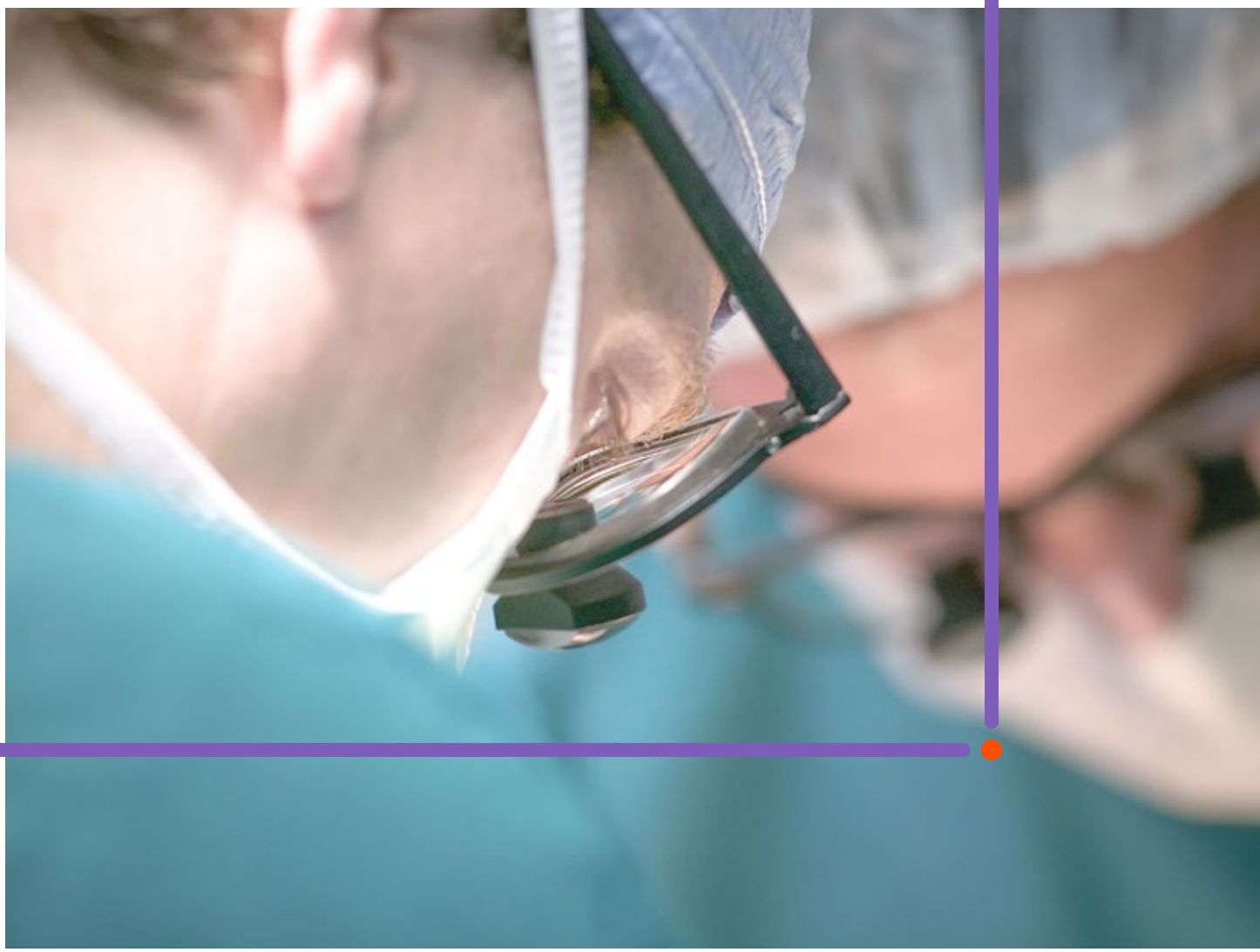
vizient™

Knee, hip, shoulder and extremity joint reconstruction technologies

Technology Watch | 2017 Volume 2



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Disclaimer: Members of the Vizient™ orthopedic staff attend clinical sessions at important scientific meetings throughout the year. The staff meets with suppliers, reviews new technologies and monitors data from pertinent clinical trials. The information is consolidated into this overview of product and practice trends in the various orthopedic segments. This document is intended to educate nonclinical hospital staff by offering insights into new and innovative technologies. Vizient staff members have no personal financial connections with the suppliers and no conflicts of interest in the development of this document. The products presented are for educational purposes. Vizient does not endorse any of the products described in this document.

Introduction

The market for implants and other products used in replacing or reconstructing knees, hips, shoulders and extremities is complex and, like other health care market segments, is going through change. Pressures from payers are forcing change, as are requirements of the Centers for Medicare & Medicaid Services' (CMS') Comprehensive Care for Joint Replacement (CJR) model. Lower hospital reimbursement for joint reconstruction and replacement is on its way; in the coming years payers, led by CMS, will drive down reimbursement by mandating efficiencies and promoting a shift towards outpatient procedures. Already, an increasing number of cases involve same-day discharges and home rehabilitation. Pressures on pricing in both the total joint reconstruction and spinal implant markets are resulting in a downward trend. These pressures will continue.

Some of the pricing pressure can be attributed to active physician involvement, as physicians assume increasingly larger roles in in supply chain decisions. Many hospitals have developed physician- and clinician-centric supply chain models. The result is lower prices for the hospitals and supplier consolidation.

No longer can hospitals afford to allow unlimited access to suppliers and their technologies. In a world where the importance of clinical data showing benefits for patient outcomes is growing, many orthopedic products will continue to struggle to demonstrate that they are better than their predecessors. Pressure on suppliers to respond will increase. The orthopedic service model, which has provided differentiation and barriers to competitive entry, may need to change; the high selling expenses inherent in that model cannot be sustained as other pressures squeeze hospitals further. DePuy Synthes, for example, is reacting to high selling expenses by charging a tray usage fee to shift costs to the hospital. Other suppliers are moving to differentiated service models to help hospitals design programs that comply with CJR requirements. Innovations in robotic-assisted surgery and navigation will increase.

The majority of orthopedic products are cleared for use in the United States through the Food and Drug Administration's (FDA's) 510(k) regulatory process, which requires a supplier to demonstrate comparability to an already-cleared product and therefore minimizes the need for clinical data. This process allows suppliers to make incremental changes in their products and increase their prices. The emerging health care market will reduce the suppliers' ability to get premium pricing on such "evolutionary" products. However, if suppliers cannot achieve higher prices, the rate of introductions of genuinely new products will slow. As in other service lines, slower introduction of new products will increase price pressure on existing products, giving hospitals an opportunity to control growing orthopedic costs.

The orthopedic market will remain complex and unsettled as long as the overall U.S. health care market continues to change. What this market looks like after changes take effect is yet to be determined. What can be anticipated is that it will be different.

Market watch

Pricing trends: change over last 12 months

The 12-month price trend and current average market pricing by product segment are shown in the tables below.

Knee reconstruction

Category	Change (%)
Total knee	↓ 2.3%
Partial knee	↓ 3.4%
Knee revision	↓ 1.3%

Hip reconstruction

Category	Change (%)
Total hip	↓ 3.8%
Partial hip	↓ 1.4%
Hip revision	↓ 5.2%

Shoulder reconstruction

Category	Change (%)
Total shoulder	↓ 2.1%
Partial shoulder	↓ 3.4%
Shoulder revision	↓ 3.0%

Joint implant average prices

All prices in the tables below are the average prices for that category of products, not selling prices for specific products. Individual hospital pricing may vary given considerations such as rebates, quality and volumes that are not included in these estimates.

Total knee construct

Supplier	Average price
DePuy Synthes	$4,060
Smith & Nephew	$3,350
Stryker	$3,890
Zimmer Biomet	$5,070

Total hip construct

Supplier	Average price
DePuy Synthes	$4,070
Smith & Nephew	$3,350
Stryker	$3,890
Zimmer Biomet	$3,880

Total shoulder construct

Supplier	Average price
DePuy Synthes	$5,550
DJO Surgical	$4,880
Exactech	$5,780
Wright Medical	$7,180
Zimmer Biomet	$6,410

Total ankle construct

Supplier	Average price
Integra Lifesciences	$12,300
Stryker	$11,980
Wright Medical	$13,480
Zimmer Biomet	$11,780

All estimated selling pricing is the averaged pricing over a category of products. These are not selling prices for specific products. Your pricing may vary given considerations such as rebates, quality and volumes that are not included.

Reimbursement watch

On April 28, 2017, CMS published a proposed rule for Medicare payment policy and reimbursement rates under the hospital Inpatient Prospective Payment System for fiscal year (FY) 2018.[1] A summary of the proposed changes follows.

Overall impact

Overall, CMS proposes a 1.6 percent increase in Medicare reimbursement rates for hospitals that report quality data and are meaningful users of electronic health records.

This update includes a 2.9 percent increase in the market basket, a −0.4 percent productivity adjustment, a −0.75 percentage point adjustment for cuts under the Affordable Care Act, a 0.46 percent adjustment to partially restore cuts made as a result of the American Taxpayer Relief Act of 2012, and a −0.6 percent adjustment to offset the estimated costs of the two-midnight rule.

CMS is also looking at post-acute facility quality reporting and reimbursement; its proposed payments to long-term care hospitals could decrease by approximately 3.75 percent in FY 2018.

Hospital Readmissions Reduction Program

CMS proposes to implement the socioeconomic adjustment approach mandated by the 21st Century Cures Act. The agency would assess readmission penalties based on a hospital's performance relative to other hospitals with a similar proportion of patients who are dually eligible for Medicare and Medicaid. CMS is forecasting that 2,591 hospitals will have their base DRG rates reduced, saving the government an estimated $564 million in FY 2018.

Hospital value-based purchasing program

CMS recommends removing Patient Safety Indicator (PSI) 90 from the safety domain beginning in FY 2019 and adopting the patient safety and adverse events composite PSI 90 measure beginning in FY 2023. In addition, CMS recommends adopting the hospital-level, risk-standardized payment associated with a 30-day episode of care for pneumonia measure for the efficiency and cost reduction domain in FY 2022. These changes are not expected to have any financial impact on hospitals.

Hospital Inpatient Quality Reporting Program

CMS proposes to reduce the number of electronic clinical quality measures hospitals must report and shorten the data reporting period, defining it as the two months following the close of the calendar year (ending Feb. 28, 2019). CMS is also proposing a Hospital-Wide All-Cause Unplanned Real Hybrid Measure, which would begin in FY 2018 and would initially be voluntary.

Technology add-on payments

The technology add-on payments in the table below are being proposed for FY 2018.

Device name	Company	Status (proposed)
FY 2018 products		
CardioMEMS system	St Jude Medical	Discontinue payment
Responsive neurostimulators	NeuroPace, Inc.	Discontinue payment
Lutonix drug-coated balloon	Bard Vascular	Discontinue payment
In.Pact Admiral drug-coated balloon	Medtronic	Discontinue payment
Magec spinal bracing	NuVasive	Discontinue payment
Blincyto (blinatumomab)	Amgen, Inc.	Discontinue payment
Gore Excluder iliac branch	WL Gore	2nd of 3 years ($5,250.00)
Vistogard	BTG International	2nd of 3 years ($37,500.00)
Defitelio	Jazz Pharmaceutical	2nd of 3 years ($75,900.00)
Praxbind (darucizumab)	Boehringer Ingelheim	2nd of 3 years ($1,750.00)

Device name	Company	Status (proposed)
Proposed FY 2018 products		
Intuity Elite	Edwards Lifesciences	Pending FY 2018 decision
Zinplava (bezlotoxumab)	Merck & Co	Pending FY 2018 decision
Stelara (ustekinumab)	Janssen Biotech	Pending FY 2018 decision
KTE-C19	Kite Pharmaceuticals	Pending FY 2018 decision
Vyxeos	Celator Pharmaceuticals	Pending FY 2018 decision
GammaTile	Isoray Medical	Pending FY 2018 decision

MS-DRG coding changes

The following changes in Medicare severity diagnosis-related group (MS-DRG) coding are being proposed for FY 2018.

- For cases in which neurostimulator generators are used for deep brain stimulation (including cases involving the use of the NeuroPace RNS neurostimulator), CMS is proposing to reassign all cases with a principal diagnosis of epilepsy from the epilepsy diagnosis to an ICD-10-PCS code combined with a device insertion, and to change the description of MS-DRG code 023 to "craniotomy with major device implant or acute complex central nervous system (CNS) principal diagnosis (PDX) with MCC [major complications/comorbidities] or chemotherapy implant or epilepsy with neurostimulator."
- For cases of precerebral occlusion or transient ischemic attack with thrombolysis, CMS proposes to add the ICD-10-CM diagnoses that are currently assigned to MS-DRG codes 067, 068 and 069 to the grouper logic for MS-DRGs 061, 062 and 063 when those conditions are sequenced as the principal diagnosis and reported with an ICD-10-PCS procedure code describing use of a thrombolytic agent. In addition, it is proposed to retitle MS-DRGs 061, 062 and 063 as "ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent" with MCC, with complications/comorbidities (CC), and without CC/MCC, respectively, and to retitle MS-DRG 069 as "transient ischemia without thrombolysis."
- For cases of transcatheter aortic valve replacement and left atrial appendage closure, CMS is proposing to reassign the four percutaneous mitral valve replacement procedures in MS-DRG codes 216 through 221 to MS-DRGs 266 and 267. In addition, the eight new procedure codes that describe percutaneous and transapical percutaneous tricuspid valve replacement procedures would be assigned to MS-DRGs 266 and 267.
- CMS is proposing to maintain the current MS-DRG assignment for revision of total ankle replacement procedures within MS-DRGs 515, 516 and 517 for FY 2018.
- For cases in which magnetic controlled growth rods (i.e., MAGEC system) are implanted, CMS is proposing that use of the MAGEC system technology alone does not constitute a spinal fusion. As a result, no new codes will be created for the use of the device.
- For cases of combined anterior/posterior spinal fusion, CMS noted that seven of the 10 new ICD-10-PCS procedure codes describing fusion using a nanotextured-surface interbody fusion device were not added to the appropriate grouper logic list for MS-DRGs 453, 454 and 455. To correct this, CMS is proposing to delete 33 procedure codes from the logic for those spinal fusion MS-DRGs.

Supplier watch

Aesculap Orthopedics

The U.S. orthopedic market is dominated by a handful of companies, but other market competitors exist outside the U.S. One of these is Aesculap Implant Systems. Orthoworld ranks Aesculap as the fifth largest orthopedic company in the global knee and hip reconstruction market. The company has a complete line of devices and instrumentation with world-class manufacturing, and has been at the leading edge of many orthopedic surgical technologies, implants and imaging. Yet within the U.S., the company is not well known. If Aesculap has its way, this may soon change: The company is expanding its U.S. market presence. When it does, it will bring a world-class portfolio and a complete line of both total joint and spine products to the U.S. orthopedic market.

Company overview

Aesculap is a subsidiary of German medical device manufacturer B. Braun Melsungen, a privately held family business. Aesculap, founded in 1867 and based in Tuttlingen, Germany, has its foundation in the manufacturing of surgical instruments, and has been providing surgical technical services for medical facilities throughout the world for 150 years. The company's products include handheld surgical instruments; implants; sutures used in neurosurgery as well as in cardiac, orthopedic, laparoscopic, reconstructive, thoracic, and gynecological surgical procedures; and electrosurgical devices and power systems. Aesculap also offers consulting, training, maintenance, and supply chain management services. The company operates in 64 countries. Its U.S. headquarters is located in Center Valley, Pennsylvania.

Aesculap Implant Systems, which traces its roots back to the early days of orthopedic surgery, offers high-end medical devices for orthopedic and spinal implant surgery. The company's portfolio includes orthopedic implants, neurosurgical and spinal implants, power systems, navigation systems, surgical instruments for open or minimally invasive approaches, sterile containers, and storage systems.

Product breadth

Aesculap offers a comprehensive line of innovative products and solutions, giving physicians the flexibility to select the most appropriate implant for the patient's needs. The company's implants and instruments can be used in a variety of surgical approaches, including minimally invasive procedures, which can decrease time in the operating room and allow clinicians to focus on patient safety and outcomes. Some of the company's products are described below.

Advanced surface technology: This seven-layer surface technology delivers outstanding surface hardness, substantially decreased wear rates and greatly improved scratch resistance. Aesculap is the only provider to offer this unique surface as an available feature on all knee implants.

IQ instrumentation: The IQ instrumentation platform offers dual-purpose instruments, fewer trays and a simplistic design that allows easy resizing and can reduce operating room time. The platform offers a wide range of soft tissue–friendly implants in 13 femoral sizes and 11 tibial sizes for a better bone fit.

Vega Knee System: The Vega system's post-cam design concept optimizes pivotal motion while greatly reducing surface stress. The system also works with Aesculap's Advanced Surface Technology to deliver exceptional kinematics and excellent wear results and jump distances.

OrthoPilot Navigation System: The OrthoPilot Navigation System is a computer-aided, image-free navigation system that was developed by Aesculap in conjunction with clinicians to enhance the surgical workflow and achieve optimal implant alignment. The system was the first CT-free computer navigation system in the U.S. and has been used in more than 340,000 procedures since 1997. Optional modules for total knee replacement, total knee arthroplasty, and unicompartmental knee arthroplasty are available.

Quintex system: Aesculap became one of the pioneers in cervical plating when it introduced the CASPAR cervical plate and the CASPAR retractor system. Since then a steady stream of cervical innovations for anterior cervical diskectomy and fusion has followed, based on applying a dynamic fixation surgical philosophy to an osteoconductive porous titanium coating. The Quintex cervical plating system offers a dynamic construct that allows for complete load sharing across the structure.

PlasmaporeXP: PlasmaporeXP is an innovative surface-enhancing technology designed to complement the polyetheretherketone (PEEK) interbody implant. The unique structure, properties and processing of the PlasmaporeXP coating results in excellent product performance. PlasmaporeXP is the culmination of Aesculap's 30 years of innovation in spinal technology and 20 years of experience with porous titanium coatings.

S4 Element MIS: The S4 Element MIS is a posterior lumbar pedicle screw fixation system that utilizes endoscope technology to provide a direct view of the surgical site, providing the advantages of minimally invasive surgery with the visualization of an open procedure.

activL artificial disc: Approved by the FDA in 2015, the activL artificial disc for single-level lumbar use is a weight-bearing modular implant consisting of two endplates and one polyethylene inlay and is intended as an alternative to fusion. It is the first artificial lumbar disc with a mobile ultra-high-molecular-weight polyethylene core that supports both controlled translational and rotational movement, similar to the movement of the healthy lumbar spine.

3-D printed components: Aesculap is investing in expanding its capacity for producing components using 3-D printing, developing and introducing a number of new joint reconstruction and spine components. The company plans to continue to develop products and enhance patient outcomes using this technology.

Aesculap compliance program

Aesculap has built its brand on providing the highest quality medical devices and support services to its customers. The company is committed to its history of providing excellence. Consistent with its commitment to demonstrate the highest ethical behavior, the company has established a comprehensive compliance program in accordance with the guidelines published by the Office of Inspector General, U.S. Department of Health and Human Services (the "OIG Guidance"). Aesculap's dedication to outstanding products and service while holding itself to the highest standard of business ethics gives hospitals the security and confidence of dealing with an outstanding supply partner.

Hospital impact

Although Aesculap is not significantly different from the other leading orthopedic and spine companies that provide world-class products, support and education, the company is able to supply all of a hospital's total joint and spinal reconstruction needs, potentially lowering costs in the process. Aesculap is a supplier that hospitals and surgeons should consider in the changing U.S. health care environment.

Technology watch

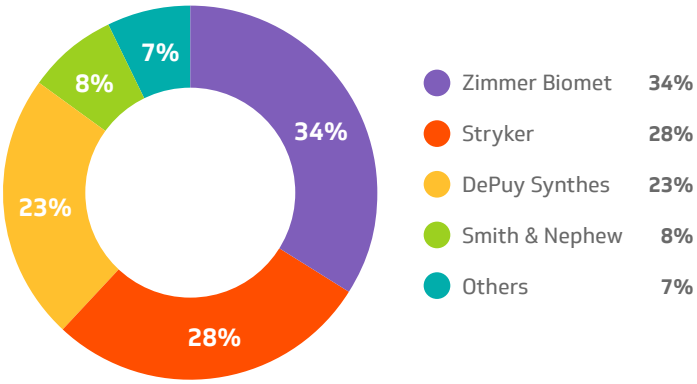
Knee and hip joint reconstruction

The number of procedures for knee and hip reconstruction in the United States continues to grow; the aging of the population and active lifestyles are driving a 3.6 percent procedural growth rate through the end of the decade. However, revenue during the same time period is growing at a slower pace of 2.7 percent.[2] The lag in sales revenue is related to the falling prices of knee and hip implants, which are driven by slowing innovation and market uncertainty.

The large joint reconstruction market has been under increasing price pressure for several years. The overall push by payers to control rising costs for medical devices is being accelerated by the introduction of the CJR bundle and the general uncertainty surrounding the future of U.S. health care policy. Even after the dust settles, however, the negative price trend in this market will continue.

The hip and knee reconstruction market has a large number of suppliers, but is dominated by only a few. The figure below shows Vizient data on the market share for major suppliers in this segment.

Large joint reconstruction market: supplier shares



The slower growth in the large joint reconstruction market has spurred major suppliers to diversify their portfolios through acquisitions in other markets (e.g., spine, neurointerventional and extremity joints) to enhance their sales. These faster-growing segments are expected to moderate the declining price pressures in the large joint market in the short term.

Recent reports have documented that selling prices for large joint reconstruction devices are higher than they should be as a result of the influence of sales representatives and high selling expenses.[3-6] We are beginning to see signals that suppliers are looking for ways to reduce services or shift costs back to hospitals in an attempt to reduce selling expenses. For example, in 2017, DePuy Synthes began charging hospitals tray delivery fees.

The product technology in the knee and hip reconstruction market segment is evolutionary. Suppliers spend millions to differentiate their products through proprietary material composition, unique additives and manufacturing techniques. These differentiators are clinically safe but offer only marginal benefits for patients. Because of the nature of the product, most of the clinical data for new hip and knee products is generated in post-marketing clinical trials, so data is generally limited at the time of product launch. Clinicians are therefore asked to extrapolate clinical results for new products from data for earlier-generation implants.

In an effort to slow falling prices, suppliers are shifting to new strategies within the large joint reconstructive market. Robotic surgical procedures are being promoted as a way to improve clinical results. Opening the door for new clinical ideas without the barriers and restrictions imposed by conventional manufacturing methods, 3-D printing is growing and driving differentiation and cost savings. Most large suppliers are also expanding their consulting offerings, focusing on the CJR bundle and operating room efficiencies.

Companies developing large joint implants

In the U.S., large joint implants are approved using the FDA's 510(k) pathway, which requires that a supplier demonstrate the safety of a new medical device by showing that it is similar to a device that is already approved and on the market. This pathway reduces regulatory requirements, lowering the costs of bringing evolutionary devices to market. It also allows devices to be introduced with minimal clinical data. Most FDA approvals are for expansions of existing product lines, expanded indications for already-approved products, or modifications of existing products. Generally, suppliers pursuing 510(k) approval will compare their new device with one of their own existing products or a similar competing product with a large market share.

The table on the next page shows joint reconstruction devices recently cleared for use in the United States.

Vendor name	Device name	510(k) no.	510(k) approval date
3Shape A/S	Ortho System	K161884	Apr 19, 2017
Amplitude Medical	Anatomic total knee system	K161414	Jan 19, 2017
Arthrex, Inc.	iBalance UKA system vitamin E tibial bearing	K161060	Dec 15, 2016
Bodycad Laboratories	Bodycad Unicompartmental Knee System	K163700	Mar 29, 2017
Consensus Orthopedics	PS2 Knee System	K160515	Dec 19, 2016
Corentec Co., Ltd.	Lospa Knee System	K160157	Dec 1, 2016
DJO Surgical — Encore	Exprt Revision Hip	K161610	Nov 9, 2016
DJO Surgical — Encore	Exprt Revision Hip system (Exprt hip distal stem, Exprt hip standard offset proximal body implant)	K163497	Mar 2, 2017
Exactech Inc.	Alteon HA Femoral Stem	K162732	Apr 26, 2017
Exactech Inc	Truliant femoral components	K170240	Feb 23, 2017
Integra LifeSciences	InSitu Hip System	K161184	Oct 14, 2016
Intellijoint Surgical Inc.	Intellijoint Hip generation 2A system	K162364	Mar 2, 2017
Kico Knee Innovation	360KS Implant Positioning System	K163405	Mar 21, 2017
Kyocera Medical Corp	Initia total hip system and Bioceram Azul head	K160895	Nov 1, 2016
LimaCorporate S.P.A.	Revision femoral stem	K161226	Feb 10, 2017
Mako Surgical Corp.	Mako total hip application	K170593	Apr 18, 2017
Materialise NV	Materialise total knee arthroplasty guide system	K162273	Nov 7, 2016
Mazor Robotics Ltd.	Mazor X	K163221	Apr 4, 2017
Medacta International SA	Moto partial knee system	K162084	Jan 3, 2017
Meril Healthcare	Destiknee total knee system	K160771	Dec 19, 2016
OmniLife science	Apex revision knee system	K163332	Apr 26, 2017
Onefit Medical	KneeEOS	K161828	Oct 3, 2016
OrthAlign, Inc.	KneeAlign 2 system	K163379	Mar 2, 2017
Orthofix SRL	Chimaera Hip Fracture System; trochanteric nailing system	K161466	Jan 24, 2017
Pantheon Medical	Pantheon Medical Balanced Plating System	K162154	Apr 24, 2017
Pega Medical Inc.	Y3 Proximal Femoral Plate System	K163003	Mar 16, 2017
Stryker Corporation	OrthoMap Versatile Hip System	K162937	Feb 23, 2017
Stryker Leibinger GmbH	OrthoMap Precision Knee system	K162341	Oct 12, 2016
Total Joint Othopedics	Klassic HD Hip System	K161073	Oct 19, 2016
United Orthopedic Corp	U2 total knee system, PSA tibial insert	K161360	Feb 1, 2017
Zimmer Biomet	Fitmore Hip Stem	K170072	Feb 7, 2017
Zimmer Biomet	Persona partial knee system	K161592	Nov 3, 2016
Zimmer Biomet	Ulna plating system	K162424	Oct 12, 2016
Zimmer Biomet	Zimmer M/L Taper hip prosthesis	K161830	Oct 26, 2016

Potential new devices

Suppliers of large joint reconstruction products each approach the market differently. Several of the larger suppliers are described below, along with their potential new products.

ConforMIS

ConforMIS, which designs and manufactures customized knee implants, both the femur and tibia, for each patient, continues to work to grow its market share. Its iFit technology platform comprises three elements:

- Implant design: Proprietary algorithms and computer software are used to design customized implants and associated patient-specific instrumentation.
- Additive manufacturing: 3-D printing technology is used to manufacture implants and certain components.
- Just-in-time delivery: Customized patient-specific implants are delivered to the hospital on the scheduled day of surgery.

ConforMIS believes this market approach and manufacturing platform creates a scalable business model that lowers inventory requirements, reduces the amount of working capital required to support operations and allows rapid product improvement and development compared with off-the-shelf implants.

iTotal hip system: The ConforMIS iTotal hip replacement system builds on the company's proprietary customized knee replacement technology, which creates implants fitted to each patient's unique anatomy and uses additive manufacturing technology. The proprietary iFit technology utilizes patient-specific technology, single-use 3-D printed instruments and a just-in-time delivery model to create a system that requires few reusable instruments. The hip replacement product is expected to be launched in 2019.

Clinical and Economic Study Comparing Customized Total Knee Replacement Implants to Off-the-Shelf Total Knee Replacement Implants

Study size: 248 patients

1:1 retrospective, single-center, single-operator study

The study, financially supported by ConforMIS, was a retrospective review of outcomes and costs for 248 consecutive patients undergoing total knee arthroplasty who were treated at a single institution and by the same surgeon. Equal numbers of patients received either a customized knee implant or an off-the-shelf (OTS) implant. Study results showed that a smaller percentage of patients treated with customized implants experienced adverse events both at discharge (3.3% vs OTS 14.1%; *P* = .003) and 90 days after discharge (8.1% vs OTS 18.2%; *P* = .023). A greater proportion of patients who received customized implants were discharged in less than three days (42.1% vs OTS 30.3%; *P* = .037). In addition, a smaller percentage of patients treated with customized implants were discharged to a rehabilitation center or other post-acute care facility (4.8% vs OTS 16.4%; *P* = .003). The total average real hospital costs were nearly identical for both the customized and OTS implant groups. The trial was not sufficiently powered to validate the study findings.

Medtronic

Medtronic acquired Responsive Orthopedics in May, but has not disclosed the terms of the deal. The acquisition does, however, signal Medtronic's expansion into the large joint market. Its strategy is to offer a value-based knee and hip replacement portfolio tied to the new bundled payment model and to launch a joint replacement program that will include not just the surgery itself, but all the services from the time a patient walks into the hospital to 90 days after the procedure. Medtronic's goal is to deliver a high-quality solution that delivers predicable clinical outcomes in a sustainable and affordable manner.

Total knee replacement system: The Medtronic total knee replacement system was approved by the FDA in 2016. The system does not have any unique features or use proprietary materials; instead, it represents a broad line of replacement components sourced to the same contract manufacturers that make implants for other large orthopedics suppliers. Medtronic plans to launch the line by July 2017; its hip offering is expected in July 2018.

Smith & Nephew

Smith & Nephew continues to expand its product portfolio in the large joint segment. Following the trends established by the larger U.S. orthopedic companies, Smith & Nephew entered the robotic surgery market with the acquisition of Blue Belt technologies and their Navio robotic-assisted system. The orthopedic robotic surgery market is growing rapidly and this acquisition gives Smith & Nephew a foothold.

Anthem Total Knee System: The Anthem system is a cruciate retaining implant design that includes cobalt-chrome femoral components and titanium tibia baseplate components, each available in femoral sizes 3-8 standard and 1-6 narrow, with right and left options, and tibia baseplates in sizes 1-8 with right and left options. Additionally, most of the Genesis II inserts, patellas and baseplates have been rebranded as Anthem to provide consistency within the system. Both Genesis II- and Anthem-branded components will remain on the market simultaneously with identical component designs. The Anthem system received 510(k) approval in May 2017 and the company anticipates market launch later in 2017.

Anthem Total Knee System

Tae Kyun Kim (South Korea), principal investigator

Study size: 196 patients

Prospective, multicenter, non-U.S. cohort study

This post-market cohort study collects relevant patient-reported clinical, surgical and radiological data from implantation of the Anthem knee system to treat degenerative joint disease at up to six clinical sites. Total study duration will be 10 years, with postoperative follow-up visits planned at 6 weeks and 1, 2, 5, 7.5 and 10 years. The study will evaluate the 10-year implant survivorship, safety and outcomes. The study began in June 2017; no clinical data is available.

Navio surgical system: Smith & Nephew, via Blue Belt, provides robotics assistance in partial knee replacement surgery. A range of expected new product launches is expanding into indications beyond partial knee replacement. The first of these new products is the total knee application, Journey II XR, for which the first procedures were completed in 2016. Given the component's kinematic design, the expectation is that patients will experience a more natural-feeling knee with better rotational stability, retaining both cruciate ligaments. This more natural and more stable knee, along with greater early mobility and increased patient satisfaction, are the goals Smith & Nephew set out to achieve with the Journey II XR system. The system is expected to launch in mid-2017 and the company plans to make XR available on the Navio platform in due course. The Navio Surgical System total knee application is expected to be released to the full market in the second quarter of 2017, pending 510(k) approval, with Smith & Nephew's Journey II, Legion and Genesis II total knee systems.

Stryker

Stryker is expanding its product breadth and focusing its selling efforts in the large joint reconstruction market in two areas: robotic surgery and 3-D printing of components. Robotic surgery is an important growth segment for Stryker; the company's acquisition and promotion of robotic surgery will continue in 2017 and beyond. Stryker-sponsored clinical trials are demonstrating patient benefit from robot-aided procedures. The difficulty and expense of conducting a randomized clinical trial looking at long-term clinical benefits limits the data available, leaving hospitals struggling to decide whether the expense of robotics justifies its cost. The complicating factor in evaluating robotic-aided surgery will be its potential impact on patient ambulation in light of CJR requirements and cost reductions.

Mako Total Knee: In March, Stryker launched the total knee arthroplasty application for use with its Mako robotic-arm–assisted system. The new indication for the robotic system must be used in combination with the company's Triathlon total knee implants. This expanded indication positions Stryker to have the only robotic technology that can be used for total knee, total hip and partial knee replacements.

3-D printed components: Stryker is investing heavily and leading other suppliers in the use and development of 3-D printed manufacturing for its medical device components, specifically its Tritanium components. Product development began with acetabular cups but is expanding quickly to other components. The ability to manufacture a more porous structure to allow greater tissue ingrowth has merit and potential patient benefits. As with similar new technologies, however, there is currently no long-term clinical data on the product's reliability or patient benefit.

Zimmer Biomet

Zimmer Biomet appears to be slowing its development of total joint replacement products, although it continues to invest in acquiring products in the spine, sports medicine and extremity joint reconstruction markets. The slower product development could also be because the company's research and development resources are focused on higher growth opportunities or because of the company's supply chain remediation problems, which are expected to be more costly than originally anticipated. The company's selling strategy appears to be shifting toward a patient-centered, more consultative approach. The Zimmer Biomet Signature Solution promotes increased hospital value through improved quality, more efficient care and enhanced procedural throughput.

Rosa robotic-assisted surgery: In 2016, Zimmer Biomet purchased France-based Medtech Innovative Surgical Technologies, which produces robotic surgery-assisted systems. While the current offering is used for minimally invasive brain and spine surgery, Zimmer Biomet is quickly developing the system's orthopedic capabilities, anticipating U.S. availability of a robotic total knee replacement procedure in 2019.

Persona uni knee: The Persona knee system is a personalized, anatomically accurate knee implant. The Persona uni knee will complete the company's partial knee portfolio with its fixed-bearing design coupled with precise and efficient instrumentation. The company anticipates full commercial launch in the second half of 2017.

Other new implants

Truliant Knee System

(Exactech, Inc.)

The Truliant knee system is a comprehensive portfolio of implants and instrumentation designed for total knee replacement. The system has the advantage of very user-friendly, ergonomic instrumentation. The system is in pilot launch with a group of U.S. surgeons; it is expected to be available on the U.S. market in 2018.

Economic impact

The economic impact of new joint reconstruction technologies will be marginal. Suppliers introducing evolutionary products at premium pricing is the biggest threat to hospital cost control initiatives, but as very few new product introductions can be shown to offer benefits that justify the price increases, hospitals and surgery centers should push back on increases unless clinical data is available that demonstrates better patient outcomes, better economics or both.

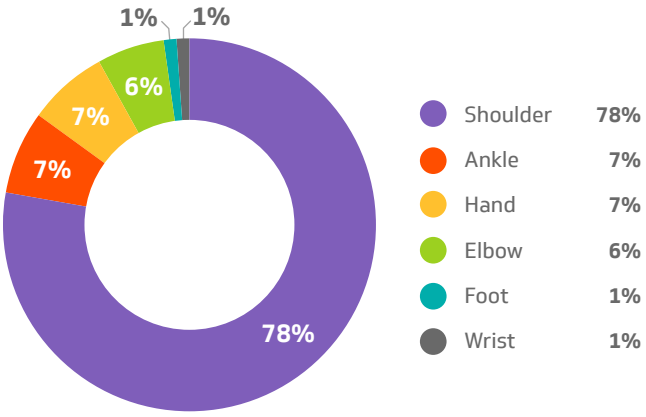
Reimbursement

Reimbursement for knee and hip reconstruction exists. Over the next several years, no new implants will be introduced that are expected to significantly affect reimbursement. The largest risk to hospital reimbursement will be the impact of bundled payments on hospitals that are required to participate in the program. The goal of the bundled program is to reduce overall payments, so the impact on each hospital will depend on the hospital's ability to develop procedures and networks with post-acute care service suppliers that can improve patient care at lower cost.

Shoulder and extremity joint reconstruction

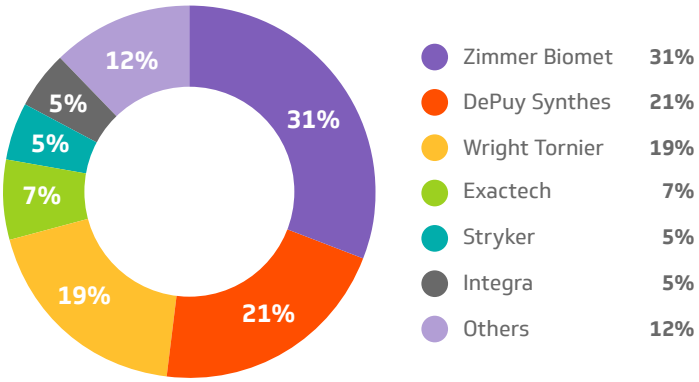
The growing U.S. market for orthopedic extremity devices includes reconstructive implants used in the shoulder, elbow, ankle, wrist, and the digits of the hand and foot. Although this market is still small compared with the total joint and spine markets, overall procedure growth is estimated at 4 to 5 percent annually over the next several years, with a total value estimated to exceed $1 billion.[7] Within the extremities market, the shoulder subsegment will drive the majority of the growth, with procedure growth estimated at 6 to 7 percent annually.[8]

Extremity joint reconstruction market



Shoulder implants make up the largest segment of the extremity joint reconstruction market. This segment was developed by smaller companies offering differentiated implants and emerging surgical techniques. Unique implants allowed these suppliers to grow the market and protect implant prices while developing a loyal physician base. Most of the successful extremity joint companies have been acquired by the larger orthopedic companies, enabling the latter to both offset the decline in pricing for their total joint reconstruction market products and broaden their product offerings to better position them to bundle products and protect market share. As the larger suppliers gain increasing control of the extremity market, the CMS may consider expanding the CJR bundle to include these types of procedures.

Extremity joint reconstruction market: supplier shares



Product technology within this market segment is both revolutionary and evolving. Products are being designed using innovative manufacturing techniques to continuously improve the ergonomics and performance of the implants. We expect to see slower research and development spending in the large joint reconstruction market segment in favor of development of extremity joints.

Companies developing extremity implants

Extremity joint reconstruction is a fast-growing market segment; many companies are working to develop products in this segment. The table below shows devices recently approved for use in the United States.

Vendor name	Device name	510(k) no.	510(k) approval date
Arthrex, Inc.	Univers Revers shoulder prosthesis system	K161782	Nov 21, 206
Blue Ortho	ExactechGPS total shoulder application, Equinoxe planning software	K162567	Apr 5, 2017
DJO Surgical — Encore	AltiVate Anatomic Shoulder System	K162024	Nov 21, 2016
Exactech Inc.	Equinoxe Reverse shoulder compression screws, Reverse shoulder glenosphere locking screw	K162325	Mar 6, 2017
FX Solutions	Humelock Reversed Shoulder System	K162455	Jan 17, 2017
Zimmer Biomet	Anatomical Shoulder Domelock Dome Centric	K161620	Nov 1, 2016
AAP Implantate AG	Loqteq Distal Lateral Humerus Plate 2.7/3.5	K161696	Nov 23, 2016
Advanced Orthopaedic Solutions	AOS Small Bone Nailing System	K163014	Jan 24, 2017
Arthrosurface, Inc.	ToeMate Hammertoe Correction System	K170350	Mar 3, 2017
DePuy Synthes	2.4/2.7mm variable angle LCP two-column volar distal radius plate, extra-long	K163046	Feb 9, 2017
Graham Medical Technologies	Osteo-Wedge II Open Wedge Bone Locking Plate System	K162179	Jan 10, 2017
KLS Martin	Level One hand plating system	K170124	Mar 9, 2017
Medline Industries	Unite ankle fracture plating system	K162829	Dec 9, 2016
Miami Device Solutions	Distal Radius Plating System	K162635	Oct 21, 2016
Newclip Technics	Foot and Hand Motion	K170012	Apr 24, 2017
Newclip Technics	Footmotion Plating System	K161448	Oct 31, 2016
Paragon 28	Titan 3-D Wedge System	K162241	Apr 3, 2017
Renovo Life, LLC	Renovo Life Small Bone IM Nail System	K161254	Nov 7, 2016
Restore Surgical dba Instratek	ToeTac 10° Hammertoe Fixation System	K161778	Nov 22, 2016
Smith & Nephew, Inc.	VLP Wrist Fracture System	K161665	Nov 15, 2016
Stryker GmbH	VariAx Distal Radius Plating System, VariAx 2 System	K162841	Feb 21, 2017
Wright Medical	Ortholoc 3Di Ankle Fracture Plating System	K163044	Jan 26, 2017
Wright Medical	Ortholoc 3Di Ankle Fusion Plating System line extension	K163650	Apr 24, 2017
Wright Medical	Ortholoc 3Di Small Bones Plating	K163039	Mar 13, 2017
XpandOrtho, Inc.	XO1 Knee Balancing System	K162237	Apr 25, 2017

New implants

Suppliers of extremity joint reconstruction products are continuing to develop implants and surgical techniques to enhance patient outcomes. The low barrier to competitive entry for these implants allows new suppliers to enter the market. Some recently introduced new products are described below.

OsteoMate Arthrodesis Implant

(Arthrosurfaces, Inc.)

The OsteoMate arthrodesis implant is composed of allograft bone and is provided preshaped, predrilled and sterile. The implant design is optimized for four-corner fusion of the hand and Lisfranc arthrodesis of the foot. Allograft bone is translucent under X-ray, allowing the physician to visualize and monitor bone ingrowth during the healing period. The product was approved for the U.S. market in April 2017.

AltiVate Anatomic Shoulder System

(DJO Surgical)

The AltiVate Anatomic Shoulder System features a short, bone-sparing humeral stem anatomically designed through morphologically based fit analysis to optimize metaphyseal fit and stability. The stem also features a proprietary porous coating that provides superior bone ingrowth. Coupled with the stem is a glenoid component with patent-pending technology encompassing tri-lobe features on the peripheral pegs for immediate fixation upon implantation. The system allows the surgeon to use a short or standard-length humeral stem with the same instrument system and introduces a new glenoid component with outstanding initial fixation. The system was launched in March 2017.

Equinoxe Preserve Stem

(Exactech, Inc.)

The Preserve stem is an expansion of the Equinoxe Platform Shoulder System. The new stem is approximately two-thirds the length of the system's current stem and features a unique polished distal tip to facilitate removal, a straight lateral fin designed for greater rotational stability and a plasma coating to aid proximal fixation. The implant provides a conservative shoulder treatment option designed to preserve humeral bone in shoulder replacement surgery. The Preserve stem is expected to be available on the U.S. market in early 2018.

Vantage Total Ankle System

(Exactech, Inc)

The Vantage total ankle is Exactech's first ankle reconstruction system and features both tibial and talar components. The implant is designed to conserve bone while allowing for both stability and mobility in total ankle arthroplasty. The curved-surface talar component is engineered to fit the anatomy of the diseased talus and restore the joint line, and both the curved talus and anatomic tibia designs are intended to improve implant stability and return anatomic kinematics. The system incorporates the press-fit bone cage design used in the company's shoulder system. The system is expected to be available on the U.S. market in mid-2017.

KinematX Total Wrist Arthroplasty System

(Extremity Medical LLC)

The KinematX total wrist arthroplasty system is designed to be a more accurate anatomic match to the normal wrist, thus preserving wrist motion for normal activities. The company expects to release the product in late 2017.

Precision Jones Fracture Screw System

(Paragon 28)

The Precision Jones Fracture Screw System comprises 120 unique screw options spread across four screw families (4.0 mm, 4.5 mm, 5.5 mm, and 6.2 mm). Solid and cannulated options for each screw length (34-60 mm; 65 mm) are available to address varying anatomies and fracture patterns. The screws are constructed from titanium alloy. The system's instrumentation is designed to facilitate placement of a K-wire high and inside the proximal portion of the fifth metatarsal. The product was launched on the U.S. market in May 2017.

Titan 3-D Wedge System

(Paragon 28)

The Titan 3-D Wedge System expands the company's portfolio of osteotomy wedges and uses the same shapes as its current Preserve brand of wedges. The porous titanium wedges, which offer surgeons an alternative to autograft and allograft bone, feature an open geometry with a 3-D scaffold that allows for blood entry, bone through-growth, and the incorporation of biologics. Each wedge has a central opening that allows for passage of a 3.5-mm or 4.0-mm screw across the osteotomy to help increase stability of the construct. The wedges do not require the use of an ancillary surface plate. The product was launched in the U.S. in April 2017.

VLP Wrist Fracture System
(Smith & Nephew)

The VLP Wrist Fracture System is a radial plating system comprising plates, screws and device-specific instrumentation. Plates, screws and locking pegs are provided in sterile packaging. Volar plate design options are offered in 3-, 4-, 5-, and 10-hole plate configurations, with both standard and wide sizes available for all sizes except the 10-hole plate, which is available in standard size only. All plate designs are available in left and right configurations. The system uses existing Smith & Nephew 2.4-mm locking and cortex screws. Expected market availability is currently unknown.

Invision Revision Ankle System
(Wright Medical)

The Invision revision ankle system completes Wright Medical's continuum of total ankle reconstruction products. The Invision system was designed to be used as a standalone construct or in conjunction with the company's other branded components. The system is full featured, with modular tibial stems, two thickness talar plates, two sagittal sizing options and more. The company anticipates market release of the system in late 2017.

Ortholoc 3Di Ankle Fracture LP System
(Wright Medical)

The Ortholoc ankle plating system is intended for fixation of fractures, osteotomies and nonunions of the distal tibia and fibula. The implant consists of straight and precontoured plates that accept nonlocking and locking screws of various lengths and diameters. All components are manufactured from titanium alloy and available sterile or nonsterile. The design features are substantially equivalent to those of other similar devices. The supplier anticipates market release of the system in late 2017.

XO1 Knee Balancing System
(XpandOrtho, Inc.)

The XO1 system uses multiple miniaturized sensors and actuators to balance the knee joint. The sterile-packaged disposable device uses a constant-pressure bellows system that wirelessly communicates with a display to offer dynamic multiaxial balance and selection of optimal thickness for the tibial component. The device provides real-time visual feedback to the surgeon for soft-tissue release. It is reportedly compatible with most total knee implant systems from major manufacturers. The device can also save an electronic record of the 3-D balance of the knee at the end of the procedure. The supplier anticipates limited U.S. product release in the second half of 2017.

Economic impact

The economic impact of new extremity reconstruction technologies will be marginal. It is anticipated that more suppliers will enter this market segment and create negative price pressures. Larger suppliers will attempt to bundle all their products for both joint reconstruction and spine surgery to maintain market share and protect average selling prices. As with other products, this market segment is rapidly commoditizing and hospitals and surgery centers should push back on any price increases unless clinical data demonstrates better patient outcomes and/or economics for the new product.

Reimbursement

Reimbursement for extremity reconstruction exists. While it has been suggested that new reimbursement codes are needed to better reflect the costs of the various procedures, no new codes are being implemented at this time. In addition, no new implants are anticipated that will significantly affect reimbursement. It is anticipated that the trend to reduce orthopedic reimbursements will continue, which will have a direct or indirect impact on this market segment.

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Notes