

ORTHOPAEDIC DEVICE COMPANY PROFILES

Preface

Hundreds of companies worldwide play in the orthopaedic space. In an effort to provide meaningful comparisons among them, ORTHOWORLD estimates device company revenue by six main categories—joint reconstruction, spine, trauma, arthroscopy/soft tissue, orthobiologics and other—apportioning revenue based on type of product. For example, a company’s extremities segment may include hardware for joint reconstruction and for trauma. We separate these, establishing estimates based upon type of product to support an “apples to apples” picture.

Our estimates are calculated with as-reported revenue numbers from public companies and privately-disclosed figures from non-public players, as well as dozens of hand-crafted revenue estimates based upon our expanding knowledge of all of the players. We continually critique and seek validation of our numbers, which is why we believe that they are the most accurate available and also why we advise you to always reference the latest installment of our reports to capture the most updated refinements. For instance, 2015 market segment revenue may appear higher in this year’s report.

The segments addressed within this report, and the technologies and revenue you can expect to find within each segment, are defined below.

Joint Reconstruction: Implants, instrumentation and surgical-assisted systems, e.g. robotics and navigation, to replace or revise failed joints in the hip, knee, shoulder, elbow, wrist, ankle and digits

Spine: Implants and instrumentation to treat degenerative disc disease, herniated discs, scoliosis, vertebral fractures: pedicle screws, plates, rods, hooks, artificial discs, motion-preserving devices, vertebroplasty/kyphoplasty systems, etc.

Trauma: Implants and instruments for internal and external use (plates, screws, intramedullary nails, pins, wires, staples, external fixators, etc.); also known as Fracture Repair

Arthroscopy/Soft Tissue Repair: Equipment and implantables, including arthroscopes, cameras/visualization systems, fluid management, handheld instruments for removal of bone and soft tissue, radiofrequency systems; artificial ligaments, screws, anchors and tacks in metal and resorbable materials, polyetheretherketone (PEEK), etc.; also known as Sports Medicine

Orthobiologics: Biologics and biochemical products such as allograft and xenograft tissue, synthetic bone graft substitutes, autologous platelet/plasma systems, cell-based repair systems, growth factors, bone proteins, anti-adhesion technologies, hyaluronic acid and viscosupplements, with application across the market segments

Other: Contains craniomaxillofacial, bone growth stimulation, bracing/soft goods and miscellaneous items like Zimmer Biomet’s forgings and Accelero and Stryker’s Performance Solutions. We constantly strive to refine this category in our ongoing effort to improve the accuracy of our market segment estimates.

Product images that appear within this report were supplied by their manufacturers.

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Introduction

We examine orthopaedics' top performers because they lead the way for the whole industry. Their size influences the entire commercialization chain—from napkin sketch to implantation to 5-, 10-, 20-year outcomes. Their size also requires bigger, bolder moves to stay competitive and maintain growth. Certainly, too, their share—59% of the market—means that their performance is a primary contributor to the health of the overall industry.

A close examination of the top five is our first step in authoring THE ORTHOPAEDIC INDUSTRY ANNUAL REPORT for the reasons just stated. We can say with complete honesty that the process of segmenting their revenue, scrutinizing the figures, seeking understanding of their strategies and all of the nuances inherent in summarizing a company's performance, well, it never gets easier. We do believe, however, that we are getting better at it.

We're pleased to report that the top five outperformed our projections (as published in the last installment of this report) by 3%. Combined, they grew by \$671.7 million, up 2.4% from 2015, as shown in Exhibit 1. While still in the low-single digits, the performance is positive and we anticipate that it will continue to be so. Here's why.

First, economic and currency instability of emerging markets did not create the same headwind that these companies experienced in 2015 and expected to continue to experience into 2016. In 2015, the top five posted ex-U.S. sales

performance from -2% to -13%, according to our as-reported numbers. In 2016, DePuy Synthes, Zimmer Biomet and Medtronic posted a loss of 1.6% or less for ex-U.S. sales, while Smith & Nephew and Stryker were in the black. Most of the challenges that occurred seemed company- and not country- or region-specific.

Second was the return of 2% to 3% growth in joint reconstruction. Nearly 47% of the top five's combined revenue derives from the joint reconstruction market. A stable U.S. and strengthened ex-U.S. market along with new product launches returned this segment to growth after posting flat knee and declining hip revenue in 2015. Joint recon remains a priority for all five. In 2016, Medtronic announced its entry into the knee and hip market with the acquisition of Responsive Orthopedics, and with that launch joined the other four in announcing solutions to assist hospitals with the tracking of bundled payment data.

Third, acquisitions boosted revenue. Zimmer Biomet completed seven transactions, Stryker five, Smith & Nephew two and DePuy Synthes and Medtronic one each. The acquisitions were spread across each of the five major orthopaedic market segments—joint reconstruction, spine, trauma, arthroscopy/soft tissue and orthobiologics.

Fourth, the top players in spine—Medtronic, DePuy Synthes and Stryker—all experienced inventory issues or inventory reductions due to a decrease in demand. All three posted a loss in 2015. In 2016,

Exhibit 1: 2016 Sales Performance for Top Five (\$Millions)

		2016	2015	\$ Change	% Change
#1	DePuy Synthes	\$9,003.5	\$8,930.8	\$72.7	0.8%
#2	Zimmer Biomet	\$7,100.9	\$6,883.2	\$217.7	3.2%
#3	Stryker	\$6,330.8	\$6,034.4	\$296.5	4.9%
#4	Smith & Nephew	\$3,250.5	\$3,163.2	\$87.3	2.8%
#5	Medtronic	\$2,930.0	\$2,932.0	-\$2.0	-0.1%
	Total	\$28,615.7	\$27,944.0	\$671.7	2.4%

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Product and Service Portfolio 

Product Matrix. DePuy Synthes participates in the shaded categories.

Joint Reconstruction	Trauma	Arthroscopy/ Soft Tissue	Spine	Orthobiologics
Shoulder	Upper/Lower IM Nails	Equipment	Artificial Discs	Allograft/Xenograft/DBM
Elbow/Radial Head	Upper/Lower Plates & Screws	Soft Tissue Fixation	Fusion	Synthetics
Finger/Hand/ Wrist	Wires/Pins/ Staples	<i>Artificial Ligaments/ Tendons</i>	Dynamic Stabilization	PRP/Cell-based/ Osteoinductive
Hip	External Fixation		Vertebroplasty/ Kyphoplasty	Soft Tissue Repair
Knee				Viscosupplementation
Ankle				
<i>Subtalar/Toe</i>				

Company leadership has prioritized knee and trauma as key growth platforms, while it continues investments in hips, infection prevention, extremities and spine. For instance, DePuy received FDA 510(k) clearance for its ATTUNE Fixed Bearing Revision system during 2016, and launched an antibiotic-coated tibial nail.

Also within 2016, the company focused on publication of various ATTUNE knee studies, including data from large registries and patient databases.

ATTUNE reportedly represents the largest research and development project in the company's history, and the ATTUNE portfolio is consistently cited as a primary contributor to U.S. sales growth, alongside the TFN-ADVANCED

Proximal Femoral Nailing System, ORTHOVISC and MONOVISC viscosupplement therapies and the company's primary hip stems.

DePuy also has taken a lead in providing value-added services to assist hospital customers. In early 2017, the company clarified the primary services that it offers for healthcare delivery: CareAdvantage and Orthopaedic Episode of Care Approach.

CareAdvantage is available in the U.S., with global rollout to occur in phases. The process identifies the health system customer's needs and objectives pertaining to the delivery of value-based care. This feeds into an action plan that includes metrics to measure results.

Strategic Activity | 2014-2016

Merger & Acquisition Activity

2014

- Acquired ETEX, a bioresorbable bone substitute materials manufacturer
- Agreed to acquire Biomet in a cash and stock transaction valued at ~\$14 billion

2015

- Sold to DJO Global the U.S. rights for Cobalt Bone Cement, Optivac Cement Mixing accessories, the SoftPac Pouch and the Biomet Discovery Elbow
- Sold to Lima Corporate the rights to the Zimmer Unicompartmental High Flex Knee (ZUK) and Discovery Elbow within Japan, the European Economic Area and Switzerland, as well as the Biomet Vanguard Complete Knee System for Denmark and Sweden
- Sold to Smith & Nephew the U.S. rights for the ZUK knee
- Completed its acquisition of Biomet

2016

- Acquired Cayenne Medical, manufacturer of soft tissue repair and reconstruction products for the knee, shoulder and extremities
- Acquired CD Diagnostics, developer of immunoassays and biomarker testing to inform treatment decisions (The companies had initially partnered in 2012 to co-develop diagnostics for musculoskeletal applications, which led to marketing of the Synovasure test for peri-prosthetic joint infection)
- Acquired Clinical Graphics, a specialist in 3D range-of-motion simulation technology for hip conditions requiring early intervention
- Acquired Compression Therapy Concepts, provider of devices to prevent deep venous thrombosis following a variety of surgical procedures
- Acquired LDR Spine in a transaction valued at ~\$1.0 billion

- Acquired Medtech, provider of surgical systems including the ROSA Spine robotic-assistive device for minimally invasive surgery
- Acquired RespondWell telerehabilitation technology, designed to provide personalized, clinician-supervised post-surgical physical therapy in a patient's home

Collaborations

2014

- Biomet Japan entered into an exclusive distribution agreement with OrthAlign for KneeAlign Total Knee Arthroplasty technology
- Zimmer entered into a distribution agreement with MiMedx for dehydrated human amnion/chorion membrane (dHACM) allograft products for non-exclusive private label marketing in the U.S. The agreement encompasses applications including reconstructive, sports medicine, trauma, extremities and spine.
- Zimmer Trauma and RTI Surgical renewed a distribution agreement for integrated plates/cables, cannulated screws and instrumentation.

2016

- Entered into an exclusive global distribution agreement for CelgenTek Innovations' N-Force Fixation System and iN3 Cement
- Entered into an exclusive agreement to globally distribute Nextremity Solutions' foot and ankle deformity correction products
- Entered into an exclusive agreement with Seikagaku for U.S. distribution of VISCO-3, a 3-injection hyaluronic acid-based viscosupplement for the treatment of knee osteoarthritis pain

Legal Developments

2014

- Biomet agreed to pay \$6 million to resolve allegations that it paid kickbacks to encourage use of bone growth stimulators and improperly billed Medicare for refurbished medical devices.

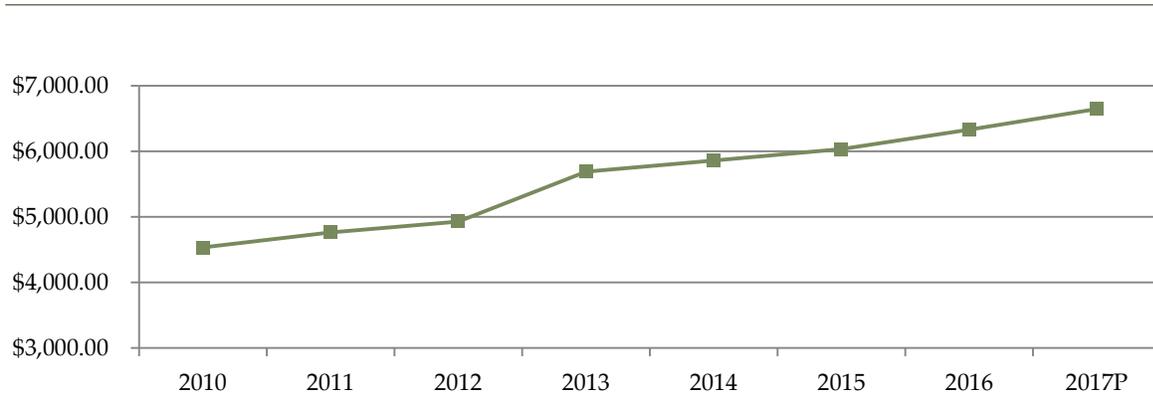
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Stryker derives about 56% of its revenue from orthopaedics, with the remainder coming from neurotechnology and medical surgical instruments.

In 2016, the company reported total revenue of \$11.3 billion, an increase of 13.9% from 2015, and net earnings of \$1.6 billion, an increase of 14% from 2015 and representing 14.5% of overall, full-company 2016 sales.

For overall full-company revenue, Stryker expects 2017 organic sales growth in a range of 5.5% and 6.5%. If constant currency exchange rates hold at current levels, sales will be negatively impacted by 1%. Exhibit 5 depicts the trajectory of orthopaedic sales from 2010 to 2017 projected.

Exhibit 5: Historical Sales: 2010 to 2017 Projected (\$Millions)



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SMITH & NEPHEW PLC

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Phone 44-20-7401-7646
www.smith-nephew.com

2016 Revenue: \$3,250.5 million
(ORTHOWORLD estimate of
orthopaedic revenue)

Employees: ~15,645

Founded: 1856, incorporated as
Smith & Nephew in 1937

Company Description

Thomas J. Smith opened a pharmacy in Hull, England in 1856. In 1896, he was joined by relative Horatio N. Smith, at which time the company became known as T.J. Smith & Nephew Limited. From this small family enterprise grew a company that, in 1914, was awarded a contract to supply £350,000 of surgical and field dressings at the declaration of World War I. It was incorporated as Smith & Nephew in 1936.

In 1986, the company entered the musculoskeletal space by acquiring Richards Medical, a U.S. company specializing in trauma and orthopaedic products. This was later followed by Acuflex Micro Surgical's arthroscopic devices (1995), shoulder and hip lines from 3M (1999); then came Oratec Interventions for \$310 million (2002), Midland Medical for \$120 million (2004) and Switzerland's Plus Orthopedics for \$899 million (2007). In 2014, the company acquired ArthroCare for \$1.7 billion. Additional acquisitions have occurred throughout the years, including those shared in this profile—particularly, distributors in certain geographic regions, and its partner Blue Belt Technologies, acquired for \$275 million in 2015.

The company itself has been the subject of numerous rumors of courtship by companies stretching back to Biomet, Johnson & Johnson and Stryker in 2011, Medtronic and Stryker in 2014 and

Stryker again in 2015. Smith & Nephew's share of the arthroscopy market and its geographic revenue split makes the company attractive. It is the second largest arthroscopy player, holding about 24% of the total market, following segment-leader Arthrex. In 2016, Smith & Nephew's arthroscopy/soft tissue revenue was ~\$560 million greater than the next ranking company DePuy Synthes, and ~\$760 million greater than Stryker, which ranks next on the list. Smith & Nephew's revenue is split nearly 50/50 in the U.S. and ex-U.S. For example, though Stryker's revenue was nearly \$3 billion more than Smith & Nephew's in 2016, the two companies' ex-U.S. revenue was nearly the same amount.

Smith & Nephew holds a 7% share of the global orthopaedic market, according to ORTHOWORLD estimates, and maintains the fourth spot among the top five players overall.

“As more procedures move from high-cost hospitals to lower-cost ambulatory surgery centers, they're going to look for mobile robotics, which we have. They're going to look for a lower cost, which we have. And they're going to look for something that isn't tied to other types or other modalities like CT scans, etc., which again we have.”

*Michael Frazzette,
Chief Commercial Officer,
Smith & Nephew*

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Revenue 

Medtronic leads the spine and orthobiologics market segments.

With \$2.9 billion in revenue, Medtronic's sales account for nearly 28% of the spine market, a 10% lead (~\$800 million) over its next-closest competitor, DePuy Synthes. Its orthobiologics sales of \$500 million account for 11% of that market segment, which is a 1% (~\$40 million) lead over second-place Sanofi.

In 2016, Medtronic experienced stronger ex-U.S. than U.S. spine sales. Specifically, sales in Japan, the Middle East, Africa, Canada and Latin America contributed to growth. A slower-than-expected ramp up of new products, as well as a restructuring of sales management in its Restorative Therapies group (under which spine and orthobiologics sales fall) contributed to overall declines.

Medtronic is expected to log revenue in joint reconstruction in 2017, though the company has not yet offered guidance.

Exhibits 1 and 2 illustrate the company's market segment sales, while Exhibits 3 offers a look at geographic sales. Medtronic cited weakness in the EMEA market and a shipping hold in Europe for InductOs as reasons for a decline in ex-U.S. growth.

Exhibit 1: Sales by Market Segment: 2016 vs. 2015

	2016	2015	\$ Change	% Change
Spine	\$2,429.0	\$2,431.0	-\$2.0	-0.1%
Orthobiologics	\$501.0	\$501.0	\$0.0	0.0%
Total	\$2,930.0	\$2,932.0	-\$2.0	-0.1%

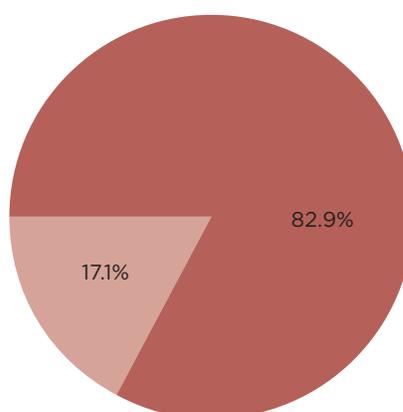


Exhibit 2: Market Segments as a Percent of Orthopaedic Sales

- Spine 82.9%
 - Orthobiologics 17.1%
- Total 100%

Exhibit 3: U.S. vs. Ex-U.S. Sales: 2016 vs. 2015

	2016	2015	\$ Change	% Change
U.S.	\$2,025.8	\$2,018.8	\$7.0	0.3%
Ex-U.S.	\$906.2	\$911.2	-\$5.0	-0.6%