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We have several data points for the orthopedics devices market size.

<i>Market Niche Size</i>			
<i>Market Size in Dollars</i>	<i>Growth Rate</i>	<i>Base Year</i>	<i>Detailed Basis for Estimate</i>
\$16.2 billion (Global)	7.2%	2007	According to Datamonitor. Growth rate was estimated at 8.7% for 2003-2007, but is projected to decelerate to 7.2%, resulting in a worldwide market size of \$22.9 billion by 2012. ¹
\$11.5 billion (U.S.)	7.7%	2007	According to Datamonitor. Growth rate was estimated at 9.5% for 2003-2007, but is projected to decelerate to 7.7%, resulting in a U.S. market size of \$16.7 billion by 2012. ²
\$13.56 billion (U.S.)	11.6%	2006	According to Frost & Sullivan. The market is projected to reach \$29.16 billion by 2013. ³
\$3.1 billion (Europe)	7.1%	2007	Growth rate was estimated at 7.6% for 2003-2007, but is projected to decelerate to 7.1%, resulting in a worldwide market size of \$4.3 billion by 2012. ⁴
\$5.44 billion (Joint Reconstruction and Replacement, U.S.)	7.4%	2006	Includes devices for hips, knees, shoulders, elbows, wrists, digits and ankles. Market is forecast to reach \$8.97 billion by 2013. ⁵
\$2.34 billion (Spinal, U.S.)	7.4%	2006	Includes "spinal fusion and fixation devices, spinal fusion stimulators, artificial discs, total disc replacement (TDR), VCF devices, and spinal orthoses." Market is forecast to reach \$4.26 billion in 2013. ⁶
\$2.09 billion (Trauma/Fixation, U.S.)	15.7%	2006	Estimated to reach \$5.8 billion in 2013. ⁷
\$1.55 billion (Braces & Supports, U.S.)	2.6%	2006	Estimated to reach \$1.86 billion in 2013. ⁸
\$2.11 billion (Orthobiologicals/Biomaterials, U.S.)	21.4%	2006	Estimated to reach \$8.22 billion in 2013. ⁹

Although the market estimates provided above differ in both size and growth rate, in terms of order of magnitude they are consistent. Regardless of which estimate is believed, the market size is still quite substantial. As a result, we do not believe this inconsistency to be problematic.

The market size and growth rate is a function of the number of people in the market and the anticipated rate of buying. As markets transition between emerging, growth, shakeout, mature, and declining, the basis for competition and the number of competitors usually changes, along with the factors influencing adoption of innovation. The number of and growth rate for customers suggests how many units might be sold.¹⁰

<i>Our Current View on the Phase of the Market</i>	
<i>Today</i>	<i>Trend</i>
Mature	Mature

Our research has found that while certain segments of the orthopedic medical devices market (such as orthobiologicals and biomaterials) appear to be in a growth phase, there are numerous indicators that the overall market has likely entered a mature phase and may remain there for the foreseeable future. For example, according to Datamonitor, the hip and knee replacement device market (which makes up 38% of the total orthopedic medical device market and accounts for nearly all of the joint reconstruction and replacement device market)¹¹ is a "mature market."¹² Frost & Sullivan refers to the overall orthopedic medical devices market as "an already mature market." Furthermore, all of the sub-segments of the orthopedic medical device market (with the single exception of orthobiologicals and biomaterials) are dominated by a small handful of companies, with one company having at least 25% of the market share in each sub-segment.¹³ Such concentration is almost always indicative of a mature market.

Markets can also be described in terms of the basis for competition (best technological performance, best value or the price/performance tradeoff that best matches the end-users' preferences, lowest cost, or best availability or the ability to get the product quickly). This dimension helps to define the context in which a commercialization strategy must be developed.

<i>Basis for Competition in the Arena</i>	
Today	Trend
Best Technological Performance	Best Technological Performance

The orthopedic medical device industry is atypical in that the end-users, patients, usually neither choose nor pay for the device that they use. Doctors generally choose the device, in consultation with the patient, that they believe will work the best, and the device is then paid for by the hospital and by insurance, either private or public.¹⁴ Furthermore, orthopedic medical devices are generally “high-cost and high quality,” and surgeons “often place low value on the hospital’s initiatives to manage the cost of its supply chain.”¹⁵ As a result, cost appears to have relatively little to do with the choice of device, and therefore consideration of the price/performance tradeoff also appears to be of little import. The competitive rivalry among major players appears to be especially intense in this market, as illegal payments meant to influence surgeons’ decisions regarding orthopedic devices have been found to be widespread.¹⁶

In each market there may be stakeholders and companies with significant market share that will influence the introduction of your technology. Some organizations or companies that will likely influence the introduction of this technology are the following:

<i>Examples of Major Competitors in the Arena</i>		
Competitor	Relevance	Web site
Zimmer	Zimmer is the U.S. market leader in joint reconstruction and replacement devices, with a 26.6% share. ¹⁷ Its Zimmer Spine division has a purpose “to design, manufacture, and distribute medical devices and surgical tools that provide comprehensive spine care solutions to improve and enhance quality of life for patients with back pain, neck pain, degenerative disc conditions, and injuries due to trauma.” ¹⁸	http://www.zimmer.com
DePuy	Owned by Johnson & Johnson, DePuy holds a 22.4% share of the U.S. joint reconstruction and replacement device market, as well as 17.1% of the U.S. spinal device market. ¹⁹ “The DePuy companies’ product portfolio addresses a range of solutions for patients and professionals including products for reconstructing damaged or diseased joints, repairing and reconstructing traumatic skeletal injuries; facilitating the treatment of spinal disorders and deformity; surgical treatment of neurological and central nervous system disorders; and devices in sports medicine for the treatment of soft tissue injuries.” ²⁰	http://www.depuy.com
Synthes	Synthes owns 47% of the U.S. trauma/fixation device market. ²¹ The company “develop[s], produce[s] and market[s] instruments, implants and biomaterials for the surgical fixation, correction and regeneration of the skeleton and its soft tissues.” ²²	http://us.synthes.com
DJO	DJO, with brands including DonJoy, Aircast and ProCare, is the “largest non-surgical orthopedic rehabilitation device company in the United States and among the largest globally, as measured by revenues.” ²³ It holds 30% of the U.S. orthopedic braces market. ²⁴	http://www.djoglobal.com/index.html
Stryker	Stryker holds 19.1% of the U.S. joint reconstruction and replacement device market, and is also active in the spinal and trauma/fixation markets. ²⁵	http://www.stryker.com/en-us/index.htm

<i>Examples of Key Stakeholders or Networking Channels with Contact Information</i>		
Stakeholder	Relevance	Contact Information
Medical Device Manufacturers Association (MDMA)	MDMA is a “trade association based in Washington, DC providing educational and advocacy assistance to innovative and entrepreneurial medical	1350 I Street NW, Suite 540 Washington, DC 20005 Tel: 202-354-7171

	technology companies.” ²⁶ Members are smaller medical device companies. ²⁷	http://www.medicaldevices.org
Orthopedic Surgical Manufacturers Association (OSMA)	Trade organization representing 37 of the largest orthopedic medical device companies in the world. ²⁸	P.O. Box 38805 Germantown, TN 38183-0805 Tel: 901-758 0806 http://www.osma.net
American Academy of Orthopaedic Surgeons (AAOS)	AAOS is the “preeminent provider of musculoskeletal education to orthopaedic surgeons and others in the world. Its continuing medical education activities include a world-renowned Annual Meeting, multiple CME courses held around the country and at the Orthopaedic Learning Center, and various medical and scientific publications and electronic media materials.” ²⁹ Also administers the American Association of Orthopaedic Surgeons, which “health policy and advocacy activities on behalf of musculoskeletal patients and the profession of orthopaedic surgery.” ³⁰	6300 North River Road Rosemont, IL 60018-4262 Tel: 847-823-7186 http://www.aaos.org
U.S. Food and Drug Administration Center for Devices and Radiological Health (CDRH)	The CDRH is responsible for the review and approval of medical devices.	1350 Piccard Drive Rockville, MD 20850-4307 Tel: 800-638-2041 http://www.fda.gov/cdrh/
National Institute of Biomedical Imaging and Bioengineering (NIBIB)	Part of the National Institutes of Health. “...Supports the design, development, evaluation and validation of medical devices and implants. This includes: exploratory research on next generation concepts for diagnostic and therapeutic devices; development of tools for assessing host-implant interactions; studies to prevent adverse events; development of predictive models and methods to assess the useful life of devices; explant analysis; improved in vitro and animal models for device testing and validation.” ³¹	6707 Democracy Blvd., Suite 202 Bethesda, MD 20892-5469 Tel: 301-451-6768 http://www.nibib.nih.gov

Users’ abilities to buy the technologies they want are constrained by relevant government regulations and by relevant industrial standards and certification requirements. These requirements indicate test and evaluation procedures that can speed market acceptance if incorporated into concurrent engineering.

Examples of Regulations, Standards, and Certifications

Identifier and Promulgator	Description	Comments
§888.3480 – §888.3565 U.S. Food and Drug Administration	Standard definitions for various types of prosthetic knee joint replacements. ³²	Includes metal, metal/composite, cemented, uncemented, and other types of prosthetics. Standards associated with CRDH’s Office of Device Evaluation. ³³
§888.3300 – §888.3390 U.S. Food and Drug Administration	Standard definitions for various types of prosthetic hip replacements. ³⁴	Includes constrained, semi-constrained, metal, metal/polymer and other types of prosthetics. Standards associated with CRDH’s Office of Device Evaluation. ³⁵
ISO 5838-1:1995 ISO 5838-2:1991 ISO 5838-3:1993 International Organization for Standardization (ISO)	These three regulations cover skeletal pins and wires, including material and mechanical requirements, Steinmann pins, and Kirschner wires. ³⁶	Part of TC 150/SC 5, which includes 24 related standards. ³⁷
Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices	“This standard establishes consistent methods to classify and define the geometric and performance characteristics of angled devices. This standard also presents a catalog of standard specifications that	ISO has no similar or equivalent standard. ³⁹

ASTM F384-06	specify material, labeling, and handling requirements, and standard test methods for measuring performance related mechanical characteristics determined to be important to the <i>in vivo</i> performance of angled devices.” ³⁸
ASTM International	

Entry barriers are obstacles that remove customer segments from the market for some period of time. They limit the size of the addressable market in general or the market share that can be captured. These barriers must be overcome or avoided to have a successful market entry. Our work to date suggests the following entry barriers may prevent customer segments from buying this type of technology for some period of time.

<i>Market Entry Barriers</i>	
<i>Name of Barrier</i>	<i>Description/Why</i>
High Concentration of Market Share	In all of the orthopedic medical device sub-segments, with the exception of orthobiologics and biomaterials, the market is dominated by a small handful of companies. ⁴⁰ Such concentration typically represents a market barrier to potential new entrants. “The global orthopedic devices market is set to see heightened consolidation activity, driven primarily by Mergers & Acquisitions (M&As) in the joint reconstruction, spinal surgery and orthobiologics market segments. In 2007-08, a total of 42 M&A deals were signed in the orthopedic devices market with joint reconstruction, spine and orthobiologics companies’ together accounting for 70% of the deal volume, according to Global Markets Direct’s medical equipment deals database. The recent devaluation in market worth of small and mid-cap companies in the orthopedic device sector in light of the financial crisis is expected to trigger fresh bouts of consolidation in the next 3-5 year period.” ⁴¹
High Percentage of Uninsured and Underinsured Americans	Approximately 42% of adults in the U.S. either did not have health insurance or did not have adequate health insurance as of 2007. ⁴²

The high percentage of uninsured and underinsured Americans likely impacts the orthopedic medical device market in two significant ways. The first is that it may cause Americans to look overseas for cheaper care. For example, in India or Thailand, a procedure that is \$200,000 in the U.S. may cost only \$10,000.⁴³ Second, people who can not afford procedures are likely to either put off or forego the implantation of orthopedic devices that are not absolutely necessary, thus diminishing the addressable market.

Market drivers are forces that strengthen or weaken the importance of end-user needs over time. Practice level drivers are micro-economic; they affect the end-user directly. They influence the selection of substitutable goods and thus affect market share. Arena level drivers affect the organizations and industrial sectors in which the end-users work. They influence the overall demand for goods like this technology and its substitutes. They affect when and how much of the total addressable market is actually going to be in the market and buying.

<i>Market Drivers</i>	
<i>Name of Driver</i>	<i>Why Significant</i>
Aging General Population	Older patients are more likely to have arthritis, osteoporosis and other issues that are addressed with orthopedic medical devices. ⁴⁴ Additionally, the baby boomer generation has an “unwillingness... to compromise with a sedentary lifestyle,” meaning that as they get older they are at increased risk for sports-related injuries requiring orthopedic devices. ⁴⁵
Increase in Obesity Rate	According to the World Health Organization, the number of overweight people worldwide is expected to increase 44% between 2005 and 2015. Since the risk of “orthopedic-related disorders” is increased in overweight people, this trend is expected to fuel demand in the orthopedic medical device market. ⁴⁶
Growth in Asia-Pacific Region	Countries such as China and Japan have huge populations that are thought to be largely under-penetrated by orthopedic medical devices. These countries will likely record the highest regional growth for this market. ⁴⁷
Cost of Titanium	Titanium is an important material to the largest sub-segment in the orthopedic medical device market, joint reconstruction and replacement. When titanium is expensive, it limits the purchasing power of manufacturers; the inverse is true when titanium is cheap. ⁴⁸
Shift Towards Less Invasive Devices	“Innovations in minimally-invasive technologies have enabled patients to now choose alternate orthopedic procedures instead of the complex and painful surgical procedures. The hip and knee implants market is already witnessing this trend. Knee and hip resurfacing are potential options for those who are seeking a more conservative alternative to total joint replacement.” ⁴⁹

Here is some additional data and links to help you understand the market

Appendix

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<i>Name of Metric</i>	<i>Description</i>
Funding Opportunities from the NIBIB	The NIBIB solicits research proposals from the entire medical device field, including orthopedics. See the following URL for more information: http://www.nibib.nih.gov/publicPage.cfm?Section=funding&Action=Opportunities . ⁵⁰
The FDA Process for the Evaluation and Approval of Orthopaedic Devices	Published in J Am Acad Orthop Surg, Vol 16, No 5, May 2008, 260-267. See http://www.jaaos.org/cgi/content/abstract/16/5/260 .
Orthopedic Device Forum	The Orthopedic Device Forum (http://www.orthopaedicdeviceforum.org/) is a place for open communication between the scientific community, government, and related industry on orthopaedic issues.

¹ "Global Orthopedics." September, 2008. Datamonitor web site (subscription required). <http://www.datamonitor.com/> (accessed March 8, 2009).

² Ibid.

³ "U.S. Medical Devices Market Outlook." February 21, 2008. Frost & Sullivan web site (subscription required). <http://www.frost.com/> (accessed March 8, 2009).

⁴ "Global Orthopedics." September, 2008. Datamonitor web site (subscription required). <http://www.datamonitor.com/> (accessed March 8, 2009).

⁵ "U.S. Medical Devices Market Outlook." February 21, 2008. Frost & Sullivan web site (subscription required). <http://www.frost.com/> (accessed March 8, 2009).

⁶ Ibid.

⁷ Ibid.

⁸ Ibid.

⁹ Ibid.

¹⁰ For a detailed discussion of the "innovativeness dimension," see Everett M. Rogers, *Diffusion of Innovations*, 4th ed. (New York: Free Press, 1995). For further readings related to market phases and innovation, see also James Utterback, *Mastering the Dynamics of Innovation* (Boston: Harvard Business School Press, 1996) and Vijay K. Jolly, *Commercializing New Technologies: Getting from Mind to Market* (Boston: Harvard Business School Press, 1997).

¹¹ "U.S. Medical Devices Market Outlook." February 21, 2008. From Frost & Sullivan web site (subscription required). <http://www.frost.com/> (accessed March 8, 2009).

¹² "Hip and Knee Replacement Market: Overview of the U.S. and European Markets." October 5, 2006. *Datamonitor*. The Healthcare Sales & Marketing Network web site. <http://salesandmarketingnetwork.com/reports.php?pipe=0000ac177000191&ID=1582> (accessed March 8, 2009).

¹³ "U.S. Medical Devices Market Outlook." February 21, 2008. From Frost & Sullivan web site (subscription required). <http://www.frost.com/> (accessed March 8, 2009).

¹⁴ Robinson, James C. "Value-Based Purchasing for Medical Devices." *Health Affairs*, vol. 27, issue 6, November/December 2008.

¹⁵ Ibid.

¹⁶ "Orthopedic Device Makers Accused of Paying Doctors." February 28, 2008. *The Washington Post*. Lexis-Nexis web site (subscription required). <http://www.lexisnexis.com/> (accessed March 8, 2009).

¹⁷ "U.S. Medical Devices Market Outlook." February 21, 2008. Frost & Sullivan web site (subscription required). <http://www.frost.com/> (accessed March 8, 2009).

¹⁸ "Zimmer Spine About Us," Zimmer web site. <http://www.zimmer.com/z/ct/op/global/action/1/id/8187/template/CP/navid/504> (accessed March 9, 2009).

¹⁹ "U.S. Medical Devices Market Outlook." February 21, 2008. From Frost & Sullivan web site (subscription required). <http://www.frost.com/> (accessed March 8, 2009).

²⁰ "About DePuy." DePuy web site. <http://www.depuy.com/Pages/aboutDepuy.aspx> (accessed March 8, 2009).

²¹ "U.S. Medical Devices Market Outlook." February 21, 2008. From Frost & Sullivan web site (subscription required). <http://www.frost.com/> (accessed March 8, 2009).

²² Synthes web site. <http://us.synthes.com> (accessed March 8, 2009).

²³ "Our Company." DJ Orthopedics web site. http://www.djglobal.com/index.asp?fuseaction=company_main (accessed March 8, 2009).

²⁴ "U.S. Medical Devices Market Outlook." February 21, 2008. From Frost & Sullivan web site (subscription required). <http://www.frost.com/> (accessed March 8, 2009).

²⁵ Ibid.

²⁶ "About MDMA." Medical Device Manufacturers Association web site. <http://www.medicaldevices.org/public/about> (accessed March 8, 2009).

²⁷ "Membership." Medical Device Manufacturers Association web site. <http://www.medicaldevices.org/public/benefits> (accessed March 8, 2009).

²⁸ "About OSMA." Orthopedic Surgical Manufacturers Association web site. <http://www.osma.net/about.html> (accessed March 8, 2009).

²⁹ "About the AAOS." American Academy of Orthopaedic Surgeons web site. <http://www.aaos.org/about/about.asp> (accessed March 8, 2009).

³⁰ Ibid.

³¹ "Medical Devices and Implant Science Program Area." National Institute of Biomedical Imaging and Bioengineering web site. <http://www.nbib.nih.gov> (accessed March 9, 2009).

³² "Recognized Consensus Standards." U.S. Food and Drug Administration CDRH web site. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD_IDENTIFICATION_NO=22184 (accessed March 9, 2009).

³³ Ibid.

³⁴ "Recognized Consensus Standards." U.S. Food and Drug Administration CDRH web site. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD_IDENTIFICATION_NO=22188 (accessed March 9, 2009).

³⁵ Ibid.

³⁶ "Osteosynthesis and Spinal Devices." International Organization for Standardization web site. http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=53116 (accessed March 9, 2009).

³⁷ Ibid.

³⁸ "ASTM F384-06." ASTM International web site. <http://www.astm.org/Standards/F384.htm> (accessed March 9, 2009).

³⁹ Ibid.

⁴⁰ "U.S. Medical Devices Market Outlook." February 21, 2008. Frost & Sullivan web site (subscription required). <http://www.frost.com/> (accessed March 8, 2009).

⁴¹ "The Future of the Orthopedic Devices Market to 2012," Reports-research.com, January 8, 2009. <http://blog.reports-research.com/the-future-of-the-orthopedic-devices-market-to-2012/> (accessed March 6, 2009).

⁴² "25 Million Americans are 'Underinsured.'" June 10, 2008. *Business Week*. Business Week web site. http://www.businessweek.com/lifestyle/content/healthday/616350.html?chan=top+news_top+news+index_lifestyle (accessed March 9, 2009).

⁴³ "U.S. Medical Devices Market Outlook." February 21, 2008. Frost & Sullivan web site (subscription required). http://www.frost.com (accessed March 8, 2009).

⁴⁴ Ibid.

⁴⁵ "World Orthopedic Devices Market- Investment Analysis and Growth Opportunities." May 29, 2007. Frost & Sullivan web site (subscription required).

<http://www.frost.com/> (accessed March 9, 2009).

⁴⁶ Ibid.

⁴⁷ Ibid.

⁴⁸ "U.S. Medical Devices Market Outlook." February 21, 2008. Frost & Sullivan web site (subscription required). <http://www.frost.com/> (accessed March 8, 2009).

⁴⁹ "The Future of the Orthopedic Devices Market to 2012," Reports-research.com, January 8, 2009, <http://blog.reports-research.com/the-future-of-the-orthopedic-devices-market-to-2012/> (accessed March 6, 2009).

⁵⁰ "Funding Opportunities." National Institute of Biomedical Imaging and Bioengineering web site. <http://www.nibib.nih.gov/publicPage.cfm?Section=funding&Action=Opportunities> (accessed March 9, 2009).

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