Manufacturing Outlook for the Orthopedic Device Market
Manufacturing Outlook for the Orthopedic Device Market

The Orthopedic Market - Segments

- **Reconstruction Devices**: Hip, Knee, Shoulder, Upper extremity, Foot & Ankle
- **Traumatology**: Fracture Repair
- **Spine**: Fusion, Motion Preservation, Vertebral Fractures, Deformations
- **Arthroscopy/Soft Tissue Repairs**: Also called “Sports Medicine”
- **Orthobiologics**: Biomaterials, Growth Factors, Bone Substitutes
- **Other**: Power Tools, Casting/Bracing systems, Soft Goods, Cement, Cement mixing systems, Pulsed Lavage/Irrigation systems, Bone Growth Stimulators, Image Guided Surgery systems, Diagnostics, etc.
Musculoskeletal conditions (150 diseases) are among the most costly illnesses to treat ($254 billion in the U.S.)

- One in 5 adults in the U.S and one in 10 Canadians suffer with osteoarthritis (OA)
- Knee osteoarthritis is as disabling as any cardiovascular disease (except stroke)
- More than 50 million fractures occur worldwide every year
- 32% of people over 18 are limited in their activity due to chronic back pain
- Cost to treat back pain conditions exceed $100 billion/year worldwide
Manufacturing Outlook for the Orthopedic Device Market

The Orthopedic Market
Marketplace vs. Demographics

Population
- 82%
- 18%

Market Distribution
- 82%
- 18%

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The Orthopedic Market

Market Dynamics - Drivers

- **Demographics**: volume – worldwide, life style (“Baby Zoomers”)
- **New Products / Technologies**: US, Europe, Japan
- **New Surgical Techniques**: US, Europe, Japan (MIS, CAS, Robotics)
- **New Materials**
- **Revision Surgery**: (mostly Western World)
- **Spinal Surgery**: huge demand worldwide
- **Trauma**: regular growth
- **“Globesity”**
- **Availability of information**: Web, DTC Ads,
- **Rapid development of certain countries** (China, India, etc.)
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The Orthopedic Market

Market Dynamics: Restraints

- **Cost Containment** pressure on healthcare systems worldwide
- Uncertainties around availability and increasing cost of raw materials
- Preventive measures and prescription of non-surgical treatments reduce number of procedures
- Uncertainty in reimbursement of new products/technologies
- Cost of R&D and regulatory constraints impedes/delay the introduction of new products
- **Intense competition** requires a high level of product differentiation and shorten product life cycle

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## Manufacturing Outlook for the Orthopedic Device Market

### The Orthopedic Market - Consolidation Trend

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OEMs</strong></td>
<td>20 transactions for approx. $3,200MM</td>
<td>20 transactions for approx. $16,000MM</td>
<td>22 transactions for approx. $6,500MM</td>
</tr>
<tr>
<td><strong>Contract Manufacturing</strong></td>
<td>4 transactions for approx. $100MM</td>
<td>13 transactions for approx. $350MM</td>
<td>5 transactions for approx. $420MM</td>
</tr>
</tbody>
</table>

**2009?**

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### The Orthopedic Market

#### 2008 Worldwide Sales ($billion) by Segment & Region

<table>
<thead>
<tr>
<th>Segment</th>
<th>U.S.</th>
<th>Ex-U.S.</th>
<th>Total</th>
<th>Change vs. 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reconstructive Devices</td>
<td>$6.7</td>
<td>$6.0</td>
<td>$12.7</td>
<td>9.0%</td>
</tr>
<tr>
<td>Trauma</td>
<td>$2.6</td>
<td>$2.3</td>
<td>$4.9</td>
<td>12.7%</td>
</tr>
<tr>
<td>Soft Tissue Repair / Arthroscopy</td>
<td>$1.9</td>
<td>$1.3</td>
<td>$3.1</td>
<td>9.8%</td>
</tr>
<tr>
<td>Spinal Implants / Instrumentation</td>
<td>$4.6</td>
<td>$1.9</td>
<td>$6.5</td>
<td>13.0%</td>
</tr>
<tr>
<td>Orthobiologics</td>
<td>$2.7</td>
<td>$1.0</td>
<td>$3.7</td>
<td>8.8%</td>
</tr>
<tr>
<td>Other</td>
<td>$3.1</td>
<td>$1.7</td>
<td>$4.9</td>
<td>6.3%</td>
</tr>
<tr>
<td>Total Market</td>
<td>$21.7</td>
<td>$14.0</td>
<td>$35.7</td>
<td>9.9%</td>
</tr>
<tr>
<td><strong>Change vs. 2007</strong></td>
<td>9.4%</td>
<td>10.6%</td>
<td>9.9%</td>
<td></td>
</tr>
</tbody>
</table>

(Source: Orhworld Inc.)
Manufacturing Outlook for the Orthopedic Device Market

The Orthopedic Market - Growth by Segment

CAGR: 13.3%

Source: JP Consulting/Orthoworld

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The Orthopedic Market

Main Players – 2008 Revenues & Market Share

- **Zimmer**: $3,894 (3) 10.9%
- **Medtronic**: $3,642 (1) 10.2%
- **Synthes**: $3,193 8.9%
- **S&N/Plus**: $2,959 (2) 8.3%
- **Biomet**: $2,093 (3) 5.9%
- **J&J-Depuy**: $4,518 12.7%
- **Stryker**: $5,547 (4) 15.5%
- **Others**: Includes more than 100 companies

Source: Medtech Insight / JP Consulting
Manufacturing Outlook for the Orthopedic Device Market

The Orthopedic Market
Trends by Segment

- **Reconstruction**
  - Mature market (except for shoulder and upper extremity)
  - Will enjoy steady growth (7 – 9% CAGR) over next 5 years
  - Hip and Knees becoming commodity products
  - Knees: Outpacing Hips (driven by “Globesity”)
  - Pressure on prices worldwide
  - Major consolidation process is (almost) over
  - More and more need for differentiation on the manufacturer side, but based upon existing technologies
  - MIS difficult to implement due to type/size of implants
  - CAS/Robotic will boost number of surgeries helping surgeon training
<table>
<thead>
<tr>
<th>Country</th>
<th>World</th>
<th>U.S</th>
<th>Europe</th>
<th>Japan</th>
<th>ROW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joint Replacement</td>
<td>2,717,000</td>
<td>1,359,000</td>
<td>802,000</td>
<td>263,000</td>
<td>293,000</td>
</tr>
<tr>
<td>Hip</td>
<td>1,378,000</td>
<td>559,000</td>
<td>510,000</td>
<td>122,000</td>
<td>187,000</td>
</tr>
<tr>
<td>Knee</td>
<td>1,100,000</td>
<td>711,000</td>
<td>210,000</td>
<td>94,000</td>
<td>85,000</td>
</tr>
<tr>
<td>Shoulder</td>
<td>118,000</td>
<td>60,000</td>
<td>37,000</td>
<td>12,000</td>
<td>9,000</td>
</tr>
<tr>
<td>Other Joints</td>
<td>121,000</td>
<td>29,000</td>
<td>45,000</td>
<td>35,000</td>
<td>12,000</td>
</tr>
</tbody>
</table>

Source: Medtech Insight / JP Consulting
The Orthopedic Market
2008 Worldwide Joint Reconstruction Sales
History & 3 Year Forecast

CAGR: 12.2%

Source: Knowledge Enterprises/JP Consulting

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The Orthopedic Market
Joint Reconstruction Segments
U.S Forecast (Units in 000) 2008-2012

Source: Medtech Insight

Global CAGR: 7.40%

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The Orthopedic Market

2008 Worldwide Trauma Sales by Segment ($ MM)

- 1,350 (27.5%)
- 1,220 (24.9%)
- 1,012 (20.6%)
- 378 (7.8%)
- 940 (19.2%)

Source: JP Consulting

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The Orthopedic Market
Trends by Segment

- **Trauma**
  - Mature market
  - Many implants have been commodity products for a long time
  - Innovation in the upper extremity segment (small bones)
  - Advancements in plates (locking plates) and nails
  - Development of non-metal implants: biodegradable (Polylactic-polyglycolic), composites, polymers (PEEK)
  - Will enjoy growth in the low double digit range for the next 5 years (Osteoporosis, China boosting # of traffic accidents)
  - Pressure on prices will continue
## Manufacturing Outlook for the Orthopedic Device Market

### The Orthopedic Market

#### 2008 Worldwide and U.S. Trauma Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>External Fixation</th>
<th>Plates Screws (internal fixation)</th>
<th>IM Nails (internal fixation)</th>
<th>Hip Screws (hip fractures)</th>
<th>Small Bones Fixation (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>U.S.A.</strong></td>
<td>223,000</td>
<td>527,000</td>
<td>476,000</td>
<td>342,000</td>
<td>618,000</td>
</tr>
<tr>
<td><strong>Ex-U.S.A</strong></td>
<td>280,000</td>
<td>661,000</td>
<td>597,000</td>
<td>510,000</td>
<td>775,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>503,000</strong></td>
<td><strong>1,188,000</strong></td>
<td><strong>1,073,000</strong></td>
<td><strong>852,000</strong></td>
<td><strong>1,393,000</strong></td>
</tr>
</tbody>
</table>

(1) Small plates + screws / pins / small screws

~5MM Procedures

Source: Windhover Information / JP Consulting
Manufacturing Outlook for the Orthopedic Device Market

The Orthopedic Market

2008 Worldwide Trauma Sales History & 3 Year Forecast

$Billion

CAGR: 14.9%

Source: JP Consulting

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The Orthopedic Market

Ex-US and U.S. Trauma Procedures / Forecast

Procedures (000) / $ (MM)

Source: Windhover Information / JP Consulting

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## Manufacturing Outlook for the Orthopedic Device Market

### The Orthopedic Market
#### 2008 Worldwide and US Spine Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Instrumented Fusions (cages, spacers, rods, hooks, pedicle screws)</th>
<th>Motion Preservation (Discs)</th>
<th>Fracture Fixation</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>U.S.A.</strong></td>
<td>438,330</td>
<td>5,070</td>
<td>247,000</td>
<td>690,400</td>
</tr>
<tr>
<td><strong>Ex-U.S.A</strong></td>
<td>166,520</td>
<td>1,650</td>
<td>93,850</td>
<td>262,020</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>604,850</td>
<td>6,720</td>
<td>340,850</td>
<td>952,420</td>
</tr>
</tbody>
</table>

Source: Windhover Information / JP Consulting

~1MM Procedures

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Manufacturing Outlook for the Orthopedic Device Market

The Orthopedic Market
US and Ex-US Spine Procedures Forecast

CAGR Fusions: 4.5% / CAGR Fractures: 20.7%

Source: Windhover Information / JP Consulting

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The Orthopedic Market

Ex-US and U.S. Spine Sales Forecast ($MM)

CAGR: 11.8%

Source: UBS / JP Consulting / Orthoworld

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The Orthopedic Market
Trends by Segment

- **Spine**
  - Growing Market
  - Will enjoy growth in the double digit range for the next 5 years (the most prevalent medical disorder in industrialized societies)
  - Prices will remain high although slightly declining
  - Increased adoption of MIS/CAS.
  - Future growth will come with 2nd generation discs (non-metal nucleus replacement), revision products, facet replacement
  - Development of non-metal implants: bioresorbable (Polylactic-polyglycolic), composites, polymers (PEEK), biogels

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## Manufacturing Outlook for the Orthopedic Device Market

### The Orthopedic Market

#### Main Players by Segment / Market Share

<table>
<thead>
<tr>
<th>Segment</th>
<th>Company 1</th>
<th>Company 2</th>
<th>Company 3</th>
<th>Company 4</th>
<th>Company 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reconstruction</td>
<td>Zimmer 25%</td>
<td>DePuy 21%</td>
<td>Stryker 18%</td>
<td>S&amp;N 11.5%</td>
<td>Biomet 11%</td>
</tr>
<tr>
<td>Trauma</td>
<td>Synthes 43.2%</td>
<td>Stryker 17.8%</td>
<td>S&amp;N 8.7%</td>
<td>DePuy 4.7%</td>
<td>Zimmer 4.5%</td>
</tr>
<tr>
<td>Spine</td>
<td>Medtronic 39.3%</td>
<td>DePuy 13.5%</td>
<td>Synthes 12.6%</td>
<td>Stryker 8.6%</td>
<td>Aesculap &amp; Nuvasive 3.9%</td>
</tr>
</tbody>
</table>

Source: JP Consulting
The Orthopedic Industry

Regulatory Aspects

Before 2007
- FDA would enforce compliance with QSR (former GMPs) with both OEMs and Contract Manufacturers
- ISO would also enforce compliance with both

After 2007
- FDA is enforcing compliance with QSR with OEMs only
- OEMs are held responsible for compliance of their suppliers with QSR
- ISO keeps enforcing compliance with both OEMs and Suppliers
- OEMs have been strongly pushing suppliers to comply with the same level of compliance as their own, leading for example most suppliers to comply with ISO 13485
Manufacturing Outlook for the Orthopedic Device Market

The Orthopedic Industry

Implant Manufacturing

- Some processes are mostly outsourced (Forging, Casting, Coating, Sterilization, etc.)
- Some OEMs tend to retain a maximum of work in house (Synthes, Biomet) whereas some, like DePuy, Medtronic tend to outsource more and more and sell plants to suppliers (4 recently)
- Less off-shore low labor cost outsourcing compared to instruments
- Main Processes: Forging, Casting, Milling, Coating, Polishing, Grinding, Wire EDM
- Proprietary processes are of course performed in house
- 25% are outsourced by OEMs
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Example of Hip Components

- Modular Hip Stem
- Ceramic-Ceramic Acetabular Cup

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Examples of Knee Components

- Total Knee
- Tibial Tray
- Unicondylar
- Patella
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Examples of Upper & Lower Extremities Implants

Shoulder

Elbow

Ankle
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Examples of Small Bones Implants

- Finger Joint
- Staple
- Great Toe Joint
- Radial Head
- Wrist
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Examples of Trauma Implants

- External Fixator
- Cortical Screw
- Cancellous Screw
- Cranial Mesh
- Locking Plate
- Plate for Wrist Fracture
Examples of Spinal Implants

- Cervical Plate
- Rod and Pedicle Screw
- Pedicle Screws
- Spinal Hooks
- Lumbar Disc
- Cages for Lumbar Fusion
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Non-Metal Components / Implants

- Polyethylene (Patella)
- Polyethylene Outside Co/Cr (metal-metal insert)
- Polyethylene inside Co/Cr (Bipolar Cup)
- Zirconia head
- Polyethylene (Tibial Tray)
- PLLA Plates
- PEEK Cages
- Silicone Finger Joint
- PLLA/PGLA Cervical Plates

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Many types of instruments

- Procedure Related: Impactors, Cutting Guides, Alignment Guides, Screw Drivers, Sizing Guides, Rod Cutters, Holders, Planers, Templates, etc.
- Orthopedic Surgery Related: Mallets, Handles, Reamers, Broaches, Blades, Awls, Drill bits, Taps, Bone Mills, Rongeurs, Osteotomes, Chucks, etc.
- General Instruments: Retractors, Distractors, Scissors, Forceps, Curettes, Spreaders, Clamps, etc.
- Power Instrument Systems: Drills, Saws

55% are outsourced by OEMs
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Examples of Instruments
Manufacturing Outlook for the Orthopedic Device Market

Examples of Instruments
Examples of Power Instrument Systems

SERIES 1000
SMALL POWER INSTRUMENTS

The Most Versatile Instruments for Small Bone Surgery
- Electric or Pneumatic
- Modular or Unitized

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**Delivery Systems**

- **Trays and Containers**
- **Function:** Deliver sterilized instruments/certain implants to the O.R.
- **Materials:** aluminum, various polymers
- **Main Mfg Processes:** metal forming, molding, extrusion, ink jet printing, assembly
- **90% are outsourced by OEMs**
Manufacturing Outlook for the Orthopedic Device Market

Examples of Delivery Systems
## Manufacturing Outlook for the Orthopedic Device Market

### Major Manufacturing Processes in Orthopedics

<table>
<thead>
<tr>
<th>Design and Engineering</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forging / Casting / M.I.M</td>
</tr>
<tr>
<td>CNC Milling / Turning</td>
</tr>
<tr>
<td>Porous Coating (Sintering, Plasma Spray)</td>
</tr>
<tr>
<td>Swiss CNC</td>
</tr>
<tr>
<td>Wire EDM</td>
</tr>
<tr>
<td>Grinding</td>
</tr>
<tr>
<td>Metal Forming / Bending</td>
</tr>
<tr>
<td>Polishing</td>
</tr>
<tr>
<td>Electro-polishing</td>
</tr>
<tr>
<td>Finishing (Tumbling, Blasting)</td>
</tr>
<tr>
<td>Tungsten Inert Gas Welding (TIGW)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Electron Beam Welding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Photo-Chemical Etching</td>
</tr>
<tr>
<td>Heat Treatment</td>
</tr>
<tr>
<td>Anodizing / Plating</td>
</tr>
<tr>
<td>Passivation/Ultrasound Cleaning</td>
</tr>
<tr>
<td>Precision Assembly, Laser Marking</td>
</tr>
<tr>
<td>Silicone Molding</td>
</tr>
<tr>
<td>Polymer Processing (molding, extrusion, machining)</td>
</tr>
<tr>
<td>Packaging / Labeling</td>
</tr>
<tr>
<td>γ / ETO Sterilization</td>
</tr>
<tr>
<td>QC Procedures</td>
</tr>
</tbody>
</table>

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Common Raw Materials used in Orthopedics

- **Titanium Alloys** (Ti-6Al-4V, Ti-6Al-4V ELI, Ti-6Al-7Nb)
- **Commercially pure Ti** (CP-1-2-3-4)
- **Co/Cr** (Co-28Cr-6Mo, Cast and wrought)
- **Stainless Steel** (316 L)
- **Oxinium** (Zirconium + Oxidized Zirconium + Niobium)
- **Polyethylene (UHMW)** (machined, compression molded, cross-linked, vitamin E stabilized)
- **Delrin, Acetal, Radel, Ultem**
- **PMMA, Calcium-Phosphates** (TCP, Hydroxyapatite)
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More Recent Materials used in Orthopedics

- **Ceramics** (Alumina-Yttrium, Alumina + ZrO₂)
- **PEEK** (Polyetheretherketone) + **PEEK/Carbon fibers**
- **Pyrolytic Carbon** (upper extremity implants)
- **Polylactic acid (PLLA), Polyglycolic acid resorbable copolymers**
- **Nitinol (Ti/Ni)** (shape memory implants like staples)
- **Silicone** (small joints)
- **Silicone Nitride** (ceramic bearings for hip/knee/spine)
- **Composites** (polymer/metal, Ca-P/PLLA, polymer/fiber, carbon composites)
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New Materials

- **Polyurethane** (replacement of P.E., discs)
- **Porous Ti** (Tritanium™, Regenerex™, BioFoam™, Gription™, Trabecular Titanium™, Stiktite™)
- **Porous Tantalum** (Trabecular Metal™)
- **Polymers for resorbable scaffolds, spacers, tendons, ligaments**
- **Polyethylene Terephtalate** (PET) (vesselplasty for VCF, mesh)
- **Coatings**: Nanowire coating on Ti, antibiotic coatings
- **Hydrophilic Polymers** (UHMWPE + Polysaccharide)
- **Hydrogels** (disc nucleus)
- **Polycrystalline Diamond** (Hip Bearings)
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Manufacturing Spending (2008)

- In-House: $6,500 (73%)
- Outsourced: $2,430 (27%)

OEMs
Contract Manufacturers

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## Manufacturing Outlook for the Orthopedic Device Market

### Capital Expenditure

<table>
<thead>
<tr>
<th>Company</th>
<th>Year</th>
<th>2008</th>
<th>2007</th>
<th>2006</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomet (*)</td>
<td>2008</td>
<td>$190MM (8%)</td>
<td>$142MM (6.7%)</td>
<td>$109MM (5.4%)</td>
<td>$97MM (5.2%)</td>
</tr>
<tr>
<td></td>
<td>2007</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wright Medical</td>
<td>2008</td>
<td>$62MM (13.3%)</td>
<td>$35MM (9.0%)</td>
<td>$29.6MM (8.7%)</td>
<td>$30.4MM (9.5%)</td>
</tr>
<tr>
<td>Stryker</td>
<td>2008</td>
<td>$95MM (2.4%)</td>
<td>$127 MM (3.5%)</td>
<td>$135MM (4.3%)</td>
<td>$183MM (6.4%)</td>
</tr>
<tr>
<td>Zimmer (*)</td>
<td>2008</td>
<td>$250MM (6.0%)</td>
<td>$192MM (5.2%)</td>
<td>$142MM (4.3%)</td>
<td>$105MM (3.3%)</td>
</tr>
<tr>
<td>Medium Size Supplier ($50MM)</td>
<td>2008</td>
<td>$2.0MM (4.0%)</td>
<td>$1.0MM (2.2%)</td>
<td>$3.7MM (9.2%)</td>
<td>$3.0MM (7.0%)</td>
</tr>
<tr>
<td>Symmetry</td>
<td>2008</td>
<td>22.8MM (5.4%)</td>
<td>$8.8MM (3.0%)</td>
<td>$20.3MM (8.3%)</td>
<td>$37.5MM (14.4%)</td>
</tr>
</tbody>
</table>

(*) Capital Expenditures may not consist of purchased manufacturing equipment, research and testing equipment only; They may include computer systems, office furniture and equipment, and plant improvement.

Source: Annual Reports

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Manufacturing Outlook for the Orthopedic Device Market

CAPEX Trends

- Largest investments in equipment are in the US and Europe (Ireland, Switzerland, UK, Germany, France)
- Both OEM and Suppliers also investing in China and India
- Nature of the business (medical), and need for automation require acquisition of most sophisticated and expensive equipment and renew them often (every 5-7 years?)
- Market size assumption: 3 to 4% of Sales? ($1.0 to 1.5 billion in 2008?)
- Impact of worldwide economy slow down in 2009 and further on?
Outsourcing is proving to be a vital strategic tool to OEMs which core competencies are R&D, Marketing, and Sales, by:

- Reducing or eliminating investments in new production capacity and in employees
- Providing manufacturing flexibility enhancing speed to market and generating cost reduction
- Providing access to highly skilled labor
- Providing access to services and technologies in the areas of delivery systems and specialized processes
Manufacturing Outlook for the Orthopedic Device Market

Outsourcing by Segments

- Delivery Systems
- Instruments
- Implants

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Outsourcing Trends

- **Market expected to increase** from 26% of OEM production costs in 2007 to 33% by 2012
- **Contract Manufacturers are** adding capacity and capabilities
- **Gradually transforming** into OEM’s strategic partners
- **On-going consolidation resulting** in larger firms that dominate the market
- **Competition intensifying** within the US and with low labor countries (China, India, Vietnam, Malaysia, etc.)
- **Attracting attention and capital** from private investors
- **Vendor consolidation trend is on-going** (OEMs reducing their vendor basis)
Manufacturing Outlook for the Orthopedic Device Market

Manufacturing Spending Forecast ($MM)

Source: P&M Corp. Finance

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Outsourcing Market Value by Capabilities ($MM)

- Forging: 345
- Casting: 115
- Texturing/Coating: 140
- Forming/Machining: 105
- Assembly: 105
- Polishing: 115
- Polymer Machining: 115
- Screws: 115
- Delivery Systems: 1020
- Packaging/Ster.: 255

Source: JP Consulting

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Threats to Traditional Manufacturing

- Slow but progressive replacement of metal by new materials
- Development of Cartilage transplant
- Resurfacing of partially damaged cartilage (Copolymers with similar properties like UHMWPE + polysaccharide)
- Potential cure for Osteoporosis (New drugs)
- Development of Tissue Engineering
- Development of Bone Substitutes
- Potential cure for Osteoarthritis (New drugs)
- Replacement of machined components by molded ones (P.E., ceramics, M.I.M.)
Manufacturing Outlook for the Orthopedic Device Market

Change in Manufacturing

- Most facilities have implemented and will continue to implement cell / lean manufacturing
- **Processing new materials** (PEEK, Ca/P ceramics, PLLA-PGLA, Bone (machined allografts))
- **Highly (mirror) polished implants**: Metal-on Metal and Resurfacing heads and cups, Co/Cr bearings (knee, disc, ankle)
- **Processing new porous materials**: porous Ti, porous Tantalum with implications on possible debris
- **Processing more smaller implants** for MIS, Spine, Small Bones
Manufacturing Outlook for the Orthopedic Device Market

Change in Manufacturing

- More and more CNC Machining Centers:
  - Implementing more automation to cut on labor cost and compete with off shore manufacturing competition
  - Unattended / Lights out manufacturing, Multi-Tasking, Done-in-One Machining
  - Palletization, Automatic Feeders and Part Catchers
  - High Capacity Tool Magazine (240 tools)
- Development of Robotics: Forging, Polishing
Impact of New Materials / New Technologies on Manufacturing

- Introduction of manufacturing processes uncommon in this industry until recently
- Vapor Deposition
- Nano Technologies
- Rapid Metal manufacturing (EBM)
- Application of Anti-Bacterial Coatings
- Implementation of Radio Frequency Identification (instruments)
Manufacturing Outlook for the Orthopedic Device Market

Impact of New Materials / New Technologies on Manufacturing

- Incorporation of sensors, micro-electronics into implants (discs, rods)
- e-Disc™ from Theken (Integra) (wirelessly transmits forces of motion and loads applied to the disc in post-recovery period)

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Impact of New Materials / New Technologies on Manufacturing

- Incorporation of sensors, micro-electronics into implants (discs, rods)
  - Monitoring of the progress of spinal fusion via a sensor placed on an implanted metal rod to measure strain (OrthoData) (in development)

- Combination of Polymers and Metals (Composites)

Epoch™ stem from Zimmer
Manufacturing Outlook for the Orthopedic Device Market

Impact of New Materials / New Technologies on Manufacturing

- CAD to Metal (Rapid Metal Manufacturing by Electron Beam Melting of Metal Powder (ARCAM AB, Sweden))

1. The part is designed in a 3D CAD program.
2. The part is built up in the Electron Beam Melting (EBM) process.
3. The result is a solid metal part.
Manufacturing Outlook for the Orthopedic Device Market

Impact of New Materials / New Technologies on Manufacturing

- Replacement of metal implants by Ceramic ones (Zirconia)
  - Kyocera (Japan) / Kinamed (USA)

Zirconia Knee Femoral Component
Alumina Components Of an Elbow
Alumina Ankle
Impact of New Materials / New Technologies on Manufacturing

- Machining of Allograft (Processed Human Bone) or Xenograft (Animal Bone)

Machined Interference Screw from Bovine Bone

Machined/Freeze-dried “Biocleansed”/low irradiated Spinal Fusion Cage and Dowel (from human femur and tibia)
Manufacturing Outlook for the Orthopedic Device Market

OEMs – Contract Manufacturers – Machine-Tool Producers

- No consultation between OEM and Suppliers in the acquisition of M.T.
- Do not forget: OEMs and Suppliers are also competitors (mfg costs, know-how, etc)
- Protection of trade secret and proprietary processes is essential on both sides

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Orthopedics continues to be the most dynamic and fast growing segment of the medical device industry. It is an industry highly capital intensive and avid of new technology. Requires more and more sophisticated, diversified and automated equipment to cut labor cost and implement new processes to deal with new specifications, tolerances and materials.
Conclusion

- US and European markets for equipment are negatively impacted by off shore manufacturing
- Technology shifts can be swift especially in terms of new materials and processes used in implants
- Consolidation on both sides (OEMs / Suppliers) generating quick changes in the players landscape
- Long term: pharma drugs, tissue engineering and Stem Cell technologies may reduce need for implants
Thank You for your Attention!