



Trends in Medical Device OEM Strategy and Implications for the Supply Chain

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Manning Advisors LLC

Merger and Acquisition, Advisory, and Financial Services

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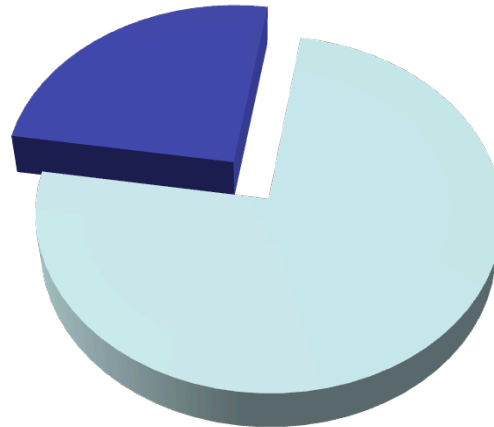


- Merger and acquisition advisor to middle-market specialty materials and precision engineering companies
 - Strategic planning and value development services
 - Market analysis and market entry planning
 - Approximately 50% of our assignments are in the medical device supply chain
 - Buy-side
 - Sell-side
 - www.manningadvisors.com for more information
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The Medical Device Industry



2015 Global Medical Device/Diagnostic Equipment Market



■ Manning 30 ■ All Others

- Total market = US\$345 billion in 2015, up 4% over 2014
- The Manning 30
 - 30 largest global device and diagnostic equipment companies
 - All have sales over \$2 billion and pushing \$3 billion
 - 75% of 2014 medical device and capital diagnostic equipment market



Four Key Trends for OEMs in 2016

- Integration of major acquisitions
- Focus on growth markets
- Embracing accountable care with new products and services
- Rationalization of manufacturing continues



Acquisition Moves To Integration

- **Top 30 were buying each other from 2013 and 2015**
 - Always purchased smaller firms for growth and still do

 - A wave of large company acquisitions
 - Medtronic-Covidien
 - Becton Dickinson-CareFusion
 - Zimmer-Biomet
 - S&N-ArthroCare
 - Pfizer-Hospira

 - Drivers:
 - Coverage and penetration of growth markets
 - By geography
 - By medical specialty → Moving to clearly defined dominance
 - Product pipelines
 - Low interest rates

 - **For 2016 the focus is execution**
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OEM Integration and Execution

- Acquirers are focused on successful integration of their purchases
 - Large promises made and to be kept
 - Great risks associated with premiums paid

- Key metrics of acquisition
 - Example - Medtronic has promised \$875 million in savings by 2017

- Pressure to execute is on non-acquiring peers as the acquirers improve their market share and performance
 - Danaher, Bard, Boston Scientific, Baxter all mention their focus in 2016 is execution of existing plans

- For the supply chain
 - OEMs are digesting
 - Adjust to new geography of market leaders
 - Likely a two to three year hiatus from the commercial earthquakes of past two years



Growth Markets

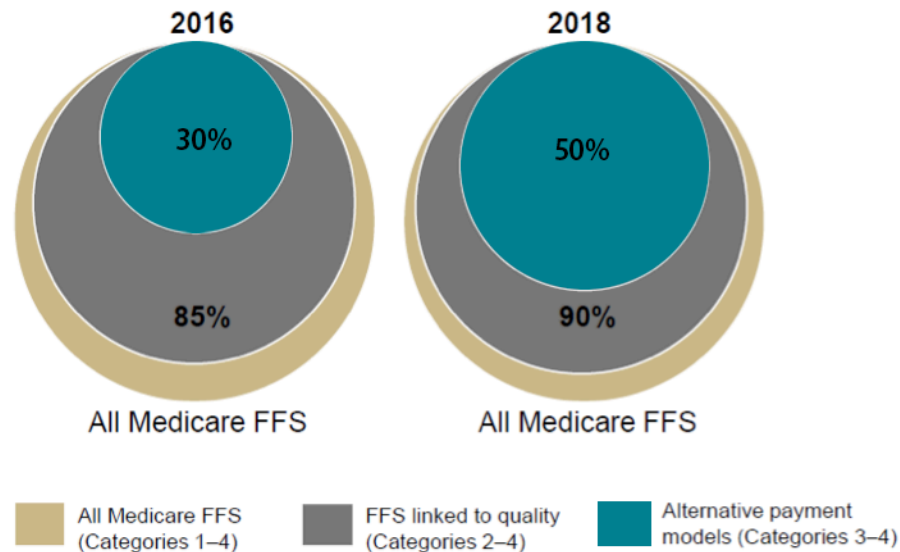
Region	Growth Rate	2014 % of Market
US/Canada	4-6%	40%
W. Europe/Japan/AUS	4-6%	29%
Growth Markets	8-18%	29%
Global	5-8%	100%

- OEM sales focus moving to growth markets
 - China and India, in particular
 - Other Asian and Latin American markets
 - Smaller growth markets in Poland, Turkey, Persian Gulf
- Different products for different markets
 - Emerging market focus on expanding healthcare, particularly infrastructure
 - Limited emerging market demand for developed country products
 - Development of “value” and “underserved” products for emerging countries vs. “premium” products in developed markets
 - Most manufacture is local for local consumption
- For the North American supply chain
 - Some opportunity on premium product exports as OEMs stress sales for affluent private-pay patients
 - Few opportunities without presence in growth economies

Accountable Care Expands



Medicare fee-for-service (FFS) payment models



Source: Centers for Medicare & Medicaid Services

- Medicare trending away from fee-for-service
- 90% Category 2-4 by 2018 → Quality of Care based reimbursement
- Drives rest of US healthcare reimbursement model



OEMs Embrace Accountable Care

- OEMs are tailoring their products to fee for value instead of fee for service

 - Selling on the basis of:
 - Lower overall costs of treatment
 - Superior patient results

 - Creation of care systems – families of products intended for use together

 - The result is a smaller number of winning OEMs in the operating room
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Examples of New, Quality of Care Products



- St. Jude CardioMEMS for advanced warning of heart failure
- Cardinal Health congestive heart failure system
- Medtronic Operating Room Management Services



St. Jude CardioMEMs HF System



- Internal wireless sensor detects rise in vascular pressure, an early warning sign of heart failure
- New standard of care
 - Warns healthcare team in advance of need to change medications
 - Automated alerts to providers, pharmacy, and patient
 - Saves an average of \$10,640 in hospitalization costs over three years vs. traditional methods
 - Medicare approved due to superior results

Cardinal Health CHF Program



- Cardinal Health is both a device company and large distributor of other OEMs products
- Studied “Top 50” hospitals for congestive heart failure (CHF)
- Found Tufts Medical Center’s combination of products and procedures:
 - Reduced hospital stay time, cut costs \$33K per case
 - Reduced Rx costs \$25K per case
 - Survival rates over national average
 - Would save 8,000 lives and \$1.3 billion per year if adopted on a national basis
- Cardinal Health promotes the Tufts results to the medical profession
- Not surprisingly, Tufts uses Cardinal Health products for CHF treatment

Medtronic ORMS



- Medtronic ORMS = Operating Room Management Services
- Core from 2014 acquisition of NGC, an Italian operating room and cath lab management company
- Medtronic currently has contracts for \$140 million annually, *exclusive of MITG products used in the facility*
- The company projects service revenue of \$650 million by FY2020
- Moving beyond cath labs to hospital-wide consulting



Outsourcing in Full Swing

- Every major OEM continues to outsource
 - Few new manufacturing facilities in developed countries
 - OEM cost of goods is steady to down over last five years
 - Every aspect of device design, approval, manufacture, and distribution process has been successfully outsourced

 - Target numbers emerging
 - OEMs will consider outsourcing if they see a 10-30% savings
 - Translates to 3 to 5 gross margin points for the OEM

 - For the supply chain - Expect growth
 - Estimated 12% global growth rate in outsourcing
 - Likely around 6-8% in United States
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Summary

- Medical device industry is growing steadily
 - Mega-mergers have created fewer, larger players who are concentrating on integrating their acquisitions
 - Sales focus shifting to growth markets
 - New products being sold on results, creating fewer winners
 - Likely rewards care systems rather than an individual device
 - Early sign of OEMs using product and services to dominate hospital departments
 - OEMs taking on the burden of demonstrating superior outcomes
 - Outsourcing will continue
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The Supply Chain





Supplier Consolidation Underway

- We are in the era of the \$100 million plus CM
 - Primarily created by acquisitions
 - Greatbatch – Lake Region/Accellent
 - Tecomet – Symmetry ortho assets, et. al.
 - Freudenberg Medical – Medventure, VistaMed, Cambus, Hemoteq
 - Creganna – Precision Wire
 - Cadence – Plainfield Precision (three units)
 - Why buy? It fits the preferred supplier profile
 - Broad portfolio of manufacturing and logistics capabilities
 - Financial size is equated with stability
 - Can afford quality systems
 - Less business for also-rans
 - In the “charmed circle” or not
 - Don’t have to be over \$100 million but it helps
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Critical Factors for Success as a Preferred CM from the OEM Perspective



- The “Show Me” Requirements
 - Show me your company will be there five years from now
 - Show me I have less quality risk than any other source, including internal manufacture
 - Show me you can make the product for less than internal costs

 - Prefer “One Neck To Choke” but the dream is not yet a common reality
 - Single point of communication, service, and responsibility for as much of the supply chain as possible
 - Many CMs still working out the details of consistent delivery, not used to managing so many activities
 - The reality of a single supplier is still not up to the promise but seems to be improving – weak execution

 - Have a Unique Selling Proposition (USP)
 - No USP permits an uneducated buyer to define you
 - Having one challenges competitors
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Is Device Design Necessary?

- No...but alliances may be wise
- CMs that can design generally win production on over 80% of projects
- Design is often self-limiting to specific classes of devices.
Critical to synch design skills and manufacturing capabilities

Proactive Planning Necessary for Preferred Status



- If accept
 - Most devices can be 100% outsourced and
 - The “Show Me” criteria hold true

- It is critical for the CM to focus ahead of the customer
 - Program management is essential for success
 - Ongoing expansion of service spectrum, cost management initiatives, and quality requirements

- Live in the future
 - Challenging in a largely reactive manufacturing setting
 - Primarily demonstrated risk reduction



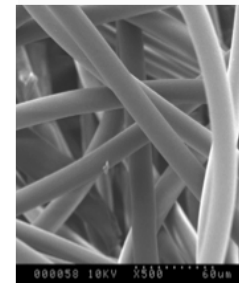
New Manufacturing Opportunities

- Electronics and informatics
 - Accountable care requires massive data collection
 - Wiring of hospitals, operating rooms, and devices
 - Creating opportunities for non-traditional CMs
 - Google working with J&J on data analysis for OR products
 - Oracle focused on hospital/device integration
 - OEMs will seek CMs with relevant experience
- Powered devices
 - On the rise as they deliver consistent results
 - Requires specialized design/manufacturing/assembly capabilities
 - Watch for smaller electronics CMs to press in on this trend
- Union of biologics and devices
 - Accelerating trend due to superior outcomes
 - Handling biologics a big step for most supply chain companies
 - Very profitable
- Personalized medicine?
 - The promise of additive manufacturing
 - Compelling economics? The jury is out

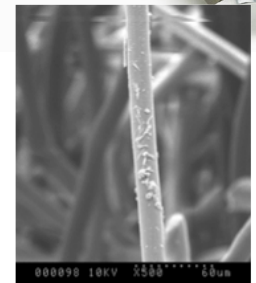


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