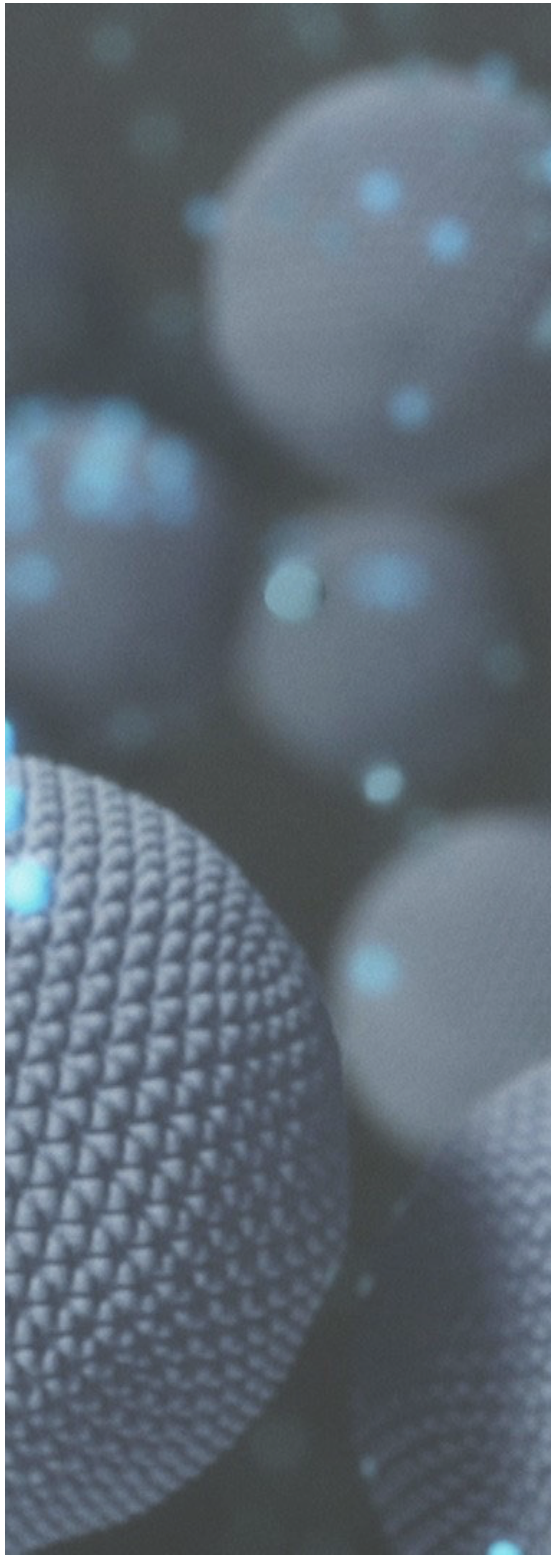


2018 GLOBAL TRENDS

Medical Device and Diagnostic OEM Strategy, Implications for the Supply Chain

February, 2018

A.S. Freeman Advisors, LLC

Merger and Acquisition, Advisory, and Financial Services

ABOUT A. S. FREEMAN ADVISORS

- Merger and acquisition advisor to middle-market specialty materials and precision engineering companies
- Broad experience in advising the medical device supply chain
- Strategic planning and value development services
- Market analysis and market entry planning
- Offering buy- and sell-side services
- Visit **www.asfreeman.com** for more information

EXECUTIVE SUMMARY

MEDICAL DEVICE OEM TRENDS

- $378 billion 2017 global OEM medical device revenues = 6.8% growth over 2016
- Large OEMs more focused on therapeutic areas which they can dominate, less on serving as general suppliers
- Value-based reimbursements (VBR) driving OEMs to combine products, networking, analytics, and facilities management into an outcome-oriented ecosystem
- New products increasingly digitally capable, networked, and located outside traditional therapeutic settings

EXECUTIVE SUMMARY

MEDICAL DEVICE SUPPLY CHAIN TRENDS

- Size and Growth - 2017 medical device supply chain revenues estimated $38 billion, growing at 10 to 11%
- Consolidation - Eight full-service contract manufacturers (CM) with revenues over $500 million represent $12 billion combined medical device supply chain revenues, just under one third of total
- Digitization - Seven of these eight CMs have their origins in electronics contract manufacturing, well-suited to manufacture digital devices and systems
- Strategy - Regardless of size, a contract manufacturer can compete if they execute in four critical areas
  - Nimble response to accelerate OEM revenue recognition
  - Greater specialized knowledge in some aspect of the device to distinguish CM from large number of capable competitors
  - First-time right quality now a necessity for winning business, not a luxury
  - Expanded supply chain offering to lessen OEM use of competing CMs

PURPOSE OF THIS PRESENTATION

ANNUAL REVIEW OF MED DEVICE TRENDS

Objectives:

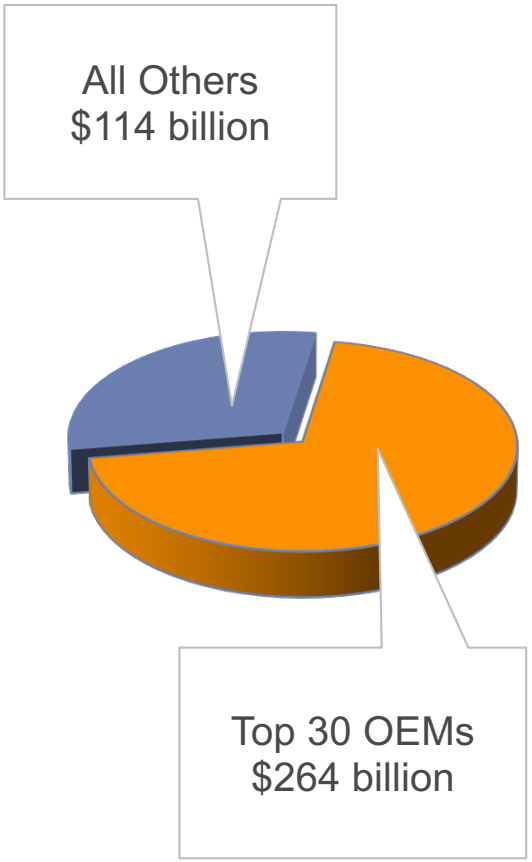
- Identify drivers of medical OEM marketplace and OEM product strategies
- Link OEM trends to impact on contract manufacturers

Main Sources:

- Public OEM presentations to the analyst community
- SEC filings
- News reports
- Third-party analysis

Past yearly reports available on request

2017 Med Device Market
Est. $378 billion



2017 GLOBAL MEDICAL DEVICE/ DIAGNOSTIC EQUIPMENT MARKET

- Total market = Estimated US$378 billion in 2017, up $25 billion over $353 billion in 2016 [1.]
- The ASFA 30
  - 30 largest global device and diagnostic equipment companies
  - All companies on the list have sales over $2 billion
  - The ASFA 30 control 70% of the global medical device and capital diagnostic equipment markets
  - 6.8% YOY revenue gain from 2016

[1.] Please see Appendix 1 of this presentation, The ASFA Top 30, for detail.

GROWTH DRIVERS

2017: A YEAR OF STRONG GROWTH FOR THE MED DEVICE INDUSTRY

4-5%

Organic Growth

Averaged for the top 30 OEMs

1%+

Acquisition Activity

$273B across all device OEMS since 2012

1%

Currency Fluctuations

just under 1% of growth

Acquisition a significant component of Top 30 growth

2017 INDUSTRY VECTORS

DRIVERS

Favorable Demographics

- Aging populations in developed countries
    - Continuing trend for next 20 to 30 years
- Expanding healthcare in developing countries
    - Healthcare services reaching new demographics
    - Focus on infrastructure spending for next ten years at minimum

Developing vs. Developed Nations

- Sub-5% organic growth in North America, Europe
    - Slower growth but higher profitability than developing countries
- Developing countries are stated OEM target for long-term growth
    - 2.5X plus growth rate in China vs. US

2017 INDUSTRY VECTORS

DRAGS

Provider, insurer consolidation pressuring OEM pricing

- Wave of hospital consolidations
  - Average 70 mergers per year in the US since 2001 -- almost 100 in 2016
  - 58% of US hospitals belong to hospital systems
  - End of the independent hospital, rise of hospital chain
  - Fewer points of sale = more sophisticated buyers
- Physician practice consolidation
  - In 2013 only 36% of US physicians were independent
  - Corporatization
  - Practices increasingly linked to hospital chains = fewer, more sophisticated buyers

Value-Based Reimbursements (VBR) becoming well-established

- Over 50% of US hospitals now accept VBR payments
- 30% of payers will be covered by Accountable Care Organizations (ACOs) by 2019
- VBR both a challenge and opportunity for device OEMs

STRATEGIC DRIVERS

FIND AND CEMENT STRATEGIES

- OEMs are shedding non-core units, picking battles they can win
  - Medtronic divests patient care supplies business to Cardinal Health
  - JNJ divests Codman Neurosurgery
  - Abbott divests eye care unit to JNJ
  - JNJ in process of divesting diabetes units
- Looking for hospital/department domination
  - BD acquired CR Bard → High-value surgical business
  - Abbott acquired St. Jude → Extension in high-value cardiac business

PRODUCT DRIVERS

NEW PRODUCT STRATEGIES EMERGING

Bundled Payments as part of VBR driving better results, new devices

Moving the treatment cycle forward to avoid costly critical care

Relocating care (and devices) to new settings

Rise of digital products

Rise of services to sell devices

BUNDLED PAYMENTS

WHAT ARE BUNDLED PAYMENTS?

- A single payment for all services/all providers regardless of outcome, a form of VBR
- Any complications or readmissions covered by the healthcare provider
- Economic argument for quality care: good outcomes can generate higher profits for providers
- Bundled payments based on the concept that good quality costs systemically less than poor quality

Omar Ishrak, CEO of Medtronic on VBR

- Fee-for-service leads to ever-escalating costs, as there is no accountability for results, only for activity
- A change is necessary before *"Healthcare becomes unaffordable"*
- Medtronic welcomes a VBR world as a chance to dominate certain market niches

BUNDLED PAYMENTS:
Low and high tech opportunities for device companies

CR BARD (BD) ADVANCE™

2013 estimated $9.8B/year cost for hospital acquired infections (HAIs)

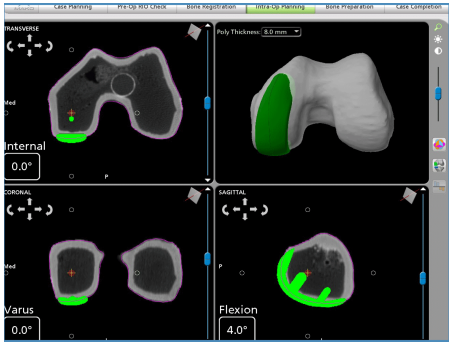
Approximately $1B from urinary catheter HAIs

Repackaging of existing devices leads to better outcomes

- A sterilized Foley catheter kit rather than gathering several components from supply cabinets
- All components in a single sterile package with less risk of contamination than combining several items from multiple locations
- No new technology, just a different approach

Takeaway: A new approach can be more effective than a new device

BUNDLED PAYMENTS: A HIGH TECH APPROACH



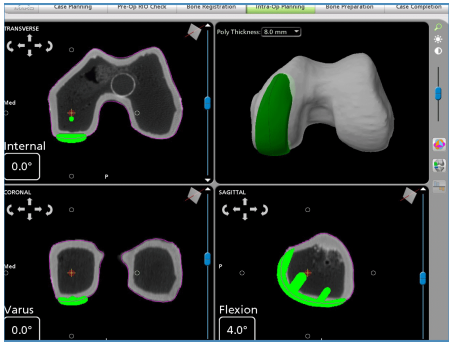
STRYKER MAKO SURGICAL ROBOT

Research on robotic knee surgery:

- Faster healing with fewer complications
- Shorter hospital stays
- Quicker return to normal functioning
- Fewer readmissions with $14,958 savings per readmission on partial knee surgeries

Mako only accepts Stryker joint replacements for full knee replacements

BUNDLED PAYMENTS: A HIGH TECH APPROACH



STRYKER MAKO SURGICAL ROBOT

Competition from Smith & Nephew Navio robot

- Fewer features but $500K robot cost vs. $1M for Mako
- Accepts joint replacements products from companies other than Smith & Nephew

TAKEAWAY: New products can improve care and reduce costs

MOVING TREATMENT FORWARD TO SAVE MONEY

Less expensive to treat disease in early stages

- Modern medicine has been "brilliantly reactive" to acute health crises, less focused on disease prevention or early detection
- Insufficient incentives under fee-for-service to concentrate on avoiding disease
- VBR: compelling economics to keep patients as healthy as possible for as long as possible

TAKEAWAY: Early diagnosis and early treatments products are filling OEM new product pipelines

MOVING TREATMENT FORWARD

ADAPTEC SENSICA UO

Measures fluid output in real time, tracking trends. Replaces haphazard manual charting

Provides early warning of kidney failure, e.g., in trauma patients

Kidney failure:

- Potentially fatal
- Leads to treatment complications
- Expensive to treat
- Results in longer hospital stays

TAKEAWAY: Treatment team can move proactively with the right data

MOVING CARE FROM TRADITIONAL SETTINGS

CARE IS MOVING FROM HOSPITALS

In the US, fewer hospital beds and shorter stays:

- American hospital beds, per capita, down 29% since 1994
- Average length of hospital stay down 18% in same period

TAKEAWAYS:

- Healthcare moving to less costly surgical centers, physicians' offices, storefront clinics, drugstores, and patient homes
- Wave of new products designed for home/retail/office use

MOVING CARE FROM TRADITIONAL SETTINGS

3M INTELLIGENT CONTROL INHALER

History of drug inhalers

- 1956 first mechanical inhaler
- 1993 first breath controlled inhaler
- 2016 “smart inhaler”
  - Reminds patient to take medicine
  - Always delivers correct dosage, regardless of breath
  - Records results, shares with patient and providers via phone or tablet
  - Primary application: asthma medication

MOVING CARE FROM TRADITIONAL SETTINGS

Scope of asthma problem in US:

- Average hospital stay of 3.6 days for 439,000 hospitalizations/yr
- 1.8 million ER visits per year
- 14.2 million physician visits
- Estimated cost of over $50 billion per year in direct and indirect costs for asthma care

Most common cause of asthma ER visits is failure to take medication regularly and properly

TAKEAWAY: Moves monitoring of medication use from doctor's office to home

PRODUCTS BECOMING DIGITAL AND CONNECTED

OEMs have recognized the power and market desirability of analytics to secure their position with healthcare providers

Alliances from outside the device industry, such as:

- Medtronic/IBM Watson for diabetes treatment
- JNJ/Google for robotic surgery

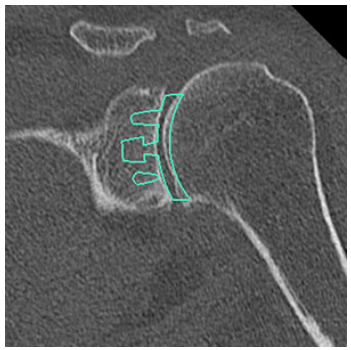
Formerly stand-alone medical devices becoming components of connected medical systems

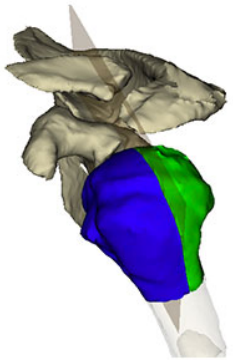
Digital networking of devices becoming necessary for marketplace success

OEMs with particularly notable digital product suites

- Medtronic
- Abbott
- Boston Scientific
- Siemens Healthineers
- Phillips Healthcare
- GE Healthcare
- Fresenius

PRODUCT BECOMING DIGITAL AND CONNECTED





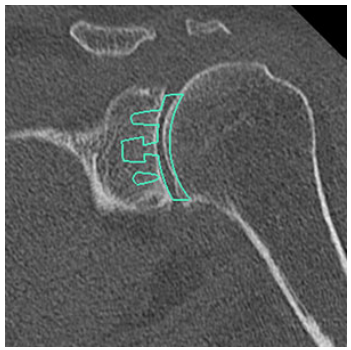
WRIGHT MEDICAL'S PACKAGING OF BLUEPRINT™ PLANNING SOFTWARE AND AEQUALIS PERFORM+™ SHOULDER SYSTEM

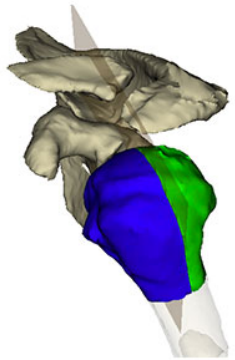
Not just products – a treatment system:

- BLUEPRINT surgical planning software
- Communications software to the OR
- Positioning and navigation functions for shoulder surgeries
- Wright Tornier Aequalis shoulders and instruments

A digital infrastructure in support of a surgical procedure

PRODUCT BECOMING DIGITAL AND CONNECTED





A surgeon can:

- Pre-plan and do a dry run of the surgery on a computer screen in their office, complete with 3D visualization
- Transmit the procedure plan to the OR and other members of the surgical team
- Use the plan to properly align instruments and implants during the surgery

Results:

- Superior alignment
- Better placement in bone
- Fewer complications and readmissions

TAKEWAY: Competitive advantage over traditional shoulder surgery products -- offering products in a connected system yields superior results

THE RISE OF DEVICE/ SERVICES ALLIANCES

OEM systems may include more than devices and data:

- Mix of product, services, expanded training, and analytics
- System integration and analytic analysis services (see above)
- OEMs with facilities management services:
  - **Medtronic**
  - **Fresenius**

THE RISE OF DEVICE/ SERVICES ALLIANCES

Medtronic Integrated Health Solutions services

- Managed cardiac catheterization labs (CLMS)
- Managed ORs (ORMS)
- Services from Medtronic, rather than just products

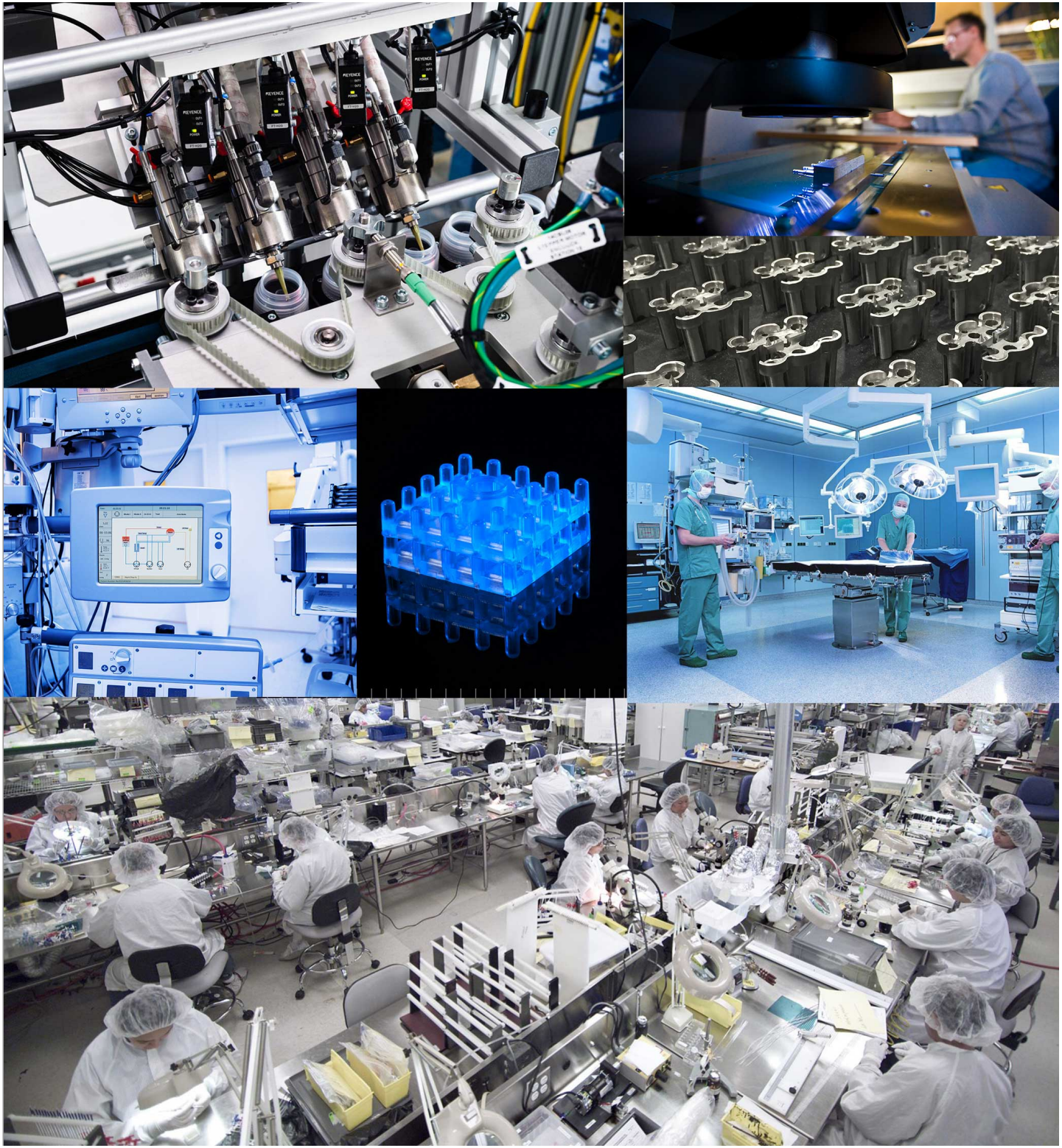
Medtronic now has over $1 billion in contracts at over 100 hospitals

Offers range of services and systems

Many contracts include guaranteed procedure costs to the hospital, including costs of Medtronic product

TAKEAWAY: Ensures Medtronic product a "place at the table" in any facility using their managed services

THE SUPPLY CHAIN



OUTSOURCED MANUFACTURING OF MEDICAL DEVICES IN 2017

HOW SIGNIFICANT WAS OUTSOURCED MANUFACTURING OF MEDICAL DEVICES IN 2017?

No single source to quantify outsourcing

- Different analysts use different sets of data
- Estimates run from $35 to $46 billion

A.S. Freeman Advisors estimated all OEM COGS in 2017:

- The average COGS for large device OEMs is 37% of revenues
- $378 billion in global device revenues x 37% = $140 billion COGS

~27% of device manufacturing is outsourced to the supply chain

- $140 billion x 27% = $38 billion of medical devices outsourced

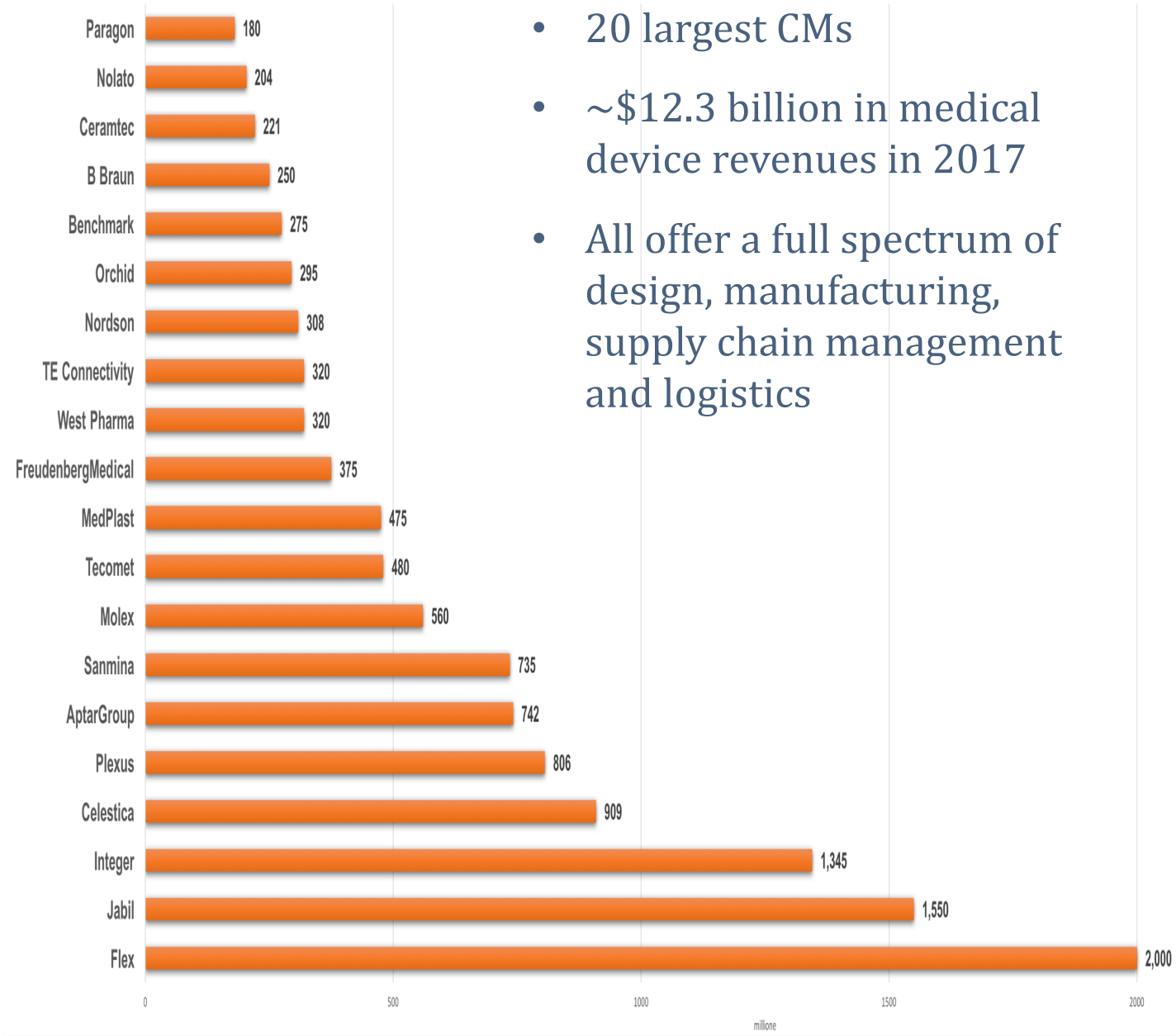
OUTSOURCING GROWTH RATE

Again, no single source of authoritative data

Estimates run from 9% to 13.5% per year through 2021

- Outsourcing more common in Asia than other regions
- Large skew created by electronic devices as few OEMs assemble their electronic products
- Soft projection: 10-11% annual growth for the next four years

WHO IS SUCCEEDING AMONG OUTSOURCERS?



Millions

- 20 largest CMs
- ~$12.3 billion in medical device revenues in 2017
- All offer a full spectrum of design, manufacturing, supply chain management and logistics

Source: PMCF

CONTINUING RISE OF THE GORILLAS

Eight of the largest 20 CMs have revenues over $500 million

- These CMs have positioned themselves to supplant the rollups of the last decade as the dominant players in outsourced medical manufacturing

Principal advantage: supply chain mastery

- Ability to source globally for best combination of price and quality
- Committed to serving the customer without necessarily manufacturing devices or components in own facilities
- Demonstrated success in managing complete product line outsourcing

FLEX MEDICAL

$2 billion subsidiary of Flex (formerly Flextronics), a leading global contract manufacturer

Sketch-to-Scale™ motto, reinforced by acquisition of Farm for medical device design

Flex Medical: 85% penetration of top med device OEMs and 144 total customers

Deep digital device expertise

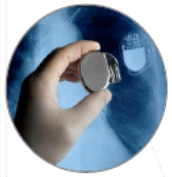
Flex Medical three areas of focus:

- Medical devices including MIS instruments
- Drug delivery systems
- Digital health

FLEX MEDICAL 2017 PRODUCT AREAS

Medical Solutions and Technology Portfolio

2017

Blood Glucose Meter 	Disposables 	Diagnostics 				
Drug Delivery devices 	Implantables 	Patient mobility 	Infusion sets 	Surgical Instruments 		
Software solutions 	CGM 	Ophthalmology 	Imaging 	Orthopedics 	Digital health 	Combination drug delivery 

flex

SUCCESS: FOUR CRITICAL FACTORS

Can smaller CMs compete with Flex and other global CMs?

Four keys must be combined:

- Nimbleness in response. OEMs will redesign much of product suite to meet VBR and digital system requirements. They cannot afford delays in revenue recognition; capability of accelerating market introduction is vital
- Greater specialized knowledge or engineering expertise to differentiate the CM from the large number of capable competitors
- First-time right quality. OEMs increasingly intolerant of quality escapes that complicate product introductions and increase costs
- Expanded supply chain capabilities. No need to match global CMs, but must be capable of providing complete devices or lines (exception: specialization in a high-value component niche)

The ASFA30

Rank		2016	2017E
1	Medtronic	$29.00	$28.88
2	Johnson & Johnson	24.90	26.16
3	GE Healthcare	17.59	18.29
4	Siemens Healthineers	15.20	16.37
5	Cardinal Health	12.40	14.80
6	Abbott	7.71	13.73
7	Phillips Health Tech	12.40	12.40
8	Becton Dickinson	12.45	12.23
9	Stryker	11.30	11.96
10	Baxter	10.16	10.38
11	Boston Scientific	8.40	8.85
12	Danaher	7.80	8.36
13	Essilor	7.50	7.70
14	Zimmer Biomet	7.68	7.66
15	B. Braun	6.80	7.30
16	Alcon/Novartis	5.80	5.95
17	3M Healthcare	5.53	5.79
18	Olympus	5.07	5.30
19	Terumo	4.49	5.01
20	Smith & Nephew	4.67	4.65
21	CR Bard/BD	3.71	3.88
22	Dentsply Sirona	3.75	3.87
23	Fresenius	3.40	3.76
24	Edwards Lifesciences	2.96	3.40
25	Getinge	3.65	3.37
26	Hologic	2.83	3.06
27	Hoya	2.81	3.04
28	Intuitive	2.70	2.98
29	Varian	2.62	2.67
30	Paul Hartmann Group	2.07	2.46
		$247.36	$264.25
	Total Market	**$353.37**	**$377.50**
	All $ in billions . Reported in US dollars.		

CONTACT

For more information or for a customized presentation

Please contact:

Tony Freeman
President
A. S. Freeman Advisors, LLC

www.asfreeman.com
(917) 868-0772

tfreeman@asfreeman.com