Disruptive Change

Medical Devices: Equipped for the Future?

Disruption is inevitable in the medical devices industry. With $34 billion at stake over the next five years, established players need to urgently revise their business models.
We live in fast-moving times. Foundations can erode overnight. Long-standing borders fall and new ones emerge, seemingly permanent relationships are thrown into turmoil, well-entrenched value-creating strategies are suddenly upended, and value chains are broken up and reconfigured in ways few had imagined. The result is that established industries can change and disappear, and household names can fail and die. Such is disruption. It can happen quickly, and the medical device industry is next in line.

Encouraging but Difficult Future

Historically, the medical device industry has been highly attractive, with 5 percent average annual growth and operating margins between 23 and 25 percent.\(^1\) Price-to-earnings ratios in the sector have typically outperformed those of the Standard & Poor’s 500 index. The industry has been relatively stable for decades. As a consequence, established players have been able to compete successfully across the device spectrum, applying common business models and processes without much need for differentiation.

The future, however, is very different—disruptive change is underway. While markets will grow, operating margins may decline by 8 points between now and 2020, as unit prices erode (see figure 1). Companies will no longer be able to earn premium margins by simply selling clinical

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\(^1\) Growth figures refer to 2005–2012. Operating margins are representative of six large-cap medical device manufacturers.
features and new devices into established market spaces. Rather, they will need to look at new segments and, particularly, new end-to-end solutions to secure additional revenue and maintain margins. Furthermore, the commercial model will change, as call points and contract decisions become centralized and purchases are increasingly predicated on comparative value and evidence of efficacy.

The value of maintaining revenue growth and avoiding the forecasted operating margin decline caused by industry disruptors is enormous. We believe that if companies take appropriate measures, revenue could continue to grow between 2 and 4 percent annually through 2020, and the operating margin decline could be offset. This would result in an additional operating profit of $24 billion across the medical device industry. Together with additional cash potential of $10 billion from working capital reductions, we estimate the cash value generation potential for the industry to be $34 billion by 2020.

Medical device manufacturers will have to look at new segments and end-to-end solutions to maintain margins.

Five Primary Disruptors That Will Transform the Industry

In early 2014, A.T. Kearney interviewed more than 30 global industry executives from 20 of the world’s leading medical device manufacturers. Together, these companies represent $80 billion in revenues and cover all main sectors, geographies, and company sizes. We asked these executives about their opinion on industry dynamics and disruptive forces, particularly in the physician-preferred segment—that is, products where the clinician has a vital influence on purchasing decisions.

These interviews, coupled with our own experience and research, have led us to identify five major disruptors that are forcing unattractive economics on companies pursuing the traditional industry business model (see figure 2).

Figure 2
Disruptive forces shaping the medical device industry

Source: 2014 A.T. Kearney Medical Device Disruptors Study
1. Power shift to payers and providers

As developed societies age and increasing numbers of people demand access to better healthcare, payers and providers are seeking to stretch their dollars further while maintaining clinical outcomes. For a long time, physician preferences were largely accepted and determined both the treatment to administer and the equipment to purchase. Increasingly, that is no longer the case. Evidence-based care is edging out clinician preferences as the decisive factor. Today, many payers and providers are evaluating medical devices statistically on the basis of their safety and procedural efficacy—and increasingly in terms of cost and value too.

In the United States, orthopedic practice—a specialty historically dominated by individual power and surgeon choice—has been progressively restructured over the past several years. As of 2013, more than 50 percent of orthopedic surgeons were employed within a healthcare system rather than operating independently (compared to around 25 percent in 2000). There are cases where orthopedic reps are being hired directly by hospitals and care systems as full-time or contract employees. Increasingly, Americans are being covered by accountable care organizations (ACOs), which bring together doctors, hospitals, and other healthcare providers to offer better-coordinated, lower-cost care. Moreover, hospital consolidation continues, with 20 percent of hospitals having been involved in M&A activity in the past five years, creating large providers and umbrella networks that coordinate care pathways and establish central functions to closely monitor costs. Under this new dynamic, provider executives or group purchasing organizations guide or mandate many purchasing decisions across the value chain, or at least constrain choices based on cost and preferred supplier lists. While physicians’ preferences still matter, their freedom to choose can no longer be taken for granted; many executives interviewed indicated that pressure for price reductions has increased notably over the past few years.

Evidence-based care is edging out doctors’ preference as a key buying factor.

A similar picture exists in Europe, where healthcare systems are seeing acute budgetary pressure and are also moving in the direction of scale. In France, procurement of public hospital equipment by tender has become the standard, with decentralized regional health agencies (ARS) monitoring high capital expenditures and making decisions based on local needs. In Germany, healthcare spending restrictions have altered purchasing behaviors; now, rather than investing in new equipment, many hospitals lease or retain older equipment and actively favor the most cost-effective medical products. In Italy, complex hospital tenders have become the most frequently used route of purchasing, and award criteria are based either on the best price or the best economic impact. In the United Kingdom, local and regional hospital consolidation has rapidly led to the emergence of purchasing organizations, with umbrella bodies such as National Institute for Health and Care Excellence (NICE) recently broadening its focus to include technology assessments for medical devices (and associated clinical practices), employing cost effectiveness definitions that many believe do not yet fully represent the wider value that some devices bring to patients, the system, and society.

2. Heightened regulatory scrutiny

Every year, device recalls hit the headlines, and in recent years they have been high profile and damaging. Regulators have responded by dramatically tightening existing regulations and inspections, and by adding new ones. For example, in the United States there have been a number of recent developments (see figure 3):

- In 2011, the U.S. Food and Drug Administration (FDA) created a class IIb categorization with higher approval hurdles (covering clinical and manufacturing data), and suggested modifying the 510(k) process.
- In 2013, a new standard took effect forcing companies to conduct a deeper assessment of device risk and safety.
- Unique Device Identifier (UDI) requirements and regulations were first outlined in 2007 to ensure greater transparency on device functionality and adverse events. The final rule book was published in 2013.

Compliance monitoring has followed: FDA audits have increased by 40 percent in the past 12 months, and the number of warning letters has risen by 24 percent over the past two years, with a commensurate increase in the overhead associated with compliance. As one CEO we interviewed put it: “The FDA is in one of its extreme cycles. But, as it also drives transparency of outcomes—unlike before—it’s very likely to stay that way.”

Figure 3
Overview of U.S. regulatory changes

2007
FDA Amendments Act significantly increases agency authority
Congress orders FDA to create UDI system

2011
Class IIb is created, involving a more stringent approval process to claim “substantially equivalent” designation (requires clinical and manufacturing data)
FDA issues implementation plan to increase predictability and efficiency of 510(k) process by improving guidance document development, enhancing reviewer training, and leveraging external expert scientists

2013
New standard forces companies to assess risk and safety of products through categorization
Final UDI rules are published, and compliance timelines are extended
Medical device excise tax is imposed

2008 2009

2010
510(k) process is revised to require better research and statistics, more complete dossiers, and stricter QSR compliance

2012
FDASIA: MDUFMA is changed to include better performance goals, audit of review process, and additional FDA resources to reduce time to approval
Establishment registration requirements change
FDA announces electronic filing requirement for medical device registration submissions

2014
Data system requirements are relaxed

Note: FDA is the U.S. Food and Drug Administration, UDI is unique device identifier, QSR is quality systems regulation, FDASIA is FDA Safety and Innovation Act and MDUFMA is Medical Device User Fee and Modernization Act.

Sources: U.S. Food and Drug Administration; A.T. Kearney analysis
In the European Union, medical devices are licensed in all EU member countries on receipt of CE mark approval. The new 2007/47/EC Medical Device Directive, to be implemented this year, creates mandatory compliance, defines increased transparency requirements, and demands more clinical data to prove the safety and efficacy of medical products before CE mark approval is granted. It also adds a mandatory post-marketing surveillance system that manufacturers must follow—and that they must document before they receive the CE mark. Outsourced design and manufacturing regulations are also targeted by the directive; manufacturers now retain the responsibility for quality compliance and cannot outsource their risk.

Although the U.S. FDA and the European Medicines Agency (EMA) regulate the two largest markets (and 75 percent of global revenues), other market regulatory schemes also remain tight. Most developing countries are adopting their own laws to regulate market access for manufacturers. It is no longer sufficient to simply obtain FDA or EMA approvals. Manufacturers have to deal with new local regulatory laws, which in some cases are even more stringent than those of the FDA or EMA.

**With $34 billion at stake by 2020, executives should be urgently evaluating the capabilities and resources they need.**

Overall, these measures are increasing manufacturers’ costs, constraining product designs, and prolonging regulatory approval times, making it more difficult to recoup investments. An industry executive bluntly told us, “Whereas before we could launch an extension product within six months, now it takes two years and costs 10 times as much.” And although there have been previous cycles of enhanced regulatory scrutiny, this time there is little expectation that a more lenient system will reemerge in the future. Regulatory and quality functions are moving from being a major “cost of doing business” to becoming a source of competitive differentiation for companies that can do it better and faster.

### 3. Unclear sources of innovation

The innovation pipeline is fractured, and it seems unlikely to be repaired. In 2013 U.S. pre-market approval submissions (that is, applications to register new devices) continued to decline, a trend seen consistently over the past decade—during which time the number of applications dropped by more than 30 percent. Over the same period, submissions for changes affecting the safety or effectiveness of already approved devices increased by a yearly average of 10 percent, indicating a systemic shift in the focus of innovation from new therapy areas to line extensions and increments.

Our interviews make clear that these trends are partly related to the increasingly burdensome regulatory landscape. For example, while new products based on incremental changes to mature devices find easy access to existing reimbursement codes in both the United States and Europe, truly innovative products that affect the way standardized procedures are conducted and increase treatment costs are only reluctantly included on the positive list of reimbursable products. Today, for a novel product to be considered, healthcare payers demand proof of its
superiority over established therapies, including clinical evidence of the technology’s medical benefits and formal evaluations of health economics. And although a device can receive market authorization without being included on positive lists, reimbursement has become increasingly crucial to achieve volume sales in the EU.

This difficult situation is aggravated by the dearth of new growth areas offering alternative clinical therapies. Although there are some niche treatment areas that constitute an exception to this rule, products in most established therapy areas (such as prosthetics, cardiology, ophthalmology, and audiology) already effectively meet patients’ and clinicians’ needs. Therefore, the search for genuinely new therapies requires a wide net of ideas and deep pockets for research and approval, with the reward for success being high compliance overheads and long times to market.

Consequently, the value generated by each dollar of R&D spend has decreased by 35 percent, from $39 in 2005 to $25 in 2012. Well-capitalized companies sitting on cash can choose whether (or how much) to invest in developing innovative new products, or they can pursue product extensions by snapping up the smaller players responsible for much of the innovation in the medical devices space. A senior vice president of R&D at one large manufacturer confessed, “Historically, we’ve never had to be good at R&D, because we just bought the next generation of products.” This model, however, is also becoming compromised, as start-ups’ access to venture capital has fallen sharply: in the United States, the medical device industry accounted for 15 percent of venture capital investments in 2009, declining to just 10 percent in 2012 and 7 percent in 2013. Although the investment environment for larger companies and transactions has rebounded in 2014, access to start-up and seed funding continues to be a major obstacle and remains in decline.

Smaller companies are further compromised in the United States by new medical device taxes that are levied on revenues rather than profit, which limits cash flows and creates disincentives to reinvest.

4. New healthcare delivery models

As health needs evolve, payers’ resource constraints intensify, and powerful analytical tools make it easier to evaluate large volumes of data, patient pathways are being modified to obtain better outcomes for less money. Increasingly, the emphasis is to shift care out of hospitals and onto cheaper platforms. Many procedures and follow-up examinations that were once routinely performed at specialized facilities are now done at an ambulatory center, at a primary-care physician’s office, or even at the patient’s home (see figure 4 on page 7). Nurse practitioners, pharmacists, therapists, and social workers are all playing a greater role across the patient pathway, supported by technology such as enhanced data and remote access and monitoring tools.

These changes affect healthcare providers and patients, as well as device manufacturers, who will need to devise new delivery models. Not only will they need to direct products to new physical locations for use by different groups of healthcare practitioners, they will also need to offer more complete, bundled, end-to-end solutions and services that go beyond the medical device itself.

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3 Forty-five percent of applications for innovative devices in the United States over the past decade were divided among more than 900 companies, illustrating the traditional sector model of innovation by small companies.
Operating in this new environment is likely to require a whole new set of capabilities, from product design and manufacturing to marketing, sales, distribution, service bundling, partnership management, and analytics.

**5. Need to serve lower socioeconomic classes**

Between 2008 and 2013, the medical device market grew by an annual average of 10 percent in Asia—including the mature Japanese market—and 9 percent in Africa and Latin America. This has led many observers to conclude that the future of the medical device industry is to be found not in traditional, developed markets but rather in the developing world.

But the evidence indicates otherwise: although North America and Europe posted lower growth rates of 5 and 2 percent respectively, they still dominate the world market, commanding 75 percent of revenue. Furthermore, given the spotlight on emerging markets, it was striking how many of the executives we interviewed were unsure about what they had gained from investments in these markets, sometimes over extended periods. They consistently described the difficulty of selling products with a “Western” cost profile and the challenges of operating under very different business models. The conclusion is apparent: success will be generated in traditional markets.

Companies seeking growth will need to focus less on broad geographies and pay more attention to targeting specific population pools and growth segments. Just as the true growth opportunity in emerging economies is the mass market, so the second-tier hospitals—in the developed West and around the world—are attracting much of society’s healthcare investment. For example, the U.S. Affordable Care Act (ACA) is focused on providing access to sociodemographic groups that
have been traditionally underserved. Indeed, examining the healthcare expenditure of U.S. states with the lowest per-capita income, and using conservative estimates of ACA-driven uplifts in access and expenditure, we calculate that there is at least a 10 percent latent growth potential in the U.S. medical device market alone.

The chief executive at a large European device manufacturer told us categorically that traditional markets, not emerging markets, will continue to drive the business agenda. However, accessing growth segments, even in traditional markets, will require new business models, lower price points, and more value-based product offerings than those of today.

Impacts and Responses

Unfortunately for established players in the medical device industry, the five disruptors outlined above are all becoming acute at the same time and are manifesting themselves in combination. Figure 5 illustrates just how dire the situation is and how it affects many of the largest sectors.

Yet even within sectors, each company faces a different set of headwinds, depending on where it competes and the specific environment in which it operates. When we interviewed direct competitors, we found that while the macro-factors held true across companies, individual experiences and prioritization depended on factors such as market geography, product life cycles, and go-to-market strategies.

The most effective strategies are therefore likely to be company specific. Today’s relatively undifferentiated business models will need to transform into ones that are far more distinctive and proprietary. As with other industries (such as consumer packaged goods) that underwent
forced business model divergence, there are already clear examples and signs of a changing, differentiated approach in the medical devices field, as seen in figure 6.

These examples, built from our client experience and published accounts, are far from exhaustive. However, several themes are starting to emerge in companies’ responses to disruptors, posing strategic questions for other executives:

- Should the business be reconfigured to target profit streams from a broader section of the value chain, and how might that help maximize margin and the performance of the core business?
- Will companies require partnerships to provide these broader solutions to the marketplace, and if so, how will they identify where and with whom to partner and how will they effectively manage and govern those relationships?
- What is the value of IT and analytics, where can advanced solutions be applied, and how can overheads be balanced by superior returns?
- Is it feasible to target ownership of all aspects of a therapy line or patient pathway, and if so, how can this be done and what unique economic value would it provide both for the company and its customers?

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**Figure 6**

**Differentiated approaches in medical devices**

<table>
<thead>
<tr>
<th><strong>Emerging business models</strong></th>
<th><strong>Competitive strategy</strong></th>
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<tbody>
<tr>
<td>Portfolio of full-service operating and diagnostic suites, encompassing devices, personnel,</td>
<td>Profit from broader value chain</td>
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<tr>
<td>infrastructure, and training</td>
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<tr>
<td>Mobile health, providing telemetry and remote monitoring to link hospitals to patients and</td>
<td>Orchestration and partnering</td>
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<tr>
<td>ambulances</td>
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<tr>
<td>First approvals for combined drug and diagnostic therapies, based on personalized medicine</td>
<td>Analytics and evidence</td>
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<tr>
<td>and advanced data analytics</td>
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<tr>
<td>Core portfolio of low-cost devices (similar to generics), after ruthlessly stripping out</td>
<td>Therapy line ownership</td>
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<tr>
<td>waste in overhead and operations</td>
<td></td>
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<tr>
<td>Partnering for last-mile delivery, sterilization, reverse and hospital inbound logistics,</td>
<td>Cost and service leadership</td>
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<tr>
<td>and workflow management</td>
<td></td>
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<tr>
<td>Investment in advanced robotic surgical manipulation devices, as a complement to orthopedic</td>
<td>Services bundled with products</td>
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<tr>
<td>instrumentation and implants</td>
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<tr>
<td>Upstream-integrated hospital groups, absorbing sales channels and developing regional</td>
<td>New distribution models</td>
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<tr>
<td>supply chain distribution</td>
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<tr>
<td>Incubator model, with open innovation, dedicated seed funding, and proximity to academic</td>
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<tr>
<td>centers of excellence</td>
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<tr>
<td>Online heavyweights investing in a medical device marketplace based on broad choice and</td>
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<td>service differentiation</td>
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Source: A.T. Kearney analysis
What aspects of the current business model create the least value, and how could they be eliminated?

What service and product combinations can increase system value without diluting margins, and how can those services be bundled and effectively offered?

What does the “war in the distribution channel” mean for the business? Would it be advisable to increase, mitigate, or exit the fulfillment business?

These new themes, strategies, and dynamics will be accompanied by a change in focus of M&A activity.

Several of the emerging business models cited in figure 6 have involved acquisitions, with the targets being service companies rather than small, innovative device firms.

We anticipate a polarization of the M&A market. There will be an increased number of large-scale acquisitions, as companies seek to expand rapidly into adjacent sectors and services and attain the scale needed to offset the expense of future innovations and investments. At the other end of the spectrum, seed investments, incubators, and open innovation will lead to equity holdings, multiple smaller acquisitions, and the need for business model integration at a much earlier stage of a company’s life cycle.

Transactions will increasingly have a geographic rationale, as companies seek to access new markets through acquisitions—and as they examine how and where they should locate their central operations to realize optimal margins.

The question for executive teams is therefore how they can navigate the disruptors and define their unique path, recognizing that the industry is starting to change focus already and the industry leaders of the future are now defining how and where they expect to compete. While the solutions will differ, everyone in this sector should be pondering the following questions:

1. **Which combination of disruptors will create the biggest challenges to the current operating model?**

At a minimum, executive teams across the sector should be actively considering the impact of each one of the five disruptors, and questioning how well their current operations are dealing with them. In the past 12 months, we have seen several leading companies organize executive off-site events specifically for this purpose.

2. **What distinctive strategies can be adopted not only to offset these disruptors, but to compete more effectively and to capture more value?**

Executives should then ask themselves how and where they can capture more value from their operations, and how they should change the way they compete to respond to specific challenges—for example by addressing strategic questions such as those listed above. The answers to these and other questions will define the targeted, distinctive approach of the future.

3. **Are the company’s internal resources fit for this purpose, what capabilities are needed, and how will this influence the approach?**

In leading companies, we have found that with such a new focus, there are often complete gaps in capability. In some of the examples in figure 6, the move into services has required setting up (or acquiring) a completely new function.
4. How can the company adapt its business model and build the resources and capabilities aligned to the distinctive way it will compete in the future?

Even as leaders are starting to define and deploy new, distinctive strategies, their overall business model has not yet been aligned to recent developments. In fact, in most cases, the new revenue streams coexist with those of the traditional model, creating complexity, governance issues, conflicts around profit sharing, and excessive overhead. In the future, changes to the operating model—including the cultural change required to embed the new approach—must inevitably follow to maximize advantage. This remains an unmet challenge, even for those companies leading the way.

Conclusions

While the future contours of the medical device industry remain to be defined, radical change is inevitable, and the companies that embrace it will both shape the industry and profit from their efforts. With $34 billion of additional cash at stake by 2020, executives should urgently be evaluating the impact of disruptors and using this information to determine what capabilities and resources they will need to build a distinctive business model that will enable them to compete in the future.

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