Pulse of the industry

Medical technology report 2012

Ernst & Young

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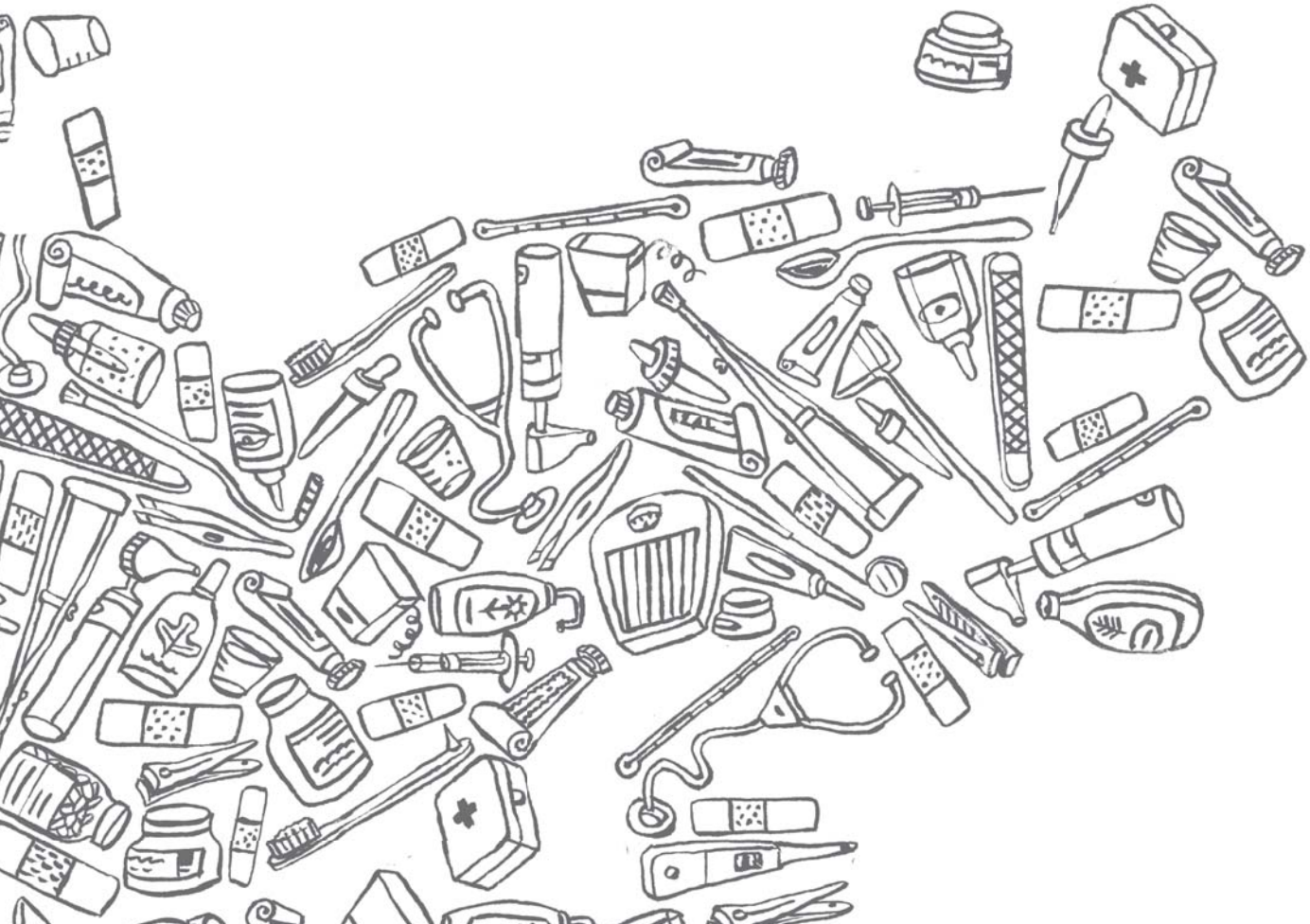

To our clients and friends

Welcome to the 2012 issue of *Pulse of the industry*, Ernst & Young's fifth annual report on the state of the medical technology industry.

Over the last couple of years, we have written about medtech's "new normal," an environment in which funding constraints, pricing pressures, comparative effectiveness research and other trends have put innovation under unprecedented strain. But many of these developments are merely manifestations of a larger trend: the need to make health care costs sustainable and the concomitant realignment of incentives around health outcomes. A range of patient-empowering, information-leveraging technologies (PI technologies) — which are blurring the lines between medical devices/diagnostics and health IT — have the potential to make health care delivery vastly more efficient and disrupt much of the medtech industry in the process. Our point of view article, "Power to the patients," examines these technologies — smartphone apps, social media, sensor-embedded smart devices and more — and discusses how established medtech will embrace business model innovation to respond.

As always, *Pulse of the industry* is rich with data on key industry metrics — financial and stock market performance, financing, and mergers and acquisitions. But like the industry we cover, our report is also being transformed. Much of the data and analysis is now moving to our new medtech data website, www.ey.com/medtechdata, where readers can find our latest analysis of industry trends.

We hope you find the new format useful, and we look forward to continuing the conversation with you.

— Ernst & Young, Global Life Science Center

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Power to the patients

In July 2012, the US Food and Drug Administration (FDA) granted marketing approval for an ingestible sensor that, when incorporated into a pill, allows users to track data on drug adherence and other key health indicators over time. Fittingly, this first-in-class technology was approved under new FDA provisions for low-risk devices that have no predicate on the market — the culmination of a four-year collaboration between regulators and the company behind the new technology, California-based Proteus Digital Health.

A few weeks later, another California-based start-up launched an iPhone app that uses the phone's front-facing camera to calculate a user's heart rate. The Cardiio app — the world's first heart-rate monitor that requires no physical connection to the human body — pulls off this feat by detecting tiny variations in the light reflected off a user's face every time his/her heart pumps blood to it. Studies have shown that Cardiio's technology is accurate to within three beats per minute. But the app does more than report a single number — it allows users to track and analyze variations in their heart rates over time, view weekly and monthly averages and more.

Meanwhile, researchers at Texas Tech University are developing a product that can predict when a person might fall — sometimes days in advance. The wearable device — which is packed with sensors that track movement patterns over time and look for significant changes in a person's gait and posture — could be a breakthrough for preventing adverse medical events in elderly patients with Parkinson's disease, epilepsy or dementia.

These are just a few examples that made news while we were writing this year's *Pulse of the industry* report. They are by no means isolated instances. Indeed, we hear about new technologies such as these several times a week. But, in a medtech industry that has a long history of iterative and incremental innovation, it is important to emphasize that these products are not merely the latest iterations of existing medical devices. Instead, they represent an entirely new class of technologies that has the potential to reinvent health care — and disrupt much of the traditional medical technology industry in the process.

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So far, health information technology (health IT) and medical devices and diagnostics (MD&D) have existed as two distinct, well-defined domains. Health IT — the use of information technology to improve health care — has largely been about electronic health records, which have typically resided only on computers in hospitals and clinics. MD&D, on the other hand, has referred to products that are regulated as Class I, II or III devices by the FDA — the universe of technologies we define as the "medtech industry" in our *Pulse of the industry* reports. Now, as Jessica Hamelin, Senior Director of Corporate Strategy at Covidien, puts it, "we are seeing a convergence that's blurring the lines between health IT and MD&D."

These disruptive new products encompass a wide spectrum of technologies and platforms, including smartphone apps, social media platforms, sensor-embedded smart devices and more. Despite their variety, however, these technologies are distinguished from traditional health IT and MD&D by two essential characteristics: they are **patient-empowering** and **information-leveraging**. In recognition of these defining attributes, we refer to them as PI technologies.

Patient-empowering. Health IT applications and data have traditionally been restricted to providers. And while some medical devices and diagnostics have been marketed directly to patients, many more have instead been aimed at providers, giving patients little say in choosing, calibrating or analyzing data from these products.

PI technologies are fundamentally different. They are aimed at, and designed for, patients. To an unprecedented degree, patients have control over these products. They are frequently on platforms that patients already use, such as smartphones and tablets. The data that these products produce is typically accessible to patients (indeed, patients increasingly expect this of their medical technologies), and it is patients who decide which providers and caregivers they will share the data with. In aggregate, these shifts give patients more control over managing and monitoring their health.

Information-leveraging. What does "information-leveraging" mean? After all, many devices (and certainly all diagnostics) have generated information well before the advent of PI technologies.

To be truly information-leveraging, however, a technology needs to do two things. First, this is not just about information but about information *technology* — i.e., PI technologies

produce data in electronic form, which makes it easier to analyze trends and combine data sets. Second, to truly leverage information, these technologies don't just report a single data point, but enable the *tracking and analyzing of data over time*.

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A key question is who has access to the information being tracked by these devices. At the very least, information-leveraging technologies provide data and analysis to medtech companies and/or physicians. The next level beyond this is liberating data from institutional silos — making it interoperable and unleashing the power of big data. Any of these options are sufficient for a technology to be information-leveraging. But for it to be a true PI technology, it is also critical that the information is leveraged by *patients*.

Accompanying this shift to PI technologies — something Eric Dishman, Intel's Global Director of Health Innovation, has termed "the consumerization of medical devices" — is a parallel shift in which all sorts of ordinary day-to-day objects are becoming sensor-embedded and assisting people in managing their health. This move — which Dishman calls "the medicalization of consumer devices" — is visible in everything from wirelessly connected, data-tracking weighing scales to running shoes that keep track of users' exercise data to sensor-embedded carpets that can detect when a senior citizen has fallen and can alert caregivers.

Outcomes and behavior: a changing business

PI technologies are not just innovations directed at the tech-savvy crowd. They have widespread revolutionary potential for the simple reason that they could provide answers to some of the biggest challenges facing health care and the medtech industry.

Over the last few years, our *Pulse of the industry* reports have explored many of the difficulties medtech companies are grappling with. We have written about the "new normal" facing medtech and the unprecedented strain this environment has placed on innovation. Restrictive capital markets have made it more challenging for many US and European companies to raise funds. Firms face new obstacles in selling to providers — their traditional customer base — because of sweeping changes in the US provider care market. Hospitals are merging, independent doctors are shuttering their practices and becoming employees of hospital systems, and cost-conscious hospitals are limiting doctors' flexibility to choose different brands in many medical device categories. The industry fears that a looming excise tax on the sale of medical devices in the US — scheduled to go into effect in January 2013 — will heighten the pressure on margins, since companies may be unable to pass the tax on to hospitals in the current market environment. Companies are concerned about changes on the reimbursement front, such as a move to comparative effectiveness research in the US and increasingly challenging health technology assessments (HTAs) in European countries. There are uncertainties in the regulatory process as well, such as the prospect of restrictions to the US 510(k) process that could increase the cost and risk of getting products approved and potential changes on the European front that could make it more challenging for companies to pursue Europe-first approval strategies.

These are valid concerns, but it is worth keeping in mind that many of these developments are merely indicators of a much larger transformation — the need to make health care costs sustainable and the concomitant move to an outcomes-based health ecosystem. For instance, the US excise tax did not appear in a vacuum — it is part of the Patient Protection and Affordable Care Act, the Obama Administration's effort to expand access and put health costs on a sustainable trajectory. Pricing pressures stemming from payers' efforts to rein in costs are similarly driving the wave of hospital consolidation. And comparative effectiveness research and HTAs are merely manifestations of the move to an outcomes-based system, in which incentives will increasingly be realigned to reward demonstrable improvements in health outcomes. Over time, medtech companies — like everyone else in health care — will increasingly find themselves in the outcomes business.

The move to an outcomes-focused ecosystem will involve a changing customer base. While the primary customer for many medical technologies has historically been the physician, medtech firms will now need to focus on understanding and serving a more diverse set of customers. **Payers** will become increasingly important, since they create economic incentives — giving them the power to determine how outcomes are measured and rewards are allocated. The world of **providers**, as already discussed, is becoming more complex, with medtech companies having to navigate an

increasingly complex maze of HTAs and consolidated purchasing functions. And, of course outcomes will ultimately depend on **patients** and patient behavior.

To succeed in the outcomes business, companies will also need to succeed in the business of behavioral change.

Indeed, to succeed in the outcomes business, companies will also need to succeed in the business of behavioral change. The main reason for this is that chronic diseases are now the biggest driver of health costs — accounting for 75% of costs in the US alone. With aging populations across several of the biggest health care markets (the US, Europe, Japan and China) — as well as rising middle classes and changing lifestyles in large markets such as China and India — the chronic disease burden is only expected to escalate over time. Add to this the fact that diet, exercise, smoking, drinking and stress management behaviors are big drivers of chronic diseases and it becomes evident that behavioral change will be increasingly critical for bringing costs under control.

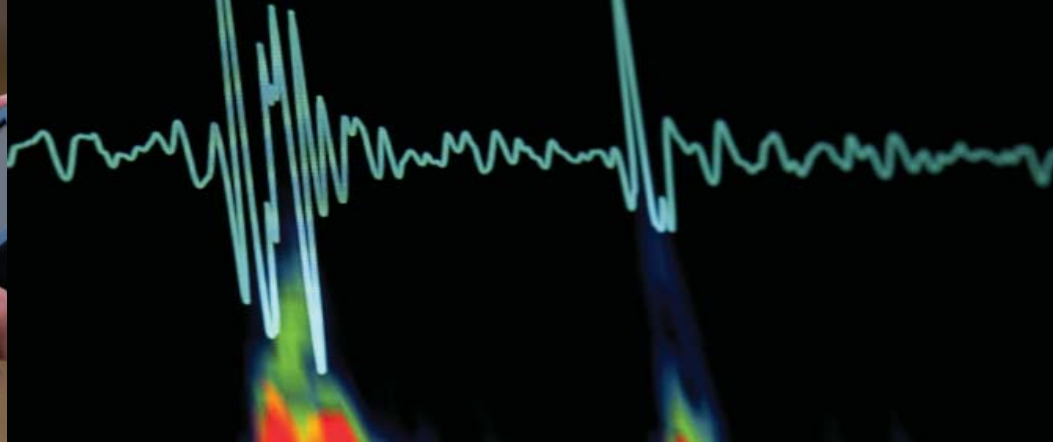
But producing behavioral change is a surprisingly difficult task. "Convenient, easy-to-use blood-pressure kiosks have been in drugstores and supermarkets for decades, but few people use them regularly," says Darrell Johnson, Vice President, CRDM Marketing at Medtronic. "The American Heart Association's Simple 7 guidelines clearly lay out the behaviors we need to change for heart health — but few people follow them, because we all want to live for today. The billion-dollar challenge in health care is figuring out how to motivate people to make good choices every single day."

Indeed, decades of educational programs have made little progress in getting people to adopt healthier lifestyles. There is hope, though, because the field of behavioral economics is now providing valuable insights about the key behavioral biases behind our suboptimal decisions. For instance, we tend to excessively discount future events (a bias referred to as "hyperbolic time discounting"), causing us to undervalue the significant future gain from exercising compared to the relatively minor inconvenience of going to the gym today. Another source of irrational behaviors is our tendency to be completely different people in "cold states" (the rational, logical mind frame in which we make a New Year's resolution to eat healthy) and "hot states" (the emotional, impulsive state in which we get tempted by an unhealthy desert).

In health care, such biases lead to two key behavioral gaps — and the good news is that PI technologies can play a key role in filling both of them:

1. Processing information. The first challenge in improving health behaviors is related to processing information. In many areas, decisions related to health care are increasingly gray, with no one right answer. Consider, for instance, issues such as early screening for prostate and breast cancer, where the leading medical experts have reversed themselves more than once on what constitutes the standard of care. In areas such as these, the optimal course of action is heavily dependent on the relative risk associated with different outcomes (e.g., the probability of a certain side effect) and an individual's preferences related to those outcomes (how much disutility the person would experience from that side effect). Today, the individuals making those decisions are typically physicians and, not surprisingly, they often impose their own preferences in guiding patients.

As changing incentives give patients more ownership over, and responsibility for, managing their own health, it will become increasingly imperative to empower them to make optimal decisions. This will require educating patients (most of whom did not go to medical school) and presenting information in neutral ways. PI technologies could be very helpful here. For instance, mobile decision-support tools (e.g., on smartphones or tablets) could provide neutrally framed information and guide patients through difficult decisions by making the daunting math easier. Patients would input their preferences, and the decision-support tool could calculate the optimal course of action based on the conditional probabilities of different outcomes.



2. Changing lifestyles. The second big behavioral gap in health care is related to changing unhealthy lifestyles. Because of the behavioral biases that cause us to excessively undervalue future outcomes, research has consistently shown that incentives are most likely to change behaviors when they are tangible and immediate.

This is another area where PI technologies can play a critical role. Smartphone apps and wirelessly connected devices can provide the timely feedback that is vital for continually motivating healthy behaviors. They can monitor compliance with drug adherence and exercise regimens and provide a wide range of biometric information. And they can do all of this far more inexpensively and seamlessly than labor-intensive alternatives such as in-home nurses or in-person meetings.

It is not surprising that the behavioral change start-ups and pilots we have seen so far consistently use PI technologies, often in conjunction with mechanisms such as gamification, social media and contracts. For instance, when Dr. George Loewenstein and other leading behavioral economists achieved dramatic improvements in medication adherence through an ingenious behavioral-incentives pilot, they used a remotely connected smart pill dispenser called the Med-eMonitor to track compliance and dole out incentives. In 2011, a start-up called Gympact created a behavioral economics-savvy contract system that rewards users for exercising regularly – and tracks compliance with an app that uses the GPS sensors in users' smartphones to figure out how often they go to the gym. (To read more about these innovative models and for a deeper dive into behavioral economics, see Chapter 2 of *Progressions 2012*.)

The transformative potential of PI technologies

More generally, what makes PI technologies game-changing is the realization that combining the P and the I – empowering patients with relevant information and analysis – creates two huge breakthroughs:

PI technologies aren't just creating and analyzing data – more and more, they are doing so in real time.

1. Real-time insights. PI technologies aren't just creating and analyzing data – more and more, they are doing so in real time. This has several advantages. First and foremost, it provides patients with timely, actionable information to better manage their health. It's one thing for patients to get key health measurements every time they visit a doctor. It's another proposition entirely for them to be empowered with wearable or implanted sensors that can monitor vital signs and alert them (or their caregivers) when something is amiss.

But since real-time information is, by definition, generated continuously, it also has the potential to provide longitudinal analytical insights to patients and others. A stream of data, when captured and combined with other data streams, can allow users to identify correlations between health outcomes and changes in medication regimes, diet, exercise and more. We are already seeing early adopters – the "quantified-self" patients – experimenting with these capabilities. As more and more technologies – from medical devices to smartphones and everyday objects – become sensor-equipped and remotely connected, and as payers continue to change incentives to encourage patients to take more responsibility for their health, we can only expect the trend to gain traction.

Health care has traditionally been delivered in two venues: hospitals and doctors' offices. It is now moving to a third "place" – wherever the patient happens to be – and PI technologies are enabling the move. (For more on health care's move to the third place, refer to *Progressions 2012*.) As health care becomes ubiquitous and real-time, it becomes easier to manage diseases and conduct remote monitoring, telemedicine and prevention – developments that will be critical for bringing health costs under control.

Even as PI technologies empower patients to manage more of their own care, information-leveraging technologies will also help providers with diagnosis and care, thanks to increasingly sophisticated analytics, artificial intelligence capabilities and big data. IBM's Watson and the Archimedes system by Kaiser Permanente are harbingers of what we are likely to see.

2. Efficiencies. Historically, medtech has not been associated with lowering medical costs. To the contrary, it is often blamed (sometimes excessively so) for contributing to cost escalation. Certainly, some technologies (e.g., imaging) have been significant factors in health care costs, because of their high price tags and the fact that existing incentives can encourage overuse.

PI technologies have the potential to reverse this trend, for two reasons. First, they are a low-cost means of achieving huge efficiencies in the delivery of health care. Remote monitoring is much cheaper than the alternatives of hospital admissions or in-home nurses. Telemedicine or self-management by patients empowered with PI technologies costs the system much less than frequent visits to doctors' offices. Using social media and sensors to give patients feedback and monitor health behaviors is less expensive than labor-intensive, in-person alternatives.

But there is a second reason why PI technologies can drive huge cost efficiencies — one that is potentially much more disruptive for established incumbents. They do not just enable more efficient health care delivery. In many cases, they could also establish radically cheaper alternatives to existing technologies. PI technologies are textbook examples of what Clayton Christensen calls disruptive technologies. Over the last half century or so, we have seen numerous examples of such disruptive technologies, from transistor radios (which disrupted their vacuum tube-based predecessors) to personal computers (which disrupted mainframes and minicomputers) and the integrated video cameras in smartphones (which disrupted stand-alone camcorders). In each case, these disruptive technologies started off as novelties and niche products that did not initially provide the functionality of established technologies. But they improved and rapidly overtook existing technologies.

Christensen also contrasts disruptive innovation with sustaining innovation — incremental improvements that evolve existing technologies. This, of course, is how most innovation in IT and medtech occurs, and it typically doesn't lower costs. Instead, with sustaining innovation — whether in PCs or pacemakers — prices remain relatively steady, while customers get more features for their money. But every now and then, we see disruptive innovations, and these breakthroughs don't just offer more features for the same price — they often establish radically lower price points.

Achieving the potential

While PI technologies hold great promise for making health care more efficient, achieving this potential will involve some systemic changes.

In this article, we have focused primarily on the shift in power to patients, but as mentioned above, the move to an outcomes-based ecosystem also involves increasingly influential payers. Even as companies focus on understanding the drivers of patient behavior, they will need to focus on the needs of payers. As cost pressures continue to build, payers are likely to adopt incentives that are truly outcomes-focused — but they are not there yet. Today, many payment systems do not have clear ways of measuring and reimbursing the value produced by PI technologies, creating a challenge for companies in the short to medium term. Still, there may be opportunities for firms to explore innovative business model opportunities within the new, increasingly holistic approaches that payers are adopting, such as accountable care organizations. We'll explore this more closely in the section on business models.

There are also regulatory issues to be worked out, as PI technologies start to blur the distinction between consumer and medical devices. In the US, the FDA is looking at this area, particularly where PI products intersect with medical interventions.

Despite these evolving issues, the disruptive potential of PI technologies is significant because they can be radically cheaper and potentially very attractive at a time when the health care system needs tremendous gains in efficiency.

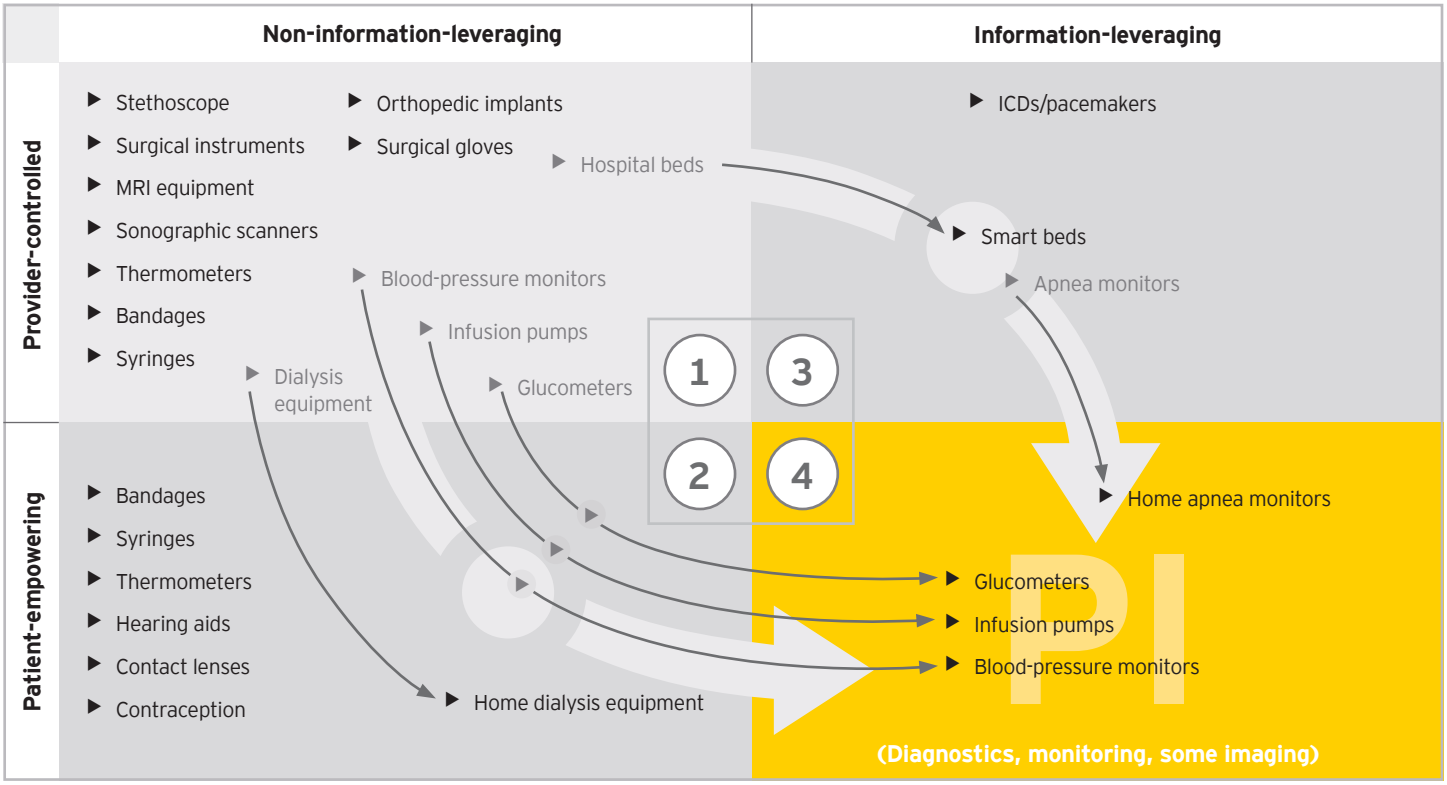
Charting the shift

The accompanying chart shows several existing technologies clustered along two dimensions: whether they are provider-controlled or patient-empowering (on the vertical axis) and the extent to which they are information-leveraging (on the horizontal axis).

Historically, the majority of medical technologies have not leveraged information. Some of these products have been targeted at patients (such as contact lenses and hearing aids — shown in Quadrant 2). Other products have been marketed to both patients and physicians (syringes, thermometers, bandages, etc.). But so far, the vast majority of medical technologies have been in Quadrant 1 — products that did not leverage information and were controlled by providers.

We are likely to see more and more products empowering patients and leveraging information.

The shift to patient-empowering, information-leveraging technologies



Source: Ernst & Young.

More and more products are migrating away from Quadrant 1. In some cases, products have started leveraging information even though they are still under the control of providers (e.g., smart beds, which are remaking the lowly hospital bed into a device that can generate and track all sorts of useful health data). In other cases, the initial move was to become more patient-empowering even though products still did not leverage information (e.g., traditional blood-pressure cuffs).

Over time, however, many of these products will end up squarely in Quadrant 4 – effectively becoming PI technologies. While the blood-pressure monitors that initially moved into patients' hands may not have been information-leveraging, the most recent iterations certainly are.

Indeed, entire classes of diagnostic equipment – from blood-pressure monitors to glucometers and the aforementioned Cardiio heart-rate monitor – are being reinvented in radically patient-friendly ways. Many of these technologies are minimally invasive, compatible with consumer technologies such as smartphones and tablets, and allow patients to track, analyze and learn from their own data.

Apnea monitors, for instance, have long been information-leveraging, but they were entirely controlled by providers. Now, sensor-embedded consumer devices such as the Zeo Sleep Manager allow patients to monitor their sleep every day. This gives apnea patients not only ownership over their data, but also more *useful* data – information that is generated in real-world conditions and provides a longitudinal panel from which to extract true insights into the behaviors and factors that exacerbate one's ailment.

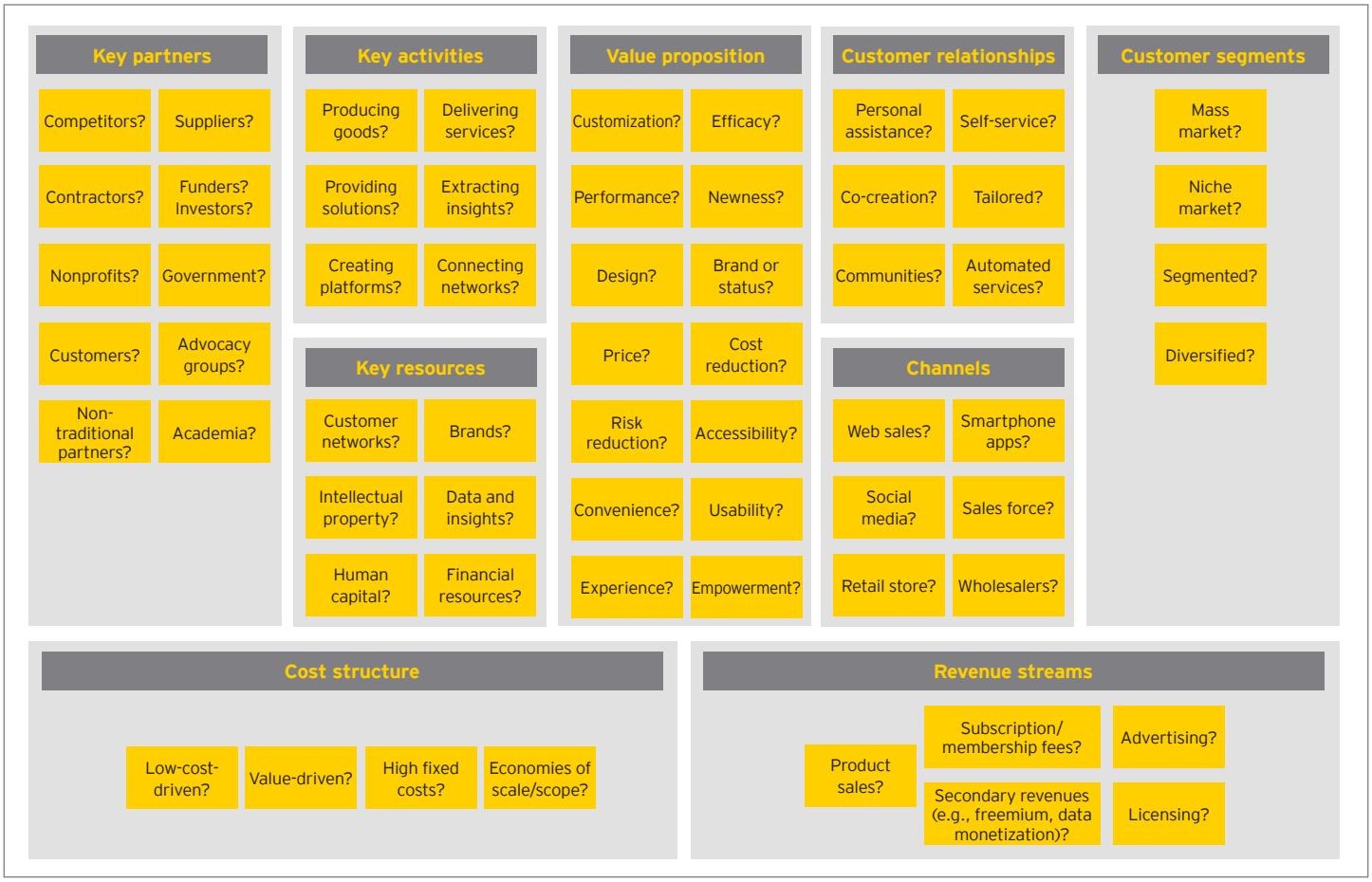
The movement is gaining steam. While many categories of products will likely always remain in hospitals or under the control of physicians, in other categories – diagnostics, monitoring equipment, even some types of imaging products – we are likely to see more and more products empowering patients and leveraging information. The shift is likely to be accelerated not just by the pace of technological innovation, but also by the huge challenges facing health care and the fact that PI technologies can play a critical role in addressing these challenges.

Implications for medtech companies: business model disruption

While not all segments of medtech will be impacted equally, the rise of PI technologies is a transformative force that will likely disrupt the existing business model in many product categories. The term "business model" is defined differently by individual academics and analysts, but a common thread through most of these definitions is that a company's business model is essentially the way in which it does three things: **creates value**, **delivers value** and **captures value**. But before a business model can create, deliver or capture value, it needs a clearly articulated **value proposition** – a new solution, a better way of delivering an existing solution, etc.

We often use the business model canvas, a framework developed by Alexander Osterwalder in his bestselling book, *Business Model Generation*. Osterwalder's canvas, as shown in the accompanying chart, uses a longer list of nine "basic building blocks." However, these are basically deeper enumerations of the key activities listed above. The three elements on the top left of the canvas articulate how a business model creates value (key activities it engages in, the key resources required and the key partners with which it collaborates). The three elements to the right (customer segments, channels and customer relationships) deal with how a business model delivers value. Lastly, the two elements along the bottom (cost structure and revenue streams) deal with how the model makes money, or extracts value.

Business model canvas



Source: Alexander Osterwalder and Yves Pigneur, Business Model Generation: A Handbook for Visionaries, Game Changers, and Challengers *(OSF, 2009).*

Medtech is certainly not the first industry to be disrupted by customer-empowering information technology. The same forces that are starting to rock medtech have buffeted scores of other industries before, and in each case, they have disrupted existing business models. Incumbents typically had to fundamentally revamp their businesses to survive — and many were unable to hold on despite their best efforts. For instance, when newspapers and magazines were disrupted by the Internet, their value propositions — which had always been based on authoritative information — changed, as increasingly empowered customers began looking for other attributes, such as instant access, tailored content and the "right" to information. The ways in which companies created value changed, as customers moved from passive recipients to co-creators armed with blogs, video journals and more. As other parts of the business model changed, incumbents found that the ways in which they had historically captured value — subscriptions and advertising — were no longer tenable in a world of liberated information and empowered customers. As a result, they are experimenting with a host of approaches to capture value differently, from paywalls to freemium models. Despite these changes, several long-standing publications have gone out of business and many others are still trying to find their way.

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This same process has repeated itself in numerous other industries, from the music business to retail trade. It is not far-fetched, therefore, to expect that the advent of PI technologies will have implications across the breadth of the medtech business model.

Value proposition. Historically, many medtech products have been developed for, and marketed to, providers. In the outcomes-focused world of PI technologies, however, the customer will increasingly be patients and the payers, and since these constituents value different attributes, there will invariably be implications for a medtech company's value proposition.

Traditionally, companies have competed on attributes such as cutting-edge features, often developed based on the feedback provided by physicians working in conjunction with embedded sales reps. In recent years, firms have already been revisiting their value propositions, as the provider market has become more challenging, thanks to hospital consolidation, stricter procurement rules and tougher HTAs. In this environment, companies have been sharpening their value propositions to differentiate their products and demonstrate how they are adding value.

As the customer base shifts increasingly to patients, firms will need to similarly focus on the features that matter to patients, many of whom will not be as literate on medical matters as health care providers. It will therefore be critical to develop offerings that are easy to understand and simple to use (e.g., through user-friendly design, education and instructions developed for laypersons). Patients will want products that are compatible with other consumer technologies and platforms. And, as already discussed, they will increasingly demand access to their data, making this a key competitive differentiator.

Since the shift to an outcomes-based ecosystem also involves increasingly influential payers, companies will need to understand the needs of these customers as well. This will involve understanding what sorts of evidence payers will find compelling and then designing offerings that can demonstrate improved outcomes and efficiencies.

These changes also have implications for where in the cycle of care companies position themselves. Historically, medtech products have focused on diagnosis and disease management. In the short to medium term, they are well positioned, because the growing chronic disease burden will inevitably lead to more activity in both of these areas. Over time, however, payers are likely to start paying more attention to prevention, since preventing these diseases through behavior modification is far cheaper than treating and managing them later. PI technologies can play a critical role in prevention, and companies may have opportunities to expand their value propositions in this direction.

Creating value. So far, medtech companies have created value by engineering, manufacturing and selling products. They have done this through a continuous process of iterative R&D, often developing the next generation of products by learning from providers and surgeons. But as health care moves to an outcomes-focused, behavior-driven ecosystem, medtech companies will create value not just by selling products, but also by demonstrably improving outcomes in cost-effective ways. This will frequently involve expanding

the offering to move beyond products to services and full-fledged solutions — for instance, in a particular therapeutic area or a defined population of patients. PI technologies will be integral in such outcomes-focused solutions, often in the context of collaborations with other entities (e.g., a collaboration between a payer, provider and medtech company that uses one or more PI technologies to improve drug compliance and disease management in a population of chronic disease patients).

Delivering value. Medtech companies have traditionally delivered value through their physician-oriented sales forces and marketing campaigns, with doctors often serving as co-creators. In the world of PI technologies, it will be important to focus not just on providers, but also on payers and patients. The key channels for reaching patients will be different, with more action gravitating toward mobile apps, social media, educational resources and other consumer platforms. Like physicians before them, patients and payers will often become co-creators (e.g., by providing feedback, ratings and input).

Earlier this year, Stryker launched a direct-to-patient marketing campaign for an artificial knee — a particularly remarkable development since these products have traditionally been marketed to the surgeons who implant them. After extensive market research, the company determined that the attribute that resonated most with patients was the product's round shape, which allowed greater range of motion than the oval-shaped implants sold by many rival firms. The company rebranded the product — which at the time was called the "Triathlon" knee in the US and the "Scorpio" in other countries — as the "Get Around Knee" to emphasize this selling point and created supporting materials online to educate patients. Stryker's shift may have been driven by an immediate concern — the need to reach out directly to patients at a time when surgeons have less flexibility to choose the brands they prefer — rather than by the longer-term shift to outcomes and PI technologies. But the company's approach may still be a harbinger of the patient-oriented education and marketing campaigns that will become increasingly common in a future of PI technologies.

Capturing value. The medtech business model has historically captured value through product sales. All of the value that companies produce has been embedded in the product, and companies have sought to capture more value by increasing their market share and establishing good prices for their products. In a world of PI technologies and outcomes-focused payers, however, value will increasingly flow to those who can improve health outcomes. As a result, demonstrating health outcomes — and data — will become increasingly critical.

Companies might therefore seek out revenue models that monetize data. They will need to contend, however, with patients' growing expectation to own their own data. This may not always be what established medtech companies have in mind. Indeed, medtech incumbents that are moving in the direction of leveraging information may be planning to own and tightly control the data generated by their products. But there is now a growing movement to "liberate data" across health care and medtech. The term was used pointedly by Todd Park, the United States Chief Technology Officer, in a talk at the TEDMED 2012 conference. Park discussed the innovative potential that could be unleashed by liberating vast amounts of data currently in government agencies and allowing the private sector to learn from it. Meanwhile, another TED talk, by a patient named Hugo Campos, has helped ignite a grassroots movement by patients to liberate the data produced by their medical devices. Campos, a heart patient who became frustrated when he was unable to get access to the data produced by his implantable cardioverter-defibrillator (ICD), founded the ICD User Group to advocate for patients' data rights.

This is not meant to imply that providers and others would be cut off from data produced by PI technologies. To the contrary, physicians and others will continue to have a key role in guiding patients, and insightful data will be an increasingly important part of their toolkit. But it is the patients who will own their data, and *patients* will decide who to share it with.

Companies can learn from other industries — financial services, retail trade, online games — where firms have built successful business models to monetize the value latent in customer data. It may be possible, for instance, to use such an approach if it gives patients some flexibility in selecting how their data is used and explicitly gives them additional capabilities or services in exchange for their data. It will also be critical to ensure that any such approaches have strong privacy and security safeguards — both to comply with regulations and because of patients' sensitivities around health data.

More broadly, medtech companies may also find opportunities in the changing world of payer incentives. For instance, as the US health care system experiments with new approaches such as accountable care organizations and patient-centered medical homes, there may be new ways of partnering to share risk and reward while using PI technologies to drive greater efficiencies in health care delivery.

The challenge of disrupting yourself

But if there are business-model opportunities in the move to PI technologies, there are also grounds for caution. The reality is that it is remarkably difficult for mature incumbent firms to disrupt their own business models — which is why, as we discussed earlier, many mature firms in industries such as retail trade and newspapers have been driven out of business by disruptive innovators.

The reality is that it is remarkably difficult for mature incumbent firms to disrupt their own business models.

In his work, Clayton Christensen has studied why this pattern repeats itself with unerring regularity. He argues that when disruptive innovations first appear, their capabilities pale in comparison to the established technologies already on the market. As a result, the new entrants are simply insufficient to meet the needs of existing customers. And since mature firms are focused on keeping their customer bases happy, they tend to initially dismiss the disruptive innovations as novelties or niches. But the new technologies are good enough to meet the needs of another set of customers — early adopters who do not need all the functionality of customers using the established technologies. And, of course, the disruptive technologies are able to rapidly improve their capabilities and soon overtake their established rivals — at which point, it is often too late for mature companies to catch up.

This pattern was certainly visible when the first personal computers emerged in the late 1970s and were initially rejected by veteran firms such as IBM because they were underwhelming machines with few practical applications. But PCs improved quickly, and Big Blue had to scramble to enter the market it had dismissed just a few years earlier. A similar story unfolded three decades later, when the first cell phone cameras emerged and were often viewed as gimmicks that did not come close to offering the image resolution or quality of stand-alone cameras. But within a few years, the quality of cell phone cameras improved and they have essentially driven stand-alone point-and-shoot cameras out of business.

Medtech may now be at a similar juncture. The devices and diagnostics that early adopters are purchasing on Apple's app store — often for as little as 99 cents — may seem like playthings compared to more serious and established medical devices. But, even if they cannot do everything that "grown up" medical devices can do, they are already offering good enough functionality to another set of customers. Consider, for instance, this excerpt from a blog post by Dr. Westby Fisher, a heart specialist whose patient downloaded the $1.99 Cardiograph app on her iPhone:

> "Was this a medical device? No, it was an iPhone app.
>
> Was it perfect? No, it wasn't. I certainly couldn't differentiate frequent PACs or PVCs from atrial fibrillation reliably. It was not an EKG, after all. But we were past that point in her evaluation. I just needed to know how often she was having her known paroxysmal atrial fibrillation and she wanted to keep a convenient record of her episodes.
>
> Was it helpful in this case? Absolutely."

PI technologies are already carving out niches for themselves with "quantified-self" patients and innovative health care providers. Today, the quality of their imaging or the accuracy of their measurements may not match those of more established technologies. But these capabilities could improve rapidly, at which point the disruptive power of PI technologies would truly be unleashed.

Medtech companies that choose to ignore these technologies do so at their own peril.

Medtech companies that choose to ignore these technologies do so at their own peril.

Guiding principles

In closing, here are five guiding principles for navigating the exciting new world of PI technologies:

1

You may not be immune. As we've said before, not every segment of medtech will be affected to the same degree by PI technologies. It may be hard to picture some products (e.g., surgical equipment) ever being controlled by patients. In other cases, one might not be able to imagine why certain products would need to become information-leveraging.

But just because we can't imagine it doesn't mean it won't happen. Indeed, when it comes to disruptive innovation — and especially when that innovation is driven by IT — history has a way of surprising us. Few of us might have thought that surgical gloves or sutures would become sensor-embedded, but researchers are now developing electronic sutures with temperature sensors and integrated heating mechanisms, as well as surgical gloves with sensors that could one day allow surgeons to identify the type of tissue they are touching and even ablate it without needing another instrument. It's not far-fetched to picture that joint replacements might similarly become rich with sensors, communicating information about wear and tear, helping patients analyze data and identifying correlations between levels of pain and different behaviors and movement patterns.

While some products will always be physician-controlled, the vast majority of technologies could at least become information-leveraging. The opportunity for medtech companies is to think about ways to move their technologies in the PI direction and figure out how they can enhance efficiency across the continuum of care.

Look for opportunities. How could your offerings empower patients or leverage information?

2

Be patient-centric and payer-savvy. Success in an outcomes-driven world means being patient-centric and payer-savvy. Medtech companies — which have a long history of engaging with physicians — will now need to build similarly deep relationships with patients and payers. This will require an understanding of how these customers' preferences are different from those of doctors and designing products accordingly. To succeed in the behavioral change business, companies will also need to understand what motivates patient behavior and design offerings best positioned to influence behavioral change and demonstrate value to payers.

More than ever, patients expect to be able to control the data generated by their medical technologies — and payers are going to gravitate toward patient-controlled data because of the potential for better prevention and disease management. Medtech companies will need to create business models that give patients more access to this data. With the right approach, patients can become more than passive recipients — they can be co-creators and force multipliers. But you have to engage with them first.

Your customer base is expanding. How are you empowering patients and engaging with payers?

3

Experiment with business models. Medtech companies are no strangers to innovation. Their entire business model is built on a ceaseless cycle of innovation. But it is now time to use those innovative strengths to revisit the business model itself. In a rapidly changing health ecosystem, business model innovation requires experimenting with multiple different approaches to figure out which ones work best. And, while product innovation has often involved acquiring start-ups with promising technologies, the increased uncertainty and diverse skills required in the new ecosystem may often require collaborating with non-traditional entrants (telecommunications firms, retailers, etc.). As companies seek to reach an increasingly diverse customer base on a growing proliferation of platforms, they will likely need not one business model, but many — the end point may well be a portfolio of business models that address the needs of different customer segments.

Innovation is moving beyond the product. How are you investing in new business models?

4

Show me the value — not the money. As they consider investments in disruptive business models, companies often start by asking the same questions they do when they evaluate investments in sustaining their traditional business models. Yet, as Clayton Christensen and others have pointed out, the financial metrics used to evaluate most business investments — discounted cash flow, net present value, earnings per share — can be "innovation killers" for disruptive-innovation experiments. Quite simply, the starting point should not be: "How much money will we make?" Instead, the first question to focus on is: "How can we change the value proposition for the customer?"

This is not to say that these business model investments do not have the potential to generate significant revenues and profits — just that those opportunities will only become clearer over time. Incentive systems may not be ideally aligned today, but as cost pressures continue to mount, payers will get there. For companies that fundamentally change the value proposition, there will be ways to monetize that value. But you have to create value first.

Focus on the right question. How are you creating value?

5

Be strategic — not defensive. In recent years, medtech leaders have been increasingly preoccupied with the challenges created by the "new normal" — sustaining innovation against a backdrop of funding challenges, regulatory reforms, looming tax hikes, sunshine laws, comparative effectiveness research and more. In a difficult business climate, this laser-like focus is understandable — even commendable.

But strong strategy is not just about playing defense against perceived threats — it's also about finding the opportunities hidden in those obstacles. The forces behind the challenges of the new normal — the need to make costs sustainable and the move to an outcomes-focused ecosystem — are also creating huge opportunities for innovative leaders in areas such as PI technologies.

At a time of growing cost pressures, the real opportunity is not in trying to hold back the tide, but in finding innovative solutions to address those pressures.

Like it or not, comparative effectiveness research is here to stay. The industry is determined to beat back a 2.3% excise tax — but even if it succeeds, the pricing pressures behind the tax are likely to resurface somewhere else. At a time of growing cost pressures, the real opportunity is not in trying to hold back the tide, but in finding innovative solutions to address those pressures.

One way or another, PI technologies are coming. Will you play defense or take the lead?

Five guiding principles for building PI business models

1. You may not be immune

Look for opportunities. How could your offerings empower patients or leverage information?

2. Be patient-centric and payer-savvy

Your customer base is expanding. How are you empowering patients and engaging with payers?

3. Experiment with business models

Innovation is moving beyond the product. How are you investing in new business models?

4. Show me the value — not the money

Focus on the right question. How are you creating value?

5. Be strategic — not defensive

One way or another, PI technologies are coming. Will you play defense or take the lead?

Guest article

Policy and personalization: fostering a robust medtech industry

David Dvorak
Zimmer
President and Chief Executive Officer
AdvaMed
Chairman

The promise of personalized health care

We stand on the cusp of a new era of personalized health care solutions. More rapid and accurate molecular diagnostic tests, advances in imaging modalities, intelligent surgical instruments and other patient-specific technologies are allowing physicians to treat their patients with a level of individualized precision unimaginable just a few short years ago.

This trend toward more personalized care will only accelerate as medical technology innovation – in which new product iterations appear on average every 18 months – continues to move forward, creating new and better medical devices and diagnostics.

This is all good news for the future of health care, as earlier detection and more targeted treatments will improve patient outcomes, saving lives, allowing patients to recover more quickly and completely, and saving valuable resources for health care systems.

Policy matters

Getting innovative technologies to physicians and their patients, however, involves a number of challenges for medtech companies both in the US and abroad, particularly in emerging markets. How we as an industry address these challenges will determine whether we succeed in fulfilling the promise of personalized approaches to health care.

First, timely patient access to safe and effective medical devices requires an efficient and predictable regulatory pathway. Physicians, patients and the medtech industry all benefit from a strong, well-functioning FDA. The recently enacted law to reauthorize the FDA medical device user fee program includes an agreement that establishes strong, measureable performance goals for the agency, along with process improvements. These built-in accountability mechanisms are essential to meeting the needs of physicians and their patients in a timely manner.

In the area of reimbursement, increasing costs and budgetary constraints are leading to payment systems that place a premium on quality and efficiency. In the US, Medicare is implementing several such payment system reforms. These changes may provide opportunities for innovative products that improve quality and create efficiencies in the delivery of care. It is important that these reforms not lose sight of what is in the interest of providers and patients, including access to the best available treatments and technologies.

In addition to an efficient regulatory and positive reimbursement environment, tax policies that support job creation, economic growth and competitiveness are necessary for a thriving and innovative medtech industry. If policy makers are interested in stimulating a strong domestic medtech industry, they will need to implement tax policies that help level the playing field for medical device companies competing in global markets and that encourage the retention and expansion of jobs, manufacturing and R&D.

Unfortunately, in the US, tax policy for the medtech industry is moving in the opposite direction, as a new 2.3% excise tax on medical device revenue is slated to go into effect 1 January 2013. Unless this tax is fully repealed, it will be a significant burden for companies, forcing them to make tough decisions as they balance the new tax with other priorities.

Fulfilling the promise

The benefits of personalized health care solutions are many, but they will not be realized without smart regulatory, reimbursement and tax policies that allow for the rapid research, development and commercialization of innovative medical technologies. The medtech industry stands ready to work with all stakeholders to ensure that patients can benefit from these technologies sooner rather than later.

Out with the status quo, in with health care for the future

Guy Lebeau, MD
Eucomed
Chairman
Johnson & Johnson
Company Group
Chairman, MD&D EMEA

These are interesting times for the medtech industry. Never before has the call for innovative technologies been so great or the pressure on health care budgets so acute. Consequently, we have to make sure that our innovations are accompanied by data and evidence on safety, efficiency and cost effectiveness. Developing technology that only marginally improves on current-generation solutions is no longer good enough. Going forward, innovation will have to be "value-based," which means it will need to offer substantial benefits over what is currently available, not only in terms of better health outcomes, but also when it comes to long-term cost effectiveness. Indeed, the two are intrinsically intertwined: healthier citizens are more active and productive, which lowers the pressure on health care budgets. It is now time for our industry to clearly demonstrate the value that we know it can deliver.

At the same time, we need to thoroughly rethink the way in which we deliver health care. It is no longer possible to treat each patient in a hospital setting. There are simply not enough health care professionals or hospital beds, and budgets are not sufficient to continue down the path of traditional health care delivery. Community care and eHealth solutions offer great potential in this respect, but the health care ecosystem is not yet prepared to deliver on this potential. If we truly want to achieve such safe, smart and sustainable health care systems, all stakeholders – medtech companies, patients, policy makers, payers, health care workers and hospital administrators – will have to come together and rethink their roles.

Equal in importance to stakeholder engagement is a regulatory regime that incentivizes the value-based innovation that health care systems need while protecting patient safety. While the current EU legislative framework may not be perfect, we should maintain elements that have been proven to work well – such as Europe's unique decentralized approach for approval – while identifying and filling gaps in the existing legislation. Patient safety will not increase by taking away the reward from those who innovate. Europe is known for providing its citizens with fast access to safe technology thanks to the region's high innovation competitiveness. I am convinced that we can remain in this privileged situation with the support of a regulatory framework that reflects this wish for safe, efficient and cost-effective innovation.

The political and economic situation in Europe is currently volatile. It is therefore more important than ever for governments to understand that health care is more than just a cost – it is an investment for a healthy and productive workforce. I believe that Europe will bounce back from these economically trying times. What will not change, however, is that demand for ever more efficient, safe and cost-effective health care will continue to rise, while the number of taxpayers contributing to European health care budgets will continue to decline. We must therefore dare to move away from the comfort of current practices.

- Companies need to take up the challenge of proving the benefits of their innovations in terms of health outcomes and economic benefits.
- Policy makers and politicians need to ensure that the regulatory framework supports future medtech innovations.
- Increasingly empowered patients will be ever more involved in managing their own health, thanks to the growing importance of areas such as e-health, m-health and telemonitoring.
- Health care professionals will have to recognize that not all health care is best delivered in hospital settings, and they should see this evolution as an opportunity, rather than a threat.
- Payers need to provide appropriate reimbursement schemes that reward innovation.

Only then will we be able to meet the health care challenges that are ahead. Change is never easy, but it is imperative. The status quo has to go. And everyone has a role to play.

Doing the right thing

Joe Kiani
Masimo Corporation
Chairman and Chief Executive Officer

This is not the first time that medtech innovation is under pressure because of cost worries. But while there is a genuine need to rein in health care cost inflation, it's worth remembering that devices only account for 5% of hospital expenditures. The unsustainable trajectory of US health care spending is instead being fueled by other causes, and policy makers and other actors in the system would do well to focus on changes that could truly bring costs under control:

Align incentives. As patients, we don't control our health care – third parties do. The FDA decides what procedures and products are safe and effective for patient use. Payers decide what that work should cost and pay for our care. Employers purchase insurance for us. And vendors, not hospitals, pay purchasing agents (group purchasing organizations) to negotiate hospital purchases. There is no natural accountability. In which other industry do companies allow their purchasing departments to be paid by the vendors from whom they are trying to negotiate the best prices – while paying a percentage of their purchases back to the very same purchasing agents? We need to change incentives so that people and organizations can be accountable and take ownership.

Invest in innovation. Despite all the advances in medicine, we still have a lot to learn about the human body and disease. Imagine the cost and quality of health care when we actually understand the root causes of diseases – and not just treat, but prevent them. To slow down investing in health innovation would be as shortsighted as failing to invest in the personal computer revolution 35 years ago. One wonders where we would have been had we listened to the cofounder of Digital Equipment Corp., who infamously said in 1977: "There is no reason for any individual to have a computer in his home." That narrow vision did not work for DEC and it would not have worked for the rest of us had we embraced it. We are better off than we were 100 years ago, when US life expectancy was 48 years. Today, it's 78, but we still can't prevent or cure cancer, nor prevent, stop and reverse heart disease. Investing in innovation doesn't drive up costs – with the right breakthroughs, it could be one of our best shots at containing costs.

Connect the dots in patient care. A disconnected understanding of the patient care pathway is another problem that costs us lives and dollars. The case of 12-year-old Rory Staunton, who died of sepsis at a New York hospital in July 2012, is a reminder of how disconnected caregivers can be from patients and their families. This is often due to the frantic pace of health care delivery by multiple stakeholders and the lack of interoperability among multiple machines in the hospitals – machines and IT infrastructure that hospitals have already paid for. If we could bring the machines and IT together with intelligent predictive algorithms, then physicians and patients could be informed of dangerous trends, lives could be saved, and process of care could be improved substantially – all of which would reduce costs.

Treat patients as human beings. We dehumanize people as soon as they become hospital patients to an extent matched only by security screening in airports. We walk into hospitals as the brave and the free and turn into voiceless hostages of an unsympathetic system. I don't buy the argument that if clinicians became too involved emotionally with their patients they might not do as good a job. Empathy has a place in health care – it offers patients and their families dignity and can go a long way to reducing stress, which is one of the biggest killers. An unsympathetic system contributes to suboptimal health care and is one of the reasons patients and their families often are eager to sue their caregivers if something goes wrong. Sometimes just "doing the right thing" can go a long way in reducing costs.

But payers, providers and regulators aren't the only ones who need to do the right thing. No matter what happens with payers, regulators and the clinical environment, the medical device industry must lead the way for uncompromising patient care, patient safety and patient dignity. That is what this industry is about. We must maintain the highest level of ethics and integrity, because our reputation is as important as the reputation of physicians and nurses. If our industry is trusted, it is less likely to be targeted for attack. Moreover, if we fail to advance innovation, we will not be true to the motivation that attracted us to medtech in the first place – creating a world in which our children and grandchildren will have less to fear from heart attacks and cancer than did our grandparents and parents.

Industry performance

Perseverance

The big picture

Despite lingering financial and regulatory uncertainties, US and European publicly held medtech companies delivered another strong performance in 2011. For both conglomerates and pure-play companies, revenue growth in 2011 outpaced 2010 growth rates. Net income increased by 14% – the third consecutive year of double-digit growth, and certainly impressive in today's challenging economic climate.

So far, the medical technology industry appears to be weathering a period of slower global economic growth. However, for an industry that was accustomed to double-digit revenue growth, considerable margins and a predictable sales-and-regulatory environment, the long-term future may still be turbulent. The industry's financial performance will likely continue to be challenged by low economic growth in developed markets, the prospect of austerity measures in many countries, a looming Eurozone debt crisis and an imminent 2.3% medical device tax in the US. And while the US Supreme Court's upholding of the Affordable Care Act has removed some of the uncertainty in the US, the regulatory environment continues to grow ever more complex around the globe.

Medical technology at a glance, 2010–11

(US$b, data for pure-play companies except where indicated)

Public company data	2011	2010	% change
Revenues	$331.7	$313.9	6%
Conglomerates	$142.3	$132.8	7%
Pure-play companies	$189.4	$181.0	5%
R&D expense	$12.6	$12.1	4%
SG&A expense	$60.3	$57.4	5%
Net income	$19.9	$17.4	14%
Cash and cash equivalents and short-term investments	$39.2	$39.4	-1%
Market capitalization	$436.1	$465.9	-6%
Number of employees	725,900	702,200	3%
Number of public companies	411	423	-3%

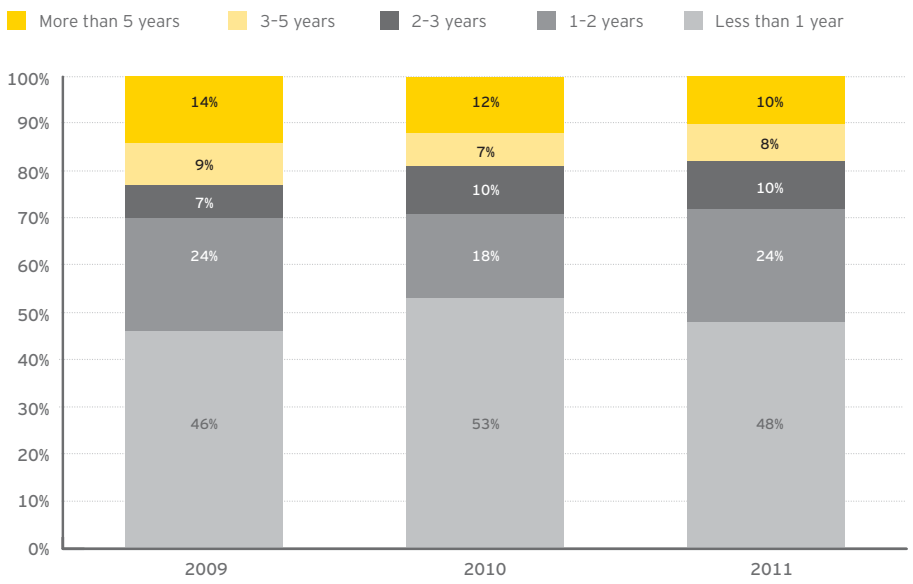
Source: Ernst & Young and company financial statement data.
Numbers may appear to be inconsistent due to rounding.
Data shown for US and European public companies.
Market capitalization data is shown for 30 June 2011 and 30 June 2012.

As payers tackle runaway health care costs, medtech will face rising pricing pressures and expanded use of comparative effectiveness – making organic growth in western markets more challenging. Efforts to heighten disease management and preventive care, and other efforts to drive efficiency within the health care system, may impact both product utilization and profitability. The cost of not adapting the traditional medtech business model to stay ahead of these trends could be disastrous.

Medtech companies – long known for innovation, reinvention and risk-taking in product development – will need to apply the same principles to business model development. These trends and implications are discussed more fully in this year's point of view article.

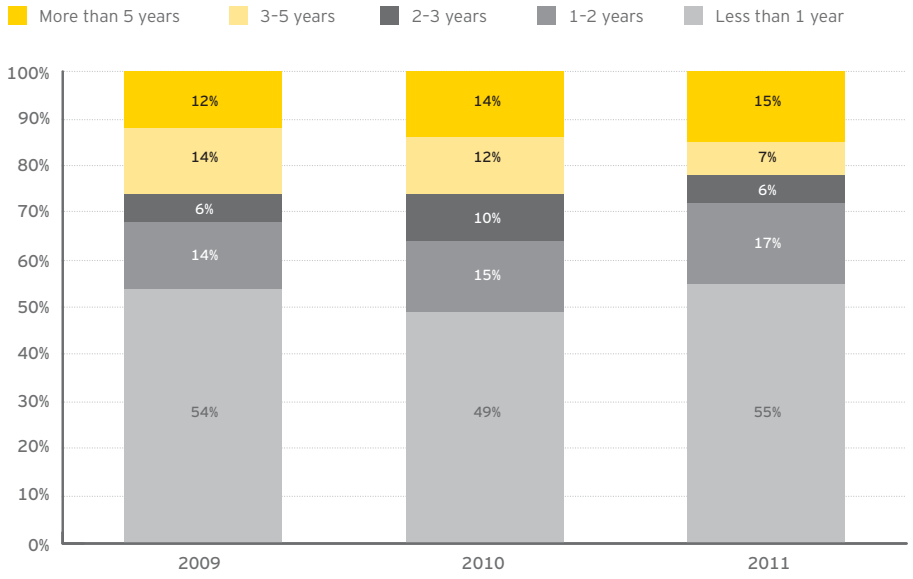
US and European publicly held medtech companies delivered another strong performance in 2011

US public medtech cash index



Source: Ernst & Young and company financial statement data.
Chart excludes companies that are cash-flow positive.

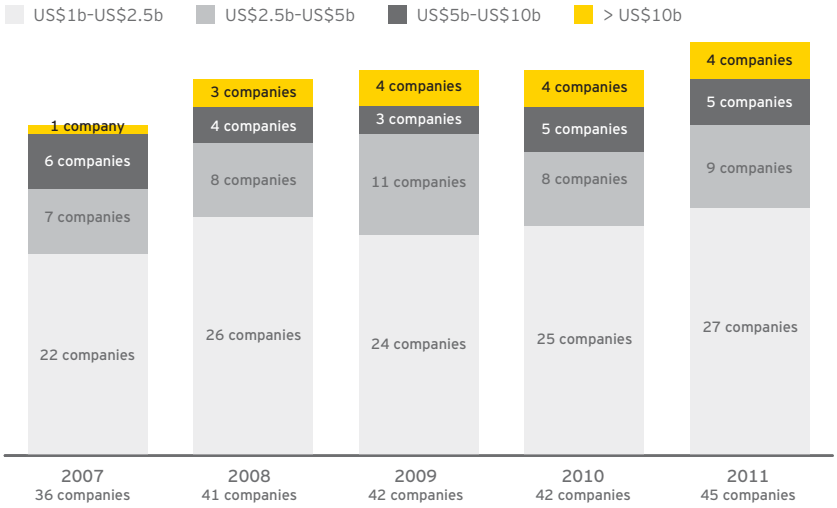
European public medtech cash index



Source: Ernst & Young and company financial statement data.
Chart excludes companies that are cash-flow positive.

The medical technology industry has seen a series of high-profile acquisitions of commercial leaders (companies with revenues exceeding US$1 billion) in recent years, including the purchase of Beckman Coulter (by Danaher Corp.) and Kinetic Concepts (by a consortium of private equity firms) in 2011. Yet, new commercial leaders continue to emerge to replace those that have exited. In fact, the ranks of commercial leaders have increased by 25% since 2007 – a figure that was aided by the induction of five companies (Amplifon, Illumina, Sartorius, Sorin Group and Teleflex) in 2011.

US and European commercial leaders, 2007–11



Source: Ernst & Young and company financial statement data.
Commercial leaders are pure-play companies with revenues in excess of US$1 billion.

United States

For the second consecutive year, US public medtechs produced positive growth across the majority of financial indicators, albeit at a lower rate than the prior year. Overall US revenues rose 4% in 2011, versus 6% in 2010, and were led by conglomerates that produced a growth rate of 7%. Prior to the economic downturn that began in 2008, the US medtech industry would typically generate double-digit top-line growth rates. However, since the recession, single-digit growth has become the norm as the industry continues to grapple with the mounting financial pressures of payers and considerable regulatory uncertainties. While top-line growth was modest in 2011, it could have been worse in the absence of a weak US dollar. Based on public company disclosures, we estimate that nearly 40% of the revenue growth by the top 10 US pure-play companies was the result of favorable foreign exchange rates. In the absence of the F/X impact of just these 10 companies, the overall US industry's growth rate would have been 3% instead of 4%, while the revenues of pure-play companies would have been below 1%. R&D expense grew by 2% – about half the growth in the top line. The increase might have been modest, but it was widespread – two-thirds of pure-play medtech companies increased their investments in R&D in 2011. In addition, three-quarters of companies increased their headcounts.

Net income increased by a solid 19%. However, this increase was boosted by the fact that companies such as Boston Scientific, Alere and Hologic incurred significant merger-, impairment- and litigation-related charges in 2010. After normalizing for the skewing impact of these charges, the industry's net income growth drops from 19% to just 2%.

US medtech at a glance, 2010–11

(US$b, data for pure-play companies except where indicated)

Public company data	2011	2010	% change
Revenues	$204.3	$196.4	4%
Conglomerates	$76.3	$71.5	7%
Pure-play companies	$128.0	$124.9	2%
R&D expense	$9.9	$9.6	2%
SG&A expense	$41.5	$40.0	4%
Net income	$13.7	$11.5	19%
Cash and cash equivalents and short-term investments	$32.7	$32.4	1%
Market capitalization	$303.8	$326.6	-7%
Number of employees	439,800	431,100	2%
Number of public companies	254	264	-4%

Source: Ernst & Young and company financial statement data.
Numbers may appear to be inconsistent due to rounding.
Market capitalization data is shown for 30 June 2011 and 30 June 2012.

US public medtechs produced positive growth across the majority of financial indicators

While the overall US growth story might have been somewhat weak in 2011 – particularly relative to the industry's past track record – the story was even worse for small medtech companies. As shown in the accompanying chart, all of the growth in revenues and R&D expense came from just 30 commercial leaders. The contrast was even more stark on the bottom line. While the net income of commercial leaders increased by an impressive 22%, the rest of the industry moved deeper into the red in 2011.

US commercial leaders and other companies, 2010–11
(US$b)

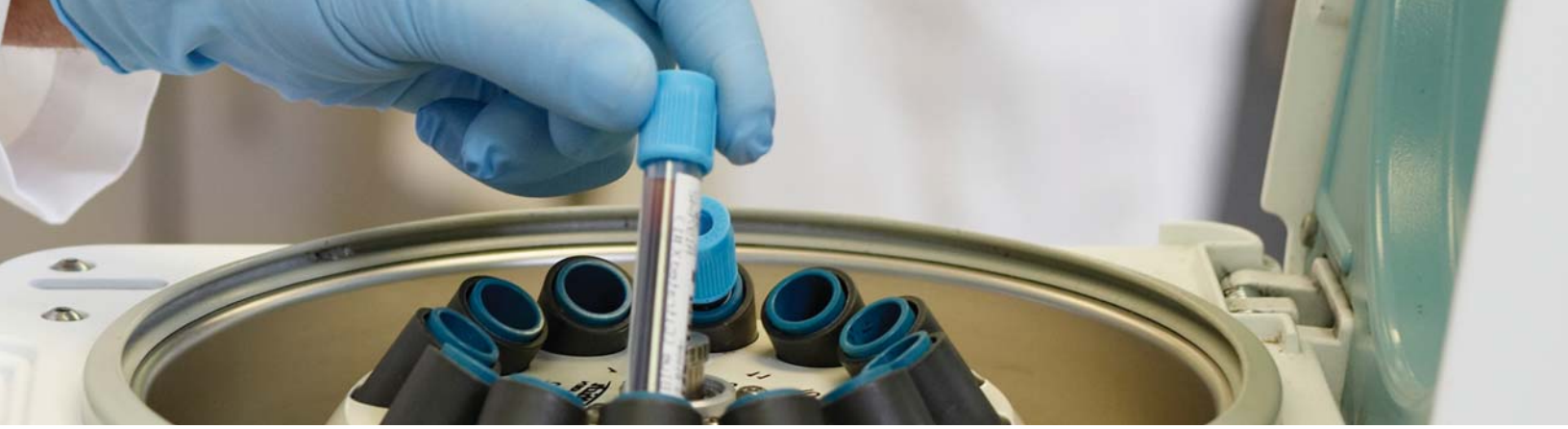
	2011	2010	% change
Commercial leaders			
Revenues	$108.1	$105.1	3%
R&D expense	$7.6	$7.3	3%
Net income (loss)	$14.3	$11.8	22%
Number of employees	358,600	350,600	2%
Other companies			
Revenues	$19.4	$19.4	0%
R&D expense	$2.3	$2.3	0%
Net income (loss)	$(0.7)	$(0.2)	-186%
Number of employees	79,000	78,700	0%

Source: Ernst & Young and company financial statement data.
Commercial leaders are pure-play companies with revenues in excess of US$1 billion.
Numbers may appear to be inconsistent due to rounding.

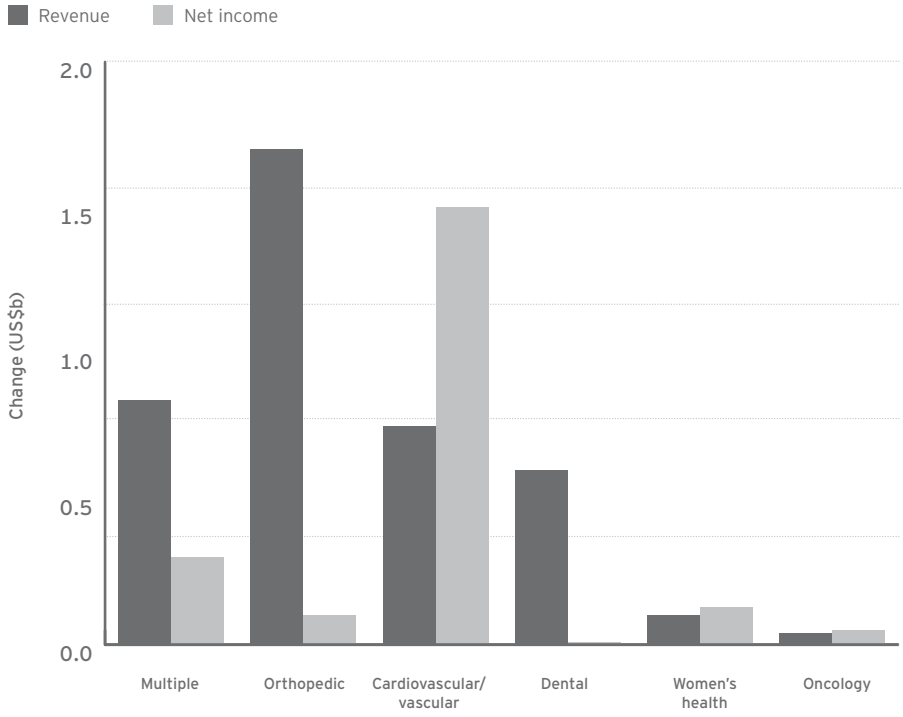
Selected US medtech public company financial highlights by region, 2011
(US$m, % change over 2010, except market cap over 30 June 2011)

Region	Revenue	Number of companies	Market capitalization 30 June 2012	R&D	Net income	Cash and cash equivalents	Total assets
Massachusetts	$29,570 7%	29 0%	$45,055 -22%	$2,085 3%	$1,849 338%	$3,635 2%	$69,350 10%
Minnesota	$22,391 0%	18 0%	$56,097 -8%	$2,329 3%	$3,986 -4%	$3,836 -18%	$40,720 8%
Southern California	$14,478 -15%	35 -5%	$47,821 -18%	$1,540 -8%	$856 -27%	$6,327 28%	$28,647 5%
New Jersey	$11,919 7%	12 -20%	$26,552 -13%	$731 7%	$1,634 -13%	$2,350 -8%	$15,962 12%
Northern California	$10,609 9%	31 0%	$48,054 17%	$1,106 9%	$1,038 4%	$4,260 -3%	$15,805 10%
Pennsylvania	$9,572 29%	9 0%	$10,168 37%	$379 34%	$1,535 26%	$3,421 22%	$19,086 46%
Michigan	$8,411 13%	3 0%	$21,184 -8%	$480 21%	$1,278 1%	$3,436 -22%	$12,513 13%
Indiana	$6,409 6%	4 0%	$13,577 -12%	$327 9%	$891 23%	$1,467 29%	$10,456 8%
New York	$2,913 8%	23 -4%	$4,761 -15%	$215 10%	$84 -14%	$696 26%	$4,556 5%
Texas	$2,379 -43%	10 -9%	$5,149 -41%	$120 -43%	$129 -72%	$556 -23%	$3,066 -47%

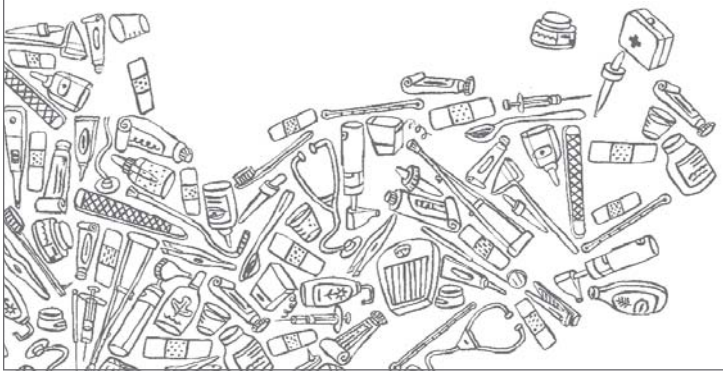
Source: Ernst & Young and company financial statement data.
Data shown for pure-play companies only.



Change in US therapeutic device companies' revenue and net income by disease category, 2010–11



Source: Ernst & Young and company financial statement data.



The combined revenues of US therapeutic device companies reached US$76 billion in 2011, an increase of 5% over the previous year, and accounted for nearly 60% of all US pure-play company revenue. All six of the largest disease categories saw their top lines increase in 2011, as well as 14 of the 16 disease categories in total. Among the top six, orthopedic generated the biggest top-line expansion, of US$1.7 billion (9% growth). This was driven in large part by Stryker and the positive impact of its acquisition of Boston Scientific's neurovascular group in early 2011. Multiple was up 4% (US$893 million) and was led by Intuitive Surgical (+27%; US$344 million), which continues to have phenomenal success with its da Vinci Surgical System.

Similar to the top line, each of the six largest disease subsegments also improved its bottom line in 2011. In particular, cardiovascular was responsible for 86% of the overall therapeutic device increase, and nearly all of that was the result of a host of impairment, transaction and litigation charges that had negatively impacted Boston Scientific's bottom line in 2010.

As for the results of the other major medtech product segments, imaging led the group with 8% revenue growth in 2011, followed by therapeutic devices, and then non-imaging diagnostics and other, which both increased their top lines by 4%. Only research and other equipment realized a decline, at -6%.

Since we first published *Pulse of the industry* back in 2008 (using 2007 figures), a number of medtech firms have seen their revenues grow significantly. It is notable that 6 of the 10 fastest-growing companies over the period 2007–11 – led by spinal device company NuVasive and Intuitive Surgical (maker of the da Vinci Surgical System) – expanded their top lines mostly through organic growth and without the assistance of sizeable mergers or acquisitions. Corning Life Sciences was the only conglomerate to make the top 10 list.

Selected fast-growing US medtechs by revenue growth, 2007–11
(US$m)

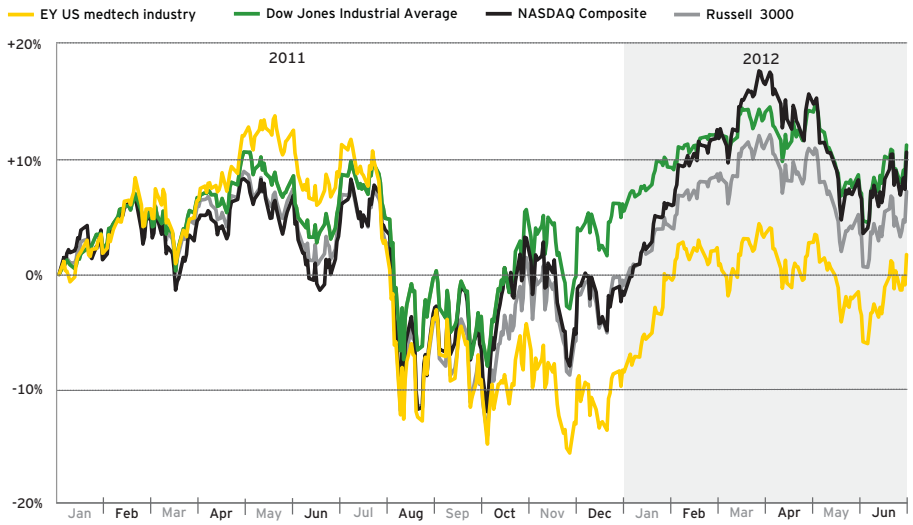
Companies	2007	2011	CAGR
NuVasive	$154	$541	37%
Alere	*$767*	*$2,387*	*33%*
Life Technologies	*$1,282*	*$3,776*	*31%*
Intuitive Surgical	$601	$1,757	31%
Illumina	$367	$1,056	30%
Hologic	*$738*	*$1,789*	*25%*
Corning Life Sciences	$305	$595	18%
Thoratec	*$235*	*$423*	*16%*
Greatbatch	$319	$569	16%
ResMed	$716	$1,243	15%

Source: Ernst & Young and company financial statement data.
Companies in italics have made significant acquisitions between 2007 and 2011.
CAGR= Compounded Annual Growth Rate.

6 of the 10 fastest-growing companies expanded their top lines mostly through organic growth

US medtech industry trailed the broader market

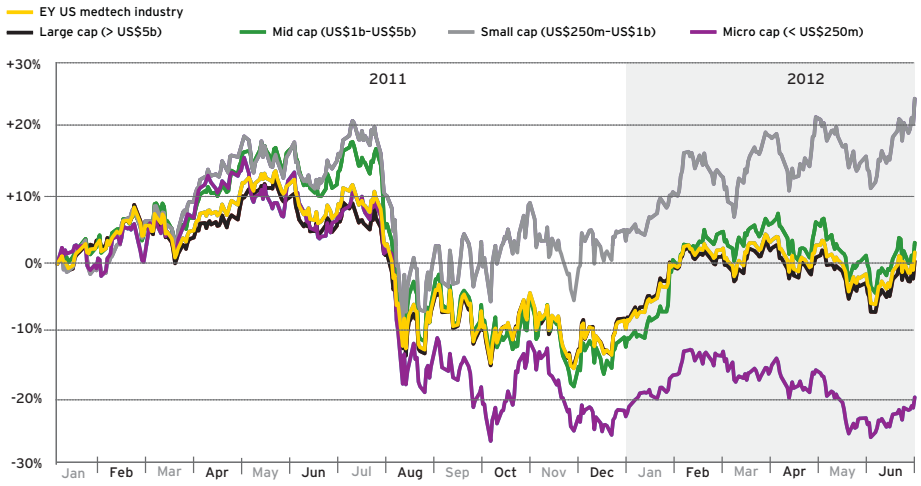
US market capitalization, 2011–H1 2012



Source: Ernst & Young and Capital IQ.

Small caps outperformed other medtech segments

US market capitalization, 2011–H1 2012



Source: Ernst & Young and Capital IQ.

Europe

In general, the European medtech industry grew at a higher rate in 2011 than in 2010. European growth also outperformed the US across the majority of financial indicators.

Top-line growth in Europe was up 8% to nearly US$127 billion in 2011 (compared to 7% in 2010) and was equally driven by both pure-play and conglomerate companies. While 83% of all European medtechs increased their revenues last year, the top line was principally bolstered by the regular cast of commercial leaders and conglomerates (such as Covidien – which is incorporated in Ireland – Siemens and Roche), as well as pure-play firms such as Sonova (+27%) and Amplifon (+22%), both of which specialize in hearing aids. With 77% of companies increasing their R&D spending, R&D bounced back from a 4% drop in 2010 to a 12% increase in 2011. Another positive sign for future growth was the fact that nearly 70% of companies added headcount, boosting headcount by roughly 15,000 over 2010. Net income growth crawled up from 3% to 5% year-over-year. Holdings of cash, cash equivalents and short-term investments were down 9% – this was largely driven by Qiagen's use of cash for a series of acquisitions, most notably for Cellestis in April 2011.

European medtech at a glance, 2010–11
(US$b, data for pure-play companies except where indicated)

Public company data	2011	2010	% change
Revenues	$127.4	$117.4	8%
Conglomerates	$66.0	$61.3	8%
Pure-play companies	$61.4	$56.1	9%
R&D expense	$2.7	$2.4	12%
SG&A expense	$18.9	$17.5	8%
Net income	$6.2	$5.9	5%
Cash and cash equivalents and short-term investments	$6.4	$7.0	-9%
Market capitalization	$132.3	$139.3	-5%
Number of employees	286,100	271,100	6%
Number of public companies	157	159	-1%

Source: Ernst & Young and company financial statement data.
Numbers may appear to be inconsistent due to rounding.
Market capitalization data is shown for 30 June 2011 and 30 June 2012.

European growth outperformed the US across the majority of financial indicators

The number of European commercial leaders increased 25% to 15 in 2011 as Amplifon, Sartorius and Sorin crossed the US$1 billion revenue threshold. As in the US, European commercial leaders were the principal engine of growth for the European industry, while the rest of the industry struggled to keep up. The chasm between the commercial leaders and other public companies has never been bigger in Europe. As the continent continues to deal with the uncertainties of the euro and government austerity measures, many smaller companies will find growth difficult, as they'll likely bear the greatest impact of increased pricing, funding and regulatory pressures.

European commercial leaders and other companies, 2010–11
(US$b)

	2011	2010	% change
Commercial leaders			
Revenues	$53.1	$47.9	11%
R&D expense	$2.1	$1.8	17%
Net income (loss)	$6.2	$5.6	11%
Number of employees	253,300	236,100	7%
Other companies			
Revenues	$7.7	$7.7	0%
R&D expense	$0.6	$0.6	-2%
Net income (loss)	$(0.2)	$0.2	-188%
Number of employees	32,800	34,900	-6%

Source: Ernst & Young and company financial statement data.
Commercial leaders are pure-play companies with revenues in excess of US$1 billion.
Numbers may appear to be inconsistent due to rounding.

Selected European medtech public company financial highlights by region, 2011
(US$m, % change over 2010, except market cap over 30 June 2011)

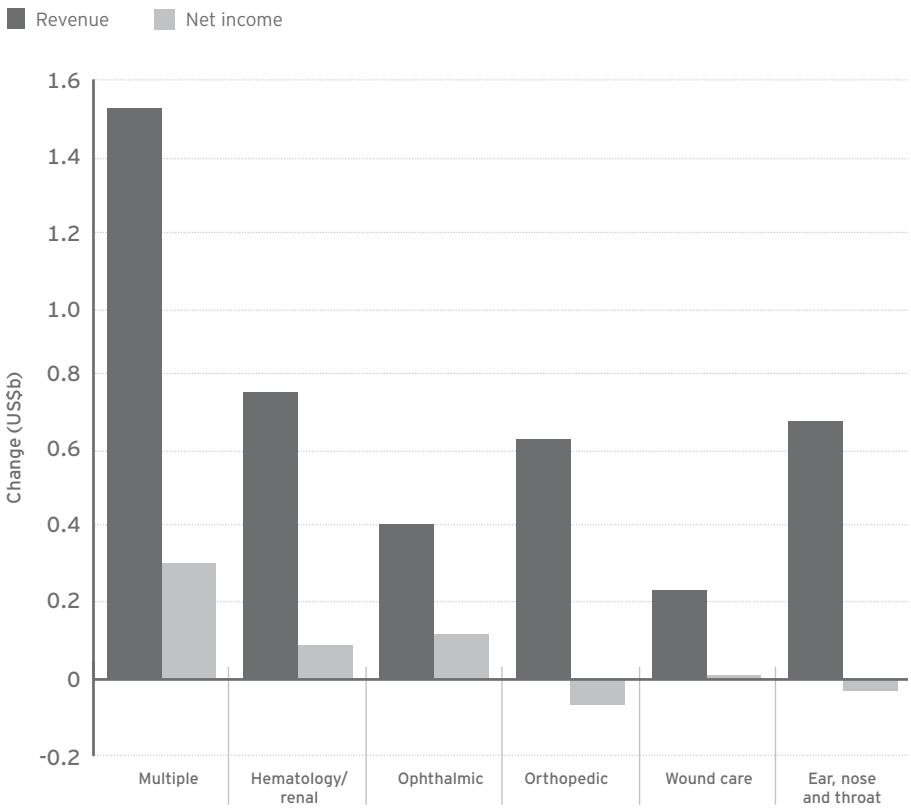
Country	Revenue	Number of companies	Market capitalization 30 June 2012	R&D	Net income (loss)	Cash and cash equivalents	Total assets
Germany	$16,917 8%	19 0%	$24,474 -5%	$274 3%	$1,250 11%	$694 28%	$23,238 14%
Ireland	$11,652 11%	2 -50%	$26,053 -2%	$557 23%	$1,884 11%	$1,574 -3%	$20,545 0%
France	$8,858 10%	15 15%	$24,156 0%	$498 4%	$898 10%	$799 7%	$12,334 23%
Sweden	$5,066 9%	29 4%	$11,332 -5%	$261 25%	$432 14%	$546 -7%	$8,452 23%
United Kingdom	$4,970 5%	21 -5%	$10,572 -9%	$221 -3%	$599 -6%	$317 -22%	$5,878 0%
Switzerland	$4,062 16%	9 0%	$11,080 -19%	$239 32%	$392 -30%	$816 -24%	$5,303 4%
Denmark	$3,660 16%	5 0%	$13,168 9%	$205 7%	$575 40%	$415 204%	$3,432 20%
Italy	$2,660 12%	4 0%	$2,107 -25%	$119 17%	$74 6%	$321 -7%	$3,460 8%
Netherlands	$1,555 30%	3 50%	$4,998 9%	$154 19%	$84 -46%	$357 -63%	$4,392 9%
Israel	$552 -15%	23 -8%	$1,523 -25%	$89 5%	($83) 87%	$367 -14%	$874 -19%

Source: Ernst & Young and company financial statement data.
Data shown for pure-play companies only.

European therapeutic device companies increased their cumulative top lines by 9% to US$51.7 billion in 2011, or 84% of all pure-play company revenue. As in the US, all six of the largest disease subsegments in Europe saw their top lines grow in 2011. Covidien, a company incorporated in Ireland but with significant operations in the US, was responsible for three-quarters of the US$1.5 billion expansion of the "multiple" segment, and Fresenius Medical Care's performance exclusively drove the nearly US$700 million growth of hematology/renal.

Top-line success didn't exactly translate to equally strong bottom-line achievement in Europe, as therapeutic device companies produced an aggregate 6% year-over-year increase. Of the top six disease categories, orthopedic and ear, nose and throat saw their net incomes drop in 2011. This was consistent with the broader group, as 9 of the 16 overall disease segments experienced negative bottom-line growth.

Change in European therapeutic device companies' revenue and net income by disease category, 2010–11



Source: Ernst & Young and company financial statement data.

all six of the largest disease subsegments saw their top lines grow in 2011

Selected fast-growing European medtechs by revenue growth, 2007–11
(US$m)

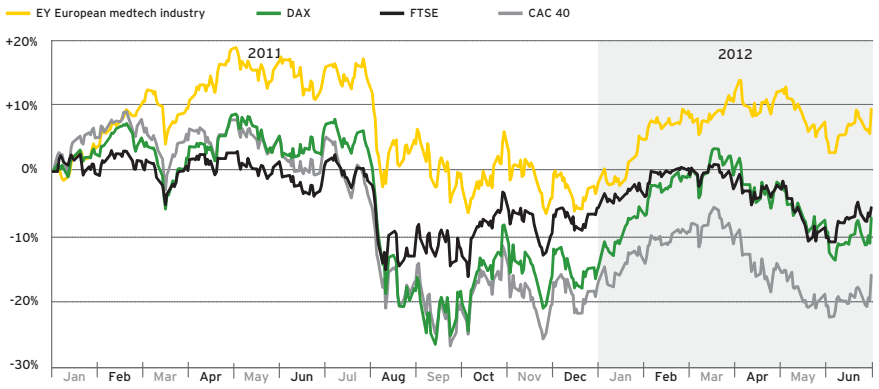
Companies	Location	2007	2011	CAGR
Fresenius Kabi	*Germany*	*$2,782*	*$5,515*	*19%*
Sonova Holding	*Switzerland*	*$926*	*$1,827*	*19%*
ELEKTA	*Sweden*	*$674*	*$1,217*	*16%*
Qiagen	*Netherlands*	*$650*	*$1,170*	*16%*
Stratec Biomedical Systems	Germany	$94	$165	15%
Sempermed	Austria	$300	$517	15%
Syneron Medical	Israel	$141	$228	13%
Given Imaging	Israel	$113	$178	12%
William Demant Holding	Denmark	$1,010	$1,501	10%
Essilor International	*France*	*$3,986*	*$5,829*	*10%*

Source: Ernst & Young and company financial statement data.
Companies in italics have made significant acquisitions between 2007 and 2011.
CAGR= Compounded Annual Growth Rate.

While the fastest-growing companies in the US were fueled largely by organic growth, the four fastest-growing firms in Europe were aided by significant acquisitions. Germany's Fresenius Kabi holds the distinction of having the biggest expansion in both real dollar and percentage terms on this list. The company's growth was in large part fueled by the addition of APP Pharmaceuticals, which it acquired for US$3.7 billion in 2008. Of the six commercial leaders on this list, five had made sizeable purchases, while the smaller "other" companies grew mostly through organic means.

European medtech outperformed the broader market

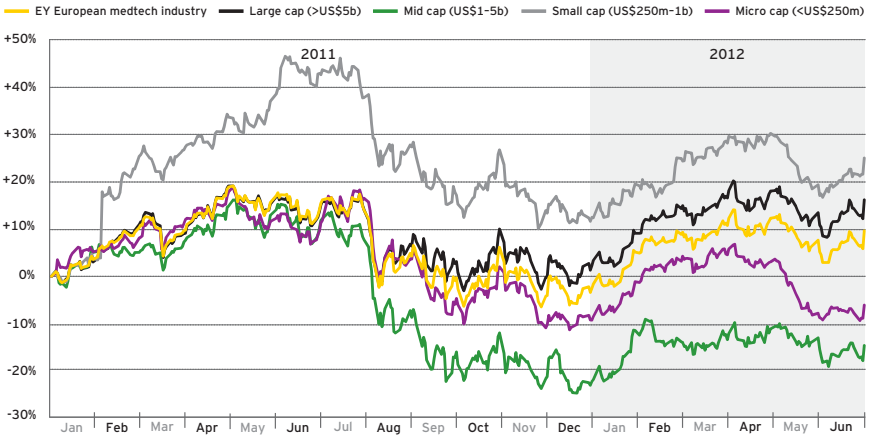
European market capitalization, 2011-H1 2012



Source: Ernst & Young and Capital IQ.

Mid caps lagged behind other segments

European market capitalization, 2011-H1 2012



Source: Ernst & Young and Capital IQ.

For more data, charts and insights, please visit ey.com/medtechdata

Debt rising

The big picture

Capital raised in the US and Europe by year (US$m)

Type	Jul 2005-Jun 2006	Jul 2006-Jun 2007	Jul 2007-Jun 2008	Jul 2008-Jun 2009	Jul 2009-Jun 2010	Jul 2010 - Jun 2011	Jul 2011-Jun 2012
Venture	$3,739	$5,408	$5,216	$4,691	$4,895	$4,031	$4,344
IPO	$1,192	$1,113	$711	$17	$345	$798	$416
Follow-on and other	$3,672	$2,365	$2,081	$1,833	$2,572	$2,317	$825
Debt	$10,215	$4,183	$3,876	$6,677	$13,482	$14,677	$21,853
Total	**$18,818**	**$13,069**	**$11,884**	**$13,218**	**$21,294**	**$21,823**	**$27,438**

Source: Ernst & Young, BMO Capital Markets, Dow Jones VentureSource and and Capital IQ.
Numbers may appear to be inconsistent because of rounding. PIPEs and convertible debt offerings included in "follow-on and other."

For the 12-month period ended June 30, 2012, US and European public medtech companies raised a remarkable US$27.4 billion, an increase of 26% over the prior 12-month period. While this total represents the largest amount raised in at least the last seven years, the increase was driven not by a fundamental shift in investor sentiment toward medtech, but by a low interest rate environment that fueled a huge growth in debt. Indeed, 80% of all capital raised in 2011–12 was in the form of debt. Funding other than debt actually declined by 22% in 2011–12 relative to the prior year.

As in the last three years, this debt financing went to a few large "commercial leaders" — nine companies raised in excess of US$1 billion each — that used this capital to fund general operations, restructure balance sheets and/or make acquisitions. Meanwhile, many smaller firms struggled to obtain funds to support their R&D and product launch efforts.

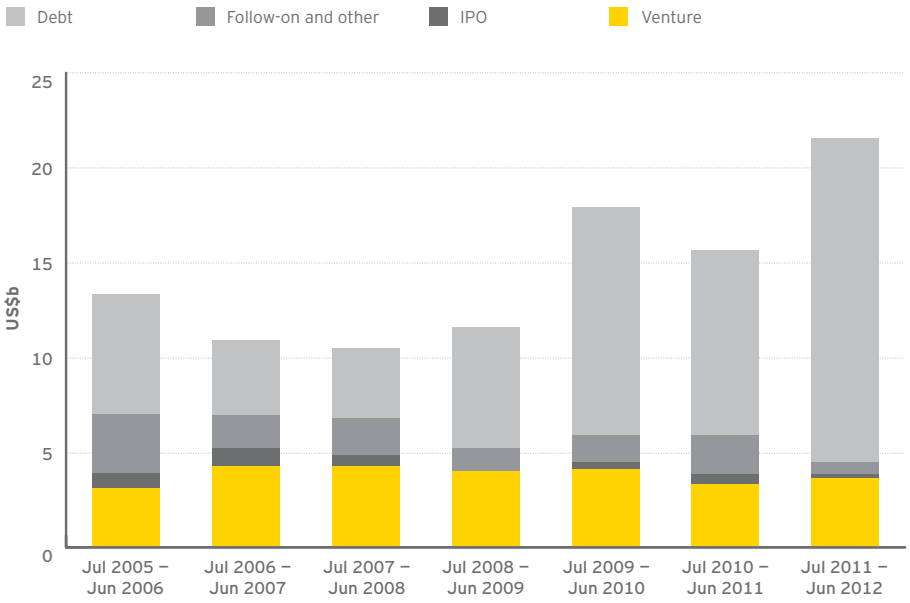
Indeed, the division between established and emerging companies has never been greater. Ongoing regulatory and pricing pressures, an anemic IPO market and ever more selective buyers have made venture capitalists — the lifeblood of emerging medtech firms — extremely cautious. Even though the overall level of venture financing has remained relatively steady since the financial crisis, the challenges have squeezed VCs' returns on investment and driven them to invest in more mature companies that offer the promise of quicker, more predictable exits. While a relatively small contingent of companies — those with novel technologies or proven management, for instance — might still attract early-round financing, many emerging firms are finding it more difficult to finance their operations.

With an increasing focus on health care costs and the value of health interventions, medtech companies can no longer count on receiving funding or reimbursement for technologies that only deliver marginal improvements to the existing standard of care, either in terms of outcomes or cost savings. The venture financing picture is also expected to remain constrained. The venture financing totals above reflect the investment of venture funds that were mostly raised prior to the financial crisis. Over the last few years, VCs have had trouble raising new funds of equal or greater size, which will translate into less capital available for emerging companies in the future. Therefore, companies will need to be increasingly selective in their development efforts and focus on technologies and/or market segments that will demonstrate an ability to improve health outcomes and reduce payer costs.

the division between established and emerging companies has never been greater

United States

US medtech financing by year



Source: Ernst & Young, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.

US medtech companies raised an announced US$21.6 billion in the 12-month period ended June 30, 2012, an increase of 43% over the prior year. Eighty percent of the total (US$17.1 billion) came in the form of debt, which surpassed the previous record of US$12 billion in 2010–11. In all, seven commercial leaders issued debt in excess of US$1 billion, including Hologic (US$3.3 billion), Kinetic Concepts (US$2.6 billion) and Thermo Fisher Scientific (US$2.2 billion).

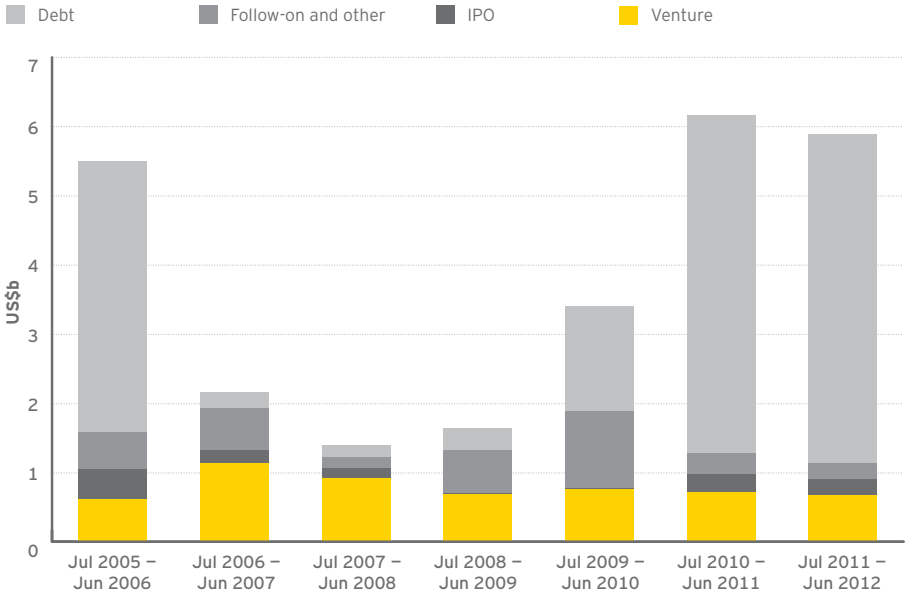
Venture capital investment was up 11% year-over-year; however, this total still lagged behind the amounts invested between July 2005 and June 2010 by 10% to 15%. IPOs continued to be few and far between, as only three US medtech companies went public for US$194 million, down from eight for US$539 million in 2010–11. And a year after Sirona Dental closed a US$800 million follow-on offering and 10 other companies had follow-on and other offerings of at least US$50 million, there were only three such financings in 2011–12, with Sequenom (US$62 million) being the largest. In all, follow-on and other offerings funding was down 71%.

Europe

Funding for European medtech companies declined in all four categories in 2011–12. However, despite the 5% decrease in year-over-year financing to US$5.9 billion, European medtechs still enjoyed the second-highest level of funding since at least 2005–06.

Similar to the US, the vast majority of funding (US$4.8 billion, or 80% of the total) came in the form of debt. Nearly 85% of European debt was raised by Fresenius Medical Care and Covidien. Fresenius Medical Care alone raised more than US$2.7 billion, which it primarily used for the acquisition of Liberty Dialysis. Venture capital investment was down for the second year in a row – reaching its lowest level (US$676 million) since 2005–06 – while eight companies went public for a total of US$222 million. Both amounts were both slightly behind the previous year's pace.

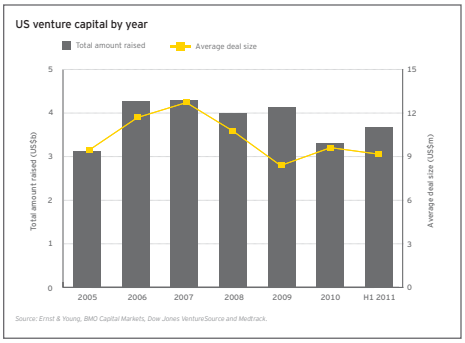
European medtech financing by year

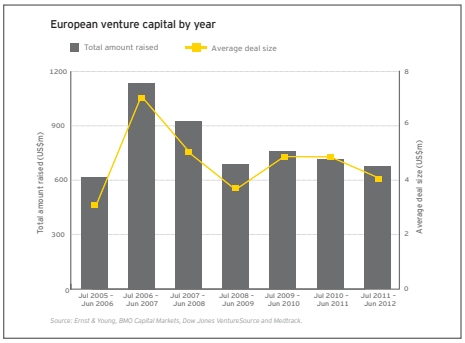


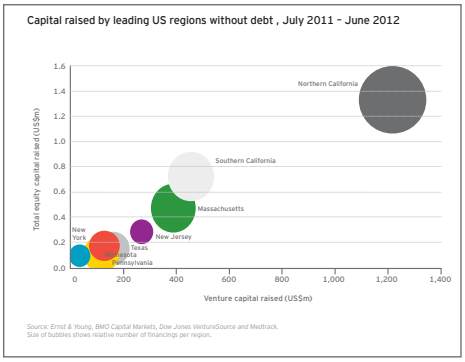
Source: Ernst & Young, BMO Capital Markets, Dow Jones VentureSource and and Capital IQ.

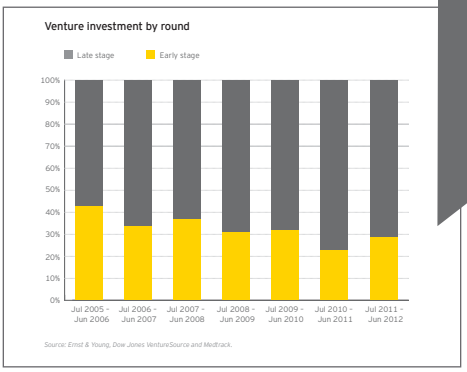
many emerging firms are finding it more difficult to finance their operations

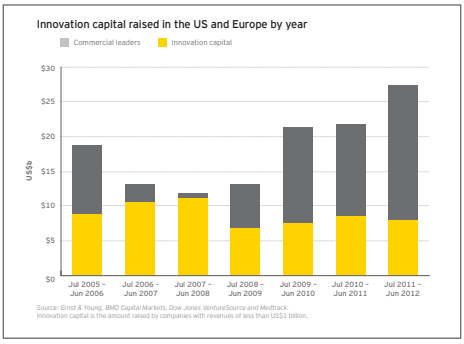
For more financing data, charts and insights, please visit ey.com/medtechdata

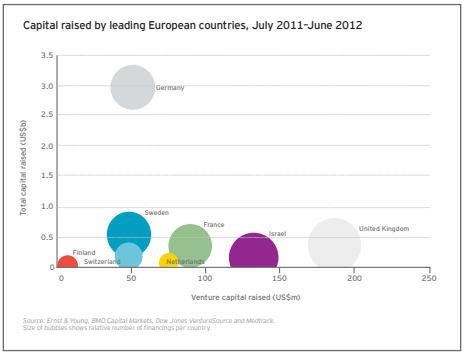


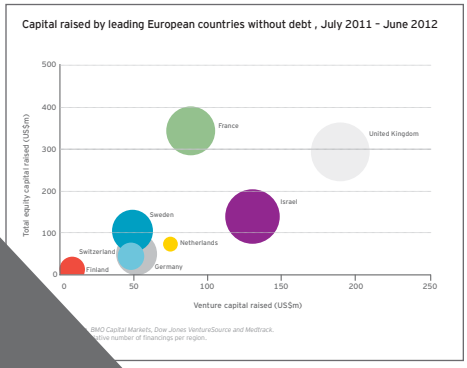


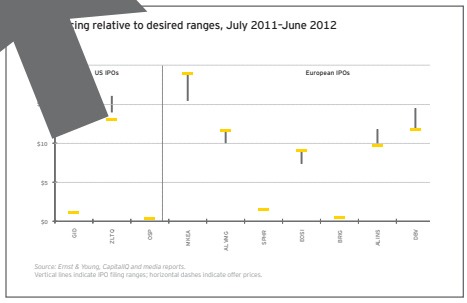


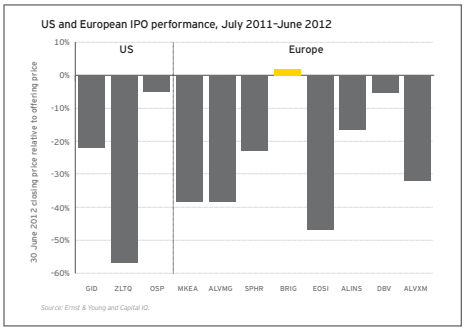


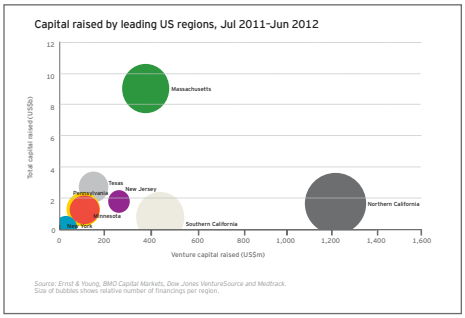












Fueling future growth

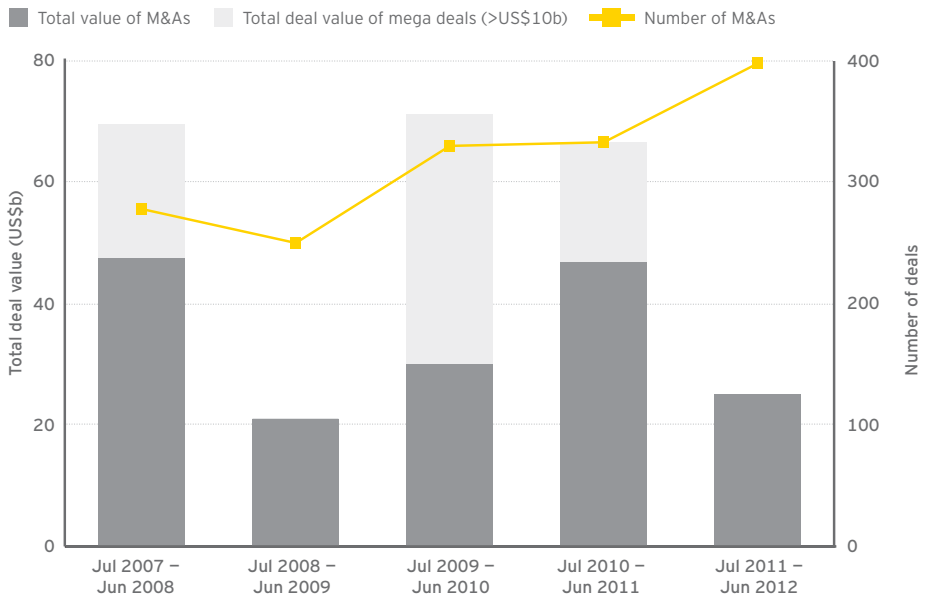
The big picture

Merger and acquisition (M&A) activity among US and European medical technology companies remained vibrant in the year ended June 30, 2012. While 2011–12's total of US$35.0 billion was well below the levels seen over the last two years, those two years were driven by megadeals done by Novartis (which paid US$41.2 billion to Nestlé for the remaining 75% of Alcon it didn't already control) and Johnson & Johnson (which paid US$19.7 billion for Synthes). On a normalized basis (after removing the impact of the aforementioned megadeals), 2011–12's total deal value was more in line with previous years – 25% below the prior year and 16% above the year before that.

Although no megadeals were consummated in 2011–12, there were eight transactions valued at more than US$1 billion, versus 12 the year before. The year's largest deal was between private equity firm Apax Partners, two Canadian pension funds and Texas-based wound care company Kinetic Concepts Inc. (KCI). The US$6.3 billion Apax/KCI deal was particularly notable, as the US$6.3 billion represented one of the largest leveraged buyouts – across all industries – since the onset of the financial crisis in 2008. Two other private equity firms were also involved in multibillion-dollar M&As: Cinven sold off Swedish diagnostics company Phadia to Thermo Fisher Scientific for US$3.5 billion, and TPG Capital acquired in vitro diagnostics maker Immucor for nearly US$2 billion.

While private equity firms have long used debt to finance their acquisitions, a number of pure-play medtech companies also took advantage of historically low interest rates to purchase assets in 2011–12. Hologic, Thermo Fisher Scientific and Fresenius Medical Care floated debt offerings in excess of US$1 billion each to help fund the purchases of Gen-Probe, (announced prior to June 30) Phadia and Liberty Dialysis, respectively.

M&As in the US and Europe (US$m)

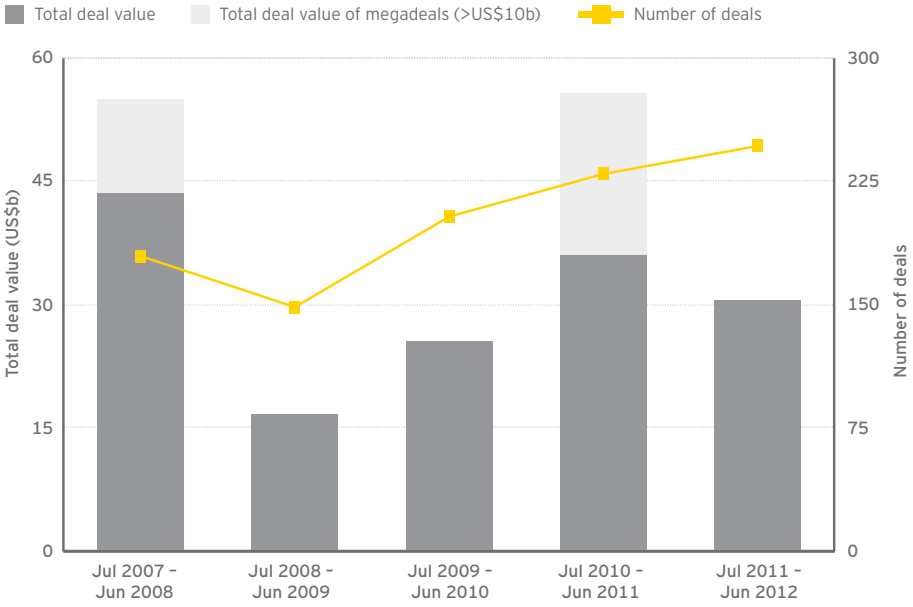


Source: Ernst & Young, Capital IQ and Thomson ONE

The total number of acquisitions leaped nearly 20% in the year ended 2011–12. While the total number of deals has increased, the number of privately held medtech firms acquired for at least US$5 million has also remained remarkably stable over the past several years. In fact, the number of private medtech companies being acquired for US$5 million or more actually jumped from 98 in 2007–08 to 105 in 2011–12, while the median deal price for those same periods shot up from US$32.2 million to US$51.6 million. So, despite real concerns about buyers becoming more selective and VCs holding portfolio companies longer, venture-backed companies are still being acquired, and at surprisingly favorable terms.

A number of current market trends portend sustained M&A activity. Health care reforms and budgetary challenges are intensifying financial pressures on payers and, ultimately, providers. As they look for ways to cut expenses and increase efficiencies, providers are increasingly turning to consolidation, physician gain-sharing agreements, price caps, vendor reductions and reduced utilization rates – all of which will continue to be a major drag on organic growth for medtech companies. These financial pressures are driving medtech companies to re-evaluate their portfolios, divest underperforming or non-core business units, or acquire assets in high-growth technologies or desirable markets – possibly leading to more M&As ahead.

US mergers and acquisitions



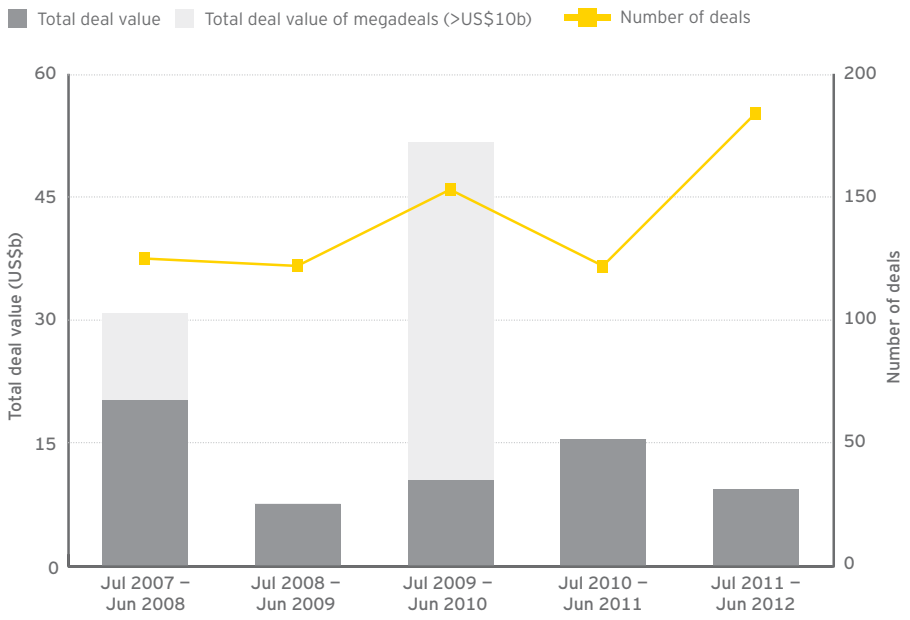
Source: Ernst & Young, Capital IQ and Thomson ONE

The value of M&As involving US medtech companies dropped 45% to US$30.6 billion in 2011–12 from the previous year. However, after normalizing the data for the US$19.7 billion Johnson & Johnson/ Synthes megadeal, the total value of M&As declined by just 16%. While the average (mean) deal size fell, the median deal size remained exactly the same year-over-year at US$53 million, and the total number of M&As (including those with unannounced deal terms) edged up from 228 to 245.

M&A activity among US and European medical technology companies remained vibrant

financial pressures are driving medtech companies to re-evaluate their portfolios

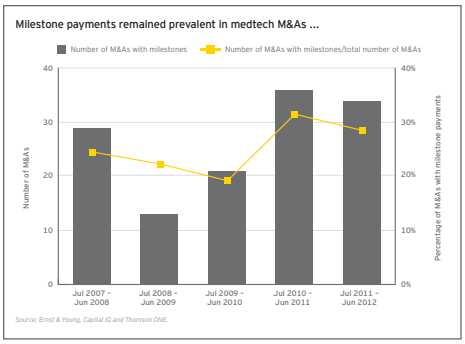
European mergers and acquisitions

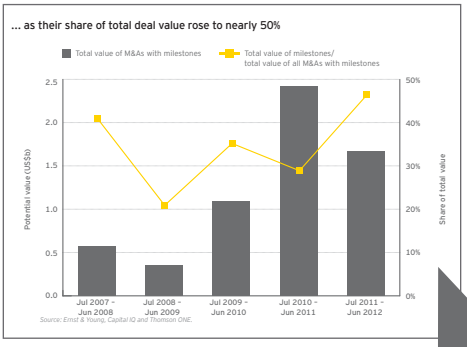


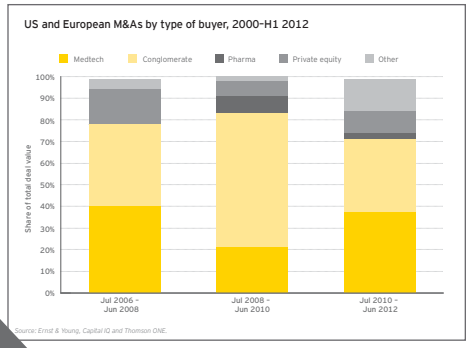
Source: Ernst & Young, Capital IQ and Thomson ONE

European medtech M&A fell to US$9.4 billion in 2011–12, a 40% decline relative to the previous 12-month period. This figure was not only the second-lowest M&A total in the past five years, but also 26% lower than the average over this five-year period, even with megadeals removed. However, on the positive side, the total number of deals – including deals with and without announced deal terms – skyrocketed from 122 to 184. French ophthalmic company Essilor International was the busiest acquirer with 21 announced M&As, while Fresenius Medical Care spent more than any other European company (US$2.5 billion). Both the average (mean) and median deal size dropped (by 56% and 7%, respectively).

For more financing data, charts and insights, please visit ey.com/medtechdata







Selected M&As, July 2011-June 2012

Acquiring company	Location	Acquired company	Location	Value (US$m)
PE consortium led by Apax Partners	United Kingdom	Kinetic Concepts	US - Texas	$6,300
Hologic	US - Massachusetts	Gen-Probe	US - California	$3,800
Thermo Fisher Scientific	US - Massachusetts	Phadia	Sweden	$3,500
Agilent Technologies	US - California	Dako	Denmark	$2,200
Asahi Kasei	Japan	ZOLL Medical	US - Massachusetts	$2,200
Fresenius Medical Care	Germany	Liberty Dialysis	US - Washington	$2,100
TPG Capital	US - Texas	Immucor	US - Georgia	$1,939
Boston Scientific	US - Massachusetts	Cameron Health	US - California	$1,350
Fujifilm	Japan	SonoSite	US - Washington	$995
Corning Life Sciences	US - New York	*Discovery Labware (Becton Dickinson)	US - New Jersey	$730
Getinge	Sweden	Atrium Medical	US - New Hampshire	$680
Royal DSM	Netherlands	Kensey Nash	US - Pennsylvania	$360

Source: Ernst & Young, Capital IQ and Thomson ONE.
Average deal size calculated using deals with announced values.
*Corning purchased the majority of BD's Discovery Labware's divisions.

US and European M&As by segment

	July 2007 - June 2011			July 2011 - June 2012		
Segment	Number of deals	Value (US$m)	% of total deal value	Number of deals	Value (US$m)	% of total deal value
Therapeutic devices	344	$128,525	68%	126	15,778	5
Ophthalmic	33	$56,295	30%	10	$187	
Orthopedic	54	$27,670	15%	17	$370	
Cardiovascular	72	$17,120	9%	18	$4,708	1
Respiratory	16	$5,987	3%	5	$59	
Non-disease specific	48	$2,178	1%	32	$1,512	
Multiple	11	$3,472	2%	11	$1,859	
Hematology/renal	13	$3,054	2%	5	$72	
Wound care	21	$2,891	2%	7	$6,495	2
Oncology	10	$881	0%	2	$335	
All others	66	$8,977	5%	19	182	
Research and other equipment	75	$38,409	20%	19	$1,069	
Non-imaging diagnostics	113	$13,140	7%	46	$10,881	38%
Other	43	$7,136	4%	21	$479	2%
Imaging	50	$2,571	1%	21	$1,671	6%

Source: Ernst & Young, Capital IQ and Thomson ONE.
Table only shows deals where values were publicly disclosed.
Figures may be inconsistent due to rounding.

US and Europe (US$m)

	Jul 2007 - Jun 2008	Jul 2008 - Jun 2009	Jul 2009 - Jun 2010	Jul 2010 - Jun 2011	Jul 2011 - Jun 2012
	276	248	328	331	396
	$69,562	$21,009	$71,261	$66,629	$35,008
	$422	$195	$440	$443	$211
	14	5	5	12	8

Defining medical technology

In this report, medical technology (medtech) companies are defined as companies that primarily design and manufacture medical technology equipment and supplies and are headquartered within the United States or Europe. For the purposes of this report, we have placed Israel's data and analysis within the European market, and any grouping of the US and Europe has been referred to as "global." This wide-ranging definition includes medical device, diagnostic, drug delivery and analytical/life science tool companies, but excludes distributors and service providers such as contract research organizations or contract manufacturing organizations.

By any measure, medical technology is an extraordinarily diverse industry. While developing a consistent and meaningful classification system is important, it is anything but straightforward. Existing taxonomies sometimes segregate companies into scores of thinly populated categories, making it difficult to identify and analyze industry trends. Furthermore, they tend to combine categories based on products (such as imaging or tools) with those based on diseases targeted by those products (such as cardiovascular or oncology), which makes it harder to analyze trends consistently across either dimension. To address some of these challenges, we have categorized medtech companies across both dimensions – products and diseases targeted. All publicly traded medtech companies were classified as belonging to one of five broad product groups:

- **Imaging:** companies developing products used to diagnose or monitor conditions via imaging technologies, including products such as MRI machines, computed tomography (CT) and X-ray imaging and optical biopsy systems
- **Non-imaging diagnostics:** companies developing products used to diagnose or monitor conditions via non-imaging technologies, which can include patient monitoring and in vitro testing equipment
- **Research and other equipment:** companies developing equipment used for research or other purposes, including analytical and life science tools, specialized laboratory equipment and furniture
- **Therapeutic devices:** companies developing products used to treat patients, including therapeutic medical devices, tools or drug delivery/infusion technologies
- **Other:** companies developing products that do not fit in any of the above categories were classified in this segment

In addition to product groups, this report tracks conglomerate companies that derive a significant part of their revenues from medical technologies. While a conglomerate medtech division's technology could technically fall into one of the product groups listed above (e.g., General Electric into "imaging" and Allergan into "therapeutic devices"), all conglomerate data is kept separate from that of the non-conglomerates. This is due to the fact that, while conglomerates report revenues for their medtech divisions, they typically do not report other financial results for their medtech divisions, such as research and development or net income.

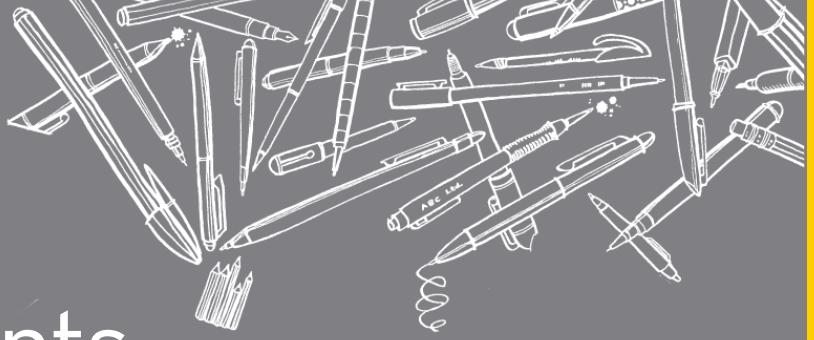
Conglomerate companies:

United States

- 3M Health Care
- Abbott: Medical Products
- Agilent Technologies: Life Sciences and Chemical Analysis
- Allergan: Medical Devices
- Baxter International: Medical Products
- Corning: Life Sciences
- Danaher: Life Sciences & Diagnostics
- Endo Health Solutions: AMS and HealthTronics
- GE Healthcare
- Hospira: Devices
- IDEX: Health & Science Technologies
- Johnson & Johnson: Medical Devices & Diagnostics
- Kimberly-Clark: Health Care
- Pall: Life Sciences

Europe

- Agfa HealthCare
- Bayer HealthCare: Medical Care
- Beiersdorf: Hansaplast
- Carl Zeiss Meditec
- Dräger: Medical
- Eckert & Ziegler: Medizintechnik
- Fresenius Kabi
- Halma: Health and Analysis
- Jenoptik: Medical
- Novartis: Alcon
- Philips Healthcare
- Quantel Medical
- Roche Diagnostics
- Sanofi: Genzyme Biosurgery
- SCA Svenska Cellulosa Aktiebolaget: Personal Care
- Sempermed
- Siemens Healthcare
- Smiths Medical



Acknowledgments

Project leadership

Gautam Jaggi and **Glen Giovannetti** once again acted as co-editors-in-chief for *Pulse of the industry*. Their strategic and thematic guidance were invaluable in the production of this report and they ensured that its entire content, from cover to cover, was clear and concise and properly touched upon each of the major themes that have been impacting the industry. Gautam also wrote the "Power to the patients" introductory article.

As the project manager for *Pulse of the industry*, **Jason Hillenbach** had responsibility for the entire content and quality of this publication. He also oversaw the analysis for much of the report's data and authored the "Industry performance" section.

Strategic direction

Special thanks to **Peter Arnold** (Senior Vice President of Innovation and Strategic Marketing, Kinetic Concepts, Inc.); **Arnaud Bernaert** (Senior Vice President, Mergers & Acquisitions, Philips Healthcare); **Nancy Briefs** (Chief Executive Officer, InfoBionic), **Jim Gilbert** (Senior Industry Executive, Welsh, Carson, Anderson & Stowe); **Jessica Hameline** (Senior Director, Corporate Strategy, Covidien); **Darrell Johnson** (Vice President, CRDM Marketing; Medtronic) and **Paul Thompson** (Vice President, IT Innovation, Medtronic) for their participation in a strategy development session for *Pulse of the industry*. They provided invaluable insights and firsthand experiences that were used as the foundation for the report's key themes and focus.

John Babitt and **Scott McGurl** provided strategic vision for this report and brought their years of experience to the identification and analysis of industry trends.

Data analysis

The research, collection and analysis of all financing, financial performance and M&A data was conducted by **Ulrike Trauth**, **Eva-Marie Hilgarth** and **Claudia Pantke**. **Chris Dumelle** assisted with data collection for several of the charts throughout the publication.

Samir Goncalves, **Jason Hillenbach, Ulrike Trauth** and **Kim Medland** conducted fact-checking and quality review of the numbers throughout the publication.

Writing and editing assistance

Russell Colton brought his incomparable skills as a copy editor and proofreader to this publication. His patience, hard work and attention to detail were unparalleled. **Richard Roback** applied his proofreading expertise throughout the report.

Design and layout

This publication would not look the way it does without the creativity of **Oliver Voigt**, who was the lead designer for the project. **David Eshenbaugh** and **Robert Fernandez** provided chart design. **Tom Varela** was the digital designer for ey.com.

Marketing and support

Public relations efforts related to the report and its launch were led by **Susan Jones**. **Greg Kelley** from the PR firm Feinstein Kean Healthcare served as an integral partner as well.

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