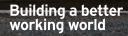
# In today's disruptive health care environment, how will medtech transform?

Pulse of the industry medical technology report 2022

The better the question. The better the answer. The better the world works.



# CONTENTS

Page

02

The year in review

#### Page

08

EY perspective

The ongoing innovation revolution in virtual and home-based care

# <sup>Page</sup>

Guest perspective

How medtech can thrive in a new era of home health care

# Page **12**

Guest perspective Reimagining medtech innovation for a wider stakeholder ecosystem <sup>Page</sup>

Guest perspective How digital transformation and personalization are reshaping the future of orthopedic medtech Page **18** 

EY perspective Next-generation medtech commercial models beyond COVID-19

#### Page

# 22

#### EY perspective

How medtech's supply chains will need to adapt to a new era in decoupling global trade

6 11

## 0 4 aus } \_D

Page 24

EY perspective

How health care worker shortages will continue to threaten medtech growth

# Page **26**

#### Databook

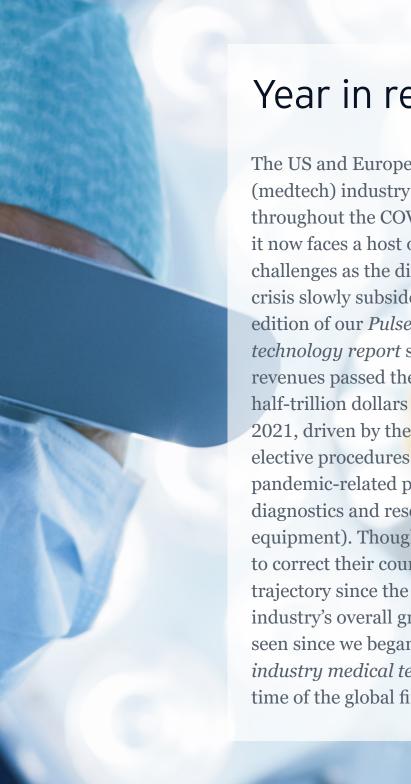
27 Financial performance 31 Financing 38 M&A 39 Data exhibit index

0000

Page



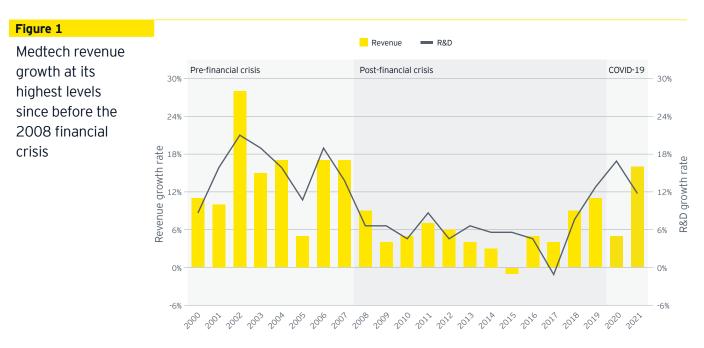
Acknowledgments



# Year in review

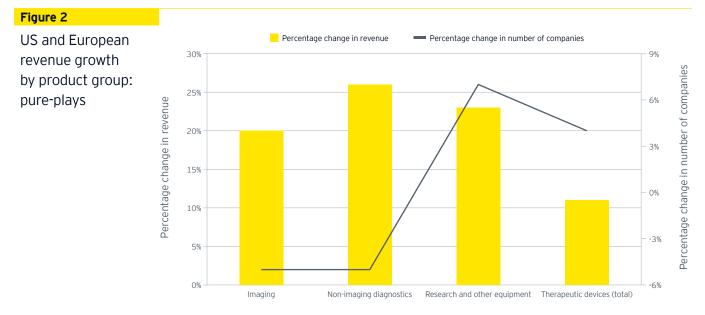
The US and European medical technology (medtech) industry has performed impressively throughout the COVID-19 pandemic, but it now faces a host of new and emerging challenges as the direct impact of the global crisis slowly subsides. As the 16th annual edition of our Pulse of the industry medical *technology report* shows, the industry's revenues passed the notable milestone of a half-trillion dollars for the first time ever in 2021, driven by the resumption of deferred elective procedures and ongoing sales of pandemic-related products (particularly diagnostics and research-related laboratory equipment). Though many medtechs have yet to correct their course on their revenue growth trajectory since the pandemic began, the industry's overall growth returned to levels not seen since we began publishing the *Pulse of the* industry medical technology report around the time of the global financial crisis in 2007.

But, as the business world continues adjusting to a new landscape that includes escalating regional and geopolitical conflicts, medtech must confront heightened business uncertainties, including persistent inflation and recessionary fears, the impact of continued lockdowns in certain geographies, ongoing global chip shortages and supply chain challenges, a constricted labor market, reduced investment in capital equipment from hospital systems experiencing increased financial pressures and a range of additional factors. The industry recorded 16% revenue growth in 2021 and a double-digit increase in R&D spending – a healthy sign of confidence in, and commitment to, its ability to keep innovating (see Figure 1). Whether medtech can sustain this impressive performance despite the challenges of 2022 remains to be seen.



Source: EY analysis, Capital IQ and company financial statement data. Data from public pure-play medtechs only.

The industry's revenue surge in 2021 extended across all product classes. Therapeutic devices – by far, the largest segment – grew 10%, with the five leading therapeutic areas (orthopedic, cardiovascular, dental, ophthalmic and women's health) all increasing their revenues by at least 16% as relatively normal clinical volumes resumed after a prolonged period of delayed and canceled procedures during the various peaks of the pandemic. The other three industry segments all recorded growth of over 20%, with non-imaging diagnostics leading them all, up 26% (see Figure 2). Consistently among the highest-performing segments in recent years, non-imaging diagnostics have attracted considerable attention as a potential enabler of precision medicine and remote care. However, the segment's robust performance in 2021 was largely driven by the huge global need for COVID-19 testing capacity. It is not yet clear whether the industry's outstanding performance in 2021 is a one-off impact of the pandemic or a secure basis for ongoing growth.

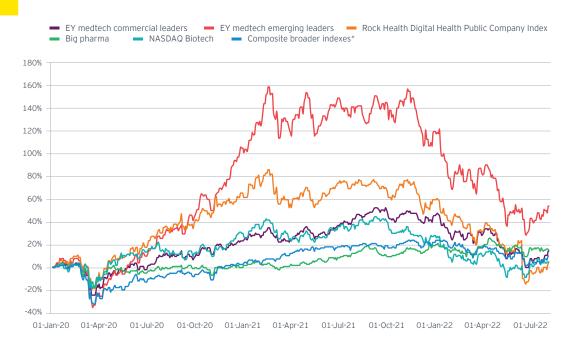


Source: EY analysis, Capital IQ and company financial statement data. Data from public pure-play medtechs only. Indeed, analysis of 2022 revenues to date suggests that medtech's growth is normalizing toward the historical average, rather than continuing the trajectory distorted by the pandemic. Companies with over US\$500 million revenue saw an average growth of 16% in 2021; however, the average increase dropped to over 6% in 2022.

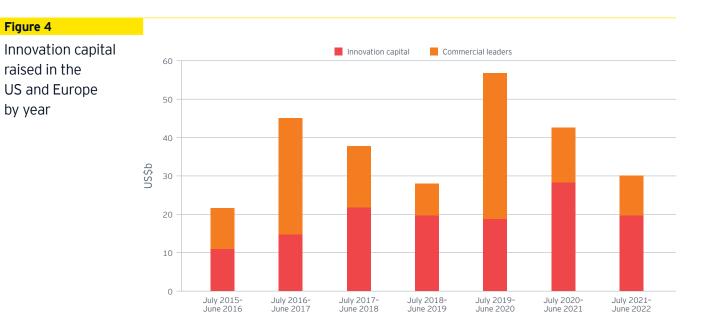
This is one indication that 2022 is presenting more challenging conditions for medtech. Another is the industry's stock performance, which peaked toward the end of 2021 (see Figure 3). At the start of 2022, medtech commercial leaders were up 47% on their composite stock price from the start of 2020, while noncommercial leaders were up 119%. By the end of July 2022, these figures had fallen to 14% and 54%, respectively, reflecting broader investor uncertainties amid heightening macroeconomic turmoil.

#### Figure 3

US and European medtech market capitalization relative to leading indexes



Source: EY Analysis and Capital IQ. Charts include companies that were active on 30 December 2021. \*Composite broader indexes refers to the daily average of leading US and European indexes: Russell 3000, Dow Jones Industrial Average, NYSE, S&P 500, CAC-40, DAX and FTSE 100. The 30% drop-off in total financing levels (which particularly impacts the smaller medtechs that drive innovation within the industry) also demonstrates how challenging the operating environment has become across the industry. Innovation capital (i.e., the capital raised by companies with less than US\$500 million in revenue) fell 35%, or nearly US\$10 billion, in the 12-month period ending 30 June 2022 (see Figure 4). In particular, the first six months of 2022 saw a rapid decline in the medtech IPO market. With special-purpose acquisition company (SPAC) deals significantly slowing and the largest venture capital investments going to late-stage financing rounds, smaller medtechs' access to the public markets looks far more constrained in 2022.



Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ. Innovation capital is the amount of capital raised by companies with revenues of less than US\$500 million.

This may increase the appeal of acquisition for smaller companies. However, after a period of sustained activity from the second half of 2020 through the whole of 2021, dealmaking has been somewhat muted in the first half of 2022. Overall, in the 12 months ending 30 June 2022, total M&A spend was up 24% on the previous 12 months, despite a 13% drop in the number of deals signed (252 compared to 288); however, that deal value was heavily concentrated in calendar 2021. John Babitt, Americas Medtech Transactions Leader, Ernst & Young LLP, anticipates that the reduced appetite for dealmaking may well continue into the new year: "Continued uncertainty in the overall financial markets continues to weigh on the M&A appetite; the overall medtech M&A and innovation ecosystem continues to remain intact, but near-term storm clouds are likely to pause transactions volumes into 2023." This slowdown, coupled with a tighter financing environment, represents a challenging operating environment for smaller medtechs.

While these metrics collectively indicate a less favorable environment for the industry in 2022, the medtech industry has demonstrated its resilience during the pandemic and will undoubtedly navigate upcoming challenges with agility. In the process, the industry will have to adapt to the changing world around it; below, we identify four key focus areas for medtech:

- Innovation. As digital technologies, data science and other fields continue to converge, the nature of medtech innovation is shifting. The industry needs to focus its innovation on new opportunities, including delivering personalized virtual care in the home and other nontraditional settings. To secure their place in the changing ecosystem, companies should prioritize using innovation as a disrupter before they are disrupted by their competitors.
- New commercial models. Catching up to other industries, medtech is increasingly connecting with its customer base via digital and other nontraditional channels, and the industry must build its omnichannel capabilities to engage in these ways.
- Supply chain transformation. The pandemic has accelerated efforts to increase supply chain resilience, including through localization and near-shoring, and medtechs will have to work with policymakers to design supply chain strategies for the future.
- Talent crisis. Recruitment, retention and engagement have become key issues for medtech, its customers and many other industries. Companies need to address this challenge by building a workforce that can deliver against their growth strategies. A fresh approach is also needed to support new types of innovation across data, AI and connected devices.

To gain deeper insights on where medtech has been and where it's headed, download the full *Pulse of the industry medical technology report*. There you'll find original perspectives on how medtech can rethink innovation to address new challenges and opportunities in commercial models, supply chain and talent management. These in-depth analyses include contributions from leading medtech executives, including Aldo Denti, Company Group Chairman of DePuy Synthes, who discusses how Johnson & Johnson's orthopedics company is taking a leading role in transforming this segment of medtech; Dan Starck, Executive Vice President (EVP) at Owens & Minor, one of the companies driving the home health care revolution; and Jason Ertel, Vice President of Engineering at Nottingham Spirk, who explores the shifting priorities for medtech innovation in the present era. In addition to these insights, the full report delivers a wealth of industry data on everything from financial performance to venture and other capital raised, M&A and R&D investment levels, Food and Drug Administration (FDA) approval trends and more, offering a comprehensive overview of the medtech industry in 2022 as it seeks to turn the challenges of disruption into opportunities for lasting transformation.



## Jim Welch

EY Global Medical Technology Leader, Ernst & Young LLP james.welch@ey.com

# The ongoing innovation revolution in virtual and home-based care



As we have highlighted over the past two years, the COVID-19 crisis has expedited health care's move away from traditional institutional channels toward home-based settings. This momentum continues in 2022, as indicated by, for example, recent moves by major drugstore chains in the US to acquire home health care platforms. As Dan Starck of Owens & Minor says in his guest perspective, "Home is the lowest-cost and preferred site of care for patients, and for companies across the health ecosystem, and home care is going to be the place to play in the future." It remains to be seen whether US and European policymakers will continue to maintain a regulatory and reimbursement environment that can support greater home-based care. The accelerated embrace of virtual care models was, in large part, a response to the disruption caused by COVID-19, and an open question remains over whether this shift will endure once the pandemic is firmly in the past. In August 2022, the Centers for Medicare & Medicaid Services (CMS) released a roadmap to end the officially ongoing public health emergency. After it ends, attention will then shift to whether (and if so, how long) the flexibilities and waivers permitted on an emergency basis will continue into 2023.

However, the past two years suggest that virtual, flexible care delivery offers benefits and improved outcomes beyond merely the ability to adapt to, and cope with, the extraordinary demands of the pandemic. Studies have shown that hospital-at-home programs can help establish a more immediate and consistent connection between patient and provider to stabilize or improve chronic conditions, prevent hospital readmission after discharge and mitigate the development of chronic conditions among relatively healthy patients. In addition, evidence shows that remote patient monitoring can reduce readmission rates, falls and adverse events while freeing up both hospital beds and health care professionals' time.

In response to the opportunities offered by these new care models, medtech companies have innovated to deliver better outcomes. improve access to underserved populations and increase detection of underdiagnosed diseases. For example, Sonavi Labs has developed an auditory device that can identify the presence of lung issues without an X-ray. "We can put it in the hands of people not very well trained medically and allow them to immediately determine whether this patient that they're seeing has pneumonia or doesn't," said Dr. llene Busch-Vishniac. Chief Innovation Officer, Sonavi Labs, in an interview with Ernst & Young LLP.

The industry's largest players have also taken note and made moves to boost their virtual care capabilities. One recent example is Medtronic's August 2022 deal with BioIntelliSense to build its remote monitoring capabilities, which the company says "will support continuous, connected care from in-hospital to home and expand our reach to help more patients in more places than ever before."<sup>1</sup> The industry must continue to embrace these opportunities. There are still issues to address beyond the regulatory and reimbursement questions, including inequitable access to the digital infrastructure (such as broadband) that is required to deliver virtual care effectively. But, working with providers, patients and policymakers, the industry can address these challenges and play a key role in innovating health care delivery in ways that offer better outcomes for all stakeholders. Medtech companies must build their capabilities to meet the patient and the provider where they are as health systems continue to evolve toward homecentered, interconnected, intelligent health ecosystems. As our guest perspectives from industry players (below) indicate, many medtech companies are now addressing these challenges around innovating for a new era of connected, customer-centered care.

<sup>1</sup> "Medtronic announces partnership with BioIntelliSense for exclusive U.S. distribution of multi-parameter wearable for continuous remote patient monitoring from in-hospital to home," *PR Newswire website*, https://www.prnewswire.com/news-releases/medtronic-announces-partnership-with-biointellisense-for-exclusive-us-distribution-of-multi-parameter-wearable-forcontinuous-remote-patient-monitoring-from-in-hospital-to-home-301615165.html, 31 August 2022.



**Dan Starck** EVP, Owens & Minor President, Patient Direct

# How medtech can thrive in a new era of home health care

As we all know, the pandemic has ushered in a new era in health care. Home is the lowest-cost and preferred site of care for patients, and for companies across the health ecosystem, and home care is going to be the place to play in the future.



This does not mean that the acute setting is going to go away for patients who need that level of care. But, aided by the pandemic, the hospital-at-home concept now has significant wind in its sails. There is both an increased desire for investment in home care and a growing number of people who want to work in home care. This is a key area of focus for industry leaders, particularly in light of the aging population in the United States and the inevitable rise in chronic disease that brings.

I joined Apria in 2012, and since we were acquired in March 2022, I have overseen the Patient Direct segment of Owens & Minor, which includes the legacy Apria Home Respiratory Therapy and Home Medical Equipment segment. The combination of these two businesses provides a very broad product line, supplying nearly every device that a chronic-care patient may need at home. Treating respiratory diseases at home has become more achievable over the last decade: We've seen technological advances as equipment becomes smaller, easier to use and more durable. We've also seen noninvasive ventilation, a highly effective therapy for the home, enter the scene.

I have witnessed how the pandemic significantly accelerated the shift toward home-based care. During its early stages, we saw patients deferring treatment because they did not want to be seen in an acute facility; moving the site of care helped to fill that void. We also witnessed the removal of regulatory and administrative barriers, enabling care to be delivered at home.

As we continue to emerge from the public health emergency, some care needs to return to the hospital setting – but, at the same time, stakeholders on all sides recognize that we should not simply try to return to business as usual overnight. That would cause chaos for hundreds of thousands of patients, including many who began treatment at home during the pandemic.

Conversely, if there were too many patients at home and too few clinicians to manage them, care would also be unmanageable. There is a care setting that's appropriate for each patient, depending on the severity and progression of their disease. The challenge is to find the right setting and maintain continuity of care. We are working with CMS and all of the relevant stakeholders to ensure that the pace of change is appropriate. To make ongoing home care possible, we need the right regulatory reimbursement environment, along with technology capabilities that enable us to maintain productivity in these care settings. Increasingly, powerful tech tools are available, from telehealth platforms to data analytics that allow stratification of patients by severity. Many companies are working on these areas of innovation, and I expect to see a big leap forward in both technology and data over the next five years. Already, we see companies investing in remote patient monitoring and data tools.

We have a very disparate, transactional health system at present, but, gradually, these areas of technological innovation are converging. Moving forward, it will be essential to bring these tools together so that whoever is managing the care has the full spectrum of all of the relevant services and data for the individual patient. Providing a comprehensive view can help put home-based care on a more secure footing as we seek to establish a post-pandemic approach that works for CMS, for the industry and for patients as well.



Jason Ertel Vice President of Engineering, Nottingham Spirk

# Reimagining medtech innovation for a wider stakeholder ecosystem

Since 2021, Ernst & Young LLP has teamed with Nottingham Spirk to create the EY-Nottingham Spirk Innovation Hub in Cleveland, Ohio.

At Nottingham Spirk, we're hitting our 50th year in business, and we've been involved in the medical device space for the last 15 years. I myself came to the company with over 20 years of experience in medical device development, and from that perspective, I've been able to see how Nottingham Spirk harnesses the value of insights to really approach innovation in a different way from how the industry traditionally works.



## **GUEST PERSPECTIVE**



When we take on a medtech project, we apply very strict criteria. We're seeking one-in-a-thousand, diamond-in-the-rough projects. If you are going to fundraise with confidence, you should be ready to put your own dollars on the table. In other words, if you want to convince someone else to invest, you also need to be convinced.

One of our recent success stories was TecTraum, which set out to be the first FDA-approved therapy for concussions. The IP is focused on cooling the blood that passes through the carotid triangle, which includes 90% of the blood that enters the brain. Our research showed that there is a gap in treatment options, with very little being done for patients over the first three days following a concussive event. We knew that cooling the blood that

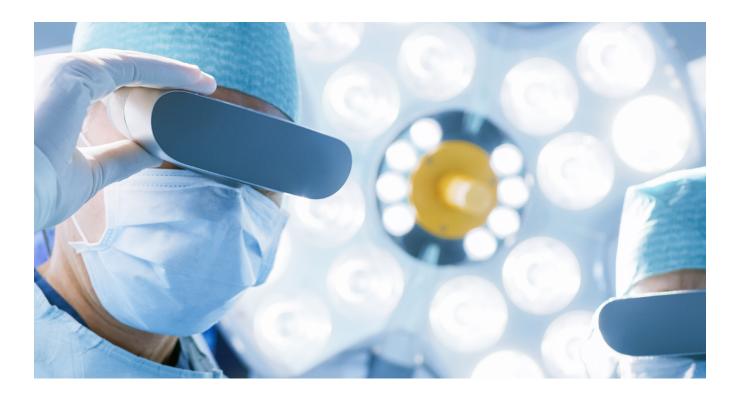
enters the brain could decrease the temperature of the brain and provide comfort if cooling was also applied to the forehead; we wanted to learn whether this therapy could reduce the clinical signs and symptoms associated with concussion, such as migraines, reduced cognition, loss of balance, vision impacts, anxiety and depression. Our pilot study showed unequivocally positive results, with the FDA acknowledging the value of our approach. Moreover, beyond this quantitative clinical success, patient feedback revealed that the product made people feel calm and relaxed. The former professional football players we worked with, for example, said that they felt amazing after using our therapy. Improving patient experience in this way is so important, and we could not ask for a stronger endorsement.

Sometimes, however, you don't see this type of resounding success immediately. Mixed results are not a very intriguing prospect, but realistically, that is often what you get. The challenge is determining what you can actually learn from the results and how to pivot from there to achieve an outstanding outcome. For larger companies, that process can be very difficult because they have to contend with shareholder pressure to demonstrate quick returns – if they don't produce value within a set period of time, they are deemed to have failed. By contrast, our process is to pivot and validate until we get on the right track. At that point, you can sprint. This approach is akin to navigating through treacherous waters to find a clear patch where the water is like glass, at which point you can engage the throttle.

With Sterifre Medical, a client partner of ours, we executed this kind of pivot. We looked at five different possible applications for Sterifre's technology, picked one and pursued it. Later, we found that it was not necessarily the right approach – the regulatory pathway was potentially too steep, the technical complexity was greater, and the potential market was smaller than we had estimated. At that point, we pivoted our approach and focused on using the technology to develop a point-of-care disinfection device. We validated this new approach. and now we have Environmental Protection Agency (EPA) registration for that product.

A major aspect of what we look for in technologies is the potential roadmap of ongoing innovation they offer. We do not want products to be one-hit wonders; we instead seek identifiable future adjacent innovations to pursue. Sterifre certainly fits that description since there's so much more we can do with that technology.

## **GUEST PERSPECTIVE**



# Designing for the wider ecosystem

From my experiences at Nottingham Spirk, I believe there are certain lessons for medtech as a whole. The industry needs to examine how it approaches innovation and must be willing to change processes where they can be improved. Often, this is a question of being honest with yourself and maintaining a spirit of humility such that you remain open to learning and evaluating questions from different perspectives.

For us, these different perspectives encompass not just the device we are designing, but also the wider ecosystem that surrounds medical device innovation. These ecosystem considerations are only going to grow in importance with the increased emphasis on home care. Aging in place, for example, is a hugely important area, where caregivers take on a heavy burden and need support. How can we design products that help us expand into delivering treatment in the home in a meaningful way? Some disease states are hard to manage outside of an acute care setting, and fields like behavioral health present significant challenges, but this is undoubtedly an important future trajectory for care. Studies have shown that being at home can reduce patients' stress and improve their outcomes. Medtechs need to help make home care a ubiquitous reality for patients.

Finally, it's also important to consider the question of cost. If you prioritize commercializing your IP above all else, regardless of the level of engineering (or overengineering) involved, you may reach the market before your competitors. But we believe that the real challenge is in making innovation work, not at any cost, but at the right cost. We need to take the end user into account, whether that be the patient, the caregiver or the parents who care for their children or parents. What will your device cost them, and what will it cost the providers who serve them? As health care expenditures rise globally, companies should be mindful of these questions in their approach to innovation.



Aldo Denti Company Group Chairman, DePuy Synthes, The Orthopaedics Company of Johnson & Johnson

# How digital transformation and personalization are reshaping the future of orthopedic medtech

The orthopedics playbook of the last 20 years is rapidly being rewritten as the field approaches a major inflection point. At DePuy Synthes, one of the oldest orthopedics companies in the world and a trusted brand among surgeons around the world for more than 125 years, we intend to play a leadership role in this evolution.



15 | Pulse of the industry 2022

Our portfolio of specialized solutions includes digitally assisted surgery, joint reconstruction, trauma, spine, biologics, craniomaxillofacial (CMF) and sports medicine - all delivering state-of-the-art orthopedic care to patients, along with providers and surgeons. As the leader in orthopedics, we are committed to a world where patients have access to care that is personalized and connected. Together with our customers, we are shaping the future of health care with technically and clinically advanced innovations that create value for the global health care system.

To accelerate the change curve and deliver meaningful innovation. we are focused on digital transformation – bringing the tech to medtech in orthopedics. Over the past several years, we have seen a faster shift toward greater adoption of digital technologies and data tools in our field – not just in the OR suite, but also along the entire patient journey and in medtech education. We are leaning into this acceleration with the aim of leveraging the power of digital tools and data to help enable more personalized, efficient, and effective patient care and provider education.

For example, robotic-assisted surgical solutions – like our VELYS Robotic-Assisted Solution, a first-ofits-kind solution currently approved for use in knee surgery – are transforming the possibilities for orthopedic surgery and have the potential to help surgeons improve care and outcomes for patients. In addition to our robotics platform, we are working on next-gen digital solutions to help optimize additional types of orthopedic surgeries.



It's worth noting that the capabilities of these new tools are not limited to the equipment itself. Take our VELYS Hip Navigation solution, which has enabled more than 75,000 hip procedures worldwide. The potential of the system is not only what it offers surgeons within the operating room, but also the tools it provides to build connections across the end-to-end patient journey. VELYS Insights, also part of the platform, provides data visualizations for surgeons, while the companion app VELYS Patient Path can help prepare patients for the procedure. Ultimately, our vision is that systems like VELYS form the cornerstone of a new and holistic digital surgery ecosystem with the potential to improve outcomes, drive greater efficiencies, and enable more collaboration and personalization of care to the patient's specific needs.

DePuy Synthes also is transforming the way we train and educate surgeons and their OR support staff on the use of our products, leveraging the power of technology to revolutionize the way our customers learn. We call it "EdTech," and it's making a huge difference in professional medical education. Today, our programs use virtual reality (VR) to help train surgeons and OR staff on medtech procedures, like robotics. With VR modules that span across all of our orthopedic specialties, doctors can now practice a procedure virtually using a VR headset and use the system's data capabilities to improve their technique and measure their progress – all from the comfort of their own home or office. It sounds like science fiction, but it's reality. Since 2021, we have trained more than 25,000 health care professionals globally with these tools and have received overwhelmingly positive feedback.

We believe that these kinds of advances in medtech will deliver better value for orthopedic patients, surgeons and hospitals. As we continue to invest in the next generation of orthopedic surgery innovation, we are confident that we can deliver a more connected. personalized health experience that is driven by data and helps deliver measurably improved outcomes. Ultimately, these advances will revolutionize how patients are treated and will catapult us into the next chapter in the history of the orthopedics field.

# Next-generation medtech commercial models beyond COVID-19



The COVID-19 pandemic has significantly changed the commercial landscape for medtech. Many of the issues it caused — such as reduced customer access, new regulatory guidance and product shortages — are likely to be long-lasting. However, many medtech companies had recognized the need to change their traditional commercial model long before the pandemic. Though the pandemic posed many challenges to medtech, it also forced the industry to experiment in new ways and at a much faster pace. As a result, medtech companies were able to demonstrate successes with alternative commercial approaches. Most medtech leaders agree that they should not revert back to the old models as the pandemic wanes. Instead, many expect to continue adapting or transforming their commercial models to be more customer-centric, value-driven and digital-enabled.



# Increasing customer centricity

The medtech industry started the shift from a product-centric model to a customer-centric model many years ago. However, the industry is still in the early stages of developing customer centricity. Traditionally, the medtech industry has been heavily product- and sales-driven. The commercial strategy and tactics are centered on customer buying processes, with the primary focus on hunting sales and closing contracts. Leading medtech companies have realized that the sales-driven approach has resulted in customer relationships that are both highly transactional and vulnerable to pricing pressures. Forwardlooking leaders are now making several concrete changes in their commercial approaches to increase customer centricity.

#### Redefining target customers to engage stakeholders throughout the care continuum

The pandemic accelerated the shift of care delivery from hospitals to alternate sites, such as ambulatory surgical centers, outpatient clinics, home-based care and remote care. This shift is pushing medtech companies to redefine their customer base and offer new products and customer engagement models. Several medtech companies have stood up dedicated commercial organizations for selected non-acute care segments with tailored go-tomarket approaches.

#### Expanding to improve customer experience across the end-to-end journey

Traditionally, companies have focused their commercial approach on sales and marketing. Leading medtech companies are expanding their commercial focus to deliver differentiated experiences across the entire customer journey. These companies started their commercial model transformation by conducting in-depth customer research, developing actionable customer segmentation and then applying a zero-based approach to redesign the future state end-to-end customer engagement model. This redesign applies across all touch points: from awareness to purchase to loyalty and advocacy.

#### Shifting from a product-focused selling approach to one centered on customer issues

With the unprecedented financial challenges caused by the pandemic, hospitals are less likely to make purchase decisions based on product features. Forward-looking companies have seen the need to move away from the traditional feature- or price-based sales model to a diseaseor procedure-based model. These companies have invested in diseasespecific evidence and equipped their sales teams to communicate diseasefocused messages. Although these efforts were slowed down by the pandemic in some cases, companies are now seeing promising results and expanding the application of the disease-focused selling approach to the rest of their portfolio.

## Continued transition to value-driven commercial models

The health care industry will continue to shift from fee-forservice models toward value-basedcare models. With the increased financial and operational challenges caused by the pandemic, hospital executives are looking for partners who understand their business, proactively offer new ideas, and are agile and flexible in tailoring their engagement models. Medtechs have a unique opportunity to become true partners to hospitals and deliver value beyond the products they supply. Leading medtech companies are making several changes to their commercial processes to be more value-driven.



#### Better customer value propositions

Leading medtech companies are upgrading their business processes by moving value proposition definition upstream before product development. Additionally, companies are establishing more robust and consistent value proposition development processes to create holistic value propositions that are relevant to customers across clinical, operational, economic, experiential and social dimensions.

#### Implementing value-based pricing

Value-based pricing, a strategy to set prices based on customer-perceived value, is widely recognized across industries as an effective approach to achieve increased profitability and sustained success. With disruptive product shortages and inflation caused by the pandemic, medtech companies have realized the need for value-based pricing and started building these capabilities to both drive profitable growth and better communicate the value story. Meanwhile, pioneering companies are investing in market access, health economics and outcomes research. and medical affairs capabilities to enable better value demonstration.

### **EY PERSPECTIVE**

## Enabling customers to achieve desired value

In a value-driven partnership, a medtech company's success is inherently intertwined with that of its customers. If hospitals succeed through using a medtech product, they will continue using it, leveraging more of it and paying a premium for it. Customer success has emerged in the medtech industry in recent years and has gained further acceptance during the pandemic. Several medtechs have deployed a customer success function to drive improved customer retention, higher revenue, increased crossselling and upselling opportunities and lower cost to serve. Ultimately, these improvements deliver higher customer lifetime value.

#### Guaranteeing value and outcome

Increased financial pressure and value-based reimbursement models mean hospitals are more open and willing to engage in value-based discussions with medtechs. Increasingly, large and multiyear partnership deals between medtechs and hospitals are including a risk-sharing component. Forward-looking companies have rolled out different value-based offerings to differentiate themselves from their competitors and protect against continued price erosion.



### Digital-enabled omnichannel model

Digital engagement in medtech is not a new concept, but it has struggled to take off. The pandemic has clearly accelerated the sector's shift toward digital approaches, and the next wave of digital commercial transformation will go beyond embedding digital into end-to-end customer engagement. Instead, it will see medtechs orchestrating a seamless and integrated omnichannel model that delivers a meaningfully differentiated customer experience.

## Digital for efficiency and cost saving

Before the pandemic, companies started exploring digital enablement as a means to drive commercial efficiency for low-priority customers or less differentiated products. Most companies were doubtful about the effectiveness of digital engagement for clinical customers, such as surgeons and oncologists, or for complex systems, such as large health systems or integrated delivery networks. During the pandemic, digital engagement became a necessity with the abrupt shift to virtual models driven by the requirement for social distancing. Many medtech commercial executives realized the additional benefits that a digital commercial model can provide beyond cost efficiency.

### **EY PERSPECTIVE**

## 66

The COVID-19 crisis is a great illustration of how quickly companies can adapt their commercial model when circumstances require it and how reluctant they are to proactively evolve their commercial model in normal times. The pandemic will eventually end, but customers and markets will continue to change. Medtech commercial leaders need to build on what they have achieved in the past two years and continuously innovate and activate flexible commercial models for their changing customers.

#### Jay Zhu

EY-Parthenon Principal, Strategy and Transactions, Ernst & Young LLP

#### **Digital-first**

Given the success of digital engagement during the pandemic, companies are now prioritizing digital content and digital engagement to deliver a digital-first approach for their customer engagement model. However, most medtech companies are still deploying multiple channels, including in-person visits, virtual calls, events, print, TV, email, social media, search engine optimization (SEO) and e-commerce, in a siloed, inconsistent way. Each channel in this multichannel model works individually and does not create an integrated experience for customers.

#### Orchestrated omnichannel engagement

It is widely agreed by many medtech executives that digital customer engagement will remain a critical element of their commercial model after the pandemic. Therefore, merely having a digital-enabled commercial model is unlikely to create meaningful differentiation after the pandemic. The future winners will be those who leap from a multichannel model to an omnichannel model that provides customers with a personalized, connected, seamless and unified experience across the entire customer journey. To design and deploy an effective omnichannel engagement model, commercial leaders need to break down the functional silos among marketing, sales, market access and customer service teams. In this way, they can design a unified omnichannel engagement strategy that blends human support, automation and self-service for every customer touch point along the journey.

The medtech industry has responded and adapted strongly to the challenges created by the pandemic in the past two years. The trends toward more customer-centric, value-driven and digital-enabled commercial models will continue after the dust settles. Redefining and optimizing the commercial model will be a key consideration for medtech leaders over the next several years. The time to act is now. And those who get it right sooner will be able to deliver unparalleled customer value and be rewarded with superior growth and profitability.

# How medtech's supply chains will need to adapt to a new era in decoupling global trade



Since 2020, supply chain resilience has been a major focus for medtech and other industries. The COVID-19 pandemic put intense pressure on global supply networks as demand spiked for key equipment, such as diagnostic reagents, personal protective equipment and ventilator components. Although the world is adapting to the challenges that the pandemic brought, the supply chain issues for medtech have not abated. Inflationary pressures continue to drive up the prices of the raw materials that the industry needs, while medtech simultaneously faces rising freight costs and shortages of key electronic components.

Notable among these components are semiconductor chips, which are required for medical devices ranging from imaging and diagnostic systems to patient monitoring devices and life-saving implants, robotic surgical systems and other hospital technologies. In a November 2021 communication to the Department of Commerce, industry advocacy group AdvaMed noted that medtech constitutes less than 1% of the total semiconductor chip market, but that many companies and their products are heavily reliant on chip supply. AdvaMed concluded that "it is critical that policymakers and chip supply chain partners work together to ensure that delivery of health care in America is not disrupted in the near term."2

Indeed, closer collaboration between policymakers and the industry will likely help medtech supply chains operate with continuity in the near future. Governments demonstrated during the COVID-19 crisis that they are increasingly willing to intervene in supply chain operations to enable greater resilience around local supplies. In the US, the Biden administration likewise published a yearlong review of public health supply chains in February 2022,

affirming its efforts to secure national supply chains, while the EU has pursued similar initiatives. As global tensions continue to increase, deeper interventions from policymakers can be expected. The last two years have seen a growing emphasis on regional self-sufficiency and an unwinding of the structures of globalization (such as the increasing marginalization of the World Trade Organization), all of which began before 2020 but accelerated during the pandemic. As such, today's fully globalized supply chain models may well give way to more hybrid models in the near future.

What this means for medtech remains to be seen. An increase in localization is one major possibility. Moves toward building a local footprint in key overseas markets could also become necessary for medtechs seeking to ensure ongoing market access.

Ultimately, the reimagined medtech supply chains of the near future likely will not involve full localization; more probable is that the industry and its stakeholders will develop hybrid models, with a mix of global and regional sites. For example, a hub-and-spoke supply chain model would see companies build regional spokes with some manufacturing and distribution capacity while other functions remain centered on a global hub. Other approaches could see companies working together (local antitrust regulations permitting) to set up joint manufacturing or warehousing operations. The industry will also likely focus on improving supply chain transparency, leveraging digital technologies and data analytics to increase end-to-end visibility across operations.

Whatever approaches the industry takes, it will need to work closely with policymakers and other stakeholders to enable the emerging supply chain models of the future to meet local and global needs while remaining financially sustainable for medtech companies. As AdvaMed noted in its communication to the Department of Commerce, medtech "is undeniably a critical sector that supports our national security,"<sup>3</sup> and governments will need to collaborate closely with the industry to empower the sector to continue fulfilling that vital strategic role.4



<sup>2,3</sup> AdvaMed, "AdvaMed Response to the Department of Commerce's Request for Public Comments on Risks in the Semiconductor Supply Chain," November 2021.
<sup>4</sup> EY, "Pharma supply chains of the future," July 2022.

# How health care worker shortages will continue to threaten medtech growth



In 2021, we saw medtech revenues rebound in part because deferred elective procedures resumed in the wake of major disruption from the initial waves of the COVID-19 pandemic. However, the industry now faces a longer-term challenge, with the capacity of health care systems to maintain procedure volumes hit by increasing workforce shortages. In part, the growing concerns about staffing recruitment and retention within health care reflect the broader societal trend that economists have styled the Great Resignation or the Great Attrition, with a reported mass exodus of employees from many industries. Yet, health care has its own specific problems, with clinicians suffering burnout after two years on the front lines of the pandemic and a reported shortage of future talent in the nursing school and medical school pipelines.

"In the early days of the pandemic, yes, there was impact on hospital capacity, but you also had patients that were just concerned about coming into the system and they stayed away," noted Michael Mussallem, CEO of Edwards Lifesciences, during a July earnings call. "We feel like patients are entering the system now and are queued up to go through and there's just a lack of capacity in hospitals, in some cases, to handle all the patients. And so that care is being postponed."<sup>5</sup> In addition, many predict further workforce issues. For example, the US Surgeon General recently pointed to a projected shortage of more than 3 million low-wage health workers in the next five years.<sup>6</sup> Half a million registered nurses are expected to retire this calendar year, and by one estimate, there will be a shortage of up to 124,000 physicians by 2034.<sup>7</sup>

One of the key issues for medtech is that these looming shortages translate into escalating costs for hospital systems – and these costs are likely to take a toll on device procurement patterns. In 2020, the first year of the pandemic, average wages for health care workers rose by 5%.<sup>8</sup> With shortages driving increased demand, the cost of maintaining staffing levels is soaring.

Already, there are indications that the pressure on hospital systems' budgeting is leading to a reluctance to invest in capital equipment, with some analyses suggesting that providers are exploring the option of leasing or renting equipment rather than buying it outright. If provider systems continue to suffer from talent-related cash constraints, the downstream impact on medtech could become significant in the near future.

Health system executives need to

focus on employee engagement and culture in the short term while developing new care models to attract and retain workers in the longer term.9 As they look for longerterm solutions, health systems will also be re-evaluating where digital tools and automation can help reduce the burden on the workforce so that clinicians can practice at the top of their training. Ineffective onboarding also can be a pain point for worker retention, so health systems should be looking to improve those experiences, along with the ongoing support they provide.

As health systems continue to tackle these staffing issues, medtechs also need to think about how they fit into these shifting models and programs – and how they can offer support and mutual assistance to their ecosystem partners.

<sup>&</sup>lt;sup>5</sup> Edwards Lifesciences, "Q2 2022 Edwards Lifesciences Earnings Conference Call," July 2022.

<sup>&</sup>lt;sup>6</sup> "New Surgeon General Advisory Sounds Alarm on Health Worker Burnout and Resignation," U.S. Department of Health & Human Services website, https://www.hhs.gov/about/ news/2022/05/23/new-surgeon-general-advisory-sounds-alarm-on-health-worker-burnout-and-resignation.html, 23 May 2022.

<sup>&</sup>lt;sup>7</sup> "AAMC Report Reinforces Mounting Physician Shortage," Association of American Medical Colleges website, https://www.aamc.org/news-insights/press-releases/aamc-report-reinforcesmounting-physician-shortage, 11 June 2021.

<sup>&</sup>lt;sup>8</sup> "US Health Care Workforce Changes During the First and Second Years of the COVID-19 Pandemic," JAMA Network website, https://jamanetwork.com/journals/jama-health-forum/ fullarticle/2789521, 25 February 2022.

<sup>&</sup>lt;sup>9</sup> EY, "How health systems can navigate the Great Resignation," October 2021.



# DATABOOK



## Medical technology at a glance (US\$b)

	2021	2020	Change	% change
Public data company				
Total revenue	\$522.5	\$450.8	\$71.7	16%
Conglomerates	\$202.5	\$174.4	\$28.1	16%
Pure-play companies	\$320.0	\$276.4	\$43.5	16%
Commercial leaders	\$296.8	\$255.9	\$40.9	16%
Emerging leaders	\$23.1	\$20.5	\$2.7	13%
R&D expense	\$28.0	\$25.0	\$3.0	12%
SG&A expense	\$100.9	\$89.5	\$11.3	13%
Net income	\$41.0	\$26.7	\$14.3	53%
Market capitalization	\$2,184.6	\$1,857.4	\$327.2	18%
Number of employees	1,064,900	958,900	106,000	11%
Number of public companies	455	443	12	3%

Source: EY analysis, Capital IQ 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 31 December 2021 and 31 December 2020.

#### Figure 2

## US and EU medtech public company revenues



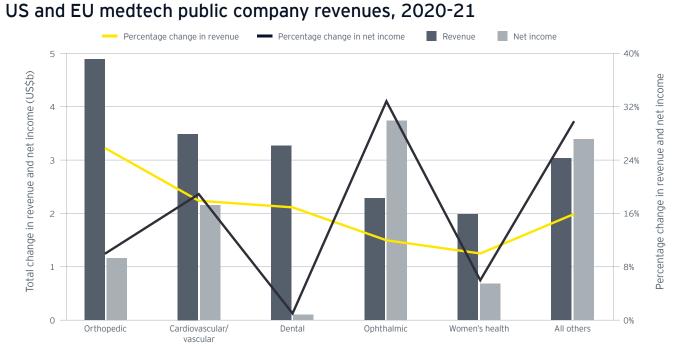
Source: EY analysis and Capital IQ. Commercial leaders are companies with revenues at or above US\$500 million. Other companies include figures for conglomerates.

- The industry's 16% growth rate in 2021 represented the fifth consecutive year of growth and a huge increase over the 6% that was recorded in 2020, with every segment of the industry performing strongly, including pure-plays (both commercial leaders (16% vs. 5%) and emerging leaders (13% vs. 10%)) and conglomerates (16% vs. 8%); in all, nearly 70% of conglomerates and 80% of pure-play (92% of commercial leaders and 78% of emerging leaders) medtechs grew their annual revenues.
- US-based medtech companies increased their revenue by 20% and European companies by 11%. The commercial leader group has almost doubled its revenues since 2013 and now consists of 73 companies, with four joining in 2021 (Maravai LifeSciences, Novocure, Repligen and Tandem Diabetes Care).
- Conglomerate Abbott (including its Diagnostics and Medical Devices divisions) took the honors for the biggest overall top-line increase, up US\$7.4 billion (33%), which was primarily driven by its Rapid Diagnostics business, while Thermo Fisher Scientific was a close second, adding US\$7 billion (22%) to

The industry's **16%** growth rate in 2021 represented the fifth consecutive year of growth.

its revenues; in all, 14 companies increased their top line by over US\$1 billion. However, this top-line growth did not universally translate into profit growth, as only 50% of companies grew their bottom line.

 Companies continued to invest in future growth, with 71% increasing their R&D spending (10 companies increased that spend by over US\$100 million); despite the war for talent, 77% of medtechs managed to increase their headcount, with 22 companies adding 1,000 or more new employees.



#### Figure 3

Source: EY analysis, Capital IQ and company financial statement data. Data shown for pure-play companies only.

### US and European medtech commercial leaders spending trend, 2010-21



- In 2021, commercial leaders launched US\$84.3 billion in capital across R&D, M&As and cash deployed to shareholders. The industry spent well above average (taking the mean from the past decade) on every one of these three activities, indicating high levels of capitalization in the sector.
- Commercial leaders directed US\$22.2 billion toward R&D, well above the past-decade average of US\$13.3 billion and up 16% on the previous year, in a positive sign of the industry's commitment to its long-term organic innovation. However, a larger share of the industry's growth capital (US\$39.3 billion) was directed toward M&A dealmaking, with inorganic growth still playing a key role in industry strategy. With dealmaking constrained by the pandemic in 2020, only US\$3.6 billion in M&A transactions was completed in the 2020 to 2021 period. The following period (2021 to 2022) saw a surge of 995%, with the total comfortably surpassing the past-decade average of US\$25.4 billion.
- The industry returned US\$22.8 billion to shareholders in the form of dividends and stock buybacks, slightly more than it deployed on R&D. This represented a 42% increase over the period from 2020 to 2021 and was again higher than the past-decade average (US\$15.5 billion). In its current cash-rich state, medtech could be expected to deploy more capital to each of these goals moving forward.



## US FDA medical device approvals (2013-H1 2022)

Source: 2022 data through the end of June; FDA website.

Figure 5

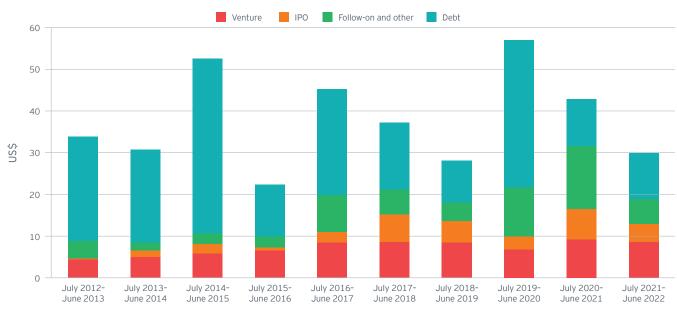
2022 is on track to see the highest number of US FDA 510(k) clearances in a decade.

- In addition, 2022 is on track to see the highest number of US FDA 510(k) clearances in a decade, with over 1,800 approvals in the first six months of the year, compared to just under 3,000 for all of 2021 which was just slightly below the average for the previous decade.
- This surge in 510(k) approvals is likely the result of the FDA's Center for Devices and Radiological Health (CDRH) negotiations around a backlog of filings that had accumulated over the course of 2020 and 2021 due to the huge increase in pandemic-related submissions prioritized by the agency, including emergency use authorizations for COVID-19 diagnostics.
- The number of pre-market approvals (PMAs) was also relatively low in 2021, with just 31 approved in total; 2022 is on course to see an even lower number of PMAs, though some industry leaders are hopeful that the recent 510(k) surge will be replicated for PMAs in the second half of the year as the industry works through the pandemic-driven backlog.

# Financing

Figure 6

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



Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ. Private investments in public equity (PIPEs) included in "follow-on and other."

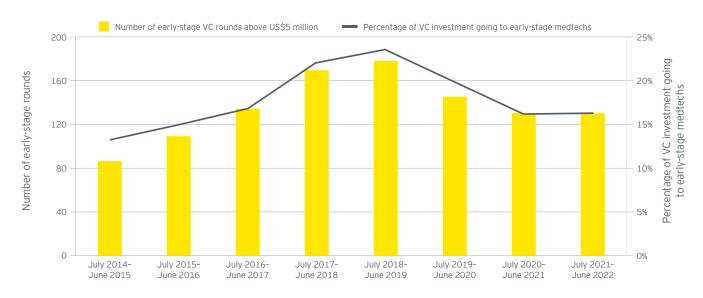
#### Figure 7

## Innovation capital raised in the US and Europe by year



Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ. Innovation capital is the amount of capital raised by companies with revenues of less than US\$500 million.

- The total capital raised by the industry dropped for the second consecutive year, falling 30% from the previous period to US\$30 billion, and well below the past-decade annual average of US\$38.8 billion during the previous decade. However, these headline figures conceal an important bifurcation, with financing levels dropping sharply in the second half of the 12-month period (the first six months of 2022) as public markets tightened; indeed, around 70% of the total raised came in the first half of the period, including 49% in the first quarter alone.
- In all, innovation capital (i.e., capital raised by companies with under US\$500 million in revenue) fell by 35% (nearly US\$10 billion) to US\$18.6 billion, with commercial leader capital falling by 20%. Among the four financing vehicles available to the sector, debt saw the smallest decline, dropping only 0.5% to US\$11.1 billion. Equity financing (i.e., financing methods exclusive of debt) fell 40% to US\$18.9 billion, with follow-on public offerings dropping 61% and the IPO market declining 39% from a very strong performance during the previous 12 months.
- Venture financing's decrease of 7% should be seen in context: the previous 12 months represented the most venture capital (VC) ever raised by the industry. In all, medtech raised US\$8.5 billion in venture funding in the 2021 to 2022 period, which was the second-highest amount generated in the past decade. Private equity (PE) capital markets have remained receptive to medtech, investing in earlier-stage companies, as well as safer bets. There are some indications that certain credit and equity PE players have also chosen to extend preferential terms to medtechs that are willing to incorporate environmental, social and governance (ESG) programs into their strategies, underscoring the growing significance of sustainability as part of the industry's value proposition.



### US and European early-stage VC rounds > US \$5 million

Source: EY analysis, Dow Jones VentureSource and Capital IQ. Early-stage rounds are seed-, first- and second-round VC investments.

### Top venture rounds, July 2021-June 2022

Company	Region	Product type (disease)	Gross raised (US\$m)	Quarter	Round type
Ultima Genomics	Northern California	Research and other equipment	600	Q2 2022	Early stage
Imperative Care	Northern California	Therapeutic devices (cardiovascular/vascular)	260	Q3 2021	Late stage
Exo Imaging	Northern California	Imaging	220	Q3 2021	Late stage
Enable Injections	Ohio	Therapeutic devices (non-disease specific)	215	Q1 2022	Late stage
Neuralink	Northern California	Therapeutic devices (neurology)	205	Q3 2021	Late stage
Opentrons Labworks	New York	Research and other equipment	200	Q3 2021	Late stage
MindMaze	Switzerland	Therapeutic devices (neurology)	125	Q4 2021	Late stage
ApiJect Systems	Connecticut	Therapeutic devices (non-disease specific)	111	Q2 2022	Early stage
MindMaze	Switzerland	Therapeutic devices (neurology)	105	Q1 2022	Late stage
Nalu Medical	Southern California	Therapeutic devices (neurology)	104	Q1 2022	Early stage
InBrace	Southern California	Therapeutic devices (dental)	102	Q3 2021	Late stage
Impulse Dynamics	Netherlands Antilles	Therapeutic devices (cardiovascular/vascular)	101	Q2 2022	Late stage
Vero Biotech	Georgia	Therapeutic devices (pulmonary)	100	Q4 2021	Late stage
Color Health	Northern California	Non-imaging diagnostics	100	Q4 2021	Late stage
MeMed Diagnostics	Israel	Non-imaging diagnostics	93	Q1 2022	Late stage
Distalmotion	Switzerland	Therapeutic devices (non-disease specific)	90	Q1 2022	Late stage
RefleXion Medical	Northern California	Therapeutic devices (oncology)	80	Q1 2022	Late stage

Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.

- Around 36% of the US\$8.5 billion in venture capital raised during the 2021 to 2022 period came from early-stage funding rounds, in line with the average of 35% from the previous decade and up from 29% the previous year. The vast majority of the largest venture rounds of the 12-month period went to late-stage companies with a few exceptions, including Ultima Genomics, which raised US\$600 million to enable it to scale up its genome-sequencing products.
- Neurology-focused medtechs were heavily represented among the top venture targets, with four of the biggest 10 rounds going to companies in this space. These included brain-chip startup Neuralink, cofounded by Elon Musk and backed by investors such as Alphabet; MindMaze, focused on providing game-like tools and therapies for rehabilitation and treatment of neurodegeneration and neural injuries; and Nalu Medical, which has developed an electrical neurostimulation system to treat pain.
- Other companies with notable fundraising rounds included the drug-delivery company Enable Injections, which developed a Sanofi-backed wearable subcutaneous drug delivery system; ApiJect Systems, which received a US\$590 million loan from the U.S. International Development Finance Corporation during the pandemic to manufacture up to 3 billion prefilled syringes; Exo Imaging, which developed a handheld ultrasound device using AI to help triage cardiac patients; and Distalmotion's development of a laparoscopic surgical robot.

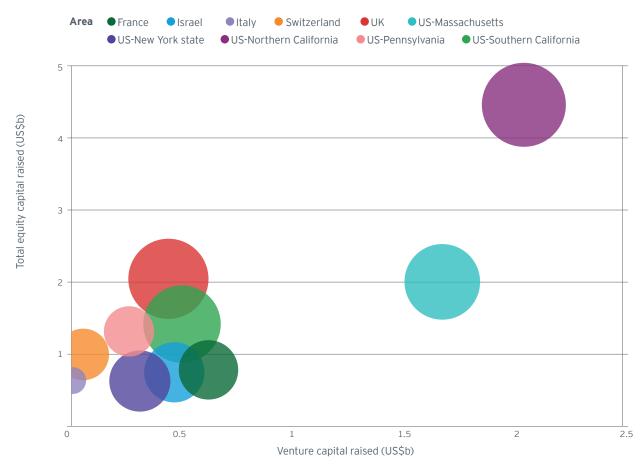
## Top IPOs, July 2021-June 2022

Company	Ticker	Region	Product type (disease)	Gross raised (US\$m)	Quarter
Oxford Nanopore Technologies	ONT	UK	Research and other equipment	814	Q3 2021
Stevanato Group	STVN	Italy	Therapeutic devices (non-disease specific)	693	Q3 2021
Medmix	MEDX	Switzerland	Therapeutic devices (multiple)	341	Q3 2021
Sight Sciences	SGHT	Northern California	Therapeutic devices (ophthalmic)	276	Q3 2021
SOPHIA GENETICS	SOPH	Switzerland	Research and other equipment	234	Q3 2021
Cue Health	HLTH	Southern California	Non-imaging diagnostics	200	Q3 2021
Cytek Biosciences	СТКВ	Northern California	Research and other equipment	200	Q3 2021
PROCEPT BioRobotics	PRCT	Northern California	Therapeutic devices (urology)	189	Q3 2021
Rapid Micro Biosystems	RPID	Massachusetts	Research and other equipment	180	Q3 2021
Paragon 28	FNA	Colorado	Therapeutic devices (orthopedic)	144	Q4 2021
RxSight	RXST	Southern California	Therapeutic devices (ophthalmic)	132	Q3 2021
IsoPlexis	ISO	Connecticut	Research and other equipment	125	Q4 2021
Modulight	MODU	Finland	Therapeutic devices (multiple)	106	Q3 2021
Sonendo	SONX	Southern California	Therapeutic devices (dental)	94	Q4 2021
ONWARD Medical	ONWD	Netherlands	Therapeutic devices (orthopedic)	88	Q4 2021

Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.

- The IPO market raised US\$4.4 billion in the period from 2021 to 2022, comfortably above the US\$3.3 billion average during the previous decade. However, almost all of this capital was raised in the first half of the year, with the first six months of 2022 adding only US\$76 million to the total. In all, 98% of IPO value was generated in the first half of the period (79% in the first quarter alone). All of the top nine IPOs over the 12-month period were executed in 2021.
- With the medtech IPO market slipping from the record heights it hit in 2021, it appears that many companies are seeking to raise more private capital and establish a growth trajectory before seeking to go public, with an eye toward building more robust clinical and commercial validation. However, the proposed spinoff of GE Healthcare as an independent company in 2023 is likely to massively boost IPO value in the sector; the Siemens Healthineers spinout in March 2018 remains one of the largest IPOs of all time across the health care sector.
- Activity in the special-purpose acquisition company (SPAC) market also dropped sharply, likely due in large part to the underwhelming performance of many of the companies that recently took the SPAC pathway to the public markets. However, one-off moves (such as Orchestra Biomedical's SPAC deal in July 2022, backed by investors, including Medtronic) indicate that, although SPACs have lost their appeal for many medtechs, they remain a potential option for some.
- European companies accounted for 55% of the total IPO funding, including the three largest deals, which saw Oxford University spinoff Oxford Nanopore Technologies complete a US\$814 million IPO; Stevenato, the Italian end-to-end provider of products, processes and services, raised US\$693 million; and Switzerland-based Medmix, a manufacturer of high-precision delivery devices, garnered US\$341 million.
- The largest US-based IPO was completed by Sight Sciences, an ophthalmic device company, which raised US\$276 million; other US IPOs included SOPHiA GENETICS, which markets a cloud-based, software-as-a-service (SaaS) analytics platform (raised US\$234 million), and Cue Health, a diagnostics company that rose to prominence for its COVID-19 test kits, which received emergency use authorization. That company successfully completed a US\$200 million IPO.

# Capital raised by leading US and European regions, excluding debt, July 2021–June 2022



Source: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.

- California continued to dominate funding in both venture capital and total equity capital raised, though the total of US\$5.2 billion fell short of the US\$10.6 billion generated across the previous 12 months (i.e., the period from 2020 to 2021). Northern California accounted for US\$3.8 billion of this total, including US\$2.1 billion of the US\$2.6 billion total venture capital raised in the state.
- Massachusetts raised US\$938 million in venture funding, making it the second-largest US region for medtech venture capital. France (US\$511 million) and Israel (US\$487 million) were the next most prominent regions.
- In terms of total equity capital raised, Massachusetts was again in the top five, with US\$1.3 billion, surpassed only by California, the UK (US\$1.8 billion) and Switzerland (US\$1.4 billion).

# M&A

#### Figure 12



#### M&A in the US and Europe by year

Source: EY analysis, Capital IQ and Thomson ONE. Chart includes deals with value disclosed (medtech deal where either acquirer or target is located in the US or Europe).

- M&A dealmaking in the medtech sector generated US\$77 billion in the 12-month period ending June 2022. The average deal size of US\$305.4 million was up 41% on the previous year but was still well below the average for the previous decade.
- In all, there were 18 deals at US\$1 billion or more (compared to 11 during the previous period) and 32 deals with US\$500 million or more (compared to 27 in the prior period). Megadeals of over US\$10 billion in value were only a small portion of the total, with Baxter's acquisition of Hill-Rom the only example.
- Non-megadeals generated US\$64.6 billion, more than in any previous year since we began tracking the industry's performance. Approximately 10% of all deals used some form of milestone payment, with milestones accounting for about 30% of those deals' total value.





- As seen with industry financing, medtech dealmaking was largely concentrated in the first half of the 12-month period from July 2021 to June 2022. The first quarter of that period (i.e., Q3 2021) accounted for 43% of the total value, with the first two quarters together accounting for 70% (US\$54.2 billion) of the value and 55% of deal volume.
- In short, the first half of the period from 2021 to 2022 was unusually active for M&A, while the subsequent three quarters decreased back to a level in line with recent average quarterly deal values. The discrepancy may be a result of macroeconomic factors restraining M&A in the second half of the period.

Figure 14			
Selected US a	and European M&	&A, July 2021	L-June 2022

Acquiring company	Location	Acquired company	Location	Value (US\$m)	Buyer's deal driver
Baxter International	Illinois	Hill-Rom	Illinois	12,400	Build scale (digital and connected care)
PerkinElmer	Massachusetts	BioLegend	Southern California	5,250	Build scale (research and other equipment)
Quidel Corporation	Southern California	Ortho Clinical Diagnostics	New Jersey	4,300	Build scale (non-imaging diagnostics)
Stryker	Michigan	Vocera Communications	Northern California	3,090	Portfolio expansion (digital and connected care)
Avantor	Pennsylvania	Masterflex	Germany	2,900	Build scale (research and other equipment)
Coloplast	Denmark	Atos Medical	Sweden	2,490	Portfolio expansion (ENT)
ICU Medical	Southern California	Smiths Medical	UK	2,450	Build scale (TD-multiple)
Thermo Fisher Scientific	Massachusetts	PeproTech	UK	1,850	Build scale (research and other equipment)
Boston Scientific	Massachusetts	Baylis Medical	Canada	1,750	Build scale (cardiovascular/vascular)
CooperSurgical	North Carolina	Generate Life Sciences	Southern California	1,600	Build scale (women's health)
Becton Dickinson	New Jersey	Parata Systems	North Carolina	1,525	Portfolio expansion (digital and connected care)
Vitrolife	Sweden	Igenomix	Spain	1,480	Build scale (non-imaging diagnostics)
GE Healthcare	Massachusetts	BK Medical	Massachusetts	1,450	Build scale (imaging)
ArchiMed	France	Natus Medical	Northern California	1,200	Build scale (TD-neurology)
Medtronic	Ireland	Intersect ENT	Northern California	1,100	Build scale (ENT)

Source: EY analysis, Capital IQ and Thomson ONE.

Chart includes deals with value disclosed (medtech deal where either acquirer or target is located in the US or Europe).

- The deals executed over the past 12 months saw several companies building scale and expanding portfolios, while others used M&A to lock in longer-term growth. Other notable strategic moves included Johnson & Johnson's November 2021 announcement that it intends to separate its consumer health business, creating a new publicly traded company, leaving the conglomerate focused on its biopharma and medtech business units. In the same month, GE announced that its GE Healthcare unit will spin off to become a separate company (with its energy and aviation units also each becoming individual entities), likely in early 2023. In both cases, these moves will potentially create more focused core medtech businesses with greater control over their own investments and strategies.
- Medtronic and Boston Scientific were among the most active players, each striking three M&A deals. Notably, digital and connected care was also a significant dealmaking driver for companies like Stryker (which paid US\$3.0 billion, including convertible notes, for Vocera), Becton Dickinson and, most notably, Baxter, which paid US\$10.5 billion to acquire Hill-Rom's suite of medical devices and hospital equipment, reflecting its ongoing company-wide digital transformation effort.
- The second-largest deal of the period saw PerkinElmer, a company that has thrived in the past two years through revenues generated by COVID-19 testing, paying nearly US\$5.3 billion to acquire BioLegend. The deal adds BioLegend's antibodies and reagents portfolio to PerkinElmer's own range of reagents and consumables, consolidating the company's standing in the research and other equipment segment.
- Quidel, which has expanded significantly due to pandemic-driven demand for its point-of-care diagnostic products, spent US\$4.3 billion to acquire Ortho Clinical Diagnostics, one of the largest pure-play in vitro diagnostic companies in the world. The combined company, now known as QuidelOrtho, will have significant scale in the diagnostics space, as well as capabilities in clinical chemistry, immunoassay and donor screening.
- Other notable deals in this segment included Avantor's US\$2.9 billion takeout of peristaltic pump and aseptic singleuse fluid transfer technology manufacturer Masterflex, as well as market leader Thermo Fisher Scientific's US\$1.9 billion acquisition of PeproTech.

## Data exhibit index

The year in review

- 3 Figure 1. Medtech revenue growth at its highest levels since before the 2008 financial crisis
- 4 Figure 2. US and European revenue growth by product group: pure-plays
- 5 Figure 3. US and European medtech market capitalization relative to leading indexes
- 6 Figure 4. Innovation capital raised in the US and Europe by year

#### Pulse 2022 Databook

- 27 Figure 1: Medical technology at a glance
- 27 Figure 2: US and EU medtech public company revenues
- Figure 3: Change in US and European therapeutic device companies' revenue and net income by disease category: pure-plays
- Figure 4: US and European medtech commercial leaders spending trend, 2010-21
- 30 Figure 5: US FDA Medical Device Approvals (2013-22)
- 31 Figure 6: Capital raised in the US and Europe by year (US\$m)
- 31 Figure 7: Innovation capital raised in the US and Europe by year
- 32 Figure 8: US and European early-stage VC rounds > US\$5 million
- 33 Figure 9: Top venture rounds, July 2021-June 2022
- 34 Figure 10: Top IPOs, July 2021-June 2022
- Figure 11: Capital raised by leading US and European regions, excluding debt, July 2021-June 2022
- 36 Figure 12: M&A in the US and Europe by year
- 37 Figure 13: M&A in the US and Europe by quarter since the beginning of the pandemic
- 38 Figure 14: Selected US and European M&A, July 2021-June 2022

# ACKNOWLEDGMENTS

### **Project leadership**

Our medtech team provided the strategic vision for the Pulse report and brought their years of experience to the analysis of the industry trends.

**James Evans**, EY Global Health Sciences & Wellness Senior Analyst, was the report's lead author. He assisted with the development of the overall storyline and wrote the primary articles, as well as several EY and guest perspectives.

**Jason Hillenbach**, EY Global Health Sciences & Wellness Knowledge Leader, was the report's managing editor, with direct responsibility for all data and trend analysis, research and the overall quality of this publication.

**Shanthi Subramanian**, EY US Health Sciences & Wellness Marketing Strategist was the report's project manager. She was closely involved with every aspect of the report.

We would like to recognize the unwavering support and sponsorship for this year's Pulse report of EY Health Sciences and Wellness Leaders **Pamela Spence**, EY Global Health Sciences & Wellness Leader, and **Arda Ural**, EY Americas Health Sciences & Wellness Leader.

#### Data analysis

Arpit Jain organized all of the collection, research and analysis of the report's data.

Jason Hillenbach conducted fact-checking and quality review of the publication's numbers.

#### Content support

**Blythe Randolph** was the report's copy editor. **Linda Parrish** was the report's proofreader. Their patience, hard work and attention to detail were unparalleled.

#### Design

**Soon Ham** was the lead designer for this project. This publication would not look the way it does without his creativity.

#### Public relations and marketing

Public relations and marketing efforts related to the report and its launch were led by Lauren Hare, Christa Sullivan and Shanthi Subramanian.

# DEFINING MEDICAL TECHNOLOGY

In this report, unless otherwise noted, medical technology (medtech) companies are defined as companies that design and manufacture medical technology equipment and supplies and are headquartered within the United States or Europe. The definition includes therapeutic device, diagnostic, drug delivery and analytical/life sciences tools and digital health companies. It excludes distributors and service providers, such as contract research organizations or contract manufacturing organizations. All publicly traded medtech companies are classified as belonging to one of five broad product groups:

- Imaging: companies that develop products used to diagnose or monitor conditions via imaging technologies, including products such as MRI machines, computed tomography and X-ray imaging equipment, and optical biopsy systems
- Non-imaging diagnostics: companies that develop 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 that develop equipment used for research or other purposes, including analytical and life sciences tools, specialized laboratory equipment and furniture
- Therapeutic devices: companies that develop products used to treat patients, including therapeutic medical devices, tools or
- Other: companies that develop products that do not fit in any of the above categories; digital health companies included in this product group

In addition to product groups, this report tracks the performance of conglomerate companies that derive a significant part of their revenues from medical technologies. Although we classify conglomerate medtech divisions by product group (e.g., GE Healthcare into Imaging and Abbott into Therapeutic devices), we report their results separately from pure-play companies. This is because, excepting revenue results, conglomerates do not report full financial numbers for their medtech divisions.

For the purposes of this report, the global data represents combined metrics from US and European medtech companies; Israel's data is analyzed as part of the European market. Foreign exchange rates converted from local currencies to US dollars are calculated on a blended annual rate. Where possible, data is analyzed across a range of dimensions, including product group (e.g., imaging or therapeutic device), therapeutic area focus (e.g., oncology or cardiovascular), company ownership (e.g., public or private) and revenue thresholds. Our taxonomy sometimes segregates companies into thinly populated categories, making it difficult to provide statistically significant results.

As part of its dealmaking evaluation, the EY team's analysis tracks the digital alliances and acquisitions signed by leading pure-play and conglomerate medtechs by therapeutic area, technology capability (e.g., sensors or artificial intelligence) and strategic purpose. Direct investments by medtechs in digital health companies have been excluded from this analysis.

#### **Conglomerate companies**

#### **United States**

- 3M: Health Care
- Abbott: Diagnostics and Medical Devices
- Agilent Technologies: Life Sciences & Applied Markets and Diagnostics & Genomics
- Baxter: Renal Care, Medication Delivery, Advanced Surgery and Acute Therapies
- Corning: Life Sciences
- Danaher: Life Sciences and Diagnostics
- General Electric: GE Healthcare
- IDEX: Health & Science
- Johnson & Johnson: Medical Devices & Diagnostics

#### Europe

- Agfa-Gevaert: Agfa HealthCare
- Dräger: Medical Devices
- DSM: Biomedical
- Eckert & Ziegler: Medical
- El En: Medical
- EssilorLuxottica: Direct to Consumer
- Fresenius: Medical Devices
- GN Store Nord: ReSound
- Halma: Healthcare
- Jenoptik: Life Sciences and Medical Technology
- Lumibird Group: Quantel Medical
- Merck KGaA: MilliporeSigma
- Royal Philips: Philips Healthcare
- Roche: Roche Diagnostics
- Semperit: Sempermed
- Smiths Group: Smiths Medical
- Zeiss: Carl Zeiss Meditec

### **EY Americas Medtech team**



Jim Welch Global Medtech Leader Ernst & Young LLP james.welch@ey.com



John Babitt Americas Medtech Transactions Leader Ernst & Young LLP john.babitt@ey.com



Jay Zhu Americas Medtech Commercial Leader Ernst & Young LLP jay.zhu1@parthenon.ey.com



Mark Ginestro Americas Medtech Strategy Leader Ernst & Young LLP mark.ginestro@parthenon.ey.com

EY | Building a better working world

EY exists to build a better working world, helping to create long-term value for clients, people and society and build trust in the capital markets.

Enabled by data and technology, diverse EY teams in over 150 countries provide trust through assurance and help clients grow, transform and operate.

Working across assurance, consulting, law, strategy, tax and transactions, EY teams ask better questions to find new answers for the complex issues facing our world today. EY refers to the global organization, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. Information about how EY collects and uses personal data and a description of the rights individuals have under data protection legislation are available via ey.com/privacy. EY member firms do not practice law where prohibited by local laws. For more information about our organization, please visit ey.com.

Ernst & Young LLP is a client-serving member firm of Ernst & Young Global Limited operating in the US.

© 2022 Ernst & Young LLP. All Rights Reserved.

US SCORE no. 17467-221US CS no. 2207-4073829 ED None

This material has been prepared for general informational purposes only and is not intended to be relied upon as accounting, tax, legal or other professional advice. Please refer to your advisors for specific advice.

ey.com