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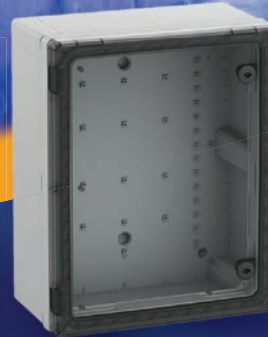
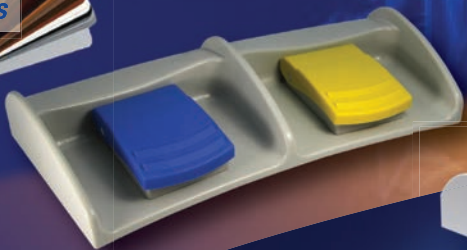
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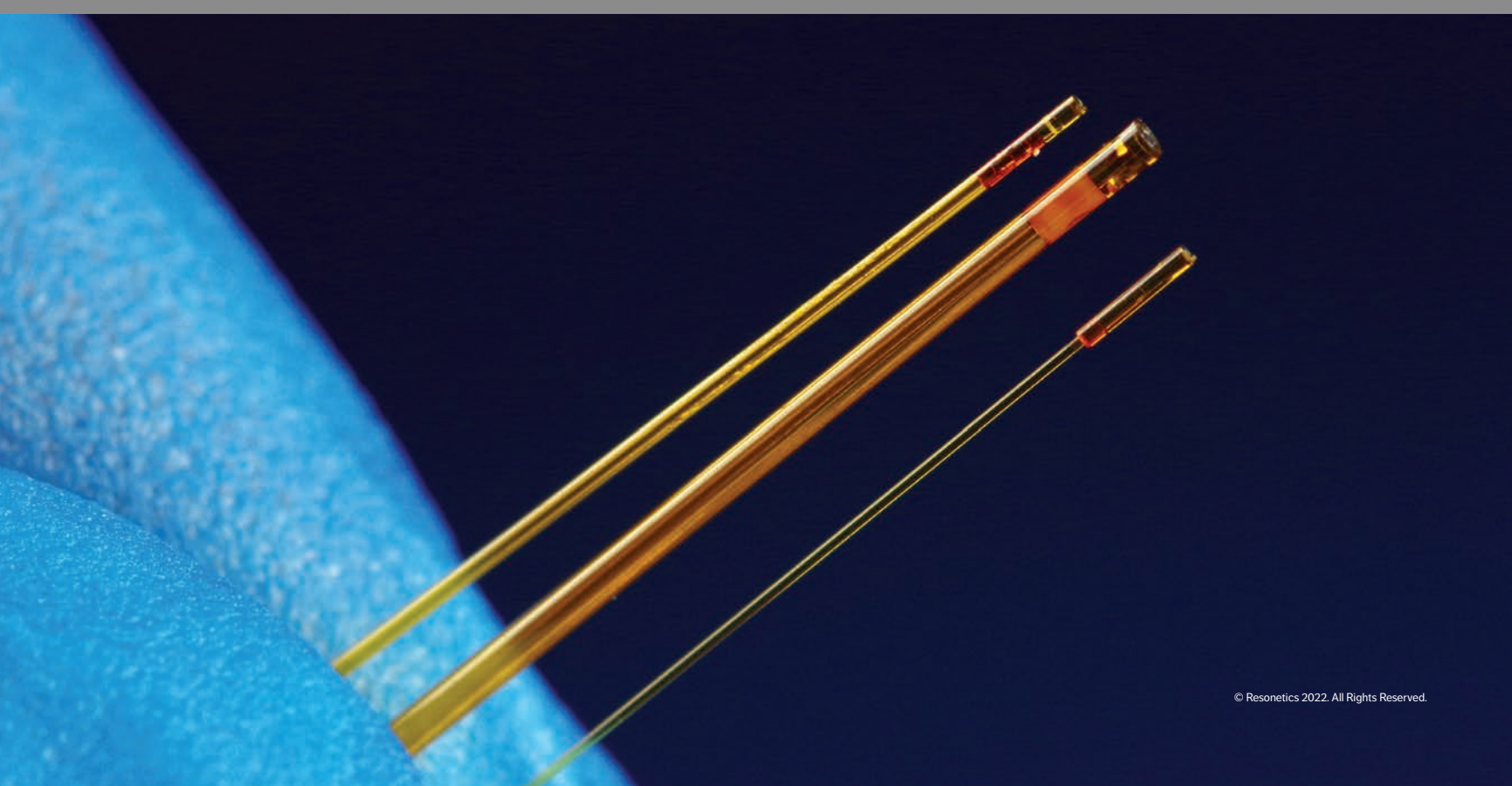
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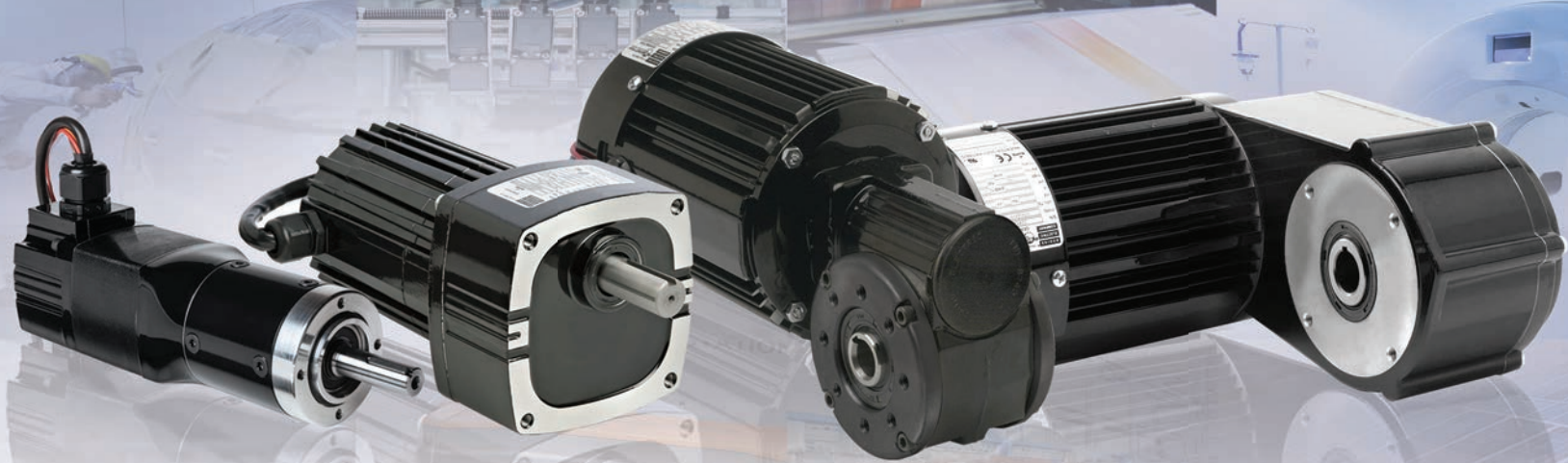


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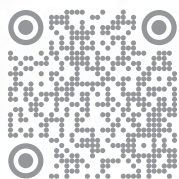
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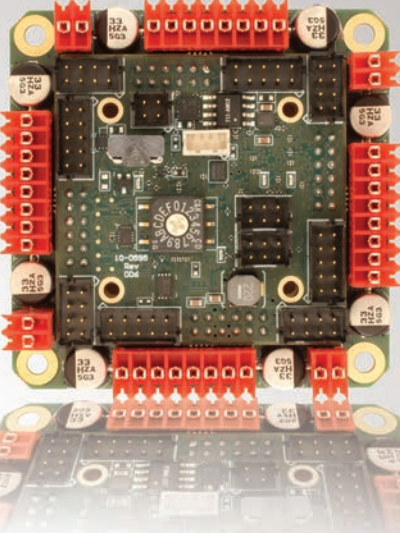
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● HERE'S WHAT WE SEE

## The Medtech Big 100 is bigger than ever

**T**he tide has turned. The Medtech Big 100 — **Medical Design & Outsourcing's** annual revenue ranking of the world's largest medical device companies — is growing again and the pump appears primed for more.

You may recall that last year's analysis of the industry's 100 largest firms revealed a year-over-year drop in combined sales as the COVID-19 pandemic turned our world upside down. We lost family, friends and colleagues. Surgeries were postponed and canceled. Supply chains snapped. Markets tanked.

Despite massive sales gains in COVID-19 diagnostics and other pandemic-related products, last year's Big 100 revenue totaled \$415.3 billion, down from \$420.3 billion the year before.

This year's Big 100 list totals \$440.9 billion, a significant move in the right direction. But the good news doesn't stop there. R&D spending is also up, and many of those investments will yield sales in the years and decades ahead. Employment is also growing again, though it has yet to return to 2019 levels.

Even with ongoing challenges such as inflation and supply chain woes, it's worth celebrating the industry's recovery from its pandemic lows. Senior Editor Danielle Kirsh has more analysis in this edition's cover story, including a ranking of the largest R&D spenders, top employers and more details on individual companies that stood out. Special thanks for this team effort are also due to Brian Buntz, Chris Newmarker — who ranks the world's largest orthopedic companies in this month's edition — and Sean Whooley.

You'll also hear from the co-founders of Sisu Global Health, which developed an autotransfusion device that's helping patients in Africa and Ukraine when bagged blood isn't available.

Also in these pages, Medtronic Supply Chain EVP Greg Smith discusses efforts to tame the supply chain at the biggest company in medtech. The former Walmart executive said he sees

**"Even with ongoing challenges such as inflation and supply chain woes, it's worth celebrating the industry's recovery from its pandemic lows."**

fewer suppliers in Medtronic's future, but also spelled out what Medtronic's looking for in its partners.

Rounding out this edition, check out Tom Salemi's preview of DeviceTalks West in Santa Clara Oct. 19-20, a collection of catheter innovations in Tubing Talks, and a look at how DeepMind's AlphaFold AI system is advancing life sciences research.

You'll read all this and much more in our latest edition of **MDO**. Enjoy — and thanks for doing your part to lift the medtech industry to new heights. 🙌



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## Two Pedal Covered FM Switch

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**M**edtech businesses are becoming stand-alone companies. That translates into new names among 2022's Medtech Big 100 ranking of the world's largest medical device companies.

Medtronic, Johnson & Johnson MedTech (which rebranded from Johnson & Johnson Medical Devices this year) and Siemens Healthineers still rank at the top of the list when it comes to revenue.

Farther down, you'll encounter new names such as Enovis and ZimVie. GE HealthCare plans to keep its name when it becomes its own independent company early next year. Will 3M's Health Care segment, due for its own 2023 spinout, do the same? And will 3M's home state of Minnesota keep the new headquarters? Time will tell.

**Medical Design & Outsourcing**

collected thousands of data points to size

up the industry's publicly traded companies and privately held firms, including annual revenue, R&D spending, employee counts, key leaders, headquarters locations across the globe, and descriptions of each company — from Abbott to Zimmer Biomet.

This project draws on data from Securities and Exchange Commission filings, facts and figures shared directly with us by the largest medical device companies, and news coverage from **MDO**, **MassDevice** and other WTWH Media Life Sciences brands.

Note that the majority of these companies operate on standard calendar years, but some have fiscal years for which we've collected data as recently as August 2022. (Medtronic's fiscal year, for example, ended on April 29, 2022.) Because we moved this year's publishing date from November to September, a few companies have data rerun

from last year's report because their fiscal years run until the end of September.

Trends we see include major conglomerates spinning out medical device companies into stand-alone businesses. Some big companies including GE HealthCare are also turning to substantial partnerships rather than outright M&A in order to stay competitive. Plus, medtech companies have had to respond to macroeconomic headwinds — which include a strong dollar making it harder for American companies to export, inflation, supply chain disruption and more.

Speaking of currency, please note that we've converted foreign currencies reported by companies to U.S. dollars using standardized Federal Reserve rates. **M**

- Executive Editor Chris Newmarker

RANK	COMPANY	2022 REVENUE (\$USD)	EMPLOYEES
1	<b>Medtronic</b>	\$31,686,000,000	95,000
2	<b>Johnson &amp; Johnson MedTech</b>	\$27,100,000,000	75,000
3	<b>Siemens Healthineers</b>	\$20,516,580,000	66,100
4	<b>Royal Philips</b>	\$20,296,000,000	78,189
5	<b>Medline Industries</b>	\$20,200,000,000	30,000
6	<b>GE HealthCare</b> (General Electric)	\$17,725,000,000	48,000
7	<b>Stryker</b>	\$17,108,000,000	46,000
8	<b>Cardinal Health</b> (Medical segment)	\$15,900,000,000	n/a
9	<b>Abbott</b> (medical device segment)	\$14,367,000,000	n/a
10	<b>Baxter</b>	\$12,784,000,000	60,000
11	<b>Henry Schein</b>	\$12,401,021,000	21,600
12	<b>Boston Scientific</b>	\$11,888,000,000	41,000
13	<b>Owens &amp; Minor</b>	\$9,785,315,000	17,300
14	<b>BD</b> (Medical segment)	\$9,479,000,000	30,000
15	<b>B. Braun Melsungen</b>	\$9,274,534,500	66,234
16	<b>3M Co.</b> (Health Care segment)	\$9,050,000,000	n/a
17	<b>Alcon</b>	\$8,222,000,000	24,389
18	<b>Fujifilm Holdings</b> (healthcare only)	\$7,298,798,252	n/a



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RANK	COMPANY	2022 REVENUE (\$USD)	EMPLOYEES
19	<b>Zimmer Biomet</b> (minus ZimVie spinoff)	\$6,821,600,000	16,800
20	<b>Olympus</b> (medical business)	\$6,710,970,503	21,898
21	<b>Terumo</b>	\$6,402,977,058	28,000
22	<b>Intuitive Surgical</b>	\$5,710,100,000	9,793
23	<b>Hologic</b>	\$5,632,300,000	6,350
24	<b>Edwards Lifesciences</b>	\$5,232,500,000	15,700
25	<b>Smith+Nephew</b>	\$5,212,000,000	18,369
26	<b>Steris</b>	\$4,585,064,000	16,000
27	<b>Fresenius Medical Care</b> (health care products)	\$4,416,740,000	30,000
28	<b>Canon Medical</b>	\$4,373,288,420	n/a
29	<b>Dentsply Sirona</b>	\$4,251,000,000	15,000
30	<b>BioMérieux</b>	\$3,983,680,000	13,000
31	<b>Align Technology</b>	\$3,952,584,000	22,540
32	<b>Mindray</b>	\$3,917,343,585	14,684
33	<b>Hoya</b> (life care segment)	\$3,710,387,837	n/a
34	<b>Sonova</b>	\$3,678,805,774	16,733
35	<b>ResMed</b>	\$3,578,100,000	8,000
36	<b>Nipro</b> (medical segment)	\$3,400,227,604	25,239
37	<b>Getinge</b>	\$3,152,564,103	10,700
38	<b>Coloplast</b>	\$2,970,336,391	12,578
39	<b>Demant</b>	\$2,932,802,548	18,116
40	<b>Bio-Rad</b>	\$2,922,545,000	7,900
41	<b>Cooper Cos.</b>	\$2,922,500,000	12,000
42	<b>Teleflex</b>	\$2,809,563,000	14,000
43	<b>Paul Hartmann</b>	\$2,716,124,000	10,628
44	<b>HU Group</b>	\$2,484,522,942	n/a
45	<b>Dexcom</b>	\$2,448,500,000	6,300
46	<b>Dräger</b> (medical division)	\$2,435,756,000	15,900
47	<b>Bruker</b>	\$2,417,900,000	7,765
48	<b>Cook Medical</b>	\$2,336,000,000	13,898
49	<b>Amplifon</b>	\$2,298,728,500	18,600
50	<b>Straumann</b>	\$2,211,286,089	9,000
51	<b>ConvaTec</b>	\$2,038,000,000	10,025
52	<b>Carl Zeiss Meditec</b>	\$1,990,424,000	3,531
53	<b>Nihon Kohden</b>	\$1,867,525,492	n/a
54	<b>Elekta</b>	\$1,695,571,096	4,631
55	<b>Integra Lifesciences</b>	\$1,542,448,000	3,800
56	<b>Enovis</b> (Formerly Colfax's Medical Technology segment, DJO)	\$1,426,188,000	5,000
57	<b>ICU Medical</b>	\$1,316,308,000	8,500
58	<b>Masimo</b>	\$1,239,153,000	2,200
59	<b>Cochlear</b>	\$1,233,286,650	n/a



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RANK	COMPANY	2022 REVENUE (\$USD)	EMPLOYEES
60	<b>Integer</b>	\$1,221,079,000	9,000
61	<b>Omron Healthcare</b>	\$1,209,941,733	n/a
62	<b>Fukuda Denshi</b>	\$1,202,640,204	n/a
63	<b>Fisher &amp; Paykel Healthcare</b>	\$1,177,190,000	7,375
64	<b>NuVasive</b>	\$1,138,988,000	2,900
65	<b>Insulet</b>	\$1,098,800,000	2,300
66	<b>Merit Medical Systems</b>	\$1,074,751,000	6,446
67	<b>LivaNova</b>	\$1,035,365,000	3,000
68	<b>Abiomed</b>	\$1,031,753,000	2,003
69	<b>ZimVie</b> (formerly Zimmer Biomet's spine and dental business)	\$1,014,600,000	2,700
70	<b>Conmed</b>	\$1,010,635,000	3,800
71	<b>Konica Minolta</b> (healthcare segment)	\$1,000,546,249	n/a
72	<b>Haemonetics</b>	\$993,196,000	2,821
73	<b>Globus Medical</b>	\$958,102,000	2,400
74	<b>Invacare</b>	\$872,457,000	3,000
75	<b>GN Hearing</b>	\$849,044,586	4,553
76	<b>Cordis</b>	\$788,000,000	3,500
77	<b>MicroPort</b>	\$778,639,000	8019
78	<b>Avanos Medical</b>	\$744,600,000	4,555
79	<b>Össur</b>	\$719,000,000	3,761
80	<b>Asahi Intecc</b> (medical field segment)	\$667,862,345	n/a
81	<b>Nikkiso</b> (medical segment)	\$665,904,953	n/a
82	<b>Ambu</b>	\$613,761,468	4,500
83	<b>Agfa-Gevaert</b> (radiology solutions segment)	\$547,520,000	2,285
84	<b>Novocure</b>	\$535,031,000	1,167
85	<b>JMS Co.</b>	\$529,579,388	5,359
86	<b>Topcon</b> (eye care business)	\$520,193,008	n/a
87	<b>Natus Medical</b>	\$473,438,000	1,400
88	<b>Orthofix</b>	\$464,479,000	1,087
89	<b>Accuray</b>	\$429,909,000	900
90	<b>Medacta</b>	\$428,458,000	1,341
91	<b>Nevro</b>	\$386,905,000	945
92	<b>iRhythm</b>	\$322,825,000	1,700
93	<b>Barco</b> (healthcare division)	\$308,570,000	3,000
94	<b>Artivion</b> (formerly CryoLife)	\$298,836,000	1300
95	<b>Glaukos</b>	\$294,011,000	727
96	<b>Inari Medical</b>	\$276,984,000	800
97	<b>AtriCure</b>	\$274,329,000	875
98	<b>Alphatec</b>	\$243,212,000	561
99	<b>Shockwave Medical</b>	\$237,146,000	657
100	<b>Cardiovascular Systems</b>	\$236,222,000	750

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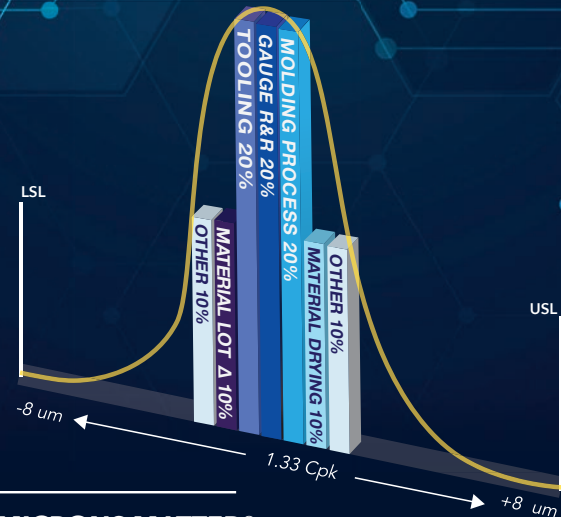
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No.  
1

# Medtronic

## Medtronic

Dublin, Ireland (operational HQ in Fridley, Minnesota)  
United States

# \$31,686,000,000\*

\*Fiscal year ended 4/29/2022

[www.medtronic.com](http://www.medtronic.com)

**2021 rank:** 1

**2022 R&D spend:** \$2,746,000,000


**Employees:** 95,000

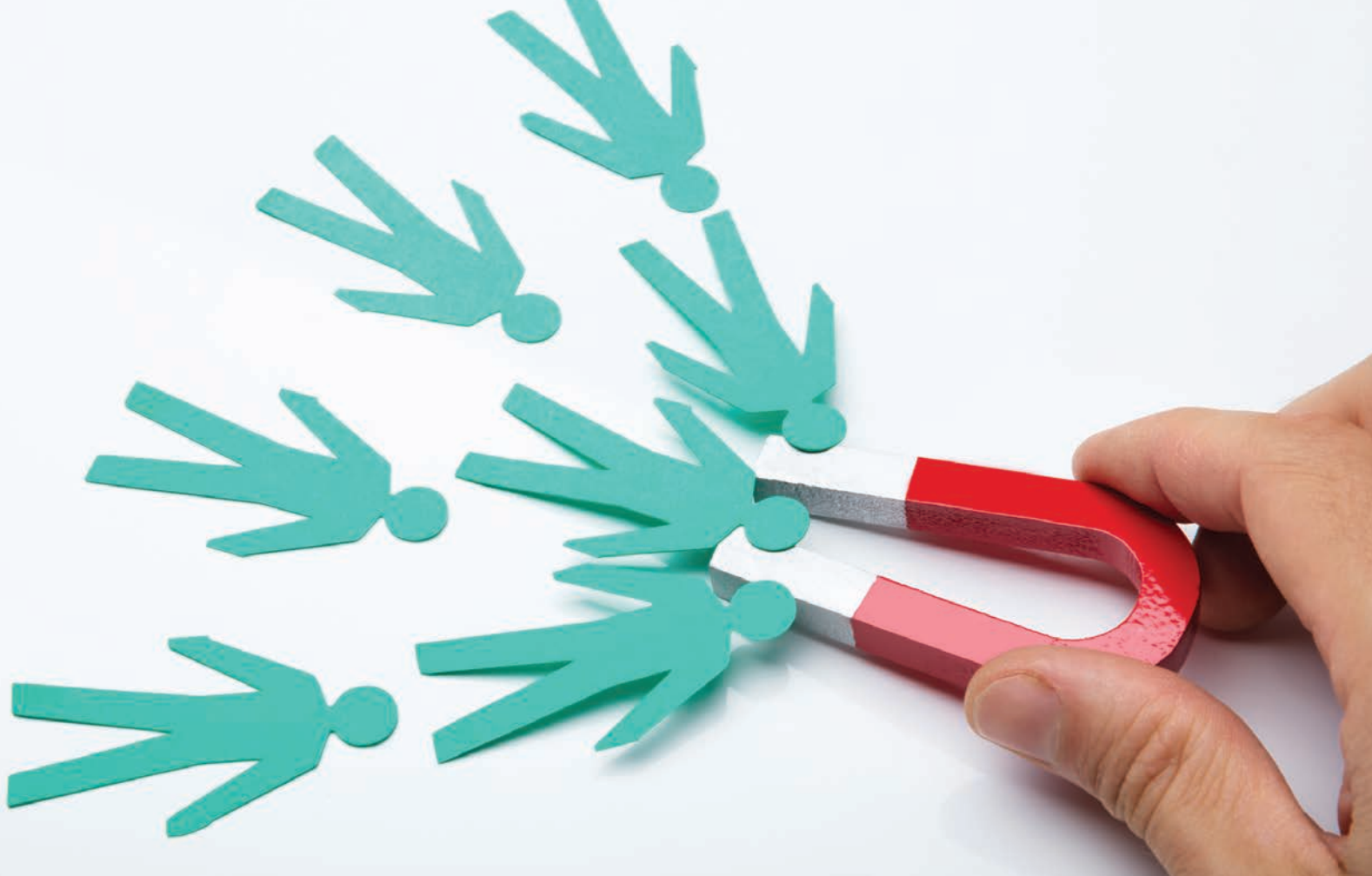
**Company CEO:** Geoff Martha, CEO

**MEDTRONIC** CEO Geoff Martha had ambitious goals when he rose into the company's corner office in 2020. That included engaging in a major reorganization to make the \$32-billion-a-year company more nimble and competitive.

But the medtech giant — top of the list among the Big 100 largest medical device companies of 2022 — has suffered a series of setbacks over the past year. There were delays in the company's pivotal ON MED study of its renal denervation system, supply chain challenges around the rollout of its Hugo surgical robotics system, and regulatory troubles for its Diabetes business.

Analysts have increasingly asked whether Medtronic can execute through an unpredictable macroeconomic environment that includes a strong dollar (which impacts the ability of U.S. companies to sell outside the country), inflation, supply chain disruption and more.

Announcing first-quarter earnings in August, Martha insisted that company leadership can get the job done: "The company continues to execute in a challenging environment, delivering organic revenue above our guidance." —CN 



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No.

2

# Johnson & Johnson

## MEDTECH

### Johnson & Johnson MedTech

New Brunswick, New Jersey  
United States

# \$27,100,000,000\*

\*Fiscal year ended 1/3/2022

[www.jnjmedtech.com](http://www.jnjmedtech.com)

**2021 rank:** 2

**2022 R&D spend:** \$2,377,000,000

**Employees:** 75,000


**Company CEO:** Joaquin Duato, CEO;  
Ashley McEvoy, EVP, medical devices

Rebranded as **JOHNSON & JOHNSON MEDTECH**, J&J's medical device business is set to have a higher profile in the company after the expected spinoff of its consumer business in 2023. Analysts, however, have suggested that J&J may be looking for another large medtech business to acquire to make MedTech's revenue more on par with the pharma business. (Needham & Co. analyst Mike Matson floated Boston Scientific as a possibility.)

But during J&J's second-quarter earnings call in July, CEO Joaquin Duato played down the M&A speculation. He emphasized that MedTech has its sights set on strengthening current strongholds.

Meanwhile, J&J's DePuy Synthes ortho business is betting that it can compete in the ortho surgical robotics space with its Velys system, which could help reduce the physical burden

of orthopedic surgery. And Ethicon is seeking to up the game in the surgical devices space with new tools such as its Echelon 3000 surgical stapler. Ethicon also secured an FDA 510(k) clearance in May for its Monarch robotic surgery system, enabling its use in both bronchoscopy and urology. The company, however, has been quiet about its next-gen Ottava robot. A lawsuit case remains active in Delaware involving former shareholders of Auris Health, who alleged that J&J executives misrepresented their intentions for the robotic surgery company when they acquired it for \$3.4 billion in 2019. J&J says the lawsuit is without merit.

In other news, Johnson & Johnson Vision announced a significant win in March with FDA approval of its Acuvue Theravision with the antihistamine Ketotifen. It's the first drug-eluting contact lens authorized for marketing in the U.S. —CN and SW 



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No.

3

# SIEMENS Healthineers

## Siemens Healthineers

Erlangen  
Germany

**\$20,516,580,000\***

\*Fiscal year ended 9/30/2021

[www.siemens-healthineers.com](http://www.siemens-healthineers.com)

**(€17,997,000,000)**

**2021 rank:** n/a\*

**2022 R&D spend:** \$1,762,440,000

**Employees:** 66,100

**Company CEO:** Bernd Montag, CEO

The German medtech giant is No. 3 among the Big 100 largest medical device companies of 2022. It has innovation roots that go back to the late 1890s, when it created its first medical X-ray device just one year after Wilhelm Conrad Roentgen discovered X-rays. Spun out of Siemens to become its own publicly traded company in 2018, **SIEMENS HEALTHINEERS** became even larger after closing its \$16.4 billion acquisition of Varian Medical Systems in 2021. Siemens Healthineers said the merger with Varian created the industry's most comprehensive cancer care portfolio. The company's cutting-edge technologies span

imaging, diagnostics and cancer therapy. Recent wins included FDA clearance to integrate the company's Cios Spin mobile cone-beam CT imaging tech with Intuitive's Ion robot-assisted bronchoscopy system. Siemens Healthineers is sticking by its outlook for its current fiscal year that ends Sept. 30, 2022, even as it grapples with an unpredictable economic environment. –CN <sup>M</sup>

*\*The 2022 Big 100 report is moving to September versus November in previous years. Because its fiscal year ends in September, Siemens Healthineers' revenue number is the same as in the 2021 report.*

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No.

4



## Royal Philips

Amsterdam  
Netherlands

**\$20,296,000,000\***

\*Fiscal year ended 12/31/2021

[www.philips.com](http://www.philips.com)

**(€17,200,000,000)**


**2021 rank:** 4

**2022 R&D spend:** \$2,131,080,000

**Employees:** 78,189

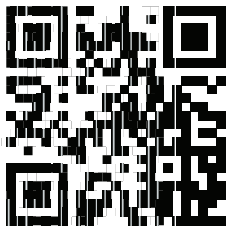
**Company CEO:** Frans van Houten, CEO;  
Roy Jakobs, incoming CEO

The all-consuming story for **PHILIPS** over the past year has been its massive recall involving more than 1 million CPAPs, ventilators and other respiratory devices. The recall has removed the Dutch medtech giant from the respiratory devices market, with reports of problems accelerating. There was news in August of 44 more deaths related to the recall. The FDA's update brought the death total to 168, with 69,000 medical device reports (MDRs) filed. Around the same time as the new FDA report, Philips announced plans for Roy Jakobs to succeed Frans van Houten as president and CEO, effective Oct. 15. Jakobs has been the company's Connected Care chief businesses leader. He took over the management of the Philips Respironics recall in June 2021.

Respiratory device problems stem from polyester-based polyurethane sound abatement foam that could break down. Foam particles could enter a device's air pathway and cause a range of potential health problems and toxic, carcinogenic effects for the user. The FDA and federal prosecutors are increasingly scrutinizing how Philips has handled the recall. On May 2, the FDA proposed an order for Philips to submit a plan for the repair, replacement or refund of the purchase price of the recalled devices. –CN 

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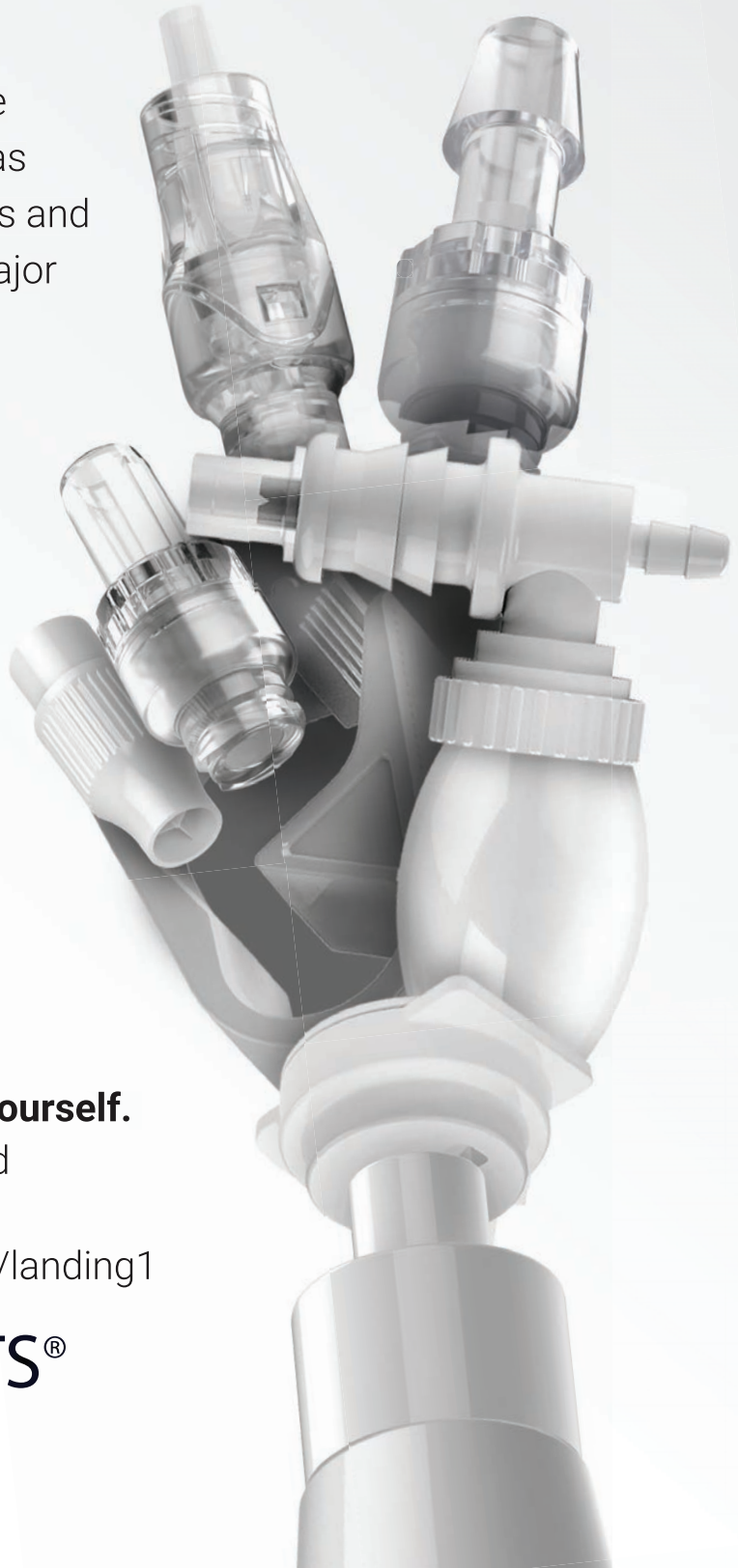
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No.  
**5**



## Medline Industries

Northfield, Illinois  
United States

**\$20,200,000,000\***

\*Fiscal year ended 12/31/2021

[www.medline.com](http://www.medline.com)

**2021 rank:** 6

**2022 R&D spend:** n/a

**Employees:** 30,000

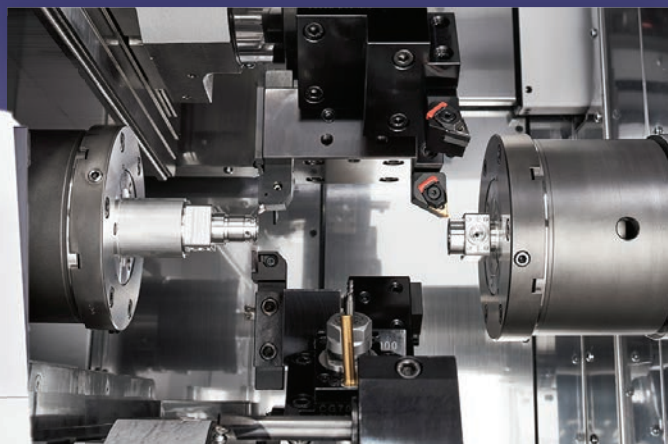
**Company CEO:** Charles Mills, CEO

Privately held **MEDLINE INDUSTRIES** is moving up in this year's Big 100 report of the largest medical device companies. Sales grew nearly 15% to \$20.2 billion last year. The medtech manufacturer and distributor added more than 230 healthcare providers to its prime vendor partnerships. Meanwhile, Blackstone, Carlyle and Hellman & Friedman made a multi-billion-dollar investment in Medline, with the Mills family remaining the largest single shareholder. Medline is spending \$1.5 billion on new distribution centers, manufacturing capabilities and IT upgrades. —CN 

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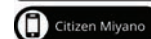
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No.  
**6**



GE Healthcare

## GE HealthCare (General Electric)

Chicago  
United States

**\$17,725,000,000\***

\*Fiscal year ended 12/31/2021


[www.gehealthcare.com](http://www.gehealthcare.com)

**2021 rank:** 7

**2022 R&D spend:** \$847,000,000

**Employees:** 48,000

**Company CEO:** Peter Arduini, GE HealthCare CEO

As it prepares to spin off as its own independent company early next year — keeping its old name — **GE HEALTHCARE** has been turning to major partnership deals versus M&A to compete better. GE HealthCare said in January that it is collaborating with Boston Scientific on cardiac care in Southeast Asia. In April, there was news of a global commercial collaboration agreement with Elekta in the radiation oncology space — a move that could help it better compete with Siemens Healthineers. An announcement soon followed of a partnership with Medtronic to offer various products and services for the growing sector of ambulatory surgery centers (ASCs) and office-based labs (OBLs). In other news, the company released its next-generation Definium 656 HD X-ray system. —CN 



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Kalamazoo, Michigan  
United States

# \$17,108,000,000\*

\*Fiscal year ended 12/31/2021

[www.stryker.com](http://www.stryker.com)

**2021 rank:** 10

**2022 R&D spend:** \$1,235,000,000

**Employees:** 46,000

**Company CEO:** Kevin Lobo, chair, president and CEO

**STRYKER** officials say they're already enjoying synergies from their \$3.1 billion acquisition of Vocera Communications, a provider of digital care coordination and communication offerings. Vocera Communications' products include the hands-free Vocera Smartbadge. In early July, the world's largest orthopedic device company boosted its revenue projections for 2022, predicting organic sales growth between 8% and 9%. However, a strong dollar and supply chain disruption present challenges when it comes to growing earnings.

Despite increased competition in the robotic orthopedic surgery space from J&J's DePuy Synthes, Zimmer Biomet and Smith+Nephew, Stryker is still enjoying increased Mako sales. Mako sales were up 19% year-over-year in Q2 2022 –CN **M**



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No.  
**8**



## Cardinal Health (medical segment)

Dublin, Ohio  
United States

**\$15,900,000,000\***

\*Fiscal year ended 6/30/2022

[www.cardinalhealth.com](http://www.cardinalhealth.com)


**2021 rank:** 8

**2022 R&D spend:** n/a

**Employees:** n/a

**Company CEO:** Jason Hollar, CEO

CFO Jason Hollar has moved up to the corner office of pharma and medtech services giant **CARDINAL HEALTH**, which is No. 8 in this year's Big 100 report of largest medical device companies. Hollar succeeds Mike Kaufmann, who has been Dublin, Ohio-based Cardinal Health's CEO for the past five years. The CEO transition comes as Cardinal Health continues efforts to refocus its Medical business after its \$1 billion sale of Cordis last year. Challenges for

the medical device business include inflation, supply chain constraints and fewer demands for personal protective equipment, according to Cardinal Health's Q4 report in August. In other news, Cardinal Health has been experimenting with drone delivery of medical supplies. Zipline and its fleet of Zip delivery drones are now flying for Cardinal Health, Novant Health and Magellan Rx Management from a hub in North Carolina. –CN 



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solutions:**

- Rapid launch
- Global reach
- Proven quality
- Optimized healthcare solutions





## Abbott (medical device segment)

Abbott Park, Illinois  
United States

**\$14,367,000,000\***


\*Fiscal year ended 12/31/2021


[www.abbott.com](http://www.abbott.com)

**2021 rank:** 11  
**2022 R&D spend:** n/a  
**Employees:** n/a

**Company CEO:** Robert Ford, CEO;  
Lisa Earnhardt, EVP medical devices

**ABBOTT** kicked off 2022 with its CEO Robert Ford delivering the first healthcare keynote ever at CES. Ford used his keynote to reveal that Abbott is developing a new category of biowearables for athletes called "Lingo." Said Ford: "We're creating a future that will bring you and your loved ones care that's more personal and precise. It's happening right now. And its potential is no less than incredible." The company has also been on a roll this year with medtech announcements:

- Abbott in January announced FDA approval of new MRI compatibility for the company's Proclaim spinal cord stimulation system.
- In February, it announced the first implant of its Aveir DR dual-chamber leadless pacemaker system in a clinical trial.
- An FDA expanded indication, also announced in February, means that an additional 1.2 million people in the U.S. with heart failure can take advantage of Abbott's CardioMEMS HF system. The system remotely monitors pulmonary artery (PA) pressure changes, providing early warning of worsening heart failure.
- In April, the company launched an upgraded version of its NeuroSphere myPath digital health app that enables doctors to more closely track their patients as they trial Abbott neurostimulation devices to address their chronic pain.
- Also in April, Abbott announced FDA approval of its Aveir single-chamber (VR) leadless pacemaker for slow heart rhythms. Abbott's Aveir is its answer to Medtronic's Micra leadless pacemakers, which won initial FDA approval in 2016.
- Abbott in May said it had received FDA clearance for its next-generation FreeStyle Libre 3 continuous glucose monitor — designed as the world's smallest and thinnest CGM sensor. —CN 



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No.  
**10**

# **Baxter**

## **Baxter**

Deerfield, Illinois  
United States

**\$12,784,000,000\***

\*Fiscal year ended 12/31/2021

[www.baxter.com](http://www.baxter.com)


**2021 rank:** 12

**2022 R&D spend:** \$534,000,000

**Employees:** 60,000

**Company CEO:** José E. Almeida, chair, president and CEO

Fresh off of closing its \$12.5 billion acquisition of Hillrom at the end of 2021, **BAXTER** has moved up two spots to No. 10 in this year's Big 100 report of the largest medical device companies. The company expects synergies from the deal to help fuel sales growth momentum over the next three years. Baxter said in May that it attributed such benefits to the impact of market expansion across the broader portfolio, plus new innovation fueled

by the expanded capabilities the company obtains through the acquisition. A major part of the merger with Hillrom involved accelerating the companies' expansion into digital and connected care offerings to enable patients to access hospital-level care at home or in other care settings. For example, Baxter is now the parent company of BardyDx and its Carnation Ambulatory Monitor, a lightweight, extended-wear cardiac ECG patch. –CN and SW 

No.

11

 HENRY SCHEIN®

## Henry Schein

Melville, New York  
United States

# \$12,401,021,000\*

\*Fiscal year ended 12/25/2021

[www.henryschein.com](http://www.henryschein.com)


**2021 rank:** 13

**2022 R&D spend:** n/a

**Employees:** 21,600

**Company CEO:** Stanley Bergman, chair, CEO and director

**HENRY SCHEIN** says it is the world's largest provider of health care products and services, primarily to office-based dental and medical practitioners, as well as alternate sites of care. It has operations or affiliates in 32 countries and territories. The Melville, New York-based company offers more than 120,000 branded products and private brand products in stock and more than 180,000 products available as special orders. Henry Schein serves its customers through two segments: Health Care Distribution, and Technology and Value-Added Services. Health Care Distribution involves consumable products, equipment, laboratory products, equipment repair services, branded and generic pharmaceuticals, vaccines, surgical products, diagnostic tests, infection-control products and vitamins. Technology and Value-Added Services provides software,

technology and other value-added services to health care practitioners and includes a small medical software business known as MicroMD. Technology and Value-Added Services also offer physicians a broad suite of services for electronic health records, integrated revenue cycle management, and patient communication. Henry Schein's financial services include practice finance solutions such as credit card billing and facilitation of loans to acquire equipment and technology, as well as solutions to broker dental practice transitions. In 2022, CFO Steven Paladino retired after 35 years with the company and was succeeded by Ronald South, Chief Administrative Officer Gerald Benjamin retired, and Michael Ettinger became chief operating officer. The company also made moves in the dental space, acquiring Condor Dental Research Co. and Midway Dental Supply. —JH 



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No.  
12

# Boston Scientific

## Boston Scientific

Marlborough, Massachusetts  
United States

**\$11,888,000,000\***

\*Fiscal year ended 12/31/2021

[www.bostonscientific.com](http://www.bostonscientific.com)


**2021 rank:** 14

**2022 R&D spend:** \$1,204,000,000

**Employees:** 41,000

**Company CEO:** Michael Mahoney, president and CEO

**BOSTON SCIENTIFIC** earlier this year spent \$1.75 billion to boost its left heart access capabilities through the acquisition of Baylis Medical. The Baylis platforms offer advanced transseptal puncture, with uses in procedures including AFib ablation, left atrial appendage closure (LAAC) and mitral valve interventions. Boston Scientific didn't stop shopping there. In June, it announced an agreement to purchase a majority stake in M.I. Tech, the Korea-based

maker and distributor of medical devices for endoscopic and urologic procedures. M.I. Tech is the creator of the Hanarostent family of conformable, non-vascular, self-expanding metal stents. In other news, Boston Scientific announced positive outcomes from studies of its Acurate Neo2 aortic valve system. The Acurate Neo2 represents the company's bid to compete again in the TAVR space, nearly two years after shutting down its Lotus program. —CN 



No.  
13

## Owens & Minor

Mechanicsville, Virginia  
United States

# \$9,785,315,000\*

\*Fiscal year ended 12/31/2021

[www.owens-minor.com](http://www.owens-minor.com)

**2021 rank:** 16


**2022 R&D spend:** n/a

**Employees:** 17,300

**Company CEO:** Edward Pesicka, president and CEO

**OWENS & MINOR** first opened in 1882 under the name Owens & Minor Drug Co. Now based in Mechanicsville, Virginia, the company started to grow beyond its pharmaceutical wholesaling background in 1981 and became a publicly-traded company in 1988.

Owens & Minor, through its subsidiary Halyard, was a big player in personal protective equipment during the COVID-19 pandemic. It distributed masks and N95 respirators to frontline workers and continued to make surgical gowns, drapes and packs, sterilization wraps, surgical accessories and equipment covers, exam gloves and other PPE. Its other two global product divisions — MediChoice and Medical Action Industries — make patient monitoring, respiratory, skin care, urology, wound care, IV start kits, procedure trays, mobility aids and more. Owens & Minor consistently ranks among the top 20 revenue earners in MDO's Big 100 rankings of the largest medical device companies.

In March 2022, the company closed its \$1.6 billion purchase of Apria, a developer of home medical equipment for respiratory therapy, sleep apnea treatment, negative pressure wound therapy, and continuous glucose monitoring. Owens & Minor combined its Byram Healthcare business with Apria to create the new Patient Direct segment. That segment — along with the Products & Healthcare Services segment combining the global products, medical distribution and services businesses — replace the company's two legacy segments. —DK and JH 





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No.  
14**BD** (Medical segment)Franklin Lakes, New Jersey  
United States**\$9,479,000,000\***


\*Fiscal year ended 9/30/2021

[www.bd.com](http://www.bd.com)**2021 rank:** n/a\***2022 R&D spend:** n/a**Employees:** 30,000**Company CEO:** Tom Polen, chair, CEO and president

Franklin Lakes, New Jersey-based **BECTON, DICKINSON (BD)** was founded in 1897 in New York City by Maxwell Becton and Fairleigh S. Dickinson. The medtech company has medical, life sciences and interventional business segments. As of the end of BD's previous full fiscal year (September 2021), the company employed approximately 75,000 associates across 62 countries. That number will have shifted by now as the company successfully spun off its diabetes business, which is now a publicly traded company called Embecta.

The company's Medical segment, which previously included the diabetes business, underwent a number of changes at the top in 2022. First, there was the appointment of Simon Campion as EVP and president of the Medical segment. BD announced in March that Alberto Mas intended to retire from the role. Campion's position was made effective on July 1, 2022, but he spent less than two months running the segment, departing in late

August for the corner office at Dentsply Sirona. Mike Garrison, who has been the worldwide president of BD Medication Management Solutions since 2020, will now be the new medical segment president.

In July, BD added to its offerings when it acquired Parata Systems for more than \$1.5 billion. Parata provides medication adherence packaging technology and perpetual inventory management, with its automation technology and software designed to enable pharmacists to focus more on clinical work and patient interactions. The company is also currently facing a shareholder lawsuit over its much-maligned Alaris infusion pump system. The lawsuit involves how the company communicated its performance amid increasingly serious issues with the platform. —SW 

*\*The 2022 Big 100 report is moving to September versus November in previous years. Because its fiscal year ends in September, BD's revenue number is the same as in the 2021 report.*

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No.  
15**B | BRAUN**  
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## B. Braun Melsungen


Melsungen (U.S. HQ in Bethlehem, Pennsylvania)  
Germany

**\$9,274,534,500\***

\*Fiscal year ended 12/31/2021

[www.bbraun.com](http://www.bbraun.com)**(€7,859,775,000)****2021 rank:** 17**2022 R&D spend:** \$491,897,160**Employees:** 66,234**Company CEO:** Anna Maria Braun, CEO

**B. BRAUN** began in Melsungen, Germany in 1839 as a pharmacy selling medical herbs through the mail. Still based in Melsungen, the company presently offers more than 5,000 different healthcare products thanks to its more than 64,000 employees across 64 countries in Asia, Europe, North America, the Pacific Rim and South America. Among its offerings are products for infusion therapy and pain management as the company seeks to tackle challenges including opioid abuse, hospital-acquired malnutrition and hazardous drug exposure — while eliminating preventable treatment errors and enhancing patient, clinician and environmental safety. The company is a full-line supplier of IV therapy products, including IV solutions and drug delivery systems. Other offerings include

products in the area of anesthesia, renal therapies, wound management and vascular access. Aesculap was initially founded in Germany in 1867 before Aesculap Inc. — the American division — was founded in 1977 in Center Valley, Pennsylvania. Aesculap AG was incorporated into the B. Braun Group in 1998 and manufactures surgical equipment, including sutures, handheld surgical instruments, implants, and electrosurgical devices and power systems. B. Braun's U.S. operations headquarters are in Bethlehem, Pennsylvania, with primary U.S. manufacturing facilities located in Allentown, Pennsylvania; Irvine, California; Carrollton, Texas; and the Dominican Republic. In 2022, the company opened a pharmaceutical manufacturing plant in Daytona Beach, Florida. —SW 

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No.  
16

# 3M Health Care

**3M Co.** (Health Care segment)Maplewood, Minnesota  
United States**\$9,050,000,000\***

\*Fiscal year ended 12/31/2021

[www.3m.com/3M/en\\_US/health-care-us](http://www.3m.com/3M/en_US/health-care-us)**2021 rank:** 18**2022 R&D spend:** n/a**Employees:** n/a**Company CEO:** Michael Roman, chair and CEO

**3M** announced in July that it plans to spin off its Health Care business by the end of 2023. The new Health Care business will be a roughly \$9-billion-a-year company focusing on wound care, oral care, healthcare IT and biopharma filtration. 3M officials said at the time that the transaction will better position Health Care to innovate. 3M plans to retain all responsibility for non-Health Care-related litigation, including what could be extremely costly legal proceedings related to the Combat Arms Earplugs. –CN 

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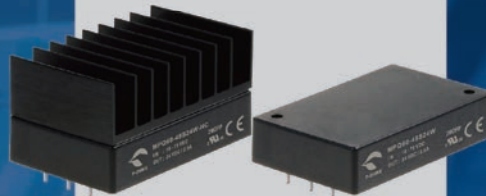
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LinkedIn

No.  
17

# Alcon

## Alcon

Geneva  
Switzerland

# \$8,222,000,000\*

\*Fiscal year ended 12/31/2021

[www.alcon.com](http://www.alcon.com)


**2021 rank:** 20

**2022 R&D spend:** \$842,000,000

**Employees:** 24,389

**Company CEO:** David Endicott, CEO

Formerly a subsidiary of pharmaceutical giant Novartis, **ALCON** spun out as a separate eye care business in 2019. The company was founded in 1945 by Robert Alexander and William Conner as a small pharmacy in Fort Worth, Texas. Its U.S. headquarters remain in Fort Worth, with global operations run out of its Geneva, Switzerland headquarters. Alcon develops ophthalmic surgical products, with a portfolio including technologies and devices for cataract, retinal, refractive surgery and advanced technology intraocular lenses to treat conditions like presbyopia and astigmatism. The surgical portfolio also

includes advanced viscoelastics, surgical solutions, surgical packs and other disposable products for cataract and vitreoretinal surgery. Meanwhile, the vision care business offers a wide range of daily disposable, reusable and color-enhancing contact lenses and a comprehensive portfolio of ocular health products. These include products for dry eye, contact lens care and ocular allergies, as well as ocular vitamins and redness relievers. In 2022, Alcon acquired glaucoma surgery device maker Ivantis for \$475 million and paid \$60 million to buy Kala Pharmaceuticals' Eysuvis pharmaceutical eye drops. —SW 





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No.  
18**FUJIFILM**


FUJIFILM Holdings Corporation

**Fujifilm Holdings** (healthcare only)Tokyo  
Japan**\$7,298,798,252\***

\*Fiscal year ended 3/31/2022

[www.fujifilm.com/us/en/healthcare](http://www.fujifilm.com/us/en/healthcare)**(JP¥801,700,000,000)****2021 rank:** 24**2022 R&D spend:** \$412,418,063**Employees:** n/a**Company CEO:** Teiichi Goto, president and CEO

**FUJIFILM** Healthcare Americas is headquartered in Lexington, Massachusetts. It offers diagnostic and enterprise imaging products and services across prevention, diagnosis and treatment. The medical imaging portfolio includes solutions for digital radiography, mammography, computed tomography, magnetic resonance imaging, ultrasound, endoscopy and endosurgery. Fujifilm's Synapse Enterprise Imaging portfolio provides healthcare professionals with imaging and data access to deliver a complete patient record. Fujifilm's artificial intelligence initiative, REiLI, combines the Tokyo-based parent

company's image-processing expertise with cutting-edge AI innovations. The In-Vitro Diagnostic portfolio provides molecular-based immunoassay technology for liver surveillance, clinical diagnostic chemicals for leading laboratories across the country, and diagnostic chemicals for OEM white labeling products. In 2022, the company won a \$405 million Defense Department contract for endoscopy tech and training. The company also launched its FDR Cross hybrid c-arm and portable X-ray system in the U.S., calling it the world's first two-in-one fluoroscopy and digital radiography system. —JH 

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100

2022 BIG100

No.  
19

ZIMMER BIOMET

**Zimmer Biomet** (minus ZimVie spinoff)Warsaw, Indiana  
United States**\$6,821,600,000\***

\*Fiscal year ended 12/31/2021

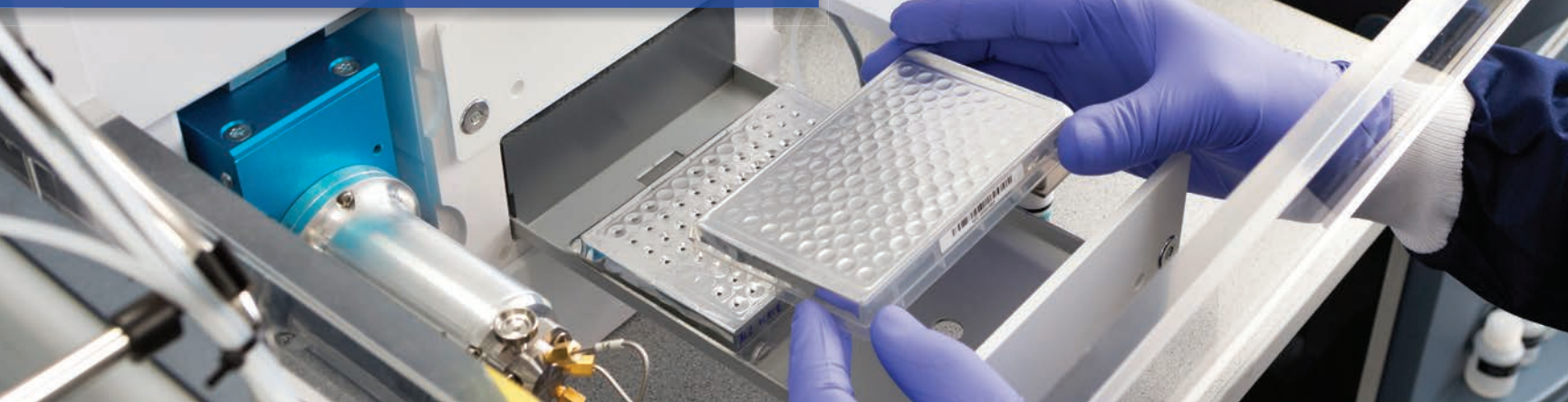
[www.zimmerbiomet.com](http://www.zimmerbiomet.com)**2021 rank:** 19**2022 R&D spend:** \$435,900,000**Employees:** 16,800**Company CEO:** Bryan Hanson, chair, president and CEO

**ZIMMER BIOMET** has had a great deal of news over the past year. It spun off its dental and spine business as ZimVie in March. ZB has also introduced new ortho surgical offerings based on AI and mixed reality. They were also the first out of the gate with smart knee implants.

"We believe our focus on innovation and the transformation of our business continues to position us well for long-term growth and continued delivery for our shareholders," CEO Bryan Hanson said during the company's Q2 earnings call in August. -CN 

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No.  
20**OLYMPUS**<sup>®</sup>**Olympus** (medical segment)Tokyo  
Japan**\$6,710,970,503\***

\*Fiscal year ended 3/31/2022

[www.medical.olympusamerica.com](http://www.medical.olympusamerica.com)**(JP¥737,133,000,000)****2021 rank:** 21**2022 R&D spend:** \$546,412,964**Employees:** 21,898**Company CEO:** Yasuo Takeuchi, CEO

Tokyo-based **OLYMPUS GROUP** makes precision machines and instruments. Its medical devices primarily serve gastroenterology, general surgery, pulmonology, bronchoscopy, urology, gynecology, otolaryngology, bariatrics, orthopedics and anesthesiology. Founded in 1919, the company developed the world's first gastrocamera in 1950 and now offers endoscopes, endoscope reprocessors, laparoscopes, video imaging systems, system integration solutions and medical services through its Endoscopy unit. Its Therapeutic

portfolio includes surgical energy devices and instruments to help prevent, detect and treat disease. There are devices for endotherapy, urology/gynecology, respiratory health and ear/nose/throat applications. In 2022, Olympus broke off Scientific Solutions — a third business unit outside of Medical Solutions that makes microscope systems for the life science industry, as well as videoscopes, nondestructive testing technology and X-ray analyzers. Scientific Solutions is now a wholly-owned subsidiary called Evident. —JH <sup>M</sup>

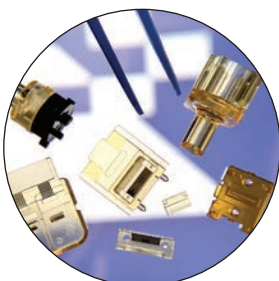
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No.  
**21****Terumo**Tokyo  
Japan●●● **\$6,402,977,058\***  
\*Fiscal year ended 3/31/2022  
**(JP¥703,303,000,000)****2021 rank:** 22  
**R&D spend:** n/a  
**Employees:** 28,000  
**Company CEO:** Shinjiro Sato, president & CEO

**TERUMO** is one of the few medical device companies with roots stretching back a full century. Founded as a thermometer manufacturer, Terumo has a diversified range of products spanning interventional cardiology, blood transfusion and cell therapy. In addition to its presence in Asia, the Tokyo-based company has subsidiaries in the EMEA region, South America and North America. Since the mid-1990s, the company has developed devices for transradial intervention, a technique involving the insertion of a catheter in the wrist to grant blood vessel access. It also makes devices for diabetes care and peritoneal dialysis treatments. In total, the company offers 50,000 products and services. In 2022, the company renamed its General Hospital Co. to Medical Care Solutions Co, reflecting the growth of in-home care and a business expansion into extensive diabetes treatment solutions. –BB <sup>M</sup>

[www.terumomedical.com](http://www.terumomedical.com)

No.  
**22****Intuitive Surgical**Sunnyvale, California  
United States●●● **\$5,710,100,000\***  
\*Fiscal year ended 12/31/2021**2021 rank:** 27  
**R&D spend:** \$671,000,000  
**Employees:** 9,793  
**Company CEO:** Gary Guthart, president & CEO

Since its founding in the 1990s, **INTUITIVE** has pioneered robotic surgery. It remains the dominant player in the space, even as a host of companies of all sizes have entered the field to compete. Intuitive's present systems on the market include the Da Vinci Xi, Da Vinci X, Da Vinci SP, and Ion.

Work continues on the next generations of Intuitive's robotic systems, CEO Gary Guthart said during the company's Q2 earnings call in July. Guthart, however, also acknowledged that deeper technological opportunities and clinical impact also mean deeper validation work. "And we're not afraid of that work. I'd rather do things that are really clinically meaningful for the customer," he said. (Guthart will deliver a keynote at DeviceTalks West, Oct. 19–20, 2022 in Santa Clara, California.) –CN <sup>M</sup>

[www.intuitive.com](http://www.intuitive.com)

No.  
**23****Hologic**Marlborough, Massachusetts  
United States●●● **\$5,632,300,000\***  
\*Fiscal year ended 9/25/2021**2021 rank:** n/a\*  
**R&D spend:** \$276,300,000  
**Employees:** 6,350  
**Company CEO:** Stephen MacMillan, CEO

Founded in 1985, Marlborough, Massachusetts-based **HOLOGIC** develops and manufactures diagnostics products, imaging systems, and surgical products. It focuses on women's health and well-being through early detection and treatment. The company successfully pivoted toward more general diagnostics during the COVID-19 pandemic, becoming a major provider of tests and testing machines for the novel coronavirus. The resulting influx of cash enabled Hologic to reactivate full-time R&D operations and send business development teams shopping for M&A opportunities. In 2022, Hologic opened an innovation center in Aix-en-Provence, France, launched new assays for COVID-19, flu and RSV, and continued to exceed Wall Street's expectations despite declining demand for COVID-19 assays and semiconductor shortages affecting the company's Breast Health business. –JH <sup>M</sup>

[www.hologic.com](http://www.hologic.com)

\*The 2022 Big 100 report is moving to September versus November in previous years. Because its fiscal year ends in September, Hologic's revenue number is the same as in the 2021 report.



No.  
**24****Edwards Lifesciences**Irvine, California  
United States● ● ● **\$5,232,500,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 26  
**R&D spend:** \$903,100,000  
**Employees:** 15,700  
**Company CEO:** Michael Mussallem, CEO

**EDWARDS LIFESCIENCES** is one of medtech's biggest heart valve makers. The Irvine, California-based company treats advanced cardiovascular disease with its numerous heart valve therapies and critical care and vascular technologies. One of Edwards' most known specialties is its transcatheter aortic valve replacement (TAVR) devices. The medtech giant also specializes in blood conservation, enhanced surgical recovery, clot management, hypotension management, infection control and sepsis shock management. In 2022, the company won FDA approval for its Mitris Resilia tissue valve replacement system but continued to face headwinds from hospital staffing shortages. Edwards Lifesciences expects FDA approval of its Pascal Precision platform later this year. –DK and JH <sup>M</sup>

[www.edwards.com](http://www.edwards.com)No.  
**25****Smith+Nephew**London  
United Kingdom● ● ● **\$5,212,000,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 25  
**R&D spend:** \$356,000,000  
**Employees:** 18,369  
**Company CEO:** Deepak Nath, CEO

London-based **SMITH+NEPHEW** specializes in advanced wound management, orthopedics and trauma and sports medicine. While announcing Q2 2022 results, company officials said they have a strategy to grow the company's orthopedics business. The plan includes initiatives such as driving operational benefits in orthopedics and transforming the business. S+N has also invested in its orthopedics business by building a new \$100 million plant in Malaysia. In other recent news, the British medtech giant announced that it will build a new R&D and manufacturing facility for its Advanced Wound Management franchise that will move the company outside of its historic home of Hull. –CN <sup>M</sup>

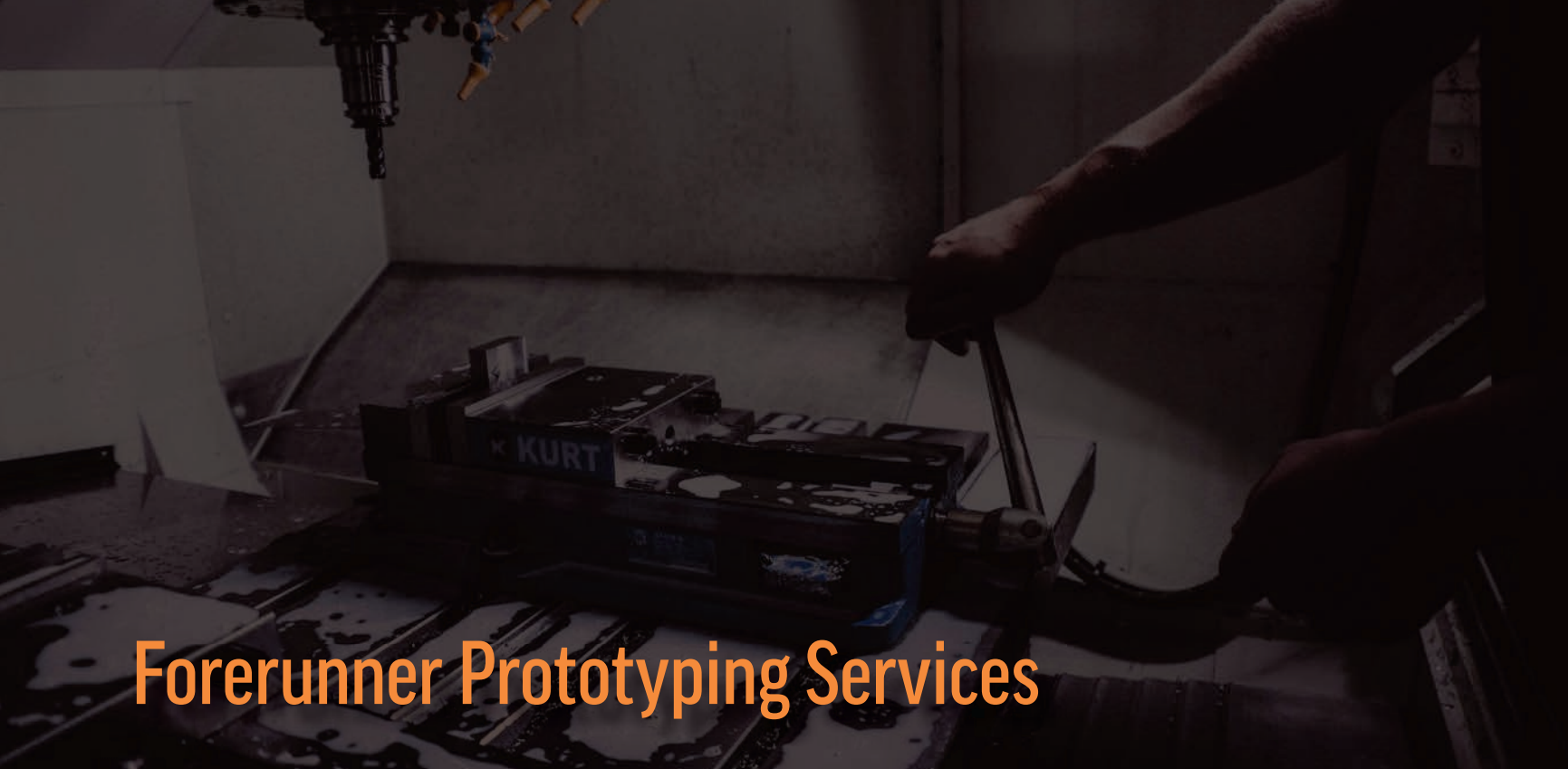
[www.smith-nephew.com](http://www.smith-nephew.com)No.  
**26****Steris**Dublin, Ireland  
(operational HQ in Mentor, Ohio)  
United States● ● ● **\$4,585,064,000\***

\*Fiscal year ended 3/31/2022

**2021 rank:** 35  
**R&D spend:** \$87,944,000  
**Employees:** 16,000  
**Company CEO:** Daniel Carestio, president and CEO

**STERIS** jumped nearly 10 positions up the Big 100 ranking in 2022 after 2021 brought a new CEO and a big acquisition contributing to top-line sales this year. The sterilization and surgical products company closed on its \$4.6 billion purchase of Cantel Medical in June 2021 and replaced Steris CEO Walt Rosebrough with Daniel Carestio the following month. Sales for the full year (through March 2022) increased nearly 40% from fiscal 2021, with year-over-year healthcare revenue growth of 32% year-over-year, applied sterilization technologies growth of 19% and life sciences growth of 15%. "While supply chain and inflation continue to be a challenge, our teams have worked to address these issues with minimal impact on our ability to serve our customers. As we look ahead at the new fiscal year, we expect another record year of performance," Carestio said while announcing the results. –JH <sup>M</sup>

[www.steris.com](http://www.steris.com)



# Forerunner Prototyping Services

Micro medical designs need to iterate fast and innovate fast—and ultimately get their product to market faster. Prototyping can often help.

But... **faster prototypes don't mean faster speed to market.**  
 And prototyping is not a one-size-fits-all type of service.

While 3D printed prototypes are indeed faster and cheaper, they may not provide the most value for the customer. Micro medical OEMs have found tremendous value in having a prototype of their design in their actual material—including bioabsorbables—so they can evaluate the physical properties of the part, especially as it may relate to other components on their device.

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Machined prototype made in a bioabsorbable resin

	3D PRINTING	MICRO MACHINING	TEST TOOLING
ACHIEVABLE TOLERANCES	±0.002"	±0.002"	±0.001"
MATERIALS FOR USE	Photopolymers	Any <i>rigid</i> thermoplastic, including bioabsorbable materials	Any thermoplastic, including bioabsorbable materials
LEAD TIME FOR PROTOTYPES	3-5 days	1-2 weeks	2-4 weeks
COST FOR PROTOTYPES	\$	\$\$	\$\$\$

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No.  
**27****Fresenius  
Medical Care**

(healthcare products)

Bad Homburg  
Germany●●● **\$4,416,740,000\***

\*Fiscal year ended 12/31/2021

**(€ 3,743,000,000)**

**2021 rank:** 28  
**R&D spend:** \$260,780,000  
**Employees:** 30,000  
**Company CEO:** Rice Powell, CEO; Carla Kriwet, incoming CEO; Dr. Katarzyna Mazur-Hofsäß, CEO of Care Enablement for Fresenius Medical Care

**FRESENIUS MEDICAL CARE** is one of the world's top providers of products and services for people with renal diseases. Severe COVID-19 cases can cause acute kidney failure, so Fresenius Medical Care expanded production of acute dialysis products at short notice at the start of the pandemic. Around the same time, FDA cleared the company's Novalung system — which reduces or eliminates the need for mechanical ventilation by pumping a person's blood through an oxygenator for gas exchange. In 2022, Fresenius Medical Care hired Carla Kriwet as CEO to replace longtime leader Rice Powell, who will retire at the end of the year. The company also spun off its Fresenius Health Partners division in a three-way merger with InterWell Health and Cricket Health. The new company provides kidney care under the InterWell Health brand. —CN and JH <sup>M</sup>

[www.freseniusmedicalcare.com](http://www.freseniusmedicalcare.com)**CORRECT  
CADENCE**

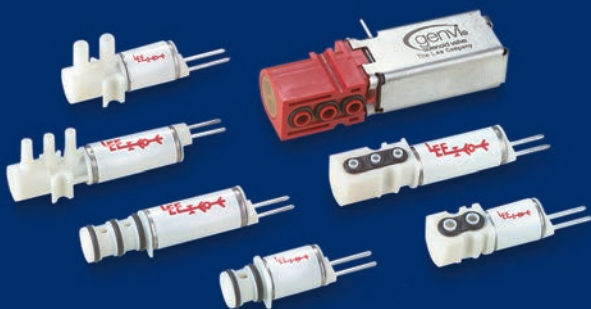
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## Canon Medical

Ōtawara  
Japan

●●● **\$4,373,288,420\***

\*Fiscal year ended 12/31/2021

**(JP¥480,362,000,000)**

**2021 rank:** n/a  
**R&D spend:** n/a  
**Employees:** n/a  
**Company CEO:** Yuji Hamada, president and CEO

**CANON MEDICAL SYSTEMS** started in 1914 with X-ray tube research by Tokyo Electric Co. A little more than 100 years later, Canon purchased the business formerly known as Toshiba Medical Systems. Canon Medical Systems offers diagnostic medical imaging products and services, including CT, MR, X-ray, ultrasound and healthcare informatics. In 2022, the company acquired Danish medtech manufacturer Nordisk Røntgen Teknik, while subsidiary Canon Medical Systems USA bought Minneapolis-based NXC Imaging. - JH

[www.global.medical.canon](http://www.global.medical.canon)



## Dentsply Sirona

Charlotte, North Carolina  
United States

●●● **\$4,251,000,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 30  
**R&D spend:** \$171,000,000  
**Employees:** 15,000  
**Company CEO:** John Groetelaars, interim CEO;  
Simon Campion, incoming CEO

As of publication in early September, Simon Campion was in the process of leaving his position as head of BD's Medical segment to become CEO of **DENTSPLY SIRONA**. He takes over for interim CEO John Groetelaars, the former Hillrom CEO who has led the dental tech company since the removal of former CEO Don Casey in April. (Previous CFO Jorge Gomez soon left his new job at Moderna.) The company's board of directors launched an internal investigation into potentially questionable financial practices. -CN

[www.dentsplysirona.com](http://www.dentsplysirona.com)



## BioMérieux

Marcy-l'Étoile  
France

●●● **\$3,983,680,000\***

\*Fiscal year ended 12/31/2021

**(€3,376,000,000)**

**2021 rank:** 29  
**R&D spend:** \$459,020,000  
**Employees:** 13,000  
**Company CEO:** Alexandre Mérieux, CEO and chair

An important player in the in vitro diagnostics space for more than 55 years, **BIOMÉRIEUX** has a presence in 44 countries and serves more than 160 countries with the support of large distributors. The company provides a wide range of diagnostic systems, reagents, software and services to detect diseases and contamination, improve people's health and bolster consumer safety. An upturn in U.S. respiratory panels demand amid the COVID-19 Delta variant wave pushed sales up 10.5% in 2021. In 2022, BioMérieux purchased San Jose, California-based Specific Diagnostics, and later launched Aurobac Therapeutics, a joint venture with Boehringer Ingelheim and Evotec to fight antimicrobial resistance. Most recently, the FDA granted Breakthrough Device Designation to BioMérieux's Specific Reveal Rapid Antimicrobial Susceptibility Test System. -CN and JH

[www.biomerieux.com](http://www.biomerieux.com)

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## Align Technology

Tempe, Arizona  
United States

●●● **\$3,952,584,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 43  
**R&D spend:** \$250,315,000  
**Employees:** 22,540  
**Company CEO:** Joseph Hogan, president and CEO

San Jose, California-based **ALIGN TECHNOLOGY** is the maker of the Invisalign clear aligner orthodontics system — an alternative to traditional braces. Started in 1997, Align Technology pioneered the invisible orthodontics market with Invisalign. The system combines digital treatment planning and mass customization. In 2011, Align acquired the iTero intraoral scanner to extend the digital treatment process of the Invisalign system. Align Technology has treated more than 12 million people to date. The company reported record-breaking sales in fiscal 2022, moving it into the top third of our rankings among the Big 100 largest medical device companies. —DK and JH <sup>M</sup>

[www.aligntech.com](http://www.aligntech.com)



## Mindray

Shenzhen  
China

●●● **\$3,917,343,585\***

\*Fiscal year ended 12/31/2021

**(RMB25,270,000,000)**

**2021 rank:** n/a  
**R&D spend:** \$423,203,324  
**Employees:** 14,684  
**Company CEO:** Li Xiting, chair

Founded in 1991, Shenzhen, China-based **MINDRAY** has three core businesses: Patient Monitoring and Life Support, Medical Imaging, and In-Vitro Diagnostics. It has 40 international subsidiaries worldwide. Over the years, it's expanded its capabilities through the 2008 acquisition of Datascope's patient monitoring business and the 2013 acquisition of ultrasound tech company Zonare Medical Systems. Zonare's software-based Zone Sonography technology (ZST) is the basis of Mindray's Living Technology, a constantly evolving architecture to meet clinicians' changing imaging needs. —CN <sup>M</sup>

[www.mindray.com](http://www.mindray.com)



## Hoya

(life care segment)

Tokyo  
Japan

●●● **\$3,710,387,837\***

\*Fiscal year ended 3/31/2022

**(JP¥407,549,000,000)**

**2021 rank:** 33  
**R&D spend:** n/a  
**Employees:** n/a  
**Company CEO:** Eiichiro Ikeda, group president and CEO

**HOYA'S** healthcare and information technology offerings include eyeglasses, medical endoscopes, intraocular lenses, optical lenses and key components for semiconductor devices. —CN <sup>M</sup>

[www.hoya.co.jp/business/medical.html](http://www.hoya.co.jp/business/medical.html)



## Sonova

Stäfa  
Switzerland

●●● **\$3,678,805,774\***  
\*Fiscal year ended 3/31/2022  
**(CHF3,363,900,000)**

**2021 rank:** 39  
**R&D spend:** \$252,077,865  
**Employees:** 16,733  
**Company CEO:** Arnd Kaldowski, CEO

Founded in 1947, **SONOVA** develops hearing instruments and cochlear implants and other products. The Stäfa, Switzerland–headquartered company has a variety of brands. Under the hearing instrument category are the brands Phonak, Unitron and Hansaton. Sonova also has the consumer hearing brand Sennheiser and the Advanced Bionics line of cochlear implants. Serving customers in more than 100 countries, Sonova announced in August 2022 that it plans to expand its footprint in China by acquiring Hysound, a company with approximately 200 clinics in 20 Chinese provinces. The company anticipates that its proposed acquisition of the Hysound chain of audiological clinics in China will close by March 31, 2023, subject to regulatory approval. –BB **M**

[www.sonova.com](http://www.sonova.com)



## ResMed

San Diego  
United States

●●● **\$3,578,100,000\***  
\*Fiscal year ended 6/30/2022

**2021 rank:** 34  
**R&D spend:** \$253,600,000  
**Employees:** 8,000  
**Company CEO:** Michael Farrell, CEO

Founded by Peter Farrell in Australia in 1989, **RESMED** remains a family affair today, with his son Michael “Mick” Farrell now CEO. It’s a position Mick Farrell has held since his father transitioned into a non-executive role in 2013. Now headquartered in San Diego, ResMed develops cloud-connected medical devices for respiratory diseases. Among its offerings are continuous positive airway pressure (CPAP) machines for sleep apnea and ventilators for treating chronic obstructive pulmonary disease (COPD) and other respiratory conditions. Health providers have used the company’s devices as alternatives to invasive ventilators during the COVID-19 pandemic. With competitor Philips sidelined by a massive recall until at least 2023, ResMed has grown as fast as its supply chain allows. In 2022, Lucile Blaise became president of ResMed’s Sleep & Respiratory Care business, replacing Jim Hollingshead after he left to become CEO of Insulet. The company also bought digital insomnia therapy app Somnio developer Mementor and announced a \$1 billion deal to buy German software company Medifox Dan by the end of the year. –SW and JH **M**

[www.resmed.com](http://www.resmed.com)



## Nipro

(medical segment)  
Osaka  
Japan

●●● **\$3,400,227,604\***  
\*Fiscal year ended 3/31/2022  
**(JP¥373,481,000,000)**

**2021 rank:** 31  
**R&D spend:** \$78,022,578  
**Employees:** 25,239  
**Company CEO:** Yoshihiko Sano, CEO and president

The Japanese company’s medical device business is especially focused on dialysis and artificial organs. **NIPRO** boasts that it is one of the leading manufacturers of dialyzers in the world. –CN **M**

[www.nipro.com](http://www.nipro.com)



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## Getinge

Gothenburg  
Sweden




**\$3,152,564,103\***

\*Fiscal year ended 12/31/2021

**(SEK27,049,000,000)**

**2021 rank:** 32  
**R&D spend:** \$139,510,490  
**Employees:** 10,700  
**Company CEO:** Mattias Perjos,  
president & CEO

The COVID-19 pandemic had a major impact on this Swedish medtech company, especially when it came to the steep rise in demand for ventilators and extracorporeal life support. In fact, the company nearly tripled its production of ventilators in 2020 and received FDA clearance for three products to expand its Servo platform of ventilators in 2021. In 2022, **GETINGE** promoted Patricia Fitch to president of the North America region, succeeding Eric Honroth. —CN and JH 

[www.getinge.com](http://www.getinge.com)





## Coloplast

Humblebæk  
Denmark

● ● ● **\$2,970,336,391\***  
\*Fiscal year ended 9/30/2021  
**(DKK 19,426,000,000)**

**2021 rank:** n/a\*  
**R&D spend:** \$115,443,425  
**Employees:** 12,578  
**Company CEO:** Kristian Villumsen, president & CEO

Humblebæk, Denmark-based **COLOPLAST** specializes in the development of ostomy, continence, interventional urology, wound and skin care products and services. The company bills itself as a leader in “intimate healthcare needs.” The international company has about 14,000 employees. In June, Coloplast won an AscenDrive agreement with Premier. The AscenDrive program standardizes the care delivery process. The company is one of two suppliers awarded the AscenDrive contract for ostomy products. In July 2022, a federal judge in Minnesota granted summary judgment to Coloplast in a transvaginal mesh lawsuit. –BB **M**

[www.coloplast.us](http://www.coloplast.us)

\*The 2022 Big 100 report is moving to September versus November in previous years. Because its fiscal year ends in September, Coloplast’s revenue number is the same as in the 2021 report.



## Demant

Smørum  
Denmark

● ● ● **\$2,932,802,548\***  
\*Fiscal year ended 12/31/2021  
**(DKK 18,418,000,000)**

**2021 rank:** 45  
**R&D spend:** \$214,968,153  
**Employees:** 18,116  
**Company CEO:** Søren Nielsen, president & CEO

The history of the Hillerød, Denmark–headquartered hearing healthcare and audio technology company stretches back to 1904. **DEMANT** manufactures hearing care products, including hearing aids and hearing implants. The company also offers diagnostic equipment and services and audio technologies. It has expanded its business with audio and video technologies for enterprises and gaming. The William Demant Foundation holds the majority of shares in Demant A/S, which is listed as a blue-chip stock on Nasdaq Copenhagen. The company operates in more than 30 countries. –BB **M**

[www.demant.com](http://www.demant.com)



## Bio-Rad

Hercules, California  
United States

● ● ● **\$2,922,545,000\***  
\*Fiscal year ended 12/31/2021

**2021 rank:** 41  
**R&D spend:** \$271,657,000  
**Employees:** 7,900  
**Company CEO:** Norman Schwartz, president & CEO

**BIO-RAD** manufactures various products for life science research and clinical diagnostic applications. The Hercules, California-based company’s diversified customer base includes universities, research institutions, hospitals, public health and commercial laboratories and biotechnology and pharmaceutical companies. Founded in 1952, Bio-Rad has steadily grown over the decades with a string of acquisitions. The company acquired human control serum supplier Environmental Chemical Specialties in 1976. It acquired AbD Serotec, a research and diagnostics company, in 2013. It bought PCR systems maker RainDance Technologies in 2017. In 2022, Bio-Rad said it would acquire outstanding shares of Warsaw, Poland–based Curiosity Diagnostics for a total consideration of up to \$170 million. –BB **M**

[www.bio-rad.com](http://www.bio-rad.com)




**Cooper Cos.**  
San Ramon, California  
United States

●●● **\$2,922,500,000\***

\*Fiscal year ended 10/31/2021

**2021 rank:** 44  
**R&D spend:** \$92,700,000  
**Employees:** 12,000  
**Company CEO:** Albert White, president and CEO

**COOPER COS.** has two business units — CooperVision and CooperSurgical — that provide products and services to advance vision care and women's health. CooperVision is a significant manufacturer of contact lenses, while CooperSurgical's portfolio focuses on women's health, fertility and diagnostics. The company purchased fertility services provider Generate Life Sciences for \$1.6 billion in December 2021 and added it to the CooperSurgical portfolio. In March 2022, Cooper launched its SightGlass Vision joint venture with EssilorLuxottica. In February, Cooper announced an \$875 million deal to buy Cook Medical's Reproductive Health business. Subject to regulatory approval, that deal is expected to close by the end of the year. – CN and JH 

[www.coopercos.com](http://www.coopercos.com)



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Product Design & Development



No.  
**42**

## Teleflex

Wayne, Pennsylvania  
United States● ● ● **\$2,809,563,000\***

\*Fiscal year ended 12/31/2021

The Wayne, Pennsylvania–based critical care and surgical tech company boasts a diverse portfolio serving the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. **TELEFLEX'S** notable brands include Arrow, Deknatel, Hudson RCI, LMA, Pilling, Rüschi, UroLift and Weck. In August 2022, the company announced a deal worth up to \$300 million to acquire Standard Bariatrics and its powered stapling technology for bariatric surgery. –CN and JH <sup>M</sup>

[www.teleflex.com](http://www.teleflex.com)

**2021 rank:** 42  
**R&D spend:** \$130,841,000  
**Employees:** 14,000  
**Company CEO:** Liam Kelly, chair, president and CEO

No.  
**43**

## Paul Hartmann

Heidenheim an der Brenz  
Germany● ● ● **\$2,716,124,000\***

\*Fiscal year ended 12/31/2021

**(€2,301,800,000)**

**THE HARTMANN GROUP** has a 200-year legacy of medical advances in wound care and skin health. The company manufactures wound dressings, absorbent incontinence products, compression and fixation bandages, and wicking fabric and pre-moistened wipes. The Hartmann Group operates in approximately 130 countries and has a prominent European presence. The company was founded in 1818. –BB <sup>M</sup>

[www.hartmann.info/en-corp](http://www.hartmann.info/en-corp)

**2021 rank:** 43  
**R&D spend:** n/a  
**Employees:** 10,628  
**Company CEO:** Britta Fünfstück, CEO

No.  
**44**

## HU Group

Tokyo  
Japan● ● ● **\$2,484,522,942\***

\*Fiscal year ended 3/31/2022

**(JP¥272,900,000,000)**

**HU GROUP** focuses on lab testing, related services and in vitro diagnostics. The Japan-based company has been seeking to promote the digitization of testing information — and using data to create a medical/health information platform. –CN <sup>M</sup>

[www.hugp.com](http://www.hugp.com)

**2021 rank:** 46  
**R&D spend:** \$66,460,306  
**Employees:** n/a  
**Company CEO:** Shigekazu Takeuchi, president and CEO

No.  
**45****Dexcom**San Diego  
United States● ● ● **\$2,448,500,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 49  
**R&D spend:** \$517,100,000  
**Employees:** 6,300  
**Company CEO:** Kevin Sayer, chair, president and CEO

The San Diego-based developer of continuous glucose monitoring (CGM) technology sat poised for a big 2022. CEO Kevin Sayer claimed at the start of the year that he planned for "more activity" than the company had ever seen, with the expected FDA clearance and launch for the next-generation **DEXCOM** G7 CGM. The company suffered a setback after having to make software tweaks to G7 on guidance from the FDA, pushing back the G7 timeline. Still, Dexcom moved forward with the launch of its differentiated Dexcom One offering, FDA breakthrough device designation for the use of its CGMs in hospitals, and more. –SW **M**

[www.dexcom.com](http://www.dexcom.com)

No.  
**46****Dräger**

(medical division)

Lübeck  
Germany● ● ● **\$2,435,756,000\***

\*Fiscal year ended 12/31/2021

**(€ 2,064,200,000)**

**2021 rank:** 40  
**R&D spend:** n/a  
**Employees:** 15,900  
**Company CEO:** Stefan Dräger, chair

Lübeck, Germany-based **DRÄGER**, which manufactures medical and safety technology products, was founded in 1889. Dräger has more than 15,000 employees worldwide and is present in over 190 countries around the globe. The company offers products and services, including emergency care, perioperative care, critical care, perinatal care and home care. –SW **M**

[www.draeger.com/en-us\\_us/Hospital](http://www.draeger.com/en-us_us/Hospital)

No.  
**47****Bruker**Billerica, Massachusetts  
United States● ● ● **\$2,417,900,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 48  
**R&D spend:** \$220,800,000  
**Employees:** 7,765  
**Company CEO:** Frank Laukien, chair, president and CEO

**BRUKER** provides scientific instruments and analytical and diagnostic products and services to enable scientists to explore life and materials at molecular, cellular and microscopic levels. German experimental physics professor Günther Laukien helped start the company in 1960, providing what the company says were the first high-resolution systems for use in analytical chemistry in the U.S. In 2022, Bruker acquired Prolab Instruments and then Optimal Industrial Automation and Technologies; terms of both deals were not disclosed. –CN and JH **M**

[www.bruker.com](http://www.bruker.com)

No.  
**48****Cook Medical**Bloomington, Indiana  
United States● ● ● **\$2,336,000,000\***

\*Fiscal year ended 12/31/2021

Founded in 1963 in Bloomington, Indiana, **COOK MEDICAL**'s first products were wire guides, needles and catheters. These days, the privately-held company — part of the Cook Group — sells a wide range of minimally invasive medical devices covering 41 medical specialties, with sales in 135 countries. In February 2022, Cook Medical announced an \$875 million deal to sell its Reproductive Health business to Cooper Cos. Subject to regulatory approval, that deal should close by the end of the year. —CN and JH <sup>M</sup>

[www.cookmedical.com](http://www.cookmedical.com)

**2021 rank:** 47  
**R&D spend:** n/a  
**Employees:** 13,898  
**Company CEO:** Carl Cook, CEO; Pete Yonkman, president

No.  
**49****Amplifon**Milan  
Italy● ● ● **\$2,298,728,500\***

\*Fiscal year ended 12/31/2021

**(€1,948,075,000)**

**AMPLIFON** is a major hearing aid retailer. Its family of products and services includes Ampli-easy, Ampli-mini, Ampli-connect, Ampli-energy, the Amplifon App, and Companion smart support. —CN <sup>M</sup>

[www.amplifonusa.com](http://www.amplifonusa.com)

**2021 rank:** 52  
**R&D spend:** n/a  
**Employees:** 18,600  
**Company CEO:** Enrico Vita, CEO

No.  
**50****Straumann**Basel  
Switzerland● ● ● **\$2,211,286,089\***

\*Fiscal year ended 12/31/2021

**(CHF2,022,000,000)**

The Swiss company is a global provider of tooth replacement and orthodontic products and services. Its brands include Anthogyr, ClearCorrect, Dental Wings, Medentika, Neodent, NUVO and **STRAUMANN**. In 2022, Straumann acquired health-tech startup PlusDental for about \$137 million. —CN and JH <sup>M</sup>

[www.straumann.com](http://www.straumann.com)

**2021 rank:** 54  
**R&D spend:** n/a  
**Employees:** 9,000  
**Company CEO:** Guillaume Daniellot, CEO



## ConvaTec

Reading  
United Kingdom

●●● **\$2,038,000,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 50  
**R&D spend:** \$94,500,000  
**Employees:** 10,025  
**Company CEO:** Karim Bitar, CEO

**CONVATEC** is an advanced wound care, ostomy care, continence and critical care and infusion care company. Founded in 1978, the company's products and devices include DuoDerm dressings, Aquacel and Hydrofiber technology, the Flexi-Seal fecal management system, and the Avelle negative pressure wound therapy system. ConvaTec has shipped more than 1 billion products and operates out of more than 80 countries. In 2022, ConvaTec acquired Triad Life Sciences — now known as ConvaTec Advanced Tissue Technologies, under ConvaTec's Advanced Wound Care business. —DK and JH <sup>M</sup>

[www.convatec.com](http://www.convatec.com)

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## Carl Zeiss Meditec

Jena  
Germany

**\$1,990,424,000\***

\*Fiscal year ended 9/30/2021

**(€1,686,800,000)**

**2021 rank:** 53  
**R&D spend:** \$273,878,000  
**Employees:** 3,531  
**Company CEO:** Markus Weber,  
 president and CEO

**ZEISS** creates and supplies technologies and application-oriented products and services for ophthalmology and microsurgery. Markus Weber, previously responsible for Carl Zeiss AG's Semiconductor Manufacturing Technology segment, succeeded CEO Ludwin Monz at the start of 2022. In April, the company acquired Kogent Surgical and Katalyst Surgical, two Missouri-based sister companies. —CN and JH 

[www.zeiss.com/meditec-ag](http://www.zeiss.com/meditec-ag)



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## Nihon Kohden

Tokyo  
Japan

●●● **\$1,867,525,492\***

\*Fiscal year ended 3/31/2022

**(JP¥205,129,000,000)**

**2021 rank:** 51  
**R&D spend:** n/a  
**Employees:** n/a  
**Company CEO:** Hirokazu Ogino, president and CEO

Yoshio Ogino founded **NIHON KOHDEN** in 1950 with a vision of bringing the power of electrical engineering to medicine. Over the decades, this Japanese company has been a pioneer in pulse oximetry, cerebral artery pressure meters, ECGs, heart monitors and fetal monitors. In 2022, the company announced plans to open a new hematology analyzer reagent factory in Haryana, India, in spring 2024. –CN and JH

[www.nihonkohden.com](http://www.nihonkohden.com)



## Elekta

Stockholm  
Sweden

●●● **\$1,695,571,096\***

\*Fiscal year ended 4/30/2022

**(SEK14,548,000,000)**

**2021 rank:** 55  
**R&D spend:** \$159,906,760  
**Employees:** 4,631  
**Company CEO:** Gustaf Salford, president and CEO

The Swedish company has been a pioneer in precision radiation medicine since its founding in 1972. The company has offices in 120 countries and a listing on Nasdaq Stockholm. In 2022, **ELEKTA** launched its Elekta Esprit radiosurgery system and signed a global commercial collaboration agreement with GE Healthcare to expand precision radiation therapy access. –CN and JH

[www.elekta.com](http://www.elekta.com)



## Integra Lifesciences

Princeton, New Jersey  
United States

●●● **\$1,542,448,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 57  
**R&D spend:** \$93,051,000  
**Employees:** 3,800  
**Company CEO:** Jan De Witte, president and CEO

**INTEGRA LIFESCIENCES** was founded in 1989 after the acquisition of an engineered collagen technology platform that was designed to repair and regenerate tissue. The company has since expanded its regenerative technology product portfolio to include numerous surgical instruments, neurosurgical devices and advanced wound products. Some of its better-known brands include AmnioExcel, Bactiseal, CerebroFlo, Certas Plus, Codman, CUSA, DuraGen, DuraSeal, MediHoney and SurgiMend. Jan De Witte succeeded Peter Arduini as CEO in December 2021 after Arduini left for the top spot at GE Healthcare. –DK and JH

[www.integralife.com](http://www.integralife.com)





## Enovis

(Formerly Colfax's Medical Technology segment, DJO)

Wilmington, Delaware  
United States

● ● ● **\$1,426,188,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 62  
**R&D spend:** n/a  
**Employees:** 5,000  
**Company CEO:** Matthew Trerotola, CEO

DJO parent company **ENOVIS** (formerly Colfax) completed the spinoff of its fabrication technology business in April. The result is that Enovis is now a major, stand-alone orthopedic device company — No. 56 in the 2022 Big 100 rankings of the largest medical device companies. Since it went stand-alone, Enovis has been engaging in tuck-in acquisitions. For example, in May, it acquired the assets of Outcome-Based Technologies' hip and knee bracing portfolio, adding the Excyabir hip brace and CryoKnee knee braces to its DonJoy bracing brand. In July, Enovis also completed the acquisition of Insight Medical and its FDA-cleared Arvis augmented reality platform for hip and knee replacement surgery. –CN **M**

[www.enovis.com](http://www.enovis.com)



## ICU Medical

San Clemente, California  
United States

● ● ● **\$1,316,308,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 59  
**R&D spend:** \$47,498,000  
**Employees:** 8,500  
**Company CEO:** Vivek Jain, CEO

**ICU MEDICAL** announced on Jan. 6, 2022 that it had completed its \$2.35 billion acquisition of Smiths Medical from the Smiths Group. Since ICU's most recent annual report did not include Smiths Medical revenue, expect it to rise in next year's Big 100 rankings of the largest medical device companies. Smiths Medical's business includes syringe and ambulatory infusion devices, vascular access, and vital care products. The merger created an infusion therapy company with estimated annual revenues of roughly \$2.5 billion. –CN **M**

[www.icumed.com](http://www.icumed.com)



## Masimo

Irvine, California  
United States

● ● ● **\$1,239,153,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 61  
**R&D spend:** \$137,234,000  
**Employees:** 2,200  
**Company CEO:** Joe Kiani, chairperson and CEO

What do health monitoring technologies and high-end audio speakers have in common? Officials at **MASIMO** decided this year that the answer was "a lot." In April, they closed on their \$1.025 billion acquisition of Sound United and its sound and home theater system brands including Bowers & Wilkins, Denon, Polk Audio and Marantz. Investors initially appeared puzzled at the deal, but they have since warmed to it. CEO Joe Kiani explained during the company's Q2 earnings call in August that Sound United will aid in the rollout of the company's next-gen biosensing smartwatch, dubbed Freedom, which is expected to roll out next year. (This year, the company is rolling out its W1 health watch.) Kiani explained earlier this year that Sound United gives Masimo immediate scale with leading retail establishments like Best Buy in the U.S. and Euronics in Europe. –CN **M**

<https://www.masimo.com>




## Cochlear

Sydney  
Australia

● ● ● **\$1,233,286,650\***

\*Fiscal year ended 6/30/2022

**(AU\$1,641,100,000)**

**COCHLEAR** was founded in Sydney, Australia, in 1981. The company develops ear implants to help people with hearing loss. Cochlear offers the Nucleus cochlear implant, the Hybrid electro-acoustic implant and the Baha bone conduction implant. In January, the company received FDA approval for extended applications of its Nucleus implants. The implants treat unilateral hearing loss (UHL) and single-sided deafness (SSD). The implants were already FDA approved for those with moderate to profound bilateral sensorineural hearing loss. –SW 

[www.cochlear.com](http://www.cochlear.com)

**2021 rank:** 66  
**R&D spend:** \$158,341,050  
**Employees:** n/a  
**Company CEO:** Dig Howitt, president and CEO

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## Integer

Plano, Texas  
United States

● ● ● **\$1,221,079,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 64  
**R&D spend:** \$51,985,000  
**Employees:** 9,000  
**Company CEO:** Joseph Dziedzic, president and CEO

Already one of the world's largest medical device contract manufacturers, **INTEGER** keeps growing even more through M&A. In December 2021, it closed on its \$220 million acquisition of Oscor — creator and marketer of various specialized implantable cardiac pacing and neurostimulation leads, venous access systems and diagnostic catheters. In April 2022, it announced that it had acquired Connemara Biomedical and its subsidiaries Aran Biomedical and Proxy Biomedical (collectively "Aran") for more than \$131 million. Aran provides development and manufacturing solutions for implantable medical devices, including proprietary medical textiles, high-precision biomaterial coverings and coatings, and advanced metal and polymer braiding. –CN **M**

[www.integer.net](http://www.integer.net)



## Omron Healthcare

Kyoto  
Japan

● ● ● **\$1,209,941,733\***

\*Fiscal year ended 3/31/2022

**(JP¥132,900,000,000)**

**2021 rank:** 60  
**R&D spend:** n/a  
**Employees:** n/a  
**Company CEO:** Yoshihito Yamada, president and CEO

Kyoto, Japan-based **OMRON** says it is the top manufacturer of home blood pressure monitors. The company has sold more than 300 million units in more than 110 countries. Its products also include EKG monitors, digital thermometers, nebulizers and transcutaneous electrical nerve stimulation (TENS) devices. It also has a line of healthcare products, including wearable blood pressure monitors and digital scales. The company was founded in 1933 as Tateishi Electric Manufacturing Co. and incorporated in 1948. –BB **M**

[www.omronhealthcare.com](http://www.omronhealthcare.com)



## Fukuda Denshi

Tokyo  
Japan

● ● ● **\$1,202,640,204\***

\*Fiscal year ended 3/31/2022

**(JP¥132,098,000,000)**

**2021 rank:** 56  
**R&D spend:** n/a  
**Employees:** n/a  
**Company CEO:** Kotaro Fukuda, chair and CEO

Tokyo-based **FUKUDA DENSHI** is an international manufacturer of electrocardiographs, patient monitoring systems and other engineered medical devices. The company's U.S. operations are headquartered in Redmond, Washington. Fukuda Denshi was originally founded in 1939. In its early history, the company created the first ECG device in Japan. –BB **M**

[www.fukuda.com](http://www.fukuda.com)

No.  
**63****Fisher & Paykel  
Healthcare**Auckland  
New Zealand● ● ● **\$1,177,190,000\***  
\*Fiscal year ended 3/31/2022  
**(NZ\$1,681,700,000.00)****2021 rank:** 58  
**R&D spend:** \$107,800,000  
**Employees:** 7,375  
**Company CEO:** Lewis Gradon, CEO

With central operations in Australia and New Zealand, **FISHER & PAYKEL HEALTHCARE** manufactures systems for use in acute and chronic respiratory care, surgery and the treatment of obstructive sleep apnea. The company markets its products in more than 120 countries globally. In 1969, Fisher & Paykel produced its first prototype respiratory humidifier. The company was founded, however, in 1934 as an importer of appliances, including refrigerators, washing machines and radios. –BB <sup>M</sup>

[www.fphcare.com/us](http://www.fphcare.com/us)No.  
**64****NuVasive**San Diego  
United States● ● ● **\$1,138,988,000\***  
\*Fiscal year ended 12/31/2021**2021 rank:** 65  
**R&D spend:** \$92,626,000  
**Employees:** 2,900  
**Company CEO:** Chris Barry, CEO

**NUVASIVE** officials expect orthopedic technology to drive the company's revenue growth this year. However, the spine surgery tech company reduced its EPS guidance in early August amid the macroeconomic pressures that many device companies presently face. Early this year, NuVasive announced that its Attrax Putty had received FDA 510(k) clearance for expanded indications in thoracolumbar interbody spine surgery. NuVasive officials say the Attrax Putty is the first synthetic bone graft with U.S. FDA indications for thoracolumbar interbody fusion. The company also describes Attrax as a relatively inexpensive biologic option. The company in July released some positive data around Attrax and Modulus XLIF, a porous titanium interbody implant, when it came to lateral lumbar interbody fusions. –CN <sup>M</sup>

[www.nuvasive.com](http://www.nuvasive.com)No.  
**65****Insulet**Acton, Massachusetts  
United States● ● ● **\$1,098,800,000\***  
\*Fiscal year ended 12/31/2021**2021 rank:** 70  
**R&D spend:** \$160,100,000  
**Employees:** 2,300  
**Company CEO:** Jim Hollingshead, president and CEO

In January, Acton, Massachusetts-based **INSULET's** Omnipod 5 became the first tubeless, wearable automated insulin delivery system cleared for marketing in the U.S. for people 6 years of age and older with type 1 diabetes. Omnipod 5 represents the latest innovation in the company's portfolio of insulin pumps and has since received FDA clearance for people aged 2 years and older with type 1 diabetes. The company has also undergone a significant leadership change, as CEO Shacey Petrovic stepped down after more than three years in the corner office due to personal reasons. The company's board handed the reins over to Jim Hollingshead, the former president of sleep and respiratory care at ResMed. –SW <sup>M</sup>

[www.insulet.com](http://www.insulet.com)




## Merit Medical Systems

South Jordan, Utah  
United States

●●● **\$1,074,751,000\***

\*Fiscal year ended 12/31/2021

Founded in 1987, **MERIT MEDICAL SYSTEMS** is a manufacturer and marketer of proprietary disposable medical devices used in interventional, diagnostic and therapeutic procedures — particularly in cardiology, radiology, oncology, critical care and endoscopy. The South Jordan, Utah-based company more than doubled its revenues in the second quarter of 2022 to nearly \$300 million. It also recently launched a new pulmonary balloon dilator and received FDA clearance for a wire-free breast localization system. —SW 

[www.merit.com](http://www.merit.com)

**2021 rank:** 68  
**R&D spend:** \$71,247,000  
**Employees:** 6,446  
**Company CEO:** Fred Lampropoulos, president and CEO

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## LivaNova

London  
United Kingdom

●●● **\$1,035,365,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 69  
**R&D spend:** \$183,414,000  
**Employees:** 3,000  
**Company CEO:** Damien McDonald, CEO

London-based LivaNova develops devices used for cardiac surgery and neuromodulation. Formed in 2015 through a merger between Houston-based Cyberonics and Milan, Italy-based Sorin, the company currently employs 3,000 people worldwide, according to its most recent annual report. In its most recent quarter (ended June 30, 2022), **LIVANOVA** company posted profits of \$16.4 million, or 30¢ per share, on sales of \$254.2 million. The company earlier this year launched a patient monitor for cardiopulmonary bypass procedures. –SW **M**

[www.livanova.com](http://www.livanova.com)



## Abiomed

Danvers, Massachusetts  
United States

●●● **\$1,031,753,000\***

\*Fiscal year ended 3/31/2022

**2021 rank:** 74  
**R&D spend:** \$163,403,000  
**Employees:** 2,003  
**Company CEO:** Michael Minogue, president and CEO

**ABIOMED** develops circulatory and oxygenation support devices, including the Impella line of implants. Based in Danvers, Massachusetts, the company was founded in 1981 and has more than 2,000 full-time employees as of its most recent annual report, with more than half located in the U.S. The company was among the 10 best-performing medtech stocks in 2021 and has carried the momentum into 2022 with the first patient implants of its Impella 5.5 with SmartAssist in Japan, followed by the first Impella BTR heart pump implant in Chicago. Despite Street-beating results in its most recent fiscal quarter, Abiomed is scaling back expectations amid tough foreign exchange rates for U.S. companies. –SW **M**

[www.abiomed.com](http://www.abiomed.com)



## ZimVie

(formerly Zimmer Biomet's spine and dental business)  
Westminster, Colorado  
United States

●●● **\$1,014,600,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** n/a  
**R&D spend:** \$61,300,000  
**Employees:** 2,700  
**Company CEO:** Vafa Jamali, president and CEO

**ZIMVIE** became an independent public company on March 1, 2022, nearly 13 months after Zimmer Biomet announced it would spin off its spine and dental businesses. CEO Vafa Jamali earlier this year said there are opportunities for growth in the spine space, but the efforts could take years to accomplish. He pointed toward cervical disc replacement and pediatric scoliosis treatments as areas with growth potential. For now, the former Medtronic executive is focused on "some operational issues to fix within our spine business," with ZimVie exiting several countries where the business had been unprofitable. –CN **M**

<https://www.zimvie.com>



## Conmed

Largo, Florida  
United States

● ● ● **\$1,010,635,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 72  
**R&D spend:** \$43,565,000  
**Employees:** 3,800  
**Company CEO:** Curt Hartman, president and CEO

**CONMED** has been active on the M&A front in 2022. The Largo, Florida-based company bought upper extremities device maker In2Bones Global for \$145 million in June, then announced an agreement to acquire bioinductive scaffold startup Biorez for up to \$250 million in August. Founded in 1970 and initially based in Utica, New York, before moving headquarters to Florida in 2021, Conmed employs approximately 3,800 people. –SW <sup>M</sup>

[www.conmed.com](http://www.conmed.com)



## Konica Minolta

(healthcare segment)

Tokyo  
Japan

● ● ● **\$1,000,546,249\***

\*Fiscal year ended 3/31/2022

**(JP¥109,900,000,000)**

**2021 rank:** 67  
**R&D spend:** n/a  
**Employees:** n/a  
**Company CEO:** Sam Errigo, president and CEO

**KONICA MINOLTA** develops a range of technologies, including optical devices and medical and graphic imaging products, such as X-ray image processing systems. The company's U.S.-based healthcare business offers medical diagnostic imaging products and services focused on digital radiography, ultrasound, precision medicine and healthcare information technology. Solutions range across the continuum of care all the way from prevention to diagnosis to treatment. –SW <sup>M</sup>

[www.healthcare.konicaminolta.us](http://www.healthcare.konicaminolta.us)



## Haemonetics

Boston  
United States

● ● ● **\$993,196,000\***

\*Fiscal year ended 4/2/2022

**2021 rank:** 71  
**R&D spend:** \$46,801,000  
**Employees:** 2,821  
**Company CEO:** Christopher Simon, CEO and president

**HAEMONETICS** technologies serve medical markets including blood and plasma component collection, the surgical suite and hospital transfusion. The Boston-based company's first-quarter results highlighted significant growth as revenues were up 14.4%, with plasma collection increasing by 42.5% year-over-year. Haemonetics also announced in June that it fully commenced operations at its new manufacturing center in Clinton, Pennsylvania. –SW <sup>M</sup>

[www.haemonetics.com](http://www.haemonetics.com)




## Globus Medical

Audubon, Pennsylvania  
United States

●●● **\$958,102,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** n/a  
**R&D spend:** \$97,346,000  
**Employees:** 2,400  
**Company CEO:** Daniel Scavilla, CEO and president

**GLOBUS MEDICAL** appears to have delivered a needed rebound during its second quarter after a Q1 earnings miss and a surprise CEO transition. The company reached another milestone in its business earlier this year with the first shipments of its Excelsius3D imaging system. Globus Medical announced the first procedures using the system in May. The mobile X-ray system is designed for 2D fluoroscopy, 2D digital radiography and 3D imaging of adult and pediatric patients. When combined with its ExcelsiusGPS, the image-guided robotic navigation improves implant placement accuracy. –CN 

[www.globusmedical.com](http://www.globusmedical.com)

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## Invacare

Elyria, Ohio  
United States

**\$872,457,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 73  
**R&D spend:** \$8,656,000  
**Employees:** 3,000  
**Company CEO:** Geoffrey Purtil, interim president and CEO

**INVACARE** makes non-acute medical equipment. Think wheelchairs, mobility scooters, walkers, pressure care and positioning tech, and respiratory products. The company this year is undergoing strategic changes centered around organizational restructuring and supply chain adjustments. As Invacare moves in a different direction, it parted ways with CEO Matthew Monaghan in August. —SW 

[www.invacare.com](http://www.invacare.com)



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## GN Hearing

Ballerup  
Denmark

● ● ● **\$849,044,586\***  
\*Fiscal year ended 12/31/2021  
**(DKK5,332,000,000)**

**2021 rank:** 75  
**R&D spend:** \$81,369,427  
**Employees:** 4,553  
**Company CEO:** Gitte Pugholm Aabo, CEO

**GN** — headquartered in Ballerup, Denmark — develops and manufactures intelligent hearing technology. It was founded in 1869, operates in more than 100 countries and employs 7,000 people. The company offers the Jabra Enhance Plus, a miniaturized true wireless earbud designed to deliver a 3-in-1 experience of hearing enhancement, music and calls. With a recent FDA ruling set to lower costs for over-the-counter (OTC) hearing aids, the company plans to launch Jabra Enhance Plus in the OTC hearing aid category. –SW **M**

[www.gn.com](http://www.gn.com)



## Cordis

Miami Lakes, Florida  
United States

● ● ● **\$788,000,000\***  
\*Fiscal year ended 12/31/2021

**2021 rank:** n/a  
**R&D spend:** n/a  
**Employees:** 3,500  
**Company CEO:** Shar Matin, CEO

Miami Lakes, Florida-based **CORDIS** joins the Big 100 rankings of largest medical device companies after Cardinal Health's sale of the business. Cardinal Health sold Cordis to private equity firm Hellman & Friedman in 2021 for \$1 billion. The deal came six years after Cardinal Health bought Cordis and its minimally-invasive cardiovascular technology from J&J for nearly \$2 billion. Cordis develops cardiovascular and endovascular products and services. The company's reach spans more than 70 countries around the world, with global headquarters in Baar, Switzerland. The company focuses on vascular closure, radial, pedal access, and intervention, among other cardiovascular challenges. –SW **M**

[www.cordis.com](http://www.cordis.com)



## MicroPort

Shanghai  
China

● ● ● **\$778,639,000\***  
\*Fiscal year ended 12/31/2021

**2021 rank:** n/a  
**R&D spend:** \$297,800,000  
**Employees:** 8,019  
**Company CEO:** Zhaohua Chang, chair

Founded in Shanghai in 1998, **MICROPOR**T develops and manufactures products for a range of medical fields, including cardiology, interventional radiology, orthopedics, electrophysiology and surgical management. The company focuses on minimally invasive medical devices for the treatment of cardiac arrhythmia disease. It has developed a family of cardiac ablation catheters, diagnostic catheters, and 3D navigation systems used by hundreds of physicians at over 600 hospitals across China and elsewhere. –SW **M**

<https://www.microport.com>



## Avanos Medical

Alpharetta, Georgia  
United States

● ● ● **\$744,600,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 76  
**R&D spend:** \$32,300,000  
**Employees:** 4,555  
**Company CEO:** Joseph Woody, CEO

Headquartered in Alpharetta, Georgia, **AVANOS MEDICAL** started in 2014 as a spinoff of Kimberly-Clark's healthcare business. The company's product line includes devices for pain management, IV therapy, and respiratory and digestive care. Initially named Halyard Health, the company rebranded as Avanos Medical in 2018. In August 2022, the company announced second-quarter results ahead of the earnings consensus on Wall Street but missed revenue guidance. The company also updated its 2022 net sales guidance to be in the range of \$815 million to \$835 million. That figure corresponds to organic growth between 1% and 4%. –BB **M**

[www.avanos.com](http://www.avanos.com)



## Össur

Reykjavík  
Iceland

● ● ● **\$719,000,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 77  
**R&D spend:** \$31,735,000  
**Employees:** 3,761  
**Company CEO:** Sveinn Sölvason, president and CEO

Reykjavík, Iceland-based **ÖSSUR** was founded in 1971 by inventor Össur Kristinsson. Össur specializes in developing orthopedics such as bracing and support products, compression therapy and prosthetics. In February, Össur launched a new Power Knee microprocessor prosthetic knee system. The "smart" Power Knee prosthesis has advanced algorithms for detecting human movement patterns. It learns and adapts to the wearer's speed and cadence in real time. While traditional prosthetics can cause wearers to expend more energy than people with intact limbs, the Power Knee lowers the energy cost of walking compared to normal microprocessor knees. It is also designed to improve symmetry in walking, standing up and ascending and descending stairs. In August, the company acquired Naked Prosthetics and its products for finger and partial hand amputees. –BB **M**

[www.ossur.com](http://www.ossur.com)



## Asahi Intecc

(medical field segment)  
Nagoya  
Japan

● ● ● **\$667,862,345\***

\*Fiscal year ended 6/30/2021

**(JP¥73,358,000,000)**

**2021 rank:** 82  
**R&D spend:** n/a  
**Employees:** n/a  
**Company CEO:** Masahiko Miyata, president and CEO

**ASAHI INTECC** creates and markets medical devices for catheter-based treatments. Think treatments involving the cardiovascular, peripheral vascular, abdominal vascular and cerebrovascular systems. The company says its interventional guide wires and microcatheters are based on over 40 years of wire innovation. –CN **M**

[www.asahi-inteccusa-medical.com](http://www.asahi-inteccusa-medical.com)



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Sensor

100

2022 BIG100

No.  
**81**

## Nikkiso

(medical segment)

Tokyo

Japan

●●● **\$665,904,953\***

\*Fiscal year ended 12/31/2021

**(JP¥73,143,000,000)**

**2021 rank:** 78  
**R&D spend:** n/a  
**Employees:** n/a  
**Company CEO:** Toshihiko Kai, president and CEO

**NIKKISO** has been a significant provider of dialysis machines in Japan and around the world; it holds more than half of the market in Japan. The company has also expanded into devices related to blood purification, perioperative and emergency settings, and surgery. It also has an artificial pancreas technology for use in clinical settings. –CN **M**

[www.nikkiso.com/products/medical](http://www.nikkiso.com/products/medical)

No.  
**82**

## Ambu

Ballerup

Denmark

●●● **\$613,761,468\***

\*Fiscal year ended 9/30/2021

**(DKK4,014,000,000)**

**2021 rank:** n/a\*  
**R&D spend:** n/a  
**Employees:** 4,500  
**Company CEO:** Britt Meelby Jensen, CEO

Ballerup, Denmark-based **AMBU**, a developer of single-use scopes for a range of applications, has undergone some massive changes recently due to self-reported troubles around making headway with its single-use scope products. Britt Meelby Jensen was named Ambu's CEO in May amid strategic changes, replacing Juan Jose Gonzalez. The company has since executed on plans to lay off 200 employees, about 4% of its 4,500-person workforce. –SW **M**

[www.ambu.com](http://www.ambu.com)

\*The 2022 Big 100 report is moving to September versus November in previous years. Because its fiscal year ends in September, Ambu's revenue number is the same as in the 2021 report.



## Agfa-Gevaert

(radiology solutions segment)

Mortsel

Belgium

● ● ● **\$547,520,000\***

\*Fiscal year ended 12/31/2021

**(€ 464,000,000)**

**2021 rank:** 80  
**R&D spend:** \$21,240,000  
**Employees:** 2,285  
**Company CEO:** Pascal Juéry, president and CEO

**AGFA** provides traditional X-ray film, hardcopy film and printers, digital radiography equipment and image processing software to hospital radiology departments worldwide. Its digital radiography systems come with its Musica image processing software. There is also the Musica workstation for image identification, acquisition and quality control. Other Agfa businesses include HealthCare IT, Offset Solutions, and Digital Print & Chemicals. –CN

<https://medimg.agfa.com>



## Novocure

Root

Switzerland

● ● ● **\$535,031,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 83  
**R&D spend:** \$201,303,000  
**Employees:** 1,167  
**Company CEO:** Asaf Danziger, CEO

Root, Switzerland-based **NOVOCURE** is an oncology company specializing in developing therapies for solid tumors. The company's tumor treating fields technology is FDA-approved for recurrent and newly-diagnosed glioblastoma and mesothelioma. In June, the company announced that a Phase 2 pilot trial investigating the use of tumor treating fields with standard-of-care chemotherapy met its primary endpoint for first-line treatment of gastric cancer. The company is also performing clinical trials testing the potential of the technology for non-small cell lung cancer, ovarian cancer, and pancreatic cancer, among others. In addition to its home base in Switzerland, the company has regional operating centers in Portsmouth, New Hampshire and Tokyo, and a research center in Haifa, Israel. –BB

[www.novocure.com](http://www.novocure.com)



## JMS Co.

Hiroshima

Japan

● ● ● **\$529,579,388\***

\*Fiscal year ended 3/31/2022

**(JP¥58,169,000,000)**

**2021 rank:** 81  
**R&D spend:** n/a  
**Employees:** 5,359  
**Company CEO:** Hiroaki Okukubo, president

Dr. Taro Tsuchiya established **JMS** in the 1960s because he saw the need for disposable medical devices to reduce adverse events related to blood transfusion. Fast forward to today, and the company provides products and services related to infusion/transfusion, infusion/nutrition, dialysis, surgical treatment, and blood/cells. The company says its development process is focused on clinical settings, finding areas that need improvement and sharing insights with healthcare professionals. –CN

[www.jmsna.net/en](http://www.jmsna.net/en)



## Topcon

(eye care business)

Tokyo  
Japan

●●● **\$520,193,008\***

\*Fiscal year ended 3/31/2022

**(JP¥57,138,000,000)**

**2021 rank:** 85  
**R&D spend:** n/a  
**Employees:** n/a  
**Company CEO:** Satoshi Hirano, president and CEO

**TOPCON** started in Tokyo in 1932 as a maker of surveying equipment. In 1970, Topcon established Topcon Instrument Corp. of America, which is currently Topcon Medical Systems. It develops and supplies diagnostic equipment for the ophthalmic community. The company in 2018 established a medical software division to develop eye care software and provide related healthcare services. Topcon's offerings cover retina, glaucoma, cataract and refractive eye care treatments. It has integrated products and services, including advanced multimodal imaging, vendor-neutral data management and remote diagnostic technology. –SW <sup>M</sup>

[www.topconhealthcare.com](http://www.topconhealthcare.com)



## Natus Medical

Pleasanton, California  
United States

●●● **\$473,438,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 84  
**R&D spend:** \$56,306,000  
**Employees:** 1,400  
**Company CEO:** Thomas Sullivan, CEO

Founded in 1987, **NATUS MEDICAL** focuses on developing technologies to screen, diagnose and treat disorders involving the brain and nervous system. In July, the investment firm ArchiMed acquired Natus for \$1.2 billion. Formerly publicly traded, Natus is now a privately-held \$500 million portfolio company of ArchiMed. On its website, Natus Medical boasts that it provides a complete portfolio of neurodiagnostic supplies. The company currently manufactures technologies for applications in electroencephalography, polysomnography, neurosurgery, neurocritical care and brain injury, among others. In late 2021, Natus named Thomas Sullivan its new president and CEO. –BB <sup>M</sup>

[www.natus.com](http://www.natus.com)



## Orthofix

Lewisville, Texas  
United States

●●● **\$464,479,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 86  
**R&D spend:** \$49,621,000  
**Employees:** 1,087  
**Company CEO:** Jon Serbousek, president and CEO

**ORTHOFIX'S** two strategic business units — Orthofix Spine and Orthofix Orthopedics — develop, make and distribute product lines in more than 60 countries. In May, Orthofix said it received FDA premarket approval (PMA) for its AccelStim bone healing therapy device. In July, the company announced a licensing partnership with LimaCorporate to combine the limb-lengthening technology of Orthofix's Fitbone intramedullary nail system with LimaCorporate's proprietary, patient-specific, 3D-printed pelvic fixation device. The company most recently launched its Virtuos Lyograft autograft substitute and marked the first clinical use. –DK and CN <sup>M</sup>

[www.orthofix.com](http://www.orthofix.com)




## Accuray

Sunnyvale, California  
United States

● ● ● **\$429,909,000\***

\*Fiscal year ended 6/30/2022

**2021 rank:** 87  
**R&D spend:** \$57,752,000  
**Employees:** 900  
**Company CEO:** Suzanne Winter, CEO and president

**ACCURAY** develops the CyberKnife system, designed to treat diseases in the head and base of the skull as well as functional disorders. The CyberKnife system employs radiosurgery but without the use of a fixed frame bolted to the patient's head. Ten-year data from a study of men and women with trigeminal neuralgia (TN) demonstrated pain relief after the image-guided robotic radiosurgery treatments. Accuray also appointed a new chief commercial officer and chief accounting officer in 2022. –SW 

[www accuray.com](http://www accuray.com)



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## Medacta

Castel San Pietro  
Switzerland



**\$428,458,000\***

\*Fiscal year ended 12/31/2021

**(€ 363,100,000)**

**2021 rank:** 89  
**R&D spend:** \$13,341,080  
**Employees:** 1,341  
**Company CEO:** Francesco Siccardi, CEO

Founded in 1999, Switzerland-based **MEDACTA** is active in joint replacement, spine surgery and sports medicine. It started with minimally invasive surgical techniques and evolved into offerings personalized for each patient. It operates in more than 40 countries. –CN

[www.medacta.com](http://www.medacta.com)





## Nevro

Redwood City, California  
United States

● ● ● **\$386,905,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 88  
**R&D spend:** \$47,665,000  
**Employees:** 945  
**Company CEO:** Keith Grossman, president and CEO

Silicon Valley-based **NEVRO** started in 2006 with the goal of helping patients suffering from chronic pain. The company's Senza SCS system provides 10 kHz therapy to tens of thousands of patients across the globe. In early 2022, Nevro announced promising 12-month data from the Senza-NSRBP randomized controlled study of its 10 kHz spinal cord stimulation technology. Since early 2021, however, the company's stock price has steadily declined. After flirting with hitting \$180 per share in January 2021, NVRO shares were trading below \$50 in late August 2022. In the positive column, Nevro reached an \$85 million settlement with Boston Scientific to settle intellectual property concerns. –BB <sup>M</sup>

[www.nevro.com](http://www.nevro.com)



## iRhythm

San Francisco  
United States

● ● ● **\$322,825,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 91  
**R&D spend:** \$38,671,000  
**Employees:** 1,700  
**Company CEO:** Quentin Blackford, president and CEO

Seeking to usurp the old-school Holter monitor for electrocardiograph monitoring and AFib detection, **IRHYTHM** has developed the Zio XT platform. The wearable includes cloud-based data analytics and machine-learning capabilities for cardiac monitoring. Founded in 2008, the San Francisco-based company's Zio service aims to offer quality clinical accuracy, positive patient experience and compliance. It also holds the promise of lower cost of care through the miniature, wearable patch that includes a breathable, waterproof outer layer and a strong adhesive with a flexible design for secure attachment on the left side of the chest. In 2022, the company continued to build its leadership team, hiring Dr. Mintu Turakhia as chief medical officer and chief scientific officer, Brice Bobzien as chief financial officer and Reyna Fernandez as chief human resources officer. Chief Commercial Officer Dave Vort resigned in July, replaced by Chad Patterson. – SW and JH <sup>M</sup>

[www.irhythmtech.com](http://www.irhythmtech.com)



## Barco

(healthcare division)  
Kortrijk  
Belgium

● ● ● **\$308,570,000\***

\*Fiscal year ended 12/31/2021

**(€261,500,000)**

**2021 rank:** 90  
**R&D spend:** n/a  
**Employees:** 3,000  
**Company CEO:** Charles Beauduin and An Steegen, co-CEOs

Kortrijk, Belgium-based **BARCO** has three core verticals that span entertainment, enterprise and healthcare. Barco's healthcare portfolio includes a host of medical displays and imaging systems. The company has display options for a range of medical specialties, including radiology, dermatology, surgery, dentistry and digital pathology. Its medical lineup includes platforms for control rooms for interventional surgery and an all-in-one skin imaging platform. The latter technology, known as the Barco Demetra is a handheld device that supports imaging needs for a variety of skin examination tasks. As part of its healthcare portfolio, Barco also offers a variety of support, maintenance, training and professional services. –BB <sup>M</sup>

[www.barco.com/en/products/medical-displays](http://www.barco.com/en/products/medical-displays)

No.  
**94****Artivion**

(formerly CryoLife)

**Kennesaw, Georgia**  
**United States**●●● **\$298,836,000\***

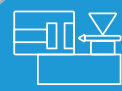
\*Fiscal year ended 12/31/2021

**2021 rank:** n/a  
**R&D spend:** \$35,546,000  
**Employees:** 1,300  
**Company CEO:** Patrick Mackin, president and CEO

Toward the beginning of 2022, CryoLife announced that it was assuming the name **ARTIVION**. The Kennesaw, Georgia-headquartered company's name is based on the words "aorta," "innovation" and "vision." The name change corresponds to a renewed focus on developing medical devices to treat aortic disease. CryoLife's original focus was the distribution of cryogenically-preserved tissues for cardiac and vascular transplant applications, including developing tissue- and adhesives-based products. From now on, Artivion will focus on developing four primary groups of products, including aortic stents and stent grafts, prosthetic heart valves, cryopreserved cardiac and vascular allografts and surgical sealants. The company has sales representation in more than 100 countries. —BB 

[www.artivion.com](http://www.artivion.com)

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## Glaukos

San Clemente, California  
United States

●●● **\$294,011,000\***  
\*Fiscal year ended 12/31/2021

**2021 rank:** 93  
**R&D spend:** \$100,999,000  
**Employees:** 727  
**Company CEO:** Thomas Burns, president and CEO

Founded in 1998, **GLAUKOS** focuses on treating ophthalmic diseases. The company has both medical device and pharmaceutical operations. In August, the company announced that its second-quarter results missed the consensus earnings forecast. In an earnings call, Glaukos Chair and CEO Thomas Burns signaled that the company is gearing up for several product launches. Burns also noted that it continues to invest in its pipeline of platform technologies for chronic eye diseases. Glaukos anticipates full-year 2022 net sales in the range of \$275 million to \$280 million. Earlier in 2022, Glaukos announced plans to make several changes to its upper ranks. –BB <sup>M</sup>

[www.glaukos.com](http://www.glaukos.com)

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## Inari Medical

Irvine, California  
United States

● ● ● **\$276,984,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 98  
**R&D spend:** \$51,018,000  
**Employees:** 800  
**Company CEO:** William Hoffman, CEO

Focused on developing devices for venous thromboembolism and patients with venous diseases, **INARI MEDICAL** has developed FDA-cleared minimally-invasive, catheter-based mechanical thrombectomy devices that can pull clots out of large vessels and eliminate the need for thrombolytic drugs. The company priced an underwritten public offering worth up to \$186.3 million in March 2022. The company was founded in 2011, gathering \$44.1 million in total funding to date. In August 2022, the company announced that it would promote its COO Drew Hykes to succeed Bill Hoffman as the company's CEO. Hykes will formally assume the CEO mantle in January 2023. Hykes began working at Inari in 2017 as chief commercial officer and was promoted to COO in 2020. —BB

[www.inarimedical.com](http://www.inarimedical.com)



## AtriCure

Mason, Ohio  
United States

● ● ● **\$274,329,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 94  
**R&D spend:** \$48,506,000  
**Employees:** 875  
**Company CEO:** Michael Carrel, president and CEO

**ATRICURE** specializes in treating atrial fibrillation. The Mason, Ohio-based company's Isolator Synergy ablation system has won FDA approval for treating persistent AFib. In April 2022, the company debuted its EnCompass Clamp as part of its Isolator Synergy ablation system. In addition, AtriCure's AtriClip left atrial appendage exclusion system products are popular LAA management devices. Its Hybrid AF therapy is a minimally invasive procedure for persistent AFib patients, while its cryoICE cryoSPHERE probe is indicated for temporary ablation of peripheral nerves to block pain in cardiac and thoracic procedures. —BB

[www.atricure.com](http://www.atricure.com)



## Alphatec

Carlsbad, California  
United States

● ● ● **\$243,212,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** 97  
**R&D spend:** \$32,015,000  
**Employees:** 561  
**Company CEO:** Patrick Miles, CEO and chair

Founded in 1990, **ALPHATEC HOLDINGS** bills itself as "more than a medical technology company." In particular, the company aims to foster innovations in spine surgery. In March 2018, Alphatec acquired the company SafeOp Surgical, which developed neuromonitoring technology intended to reduce the risk of nerve injury during surgery. In June 2021, Alphatec finalized its acquisition of EOS Imaging, the developer of orthopedic medical imaging technology. The company says the acquisition supports its quest to facilitate an integrative approach to spine surgery that reduces clinical variability while increasing predictability. For 2022, the company projects full-year sales of \$325 million, which equates to 34% year-over-year growth. —BB

[www.atecspine.com](http://www.atecspine.com)



## Shockwave Medical

Santa Clara, California  
United States

●●● **\$237,146,000\***

\*Fiscal year ended 12/31/2021

**2021 rank:** n/a  
**R&D spend:** \$50,544,000  
**Employees:** 657  
**Company CEO:** Doug Godshall, president and CEO

**SHOCKWAVE MEDICAL** has proprietary cardiovascular disease treatment tech involving local delivery of sonic pressure. Sales more than tripled to \$237 million last year amid the U.S. launch of the company's Shockwave C2. The company expects revenue to roughly double again this year to a range of \$465 million to \$475 million. —CN <sup>M</sup>

[www.shockwavemedical.com](http://www.shockwavemedical.com)



## Cardiovascular Systems

St. Paul, Minnesota  
United States

●●● **\$236,222,000\***

\*Fiscal year ended 6/30/2022

**2021 rank:** 92  
**R&D spend:** \$36,720,000  
**Employees:** 750  
**Company CEO:** Scott Ward, CEO

St. Paul, Minnesota-based **CARDIOVASCULAR SYSTEMS** specializes in developing devices for peripheral and coronary artery disease. Its product lineup includes patented orbital atherectomy systems (OAS) for peripheral and coronary applications. In March 2022, the company named Dr. Jeffery Chambers as its chief medical officer. Chambers had previously served as the primary investigator for a pivotal trial for an investigational orbital atherectomy device used in coronary arteries. In the same month, the company announced results from first-in-human procedures using its Propel percutaneous ventricular assist device. The company said that the Propel device performed as intended and provided uninterrupted hemodynamic support leading to successful revascularization. —BB <sup>M</sup>

[www.csi360.com](http://www.csi360.com)



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MEDTECH'S 100 LARGEST PLAYERS

# BIG 100

DANIELLE KIRSH  
SENIOR EDITOR

## Medtech sales reach a record high as R&D spend and employee counts climb

**T**he medtech industry is bouncing back from the economic fallout caused by the COVID-19 pandemic, according to an analysis of our Medtech Big 100 data.

The medical device industry has seemingly recovered from the economic headwinds caused by the COVID-19 pandemic, according to a *Medical Design & Outsourcing* analysis of financial data from the 100 largest companies' most recent annual results.

More than half of the companies listed in this year's Big 100 ranking reported positive growth over their prior-year sales. Total revenue,

research spending and employment figures were up significantly as the industry adjusts to a world with COVID-19 challenges.

For this analysis, we compared the performance of the Big 100 companies in 2021 and early 2022 with their results in 2020. Due to the increasing strength of the U.S. dollar, our analysis uses foreign currencies in the year-over-year analyses for companies that don't report sales in dollars.

Overall, aggregate revenue for our 2022 Medtech Big 100 companies increased to \$440.9 billion, up from \$415.3 billion in 2020 for last year's Big 100 companies, \$420.3 billion in 2019 and \$374.4 billion in 2018.

**Medtech Big 100 revenue bounces back to an all-time high**

Companies that topped the list of increased sales were heart, orthopedic and dental device companies, a stark difference from last year when diagnostics and imaging experienced the most growth. Overall, elective procedures appear to be recovering as health providers seek a new normal despite staffing shortages. This year has its own host of macroeconomic challenges: a strong U.S. dollar that makes American companies less competitive overseas, inflation, supply chain challenges and more.

*(continued on page 100)*



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Still, the medical device industry is demonstrating adaptability.

"Staffing issues are still plaguing parts of the industry and inflation is a risk and currencies for a lot of the large multinationals are risks. I don't want to diminish those," Ryan Zimmerman, medtech analyst at BTIG, told **MDO**. "And I'd say we're probably in a tougher macro environment than we've seen over the past few years. That aside, there are pockets of good underlying fundamental growth on ... a mix of some of the large companies, but also some of the more niche sub-segments."

More than half of the companies on this year's list reported year-over-year sales gains. Three companies in particular had sales growth of more than 50%. Most notably, Inari Medical nearly doubled its revenue to \$276.9 million (98.3% growth) for its most recent fiscal year. Alphatec followed at 67.9% year-over-year while Align Technology was the third-fastest-growing company at 59.9%.

Fisher & Paykel Healthcare reported the largest sales loss on the list, with a 14.7% decrease to NZ\$1.68 billion in its most recent fiscal year compared to 2020.

In 2019, the respiratory care device manufacturer broke NZ\$1 billion in sales for the first time — and nearly doubled that figure with NZ\$1.97 billion in 2021 as COVID-19 drove demand for nasal high flow therapy.

Hospital respiratory support for COVID-19 patients appears to have peaked in many parts of the world, and Fisher & Paykel Healthcare's hospital sales dropped 19% in fiscal 2022, Board Chair Scott St. John told investors in his annual report.

"For a long time into the future, we will remember 'the COVID years,'" St. John wrote. "No doubt, they have been transformative. In addition to F&P products helping millions of patients, the adaptations required to meet surges in demand have moved us closer to our long-term growth aspirations. That transformation is accelerated by the boost in our installed base of hospital hardware that we achieved."

**Big wins for Inari Medical**

Inari Medical had a breakthrough year. Its revenue nearly doubled and R&D expenditures nearly tripled to \$51 million, with R&D spend equal to roughly 18.4% of Inari's revenue.

The Irvine, California-based company credited its fiscal 2021 gains to its continued U.S. commercial expansion and new product launches throughout the year. The company makes minimally invasive, catheter-based mechanical thrombectomy devices that remove large clots in blood vessels to eliminate the need for thrombolytic drugs. Its FlowTrieve won FDA 510(k) clearance in 2018.

"We felt really good about the execution generally in 2021, facing exactly the same sets of headwinds that all of our peers have communicated repeatedly over the last two years really: staff shortages and resource limitations, access issues and alike," CEO Bill Hoffman said

during an earnings call in February. "So we feel really good about executing in this environment and I suspect we might even have another gear just in terms of the crispness of our execution as the operating environment return to something that's a bit more constructive."

**R&D speeds up amid economic headwinds**

Medical device companies appear to be betting they can innovate their way through challenging times. Large medical device companies' research and development spending grew more than \$1.1 billion — or 5.1% — to \$23.4 billion during their most recent fiscal years.



Novocure Chief Financial Officer  
**Ashley Cordova**



Inari Medical CEO  
**Bill Hoffman**



BTIG medtech analyst  
**Ryan Zimmerman**

**"For a long time into the future, we will remember 'the COVID years.' No doubt, they have been transformative."**



Among the 59 companies that report this metric, the average R&D increase year-over-year was 17.5%. Of those companies, five firms spent more than 20% of their revenue on R&D: MicroPort, Novocure, Glaukos, Shockwave Medical and Dexcom.

MicroPort, a new addition to this year's Big 100 ranking, topped the list with an R&D spend of \$297.8 million, or 38.2% of its revenue. The Shanghai, China-based company develops medical devices like drug-eluting stents for numerous applications, including cardiovascular, orthopedics, cardiac rhythm management, electrophysiology, endovascular, neurovascular, surgical robots and more.

Root, Switzerland-based Novocure, which develops electric fields that disrupt cancer cell division called Tumor Treating Fields, had R&D expenditures equal to 37.6% of its revenue. It reported \$201.3 million in research spending, representing a 52.5% increase over its previous fiscal year.

"We believe one of our best uses of capital is research and development," Novocure Chief Financial Officer Ashley Cordova said in an earnings release in February. "Our R&D initiatives are designed to unlock new cancer indications, expand addressable patient populations and enhance our product offer.

"2021 was a record year for R&D investment, as we invested more than \$200 million for the first time," she continued. "For perspective, we invested \$132 million in R&D in 2020 and \$79 million in 2019. While we expect the level of R&D investment to stabilize over time, in 2022 we plan to pursue incremental R&D investments intended to unlock additional indications and excess the greatest number of patients."

Five companies grew their R&D expenses by more than 50% year-over-year: Inari Medical (177.3%), Sonova (95.5%), Alphatec (70.8%), Medacta (65.6%) and Novocure (52.5%).

Meanwhile, 14 companies reduced their R&D expenditures year-over-year: Cooper Cos., Royal Philips, B. Braun Melsungen, BioMerieux, GE HealthCare, iRhythm, Avanos Medical, Elekta, Natus Medical, GN Hearing, Cardiovascular Systems, Nipro (medical segment), Getinge and Invacare.

### Medtech employment grows at the largest companies

Employment in the medtech industry is on the rise. There were 1,268,924 employees at the Medtech Big 100 companies that report human capital in their annual reports.

Compared to 2021, that is a 6.4% increase in headcount. Medtech companies grew their workforces 7.8% on average among each of the 71 companies that report headcounts.

Alphatec and Inari Medical expanded their workforces significantly throughout 2021. Alphatec's employee base rose 89.5% to 561 and Inari Medical's workforce grew 75.4% to 800.

The next highest percentage of growth was by Fisher & Paykel Healthcare, which added 1,587 employees in fiscal 2021, representing a 27.4% change.

"I personally think people were fearful going into this earnings season





because of the lingering impacts of all the headwinds," Zimmerman said when asked for his perspective on the general tone of medtech executives on recent earnings calls. "And you generally saw a more resilient sector this earnings season that wasn't as bad as we expected. Sure, currencies are concerning, inflation's still concerning, but the supply chain has gotten marginally better — or at least it has not gotten materially worse.

"It feels like the big issue the first half of this year is around supply, and it feels like the supply chain headwinds may be easing in the back half of the year," he continued. "And so that's probably the bigger takeaway."

**MDO** will continue to track these companies for further analysis in 2022 and beyond. **M**

— Managing Editor Jim Hammerand contributed to this report.

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## R&D ranking by total spend:

RANK	COMPANY	R&D SPEND
1	<b>Medtronic</b>	\$2,746,000,000
2	<b>Johnson &amp; Johnson MedTech</b>	\$2,377,000,000
3	<b>Royal Philips</b>	\$2,131,080,000
4	<b>Siemens Healthineers*</b>	\$1,762,440,000
5	<b>Stryker</b>	\$1,235,000,000
6	<b>Boston Scientific</b>	\$1,204,000,000
7	<b>Edwards Lifesciences</b>	\$903,100,000
8	<b>GE HealthCare (General Electric)</b>	\$847,000,000
9	<b>Alcon</b>	\$842,000,000
10	<b>Intuitive Surgical</b>	\$671,000,000
11	<b>Olympus (medical business)</b>	\$546,412,964
12	<b>Baxter</b>	\$534,000,000
13	<b>Dexcom</b>	\$517,100,000
14	<b>B. Braun Melsungen</b>	\$491,897,160
15	<b>BioMerieux</b>	\$459,020,000
16	<b>Zimmer Biomet (minus ZimVie spinoff)</b>	\$435,900,000
17	<b>Mindray</b>	\$423,203,324
18	<b>Fujifilm Holdings (healthcare only)</b>	\$412,418,063
19	<b>Smith+Nephew</b>	\$356,000,000
20	<b>MicroPort</b>	\$297,800,000
21	<b>Hologic*</b>	\$276,300,000
22	<b>Carl Zeiss Meditec</b>	\$273,878,000
23	<b>Bio-Rad</b>	\$271,657,000
24	<b>Fresenius Medical Care (health care products)</b>	\$260,780,000
25	<b>ResMed</b>	\$253,600,000
26	<b>Sonova</b>	\$252,077,865
27	<b>Align Technology</b>	\$250,315,000
28	<b>Bruker</b>	\$220,800,000
29	<b>Demant</b>	\$214,968,153
30	<b>Novocure</b>	\$201,303,000
31	<b>LivaNova</b>	\$183,414,000
32	<b>Dentsply Sirona</b>	\$171,000,000

## R&D ranking by percentage of revenues:

RANK	COMPANY	REVENUES (\$USD)	R&D SPEND	% OF REVENUES
1	<b>MicroPort</b>	\$778,639,000	\$297,800,000	38.2%
2	<b>Novocure</b>	\$535,031,000	\$201,303,000	37.6%
3	<b>Glaukos</b>	\$294,011,000	\$100,999,000	34.4%
4	<b>Shockwave Medical</b>	\$237,146,000	\$50,544,000	21.3%
5	<b>Dexcom</b>	\$2,448,500,000	\$517,100,000	21.1%
6	<b>Inari Medical</b>	\$276,984,000	\$51,018,000	18.4%
7	<b>LivaNova</b>	\$1,035,365,000	\$183,414,000	17.7%
8	<b>AtriCure</b>	\$274,329,000	\$48,506,000	17.7%
9	<b>Edwards Lifesciences</b>	\$5,232,500,000	\$903,100,000	17.3%
10	<b>Abiomed</b>	\$1,031,753,000	\$163,403,000	15.8%
11	<b>Cardiovascular Systems</b>	\$236,222,000	\$36,720,000	15.5%
12	<b>Insulet</b>	\$1,098,800,000	\$160,100,000	14.6%
13	<b>Carl Zeiss Meditec</b>	\$1,990,424,000	\$273,878,000	13.8%
14	<b>Accuray</b>	\$429,909,000	\$57,752,000	13.4%
15	<b>Alphatec</b>	\$243,212,000	\$32,015,000	13.2%
16	<b>Cochlear</b>	\$1,233,286,650	\$158,341,050	12.8%
17	<b>Nevro</b>	\$386,905,000	\$47,665,000	12.3%
18	<b>iRhythm</b>	\$322,825,000	\$38,671,000	12.0%
19	<b>Artivion (formerly CryoLife)</b>	\$298,836,000	\$35,546,000	11.9%
20	<b>Natus Medical</b>	\$473,438,000	\$56,306,000	11.9%
21	<b>Intuitive Surgical</b>	\$5,710,100,000	\$671,000,000	11.8%
22	<b>BioMerieux</b>	\$3,983,680,000	\$459,020,000	11.5%
23	<b>Masimo</b>	\$1,239,153,000	\$137,234,000	11.1%
24	<b>Mindray</b>	\$3,917,343,585	\$423,203,324	10.8%
25	<b>Orthofix</b>	\$464,479,000	\$49,621,000	10.7%
26	<b>Royal Philips</b>	\$20,296,000,000	\$2,131,080,000	10.5%
27	<b>Alcon</b>	\$8,222,000,000	\$842,000,000	10.2%
28	<b>Globus Medical</b>	\$958,102,000	\$97,346,000	10.2%
29	<b>Boston Scientific</b>	\$11,888,000,000	\$1,204,000,000	10.1%
30	<b>GN Hearing</b>	\$849,044,586	\$81,369,427	9.6%
31	<b>Elekta</b>	\$1,695,571,096	\$159,906,760	9.4%
32	<b>Bio-Rad</b>	\$2,922,545,000	\$271,657,000	9.3%

\*The color codes correspond to the top 10 R&D spenders.

Note: This ranking excludes companies with non-medical device operations that do not break out R&D spending by division and companies that do not disclose R&D spending. A handful of companies that end their fiscal years in September are marked with an asterisk; their fiscal 2021 figures are listed instead.



## R&amp;D ranking by total spend (continued)

RANK	COMPANY	R&D SPEND
33	Abiomed	\$163,403,000
34	Insulet	\$160,100,000
35	Elekta	\$159,906,760
36	Cochlear	\$158,341,050
37	Getinge	\$139,510,490
38	Masimo	\$137,234,000
39	Teleflex	\$130,841,000
40	Coloplast*	\$115,443,425
41	Fisher & Paykel Healthcare	\$107,800,000
42	Glaukos	\$100,999,000
43	Globus Medical	\$97,346,000
44	ConvaTec	\$94,500,000
45	Integra Lifesciences	\$93,051,000
46	Cooper Cos.	\$92,700,000
47	NuVasive	\$92,626,000
48	Steris	\$87,944,000
49	GN Hearing	\$81,369,427
50	Nipro (medical segment)	\$78,022,578
51	Merit Medical Systems	\$71,247,000
52	HU Group	\$66,460,306
53	ZimVie (formerly Zimmer Biomet's spine and dental business)	\$61,300,000
54	Accuray	\$57,752,000
55	Natus Medical	\$56,306,000
56	Integer	\$51,985,000
57	Inari Medical	\$51,018,000
58	Shockwave Medical	\$50,544,000
59	Orthofix	\$49,621,000
60	AtriCure	\$48,506,000
61	Nevro	\$47,665,000
62	ICU Medical	\$47,498,000
63	Haemonetics	\$46,801,000
64	Conmed	\$43,565,000
65	iRhythm	\$38,671,000
66	Cardiovascular Systems	\$36,720,000
67	Artivion (formerly CryoLife)	\$35,546,000
68	Avanos Medical	\$32,300,000
69	Alphatec	\$32,015,000
70	Össur	\$31,735,000
71	Agfa-Gevaert (radiology solutions segment)	\$21,240,000
72	Medacta	\$13,341,080
73	Invacare	\$8,656,000

## R&amp;D ranking by percentage of revenues (continued)

RANK	COMPANY	REVENUES (\$USD)	R&D SPEND	% OF REVENUES
33	Fisher & Paykel Healthcare	\$1,177,190,000	\$107,800,000	9.2%
34	Bruker	\$2,417,900,000	\$220,800,000	9.1%
35	Johnson & Johnson MedTech	\$27,100,000,000	\$2,377,000,000	8.8%
36	Medtronic	\$31,686,000,000	\$2,746,000,000	8.7%
37	Siemens Healthineers	\$20,516,580,000	\$1,762,440,000	8.6%
38	Olympus (medical business)	\$6,710,970,503	\$546,412,964	8.1%
39	NuVasive	\$1,138,988,000	\$92,626,000	8.1%
40	Demant	\$2,932,802,548	\$214,968,153	7.3%
41	Stryker	\$17,108,000,000	\$1,235,000,000	7.2%
42	ResMed	\$3,578,100,000	\$253,600,000	7.1%
43	Sonova	\$3,678,805,774	\$252,077,865	6.9%
44	Smith+Nephew	\$5,212,000,000	\$356,000,000	6.8%
45	Merit Medical Systems	\$1,074,751,000	\$71,247,000	6.6%
46	Zimmer Biomet (minus ZimVie spinoff)	\$6,821,600,000	\$435,900,000	6.4%
47	Align Technology	\$3,952,584,000	\$250,315,000	6.3%
48	ZimVie (formerly Zimmer Biomet's spine and dental business)	\$1,014,600,000	\$61,300,000	6.0%
49	Integra Lifesciences	\$1,542,448,000	\$93,051,000	6.0%
50	Fresenius Medical Care (health care products)	\$4,416,740,000	\$260,780,000	5.9%
51	Fujifilm Holdings (healthcare only)	\$7,298,798,252	\$412,418,063	5.7%
52	B. Braun Melsungen	\$9,274,534,500	\$491,897,160	5.3%
53	Hologic	\$5,632,300,000	\$276,300,000	4.9%
54	GE HealthCare (General Electric)	\$17,725,000,000	\$847,000,000	4.8%
55	Haemonetics	\$993,196,000	\$46,801,000	4.7%
56	Teleflex	\$2,809,563,000	\$130,841,000	4.7%
57	ConvaTec	\$2,038,000,000	\$94,500,000	4.6%
58	Getinge	\$3,152,564,103	\$139,510,490	4.4%
59	Össur	\$719,000,000	\$31,735,000	4.4%
60	Avanos Medical	\$744,600,000	\$32,300,000	4.3%
61	Conmed	\$1,010,635,000	\$43,565,000	4.3%
62	Integer	\$1,221,079,000	\$51,985,000	4.3%
63	Baxter	\$12,784,000,000	\$534,000,000	4.2%
64	Dentsply Sirona	\$4,251,000,000	\$171,000,000	4.0%
65	Coloplast	\$2,970,336,391	\$115,443,425	3.9%
66	Agfa-Gevaert (radiology solutions segment)	\$547,520,000	\$21,240,000	3.9%
67	ICU Medical	\$1,316,308,000	\$47,498,000	3.6%
68	Cooper Cos.	\$2,922,500,000	\$92,700,000	3.2%
69	Medacta	\$428,458,000	\$13,341,080	3.1%
70	HU Group	\$2,484,522,942	\$66,460,306	2.7%
71	Nipro (medical segment)	\$3,400,227,604	\$78,022,578	2.3%
72	Steris	\$4,585,064,000	\$87,944,000	1.9%
73	Invacare	\$872,457,000	\$8,656,000	1.0%



## Headcount rankings

Here's how many employees each company reported, either in their most recent annual reports (as of Sept. 1, 2022) or provided directly to **MDO**.

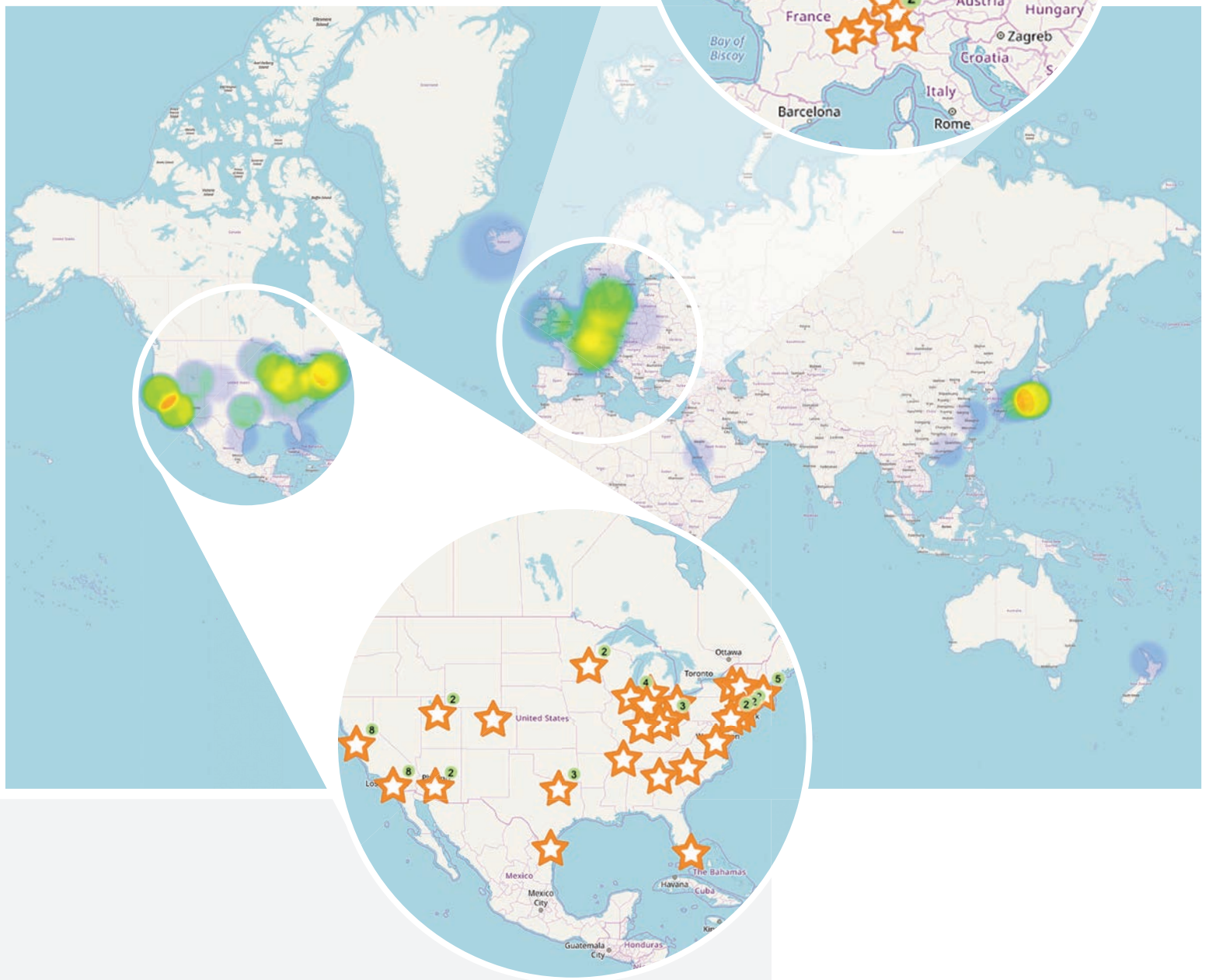
RANK	COMPANY	EMPLOYEES
1	<b>Medtronic</b>	95,000
2	<b>Royal Philips</b>	78,189
3	<b>Johnson &amp; Johnson MedTech</b>	75,000
4	<b>B. Braun Melsungen</b>	66,234
5	<b>Siemens Healthineers</b>	66,100
6	<b>Baxter</b>	60,000
7	<b>GE HealthCare (General Electric)</b>	48,000
8	<b>Stryker</b>	46,000
9	<b>Boston Scientific</b>	41,000
10	<b>Medline Industries</b>	30,000
11	<b>Becton, Dickinson (medical segment)</b>	30,000
12	<b>Fresenius Medical Care (health care products)</b>	30,000
13	<b>Terumo</b>	28,000
14	<b>Nipro (medical segment)</b>	25,239
15	<b>Alcon</b>	24,389
16	<b>Align Technology</b>	22,540
17	<b>Olympus (medical business)</b>	21,898
18	<b>Henry Schein</b>	21,600
19	<b>Amplifon</b>	18,600
20	<b>Smith+Nephew</b>	18,369
21	<b>Demant</b>	18,116
22	<b>Owens &amp; Minor</b>	17,300
23	<b>Zimmer Biomet (minus ZimVie spinoff)</b>	16,800
24	<b>Sonova</b>	16,733
25	<b>Steris</b>	16,000
26	<b>Dräger (medical division)</b>	15,900
27	<b>Edwards Lifesciences</b>	15,700
28	<b>Dentsply Sirona</b>	15,000
29	<b>Mindray</b>	14,684
30	<b>Teleflex</b>	14,000
31	<b>Cook Medical</b>	13,898
32	<b>BioMerieux</b>	13,000
33	<b>Coloplast</b>	12,578
34	<b>Cooper Cos.</b>	12,000
35	<b>Getinge</b>	10,700
36	<b>Paul Hartmann</b>	10,628
37	<b>ConvaTec</b>	10,025
38	<b>Intuitive Surgical</b>	9,793
39	<b>Straumann</b>	9,000
40	<b>Integer</b>	9,000
41	<b>ICU Medical</b>	8,500
42	<b>MicroPort</b>	8,019
43	<b>ResMed</b>	8,000

RANK	COMPANY	EMPLOYEES
44	<b>Bio-Rad</b>	7,900
45	<b>Bruker</b>	7,765
46	<b>Fisher &amp; Paykel Healthcare</b>	7,375
47	<b>Merit Medical Systems</b>	6,446
48	<b>Hologic</b>	6,350
49	<b>Dexcom</b>	6,300
50	<b>JMS Co.</b>	5,359
51	<b>Enovis (Formerly Colfax's Medical Technology segment, DJO)</b>	5,000
52	<b>Elekta</b>	4,631
53	<b>Avanos Medical</b>	4,555
54	<b>GN Hearing</b>	4,553
55	<b>Ambu</b>	4,500
56	<b>Integra Lifesciences</b>	3,800
57	<b>Conmed</b>	3,800
58	<b>Össur</b>	3,761
59	<b>Carl Zeiss Meditec</b>	3,531
60	<b>Cordis</b>	3,500
61	<b>LivaNova</b>	3,000
62	<b>Invacare</b>	3,000
63	<b>Barco (healthcare division)</b>	3,000
64	<b>NuVasive</b>	2,900
65	<b>Haemonetics</b>	2,821
66	<b>ZimVie (formerly Zimmer Biomet's spine and dental business)</b>	2,700
67	<b>Globus Medical</b>	2,400
68	<b>Insulet</b>	2,300
69	<b>Agfa-Gevaert (radiology solutions segment)</b>	2,285
70	<b>Masimo</b>	2,200
71	<b>Abiomed</b>	2,003
72	<b>iRhythm</b>	1,700
73	<b>Natus Medical</b>	1,400
74	<b>Medacta</b>	1,341
75	<b>Artivion (formerly CryoLife)</b>	1,300
76	<b>Novocure</b>	1,167
77	<b>Orthofix</b>	1,087
78	<b>Nevro</b>	945
79	<b>Accuray</b>	900
80	<b>AtriCure</b>	875
81	<b>Inari Medical</b>	800
82	<b>Cardiovascular Systems</b>	750
83	<b>Glaukos</b>	727
84	<b>Shockwave Medical</b>	657
85	<b>Alphatec</b>	561



## Where are the headquarters?

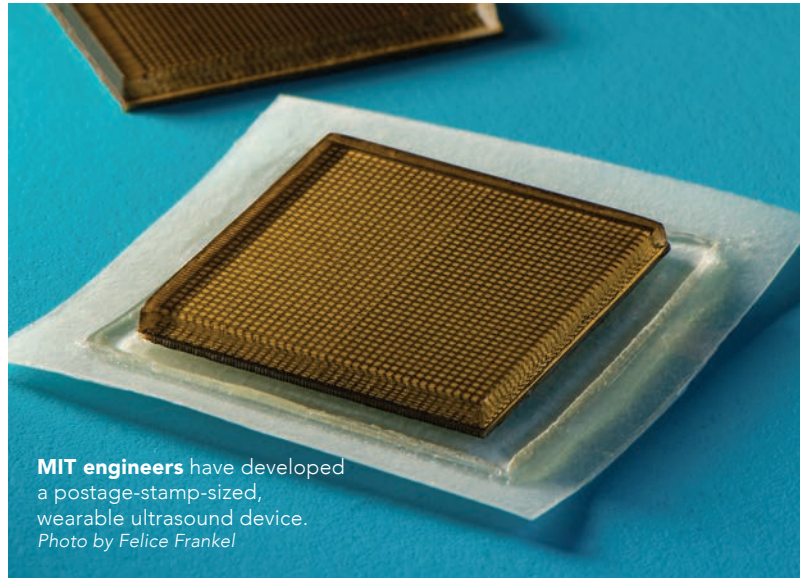
The headquarters of the largest medical device companies in the world are concentrated in several regions in the U.S., including California, Massachusetts and Minnesota. Internationally, major medtech hubs are located in Japan, Germany, Ireland and more. **M**





## MIT researchers report advances in implant design and ultrasound imaging

An inflatable drug delivery implant advances artificial pancreas efforts, while stamp-sized ultrasound stickers represent ‘a breakthrough in wearable devices and medical imaging.’



MIT engineers have developed a postage-stamp-sized, wearable ultrasound device. Photo by Felice Frankel



Jim Hammerand | Managing Editor

**M**echanically inflating and deflating an implantable device for 10 minutes a day prevents immune cells from building the scar tissue that has been a major obstacle for artificial pancreas researchers.

That’s according to new findings from a team of MIT engineers who built mechanical deflection into a two-chambered, soft polyurethane device tested on mice. By pumping up and down for five minutes every 12 hours, the device prevented immune cells from accumulating and building scar tissue without immunosuppressants.

The researchers reported fewer neutrophils surrounding the device in the short term. And when scar tissue

“We’re using this type of motion to extend the lifetime and the efficacy of these implanted reservoirs that can deliver drugs like insulin, and we think this platform can be extended beyond this application,” said Ellen Roche, the study’s co-senior author and an MIT School of Engineering associate professor.

The device could allow for the delivery of pancreatic islet cells acting as a bioartificial pancreas, immunotherapy for ovarian cancer and drugs to prevent heart failure in heart attack patients.

“You can imagine that we can apply this technology to anything that is hindered by a foreign body response or fibrous capsule, and have a long-term effect,” Roche said. “I think any sort of implantable drug delivery device could benefit.”

**“You can imagine that we can apply this technology to anything that is hindered by a foreign body response or fibrous capsule, and have a long-term effect.”**

did eventually form, the researchers described an unusual structure of highly aligned collagen fibers instead of the tangled fibers that can lead to device failure within weeks. The aligned structure of the scar tissue that formed around the actuated devices may be easier for drug molecules to pass through.

The researchers created a larger version of the device (120 x 80 mm) and successfully implanted it in the abdomen of a human cadaver using a minimally invasive surgical technique. They plan to add the ability to deliver stem-cell-derived pancreatic cells that could automatically monitor and manage glucose levels.

*(continued on page 108)*

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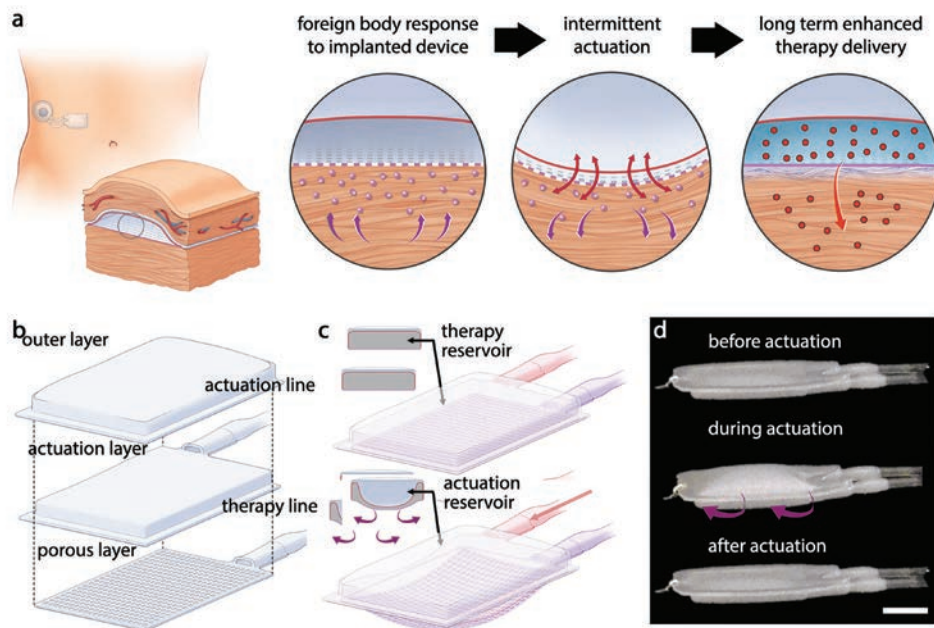


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## DESIGN



**An actuator repeatedly inflates** and deflates the drug delivery implant for five minutes every 12 hour, preventing immune cells from accumulating around the device.  
Image courtesy of MIT

"The idea would be that the cells would be resident in the reservoir, and they would act as an insulin factory," Roche said. "They would detect the levels of glucose in blood and then release insulin according to what was necessary."

### Wearable, stamp-sized ultrasound stickers for continuous imaging

Another team of MIT engineers is working to make getting an ultrasound as simple as buying a book of stamps.

They've developed a postage-stamp-sized ultrasound device that can be stuck to the skin and worn for continuous imaging of internal organs over 48 hours.

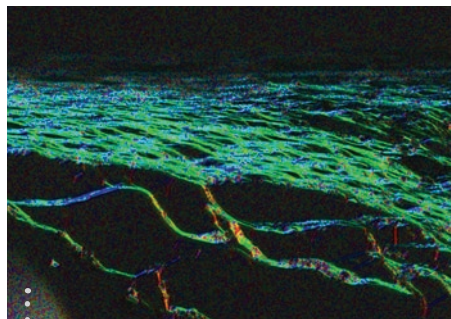
Once the engineers work out wireless connectivity, the ultrasound stickers could be worn by patients at home or on the go, even during exercises like jogging, biking and lifting weights, they said. The ultrasound stickers could be used to monitor internal organs, tumor progression, fetal development or even the point of a workout regimen where further exertion will lead to muscle overuse and soreness.

"We envision a few patches adhered to different locations on the body, and the patches would communicate with your cellphone, where AI algorithms would analyze the images on demand," said Xuanhe Zhao,

a professor of mechanical engineering and civil and environmental engineering at MIT. "We believe we've opened a new era of wearable imaging: With a few patches on your body, you could see your internal organs."

Zhao was the study's senior author, joined by lead authors Chonghe Wang and Xiaoyu Chen, and co-authors Liu Wang, Mitsutoshi Makihata, and Tao Zhao at MIT, plus Mayo Clinic's Hsiao-Chuan.

A wearable ultrasound imaging tool "would have huge potential in the future of clinical diagnosis," Wang said. "However,



**When scar tissue forms** around the inflatable implant, it has an aligned architecture that allows drugs to pass through more easily.  
Image courtesy of MIT

the resolution and imaging duration of existing ultrasound patches is relatively low, and they cannot image deep organs."

The MIT ultrasound sticker is about 3 mm thick and has a stretchy adhesive layer with a rigid array of transducers, which allows the device to conform to the skin so it can generate clearer, more precise images, Wang said. Two layers of elastomer in the adhesive layer encapsulate a middle layer of solid, water-based hydrogel for sound wave transmission.

"The elastomer prevents dehydration of hydrogel," Chen said. "Only when hydrogel is highly hydrated can acoustic waves penetrate effectively and give high-resolution imaging of internal organs."

The researchers used their prototypes on healthy individuals and watched their blood vessels change diameter when seated and standing, saw the stomach stretching and shrinking as volunteers drank and passed juice, observed the heart changing shape during exercise and even spotted bright patterns indicating microdamage in muscles during workouts.

In addition to the wireless efforts underway, the team is developing software algorithms to interpret the ultrasound imagery and offer diagnoses.

"We imagine we could have a box of stickers, each designed to image a different location of the body," Zhao said. "We believe this represents a breakthrough in wearable devices and medical imaging."



MIT School of Engineering  
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## How IP protection is enabling robotic surgery innovation

Vicarious Surgical has been generating buzz in the robotic surgery space, but none of it would happen if IP protection wasn't shielding the value of its technology.



Image courtesy of Vicarious Surgical



**Chris Newmarker** | Executive Editor

**C**ount Vicarious Surgical among a group of relatively young surgical robotics companies seeking to innovate and make a difference in a space that has been dominated by Intuitive. Vicarious' technology uses proprietary human-like surgical robots combined with 3D visualization to transport surgeons inside the patient to perform minimally invasive surgery.

Vicarious Surgical CEO Adam Sachs announced on his latest earnings call that the Waltham, Massachusetts-based company has completed the design of its Beta 2 robotic surgery platform. It's beginning the integration phase of the build, and the company has inked center of excellence agreements with the nationwide HCA Healthcare as well as University Hospitals in northern Ohio to further development.

IP protection is crucial for Vicarious Surgical success, said Carolina Säve, a patent attorney who joined Vicarious in January 2022 as its director of intellectual property.

"At the end of the day, the company's value will depend on how strong the patent portfolio is and how much IP ownership we have been able to retain," she said.

Säve — along with Greenberg Traurig shareholders Roman Fayerberg and Todd Basile — recently answered questions from **Medical Design & Outsourcing** regarding what medtech insiders need to know about IP protection in the robotic surgery space.

### **MDO: How does Vicarious Surgical go about accomplishing its IP protection?**

**Säve:** We have been working to align the IP strategy with the business strategy, which has allowed us to identify any gaps in the IP strategy. By having a strong line of communication between marketing, IP and R&D, we can align our goals and build a stronger patent portfolio. To build that strong portfolio, we also have to file early and often as we move forward in development, trying to capture each improvement as we move toward completing our system. The other component that has been important for us is ensuring we have ownership of our IP as we work with third parties in development agreements or the like. We consider IP ownership before entering into any agreement to avoid any disputes down the line. Similarly, we obtain inventor assignment signatures early on to maintain a clean line of ownership.

As we move toward manufacturing our system, we're also instituting internal protocols of trade secrets on any parameters, fine-tuning of our system components, or the software running parts of our system.

### **MDO: What is particularly unique regarding IP protection in the medical robotics space?**

**Säve:** Our robotic system includes many different technologies — mechanical, software, control systems, electrical, etc. *(continued on page 112)*



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Registered patent attorney  
at Greenberg Traurig  
**Todd Basile**



Registered patent attorney  
at Greenberg Traurig  
**Roman Fayerberg**



Vicarious Surgical Director  
of Intellectual Property  
**Carolina Säve**

— so our IP strategy also has to consider how we protect all of these different technologies, whether that is drafting a variety of patent claims for one component or considering other types of protection such as trade secrets. This also means fostering collaboration with different engineering teams and ensuring each technical team understands each other's goals. For example, our mechanical and software teams need to see eye to eye.

We have also developed a new incentive program as another process for capturing the ideas of our engineers. This has allowed me to work closely with the engineers and also help foster collaboration between the different teams.

**MDO: I suspect all the software involved presents some unique challenges?**

**Basile:** It's hard to protect something if you don't understand it, and let's face it, most folks aren't software engineers. So yes, the software presents the additional challenge of figuring out what's going on before determining how to protect it. I think the key here is to look at software as embodying a methodology that, at its essence, can be communicated by a flow chart: "If this, then that." If you can work with your engineers to get to that point, the tech becomes more digestible and you can identify what's valuable to protect.

The next challenge is deciding how best to protect various types of software employed in surgical robotics. Take, for example, autonomous navigation to a surgical site. Most navigation software will use sensors to detect certain trigger events, such as getting too close to an artery wall or nerve. A trigger event then causes the robot to take some action in response, such as stopping or turning away. Often competitors can reverse engineer this sort of functionality when it is based on nonproprietary sensors, so maybe you opt for patents in these cases. Conversely, when navigation relies on software-intensive computer vision, the machine learning approaches you used to train your computer vision, as well as the underlying data pool and resulting algorithms, likely are not outward-facing. Thus, you might opt for trade secret protections in these cases.

Last but not least, patent eligibility is always something you've got to consider when discussing software. The rule of thumb is that software must provide some technological innovation or improve other technologies to be patentable. For example, you can't just automate processes on a generic computer that could otherwise be done by hand. Fortunately, with surgical robotics, much of the software is sensing- and controls-related, meaning your software improves the real-world functionality of a robot. Likewise, software that trains robot AI from a data pool is often considered transformative enough to be patent-eligible, especially since the result is making robots capable of doing technologically innovative things. So, while there are exceptions, patent eligibility is not as much of a concern when talking about robotics software.

**MDO: What are the top questions that entrepreneurs starting surgical robotics companies need to ask as they start working with patent attorneys on an IP protection strategy?**

**Säve:** Outside counsel should ensure that they understand the business goals and track how the goal changes as the development evolves. This can help identify gaps in IP strategy. Landscape searches are important early on as well to provide outside counsel with an understanding of the field, trends in the industry, what competitors are doing, identifying gaps/opportunities in the markets, and also seeing what areas to avoid.

Freedom to operate (FTO) searches are also important, both at different stages of development and for different system components. It is helpful to collaborate with outside counsel on an early design's overall FTO. Then you can bring the analysis in-house as you use clearance search results for specific components during the development stages. As you begin to finalize the system, it is an opportunity to again collaborate with outside counsel on an overall FTO. It is often insufficient to rely on just one FTO: Your system will change, sometimes drastically, and it is important to capture these changes in this type of analysis. Collaboration with outside counsel for an overall system FTO is important to prevent any views of conflict of interest, while an in-house team can often handle that analysis as a tool during the development process.

**Fayerberg:** I agree that when starting to work with patent attorneys, it is important to find outside patent counsel who not only understand the technology but are also willing and able to understand the business goals and help craft the patent strategy accordingly. They should also look for attorneys with a strong record of helping young companies through different stages of growth. There are different considerations when working with emerging companies versus larger, more established companies. Obviously, budget is one of them. How do you build a valuable IP position with limited resources? For emerging companies, in my experience, the technology evolves rapidly and you want attorneys who understand that and can prepare patent applications that will cover not only the technology at the time of drafting but will remain valuable as the technology evolves. Also, entrepreneurs should look for attorneys who understand the industry and can help find valuable opportunities in the industry that is becoming crowded.


**Basile:** “What are my goals? What technologies should I be protecting? What protections make the most sense for each?”

**MDO: Are there new legal trends that people in the surgical robotics space need to be aware of?**

**Säve:** As we mentioned, software is very much a part of surgical robotics today, and with that comes the consideration of data collection and usage. The industry aims toward autonomy and real-time feedback during a surgical procedure. So what about all that data? Agreements now must include considerations of who owns the data that is collected, how is it being stored, who can use it, and how it can be used. For example, how can a company like Vicarious Surgical have access to that data for our systems to keep learning and improving using that data? There is also the consideration of privacy, given that this data includes patient identifying information. How is that information encrypted so that the

data related to it can be used for machine learning? These will all be important factors that will shape how the future of surgical robotics might look.

**Basile:** For sure, data is an asset and it can be quite valuable. Companies in this space are wise to consider data ownership and access as part of their overall IP and business strategy.

**Fayerberg:** On a fun note, one interesting trend that has been developing in patent law is whether a patent can be granted on an invention by an artificial intelligence — by itself without a human inventor. Recently, the Federal Circuit heard an appeal from a court decision that has barred an AI-generated invention from being patented. In contrast, the South African Patent Office has granted a patent for the same AI-generated inventions. I do not expect the current generation of medical robots to become inventors, but you never know. 

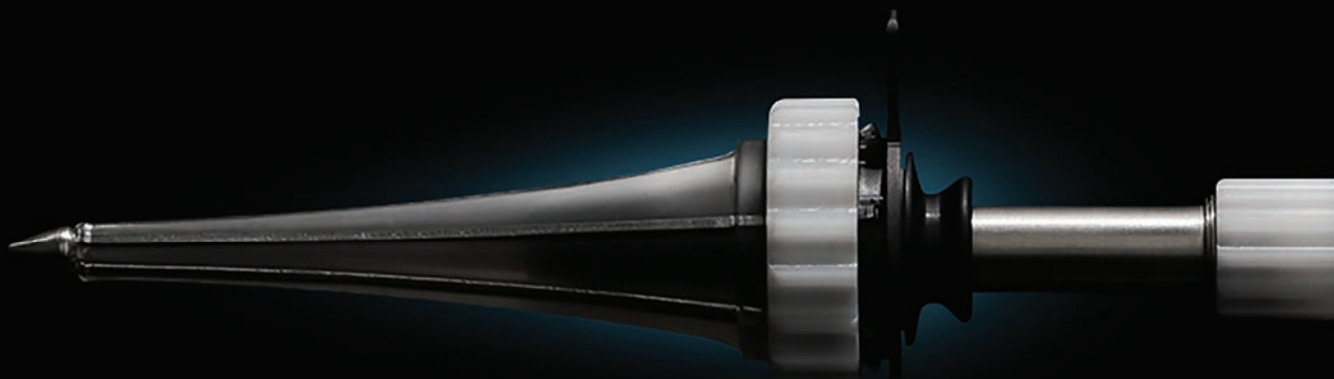


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**Minnetronix  
Medical's  
MindsEye**  
expandable port  
Photo courtesy of  
Minnetronix Medical

## Contract manufacturer Minnetronix Medical launches its first in-house product, MindsEye

Minnetronix Medical's MindsEye is the first device that the contract developer and manufacturer took from concept through commercialization.



**Jim Hammerand** |  
Managing Editor

**M**innetronix Medical has launched MindsEye, making it the first medical device that the contract developer and manufacturer has conceived and commercialized.

St. Paul-based Minnetronix Medical's MindsEye is the first expandable brain access port on the market. The FDA cleared the device under the 510(k) pathway in August 2020.

The minimally invasive device gives neurosurgeons deep brain access and visualization as they treat strokes, cancer and other conditions. The device features a flexible sheath made of cyclic olefin copolymer (COC) and an aluminum obturator. MindsEye won the Minnesota Technology Association's TEKNE award for best medical technology and device in 2021.

"Its benefits to neurosurgeons — such as expandability, easier insertion and removal, and transparency that minimizes glare and allows surgeons to see surrounding tissue — are truly unique,"

Tulane University neurosurgeon Dr. Johnny Delashaw said in a statement. "The MindsEye expandable port has raised the bar for standard of care in neurosurgery and will improve patient outcomes."

### **Why MindsEye matters for Minnetronix Medical and its customers**

Minnetronix Medical VP and GM Matt Adams said he's not aware of another contract development and manufacturing organization that has taken its own product down the entire road to commercialization, from conception through product development and design, pricing, reimbursement and sales forecasting, clinical trials and regulatory clearance, sales training and scale manufacturing.

"You've now got a contract development and manufacturing house that lives in the exact same world as its customers and can use that experience to create a better experience for our traditional service customers," Adams said in an interview.

*(continued on page 117)*

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Minnetronix  
Medical VP and GM  
**Matt Adams**

Mizuho America will distribute the device in the U.S.


"For a partner like Mizuho, we were able to provide them with a complete product, all done, cleared, already been used in humans, along with the salesforce training so that what they get is a complete product dropped in their sales bag, their salesforce trained with no R&D and no regulatory risk," Adams said. "They're just immediately into selling mode."

Mizuho America VP of Sales William Delaney said in a statement, "We now consider Minnetronix a partner for new device ideas and finished products. Since they handled all the steps in creating the MindsEye expandable port, we can concentrate on bringing it to market by leveraging the strength of our distribution channel to accelerate adoption and enhance patient outcomes."

#### **Minnetronix Medical products in development**

Minnetronix Medical has two other products in development: the Minnetronix Neurapheresis Cerebrospinal Fluid Treatment Platform for removing blood from spinal fluid, and the AI-based DepiCT Neuroimaging Platform.

The company has not yet picked commercial partners for those programs, but has just started that process for Neurapheresis and will follow with DepiCT, Adams said.

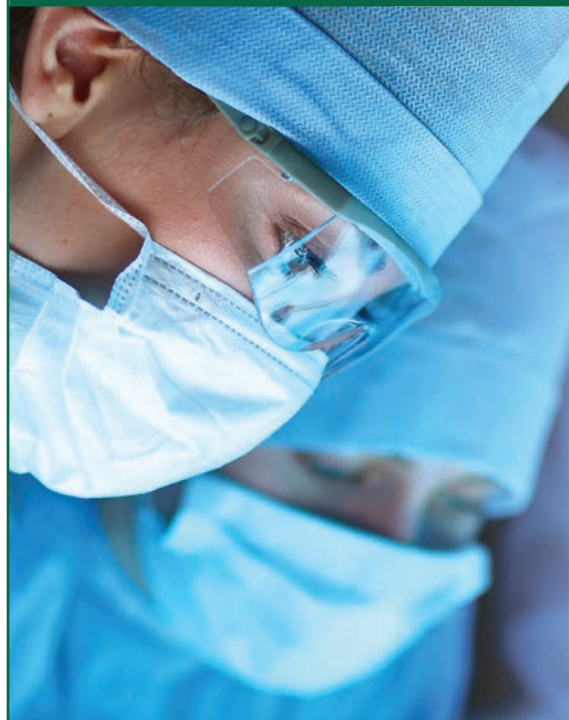
"We are actually available for the right partners right now," he said. 



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## 7 ways DeepMind's AlphaFold is being used in life sciences

The artificial intelligence system's protein structure predictions are accelerating drug discovery, fighting antibiotic resistance and offering new windows into diseases, cells and genetics.



**Brian Buntz** |  
Pharma Editor

**A**lphabet subsidiary DeepMind has announced that its AlphaFold AI system has predicted the structure of more than 200 million proteins, representing almost every known cataloged protein.

In addition, AlphaFold and its partner, the EMBL's European Bioinformatics Institute, announced that the recent release expanded the database by more than 200 fold, from almost 1 million to more than 200 million structures.

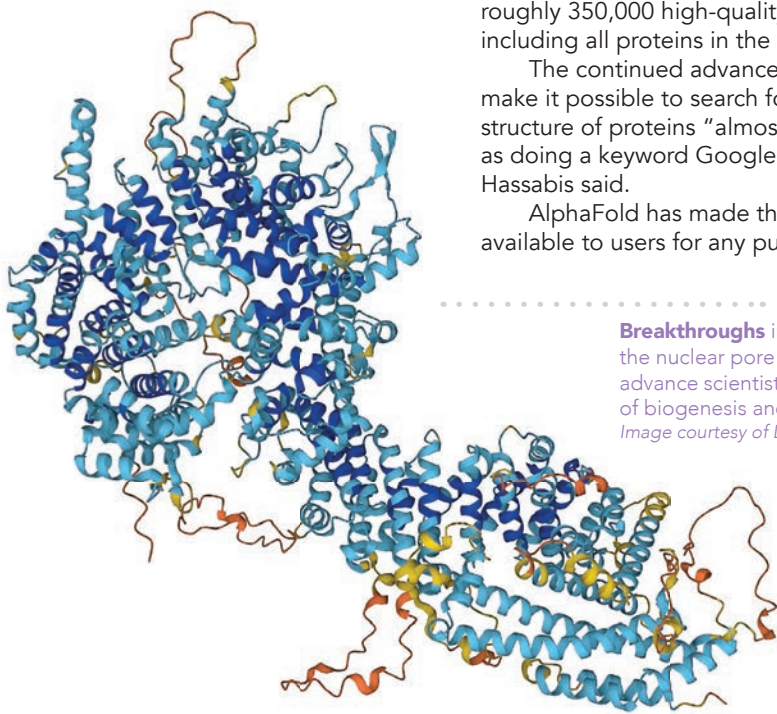
"When we launched the database last July, it was sort of recognized as a pretty big leap forward for biology," DeepMind founder and CEO Demis Hassabis said in a news conference.

The release last year included roughly 350,000 high-quality predictions, including all proteins in the human body.

The continued advances of AlphaFold make it possible to search for the 3D structure of proteins "almost as easily as doing a keyword Google search," Hassabis said.

AlphaFold has made the data freely available to users for any purpose.

**Breakthroughs** in understanding the nuclear pore complex could advance scientists' understanding of biogenesis and regulation.  
*Image courtesy of DeepMind*



Here are seven examples of how the AI system is helping fuel progress in life sciences research.

### 1. Accelerating discovery of drugs for neglected diseases

The Drugs for Neglected Diseases Initiative (DNDi) is using AlphaFold to create new medicines for neglected diseases that disproportionately affect those in developing countries. Specifically, the protein-folding database could accelerate the identification of molecules to treat neglected diseases.

Examples of such diseases include Chagas disease, which is spread by the parasite *Trypanosoma cruzi*. Chagas disease is common in Mexico, Central America and South America. Another example is leishmaniasis, a parasitic disease found in tropical and subtropical regions as well as southern Europe.

DNDi now has more than 20 new chemical entities in its portfolio. DNDi is also working to enable researchers in low-income countries to play a more active role in drug discovery.

### 2. Combating antibiotic resistance

In 2019, CDC estimated that antimicrobial resistance costs the U.S. economy \$55 billion annually, including \$20 billion in healthcare costs and another \$35 billion in lost productivity. Antibiotic resistance is also fueling the emergence of "superbugs."

Professors Marcelo Sousa and Megan Mitchell from the University of Colorado, Boulder, are using AlphaFold to study proteins involved in antibiotic resistance.

AlphaFold has helped the researchers identify protein structures they could confirm with crystallography.

*(continued on page 120)*

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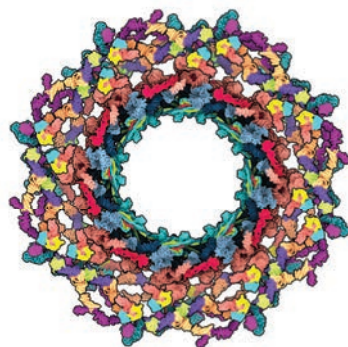


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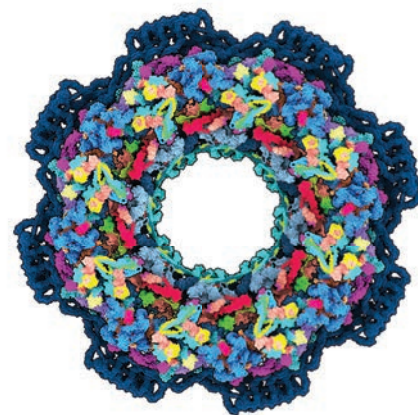
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DeepMind founder and CEO  
**Demis Hassabis**



Previous model



Current model

**The Plasmodium falciparum** gametocyte surface protein, Pfs48/45, could be a target for malaria vaccines. *Image courtesy of DeepMind*

For example, Sousa used this technology to identify a bacterial protein structure in approximately 30 minutes that had proven hard to identify for 10 years.

**The previous** nuclear pore model on the left lacks the sophistication of the revised model on the right. *Image courtesy of DeepMind*

**3. Studying the nuclear pore complex**  
An international research team is working to uncover the secrets of nuclear pore complexes (NPCs), which could be the largest complexes in human cells. NPCs are involved in the transport between the nucleus and cytoplasm and various cellular processes.

Using AlphaFold with Cryo-EM, the researchers have built an almost complete structure of the NPC scaffold. The research project could pave the way for an improved understanding of NPC function, biogenesis and regulation.

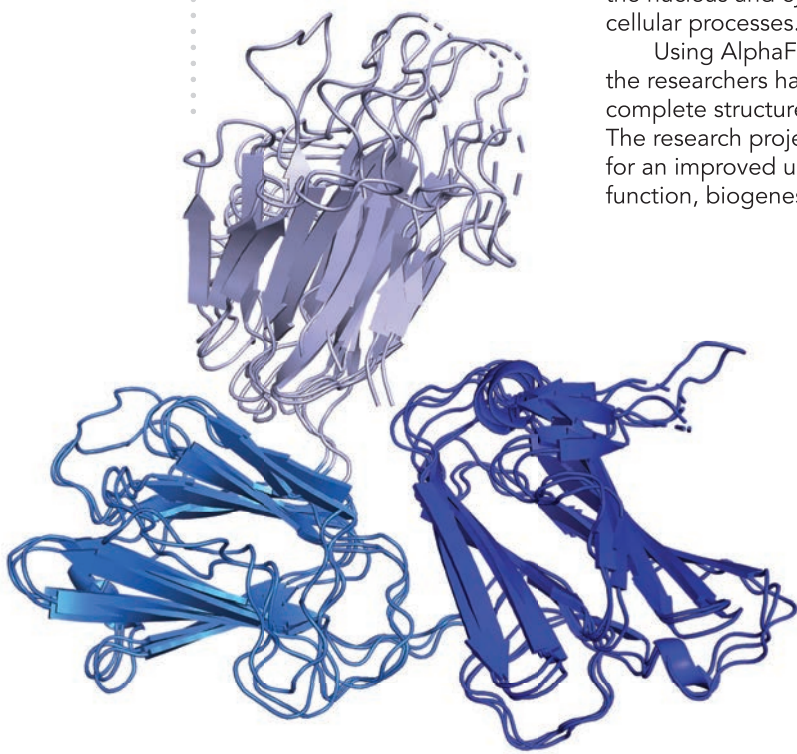
Researchers involved in the project hailed from the Max Planck Institute of Biophysics; European Molecular Biology Laboratory; Harvard Medical School; University of California, Berkeley; SLAC National Accelerator Laboratory; Westlake University; and Tsinghua University.

**4. Developing a novel malaria vaccine**  
The University of Oxford and the National Institute of Allergy and Infectious Diseases (NIAID) are collaborating on developing a multi-component malaria vaccine.

While WHO endorsed the first malaria vaccine last year, its efficacy in curbing transmission could be limited. Vaccine immunogens that prevent transmission of the parasite-carried malaria could block transmission of the virus.

Researchers at Oxford and NIAID identified the first full-length structure of Pfs48/45 with crystallography and AlphaFold. The research could pave the way for the development of future Pfs48/45-based vaccine immunogens.

**5. Studying genetic variation**  
Pedro Beltrao, a professor at ETH Zurich, is working to uncover how DNA changes inform traits, including predisposition to some diseases. "Ultimately, what we'd like to have eventually is a model that tells us exactly how a person is going to change,



or what traits they will have if they carry a mutation in a particular position in their DNA," Beltrao said in a statement.

Beltrao used AlphaFold to study the evolution of proteins across the history of life, helping uncover the proteins present in the ancestral cell. Deciphering which DNA mutations are involved in traits also involves determining which mutations have essentially no impact on proteins. The research also involved studying how multiple proteins work together to perform functions.

"We can now trace back the evolution of proteins for longer periods of the evolutionary timescale," Beltrao said.

While AlphaFold helped Beltrao study the sequences between proteins in various species over time, the technique loses accuracy the further it regresses into the past.

#### 6. Gauging the impact of rotavirus on gastroenteritis

Researchers at Baylor College of Medicine, Lawrence Berkeley Laboratory and Emory University School of Medicine are studying the differences in rotavirus groups A, B and C.


While rotavirus groups A and C mainly infect young children, group B is primarily a problem for adults. In addition, rotavirus group B strains remain less well understood than the other strains.

With AlphaFold, the researchers identified a new fold in rotavirus group B that could help explain why the strain tends to infect a different demographic than the other two strains.

#### 7. Shedding light on Parkinson's

An international research team has explored the use of AlphaFold to model the structure of stress-inducible phosphoprotein 1 (STIP1), exploring its role as a neuroprotective factor guarding against Parkinson's disease.

Currently, therapies that treat Parkinson's tend to focus on symptomatic relief. No neuroprotective agents are approved to slow the rate of neurodegeneration associated with the disease.

Researchers involved in the project were affiliated with Duke-NUS Medical School, Singapore General Hospital, A\*STAR, Tan Tock Seng Hospital, National University of Singapore and Southern Medical University Guangdong. 



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## Connected device design for the real world: Managing the development process



**Philip Remedios** |  
BlackHägen Design

Medtech device engineering for distance care involves complex patient usability requirements, tech challenges and people management skills.

**S**ystems design, wireless design, cloud architecture, usability engineering, integrated artificial intelligence (AI) and machine learning (ML), cybersecurity — the list of technical requirements to consider seems endless when it comes to designing a connected medical device.

While an existing product might look the same as a connected device, the product design is fundamentally more complicated. Connectivity requirements launch the design process into a larger network of associated products and processes in a wider and interdependent ecosystem.

This article highlights development strategies for patient-operated devices that embrace technology (AI, ML, sensors) and meet regulatory requirements. It will explain how applying good human factors principles to the design process will lead

to safer and more effective designs. We'll also define the technical challenges in developing a connected device and look at the partnerships necessary to drive future innovation.

### **Acceleration of distance care practices**

COVID certainly is an accelerant to instigate more focus on the needs of patient-operated healthcare. In fact, the practice of in-home monitoring and drug delivery has become so widespread that "distance care" is now a common term that includes everything from wearables to in-home devices for real-time monitoring, therapy and chronic drug delivery applications.

Secure data collection and transfer to professional healthcare providers for oversight and interaction are powerful features in these new devices.

*(continued on page 124)*

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Many also include sophisticated embedded intelligence that not only provides optimized performance but also feeds vital data into remote databanks for analysis and AI advancement. In addition, the latest smartphone computing capabilities, telemetry and imaging features are increasingly leveraged to reduce device costs.

The development of more sophisticated and even smarter devices for patient self-care is expected to continue. But in the design and development processes, manufacturers must be particularly cognizant of the added usability requirements for the patient. Just the demographic and psychographic variations among patients present numerous design challenges to overcome comorbidity-driven limitations such as strength, vision, dexterity and social/cultural variabilities to assure predictable operability and use safety.

### **Usability engineering provides the platform for design**

Usability engineering requires several steps: discovery research, design confirmation and risk-based validation through user studies. This approach provides an opportunity to identify and mitigate potential end-user challenges, which may be demographic, i.e. anatomical, economic, psychographic and cultural variation. It also considers patient safety if potential or actual comorbidities are involved. The environment in which the device will be used is also identified if, for instance, hygiene or hazardous situations cannot be predicted. The usability approach also looks at how the device can be designed to blend inconspicuously into a home setting or, if wearable, can be non-intrusive or perhaps worn comfortably under a patient's clothing. It additionally considers regulatory requirements upfront so specific issues can be adequately addressed during the design process.

While this human factors approach supports a comprehensive roadmap, there are several other considerations when it comes to the successful development of a connected device.

### **Getting the wireless and medtech design teams in sync**

One of the emerging challenges of connected medical device design is that wireless design has historically resided

within consumer and commercial industries and therefore has not been subjected to stringent medtech design controls requirements (ISO 13485, ISO 14971, 21 CFR Part 820).

This creates unfamiliar development methodologies for these wireless engineers who are not familiar with the specific and complex design process requirements needed for medical devices and the patients that will need to operate them in a safe and effective manner. Quality and risk management standards applied to the combined ecosystem of wireless and medtech design teams often create misaligned procedural expectations that may result in development delays and associated cost increases.

Professional and cultural disconnects between an integrated wireless and medtech design team can lead to inefficient development methodologies. This leads to human resource issues, necessitating the need for a new type of management resource that understands both professional cultures and has solutions to enhance workplace cohesion and efficiency.

The solution to this challenge may sound simple, but recruiting project managers who can demonstrate superior skills to manage these disparate teams both individually and as an integrated team is not a trivial matter. We should expect to see specialized academic cross-training of these connected medtech managers in the near future.

### **Overcoming challenges with technology standards**

Further complicating device design and development for connected devices is that wireless telemetry protocols and hardware are not standardized internationally, making it virtually impossible to develop a single device that will be able to operate globally.

Regional differences in radio standards and institutional infrastructure require multiple design versions or duplicated components (like global cellphones), further complicating R&D for device manufacturers.

And various design versions need to not only meet regional standards (for example, set by the FCC in the U.S.) but also must be created to meet specific global regulatory requirements.

### **The future promises innovation**

As AI and ML technologies continue to mature from consumer to medical platforms, corporate partnerships and incentive subsidies will be desirable to share in the substantial design/development overhead necessary to build, test and validate robust and reliable software algorithms required to guide and control medical devices.

Additionally, support is needed from governments, related industries and clinical and insurance communities. Without this support, the return on investment for manufacturers is difficult to predict and may stall the pace of new technology integration into the design process.

With appropriate concurrent commitments from all of these entities, the advancement of this new and exciting medtech paradigm can absolutely elevate opportunities for patients to interact with their clinicians to improve healthcare at reduced operating costs. **M**



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## FDA details plans to expand remote safety assessments for device makers

Remote regulatory assessments won't replace inspections, but the FDA offered new draft guidance for virtual visits beyond the pandemic.



**Jim Hammerand** |  
Managing Editor

**T**he FDA wants to keep and expand its ability to remotely conduct safety assessments even after the COVID-19 pandemic.

The federal agency recently detailed its plans in new draft guidance for remote regulatory assessments (RRAs) covering all FDA-regulated products. FDA staff started conducting remote assessments when unable to travel due to COVID-19 restrictions, and regulators said RRAs will continue to be valuable beyond the pandemic.

RRAs have been as simple as reviewing records, but also include voluntary interactive evaluations such as livestreaming video of operations, teleconferences and screen sharing.

### **Are FDA remote assessments mandatory for medical device manufacturers?**

Medical device manufacturers won't be required to participate, but it will be mandatory for drug manufacturing facilities, including those involved with drug-led drug-device combinations.

The FDA said it won't take enforcement action against a company for declining a voluntary RRA request, but warned of potential consequences.

"FDA may not be able to provide an applicant with a timely decision on an application or product's approval, clearance, or authorization if we lack information about an establishment referenced in the marketing submission," the FDA said.

And if the FDA can't get the information it wants through a voluntary RRA, it could move forward with an inspection or other actions.

A drug maker that refuses a mandatory RRA or withdraws cooperation could find itself in violation of the Federal Food, Drug and Cosmetic Act.

### **How will FDA decide whether to conduct a remote evaluation?**

The FDA said it will use RRAs "according to a risk-based approach that best protects public health" to optimize its resources and to give more scheduling flexibility to the companies it regulates. For now, the FDA said it will not take requests for RRAs.

The agency said remote assessments might be appropriate if a facility has a history of compliance or when FDA staff can't travel due to pandemics, disasters or other unstable situations.

*(continued on page 128)*



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The FDA might use an RRA to help with oversight or regulatory decisions, listing examples such as preparation for a scheduled inspection, following up on consumer complaints, verifying corrective actions or supporting review of a marketing submission. When considering the use of an RRA, the FDA said it may consider a company's location, inspection history and complexity of product and process, with different parts of the FDA assessing risk differently based on the product.

The FDA performed more than 1,470 RRAs in the U.S. and more than 600 at foreign entity establishments over the past two years.

"As a result of these RRAs, we've identified unreported adverse events, gathered information to add products that appear to be violative to import alerts, evaluated the status of companies correcting issues from a previous inspection and helped the agency make regulatory decisions for product premarket submissions," the FDA said. "RRAs are effective in getting essential information to regulators, enabling the FDA to intervene when needed and use agency resources more efficiently to do so."

## "RRAs are not intended to limit or replace other established means of obtaining information necessary for FDA to accomplish its public health mission outside of inspections."

### Will remote assessments replace FDA inspections?

RRAs won't replace inspections and won't be used simultaneously with inspections, but might come before or after. The FDA does not consider RRAs as inspections because FDA officials or employees don't physically enter the facility and won't issue a Form 482 or Form 483.

"RRAs are not intended to limit or replace other established means of obtaining information necessary for FDA to accomplish its public health mission outside of inspections, including, among other things, applicant information request letters, registration confirmations, meetings, product submission or application assessments, or follow-up communications during outbreaks or other emergencies," the agency said.

"Similarly, if, for example, FDA calls an establishment to inform them that a submission or application is missing certain information, this is not an RRA. Although these activities may be conducted remotely, the Agency does not consider these RRAs."

### What happens during an FDA remote assessment?

The FDA said some RRAs might just require a company to find and deliver records, documents or other information for the FDA's review. RRAs could also involve virtual meetings with the FDA and a company's personnel to review information, systems and operations. Pre-recorded video or livestreams could also let FDA staff examine facilities, operations, data and information.

During the process, the FDA may provide updates on observations and outstanding issues. When the RRA is completed, FDA may meet with a facility's management and present a written list of

observations, if there are any.

Those observations would cover conditions or practices that indicate a potential violation of laws enforced by FDA. This list could be released as public information if requested under the Freedom of Information Act.

Companies are encouraged to respond during the meeting and/or offer written responses within 15 business days. The FDA will consider those responses and any corrective actions in that time before taking further action or issuing a decision.

### What records can the FDA request through a remote assessment?

The FDA said it will try to minimize the volume of records it requests, but that requests are similar to information

sought during an inspection and could include any records or information needed to determine compliance with FDA regulations.

Those records can include:


- Production lot or batch records and product-specific information such as periodic product reviews, product quality reports, equipment records, process validation records and Current Good Manufacturing Practice-related reports, test results, product complaints or other information
- Summaries or lists of records
- Read-only access to electronic databases or database walk-throughs, data queries or summary data
- Standard operating procedures and records of quality control and FDA compliance
- Records or data related to the reporting or conduct of FDA-regulated research

The FDA said records should be provided in an electronic format via a secure channel provided by FDA. Paper documents should be scanned and saved as PDFs if possible. The FDA may request that documents be in English or be accompanied by a translation.

### Where can I learn more about the FDA's remote assessment proposal and comment on it?

The FDA's RRA guidance can be downloaded as a 17-page PDF. The guidance was developed by the FDA Office of Regulatory Affairs in cooperation with the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Food Safety and Applied Nutrition, the Center for Tobacco Products, the Center for Devices and Radiological Health, and the Center for Veterinary Medicine at the FDA.

The FDA is encouraging comments on the draft guidance by Sept. 23, 2022.

Go to [wtwh.me/FDARRA](https://www.fda.gov/oc/2022/09/01/fda-remote-assessment) for links to the guidance document and commenting portal. 

# The Silbione® Difference

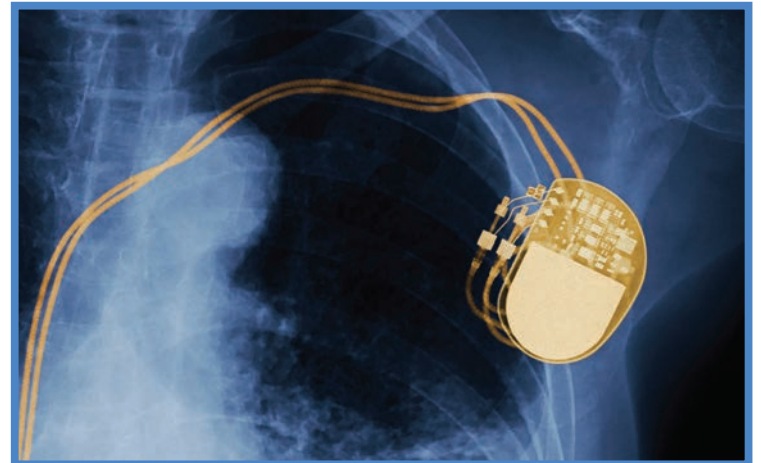
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**Sapient 3** transcatheter pulmonary valve system with Alterra adaptive pre-stent  
Image courtesy of Edwards Lifesciences



## Six top tubing technology innovations

A half-dozen catheters, stent systems and related medical tubing products are up for high honors at next month's 2022 Prix Galien USA awards.



**Danielle Kirsh** |  
Senior Editor

**T**ubing technology represents about one-fourth of the medical device technologies nominated for the Galien Foundation's 2022 Prix Galien USA awards.

The annual Prix Galien awards highlight devices, biotechnology and pharmaceutical products designed to improve the human condition. Nominees need to be FDA-approved for the market within the last five years and show major potential to affect healthcare. The winners will be announced in October.

"Every year, evaluating and recognizing the amazing submissions that come through for the Prix Galien Awards is one of the greatest honors," said Dr. Sue Desmond-Hellmann, chair of the Prix Galien USA award committee. "The commitment and dedication of the innovators who develop these products never cease to amaze the awards committee."

This year, the foundation nominated 24 medical device innovations, including these six products made possible by medical tubing technology.

### **Edwards Lifesciences Sapient 3 transcatheter pulmonary valve system with Alterra adaptive pre-stent**

Edwards' Sapient 3 transcatheter pulmonary valve system with Alterra adaptive pre-stent is a catheter-based stent and artificial heart valve for treating patients whose right ventricular outflow tract becomes too leaky.

Alterra, the catheter-based stent, is made from self-expanding nickel-titanium, while the Sapient 3 artificial heart valve is made of cow tissue attached to a balloon-expandable, cobalt-chromium frame for support. The system is approved for use in pulmonary valve replacement when a patient's pulmonary valve conduit or artificial pulmonary valve stops working properly. It won FDA approval expansion in January to treat the right ventricular outflow tract.

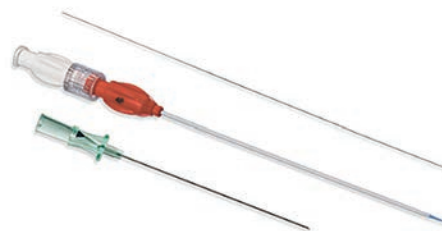
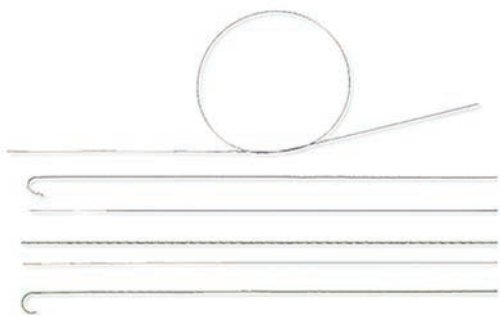
To begin treatment using the Sapient 3 transcatheter pulmonary valve system with Alterra adaptive present, a doctor inserts a catheter through a large vein in the leg.

*(continued on page 132)*



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## TUBING TALKS

The catheter has a compressed Alterra stent at the end and is pushed through the blood vessels until it reaches the pulmonary valve. The stent is released and anchors to a patient's right ventricular outflow tract, and the Sapien 3 valve is deployed through a balloon catheter and pushed until it reaches the location of the Alterra stent.

Once the artificial valve is in place, it is expanded by a balloon and anchored inside the Alterra stent and functions the same as the old valve by opening and closing like a door to force blood to flow in the correct direction.

### **Olympus America's BF-UC190F endobronchial ultrasound bronchoscope**

The BF-UC190F endobronchial ultrasound bronchoscope (EBUS) is Olympus's latest generation of its endoscopy devices. The EBUS is used for the diagnosis and staging of lung cancer. It allows optimal angulation and an improved approach to difficult-to-reach target sampling sites for enhanced access and control.



**BF-UC190F**  
endobronchial  
ultrasound  
bronchoscope  
*Image courtesy  
of Olympus*

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Olympus designed the EBUS with a compact distal tip and increased scope angulation to enhance the maneuverability to reach lymph node stations in the mediastinum and hilum parts of the lung. It was a decreased forward oblique angle of 20° to enable easier endoscopic orientation to allow the operator to keep the endoscopic image in full field of view while navigating the airways during a procedure.

The newer iteration of the EBUS has improved needle orientation with a steeper puncture angle to provide a more perpendicular needle orientation toward the target for smoother target penetration between cartilage rings and other critical vessels.

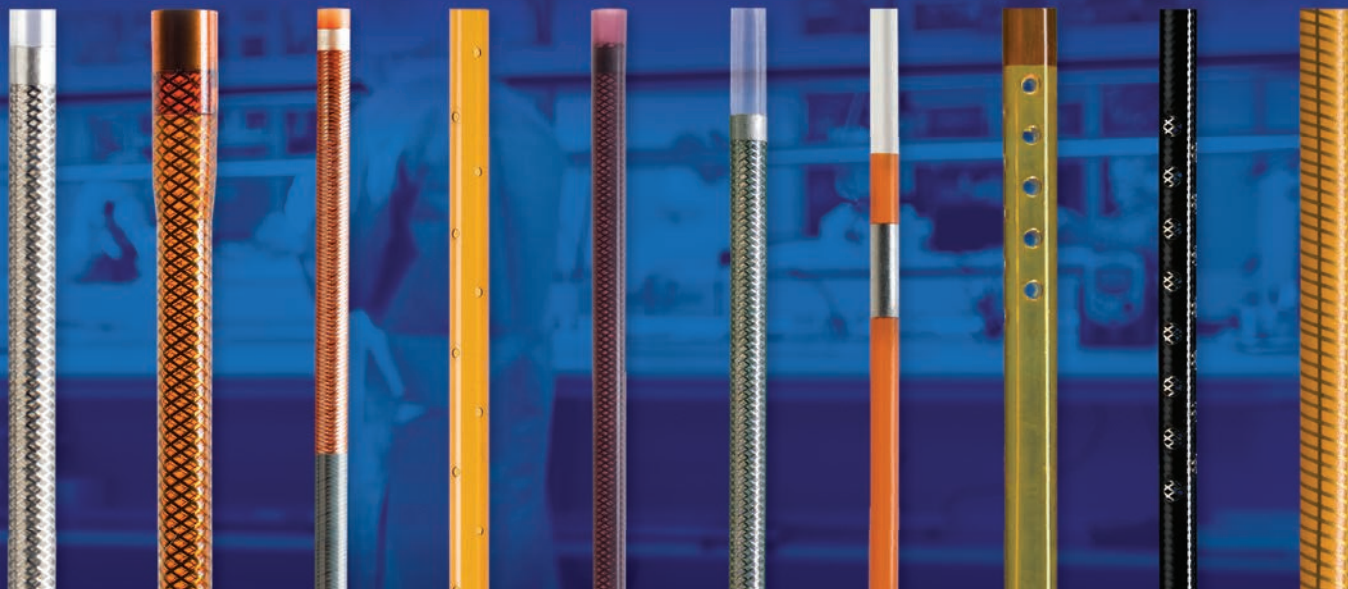
**Baylis Medical's VersaCross transseptal platform**

The VersaCross catheter is a left-heart access device that can be used as a guidewire, transseptal puncture device or an exchange rail for delivering therapy sheaths. Toronto-based Baylis Medical, acquired by Boston Scientific

in February, designed the VersaCross with an atraumatic radiofrequency tipped pigtail wire to achieve access and then serve as an exchange wire to reduce the number of exchanges through a procedure.



• **VersaCross** transseptal platform  
 • Image courtesy of Boston Scientific



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PureWick™ Urine Collection System

PureWick™ Female External Catheter

PureWick female external catheter and PureWick urine collection system  
Image courtesy of BD



Venovo venous stent system  
Image courtesy of BD

### BD's PureWick female external catheter and PureWick urine collection system

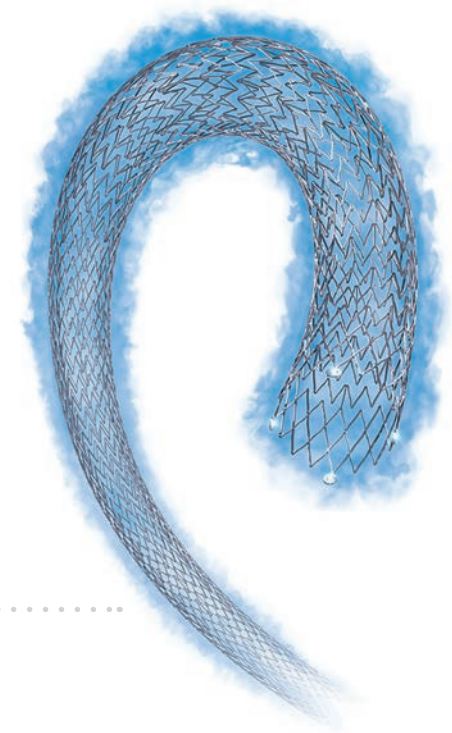
The PureWick female external catheter is a noninvasive urine output management system for female patients. Franklin Lakes, New Jersey-based BD designed the catheter to “wick” urine away from the patient and into a designated collection canister — the PureWick urine collection system — to manage female urinary incontinence.

### BD's Venovo venous stent system

The Venovo venous stent system is a treatment option for patients with symptomatic iliofemoral venous outflow obstructions. BD designed the system for the iliofemoral veins to provide an optimal balance between radial force, flexibility and compression resistance. It comes in a broad range of sizes with diameters up to 20 mm and stent lengths up to 160 mm. Venovo was also a nominee for Prix Galien's best medical technology award in 2020 and 2021.

### Boston Scientific's Eluvia drug-eluting vascular stent system

The Eluvia drug-eluting vascular stent system is a drug delivery device for the treatment of peripheral artery disease. Eluvia uses a drug-polymer combination to deliver the chemotherapy drug paclitaxel over the course of a year. It has a hydrophobic Promus polymer that protects the drug from dissolving in the blood and allows for highly-controlled drug delivery to the target lesion. Eluvia reduces downstream particulates and has low systemic drug exposure with no measurable levels of paclitaxel in the bloodstream within 30 minutes, according to the company. <sup>M</sup>



Eluvia drug-eluting vascular stent system  
Image courtesy of Boston Scientific



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# The 10 largest orthopedic device companies in the world

Stryker, Johnson & Johnson’s DePuy Synthes and Zimmer Biomet lead our annual ranking of the world’s largest orthopedic device companies.

**W**ith elective procedure numbers rebounding after the darkest days of the COVID-19 pandemic, sales at most of the world’s largest orthopedic device companies increased by double-digit percentages during their most recent fiscal years.

Here are the world’s 10 largest orthopedic device companies, ranked by ortho business revenue pulled from their most recent annual reports:



**Chris Newmarker** | Executive Editor

### 1. Stryker

With a strong order book for capital equipment and implant sales momentum, Stryker recently boosted its revenue projections for 2022, predicting organic sales growth between 8% and 9% for the year.

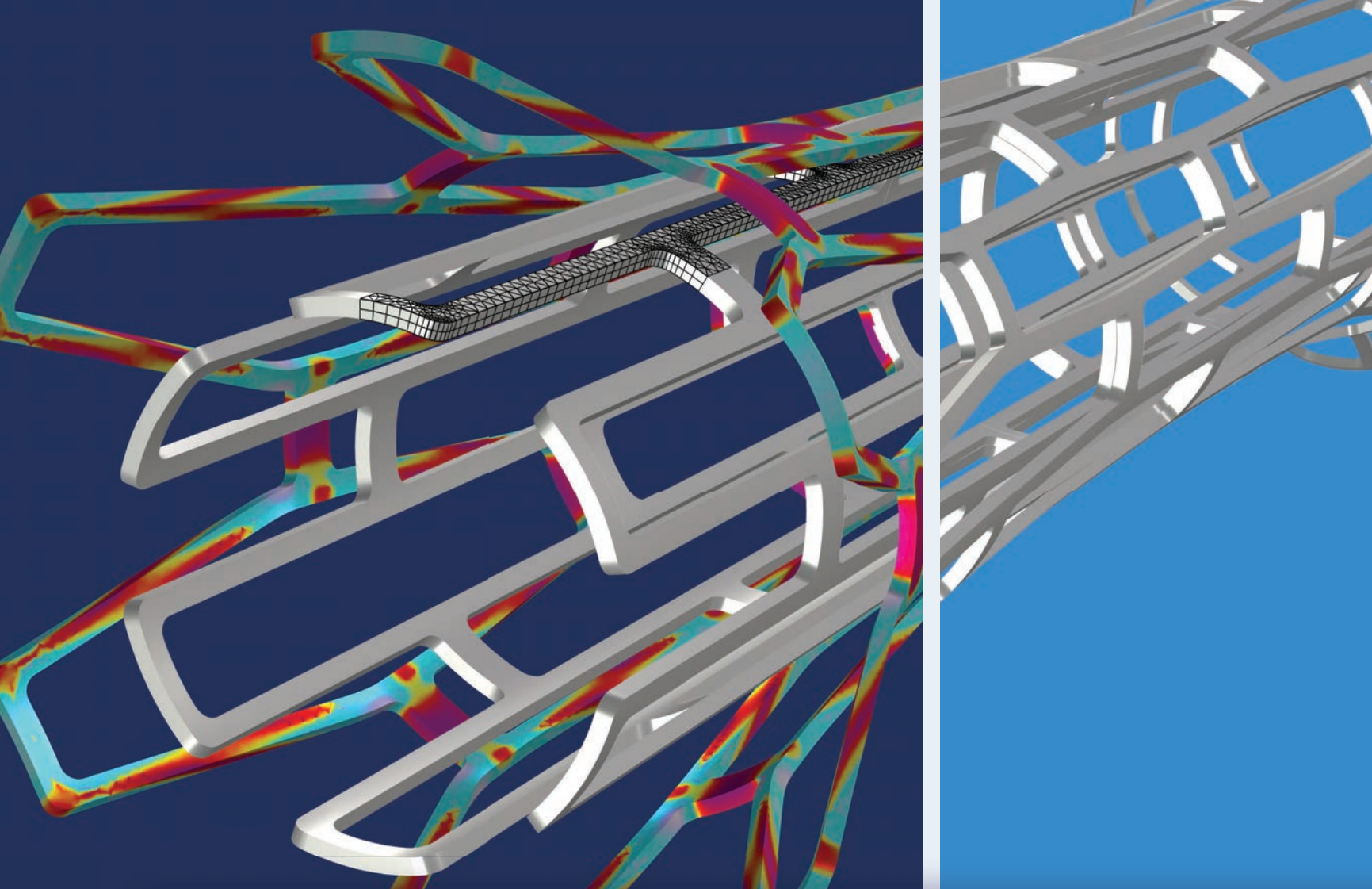
The world’s largest

orthopedic device company, however, scaled back its earnings range amid the foreign currency exchange environment. Like most manufacturers, Stryker said its supply chain is presenting challenges, too.

“We continue to invest in R&D at a healthy ratio of sales, demonstrating our continued focus on new product pipelines,” CEO Kevin Lobo said during Stryker’s Q2 2022 earnings call on July 26. Company officials are also excited about the synergies that Stryker is already realizing from its \$3.1 billion acquisition of Vocera Communications, a provider of digital care coordination and communication offerings including the hands-free Vocera Smartbadge.

*(continued on page 138)*

	LARGEST ORTHOPEDIC DEVICE COMPANIES	ANNUAL REVENUE (% CHANGE)	HEADQUARTERS
1	<b>Stryker</b>	\$17.1 billion (+19.2%)	Kalamazoo, Michigan
2	<b>Johnson &amp; Johnson – DePuy Synthes</b>	\$8.6 billion (+10.6%)	Locations: Raynham, Massachusetts.; West Chester, Pennsylvania; Warsaw, Indiana; Palm Beach Gardens, Florida
3	<b>Zimmer Biomet (minus ZimVie spinoff)</b>	\$6.8 billion (+11.6%)	Warsaw, Indiana
4	<b>Medtronic – Cranial &amp; Spinal Technologies</b>	\$4.5 billion (+3.9%)	Locations: Memphis, Tennessee; Louisville, Colorado
5	<b>Smith+Nephew (Orthopaedics + Sports Medicine)</b>	\$3.7 billion (+14.3%)	London
6	<b>Enovis (Formerly Colfax’s Medical Technology segment, including DJO)</b>	\$1.4 billion (+27.3%)	Wilmington, Delaware
7	<b>NuVasive</b>	\$1.1 billion (+8%)	San Diego
8	<b>Globus Medical</b>	\$958 million (+21.4%)	Audubon, Pennsylvania
9	<b>ZimVie (Spine business)</b>	\$540 million (+2.1%)	Westminster, Colorado
10	<b>Orthofix</b>	\$465 million (+14.2%)	Lewisville, Texas



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## ● ORTHOPEDICS

### 2. Johnson & Johnson – DePuy Synthes

DePuy Synthes officials see the Johnson & Johnson business better enabling the personalization of orthopedic surgery, creating better outcomes. That was a big takeaway when five J&J executives spoke about the shift toward digital at DeviceTalks Boston in May.

“We’re not adopting technology just for technology’s sake. We’re adopting technology because it’s meeting clear, unmet needs,” said Rajit Kamal, worldwide president, sports medicine/shoulder reconstruction at DePuy Synthes.

Recent DePuy Synthes wins include the Inhance system receiving FDA clearance for total shoulder arthroplasty and adding the Cementless Fixed Bearing knee and Medial Stabilized knee to its Attune Knee portfolio. The company is betting it can compete in the ortho surgical robotics space with its Velys system, which could help reduce the physical burden of orthopedic surgery. Earlier this year, DePuy Synthes acquired Tennessee-based CrossRoads Extremity Systems and its range of procedure-specific, sterile-packed implants and instrumentation systems cleared for lower extremity indications.

### 3. Zimmer Biomet

Zimmer Biomet has had a great deal of news over the past year. It spun off its dental and spine business as ZimVie in March. ZB has also introduced new ortho surgical offerings based on AI and mixed reality. They are also pioneering smart ortho device implants, being the first to offer smart knee implants.

In early August, Zimmer Biomet reported second-quarter results that handily beat the consensus forecast on Wall Street, upping its full-year forecast for 2022. A host of U.S. companies in medtech and other industries are reporting macroeconomic headwinds related to foreign exchange rates, inflation, supply chain challenges and more. ZB officials, however, appear to be making a bet that they can innovate their way out of rough economic seas. CEO Bryan Hanson pretty much said it during the company’s Q2 earnings call: “We believe our focus on innovation and the transformation of our business continues to position us well for long-term growth and continued delivery for our shareholders.”

### 4. Medtronic – Cranial & Spinal Technologies

In the spine space, Medtronic had record quarters with its Mazor robotics system and StealthStation navigation

**“We continue to invest in R&D at a healthy ratio of sales, demonstrating our continued focus on new product pipelines.”**

system, CEO Geoff Martha said during the medtech giant’s Q4 earnings call in May. “The ongoing launch of our Catalyft expandable titanium interbody system and the rollout of our enabling technologies continues to differentiate us in spine,” Martha said.

Recent spine wins for Medtronic include FDA 510(k) clearance and breakthrough device designation for its LigaPASS 2.0 ligament augmentation system for spine surgery and FDA clearance of its UNiD spine analyzer v4.0 planning platform. On the flip side, the spine business was facing slowing distributor purchases in China ahead of a potential national volume-based tender as the Chinese government seeks to rein in healthcare costs.

### 5. Smith+Nephew

The most recent earnings report from Smith+Nephew in late July showed an overall loss in revenue, and its orthopedics business experienced a revenue decline of 1.1% in Q2, noting supply chain challenges and a new hip and knee volume-based procurement program in China. However, company officials say they have a strategy to grow the orthopedics business.

“Orthopedics continues to be held back by execution and supply chain challenges,” CEO Deepak Nath said in a news release. “In the last three months, I have reviewed the business and, together with the team, we have developed a comprehensive plan to drive better execution at pace.”

The plan includes initiatives such as driving operational benefits in orthopedics and transforming the business. Smith+Nephew also recently invested in its orthopedics business by building a new \$100 million manufacturing facility in Malaysia.

### 6. Enovis

Enovis — the parent company of DJO Global — completed acquisitions and spinoffs this year to strengthen its position in the orthopedic device industry.



Stryker CEO  
**Kevin Lobo**



DePuy Synthes Worldwide  
President, Sports Medicine/  
Shoulder Reconstruction  
**Rajit Kamal**



Zimmer Biomet CEO  
**Bryan Hanson**



Smith+Nephew CEO  
**Deepak Nath**

In May, the company acquired assets of Outcome-Based Technologies' hip and knee bracing portfolio, adding the Excyabir hip brace and CryoKnee knee braces to its DonJoy bracing brand. Enovis also completed the acquisition of Insight Medical and its FDA-cleared Arvis augmented reality platform for hip and knee replacement surgery earlier this month.

In early August, the company reported Q2 results that beat Wall Street's expectations on earnings but missed on revenue. It joined the host of medtech companies scaling back earnings projections for the year amid macroeconomic headwinds.

### 7. NuVasive

NuVasive remains on track to grow its revenue more than 6% in fiscal 2022, and its orthopedic technology is expected to drive the growth. However, the company reduced its EPS guidance in early August amid the macroeconomic pressures that many device companies presently face.

The spine surgery tech company recently released data from a study of its Attrax Putty porous interbody implant and synthetic bone graft substitute and a porous titanium interbody implant, Modulus XLIF for lateral lumbar interbody fusions. Nuvasive said the fully porous architecture and favorable environment for bone in-growth and supported a less invasive XLIF procedure that was clinically and economically beneficial.

In April, NuVasive reported successful data that demonstrated significantly greater success rates with its Simplify disc at the 24-month follow-up compared to anterior cervical discectomy and fusion when used for

two-level cervical total disc replacement. The implant allows for enhanced visualization through MRI postoperatively compared to alternative devices.

### 8. Globus Medical

Globus Medical during its second quarter delivered on a needed rebound after a Q1 earnings miss and a surprise CEO transition, said BTIG analyst Ryan Zimmerman as he kept his Buy rating on GMED shares. "To some extent, investors are flying blind in terms of where GMED is heading longer-term strategically (and how it reaccelerates core spine), but at the same time, we expect GMED to drive growth through competitive rep hires, pull through from Enabling Technology, and new product introductions; all of which are expected to pick-up as we move into FY23."

Globus Medical reaffirmed its full-year 2022 guidance of \$1.025 billion in net sales and non-GAAP EPS of \$2.10.

The company reached another milestone in its business earlier this year with the first shipments of its Excelsius3D imaging system. Globus Medical announced the first procedures using the system in May. The mobile X-ray system is designed for 2D fluoroscopy, 2D digital radiography and 3D imaging of adult and pediatric patients. When combined with its ExcelsiusGPS, the image-guided robotic navigation improves implant placement accuracy.

Early feedback was "extremely positive," CEO Dan Scavilla said in May. He called the imaging system "an excellent example of Globus Medical's innovation engine, which will drive momentum and provide a platform for continued growth as we progress in 2022 and beyond."

### 9. ZimVie (spine business)

Zimmer Biomet's latest spinoff, ZimVie, became an independent public company on March 1, nearly 13 months after Zimmer Biomet announced the move.

ZimVie reported \$540 million worth of spine sales for calendar year 2021, while the spinoff's other business — dental — did \$469 million for the year.

CEO Vafa Jamali earlier this year said there are opportunities for growth in the spine space, but the efforts could take years to accomplish. Two examples of the growth opportunity are cervical disc replacement and pediatric scoliosis treatments.

The former Medtronic executive also set his sights on "some operational issues

to fix within our spine business," saying ZimVie would exit several countries where the business has been unprofitable.

"That opens up a ton of management time and energy. It just frees us up. ... We're doing a lot of work with our inventory and how we manage our sets. So this really gives us a chance to sort of stabilize and then to grow from there." Jamali said. "We're going to have a year of resetting and sorting out all these pieces. And then you'll see us accelerate on some of the more innovation-focused areas and goals."


Facing greater than anticipated foreign exchange headwinds, ZimVie announced during its Q2 earnings report that it is reducing its full-year revenue forecast to \$915 to \$930 million versus prior guidance of \$1 billion.

### 10. Orthofix

Orthofix named Kimberley Elting as its global orthopedics business president in April. Eluting was previously chief legal and development officer and held other leadership roles in the areas of regulatory and quality, business development and corporate communications at the orthopedic implant purveyor.

In May, Orthofix said it received FDA premarket approval (PMA) for its AccelStim bone healing therapy device. In July, the company announced a licensing partnership with LimaCorporate to combine the limb-lengthening technology of Orthofix's Fitbone intramedullary nail system with LimaCorporate's proprietary, patient-specific, 3D-printed pelvic fixation device. The company most recently launched its Virtuos Lyograft autograft substitute and marked the first clinical use.

In early August, the company lowered its financial outlook for the year. It now anticipates fiscal 2022 net sales to be in the range of \$455 million to \$465 million, down from its previous outlook of \$475 million to \$490 million.

Said CEO Jon Serbousek: "We had solid operational execution, despite the challenges that macro headwinds continue to present, including continued hospital staffing shortages, complex spine procedure softness, and patients deferring care due to economic pressures. In addition, currency fluctuations during the quarter dampened reported revenue results." 

*Managing Editor Jim Hammerand and Senior Editor Danielle Kirsh contributed to this story.*



ZimVie CEO  
**Vafa Jamali**

# Autotransfusion

device maker ships units to Ukraine



JIM HAMMERAND  
MANAGING EDITOR

*Sisu Global Health's Hemafuse is an autotransfusion device for collecting, cleaning and reusing a surgery patient's lost blood.*



Photo courtesy of Sisu Global Health

The developer of an autotransfusion device for collecting and cleaning a patient's lost blood is sending hundreds of units to Ukraine as casualties climb from the Russian invasion.

Baltimore-based Sisu Global Health has already sent 1,005 of its Hemafuse devices to hospitals in Kyiv and is planning a third shipment of 500 more any day now, co-founder and President Gillian Henker said.

"We were talking amongst our management team and our shareholders and saying we really want to do something for Ukraine," Henker said in an interview with **Medical Design & Outsourcing**. "And we really see Hemafuse as a great fit."

After those first conversations in March, the company raised \$110,000 in partnership with nonprofit FINCA International and worked with other partners to send the kits to Ukraine. They

hope to be able to send another 500 in a fourth shipment, Henker said.

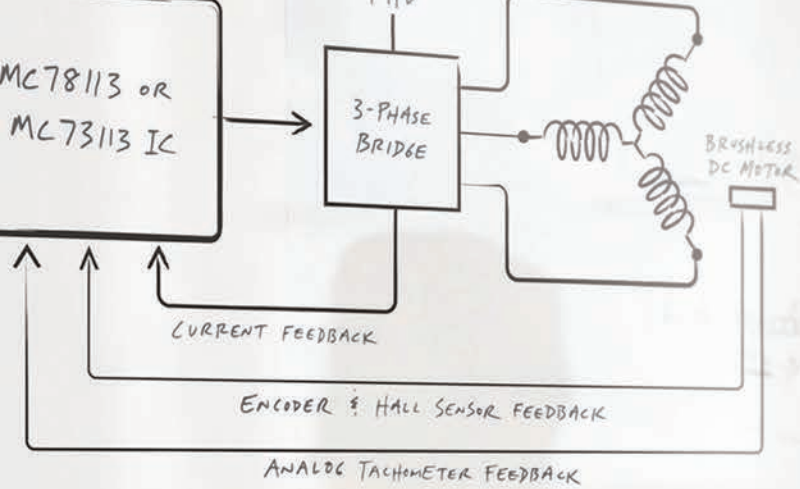
Hemafuse is a handheld device that uses a Yankauer suction tip to salvage blood from a patient with internal bleeding so the blood can be reused in the patient if donor blood is unavailable or in limited supply. The device can be reused about 25 times.

The device can be used for ruptured ectopic pregnancies, burst spleens and livers, coronary artery repairs, total hip replacements, abdominal aneurysms and myomectomies. A patient who receives their own blood won't reject the blood or be infected by someone else's bloodborne pathogen.

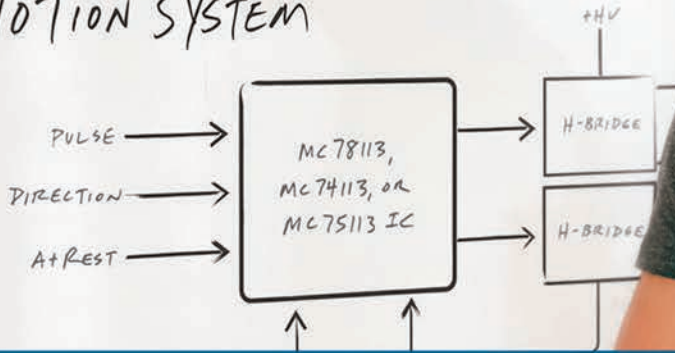
"Your own blood is better than someone else's," Henker said. "With this device, you want to make sure that it maintains the quality of that blood and gives that best blood back to that same patient."

*(continued on page 142)*





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MOTION CONTROL AT ITS CORE

Blood is in high demand on and off the battlefield. The American Red Cross declared its first-ever blood crisis this year, citing a decline in donations in the COVID-19 pandemic.

"There are community hospitals in the U.S. that are in rural areas that don't have blood banks in their facilities," Henker said. "They might only have one or two units on hand for emergencies, especially certain components that help with clotting or stopping the bleeding. We see Hemafuse as a great product to have on hand for more rural community hospitals, and what you might think of as rural or community could just be the next county or two counties over from a major city.

**How the Hemafuse autotransfusion device was developed and designed**

Henker said she was in a Sub-Saharan Africa hospital in 2010 when she was asked her blood type for a maternal patient who needed a transfusion. Henker wasn't a match, but someone else was, and the mother's life was saved. "That's

where the idea and the invention of Hemafuse came about," she said.

Four years later, Henker and co-founders Carolyn Yarina and Katherine Kirsch launched Sisu Global Health.

"The formation of Sisu Global was Jill recruiting me in on the idea and building something stronger together," said Yarina.

They interviewed doctors, nurses and techs in West Africa to learn more about their challenges before developing prototypes. Early prototypes were 3D-printed and super-glued together, with Henker testing fluid dynamics in her bathtub.

"There were a number of different fun things with roommates walking in and me being like, 'Hey, no worries. I'm making a medical device here,'" Henker said.

Henker and other engineers started

with several different designs, but the device's current form of an oversized syringe won for simplicity.

"The giant syringe was a really big breaking point for the team. You see it and you have an intuition on how it should be used," Henker said. "Especially with our shipments that we've had to Ukraine, we haven't had the most interaction with those clinicians at the moment."

*(continued on page 144)*



**Sisu Global Health** co-founders Gillian Henker (left) and Carolyn Yarina  
Photo courtesy of Sisu Global Health



**The Hemafuse** autotransfusion device collects and filters a patient's own blood for reuse.  
Photo courtesy of Sisu Global Health



# Full Product Lifecycle

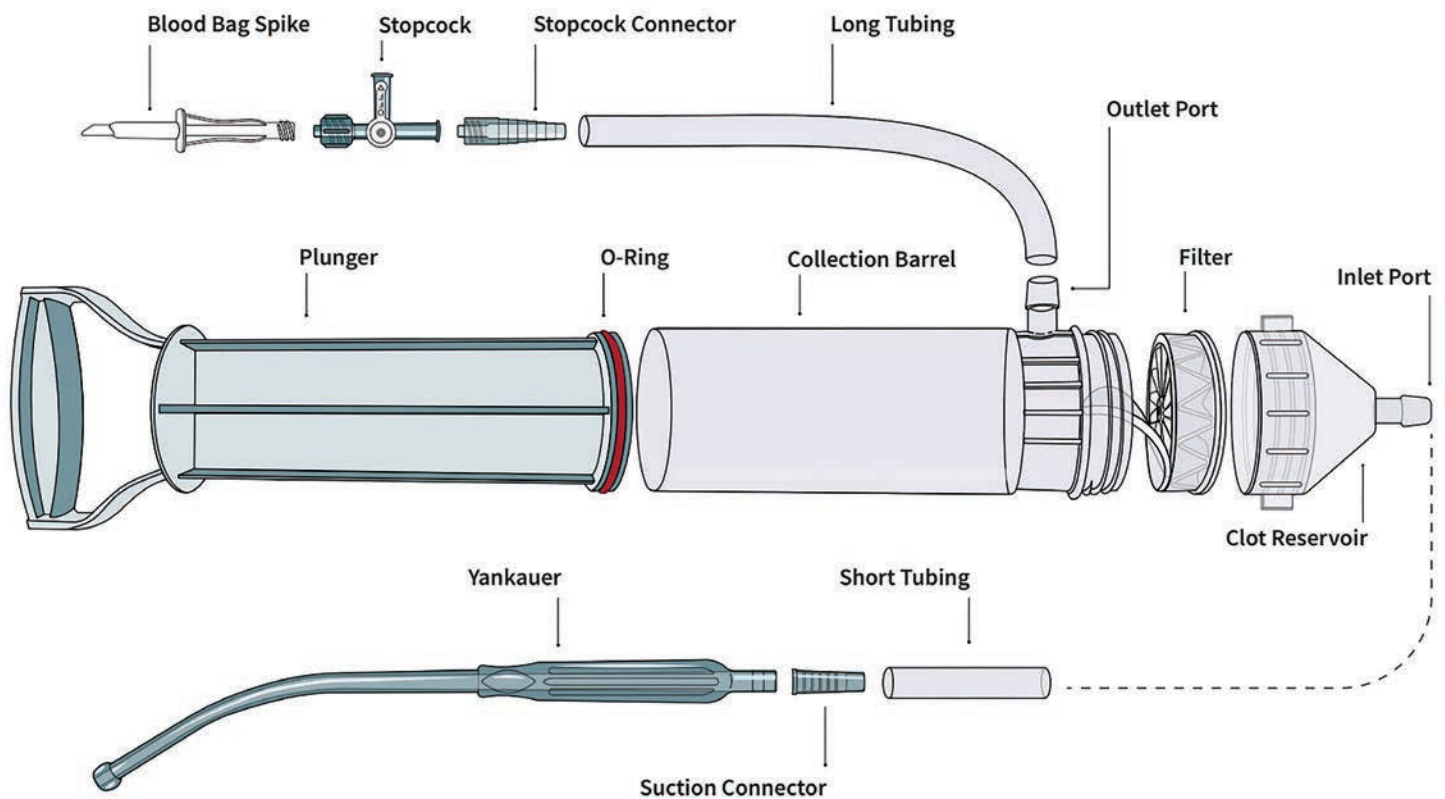
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**The Hemafuse** autotransfusion device is made mostly of high-heat plastics. Photo courtesy of Sisu Global Health

"We've translated, of course, our instructions for use and our manuals, but we are relying on the design of the device to help it be simple for them to intuitively use it in the field," she said.

The Hemafuse pump is mainly injection molded with high-heat plastics in the U.S., with one part made in Asia and assembly in Baltimore by Harbor Designs & Manufacturing.

The filter is a polyester-like dual mesh that removes blood clots, particulate, bone fragments and tissue. The filter is folded in a specific way to increase surface area and flow, Henker said.

"The more surface area you have, the greater flow can go through it and our device can get you several units of blood in a couple of minutes," she said.

Sisu Global Health launched the device in Kenya and Ghana in 2019 and won FDA 510(k) clearance last summer.

"I'm most excited for these next phases that Jill has been leading the product into," Yarina said, "not only the continued scale within different countries in Africa and Southeast Asia, but her

leadership into the new markets in India and also the U.S. — particularly the U.S. military — that are going to be upcoming in the near future."

#### **Design challenges and lessons learned**

Henker learned some important design lessons through the development of Hemafuse.

"Do the best you can to think about what you need to do now to get to the next stage, not how do you go all the way to the end," she said.

She offered the example of Hemafuse's 3D-printed prototypes.

"What do we need to get on board with that stage of development — customer interest, medical needs identified, different proof of concepts modeling, even if it's not the most sophisticated — to then get to the next stage of funding? With a 3D-printed prototype, we were able to get a grant that launched us into being able to do more manufacturing, biocompatibility and sterilization testing, which allowed us to do our first clinical study."

The hardest challenge of designing Hemafuse was maintaining simplicity throughout the device and limiting the number of parts, work that continues to this day.

"Probably within the next year, we're going to be looking at streamlining our production and making things easier for some of our users, especially if they need a little bit more time to put together the device," Henker said. "We're looking at increasing that use factor and streamlining production."

Yarina said Sisu Global Health is negotiating for expansion into new markets and looking for more partners.

"The product is ready for scale, it's ready for additional countries," Yarina said. "It's all about having the right partners: medical device distributors, medical NGOs or different partners. ... The biggest piece for a novel technology is awareness." 



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**Greg Smith** is Medtronic's EVP of global operations and supply chain.  
Photo courtesy of Medtronic

# SUPPLY CHAIN EVP **GREG SMITH** sees fewer suppliers in Medtronic's future

All eyes are on Medtronic's global operations and supply chain leader as he works to modernize its operations and scrutinize suppliers.

**JIM HAMMERAND**  
MANAGING EDITOR

**EVP** of Global Operations and Supply Chain Greg Smith anticipates fewer suppliers in Medtronic's future, he said in his first published interview since joining the medical device manufacturer in April 2021.

Smith was previously EVP of U.S. supply chain at Walmart and SVP of global operations at Goodyear Tire & Rubber Co. His more than three decades of experience also includes time at ConAgra Foods, United Signature Foods, VDK Frozen Foods and Quaker Oats.

Around the same time that he joined Medtronic, semiconductors and resins were in short supply following the February 2021 cold snap that took the Texas power

grid down and halted operations at semiconductor factories and petrochemical plants for weeks.

Add that to the COVID-19 pandemic and its lockdowns in China, labor issues in the U.S. and abroad, global logistics problems for freight by ship, truck and rail, increasing cyberattacks and Russia's invasion of Ukraine, and you've got what Smith called the hardest two years in his career.

"There are signs on the horizon of certain things getting better, but I think it's still going to be a ways before we work certain issues out," Smith said in an interview with DeviceTalks Editorial Director Tom Salemi. (continued on page 148)

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"Semiconductors has been a real challenge this last year and a half," he said. "There's not a clear picture as you go forward about the implications of semiconductors. (There's) a lot of work underway to bring more capacity to market, but also a lot of consumption, a lot of demand against that scarce commodity. So there's a lot of work that's going to be done. And I think it's going to linger with us for a while."

Facing pressure in late May from analysts after supply chain issues got out of control, Medtronic CEO Geoff Martha assured them that Smith is driving ongoing improvement.

"We're well down the path of remaking our global ops and supply chain to provide that resiliency that we just haven't had," Martha said. "And we started that over a year ago, centralizing the function and building a very strong leadership team under Greg, bringing in new people from different industries, investing in all kinds of tools and technology and operating mechanisms for this. I'm confident we're going down the right path there. I'm glad that we started when we did. I wish we would have started even earlier."

#### Medtronic's strategic suppliers

Smith said Medtronic is doubling down on its base of strategic suppliers, emphasizing that this critical group of partners will only become more important in the future.

He defined a strategic supplier as "someone that can meet our quality needs, can meet the service that we require, are cost-competitive and drive continuous improvement, and then ultimately ones that we can partner with on innovation and to be able to help bring new ideas to us that we can work with to be able to even provide better products."

Part of the process will be a strategic search for supply chain gaps and issues where new suppliers can help while replacing suppliers that aren't performing to Medtronic's satisfaction.

"We're encouraged by the potential partners that exist out there. ... There are a lot of suppliers that have weathered this storm incredibly well. There have been others that have been impacted significantly," Smith said. "We want to make sure that we have the right partners that can weather the storms and to make sure that we're thinking ahead of storms and ensuring that we have the right proactive relationships, but meeting those tenets that I described."

That means "much more scrutiny on the choices that we make around supply base," Smith said.

"It's to evaluate the suppliers we have and as we look to our future, to make sure that we are putting forth the diligence of ensuring that the folks that we partner with are the ones that are most strategically

aligned. We're important to them. They're important to us, and they can meet those parameters that we described."

Asked by Salemi whether Medtronic's list of suppliers would be longer or shorter two years from now, Smith said he anticipates it will be shorter.


"We want to partner with the right supply base, (and) we have the opportunity to align with strategic suppliers. That'll probably be less than what we have today," he said.

#### Medtronic's supply chain opportunity

Smith identified the medtech industry's high inventory levels as one of the biggest opportunities for Medtronic.

"It's certainly a focus for us to be much better in our integrated business planning so that we've got more accurate signals of demand, and then we can run the supply requirements across our network to make sure that we are able to service at a high level while reducing working capital and reducing inventory levels," Smith said. "In our industry, our levels of inventory are somewhat high. Others do much more complex business with a lot less inventory, but it comes down to them mastering and ... understanding what the customer needs when they're going to need it, and to be able to connect all their planning and their execution systems to be able to deliver against that. Those are big opportunities that we see ahead for Medtronic."

Smith is working with a more complicated supply chain than at Walmart or Goodyear, with so many parts and components coming from a wide variety of suppliers to make just a single medical device. But "it really comes down to right product, right place, right time," he said.

"The better you service your customer, the better you get the repeat on the business and build your brand," Smith said. "And that's what everybody seeks to do. There are nuances clearly. You know, regulated industries, non-regulated industries, just different ways of going to market, different points of distribution, different nodes, you know, different customer base. So I'd say every industry's a little bit different, but at the end of the day, the fundamentals are there yet you care greatly about your people and you want to make sure that they're working in a safe environment. You hold the quality to the highest degree, working on servicing the customer and doing it in a very effective and a very efficient way." 



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Greg Smith explains how Medtronic is working with suppliers to forge a stronger supply chain

with  
**Greg Smith**  
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# SHOW PREVIEW

## Join us at DeviceTalks West, the World's Fair of Medtech

October's DeviceTalks West conference is focused on the future.



**Tom Salemi**  
DeviceTalks Editorial  
Director

**T**he best-seller "Devil in the White City" may have darkened the perception of world's fairs, but these international convocations have long presented visitors with an optimistic and hopeful view of the future, thanks in no small part to new technology. (The next one is scheduled for 2025 in Osaka, Japan, by the way.)

I like to think we'll be following similar guidelines at the upcoming DeviceTalks West conference, which will be held on Oct. 19–20 at the Santa Clara Convention Center.

This event will bring together executives from **Abbott, Boston Scientific, Edwards Lifesciences, Intuitive, Johnson & Johnson, Medtronic, Outset Medical, Penumbra, Shockwave, Zimmer Biomet** and many others.

We built this year's DeviceTalks West conference with the future in mind.

The medical device industry is crossing the chasm into novel technologies that will accelerate new product development and manufacturing. Let's walk through some of those opportunities we'll address at the conference.

### Artificial intelligence

AI promises to turn medical devices into an even more essential part of patient care, delivering vital data to clinicians and assessing treatment for patients. Over those two days, we'll have several conversations centered around AI.

Medical device makers working to understand the power of AI will learn how Boston Scientific and **IBM Research** used custom AI and a cloud-based platform to discover new biomarkers that do a more effective job of assessing pain.

Medtronic will reveal the role AI plays in its gastrointestinal tools.

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Finally, in a presentation from **Goodwin Procter** attorneys, entrepreneurs entering the space will get essential legal advice on protecting their AI-related intellectual property.

### Bioelectronic medicine

For well over a decade, medical technology companies have been developing devices using electricity as a therapeutic. Now that the sector has matured, startup founders and device executives need to understand

how large OEMs like Medtronic will compete in this market.

In a keynote presentation, Brett Wall, Medtronic executive vice president and neuroscience president, will explain how the company sees bioelectronic medicine impacting the future of medical devices.

### Surgical robotics

Intuitive literally invented the surgical robotics market. But this isn't stemming the tide of companies large and small looking to grab their share in this growing industry.

How is Intuitive responding? In a keynote interview, Intuitive CEO Gary Guthart will explain how Intuitive is using its expertise, significant R&D capabilities and its financial might to protect its top spot against all comers.

### New care settings

The pandemic advanced this movement by half a decade or more. Companies like Outset Medical have been working hard toward developing devices that allow patients to receive life-saving care outside of traditional clinical settings.

CEO Leslie Trigg, in a keynote interview, will explain how Outset successfully rode this wave — and avoided some potential wipeouts — toward commercial success of its Tablo dialysis system.

Outset engineers will also be on hand to share their expertise in creating complex devices that can be used at home.

### Smart sensors

Zimmer Biomet paved the way to incorporate data-collecting sensors into its orthopedic implants through a groundbreaking partnership with **Canary Medical**.

In 2021, Zimmer Biomet obtained FDA approval for the Persona IQ, a combination of Zimmer's knee implant with Canary Medical's sensor technology that measures and determines range of motion, step count, walking speed and other gait metrics.

In this discussion, we'll hear from principals at both companies about how the collaboration started and, more importantly, where this use of cutting-edge sensor technology can take the orthopedic implant market.

### Using patient data

**Evidation** has developed a data-collection platform capable of tracking patient information through wearables.

Evidation helped Moderna conduct a digitally enabled, at-home study that examined COVID-19 antibody responses. Results of the study released last month suggested individuals who received Moderna vaccinations and boosters had more durable antibody levels than those receiving Pfizer shots.

In the opening keynote interview, co-CEO Deborah Kilpatrick will explain how Evidation is helping companies collect and make sense of patient data that could aid in device design, clinical testing and performance in value-based environments.

### Doctor's orders

Medical device makers building tools and devices for hospitals need an even stronger understanding of how technology can find a home in patient care. Physicians increasingly are looking toward data and tools to improve efficiency and performance.

In a panel concluding the first day of the conference, clinical leaders from Abbott, Boston Scientific and Edwards Lifesciences will share their perspectives on how medical device developers can help hospitals innovate their way out of current challenges.

### Digital device development tools

Device makers will have the opportunity to learn about digital technologies that can accelerate new device development.

Attendees will explore how combining virtual technologies, analytics and AI can lead to the development of a virtual twin, a predictive model that can shed light on how medical devices will function.

In addition to expediting development, the virtual tools offered by **Dassault Systèmes** can also be used to develop virtual sites for clinical trials, making it faster and less expensive to secure regulatory approval.

We'll be talking about headwinds such as the supply chain crisis, as well as global IP protection, the future of R&D and pressures from the FDA.

We'll also hear from outstanding startup leaders like Kelly Ashfield about building startups that last. Ashfield is COO of **Materna Medical**, which just closed on a \$22 million Series B round.

Attendees walking our exhibit floor won't see futuristic structures or towering monuments. But what they will see — and hear — over those two days will give them the knowledge and tools to build a more promising future for medtech. **M**



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