DEVICE TAX REPEALED!
TO OUR MEMBERS

As anyone who works in the medical technology industry knows all too well, there are numerous hurdles that innovators must overcome as they seek to bring life-saving and life changing cures and therapies to patients. Through regulatory and reimbursement challenges, to protecting one’s intellectual property rights, there is no easy path to success. Still, with full appreciation of the road before them, hundreds of thousands of Americans dedicate their lives each day to navigate this maze, all in the hopes of improving patient care, alleviating human suffering, and bettering the quality of life for patients and their families. In that spirit, our collective work over the years has changed the lives of countless individuals and families. Our innovations continue to save lives, lower the total cost of care, and provide hope to the world for a better, healthier tomorrow.

It is no surprise that our industry is made up of so many passionate and talented individuals, as we all know how much is on the line and what we are ultimately working towards. Similarly, in order to remove some of these hurdles and to improve the environment for innovation, it is critical that we remain committed to enact policies and legislation that support our ecosystem. The policy arena is also fraught with frustrations, disappointments and near-misses, but we remain undeterred in working to establish reasonable and predictable frameworks of rules and regulations for our industry. Whether in the laboratory or the halls of Congress, the journey is well worth it!

There is perhaps no better example of our industry’s determination in the policy arena than the path to fully and permanently repeal the medical device excise tax. While it took almost ten years to achieve this legislative milestone, it is a testament to how consistent and passionate advocacy can result in bipartisan legislating to improve our ecosystem in support of further innovation.

It is important that we use this success as a springboard to the numerous other policy issues MDMA and other stakeholders are focused on. The MDUFA V reauthorization process begins this year, and as we have seen in the past, there are numerous interest groups and parties who are seeking to undermine what is the absolute gold standard in establishing the safety and efficacy of medical devices. It was not that long ago when the regulatory process lacked predictability and transparency, which was punishing patient care and innovation. While the FDA has made major improvements, we must remain vigilant to ensure that we do not take any steps backwards.

Also, in the many years that we have worked in this industry, there has perhaps never been a more frustrating period to seek fair and reasonable reimbursement for medical technologies. As companies increasingly face the “valley of death” where they have no reimbursement despite successfully achieving FDA approval or clearance, MDMA is leading the efforts to expedite patient and provider access to medical devices.
All these issues come on the heels of transformative changes in many other areas impacting medical technology innovation, including digital health, cybersecurity, international developments, compliance and much more. While there is no shortage of challenges confronting us, MDMA remains focused and committed on being the voice for the innovative and entrepreneurial sector of our industry.

If you are not a member of MDMA, we strongly encourage you to join this energetic and passionate organization. Your involvement in MDMA’s advocacy, education, and outreach efforts bolster our collective voice and improve our ability to continue advancing policies that support the important work you are doing on behalf of patients. As we have seen over time, presidential election years are very tumultuous, both for Members of Congress and those seeking to join their ranks. The debate over additional reforms to the health care delivery system and other policies remain at the forefront of Americans and policymakers, and this serves a reminder to share the value of medical technology in improving outcomes, access and the affordability of care.

Working together, we will make sure that the United States continues to lead the world in the important endeavor of saving and changing lives.

Sincerely,

Jeff McCaulley
Chief Executive Officer
Avalign Technologies, Inc.
Chairman, MDMA

Mark Leahey
President & CEO, MDMA
Medical Device Tax Repeal Roadmap

When the device tax was first proposed in 2009, MDMA was the only national medical device trade association that consistently opposed this tax on innovation. We ran advertisements, sent letters to Congress and organized a small but dedicated coalition to fight the tax during the Affordable Care Act (ACA) debate. While many thought it was a fool’s errand, thanks to the engagement and the support of a broad coalition of stakeholders that grew over the years, medical technology innovators no longer face the threat of diverting precious resources to pay the medical device tax!

Innovation isn’t all that suffers from a tax on medical devices. The proposed tax on medical device companies will be felt by everyone. The majority of these companies are small businesses that work tirelessly to provide remedies, seek cures and put patients first. But this tax will make it harder for all companies to compete and likely stifle innovations and technologies of the future. Americans deserve the best care we can provide them, not this tax.

As the ACA was being debated, MDMA ran the only print and radio advertisements arguing against the medical device tax.

Before final passage, MDMA argued that the device tax would be devastating to innovation and jobs.

MDMA conducted the first industry survey to gauge the impact of the tax, sharing with Congress and the media, and mobilized the industry to push for House passage of repeal.

MDMA-led coalition letter of over 1,000 signatories urging a repeal delivered to Congress, and placed dozens of op-eds from our members on the issue.

Members of MDMA’s Board of Directors testified in Congress about the impact the device tax would have, and conducted “fly-ins” that supported a Senate vote where 79 Members voted to support repeal.

Collective efforts resulted in the first two-year suspension of the device tax.

Ongoing outreach led to an additional two-year suspension of the tax.

Built growing bipartisan support and partnered with allies who were seeking to repeal other ACA taxes. A ten year journey is completed with a FULL and PERMANENT repeal of the medical device tax.
Federal Policy Highlights

**MEDICAL DEVICE TAX**

2019 marked the end of our ten year journey to repeal the medical device tax. As the year began, MDMA and our members successfully worked to increase bipartisan support for the House and Senate repeal bills. The numerous Congressional fly-ins, grassroots activities, Op-Eds, social media outreach and much more all built positive momentum. When the “Cadillac Tax” repeal bill passed the House in July, MDMA understood the importance of leveraging the strong bipartisan vote with our repeal efforts. We conducted joint Capitol Hill meetings with coalitions seeking to repeal other ACA taxes in the fall which led to our ultimate success in December.

**FDA**

2019 continued with efforts to fundamentally change the way medical devices are regulated in the United States. While various stakeholders sought to undermine what is the gold standard of reviewing medical technologies, MDMA was vigilant in sharing the powerful track record of the FDA’s pre and post-market processes, and ensuring that the public and policy makers had the complete picture.

MDMA communicated directly with Members of Congress and committees of jurisdiction to share the facts about putting recalls and adverse events in proper context, and highlighted the industry’s tremendous safety record over decades of device approvals and clearances. While antagonists were focused on a half dozen examples over two decades, MDMA was reminding policy makers that there are nearly 200,000 medical devices currently on the market in the United States that are improving patient care for hundreds of millions of Americans.

The MDUFA reauthorization process will begin in 2020, and MDMA will continue to be the voice of the innovative and entrepreneurial sector of our industry during these negotiations. We will remain focused on making the premarket review process more consistent, transparent and reasonable. In addition, we will seek administrative reforms that make the process more efficient for FDA and innovators, not requiring a huge infusion of new staff.

Ethylene oxide (EtO) sterilization of medical devices was an issue that rose to the forefront of MDMA’s policy priorities in 2019. Various media outlets, state and federal legislators and regulators questioned the role of EtO as a sterilization modality for medical devices. MDMA engaged state legislators, Members of Congress, the Food and Drug Administration (FDA), Environmental Protection Agency (EPA) and industry representatives for balanced discussions on the appropriateness of EtO for the sterilization of medical devices as well as the development of alternative and more sustainable protocols. In November 2019, our efforts culminated with a presentation at an FDA advisory committee meeting where we reiterated support of safe and effective use of EtO where no alternatives exist and raised awareness to the severe impacts a ban on EtO would have on patient access and our country’s critical medical products supply chains. We also expressed our commitment to working in good faith with regulators to find and validate alternatives over appropriate timelines. This work will continue in 2020, with an emphasis on encouraging collaboration between FDA and EPA.
REIMBURSEMENT

Narrowing the gap between the regulatory and reimbursement decisions for innovative technologies remains a top priority for MDMA, and we focused on working directly with HHS, CMS, Congress and private payors to advance much-needed changes to the processes.

CMS Administrator Seema Verma addressed MDMA’s Annual Meeting in 2019 and highlighted the importance of expediting patient and physician access to the cures and therapies developed by our industry. Administrator Verma also unveiled a number of new policies designed to spur the use of new medical technologies. These included more frequent issuing of HCPCS codes, more transparency from MACs related to local coverage decisions and a streamlined process for FDA designated “breakthrough” devices to qualify for New Technology Add-on Payments (NTAP) under the IPPS and Pass-Through Payments (PTP) in the OPPS. CMS also established new technology add-on payments related to ESRD.

While these payment reforms are welcomed, true patient access will not be realized unless they are accompanied by coverage reforms that allow for faster coverage for innovative medical technologies. MDMA has been advocating for transitional coverage for innovative medical technologies for many years and we were encouraged that the Administration was working on a proposed rule that would accelerate coverage for novel technologies. While the rule was not published in 2019, we remain confident that it will be released for comment and finalized in 2020.

Beyond our work with CMS, MDMA remained actively engaged with our members and private payers to explore ways to make the coverage process more transparent and predictable. This included developing a “best practices” document that incorporates elements recognized globally to generate and review evidence for the purpose of coverage decisions.

Finally, MDMA continued our ongoing work with the American Medical Association (AMA) to improve the CPT process. Concerns around the lack of clarity of what constitutes “widespread use” and the CPT panel converting Cat I applications to Cat III without the applicants consent were elevated to AMA leadership and we continue to seek reforms. MDMA also has pushed for the AMA to eliminate the US data requirements for medical technologies approved by the AMA with only OUS data.

MDMA remains committed to working with HHS, CMS, Congress and all stakeholders to help improve the reimbursement landscape so that patients throughout the United States get timely access to medical technology innovation.

PAIN MANAGEMENT

In 2019, MDMA maintained our commitment to advocating for greater patient access to opioid sparing medical devices and raising awareness among patients and providers to the appropriate role these technologies can – and should – play in helping patients manage their acute and chronic pain. 2019 marked the first full year of the MDMA Pain working group, and members took advantage of a number of educational and advocacy activities. Some of those activities included:

Teleconferences & Information Sharing – Company representatives spoke directly with other working group members on challenges and opportunities facing their companies as well as nearly weekly email communications on important pain policy topics and unique opportunities to weigh in with various public and private stakeholders.

Legislative Oversight & Advocacy – Members provided feedback on oversight and implementation of key provisions included in pain and opioid legislation and weighed in directly with their Members of Congress to communicate the value of their technology to patients suffering from pain.

Letter Writing & Comment Drafting – Working group members shaped positions taken on pain policy in dozens of letters and comments to Members of Congress and Congressional committees, as well as to HHS, CMS, FDA, private insurance companies and more.

We will continue our passionate advocacy in the coming years which will focus on access and awareness for opioid sparing medical devices at the state and federal level. We encourage you to get involved in MDMA’s Pain Working group today!
MDMA provides numerous programs, events, webinars, working groups and more where medical technology innovators learn the latest insights and strategies, share best-practices and network with leaders from across the country.
**CYBERSECURITY**

MDMA’s cybersecurity working group serves as a key channel to disseminate timely and relevant information to medtech innovators as they institute and strengthen their cybersecurity functions. As cyber issues become more and more integral to the design of innovative technologies and integrated into supply chains and other critical core operations, MDMA has established a partnership with the Healthcare & Public Health Sector Coordinating Council (HSCC). The HSCC is a public-private organization focused on the development and dissemination of sector-wide recommendations and guidance to help facilitate sector-wide mitigation, response and resilience to cybersecurity threats. MDMA and our members also participate in the Joint Cybersecurity Working Group and various task groups.

Significant work products from these task groups completed in 2019 include:

- The Joint Security Plan (JSP)
- Health Industry Cybersecurity – Matrix of Information Sharing Organizations
- Healthcare Industry Cybersecurity Workforce Guide
- Health Industry Cybersecurity Practices

In addition, members were also able to participate in teleconferences and webinars with various industry experts to receive updates on legislative, legal and commercial activities that could impact their companies.

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**PATENTS**

MDMA has long recognized how important it is for our members and the industry to have a strong system in place that protects patent rights, enabling innovators to attract investments to fund new cures and therapies, while fighting against any infringement in the United States or abroad.

In 2019, MDMA continued its close work with PhRMA, BIO, the National Venture Capital Association and others to raise awareness with Members of Congress about the importance of patents for innovation. This broad coalition of innovators has come together to support the “Stronger Patents Act” and legislation to reform Section 101 of the Patent Act to strengthen the patent system.

While Congress did not take any votes on substantive patent legislation in 2019, the Senate Judiciary Subcommittee on Intellectual Property held three days of hearings on the state of patent eligibility. In addition, the USPTO revised guidance to clarify the patent eligibility tests used by their office.

MDMA will continue to be the lead voice for medical technology innovators in securing and strengthening intellectual property rights.
INTERNATIONAL

MDMA continued to provide comprehensive analysis and advocacy on international issues to keep our members up to date on the latest issues, trends and other activities taking place throughout the world that would impact access to medical technology. MDMA does so through numerous means including newsletters, calls with international experts, trips to strategic markets and much more.

2019 was a busy year in numerous markets, with many of these developments ongoing through 2020 as well. Some of the issues MDMA worked on and continue to engage on include:

- **EU-MDR (Medical Device Regulation)**
  MDMA was active in working with the EU as they established their new MDR. The transition period for the new MDR from the existing MDD (Medical Device Directive) will end on May 26, 2020. Over the year less than a dozen Notified Bodies were created that would be able to certify products to the new MDR, with only 8 more hoping to be named in the first quarter of 2020. Lower risk and quasi-medical devices are being given more time to be certified to the MDR. Quality inspections are also likely to be focused on higher-risk products. CE Marks obtained under the MDD or recertified to the MDR are likely to be accepted longer than anticipated as sufficient especially if bottlenecks begin to occur in the supply chain. Ultimately, individual EU Member states can decide what to accept for use in their particular territory if unanticipated or severe disruptions begin to occur.

- **UK-EU and U.S.-EU Trade Agreements**
  As a result of BREXIT activity throughout 2019, the UK and the EU will negotiate a trade agreement over the coming months between the two trading blocs. The agreement must address the rules governing the movement of people, goods and services. It will also address issues such as full or partial mutual recognition of regulatory rules governing medical devices. UK authorities have said that a CE mark will be viewed as sufficient in the UK with no additional regulations required.

- **USMCA**
  The proposed new US-Mexico-Canada Agreement was finalized over the course of 2019, and signed into law in each of the three participating countries in January 2020. The agreement contains improvements for the medtech sector including greater regulatory transparency, greater mutual recognition and harmonization of regulation efforts and a consultative mechanism that can be used if there are problems or disputes over access or treatment of U.S. medtech firms. The USMCA also contains improved Intellectual Property (IP) protections and safeguards.

Finally, MDMA also worked with numerous officials in China and India as these two trading partners continued to spar with the United States over imports and exports, and we will continue to advocate for innovative medical technology manufacturers as trade deals are negotiated in these international markets.

LEGAL AND COMPLIANCE

MDMA continued to work closely with our members to understand their compliance priorities and keep them up to date on enforcement trends and regulatory developments, as well as industry “best practices” to help companies maintain a robust compliance program. We also worked with our members to update MDMA’s Code of Conduct to address evolving ethical norms and enforcement trends.

Legal and Compliance activities in 2019 included:

- Hosted regular calls to keep members up-to-date on important legal and compliance developments
- Provided Compliance Toolkit Resources, including transparency reporting and compliance program materials
- Conducted three in-person Compliance Working Group roundtables to discuss emerging trends and share best practices
- Adoption of the “Revised MDMA Code of Conduct on Interactions with Healthcare Providers”
2019 Programs

2019 FDA FORUM • MARCH 14-15, 2019 • PALO ALTO, CA
MDMA hosted over 180 attendees and hosted TEN FDA officials, in person, at our 2019 FDA Forum in Palo Alto. This incredible turnout made for an exceptional event which allowed industry leaders to discuss critical issues affecting the medical technology industry. Topics included navigating the 510k program, explaining the De Novo program, PMA review considerations, key issues impacting IVD’s, digital health and much more! Attendees had numerous opportunities to pose questions directly to FDA officials and expert panels which led to insightful and interactive sessions.

2019 ANNUAL MEETING • MAY 1-3, 2019 • WASHINGTON, DC
MDMA hosted another successful Annual Meeting in Washington, DC where over 150 attendees were able to network and hear from top policy makers, as well as to get the latest insights from some of the most dynamic executives in our industry. Keynotes included an address from CMS Administrator Seema Verma, an FDA address from Amy Abernathy, the Principal Deputy Commissioner of FDA, an interactive “Town Hall Meeting” with CDRH Director Jeff Shuren and an update from Tamara Syrek Jensen, the Director of the Coverage and Analysis Group at CMS.

Other popular panels included a NESTcc update, a discussion of EU Medical Device Regulation and BREXIT and much more. Additionally, we examined the impact of medical technology on patient care and heard powerful stories of how the industry is rising to the challenges that patients and providers face today.
12TH ANNUAL MEDICAL TECHNOLOGY EXECUTIVE FORUM
SEPTEMBER 13, 2019 • PALO ALTO, CA
MDMA hosted over 150 CEOs and senior executives at our Annual Medical Technology Executive Forum in Palo Alto, CA. Participants gathered to hear from a compelling lineup of speakers from industry, FDA, and more on challenges and opportunities facing our industry.

CDRH Director Jeff Shuren answered member questions and provided updates on numerous FDA reforms during the CDRH Update session. Additionally, during the Lessons Learned from Industry Leaders session, Dr. Thomas Fogarty, MD, Founder & Director of the Fogarty Institute for Innovation and Mir Imran, Chairman & Founder of InCube Labs, discussed where they see the industry moving in the 21st Century, and how today’s entrepreneurs can overcome the headwinds we all confront and address the pressing needs facing patient care.

22ND ANNUAL COVERAGE, REIMBURSEMENT & HEALTH POLICY CONFERENCE
NOVEMBER 13-14, 2019 • WASHINGTON, DC
MDMA held another successful Coverage, Reimbursement & Health Policy Conference in Washington, DC. Over 100 attendees had the unique opportunity to ask questions from some of the leading experts from the Centers for Medicare and Medicaid Services (CMS). CMS is currently examining numerous initiatives to improve outcomes and promote value-based health care, and the CMS Director of the Coverage and Analysis Group, Tamara Syrek Jensen, shared how the agency is working to improve patient and provider access to medical technologies.

Additionally, the current CMS Ombudsman, James Bailey, presented about the role the Ombudsman plays to address coding, coverage and payment issues and the Senior Advisor to HHS Secretary, William Brady, enlightened attendees about what priorities the agency has for 2019 and beyond.
THE VALUE OF MDMA

**Access to resources** that inform your regulatory, reimbursement, market access & other strategies.

**Leverage a knowledgable & responsive organization** with a network to find solutions to the inevitable barriers & roadblocks innovative companies face.

**Establish or enhance engagement** with your Members of Congress & key policy makers in Washington.

**Real time access to policy issues** impacting the industry.

**Opportunities to shape policies** that promote patient access & innovation.

“Whether the challenges require advocacy in Congress, FDA or any agency that can impact the med tech ecosystem, MDMA is the leading voice for innovative and entrepreneurial medical device companies. Their efforts on our behalf will help ensure that the 21st century will be just as dynamic for innovation as was the last.”

— Josh Makower, Founder & Executive Chairman, Exploramed and General Partner, NEA

**Founded by a handful of MedTech innovators in 1992,** MDMA has become the voice representing the industry, with a proven track record of success, helping companies navigate Capitol Hill, federal regulators & more.
# MDMA Board of Directors

The MDMA Board of Directors represents a broad cross section of our membership and the medical device industry. Voting members include:

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<thead>
<tr>
<th>Name</th>
<th>Title/Role</th>
<th>Company/Institution</th>
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<tbody>
<tr>
<td>Jeff McCaulley</td>
<td>Chief Executive Officer</td>
<td>MDMA Chairman, Avalign Technologies</td>
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<tr>
<td>Paul LaViolette</td>
<td>Immediate Past MDMA Chairman</td>
<td>SV Health Investors</td>
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<tr>
<td>Wil Boren</td>
<td>President, Advanced Surgery</td>
<td>Baxter Healthcare Corporation</td>
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<td>Paul Buckman</td>
<td>President, North America</td>
<td>LivaNova, PLC</td>
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<td>Michael Carrel</td>
<td>President &amp; CEO</td>
<td>AtriCure</td>
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<td>Joe Damico</td>
<td>Founding Partner &amp; Senior Advisor</td>
<td>RoundTable Healthcare Partners</td>
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<tr>
<td>Ryan Drant</td>
<td>Founder and Managing Partner</td>
<td>Questa Capital</td>
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<td>Greg Fredde</td>
<td>EVP Business Development</td>
<td>Merit Medical Systems, Inc.</td>
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<td>Doug Godshall</td>
<td>President &amp; CEO</td>
<td>Shockwave Medical, Inc.</td>
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<td>Scott Huennekens</td>
<td>Executive Chairman</td>
<td>Acutus Medical</td>
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<td>Walt Humann</td>
<td>President &amp; CEO</td>
<td>OsteoMed, LLC</td>
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<td>Jennifer Kerr</td>
<td>President, Cook Research Incorporated</td>
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<td>Joe Kiani</td>
<td>Chairman &amp; CEO</td>
<td>Masimo Corporation</td>
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<td>Justin Klein</td>
<td>Co-Founder and Managing Partner</td>
<td>Vensana Capital</td>
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<td>George Leondis</td>
<td>President &amp; CEO</td>
<td>Argon Medical Devices, Inc.</td>
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<td>Matt Link</td>
<td>President</td>
<td>NuVasive, Inc.</td>
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<td>Pat Mackin</td>
<td>President &amp; Chairman</td>
<td>CryoLife, Inc.</td>
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<td>James Mazzo</td>
<td>Global President Ophthalmic Devices</td>
<td>Carl Zeiss Meditec Inc.</td>
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<td>J. Casey McGlynn</td>
<td>Partner</td>
<td>Wilson Sonsini Goodrich &amp; Rosati</td>
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<td>Michael Onuscheck</td>
<td>President, Global Business &amp; Innovation</td>
<td>Alcon Laboratories, Inc.</td>
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<td>Rick Packer</td>
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<td>Robert Perry</td>
<td>SVP, Device R&amp;D</td>
<td>Allergan plc</td>
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<td>David Pierce</td>
<td>EVP &amp; President MedSurg</td>
<td>Boston Scientific</td>
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<td>Jason Richey</td>
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<td>Walt Rosebrough</td>
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<td>Benson Smith</td>
<td>Chairman</td>
<td>Teleflex Incorporated</td>
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<td>Spencer Stiles</td>
<td>Group President, Orthopaedics &amp; Spine</td>
<td>Stryker Corporation</td>
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To learn more...

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