

AMDD *Vol.34*

NEWSLETTER

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Striving to Provide Optimal Healthcare in Japan

On behalf of the American Medical Devices and Diagnostics Manufacturers' Association (AMDD), I would like to extend my New Year's greetings to each of you for 2021.

These are undoubtedly challenging times with COVID-19 touching all of our lives in some way. I would like to offer my heartfelt sympathy to all those who have suffered directly and indirectly from the virus. I would like to also express my sincere respect and gratitude to the medical practitioners that continue to risk their own safety in order to treat patients, and all those struggling as we continue to fight the spread of infections.

AMDD's Role Brought into Sharper Focus

Reflecting on the past year, COVID-19 seemingly spread across the world in the blink of an eye. As infection numbers rose in every continent, remarkable efforts were made in every country and region to prevent and minimize the spread.

Of course, prevention is just one step in a much larger global undertaking. 2020 was also the year when governments and the public became acutely aware of the challenges facing healthcare systems and the importance of public health. Japan was no exception. Having long understood the academic importance of healthcare, AMDD's member companies quickly gained a deeper awareness of the practical role we play, including the enormity and significance of the social responsibility we hold for ensuring a stable supply of medical devices and in-vitro diagnostics (IVDs), developing personnel, and providing the information necessary to support these.

Now is the Time for Healthcare Innovation

The pandemic is not something one country alone can deal with. The international frameworks that make it possible to quickly and efficiently leverage global resources are extremely important. Maintaining the stable production and supply of goods that support healthcare during both emergencies and ordinary times, and building a system that ensures optimal healthcare for all patients in Japan has arisen as a critical issue.

It was with this in mind that AMDD submitted a proposal last year to the Ministry of Health, Labour, and Welfare with a goal of setting reasonable healthcare costs and creating value-based healthcare that improves outcomes for anyone receiving treatment. The proposal

consists of five key aims: (1) to maintain an environment in which medical facilities can comprehensively propose options to patients for high-quality medical technology, (2) to create structures that make it possible for medical institutions to provide high-quality medical technology, (3) to evaluate outcomes, (4) to flexibly utilize diverse evidence, and (5) to revise the framework for evaluating technology.

Even times of crisis have the power to accelerate innovation. There has never been a better time to introduce cutting-edge technology and for Japan to assume its place at the forefront of global healthcare innovation through teamwork between companies and groups beyond the limitations of the current framework. AMDD has a long record of working toward appropriately evaluating and reflecting the value of innovative medical technology and achieving a healthcare system that makes society healthier, and we are strengthening our resolve to continue these efforts.

Office Restructure to Encourage Innovation

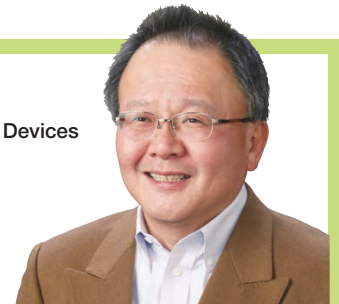
Taking the principles of our value-based healthcare proposal and applying them to our own organization, we implemented an office restructure in January this year. Aligned with our slogan of "Enabling a healthier Japan," these changes will make it easier to put proposals and new thinking first. AMDD aims to contribute to healthcare in Japan by proactively proposing policies, while cooperating with the Japanese government, related industry groups, and academic societies, and continuing to coordinate with the U.S. government and the Advanced Medical Technology Association (AdvaMed), headquartered in the U.S.

We thank you for your continued support and guidance this year, as together we strive toward a safer, healthier 2021 and ultimately providing optimal healthcare in Japan.

Kazuya Ogawa

Chairperson, American Medical Devices and Diagnostics Manufacturers' Association (AMDD)

Chairman and President
Zimmer Biomet G.K.



All opinions in the newsletter are the views of the authors and do not represent the views of AMDD or its activities.

Expert Interview:

The Role of Medical Manufacturers at Medical Facilities

Advanced technology is required in order to use many medical devices such as intracardiac catheters and pacemakers. Clinical use of such devices in actual patients requires extensive training to master techniques, while those providing the training must have deep knowledge of treatment options.

It's within this context that we met online with Dr. Kyoko Soejima (Professor and Chief of Cardiology, Kyorin University Hospital) for this interview to discuss the roles and significance of medical device manufacturers, the support manufacturers are expected to provide even during the COVID-19 crisis when face-to-face contact is limited, and other issues that should be resolved.

Manufacturers and Physicians Improving Healthcare Together as "One Team"

Q. What role do medical device manufacturers normally play in medical facilities?

Dr. Soejima: Manufacturers usually provide training when a new medical device is introduced, but it helps if they can also be available to give advice should problems occur, such as malfunctions during treatment. If there are multiple treatment options, I am grateful when manufacturers can give me their professional opinion based on specialist knowledge.

Q. What has been most difficult during the COVID-19 crisis, and has this impacted your expectations of manufacturers at all?

Dr. Soejima: In order to prevent infections at medical facilities, in-person activities have been regulated, and face-to-face support from manufacturers has been limited. There may have been cases when this caused a hindrance in hospitals struggling with insufficient personnel.

However, experiencing the COVID-19 crisis has allowed me to better understand the different ways in which manufacturers can support. With in-person activities restricted, I have found ways to access detailed advice and efficient support even remotely. In the past, it wasn't uncommon for a manufacturer staff member to spend all day with the hospital, but now I don't think that's necessary. Having staff members from several manufacturers constantly on standby in hospital hallways or waiting in their cars for a long time probably affects their motivation. I'm also against that from the perspective of achieving sustainable healthcare that doesn't waste personnel or add unnecessary personnel costs by cutting that which can. I have always liked healthcare setups like the U.S. where the manufacturers are on equal ground with the physicians. I would like to improve awareness and create an environment where both manufacturers and physicians can deal with patients as one team, and the manufacturer's side can also focus on developing their personnel. COVID-19 has simply made me feel that even more strongly now.

Q. Please tell us more of what you mean by the concept of "one team"?

Dr. Soejima: Compared to the U.S., people in Japan tend to be hesitant when talking to physicians, and there is a culture of not speaking up. Manufacturers share the same goal as physicians do - to achieve the best treatment for patients. I want manufacturers to be able to speak up without hesitating as an equal. For that to happen, I would also like manufacturers to ensure they have a thorough knowledge of our devices and systems, so that we can rely on them. So when I say "one team," I'm imagining taking pride and joy in the areas we are responsible for and being able to share a sense of unity that we are doing our best for the patients. I think it's important to have an awareness of and take pride in healthcare in which our efforts and knowledge always lead to positive outcomes. This is what I tell students every day.

Q. How do you reconcile the concept of "one team" with competition between manufacturers?

Dr. Soejima: I think competition and friendly rivalry are necessary ingredients for things to progress. For example, at this hospital, we are using three types of heart mapping systems. It's useful for difficult cases as we can increase the range of treatment options by looking at information from systems made by three different companies.

Those with a thorough knowledge of their products can fairly judge the appropriateness of their use, including cases when they may not be appropriate. By addressing concerns over such devices in an objective way, they may also spot the advantages of competitor products and share that important information with team members when needed most. If everyone first and foremost has a shared goal of consistently doing what's in the best interests of patients, I don't think there will be unnecessary competition and emphasis will be placed on improving the technology through friendly rivalry.

Achieving Sustainable Healthcare through Regulatory Reforms and Faster Adoption of Remote Healthcare

Q. How has your experience of COVID-19 shaped your view of issues for the future?

Dr. Soejima: My impression is that Japan's efforts to increase the adoption of remote healthcare have been slower than Europe, North America, and China. Remote healthcare had not progressed that much in the U.S. either, but really started to gain momentum during the pandemic. Japan still needs to address the issue of patient awareness, but frustratingly the government response has been slow.

The year 2025, when baby boomers will be at least 75, is just around the corner. If we don't establish simpler, lower-cost healthcare, we can't hope for sustainable healthcare to continue at the same level we're accustomed to. This is why it's so critical that digital healthcare makes progress. The Digital Administration was created and the idea of permanently enabling online diagnosis was raised, but Japan's healthcare is lagging behind the world. I strongly hope that Japan's

government will make drastic regulatory reforms and swift progress of digital measures needed for Japan's healthcare system to survive.

Dr. Kyoko Soejima, M.D.

Professor/Chief of Cardiology, Kyorin University Hospital

Graduated from Keio University School of Medicine, Tokyo, Japan in 1989, and attended internship and residency at Keio University Hospital. Clinical electrophysiology fellowship at Brigham and Women's Hospital, U.S. and Assistant Professor there in 2003. Associate Professor at Cardiovascular Medicine of Miami University, U.S. Currently Professor and Chief of Cardiology at Kyorin University Hospital in Tokyo.



Minimizing the Indirect Impacts of COVID-19

I would like to thank all the healthcare providers who are rising to the challenge of helping COVID-19 patients. I would also like to express my respect to the staff of AMDD member companies who are facing challenges such as restrictions to our normal working practices and insufficient distribution from production countries, continue to oversee the supply chain, deliver needed devices and provide vital information to medical facilities.

Concerns over new infections continue to significantly impact the ability to deliver normal healthcare. Medical institutions and patients alike are choosing to postpone consultations, tests and scheduled surgeries. While holistic data on this issue remains hard to come by, the U.S. recently announced that treatments such as PCI by cardiovascular medicine departments have fallen by almost 50%.^{*1} Another report indicated that the pandemic has resulted in a significant reduction in surgeries on patients with serious life-threatening illnesses.^{*2} According to the Japan Surgical Society and related societies, even if things return to normal capacity, it would take almost a year to perform the surgeries canceled during April and May of last year alone. This suggests there are lives that could have been saved by normal treatments during ordinary times, and patients who have progressive diseases are being exposed to higher risks.

Everyone is hoping that the situation will return to normal as soon as possible and that treatments will return to pre-pandemic levels. In the meantime, AMDD member companies continue to provide much-needed diagnosis and treatment devices, and will take measures to prevent infection equivalent to those of medical practitioners in hospitals. It is my wish to continue working closely with all of you in supporting the healthcare system to overcome these challenges.

*1: [https://www.ajconline.org/article/S0002-9149\(20\)30565-8/fulltext](https://www.ajconline.org/article/S0002-9149(20)30565-8/fulltext)

*2: https://www.ahajournals.org/doi/abs/10.1161/circ.142.suppl_3.15347

Kosuke Kato

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Unified Efforts Ensure Stable Supply of Medical Devices

Akira Yokoyama, Chairperson, AMDD Distribution & IT Committee

AMDD has been conducting surveys with member companies to understand the pandemic's impact on operations and ways to ensure a stable supply of medical devices during this time.

Of the 34 companies that responded, 26 said that "Imports from overseas were affected," while 14 said that "The quantity arriving continues to be less than desired." However, it is clear that at this stage the overall stable supply of products has been maintained thanks to companies' considerable combined efforts, including fully utilizing global networks, and finding online solutions for handling orders and alternative ocean freight transport options.

Member Companies Step Up CSR Activities in Response to Pandemic

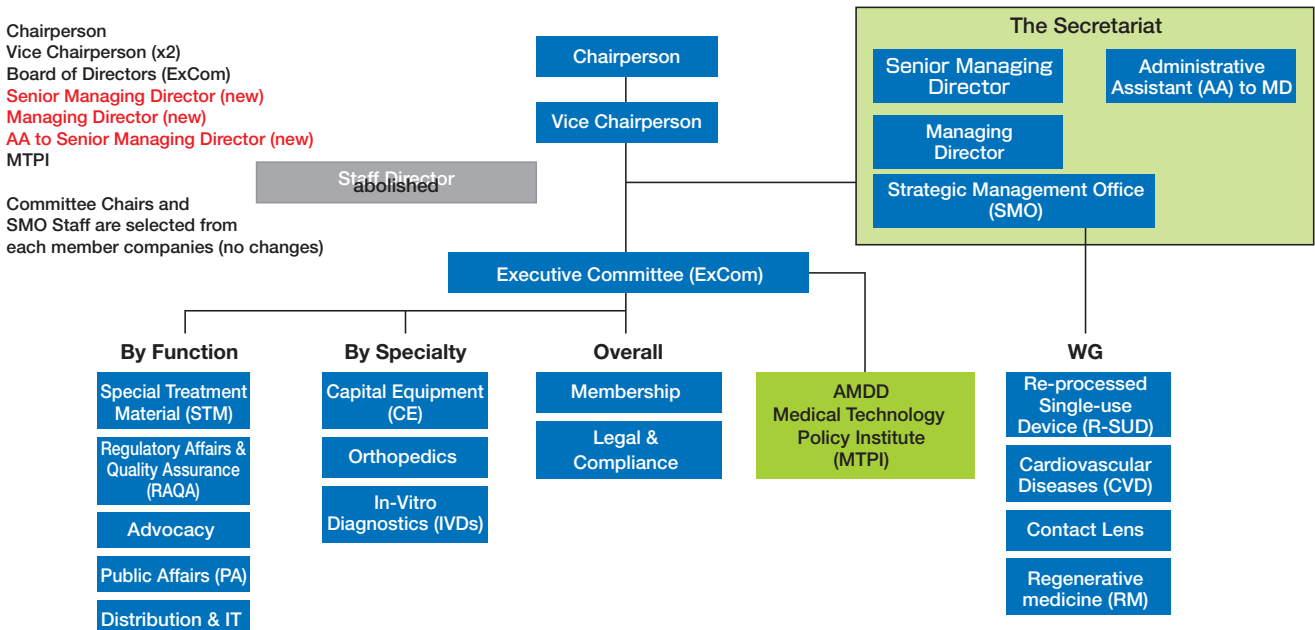
AMDD member companies are operating in an emergency situation and making every effort to ensure a stable supply of medical devices and IVDs that need to be imported from outside of Japan. And yet many member companies (particularly those with U.S. headquarters) are also actively working to develop additional products and technologies related to COVID-19 countermeasures. These include developing vaccines and drugs used in testing, as well as a remote patient monitoring system, and increasing the production of artificial respirators. Moreover, member companies that manufacture medical protective equipment are also engaging in an impressive variety of CSR initiatives, including providing PPE to medical practitioners at no charge, and providing monetary support to various groups involved in the global fight against COVID-19.

AMDD's New Office Structure Starts in January 2021

AMDD held an extraordinary general meeting on Nov. 26, 2020, during which measures were approved to partially change articles and rules of association to enable the introduction of a new office structure that began on January 1, 2021.

These revisions to the office structure aim to strengthen AMDD's activities as an industry group and improve the sustainability of the organization. Key changes include replacing the previous Staff Director position with Senior Managing Director, Managing Director, and Administrative Assistant positions established as new full-time positions. The role of the new Senior Managing Director is to assist the Chairperson and Vice-chairs, carry out office work, and lead strategic planning. Upon these changes, Shigeyuki Masukawa assumed the post of Senior Managing Director on January 1, 2021. The existing committees and active working groups remain unchanged.

[AMDD Organization with New Secretariat]



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