経済産業省

Initiatives to support the expansion of Japanese medical devices into overseas markets

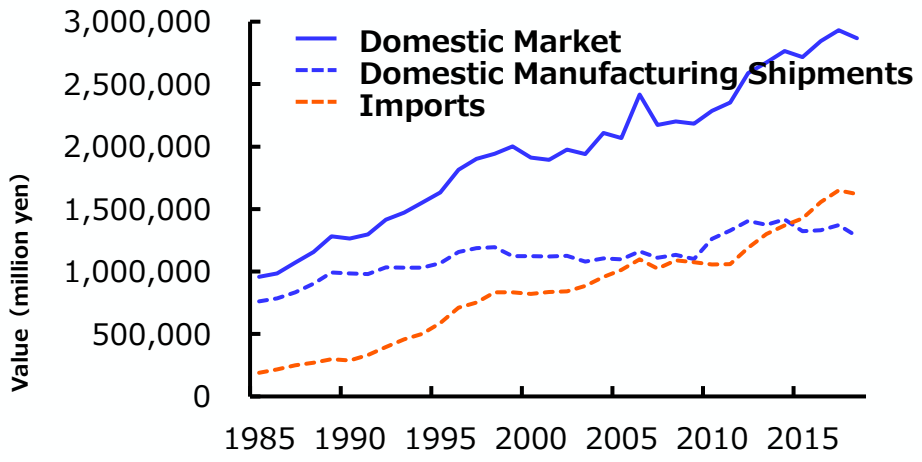
September 17, 2025

Ministry of Economy, Trade and Industry

Issues in the Japanese medical device market

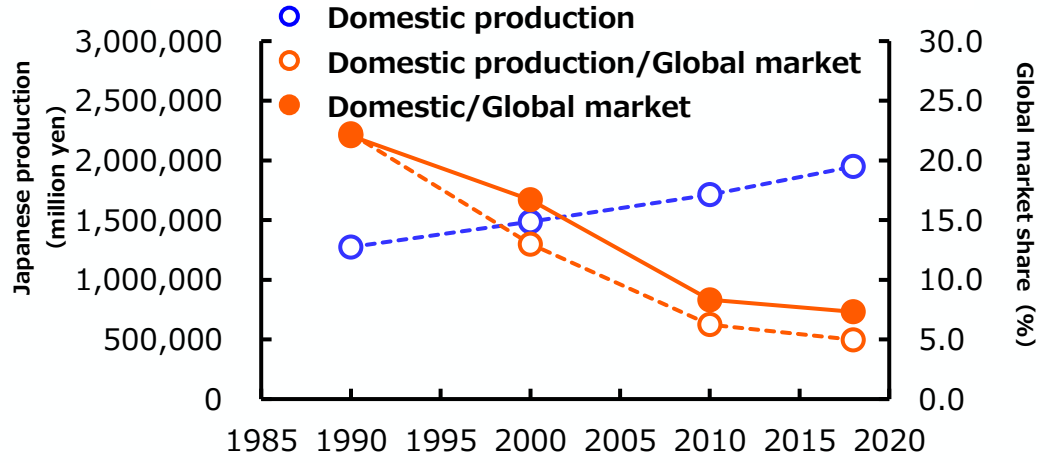
- **The global medical device market is growing at a higher rate than other industries** and **is expected to continue to grow at a sustained rate.**
  (CAGR is over 5% for both 2018-2022 actual and 2023-2027 forecast) ※CAGR: compound annual growth rate
- In Japan, the value of medical device imports has continued to increase along with market growth, and given that **the value of domestic manufacturing shipments has not changed significantly, most of the growth has been absorbed by imports.** There has also been a marked decline in the share of domestic production value in the global market.
- The challenge is **to strengthen domestic companies' ability to develop innovative products and enhance their international competitiveness**.

Japanese manufacturing/shipment and imports



Source: Statistics of Production by Pharmaceutical Industry. Created by METI. Japanese market is the value of "Japanese shipment" and Japanese manufacturing/shipment is calculated as "Japanese production – imports".

Japanese production in the global market

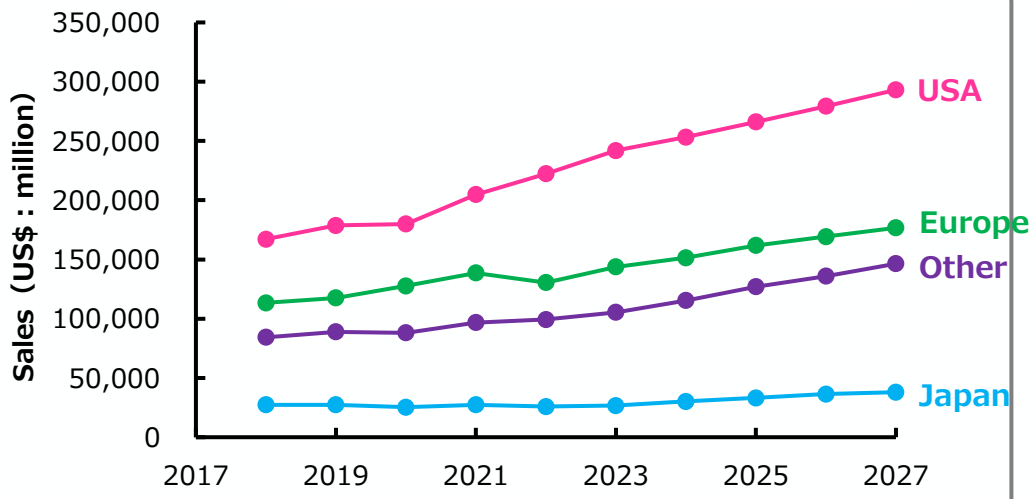


Source: Worldwide Medical Devices Market Forecasts and Statistics of Production by Pharmaceutical Industry. Created by METI. Global market calculated as 1 USD = 100 yen for all decades.

Status of Japanese Medical Device Industry in the Global Market and the Need to Capture the US Market

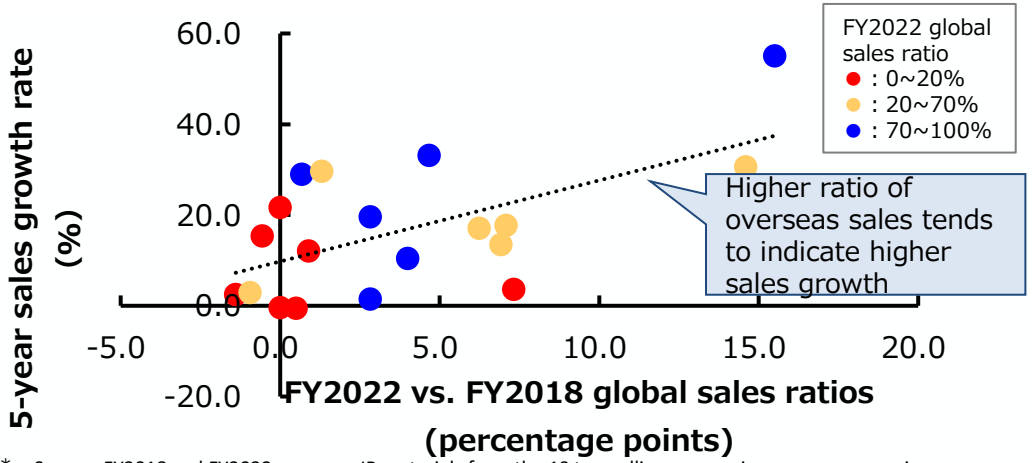
- **By 2027, the U.S. market is projected to grow about 1.75 times faster than in 2018, reaching $290 billion, while the Japanese market is projected to grow only about 1.39 times faster.**
- The situation of domestic operators' overseas expansion is polarized, **with many of them relying heavily on the Japanese market**. Therefore, **the growth of domestic operators requires the acquisition of overseas markets**.
- Japan has the potential to create medical devices that can be used in overseas markets by improving the development environment, as the country has both world-class medical standards suitable for searching for needs and the manufacturing technology to realize solutions.

Medical device sales, by country



Source: Worldwide Medical Devices Market Forecasts (July 2023), Fitch Solutions. Created by METI.
CAGR: Calculated for the 9 years from 2018 to 2027 (predicted).

Correlation between overseas sales ratio growth and sales growth rate (FY2018-2022),



* : Source: FY2018 and FY2022 company IR materials from the 19 top-selling companies among companies specializing in medical devices or related businesses with 85% or more sales. Created by METI. Companies whose Japanese sales exceeded 90% and without global sales in their IR materials were approximated to 5%.

Strategies to capture overseas markets for advanced medical devices: The importance of the U.S. market

- In order to achieve growth by acquiring overseas markets, it is important **to expand into the U.S. market.** Obtaining approval in the U.S. market and gaining recognition as a standard treatment method will lead to the acquisition of overseas markets.
- **To be deployed in the U.S. market, it is important that the technology is necessary to solve unmet needs in healthcare** (e.g., no/inadequate treatments)
- On the other hand, in order to capture the U.S. market, it is generally necessary to demonstrate solutions to medical needs through clinical trials, etc. **that require billions of yen in funding**, and this requires a large amount of development cost.

Examples of Overseas Expansion of ASAHI INTECC Co.

・ Since 2004, the company has expanded its **overseas sales ratio by approximately 50 percentage points**. **Sales increased 12-fold and grew to become the 19th largest medical device manufacturer in terms of sales**. (2022 vs. 2004)

【 Unmet Needs in Healthcare 】

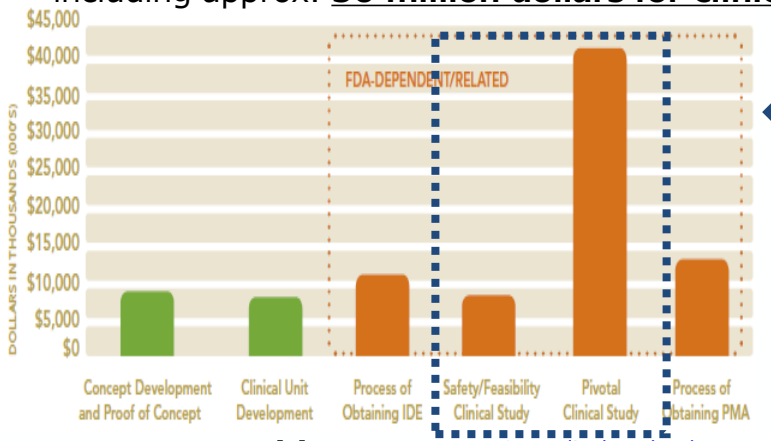
- If a coronary artery becomes completely blocked for a long period of time, it must be treated surgically, which was a great burden for the patient 。

【 Technology that solved unmet needs 】

- By applying the ultrafine stainless steel wire rope technology cultivated in the industrial equipment field, the company has developed a technology to catheterize blocked coronary arteries by passing a thin wire through the artery without surgical intervention.
- Reports from academic societies in Japan and the U.S. have demonstrated an increase in the success rate of the treatment, and it is now widely recognized as a common treatment method in the U.S. as well

Cost of obtaining FDA approval for innovative medical devices in the U.S.

Total development cost: approx. 94 million dollars, including approx. **50 million dollars for clinical trials**



[1] FDA Impact on U.S. Medical Technology Innovation, 2010

Vision for the Medical Device Industry

- We identified the direction for the growth of this industry as a high-valued industry to be a repetition of two cycles: R&D investment to create innovation and return on investment through global expansion.

1 Creating companies that embark on global expansion, including the United States

➢ **Strengthening Competitiveness by Generating Evidence and Supporting Network Building for US Expansion**

- We aim to strengthen our product competitiveness by building evidence through clinical trials and such, which is necessary for capturing the US market, and to establish product value globally through our expansion into the US market
- We will develop products that conform to the unique systems and business practices of the United States through communication and partnerships with appropriate stakeholders, such as local businesses in charge of distribution, clinical 17 experts, government agencies, insurance companies, relevant academic societies, and standardization organizations.

➢ **Improving the Environment and Support for Building Networks That Facilitate Global Expansion**

- We aim to strategically develop competitive products and launch them in the global market from the beginning.
- We aim to build human resources and a supportive environment that can lead global clinical research to build evidence for improving product competitiveness.
- We aim to simplify the acquisition of marketing approval in the destination country.

2 Establishing an R&D Environment That Fosters Innovation

➢ **Promoting the development of medical devices using AI and other digital technologies**

- Actively utilizing medical data obtained from the high level of medical care that exists in Japan for the technological development and strengthening of competitiveness of advanced medical devices, we aim to implement them in society and form markets through the demonstration of the medical device value in terms of medical utility and economic efficiency using AI and other digital technologies.

➢ **Strengthening Collaboration with and Acceleration of Startups by Major Companies**

- The aim is for major companies, VCs, medical institutions, research institutes, and countries to participate as we build a model in which Japanese SUs commercialize innovative ideas from Japan, which has one of the world's highest levels of medical care, with major companies launching them globally.

Strategies for Medical Device Industry Growth

【Present Situation】

- While the global market for medical devices is growing significantly, domestic production remains flat, and **competitiveness is declining**.
- For the growth of the domestic medical device industry, it is important to accelerate the creation of innovation based on the premise of global expansion. In addition, **the role of medical device companies that have overseas sales channels and are responsible for the global expansion of innovation is extremely important**.
- Regarding innovation, in-house R&D by medical device companies is strong for growth in existing fields and businesses, while **R&D utilizing external resources such as start-ups is strong for expansion into new fields and businesses.** There is a trend toward business acquisitions to expand portfolios in the therapeutic area and acquisitions to complement technologies in the diagnostic area. On the other hand, **in Japan, the company faces challenges in capturing external innovation from medical device companies**.
- In addition, 7 of the top 20 Japanese companies in terms of sales have expanded overseas (accounting for more than 50% of total sales), and **there are challenges in expanding overseas sales channels.**

【Policy Focus】

- **Medical device companies**

→**Incorporating external innovation to compete globally**

- **Medical device companies (Overseas sales ratio: Low)**

→**Establishment of sales channels for U.S. expansion**

- **Startups**

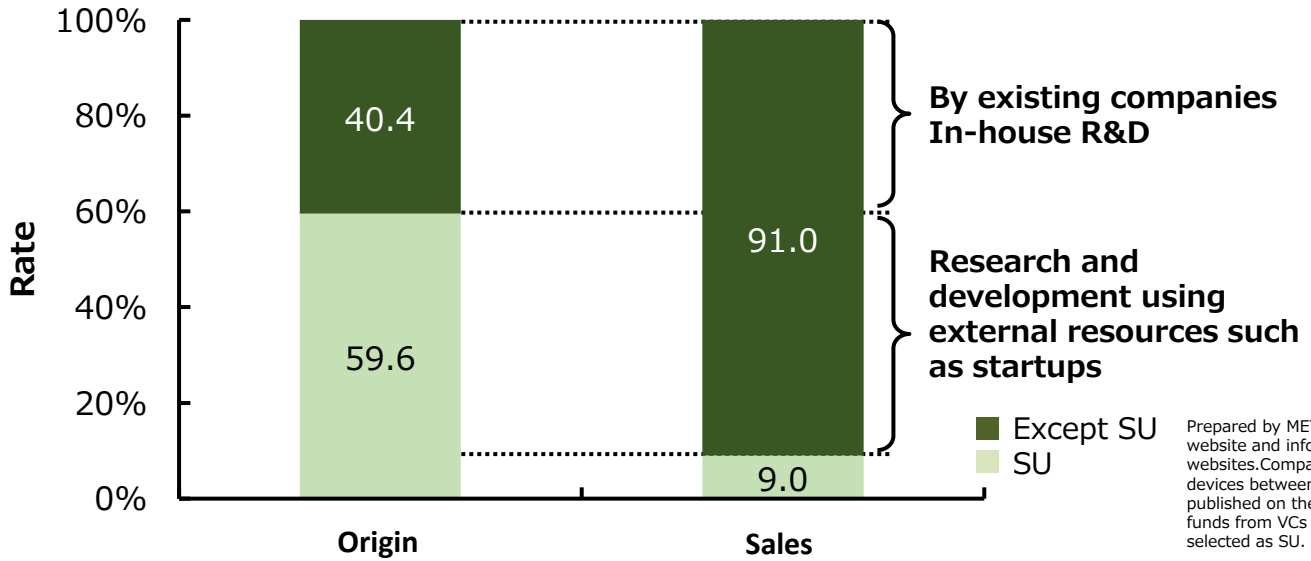
→**Selection of support areas for collaboration and out-licensing with medical device companies**

→**Focused support for R&D and commercialization in these areas**

Creation of Medical Device Innovations and Global Expansion

- In the market entry strategy for medical devices, sales and dissemination strategies before and after the launch, such as acquiring and expanding sales channels and providing guidance to physicians, are extremely important, and **innovations need to be placed on the sales infrastructure of existing companies for global deployment**. Both existing companies and start-ups are responsible for creating innovations in medical devices, but approximately 90% of the global deployment of innovations is handled by existing companies.
- For existing companies, in-house R&D (in-house R&D) is conducted to improve their core technologies, but for innovations for growth by expanding into new fields and businesses, it is difficult to invest by themselves in terms of success rates, etc., and acquiring resources from startups is the most important resource.

Classification of development origin companies and sales companies of new medical devices of foreign origin approved in Japan

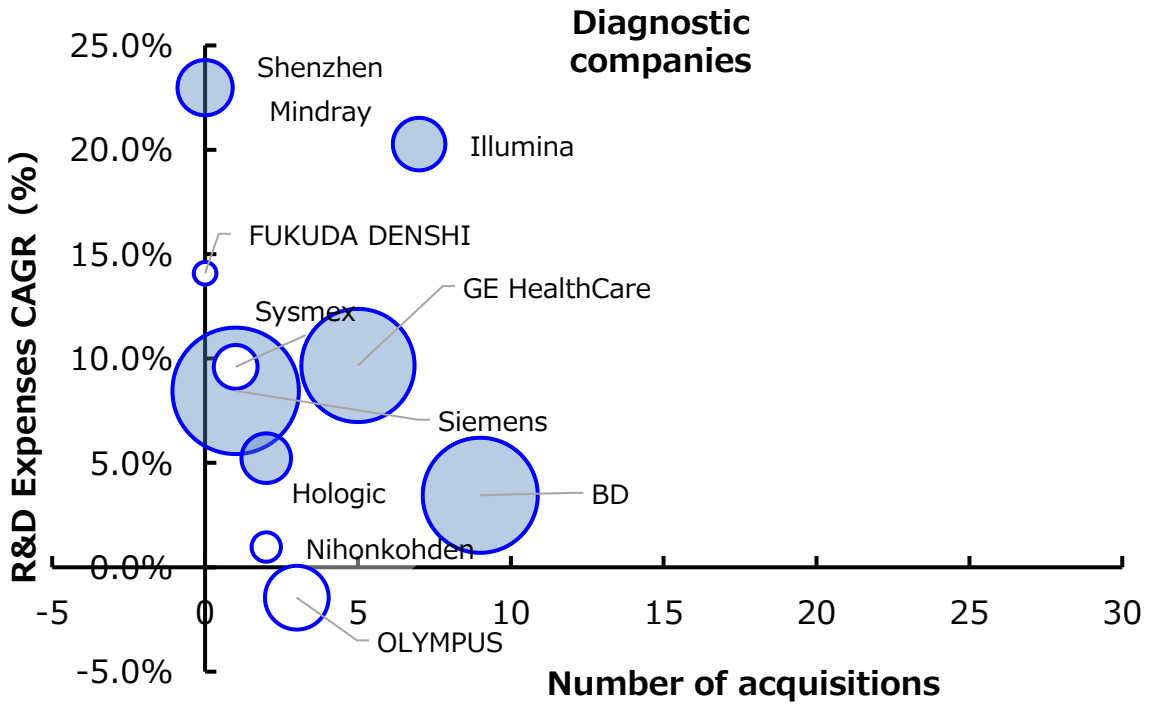


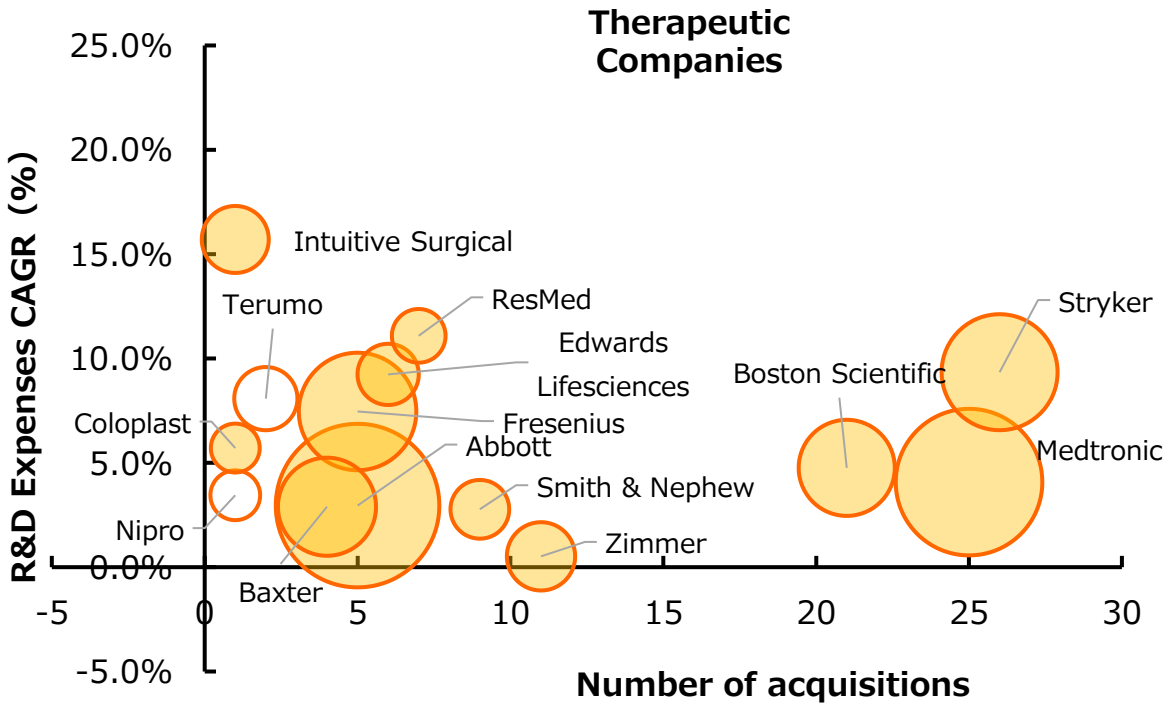
Prepared by METI based on the application summaries published on PMDA's website and information from Crunchbase, Pitchbook, and company websites.Companies that have developed products approved as new medical devices between 2012 and 2022, as listed in the application summaries published on the PMDA's website, were selected.Companies that had raised funds from VCs on Crunchbase, Pitchbook, and each company's website were selected as SU.

Comparison of foreign and major domestic investments (R&D, M&A)

- Both the growth in R&D expenditures and the number of acquisitions by major Japanese firms, regardless of whether they are diagnostic or therapeutic, tend to be small compared to those of major foreign firms.
- Issues in research and development (horizontal division of labor) using startups, etc., which is particularly important for innovation for growth through expansion into new fields and businesses.

Number of acquisitions and growth in R&D expenditures for global and domestic firms （2019-2023） Bubble size ：2023Total Sales



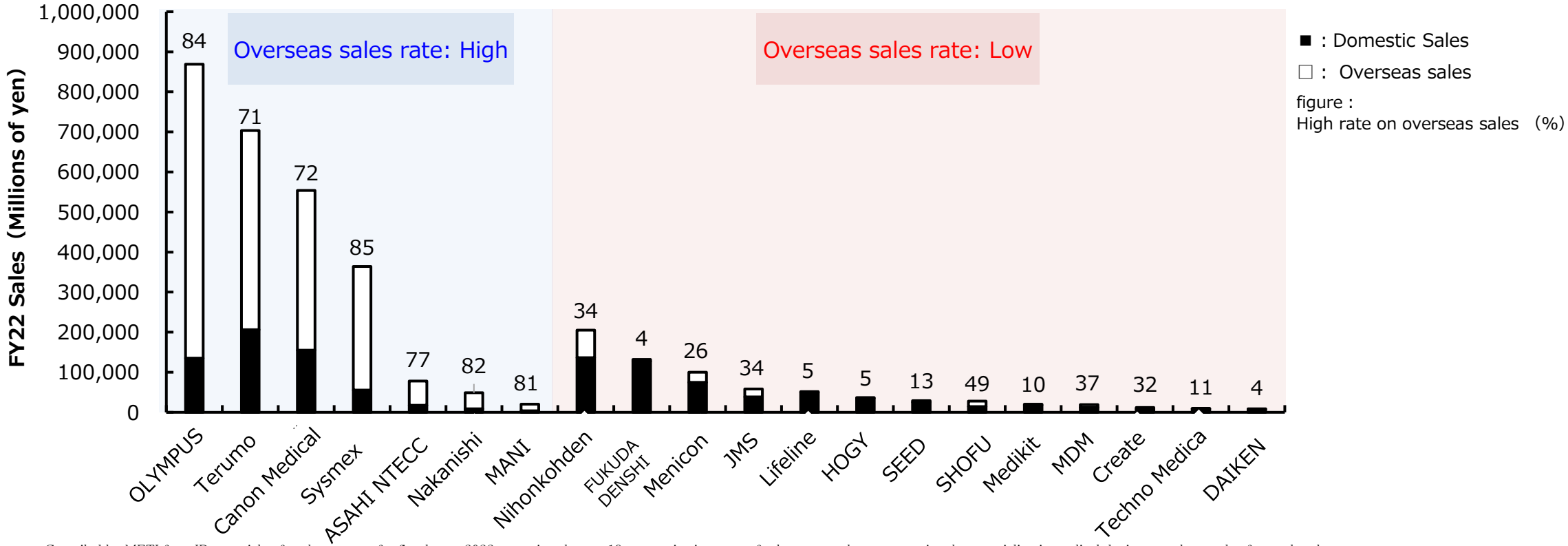


Domestic companies are the top 6 companies in terms of sales in FY2023 that specialize in medical devices or whose related businesses account for 75% or more of their total sales. Global companies are the top 25 companies in terms of sales among companies that specialize in medical devices or whose related businesses account for 75% or more of their total sales (sales are converted into US dollars using the exchange rate at the end of FY2023 for each company. The top 25 global companies were selected from Crunchbase and IR materials of each company based on the following criteria: Number of acquisitions: CrunchbaseNumber of acquisitions: Number of acquisitions within 15 years at the time of acquisition announcement from Crunchbase. R&D CAGR: Calculated based on each company's publicly announced information (Japanese companies are calculated in yen; other companies are converted to U.S. dollars using the exchange rate at the end of each company's FY).

Overseas Expansion of Domestic Medical Device Companies

- Among the top 20 domestic companies in terms of sales, **7 companies have overseas sales ratio of more than 50%**, and it is necessary to use these existing companies as an outlet for innovation and **to expand exports to existing companies with low ratio of overseas sales.**

Overseas sales ratio of the top 20 domestic sales companies

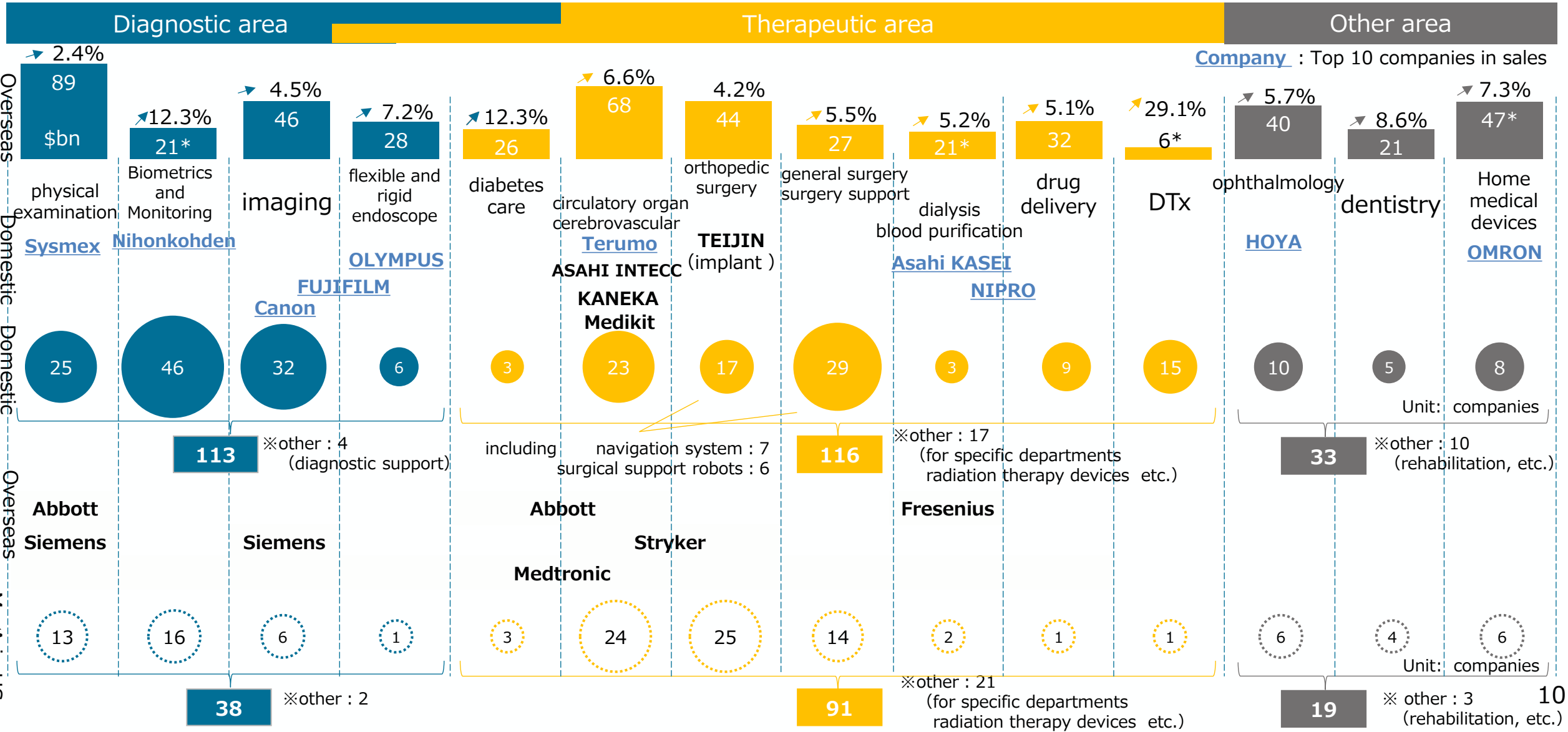


Compiled by METI from IR materials of each company for fiscal year 2022, covering the top 19 companies in terms of sales among those companies that specialize in medical devices or whose sales from related businesses account for 85% or more of their total sales. Companies whose domestic sales exceed 90% and whose IR materials do not include overseas sales were assumed to approximate 5%.

＊Prepared for Canon Medical from IR materials and website information for fiscal year 2023. :(https://www.medical.canon/jp/recruit/newgradu/special/special06.html)。

Distribution of major domestic companies and startups

- In the diagnostic area, there are many similarities in the distribution of domestic majors and Sus.
- The other side, in the therapeutic area, there are areas where only SUs are present, and majors are absent.



Strategies for future growth of the medical device industry

Role		Medical device companies		Startups
		High rate of overseas sales	Low rate of overseas sales	
Innovation Creation	Current Status /Issues	● Need to create innovations that have high synergy with the company's own sales infrastructure. ● In-house R&D and open innovation with a dual focus ● Need to improve corporate strength to expand investment scale ● Capital policy that facilitates R&D investment	● Need to acquire competitive products to build overseas sales channels. ● In-house R&D and open innovation with a dual focus	● Innovative ideas and seeds, but lack of funds for non-clinical and clinical trials with a view to overseas expansion ● Development aimed at global expansion from the beginning is essential ● Lack of business strategy for out-licensing to medical device companies
	Policy	● Promote use of R&D tax credits ● Promote use of open innovation tax credits	● Promote use of R&D tax credits ● Promote use of open innovation tax credits	● Research and development assistance ● Commercialization accompaniment support (matching with medical device companies)
Global Expansion	Current Status / Issues	● Utilize overseas sales channels in the U.S. and other countries to sell acquired products ● Expand sales channels for global expansion and regulatory compliance ● Limited information and collaboration with domestic startups	● Need to build overseas sales channels in the U.S. and other countries with highly competitive products ● Limited information and collaboration among domestic startups	*Licensing to medical device companies through M&A, etc., and monetization on the sales infrastructure of medical device companies
	Policy	● Global expansion support ● Matching support with domestic SUs	● Global expansion support ● Matching support with domestic Sus	● Global expansion support ● Matching support with domestic Sus

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Current Support Measures

R&D support for medical devices by METI

- Support is provided in each phase from basic research to post-launch.

($1=¥150)

	Basic research	Applied research	Preclinical/Clinical	Post-launch
Development for domestic	**Next Generation Health Tech Startup Development Support Project** **Period : FY2024～2028 （FY2024 : 600million yen）** **Targets : Startups** Growth promotion through initial research support for startups	**Next Generation Medical Devices Development Promotion Project** **Period : FY2025～2029 （FY2025 : 2400million yen）** **Targets : Startups/SMB/Majors** Support for development of advanced medical devices and systems	**Medical-engineering Collaboration for Global Expansion Project** **Period : FY2025~2029 （FY2025 : 1400million yen）** **Targets : Startups/SMB** Cooperation between SMEs, SUs and medical institutions	**Project to accelerate the development and adoption of digital healthcare products** **Period : FY2025 （FY2024 Supplemental Budget : 920million yen）** **Targets : Startups** Support for evaluation of economic value of introducing SaMD
Development For overseas			**Establishment of accompaniment support for overseas expansion**	

Expectations for SaMD

- Sophisticated IT and AI technologies have led to **the emergence of software that is directly effective in the treatment, diagnosis, and prevention of diseases.** As a new solution to unmet medical needs, the competition to develop such software for various diseases is accelerating, and it is expected to **become a global growth industry**.

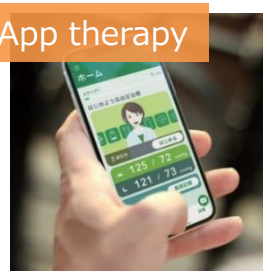
Cases in therapeutic areas (hypertension treatment)

Conventional treatment

Drug therapy

Therapeutic SaMD

App therapy



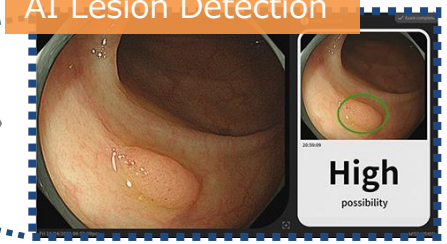
Case study in the diagnostic area (colonoscopy)

Conventional treatment

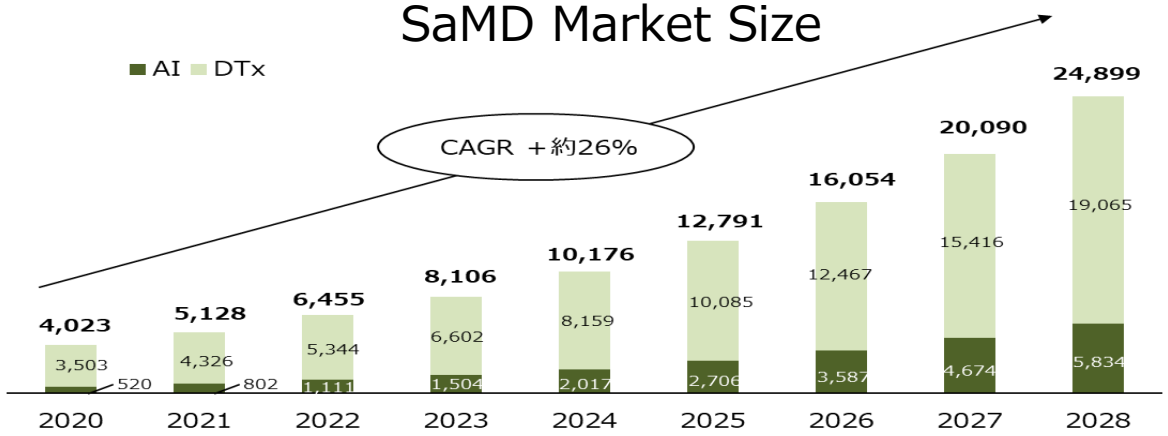
colonoscopy

Diagnostic SaMD

AI Lesion Detection



SaMD Market Size

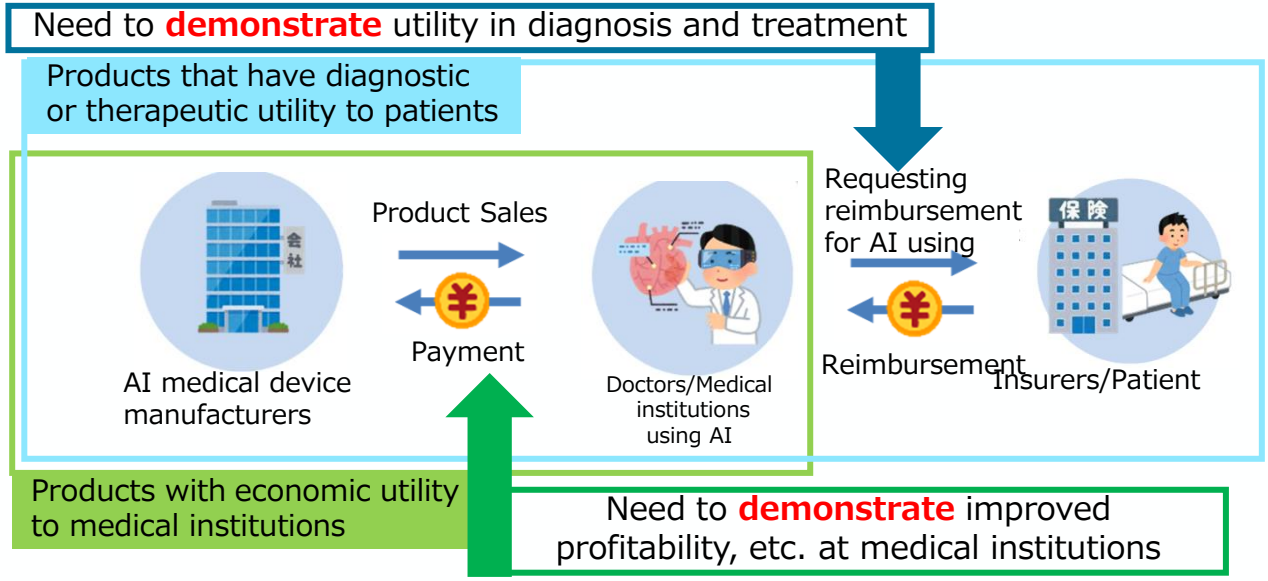


Exhibits: Artificial Intelligence Ai In Diagnostics Market (GVR), AI-Enabled Medical Imaging Solutions Market (BIS Research), Digital Health Market Trend Survey in the US (JETRO), various public information

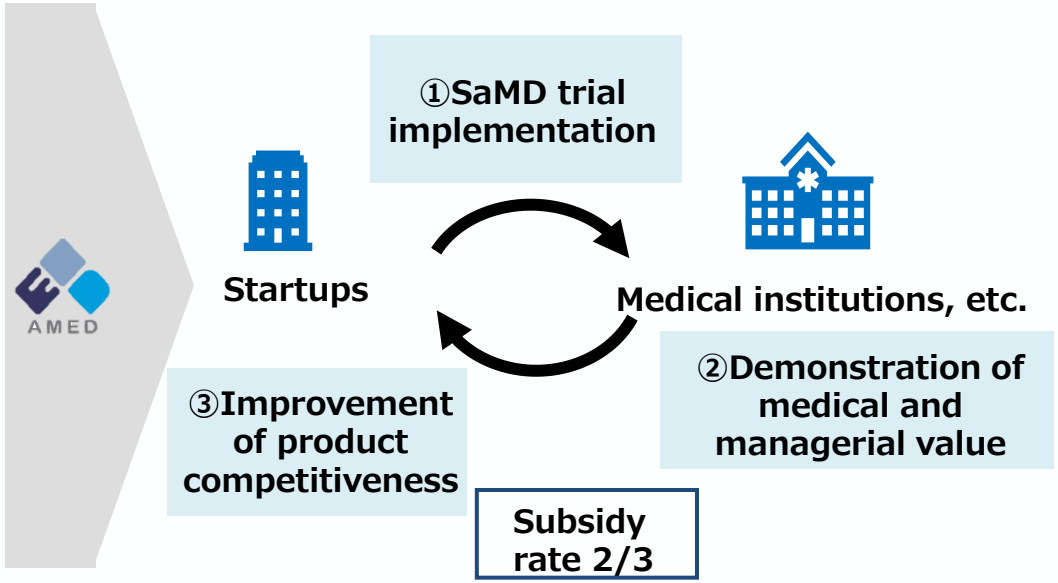
Project to accelerate the development and adoption of digital healthcare products (FY2024 Supplemental Budget : 920 million yen (6.1 million dollars ($1=¥150)))

- In order to promote the introduction of SaMD to medical institutions, it is necessary to demonstrate the specific benefits of SaMD introduction, such as improved operational efficiency and profitability.
- To quantitatively evaluate the usefulness of SaMD introduction, support will be provided for joint research between development companies and medical institutions.
- **February 28 - March 28,2025 Open call on AMED HP**

The Need for Demonstration in SaMD market developing

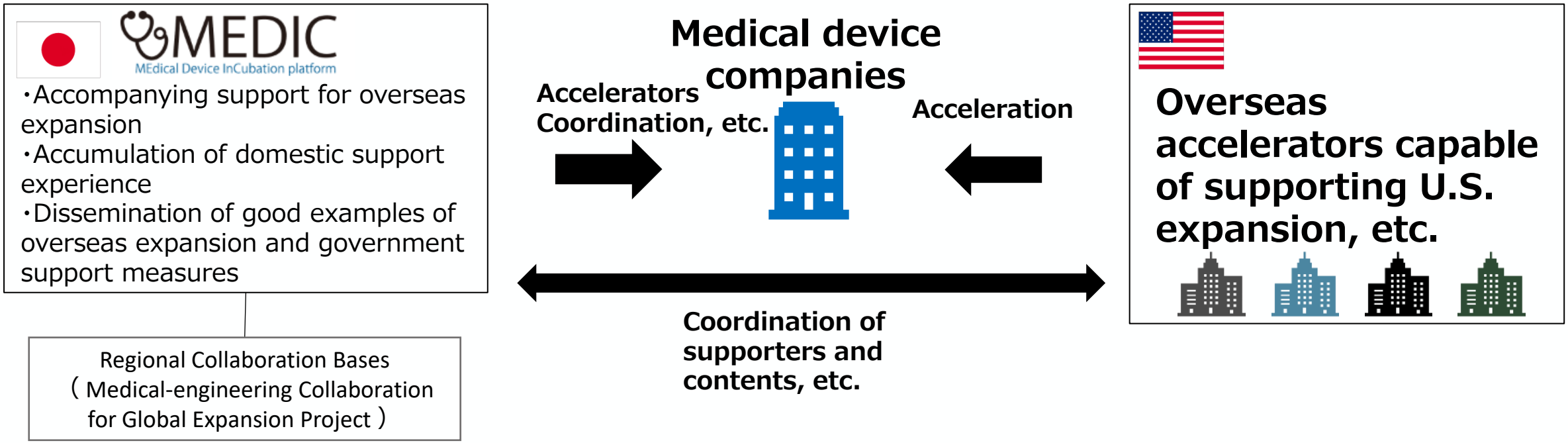


Support for joint research through collaboration between companies and hospitals



Establishment of accompaniment support for U.S. Expansion
<MEDIC Strengthening①>

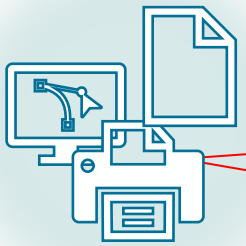
- Added a function to MEDIC（MEdical Device InCubation platform） to provide support for accompanying international expansion.
- Support for development and sales strategies, including clinical trials, and other aspects of development and sales strategies, while leveraging **accelerators specializing in U.S. expansion**, etc.
- Build a system that can return knowledge and networks to the medical device industry by accumulating overseas expansion support achievements in MEDIC.



Support for collaboration between startups and major companies
<MEDIC Strengthening②>

- **Support an environment in which domestic start-ups can develop products that meet the needs of major companies from the early development stage.**
- The goal is to create a model in which domestic startups put innovative ideas originating in Japan to practical use, and major companies expand them to global markets.

Domestic startups



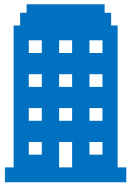
Product developing targeting 「Possible areas for open innovation」

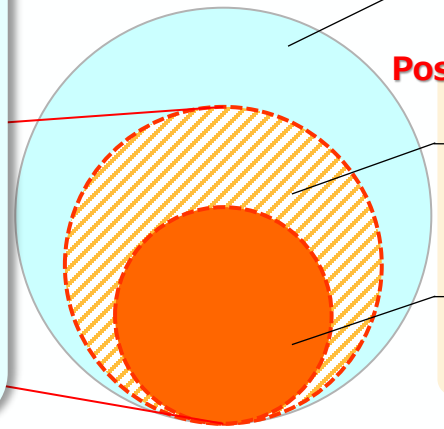
MEDIC
MEdical Device InCubation platform

To strengthen collaboration with major companies to promote product development targeting Majors'「Possible areas for open innovation」

- **providing an opportunity for major companies and Startups to collaborate**
- **Providing continuous acceleration**
- **Dissemination of major needs（Areas of potential focus）**

Major companies





Areas outside of business strategy

・Areas with no focus

Possible areas for open innovation

Areas of potential focus

・High affinity with core area, etc.

Core area

・Essential area of companies

MedTech ROUND ~MedTech Startups Acceleration Program~ （Sep.2024～Feb.2025 ）

<Themes based on their business portfolios>

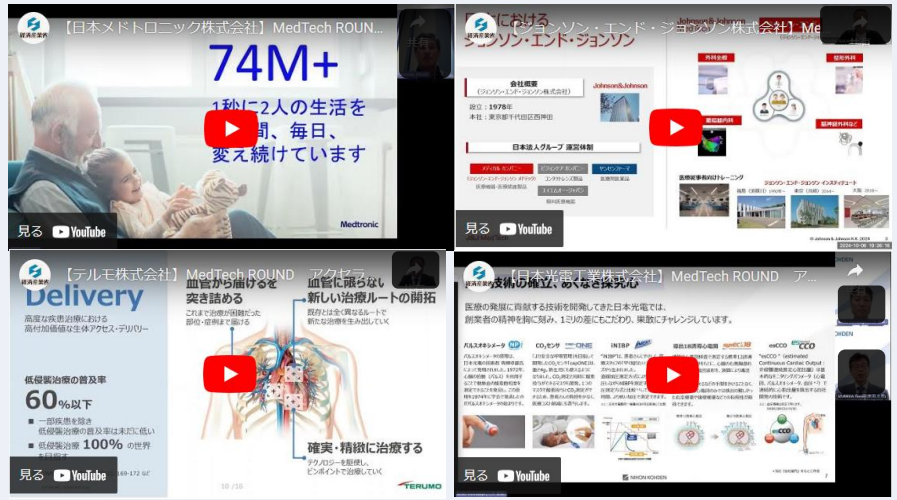
Johnson & Johnson
Solutions to Surgical Complications
手術による合併症へのソリューション

Terumo
Solutions aimed at contributing to “solving issues in the medical field,” “evolution of medical systems,” and “improvement of patients' quality of life
「医療現場の課題解決」、「医療システムの進化」、「患者さんのQOL向上」への貢献を目指したソリューション化

Nihonkohden
Biometric measurement technology that is both minimally invasive and highly accurate
低侵襲と高精度を両立する生体情報計測技術

Medtronic
Let’s create something beyond imagination!
想像を超えるものを共に創り出しましょう！－世の中により良いアウトカムをもたらす／インサイトに基づく治療を提供する／人を第一に考えたエクスペリエンスを提供する／患者さんの人生を変える、ソリューションの創出－

<Majors’ Mini-reverse pitch>



Majors Recruitment / Theme Setting → **SUs Recruitment/Screening** → **Acceleration** → **Final Pitch**

<Majors･SU matching>

Johnson & Johnson
･Carbgem

Nihonkohden
･MeDiCU
･AMI

Terumo
No matching

Medtronic
･Adriakaim
･AIST(Before starting a business)
(National Institute of Advanced Industrial Science and Technology)

<Acceleration>

･Conducted once every two weeks
･Brush up business plans
･Brush up presentations for Final pitch

<Accelerators Information exchange>

･Networking and sharing of challenges, experiences and know-how of accelerators

<Business Plan Proposal by SU>

･English Presentations to the management of major companies
･Selection of outstanding companies
･Networking