



**経済産業省**

*Ministry of Economy, Trade and Industry*

# **Industrial Policies for Medical Devices Carried Out by the Ministry of Economy, Trade and Industry**

**December 2016**

**Ministry of Economy, Trade and Industry,  
Commerce and Information Policy Bureau  
Medical and Assistive Device Industries Office**

# Items

## ○ Trends in Japan's medical device industry

○ Industrial policies for medical devices carried out by the government overall and by the Ministry of Economy, Trade and Industry

☆ Medical device development across all of Japan

Promotion of collaboration between medicine and industry: Construction of the “Network for Supporting Development of Medical Devices”

Development of the most advanced medical devices in the world

☆ Arrangement of a regulatory and institutional environment to facilitate medical device development and commercialization

☆ Promotion of overseas deployment with medical devices and technology integrated together with services

# Categories of Medical Devices

## (1) Treatment devices



Artificial joints



Catheters

Cardiac pacemakers



Syringes

Heart-lung machines (roller pumps, artificial lungs)



## (2) Diagnostic devices



PET and PET-CT systems

Endoscopes (videoscopes)



Ultrasound diagnostic equipment

MRI



X-ray photography film, thermometers, sphygmomanometers, electrocardiographs, etc.

## (3) Other devices



Dental materials  
Dental units

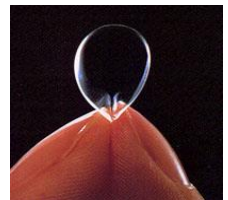
Home-use massage equipment



Surgical gloves



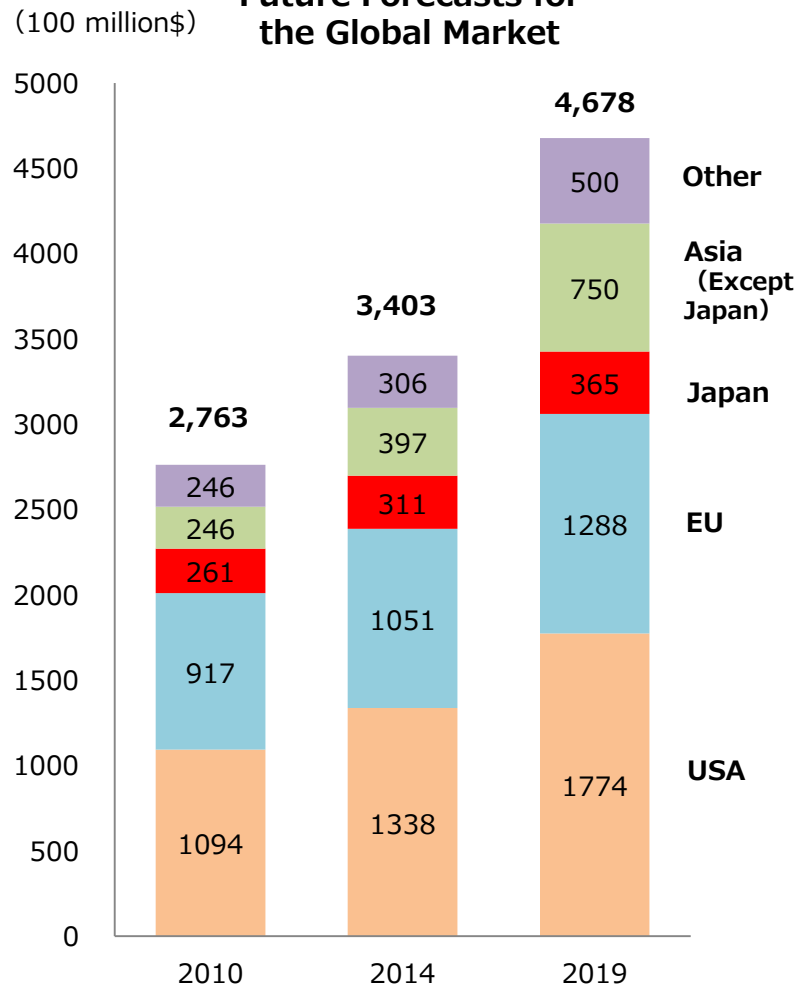
Contact lenses



# Trends in the Global Medical Device Market

- With the progress of aging populations and the expansion of medical demand in developing countries, the global market is growing.
- **Imports and exports** of medical devices in Japan are **expanding**.  
(Compared to previous year, imports and exports increased approximately 5% and 8% respectively)

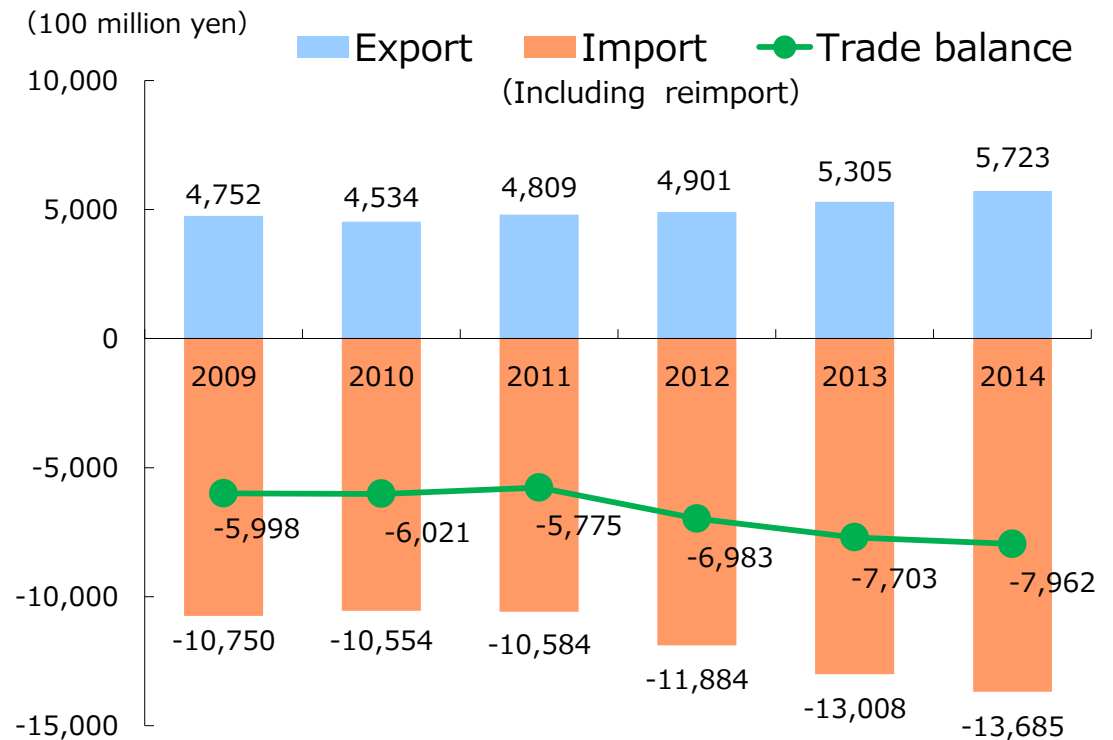
**Future Forecasts for the Global Market**



(Source) Worldwide Medical Market Forecasts to 2019

**Shifts in Import and Export Amounts in Medical Devices**

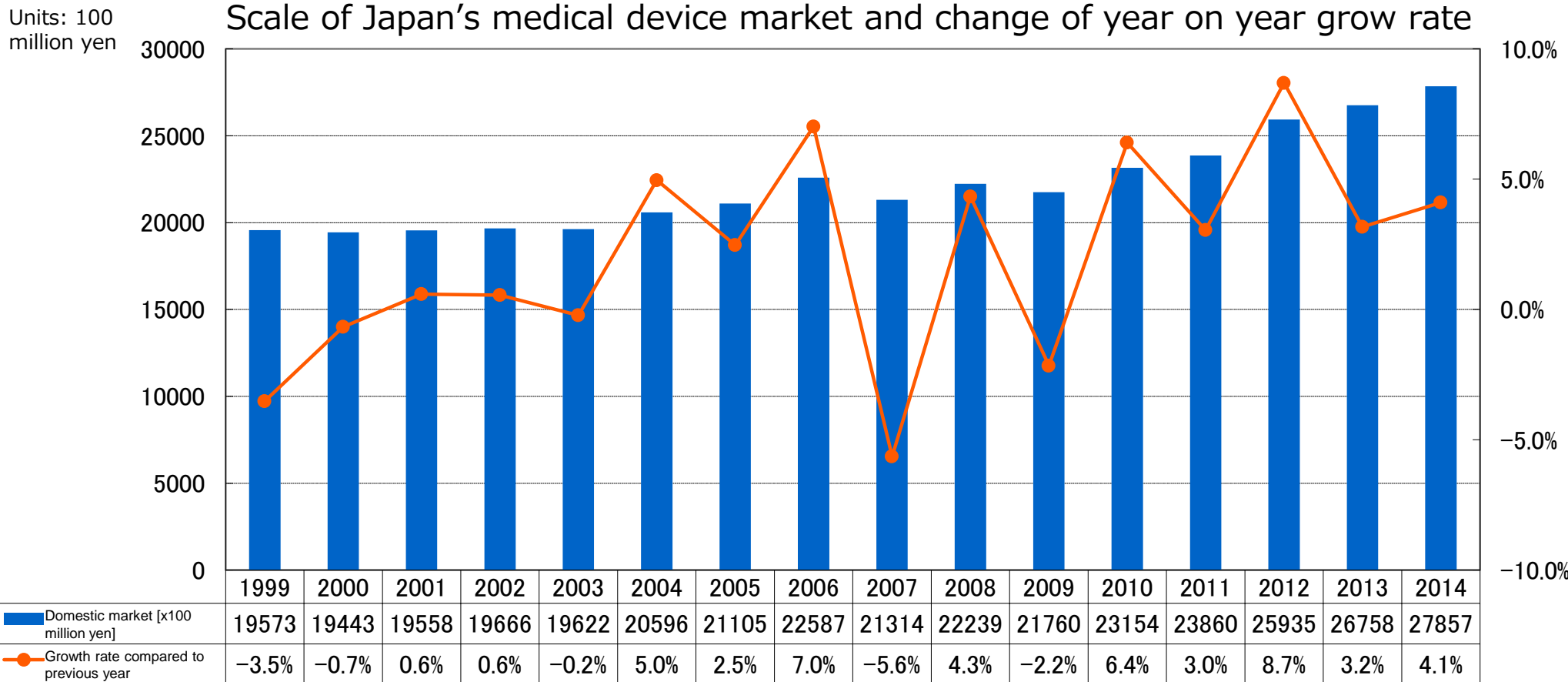
- Trade balance in 2014 amounted a deficit of approximately 800 billion yen (Exports: 572.3 billion yen – Imports: 1368.5 billion yen).
- ※ It is estimated that reimport from overseas consists of approximately 20 % of imports.



Source: Ministry of Health, Labour and Welfare  
"Statistics of Production by Pharmaceutical Industry"

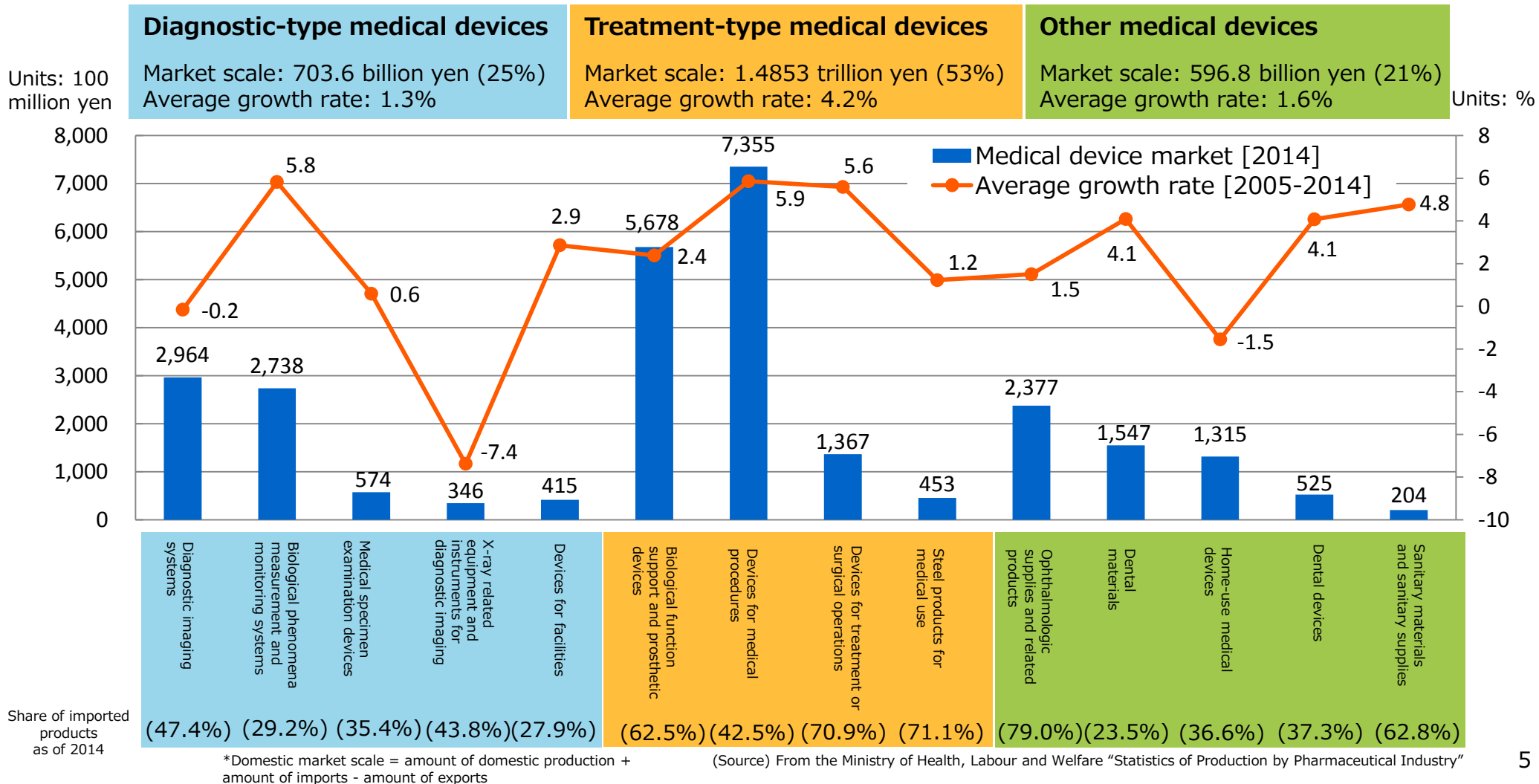
# Trends in Japan's Medical Device Market

- The scale of Japan's medical device market has been **on the rise since 2004**, growing to a level of approximately 2 trillion yen.  
It reached **approximately 2.8 trillion yen in 2014, the largest scale ever attained up to this point.**
- Medical expenses in Japan amounted to 40.1 trillion yen in fiscal year 2013. The medical device market consisted of slightly less than 7% of that total.



# Structure of Japan's Medical Device Market

○ Within the medical device market (roughly 2.8 trillion yen), **treatment devices (catheters, pacemakers, etc.) account for 53%, and diagnostic devices (endoscopes, CT, MRI, etc.) account for 25%**, based on monetary amounts. In general, treatment devices have a high growth rate and a large market scale. However, treatment devices also have a relatively high proportion of imports.



# Items

- Trends in Japan's medical device industry
- **Industrial policies for medical devices carried out by the government overall and by the Ministry of Economy, Trade and Industry**

☆ Medical device development across all of Japan

Promotion of collaboration between medicine and industry: Construction of the “Network for Supporting Development of Medical Devices”

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☆ Arrangement of a regulatory and institutional environment to facilitate medical device development and commercialization

☆ Promotion of overseas deployment with medical devices and technology integrated together with services

# “2015 Amendment to Japan Revitalization Strategy”

<Excerpt> (June 30, 2015 Cabinet approval)

## ○ **Development and industrialization of outstanding medical devices, etc. produced by Japan, that gather and concentrate its manufacturing ability**

In order to realize the improvement of quality and efficiency of medical care and the extension of healthy life expectancy based on medical needs, and to revitalize the medical device industry, **the development and industrialization of unique, revolutionary medical devices that are the most advanced in the world will be accelerated**, and those results will be returned to the people.

To accomplish this, **intellectual properties for developed medical devices will be obtained and strategic activities for them will be advanced**. Also, measures including the **promotion of international standardization of medical devices** developed in Japan, the **development of local human resources** to operate Japan-developed medical devices, and **the associated international deployment of medical devices** will be advanced through collaboration among industry, the government, and academia.

Furthermore, in order to promote the development and industrialization of medical devices by business operators, universities, and other local parties with technical skills, the **“Network for Supporting Development of Medical Devices” will be promoted** to continuously support medical devices from their initial stages of development to their industrialization. Plans will be made to enhance the **development of human resources for consulting** required for this goal, and support for development business operators in various situations such as understanding medical needs, carrying out market cultivation including international deployment, and executing pharmaceutical affairs applications, will be strengthened.



# Regulations According to the Pharmaceutical and Medical Device Act

In the Pharmaceutical and Medical Device Act (executed on November 25, 2014), medical devices are classified into **3 categories** according to their level of danger to the human body from lowest to highest, as **General Medical Devices, Controlled Medical Devices, and Specially Controlled Medical Devices** (there are 4 categories in international classifications).

|                                    | General Medical Devices   | Controlled Medical Devices   | Specially Controlled Medical Devices  |    |
|------------------------------------|---|--|---|----|
| Class                              | I   | II   | III   | IV |
| Classifications according to risk  | Nearly zero risk of impacting human life or health  | Some risk of impacting human life or health  | Risk of severely impacting human life or health   |    |
| Retailers                          |   | <div>← Notification →</div>  | <div>← Specially Controlled Medical Device Retailers Permission →</div>   |    |
| Marketing Authorization Holders *1 | <div>← Third-Class Medical Device Marketing Authorization Holders Permission →</div>          | <div>← Second-Class Medical Device Marketing Authorization Holders Permission →</div>  | <div>← First-Class Medical Device Marketing Authorization Holders Permission →</div>  |    |
| Manufacturers *2                   | <div>Registration (simplified from "Permission" according to the amendments to the act)</div> |  |   |    |
| Procedures for Medical Devices     | <div>Notification</div>   | <div>Certification or Approval</div> <div>For items with certification standards, third-party "Certification" by private registration certification institutions is possible. For all other items, "Approval".<br/>("Certification" is possible for some Class III items according to the amendments to the act)</div> | <div>Approval</div> <div>For each item, the quality, performance, effects/results, safety, and other attributes will be reviewed by PMDA.</div> |    |
| Example medical devices            | •Electrically-operated patient beds • Stethoscopes<br>•Sphygmomanometers •Scalpels •Scissors  | •X-ray diagnostic equipment •MRI • Endoscopes<br>•Contrast media injection equipment • Electronic thermometers   | •Cardiac catheters •Central vein catheters<br>•Mechanical artificial hearts •Artificial heart valves •Radiation therapy equipment               |    |

\*1: Self-production and production commissioned to another party are allowed. Either will require "Permission".

\*2: Only production whose commission is received is allowed.

# Overview of the Japan Agency for Medical Research and Development (AMED)

## Japan Agency for Medical Research and Development (AMED)

- Findings for advancing research and development in medical fields based on medical field research promotion plans.
  - (1) Centralize the budgets for research and development in medical fields for each Ministry.
  - (2) Provide comprehensive support from basic research to practical implementation.

\*Established on April 1, 2015. Chairperson: Makoto Suematsu (former Dean of Keio University School of Medicine).  
Budget for fiscal 2016: 126.5 billion yen (+17.5 billion yen subsidy from the reserve fund in budget).  
Number of personnel: roughly 300 (of these, 102 are full-time personnel).

Fiscal year 2016  
budget amounts

59.9 billion yen

47.8 billion yen

18.5 billion yen

### <Competent Ministers>

Prime Minister  
Responsible for "general  
coordination"

Minister of Education,  
Culture, Sports, Science  
and Technology  
Responsible for "basic  
research"

Minister of Health,  
Labour and Welfare  
Responsible for "clinical  
research"

Minister of Economy,  
Trade and Industry  
Responsible for "practical  
implementation"

### Efforts by the Ministry of Economy, Trade and Industry (budget amounts for fiscal year 2016)

#### Medical device development across all of Japan (9.89 billion yen)

- Development of Medical Devices and Systems for Advanced Medical Services (4.39 billion yen)
- Development of Medical Devices through Collaboration between Medicine and Industry (3.5 billion yen)
- Project to Promote the Development and Introduction of Robotic Devices for Nursing Care (2.0 billion yen)

#### Creation of pharmaceuticals across all of Japan (5.62 billion yen)

- Development of Fundamental Pharmaceutical Production Technology to Realize Next-Generation Medical Care and Diagnosis (5.62 billion yen)

#### Concept of a Highway Program for Realization of Regenerative Medicine (2.5 billion yen)

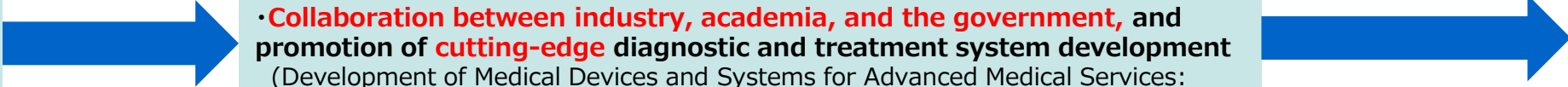
- Project Focused on Developing Key Evaluation Technology: Evaluation for Industrialization in the Field of Regenerative Medicine (2.5 billion yen)

# Overall Situation of Industrial Policies for Medical Devices Promoted by the Ministry of Economy, Trade and Industry

Market cultivation,  
planning of designs and  
concepts

Development, clinical trials,  
manufacturing, provision of  
services

Sales,  
marketing

- 
- Development of the **most advanced medical devices in the world**
  - **Collaboration between industry, academia, and the government, and promotion of cutting-edge** diagnostic and treatment system development  
(Development of Medical Devices and Systems for Advanced Medical Services: budget amount for fiscal year 2016 - 4.39 billion yen)

- Development of medical devices through **collaboration between medicine and industry**
- Facilitate **collaboration between corporations, universities, and other parties** possessing manufacturing technology, with medical institutions, to develop and implement devices that can answer **the needs of medical sites**  
(Development of Medical Devices through Collaboration between Medicine and Industry: budget amount for fiscal year 2016 - 3.5 billion yen)

- Arrangement of **business environments**
- Formulation of evaluation indices and **development guidelines** that allow smooth development and reviews
- Acceleration of **international standardization** for overseas deployment

- Acquisition of **overseas markets**
- **Integrated deployment** of medical devices and services  
(advancement of medical technology and service bases)  
(support system in collaboration with MEJ, JICA, etc.)

- Support by the **Network for Supporting Development of Medical Devices**
- Provide **continuous support** according to development stages in the form of **“accompanying consultation”**
- Comprehensively mobilize development institutions and provide **one-stop** support such as for discovering medical site needs and for industrialization (approval and authorization, intellectual properties, market cultivation, finances).

# Items

- Trends in Japan's medical device industry
- Industrial policies for medical devices carried out by the government overall and by the Ministry of Economy, Trade and Industry

## ☆ Medical device development across all of Japan

**Promotion of collaboration between medicine and industry: Construction of the “Network for Supporting Development of Medical Devices”**

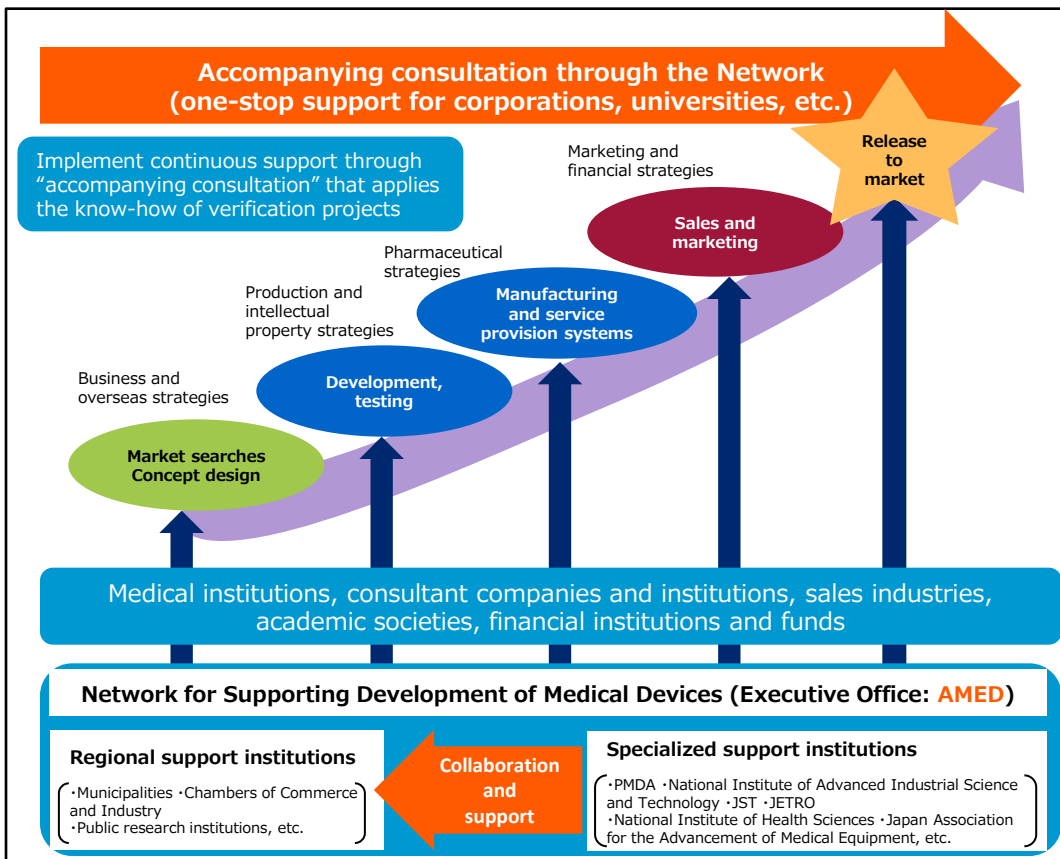
**Development of the most advanced medical devices in the world**

- ☆ Arrangement of a regulatory and institutional environment to facilitate medical device development and commercialization
- ☆ Promotion of overseas deployment with medical devices and technology integrated together with services

# Development of Medical Devices through Collaboration between Medicine and Industry (budget amount for fiscal year 2016 - 3.5 billion yen (3.19 billion yen))

- Actively apply Japan's manufacturing technology to medical devices (support for new entry and deployment to other fields).
- **Relevant ministries** (Ministry of Health, Labour and Welfare; Ministry of Education, Culture, Sports, Science and Technology) or **relevant institutions** (PMDA, National Institute of Advanced Industrial Science and Technology, JST, JETRO, etc.) will **collaborate** and provide continuous one-stop support from the development stage to industrialization. Additional **collaboration with organizations such as regional municipalities and public research institutions** can further strengthen the support system at the regional level, which can lead to expanding the scope of Japan's medical device industry.

## Provide one-stop support for each stage of development



## Application of manufacturing technology

With collaboration between small- to medium-sized companies possessing advanced manufacturing technology, and medical and other institutions (**collaboration between medicine and industry**), promote the development and implementation of devices that **can answer the needs of medical sites**.

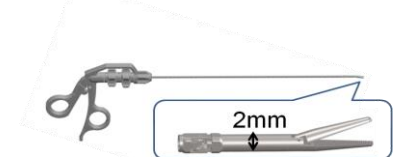
### <Medical device development examples>



Dentapac Kokoro

#### Japan Dental Trade Association (Tokyo)

The Japan Association for Dental Science, the Japan Dental Association, and the Japan Dental Trade Association **collaborated together from the initial stages of development**, to develop a specialized package of equipment for **home-visit dental treatment**.



Super-fine forceps for endoscopic surgery

#### Suzuki Precision (Tochigi Prefecture)

By applying **manufacturing technology for extremely fine precision components for automobiles and other applications** (machining technology), super-fine forceps used in minimally-invasive single port endoscopic surgery were developed.

➡ KPI: Aim to expand the scale of the domestic medical device market by roughly the year 2020.

# Issues for the Development and Implementation of Medical Devices

## (1) Understanding the needs of medical sites is difficult

In contrast to standard industrial product development, **information on users (medical sites) is not readily obtained**, causing difficulties in developing and improving products to meet their needs.

- Even if products are created, if they are based on the opinions only of specific physicians, their marketability will not be clear.

## (2) Creating strategies for industrialization, intellectual properties, financing, etc. in anticipation of specific sales is difficult

**Cultivation of sales markets to medical institutions is difficult**, so even if products are developed, it is not easy to link them to sales.

- Difficulties in matching the seeds of technology, components, processing, etc. possessed by small- to medium-sized companies, venture companies, universities, etc. to the needs of large companies such as medical device manufacturers.
- If explanations and evidence on the safety and effectiveness of devices are insufficient, they will not be introduced to medical sites.

## (3) Addressing systems related to the Pharmaceutical Affairs Act (Pharmaceutical and Medical Devices Act) is difficult

**Formulating development plans and clinical test plans, securing medical sites to carry out clinical tests, preparing pharmaceutical application forms**, and other tasks to prepare for procedures involving the Pharmaceutical Affairs Act require **a high level of specialization**, making it difficult to address them.

- Planning road maps up to product implementation is difficult, and there is insufficient knowledge on implementing clinical tests, so those tasks require significant time and expenses.

Continuous support and consultation by specialists are required.

## (4) Executing initiatives for medical device development in individual regions is difficult

Although initiatives to support medical device development are being started in individual regions, there is **insufficient knowledge and information to support them**, and so adequate support cannot be provided.

Mechanisms to support initiatives for developing medical devices in local regions are required.

# Device Development through Collaboration between Medicine and Industry (Network for Supporting Development of Medical Devices)

- The **Network for Supporting Development of Medical Devices** was launched on October 31 of last year, under collaboration by the Cabinet Secretariat, the Ministry of Health, Labour and Welfare, and the Ministry of Education, Culture, Sports, Science and Technology to provide **continuous support** according to the development stage of medical devices.
- A one-stop window was set up at the Executive Office support institution and **71 regional support institutions** (municipalities, public research institutions, Chambers of Commerce and Industry, etc.).
- There has been a substantial response with roughly **940 consultation cases**. Among them, there were roughly **300 accompanying consultation cases**.
- A substantial response **from different industries**, such as electrical and electronics industry, optical industry, is increasing.
- The **accompanying consultation in a regional area** was started, such as Osaka city, Kobe city and Hiroshima city.

## Accompanying consultation through the Network (one-stop support for corporations, universities, etc.)

Implement continuous support through "accompanying consultation" that applies the know-how of verification projects

Marketing and financial strategies

Release to market

Sales and marketing

Manufacturing and service provision systems

Pharmaceutical strategies

Production and intellectual property strategies

Development, testing

Market searches  
Concept design

Business and overseas strategies

Medical institutions, consultant companies and institutions, sales industries, academic societies, financial institutions and funds

Network for Supporting Development of Medical Devices (Executive Office: **AMED**)

Regional support institutions

・Municipalities ・Chambers of Commerce and Industry  
・Public research institutions, etc.

Collaboration and support

Specialized support institutions

・PMDA ・National Institute of Advanced Industrial Science and Technology ・JST ・JETRO  
・National Institute of Health Sciences ・Japan Association for the Advancement of Medical Equipment, etc.

## One-stop window

(Executive Office support institutions, regional support institutions)  
\*Business operators or other parties fill out an **application for a consultation**.

## Interview

\*Interviews are held based on the **application**, and the content of support is investigated.

## Formation of support team

\*A **support plan** is prepared and executed.

## Implementation of accompanying consultation

・Consultation using examination chart  
・Dispatched consultation to local sites  
・Updates to examination charts and support plans  
・Referral of paid support

## Network for Supporting Development of Medical Devices: Consultation Reception Form

|         |                       |
|---------|-----------------------|
| 作成日     | 年 月 日                 |
| コンタクト方法 | ( ) 対面 ( ) 電話 ( ) その他 |
| 場所      |                       |
| 企業名     |                       |
| 所属・役職   |                       |
| 相談者名    |                       |
| 電話番号    |                       |

Accompanying consultants, specialized support institutions  
(PMDA, National Institute of Health Sciences, National Institute of Advanced Industrial Science and Technology, etc.)

## 支援計画

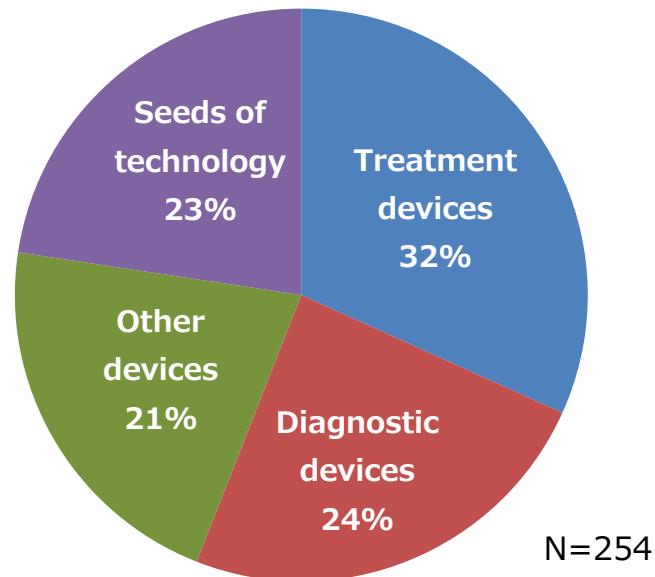
|      |  |
|------|--|
| 企業名  |  |
| 相談件名 |  |

|                     | 2014(H26)年度 |                  |         |       |
|---------------------|-------------|------------------|---------|-------|
|                     | 4月～6月       | 7月～9月            | 10月～12月 | 1月～3月 |
| 要素技術開発              |             |                  |         |       |
| 試作機開発・改良<br>※製品別に記載 | 試作品開発(一次)   | 試作品開発(二次・最終)仕様検討 |         |       |
|                     |             | 包装形態検討           | 安全性・耐久性 |       |

# Category of medical devices and consultations

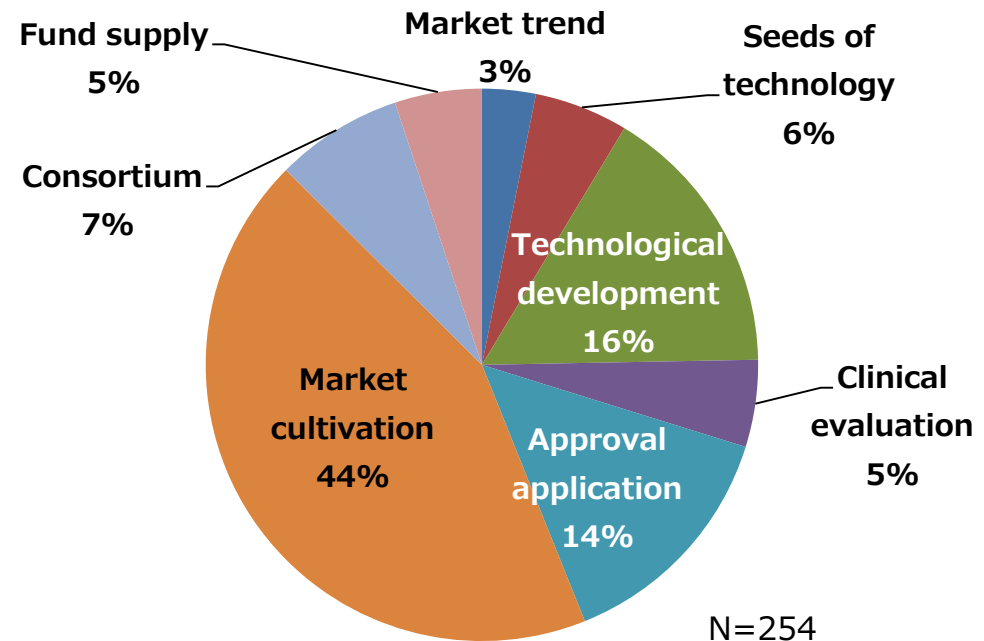
## 1. Category of medical devices

- **Treatment devices (32%)**
- **Treatment devices:** Respiratory treatment device, balloon catheter, laser treatment device, stent, etc.
- **Diagnostic devices:** Electroencephalograph, electrocardiographic monitor, electronic stethoscope, etc.
- **Other devices:** Dental implants, etc.



## 2. Category of consultation cases

- **Market cultivation (44%)**
- **Technological development:** Technology development and evaluation for trial model.
- **Approval application:** Classification of medical devices.
- **Market cultivation:** Information of distributing agents and overseas expansion.

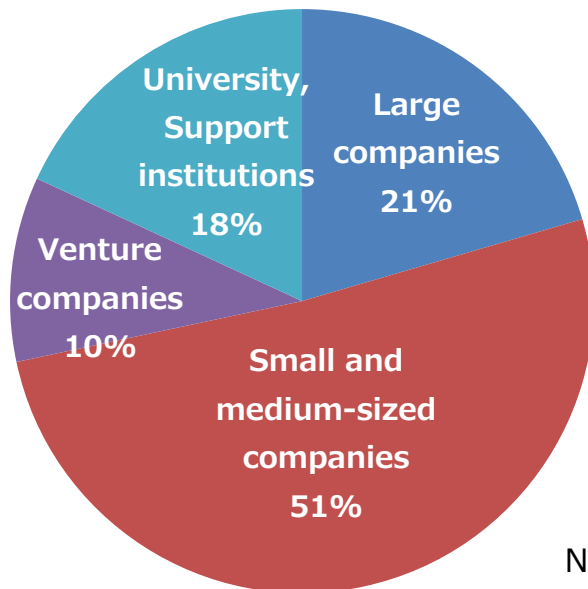




# Company size and category of companies

## 3. Category of company size

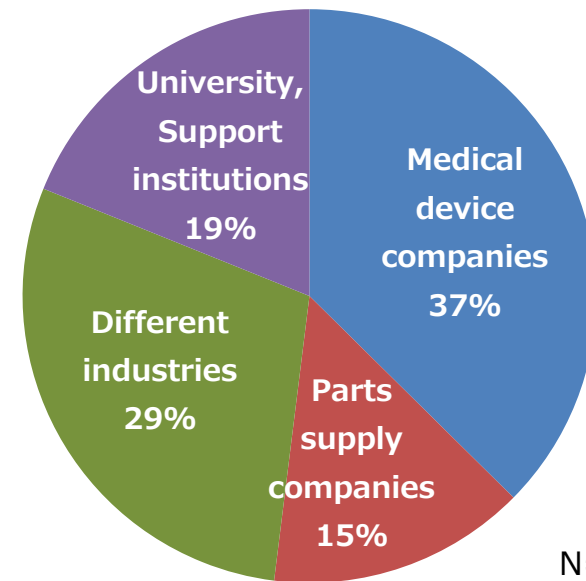
- **Small and medium-sized companies (51%).**
- **Large companies:** Entrance from different industries, etc.
- **Small and medium-sized companies:** Seeds of technology and business strategy, etc.
- **Venture companies:** Medical software, etc.



N=254

## 4. Category of companies

- **Medical device companies (37%) .**
- Percentage of parts supply companies (**Automobile component, Precision work**) is 15%.
- **Percentage of different industries** (non-medical device companies) is 29%.



N=254

# Network Initiatives (National Meetings, Handbook)

## “The 2<sup>nd</sup> National Medical Device Development Meeting”

- Held on January 29, 2016

A total of 300 participants from a wide variety of fields.

### <Major Participants>

- Relevant ministries and agencies: Cabinet Secretariat (Headquarters for Healthcare Policy); Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour and Welfare; Ministry of Economy, Trade and Industry
- Specialized support institutions: National Institute of Advanced Industrial Science and Technology, NEDO, National Institute of Health Sciences, PMDA, Organization for Small & Medium Enterprises and Regional Innovation, MEJ, JETRO, Innovation Network Corporation of Japan, Regional Economy Vitalization Corporation of Japan, Japan Association for the Advancement of Medical Equipment
- Corporations, regional support institutions, universities and hospitals, industry groups, financial institutions, etc.

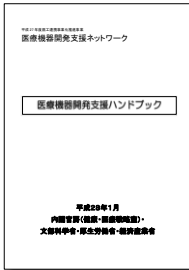


## “Medical Device Development Support Handbook”

Support policies of relevant ministries and agencies, specialized support institutions, and regional support institutions are collected in a single volume and distributed.

(available for download from the Network website)

<http://www.med-device.jp>



### <Handbook Structure>

#### Network for Supporting Development of Medical Devices

##### Discovering Seeds of Technology

- Ministry of Education, Culture, Sports, Science and Technology, JST

##### Technological Development

- Ministry of Economy, Trade and Industry, The Small and Medium Enterprise Agency, National Institute of Advanced Industrial Science and Technology, public research institutions, NEDO, etc.

##### Clinical Evaluation

- Ministry of Health, Labour and Welfare (Project to Build Foundations to Support and Incentivize Development of Medical Devices Made in Japan)

##### Safety Evaluation, Pharmaceutical Application

- National Institute of Health Sciences, PMDA

##### Market Cultivation, Management Consultation

- Organization for Small & Medium Enterprises and Regional Innovation, MEJ, JETRO, Yorozu Support Base

##### Fund Supply

- Innovation Network Corporation of Japan, Regional Economy Vitalization Corporation of Japan

##### Regional Support Institutions

- Support measures by regional support institutions from various regions nationwide

# Scheme for an extraction of clinical needs in a medical field

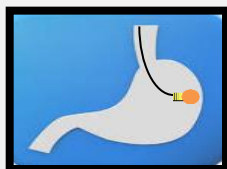
- In order to accelerate a development of medical devices by reflecting clinical needs, two kinds of clinical needs from hospitals are extracted: **1. Improvement clinical needs from a daily medical treatment,** **2. Innovative clinical needs in core hospitals and central medical institutions.**
- Clinical needs are brushed up by a **committee of experts in AMED**, and connected to a regional support institute and a company.

## Hospital

We want to apply bioabsorbable stents to a stenosis treatment.



We need an innovative endoscopic examination without pain.



## Idea Box

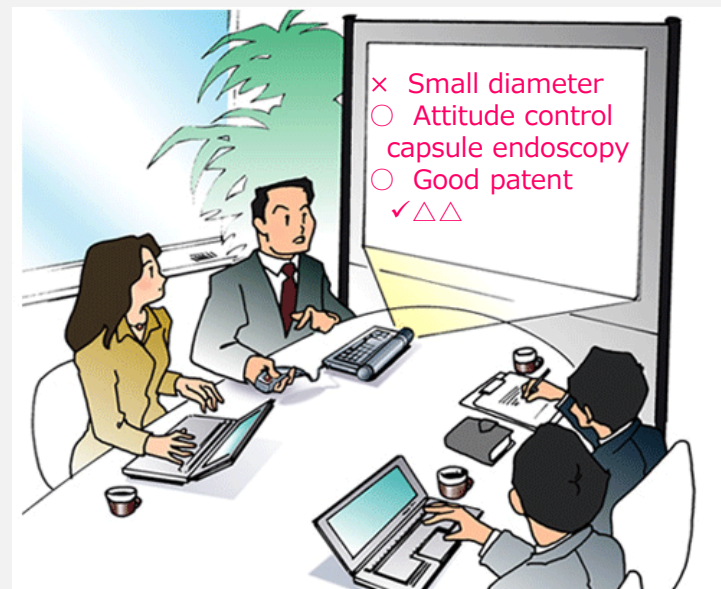


Clinical  
needs



Evaluation

## AMED (Committee of Experts)



Clinical needs are brushed up by a committee of experts in AMED, and connected to a regional support institute and a company.

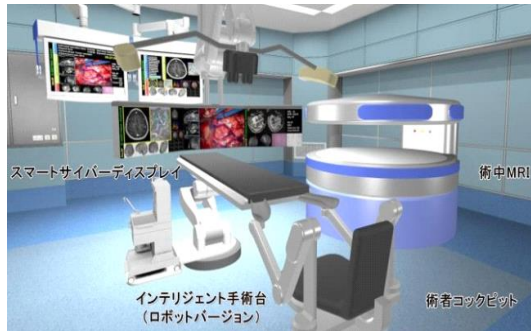
# Development of Medical Devices and Systems for Advanced Medical Services

(budget amount for fiscal year 2016: 4.39 billion yen (4.15 billion yen))

- Fully apply Japan's strengths including robot technology and diagnostic technology, and with a focus on **high-priority fields (surgery assistance robots, artificial tissue and organs, minimally-invasive treatment, diagnostic imaging, home health care)**, develop and implement **the most advanced medical devices and systems in the world** including surgery support technology, diagnostic equipment to discover illnesses at early stages, and minimally-invasive treatment equipment, with collaboration from various ministries.
- In specific terms, corporations, universities, and other parties with cutting-edge technology would form consortiums, and advance the development of medical devices with high development costs and risks with relatively long periods of time required for development.

## <Examples of technological development>

### Applications of robots and ICT technology

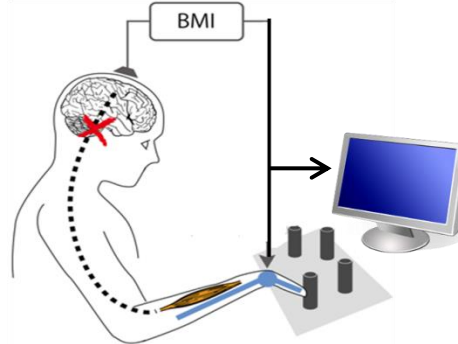


#### Smart treatment rooms

✓ Individual medical devices in operating rooms are connected to each other, to allow **information on patients and medical devices to be centrally managed and shared** with operation staff, and to **support diagnosis and treatment procedures** during surgery.

✓ Applicable information can be **applied for uses such as post-surgery follow-up procedures and physician training**.

### Technology for the recovery of bodily tissue and functions



#### Systems for supporting the recovery of movement functions

✓ **Support can be provided for recovery from severe paralysis** by moving the hands or feet in response to the conditions of detected brainwave activity.

✓ **Rehabilitation content can be automatically set** according the extent of recovery.

### Low-invasiveness, high-precision treatment technology



#### High-precision radiation therapy equipment

✓ By specifically identifying locations of cancer with high precision, **radiation can be applied on a concentrated basis to cancer cells** in the lungs or other organs that are constantly functioning for purposes such as respiration.



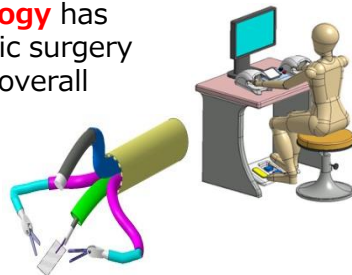
**KPI: Aim to practically implement 5 or more types of revolutionary medical devices by roughly the year 2020.**



# [Reference] Major Research and Development Projects Currently Being Implemented

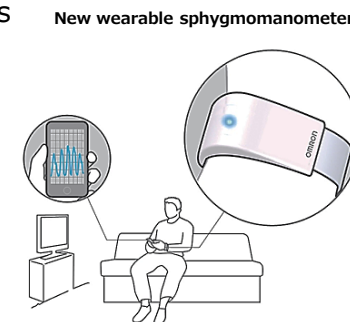
## Flexible endoscopic surgery system

- Using rigid endoscope robots in surgery for pancreatic cancer and other disorders is difficult, and so abdominal operations are still the mainstream procedure.
- A combination of Japan's strengths in flexible endoscopes and **robot technology** has led to the development of an endoscopic surgery system allowing physicians to have an overall view of the operating field during its use.



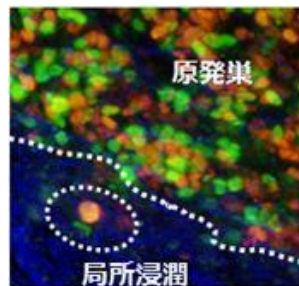
## Diagnosis support technology applying ICT

- While the **application of ICT technology** in medical fields has advanced, measures for tabulating and analyzing collected medical information and other resources and then applying it to treatment are still being developed.
- Diagnosis support devices and systems integrated with new devices are being created, and systems enabling the use of **quantified medical information at clinical sites** are being developed.



## Minimally-invasive analysis technology for cancer

- The tissue that is formed in cancer cases and its characteristics affect the difficulty of its treatment, and if it has proceeded to spread from the primary tumor at the stage of discovery, treatment becomes particularly difficult.
- Cutting-edge **imaging technology** is being applied to minute cancer cells that have spread to lymph nodes or other regions, and technology is being developed to identify and evaluate tissues and parts of the body where they have formed, with **low invasiveness and high precision**.

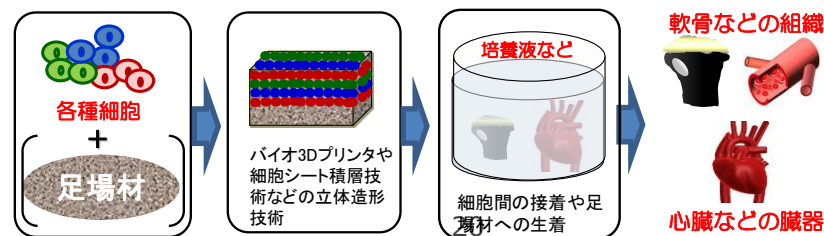


Visualizing cancer cells with optical technology

## 3-dimensional bio-implants

Creation of 3-dimensional tissue and organs using iPS cells or other methods

- With the goal of practical implementation of regenerative medicine products, 3-D modeling technology such as **bio 3-D printers or cell sheet lamination technology** is being used to create 3-dimensional tissue and organs including bones, blood vessels, and hearts.



# [Reference] The 6th Robot Awards (Medical-Related Division)

## Fully-automated continuous thin-slicing apparatus

### Tissue-Tek Smart Section

Sakura Finetek Japan Co., Ltd., etc.

- **Full automation of the work processes** for sample collection from patient specimens, which had been the work of technicians carrying out pathological diagnosis.
- At the same time, misidentification of specimens and mixtures of differing samples can be prevented to achieve **improvements in safety**, specimens (sections) can be collected with low variation, and **accuracy can be improved** through quality checks and storage.



## Surgical assistance robot iArmS

Denso Co., Ltd., etc.

- Surgical operations involving blood vessels and sutures 1 mm in size or smaller can require more than 12 hours to perform. The burden of this work can be reduced by fixing a physician's arm in place **to assist his or her motion**.
- Through the use of sensor and motor technology, a physician is able to freely move to a desired position (**high operability**) but also has his or her arm secured in place during operation, reducing trembling and fatigue of the arm (**high safety**).



# Items

- Trends in Japan's medical device industry
- Industrial policies for medical devices carried out by the government overall and by the Ministry of Economy, Trade and Industry

☆ Medical device development across all of Japan

Promotion of collaboration between medicine and industry: Construction of the “Network for Supporting Development of Medical Devices”

Development of the most advanced medical devices in the world

☆ **Arrangement of a regulatory and institutional environment to facilitate medical device development and commercialization**

☆ Promotion of overseas deployment with medical devices and technology integrated together with services

# Formulation of Medical Device Development Guidelines (Manuals)

## Medical Device Development Guidelines (Manuals)

Prepare **industrial evaluation standards**, etc. to be considered at the time of development.



## Evaluation indices for next-generation medical devices

Prepare **evaluation indices** to be used in reviews, based on regulatory science.

| Medical Device Development Guidelines (Manuals)<br>[Ministry of Economy, Trade and Industry]<br>31 cases   | Evaluation indices for next-generation medical devices<br>[Ministry of Health, Labour and Welfare]<br>25 cases  |
|--|---|
| (Major guidelines) <ul style="list-style-type: none"><li>○ High-performance artificial heart systems</li><li>○ Fracture reduction support systems</li><li>○ Custom-made bone connecting materials</li><li>○ Custom-made artificial knee joints</li><li>○ <b>Basic concepts (manuals) for health software development</b></li><li>○ Guidelines (manuals) for confirming compatibility in operating procedure changes for human cell culturing processes</li></ul> | (Major evaluation indices) <ul style="list-style-type: none"><li>○ Evaluation indices for clinical evaluation of next-generation high-performance artificial hearts</li><li>○ Evaluation indices related to fracture reduction support equipment</li><li>○ Evaluation indices related to custom-made implants of bone connecting materials for plastic surgery</li><li>○ Evaluation indices related to custom-made artificial knee joints for plastic surgery</li><li>○ Evaluation indices related to custom-made artificial hip joints</li></ul> |



# Review of Regulations Involving Stand-Alone Software (Programs)

- According to the amendments of the Pharmaceutical Affairs Act, **stand-alone programs** are subject to regulations

Pharmaceutical and Medical Device Act



Software component  
(program)

Software  
installed in  
general-purpose  
equipment

**Programs considered alone shall be subject to the regulations of the Pharmaceutical and Medical Device Act.**

- **Operation in the industry**  
(applying to software not subject to laws and regulations)
  - In August 2014, the **Good Health Software Promotion Council (GHS)** was established.
  - Based on “Development Guidelines (Manuals)”, **“Voluntary Industry Standards”** are prepared by operating entities.
  - Individual corporations make **“Self-Declarations of Conformity”** and publicly release information necessary to secure their objectivity.

[Example of products subject to self-declarations of conformity]

- Clinical information system (Nihon Kohden)  
Consolidation and sharing of waveform data and information obtained from monitors, such as electrocardiograms and blood pressure data in addition to measurement data from bedside monitors and various devices.
- Comprehensive health system (Toshiba Medical)
- Electronic medical chart system (Kameda Healthcare Informatics), etc.

# Items

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# Issues Related to the International Deployment of Medical Services and Devices

- The importance of international deployment of medical services and devices is clearly indicated in the “Japan Revitalization Strategy” and “Health and Medicine Strategy”. **Awareness of this matter by corporations, universities, and other parties is rising, and initiatives for international deployment are being strengthened.**
- In order to further advance international deployment, **the construction of effective business models for entering the markets of other countries** and **the enhancement of collaboration with related ministries and agencies** will be required.

## Current situation

### (1) Activities of corporations

- There are steps underway to strengthen internal systems to enhance initiatives intended for international deployment.
- Steps to form joint projects with local medical institutions.

### (2) Activities of universities

- Strengthen collaboration with overseas universities, focusing on medical human resource development.

(Example) Nagoya University + Hue University College of Medicine and Pharmacy (Vietnam):

Cooperation with human resource development in the endoscopic medicine field

Tokyo Medical and Dental University + University of Sao Paulo (Brazil):

Cooperation with human resource development in the colon cancer examination field

International University of Health and Welfare + University of Medicine 1, Yangon (Myanmar)

Cooperation with human resource development in the medical image interpretation and pathological diagnosis fields

## Future issues

### (1) Necessity for market cultivation through steps such as effective business models, human resource development, and system construction

- Breaking away from the business of simply “selling off” medical devices on a unit-by-unit basis.
- Construction of networks with major local academic societies, universities, and other parties, and market cultivation through them.
- Reduction of business and investment risks (diversification of investment formats)

### (2) Necessity for enhanced collaboration between related ministries and agencies

- Apply support systems and initiatives by related ministries and agencies on a flexible basis, according to the above business models.

# Support Projects for Medical International Deployment Implemented by the Ministry of Economy, Trade and Industry (Overview)

- Since the 2011 fiscal year, projects that show promise for the **international deployment of medical devices and services (outbound)** have been adopted through public invitation, and support has been provided for their FS studies and verification. Up to fiscal 2014, **FS studies and verification projects were implemented for approximately 60 cases in 19 countries. From the 2015 fiscal year, the adoption criteria, such as the effectiveness of project deployment methods, will be clarified**, and strategic and prioritized support will be provided.
- **Initiatives to facilitate the reception of foreign patients (inbound) will also be expanded.**

2011 to 2014 fiscal years

## Promotion Project for the Internationalization of Medical Devices and Services (1 billion yen)

(1) Project for Overseas Deployment Verification and Profitability Investigation

➤ Publicly-invited commissioned project

➤ Adopts a wide variety of projects from various fields

[Adopted cases] Fiscal 2011: 8

Fiscal 2012: 22

Fiscal 2013: 29 (\*)

Fiscal 2014: 21

(2) MEJ mission dispatch, staging of overseas seminars

(3) Inbound environment arrangement projects  
(actual inbound situation research projects, domestic seminars)

\* In fiscal 2013, a revised budget (Accelerating Project for Overseas Development of Japanese Medical Technologies and Services: 2 billion yen) was applied, and additional support was provided to promising projects from among the initial budget adoption projects.

2015 fiscal year

## Project for Advancing the Creation of Medical Technology and Service Bases (740 million yen)

### (1) Research Project for Advancing and Verifying the Creation of Medical Bases

➤ Publicly-invited subsidized project (2/3 subsidy for small-to medium-sized companies, 1/2 subsidy for large companies)

➤ Provide support on a prioritized basis according to criteria such as competitiveness of medical devices and effectiveness of business deployment methods.

➤ Public invitation period: May 19 to June 9, 2015

➤ Adopted cases: 12

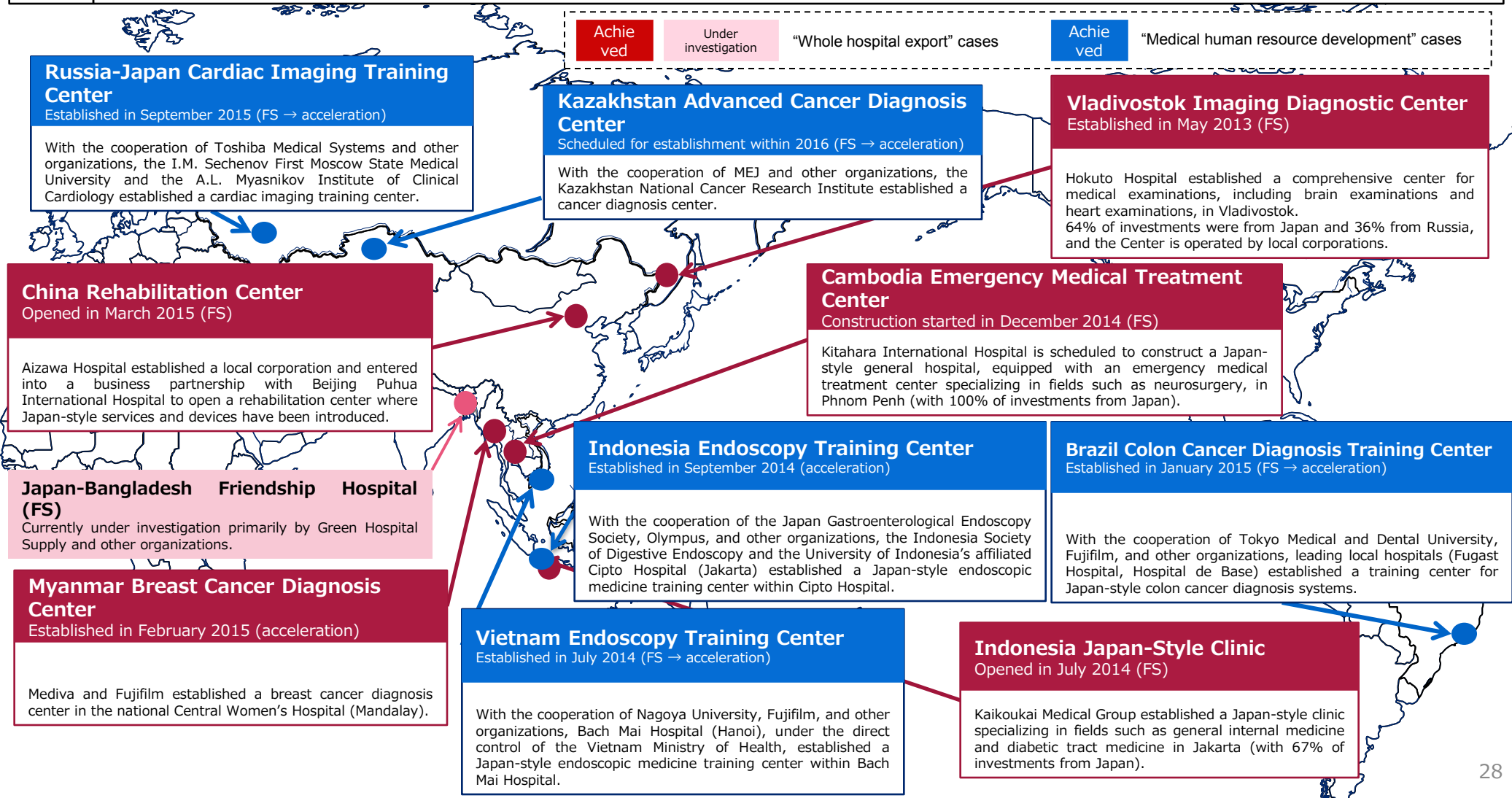
### (2) MEJ mission dispatch, staging of overseas seminars

(3) Inbound environment arrangement projects  
(inbound verification research projects, domestic seminars)

Further collaboration with JICA (ODA projects, private collaboration projects, etc.), HIDA (human resources development projects), and JETRO

# Status of Initiatives to Create New Business Models

- In outbound verification projects currently being implemented by the Ministry of Economy, Trade and Industry, **projects based on new business models** are being formed.
- (1) **Diversification of the “Whole Hospital Export” model**: Construction of project models for appropriate division of business and investment risks
- (2) **Market cultivation through medical human resource development**: Establishment of training centers in teaching hospitals and other locations



# [Reference] Market Cultivation in Combination with Human Resource Development

- With mutual cooperation between **Japanese and Indonesian academic societies, universities, and corporations**, a Japan-style endoscopic medicine training center was established in **Cipto National Hospital, a core hospital (teaching hospital)**.
- **Practical instruction is being provided to Indonesian physicians** at this center. Furthermore, a system was established where physicians who have completed this training are **certified as physicians who have acquired technical proficiency** in current endoscopic medicine by the Indonesian Society of Digestive Endoscopy.
- **By conducting training at a teaching hospital**, Japan-style endoscopic medicine can be spread and expanded, to develop endoscopic medicine and **expand the market for Japan-produced endoscopes**.

**(1) Project is formed by related parties from both Japan and Indonesia.**

[Japan side]

- Japan Gastroenterological Endoscopy Society
- Kobe University
- Olympus

[Indonesia side]

- Indonesian Society of Digestive Endoscopy
- University of Indonesia
- Cipto National Hospital

**(2) Establish a Japan-style endoscope training center in Cipto Hospital.**



**\*Part of the establishment expenses were subsidized by the Ministry of Economy, Trade and Industry.**

**(3) Carry out training for Indonesian physicians and certify physicians who have completed the training.**



# Future Direction

- By **encouraging original ideas from private business operators** and also **planning for more effective collaboration with the initiatives of related ministries and agencies**, we will strategically promote the international deployment of medicine with government and the people united together.

## (1) Diversification of the “Whole Hospital Export” model (establishment of Japan-style medical bases) model

- Give priority to supporting projects with the potential to be **“showcase projects”** for Japan-style medical services and Japan-produced medical devices.
- Actively support projects for arranging **bases that can provide diagnostic and examination services contributing to early detection and treatment of illnesses**, and **bases that have the potential to become locations that send patients to Japan**.
- Also actively support projects that do not only involve investments from Japan, but involve **joint investments with local partners**.
- Promote the application of **investments and financing by institutions such as public sector financial institutions**.  
(Example)
  - Application of financing by JICA
  - Application of financing by the Innovation Network Corporation of Japan

## (2) Market cultivation for medical devices and services through measures such as medical human resource development and construction of systems

- Support initiatives based on collaboration with **medical institutions such as academic societies, university hospitals, and university faculties of medicine**.
- Support initiatives that are **packaged together with medical human resource development**.  
(Examples) • Establish Japan-style medical training centers in locations such as **teaching hospitals**.
  - Implement training in Japan that accepts human resource training participants.
- Support initiatives that can lead to **establishing systems** in target countries.  
(Example) • Establish certification systems for physicians who have acquired skill in Japan-style medicine.
  - Establish systems for testing the performance of devices.
- Enhance initiatives that apply synergistic effects with **ODA projects**.  
(Example) Construct bases that provide Japan-style medicine to medical institutions supported by ODA.

→ Support through initiatives such as MEJ mission dispatch / Further collaboration also with initiatives by related ministries and agencies, JICA , and other organizations