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
- Cardiac pacemakers
- Catheters
- Syringes
- Heart-lung machines (roller pumps, artificial lungs)

(2) Diagnostic devices
- PET and PET-CT systems
- Endoscopes (videoscopes)
- MRI
- Ultrasonic diagnostic equipment
- X-ray photography film, thermometers, sphygmomanometers, electrocardiographs, etc.

(3) Other devices
- Dental materials
- Dental units
- Home-use massage equipment
- Surgical gloves
- Contact lenses
With the progress of aging populations and the expansion of medical demand in developing countries, the global market is growing. Import 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

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) Worldwide Medical Market Forecasts to 2019

○ 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.

Source: Ministry of Health, Labour and Welfare
“Statistics of Production by Pharmaceutical Industry”
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.

**Structure of Japan’s Medical Device Market**

**Diagnostic-type medical devices**
- Market scale: 703.6 billion yen (25%)
- Average growth rate: 1.3%

**Treatment-type medical devices**
- Market scale: 1.4853 trillion yen (53%)
- Average growth rate: 4.2%

**Other medical devices**
- Market scale: 596.8 billion yen (21%)
- Average growth rate: 1.6%

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.

**Share of imported products as of 2014**
- Diagnostic Imaging: 47.4%
- Biological phenomena measurement and monitoring systems: 29.2%
- Medical Specimen examination devices: 35.4%
- X-ray related equipment and instruments for diagnostic imaging: 43.8%
- Devices for facilities: 27.9%
- Biological function support and prosthetic devices: 62.5%
- Devices for treatment or surgical operations: 42.5%
- Medical products for medical use: 70.9%
- Ophthalmologic supplies and related products: 71.1%
- Dental materials: 79.0%
- Dental devices: 23.5%
- Home-use medical devices: 36.6%
- Dental supplies: 37.3%
- Dental devices: 62.8%

(Source) From the Ministry of Health, Labour and Welfare “Statistics of Production by Pharmaceutical Industry”
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☆ Medical device development across all of Japan

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  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 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.
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).

<table>
<thead>
<tr>
<th>Classifications according to risk</th>
<th>General Medical Devices</th>
<th>Controlled Medical Devices</th>
<th>Specially Controlled Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>I</td>
<td>II</td>
<td>III</td>
</tr>
<tr>
<td>Nearly zero risk of impacting human life or health</td>
<td>Some risk of impacting human life or health</td>
<td>Risk of severely impacting human life or health</td>
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<table>
<thead>
<tr>
<th>Retailers</th>
<th>Notification</th>
<th>Specially Controlled Medical Device Retailers Permission</th>
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</thead>
<tbody>
<tr>
<td>Marketing Authorization Holders *1</td>
<td>Third-Class Medical Device Marketing Authorization Holders Permission</td>
<td>First-Class Medical Device Marketing Authorization Holders Permission</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturers *2</th>
<th>Registration (simplified from “Permission” according to the amendments to the act)</th>
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<tbody>
<tr>
<td>Procedures for Medical Devices</td>
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<tr>
<td>“Notification”</td>
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</table>

| “Certification” or “Approval”     |                                                                                     |

For items with certification standards, third-party “Certification” by private registration certification institutions is possible. For all other items, “Approval”. (*“Certification” is possible for some Class III items according to the amendments to the act)*

<table>
<thead>
<tr>
<th>Example medical devices</th>
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<tr>
<td></td>
<td>Electrically-operated patient beds</td>
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</table>

*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)

- 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

- 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**

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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.

Suzuki Precion
(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.
(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.

(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.
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

Release to market

Marketing and financial strategies

Pharmaceutical strategies

Development, testing

Manufacturing and service provision systems

Sales and marketing

Market searches

Concept design

Production and intellectual property 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.

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.

Collaboration and support

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

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

Network for Supporting Development of Medical Devices: Consultation Reception Form

Support plan

<table>
<thead>
<tr>
<th>作成日</th>
<th>年 月 日</th>
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<tbody>
<tr>
<td>コンタクト方法</td>
<td>( ) 対面</td>
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<tr>
<td>場所</td>
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<td>企業名</td>
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<td>所属・役職</td>
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<td>連絡者名</td>
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<tr>
<td>電話番号</td>
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Support plan

<table>
<thead>
<tr>
<th>2014年度年度</th>
<th>4月～6月</th>
<th>7月～9月</th>
<th>10月～12月</th>
<th>1月～3月</th>
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Support plan
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.

- Fund supply 5%
- Consortium 7%
- Market trend 3%
- Seeds of technology 6%
- Market cultivation 44%
- Technological development 16%
- Approval application 14%
- Clinical evaluation 5%

N=254
### 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.

### 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%.
“The 2nd 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**

**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.
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.

**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.
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).

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.
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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.

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<tbody>
<tr>
<td>(Major guidelines)</td>
<td>(Major evaluation indices)</td>
</tr>
<tr>
<td>○ High-performance artificial heart systems</td>
<td>○ Evaluation indices for clinical evaluation of next-generation high-performance artificial hearts</td>
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<tr>
<td>○ Fracture reduction support systems</td>
<td>○ Evaluation indices related to fracture reduction support equipment</td>
</tr>
<tr>
<td>○ Custom-made bone connecting materials</td>
<td>○ Evaluation indices related to custom-made implants of bone connecting materials for plastic surgery</td>
</tr>
<tr>
<td>○ Custom-made artificial knee joints</td>
<td>○ Evaluation indices related to custom-made artificial knee joints for plastic surgery</td>
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<tr>
<td>○ Basic concepts (manuals) for health software development</td>
<td>○ Evaluation indices related to custom-made artificial hip joints</td>
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<tr>
<td>○ Guidelines (manuals) for confirming compatibility in operating procedure changes for human cell culturing processes</td>
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Collaboration
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)

- 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.
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○ 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
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.

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### 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)

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### 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)

* 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.
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.

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**Russia-Japan Cardiac Imaging Training Center**
Established in September 2015 (FS → acceleration)

With the cooperation of Toshiba Medical Systems and other organizations, the I.M. Sechenov First Moscow State Medical University and the A.L. Myasnikov Institute of Clinical Cardiology established a cardiac imaging training center.

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**Kazakhstan Advanced Cancer Diagnosis Center**
Scheduled for establishment within 2016 (FS → acceleration)

With the cooperation of MEJ and other organizations, the Kazakhstan National Cancer Research Institute established a cancer diagnosis center.

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**Cambodia Emergency Medical Treatment Center**
Construction started in December 2014 (FS)

Kitahara International Hospital is scheduled to construct a Japan-style general hospital, equipped with an emergency medical treatment center specializing in fields such as neurosurgery, in Phnom Penh (with 100% of investments from Japan).

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**Brazil Colon Cancer Diagnosis Training Center**
Established in January 2015 (FS → acceleration)

With the cooperation of Tokyo Medical and Dental University, Fujifilm, and other organizations, leading local hospitals (Fugast Hospital, Hospital de Base) established a training center for Japan-style colon cancer diagnosis systems.

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**Vietnam Endoscopy Training Center**
Established in July 2014 (FS → acceleration)

With the cooperation of Nagoya University, Fujifilm, and other organizations, Bach Mai Hospital (Hanoi), under the direct control of the Vietnam Ministry of Health, established a Japan-style endoscopic medicine training center within Bach Mai Hospital.

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**Indonesia Japan-Style Clinic**
Opened in July 2014 (FS)

Kaikoukai Medical Group established a Japan-style clinic specializing in fields such as general internal medicine and diabetic tract medicine in Jakarta (with 67% of investments from Japan).

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**Japan-Bangladesh Friendship Hospital (FS)**
Currently under investigation primarily by Green Hospital Supply and other organizations.

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**China Rehabilitation Center**
Opened in March 2015 (FS)

Aizawa Hospital established a local corporation and entered into a business partnership with Beijing Puhua International Hospital to open a rehabilitation center where Japan-style services and devices have been introduced.

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(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.

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

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