Dental Devices & Materials in Japan

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1. Introduction

1.1. Report Description

This market report offers an overview of the Japanese Dental Devices and Materials market by analysing macro trends and their impact on the market and segments by products. Further, it discusses the key market drivers, restraints and opportunities extant in the Japanese market.

The purpose of this report is to provide factual information as well as recommendations and advice that will be of immediate benefit and use to foreign companies interested in entering or leveraging their positions in the Japanese Dental Devices and Materials market.

1.2. Research Methodology

This report is built using data and information sourced from proprietary databases and secondary research. It considers various available Japanese-language sources via membership to the largest repository of Japanese-language materials in the world (Japan’s Marketing Data Bank). English-language sources have also been searched, although Japanese-language sources took precedence.

2. Summary

Data on Japan’s hyper-aging population show that the elderly will make up a significant demographic force in the future and represent great potential for products and services that complement healthy living, provide added convenience and have an impact on individuals’ quality of life. The relationship between the medical and dental fields is becoming more apparent. This report gives an overview of current Dental Devices and Materials market development, considering macro trends impacting the market as well as broader categories; products, key market drivers, restraints and future opportunities of the market including guidelines that need to be considered by foreign manufacturers when entering the Japanese market.
3. Macro Trends impacting the Dental Devices and Materials Market in Japan

3.1. Aging of Japanese Population

One of the most important macro trends defining the Japanese market is that it has the most rapidly aging population in the world. In March 2013, the Ministry of Internal Affairs and Communications (MIC) announced the total population of Japan was 126.39 million people. The number of elderly people aged 65 or over surpassed 30 million for the first time (30.83 million), constituting 24% of the total population and marking a record high.

Reference: http://www.nikkei.com/article/DGXNASFS2704B_Y3A820C1MM8000/

This percentage of elderly in the population is the highest in the world and is projected to rise to 38.8% by 2050 (Fig. 1).

Figure 1: Changes in the population pyramid

![Population Pyramid](image)

Source: Statistic Bureau, MIC; Ministry of Health, Labour and Welfare (MHLW), 2013

The growth in the number of older people has been matched by a shrinking of the younger population. In 1950 those aged under 15 made up 35.4% of the total population, but this had fallen to 13.0% by 2012 and will fall further to approximately 9.7% by 2050. Note also that those of working age (15-65) constituted 62.9% of the population in 2012 (two thirds) but will account for only 51.5% (half) by 2050.

The speed of Japan's population aging is much faster than the experienced by advanced Western European countries or the USA, but the trends are similar throughout the industrialized world. The aging of
the population has been intensified by falling birth rates and increasing longevity as a result of better medical care.

With all this in mind, it is clear that the elderly will make up a significant demographic force in the future and represent great potential for products and services that complement healthy living, provide added convenience and have an impact on their quality of life.

3.1.1. Oral Healthcare in Japan

The aging of Japan dramatically impacts the nation’s healthcare system (in general) and oral healthcare and dentistry (specifically) since it is widely recognized that oral health is fundamental to general health. In 2013, the Japanese Dental Association began to emphasize the link between diabetes and oral health and, overall, the relationship between the medical and dental fields is starting to grow.

The Japan Dental Association and other private organizations have promoted dental health for many years. Activities for spreading the concept of dental hygiene have been conducted as part of educational drives. In the past, dental health measures focused on decayed teeth and applied mainly to young children at a time of life rendering them particularly susceptible to tooth decay. These measures included dental health examinations for 18-month-olds and three-year-olds, and oral examinations and health guidance for expectant and nursing mothers as well as babies and toddlers. Due to the increase in the aging population in recent years, however, dental health measures have focused on periodontal diseases to promote dental health services for adults and the aged.

Multiple studies have shown that people with periodontal diseases are more likely to develop other physical diseases compared to people without periodontal diseases. A special foundation study on oral health and aspiration pneumonia showed that better oral health care could help prevent aspiration pneumonia among bedridden elderly people. Also, with Japan’s aging population, the people aged 35 or above (especially those between the ages of 55 and 74) are expected to have increasingly high dental consultation needs, since people in that age group have the greatest need for dental care according to the Ministry of Health, Labour and Welfare (MHLW).


3.1.2. Government Expenditures

According to Japan’s Ministry of Finance (MOF), social security costs amounted to 29.1224 trillion yen, or 31% of the total annual government expenditure of 2013 (Fig. 2). The Ministry of Health, Labour and Welfare (MHLW) budgeted 53.6 billion yen for “functional enhancement of the medical supply system” and 92 million yen for “promotion of dental health-care measures.” Due to the aging trend, the budget related to the medical field will be increased in 2014 (Table 1).
Figure 2: Amount of General Account Annual Government Expenditures

Table 1: Calculated Government Expenditures of Dental Healthcare

<table>
<thead>
<tr>
<th>Article</th>
<th>Budget 2013</th>
<th>Budgetary Request 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Main item</td>
<td>Sub item</td>
</tr>
<tr>
<td>Providing safe and high-quality medical</td>
<td>Functional</td>
<td>Promotion of dental</td>
</tr>
<tr>
<td>and nursing care</td>
<td>enhancement</td>
<td>healthcare measures</td>
</tr>
<tr>
<td></td>
<td>of medical</td>
<td></td>
</tr>
<tr>
<td></td>
<td>supply system</td>
<td></td>
</tr>
<tr>
<td></td>
<td>536</td>
<td>0.92</td>
</tr>
</tbody>
</table>

* The measures secure a promotion of oral and dental insurance policies based on the situations in each area and considering different requirements such as an offer of dental care insurance services for disabled people and those who require nursing care, training of those who are responsible for it, and cooperation with doctors and dentists to demonstrate the safety and effects of pioneer approaches.

Source: “Main Articles List of Budgetary Request” by Ministry of Health, Labour and Welfare, 2014
3.1.3. Medical Insurance System (General Health Care)

Japan's health insurance system, which covers medical and dental care, was made obligatory to all citizens in 1961 and is operated by either the national or local government. While there are several official Japanese health insurance systems, all citizens must be covered by one of them. Patients are free to choose whether or not to take advantage of health insurance treatment.

Japan's health insurance system is broadly divided into two categories; employees and national. The employee plan covers company employees, while the national plan covers residents of the same area, who are insured by the local government.

The system operates with the insurer collecting insurance payments from the insured. Under the present health insurance system patients make partial payments of the actual medical charges to the hospital or clinic, and the Social Insurance Medical Care Fee Payment Fund reimburses the hospital or clinic for the medical treatment given. Thus, the patient and the review/reimbursement organization share the medical expenses.

The previously discussed development of Japan as a hyper-aging and child-poor society is reflected in increasing national healthcare expenditures. Nearly half of the expenditures are spent on insured people aged 65 and older suffering from adult diseases, e.g., malignant neoplasm, ischemia disease or diabetes, with an observed tendency to increase national healthcare expenditures in coming years. As figure 3 shows, adult diseases constitute 56% of diseases resulting in fatalities.

Figure 3: Cause-specific Death Rate in 2012

Due to the necessity of handling increasing health expenditures, the Japanese Government implemented a new insurance scheme, named "Health Insurance for the Old-Old" for those aged 75 and older in 2008. It established new insurance bodies and intended to ensure the funding of health care for the elderly by clarifying responsibilities. It aims to increase transparency regarding who pays for the healthcare costs of...
the elderly by establishing the new insurance plan, separated from other insurance options, and making explicit rules regarding who contributes how much to health care for the aged.

Under the previous system, the elderly were enrolled either with various public health insurers or were co-insured with their working (adult) children at no charge, as well as being covered by the Health Care for the Aged scheme. This scheme received cross-subsidies from public health insurers as well as subsidies from the general budget of national and local governments. Therefore, the relationship between who pays the premium and whom the insurance reimburses was complex and difficult to understand.

Since those subsidies to the Health Care for the Aged scheme were projected to increase dramatically in the next 10 years, the new insurance scheme establishes a more accountable and transparent system.

Overview of the Japanese Medical Insurance System in Japan:

- 75 years or older: 10% co-payment – Those with income comparable to current workforce have a co-payment of 30%
- 70-74 years old: 20% co-payment* – Those with income comparable to current workforce have a co-payment of 30%
- Start of compulsory education to 69 years old: 30% co-payment – Yet to start compulsory education 20% co-payment

* Frozen at 10% for the 12-month period from April 2008

Reference: http://www.mhlw.go.jp/bunya/iryouhoken/iryouhoken01/dl/01_eng.pdf

Medical Insurance System (Dental Care)

Dental care costs are handled differently depending on some factors such as cavity development, cavity numbers, and patients either covered/ uncovered by insurance. All surgical and conservative treatments and certain prosthetic treatments are included in the scope of benefits under the health insurance program. Certain prosthetic, implant and orthodontic treatments are not covered. In such cases, dental fees are negotiated between the dentist and patient, with the patient paying the entire sum directly to the practitioner.

Dentistry Medical Treatment Special Contract

Some insurance companies offer a so-called “dentistry medical treatment special contract” that covers additional treatments such as crowns, pontics, and implants that are usually services not covered by insurance. Such contracts are projected to increase due to a higher demand for aesthetic dentistry.
3.1.4. Initiatives and Programs to Promote “Oral Healthcare” and “Dental Care”

Oral health care is not only an effective strategy for the prevention, early diagnosis, and treatment of orofacial disease and disorders, but also an essential component of general health promotion programs. Thus, various efforts are being made to promote dental health over a person’s lifetime.

Since 1989, The Ministry of Health, Labour and Welfare (MHLW) has been promoting the so-called “8020 Movement” aiming to help Japanese people keep 20 or more of their own teeth until reaching age 80. Furthermore, in December 2000, the Japan Dental Association proposed the establishment of the “8020 Promotion Foundation,” that has been active in promoting better oral health among the Japanese population over proceeding years.

The “Kenko, or Health, Nippon 21” plan as proposed by Ministry of Health, Labour and Welfare in 2001 established oral health objectives for each stage of life based on:

1) Preventing dental cavities for preschool children
2) Preventing dental cavities for children of school age
3) Preventing periodontal diseases in adults
4) Preventing loss of teeth

With regard to preventing loss of teeth, the plan set out a dental health objective to be attained by 2010, which was to increase the percentage of people who still have 20 of their own teeth at age 80 to 20% or more and 50% or more at age 60. According to a 2011 final assessment by the Ministry of Health, Labour and Welfare’s (MHLW) “The Team of Healthy Japan Assessment Effort” promoted actions are leading to positive results. 26.8% of 80 years old people had more than 20 of their own teeth and 56.2% kept more than 24 teeth at age 60.

Reference: http://www.8020zaidan.or.jp/english/index.html

In addition to the dental instruction as part of school education and promotions of the “8020 Campaign,” the Japanese government established the Long-Term Care Insurance Law and insurance for the handicapped. Furthermore, a measure pertaining to waiving of fees, under the in Health and Medical Service Law, for the Elderly has been carried out. In connection with these initiatives, trials for keeping QDL (quality of daily living) and ADL (active daily living) have been conducted.

The “8020 Campaign” and “Health Japan 21” are complementary to each other and the projects to accomplish the goals of “Health Japan 21” have been implemented within the framework of the “8020 Campaign.” As dental health was explicitly stated as a key point in the Health Promotion Act, further promotion of lifelong dental health projects (e.g., 8020 Campaign), such as creating forums and conducting research in 2014, is expected.

The elderly also have caused the regulations and work roles pertaining to hygienist’s to expand. Dentists and hygienists are now visiting nursing homes together, and visiting the elderly in their own homes, to help them brush their teeth and restore their bite function. The biggest problem is that some of the elderly can’t swallow. It’s very important for the dentist and hygienist to work together to solve this problem. Dentists and
Hygienists are also working with local and city leaders to establish oral health care programs to help the elderly and handicapped. Some hygienists even have contracts with the local governments to help provide services.


Dental technicians in Japan must have a license (national certification) and fabricate dentures (false teeth), dental prosthesis (implants/crowns), and perform other procedures based on prescriptions written by dentists. Manufacturing dentures and crowns suitable for various patients is made possible through close cooperation with dentists. The early development of a concept of team medicine that includes dentists and dental technicians, as well as dental hygienists, has led to a sophisticated level of dental care.

3.2. Dental Aesthetic and Preventive Dental Care

According to the “Dental Device Industry Vision,” issued in 2007 by the Japanese Association for Dental Science and the Japan Dental Trade Association, Japanese people are becoming more conscious about their oral health and dental aesthetics. This has led to increased demand for aesthetic dental services such as straightening teeth, correcting overbites or preventing bad breath. The Vision refers to a survey that states that only 45% of people are satisfied with their oral health, whereas the ratio of people who are satisfied with their general health is closer to 70%.

The main perceived problems regarding oral health are teeth colour, teeth alignment and bad breath, etc. On the one hand 80% of Japanese think it is necessary to have regular check-ups at dental clinics while on the other hand the number of people who actually attend check-ups frequently is as low as 25%. However, 55% of the respondents are willing to pay even more in order to receive advanced dental work such as dental implants, orthodontics, etc., that are not reimbursed by National Health Insurance (NHI).


3.3. Advancement in Diagnostic and Treatment Technologies

Cavity treatments and prosthetic treatments have mainly been conducted as general treatments at dental clinics. However, the prevalence of dental diseases has been changing significantly due to progressive treatment technologies and the decrease in cavity prevalence rates thanks to raised consciousness of cavity-prevention (Fig. 4). Other influences/impacts are an enhancement of conservative treatments, i.e., preserving the patients teeth condition as much as possible, and an increase in the rate of gum disease due to an increase “surviving teeth” numbers.
Figure 4: Dental Disease Structure (Main Cause of Dental Extraction)

Dental Caries, 32.4%
Gum Disease, 41.8%
Fractured Tooth, 11.4%
Others, 12.6%
Correction, 1.2%
Invalidity, 0.6%
N/A, 0.1%

Source: “The Report of Main Cause of Permanent Teeth Extraction Study” by 8020 Promotion Foundation
4. Market Overview

4.1. Definition of Dental Devices and Materials in Japan

According to Japan’s Pharmaceutical Affairs Law (PAL), Article 2 Appendix, Dental Devices and Materials are considered to be products within the Medical Devices Market.

Dental Devices are applied in diagnosis, treatment and prevention of various dental diseases. The Dental Pharmaceutical Affairs Act classified Dental Materials as (Table 2) – 1) materials put in the oral cavity, e.g., dental metal, dental crowns, baseplates, and dental root canal filler, or 2) other materials, e.g., material for dental impressions, dental wax, dental plaster and plaster material, and dental grinding materials.

Table 2: Dental Materials Controlled by Pharmaceutical Affairs Act

<table>
<thead>
<tr>
<th>1) Materials Put in the Oral Cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dental Metals</strong></td>
</tr>
<tr>
<td>Dental crown, baseplate, and needle metals used for dental filling or artificial teeth adjustment, such as dental gold bullion, dental gold and silver palladium, dental nickel chrome alloy plate, dental cobalt chrome alloy plate, dental cobalt chrome alloy wire</td>
</tr>
</tbody>
</table>

| **Dental Crown Materials**          |
| Materials used as dental crowns for adjustment of porcelain and resin teeth, and materials used for adjustment of artificial teeth such as dental crown plastic and dental porcelain |

| **Dental Baseplates**               |
| Materials used for adjustment of baseplates, such as baseplate plastic |

| **Dental Root Canal Fillers**       |
| Materials to fill a tooth root, such as dental gutta percha |

| **Dental Grinding Materials**       |
| Materials used for connecting gold crowns or filling of carious pits, such as dental phosphoric acid zinc cement, dental silicate acid, and temporary stopping |
2) Materials Not Put in the Oral Cavity

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Impressions</td>
<td>Materials used for impression taking in adjustment of artificial teeth, such as modelling compound and alginate for dental impressions</td>
</tr>
<tr>
<td>Dental Waxes</td>
<td></td>
</tr>
<tr>
<td>Dental Plaster and Plaster Materials</td>
<td>Dental plasters such as dental calcined plaster and dental refractory investment</td>
</tr>
<tr>
<td>Dental Grinding Materials</td>
<td>Materials used for grinding or cutting dental Carborundum disks and dental diamond point</td>
</tr>
</tbody>
</table>

Source: “Examination Encyclopedia Classified by the Type of Business – 3rd edition”, Kinzai Institute for Financial Affairs, February 2012
4.2. Market Size

The total market size for medical equipment in Japan in 2012 was valued at approximately 1.9 trillion yen according to the Pharmaceutical Industrial Production Vital Statistics Annual Report issued in 2013.

In 2012 the net production of Dental Materials decreased by 4.0% compared to 2011, while Dental Devices decreased by 0.7% (Table 3). The Dental Materials composition ratio of all medical equipment was 6.0%, and 2.3% for Dental Devices.

Table 3: Net Production of All Medical Equipment, 2012

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Categories</th>
<th>Net Produce vs. 2011</th>
<th>Composition Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2012 million</td>
<td>2011 million</td>
</tr>
<tr>
<td>1</td>
<td>Operating Equipment and Supplies</td>
<td>468,166</td>
<td>437,399</td>
</tr>
<tr>
<td>2</td>
<td>Medical Imaging Systems</td>
<td>292,526</td>
<td>268,054</td>
</tr>
<tr>
<td>3</td>
<td>Vital Function Auxiliary and Vicarious Components</td>
<td>288,347</td>
<td>265,944</td>
</tr>
<tr>
<td>5</td>
<td>Medical Laboratory Test Devices</td>
<td>158,694</td>
<td>145,221</td>
</tr>
<tr>
<td>6</td>
<td>Dental Materials</td>
<td>113,094</td>
<td>117,791</td>
</tr>
<tr>
<td>7</td>
<td>Home Medical Care Devices</td>
<td>80,664</td>
<td>89,975</td>
</tr>
<tr>
<td>8</td>
<td>Devices and Materials Related to Medical Imaging X-ray</td>
<td>61,516</td>
<td>72,782</td>
</tr>
<tr>
<td>9</td>
<td>Ophthalmologic Materials and Related Products</td>
<td>56,422</td>
<td>50,879</td>
</tr>
<tr>
<td>10</td>
<td>Dental Devices</td>
<td>43,724</td>
<td>44,013</td>
</tr>
<tr>
<td>11</td>
<td>Curative or Surgical Devices</td>
<td>40,186</td>
<td>42,348</td>
</tr>
<tr>
<td>12</td>
<td>Clinical Equipment and Supplies</td>
<td>27,772</td>
<td>26,059</td>
</tr>
<tr>
<td>13</td>
<td>Copper Equipment</td>
<td>16,249</td>
<td>15,566</td>
</tr>
<tr>
<td>14</td>
<td>Hygiene Materials</td>
<td>4,570</td>
<td>4,864</td>
</tr>
</tbody>
</table>

4.3. Market Segmentation

4.3.1. Breakdown of Key Dental Devices Products

The Dental Devices market in Japan (Table 4) covers nine main segments: Dental Chair units, Computers, Panorama Roentgen, X-Ray CT combinations with Panorama, dedicated X-Ray CT, Digital Image Systems, Laser Therapy Equipment, Dental Roentgen and Microscopes.

R&D published a market overview from 2012 in its “Dental Devices and Materials Yearbook 2014” and according to that, dental chair units have the biggest market share with 34.4 billion yen, followed by X-Ray CT combination with Panorama (22.7 billion yen) and dental computers (19.8 billion yen). These products have market shares of more than 10 billion yen each. The growth market is for X-ray CT Combinations with Panorama, which realised 51.8% growth, which means it has become more general, with sales in 2013 expected to increase by more than 10%. Sales of chair units had been decreasing since 2006 through 2010, and only increased slightly during 2011 and 2012 because X-ray CT Combinations with Panorama, which has been dominating the dental device market, made the budget distribution ration shift, with a part of it returning to the chair unit market, R&D assumes.

Table 4: Market Share of Dental Devices (Top 9 Products)

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2013 Forecast</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Growth</td>
<td>Growth</td>
</tr>
<tr>
<td>Chair Unit</td>
<td>34,405</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>39,185</td>
<td>13.9</td>
</tr>
<tr>
<td>Dental Computer</td>
<td>19,802</td>
<td>4.0</td>
</tr>
<tr>
<td></td>
<td>20,824</td>
<td>5.2</td>
</tr>
<tr>
<td>Panorama Roentgen</td>
<td>6,921</td>
<td>-11.9</td>
</tr>
<tr>
<td></td>
<td>6,770</td>
<td>-2.2</td>
</tr>
<tr>
<td>X-ray CT Combinations with Panorama</td>
<td>22,694</td>
<td>51.8</td>
</tr>
<tr>
<td></td>
<td>25,312</td>
<td>11.5</td>
</tr>
<tr>
<td>Dedicated X-ray CT</td>
<td>1,911</td>
<td>15.4</td>
</tr>
<tr>
<td></td>
<td>1,980</td>
<td>3.6</td>
</tr>
<tr>
<td>Dental Roentgen</td>
<td>681</td>
<td>-13.9</td>
</tr>
<tr>
<td></td>
<td>676</td>
<td>-0.7</td>
</tr>
<tr>
<td>Digital Image System</td>
<td>4,386</td>
<td>-6.1</td>
</tr>
<tr>
<td></td>
<td>4,593</td>
<td>4.7</td>
</tr>
<tr>
<td>Microscope</td>
<td>1,504</td>
<td>-1.3</td>
</tr>
<tr>
<td></td>
<td>1,672</td>
<td>11.2</td>
</tr>
<tr>
<td>Laser Therapy Equipment</td>
<td>4,927</td>
<td>2.8</td>
</tr>
<tr>
<td></td>
<td>4,970</td>
<td>0.9</td>
</tr>
<tr>
<td>Total</td>
<td>97,231</td>
<td>9.2</td>
</tr>
<tr>
<td></td>
<td>105,982</td>
<td>9.0</td>
</tr>
</tbody>
</table>

*Digital Image Systems is total of CCD (Dental Panorama) and IP

4.3.2. Breakdown of Key Dental Materials and Metals

In 2012, total market sales of dental materials, correction materials, internal anchoring systems, implants and metals were 142.7 billion yen, a decline of 4.8% compared to 2011. The market for implants had been expanding because dentists, who wanted to increase their revenue by introducing medical treatment at patient’s own expenditure into their treatment, have been increasing and implants had become more popular among patients. However, this demand has been decreasing rapidly because of the influence of the recession and negative reports in the mass media.

On the other hand, the ceramics market increased by 23.5% in 2012 due to the spread of CAD/CAM and the appearance of new materials. Total sales of all ceramics are forecasted to have reached 143.2 billion yen (0.4% up) in 2013. R&D assumes that sales of dental materials in 2013 will increase by 2.4% because all ceramics will continue rising, although implant sales will decrease by 3.8%, and dental materials will remain at the same level because metal prices will rise in spite of decreasing volumes.

“Dental Metals” refer to Gold and Silver Palladium Alloys, Porcelain-fused-to-metal Alloys, Gold Alloys (Platinum and Added Alloys included), Silver Alloys and Other Dental Metals. They shared 59% of the entire market mentioned above in 2012, a significant decrease of 6.3% compared to 2011 due to rising metal costs. It was expected that this trend would stop in 2013 and increase by 0.4%.
Table 5: Market Share of Main Dental Materials and Metals

<table>
<thead>
<tr>
<th>Products Categories</th>
<th>2012</th>
<th>2013 Forecast</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Growth</td>
<td>Growth</td>
</tr>
<tr>
<td>Enhanced Resin Glass Ionomer Cement</td>
<td>2,850</td>
<td>-1.2</td>
</tr>
<tr>
<td>Adhesive Resin Cement</td>
<td>3,875</td>
<td>5.1</td>
</tr>
<tr>
<td>Other Adhesive Cements</td>
<td>500</td>
<td>-5.7</td>
</tr>
<tr>
<td>Composite Resin</td>
<td>4,550</td>
<td>1.1</td>
</tr>
<tr>
<td>Bonding Materials</td>
<td>3,505</td>
<td>2.6</td>
</tr>
<tr>
<td>Rubber Impression Materials</td>
<td>2,924</td>
<td>0.5</td>
</tr>
<tr>
<td>All Ceramics</td>
<td>1,815</td>
<td>23.5</td>
</tr>
<tr>
<td><strong>Dental Materials Total</strong></td>
<td>32,202</td>
<td>1.7</td>
</tr>
<tr>
<td><strong>Correction Materials (Except for machines and equipment)</strong></td>
<td>6,064</td>
<td>5.8</td>
</tr>
<tr>
<td><strong>Internal Anchoring System (Implant Anchor)</strong></td>
<td>188</td>
<td>-0.5</td>
</tr>
<tr>
<td><strong>Implants Total</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fixtures</td>
<td>13,158</td>
<td>-11.6</td>
</tr>
<tr>
<td>Abutments / Superstructure Bodies</td>
<td>7,538</td>
<td>-9.8</td>
</tr>
<tr>
<td>Fixtures</td>
<td>20,696</td>
<td>-10.9</td>
</tr>
<tr>
<td><strong>Dental Metals Total</strong></td>
<td>83,543</td>
<td>-6.3</td>
</tr>
<tr>
<td><strong>Inclusive Sum</strong></td>
<td>142,693</td>
<td>-4.8</td>
</tr>
</tbody>
</table>

4.3.3. Increase in Number of Dental Businesses

The target groups for Dental Devices and Materials can be defined as: dentists, hygienists and technicians. According to Statistics Japan and Japan Dental Technologists Association, the following numbers of dental professionals were operating in Japan in 2012: 108,123 hygienists and 34,613 dental technicians. The Ministry of Health, Welfare and Labour (MHLW) counted 102,551 dentists operating in Japan in the same year.

All types of dental businesses have experienced consistent growth over the past five years and, in particular, the number of dentists and hygienists has increased recently.

Dental hygienists work mostly in clinics, and in hospitals and public/ private health centers, in that order. The number of dental hygienists currently exceeds 108,000, which is greater than the number of both dentists and dental technicians (Figure 5). This indicates the growing importance of dental hygienists in dentistry in Japan and an increase in public demand for their services. This may also reflect the inclusion of insurance-covered dental health guidance as part of their duties. Indeed, it has been confirmed that dental clinics with more dental hygienists make higher profits.

Statistics Japan counts 68,384 dental clinics, and the Ministry of Health, Welfare and Labour (MHLW) registered 19,706 dental laboratories in 2012. The increasing number of dental clinics and practitioners enables end-users to avail of dental care services at a larger level.

References:
http://stats-japan.com/t/kiji/10348;
http://www.jda.or.jp/dentist/index_9.html;
http://www.jdha.or.jp/dh/info_employ.html;
http://www.mhlw.go.jp/toukei/saikin/hw/ishi/12/dl/kekka_2.pdf;
4.4. Market Trends

Japan is the third largest market in healthcare industry in the world and is expected to grow steadily in the next few years with increasing imports of dental devices and materials. Key drivers are Japan’s aging population and rising public awareness about preventive dental care, modern dental treatment and dental aesthetics.

Thus, Japan continues to be an important profit center for foreign dental device and material manufacturers. Advanced digital imaging equipment such as panoramic dental imaging systems, dental implant materials, advanced dental laboratory technologies such as CAD/CAM systems, preventive technologies, etc., are potential future fields for business.
5. Competitive Environment

5.1. Key Domestic Manufacturers of Dental Devices

The nine largest manufacturers of dental devices in Japan realised sales of 64.21 billion yen in 2012, an increase of 3.1% compared to 2011. Six of the nine recorded increased sales, while two competitors reported a fall and one was able to hold its 2011 position.

According to R&D, the leading manufacturer, Morita Mfg. Corp, captured a share of 22.8% of the market in 2012, an increase of 6.6%. Morita is known for its production of “Space Line" chair units, and generated sales of 14.63 billion yen in 2012 after a decrease the year before.

Asahi Roentgen's 2013 sales are estimated to be 48.7 billion yen, in which the influence of price reduction in all dental devices can be seen, and expected to remain at the same level as 2012, or perhaps even decrease somewhat.

Yoshida Seiko’s 2013 sales are estimated to be 30.9 billion yen, thanks in part to successfully marketing their “Nova Series” chair unit and portable roentgen “X Shot.”

R&D estimates that drastic sales increases for each manufacturer will be seen for 2013 due to rising demand before the consumption tax hike in April 2014.

Table 6: Main Top 9 Manufacturers of Dental Devices, Sales Figures

<table>
<thead>
<tr>
<th></th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Share</td>
<td></td>
</tr>
<tr>
<td>Morita Mfg. Corp.</td>
<td>13,730</td>
<td>22</td>
</tr>
<tr>
<td>Yoshida Dental Mfg. Co., Ltd.</td>
<td>11,680</td>
<td>18.8</td>
</tr>
<tr>
<td>Takara Belmont</td>
<td>9,900</td>
<td>15.9</td>
</tr>
<tr>
<td>Osada Electric Co., Ltd.</td>
<td>7,000</td>
<td>11.2</td>
</tr>
<tr>
<td>GC Corporation</td>
<td>6,000</td>
<td>9.6</td>
</tr>
<tr>
<td>Asahi Roentgen Ind. Co., Ltd.</td>
<td>5,030</td>
<td>8.1</td>
</tr>
<tr>
<td>Morita Tokyo Mfg. Corp.</td>
<td>4,720</td>
<td>7.6</td>
</tr>
<tr>
<td>Yoshida Seiko, Ltd.</td>
<td>2,730</td>
<td>4.4</td>
</tr>
<tr>
<td>King Industrial Co., Ltd.</td>
<td>1,470</td>
<td>2.4</td>
</tr>
<tr>
<td>Total</td>
<td>62,270</td>
<td>100</td>
</tr>
</tbody>
</table>

(R&D Forecast)

5.2. Key Domestic Manufacturers of Dental Materials (Except for Metals)

Leading Japanese manufacturers of Dental Materials (except for metals) by sales figures (Table 7) are 1) GC Corporation, 2) SHOFU Inc., 3) 3M Health Care Limited, 4) Dentsply-Sankin K.K, 5) Kuraray Noritake Dental Inc. and 6) Nisshin Japan Ltd.

GC Corporation shows an overwhelming strength as a comprehensive dental materials manufacturer, while 3M Healthcare has been expanding its sales step by step in this market, with a projected growth of 9.8% in 2012. Nisshin Japan Ltd. was forecasted with the most significant decrease of -9.6% in 2012.

Table 7: Main Manufacturers of Dental Materials (Except for Metals), Sales Figures

<table>
<thead>
<tr>
<th></th>
<th>2011</th>
<th>Growth</th>
<th>2012 Forecast</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>GC Corporation</td>
<td>16,930</td>
<td>1.8</td>
<td>17,070</td>
<td>0.8</td>
</tr>
<tr>
<td>SHOFU INC.</td>
<td>9,190</td>
<td>1.4</td>
<td>9,200</td>
<td>0.1</td>
</tr>
<tr>
<td>3M Health Care Ltd.</td>
<td>5,620</td>
<td>2.3</td>
<td>6,170</td>
<td>9.8</td>
</tr>
<tr>
<td>Dentsply-Sankin K.K</td>
<td>4,600</td>
<td>-2.7</td>
<td>4,570</td>
<td>-0.7</td>
</tr>
<tr>
<td>Kuraray Noritake Inc.*</td>
<td>3,740</td>
<td>-3.9</td>
<td>5,300</td>
<td>-</td>
</tr>
<tr>
<td>Nisshin Japan Ltd.</td>
<td>885</td>
<td>-3.8</td>
<td>800</td>
<td>-9.6</td>
</tr>
</tbody>
</table>

* The numbers of Growth Forecast in 2012 exclude Kuraray Noritake Dental Inc.* (R&D Forecast)


5.3. Key Domestic Manufacturers of Dental Metals

The Dental Metals market is dominated by 1) GC Corporation, 2) Yamamoto Precious Metal Co., Ltd. and 3) Ishifuku Metal Industry Co., Ltd. (Table 8).

While Ishifuku Metal Industry Co., Ltd. and GC Corporate reported success in 2011 with an increase in sales of 28.5% and 23.3%, respectively, the trend was forecast to slow down and projections of a fall in sales for ISHIFUKU Metal Industry Co., Ltd. in 2012 were made. Yamamoto Precious Metal CO., Ltd. and Asahi Pritech are forecast to experience greatest decrease (-12.9%) in 2013.

In comparison IDS Co., Ltd. is recognised as the big winner with an expected steady growth over the last three years and 18.5% forecast for 2013.
Table 8: Main Top 10 Manufacturers of Dental Metals, Sales Figures

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>2012</th>
<th>2013 Forecast</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>GC Corporation</td>
<td>17,910</td>
<td>19,437</td>
<td>8.5</td>
</tr>
<tr>
<td>Yamamoto Precious Metal CO., Ltd.</td>
<td>15,485</td>
<td>13,495</td>
<td>-12.9</td>
</tr>
<tr>
<td>ISHIFUKU Metal Industry Co., Ltd.</td>
<td>14,339</td>
<td>15,457</td>
<td>7.8</td>
</tr>
<tr>
<td>Tokuriki Honten Co., Ltd.</td>
<td>10,355</td>
<td>10,300</td>
<td>-0.5</td>
</tr>
<tr>
<td>Ohura Precious Metal Industry Co., Ltd.</td>
<td>3,410</td>
<td>3,455</td>
<td>1.3</td>
</tr>
<tr>
<td>IDS Co., Ltd.</td>
<td>2,955</td>
<td>3,502</td>
<td>18.5</td>
</tr>
<tr>
<td>Dentsply-Sankin K.K</td>
<td>2,655</td>
<td>2,545</td>
<td>-4.1</td>
</tr>
<tr>
<td>Daishin Trading Co., Ltd.</td>
<td>1,250</td>
<td>1,300</td>
<td>4.0</td>
</tr>
<tr>
<td>Asahi Pritech</td>
<td>1,184</td>
<td>1,337</td>
<td>-12.9</td>
</tr>
<tr>
<td>Heraeus Kulzer Japan Co., Ltd.</td>
<td>1,140</td>
<td>1,000</td>
<td>-12.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>70,683</td>
<td>71,828</td>
<td>1.6</td>
</tr>
</tbody>
</table>

(R&D Forecast)


5.4. Import Market

Japan is a net importer of dental laboratory equipment such as CAD/CAM systems; dental metals; dental crown materials; dental impression materials; dental wax products; dental casting and investment materials; abrasive and polishing materials; and other dental materials such as dental implants.

5.5. List of Key Importers of Dental Devices and Materials

In 2012, the import of Dental Devices accounted for 1.2% of total Japanese medical equipment imports (Table 9). The top five key supplier countries are 1) Germany, 2) USA, 3) Switzerland, 4) Sweden and 5) Canada.

The import ratio of Dental Materials made up 2.5% of total medical equipment in 2012 and has been dominated by 1) Ireland, 2) USA, 3) Switzerland, 4) Sweden, and 5) Germany.
### Table 9: Import Volume of Medical Equipment by Key Countries

<table>
<thead>
<tr>
<th>Rank</th>
<th>Categories</th>
<th>Import Amount</th>
<th>Composition Ratio</th>
<th>Top 5 Countries and Import Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2012</td>
<td>2011</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>million yen</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2012</td>
<td>2011</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>million yen</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Dental Materials</td>
<td>29,764</td>
<td>29,271</td>
<td>2.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ireland: 6,099</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>USA: 6,076</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Switzerland: 5,732</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sweden: 5,286</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Germany: 2,959</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Dental Devices</td>
<td>13,706</td>
<td>14,147</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Germany: 6,596</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>USA: 3,482</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Switzerland: 1,202</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sweden: 720</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Canada: 288</td>
<td></td>
</tr>
</tbody>
</table>

Table 9: Import Volume of Medical Equipment by Key Countries

6. Distribution Channels

In general, Japanese distribution channels involve more layers of distribution than in other markets, which increases the cost to the end-user. Secondary wholesalers distribute 83.9% of Dental Devices and Materials to dental clinics (Fig. 6). However, direct sales of some products, such as dental implant related products, from manufacturers/ importers (bypassing wholesalers) have been gradually increasing.

In 2011, Dental Devices manufacturers mainly entered the market “via direct distribution to stores” (48.8%). The reason is that major companies such as Morita Tokyo MFG. Co. and Yoshida Dental MFG are selling their products via the same channel. The second biggest part including OEM with 13.3% of the total distribution channel includes dental retailing (“second distribution to stores”).

On the other hand, Dental Material manufacturers shared 56% “via dental retailing (indirect distribution to stores)” in 2011, and 19% “via dental first distribution to stores”, which indicates that the second distribution ratio is more important than the first distribution compared to Dental Devices manufacturers due to the fact that major material manufacturers such as GC Corporate and Shofu Inc. adopt dealership systems and usually deliver their retailing directly.

Also, due to the growth of the Internet, mail order has become an important alternative (and growing) distribution channel. Major items sold through mail order services include disposable items (masks, gloves, etc.), preventive dental products and dental alloys.

Figure 6: Distribution by Type of Business 2011

7. Regulatory Environment

As mentioned in chapter 4, Dental Devices and Materials are parts of the Medical Devices market. Therefore, they are regarded as objectives of the regulations under the Pharmaceutical Affairs Law (PAL) or Pharmaceutical Affairs Act of Japan, passed in 1960. It regulates the manufacturing, importation, and sale of drugs and medical devices in Japan.

The regulations and processes refer to Medical Devices in general but point out specific information that should be considered when entering the market with Dental Devices and Material products.

7.1. Typical Path to Product Launch

Pharmaceutical Affairs Law (PAL)

a) License for Marketing Authorization Holder (MAH)/ License for Manufacturer/ License for Repairing

In applying for the license for Marketing Authorization Holder, documents must be submitted to the local government, proving that the company’s Good Quality Practice (GQP) and Good Vigilance Practice (GVP) are adequate and have the license of the marketing supervisor-general. The required license (1st to 3rd kind) depends on the classification of medical equipment (Class I to III). Furthermore, the license is required by factories.

It is classified that Class I has the lowest risk and Class IV has the highest risk in the case of problems with human bodies:

(General Medical Devices): e.g., Dental technical equipment, X-ray films

(Controlled Medical Devices): e.g. Dental alloys, Blood-pressure gauge

(Specially Controlled Medical Devices): e.g. Contact lens

(Specially Controlled Medical Devices): e.g. Heart pacer

After packing, labeling, storage and delivery to market, ia “License for Manufacturer for Specially Controlled Medical Devices and/ or Special Maintenance Medical Devices” and “License for Repairing” after maintenance is required.
b) Approval of the Status as Recognized Foreign Manufacturer/ Approvals of Manufacturing and Marketing

In the case that the medical devices are manufactured in foreign plants, the foreign manufacturer must have the “Approval of the Status as Recognized Foreign Manufacturer” as well as the license for MAH for Japanese manufacturers based on PAL. The Approval of the Status as Recognized Foreign Manufacturer:

- ... Is conducted by Minister of MHLW
- ... Is given to each plant and each item
- ... Has 5 years available period
- ... Needs the procedure for apply and some charges
- ... Is inspected by PMDA if foreign manufacturer is matching to the standard to establish in a MHLW Law (Regulations for Buildings and Facilities for Pharmacies) or not

Figure 7: Approval Process of the Status as Recognized Foreign Manufacturer/ Approvals of Manufacturing and Marketing

The Inspection regarding overseas manufacturer

Source: Pharmaceutical and Medical Devices Agency

Therefore, they must apply for the Status as Recognized Foreign Manufacturer to the Pharmaceuticals and Medical Devices Agency (PMDA), and also apply for “Approvals of Manufacturing and Marketing” to the Minister of the Ministry of Health, Labour and Welfare (MHLW) or apply for “Certification of Manufacturing and Marketing” to the Accredited Certification Body. Some devices classified as general medical ones need the approval and also submission of written notice pertaining to manufacturing and marketing by items.
Controlled medical devices assigned by Minister of Ministry of Health, Labour and Welfare (MHLW) need third party notification, and others need only the Minister's approval.

c) Submission of Written Notice Pertaining to Import

Japanese Importers must submit “Written Notice Pertaining to Import” to the Department of Human Services in their territory for customs clearance.

d) Obligation of Indication/ Others

Based on PAL, the name of the manufacturer and marketer, product name and manufacturer number/ code must be indicated to avoid misunderstanding.

7.2. Regulations and Restrictions

**Electrical Appliances and Materials Safety Act**

In the case of electric or electric-heating medical devices, this act is applied. Japanese importers who will import these kinds of devices must submit the written notice pertaining to import business of electrical equipment to the Minister of Economy, Trade and Industry within 30 days since they started importing them. These kinds of devices must match to the codes and standards defined by Ministry of Economy, Trade, and Industry (METI).

**Industrial Standardization Act (Japan Industrial Standards: JIS-Kikaku) / Other Industrial Standards**

Regarding the certification of controlled medical devices by the registered certification body, the devices can be required to match JIS Codes. For example, some medical devices must be checked to match the Electromagnetic Compatibility Standard (EMC-Kikaku) (JIST0601-1-2) so that they can avoid the risk of mishap caused by electromagnetic rays. In the some cases, it must be matched to the standards of Japan Medical Imaging and Radiological Systems Industries Association (JESRA).

Furthermore, Japanese importers take over responsibilities for Product Liability Act (PL Act), Consumer Products Safety Act (the system for reporting and publishing serious accidents), and some acts related to recycling and medical waste. In some cases, they must also have responsibilities under the Radio Act, Radiation-proof Act, and Medical Service Act.

In addition to the obligation of indication defined in the PAL exists a “Fair Competition Code and Enforcement Regulations about the Limit of Premiums Offer in the Medical Devices Business” that defines restrictions in sales.
7.3. Market Entry for Foreign Companies

If foreign manufacturers apply or import and sell medical devices or medicines in Japan, they must appoint a Japanese company who has the license of MAH for medical devices and medicines. The appointed MAH is obliged to conduct the Good Quality Practice (GQP) and Good Vigilance Practice (GVP) domestically.

Foreign manufacturers require the Status as Recognized Foreign Manufacturer based on Art. 13-3 in PAL. In order to understand specific requirements and processes, foreign manufacturers engage consulting companies that help them with market entry in Japan (approval and licensing process).

For an overseas company wishing to enter the Japanese market, it is essential to develop a regulatory strategy based on a solid understanding of its duties as a foreign manufacturer as well as the options available, and the pros and cons of each.

7.4. Labeling and Packaging

After the MAH has conducted the customs clearance of medical devices and released the products, Japanese labeling and packaging manufacturers receive them. According to the PAL, labeling, packaging, and warehousing are defined as “manufacturing” activities and therefore require a Packaging Manufacturer License.

Most foreign companies conduct labeling and packaging in their foreign (outside Japan) facilities, but warehousing in Japan can't be avoided. Therefore, it is required to appoint a Japanese labeling and packaging manufacturer that can be found with the help of a consulting company.

References: http://www.jetro.go.jp/world/japan/qa/importproduct_14/04M-010754

7.5. Tax Matters

In general, Medical Devices are treated as duty free products and so are most Dental Devices and Materials, depending on the material(s) the product is made from.

Table 10: Examples of Taxes for Dental Devices and Materials

<table>
<thead>
<tr>
<th>Description</th>
<th>General</th>
<th>WTO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Injection</td>
<td>Free</td>
<td>(Free)</td>
</tr>
<tr>
<td>Dental Metal Tube Acus and Surgical Needle</td>
<td>Free</td>
<td>(Free)</td>
</tr>
<tr>
<td>Dental Chair</td>
<td>Free</td>
<td>(Free)</td>
</tr>
<tr>
<td>Dental Wax and Impression Material</td>
<td>4.6%</td>
<td>Free</td>
</tr>
</tbody>
</table>

Source: Customs Tariff Schedule (January, 2014): Trade Statistics of Japan
8. **Outlook of Important Future Fields: Excerpt of the “Vision of New Dental Devices and Technology Industries 2012” Including Relevant Agendas**

In 2007, the Japanese Association for Dental Science and the Japan Dental Trade Association issued the “Dental Device Industry Vision.” It received re-confirmation in 2012 and has been supplemented with agendas referring to the themes of “Elderly People” and “Home Care” by Japan’s government policy.

8.1. **Domestic Dental Implants and Development of Dental CAD/CAM Technology**

The expansion in the early commercialization of domestic dental implants and the development of dental CAD/CAM technology need to be promoted. Moreover, it is necessary to develop further advanced high-functional products such as dental crowns, restored prosthesis, pursuing implant upper structure and vital affinity in order to support and construct the international sales network.

8.2. **Diagnostic Technologies**

The practical use of diagnostic technologies (diagnostic research about genes, saliva, and bones) need to be planned, and preventive action for people on an individual basis should be designed based on the result of the diagnosis.

8.3. **Aesthetic Treatments**

The establishment of treatment techniques which meet the growing demand of people, such as correction, aesthetics, whitening, articulation, dental diagnosis at home, bad breath and anti-aging, etc.

8.4. **Efficiency and Traceability in Dental Distribution Channels**

The correct and speedy communication of information and the enhancement of maintenance shall be improved. At the same time, it is necessary to use barcodes for efficiency and rationalization of distribution. Furthermore, IT promotion and maintenance systems need to be prepared.

8.5. **Domestic Cooperative Relationship for Global Competitive Strength**

Integration and cooperative relationships among domestic companies need to be constructed in order to reinforce international competitive strength. Since Japanese companies have a lot of specific technologies they would be expected to enjoy synergy effects by collaborating with each other in a system of M&A.

8.6. **Oral Care for Elderly People**

Japan’s aging society forces the need to develop dental devices for prevention of aspiration pneumonia at home and assist-devices for mastication function in prevention of dementia to expand the QOL and ADL of elderly people.
8.7. **Home-care Equipment**
Development of comprehensive home-care equipment: The “Dental Devices Development Small Committee” develops concepts for launching the following themes:
- Portable lighting equipment for dental care at home
- Dental treatment physique movement backrest for bedridden senior citizens
- Information network system for dental care at home
- Portable dental care general unit for dental care at home
- Artificial teeth repairing kit for dental care at home
- Impression taking and bite taking kit for dental care at home
- Disposable brush for artificial teeth and oral care brush in the oral cavity
- Oral moisturizing agent for dental care

8.8. **New Materials for Dental Crowns**
Development of new materials for dental crowns: Clinics, government and industry incumbents need to cooperate to develop new materials for next generation dental crowns of equal quality to Gold and Silver Palladium Alloy which has high level properties.

8.9. **Others**
- Team dental care
- Development of early discovery system for gum disease which is called the “6th complication of diabetes”
- Enlightenment to finish dental care before cancer treatment to prevent the effects of anticancer agents
- Organizational action plan to prevent NCD (Non-Communicable Diseases)

Reference: “The vision of new dental devices and technology industries 2012 – the fulfilment of healthy and long-lived society by world-class dental devices and technology industries”
9. Support to Large-scale Disaster

The Great East Japan earthquake (March 11, 2011) caused unexpected devastation to the lives of many people. Many victims were obliged to live as refugees under intolerable conditions. Some of them were elderly and/or had illnesses, and over 2,500 of these refugees have died related to the earthquake as of May 2013, indicating proliferation of disease due to poor conditions.

Some of these include patients of aspiration pneumonitis and infectious diseases caused by bad oral condition.

Dental measures in the case of large-scale disaster would be needed as follows from the point of view of dental equipment and technologies:

- Development of portable on-site dental care units and materials:
  Dental care units with compact electric power source, disposable mirrors, disposable pin sets, etc.
- Deployment of dental devices and materials sets related to identification:
  Lighting devices, portable X-ray devices, etc.
- Maintenance of medical information network and database for identifying patients
- Development of dental materials which have innovative dental disease prevention functions:
  Prosthetic appliances of dental crowns and artificial crowns which are antibacterial, bacteriostatic or have anti-plaque properties

Reference: http://www.minpo.jp/pub/topics/jishin2011/2013/05/post_7092.html
10. Market Best Bets for EU Companies Approaching the Japanese Market

Conclusions and Recommendations as to High Potential Areas for EU Companies: Opportunities, Restraints and Future Fields

As previously mentioned, Japan is the world’s third largest market in the healthcare industry with increasing imports of dental devices and materials.

On the international stage, a reorganization and integration of manufacturers and distributors has been progressing, causing concern about the international competitiveness of Japanese companies. It is observed that overseas manufacturers acquire domestic Japanese distributors in order to enter the domestic dental market. On the other hand, the top 10 global manufacturers include only one Japanese company, emphasizing a limited presence in the global market.

As a consequence, in 2012 the Dental Care Technology and Innovation Promotion Council suggested the following technologies to support Japanese companies in successfully competing with international manufacturers (Table 11).

<table>
<thead>
<tr>
<th>Category</th>
<th>Dental Care Technologies to be Targeted for Overseas Competition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Particularly high ratio exporting products in Japan *1)</td>
<td>Adhesive filler, dental drive device and hand piece</td>
</tr>
<tr>
<td>High ratio exporting products in Japan</td>
<td>Dental care image diagnosis device, dental unit, dental ceramics</td>
</tr>
<tr>
<td>Almost same ratio exporting and importing products in Japan *2)</td>
<td>Corrective equipment and materials, endodontic care equipment and materials, dental pit and fissure mounting medium</td>
</tr>
<tr>
<td>Particularly high ratio importing products in Japan</td>
<td>Complete denture and partial denture, dental diagnosis device</td>
</tr>
<tr>
<td>High ratio importing products in Japan</td>
<td>Dental CAD/CAM device, dental implant, jaw movement and biting force diagnosis device, dental ceramics (dental cutting ceramics)</td>
</tr>
</tbody>
</table>

*1) “Particularly” defined that either import or export is less than 20% against the other.
*2) “Almost same” defined that import or export is 80% - 120% against the other.

It can be said that foreign manufacturers should have chance to enter into these markets to compete with Japan manufacturers.

Especially, Dental implant and CAD/CAM are weak markets in import and export in Japan. At the same time, researches in these fields are mainly following in the footsteps of foreign technologies. Japanese manufacturers will try to appeal with “Made in Japan” to overseas buyers in cooperation with academic societies and government, especially in the area of medical devices and systems, with particular reference to the experience as an elderly society.

**Revised Japanese Pharmaceutical Law Approved in November, 2013**

The Japan medical devices market is expected to grow, in the context of an elderly society, and technological innovation and even firms from other industries have been paying attention to it. While this market used to be regulated by the PAL, the provision of which were not always pertinent in the case of medical devices. However, the Japanese government has been looking at this field as a growing industry and considering deregulation for the purpose of the enhancement of competitiveness.

The government approved the “Revised Japanese Pharmaceutical Law” in November 2013, which includes the promotion of medical devices development, the speeding up of examination processes, and reducing the hurdles/ burdens faced by companies attempting to enter into the medical industry. This law will be enforced within a year. Under this law, it is hoped that Japanese companies will their domestic market share and strengthen their overseas competitiveness. Therefore, international competition will potentially increase in the future.

*Reference: http://www.meti.go.jp/policy/mono_info_service/healthcare/kokusaika/downloadfiles/about.pdf*
11. Appendices

11.1. List of Local Competent Authorities and Related Organizations including Contact Details

Ministry of Health, Labour, and Welfare
1-2-2, Kasumigaseki, Chiyoda Ward, Tokyo 100-8916
Tel +81-3- 5253-1111

Japan External Trade Organization (JETRO)
Arc Mori Bldg. 6F, 1-12-32, Akasaka, Minato Ward, Tokyo, 107-6006
Tel +81-3-3582-5511

National Federation of Health Insurance Societies (Kenpo-ren)
1-24-4, Minami-Aoyama, Minato Ward, Tokyo, 107-8558
Tel +81-3-3403-0915

Consuls of Dental Care Technological Innovation Promotion
2-16-14, Kojima, Taito Ward, Tokyo, 111-0056
Tel +81-3-3851-0324

Japan MDC: Specialized services in regulatory consulting for medical devices
https://www.j-mdc.com

Customs and Tariff Bureau (Ministry of Finance Japan)
3-1-1, Kasumigaseki, Chiyoda-ku, Tokyo, 100-8940
Tel +81-3-3581-4111

Pharmaceuticals and Medical Devices Agency (PMDA)
New Kasumigaseki bldg 6F West, 3-3-2, Kasumigaseki, Chiyoda Ward, Tokyo, 100-0013
Tel +81-3-3506-9506

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11.4. Sources and Bibliography

Publications

3. “The 12th Gyoshu-betsu Shinsa Jiten, the 3rd” (General Incorporated Association, Financial Circumstances Study Group; February 2012)
5. “New strategy for better geriatric oral health in Japan: 80/20 movement and Healthy Japan 21.” (Department of Preventive Dentistry, Nagasaki University School of Dentistry, Japan; June 2001)
9. “The vision of new dental devices and technology industries 2012 – the fulfillment of healthy and long-lived society (World-class Dental Devices and Technology Industries; July 2012)

Websites

1. Nikkei: http://www.nikkei.com
3. 8020 Foundation: http://www.8020zaidan.or.jp
5. Japan Dental Association: http://www.jda.or.jp
7. Japan Dental Hygienists’ Association: http://www.jdha.or.jp
8. Japan Dental Technologists Association: http://www.nichiqi.or.jp
10. Fukushima Prefecture, Local Newsportal: http://www.minpo.jp
12. Pharmaceutical and Medical Devices Agency: http://pmda.go.jp
15. Medical Insurance System(Kenpo-ren’s website): http://www.kenporen.com/jigyonushi/m_state/

List of companies and organisations mentioned in the report:
Top 9 Manufacturers of Dental Devices (excerpt)

3. Takara Belmont: http://www.takarabelmont.co.jp
4. Osada Electric Co., Ltd.: http://www.osada-electric.co.jp
5. GC Corporation: http://www.gcdental.co.jp/index.html
8. Yoshida Seiko Ltd.: http://yoshidaseiko.co.jp

Top 12 Manufacturers of Dental Materials (exc. Industrial Corporation):
http://www.gcdental.co.jp/index.html
1. SHOFU INC.: http://www.shofu.co.jp/global/index.php
2. 3M Health Care Limited: http://www.mmm.co.jp/hc/

Top 10 Manufacturers of Dental Metals (excerpt)

2. GC Corporation: http://www.gcdental.co.jp/index.html
3. Yamamoto Precious Metal CO., Ltd.: http://www.yamakin-gold.co.jp
4. Tokuriki Honten Co., Ltd.: http://www.tokuriki-kanda.co.jp
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