Silicon Valley's "Ecosystem" for the Development of Medical Devices
--- What are Its Lessons for Japan? ---

1. Overview of the Medical Devices Industry

- Medical devices are a growth industry in Japan and are expected to be a major sector of the economy for generations to come. This report looks at the most competitive medical devices industry in the world, that of the United States. Focusing on the medical devices industry in Silicon Valley, we study its mechanisms for development and probe the sources of its strength. Our findings form the basis for a forecast for the medical devices industry in Japan – and for suggestions on how it can become stronger and more competitive.
- As of 2011, the global medical devices industry was worth some 300 billion US dollars. Projections calls for it to grow at an annual rate of 6.4% from now through 2017 – the result of factors such as the growth and aging of the world population, economic development in emergent nations, and the growing sophistication of medical instruments (Figure 1-1).
- At about 2.4 trillion yen (about USD 24.65 billion), Japan's medical devices industry accounts for one-tenth of the world market. It ranks second only to the U.S. industry, which has a global market share of 25%. Japan's industry has been growing at a rate of 2.3% annually since 1995 (Figures 1-2, 1-3).
- Nevertheless, the share of imports in the Japanese market is rising. While on a slight decline at the moment, the import ratio rose from 36% in 1995 to 44% in 2011. More than half of all therapeutic medical devices sold in Japan are imports, including one hundred percent of artificial heart valves and pacemakers (Figures 1-3, 1-4). Japan runs a trade deficit of some 580 billion yen (about USD 6 billion) in medical equipment, therapeutic devices primarily. With the exception of certain diagnostic devices, its competitive position in the global market is weak (Figure 1-5).

Figure 1-1 The Global Medical Devices Market

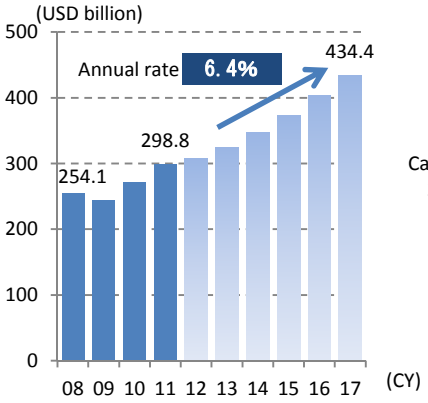
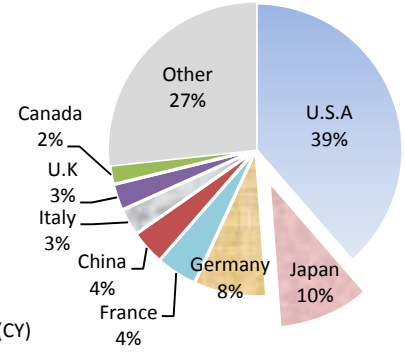


Figure 1-2 National Breakdown of the Global Medical Devices Market



Notes, Figs. 1-1, 1-2
1. Source: *Medistat Worldwide Medical Market Forecasts to 2017*, Espicom Business Intelligence.
2.Figures for 2012 on are predicted values.

Figure 1-4 Breakdown of Import Ratios, by Category (selections from 2011)

Category	Domestic market (JPY billion)	Import ratio (%)
Artificial heart valves	15.6	100
Cardiac pacemakers	26.0	100
Respirators	27.0	97
Prosthetic joints, artificial bone	145.6	79
MRIs	35.1	61
Stents	79.7	54
Tubes and catheters	266.6	42
Medical X-ray computed tomography scanners	45.5	39
Ultrasound imagery diagnostic equipment	47.3	36
Medical endoscopes	151.4	7
Therapeutic total	1,256.3	51
Diagnostic total	612.4	28
Medical devices total	2,386.0	44

Figure 1-3 Changes in the Scale of Japan's Medical Devices Industry

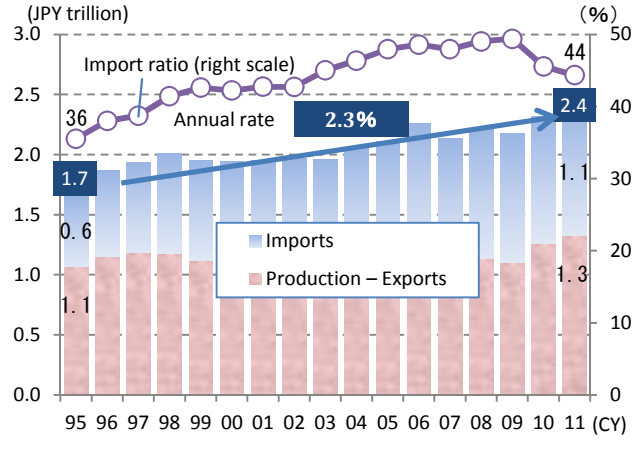
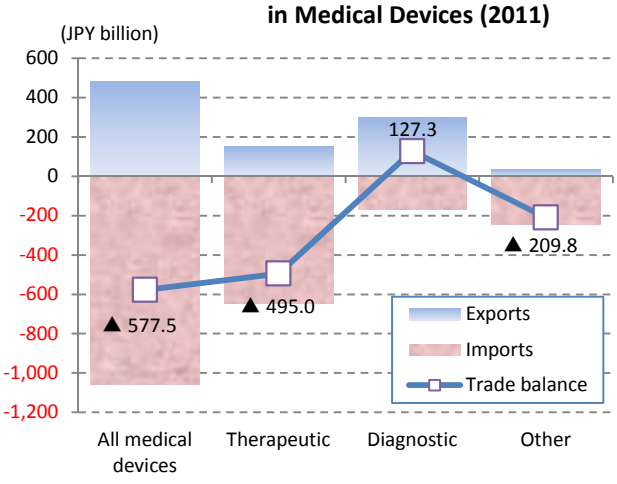


Figure 1-5 Balance of Trade in Medical Devices (2011)

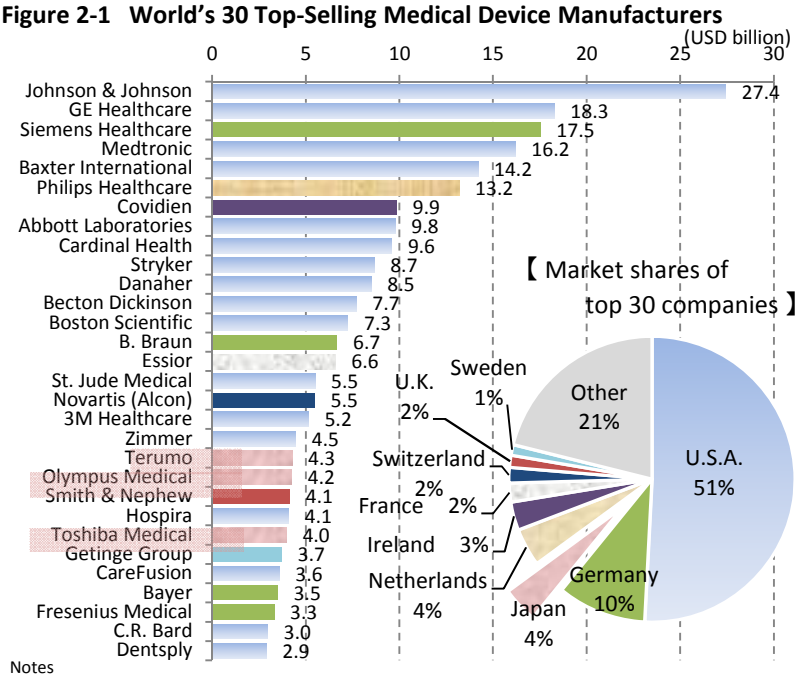


Source for Figs. 1-3 through 1-5: *Annual Statistics on Pharmaceutical Production*, Ministry of Health, Labor and Welfare.

2. The Competitiveness of America's Medical Devices Industry

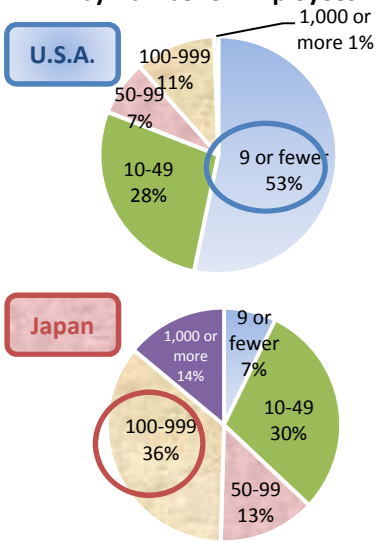
- Of the world's thirty largest medical device manufacturers in terms of sales, only three are Japanese; these account for a mere 4% of the global market. By contrast, seventeen U.S. firms are in the top thirty, with Johnson & Johnson in first place. Taken in total, these seventeen firms account for over half of all sales in the world market (Figure 2-1).
- One way to measure international competitiveness is from the standpoint of patents. Almost 70% of the world's patents on medical devices are held by companies registered in the U.S. For products such as stents and cardiac pacemakers, the U.S. share rises to more than 90%. These figures point to the overwhelming competitive power of American firms in the global market for medical devices (Figure 2-2).
- When the number of medical device manufacturers in the U.S. and the number of patents held by those firms were analyzed in terms of workforce size, it was found that a majority of companies, ventures or otherwise, had nine or fewer employees. More than a quarter of all patents in the U.S. are held by companies with fewer than fifty employees. In Japan, less than 10% of the industry's firms have nine or fewer employees, and over 90% of patents are held by companies with a workforce of one hundred persons or more. These findings suggest that the important presence of venture companies is a big factor in the competitiveness of the U.S. industry (Figures 2-3, 2-4).

Figure 2-1 World's 30 Top-Selling Medical Device Manufacturers



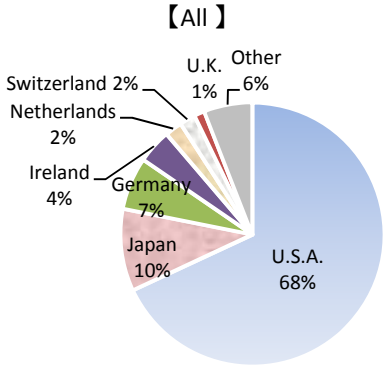
Notes
1. Source: *Top 30 Medical Device Manufacturers (by FY2012 revenue)*, Rodman Media Medical Product Outsourcing (MPO).
2. Size of world market based on Epsicom predicted values (2012).
Figures in parentheses indicate number of firms.

Figure 2-3 Medical Device Manufacturers by Number of Employees



Sources: *FY2011 Survey on the Pharmaceutical and Medical Device Industries*, Ministry of Health, Labor and Welfare; *2011 Country Business Patterns (NAICS)*, United States Census Bureau.

Figure 2-2 International Comparison of Numbers of Medical Device Patents

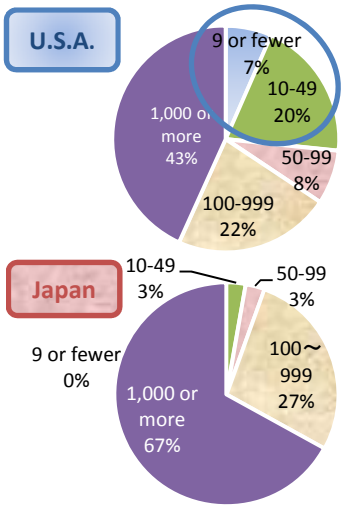


【Selected Leading Medical Devices】

(%)

Category	U.S.A.	Japan
Stents	91	1.5
Cardiac pacemakers	91	0.3
Catheters	89	4.8
Artificial joints	82	—
MRIs	55	11
Medical X-ray computed tomography scanners	44	23
Ultrasound imagery diagnostic equipment	36	22
Medical endoscopes	33	47

Figure 2-4 Holdings of U.S. Medical Device Patents, by Size of Workforce

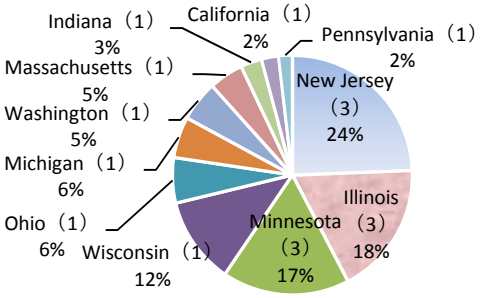


Notes, Figs. 2-2, 2-4
1. Prepared from data issued by Intellectual Property Information Services Co., Ltd.
2. Covers firms holding 20 or more U.S. patents on medical devices as of June 30, 2013.

3. Silicon Valley's Position in the U.S. Medical Devices Industry

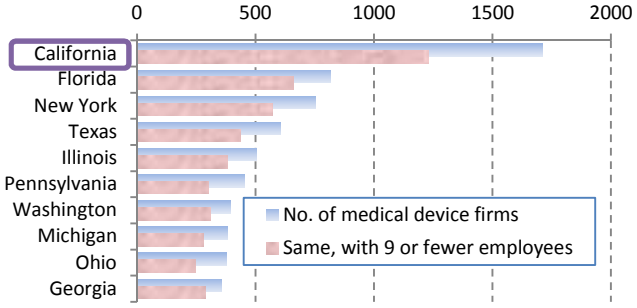
- Although most of America's top seventeen manufacturers of medical devices are headquartered in New Jersey, Illinois and Minnesota (Figure 3-1), California stands out in terms of medical device clusters (of venture firms and others) employing nine or fewer persons (Figure 3-2).
- Firms headquartered in Minnesota, Massachusetts and New Jersey account for the largest numbers of patents, but some 80% of each state's patents are owned by large individual firms such as Medtronic, Boston Scientific, and Johnson & Johnson. California again stands out in terms of the number of companies holding patents, indicating that the state is home to a great number of technologically advanced firms (Figure 3-3).
- A large percentage of the patents held by leading U.S. medical device makers derive from external sources, including companies they have acquired (Figure 3-4). Leading firms headquartered elsewhere will often achieve growth by taking in technologies or products developed by venture firms in California and other states, a process which, to a great extent, gives the U.S. medical devices industry its outstanding competitiveness.
- California, and especially Silicon Valley, is where the largest amount of venture capital is invested in the medical devices field (Figure 3-5). Many of the major firms recently acquired by leading medical device makers are to be found in Silicon Valley (Figure 3-6). Johnson & Johnson and other industry leaders have established their own venture capital branches there (venture arms and corporate venture capital) and actively gather information on promising venture businesses. Clearly, Silicon Valley has grown into a premier producer of top-quality venture firms in the medical devices industry.

Figure 3-1 Locations and Shares of the 17 Top-Selling U.S. Firms



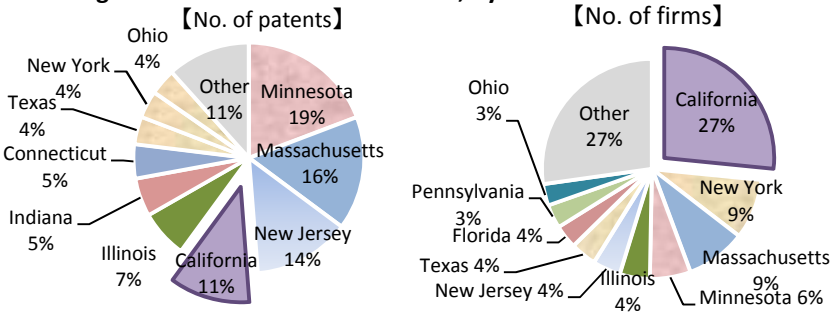
Notes
Source: *Top 30 Medical Device Manufacturers (by FY 2102 revenue)*, Rodman Media Medical Product Outsourcing (MPO).
Figures in parentheses indicate numbers of firms.

Figure 3-2 10 U.S. States with the Largest Numbers of Medical Device Firms



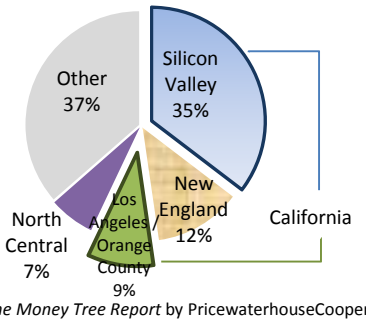
Source: *2011 Country Business Patterns (NAICS)*, United States Census Bureau.

Figure 3-3
U.S. Holdings of Patents on Medical Devices, by State



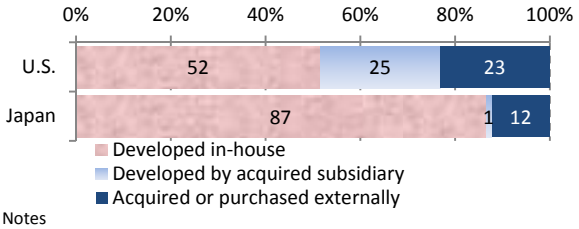
Notes
1. Prepared from data issued by Intellectual Property Information Services Co., Ltd.
2. Covers firms holding 20 or more U.S. patents on medical devices as of June 30, 2013.

Figure 3-5
Venture Capital Investment, by Region (Medical devices; total for 2003-2012)



Source: *The Money Tree Report* by PricewaterhouseCoopers and National Venture Capital Association, based on data from Thomson Reuters.

Figure 3-4 Comparison of Patent Holdings by Japanese and U.S. Medical Device Makers



Notes
1. Prepared from data issued by Intellectual Property Information Services Co., Ltd.
2. Covers all U.S. medical device patents held by the 3 top-selling firms as of June 30, 2013.
3. "Acquired subsidiaries" refers to subsidiaries acquired since 1990.

Figure 3-6 Some Recent Acquisitions of Silicon Valley Firms by Leading U.S. Medical Device Manufacturers

Medical device firm	Acquired firm	When acquired
Johnson & Johnson	Alza Corporation	2001
	Acclarent Inc.	2010
	Micrus Endovascular	2010
Medtronic	Ardian	2011.01
	PEAK Surgical	2011.08
Stryker	Concentric Medical	2011.10

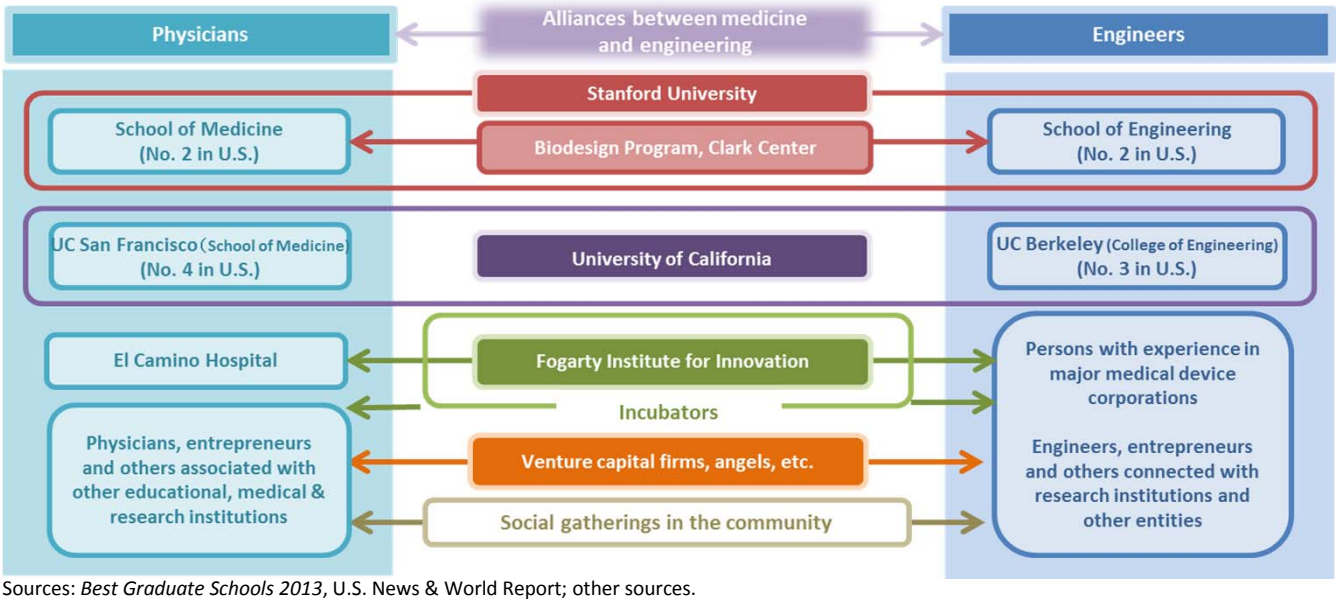
Source: Corporate investor relations materials; other.

4. Factors Supporting Medical Device Development in Silicon Valley (1)

--- New Ideas Grow Out of Alliances between Medicine and Engineering ---

- The explanation for the large number of medical device companies in Silicon Valley lies in its environment, which favors the development of new ideas in the field, coupled with a well-developed support system for the commercialization of products. These factors create an “ecosystem” that effectively ensures a smooth flow of progress from start-up to commercialization.
- Ideas for high-quality, highly marketable products originate not in technology, but in the needs of physicians and in the alliances and cooperation that develops between physicians and engineers. This connection between medicine and engineering is well developed in Silicon Valley (Figure 4-1).
- Silicon Valley is the home of two world-renowned universities, Stanford University and the University of California. Each year both schools graduate outstanding doctors and engineers from medicine and engineering schools that are second to none in the U.S. At Stanford, the Clark Center was established to promote interdisciplinary research in medicine and engineering. At the Center’s Biodesign Program, students mentored by business people learn how to innovate by solving the problems involved in connecting medicine with engineering – from identifying clinical needs and formulating ideas to creating commercialization plans.
- The region has numerous incubators, venture capital firms, and angels, all of which play vital roles in linking medicine and engineering. Meetings and social gatherings also offer opportunities for interchange between the medical and engineering communities.
- California accounts for 20% of all of America’s university-held patents involving medical devices, the greatest numbers being held by the University of California and Stanford University. All schools holding the greatest numbers of patents maintain connections with top U.S. medical institutions. With its concentrations of outstanding medicine and engineering schools, connections with top medical institutions, and the presence of intermediaries linking the medical and engineering disciplines, Silicon Valley has optimum conditions for the generation of good ideas for medical devices.

Figure 4-1 Alliances between Medicine and Engineering in Silicon Valley



Sources: *Best Graduate Schools 2013*, U.S. News & World Report; other sources.

Figure 4-2
Percentages of Medical Device Patents Held by U.S. Universities, by State

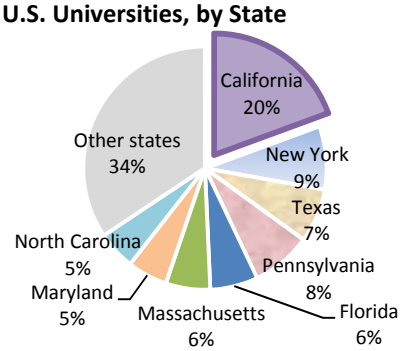


Figure 4-3 Top 5 Patent-holding Universities in the U.S.

	University	No. of patents	Medical institution	U.S. ranking
1	University of California	200	UCSF Medical Center	7
			UCLA Medical Center	5
2	University of Texas	166	MD Anderson Cancer Center	1 (in cancer)
3	Stanford University	139	Stanford Hospital and Clinics	-
4	Johns Hopkins University	123	John's Hopkins Hospital	1
5	Massachusetts Institute of Technology	116	Massachusetts General Hospital	2

Notes for Figs. 4-2, 4-3

1. Sources: Data from Intellectual Property Information Services Co., Ltd.; *Best Hospitals 2013-14*, U.S. News & World Report.
2. Covers universities holding 20 or more U.S. patents on medical devices as of June 30, 2013.

5. Factors Supporting Medical Device Development in Silicon Valley (2)
--- An Ecosystem Supportive of Commercialization ---

- Silicon Valley excels in turning original ideas and technologies into marketable products and businesses. This is one of the major qualities setting it apart from other areas of the U.S. and elsewhere.
- The many incubators, venture capital providers and angels clustered in Silicon Valley not only play a huge role in linking the disciplines of medicine and engineering (as discussed earlier); they provide entrepreneurs with space, funding, and, most importantly, support in commercializing their ideas.
- The region is rich in the resources and infrastructure required at each development stage, including laboratories for animal testing, companies with advanced technologies such as ICT, and consultants specializing in intellectual property and government approvals. Their presence gives Silicon Valley important advantages. Incubators and other support entities support the rapid commercialization of ideas into marketable products, by, for example, ①introducing these resources and offering them to entrepreneurs; ② providing experienced business people and physicians to serve as mentors; and ③introducing leading medical device manufacturers as exit partners. In the medical devices field, commercialization and marketing possibilities are key considerations from the first stages of development. A venture company's success will depend on keeping this in mind (Figures 5-1, 5-2).
- The involvement of physicians is crucial throughout the development process. Doctors start many firms themselves, and will often serve as mentors based on advisory contracts, stock options or other forms of compensation. In this way they augment the mentors available through incubators and other support bodies. The ease of finding such medical experts is an enormous advantage for Silicon Valley.
- Another of the area's strengths is the effectiveness with which the conception of an idea proceeds to its acquisition by a leading medical device company and on to its entry onto the market as a top-quality product. Entrepreneurship and innovation are woven into the region's ecosystem (Figure 5-3). Armed with their experience, successful entrepreneurs often set up incubators, venture capital firms or consultancies through which they support further generations of entrepreneurs. By becoming part of the resources and infrastructure supporting Silicon Valley, they ensure that its ecosystem continues to function.

Figure 5-1
Functions of Incubators and Other Support Entities

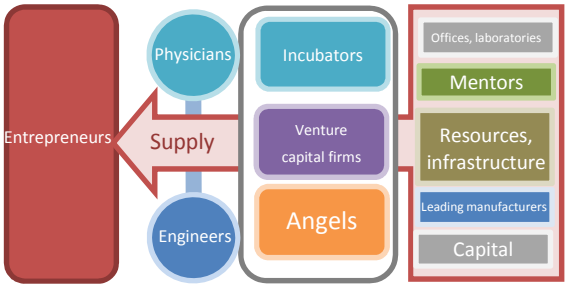
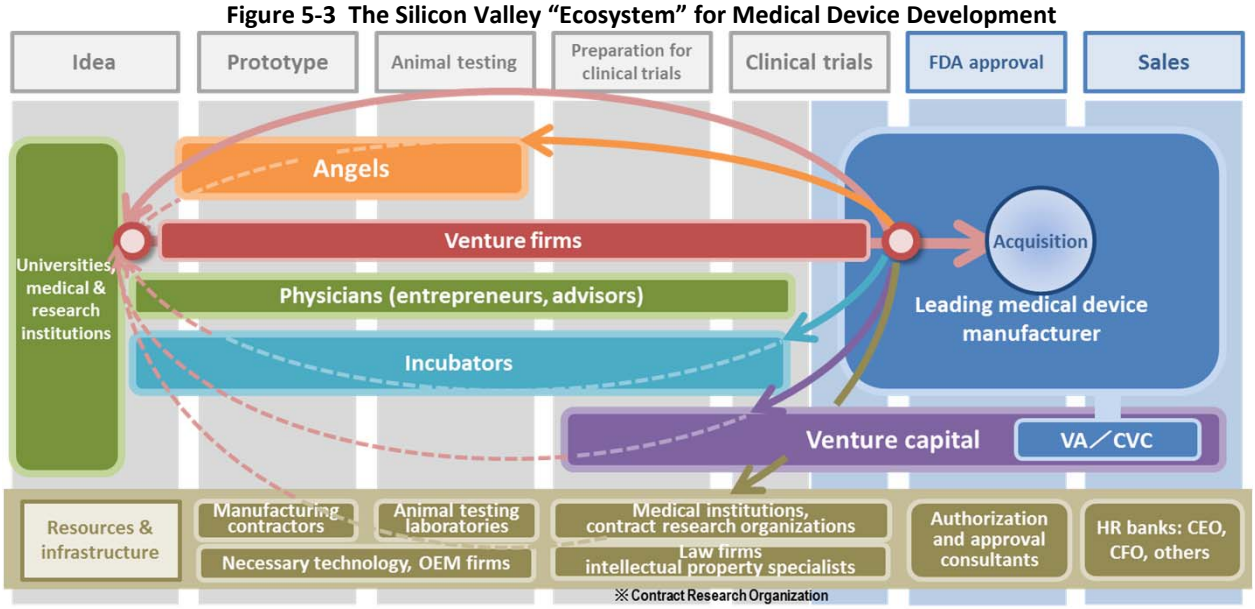


Figure 5-2
Major Incubators and Other Support Entities in Silicon Valley

Category	Name	Summary
Incubators	Fogarty Institute for Innovation (FII)	Founded in 2007 by Thomas Fogarty, inventor of the balloon catheter. Located in El Camino Hospital.
	The Foundry	Founded in 1998 as an incubator specializing in medical devices.
	Exploramed	Founded in 1995 as an incubator specializing in medical devices.
Angels	Life Science Angels	Group of angel investors specializing in the healthcare field. Over 40 projects undertaken. Also provides commercialization support.

Figure 5-3 The Silicon Valley "Ecosystem" for Medical Device Development



Source for Figs. 5-1 through 5-3: Various data

6. Reference: The Silicon Valley "Ecosystem" for Medical Device Development: Some Examples

・Two of Silicon Valley's strengths as a site for medical device development are the wealth of ideas that result from collaboration between the area's physicians and engineers and an ecosystem that provides enormous support for commercialization. Each of these strengths is illustrated by the following selected cases, as summarized by the Stanford Biodesign Program and the Fogarty Institute for Innovation (FII).

［The Stanford Biodesign Program］

・This Stanford University program aims at nurturing innovators in the medical devices field. Two courses of study, a one-year Biodesign Course and a two-year Biodesign Innovation Fellowship, are offered at the Clark Center, a building especially designed to foster connections between the departments of medicine and engineering.

・Participants in each course study the entire flow of venture business for medical devices, including ①market research, ②idea selection, ③competitor analysis, ④provisional patent preparation and application, ⑤ prototype preparation, ⑥pharmaceutical and insurance repayment strategies, ⑦business plan preparation, ⑧clinical development strategy, and ⑨fund procurement and exit strategies, based on unmet needs identified at the clinical site. At the end of the course each student gives a presentation before actual Silicon Valley investors who evaluate their work.

・The first six months of the Fellowship course are spent identifying needs in the medical field. Students split up into small groups to visit hospitals, where, by witnessing medical care in practice and observing and interviewing physicians, nurses and patients, they develop their ability to discover unmet needs.

・The students produce one to two hundred ideas for each need discovered. Individual ideas are studied to identify potential users, and are then refined through a process of interviews with interested parties to determine their likely effectiveness. Finally, the students consider the kinds of technologies that will be needed to put each idea into practice.

・The principal instructors are with the Business School and the School of Engineering, but business people, pharmaceutical consultants, investors, FDA inspectors, and others from outside the university also take part as lecturers and mentors. In this way, the program helps students develop the thinking and skills required to innovate with the aim of solving problems and in light of actual clinical needs.

［Fogarty Institute for Innovation（FII）］

・The Fogarty Institute for Innovation is an incubator founded in 2007 by the legendary Thomas Fogarty, an innovator and entrepreneur who invented the balloon catheter and many other revolutionary therapeutic devices and played an instrumental role in the establishment of numerous companies in the medical devices field. FII has its offices and laboratories within El Camino Hospital, the core medical center for Silicon Valley. In addition to Mr. Fogarty, the staff includes a number of physicians with experience in the business world.

・The laboratory is equipped with simple tools and materials commonly used in the production of medical apparatus. By making simple devices, a creator can quickly determine the rightness of an idea or working principle. The laboratory's location is an enormous advantage, as participants can obtain advice and feedback from the hospital's physicians at any time.

・The Institute does not only provide work space, but also regularly offers mentoring by physicians and the staff of medical device manufacturers; presentations and advice from venture capitalists; information sessions on subjects such as pharmaceutical approval and intellectual property; and many other forms of support for commercialization.

・Since its founding, FII has supported more than ten entrepreneurs and venture firms, three of which have graduated and moved to independent offices. In addition to backing venture firms, FII provides programs in clinical research, clinical testing and staff development.

・That Silicon Valley's ecosystem for medical device development is functioning effectively is evident from these two cases. Alliances between medicine and engineering create an infrastructure promoting innovation aimed at solving problems and deriving from actual clinical needs; mentoring by business people, as well as doctors with business experience, provide essential guidance.

Notes

1.Comments on the Stanford Biodesign Program summarized or quoted from Fumiaki Ikeno, Chief Researcher Stanford University School of Medicine, Personnel Development in the U.S. Medical Devices Industry: University Education – the Stanford Biodesign Program, contributed to the quarterly Biophilia, 2012.Vol. 1. No.2.

2.Comments on the Fogarty Institute for Innovation sourced from the Institute's website; materials provided by the Institute; The Fogarty Institute for Innovation: A Device Incubator for Difficult Times, a special report in In Vivo magazine, July-August 2011.

7. What Japan Must Do to Promote Development of the Medical Devices Industry

- The Japan Revitalization Strategy, passed by the Cabinet in June 2013, recommended a number of measures aimed at developing Japan's medical devices industry. These included establishing a Japanese version of the U.S. National Institutes of Health (NIH), speeding up examinations by strengthening the Pharmaceutical and Medical Devices Agency (PMDA), and utilizing Medical Excellence Japan (MEJ), a general incorporated association, to promote international healthcare development. These measures are expected to lead to more effective and efficient funding particularly at the basic research stage and, for finished products, a stronger system of approvals, licensing and sales(Figure 7-1).
- But further steps must be taken in order to make the Japanese medical device industry more competitive. Japan needs to develop the people, infrastructure, and matching capability required to produce superior ideas through coordination between people in medicine and engineering and to commercialize items which are deemed marketable (Figure 7-2).
- Japan's leading medical device manufacturers are hardly poor in resources. Compared with the United States, however, Japan not only has fewer large corporations, but a lower level of labor mobility, making it difficult to share the knowledge and skills of larger firms with the general community. In order to raise the level of Japan's medical devices industry as a whole, it will be vital to look beyond the confines of the major firms and utilize outstanding ideas, technologies, and other resources offered by outside individuals, midsize firms and SMEs.
- In Japan, development usually proceeds not from clinical needs, but rather from technological "seeds" produced by specific companies. This situation raises issues such as the following: ①Coordination between medical and engineering professionals is inadequate, which hinders the adequate understanding of clinical needs; ②Companies tend to limit the technologies required to resolve medical needs to those developed in-house; and ③Because companies fail to see development from a commercial perspective from its earliest stages, finished products do not always prove marketable. The kind of innovation practiced in Silicon Valley – aimed at solving problems and deriving from actual clinical needs – is not to be found in Japan.
- Idea generation; basic research: Japan does not have a professional development program like Stanford's Biodesign Program; nor are there many development courses for physicians that give consideration to the development of medical devices. By contrast, many university medical courses in the United States include medical device development among their subjects, as well as allowing students to gain work experience with medical device manufacturers. There are not enough venues in Japan where engineers can get to know the needs of physicians. The acquisition of technologies is also easier in Silicon Valley, where there exists a community-wide network of information.
- Animal testing and clinical trials: There are few laboratories in Japan where testing can be done on large animals. There is a particular shortage of facilities adapted for good laboratory practice (GLP) and of personnel qualified to conduct testing adhering to GLP. Few hospitals cooperate in large-scale clinical trials, and there are only a limited number of clinical research coordinators (CRC) and contract research organizations (CRO) in the medical devices field. The cost of clinical trials is higher in Japan than in the United States, and few systems or organizations provide the financial support that can mean life or death to a device developer.
- Commercialization: Silicon Valley's greatest strength is that commercialization is taken into account from the very first stages of development. In Japan important resources are in short supply, including mentors with business experience, intellectual property consultants, approval and licensing professionals, and incubators and venture capital firms offering these resources and others. Japan also needs a system by which developers can be matched up with larger firms in order to benefit from the latter's organizational and financial strength.

Figure 7-1
Major Medical Devices and the Japan Revitalization Strategy

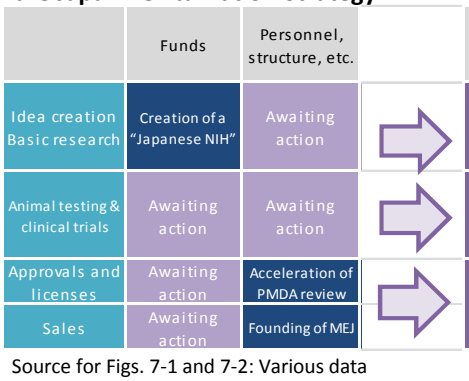


Figure 7-2
What Silicon Valley Can Teach Us About the Development and Commercialization of Top-quality Medical Devices

	People	Infrastructure Environment	Matching ability Funding
Idea creation Basic research	People capable of producing marketable ideas	Places/opportunities for identifying clinical needs through coordination between medicine and engineering	Matching with required technologies (midsize or smaller companies)
Animal testing & clinical trials	People qualified to carry out testing according to GLP Clinical research coordinators	Animal testing labs Medical institutions to cooperate in clinical trials Contract research organizations	Capital supply from clinical trials through commercialization
Commercialization	Experienced mentors to guide commercialization	Intellectual property consultants and other infrastructure supporting commercialization	Matching with large corporations (Acquisitions, tie-ups)

Source for Figs. 7-1 and 7-2: Various data

8. Development Outlook for the Japanese Medical Devices Industry

--- Drawing from Silicon Valley to Foster Open Innovation: The Possibilities ---

- Certain key technologies are needed for the development of medical devices (Figure 8-1). Companies holding core technologies are numerous in Japan, and if their technologies can be used effectively, this will go a long way toward boosting the competitiveness of Japan's medical devices industry.
- Japan needs to develop the people, infrastructure, and matching capability discussed earlier. It must also offer better support for cooperation between medicine and engineering and for the commercialization of ideas. One method would be for local government to lead the way. Special districts, or clusters, would be formed within individual regions, each having its own uniqueness or strength. Drawing on these, local government itself would take the role of incubator by ①promoting cooperation between medicine and engineering by liaising between medical practice and business, utilizing local universities or university hospitals to help identify needs and carry out clinical trials; ②providing resources, such as animal testing labs, intellectual property consultants, and persons with experience working for leading medical device corporations; and ③ creating a system whereby midsize and smaller companies with necessary component technologies could be matched with larger firms that in the end would be responsible for selling the product (Figure 8-2).
- Japan needs to nurture people who can generate ideas that will lead, ultimately, to a marketable product. It must provide suitable venues and funding. But it also must develop incubators and venture capital firms capable of supporting commercialization. This is a mid-to-long-term project that will require a substantial amount of time. With many other domestic issues also calling for action, it will be a challenge to improve the competitiveness of Japan's medical devices industry as rapidly as possible. But an effective solution can be found in pursuing open innovation that draws on Silicon Valley's strengths.
- For example, one can envision a model in which ideas or "seeds" produced during basic research are brought to the Fogarty Institute for Innovation and commercialized using Silicon Valley's resources along with Japanese component technologies. A large Japanese corporation would then acquire the product, taking charge of approvals, licenses and the sale of the finished item. The large Japanese firm might contribute funds or enter into a tie-up with an incubator in Silicon Valley (Figure 8-3).
- Another model might feature exchange: Staff of the Stanford Biodesign Program would come to work in Japan, with Japanese researchers working at Stanford, the Fogarty Institute for Innovation, or a similar institute in Silicon Valley. This would give Japanese researchers excellent opportunities to develop their talents.
- If Japan is to have a more competitive medical devices industry, it is time to build a Japanese framework that fosters innovation aimed at resolving problems through cooperation between medicine and engineering. Alliances with Silicon Valley can be a significant element in this process.

Figure 8-1
Key Technologies of Medical Devices

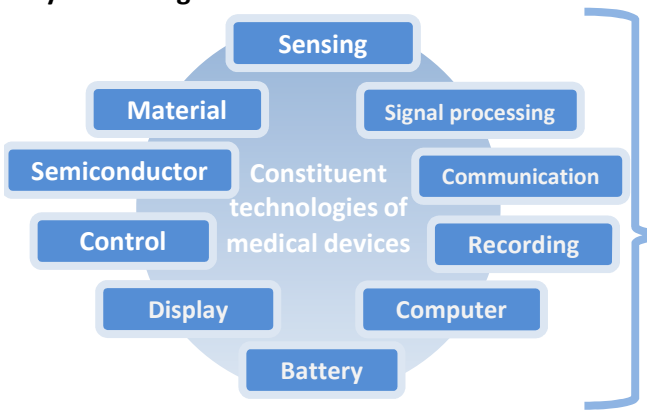


Figure 8-3 Medical Device Development via Open Innovation involving Silicon Valley

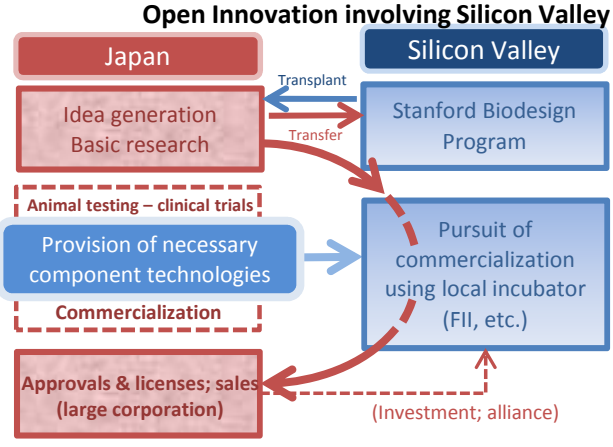
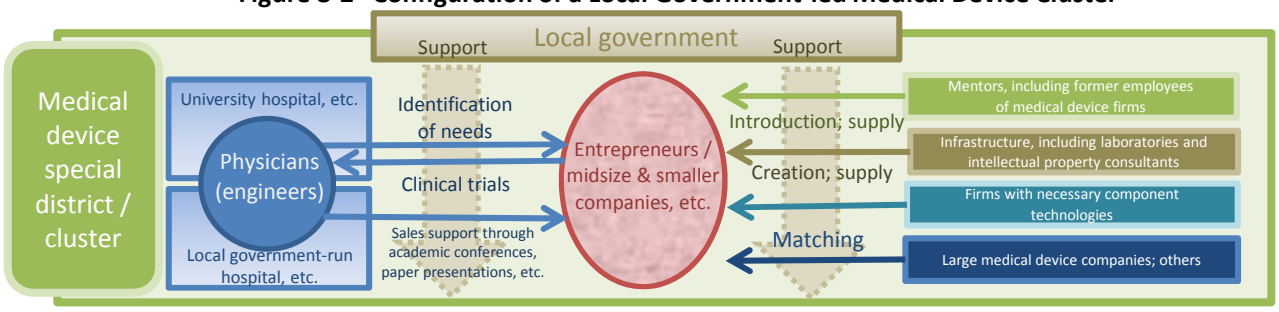


Figure 8-2 Configuration of a Local Government-led Medical Device Cluster



Sources for Figs. 8-1 through 8-3: Various data

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