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Boston Scientific and Medinol (A)

As 2001 opened, Boston Scientific seemed at a critical point in its rapid rise to leadership in the medical device industry. The Natick (Massachusetts) company had reported on February 6 that fourth-quarter profits fell 19%, as the company lost share in its core product, coronary stents. At the same time, Boston Scientific was having difficulty in its effort to acquire Medinol, the Israeli company that had been its primary stent supplier for a decade.

This was the company's second high-profile bid to acquire Medinol. In 1997 it tried to do so after Medinol signaled its intentions to go public. Boston Scientific's buyout offer was rejected, but Medinol subsequently scrapped its plans to go public. In 2001 Boston Scientific possessed a 22% stake in the Israeli company.[1]

As competition intensified in the market for coronary stents, Boston Scientific had become increasingly concerned about the performance of the alliance. While the partnership had originally jump-started Boston Scientific's late entry into the market, the way in which benefits and risks were shared was now at issue. According to analysts, Medinol received larger margins from the alliance than did Boston Scientific. Also, Medinol was Boston Scientific's sole supplier of heart stents, which raised concerns about the risk to Boston Scientific of supply interruptions.

While executives at Boston Scientific considered their options to regain market share in the stent market, they received more bad news: Medinol's Chief Executive Officer Judith Richter had rejected the current buyout offer from Boston Scientific. Should Boston Scientific now its buyout offer? If not, what would become of the alliance?

The Market for Treating Coronary Artery Disease [2]

The human cardiovascular system consists of the heart, arteries, and veins. Blood vessels are responsible for circulating blood throughout the body. Arteries carry oxygenated blood away from the heart, while veins transport deoxygenated blood back to the heart. As the body ages, cholesterol or other fatty materials can accumulate inside the artery walls, obstructing normal blood flow. Left untreated, this condition may cause a heart attack.

Research Assistants Voralak Suwanvanichkij (MBA '05) and Daniel Goldsmith (MBA '06) prepared this case under the supervision of Professor Benjamin Gomes-Casseres as the basis for class discussion, rather than to illustrate either effective or ineffective handling of an administrative situation. The case is based on public sources and has not been reviewed by company officials.

The World Health Organization estimated that approximately 16 million adults worldwide died of cardiovascular disease in 2000.[3] In 2002, this disease accounted for almost half a million deaths, or one of every five deaths in the United States. Additionally, the angina (chest pain due to coronary heart disease) affected an estimated 6.4 million people in the United States and was growing by roughly 400,000 new cases every year.[4]

Cardiovascular medicine changed drastically in the 1970s, especially in the United States. Prior to that time, the treatment of heart disease involved surgery performed on the open heart, requiring blood flow to be diverted through a heart-lung machine. Open-heart surgery was an extremely invasive procedure that required long hospital stays and lengthy recovery times, which posed additional risks, such as infection and severe internal bleeding.

An alternative procedure, introduced in the late 1970s, was balloon angioplasty, a procedure in which a catheter is threaded through the blockage in the artery, and a thin, un-inflated balloon is passed to the tip of the catheter. Once positioned in the artery, the balloon is inflated to flatten fatty deposits, press open the blockage, and create a channel that increases blood flow to the heart. The balloon on the delivery catheter is then deflated and the delivery catheter is removed from the patient. While much less invasive and with shorter recovery times (patients are usually discharged home the next day and can resume routine activities within a few days), angioplasty posed the threat of "restenosis," or the re-closure of the artery. As angioplasty was widely utilized, restenosis became one of the biggest problems of interventional coronary treatment. Restenosis, caused by an overgrowth of normal tissue that occurs during healing, generally occurred in about 40 percent of patients within six months of angioplasty. Patients, therefore, often required repeated angioplasty treatments to keep arteries open. (See **Exhibit 1** for comparative data on different coronary treatment techniques.)

By the early 1990s, medical researchers sought to mitigate the occurrence of restenosis by implanting a bare metal stent into a patient's artery after angioplasty. A tiny stainless steel device that is comprised of wire-mesh tubes, the stent provided additional mechanical "scaffolding" that is permanently implanted to keep cleared arteries from re-closing. Researchers found that stents reduced the incidence of restenosis by 20-30% in patients. (See **Exhibit 2** for description of stent.)

The company to market metal stents successfully was Johnson & Johnson's Interventional Systems in 1994. Boston Scientific, along with another company, Guidant, had started development of their own stents in the mid-1990s, attempting to differentiate themselves through stent design and delivery systems, including increased scaffolding or strength in keeping an artery open. The early stent development attempts at Boston Scientific resulted in mixed success, because its stents had trouble reducing restenosis. Instead, Johnson & Johnson's superior *Palmaz-Schatz* stent enjoyed market dominance, and by 1996, Johnson & Johnson had sold approximately one million stents worldwide, charging approximately $2,000 per stent that year. Late in 1997, bare metal stents, used in operations performed nearly 750,000 times worldwide that year, overtook balloon-only procedures in volume, accounting for approximately 40 percent of all worldwide cardiac surgery procedures (see **Exhibit 3**).

The Partners [5]

Boston Scientific

Boston Scientific was formed in 1979 by John Abele and Pete Nicholas to acquire an equity interest in Medi-tech, Inc., a medical device development company. Medi-tech's initial products included a family of steerable catheters that were used in some of the first minimally invasive surgical procedures performed. Under Nicholas's leadership, Boston Scientific grew from a start-up with 38 employees to a global multi-billion dollar corporation with 14,000 employees by the late 1990s. The company operated two manufacturing facilities in Galway and Cork, Ireland, possessed direct marketing and sales subsidiaries in more than 25 countries, and had entered into distribution arrangements in more than 60 countries.

The company's focus on minimally invasive devices and procedures for both vascular and non-vascular functions fueled Boston Scientific's tremendous growth. The company later aggressively pursued strategic acquisitions and alliances to take advantage of growth opportunities in a diverse set of medical related industries. During the late 1990s, when Medinol joined its efforts, the firm acquired nine companies engaged in a variety of medical devices ranging from incontinence devices, vascular grafts, specialty urology/endoscopy forceps, endovascular stent grafts, and neuro-endovascular catheters and detachable coils.

At the time, Boston Scientific was actively engaged in a number of alliances, including the following:

Alliance Partner	Nature of Alliance	Product Type
Nitinol Medical Technologies Inc.	Exclusive license and development agreement	Vascular and nonvascular stents
Urologix, Inc.	Exclusive worldwide distribution rights, excluding Japan and the US	Microwave thermotherapy system to treat BPH
Aida Engineering, Ltd.	Joint venture	Synergo(TM) device to treat bladder cancer
Angiotech Pharmaceuticals, Inc.	Co-exclusive license	Use of paclitaxel on intraluminal devices to inhibit restenosis

As discussed in the company's annual 10-K Security and Exchange Commission filings, these acquisitions and alliances helped "to round-out and fill-in gaps in [the] product lines, allowing [Boston Scientific] to offer one of the broadest product lines in the world for use in minimally invasive procedures." A cornerstone of Boston Scientific's business strategy in the 1990s was to quickly enter device markets and try to capture leading or strong market share positions in each of the markets in which it competed: cardiology, electrophysiology, gastroenterology, neuro-endovascular therapy, radiology, urology, and vascular surgery.

Additionally, the acquisitions and alliances had helped Boston Scientific reach "a strategic mass, which has enabled [the company] to compete more effectively in, and better absorb the pressures of, the current healthcare environment of cost containment, managed-care, large buying groups, and hospital consolidations." Recent financial results of Boston Scientific are in **Exhibit 4.**

Medinol

Israel-based Medinol[6] was a start-up that focused "primarily on the stent technology, more than the stent business."[7] The company was founded in 1992 by Kobi Richter, his wife Judith, and Gregory Pinchasik, who met the Richters by chance as he solicited Kobi for driving directions to the beach. Kobi Richter had served 22 years in the Israeli air force and had received his Ph.D. in brain science from Tel Aviv University. He became Medinol's Chief Technology Officer, while Judith Richter served at Chief Executive Officer. She had a Ph.D. in organizational psychology and taught management at Tel Aviv University. A Russian immigrant, Pinchasik served as the company's Chief Engineer, and was responsible for designing many of Medinol's stent technologies. Medinol remained privately held as the company grew to employ approximately 130 people.

During the 1990s, the company gained international attention for its flexible stent designs. Its *NIR* stent marked the company's foray into the medical device industry; NIR stood for "new intra-vascular rigid flex," but the device was also named for Maj. Nir Poraz, an Israeli officer who died in a failed operation to rescue a kidnapped soldier in 1994.

In addition to the superior design, Medinol's NIR stent was produced using a unique and efficient manufacturing process developed by Kobi Richter. The usual method of manufacturing involved cutting the stent by a laser beam out of a tube of metal and then electro-polishing the device. In Medinol's patented method, multiple stents were photo-chemically etched on a flat metal sheet. Individual stents were then cut out of the panel, folded into cylinders, welded, and electro-polished. Medinol's manufacturing method was substantially more cost-efficient in producing a high-quality stent than traditional methods. Competitors had not successfully replicated the manufacturing process, and Medinol believed its stents could be sold for margins of up to 80%, compared to competitors' typical margins of around 35%.[8] Despite Medinol's strengths in design and manufacturing, its lack of market capability limited Medinol from commercializing the stent by itself.

The Supply Alliance

Several major device companies Medinol the company to commercialize the NIR stent. In 1995, Medinol originally entered into acquisition negotiations with Johnson & Johnson. It was estimated that J&J offered $360 million for Medinol.[9] It is unclear what transpired in these talks, but a dispute arose between the Richters, the controlling shareholders in the company, and Professor Benad Goldwasser, who as an original investor held a 13% interest in the company. Medinol broke off acquisition talks and Goldwasser sued the Richters, claiming "the couple started behaving in a deviant manner, keeping the other partners away from the negotiations."[10] Goldwasser also contended that "the couple finally realized that the company had a highly

significant potential," leading to pressure and threats against the other shareholders. According to Goldwasser, the Richter's actions resulted in most of the original investors separating from the company.[11]

After the failed takeover attempt by Johnson & Johnson, Boston Scientific entered into negotiations with Medinol. Later that year, Boston Scientific signed a 10-year exclusive worldwide "Supply Agreement" with Medinol. At the time, both companies viewed the NIR stent as a promising innovation in both stent flexibility and durability—key components that often work against each other. Medinol would develop and manufacture the stents in Israel and supply them to Boston Scientific, who would bundle them with balloon-delivery systems, obtain regulatory approval in the United States (and elsewhere), and market the devices through its global sales channels. Boston Scientific also purchased a 22% interest in Medinol (in the process acquiring Goldwasser's 13%); this left the Richters and Pinchasik with 64% and 14% ownership shares.

Key Terms of the Alliance [12]

The Supply Agreement provided that, among other things, Medinol and Boston Scientific would:

- Jointly participate in a development program for the future generation of stents, including exchanging development/manufacturing equipment, sharing intellectual property, and enjoying limited shared access to one another's offices.

- Form a joint "Steering Committee" to direct the business of the venture.

- Discuss marketing, distribution, and sale of stents, including Medinol training of Boston Scientific sales and marketing executives on how to sell NIR stent products.

- Consult each other in connection with the retention or termination of key employees primarily engaged in the stent business, as well as cross-training Boston Scientific staff at Medinol facilities to create a common knowledge base and promote quality control.

- Disclose to each other all inventions, ideas, and improvements relating to stents conceived during the term of the agreement and make all such inventions, ideas and improvements available for incorporation into the stent specifications.

- Submit petitions jointly to the FDA for all approvals necessary for the manufacture, marketing, distribution and sale of stents to be sold in the US, and agree on the content of all submissions (or note where the two companies diverge).

The Supply Agreement also originally set forth a specific transfer price scheme. Boston Scientific would pay Medinol on a quarterly basis thirty percent of the average sales price of Medinol stents sold by Boston Scientific in the preceding quarter. Boston Scientific also agreed to provide Medinol with quarterly sales reports, and keep complete records of net sales to be routinely turned over to Medinol accountants to ensure complete payment.

Sharing and Ownership of Intellectual Property When the supply agreement was signed, Medinol and Boston Scientific also entered into a "Confidentiality and Non-Disclosure Agreement" that imposed a restriction on Boston Scientific not to disclose Medinol's confidential information, intellectual property, and trade secrets to third parties. The clause specified that:

> [Boston Scientific] will not disclose the confidential information to any party whatsoever, except to those of its employees having a need to know, will use the confidential information only for the purpose(s) of equity investment, exclusive distribution and/or acquisition or other business relationships between the parties and for no other purpose whatsoever and will use at least the same measures to protect the confidential information that it uses to protect its own confidential information. In this clause confidential information is defined as "information concerning the disclosing party's past, present and future research development and business activities and the results there from, including but not limited to the NIR stent.

At certain times in the alliance, Medinol provided training to Boston Scientific sales and marketing executives on how to sell NIR stent products. Also, Boston Scientific employees, including about twenty quality control personnel from the Ireland facility, came to work or to be trained at the Medinol facilities for various lengths of time in order to create a common knowledge base and improve quality control.

Another important section of the Supply Agreement regarded future technological developments in stents. While the Supply Agreement included clauses that specifically guided pricing, on the issue of technology development and ownership the agreement was more vague. In general, the relationship between the two companies regarding technology development was intended to be far reaching. The companies agreed to promptly report and disclose to each other all stent developments and to make all such stent developments available to each other.

When first developed, the NIR stent was a technological and commercial leap forward in the market. Soon, however, both companies had their eye on next generation technology that would improve the performance of the stents by coating them with medicine and by improving the system that delivered the stent to the patient. When the alliance was formed, the companies agreed to "jointly identify research and develop programs relating to stents" and to "consult with each other in good faith before approving and initiating any new development programs or clinical trials."[13] The company that developed the next generation stents, however, would retain control of the intellectual property. At the end of the agreement and under certain circumstances during the agreement, such as a breach of contract by one of the companies, the company that developed the next-generation stent would be free to profit from those stents outside of the alliance.

Transfer Prices Medinol and BSC would mutually profit from the venture's commercial sales of stents and stent delivery systems under a fixed formula. Set forth in the Supply Agreement, Medinol and Boston Scientific would share expenses, including development costs and legal expenses relating to patent rights, and would share stent revenue on a 70% (Boston Scientific) and 30% (Medinol) basis.[14] Based on an average retail price of $2,000 per stent,

Exhibit 5 shows an estimate of each party's contribution and profits per device. According to Kobi Richter, Medinol's efficient manufacturing process allowed them to retain approximately 20% of the 30% they received of each sale, while Boston Scientific received about 7% profit of their 70% share.[15]

While Boston Scientific originally signed on to the pricing scheme, the company had become concerned about the future stability of the transfer prices. As competition in the stent market intensified, the average market selling prices for stents was forecast to drop. Meanwhile, to improve its product positioning, Boston Scientific and Medinol might need to make improvements to the NIR stents, potentially raising average production costs. If higher-costing stents were sold as average selling prices decline, gross margins for both partners could be negatively impacted, although it would be unclear who would be hurt more by market dynamics.[16]

Security of Supply Because Medinol would be responsible for filling the demand generated by Boston Scientific's sales efforts, the agreement also included provisions guiding the management of stent supply. One such clause required supply forecasting by Boston Scientific, providing that a twelve-month forecast of stents, including supplemental monthly orders, would be delivered monthly to Medinol. In addition to the forecasted amounts, Medinol would fill the supplemental orders "to the extent they occur in the fourth, fifth or sixth months of the current forecast and are between 80% and 125% of the forecasted amounts." In order to satisfy Boston Scientific's orders for stents, Medinol agreed to establish two commercial volume production lines for the manufacture of NIR stents in Israel.

Under the agreement, Medinol was to become Boston Scientific's primary source of stents for at least ten years. The only exception was an additional commercial volume manufacturing line, named the "alternative line," that was to be installed by Medinol engineers at a Boston Scientific facility. Under certain circumstances, Boston Scientific would be able to activate this line; the main contingencies considered at the time of the supply agreement were a failure of Medinol to supply Boston Scientific with its forecast or a supply disruption due to a terrorist-related incident in Israel. In these cases, Boston Scientific would have means of guaranteeing supply. Medinol trained Boston Scientific manufacturing personnel for the alternative line, which was to be located in Ireland. Without a qualifying contingency, however, Boston Scientific was not permitted to use the alternative line, except to manufacture a nominal number of stents to keep the equipment in good working condition.

Despite the advance planning, supply challenges would add tension to the relationship. Because of rapid growth in stent-related surgeries, there was not enough product in the market to fulfill demand. Supply in the U.S., at times dipped to around 35 to 40 percent of total demand.[17] Boston Scientific's 2000 Annual Report mentioned the supply problem and noted that the company's "ability to manage its relationship with Medinol could impact future operating results." Boston Scientific also reported to investors that "any unforeseen delays, stoppages or interruptions in the supply and/or mix of NIR stent inventory could adversely affect the operating results…and [Boston Scientific] has less control over inventory manufactured by third parties as compared to inventory manufactured internally."[18]

Future Challenges

Despite concerns the two companies had over price and supply issues, many analysts thought that the relationship was proceeding smoothly. As allowed by the alliance, both companies engaged in research and development for next-generation improvements of the NIR stent. Medinol developed a suite of possible successors to the NIR, with the next-generation NIRflex emerging as the most promising successor. Boston Scientific, meanwhile, developed its own next-generation products, such as the NIR Sine and NIR Sine II, simultaneously with Medinol's development of the NIRflex. Under the 10-year agreement, however, Boston Scientific was obligated to sell comparable Medinol made stents first, and would be forced to pay Medinol royalties if it substituted its own product for a Medinol product.

As the alliance moved closer to the end of the 10-year agreement, both parties wanted to assure that progress was made towards their goals. Boston Scientific remained focused on assuring its supply of stents, while also increasing its own technological ability in stent development. The high-profile failure of the Medinol purchase was a setback to the company though, and observers wondered what would be next for Boston Scientific and the alliance. The stakes were high, as Boston Scientific competed against major players in the medical device market (**Exhibits 6** and **7**).

Exhibit 1 Coronary Heart Devices Introduced in 1970s-2000s

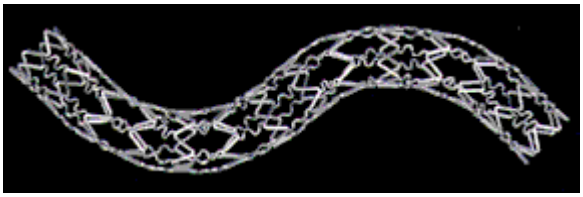
Treating Coronary Disease
US market

Device	Components*	Life span	Re-closure (restinosis) rate
Balloon Angioplasty	Guide wire (catheter), balloon	Late 1970s to 2003	40%
Coronary Stents (implanted after angioplasty)	Bare stent, delivery system	Early 1990s to 2003	20-30%
Drug Eluting Stents	Bare stent, drug coating, delivery system	2003 to present	<5%

*Stents are generally sold bundled with delivery systems such as balloon catheters

Source: Case writer analysis.

Exhibit 2 Diagram of a Stent and Implantation Process



Source: http://www.harthosp.org

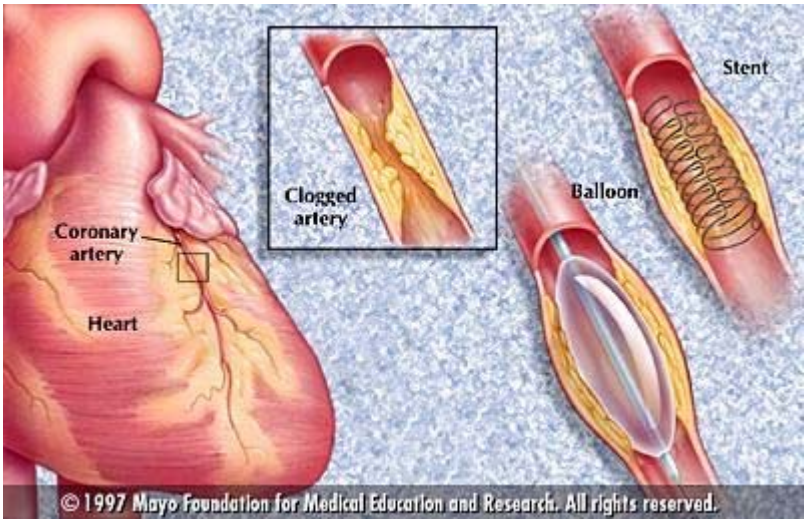
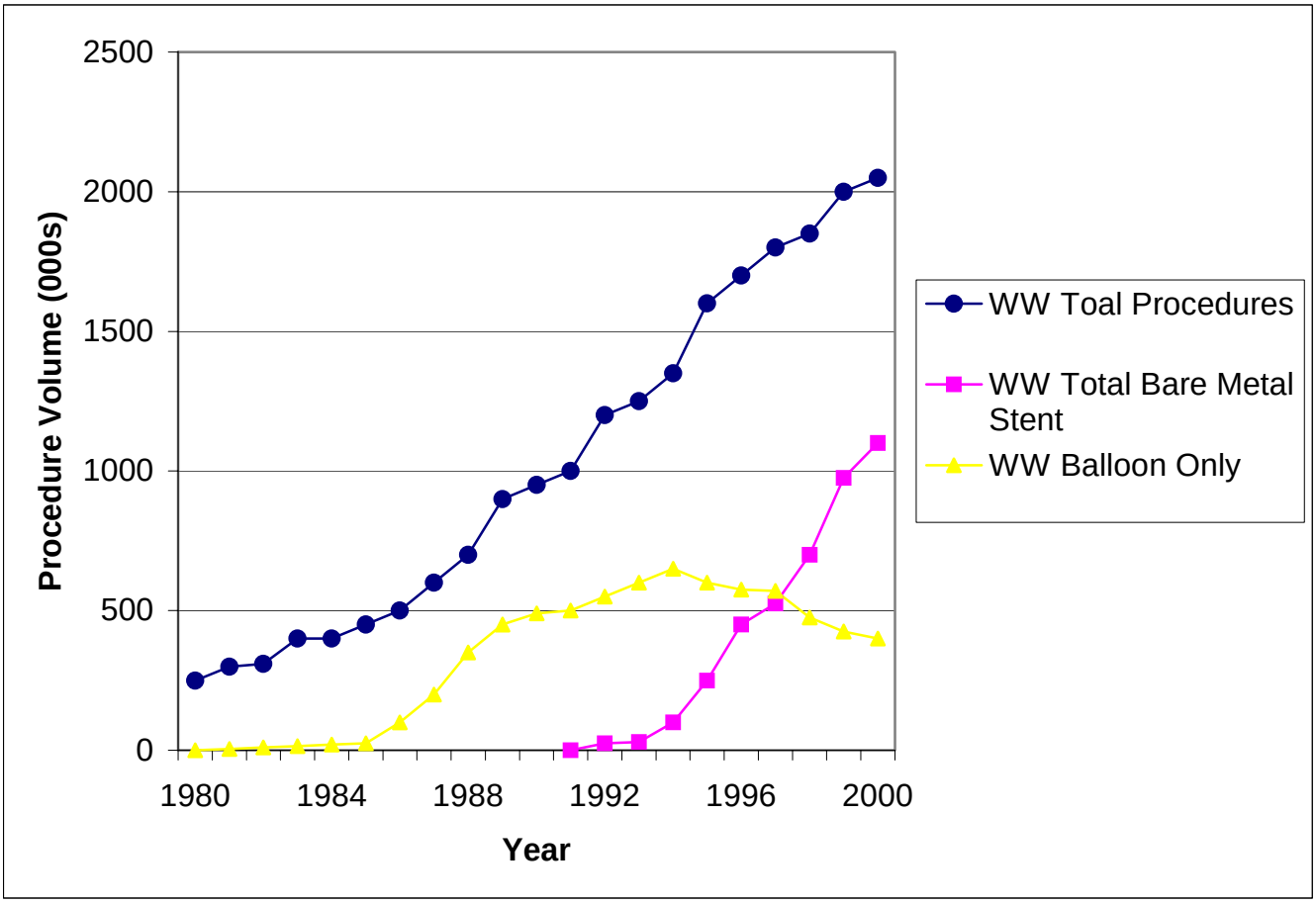


Exhibit 3 Cardiac Surgery Procedure by Volume by Year (000)



Source: Adapted from HBS Case 9-804-180 (Conor Medsystems)

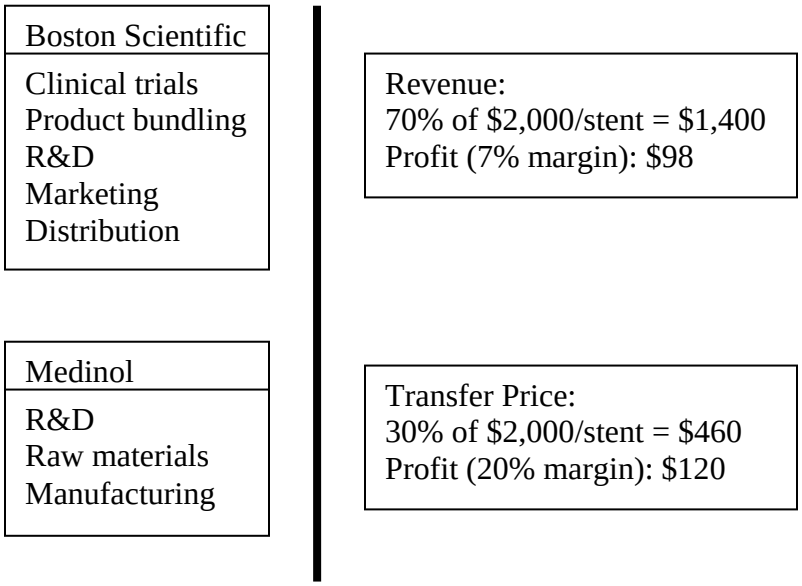
Exhibit 4 Boston Scientific Financials, 1995-2001

Income Statement (mill $) Year Ended Dec. 31	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**
Net sales	1,191	1,551	1,872	2,234	2,842	2,664	2,673
COGS	343	428	550	735	986	832	919
Gross profit	848	1,123	1,322	1,499	1,856	1,832	1,754
Selling, general and admin. expenses	392	516	688	755	842	867	926
Amortization expense				53	92	91	136
Royalties	26	17	22	31	46	37	35
Research and development expenses	106	135	167	200	197	199	275
Purchased research and development	68	110	29	682			282
Restructuring and other related charges	204	32	146	(15)	(10)	58	
Litigation settlements, net							
Operating income	52	313	270	(207)	689	580	100
Other income (expense)	11	(10)	(10)	(68)	(127)	(53)	(56)
Taxes	81	136	98	(11)	191	154	98
Net Income (loss)	**(18)**	**167**	**141***	**(264)**	**371**	**373**	**(54)**

* Includes cumulative effect of change in accounting of ($21,000)

Source: Boston Scientific Annual Reports.

Exhibit 5 Boston Scientific and Medinol Revenue and Profits per Stent



Source: Adapted from analyst reports; case writer analysis

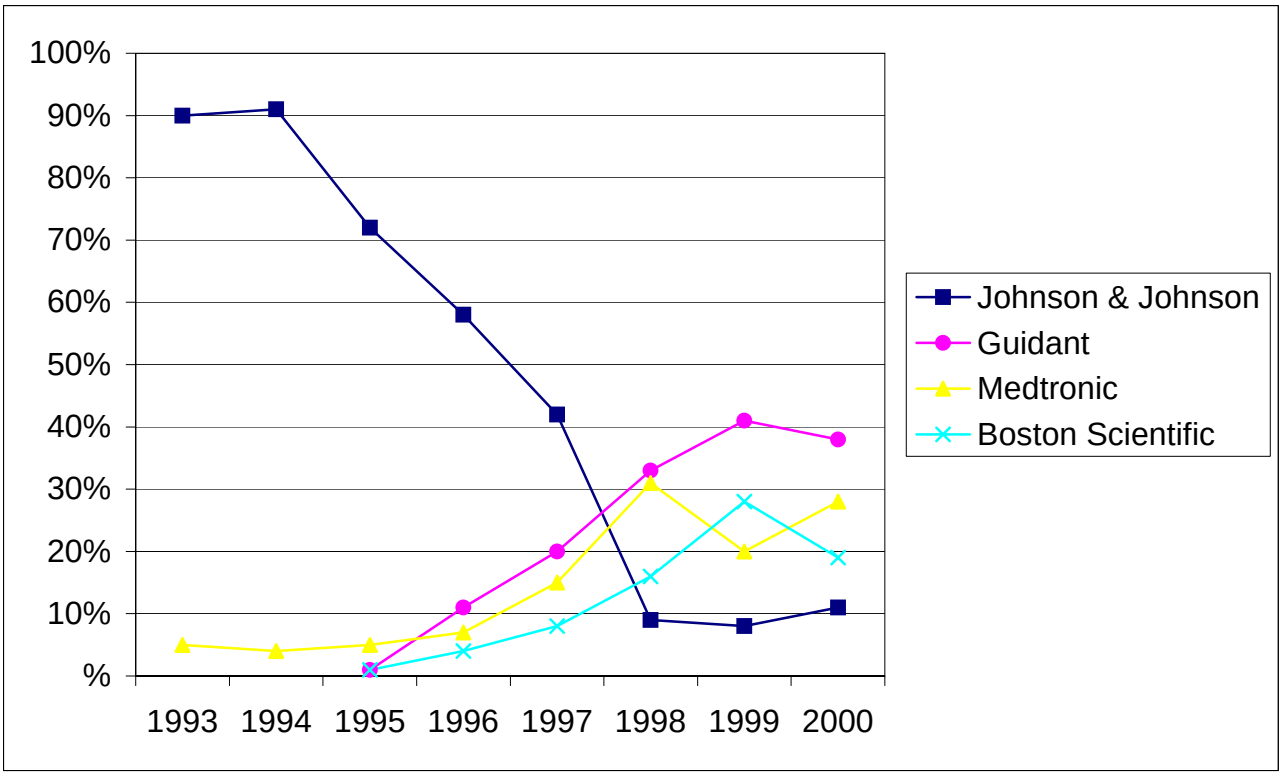
Exhibit 6 Global Players in Coronary Stent Market

FY2002

	Boston Scientific	Guidant	Johnson & Johnson	Medtronic
Headquarters	Natick, MA	Indianapolis, IN	New Brunswick, NJ	Minneapolis, MN
Year founded	1979	1994	1886	1949
Number of employees	14,400	11,500	105,100	27,700
Revenues ($, millions)	2,000	3,200	36,300	6,400
Net income ($, millions)	370	611	6,600	980
Market value ($, billions)	17.2	10.8	164.1	53.8
2000 Stent revenues as % of total	16%	23%	0.50%	10%
2002 Stent revenues as % of total	11%	20%	1%	8%
2006 Proj. stent revenues as % of total	31%	14%	2%	3%

Source: Adapted from HBS Case 9-804-180 (Conor Medsystems), company Web sites, and Forbes.com

Exhibit 7 Worldwide Market Share for Bare Metal Stents



Source: Adapted from HBS Case 9-804-180 (Connor Medsystems)

Endnotes

[1] "A Boston Marriage?", Business Week, Feb 19, 2001

[2] Portions of this section adapted from "Conors Medsystems," HBS Case No. 9-804-180

[3] National Center for Health Statistics Web site, http://www.cdc.gov/nchs (accessed on April 28, 2005)

[4] American Heart Association Web site, http://www.americanheart.org (accessed on April 28, 2005)

[5] Portions of this section, including figures, adapted from company Web site, <http://www.bostonscientific.com> (accessed in March 2005) and SEC filings (specifically Form 10-K) from 1995 to 2000.

[6] Portions of this section, including figures, adapted from company Web site, <http://www.medinol.com> (accessed in April 2005).

[7] Windhover Information Inc. "Medinol: Can Technology Still Win in Stents?" *In Vivo: The Business & Medicine Report*, October 2002.

[8] Confidential Source A1; see reference in (C) case

[9] Ibid.

[10] Ibid.

[11] Ibid.

[12] Confidential Source A2; see reference in (C) case

[13] Confidential Source A3; see reference in (C) case

[14] While the breakdown of revenue sharing and profit is not verified, this information is published on Medinol's Web site, <http://www.medinol.com> (accessed in March 2005).

[15] Confidential Source A1; see reference in (C) case

16 Boston Scientific Corporation. Annual Report 2000: Boston Scientific Corp., 2001.

17 Arner, Faith. "When Will this Stent See Circulation?" Business Week. 22 September 2003.

18 Boston Scientific Corporation. Annual Report 2000: Boston Scientific Corp., 2001.