Medinol is bracing for battle

• By YEHEZKEL LAING

If you want to make $3,000 for a piece of metal that measures half the size of your pinky and weighs less than a gram you should seriously consider developing stents.

What started out as a niche market in the early Nineties is expected to explode into a $6 billion mega-industry for this deceptively simple, potentially life-saving device.

Until recently a major player in the field was Jerusalem-based Medinol. The company, which was founded in the 1993, teamed up with stent giant Boston Scientific Company in 1997 and together they captured some 40 percent of the market.

In 2000, however, Medinol accused BSC of stealing its technology and the two companies parted ways in 2002. Now, closely held Medinol is trying to build up its market share from scratch.

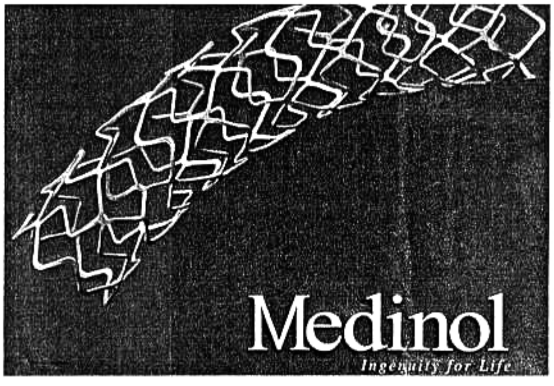
Medinol was founded by Dr. Kobi Richter, one of the founders of Orbotech, his wife Judith, a lecturer at the Recanati Business School of Tel Aviv University, and Gregory Pinchasik, an engineer who emigrated to Israel from Russia. The Richters currently hold a 64% share of Medinol while Pinchasik holds 12%.

Pinchasik met the Richters a little over a decade ago when he was driving through Ramat Hasharon with his daughter on his way to the beach. It was the month of February. On his way he stopped and asked directions from a man tending his yard – Koby. While he was giving him directions his wife came over, curious to meet this man who was taking his daughter to the beach in the middle of winter. The two families became acquainted and the Israelis decided to take the immigrant family under their wings. The two men ended up hitting it off and using the Richters private funds set up Medinol.

The company started manufacturing the NIR stent, named after Maj. Nir Poraz who was killed in 1994 in an attempt to release IDF soldier Cpl. Nahshon Wachsman – kidnapped by Hamas terrorists.

Stents are tiny wire mesh tubes used to clear and keep open clogged coronary (heart) arteries allowing blood to flow freely through it. Almost as important as the device itself is how it is introduced into the body. Stents are inserted via a thin plastic tube called a catheter. The catheter is inserted through an incision near the groin and snaked up to a clogged section of artery. On the end of the catheter is a balloon and on the balloon is the stent. Once the stent reaches the blocked passage the balloon is inflated expanding the device permanently to several times its size, pressing back the blockage and acting like a brace to keep it open. The balloon is then deflated and the catheter is pulled out of the body. Importantly, stenting is a non-surgical treatment and is referred to as only a procedure and not an operation. Only a local anesthetic is required for the procedure and the entire process can take less than 30 minutes.

The procedure is often performed in conjunction with angioplasty which is performed to widen a narrowed coronary artery. In angioplasty a balloon is inflated in the narrowed artery and this pushes open the walls of the artery.



Medinoal's flagship product the NIR stent

Stents are hard to produce because they must comprise contradictory qualities. On the one hand they must be small enough so they can easily be inserted but they must be able to expand to a large enough size to keep open the blocked artery. They also must be soft enough to be expandable yet strong enough to keep the artery from closing again.

HISTORIANS SAY that as early as 3000 BCE Egyptians performed bladder catheterizations using metal pipes. The invention of the modern coronary stent is credited to Dr. Charles Dotter, who developed his first stent in 1969 and implanted it in a dog.

Meanwhile in 1977 in Zurich, a young physician named Andreas Gruentzig inserted a catheter into a patient's coronary artery and inflated a tiny balloon, successfully opening a blockage and restoring blood flow to a human heart.

The first commercial stents were implanted in subjects with heart disease in 1986, even though they had previously been used in a number of medical and surgical disciplines. Between 1993-1997 stents became commonplace and in 1997 alone more than one million angioplasties were performed worldwide, making angioplasty the most common medical intervention in the world.

Today analysts say that the stent market, which is already lucrative, is on the verge of exploding. According to Goldman Sachs and Co. the US coronary stent market alone was worth $1.4b in 2002. This jumped to $2.2b in 2003 and it is expected to double to almost $4b. in 2004 reaching $6b. by 2006. The European market, which is much smaller, is today estimated at $600m.

The market is dominated by three major players which keep one-upping each other. The biggest player is Johnson and Johnson (J&J) which pioneered the stent market in the 1990s. Though it quickly lost market share, it still holds the largest percentage. The other two are Boston Scientific and Guidant. In 2001 J&J and BSC both held approximately a 40% share of the market and Guidant only 10% but in 2002 Guidant skyrocketed to a 40% share while BSC fell to 15%. In 2003 they again exchanged places.

The market, as can be seen, is extremely volatile. Cardiologists are quick to adopt the latest technologies and just as quick to drop them when a newer one comes along. Most of market is for coronary stents though there are stents for other parts of the body. This market is valued at several hundred million dollars worldwide.

The latest development in the field is drug eluting stents. The drugs keep scar tissue from reclogging arteries and the new stents are believed to reduce the failure rate for the device by up to 60%. The drugs themselves require a special polimer to connect them to the metallic stents. The new technique has also been boosted by a promise by American health insurance companies to reimburse hospitals for the procedure. As a result, these superior stents are expected to capture up to 90% of the market by 2006. J&J introduced Cypher, the first drug eluding stent last April.

But the new trend could prove disastrous for Medinol which doesn't have any drug-coated stents. The company, however, said it is not worried.

"We are working on stent that is applied along with a systemic drug, meaning a drug which works on the whole body and not just the area where the stent is located," said Tamara Sugar – vice president of finance, administration and marketing. She said the drug comes from a company called Biorest.

Medinol also has a few other tricks up its sleeve. The company says it has developed a significantly superior production method for the device. Most stents are made by carving out a slotted metal tube with a laser. The process is time consuming and makes it hard to check the stent for defects.

Medinol's stents are made out of a flat piece of metal which are first photo-chemically etched with a design pattern then bent into tube shape and soldered. In the final stage the stents are electro-polished. The method, which is much easier to perform than conventional methods, also makes it easier to check for defects.

Most importantly it is significantly faster. Medinol says that its competitors' method requires them to manufacture their stents in serial method one at a time while it can manufacturer in a parallel manner allowing it to make up to a thousand stents at once. The bottom line is that Medinol can produce its stents for a cost of about 1/15th of its competitors. While its competitors sell their stents for about $2,700 a piece Medinol's sells for only $1,000.

Medinol has also developed a special bendable stent. Due to the movement of the body, over time a stent may become bent thereby causing the blood flow to be cut significantly. The company therefore designed the new NIRflex which keeps its shape even after it is bent, allowing the blood to continue to flow normally. In November the US Food and Drug Administration (FDA) approved the new stent.

MEDINOL'S SUCCESS in the market began in November 1995 when it formed a joint venture in the cardiovascular stenting field with the Boston Scientific Corporation (BSC). Medinol developed and manufactured the stents, while BSC supplied the catheters and marketed them world wide. Medinol received 23% of the user price in return for supplying the stents and BSC retained 77% in return for supplying the delivery systems.

In April 2000, after the venture had existed for over four years, Medinol said it learned of a hidden agenda at BSC which had begun in 1997. The scheme consisted of slowly freezing Medinol out and "Bringing a Better Deal to BSC" (nicknamed BBD by Boston Scientific) to enjoy Medinol's assets in the venture.

To achieve its objective, Medinol says BSC created a "shell company" in Ireland with no traceable links to BSC. The shell company that operated under the name BBD was designed to duplicate Medinol's special manufacturing method and later on of its patented NIRflex stents. The operation of BBD was then aimed at arriving at a capacity of 40,000 of what it called "BSC NIR stents" per month. According to Medinol BSC forecasts and plans slowly began shifting to be in synchrony with the developing capacity in BBD and the forecasts of orders from Medinol started falling to a level that would be supplemented by BBD stents in BSC's internal forecasts.

Medinol says Boston Scientific's attempt to defraud it was eventually revealed by Ernst & Young, Boston Scientific's outside auditors. BSC in its financial statements failed to reveal its ties to BBD. The auditors insisted that BSC correct its financial statements and specify that BBD was wholly owned by BSC. In April 2000, BSC was forced to reveal its ownership of BBD to the Irish governmental authorities. As a result, BSC's CEO – Jim Tobin – handed Medinol a chronology describing the scheme.

In spite of the discovery, shortly thereafter Medinol entered into negotiations with BSC to buy it out. Company spokesman Avigail Marks explains.

"We didn't want to get involved with a five-year legal battle so we told them buy us out and that will be the end of the story."

For BSC stent sales were less profitable than their competitors who produce their own. While competitors were making up to 90% profit margin on sales, BSC was making only about 65%. Hence the desire to buy Medinol.

"If we owned [Medinol], we wouldn't have to see that gross profit leak out of the company," CEO Tobin said at the time.

IN MID 2000 BSC began talks to buy Medinol, of which it already held 22%. Analysts had pegged the company at about $1.5b. but it is believed that the Richters wanted $2.5b. BSC refused. Sugar, meanwhile, said that the whole deal was a bluff.

"BSC never intended to buy Medinol. The negotiations were only a ploy for BSC to buy time so it could copy the NIRflex."

When the talks looked as if they might fail Tobin said cryptically, "However the Medinol negotiations are ultimately resolved, we have alternatives open to us." Medinol eventually decided to file a complaint with the court in the Southern district of New York State. In the complaint Medinol sought damages for the sabotaging of the venture activity over the last four years. The defendants – BSC and some of its managers – are being sued for the damage they caused Medinol and for punitive damages as a Racketeer Influenced and Corrupt Organization (RICO). The case has yet to go to trial.

In June, a German court found BSC guilty of infringing on the patents of Medinol. It ruled that BSC's Express and Taxus stents infringed on several Medinol patents. And in December a Dutch court ruled that J&J's Cypher stent infringes on Medinol patents. J&J and BSC were subsequently forbidden by the courts to sell their stents in Germany and Holland.

The victories, however, may be Pyrrhic ones. Medinol did not manage to secure a cross border injunction from the courts which means that while BSC and J&J cannot sell their product directly in Germany and Holland they can be imported. Worse for Medinol, BSC has come out with a new stent called the Liberte which analysts say does not infringe Medinol patents.

Even if Medinol did win the case, the technology is moving so fast that by the time the courts decide, the technology will be obsolete. The best Medinol can hope for is a one time payment for proving its technology was stolen.

Lawsuits are common in the industry. In November, a US federal court judge denied a motion by J&J to keep BSC's Taxus drug-eluting stent off the market for alleged patent violations.

"The industry has always been very litigious and it always will be," said Bruce Jacobs, an analyst for Deutsche Bank. He said this is because people have different ideas as to what constitutes Intellectual Property .

Can Medinol break back in? Goldman Sachs does not even include Medinol in its forecast of market shareholders in the next few years. But Medinol dismisses the pundits.

"Analysts don't know what we are up to," said Sugar. "We are not a public company and we are not required to report our plans to our shareholders."

Medinol recently teamed up with privately-owned Gore and Associates, the maker of the well-known Gore-tex fabric, with annual revenues of $1.35b. In a deal similar to the one it had with BSC, Medinol will provide the stents, while Gore, via its medical division, will provide the catheters and market the stents in the US.