

## MassDevice Q & A: Boston Scientific co-founder John Abele

Mass Device



There aren't many multi-billion-dollar companies that can say they got their start in the basement of a Catholic church rectory. Still fewer can claim a connection to a famous Czech mystic credited with pioneering research into human consciousness (and, not incidentally, with inventing the steerable catheter).

But according to co-founder John Abele, Boston Scientific Corp. (NYSE:BSX) can. The Natick, Mass.-based medical device maker got its start with the steerable catheter invented by Itzhak Bentov, leveraging the platform into a family of catheter-based products that changed the way medicine is practiced.

In a lengthy interview, the first installment of which appears here, Abele told **MassDevice** about Boston Scientific's connection with Bentov and his Belmont, Mass.-based lab, why his invention was so revolutionary and how the company won over early skeptics.

**MassDevice:** Tell us about the early days of Boston Scientific. Was there an "Aha!" moment when you knew you had a nascent idea for which the time had come?

**John Abele:** A little bit of yes and no. In the very early days the predecessor to Boston Scientific was a company called Medi-tech, located in Watertown, Mass. Medi-tech started in the late 60s and was actually all around one inventor named [Itzhak Bentov](#) [1]. He was a very inventive person, but also a person who was not the type you would normally think would be an inventor. He was a very spiritual person, he did meditation, he was a very soft-spoken person. He was interested in how the brain worked and actually attached electrodes to his head which were connected to a function generator in which he could change the wave shape and the power and learned about how the brain interprets these different frequencies. He was sitting on a chair with a dead-man's switch so that if he fell over the

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machine would turn off. He was actually born in Czechoslovakia, parents wiped out by the Nazis, emigrated to Palestine, later Israel, and wound up speaking something like 11 languages. It turns out he was a very eloquent person, he could explain complex ideas very well.

He had a shop where he started in the basement of a rectory of a Catholic church in Belmont, Mass. One of his inventions was a [steerable catheter](#) [2], a fairly complex thing. He was doing it at the request of a number of physicians at the Beth Israel Hospital in Boston. In the basement of this rectory in the Catholic church he had the most amazing collection of tools. He had a chemistry lab, he had an electronics lab, he had a miller so he could mill and shape steel or wood or plastic, he had an extruder so he could work with polymers. He would literally make his own polymers or at least mix different polymers in order to get what he wanted. As a result, he was kind of a renaissance person, technologically as well as intellectually.

This steerable catheter was the beginning of Medi-tech, which was then the beginning of Boston Scientific. I met him at that time and joined the company with an option to buy it and took that company, with its steerable catheter — this was before the FDA, I might add. The FDA started regulating medical devices in 1976, at least that's when the law was passed, but it took almost another five or 10 years for them to figure out the way to regulate this complex collection of thousands of little companies. Very, very different from the pharmaceutical world.

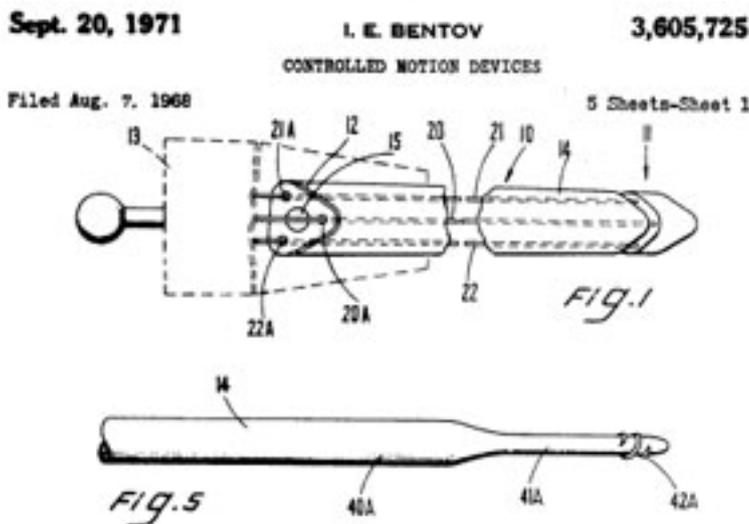
But it meant that if you were developing products in that era, what you did is you went to a doctor and said, "What do you want?" And they would describe it, you'd build it and they would test it out. Sometimes they would try it in people. Some people say, "How horrible! Weren't you putting people at risk?" And I say, "Well, not actually." That's the way everybody was treated and in fact, if you had a company behind you to make the devices, they were probably going to be safer than the jury-rigging that went on in the hospitals where they were trying to deal with very specific patient problems.



*John Abele*

So the steerable catheter was requested by a radiologist and a gastroenterologist. What they were interested in doing was seeing if they could get a catheter from the mouth into the common duct. The [common duct](#) [3] goes from the duodenum, just beyond the stomach, and it connects the liver, the pancreas and the gallbladder to the duodenum. As it turns out, we actually had some doctors who were able to do that radiologically. It was only many years later that the gastroenterologists started to use flexible endoscopes and were able to use catheters through an endoscope to access that same part of the body. It was considered pretty dramatic at the time.

When I saw that, to me this wasn't a product, it was a platform for a family of products. The idea of being able to manipulate this catheter seemed very powerful to me. Most catheters at that time were, in many cases, cut and shaped by the user, by the physicians themselves. USCI [[United States Catheter & Instrument](#) [4]], another Massachusetts company, made pre-formed catheters that could be torqued, meaning that if you twist one end the other end tends to follow rather than wrapping up like limp spaghetti.



*Detail from Bentov's 1971 patent*

But this one was different. Instead of needing to rotate it, it worked like a marionette. It had a special extrusion with a central lumen and then four holes in the wall. In the four holes, wires were inserted and connected to a ring at the tip, so when you pulled one of those wires the catheter would deflect in the direction you pulled it. You could aim it in any direction without having to twist it. That was kind of neat. More important than that, it wasn't a single extrusion. The extrusion was connected to softer sections of extrusion as you got closer to the tip, so it was preferentially softer toward the end of the catheter.

The thing that was attractive to me, because I had worked in a medical company since 1960 and had actually sold some of the first pacemakers Medtronic made — the company I worked for distributed Medtronic and Medtronic distributed our products, which were lab instruments. I had ended up running that company for an owner who wanted to hold it very tight, and I wanted to do something on my own. So I went looking for opportunities and this Itzhak Bentov was, to my mind, the

perfect answer. A startup operation, a brilliant inventor, a guy who could respond to ideas very quickly in an environment where we didn't have the regulatory — of course I didn't know then that that was a wonderful thing — but in any case we were able to take that product and literally create a family of different products. Catheters made for the GI tract, catheters made for arteries and veins, catheters made for the urological tract, and because it could be steered using radiologic guidance, it meant that the ability for the physician to access all of these organs with a catheter was dramatically improved.



### *Medtronic's first pacemaker*

More interesting, however, and if you will the big moment, my concept was, "Gee, we're there diagnosing these problems where we can get these catheters into these incredible corners of the body. Why, if we're diagnosing the problem, don't we fix it at the same time?" Now that doesn't sound like a terribly new idea or a bold or innovative idea, but as it turns out, it was innovative compared to the way people were thinking at that time. That's partly because of the way medicine is organized, where you have these different silos and people specialize in these very narrow areas of expertise.

The opportunity is recognizing, by looking at what they do differently, how you can improve and extend the ability of any one of these to do more. To diagnose more with less trauma and so forth, and to, in many cases, treat. You can remove debris that's established there, it might be a clot, it might be a stone in a kidney or a foreign body in the lung or GI tract. We made little baskets that went with that catheter and gradually built up a collection of devices. We were perhaps typical of companies at that time, in that we were going after a lot of different applications. The business expert would say, "You've got to focus." Well, that's easy for the business expert to say, but my response was, "Focus on what?" The problem is we've got lots of opportunities; we're looking for one that has some legs to it, but an awful lot of what we were doing were used by just a few people. Even though the physicians would look at this thing and say, "Wow, what a great product," it would sit on their desk after they bought it and they wouldn't use it. We had to find champions who could not only endorse the product, but teach others all about the

unique ways in which it could enhance a medical practice, and that's what we did.

Rather than go after physicians who were famous names — and in fact, most of them, if they were surgeons, they were very suspicious of us, they didn't like us — but there were some cowboys in the various specialties. They were the classic early adopters and they would do it. The only problem is they weren't very credible, because they exaggerated, they weren't as thorough as we would like them to be. But among those cowboys we found a few people whom we predicted would become leaders themselves. They were not only good in terms of the skills of manipulating a catheter, but they were good writers, they wrote what they did and documented it, they were good speakers, they were great teachers. That, of course, was essential for us because we were creating totally new markets. Our philosophy was, we develop technology that leads to products that lead to procedures that reduce risk, trauma, cost and time.

**MassDevice:** Was there a moment when you knew Boston Scientific had arrived, that it was destined to be a juggernaut?

**JA:** It was really quite a while. I did not get into this business to flip it, it wasn't a financially driven thing. [As it turns out I did fine](#) [5], thanks, but I wanted to build an enterprise. I wanted this to grow and see it applied in different places.



*John Abele*

You have to have the financial discipline or you don't stay alive. I remember those early days, when I might have a \$5,000 month and try to figure out how I was going to pay the bills, which is the classic startup thing everybody goes through. But we had the benefit of not being regulated to death. I respect what the FDA is doing. It's the dilemma of how do you protect patients and yet encourage innovation, which is also protecting patients. In the device world, very unlike the pharmaceutical world, technology iterates. You build something, you go out and try it, you learn, you adapt and you go out again. As a result, in that environment we were able to do tons of things. I actually used to put together little packages of extrusion and wires and tools and give them to physicians who wanted to do this themselves. So I had a little sort of a care package and it was kind of fun, because my doctors became my R&D team.

**MassDevice:** I'd like to read you something you [said](#) [6] back in October 1996, about Andreas Gruentzig's impact on coronary medicine:

"I'm always fascinated with how do you assess new technology, particularly in the

climate of technology which is constantly changing. Not only is the technology changing, but your knowledge of anatomy, procedure is changing, the success rate is changing, your ability to see things is changing, your ability to use drugs, your ability to select patients and follow-up patients is changing. How do you choose, determine when a procedure is safe to be used widely in that environment? [Gruentzig] established a way of doing that. And that was the registry concept. And despite the fact that I think it's probably one of the most successful complicated procedure introductions in the history of medicine, today we've kind of reverted back, probably for legal and regulatory reasons, to a less effective, more bureaucratic process. And hopefully we'll dig our way out and discover, or rediscover what Gruentzig taught so many of us."

Nearly 14 years later, it seems as though both parts of that observation still hold: That technology's advance keeps accelerating, yet the means of evaluating efficacy and safety have become even more hidebound. Do you see a way around that dilemma?

**JA:** Only partially. First of all, what we did and what all the other companies did is we went overseas. In fact, to me, I guess because I was a physics and philosophy major in college and that's always sort of stuck with me, the ethics of how we do what we do was very important to me. I was also very sick as a kid and spent many years in Children's Hospital and I appreciate what physicians did for me. They tried things out that, in today's environment, they wouldn't be allowed because it had failed. I was very appreciative of that. So I said, "Look, whether these patients are in Europe, the U.S. or India, wherever they might be, the key to the ethics of if you should do something is the comparison of what's the alternative." It's compared to what? And the "what" isn't an absolute. It's not being treated in a famous hospital by a famous surgeon — and of course that's no guarantee of success either — the idea is that you take that iterative process, using all of the knowledge you have, and that's what good physicians do.

I think the public is misled into thinking that some procedures are totally safe. Well, that's just not true at all. Every procedure is, to a certain extent, an experiment. When we recognized that, we began to create a network of individuals across a number of fields. We didn't just stick with the heart or cardiology or even radiology. We went everywhere, because hey, the body is made up of tubes and we had a great new tool for getting to different spots of the body. So we were constantly evolving that.

As it turns out we got a few docs who came upon a procedure and the procedure turned out to be very valuable. The first one actually was a way of removing retained stones from the gallbladder or from the common duct. After gallbladder surgery in the early 70s, in about 10 percent of the cases a stone would be left behind and that stone would end up jamming the common duct and the patient would turn yellow, they'd be jaundiced. What usually happened was that the doctor had to re-operate. That's a disaster, obviously for the patient because that's a painful operation with a long recuperation period, and also for the physician. It's a potential lawsuit and all of that sort of stuff.

Well, we found a doctor who developed a technique with our steerable catheter of going in through the drainage tract which is left when you do one of those operations. You leave a tube to drain fluids; that creates a tract that we could put a steerable catheter through and go in. Time and time again we took a procedure where the alternative was surgery and turned it into a 20-minute stone removal thing. It was, obviously for those physicians who needed it — and by the way it was mostly surgeons, although it was mostly done by radiologists — but the surgeons said that was a lifesaver for them.

So unlike a lot of the criticism we got from surgeons, this is one they liked because it helped them out greatly. By and large medicine is very slow to appreciate new stuff. Every thing we did ended up being disruptive. Not by intention, it's just that's what it was. Sometimes it led to a different physician doing the same procedure. Some of these specialties that started out primarily as diagnostic — cardiology or gastroenterology, people don't think of that now but that's the way it was — and so they took over the procedures that the surgeons used to own.

[SOURCE](#) [7]

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### Links:

[1] [http://en.wikipedia.org/wiki/Itzhak\\_Bentov](http://en.wikipedia.org/wiki/Itzhak_Bentov)

[2] <http://patimg1.uspto.gov/.piw?docid=03605725&PageNum=1&&IDKey=33C7A4A01D45&HomeUrl=http://pimg-piw.uspto.gov/>

[3] <http://www.medterms.com/script/main/art.asp?articlekey=2804>

[4] <http://www.fundinguniverse.com/company-histories/CR-Bard-Inc-Company-History.html>

[5] [http://www.forbes.com/lists/2009/10/billionaires-2009-richest-people\\_John-Abele\\_111R.html](http://www.forbes.com/lists/2009/10/billionaires-2009-richest-people_John-Abele_111R.html)

[6] <http://www.ptca.org/archive/interviews/970703int.html>

[7] <http://www.massdevice.com/features/massdevice-qa-boston-scientific-co-founder-john-abele>