Feature

Magic Touch

Concept Medical has created a niche for itself with its innovative drug-coated stent and balloon catheter for diabetic heart patients

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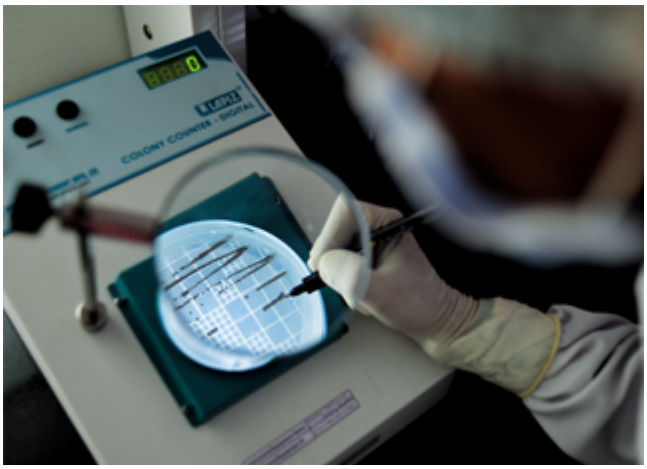
Manish Doshi, founder, Concept Medical

Seated in his office in an unassuming residential locality of Surat, Manish Doshi is a picture of determination and resilience. His firm belief in the power and necessity of innovation is formidable. While he attributes his entrepreneurial and risk-taking tendencies to his '*Gujarati* DNA', what sets his companies, Concept Medical and Envision Scientific, apart from other *Gujarati*-run enterprises, is their strong R&D backing.



Despite their Indian roots, what sets Concept Medical and Envision Scientific apart, is their strong research and development backing

His companies' motto is 'Advancing Innovation' and has developed an innovative drug-coated stent and balloon catheter, with around 30 international patents to their credit. That is indeed a big number by Indian innovation standards. What makes this all the more remarkable is that Doshi has no medical background; he is a textile engineer by training. The development process was long and arduous, taking Doshi and his team seven years and $10 million to develop a marketable product. Doshi had learnt the importance of intellectual property rights the hard way, after he was sued for €25 million by Boston Scientific in the 2000s due to his previous stint at Sahajanand Medical Technologies. He lost the case, but had to shell out only €1,400 since his product was still in the clinical trial phase and was prohibited from commercialising it in Europe. Today, his products have received regulatory approval in Europe. Next, he has his sights set on USA, known for its rigorous FDA processes and also the biggest stent market in the world, with 2.5-3 million stents used every year.

According to Doshi, around seven to eight million drug-eluting (releasing) stents are used during angioplasties the world over every year, valued at around $8 billion. Of the total, 0.45 million are used in India, a number which has grown from 15,000 in 1998, when Doshi first entered the stent market. The global CAGR for stents is a moderate 5%. But what do stents, these nondescript metal tubes, exactly do?

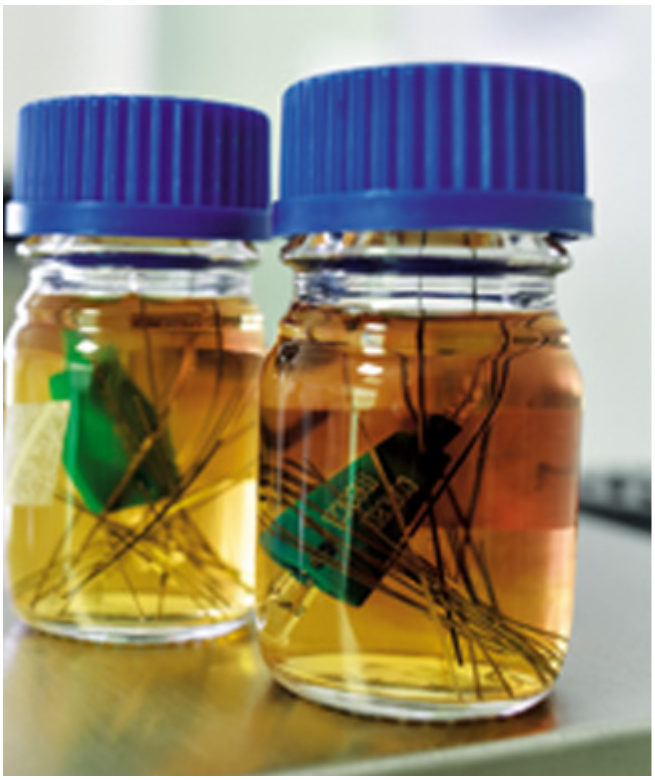
Matters of the heart

Stents, which are metal or plastic mesh tube-like structures, are mainly used during angioplasties. This is how the process pans out. After patients come to doctors complaining of chest pain (angina), doctors recommend them for an angiography where the degree of blockage is ascertained by an inserted camera. If the degree of blockage is significant, an angioplasty is performed on the patient. During angioplasty, a minimally invasive procedure, a stent is inserted into the artery. The stent is surrounded with a drug-coated balloon, which expands during the operation thereby widening the affected artery, a process hence referred to as balloon angioplasty. During balloon angioplasty, the stent is placed into the affected artery to allow unrestricted blood flow.

Previously, bare-metal stents were used during angioplasties. However, because the arterial walls were damaged during balloon expansion, this meant a high chance of restenosis i.e. reoccurrence of arterial blockage. To reduce the chance of this, drug-eluting stents are now used. These release the drug into the arterial wall to treat clotting and cell aggregation thereby reducing chances of re-blockage. An Indian study in 2010 found that 23% of drug-eluting stent patients developed restenosis, compared to 49% for bare-metal stent patients.

A patent of its own

Doshi has developed two products: a drug-eluting stent branded as Abluminus and a sirolimus-coated balloon catheter branded as MagicTouch. Abluminus is targeted at diabetics. Doshi says that diabetic patients are more prone to calcification, and have more significant blockages. In Abluminus, both the stent and balloon are coated with sirolimus which uses a biodegradable polymer matrix for sustained and effective drug release. Doshi says, “In most stents, only the stent is coated with the drug which often doesn’t treat the entire affected area. In diabetics, this means a lot of affected area is left untreated, which leads to re-blockage. In our product, both the stent and balloon are coated, and the balloon is inflated for 45 seconds instead of the usual 15 seconds. This treats maximum blockage.” Doshi claims that clinical outcomes display a re-blockage rate of 2.4%, compared with 10-14% for other products.



With 70% export sales, around 40,000 patients have benefited from the drug-eluting stent and around 3,000 from the sirolimus-coated balloon so far

MagicTouch, on the other hand, is used in patients suffering from blockages in small arteries where usage of stent is not feasible. “This requires a sirolimus-coated balloon. The balloon delivers the drug within 60 seconds and drug release happens in the tissue for 30 days.” The sirolimus balloon is an emerging technology that is addressing some of the limitations of stents. One benefit of the balloon is that after the operation, patients have to take an antibiotics course for 45 days, compared with an antiplatelet therapy course that takes around one or two years.

The biggest challenge in developing MagicTouch was that sirolimus was an unstable molecule with weak binding properties, thereby making it difficult to ‘stick’ to the balloon. Its bio-availability was also less. This is in contrast to paclitaxel, which has strong binding properties, but is controversial among cardiologists because of its toxicity, says Doshi. The efforts have, however, paid off. Doshi was bestowed the Marico Innovation Foundation’s ‘Innovation for India Award’ this year.

Hitting the market

Doshi manufactures the stents and balloons at a sleek sterilised manufacturing facility in Surat, with proprietary drug-coating machines to boot. It has a daily

production of 150 drug-eluting stents as of now, but they plan to expand soon. He employs 82 people, including 18 marketing employees. He credits his dedicated team for the innovation and says the company has witnessed less than 1% attrition rate.

His products are sold in 56 countries so far, with 70% of sales derived from exports. So far, around 40,000 patients have benefited from his drug-eluting stent and around 3,000 from the sirolimus-coated balloon. Eventually, he expects exports to account for 90% of revenue.

This is because his products haven't taken off in India as Doshi expected it to. While doctors are appreciative of the technology, there are too many vested interests which prevent the widespread introduction of new technology. Doshi, however, has the backing of leading cardiologists such as Sameer Dani from Ahmedabad and Devang Desai of Hridayam Heart Care Clinic, Surat.

With this technology, there is a lesser chance of reblockage, less clotting, and the effects are long-lasting

- Dr Devang Desai
Cardiologist, Hridayam Heart Care Clinic

Desai, who has conducted 220,000 angioplasties over a 25-year career, says, "The technology is ideal for diabetic patients and those with smaller arteries. There is a lesser chance of re-blockage, less clotting, and the effects are long-lasting," he says.

The cost of his drug-eluting stent and balloon is around ₹60,000-65,000 for patients (the balloon is sold at 30% premium to drug-eluting stents in European markets because of its uniqueness). Usually, hospitals often make a margin by buying a stent at ₹20,000-30,000 and selling it at around ₹1 lakh. Doshi hopes that this will soon be taken care of by a price cap on coronary stents that the government is planning to

impose by including them in the National List of Essential Medicines (NLEM). However, experts fear that this price cap can obstruct the introduction of technologically advanced stents.

Global calling

Given the export-market focus, the parent company is registered in USA as Concept Medical Inc. This is because Doshi plans to raise private equity funding to expand operations in the United States. He is not interested in getting PE funding in India since he won't get a good valuation because of lack of understanding of new technology. "Here in India, we don't get value; they go by EBITDA, balance sheet, but this is an R&D company, it cannot have a balance sheet," he says. The introduction of the product in USA will require a 'huge human trial' and Doshi will require funding of around $20 million for this. "Many companies are approaching us for the US rights and are ready to go through the US FDA process," he says.

The two companies — Concept Medical and Envision Scientific — have different holding structures. Concept Medical is run in partnership with Doshi's Brazilian distributors, who he has known since 2001 at his previous role at Sahajanand. The Brazilian partners have invested the money, while Doshi has headed technology, which is remarkable considering Doshi has no medical background. Envision Scientific is co-promoted by Indian promoters, but Doshi is the bridge between the two as a founder of both, and the brain behind R&D. "I am personally involved with the team. Since I am constantly in touch with the market, I have market feedback. At the same time, I am connected to our scientific advisory board, so I act as the bridge between the R&D team and the market," he says. His scientific advisory board includes authoritative names from the cardiovascular world such as Martin Leon, director, Center for Interventional Vascular Therapy, Columbia University. This helps Doshi with credibility, as doctors are often uncertain about collaborating with an Indian company, given India's poor global reputation for innovation.

Easy passage: Concept's drug-eluting stent being used at Unicare Heart Hospital in Surat

"There is always resistance abroad. However, the acceptability level is growing, and in countries like Italy it is very high. Italy is now delivering almost as much revenue as India," he says. At the same time, Doshi is popularising his technology in Europe by entering into a partnership with two French and one Spanish company, which import the product from India and then market it under their brand name. "You won't even see 'Made in India' anywhere on the box," says Doshi.

Going ahead, Doshi plans to develop a drug-coated balloon that addresses inflammation after kidney transplants. "Generally, narrowing happens after renal transplant. It's the same problem, except it's in the renal area. We are trying to come up with a solution where balloon inflates after transplantation, and delivers the drug which remains for 45 days. You don't have to take the tablet," he says.

He is also developing a completely dissolvable stent called IMBIBE. While similar products already exist, Doshi is addressing some of the deficiencies in the current generation of products. Evidently, Doshi has an agile mind, an amalgamation of sound technical knowledge and canny *Gujarati* business instinct, always on the lookout for technological opportunities in the limitations of current products. He points at his smartphone and says, "When Graham Bell invented the telephone, could he have imagined it would lead to this?" Doshi realises that technological improvements are essentially incremental, and it is this attitude that lies at the very heart of innovation.