

Hottest New Start-up: Consure Medical

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Though his first start-up failed in 2004, Mr Nishith Chasmawala's relentless entrepreneurial pursuit today is helping millions of patients worldwide through his new start-up, Consure Medical, which develops novel critical care products. Its first product is a novel device to manage fecal incontinence.

The genesis of the New Delhi-based <u>start-up</u> was at the Standord-India Biodesign Fellowship, a program designed to train next-gen <u>medical technology</u> innovators in India.

It was at this program both the founders, Mr Nishith Chasmawala and Mr Amit Sharma met together, who are now Consure's CEO and Director of Products respectively.

Novel Portfolio

Consure Medical was started in 2012. Both the founders were veterans of the medical device industry and have launched novel class II and III devices in the US, EU and Japan.

The <u>start-up</u> is developing and commercializing a novel portfolio of critical care devices that work across a continuum of care settings.

Its first product - Qora SMK - provides a novel means to manage fecal incontinence in non-ambulatory patients.

Worldwide more than 100 million patients are incontinent each year, and rely on either an absorbent pad (adult diaper) or a fecal drainage device.

The use of pads manifests dermatitis, maceration, increases the length of stay, and has direct impact on healthcare costs.

Though drainage devices contain fecal exudate in a bag, and hence avoid complications of pads, they have a very narrow indication of use and manifests complications like necrosis and sphincter dysfunction.

With the Qora technology, Consure reimagined management of fecal incontinence by developing a novel drainage catheter that can be used with varying stool consistencies or rectal tone on patients across a continuum of care facilities.

More importantly, this technology can be used by a minimally trained person at costs that are comparable or lower than the cost of using a diaper.

The patented Qora SMK has been cleared by the USFDA (US Food & Drug Administration), making Consure one of the few medical device companies in India that has its core patents granted in key geographies and regulatory clearances in place.

Similar to the latent need of incontinence, Consure today has 4 products in its development pipeline, and is targeting commercial launch of these additional products by the fourth-quarter in 2016.

Before starting Consure, Mr Nishith was in charge of the core-technology development team at Kyphon (USA), which was acquired by Medtronic in 2007 for \$4.2 billion. He had a great passion to wanting to directly impact the healthcare ecosystem in India, and was exploring ways to come back to India.

Mr Amit, prior to joining him, was a founder of a design and development <u>start-up</u>. He was looking out for a more refined focus to create a lasting impact.

Purely from a design perspective, he saw an inherent conflict of interest in a consulting model because, at the cost of amazing product design, clients always gravitated towards a 'fit' within their existing portfolio and business model. He wanted to start a medical device company that was not encumbered by legacy products and addressed latent clinical needs by imbibing brilliant design methodology and user experience.

Mr Nishith holds a BS in Plastics Engineering from UMASS Lowell (University of <u>Massachusetts</u>), USA; Mr Amit holds a BS in Mechanical Engineering from Indraprastha University, and a MS in Design from Indian Institute of Technology (IIT) Delhi.

Mapping Trends

While exploring entrepreneurial opportunities, the founders repeatedly saw three macro trends that increased their curiosity and led to a deeper analysis.

"We saw that medical devices are designed, developed and commercialized in silos and nobody had any qualms about it... Due to increased awareness, accountability via regulations, budgetary constraints and smart policies being implemented via Affordable Care Act (Obama Care), we saw that care facilities were getting more cost-conscious when making purchasing decisions," explains Mr Nishith.

Clinical safety, efficacy and regulatory clearances were obligatory requirements for medical device companies. To be commercially successful, companies needed to demonstrate a clear health-economic value proposition of their technologies versus existing standards of care.

He continues, "We saw a unique opportunity in developing products for the clinical setting with the least amount of resources and then try to stretch its feasibility all the way up to ICU or trauma care. Again, breaking the silo model to focus on continuum of care and reduce costs."

Mr Nishith notes that to overcome legacy health challenges, innovators in India are leading a silent transformation in delivery of health services and access to affordable healthcare.

"These models, though at a nascent stage, are a beacon of the shifting healthcare paradigm that other economies can emulate. By virtue of being in India, and with a deep focus on the Indian healthcare market, we saw a unique opportunity to disrupt distribution models to eradicate corruption, expand access to healthcare and alleviate overall health economic costs," observes Mr Nishith. "Mind-mapping of these macro trends and identifying latent clinical needs in different care settings was the genesis of Consure Medical."

Lessons From The Past

The founders had learnt a lot from their previous start-ups.

"For 2 years Consure was in stealth mode and relied solely on grants and subsidies from government and corporates. During this time, the company focused on one product, completed its development, contract manufacturing and First in Human (FIH) safety study before approaching any investors. Besides capital, the main challenges were lack of local subject matter expertise and lack of a medical device ecosystem," says Mr Nishith.

During initial stages, both the founders bootstrapped the company forgoing salary for almost 2 years, and relied on grants and friends in the industry to get to a significant clinical milestone.

The Series A investment was led by India Innovation Fund, Indian Angel Network, India Venture Partners and Mr Shrikumar Suryanarayan (Chairman and Co-founder, Sea6 Energy, & former President of R&D at Biocon).

Immediately post Series A, the company also secured two international grants enabling the company to extend its runway and aim for a bigger milestone.

Mr Nishith comments, "We are very fortunate to have supportive and patient investors with a long-term focus. Our investors have perfected the art of staying involved and helping out in a very non-intrusive manner. We believe there is always more capital that is chasing fewer good deals in general. Healthcare is considered to a very robust industry from an investment perspective, which augurs well for entrepreneurs that want to create value and make lasting impact to healthcare."

Consure has achieved major regulatory and intellectual property milestones in half the timeline of a typical Silicon Valley medtech start-up with about one-tenth the financing over the last three years.

IPO-Ready By 2019

At the moment, Consure is targeting intensevists, critical care nurses and CEOs of hospitals. "We make sophisticated devices that are very consumer-centric in design, but still require a prescription for use. We are also in conversations with large distributors and strategic partners to expand commercialization in different geographies," points Mr Nishith.

Being an advanced development stage and early commercial stage company, it is executing a customized commercial strategy in India, USA and Japan.

"We have our hands full with India, the US and Japan. Outside of these markets, we will expand along with a strategic partner or a distributor. We are working with index sites and key opinion leaders in India and the US," Mr Nishith reveals.

The start-up hopes to be IPO-ready by 2019.

He says that New Delhi is a favorable destination for medical devices start-ups. "Gurgaon has the highest concentration of large medical device companies. It also has lots of big hospitals in and around Delhi. There is reasonably strong manufacturing base in Faridabad, Gurgaon, Chandigarh and Baddi in Himachal Pradesh," he states. "Personally for a global medical device company like ours - I like the airport and flight options of Delhi. Probably the best in the country with Mumbai being the second in terms of connectivity."

Mr Nishith feels that most medical device entrepreneurs are not interested in entrepreneurship.

"They are extremely motivated to solve a clinical problem or commercialize a novel technology, which is usually related to a

deep emotional attachment. Often times, being an intrapreneur or collaborating with another company has higher odds of commercial success, than starting up on your own," he ends.