

MEDICAL DEVICES TECHNOLOGY ALERT

Service: Medical Devices Technology Alert. Pain Therapy Device for Prolonged Pain Relief; World Synchronous Teleradiology; Calcium Phosphate Nanoparticles for Bioimaging

Chapter: SPEEDING TIME TO MARKET

Price:

Date Published: 16 Jan 2009

SPEEDING TIME TO MARKET

One of the great challenges in bringing a new medical device to market is producing it in sufficient quantities for commercialization. "When scientists have an idea, they often tinker around too much in hospitals and universities without approaching someone like us to give them good perspectives on the engineering and manufacturing side for the design controls [that] the US Food and Drug Administration (FDA) will look for when they submit their idea," said Milton Frank, president of Nexcore Technology Inc., an original equipment manufacturer (OEM) of medical devices based in Waldwick, New Jersey. "There is a lag because nothing has been done by the book to commercialize a product. When this is done, it puts a crimp in the commercialization process. We pick up the ball for physicians and bring them in line with FDA guidelines."

A case in point is Nexcore providing manufacturing and engineering expertise for the Polar Wand endoscopic cryotherapeutic device. It was originally developed by GI Supply of Camp Hill, Pennsylvania, with design by The Bolt Group, Charlotte, North Carolina. "We are an OEM manufacturer of medical devices and are approved to manufacture finished products. Unlike some companies that only make subassemblies, our customers can accept our products and place them into the marketplace. This is an advantage when companies like GI Supply are well-versed in the molding of products, not the design of capital equipment," explained Frank.

The Polar Wand is a portable cryosurgical device for endoscopic ablation of the gastrointestinal (GI) tract to control bleeding from mucosal lesions of the GI tract in patients resistant to conventional endoscopic therapy. Physicians use a foot pedal to deliver cryogenic carbon dioxide through a single-use spray probe. The sudden expansion of the carbon dioxide (CO₂) results in extreme drops in temperature in accordance with the Joule Thompson effect. The ease of operation, low-cost, noncontact spray treatment, and the ability to target large areas of the GI tract, thereby reducing surgical procedure time, made the Polar Wand a promising medical device when it was designed in May 2008, but it is not yet ready for market.

"Although the product was nicely designed, the assembly production of the cryotherapeutic device took too much time, which is often the case," remarked Frank. Nexcore addressed the mass production by outsourcing a plastic material to one of its vendors and making some engineering modifications to shorten assembly time. "In general, it's not a big deal to make eight pieces, and spend three hours putting each of them together, but 50 pieces in a first production run cannot consume so much time. Manufacturing has to be readily duplicated. "There was also a challenge in packaging the oddly shaped, four-foot-high Polar Wand so that it could be shipped to hospitals, unpacked and used. In parallel, Nexcore reached out to a packaging consultant Frank had worked with for 20 years to accommodate the oddly-shaped Polar Wands. "The first prototypes built were sent to a trade show to launch the device, so it was crucial that they were easily unpacked and ready for use," stated Frank, whose company began shipping the Polar Wands in October.

Nexcore's president commented that the Polar Wand illustrates trends in the development of endoscopic cryotherapeutic devices, including minimizing procedure time, and providing a noncontact to prevent tissue from sticking to the instrument. "Another trend I see is that there are people looking at endoscopic cryotherapeutic devices as a possible cancer treatment by ablating cancerous lesions," noted the executive.

The New Jersey OEM has years of experience conducting business with medical device developers who, as Frank put it, "are interested in razors not the razor

blades, that is, the control equipment. We provide: developing the equipment, complaint handling, customer service, and trending repairs so that they can divorce themselves from the business they don't want to be involved in. For example, we will investigate why resistor number three failed and proactively go to our customer and tell them what they need to look at to fix these. Although this is not a paid part of our service, we see it as adding value," concluded Frank.

Details: Milton Frank, President, NEXCORE Technology Inc., 150 Hopper Avenue, Waldwick, NJ, 07463. Phone: 201-968-9400, Ext. 202. URL: www.nexcoretech.com. E-mail: sales@nexcoretech.com.