Background
Medtronic is the world’s largest medical device company with more than 85,000 employees operating in more than 160 countries. The company was founded by Earl Bakken and his brother-in-law, Palmer Hermundslie, and is today managed through four main business groups treating nearly 40 medical conditions. Within its Cardiac Vascular Group, the Cardiac Rhythm and Heart Failure business (CRHF) developed the first wearable, battery-powered heart pacemaker to treat abnormally slow heart rates. Since then, the unit has expanded its expertise in electrical stimulation to treat other cardiac rhythm diseases, and moved into overall disease management by adding diagnostic tools and building monitoring capabilities into many of its devices.

One of these diagnostic tools is the Reveal LINQ™ Insertable Cardiac Monitor (ICM), the smallest ICM available to patients which allows physicians to continuously and wirelessly monitor a patient’s heart. The device proved to show progressive thinking and innovation in healthcare technology, as well as providing a revolutionary safe way to monitor patient cardiac activity, and was subsequently awarded the 2014 Institution of Engineering and Technology (IET) Innovation Award for Healthcare Technologies.

Development
Unlike conventional monitoring methods, the Reveal LINQ ICM is a continuous, long-term cardiac monitor that automatically detects and records abnormal heart rhythms for up to three years. Placed just beneath the skin through a small incision of less than 1 cm in the upper left side of the chest, the Reveal LINQ ICM is often nearly invisible to the naked eye once inserted. The device is placed using a minimally invasive insertion procedure, which simplifies the experience for both physicians and their patients.

One of the heart conditions that can be detected by long-term continuous monitoring is atrial fibrillation (AF), a common cardiac condition defined by irregular or rapid heartbeats. Failure to recognize and treat AF can lead to strokes, as patients with AF are five times more likely to have a stroke. Undiagnosed AF is believed to be responsible for a significant portion of strokes of unknown causes (cryptogenic strokes). However, because AF often has no symptoms and may occur infrequently, it may not be detected by conventional monitoring techniques, such as in-hospital monitoring, electrocardiography or traditional ambulatory cardiac monitors.
Coining the philosophy “deep miniaturization,” Medtronic’s engineers set out to radically reduce the size of medical devices by nearly 90 percent, while continuing to improve the existing technology. Some of these improvements with Reveal LINQ included increased data memory by 20 percent and improved algorithms which accurately detect atrial fibrillation (AF) in 98.5 percent of patients.

Mark Phelps, Sr. Director of Diagnostics & Monitoring Research and Development at Medtronic “Our engineers first needed to show senior management that they could miniaturize medical devices by such a drastic degree without losing crucial features – a risky move, but one that was guaranteed to disrupt the market if successful.”

“Once funding was disrupted for the deep miniaturization project, the team started out by dismissing everything they had been taught about product development. Instead, they decided to examine existing problems facing products today, set an end goal, and then look at it functionally in ways that they had never thought of before.”

What developed was a new way of working within the medical device industry – engineers in technology development, product development, manufacturing and quality analysis began working hand-in-hand, assembling micro-chips in new configurations that resulted in a massive leap in product technology. It was here that LINQ progressed from concept to prototype.

With all of these disciplines collaborating within one facility, the product wasn’t the only thing that was being advanced – the development timeline was significantly accelerated as well. So much so, that by the time the devices moved from prototype to commercial production, the manufacturing team had to completely rethink how they were going to develop these devices, as they were too small and too light to fit onto existing chip boards and into holding trays.

**Results**

In February 2014, Medtronic announced the U.S. Food and Drug Administration (FDA) 510(k) clearance, CE (Conformité Européenne) Mark, and subsequently the Reveal LINQ ICM was ready for its global launch. This marked the first point of success for the device as it became commercially available for physicians all over the world. The successes of the team provided a good submission for the 2014 IET Innovation Awards, a submission which proved to stand out amongst its competitors. Recognised for the far-reaching social and economic benefits of the device, Reveal LINQ secured the healthcare technologies award.

Mark Phelps comments: “The IET has always carried a lot of prestige and authority for engineers all over the world and provides the perfect home for us to share our story. This journey is one that demonstrates what could be achieved in an industry that is ready for innovative thinking and rapid change. We were aware of the prestige and authority that the IET carries and this proved to be a great opportunity for us to share our story with this global community.”

As stated in the March 2015 quarterly earnings call, the Reveal LINQ ICM is already on the order of up to about a half-billion dollars in annualized sales, with the potential to hit $1 billion to $2 billion in peak year sales.

**Next Steps**

The team at Medtronic is committed to improving the lives of people through our medical technologies. With changing healthcare demands, companies that deliver health products and services must be willing to do things differently.

Nina Goodheart, Vice President and General Manager of the Medtronic diagnostics business “As the company goes forward, it will continue working to improve healthcare by addressing the needs of more people, in more ways and in more places around the world, just as Reveal LINQ has done to date.

“Recognition by the IET Innovation Awards further validates the importance of this revolutionary technology for patients worldwide and applauds our engineers’ deep commitment to improving patient care with the most advanced technology.”