

OVERVIEW

Lake Region Medical is a family owned OEM business, which was founded in Chaska, Minnesota in 1947 by Mr. Joseph Fleischhacker to supply pacing lead coils to local medical device companies. In 1994, they opened a plant in New Ross, in the south east of Ireland, employing 15 people to service the growing European market.

Today, Lake Region Medical Limited is the largest global manufacturer of diagnostic guidewires, supplying to the medical device industry. The site in New Ross currently markets to customers in more than 30 countries worldwide. It is estimated that a Lake Region Medical product is used somewhere in the world every 1.5 seconds.

ACHIEVEMENTS

Since Lake Region Medical Limited began its lean journey in June 2003, the continuous improvement culture has remained an integral part of the entire company's strategy.

Productivity:

The initial kaizen events proved to be extremely successful, resulting in significant efficiency gains by reducing employee movement, part travel distance, inventory, scrap and footprint. These laid the groundwork for a safer, more efficient, organized and visual workplace. Examples of such improvements;

- 297% gain in productivity in High Volume Assembly
- 379% efficiency gain in Specialty Assembly

TPM was first applied in 2005 to tackle bottleneck processes and maximize the capability of existing equipment. This was incredibly successful with the results enabling the company to significantly increase output without any associated capital investment. TPM facilitated a higher degree of employee involvement and helped to create an environment where operators, supervisors, maintenance, quality and engineers work together to improve their own equipment performance, processes and workplaces.

- 74% increase in cores produced per operator per week
- 77% increase in coils produced per operator per week
- Improved OEE on coil-winders from 64% up to 82%

Environment, Health & Safety:

Protecting the health and welfare of our employees is a top priority. Systems have been developed throughout the plant to promote health & safety awareness and minimize employees' exposure to injury through the creation of a safer workplace.

Lake Region Medical Limited is also committed to protecting the environment. Committees with employee representatives meet regularly to look at ways of reducing first-aid incidents and accidents and to focus on energy and waste reduction while encouraging recycling and reuse. Quarterly training courses are held in-house for the Emergency Response Team (ERT), safety and first-aid representatives.

Some of the improvements made include;

- 95% reduction in days lost due to accidents since 2004
- 30% reduction in waste sent to landfill over last 6 years
- 23% reduction in energy consumed per unit since 2006

Quality:

Lake Region Medical Limited's quality policy is built on designing, developing and manufacturing products which exceed our customers' expectations while meeting all relevant regulatory standards. In line with this principle, in 2008 we began working on the introduction of standard work as a foundation for structured problem solving. The Toyota eight step problem solving methodology is used to identify the root cause and develop countermeasures to tackle the highest recurring quality issues. Significant results to date include;

- 89% reduction in MRRs for burrs (HV Precoat)
- 60% reduction in MRRs for core-retraction (HV Precoat)
- 86% reduction in MRRs for doc errors (HV)
- 71% reduction in MRRs for floating cores (HV Uncoat)
- 32% reduction in small diameter rework (LV Uncoat).

In the majority of cases these countermeasures were captured as standard work methods and documented in the form of job breakdown sheets (taken from TWI). To support the sustainment and to monitor adherence of standard work a system of audits has been developed. This system is further supported by the redefinition of the roles and responsibilities of first and second tier supervisors.

Delivery:

Lake Region Medical Limited is dedicated to fulfilling customers' needs through service excellence. We aim to meet or exceed our expected customer delivery dates and hold a very tight shipping window. We pride ourselves on efficient lead times which out perform the best in the industry. These are supported by a tightly managed system of kanbans, consignment stock, VMI and blanket call-offs. All of this ensures that we optimize inventory levels, both in-house and for our customers.

Cost:

With over 80% of Lake Region Medical Limited's products now being sold to the US market, and paid for in US dollars, the strength of the dollar has had a major effect on profit margins. This, along with the rising costs of labour, raw materials and in particular energy over the past number of years has put enormous pressure on the company to focus on absorbing these costs through C.I. rather than passing them on to the customer.

- 33% reduction in freight costs per sales since 2005

Awards & Recognition:

- ISO 13485 (2003)/ ISO 14001 (2004) Env. Mgt. System
- FDA 21 CFR 820
- MHLW 169 (Japan)
- OHSAS 18001 (2007) Safety Management System
- AEO Certification
- ICBE Best Practice/Networker of the Year Award 2009
- National Irish Safety Organisation Awards 2010 & 2011
- IMDA Med Tech Excellence Award (Bronze prize) 2011
- Shingo Bronze Medallion 2012

OUR PEOPLE

Lake Region Medical Limited currently employs over 650 people at its plant in New Ross which is situated on a ten acre site. We are very much a multicultural company with people from over fifteen different countries working here.

"I believe the things that Joe did for others will replicate themselves and enrich the world among people who never even knew him – which, I believe is the true test of the value of a man's life and allows him to live on in the form of what he left behind."

The company is focused on creating an environment where all employees are aware that the products they make each day are minimizing patient suffering throughout the world. Lake Region Medical Limited employees build every guidewire with the same care and attention that they would if it was intended for a family member.

The ethos of the company is built around protecting the dignity and respect of each individual as well as supporting them to reach their full potential. To achieve this, a set of behavioral standards was developed in 2008. Examples of these standards include;

- "Seek to understand before reacting"
- "Do the right thing not the easy thing"
- "Don't walk past, do something to make it better"

We believe that the key to having an engaged workforce is honest and open communication. Measures in place to support this are:

- Daily production walkabout by directors, senior managers & support groups
- Weekly supervisor briefings with direct reports
- Quarterly employee briefings conducted by the directors in each area of the plant
- Open door policy

Being a good corporate citizen and playing a supportive role in the local community is important to our company. Benchmarking visits to Lake Region Medical Limited from manufacturers based in both Ireland and the United Kingdom are a regular occurrence. This presents an opportunity for all our employees to showcase their achievements, while visitors witness at first hand practical examples of our lean implementation and C.I. initiatives.

Lake Region Medical Limited has always taken an active role in both local and international charity initiatives. Every year since 2008, four employees are selected as volunteers to travel to Malawi or Tanzania to assist in education and building projects. Our in-house fundraising committee organizes regular events to support this, along with a number of local charities such as the Local Hospice, Community Hospital & Meals on Wheels.

OUR PROCESS

Lake Region Medical Limited first began its lean journey in June 2003 with a number of Kaizen events facilitated by external consultants aimed at removing waste and cost from our processes. As our knowledge of lean / C.I. grew, our focus broadened towards improving all elements of our business in an effort to guarantee customer satisfaction.

Today, almost eight years later, a culture of continuous improvement lies at the heart of the company's strategy. For example lean tools such as TPM, value stream mapping, eight step problem solving etc. are now practiced on a daily basis and the results are visible throughout the plant. Lake Region Medical Limited is also very committed to creating lean / C.I. expertise internally. To date, five employees have received their Lean Manufacturing MSc from Cardiff University while Toyota's eight step problem solving is mandatory training for all our Supervisors, Engineers, Managers and Directors.

OUR PRODUCT

A guidewire is a medical device used in diagnostic, interventional and therapeutic procedures for neuro, endovascular and coronary applications. As its name describes, a guidewire is used to guide a catheter or similar device into place, which will aid a procedure, primarily in the cardiology and radiology fields. The majority of diagnostic guidewires consist of three main components; (1) a coil which forms the outer sheath, (2) inside this the tapered core provides stiffness and steerability characteristics and finally, (3) a safety ribbon is welded to both ends of the coil to prevent the guide from unraveling.

All of these components are made from medical grade stainless steel wire of different profiles. Lake Region Medical guidewires are available in a vast number of configurations with:

- Diameters ranging from 0.014" to 0.095"
- Lengths ranging from 0.2m to 5m
- Cores with different complexities of taper profiles
- PTFE, silicone or hydrophilic coatings
- Electrically etched with depth indicating marks

OUR PLANT

The Lake Region Medical Limited plant opened in New Ross in 1994, and began producing approximately 4,000 diagnostic guidewires a week, shipping to a small number of European customers. It has since grown and now manufactures over 600,000 products each week with an ever growing product range, shipping to over thirty countries worldwide. Each year approximately 30 million of these devices are used in interventional, therapeutic and diagnostic procedures that enhance or extend the lives of millions of patients worldwide.

OUR CORPORATION

Today, Lake Region Medical is still wholly owned by the Fleischhacker family, headquartered from Chaska, Minnesota (USA). There are manufacturing facilities in Chaska as well as New Ross and Galway (Ireland) and a business office in Shanghai (China). Lake Region Medical Limited is the European manufacturing base for the company and in 2009, the company bought Irish owned medical device company Brivant Limited in Galway to act primarily as a research & development site to strengthen the company's presence in the interventional and peripheral guidewire marketplace.

Over the past 50 years, Lake Region Medical has grown to become the world's largest OEM and contract manufacturer of wire formed medical devices and components specializing in minimally invasive devices for cardio, endo and neurovascular applications with in excess of 75% of the world market. Lake Region Medical currently employs over 1,600 people worldwide and altogether sells to customers in more than 50 countries.

For more information, please contact:

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Lake Region Medical Customer