

OVERVIEW

Lake Region Medical was founded in Chaska, Minnesota in 1947 by Mr. Joseph Fleischhacker. Originally established to manufacture fishing lures & tackle, the company moved in to the medical device industry in 1960 to supply pacing lead coils for the first heart pacemaker. In 1994, the New Ross plant opened, in the south east of Ireland, to service the growing European market.

Today, Lake Region Medical is a global leader in the development and manufacture of access, delivery, and retrieval devices for minimally-invasive procedures. The site in New Ross is the largest global manufacturer of diagnostic guide wires, supplying to the medical device industry and currently markets to customers in more than 30 countries worldwide. It is estimated that a Lake Region Medical guide wire is used somewhere in the world every 1.5 seconds.

ACHIEVEMENTS

Since commencing our lean journey in June 2003, we have developed a culture of continuous improvement which continues to delivered significant improvements across all areas of our business.

Safety, Health & Environment:

Looking after the health and wellbeing of our employees is our number one 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 is fully committed to protecting the environment. Focus groups with employee representatives meet regularly to look at ways of improving energy usage and waste generation while encouraging recycling and reuse. Intensive scenario training takes place quarterly for the Emergency Response Team (ERT), and we carry out ongoing safety and first-aid training for all representatives.

Some of the EHS improvements we have made include;

- 44% reduction in lost time incidents since 2011
- 10% reduction in first aid incidents since 2011
- Successful introduction of near miss system with over 500 near misses reported in 2014
- 10 health promotion activities held in 2014 involving over 80% employee participation
- Over 90% of all waste being diverted from landfill

Quality:

Lake Region Medical's quality policy is built on designing, developing and manufacturing products which exceed our customers' expectations while achieving compliance with all of our relevant regulatory standards. Since the plant opened in 2005, with >350 million guide wires shipped from the New Ross facility, it is a testament to the processes and systems in place that there has never been a single product recalled.

Significant results to date include;

- 9.6% increase in work orders completed right first time over last 10 years
- Over 100 problem solving projects completed each year since 2012

Productivity / Cost:

As an Original Equipment Manufacturer operating in a highly competitive market Lake Region Medical need to be continuously focused on reducing costs through the application of lean in order to contain increases in salaries, raw materials and utilities rather than passing them on to our customers. Because all of our employees are trained to a minimum of lean fundamentals, we have a high degree of employee involvement. This investment in lean training has helped to create an environment where all employees work together to identify waste and non value adding activities with a view to eliminating or reducing them. In production areas once processes have reached a high level of lean maturity the next phase involves our in-house design & machine build team who attempt to automate it.

Examples of cost & productivity improvements include;

- 450% gain in productivity (parts per person per hour) in high volume uncoat assembly since 2003
- 50% improvement in coating productivity through the application of standard work in 2014
- Improved OEE on coil winders from 64% up to 87%
- 85% reduction in manufacturing lead time for our main value stream
- Sales revenue per employee improved by 15% since 2006
- >25% reduction of inventory value in 2014

Delivery:

Lake Region Medical is dedicated to exceeding our customers' expectations through service excellence. We pride ourselves on efficient lead times which outperform the best in the industry. These are supported by a tightly managed system of kanbans, consignment stock, VMI portals and blanket call-offs. All of this ensures that we optimize inventory levels, both in-house and for our customers.

Morale:

We believe every employee can make their own unique contribution to the company and wider community. This is why we educate, empower and involve employees in all aspects of our business in order to challenge them to develop effective solutions to continually improve.

- 76% of promotion opportunities filled internally in 2014
- >1100 improvement cards closed annually since 2012
- >€200,000 raised for charity since 2008

Certifications:

- ✓ FDA 21 CFR 820
- ✓ ISO 13485:2003 – Quality Management System
- ✓ ISO 14001:2004 – Environmental Mgmt. System
- ✓ OHSAS 18001:2007 – Safety Mgmt. System
- ✓ Japanese MHLW Ministerial Ordinance No.169
- ✓ Authorised Economic Operator (AEO) Status
- ✓ AMIS Standard for Maintenance

Awards:

- ✓ Irish Safety Award 2010, 2011, 2012, 2013 & 2014
- ✓ Irish Heart Foundation Healthy Workplace Award 2014
- ✓ Irish Institute of Training & Development Award 2013
- ✓ Irish MedTech Company of the Year 2012
- ✓ Shingo Bronze Medallion in 2012
- ✓ Irish Centre for Business Excellence Award 2010

OUR PEOPLE

Lake Region Medical currently employs over 750 people at our facility in New Ross which is located on a ten acre site. We are very much a multicultural company with people from over seventeen different countries working here. The company is focused on creating an environment where all employees value the fact that the products they make each day are minimizing patient suffering throughout the world. Lake Region Medical employees build every guide wire 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 company values and key behaviours were developed in 2013. These values are Respect, Commitment, Continuous Improvement, Enterprise Alignment, Integrity & Leadership. A peer recognition system is in place to publicly acknowledge employees who display these values and recognize them as our role models.

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

- Daily 'gemba meetings' attended by directors, senior managers, associates & support personnel
- Weekly supervisor briefings with direct reports
- Bi-monthly breakfast sessions with our site leader, HR director and group of employees
- Quarterly employee briefings conducted by the managers in each area of the plant
- Our 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 from companies throughout Ireland, the United Kingdom and from further afield 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 Shingo journey. Lake Region Medical has always taken an active role in charity initiatives. In 2008, a formal charity fundraising committee was established to organize regular events to generate fun and raise funds. Every year employees select a local and national charity to which the funds raised in that year will be donated. As well as donating over €200,000 to charity, 16 of our employees have travelled to Africa as volunteers to assist in education and building projects.

OUR PROCESS

Lake Region Medical first began our lean journey in June 2003 with a number of kaizen events facilitated by external consultants aimed at removing waste 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. To support this strategy, in 2004 an enterprise excellence group was established to engrain a culture of continuous improvement. Today, lean tools such as TPM, value stream mapping, standard work, scientific problem solving etc. are practiced on a daily basis at a front line level and the results are visible throughout the plant.

We have built robust systems to support our processes and improvement activities. Lake Region Medical is very committed to creating lean / C.I. expertise internally. We strive to develop a range of levels of knowledge throughout the organization, to include subject matter experts in lean, six sigma, facilitation, VSM, TWI, etc. We have an internal training academy in place since 2012 where we train employees to a national accredited certificate standard over a 3 month period. All employees have been trained on lean fundamentals, while scientific problem solving has to date been delivered to over 350 of our employees.

OUR PRODUCT

A guide wire is a medical device used in diagnostic, interventional and therapeutic procedures for neuro, endovascular and coronary applications. As their name describes, guide wires are 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 guide wires consist of three main components; (1) a coil which forms the outer sheath, (2) inside this, a 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 guide wires 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 New Ross plant opened in 1994, and began producing approximately 4,000 diagnostic guide wires 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 30 countries worldwide. Each year approximately 30 million of these devices are used in Cardiovascular, Stimulation Therapy, Peripheral, Neurovascular, Urology, and Vascular Access procedures that enhance or extend the lives of millions of patients worldwide.

OUR CORPORATION

Today, Lake Region Medical is part of a multi-national business since being acquired by Accellent in March 2014. There are 16 manufacturing facilities located across the globe with our corporate headquarters situated in Wilmington, Massachusetts (USA).

For more information, please contact:

Noel Hennessey – Director of Continuous Improvement
Lake Region Medical, Butlersland, New Ross,
Co. Wexford, Ireland.

Phone: +353 51 440550

Fax: +353 51 440501

E-mail: noel.hennessey@lakeregionmedical.com