



PRESS RELEASE

NEW CUTTING EDGE PROCEDURE COULD FILL TREATMENT GAP IN GORD

Wednesday 27 April 2011 – The first person in the UK has had the LINX™ Reflux Management System implanted – a simple procedure designed to support the body’s oesophageal sphincter in eliminating the symptoms of chronic Gastro-Oesophageal Reflux Disease (GORD).¹

GORD is very common with approximately 1 in 5 people having at least one episode a week.² Common symptoms include heartburn, regurgitation and chest pain, these can be severe and persist over time.² When GORD is left untreated serious complications can occur, such as Barrett’s oesophagus (a pre-cancerous condition) and oesophageal cancer.³

Proton Pump Inhibitors are typically prescribed to relieve symptoms but they do not prevent reflux. Consequently, many people still experience symptoms of GORD even at regular or high doses of medication.^{4,5,6} This can result in patients returning to their doctor on a number of occasions. Until this point the only other option healthcare professionals have been able to recommend is fundoplication (a surgical procedure that involves wrapping part of the stomach around the oesophagus) which is usually reserved for severe cases of GORD and has varying success rates depending on the experience of the surgeon.⁷

The LINX™ System offers a completely new treatment option for people whose symptoms are not well controlled by medication but are not severe enough to warrant a fundoplication.

The LINX™ System is a small, flexible band of interlinked titanium beads with magnetic cores that is placed laparoscopically around the oesophagus just above the stomach. The magnetic attraction between the beads keeps the lower oesophageal sphincter closed to prevent reflux while opening during swallowing. This innovative technology means the LINX™ System can eliminate the symptoms of GORD without needing to alter the anatomy of the stomach.¹ Laparoscopic implantation of the LINX™ System can be completed in less than an hour, with patients able to resume a normal diet the next day and return to normal activities within a week.¹

A one and two year follow up study of the LINX™ System showed excellent relief of GORD symptoms and significantly reduced levels of acid exposure in the oesophagus.¹ The LINX™ System was shown to be highly effective with 86% of people stopping medication for GORD and 86% satisfied with their condition two years after the LINX™ procedure.¹

Dr David Ashton, Medical Director of LINX™ Reflux Surgery, the company that delivers the LINX™ procedure, says:

“Nearly 200 people with chronic GORD have benefited from the LINX™ System to date and the research has been very encouraging. This simple procedure can be completed in less than an hour and patients can resume a normal diet the next day and return to normal activities within a week. It starts working immediately offering patients relief from the symptoms of GORD and a quick return to normal life.”

Patients who are considering the LINX™ System can access a simple self-assessment questionnaire to help them assess whether this may be a suitable treatment option for them [see attached questionnaire].

Notes to editors

To find out how people can access the LINX™ Reflux Management System go to:

<http://www.linxrefluxsurgery.com>

For further information or to arrange an interview with a case study or expert please contact:

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LINX™ Reflux Management System

- The LINX™ System offers a new treatment option for GORD, eliminating symptoms through a simple, reversible procedure.¹
- The LINX™ System is a small, flexible band of interlinked titanium beads with magnetic cores that help the LOS resist opening to gastric pressures, creating a barrier to reflux of acid and bile.¹
- Swallowing forces break the magnetic bond to allow food and drink to pass normally through the LOS. The magnets then close the LOS immediately after swallowing to restore the body’s natural barrier to reflux of acid and bile.¹
- The LINX™ System starts to work as soon as it is in place and patients should be able to resume a normal diet the next day and can usually return to normal activities in less than a week.¹

About Torax

Torax Medical was founded in 2002 with the mission of creating a better treatment option for patients suffering from Gastro-Oesophageal Reflux Disease (GORD). Through these efforts, Torax has pioneered a new technology platform called Magnetic Sphincter Augmentation (MSA) which may be applied to a variety of conditions throughout the body. The LINX™ Reflux Management System for the treatment of GORD is currently under clinical investigation; active research is ongoing in other fields of use. The LINX™ System has received CE Mark and is currently being used to treat patients with GORD in Italy and Germany. Torax Medical is a privately held corporation that is based in the United States.

References:

- 1) Bonavina L, DeMeester T, Fockens P, et al: Laparoscopic sphincter augmentation device eliminates reflux symptoms and normalizes esophageal acid exposure: one and two year results of a feasibility trial. *Annals of Surgery* 2010; 252: 857-862
- 2) NHS Choices website: <http://www.nhs.uk/conditions/Cancer-of-the-oesophagus/Pages/Introduction.aspx> [last accessed March 2011]
- 3) Macmillan Cancer Support website: <http://www.macmillan.org.uk/Cancerinformation/Cancertypes/Oesophagusgullet/Pre-cancerousconditions/Barrettsoesophagus.aspx> [last accessed March 2011]
- 4) Dean B, Gano A, Knight K, et al: Effectiveness of proton pump inhibitors in nonerosive reflux disease. *Clin Gastroenterol Hepatol* 2006; 2: 655-656
- 5) Sharma N, Agrawal A, Freeman J, Vela M, Castell D: An analysis of persistent symptoms in acid-suppressed patients undergoing impedance-pH monitoring. *Clin Gastroenterol Hepatol* 2008; 6: 521-524
- 6) AGA Institute: GERD patient study – patients and their medications. Harris Interactive, 2008.
- 7) Vakil N, Shaw M, Kirby R: Clinical effectiveness of laparoscopic fundoplication in a US community. *Am J Med* 2003; 114: 1-5