

**Upcoming Training Dates**

**March**

- March 7 & 8
- March 27 & 28

**April**

- April 2 & 3
- April 11 & 12

**May**

- May 2 & 3
- May 14, 15, 16

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**What's New?**



Portugal is the most recent country to introduce Endoluminal Fundoplication (ELF) for the treatment of GERD. The commercial release of EsophyX in Europe has been limited with Portugal being the 7th country to begin treating GERD patients using an endoluminal approach.

In January at Santa Maria Hospital (Lisbon), Prof. Henrique Bicha Castelo and Dr. José Girão treated their first patients. Prof. Castelo says, "EsophyX is a very promising technology especially for those patients as identified in the registry protocol. We believe the learning curve is short. After our 5th patient, we felt very comfortable with the procedure and the device."

In February, Prof. Francisco Castro e Souza and Prof. Guilherme Tralhão from Coimbra University Hospital were the second team to begin treating GERD patients with EsophyX. Prof. Souza says "EsophyX is a great advance in the conservative treatment of GERD especially for patients with small hiatal hernias <2-3 cm. It promotes collaboration between GIs and surgeons."

Endotécnica is the global partner managing EndoGastric Solutions' products in Portugal.

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**EndoGastric Solutions™ Training Newsletter**



**Case of the Month – Submitted by Repici A., Rosati R., Barbera R.**



A 47 yrs old female, with a long history of dyspepsia, was seen in our outpatient clinic. The main symptoms were chest pain during meals and at bedtime resulting in several upper G-I endoscopies performed, revealing a hiatus hernia and distal esophagitis. On a high dose of PPI (80 mg/day esomeprazole) symptoms were well controlled, with a prompt relapse when discontinued. The patient is a non-smoker, very thin woman (BMI 19), not pregnant and no major diseases in her medical history.

An endoluminal fundoplication technique (ELF), was proposed to the patient. The patient fulfilled the inclusion criteria and was enrolled in our study and into the REFER registry.

An upper gut endoscopy was performed off of PPI for 15 days and revealed a Grade B esophagitis (Los Angeles classification) and a 1 cm long hiatus hernia. These findings were confirmed with a barium esophageal transit. A stationary esophageal manometry was performed (normal LES pressure and valid, coordinated esophageal peristalsis) followed by a MII-pH/24 hr recording (Table 1). This test revealed a severe esophageal reflux. The GERD HRQL score was 51 (nv < 20).

Table 1	Pre Acid	Post Acid	Pre Non-acid	Post Non-acid	Pre Total	Post Total
<b>Impedance bolus exposure</b>	12.6	7.1	0.9	1.1	13.5	8.1
<b>No. reflux</b>	63	37	16	17	79	54
<b>Chest pain</b>	63%	0%	79%	18%		
<b>Heartburn</b>	21%	0%	87%	14%		

In June, the patient underwent an ELF treatment for her symptomatic reflux disease (Figure 1). Eighteen (18) polypropylene fasteners were deployed forming an interrupted suture line at

the base of the gastro-esophageal (G-E) valve. The new G-E valve was 2 cm in length and 230° in circumference (Figure 2). The procedure lasted 80 minutes and there were no adverse events.



Fig. 1 Pre-procedure valve Fig. 2 Post-procedure valve

On the 3<sup>rd</sup> hospital day, after an esophageal transit study the patient was discharged on a liquid diet for the next 2 weeks.

A clinical evaluation was performed 6 months later. The patient felt well off of PPI, taking sodium alginate on demand. The MII-pH data on reflux (Table 1). Regular findings of a partial fundoplication were seen on upper G-I endoscopy and radiologically (Figure 3).

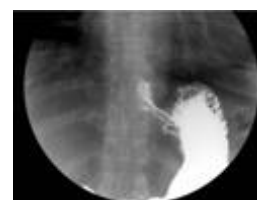


Fig. 3 Post-procedure transit image

Promising improvements in both objective and symptomatic parameters for GERD are observed at the 6 months follow-up using this endoluminal fundoplication technique. Special thanks to Vanessa Zani (ab medica).

**Submit cases for future publications to Maureen Kress at mkress@endogastricsolutions.com.**

**EGS News – First Annual EndoGastric Solutions™ Users Meeting**

The 1<sup>st</sup> EndoGastric Solutions (EGS) users meeting was held January 19-20 at the historical Danieli Hotel in Venice, Italy. Over 130 attendees from all over Europe joined us for the event. The EsophyX™ clinical results from phase 1, phase 2 and the registry were presented by Professors Cadière, Buset and Cremer respectively – and showed consistent performance across the clinical studies and commercial use. Tips on performing the endoluminal fundoplication (ELF) procedure were shared, and sites that performed a large volume of the best outcomes. procedures presented their experiences with the EsophyX device. Drs. Bouvy and Van Dam discussed their experience with the first 28 patients treated at AZM in Maastricht, Netherlands and the powerful patient response to the media and press attention that their early cases generated. The experience at Humanitas in Milan, Italy by Professors Rosati and Repici were also presented. Excellent advice was provided from our experienced users regarding patient management to ensure the best outcomes. EGS management presented the future vision of the company, and prototypes of the devices in development were available for users to see and provide feedback for future engineering efforts. EGS' second product, StomaphyX™, was also released at the meeting. Mark your calendars now for the second annual EGS Users Meeting the third weekend in January, 2008 – location to be determined.

## Training Tips – Insufflation Issues

The need for optimal exposure and ideal visualization are key to performing a safe and effective Endoluminal Fundoplication (ELF) procedure with EsophyX. There are times when optimal intragastric space cannot be achieved and/or maintained by standard insufflation means via the endoscope. This can be frustrating for the team resulting in procedure delays while waiting for visualization to resume. Various troubleshooting techniques have been attempted to enhance insufflation.

From our current users, here are some helpful ideas to assist in maintaining constant and optimal insufflation:

- Inspect integrity of endoscope seal of device
- Ensure scope diameter is > 7,6 mm
- Verify insufflation channel works. Evaluate air flow
- Check that the insufflation and irrigation valves of the endoscope are attached securely. Replace if necessary
- Verify that the support block is in place on the device. Air can leak through the fastener's channels
- Consider positioning patient supine especially obese patients and patients with enlarged liver
- Verify EsophyX is correctly placed and invaginator holes are not intragastric
- Install a second insufflation line through the endoscope working channel. Increase insufflation manually using a rubber hand pump (Figure 1), a rubber foot pedal pump (Figure 2) or an insufflator



Fig. 1: Hand pump



Fig.2: Foot pedal pump

**NOTE:** Insufflation needs to be regulated carefully to decrease post-procedure abdominal discomfort. Insufflate only as needed to visual and deploy fasteners safely.

- Use adequate insufflation as noted when rugae (mucosal folds) appear slightly flattened except when retracting the helical retractor and massaging the valve tissue
- After fastener deployment at each position stop insufflation
- Evacuate excess air from stomach at end of procedure

### Global Partners Contact Information

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South Africa	SA Biomedical	+27 21 697 9100
Spain	Palex	www.palexmedical.com
UK	Elemental Healthcare	www.elementalhealthcare.com

## EsophyX™ Trained Teams

Below are all the customers trained in the use of the EsophyX device used to perform the ELF procedure.

### Belgium

C.H.U St. Pierre

Prof. Michel Buset  
Prof. Guy-Bernard Cadière  
Dr. Vinciane Muls

Cliniqué de Parc Leopold

Dr. Amin Rajan  
Dr. Alexander Sarafidis

Hôpital Erasme

Prof. Jacques Devière  
Dr. Pierre Eisendrath  
Dr. Hubert Louis

Clinique St. Joseph (Liège)

Dr. Boris Bastens  
Dr. Joseph Weerts

A.Z. Vrije Universiteit Brussel

Prof. Fazia Mana  
Dr. Filip Sermon

A.Z. St. Blasius

Prof. Michel Cremer  
Dr. Jacques Himpens

U.Z. Gasthuisberg, Leuven

Dr. Joris Arts  
Prof. Raf Bisschops  
Dr. Philip Caenepeel

Cliniques Universitaires de St. Luc (UCL)

Prof. Pierre Deprez  
Prof. Hubert Plessevaux

### France

CHU d' Angers

Prof. Jean-Pierre Arnaud  
Prof. Jean Boyer  
Dr. Emilie Lermite

CHU Hôpital Civil—Strasbourg

Dr. Dimitri Coumaros  
Prof. Bernard Dallemagne

CHU Edouard Herriot—Lyon

Prof. Thierry Ponchon  
Dr. Sabine Roman

CHU Rangueil—Toulouse

Prof. Louis Buscail  
Prof. Jean Escourrou  
Prof. Gilles Fourtanier

### Germany

Charité Universitätsmedizin

Dr. Alex Eckardt  
Prof. Thomas Röscher

Klinikum Großhadern

Dr. Thomas Hüttl  
Dr. Reinhold Lang  
Dr. Fritz Spelsberg

### The Netherlands

A. Z. Maastricht

Dr. Nicole Bouvy  
Dr. Wim Hameeteman  
Dr. Ger Koek  
Dr. Ronald van Dam

't Lange Land Ziekenhuis Zoetemeer

Dr. Dirk Boland  
Dr. Pieter van Rijn

Ziekenhuis Rijnstate Arnhem

Dr. Ernest J. Spillenaar Bilgen  
Dr. Peter Wahab

U. M. C. Utrecht

Dr. Ivo Broeders

Meander Medisch Centrum

Dr. Mattis Schwartz

Catharina Ziekenhuis Eindhoven

Dr. Jack Jakimowicz  
Dr. Jan van Spreeuwel

U. M. C. Groningen

Dr. Vincent Nieuwenhuijs  
Dr. Frans Pieters

U.M. C. Amsterdam

Dr. Miguel Craanen  
Dr. Mikael Questa

Amphia Ziekenhuis Breda

Dr. Rogier Crolla  
Dr. Robert Eichhorn

Westfries Gasthuis Hoorn

Dr. Edo Schejde  
Dr. Johan Schmidt

### Italy

Policlinico San Donato

Dr. Davide Bona  
Prof. Luigi Bonavina

Istituto Clinico Humanitas

Dr. Alessandro Repici  
Prof. Riccardo Rosati

Ospedale San Raffaele

Dr. Enzo Masci  
Prof. Pier Alberto Testoni

Ospedale Evangelico

Dr. Alberto Arezzo  
Dr. Gino Battistini

Ospedale di Schio

Dr. Angelo Cerofolini  
Dr. Frederik Jorizzo

Policlinico Universitario A. Gemelli

Prof. Guido Costamagna  
Dr. Massimiliano Mutigani

Policlinico Umberto I

Prof. Nicola Basso  
Dr. Alfredo Genco

Ospedale Santa Chiara

Dr. Paolo Parise  
Dr. Biagio Solito

P.O. Dei Pellegrini

Prof. Bruno De Luca  
Dr. Leonardo De Luca

### Portugal

Santa Maria Hospital

Prof. H. Bicha Castelo  
Dr. Pinto Correia

Dr. José Girão da Fonseca

Dr. António Marques  
Dr. Manuel Martins Alves

Coimbra Medical

Prof. Francisco Castro e Sousa  
Prof. José Guilherme Trilhão

Dr. Maria Helena Goulão

Hospital de Viana do Castelo

Dr. Luis Lopes  
Dr. João Ramada

### South Africa

Kingsbury Hospital

Dr. John Marr  
Dr. Charles Simonsz

City Hospital

Dr. Johan Potgieter

### Spain

Hospital Virgen Del Rocío

Dr. Ovidio Belda Laguna  
Dr. Salvador Sobrino Rodriguez

Virgen Macarena Hospital

Dr. Francisco Bautista  
Dr. Manuel Rodriguez Tellez  
Mercedes Torres Rodriguez

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