**Advice to Physicians on the Management of European and UK patients**

**with an EndoStim Implant**

1. **Patient Follow-up visits.** EndoStim closed for financial reasons, not because of any safety concerns. If the patient is well from a reflux point of view, then no interventions or checks are necessary except an optional periodic check to make sure the device is functioning properly.

If there is a situation of recurrent reflux that requires consideration of another therapy then it would be appropriate to check the working of the device in situ. An EndoStim wand and tablet programmer are necessary to perform the check. If you do not have access to a programmer, please contact [EndoStimtechnical@gmail.com](mailto:EndoStimtechnical@gmail.com) to be referred to a center with a programmer.  
  
Clinician manuals, programmer manuals, patient manuals, and patient ID cards in multiple languages are posted on [www.endostim.com](http://www.endostim.com) .

1. **Battery Life and Replacements**. It is possible that the battery may stop working but the symptoms remain well controlled for some period of time. This is because in some patients the sphincter may have been retrained by the neuromodulation and also the distensibility of the lower oesophagus may be somewhat limited by the fibrosis around the butterflies and electrodes. In such a circumstance then removal of the IPG alone (a local anaesthetic procedure) is the least invasive intervention. The additional option of removing the electrodes, is just that – an option where the pros and cons should be considered. The advantage of leaving the electrodes alone is that this avoids any risk of surgical intervention, or risk of the general anaesthetic. The primary disadvantage is that the patient’s access to MRI will be limited to the certain types of MRI equipment. The expected battery life of the device is approximately 6.5 years.

If a time comes when the symptoms recur and the battery life has ended then there will likely not be an option of battery replacement unless EndoStim is purchased out of bankruptcy or another manufacturer offers a similar device. If device replacement becomes available, it will be posted on [www.endostim.com](http://www.endostim.com) .

1. **Explants**. “Instructions for Explanting” is given in a separate document posted on [www.endostim.com](http://www.endostim.com) . Minimal tissue disruption at the time of device removal is advised in order to facilitate an alternative surgical intervention, such as fundoplication should that be planned.
2. **MRI compatibility**. This is in the Clinician Manual on page 33 – 42. Clinician manuals and programmer manuals are available as separate attachments posted on [www.endostim.com](http://www.endostim.com). In the instructions, there is a statement about not using a simple magnet to switch off an IPG before an MRI scan of the body (does not apply to head or limb scans). The magnet can effectively suspend therapy for 24 hours, but it cannot assess for a lead break (hence the Programmer). If there is a lead break, then there is a strong possibility that heating occurs at the electrodes that could ablate the surrounding tissue and/or be painful.  It is not known how much tissue would be ablated/damaged. A Programmer can detect a broken lead, at which point the patient would be limited to head/extremities (no RF body coil use) or have the lead extracted.