Side Effects

Serious adverse events (In accordance to MEDDEV 2.12–1 Guidelines on a medical devices Vigilance System)

Have there been any serious adverse events since last visit that might be due to endobarrier (if endobarrier has been removed and all serious adverse events have already been recorded please tick ‘Not applicable’).  Yes ☐ No ☐ Not applicable ☐

If there has been a serious adverse event that might be due to endobarrier and it has not already been recorded please tick all of the following which apply:

- Death: No ☐ Yes ☐ Uncertain ☐
- Life threatening: No ☐ Yes ☐ Uncertain ☐
- Led to hospitalisation or prolongation of hospitalisation: No ☐ Yes ☐ Uncertain ☐
- Led to medical or surgical intervention: No ☐ Yes ☐ Uncertain ☐
- Led to permanent impairment of a body function or permanent damage to a body structure: No ☐ Yes ☐ Uncertain ☐
- Led to early removal of Endobarrier: No ☐ Yes ☐ Uncertain ☐ (If Yes please give date of removal dd/mm/yyyy ______/______/______)
- Any event you judge to be serious: No ☐ Yes ☐ Uncertain ☐

If any of the above yes or uncertain tick all of the following which apply:

- Patient death with Endobarrier in situ: No ☐ Yes ☐
- Patient death which might be due to Endobarrier: No ☐ Yes ☐ Uncertain ☐
- Major bleeding: No ☐ Yes ☐ Uncertain ☐
- Migration/Movement of Endobarrier: No ☐ Yes ☐ Uncertain ☐
- Liner Obstruction: No ☐ Yes ☐ Uncertain ☐
- Hepatic Abscess: No ☐ Yes ☐ Uncertain ☐
- Pancreatitis: No ☐ Yes ☐ Uncertain ☐
- Surgical Removal: No ☐ Yes ☐ Uncertain ☐
- Oesophageal perforation: No ☐ Yes ☐ Uncertain ☐
- Other perforation: No ☐ Yes ☐ Uncertain ☐
- Gastrointestinal intolerance (eg nausea/vomiting/abdominal pain): No ☐ Yes ☐ Uncertain ☐

Other – please specify __________________________

Please give detail re any definite or possible serious adverse event
Any other patient comments?  Any other doctor/nurse comments?  

The Worldwide Endobarrier Registry is an independent registry hosted by the Association of British Clinical Diabetologists (ABCD). It is supported by an unrestricted grant from Gi Dynamics, Inc.