Worldwide Endobarrier Registry – Follow-up Visit

Date / / (dd/mm/yyyy)

Name of Clinician

Identification Number

Forename

Surname

Date of Birth / / (dd/mm/yyyy)

Gender Male ☐ Female ☐

AFFIX PATIENT LABEL HERE

Which follow-up visit is this?

After endobarrier insertion (whilst device still implanted) ☐ OR

After endobarrier removal ☐

If first visit after removal, indicate date of removal Date / / (dd/mm/yyyy)

If endobarrier removed prematurely, please record the reason in the section headed "Serious adverse events"

Does the patient have any new medical problems (not recorded in baseline questionnaire) OR have any of the baseline medical problems resolved?

☐ Yes ☐ No

Details if Yes _____

_____

Measurements and Tests

Blood Pressure SBP ____ mmHg DBP ____ mmHg Date / / (dd mmm yyyy)

Current Weight ___.__ kg Date / / (dd mmm yyyy)

HbA1c ____ % ____ mmol/mol Date / / (dd mmm yyyy)

Hb ____ g/l ____ g/dl **Plt** ____ x10⁹/l Date / / (dd mmm yyyy)

Lipids TChol ____ mmol/L ____ mg/dL LDL ____ mmol/L ____ mg/dL HDL ____ mmol/L ____ mg/dL Trigs ____ mmol/L ____ mg/dL Date / / (dd mmm yyyy)

Biochemistry ALT ____ U/l AST ____ U/l GGT ____ U/l Bili ____ micromol/l ____ mg/dL Albumin ____ g/l ____ g/dl Date / / (dd mmm yyyy)

Serum Cr ____ micromol/l ____ mg/dL Date / / (dd mmm yyyy)

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 ☐ **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

Side effects ascribed to Endobarrier since last visit : No ☐ Yes ☐ Yes but transient ☐ Yes, continuing ☐ Not Applicable (endobarrier already removed) ☐

If Yes, please tick all that apply: Nausea ☐ Vomiting ☐ Abdominal pain ☐ Constipation ☐ Diarrhoea ☐ Bloating ☐ Belching ☐

Flatulence ☐ Dyspepsia ☐ Back pain ☐ Other _____

Please tick worst side effect: Nausea ☐ Vomiting ☐ Abdominal pain ☐ Constipation ☐ Diarrhoea ☐ Bloating ☐ Belching ☐

Flatulence ☐ Dyspepsia ☐ Back pain ☐ Other _____

This worst side effect: Is continuing ☐ Was transient ☐; if transient how long did it last (weeks) _____

Severity? Mild ☐ Moderate ☐ Severe ☐

Please give any other comments regarding side effects here

Was there hypoglycaemia ☐ No ☐ Yes ☐ Uncertain

Number of events since last visit (best estimate)

☐ **Minor Hypoglycaemia** - Self-treated; defined by symptoms – glucose values may be taken into account but not required

☐ **Severe Hypoglycaemia** – required assistance of another person to treat hypoglycaemia (defined as patient could not have self treated – exclude cases where patient could have self-treated but a kind person helped)

Record current medication, before any changes made at this visit

Metformin	Metformin **Total dose including any in combined preparations**	Total Dose	mg/Day
Sulphonylurea	Glimepiride Glipizide Chlorpropamide Gliclazide Gliclazide MR Gliclazide SR Tolbutamide Glibenclamide Other	Total Dose	mg/Day
Pioglitazone	Pioglitazone **Total dose including any in combined preparations**	Total Dose	mg/Day
Meglitinides	Nateglinide Repaglinide	Total Dose	mg/Day
Alpha – glucosidase inhibitors	Acarbose	Total Dose	mg/Day
GLP-1 receptor agonists	Exenatide (Micrograms/day) Liraglutide (Milligrams/day) Lixisenatide (Micrograms/day) Exenatide QW (Micrograms/week)	Total Dose	mcg/mg/Day/ Week
DPP4 inhibitors	Sitagliptin Vildagliptin Saxagliptin Linagliptin Alogliptin	Total Dose	mg/Day
SGLT2 inhibitors	Dapagliflozin Canagliflozin Empagliflozin	Total Dose	mg/Day
Insulin – total dose		Total Dose	IU/Day
Other antidiabetic medications	Or medications which could affect glycaemic control		
Anti-obesity medication	Orlistat (Xenical)	Total Dose	mg/Day

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.