

## **Gastric Balloon Terms & Conditions**

The Orbera 6 month balloon, Orbera 365 balloon and Spatz balloon ((hereinafter referred to as gastric balloon or the procedure) offer a simple, safe and effective method for combating obesity. Their role in helping patients to lose weight and maintain that weight loss is proven. However, it is vitally important to understand that the gastric balloon is a medical device being used in a medical context. It is not a toy or a gimmick that will do all the work for you. Consequently, we would ask that you read and understand the following:

### **Regarding the Procedure – You understand that:**

The procedure is an elective procedure, requested by you.

That you have been consulted by staff of the National Obesity Surgery Centre and you have had every opportunity to discuss the procedure.

That the pros and cons and risks and complications of the procedure will be discussed with you by your Consultant Surgeon/Consultant Gastroenterologist.

That the procedure will be undertaken by a Consultant Surgeon/Consultant Gastroenterologist.

That the procedure will almost always require either no sedation at all or only a light sedation, which will be administered by the Consultant Surgeon, Consultant Gastroenterologist or Consultant Anaesthetist, as appropriate.

That the procedure may rarely require a general anaesthetic, which will be administered by a Consultant Anaesthetist.

That the procedure is carried out on a day case basis, but may rarely require an overnight stay which is not included in your package.

That there are potential risks and complications with any sedation and/or general anaesthetic and that these are to be discussed with the Consultant Surgeon, Consultant Gastroenterologist or Consultant Anaesthetist, as appropriate. However, notwithstanding any subsequent discussions with the Consultant, you accept and understand that these complications include but are not limited to the following:

- Adverse reactions to the anaesthetic drugs or any other medications that may have to be administered.
- Damage to teeth.
- Sore throat.
- Damage to the vocal cords.
- Heart complications, including cardiac arrest.
- Lung complications, including aspiration of stomach contents, chest infection, pulmonary embolism.
- Thromboembolism.
- Hyperpyrexia.
- Death.

You confirm that you understand these anaesthetic complications to be extremely rare in an otherwise fit and healthy patient undergoing a routine non-urgent sedation/general anaesthetic under the care of an NHS Consultant.

### **You understand that:**

The procedure itself involves passing an endoscope through the mouth, down the gullet and into the stomach, where a thorough examination will be undertaken prior to insertion of the gastric balloon.

There are potential risks and complications with any endoscopic examination and that these are to be discussed with the Consultant Surgeon/Consultant Gastroenterologist. However, notwithstanding any subsequent discussions with the Consultant Surgeon/Consultant Gastroenterologist, you accept and understand that these complications include but are not limited to the following:

- Abdominal discomfort because of the air pumped into the stomach to distend it.
- Injury to the gullet or stomach (including perforation - very rare).
- That any such injury may result in bleeding and/or perforation.
- That any such injury may require further emergency surgery and that you specifically consent to any such emergency surgery.
- Inhalation of gastric contents (very rare).

**You understand that:**

If any abnormality is found during the examination, the procedure may have to be abandoned, perhaps permanently.

Following the examination, the gastric balloon will be passed through the mouth, down the gullet and into the stomach where its position will be confirmed endoscopically and then it is inflated with sterile saline in which there is a blue dye.

That there are potential immediate risks and complications associated with insertion of the intragastric balloon, and that these are to be discussed with the Consultant Surgeon/Consultant Gastroenterologist. However, notwithstanding any subsequent discussions with the Consultant Surgeon/Consultant Gastroenterologist, you accept and understand that these complications include but are not limited to the following:

- Injury to the gullet or stomach (including perforation - very rare).
- Bleeding due to trauma (very rare).
- Rupture of the gullet or stomach on inflation of the intragastric balloon (extremely rare).

**You understand that:**

Medications, other treatment and/or surgery may be necessary during the course of the procedure should any complications arise, and you specifically consent to these also.

Even once the gastric balloon is successfully inserted, other complications may arise and that these are to be discussed with the Consultant Surgeon/Consultant Gastroenterologist. However, notwithstanding any subsequent discussions with the Consultant Surgeon/Consultant Gastroenterologist, you accept and understand that these complications include but are not limited to the following:

- Psychological balloon intolerance.
- True balloon intolerance.
- Dehydration due to prolonged sickness may require IV fluids at your local A & E or your closest hospital.
- Metabolic problems +/- renal failure/thiamine deficiency.
- Reflux oesophagitis.
- Gastric erosions +/- bleeding.
- Gastric ulcers +/- perforation.
- Gastric outlet obstruction/balloon impaction.
- Acute gastric dilatation.
- Balloon deflation.
- Spontaneous evacuation of the balloon at stool.
- Intestinal obstruction.
- Infections.
- Alterations in bowel habit.

You understand that if any complications do arise, you will contact the National Obesity Surgery Centre or the NOSC emergency out of hours service immediately and accept their advice regarding care. If you need to be moved to a High Dependency Unit or alternative hospital for specialist care, costs are not included in the NOSC package.

Your package does not include overnight accommodation which will be charged for separately.

**Regarding Weight Loss**

The gastric balloon is an accepted method of treatment for mild to moderate obesity in adults in the United Kingdom and throughout Europe. This procedure is being undertaken to help you control your weight.

In recorded discussions with the NOSC, you have confirmed that you have a long history of obesity and a poor relationship with food, and that you have tried alternative forms of treatment over many years and all have been unsuccessful, and that all other treatment modalities have been discussed with you, including (inter alia) general dietary control, very low calorie diets, anti-obesity medications and anti-obesity surgery.

After all these discussions relating to alternative treatment modalities we have agreed that the very best course of treatment for you is the gastric balloon.

### **You understand that:**

The gastric balloon is a training tool to help with behaviour modification and that you must participate in a dedicated follow-up programme of behavioural modification and support to increase its chance of success.

Consequently, that you will do all that you can to help yourself in this process, including attending all review appointments in person or by telephone.

You have been advised that, following removal of the intragastric balloon, a further follow-up programme of behavioural modification and care will be required and that you will attend all appointments for this, and follow all advice given to you.

No specific assurance has been given to you about the amount of weight that you may lose.

The gastric balloon must be removed within a period of six or twelve months depending on which balloon you chose and you hereby also consent to its removal at that time.

### **Regarding Unforeseeable Circumstances**

#### **An Abnormality Found at Endoscopy - You understand that:**

If during your endoscopy an abnormality is found, it may not be possible to insert the gastric balloon, perhaps permanently.

If, following endoscopy, it is not possible to insert your gastric balloon at all, including at any time in the future:

- You will receive a refund of any monies remaining after all incurred costs have been deducted. Costs will include Surgeon, Anaesthetist, hospital and administration fees and cost of the device if applicable (but not limited to). An approximate cost of private treatment where the gastric balloon cannot be fitted could be in excess of £1,000.00.
- The administration fee is £225.00; other fees may vary from hospital to hospital.

If, following endoscopy, you are found to have a treatable benign condition that merely means your balloon placement has to be postponed, the decision as to whether to be treated and then proceed is entirely yours:

- If you decide to proceed, you understand that costs have already been incurred and there will be additional costs to pay.

If during the Endoscopy you are unable to swallow the balloon, please note that costs will have been incurred for the Endoscopy and the balloons itself, these fees can be in excess of £2000.00.

#### **Failure To Follow Eating/Fasting Instructions - You understand that:**

Failure to follow pre-insertion eating and fasting instructions may result in your procedure being abandoned.

If food is found in your stomach and it is not possible to insert the intragastric balloon:

- Should you decide to proceed at a later date, you understand that costs have already been incurred and there will be additional costs to pay. Costs will include Surgeon, Anaesthetist, hospital and administration fees and cost of the device if applicable (but not limited to). The approximate cost of private treatment where the balloon cannot be fitted could be in excess of £1,000.00.
- If you decide not to reschedule you will receive a refund of any monies remaining after all incurred costs have been deducted. Such costs will include Surgeon, Anaesthetist, hospital and administration fees and cost of the device if applicable (but not limited to). The approximate cost of private treatment where the balloon cannot be fitted could be in excess of £1,000.00.

- The administration fee is £225.00; other fees may vary from hospital to hospital.

### **Balloon Intolerance**

If your Consultant Surgeon/Consultant Gastroenterologist confirms that you have a genuine medical intolerance (extremely rare) your balloon will be removed immediately. No refund will be given as all costs have been incurred.

If you choose to have your balloon removed early for whatever reason, no refund will be given.

If you choose not to complete or participate in the NOSC Gastric Balloon Support Programme for any reason including following early removal of your balloon, no refund will be given. As reported by the manufacturers of the Balloon, Apollo Endo early balloon removal rate due to intolerance is around 7% of 68 studies and these figures are publicly available from recognised journals.

### **Spontaneous Balloon Deflation/Intestinal Obstruction – You understand that:**

Spontaneous balloon deflation is an unusual event in patients who take all their prescribed medication and who attend for balloon removal within the stated six or twelve months. If you suffer from this complication, you may notice your urine and/or stools change colour:

- You must contact the National Obesity Surgery Centre immediately or the NOSC emergency out of hour's number.
- The balloon will be removed endoscopically if, as is almost certainly the case, the balloon is still in the stomach.
- If you do not contact NOSC immediately and the balloon has already left the stomach, you understand that you will be liable for any costs incurred.
- Your progress will be monitored closely and may require hospital admission, x-rays or other investigations which are not covered in your NOSC package.
- Both the National Obesity Surgery Centre and the gastric balloon manufacturers will contact you about what to do next regarding re-insertion of a new balloon if the event occurs within the twelve month period. This will depend upon how long the gastric balloon has already been in place and your own wishes. If spontaneous deflation occurs during the twelve month placement of the gastric balloon, a replacement will be issued by the manufacturer and no refund will be given.

### **Failure to Lose Weight**

With any medical procedure or biological process there is a range of success recorded. Some patients just naturally do better than others, some may even cheat and continue to eat or drink very high calorie liquidised food. The NOSC Gastric Balloon Programme is specifically set up to maximise each patient's own potential for success. We are therefore unable to offer any refund whatsoever in the event that patients are disappointed with the results of their gastric balloon.

### **Important**

The National Obesity Surgery Centre insists that the gastric balloon be removed within the stated six or twelve month period. The full fee for this removal is included within the initial all-inclusive payment. If you fail to attend for balloon removal at this time, any and all complications that ensue thereafter will be at your own risk and your own expense. Failure to attend an appointment for gastric balloon removal with less than forty-eight hours (working hours) cancellation notice will incur a fee of £850.00.

If you fail to have your gastric balloon removed at the six or twelve month due date, an additional arrangement fee of £850.00 will be incurred plus any further medical costs involved in a late removal procedure.

It is not always possible to return to the same hospital for the removal of your balloon. Occasionally, due to unforeseen circumstances, you may be booked into another hospital for the removal procedure.

If you arrange your own balloon removal this will not be covered in your contract and no costs will be reimbursed. All appointments must be booked through ourselves.

## **Cancellation Policy**

If for any reason you need to postpone or re-schedule your procedure and you have paid in full, there will be no additional charge to move your appointment date.

If you simply wish to cancel and have paid in full, as long as you notify the NOSC one week prior to procedure, a full refund will be issued less an administration charge of £450.00.

If you have paid a deposit and received your pack (including medication) and wish to cancel, an administration fee of £345.00 will be deducted and the balance of your deposit refunded.

If you do not give NOSC forty-eight working hours notice, an administration charge of £450.00 will apply plus a hospital and surgeon cancellation fee of £850.00.

You must talk to one of the Patient Advisors if you wish to make a cancellation, leaving a message will not be sufficient to cover a cancellation.

Consultation fees are non refundable.

**Please note that all incoming and outgoing calls are recorded for training and monitoring purposes.**