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Intragastric Balloon Consent Form

THESE INSTRUCTIONS WILL HELP YOU PREPARE FOR YOUR GASTROSCOPY AND INTRAGASTRIC BALLOON PLACEMENT. WE ASK THAT YOU READ THEM CAREFULLY.

- If you have ever had complications or serious side effects following any previous gastroscopy exam please call to discuss this with our nurse before your appointment.
- Please inform the nurse before the gastroscopy of any health problems or physical disabilities you may have, eg: hearing loss or decreased mobility.
- If you are over 70 years of age, diabetic or suffer from hypotension (low blood pressure), please make sure you were given a morning appointment.
- Please bring with you your Referral from your Physician together with any Medical Reports (such as blood test results or ultrasound report) relevant to your present condition.
- Bring with you a list of your Current Medications and also of your Allergies (to food & medication). These lists will be put in your file.
- Please arrive 30 minutes before the time of your appointment so that you may sign the consent form and prepare for the examination. Please let us know in advance (72 hrs preferred) if you have to cancel or change your appointment.
- You will not be able to drive for 8 hours after the exam – We suggest you come to your appointment accompanied by a friend or relative.

GASTROSCOPY – INFORMATION AND PREPARATION

A Gastroscopy is an examination in which a flexible tube (endoscope) with a miniature camera on the end is passed through the mouth and back of the throat into the upper digestive tract. It allows the physician to inspect the lining of the oesophagus, stomach and duodenum (the first portion of the small intestine). The exam usually takes 10 to 15 minutes and will be done prior to the placement of the Intragastric Balloon to make sure there is no abnormality.

If ulcers, inflammation or any other abnormality is seen a small piece of tissue can be taken (biopsy) for examination in the laboratory: this does not necessarily mean that they are cancerous. Polyps can also be removed. Certain abnormalities may preclude the placement of the Intragastric Balloon.

The feeling of the tube at the back of your throat may cause discomfort but rest assured that

the tube will not affect your breathing. You will be offered intravenous sedation to minimize any discomfort, which will help you relax and prevent “gagging”. A local anaesthetic may be sprayed onto the back of your throat to reduce the uncomfortable feeling.

You will be monitored in the recovery room of the clinic until the sedation wears off (approximately 30-45 minutes). Your throat may be sore for a few hours and you may feel bloated for a few minutes after your exam, but normally you will be able to resume your regular diet after 30 minutes. Please note that the medication(s) used to sedate you may impair your reflexes and judgment for the rest of the day.

It is therefore strongly recommended that you be accompanied home. Do not drive or operate any machinery for a period of 8 hours after the exam even if you feel capable of doing so.

The medication administered may be excreted in breast milk and may also be transferred into the placenta. Nursing mothers should inquire well in advance of their appointment with the nurse or the physician performing the exam for more information and precautions to be taken.

Gastroscopy does not stimulate contraction of the uterus and can be performed during pregnancy, without the administration of sedatives. The consent of the specialist performing the gastroscopy is required prior to the exam.

Possible Complications of Gastroscopy

Gastroscopy (with or without biopsy or polypectomy) is associated with a very low risk of complications when performed by specialized physicians. A perforation - a tear through the wall of the oesophagus or stomach, which may cause leakage of the digestive fluids - can occur. This rare complication may be managed simply by aspirating the fluids until the opening seals. Antibiotic treatments or surgery may be required. Bleeding may occur after a biopsy or removal of a polyp but it is usually minor and stops on its own or it can be controlled by cauterization. It is extremely rare that transfusion is needed or surgery has to be performed to stop the bleeding. Adverse or allergic reactions to the medications are possible and can be controlled with specific medications. Localized irritation of the vein may occur at the site of medication injection. A tender lump develops which may remain for several weeks to months but this will go away eventually.

You will need to follow the instructions below concerning medications if:

You are taking Coumadin or Plavix (anti-platelet) You are diabetic You are taking medication containing aspirin on a regular basis (eg Entrophen) Should you need additional information or clarification after reading the following instructions, kindly inquire with the nurse or the physician performing the exam well in advance of your appointment.

* You must stop taking all anticoagulants (medication which thins the blood) - in order to prevent bleeding. Stop taking Coumadin 4 days prior to the gastroscopy Stop taking Plavix (antiplatelet) 10 days prior to the gastroscopy. Stop taking all medications which contain aspirin 10 days prior to the gastroscopy.

Please check your medication with your pharmacist.

* You must stop taking any oral medication for diabetes - in order to prevent hypoglycemia. Stop taking Glucophage/Metformin, Diabeta, etc. from the time you begin the preparation: “clear liquid diet or fasting” * If you are insulin-dependent;

- On the day of the gastroscopy – do not take any insulin in the morning - in order to prevent hypoglycemia. You can start taking your medication again when the exam is over and you are eating normally.

* If you are taking medication for high blood pressure, it is advisable not to take it on the

morning of the gastroscopy - in order to prevent hypotension (low blood pressure). Other medications such as Advil, Tylenol... should not be taken before the exam (during fasting period) unless essential. If we advise you to take your medication, please take it with only a little water. Before you stop taking any medication, please check with your referring physician.

If for any reason you cannot follow the instructions above or if you need more information please call the nurse at our clinic: 03 9331 3122 at least 24hrs before your appointment (please leave a message and the nurse will call you back).

INTRAGASTRIC BALLOON PLACEMENT – INFORMATION

An Intra-gastric Balloon (IGB) is a balloon-like device which is placed in the stomach and inflated during a Gastroscopy procedure. Floating in the stomach the IGB creates a sensation of satiety (fullness) which allows patients to eat less and thereby lose excess weight.

The inflated IGB stays in the stomach for a maximum of 6 months during which time patients are followed carefully by our medical specialists.

A nutritionist will work with patients to provide dietary counselling. Their progress will be monitored with respect to weight and waist circumference. Patients learn how to establish a balanced and healthy diet and also how to be satisfied with smaller portions. This is essential to maintain weight loss after the IGB has been removed.

We anticipate that almost all our patients will lose weight during the six months the IGB is in the stomach. Many will be able to maintain this weight loss. Those patients who have difficulty in keeping the excess weight off will be informed of all other available treatment options.

Candidates for IGB

The manufacturer recommends that the Orbera Balloon not be used for more than six months at a time. The most suitable candidates for this therapy are:

- Patients with moderate obesity (BMI 30 – 40) which places them at serious medical risk
- Patients with severe obesity (BMI >40) who are awaiting definitive surgery (isolated gastric bypass or gastric banding)
- Severely obese patients with co-morbid conditions which make them high-risk for surgery or anesthesia.

Placement of the IGB

Placement of IGB is carried out in an Endoscopy Suite. Intravenous conscious sedation is administered and the throat is sprayed with local anesthetic. Endoscopic examination of the upper gastrointestinal tract is performed. The endoscope is then withdrawn. The IGB in its collapsed state is introduced into the stomach via the mouth. Once in the correct position the IGB is inflated with air and the introducer tube is detached and removed. The entire procedure takes about 15 or 20 minutes. Patients are carefully monitored during the endoscopic procedure and during a short recovery period until they are fully alert.

Removal of the IGB

Removal of the IGB is also carried out in an Endoscopy Suite with the patient once again given conscious sedation and local anesthesia to the throat. A special needle is inserted

though the endoscope to puncture and deflate the IGB. Once it is fully deflated it is grasped with specially designed forceps and removed via the mouth. Removal of the IGB usually takes between 15 and 30 minutes. Patients are monitored during IGB removal and recovery until they are fully alert.

Possible Complications of Intra-gastric Balloon Use

In addition to the Possible Complications associated with Gastroscopy (already outlined in GASTROSCOPY – INFORMATION AND PREPARATION), there are several others associated with the use of the IGB. It should be noted that these complications are very rare when the IGB is placed by a trained specialist:

During endoscopy and the placement or removal of the IGB –

- Injury to the throat, esophagus or stomach, causing bleeding or even perforation may occur requiring surgical repair.

While the IGB is in place:

- Gastric ulcers or erosions may be caused by the pressure on gastric mucosa • Obstruction of the gastro-intestinal tract may result if a balloon leaks and moves from its

correct position. Surgical removal of the balloon may then be necessary. Adverse reactions to the presence of the IGB:

- Nausea, vomiting, heartburn, reflux, bloating and cramps may occur. These symptoms are often temporary and can usually be treated with medications. In the rare cases where vomiting does not subside, the IGB may have to be removed.

If the IGB causes intolerable or untreatable side effects it can be removed at any time.

Important Points to Review:

___ I will stop taking all blood thinners and all other medications as specified on this form.

___ I will properly follow the Preparation to clear my stomach.

___ I will bring a list of all my medications & allergies to my Gastroscopy-IGB Placement appointment.

___ I will not drive or operate machinery for 8 hours after the procedures were performed under sedation.

___ I am aware that the medication administered may be excreted in breast milk. If I am breast-feeding, I will enquire with the nurse or my physician well in advance for the precautions to take.

___ I am aware that these procedures cannot be performed during pregnancy without a specialist's consent.

GASTROSCOPY AND INTRAGASTRIC BALLOON PLACEMENT - INFORMED CONSENT

I understand that the Gastroscopy procedure (which is part of MD Specialists' Upper Gastro-Intestinal Diagnostic and Treatment Program) and Intra-gastric Balloon Placement that I am hereby requesting requires, among other things, the presence of a registered nurse for monitoring during and after sedation and also that of an endoscopy assistant during the full

duration of the procedure.

I specifically request their presence and accept to pay the related fees. I have been informed that these fees are not reimbursable by the provincial health insurance (Medicare) or by most private health insurances.

I have read and understood the contents of both GASTROSCOPY-INFORMATION AND PREPARATION and PLACEMENT OF INTRAGASTRIC BALLOON - INFORMATION including the risks and possible complications that are associated with both procedures. The procedures and their associated risks and possible complications have been clearly explained to me. I had the opportunity prior to the procedures to direct all my questions to the attending doctor and was given satisfactory answers.

I am not breast-feeding: _____(Patient's signature).

I am not pregnant and do not think I may be pregnant: _____(Patient's signature).

I, _____ hereby give my consent to Dr Froomes to perform a Gastroscopy (with or without biopsy / polypectomy) and Intra-gastric Balloon Placement on me.

_____ (Patient's Signature)

_____ (Date)

_____ (Witness)

_____ (Doctor's Signature)

Please bring this consent form (unsigned) with you on the day of your Gastroscopy-IGB Placement Thank You !