

Patient Name:
Date of Birth:

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Associate Professor of Surgery

Informed Consent
Use of an endoscopic operating system to induce earlier Satiety
(POSE Procedure – Primary Obesity Surgery Endolumenal)

The Procedure:

The g-cath suture anchor delivery catheter and accessory equipment have all been cleared by the EU (European Union) for use in pulling tissue together to make “folds” on the inside of the stomach. So far, it has been used in thousands procedures worldwide.

The instruments that your physician will use include a gastroscope, a slim endoscope and the IOP. The IOP includes an access device that is a flexible tube with channels or openings inside to allow instrument passage, grasping instruments on flexible shafts to help manipulate and grasp tissue, and tissue anchors that are made of polyester and a small amount of metal that are used to hold tissue together. It is thought that these anchors help prevent expansion of the stomach to food, thus eliciting earlier and longer satiety to assist with weight loss.

This procedure will be done under general anesthesia. You will be asleep and unaware of the procedure. The procedure will last approximately 1-1.5 hours.

Once you are asleep, a gastroscope will be inserted into your mouth and passed down into your stomach so that your physician can examine your stomach and confirm that your anatomy will allow use of the IOP.

If you have more questions, ask your physician to show you a picture of the device, and how it works to reduce the size of the gastric stomach.

Post Procedure:

Your doctor may keep you overnight for observation. You may experience some sore throat, abdominal or shoulder discomfort, nausea or vomiting for a day or two. Most do not get these symptoms. After you are discharged from the hospital (typically in less than 23 hours); you will initially be placed on a specified calorie-restricted diet during the first 4 weeks following your procedure. The 1st week will be all liquids which will slowly be advanced to a solid diet by the 5th week. The diet will be similar to what is routinely given after other bariatric surgical procedures. This will give the sutures in your stomach time to heal. Following the 5th week; you will be counseled to follow a diet that provides a maximum number of calories, a specific amount of protein and a minimum quantity of liquids.

Possible Risks:

This endolumenal procedure may cause all, some or none of the side effects listed below. Most side effects are minor; however, some may be serious, permanent, or even cause death. If you have any side effects, report them to your physician immediately. To date, over 1500 cases have been done with the IOP worldwide. There have been no deaths. Serious adverse events have occurred at a very low rate (under 1.7%). However, there is risk with any procedure and below are possible risks:

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Risks that may be associated with general anesthesia are rare but include:

- Allergic reaction
- Liquid from your stomach may get into your lungs which could cause pneumonia
- Irregular heartbeats
- Heart attack
- Death

Your anesthesiologist will discuss these risks with you before your procedure.

Risks that may be associated with the endolumenal procedure include:

Common:

- Temporary sore throat
- Some abdominal or shoulder pain

Uncommon:

- Ulcer (a sore that is difficult to heal) of the lining of the stomach that may require treatment with medication

Rare:

- Bleeding
- Perforation (a small hole in the tissue)
- Laceration (tear in the tissue)
- Fistula (an open connection)
- Peritonitis (infection or irritation of the abdominal cavity)
- Abscess (collection of infection)

Risks may occur that are unknown or unexpected. Some of these listed risks are based upon similar procedures using the same devices. It is not known how often some of the risks might actually occur. It is also possible that the tissue sutures could become loose, in which case they will pass through the intestines and out of the body without harm.

Your responsibilities before having this procedure

You are less at risk of problems if you do the following:

- Bring all your prescribed drugs, those drugs you buy over the counter, herbal remedies and supplements and show your doctor what you are taking.
Tell your doctor about any allergies or side effects you may have.

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- Do not drink any alcohol and stop recreational drugs 24 hours before the procedure. If you have a drug habits please tell your doctor.
- If you take Warfarin, Persantin, Clopidogrel (Plavix or Iscover), Asasantin or any other drug that is used to thin your blood ask the doctor ordering the test if you should stop taking it before the procedure as it may affect your blood clotting.
Do not stop taking them without asking your doctor.
- Tell your doctor if you have;
 - heart valve replacement surgery
 - received previous advice about taking antibiotics before a dental treatment or a surgical procedure. If so, you may also need antibiotics before the procedure.

Preparation for the procedure:

Your stomach must be empty for the procedure to be safe and thorough, so you will not be able to eat or drink anything for at least six hours before the procedure.

What are the safety issues?

Sedation will affect your judgment for about 24 hours. For your own safety and in some cases legally;

- Do NOT drive any type of car, bike or other vehicle. You must be taken home by a responsible adult person.
- Do NOT operate machinery including cooking implements.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, take other mind-altering substances, or smoke. They may react with the sedation drugs.
- Have an adult with you on the first night after your surgery.

Notify the hospital Emergency Department straight away if you have;

- severe ongoing abdominal pain
- trouble swallowing
- a fever
- sharp chest or throat pain
- Have redness, tenderness or swelling for more than 48hours where you had the injection for sedation (either in the hand or arm).

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Alternative treatments:

Other options available to you include trying to lose weight with diet and exercise alone, or having an open or laparoscopic surgical procedure performed. Your physician may review these with you.

Please ask your Doctor if you have any questions about your procedure

Contact _____ at _____

To treat my condition has been explained to me as being:

Informed Consent:

I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic/sedation required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care. The procedure may include a blood transfusion.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor.
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.

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- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- On the basis of the above statements,

I request to have the procedure

Name of the patient:

Name of Witness

Signature:

Signature:

Date:

Doctor/delegate statement:

I have explained to the patient all the above points and I am of the opinion that the patient/substitute decision maker has understood the information.

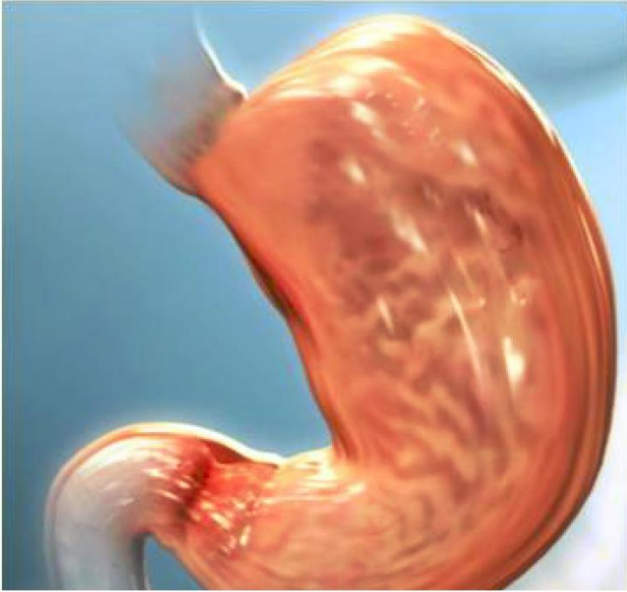
Name of

Doctor/delegate: Karl Miller, MD

Signature:

Date:

Patient Name:
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Stomach before POSE



Stomach after POSE

Notes