

IMPORTANT: PLEASE BRING THIS SIGNED CONSENT INTO HOSPITAL WITH YOU

## SENARATH WERAPITIYA

### GENERAL SURGEON

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## ONE ANASTOMOSIS GASTRIC BYPASS (OMEGA LOOP / MINI GASTRIC BYPASS)

### Operative Treatment Consent Agreement:

My signature and comments in this **seven page** form are meant to demonstrate that I understand and completely agree that I have been given an appropriate level of pre-operative education and information about obesity, the risks of obesity and a detailed description of the proposed surgery and its possible benefits and the risks of surgery.

I also had an opportunity to understand the surgical procedures available in general which included the gastric band option, the sleeve gastrectomy option, other gastric bypass options with a detailed reference to a **one anastomosis gastric bypass** in particular.

I understand that this consent form is designed to provide written confirmation of these discussions with my surgeon and the effort of this long document is purposefully intended to make me think over my decision to have surgery once again. I understand that it is my responsibility and right to ask and clarify any doubts before completing this document.

I confirm that I have extensively reviewed the decision to proceed with this weight loss surgery. I have extensively reviewed the decision to proceed with **one anastomosis gastric bypass** surgery as a weight loss operation with the help of my supportive family and my Doctor and I wish to consent to go forward with the proposed **one anastomosis gastric bypass** procedure.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

### Reason for me to choose Obesity Surgery:

I recognize that I am overweight/obese. I understand that obesity has been shown to increase risk of death from a variety of medical illnesses. I understand that obesity places individuals at an increased risk of diabetes, high blood pressure, respiratory disease, heart disease, high cholesterol, stroke, arthritis, clotting problems and cancer, all of which can increase the risk of disability and may even cause premature death.

Considering the health benefits of weight loss, I have a strong reason to make every endeavor to lose weight and try to get as close to the normal body weight range as possible.

In my own experience I have not been able to maintain a healthier weight following diet and exercise with my own best efforts. This is the reason why I am considering surgery as a weight loss option, fully understanding the quite drastic nature of this option.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

## Proposed Procedure: One anastomosis gastric bypass

I understand the procedure that I have agreed to undergo for the treatment of obesity is the **one anastomosis gastric bypass**. My surgeon, with the help of the dietitian and other support staff, have given me a detailed explanation of the **one anastomosis gastric bypass** procedure as well as other surgical options including the gastric band procedure, the sleeve gastrectomy procedure and other gastric bypass procedures.

I have been provided with drawings, written and verbal information of this procedure and I have been strongly encouraged to make every reasonable effort to investigate and understand the details of the operation.

I understand the **one anastomosis gastric bypass** operation is both restrictive and a malabsorptive procedure. This operation involves creating a long narrow stomach tube with a join between a loop of small bowel and the far end of the stomach tube. The join is placed 200 cm from the top end of the small bowel bypassing the first two metres of the small bowel.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

## Risks of the Proposed one anastomosis gastric bypass

Just as there may be some expected benefits from the **one anastomosis gastric bypass** procedure in my case, I understand that all surgical procedures including the proposed **one anastomosis gastric bypass** procedure involve risks.

### 1. Bleeding:

Surgery involves incisions and cutting that can result in bleeding complication, from minor to massive bleeding, which may require blood transfusion, emergency surgery and may even lead to death in extremely rare circumstances. Bleeding is most serious if it is within the abdominal cavity and the bleeding can occur into the intestine from the bowel joint or into the abdominal cavity.

**For patients on blood thinners and or blood pressure medication** - I know that blood thinners can lead to higher chance of bleeding after surgery and hence the need for me to stop such medication under medical supervision prior to surgery. Uncontrolled high blood pressure is another factor that may increase the risk of bleeding and I know the importance of taking my blood pressure medication as usual.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

### 2. Leak:

I know that after this surgery, stapling and stitching is involved creating the stomach tube and the new join. These staple and suture lines are meant to be water tight without any leakage of intestinal content to the abdominal cavity. I understand that there is a rare risk of leaking (1 – 2%), particularly in the first two weeks after the surgery. Leaking from the staple line/bowel join is a serious problem. The leak will allow stomach acid, bile, bacteria and digestive enzymes to escape into the abdominal cavity causing severe infection (peritonitis) that may even be potentially lethal.

I understand that strictly following the prescribed post-operative diet is important minimizing the chance of a leak. I also understand that if I am worried about the possibility of a leak, I have to inform Dr. Werapitiya directly without delay.

I know if a leak is suspected, I may have to undergo further tests including x-rays and emergency surgery. I am aware that the emergency surgery usually involves placement of multiple drains and nasal feeding tube. I am also aware that resolution of a leak can take a long period of time, usually requiring me to have in hospital care for a long period of time, sometimes weeks or even months. In the process, I may also require intensive care treatment or transfer to a different hospital for optimal care. I understand the risk of leak is higher if **one anastomosis gastric bypass** is done as a revision surgery following failure of a previous gastric band or a sleeve surgery.

I also clearly understand that this complication can very rarely, be lethal.

**To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_**

**3. Infection:**

The most serious infection is peritonitis associated with a leak which is fortunately extremely rare. There is also a chance of other minor infections like wound infection, bladder infection etc.

**To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_**

**4. Blood Clot:**

Also called deep vein thrombosis (DVT) and pulmonary embolus. I understand that this is an exceedingly rare complication, but it can even lead to death. I understand that blood thinning medications will be administered while I am in hospital to minimize the risk of blood clotting and calf compression stocking's will be used. I also understand that from my part, it is important that I get out of bed as early as possible and move my feet and legs to try and help prevent blood clots. I also understand the importance of preventing dehydration and keeping up with my fluids.

**To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_**

**5. Nausea, Vomiting and Headache:**

I understand that it is common and not unusual for me to feel some nausea, vomiting and headache. This is partly as a result of the fasting period prior to the surgery leading to some degree of dehydration, the effects of the anaesthesia and pain relief medication that I am going to be receiving as well as the effects of the surgery. I understand that the powerful pain medication that I am going to be on will increase the chance of nausea and I understand the importance of seeking help with anti-nausea medication early to minimize the chance of vomiting.

**To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_**

**6. Laparoscopic entry associated risks:**

Laparoscopic surgery uses punctures to enter the abdominal cavity which can lead to abdominal organ injury, (bowel, spleen, liver etc.) or lead to a puncture of a vessel that can lead to bleeding and even death in rare circumstances.

**To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_**

**7. Anaesthetic complication:**

I understand that general anaesthesia these days is very safe, however, it is not without complications. I understand I will have a full description of the anaesthetic associated complications from my anaesthetist. I understand that I have been provided with the contact details of my anaesthetist and I am supposed to make an appointment with my anaesthetist prior to my operation.

**To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_**

**Long Term Complications:**

**8. Indigestion, Acid/Bile reflux:**

I am aware that acid reflux can happen after this operation leading to heartburn and regurgitation of fluid or food content. I also understand that this is particularly going to be the case in people who have had gastro-oesophageal reflux prior to having the operation.

The new join between the stomach tube and the intestine is designed to minimise the chance of bile in the intestine refluxing back into the stomach. I am aware however, if this happens, this can lead to bile gastritis. In the rare instance where bile in the stomach tube refluxes into the oesophagus, it can also lead to injury to the oesophagus. I am aware that there has been concern of oesophageal cancer in the long term as a result of bile reflux. However up to date there has been no reported cases of oesophageal cancer after this procedure. To manage severe bile reflux anti-reflux surgery, reversal/revision of the bypass or conversion to Roux-en-Y bypass may be necessary.

**To confirm that you have understood the paragraph above, please initial here:\_\_\_\_\_**

### **9. Anastomotic ulcer:**

I know that I may develop an ulcer at the join between the stomach tube and the small bowel. I also understand that smoking, heavy alcohol use, H pylori infection and non-steroidal anti-inflammatory medications (Aspirin, Ibuprofen, Voltaren etc.), can lead to an increased chance of ulcer formation. I am also aware that strong acid suppression medication (esomeprazole) is used in the first 6 months after surgery to minimize the ulcer risk. I understand a proportion of ulcers can go on to have further serious complications like perforation and severe bleeding which are surgical emergencies. I also understand that in rare circumstances, when the ulcer fails to heal with medication there may be a necessity for the operation to be reversed or revised.

**To confirm that you have understood the paragraph above, please initial here:\_\_\_\_\_**

### **10. Dumping Syndrome:**

I understand that dumping syndrome can occur in some patients after gastric bypass surgery, (symptoms of dumping syndrome include weakness, sweating, nausea, diarrhoea, palpitation and dizziness soon after a meal). I also understand the heavy load of refined sugars/refined carbohydrates, rapid eating, drinking while eating are all factors that may increase the risk of dumping. I also understand if it becomes a disabling problem, it may require reversal of the bypass operation.

**To confirm that you have understood the paragraph above, please initial here:\_\_\_\_\_**

### **11. Bowel Obstruction:**

Any abdominal operation can lead to post-operative scarring which may lead to bowel obstruction. I understand the chance of this is minimally invasive with key hole (laparoscopic) surgery. With the changes of the orientation of the small bowel after **one anastomosis gastric bypass**, bowel obstruction can also rarely happen due to prolapsing of the bowel through tight spaces that are created as a result of the operation.

**To confirm that you have understood the paragraph above, please initial here:\_\_\_\_\_**

### **12. Hair loss:**

Many patient's develop hair loss for a period after the operation. When this occurs it usually starts about 3 – 4 months after surgery and resolves about 7 – 9 months after the operation. This usually responds to the increased oral intake of protein and vitamins, but it may only recover partially.

**To confirm that you have understood the paragraph above, please initial here:\_\_\_\_\_**

### 13. Vitamin and mineral deficiencies:

After **one anastomosis gastric bypass** there is malabsorption of many vitamins and minerals. I understand that I need to take vitamin and mineral supplements **for life** to protect myself from these problems. I also know that I need to have yearly blood tests to measure the blood levels of these vitamins and minerals. I have been given detailed written information regarding the nutritional supplements by my bariatric dietitian.

Common deficiencies that can occur after a **one anastomosis gastric bypass** include iron, vitamin D and calcium deficiency, B12, thiamine and folate deficiencies.

I know that in some cases the deficiencies can be so severe that they can lead to brain or nerve damage and the operation may have to be reversed as a result.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

### 14. Inadequate weight loss:

I recognize that the **one anastomosis gastric bypass** surgery is not by any means a perfect treatment and that one of the risks that I face is a real possibility of inadequate weight loss following this surgery. I also recognize that I may lose enough weight in the short term but may also lead to late weight regain. I understand that I need to follow the dietitian's instructions and continue my follow up commitments with the dietitian and the surgeon to minimize the chance of this happening.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

### 15. Extensive weight loss:

I clearly understand that I might suffer malnutrition and lose too much weight. I am well aware that some patient's sustain excessive weight loss after weight loss operations. I understand that excessive weight loss may require surgical revision or reversal of the **one anastomosis gastric bypass** procedure to prevent malnutrition, vitamin and mineral deficiencies or even death.

I am aware that almost up to 1% of people may lose an excessive amount of weight. As a part of this agreement I promise and agree to monitor my weight and health carefully and if excessive weight loss occurs, I will submit to early and appropriate treatment.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

### 16. Mechanical Issues:

Narrowing (stricture) of the join between the stomach and the small bowel can occur after this operation, which may require further endoscopic procedures or even surgery.

Mechanical issues associated with the stomach tube can develop in the form of segmental dilatation leading to a pouch or some narrowing that may require further surgery.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

### 17. Port site hernia (Incisional hernia):

Extremely rarely contents within the abdominal cavity can protrude through the muscle slits at the sites of access ports known as a port site incisional hernia. This can be easily corrected with surgery.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

## 18. Complication of Pregnancy:

I understand that obese pregnant women are at higher risk for an adverse peri-natal outcome. I am also aware that there are well known risks to the patient and the baby after surgery for morbid obesity. Vitamin and mineral deficiencies can put the new born babies of gastric bypass mothers at risk.

### **NO PREGNANCY SHOULD OCCUR FOR THE FIRST 12 MONTHS AFTER THE OPERATION.**

Gastric bypass has been shown to cause multiple types of vitamin and mineral deficiencies including iron, B12, folate, thiamine, vitamin D, calcium and many others. Many of these deficiencies have been shown to cause birth defects or are suspected that they could cause birth defects.

We also know that many patients who lose weight, feel that they are well after surgery and forget to take their vitamins.

I understand and take full responsibility to be certain not to miss any of my vitamins and obtain a specialist obstetric consultation if I decide to go ahead with pregnancy following surgery.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

## 19. Unplanned Pregnancy:

### ***Warning to women using oral contraceptive pills.***

Typical failure rates among pill users can be as high as 12 – 20 % according to some surveys. Other factors that have been shown to increase the risk of pill failure are smoking, diarrhoea, vomiting, drug interaction, systemic illness, psychological stress and menstrual disturbances. Therefore, it is important to recognize that birth control pills may not be an effective method of birth control after ***one anastomosis gastric bypass***. Until those factors have resolved, we have found in many cases that hormonal methods of birth control fail after ***one anastomosis gastric bypass***. Couples need to plan another form of non-hormonal birth control for the first 6 – 12 months after surgery. The Depo-Provera injection has been associated with cases of marked nausea in post ***one anastomosis gastric bypass*** patients.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

## 20. Depression:

Depression and anxiety are common medical illnesses and have been found to be particularly common after weight loss operations.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

## 21. Osteoporosis:

There is a growing appreciation that weight loss procedures may be associated with the development of osteoporosis and bone disease. Gastric surgery and weight loss in morbidly obese individuals can cause increased bone resorption and increased bone loss. Treatment and prevention includes Calcium and Vitamin D supplementation and increased activity.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

**Unexpected Outcomes:**

I know that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantee has been made about the results that may be obtained from this procedure.

I am aware that in the practice of medicine other unexpected problems, risks or complications not discussed may occur. I also understand that during the course of the proposed procedure, unforeseen conditions may be revealed requiring the performance of additional procedures, and I authorize such procedures to be performed. I further acknowledge that no guarantee or promises have been made to me concerning the results of any procedure or treatment.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

**Importance of follow- up**

I recognize that the proposed **one anastomosis gastric bypass** is a serious undertaking with known long-term risks.

To minimize this risk and to enable them to be detected at an earlier stage and enable prompt treatment, I understand the importance of regular and life-long follow up.

I promise that I will make every effort to follow Dr Werapitiya's directions to protect myself from these problems that may be associated with the gastric bypass procedure.

I also promise to return to my surgeon's clinic at 1, 3 and 6 months following surgery and every year thereafter for evaluation and further education.

To confirm that you have understood the paragraph above, please initial here: \_\_\_\_\_

**Consent to Procedure and Treatment**

Having read this form and talked to my surgeon, my signature below acknowledges that I voluntarily give my authorization and consent to the performance of one anastomosis gastric bypass (omega loop / mini gastric bypass) as described by my surgeon.

.....  
Patient signature

.....  
Date

.....  
Print Patient Name

.....  
(Witness) – Dr Senarath Werapitiya

.....  
Date