Laparoscopic Sleeve Gastrectomy

Operative Treatment Consent Agreement:

My signature and comments in this **eight 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 and the risks of obesity. I have been given a detailed description of the proposed surgery and its possible benefits and risks.

I had an opportunity to understand the surgical procedures available for weight loss including the gastric band option, the **sleeve gastrectomy** option and gastric bypass options. We had a detailed discussion regarding **sleeve gastrectomy** in particular.

I understand that this consent form is designed to provide written confirmation of these discussions with my surgeon. The effort required to complete 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 questions 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 **sleeve gastrectomy** 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 **sleeve gastrectomy** 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 the 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 healthy 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: sleeve gastrectomy

I understand the procedure that I have agreed to undergo for the treatment of obesity is the **sleeve gastrectomy**. My surgeon, with the help of the dietitian and other support staff, have

given me a detailed explanation of the **sleeve gastrectomy** procedure as well as other surgical options including the gastric band procedure, and 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 **sleeve gastrectomy** operation is primarily restrictive with some hormonally driven metabolic benefits. This operation involves reducing the stomach capacity from its normal size of 1500ml down to a cup size (250ml). This is achieved by removal of close to 70% of the stomach with a keyhole (laparoscopic) operation. I understand that this operation is not reversible.

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

Risks of the Proposed sleeve gastrectomy

Just as there may be expected benefits from the **sleeve gastrectomy** procedure in my case, I understand that all surgical procedures including the proposed **sleeve gastrectomy** procedure involve risks.

1. Bleeding:

Surgery involves incisions and cutting that can result in bleeding, from minor to massive bleeding, which may even lead to death in extremely rare circumstances. Management of bleeding after surgery may require blood transfusion and emergency surgery. Bleeding is most serious when it is within the abdominal cavity with the potential risk of delayed recovery and chance of infection in the short term.

For patients on blood thinners and or blood pressure medication - I know that blood thinners can lead to a 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: (the most feared complication)

I know that with **sleeve gastrectomy**, stapling is involved in creating the stomach tube. The staple line is meant to be water tight without any leakage of stomach content to the abdominal cavity. I understand that there is a rare risk of leaking (1 – 2%), particularly in the first three weeks after the surgery when tissue healing is incomplete. Leaking from the staple line is a serious problem. The leak may allow stomach acid, bile, bacteria and digestive enzymes to escape into the abdominal cavity causing severe tissue damage and infection (peritonitis) that may even be potentially lethal. Common symptoms of a leak are abdominal pain, nausea, fever, increased heart, increased respiration and feeling sick.

I understand that strictly following the prescribed post-operative diet is important in 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 possibly emergency surgery. I am aware that the emergency surgery usually involves placement of multiple drains and a 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 **sleeve gastrectomy** is done as a revision surgery following failure of a previous gastric band.

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 a very rare complication, but if it occurs, can 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 stockings 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 for me to feel some nausea and headache following surgery. There may also be vomiting. 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 itself. 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. I understand that this risk is higher after previous open abdominal surgery due to possible intra-abdominal adhesions (scar tissues).

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 possible 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 there is a high chance of long term Gastro Oesophageal Reflux disease (GORD) after **sleeve gastrectomy**. Patients predominantly with heart burn may need to take strong acid suppression medication to treat GORD. I am aware that in the long term about 30% of post **sleeve gastrectomy** patients are on daily anti-reflux tablets. Patients with fluid reflux and possible aspiration symptoms may also need further surgical treatment for symptom control. The tyypical anti-reflux operation (fundoplication) is not possible with the available small stomach . Although not proven there is concern that **sleeve gastrectomy** also may increase the risk of Barrett's oesophagus due to chronic reflux. Barrett's oesophagus is a pre-cancerous condition that may require regular endoscopies for monitoring.

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

9. Vitamin and mineral deficiencies:

Like after any bariatric operation, after **sleeve gastrectomy** there is high chance of vitamin and mineral deficiencies. 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 at least 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 **sleeve gastrectomy** include iron, vitamin D, calcium, 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:__________

10. 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:__________

11. Inadequate weight loss/ weight regain:

I recognize that the **sleeve gastrectomy** surgery is no 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 regain weight at a later stage. 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:___________

12. Extensive weight loss:

I clearly understand that I might suffer malnutrition and lose too much weight. I am well aware that some patients sustain excessive weight loss after weight loss operations. I understand that excessive weight loss may require intense medical management including in hospital care and intravenous or tube feeding to prevent malnutrition, vitamin and mineral deficiencies or even death.

I am aware that 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:___________

13. Mechanical Issues:

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

Most patients take a few weeks to get used to the restriction offered by the new anatomy of **sleeve gastrectomy**. Rarely, there can be significant delay in being able to progress through the stages of post-surgery diet. In rare situations endoscopic balloon dilatation of the stomach tube may become necessary. Rarely, there may be narrowing in the region of the mid part of the stomach where it turns, known as angularis. This can lead to obstructive symptoms and food intolerance. This may require corrective surgery, albeit uncommonly.

After **sleeve gastrectomy** the stomach is supposed to be a narrow tube of uniform width which is constructed with the help of a calibration tube during surgery. Over the next few years, the high pressure within the stomach tube can lead to distension, which commonly happens at the thin walled top part of the stomach tube forming a pouch. Attachments of the stomach to the diaphragm are weakened during **sleeve gastrectomy** causing a risk of the top part of the stomach tube migrating into the chest cavity (hiatus hernia). These factors can lead to problems of meal comfort and fluid reflux and regurgitation. Corrective surgery may become necessary when symptoms are troublesome.

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

14. 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 weight loss surgery for morbid obesity. Vitamin and mineral deficiencies can put the new born babies of post **sleeve gastrectomy** mothers at risk.

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

Sleeve gastrectomy 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:__________

15. Unplanned Pregnancy:

Warning to women using oral contraceptive pills.

Typical failure rates among pill users can be as high as 5.5 % 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. It is important to recognize that birth control pills may not be an effective method of birth control after **sleeve gastrectomy**. Couples need to plan another form of non-oral birth control starting from a few months before and for the first 6 – 12 months after surgery.

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

16. Dumping Syndrome:

I understand that dumping syndrome is primarily a problem after gastric bypass surgery but very rarely can occur after **sleeve gastrectomy** in some patients. Symptoms of dumping syndrome include weakness, sweating, nausea, diarrhoea, palpitation and dizziness soon after a meal. I also understand that consuming a heavy load of refined sugars/refined carbohydrates, rapid eating, and drinking while eating are all factors that may increase the risk of dumping.

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

17. Bowel Obstruction:

Any abdominal operation can lead to post-operative scarring which may lead to bowel obstruction.

I understand the chance of this is minimal with key hole (laparoscopic) surgery.

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

18. 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:__________

19. Depression:

Depression and anxiety are common medical illnesses and have been found to be particularly common after weight loss operations. It is important that you have the full support of your family. I understand the need to seek help early from my GP or notify my surgeon in the event of unusual mood changes.

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

20. 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 weight bearing 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 (eg. Repair of a hiatus hernia, release of bowel adhesions). 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 **sleeve gastrectomy** 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 **sleeve gastrectomy** procedure.

I also promise to return to my surgeon's clinic at 1, 3, 6 and 12 months following surgery and every year thereafter for evaluation and further education.

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

Operative Treatment Consent Agreement – Laparoscopic Sleeve Gastrectomy

IMPORTANT
PLEASE BRING THIS SIGNED CONSENT INTO HOSPITAL WITH YOU

Consent to Procedure and Treatment

Having read this form and talked to Dr. Werapitiya, my signature below acknowledges that I voluntarily give my authorization and consent to the performance of **sleeve gastrectomy** as described by my surgeon.

....	....
Patient signature	Date

....
Print Patient Name

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

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