

PATIENT CONSENT TO MEDICAL TREATMENT AND / OR SURGICAL PROCEDURE AND ACKNOWLEDGMENT OF RECEIPT OF MEDICAL INFORMATION

READ CAREFULLY BEFORE SIGNING

TO THE PATIENT: As you consider medical treatment / surgery, Louisiana law requires us to tell you (1) the nature of your condition, (2) the general nature of the medical treatment / surgery, (3) the risks of the proposed treatment / surgery, (4) reasonable therapeutic alternatives and material risks associated with such alternatives, and (5) risks of no treatment. You should not sign this document until you feel that all five matters have been addressed to your full satisfaction. You have the right, as a patient to be informed of your condition and the recommended surgical, medical or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved with such procedure.

In keeping with Louisiana law of informed consent, you are being asked to sign a confirmation that we have discussed all these matters. We wish to inform you as completely as possible. Please read this form carefully. Ask about anything you do not understand and we will be pleased to explain.

1. Patient Name: _____

2. Procedures: 1. LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING

2. INTRAOPERATIVE EGD Esophagogastroduodenoscopy

3. _____

**YOU ARE ASKED TO PLEASE READ THIS DOCUMENT VERY CAREFULLY!
AS YOU READ EACH PARAGRAPH, YOU ARE ENCOURAGED TO DISCUSS
ANY QUESTIONS ABOUT IT WITH YOUR SURGEON. YOU WILL BE
REQUIRED TO INITIAL NEXT TO EACH PARAGRAPH TO INDICATE YOUR
UNDERSTANDING OF ALL MATERIAL CONTAINED IN THE PARAGRAPH.**

(1) PREOPERATIVE INFORMATION AND EDUCATION:

My initials in this form are meant to demonstrate that I agree that I have been given extensive preoperative education and information about my condition of obesity, the risks of obesity and the risks and possible benefits of the Laparoscopic Gastric Banding procedure, herein after referred to as LAP BAND. I understand that this consent form is designed to provide a written confirmation of my discussions with Dr. Chung and the extensive educational process that I have participated in with regards to this procedure.

I understand that this effort is intended to make me think over my decision to have surgery once again. I confirm that my family, Dr. Chung and I have extensively reviewed the decision to proceed with this weight loss surgery. This document is written record of my efforts to be well informed about my decision to proceed with the operation. I can confirm that I wish to consent to go forward with the proposed LAP BAND procedure.

- **If you agree that everything in the above paragraph is correct, initial here**

(2) MY CONDITION / DIAGNOSIS:

I recognize that I am severely overweight. The National Institute of Health has concluded that a BMI of 40 or higher indicates morbid obesity. I understand that this level of obesity has been shown to be dangerous, unhealthy and increase my risk of death from a variety of medical illnesses. I affirm that I understand that many scientific studies conclude that persons of this level of obesity are at increased risk of disability, respiratory disease, high blood pressure, heart disease, high cholesterol, stroke, diabetes, arthritis, clotting problems, cancer and death as well as other serious and less serious medical illnesses and should be considered for surgery to help them to lose weight.

- ❖ **My preoperative weight is _____ lbs.**
- ❖ **My height is _____ foot _____ inches**
- ❖ **Thus, according to the Body Mass Index Table, my BMI is _____**

- **If you agree that everything in the above paragraph is correct, initial here**

(3) CONTROVERSY IN MEDICINE / DISAGREEMENTS OVER THE SURGICAL TREATMENT OF OBESITY

I understand that there are many different types and variations of surgical procedures being performed for weight loss in American at this time. I also know that although many studies document the value of surgery for obesity, there remain many physicians and surgeons who are opposed to the idea of the surgical treatment of obesity. I understand that there are also many NONSURGICAL alternatives to this procedure. I could have chosen medication, diet changes or exercise to attempt weight loss.

Table 1. Different Types of Weight Loss Surgery

TYPES OF WEIGHT LOSS SURGERY	
❖	Laparoscopic Gastric Bypass (Roux-en-Y)
❖	Silastic Ring Vertical Gastric Bypass
❖	Micro pouch Gastric Bypass
❖	Long Limb Gastric Bypass
❖	Biliopancreatic Diversion
❖	Biliopancreatic Diversion with Duodenal Switch
❖	Gastric Band
❖	Laparoscopic Gastric Band
❖	Laparoscopic Adjustable Gastric Band
❖	Vertical Banded Gastroplasty
❖	Laparoscopic Vertical Banded Gastroplasty
❖	Others

I know that because of the numerous problems and complications that can occur with weight loss surgery many physicians and surgeons prefer to avoid all types of weight loss surgery entirely. I realize that there are a variety of different types of weight loss surgery, some of which are shown in the table here and I have been encouraged to research each of these procedures.

I understand that it is Dr. Chung’s feeling that no one of these surgical choices is necessarily bad, but I recognize that each type of surgery has its own associated risks and complications that keep any one of them from becoming universally adopted. It demonstrates that surgery for obesity has not yet reached a “perfect” surgical solution. The number and the great variety of the different types of surgery offered for the treatment of obesity suggests that the development of the surgical treatment of obesity is not complete, that there are opportunities for enhancement of the presently available surgical options and that continued assessment of new innovations in surgical procedures is appropriate.

I know that I could have chosen any one of these other types of surgical procedures but after a slow, careful and detailed investigation, I have decided to have LAP BAND. I know that the LAP BAND is not perfect, (see risks and complications) but after reviewing all of the information I feel comfortable that my family, Dr. Chung and I agree that this procedure is the best choice for me.

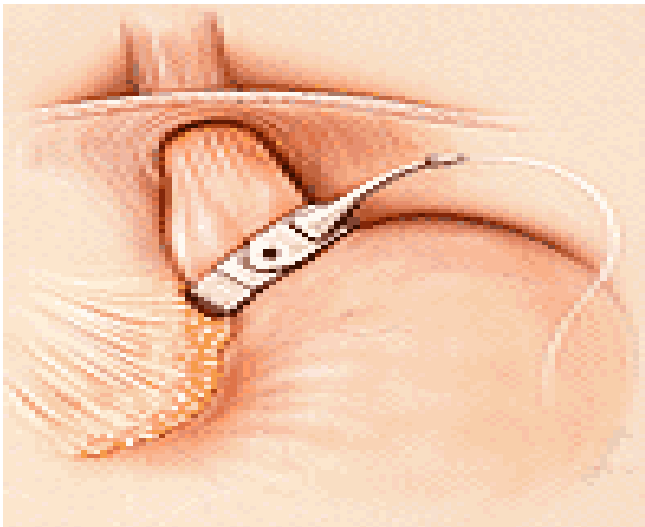
- If you agree that everything in the above paragraph is correct, initial here

(4) LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING (LAP BAND):

The LAP BAND: I understand that the procedure that Dr. Chung has recommended for the treatment of my obesity is the LAP BAND. Dr. Chung has provided me with a preoperative handbook which includes drawings and information about the procedure. He has also given a verbal description of the operation. He has encouraged me to talk with patients who have previously undergone the surgery and has strongly encouraged me to make every effort to investigate and understand the details of the operation as well as the changes that must be in my life following the operation.

Procedure in detail: LAP BAND is a purely restrictive procedure. Please refer to the following diagram to visualize the steps of the procedure:

- A Bioenterics gastric band is placed around the upper portion of the stomach near the esophagus. Several sutures are placed to help maintain the position of the band. The gastric pouch measures only about 1-2 ounces but is not separated from the remainder of the stomach.
- The band is left deflated, meaning zero saline is added to the band.
- The port for which the saline will be injected or withdrawn to adjust the band will be placed just above the rectus abdominus, one of the major abdominal muscles, just above my belly button. This port will be secured into place with four sutures to serve as an anchor. I will have a slightly larger incision above my port which is used for insertion of the port.



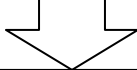
LAP BAND ANATOMY

If you agree that everything in the above paragraph is correct, initial here

(5) RISKS / BENEFITS OF PROPOSED PROCEDURE:

Just as there may be some expected benefits from the LAP BAND procedure proposed in my case, I also understand that all medical and surgical procedures, including LAP BAND involve risks. I have been told and I understand that my obesity increases my risks of these problems and complications.

**IF YOU
UNDERSTAND
AND AGREE
INITIAL HERE**



LIKELIHOOD:

C = Common

U = Uncommon

V = Very uncommon

COMPLICATION

DESCRIPTION

C	U	V			
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Allergic reactions	All kinds of allergic reactions are possible, from minor reactions such as a rash to a sudden overwhelming reaction that can cause death.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Anesthetic complications	Anesthesia used to put you to sleep for the operation can be associated with a variety of different complications up to and including death.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Bleeding	Surgery involves incisions and cutting that can result in bleeding complications, from minor to massive, that can lead to the need for emergency surgery, transfusion or death.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Blood Clots	Also called Deep Vein Thrombosis (DVT) and Pulmonary Embolus can sometimes cause death. I understand that I need to get out of bed the evening after surgery and move and flex my feet and legs to help prevent clots from forming in my legs.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Infection	Including wound infections, port site infections, bladder infections, pneumonia, skin infections and deep abdominal infections that can sometimes lead to death.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Narrowing (stricture)	Narrowing (stricture) or ulceration of the esophagus or pouch can occur after the operation which could require emergency surgery, intensive care and can sometimes lead to death. To protect your new stomach from ulcers, you must never again take aspirin, or aspirin like drugs such as Motrin, Ibuprofen, Naprox, Relafen or other similar drugs.	<input type="checkbox"/>

<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Indigestion, Acid/Bile Reflux or ulcers	The operation can sometimes lead to severe nausea, vomiting, indigestion, abdominal pain, gastritis or ulcers. This can be severe and can last for days, weeks and possibly even longer. This is especially likely if you have had previous problems with nausea, abdominal pain or ulcers. Nausea is much more common in women than men. Women who have been treated with any type of hormone therapy are much more likely to have nausea and vomiting after surgery.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Bowel obstruction	Any operation in the abdomen can leave behind scarring that can put the patient at risk for later bowel blockage or obstruction. The bowel can twist, obstruct and even perforate leading to serious complications, even death.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Laparoscopic Surgery Risks	Laparoscopic surgery uses punctures to enter the abdomen and this can lead to abdominal injury, bleeding and even death.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Side Effects of Drugs	All drugs have inherent risks and complications and in some cases can cause a wide variety of side effects, reactions and in some cases even death.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Loss of Bodily Function	The performance of surgery and anesthesia can stress the body's systems leading to a variety of complications including stroke, heart attack, limb loss and other problems related to operation and anesthesia.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Risks of Transfusion	Including Hepatitis and AIDS from the administration of blood and/or blood components. These illnesses are serious and can be fatal.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Hernia	Cuts and incisions in the abdominal wall can lead to hernias after surgery. Hernias can lead to pain, bowel blockage, obstruction and even perforation and death in some cases. Treatment of hernias usually requires another operation.	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Hair Loss	Many patients develop hair loss for a period after the operation. When this occurs, it usually starts at 3-4 months following the surgery and resolves at 7-9 months. This usually responds to increased oral intake of protein and vitamins but it may be permanent.	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vitamin and Mineral Deficiencies	After Bariatric surgery there is sometimes a lack of vitamins and minerals. Patients MUST take vitamin and mineral supplements forever to protect themselves from these problems. You also need to have yearly blood tests to measure the blood levels of these vitamins and minerals. Common deficiencies following this surgery are iron, calcium, B12 and folate.	<input type="checkbox"/>

Inadequate Weight Loss

WARNING: Remember that you might not lose weight after the operation.

There are patients that will fail any type of weight loss surgery. Inadequate weight loss is a risk of all types of weight loss surgery and all types of weight loss treatment.

I recognize that the LAP BAND is not by any means a perfect treatment and that one of the risks is a real possibility of inadequate weight loss following my LAP BAND surgery.

Excessive Weight Loss

Some patients sustain excessive weight loss after the operation and may require reversal of the bypass to prevent severe malnutrition, nausea, or vitamin and mineral deficiencies or death.

Complications of Pregnancy

Vitamin and mineral deficiencies can put the newborn babies of LAP BAND mothers at risk. Pregnancy should be discussed with both your OB/Gyn as well as your surgeon. To prevent malnutrition, inability to take in enough nutrition to properly support your baby or excessive nausea and vomiting, it is typically recommended that all saline be withdrawn from your band during pregnancy. The saline can be reinserted at a date after delivery.

Gallstones

Reducing the amount of food intake can reduce the amount of bile secreted by the gallbladder. This can lead to accumulation of bile in the gallbladder, which can cause formation of gallstones. Gallstones can become painful and require surgery to remove the gallbladder. This can also lead to inflammation of the liver and /or pancreas.

Depression

Depression and anxiety are common medical illnesses and have been found to be particularly common after operation.

Cancer

Cancer can occur in anyone. Many cancers are more common in obese as compared to thin patients. Overweight men have a significantly higher rate of prostate cancer. Obese women have higher risks of developing breast cancer and cancer of the uterus and ovaries. It is expected, but not certain, that with weight loss you will have an overall decrease in your risk of cancer.

Loose skin

It is common for persons who experience extensive weight loss to have loose skin in areas which were previously much larger. For cosmetic reasons, you may desire to have additional procedures to remove the excess skin.

Breathing difficulty

Occasionally following surgery, patients can develop pneumonia or other breathing problems requiring prolonged need for ventilator. Your pulmonary status will be evaluated prior to surgery, however, breathing complications can effect you. Patients are strongly encouraged to stop smoking at least one month prior to the procedure.

Diarrhea or excessive flatulence

Patients can experience diarrhea or excessive gas due to rapid transit of food to the colon. This condition may simply last during the adjustment period or can be permanent.

Band displacement (PROLAPSE)

Despite all efforts to secure the band in the proper with regards to the stomach and esophagus, it is possible for the band to become dislodged and shift positions. When the band shifts, it is possible for the stomach to become prolapsed over the band, causing food to become trapped in this area. If you would like more information on band prolapse, including a diagram, please ask Dr. Chung now.

Band erosion

The Lap is made of a material that is not naturally found in the body. Thus, it is a foreign object. I realize that any time a foreign object is inserted into the body, it is the body's natural defense to try to reject the object. I understand that when this happens, the band could possible erode through the tissue of my stomach, requiring removal of the band and repair of the damaged tissue. Damage caused by erosion could be permanent and can lead to death.

Port site infection

As with the band, the port is also a foreign object being inserted into my body and has the chance of being by my body or becoming infected, requiring removal of the port. If my port becomes infected and required removal, the port must be replaced at a later date and will be my financial responsibility.

Need for removal of band

For multiple reasons as listed above, complications from the band may require removal of my band. It is my It is understood that the band is a foreign object and dependent upon how my body reacts to this object, the band may or may not be well tolerated.

Death

This is a major and serious operation. It may lead to death from complications. While uncommon, you must be aware that death can occur following this procedure, just as any procedure.

(6) PATIENT RESPONSIBILITY:

I recognize that an operation upon my stomach and upper digestive tract is a serious undertaking with known long term risks that Dr. Chung has described to me. I am committed to fulfilling Dr. Chung's instructions for long term follow-up. I promise I will make every effort to follow his directions to protect myself from these and other problems associated with the bypass. I will follow the advice of my surgeon as well as the various team members of the Obesity Surgery Center. This is to include lifestyle changes as educated, diet changes as educated, daily vitamins, postoperative follow-up as directed and all testing as ordered.

I will not leave the Lake Charles area following surgery until I have been approved by Dr. Chung for discharge from the area.

I will return to my follow-up appointments for further evaluation and education. In extraordinary circumstances in which I cannot reach Dr. Chung or Obesity Surgery Center for my follow-up, I will make certain that I seek a qualified doctor to resume my care. I understand that it is my sole responsibility to ensure the continued success of this procedure.

- **If you agree that everything in the above paragraph is correct, initial here**

(7) 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 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 guarantees or promises have been made to me concerning the results of this or any procedure.

- **If you agree that everything in the above paragraph is correct, initial here**

(8) ACKNOWLEDGMENTS:

The available alternatives to the LAP BAND, including Laparoscopic Gastric Bypass, diet and exercise or drug treatments, have been explained and discussed in detail with me. The potential benefits and risks of the proposed LAP BAND have been discussed with me in detail. I understand what has been discussed with me as well as the contents of this consent form, and I have been given the opportunity to ask questions and received satisfactory answers.

- **If you agree that everything in the above paragraph is correct, initial here**

(9) AUTHORIZATION FOR RELEASE OF MEDICAL INFORMATION:

I hereby confirm that I freely approve of the release of my medical information for the purposes of education and advocacy of the rights of obese patients and I have not in any way been coerced into this authorization. I recognize that I can refuse to approve of the use of my personal medical information with no negative impact upon my care or treatment by Dr. Chung or his staff. I have had the opportunity to consider whether or not to approve the use of my personal information. I hereby authorize Dr. Chung and his staff to use any portions or parts of my medical records and information pertaining to medical history, physical condition, services rendered or treatment given for the purposes of education of future patients.

_____ My name and photographs may be used for education and clinical data.

_____ I wish for my name and photographs to be withheld from public knowledge.

- **If you agree that everything in the above paragraph is correct, initial here**

(10) CONSENT TO PROCEDURE AND TREATMENT:

Having read this form, talked with Dr. Chung and feeling confident that I have received adequate preoperative education, my signature below acknowledges that:

I voluntarily give my authorization and consent to the performance of LAP BAND as described above, administration of blood and/or blood components if needed and any procedures necessary during the operation.

I understand that at this or any point prior to surgery, I can decide against this or any procedure and I will have my decision fully supported by Dr. Chung and staff. I understand that my best interest is the priority and I make this decision freely.

PATIENT SIGNATURE

DATE

WITNESS

DATE

KEITH CHUNG, M.D.

DATE

PATIENT NAME: _____

PROCEDURE: **INTRAOPERATIVE ESOPHAGOGASTRODUODENOSCOPY**

**During your procedure, a lighted scope will be passed through your mouth down into your newly formed pouch.

MATERIAL RISKS OF PROCEDURE:

Common Uncommon Very Uncommon

- 1. Infection.
- 2. Bleeding which may require transfusion and/or surgery.
- 3. Perforation of esophageal wall which may require surgery.
- 4. Cardiac arrhythmias (irregular heartbeat).

<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

PHYSICIAN – KEITH CHUNG, M.D.

PATIENT

WITNESS

DATE OF CONSENT

**AMERICAN SOCIETY OF
ANESTHESIOLOGIST CLASSIFICATIONS**

- Class I – Normal healthy patient
- Class II – A patient with a mild systemic disease
- Class III – A patient with a severe systemic disease which limits activity but not incapacitating.
- Class IV – A patient with incapacitating systemic disease which is a constant threat to life.
- Class V – A moribund patient, not expected to survive 24 hours with or without procedure.