



## INFORMED CONSENT FOR LAPAROSCOPIC GASTRIC BYPASS SURGICAL PROCEDURE



PRIVATE  
**Anadolu  
Hospital**

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HD.RB.IN.07.03	22.03.2022	-	00
Reason for revision:			

Patient Information			
Name and Surname		Protocol Number	Department
Birth Date		Physician Signature	

### Dear Patient, Dear Patient's Parent

Please read the form carefully and answer the questions!

Your physician will inform you about the course of this treatment, its various forms and risks before the treatment, and at the end of this, you will be able to decide whether or not to perform the treatment with your free will. This form has been prepared to help you prepare for your interview with your doctor.

You should be involved in any and all decisions concerning surgical procedures your doctor has recommended. Sign this form only after you understand the procedure, the anticipated benefits, the risks, the alternatives, the risks associated with the alternatives and all of your questions have been answered.

I, \_\_\_\_\_, hereby authorize Dr. \_\_\_\_\_ and any associates or assistants the doctor deems appropriate, to perform Laparoscopic Gastric Bypass surgery.

The doctor has explained to me the risks of obesity and the benefits of a Laparoscopic Gastric Bypass; however, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the procedure. I also authorize the administration of sedation and/or anesthesia as may be deemed advisable or necessary for my comfort, wellbeing and safety.

**Condition.** I recognize that I am severely overweight with a weight of \_\_\_\_\_ lbs. at \_\_\_\_\_ ft. \_\_\_\_\_ inches tall, and a BMI of \_\_\_\_\_. My surgeon or surgeons have clearly explained to me that this level of obesity has been shown to be unhealthy and that many scientific studies show that persons of this level of obesity are at increased risks of 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.

**Commitment.** I am committed to long-term follow-up with my surgeon or surgeons and to make every effort to follow his/her directions to protect myself from these and other problems associated with Gastric Bypass. I understand that to be effective, I need to make a life-long commitment to lifestyle changes, which may include, but are not limited to, dietary changes, an exercise program, and counseling. I understand that I will need to maintain proper nutrition, eat a balanced diet, and take vitamin and mineral supplements for the rest of my life. I will also be required to maintain follow-up medical care for my lifetime. Laboratory work will be required at least annually and perhaps more often, as directed by a physician.

**Pre-operative Requirements.** I have completed the Physician-Supervised Multidisciplinary Program, which included Dietary Therapy - a discussion of dietary history and a nutritional visit by either (a physician, dietitian or nutritional counselor) as well as a physician-supervised dietary therapy which included low calorie intake for 3 months or very low calorie intake within 6 months of the scheduled surgery, Physical Activity, and Behavior Therapy/Support. Since the time of my initial evaluation to the date of surgery, I have either maintained my weight or have not gained greater than 5 pounds.

**Post-operative Requirements.** I agree to participate in a post-surgical multidisciplinary program that includes diet, physical activity, and behavior modification.

**Proposed Procedure.** I understand that the procedure that my surgeon or surgeons have recommended for the treatment of my obesity is the Laparoscopic Gastric Bypass. My surgeon or surgeons have provided a detailed explanation of the medical history of the development of the surgical treatment of obesity, the gastric bypass as a treatment of obesity, the development of laparoscopic (minimally invasive) surgery and the Gastric Bypass. I have been strongly encouraged to make every effort to investigate and understand the details of the operation.

I understand the nature of the Bypass will be done laparoscopically and entails the use of a fiberoptic endoscope along with special endoscopic instruments and staplers to facilitate completing the procedure with smaller incisions than in an open approach. It has been further explained to me that the laparoscopic approach to Gastric Bypass surgery to treat morbid obesity is effective in achieving weight loss and in improving comorbidities and quality of life while reducing recovery time and perioperative complications.

The laparoscopic gastric bypass procedure involves making several small incisions through which the surgeon(s) insert



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laparoscopic instruments to perform the surgery. The procedure is designed to make a small reservoir ("pouch") for food at the upper end of the stomach with a capacity of about 2 oz. This pouch is connected to the upper small intestine by a new small anastomosis (outlet) of about ½ inch (1.2 cm) in diameter. The ingested food thereby bypasses the majority of the stomach, which remains alive and undisturbed, but functional otherwise. In other words, the majority of the stomach does not have food passing through. The nature and purpose of this operation is to functionally limit the amount of food or liquid intake at any given time. There may be a small component of malabsorption, at least initially. This procedure is often associated with fairly rapid weight loss initially, which stabilizes over time. With this limited intake, if you eat too much at one meal, you may feel discomfort and may even vomit until you learn the capacity of your "new" stomach.

**Risks/Possible Complications.** The doctor has explained to me that there are risks and possible undesirable consequences associated with a Laparoscopic Gastric Bypass including, **but not limited to:**

1. Abscess
2. Adult Respiratory Distress Syndrome (ARDS)
3. Allergic reactions
4. Anesthetic complications
5. Atelectasis
6. Bleeding, blood transfusion, and associated risks
7. Blood clots, including pulmonary embolus (blood clots migrating to the heart and lungs) and deep vein thrombosis (blood clots in the legs and/or arms)
8. Bile leak
9. Bowel obstruction
10. Cardiac rhythm disturbances
11. Complications in subsequent pregnancy (no pregnancy should occur within the first year after surgery)
12. Congestive heart failure
13. Dehiscence or evisceration
14. Depression
15. Dumping syndrome
16. Death.
17. Encephalopathy
18. Esophageal, pouch or small bowel motility disorders
19. Gout
20. Hernias, incisional (including the port sites for laparoscopic access) and internal
21. Inadequate or excessive weight loss
22. Infections at the surgical site, either superficial or deep including port sites for laparoscopic access. These could lead to wound breakdowns and hernia formation.
23. Injury to the bowels, blood vessels, bile duct, and other organs
24. Injury to adjacent structures, including the spleen, liver, diaphragm, pancreas and colon
25. Intestinal leak
26. Kidney failure
27. Kidney stones
28. Loss of bodily function (including from stroke, heart attack, or limb loss)
29. Myocardial infarction (heart attack)
30. Narrowing of the connection between the stomach and small bowel
31. Need for and side effects of drugs
32. Organ failure
33. Perforations (leaks) of the stomach or intestine causing peritonitis, subphrenic abscess or enteroenteric or enterocutaneous fistulas
34. Pleural effusions (fluid around the lungs)
35. Pneumonia
36. Possible removal of the spleen
37. Pressure sores
38. Pulmonary edema (fluid in the lungs)



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39. Serious intra-abdominal infection such as sepsis or peritonitis

40. Skin breakdown

41. Small bowel obstructions

42. Staple line disruption

43. Stoma stenosis

44. Stroke

45. Systemic Inflammatory Response Syndrome (SIRS)

46. Ulcer formation (marginal ulcer or in the distal stomach)

47. Urinary tract infections

48. Wound infection

**a. Nutritional complications include but are not limited to:**

1. Protein malnutrition

2. Vitamin deficiencies, including B12, B1, B6, folate and fat soluble vitamins A, D, E, K

3. Mineral deficiencies, including calcium, magnesium, iron, zinc, copper, and other

4. Uncorrected deficiencies can lead to anemia, neuro-psychiatric disorders and nerve damage, that is, neuropathy

**b. Psychiatric complications include but are not limited to:**

1. Depression

2. Bulimia

3. Anorexia

4. Dysfunctional social problem

**c. Other complications include but are not limited to:**

1. Adverse outcomes may be precipitated by smoking

2. Constipation

3. Diarrhea

4. Bloating

5. Cramping

6. Development of gallstones

7. Intolerance of refined or simple sugars, dumping with nausea, sweating and weakness

8. Low blood sugar, especially with improper eating habits

9. Vomiting, inability to eat certain foods, especially with improper eating habits or poor dentition

10. Loose skin

11. Intertriginous dermatitis due to loose skin

12. Malodorous gas, especially with improper food habits

13. Hair loss (alopecia)

14. Anemia

15. Bone disease

16. Stretching of the pouch or stoma

17. Low blood pressure

18. Cold intolerance

19. Fatty liver disease or non-alcoholic liver disease (NALF)

20. Progression of pre-existing NALF or cirrhosis

21. Vitamin deficiencies some of which may already exist before surgery

22. Diminished alcohol tolerance

**d. Pregnancy complications were explained as follows:**

1. Pregnancy should be deferred for 12 to 18 months after surgery or until the weight loss is stabilized

2. Vitamin supplementation during the pregnancy should be continued

3. Extra folic acid should be taken for planned pregnancies

4. Obese mothers have children with a higher incidence of neural tube defects and congenital heart defects

5. Pregnancy should be discussed with an obstetrician



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6. Special nutritional needs may be indicated or necessary
7. Secure forms of birth control should be used in the first year after surgery
8. Fertility may improve with weight loss

Further, any of these risks or complications may require further surgical intervention during or after the procedure, which I expressly authorize.

I also understand that some or all of the complications listed on this form and also explained to me may exist whether the surgery is performed or not, in that gastric bypass surgery is not the only cause of these complications.

**Alternative Procedures.** In permitting my doctor to perform this procedure, I understand that unforeseen conditions may necessitate change or extension of the original procedure(s), including completing the operation by way of the conventional open surgical approach, or a different procedure from what was explained to me. I therefore authorize and request that the above-named physician, his assistants or designees to perform such procedure(s) as may be necessary and desirable in the exercise of his/her professional judgment.

In the unlikely event that one or more of the above complications may occur, my physician(s) will take appropriate and reasonable steps to help manage the clinical situation and be available to me and my family to address our concerns and questions.

The reasonable alternative(s) to the procedure(s), as well as the risks to the alternatives, have been explained to me. These alternatives include, **but are not limited to**, open gastric bypass, vertical banded gastroplasty, various diet exercise and drug treatments, or no surgery at all.

Physician's Notes	
Physician's Stamp-Signature-Date-Time	

### Consent Statement of the Patient or patient's parents

- I informed by the doctor with necessary explanations. I understood the issues I need to pay attention to before and after the treatment.
- I got detailed information about what the planned treatment is, its necessity and other treatment options, their risks, the consequences that may arise in the absence of treatment, the probability of success and side effects of the treatment.
- It was explained that during the treatment, all documents and samples related to me can be used for educational purposes.
- My doctor answered all the questions in a way that I can understand, I got information about the people who will make the treatment.
- I know the meaning of the informed consent form.
- I know that I do not have to consent to the treatment if I do not want to, or I know that I can stop the procedure at any stage.

**Please with your handwriting, write 'I have read, understood and accept this 5-pages form. 'and sign.**

The patient or patient's parent / relative (degree )				
Name and Surname	Sign	Place	Date	Hour

**NOTE: If the patient is unable to give consent, the identity information and signature of the person whose consent is obtained is taken.**



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- Both parents of the patient must sign. If only one of the parents has the signature, the signer must prove that patient is taking care of the child himself or has the other guardian's consent.
- Unless I have a written request for removal, for the same repeated procedures, for example dialysis, blood transfusion, waist fluid removal, in other cases where a series of medical or surgical treatment will be applied in the same way during the hospitalization, etc. this consent will be valid.

❖ **The person providing communication in cases where direct communication with the patient cannot be established,**

I explained the information in the 'Informed Consent Form' to the patient, patient's parents or relatives as best I could.

Name and Surname	Adress	Date	Sign

<b>Prepared By</b>	<b>Controlled By</b>	<b>Approved By</b>
<b>General Surgeon</b>	<b>Quality Director</b>	<b>General Director</b>