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Version 03/17

Consent Form for

Bariatric weight-losing surgery

Morbid obesity is a risk factor for the development of diseases such as diabetes, hypertension, sleep apnea, excess lipids in the blood, heart diseases, and it impairs both quality of life and life expectancy.

The purpose of bariatric surgery is to allow a significant reduction in weight for obese patients who have not been able to reduce their weight by conservative means such as diets, sports or medication. In these surgeries, the volume of the stomach is reduced to induce a feeling of satiety after eating a small amount of food; Such volume reduction is done by narrowing the stomach with a ring, or by removing part of it by through gastric sleeve surgery, or by reducing it and creating a bypassing food route that allows it to pass directly to the small intestine through gastric bypass surgery.

The removal of a part of the stomach, or its bypass reduces the secretion of the hunger hormone (ghrelin) from the stomach, at the same time with an increase in the secretion of various satiety hormones from the small intestine, thus creating an early feeling of satiety. In gastric bypass surgery, the direct passage of food from the stomach to a more distant part of the small intestine also creates an element of sub-absorption of some of the food being consumed. After surgery, a long term follow up by a multidisciplinary team that includes a surgeon, a dietitian and a psychologist or a social worker, should be maintained to obtain support, appropriate diet directions, including essential vitamin supplements and guidance for a healthy lifestyle, including physical exercise.

The main types of surgery currently available for treating morbid obesity are:

1. **Surgery for narrowing the stomach with a ring.**
2. **Gastric sleeve surgery.**
3. **Gastric bypass surgery with two anastomoses.**
4. **Gastric bypass surgery with one anastomosis.**
5. **Duodenal bypass surgery with two anastomoses.**
6. **Duodenal bypass surgery with one anastomosis.**
7. **Biliopancreatic Diversion surgery.**

All types of surgery are performed using a closed, minimally invasive (for laparoscopy) procedure, or an open procedure via a midline incision of the abdominal wall, at the discretion of the surgeon. In any case, the operation is performed under general anesthesia.

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After the operation, a ventral lumen, nasal tube in the nose to drain the stomach, and a catheter to drain the bladder may remain for several days. Within 1-2 days after the surgery the patient should start drinking, as per the surgeon's instructions. Then he should proceed with liquid, porridge, soft and normal diet, as per the dietician's instructions.

Other operations may be necessary during the primary surgery, such as: diaphragmatic hernia repair, cholecystectomy, abdominal hernia repair, removal of a previous ring. If necessary, consent to these additional operations shall be signed on a separate form, designated for these operations.

Name of patient:

Last name	First Name	ID.	Father's Name

I hereby declare and confirm that I received a detailed oral explanation from Dr.:

Last name	First Name

regarding the need for the surgery:

hereinafter: the "Primary surgery" and other operations:

I hereby declare that I have been informed of the common side effects after this surgery, including: nausea, pain, heartburn, or vomiting, which are expected to disappear within a few days.

In addition, I've been explained about possible complications and risks, including: bleeding, infection, thrombosis of the limbs, pulmonary embolism, leakage from the stomach, the esophagus or the intestine, and rarely also spleen damage, which will require its removal. I have also been informed of possible complications that can occur weeks, months, or even years after the primary surgery, such as stenosis of the gastric sleeve, stenosis of the anastomosis in bypass surgery, intestinal obstruction, excessive septic sub-absorption, rupture of the surgical scar, slipping of the ring or its penetration into the stomach, pipe disconnection or damage, or infection of the subcutaneous reservoir. It was explained to me and I understood that these complications could lead to additional surgeries for their repair or additional hospitalization.

I understood that in very rare cases, the primary surgery may cause death.

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It was explained to me and I understood that the patient's cooperation and strict adherence to the instructions of the treating staff, as well as to the necessary changes in his/her eating habits, are precondition for the success of the surgery and the maintenance of optimal weight.

It was explained to me and I understood that even in the case of a successful operation, there may not be sufficient weight loss, due to the lack of adjustment to the surgery, lack of change in eating and lifestyle habits, and excessive consumption of calories.

It has been explained to me that a minor invasive surgery (laparoscopic) may become an open surgery, as per the surgeon's discretion.

I hereby declare and confirm that I have been given an explanation and that I understand that it is possible that during the course of the operation it will become necessary to expand its scope, change or take other or additional procedures to save lives and prevent bodily harm. Therefore, I also agree to the extension, modification or performance of other or additional procedures, including additional surgical procedures which, in the opinion of the hospital physicians, will be necessary or vital during the operation.

It was explained to me that the operation is performed under general anesthesia and that explanations regarding such anesthesia will be provided to me by an anesthesiologist.

I acknowledge that if the medical center has a university branch, students mat take part in the evaluation and treatment process, under full supervision.

I acknowledge and agree that the primary surgery and all the main procedures will be performed by the person whom this will be assigned to as per the procedures and instructions of the Medical Center, and that I have not been promised that these will be performed, in whole or in part, by a certain specific person.

I hereby give my consent to perform the primary surgery:

Date	Time	Patient's signature

Name of guardian (Relatedness to patient)	Guardian's signature (in the case of incompetent minor or mentally ill)

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I hereby confirm that I have orally explained to the **patient/guardian/Patient's translator** all of the above in the required detailing and that he/she signed a consent before me after I was convinced that he/she fully understands my explanations.

Physician's name (Stamp)	Physician's signature	Date and time

Translator's name	His relatedness to the patient

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Appendix A - Consent Form for

Bariatric weight-losing surgery

Information for the patient prior to signing an informed consent to perform bariatric surgery Complications in gastric surgery

Although the surgery is considered relatively safe, the surgery is a large and complex surgery and complications and side effects are possible, which must be known before signing a consent to surgery. It is important to know that the laparoscopic approach does not reduce the likelihood of complications but does reduce pain, discomfort, scars and recovery time after surgery.

The surgeon will discuss with you the possible complications and side effects prior to your informed consent to surgery. There may be additional side effects that cannot be foreseen. Make sure that all the questions were answered before signing an informed consent form for bariatric surgery.

Risks associated with general anesthesia:

- The risk of complications associated with general anesthesia is higher in obese patients.
- Insertion of a respirator tube into the mouth is called intubation in English. Especially in the case of people who are overweight, the anesthetists might have difficulty in performing this task. This difficulty causes a decrease in the amount of oxygen in the body, which can cause damage to the brain or heart. To reduce this risk, the intubation process may be performed under local anesthesia, while you are awake. After this operation, and before the surgery begins, the anesthesiologist will anesthetize you.
- During intubation you may vomit and cause stomach contents to reach the lungs. This complication is called aspiration and can cause pneumonia. Pneumonia is a life-threatening complication. It is very important that you do not drink or eat starting from midnight before the surgery. You can take a sip of water while taking medication on the day of surgery.
- Most people have symptoms of sore throat and dry throat for 3-5 days after surgery.
- The intubation process can cause partial fracture, displacement or teeth loosening. It is important to discuss this issue with the anesthesiologist and let him know about any problems with your teeth. Braces or dentures must be removed before surgery.

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- There is a risk of a stroke or a heart attack, especially in older patients with a history of heart problems.

- There is a risk of nerve damage in the hands and feet that will cause problems in sensation and even in the movement of the limbs. This phenomenon is related to the position on the operating table and is almost always temporary. We are working hard to prevent such complications.

Short-term complications after surgery

- **Leaker, abscess, and infection**: Leaker is a hole in the anastomosis, stomach or intestine. In such situation, non-sterile content from the stomach leaks into the abdominal cavity and causes infection. The contents of the intestine contain bacteria and can cause major infection that can cause edema, increased heart rate and sometimes the formation of an abscess. This is a major complication that may require prolonged hospitalization. Without treatment, this complication involves severe morbidity and even mortality. Gastric leaker is one of the most severe complications, the risk rate of leaker complications is 1% -2% in gastric bypass surgery and up to 5% after gastric sleeve surgery.

- **Bleeding and/or damage to internal organs**: Another dangerous early complication is bleeding, which results from damage to the blood vessels, liver, spleen, or stomach or intestine cutting. The incidence of hemorrhages among patients ranges between 0.5% and 5% - a fairly large range of differentiation, which depends, inter alia, on the surgeon's skills and the means used by the surgeon. The risk rate of surgical bleeding is 1% -2%. In most cases, there is no need for treatment but only for monitoring the bleeding. In some patients, bleeding causes a blood pressure drop and rapid pulse, which requires blood transfusions. In a few cases, a second surgery is needed to locate and treat the source of the bleeding.

- **Pneumonia**: Infection in one or both lungs after surgery. The recommended treatment to avoid pneumonia is deep breathing, coughing and phlegm, as well as early mobilization starting from the return to the ward after surgery.

- **Blood clots**: During and after surgery, blood flow is slower due to the prolonged lying in bed and the decreased mobility, which might lead to the formation of blood clots. Blood clots may block blood vessels and prevent blood from reaching all parts of the body. Blood clots can also break down partially and flow through the blood vessels toward the lungs. This is called pulmonary embolism. This is a condition in which a blood clot is sent to the lungs, usually through one of the veins in the legs. The clot obstructs the blood flow in the pulmonary blood vessels. Prevention of this complication involves using elastic socks before and after the surgery, early mobilization of the patient after surgery and blood thinning medication.

- **Intestinal obstruction**: A scar may develop in the abdominal cavity after the surgery. These scars are called adhesions. Most bowel obstructions occurs several days after

surgery. At this stage the adhesions are soft and separate and dissolve on their own. Sometimes intestinal obstruction may occur several years after surgery due to these adhesions. This phenomenon occurs due to torsion or intestinal dislocation. Emergency surgery is necessary to solve this problem. Early detection is necessary in order to prevent damage to the blood supply to the intestines and to gangrene in this area.

- **Gastric outlet blockage**: During a gastric bypass surgery, the stomach is connected to the small intestine. After surgery, edema/swelling develops around the anastomosis area. Edema causes difficulty in swallowing fluids and saliva. Usually this phenomenon disappears after a few days. The healing process can cause scarring. The scar causes the tissue to shrink. This process further reduces the diameter of the opening and makes it harder for food to pass through. Blockage of the stomach outlet can also cause vomiting. This opening can be expanded with a special balloon inserted through the mouth. This complication appears in less than 0.5% of the cases. The risk rate of narrowing and/or adhesions of the gastric esophagus and/or the small intestine is 3% -5%.

- **Death**: The risk rate of death after bariatric surgery is less than 0.3%.

Side Effects After Surgery:

- **Nausea and vomiting**: 30-60% of patients after bariatric surgery will experience vomiting. Most vomiting reports occur during the first months after surgery, during which the patients adjust to the new eating habits, yet vomiting may persist even after several years since the surgery. Vomiting after bariatric surgery can occur due to medical causes, which requires finding out the cause using endoscopy (insertion of a tube containing an optical fiber) and/or gastrointestinal imaging. However, vomiting often occurs due to improper eating, such as when consuming too much food, poor chewing, fast eating, lack of food/beverage separation, or too much time between meals. In a ring surgery, one of the most common causes of this complication is an over-tightening of the ring across the stomach. Excessive vomiting following ring surgery were found to be one of the main reasons for the development of serious complications, including inflammation of the stomach and esophagus, or the ring slippage. In sleeve surgery and gastric bypass surgery vomiting may be caused due to constipation or gastrointestinal sclerosis. Vomiting can lead to loss of fluids and salts, which in turn can lead to dehydration and other health risks. Furthermore, frequent vomiting can lead to a sharp drop in vitamin B1 (thiamine) contents in the blood, a condition that may entail the risk of neurological disorders, and therefore in case of frequent vomiting, a supplement of this vitamin should be administrated orally or intravenously. In addition, chronic vomiting can damage various parts of the digestive tract, including the teeth, as a result of acid rising from the stomach upward.

- **Diarrhea and/or constipation**: Diarrhea or fluid feces are potential side effects, especially after duodenal bypass surgery. The average patient after a duodenal

bypass has 2-3 soft defecations per day, but in some cases patients experience more than 10, and sometimes even up to 20, defecations a day. Diarrhea may also occur after mini gastric bypass surgeries and a gastric bypass but is less common after sleeve and ring surgeries. It should be noted that diarrhea may occur in the first few weeks after bariatric surgery, in which the diet is based on liquid foods only, and in most cases also include liquid milk products. Constipation usually occurs after ring, sleeve or gastric bypass surgery, and less after duodenal bypass. The causes for constipation after bariatric surgery are low fluid and food intake, low fiber intake, and physical gastrointestinal changes due to surgery. In case of significant constipation or diarrhea, consult your surgeon or dietitian for advice on appropriate treatment.

- **Dehydration or loss of body fluids**: Dehydration is a common and dangerous complication after bariatric surgery. It was found that about one-third of the referrals to emergency rooms after surgery are attributed to this reason. The risk of dehydration increases especially when there is insufficient fluid intake or post-surgery vomiting. The risk rate of dehydration after surgery is about 5%.

- **Dumping Syndrome**: Gastrointestinal dumping syndrome occurs in 40% -76% of patients after gastric bypass surgery, and may occur at much lower rates even after a sleeve surgery. High consumption of sugars can lead to a "Dumping syndrome", manifested by sweating, palpitations and paleness as a result of the rapid passage of food from the stomach to the intestines, and a decrease in blood sugar levels. Therefore, it is important to reduce the intake of sugars after surgery.

- **Post-meal hypoglycaemia**: This complication, characterized by low blood sugar levels that occur about two hours after a meal, is most common among gastric bypass surgery patients. The symptoms result from hypoglycemia in the brain cells, which leads to confusion, loss of consciousness and seizures that can develop months or even years after surgery. The cause of the disorder appears to be excessive insulin secretion in response to the meal. Increased insulin sensitivity after gastric bypass surgery is well documented in the literature, but the cause of hypoglycemia in some patients is not yet clear.

- **Gallstones**: Gallstones are actually chunks of cholesterol and other substances that are formed in the gall bladder. Gallstones are common among bariatric surgery patients and more than a third of them develop them within a few months after the surgery. A rapid and significant reduction in weight was found to increase the risk of developing gallstones. This occurs not only following bariatric surgery but also after an acute diet. In a large number of cases gallstones can cause nausea, vomiting, hepatitis and abdominal pain. 15% -25% of those undergoing weight-loss surgery need surgery to remove the gallbladder.

- **Kidney stones**. The phenomenon of kidney stone formation was found to be characteristic of gastric bypass surgery specifically. Studies show that in patients

undergoing these surgeries there is an increased level in urine levels of a substance called oxalate, which crystallizes over time and forms kidney stones. The risk of developing increased oxalate level in urine among patients undergoing gastric bypass surgery is well documented in studies indicating that this problem, known as hyperoxaluria, puts bariatric surgery patients not only at risk for developing kidney stones but also for a kidney failure.

- Sub-absorption and lack of minerals and vitamins: The appearance of nutritional deficiencies after bariatric surgery is a common phenomenon that results from various factors, and which depends on the type of surgery and its effect on the absorption and digestion process, pre-surgery condition, the appearance of vomiting, intolerance to various foods and poor eating habits. These deficiencies are extensive and particularly significant in gastric bypass and duodenal bypass surgery, which rely on reducing absorption, but also occur in ring and sleeve surgery, which rely on reducing the stomach size. For these reasons, regular taking of vitamin and mineral supplements throughout one's entire life in all types of bariatric surgery is essential for maintaining the health and functioning of the body, and for preventing nutritional deficiencies that can lead to various complications including anemia, decreased bone mass density and various neurological disorders. Blood tests that include vitamin and mineral tests should be performed once every three months during the first year, once every six months during the second year and then once a year. When the recommendation is lifetime monitoring.

- **Osteoporosis and bone loss**: Bariatric surgery patients are at risk for fracture and osteoporosis due to rapid weight loss and post-surgery absorption changes. Therefore, after bariatric surgery, calcium and vitamin D supplements should be taken regularly.

- **Food intolerance**: Low tolerance to food may occur mainly in the short term after bariatric surgery, and it tends to improve over time. However, in some cases, the phenomenon of intolerance becomes chronic. In these cases, avoidance of certain foods may develop, and there may be an adjustment to inappropriate eating habits, which increases the risk of nutritional deficiencies, insufficient weight loss and difficulty in maintaining long-term weight loss.

- **Post-surgery weight gain**: regaining all or part of the weight that was lost appears among approximately 30% of bariatric surgery patients, and usually occurs within two years after surgery. In general, surgeries that involve a sub-absorption mechanism (gastric bypasses and duodenal bypass) are less associated with weight gain than surgeries that restrict only the volume of the consumed food (ring and sleeve). The main reasons for weight regain after surgery result from lack of adherence to dietary and lifestyle rules, including insufficient physical activity, and failing to visit the follow-up clinic regularly.

- **Heartburn, reflux (gastroesophageal reflux)**: Heartburn is a common symptom, especially after ring or sleeve surgery, in which acid in the stomach rises to the

esophagus and causes a sensation of "burn" or pain in the mid chest or at the base of the neck. The main cause of reflux is impairment in the function of the sphincter located between the esophagus and the stomach. Less frequent complaints may include food-return to the mouth, difficulty in swallowing, chronic cough or wheezing. There are four types of treatments for reflux, which include behavioral therapy, medication, endoscopic therapy, and surgical treatment.

- **Abdominal pain, ulcers and bleeding**: Could develop after surgery. Gastrointestinal bleeding due to ulcers in the stomach and duodenum might occur after surgery. The risk of bleeding is 5% to 10%.

- **Hair loss**: Hair loss occurs due to the great stress experienced by the body under surgery and the massive weight loss during the first few months. The typical type of hair loss among surgery patients is even thinning of the hair across the scalp, without creating areas of baldness, resulting from a disruption to normal hair growth. Usually, this condition balances after about 6-12 months. In the case of hair loss that starts six months after the surgery or which lasts over a year, the causes may also be nutritional deficiencies, continued weight loss, and essential eating problems (such as vomiting). Balanced nutrition that includes sufficient consumption of protein and recommended food additives could moderate this phenomenon.

- **Emotional changes**: Some patients suffer from mood swings and/or post-surgery emotional changes.

- **Infertility issues**: Obesity is one of the most common fertility problems among women. An examination of the effect of bariatric surgery on women's health revealed that they contribute better fertility, reduce excess weight gain during pregnancy, and prevent pregnancy complications in the mother and the fetus. There is a consensus regarding the recommendation to wait 12-18 months after surgery before getting pregnant, yet the preferred timing for pregnancy is when the woman reaches a point where both its nutrition and weight are balances. Pregnancy after bariatric surgery is considered a pregnancy at risk which requires the supervision of a multidisciplinary team that includes a Maternal-Fetal Medicine specialist, a bariatric surgeon and a dietician. Rapid weight loss significantly increases women's fertility, and thus could lead to pregnancy more easily. In addition, it is recommended that all women of childbearing age who have undergone bariatric surgery receive advice from a treating physician or gynecologist about non-oral contraceptives.

- **Excess skin**: It should be taken into account that after the surgery and its subsequent weight loss, excess skin may appear in different areas of the body. The extent of the phenomenon depends on the age of the patient, the amount of kilograms lost and the skin's characteristics, and the scope of this phenomenon cannot be predicted. If skin excesses are significant and interfere with daily functioning, plastic surgery may be considered to remove the excess skin that appears due to drastic weight loss. It is recommended to wait with such plastic

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surgery intervention until the weight loss has stabilized (usually 12-18 months after surgery) and eating quality is good.

- **Changes in the absorption of drugs and alcohol**: Bariatric surgery affects the anatomy of the digestive system and the absorption of various substances in the intestines. The implications of these surgeries on medicine absorption may have critical effects on the patient's condition. There is not enough information on the subject from controlled studies that monitored patients, yet laboratory studies and evidence from case studies and case series indicate that these surgeries have an effect on the absorption of various medicines, their metabolism, their dispersion in the body tissues, and the time it takes for the medicine to be released from the body.

Patient's name

Last name	First name	ID.	Father's name

I hereby declare and confirm that I received a detailed oral explanation from Dr.:

Last name	First Name

I hereby confirm that I have orally explained to the **patient/guardian/Patient's translator** all of the above in the required detailing and that he/she signed a consent before me after I was convinced that he/she fully understands my explanations.

Physician's name (Stamp)	Physician's signature	Date and time