Patient Name-Surname : Date of Birth:

Date : Protocol No :

GENERAL INFORMATION

You have the inherent right to be informed about your medical condition, as well as all medical/surgical treatment and diagnostic procedures that are recommended for the treatment of your disease. You are responsible for determining whether or not to consent to the procedure after understanding the potential risks and benefits of medical treatment and surgical interventions. The objective of this elucidation is not to induce anxiety or fear in you, but rather to enable you to participate more actively in the decision-making process regarding your health. If desired, all health-related information and documents may be provided to you or a relative who you deem suitable. We have developed this form to assist the attending physician in informing you of the risks associated with the proposed treatment/intervention and alternative treatment methods. It is imperative that you thoroughly review this consent form and sign it only after the physician has addressed any questions you may have regarding the relevant procedure.

WHAT YOU NEED TO KNOW ABOUT YOUR DISEASE

A hernia was discovered in the canal where the oesophagus enters the abdominal cavity as a consequence of the examinations and investigations conducted at our hospital, where you presented withyour complaint. Indigestion, bloating, and reflux (the egress of stomach contents into the oesophagus) are the most common symptoms of this hernia, which is the displacement of the stomach into the chest cavity. At times, it leads to the strangulation of the intestine or of the stomach. A surgical repair is the recommended treatment for this disease.

ANESTHESIA

For information about anesthesia and the risks involved, see the "about anesthesia" information pages. If you have any concerns, you can talk to your anesthesiologist. If you have not been given an information sheet, please ask for one.

WHAT KIND OF TREATMENT/INTERVENTION WILL BE APPLIED (SHOULD INCLUDE INFORMATION ABOUT ALTERNATIVE TREATMENTS):

The specialist in question will provide you with a comprehensive explanation of the anaesthesia and potential risks, and you will be required to sign an additional consent and information document. This is due to the fact that the operation will be conducted under general anaesthesia. We intend to perform an operation on you in order to reposition the herniated organs and repair the enlarged canal. The surgeon will determine the appropriate type of intervention (closed/open surgery) and may modify it in accordance with the disease's condition. For instance, the disease's inappropriateness and the emergence of undesirable conditions may necessitate the use of open surgery (thoracotomy) in surgery that was initially performed as closed surgery. In certain instances, the operation may be terminated due to technical impossibilities, or it may be necessary to perform a skin mouthing rather than a reconstruction. You will be considered to have consented to all of these procedures if you consent to the operation. The final stage of the operation involves the insertion of one or two drainage tubes, which are tubular plastic tubes connected to a tube containing water, between the lung and the inner membranes of the chest cage. An additional drain tube may be inserted into the abdominal

cavity and, upon its opening, into the neck. The removal of these drains is contingent upon the progression of the disease. Unanticipated or undesirable circumstances may arise during these planned procedures. Additional interventions may be implemented in this scenario, provided that they are the most suitable for your health. The operation is expected to last for approximately two hours. The duration of this procedure may fluctuate based on its size.

EXPECTED BENEFITS OF THE PROCEDURE

The recommended treatment is surgical repair of the hernia. With surgical treatment, there is a possibility of 80-85% recovery from the disease

CONSEQUENCES OF NOT HAVING THE PROCEDURE

Existing complaints may persist or even increase. The blood supply to the herniated organs may be impaired by strangulation of the stomach or intestine, and undesirable or even fatal conditions may develop.

ALTERNATIVE TREATMENT METHODS AND RISKS

In simple hernias, drugs that reduce acid secretion and regulate digestion and bowel movements can be used. Hernia repair can be performed with endoscopic methods, but surgical repair is necessary for advanced hernias.

RISKS AND COMPLICATIONS

The rate of adverse events, some of which are described below, is around 20%. In rare cases, these may require reoperation.

Bleeding Apart from bleeding up to a certain amount, which is considered clinically insignificant, bleeding that is serious and requires emergency surgery can be seen in rare cases.

Oralization or suture line leaks: Rarely, some or all of the esophagus may have to be removed during surgery and mouthing may be performed using the stomach/intestine instead. In some of these patients (10% on average), leakage occurs due to insufficient healing of the suture line when oral feeding is resumed on the 7th-8th day after surgery. This is a serious condition that prolongs hospitalization and can rarely lead to death. While these leaks sometimes heal on their own, sometimes they may require reoperation.

Prolonged air leak: It is expected and normal for air to pass from the lung between the lung and the inner membranes of the chest cage for a certain period of time and for the air to come out through the drain we have placed in this area. However, if this period exceeds 5-7 days, it is an undesirable condition called prolonged air leak, which may require reoperation to repair the air leak.

Atelectasis: Another undesirable condition is the deflation of part or all of the lung, called atelectasis, which occurs after surgery due to reasons such as not doing enough respiratory exercise, coughing and sputum production, inactivity, inflammation, smoking until recently, and COPD. Although this condition can initially be overcome with medications, respiratory physiotherapy and suctioning of sputum through a nasal probe (nasotracheal aspiration), a procedure called bronchoscopy can be performed to remove accumulated and condensed sputum. This procedure consists of entering the obstructed bronchus through a tube under local anesthesia with FOB (Fiberoptic bronchoscopy) or under general anesthesia and suctioning out the phlegm with a vacuum-acting device.

Heart arrhythmia: This is particularly common during or after long and major surgeries. In this case, your heart rhythm may sometimes be monitored and you may need to stay in intensive care for early detection

and treatment of other unwanted heart and circulatory disorders.

Heart attack Especially in patients over the age of 40, a heart attack can occur during or after long and major surgeries such as lung and esophageal surgeries, which may burden the heart, even if it is not detected in preoperative examinations. This condition can be treated without any problems, but it can also lead to serious problems that may result in death.

Inflammation Various inflammations may occur after surgery. Pneumonia, empyema, wound site infections, synthetic graft infection are the most common ones.

In case of **pneumonia**, necessary antibiotic treatment will be initiated, the appropriateness of antibiotics will be monitored according to your sputum and blood culture results and respiratory exercises will be applied.

Similarly, **in case of wound site inflammation,** necessary antibiotic treatment will be initiated, if necessary, wound site culture will be taken to check the appropriateness of antibiotics and you will be followed up with dressings as often as necessary.

Patients who develop **respiratory failure after surgery** may be connected to a respiratory device called mechanical ventilation. Both the condition itself that causes respiratory failure and the mechanical ventilation applied for its treatment can lead to pneumonia, widespread body inflammation, mixing of inflammation into the blood, organ failures, stomach and duodenal ulcers, bleeding, disruption of the body's acid-base balance, damage to the lung tissue due to pressure, and ultimately air accumulation between the lung membranes and some undesirable conditions leading to death.

Empyema It is the accumulation of inflammatory fluid between the lung and the inner membranes of the thorax. In this case, if a drain has been removed, a new drain will be placed, the fluid will be drained, appropriate antibiotics will be started, and in some cases, the space between the lung and the inner membranes of the chest cage will be washed with antibiotic fluids with varying frequency. This treatment may continue until the drainage (the amount of fluid coming into the tube) stops.

Vein thrombosis: Sometimes, due to prolonged lying and inactivity, clots may accumulate in the veins of the legs (deep vein thrombosis). Deep vein thrombosis can develop more easily in cases of cancer, smoking, advanced age, certain hereditary diseases, certain blood diseases, heart and circulatory disorders, previous trauma, obesity, use of certain medications and chemotherapy treatment. In this disease, which itself requires long-term anticoagulant treatment, a clot that usually forms in a leg vein can break off and travel to the vein leading to the lung (pulmonary embolism). This is life-threatening and can lead to complications ranging from mild chest pain to death. To prevent this from happening, you will be mobilized as early as possible and given anticoagulants. However, these undesirable situations can still occur.

Relapse There may be a recurrence of your disease after surgery.

Other complications: Temporary or permanent hoarseness, development of abscesses in the lung tissue or chest wall, fluid collection between the lung and the inner membranes of the chest cage (chylothorax) due to damage to the vessel-like structure that collects the lymph fluid absorbed from the intestine, mild numbness at the incision site, development of permanent scarring, headache, prolonged pain at the site of surgery, face, Loss of function related to eyebrow, hearing, swallowing, eye and eye movements, urinary or bladder control, droopy eyelids, disability due to tissue or organ damage or the need to use medication, hormones or devices for life, short or long term pain-numbness due to positioning during surgical procedures may develop.

Problems defined in the medical literature may develop due to the use of drugs and medical equipment used during and after surgery. In addition, decreased respiratory and physical performance capacity, respiratory failure, fever due to the administration of blood and blood products, blood reactions, renal failure, cessation of blood production as a result of bone marrow failure, jaundice, diseases such as hepatitis and AIDS, which are transmitted through blood, may occur. In addition, sudden cardiac arrest, allergies, organ failure, epileptic seizures and other undesirable conditions, although rare, are situations that you should be aware of and can be encountered.

Death: The incidence of death due to the surgery itself or postoperative adverse events is around 5%.

CONSIDERATIONS FOR **THE PATIENT AFTER THE PROCEDURE**

You may need to be followed up in intensive care after surgery. Depending on possible complications such as respiratory failure, you may be placed on a ventilator and put to sleep. Immediately after surgery, a drainage tube or tubes are usually inserted into a jar with fluid (drain bottle) or a valve system (Heimlich valve). Tubes placed outside the chest cavity may be open or connected to another bag at the end. After the procedure, this bottle or valve must be carried with the tube until the end of the thoracostomy and protected from contaminated areas. If it is a drain jar, it should be carried in such a way that the lowest point of the jar never exceeds the knee level, and care should be taken to keep the jar flat. If you need to move the jar outside of these situations, please ask for help from health personnel. You will not be given food by mouth for a while (on average 7 days), you will be fed intravenously. After a period of time you may be asked to do a variety of activities, including walking, breathing deeply, coughing, and using various devices for breathing exercises. During your stay, you will be given various medications intravenously, intramuscularly, subcutaneously, by mouth or by inhalation. All these measures are intended to help you recover sooner and to prevent undesirable conditions from occurring. Although the average length of your hospital stay is 10 days, this period may vary depending on conditions such as recovery and the occurrence of undesirable conditions. You will be asked to continue some medications after discharge. How long and how you will use the medication and when you will come to the outpatient clinic will be explained to you in detail by your doctor and will be recorded on your epicrisis so that you do not forget. The removal of your stitches is 7-10 days after surgery depending on the condition of your wound. After you are discharged, your eating habits will have to change. For example, while you were eating 3 meals a day and 2 plates of food, after the surgery you will reduce the amount of meals but you will have to increase the number of meals. In other words, you will eat 6 meals a day, but you will be able to eat half or 1 plate of food in one meal.

PERSONAL INFORMATION

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Medications Used: Bleeding Time:

Allergy Other Diseases:

Patient Name Surname :..... Signature:.....Date/Time:.....

Physician Name Surname :..... Signature:.....Date/Time:.....

I consent to the review of clinical information from my medical records for medical study, medical research and for the advancement of physician education; provided that the patient confidentiality rules in the patient

rights regulation are adhered to. I consent to the publication of research results in the medical literature as long as patient confidentiality is maintained. I am aware that I can refuse to participate in such a study and that this refusal will not adversely affect my treatment in any way.

Photography/ Viewers: I give my consent for the procedure to be photographed or videotaped for scientific, medical or educational purposes, including appropriate parts of my body, provided that the images do not reveal my identity. I also give my consent for qualified observers to be allowed in the operating room during the surgery for the purpose of enhancing medical education. I have read and understood the contents of the informed consent form. All blanks on this form were filled in before I signed and I received a copy.

Patient Consent:

I understand that medical practices are not an exact science and that no guarantee can be given about the outcome or treatment. I was given detailed information about my condition, the procedure to be performed and its risks, and treatment options in the consent document and in my interview with the physicians. We declare that we are aware that the responsibilities in this regard belong to us and that we accept and consent to the surgery without any violence, suggestion, material or moral pressure.

I am aware that the use of medical devices such as X-ray, scopy, ultrasonography, scintigraphy, computed tomography, magnetic resonance, etc. may be required during interventions; I am aware that I may be exposed to rays that may cause negative effects on my health in some of these devices / applications, and I approve the use of these medical devices if deemed necessary

I understand that in very rare cases, an unprecedented situation may arise during the procedure and in this case, I give my consent and permission for the team to take such action as they deem appropriate.

I sign this form without any further explanation, without being under any pressure and consciously.

Patient Name Surname : Date/Time :

Signature :

or

Patient Guardian/Relative Date/Time :

Name Surname : Signature :

(Proximity.....)

Sufficient and satisfactory explanations have been made by me to the patient / patient's relative whose name is written above about his/her disease, the intervention to be performed, the reason and benefits of this intervention, the care required after the intervention, the expected risks, the type of anesthesia to be applied if necessary for the intervention, and the risks and complications of anesthesia. The patient/caretaker has read and signed this form with his/her own consent that he/she has been sufficiently informed about his/her admission.

Physician Name Surname : Date/Time:

Signature :