INFORMATION AND AUTHORIZATION FORM FOR THE PERFORMANCE OF A**TRANSORAL ENDOSCOPIC ULTRASOUND TOTAL LARYNGECTOMY (TOUSS TL)** FOR THE TREATMENT OF …

Name and surname: .....
..... Age: ..... ID: .....
..... Clinical History nº: .....
..... Process diagnosis: ..... Date: .....
..... Informing doctor: .....
..... Collegiate number: .....

Written consent PENDING ON AGREEMENT AND ENDORSEMENT by the Spanish National Otolaryngology and Facial Pathology Society.

The objective of this form is to explain, easily and clearly, the procedure known as TRANSORAL ENDOSCOPIC ULTRASOUND TOTAL LARYNGECTOMY (TOUSS TL), as well as the most important aspects of the post operational phase. It'll also explain the most frequent complications that could come up due to this intervention.

BRIEF DESCRIPTION OF THE SURGICAL PROCEDURE. The Total Laryngectomy is the technique that seeks for the complete removal of the larynx. It is carried under general anaesthesia and consists of a removal of the larynx and sometimes, a part or the totality of annexed structures, such as the trachea, the base of the tongue, the thyroid gland, pharynx, oesophagus, cervical muscle tissue, etc. Anything that can be affected by a malign lesion. It is a surgery that could be classified as minimally invasive, as it is designed to lower the amount of bleeding from the sectioning of tissue. It is also aimed at reducing the possible damages during and after the surgery with conventional methods, though these damages are always a factor, which vary depending on the location and extension of the lesion to be removed. As in any minimally invasive surgery, there are possibilities that the complications of the surgery would call for a conventional approach as an alternative measure, though this is an exceptional case. If due to a specific physiological difficulty of the patient the exposure of the lesioned area is not sufficient, and therefore, affecting the success of the surgery, the procedure could be suspended or transformed into a more convenient one. This intervention is made with a small incision at the base of the neck and a device placed in the mouth that allow, with the help of and endoscope and an ultrasound forceps, and no further incisions, the complete removal of the larynx. Though the larynx is the focal point of the procedure, this surgery is associated with the extirpation of the ganglia in the cervical area, generally on both sides. If it is associated to an emptying of the area, the incision may extend from the one of the auriculas to the base of neck, and to the other auricula. After removing the larynx, and so the patient can keep breathing correctly, the trachea will be brought up permanently. There will be an orifice in the frontal area of the neck, called tracheo-oesophageal puncture and that needs to be open permanently with the help of a cannula. In the first days after the surgery it will be necessary to instill fluidizers through the orifice and to hoover the secreted substances. Food will be supplied though a catheter until the throat is completely scarred over, when the feeding through the moth will start gradually. To the specialist discretion, a drainage tube might be placed at the base of the neck. This will ease the process of removing blood and the scarring of the neck's open tissue. In this case, the drainage tubes are very frequently used, and are generally removed a few days after.

The first to first few days after the intervention the patient will remain hospitalized for a better monitoring of their progress. First in intensive care, but then moved to the hospitalization floor for a more relaxed vigilance. The doctor could decide to use a catheter installed through the nose, or exceptionally directly to the stomach (this is called a gastrostomy). This will remain this way until the doctor decides it is possible for the patient to start eating normally. If no problems come up, the scarring process lasts between 10 and 12 days, period when the patient will remain hospitalized. This time might be stretched or shrunk. After this general period the patient may start eating orally, if not counter-indicated by the specialist. In the first hours after the surgery some blood is likely to appear in the saliva, as well as digested blood vomit, because of the blood swallowed during the intervention. For the same reason, dark faeces are normal in the following days. Bad breath is also very common. During this period, factors as fever, haemorrhage, other complications, as well as the scarring process. After the hospital discharge, the patient will have an outpatient period of check-ups, getting as many as esteemed necessary. In some cases, radio and quimotherapy will be necessary after the surgery for the completion of the treatment.

As a result of this surgery the patient will lose permanently their laryngeal voice. Nevertheless, the patient can learn esophageal voice techniques with the phonation fistulas, through a prosthesis that joins together the trachea and pharynx or a laryngophone. Through these resources, the patient will be able to speak again. When this comes, the doctor will recommend the most suitable option for your case. The removal of the larynx implies that the trachea will be brought up to the exterior. This means the patient will be breathing though a visible hole in the frontal base of the neck. So that this orifice remains permeable, a special cannula is required, made of different materials and in different models. What's more, as the breathing orifice is permanently connected to the exterior, the patient won't have the ability of keeping air inside their lungs. This will translate in a loss of strength, to lift weights, and difficulties to carry certain tasks, like defecation, childbirth, etc. Also, the processes of coughing, smelling and sneezing will be modified. If NOT EFECTUATED the lesions that justified the therapy might persist, or the expected diagnose will no longer apply. If the intervention was recommended due to the presence of a malign tumour, the evolution of said tumour in a local, regional or long distance will lead to the patient's death (what it is known as metastasis). This extension might make the swallowing difficult, as well as provoke asphyxiation, infections and haemorrhage. If the treatment designated is not to be carried out, the doctor won't have the necessary diagnostic elements for the optimal treatment.

LIKELY BENEFITS Complete recovery form the illness with less mutilation and incapacitation consequences.

ALTERNATIVE PROCEDURES They can be radiotherapy and quimotherapy, with varying results depending on the case. Surgically, there are other alternatives, such as open surgery or a transoral approach with different tools (robotic surgery). Nowadays, the three methods are combined to optimize results. Your doctor will be advised by a board of specialists and then present you with the best option.

MOST FREQUENT RISKS DURING THE PROCEDURE

Dry mucus might congregate in the cannula used for the tracheotomy, in the trachea or the bronquial tubes. This might lead to difficulties in breathing. That's why in the first days after the surgery it will be necessary to instill fluidizers through the tracheostoma and to hoover the secreted substances. The first days there is a haemorrhage risk due to the compromising of veins and arteries in the neck, which could require a blood transfusion, cardiovascular consequences, a haemorrhagic shock and even a second intervention. Also, fistulas might appear – tissue that connects the interior of the pharynx

with the area where saliva is, that could lengthen the scarring process and even lead to a new intervention. The electric forceps are very frequently used by the surgeon during this procedure. With it, the specialist makes small incisions and cauterizes small blood vessels that might be open. Even though extreme precautions are taken when this equipment is used, they might leave some burns in the proximities of the lesioned area or in common places the doctor might place the X ray fil, like the patient's thigh of back. The tracheostoma might get infected, as well as the respiratory system, manifested in tracheitis, bronchitis or pneumonitis. Dysphagia (difficulty in the swallowing) is also very common. A cervical or thoracic emphysema might also appear (little air bubbles in the neck or thorax) or a necrosis (destruction) of the soft areas of the neck. Fistulas may appear connecting the throat or mouth to the neck's exterior, which might need extended treatment or even a second surgery. It is possible that the disease will reappear, short term or long term. Due to stress, a gastroduodenal ulcer might develop. Depression is also a possible side effect due to stress.

Though not further described, the ultrasound forceps might cause burns on face, lips, mouth and aerial cavities, due to accidental contact with the high temperature oscillating bar. Nevertheless, these are temporary and recovered from fully. It is possible that the oxygen and anaesthetic gases might ignite due to the usage of methods other than the ultrasound for cutting or handling bleeding. Also, the Transoral tools might cause dental lesions. It is possible that the disease will reappear, short term or long term. Above all that the complications that come with any surgical procedure cannot be ignored, and the ones associated with general anaesthesia. Even when a complete pre-operatory study is carried, and every step of the procedure is performed with maximum care, there is a register of 1 death in every 15.000 surgeries operated under general anaesthesia, and as a consequence of the latter. This risk increases with age and the existence of other diseases, as well as their gravity.

RISKS RELATED TO PERSONAL AND PROFESSIONAL CIRCUMSTANCES, OBSERVATIONS AND COUNTER-INDICATIONS AND SIGNATURES

I declare I have been informed by the specialist of the most relevant aspects of the surgery that is to be performed to me, of its normal evolution, possible complications and risks, counter-indications, the consequences that would come if I were not to agree to it and the alternatives to the method chosen. I am satisfied with the information provided. I have been able to ask all of the questions I esteemed necessary and they have all been resolved. Also, I declare I haven't concealed any relevant information for my case, or any habits that may be relevant to the doctor conducting my treatment. I know that, amongst the medical team that will be present the day of the operation, I will be operated by the most suiting doctor for my case. I give my permission for the specialist to take as many biological samples and photographs as needed to aid and document the process. I understand that, even though the medical team who will attend me are going to thoroughly observe the hygiene measures, the operation and hospital stay are a factor to hospital infections, which are not frequent, yet possible. In the scenario that the surgeon found new factors to the disease or a new pathology that would require the modification of the procedure already agreed on significantly, the surgeon will previously consult with the person authorized by me to decide on this matter. I authorize the doctor to make the most convenient decision in my health's favour only when the situation puts my life at risk. I understand that the doctor might finish the operation without having tackled all of the objectives when in face of unforeseen circumstances that would require my express authorization. I understand this document informs me about the most frequent and relevant risks and complications of the procedure. Nevertheless, the doctor will be able to give me complementary information on all the possible risks and complications of this

particular procedure. All in all, I consider the information provided in this document and the doctor to be sufficient and well suited to understand the process fully, with its possible risks and complications. After all of it, I GIVE MY AUTHORIZATION TO GO THROUGH THIS INTERVENTION, also understanding my right to revoke this authorization at any time.

In_____, _____, 20___

Signed: _____ Signed: _____
The patient The specialist

LEGAL GUARDIAN OR RELATIVE MR./MRS./MS. ..... , I.D. ..... and as ..... , is aware that the patient whose information is at the beginning of the document is not competent to decide at the moment, and therefore takes the responsibility to decide in their place in the same terms that the patient would. In _____, ____ _____ , 20___

Signed: _____
The legal guardian

REVOCATION OF CONSENT Hereby, I NULIFY any authorization given in this document, which isn't valid from the moment of the signature. I have been presented with the consequences that this annulation may have according to my progress, and, therefore, I understand and accept them. In _____, _____ de 20___

Signed: _____

The patient/Legal guardian