INFORMATION AND AUTHORIZATION FORM FOR THE PERFORMANCE OF A **TRANSORAL ENDOSCOPIC ULTRASOUND SURGERY (TOUSS)** 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 SURGERY (TOUSS), as well as the post operational phase. It'll also explain the most frequent complications that could come up due to this intervention. BRIEF DESCRIPTION OF THE PROCEDURE. The TRANSORAL ENDOSCOPIC ULTRASOUND SURGERY (TOUSS) is a technique whose final purpose is the removal of lesions located on the oral cavity pharynx or larynx, whether it is for diagnostic or therapeutic reasons. This is done through the mouth, with an endoscope being inserted for visualization and an ultrasound forceps used for the actual removal. It is a surgery that could be classified as minimally invasive and 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. It is possible that the patient will need to be hospitalized in the UIC for a period of post-operational vigilance, although it will only be needed in specific cases. Afterwards, they will be transferred to the main floor, where the healing process will continue. After the intervention the patient will feel some pain, which could be intensified by swallowing and could extend from the area intervened and as far as to the inner ear. Because this could last up to two weeks, sometimes more, the patient will need painkillers provided. 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. Because it is frequent that the patient won't be able to eat normally at the beginning, the doctor could decide to use a catheter installed through the nose, or exceptionally directly to the stomach (this is called a gastrostomy). The betterment of the

swallowing is progressive. There are situations in which this procedure will need of a tracheotomy (a way of communicating the trachea with the exterior with a tube to easy the breathing for the patient). The tracheotomy could remain open if needed, during subsequent radiotherapy or if the scarring process doesn't allow the doctor to close it. The tracheotomy requires special care. Nevertheless, the Transoral Endoscopic Ultrasound Surgery is designed to evade said tracheotomy, the mentioned catheters and the other functional problems at the best of cases. The intervention can lead to physical consequences, that will vary depending on the area affected and are normally attenuated in comparison to the conventional methods. The hospital stay may vary depending on the case, though the minimally invasive approach is associated with a reduced hospitalization time. 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. 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 (laser and 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 There could be a haemorrhaging episode that might require for a new operation, a blood transfusion or even cardiovascular complications. The surgical wound might get infected, as well as the respiratory system, leading to possible tracheitis, bronchitis, or pneumonitis. Dry mucus might congregate in the cannula used for the tracheotomy (if one is performed), in the trachea or the bronquial tubes. This might lead to difficulties in breathing. The patient might develop an oedema, an inflammation and shrinking of the larynx (what we call laryngeal stenosis) or the apparition of synechias (scar tissue flanges). This could also lead to respiratory difficulties. Said difficulties will need of a medical treatment, the performance of a tracheotomy (if not previously done) and even keeping the cannula inside the patient (if this was the case, due to a previous tracheotomy). Moreover, dysphagia (difficulty with the swallowing) might happen, and choking due to false paths of swallowing. This is generally temporary, but it could remain as a medical consequence. 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 very exceptional, but the patient might suffer a perichondritis (an inflammation of the larynx's cartilages), an osteitis (inflammation of the bone) or a necrosis (destruction) of the soft areas of the neck. A

cervical or thoracic emphysema might also appear (little air bubbles in the neck or thorax). 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