THYROID SURGERY (SURGICAL TREATMENT OF STRUMA) <u> OPERATION AN DER SCHILDDRÜSE (STRUMA-OP)</u>

Information and medical history for patients for preparation of the required pre-procedure interview with the doctor

 Γ_{Clin}



Clinic / Doctor:	Patient data:
Ammeriand Klinik CmbH and for the	
First surgery Ersteingriff	☐ right lobe rechter Lappen ☐ left lobe linker Lappen
Repeated surgery (e.g. recurrent struma)	Partial removal Teilentfernung I full removal vollständige Entfernung

on (date): am (Datum): _

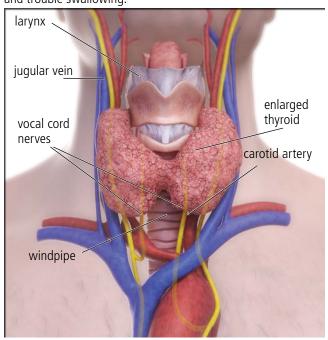
Dear patient,

you have been diagnosed with an abnormal enlargement of your thyroid (struma), which is to be treated surgically.

This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you the advantages and disadvantages of the scheduled procedure compared with alternative methods available, and inform you of any risks specific to your case. The doctor will answer all of your questions in order to reduce any fears or concerns you may have. You may then consent to the procedure suggested to you. Your doctor will provide you with a copy of the completed and signed form after the interview.

CAUSES OF THE DISEASE

The thyroid produces certain hormones in the body and stores iodine ingested with our food to be used in hormone production. An enlarged thyroid (a so-called struma or goiter) can be caused by a lack of iodine, certain diseases of the thyroid (Graves' disease), inflammation or also by benign or malignant nodules that have formed in the thyroid tissue (so-called "hot" or "cold" nodules). A severely enlarged thyroid can lead to constriction of the windpipe and the oesophagus, leading to shortness of breath and trouble swallowing.



COURSE OF OPERATION

The treatment will be carried out under general anaesthesia, regarding which you will receive a separate information sheet.

Access to the thyroid is usually effected via a horizontal incision in the skin in the lower section of the throat (collar incision).

The length of the incision is usually between four and five centimetres; however, it depends on the size of the thyroid. The thyroid is then exposed, blood flow to the supplying blood vessels is cut off and they are severed. In order to prevent damage to the vocal cord nerves during the operation, which are located in close proximity to the thyroid, their function is usually monitored during the operation with a measuring device (so-called neuromonitoring). Smaller nodules can be treated in minimally invasive surgery. This involves a two-centimetre-incision through which a small camera is inserted all the way to the thyroid. The doctor can view the operation area via the camera and remove the lumpy tissue. Depending on the type of disease, the parts of the thyroid to be removed vary in size:

☐ Surgery in case of benign enlargement/nodule:

In this procedure, all lumpy thyroid tissue is removed. Depending on the extent of the nodules, the entire organ may have to be removed. If the nodules are limited to one side of the thyroid, it may suffice in some cases to remove only one thyroid lobe.

Surgery in case of malignant alterations:

In this procedure, the thyroid is removed entirely, including all of the local lymph nodes and further throat tissue.

☐ Surgery in case of thyroid hyperfunction:

In case of a hyperfunction of the thyroid, as with Graves' disease, a large part of the thyroid is usually removed. This is the only way to remedy the effects of hyperfunction.

Your doctor will explain to you which procedure is applicable in your particular case.

If a malignant disease is suspected, the removed tissue is often examined even while the surgical procedure is still under way (so-called frozen section).

At the end of the operation, small plastic tubes, so-called drains,

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are inserted into the wound in order to allow for wound secretion to be drained from it. The wound is then sutured or closed with clips and treated with a dressing.

POSSIBLE ADDITIONAL MEASURES

If the thyroid is so large that it protrudes into the chest, the upper part of the sternum of the entire sternum may have to be divided (sternotomy) in order to be able to remove the tissue entirely.

If there are any complications during minimally invasive surgery (such as stronger bleeding), the skin incision may have to be made larger.

If the frozen section analysis shows that there is malignant tissue present, the entire thyroid will have to be removed, including the lymph nodes if need be.

A thyroid carcinoma may also be discovered during the histological examination after the operation, making a second operation necessary in order to remove the remainder of the thyroid and, if needed, the lymph nodes.

ALTERNATIVE METHODS

In certain cases, an enlargement or hyperfunction of the thyroid can also be treated with medication or radioactive iodine therapy. Depending on the type of disease, the different methods can possibly also be combined.

Your doctor will explain to you why he would recommend surgery in your particular case.

PROSPECTS OF SUCCESS

Surgery usually results in significant improvement of the patient's symptoms. Depending on how much thyroid tissue had to be removed, the patient will have to take thyroid hormones in the form of tablets for the rest of their life.

If the parathyroid glands had to be removed, the patient will have to take vitamin D and calcium permanently.

The scar will be firm and red for the first few weeks, but it will become softer and paler with time.

If the thyroid wasn't removed entirely, lumpy tissue may grow back over time (recurrent struma) in some cases. The procedure may then have to be repeated. However, recurrent struma surgery involves much higher risks.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Unless specifically instructed otherwise, please adhere to the following guidelines:

Preparation:

Medication: Please inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASS], Marcumar®, Heparin, Plavix®, Ticlopidin, Clopidogrel, Eliquis®, Lixiana®, Xarelto®, Pradaxa® and metformin-containing antidiabetic medicines, so-called biguanides) or have taken irregularly over the course of the past eight days prior to the procedure (for instance pain killers such as ibuprofen, paracetamol). This includes any over-the-counter medication and herbal remedies. Your doctor will let you know if and for how long you should stop taking your medication.

Aftercare:

Post-surgical pain can usually be alleviated with medication.

On the day of the operation, you will already be allowed to eat and move around again. You doctor will provide you with specific instructions.

If the throat muscles had to be severed horizontally due to the size of the struma during surgery, you should refrain from extreme head movements for the first two weeks after surgery. If in doubt,

please consult your doctor.

If you are to take thyroid medication after the operation, please take it conscientiously.

Please inform your doctor immediately should you experience wound pain, fever, trouble swallowing, hoarseness, a loss of your voice or shortness of breath after surgery. Symptoms pointing to a convulsive seizure, such as muscle cramps, e.g. around the eyes or the mouth, paraesthesia in the extremities, unnatural hand position (Trousseau sign of latent tetany), diarrhoea, increased heart rate or tear flow, require immediate medical attention. They may occur even days after the procedure.

POSSIBLE RISKS, COMPLICATIONS AND SIDE EFFECTS

It is well known that any medical procedure is accompanied by certain risks. If complications occur, they may sometimes require additional treatment or surgery and, in extreme cases, can sometimes even be life-threatening or lead to permanent damage — even after some time. Please understand that, for legal reasons, any possible risks associated with this procedure must be listed, even if some of these only occur in exceptional cases. During the interview, your doctor will inform you of any risks specific to your case. You may also choose to waive a detailed explanation. In that event, please pass over this section on risks and confirm your waiver with your signature in the final section of this form.

Injuries of neighbouring organs (e.g. windpipe, oesophagus), vessels and nerves are generally possible. Additional surgical measures may then have to be taken. The risk of such injuries is increased in recurrent struma surgery, under unusual anatomical conditions, with inflammation or malignant tissue alterations.

Bleeding can usually be stopped immediately during the operation. Post-procedure bleeding may occur in some cases. If the windpipe is constricted by strong bleeding, leading to shortness of breath, a new surgical intervention may be required. Should severe blood loss occur, the use of donor blood/blood components (**transfusion**) may be required. This can lead to transmission of diseases, such as hepatitis in very rare cases (causing dangerous inflammation of the liver), HIV in extremely rare cases (causing AIDS), BSE (causing a form of Creutzfeldt-Jakob disease) or also of other dangerous — even unknown — diseases.

Occasionally, a **contusion or hyperextension of the vocal cord nerve** will lead to temporary **one-sided paralysis of the vocal cords** (paralysis of the recurrent nerve) including hoarseness, impaired speech, trouble swallowing or shortness of breath. If the vocal cord nerve is severed completely, **permanent paralysis** will result.

If both vocal cord nerves are damaged, a **two-sided vocal cord paralysis** with strongly impaired speech and trouble breathing will result. This may require vocal cord surgery or a cut in the windpipe (tracheotomy).

An **injury of the sympathetic nervous system** can lead to pupil constriction, a sunken eyeball and a droopy upper eyelid (Horner syndrome).

In rare cases, damage to the superior laryngeal nerve (N. laryngeus superior) may lead to a weakened coughing reflex or a temporary, rarely permanent, disturbance of voice formation involving a loss of the higher notes and impairment of the singing voice.

In very rare cases, damage to the phrenic nerve (N.

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phrenicus) may occur, leading to a weakened or even paralysed breathing activity of the diaphragm.

You may experience temporary **neck pain** and **swelling of the mucous membrane of the throat** after surgery.

On very rare occasions, unnatural connections (**fistula**) between the windpipe or the oesophagus and the surface of the body may form. Surgical intervention will then be required.

During the operation, the **parathyroid glands** may be accidentally removed or damaged. Since they produce hormones which are important in calcium metabolism, a calcium imbalance may result. This can lead to **muscle cramps** (tetany), which can usually be treated successfully with medication. If the parathyroid glands were damaged only slightly, hormone production will usually resume after some time. If the parathyroid glands were removed entirely, they can also be reimplanted (for instance in the throat muscle) in some cases.

Allergic reactions, for instance to medication or latex, can lead to skin rash, itching, swelling, nausea and coughing. Severe reactions such as shortness of breath, spasms, tachycardia or **life-threatening circulatory shock** are rare. They may then result in permanent organ damage, such as brain damage, paralyses or kidney failure requiring dialysis.

Damage to the skin, soft tissue or **nerves** - for instance through injections, bruising, syringe abscess, disinfectants or despite proper positioning - may occur. Numbness, paralysis and pain may then result. They are usually temporary. Permanent nerve damage or tissue death rarely occur, scars may remain.

Small nerves in the skin can be severed during surgery and lead to temporary or, in rare cases, even **permanent numbness** around the surgical scar.

Irritation of the vagus nerve may lead to **cardiac arrhythmia**. Cases of **cardiac arrest**, requiring resuscitation and possibly leading to permanent organ damage, are rare.

Infections are rare and can be treated successfully with antibiotics in most cases, surgical treatment will rarely be required. In extreme and exceptional cases, an infection that has spread beyond control can lead to **life-threatening blood poisoning** (toxaemia).

Sometimes **blood clots** (**thromboses**) may form, causing obstruction of a blood vessel (**embolism**). Such blood clots may then travel to other parts of the body and block the vessels of other organs. This may then lead to e.g. **stroke**, **kidney failure requiring dialysis** or **lung embolism** and result in permanent damage. If anticoagulant agents are administered to prevent formation of blood clots, the risk of bleeding or post-procedure bleeding is increased. If Heparin is administered, it may lead to a severe immune response (HIT) involving clotting of the platelets (thrombocytes) and obstruction of veins and of arteries.

If air enters into a blood vessel during surgery, it may lead to **air embolism**, possibly resulting in severe blood flow or circulatory disturbances.

With patients predisposed to delayed wound healing or **wound healing disorder**, cosmetically unattractive scarring and abnormal proliferation of scar tissue (keloids) may occur. This may require corrective surgery.

A **division of the sternum** increases the risk of injuring vessels, nerves and neighbouring organs (e.g. the lungs). If wound healing is disturbed, the sternum may not heal properly. Further surgical intervention may then be required. The procedure may lead to **injury of the lining of the lungs** (pleura) resulting in air entering into the chest and pushing aside the lungs (**pneumothorax**). In order to remove the air and improve breathing, a surgical drain may then have to be inserted.

Questions about Your Medical History

Please fill in the following questionnaire carefully before your information talk. Please tick the applicable box! It goes without saying that your information will be treated confidentially. The information you provide will help the physician to better assess the risks in your particular case, to advise you on the complications that could occur, and to take any steps needed to prevent complications and side effects.

Gender: M / F, age:	years, weig Jahre, Gewicht:	th: kg, height: kg, Größe: ci	C	m
Information about medications: Do you regularly require blood thinning medications (anticoagulants) or have you taken any or have any been injected during the past 8 days? Aspirin® (ASS), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Ticlopidin, Xarelto®. Angaben zur Medikamenteneinnahme: Benötigen Sie regelmäßig blutgerinnungshemmende Mittel oder haben Sie in der letzten Zeit (bis vor 8 Tagen) welche eingenommen bzw. gespritzt? Aspirin® (ASS), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Ticlopidin, Xarelto®.]yes □no	Medications, ☐ foods, ☐ contrast media, ☐ iodine, ☐ sticking plaster, ☐ latex (e.g. rubber gloves, balloons), ☐ pollen (grass, trees), ☐ anaesthetics, ☐ metals (itching caused by metal spectacles frames, jewellery, jeans buttons). Allergie/Überempfindlichkeit? ☐ Medikamente, ☐ Lebensmittel, ☐ Mod. ☐ Pflaster, ☐ Latex (z.B. Gummihandschuhe, Luftballon), ☐ Pollen (Gräser, Bäume), ☐ Betäubungsmittel, ☐ Metalle (z. B. Juckreiz durch Metallbrillengestell, Modeschmuck oder Hosennieten). Any other:		no
Any other:Sonstiges: When did you take the last dose? Wann war die letzte Einnahme?		Heart, circulatory or blood vessel diseases? ☐ Heart attack, ☐ chest pain and/or tightness (angina pectoris), ☐ heart defect, ☐ irregular heart rhythm, ☐ inflammation of heart muscle, ☐ heart valve disease, ☐ shortness of breath while climbing stairs, ☐ heart surgery (possibly with insertion of an artificial heart valve, pacemaker, defibrillator), ☐ high blood pressure, ☐ low blood pressure, ☐ stroke, ☐ varicose veins, ☐ inflammation of a vein, ☐ thrombosis, ☐ embolism. Herz-/Kreislauf-/Gefäß-Erkrankungen? ☐ Herzinfarkt, ☐ Angina pectoris (Schmerzen im Brustkorb, Brustenge), ☐ Herzfehler, ☐ Herzrhythmusstörungen, ☐ Herzmuskelentzündung, ☐ Herzdappenerkrankung, ☐ Luftnot beim Treppensteigen, ☐ Herzoperation (ggf. mit Einsatz einer künstlichen Herzklappe, Herzschrittmacher, Defibrillator), ☐ hoher Blutdruck, ☐ inedriger Blutdruck, ☐ Schlaganfall, ☐ Krampfadern. ☐ Venenentzündung. ☐ Thrombose, ☐ Embolie.	_	□no
Do you take any other medications? Werden andere Medikamente eingenommen? If so, which ones: Wenn ja, bitte auflisten:	yes □ no			
(Please include non-prescription medications, herbal and other natural etc.) (Auch rezeptfreie Medikamente, natürliche oder pflanzliche Heilmitte Have you ever had radiotherapy in the neck area? Haben Sie schon einmal eine Strahlentherapie im Halsbereich erhalten?				
Are you pregnant? □ not certain □ nicht sicher	yes □ no	-	□yes	□no
Do you smoke? If so, what and how much daily: Rauchen Sie? Wenn ja, was und wie viel täglich:	yes 🗆 no	Any other:Sonstiges:		
Do you have or have you ever had any of the fodiseases: Liegen oder lagen nachstehende Erkrankungen vor: Blood diseases / blood clotting disorders? Increased bleeding tendency (e.g. frequent nose bleeds, increased post-operative bleeding, increased bleeding from minor injuries or after dentist treatment, stronger or longer menstrual bleeding), tendency to bruise (frequent bruising possibly for no particular reason). Bluterkrankung/Blutgerinnungsstörung? Frhöhte Blutungs-neigung (z.B. häufiges Nasenbluten, verstärkte Nachblutung nach Operationen, bei kleinen Verletzungen oder Zahnarztbehandlung, verstärkte oder verlängerte Regelblutung), Neigung zu Blutergüssen (häufig blaue Flecken auch ohne besonderen Anlass).		Communicable (contagious) diseases? Hepatitis, tuberculosis, HIV. Infektionskrankheiten? Hepatitis, Tuberkulose, HIV. Any other: Sonstiges:	□yes	no
		Predisposition to impaired wound healing, abscesses, fistulas, excessive scar formation (keloids)? Neigung zu Wundheilungsstörungen, Abszessen, Fisteln, starker Narben-Bildung (Keloide)?	າ □ yes	□no
		Any other acute or chronic diseases / illnesses? Nicht aufgeführte akute oder chronische Erkrankungen? Please describe: Bitte kurz beschreiben:	☐ yes	□ no

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Medical documentation for the informative interview Ärztl. Dokumentation zum Aufklärungsgespräch To be completed by the doctor Wird vom Arzt ausgefüllt Über folgende Themen (z. B. mögliche Komplikationen, die sich aus den spezifischen Risiken beim Patienten ergeben können, nähere Informationen zu den Alternativmethoden, Erfolgsaussichten) habe ich den Patienten im Gespräch näher aufgeklärt:	Patient's refusal Ablehnung The doctor has provided me with detailed information regarding the procedure at hand and has also pointed out the disadvantages of rejecting it. I have understood the information provided to me and reject the procedure suggested to me. Die Ärztin/der Arzt hat mich umfassend über die vorgeschlagene Maßnahme und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und lehne die mir vorgeschlagene Maßnahme ab. Place, date, time [Ort, Datum, Uhrzeit]
	Refusal of patient / legal guardian / witness if applicable [Ablehnung Patientin / Patient / Betreuer / ggf. des Zeugen]
	DECLARATION OF CONSENT
	Please tick the appropriate boxes and confirm your statement with your signature below:
	☐ I hereby confirm that I have understood all sections of this form. I have read the entire form (5 pages). During the pre-procedure interview with the doctor
	explanation. However, I hereby confirm that the doctor instructed me regarding the necessity of the procedure, its type and scope as well as the fact that all medical procedures are accompanied by certain risks. Ich verzichte bewusst auf eine ausführliche Aufklärung. Ich bestätige hiermit allerdings, dass ich von der Ärztin/dem Arzt über die Erforderlichkeit der Maßnahme, deren Art und Umfang sowie über den Umstand, dass alle medizinischen Maßnahmen Risiken bergen, informiert wurde.
Capability to give wilful consent:	I hereby confirm that I do not have any additional questions and do not need more time for consideration. I consent to the procedure proposed. I have answered the questions regarding my medical history (anamnesis) fully to the best of my knowledge. Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkzeit benötige. Ich stimme der vorgeschlagenen Maßnahme zu. Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.
Fähigkeit der eigenständigen Einwilligung: The patient is capable of making a decision on the recommended procedure on his/her own and giving his/her consent for the procedure. Der/Die Patient/in besitzt die Fähigkeit, eine eigenständige Entscheidung über die empfohlenen Maßnahme zu treffen und seine/ihre Einwilligung in den Eingriff zu erteilen.	I confirm that I am capable of following the instructions given to me by my doctor. Ich versichere, dass ich in der Lage bin, die ärztlichen Verhaltenshinweise zu befolgen.
The patient is represented by a custodian with a custodian's card which states that he/she is also responsible for the patient's healthcare, or by a trusted person with a healthcare proxy. These persons are capable of making a decision in the best interest of the patient. Die Patientin/Der Patient wird von einem Betreuer mit einem die Gesundheitssorge umfassenden Betreuerausweis oder einer Vertrauensperson mit einer Vorsorgevollmacht vertreten. Diese sind in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.	☐ I agree that my copy of this explanatory form may be sent to the following e-mail address: Ich bin damit einverstanden, dass meine Kopie dieses Aufklärungsbogens an folgende E-Mail-Adresse gesendet wird:
☐ Custodian's card ☐ healthcare proxy ☐ advance healthcare directive has been submitted.	e-mail address [E-Mail-Adresse] Place, Date, Time [Ort, Datum, Uhrzeit]
☐ Betreuerausweis ☐ Vorsorgevollmacht ☐ Patientenverfügung liegt vor.	
Place, date, time [Ort, Datum, Uhrzeit]	Signature of the patient / legal guardian(s) [Unterschrift Patientin / Patient / Betreuer] Copy/Kopie:
Doctor's signature [Unterschrift der Ärztin/des Arztes]	received/erhalten Waived/verzichtet Signature Copy received/waived Kopieerhalt/-verzicht