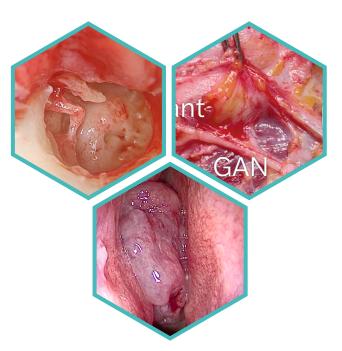




AOI Team 2022-23 presents Uniform Surgical Consent Booklet 1.0



Chief Editor

Dr Bharathi M B

Editors

Dr Kaushal Sheth Dr Nandu Kolwadkar Dr Samir Bhargava Dr Yogesh Dabholkar Dr Seemab Shaikh Dr Rupali Patil Jain Dr Ravi Sachidananda Dr Amit Kumar Keshri Dr Sandhya D



Association of Otolaryngologists of India

Office Bearers 2022-2023

Dr Bharathi M B

President

Dr Nandu Kolwadkar

President Elect

Dr Samir Bhargava

Immediate Past President

Dr Kaushal Sheth

Hon Secretary

Dr Yogesh Dabholkar

Treasurer

ADVISORS

Dr Sudhakar Vaidya Dr Viral Chhaya

Dr Deepak Haldipur Dr Satyaprakash Dubey

Dr Sanjay Agarwal Dr Ravi Ramalingam

Dr Sunil Narayan Dutt

Editorial Chairman- IJOHNS

Dr Vikas Gupta

Editor

GOVERNING BODY MEMBERS

Dr Amit Kumar Keshri Dr C V Srinivas

Dr Kshitij Patil Dr Pawan Singhal

Dr Poonathpur Lakshmi Dr Shalini Jadia

Dr Utpal Jana Dr Vikram Khanna

Dr Vishwas K V

EDITORIAL BOARD MEMBERS

Dr Lathadevi H T Dr Rajiv Pachauri

EXPERT COMMITTEE MEMBERS



Dr Bharathi M BPresident



Dr Nandu Kolwadkar President Elect



Dr Samir Bhargava Immediate Past President



Dr Kaushal Sheth Hon Secretary



Dr Yogesh Dabholkar Hon Treasurer



Dr Seemab Shaikh
HOD, Dept. of ENT
Inamdhar Multi Speciality Hospital
Consultant, KEMH &
Sahyadri Group of Hospitals, Pune



Dr Rupali Patil Jain ENT Surgeon, Allergologist & Medicolegal Consultant Amaravati



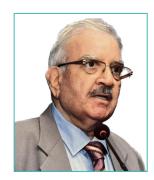
Dr Ravi Sachidananda
Consultant ENT, Head & Neck Surgeon
Director, People Tree Hospital
Bangalore



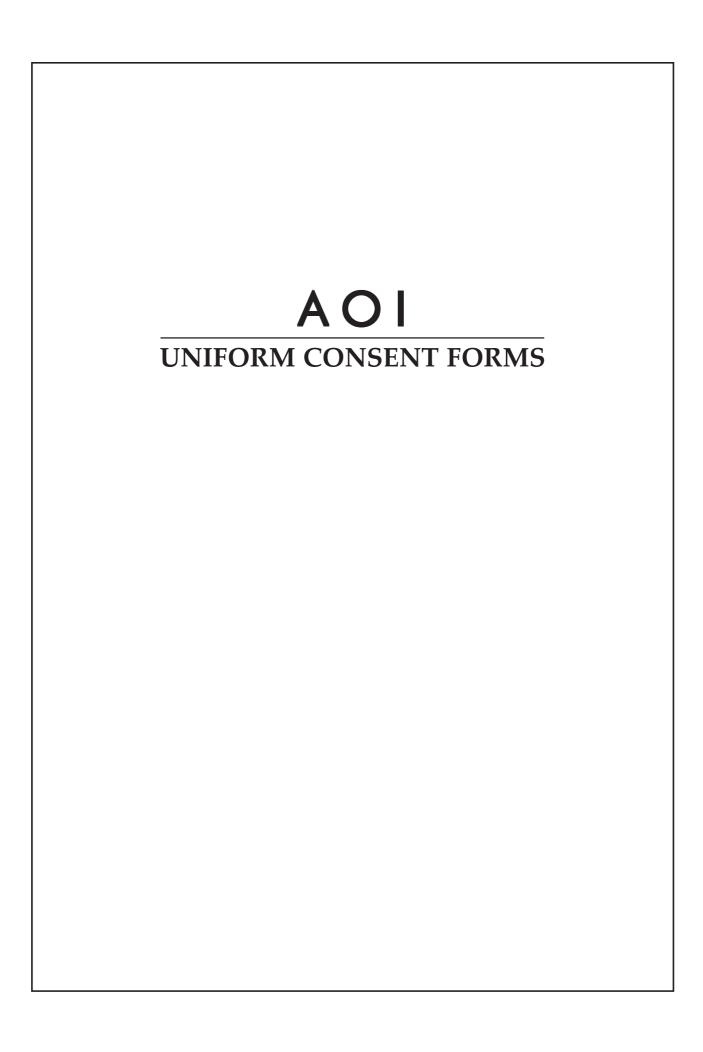
Dr Amit Kumar Keshri Consultant ENT Surgeon SGPGI, Lucknow



Dr Sandhya D
Consultant ENT Surgeon
JSS Medical College & Hospital
Mysore



Dr Lalit Kapoor
President, Federation of Assn. of
Medical Consultants of India (FAMCI)
Medical Director
Shakuntala Memorial Hospital







From the Desk of the President

Dear friends,

Seasons greetings to everyone!

It gives me great pleasure to present this handy booklet on "Uniform Surgical Consent Booklet" for ENT, Head & Neck surgeries from the Association of Otolaryngologists of India. Our team of experts have painstakingly compiled consent forms which also include *Patient Information Leaflets* for each surgery, for our ready use.

As we are aware, Medicolegal cases upon Doctors are on the rise globally, making it the need of the hour for us to have documents that can support us legally, if the need arises. Although it is a common practise across the country to obtain consents from the patients prior to every surgery, the consents vary from institution to institution. As an organization, The AOI took this enormous step to draft a common format of obtaining consents, under the guidance of experts in the field of Otorhinolaryngology as well as Medicolegal experts. The objective was to prepare a simple yet comprehensive consent forms for all ENT, Head & Neck surgeries, that can be readily used by all ENT, Head & Neck Surgeons in the country. This year, we have released the first Edition of the Uniform Consent Forms wherein, we have integrated the routinely performed ENT, Head & Neck surgeries. In the coming year, we propose to include advanced surgeries as well so as to provide a comprehensive manual that can be used by the ENT, Head & Neck fraternity.

When I took over as the President of AOI in 2022, I pledged to complete this mission on a priority basis and today I am happy to put this work forward, before all of you. A task of this enormity would not have been possible without the help and hard work of all those involved in preparing this. I could not thank them enough for all the extra hours that they have put into it to make this possible.

I profusely thank our legal experts who have assiduously verified the documents and have given us valuable inputs and guidance in creating them.

The entire team has worked hard for constructing and compiling these documents and we hope they will be put to good use in our clinical practise.

I wish you all a safe and successful ENT, Head & Neck practice.

Regards

Dr Bharathi M B

President

Association of Otolaryngologists of India



From the Desk of Experts

Dr Lalit Kapoor

Medical Director Shakuntala Memorial Hospital

It is indeed extremely heartening to to see the results of a determined and single-minded effort to publish templates of Procedure specific Consent forms in ENT surgery .

Needless to say this has happened not a day too soon as current trends of court judgments seem to fasten liability on surgeons on account of what they consider inadequate surgical consent of the patient .

Formulating operation specific consents was thus the need of the hour . My heartiest congratulations to all those who have rendered this outstanding and invaluable service to fellow practitioners by putting together this exercise and making the near-ideal formats for specific informed consent .

My very best wishes for a legally safe and and ethical practice. These set of Consent forms will certainly go a long way in achieving this.



From the Desk of Experts

Dr Seemab Shaikh

Consultant ENT Surgeon at KEMH, Pune

The present-day scenario in India entails the need for a uniform surgical consent form for maintaining the requisite clarity and transparency with the patients and their attenders.

The reduced trust in doctors and the increasing trend of medicolegal issues calls for a uniform surgical consent booklet to make sure that the patients are cognizant of the situation and what they are dealing with, to maintain utmost care and caution in informing the patients and their attenders everything that they need to be informed, to have everything documented in black and white, and finally since doctors are also humans and patients get a clear understanding that certain things are beyond the control of the surgeon.

A universal consent form across India is the need of the hour, so as to reduce the grey areas in working patterns by making sure everyone is on the same page with respect to the surgical consents.

Dr Rupali Patil Jain

ENT Srgeon, Allergologist & Medicolegal Consultant

Informed consent is mandatory before any invasive procedure. Every human being of adult years and sound mind has a right to determine what shall be done with his own body;and a surgeon who performs an operation without his patient's Consent commits an assault which for which he is liable in damages. That invasion of body without consent of holder is considered unconstitutional.

The principles of informed consent have been delivered by Supreme Court in a landmark judgement -Samira Kohli vs Dr Prabha Manchanda in jan 2008. Every ENT surgeon must know these principles. There should be a separate consent for every procedure because the steps of every procedure, risks involved and Alternative treatment differ in every patient. The information given to patient should be of that extent which is accepted as normal and proper by a body of Medical men skilled and experienced in the particular field.

To make things easy for every AOI member, AOI body has prepared these Procedure specific consent forms, keeping Supreme Court guidelines in mind.

We all hope each and every AOI member takes advantage of this and practices safely.

I wish each one of you a litigation free practice.





Index

General Consents 1. Consent for admission to hospital 2. Consent for discharge against medical advice 3. High risk consent. 4. Consent for blood/blood product transfusion 5. Consent for Anaesthesia **Consent for Ear Surgeries** 1. Myringotomy 2. Tympanoplasty . 3. Mastoidectomy for COM- Mucosal type 4. Mastoidectomy for COM- squamous type . 5. Stapedotomy **Consent for Nose Surgeries** 1. Septoplasty 2. Functional Endoscopic Sinus Surgery 3. Benign Tumours of the Nose and PNS **Consent for Throat Surgeries** 1. Adenoidectomy . 2. Tonsillectomy 3. Direct Laryngoscopy 4. Rigid Esophagoscopy 5. Micro/Endo laryngeal surgery. 6. Sistrunk Operation 7. Tracheostomy 8. Thyroidectomy 9. Parotidectomy 10. Neck dissection 11. Composite resection and Reconstruction





How to use the Uniform Consent Forms

- 1. The AOI has come up with Uniform Consent Forms specific to the surgeries keeping in mind the changing Medico Legal scenario in the country.
- 2. Each consent form has an initial content which is Patient Information related to the specific disease and the surgery, which every patient undergoing the surgery must know prior to signing the Undertaking while giving consent for undergoing the surgery.
- 3. We have also incorporated a section on General Consents which are self-explanatory documents. These documents have general information for the patients and have been curated in consultation with various Medico Legal experts.
- 4. While counselling the patient for the surgery, it is advisable to provide these forms to the patients to go through the general information about the disease and the surgery.
- 5. A few blanks have been left in the form which can be used to fill individual risks and medical issues that the patient may have
- 6. Each consent form must be signed by the patient/guardian (in case of a minor), the treating doctor, and two witnesses, one from the patient's side and one from the doctor's side.
- 7. If the patient wants to put a thumb impression or cannot read the language, it must be documented that the details were explained to him/her in a language they follow before taking the signature/thumb impression.





Consent for Admission to the Hospital

- **I.** I understand the administrative rules and regulations of the hospital which include but are not limited to the following
 - 1. I am aware of the different types of rooms/wards in the hospital and their respective medical infrastructure and amenities.
 - 2. I understand that a responsible attender must be available with me during the entire stay in the hospital.
 - 3. I am also aware of the timings allotted for visitors in the hospital.
 - 4. I understand that I may be asked to provide photo ID proof and a proof of residence of the patient at the time of admission
 - 5. I understand that I must not carry valuables with me in the hospital and that the hospital will not be held responsible for any loss of personal belongings or valuables during my stay in the hospital
 - 6. I understand that smoking and drinking is not allowed in the hospital
 - 7. I understand that the hospital cannot be held responsible for accidents due to any natural calamity or unforeseen circumstances.
 - 8. I authorise the house keeping and the other staff to manage the relevant activities during my stay in the hospital
- II During my stay in the hospital, I authorise the healthcare facility and the medical and paramedical staff
 - 1. to provide such diagnostic and therapeutic procedures and treatment as deemed necessary in their judgement for my care. These may include I. V infusions, Catheterizations, Ryles tube feeding, Enema, shaving to prepare relevant parts etc. The above list is indicative and not exhaustive.
 - 2. to dispose of any specimen that may be obtained during my stay in the hospital such as blood, body tissues, secretions or organs.

III During my stay in the Hospital

- 1. I authorise another qualified doctor to take care of my treatment in the absence of my treating doctor.
- 2. I authorise the medical and paramedical staff to reveal my healthcare record t another Health care facility if deemed necessary
- 3. I authorise the Hospital to provide my health records to the Government authorities if necessary
- 4. I authorise the Hospital to provide my health record documents for medical reimbursement and insurance.



- 5. I agree to cooperate with the doctors and the Nursing staff and will follow their advice regarding my overall treatment.
- 6. I agree to provide all my past medical and treatment details as well as allergies to my treating doctor.
- 7. I consent to the use of my medical and treatment details for academic and research purposes in the form of publications and presentations provided the picture or the descriptive texts do not reveal my identity.
- **IV** I have been made to understand the rules and regulations of the billing department of the hospital as stated below.
 - 1. I have been informed about the estimate of my bill
 - 2. I have been explained that the final bill may vary from the estimated bill depending on the course of my stay and treatment and various services provided.
 - 3. I have been made to understand the advance payment policy of the hospital
 - 4. I understand that in case of medical insurance, the responsibility of getting the claim approved is mine and in the event the Insurance company does not provide the sanction letter till the time of discharge, I will still have to settle the whole bill.
 - 5. I also understand that from the time the doctor declares the patient to be discharged, a fair amount of time will be required to finalise the bill.
- V I understand that no guarantee about the result or outcome of the treatment has been given to me.
- VI I hereby give a free informed consent willingly without any influence, coercion or mistake of facts.

Note: If the patient is less than 18 years/ not in a physical or mental condition to give consent, the consent is to be obtained by an Authorised Representative (Parents or Legal Guardian in the case of a child).

| Patient / Authorised Representative Signature |
|---|
| Date & Time |
| Relation to the patient |



Discharge against Medical Advice

| I aged |
|--|
| residing at |
| |
| equest the discharge of Mr/Mrs/Miss/Baby |
| aged residing at |
| |
| Even though the treating doctor, Dr |
| nas not told for discharge. |
| |
| State the following |
| 1. I have understood the present medical condition of the patient, |
| the need to |
| continue the treatment and the consequences of discontinuing the current treatment. |
| 2. I have understood the above information and still wish to leave the hospital even though |
| the treating doctor has not told for a discharge |
| 3. I have been given the details of the treatment given so far and the follow up advice. |
| 4. I have been advised to not stop the treatment immediately but to avail the rest of the care from a health care facility of my choice. |
| I declare that this decision has been made by my free will in a sound mind without any nfluence or coercion or mistake of facts. |
| Patient / Authorised Representative Signature: |
| Date & Time |
| Relation to the Patient |



High Risk Consent

| I | aged |
|--|---|
| residing at | |
| explained that I / my | |
| Mr/Mrs/Miss/Baby | |
| Aged / Gender residing at | |
| | am/is |
| suffering from | |
| Dr | |
| I state as under | |
| 1. I have been explained about the medica prognosis of the condition | l condition, the proposed treatment and the |
| OR | |
| I have been explained that there has been a and is serious. | sudden deterioration in the patient's condition |
| 2. I have been made aware that despite all patient. | efforts there could be a risk to the life of the |
| Unit and may require further interventi | e a need t shift the patient to Intensive Care ons/surgery or other emergency proceduresin addition to and different from those |
| | ed information and give a free willing consented with the proposed line of management |
| | |
| | |
| Patient / Authorised Representative Signature | : |
| Date & Time | |
| Relation to the Patient | |



Consent for Transfusion of Blood / Blood Products

| I | aged |
|--|----------|
| residing at | · · |
| | |
| my free and valid consent for transfusion of Blood and Blood | O |
| (relation) Mr/Mrs/Miss/Baby | residing |
| ataged / g | ender |
| residing at | |
| | |

Blood transfusion is a life saving medical procedure. It is a process by which blood stored in the Blood Bank can be infused into our body through an IV infusion. Blood can be given as whole blood or as components such as Packed red Blood Cells(PRBC), Platelets, Plasma and Cryoprecipitate. Blood and its products are processed in the Blood Bank and are tested for the Blood Group, Hb concentration and the presence of various Viruses and Bacteria. The blood to be transfused is ross matched with that of the person receiving it and only once the compatibility is confirmed it is released from the blood Bank. The staff nurse/doctor further confirms that it has been certified by the blood bank and only then it is transfused to the patient. In spite of prior checking, Blood transfusion can cause allergic reactions in the person receiving it and hence these patients are monitored during the period of transfusion.

- ⁿ I have been informed that I/my patient require/s a blood transfusion due to heavy blood loss during surgery/deficiency of a specific component due to medical or genetic causes.
- ⁿ I state that I/ my patient have been informed about the transfusion options available and expected benefits of the transfusion.
- I understand that Blood and Blood products have been prepared and tested in accordance with the rules established by national Regulation. However, there is still a slight chance that an adverse reaction can occur such as fever with or without chills and rigor, itching and hives which are treatable. Rarely an unpredictable life threatening event can also occur.
- ⁿ I have been informed that despite mandatory screening for blood borne infections such as HIV, Hepatitis B, Hepatitis C, Syphilis and Malaria, the risk of acquiring these infections cannot be totally eliminated.
- ⁿ I understand that the doctor or nurse administering the blood or its products has no way of determining if it will be suitable or not before starting the transfusion.
- ⁿ I have been explained the benefits of this procedure that it quickly replenishes the specific deficiency in the blood which no other treatment can do.
- n I understand that the doctor may use alternatives in terms of oral tablets or injections only in case the need to replenish the blood or its products is not immediate and urgent.
- $_{\rm n}\,$ I understand that refusal of blood or its products in an emergency situation can pose to be life threatening .



ⁿ I state that I have been encouraged to ask questions about the procedure and has been answered well.

I hereby give a free informed consent willingly without any influence , coercion or mistake of facts.

| Patient / Authorised Representative Signature : |
|---|
| Date & Time |
| Relation to the Patient |



Angesthesia Consent Form

| Patient 's Name: | |
|--|--|
| Age:Sex:M/F | I P No: |
| I (Patient / Authorised representative | e) |
| ` 1 | ned that I/He/She will have to undergo an operation/ |
| diagnostic procedure | under |
| anaesthesia. | |

It has been explained to me in a language I understand that all forms of anaesthesia involve some risks. Although rare, unexpected severe complications with anaesthesia can occur and involve remote possibility of infection, bleeding, drug reactions, blood clots, loss of sensation, loss of limb function, paralysis, stroke, brain damage, heart attack or death. I understand that it is not possible to list every conceivable complication of anaesthesia.

I understand that these risks apply to all forms of anaesthesia and that additional or specific risks maybe applicable to the specific type of anaesthesia.

Local anaesthesia- Injection will be given to the part which has to be operated. The local part will get anaesthetised and no pain will be felt there during surgery.

Local anaesthesia with sedation- Along with Injections given in local part to be operated I will also be sedated by giving required drugs intravenously due to which I will feel no pain and will sleep during my surgery.

Total Intravenous Anaesthesia(TIVA) for surgeries on airway- this is done by giving intravenous anaesthetic agent with mask ventilation/ high flow oxygen without putting a tube into the airway

General Anaesthesia involves injection of a drug into the bloodstream, breathed into the lungs or administered by other routes. A tube maybe placed into the windpipe resulting in a total unconscious state. Risks involved are mouth or throat pain, hoarseness, awareness under anaesthesia, injury to blood vessel, Headache, blurred vision, bruising at site of injection or drugs, nausea or vomiting, temporary difficulty in speaking damage to teeth, lips, gums, tongue.

Some of the extremely rare complications are Asthmatic reaction; Allergy to drugs; Drug interactions; Loss of sensation; Blood clots; Bleeding, Infection Loss of limb function, Paralysis, Stroke; Brain haemorrhage; Heart attack, aspiration, pneumonia.

The reactions following a local anaesthetic are pain and tingling at the site of injection, fall in BP, light headedness, blurred vision, twitching of the muscles .

The risks of the procedure are more likely if I am a smoker, have high blood pressure, asthma, Diabetes, overweight and H/o heart disease. Cardiac arrest and Death as a result of this procedure is rarely possible

I understand that the type(s) of anaesthesia used for my/his/her procedure is determined by many factors including my/his/her physical condition, the type of procedure to be performed, my doctor's preference and my/his/her own preference.

I understand that sometimes a local anaesthetic with or without sedation may not succeed completely and therefore another technique may have to be used.



I understand that my/his/her pre-existing medical problems may pose a greater risk of developing complications during and following anaesthesia.

| Individual risks to be explained by the Anaesthetist |
|--|
| 1 J |
| |
| |
| |

I ACKNOWLEDGE THAT:

- ⁿ The doctor has explained the type of Anaesthesia required for this procedure, risks of anaesthesia especially the risks that are specific to me and all other alternatives available.
- The type of anaesthesia technique used during my procedure is decided depending on many factors like my disease nature, type of surgical procedure, my physical condition, Doctor's preference as well as my own desire.
- ⁿ That sometimes a particular type of anaesthesia may not be successful on me and so another technique may have to be used or added.
- That in the event of hemodynamic instability or a delayed recovery from anaesthesia after the procedure, I may need to be artificially ventilated for a necessary period as decided by my anaesthetist. I maybe even needed to shifted to an ICU in case of any complication.
- ⁿ That I was been able to ask questions and Doctor has answered my specific queries and concerns about this procedure.

I understand all the above-mentioned details and give my consent willingly for the anaesthesia with sound mental state without any undue influence, coercion, fraud, misrepresentation or mistake of facts

I also consent to an alternate type of anaesthesia if the need arises, as deemed appropriate by my treating doctor

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |

| | EAR SURGERIES |
|--------------|--|
| 1. My | yringotomy with or without Grommet |
| 2. Ty | mpanoplasty |
| 3. Ma | astoidectomy for Chronic otitis media – mucosal type |
| 4. Ma | astoidectomy for Chronic otitis media – squamosal type |
| 5. Sta | pedotomy |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |





Myringotomy With Or Without Tube (Grommet) Placement

Part A: Patient Information Leaflet

You have been advised the above operation. Please go through the following information about the procedure.

What is Myringotomy?

A Myringotomy is a surgical procedure performed on your tympanic membrane (ear drum) to drain fluid from your middle ear. In some cases, a small tube shaped like a dumbbell may have to be placed in the opening to drain the fluid and prevent the fluid from accumulating. This procedure is carried out in unresolved 'Acute Otitis Media' and 'Secretory Otitis Media'.

What is the Procedure of Myringotomy?

Myringotomy, with or without tube insertion, may be performed under General Anesthesia to keep you comfortable but it may also be done under local or topical anesthesia. The procedure is done using an endoscope or microscope so that your eardrum can be seen clearly.

Next, a tiny hole is created in your eardrum to drain the fluid from the middle ear. The fluid drained might be sent for microbiological examination.

In some cases the surgeon may place a small tube made of silicon or Teflon to drain the fluid subsequently and help in pressure equalization. The procedure takes about 15 to 20 minutes.

No stitches are required because the incision will heal on its own. The surgeon will advise you to keep the ears dry till the time the tube is in place. The tube is expected to fall off naturally or may be removed by the surgeon within 6 months to a year.

What are the Potential benefits of this procedure?

- n Reduction in frequency of ear infections
- n Reduce hearing loss caused by fluid build-up
- n Ease ear pain and pressure

What are the risks and complications of Myringotomy?

Like any surgical procedure, there are some potential risks and complications of the procedure:

- ⁿ There could be an early extrusion of the tube (Grommet) which may need re-insertion
- ⁿ There might be a need for surgical removal of tube in case it does not fall off spontaneously
- n A permanent hole may remain in your eardrum that does not heal.
- ⁿ There could be thickening of your eardrum that could cause hearing problems
- n There is a possibility of a surgical injury to your eardrum



- n There may be excess bleeding at the time of the surgery
- n There is a possibility of developing infection of the middle ear
- ⁿ Chronic drainage may occur in the event of water entry into the middle ear through the tube.

Alternative treatment

Use of medications such as antibiotics, anti-allergy measures and decongestants. However, it does not assure the clearance of the disease and there is a possibility of progression of hearing loss.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient : |



Part B: Informed Surgical Consent - Myringotomy

| I (Patient / authorized representative), |
|--|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| admitted on |
| I/he/she have/has been diagnosed with |
| The procedure planned for the treatment of my/his/her condition(s) has been explained to me by treating surgeon namely: |
| Myringotomy (Incision of Ear drum) and placement of Plastic tube. |
| I have read the Patient Information Sheet, given to me and pertaining to the above procedure and have understood the same. |
| I have been explained and have understood the need for surgery. |
| Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me. |
| Though safe and effective in the majority of cases potential rare complications have been informed to me: |
| n Early extrusion of the tube (Grommet) which may need re-insertion |
| n Need for surgical removal of tube in case it does not fall off spontaneously |
| n A permanent hole in your eardrum that does not heal. |
| n Hardening of your eardrum that could cause hearing problems |
| n Surgical injury to your eardrum |
| n Excess bleeding |
| n Infection |
| n Chronic drainage |
| n Anesthesia complications |
| I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all. |
| The doctor has explained that due to my/his/her additional medical conditions such as |
| there might be specific additional risks such as |
| |
| |

I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.



I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient : |
| |
| Signature |
| Date & Time |
| Name (witness) |
| |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



Tympanoplasty

PART A: Patient Information Leaflet

You have been advised the above operation. Please go through the following information about the procedure.

Why do I need Tympanoplasty?

There is a hole in the ear drum called a 'perforation'. This can be caused by chronic otitis Media which is an infection in the middle ear or due to trauma. Small perforations may heal by themselves, but if it does not close, you will need surgery.

What is Tympanoplasty?

Tympanoplasty is the surgical repair of the hole in the eardrum (Tympanic Membrane) with or without the repair of the chain of bones (ossicles - which help in sound transmission to the inner ear) in the middle ear which will be decided by the doctor depending on the condition. This procedure can be done through the ear or an incision given behind the ear using an Endoscope / Microscope.

For the repair of the hole in the ear drum, a piece of tissue, known as a graft, will be taken from the ear or the area behind the ear. The tissue used could also include fat from the ear lobule or a piece of cartilage from the ear in which case an additional incision will be placed over the ear. With the support of the graft, the eardrum will heal and the hole gets closed. To correct the defect in the ossicles, either a piece of cartilage or one of the ossicles or a prosthesis (which may be metallic/ plastic may be used.) Additionally, the aeration pathway to the middle ear is opened if found blocked.

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

- n Endoscopic or microscopic examination of the ear
- n Audiometry to know the type and extent of your hearing loss
- n HRCT scan of the temporal bones in which the middle ear is housed might be asked for

What are the Potential benefits of this procedure?

- n Removal of chronic infection,
- n Repair of the perforation on the Tympanic Membrane,
- Prevention of water from entering the ear and causing recurrent infection
- n A possibility of an improvement in hearing which again depends on the type of hearing loss
- The surgeon might decide to open the mastoid (a bone related to the middle ear), based on the intraoperative findings. (Separate Mastoidectomy consent has to be obtained)



Alternative treatment

If you do not wish to undergo the surgery, you can leave the ear as it is along with intermittent antibiotics for infection and management of allergies if any. In that case, the hole in the eardrum will remain the same, and hearing loss will either remain the same or might worsen in the future.

What are the risks and complications of this procedure?

Tympanoplasty – specific risks

- n There might be a temporary loss of sensation in the operated ear.
- n There can be a bleed or clot behind the ear.
- Infection in the operated ear may rarely occur. If this were to happen, it could potentially cause the failure of the eardrum repair. Occasionally, there might be a failure of the graft to take hold with the result of a persistent perforation and may require a repeat surgery
- n Ringing in the ear and dizziness may occur which may be temporary or permanent
- n A partial or complete loss of hearing may occur rarely.
- ⁿ There may also be no improvement in hearing after this surgery despite the repair of the perforation or the middle ear bones.
- ⁿ Alteration in my taste sensation or a metallic taste, which may take many months to resolve.
- The nerve that controls the facial expression called the facial nerve also runs through the middle ear. If the bony canal through which the nerve runs is deficient, this nerve may be injured, which will cause weakness or paralysis of the muscles of one side of the face. This may be temporary or permanent.
- ⁿ Abnormal scar tissue formation may occur which might result in a wide, red scar for which another surgical procedure might be required.

| Signature Patient / Authorised Representative : | |
|---|--|
| Relation to the patient : | |
| Date & Time | |



PART B: Informed Surgical Consent - Tympanoplasty

| I (Patient / authorized representative) | |
|--|--|
| relation to the patient (in case of authorized representative) | |
| of the patient named | |
| Age / Sex IP No. / OP No | |
| admitted on | |
| I/he/she have/has been diagnosed with | |
| And I have been explained the need for surgery | |
| This Thave been explaned the need for surgery | |

I have read the Patient Information Sheet, given to me and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- n There might be a temporary loss of sensation in the operated ear.
- n There can be a bleed or clot behind the ear.
- ⁿ Infection in the operated ear may rarely occur. If this were to happen, it could potentially cause the failure of the eardrum repair. Occasionally, there might be a failure of the graft to take hold with the result of a persistent perforation and may require a repeat surgery
- n Ringing in the ear and dizziness may occur which may be temporary or permanent
- n A partial or complete loss of hearing may occur rarely.
- ⁿ There may also be no improvement in my hearing after this surgery despite the repair of the perforation or the middle ear bones.
- n I may experience an alteration in my taste sensation or a metallic taste, which may take many months to resolve.
- The nerve that controls the facial expression called the facial nerve also runs through the middle ear. If the bony canal through which the nerve runs is deficient, this nerve may be injured, which will cause weakness or paralysis of the muscles of one side of my face. This may be temporary or permanent.
- ⁿ Abnormal scar tissue formation may occur which might result in a wide, red scar for which another surgical procedure might be required.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.

The doctor has explained that due to my/his/her additional medical conditions such as there



might be specific additional risks such as.....

I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



Mastoidectomy for Chronic Otitis Media (COM) – Mucosal Type

PART A: Patient Information Leaflet

What is Mastoidectomy?

Mastoid is the bone that is present behind the ear lobe(pinna). Mastoidectomy is done either endoscopically/microscopically through a small incision in the ear canal/behind the ear. The mastoid bone is opened with a drill and the disease is completely removed from the air cells in the mastoid bone as well as the middle ear. This surgery is done when the ear infection and discharge continues to persist inspite of medical therapy. This will be followed by a Tympanoplasty (refer to the Patient Information leaflet on Tympanoplasty), for closing the hole in the eardrum as well as repair of the chain of bones in the middle ear if required.

What investigations will I be asked to undergo?

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

- n Endoscopic or microscopic examination of the ear
- n Audiometry to know the type and extent of your hearing loss
- n HRCT scan of the temporal bones in which the middle ear is housed

What are the benefits of the surgery?

The main benefits are cessation of ear discharge and an improvement in the hearing. What are the Alternatives to this surgery?

Leave the ear as it is and treat the recurrent attacks of ear infections with repeated doses of antibiotics. In that case, the disease will remain as it is and hearing loss may progress over time.

What are the risks and complications of this surgery?

- n There might be a temporary loss of sensation in the operated ear.
- ⁿ There can be a bleeding or clot behind the ear.
- ⁿ Patient may experience an alteration in my taste sensation or a metallic taste, which may take many months to resolve.
- ⁿ The nerve that controls the facial expression called the facial nerve also runs through the middle ear and mastoid. It may get injured and can lead to partial or complete palsy of one-half of the face.
- ⁿ Usually, the hearing improves after the surgery, but rarely in some people nerve deafness may occur.
- ⁿ Abnormal scar tissue formation may occur which might result in a wide, red scar for which another surgical procedure might be required.

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Informed surgical consent - Mastoidectomy for Mucosal Type

| I (Patient / authorized representative), |
|---|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No |
| admitted onand under |
| I/he/she have/has been diagnosed with |
| |
| And I have been explained the need for surgery |
| I have read the Patient Information Sheet, given to me and pertaining to the above proce- |

dure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- n There might be a temporary loss of sensation in the operated ear.
- There can be a bleeding or clot behind the ear.
- n I/he/she may experience an alteration in my/his/her taste sensation or a metallic taste, which may take many months to resolve.
- n The nerve that controls the facial expression called the facial nerve also runs through the middle ear and mastoid. It may get injured and can lead to partial or complete palsy of one-half of the face.
- ⁿ Usually, the hearing improves after the surgery, but rarely in some people nerve deafness may occur.
- n Abnormal scar tissue formation may occur which might result in a wide, red scar for which another surgical procedure might be required.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.

| The doctor has explained that due to my/his/her | additional medical conditions such as |
|---|---------------------------------------|
| | there |
| might be specific additional risks such as | |
| 81 | |
| ••••••••••••••••••••••••••••••••••••••• | |

I understand that no guarantee has been made that the procedure would improve my/his/ her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it



will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| |
| Signature |
| Date & Time |
| Name (witness) |
| |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



Mastoidectomy for Chronic Otitis Media- Squamosal type

PART A: Patient Information Leaflet

What is Cholesteatoma?

Cholesteatoma is a sac of infected skin from the eardrum extending into the middle ear. This sac of skin can grow larger and can cause repeated infections of the middle ear. It can also cause erosion of bone around it like the middle ear bones (responsible for sound transmission), the semi-circular canals (responsible for detection of movement and balance), the bony facial nerve canal (where Facial Nerve which controls facial expressions is housed), or the bone surrounding the brain, and can lead to hearing loss, nerve palsy, imbalance, and brain infection. This disease can extend into the bone behind the ear called the mastoid.

What is the treatment for Cholesteatoma?

Mastoidectomy with Tympanoplasty (different types are there) under General Anesthesia or Local Anesthesia

What is Mastoidectomy, specifically for Cholesteatoma?

Mastoidectomy is done endoscopically/microscopically through a small incision either in the ear canal or behind the ear. The mastoid bone is opened with a drill and the disease is completely removed from the air cells in the mastoid bone as well as the middle ear. Once the bony covering of the mastoid is removed, the resultant defect is called a mastoid cavity which is then left to open into the ear canal for future inspections of the cavity. Some surgeons may close this cavity with bone, cartilage, or muscle from around the ear and this decision will be made by the surgeon. The opening of the ear canal is made bigger to facilitate inspection of the cavity. Along with this, middle ear bone reconstruction will also be done.

What are the benefits of this surgery?

The only safe and effective way of treating cholesteatoma is by undergoing surgery and leaving it untreated will lead to various complications as stated above

Alternate treatment

There is no alternate treatment for cholesteatoma. But those who are not fit to undergo surgery/ having those minimal disease, will be asked to come for frequent follow ups for microscopic/ endoscopic examination to identify progression of the disease. In that case, a surgery might be warranted.

What are the risks and complications of this procedure?

Mastoidectomy-specific risks:

- n There might be a temporary loss of sensation in the operated ear.
- n It is common to experience some unsteadiness for a few days after mastoidectomy. Sudden head movements may cause dizziness for a few weeks. On rare occasions, prolonged dizziness may occur.



- n There can be a bleeding or clot behind the ear.
- ⁿ You may experience an alteration in my taste sensation or a metallic taste, which may take many months to resolve.
- ⁿ The nerve that controls the facial expression called the facial nerve also runs through the middle ear and mastoid. It may get injured and can lead to partial or complete palsy of one-half of the face.
- ⁿ Recurrence or residual disease may be there and the chance is higher with more extensive cholesteatoma.
- ⁿ If the disease involves the middle ear bones, they will need to be removed , in which case there will be worsening of hearing.
- ⁿ Abnormal scar tissue formation may occur which might result in a wide, red scar for which another surgical procedure might be required.
- ⁿ You may experience some ear discharge, even after complete removal of the cholesteatoma due to the large cavity after surgery. This discharge, though not harmful, may be bothersome and necessitate regular visits to your doctor for ear cleaning.

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Informed surgical consent - Mastoidectomy for Squamosal Type

| I (Patient / authorized representative), |
|--|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No |
| admitted on and under |
| I/he/she have/has been diagnosed with |
| And I have been explained the need for surgery |
| I have read the Patient Information Sheet given to me and pertaining to the above proce- |
| I have read the Patient Information Sheet, given, to me and pertaining to the above proce- |

I have read the Patient Information Sheet, given to me and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- n There might be a temporary loss of sensation in the operated ear.
- n There can be a bleeding or clot behind the ear.
- ⁿ It is common to experience some unsteadiness for a few days after mastoidectomy. Sudden head movements may cause dizziness for a few weeks. On rare occasions, prolonged dizziness may occur.
- ⁿ I/he/she may experience an alteration in my taste sensation or a metallic taste, which may take many months to resolve.
- The nerve that controls the facial expression called the facial nerve also runs through the middle ear and mastoid. It may get injured and can lead to partial or complete palsy of one-half of the face.
- n Recurrence or residual disease may be there and the chance is higher with more extensive cholesteatoma.
- ⁿ Abnormal scar tissue formation may occur which might result in a wide, red scar for which another surgical procedure might be required.
- $_{\rm n}$ If the disease involves the middle ear bones, they will need to be removed , in which case there will be worsening of hearing.
- ⁿ I may experience some ear discharge, even after complete removal of the cholesteatoma due to the large cavity after surgery. This discharge, though not harmful, may be bothersome and necessitate regular visits to the doctor for ear cleaning.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.



| <u> </u> |
|---|
| The doctor has explained that due to my/his/her additional medical conditions such as |
| might be specific additional risks such as |
| I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care. |
| I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience. |
| I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health. |
| I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital. I understand that photographs and video footage may be taken during my/his/her opera- |
| tion and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo) I have been explained in a language I understand and I hereby give my free and volun- |
| tary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts. |
| I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction. |
| Signature |
| Date & Time |
| Name |
| (Patient / Authorized representative) |
| Relation to the patient: |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| |

Designation & Reg. No.



PART A: Patient Information Leaflet

Why do I need a Stapedotomy?

You will be advised stapedotomy if you have a condition known as Otosclerosis. Otosclerosis is a disease in which there is a abnormal change in the small bone (Stapes) which is present in the middle ear which causes fixity of the chain of bones and leads to hearing loss.

What is Stapedotomy?

In stapedotomy, a part of the immobilized Stapes bone called the 'suprastructure' is removed and replaced by a prosthetic device called a piston (Teflon/Metallic). A small hole is made on the footplate of stapes to place the piston, using Hand burr/ Skeeter/LASER. This prosthetic device allows the bones in the middle ear to move. This procedure is done through the ear canal using a Microscope/Endoscope. A small piece of fat may be taken from the ear lobule through a separate incision, for fixing the piston in its place.

Otosclerosis affects both ears and only one ear will be operated on at a time, preferably the worse-hearing ear

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

- n Endoscopic or microscopic examination of the ear
- n HRCT scan of the temporal bones in which the middle ear is housed
- n Audiometry to know the type and extent of your hearing loss

Potential benefits of this procedure

Improvement or complete restoration of the hearing.

Upon opening the middle ear, there is a possibility of an aborted attempt if the surgeon finds abnormal anatomy(low lying facial nerve/ persistent stapedial artery/ high promontory), which might make it risky to proceed with the procedure.

Alternative treatment

If you do not wish to undergo the surgery , the alternative is to use hearing aids, which will not alter the course of the disease. However, there is a possibility of a further worsening of hearing in the future.

Stapedotomy-specific risks

- n Ringing in the ear and dizziness may occur which may be temporary or permanent
- n A partial or complete loss of hearing may occur rarely.
- ⁿ There may also be no improvement in hearing after this surgery despite the replacement of the fixed bone by a prosthesis
- n Alteration in my taste sensation or a metallic taste may take many months to resolve.



- ⁿ The nerve that controls the facial expression called the facial nerve also runs through the middle ear. Although extremely rare, this nerve may also be injured, which will cause weakness or paralysis of the muscles of one side of the face. This may be temporary or permanent.
- ⁿ The prosthesis placed may get displaced in which case there will be no improvement in hearing.
- ⁿ Perilymph gusher- in which case the surgeon might be able to place the piston, but the patient might develop Sensorineural hearing loss.

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



Part B: Informed Surgical Consent - Stapedotomy

| I (Patient / authorized representative) |
|---|
| elation to the patient (in case of authorized representative) |
| f the patient named |
| age / Sex IP No. / OP No |
| dmitted on and under |
| I/he/she have/has been diagnosed with |
| And I have been explained the need for surgery |
| I have read the Patient Information Sheet, supplied to me and pertaining to the above |
| rocedure and have understood the same. |

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and including:

- n There might be a temporary loss of sensation in the operated ear.
- n Ringing in the ear and dizziness may occur which may be temporary or permanent
- n A partial or complete loss of hearing may occur rarely.
- ⁿ There may also be no improvement in my hearing after this surgery despite the replacement of the fixed bone by a prosthesis
- ⁿ I/He/She may experience an alteration in my/his/her taste sensation or a metallic taste which may take many months to resolve.
- The nerve that controls the facial expression called the facial nerve also runs through the middle ear. Although extremely rare, this nerve may also be injured, which will cause weakness or paralysis of the muscles of one side of my face. This may be temporary or permanent.
- ⁿ The prosthesis placed may get displaced in which case there will be no improvement in hearing
- Perilymph gusher- in which case the surgeon might be able to place the piston, but I/ he/she might develop Sensorineural hearing loss.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.

| The doctor has explained that due to my/his/her | additional medical conditions such as |
|---|---|
| | there might be specific ad- |
| ditional risks such as | <u> </u> |
| | |
| | *************************************** |

Cianatura



I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient : |
| |
| Signature |
| Date & Time |
| Name (witness) |
| |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



NASAL SURGERIES

- n Septoplasty
- n Functional Endoscopic Sinus Surgery
- $_{\mbox{\tiny n}}$ Surgery for Benign Tumours of the Nose and Paranasal Sinus



Septoplasty

PART A: Patient Information Leaflet

What is Septoplasty and when is it done?

It is a surgical procedure for the correction of a bent or deviated nasal septum which separates the two nasal cavities. It might require removal or re-fashioning of a part of the cartilage or bone or both. It is performed entirely within the nose, with or without the use of an endoscope, and leaves no visible scars on the nose. Other related nasal symptoms like allergy, external deformity, and sinusitis may not improve with this treatment. It may be combined with Rhinoplasty for correction of external deformity or FESS for the treatment of sinusitis.

What are the potential benefits of this procedure?

Possibility of an improvement in Nasal obstruction and its sequele

What is the Alternative treatment?

Additional treatment options might address associated problems like nasal blockage, head-ache, occasional bleeding, sinusitis, and post-nasal drip temporarily by the use of nasal spray and nasal douching but that may not improve the primary pathology.

What are the other surgeries for the septum?

The other surgery for septal deviation is Sub Mucosal Resection which will be decided by your Surgeon based on the type of deviation.

What are the risks and complications of this procedure?

Septoplasty-specific risks

- n Bleeding may occur rarely
- There is a possibility of developing infection which might lead to collection of pus within the septum
- n Occasionally a hole(perforation) may form within the septum
- Rarely the shape of the nose may change with a deformity called as Saddle nose deformity
- n There is a rare possibility of a leak of the brain fluid called CSF through the nose
- ⁿ The infection from the nose may track towards the brain resulting in ,meningitis although it is very rare.
- ⁿ There may be the bands that might form within the nose called Synechiae which is due to abnormal healing process
- n No or incomplete relief of nasal blockage or associated headache

Date & Time



| n Persistence of the sinus infection/ allergy may necessitate repeated procedures. |
|--|
| |
| Signature Patient / Authorised Representative : |
| Relation to the patient: |



PART B: Informed Surgical Consent – Septoplasty

| I (Patient / authorized representative) |
|---|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No |
| admitted on and under |
| I/he/she have/has been diagnosed with |
| And I have been explained the need for surgery |
| I have read the Patient Information Sheet, given to me and pertaining to the above proce- |
| dure and have understood the same. |

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

Risks associated with the procedure are

- n Bleeding may occur rarely
- ⁿ There is a possibility of developing infection which might lead to collection of pus within the septum
- n Occasionally a hole(perforation) may form within the septum
- Rarely the shape of the nose may change with a deformity called as Saddle nose deformity
- n There is a rare possibility of a leak of the brain fluid called CSF through the nose
- The infection from the nose may track towards the brain resulting in ,meningitis although it is very rare.
- There may be the bands that might form within the nose called Synechiae which is due to abnormal healing process
- n No or incomplete relief of nasal blockage or associated headache
- n Persistence of the sinus infection/ allergy may necessitate repeated procedures.

Common consequences of surgery might include temporary breathing through the oral cavity due to bilateral nasal packing which might cause headache, post-nasal drip, increased watering of eyes, sense of nasal regurgitation, pain, and blood-stained nasal discharge. Improper nasal hygiene can even lead to excoriation of the surrounding skin. I have been explained regarding the need for nasal wash/ sprays to dislodge crusts that will form post-surgery. I have been explained that failure to do so might cause nasal infection.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.



| AOI OIIIIOIIII COIIseitts |
|--|
| The doctor has explained that due to my/his/her additional medical conditions such as |
| might be specific additional risks such as |
| I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care. |
| I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience. |
| I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health. |
| I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital. |
| I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo) |
| I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts. |
| I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction. |
| Signature |
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |

Designation & Reg. No.



Functional Endoscopic Sinus Surgery

PART A: Patient Information Leaflet

Why do I need Functional endoscopic sinus surgery?

The Infection in the Paranasal sinuses (Maxillary/Ethmoid/Frontal /Sphenoid) of one or both sides of the nose may be Allergic, bacterial, or Fungal in origin with or without polyps in the nasal cavity.

It may be associated with abnormalities of Turbinates(Inferior/Middle /Superior) or Deviated nasal septum (Bony/Cartilagenous)

It may rarely involve the eye socket or its wall or Dura (the lining of the brain) in cases of Fungal or severe bacterial Infection.

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

- n Examination of the nasal cavity by using diagnostic nasal endoscopy.
- n CT Paranasal sinuses

What is Functional endoscopic sinus surgery?

Surgical procedure for the removal of polyp/pus from one or all the involved sinuses as mentioned above along with adequate widening of sinus opening in case of Maxillary/Frontal/Sphenoid and Ethmoidectomy in case of Ethmoid sinus for removal of diseases. The procedure may also involve removal of a part of the cartilage/ bone of the nasal septum to gain exposure to sinuses and removal of one of the turbinates (bony scrolls on the side walls within the nose) to remove the diseases.

It is performed entirely within the nose, with the use of an endoscope, and leaves no visible scars on the nose

The surgical process may involve the use of powered instruments like microdebrider, coblation, balloon sinuplasty system, and drills for optimal outcomes.

Potential benefits of this procedure

Surgery will open all the sinuses for ventilation and provides an easy reach of topical drugs. But it may not cure the primary pathology like Allergy and fungal infections and post-surgery long-term medical therapy is required to keep the disease in control.

What is the Alternative treatment?

Long-term Local and Systemic medical therapy using oral/injectable antibiotics, steroid nasal sprays, and anti-histaminic agents may be helpful for some patients who are deferring/not fit for surgery.



What are the risks and complications of this procedure?

FESS specific risks:

- n Bleeding
- n Infection with the possibility of pus discharge, post nasal drip
- n Injury to the dura leading to CSF leak
- n Meningitis which is highly likely in cases of Dural Involvement
- n Injury to orbit/ optic nerve, deterioration of vision
- n Synechiae formation (bands within the nose due to improper healing)
- n Recurrence of the polyp or fungal infection
- ⁿ No or incomplete relief of nasal blockage or associated headache.

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient: |
| Date & Time |



PART B: Informed Surgical Consent – Functional Endoscopic Sinus Surgery

| I (Patient / authorized representative), |
|---|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No |
| admitted on and under |
| I/he/she have/has been diagnosed with |
| And I have been explained the need for surgery |
| I have read the Patient Information Sheet, given to me and pertaining to the above procedure and have understood the same |

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- n Bleeding
- n Infection with the possibility of pus discharge, post nasal drip
- n Injury to the dura leading to CSF leak
- Meningitis which is high in cases of Dural Involvement
- n Injury to orbit/ optic nerve, deterioration of vision
- n Synechaie formation
- n Recurrence of the polyp or fungal infection
- n No or incomplete relief of nasal blockage or associated headache.

This surgery may not address associated problems like headache, and vision issues.

Common consequences of surgery might include temporary breathing through the mouth due to bilateral nasal packing which might cause headache, increased watering of eyes, postnasal drip, sense of nasal regurgitation, pain, and blood stain nasal discharge. Improper nasal hygiene can even lead to excoriation of the surrounding skin.

I have been explained regarding the need for nasal wash/ sprays to dislodge crusts that will form post surgery. I have been explained that failure to do so might cause nasal infection.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.

| The doctor has explained that due to my/his/her | additional medical conditions such as |
|---|---------------------------------------|
| | there |
| might be specific additional risks such as | |
| 8 | |
| | |



I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.



Benign Tumors of the Nose and Paranasal Sinus

PART A: Information on Benign Tumors of the Nose and Paranasal Sinus

What are Benign Tumours of the Nose and Paranasal Sinuses?

Tumoral mass (commonly seen are Inverted Papilloma/JNA/Fibro-osseous) lesion in the nasal cavity, Nasopharynx, and Paranasal sinus (Maxillary/Ethmoid/Frontal /Sphenoid) of one or both sides of my nose which is a vascular growth in above areas and it may be associated with involvement of other nasal structure like turbinates (Inferior/Middle/Superior), Tear drainage system or nasal septum (Bony/Cartilagenous)

In rare cases, It may involve eye socket or its wall, Skull base, or Dura in some cases

The Doctor might ask you to get the following investigations before deciding on your surgery

- n Examination of the nasal cavity by using diagnostic nasal endoscopy.
- n CT Paranasal sinuses
- n CECT/MRI Contrast Paranasal sinuses to know about the extension of tumor
- n Biopsy and Histopathological examination of the tissue

How is the tumour removed?

The mass can be removed either endoscopically or by an open approach. The procedure may involve opening of Maxillary/Frontal/Sphenoid and Ethmoid sinus for remov al of disease or to gain access to tumoral mass. The procedure may also involve removal of a part of the cartilage/ bone of the nasal septum to gain exposure to sinuses and removal of one of the turbinates to remove the diseases. Surgical procedures may also involve the removal of bone around the nose and cutting of the tear duct which drains tears from the eye to the nose to gain wide exposure to the nasal cavity.

The surgical process may involve the use of powered instruments like microdebrider, coblation, vascular clips, Nerve monitor, Colour Doppler and drills for optimal outcomes.

What are the Alternative treatments?

Depending upon the hisotopathology, the Surgeon will discuss the alternative treatments with you.

What are the Specific risks and complications?

- n Bleeding
- n Residual and recurrence of disease
- n Infection with the possibility of pus discharge, post nasal drip
- ⁿ Injury to the dura leading to CSF leak, Meningitis which is high in cases of Dural Involvement
- n Injury to orbit/ optic nerve, deterioration of vision



- n Synechaie formation,
- ⁿ Formation of a polyp during the healing process
- $_{\mbox{\scriptsize n}}$ $\,$ No or incomplete relief of nasal blockage or associated headache.
- $_{\rm n}$ $\,$ Possible need for further surgery/radiation therapy/Chemotherapy depending on final histopathology report

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Informed Surgical Consent – Benign Tumors of the Nose and Paranasal Sinus

| I (Patient / authorized representative) |
|---|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No |
| admitted on and under |
| I/he/she have/has been diagnosed with |
| And I have been explained the need for surgery |
| I have read the Patient Information Sheet, supplied to me and pertaining to the above |
| procedure and have understood the same. |

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and which include:

- n Bleeding
- n Residual and recurrence of disease
- n Infection with the possibility of pus discharge, post nasal drip
- ⁿ Injury to the dura leading to CSF leak, Meningitis which is high in cases of Dural Involvement
- n Injury to orbit/ optic nerve, deterioration of vision
- n Synechaie formation,
- Formation of a polyp during the healing process
- No or incomplete relief of nasal blockage or associated headache.
- Possible need for further surgery/radiation therapy/Chemotherapy depending on final histopathology

Common consequences of surgery might include temporary breathing through the mouth due to bilateral nasal packing which might cause headache, lacrimation, post-nasal drip, sense of nasal regurgitation, pain, and blood stain nasal discharge. Improper nasal hygiene can even lead to excoriation of the surrounding skin.

I have been explained regarding the need for nasal wash/ sprays to dislodge crusts that will form post surgery. I have been explained that failure to do so might cause nasal infection.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.

The doctor has explained that due to my/his/her additional medical conditions such as there



| might | be | specific | additional | risks | such | as | ••••• | ••••• | • | ••••• | ••••• | ••••• | •••••• | ••••• |
|-------|----|----------|------------|-------|------|----|-------|-------|---|-------|-------|-------|--------|-------|
| | | | | | | | | | | | | | | |

I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient : |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



THROAT/ HEAD AND NECK SURGERIES

- 1. Adenoidectomy
- 2. Tonsillectomy
- 3. Rigid Direct laryngoscopy
- 4. Rigid Esophagoscopy
- 5. Micro/Endo laryngeal Surgery
- 6. Thyroglossal Cyst
- 7. Tracheostomy
- 8. Thyroidectomy
- 9. Parotidectomy
- 10. Neck dissection
- 11. Composite Resection and Reconstruction



Adenoidectomy

PART A: Patient Information on Adenoidectomy

Why is Adenoidectomy needed?

Adenoidectomy is the treatment for Chronic Adenoid enlargement. Adenoids are lymphoepithelial tissue situated behind the nasal cavities (nasopharynx). It may get enlarged in children due to repeated infections of the upper respiratory tract. When enlarged, it may block the opening of the Eustachian tube, which is a communication between the back of the nose and the middle ear. Adenoid enlargement can cause nose block, open mouth breathing, snoring, disturbed sleep, decreased concentration, poor scholastic performance, ear-blocking sensation, middle ear infections and deafness if left untreated.

What is Adenoidectomy?

It is the surgical removal of the enlarged adenoid which is situated behind the nose. It is usually done using an endoscope along with powered instruments like microdebrider/coblator. It can also be done using a curette. In both techniques, instruments are passed into the nasopharynx via the mouth. A mouth gag is placed for mouth opening and easy visualization of the oral cavity and oropharynx. No incisions are placed externally and there will be no visible scars due to the surgery.

This surgery is done under General Anesthesia.

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

- ⁿ Examination of the nasopharyngeal region via diagnostic nasal endoscopy (DNE)to look for enlarged adenoids
- n X-RAY Nasopharynx soft tissue lateral view

What are the potential benefits of this procedure?

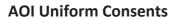
Possibility of an improvement in symptoms such as nose block, mouth breathing, snoring, and ear-blocking sensation.

What is the alternative treatment?

Use of medications such as nasal drops/spray may give temporary symptomatic relief. But the underlying problem may or may not get relieved by these medications alone.

What are the Adenoidectomy-specific risks and complications?

- ⁿ Intraoperative bleeding.
- n Postoperative infections.
- In case of endoscopic surgeries injury to the parts within the nasal cavity and behind the nose (injury to the septum, lateral wall of the nose, torus tubaris, or Eustachian tube orifice may happen).





- $_{\rm n}$ Injury to the structures in the mouth -
- ⁿ Chances of trickling of blood into the lungs which can give rise to lung infections.
- n Recurrence and persistence of symptoms

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient: |
| Date & Time |



PART B: Informed Surgical Consent - Adenoidectomy

| I (Patient / authorized representative), |
|---|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No |
| admitted on |
| |
| I/he/she have/has been diagnosed with |
| And I have been explained the need for surgery |
| I have read the Patient Information Sheet, supplied to me and pertaining to the above |
| procedure and have understood the same. |

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- n Intraoperative bleeding.
- n Postoperative infections.
- n In case of endoscopic surgeries injury to the parts inside the nose and behind the nose.
- n Injury to the structures within the mouth
- n Chances of trickling of blood into the lungs in turn giving rise to lung infections
- n Recurrence and persistence of symptoms

| The doctor has explained that due to my/his/her | additional medical conditions such as |
|---|---------------------------------------|
| | there |
| might be specific additional risks such as | |
| 8 1 | |
| *************************************** | |

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me /him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.

I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.



I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient : |
| |
| Signature |
| Date & Time |
| Name (witness) |
| |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No |



Tonsillectomy

PART A: Patient Information Leaflet

Why do I need Tonsillectomy?

Tonsils are pairs of soft tissue masses situated at the back of the throat (oropharynx). When it gets infected repeatedly, it may enlarge leading to acute/chronic tonsillitis. The patient may have symptoms such as throat pain, difficulty in swallowing, pain during swallowing, and fever spikes.

How is Tonsillectomy performed?

In tonsillectomy, after proper positioning, a mouth gag is placed for mouth opening and easy visualization of the mouth. No incisions are placed outside the throat and there will be no visible scars due to the surgery. Enlarged tonsils are visualized and are removed by using surgical instruments. Sometimes, a powered instrument called a Coblator /Laser might be used.

What are the potential benefits of this procedure:

There can be a reduction in in symptoms such as throat pain, difficulty, and pain during swallowing as well as fever episodes.

What is the alternative treatment:

The use of medications such as antibiotics and painkillers may give symptomatic relief during an active infection, but a permanent solution is a surgery.

What are the Tonsillectomy-specific risks and complications:

- ⁿ Intraoperative bleeding.
- n Postoperative infections.
- n Bleeding from the mouth after the surgery, and occasionally a week after the surgery
- Injury to the structures in the mouth -
- n Chances of trickling of blood into the lungs which can give rise to lung infections.
- n Recurrence and persistence of symptoms

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Informed Surgical Consent – Tonsillectomy

| I (Patient / authorized representative) |
|---|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No |
| admitted on |
| I/he/she have/has been diagnosed with |
| And I have been explained the need for surgery |
| I have read the Patient Information Sheet, given to me and pertaining to the above proce- |
| dure and have understood the same. |

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- n Intraoperative bleeding.
- n Postoperative infections.
- n Bleeding from the mouth after the surgery, and occasionally a week after the surgery
- n Injury to the structures in the mouth
- n Chances of trickling of blood into the lungs which can give rise to lung infections.
- n Recurrence and persistence of symptoms

It has been explained that throat and oral hygiene has to be maintained by gargles after the surgery and failure to do so can lead to infection and bleeding.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/his/her prognosis and risks of not undergoing the surgery at all.

| The doctor has explained that due to my/his/her | additional medical conditions such as |
|---|---------------------------------------|
| | there |
| might be specific additional risks such as | |
| | |
| | ••••• |

I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.



I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| |
| Signature |
| Date & Time |
| Name (witness) |
| |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



Direct Laryngoscopy

PART A: Patient Information Leaflet

What is Direct Laryngoscopy

Direct Laryngoscopy is the examination of the throat(pharynx) and wind pipe(larynx) under general anesthesia/local anaesthesia. This is done to find and treat problems with the throat and wind pipe.

A short metallic tube (laryngoscope) is passed through the mouth into the larynx. This is done usually to look for the presence of a foreign body or growth which is causing difficulty in breathing /swallowing . If a growth is seen, a small piece of the tissue is taken (biopsy) and sent for examination. In the case of a visualized foreign body, it is removed to relieve the obstruction.

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

Blood tests/ CECT scan of the neck

What are the potential benefits of this procedure:

The intended benefit of the procedure is to diagnose the underlying disease and remove the offending disease and to prevent the progress of the illness.

What are the alternatives to this procedure?

Not undergoing the procedure would lead to progress of the disease in the case of a tumour and persistence of the obstruction or the collection of pus due to infection in the case of a foreign body. The final biopsy report, if in case of growth is confirmatory and you may need further surgery/medical treatment or radiotherapy depending upon the results. Despite surgical and medical treatment, there can be a recurrence of the problem in some cases.

What are the risks and complications of this procedure?

Direct Laryngoscopy procedure -specific risks

- Bleeding and Infections (Generally settles with medical treatment)
- ⁿ Teeth injury there is a risk that the metal tubes may chip your teeth or dental caps or crowns. If there is a loose tooth, you are advised to inform your doctor and there is a possibility that it might come off
- n Sore throat and pain for a couple of days
- ⁿ Symptoms might persist and may require additional treatment based on the biopsy report.

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Informed Surgical Consent - Direct Laryngoscopy

| I (Patient / authorized representative) |
|--|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No. |
| admitted on |
| |
| I/he/she have/has been diagnosed with |
| And I have been explained the need for surgery |

I have read the Patient Information Sheet, given to me/him /her and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- n Bleeding and Infections (Generally settles with medical treatment)
- ⁿ Teeth injury there is a risk that the metal tubes may chip my/his /her teeth or dental caps or crowns. If there is a loose tooth, there is a possibility that it might come off
- n Sore throat and pain for a couple of days
- Symptoms might persist and may require additional treatment based on the biopsy report

I acknowledge that the doctor has explained my/his /her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/ him/ her as well as my/him /her prognosis and risks of not undergoing the surgery at all.

| The doctor has explained that due to my/his/her | additional medical conditions such as |
|---|---------------------------------------|
| | there |
| might be specific additional risks such as | |
| 0 1 | |
| | |

I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.



I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo) .

I was given the opportunity to ask questions and raise concerns about the procedure to my/her/his doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient : |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No |



Rigid Esophagoscopy

PART A: Patient Information Leaflet

What is Rigid Esophagoscopy:

Rigid Esophagoscopy is the examination of the throat and food pipe under general anesthesia. This is done to find and treat problems with the food pipe.

A short metallic tube (esophagoscope) is passed through the mouth into the food pipe. This is done usually to look for the presence of a foreign body or growth which is causing difficulty in swallowing. If a growth is seen, a small piece of the tissue is taken (biopsy) and sent for examination. In the case of a visualized foreign body, it is removed to relieve the obstruction. Sometimes, there can be narrowing of the food passage called strictures or bleeding from the food passage. Rigid esophagoscopy can be done in these cases to help in the diagnosis as well as to treat the condition.

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

Blood tests/upper GI endoscopy and CECT scan of the neck

What are the potential benefits of this procedure:

The intended benefit of the procedure is to remove the offending lesion and to prevent the progress of the illness.

What are the alternatives to this procedure?

Not undergoing the procedure would lead to progress of the disease in the case of a tumour and persistence of the obstruction or the collection of pus due to infection in the case of a foreign body. In the case of a growth, final biopsy report is confirmatory and you may need further surgery/medical treatment or Radiotherapy depending upon the results. Despite surgical and medical treatment, there can be a recurrence of the problem in some cases.

What are the risks and complications of this procedure?

Rigid Esophagoscopy: procedure-specific risks

- n Bleeding and Infections (Generally settles with medical treatment)
- ⁿ Teeth injury there is a risk that the metal tubes may chip your teeth or dental caps or crowns. If there is a loose tooth, you are advised to inform your doctor and there is a possibility that it might come off
- n Sore throat and pain for a couple of days
- Symptoms might persist and may require additional treatment based on the biopsy report
- Perforation of the food passage If the surgeon needs to take a biopsy or stretch the food passage during the procedure, there is a very small risk of a tear in the lining of





this passage. This sometimes causes a leak through the wall of the passage. If this happens, the patient has to stay in the hospital and not eat or drink anything. They will then be fed with either a small tube through the nose into the stomach or through a drip into a vein in arm. This allows them to get special liquid food, while the leak in the wall of the food passage heals up (very rarely they might need additional surgery)

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Informed Consent for Rigid Esophagoscopy

| I (Patient / authorized represen | ntative) | |
|-------------------------------------|--------------------|--|
| relation to the patient (in case of | | |
| of the patient named | • | |
| Age / Sex | | |
| admitted on | | |
| | | |
| I/ne/sne nave/nas been diagno | osea with | |
| And I have been explained the | e need for surgery | |

I have read the Patient Information Sheet, given to me/him /her and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes;

- n Bleeding and Infections (Generally settles with medical treatment)
- ⁿ Teeth injury there is a risk that the metal tubes may chip my/his /her teeth or dental caps or crowns. If there is a loose tooth, there is a possibility that it might come off
- n Sore throat and pain for a couple of days
- ⁿ Symptoms might persist and may require additional treatment based on the biopsy report.
- Perforation of the food passage If the surgeon needs to take a biopsy or stretch the food passage during the procedure, there is a very small risk of a tear in the lining of this passage. This sometimes causes a leak through the wall of the passage. If this happens, i/he /she have/has to stay in the hospital and not eat or drink anything. I/he/ she will then be fed with either a small tube through the nose into the stomach or through a drip into a vein in arm. This allows me /him /her to get liquid food, while the leak in the wall of the food passage heals up (very rarely I/he/she might need additional surgery)

I acknowledge that the doctor has explained my/his /her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/ him/ her as well as my/him /her prognosis and risks of not undergoing the surgery at all.

| The doctor has explained that due to my/his/her | additional medical conditions such as |
|---|---------------------------------------|
| | there |
| might be specific additional risks such as | |
| 8 | |
| •••••••••••••••••••••••••••••• | ••••••••••• |



I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have read the Patient Information Sheet, supplied to me/him/her and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for procedure

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I was given the opportunity to ask questions and raise concerns about the procedure to my/her/his doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



Micro/Endo Laryngeal Surgery

PART A: Patient Information Leaflet

What is Micro/Endo laryngoscopy?

Micro/Endolaryngoscopy is the examination of the larynx (voice box) under general anesthesia. This is done to find and treat problems with the voice box.

A short metallic tube (laryngoscope) is placed through the mouth into the voice box. A microscopic surgery is done with very fine surgical instruments (sometimes with a Laser or coblator) with the intent to remove the lesion (whole or part). A small part of the lining of the voice box is sent for laboratory examination.

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

Blood tests/outpatient stroboscopy/ video Laryngoscopy and CECT scan of the neck

What are the potential benefits of this procedure

The intended benefit of the procedure is to remove the offending lesion and to prevent the progress of the illness.

What are the alternatives to this procedure?

Not undergoing the procedure would lead to pressure symptoms like airway obstruction/progress of the disease. The final biopsy report is confirmatory and you may need further surgery/medical treatment or Radiotherapy depending upon the results. Despite surgical and medical treatment, there can be a recurrence of the problem in some cases.

What are the risks and complications of this procedure?

Micro laryngeal surgery-specific risks

- $_{\rm n}$ $\,$ Bleeding and Infections (Generally settles with medical treatment)
- Teeth injury there is a risk that the metal tubes may chip patients teeth or dental caps or crowns. If there is a loose tooth, they are advised to inform doctor and there is a possibility that it might come off
- n Sore throat and pain for a couple of days
- ⁿ Symptoms might persist and may require additional voice therapy or more treatment based on the biopsy report
- Perforation of the food passage If the surgeon needs to take a biopsy or stretch the food passage during the laryngoscopy, there is a very small risk of a tear in the lining of this passage. This sometimes causes a leak through the wall of the passage. If this happens, the patient has to stay in the hospital and not eat or drink anything. Patient will then be fed with either a small tube through the nose into the stomach or through



a drip into a vein in arm. This allows them to get special liquid food, while the leak in the wall of the food passage heals up (very rarely you might need additional surgery)

Airway obstruction-This is extremely rare in non-cancerous conditions but can happen in the potentially cancerous or cancerous lesion of the voice box. In such a case, they will need a opening in front of the lower neck (Tracheostomy) to help you breathe by a cut made in the neck to the windpipe.

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Informed Surgical Consent - Micro/Endo Laryngoscopic Surgery

| I (Patient / authorized represen | ntative) | |
|-------------------------------------|--------------------|--|
| relation to the patient (in case of | | |
| of the patient named | - | |
| Age / Sex | | |
| admitted on | | |
| | | |
| I/ne/sne nave/nas been diagn | osea with | |
| And I have been explained the | e need for surgery | |

I have read the Patient Information Sheet, given to me and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- n Bleeding and Infections (Generally settles with medical treatment)
- ⁿ Teeth injury there is a risk that the metal tubes may chip my/his/her teeth or dental caps or crowns. If there is a loose tooth, there is a possibility that it might come off
- Sore throat and pain for a couple of days
- ⁿ Symptoms might persist and may require additional voice therapy or more treatment based on the biopsy report
- Airway obstruction-This is extremely rare in non-cancerous conditions but can happen in the potentially cancerous or cancerous lesion of the voice box. In such a case, I/he/she will need a tracheostomy to help me breathe by a cut made in the neck to the windpipe.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.

| The doctor has explained that due to my/his/her | additional medical conditions such as |
|---|---------------------------------------|
| | there |
| might be specific additional risks such as | |
| 8 | |
| •••••••••••••••••••••••••••••••• | |

I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it



will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| |
| Signature |
| Date & Time |
| Name (witness) |
| |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



Sistrunk Procedure for Thyroglossal Cyst

PART A: Patient Information Leaflet

What is Thyroglossal cyst?

Thyroglossal duct cysts result from faulty embryological development of the thyroid gland. During embryological development in the mother's womb, the thyroid gland develops from tissue located in the base of the tongue. This tissue migrates down to the neck and reaches its final destination in front of the trachea. During its descent, the thyroid gland remains connected to the base of the tongue by the thyroglossal duct, this disappears when the thyroid gland reaches the final position in the neck.

Persistence of this embryonic duct results in the formation of a cyst that will fill up mucus and fluid. Large cysts could cause difficulty in swallowing and airway obstruction. Occasionally, they get infected and form abscesses that require incision and drainage. Thyroglossal duct cysts are frequent in children and adolescents. Cancer in a thyroglossal duct cyst is extremely rare (about 1%) and is more likely to occur in females between 30 and 40 years of age.

What is the treatment?

Treatment is surgical. This operation is called the Sistrunk procedure wherein the cyst along with the attached duct and a piece of bone called hyoid is removed. By this technique the chance of the cyst coming back is minimal

Surgical treatment is directed at the removal of the cyst and the connected duct. The duct is followed superiorly to the base of the tongue. A small piece of the hyoid bone is also removed with the cyst and the attached duct. This operation is called the Sistrunk procedure.

What are the potential risks and complications of the procedure?

- n Post-operative infection
- n Bleeding
- n A very small risk of injuring the nerve which supplies the tongue (hypoglossal) which may impair the movement of food in the mouth
- n Thyroglossal duct cyst has a small chance of regrowing if small portions of the tissues remain after surgery.

Additional medical conditions like advanced age, smoking, diabetes, heart disease, lung issues, or kidney and liver problems can influence the general outcome by increasing the risk of Clot, PE, heart attack, stroke and risk of death, etc

What are the alternative treatment available?

There is no alternative medical treatment and leaving it increases the chance of Infection of the cyst before surgery and can make the removal of the cyst more difficult and increase the chance for regrowth. In adults, thyroid cancer can occur inside a thyroglossal duct cyst and may require more extensive surgery.

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient: |
| Date & Time |



PART B: Informed Surgical Consent – Sistrunk operation for Thyroglossal Cyst

| I (Patient / authorized representative) |
|--|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No |
| admitted on |
| |
| I/he/she have/has been diagnosed with |
| And I have been explained the need for surgery |

I have read the Patient Information Sheet, given to me and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- n Post-operative infection
- n Bleeding
- ⁿ A very small risk of injuring the nerve which supplies the tongue (hypoglossal) which may impair the movement of food in the mouth
- ⁿ Thyroglossal duct cyst has a small chance of regrowing if small portions Of the tissues remain after surgery.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.

| The docto | or has explained tha | t due to my/his/her | additional medical conditions such as |
|-----------|----------------------|---------------------|---------------------------------------|
| | | | there |
| | | | |
| 0 1 | | | |

I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.



I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient : |
| |
| Signature |
| Date & Time |
| Name (witness) |
| |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



Tracheostomy

PART A: Patient Information Leaflet

Why do I need Tracheostomy?

It is done for patients needing

- Prolonged mechanical ventilation (respirator), replacing the endotracheal tube that is already present in the patient.
- Destruction of the upper airway due to scar or tumor or vocal cord paralysis or severe infection
- n Improving the ability to manage secretions in a patient who is chronically aspirating (choking on their saliva).
- n Rarely for sleep apnea

What is Tracheotomy?

Tracheotomy is a life-saving procedure in which a tube (typically an inert plastic or silicone tube) is surgically inserted through an incision in the lower part of the neck, into an opening created in the trachea (windpipe) below the level of the larynx (voice box).

What are the potential benefits of this procedure?

It is a life-saving procedure in patients having block in the upper airway. It provides an alternate pathway to breath.

In patients who have prolonged ventilator requirement:

- n It reduces injury to the oral cavity and voice box caused by prolonged use of orotracheal tube.
- ⁿ It aids in easier clearance of secretions from the lungs which reduces the chances of lung infections / faster recovery from lung infections

What are the Tracheostomy-specific risks and complications?

Complications that may arise during the tracheostomy procedure or soon thereafter include:

- n Bleeding
- Air trapped around the lungs (pneumothorax)
- n Air trapped in the deeper layers of the chest(pneumomediastinum)
- n Air trapped underneath the skin around the tracheostomy (subcutaneous emphysema)
- Damage to the swallowing tube (esophagus)
- n Injury to the nerve that moves the vocal cords (recurrent laryngeal nerve)



ⁿ A tracheostomy tube can be blocked by blood clots, mucus, or pressure on the airway walls. Blockages can be prevented by suctioning, humidifying the air, and selecting the appropriate tracheostomy tube.

Later Complications that may occur while the tracheostomy tube is in place include:

- n Accidental removal of the tracheostomy tube (accidental decannulation)
- n Infection in the trachea and around the tracheostomy tube
- The windpipe itself may become damaged for several reasons, including pressure from the tube; bacteria that cause infections and form scar tissue; or friction from a tube that moves too much

Delayed Complications that may result after the longer-term presence of a tracheostomy include:

- n Thinning (erosion) of the trachea from the tube rubbing against it (tracheomalacia)
- ⁿ Development of a small connection from the trachea (windpipe) to the esophagus (swallowing tube) which is called a tracheoesophageal fistula
- ⁿ Development of bumps (granulation tissue) that may need to be surgically removed before decannulation (removal of trach tube) can occur
- ⁿ Narrowing or collapse of the airway above the site of the tracheostomy, possibly requiring an additional surgical procedure to repair it
- ⁿ Once the tracheostomy tube is removed, the opening may not close on its own. These may need closure surgically.

Additional medical conditions like advanced age, smoking, diabetes, heart disease, lung issues, or kidney and liver problems can influence the general outcome by increasing the risk of Clot, Pulmonary Embolism, heart attack, stroke and risk of death, etc

Sequalae includes – Inability to speak

- Sometimes need for tube to remain permanently
- Need of suction apparatus at home
- Temporary or permanent swallowing issues
- will not be able to swim

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Patient Informed Surgical Consent – Tracheostomy

| I (Patient / authorized representative) | • |
|--|---|
| relation to the patient (in case of authorized representative) | |
| of the patient named | |
| Age / Sex IP No. / OP No | |
| admitted on and under | |
| | |
| I/he/she have/has been diagnosed with | |
| And I have been explained the need for surgery | |

I have read the Patient Information Sheet, supplied to me and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- n Bleeding
- n Air trapped around the lungs (pneumothorax)
- n Air trapped in the deeper layers of the chest(pneumomediastinum)
- n Air trapped underneath the skin around the tracheostomy (subcutaneous emphysema)
- Damage to the swallowing tube (esophagus)
- n Injury to the nerve that moves the vocal cords (recurrent laryngeal nerve)
- A tracheostomy tube can be blocked by blood clots, mucus, or pressure on the airway walls. Blockages can be prevented by suctioning, humidifying the air, and selecting the appropriate tracheostomy tube.

Later Complications that may occur while the tracheostomy tube is in place include:

- n Accidental removal of the tracheostomy tube (accidental decannulation)
- n Infection in the trachea and around the tracheostomy tube
- ⁿ The windpipe itself may become damaged for several reasons, including pressure from the tube; bacteria that cause infections and form scar tissue; or friction from a tube that moves too much

Delayed Complications that may result after the longer-term presence of a tracheostomy include:

n Thinning (erosion) of the trachea from the tube rubbing against it (tracheomalacia)



- n Development of a small connection from the trachea (windpipe) to the esophagus (swallowing tube) which is called a tracheoesophageal fistula
- n Development of bumps (granulation tissue) that may need to be surgically removed before decannulation (removal of trach tube) can occur
- ⁿ Narrowing or collapse of the airway above the site of the tracheostomy, possibly requiring an additional surgical procedure to repair it
- ⁿ Once the tracheostomy tube is removed, the opening may not close on its own. These may need closure surgically.

Sequalae includes – Inability to speak

- Sometimes need for tubes permanently
- Need of suction apparatus at home
- Temporary or permanent swallowing issues
- Will not be able to swim

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.

| The doctor has explained that due to my/his/her | additional medical conditions such as |
|---|---------------------------------------|
| | there |
| might be specific additional risks such as | |
| 0 1 | |
| | |

I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)





I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| Signatura |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



Thyroidectomy

PART A: Patient Information Leaflet

Why do I need Thyroidectomy?

Thyroidectomy is generally done for

- n Removal of the tumor in the thyroid gland to aid in diagnosis
- n For removal of tumor which are cancerous or tumors that are suspicious of cancer
- ⁿ Enlargement of glands may be unsightly and can give rise to swallowing or breathing difficulties.
- ⁿ And rarely for Overactive glands (The gland may produce excessive amounts of thyroid hormones)

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

- n Blood tests for information regarding the functioning of Thyroid gland.
- n Ultrasound: This test uses sound waves to determine the structure of the thyroid gland.
- ⁿ Fine needle aspiration: A fine needle is used to obtain a sample of cells from the gland. These are examined under the microscope in the laboratory. This will give information about the nature of cells in the thyroid.
- Laryngeal Assessment: A small telescope is used to assess the function of the vocal cords, before any surgery and any more which your doctors deem appropriate to get a clear picture of your diagnosis

How is Thyroidectomy performed?

Surgery may consist of a total thyroidectomy (removing the entire gland) or a hemithyroidectomy (removing a single lobe and the isthmus). It is performed under general anesthesia. It is done by an incision made in the neck where Thyroid is isolated and removed, taking care to prevent injury to nerves and the parathyroid glands. A drain (straw-like tube) may be placed to prevent blood from collecting below the skin. You would be able to go home after drain removal.

What are the potential benefits of this procedure?

The intended benefit of the procedure is to remove the gland to prevent the progress of the illness. Not undergoing the procedure would lead to pressure symptoms like airway obstruction/progress of cancer/or Hormonal imbalance. The final biopsy report is confirmatory and you may need further surgery/ medical treatment based on it.

Alternative treatment:

The alternative to undergoing the surgery include but not limited to serial Ultrasound



scans, serial FNACs as well as medications in case of variations in the serial Thyroid hormonal values. However, they may not alter the course of the disease or cause variations in size of the gland. In the case of a malignant tumor of the gland, this may lead to progression of the disease with associated risks.

What are the Thyroidectomy-specific risks and complications?

- Bleeding: Blood can accumulate beneath the skin. This occurs in less than 1% of patients. Due to the location of the thyroid pressure, bleeding can cause breathing difficulties. It may be necessary to relieve this pressure by opening the wound.
- Noice changes: Nerves that control your voice box run very close to the thyroid. There is a slight risk (less than 2%) of injury to this nerve, leading to hoarseness. This is usually temporary but can also be permanent.
- Low Calcium: Parathyroid glands control calcium levels in the blood; they lie at the four corners of the thyroid gland. Every effort is made to preserve them; however, they may be traumatized by the operation and take some time to return to normal function. Calcium supplements may be required if the levels are low and some may require long-term supplementation
- ⁿ Infection: This is rare (less than 0.5%) and is easily treated with antibiotics.
- n Hypothyroidism: This occurs if the entire thyroid is removed, and a long-term replacement is required. If only part of the thyroid is removed this is less common.
- ⁿ Additional medical conditions like advanced age, smoking, diabetes, heart disease, lung issues, or kidney and liver problems can influence the general outcome by increasing the risk of Clot, PE, heart attack, stroke and risk of death, etc

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Informed Surgical Consent – Thyroidectomy

| I (Patient / authorized represen | ıtative) | |
|-------------------------------------|--------------------|---|
| relation to the patient (in case of | | |
| of the patient named | - | , |
| Age / Sex | | |
| admitted on | | |
| | | |
| | | |
| And I have been explained the | e need for surgery | |

I have read the Patient Information Sheet, supplied to me and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- Bleeding: Blood can accumulate beneath the skin. This occurs in less than 1% of patients. Due to the location of the thyroid pressure, bleeding can cause breathing difficulties. It may be necessary to relieve this pressure by opening the wound.
- ⁿ Voice changes: Nerves that control your voice box run very close to the thyroid. There is a slight risk (less than 2%) of injury to this nerve, leading to hoarseness. This is usually temporary but can also be permanent.
- Low Calcium: Parathyroid glands control calcium levels in the blood; they lie at the four corners of the thyroid gland. Every effort is made to preserve them; however, they may be traumatized by the operation and take some time to return to normal function. Calcium supplements may be required if the levels are low and some may require long-term supplementation
- n Infection: This is rare (less than 0.5%) and easily treated with antibiotics.
- ⁿ Hypothyroidism: This occurs if the entire thyroid is removed, and a long-term replacement is required. If only part of the thyroid is removed this is less common.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.

| The doctor has explained that due to my/his/her | additional medical conditions such as |
|---|---------------------------------------|
| | there |
| might be specific additional risks such as | |
| | |
| | |



I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)

I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No. |



Parotidectomy

PART A: Patient Information Leaflet

What is Parotidectomy?

Parotidectomy is the surgical removal of part or all of the parotid gland. The parotid gland is a gland in the front of the ear which produces saliva. Swelling occurs in the parotid gland due to abnormal overgrowth of some parts of the salivary glands (a parotid gland tumor). Mostly they are benign, which means that they are not cancerous (malignant). Rarely, malignant tumors can also occur in the gland. It is known that 80% of these lumps are benign (non-cancerous lumps) and need to be removed as they might turn malignant(cancerous) or become very big and unattractive and cause pressure symptoms. Lastly, to know the exact nature of the tumor.

The Doctor might ask you to get the following investigations before deciding on your surgery

- ⁿ Ultrasound: This test uses sound waves to determine the structure of the tumor (sometimes CT or an MRI scan)
- ⁿ Fine needle aspiration: A fine needle test is used to obtain a sample of cells from the gland. These are examined under the microscope in the laboratory. This will give information about the nature of cells in the tumor

How is Parotidectomy performed?

The operation is performed under general anesthesia, which means that you will be put to sleep during the operation. This is done by an incision (cut) made in front of the ear down to the neck. The tumor is removed meticulously with the intent to preserve the facial nerve function. At the end of the operation, the surgeon will place a drain (plastic tube) through the skin to prevent any blood clots from collecting under the skin. You will go home once the drain is removed.

What are the potential benefits of this procedure

The intended benefit of the procedure is to remove the gland and prevent the progression of the illness. Not undergoing the procedure would lead to pressure symptoms, facial palsy, and risk of progression to cancer. The final biopsy report is confirmatory and you may need further surgery/medical treatment/radiation treatment.

What are the alternative treatment available?

Alternative to undergoing the procedure is observation ,repeated USG, excision biopsy when appropriate.

What are Parotidectomy-specific risks and complications?

Facial weakness: The facial nerve passes right through the parotid gland. This nerve makes the muscles of the face move and if it is damaged during the surgery, can lead to



a weakness of the face (facial palsy). Although every effort is made to preserve the nerve there is a risk of injury to the nerve when the tumor has been very close to the nerve. Temporary weakness of the face can occur that can last for a few weeks. (In about 15-20% of cases). In 5% of cases, there is a permanent weakness of the face following this sort of surgery for aggressive tumors.

- Numbness of the Ear lobule and Face, Facial hollow at the site of surgery: The skin on the site of surgery is numb for some weeks after the operation, and in some patients, the ear lobule may be numb permanently.
- ⁿ Salivary collection: In 2-5% of patients, the cut surface of the parotid gland leaks a little saliva, this might need to be aspirated a few times
- ⁿ Frey's syndrome: Some patients find that after this surgery their cheeks can become red, flushed, and sweaty whilst eating. This might require topical medications.
- ⁿ Blood clot: A blood clot can collect beneath the skin (a hematoma). This occurs in about 4% of patients and it is sometimes necessary to return to the operating theatre and remove the clot and replace the drain. Infection (2%) is a rare possibility of needing antibiotics for some time.
- ⁿ Tumor recurrence: There is a small risk of the tumor coming back (1 to 5% based on the type of tumor). It is higher for an advanced cancerous tumor.

Additional medical conditions like advanced age, smoking, diabetes, heart disease, lung issues, or kidney and liver problems can influence the general outcome by increasing the risk of Clot, PE, heart attack, stroke, and risk of death, etc.

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Informed Surgical Consent - Parotidectomy

| I (Patient / authorized representative) |
|--|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No. |
| admitted on and under |
| I/he /she have/has been diagnosed with |
| |
| And I have been explained the need for surgery |
| |

I have read the Patient Information Sheet, supplied to me and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and it includes:

- ⁿ Facial weakness: The facial nerve passes right through the parotid gland. This nerve makes the muscles of the face move and if it is damaged during the surgery, can lead to a weakness of the face (facial palsy). Although every effort is made to preserve the nerve there is a risk of injury to the nerve when the tumor has been very close to the nerve. Temporary weakness of the face can occur that can last for a few weeks. (In about 15-20% of cases). In 5% of cases, there is a permanent weakness of the face following this sort of surgery for aggressive tumors.
- ⁿ Numbness of the Ear lobule and Face, Facial hollow at the site of surgery: The skin on the site of surgery is numb for some weeks after the operation, and in some patients, the ear lobule may be numb permanently.
- Salivary collection: In 2-5% of patients, the cut surface of the parotid gland leaks a little saliva, this might need to be aspirated a few times
- ⁿ Frey's syndrome: Some patients find that after this surgery their cheeks can become red, flushed, and sweaty whilst eating. This might require topical medications.
- ⁿ Blood clot: A blood clot can collect beneath the skin (a hematoma). This occurs in about 4% of patients and it is sometimes necessary to return to the operating theatre and remove the clot and replace the drain. Infection (2%) is a rare possibility of needing antibiotics for some time.
- Tumour recurrence: There is a small risk of the tumor coming back (1to 5% based on the type of tumor). It is higher for an advanced cancerous tumor.

I have been explained the possible need for post-operative ventilatory support or transfusion of blood or blood products.

I acknowledge that the doctor has explained my/his/her medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/him/her prognosis and risks of not undergoing the surgery at all.



| AOI Unitorm Consents |
|--|
| The doctor has explained that due to my/his/her additional medical conditions such as there |
| might be specific additional risks such as |
| I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care. |
| I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience. |
| I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health. |
| I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital. |
| I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo) |
| I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts. |
| I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction. |
| Signature |
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |

Name of the Doctor taking the consent

Designation & Reg. No.



Neck Dissection

PART A: Patient Information Leaflet

Why do I need Neck Dissection?

Neck dissection is generally done to remove the cancerous lymph nodes from the neck. Lymph nodes are small structures that are part of the immune system and are present all over the body that work as filters for foreign substances, such as cancer cells and infections. Each node drains a particular area of the body. Cancers of the head and neck region spread to these lymph glands. Once a cancer cell has been 'caught' by a lymph node it can grow and multiply there, and in time can spread to other groups of lymph nodes. Most cancers that start in the head and neck region can spread from these lymph glands to other parts of the body; these are called metastases or secondaries. In advanced stages, it can spread to the lungs or liver.

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

- n Blood tests for information regarding the functioning of the Body.
- n Ultrasound: This test uses sound waves to determine the structure of the lymph nodes.
- ⁿ Fine needle aspiration: A fine needle is used to obtain a sample of cells from the gland. These are examined under the microscope in the laboratory. This will give information about the nature of cancer cells
- n CT neck and Chest or sometimes MRI or PET scan (to ascertain spread)

How is Neck Dissection performed?

This can either be complete or in groups of lymph nodes (selective neck dissection). This operation is carried out if there is evidence of neck nodal spread or if there is a strong suspicion that one or more groups might be involved. Additional structures like (veins, nerves, and muscles) that are grossly involved might require removal to control the spread. In both types of operation, all the tissues are sent for histological examination to know the extent of the spread

The operation is performed under general anesthesia which means that the patient will be put to sleep throughout the procedure. There will usually be one or two long cuts made in the neck. Many a time the neck dissection only forms a part of the procedure, which will include the removal of the main tumor. At the end of the operation, the patient will have 1 or 2 drain tubes coming out through the skin and stitches or skin clips on the skin, neck may look flatter and stiff post-surgery.

What are the potential risks and complications of this procedure?

ⁿ Injury to the Accessory nerve: This is the nerve to one of the muscles of the shoulder. Every effort is made to preserve this nerve but sometimes it needs to be removed because



it is engulfed by the tumor. In this case, the shoulder will become a little stiff, and it can be difficult to lift the arm above the shoulder. Lifting heavy weights may also be difficult and might need physiotherapy for the shoulder.

- ⁿ Injury to the Hypoglossal nerve: This is the nerve that helps the tongue to move. This has to be removed rarely due to the involvement of the tumor. This might impair clearing food from the mouth and might affect swallowing
- ⁿ Injury to the Marginal Mandibular nerve: This nerve is also at risk during the operation, although we try hard to preserve it. If it is damaged, the corner of my mouth will be a little weak. This is most obvious when smiling.
- Stiff Neck and numbness: Some patients find that their neck is stiffer after the operation. The skin of the neck will be numb after the surgery. This will improve over time to some extent, but should not expect it to return to normal.
- ⁿ Injury to Greater Auricular nerve: this is the nerve that supplies the skin around the ear. You might experience some numbness around the ear if this nerve is sacrificed for the sake of disease clearance.
- ⁿ Injury to phrenic nerve (rare): it supplies the main muscle responsible for breathing. You may experience shortness of breath. This is a very rare complication which may occur in advanced stages of malignancy.
- n IJV thrombosis formation of blood clot within the major vein in the neck.
- Blood Clot: Sometimes the drain tubes which were put in during surgery can become blocked, causing blood to collect under the skin and form a clot (hematoma). If this occurs it is usually necessary to return to the operating room to remove the clot and replace the drains.
- ⁿ Chyle leak: Chyle is the tissue fluid, which runs in lymph channels. Occasionally one of these channels called the thoracic duct leaks after the operation. If this occurs, lymph fluid or chyle can collect under the skin, in which case I may need to be kept in the hospital longer and sometimes need to be taken back to the theatre to seal the leak. Other complications like wound dehiscence and infections are rare.

Additional medical conditions like advanced age, smoking, diabetes, heart disease, lung issues, or kidney and liver problems can influence the general outcome by increasing the risk of Clot, PE, heart attack, stroke and risk of death, etc

| Signature Patient / Authorised Representative : |
|---|
| |
| Relation to the patient: |
| • |
| Date & Time |
| |



PART B: Informed Surgical Consent – Neck Dissection

| I (Patient / authorized representative | ve) | |
|---|---------------|---|
| relation to the patient (in case of aut | • | |
| of the patient named | - | • |
| Age / Sex | | |
| admitted ona | | |
| | | |
| I/he /she have/has been diagnosed | WIIII | |
| And I have been explained the need | d for surgery | |

I have read the Patient Information Sheet, supplied to me/ him/her and pertaining to the above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and which include:

- Injury to the Accessory nerve: This is the nerve to one of the muscles of the shoulder. Every effort is made to preserve this nerve but sometimes it needs to be removed because it is engulfed by the tumor. In this case, the shoulder will become a little stiff, and it can be difficult to lift the arm above the shoulder. Lifting heavy weights may also be difficult and might need physiotherapy for the shoulder.
- ⁿ Injury to the Hypoglossal nerve: This is the nerve that helps the tongue to move. This has to be removed rarely due to the involvement of the tumor. This might impair clearing food from the mouth and might affect swallowing
- ⁿ Injury to the Marginal Mandibular nerve: This nerve is also at risk during the operation, although we try hard to preserve it. If it is damaged, the corner of my/his/her mouth will be a little weak. This is most obvious when smiling.
- Stiff Neck and numbness: Some patients find that their neck is stiffer after the operation. The skin of the neck will be numb after the surgery. This will improve over time to some extent, but should not expect it to return to normal.
- Blood Clot: Sometimes the drain tubes which were put in during surgery can become blocked, causing blood to collect under the skin and form a clot (hematoma). If this occurs it is usually necessary to return to the operating room to remove the clot and replace the drains.
- ⁿ Chyle leak: Chyle is the tissue fluid, which runs in lymph channels. Occasionally one of these channels called the thoracic duct leaks after the operation. If this occurs, lymph fluid or chyle can collect under the skin, in which case I/he/she may need to be kept in the hospital longer and sometimes need to be taken back to the theatre to seal the leak. Other complications like wound dehiscence and infections are rare.

I acknowledge that the doctor has explained my medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/his/her prognosis and risks of not undergoing the surgery at all.



| AOI OIIIIOIIII COIISEIILS |
|--|
| The doctor has explained that due to my/his/her additional medical conditions such as there |
| might be specific additional risks such as |
| I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care. |
| I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience. |
| I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health. |
| I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital. |
| I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo) |
| I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts. |
| I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction. |
| Signature |
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient: |
| Signature |
| Date & Time |
| Name (witness) |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |

Designation & Reg. No.



Composite Resection and Reconstruction

PART A: Patient Information Leaflet

Why do I need this surgery?

It is done in patients having cancer of the mouth. This will require surgical removal of the tumor from the mouth. Lymph nodes are small structures that work as filters for foreign substances, such as cancer cells and infections. Each node gets drainage from a particular area of the body. The nodes in the neck drain the swallowing and breathing tubes. Cancer of the head and neck region spread to these lymph glands. Once a cancer cell has been 'caught' by a lymph node it can grow and multiply there, and in time can spread to other groups of lymph nodes. Most cancers that start in the head and neck region can spread from these lymph glands to other parts of the body; these are called metastases or secondaries. In advanced stages, it can spread to the lungs or liver

Before the procedure, your doctor might ask for some / all of these tests in order to plan the surgery:

- n Blood tests for information regarding the functioning of the Body.
- n Ultrasound: This test uses sound waves to determine the structure of the lymph nodes.
- ⁿ Fine needle aspiration: A fine needle is used to obtain a sample of cells from the gland. These are examined under the microscope in the laboratory. This will give information about the nature of cancer cells
- n CT neck and Chest or sometimes MRI or PET scan (to ascertain spread)

How is this Procedure done?

The tumor has to be removed completely from the place of its origin to prevent spread. This is done from the mouth or through the cut in the neck. This is a complex operation of 7 to 8 hrs where 2 to 3 surgeries are combined with an intent to cure or control cancer. Apart from the tongue, part/full of the diseased bony framework will need to be removed along with neck dissection. In many situations reconstruction of the defect is needed by skin, muscle, or bone. This will be harvested from a nearby or a distant site. This decision will be done by your doctor based on stage, age, and functional requirements.

Neck dissection is generally done to remove the cancerous lymph nodes from the neck. This can either be complete or in groups of lymph nodes (selective neck dissection). This operation is carried out if there is evidence of neck nodal spread or if there is a strong suspicion that one or more groups might be involved. Additional structures like (veins, nerves, and muscles) that are grossly involved might require removal to control the spread. In both types of operation, all the tissues are sent for histological examination to know the extent of the spread

The operation is performed under general anesthesia which means that the patient will be put to sleep throughout the procedure. There will usually be one or two long cuts made in the neck. Many a time the neck dissection only forms a part of the procedure, which will



include the removal of the main tumor. At the end of the operation, I will have 1 or 2 drain tubes coming out through the skin and stitches or skin clips on the skin, the neck may look flatter and stiff post-surgery.

What are the potential complications of surgery and sequelae-

- Injury to the Accessory nerve: This is the nerve to one of the muscles of the shoulder. Every effort is made to preserve this nerve but sometimes it needs to be removed because it is engulfed by the tumor. In this case, the shoulder will become a little stiff, and it can be difficult to lift the arm above the shoulder. Lifting heavy weights may also be difficult and might need physiotherapy for the shoulder.
- ⁿ Injury to the Hypoglossal nerve: This is the nerve that helps the tongue to move. This has to be removed rarely due to the involvement of the tumor. This might impair clearing food from the mouth and might affect swallowing
- ⁿ Injury to the Marginal Mandibular nerve: This nerve is also at risk during the operation, although we try hard to preserve it. If it is damaged, the corner of my mouth will be a little weak. This is most obvious when smiling.
- ⁿ Stiff Neck and numbness: Some patients find that their neck is stiffer after the operation. The skin of the neck will be numb after the surgery. This will improve over time to some extent, but should not expect it to return to normal.
- Blood Clot: Sometimes the drain tubes which were put in during surgery can become blocked, causing blood to collect under the skin and form a clot (hematoma). If this occurs it is usually necessary to return to the operating room to remove the clot and replace the drains.
- ⁿ Chyle leak: Chyle is the tissue fluid, which runs in lymph channels. Occasionally one of these channels called the thoracic duct leaks after the operation. If this occurs, lymph fluid or chyle can collect under the skin, in which case I may need to be kept in the hospital longer and sometimes need to be taken back to the theatre to seal the leak. Other complications like wound dehiscence and infections are rare.

Additional medical conditions like advanced age, smoking, diabetes, heart disease, lung tissue, or kidney and liver problems can influence the general outcome by increasing the risk of -Failure to decannulate, leg clot, a clot in the lung, heart attack, Lung infection, stroke and risk of death, etc.

| Signature Patient / Authorised Representative : |
|---|
| Relation to the patient : |
| Date & Time |



PART B: Informed Surgical Consent – Composite Resection and Reconstruction

| I (Patient / authorized representative), |
|--|
| relation to the patient (in case of authorized representative) |
| of the patient named |
| Age / Sex IP No. / OP No |
| admitted on and under |
| |
| I/he /she have/has been diagnosed with |
| And I have been explained the need for surgery |
| I have read the Patient Information Sheet, supplied to me/ him/her and pertaining to the |

above procedure and have understood the same.

I have been explained and have understood the need for surgery.

Expected benefits of the surgery as listed in the Patient Information Sheet have been explained and understood by me.

I have been explained the risks and complications of the above-mentioned surgery and which include:

- Injury to the Accessory nerve: This is the nerve to one of the muscles of the shoulder. Every effort is made to preserve this nerve but sometimes it needs to be removed because it is engulfed by the tumor. In this case, the shoulder will become a little stiff, and it can be difficult to lift the arm above the shoulder. Lifting heavy weights may also be difficult and might need physiotherapy for the shoulder.
- n Injury to the Hypoglossal nerve: This is the nerve that helps the tongue to move. This has to be removed rarely due to the involvement of the tumor. This might impair clearing food from the mouth and might affect swallowing
- Injury to the Marginal Mandibular nerve: This nerve is also at risk during the operation, although we try hard to preserve it. If it is damaged, the corner of my/his/her mouth will be a little weak. This is most obvious when smiling.
- Stiff Neck and numbness: Some patients find that their neck is stiffer after the operation. The skin of the neck will be numb after the surgery. This will improve over time to some extent, but should not expect it to return to normal.
- Blood Clot: Sometimes the drain tubes which were put in during surgery can become blocked, causing blood to collect under the skin and form a clot (hematoma). If this occurs it is usually necessary to return to the operating room to remove the clot and replace the drains.
- Chyle leak: Chyle is the tissue fluid, which runs in lymph channels. Occasionally one of these channels called the thoracic duct leaks after the operation. If this occurs, lymph fluid or chyle can collect under the skin, in which case I/he/she may need to be kept in



the hospital longer and sometimes need to be taken back to the theatre to seal the leak. Other complications like wound dehiscence and infections are rare.

If a bone flap is harvested these need to be fixed to the residual bone on the bony framework of the face with a screw and plate. The risks of such procedure include bleed, infection, failure of the flap in 2 to 5 percent, re-exploration, donor site deformity or defect

I understand that the intended benefit of the procedure is to remove the Lymph gland to prevent the progression of the illness.

I also understand that not undergoing the procedure would lead to pressure symptoms like airway obstruction/progress of cancer and death.

I understand that the final biopsy report is confirmatory and I may need further surgery/medical treatment or Radiotherapy

I acknowledge that the doctor has explained my medical condition, the procedure planned, its benefits and risks, alternate treatment options available to me/him/her as well as my/his/her prognosis and risks of not undergoing the surgery at all.

| The doctor has explained that due to my/his/l | |
|--|--|
| there might be specific additional risks such as | |

I understand that no guarantee has been made that the procedure would improve my/his/her condition although it has been carried out with utmost professional care.

I am aware and agree that it cannot be guaranteed that, the entire procedure or a part of the procedure will be performed by a specified person. However, I have been assured that it will be performed by or under the supervision(in case of a trainee performing the surgery) of a person with appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my/his/her life or to prevent serious harm to my/his/her health.

I understand that tissues removed during surgery will be sent for Histopathology and the final histopathology report will find the exact pathology. I/he/she may need to undergo further treatment depending on the final histopathology report, the tissues removed may be retained for tests for a while and then disposed of sensitively by the hospital.

I understand that photographs and video footage may be taken during my/his/her operation and they may be used for teaching purposes. (My/his/her identity will still be kept confidential in any video or photo)





I have been explained in a language I understand and I hereby give my free and voluntary consent in a fully alert state of mind and without coercion, undue influence, fraud, misrepresentation or mistake of facts.

I was given the opportunity to ask questions and raise concerns about the procedure to my/his/her doctor and they were discussed to my satisfaction.

| Signature |
|---|
| Date & Time |
| Name(Patient / Authorized representative) |
| Relation to the patient : |
| |
| Signature |
| Date & Time |
| Name (witness) |
| |
| Signature |
| Date & Time |
| Name of the Doctor taking the consent |
| Designation & Reg. No |