CONSENT FOR LAPAROSCOPIC FUNDOPLICATION

PROPOSED TREATMENT

The doctor has explained that I, (name) ……………………………………………………………………………………….…,

have ……… and that

this condition requires **……………………………………………………………………………………………………….**

What is gastro-oesophageal reflux disease?

Gastro-oesophageal reflux disease (GERD) occurs when the acidic contents of the stomach flow backwards into the oesophagus causing inflammation of the lower oesophagus (oesophagitis). This may lead to a number of symptoms including heartburn, regurgitation of semi-digested food, difficulty swallowing and pain on swallowing. In addition, you may also experience welling up of a foul tasting fluid into the back of your mouth; you might also notice fluid welling up when you bend over to tie your shoes or to lift something up. Rarely, GERD may be associated with chest conditions such as asthma and may also lead to problems with tooth decay.

GERD occurs when there is a failure of the valve (sphincter) at the lower end of your oesophagus (food pipe). This valve should prevent fluid from the stomach passing back up your oesophagus, but in patients with GERD this is not the case and fluid from the stomach can pass freely into the oesophagus. Although not the cause, patients with GERD frequently also have a hiatus hernia. This occurs when the upper part of the stomach and valve in the lower part of the oesophagus sit in the chest cavity, rather than the abdominal cavity.

What are the options for treating gastro-oesophageal reflux?

The majority of patients who have gastro-oesophageal reflux treat their condition with simple over the counter medicines, (for example: Rantac), and other medications that can be brought from the chemist that reduce the acidity in the stomach.

If these simple measures do not work then patients are commonly prescribed tablets that reduce the acid levels in the stomach. These drugs are collectively known as Proton Pump Inhibitors (PPIs, for example: Lansoprazole, Omeprazole, Esomeprazole, Pantoprazole and Rabeprazole). These drugs are highly effective at relieving the symptoms of gastro-oesophageal reflux; they do not do anything to the sphincter at the lower end of the oesophagus.

Sometimes patients notice that an improvement in their symptoms if they loose weight or by giving up alcohol and smoking. We therefore generally advise people, who have severe reflux disease, to follow these measures and also to avoid eating large meals late at night and drinking large amounts of caffeine containing drinks and loosing weight.

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What is the aim of surgery?

Surgical operations for reflux disease aim to prevent acid reflux by reinforcing the valve mechanism at the lower end of the oesophagus so that the fluid cannot reflux into the oesophagus from the stomach. The sphincter mechanism itself cannot be directly repaired. Instead it is reinforced by buttressing the valve mechanism with the upper stomach.

Surgical treatment for acid reflux disease has been around for many years but has become more popular in recent times as key hole methods (laparoscopic) for carrying out the surgery have been developed and it is also related to the increased number of patients who suffer with GERD.

Who is suitable for surgery?

Surgery can potentially benefit the majority of patients who have troublesome acid reflux disease. However, it is important that you are fully aware of the different options for treating your reflux disease before going through an operation.

It is critical that a precise diagnosis of gastro-oesophageal reflux disease is made prior to surgery. It is most important to be certain that reflux is causing your symptoms. There are many other conditions of the oesophagus and stomach that can cause symptoms which may be interpreted as reflux. These other conditions are not helped by surgery and may be made worse. Therefore, your surgeon & gastroenterologist will carefully decide whether surgery is likely to help your symptoms.

The majority of patients who wish to explore the possibility of surgical treatment are those who have severe reflux symptoms that are inadequately relieved by taking medication. Some patients have the desire not to stay on long-term medication, or have had side effects from the PPI medications they have been prescribed.

What tests do I need before the operation?

Before you have a surgical treatment for your gastro-oesophageal reflux, it is important that we confirm that this is the problem that you have as other conditions can mimic GERD and they would not be helped by this type of surgery. You will undergo an endoscopy test to have a look to see if you have oesophagitis, (inflammation of food pipe), or a hiatus hernia.

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You will also be asked to undergo some tests of your oesophagus to make sure that the muscles within the oesophagus work properly and strongly when you swallow. You will also be asked to undergo a test where a fine catheter tube is placed down your nose for a 24 hour period; this catheter tube measures the acid (pH level) in your lower oesophagus and allows us to confirm that you have an abnormal degree of acid reflux. You may be asked to undergo some form of image like CT scan or MRI scan.

We will also ask you about your response to acid reducing medications as frequently patients who respond well to these medications do well after surgery.

During the procedure (operation/treatment) itself

Before your operation you will be taken to the operating theatre and the anaesthetist will insert a plastic tube (drip) in your hand or arm through which you will be given an injection which will make you sleepy. During the operation the anaesthetist will stay with you at all times and you are closely monitored. Monitoring machines will measure your heart rate, blood pressure and oxygen levels within your blood.

While you are asleep a fine tube will be passed through your nose into your stomach to drain the air off the stomach; this will be removed at the end of the procedure.

We perform this type of surgery using a keyhole (laparoscopic) approach. This allows us to use long thin instruments and cameras to work inside your abdomen, using small incisions rather than through a traditional large incision.

There is always a small chance (5%) that a larger incision will be made on the abdomen. This is done if the operation is unable to be completed using the key hole technique or if there is a complication such as bleeding that cannot be controlled using a key hole technique.

This approach means that you experience much less pain after the operation and thus, able to recover more quickly.

When the special keyhole (laparoscopic) instruments have been inserted the liver is lifted out of the way with a special instrument allowing us to identify the lower oesophagus and stomach, where we will do the actual operation. This area is freed up preserving the nerves that lie around this area that control your intestine. The upper part of the stomach (fundus) is then freed from its attachments. This involves dividing some small blood vessels that run between the fundus and the spleen.

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Once the fundus of the stomach and the oesophagus are completely mobile the stomach is manipulated around the back of the oesophagus and stitched over the front of the oesophagus and back to the stomach (this is called a fundoplication). If you have had a hiatus hernia the diaphragm through which the hernia was extending will also be repaired using some stitches.

The incisions will be closed with dissolving sutures and injected with local anaesthetic so that you are comfortable when you wake up. Your wounds will be closed with dressings.

After the procedure

You will wake up in the recovery room after your operation. You might have an oxygen mask on your face to help you breathe. You might also wake up feeling sleepy.

After the operation, you will have a small, plastic tube in one of the veins of their arm. This will be attached to a bag of fluid (called a drip), which provides your body with fluid until you are well enough to eat and drink by yourself.

While you are in the recovery room, a nurse will check your pulse and blood pressure regularly. When you are well enough to be moved, you will be taken to a ward.

It is very important that you are not sick and you will be given a number of anti-sickness medications while you are asleep.

If, after the operation you feel at all sick, you must immediately inform the nurses looking after you.

After your operation, one day after operation, you will be allowed to drink water and then progress onto other fluids during the day as you feel able and are not feeling sick.

You will be monitored carefully and given regular painkillers and anti-sickness medications to prevent sickness occurring.

The day after your operation, you will be seen by the surgical team and provided you are well you will be allowed to start eating soups and simple soft food.

We advise you during this period to avoid liquids that are either particularly hot or cold, but generally take tepid fluids. We would also caution against taking fizzy drinks.

We would expect you to be discharged home one to two days after your operation.

Serious or frequently occurring risks:

Keyhole (laparoscopic) surgery for acid reflux disease is a safe procedure. However, there are potential risks involved in any form of surgery and we believe that it is important that you are aware of these.

- Damage to the spleen**.** During the part of the operation discussed earlier, the small blood vessels between the spleen and the upper part of the stomach (fundus) are cut using special instruments that seal the blood vessels before they are divided. However, sometimes damage to the spleen can occur. Frequently this can be controlled simply using the keyhole method, however, if the spleen were to sustain more severe injury this may require conversion to an open cut operation with the potential of removal of the spleen.
- Damage to the oesophagus. When the oesophagus is being freed up inside your abdomen there is a risk that it can be damaged. If this is seen at the time of the operation it can be repaired simply and the operation will be completed using the keyhole method, or it may mean you need to stay in hospital for a slightly longer period of time to ensure that it heals up well.
- Severe swallowing difficulty. While we expect you to notice things go down more slowly after your operation, a few patients experience severe problems with swallowing in the first few days after their operation. If this occurs, it may be necessary to perform a second keyhole operation to loosen or remove some of the stitches we have put in.

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- Wound infection. These are rare with keyhole surgery and if they do occur can be treated simply with antibiotics.
- Damage to other organs inside your abdomen. This is a rare complication of keyhole surgery but it has been recognized that during the insertion of instruments into the abdominal cavity damage can occur to any other intra-abdominal organs, including the intestine, liver and blood vessels. If this were to occur then it is likely that the approach to the operation would have to be changed from a keyhole approach to an open approach.
- Chest infection. Because you are relatively comfortable and able to easily mobilise after the operation, chest infections are rare. If a chest infection did occur it could be treated with antibiotics.
- Deep vein thrombosis (DVT) and pulmonary embolus - All surgery carries varying degrees of risks of thrombosis (clots) in the deep veins of your leg. In the worst case a clot in the leg can break off and travel to the lung (pulmonary embolism). This can significantly impair your breathing. To prevent these problems around the time of your operation and following your operation we give you some special injections to 'thin' the blood. We also ask you to wear compression stockings on your legs before and after surgery and also use a special device to massage the calves during the surgery. Moving about as much as you can, including pumping your calf muscles in bed or sitting out of bed as soon as possible reduce the risk of these complications.
- Conversion to an open operation. We always warn people who are undergoing a keyhole procedure that there is a small risk that if the operation is technically not possible to complete through a keyhole technique we will make an open cut. If this is necessary, it will result in a larger scar and more post-operative discomfort and, inevitably, a longer stay in hospital.
- Scarring – Any surgical procedure that involves making a skin incision carries a risk of scar formation. A scar is the body's way of healing and sealing the cut. It is highly variable between different people. All surgical incisions are closed with the utmost care, usually involving several layers of sutures. The sutures are almost always dissolvable and do not have to be removed. The larger an incision the more prominent it will be. Despite our best intentions, there is no guarantee that any incision (even those only 1-2 cm in length) will not cause a scar that is somewhat unsightly or prominent. Scars are usually most prominent in the first few months following surgery, however, tend to fade in colour and become less noticeable after a year or so.
- Requirement for re-operation – It is unlikely (5%), although possible, that some time after the operation you may need a further procedure related to the fundoplication. This is because it possible for things to move slightly inside or for sutures to give way. If this is the case this may need to be corrected with another operation to revise the fundoplication. In very rare cases coughing, heaving or vomiting in the first few days after the operation can cause things to move or a suture to give way. This then may require another operation to correct things.
- Other complications – We have tried to describe the most common and serious complications that may occur following this surgery. It is not possible to detail every possible complication that may occur following any operation. If another complication that you have not been warned about occurs, we will treat it as required and inform you as best we can at the time. If there is anything that is unclear or risks that you are particularly concerned about, please ask.

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After the procedure

The operation aims to increase the pressure of the valve mechanism at the lower end of your oesophagus . You will, therefore, notice that in the first few weeks after your operation it is more difficult to swallow food than it was before your operation. This is entirely normal and advice is given later on in this information sheet as to the type of food you should be eating during this period.

You need to be very careful about eating foods of a coarser texture, such as bread or red meat. If these are eaten too quickly or too large a mouthful is swallowed they may become stuck in the lower end of the oesophagus.

Because the valve has been tightened it is difficult for patients to belch and this can lead to painful trapped wind. In a similar manner, it is also difficult for patients to be sick. All these symptoms do improve with time, but it is important that you avoid precipitating these symptoms as much as possible in the early post-operative period.

Approximately 50% of the patients who have this operation notice that they pass more wind through their bottom after the operation. Simple medications that absorb gas can be obtained over the counter at a chemist.

Eating and drinking

- We advise you to eat food that is soft, sloppy and easy to swallow. This means avoiding foods that contain large pieces (for example, bread or red meat).
- Always take your time eating and chew your food very well.
- If you are having difficulties swallowing initially, we advise you to only take foods of a consistency that are able to sucked up a straw. After about two weeks you should be able to increase this to sloppy foods such as mashed or vitamised foods for another two weeks.
- Foods like soups, pasta, mashed vegetables and mince are suitable.
- You should avoid fizzy or gassy drinks that might make you feel bloated. This is because you are generally less able to belch or burp due to the surgery.

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When you can resume normal activities including work

After your operation we would expect you to make a quick recovery from your surgery. You are able to resume normal activities as you feel comfortable. In general, you can resume driving a week or so after your operation. We would advise against extreme physical activity (weight lifting or heavy lifting), for about a month after the operation so that all the swelling and post-operative effects have settled down.

Follow up

You will be seen in the surgical clinic six weeks after your operation to assess your progress. During the first six weeks after your operation we would expect you to experience some difficulty with your swallowing and will advise you regarding the diet you should stick to. In general, you should avoid eating chunky food (for example, pieces of meat) and dry foods (for example, bread) for the first six weeks

after your operation. We believe that it is important that we monitor the effects of your operation over a long period of time to ensure that the good results of the surgery are maintained.

DECLARATION BY PATIENT

I acknowledge I have read this form and the surgeon has informed me about the procedure, alternative treatments and answered my specific queries and concerns about this matter.

- I acknowledge that I have discussed with the surgeon any significant risks and complications specific to my individual circumstances that I have considered in deciding to have this operation.
- I understand my medical condition and agree to undergo the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- I understand that a doctor other than the specialist surgeon may be part of the procedure.
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I have received a copy of this form to take home with me.

Signature of patient: Date

Signature of witness or relative:

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DECLARATION BY DOCTOR

- I declare that I have explained the nature and consequences of the operation to be performed, and discussed the risks that particularly concern the patient.
- I have given the patient an opportunity to ask questions and I have answered these.

Doctor's signature Date

Dr Sandeep Nayak