



Patient
Label

Surgical Procedures for Treatment of Pelvic Organ Prolapse in Women

PATIENT INFORMATION LEAFLET

About this leaflet:

This leaflet gives you detailed information about the operations being proposed and its alternatives. It includes advice from Scottish consensus panels, the relevant national organisations and other evidence-based sources, for example the Cochrane Collaboration. It is, therefore, a reflection of best practice in the UK. The information is intended to supplement any advice you may already have been given by your GP or surgeon.

Please take your time to read it carefully and write down any questions and expectations (see page 18) to discuss with your surgeon.

Acknowledgement:

This leaflet contains information and an information checklist based on original booklets developed by The Scottish Government Working Group with input from representatives of the Royal College of Obstetricians and Gynaecologists (RCOG), the British Association of Urological Surgeons (BAUS) and patient support groups, with reference to national guidance.

Disclaimer:

The authors cannot be held responsible for errors or any consequences arising from the use of the information contained. As current evidence is incomplete and further evidence will be available in due course, the UK Mesh Working Group will review and consider updating this leaflet every two years. Please make sure you are reading the latest document.

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Explanation of Terms (alphabetical):

Vaginal Adhesions: Bands of scar sticking vaginal tissues together.

Augmented Repair: Use of a synthetic implant, inserted vaginally or abdominally, to restore organ support.

Catheter: Temporary flexible tube to drain urine following surgery.

Exposure (Erosion): An implant (mesh) is partly exposed inside the vagina, bladder or rectum.

Fascia: A sheet of supporting fibrous tissue that holds body organs in their correct positions.

Fascial Repair: Use of native (your own tissue) tissue (fascia and ligaments) to restore organ support.

Fistula: Abnormal connection between organ (e.g. vagina and bladder).

Graft: A sheet of absorbable biological material commonly made from either bovine (cow) or porcine (pig) sources. Such tissues are highly processed so that only a fibrous material remains.

Implant: A flat strip of a synthetic structure made from absorbable (graft) or non-absorbable (mesh) material.

Ligament: A condensation of fascia to form a tough band of fibrous tissue for stronger organ support.

Mesh: A net-like fabric with open spaces between the strands of the net. It is a permanent plastic implant usually made from the non-absorbable polypropylene (prolene) material.

Trocar: A pointed surgical instrument used to insert a material implant into the body.

Urethra: The water-pipe from the bladder to the outside.

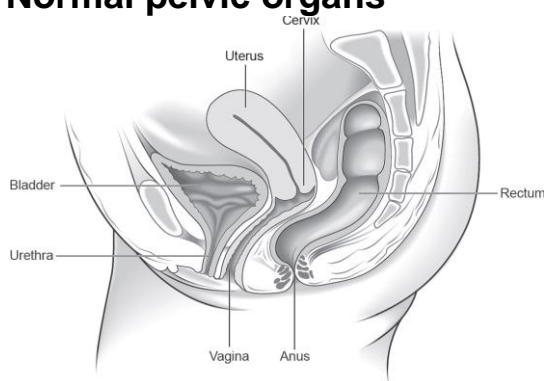
What is Pelvic Organ Prolapse (POP)?

The pelvic organs (uterus, bladder and bowel) are supported by your pelvic floor muscles, fascia and ligaments. If this support is weakened by childbirth, menopause and/or ageing, you may experience prolapse or herniation of these organs. Conditions that cause excessive pressure on the pelvic floor such as obesity, chronic cough, chronic constipation, and heavy lifting may be additional factors in development of POP. Prolapse may arise in the front wall of the vagina (cystocele), back wall of the vagina (rectocele) or the uterus / top of the vagina (uterine and vault prolapse, where the uterus was prior to hysterectomy, see illustrations below). Many women have prolapse in more than one compartment at the same time.

Symptoms of POP may affect quality of life and are mainly a feeling of a lump or bulge inside and/or outside the vagina, a heavy dragging feeling in the vagina and discomfort during sexual intercourse. Bladder symptoms may also be present such as slow urinary stream, a feeling of incomplete bladder emptying, urinary frequency, urgent desire to pass urine and stress urinary incontinence. Bowel symptoms such as difficulty moving the bowel or a feeling of not emptying properly, or needing to press on the vaginal wall to empty the bowel are common in patients with POP. According to the degree of descent, there are 4 stages of POP. Women with stage 1 POP usually have mild or no symptoms, and rarely require treatment.

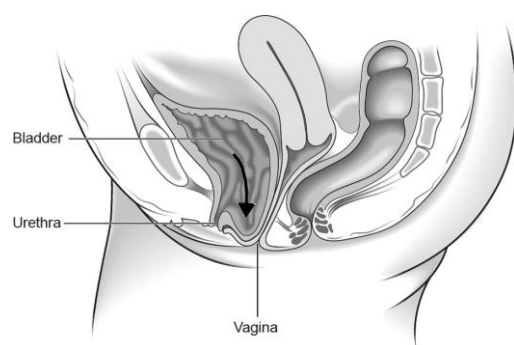
Illustrations of Pelvic Organ Prolapse*:

a) Normal pelvic organs



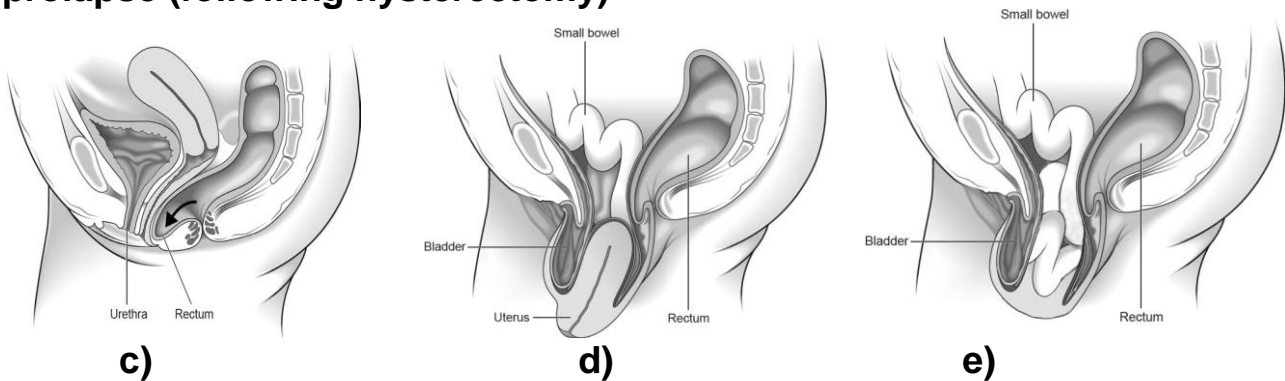
a)

b) Front (anterior) prolapse



b)

c) Back (posterior prolapse) d) Uterine prolapse e) Vaginal apex/vault prolapse (following hysterectomy)



*Reproduced with permission from the Royal College of Obstetricians and Gynaecologists (RCOG), May 2015.

Non-Surgical Options:

There are several non-surgical options for women with POP as follows:

- **Pelvic floor exercises:** Training the pelvic muscles may improve the support of pelvic floor and reduce symptoms. Exercising pelvic muscles in the long-term is recommended to maintain their strength. The clinician should discuss the merits of pelvic floor exercises with you as on occasion this can lead to an improvement in your condition.
- **Vaginal pessaries:** These are plastic or silicone devices that come in various shapes and sizes. They fit into the vagina to provide mechanical support to the prolapsed organs, thus relieving symptoms. Please ask your doctor/surgeon for more information. There are many different types and ways of using pessaries. They are ideal for patients unsuitable for or not ready for surgery.
- **Estrogen Cream:** The use of vaginal hormone cream (estrogen) may be recommended in addition to conservative treatment options as it may help some of your symptoms.
- **Do nothing:** If the sensation of bulge is not troublesome, it is not necessary to have treatment. Symptoms may remain the same or get worse, or sometimes even improve over time especially with mild prolapse. A patient with more severe prolapse is unlikely to improve without the use of a pessary or surgery. POP is not life threatening although it may affect the quality of your life. You can reconsider your options at any time.

If you would like more information on any of the options above, please ask your surgeon for the relevant leaflet and familiarise yourself with the pros and cons.

Surgical Treatment:

If non-surgical treatment options have not been successful or are not appropriate, then surgical intervention may become necessary. The aim of surgery is to restore support of the prolapsing organ and remove the bulge sensation. Bladder or bowel symptoms, low-back pain and sexual problems may occur in women with prolapse, but are very common symptoms in the absence of prolapse as well. They will only improve after surgery if they were related to the prolapse.

While surgery can be performed through the vagina or abdomen (open or keyhole), this leaflet discusses only vaginal surgery (which is still a major operation) to restore support and function. If, in addition to vaginal wall prolapse, you also have prolapse of the womb or vaginal vault (the vault is the top of the vagina following hysterectomy), your surgeon may suggest an additional procedure (vaginal or abdominal, open or keyhole). Please ask for the relevant leaflet(s).

Pregnancy and Surgery: There is an anticipated increased risk of failure of the surgical procedure following pregnancy and childbirth. If you plans to have children in the future, it is normally recommended that you delay surgery until your family is complete (especially if using a permanent implant). Please discuss this with your GP and surgeon. If you do undergo surgery, and subsequently become pregnant, you may be advised to have a Caesarean section.

Vaginal Closure Procedure: If prolapse is advanced and you are certain you will not be sexually active in the future, occasionally an alternative surgical option of vaginal closure may be offered and your clinician will discuss this with you in detail.

Surgical Procedures:

Vaginal surgery can be performed using the following procedures:

- **Fascial or natural tissue repair:** This uses your own tissues and is a long-established procedure.
- **Biological graft implant repair:** This procedure uses a temporary implant to enhance the support until additional natural tissues grow in its place. The graft will be absorbed into the body and disappear after a few months/years.

- **Polypropylene (Prolene) mesh implant repair:** This remains inside the body permanently. There are two methods of use:
 - 1) Mesh-inlay: Mesh is cut to the desired size and placed through a single incision inside the vagina.
 - 2) Mesh-kit: Already-cut mesh is placed using a trocar that may require outside skin incisions in the groin area.

Do I need a vaginal implant?

The use of vaginal implants began in the 1990's, aimed at providing better support. Although scientific evidence is so far limited, vaginal implant surgery is sometimes used for recurrence of prolapse symptoms after unsuccessful fascial/native tissue repair. Implant surgery to the front wall of the vagina may give better results (compared to back wall) in terms of less recurrence.

While vaginal repair using an implant has better anatomical success in achieving cure or improvement of prolapse symptoms from a single operation, this has to be weighed against added risks and complications compared to natural tissue repair procedures. These are set out in table 2 on page 13.

The following table shows a summary of pros and cons* of each of the three options. For detailed information, see table 2 on page 13.

Comparison	Fascial Repair	Biological Graft Repair	Polypropylene Mesh Repair**
Supporting structure	Own native tissues (fascia and/or ligaments)	Absorbable graft	Non-absorbable mesh
Success Rate	Lowest	Moderate	Highest
Long-term pelvic pain	Lowest risk	Moderate risk	Highest risk

*Please see below for details of the risks and complications

* **Trocars are sometimes required during vaginal repair using polypropylene (mesh-kits). Where trocars are used, there may be an increased risk of organ, blood vessel or nerve injury. Further evidence on the risks of injury or functional problems may become available when more research is published.

During the procedure

You and your consultant will have agreed which procedure should be used, based on your symptoms and examination findings in clinic. The decision will take account of your previous surgical history and your own wishes.

- The procedure is usually performed as inpatient and most patients go home after a relatively short length of stay.
- You will be given a general, spinal or local anaesthetic and/or sedation. The type of anaesthesia will be discussed by your anaesthetist/surgeon and depends on the nature of your surgery, your health as well as your wishes.
- If surgery is to be performed using your own tissues, a cut is made in the front (or back) wall of the vagina over the area of the bulge. Repair is carried out and sutures used to bring your own tissues (fascia) together to support the bladder/rectum. The vaginal skin is closed with dissolvable stitches.
- If a synthetic mesh implant is inserted with a trocar, there may be additional smaller skin cuts. Single-incision mesh procedures have no cuts outside the vagina (see table 2). If implants are placed in the front (anterior) wall of the vagina, a cystoscopy (camera looking into bladder) procedure will be performed to ensure your bladder has not been injured during this process.
- Your surgeon may also recommend that other procedures be carried out during the operation. For example; having a continence procedure, if you have stress urinary incontinence, or carrying out either a womb suspension procedure or a hysterectomy if your womb is prolapsed. When you are relaxed under the anaesthetic, other areas of prolapse can sometimes become obvious and may need intervention. Any additional procedure will of course be discussed and agreed with you beforehand.

After the procedure

- You will be taken back to the ward, where the nurses will look after you. Painkillers will be given as required and you may eat and drink later on that day.
- You may or may not have a catheter inserted during the operation. After it is removed, your bladder emptying will be checked. This is done by a routine bladder ultrasound scan and once staff are happy that the bladder empties well, most women can go home on that day. If not, a catheter may need to be used for some time.

- There may be some vaginal bleeding (like the end of a period) and you may need to wear a sanitary pad/liner, rather than a tampon for a few days. You may have vaginal gauze placed in your vagina to help control any bleeding.
- You may also be advised to use vaginal oestrogen cream or tablets for a few weeks after surgery.
- Your clinician will discuss with you when you can resume light activities most suitable for you. More strenuous tasks and heavy lifting should be avoided for eight weeks.
- Return to work will depend on the type of work you do. Please ask your doctor for his/her opinion and if you require a "Fitness for work" certificate.
- You should refrain from sexual intercourse for 6-8 weeks following your procedure.
- It is very important that you avoid constipation by ensuring you drink plenty of fluid and eat fruit and vegetables. On the advice of your clinician, laxatives and/or suppositories may be required to help your bowels work better. It is advisable to continue with any physiotherapy advice you have been given prior to your procedure.
- Your doctor will advise you on follow-up plan after surgery.

For more information on recovery, please ask your doctor for the detailed Recovery Leaflet or visit the following web link:

<https://www.rcog.org.uk/en/patients/patient-leaflets/mid-urethal-sling-operation-for-stress-urinary-incontinence/>

For more information on physiotherapy following your procedure, please ask your doctor or visit the following web link:

<http://www.csp.org.uk/sites/files/csp/secure/pogp-ffsurgery1.pdf>

How to understand level of risk?

The tables below are designed to help you understand the risks associated with surgery. The terms used to denote the degree of risk in the main table are explained here:

Term	Equivalent numerical ratio	Equivalent environment
Very common	1/1 to 1/10	One person in a family
Common	1/10 to 1/100	One person in a street
Uncommon	1/100 to 1/1000	One person in a village
Rare	1/1000 to 1/10 000	One person in a small town
Very rare	Less than 1/10 000	One person in a large town

General Risks of Surgery

Any surgical procedure has risks and potential problems. The following are possible problems that you may experience:

- **Anaesthetic risks:** These are **rare** unless you have specific medical problems. Your anaesthetist will discuss this with you in detail. Death is very rare.
- **Bleeding:** You should expect some vaginal bleeding after the operation. The risk of major bleeding, which is severe enough to need a blood transfusion, is small / **uncommon** but it can happen with any operation.
- **Infection:** The risk of infection with any surgery is common, and you will receive antibiotics in theatre to reduce such risk. The vagina is considered a 'clean but not sterile' surgical field which will not be fully clear of bacteria prior to surgery. Despite receiving routine antibiotics, a urine infection is common while a wound infection is uncommon. Serious hospital-acquired infections (e.g. MRSA and Clostridium Difficile) are rare.
- **Deep Vein Thrombosis (DVT):** A clot in the deep veins of the leg. While the overall risk is common (4-5%), the majority pass unnoticed and resolve spontaneously. It is rare for a clot to migrate to the lungs and cause serious problem following an operation that takes only a short time (less than 1% of those who get a clot). However, there have

been deaths following such clots and, therefore, special stockings and/or injections to thin the blood are provided to all patients.

- **Additional risks:** The risks of any surgical procedure are increased above the average risks if you have any significant medical conditions, if you are over-weight or if you have previously had surgery for a similar problem.

Risks of not having this procedure
(Doctor to document in space provided)

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Is there any research being carried out in this area?

There may be national and local research studies in these areas and you may be invited to participate.

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Table 2: Specific Complications and Risks Following Prolapse Surgery*

Complication/ Risk	Risk of occurrence with				Notes
	Fascial Repair	Biological Graft Repair	Polypropylene Mesh Inlay	Polypropylene Mesh-kit	
Graft / Mesh exposure (erosion) into the vagina	Not applicable	Very Rare	Common	Common	The vaginal skin over the implant may not heal properly or get infected. This could also be due to inflammation, foreign body reaction** or an unusual immune response. It can happen years after surgery. Further surgery *** may be required to cover the implant or to partly remove it.
Failure of the procedure and recurrence of prolapse symptoms	Common	Common	Common	Common	Persistence or recurrence of POP symptoms after some time. Recurrence can occur in the same or in a different area of the vagina. With mesh repair the recurrence rate is less than with facial repair.
Recognised damage to the bladder or urethra during the procedure	Uncommon	Uncommon	Uncommon	Common	Highest risk with anterior mesh placement using trocars. A camera to look inside the bladder maybe required during such surgery to check for damage. When discovered during the procedure, the implant is removed and replaced correctly. Long-term problems following this complication are unlikely.
Stress urinary incontinence	Common	Common	Common	Very Common	Leakage on coughing or sneezing may occur, worsen or improve following bladder prolapse surgery, depending on patient's pre-operative status. Continence surgery may be required in the future.

Problems with the need to pass water more often than normal or having trouble getting to the toilet in time	Common	Common	Common	Common	Overactive bladder symptoms may occur, worsen or improve following surgery, depending on patient's pre-operative status. Physiotherapy and/or drug treatment may be required.
Temporary problems emptying bladder fully	Common	Common	Common	Common	Bladder emptying problems may occur, worsen or improve following surgery. Short-term intermittent self catheterisation may be required for a period of time.
<i>Temporary</i> pain in the pelvis, groin or at the implant site in the vagina or during sexual intercourse.	Rare	Common	Common	Common	Often resolves spontaneously or with painkillers.
<i>Long-term</i> pain in the pelvis groin or at the implant site or during sexual intercourse (due to vaginal adhesions and/or scarring).	Unknown but would appear to be rare.	Uncommon	Uncommon	Uncommon	Could be due to nerve damage or irritation. The condition may continue for months or years. Referral to pain specialists and/or repeat procedures *** to remove the implant may be necessary.
Recognised damage to the bowels during the procedure	Uncommon	Uncommon	Uncommon	Uncommon	Can happen only with posterior vaginal wall surgery. When discovered during the procedure, an abdominal operation may be required to correct the damage, which may

					include a temporary colostomy bag (rare). Long-term problems following this complication are rare .
Persistent problems emptying bladder fully with recurrent urinary tract infections	Uncommon	Uncommon	Uncommon	Uncommon	If the condition continues for several weeks or months, it may require short-term self-catheterisation or further surgery to remove the implant ^{***} . Prolapse symptoms may return and you may need further surgery.
Mesh erosion into the bladder, urethra or bowel	Not applicable	Unknown but thought to be rare	Unknown but thought to be rare	Rare	This may lead to fistula formation and can occur years after surgery. Could be due to spontaneous implant displacement or unrecognised damage to the bladder, urethra or bowel during the procedure. Requires further surgery to remove ^{***} the implant.
Long-term problems emptying bladder fully with or without recurrent urinary tract infections	Unknown but thought to be rare	Unknown but thought to be rare	Unknown but thought to be rare	Unknown but thought to be rare	If the condition continues, it may require long-term self-catheterisation.
Death	Very rare	Very rare	Very rare	Very rare	

Further notes on risks

*The risk levels quoted are those reported in medical literature and confirmed /endorsed by the National Institute for Health and Care Excellence. Data from large relevant registries are not yet available at the time of writing this leaflet. **As current evidence is incomplete and further evidence will be available in due course, this booklet will be updated every two years. Please make sure you are reading the up-to-date version.**

****Foreign body reaction** to the mesh material could lead to inflammation, scarring, infection and mesh exposure. This could be due to an unusual immune response; however, there is currently no good evidence to support a link to autoimmune diseases, at the time of writing this document.

*** **Risks if the mesh implant is to be removed:** Repeat procedures may be necessary and, as the mesh implant is meant to be permanent, complete removal may not be possible to do safely. As mesh removal procedures carry higher risks of organ and nerve damage, referral to a different hospital (with a surgical team experienced in mesh removal) may be required. Even after complete removal, symptoms may persist or worsen. Partial or complete removal of the mesh implant may result in the operation no longer working so you may need further surgery for prolapse.

Your individual risk: The risks of any surgical procedure are increased above the average risks if you have any significant medical conditions (such as diabetes), if you smoke, are over-weight or if you have previously had surgery for a similar problem. Please discuss your own individual risks with your surgeon.

Pregnancy and Childbirth: Mesh implants are permanent and it is strongly recommended you consider this procedure only after your family is complete. While it will not affect your ability to get pregnant, little is known about risks during pregnancy and childbirth. A Caesarean section may be recommended. Please discuss with your GP and surgeon if you intend to have more children.

Information and support

- Physiotherapy Services - Telephone: Opening hours:
- Continence Services - Telephone:..... Opening hours:
- Gynaecology Inpatient Ward - Telephone:Opening hours:
- Your GP - Telephone:..... Opening hours:
- Scottish Mesh Helpline - Telephone: 07824537938 Opening hours: Mon 16:30 to 18:30 Thurs 09:00 to 11:00

Useful Resources

- The British Society of Urogynaecology
www.bsug.org.uk/patient-information.php
- The British Association of Urological Surgeon www.baus.org.uk
- NHS Choices: Pelvic Organ Prolapse Leaflet
www.nhs.uk/conditions/prolapse-of-the-uterus/pages/introduction.aspx
- The Royal College of Obstetricians and Gynaecologists: Pelvic Floor Repair Operation www.rcog.org.uk/en/patients/patient-leaflets/pelvic-floor-repair-operation/
- International Urogynaecological Association
http://c.ymcdn.com/sites/www.iuga.org/resource/resmgr/brochures/eng_popp.pdf
- Medicines & Healthcare products Regulatory Agency (MHRA): safety of vaginal meshes for pelvic organ prolapse
www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf
- MHRA reporting of adverse incidents involving medical device
<https://yellowcard.mhra.gov.uk/devices/?type=mop>

There are currently the following patient self-help groups in the UK:

www.tvtinfo.wordpress.com www.patientopinion.org.uk
www.tvt-messed-up-mesh.org.uk www.scottishmeshsurvivors.com

Note: If you do not have access to Internet, please ask your GP/Surgeon for paper copies of these leaflets

Disclaimer: The NHS is not responsible for the content and does not necessarily endorse the information published in the above websites.

Questions to my Surgeon

Having read the leaflet, please write down any questions you may wish to ask your surgeon.

Example questions:

- Do I need prolapse surgery?
- Which of my symptoms is the surgery aimed at improving?
- Do I need a vaginal mesh/graft implant?
- Is my own individual risk different from those mentioned in the leaflet?
- Are your success and complications rates comparable to national figures?
- What sexual problems may be encountered with use of mesh and traditional surgery and/or other procedures?
- What happens if surgery does not work?
- What would happen if I had a complication?
- If I had a complication related to the mesh, can the mesh be removed safely and completely?
- Is there anything I can do myself to help make my surgery more successful?
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My expectations from surgery

What do you expect the operation to do for you?
What activity do you expect to be able to do again after surgery?

Example expectations for discussion with your surgeon:

- Treat the bulge.
- Feel more comfortable.
- Be able to exercise or do sport regularly.
- Be more socially confident.
- Enjoy sexual life in general.
- Reduce my bladder problems
- Reduce my bowel problems
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Information Checklist*

Please read the following points and write your initials in the boxes next to each statement.

I confirm that I have read and understood all the information in the booklet to the best of my ability including:

The details of the procedure proposed and the desired outcome

All available alternatives of this procedure and their advantages and disadvantages

All information on possible risks including my own

All my questions were answered

Signatures

Signed (Patient):

Name of Patient (PRINT).....

Date:

Signed (Health professional)

Name (PRINT):

Designation:

Date:

***This is not a consent form.**

This information checklist ensures your understanding of all the important information regarding this procedure. Your surgeon will then obtain your consent to undergo the procedure by signing a separate document.