Informed consent form for operation to remove mesh

Surname: …… First name: .....Date of birth:.....

Dear Patient,

The explanations below are intended to inform and not to unsettle you. They are part of your preoperative briefing. The planned procedure will be discussed with you in person. Please ask about anything that you feel is unclear or important, but also let us know if you prefer not to know too much about what the upcoming operation involves.
The operation may take place under regional anaesthesia (spinal cord) or general anaesthesia (deep sedation). Your anaesthetist will explain the advantages, disadvantages and risks associated with the anaesthetic procedure.

Reasons for the procedure:
The artificial mesh used in previous surgery can cause abdominal pain (e.g. from scarring), problems or pain when emptying the bowels, difficulties during sexual intercourse, chronic discharge or continuous loss of urine (fistulation, or the formation of abnormal connections between organs such as your bladder and vagina). Since conservative measures such as topical hormones, physiotherapy, stool-regulating medicines and painkillers do not help,
follow-up surgery is required.
The intention is to remove mesh from inside you. The mesh will have been used to treat

☐ incontinence

☐ blood sedimentation.

The removal of the mesh is recommended in your case because of the following problems:

_____

_____

_____

Surgical method
The operation will involve small abdominal incisions (laparoscopy) or one larger abdominal incision. It may also make sense to support surgical steps from the vagina or to operate solely from the vagina.

Surgical technique
If necessary, other specialists (in colorectal surgery, urology or similar) may be consulted if your bowels, bladder or ureters are affected or if there is fistulation. This will be discussed with you prior to the procedure.
The mesh will be gradually detached from your tissue and removed. The wound will be closed layer by layer and the access points will be closed by stitching. In rare cases and in cases involving extensive adhesion or severe bleeding, it may only be possible to continue the operation by fully opening your abdomen. Supplementary cystoscopy (bladder examination) may be helpful. If the mesh is close to the ureters, it may be necessary to splint them using a special catheter. Should it be impossible to exclude the possibility of the intestine being involved, a colonoscopy may be helpful.

_____

_____

_____

In the event of serious complications – for example if the mesh cannot be completely removed or if there is major blood loss or unexpected findings – you may have to have one or more follow-up procedures.

Risks and complications

During the operation, there may be bleeding that has to be stopped without delay. In rare cases, there may be post-operative bleeding that may have to be resolved by means of a second operation. It is very uncommon for blood substitutes or donated blood to have to be used.

Adjacent organs, including the bladder, urethra, ureters, intestines, blood vessels, nerves and bones, may suffer damage. Treating this damage may necessitate further surgical access (laparoscopy, abdominal incision).

The risk of inflammation, wound healing disorders, thromboses (blood clots) and embolisms cannot be completely ruled out despite medical progress and prevention with injections. The risk is elevated in certain patients, including overweight or bedridden patients and smokers. Skin swelling and shoulder, throat and abdominal pain may occur immediately after a laparoscopy.

In rare cases, fistula – abnormal connections between organs, such as between the bladder or urethra and the vagina – may form, causing long-term incontinence.

There is a risk that you may experience further blood sedimentation and/or urinary incontinence and problems emptying your bowels after the mesh has been removed. This is a risk that it is difficult to assess before the operation.

If pain is one of the reasons why you have been advised to have the mesh removed, there is a possibility that the pain will persist despite the mesh having been successfully removed. In this case, you may require further treatment in the form of physiotherapy, special pain treatment and medication.

Adhesions in the abdominal cavity following laparoscopy and/or abdominal incision may cause intestinal blockage at a later point in time.

Even when equipment has been properly stored and correctly connected, pressure and other damage to nerves and soft tissue may occur in very rare cases during surgery. However, this rarely results in permanent problems (e.g. numbness or painful discomfort) or scarring.

After the operation

A urinary catheter will generally be inserted during the procedure to permit problem-free bladder emptying. Depending on the surgical technique used, this catheter will either be removed immediately after the operation or left in place for a few days. If you have difficulty emptying your bladder, you may have to have a catheter reinserted or be catheterised for one or more days. It takes four to six weeks for the vaginal incision to heal, and discharge will generally increase during this period. You should avoid sexual intercourse throughout healing. You will be able to shower after the operation.

Cost

Your health insurer is obliged to pay for the operation. If you have additional insurance, make sure that cost coverage has been clarified.

Your questions

_____

_____

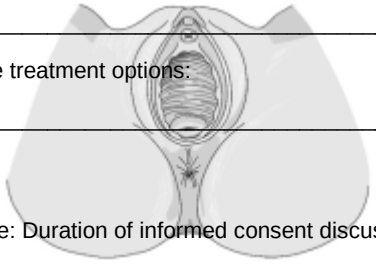
Informed consent discussion Interpreter: _____

Proposed operation:

This informed consent form has been reviewed by the Swiss Medical Association's (FMH's) Legal Department

Doctor's notes on informed consent discussion

(reason for dispensing with discussion if not performed, individual risk-enhancing factors: age, heart disease, obesity, etc.).



☐ Alternative treatment options:

Date: Time: Duration of informed consent discussion:

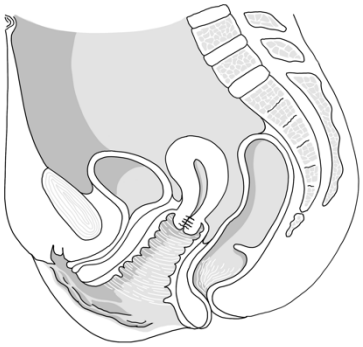
Treatment order:

☐ Dr. _____ has held an informed consent discussion with me. I have understood the explanations and was able to ask any questions I had.

I consent to the planned procedure and to the changes and extensions that have been discussed with me and which may prove to be necessary during the operation (see "Proposed operation").

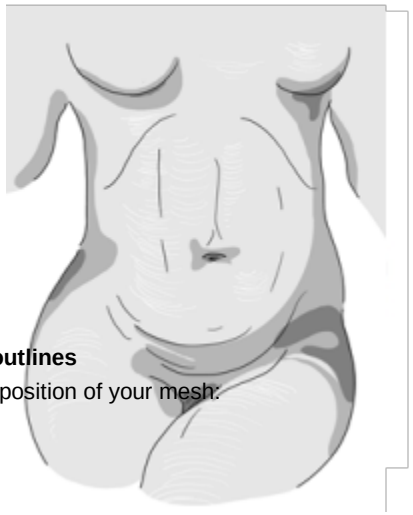
Place, date: Patient:

☐ The text on the front page was discussed with the patient, her questions were answered and a written copy of this discussion was given to her.



Place, date: Doctor:

☐



Operation outlines

This is the position of your mesh:

This informed consent form has been reviewed by the Swiss Medical Association's (FMH's) Legal Department