

Patient's informed consent to the provision of medical services
No-scalpel vasectomy - interruption of the vas deferens for contraceptive purposes

Patient's name and surname:

Date of birth/birth number (if assigned):

Patient identification number (if assigned):

štítek/label

Vasectomy (tick as applicable): bilateral

In case of single testicle right left

I. INFORMATION ON THE NATURE OF THE DISEASE

The purpose of this procedure is to interrupt the vas deferens and ligate (tie off) the ends to ensure they are impassable, thereby resulting in male sterility (infertility)

The procedure leads to permanent sterility. Although the patency of the vas deferens may be restored surgically, this does not guarantee the restoration of fertility. However, if fertility is not restored, it is possible to obtain sperm from the testes surgically in the context of assisted reproduction. In these cases, however, the patient must pay all financial costs associated with this procedure.

II. DESCRIPTION OF PROPOSED METHODS AND PROCEDURES

A vasectomy, or bilateral ligation of the vas deferens, is a sterilisation procedure that is performed by surgically opening the scrotum, locating, ligating and interrupting the vas deferens. Although a man can have normal sexual intercourse and orgasm after a vasectomy, his ejaculate does not contain sperm and thus fertilisation of the ovum and conception cannot occur after a vasectomy.

However, the man does not become sterile immediately after the procedure. There should be an interval of 3 months, during which at least 24 ejaculations occur to clear sperm from ejaculatory pathways, followed by a semen analysis. If sperm persist in the ejaculate, it will be necessary to consult a physician.

The medical procedure will take place as follows:

The operation is performed on an outpatient basis. With the patient in a supine position, the surgeon first applies disinfects the site, then local anaesthesia, and palpates the vas deferens. He first clamps the vas deferens and then inserts special forceps through the skin and pulls the vas deferens outside the scrotum at the injection site. Part of the vas deferens is then cut, ligated with non-absorbable material and the ends of the vas deferens are sealed. Both stumps are then placed back into the scrotal cavity. In case of a bilateral vasectomy, the same procedure is performed on the opposite vas deferens.

In a no-scalpel vasectomy, it is usually unnecessary to suture the wound, which is about 3 millimetres long, so it is left to heal naturally. An antibiotic ointment is applied to the wound and the wound is covered with a sterile plaster.

III. RISKS OF THE PROCEDURE

Every medical procedure is associated with certain risks. There are risks associated with local anaesthesia on one hand, while complications may also arise during or after the procedure itself. Even when following the correct procedure in compliance with relevant professional duties and standards (lege artis procedure), risks and complications may arise, including:

Postoperative pain in the scrotal region (this is mild to moderate), which is transient and usually passes on its own; common analgesics (painkillers) can be used.

Haematoma (bruising) – may manifest as soft swelling and purple discolouration of the wound, large haematomas

are rare – they may take a while to disappear, and it may be necessary to drain/surgically clean the haematoma in some cases.

An infection of the wound may occur in a small number of cases; standard treatment is given in this case (including the administration of antibiotics).

In cases of chronic inflammation of the epididymis, acute inflammation of the epididymis may occur after a vasectomy, which is treated with antibiotics or surgical drainage.

Cases of chronic testicular or epididymal pain after a vasectomy have been reported. In case of persistent chronic pain, the vas deferens can be reconnected (vaso-vasoanastomosis), or the painful epididymis can be removed (epididymectomy), which does not affect the hormonal function of the testes; alternatively, the nerves supplying the testes can be severed (testicular denervation).

Psychological changes have been reported in rare cases, which manifest as a feeling of inadequacy and futility due to infertility and may result in a decline in sexual potency.

IV. ALTERNATIVES TO THE PROCEDURE

Conventional vasectomy (scalpel) – the no-scalpel method has a lower incidence of complications compared to conventional vasectomy.

Ligation of the vas deferens WITHOUT interruption of its pathway – this method does not guarantee 100% certainty of the expected outcome - contraception

Medication – an effective tablet or other contraceptive for men is not currently available in the EU

Use of a condom – is not a permanent method of contraception, and has a higher risk of failure than a vasectomy. A possible alternative for the couple is a similar procedure for women – **laparoscopic sterilisation** - interruption of both fallopian tubes, or the use of **hormonal contraception**.

V. POSSIBLE RESTRICTIONS AFTER THE PROCEDURE

The patient may experience some discomfort around the wound for the first few days after surgery. An ice pack wrapped in a towel can be applied to the scrotal region to prevent swelling. Spending a prolonged time in water (bath, swimming pool, hot tub, ...) is not recommended until the wounds have healed. Showering is permitted. A sauna and physical exertion or sports are also prohibited for 3 days after the procedure. No further restrictions or changes in medical fitness apply after the wounds have healed.

A wait of at least three days after the procedure is recommended before commencing sexual activity. It should also be remembered that a vasectomy does not protect you against the transmission of sexual diseases.

VI. DETAILS OF THE TREATMENT REGIMEN AND PREVENTIVE MEASURES

It should be kept in mind that the patient will not be considered sterile (infertile) until 12 weeks after the procedure, following confirmation by a physician. Other contraception should be used during sexual intercourse for the first 3 months after surgery. Only after an examination of the ejaculate and the fulfilment of EAU (European Society of Urology) criteria for sperm analysis after the procedure can the vasectomy be considered a functional contraceptive method.

If motile sperm is found in the ejaculate more than 3 months after a vasectomy, an examination by the surgeon will be necessary.

VII. PATIENT'S CONSENT

I, the undersigned, declare that I was fully informed about my state of health and the reasons leading to the planned procedure and treatment by the attending physician sufficiently in advance.

I consent to the proposed procedure and treatment, including hospitalisation. The physician has acquainted me in detail with the treatment regimen, the nature of the proposed procedure, its advantages and success rate in a clear and comprehensible manner.

I further declare that I have been clearly instructed by the physician about the permanent consequences and possible risks of the procedure, its alternatives, including their risks and consequences, but also other serious matters related to the treatment. The physician has also informed me of possible restrictions to my normal way of life and ability to work after the procedure. I was given enough time to study the written part of this information. I had the opportunity to ask the physician questions about anything I didn't understand. I have been informed of my right to freely decide on the procedure for the provision of healthcare services, unless this right is excluded by law.

I further declare that I have informed the attending physician of all facts relevant to the assessment of my state of health and the choice of optimal treatment (in particular medical information). I accept that if this declaration is untrue, neither the healthcare provider nor the attending physician shall be held responsible for the consequences.

I have been informed and instructed that a situation may arise during the procedure that may require exceeding this authorisation (e.g., to protect my health). In such a case, I authorise the physician to execute all necessary steps and procedures at his/her discretion based on his/her professional decision. I also consent to the performance of open surgery, if necessary. I declare that I have been acquainted with the healthcare provider's current price list for services and I undertake to duly pay the amounts stated therein and charged to me on time, if they are not covered by public health insurance.

I confirm that the physician has explained that the proposed medical procedure/service is not guaranteed to achieve the expected result.

Note: there must be an interval of at least 14 days between the provision of information and granting of consent, with consent being given immediately prior to the start of the procedure

In Prague, on:

Patient's signature:

VIII. PHYSICIAN'S DECLARATION:

I confirm that I have instructed the patient as indicated above in an appropriate manner, in particular I have clearly and comprehensibly explained the contents of this information, and above all, acquainted the patient with the nature of the procedure, its risks and complications.

In addition to the above, the patient was instructed about the risks and possible complications of the procedure with respect to his/her state of health. The patient understood these instructions and had the opportunity to ask the instructing physician questions, which were clearly answered.

In Prague, date:

Physician's first name, surname and signature:

Physician's notes, if any: