

VASECTOMY INFORMATION AND CONSENT

You will be asked to read through entirely and initial in the box at the bottom of each page

Purpose of the operation:

The intent of this operation, known as a bilateral partial vasectomy, is to render you sterile (i.e., unable to cause a pregnancy in a female partner). You should also understand that there is only a remote possibility of reversing the state of infertility once achieved thus should always be regarded as “irreversible”.

Nature of the operation:

The vas deferens are the tubes which conduct sperm from the testicles and there is ordinarily one tube from each testicle. Bilateral partial vasectomy means dividing and closing each of these tubes and separating the severed ends. A segment will be removed and sent to the pathology lab to validate that it is vas deferens. The skin incisions in your scrotum will be closed with absorbable suture which will dissolve within 2-3 weeks.

Anesthesia for the operation:

The operation will be performed under local anesthesia in the office. The skin of the scrotum and the nerves to the tubes to be severed will be numbed by injection of the anesthetic and you will be fully conscious. At least one injection will be given on each side of the scrotum. This will feel like a bee sting. Sometimes discomfort or pulling is experienced in the area of the groin and testicles but you will not feel anything sharp or painful.

After the operation:

The local anesthetic will begin to wear off within two to four hours. Once you pick-up your antibiotic and pain medication it is imperative that you go straight home following the procedure. Take the prescribed antibiotic until all gone. The pain medication is available to use as needed. An ice pack or bag of frozen vegetables should be used on the scrotum (30 minutes on, 30 minutes off). You are required to limit activities and stay off your feet as much as possible for two to three days and use an athletic support or tight cotton briefs at all times for the first week. You may return to work in two to three days, provided this does not involve very strenuous activity, which should be limited during the first week (ie. working out, lifting heavy, riding a bike). Sexual activity can be resumed in one week, keeping in mind you must use some form of birth control as you ARE NOT STERILE at this point.

Minor postoperative expectations:

1. Mild bruising & scrotal swelling
2. Tenderness around the incision sites and testicles
3. Discharge from the edges of the skin incision

Postoperative complications which can occur include:

1. Epididymitis – painful swelling of the tissues within the testicles, which might include swelling of the testicles (epididymo-orchitis). The resolution of this inflammatory process, if it occurs, may take several weeks or longer.
2. Sperm Granuloma – persistent tender swelling beneath the skin incision above the testicles. This is commonly due to leakage of sperm from the severed ends of the tubes into the tissues causing an inflammatory reaction.
3. Hematoma - hemorrhage due to undetected bleeding into the scrotal sac. In this instance, the scrotum may become swollen and discolored and may require a second incision to drain the accumulated blood.
4. Abscess – pus may form within the scrotum and require a second incision so it may be drained.
5. Recanalization - the ends of the vas may rejoin themselves. The procedure may have to be redone if the semen analysis continues to show (+) for sperm following multiple semen analysis test(s).

Failure of bilateral partial vasectomy

It is essential that you understand you are NOT sterile immediately after the operation. A period of 8-12 weeks will need to pass before you are asked to have your semen examined at the lab. You will not be “cleared” to go without other contraceptive protection until you have had two consecutive negative semen analysis. The vasectomy will sometimes fail to produce sterility and this occurs up to 4% of the time. It is your responsibility to have your semen examined periodically and understand that two negative semen checks are not an absolute guarantee against future pregnancy due to the remote possibility of Recanalization.

PUBLIC STATEMENT REGARDING VASECTOMY AND PROSTATE CANCER

The February 17, 1993 issue of the Journal of the American Medical Association includes two reports of research studies regarding vasectomy and prostate cancer. The research, conducted by Giovannucci at Harvard Medical School, found in patients studied that vasectomy was associated with a small increased risk of prostate cancer.

Although the relationship between prostate cancer and vasectomy was weak in these studies, the findings are still noteworthy and should not be ignored. Neither should the public nor medical professionals overreact to this new information.

Review of other large studies

To best understand the new studies, they must be viewed in light of other similar research on this topic. Two other large studies of similar design conducted in the United States have yielded information on vasectomy, prostate cancer and medical conditions. Both of these long-term studies were highly reassuring about the safety of vasectomy not only in terms of prostate cancer but also in regards to other conditions.

In a study of Kaiser Permanente Health care members, Stephen Sidney and his colleagues found no increased risk for prostate cancer among vasectomized men. In the study conducted in four cities, Frank J. Massey from the University at Los Angeles and his colleagues found a reduced risk of prostate cancer among vasectomized men.

The two new studies reported in the Journal of the American Medical Association found only a small increased risk for prostate cancer among vasectomized men. Medical researchers interpret such a small increase as a weak association that may be due to chance or bias.

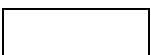
Biologic Mechanism

Before a causal relationship can be established between any disease and a particular factor, a biologic mechanism must exist. According to Giovannucci and his colleagues, reductions in prostate secretions or changes in the immunologic mechanism after vasectomy could be the biologic link between vasectomy and prostate cancer. But most experts do not agree with them.

In 1990, two other medical studies found a link between prostate cancer and vasectomy, but they involved small numbers of men, and the case-control research design has significant limitations. Nevertheless, concerns about the issue prompted the World Health Organization to convene a 1991 meeting of 23 international experts to review all research regarding vasectomy and prostate cancer. The experts concluded that there was no plausible biologic mechanism for a relationship between vasectomy and prostate cancer. The WHO has reviewed the two new Giovannucci studies and has concluded that vasectomy should still be offered to men, provided men review appropriate information about the risks and benefits.

Conclusion

The Association for Voluntary Surgical Contraception has consulted with the authors of the new studies, medical researchers, urologists and national as well as international family planning and research organizations. The findings of the Giovannucci studies are of potential public health importance in countries where prostate cancer is common but may be much less so in countries where the disease is rare.



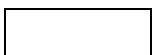
For men considering vasectomy and for men who have had vasectomies: All contraceptive methods carry some risk. The general population, these risks are lower than those associated with pregnancy. When making decisions about contraceptive, each individual or couple must decide how to weigh the various risks in light of their particular circumstances.

Since the relationship between vasectomy and prostate cancer is unproven and the method of carcinogenesis is unknown, reversal of vasectomy to reduce the risk of prostate cancer is not recommended.

The American Cancer Society recommends that all men over the age of 50, including men who have had vasectomies undergo regular prostate screening exam using the most sensitive methods available for early detection. AVSC encourages all men to follow these recommendations.

Approximately 1 in 11 men in the United States develop prostate cancer; most men have never undergone vasectomy. Prostate cancer occurs most frequently in men 80 years or older. In the US, the disease is more common in black men than in white men. For more information about prostate cancer, men should ask their doctors, the local office of the American Cancer Society or the American Urological Association.

If you have further questions, please do not hesitate to call one of us. If you would like a bibliography of references, please ask.



SOUTHEAST VALLEY UROLOGY
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1501 North Gilbert Road, Suite 204 Gilbert, AZ 85234
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CONSENT FOR SURGERY

****No Aspirin or Blood Thinners for at least 7 days prior to surgery****

This includes Ibuprofen, Advil, Aspirin, Coumadin, Plavix, etc. Tylenol is OK to take.

I hereby authorize Frank L. Simoncini, D.O., F.A.C.O.S. / Namir J. Shaba, D.O. and or assistants as may be selected by said physician to treat the following condition(s):

FERTILE MALE DESIRING STERILIZATION VIA VASECTOMY

The procedure planned for the treatment of my condition(s) have been explained to me by my physician and are listed below:

REMOVAL OF A SMALL SECTION OF THE VAS DEFERENS FROM BOTH SIDES (BILATERAL VASECTOMY)

Possible risks associated with the procedure:

1. Inflammation or infection of the testicle(s) or epididymitis
2. Possible re-joining of the vas deferens end(s) resulting in fertility and the possibility to cause pregnancy
3. Chronic testicular discomfort or sperm granuloma
4. Unrecognized long term effects of vasectomy
5. Long term effects of vasectomy are still uncertain and may be associated with increase risk associated with risk of prostate cancer

Alternative therapy: Other forms of contraceptive, male or female

I certify that this two (2) page form has been explained to me and that I have read it or have had it read to me and that I understand its contents:

Patient/Guardian Signature: _____ **Date:** _____

Print name: _____ **Witness:** _____

Our state laws guarantee that you have both the right and obligation to make decisions regarding your health care. Your physician can provide you with the necessary information and advise, but as a member of the health care team, you must enter into the decision-making process. This form has been designed to acknowledge your acceptance of treatment recommended by your physician.

The information that follows is the text from a standardized Surgical Consult form. It is used for the most minor of procedures and the most complicated and serious ones. It is not meant to frighten you but rather to inform you that ALL procedures carry some risks. Many operations, for instance, have only the remotest chance of needing blood transfusions but yet blood transfusions are mentioned. This form hopefully will allow you to better understand your upcoming operation. If you don't understand something...ASK!

I recognize that during the course of the operation, post-operative, medical treatment, anesthesia or other procedures, that unforeseen conditions may necessitate additional or different procedures than those set forth. I therefore authorize my physician and their assistants or designees to perform such surgical or other procedures as are in the exercise of their professional judgment necessary and desirable. The authority granted under this paragraph shall

extend to the treatment of all conditions that require treatment and are not known to my physician at the time the medical or surgical procedure is commenced.

I realize that all procedures have risks and potential complications. I have been informed that there are significant risks such as blood loss, infection, and cardiac arrest that can lead to permanent or partial disability or death, which may be attendant to the performance of any procedure. I realize that in those cases where an incision is needed, that infection, incisional pain or hernia formation (weakness or bulging) can occur and may require further treatment or procedures.

I realize that the list of risks and complications on this form may not include all possible or known risks of the intended surgery but is a list of the more common or severe ones. I realize that new risks may exist or may be found in the future that are not mentioned on this consent form.

I acknowledge that no warranty or guarantee has been made to me as to the results of my procedure or cure of my condition.

I consent to the administration of anesthesia by my attending physician, by and Anesthesiologist or other qualified party under the direction of a physician as may be deemed necessary. I understand that all anesthetics involve risks and potential complications and possible serious damage to vital organs such as the brain, heart, lungs, liver and kidneys and that in some cases may result in paralysis, cardiac arrest and/or brain death from both known and unknown causes.

I consent to the use of transfusions of blood and blood products as may be deemed necessary by my physicians. I understand that diseases can be transmitted via these blood products, including AIDS and Hepatitis.

I acknowledge that any tissues or parts removed surgically may be disposed of by the office, hospital or physician in accordance with accustomed practice.

I understand that any aspect of this consent form that I do not understand can be explained to me in further detail by asking my physician(s) or their associates.

I certify that my physician has informed me of the nature and character of the proposed treatment, the anticipated results of the proposed treatment, of the possible alternative forms of treatment and the recognized serious possible risks, complications and the anticipated benefits involved in the proposed treatment and the alternative forms of treatment including non-treatment.

I further acknowledge that I do have a driver with me that will be transporting me after the procedure and that I understand that if no driver is present prior to the procedure being done, that I will have to wait in the waiting room for 15 to 20 minutes following the procedure before leaving.

Patient or Guardian Initials _____

The medical procedure or surgery stated on this form (page 1), including the possible risks, complications, alternative treatments (including non-treatment) and anticipated results, was explained to the patient or his/her representative before the patient or his/her representative consented:

Physician Signature _____ **Date** _____

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PATIENT NAME: _____

APPOINTMENT DATE: _____

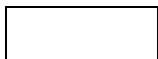
ARRIVAL TIME: _____ APPT. TIME: _____

SCHEDULED WITH: DR. FRANK SIMONCINI DR. NAMIR SHABA

YOU ARE REQUIRED TO READ THROUGH THIS PACKET ENTIRELY, INITIAL IN THE BOX AT THE BOTTOM OF EACH PAGE & SIGN THE "CONSENT FOR SURGERY" FORM. PLEASE BRING ALL PAGES OF THIS PACKET, THE NEW PATIENT FORMS ALONG WITH YOUR INSURANCE CARD & A PHOTO ID ON THE DAY OF YOUR SCHEDULED PROCEDURE.

Pre-Vasectomy Instruction & Information

1. Shave all the hair from the upper scrotum. This means just under the penis onto the scrotal sac. The area shaved should measure about 2-3 inches around. You should do this in the morning of the procedure. Lather the scrotum with soap and water and shave with a safety razor. After shaving the area, thoroughly wash the penis and scrotum, then shower or bathe to remove all loose hairs. If needed, wash the area again just before coming in for the procedure.
2. Bring a scrotal support (jock strap, suspensory or tight jockey or brief underwear).
3. Wear comfortable, loose pants or shorts on the day of your procedure.
4. You should have someone with you on the day of your procedure that is able to drive you home. If you do not bring anyone with you, we will ask that you wait in the waiting room for 15-20 minutes following your procedure.
5. Refrain from eating a large meal prior to your procedure. You may have a small breakfast and drink normally.
6. **Do not take any products containing blood thinners for 7-10 days prior to your procedure.** This includes Ibuprofen, Aleve, Advil, Coumadin, Plavix, etc.. We will not perform your procedure if you have been taking any of these types of agents!! Tylenol is ok to have.
7. ****It is the responsibility of the patient to know what your benefits are for the procedure. You should contact your insurance company prior to the procedure to inquire about coverage for: OFFICE VISIT CONSULT 99204, VASECTOMY 55250 & VAS DEFERENS PATHOLOGY SPECIMEN 88302 x 2.** Our office will perform a benefit investigation a few days prior to the appointment and let you know what we will need to collect up front when you arrive for the procedure. **All deductible, co-insurance & co-pay amounts quoted as patient responsibility will need to be collected at the time of service. Quoted benefits are only an estimate and not a guarantee of coverage or payment through your insurance. Once the claim process' there may be additional amounts owed based on your coverage.**
8. It is recommended that the vas deferens removed during the procedure be sent to a pathology lab to confirm they are vas deferen anatomy. There will be an additional charge from the lab if your insurance does not cover this service. The service code for this is: **VAS DEFERENS PATHOLOGY SPECIMEN 88302 x 2**
If you DO NOT wish to have this performed, let us know upon checking in and we will have you sign a waiver declining the test.
9. ****There is a charge of \$200 for appointments not cancelled at least 48 hours in advance. This is not billable to your insurance company and you will be responsible for payment.**



POST VASECTOMY INSTRUCTIONS

YOU ARE NOT STERILE AT THIS POINT!! YOU MUST CONTINUE TO USE SOME FORM OF BIRTH CONTROL!!

1. It is recommended that you wait at least **7 days before resuming sexual activities**. You may resume sexual activity if you are not having any discomfort. However, having ejaculations too soon after a vasectomy may increase the chance of rejoining of the tubes.
2. Ejaculations help to clear the passage of sperm but you and your sexual partner must use some other method of birth control until you are told that you may discontinue its use.
3. **For the day of the procedure and two days following, do not do any work that requires lifting, pushing or straining, etc. You should try to stay off your feet as much as possible keeping your legs elevated. Use an ice pack or bag of frozen vegetables on the scrotum (30 minutes on, 30 minutes off). Take the prescribed antibiotics until gone and the pain medication as needed. Doing too much too soon could result in prolonged healing.**
4. Keep the incisions dry for two days following the operation. Thereafter you may resume normal bathing. Do not scrub the incision site.
5. Some black and blueness (bruising), draining (oozing), from the incision, swelling or mild tenderness of the scrotum are not unusual. Also, the edges of the incision may pull apart and heal rather slowly and sometimes a knot may be present which remains for several months. These are all part of the normal healing process and are nothing to worry about.
6. Wear a suspensory or athletic supporter only as long as you seem to need it for comfort
7. The sutures placed do not have to be removed. They are absorbed and will drop off by themselves usually within 10 days but often take longer.

POST VASECTOMY SEMEN SAMPLES

1. Our office will supply you with collection instructions, lab orders and sterile containers in order to perform the semen analysis.
2. **You must wait a minimum of 2 months AND have 30 ejaculations or more before you begin submitting semen samples to the lab.** The longer you wait with more ejaculations before submitting samples, the greater your chance of having negative results.
3. **Follow the collection instructions entirely in order to avoid having sample(s) submitted incorrectly.** *Make sure the lid is on the specimen securely. You cannot do specimens on the weekend. And if using Lab Corp, you must make an appointment.*
4. Contact our office 2-3 days after submitting a sample to obtain the results.
5. Wait at least 1 month between each sample submitted. If you have a positive (+) result, you are advised to wait at least 1+ months before submitting the next sample.
6. **You MUST have two (2) consecutive negative samples before you are cleared to go without protection.**
7. Charges for the semen analysis will be billed by the lab. They will submit the charges to your insurance or to you directly if you are self pay. Each sample runs about \$50. Remember, the longer you wait the better your chances are of getting negative results.

