VASWEB VASECTOMIES AND REVERSALS

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GENTLE TOUCH® (NO-SCALPEL NO-NEEDLE) VASECTOMY

Vasectomy is a method of birth control chosen by more than 500,000 men each year in the United States. It is a simple, safe procedure that is more than 99% effective in preventing unwanted pregnancy. Vasectomy does not affect one's manliness in any way because it has no effect on the male hormones produced by the testes. Sex drive, the ability to attain and maintain erections, and the sensation of orgasm usually remain the same following vasectomy. Since the procedure only prevents sperm from entering the semen (ejaculate) and since sperm comprise only 2-5% of the semen volume, most men notice no change in the male reproductive fluids.

Vasectomy is performed in the office under local anesthesia and most patients agree that it hurts about as much as having a blood sample drawn from the arm, though many say not at all. Since May of 2003, we have used a spray applicator (MadaJet®) to deliver a stream of anesthetic so fine that it numbs the skin and penetrates to a depth of about 3/16 of an inch, enough to surround and anesthetize each vas tube in turn as it is lifted into position beneath the skin. After cleansing and draping the scrotum in a sterile field as the anesthetic takes effect, one vas tube is manipulated back into position just underneath the area of numb skin. It is held against the skin with special fixation forceps, then drawn through a small opening in the skin, divided, and the upper cut end cauterized so that it will seal by scarring. A suture tie or small metal (titanium) clip is used to close the vas sheath around the upper end so that the ends are placed out of alignment, separated by a tissue layer, and less likely to grow back together. (No, you won't set off airport alarms and your scrotum won't explode in an MRI machine.) The vas ends are released back into the scrotum and the other vas is brought out through the same opening and treated similarly. No sutures are required; the small opening will usually seal up within a day.

Partners are welcome to accompany patients and watch the procedure.

The patient is asked to minimize physical activity for 48 hours. He may return to work and normal sexual activity 2 days after the procedure.

Vasectomy reversal is a three-hour procedure that results in return of sperm to the semen about 85% of the time overall. Success rates decrease with time after vasectomy, ranging from 97% sperm recovery and 75% pregnancy within 3 years of vasectomy to 65% sperm recovery and 30% pregnancy when the interval has been longer than 15 years. Because reversal attempts are not always successful, vasectomy should be considered a permanent and irreversible procedure.

For patients without an insurance plan with which our office is contracted, our practice charges \$590.00 for the vasectomy procedure. Those with an insurance plan with which our office is contracted and which covers vasectomy are asked to pay the "allowable" for their plans: examples as of 2/6/24 (subject to change) are: Aetna \$448.82; BCBS \$484.83; Cigna variable but we are told to use \$554.64 as of Aug 2023; United \$493.27. This fee covers follow-up visits (if necessary) and semen checks in the office to be sure no sperm remains in the ejaculate. So much information is available online at www.vasweb.com that a preliminary consultation visit is not required, but we would be happy to meet personally with any patient who would like to do so prior to his procedure, and for this visit there is no charge. (We usually require separate visits or preliminary telephone consultations for childless men in their 20's, just so they have plenty of time after the consultation visit or call to consider alternatives.) In addition, the online pre-registration process allows us to review the surgical and medical histories of each patient before the procedure so that we can speak personally by phone if we identify any issues that may be cause for concern. Unless the patient's vasectomy is being covered under Title 10 through a county health department, we require a \$150 deposit to schedule a procedure. We require the balance payment at the time of service. We submit a claim to plans with whom we are contracted and reimburse the patient the amount that he paid or that insurance paid, whichever is less. For reimbursement from an insurance company with whom we are not a contracted provider, we will provide an itemized receipt which the patient sends to his insurance carrier.

INSTRUCTIONS BEFORE YOUR VASECTOMY

- If your partner has already had a tubal ligation (female sterilization), of if she is pregnant now and may have a tubal ligation during a
 Caesarean delivery, please tell our staff that you would like to speak with Dr. Stein or Dr. Galante before your vasectomy.
- 2. Review the Vasectomy page at www.vasweb.com. Understand the Alternatives to Vasectomy.
- 3. Understand the Instructions Following Vasectomy below so that you know what to expect.
- 4. Please shave the underside of the penis and the front wall of the scrotum on the evening before your vasectomy. A bit of alcohol is used to clean the skin before use of the MadaJet® and it can sting slightly right after a fresh shave if the skin is chafed.
- 5. Use **no powder or deodorant** in the genital area on the day of your procedure.
- Please wear tight supportive underwear or an athletic supporter (jockstrap) to the office on the day of your procedure.
- 7. Be prepared to sign the operative **consent** sheet (pages 3 & 4 below) upon your arrival in the office.
- 8. Driving home: It is not required, but, if possible, arrange to have someone drive you home. We have had numerous patients (1 in 200) pass out during or minutes after their vasectomies, and a few patients have passed out in the car while being driven home. In our practice, no patient has had an accident while driving himself home, but in other busy vasectomy practices in Canada, about 1 in 10,000 patients has had an accident while driving home, never fatal. If you must drive yourself, drive in the right lane, so that you can pull over at the slightest hint of delayed lightheadedness. Also, a flat tire or fender bender could lead to complications.
- 9. Plan to **do nothing** but recline at home on the evening of the vasectomy.
- 10. Do not take any aspirin-containing medication for five days before the procedure.
- 11. If your insurance company or HMO requires **authorization**, be sure to bring it or call our office (813-536-1430) a day or two before your vasectomy to see whether we have received it.
- 12. If your procedure is covered through a county health department under Title 10, we will call you to arrange a date and time when we receive the paperwork, or you may call us at 813-536-1430 if it seems to be taking too long.
- 13. If you are taking **TESTOSTERONE** for "low T" please list it as one of your medications when you do the Online Registration and read the info HERE.
- 14. Eat before your procedure, a normal breakfast or lunch. Nervous men who do not eat beforehand are more likely to become lightheaded during or after their vasectomies.
- 15. If you have no insurance and are paying \$590 (\$390 if you are a training case), you will pay a \$150 deposit when filling out the online registration and \$440 (\$240 if you are a training case) immediately before the procedure. If you have insurance though a plan with which are contracted, you will pay a \$100 deposit when filling out the online registration and your plan's contracted allowable (less the \$100 deposit) immediately before the procedure. We will submit a claim for you. If we are paid by your insurance carrier, that amount or what you paid (whichever is less) will be refunded to you. For men with insurance plans with whom we are not contracted, we will provide an itemized and coded receipt which can be sent to the plan for possible reimbursement.

INSTRUCTIONS FOLLOWING VASECTOMY

- 1. Spend a quiet evening at home, reclining in bed or on the sofa. Minimize activity. You may sleep on your back, side, or front side.
- 2. **Avoid aspirin** for 2 days after the vasectomy. You may take **acetaminophen** (Tylenol or generic) if you have any discomfort, as well as **ibuprofen** (Motrin, Nuprin, Advil or generic) and **naproxen** (Aleve or generic) which are both pain medications and anti-inflammatory drugs. If you feel no discomfort for 2 days, then have some pain on days 3-5, don't worry. Your body goes through a series of steps in adjusting to the new arrangement, and sometimes the later steps are more noticeable than the earlier steps. See #10 below.
- 3. No need for ice packs, but you may try one if you have discomfort that responds only partially to acetaminophen.
- 4. You may remove your tight underwear or **scrotal support** and take a daily **shower** starting the morning after the procedure. Wear them whenever you are up and around for the next 2 days, during sports for the next 7 days.
- 5. On the **day after the procedure**, you may walk and drive as much as you like, but no sports, yard work, swimming, or heavy lifting. If your job is sedentary (office work or supervisor), you may return to work.
- 6. **Two days after** the procedure, you may return to more strenuous work and regular activities, including swimming, wearing your scrotal support. **When pain is gone and tenderness is minimal**, you may return to the **gym** or to **running** or to **cycling**, but on the **first day** back, do ½ **of your usual workout**: half the weight, half the reps, half the speed, half the distance, etc. If pain does not return, you may do your regular workout the next day. While we have no data, it makes sense intuitively not to engage in activities that involve direct pressure to the testicles for about a week: riding a horse or rodeo bull, riding a sport bike (crotch rocket), or racing motocross.
- 7. When you no longer have any pain and only minimal tenderness, you may **ejaculate**. I have always recommended waiting at least **2 days**, but the American Urological Association Vasectomy Guidelines recommend that men **wait a week**. Polls of our own patients do not indicate a benefit to waiting more than 2 days if pain is gone by then. **Blood in the semen** for the first few ejaculations, or even a month after vasectomy, is not common, but is also no reason for concern. **Use other forms of contraception until you are told by my staff that your semen is sperm-free**.
- Since no sutures are used to close the small skin opening, a follow-up visit is not required. But if you have undue discomfort or any concerns, please call us. About 10% of men will still have some discomfort at 1 week, 3% at one month, and fewer than 1% at 6 months.
- 9. It is normal to have some **discoloration of the skin** around the puncture site. Some men will develop considerable discoloration of the scrotum about **4 days after the vasectomy**. Blood from the deep vasectomy site comes to the surface as a purplish-blue mark, gets darker and spreads out like an oil slick, then gradually dissipates.
- 10. Some men (about one in 20) will develop **swelling and discomfort** on one or both sides, starting 3 days to 3 months following vasectomy. This usually represents an exaggerated form of the normal inflammatory response necessary for sperm absorption and recycling. It is best managed with a 5-7-day course of **ibuprofen** 600 mg 3 times per day.
- 11. At least twelve (12) weeks AND 20 ejaculations after your vasectomy, mail or bring a semen sample to our office.
 - If you are **bringing** the sample, it should be in a small container with a lid, such as a pill bottle, baby food jar, 35mm film canister, etc. Please do not bring the sample in a condom or baggie as we will be unable to retrieve a specimen adequate to be checked and you will be asked to return with another sample in a container with a lid. The sample should be produced on the day of the examination but can be 3-4 hours old. If sperm are seen you will be asked to continue other means of birth control and return with a second specimen in 2-3 weeks.

If you are **mailing** the sample, use the mailer and follow the instructions provided. If you have not received an email with the results, call 813-536-1430 about 5 days after you mail your sample **to obtain the results**. If sperm are still seen, we will send another mailer to be returned with a sample to the same office 3-4 weeks after the first sample. Because of rising postal fees, we charge \$10 for a replacement mailer if you lose the one that we provide.

VASECTOMY - SIDE EFFECTS, POSSIBLE COMPLICATIONS, ALTERNATIVES & INFORMED CONSENT

Vasectomy provides the **most effective**, permanent means of surgical contraception. When compared with other contraceptives, it has one of the lowest incidences of side effects, considering that pregnancy is a side effect of alternative contraceptive failure. No deaths have been attributed to vasectomy in the USA. Large-scale studies show that the overall incidence of complications is less than 5 per 100 vasectomies performed.

Minor side effects immediately following vasectomy may include discomfort, swelling and/or bruising of the scrotal skin, all of which usually disappear without treatment. Some men (about 1 in 20) will experience swelling and a low-grade ache in one or both testes anywhere from three days to six months after the procedure. This is probably due to an exaggerated form of the body's natural response to the obstruction caused by the vasectomy. It usually responds nicely to an anti-inflammatory drug (such as ibuprofen) 400-600 mg 3 times per day and almost never lasts for more than a week or two but for rare patients, fewer than 1 in 100, swelling and discomfort will occur more than once and/or will be severe enough to require prescription pain medications, stronger anti-inflammatory drugs, and one or more days off from work. About 1 in 100 men will develop a grape-sized hematoma (blood clot) on one side after use of the spray applicator for anesthesia. That causes more noticeable and prolonged (7-10 days) discomfort on that side, but usually does not require prescription pain pills.

Early complications such as hemorrhage and infection can occasionally occur after any surgery. Based on large-scale studies, the overall incidence of either hematoma (a blood clot in the scrotum) or infection is less than 2% of the vasectomies performed. As of February 2024, Drs. Stein, Galante, and a prior associate have collectively performed over 52,000 vasectomies. Fifteen patients have developed blood clots in the scrotum, larger than a walnut. Twelve did not require surgical drainage, but swelling did keep them quite tender for 2 to 4 weeks post-op. One man did require same-day admission to the hospital and surgical drainage of the blood clot under general anesthesia in the operating room, another required surgical drainage through a 1-2 inch incision in the office, and a third opted to undergo partial removal of an old clot about one month after his procedure. Seven severe infections have occurred: the patients had prolonged discomfort and progressive swelling on one side; one even had to be hospitalized with sepsis (systemic infection). All responded to oral (or intravenous) antibiotics, but 4 eventually developed a walnut-sized abscess that drained spontaneously or required office drainage through a half-inch incision and a two-week period of local wound care. Three milder infections caused vasectomy site swelling and, in one case, even discomfort with urination, but they responded quickly to antibiotics. In the medical literature, there is one report of infection resulting in death: that's one case out of many millions of vasectomies. Post-procedure fainting can occur even hours after vasectomy. If it occurs while driving or standing, significant injury can occur.

Long term, vasectomy can lead to the following **conditions**:

- 1. A <u>sperm **granuloma**</u> is a pea sized sometimes-tender mass which results when the body reacts to and walls off sperm which may leak from the lower (testicular) end of the cut vas. A sperm granuloma may actually enhance the likelihood of reversal success. Some are tender enough to require removal in the office under local anesthesia.
- 2. A few (perhaps 5%) of patients will experience <u>periodic tenderness</u> of the <u>epididymis</u>, the tube behind the testis in which sperm are resorbed by white blood cells after vasectomy. Since this resorption process is a form of inflammation, it nearly always responds to a short course (3-7 days) of an over-the-counter anti-inflammatory drug such as ibuprofen. +++ <u>Post-vasectomy pain syndrome</u> is defined as *testicular pain* (on one or both sides) for greater than 3 months after having a vasectomy, severe enough to interfere with daily activities and causing a patient to seek medical attention. Because pain is so subjective, reported rates vary but compiled data would suggest that this is a significant problem for 1-2% of vasectomy patients, though it seems to be less common than this in our practice. Vasectomy reversal, removal of the epididymis, or a special procedure called neurolysis (all **major** procedures) may be required to alleviate the discomfort. +++ In addition, in our practice, about 1-2 patients per year (about 1-2 in 2500) develop prolonged vasectomy site tenderness for which they eventually choose to undergo another **minor** office-based vasectomy procedure on one side to remove the tender spot. Thus, out of over 48,000 patients, 12 (about **one in 4000**) have considered or required a **second MAJOR procedure** to manage pain, and another 20 (about 1 in 1500) have required a **second MINOR procedure** to manage pain or local tenderness. It seems that the rate in our practice is lower than that reported elsewhere, perhaps because of differences in technique between surgeons, but the risk is still very real.
- 3. Recanalization is the re-establishment of sperm flow from the testis up to the rest of the reproductive tract by virtue of the cut ends of the vas growing back together after vasectomy. Early recanalizations occur during the healing process. They are detected at the time of follow-up semen checks when live (moving) sperm or significant numbers of non-motile (not moving) sperm are still seen in semen specimens six months after the vasectomy. An unwanted pregnancy does not occur if the couple has used other forms of contraception as advised. It obviously requires that the procedure be repeated and there is no charge for the second procedure. Up until late 1990, when we started separating the vas ends with a tiny clip, we had 3 patients with this complication out of about 1500 (1 in every 500). Since then, and of about 50,000 vasectomies, we have had another 25 early failures (1 in every 2000), fewer since some changes in technique in 2007. Late recanalization, return of live sperm to the semen at some time after the semen has been confirmed to be sperm-free by microscopic examination, is also very rare. I have had direct experience with this problem 23 times. One man caught it on a routine semen check performed "just to be sure" he was still sperm-free, before a pregnancy occurred. The other 22 men caused pregnancies and then were confirmed to have sperm in their semen. Another two men caused DNA-documented pregnancies without detectable sperm in the semen, but they have "no doubt" that no other man was involved. As the years go by, other cases of delayed failure of our own vasectomies may occur, so the number may rise. But considering these 26 cases out of 52,000 and reports in the literature, late failure resulting in pregnancy is possible but rare, odds being about one in 2000 over the lifetime of the patient, a rate of failure MUCH lower than with any other form of contraception. Our office does not require
- 4. <u>Anti-sperm antibodies</u> do appear in the blood of about half of the patients who undergo vasectomy and patients who develop antibodies may have a lower chance of causing a pregnancy even when a successful vasectomy reversal allows sperm to re-enter the ejaculate. These antibodies have no influence on health status otherwise.
- 5. An article reporting a modest association between vasectomy and <u>prostate cancer</u> was published in the Journal of Clinical Oncology (JCO) on September 20, 2014. There have been many articles since then confirming the absence of an association, and the American Urological Association has reaffirmed that **vasectomy is not a risk factor for prostate cancer**, and it is not necessary for physicians to routinely discuss prostate cancer in their preoperative counseling of vasectomy patients.

6. There are reports on the Internet in which contributors claim that they experienced a <u>decrease in erectile function, libido, or climax intensity</u> after vasectomy. In 2006, we mailed 400 surveys to men whose vasectomies had been done more than six months prior to the survey. One hundred nineteen (119) surveys were returned, and THESE ARE THE RESULTS OF THAT SURVEY:

(There is nothing here for YOU to circle or fill out.)

Since your vasectomy, how have the following changed?	Much	Slightly	No change	Slightly	Much
	less	less		more	more
Sex drive (libido)	2	4	92	16	2
Ability to obtain and maintain erections	0	5	110	4	0
Rigidity (stiffness) of erections	0	5	109	4	1
Strength of orgasm (climax) sensation	0	6	98	12	1
Semen volume (the amount of fluid that comes out when you ejaculate)	5	16	86	12	3

There is no physiological explanation for these changes, either positive or negative, but men should consider the slight possibility of a negative influence of vasectomy on their sexual responses.

There are a number of alternatives to vasectomy:

- 1. Barrier methods. You could wear a condom, your partner could use a diaphragm, or you could use both together.
- 2. **Spermicides.** There are *foams and creams* that can be placed into the vagina before intercourse to kill sperm before they can fertilize your partner's eggs. Spermicides can be used alone or in combination with barrier methods.
- 3. Hormonal methods. Your partner may use birth control *pills*, *shots*, *patches*, *or implants* to prevent the release of eggs from the ovaries or the implantation of fertilized eggs into the uterus (womb). *Emergency Contraception* (EC, Plan B, or the "morning-after" pill) will prevent pregnancy if taken within 72 hours of intercourse during which no contraception was used, or during which a condom slipped off or broke.
- 4. Intrauterine device (IUD). Your partner may have a small device placed into her uterus to decrease the likelihood of fertilization (sperm and egg coming together) and to prevent implantation of fertilized eggs into the uterus.

All of these **alternatives** are less effective than vasectomy, but they **are reversible**. You should be familiar with them before proceeding with vasectomy. Please ask us if you would like more information, and feel free to postpone your vasectomy if you need more time to evaluate information about alternatives.

There is no form of fertility control except **abstinence** that **is free of potential complications**. Vasectomy candidates must weigh the risks of vasectomy against the risks (for their partners) of alternative means of contraception as well as the risks associated with unplanned pregnancy and either induced abortion or childbirth. Vasectomy provides a means of permanent birth control with a minimum likelihood of complications and maximum chances of effectiveness and safety.

FEES

Patients without an insurance plan that covers vasectomy through our office are asked to pay \$590.00 for the procedure: a \$150 deposit to secure an appointment, then \$440 (\$240 for training cases) at the time of service. If you are a member of a health plan with whom we have a contract, you will pay a \$150 deposit at registration and your insurance plan's allowable at the time of service. If we are paid, we will then pay you back the amount that insurance paid or the amount that you paid, whichever is less. Examples of these rates as of 2/6/24 (subject to change) are Aetna \$448.82; BCBS \$484.83; Cigna variable but we are told to use \$554.64 as of Aug 2023; United \$493.27. Patients whose vasectomies are being covered by Title 10 through a county health department pay us nothing.

CONSENT FOR STERILIZATION

I, the undersigned, request that Douglas G. Stein, MD or Alex E. Galante, MD perform a bilateral vasectomy, a procedure to produce obstruction of the vas deferens for the purpose of producing sterility. I understand there can be **no absolute guarantee** that this or any procedure will be successful. It is understood, however, that my semen will be checked following the operation. I understand that contraception must be practiced until there are no sperm present. I also understand that while the reversal success rate is quite good, it is not 100%, and vasectomy should therefore be considered a permanent or non-reversible procedure. I recognize a small chance that I might have to come to Dr. Stein and Galante's Lutz/Tampa office or go to a hospital for evaluation and treatment of a very rare complication. By consenting to vasectomy and accepting the risks outlined above, I release Drs. Stein and Galante from liability for time lost from work, salary unearned, and medical expenses incurred to treat complications.

I have read and understand all paragraphs of this double-sided single-spaced document.			
Patient's Signature:	Wife's Signature (optional):		
Witness:	Date:		

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