## 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 2019, Drs. Stein and Curington have collectively performed over **48,000 vasectomies**. <u>Fifteen</u> 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. <u>Three</u> severe **infections** have occurred: the patients had prolonged discomfort and progressive swelling on one side, partially responsive to oral antibiotics, but eventually maturing to a painful walnut-sized abscess requiring office drainage through a half-inch incision and a two-week period of local wound care. A fourth infection looked like it would develop into abscess but resolved with antibiotics. <u>Two</u> milder infections caused vasectomy site swelling and, in one case, even discomfort with urination, but they responded quickly to antibiotics.

## 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.
- 2. A few (perhaps 5%) of patients will experience <u>periodic tenderness</u> of the epididymis, 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. Vasectomy reversal, removal of the epididymis, or a special procedure called neurolysis (all **major** procedures) may be required to alleviate the discomfort. About 2 patients per year (about 1 in 1500) 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 40,000 patients, eight (about **one in 5000**) 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 42,000 vasectomies, I have had another 6 early failures (1 in every 6000). 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 21 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 20 men caused pregnancies and then were confirmed to have sperm in their semen. Another two men caused DNA-documented pregnancies, but had no sperm in their semen on multiple tests (the veritable "one got through"), and another three caused non-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 my own vasectomies may occur, so the number may rise. But considering these 26 cases out of 42,000 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. My office does not require another semen check after the absence of sperm has been confirmed, but patients may return with or mail a second sample any time after vasectomy to achieve an added index of confidence. There is no charge for the exam, but we ask \$10 to send to you a mailer.
- 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. Based on an updated meta-analysis of this and many other articles that have addressed this topic through the years, the American Urological Association reaffirmed on November 7, 2014 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. There have been many articles since then confirming the absence of an association.

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:

Since your vasectomy, how have the following changed?	Much less	Slightly less	No change	Slightly more	Much more
Sex drive (libido)	2	4	92	16	2
Ability to obtain and maintain <b>erections</b>	0	5	110	4	0
Rigidity (stiffness) of <b>erections</b>	0	5	109	4	1
Strength of <b>orgasm</b> (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. We will not apply for your insurance without payment at the time of the procedure unless you are a member of a <u>health plan</u> with whom we have a contract and we have confirmed pending payment. We are now checking for insurance coverage beforehand for those patients who have insurance with companies with whom we are a provider. If vasectomy is covered under your plan but you have a high deductible, you will be informed beforehand and will be asked to pay the contracted rate at the time of the procedure. Examples of these rates as of 6/14/17 (subject to change) are **Aetna** \$448.82; **AvMed** \$450.00; **BCBS** \$484.83; **Cigna** \$460.45; **United** \$493.27. Patients whose vasectomies are being covered by the **VA**, or by **Title 10** through a county health department, pay us **nothing**.

## **CONSENT FOR STERILIZATION**

I, the undersigned, request that Douglas G. Stein, MD or John G. Curington, 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 <u>contraception must be practiced until there are no sperm present</u>. 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 Curington'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 Curington 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

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Date