To vasectomy candidates of Drs. Doug Stein and John Curington:

Once vasectomy patients ourselves, we have enjoyed the benefits of our own vasectomies for many years. Impressed with the benefits of vasectomy, both personal and social, we promote and provide vasectomy services at a number of county health departments and Planned Parenthood facilities. Because of some variation in the counseling information provided in these facilities, we like to standardize the information received and have patients sign the same permit that we use in our private office.

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 developed countries. We know of one case of infection following vasectomy in Germany that resulted in a need for surgical removal of one testicle. We have had no cases of loss of a testis, but patients should consider it an exceedingly remote possibility. 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 two weeks 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.

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 October 2017, I have performed over 42,000 vasectomies. Twelve patients have developed blood clots in the scrotum; nine 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. Two severe infections have occurred: the patients had prolonged discomfort and progressive swelling on one side, not responsive to oral antibiotics, 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. Two 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 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. Occasionally this will be tender enough that removal is required, but most patients do not experience discomfort unless they are actually squeezing on the small mass. A sperm granuloma may enhance the likelihood of reversal success.
- A few (perhaps 5%) of patients will experience periodic tenderness 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. Post-vasectomy pain syndrome 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 may be required to alleviate the discomfort. Two of my vasectomy patients have been bothered enough by low-grade discomfort on one side that they have considered removal of the epididymis on that side; two others have had intermittent discomfort on both sides severe enough that they underwent vasectomy reversal; and two others have undergone neurolysis, which is division of nerves through small groin incisions to relieve pain. Since 1983, seven patients have experienced prolonged vasectomy site pain. For one patient, the pain was so severe that he was unable to work for a month after the procedure. Six other patients had prolonged vasectomy site tenderness for which they eventually chose to undergo another vasectomy procedure on one side to remove the tender spot. Thus, out of over 40,000 patients, twelve (less than one in 3000) have considered or required a second procedure to manage pain. So 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.
- 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. Most early recanalizations occur during the healing process and are detected at the time of follow-up semen checks (live sperm are seen). 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 40,000 vasectomies, we have had another 15 early failures (about 1 in every 3000). One was in a man who presented quite a vasectomy challenge because of scarring from scrotal surgery as a baby. Ten other men had live sperm on all samples checked for 6 months after their vasectomies, and four others had no live sperm but enough non-living sperm eight months after vasectomy that we chose to repeat the procedure. 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 12 times, plus two additional cases of DNA documented paternity by men with no sperm in their semen (the veritable "one got through"). From these cases and reports in the literature, late failure resulting in pregnancy is possible but rare, odds being less than one in 3000, 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 4 months after vasectomy to achieve an added index of confidence; and we will examine semen at no charge on any vasectomy patient throughout his lifetime as often as he desires.
- 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 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. The February 17, 1993 issue of the <u>Journal Of The American Medical Association</u> contained 2 studies (by the same research group) suggesting that vasectomy was associated with a small increased <u>risk of **prostate cancer**</u> in their study groups (almost 30,000 patients in 1 study and almost 40,000 patients in the other study). Because the question was initially raised by 2 studies back in 1990, the World Health Organization convened a 1991 meeting of 23 international experts to review all research regarding vasectomy and

prostate cancer. They concluded that there was no plausible biologic mechanism for a relationship between vasectomy and prostate cancer. Some medical researchers interpreted the small increased risk noted in the 1993 studies as a weak association that may be due to chance or bias. Many studies published since then show no relationship between vasectomy and the risk of prostate cancer. Because the question of a relationship has been raised, however, the American Urologic Association recommends that men who have had vasectomy and are over 40 have an annual rectal exam and prostate cancer screening blood test (PSA). This is the same recommendation made by the AUA for all men of age 50-70. Our office has copies of these and other research studies, available to any patient upon request.

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 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, or the "morning-after" pill) will prevent pregnancy if taken within 72 hours of intercourse during which no contraception was used.
- 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.

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Patients who pay cash for vasectomies are given a discounted rate of \$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 health plan with whom we have a contract. Insurance carriers of patients who ask that we work with their contracted PPO or HMO are charged \$700.00 because much more office work is involved, payments are often delayed, and insurance companies expect us to charge that much. Indeed, some health plans feel that \$590.00 is less than the usual and customary fee for this procedure, but we want to keep vasectomy within the financial grasp of uninsured cash patients. 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. There are so many different health plans, that we have tried to simplify our office procedure and give you these 2 options. If you have any questions, please don't hesitate to ask.

The semen must be checked following the operation. Contraception must be practiced until you are told by our office that there are no sperm present. Vasectomy reversal attempts are not all successful and vasectomy should therefore be considered a permanent and not reversible procedure. Vasectomy does not protect against sexually transmitted infections (STI's). There is a small chance that the vasectomy patient who has his procedure by us at a location other than my Tampa office may have to drive to the Tampa office or go a hospital for evaluation and treatment of a very rare complication. This would be at the patient's expense. By consenting to vasectomy, the patient releases us and the facility in which his vasectomy is performed from liability for time lost from work and salary unearned.

Thank you,	
Doug Stein.	M.D

I have read every paragraph of this double-sided single-spaced information sheet and agree to its terms. I have been given an opportunity to direct questions to Dr. Stein or Dr. Curington and the facility staff.

Patient's signature		Print name
Witness	Date	Patient's Telephone () -
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