

# INFORMED CONSENT

Title of Research: Intra Vas Device (IVD) as a Means of Male Reproductive Sterilization Feasibility Study

Investigator: Douglas G. Stein, MD

Before agreeing to participate in this research study, it is important that you read the following explanation of this study. This statement describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. Also described is your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of this study. In order to participate in this study you must meet certain study requirements. Dr. Stein will discuss these requirements with you.

## What is the purpose of this research?

You are being asked to participate in a research project to investigate a device called the Intra Vas Device (IVD), which is intended to block the vas deferens (the duct that transports sperm) and thus accomplish male reproductive sterilization. The purpose of this study is to determine if the IVD is successful at blocking the sperm.

## How long will I be in the study and how many other people will be in the Study?

Your participation in this Study can last for up to 30 months. This Study has two phases: The first stage can last up to 6 months, and the second stage can last up to 24 months. 90 subjects at four different institutions will be invited to participate in this study.

## What is the explanation of the procedure and what will be asked of me?

During your first visit, Dr. Stein will do a physical examination and you will be asked for a semen sample, which can be produced at home on the day of the procedure before your arrival. A special sterile container will be provided to you by our office to obtain the sample. You will need to masturbate and collect the entire ejaculate into the container. Further instructions on collecting the semen sample will be given to you by our office.

On the day of your procedure, you will also be asked to complete a short survey that will ask you questions regarding your current sexual function. You will then be given a local anesthesia to help with any discomfort you may experience during the procedure. The IVD consists of tubular silicone plugs. Two IVD's are inserted into each vas deferens to block the flow of sperm. Insertion of the IVD's will be accomplished by making a small opening on the front surface of your scrotum to gain access to the vas deferens. A small hole will then be made into the vas deferens and two plugs inserted. The plugs will be anchored with a suture. The above steps will then be repeated on the opposite vas through the same skin opening. When your surgery is completed, a dressing is applied to the small wound in your scrotum.

If for some reason Dr. Stein cannot implant the IVD he will discuss other vasectomy options with you. If you choose to have a vasectomy at this time, the Sponsor of this study will cover the costs. It will not cost you anything to have a vasectomy if the IVD cannot be implanted. As part of this Study you will still need to return to our office two weeks after your attempted IVD implant

for your Dr. Stein to exam you. You will then be contacted by telephone in 8 weeks by your Study Coordinator in our office who will ask questions regarding your procedure and record this information. This phone call usually takes less than 30 minutes. After you have completed the telephone interview your participation in this study has been completed.

If the IVD implant is successful, beginning the first month after your IVD implant you will need to provide a monthly semen sample for a period of up to six months. At the first month follow-up you will need to return to your clinic for a physical examination and to submit a semen sample. After this visit you will need to drop off a semen sample monthly for up to 6 months after your IVD implant. A special sterile container will be provided to you by our office to obtain the sample. You will need to masturbate and collect the entire ejaculate into the container, record the date and time of collection on the container, and deliver the container to our office on the same day it is collected. Further instructions on collecting, storing, and transporting the semen sample will be given to you by your laboratory and/or clinic.

The sample will be analyzed to test if the IVD has been successful at blocking your sperm. You will not need to return to our office during this time unless a complication arises. When your samples have shown that your sperm has been successfully blocked for two consecutive months, you will then enter the second phase of this study. ***It is important that you continue to use another form of intercourse protection until Dr. Stein has informed you that the IVD placement was successful at blocking your sperm.***

If Dr. Stein informs you that your procedure was successful you will enter the second phase of this study. During this phase of the study you will not be seen in our office until your 24 month follow-up unless Dr. Stein determines you need to be seen more frequently. During the 24 month follow-up visit Dr. Stein will perform a physical exam, you will again complete the sexual function survey, and you will need to submit a semen sample. In addition, the Study Coordinator will contact you by telephone at 6 months and 12 months to collect and record information regarding possible redundant contraceptive methods used, and any negative effects related to your procedure. This interview is expected to take less than 30 minutes. You will also need to submit a semen sample to our office at 12 months after you have entered the second phase of this study. To get the semen that will be analyzed, you will be asked to masturbate and drop off the sample at our office per our instructions. Your participation in the study will then be complete after you have completed your phone interview and submitted a semen sample at 24 months.

If your semen samples do not demonstrate that your procedure was successful at blocking your sperm within 6 months from the time of the IVD procedure, your procedure will be considered a failure and your participation in the study will end at this time. If your procedure was not successful Dr. Stein will then discuss other vasectomy options with you. If you choose to have a vasectomy due to failure of the IVD, this procedure will be at no cost to you.

#### What are the risks and discomforts?

The most frequent side effects associated with any vasectomy include fainting or seizures during implantation, infection, damage to the vas deferens, and bleeding and/or pain at the site of incision. If for any reason the IVD implant needs to be removed, it would require another surgery to remove it. If the IVD needs to be removed, information on the removal procedure will be collected. Although rare, additional risks are similar to other vasectomy procedures and include unplanned hospitalization, persistent or significant pain in scrotum area, other significant persistent or permanent physical or psychological harm or disability, and death.

### Are there other risks?

Other risks would include an unplanned pregnancy due to failure of the IVD or to you not following the Study Doctor's orders. You should be aware that there may be additional risks to you while being in this study that are unanticipated.

### What are the possible benefits of the Study?

The possible benefit of this Study is that reproductive sterilization will occur. Your participation may benefit other people in the future. However, you should be aware that you may not benefit from participating in this Study.

### What if new information becomes available about the Study?

During the course of this Study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

### What other choices do I have if I do not participate?

There are alternative vasectomy methods available to you and you will be given an opportunity to discuss these alternatives, if you have not already done so, with Dr. Stein.

If you choose not to participate in this Study, or choose to withdraw from the study at anytime, Dr. Stein will discuss alternate vasectomy methods available. You do not need to participate in this Study to have a vasectomy.

### Will I be paid for being in this Study?

For each scheduled follow-up visit you complete, conducted in our office or by telephone, you will be paid for your time and inconvenience at a rate of \$50.00 for each follow-up. If you complete all scheduled visits and submit all semen samples required, in the required time, you will be paid an additional \$200.00 for your time and inconvenience. This final payment will be paid to you after you have completed your final 24 month follow-up visit.

### Will I have to pay for anything?

All Study-required procedures and the Study devices will be free for you, meaning they will be provided without charge to you. You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened if you were not in the Study.

### What happens if I am injured or hurt during the Study?

If you have a medical emergency during the study you may contact Dr. Stein at 813-972-1365. You may also contact your own doctor, or seek treatment outside of the Study but you need to be aware that any costs that come from this are your responsibility.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise available.

If you have an illness or injury during this research trial that is not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

### When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your Study Doctor, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Study Investigator (Dr. Stein) feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the Study Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

### Who can see or use my information? How will my personal information be protected?

The investigator and staff involved with the study will keep your personal health information collected for the study strictly confidential. The information collected during this study may be inspected by the FDA. Please refer to the separate "Confidentiality & Privacy Rights" document that explains more specifically how your personal information will be protected.

Who can I call about any questions or my rights as a research subject?

This document explains your rights as a research subject. If you have questions regarding your participation in this research study or if you have any questions about your rights as a research subject don't hesitate to speak with your Study Doctor. Concerning your rights as a research subject, you may also contact \_\_\_\_\_.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting Dr. Stein's office to use your personal health information collected about you for research purposes. You are also allowing your Study Clinic to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. You will also be given and be required to sign the "Confidentiality & Privacy Rights" form that contains more information about the privacy of your health information.

_____	_____	_____
Name of Subject (Please Print)	Signature of Subject	Date

_____	_____	_____
Name of Person Obtaining Consent (Please Print)	Signature	Date