

Specialists In Reproductive Medicine & Surgery, P.A.

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Excellence, Experience & Ethics



Cryopreservation of Sperm *Patient Information*

General:

Specialists in Reproductive Medicine & Surgery, P.A., (SRMS), along with **XYTEX Corporation**, will cryopreserve sperm and store the material for later use. Cryopreservation is a process wherein sperm are stored at very low temperatures so that the sperm may eventually be thawed and used for conception.

SRMS & Their Responsibilities:

SRMS is a Reproductive Endocrinology and Infertility practice located in Southwest Florida. A Reproductive Endocrinologist, highly trained Andrologist/Embryologists as well as specially trained nurses and ancillary personnel staff the facility.

SRMS will perform a detailed semen analysis, cryopreserve a sample, thaw the test sample and repeat a semen analysis to verify that the specimen can tolerate the cryopreservation and thaw process.

XYTEX Corporation & Their Responsibilities:

For those men whose sperm production is likely to fall (i.e., cancer) and are wanting long-term cryopreservation (> 6 months), a total of three ejaculates will usually be requested over a five-day period, prepared and sent to XYTEX Corporation. XYTEX has also requested that the results of the blood tests be forwarded to their office.

XYTEX is a licensed clinical laboratory for long-term storage of reproductive cells. It is located near the Medical College of Georgia in Augusta, Georgia. XYTEX adheres closely to Federal and American Society For Reproductive Medicine guidelines regarding the cryopreservation of sperm as well as a host of other regulatory agencies and has been open since 1975.

Upon written request, XYTEX will make periodic tests at no charge on the semen in storage to determine the amount of cellular deterioration that has taken place. These results will be mailed to your physician. Upon written request, XYTEX will discontinue storage at any time.

Reasons for Cryopreservation:

There are a host of reasons why men may want to cryopreserve their sperm:

- The male partner will not be available or unable to provide when insemination (intrauterine insemination: IUI) or in vitro fertilization (IVF) procedures on their partners are to be performed (A single specimen may be requested rather than three).
- The sperm concentration is so low and there is a concern that it may worsen (i.e., following a vasectomy reversal with resulting poor semen quality)

- When is has been greater than five years since a vasectomy and the patient is considering freezing their sperm at the time of the reversal procedure.
- Men who undergo surgery or medical therapy that may lead to sterility may want to consider sperm cryopreservation
- Prior to cancer therapy including radiation, surgery and/or chemotherapy
- Men who go to war when they are concerned that they may be killed or wounded and unable to father a pregnancy

How the Cryopreservation Procedure is Performed:

The first step is for the male patient to become familiar with the overall process (i.e., read this packet carefully).

If the specimen is to be used for a current sexual partner (i.e., IVF) within a short period of time, usually only a single specimen will be cryopreserved and will be maintained on-site if it is intended that the specimen will be used within a few months of cryopreservation.

If the specimen is to be stored for other reasons, such as cancer, it is required that blood testing takes place prior to storage. If the testing is abnormal (i.e., HIV is positive), special arrangements will need to be made at the long-term storage facility. If the blood work is normal, a semen specimen is collected cryopreserved in liquid nitrogen. If possible, a very small aliquot of the specimen will be frozen separately. This very small sample will then be thawed and screened for survivability/viability. Although rare, severely abnormal specimens may not survive the freezing and thawing process.

If the specimen is able to survive the freeze/thaw process, two additional samples may be recommended, depending upon the reason for cryopreservation. Ideally, collection of the specimens should be spaced about 48 hours apart, although this may not always be possible.

For long-term storage, the specimen will sent to XYTEX Corporation.

How The Sperm Will Be Used Later:

Semen will only be removed from storage upon your written authorization and may be sent to essentially any location in the world. Transportation overseas, however, is possible but is admittedly a bit more complicated.

If there are enough sperm available, using ovulatory predictors on the female partner (urine test kits), ovulation will be determined and sample containers containing the semen will be thawed and the sperm then placed relatively painlessly into the uterus called an IUI procedure.

If there are very few sperm noted on semen analysis both before and after thaw, other assisted reproductive Technologies, such as donor insemination and In Vitro Fertilization combined with the direct injection of a single sperm into your partner's egg called Intra-Cytoplasmic Sperm Injection (ICSI). ICSI is offered here at SRMS as well as other Reproductive Endocrine programs.

Adoption may be offered, but many of the medical/surgical indications for sperm cryopreservation make it less likely that an adoption will be granted.

Consequences of Using Frozen Sperm:

Thousands of babies have been conceived through the use of frozen sperm. The likelihood of a spontaneous pregnancy loss, stillbirths or an abnormal offspring is not increased when using this process. Healthy babies have been born from sperm stored longer than 20 years (perhaps thousands!).

It should be noted, though, that the chance of becoming pregnant with the relatively healthy frozen sperm ranges near 16-18% per month, depending upon the age of the woman and the quality of the thawed sperm. This is close to the normal pregnancy rate seen with fresh sperm in a young healthy couple.

The liquid nitrogen will slow but not stop the aging process of the sperm. This aging process will eventually lead to a loss of fertility potential. We encourage (although do not mandate) the use of the sperm within three years of the initial cryopreservation process.

Insurance and Payment Concerns:

Medicaid and Medicare will generally not cover this procedure. Private insurance companies infrequently cover long-term storage fees although they may assist in the evaluation steps. SRMS will provide the patient with the necessary information to file but will not file directly to an insurance company unless it is a covered service and SRMS participates in the insurance program.

Legal Issues:

There is no guarantee of future survival of cryopreserved sperm. Even if the sperm survive the freeze/thaw process, no guarantee is given regarding the capacity of the sperm to fertilize and result in a pregnancy. XYTEX reserves the right to withhold the transfer of the specimens if outstanding payments have not been paid. XYTEX also reserves the right to dispose of the semen in the event of failure to pay within a reasonable period of time.

XYTEX and SRMS request that the **Cryopreservation of Sperm SRMS Consent** and **Long Term Storage** forms be completed prior to any testing.

If XYTEX is not notified of a change of address, and the account is 6 months past due, XYTEX may remove the semen from storage. This may seem harsh, but the potential of storing thousand of straws or vials for an indeterminate amount of time is concerning.

The offspring that are created after the death of a parent from cryopreserved eggs and sperm may or may not be entitled to inherit from the deceased parent's estate. This legal issue remains relatively untested in many States. It would appear that the following might assist some families in securing the inheritance and/entitlements (i.e., Social Security) of the potential future offspring:

1. It must be clear that the child that is created from cryopreserved sperm/eggs is related to the parent who passed away. DNA fingerprinting (buccal smear) with a secure chain of evidence may assist in this.
2. It needs to be established that the dead parent consented to the "posthumous" (after death) conception. This may need to be outlined in a Last Will & Testament or in some other document such as a consent and/or acknowledgment.
3. It is urged that the parent, before death, make it clear, in writing, if possible, that they want the child/children to be supported (i.e., inherit the estate).

It is clear that the above comments should not be misconstrued as legal advice. Upon request, we would be happy to refer you to a Southwest Florida Attorney, Harold S. Eskin, Esq., who is well versed in Florida reproductive law (www.LegalSurrogacy.com).

This Packet Of Information And Additional Legal Documents:

SRMS has done the best they can to simplify the cryopreservation process. Even so, there are a number of complexities that must be reviewed.

It is essential that you read this entire packet and understand all of the material. If you do not understand the materials provided, please schedule a discussion with one of the nurses or physicians. ***Be sure, however, to read all materials thoroughly before making the appointment.*** Additional time spent by the staff will be billed accordingly.

Below is a summary of the enclosed XYTEX documents for those patients who will need long-term storage facilities:

Document Title	Comments
XTS Patient Billing Information	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> This covers the annual storage fees. <input checked="" type="checkbox"/> The blood testing listed second to the bottom is up to you. Most often, this is tested by SRMS or your referring physician. If your referring physician performs the tests, be sure that SRMS received a copy of the test results and it is best to include a copy to XYTEX. <input checked="" type="checkbox"/> At the bottom of the sheet, ignore the "Evaluation of Samples" option – SRMS will perform this test on your first collection.
Consent To Perform HIV Test	<input checked="" type="checkbox"/> If XYTEX is to perform the screening blood tests (including HIV, please sign this consent. If SRMS is to do the testing, a separate consent will be signed (Testing For Sexually Transmitted Diseases).
Billing Information For Transferring Client Depositors From Another Bank	<input checked="" type="checkbox"/> This simply reviews the billing of the transfer of your sperm from SRMS to XYTEX. Please fill out what you can and SRMS will complete the rest of the information.
XYTEX Tissue Services Release To Transfer Form	<input checked="" type="checkbox"/> This consent allows SRMS to send the cryopreserved specimens to XYTEX. Please fill out what you can and SRMS will complete the rest of the information.
XYTEX Semen Storage Agreement	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> This is the most complex section of the consents. Please take your time. Please remember that there are many reasons that men cryopreserve their sperm and they may not pertain to your particular situation. Most often, the "Client Depositor" reflects your current circumstances. <input checked="" type="checkbox"/> Please pay particular attention to "7. Disposition Upon My Death:" segment. This topic should also be covered in your Last Will & Testament.

SRMS will require that all of these materials be completed and we will forward them to XYTEX with your specimen(s).

Physician Referral:

When appropriate, we will ask that your physician contact our office either by phone, FAX or by letter. We need only have a prescription stating the need for semen cryopreservation, although a brief summary letter would be most appreciated. Other information such as a time frame for potential medical/surgical therapy would be helpful in scheduling the analyses since many of these will need to be done in a very timely manner. Once SRMS has been contacted, the patient may call to set up an appointment for the blood work and first semen analysis. We have learned that it is essential for the patient to have a consultation with one of the SRMS physicians. ***This is a mandatory part of the***

process. All laboratory results will be mailed to the referring physician so specific questions regarding the results will be handled through your personal physician.

Additional Information:

Specialist In Reproductive Medicine & Surgery, P.A. 12611 World Plaza Lane Fort Myers, FL 33907 Phone (239) 275-8118 FAX: (239) 275-5914	XYTEX Corporation 1100 Emmett Street Augusta, GA 30904 Phone: (800) 277-3210 Fax: (706) 733-0130
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