

IRB NUMBER: 106872091703

LOYOLA UNIVERSITY MEDICAL CENTER

MAYWOOD, ILLINOIS

Department of Urology

INFORMED CONSENT

Patient's Name: _____

Medical Record Number: _____

Project Title: A Study of the Safety and Effectiveness of the Mentor Soft-Solid Testicular Prosthesis (SSTP)

This project will undergo re-review on or before 09/17/2004.

Patient Information:

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.
2. We do not know if you will personally benefit from taking part in the research but the knowledge obtained may help health professionals better understand the use and effectiveness of a soft-solid testicular implant.
3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.
4. If during your participation in the research project, new information becomes available which would be important for you to know, you and your doctor will be notified.

The purpose of the research and how it is to be done and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

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PURPOSE OF STUDY: You are being asked to consider participating in this project because you have decided to have a testicular prosthesis.

The Soft-Solid Testicular Prosthesis (device) is made by Mentor (Sponsor). This device is used for cosmetic replacement of a testicle. Mentor is studying how well the device works as well as the safety of the device. This is a 12-month research study of about 60 males, enrolled by doctors throughout the United States. Your doctor will be paid for his/her involvement. The device to be studied is sold outside the United States, but is only available in the United States through this study. Information on how your testicular appears after implantation of your device and on any complications or problems that may happen because of the prosthesis will be collected and reported to the Sponsor. To learn more information about how effective the device is, you will be given Quality of Life Questionnaires (questions that ask about your life) to complete before surgery and at six months after your surgery.

The Soft-Solid Testicular Prosthesis is a research device.

DESCRIPTION AND EXPLANATION OF PROCEDURES:

The Mentor Soft-Solid Testicular Prosthesis can be used when cosmetic testicular replacement when the natural testicle has been removed. The device approximates the weight, shape and softness of the normal testicle. The prosthesis is available in five sizes - extra-small, small, medium, large and extra-large. The device is made of a molded silicone elastomer shell, filled with silicone elastomer. One end of the device has a thick patch which your surgeon can use to suture (hold in place) the device.

Description of Operation:

Your doctor will explain the particular type of implant that will be used, how and where it will be placed and the type of anesthesia to be used. He/she will also give you an overall description of the operation. This may not be a one-time operation. Further procedures involving the management of potential complications (problems) may be needed.

Your surgeon will explain the post-operative (after surgery) course of treatment.

Procedures

You must be willing to come in to visit your doctor for check-ups at 2 weeks, and 6 and 12 months after your operation. The information gathered from these visits is important in the study of these devices. If you move, your doctor will arrange for you to go to another doctor in your new area.

At each visit, your doctor will do an exam (testicular measurement and appearance) and ask you some questions so that the Sponsor may assess the success of the surgery and the ability of your implant to function. At the six month exam, you will also be given a Quality of Life questionnaire to complete during your scheduled office visits. Your

doctor will not read your answers to the questionnaires. Your responses to the questionnaires will be compiled with those responses of other patients and then analyzed.

The study requires follow-up visits at 2 weeks and 6 and 12 months. Each visit will take about 30-60 minutes. You are agreeing to continue in the study for the entire 12 months and to go to your doctor to be seen for these three follow-up visits. If you do not go to your scheduled follow-up visits and your doctor's office cannot find you, the Sponsor may do an address search to find you and ask you about your medical conditions.

DURATION:

You will be followed on this trial for approximately 12 months from the time of your first visit.

RISKS/DISCOMFORTS:

Anesthesia is needed for this operation. The risks and discomforts of this operation are about the same as with any surgical procedure. This operation may have some risks and unknown complications either before or after the operation.

Possible reactions and complications should be discussed between you and your surgeon and understood by you before your operation. The sponsor depends on your doctor to tell you all of the potential risks and complications associated with the proposed surgical procedure and prosthesis. This includes providing a comparison of the risks and complications of alternative procedures and prostheses.

The medication given to you, the surgical procedure, as well as your body's reaction, response or degree of intolerance to the implant may cause complications. Some complications may require that the implant be removed.

Potential Complications

The Sponsor is aware that complications may occur over an undefined period of time and long-term results cannot be guaranteed. You should be made aware of the possibility of complications. Reported complications include, but are not limited to the following:

Rupture of the Implant: Mentor is aware that a small percentage of devices may rupture over an indefinite period of time. Cases of implant rupture include, intraoperative (during surgery) or postoperative (after surgery) trauma; excessive stresses or manipulations that may occur during daily routines including purposeful trauma such as that which can occur during vigorous exercise, athletics, manual massage and intimate physical contact; any abnormal stress or trauma to the groin area; mechanical damage prior to or during surgery; abrasion to the shell of the implant; damage from surgical instruments; and damage from causes which are unknown.

Infection: Infection, manifested by swelling, tenderness, pain and fever, may appear in the immediate postoperative period or at any time after insertion of the implant. Some infections may be difficult to diagnose. If infection does not subside promptly with the appropriate treatment, removal of the implant is indicated.

Extrusion of Implant/Interruption of Wound Healing: Skin damage, sloughing, or wound separation may result from undue tension of the skin overlying the implant, trauma to the skin during surgical procedures or inadequate tissue coverage inhibiting circulation. Subsequent exposure and/or extrusion (implant shifts externally) of the implant may occur.

Hematoma: Large hematomas, manifested by enlargement, tenderness and discoloration of tissue may, if untreated, lead to extrusion of the implant.

Fluid Accumulation: Excessive postoperative fluid accumulation and transient reaccumulation of fluid around the implant may occur.

Dissatisfaction with Cosmetic Results: Incorrect implant size and misplacement or migration (movement of implant from original position) of implants may interfere with a satisfactory cosmetic result.

Calcium Deposits: Any surgery or injury to the testicle can produce small spots of calcium in the testicle(s) which can be seen on x-rays. These deposits may not occur until years after implant surgery. They are benign and cause no problems but must be differentiated from the calcium that is often seen in testicular cancers. A biopsy may be necessary to make this distinction.

Other: Undue firmness of the scrotum resulting from contracture of the scar tissue that forms around the implant may occur. Postoperative formation of scar tissue around a testicular implant is the body's normal response to a foreign object. Discomfort, pain, excessive firmness, increased awareness of the implant and/or displacement of the implant may occur from the scar tissue formation and require surgical treatment. The implant may become difficult to remove if the degree of scar tissue is significant.

The long-term effects of this device have not been clearly established in animal studies and therefore are not fully known.

Undetermined Risks

In addition to these known risks, there are unanswered questions about silicone implants which mostly apply to silicone gel-filled breast implants. Certain risks that may be associated with silicone gel will not occur with these Soft-Solid testicular implants, as the filler is not gel. If you were to cut the device in half, the filler would not slump and run like a liquid, but instead would maintain its shape, and have the consistency of firm gelatin. However, since both breast implants and Soft-Solid testicular implants have a silicone shell, there may be similar long-term effects such as;

Connective Tissue Disorders: There have been reports describing an association between certain silicone-based products and certain connective tissue disorders. These are a group of disorders in which the body reacts to its own tissue as though it was foreign material. These disorders can cause long-term, serious, disabling health problems. Symptoms may include pain and swelling of joints, tightness, redness or swelling of the skin, swollen glands or lymph nodes, unusual and unexplained fatigue, swelling of the hands and feet, and unusual hair loss. Generally, people who have these relatively rare connective tissue disorders experience a combination of these and other symptoms.

Some cases of these disorders have been reported in women with breast implants. Since this device is made from materials similar to breast implants, this information may be relevant to you. Some women implanted with breast implants have reported a reduction in symptoms after their implants were removed.

Manufacturers are sponsoring large-scale scientific studies to explore whether a possible link exists between silicone breast implants and connective tissue disorders; however, to date, there is no evidence to suggest that the prevalence of these disorders is greater among women who have received silicone implants than among the general age-matched female population.

Neurological Symptoms: There have been some reports of patients experiencing neurological symptoms at variable times after breast implant surgery. Some of the complaints have involved difficulties with vision, sensation, muscle strength, walking, and balance. These reports do not prove a link between the implants and neurological problems.

Cancer: There is presently no established scientific evidence that links silicone testicular or breast implants with cancer. However, the possibility cannot be ruled out.

Degradation/Toxicity: The medical literature suggests that degradation and particle shedding (silicone particles dislodged from the surface of the implant due to rubbing) of a silicone elastomer shell, such as that used for the Soft-Solid testicular implant, may occur in the capsule that normally develops around the implant and in draining lymph nodes. Further research is being undertaken to determine the effects of degradation and the possibility of toxicity.

Biocompatibility: Reports in the medical literature suggest that biocompatibility responses may be affected by different biomedical materials, such as silicone.

Birth Defects: Preliminary animal studies show no evidence that birth defects are caused by silicone implants. However, to rule out that possibility for humans, further scientific studies are necessary to show whether or not testicular implants are associated with birth defects.

Your doctor will discuss any additional information about the risks of Soft-Solid testicular implants and your surgical procedure. Testicular implants are not considered to be lifetime implants. The expected life of the implant is unknown.

BENEFITS:

If you have this device implanted, you may gain a more normal and natural appearance to your scrotum (the sac beneath your penis, which contains your testicles). There may also be psychological benefits to having testicular implantation. Your surgeon will review all the possible benefits of this device with you and ask you about what you hope to gain from the surgery. However, we do not know if you will benefit from participating in this research project.

Mentor, the sponsor of this research, may benefit financially if, based on the results of research the Food and Drug Administration allows them to sell the device for the treatment of patients.

ALTERNATIVES:

You do not have to participate in this project to receive care and treatment at Loyola University Medical Center. There may be other prostheses you can have. You can also decide not have a testicular prosthesis.

Other options to the device used in this study include being implanted with Mentor's Saline-filled Testicular Prosthesis.

Your doctor has discussed other options with you along with their risks and benefits.

FINANCIAL INFORMATION:

You are responsible for all costs associated with your care including the cost of the testicular prosthesis.

Your operation and costs may or may not be covered by insurance.

To compensate you for the time you will spend going to office visits and filling out the Quality of Life questionnaire, the Sponsor will send you a check for \$100 when they receive your Baseline forms and notice of the operation. You will also receive \$50 for your two week visit, \$50 for your six month visit, and \$100 for your 12 month visit. Hence, if you return for all visits, you may receive a compensation up to \$300.

RESEARCH RELATED INJURY:

If you are injured or have problems as a result of participating in the research, your doctor will take the necessary steps to diagnose and treat the condition. You will be billed for the cost of care of the problem or problems.

Compensation (money) for physical (bodily) injuries or medical treatment due to your participation in this study is not routinely available from the Sponsor.

If you think you have an injury caused by the study device you should call your doctor.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results and how you do. The information will be collected by David Hatch, M.D., the study physician(s), the research nurses, data administrators and secretaries. Information about you will be provided to Loyola University of Chicago, Mentor Corporation, the research sponsor, its data collection and study verification agencies and/or government regulatory agencies such as the Food and Drug Administration. In this way we will learn about the safety and efficacy of a soft-solid testicular implant.

The information we will collect and send includes:

- _____ DEMOGRAPHIC INFORMATION (e.g., INITIALS, DOB, ETHNIC ORGIN)
- _____ MEDICAL RECORD (INCLUDING BUT NOT LIMITED TO HISTORY AND PHYSICAL EXAM NOTES, PROGRESS NOTES, CONSULTATION REPORTS, LABORATORY TEST RESULTS, OPERATIVE REPORTS.

We will collect and provide this information about you for as long as you are in the study.

It is possible that the sponsor, Mentor Corporation, research nurses, its data collection and/or study verification agencies, data administrators, or the Food and Drug Administration will come to Loyola University Medical Center ("LUMC") and view the medical record (which contains personal medical information about you) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information LUMC is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

Withdrawal of Consent: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your

consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor.

If you withdraw from the study, you will need to contact your physician(s) to discuss what other options may be available.

If you withdraw from the study we will ask that you sign the form attached to this consent and send it to Dr. David Hatch, or give it to the study staff. Your withdrawal from the study will not have any affect on any actions by LUMC taken before the attached form is received by LUMC.

Your study doctor, the Institutional Review Board (IRB), the regulatory authorities, or Mentor Corporation may terminate the study at any time with or without your consent. Your study doctor may choose to take you out of the study because of unexpected or serious side effects or treatment non-compliance.

CONSENT

I have fully explained to _____ the nature and purpose of the above described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-216-5099

(Signature)

Date

Dr. David Hatch, who is the principal investigators for this study, or [his/her] associates will be available to answer any questions you may have. He can be reached at: 708-216-8525.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact Dr. Kenneth Micetich, Chairman, Institutional Review Board for the Protection of Human Subjects-Medical Center (708-216-4608).

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

Date: _____
(Signature: Patient or parent)

Date: _____
(Signature: parent)

Date: _____
(Signature: Witness)

LU # A Study of the Safety and Effectiveness of the Mentor Soft-Solid Testicular Prosthesis (SSTP)

**REVOCATION OF AUTHORIZATION TO RELEASE
PROTECTED HEALTH INFORMATION (PHI)**

I, _____, hereby revoke my consent to participate in the A Study of the Safety and Effectiveness of the Mentor Soft-Solid Testicular Prosthesis (SSTP) at Loyola University Medical Center (“LUMC”). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information to Mentor Corporation as outlined on the consent form, which I signed on _____. I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

Patient Name or Personal Representative

Date

Please return this form to:

Dr. David Hatch
Dept of Urology, Build 54, Rm 237
Loyola University Medical Center
2160 South First Avenue
Maywood, Illinois 60153