



A Patient's Guide to

# *TESTICULAR IMPLANTS*

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## INTRODUCTION

A number of published studies have described the negative psychological effects that can result from the loss or absence of a testicle. These and other studies have suggested that the cosmetic benefits of testicular implants (also called testicular prostheses) lead to emotional benefits and have demonstrated high levels of patient satisfaction. I have compiled this guide to give my patients information on testicular implants. The information has been garnered from published papers, internet based research and my own experience. I have referenced many of these sources, when possible, at the end of this guide.



## HISTORY

The first report of a testicular prosthesis was by Girdansky and Newman in 1941. They used an ovoid Vitallium implant. Vitallium is a commonly used bioinert material which is an alloy of cobalt, chromium, and molybdenum used in dentistry and orthopedic surgery. Their report was followed by others who have used a myriad of substances including Lucite, glass, Gellfoam, Dacron, polyethelene and silicone. The first commercially available device consisted of silicone shell filled with silicone gel. It was the most commonly implanted device between 1973 and 1992.

A series of legislative initiatives have had tremendous impact on the use of these implants. In 1976 Congress gave the FDA the authority to regulate these devices. Devices that existed prior to the 1976 legislation were not reviewed for their safety and efficacy until additional legislation termed the Safe Medical Devices Act was enacted in 1990. This act also mandated that manufacturers of what was referred to as “high risk devices” including the gel filled silicone device, keep records of the identity and address of patients implanted with these devices.

Most likely due to this legislation and the controversy surrounding silicone gel leakage from breast implants, manufacturers of gel filled silicone testicular prosthesis stopped production of these devices in 1992.

## THE CONTROVERSY BEHIND SILICONE PROSTHESES

First, let me point out, that there is no published data that demonstrates that silicone prosthetics cause human disease. The concern however, is whether silicone or the silicone gel that had been used in the older prosthetic devices leaks from the implant and acts as an antigen...a foreign body that activates the immune system causing an autoimmune disease. An autoimmune disease is a disease process in which the body’s own immune system acts against the itself causing inflammation and scarring in otherwise healthy tissue.

What they term human adjuvant disease includes several common disease processes of rheumatoid arthritis, scleroderma, systemic lupus erythematosus among others. What is important to note is that all disease processes described have been associated with silicone breast implants but not silicone testicular prostheses.

## Indications for Implantation

Testicular implants may be an appropriate choice for children with undescended testicles or torsion of the testicles. Torsion is an extreme rotation or twisting of one or both testicles that can result in damage that requires removal of the testicle. Adult males also can experience torsion in addition to other traumatic injuries or testicular cancer, all of which may require removal of a testicle. In the cases of an undescended testicles, an attempt is made to find

and remove the undescended testicle. Additionally, men that have very small, non-functioning testis may be candidates for a testicular implant.

## Alternatives to Implantation of a Testicular Prosthesis

Although the testicular prostheses can create or restore a more normal cosmetic appearance of a testes-containing scrotum, the alternative to implant placement is simply no treatment. Not having treatment will require leaving a partially empty or completely empty scrotum. Another alternative (except for men with testicular cancer) is a procedure called subcapsular orchiectomy, which removes the testicle tissue from the capsule. The empty capsule is left in the scrotum. Although this tissue removal provides a smaller scrotal structure, it may be preferable to the alternative of an empty scrotum as described above.

## Contraindications to Implantation of a Testicular Prosthesis

There are several conditions that could increase the risk of injury from testicular implants or make device implantation difficult or impossible. These contraindications include infection and untreated cancer. It's important to know that a testicular implant is strictly for cosmetic appearances only, and in no way functions like a natural testicle.

## Types of Implants currently available

There are three types of implants currently available. However, only one, the Mentor saline-filled testicular implant has received approval from the FDA for implantation as a testicular prosthesis. The other two, Silimed's Silicone Elastomer device and Mentor's Soft-Solid Device are available for implantation only as part of a research protocol, of which I am an authorized, principal investigator and surgeon.

### *The Mentor Saline Filled Testicular Prosthesis*



This device is about the same weight, shape and softness of a normal testicle. It comes in four sizes – extra-small, small, medium and large. The implant is made of a molded silicone elastomer shell that is approximately 0.035 inches thick. It is not visible on x-ray.

The device is filled with saline at the time of surgery and just prior to implantation. It includes a self-sealing injection site at one end that allows for filling with a sterile saline solution. On the opposite end of the implant is a silicone elastomer tab that enables suturing and securing the implant into a set position, if this is desired.

### *Mentor Soft-Solid Testicular Prosthesis Study Description*



Mentor is conducting a clinical study to evaluate the safety and effectiveness of a Soft-Solid Testicular Prosthesis (SSTP). In this nationwide study, 60 patients enrolled at up to 10 study sites will be implanted with Mentor Soft-Solid Testicular Prosthesis and followed for 1 year. This prosthesis has been approved and implanted in Europe for several years.

The Mentor Soft-Solid Testicular Prosthesis is indicated for cosmetic testicular replacement when the natural testicle has been removed. The weight, shape, and texture of Mentor soft-solid testicular implants is designed to approximate normal testicles, providing patients with a more natural looking and feeling scrotum. They are intended to aid in the restoration of a normal physical appearance for male patients of all ages with one or more missing testicles.

The SSTP is available in five sizes: Extra-small, Small, Medium, Large, Extra-large. The device consists of a molded silicone elastomer shell, ranging from 0.012 - 0.018 inches thick, filled with cured silicone elastomer. A silicone elastomer Dacron reinforced patch for suturing the prosthesis in position is located at one end of the device shell.

#### Device Dimensions

Device Size	Dimensions	Volume (cc)
Extra-Small	2.5 x 3.3 cm	10.8
Small	2.8 x 3.6 cm	14.8
Medium	3.4 x 3.9 cm	24.4
Large	3.9 x 4.5 cm	34.8
Extra-Large	4.0 x 5.0 cm	42.1

At the present time, patient enrollment for this study is continuing. Males may be included in the study if they are currently missing a testicle or will be undergoing removal of a testis.

While patients or their insurance will have to pay for the surgery, Mentor provides the implant at no-cost and there is monetary compensation for the patients participating in the study.

Mentor Soft-Solid Testicular Prostheses are investigational devices, limited by law to investigational use. These products are only available to surgeons, such as myself, who are recognized as Clinical Investigators in an approved Investigational Protocol for testicular implantation. For more information, please contact our office.

### *Silimed's Silicone Elastomer Implant*



The Silimed Testicular Implant is composed of an envelope made of chemically and mechanically resistant silicone elastomer which is thin, soft, smooth of surface and contains a certain amount of elastomer whose shape, density and overall consistency have been chosen to make it as similar as possible to the shape and feeling of the human testis it replaces. All materials used are medical grade and proven to be biocompatible (is safe and tolerated well by the body).

The silicone envelope membrane is made of a compound of dimethyl polysiloxane and dimethyl fluoro silicone copolymer. The silicone envelope is filled with an elastomer mixture of reinforced dimethyl methylvinyl siloxanes with reinforced dimethyl methylhydrogen siloxanes. Applied Silicone Corporation manufactures the material. Silimed Silicone Testicular Implant are available in 5 sizes. This is only available to surgeons, such as myself, who are recognized as Clinical Investigators in an approved Investigational Protocol for testicular implantation.

## **SURGICAL CONSIDERATIONS**

Testicular surgery requires an incision. As with any surgical procedure, there are risks such as infection, delayed wound healing, fluid collection, hematoma formation (a collection of blood inside the body in and around where the incision is made), bleeding and possible reactions from anesthesia. These complications are uncommon. Small areas of fluid collection and small hematomas will be absorbed by your body.

In addition to these known risks, there are unanswered questions about silicone implants, which, as previously discussed, mostly applies to silicone gel-filled breast implants. Certain risks that may be associated with silicone gel will not occur with the newer devices including the saline-filled, soft-solid or silicone elastomer devices. However, since all types of currently available implants have a silicone rubber envelope, they may be associated with certain specific risks and complications.

There are several different accepted surgical approaches that can be used to insert your testicular implant. I will discuss with you the method that would be most appropriate choice for your individual case. It is important to know that implantation of a testicular prosthesis may not be a one-time procedure. Any complications from your surgery may require further procedures.

Most patients experience some minor discomfort during the first 24 to 48 hours after your procedure. I will prescribe painkillers to take if needed. You'll probably be instructed to keep your surgical bandages on your scrotum for at least a few days. Most likely you will feel fatigued and your scrotum will be swollen, tender and sensitive to physical contact for some time. However, your ability to urinate should not be affected.



Although every person's recovery time is different, you should be able to resume most of your daily activities within a week to ten days. Remember to be patient, and try not to rush your recovery time. More specific information follows. Should any problems occur after your procedure, immediately contact me. This is especially important if you have a high temperature, or

if your scrotum becomes excessively swollen (enlarged beyond its normal size), painful, red or inflamed.

## ***PREOPERATIVE PREPARATION***

For any elective surgery you should be in the best of health. It is important to let my office know if you have any other health problems which might necessitate consultation with an internist prior to your surgery. Also you should avoid aspirin and aspirin like products (e.g. ibuprofen) and stop all herbal supplement for a week before your surgery.

The week before surgery you will be asked to report to the Ambulatory Surgical Center at which time a medical history, complete examination and necessary laboratory tests will be performed by staff of the Surgery Center.

Testicular implant surgery is usually performed on an outpatient basis (no overnight stay). However, for those patients with significant underlying medical problems, a brief hospital stay might be required. I will discuss with you at your consultation which approach is best suited for you. Your anesthesiologist and I will also discuss with you the various types of anesthesia available, and which might be best for you, prior to your surgery. These options usually include a general anesthesia (you'll be asleep) spinal or local anesthesia (applied locally to the scrotum).

## ***SPECIFICS ABOUT THE PROCEDURE***

On the day of your surgery, you will report to the Ambulatory Surgical Center at least one hour before surgery and must be accompanied by someone capable of driving you home. You will not have eaten nor drunk anything since dinner the night before. I will meet with you prior to surgery to examine you and answer any questions.

Your procedure will usually take between 30 and 60 minutes. The procedure is performed under either a local, general or a spinal anesthetic, all of which are extremely safe and effective. These options will be discussed in detail with you by the anesthesiologist prior to the procedure.

You will usually remain in the recovery room for a minimum of one hour and as long as you need until you feel comfortably alert for travel.

## POST-OPERATIVE CARE

- *A small amount of bright red blood is to be expected. DO NOT be alarmed if you feel that the amount is excessive--call my office.*
- *At the time of discharge from the Ambulatory Surgical Center you will have been given prescriptions for pain medication and, occasionally, antibiotics. When taking pain medication, be careful as you walk or climb stairs. Dizziness is not unusual.*
- *Do not drive the first day after the surgery, but you can ride in a car if someone else is driving.*
- *You may shower 48 hours after the surgery. Keep the dressing dry until then.*
- *Swelling and black and blue are normal.*
- *If your job involves only desk work and very light activity, you may return 2 or 3 days after the surgery. It is likely that you will have some discomfort for the first few days after surgery.*
- *No heavy work or sports are allowed for 1 week post-operatively.*

- *No sexual intercourse is allowed for 1 week post-operatively.*
- *You will need to wear an athletic supporter (jock strap) for 1 week post-operatively.*
- *You may resume normal activities as you feel up to it.*
- *There are no stitches that need to be removed.*

If you experience any other problems, questions or complications after your surgery, please call me.

## CONSIDERATIONS AND POTENTIAL COMPLICATIONS

You should know that testicular implants, like other medical implant devices, should not be considered lifetime devices. There is the chance, though minimal, that the body could have an adverse reaction to the implant, or that the implant may either rupture or leak (or both). These will require the implant to be removed.

The long-term rates of deflation when the saline-filled is utilized and re-surgery are currently not known; however, long term studies are presently underway to access these issues .

Based on the information from the clinical studies of the saline-filled testicular implant, approximately 1 in 30 patients require re-surgery within the first year to either remove or adjust the implant. Testicular implants placed in a small child may need to be replaced by a larger implant as the child matures and grows, if the child or his parents wish to maintain a size that closely matches the child's other healthy testicle. In addition, infection or extrusion (when the implant shifts and presses out through the skin) may also require additional surgery.



## ***POSSIBLE SIDE EFFECTS***

*As with any surgery, there are potential side effects from the implantation of a testicular prosthesis. Although rare, you should be aware that these adverse effects can occur. These will be discussed with you at the time of your initial consultation.*

A body's natural response to any implanted object is to reject it. The body's rejection response depends in part on the biocompatibility of the materials that make up the implanted device. Biocompatibility is the ability of an object or substance to blend with the body's natural tissues without creating a harmful response. The more biocompatible a material is, the less the body will reject it.

Scientists are continually seeking new materials that are more biocompatible. The most common biocompatible material available today for testicular implants is silicone, which is used in many medical and consumer products.

As a natural reaction to any device placed in the body, scar tissue may form around a testicular implant. This is called a capsule. In some men, the capsule can contract, causing a condition known as fibrous capsular contracture. This can result in a hardening of the testicular implant, which may cause discomfort or pain. Fortunately, medical research has shown incidences of fibrous capsular contracture to be low in testicular implant cases.

I will discuss any additional information about the risks of testicular implants specific to your surgical procedure. You are encouraged to read the Product Insert Data Sheet, which is available for each of the devices and will be provided to you at your request.

## ***PATIENT SATISFACTION WITH THE DEVICE***

The only data currently available that defines patient satisfaction with a testicular prosthesis is for the Mentor saline filled device, since it

is the only device currently approved by the FDA for implantation and therefore the only device required to have this type of testing performed. In the premarket study the following data was reported:

### **Effectiveness**

The effectiveness of the implant is based on the following results of the Core Study:



Physician measurements documented that the implanted device adequately mimics the size of the natural testicle.

The cosmetic appearance and firmness of the implanted device was rated as normal by physicians. Using standardized questionnaires, patients recorded high levels of satisfaction with the implant, as well as increased levels of how they viewed their body in sexual activities. Additionally, there was no decline in either self-esteem or body esteem, as

assessed using the Rosenberg Self-Esteem Scale and the Body Esteem Scale.

### **Safety**

The main complications noted in these studies were as follows:

- \* Pain and/or discomfort occurred in approximately 10% of patients.
- \* Temporary swelling at the implant site in approximately 3% of patients.
- \* Extrusion of the implant in approximately 2% of the patients.
- \* Infection at the implant site in approximately 1% of patients.
- \* Displacement/migration of the implant in approximately 2% of patients.

Approximately 1 in 30 patients required resurgery within 1 year after device implantation in these studies, usually to remove the implant. The most common reason for implant removal was extrusion of the implant.

## WHAT TO DO NEXT

If you feel a testicular implant is something you would like to explore



further please give us a call to make an appointment. I will first have you complete questionnaires about your health history. I will then examine you, obtain a urine sample for testing, review the procedure as well as show you all the implants currently available. We will then discuss the differences between them. If you decide that one of the investigational devices is best for you we will review the study protocol and consent for that device. During the hour or more that we spend together there will be plenty of time to ask any questions

you have and obtain the information you need to make a decision as to whether the procedure is right for you and as to which prosthesis is best for you.

I have many patients that are from another state or another country. I have found that it is most convenient for the patient arrange for a consultation the day prior to the scheduled procedure. In order

to schedule the consultation (and procedure) I will request the questionnaires to be completed prior to scheduling the consultation/ procedure. I will review the medical information submitted and discuss with you any testing that might be required.

## ABOUT BRUCE R. GILBERT, M.D., PH.D.

Dr. Bruce R. Gilbert is Urologist who has been in Private Practice in Great Neck, Long Island, New York for the past 15 years. He specializes in complex microsurgical procedures for male fertility and sexual function and has performed over a thousand microsurgical procedures.

He completed his medical education at the Cornell Medical College and his Urological and Microsurgical training at The New York Hospital-Cornell Medical Center in New York City. He is certified by the American Board of Urology, the American Board of Medical Acupuncture and the American Board of Bioanalysis. He is also a Fellow of the American College of Surgeons.

He is a Clinical Associate Professor of Urology and a Clinical Associate Professor of Male Reproductive Medicine and Surgery at Cornell University Medical College and is on the attending staff at several local hospitals. He is a well published researcher and has written many book chapters, journal articles and abstracts in the field. He is also licensed to practice Medical Acupuncture and is active in researching complementary and integrative approaches to Urological disease. He has additional board certification as a High Complexity Laboratory Director and is the Medical Director of New York Cryo, a licensed and accredited long term storage sperm bank, and the Men's Fertility Laboratory, a licensed referral andrology laboratory. He has been selected as one of "America's Top Physicicans" and is listed in the "Guide to America's Top Physicians" published by the Consumers' Research Council of America, Washington, DC.