DRAFT

Saline-Filled Testicular Prostheses **Product Insert Data Sheet**

CAUTION: Federal law restricts this device to sale or on the order of a physician or properly licensed practitioner.

DEVICE DESCRIPTION

The Mentor Saline-Filled Testicular Prosthesis approximates the weight, shape and softness of the normal testicle. The prosthesis is available in four sizes - extra small, small, medium, and large. The device consists of a molded silicone elastomer shell, approximately 0.035 inches thick, with a self-sealing injection site located on one end of the prosthesis. This injection site allows the implanting surgeon to fill the device with sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection. On the end opposite of the fill site is a silicone elastomer tab for suturing the prosthesis in position if desired. The device is not visible on x-ray.

INDICATIONS FOR USE

The Mentor Saline-Filled Testicular Prosthesis is intended for use when cosmetic testicular replacement is indicated i.e., in the case of agenesis or following the surgical removal of a testicle.

CONTRAINDICATIONS

The implantation of testicular prostheses is contraindicated in the presence of infection or untreated neoplasm.

WARNINGS

Implantation of a testicular prosthesis in patients with pre-existing varicoceles may result in persistent pain.

Testicular implants should not be considered lifetime implants due to the inherent nature of silicone implants, implant procedures, and potential individual psychological reactions.

This device contains solid silicone elastomer. The risks and benefits of implanting this device in patients with lupus (e.g., SLE or DLE), scleroderma (e.g., progressive systemic sclerosis), myasthenia gravis, or documented sensitivity to silicone should be carefully considered. The issue of the possible relationship between silicone and various diseases has been and continues to be the subject of scientific and medical debate.

Sepsis, hemorrhage or thrombosis may result from the placement of any foreign object in the body.

Excessive inflation of the implant or use of an excessively large implant may result in tissue necrosis/thrombosis.

Excessive fibrous capsular formation or contracture may occur around any implant placed in contact with soft tissues. The incidence and severity of this occurrence may increase if postoperative local hematoma or infection occurs.

PRECAUTIONS
Surgery-Related:

Each prosthesis should be checked for patency prior to surgery and continuously monitored throughout the surgical procedure to ensure that the structural integrity of the implant is not compromised in any way. The prosthesis should not be implanted following any modification to its original design. A prosthesis which has been damaged or upon which repairs have been attempted should not be implanted. A standby prosthesis should be available at the time of surgery.

Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, it is recommended that the prosthesis not be implanted until the bleeding is controlled.

If a physician treats a hematoma or serous fluid accumulation by aspiration, or a biopsy is performed, care must be taken to avoid damaging the implant. These procedures present the possible risk of implant puncture or deflation.

Implantation of the Saline-Filled Testicular Prosthesis may be difficult or impossible in patients with inadequate scrotal tissue to cover the prosthesis, patients who have undergone prior pelvic radiation therapy, or patients whose wound healing abilities are compromised (e.g., uncontrolled diabetes, poor circulation).

Preexisting infection should be treated and resolved before implantation of the prosthesis.

Any surgeon implanting testicular prostheses should be familiar with the currently available techniques for measuring the patient, determining the implant size, and performing the surgery.

Lint, dust, talc, surgical glove powder, drape and sponge lint, skin oils, and other surface contaminants may cause foreign body reactions. Strict adherence to clean aseptic techniques should be maintained to prevent contamination of the implant and possible complications. Surgical instruments and gloves should be rinsed clean of contaminants before handling the implant.

The silicone elastomer shell may be easily cut by a scalpel or ruptured by excessive stress, manipulation with blunt instruments or penetration by a needle. In particular, extreme care should be taken not to damage the prosthesis with surgical instruments at the time of incision closure. Damage to the shell of the prosthesis may occur, resulting in immediate or delayed shell leakage.

Inadvertent puncture of the testicular prosthesis through any location other than the centermost portion of the injection port during filing and/or subsequent fluid adjustment will damage the

device and result in fluid leakage. The filling needle must only penetrate the injection port as close to the center as possible and must not contact any other part of the device.

Do not contact the implant with disposable, capacitor-type cauterizing devices as damage to the shell of the prosthesis may result.

Only the suture tab of the prosthesis is suitable for the suture placement. The suture must be tied through the punched hole in the suture tab.

Any subsequent surgical procedures in the area of the implant should be undertaken with extreme caution as damage to the implant could occur. In the event that the implant is damaged it must be removed.

Device-Related:

The action of drugs (such as antimicrobials, chemotherapy agents or steroids) in contact with the prosthesis has not been tested by the manufacturer, and their use cannot be recommended. Each physician who chooses to use drugs in combination with this prosthesis must assure compatibility of the drug with silicone elastomer.

Do not introduce or make injections of drugs or other substances into the implant. Such injections through the implant shell may compromise the product's integrity, causing it to leak fluid and eventually deflate.

Use only sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. Solution for Injection to fill the implant.

Do not use product that has been damaged or opened packaging, as sterility may be compromised.

This device is sold sterile for single use only, and should never be resterilized. In the event the product becomes contaminated prior to use, the device should be returned to Mentor for replacement.

Mentor is aware that a small percentage of saline-filled implants will leak over an undefined period of time and long-term results cannot be guaranteed. Prospective patients should be made aware of the possibility of deflation.

Patient-Related

A thorough preoperative consultation should include a discussion between the patient and physician of all available treatment options and their risks and benefits.
The implantation of this device should only be considered in patients whom the physician determines are adequate surgical risks.

Postoperatively, patients or their representatives should be instructed how to distinguish the prosthesis from normal scrotal tissue.

Physicians who examine such patients should be informed that the patients have artificial testicle(s) in order to prevent unnecessary surgical exploration.

ADVERSE EVENTS

A clinical trial (the "Core Study") was conducted to determine the safety and effectiveness of the Mentor Saline-Filled Testicular Prosthesis. A total of 149 patients were enrolled into this Core Study, 124 of whom had been followed for at least 1 year. To collect additional safety data while the Core Study was ongoing, a separate Adjunct Study was performed. A total of 209 subjects were enrolled into the Adjunct Study, 68 of whom had been followed for 1 year. The following device and procedure-related adverse events (complications) were noted during the Core Study:

Adverse Event Category	Number (%) of Patients	Mean (Range) Onset Time in Days
Pain	8 (5.4%)	127 (1-661)
Discomfort	6 (4.0%)	167 (1-668)
Edema	4 (2.7%)	2 (1-4)
Extrusion	3 (2.0%)	28 (16-39)
Displacement/Migration	3 (2.0%)	36 (29-42)
Genitalia Hematoma	2 (1.3%)	1
Keloid Formation	2 (1.3%)	112 (39-184)
Implant Deflation	1 (0.7%)	35
Fluid Accumulation (inguinal area)	1 (0.7%)	11
Constipation	1 (0.7%)	1
Fibrosis	1 (0.7%)	207
Granuloma	1 (0.7%)	8
Mobile Implant	1 (0.7%)	42
Neuropathy (leg)	1 (0.7%)	1
Numbness (heel)	1 (0.7%)	1
Suture Abscess	1 (0.7%)	33

A total of five Core Study patients underwent resurgery during the study period. These five resurgeries consisted of four device explantations (in the three cases of extrusion and one case of displacement/migration) and one surgery to relieve dense adhesive bands that formed in the scrotum (in one of the patients listed as experiencing displacement/migration). Using a Kaplan-Meier Survival Analysis, the probability of a patient experiencing a resurgery within 1 year was 2.8% (upper 95% confidence limit = 5.5%).

In addition to the complications reported in the Core Study, the following adverse events were reported during the Adjunct Study: infection (n=4), displacement/migration (n=2), leakage (n=1), extrusion (n=1), hives (n=1), inadequate position (n=1), pain (n=1), and unnecessary incision (n=1). A total of six Adjunct Study patients underwent resurgery within the 1 year of device implantation, consisting of four device explantations (in one case each of extrusion, leakage, pain, and hives) and two surgeries (both reposition the implant in cases of displacement/migration and inadequate position).

The following risks of testicular prostheses or their materials have been reported in the medical literature, but did not occur during either the Core or Adjunct Studies: erosion and immune-related connective tissue diseases. No patients died in either study.

CLINICAL STUDIES

Study Design:

A prospective , multicenter, baseline-controlled clinical trial (the "Core Study") was performed to evaluate the safety and effectiveness of the Mentor Saline-Filled Testicular Prosthesis. This trial was designed to assess the impact of the device on the scrotal anatomy, patient quality of life, and adverse events. As noted above under "Adverse Events," a separate study (the "Adjunct Study") was conducted to collect supplemental safety data while the Core Study follow-up was ongoing.

One hundred and forty-nine (149) male patients, ranging in age from 6 months to 76 years were enrolled in the Core Study. All patients missing one or both testes or scheduled for orchiectomy were enrolled, provided they did not present with an infection or abscess, a prior silicone implant (including any prior testicular prosthesis), a history of immune-related connective tissue disease, a history of poorly controlled diabetes, or any other condition that would prevent the implantation or evaluation of a testicular prosthesis. Approximately half of the patients were < 18 years of age, and 18% required bilateral implants. Approximately 75% of patents were missing their testicle(s) at the time of enrollment, while the remaining patients were scheduled for orchiectomy of one of both testicles. The majority of devices were implanted using either inguinal (70%) or scrotal (22.7%) incisions. The decision as to the surgical approach was based on the surgeon's discretion. Follow-up examinations were performed at 1 month, 6 months, and 1 year post-implantation. The results of follow-up visits through 1 year are available for 124 subjects. In addition, 18-month and 2-year follow-up data were obtained in the majority of subjects. Long term rate of rupture and resurgery are unknown, however a 5-year study is currently being conducted to assess these potential complications.

The Core Study provided the following results:

Assessment of Testicle/Prosthesis Volume:
Estimates of testicle/prosthesis size were made by the physician using a Prader Orchiometer. Among patients missing one or both testes at baseline, implantation of the Mentor Saline-Filled Testicular Prosthesis resulted in a significant increase in testicular volume. For patients with both testes present at enrollment (but scheduled for orchiectomy), post-implant testicular size remained stable.

Physician Assessment of Cosmetic Appearance:
The cosmetic appearance and firmness of the device was rated by the physician at baseline at each follow-up period. At each visit, statistically significant improvement from baseline in cosmetic appearance was observed. Additionally, the physician rated the implanted device as having normal firmness in 94-99% of subjects at each visit.

Patient Assessment of Quality of Life

The impact of the device on patient quality of life was assessed using the following questionnaires: Patient Assessment Instrument (satisfaction questionnaire), Rosenberg Self-

Esteem Scale, Body Esteem Scale (Physical Attractiveness subscale), and the Body Exposure in Sexual Activities Questionnaire. Due to the nature of the questions being assessed, this information was only obtained on patients 13 years of age (18 years of age for the Body Exposure in Sexual Activities Questionnaire). There were significant increases from baseline in the mean follow-up scores for the Patient Assessment Instrument and Body Exposure in Sexual Activities Questionnaire. 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.

PATIENT EDUCATION AND INFORMED CONSENT

The surgical procedures associated with the use of testicular implants are not without potential complications and risks. The use of this product is an elective procedure. The patient should be counseled prior to surgery regarding the benefits and possible risks associated with testicular implants and alternative procedures. Patients should be advised that testicular implants should not be considered lifetime implants due to the inherent nature of silicone implants, implant procedures and potential physiological reactions.

It is the responsibility of the individual surgeon to decide the best method by which to counsel a patient prior to surgery. Mentor recommends that physicians provide all prospective patients with a copy of the Patient Education Guide ("Important Information to Remember about Testicular Implants") for review before surgery is scheduled. Mentor also relies upon the surgeon to advise the patient of all potential complications and risks associated with the use of testicular implants.

Later replacement of testicular prostheses implanted in young males should be considered an elective procedure for cosmetic purposes only.

Postoperatively, patients should be instructed how to distinguish the prosthesis from normal testicles during self-examination for cancer. In addition, patients should be instructed to inform other physicians that they have either one or two artificial testicles, in order to prevent unnecessary surgical exploration.

How Supplied

The Mentor Saline-Filled Testicular Prosthesis is supplied individually in a sterile double-wrap packaging system. The double-wrap system facilitates the preferred method of sterile-product transfer from the circulating area to the sterile field. The prosthesis is supplied with a prepackaged infusion line connected to a luer adapter and a 21 gauge butterfly needle, and two needle stops. The device is sterilized by the following method:

PRODUCT	STERILIZATION METHOD	SYMBOL
Saline-Filled Testicular Prosthesis	Gamma Sterilization	STERILE R

CLEANING AND STERILIZATION

The Mentor Saline-Filled Testicular Prosthesis is supplied sterile and is for single use only.

Caution: This device should never be resterilized. In the event the product becomes contaminated, it is recommended that the device be returned to Mentor for replacement.

FILLING SOLUTION

Caution: Use sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. Solution for Injection to fill the implant.

INSTRUCTIONS FOR USE

The implantation of saline-filled prostheses for testicular replacement involves a variety of surgical techniques; therefore the surgeon is best advised to use the method which his/her own practice and discretion dictate to be best for the patient. In the clinical study, prophylactic antimicrobials were administered at the time of implantation surgery in approximately 95% of the implantation cases.

FILLING PROCEDURE

Overfilling

The prosthesis is initially overfilled with saline (Over-Fill Volume Range). Air and saline are then evacuated to reduce the saline fill volume in the prosthesis to within its Final-Fill-Volume Range. Please consult the Saline Fill-Volume Chart for the acceptance range of Over-Fill-and Final-Fill-Volumes for each size prosthesis.

SALINE FILL-VOLUME CHART

Catalog #	Testicular Size	Over-Fill-Volume Range		Final-Fill-Volume Range	
		Lower Limit	Upper Limit	Lower Limit	Upper Limit
450-1323	Extra Small	7cc	9cc	5cc	6cc
450-1325	Small	10cc	12cc	8cc	9cc
450-1327	Medium	13cc	15cc	11cc	12cc
450-1329	Large	17cc	19cc	15cc	16cc

1. Fill a 20 cc (or larger) syringe with the appropriate Over-Fill Volume Range of sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection, based on the Saline Fill-Volume Chart.

2. Connect the Luer hub of the infusion line to the syringe. Place the needle stop on the butterfly infusion needle. Insert the butterfly needle into the center of the injection port, which is located on the end of the prosthesis opposite the suture tab site. It can be easily located as a lightly depressed area encircled by the Mentor name and serial number.

   Caution: Use only the 21 gauge butterfly needle and the needle stop provided with the prosthesis for the filling procedure. The needle must only penetrate the injection port, preferably as close to the center as possible and must not contact any other part of the prosthesis. Puncture of the prosthesis through any location other than the injection port

will damage the device and result in fluid leakage. Discard any device that is punctured in any location other than the injection port.

3. Do not evacuate air from the prosthesis. Position the testicular prosthesis with the injection port at the top. Position the syringe so that air released from the prosthesis will travel into the syringe (see figure 1).

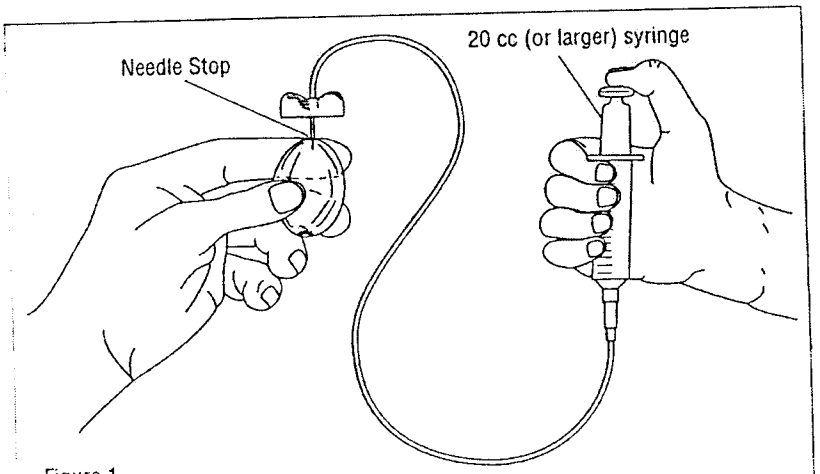

Figure 1
Position of the testicular prosthesis with injection port at top, and position of the syringe ready to fill prosthesis.

Figure 1

4. Overfill the prosthesis by injecting saline into the prosthesis according to the Over-Fill-Volume Chart. Release the syringe plunger, allowing the compressed air in the prosthesis to be drawn into the syringe.

5. If all the air is not evacuated from the prosthesis, repeat Step 4 (fill prosthesis again, and release the syringe plunger to allow the remaining air and excess saline to vent to the syringe). After the air and excess saline have vented to the syringe, the device should contain the Final-Fill-Volume Range listed in the Saline Fill-Volume Chart. Remove needle slowly to aspirate any remaining air bubble.

Caution: The injection port may be pierced no more than five (5) times within the port area, permitting adjustment of the fluid volume if desired. All filling and expulsion of air must be done before implantation. Discard any device pierced more than 5 times in the port area.

Caution: Do not attempt to adjust the fill volume of this device postoperatively.

Suture Tab
A Suture tab is provided on the end of the implant opposite the injection port for suturing the prosthesis into position if desired. If a suture is used, it must only be tied through the punched hole in the suture tab.

Caution: The suture must be placed through the pre-punched hole in the suture tab. Suture placement in any area other than the pre-punched hole will result in damage to the device.

PRODUCT EVALUATION

Mentor requests physicians to notify the company of any complications which may develop with the use of this device, and requests return of any explanted components. For safe handling during shipment and upon receipt, Mentor requests that devices be decontaminated prior to shipment. This is requested even though Mentor will autoclave-sterilize any opened product returned. Alteration for the purposes of venting to prevent additional damage will be performed as required. If explantation is necessary, Mentor may analyze the explanted device, and the patient and physician may be asked to allow Mentor to perform tests that might alter the condition of the device.

Any complications from the use of this device should be brought to the immediate attention of: Quality Assurance, Product Evaluations Department, Mentor, 1601 West River Road North, Minneapolis, MN 55411; Toll free (800) 338-7908 in USA, or outside USA call (612) 588-4685.

RETURNED GOODS POLICY

U.S. Customers
Authorization must be received from Mentor prior to the return of merchandise. Merchandise returned must have all manufacturer's seals intact and be returned within 30 days from date of invoice to be eligible for credit or replacement. Please contact the Mentor Customer Service Department for details. To obtain a Return Authorization number call (800) 235-5731, or FAX (805) 967-7108. Returned products may be subject to restocking charges. Mentor does not accept returns on Special Order Devices

International Customers
Authorization for return of merchandise should be obtained from your respective dealer. Other conditions noted above also apply.

LIFETIME REPLACEMENT POLICY

Mentor's replacement policy provides that the Saline-Filled Testicular Prosthesis will be replaced by Mentor upon request of the purchaser for any reason. The replacement policy does not cover surgical or hospital costs, and is limited to replacement of the prosthesis.

PRODUCT INFORMATION DISCLOSURE

Mentor excludes all warranties (except the Replacement Policy above), whether written or oral, statutory, express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability, fitness or design. Mentor shall not be liable for any direct, incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. No representation or other affirmation of fact, including but not limited to statements regarding suitability for use, or performance of the product shall be or be deemed to be warranty by Mentor for any purpose. Mentor neither assumes nor authorizes any other or additional liability or responsibility in connection with this product.

PRODUCT ORDER INFORMATION

U.S. Customers

To order directly in the USA or for information on Special Order Devices, please contact the Mentor Urology Products Customer Service Department, Mentor, 201 Mentor Drive, Santa Barbara, CA 93111, toll free telephone (800) 235-5731.

International Customers

For product information or to order directly, contact your local Mentor products distributor or the International Customer Service Department at Mentor, 201 Mentor Drive, Santa Barbara, CA 93111 USA. Telephone (805) 879-6000; FAX (805) 967-7108.

References

Literature references are available upon request from:

Mentor
Literature Services Department
201 Mentor Drive
Santa Barbara, CA 93111 USA
Toll free (800) 525-0245

Covered by one or more of the following U.S. Patents: 5,725,507; 5,632,777; 5,558,829; 5,653,757. Other patents pending.