

THE REED CENTRE
for Ambulatory Urological Surgery
1111 KANE CONCOURSE
BAY HARBOR ISLANDS, FLORIDA 33154
Phone (305) 865-2000 / Fax (305) 865-2002

INFORMED CONSENT FOR PENILE GIRTH ENHANCEMENT USING AlloDerm STRIPS

1. I hereby request and authorize Dr. Harold M. Reed, assisted by his designated personnel to perform the urological operation entitled "Girth Enhancement using AlloDerm Strips" in an effort to enlarge my penile shaft circumference. AlloDerm is acedaveric, acellular dermal graft processed at a tissue laboratory, and treated to remove any bacteria or viruses. **AlloDerm is not FDA approved specifically for use in the penis**, but is approved as a tissue expander for contour deficiencies.
2. Dr. Reed has discussed his case experience with me but has not made any promise of a specific performance or guaranteed either expressly or by implication a result.
3. Any patients considering AlloDerm must be prepared to stay for 4 additional days (surgery is the zero day) at a nearby motel, either the Bay Harbor Inn or the Whitehouse Inn on the Bay so I can see you daily as necessary. You will be requested to be on bed rest (flat or on your side) except for using the rest room or sitting up to eat. Early mobility is the great enemy of graft survival.
4. Post-operative swelling of the penis is to be expected and may last from six to eight weeks.
5. Patches of induration or firmness under the penile skin may be felt for a period of time up to a few months. This in itself should not interfere with sexual activity, once superficial wound healing is complete.
6. Some diminution of initial gain in penile circumference is to be expected as a result of resolution of surgical edema (swelling).
7. In this procedure the leading edge of the AlloDerm strips are introduced just behind the rim of the head of the penis.
8. The penis is not to be used for penetrating sex for at least 6 weeks to permit optimal healing. Physical trauma to the penis and undue pressure and squeezing is to be avoided. Such events during the first few weeks can lead to unwanted bruising, displacement of the AlloDerm strips, and separation of the incision.
9. I have discussed this procedure with my sexual partner or "significant other" and have gained their approval, or after careful consideration of my situation and relationship have decided to proceed. I and my partner are aware that there will be a period of sexual abstinence, and can appreciate the emotional consequences of this

hiatus, as well as any unanticipated complications stemming from this procedure.

10. I have not been treated by a psychologist, psychiatrist, or physician for any emotional disorder, nor do I believe I have any significant emotional disorder presently.

11. I have abstained from smoking for 2 weeks prior to this procedure and will abstain for 2 months following this procedure.

12. Complications of this procedure include transient loss of sensitivity, pain or discomfort, infection, a collection of blood under the skin (hematoma), a collection of serum under the skin (seroma), separation of incisional margins (dehiscence), transient black and blue bruising (ecchymosis), deviation of hanging or erect position of the penis post surgery, possible calcific deposits, graft fibrosis, shifting of the graft, contour irregularities, and possible loss of penile shaft skin secondary to pressure effects from the grafting process. I can appreciate that with any surgical procedure there may be unforeseen complications as well and any complications may be serious and require extensive follow-up care.

13. I will call Dr. Reed immediately if there are any concerns and keep my follow-up appointments with him.

14. The patient consents to medical photography before, during and after treatment, and that these photographs become the property of Dr. Harold M. Reed, and may be utilized for but not limited to publications in scientific journals, or presentation in a manner related to medical practice.

15. I have been given a choice of anesthesia and also anesthesia providers, i.e. anesthesiologist versus CRNA versus certified P.A. The administration of anesthesia should an anesthesiologist be employed, the administering is an independent function and any questions regarding anesthetic management should be addressed directly to the anesthesiologist. A remote complication of general anesthesia is inadequate intubation, and a remote complication of spinal anesthesia is inadequate pain control.

16. I have seen before and after photos of anonymous patients of Dr. Reed and the areas of intended incisions have been shown to me as well by photography.

17. Regarding penile girth enhancement by the above described techniques, no community or national standards have yet been established. Although AlloDerm has been used since 1992 for burn patients and since 1994 in reconstructive plastic surgery, experience with AlloDerm application to the penis is limited and should be considered in clinical trials. To date more than 25,000 patients have received AlloDerm grafts. Regarding penile girth enhancement, the subject is remains controversial.

18. I, the patient, have had an opportunity to question and discuss with Dr. Reed: any unfamiliar medical terminology, as well as any concepts mentioned in this consent; any

further questions relating to this procedure; anticipated post-operative course, alternatives and risks. I have not been rushed either during my consultation or before being asked to sign this consent.

19. I am aware that Dr. Harold M. Reed has elected under the provisions of Florida State law not to carry professional liability insurance.

20. I understand the maintenance of personal hygiene, especially genital cleanliness is extremely important in preventing post-operative infection.

22. I have read and understood the above described informed consent as well as Dr. Reed's list advisories on the procedure. I have had an opportunity to discuss treatment alternatives including behavioral modification, or simply accepting my situation as is, and understand the advantages and disadvantages of each treatment alternative.

I have read and signed the above consent in the presence of a witness whose signature appears below, after I have had an opportunity to question Dr. Reed regarding any unfamiliar medical terminology.

Dr. Reed has a proprietary interest in this CENTRE. You may wish to consider alternative sites for evaluation and treatment.

Pursuant to statute 64B8-9.0091, (FAC), this surgical facility is not operating as an ambulatory surgical centre (ASC) for the purposes of this consent.

_____	_____
PATIENT	DATE

WITNESS	DATE

I have personally discussed with the patient the above described proposed surgery, its risks and potential complications, as well as the alternatives available.

Pursuant to statute 64B-8-9.0091 (FAC), this surgical facility is not operating as an ambulatory surgical centre (ASC) for the purposes of this consent.

HAROLD M. REED, M.D.