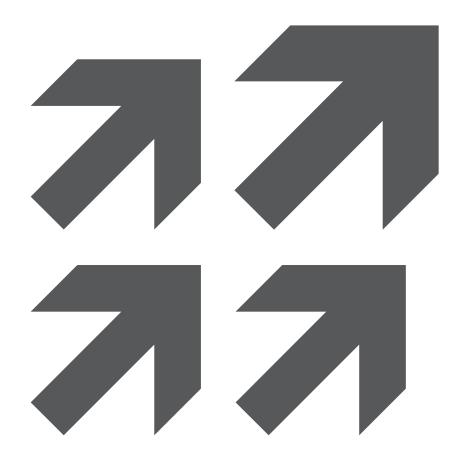
Patient-Physician Surgical Agreement Forms



Surgical procedures

- 1. **Penile lengthening surgery.** Penile lengthening surgery is performed by making a small curvilinear incision in the pubic region. The penile lengthening procedure requires separation of the penis from its attachment to the pubic bone. A portion of the human penis is attached by several ligaments to the pubic bone. In the penile lengthening procedure, the fundiform and suspensory ligaments, as well as all collateral ligaments, are incised in order to separate the shaft of the penis from its attachment to the pubic bone. This separation provides additional length of the penis to be seen in the flaccid position only. Occasionally, patients will gain some length in the erect position as well.
- 2. **Girth enhancement surgery.** Girth enhancement of the penis is accomplished by the insertion of either a dermal fat graft (DFG) or AlloDerm[®] along the shaft of the penis. The graft is placed semi-circumferentially from the base of the penis up to the head of the penis. This procedure requires a small curvilinear incision in the pubic region and a second semi-circular incision behind the glans of the penis. AlloDerm[®] is a registered trademark of LifeCell Corporation.
- 3. **Glanular enhancement surgery.** Glanular enhancement is achieved by surgically placing either a dermal fat graft (DFG) or AlloDerm inside the glans of the penis. When combined with girth enhancement, this procedure does not require any additional penile incisions. After a space (pockets) for the graft is created inside the glans of the penis, the graft is placed through a semi-circular incision behind the glans of the penis.
- Penile Dual Augmentation[™] surgery. Penile Dual Augmentation surgery consists of two of the three procedures listed above.
 Penile Dual Augmentation[™] is a trademark of Alexander Krakovsky.
- 5. Penile Triple Augmentation[™] surgery. Penile Triple Augmentation surgery consists of all three of the procedures listed in items one through three above. Penile Triple Augmentation[™] is a trademark of Alexander Krakovsky.

I (the patient) have read and understand the above *Surgical procedures* information describing the procedure(s) pertaining to my surgery.

Patient name (please print)	Witness name (please print)
Patient signature	Witness signature

Surgical procedures (continued)

- 6. **Second augmentation surgery.** Second augmentation surgery consists of one or two of the procedures listed in items one through three above performed on someone who has already undergone one of the other procedures listed in items one through three above.
- 7. **Reconstruction surgery.** Reconstruction surgery consists of surgery to correct problems caused by a previously failed phalloplasty surgery that was performed with free fat transfer (FFT), dermal fat graft (DFG), or AlloDerm.
- 8. **Scrotal web resection (scrotoplasty).** Scrotal web resection (scrotoplasty) is accomplished by excising extra skin from the scrotum.
- 9. **Pubic and/or breast liposuction.** Pubic/breast liposuction is accomplished by using standard liposuction techniques. This procedure can be performed independently, or in conjunction with one of the procedures listed above.

I (the patient) have read and understood the above *Surgical procedures* information describing the procedure(s) pertaining to my surgery.

Patient name (please print)	Witness name (please print)
Patient signature	Witness signature

Consent for surgery

I (the patient) authorize the surgeon, Dr. Alexander A. Krakovsky, to perform upon myself the following surgical procedures:

- 1. Penile lengthening surgery by releasing and separating the suspensory, fundiform and all collateral ligaments from the pubic bone and the shaft of the penis.
- 2. Penile girth enhancement surgery by inserting either a dermal fat graft (DFG) or AlloDerm[®] under the skin from the base of the penis up to the head of the penis. AlloDerm[®] is a registered trademark of LifeCell Corporation.
- 3. Penile glanular enhancement surgery by inserting either a dermal fat graft (DFG) or AlloDerm inside the glans of the penis.
- 4. Girth and glanular enhancement surgery, consisting of both penile girth enhancement surgery and penile glanular enhancement surgery procedures.
- 5. Penile Dual Augmentation[™] surgery, consisting of penile lengthening surgery and penile girth enhancement surgery procedures.
- 6. Penile Triple Augmentation[™] surgery, consisting of penile lengthening surgery, penile girth enhancement surgery and penile glanular enhancement surgery procedures.
- 7. Second augmentation surgery, consisting of one or two of the procedures listed above performed on someone who has already undergone one of the other procedures listed above.
- 8. Reconstruction surgery, consisting of correction of problems caused by a previously failed phalloplasty surgery that was performed with free fat transfer (FFT), dermal fat graft (DFG), or AlloDerm.
- 9. Scrotal Web Resection (Scrotoplasty) by excising extra skin from the scrotum.
- 10. Pubic and/or Breast Liposuction by using standard liposuction techniques in conjunction with one of the procedures listed above.

Penile Dual Augmentation™ is a trademark of Alexander Krakovsky.

Penile Triple Augmentation™ is a trademark of Alexander Krakovsky.

I (the patient) have read and understand the Consent for surgery listed above.

Patient name (please print)	Witness name (please print)
Patient signature	Witness signature
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Risks and potential complications that may occur with surgery

Hematoma

A hematoma is a collection of the blood in a location where it is not usually found, such as outside of the blood vessel. This may occur due to the bleeding of a small vessel during surgery. Small hematoma formations may be left untreated and allowed to resolve spontaneously. A larger hematoma must be drained through an additional incision or by aspiration. Sometimes it must be drained surgically.



Infection

With any skin opening there is a high possibility for infection to occur. Even without a skin opening, using the best surgical techniques in an optimal operating room situation, infection has been known to occur. Treatment is usually symptomatic. In the majority of cases, it includes the use of antibiotics and a conservative approach. Rarely does it require surgical treatment with wound cleaning, closure, and drainage. Sometimes, in the event of severe infection, the graft must be removed.



Ecchymosis

Ecchymotic areas ("black and blue" bruises, or reddened skin areas) occur with moderate frequency. This is the result of the surgical procedure. Usually, the discoloration is mild and disappears after about seven to ten days.

Patient	Initials	

Swelling

Post-surgical swelling usually occurs. This is the result of the surgical procedure and disappears after about seven to ten days.



I (the patient) have read and understand the Risks and potential complications
that may occur with surgery listed above.

Patient name (please print)	Witness name (please print)
Patient signature	Witness signature

Risks and potential complications that may occur with surgery (continued)

Wound separation

Wound separation may occur if stress is applied to the incision line too early during the healing process (during the first six to eight weeks). The patient must follow the surgeon's instructions meticulously to prevent this from happening. The most likely cause of wound separation is poor erection control. Wound separation may or may not require further surgery. The surgery could be limited to simple wound closure or may require removal of the graft.



Retraction/loss of length

Some patients experience temporary post-surgical penile retraction. These patients require intensive post-surgical stretching/traction physiotherapy exercises and medical/surgical treatment. In rare instances, retraction may remain.

A very small percentage of the patient population (about 1% to 2%) develops keloid scar tissue in the surgical area. For some populations, particularly those with darker skin, such as African-Americans or Hispanics, the rate of keloid scarring, and therefore the chances of permanent retraction, are up to 15 times higher than for the general population. Keloid scarring occurs when scar tissue continues to multiply after a scar has closed the wound. Keloid scars sometimes extend into areas that were not even injured. The result is a large, tough, irregular, unattractive mound of scar tissue that builds above the surface of the skin (in this case, on the penis), and can continue to grow over time. Keloids can itch or even cause pain if touched. There is no guarantee that available treatments will remove or reduce a keloid. Unlike normal scars, keloids can also extend beneath the surface of the skin into the subcutaneous skin layers and cause severe retraction. In penile cosmetic surgery, formation of a keloid scar leads to permanent penile retraction that cannot be treated medically or surgically.

Patient Initials

I (the patient) have read and understand the *Risks and potential complications that may occur with surgery* listed above.

Patient name (please print)	Witness name (please print)
Patient signature	Witness signature

Risks and potential complications that may occur with surgery (continued)

No significant length gain or no length gain

Even in the best of hands, some patients show no significant length gain or no length gain. These patients lack that portion of the penis that is normally attached by ligaments to the pubic bone and can be released. Therefore penile detachment does not give these patients any length gain. This situation is uncommon, but may occur.

Patient Initials

Temporary or permanent loss of sensation

Temporary loss of sensation may occur as with any surgical skin incision. Usually, sensation returns during the first three to six months of the healing process. Permanent loss of sensation is extremely rare, but may occur.

Patient Initials

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Erectile dysfunction or impotence

Erectile dysfunction as a result of cosmetic penile enlargement surgery has never been described and/or reported in the medical literature, on the internet, or in any other media. However, because any surgical procedure performed on human sexual organs carries some potential risks that may lead to a change in sexual sensation, such a change could be a cause of sexual dysfunction, including erectile dysfunction.

Patient Initials

I (the patient) have read and understand the *Risks and potential complications that may occur with surgery* listed above.

Patient name (please print)	Witness name (please print)
Patient signature	Witness signature

Expected results of surgical procedures

THE PATIENT MUST HAVE REALISTIC EXPECTATIONS OF THE RESULTS OF PENILE SURGERY.

1. **Penile lengthening surgery.** A post-surgical increase in length can not be guaranteed. The patient should not expect a tremendous increase in the length of the penis. This increase varies from person to person, and may or may not fall into the normal range of one-half to one-and-one-half additional inches in the flaccid position. The length gain varies with every patient and depends upon the portion of the penis that is available after separation from the public bone. Ligament length and the portion of the penis that is available for lengthening are unknown before surgery and vary from person to person. In addition, to achieve an optimal result, the patient must follow a post-surgical penile physiotherapy exercise/ stretching program for up to one year after surgery. Occasionally, a patient experiences retraction after the surgery and may find that his penis is even shorter after the surgery than it was before the surgery, and the penis length remains the same as before the surgery.

The surgery may or may not lower the angle of erection 10% to15%.

Penile lengthening surgery is a cosmetic surgical procedure and affects the flaccid penile length only. Occasionally, a patient may also gain penis length in the erect state. The lengthening surgery is not likely to have any physiologic effect on penis function; is not likely to affect the strength or duration of an erection; and is not likely to correct or cause impotence.

Patient Initials

2. **Girth enhancement surgery.** Whether using a dermal fat graft (DFG) or AlloDerm[®], shaft circumference enlargement depends largely on the quantity of implanted skin. This enlargement may vary from a 10% increase to a 30% increase over the existing pre-operative circumference size depending on the number and size of the grafts used during this surgery.

AlloDerm[®] is a registered trademark of LifeCell Corporation.

Patient Initials

I (the patient) have read and understand the Expected results of surgical
procedures listed above.

Patient name (please print)	Witness name (please print)
Patient signature	Witness signature

Expected results of surgical procedures

(continued)

3. **Glanular enhancement surgery.** Whether using a dermal fat graft (DFG) or AlloDerm, glanular enhancement also depends on the quantity of implanted skin. This enhancement may vary up to a 15% increase over the existing pre-operative circumference size depending on the number and size of the grafts used during this surgery.

Patient Initials

To date, and to our knowledge, there have been no reports in the medical literature, on the internet, or in any other media of post-operative sexual dysfunction or permanent sensation changes related to phalloplasty surgical procedures. However, all surgeries entail risks of complications and potential adverse effects that may not be known or recorded in medical literature. The surgery is performed under IV conscious sedation or under general anesthesia. Post-surgical pain is usually minimal and controlled by mild analgesics. There is also no established age limit for this surgery. Therefore, it should be considered similar to general plastic/cosmetic surgery in terms of limitations.

Patient Initials

The vast majority of plastic/cosmetic surgical procedures are elective and are performed, ideally, on healthy individuals. Medical clearance from a primary care physician is always appreciated. If the patient has preexisting medical conditions, he must be cleared by his physician for this type of cosmetic surgery. Individuals suffering from chronic heart, lung, liver, vascular, rheumatologic and immunologic disorders (such as HIV) may not be a good candidate for this type of elective surgery. The surgeon may elect not to perform phalloplasty surgery on any patient if he believes that the patient may not respond well to the surgery or if he believes that the patient has unrealistic expectations of the surgery.

Patient Initials	

I (the patient) have read and understand the Expected results of surgical
procedures listed above.

Patient name (please print)	Witness name (please print)	
Patient signature	Witness signature	

Expected results of surgical procedures (continued)

Due to temporary swelling, there may be some transitory decreased skin sensation which should return to normal within several weeks. Cosmetic penile augmentation will most likely have no physiological effect on penile function. One must bear in mind that any surgical procedure carries with it risks, though they occur infrequently, such as bleeding, infection, or complications from anesthesia.

Patient Initials

Specifically, after lengthening surgery only, or after lengthening surgery performed as a part of a combination augmentation surgery (Penile Dual Augmentation[™] surgery and/or Penile Triple Augmentation[™] surgery), the patient may develop retraction (penis shortening) instead of penis lengthening, or have no penis size length change at all. This happens on rare occasions (in about 6% or 7% of these surgeries).

Patient Initials

Penile Dual Augmentation[™] is a trademark of Alexander Krakovsky. Penile Triple Augmentation[™] is a trademark of Alexander Krakovsky.

I (the patient) have read and understand the *Expected results of surgical procedures* listed above.

Patient name (please print)

Witness name (please print)

Patient signature

Agreement as to resolution of concerns

I (patient name) ______ understand that I am entering into a contractual relationship with Alexander A. Krakovsky MD, PhD for professional care. I further understand that meritless and frivolous claims for medical malpractice have an adverse effect upon the cost and availability of medical care to patients and may result in irreparable harm to a medical provider. As additional consideration for professional care provided to me by Dr. Alexander Krakovsky,

I (patient name) ______ agree not to initiate or advance, directly or indirectly any meritless or frivolous claims of medical malpractice against Alexander A. Krakovsky MD, PhD.

Patient and physician agree that this Agreement is binding upon them individually and their respective successors, assigns, representatives, personal representatives, spouses and any other dependents.

Patient and physician agree that these provisions apply to any claim for medical malpractice whether based on a theory of contract, negligence, or any other theory of recovery.

Patient acknowledges that he/she has been given ample opportunity to read this agreement and to ask questions about it.

This Agreement is effective from the date of treatment.

I (the patient) have read and understand this Agreement as to resolution of concerns.

Patient name (please print)

Witness name (please print)

Patient signature

Informed consent for phalloplasty

Regarding procedure(s):

PROCEDURES CANNOT BE GUARANTEED

This document constitutes your informed consent to the phalloplasty procedure(s) named above. You **must** read it carefully so that you fully understand the expected benefits and possible risks **before** you agree to undergo this procedure.

- 1. The required pre-surgery lab work includes CBC, PT, PTT, a routine chemistry panel, and a urine panel. Blood work must also include HIV and Hepatitis C tests. If the patient is over 45 years old, he must have an EKG, and smokers must have a chest x-ray.
- 2. The surgery is performed by a trained phalloplasty surgeon, in an outpatient surgical suite, and is not covered by medical insurance.
- 3. The patient must follow the timelines and guidelines in the *Phalloplasty Timelines* & *Guidelines (PT&G)* booklet and the *Surgery Preparation & Follow Up Checklist (SP&F)*. These timelines and guidelines include, but are not limited to the following.
 - a. The pubic region remains sore for up to ten (10) days, but the patient may return to non-physical work within three to four days (3-4) after surgery. Physical labor can be resumed four (4) weeks after surgery, after clearance by the surgeon.
 - b. The patient is not allowed to take a shower for fourteen (14) days after surgery, and is not allowed to take a shower with the surgical area unprotected for twenty-one (21) days after surgery. The patient is not allowed to take baths or immerse himself in water for at least six (6) weeks after surgery.
 - c. We insist on no sexual activity of any kind including, but not limited to, vaginal intercourse, oral and/or anal sex, and masturbation. The patient is not allowed to perform any type of sexual activity under any circumstances for at least:
 - \cdot three (3) weeks after lengthening surgery;
 - \cdot six (6) weeks after girth, glans, and/or multiple augmentation surgeries; and
 - · eight (8) weeks after reconstruction surgery,

and until healing is complete. The patient must be cleared by the surgeon before resuming sexual activity.

- d. The patient is not allowed to smoke from two (2) months before surgery until two (2) months after surgery.
- e. The patient is not allowed to drink alcohol from one (1) month before surgery until one (1) month after surgery.

Patient name (please print)	Witness name (please print)	
Patient signature	Witness signature	

- 4. As with any surgical procedure, negative results may occur due to certain behaviors, such as those described above. These behaviors include, but are not limited to, the following:
 - a. A person who smokes will most likely have problems with healing and infection.
 - b. A person who drinks alcohol may have problems with their blood-clotting mechanisms.
 - c. Any type of sexual activity, including masturbation, before the healing process is completed can cause complications that lead to wound opening, infection and possible loss of the graft. **Sexual relations and/or masturbation before the healing process is complete will cause complications that lead to wound opening, subsequent infection and the possible loss of the grafts.**
 - d. Poor hygiene and poor wound care potentially will lead to infection and loss of the graft.
 - e. A person who does not follow medical instructions for this surgery is potentially prone to many complications, including infection and loss of the graft. A person, who does not follow postoperative instructions, will be responsible for all potential risks and complications.
 - f. A person who is not able to control an erection (during the day and/or during the night) is prone to wound opening, infection and loss of the graft.
- 5. I (the patient) ______ am submitting myself to the procedure described in this informed consent document dated ______ with full knowledge of these matters, and I specifically release Alexander A. Krakovsky MD, his assistants, and other physicians and/or nurses who participate in my surgery and/or my care in any way, as well as his agents and employees from any liability to me as a result of the above described surgery/surgeries or any condition that may subsequently develop.
- 6. If you are a current smoker or drink alcoholic beverages, do not sign this consent or have surgery until you have stopped smoking for a period of two (2) months before the surgery and have not been drinking alcohol for a period of one (1) month before the surgery.

I (the patient) have read and understand the information on this page for
Informed Consent for Phalloplasty.

Patient name (please print)	Witness name (please print)	
Patient signature	Witness signature	

not to smoke for sixty (60) days after the surgery.

7. I (the patient) have not smoked in the last sixty (60) days.

Patient Initials	
8. I (the patient) a	gree



9. I (the patient) have not drunk alcoholic beverages in the last thirty (30) days.



10. I (the patient) agree not to drink alcohol for thirty (30) days after the surgery.



11. I (the patient) understand that any types of sexual activity before the healing process is complete can cause complications that lead to wound opening, infection and possible loss of the graft following the surgery, and I agree not to participate in any type of sexual activity, including masturbation, for the time period listed here for my surgery:

- \cdot at least three (3) weeks after lengthening surgery;
- \cdot at least six (6) weeks after girth, glans, and/or multiple augmentation surgeries; and
- \cdot at least eight (8) weeks after reconstruction surgery,

and until my healing is complete and I am cleared to participate in sexual activity by the surgeon.



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12. I (the patient) will do my best to follow the surgeon's recommendations and to take all necessary precautions to control my daily and/or nightly erections to prevent possible wound opening, infection and loss of the graft.

Patient	Initials	

Patient name (please print)	Witness name (please print)	
Patient signature	Witness signature	

13. I (the patient) have read and initialed and agree to follow the timelines and guidelines in the *Phalloplasty Timelines & Guidelines (PT&G)* booklet and the *Surgery Preparation & Follow Up Checklist (SP&F)* that have been provided to me.

Patient Initials	

14. I (the patient) undertake full and complete responsibility for any complications if I knowingly or not knowingly, intentionally or unintentionally violate any of the above.



15. I (the patient) understand that the surgery is to be performed by Dr. Alexander A. Krakovsky. I have previously received and carefully read the printed materials regarding the surgery to be performed that is described in this consent. I also acknowledge that Dr. Alexander Krakovsky personally and fully explained the surgery and the risks and possible complications of the procedure(s) to me. I further acknowledge that Dr. Alexander Krakovsky has answered all of my questions to my satisfaction.

Patient Initials

16. I (the patient) understand that the nature and purpose of the procedure(s) is cosmetic, and the **results cannot be guaranteed**. I understand that the results vary from patient to patient and surgeon to surgeon. No one has given me a guarantee of results for this surgery.

Patient Initials

17. I (the patient) understand that Dr. Alexander Krakovsky will perform this surgery exercising his experienced, professional judgment. I also understand from reading the written materials and listening to the surgeon's personal professional explanation that problems may arise that are beyond his control as a surgeon. I am very well aware of this fact, and of the potential significant risks involved, and have fully discussed them with Dr. Alexander Krakovsky.

Patient Initials

Patient name (please print)	Witness name (please print)
Patient signature	Witness signature

18. I (the patient) understand that unforeseen problems may occur during the course of the surgery and I (the patient) give my full and informed consent to Dr. Krakovsky, as well as other personnel Dr. Krakovsky deems necessary, such as technical assistants and other health care providers, to treat any problems according to his best medical and surgical judgment. This consent is to extend to treatment of any condition not known at the start of the surgery by Dr. Alexander Krakovsky.

Patient Initials	

19. I (the patient) understand that re-operation is one of the risks of surgery. Subsequent operation(s) may be necessary due to unknown or unforeseen causes, or as a result of, but not limited to, infection, open wounds that need to be re-stitched, or other complications.

Patient Initials

20. I (the patient) have completed the *Phalloplasty Surgery Screening Questionnaire*, and in that document have informed Dr. Krakovsky of all my pre-existing physical conditions, health and surgical history, family medical history, medications and supplements, and medications to which I am allergic, and my reactions to them. I agree to inform Dr. Krakovsky if subsequent changes in my health alter the information in the Screening Questionnaire.

Patient Initials

21. I (the patient) was given the opportunity to ask any questions about my surgery and I have received satisfactory answers to all my questions.



22. I (the patient) consent to the taking of photographs before, during and after the surgical procedure(s) for the purposes of record keeping and the improvement of general medical knowledge and education.

Patient Initials	

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I (the patient) have read and understand the information on this page for
Informed Consent for Phalloplasty.

Patient name (please print)	Witness name (please print)
Patient signature	Witness signature

23. I (the patient) consent to such testing of my bodily fluids or tissues as is considered necessary by Dr. Alexander A. Krakovsky, including HIV antibody/ antigen testing (also known as the AIDS virus).

Patient Initials	

24. I (the patient) consent to the disposal by Dr. Alexander Krakovsky of any tissue he removes from my body during the surgery in any way he believes medically and legally proper.



25. I (the patient) understand that I am to keep my follow-up appointment for post-operative care. I agree to notify Dr. Alexander Krakovsky immediately of any problems that might arise following my surgery by calling Dr. Krakovsky's emergency line at 858-551-9502. I will not treat myself contrary to Dr. Alexander Krakovsky instructions.

Patient Initials

Patient name (please print)	Witness name (please print)
Patient signature	Witness signature

Post-operative emergency instructions

If any problems arise, please call the surgeon immediately on his office **emergency line at 858-551-9502**. The surgeon, or his assistant, will endeavor to call you back as soon as he is able, usually within a couple of hours. At times he may be out of the area for a few hours. Do not hesitate to call about anything of concern.

Any problems should be brought to the surgeon's immediate attention, such as: pain not relieved by the prescribed medications; unusual or increased redness; fever; swelling; bleeding; extreme warmth of the surgical area; insomnia; anxiety; malaise; weakness; chills; incision drainage; wound separation; or any other conditions of concern. If you are unable to reach the surgeon, or if you have any health concerns, you (the patient) will proceed to the nearest Emergency Room for evaluation and treatment.

I (the patient) have read and understand these *Post-operative emergency instructions*.

Patient name (please print)

Witness name (please print)

Patient signature

Surgeon's statement

I, Alexander Krakovsky, M.D., have completed the following steps in preparation for

surgery for the patient (patient name), ____

- 1. I have taken a history and performed a preoperative physical exam for this patient.
- 2. I have evaluated the patient's current medications.
- 3. I have obtained a history of the patient's allergies.
- 4. I have discussed in detail with the patient the procedure that he will be undergoing.
- 5. I have discussed with the patient the content of all Patient-Physician Agreement Forms that he has signed, including benefits, risks and potential complications that may occur with the surgery; expectations of the patient with regard to the surgery, including pre- and post-surgical expectations; expected results of the surgical procedure, as detailed in the Surgery Preparation and Follow Up Checklist and the Phalloplasty Timelines & Guidelines documents; and post-operative emergency instructions.
- 6. I have answered all questions asked by the patient.
- 7. The patient has expressed his understanding of the above, and his wish to proceed with the surgery, and I have set a date for surgery with the patient.

I, Alexander Krakovsky, M.D., hav	e read and understand this Surgeon's
statement.	

Surgeon's name (please print)

Witness name (please print)

Surgeon's signature