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CONSENT FOR ELECTIVE PENILE ENHANCEMENT SURGERY

NOTE – NO SMOKING 30 DAYS BEFORE AND AFTER SURGERY

Notice to Patient

State law guarantees that you, the patient, have both the ***right*** and ***obligation*** to make decisions concerning your health care. While your physician can provide you with the necessary information and advice, only you can make the decision whether or not to proceed with any treatment. This form has been designed to acknowledge that you have been provided the information necessary to render your consent and agreement to the treatment recommended by your physician informed in the legally required sense.

If you don't understand anything explained or described in this form, it is important that you ask your physician to explain it to you, to ensure that you are fully informed.

I _____, hereinafter "Patient"
hereby authorize _____, hereinafter "Physician" and/or his agents, employees, partners and/or assistants selected by said physician to treat the following condition(s):

ELECTIVE PENILE ENHANCEMENT, COSMETIC AUGMENTATION OF PENIS

The procedures planned for the treatment of my condition(s) have been explained in detail to me by Physician and/or a qualified member of his medical team and are described as follows:

PLACEMENT OF SUBCUTANEOUS SILICONE BLOCK (HIMPLANT™) UNDER THE PENILE SKIN ("PROCEDURES")

I have (a) been advised by Physician, orally, through an animated video, and in writing of the possible risks, benefits, alternatives, and the likelihood of complications associated with the foregoing procedure(s), including, without limitation, the risks listed below; (b) been advised not to consume any aspirin products for 14 days before and after the aforementioned surgical procedure; (c) been provided an opportunity to ask questions regarding the aforementioned procedure(s) and the risk(s), benefits, and alternatives thereto, including the option of undergoing no surgery; and (d) have had all of my questions answered to my satisfaction.

I hereby certify that I have not taken any medication(s), supplements, vitamin products, or illicit substances except those I have disclosed in writing to Physician or any medications that may have been ordered or prescribed by Physician. I also certify that I am not under the influence of any undisclosed medication(s) or illicit drugs, and that no undisclosed medications have been administered to me by any other healthcare provider, which may might impair my ability to consent to the procedure referenced herein. I further certify that I have been provided with an opportunity to review this consent form and have any questions I may have concerning the same answered to my satisfaction.

I certify that I speak, understand, and read the English language fluently. To the extent I have not, I certify that I have been informed and understand that I have the right to an interpreter and have been offered an interpreter to interpret and explain the contents of this document to me before I sign it.

POSSIBLE RISKS AND COMPLICATIONS OF WHICH I HAVE BEEN ADVISED, INCLUDE, BUT ARE NOT LIMITED TO:

POSSIBLE RISKS AND COMPLICATIONS	**PATIENT INITIALS**
INFECTION OR EROSION OF SILICONE BLOCK REQUIRING REMOVAL	
CONTINUOUS BENDING OF THE PENIS, INSTABILITY AND/OR WRINKLING, BENDING, AND/OR KINKING OF PENIS AND/OR IMPLANT IN ERECT AND FLACCID STATES	
PATIENT OR PARTNER DISSATISFACTION WITH RESULTS	
EXTENDED PENILE OR SCROTAL PAIN AND DISCOMFORT	
LACK OF SENSATION ON PARTS OF PENIS AND/OR NERVE INTERRUPTION CAUSING NUMBNESS AND LOSS OF SENSITIVITY	
INFECTION OF INCISION REQUIRING FURTHER TREATMENT	
MODERATE TO SEVERE SCAR TISSUE FORMATION, FIBROSIS, AND/OR POSSIBLE DETACHMENT OF SUTURES	
PENILE SHORTENING AND/OR POSSIBLE PENILE IMPLANT MISALIGNMENT	
CUTANEOUS HYPERSENSITIVITY, MODERATE FOREIGN BODY REACTION, POSSIBLE URETHRAL DAMAGE	
SKIN NECROSIS REQUIRING SKIN GRAFT OR SECONDARY CLOSURE, SWELLING, ERYTHEMA, AND/OR SHARP WRINKLES	

LOCALIZED GRANULOMATOUS REACTIONS AND/OR SKIN PIGMENTATION	
ABSCESS FORMATION AND/OR COLLECTION OF FLUID (SEROMA)	
A COLLECTION OF BLOOD UNDER THE SKIN (HEMATOMA) AND/OR BLEEDING AND/OR TRANSIENT BLACK AND BLUE BRUISING (ECCHYMOSIS)	
EXTENDED SEMI ERECTED NON-DROPPED PENIS AND/OR PENILE DEFORMITY	
PENILE RETRACTION IN ERECT AND FLACCID STATES	
POSSIBLE IMPOTENCE REQUIRING ADDITIONAL TREATMENT	
POSSIBLE LOW URINARY TRACT DIFFICULTY AND/OR URINARY RETENTION	
REMOVAL OF IMPLANT MAY RESULT IN PENILE RETRACTION, SCAR FORMATION, AND OTHER POTENTIAL COMPLICATIONS, NECESSITATING ADDITIONAL TREATMENT	

I HAVE ALSO BEEN ADVISED THAT ALTERNATIVE THERAPY MAY INCLUDE OBSERVATION OR NOT UNDERGOING SURGERY

I recognize that during the course of the surgical procedure referenced above, unforeseen conditions may necessitate additional or different procedures than those set forth. **By signing below and initialing this paragraph, I authorize Physician and his assistants, associates, or designees, to perform whatever surgical or other procedures as are in their professional, clinical judgment deemed necessary and desirable.**

I have been informed that there are significant risks associated with any surgical procedure conducted under general anesthesia, including the aforementioned procedure, and that these include but not limited to severe loss of blood, infection and cardiac arrest that can lead to or result in death or permanent or partial disability, which may be attendant to the performance of any procedure. I realize that in those cases where an incision is needed, infection, incisional pain, or hernia formation (weakness or bulging) can occur and may necessitate further treatments or procedures.

I realize that this list of risks and possible complications **does not include all possible risks of the aforementioned surgical procedure but is limited to the more common or severe ones.**

I understand that my penis has natural wrinkles in the skin, which may cause the implant to protrude at times while my penis is in a flaccid state. A small fold in the implant can also occur when the implant is under compression. When the penis is flaccid and retracted, the implant may compact and compress, which can cause the fold to potentially occur as a result of the natural wrinkles in my skin. This fold will disappear with stretching of the penis or with erection. This is natural and a part of the healing process of which I have been informed and I acknowledge and accept this risk.

I understand there could be temporary changes in my penile length due to the restriction of the skin and potential scar tissue. The extent of this change depends on how my physiology and anatomy heal and is different for each individual patient. I am fully aware that a temporary change in my penile length is a part of the healing process.

I understand that there is a possibility of a temporary or long-term change in sensation due to the skin of my penis stretching to accommodate the subcutaneous penile implant or potential damage to the nerves.

I understand the following: That the Himplant may increase the girth of the penis within 9-12 months after the procedure (results may vary). Any additional flaccid penile length will depend on the anatomy and pathology of the individual patient, such as tight suspensory ligament and retractile penis, and may occur 12 months after the procedure (again, results may vary). Any increases in flaccid or erect length are unpredictable. The skin from the lower part of the pubic area typically gradually descends towards the penis in order to potentially increase the flaccid length of the penis. The penile skin at the time of surgery accommodates the implant to provide any girth enhancement to the penis. Further girth enhancements, if any, are typically progressive over the course of months as a capsule forms and other expected changes occur. I acknowledge and understand these points, and I understand that this procedure carries no guarantees or warranties. Any further changes to flaccid or erect girth or length after the procedure are unpredictable, and if they occur at all, they typically take 12-24 months to materialize fully (individual results will vary).

I acknowledge that no warranty or guarantee has been made to me as the result of my procedure or treatment of my condition.

I have been offered an independent pre-surgical psychological evaluation for this procedure and
I declined accepted to undergo such evaluation.

I consent to the administration of anesthesia by Physician, an anesthesiologist, and/or another licensed and qualified party. I understand that all anesthetics involve risks and potential complications and possible serious damage to vital organs such as the brain, heart, lung, liver, and kidney, and in some cases, may result in paralysis, cardiac arrest and/or brain death from both known and unknown causes.

I consent to the use of transfusions of blood and blood products as may be deemed necessary by my physician. I understand that diseases can be transmitted via these blood products, including AIDS and hepatitis.

I acknowledge that any tissues or parts removed surgically may be disposed of by the hospital, surgery center, or Physician in accordance with accustomed practice.

I acknowledge that previously unknown allergic reaction(s) to any medications used in the pre-and post-operative treatment may occur.

I understand that as part of the surgical procedure, a surgical drain is inserted. I understand that it is my responsibility as a patient to follow the detailed instructions which have been provided to me orally and in writing regarding the surgical drain. Moreover, it I understand that it is my responsibility to attend my final appointment after the procedure to have the surgical drain removed. If I decide not to attend my final appointment, which is against medical advice, it is my responsibility to find and seek a medical professional who will remove the surgical drain, and I will be responsible for all costs associated with this surgical drain removal. Physician will in no way accept any responsibility for any complications if I, the patient, decide not to follow the surgical drain instructions or if I decide to have the surgical drain removed by a medical professional not affiliated with Physician. Moreover, I understand that it may not be possible or appropriate for my surgical drain to be removed at my final scheduled visit. If this is the case, I understand that it is my responsibility to make alternative travel plans at my own cost to allow for the surgical drain to be removed at a time that is medically appropriate. Finally, I acknowledge that although unlikely, there are risks and complications specifically associated with the surgical drain, including breakage of the drain, infection, pain, soreness, and other potential complications and risks. These risks and complications may require additional medical or surgical intervention.

I understand the following: That the removal of the surgical drain involves a minor procedure under local anesthesia that typically carries minimal risk. Possible risks and complications include, but are not limited to, infection, pain (especially at the incision site), bleeding, delayed or non-healing, and possible breakage of the surgical drain. Addressing these complications may involve a subsequent procedure, which carries its own potential risks and complications, which will be discussed in advance of the procedure.

I acknowledge that I fully understand all the contents of this consent form and that I have been encouraged and provided an opportunity to ask my physician(s) and/or their associates to explain any aspects of this consent form that I do not understand.

I certify that Physician has fully informed me of the nature and character of the proposed treatment, of the anticipated results of the proposed treatment, of the possible alternative forms of treatment, including non-treatment; and the recognized serious possible risks, complications, and the anticipated benefits involved in the proposed treatment.

I understand that sexual activity, including masturbation, must be avoided post-surgically, until I receive clearance from Physician or his medical staff and his medical staff. I further understand that frequent masturbation and/or other types of traumatic sexual activity and/or a history of frequent masturbation and/or other types of traumatic sexual activity and/or use of a penile vacuum and/or any manipulation of

the penis may cause trauma, bleeding, micro bleeding, adhesion, scar tissue formation in the penis, and other potential adverse events, which may also cause retraction of the penis among other potential outcomes. I agree not to engage in such activities until cleared by Physician to do so.

I understand that patients who have had any previous penile and/or genital surgeries/procedures, including, but not limited to, fat injection, suspensory ligament division, AlloDerm insertion, PMMA insertion, and others, are typically NOT candidates for the silicone implant insertion procedure. I certify that I have disclosed in writing in advance to Physician if I have received any previous penile and/or genital surgeries/procedures at any time. I acknowledge that failure to make such a disclosure in writing to Physician of any such prior procedure, should such disclosure failure be ascertained intraoperatively, will result in the implant not being inserted during the operation at the Physician's sole and absolute discretion, and I understand and accept that I will be responsible for any and all costs and fees associated with the surgery, regardless of implant placement.

I understand that any photograph(s) or videos shown to me were used only to illustrate past benefits for others from this type of surgery, and no promises or guarantees were made as to specific or similar results for me. Permission is given for photographs or videos of me to be taken and used for scientific purposes, research purposes, and other purposes at the sole and absolute discretion of Physician.

I agree to abide by all post-operative and/or rehabilitative instructions that have been provided to me. All have been explained to me in detail both in writing and orally. I understand that some but not all patients have to be in a convalescent state with a generous amount of bed rest for the first week after surgery and for one to two months after surgery. I will not engage in any stressful physical activity including excessive bending, lifting, or participation in any sports post surgically until cleared by Physician. I will abstain from all sexual activity, including masturbation, oral sex, anal sex, and vaginal penetration, until cleared by Physician. I also agree not to manipulate my penis, engage in any rigorous activity, or induce erections (even to take post-operative photos for Physician) unless instructed by Physician. I will not use any medications, penile stretchers, penile pumps, penile extenders, lotions, creams, etc., particularly in the genital area, unless instructed by Physician. I also understand that recovery is highly individual and may vary significantly in any particular case. I understand that full rehabilitation can take considerable time, including months or years. I understand that any deviation from the post-operative instructions I receive is likely to increase the risk of complications, which may require additional treatment, including potential additional surgery and/or removal of my implant.

I understand that consistent and engaged post-op care is essential and that certain activities can negatively impact my postoperative course. I understand, for example, that cigarette smoking, excessive alcohol consumption, and any sexual activity prior to clearance may damage the implant and may cause infections and other complications.

I understand that frequent masturbation and/or other types of traumatic sexual activity and/or other types of traumatic sexual activity may cause micro trauma, micro bleeding, adhesion, and/or scar tissue formation in the penis, which may cause retraction of the penis among other potential outcomes.

I understand that certain groups of patients are predisposed to scar tissue formation (e.g., African American patients) that can damage the patient's skin. As a result, in this group of patients, there exist higher risks of penile curvature, shortening, and other deformities due to scar tissue formation. I

understand that I may be predisposed to scar tissue formation. Scar tissue formation may require additional treatment, including, but not limited to surgery, which has its own risks and complications.

I understand that any changes in erect length, if any, are unpredictable and are dependent on my individual anatomy and physiology. I understand that there may be no added length on erect state and there may even be loss of length as a result of skin limitation and/or scar tissue formation.

I understand that a medium or large-sized supra-pubic fat pad can interfere with the stretching and elongation process of the penis by applying pressure and weight on the base of the penis and the implant, particularly in an upright position. I acknowledge that the pressure and weight caused by the fat pad may retract or pull the penis inside, in opposition to the implant, and may damage the implant. I understand that to achieve the best possible result after the penile implant procedure, Physician highly recommends that I reduce the size of the fat pad as much as possible through regular exercise, healthy eating habits, and other actions under the supervision of specialists and after I have been cleared to exercise by Physician.

I understand that the final size of the implant will be determined intra-operatively by Physician in consideration of my anatomy, safety, and appearance as well as the chance of successful recovery. Physician will take into consideration the patient's desires and wishes however will uphold, above all else, the patient's safety, health, and aesthetics.

I understand that if I choose to obtain post-operative care from another medical professional, or to undergo any related procedures performed by other professionals, Physician will not be responsible or liable for any adverse events (physical or psychological) that may result from such procedures or treatments.

I agree to abstain from manipulating my penis for 6-8 weeks or more to allow my implant to incorporate into my body and for the sutures to bind securely to the underlying tissues. I understand that manipulation can result in detachment of the sutures and sharpening of the edges and other possible risks and complications which may require surgical intervention including but not limited to removal of the implant. I understand that should such manipulation occur and result in these conditions, any subsequent repairs will be at my own cost.

I agree to inform and consult with Physician before undertaking any additional elective surgeries for three months following my penile enhancement surgery and I understand that Physician is unlikely to clear me for any additional elective procedures within three months of my implant procedure.

I give my full, voluntary, and irrevocable consent for all matters and information in and related to my patient file and procedure — including but not limited to photography and videography of my genitalia and other relevant body areas before, during, and after the procedure — to be used and disclosed by the practice and/or its affiliates and his authorized agents for the following purposes:

- Scientific publication, clinical investigation, and research;

- Educational presentations and professional seminars;

- Advertising and marketing in all forms of media (including digital, print, website, and social media);

- Any other purpose at the sole and absolute discretion of the practice, provided that any personally identifiable information will be de-identified unless I expressly authorize otherwise in writing.

I understand that any photograph(s) or videos shown to me were used only to illustrate past benefits for others from this type of surgery, and no promises or guarantees were made as to specific or similar results for me. I understand that my consent grants the practice and its agents a perpetual, worldwide, royalty-free, and unrestricted right to use such materials for the above purposes.

I have discussed this procedure with my sexual partner or "significant other" (if I have one) and have gained their approval, or elected no to do so, and after careful consideration of my situation and relationship, have decided to proceed. I am aware that there will be a period of sexual abstinence required after this procedure and can appreciate the emotional consequences of this hiatus on myself and my partner, and that any unanticipated complications stemming from this procedure may also take a toll. I certify that I have not been diagnosed or treated by a psychologist, psychiatrist, therapist, or physician for any personality or emotional disorder that I have not disclosed to Physician.

I understand and accept that given the fixed costs associated with the procedure, I understand that Physician cannot provide refunds after the surgery has been performed.

My decision to have this operation is not made in ignorance of the risks of surgery.

I agree to discuss any questions, issues, complications, concerns, dissatisfaction, or questions regarding surgical follow-up with Physician directly, should they arise. I understand and acknowledge that currently, very few physicians have the extensive knowledge about the implant and implantation procedure that is required to provide advice, counsel, and treatment about post-operative care. I understand that as a result, Physician encourages me to contact him or one of the other physicians trained and certified to implant the Himplant with any questions regarding post-operative care, recovery, support, complications, concerns, or dissatisfaction. I understand that I am also encouraged to maintain contact with Physician even if I seek care or a second opinion elsewhere. I understand that Physician highly discourages me from seeking information about my implant, the implantation procedure, and post-operative care from unreliable sources, including but not limited to the internet, as the information provided by such sources can be false, uninformed, misleading, or inaccurate. I understand that this encouragement does not limit my right to seek medical advice wherever I choose, including second opinions from other medical professionals. However, I acknowledge, accept, and agree that if I seek post-operative care with a medical professional other than physician, Physician may not be liable for any harm or injury that results.

I have been informed and understand that the time frame of healing, recovery, outcome, and penile size gains may vary from person to person. It may take one year or longer from the date of the surgery for gains in penile size to develop. I understand and acknowledge that attempting to rush healing or alter or adjust my surgical outcome by using methods or devices not approved by Physician can result in adverse reactions and consequences for which Physician will not be liable.

To the fullest extent permitted by law, on behalf of myself, my heirs, and my assigns, I release, Physician and all his associates and affiliates, including all past, present, and future professional corporations or partnerships owned in full or in part by Physician, all past, present, and future agents or employees of Physician or any of his medical professional corporations or partnerships, all distributors, device manufacturers, anesthesiologists, surgery centers, or other physicians or health entities who may have participated in my care with Physician's authorization from liability for any harm or injury related to or resulting from the aforementioned medical care. I understand that such care is elective and that I can chose not to undergo the aforementioned procedure and care or seek similar or identical procedures or care from another physician if I do not wish to sign this waiver, and that this waiver is therefore not compelled or unconscionably obtained. I also understand that under California law, such waiver will not excuse gross negligence or intentional torts. I ALSO WAIVE, TO THE FULLEST EXTENT PERMISSIBLE BY APPLICABLE LAW, WITH RESPECT TO ANY DISPUTE, THE RIGHT TO PARTICIPATE IN A CLASS ACTION, PRIVATE ATTORNEY GENERAL ACTION, OR OTHER REPRESENTATIVE ACTION IN COURT OR ARBITRATION, EITHER AS A CLASS REPRESENTATIVE OR CLASS MEMBER, AND THE RIGHT TO JOIN OR CONSOLIDATE CLAIMS WITH CLAIMS OF ANY OTHER PERSON.

I acknowledge that the Pre-Formed Penile Silicone Block Implant has been cleared by the FDA and is not FDA-approved. I understand that FDA clearance means that the FDA has reviewed relevant information and determined that the device is substantially equivalent to a market predicate. I further acknowledge that FDA clearance does not in any way denote official approval of the device. Neither the physician, manufacturer, distributor, or any affiliated entities have made any representation that creates an impression of official approval of the implant.

I certify that I have been given the opportunity to ask all my questions and fully discuss the procedure and this consent form and its contents with Physician. I choose to move forward with the insertion of a subcutaneous penile implant.

I also certify that I was given the option and opportunity to take a copy of this form home for further review at my leisure before signing it, and that I have read it or have had it read to me and that I fully understand its contents.

Patient or Guardian Signature _____ Date _____ Time_____

Patient Name (print) _____

Witness Signature_____ Date: _____

Physician's Signature_____ Date: _____