Plastic Surgery & Dermatology Associates (PSDA) FACIAL AUGMENTATION SURGERY INFORMATION SHEET AND INFORMED CONSENT

Instructions

This is an informed consent document that has been prepared to assist your plastic surgeon to inform you concerning facial augmentation surgery, its risks, and alternative treatment.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon.

INTRODUCTION

Facial augmentation surgery is an operation frequently performed by plastic surgeons. This surgical procedure is performed when a there is a defect or deformity of the face is significant enough to warrant augmentation or change appearance. Facial augmentation surgery usually involves placing a permanent prosthetic or implant or exposing the area to re-aligning the bone parts using plates. These plates can be steel based or absorbable and usually are necessary only until the augmentation heals. These plates are small and are usually left in place after healing unless they are visible or cause some discomfort. The goal of facial augmentation surgery in the area of the chin, forehead, or cheek is to try to return a patient to enhance a deficit to improve appearance with the least amount of scarring. Facial augmentation includes: facial implants, cheek implants, jaw or chin implants (genioplasty), ear implants (Otoplasty), and skull implants (cranioplasty). Facial augmentation surgery may require the expertise of a number of different types of surgeons to optimize the results

Not all facial defects or deformities require surgical intervention. A number of different opinions exist among plastics surgeons on what needs or does not need surgery. Most surgeons agree that cosmetic surgery should be performed when the deficit is substantial and the underlying bone structures do not require substantial realignment. Most experienced cosmetic plastic surgeons lean toward prosthetics for most cosmetic deformities of the facial structures. In certain areas of the face deficiencies can be addressed with enhancements of the overlying soft tissue with fat or temporary fillers. Not all facial deficiencies require the same approach or treatment and a detailed discussion with your plastic surgeon regarding the risks and benefits of surgery is important before surgery. A second opinion is always a good idea when making a decision regarding facial augmentation surgery.

ALTERNATIVE TREATMENT

Alternative forms of management consist of not undergoing facial augmentation surgery. Certain types of deficiencies such as chin defects rarely improve without surgery. Other defects of the face or jaw may require more extensive bone enhancement. The risks and potential complications associated with alternative forms of treatment should be discussed with your surgeon.

RISKS OF FACIAL AURGMENTATION SURGERY

With any type of activity there is inherent risk. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not

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experience the following complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of facial fracture surgery.

<u>Bleeding</u> – It is possible, though unusual, that you may have problems with bleeding during or after surgery. Should postoperative bleeding occur, it may require emergency treatment to stop the bleeding or blood transfusion. Do not take any aspirin or anti-inflammatory medications for ten days before surgery. as this contributes to a greater risk of bleeding. Hypertension (high blood pressure) that is not under good medical control may cause bleeding during or after surgery. Accumulations of blood under the skin may delay healing and cause scarring.

<u>Infection</u> – Infection is quite unusual after surgery. Should an infection occur, additional treatment including antibiotics may be necessary. If a metal plate becomes infected it may need to be removed. Exposed implants may need to be removed. If an implant becomes infected it will need to be removed for a period of time. In some cases a new implant may be contraindicated and a staged reconstructive procedure may be required to address resulting deformities. Infection is one of the most devastating complications associated with facial augmentation. Infection rates following cosmetic surgery range between 1-2% and are much higher following facial reconstruction.

<u>Blood clots / deep vein thrombosis</u> – Facial augmentation operations usually require some time in the operating room. Although any operation can be associated with a blood clot in the legs, it is more common following more lengthy operations. It is important to note that birth control pills and other medications can increase your risk of this problem. After surgery patients must make every effort to be active and ambulate while in the hospital and at home. Deep vein thrombosis can be a potentially life threatening complication that may require further medical care and expense.

<u>Fluid collections or Seroma</u> – Fluid collections can form in the period following facial surgery. These collections are called "seromas" and may be prevented by the use of compression dressings or drains. If the patient develops a fluid collection it may require further treatments.

<u>Skin Contour Irregularities</u>- Contour and shape irregularities may occur after facial augmentation surgery. Visible and palpable wrinkling may occur. Residual skin irregularities at the ends of the incisions are always a possibility. This may improve with time, or it can be surgically corrected.

<u>Sutures</u>- Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires removal.

<u>Skin Discoloration / Swelling-</u> Some bruising and swelling normally occurs following breast surgery. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

<u>Scarring</u> – Although good wound healing after a surgical procedure is expected, abnormal scars may occur both within the skin and deeper tissues. Scars may be unattractive and of different color than surrounding skin. There is the possibility of visible marks from sutures. Additional treatments including surgery may be needed to treat scarring.

<u>Damage to deeper structures</u> – Deeper structures such as nerves, tear ducts, blood vessels, and muscles may be damaged from the injury or during the course of surgery. The potential for this to occur varies with the type of facial fracture surgery performed. Injury to deeper structures may be temporary or permanent.

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<u>Hardware and Deeper Sutures</u>- Some surgical techniques use small screws, metal plates, or wire sutures to help stabilize boney structures. These items may be noticed by the patient following surgery. It may be necessary to remove these at a later time.

<u>Unsatisfactory result</u> – There is the possibility of an unsatisfactory result from the facial augmentation surgery. The possibility of is greater if the facial deformity is more extensive or severe. The surgery to correct the deficit may result in unacceptable visible or tactile deformities, loss of function, or structural mal-position. You may be disappointed that the results of facial fracture surgery do not meet your expectations. Additional surgery may be necessary should the result of facial augmentation surgery be unsatisfactory.

<u>Numbness</u> – There is the potential for permanent numbness within the skin after facial augmentation surgery. The occurrence of this is not predictable. Diminished (or loss of skin sensation) sensation of the face, mouth, forehead, or other area may not totally resolve after surgery.

<u>Asymmetry</u> – The human face is normally asymmetrical. There can be a variation from one side to the other in the results obtained from facial augmentation surgery.

<u>Chronic pain</u> – Chronic pain may occur very infrequently after facial augmentation surgery and usually relates to the severity or location of the trauma.

<u>Skin disorders/skin cancer</u> – Facial augmentation surgery is a procedure to restore an acquired deformity of the face via an internal and external approach. Skin disorders and skin cancer may occur independently of facial surgery.

<u>Allergic reactions</u> – In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during pregnancy and prescription medicines. Allergic reactions may require additional treatment.

<u>Delayed healing</u> – Wound disruption or delayed wound healing is possible. Some areas of the face may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue.

<u>Long term effects</u> – Subsequent alterations in facial appearance may occur as the result of aging, sun exposure, or other circumstances not related to facial augmentation surgery. Future surgery or other treatments may be necessary to maintain the results of a facial augmentation operation.

<u>Size and Shape</u> – Dr Lowe cannot guarantee size or shape after facial implant surgery. Dr. Lowe will do his best to get an idea of the size of the implant you desire and to achieve a practical result. The fact is that there are technical restrictions and limits in implant technology that does not necessary allow the patient to always pick the size or shape.

<u>Implants-</u> Facial implants, similar to other medical devices, can fail. When a silicone gel-filled implant ruptures, the gel material is usually contained within the scar tissue surrounding the implant. In some cases, the gel may escape beyond the capsule layer and go into the face tissue itself. Rupture of an implant may or may not produce local firmness in the region. Rupture can occur as a result of an injury, from no apparent cause (silent rupture), or during normal activity. It is possible to damage an implant before, during, or after surgery. Damaged or broken implants cannot be repaired. Ruptured or damaged implants require replacement or removal.

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<u>Capsular Contracture-</u> Scar tissue, which forms internally around the facial implant, can tighten and make the face firm and possibly painful. Excessive firmness of the face can occur soon after surgery or years later. The occurrence of symptomatic capsular contracture is not predictable. The incidence of symptomatic capsular contracture can be expected to increase over time. Capsular contracture may occur on one side, both sides or not at all. It is more common with certain facial implants than with others. Treating capsular contracture may require surgery, implant replacement, or implant removal. Capsular contracture may reoccur after these surgical procedures.

<u>Implant Extrusion / Tissue Necrosis-</u> Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant through the skin. Tissue breakdown (necrosis) has been reported with the use of steroid drugs, after chemotherapy/radiation to breast tissue, due to smoking, microwave diathermy, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. An implant may become visible at the surface of the face as a result of the device pushing through layers of skin. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary. Permanent scar deformity may occur.

<u>Jaw Problems</u> – Patients with jaw deformities may experience a number of problems with or without surgery. Often it is not possible to restore the normal bite or occlusion of the teeth after surgery. However, it is more likely to have a normal bite with certain surgery than without in most cases. Jaw surgery often requires wiring the mouth close that will result in a modification in diet and weight loss. Patients may develop jaw pain, TMJ, or arthritis after jaw surgery that may result in permanent disability or require more surgery. Certain jaw surgery has a higher rate of injection and plate exposure due to the proximity of the injury to the mouth and bacteria there in. Sometimes further operations or dental procedures may be required following jaw reconstruction.

<u>Augmentation of Eye or Cheeks</u> – Facial augmentation around the eye or cheek may result in double vision and deformity depending on the total area of involvement. Surgery around the eye can result in loss of vision, double vision, or deformity. Some patients require an over-night stay in the hospital to observe for complications following repair. Surgery around the eye is associated with chronic swelling and lower eyelid mal-position. Many of these symptoms will resolve in several months to a year. Patients may require further operations or procedures in the future depending on the issue.

<u>Cheek Surgery -</u> Repair of deformities of the cheek often require multiple incisions. These incisions will usually be placed on the forehead, eyelid, and mouth. Cheek deformities are often associated with factures or trauma around the eye. Patients often experience numbness before and after surgery. Augmentation in proximity to the sinus can result in complications such as infection or asymmetry.

<u>Forehead Surgery</u> – Facial augmentation of the skull and forehead often require the expertise of multiple doctors. Fractures in this area may require long scalp or forehead incisions. These deformities can be complicated by chronic drainage of brain fluid or chronic infection. Your surgeon will inform you of your long term risk and benefits of surgery.

<u>Nasal Deformities</u> – Facial deformities are often associated with nasal injury or birth defects. Often the nasal region will require fracture with reduction or splinting depending on the severity of the injury. Injury to the nose may result in long term problems with breathing or deformity. Revision surgery may be required if a problem develops in this area. Some patients will not notice a problem for many years.

<u>Surgical Incisions</u> – Facial augmentation surgery often require multiple incisions. Incisions are usually placed in the mouth, upper and lower eyelid, or forehead. Your surgeon will explain to you where your incisions typically will be placed. It should be noted that incisions may need to be extended to

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adequately place the implants. The rule usually is the more severe the deformity the more likely the incisions will be more noticeable or visible. Many incisions are place inside the mouth.

<u>Surgical anesthesia</u> – Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation. Please discuss the risk of anesthesia with the anesthesiologist performing the procedure.

<u>Shock-</u> In rare circumstances, your surgical procedure can cause trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Cardiac and Pulmonary Complications- Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary and fat emboli can be life-threatening or fatal in some circumstances. Air travel, inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of blood clots or swollen legs that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

ADDITIONAL ADVISORIES

<u>Long-Term Results-</u> Subsequent alterations in facial appearance may occur as the result of aging, weight loss or gain, sun exposure, pregnancy, menopause, or other circumstances not related to nasal injury repair surgery. Future surgery or other treatments may be necessary.

<u>Female Patient Information</u>- It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you believe you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

<u>Intimate Relations After Surgery</u>. Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and control bleeding. It is wise to refrain from sexual activity until your physician states it is safe.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray)-

Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

____I am a non-smoker and do not use nicotine products. I understand the risk of second-hand smoke exposure causing surgical complications.

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____I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

Mental Health Disorders and Elective Surgery- It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

<u>Medications-</u> There are many adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions, and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and splints should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

Most health insurance companies do not cover surgical operations to treat cosmetic facial deformities. Coverage for future reconstructive procedures following facial injury can vary, depending on your health care insurance company's policies. The repair or reconstruction of long term deformity or other problems resulting from facial asymmetry, deformities, or trauma may be denied by your insurance company. **Most insurance plans exclude coverage for secondary or revisionary surgery.** Please carefully review your health insurance subscriber-information pamphlet.

ADDITIONAL SURGERY NECESSARY

There are many variable conditions in addition to risks and potential surgical complications that may influence the long term result from facial augmentation surgery. Even though risks and complications occur infrequently, the risks cited are particularly associated with facial surgery. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. Sometimes it is necessary to perform additional surgery to improve your results.

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FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. In signing the consent for this surgery/procedure, you acknowledge that your have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no surgery. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

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CONSENT FOR SURGERY/PROCEDURE or TREATMENT

	I have received the following information sheet: FACIAL AUGMENTATION SURGERY INFORMATION SHEET AND INFORMED CONSENT
2.	I recognize that during the course of the operations and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I, therefore, authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3.	I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4.	I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5.	I consent to the photographing or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6.	For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7.	I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8.	I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
9.	 IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND: A. The above treatment or procedure to be undertaken. B. There may be alternative procedures or methods of treatment. C. There are risks to the procedure or treatment proposed including those listed on pages of the Informed Consent for Facial Augmentation Surgery information sheet. D. I have read, understood, and have had the opportunity to ask questions concerning the above, as well as the Informed Consent information sheet. E. I am satisfied with the explanation.
I C	CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9).

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Witness

Date