The Office of Dr. Kay Durairaj, MD, FACS

INFORMED CONSENT – KYBELLA (DEOXYCHOLIC ACID) INJECTION

INSTRUCTIONS

This is an informed-consent document which has been prepared to help your plastic surgeon inform you concerning Kybella (deoxycholic acid) injection therapy, its risks, and alternative treatments.

This consent covers injection using:

Kybella (deoxycholic acid), a non-human and non-animal derived version of deoxycholic acid to destroy fat cells in the submental region/ double chin, with or without local anesthesia.

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 this procedure as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

The injection will utilize Kybella® (deoxycholic acid), which has been FDA-approved for the cosmetic treatment of submental fullness (also known as “double chin” or fat under the chin).

Kybella is intended to reduce the fatty bulk of the submental region. In some cases, it has been associated with skin and soft tissue tightening of the neck and submental area, but the primary purpose of Kybella is not to address loose skin.

In FDA studies, Kybella patients were treated using 1-4 vials of product per treatment session, over the course of 1-6 sessions, each spaced out by at least one month. Fat destruction was permanent, although results were variable depending on patient-specific anatomy and other factors.

All medical and cosmetic procedures carry risk and may cause complication, and some uses may be considered “off-label” by the FDA. The purpose of this document is to make me aware of the nature of this procedure and its risks in advance, so that I can decide whether or not to proceed with this or these procedures.

Occasionally, slight swelling and/or bruising may appear and last for several days after the administration. The risk of bruising may be increased in those using substances that reduce blood clotting such as aspirin or other nonsteroidal, anti-inflammatory drugs. Some patients may experience prolonged redness, swelling, hyperpigmentation (dark spots/burns), hypopigmentation (light spots), crusting, tenderness, and rarely pustules can form. Cold sores may become re-activated. In addition, any injection/treatment carries a minimal but potential risk of infection. Although rare, there is also a very minimal risk of injuring a blood vessel, which could result in a scab or scar formation with the possibility of blockage of blood flow and circulation to nearby sites. Resulting fat cells may be palpable, visible, or asymmetric. Furthermore there is risk of: Marginal mandibular nerve (MMN) injury resulting in an asymmetric smile, Dysphagia (difficulty swallowing), Submental hematoma/bruising, edema/swelling, pain, numbness, erythema, induration, paresthesia, nodule, pruritus, skin, tightness, site warmth, headache, oropharyngeal pain, hypertension, alopecia (hair loss at injection site), and/or nausea.

Side-effects may include headaches, twitches, abnormal facial expressions, production of antibodies, or even no effect. Although there are no significant reports of allergy to deoxycholic acid, there is always a remote possibility of forming allergic reactions to injected substances. These medical treatment options should not be used in individuals who had experienced the above hypersensitivity or those with severe allergies to its contents, or by women who might be pregnant or breast-feeding. If I am pregnant, I could be exposed to medications and anesthetics that may cause birth defects or miscarriage. Benefits of these treatments include permanent destruction of fat cell in the area injected. In this case, the area of interest is limited to the submental region (double chin) and neck. However, no guarantee of an effect can be made and multiple treatments are usually required. I hereby voluntarily consent to this treatment and ongoing future treatments several times a year for several years until I rescind my consent.

ALTERNATIVE TREATMENTS

Alternative forms of management include not treating the submental fat or fullness by any means. Improvement of submental fullness may be accomplished by other treatments: submental liposuction, surgical defatting, facelift or necklift surgery, laser or ultrasound treatments, or other thermal or cooling treatments, when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

RISKS OF KYBELLA -INJECTIONS

Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of Kybella® injections. Additional information concerning Kybella may be obtained from the package-insert sheets supplied by Allergan Aesthetics.

Problems associated with the use of Kybella can relate to normal occurrences following injections, or potential complications following injections.

Normal Occurrences During Kybella Injections

Bleeding and Bruising: It is possible, though unusual, to have a bleeding episode from a Kybella injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba and other "herbs / homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before or after Kybella injections.

Swelling: Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

Pain: Discomfort associated with injections is normal and usually of short duration.

Specific Risks of Kybella Injections

Needle Marks: Visible needle marks from the injections occur normally and resolve in a few days.

Acne-Like Skin Eruptions: Acneiform skin eruptions can occur following the injection of tissue Kybella. This generally resolves within a few days.

Skin Sensitivity: Skin rash, itching, tenderness and swelling may occur following injections. After treatment, you should minimize exposure of the treated area to excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. If you are considering laser treatment, chemical skin peeling or any other procedure based on a skin response after Kybella treatment, or you have recently had such treatments and the skin has not healed completely, there is a possible risk of an inflammatory reaction at the implant site.

Erythema (Skin Redness): Erythema in the skin occurs after injections. It can be present for a few days after the procedure.

Infection: Although infection following injection of Kybella is unusual, bacterial, fungal, and viral infections can occur. **Herpes simplex virus** infections around the mouth can occur following facial injection treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Under / Over Correction: The injection of Kybella to reduce submental fullness may not achieve the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of Kybella due to factors attributable to each patient's situation. If under correction occurs, you may be advised to consider additional injections of Kybella.

Asymmetry: The human face is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filer injections. There can be a variation from one side to the other in terms of the response to injection. This may require additional injections.

Damage to Deeper Structures: Deeper structures such as nerves and blood vessels may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent. This can cause difficulty swallowing, asymmetry of the smile, drooling, or difficulty with speech. Most nerve injuries reported have been self-limited and have resolved on their own.

Skin Lumpiness: Lumpiness can occur following the injection of Kybella. This tends to smooth out over time. In some situations, it may persist for long periods of time.

Granulomas: Painful masses in the skin and deeper tissues after a Kybella injection are extremely rare. Should these occur, additional treatments including surgery may be necessary. Kybella should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives).

Migration of Kybella: The Kybella substance may migrate from its original injection site and produce fat degradation in adjacent tissue or other unintended effects.

Skin Necrosis: It is very unusual to experience death of skin and deeper soft tissues after injections. Skin necrosis can produce unacceptable scarring. Should this complication occur, additional treatments, or surgery may be necessary.

Allergic Reactions and Hypersensitivity: As with all biologic products, allergic and systemic anaphylactic reactions may occur. Kybella should not be used in patients with a history of multiple severe allergies, severe allergies manifested by a history of anaphylaxis, or allergies to gram-positive bacterial proteins. Allergic reactions may require additional treatment.

Drug and Local Anesthetic Reactions: There is the possibility that a systemic reaction could occur from either the local anesthetic or epinephrine used for sensory nerve block anesthesia when Kybella injections are performed. This would include the possibility of light-headedness, rapid heartbeat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Antibodies to Kybella: Presence of antibodies to Kybella® may reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to Kybella® is unknown.

Accidental Intra-Arterial Injection: It is extremely rare that during the course of injection, Kybella could be accidentally injected into arterial structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection of Kybella is unknown and not predictable.

Scarring: Kybella should not be used in patients with known susceptibility to keloid formation or hypertrophic scarring. The safety of patients has not been studied.

Unsatisfactory Result: Kybella injections alone may not produce an outcome that meets your expectations for improvement in submental fullness. There is the possibility of a poor or inadequate response from Kybella injection(s). Additional injections may be necessary. Surgical procedures or other treatments may be recommended in additional to additional treatments.

Unknown Risks: The long term effects of Kybella are unknown. The possibility of additional risk factors or complications attributable to the use of Kybella® may be discovered.

Pregnancy and Nursing Mothers: Animal reproduction studies have not been performed to determine if Kybella® could produce fetal harm. It is not known if Kybella® or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive Kybella® treatments.

Drug Interactions: It is not known if Kybella® reacts with other drugs within the body.

Long-Term Effects: Kybella® results in permanent destruction of fat cells in the submental area. Subsequent alterations in the submental area may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to Kybella® injections. Future surgery or other treatments may be necessary. Kybella® injection does not arrest the aging process or produce permanent tightening of the skin.

ADDITIONAL ADVISORIES

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

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.

Sun Exposure – Direct or Tanning Salon: The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

Medications and Herbal Dietary Supplements: There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with clotting and can cause more bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Alleve. It is very important not to stop drugs that interfere with platelets, such as Plavix, which is used after a stent. It is important if you have had a stent and are taking Plavix that you inform the plastic surgeon. Stopping Plavix may result in a heart attack, stroke and even death. 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.

Travel Plans: Any surgery holds the risk of complications that may delay healing and delay your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

ADDITIONAL TREATMENT NECESSARY

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of Kybella® injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Kybella® injections. 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.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for Kybella® injections used to treat medical conditions. Please carefully review your health insurance subscriber information pamphlet.

FINANCIAL RESPONSIBILITIES

The cost of Kybella injection may involve several charges. This includes the professional fee for the injections, follow-up visits to monitor the effectiveness of the treatment, and the cost of the material itself. It is unlikely that Kybella injections to treat cosmetic problems would be covered by your health insurance. 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 injections and will also be your responsibility. **In signing the consent for this surgery/procedure, you acknowledge that you 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). 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 of the facts pertaining to 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.

The Office of Dr. Kay Durairaj, MD, FACS

INFORMED CONSENT – KYBELLA (DEOXYCHOLIC ACID) INJECTION

CONSENT FOR SURGERY/ PROCEDURE or TREATMENT

1. I hereby authorize Dr. Kay Durairaj and such assistants as may be selected to perform the following procedure or treatment: **KYBELLA INJECTION** (with or without local anesthesia) in the submental area. I have received the following information sheet: **INFORMED CONSENT – KYBELLA INJECTION**

2. I recognize that during the course of the procedure 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 understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

5. I consent to be photographed or televised before, during, and after 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 treatment room.

7. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.

8. I understand that the surgeon's fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.

9. I realize that not having the procedure is an option.

10. 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

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-10).
I AM SATISFIED WITH THE EXPLANATION. I READ/UNDERSTAND PAGES 1 - 7 OF THIS CONSENT FORM.

_____	_____	_____
Patient Signature	Patient Printed Name	Patient Date of Birth

Date_____ Witness _____