CONSENT FOR KYBELLA - INJECTABLE FAT REDUCTION

INSTRUCTIONS This is an informed-consent document which has been prepared to help your plastic surgeon inform you concerning fat reduction with an injectable medication, its risks, and alternative treatments. 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 physician.

- **INTRODUCTION**
  - Kybella is a medication that is injected under the skin to disrupt fat cells and reduce the amount of fat in the treated are. The current FDA approved use is for the area under the chin (double chin). Use of Kybella in other areas is considered "off-label" and safety and effectiveness is not known. It may take 1 to 2 months to see the final results and typically 2 to 4 treatments are needed. In some cases, there may be no improvement in the treated area. The results are expected to be long-lasting but depend on other factors such as aging and your individual body weight and composition.
- **ALTERNATIVE TREATMENTS**
  - Alternatives include not performing the treatment at all. Other alternative treatments which vary in sensitivity, effect and duration include nonsurgical fat reduction with heat energy or cold therapy, liposuction, and surgical fat removal.
- **DISCLAIMER OF "OFF-LABEL" USE**
  - Currently, Kybella is approved for use in the fatty tissue under the chin. However, once a product is FDA approved, it may be used in other areas of the face and body as determined by a medical professional. Therefore, Kybella may include off-label use in an effort to give the best result possible.
- **RISKS OF FAT REDUCTION INJECTIONS**
  - Every procedure involves a certain amount of risk, and it is important that you understand the risks involved. 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 complications, you should discuss each of them to make sure you understand the risks, potential complications, and consequences of fat reduction injections.
  - Pain

    Kybella is injected into the skin using a fine needle to reduce injection discomfort. You may choose to anesthetize the treatment area either topically, with a local block or both. Pain and tenderness should be expected AFTER treatment and is usually temporary, resolving in 3 to 7 days Please consult your physician about pain management.

  - Skin Disorders
    - It is common to have a temporary redness, bruising, and swelling following a treatment. This will usually subside after several days to a week. Minimize exposure of treated areas to excessive

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sunlight, UV lamp exposure, and extreme cold weather until any swelling and redness have disappeared. Avoid use of alcohol for the next 24 hours. While very rare, scarring can occur following treatment. Occasionally, treatment may produce nodules under the skin which might be seen or felt by the patient. These typically resolve over time but may require further treatment.

- Bleeding and bruising
  - Pinpoint bleeding is rare, but can occur following treatments. Bruising is common following treatments. Rarely, bruising can last for weeks or months and might even be permanent. Patients using Aspirin, Ibuprofen, Advil, Motrin, Nuprin, Aleve, garlic, Gingko Biloba, Vitamin E, or blood thinners have an increased risk of bleeding or bruising at the injection site.
- Unsatisfactory results
  - There is the possibility of a poor or inadequate response from Kybella injections. There might be an uneven appearance of the treated areas. In most cases this uneven appearance can be corrected by more injections in the same or nearby areas. In some cases, though, this uneven appearance can persist for several weeks or months. 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.
- Allergic reactions
  - Kybella should not be used in individuals with a known previous history of reactions. In rare cases, local allergies to tape, preservatives used in cosmetics or topical preparations have been reported. Systemic reactions (which are more serious) may result from prescription medicines.
- Infection
  - Although infection following Kybella injections is rare, bacterial, fungal, and viral infections can occur. Additional treatments or antibiotics may be needed. Most cases are easily treatable but, in rare cases, permanent scarring in the area can occur.
- Swelling
  - Some swelling (edema) is common after Kybella injection and tends to resolve in a few days. In rare cases, swelling may last a few weeks or months.
- Lumps and tissue irregularities
  - Some lumps or irregularities are possible but usually resolve with time or gentle massage.
- Damage to deeper structures
  - Although extremely unlikely, deeper structures such as nerves, and blood vessels, may be damaged during the course of injection.
- Asymmetry
  - The human body is normally asymmetrical with respect to structural anatomy and function. There can be a variation from one side to the other in terms of the response to Kybella injection.
- Pain
  - Discomfort associated with Kybella injections is common and resolves after a few days.
- Unknown risks
  - The long term effect of this treatment on tissue is unknown. There is the possibility of additional risk factors may be discovered.
- Difficulty Swallowing
  - While extremely rare, you may experience difficulty swallowing that usually resolves within a few days

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- Unsatisfactory result
    - There is the possibility of a poor or inadequate response from Kybella injection. Additional injections may be necessary. Surgical procedures or treatments may be needed to improve results after injection.

- **Long-term effects**

  Subsequent alterations in appearance may occur as the result of aging, weight loss of gain, sun exposure, or other circumstances not related to this treatment. This procedure does not stop the aging process or produce permanent tightening of the skin. Future surgery or other treatments may be necessary.

- **Pregnancy and nursing mothers**

  Animal reproduction studies have not been performed to determine if Kybella injections could produce fetal harm. It is not known if Kybella can be excreted in human milk.

- **Nerve Injury**

  Although rare, nerves around the treatment area may be affected by the injection resulting muscle weakness which can cause asymmetry or difficulty swallowing. This is temporary and not life threatening.

- **HEALTH INSURANCE**

  Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Please carefully review your health insurance subscriber information pamphlet.

- **ADDITIONAL TREATMENT NECESSARY**

  There are many variable conditions in addition to risk and potential complications that may influence the long term result of treatment. 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.

- **FINANCIAL RESPONSIBILITIES**

  The cost of 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 injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from this treatment.

- **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.

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However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your physician may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the 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 KYBELLA - INJECTABLE FAT REDUCTION

1. I hereby authorize Ziad Sara, MD and such assistants as may be selected to perform the following procedure or treatment: Fat Reduction Injection KYBELLA (DEOXYCHOLIC ACID)

   I have received the following information sheet: INFORMED CONSENT for INJECTABLE FAT REDUCTION

2. I recognize that during the course of the treatment, 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 involves 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 treatment room.
7. 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 (1-7). I AM SATISFIED WITH THE EXPLANATION.

_____
Patient Signature

_____
Witness

Date_____