

INFORMED CONSENT FOR
INJECTABLE FAT REDUCTION

KYBELLA (DEOXYCHOLIC ACID)

(PLEASE REVIEW AND BRING WITH YOU ON THE DAY OF YOUR PROCEDURE)

PATIENT NAME _____



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INSTRUCTIONS

This is an informed-consent document which has been prepared to help your plastic surgeon(s) 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 plastic surgeon(s).

INTRODUCTION

Kybella is a medication that is injected under the skin to disrupt fat cells and reduce the amount of fat in the treated area. 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 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.

Hair loss in treatment area – It is possible that there may be hair loss in the area that is treated with **Kybella**. The hair may return after a few months, but it is possible that the hair loss may be permanent.

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.

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 or 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.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon(s) 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.

CONSENT FOR SURGERY/ PROCEDURE or TREATMENT

1. I hereby authorize Dr. Karol Gutowski and /or Dr. Julia Kerolus 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 operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician(s) 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(s) 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 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

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9).
I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____

AUTHORIZATION & CONSENT FOR RELEASE OF MEDICAL IMAGES

It is important that you read this information carefully and completely. After reviewing, please sign the consent as proposed by Dr. Gutowski and/or Dr. Kerolus or their representatives.

INTRODUCTION

Medical images (photographs, slides, videos, interviews or any other images of you, or components of your medical record) may be taken before, during, or after a surgical procedure or treatment. These images may be needed to document your medical condition, used as supporting material for authorizing medical coverage and payments, and treatment planning. Consent is required to take, use and release such images. Since Drs. Gutowski and Kerolus are also educators of other physicians, researchers, and medical writers, your images may be used for other purposes as described below.

1. CONSENT TO TAKE PHOTOGRAPHS, SLIDES, DIGITAL IMAGES, AND VIDEOTAPES

I hereby authorize Dr. Gutowski or Dr. Kerolus and/or their associates to take any images before, during and after my treatments or surgeries.

2. CONSENT FOR RELEASE OF PHOTOGRAPHS/SLIDES/VIDEOTAPES

I hereby authorize Dr. Gutowski and/or Dr. Kerolus and their associates to use any of these images for professional medical purposes deemed appropriate including but not limited to showing these images on public or commercial television, electronic digital networks including the internet, print or visual or broadcast media, for purposes of examination, testing, credentialing and/or certifying purposes for purposes of medical education, patient education, lay publication, or during lectures to medical or lay groups, for marketing and advertising, and for use in supporting documentation for insurance or third-party payer purposes, medical teaching, research or dissemination of medical information to medical and nonmedical audiences, including, but not limited to, journal or book publications, presentations, conferences, and print marketing material (magazine, newspaper, etc) or electronic media (television, internet, etc).

3. CONSENT FOR RELEASE TO PROFESSIONAL ORGANIZATIONS

I further authorize Dr. Gutowski and/or Dr. Kerolus and their associated to release such images to the American Society of Plastic Surgeons (ASPS), the American Society for Aesthetic Plastic Surgery (ASAPS), the American Board of Plastic Surgery (ABPS), the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS), and the American Board of Facial Plastic and Reconstructive Surgery (ABFPRS). I provide this authorization as a voluntary contribution in the interests of public education. The images may be used for publication in print, visual or electronic media, specifically including, but not limited to, medical journals (such as *Plastic and Reconstructive Surgery*, *Annals of Plastic Surgery*, *Aesthetic Plastic Surgery*), textbooks, lay publications, patient education or during lectures for the purpose of informing the medical profession or the general public about plastic surgery methods, medical education or examination material by ASPS, ASAPS, ABPS, AAFPRS and ABFPRS. I understand that such images shall become the property of ASPS, ASAPS, ABPS, AAFPRS and ABFPRS and may be retained or released by these organizations for the limited purpose mentioned above. I also grant permission for the use of any of my medical records including illustrations, photographs, video or other imaging records created in my case, for use in examination, certifying and/or re-certifying purposes by ABPS and ABFPRS.

I understand that I will not be identified by name in any release of these materials but in some cases the images may contain features that may make my identity recognizable. I release and discharge Dr. Gutowski and/or Dr. Kerolus and all parties acting on their authority from all rights that I may have in these images, and from any claims that I have related their use in the above mentioned manner.

I also release Dr. Gutowski and/or Dr. Kerolus and any employees or agents from all liability, including any claims of libel or invasion or privacy, directly or indirectly connected with, arising out of or resulting from the taking and authorized use of these images or recorded interviews. I understand that I have the right to request cessation of recording or filming at any time.

I understand that I will not be entitled to monetary payment or any other consideration as a result of any use of these images and /or my interview.

Patient Name _____

Patient Signature _____ Date _____

Witness or Guardian/Parent _____ Date _____