KYBELLA® CONSENT FORM

HINGHAM MEDICAL AESTHETICS

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INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about KYBELLA® injections, its risks, as well as alternative treatment(s).

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 as proposed by your provider and agreed upon by you.

GENERAL INFORMATION

This injection will utilize a deoxycholic acid to improve the appearance of moderate to severe convexity or fullness associated with submental fat in adults. Deoxycholic acid has been FDA approved for the cosmetic treatment of moderate to severe fullness in the area under the chin.

Injections are customized for every patient, depending on his or her particular needs. They are not designed to stop the process of aging. They can, however, temporarily diminish the look of fullness in the area under the chin.

These injections may be performed as a singular procedure, in combination with other treatments such as botulism toxins, or as an adjunct to a surgical procedure.

Multiple treatments may be necessary in order to produce the desired effect of deoxycholic injections.

ALTERNATIVE TREATMENTS

Alternative forms of management include not treating the "double chin" by any means. Improvement of an excessive deposit of fat under the chin may be accomplished by other treatments: submental liposuction, submental liposuction, platysma plication, and facelift. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

INHERENT RISKS OF DEOXYCHOLIC ACID 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 with your physician to make sure you understand the risks, potential complications, limitations, and consequences of deoxycholic acid injections. Additional information may be obtained from the package-insert sheets supplied by the manufacturers.

SPECIFIC RISKS OF OF DEOXYCHOLIC 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. Injury to the blood supply and 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 filler 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. Pain and tenderness are expected after treatment and should not last longer than 7 days. Please consult your physician about pain management.

NUMBNESS:

Numbness around the injection area may occur. This is temporary and should revolve within a few days.

DYSPHAGIA:

On rare occasions, difficulty swallowing may occur. Cases of dysphagia should resolve within 1-81 days.

FACIAL NERVE DAMAGE:

Although rare, nerves around the treatment area may be affected by the injection, resulting in muscle weakness. Nerve injuries should resolve within a few days but may take up to 1 year to improve.

SKIN HARDNESS IN TREATMENT AREA:

Rarely, skin hardness may occur in the treatment area. This is temporary and should resolve within a few days.

DESTRUCTION OF SKIN CELLS IF INJECTED INTO SKIN:

KYBELLA® can destroy skin cells, if inadvertently injected into the skin.

NEEDLE MARKS:

Visible needle marks from the injections occur normally and resolve in 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.

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 KYBELLA® injection is unusual, bacterial, fungal, and viral infections can occur. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

ASYMMETRY:

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

SKIN NECROSIS:

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

ALLERGIC REACTIONS AND HYPERSENSITIVITY:

Allergic and systemic anaphylactic reactions may occur. Deoxycholic acid injections 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. Severe allergic reaction is rare but may occur. Allergic reactions may require additional treatment.

UNSATISFACTORY RESULT:

KYBELLA® injections alone may not produce an outcome that meets your expectations for improvement in treatment of under chin fullness. There is the possibility of a poor or inadequate response to the injection(s). Additional injections may be necessary. Surgical procedures or other treatments may be recommended along with additional treatments. Unsatisfactory results may NOT improve with each additional treatment.

UNKNOWN RISKS:

The long-term effect of deoxycholic acid is 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 deoxycholic acid could produce fetal harm. Risk of major birth defects and miscarriage is unknown. 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 deoxycholic acid injection treatments.

DRUG INTERACTIONS:

It is not known if deoxycholic acid reacts with other drugs within the body.

LONG-TERM EFFECTS:

Deoxycholic acid injections should not be considered as a permanent treatment for the correction of submental fullness. Subsequent alterations in face appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to KYBELLA® injections. Deoxycholic acid injection does not arrest the aging process. Future surgery or other treatments may be necessary.

ADDITIONAL TREATMENT NECESSARY:

There are many variable conditions in addition to risks and potential complications that may influence the long-term result of deoxycholic acid 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 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.

ADDITIONAL ADVISORIES

DRUG REACTIONS:

Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important for you to inform your physician of any problems you have had with any medication or allergies to medication, prescribed or over the counter, as well as medications you now regularly take. Provide your provider with a list of medications and supplements you are currently taking.

UNSATISFACTORY RESULT:

Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. The more realistic your expectations as to results, the better your results will appear to you. Some patients never achieve their desired goals or results, at no fault of the provider. You may be disappointed with the results of treatment. It may be necessary to perform additional treatments to improve your results. Unsatisfactory results may NOT improve with each additional treatment.

IMPORTANT COMMITMENTS/TRAVEL PLANS:

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

LONG - TERM RESULTS:

Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your procedure.

PREGNANCY AND BREAST FEEDING:

Treatment should not be performed during pregnancy. Let your provider know if you are, recently were, or plan to become pregnant.

FEMALE PATIENT INFORMATION:

It is important to inform your provider 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 PROCEDURES:

It is important that all patients seeking to undergo elective procedures have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional procedures and often are stressful.

Please openly discuss with your provider, prior to treatment, 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 procedures, effects on mental health cannot be accurately predicted.

OFF - LABEL FDA ISSUES:

There are many devices, medications and injectable fillers and botulinum toxins that are approved for specific use by the FDA, but this proposed use is "Off-Label", that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your provider believes it to be safe and effective.

PATIENT COMPLIANCE:

Follow all provider instructions carefully; this is essential for the success of your outcome. Personal and vocational activity needs to be restricted. It is important that you participate in follow-up care, return for aftercare, and promote your recovery.

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 a decision not to proceed with treatment. This document is based on a thorough evaluation of scientific literature and relevant clinical practices to describe a range of generally acceptable risks and alternative forms of management of a particular disease or condition. 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 provider 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.

AUTHORIZATION (S):

_____ (Patient Initials) I acknowledge that I have been informed about the Off-Label FDA status of KYBELLA® and I understand it is not experimental and accept its use.

_____ (Patient Initials) For women: I confirm that I am not pregnant or breastfeeding and do not intend to become pregnant anytime during the course of treatment.

_____ (Patient Initials) Before and after treatment instructions have been discussed with me. The procedure, potential benefits and risks, and alternative treatment options have been explained to my satisfaction.

_____ (Patient Initials) I understand that my treatment is purely elective, that the results may vary with each individual, and multiple treatments may be necessary.

_____ (Patient Initials) I have read and understand all information presented to me before consenting to treatment.

_____ (Patient Initials) I have had all my questions answered. I freely consent to the proposed treatment.

I, _____ hereby authorize _____ to perform KYBELLA® injection on me. I understand that I am a patient of Hingham Medical Aesthetics, a medical practice led by a Harvard-trained Board Certified Plastic Surgeon with over two decades or medical aesthetic experienced, and that my licensed provider is an employee of the practice.

_____

PATIENT SIGNATURE DATE TIME

and/or

_____

RESPONSIBLE RELATIVE OR GUARDIAN RELATIONSHIP

_____

PROVIDER'S NAME PROVIDER'S SIGNATURE