



# CANADIAN PLASTIC SURGERY CENTRE

## **Informed Consent** **Kybella® - Deoxycholic Acid Injection**



AMERICAN SOCIETY OF  
PLASTIC SURGEONS®

## **INSTRUCTIONS**

This is an informed consent document that has been prepared to help inform you about deoxycholic acid injection therapy, its risks, and alternative treatments.

This consent covers injection using:

\_\_\_ **Kybella®** - Deoxycholic acid is a man-made substance that assists with fat absorption. It destroys fat cells when injected into the body.

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 form for this procedure as proposed by your plastic surgeon 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 cosmetic treatment of moderate to severe fullness in the area under the chin.

Injections are customized to each 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 should be based on a comparison between the risks and the potential benefits. 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 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 of varying intensities are expected after treatment, and should not last longer than 7 days. Please consult your physician regarding pain management.

If you are a chronic pain patient followed by a pain therapy practitioner, you may be asked to see this practitioner preoperatively to assist you in the management of your pain disorder in the postoperative period. Chronic pain may occur very infrequently because of nerves becoming trapped in scar tissue or because of tissue stretching. There are nerve endings that may become involved with healing scars from surgery. While there may not be a major nerve injury, the small nerve endings may become too active during the healing period, producing a painful or oversensitive area due to the small sensory nerves involved with scar tissue. Often, massage and early nonsurgical intervention resolve this. It is important to discuss postsurgical pain with your surgeon.

**Numbness:**

Numbness around the injection area may occur. This is temporary and should resolve 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:**

On rare occasions, 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 normally occur and resolve 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 conditions 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, hospitalization, or additional surgery may be necessary. It is important to tell your surgeon of any other infections, such as a history of methicillin-resistant Staphylococcus aureus (MRSA) infections, an open wound, ingrown toenail, insect bite, tooth abscess, or urinary tract infection. Infections in other parts of the body may lead to an infection in the operated area. Postoperative infections often result in more extensive scarring and predispose to revision surgery.

**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 variation between one side of the face to the other in terms of response to injection. This may require additional injections.

**Skin Necrosis:**

It is very unusual to experience loss of skin and deeper soft tissues after Kybella® 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 reactions are rare but may occur. Serious systemic reactions including shock (anaphylaxis) may occur in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment. It is important to notify your physician of any previous allergic reactions.

**Unsatisfactory Result:**

Kybella® injections alone may not produce an outcome that meets your expectations for improvement in treatment of under chin fullness. There is a possibility of a poor or inadequate response to the injection(s). Additional injections may be necessary. The more realistic your expectations are, the better your results will appear to you. Some patients never achieve their desired goals or results, at no fault of the surgeon or surgery. You may be disappointed with the results of treatment. 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 effects of deoxycholic acid 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 yet 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 facial appearance may occur as a 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, regarding the results that may be obtained.

## **GENERAL RISKS OF SURGERY/PROCEDURES**

### **Scarring:**

All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, this surgery will result in long, prominent scars that are permanent. Abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color from the surrounding skin. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is a possibility of visible marks in the skin from sutures. These scars may become raised, red, or discolored in the first few weeks/months, but usually settle down over time. However, some patients are prone to “hypertrophic” or “keloid” scars, which are prominent, raised, red scars that do not settle. Further treatments with medications and/or surgery may be required.

### **Firmness:**

Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may be necessary.

### **Damage to Deeper Structures:**

There is the potential for injury to deeper structures including nerves, blood vessels, lymphatics, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

### **Fat Necrosis:**

Fatty tissue found deep in the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is a possibility of contour irregularities in the skin that may result from fat necrosis.

### **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 surgeon with a list of medications and supplements you are currently taking.

### **Travel Plans:**

Any procedure holds a risk of complications that may delay healing and 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 the procedure can be timed accordingly. There are no guarantees that you will be able to resume all activities in the desired timeframe.

### **Future Pregnancy and Breastfeeding:**

This procedure is not known to interfere with pregnancy

### **Female Patient Information:**

It is important to inform your plastic surgeon if you use birth control pills or estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, meaning there may be a risk of unplanned 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 are often 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.

**ADDITIONAL SURGERY NECESSARY (Re-Operations):**

There are many variable conditions that may influence the long-term result of surgery. It is unknown how your tissue may respond or how wounds will heal after surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of body structures. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are associated with this surgery. Other complications and risks can occur but are less common. 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, regarding the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon will discuss the options available should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology, and lab testing.

**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 that 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**

## CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. Quinton Chivers and such assistants as may be selected to perform **Kybella® - Deoxycholic Acid Injection**.

I have received the following information sheet: **Kybella® - Deoxycholic Acid 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 procedures that are in the exercise of his or her professional judgment and deemed 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 understand there are no warranties or guarantees, implied or specific regarding my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All 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 being 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 procedure room.
7. I authorize the release of my Ontario Health Insurance Plan number to appropriate agencies for legal reporting and medical-device registration, if applicable.
8. I understand that the surgeons' 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. I opt out of having this procedure \_\_\_\_\_.
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.

\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

Date/Time \_\_\_\_\_ Witness \_\_\_\_\_