CANADIAN PLASTIC SURGERY CENTRE

Informed Consent

Hyaluronic Acid Filler Injection

AMERICAN SOCIETY OF PLASTIC SURGEONS®

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you about hyaluronic acid-based (non-animal stabilized) tissue filler injection therapy, its risks, and alternative treatments. Hyaluronic acid is a naturally occurring sugar that is found in all mammals. It is a material that is contained in various soft tissues. Unlike other fillers, hyaluronic acid fillers may be undone by injecting an enzyme to dissolve them into the body.

This consent form covers injection using:

___**Hylaform®** - Hyaluronic acid is a naturally occurring sugar that is found in all mammals. It is a material contained in various soft tissues. Hyaluronic acid can be synthetically produced from animal tissues, chemically stabilized, and purified for use as an injectable soft tissue filler (animal-origin, stabilized hyaluronic acid, INAMED). Hylaform® has been FDA approved to treat areas of facial wrinkling and soft tissue depressions.

___**Juvederm™ & Voluma Products®** - Juvederm™ Ultra/Ultra Plus/Voluma® injectable gel is a colorless hyaluronic acid gel that is injected into facial tissue to smooth wrinkles and folds, usually around the nose and mouth. Hyaluronic acid is a naturally occurring sugar found in the human body. The role of hyaluronic acid in the skin is to deliver nutrients, hydrate the skin by holding in water, and to act as a cushioning agent.

___**Restylane Products®** - Restylane®, Restylane Silk®, Restylane Lyft® is a naturally occurring substance that is found in all mammals. It is a material that is found in various soft tissues. Restylane® can be synthetically produced through a process of bacterial fermentation, chemical stabilization, and purification for use as an injectable soft tissue filler (non-animal, stabilized hyaluronic acid, Medicis Aesthetics). The hyaluronic acid in Restylane® is biocompatible and is a non-animal product; there is little risk of animal-based disease transmission or allergic reactions. Restylane® has been FDA approved for cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions.

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

The injection will utilize a stabilized hyaluronic acid used to smooth moderate to severe facial wrinkles and folds around the nose and mouth or shape facial contours. Hyaluronic acid has been FDA approved for the cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions.

Filler injections are customized to each patient, depending on his or her particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips. Fillers cannot stop the process of aging. They can, however, temporarily diminish the look of wrinkles and soft tissue depressions.

Filler injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. Filler injections require regional nerve blocks or local anesthetic injections to diminish discomfort. Soft tissue fillers produce temporary swelling, redness, and needle marks, which resolve after a few days.

Continuing treatment is necessary in order to maintain the effect of fillers over time. Once injected, fillers will be slowly absorbed by the body. The length of the effect of injections is variable.

ALTERNATIVE TREATMENTS

Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished using other treatments: laser treatment, chemical skin-peels, dermabrasion, or other skin procedures, alternative types of tissue fillers, or surgery such as a blepharoplasty, face, or brow lift when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

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

SPECIFIC RISKS OF HYALURONIC ACID FILLER INJECTIONS

Bleeding and Bruising:
It is possible, though unusual, to have a bleeding episode from a filler 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:
You may experience pain after your procedure. Pain of varying intensity and duration may occur and persist after procedure. Discomfort associated with injections is normal and usually of short duration. 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.

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

Acne-like Skin Eruptions:
Acneiform skin eruptions can occur following the injection of tissue fillers. These generally 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. If you are considering laser treatment, chemical skin peeling, or any other procedure based on a skin response after filler 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. Damage to the skin or lips may occur.

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

Vision Abnormalities:
Vision abnormalities, including blindness, may occur in rare instances.

Infection:

Patient Initials _____

Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth can occur following a tissue filler treatment. This applies to both individuals with a history of herpes simplex virus infections and individuals with no known history of herpes simplex virus infections in the mouth area.

_____I have a history of cold sores (please notify your physician)
Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Infection, although uncommon, can occur after surgery. Should an 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.

Stroke:
In rare cases, dermal fillers can block oxygen supply to the brain, resulting in a stroke.

Under/Over Correction:
The injection of soft tissue fillers to correct wrinkles and soft tissue contour deficiencies 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 tissue fillers due to factors attributable to each patient's situation. If under correction occurs, you may be advised to consider additional injections of tissue filler materials.

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 filler injections. There can be a variation from one side to the other in terms of response to the injection. This may require additional injections.

Damage to Deeper Structures:
Deeper structures such as nerves and blood vessels, lymphatics, and muscles may be injured 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.

Skin Lumpiness:
Lumpiness can occur following the injection of fillers. This tends to smooth out over time. In some situations, it may be possible to feel the injected tissue filler material for long periods of time.

Visible Tissue Filler Material:
It may be possible to see any type of tissue filler material that was injected in areas where the skin is thin.

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

Migration of Filler:
The filler substance may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

Leakage or Rupture of the Filler Material:
In rare cases, leakage or rupture of the filler material at the injection site or through the skin may occur, which may be caused by a tissue reaction or infection.

Patient Initials _____

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.

Open or Draining Wounds:
Rarely, the filler substance may cause an infection (biofilm formation) or possible necrosis of the area from blood-vessel occlusion, resulting in decreased blood flow to the affected area, which can result in poor healing.

Allergic Reactions and Hypersensitivity:
As with all biologic products, allergic and systemic anaphylactic reactions may occur. Fillers 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. Allergic reactions may require additional treatment.

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

Antibodies to Fillers:
The presence of antibodies to hyaluronic acid tissue fillers may reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to hyaluronic acid tissue fillers is unknown.

Accidental Intra-arterial Injection:
In extremely rare cases, during injection fillers may accidentally be injected into arterial structures, producing 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 fillers is unknown and not predictable.

Scarring:
Procedures can leave scars, some more visible than others. Although good wound healing after a surgical procedure is expected, 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. Fillers should not be used in patients with known susceptibility to keloid formation or hypertrophic scarring. The safety of patients with respect to scarring has not yet been studied. Further treatments with medications and/or surgery may be required.

Unsatisfactory Result:
Filler injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is a possibility of a poor or inadequate response from filler 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 effects of hyaluronic acid filler beyond one year are unknown. The possibility of additional risk factors or complications attributable to the use of hyaluronic acid filler as a soft tissue filler may be discovered.

Patient Initials _____

Combination of Procedures:
The safe use of tissue fillers with Botox or other dermal therapies has not been evaluated in a controlled, clinical study.

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

Drug Interactions:
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.

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

Long-term Effects:
Hyaluronic acid filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the hyaluronic acid filler material is slowly absorbed by the body, and wrinkles or soft tissue depressions will reappear. Continuing hyaluronic acid filler treatment (injections) is necessary in order to maintain the effect of hyaluronic acid filler. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to hyaluronic acid filler injections. Future surgery or other treatments may be necessary. Hyaluronic acid filler injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

Additional Treatment Necessary:
There are many variable conditions in addition to risks and potential complications that may influence the long-term result of filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are specifically associated with hyaluronic acid filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatment 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 WARNINGS:
Dermal Fillers should NOT be Used if Any of the Following Apply:

- Skin is infected or inflamed. Soft tissue filler injection should be delayed until the inflammatory condition has been managed.
- Skin is prone to excessive scarring (keloids) and/or thick scarring (hypertrophic scars).
- Bleeding disorder is known.
- History of severe allergies or anaphylaxis is known.
- Allergy to collagen or eggs is known.
- Allergy to animal product is known.
- Allergy to lidocaine is known.
- Allergy to bacteria is known.

Although these fillers may be removed through surgery or by injection of a medication to "dissolve" the hyaluronic acid filler, the same adverse events typically associated with surgery may occur. It may be difficult to remove the filler material.

The safe use of tissue fillers repeatedly over a long period has not been evaluated in a controlled, clinical study.

The safety of these products is unknown when used during pregnancy, while breast-feeding, or in patients under 18 years of age.

Patient Initials _____

GENERAL RISKS OF SURGERY/PROCEDURES

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.

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.

Allergic Reactions:
In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations, or injected agents have been reported. 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:
Although good results are expected, there is no guarantee or warranty expressed or implied, regarding the results that may be obtained. 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. It may be necessary to perform additional treatments to improve your results. Unsatisfactory results may NOT improve with each additional treatment.

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.

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.

Patient Initials _____

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

Patient Initials _____

CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. Quinton Chivers and such assistants as may be selected to perform **Hyaluronic Acid Filler Injection.**

   I have received the following information sheet: **Hyaluronic Acid Filler 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 _____

Patient Initials _____