



Instructions

This is an informed-consent document which has been prepared to help inform you concerning PCG Tissue Filler injection therapy, 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.

Introduction

Collagen is a naturally occurring substance that is found within all mammals. Porcine collagen gel is synthetically produced by a process linking strands of collagen with ribose, a sugar molecule. It is purified and packaged for use as a tissue filler.

PCG tissue filler has been approved to treat areas of moderate to deep facial wrinkles such as nasolabial folds.

PCG tissue filler injections are customized for every patient, depending on their particular needs. These can be performed in areas involving the face. PCG tissue filler cannot stop the process of aging. It can however, temporarily diminish the appearance of wrinkles and soft tissue depressions. PCG Tissue Filler injections may be performed as a singular procedure, in combination with other treatments such as neurotoxins, or as an adjunct to a surgical procedure. PCG tissue injections require regional nerve blocks or topical anesthetic to diminish discomfort. Soft tissue fillers produce temporary swelling, redness, and needle marks, which resolve after a few days time.

Continuing treatments are necessary in order to maintain the effect of tissue fillers over time. PCG tissue filler once injected will be slowly absorbed by the body. The length of effect for tissue filler 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 by other treatments: laser treatments, chemical skin-peels, other skin procedures, or dermabrasion, 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.

Risks Of Pcg Tissue Filler Injections

Every procedure to inject soft tissue filler materials 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, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of PCG tissue filler injections. Additional information may be obtained from the package-insert sheets supplied by the manufacturer.

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve PCG tissue filler.

Normal occurrences during tissue filler injections, including PCG Tissue Filler

Patients undergoing injections of PCG tissue filler may normally experience the following events:

Bleeding and Bruising - It is possible, though unusual, to have a bleeding episode from an injection or local anesthesia used during the procedure. 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, Ginko 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 injections. Bleeding and bruising can produce permanent tissue color changes.

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.

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

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

Acne-like skin eruptions - Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.

Skin Lumpiness - Lumpiness can occur following the injection of PCG tissue filler. 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.

Asymmetry - The human face and eyelid region 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 the response to PCG tissue filler injection. This may require additional injections to improve your outcome.

Pain - Discomfort associated with tissue filler injections is normal and usually of a short duration. It is possible to have a fainting episode (vasovagal) from discomfort or anxiety about the injections.

Complications (adverse events)

Potential complications attributable to the injection of soft tissue fillers, including PCG tissue filler:

Infection - 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 past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Damage to deeper structures - Deeper structures such as nerves, blood vessels, and the soft tissues may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

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.

Skin Necrosis - It is very unusual to experience death of skin and deeper soft tissues after PCG tissue filler injections. Skin necrosis can produce unacceptable scarring. Should this rare complication occur, additional treatments, or surgery may be necessary.

Granulomas - Painful masses in the skin and deeper tissues after a tissue filler injection are extremely rare. Should these occur, additional treatments including antibiotics or surgery may be necessary. Granulomas may produce scarring within the skin and deeper structures.

Allergic Reactions and Hypersensitivity - Individuals with a dietary allergy to pork and pork-derived products should not undergo PCG injections. It is unknown if PCG tissue filler is associated with serious systemic anaphylactic allergic reactions. Allergic reactions may require additional treatment.

Antibodies to PCG TISSUE FILLER - Presence of antibodies to tissue fillers may in theory reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to tissue fillers is unknown.

Accidental Intraarterial injection - It is extremely rare that during the course of injection, that tissue filler could be accidentally injected into arterial structures and produce 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 is unknown and not predictable.

Under/Over Correction - The injection of soft tissue fillers to correct wrinkles and soft tissue contour deficiencies may not produce 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. Over correction with PCG may require removal of tissue filler material.

Additional Advisories

Advisories for patients considering non-permanent tissue filler injections:

Off-label usage of PCG - PCG is labeled for specific use approved to treat areas of moderate to deep facial wrinkles such as nasolabial folds. The use of PCG for other conditions and disorders would be considered "off-label" usage by your physician. FDA defines off label use as, "Use for indication, dosage form, dose regimen, population or other use parameter not mentioned in the approved labeling." The FDA recognizes that off label use of drugs by prescribers is often appropriate and may receive endorsement from published literature. PCG may be used according to a physician's practice to treat other conditions.

Unsatisfactory Result - PCG tissue filler injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response. Additional injections may be necessary. Surgical procedures or other treatments may be recommended in addition to tissue filler treatments.

Unknown Risks - There is the possibility that additional risks and complications attributable to the use of tissue fillers may be discovered.

Migration of Tissue Filler - Product may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

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

Combination of Procedures - In some situations, neurotoxin injections or other types of tissue filler materials may be used in addition to PCG tissue filler in order to specifically treat areas of the face or to enhance the outcome from tissue filler therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with tissue fillers is unknown. The effect of PCG tissue filler injections into tissue that has been formerly treated with other types of temporary or permanent tissue fillers is unknown.

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

Drug Interactions - It is not known if PCG tissue filler reacts with other drugs within the body.

Long-Term Effects - PCG tissue filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the PCG tissue filler material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing PCG tissue filler treatment (injections) are necessary in order to maintain the effect. 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 tissue filler injections. Future surgery or other treatments may be necessary. Tissue filler injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

Health Insurance

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for tissue filler injections used to treat medical conditions. 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 PCG tissue filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with PCG tissue filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. You are advised to seek medical care should complications or adverse events occur after tissue filler treatments. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained with the use of PCG tissue filler injections. The practice of medicine and surgery is not an exact science.

Financial Responsibilities

This treatment provides a defined amount of PCG tissue filler for the treatment of wrinkles and other conditions. If additional interim injections of PCG tissue filler are needed in order to maintain or improve results, you will be responsible for these costs in addition to the cost of this treatment session. It is unlikely that tissue filler 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 PCG tissue filler injections. You would also be responsible for additional forms of treatments or surgery recommended to improve the appearance of facial wrinkles and soft tissue depressions.

In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

Disclaimer

Informed-consent documents are used to communicate information about the proposed 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 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.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. Cabbabe and such assistants as have been selected to perform the following procedure or treatment:

_____PORCINE COLLAGEN GEL TISSUE FILLER INJECTIONS:_____

I have received the following information sheet:
INFORMED-CONSENT for PCG TISSUE FILLER Injection

2. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
3. I consent to the administration of local anesthesia (regional nerve blocks , direct infiltration, or topical) to diminish discomfort of injection.
4. 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.
5. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
6. 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
 - d. THAT I ACCEPT RESPONSIBILITY FOR THE CLINICAL DECISIONS MADE ALONG WITH THE FINANCIAL COSTS OF ALL FUTURE TREATMENTS TO REVISE, OPTIMIZE OR IMPROVE OUTCOMES.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-6). I AM SATISFIED WITH THE EXPLANATION THAT I HAVE RECEIVED BEFORE DECIDING TO UNDERGO THE TREATMENT OR PROCEDURE. I ACCEPT RESPONSIBILITY FOR THE RISKS, CONSEQUENCES, AND BENEFITS OF THIS DECISION.

Patient or Person Authorized to Sign for Patient _____

Date _____

Witness _____