Informed Consent

Hyaluronic Acid Filler Injection

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INSTRUCTIONS

This is an informed consent document to help you learn about hyaluronic acid-based (non-animal stabilized) tissue filler injections. It will outline the risks and alternative treatments.

This consent form covers injections using _____ hyaluronic acid-based product(s).

It is important that you read the whole document carefully. Please initial each page. Doing so means you have read the page. Signing the consent agreement means that you agree to the surgery that you have talked about with your plastic surgeon.

GENERAL INFORMATION

Hyaluronic acid is a natural sugar found in your body's soft tissues. Several filler products are made using different types of hyaluronic acids. This means that each product is unique. These fillers are used to add volume to soft tissues in areas where you might have a physical issue or where you simply might not like how it looks. They can also be used to smooth out moderate or bad wrinkles. It's possible to undo the effects of hyaluronic acid fillers by injecting an enzyme that dissolves them. Fillers cannot stop you from aging. They can only make your wrinkles smoother or make any dents look less noticeable for a short time.

Hyaluronic acid filler injections aren't permanent. Over time, your body will slowly absorb the filler material. This means your wrinkles or dents will come back. You must get more treatments or injections to keep seeing results. You may also notice changes in the way your face or eyelids look. This may have nothing to do with the hyaluronic acid injections. These can be caused by aging, weight loss or gain, sun exposure, or other things. To get the results you want, you may need other treatments, including surgery, in the future.

Using soft tissue fillers may cause swelling, redness, acne-like marks, and needle marks. These go away after a few days. Because of this, you may not want to get filler injections right before a big event.

OTHER TREATMENTS

There are other options for treating wrinkles or dents. You may also choose not to have any treatment at all. You can go in for other options like laser treatment, chemical skin peels, skin-resurfacing, or other skin procedures. You can also use other types of tissue fillers. Some people may choose to have surgery to remove or move tissues. Every treatment has its own risks and potential problems.

RISKS OF HYALURONIC ACID FILLER INJECTIONS

Every procedure has risks. It is important that you understand the risks and the possible problems that can result from them. All procedures have limits. Choosing to have this procedure means comparing the risks and benefits. Most patients do not face the issues you'll learn about, but you must talk about them with your plastic surgeon. Make sure you understand the risks and possible outcomes of hyaluronic acid filler injections. You can get more information from the package-insert sheets supplied by the manufacturers of these products.

Filler injections may affect your skin in ways you do not like. Talk to your provider about everything you have planned that might affect your skin. This can include many things, from other treatments you want to have like lasers and peels to exercise, using a sauna or hot tub, and even facing weather conditions like extreme heat, cold, or sun.

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SPECIFIC RISKS OF HYALURONIC ACID FILLER INJECTIONS

Bleeding and Bruising:

You may see bruising or bleeding after your treatment. The person who does your injection will try to keep this from happening, but it's still a normal side effect. That's because there are a lot of blood vessels in your face and everyone's face is a little different. If you see bruising or bleeding, there are several things your doctor might suggest treating it. You might be told to wait to see if it goes away or use certain creams or medications. You may even need surgery if the problem is very bad. Certain medications and supplements tend to cause bruising or bleeding. It's very important to tell your doctor if you're taking aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, vitamin E, ginkgo biloba, or any other herbs, supplements, or homeopathic remedies. These could be prescription or over the counter.

Scars:

If you have a history of developing excessive or thick scars (keloid or hypertrophic scars), you should not use fillers. No studies have shown whether it's safe for patients with this kind of scarring to get filler treatments.

Skin Sensitivity and Allergies:

It's normal to have some skin redness, rash, itching, tenderness, or swelling after injections. It's also possible that you may be allergic to something in the injection. These allergies can be mild or may even lead to death. You can have a reaction to products that you used without problems in the past. If you have continued or worsening itching, redness, tenderness, pain, or swelling after the injection, please tell your doctor at once.

Infection:

It is rare but possible to get a bacterial, fungal, or viral infection after getting a filler injection. If you do get an infection, you may need more treatment, including antibiotics. Herpes simplex virus infections can develop near the mouth after a filler treatment. This may happen to both individuals with a history of herpes simplex virus infections and those with no known history.

_____I have a history of cold sores (please tell your doctor)

Prescribed medicine must be taken both before and after treatment to prevent infection from this virus.

Under/Over Correction:

Soft tissue filler injections to fix wrinkles and problems with the shape of your face may not give you the results you want. The amount of correction made may be less or more. Each person's tissue injection filler process is different and cannot be controlled in the same way. If under-correction occurs, you may be asked to go in for more filler injections. If overcorrection occurs, you may need to dissolve the filler with an enzyme injected into the area.

Asymmetry:

Everyone's face is different on each side. This asymmetry is normal. It may not be possible to get or maintain perfect symmetry with tissue filler injections. Each side of your face might react differently to the treatment. You may need more injections to fix this.

Poor Results:

Filler injections alone may not give you the results you want when it comes to fixing wrinkles or dents in your skin and face. You might not have a good response to the treatment. You may need more injections.

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You may also need surgery or other treatments to get the results you want. Results you're not happy with may NOT improve with more treatment.

Migration of Filler:

The filler may move from the original injection site. This may make the area around it look puffy or full. There may also be other side effects.

Skin Lumps:

You might see some lumps after having fillers injected. These tend to go away with time. In some cases, you might feel the injected filler material for a long time after your treatment.

Granulomas:

Although it's very rare, some people have painful bumps in the skin and deeper tissues (called "granulomas") after a filler injection. These may appear weeks or months after your injection. If this happens, you may need more treatment like injections, steroids, or even surgery. The injections may contain enzymes to dissolve the fillers.

Leakage of the Filler Material:

In rare cases, the filler material can leak around your injection site or even through your skin.

Damage to Deeper Structures:

Deeper structures such as nerves and blood vessels may be injured during the injection. These injuries might heal quickly but they could be permanent.

Skin Necrosis (Tissue Death):

It is very rare to have skin or tissue death (called "necrosis") after an injection. This can happen either where you got your injection or in a place that wasn't treated. Tissue death can form scars that don't look good. Tissue death may need more treatment, such as wound care or surgery.

Accidental Intra-Arterial Injection:

In very rare cases, the filler may accidentally be injected into your blood vessels instead of under your skin. This can block your blood flow. What happens if your blood flow is blocked will vary depending on where the block is. If your skin is affected, you might have skin loss or wounds. If your eye is affected, you might lose your eyesight or go blind. If your brain is affected, you might have a stroke. The risks and outcomes of such accidental injections is not known or predictable.

Antibodies to Fillers:

Your body may produce antibodies to hyaluronic acid tissue fillers. If it does, the results of future injections may be less effective. You may also have a bad reaction to other injections in the future. We don't know yet if there are any other health risks caused by these antibodies.

Unknown Risks:

We don't know the long-term effects of hyaluronic acid fillers beyond one year. We might learn about other risk factors or problems caused by using hyaluronic acid products as a soft tissue filler.

Combination of Procedures:

As of now, there are no clinical studies on whether it's safe to use hyaluronic acid along with Botox or other skin therapies.

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Pregnancy and Nursing Mothers:

There are no animal studies to determine if using hyaluronic acid fillers can hurt a developing baby. We don't know if hyaluronic acid fillers or the products created in the body when the fillers are broken down appear in human milk. Pregnant women and nursing mothers shouldn't get hyaluronic acid filler treatments.

Drug Interactions:

We don't know if hyaluronic acid fillers react with other drugs in the body.

Additional Treatment:

Many things can affect the results of your filler injections. Even though the risks and problems described here are rare, they sometimes happen to people who get hyaluronic acid filler injections. You may have other problems and risks. These are even more rare. If you have problems after your procedure, you may need more treatment or surgery. Although most people will see good results, there is no guarantee for the results.

GENERAL WARNING:

Dermal fillers should NOT be used if you have any of the issues listed here:

- Skin is infected or swollen. You should have your soft tissue filler injection only after the swelling is under control.
- Skin is prone to scars (keloids) and/or thick scars (hypertrophic scars)
- Known bleeding disorder
- History of severe allergies or shock
- Known allergy to collagen or eggs
- Known allergy to any animal product
- Known allergy to lidocaine
- Known allergy to any bacteria

Surgery can remove these fillers. You can also remove them by injecting medication to dissolve the hyaluronic acid filler. These treatments have their own risks. It may be difficult to remove the filler material.

As of now, there are no clinical studies on whether it's safe to continue use tissue fillers for a long time.

We don't know if it's safe to use these products during pregnancy, while nursing, or if you're under 18 years old.

DISCLAIMER

Informed consent documents give you information about a surgery you are considering. These documents explain the risks of that surgery. They also discuss other treatment options, including not having surgery. This document is made after a full review of scientific literature and clinical practices. They describe a range of common risks and other forms of management of a disease.
However, informed consent documents can't cover everything. Your plastic surgeon may give you more or different information. This may be based on the facts of your case.

Informed consent documents are not meant to define or serve as the standard of medical care. Standards of medical care are determined based on the facts involved in an individual case. They may change with advances in science and technology. They can also change with the way doctors practice medicine.

 _____ **Patient Initials**
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It is important that you read the above information carefully and get all your questions answered before signing the consent agreement on the next page.

 _____ **Patient Initials**

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CONSENT FOR PROCEDURE OR TREATMENT

1. I permit Dr. Thomas Jeneby and the doctor's assistants to give me the **hyaluronic acid filler injection.**
2. I got the information sheet on **hyaluronic acid filler injections.**
3. I understand that, during the procedure, an unexpected situation may require a different medical procedure than the procedure listed above. I permit the doctor listed above, the assistants, and/or designees to provide any treatment(s) that my doctor thinks are needed or helpful. My permission includes all treatments that my doctor does not plan to do at the start of the procedure.
4. I understand what my surgeon can and cannot do. I understand that no warranties or guarantees have been hinted at or stated outright about the outcome of the procedure. I have explained my goals. I understand which outcomes are realistic and which are not. All my questions have been answered. I understand the procedure's risks. I am aware of other risks and possible issues, benefits, and options. I understand and choose to have the procedure.
5. I agree to the anesthetics and medications that are needed or helpful. I understand that all types of anesthesia have risks and may result in complications, injury, and even death.
6. I am aware of the serious risks to my health when blood products are used. I agree to my doctor using them if my doctor, assistants, and/or designees think they are needed or helpful.
7. I agree to the disposal of any tissue, medical devices, or body parts taken out during or after the procedure. I also agree to any additional surgeries or treatments that are needed or helpful.
8. I agree to have parts of my body photographed or televised appropriately before, during, and after the procedure for medical, scientific, or educational reasons, if the pictures do not reveal my identity.
9. For medical education, I agree that onlookers can be in the operating room.
10. I permit my Social Security Number to be given to the right agencies for legal reasons and medical device registration, when necessary.
11. I agree to the charges for this procedure. I understand that the doctor's charges are separate from the charges for the hospital and the anesthesia. I understand that there may be more charges if more procedures or treatments are needed or helpful. I agree to those charges, if any.
12. I understand that not having the procedure is an option and that I can opt out of having the procedure.
13. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
    a. THE ABOVE PROCEDURE TO BE PERFORMED
    b. THERE MAY BE OTHER SURGERIES OR TREATMENT OPTIONS
    c. THERE ARE RISKS TO THE PROCEDURE

I CONSENT TO THE PROCEDURE AND THE ITEMS THAT ARE LISTED ABOVE (1-13).
I UNDERSTAND THE EXPLANATION AND HAVE NO MORE QUESTIONS.

_____

Patient or Person Authorized to Sign for Patient Date/Time

_____

Witness Date/Time

_____ Patient Initials

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