Informed Consent

Soft Tissue Filler Injection

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INSTRUCTIONS

This is an informed consent document to help you learn about tissue filler injection therapy. It will outline the risks and other treatments.

This consent form covers injections using _____ 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

"Fillers" is a broad term. It includes many different products that can be used to add volume to soft tissues in areas where you have medical issues. It can also be used to fix areas where you don't like how you look. Fillers can smooth out wrinkles, restore fullness, or add volume. Each filler is made of a different material and has different purposes. Some fillers last longer than others and are considered permanent, though some last for a long time. Most fillers give you visible results at once. Some like Sculptra increase fullness over time. Some fillers (such as "hyaluronic acid fillers") can be reversed by injecting certain enzymes. Other fillers cannot be easily reversed.

Fillers cannot stop you from aging. They can only make wrinkles, lines, and other appearance issues less obvious for a short time. You'll need to keep having filler injections to keep seeing results. You may also notice changes to your appearance and your eyelids. These changes may have nothing to do with the filler injections. These can be caused by aging, weight loss or gain, sun exposure, or other things. To see the results you want, you may need other treatments or surgery in the future.

Using soft tissue fillers may cause temporary swelling, redness, acne-like skin eruptions, 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 in your face. You may also choose not to have any treatment at all. You can go in for other treatments like laser treatment, chemical skin peels, skin resurfacing, or other skin procedures. You can also go in for other types of tissue fillers. Some people may choose to have surgery to remove or move tissues. All treatments have their own risks and problems.

RISKS OF 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 filler injections. You can get more information from the package-insert sheets given by the manufacturers of these products.

Filler injections may cause more harm and trauma to your skin. Talk to your provider about everything you have planned that might affect your skin. Discuss treatments you want to have like lasers and peels. You must also talk about exercise, using a sauna or hot tub, and facing weather conditions like extreme heat, cold, or sun.

SPECIFIC RISKS OF FILLER INJECTIONS

Bleeding and Bruising:

You might have bruising or bleeding after your treatment. That's because there are a lot of blood vessels in your face that vary in shape and size. The person who does your injection will try to keep this from happening, but it's still a normal side effect. If you notice bruising or bleeding, your doctor might suggest

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various methods to treat it. You may be asked to wait to see if it goes away. You can use certain creams or medications, or even have surgery if the problem is very bad. Certain medications and supplements can make you more likely to bruise or bleed. Tell your doctor about all the medications and supplements you are taking. It's 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.

Scars:

If you have a history of developing thick or obvious scars (keloids or hypertrophic scars), you should not get filler injections. No studies have shown if it's safe for patients with this kind of scarring to get filler treatments.

Skin Sensitivity and Allergies:

It's normal to have skin redness, rash, itching, tenderness, or swelling after injections. You may also be allergic to something in the injection. Such allergies can be mild or life-threatening. You can have a reaction to products that you used without any problems in the past. If you have continued or worsening itchiness, redness, tenderness, pain, or swelling after the injection, tell your doctor at once. For some types of fillers, your doctor may give you a "test dose" to check if you're sensitive to the product before the actual treatment.

Infection:

Although it is rare, you may get a bacterial, fungal, or viral infection after a filler injection. If you get an infection, you may need more treatment, like antibiotics. Herpes simplex virus infections around the mouth can develop after a tissue filler treatment. This can happen even if you don't have a history of herpes.

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

You may need to take specific medications before and after your treatment. This is to prevent issues related to 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 and a hyaluronic acid filler was used, you may be injected with an enzyme to dissolve the filler.

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 respond well to the treatment. You may need more injections. You may also need surgery or other treatments to get the results you want. Results that you are 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.

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Skin Lumps:
Lumps may form after filler injections. These may be felt or even seen. They usually go away with time. In some cases, you may feel the injected filler material for a long time after treatment.

Granulomas:
It's very rare, but you may develop painful bumps in the skin and deeper tissues (called "granulomas") after a filler injection. These may appear weeks or months after your injection. If you notice painful bumps, you might need more treatment. You may be given steroids or enzyme injections to dissolve the filler. You may also have to go in for surgery to fix this.

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 like nerves and blood vessels may get injured during the injection. These injuries may or may not 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 an area that wasn't treated. Tissue death can create scars, including ones that look bad. If you have tissue death, you may need more treatment, like wound care or surgery.

Accidental Intra-Arterial Injection:
In very rare cases, a filler may be accidentally injected into your blood vessels instead of under your skin. This can block your blood flow. The effect of this 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 may have eyesight problems or go blind. If your brain is affected, you might have a stroke. No one knows the exact risks and problems of accidentally injecting fillers into blood vessels. It is impossible to predict if this will happen.

Antibodies to Fillers:
Your body may form antibodies to the fillers. If it does, the results of future injections may be less effective. You may also have a reaction to other filler injections. We don't know about other health risks caused by these antibodies.

Unknown Risks:
We don't know much about the long-term effects of soft tissue fillers beyond a year. Scientists may discover more risk factors or problems related to using soft tissue fillers in the future.

Combination of Procedures:
As of now, there are no clinical studies showing if tissue fillers can be safely used with Botox or other skin therapies.

Pregnancy and Nursing Mothers:
There are no animal studies that demonstrate if fillers can hurt a developing baby. We don't know if fillers or the products that are created in the body when it is broken down can show up in human milk. If you are pregnant or nursing a baby, you shouldn't get soft tissue filler treatments.

Drug Interactions:
We don't know if soft tissue fillers react with other drugs in the body.

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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 soft tissue 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 following issues:

- Skin is infected or swollen. You should have your soft tissue filler injection only after the swelling is under control.
- Skin is prone to scarring (keloids) and/or thick scarring (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

There are no controlled clinical studies that suggest if it's safe to use tissue fillers for a long period of 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.

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 **soft tissue filler injection.**
2. I got the information sheet on **soft tissue 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 PROCEDURES 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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