Informed Consent

Facial Volume/Filler Injection

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INSTRUCTIONS

This is an informed consent document to help you learn about facial filler injections. It will outline the risks and alternative treatments.

This document covers procedures that use the following:

___ **Sculptra®** – Sculptra® Aesthetic is a manmade material that uses poly-L-lactic acid. This is naturally absorbed by the body and works to replace lost collagen. Poly-L-lactic acid has been used for many years in dissolvable stitches. It helps to change some of the things that can cause your face to look old. It takes 6 to 8 weeks to see results. These results can last for up to 2 years. Side effects of Sculptra® Aesthetic may include discomfort at the injection site, redness, bruising, bleeding, itching, and swelling. Other side effects may include small lumps under the skin that you might notice if you press the treated area. Larger lumps may form later, after your treatment. These may or may not be inflamed and may change your skin color. A clinical study indicated that the number of small and large lumps was low and most of these went away without treatment.

___**Radiesse®** – Radiesse® is an injectable filler made of smooth calcium hydroxylapatite (CaHA) microspheres in a gel carrier. Radiesse® is injected under the skin. It instantly fixes facial wrinkles. Over time, your body absorbs the gel, allowing collagen to slowly form where it was injected. Studies show that the results last for a year or more in most people. These results are long-lasting but not permanent. The CaHA microspheres naturally break down over time in your body.

___**Bellafill®** – Bellafill® improves nasolabial folds (folds near your mouth and nose). If you are over 21 years, it can also be used to treat bad acne scars on your cheeks (that is, moderate to severe acne scars formed from wasted tissue). You should not use Bellafill® if you have had a positive reaction to the Bellafill® Skin Test, have a bleeding disorder, or if you likely to form thick scars. You should not use Bellafill® if you have a history of severe allergies, have known cow collagen allergies, or are allergic to lidocaine. You may have temporary swelling, redness, pain, bruising, lumps/bumps, itching, and changes in skin color where you've been treated with Bellafill®. These side effects usually go away within a week. You may develop lumps or bumps more than a month after treatment and these lumps may not go away. It is rare, but you might also have a rash or itching more than 48 hours after treatment. You might also notice continued swelling or redness, lumps/bumps, or acne around the area that's been treated. You may also feel more sensitive in the area that has been treated. It is rare, but you may develop small bumps called "granulomas." If you do, you may need more treatment. Tell your plastic surgeon at once if you notice anything unusual with your skin in the area that's been treated. This treatment is generally considered safe for up to 5 years based on a 5-year Post Approval Study with 1,008 patients.

_____ - There may be new facial volume/injection fillers in the future. Check with your doctor about their FDA approval and safety. Treatments like this are not permanent. Ask your doctor how long each treatment might last. You should also talk to your doctor about what you can reasonably expect from each treatment and how it might affect how you look.

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

Filler injections are different for every patient, depending on his or her needs. These treatments can be done to parts of the face, like the eyelids, forehead, and lips. Fillers do not stop you from aging. However, they can temporarily smooth out wrinkles and make dents in your skin look less obvious.

Filler injections can be done on their own or combined with other treatments such as Botulina Toxin A (BTA). They can also be done along with a surgery. To make them less painful, filler injections need to be

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done with a nerve block or local anesthetic. If you use a soft tissue filler, you may have some temporary swelling, redness, and needle marks, which will go away after a few days.

Fillers are not permanent. You'll need to have more treatment to see the same results over time. Your body will slowly absorb the fillers. How long this takes and how long the results last will vary for every person.

OTHER TREATMENTS

There are other ways to treat wrinkles and dents in your face. You can also choose to not to have any treatment. Other treatment options are laser treatment, chemical skin peels, skin resurfacing, or other skin procedures. You might also choose a different type of tissue filler. Another option includes surgery like a blepharoplasty (eyelid lift), face lift, or brow lift. All treatments have their own risks and potential problems.

RISKS OF FACIAL VOLUME/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 a 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 facial volume/filler injections.

SPECIFIC RISKS OF FACIAL VOLUME/FILLER INJECTIONS

Bleeding and Bruising:

Although it is rare, you may have bleeding after a filler injection or if local anesthesia is used for your treatment. You might see bruising or your blood vessels might be injured. If you have bleeding problems, you might need emergency treatment or surgery. You are more likely to bleed if you take certain medications and supplements. These include aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, vitamin E, ginkgo biloba, and other herbs and homeopathic remedies. Be sure to tell your doctor about every medication you're taking.

Swelling:

It's normal to have some swelling (edema) after getting your injections. This usually goes away after a few days. If the swelling doesn't go away within a week, you may need more treatment. Swelling around your lower eyelid may last for a longer time.

Pain:

You may have some pain or discomfort after an injection. It usually doesn't last very long. It is rare to have pain that lasts.

Needle Marks:

It's normal to have some visible needle marks after an injection. These usually go away after a few days.

Acne-Like Skin Eruptions:

You might notice small bumps that look like pimples (called "acneiform skin eruptions") after getting a filler injection. These usually go away within a few days.

Skin Sensitivity:

You might have a skin rash, itching, tenderness, and swelling after your injections. After treatment, you should be careful to protect your skin until the swelling or redness goes away. Avoid getting too much sun. Don't use UV lamps. Avoid really cold weather. If you are thinking about getting laser treatment, chemical skin peels, or any other skin procedure after filler treatment, you may want to wait. If you've had treatments like this recently and your skin hasn't fully healed, you could have more swelling, bruising, or redness from the injections. You might have problems with your skin or lips.

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Skin Loss:
It's rare but possible that filler might be injected into your blood vessels instead of under the skin. If this happens, you might develop a bubble or clot in your blood vessels (embolization). This may reduce or stop blood flow to your skin, which could lead to skin loss. If this happens, the skin in that area could get very pale or become fully white and could hurt a lot. If you notice anything like this, tell your doctor at once. You may need more treatment to fix the blood flow and prevent skin loss.

Erythema (Skin Redness):
It's normal for your skin to be red for a few days after the procedure.

Vision Abnormalities:
In rare cases, you might have problems with your eyesight or even blindness after a filler injection.

Infection:
It is rare but possible to get a bacterial, fungal, or viral infection after getting a filler injection. 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 of it. Prescribed medicine must be taken both before and after treatment to prevent infection from this virus. If you get any type of skin infection, you may need more treatment including antibiotics.

Stroke:
In rare cases, filler injections can block the oxygen going to your brain, causing a stroke.

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.

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.

Damage to Deeper Structures:
Injections might injure your nerves, blood vessels, muscles, and other structures. The risk of this happening depends on the type of treatment. Injuries to deeper structures may be temporary or permanent.

Skin Lumps:
You might notice lumps in your skin after a filler injection. This is likely to go away over time. Some people may feel the injected tissue filler material for a long period of time.

Visible Tissue Filler Material:
If your skin is very thin, you might see the injected tissue filler material under the skin.

Granulomas:
It's rare, but you might develop painful bumps in your skin and deeper tissues (called "granulomas") after a filler injection. If you see these, you might need more treatment, like surgery. Don't use fillers in areas where you have swelling or an infection. Do not get an injection if you have cysts, pimples, rashes, or hives.

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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.

Leakage or Rupture of the Filler Material:
It's rare for the filler material to leak or burst through the skin where it's been injected. This may be caused by a bad reaction or by an infection.

Skin Necrosis (Tissue Death):
It is very rare for your skin and deeper soft tissues to be damaged after injections. Skin loss can form scars. If this happens, you may need more treatments or surgery.

Open or Draining Wounds:
In rare cases, the filler material may cause an infection (biofilm formation) in your body. Your skin or tissue may die from a blocked blood vessel. This might result in less blood flow causing you to heal poorly.

Allergic Reactions and Hypersensitivity:
It's possible to be allergic to the materials used in filler injections. These allergies can be very serious and may even lead to death. You shouldn't use fillers if you have a history of bad allergies, including multiple allergies, allergies resulting in shock (anaphylaxis), or allergies to gram-positive bacterial proteins. Having a severe allergic reaction is rare, but it can happen. If you have an allergic reaction, you may need more treatment. If you choose fillers like Bellafill, you will need to be tested for allergies.

Drug and Local Anesthetic Reactions:
It's possible to have a reaction to the local anesthetic or the epinephrine used in the procedure. You may develop a sensory nerve block. These reactions may include feeling light-headed, having a fast heartbeat (tachycardia), or fainting. If this happens, you may need more treatment.

Antibodies to Fillers:
Your body may produce antibodies to the filler. If it does, the results of future filler injections may be less effective. You may also experience a reaction to other filler injections in the future. We don't yet know if there are any other health risks caused by these antibodies.

Accidental Intra-Vascular Injection:
In rare cases, fillers could accidentally be injected into your blood vessels instead of under your skin. This might block blood flow. Blocked blood flow to the face can cause skin loss or make the tissue die. Blocked blood flow to your eye can affect your vision or cause blindness. Scientists are still learning about the risks and consequences of accidentally injecting fillers into the blood stream. That means we can't predict what might happen after an injection.

Scars:
If you tend to scar easily or are likely to develop noticeable scars (keloids or hypertrophic scars), you shouldn't get filler injections.

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. You may also need surgery or other treatments to get the results you want.

Unknown Risks:
We don't know the long-term effects of using tissue fillers beyond one year. We might learn about other risks or problems caused by using tissue fillers in the future.

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Pregnancy and Nursing Mothers:

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

Drug Interactions:

We don't know if tissue fillers react with any other drugs in the body.

Long-Term Effects:

Facial volume/filler injections won't fix your wrinkles or dents in your skin forever. Over time, your body will slowly absorb most filler material and your wrinkles will come back. You have to get more injections to keep seeing results. You will see other changes to your face and eyelids with time, owing to natural processes like aging, weight loss or gain, sun exposure, or other factors not related to filler injections. To keep looking the way you want to, you might need surgery or other treatments in the future. Volume/filler injections do not stop you from aging. They won't permanently tighten your skin.

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 facial volume/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 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

Although surgery can remove these fillers, there is a risk to having any surgery. It may be difficult to remove the filler material.

As of now, there are no clinical studies on whether it's safe to continue to 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.

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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.

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CONSENT FOR PROCEDURE OR TREATMENT

1. I permit Dr. Thomas Jeneby and the doctor's assistants to give me a **facial volume/filler injection.**
2. I got the information sheet on **facial volume/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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