This document is designed to help inform you about Juvéderm® tissue filler injection therapy, its risks, and alternative treatments. It is important that you read this information carefully and completely.

**General Information**

Juvéderm® is a stabilized hyaluronic acid approved by the FDA for injection into facial tissue to smooth wrinkles and folds, especially around the nose and mouth. Hyaluronic acid (HA) is a naturally-occurring sugar found in various soft tissues in the human body. The role of hyaluronic acid in the skin is to deliver nutrients, hydrate the skin by holding water, and to act as a cushioning agent. HA can be synthetically produced from a process of bacterial fermentation, chemically stabilized, and purified for use as an injectable soft tissue filler.

Juvéderm® injections are customized for each patient, depending on his or her needs. These injections can be performed in areas involving the face and eyelid region, forehead, and lips. It cannot, however, stop the process of aging. It can temporarily diminish the look of wrinkles and soft tissue depressions. These injections may be performed as a single procedure, in combination with other treatments such as Botox®, or as an adjunct to surgical procedure.

Continuing treatments are necessary in order to maintain the effects of Juvéderm® over time. Once injected, it will be slowly absorbed by the body. The length of effect is variable per individual; however, studies have shown the results may last between 9 months and 1 year.

**Procedure**

1. After the areas have been thoroughly cleaned with alcohol and an antibacterial cleaning solution, Juvéderm® is injected under the skin in the areas of the face to be filled via a small gauge needle (usually 27-30G) and a syringe.

2. An anesthetic (numbing medicine) may or may not be used. Prior to Juvéderm® injections (30-45 minutes), a topical anesthetic (BLT cream) may be applied to reduce discomfort. Ice is also used throughout the procedure to help minimize bruising and swelling as well as to provide local anesthetics. Juvéderm® Ultra XC and Ultra Plus XC contain a small quantity of local anesthetic (lidocaine) which significantly reduces discomfort. Please inform your physician if you have a known allergy or sensitivity to local anesthetics.

3. The depth of the injection(s) will depend on the depth of the wrinkle(s) and the location(s). Multiple injections may be necessary depending on the site, depth of wrinkle, and technique used.

4. Following each injection, the sites may be gently massaged to help the Juvéderm® conform to the contour of the surrounding tissues.

5. After the first treatment, additional treatments of Juvéderm® may be necessary to achieve the desired level of correction. Periodic touch-up injections help sustain the desired level of correction.

**Alternative Treatments**

Improvement of skin wrinkles and soft tissue depressions may also be accomplished by other treatments. Options include laser skin surface treatments, chemical peels, microdermabrasion, Botox® injections, alternative types of skin fillers, or surgery such as face lift, brow lift, or eyelid lift, when indicated. Other options not mentioned here may exist. Risks and potential complications are associated with alternative forms of medical and surgical treatment.
**Injection Site Side Effects**

Although a very thin needle is used, common injection-related reactions could occur. These include: redness, pain/tenderness, swelling, bruising, discoloration, or itching at the injection site. You could experience increased bruising or bleeding at the injection site if you are using substances that prolong bleeding such as Plavix, Coumadin, aspirin, other non-steroidal anti-inflammatory drugs such as ibuprofen (Motrin, Advil) or naproxen (Aleve, Naprosyn) or certain herbal products such as ginkgo biloba, ginger, garlic, feverfew or vitamin E.

Occasionally, visible lumps/bumps may occur temporarily following the injection; however, these tend to smooth out over time. In some cases, it may be possible to see any type of tissue filler injected in areas where the skin is thin.

Juvéderm® should NOT be used in patients with a history of multiple severe allergies, severe allergies, allergies manifested by a history of anaphylaxis, or allergies to gram-positive bacterial proteins. Allergic reactions may require additional treatment.

Skin rash, itching, tenderness, and swelling may occur due to skin sensitivity to Juvéderm®. After treatment, you should minimize exposure of the treated areas to excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. You should also avoid strenuous exercise or alcohol for at least 24 hours after treatment. If you are considering laser treatment, chemical skin peeling, microdermabrasion, or any other procedure (based on skin response) or if you have had such treatments and the skin has not completely healed, there is a possible risk of an inflammatory reaction in the injection site.

The human face is normally asymmetrical in appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with fillers. There can be variation from one side to the other in terms of response and you may require additional injections.

**Risks of 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. Every procedure also has limitations. 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 and limitations of Juvéderm® injections.

**Infection** — Although unusual, bacterial, fungal, viral infections, and/or pustules 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 and individuals with no known history of herpes simplex virus infections in the mouth area. Specific medications may 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 and/or corticosteroids may be necessary.

**Necrosis** — It is very unusual to experience death of skin and deeper soft tissues after dermal filler. This can occur when filler compresses a blood vessel and inhibits the blood supply to a part of the face. The most common symptoms are pain at a location, other than the injection site, and/or discoloration to the area of the face supplied by the affected blood vessel. Treatment includes hot packs, massage, applying nitrapaste to cause dilation of the blood vessels and 3...
possibly injecting the affected area with hyaluronidase, a protein that will help dissolve the HA filler. Let your injector know if you have a known allergy to bee or vespid stings, since those individuals are at a higher risk for hyaluronidase sensitivity owing to the presence of hyaluronidase in venom. There is a very rare risk of skin necrosis, blindness and stroke, especially if used around the eyes, nose, or frown lines.

**Granulomas** – This is a special type of inflammatory reaction in which a ball-like collection of immune cells forms when the immune system attempts to wall off substances that it perceives as foreign but is unable to eliminate. These reactions may be caused by allergy to the material or immunologic response to the protein in the HA preparations. They may present as warm, red, tender nodules under the skin in the area injected with HA. Treatment may consist of intralesional steroid injections, oral antibiotics, or hyaluronidase injections.

**Scarring** – Although this is rare for most patients, you should not attempt Juvéderm® injections if you are highly susceptible to keloid or hypertrophic scarring.

**Additional Advisories**

**Unsatisfactory Results/Long-term Effects** – Dermal fillers 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 and additional injections may be necessary. Dermal fillers should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the filler material is slowly absorbed by the body and wrinkles or depressions with reappear. Continuing treatments are necessary to maintain the effect. Surgical procedures or other treatments such as Botox®, microdermabrasion, laser skin surface treatments, or chemical peels may be recommended in addition to Juvéderm® treatments.

**Pregnancy & Nursing Mothers** – Studies have not been performed to determine if dermal fillers could cause fetal harm nor is it known if their breakdown can be excreted in human breast milk. It is not recommended that pregnant women or nursing women receive dermal fillers.

It is important that you read the above information carefully and have all your questions answered before signing the consent below.

1. I hereby authorize Holtorf Medical Group to perform the following treatment: Juvéderm® Ultra/Ultra XC, Juvéderm® Ultra Plus/Ultra Plus XC, Juvéderm® Voluma XC, Restylane® Lyft, Silk, and Restylane®.

2. I have read and received a copy of this informed consent document as well as a copy of the Juvéderm® information sheet.

3. I grant authority to administer additional related medical treatments as deemed necessary or advisable in the diagnosis and treatment of my condition.

4. 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.

5. I have informed my physician of my medical history. I clearly understand that I cannot be treated with HA fillers:
   - if I am pregnant or breast feeding
   - in areas with inflammation or infectious skin problems
   - if I have a past history of autoimmune disease or immunotherapy treatments not yet approved and/or discussed with my treating physician
   - if I have a tendency to develop hypertrophic scarring

6. I acknowledge that no guarantee has been given by anyone affiliated with Holtorf Medical Group as to the results that may be obtained by this treatment.

7. I consent to be photographed before, during, and after the procedure(s) for the purpose of recording documentation.

8. I realize that this procedure is optional.

I consent to the treatment and/or procedure. I have read and fully understand the information contained within this document, including items 1-8 detailed above. I have had ample time to consider the information from my physician. I am satisfied with the explanation and all of my questions have been answered.

______________________________           ____________________________
Patient Name (print)                              Date

______________________________           ____________________________
Patient Signature (HMG) Witness Signature