DERMAL FILLER TREATMENTS

Clinical Policies and Procedures

DERMAL FILLER TREATMENTS

CLINICAL POLICIES AND PROCEDURES

PURPOSE

To ensure safe and effective treatment of clients undergoing dermal fillers administration at the **Graceful Changes Health and Wellness** the following policies and procedures have been developed. Dermal Fillers are defined as hyaluronic acid injectable products and hyaluronic acid injectable products with calcium hydroxyapatite (Radiesse).

POLICY

A Registered Nurse [RN], Physician Assistant or licensed medical personnel with current state licensure shall be able to assess, consult and treat clients with dermal fillers following the guidelines set herein. In the state of **MISSOURI** the medical director or a physician assistant must perform a good faith examination prior to the use of dermal fillers.

SETTING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel can perform the administration of dermal fillers in various settings and locations, such as but not limited to:

- Physician Office
- Satellite clinic / health care office(s)
- MedSpa Setting authorized by the Medical Director
- Health Club Setting[1] authorized by the Medical Director

All dermal filler administration procedures shall be performed in a clean, safe environment, equipped with proper sharps disposal system, and universal precautions in place.

SUPERVISION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary.

All adverse reactions shall be reported immediately to the Medical Director. Adverse reaction(s) shall be documented in the client's chart.

[1] California Business & Professions Code Section 2725 and California Code of Regulations, Section 1470-1474; Health Club Setting does not meet California performance standards. May apply in other states.

PATIENT CONDITIONS

The Registered Nurse [RN], Physician Assistant or licensed medical personnel will not knowingly treat any clients with a history of anaphylaxis, clients taking immunosuppressive medication, clients with infection over the injection area, or pregnant clients.

DERMAL FILLER ADMINISTRATION PROCEDURE

The Physician, Registered Nurse [RN], Physician Assistant or licensed medical personnel will:

1. Complete assessment and a medical history questionnaire with all new clients.

2. Clients with a history of anaphylaxis, clients taking immunosuppressive medication, clients with infection over the injection area, or pregnant clients will be denied treatment.

3. Clients with a history of herpes simplex over the injection area must be pre-treated with acyclovir 400mg three times per day for 5 days and a further 2 days after treatment.

4. Upon passing medical screening, client will be fully informed of risks, benefits, and potential adverse reactions and an informed consent will be signed.

5. All dermal filler products will be stored and administered at room temperature.

6. Topical anesthesia (i.e. BLT prescription formulation) may be used 30 minutes prior to procedure.

7. Clients are injected while in upright seated position unless otherwise instructed for particular areas.

8. Client should remove any make-up from face and wash with mild soap and water. Swab treatment area with alcohol or other antiseptic.

9. Prior to administration the Registered Nurse [RN], Physician Assistant or licensed medical personnel will map out points of injection

10. Dermal Fillers are packaged for single use only. The needle is a 30 gauge needle. The needle is mounted on the syringe Luer-lock as per manufacturer instructions. The depth of injection is 1mm for superficial lines and 2mm for deeper lines.

11. Insert needle into the dermis at a depth of 1-2mm at an angle of 30 degrees parallel to the length of the wrinkle with the bevel facing upwards.

12. Prior to injecting product, aspirate the syringe to ensure that the needle was not placed into a vessel.

13. Inject slowly and retract, prior to exiting the skin with the needle - stop injecting.

14. No blanching should occur with the injection. If it does, stop the injection and massage the skin until it returns to its normal color.

15. Multiple injections should be placed serially along the length of the depression.

16. Massage the injected area to even out any lumps or bumps.

17. After the treatment, swab the area with hydrogen peroxide or alcohol and apply an ice-pack if patient is experiencing any discomfort.

18. When procedure is completed the client should be instructed to avoid strenuous exercise, sun exposure and alcohol for 24 hours.

19. Use of dermal fillers should be limited to 1.5 mL per treatment site or less.

RECORD KEEPING

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall be responsible for maintaining client records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, treatment sites, number of injections, solution/concentration used, and the client response to treatment.

Dermal Filler Patient History

Name: _____ Date: _____

Address: _____

Telephone: _____ Cell: _____

Date of Birth: _____

Consent signed: Yes No Date: _____

Previous Dermal Filler Yes No Date: _____

Complications: Yes No Date: _____

Type Dermal Fillers: _____

History of Anaphylactic Shock: Yes No Date: _____

History of Allergies: Yes No Date: _____

Medications

Asprin Yes No

Anti-Inflammatories Yes No

Anticoagulants Yes No

Steroids Yes No

Non-Steroidals Yes No
(i.e. Advil, Aleve, Celebrex)

_____

_____

Supplements

Ginko Biloba Yes No

Vitamin A Yes No

Vitamin E Yes No

Garlic Yes No

Flax Oil Yes No

_____

_____

Do you have at present, any history of the following medical conditions?

Have you had in the past, any history of the following medical conditions?

1. Multiple Severe Allergies Yes No

2. HX of Herpes around the Lips Yes No

3. Immunosuppressive Therapy Yes No

4. Autoimmune Disease Yes No

5. Other Medical History Yes No

(if you answered Yes to any one of the above please explain below)

Comments:

_____

_____

_____

_____

_____

I have answered the above questions to the best of my knowledge

.

_____ _____

Signature Date

Dental Infiltrate Consent

I, _____ understand that a Dental Infiltrate will be performed to provide temporary relief of discomfort associated with the administration of dermal filler. I understand that Dental Infiltrates are not 100% effective, but should reduce pain in most cases. The risks of a Dental Infiltrate include bleeding, infection, and adverse reaction to the anesthetic.

_____ (Initial) I do not have any hypersensitivity to any local anesthetic agents, nor do I have a history of malignant hyperthermia.

I have read and understand this consent and all of my questions have been addressed and answered to my satisfaction. I have no contraindicating factors, and thereby grant permission for a Dental Infiltrate. I certify that if any changes occur in my medical history/health or regime, that I will notify this office as soon as possible.

_____

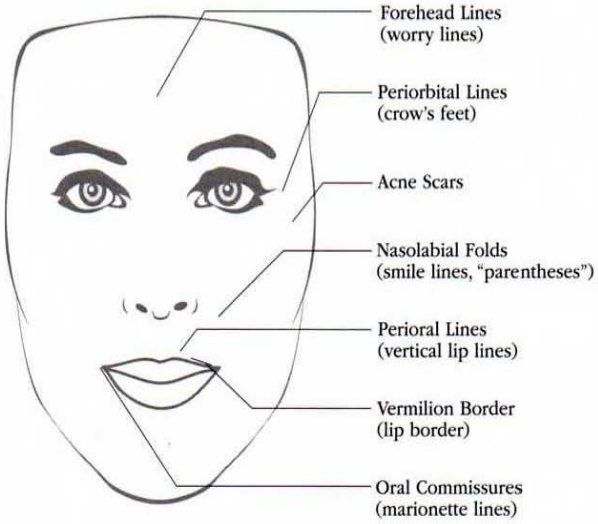
_____
Client (Print Name) Signature Date

_____

_____
Witness (Print Name) Signature Date

TREATMENT RECORD (SAMPLE)

INDICATE AREAS TREATED AND TREATMENT NOTES*



Notes: _____

TREATMENT RECORD

Date Treated *month/day/year*	Affix Lot Number Label	Area(s) Treated and Treatment Notes
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP. DATE NO DE LOT / CODE / DATE DE PEREMPTION 00K131B / 5025A / 2005 - 10 SAMPLE	❑ Forehead Lines ❑ Periorbital Lines ❑ Acne Scars ❑ Nasolabial Folds ❑ Perioral Lines ❑ Vermilion Border ❑ Oral Commissures ❑ Other: _____ Notes: _____
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP. DATE NO DE LOT / CODE / DATE DE PEREMPTION 00K131B / 5025A / 2005 - 10 SAMPLE	❑ Forehead Lines ❑ Periorbital Lines ❑ Acne Scars ❑ Nasolabial Folds ❑ Perioral Lines ❑ Vermilion Border ❑ Oral Commissures ❑ Other: _____ Notes: _____

*JUVÉDERM™ is not appropriate for every treatment area. JUVÉDERM™ is indicated for the treatment of moderate to severe facial wrinkles and folds.

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TREATMENT RECORD (CONTINUED)

Date Treated *month/day/year*	Affix Lot Number Label	Area(s) Treated and Treatment Notes
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP DATE NO DE LOT / CODE DU PRODUIT / DATE DE PEREMPTION 00K131B / 5026A / 2005 - 10 EXAMPLE	☐ Forehead Lines ☐ Perioral Lines ☐ Periorbital Lines ☐ Vermilion Border ☐ Acne Scars ☐ Oral Commissures ☐ Nasolabial Folds ☐ Other: ______ Notes: ______
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP DATE NO DE LOT / CODE DU PRODUIT / DATE DE PEREMPTION 00K131B / 5026A / 2005 - 10 EXAMPLE	☐ Forehead Lines ☐ Perioral Lines ☐ Periorbital Lines ☐ Vermilion Border ☐ Acne Scars ☐ Oral Commissures ☐ Nasolabial Folds ☐ Other: ______ Notes: ______
	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP DATE NO DE LOT / CODE DU PRODUIT / DATE DE PEREMPTION 00K131B / 5026A / 2005 - 10 EXAMPLE	☐ Forehead Lines ☐ Perioral Lines ☐ Periorbital Lines ☐ Vermilion Border ☐ Acne Scars ☐ Oral Commissures ☐ Nasolabial Folds ☐ Other: ______ Notes: ______
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	Affix label to patient chart. Apposer au dossier du patient. 1.0mL LOT NO. / CODE / EXP DATE NO DE LOT / CODE DU PRODUIT / DATE DE PEREMPTION 00K131B / 5026A / 2005 - 10 EXAMPLE	☐ Forehead Lines ☐ Perioral Lines ☐ Periorbital Lines ☐ Vermilion Border ☐ Acne Scars ☐ Oral Commissures ☐ Nasolabial Folds ☐ Other: ______ Notes: ______

Post Treatment Form For Patients

After your treatment with dermal fillers, you might have some redness and swelling. This is normally less than seven (7) days.

1) Cold compresses may be used immediately after treatment to reduce swelling. If the inconvenience continues beyond seven (7) days or if other reactions or side effects occur, please contact the doctor.

2) Avoid touching the treated areas within six (6) hours following treatment. Do not massage the injection sites day of the injections. After that, the area can be gently washed.

3) You may shower and place make-up the following day.

4) Sunbathing and cold outdoor activities should be avoided until any redness or swelling disappears.

5) Avoid exercise and alcohol for six (6) hours after treatment.

6) Take anti-inflammatories if you have any pain; this should be enough. You might develop a headache as a consequence of the injections.

7) You might see some bruising occurring one (1) to two (2) days after injections at any of the injection sites. These will eventually go away in several days.

8) If you have previously suffered from facial cold sores, there is a risk that the needle punctures could contribute to a recurrence. Speak to the doctor about medications that may minimize a recurrence.

9) We generally like for you to return for a post injection appointment in five (5) to seven (7) days.

REQUIREMENTS FOR CLINICAL PERSONNEL

TRAINING / EDUCATION

The Registered Nurse [RN], Physician Assistant or licensed medical personnel shall receive specialized training [and be certified] in the administration of DERMAL FILLERS. A Medical Doctor, Doctor of Osteopath, Advanced Practice Nurse experienced in this procedure, or a teaching institution specializing in this procedure, may perform this training and certification. The medical personnel performing these procedures must successfully complete the Dermal Filler Training Program for present products used and for products to be used in future periods.

COMPETENCIES & DOCUMENTATION

The Medical Director and/or [applicable licensure], shall

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate of the competence of the Registered Nurse [RN], Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse, Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

Informed Consent for Juvederm® Injections

INSTRUCTIONS
This is an informed consent document which has been prepared to help us inform you concerning Juvederm® Restylane products, Belotera, Revanessa, or RHA collection (Non-Animal Stabilized Hyaluronic Acid, Allergan©) 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.

INTRODUCTION
Juvederm® Restylane products, Belotera, Revanessa, or RHA collection is a stabilized hyaluronic acid used to smooth moderate to severe facial wrinkles and folds around the nose and mouth or shape facial contours. Juvederm® Restylane products, Belotera, Revanessa, or RHA collection has been FDA approved for the cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions. Hyaluronic acid is a naturally occurring substance that is found within all mammals. It is a material that is contained in various soft tissues. Hyaluronic acid can be synthetically produced from a process of bacterial fermentation, chemically stabilized, and purified for use as injectable soft tissue filler (non-animal, stabilized hyaluronic acid, Allergan©). The hyaluronic acid in Juvederm® Restylane products, Belotera, Revanessa, or RHA collection is biocompatible and is a totally non-animal product; there is little risk of animal-based disease transmission or allergic reaction. Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips. Juvederm® Restylane products, Belotera, Revanessa, or RHA collection cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles and soft tissue depressions. Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injections may require regional nerve blocks or local anesthetic injections or topicals to diminish discomfort. Soft tissue fillers, including Juvederm® Restylane products, Belotera, Revanessa, or RHA collection, 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 Juvederm® Restylane products, Belotera, Revanessa, or RHA collection over time. Juvederm® Restylane products, Belotera, Revanessa, or RHA collection once injected will be slowly absorbed by the body. The length of effect for Juvederm® Restylane products, Belotera, Revanessa, or RHA collection 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, or other skin procedures, 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 HYALURONIC ACID 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. In addition, every procedure 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, potential complications, limitations, and consequences of Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injections.

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections.

Bleeding and Bruising

It is possible, though unusual, to have a bleeding episode from a Juvederm® Restylane products, Belotera, Revanessa, or RHA collection 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, ginkgo 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 or after Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injections.

Pain Discomfort

Pain Discomfort associated with Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injections is normal and usually of short duration. 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) in the skin occurs after injections. It can be present for a few days after the procedure. 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 Juvederm® Restylane products, Belotera, Revanessa, or RHA collection. 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.

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.

Asymmetry

The human face is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filer injections. There can be a variation from one side to the other in terms of the response to Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injection. This may require additional injections.

Skin Sensitivity

Skin rash, itching, tenderness and swelling may occur following Juvederm® injections. After treatment, you should minimize exposure of the treated area to excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. If you are considering laser treatment, chemical skin peeling or any other procedure based on a skin response after Juvederm® Restylane products, Belotera, Revanessa, or RHA collection treatment, or you have recently had such treatments and the skin has not healed completely, there is a possible risk of an inflammatory reaction at the implant site.

Damage to Deeper Structures

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

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.

Skin Necrosis
It is very unusual to experience death of skin and deeper soft tissues after Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injections. Skin necrosis can produce unacceptable scarring. Should this complication occur, additional treatments, or surgery may be necessary.

Allergic Reactions and Hypersensitivity
As with all biologic products, allergic and systemic anaphylactic reactions may occur. Juvederm® should not be used in patients with a history of multiple severe allergies, severe allergies manifested by a history of anaphylaxis, or allergies to gram-positive bacterial proteins. Allergic reactions may require additional treatment.

Scarring
Juvederm® Restylane products, Belotera, Revanessa, or RHA collection should not be used in patients with known susceptibility to keloid formation or hypertrophic scarring. The safety of patients has not been studied.

Granulomas
Painful masses in the skin and deeper tissues after a Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injection are extremely rare.
Should these occur, additional treatments including surgery may be necessary.

Skin Disorders
Juvederm Restylane products, Belotera, Revanessa, or RHA collection should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives). In rare instances, granuloma or abscess formation, localized necrosis and urticaria have been reported.

Antibodies to Hyaluronic Acid
Presence of antibodies to hyaluronic acid tissue fillers may reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to hyaluronic acid tissue fillers is unknown.

Accidental Intra-Arterial Injection
It is extremely rare that during the course of injection, Juvederm® Restylane products, Belotera, Revanessa, or RHA collection 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 of Juvederm products, Restylane products, Belotera, Revanessa, or RHA collection is unknown and not predictable.

Under / Over Correction
The injection of soft tissue fillers including Juvederm® products, Restylane products, Belotera, Revanessa, or RHA collection to correct wrinkles and soft tissue contour deficiencies may not achieve 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.

Migration of Hyaluronic Acid®
Juvederm® Restylane products, Belotera, Revanessa, or RHA collection 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 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 heartbeat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Unsatisfactory Result
Juvederm® Restylane products, Belotera, Revanessa, or RHA collection 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 from Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injection(s). Additional Juvederm® ,Restylane products, Belotera, Revanessa, or RHA collection injections may be necessary.

Unknown Risks
The long term effect of Juvederm®, Restylane products, Belotera, Revanessa, or RHA collection beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of Juvederm, Restylane products, Belotera, Revanessa, or RHA collection as a soft tissue filler may be discovered.

Combination of Procedures
In some situations, Botox® injections or other types of tissue filler materials may be used in addition to Juvederm® Restylane products, Belotera, Revanessa, or RHA collection 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 Juvederm® Restylane products, Belotera, Revanessa, or RHA collection is unknown.

Pregnancy and Nursing Mothers
Animal reproduction studies have not been performed to determine if Juvederm® ,Restylane products, Belotera, Revanessa, or RHA collection could produce fetal harm. It is not known if Juvederm® ,Restylane products, Belotera, Revanessa, or RHA collection or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive Juvederm® Restylane products, Belotera, Revanessa, or RHA collection treatments.

Drug Interactions
It is not known if Juvederm® ,Restylane products, Belotera, Revanessa, or RHA collection reacts with other drugs within the body.

Long-Term Effects
Juvederm®, Restylane products, Belotera, Revanessa, or RHA collection injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the Juvederm® Restylane products, Belotera, Revanessa, or RHA collection material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing Juvederm® Restylane products, Belotera, Revanessa, or RHA collection treatment (injections) is necessary in order to maintain the effect of Juvederm Restylane products, Belotera, Revanessa, or RHA collection. 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 Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injections.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same.

ADDITIONAL TREATMENT NECESSARY

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Juvederm Restylane products, Belotera, Revanessa, or RHA collection injections. There is no guarantee or warranty expressed or implied, on the results that may be obtained.

FINANCIAL RESPONSIBILITIES

The cost of Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injection may involve several charges. Additional costs of medical treatment would be your responsibility should complications develop from Juvederm® Restylane products, Belotera, Revanessa, or RHA collection injections.

DISCLAIMER

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

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.

I have read and understand the following Informed Consent Material for my specific procedure:
JUVEDERM® Restylane products, Belotera, Revanessa, or RHA collection

The risks, benefits, and alternatives of the procedure(s) were explained to me. I understand the specific risks in the consent material for my surgery and understand the significant risks of bleeding, infection, blindness, injury to neighboring structures, capsule contracture(if implants involved), lumpiness, asymmetry, pulmonary emboli, deformity, skin loss or necrosis, healing problems, poor scars, loss of sensation(feeling), appearance/psychological changes, unsatisfactory result, need for future revision surgery and anesthesia. I understand the anticipated results and limitations of the surgery procedure(s).

The following instructions were explained to me:

Pre and Post procedure instructions, DVT prevention instructions, and medications to avoid instructions. I agree to follow all instructions, to follow up as directed, and to notify the office if any problems or questions arise.

_____		_____
Patient Signature	Date	Witness Print Name
_____		_____
Witness Signature	Date	Witness Address Line 1

INFORMED CONSENT–RESTYLANE® INJECTION

INSTRUCTIONS
This is an informed consent document which has been prepared to help your plastic surgeon inform you concerning Restylane® (Non-Animal Stabilized Hyaluronic Acid, Galderma/Medicis Aesthetics) 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 by your physician and agreed upon by you.

GENERAL INFORMATION
Restylane® is a stabilized hyaluronic acid used to smooth moderate to severe facial wrinkles and folds around the nose and mouth or shape facial contours. Restylane® has been FDA approved for the cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions.

Hyaluronic acid is a naturally occurring substance that is found within all mammals. It is a material that is contained in various soft tissues. Hyaluronic acid can be synthetically produced from a process of bacterial fermentation, chemically stabilized, and purified for use as an injectable soft tissue filler (non-animal, stabilized hyaluronic acid, Galderma/Medicis Aesthetics). The hyaluronic acid in Restylane® is biocompatible and is a totally non-animal product; there is little risk of animal-based disease transmission or allergic reaction.
Restylane® injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips.

Restylane® cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles and soft tissue depressions. Restylane injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. Restylane® injections require regional nerve blocks or local anesthetic injections to diminish discomfort. Soft tissue fillers, including Restylane®, produce temporary swelling, redness, and needle marks, which resolve after a few days.

Continuing treatments are necessary in order to maintain the effect of Restylane® over time. Restylane® once injected will be slowly absorbed by the body. The length of effect for Restylane® 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 alternative types of tissue fillers. Risks and potential complications are associated with alternative forms of medical or surgical treatments.

RISKS OF RESTYLANE® 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. In addition, every procedure 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, potential complications, limitations, and consequences of Restylane® injections. Additional information concerning Restylane® 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, including Restylane®. Additional advisory information should be reviewed by patients considering tissue filler treatments that involve Restylane®.

Normal Occurrences during Tissue Filler Injections include:

Bleeding and Bruising
It is possible, though unusual, to have a bleeding episode from a Restylane® 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. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo 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 or after Restylane® injections.

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 Restylane®. 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.

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.

Asymmetry
The human face is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filer injections. There can be a variation from one side to the other in terms of the response to Restylane® injection. This may require additional injections.

Pain
Discomfort associated with Restylane® injections is normal and usually of short duration.

Skin Sensitivity
Skin rash, itching, tenderness and swelling may occur following Restylane® injections. After treatment, you should minimize exposure of the treated area to excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. If you are considering laser treatment, chemical skin peeling or any other procedure based on a skin response after Restylane® treatment, or you have recently had such treatments and the skin has not healed completely, there is a possible risk of an inflammatory reaction at the implant site.

RISKS OF RESTYLANE® INJECTIONS

Damage to Deeper Structures

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

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.

Skin Necrosis

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

Allergic Reactions and Hypersensitivity

As with all biologic products, allergic and systemic anaphylactic reactions may occur. Restylane® should not be used in patients with a history of multiple severe allergies, severe allergies manifested by a history of anaphylaxis, or allergies to gram-positive bacterial proteins. Allergic reactions may require additional treatment.

Scarring

Restylane® should not be used in patients with known susceptibility to keloid formation or hypertrophic scarring. The safety of patients has not been studied.

Granulomas

Painful masses in the skin and deeper tissues after a Restylane® injection are extremely rare. Should these occur, additional treatments including surgery may be necessary.

Skin Disorders

Restylane® should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives). In rare instances, granuloma or abscess formation, localized necrosis and urticaria have been reported.

Antibodies to Restylane®

Presence of antibodies to hyaluronic acid tissue fillers may reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to hyaluronic acid tissue fillers is unknown.

Accidental Intra-Arterial Injection

It is extremely rare that during the course of injection, Restylane® 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 of Restylane® is unknown and not predictable.

Under /Over Correction

The injection of soft tissue fillers including Restylane® to correct wrinkles and soft tissue contour deficiencies may not achieve 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.

Migration of Restylane

Restylane 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 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 heartbeat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Unsatisfactory Result
Restylane® 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 from Restylane® injection(s). Additional Restylane® injections may be necessary. Surgical procedures or other treatments may be recommended in additional to Restylane® treatments.

Unknown Risks
The long term effect of Restylane® beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of Restylane as a soft tissue filler may be discovered.

Combination of Procedures
In some situations, Botox® injections or other types of tissue filler materials may be used in addition to Restylane® 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 Restylane® is unknown.

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

Drug Interactions
It is not known if Restylane® reacts with other drugs within the body.

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

ADDITIONAL ADVISORIES

Female Patient Information
It is important to inform your physician if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Mental Health Disorders and Elective Surgery
It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your physician, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many

individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

Sun Exposure–Direct or Tanning Salon

The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

Medications and Herbal Dietary Supplements

There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with clotting and can cause more bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Alleve. It is very important not to stop drugs that interfere with platelets, such as Plavix, which is used after a stent. It is important if you have had a stent and are taking Plavix that you inform the physician. Stopping Plavix may result in a heart attack, stroke and even death. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Travel Plans

Any surgery holds the risk of complications that may delay healing and delay your return to normal life. Please let the physician know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

-

Label FDA Issues

There are many devices, medications and injectable fillers that are approved for specific use by the FDA, but this proposed use is “Off-Label”, that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your physician believes it to be safe and effective.

Examples of commonly accepted “Off-Label” use of drugs or devices include the use of aspirin for prevention of heart disease, retinoids for skin care, and injection of botulinum toxin for wrinkles aroundthe eyes.

____ I acknowledge that I have been informed about the Off-Label FDA status of Restylane® and I understand it is not experimental and accept its use.

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 Restylane® 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 Restylane® injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Restylane® injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

FINANCIAL RESPONSIBILITIES

The cost of Restylane injection may involve several charges. This includes the professional fee for the injections, follow-up visits to monitor the effectiveness of the treatment, and the cost of the material itself. It is unlikely that Restylane injections to treat cosmetic problems would be covered by your health insurance. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome.

Additional costs may occur should complications develop from the injections and will also be your responsibility. 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.

___ I understand and unconditionally and irrevocably accept this.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed surgical 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 plastic surgeon may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the current 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.

I hereby authorize Dr._____ and such assistants as may be selected to perform the following procedure or treatment: RESTYLANE INJECTION (list the anatomic areas where Restylane will be injected)

1. I have received the following information sheet: INFORMED CONSENT – RESTYLANE INJECTION
2. I recognize that during the course of the procedure and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. 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.
4. I understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
5. I consent to be photographed or televised before, during, and after 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.
6. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
7. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical device registration, if applicable.
8. I understand that the physician's fees are separate from the anesthesia charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
9. I realize that not having the procedure is an option.

10. 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

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-10). I AM SATISFIED WITH THE EXPLANATION.

_____
Patient or Person Authorized to Sign for Patient

Date_____

Witness _____

Treatment Informed Consent

I _____, understand that I will be injected with

HYALURONIC ACID Dermal Filler in the following areas: _____

_____.

HYALURONIC ACID Dermal Filler is a resorbable hyaluronic-acid-based dermal filler approved by the United States Food and Drug Administration for the correction of moderate-to-severe facial wrinkles and folds, such as nasolabial folds.

Risks and complications that may be associated with HYALURONIC ACID Dermal Filler and the injection procedure include, but are not limited to:

1. Facial Bruising, Redness, Swelling, Itching and Pain: I understand that there is a risk of bruising, redness, swelling, itching and pain associated with the procedure. These symptoms are usually mild and last less than a week, but can last longer. Patients who are using medications that can prolong bleeding, such as aspirin, warfarin, or certain vitamins and supplements, may experience increased bruising or bleeding at the injection site.

2. Nodules, and palpable material: I understand that there is a risk that small lumps may form under my skin due to the HYALURONIC ACID filler material collecting in one area. I also understand that I may be able to feel the HYALURONIC ACID filler material in the area where the material has been injected. Any foreign material injected into the body may create the possibility of swelling or other local reactions to a filler material.

3. Accidental Injection into a Blood Vessel: I understand that HYLAURONIC ACID Dermal Filler can be accidentally injected into a blood vessel, which may block the blood vessel and cause damage of potentially large areas of distant tissue, or potentially even a heart attack, stroke or blindness.

4. Infection: As with all transcutaneous procedures, I understand that injection of any filler material carries the risk of infection.

5. History of Herpes Infection: I understand that there is a risk that injection of any filler material carries the risk of a recurrence of an outbreak of herpes (fever blisters/cold sores/shingles) and that the outbreak may be severe in nature. I have disclosed to the health care provider my medical history and, in particular, disclosed prior herpes outbreaks.

6. Allergic Reactions: I understand that HYALURONIC ACID Dermal Filler should not be used in patients with severe allergies, a history of anaphylaxis, or history or presence of multiple severe allergies or hypersensitivity to any of the ingredients in HYALURONIC ACID Dermal Filler, especially gram-positive bacterial proteins and hyaluronic acid.

7. Migration: I understand that BELOTERO BALANCE Dermal Filler, as with any filler material, may move from the place where it was injected.

8. Duration of Effect: I understand that the outcome of treatment with HYALURONIC ACID Dermal Filler will vary among patients. In some instances, additional treatments may be necessary to achieve the desired outcome.

9. Concomitant Dermal Therapies: I understand that the safety of HYALURONIC ACID Dermal Filler with concomitant dermal therapies such as epilation, UV irradiation, or laser, mechanical or chemical peeling procedures has not been evaluated in controlled clinical trials. If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with HYALURONIC ACID Dermal Filler before the skin has healed completely, there is an increased risk of inflammatory reaction at the injection site.

10. Keloids/Scarring: I understand that the safety of HYALURONIC ACID Dermal Filler in patients with known susceptibility to keloid formation or hypertrophic scarring has not been studied.

11. Pregnancy/Age: I understand that the safety of BELOTERO BALANCE Dermal Filler for use during pregnancy, in breastfeeding females or in patients under 21 years of age has not been studied.

12. Recurrent Sore Throat/Osler Rendu: I understand that the safety of HYALURONIC ACID® Dermal Filler in patients with known susceptibility to recurrent sore throat, or Osler Rendu endocarditis has not been studied.

13. Annual Treatment Volume: I understand that the safety of injecting HYALURONIC ACIDDermal Filler in volumes greater than 6.0 mL per year has not been studied.

14. Interactions: I understand that the interaction of HYALURONIC ACID Dermal Filler with drugs or other substances or implants has not been studied**.**

The above list is not meant to be inclusive of all possible risks associated with HYALURONIC ACID Dermal Filler or dermal fillers in general, as there are both known and unknown side effects and complications associated with any medication or dermal filler injection procedure. I understand that medical attention may be required to resolve complications associated with my injection.

I understand that I should minimize exposure of the treated area to the sun, heat and extreme cold weather for approximately 24 hours after treatment or until any initial swelling or redness goes away and puncture sites have healed.

I have discussed the potential risks and benefits of HYALURONIC ACID Dermal Filler with my health care provider. I understand that there is no guarantee of any particular results of any treatment.

I understand and agree that all services rendered will be charged directly to me, and I am personally responsible for payment. I further agree, in the event of non-payment, to bear the cost of collection, and/or court costs and reasonable legal fees, should they be required. By signing below, I acknowledge that I have read the foregoing informed consent, have had the opportunity to discuss any questions that I have with my doctor to my satisfaction, and consent to the treatment described above with its associated risks. I understand that I have the right not to consent to this treatment and that my consent is voluntary.

I hereby release the doctor, the person performing the BELOTERO BALANCE Dermal Filler injection and the facility from liability associated with this procedure.

_____ _____

Patient Signature Date Witness Print Name

_____ _____

Witness Signature Date Witness Address Line 1

_____

Witness Address Line 2

RADIESSE® Informed Consent

I, understand that I will be injected with RADIESSE Volumizing Filler in the following areas: .
RADIESSE® Volumizing Filler is a resorbable implant product approved by the United States Food and Drug Administration for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. Risks and complications that may be associated with RADIESSE Volumizing Filler and the implant procedure include, but are not limited to:

1. Facial Bruising, Redness, Swelling, Itching and Pain: I understand that there is a risk of bruising, redness, swelling, itching and pain associated with the procedure. These symptoms are usually mild and last less than a week but can last longer. Patients who are using medications that can prolong bleeding, such as aspirin, warfarin, or certain vitamins and supplements, may experience increased bruising or bleeding at the injection site.

2. Nodules, and palpable material: I understand that there is a risk that small lumps may form under my skin due to the RADIESSE Filler material collecting in one area. I also understand that I may be able to feel the RADIESSE Filler material in the area where the material has been injected. Any foreign material injected into the body may create the possibility of swelling or other local reactions to a filler material.

3. Nodules in Lips: I understand that RADIESSE Volumizing Filler should not be injected in the lips. There are published reports of nodules associated with the use of RADIESSE Filler injected in lips.

4. Migration: I understand that the RADIESSE Volumizing Filler, as with any filler material, may move from the place where it was injected.

5. Infection: As with all transcutaneous procedures, I understand that injection of any filler material carries the risk of infection.

6. History of Herpes Infection: I understand that there is a risk that injection of any filler material carries the risk of a recurrence of an outbreak of herpes (fever blisters/cold sores/shingles) and that the outbreak may be severe in nature. I have disclosed to the health care provider my medical history and, in particular, disclosed prior herpes outbreaks.

7. Allergic Reactions: I understand that RADIESSE Volumizing Filler should not be used in patients with severe allergies, a history of anaphylaxis, or history or presence of multiple severe allergies or hypersensitivity to any of the ingredients in RADIESSE Filler.

8. Keloids/Scarring: I understand that the safety of RADIESSE Volumizing Filler in patients with known susceptibility to keloid formation or hypertrophic scarring has not been studied.
9. Accidental Injection into a Blood Vessel: I understand that RADIESSE Volumizing Filler can be accidentally injected into a blood vessel, which may block the blood vessel and cause local tissue damage, or potentially even a heart attack or stroke.
10. Radio-opacity: I understand that RADIESSE Volumizing Filler is radio-opaque and is visible on CT Scans and may be visible in x-rays.

11. Duration of Effect: I understand that the outcome of treatment with RADIESSE Volumizing Filler will vary among patients. In some instances, additional treatments may be necessary to achieve the desired outcome.

12. Concomitant Dermal Therapies: I understand that the safety of RADIESSE injectable implant with concomitant dermal therapies such as epilation, UV irradiation, or laser, mechanical or chemical peeling procedures has not been evaluated in controlled clinical trials. The application of laser or other energy-based treatments within weeks of RADIESSE treatment is not recommended as such treatments may alter the characteristics of RADIESSE injectable implant. If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with RADIESSE injectable implant, there is a possible risk of eliciting an inflammatory reaction at the implant site. This also applies if RADIESSE injectable implant is administered before the skin has healed completely after such a procedure.

No studies of interactions of RADIESSE Volumizing Filler with drugs or other substances or implants have been conducted.

This above list is not meant to be inclusive of all possible risks associated with RADIESSE Volumizing Filler or dermal fillers in general, as there are both known and unknown side effects and complications associated with any medication or dermal filler injection procedure. I understand that medical attention may be required to resolve complications associated with my injection.

I understand that I should minimize exposure of the treated area to the sun or heat for approximately 24 hours after treatment or until any initial swelling or redness goes away. The safety of RADIESSE Volumizing Filler for use during pregnancy or in breastfeeding women has not been established.

I have discussed the potential risks and benefits of RADIESSE Volumizing Filler with my doctor. I understand that there is no guarantee of any particular results of any treatment. I understand and agree that all services rendered will be charged directly to me, and I am personally responsible for payment. I further agree, in the event of non-payment, to bear the cost of collection, and/or court costs and reasonable legal fees, should they be required. By signing below, I acknowledge that I have read the foregoing informed consent, have had the opportunity to discuss any questions that I have with my doctor to my satisfaction, and consent to the treatment described above with its associated risks. I understand that I have the right not to consent to this treatment and that my consent is voluntary. I hereby release the doctor, the person performing the RADIESSE Filler injection and the facility from liability associated with this procedure.

_____ _____

Patient Signature **Date**

DEVELOPMENT & APPROVAL OF STANDARDIZED PROCEDURE

The Clinical Policies and Procedures for the Administration of DERMAL FILLERS have been developed jointly by the Medical Director, Administrator, Advanced Practice Nurse and/or Registered Nurse. This procedure shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

_____ _____

Nurse Date

_____ _____

Medical Director Date

_____ _____

Administrator Date

PERSONNEL AUTHORIZED TO PERFORM PROCEDURE

NAME	DATE
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____