

BELOTERO BALANCE® Treatment Informed Consent

I, _____ understand that I will be injected with BELOTERO BALANCE Dermal Filler in the following areas: _____

BELOTERO BALANCE 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 BELOTERO BALANCE 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 BELOTERO BALANCE filler material collecting in one area. I also understand that I may be able to feel the BELOTERO 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 BELOTERO BALANCE 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 BELOTERO BALANCE 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 BELOTERO BALANCE 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 BELOTERO BALANCE 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 BELOTERO BALANCE 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 BELOTERO BALANCE 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 BELOTERO BALANCE® 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 BELOTERO BALANCE® 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 BELOTERO BALANCE Dermal Filler in volumes greater than 6.0 mL per year has not been studied.
- 14. Interactions:** I understand that the interaction of BELOTERO BALANCE 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 BELOTERO BALANCE 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 BELOTERO BALANCE 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