THE FACE OF COOL

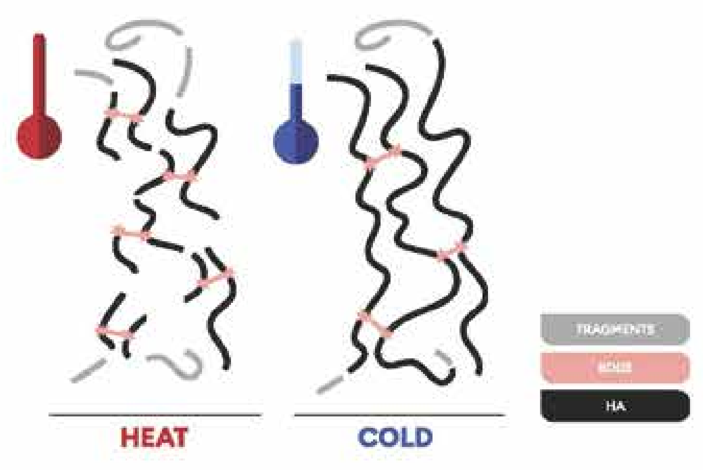
The First Advanced Injectable Hyaluronic Acid Technology Launched in a Decade

Evolysse™ is the next-generation injectable hyaluronic acid made with Cold-X™ Technology.

Evolysse Smooth and Evolysse Form soften wrinkles that form in dynamic areas of the face, such as the nasolabial folds.

Evolysse™ by evolus

Cold-X Technology: Temperature Matters



Preserve

Cold-X Technology uses near-freezing temperatures aimed at preserving the natural structure of the HA molecule.

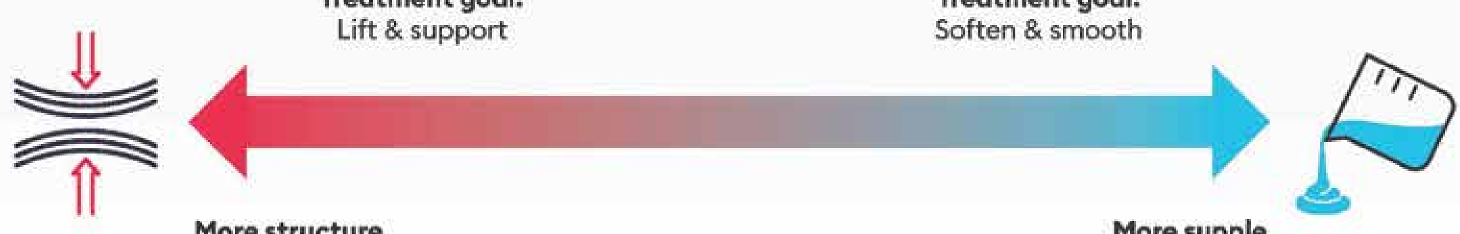
Perform

This results in a gel with desirable viscoelastic properties that performs in the treatment area and is designed to feel natural in the facial tissues.

Designed to Achieve a Range of Treatment Goals for Dynamic Facial Wrinkles or Folds

Evolysse Form
Treatment goal:
Lift & support

Evolysse Smooth
Treatment goal:
Soften & smooth



More structure | **More supple**

The Results Are Clear

Evolysse Form

BEFORE | ~~Aeeeeeeee ER~~

Actual patient. Individual results may vary. 1 mL in the nasolabial fold. 12 months after treatment.

Evolysse Smooth

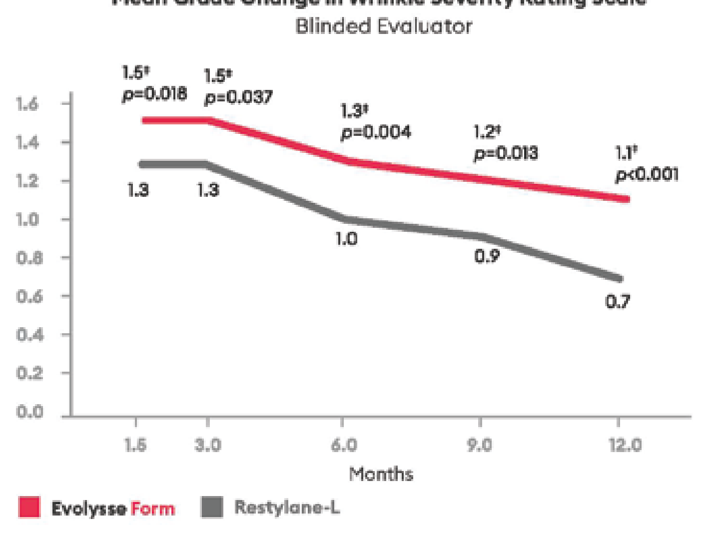
BEFORE | AFTER

Actual patient. Individual results may vary. 1.3 mL in the nasolabial fold. 9 months after treatment.

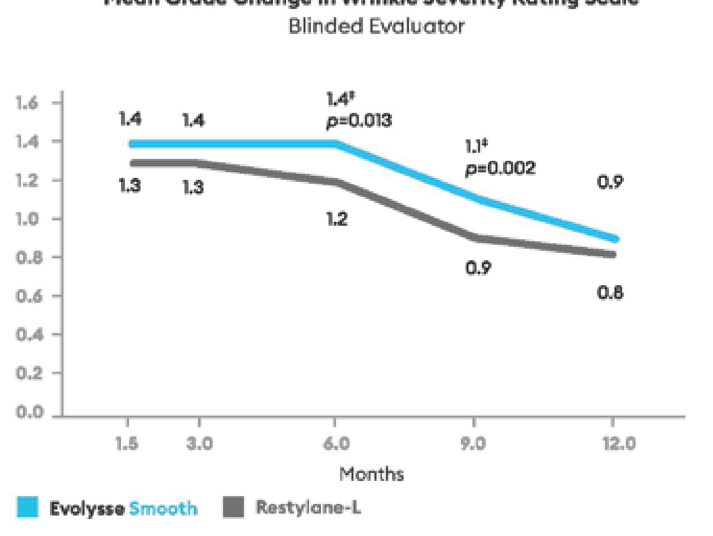
Proof From the Pivotal Clinical Study*

Both **Evolysse Form** and **Evolysse Smooth** met the primary endpoint of non-inferiority vs Restylane-L[†] with corresponding p-values <0.001[1,2]

Mean Grade Change in Wrinkle Severity Rating Scale
Blinded Evaluator



Mean Grade Change in Wrinkle Severity Rating Scale
Blinded Evaluator



Evolysse Form showed statistically significant differences[§] compared to Restylane-L at all measured timepoints for the entire 12-month study period[2]

Evolysse Smooth showed statistically significant differences[§] compared to Restylane-L at 6 and 9 months—**even though 20% more Restylane-L was used**[1]

*Study design: a double-blind, prospective, randomized, active control pivotal study consisting of split-face treatment for 2 arms (140 total participants). In arm 1, 70 participants received split-face treatment of Evolysse Form in 1 nasolabial fold (NLF) vs control (Restylane-L) in the other NLF; in arm 2, 70 participants received Evolysse Smooth in 1 NLF vs control (Restylane-L) in the other NLF.

†The primary endpoint was non-inferiority vs control at 6 months as determined by a photographic review panel using the WSRS. Non-inferiority at 6 months based on the primary endpoint analysis for Evolysse Form (95% CI [-0.500, -0.032], p<0.001) and primary endpoint analysis for Evolysse Smooth (95% CI [-0.416, -0.019], p<0.001).

‡Statistically significant.

§Based on Wrinkle Severity Rating Scale Blinded Evaluator assessments.

CI=confidence interval.

Safety Is Cool[1,2]

In the head-to-head clinical study vs Restylane-L, there were no delayed onset nodules with Evolysse Form or Evolysse Smooth.

The most common side effects were temporary and at the injection site, such as tenderness, swelling, bruising, pain, redness, and lumps. Most common treatment responses were mild or moderate and resolved within 1 week. All treatment-emergent adverse events were mild to moderate in severity.

References: 1. Evolysse Smooth Directions for Use. Newport Beach, CA: Evolus, Inc. 2025. **2.** Evolysse Form Directions for Use. Newport Beach, CA: Evolus, Inc. 2025.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

EVOLYSSE™ SMOOTH and EVOLYSSE™ FORM are indicated for dermal and subdermal injection to correct moderate to severe dynamic facial wrinkles and folds (such as nasolabial folds) in adults 22 years and older.

IMPORTANT SAFETY INFORMATION

Contraindications

These products should not be used in patients who have severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies, and should not be used in patients with a history of allergies to Gram-positive bacterial proteins or lidocaine.

Warnings

- Do not inject into blood vessels. Introduction of these products into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care during injection (e.g., after insertion of the needle and just before injection, withdraw plunger rod slightly to aspirate and verify the needle is not intravascular, inject the product slowly, apply the least amount of pressure necessary). Rare but serious adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported, and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms: changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate healthcare specialist should an intravascular injection occur.
- Defer use of these products at specific sites with an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection until the underlying process has been controlled.

Precautions

- EVOLYSSE products should only be used by healthcare professionals who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the injection site.
- Discuss all potential risks of EVOLYSSE injections, including signs of potential complications, with patients prior to treatment.
- The safety and effectiveness for the treatment of other areas have not been established in controlled clinical studies.
- The safety for use in sites with proximity to other implants (including permanent implants) has not been studied.
- Injection into patients with a history of facial herpetic eruption may reactivate herpes infection.
- The safety for use during pregnancy, breastfeeding, or in patients under 22 years has not been established.
- The safety in patients with known susceptibility to keloid formation, hypertrophic scarring, or pigmentation disorders has not been studied.
- Use with caution in patients with an autoimmune disorder or on immunosuppressive therapy.
- Patients taking medication that can prolong bleeding (e.g., aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at injection sites.
- Treatment carries a risk of infection. Follow standard precautions.
- If laser treatment, chemical peeling, or any other procedure based on an active dermal response is considered after treatment, or before the skin has healed after such procedures, there is a possible risk of eliciting an inflammatory reaction at the implant site.
- Patients may experience late onset adverse events with use of soft tissue fillers.
- EVOLYSSE products contain lidocaine. Use with caution if local anesthetics are used concurrently.
- Injection of EVOLYSSE products too superficially or in areas with limited soft tissue support or thin skin may result in skin contour irregularities, palpable lumps, and/or bluish discoloration.
- Advise patients to minimize exposure of the treated area to extreme temperatures (e.g., intense cold or sauna) until any local inflammation has resolved.

Adverse Events

The most common reported side effects for EVOLYSSE products were tenderness, swelling, lumps, bruising, redness, pain, discoloration, and itching. The majority were mild or moderate in severity.

To report an adverse event with any EVOLYSSE product, please contact Evolus Customer Experience at 1-877-386-5871. Please visit www.EvolusRx.com for more information.

EVOLYSSE products are available only by a licensed physician or properly licensed practitioner.

Please see Directions for Use at www.EvolusRx.com

Want to Learn More?

Evolysse™ by evolus

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US-EVY-2500035