

Galderma Announces FDA Approval of *Restylane*[®] Silk as the First HA Dermal Filler Approved for Injection via Cannula

New Injection Technique Seeks to Increase Treatment Options for Aesthetic Professionals Providing the Highly-rated Lip Filler¹

Fort Worth, TX – (October 12, 2017) – Galderma, a global leader focused on medical solutions in skin health, announced today it has received U.S. Food and Drug Administration (FDA) approval for the use of a small blunt tip cannula with *Restylane*[®] Silk for lip augmentation.² *Restylane*[®] Silk was the first FDA-approved hyaluronic acid (HA) dermal filler specifically designed for lip augmentation and the smoothing of wrinkles around the mouth in patients 21 years of age and older and is now the first HA dermal filler to be approved for lip injection via cannula.² A small blunt tip cannula is a thin, flexible tube with a small opening on the side that can provide an effective means to inject HA dermal fillers in the lips.³ This approval for *Restylane*[®] Silk expands the array of approved lip injection techniques for medical professionals.

“In the ever-evolving landscape of aesthetic procedures, medical professionals are continuously looking for new tools and treatment options to ensure our patients are receiving optimal treatment outcomes for their specific needs,” said Sabrina Fabi, MD, a San Diego-based Dermatologist. “The ability to use a cannula is a welcome addition to my toolkit, as studies have shown that a small blunt tip cannula demonstrates a suitable safety profile, while achieving the desired fullness to the upper and lower lips.”

“A commitment to continuous innovation in support of aesthetic professionals to achieve high patient satisfaction with natural looking results is our core focus,” said Alisa Lask, VP & General Manager of Galderma’s U.S. Aesthetic & Corrective business. “The *Restylane*[®] family currently offers the broadest offering of HA facial dermal fillers in the U.S. With the launch of *Restylane*[®] Refyne and *Restylane*[®] Defyne earlier this year and this new approval, 2017 is an exciting year for patients and aesthetic professionals who use the *Restylane*[®] brands.”

About the Cannula Study²

The multicenter, open-label, prospective study was conducted to assess the safety and efficacy of *Restylane*[®] Silk in conjunction with the use of a small blunt tip cannula for lip augmentation. The 12-week study took place in four centers across the U.S., with 60 male and female subjects

23 years of age or older. At 12 weeks, 98 percent of subjects were observed to have improvement in both the upper and lower lip by the treating investigator, as assessed by the Global Aesthetic Improvement Scale (GAIS), a global 7-point scale for aesthetic improvement in appearance.

Following treatment, no severe related adverse events were observed. Furthermore, a vast majority of subjects (81.7 percent) did not experience a treatment emergent adverse event (TEAE). The majority of reported subject diary symptoms were assessed as mild, with the exception of swelling, and the vast majority of all subject diary symptoms were resolved within seven days.

About Restylane®

With over 30 million treatments worldwide and counting⁴, the *Restylane*® family of hyaluronic acid dermal fillers is used to help smooth facial wrinkles and folds, such as nasolabial folds (*Restylane*®-L, *Restylane*® Refyne, *Restylane*® Defyne and *Restylane*® Lyft with Lidocaine), create fuller and more accentuated lips (*Restylane*® Silk and *Restylane*®-L), and add lift and volume to the cheeks (*Restylane*® Lyft with Lidocaine). All *Restylane*® products work to enhance facial features and give long-lasting, yet non-permanent results.

To learn more about the *Restylane*® family of products, visit www.RestylaneUSA.com.

About Galderma

Galderma, Nestlé Skin Health's medical solutions business, was created in 1981 and is now present in over 100 countries with an extensive product portfolio to treat a range of dermatological conditions. The company partners with health care practitioners around the world to meet the skin health needs of people throughout their lifetime. Galderma is a leader in research and development of scientifically-defined and medically-proven solutions for the skin, hair and nails.

Strategic brands in the U.S. include Epiduo® Forte Gel, Oracea® Capsules, Mirvaso® Gel, Soolantra® Cream, Cetaphil®, Differin® Gel OTC, *Restylane*®, *Restylane*® Silk, *Restylane*® Lyft with Lidocaine, *Restylane*® Refyne, *Restylane*® Defyne, Dysport® and Sculptra® Aesthetic.

For more information, please visit www.galdermausa.com and www.galderma.com.

To earn exclusive rewards, bonuses and discounts on Galderma's aesthetic treatments, join the ASPIRE Galderma Rewards program. To learn more about ASPIRE, visit www.aspirerewards.com.

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Important Safety Information

The *Restylane* family of products includes *Restylane*[®], *Restylane-L*[®], *Restylane*[®] *Lyft with Lidocaine*, *Restylane*[®] *Silk*, *Restylane*[®] *Refyne*, and *Restylane*[®] *Defyne*.

APPROVED USES

Restylane[®] and *Restylane-L*[®] are for mid-to-deep injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. *Restylane*[®] and *Restylane-L*[®] are also indicated for injection into the lips in patients over the age of 21.

Restylane[®] *Lyft with Lidocaine* is for deep implantation into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and for cheek augmentation and for the correction of age-related midface contour deficiencies in patients over the age of 21.

Restylane[®] *Silk* is for lip augmentation and for correction of perioral wrinkles in patients over the age of 21.

Restylane[®] *Refyne* is for mid-to-deep injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in patients over the age of 21.

Restylane[®] *Defyne* is for mid-to-deep injection into the facial tissue for the correction of moderate to severe deep facial wrinkles and folds, such as nasolabial folds, in patients over the age of 21.

Are there any reasons why I should not use products within the *Restylane*[®] family? (Contraindications)

To ensure a safe procedure, your doctor will talk to you about your medical history to determine if you are an appropriate candidate for treatment. You should not use products within the *Restylane* family if:

- You have severe allergies with a history of severe reactions (anaphylaxis)
- You are allergic to lidocaine or to any of the gram-positive bacterial proteins used to make hyaluronic acid
- You are prone to bleeding or have been diagnosed with a bleeding disorder

Are there other precautions that I should discuss with my doctor?

- Tell your doctor if you are breastfeeding, pregnant, or trying to become pregnant. The safety of these products for use during pregnancy, or in women who are breastfeeding, has not been studied
- *Restylane, Restylane-L, Restylane® Lyft with Lidocaine, Restylane Refyne and Restylane Defyne* are intended to treat facial wrinkles and folds, such as nasolabial folds. *Restylane* and *Restylane-L* are also intended for lip enhancement. Treatments in other areas of the face have not been evaluated in clinical studies.
- The safety and effectiveness of *Restylane® Silk* for areas other than the lips and perioral area have not been evaluated in clinical studies
- Tell your doctor if you have any history of scarring, particularly thick and stiff scars, or any pigmentation (skin color) disorders. These side effects can occur with hyaluronic acid fillers in general.
- Tell your doctor if you are planning other laser treatments or a chemical peel, as there is a possible risk of inflammation at the treatment site if these procedures are performed after treatment
- Patients who experience skin injury near the site of injection with these products may be at a higher risk for side effects
- Tell your doctor if you are on any medications to decrease your body's immune response (immunosuppressive therapy). Using these medications may increase your risk of bruising or bleeding at the gel injection site.
- Tell your doctor if you are using any "blood thinners" such as aspirin, warfarin, or any other medications that affect bleeding. Using these medications may increase your risk of bruising or bleeding at the gel injection site.
- The use of these products on gel injection sites with skin sores, pimples, rashes, hives, cysts, or infections should be postponed until healing is complete. Use of product in these areas could delay healing or make your skin problems worse.

What are the possible side effects?

The most commonly observed side effects are swelling, redness, pain, bruising, headache, tenderness, lump formation, and itching at the injection site. These are typically mild in severity and typically resolve in less than 7 days in nasolabial folds and less than 14 days in lips. Serious but rare side effects include delayed onset infections, recurrence of herpetic eruptions, and superficial necrosis at the injection site.

One of the risks with using this product is unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin.

As with all skin injection procedures, there is a risk of infection.

To report a side effect with any of the *Restylane* products, please call Galderma Laboratories, L.P. at 1-855-425-8722.

The *Restylane* family of products is available only through a licensed practitioner. Complete Instructions for Use are available at www.RestylaneUSA.com.

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¹ RealSelf.com. “*Restylane*® Silk” Accessed on July 13, 2017. Retrieved from:

<https://www.realself.com/restylane-silk>

²*Restylane*® Silk via Cannula Instructions for Use. Fort Worth, TX: Galderma Laboratories, L.P., 2017.

³ Zeichner, JA & Cohen, JL. Use of Blunt Tipped Cannulas for Soft Tissue Fillers. *J Drugs Dermatol.* 2012;11(1):70-72. <http://jddonline.com/articles/dermatology/S1545961612P0070X/1>

⁴ Data on file. Global Launch Learnings. Fort Worth, TX: Galderma Laboratories, L.P., 2016.