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Allergan gets FDA nod for Juvéderm VOLUMA XC

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FDA approval for the use of Juvéderm VOLUMA® XC, a hyaluronic acid gel dermal filler for Mid-Face Injection Via Cannula

Allergan plc has received U.S. Food and Drug Administration (FDA) approval for the use of Juvéderm VOLUMA® XC, a hyaluronic acid gel dermal filler, with a TSK STERiGLIDE™ cannula for cheek augmentation to correct age-related volume deficit in the mid-face in adults over 21. A cannula is a thin, flexible tube with a rounded tip that can serve as an effective delivery system. Use of a cannula allows for injection of Juvéderm VOLUMA® XC in the cheek area. The TSK STERiGLIDE™ has a unique design compared to other cannulas available on the market and features a patented tip design with a near-tip delivery port for precise product placement.

"As a physician, I have used the Juvéderm Collection of Fillers for 13 years, so I am thrilled that the FDA has approved the use of cannula with Juvéderm VOLUMA® XC for mid-face volume deficit. With this latest approval, I have another effective option to provide volume and contour in the mid-face area. I can tailor my treatment approach for each patient while safely providing the aesthetic outcomes they wish to achieve," says Dr. Dee Anna Glaser, a board-certified dermatologist in St. Louis and clinical trial investigator.

"At Allergan, we are committed to driving innovation in medical aesthetics as well as providing best-in-class injector training to our customers," says Carrie Strom, Senior Vice President of U.S. Allergan Medical Aesthetics. "With this approval, Allergan will be able to educate on facial anatomy and injection techniques that will help healthcare providers administer treatment with Juvéderm VOLUMA® XC safely to achieve optimal patient satisfaction."

A multicenter, split-face, investigator-blinded, non-inferiority study was performed to assess the safety and effectiveness of Juvéderm VOLUMA® XC for correction of age-related volume deficit in the mid-face with the use of a TSK STERiGLIDE™ cannula versus a needle. The 12-week study took place in seven sites across the U.S. with 60 subjects. All subjects completed the study. Results demonstrated comparable performance, safety profile and patient satisfaction between cannula and needle injection.

Within the Juvéderm Collection of Fillers, this is the first approval for the use of cannula. Juvéderm VOLUMA® XC was first

approved by the FDA in 2013 and is formulated with Allergan's proprietary VYCROSS® technology, which blends different molecular weights of hyaluronic acid, contributing to the gel's duration and is proven to last in the mid-face area for up to 24 months with optimal treatment. Juvéderm VOLUMA® XC is currently the best-selling Juvéderm product in the US.