U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Adverse Events Associated with Use of Enhancement Medical's "Expression" Intranasal Splint as a Dermal Filler

Date Issued: August 5, 2014

Audiences:

- Consumers considering a procedure using a dermal filler (also known as a "wrinkle filler" or "soft tissue filler")
- Health care providers who are licensed to inject dermal fillers
- Professional societies with a focus on augmentation and reconstruction related medical procedures

Specialties: Dermatologists, Plastic Surgeons, Dentists, Nurses, Physician Assistants, Certified Medical Assistants, Aestheticians

Product:

Expression, manufactured by Enhancement Medical LLC, is listed with the FDA as an intranasal splint, and is intended to minimize bleeding and swelling and to prevent adhesions (sticking together) between the septum and the nasal cavity. Intranasal splints are placed in the nasal cavity after surgery or trauma and are usually constructed from plastic, silicone, or absorbent material.

Expression consists of hyaluronic acid that is packaged in a syringe. When used as an intranasal splint the hyaluronic acid gel functions as a protective lubricating gel, a use that presents low risk to patients. FDA has received reports of Expression being used as a dermal filler to fill in wrinkles on the face. Expression has not been approved for this use. Other devices approved for this use as dermal are class III devices, meaning they pose a higher risk to patient safety.

Purpose:

The FDA has become aware of adverse events associated with the unapproved use of the Expression product as a dermal filler. The FDA has not approved this product for use as a dermal filler and recommends that health care providers stop using Expression by Enhancement Medical LLC as a subcutaneously administered substance.

Summary of Problem and Scope:

The FDA has become aware of adverse events associated with the use of Expression (also known as Expression Injectable) as a dermal filler. These events have included swelling, tenderness, firmness, lumps, bumps, bruising, pain, redness, discoloration, itching, and the development of hard nodules.

The FDA has received a report of a patient developing firm masses in the face after being injected with the Expression product, which was used as a dermal filler. An attempt was made to dissolve the masses, but the report notes that the patient was left with an "obvious deformity."

Although Expression contains components similar to FDA-approved dermal fillers, all FDA-approved injectable dermal fillers are class III (high-risk) medical devices and manufacturers are required to submit a premarket application, that includes clinical data supporting safety and effectiveness, for the FDA's review prior to marketing the dermal filler in the United States. The FDA has not received or reviewed data on the safety and effectiveness of Expression for use as a dermal filler. While the adverse events reported appear similar to those that may arise from injection with FDA-approved dermal fillers, without reviewing clinical data supporting the safety and effectiveness the cannot not fully understand the nature, severity, or rate of occurrence of adverse events associated with Expression and has no assurance of this product's safety or effectiveness when used as a dermal filler.

For the reasons noted above the FDA recommends health care providers stop using Expression as a dermal filler.

Recommendations:

For People Undergoing Procedures that Use Dermal Fillers:

- Only receive dermal filler injections from a licensed health care provider.
- Ask your health care provider if the dermal filler they are using is **FDA-approved (/MedicalDevices/ProductsandMedicalProcedures/CosmeticDevices/WrinkleFillers/ucm227749.htm)** and appropriate for the procedure you are undergoing.
- Discuss the possibility of adverse reactions to dermal fillers with your health care provider.
- If you received a dermal filler injection and are experiencing adverse events (i.e., swelling, tenderness, firmness, lumps, bumps, bruising, pain, redness, discoloration, itching, and the development of hard nodules), contact your health care provider.
- If you have already received treatment with Expression as a dermal filler, discuss appropriate monitoring with your health care provider.

For Health Care Providers:

- Discontinue use of Expression from Enhancement Medical as a dermal filler.
- When choosing a dermal filler, use the list of **FDA-approved fillers (/MedicalDevices/ProductsandMedicalProcedures/CosmeticDevices/WrinkleFillers/ucm227749.htm)**.
- If you are aware of a patient who has received treatment with Expression as a dermal filler, monitor them for adverse events and refer them for corrective treatment when appropriate.
- If you become aware of a patient experiencing an adverse event related to the use of Expression, please **report the event to the FDA (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)**.

FDA Activities:

The FDA issued a **warning letter to Enhancement Medical LLC (/ICECI/EnforcementActions/WarningLetters/2014/ucm400813.htm)** on June 4, 2014, advising the company of multiple quality system, correction/removal, and medical device reporting violations that were revealed during an inspection.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

If you suspect or experience a problem with Expressions from Enhancement Medical LLC, we encourage you to file a voluntary report through **MedWatch, the (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)FDA Safety Information and Adverse Event Reporting program (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)**. Health care personnel employed by facilities that are subject to **FDA's user facility reporting requirements (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)** should follow the reporting procedures established by their facilities.

Contact Information:

If you have questions about this communication, please contact the Division of Industry Communication and Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041, or 301-796-7100.

Other Resources

- **FDA-Approved Dermal Fillers (/MedicalDevices/ProductsandMedicalProcedures/CosmeticDevices/WrinkleFillers/ucm227749.htm)**
- **A Consumer's Guide to Reporting Problems to FDA (/ForConsumers/ConsumerUpdates/ucm095859.htm)**