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

# Unintentional Injection of Soft Tissue Filler into Blood Vessels in the Face: FDA Safety Communication

**Date Issued:** May 28, 2015

**Audiences:**

- Health care providers who inject patients with facial soft tissue fillers
- Health care providers who treat patients following unintentional injection of soft tissue fillers into blood vessels
- People considering, or who have had, procedures that use soft tissue fillers

**Specialties:** Dermatologists, plastic surgeons, cosmetic surgeons, dentists, and other medical providers who treat patients using soft tissue fillers; other health care providers who may treat patients following unintentional injection of soft tissue filler into blood vessels, such as ophthalmologists, neurologists, and neurosurgeons.

**Product:**
Soft tissue fillers, also called dermal fillers, injectable facial implants, or wrinkle fillers, can create a smoother or fuller appearance of the face. They are FDA-approved to reduce the appearance of wrinkles or to augment lips or cheeks.

Soft tissue fillers are injected directly into a treatment area. Successful results will depend on the patient's overall health and skin condition, the skill of the health care provider, the location of injection and the type of filler used. Patients may need more than one injection to get the desirable smoothing/filling effect.

Soft tissue fillers should be injected only by health care providers who have appropriate training and experience and who are knowledgeable about the anatomy at and around the injection site.

**Purpose:**
The FDA is alerting health care providers and consumers about the possibility of rare, but serious, injuries that may occur due to unintentional injection of soft tissue filler into blood vessels in the face.

**Summary of Problem and Scope:**
The FDA has reviewed information that suggests unintentional injection of soft tissue fillers into blood vessels in the face can result in rare, but serious side effects. Unintentional injection can block blood vessels and restrict blood supply to tissues. Sometimes this can result in embolization. This means the filler material has traveled to other parts of the body. This can cause vision impairment, blindness, stroke and damage and/or death of the skin (necrosis) and underlying facial structures.

While unintentional injections into blood vessels may occur with injection sites anywhere on the face, the FDA's review of **literature (http://asj.oxfordjournals.org/content/33/6/862.abstract)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** and adverse event reports submitted to the FDA identifies certain injection locations where blood vessel blockage have been reported more often. These sites include the skin between the eyebrows and nose (glabella), in and around the nose, forehead, and around the eyes (periorbital region).

**Recommendations:**

**For Health Care Providers:**

- Do not inject soft tissue fillers if you do not have the appropriate training or experience.
- Make sure that you are familiar with the anatomy at and around the site of injection, keeping in mind that **blood vessel anatomy (http://journals.lww.com/plasreconsurg/Citation/2014/05000/Discussion New Anatomical Insights on the Course.6.aspx)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** can vary among patients.

- Before injection, thoroughly inform the patient of all risks of the procedure and the specific product you intend to use.
- Note that the **approved indications (/MedicalDevices/ProductsandMedicalProcedures/CosmeticDevices/WrinkleFillers/ucm227749.htm)** for use of soft tissue fillers vary depending on the product. The FDA may not have reviewed use of soft tissue fillers in some locations in the body.
- Take extra care when injecting soft tissue fillers, for example inject the product slowly and apply the least amount of pressure necessary.
- Know the **signs and symptoms (http://asj.oxfordjournals.org/content/33/6/862.abstract) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** associated with injection into blood vessels, and have an updated plan detailing how you plan to treat the patient if this should this occur. This may include on-site treatment and/or immediate referral to another health care provider for treatment.
- Immediately stop the injection if a patient exhibits any signs or symptoms associated with injection into a blood vessel, such as changes in vision, signs of a stroke, white appearance (or blanching) of the skin, or unusual pain during or shortly after the procedure.
- Tell patients that they should seek immediate medical attention after the procedure if they experience signs and symptoms associated with injection into a blood vessel.
- Educate health care facility employees on how to quickly assist patients that report signs and symptoms of filler complications. They must understand how to instruct the patient to receive appropriate medical care.
- **Report to the FDA** and the manufacturer if you become aware of a patient experiencing an adverse event associated with unintentional injection of soft tissue filler into a blood vessel.

**For Consumers:**

- Before deciding to have soft tissue filler injections, talk with your health care provider about appropriate treatment injection sites and the risks associated with the procedure.
- Be aware that FDA reviewed and **approved (/MedicalDevices/ProductsandMedicalProcedures/CosmeticDevices/WrinkleFillers/ucm227749.htm)** different products for use in certain areas of the face. The FDA may not have reviewed the use of certain soft tissue fillers for all locations in the body.
- Ask your health care provider about their training and experience injecting soft tissue fillers in the face.
- Read and discuss the patient labeling for the specific filler you are receiving. Your doctor can provide this information, or you can find it on the **FDA's website (/MedicalDevices/ProductsandMedicalProcedures/CosmeticDevices/WrinkleFillers/ucm227749.htm)**.
- Seek immediate medical attention if you develop symptoms such as unusual pain, vision changes, a white appearance of skin near the injection site, or any **signs of a stroke (http://www.nlm.nih.gov/medlineplus/stroke.html)** (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion) during or shortly after the procedure.

**FDA Actions:**

After reviewing additional information on this subject, the FDA is working with manufacturers to update their labeling. The requests asks that the labeling include additional warnings, precautions, and other statements about the risk of unintentional injection into blood vessels, consistent with the recommendations in this communication, so that both health care providers and patients would have a better understanding of the risks.

The FDA continuously monitors reports of injuries caused by soft tissue fillers. With the increased popularity of soft tissue fillers, more information is available about unintentional injection into blood vessels. While current labeling includes some information about this risk, the FDA believes that additional information can be included in the labeling to better inform health care providers and patients.

**Reporting Problems to the FDA:**

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

If you suspect or experience a problem with soft tissue fillers, we encourage you to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**. Health care personnel

employed by facilities that are subject to **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

**Additional Resources**

- **Soft Tissue Fillers (Dermal Fillers) (/MedicalDevices/ProductsandMedicalProcedures/CosmeticDevices/WrinkleFillers/UCM2007470.htm)**
- **Soft Tissue Fillers Labeling Request Letter to Industry (/downloads/MedicalDevices/ResourcesforYou/Industry/UCM448274.pdf)**
- Carruthers, J., Fagien, S., Rohrich, R., Weinkle, S., & Carruthers, A. (2014). **Blindness caused by cosmetic filler injection: a review of cause and therapy (http://journals.lww.com/plasreconsurg/Abstract/2014/12000/Blindness_Caused_by_Cosmetic_Filler_Injection__A.16.aspx)** *(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)*. *Plastic & Reconstructive Surgery*.
- Ozturk, C. N., Li, Y., Tung, R., Parker, L., Piliang, M. P., & Zins, J. E. (2013). **Complications Following Injection of Soft Tissue Fillers (http://asj.oxfordjournals.org/content/33/6/862.abstract) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**. *Aesthetic Surgery Journal*, 862-877.
- Carruthers, J. (2014). **Discussion: New Anatomical Insights on the Course and Branching Patterns of the Facial Artery: Clinical Implications of Injectable Treatments to the Nasolabial Fold and Nasojugal Groove (http://journals.lww.com/plasreconsurg/Citation/2014/05000/Discussion__New_Anatomical_Insights_on_the_Course.6.aspx) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**. Plastic & Reconstructive Surgery, 1083-1084

**Contact Information:**

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


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