

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

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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://asi.oxfordjournals.org/content/33/6/862.abstract) (<http://asi.oxfordjournals.org/content/33/6/862.abstract>) and (<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 (periocular 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) (<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.