

FDA warns against using at-home dermal filler 'pens'

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(HealthDay)—Plumped-up lips, wrinkle-free foreheads—they're all part

of the promise of dermal fillers, most reliably received at a cosmetic surgeon's clinic.

But cheaper, unapproved "at home" dermal filler pens, bought without a prescription, are another much more dangerous option, according to the U.S. Food and Drug Administration.

These pen devices use [high pressure](#) to force dermal filler into the body without a needle.

"The FDA's priority is protecting patients, who may not be aware of the serious adverse events that have been reported in connection with their use, such as permanent damage to the skin, lips and eyes," Dr. Binita Ashar said in an agency news release. She directs the Office of Surgical and Infection Control Devices in FDA's Center for Devices and Radiological Health.

Seeking to bypass more expensive—but much safer—injections from trained professionals, some consumers are using the over-the-counter devices to reduce wrinkles, increase lip volume or change the shape of the nose. Users typically fill the "pen" with a product that's bought separately.

But Ashar said her agency "is warning the public and [health care professionals](#) not to use needle-free devices such as hyaluron pens for injection of hyaluronic acid or other lip and facial fillers, collectively and commonly referred to as dermal fillers or fillers."

"These unapproved needle-free devices and fillers are often sold directly to customers online, bypassing consultation with a licensed health care provider, a critical safety measure for patients to make informed decisions about their personal health," she said.

Want to get dermal fillers? Then stick to procedures done in a clinical setting by licensed [health care providers](#) using FDA-approved fillers with needles or cannulas (thin tubes), the FDA advised.

One [plastic surgeon](#) applauded the FDA's stance.

"I do not support the use of this injector product," said Dr. Thomas Romo III, a plastic and facial reconstructive surgeon at Lenox Hill Hospital in New York City.

"The FDA is monitoring online platforms for these unapproved needle-free devices as well as dermal fillers intended for use with needle-free injection devices," Romo said. He believes there are many factors upping the danger for consumers who try them.

"First, using pressure instead of a needle to force Dermal Fillers through the skin can cause local skin reactions and problems," Romo said. "This includes bruising, swelling, blocked blood vessels and permanent skin or lip loss."

Uneven, unsightly results can occur because the pen devices simply aren't precise enough, he explained.

"Pressure causes the product to go into the area of least resistance," Romo said, and that "can cause bumps and asymmetry of the lip." People using them at home may not understand the anatomy of parts of the face such as the mouth and lips.

"Also, sterile cleaning is necessary between injected individuals and this may not be performed in nonprofessional settings," Romo added. "This could lead to blood-borne infections like hepatitis and AIDS."

According to the FDA's Ashar, some of the outcomes following on the

use of unapproved products like dermal filler pens "may be irreversible."

More information: Harvard Medical School has more on [dermal fillers](#).

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