

US FDA Safety Communication on Illegal use of Injectable Silicone for Body Contouring and Associated Health Risks

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The US Food and Drug Administration (FDA) issued a safety communication warning consumers and healthcare professionals about serious injury and disfigurement resulting from injectable silicone or silicone products that are falsely marketed as FDA-approved dermal fillers to enhance the size of your buttocks, breasts, and other body parts [1].

We are concerned about unsafe permanent injectables, silicone, oils, and PMMA being marketed for body contouring by unlicensed providers. We have seen serious adverse events as a result from these products, sometimes from industrial-grade silicone, being used for unapproved medical purposes [2–5]

Consumers should be aware that injectable silicone used for body contouring is not FDA-approved and can cause serious side effects that can be permanent, or may even lead to death. Side effects can include ongoing pain and serious injuries, such as scarring, tissue death, and permanent disfigurement; if the silicone migrates beyond the injection site, it could cause an embolism (blockage of a

blood vessel), stroke, infections, and death. Serious complications can occur immediately or develop weeks, months, or years later [6, 7].

If you have received unapproved silicone beauty injections, you may be at risk of complications.

Safety Tips for Patients

Please consider the following advice [1].

1. *Never* get any type of permanent filler or liquid silicone injected for body contouring or enhancement purposes. This means you should never get breast fillers, “butt fillers,” or fillers for spaces between your muscles. These products, which include certain types of injectable silicone, can be dangerous, can cause serious injury and even death.
2. *Never* buy dermal fillers on the Internet as they may be fake, contaminated, or harmful.
3. *Never* get injectable fillers from unlicensed providers or in non-medical settings, e.g., hotels or private homes.
4. *Always* work with a licensed healthcare provider who uses FDA-approved products for treatments.

ISAPS has Identified the following talking points:

1. Silicone injections for body contouring are often performed by unlicensed and non-medical practitioners in non-clinical settings, e.g., residential homes or hotels [8].
2. Awareness for physicians, their staff, and patients is key. In the presence of silicone-free material injected into the breast, patients should be evaluated by a board-certified plastic surgeon.

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3. An uncertain danger is whether silicone injections may cause autoimmune diseases (i.e., ASIA) [9].
4. The presence of silicone-free material injected into breasts and buttocks generates a chronic inflammatory reaction, of the type characteristic of foreign body granulomas, with cutaneous erythema, nodules, and cutaneous retractions. In the case of the breast, all of them impede certainty during breast self-examinations, confuse clinical examinations by physicians, and alter all the various imaging studies, whether that is mammography, breast ultrasound, or MRI6.
5. There is no doubt that breast siliconomas interfere with imaging studies and, thereby, may delay the early detection of breast cancer, due to the numerous difficulties they cause in breast evaluation [6].
6. Many of these patients are in an age group highly susceptible to breast cancer, and some worry that one or more of their silicone-induced lesions are, in fact, neoplastic. It is practically impossible to rule out cancer as the cause of one or more of the hard nodules commonly exhibited by these patients. Changing nodule characteristics results in more confusing follow-up exams, rather than being helpful.
7. In injection-induced breast siliconomas, surgery is the only preventive option which, though often effective, has definite drawbacks.
8. For silicone injections in the buttocks, open surgery is the only preventive option in order to avoid devastating complications.
9. The surgical approach must also be multidisciplinary, enlisting the services of a psychologist, a clinical immunologist, a mastologist, and a plastic surgeon.

For this initial communication, we recommend the following guidelines:

- a. We encourage consumers who may have received injectable silicone to seek immediate medical attention.
- b. If you experience problems such as difficulty breathing, chest pain, signs of a stroke (including sudden difficulty speaking, numbness, or weakness in the face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), it may be a life-threatening situation and you need to seek immediate medical attention.
- c. For those who are considering a body contouring procedure, talk with a healthcare provider about appropriate treatment options and the risks associated with the procedure.

- d. Those who have been offered or have received injectable silicone for body contouring from an unlicensed provider are encouraged to use the FDA website to Report Suspected Criminal Activity [10].

With our communication today, we hope to raise public awareness – about the short- and long-term risks of injecting silicone or oils directly into the body – and encourage consumers to choose a licensed plastic surgeon when considering any type of cosmetic enhancement.

This patient safety advisory was developed by Gustavo Emilio Schenone, MD PhD (SG Medical Group and Department of Plastic and Reconstructive Surgery, University of Buenos Aires, Argentina) and Douglas Narvaez Riera, MD, (Head Plastic Surgeon, Centro Clinico Valentina Canabal, Barquisimeto, Venezuela). Montserrat Fontbona, MD (ISAPS Patient Safety Committee Chair), and Lina Triana, MD (ISAPS President) provided editorial assistance.

ISAPS Patient Safety Committee

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