

Urgent Safety Communication

US.FDA Warns Against Use of Injectable Silicone for Body Contouring and Enhancement

Device/ Product Name:	Injectable Silicone for Body Contouring and Enhancement
Problem:	<p>Saudi FDA would like to bring to your attention the safety alert from US.FDA regarding Injectable Silicone for Body Contouring and Enhancement. The use of injectable silicone is not approved to enhance or augment the body. Such use can lead to ongoing pain, infections, and serious injuries, such as scarring and permanent disfigurement, embolism (blockage of a blood vessel), stroke, and death.</p> <p>The only US.FDA-approved injectable silicone is silicone oil used for specific intraocular ophthalmic (inside the eye) use.</p>
Recommendation/Actions:	<ul style="list-style-type: none"> • Do not inject silicone to achieve breast, muscle, or buttocks enhancement. • Educate health care facility staff on how to quickly identify and assist patients who report signs and symptoms of complications from injectable silicone. • Discuss the benefits and risks of US.FDA-approved options for body contouring with patients.

For further information, please **see the Safety Communication** issued by the US.FDA. ([Click Here](#))

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245
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Sincerely,
NCMDR Team