INJECT AT YOUR OWN RISK

After a decade-long ban by the FDA, liquid silicone is back. But is the controversial wrinkle filler safe, or is it a medical powder keg? **By Joan Kron**

In a spotless blue examining room on Manhattan's Upper East Side, five syringes, each slimmer than a mascara wand, sit on a stainless-steel tray. They are loaded with a clear substance that has a clouded past: liquid silicone, the controversial wrinkle plumper. New York dermatologist Norman Orentreich has referred to the substance as "the gold standard of wrinkle fillers." Beverly Hills dermatologist Marvin Rapaport calls it "a time bomb." In 1992, the U.S. Food and Drug Administration slapped a ban on silicone for injections in the body, citing its safety to be "unproven."

But Rhoda S. Narins, the dermatologist preparing to inject the contents of these syringes into a patient's face, isn't breaking the law—she's just bending it. A legal loophole that many doctors are squeezing through (with the FDA's full knowledge) allows them to use a particular type of silicone to plump up lips, lines, and facial hollows.

"I begged Dr. Narins to give me silicone," says the woman on the treatment table, an interior designer with expensive highlights in her shoulder-length blonde hair. "I'm sick and tired of having collagen injections over and over again. After paying $1,350 for three syringes the last time, I said, 'That's it. I want something permanent.' I'd rather come a few times this year for silicone, because then it lasts forever."

In the race against time, the syringe, not the scalpel, is the instrument of choice, especially among younger women. But the only injectables allowed in the United States for filling wrinkles are temporary, and treatments must be repeated two or three times a year. This is a distinct benefit if the patient develops an inflammation or the doctor inadvertently overdoes it. ("Thank God my mistakes don't last forever," says Beverly Hills dermatologist Arnold Klein, who uses a large quantity of collagen, a temporary filler approved by the FDA.) But repeated refills—and payments—are giving many women injection fatigue. "Patients hate being bruised so frequently and hate waiting for the swelling to go down," says New York dermatologist Howard Sobel.

The surgical tray holds a doctor's proper tools for liquid silicone injections.

Currently, there are no permanent injectable fillers approved for cosmetic use in the United States, but that could change if the FDA sanctions SilSkin, an extremely purified form of liquid silicone engineered expressly for wrinkle filling, in trials now. If no side effects appear, SilSkin could be FDA-approved by 2004. But right now, the decorator's desire for permanence can be fulfilled only by Silikon 1000, a liquid silicone cleared by the FDA in 1997 only to treat detached retinas. But, once approved, it can be used to fill wrinkles, whether the FDA likes it or not. When physicians and patients privately discuss facial line fillers, silicone is the proverbial elephant in the room.

Narins dips a tiny cotton swab in a brown antiseptic, and maps out her path for the injections. Because Silikon 1000 is thicker than the previous silicone formula, shots require a larger needle and some force. "I have a powerful thumb," Narins says. She starts with the cheeks, a controversial area because any material placed here could drift from its original position. She pierces the flesh and pushes the plunger on the syringe. Stab, plunge, stab, plunge, stab, plunge. Each thrust deposits a microdroplet of silicone, the size of a pinhead, well below the surface of the skin. In four weeks, each droplet should be encapsulated and anchored by the body's own collagen, in the form of scar tissue. The decorator will return for another round of shots—and another—until her facial lines are filled and almost flush with the rest of the skin.

The patient is stoic as blood trickles down her cheeks and a nurse applies

New Yorker—a transsexual known as Natasha—who posed as a plastic surgeon and allegedly injected a "breast-building" material into one victim who subsequently required a double mastectomy due to a severe infection.

In Florida, Enrique Torres, the ULAO's colorful chief investigator, launched "Operation Hot Lips" when he and another inspector visited beauty shops in Miami Beach asking about lip injections "for a girlfriend." At most of the salons, the undercover duo was handed a card listing a woman's name and phone number—and "lo and behold, she's unlicensed," Torres says. "Eventually, every one of them was arrested." An injector whose referrals came from a cosmetics saleswoman working at Saks Fifth Avenue in Bal Harbor, Florida, was apprehended. (Saks salespeople have never been allowed to make such recommendations.) To date, Torres has helped local Florida police departments shut down more than 50 injection ventures. However, he says, "We haven't scratched the surface."

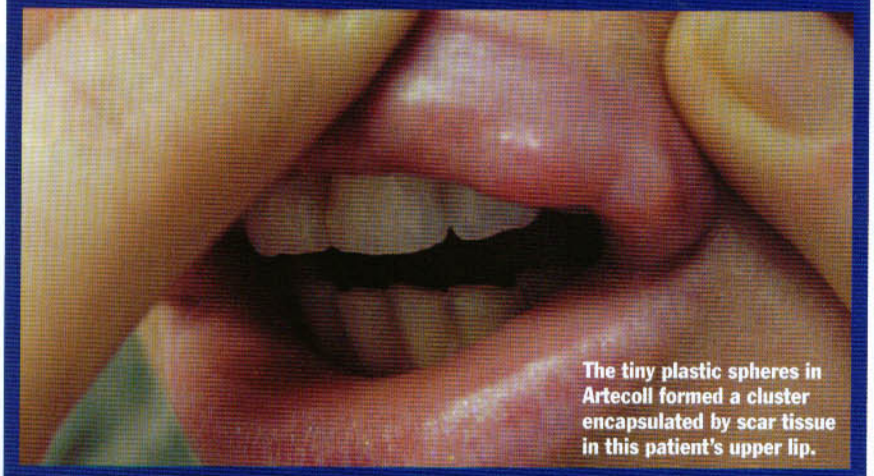
In a sensational Miami case two years ago, Vera Lawrence, a 53-year-old government secretary, died after having her buttocks injected with 36 shots of industrial silicone, causing a fatal embolism. Another woman received 800 shots of silicone (dispensed from an iced-tea pitcher) in her buttocks and thighs that migrated to her ankles, cutting off the blood supply. Rather than amputate her feet, dermatologist Leslie Baumann at the University of Miami is trying to have the material surgically removed. Even professionals who should know better are falling for these operations: A nurse who thought she was getting cheap collagen injections for her laugh lines from a little-known doctor saw her face puff up like a blowfish. Emergency room doctors blamed it on silicone.

Carlos Wolf, a Miami facial plastic surgeon, describes the typical silicone complications as "lips that look bigger than the face, swollen folds under the eyes, and puffed-up cheeks that look like someone on steroids or having an allergic reaction." Wolf, who has treated these problems on many such patients, explains that the only recourse, other than surgery, is "monthly steroid injections to dampen the foreign-body reaction." Two patients who came to Miami dermatologist Mariano Busso with silicone complications had to be admitted to the hospital with massive inflammation, which still hasn't cleared up. "The redness and the fever do not respond to antibiotics," he explains. "And even though they see horror stories on TV, each patient thinks, It's not going to happen to me."

When Stephanie*, a 32-year-old real estate broker, told the receptionist at a spa that she was tired of paying for collagen injections in her lips, the spa worker slipped her the name of a woman who injects "permanent collagen," even though there is no such thing. "The first time, I met her at a friend's condo," Stephanie says. "The woman showed us her before-and-after book, which looked good. She said it was permanent collagen with nutrients and vitamins and that it came from Colombia, where it is legal." Stephanie liked the results in her lips (as well as the cheaper price) and wanted injections in her smile lines. This time, she went to the woman's apartment, north of

Not her real name

THE NEXT INJECTABLE



The tiny plastic spheres in Artecoll formed a cluster encapsulated by scar tissue in this patient's upper lip.

Artecoll—the permanent wrinkle filler made from Plexiglas-like microspheres suspended in collagen with an added painkiller—may well receive FDA approval next year for use in smile lines and acne scars. Yet, like silicone, its success is shadowed by some nagging problems.

Clinical trials in the United States to demonstrate Artecoll's safety have been completed, but the FDA has not yet given Artecoll its blessing. Those who want the injections travel to Europe or Canada, where it was approved in 1998. The claim by Artes Medical, a distributor of Artecoll, that Elizabeth Hurley's lips owe their lusciousness in part to Artecoll hasn't hurt its mystique. (Hurley says she's never used Artecoll and has never heard of it.) Though cleared in over 30 countries, including Switzerland, four Swiss medical groups issued a warning last December about permanent fillers.

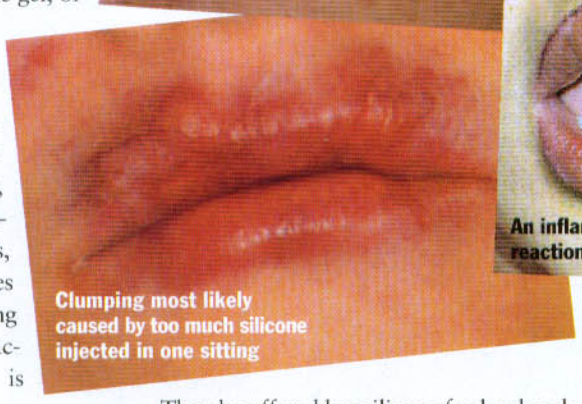
The concoction works on the irritation principle, much like seeding an oyster. Initially, the collagen produces the fullness, but then dissipates; three or four months later, scar tissue surrounds each plastic ball, providing long-term augmentation. Enthusiasm for Artecoll turned to concern in March, when a former president of the Canadian Society for Aesthetic Plastic Surgery, Claudio De Lorenzi, told the *Toronto Star* that he has stopped using Artecoll in the lips because he and several colleagues found "long-lasting bumps in patients' lips after injection with the filler" and that continuous movement of the lips can cause the beads to clump and form hard lumps. In response, Canderm Pharma, the Canadian distributor of Artecoll, says that the lumps are likely from "overfill, due to uneven dispersion of material," and respond well to cortisone shots. De Lorenzi says that while cortisone may soften the area, surgical excision may be the only remedy.

COURTESY OF CLAUDIO DE LORENZI, M.D.

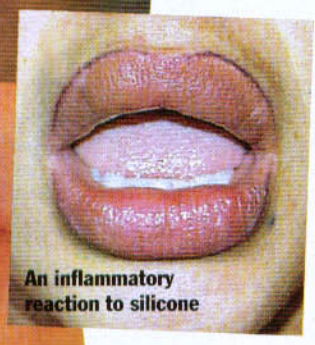
pressure and ice packs. As the needle approaches the smile lines near her nose, an area that is particularly sensitive to pain, the designer squeezes the nurse's hand. "No pain, no gain," she says, smiling wanly. Ten minutes, many hand squeezes, and 80 evenly spread droplets later, the syringes are almost empty.

Silicone is present in countless products. It makes lipstick shine, keeps spray deodorants from clogging, and gives hair serums their frizz resistance. Industrial silicones grease the landing gear of airplanes and boat hinges; medical-grade silicones coat the insides of syringes, making them easier to empty. Depending on how silicon, a common element in sand, is combined with oxygen, carbon, and hydrogen—the end result can be silicone oil (also called liquid silicone), silicone gel, or a hard, rubber-like substance. Silicone formulations are almost always compounds, containing perhaps 20 percent silicone and 80 percent other ingredients, including a wide array of impurities—toxins, trace metals, mineral oils. These impurities are fine for waterproofing boots, but alarming and unacceptable if the mixture is injected under the skin.

Unlicensed work: Silicone migration ten years after the initial injection in the corner of the eye



Clumping most likely caused by too much silicone injected in one sitting



An inflammatory reaction to silicone

Marvin Rapaport is liquid silicone's most outspoken critic. He acknowledges that many people have had no adverse reaction to injectable silicone, but he is adamant that the substance has the potential for great harm. Rapaport is not alone in his concerns; many cases have been reported in medical journals, documenting complications such as chronic cellulitis (inflammation of connective tissue), nodules or ulcers, and infections, occurring anywhere from 2 to 35 years after the injection. In the past, "whenever a patient showed side effects from silicone injections," wrote Rapaport in an editorial for *Dermatological Surgery*, "it was argued it was the wrong amount, the wrong material, or the wrong practitioner."

A New York patient named Tricia* believes that the silicone fluid, the technique, and the amount used were all correct in her case. In late 1991, when she was 33 years old, Tricia consulted a doctor about a small pockmark on the side of her nose. The Park Avenue dermatologist injected the blemish with a drop of medical-grade, liquid silicone. Then he offered her silicone for her laugh lines. She still recalls his words. "You'll stay looking young for a long time."

A month later, she went back for more, and would have returned for a third round, had the FDA not banned liquid injectable silicone. Two years afterward, the injected side of Tricia's nose began growing, and raised bumps appeared in her laugh lines. Tricia went to a plastic surgeon, who told her this was a reaction to the silicone, and that Tricia had little recourse, since silicone is almost impossible to remove. Instead, he built up the uninjected side of her nose with cartilage from her ear to balance the nostrils. "Can you imagine making your nose larger, on purpose?" Tricia says, stupefied. After continued inflammation in the silicone-treated nostril, another doctor tried lasering it to smooth out the bumps. That nostril started shrinking, which looked even stranger. As for the lumps in her laugh lines, a fourth doctor told her nothing could be done for them. "So, where others have a crease, I have a raised line," Tricia says. "How do you camouflage bumps with makeup? I just want to hide my face."

Too many women are rushing into injections without exploring the possible risks, says Diane Madfes, a New York dermatologist. Nothing illustrates this more vividly than the rise in silicone parties hosted by itinerant injectors. "There are women who would stuff a Vuitton bag in their face if someone said it was permanent," says dermatologist Arnold Klein, who predicts the widespread availability and use of permanent fillers "will be a disaster."

To try to prevent such debacles, Florida's department of health has taken an aggressive approach by establishing the Unlicensed Activity Office (ULAO). Since 1998, detectives on the force have been working to catch and convict unlicensed injectors, some of whom fly to Florida from Venezuela or Brazil, hole up in a hotel room or condominium, give shots of silicone of unknown purity and sterility, and then leave town before complications surface.

Illegal injections are becoming an increasing problem—and not just in Florida. In July, a husband and wife team, Iris and Eliezer Fernandez, were arrested in New York for giving injections to at least two people who developed life-threatening infections and were left disfigured. At press time, investigators have not revealed whether the infections were caused by dirty needles or by the wrinkle-filler Hyacell, a type of hyaluronic acid that is not FDA-approved. Still at large is another

**Not her real name*

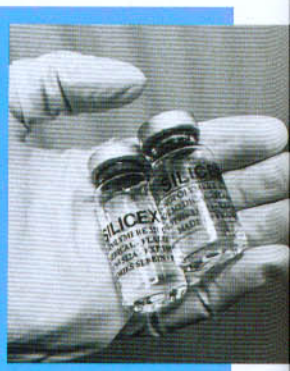
Miami—even after seeing the TV reports of Vera Lawrence's death. Two months later, Stephanie noticed bumps in her lips, which were worrisome enough to make her consult a local dermatologist, Helen Donatelli, who diagnosed migration. "We don't know what these people are injecting," Donatelli says.

There is no national or international standard of purity for silicone. In the 1970s and '80s, most of the injected silicone had a viscosity of 350 centistokes (the consistency of castor oil) and was labeled "medical grade"—which may have given patients a false sense of security. Today the producers of medical-grade silicones have a warning on the containers: *Not for Human Injection.* "Silicone can be as pure as Evian water, or as polluted as the water in the dirtiest river—and all degrees in between," says Wayne Richard, a medical-device developer and CEO of Richard-James, Inc. the company that developed Silikon 1000 and now SilSkin.

The FDA has had a long and adversarial history with liquid-silicone injectors. According to a 1992 Congressional Report, the agency tried for three previous decades, without luck, to control its sale and usage. Studies of silicone shots were begun and then discontinued because of poor record keeping.

But Norman Orentreich, a dermatologist with a following of wealthy and famous patients, attracted the attention of the FDA when he "spoke publicly about his practice [of injecting silicone in thousands of women]," according to the FDA report and published articles about his results. When the FDA warned Orentreich in the mid-'80s that he needed a special exemption to work with silicone, his lawyers responded that the FDA had no jurisdiction, since there was no interstate commerce involved, and that Orentreich "used industrial-grade silicone," which he bought locally and filtered and sterilized himself. (An internal 1984 FDA memo noted that "we have reason to believe that Mrs. Nancy Reagan has been treated by Dr. Orentreich.")

TESTING SILICONE



Inspector Torres gave *Allure* samples of Silicex (a French-made silicone oil) confiscated in a Florida raid for analysis (right). One bottle labeled 350 C's (a measure of viscosity) was only 96.38 C's, according to Galbraith Laboratories in Knoxville, Tennessee. This could be the result of poor manufacturing or later dilution. Rhoda S. Narins explains that "a silicone oil with such low viscosity"—as runny as thin maple syrup—"could certainly move around the face after injection."

When the agency threatened legal action in February 1992, Orentreich and his partners agreed to stop injecting silicone. That same month, CBS's *60 Minutes* aired a devastating report detailing the possible dangers of liquid-silicone injections and revelations about malpractice suits against Orentreich. After that exposé, few doctors expected to see the return of liquid silicone for wrinkle filling—much less an FDA-sanctioned study of it with an Orentreich listed among the physician injectors. And yet this is exactly what has happened, as Norman Orentreich's dermatologist son, David, among other physicians, is testing the substance

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SilSkin for the FDA trial. (Both Norman and David Orentreich declined to be interviewed for this article.)

SilSkin is the first and only liquid silicone to get FDA clearance for clinical trials in wrinkles. It has barely any detectable impurities—a claim that no other silicone formula in the United States has been able to make. Its manufacturer, Richard-James, Inc., also presented the FDA with results of autopsies of past silicone users showing that material injected years earlier had not drifted.

In the first phase of this FDA trial, 28 patients will be followed for a year as they receive SilSkin injections in wrinkles on one side of the face and collagen on the other. In all, 150 patients will participate in testing. Jeffrey Dover, associate professor of dermatology at Yale Medical School and one of the four physicians testing SilSkin, says, "We're all a little anxious because liquid silicone has an unpleasant past, but we're also very excited at the prospect of having a product for permanent correction with a compelling result." Still, Marvin Rapaport wonders if a study that follows silicone-injection patients for only one year can begin to assess complication rates.

Some women, including the interior designer, are happy with the results of their shots. "My face looks better and you don't see a major change. I trust my doctor." But trusting one's doctor doesn't mean turning a blind eye to the risks. Mark Gorney, medical director of the Doctors Company, the major insurer of plastic surgeons, says that even if a patient is going to a reliable doctor, she has a right to ask, "Where is the injector getting the silicone?" "Who is making it?" "Can the doctor guarantee that it is pure surgical grade?"

"Judging from data I've seen recently, they are getting good results in the lips," Gorney says. "Liquid silicone in small quantities, five cc's or less, probably does no harm when injected, but it has to be pure and sterile. But once the use starts, where will it stop? Greed exceeds scruples, and our past experience has been nothing short of catastrophic." Carlos Wolf says it more succinctly: "Women want a permanent solution to beauty problems—and some of them end up with a permanent disaster."◆