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## FDA Approves Adjustable Facial Implant

Physicians and patients looking for permanent, adjustable facial augmentation are discovering the VeraFil™ implant from Evera Medical (Foster City, Calif.). The implant was recently cleared in the U.S. for tissue augmentation in the periorbital areas. Outside the U.S., the technology is incorporated into a product called FulFil, which has been granted the CE mark for augmentation anywhere in the face, including the lips and nasolabial folds.

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# New Adjustable Facial Implant Offers Permanent Results

By Kevin A. Wilson, Contributing Editor

Photos courtesy of James Newman, M.D.



Lips before Tx

Lips after Tx

“Being able to adjust the amount of saline solution in the implant allows us to tailor the fill volume, up or down, during implantation. This option makes VeraFil very versatile.”

“We are excited about the FDA clearance for the periorbital area,” said James Newman, M.D., medical director of Premier Plastic Surgery in San Mateo, Calif. “We use VeraFil on an off-label basis in the lips, but also in the chin and nasolabial fold. VeraFil has an advantage over injectable fillers in that most injectables are temporary. When we can offer long lasting correction with a soft, natural consistency, it really perks patient interest. They like the augmentation effect, especially in the lips.” Dr. Newman has performed the procedure both inside and outside the U.S.

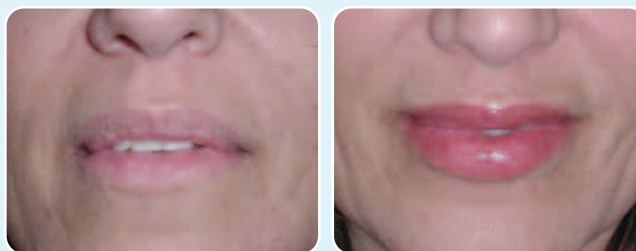


**James Newman, M.D.**  
Medical Director  
Premier Plastic Surgery  
San Mateo, CA

The technology in FulFil and Verafil is a thin-walled, dual-layer, saline-filled implant with adjustable fill volume and a self sealing fill valve. According to Dr. Newman, the thin expanded polytetrafluoroethylene (ePTFE) outer membrane, is semi-porous on a microscopic level, allowing for limited tissue ingrowth, which stabilizes the implant, but eliminates the potential for thick encapsulation. “This means allergy testing is not necessary. There is also a glide plane between the ePTFE membrane and inner silicone membrane. These layers can expand and contract without tearing.” Because VeraFil has viscoelastic properties, matching those of human tissue, “the implant does not impede tissue movement, which is especially helpful for lip augmentation,” Dr. Newman added. Minimized

relative motion between tissue and implant also means rapid incorporation into the tissue.

Photos courtesy of James Newman, M.D.

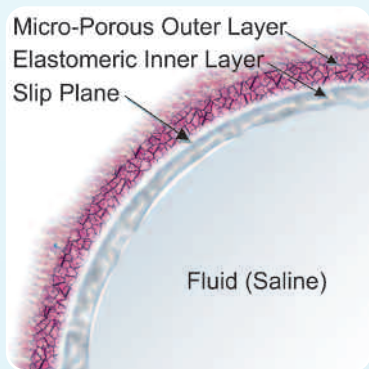


Lips before Tx

Lips after Tx

Michael Jasin, M.D. medical director of the Jasin Facial Rejuvenation Institute in Tampa, Fla., uses VeraFil primarily for lip augmentation. “VeraFil has also been used successfully on the nasolabial folds and I look forward to learning more about its use around the orbit in the tear trough region,” he noted. “We have two subsets of patients using VeraFil for lips. Most want lip enlargement, the traditional use for lip implants. The other group is looking for volume but doesn’t necessarily want their lips to look much larger. Being able to adjust the amount of saline solution in the implant allows us to tailor the fill volume, up or down, during implantation. We can give lips more definition without significantly altering the size. This option makes VeraFil very versatile.”

According to Miles Graivier, M.D., medical director of the North Atlanta Plastic Surgery and Day Spa in Roswell, Ga.,



VeraFil Implant

“VeraFil is the first permanent implant I’ve used (on an off-label basis) that will meet a variety of lip augmentation needs with results that are easy to reproduce.”

predictability is a major advantage of the new implant. Pleased with Fulfil’s FDA clearance (as VeraFil) for periorbital use, Dr. Graivier also uses VeraFil for lip augmentation. “We have a good handle on short-term augmentation with hyaluronic acid (HA) products like Restylane® (Medicis Corp., Scottsdale, Ariz.), and Juvederm® (Allergan Inc., Irvine, Calif.), but in long-term augmentation, we’ve had no products that are predictable, soft and stretchable. In natural long-term products, such as rolled AlloDerm (LifeCell Corp., Branchburg, N.J.), predictability is an issue because you can’t tell how much product is going to be resorbed, especially in the over 55 population. Tissue grafts also have predictability questions associated with irregularities or cysts. VeraFil is the first permanent implant I’ve used (on an off-label basis) that will meet a variety of lip augmentation needs with results that are easy to reproduce.” Dr. Graivier added that photometric analysis has shown increases in lip volume of about 43% to 45% for the upper and lower lip, respectively.

According to Dr. Graivier, the problem with most ePTFE products such as Advanta (Atrium Medical Corporation, Hudson, N.H.), is that the tissue will actually grow through the implant, making it very firm and stiff. “This limits stretching of the implant, which is especially visible when the patient puckers. Dr. Graivier added that just about any patient is suitable for treatment with VeraFil, although results won’t be as good for patients with lip asymmetry because of the symmetrical nature of the implant. “There has been success with patients who have had secondary cleft lip repair and need some volume. Patients with thin skin may also be unsuitable.”

VeraFil and FulFil are currently available in eight different sizes, defined by length (3, 4 or 5 cm) and diameter (4.5, 5.5 or 6.5 mm). “For the upper lip, I usually use the 5 cm size; for the lower lip, the 4 cm,” Dr. Graivier noted.

Anesthesia is limited to nerve blocks, which minimizes the need for supplemental injections of local anesthetic. “We want to limit directly injected local anesthetic to avoid distorting the anatomy and size of the lip,” explained Dr. Jasin. “We’re promoting a two incision technique, one at either oral commissure. I use a metal trocar to form a subdermal plane that I dilate with scissors to make a larger pocket. This creates a little more space for free expansion of the implant. It is also essential to place the implant deep enough to create adequate tissue coverage. The implant has its own sheath which is threaded through the lip, then removed once we’ve threaded the implant.”

“During inflation, we want to make sure the lips aren’t pulled too far in the medial or lateral plane,” continued Dr. Jasin. “We’re also watching tissue response and proper positioning.” Maximum inflation with the antibiotic-infused saline solution is 0.4 cc for the 4.5 mm implant and 0.7 cc for the 6.5 mm implant. “We can fully inflate or use less saline if that’s appropriate. This gives us latitude at the time of placement.”

Closure of the wounds requires one or two stitches. “Overall, you’re looking at a 20 to 30 minute procedure,” Dr. Jasin said. “An experienced plastic surgeon could learn this quickly, maybe with two or three cases, after observing the



**Miles Graivier, M.D.**  
Medical Director  
North Atlantic Plastic  
Surgery and Day Spa  
Roswell, GA

“There has been no migration, infection, erosion or capsular contraction. VeraFil is not an injectable so there will not be granulomas.”

technique. They need to learn to tuck in the ends and withdraw the fill tube, but otherwise it's straight forward, especially for practitioners familiar with other implants such as Advanta." Post-operative care is limited to prophylactic antibiotics. Antivirals may be warranted if the patient has a history of severe herpetic eruptions.

Follow-up is approximately seven days after implantation, to remove sutures and examine the implant, plus additional follow-up to monitor the augmentation, if the doctor or patient wishes, according to Dr. Graivier. "Over-the-counter medications should handle pain management. Most patients are back to work within 24 to 48 hours."

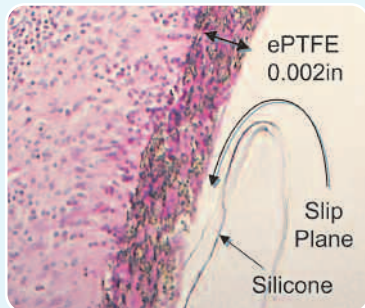
As for adverse effects, Dr. Graivier's experience has been favorable to date. "The series of 148 lip implants done outside the U.S. included only one that required a replacement, and I haven't seen any adverse effects in my series," he said. "I had five out of 30 with palpability of the distal tab, which didn't bother the patient. I had one implant that I needed to trim and bury deeper in the tissue, which took all of ten minutes to do under local anesthesia. There has been no migration, infection, erosion or capsular contraction. VeraFil is not an injectable so there will not be granulomas. The patient will walk out of the office with a swollen lip, which may subside within 48 hours or last up to seven days. Patients have the same amount of swelling as they have with the injectables." Dr. Newman concurred. "We expect to see swelling or bruising, but not the adverse effects traditionally associated with lip augmentation."

Reversibility, according to Dr. Newman, is what separates Fulfil from injectables, especially for the lips. "We can all do a fine job of plumping up the lip with dermal fillers. The problem is getting the same result each and every time. You may need several procedures totaling two or three syringes of filler, much of which may be wasted trying to create deep volume. And repetitive injections mean repetitive downtime, which adds up and patients get tired of this quickly. With the Evera technology you basically get 80% to 100% correction the first time."

"And if the patient doesn't like the correction, the practitioner may simply remove the implant or change it for a different size, Dr. Newman added. "The implant can be removed through a small incision, I've done this and it's easy. This makes the procedure completely reversible, which is not true for injectable fillers." Dr. Newman may use injectable fillers for finesse work after implantation.

Although VeraFil works well by itself, it can be used in conjunction with dermal fillers. "You can sharpen the cutaneous vermilion junction if you're careful about shortening the upper lip, but VeraFil is usually sufficient," said Dr. Graivier. "HA injectables may be helpful for augmenting the edge of the lip. You have to be careful not to puncture the implant, however."

"Patients typically ask for Restylane because they aren't sure how they'll like the augmentation. Therefore shorter-term products are good until the patient reaches a certain comfort level with the correction," Dr. Jasin noted.



Subdermal porcine VeraFil implant. At 10 weeks, note complete cellular incorporation limited to thin ePTFE layer. Silicone liner, attached to ePTFE only at ends, creates slip plane. (Folding away from ePTFE surface is artifact of preparation.)

“This is not a difficult procedure and can be done in the office with local anesthesia, so it would be easy for dermatologists or other practitioners to perform.”

The three physicians agreed that although the Fulfil procedure costs more than dermal filler injections, the Fulfil procedure is cost-effective. Injectables are less expensive per procedure, but Fulfil is basically permanent. Much depends on the number of implants used.

“Considering the more favorable, predictable and longer lasting results, the cost is worth it,” said Dr. Newman. “A patient who needs two or three syringes of filler will need only one VeraFil procedure for correction. And with fillers, patients need to return for more correction in six months and they may not be able to afford three syringes over and over. Even if you use fillers in conjunction with VeraFil, the cost will not be higher in the long run. VeraFil essentially pays for itself in about two years.”

Dr. Graivier added, “I don’t think Fulfil will replace products like Restylane but it’s the first permanent product that’s predictable, stretchable, soft and easy to implant both around the orbit as well as in the lips, and potentially other regions of the face. VeraFil will be a very sought-after product.” He also noted that dermatologists or dermatologic surgeons may use VeraFil in a limited capacity. “This is not a difficult procedure and can be done in the office with local anesthesia, so it would be easy for dermatologists or other practitioners to perform. The implant goes about 50% under the dry vermillion and 50% under the wet vermillion. I use a small dissecting scissor and make sure the pocket I’m making is large enough to accommodate the implant. I don’t recommend using a trocar for the dissection because this limits the size your implant can expand and stretch. I make small incisions

about 1 cm away from the commissure. Early on I recommend two incisions in each lip and then go to one incision as you become more comfortable.”

“Dermatologists usually limit their practice to injectables, but those who do surgery may take on VeraFil if they are comfortable with the invasiveness of the procedure,” Dr. Jasin said.

As for the future, Dr. Newman believes that the use of different shapes and sizes for anti-aging facial augmentation has potential. “I expect that Evera will produce devices of the next generation that can be adjusted after implantation. There will likely be a part of the membrane that can be safely punctured percutaneously to either add or subtract volume. A lot of doctors and patients will be interested in this, especially for chin augmentation.”

Dr. Graivier foresees being able to do more as Evera continues to improve the design of their technology. “Evera has recently refined the manufacturing process to soften the ends in the next generation of implants. And the engineers have been very responsive to our feedback. VeraFil will be extremely useful in areas such as the nasolabial folds, tear troughs, cheek, chin and orbital floor. I can see it used for reconstruction to correct soft-tissue atrophy in one side of the face vs. the other, Poland Syndrome, or possibly even for other areas of the body, especially when the implants can be percutaneously adjusted.”