



# Artefill

## NEW STUDY INDICATES STRONG, LONG-TERM SAFETY PROFILE

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Artefill® was the first non-resorbable soft tissue filler to be cleared by the U.S. Food and Drug Administration. This advanced polymethylmethacrylate (PMMA) microsphere containing dermal filler was cleared by the FDA in October 2006 and is the

It is well established that PMMA microsphere surface characteristics, purity, and microsphere size are critical factors that influence product safety. Although microsphere quality in PMMA containing products available around the

owners of Artefill along with its current owner and manufacturer (Suneva Medical, San Diego, CA) have invested significant resources to improve the physical/chemical properties, formulation, and processing of Artefill to distinguish it from these earlier generation PMMA microsphere products. Artefill now differs from these products in that it meets FDA standards for microsphere size uniformity and purity (<1% of all microspheres in the product can be <20 microns in size).

As part of the FDA clearance, Artefill's previous owners were required to complete a long-term, longitudinal, open label safety and patient satisfaction surveillance study. The study is designed to evaluate Artefill's

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only permanent filler currently available in the U.S. market today. To date, more than 20,000 patients have been treated with Artefill.<sup>1</sup>

world has improved in recent years, healthcare providers may have misconceptions regarding the safety of newer PMMA fillers, such as Artefill. The previous

safety and patient satisfaction for nasolabial fold (NLF) correction over a five-year period. Our practice along with twenty-two other leading practices around the country began enrolling patients in 2007. When the study is completed it will be the largest, with over 1,000 patients, and longest duration prospective U.S. safety study of any dermal filler.

## ARTEFILL STUDY OVERVIEW

The twenty-three (23) center, prospective, open-label study enrolled 1,008 patients beginning in September 2007. The total patient mix is 89 percent female, 11 percent male, and the average age is 54 years.

short-acting fillers but was looking for a long-term therapeutic approach for NLF correction. As part of the study, patients received bilateral NLF treatment with Artefill and up to two “touch-ups” after 30 and 60 days, until full correction was achieved.

Potential adverse events and patient satisfaction data are being reported by all patients at 2, 6, 12, 18, 24, 36, 48, and 60 months to assess the presence or absence of adverse events, patient satisfaction, and any changes in health. Normal injection site reactions such as swelling, minor redness, or bruising lasting less than thirty (30) days post injection are not being reported as an AE as the focus is on AEs occurring >90 days or more after

the three identify the lesion as a granuloma, then it is classified as a granuloma. If one of the three believes it is a granuloma, the panel must convene and collectively decide on the classification. If the panel is unable to decide on the classification, the lesion is classified “unknown—granuloma not ruled out.” All study patients will complete a final in-office visit at sixty (60) months. At this timepoint pictures of all patients will be taken.

An interim analysis of data from 991 patients was completed at about eighteen (18) months from the beginning of the study. Twenty-two (22) of the 1,008 patients enrolled dropped out during the eighteen (18) month follow-up period. Possible granulomas were ruled out by biopsy and histology as described above, and patient satisfaction was measured with a 5-point scale.

## 18-MONTH INTERIM RESULTS

All of the patients are at or past six (6) months post-initial injection with Artefill; 829 subjects are at or past twelve (12) months post-initial injection; and 245 patients are at or past eighteen (18) months post-initial injection. The mean volume injected for each patient was 1.25 cc per NLF (range 0.1-5.2 cc) or a mean of 2.5 cc total per patient. This represents an average of ~3 syringes used (each syringe contains 0.8 cc).

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Patients are predominantly Caucasian and non-Hispanic, which are typical demographics for filler products. All the enrolled patients had no recent history of NLF correction and met all approved device label criteria. Our practice enrolled, treated, and is now tracking 42 of the 1,008 patients. Each patient was previously treated with

treatment. Potential subject-reported AEs after the last ninety (90) day visit are followed up by phone and/or office visit if AE is deemed device related, and all nodules or bumps that are possible granulomas are biopsied for histological analysis.

A panel of three dermatologists examines the histology of the lesion. If two of

The incidence of device-related AEs to date is ~7% with a mix/frequency of AE type that compares favorably with the current Artefill label. In fact, all AEs were consistently slightly lower than the current Artefill label. No device-related SAEs have been reported. Four lesions were identified and biopsied. Three (3) were classified as unremarkable. One (1) was classified as a granuloma. This granuloma responded completely to medical treatment consisting of two intra-lesional injections of triamcinolone and 5-fluorouracil, combined with oral antibiotics. The resolved granuloma left no cosmetic effect.

Patient satisfaction with Artefill at eighteen (18) months was high with the majority of patients (88%) being very satisfied or satisfied with the results. The percentage of satisfied or very satisfied patients was consistent across timepoints of 6, 12, and 18 months, suggesting that the level

of correction has remained stable to date.

### ANALYSIS OF INTERIM RESULTS

The interim results of this long-term study suggest that Artefill's safety profile is consistent with, and possibly more favorable than, the approved device label. These data also further support the findings from the pivotal clinical study - that Artefill is a safe, effective treatment option for NLF. In addition, the high and consistent patient satisfaction through eighteen (18) months post-treatment is a testament to the long-lasting effects of Artefill.



Before (top) and 18 months After (bottom) Artefill Treatment. Photos courtesy of Dr. Sadick.



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Before (left) and 18 months After (right) Artefill Treatment. Photos courtesy of Dr. Sadick.



Before (left) and 18 months After (right) Artefill Treatment. Photos courtesy of Dr. Sadick.

To date, the incidence of granulomas in this study is less than 0.1%. The one confirmed case was easily treated and responded completely without sequelae after medical treatment. It is our belief that these interim safety results appear analogous to other marketed fillers such as Juvederm and Restylane, and the high patient satisfaction rating suggests lasting NLF correction.

## DISCUSSION & CONCLUSION

In our experience, Artefill has proved to be an extremely safe and predictable soft tissue filler. We believe these initial study results are very positive and should alleviate any concerns regarding the safety of this third generation PMMA filler, especially as the incidence of

granulomas continues to be small and within the percentages reported for other U.S. approved fillers. The clinical investigators will continue to publish additional interim analyses of the data as this study progresses. **ARTIFILL**

### Reference

1. Internal Data, Suneva Medical.

### Disclosure

Dr. Sadick is a clinical investigator for Suneva Medical, manufacturer and owner of Artefill.

Visit the Artefill website for additional safety and efficacy data: [www.artefill.com](http://www.artefill.com).

For corporation information, visit the Suneva Medical website: [www.sunevamedical.com](http://www.sunevamedical.com).



## About the Author

**Neil Sadick, MD, FAAD, FAACS, FACP, FACPh**, is one of the most renowned dermatologists and researchers, and his multiple discoveries have strongly influenced and transformed the future of dermatology.

Dr. Sadick's prestigious list of titles range from Clinical Professor of Dermatology at Weill Cornell Medical College, to President of the Cosmetic Surgery Foundation, Member of the Board of Examiners for the International Society of Hair Restoration Surgery, to Global Medical Advisor for Christian Dior Beauty, to name a few.

He holds four board certifications: Dermatology, Cosmetic Surgery, Internal Medicine, and Hair Transplantation.

Dr. Sadick is author, or co-author, of close to 300 articles in peer-reviewed scientific journals and has contributed more than 75 chapters of medical books. In addition, he has written or edited more than 10 books on cosmetic surgery, hair, and vein treatment. Dr. Sadick has also been a guest lecturer at more than 500 medical seminar classes and workshops worldwide.

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