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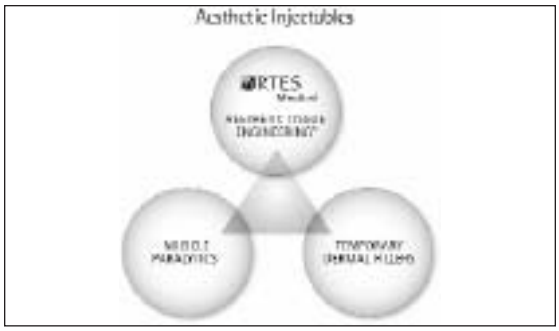
ARTES MEDICAL'S PERMANENT MICRO-INJECTABLE NEARS FINAL FDA APPROVAL

The anticipated approval by the FDA of **Artes Medical**'s permanent aesthetic injectable micro-implant for the treatment of nasolabial folds marks the first time a safe, permanent, injectable dermal filler will be available in the United States. Artes Medical's pre-market approval application (PMA) has been deemed approvable by the FDA. The microsphere technology has undergone two decades of clinical research and product development resulting in a new category of dermal injectable based on **Aesthetic Tissue Engineering**™ that works by stimulating production of the patient's own natural collagen. Clinical trials of this new platform technology have been completed in the United States (*1*), and the prior generation has been used safely and effectively in more than over a quarter of a million patients outside the United States (*2, 3*).



Artes Medical is creating a new category of dermal injectable, Aesthetic Tissue Engineering™. Temporary dermal fillers such as collagen and hyaluronic acid undergo degradation within 3 to 6 months. Wrinkle correction with the Artes Medical permanent micro-injectable endures because it becomes part of the patient's own tissue.

Unique Mechanism of Action

The Artes Medical micro-injectable is an intradermal formulation of precision-filtered microspheres suspended in purified bovine collagen gel that is injected into the patient's wrinkle or fold. The microspheres are made of polymethylmethacrylate (PMMA), one of the most time-tested synthetic implant materials known to medicine. The bovine collagen initially serves to maintain an even distribution of the microspheres in the implant. Three weeks post-implantation, the denatured collagen begins to be absorbed while the microspheres stimulate fibroblasts to produce autologous collagen in its place. The microspheres continue to stimulate the remodeling of connective tissue, thus building volume under wrinkles and folds. The aesthetic effects are enduring because the microspheres are individually encapsulated with autologous collagen and reside permanently in the dermis.

Safety

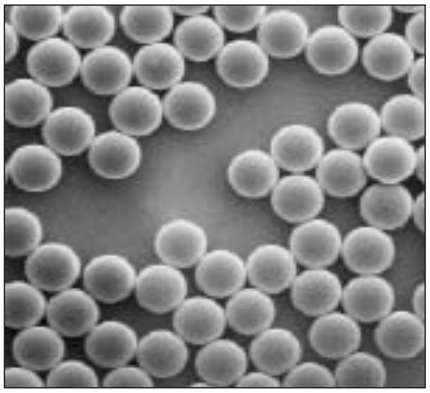
The safety of this permanent micro-injectable is the result of continual refinement of the microspheres and collagen since 1989 (*2*). Both components comply with strict FDA requirements. Medical-grade PMMA has been used safely in surgical implants for more than 60 years (*4*). The spherosity and electrically neutral surface of the microspheres make them fully biocompatible. The optimal diameter of the microspheres has been determined to be 30 to 42 microns, a size too large to be phagocytized by macrophages, which prevents migration of the microspheres from the injection site. In addition to size constraints, the microspheres are further immobilized as they become part of the patient's own tissue, thus preventing the implant from dislocating from the injection site.

The bovine collagen component used in this newest generation of permanent micro-injectable also has also been improved to maximize safety. A skin test will be required to identify patients sensitive to bovine collagen. The calf hides that Artes Medical uses to produce its collagen carrier are obtained from a closed herd located in the United States. This formulation of purified bovine collagen, plus the Artes Medical PMMA microspheres, constitutes a Class III Medical Device that meets rigorous FDA and cGMP manufacturing standards.

Efficacy

The introduction of this permanent micro-injectable into the marketplace is expected to expand current aesthetic injectable treatment options. In contrast

with to temporary dermal fillers, the FDA considers this new technology to be a permanent injectable micro-implant. The enduring effects of the technology are due to a natural process wherein human connective tissue begins to fill the space between the PMMA microspheres within 3 weeks following implantation, replacing the denatured bovine collagen. The clinical and scientific features of this permanent micro-injectable, including safety, histology, aesthetic results, and product evolution, have been documented in an extensive body of peer-reviewed literature (*1, 2, 5—7*). This technology answers an overwhelming demand for truly long-lasting wrinkle correction.



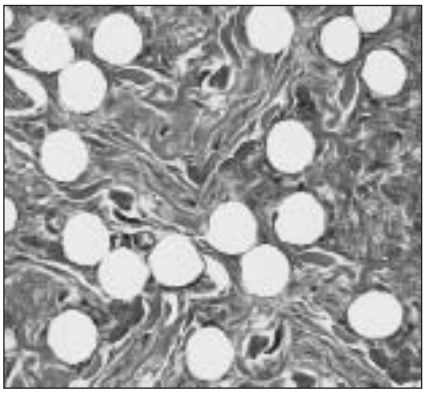
Round, uniformly sized PMMA microspheres before implantation.

Ease of use

This new technology is designed to be convenient for both physicians and patients. Using a tunneling technique, the Artes Medical micro-implant is injected into the reticular dermis, just above its junction with the subcutaneous fat. The micro-injectable contains 0.3% lidocaine for patient comfort. The procedure will take place in the physician's office, immediately after which the patient can resume normal activities. The degree of correction can be tailored to the patient's desires in more than one session. Because the micro-injectable is long-lasting, physicians should exercise more care than with the administration of temporary dermal fillers. The Artes Medical Physician Accreditation Program will provide in-depth training in the tunneling injection technique.

Summary

Artes Medical's Aesthetic Tissue Engineering™ platform technology has the potential to assume a unique position in the aesthetic injectable market. It answers the widespread demand for a safe, effective, and permanent micro-injectable capable of correcting soft tissue wrinkles and folds. Furthermore, the technology potentially lends itself to therapeutic applications such as GERD, stress urinary incontinence, and spinal disk degeneration, all of which will be clinically evaluated. All therapeutic and aesthetic products will be manufactured in a dedicated, state-of-the-art, GMP-compliant facility established in San Diego, California. Pending FDA approval for cGMP manufacturing, Artes Medical anticipates final FDA approval of this permanent micro-injectable. Patients can look forward to a new category of aesthetic injectable, one that unlocks the natural rejuvenating capabilities of human skin.



A stained section from a mature implant showing encapsulation of each microsphere with autologous connective tissue.

For more information concerning Aesthetic Tissue Engineering, call Artes Medical at 1-858-550-9999; fax at 1-858-550-9997; or visit the company's Web site at www.artesmedical.com.

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