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Is Lipodiisolve Safe?

The American Society of Aesthetic Lipodissolve [ASAL] objects to the inclusion of "Lipodissolve" in the recent warning against injection therapy (MESOTHERAPY) for localized fat reduction issued by the American Society of Aesthetic Plastic Surgery [ASAPS]. The procedure, Lipodissolve was introduced by the founders of ASAL in 2001 as distinct from "Mesotherapy".

The ASAL took care to include ingredients which were safe and whose mechanism of action was understood. The ASAL diligently limited training only to physicians and their nurses to perform the procedure. The ASAL and its original cohort, "Network Lipolysis", thus trained more than 300 physician in Europe, and so far, more than 200 physicians in the United States. ASAPS is incorrect in stating that there are no data relative to the effectiveness and safety of the procedure.

As it relates to Lipodissolve, several thousand treatment sessions have been reported in European and American peer reviewed journals demonstrating: a) objective evidence of improvement, based on actual measurements and pictures, in approximately 90% of the patients, and b) a paucity of serious side effects.^{1-4,6,7} Serious side effects reported with liposuction such as death, fluid overload, epinephrine and lidocaine toxicity, thrombosis, fat embolism and complications of general anesthesia have not been reported with Lipodissolve therapy.⁵

The main ingredient in the Lipodissolve formula is phosphatidylcholine [PC], a lipid. It is dissolved in a bile salt [deoxycholate], which is how it exists in bile where it helps to breakdown the ingested fat cells and digests fat on a daily basis. When injected in to the unwanted superficial body fat, it similarly breaks down fat cells and "digests fat", as it does naturally in proximal duodenum. In the subcutaneous area the dead fat cells are then gradually removed by the body's physiologic repair mechanisms, the same way as after any trauma or even after liposuction which leaves dead fat cells in the area to be

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removed by similar physiologic processes. PC along with other phospholipids are significant dietary source of essential fatty acids. Mammalian cell membranes are primarily composed of PC and other phospholipids mixed with cholesterol esters and salts to maintain fluidity. In other words it is not some foreign or toxic substance.

ASAPS's statement that this "procedure is not FDA approved" is misleading. FDA approves drugs and devices, not procedures. ASAL maintains that there is no FDA approval requirement relative to phosphatidylcholine for two reasons. One, it is a "supplement" and as such has been used for years for liver health, cholesterol and other possible benefits. Supplements do not require FDA approval and can be administered by injection, (as are vitamins and minerals as in Meyer's cocktail, intravenous nutrition or hyper-alimentation consisting of amino acids, vitamins, minerals, lipids, and others. Second, in Lipodissolve, the ingredients are mixed by a compounding pharmacist upon a physician's order for specific a patient, which does not require FDA approval [FDA Modernization Act Section 503a Compounding Pharmacy]. Lipodissolve is not a surgical procedure. Accordingly, ASAL has compiled an advisory board that includes highly credentialed physicians with diverse but relevant backgrounds in the fields of dermatology, aesthetic surgery and internal medicine.

These individuals are experienced clinicians, speakers, writers, researchers and teachers, and provide advice regarding the procedure and its evolution. They conduct training workshops for other physicians in the U.S. So far the North American advisers have performed more than 2,000 Lipodissolve procedures with satisfactory results in more than 90% of the patients - without any serious side effects. The ASAL has an on going monitoring process to record these events.

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