

BEFORE USING *DERMA VEIL*® PLEASE READ THE FOLLOWING INFORMATION.
IF YOU HAVE ANY QUESTIONS REGARDING THESE GUIDELINES CONTACT YOUR
LOCAL DISTRIBUTOR OR MEDINTER, LTD. AT: medicalsupport@medintergroup.com
YOU CAN ALSO REFER TO OUR WEB PAGE AT www.medintergroup.com

SALE AND USE OF THIS PRODUCT IS ONLY PERMITTED TO LICENSED MEDICAL PHYSICIANS

I. DEVICE DESCRIPTION

Derma Veil is a lyophilized low viscosity, non-toxic, bioabsorbable and biodegradable tissue reconstructive material with the following characteristics:

- Injectable single use medical device incorporated as a hydrophilic matrix. Its active principle is composed of glycolic acid (GA) bound to the polymeric column of polylactic acid [**PURASORB® Poly (L-lactide)**] both of which are homogeneously dispersed throughout and their rate of release is controlled by diffusion, prolonging a sustained repairing action through the slow dissolution of the compound.
- Immunologically inactive, biocompatible and absorbable and is degraded by hydrolysis. The degradation begins first by water diffusion in the material, initially at the more amorphous zones, followed by hydrolysis, material fragmentation and finally, a more extensive hydrolysis along with phagocytosis, diffusion and metabolization. Elimination occurs primarily through the respiratory tract.

Each box of *Derma Veil* contains 2 vials and an *Instruction for Use* leaflet.

Each vial of *Derma Veil* is made of transparent borosilicate glass, sealed with a siliconized halobutyl stopper secured by an aluminum ring with a "flip off" plastic cap. The vial has 10 mL capacity and contains 236.14 mg of a lyophilized, Sterile, pyrogen free, crystalline white powder of asymmetric micro-particles (40 to 60 µm) made of:

- a. POLYLACTIC ACID a biocompatible, biodegradable synthetic polymer for medical applications, [**PURASORB® Poly (L-lactide)**]
Also known as
(synonyms): Poly-L-lactide, Polylactide PL, PLLA, PLA.
- b. GLYCOLIC ACID a biocompatible, biodegradable, high purity hydroxyacetic acid monomer for medical applications,
- c. CARBOXY METHYL CELLULOSE SODIUM (USP),
- d. MANNITOL (USP),
- e. POLYSORBATE 80 (NF).

Derma Veil may be stored at temperatures between 15° C and 30° C.
Derma Veil does not require refrigeration.

II. INTENDED USE

Derma Veil is applied by subdermal injection to treat moderate to severe facial fat loss (lipoatrophy) caused by degenerative changes that occur due to illness or advanced age. Its application triggers a foreign body reaction promoting a glucosamine biosynthesis that increases cellular interactions favoring the production of new collagen. The process generates histological changes that provide greater fullness to the cutaneous tegument.

These functions provide turgence to collapsed areas while diminishing skin depressions such as wrinkles, creases and minor scars.

- a. *Derma Veil* is a treatment that requires a minimum of two sessions separated by 3 weeks (20 days).
- b. *Derma Veil* is activated prior to use by adding preferably 8mL of Physiological Saline Solution (0.91% w/v of NaCl, about 300 mOsm) or 8mL of Sterile Water for Injection (pyrogen and preservative free). Once activated, the formula becomes a suspension of relative viscosity.
- c. *Derma Veil* should be injected using a sterilized 26G ½ (0.45mm x 13mm) needle.

III. CONTRAINDICATIONS

- a. *Derma Veil* should not to be used in patients with hypersensitivity or allergy to any of the components in the formula. (Refer to section 1.a-e).
- b. *Derma Veil* should not to be used in patients with a history or presence of severe allergies.
- c. *Derma Veil* should not to be used if a dermatological condition or an active inflammatory process or infection is present.
- d. The safety of *Derma Veil* for use in women who are pregnant, suspected of being pregnant or who are lactating has not been established.
- e. Do not inject *Derma Veil* in woman's breast region due to potential imaging interference during diagnostic procedures. (Refer to section 5.k).
- f. Do not inject *Derma Veil* in patients who have a history or susceptibility to hypertrophic scarring or keloid formation.
- g. Do not inject *Derma Veil* in patients with bleeding disorders or patients who are using medications that can prolong bleeding, such as Heparin, Plavix or aspirin (refer to sections 5.g & 5.h).
- h. Do not use *Derma Veil* if other fillers/implants have been used within six (6) months prior to a programmed treatment and **never** use *Derma Veil* if silicone or methacrylate fillers/implants are present.

IV. WARNINGS

- a. *Derma Veil* is only for the use of licensed physicians familiar with injectable fillers.
- b. *Derma Veil* can only be used for intradermal application. Never apply the product in the epidermis (superficially) or in subcutaneous tissue.
- c. Use caution when injecting *Derma Veil*; once the needle has been inserted, draw back the plunger momentarily to ensure that a blood vessel has not been punctured, injecting product into blood vessels could cause an occlusion that may result in an infarction or embolism that could produce scarring or necrosis.
- d. Use caution when injecting *Derma Veil* in areas where the tissue is thin such as; temples, glabella, lateral orbital rim (crow's feet). These applications require skill and well developed practice.
- e. The safety of *Derma Veil* for use in sub-orbital region has not been studied or evaluated and should be avoided.
- f. The safety of *Derma Veil* for use in the red area of the lips (vermillion) has not been studied or evaluated and should be avoided.
- g. Do not overfill a contour deficiency because the depression should slowly diminish as the benefits of the product become evident during the following weeks after the sessions.
- h. The following reactions to the injection of local anesthesia and/or *Derma Veil* during/after a treatment session have been observed consisting mainly of short-term (i.e., a few

hours to 5 days) duration: ecchymosis, erythema, edema, hematoma, and bleeding (Refer to sections 5. g & 5.h).

- i. Patients have expressed various levels of discomfort/pain caused by the injection of *Derma Veil*, as well as due to the implant's presence (Please refer to the *Clinical Studies* section in our webpage: www.medintergroup.com).
- j. Do not use *Derma Veil* in the presence of a dermatological condition, infection or an active inflammatory process such as rashes, hives, and other skin eruptions until the condition has been resolved.
- k. Do not mix *Derma Veil* with other products. No studies or analysis have been made to evaluate the interactions of *Derma Veil* with other substances, drugs, anesthetics, fillers, implants or prosthesis.
- l. Do not use *Derma Veil* in the presence of other dermal fillers injected within six months prior to a treatment program with *Derma Veil*®
- m. Do not use *Derma Veil* in the presence of silicone or methacrilate implants.
- n. Do not use *Derma Veil* if a weight control treatment is in progress or projected within four (4) months after a programmed last session of treatment (weight loss may cause volume increase to appear disproportional).
- o. The safety and effectiveness of *Derma Veil* has not been established beyond two years.
- p. Each vial of *Derma Veil* is for single use only.
- q. Do not re-sterilize *Derma Veil*.
- r. Do not freeze *Derma Veil*.
- s. Once the security seal of *Derma Veil* has been broken the sterility of the device cannot be guaranteed.
- t. When receiving *Derma Veil* do not use the product if the security seal is damaged or has signs of having been tampered with. Report immediately the anomaly to the authorized distributor or to the manufacturer. The product will be replaced as soon as possible.

V. PRECAUTIONS

- a. Injection sessions must be conducted observing *Good Medical Practice* (GMP).
- b. All injection procedures have contamination risk factors; observe *Body Substance Isolation* (BSI) precautions and strict aseptic methods to prevent infection and/or contagion associated with injectable materials.
- c. Routinely clean and disinfect equipment and furnishings in patient care areas.
- d. Observe *Universal Precautions* (UP) when handling syringes and needles to avoid injury and contamination during activation and application of *Derma Veil*.
- e. Handle and dispose of used vials, syringes and needles with *Universal Precautions* (UP) guidelines and applicable local government regulations; avoid recapping used needles, avoid removing used needles from disposable syringes, avoid bending, or manipulating used needles by hand. Place used sharps in puncture-resistant containers.
- f. The use of *Derma Veil* in combination with other fillers and/or muscle inhibitors (i.e., Botulinum toxin) during the same treatment session has not been studied or evaluated and should be avoided.
- g. There is an increased risk of bleeding and hematoma formation at the injection site for patients taking blood thinning medications (anti coagulant therapy) or who have a coagulation deficiency.
- h. Suspend the use of aspirin based products 5 days before the start of the treatment.
- i. If a treatment based on an active dermal response (i.e., laser, mechanical or chemical peeling, UV irradiation) is considered prior to, or after the application of *Derma Veil*, there is the risk of causing an inflammatory reaction in the area where *Derma Veil* was

implanted. For such treatments a minimum of 30 days is recommended before or after the last application of *Derma Veil*.

- j. The patient should be informed to limit sun exposure of the treated area and not to use UV lamp systems for 48 hours following the application of *Derma Veil* or until any swelling and/or redness has totally subsided.
- k. It has not been determined if *Derma Veil* is radiopaque. The asymmetric micro particles of the compound may be visible on scans, ultrasound, standard radiography, magnetic resonance imaging (MRI), or computer tomography (CT). Patients should know that the device may be radiopaque and inform their treating physician, specialist, radiologist or healthcare professional of the presence of *Derma Veil*.

VI. ADVERSE EVENTS

- a. During the Government controlled studies conducted with *Derma Veil* (2001-2003 & 2002-2005) several adverse events occurred caused by trauma to the tissues by the puncture of the needle during application of anesthesia or the implant. The most frequent adverse reactions registered in the participants were erythema and ecchymosis. Also there were several cases of edema and hematoma as well as some bleeding.
- b. None of the participants showed serious reactions, or secondary complications of any nature neither during the investigation's treatment sessions, nor afterwards during the close to two year's observation periods of each study.
- c. Participants expressed various levels of pain caused by the injection of anesthesia and the implant, as well as due to the sensation of the implant's presence. In every case, an ice compress was applied to the participants for a few minutes to diminish blood flow. Afterwards topical anesthesia (*Anestop – Pro-Medic*) was applied to diminish pain due to the needle's puncture when applying local anesthesia (*Xylocaine, 2% lidocaine – Astra Zeneca*) to neutralize in turn the pain of the injection to infiltrate the product.
- d. (Please refer to our web page - www.medintergroup.com - Clinical Studies section for recorded adverse events and levels of pain).

VII. POST MARKETING USE REPORTS:

The following adverse events were reported by commercial users of Glicolact (former brand name 2003-05) and *Derma Veil* (Brand name since 2005) in Mexico, most of which had been observed during the clinical studies:

- a. Bleeding has been occasionally reported as a non-serious event, typically referred to in association with the puncture of the needle during application of anesthesia and/or *Derma Veil*, with the reaction immediately evident as the needle is pulled out from the injection point. The event being resolved after pressing the site with gauze for a few seconds to a minute or two. As a consequence the area would develop an ecchymosis and/or erythema reaction.
- b. Ecchymosis (bruising) and/or erythema (redness) have been reported as the most common and frequent non-serious adverse reactions immediately evident within a few minutes after the injection procedure with the event being resolved after 15 to 20 minutes of application of ice compresses, and in some cases 12 to 48 hours after continuing with ice compress applications at home with some doctors also prescribing topical cream (corticosteroids) application until the event is resolved.
- c. Edema and hematoma have been reported as a non-serious adverse reaction, typically referred to in association with trauma to the tissues by the puncture of the needle during application of anesthesia and/or *Derma Veil*. Time to onset ranged from half hour

to 24 hours. Events resolved within 5-6 days without sequel. Relief prescriptions included anti-inflammatory, corticosteroids, and/or analgesics.

- d. Acute pain, significant bruising and itching have been reported 8 to 24 hours after treatment session. Relief prescriptions included anti-inflammatory, corticosteroids, and/or analgesics. Events resolved within 5-7 days after treatment session without sequel.
- e. Significant edema has been reported associated with pain. The events were mostly transitory. Relief prescriptions included anti-inflammatory, corticosteroids, and/or analgesics. Events resolved within 8-10 days without sequel.

VIII. PREPARATION FOR USE

a. TREATMENT SESSION

- It is recommended that the physician and assistant(s) use lab coats, surgical masks and caps, glasses or protective visors and sterilized surgical gloves.
- Put a cap and a bib on the patient.
- Perform a general cleaning of the area to be treated (asepsis with surgical soap and/or iodine).
- Apply topical anesthetic to reduce discomfort when inserting the needle. It is recommended (in some cases necessary) to apply local anesthesia (xylocaine 2% without epinephrine) subject to the physician's discretion.
- Never mix *Derma Veil* with any anesthetic or other products (refer to sections 4. k, l, m & 5.f).

b. SUPPLIES.

- The following items (supplied by the physician) are required for the application of *Derma Veil*:
 - ✓ Physiological Saline Solution or Sterile Water for Injection (SWFI).
 - ✓ Sterilized Syringes ranging from 2 mL to 10 mL (Single Use)
 - ✓ Sterilized 18g 1 ½ TW (1.2mm x 38mm) needles to mix and retrieve product.
 - ✓ Sterilized 26g ½ (0.45mm x 13mm) needles, to inject the patient (single use).
 - ✓ Sterile surgical gloves.
 - ✓ Caps, glasses or protective visors, mouth covers (recommended).
 - ✓ Vortex (optional)
 - ✓ Patient preparation, treatment and post-treatment supplies (i.e. bibs, asepsis supplies, topical & local anesthesia, sterilized gauze, ice packs, anti-inflammation cream).

c. ACTIVATION OF PRODUCT:

Derma Veil is activated by injecting into the vial preferably 8 mL of Physiological Saline Solution (0.91% w/v of NaCl, about 300 mOsm) or, optional, 8mL of Sterile Water for Injection (SWFI) - pyrogen and preservative free.

d. PROCEDURE:

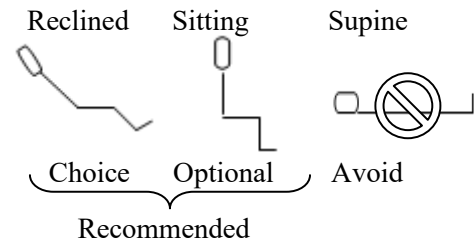
- Place a sterilized 18g needle into a sterilized 10 mL syringe and retrieve 8 mL of Physiological Saline Solution (PSS) or Sterile Water for Injection (SWFI).
- Remove and discard the plastic cap (flip off) and clean the stopper with antiseptic.
- Insert the needle in the center of the stopper on the *Derma Veil* vial.
- Hold the vial at an inclination of 45° in relation to the syringe and press the plunger slowly while rotating the vial at the same time until the 8 mL of Physiological Saline

Solution or Sterile Water for Injection has been fully introduced in the *Derma Veil* vial.

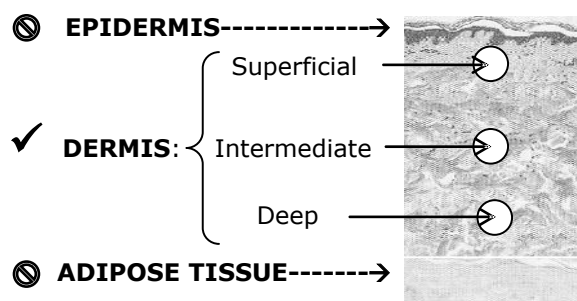
- Without shaking the vial, let the mixture rest for approximately 10 minutes.
- At the end of the 10 minutes, shake the vial vigorously by hand or use a mechanical mixer (vortex) until the suspension has a homogeneous aspect, completely uniform and without lumps.

e. APPLICATION PROCESS.

- Place the patient in a reclined or sitting position, under good lighting (i.e. halogen lamps) and use magnifying glasses to have a clear and precise observation of the area of application. It is not recommendable to treat the patient lying down (supine position).



- ***Derma Veil*® can only be used for intradermal application.** The product is applied in the dermis exclusively:



APPLICATION REGIONS

Glabella, Temporal & Upper Lips Rim.

Attention, all superficial applications require skill and well developed practice.

Zygomatic Malar, Nasal-Labial, Smile Lines & Mandible

Malar, Nasal & Mandible.

NEVER INJECT THE PRODUCT IN THE EPIDERMIS OR ADIPOSE TISSUE

- The security and effectiveness of the infiltration process depends on adequate insertion of the needle, dosage of product and deposit pattern as well as the precautions taken to prevent and attend to an eventual contingency.
- Injecting proficiency and methodology are fundamental in the application of *Derma Veil*. Seminars and workshops for the use of *Derma Veil* are permanently programmed by *Medinter, Ltd.* and provide the opportunity to enhance basic injecting skills. For a program of our workshops and/or seminars please contact your regional distributor or Medinter, Ltd. at workshops@medintergroup.com
- Once the product has been activated and the suspension is homogenous, using the 10 mL syringe with the sterilized 18G needle, retrieve the amount of product that will be implanted in the patient for the specific application sequence. It is recommended to infiltrate between 0.2 mL to 1.0 mL per application depending on the area being treated.
- Once the desired amount is obtained, substitute the 18G needle for a sterilized 26G needle to implant the product in the patient.
- Expel a few drops of product from the 26G needle to eliminate any air from the syringe.
- The product should be infiltrated slowly using a small volume syringe (3 cc with a sterilized 26G needle) which allows a better control of the pressure needed to drive the plunger.

- With a swift and steady movement, introduce with bevel-up the 26G needle on the intended area at a 30° to 45° angle from the patient's skin surface. A slow or hesitant insertion may tear the tissue with the possibility of generating an edema or hematoma and probably obstruct the needle.
- Once the needle has been inserted in the target area, draw back the plunger momentarily to ensure that a blood vessel has not been punctured (refer to section 4. c) and then drive the needle to the required depth of the area being treated.
- The suspension is infiltrated by slowly pressing the plunger while withdrawing the syringe gradually to achieve a uniform and consistent infiltration of the product. This method ("tunnel" technique) should be strictly observed in order to achieve optimal results when using this product. The same technique should be strictly observed when applying crossed insertions ("grill" system) or elliptic insertions.
- When more product is required remove and discard the used 26G needle and put again the 18G needle used to retrieve product.
- It is recommended to replace the used 26G needle for a new sterilized 26G needle for every ensuing application (prevent contamination).
- Shake the vial again before each application (manually or with a vortex).
- At the end of the session, it is advisable to lightly massage the treated areas in order to properly disseminate the product in a homogeneous manner.
- The intermittent application (2x2 minutes on & off) of sterilized ice packs for 6 to 8 minutes on the target areas is also recommended to reduce the risk of ecchymosis or edema.

NOTICE: **DO NOT RE-USE THE PRODUCT.** Derma Veil is for single use only.
DO NOT USE BEYOND EXPIRATION DATE.
DO NOT ATTEMPT TO RE-STERILIZE THE PRODUCT.
DO NOT USE THE PRODUCT IF THE SECURITY SEAL IS DAMAGED OR HAS BEEN VIOLATED. Report the incident to the authorized distributor or to the manufacturer. The product will be replaced as soon as possible.

IX. INDIVIDUALIZATION OF TREATMENT.

- a. The number of injection sessions required depends on the assessment of the diagnosed state of the patient. A treatment program requires a minimum of two sessions and could go as high as five or more (i.e. during the 2^d clinical trials 14 patients with severe lipoatrophy were assigned three to four sessions with only 2 cases where five sessions were recommended). All sessions must be separated by a minimum of 20 days.
 - The product is activated with 8 mL of Physiological Saline Solution. Sterilized Water for Injections may also be used. Once activated, the formula becomes a suspension of relative viscosity and is implanted via intra-dermal injection.
- b. Prior to the start of a *Derma Veil* program: The treating physician should personally give the patient the following information:
 - The characteristics of *Derma Veil* as filler and what in principle may be expected, considering that the response to the treatment varies from person to person.

- The probable benefits as well as risks in the use of *Derma Veil* and that:
 - ✓ Prior to injecting *Derma Veil*, application of topical anesthesia is recommended at the insertion point and local anesthesia may be required in some cases.
 - ✓ It is certain that as a result of the injection procedure some degree of bruising and redness will result and what remedies are available,
 - ✓ There is a high probability of other adverse events occurring such as edema, hematoma or other more serious reactions.
- In three to four days after the initial application, the effects will diminish almost disappearing, giving the impression that the product has been absorbed:
 - ✓ The vanishing effect is due to the elimination by the organism of the Physiological Saline Solution or Sterilized Water for Injection.
 - ✓ *Derma Veil's* composite remains attached to the tissues stimulating production of new collagen, this reaction of the organism gradually causes the histological pattern to normalize and the treated area slowly shows the effect of the implant.
 - ✓ After the second or subsequent applications, the physical and visual effects remain visible. Clinical studies have demonstrated that in certain cases the results have lasted for over 2 years.

X. DISTRIBUTION.

- a. Each box of *Derma Veil* is delivered with an *Instruction for Use* leaflet. The box contains two vials; each vial has 10 mL volume and is made of transparent borosilicate glass, sealed with a siliconized halobutyl stopper secured by an aluminum ring with a "flip off" plastic cap. Each vial contains 236.14 mg of a lyophilized, Sterile, pyrogen free, crystalline white powder of asymmetric micro-particles (40-80 µm) structured as described in Section N° 1 "Device Description".
- b. The *Derma Veil* box and the label in each of the vials contained in the box have the following markings:
 Manufacturer's name & address, Manufacture date, Expiry date, Lot number, Sterilization method and pyrogen free indication, Minimum/maximum storage temperature, Read Instructions before Use symbol and *Derma Veil's* barcode.

XI. STORAGE, STERILITY AND DISPOSAL

- a. Shelf life of a sealed vial is 24 months from manufacturing date. Expiration date is indicated on box exterior and on the label of each vial.
 - Keep *Derma Veil* in dry storage, away from humidity and light, at a temperature between 15° C (59° F) and 30° C (86° F). Refrigeration is not necessary.
- b. Dispose of empty vials and syringes as per appropriate safety regulations and biohazard techniques (refer to section 5. e).

MANUFACTURED By:

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