

H. PREPARATION FOR USE

1. TREATMENT SESSION

- 1.1** It is recommended that the physician and assistant(s) use lab coats, surgical masks and caps, glasses or protective visors and sterilized surgical gloves.
- 1.2** Put a cap and a bib on the patient.
- 1.3** Perform a general cleaning of the area to be treated (asepsis with surgical soap and/or iodine).
- 1.4** 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.
- 1.5** Never mix *Derma Veil* with any anesthetic or other products (refer to sections IV. 11, 12, 13 & V.6).

2. SUPPLIES.

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

3. ACTIVATION OF PRODUCT:

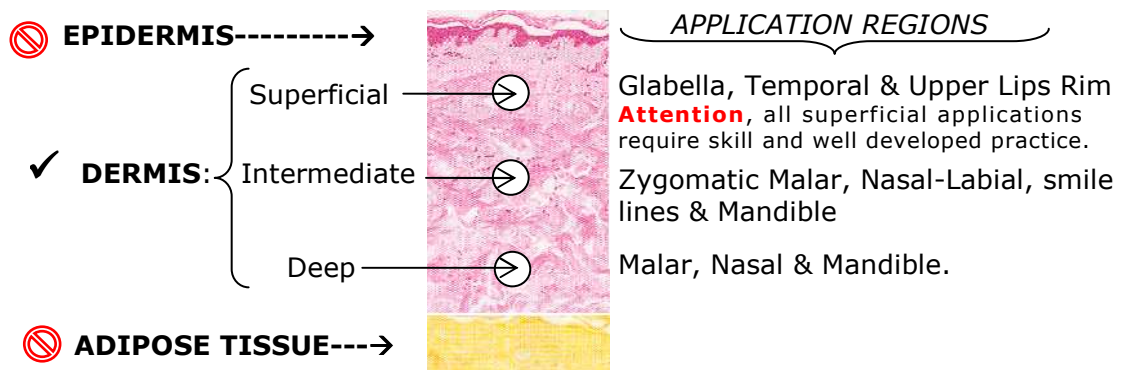
- 3.1** *Derma Veil* is activated by injecting into the vial preferably 8 mL of Physiological Saline Solution (0.91% [w/v](#) of [NaCl](#), about 300 [mOsm](#)) or, optional, 8mL of Sterile Water for Injection (SWFI) - pyrogen and preservative free.

4. PROCEDURE:

- 4.1 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).
- 4.2 Remove and discard the plastic cap (flip off) and clean the stopper with antiseptic.
- 4.3 Insert the needle in the center of the stopper on the *Derma Veil* vial.
- 4.4 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.
- 4.5 Without shaking the vial, let the mixture rest for approximately 10 minutes.
- 4.6 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.

5. APPLICATION PROCESS.

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



NEVER INJECT THE PRODUCT IN THE EPIDERMIS OR ADIPOSE TISSUE

- b.** 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.
- c.** 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
- d.** Once the product has been activated and the suspension is homogenous, using the 10 mL syringe with the sterilized 18 gauge 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.
- e.** Once the desired amount is obtained, substitute the 18G needle for a sterilized 26G needle to implant the product in the patient.
- f.** Expel a few drops of product from the 26 G needle to eliminate any air from the syringe.
- g.** The product should be infiltrated slowly using a small volume syringe (3 cc with a sterilized 26 G needle) which allows a better control of the pressure needed to drive the plunger.
- h.** With a swift and steady movement, introduce with bevel-up the 26 gauge 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.
- i.** 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 IV. 3) and then drive the needle to the required depth of the area being treated.
- j.** 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.
- k.** When more product is required remove and discard the used 26 gauge needle and put again the 18G needle used to retrieve product.

- l.** It is recommended to replace the used 26 gauge needle for a new sterilized 26 gauge needle for every ensuing application (prevent contamination).
- m.** Shake the vial again before each application (manually or with a vortex).
- n.** 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.
- o.** 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.