

# Reborn<sup>TM</sup>

Poly L-lactic Acid Hydrogel—Mesoderm

## INSTRUCTIONS FOR USE

Before using Reborn<sup>TM</sup> PLLA Hydrogel Filler(Mesoderm), please read the following information.

If you have any questions regarding these guidelines, contact your local distributor or Jilin Folialux Bio-Tech Co. Ltd at: [info@foliallux.com](mailto:info@foliallux.com).

You can also refer to our website at [www.foliallux.com](http://www.foliallux.com).

## 1. DEVICE DESCRIPTION

Reborn<sup>TM</sup> PLLA Hydrogel Filler(Mesoderm) is a hydrogel colloidal liquid with the following characteristics: injectable single use medical device incorporated with a hydrophilic matrix. Its active principle is lactic acid [Poly (L-lactide)] which is homogeneously dispersed throughout and the rate of release is controlled, prolonging a sustained repairing action through the slow dissolution of the compound.

-Poly(L-lactide) is a biodegradable material with good bio-absorbability and bio-compatibility. It is widely used in the field of medicine, such as for one-time infusion equipment, medical surgical suture, drug delivery carriers, tissue engineering scaffolds, bone anchors, injectable microcapsules, microspheres, implants, elastomer materials for organ support. In 2004, PLLA became FDA-certified regenerative medical material for facial filling. Initially used for filling facial depressions in patients with advanced AIDS

- After Reborn<sup>TM</sup> PLLA Hydrogel Filler(Mesoderm) is injected into the body, it is degraded into L-lactic acid by biochemical reactions. L-lactic acid is a natural substance in the body, it's not only the natural moisturizing factor for skin, but also can stimulate the proliferation of skin fibroblasts and secrete new collagen, the new generated collagen repairs the fractured collagen fibers, prop up the wrinkles, increase skin elasticity and thickness, at the same time, transfer cellular mesenchyme with migration effect, thus tenderization and whitening and control of water and oil balance. Subcutaneous capillaries migrate to avascular or less vascular areas, providing oxygen and essential nutrients to tissues, promoting keratinocyte migration, proliferation, differentiation, and improving the sensitive skin caused by the excessive thin of cuticle, it makes skin moist and soft, shiny and translucent, and restores elasticity to achieve a youthful skin status.

Each box of Reborn™ PLLA Hydrogel Filler(Mesoderm) contains 1 syringe. Each syringe of Reborn™ PLLA Hydrogel Filler(Mesoderm) is made of transparent PVC, it contains 2ml made of:

- a. Poly(L-lactide)-block-poly(ethylene glycol) ,also known as: PLLA-PEG
- b. Balanced salt
- c. Water

Reborn™ PLLA Hydrogel Filler(Mesoderm) should be stored at temperatures between 5°C and 20°C. Refrigeration is recommended

## 2. INTENDED USE

Reborn™ PLLA Hydrogel Filler(Mesoderm) is applied by subdermal injection to treat facial wrinkle increased, large pores, the skin lost elasticity, facial redness and redness increased, chapped skin, poor water retention and gloss deterioration, skin pigmentation, acne scars and other issues which is caused by environment, diet, lifestyle, aging. Its application triggers a foreign body reaction promoting a glucosamine biosynthesis that increases cellular interactions favoring the production of new collagen.

- a. Reborn™ PLLA Hydrogel Filler(Mesoderm) is treated by a course, usually requiring two to three treatments, and the second time is at least four weeks after the first therapy. The effect is cumulative in the course of treatment. The duration time varies slightly according to the facial status and the basic conditions of the patients. In order to keep a good therapeutic effect, it is recommended to apply this treatment every 3 months after the 1st therapy.
- b. Reborn™ PLLA Hydrogel Filler(Mesoderm) should be injected using a mesogun( needleless or with needles)or injected by a 30G needle.

## 3. CONTRAINDICATIONS

- a. Reborn™ PLLA Hydrogel Filler(Mesoderm) should not to be used in patients with hypersensitivity or allergy to any of the components in the formula (Refer to section 1. a-c) .
- b. Reborn™ PLLA Hydrogel Filler(Mesoderm) should not to be used in patients with a history or presence of severe allergies.
- c. Reborn™ PLLA Hydrogel Filler (Mesoderm) should not to be used if a dermatological condition or an active inflammatory process or infection is presented.
- d. The safety of Reborn™ PLLA Hydrogel Filler (Mesoderm) for use in women who are pregnant, suspected of being pregnant or who are lactating has not been established.
- e. Do not inject Reborn™ PLLA Hydrogel Filler(Mesoderm) in woman's breast region due to potential imaging interference during diagnostic procedures.

(Refer to section 5.1)

- f. Do not inject Reborn™ PLLA Hydrogel Filler(Mesoderm) in patients who have a history or susceptibility to hypertrophic scarring or keloid formation.
- g. Do not inject Reborn™ PLLA Hydrogel Filler(Mesoderm) 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.f& 5g).
- h. Do not use Reborn™ PLLA Hydrogel Filler(Mesoderm) if other fillers/implants have been used within three(3)months for a programmed treatment.

## 4. WARNINGS

- a. Reborn™ PLLA Hydrogel Filler(Mesoderm) can be used for intradermal application or in subcutaneous tissue.
- b. The safety of Reborn™ PLLA Hydrogel Filler(Mesoderm) for use in the red area of the lips(vermillion) has not been studied or evaluated and should be avoided.
- c. Stop the injection and check when the patients have expressed various levels of discomfort/pain caused by the injection of Reborn™ PLLA Hydrogel Filler(Mesoderm).
- d. Do not use Reborn™ PLLA Hydrogel Filler(Mesoderm) 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 .
- e. Do not mix Reborn™ PLLA Hydrogel Filler(Mesoderm) with other products. No studies or analysis have been made to evaluate the interactions of Reborn™ with other substances, drugs, anesthetics, fillers, implants or prosthesis.
- f. Do not use Reborn™ PLLA Hydrogel Filler(Mesoderm) in the presence of other dermal fillers injected within three months prior to a treatment program.
- g. Do not use Reborn™ PLLA Hydrogel Filler (Mesoderm) in the presence of silicone or methacrylate implants.
- h. Each syringe of Reborn™ PLLA Hydrogel Filler(Mesoderm) is for single use only .
- i. Do not re-sterilize Reborn™ PLLA Hydrogel Filler(Mesoderm) .
- j. Do not freeze Reborn™ PLLA Hydrogel Filler(Mesoderm).
- k. Once the security seal of Reborn™ PLLA Hydrogel Filler( Mesoderm) has been broken the sterility of the device cannot be guaranteed. Report immediately the anomaly to the authorized distributor or to the manufacturer. The product will be replaced as soon as possible.

## 5. PRECAUTIONS

- a. Injection sessions must be conducted observing Good Medical Practice (GMP).
- b. Routinely clean and disinfect equipment and furnishings in patient care

- areas.
- c. Observe Universal Precautions(UP) when handling syringes and needles to avoid injury and contamination during activation and application of Reborn™ PLLA Hydrogel Filler(Mesoderm)
  - d. Handle and dispose of used syringes and needles with Universal Precautions (UP) guidelines and applicable local government regulations, avoid recapping used needles.
  - e. The use of Reborn™ PLLA Hydrogel Filler(Mesoderm) 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.
  - f. 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.
  - g. 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 Reborn™ PLLA Hydrogel Filler (Mesoderm), there is the risk of causing an inflammatory reaction in the area where Reborn™ was implanted. For such treatments a minimum of 30 days is recommended before or after the application of Reborn™ PLLA Hydrogel Filler (Mesoderm).
  - j. The patients 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 Reborn™ PLLA Hydrogel Filler(Mesoderm) or until any swelling and/or redness has totally subsided
  - k. It has not been determined if Reborn™ PLLA Hydrogel Filler(Mesoderm) 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 Reborn™ PLLA Hydrogel Filler (Mesoderm).

## 6. POST MARKETING USE REPORTS

Ecchymosis(bruising) and/or erythema (redness) have been reported as the most common and non-serious frequent adverse reactions. Immediately evident within a few minutes after the injection procedure with the event being resolved after 15 to 20 minutes 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.

## 7. 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 sterile 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 Reborn™ with any anesthetic or other products.

#### **b. SUPPLIES**

The following items (supplied by the physician) are required for the application of Reborn™ PLLA Hydrogel (Mesoderm):

- Lidocaine surface anesthetic ointment
- Needleless and needles water mesotherapy injector or 30G needle.
- Power supply.
- Sterilized 5 needles or 9 needles (no need for needleless water mesotherapy injector) or 30G needle to inject the patient (single use)
- Sterile surgical gloves.
- Caps, glasses or protective visors, mouth covers.
- Patient preparation, treatment and post-treatment supplies (i.e. bibs, asepsis supplies, topical local anesthesia, sterilized gauze, ice packs, anti-inflammation cream).

#### **c. PROCEDURE**

- Remove the 2mL sterile syringe from the aluminum foil bag and fit the booster into the syringe.
- Remove and discard the front part of the syringe (flip off) and clean with alcohol cotton ball.
- Install the entire syringe onto the water mesotherapy gun or 30g needle.
- Adjust the depth of the water mesotherapy gun needle (recommended: 0.9-1.6 mm) and the liquid flow (according to the patient's degree of facial)

#### **d. INJECTION 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.
- Reborn™ PLLA Hydrogel Filler (Mesoderm) can only be used for intradermal application. The product is applied in the dermis exclusively.
- 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.
- Discharge a few drops of products from syringe needle (needleless or with needle), to eliminate the air in the syringe.
- With a swift and steady movement, introduce needle on the intended area at a 90° angle from the patient's skin surface (for Mesotherapy Gun injection).

A slow or hesitant insertion may tear the tissue with the possibility of generating edema or hematoma probably obstruct the needle.

- Move the syringe needle of the Mesotherapy Gun quickly, until all injected area complete the injection.
- If the needle is bent or not sharp, it is recommended to replace the needle.
- After injection, it is recommended to massage by erythromycin eye ointment.
- 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.

■ **NOTICES:**

DO NOT RE-USE THE PRODUCT. Reborn™ PLLA Hydrogel Filler(Mesoderm) 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 immediately the incident to the authorized distributor or to the manufacturer. The product will be replaced as soon as possible.

## 8. INDIVIDUALIZATION OF TREATMENT

- a. The number of injection sessions required depends on assessment of the diagnosed state of the patient.
- b. Prior to the start of a Reborn™ PLLA Hydrogel Filler(Mesoderm) program: The treating physician should personally give the patients the following information:
  - The characteristics of Reborn™ PLLA Hydrogel Filler(Mesoderm) as filler 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 Reborn™ PLLA Hydrogel Filler(Mesoderm) and that:
    - Prior to injecting Reborn™ PLLA Hydrogel Filler(Mesoderm), 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 occur and remedies are available
    - Reborn™ PLLA Hydrogel Filler(Mesoderm)'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 over 1 year.

## 9. STORAGE, STERILITY AND DISPOSAL

- a. Shelf life of a sealed syringe is 12 months from manufacturing date.
  - Keep Reborn™ PLLA Hydrogel Filler(Mesoderm)in dry storage, away from humidity and light, at a temperature between 5°C (41°F) 和 20°C (68°F) . Refrigeration is recommended.
- b. Dispose of empty syringes as per appropriate safety regulations and biohazard techniques (refer to section 5. d).

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