Reborn™

Poly L-lactic Acid Dermal Filler

INSTRUCTIONS FOR USE

Before using Reborn ™ PLLA Dermal Filler, 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.
You can also refer to our website at www.folialux.com.

1. DEVICE DESCRIPTION

Reborn ™ PLLA Dermal Filler 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 poly lactic acid [Poly (L-lactide)] 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.

Each vial of Reborn ™ PLLA Dermal Filler is packed by transparent borosilicate glass, sealed with a siliconized halobutyl stopper secured by an aluminum ring with a “flip off” plastic cap. The vial has 15 mL capacity and contains 360/240 mg of a lyophilized, sterile, pyrogen free, crystalline white powder of asymmetric micro-particles (3 to 10 μm) made of:

a. POLY LACTIC ACID microspheres[Poly (L-lactide)] Also known as (synonyms): Poly-L-lactide, PLLA
b. Medical supplements

2. INTENDED USE

Reborn ™ PLLA Dermal Filler 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 glucosaline 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 processes provide tenseness to collapsed areas while diminishing skin depressions such as wrinkles, creases and minor scars.

a. Reborn ™ PLLA Dermal Filler is treated by a course, usually requiring 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 three to four months after the first therapy.

b. Reborn ™ PLLA Dermal Filler is activated prior to use by adding preferably 10ml of Physiological Saline Solution (0.91% w/v of NaCl, about 300 mOsm) or 10mL of Sterile Water for Injection (pyrogen and preservative free). Once activated, the formula becomes a suspension of relative viscosity.

c. Reborn ™ PLLA Dermal Filler should be injected using a sterilized 26/27/29G/30G ½ needle.

3. CONTRAINDICATIONS

a. Reborn ™ PLLA Dermal Filler should not to be used in patients with hypersensitivity or allergy to any of the components in the formula. (Refer to section 1.a-d).

b. Reborn ™ PLLA Dermal Filler should not to be used in patients with a history or presence of severe allergies.

c. Reborn ™ PLLA Dermal Filler should not to be used if a dermatological condition or an active inflammatory process or infection is present.

d. The safety of Reborn ™ PLLA Dermal Filler 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 Dermal Filler in patients who have a history or susceptibility to hypertrophic scarring or keloid formation.

f. Do not inject Reborn ™ PLLA Dermal Filler 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& 5.g).

g. Do not use Reborn ™ PLLA Dermal Filler if other fillers/implants have been used within six (6) months prior to a programmed treatment and never use Reborn ™ PLLA Dermal Filler if silicone or methacrilate fillers/implants are present.

4. WARNINGS

a. Reborn ™ PLLA Dermal Filler is only for the use of licensed physicians familiar with injectable fillers.
b. Reborn ™ PLLA Dermal Filler can be used for intradermal applicationor in subcutaneous tissue, but each part use different amount .
c. Use caution when injecting Reborn ™ PLLA Dermal Filler;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 scaring or necrosis.
d. Use caution when injecting Reborn ™ PLLA Dermal Filler in areas where the tissue is thin such as: temples, glabella, lateral orbital rim (crow's feet). These applications require skill and well developed practices.
e. The safety of Reborn ™ PLLA Dermal Filler for use in the red area of the lips (vermillion) has not been studied or evaluated and should be avoided.
f. 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.
g. Stop the injection and check when the patients have expressed various levels of discomfort/pain caused by the injection of Reborn ™ PLLA Dermal Filler, as well as due to the implant's presence.
h. Do not use Reborn ™ PLLA Dermal Filler 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.
i. Do not mix Reborn ™ PLLA Dermal Filler 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.
j. Do not use Reborn™ in the presence of other dermal fillers injected within six months prior to a treatment program with Reborn ™ PLLA Dermal Filler.
k. Do not use Reborn ™ PLLA Dermal Filler in the presence of silicone or methacrilate implants.
l. Do not use Reborn ™ PLLA Dermal Filler 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).
m. Each vial of Reborn ™ PLLA Dermal Filler is for single use only.
n. Do not re-sterilize Reborn ™ PLLA Dermal Filler.
o. Do not freeze Reborn ™ PLLA Dermal Filler.
p. Once the security seal of Reborn ™ PLLA Dermal Filler has been broken the sterility of the device cannot be guaranteed.
q. When receiving Reborn ™ PLLA Dermal Filler, 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.

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 Dermal Filler.
d. 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.
e. The use of Reborn ™ PLLA Dermal Filler 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.
h. 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 Dermal Filler, 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 last application of Reborn™.
i. 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 Reborn ™ PLLA Dermal Filler or until any swelling and/or redness has totally subsided.
j. It has not been determined if Reborn ™ PLLA Dermal Filler 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 Dermal Filler.

6. POST MARKETING USE REPORTS

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.

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 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 Reborn ™ PLLA Dermal Filler with any anesthetic or other products (refer to sections 4. j, k, l & 5.e).

b. SUPPLIES.

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

-Physiological Saline Solution or Sterile Water for Injection (SWFI).

-Sterilized syringes ranging from 2 mL to 15 mL (Single Use)

-Sterilized 18g 1 ½ TW (1.2mm x 38mm) needles to mix and retrieve product.

-Sterilized 26/27/29/30/G ½needles, 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:

Reborn ™ PLLA Dermal Filler is activated by injecting into the vial preferably 10 ml of Physiological Saline Solution (0.91% w/v of NaCl, about 300 mOsm) or, optional, 10ml of Sterile Water for Injection (SWFI) - pyrogen and preservative free.

d. PROCEDURE:

- Place a sterilized 18g needle into a sterilized 15 mL syringe and retrieve 15 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 Reborn ™ PLLA Dermal Filler 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 10 mL of Physiological Saline Solution or Sterile Water for Injection has been fully introduced in the Reborn ™ PLLA Dermal Filler 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. 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 Dermal Filler 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.
- Injecting proficiency and methodology are fundamental in the application of Reborn ™ PLLA Dermal Filler.
- Once the product has been activated and the suspension is homogenous, using the 15 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/27G/29G/30G needle to implant the product in the patient.
- Expel a few drops of product from the 26G/27G/29G/30G needle to eliminate any air from the syringe.
- The product should be infiltrated slowly using a small volume syringe (2-3 cc with a sterilized 26G/27G/29G/30G 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/27G/29G/30G 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 the18G 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. Reborn ™ PLLA Dermal Filler 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.

8. 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 several sessions and could go as high as five or more (i.e. during the 2nd 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 10 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 Reborn ™ PLLA Dermal Filler program: the treating physician should personally give the patient the following information:

- The characteristics of Reborn ™ PLLA Dermal Filler 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 Reborn™ and that:
  - ✓ Prior to injecting Reborn ™ PLLA Dermal Filler, 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.
- ✓ Reborn ™ PLLA Dermal Filler'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.

9. PACKAGE

The Reborn ™ PLLA Dermal Filler 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, Minimum/m aximum storage temperature, Read Instructions before Use symbol.

10. 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 Reborn ™ PLLA Dermal Filler in dry storage, away from humidity and light, at a temperature between 5ºC（41ºF）and 30ºC（86ºF）. Refrigeration is not necessary.

b. Dispose of empty vials and syringes as per appropriate safety regulations and biohazard techniques (refer to section 5. d).

MANUFACTURED By: Jilin Folialux Bio-Tech Co., Ltd., FAW-Sihuan Xufa Workshop Building B1B2, around 500 meters on the east of Xinggong Road and Haier Street intersection,Kuancheng District,Changchun City,Jilin Province,China 130000
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