

**Shelf life:** Two years (24 months)

**Storage:** Room temperature (5°C-25°C), avoid light and freezing

**Package unit:** 1 pre-filled syringe / 1 box

**Composition:** Polycaprolactone 210 mg per one syringe  
Volume of One syringe: 1.0 ml

**Intended Use:** It is intended to be used for facial tissue augmentation for dermal implantation.

**Intended User:** Specialist in the fields of dermatology or plastic surgery

**Indication:** It is indicated to be used for facial tissue augmentation for mid-to-deep dermal implantation for the correction of moderate to severe facial wrinkles and folds.

## Directions for the use

### A. Warning:

- 1) Injection to intradermal or upper part of periosteum.
- 2) Does not resterilize at the time of use.
- 3) Avoid injecting it to blood vessel which is likely to cause occlusion of blood vessels (tissue necrosis due to It).
- 4) Avoid using it by mixing it with other products.
- 5) Do not re-use it.
- 6) Check and see if sterile condition is not damaged before use.
- 7) Check the expiry date on the label of the product (Shelf life: 2 years)

### B. Patient Group and contraindication

- 1) Prohibit using it to below groups.
  - Patients who are known to hypersensitive to Polycaprolactone
  - Patients should be more than 19-years-old
  - Women who are pregnant or breastfeeding
  - Patient who showed anaphylaxis to raw materials of filler
  - Patient who has history of serious allergy or anaphylaxis
  - Patients with bleeding disorders or patients taking thrombolytic agents or anticoagulants
  - Patients receiving NSAIDs, coagulation inhibitors, anticoagulants, immunosuppressants
  - Patients who has allergic disease, autoimmune disease, sarcoid granulomatous pathology, oslers endocarditis patient
  - Patients with serious allergies, anaphylaxis
  - Patients who tend to have hypertrophic scars
  - Patients with a history of streptococcal disease
  - Patients who is children and adolescents, minors

2) Do not inject into inflammatory or infected skin

3) Do not use with laser treatment, chemical peeling or peeling

### C. Precautions for use

- 1) Comply with general precautions at the time of injection to intradermal or upper part of periosteum.
- 2) Always be careful because danger of infection is intrinsic.
- 3) There should be sufficient anatomic knowledge on the part where injection is made.
- 4) Avoid injecting it to the part where permanent implant was made.
- 5) Until disappearance of edema or sense of heat at the part where injection is done, the patient shall not expose the part where injection is made to sizzling heat or extreme coldness.
- 6) Avoid using it to patient who anticipate to have more result than effect of treatment.
- 7) For the case where this product is injected to the part where it is being treated with other filler, there is no verified result.
- 8) Doing make-up during 12 hours after the injection is prohibited. Long-term exposure to sunlight, UV, gel or sauna (sweating bathroom) is prohibited for 2 weeks after the injection.
- 9) Severe side-effect such as blindness, etc. may happen in case of injection into blood vessel, and therefore, using it to the eye contours (eye circle or eyelids) where its injection into blood vessel is highly likely is prohibited. Special attention shall be paid at the time of using it.
- 10) There was no established result on safety and effectiveness for the case of using it for a long period beyond the time which is established by clinical research.
- 11) There was no established result on safety and effectiveness about lip broadening treatment.
- 12) Injection to patient who has history of herpetic eruption may lead to the recurrence of it.
- 13) No safety is guaranteed to patient who tend to develop keloid scarring, hyperpigmentation and hypertrophic scarring.
- 14) This operation shall be carried out by doctor who is sufficiently trained for such operation.
- 15) Doctor shall sufficiently explain to patient about indications, contraindications and potential side-effects before injection. Disinfect the treatment site thoroughly before the procedure.

#### D. Incompatibility and mutual interaction

Precipitation reaction may be caused by quaternary ammonium salts such as benzalkonium chloride which is sterilant. Accordingly, this product shall not be stored with such materials or avoid contact with operation equipment which uses such materials. There was no verification for the case of using this product together with other medicine or equipment.

#### E. Expected side-effects

- 1) After injection, symptom such as bruising/hematoma, redness, swelling, pain, tenderness, itching, rash, lumps/nodules, Inflammation/infection, and Induration may appear, and it shall disappear for itself after 1~2 weeks.
- 2) It is necessary to inform the people concerned that immediately or after lapse of a certain period of time, the following symptoms may appear. When such symptom appears, it is necessary to report it to the seller.
- 3) After injection, inflammation (red fever, redness, edema) accompanied by cut wound or pain may persist about a week.
- 4) After injection of Polycaprolactone, abscess and oversensitive reaction may appear and so due precaution shall be taken.
- 5) If inflammation reaction persists more than a week or other side-effects appear, then heal it through immediate consultation with medical professional.

#### Method of use

##### A. Preparatory requirement before use

- 1) This product is medical device therefore it shall be used by licensed medical professionals.
- 2) Before using it the doctor shall provide sufficient explanation to the patient about indications, contraindications and potential side-effects of this product.
- 3) Before its use it is necessary to check and see if sterilized condition is damaged or not.
- 4) Check the effective period on the label of the product.

##### B. Sequence of manipulation and method of use

- 1) Before use, disinfect the part subjected to injection thoroughly.
- 2) Carry out partial anesthesia when required.
- 3) Insert needle to injection syringe.
- 4) A certain amount of this product is injected into skin where the injection is required according to judgement of medical professional and when required repetitive injection may be made.
- 5) After injection the part where injection is made shall be shaped by tip of hands.

6) Regular additional injection is required or demanded in order to maintain improved condition.

#### C. Method of storage and management after use

- 1) It is disposable and therefore, make sure to dispose of it after use.
- 2) Never re-sterilize and use it again.

#### Recommendation for Needle

The sterile needle should be connected with our device to inject the pre-filled solution into the patient and the needle is not a component of the device so a user should buy the sterile needle separately and we recommend using a sterile 30 gauge needle with our device.

DEXLEVO

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#### Description of Symbol

Symbol	Description	Symbol	Description
	Temperature limitation		Use by
	Sterilized using steam or dry heat		Date of manufacture
	Lot number		CE-marked according to Medical Device Regulation
	Attention, see instructions for use		Don't use if package is damaged
	Manufacturer		Consult instructions for use
	Authorized representative in the European Union		Keep away from sunlight
	Do not re-sterilize		Do not re-use
	Keep dry		