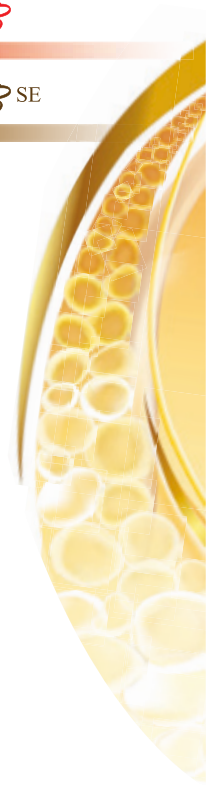
PROSTROLANE

Inner-B
2 ml

Inner-B SE
1 ml



Description
Prostrolane Inner_B / Inner_B^{SE} are a transparent gel supplied in a glass syringe. The product is for single use only. Prostrolane Inner_B / Inner_B^{SE} are a sterile medical device, dermal resorbable implant that contains a non-cross-linked Sodium Hyaluronate and peptide complex (Nonapeptide-32, Pentapeptide-43, Tripeptide-41, Octapeptide-11). Sodium Hyaluronate is non-animal origin and biocompatibility material. The Role of Sodium Hyaluronate in the skin is to deliver peptide, hydrate the skin by holding in water, and to act as a cushioning agent. Peptide complex consists of 4 kinds peptides that short chain of amino acids linked by peptide bonds. The role of the peptide complex is enhanced the moisturizing effect, improve the appearance of cellulite skin and delays the degradation of Sodium Hyaluronate. Peptide complex with Sodium Hyaluronate is degradation within 4 weeks. Each carton contains two traceability labels and 1 prefilled syringe (2ml Prostrolane Inner_B or 1ml Prostrolane Inner_B^{SE}).
(one to be given to the patient, and another to be kept by the doctor in the patient's file)

Composition
PBS (Phosphate Buffered Saline),
Sodium Hyaluronate (0.7%),
Peptide complex (Nonapeptide-32, Pentapeptide-43, Tripeptide-41, Octapeptide-11)

Indication and usage
Prostrolane Inner_B / Inner_B^{SE} are indicated for softening dermal surface irregularities, specifically formulated for cellulite depression skin.
- Site of Application:
Face(double chin), abdomen, buttocks, back of the thighs
- Recommended usage volume :
Face(double chin) : 4ml / area (Maximum : 10ml / area)
Abdomen, buttocks, back of the thighs : 12ml / area (Maximum : 20ml / area)
- Frequency :
1 session / 2 weeks (1 protocol = 4~6 sessions average) (repeat protocol as necessary)

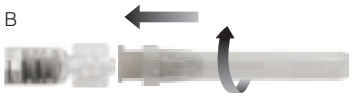
Treatment procedure
Pretreatment Guidelines Prior to treatment, the patient should avoid taking aspirin, nonsteroidal anti-inflammatory medications, St. John's Wort, or high doses of Vitamin E supplements. These agents may increase bruising and bleeding at the treatment site.

1. It is necessary to counsel the patient and discuss the appropriate indication, risks, benefits and expected responses to the Prostrolane Inner_B / Inner_B^{SE} treatment. Advise the patient of the necessary precautions before commencing the procedure.
2. Assess the patient's need for appropriate anesthetic treatment for managing comfort, i.e., topical anesthetic, local or nerve block.
3. The patient's face should be washed with soap and water and dried with a clean towel. Cleanse the area to be treated with alcohol or another suitable antiseptic solution.
4. Sterile gloves are recommended while using Prostrolane Inner_B / Inner_B^{SE}.
5. Before treatment, press rod carefully until a small droplet is visible at the tip.
6. Prostrolane Inner_B / Inner_B^{SE} are administered using a thin gauge needle (27G x 13mm or 30G x 13mm) that is sterilized. The sterilized needle is inserted at an approximate angle of 90 degrees to the length of the injected site. Prostrolane Inner_B / Inner_B^{SE} should be injected into deeply in the dermis. If Prostrolane Inner_B / Inner_B^{SE} are injected too superficially this may result in visible lumps and/or bluish discoloration.
7. Inject Prostrolane Inner_B / Inner_B^{SE} applying even pressure on the plunger rod. It is important that the injection is stopped just before the needle is pulled out of the skin to prevent material from leaking out or ending up too superficially in the skin.
8. Only correct to 100% of the desired volume effect. Do not overcorrect. With cutaneous deformities the best results are obtained if the defect can be manually stretched to the point whereit is eliminated. The degree and duration of the correction depend on the character of the defect treated.
9. Typical usage for each treatment session is specific to the site as well as wrinkle severity. Or to apply on the cleared skin surface, to wait for full absorption.
10. After treatment, stick the traceability label on the patient's medical record.

Direction for Assembly
Assembly of 27G or 30G (Hypodermic needles) needle to syringe. For safe use of Prostrolane Inner_B / Inner_B^{SE}, it is important that the needle is properly assembled. Improper assembly may result in separation of the needle and syringe during injection.

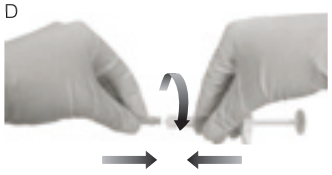
A

B



C

D



(1) Unscrew the tip cap of the syringe carefully. (A)
(2) Grasp the narrow part of the needle shield loosely; mount the needle on the Luer-Lock (B) by turning it clockwise until you feel counter-pressure. Grasp the wider part of the needle shield firmly.
(3) Press and turn the needle shield 90° (a quarter turn). The quarter turn is necessary to lock the needle onto the syringe.
(4) Pull off the needle shield.
(5) Use the thumb and forefinger to hold firmly around both the glass syringe barrel and the Luer-Lock adapter. Grasp the needle shield with the other hand. To facilitate proper assembly, both push and rotate firmly.

Contraindications
Prostrolane Inner_B / Inner_B^{SE} must not be used:
- for the combination with peeling, laser treatment or ultra-sound,
- if the patient has cutaneous disorder, inflammation or infection at the treatment site or near to this site,
- in the case of patients have a known hypersensitivity to hyaluronic acid, with a history of severe allergy or anaphylactic shock,
- in case of the patients with autoimmune diseases,
- Due to possible interactions with other filling implants, which have not been researched, it is inadvisable to use Prostrolane Inner_B / Inner_B^{SE} into sites in the presence of other filling implants.
- in pregnancy, breast-feeding mother, and in children or minors under 18 ages
- for patients with bleeding disorders, skin color disorders

Warnings and Side Effects
• Avoid applying on skin products other than those advised by doctor.
• The doctor must inform the patient of possible local reactions related to the implantation of this resorbable device.
• Should any inflammatory reaction or any other side effect not disappear within a week, the patient must inform the clinician about it immediately.
• The doctor is requested to report any notable side effect related to the Prostrolane Inner_B / Inner_B^{SE} to Caregen Co., Ltd. through the website, www.caregen.co.kr by fax at + 82-31-452-3869.
• Defer use of Prostrolane Inner_B / Inner_B^{SE} at specific sites in which an active inflammatory process (Skin eruptions such as cysts, pimples, rashes, or hives) or infection is present until the process has been controlled.
• Prostrolane Inner_B / Inner_B^{SE} are packaged for single patient use. Do not re-sterilize. Do not use if package is opened or damaged.
• Do not use Prostrolane Inner_B / Inner_B^{SE} after the expiry date printed on the package.
• Prostrolane Inner_B / Inner_B^{SE} should not be mixed with other products before implantation of the device.
• Do not inject into blood vessels.
• Do not inject into eyelids

Precautions
• In case of allergic risk, a test should be done before the first injection. The test results must be attached to the patient's medical record.
• Health care practitioners are encouraged to discuss all potential risks of injection with their patients prior to treatment and ensure that the patients are aware of signs and symptoms of potential complications.
• In order to minimize the risks of potential complications, the product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
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• As with all transcutaneous procedures, Prostrolane Inner_B / Inner_B^{SE} implantation carries a risk of infection. Standard precautions associated with injectable materials should be followed.
• Prostrolane Inner_B / Inner_B^{SE} filler injection may cause hyperpigmentation at the injection site.
• Bruising or bleeding may occur at injection sites.
• Prostrolane Inner_B / Inner_B^{SE} are a transparent gel without particulates. In the event that the content of a syringe shows signs of separation and/or appears cloudy, do not use the syringe. Glass is subject to breakage under a variety of unavoidable conditions. Care should be taken with the handling of the glass syringe and with disposing of broken glass to avoid laceration or other injury.
• Prostrolane Inner_B / Inner_B^{SE} should not be mixed with other products before implantation of the device.Patients should minimize exposure of the treated area to excessive sun, UV lamp exposure and extreme cold weather at least until any initial swelling and redness resolved.
• After use, syringes and needles should be handled as potential biohazards. Disposal should be in accordance with accepted medical practice and applicable local, national requirements.

Storage condition
Store between 2℃~25℃. Protect from freezing and sunlight. Make sure there are no visible signs of damage to the packaging before use.

Shelf life
2 years under recommended conditions.

Manufactured by Caregen Co., Ltd.
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Do not reuse

Use by

STERILE — Sterilized using steam or dry heat

LOT — Lot number

Date of manufacture

Attention, see instruction for use

CE 2265 — CE Mark and identification number of Notified Body

Manufacturer

Don't use if packages is damaged

EC REP — Authorised representative in the EC

Consult instructions for use

2 STERILIZE — Do not re-sterilize

Keep away from sunlight

2℃ 25℃ — Temperature limitation

Caregen Co., Ltd.
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