Juvelook

PLA/HA Soft Tissue Injectable Implant

DISPOSABLE MEDICAL DEVICE

www.vaim.co.kr

Product name: Soft Tissue Injectable Implant
Brand name: Juvelook
Model name: Juvelook

【Product Permit Number】

17-972

【Product Definition】

White lyophilized powder

【Intended Use】

Device is intended to be used for intradermal and subcutaneous implantation to fill skin depressions as to restore and enhance soft tissue volume. It is recommended to be used for reconstructive purposes in the treatment for morphological asymmetry.

【Intended Patient Population】

Adult male or female aged 19 years or above.

【Intended User】

The product should be handled and used by a plastic surgeon and dermatologist with special knowledge and skill after fully comprehending the product itself and its directions to use.

【Contact Area】

Facial derma layer

【Sterilization】

- Sterilization method: EO sterilization
- Sterilization assurance level: SAL 10^{-6}
- Applied standard: ISO 11135
- Ethylene Oxide concentration: EO 20%, CO_2 80%
- Sterilization exposure time: 150 ± 10min
- Sterilization pressure: 1.0 ± 0.2 Bar
- Sterilization humidity: 40 ~ 90%
- Aeration time: More than 7 hours

This product is single use.

【How Device Achieves Its Intended Purpose】

The product should be injected only to the lower layers of the dermis or the layers of the hypodermis.

【Principles of Operation】

① After the HA is dissolved in deionized water at a concentration of 0.5 ~ 1%, the PLA microparticles are put into the HA solution so that the microparticles spread evenly over the solution.
② PLA microparticles are injected into the submerged subcutaneous and subcutaneous tissues to maintain volume. When HA is dissolved in water, it becomes a highly viscous solution and serves as a carrier to inject PLA microparticles, which are powder, with a syringe. When HA is injected into skin tissues, it breaks down and is absorbed into the body.
③ The PLA microparticles are injected into the subcutaneous tissue that is recessed to fill the depressed area, thereby restoring the skin.
④ Between 1 and 2 days after the procedure, the sterilized distilled water and HA used at the time of injection are absorbed into the body and disappeared from the operation site. The PLA microparticles maintain their morphology in the injected tissue for a period of time (12 to 24 weeks) and then gradually decompose and are completely degraded and absorbed within one to two years.
⑤ The PLA microparticles are injected into the depressed site to fill the site, thereby reconstructing the asymmetric site to achieve a balance. When HA is dissolved in water, it becomes a highly viscous solution and serves as a carrier to inject PLA microparticles, which are powder, with a syringe. It has no therapeutic effect.

【Mechanism of Action】

Injectable PLA [Poly (D, L-lactide)] Filler is a white solid which is lyophilized mixed with PLA (Poly-D, L-lactic Acid) and HA (Sodium Hyaluronate). When used, it is suspended in sterilized distilled water and made into a gel state, which can be injected into a syringe. When injected on the face, PLA micro-particles temporarily improve soft tissue volume by being physically filled subcutaneously. HA is used as a carrier to help inject the micro-particles into the syringe. This device is an implantable synthetic or biological compound used as a space-occupying substance in the anatomical reconstruction or improvement of body tissue. The device is typically a solid or fluid material that is surgically implanted or injected during simple cosmetic procedures, cosmetic plastic surgery, or reconstruction of pathologic or traumatic deformities.

【How to Use】

① Check the packaging of the product for damage.
② Check for deformation or foreign matter on the product.
③ Be sure to read the instructions before use.
④ Perform product suspension under aseptic conditions without microbial contamination.
⑤ Remove the vial's aluminum cap and wipe the rubber stopper with disinfectant.
⑥ Connect 18G sterile needle and inject sterilized distilled water into the vial.

Model	Sterile water for injection
Juvelook	0.75 ml

⑦ Mix sterilized distilled water with a product for 3 minutes with a vortex mixer.
⑧ Wait for 5 minutes and mix again for 3 minutes with a vortex mixer.
⑨ Check the condition of the product and repeat step 8 two or three times to suspend.
⑩ Prepared products should be used immediately, and any remaining product should be discarded.
⑪ Immediately before use, wipe the rubber stopper with a disinfectant. Connect the 18G sterile needle to a 1ml sterile syringe and take 0.8~1.2ml of the product.
⑫ Connect a 25gauge sterile needle (or 25G sterile cannula needle) to the syringe containing the product. Then inject the product into the patient's face.

【How to Store and Manage】

① Do not re-sterilize.
② Because it is a disposable product, do not reuse the product that has been opened or used.
③ Dispose of used syringe, needle, and remaining product to designated collection container.
④ Do not store in environment of more than 40 degrees because it is vulnerable to high temperature.
⑤ To prevent damage to the product, do not apply strong impact when handling.

【Warnings】

① A doctor who is well trained in the procedure of the product should perform the procedure.
② Before the procedure, the doctor should explain to the patient about the taboo, symptom, and potential side effects of the product.
③ Ensure sterilization is not impaired before use.
④ Check the expiration date of the product.
⑤ Avoid use in vessels that block blood vessels and cause tissue necrosis.
⑥ Serious side effects such as loss of vision may occur when injected into blood vessels. Therefore, it is not recommended to use the area near the eyes.
⑦ It should not be used until infection and inflammation are controlled or resolved.
⑧ The safety and efficacy of the procedure to enlarge the lips is not established.
⑨ Procedure of a patient with a herpetic eruption may cause herpes to recur.
⑩ The safety of patients with keloid formation, hyperpigmentation, and hypertrophic scar has not been established.

⑪ Safety and efficacy for long-term use beyond the period of clinical studies have not been confirmed.
⑫ The product is used only for dermal layer and subcutaneous layer.
⑬ Do not inject products into shallow skin layers to prevent papules or nodules. Papules or nodules can be caused by inappropriate procedures (injection into skin surface, an excessive amount of injection). Massaging the injection site to distribute the product evenly can minimize the incidence of papules and nodules.
⑭ One product is used for one patient to prevent contamination. Do not re-use or re-sterilize the product. Do not use if the package is opened or damaged.
⑮ Be careful not to inject into blood vessels. When injected into the vasculature, it can block the vasculature and cause skin infarction or embolism.
⑯ The effect of the product appears slowly over several weeks, so do not inject too much into the same area.
⑰ Do not inject into the lips.
⑱ The reconstituted suspension should be used immediately after reconstitution according to the reconstitution method before the injection procedure.
⑲ Preventive measures are necessary if there is a possibility of contact with the patient's body fluids because there is a risk of infection during product infusion.
⑳ Connect a 25gauge sterile needle (or 25G sterile cannula needle) to the syringe containing the product. Then inject the product into the patient's facial wrinkles.
㉑ Interactions with other drugs, ingredients and implants have not been studied.

【General Precautions】

① Use of the product should be done only after the doctor has thoroughly read the instruction manual.
② The injection site should be cleaned with a disinfectant and should not be inflamed or infected.
③ Patients receiving anticoagulants are at risk of hematoma or local bleeding at the injection site.
④ Care should be taken when injecting thinner skin areas, such as periorbital area, because of the high risk of papules or nodules.
⑤ Safety in patients sensitive to keloid formation and hypertrophic scarring was not established. Do not inject into patients with keloids.
⑥ Ensure that the injection site is not exposed to sunlight until the swelling and redness appearing at the beginning of the procedure disappear. Also, be careful not to expose to UV lamp.
⑦ The product was evaluated for safety and efficacy for improvement of nasolabial fold in a 24-week clinical trial. Safety and efficacy for long-term use beyond the period of clinical studies have not been confirmed.
⑧ Products are forbidden to be used by minors.
⑨ Do not use for people with abnormal liver function or people with abnormal blood clotting.
⑩ Do not use it on people who have inserted a soft form or silicone implant on their face.
⑪ Do not use it for people with a history of hypersensitivity reactions or allergic reactions to anaphylaxis, Poly-D, L-lactic acid; PLA, or sodium hyaluronate.
⑫ Do not use for people with reduced immunity.
⑬ Do not use it for people who have side effects with lidocaine.

【Predicted Side-effects】

① Injection site reaction
  a) Hemorrhage
  b) Pain
  c) Induration
  d) Swelling
② Immune system abnormality
  a) Hypersensitivity Angioedema
  b) Skin sarcoidosis
③ Inflammation and Infection
  a) Injection site infection including cellulitis
  b) Staphylococcal infection
  c) Abscess
④ Skin and subcutaneous tissue abnormalities
  a) Bruising
  b) Hematoma
  c) Atrophy, Skin hypertrophy
  d) Erythema
  e) Urticaria
  f) Telangiectasis
  g) The papules of subcutaneous are mostly invisible. It is usually diagnosed by hand but there are no symptoms.
  h) Visible nodules, including nodules of periorbital, can occur and may be accompanied by inflammation or discoloration. Nodules appearing after injection can be minimized through proper use.
  i) Subcutaneous nodules may appear late and last (within 1 to 14 months after injection) for up to two years: It may be necessary to remove the nodules by intralesional corticosteroid therapy or surgically.
  j) Granuloma
  k) Scarring
  l) Skin discoloration

【Interaction】

Interactions with other drugs, ingredients and implants have not been studied.

【Use about pregnant women, lactating women, pregnant women, newborn babies, infants, children, the elderly】

Do not use because the safety of pregnant women, lactating women and people under 19 years old is not established.

【Contraindication】

① Do not inject product when there is acute or chronic skin disease at the injection site or its periphery.
② Do not use for people who are sensitive to product ingredients.
③ There are cases of granuloma on the nasolabial fold due to bacterial infection caused by periodontitis during clinical trials of the product. Therefore, it is prohibited to use for persons with acute or chronic periodontitis or gum disease.
④ Do not use because the safety of pregnant women, lactating women and people under 19 years old is not established.

【Expiration Date】

Expiration date: 2 years from the date of sterilization

【Storage】

Store at room temperature (1~ 30℃). Do not freeze.

【Packing Unit】

1 Vial/Box

【Manufacturer】

VAIM Co., Ltd.

103, 79, Uiryodangi-Gil, Okcheon-Eup, Okcheon-Gun, Chungcheongbuk-Do, 29055, Rep. of Korea

14, Techno 3-ro, Yuseong-gu, Daejeon, 34012, Rep. of Korea

【EC/REP】

JaviTech e.K
EU representative address/ Sachsenhausener 16, 65824
Schwalbach am Taunus, Germany
Telephone/ +49-6196-4021549, Email/ info@javitech.de

Symbol	Description
	Date of Manufacture
	Manufacture
	European Community Authorized representative
	CE mark
	Sterilized using ethylene oxide
	Do not re-sterilize
	Do not re-use
	Fragile, handle with care
	Batch Code
	Use by date
	Temperature limit
	Consult instruction for use
	Do not use if package is damaged
	Keep away from rain
	Caution, consult accompanying documents
	Keep away from sunlight

Disposable
MedicalDevice
ReuseForbidden

LENISNA

DISPOSABLE MEDICAL DEVICE

PLA/HA Soft Tissue Injectable Implant

Product name: Soft Tissue Injectable Implant
Brand name: LENISNA
Model name: Lenisna50, Lenisna200

【Product Permit Number】

17-972

【Product Definition】

White lyophilized powder

【Intended Use】

Device is intended to be used for intradermal and subcutaneous implantation to fill skin depressions as to restore and enhance soft tissue volume. It is recommended to be used for reconstructive purposes in the treatment for morphological asymmetry.

【Intended Patient Population】

Adult male or female aged 19 years or above.

【Intended User】

The product should be handled and used by a plastic surgeon and dermatologist with special knowledge and skill after fully comprehending the product itself and its directions to use.

【Contact Area】

Facial derma layer

【Sterilization】

- Sterilization method: EO sterilization
- Sterilization assurance level: SAL 10^{-6}
- Applied standard: ISO 11135
- Ethylene Oxide concentration: EO 20%, CO_2 80%
- Sterilization exposure time: 150 ± 10min
- Sterilization pressure: 1.0 ± 0.2 Bar
- Sterilization humidity: 40 ~ 90%
- Aeration time: More than 7 hours

This product is single use.

【How Device Achieves Its Intended Purpose】

The product should be injected only to the lower layers of the dermis or the layers of the hypodermis.

【Principles of Operation】

① After the HA is dissolved in deionized water at a concentration of 0.5 ~ 1%, the PLA microparticles are put into the HA solution so that the microparticles spread evenly over the solution.
② PLA microparticles are injected into the submerged subcutaneous and subcutaneous tissues to maintain volume. When HA is dissolved in water, it becomes a highly viscous solution and serves as a carrier to inject PLA microparticles, which are powder, with a syringe. When HA is injected into skin tissues, it breaks down and is absorbed into the body.
③ The PLA microparticles are injected into the subcutaneous tissue that is recessed to fill the depressed area, thereby restoring the skin.
④ Between 1 and 2 days after the procedure, the sterilized distilled water and HA used at the time of injection are absorbed into the body and disappeared from the operation site. The PLA microparticles maintain their morphology in the injected tissue for a period of time (12 to 24 weeks) and then gradually decompose and are completely degraded and absorbed within one to two years.
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【How to Use】

① Check the packaging of the product for damage.
② Check for deformation or foreign matter on the product.
③ Be sure to read the instructions before use.
④ Perform product suspension under aseptic conditions without microbial contamination.
⑤ Remove the vial's aluminum cap and wipe the rubber stopper with disinfectant.
⑥ Connect 18G sterile needle and inject sterilized distilled water into the vial.

Model	Sterile water for injection
Lenisna50	0.75ml
Lenisna200	3ml

⑦ Mix sterilized distilled water with a product for 3 minutes with a vortex mixer.
⑧ Wait for 5 minutes and mix again for 3 minutes with a vortex mixer.
⑨ Check the condition of the product and repeat step 8 two or three times to suspend.
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【Predicted Side-effects】

① Injection site reaction
  a) Hemorrhage
  b) Pain
  c) Induration
  d) Swelling
② Immune system abnormality
  a) Hypersensitivity Angioedema
  b) Skin sarcoidosis
③ Inflammation and Infection
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【Expiration Date】

Expiration date: 2 years from the date of sterilization

【Storage】

Store at room temperature (1~ 30°C). Do not freeze.

【Packing Unit】

1 Vial/Box

【Manufacturer】

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14, Techno 3-ro, Yuseong-gu, Daejeon, 34012, Rep. of Korea

【EC/REP】

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EU representative address/ Sachsenhausener 16, 65824
Schwalbach am Taunus, Germany
Telephone/ +49-6196-4021549, Email/ info@javitech.de

Symbol	Description
	Date of Manufacture
	Manufacture
EC REP	European Community Authorized representative
CE 2764	CE mark
STERILE EO	Sterilized using ethylene oxide
	Do not re-sterilize
	Do not re-use
	Fragile, handle with care
LOT	Batch Code
	Use by date
	Temperature limit
	Consult instruction for use
	Do not use if package is damaged
	Keep away from rain
	Caution, consult accompanying documents
	Keep away from sunlight