Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.

Pack description

This pack contains one prefilled syringe of 1.0 ml sterile viscoelastic implant with an aesthetic purpose and two 27G x ½″ disposable sterile needles to be attached to the syringe for injection, co-packaged within one blister. Besides the blister, each box contains three patient record labels, instructions for use healthcare professionals including the international implant card and a Link to the patient information leaflet. The blister containing the syringe and needles has not been sterilized. For correct assembly of the syringe and needle, please refer to the pictures ❶ to ❻. Information on the folding box refers to the pack.

Viscoelastic implant – instructions for use

Technical description: The device is a sterile, absorbable, biodegradable, viscoelastic, clear, transparent, isotonic, and homogenised injectable gel implant used as soft tissue filler without an intended medical purpose. It is intended for single use, is non-active, and without measuring function. It is steam sterilized in the syringe representing the sterile barrier. No animal or human tissues or cells or their derivates are used during manufacturing or as raw materials. The medicinal product lidocaine hydrochloride (lidocaine HCl) is integrated into the device. The ancillary role of lidocaine HCl is to reduce pain/discomfort due to the injection.
The viscoelastic implant is stored in a prefilled syringe. The intended use of the prefilled syringe is to serve as the sterile barrier system for the viscoelastic implant. The syringe (in combination with a hypodermic needle) is intended to serve as the delivery system for the viscoelastic implant.

Composition: The viscoelastic implant consists of cross-linked hyaluronic acid (present as sodium hyaluronate), obtained from *Streptococcus equi* bacteria, supplemented with lidocaine HCl, and is phosphate buffered at a pH of 6.7–7.3. It contains 2.5 % sodium hyaluronate, 0.79 % sodium chloride, 0.23 % disodium phosphate dodecahydrate, 0.05 % sodium dihydrogen phosphate dihydrate, 0.3 % lidocaine HCl (as anaesthetic), and ≤ 2 ppm 1,4-butanediol diglycidyl ether (BDDE; as crosslinking agent) dissolved in water for injection. The average molecular weight for the hyaluronic acid raw material is 2.5–3.2 x 10^6 Dalton (calculated from intrinsic viscosity). Hyaluronic acid is crosslinked with a mean degree of 1–2 % (determined by quantitative NMR) and a typical particle size of approx. 320 µm (determined by laser diffraction analysis).

Indications: The viscoelastic implant is indicated to correct moderate to severe midface volume deficit.
It must be administered by deep subcutaneous and/or supraperiosteal injection.

Intended purpose: The intended aesthetic purpose of the viscoelastic implant is to restore facial volume.

Intended consumer: The intended consumers are adults 18 years of age or older requesting aesthetic hyaluronic acid filler treatments.

Intended user: The intended user is an appropriately trained healthcare professional who is qualified or accredited in accordance with national law. The viscoelastic implant is not intended to be used by lay persons.

Contraindications: The viscoelastic implant must not be used in:
- consumers who tend to develop hypertrophic scars, have pigment disorders or have a susceptibility to keloid formation as the treatment may trigger these complications. |
- consumers who are known to be hypersensitive to hyaluronic acid, gram-positive bacterial proteins, lidocaine hydrochloride or to amide-type local anaesthetics as the treatment may trigger allergic reactions of different grades of severity. | - pregnant or breast-feeding women. |
- individuals younger than 18 years of age.

Warnings: As long as the syringe is stored in its originally sealed blister, the viscoelastic implant inside the intact syringe is guaranteed to be sterile until the use-by date printed on the folding box and the label on the syringe. A compromised sterile barrier may lead to a non-sterile implant that could cause bacterial infections associated with skin inflammation and irritation, erythema, pain, fever and abscess. Therefore do not use the syringe beyond the use-by date or if it is cracked or broken. Do not use a syringe with an open or shifted tip cap, a loose Luer-Lock adapter or from an opened or damaged blister. Do not transfer the viscoelastic implant to another application device as this may cause contamination. Do not re-use the syringe or needle as it creates a potential infection risk for consumers or users.
Increased injection force may hamper device delivery into intended location which may cause device dislocation, subcutaneous nodules or vasoconstriction leading to ischaemia, necrosis or loss of vision. Therefore do not use any other needle than included in this pack and do not manipulate/bend the needle.
Avoid injection into blood vessels and nerves. To prevent accidental intravascular injection, careful aspiration prior to injecting is recommended. Negative aspiration cannot be relied upon to avoid vascular complications.
Rare but serious adverse events associated with intravascular injection of soft tissue fillers in the face and tissue compression have been reported. This can lead to the occlusion of vessels, vasospasm and vascular compromise, resulting in ischaemia, temporary or permanent visual impairment, loss of vision, ophthalmoplegia, stroke, skin necrosis, and damage to underlying structures. Immediately stop the injection if a consumer exhibits any of the following symptoms: changes in vision, signs of a stroke, pallor, or unusual pain during or shortly after the procedure. Consumers must receive prompt medical attention and may require further evaluation by an appropriate specialist if an intravascular injection or tissue compression is suspected.
The implanted viscoelastic gel is safe in a magnetic resonance environment. The delivery system is potentially infectious after use and must be discarded in a sharps disposal container.

Precautions for use: Avoid areas presenting cutaneous, inflammatory and/or infectious processes (e.g. acne, herpes) as this may lead to the proliferation of infection or an aggravation of the present condition. Avoid injecting into tendons, ligaments or muscles as this may cause pain and interferes with known performance and safety of the device. Avoid using the viscoelastic implant in association with laser therapy, chemical peeling, dermabrasion or mesotherapy as this may cause skin inflammation/irritation and interferes with known performance and safety of the device. There are no available clinical data (efficacy, tolerance) about injecting the viscoelastic implant into an area which has already been treated with any other filling product or botulinum toxin. Avoid injecting in an area that has been previously treated with permanent fillers as this could potentially aggravate latent adverse events or interfere with the aesthetic outcome of the treatment. To avoid a possible risk of implant mobility and impaired wound healing, the consumer should be advised not to massage the treatment site for two days following the injection. To avoid additional stress to the skin, consumers should be advised not to apply any make-up for 12 hours after the injection and to avoid strenuous exercise and exposure to extensive sun or heat in the first 48 hours. Lidocaine HCl contained in the viscoelastic implant may cause local redness or hypersensitivity. For healthy adults, it is recommended that the maximum total dose of lidocaine HCl does not exceed 300 mg (or 4.5 mg/kg body weight, whichever is less) per session. Overdosing with lidocaine HCl is very unlikely considering the low amount present in the viscoelastic implant. When using additional forms of lidocaine HCl concurrently (e.g. topical administration or through injection), the maximum total dose should be considered. The concomitant use of other local anaesthetic agents or agents structurally related to amide-type local anaesthetics should also be considered, as the systemic toxicity effects may be additive. Early symptoms of lidocaine toxicity are circumoral numbness, tongue paraesthesia, and dizziness. There are incompatibilities between sodium hyaluronate and quaternary ammonium compounds such as benzalkonium chloride solutions. Therefore, the viscoelastic implant should never be put in contact with these substances or with medical-surgical instruments that have been in contact with these substances.

Limitations: Consumers on anticoagulant therapy or consumers receiving platelet aggregation inhibitors (e.g. acetylsalicylic acid) should not be treated with this viscoelastic implant without consulting their physician beforehand. For consumers with a history of autoimmune or connective tissue disease and/or who are receiving immune (-modulation) therapy, or with a history of severe allergies or anaphylactic shock, treatment decisions need to be taken on a case-to-case basis. For consumers presenting with an active or evolving autoimmune disease, the treatment is not recommended.

Undesired side effects: Users must inform the consumers that there are potential side effects and/or incompatibilities associated with the implantation of this viscoelastic implant, which may occur immediately or may be delayed. They are generally mild and transient in nature, but may last for a few days.
It is, therefore, important to take these possible complications into account before initiating the treatment.
Undesired side effects observed at the injection site during the clinical study: coldness, haematoma, itching sensation, pain, skin discolouration (incl. erythema), subcutaneous nodule, swelling/oedema.
Additional undesired side effects were observed after introduction to market: abscess, bacterial infection, capsular contracture, granuloma, herpes simplex reactivation, skin burning sensation, skin inflammation/irritation.
When used outside the intended indication outlined in these instructions for use, following additional undesired side effects were observed: difficulty chewing, discomfort, headache, hypersensitivity/allergic reaction, hypoaesthesia, neuralgia, obstruction/occlusion.
The following undesired side effects have been observed with similar viscoelastic implants and are considered as potential risks for this device: angioedema, bruise/contusion, device dislocation, foreign body embolism, haemorrhage/bleeding, loss of vision, medical device site induration, necrosis, numbness, presyncope, paraesthesia, skin disorders, syncope/fainting, vasculitis, vasospasm.
Consumers must be told to seek medical advice as soon as any undesired side effects occur. The physician should treat these side effects appropriately.
The following is a selective list of treatment options for some of the most common side effects in the context of hyaluronic acid dermal fillers (please refer to specialised guidance documents for detailed information):
Bleeding, haematoma, seroma may be prevented or decreased by applying a manual or cold compress, and applying a compressive bandage. As adjuncts arnica cream or gel and topical Vitamin K may be used. Reactive swelling and oedema may be prevented or decreased by applying a manual or cold compress, oral antihistamines or oral corticosteroids. For abscesses and bacterial infections (incl. fever), medical treatment, including appropriate antibiotic therapy, must be initiated by a physician. Non-inflammatory nodules are generally caused by an abundance of product (overdosing); local steroids or 5-fluorouracil injections are not recommended. Surgical excision may be offered, or one may elect to camouflage the asymmetries until the substance is metabolised. For late or delayed onset inflammatory reaction, including infections and granulomas, antibiotic therapy or surgical excision may be offered. Allergic reactions and hypersensitivity to hyaluronic acid are in general rare and self-limiting and resolve with supportive measures within a few hours or days. Severe allergic reactions with immediate substantial swelling, angioedema, airway obstruction, and anaphylactic shock may occur, but are very rare. It is, therefore, recommended to have an epinephrine pen to hand during procedures in case of emergencies. Mast-cell mediated allergic reactions may respond to oral antihistamines. Delayed hypersensitivity (days to weeks post-injection) usually resolves without untoward consequences but may be treated with oral or local steroids depending on the severity of the reaction.
The allergen should be removed if possible.
Please report undesired side effects and serious incidents to the manufacturer through complaint@croma.at or refer to the contact information. Please also report any serious incident related to the use of this device to the competent authority of the member state in which the user and/or consumer is established.

Instructions for good administering practice of the viscoelastic implant: In order to minimise the risks of potential complications, this viscoelastic implant should only be used by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law. Good clinical practice guidelines need to be adhered to and treatment carried out in the healthcare professional's office or other medical environment. Please use appropriate personal protective equipment. The skin should be thoroughly cleaned, degreased and disinfected prior to injection of the viscoelastic implant and an appropriate aseptic technique should be employed throughout the procedure. There are no specifically recommended topical antiseptics, but chlorhexidine, chloroxylenol, iodophors, alcohol, and iodine are considered appropriate. The viscoelastic implant must only be injected into non-inflamed, healthy skin.
It must be administered by deep subcutaneous and/or supraperiosteal injection. Too superficial placement or an uneven distribution of the injected viscoelastic implant may lead to device visibility through the skin or Tyndall effect.
The following injection techniques were used successfully during the clinical investigation of this viscoelastic implant, the choice of technique depending on user preference: tunnelling, fanning, serial puncture, cross-hatching, and the tower technique. Linear threading, serial threading, and the bolus technique have also been applied successfully with similar viscoelastic implants. Use the sterile 27G x ½″ needle which is packaged with the syringe and slowly inject with the least amount of pressure necessary. The insertion of the needle may lead to superficial needle stick/puncture wounds. Lateral movements of the needle must be avoided since these can result in a fan-like dissection of the sub-epidermal plane and vascular damage, thus increasing the risk of local undesired side effects such as haematoma, swelling, skin discolouration, pain or tenderness at the injection site. If the needle is blocked, do not increase the pressure on the plunger rod, but stop the injection and replace the needle. Inject low volumes in two or more sessions instead of high volumes in one session. Avoid overcorrection. The amount injected will depend on the volume deficit to be corrected and the area to be treated. The scale on the syringe serves as an orientation for the user. The maximum applied dosage substantiated by clinical data is up to 8 ml per consumer injected for midface volume deficit in the initial treatment, and up to 7 ml in touch-up treatments. After the injection, healthcare professionals may perform a light massage in order to distribute the viscoelastic implant uniformly.
The consumer should be asked to remain on site for 30 minutes after the injection to detect signs of pallor caused by arterial occlusions. There is no need for a mandatory follow-up.

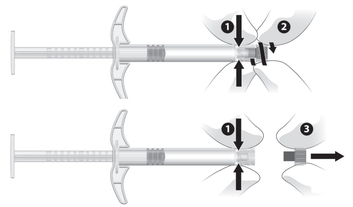
Device performance: At the primary endpoint (Week 4 assessment) of the clinical investigation 100 % of the intended to treat subjects demonstrated ≥ 1 grade improvement compared with the baseline status and 69.2 % demonstrated ≥ 2 grade improvement on the Midface Volume Deficit Severity Scale (MVDSS). The treatment effects at Weeks 4 and 12 were similar; from Week 24 to Week 52 the effects gradually decline with 77.0 % of subjects still showing ≥ 1 grade improvement in their midface volume deficit severity score at Week 52. The viscoelastic implant is for non-medical aesthetic use only and has no clinical benefit but provides an aesthetic benefit to the consumer measured by Global Aesthetic Improvement Scale (GAIS). The investigator as well as the majority of subjects observed an improvement of their volume deficit for up to one year. Additionally, subject satisfaction was evaluated during the study. At time points up to 36 weeks over 90 % and after 52 weeks over 78 % of the subjects were either 'very satisfied' or 'satisfied' with the results of the treatment. A new injection may be placed at a previously injected location from two weeks after the original treatment. Based on the available data, the lifetime of the implanted product is determined to be 12 months.

International implant card and patient information leaflet: For Patient Information Leaflet please see www.cromapharma.com/productinformation/australia/saypha and inform the consumer before treatment. The international implant card is part of this information for use and must be handed out to the consumer to allow traceability. Three adhesive patient record labels are enclosed in the box. One of these labels must be detached and affixed to the field "PATIENT RECORD LABEL" on the implant card. The healthcare professional must fill in the following information: - name of the consumer or consumer identification | - date of implantation | - name and address of the healthcare institution which performed the implantation | - location, number and volume of the injections (please use the facial outline on the implant card to record this information).
In case the information on the patient record label is not legible or the labels are missing, please copy the UDI-DI and LOT number from the label on the syringe. In case you use more than one syringe during the course of a treatment session, please provide the consumer with a separate implant card for each syringe.

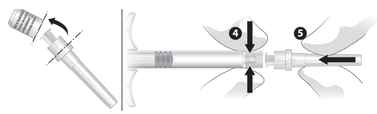
Storage: The device should be stored in the original blister and folding box at 2–25 °C / 36–77 °F, in a dry place and protected from sunlight, heat and frost. Do not use the device if it has been stored outside of these conditions since proper functionality can only be guaranteed if stored correctly. The syringe is made of glass, handle with care (risk of laceration when broken).

K-Pack II Needle 27G x ½″ (0.4 x 12 mm) TW
For further information on the safety and performance of the needles in this pack please see safetyinfo.terumo-europe.com.

Instructions for the correct assembly of syringe and needle:
Hold the Luer-Lock adapter as shown in ❶
To remove the tip cap, twist ❷ and pull carefully ❸



Following the instructions above will prevent the trapping of air bubbles
Hold the syringe as shown in ❹
Open the enclosed needle container and insert the needle firmly ❺

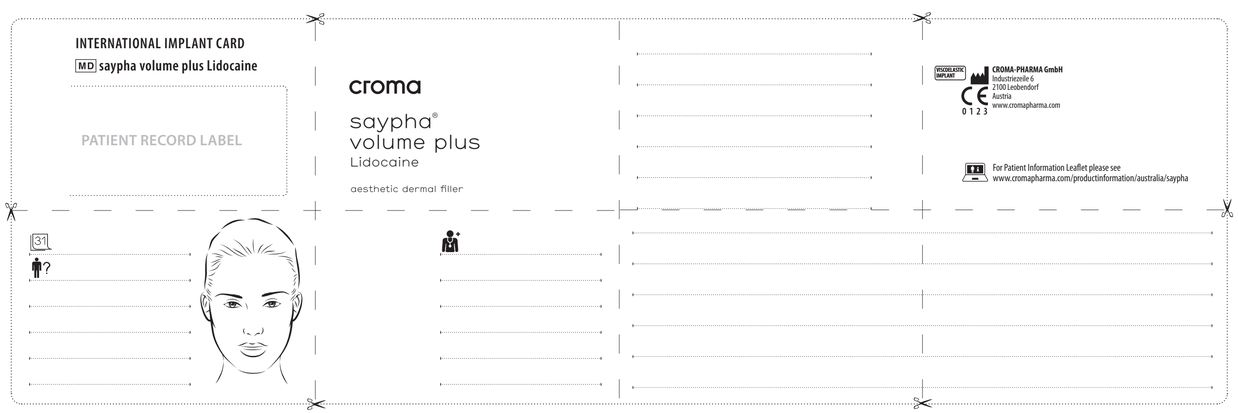


Holding the Luer-Lock, tightly secure the needle by twisting it clockwise ❻

Applied harmonized standards and Regulations:
Commission Implementing Regulation (EU) 2022/2346 Annex I and Annex IV,
Fully applied standards: EN ISO 13485:2016+A11:2021
EN ISO 14971:2019+A11:2021
Applicable parts applied: EN ISO 10993-9:2021
EN ISO 10993-10:2023
EN ISO 10993-12:2021
EN ISO 10993-17:2009
EN ISO 10993-18:2020
EN ISO 10993-23:2021
EN ISO 11607-1:2020
EN ISO 11737-1:2018
EN ISO 15223-1:2021

Explanation of international symbols:

31	Date of implantation
	Patient identification
	Health care centre or doctor
	Patient information website
UDI	Unique device identifier
LOT	Lot number
MD	Medical device
	Manufacturer
VISCOELASTIC IMPLANT	Viscoelastic implant
18+	Adults 18 years of age or older
	Caution
	Consult instructions for use
	Keep dry
2°C 25°C	Temperature limit
	Keep away from sunlight
	Fragile, handle with care
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Do not resterilize
REF	Reference number
SN	Serial number
	Use by
	Date of manufacture
PROCEDURE PACK PRODUCER	Procedure pack producer
PREFILLED SYRINGE	Prefilled syringe for single use
NEEDLE	Sterile needle for single use
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system
STERILE	Sterilized using steam
STERILE EO	Sterilized using ethylene oxide
	Non-pyrogenic
	Contains a medicinal substance



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