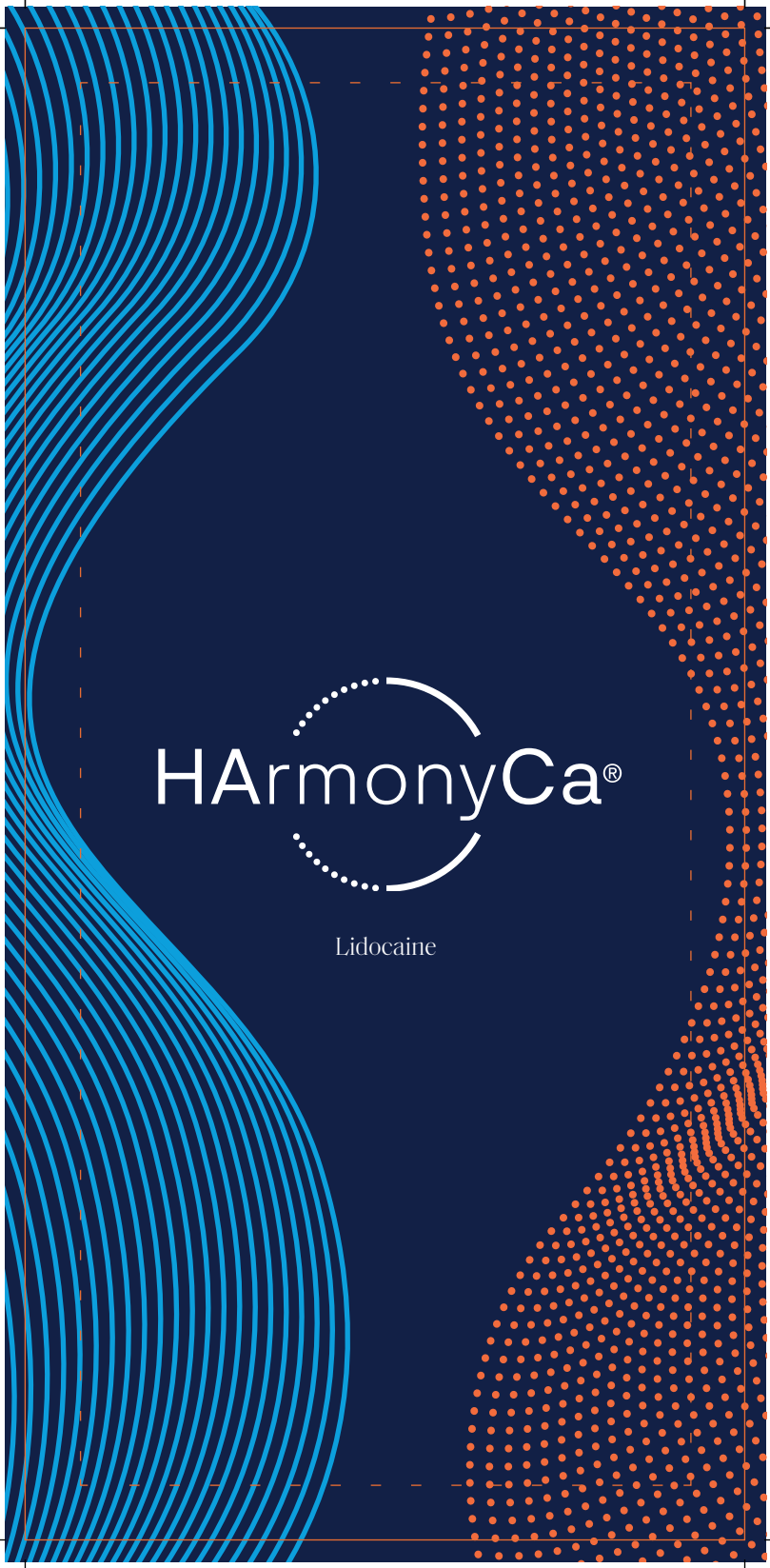
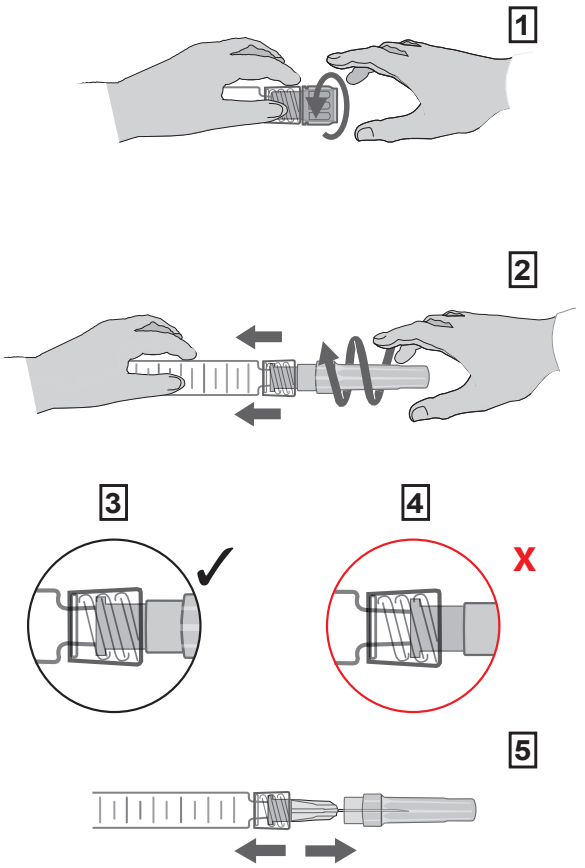

HArmonyCa®
Lidocaine

FIGURE 1: NEEDLE SYRINGE ASSEMBLY



Instructions for Use

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To be sold by retail on prescription of dermatologists or plastic surgeons only

HARMONYCA® LIDOCAINE *INJECTABLE FACIAL IMPLANT*

1. COMPOSITION:

Each 1.25 ml syringe contains:
Calcium hydroxyapatite microspheres of 25-45 microns diameter 1184 mg
Sodium Hyaluronate 19 mg
Lidocaine Hydrochloride 4 mg
Phosphate Buffer q.s. 1.25 mL

2. DESCRIPTION:

HArmonyCa® Lidocaine is a sterile, non-pyrogenic, viscous, opaque, injectable, semi-solid, and bio-degradable dermal implant. It consists of synthetic calcium hydroxyapatite microspheres, formulated to a concentration of 55.7%, suspended in a cross-linked sodium hyaluronate gel from a non-animal source, and is provided in a 1.25 mL prefilled graduated, glass syringe. The implant is intended for sub-dermal and deep dermal use in specific facial regions.

The product contains 0.3% (w/v) lidocaine HCl to reduce pain during treatment.

Calcium hydroxyapatite microspheres of 25-45 microns diameter	55.7% (w/w)
Cross-linked sodium hyaluronate gel	20 mg/mL
Lidocaine hydrochloride	3 mg/mL
Phosphate buffer solution	q. s. 1.25 mL

3. PACKAGE CONTENT:

Each box contains 2 pre-filled syringes, 1.25 mL each with 2 single-use 27G 1/2" thin-wall sterile needles. The supplied needles are sterlised by irradiation.

4. INTENDED USE / INDICATIONS:

HArmonyCa® Lidocaine is a dermal filler intended for facial soft tissue augmentation and should be injected into the deep dermal, sub-dermal and supraperiosteal layers. The lidocaine in the product is for reducing pain during treatment.

5. CONTRAINDICATIONS:

Do not inject HArmonyCa® Lidocaine into:

- Periocular, glabellar, perioral areas and lips;
- Epidermis or superficial dermis;
- Blood vessels or highly vascularized areas;

HArmonyCa® Lidocaine is contraindicated in the following patient groups:

- Patients with a history of anaphylaxis or multiple severe allergies.
- Patients with a known sensitivity to any of the product components.
- Patients suffering from skin disease or abnormal skin conditions.
- Patients with impaired wound healing due to systemic disorders, medicinal drugs or unhealthy or poorly-vascularized tissue.
- Patients with known hypersensitivity to lidocaine or to other amide-type local anesthetics.
- Patients with conditions for which lidocaine is contraindicated.
- Pregnant or breastfeeding women.

6. WARNINGS:

- Be cautious to not inject into blood vessels. Intravascular injection may lead to occlusion, ischemia, infarction, and necrosis of local or distant tissues.
- Product use at sites with an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection or tumor should be deferred until the underlying process has been controlled.
- Do not overcorrect. Excessive volume can contribute to the pathogenesis of edema, vascular compromise, ischemia and tissue necrosis.
- The safety of the product has not been evaluated in diabetic patients.
- HArmonyCa® Lidocaine must not be injected into tissues that may be harmed by the volumizing properties of dermal fillers.
- HArmonyCa® Lidocaine must not be injected into or via scar, cartilage, compromised tissues.
- Avoid contact of HArmonyCa Lidocaine with quaternary ammonium salts such as benzalkonium chloride.

7. PRECAUTIONS:

HArmonyCa® Lidocaine is intended for single use and single patient only.

- Do not resterilize.
- Do not use if the package and/or syringe are opened or damaged.
- Only the content of the syringe is sterile.
- Based on preclinical evaluation, patients should be limited to 6.25 mL injectable gel per treatment session, and 20 mL per year, per 60 kg (130 lbs) body mass. The safety of injecting greater amounts has not been established.
- As with all transcutaneous procedures, soft tissue filler implantation carries a risk of infection. Standard precautions associated with injectable materials should be followed.
- The safety in patients with known susceptibility to keloid formation, hypertrophic scarring, inflammatory skin conditions, or pigmentation disorders has not been studied.
- The safety of the products has not been evaluated in patients with a history of connective tissue disease, active bleeding disorders, active hepatitis, clinically significant abnormal laboratory findings, cancer, history of stroke/myocardial infarction, autoimmune disease or autoimmune deficiency or under immunosuppressive therapy.
- This product should not be used simultaneously with ultrasound-based treatments, laser treatment, mechanical or deep chemical peels, UV irradiation, or dermabrasion. This product should not be used simultaneously with superficial skin peels that result in a significant inflammatory reaction.
- This product is to be used as supplied. Modification or use of the product outside the Instructions for Use may adversely impact the sterility, homogeneity, and/or performance of the product.
- The safety for use in areas with a pre-existing permanent implant or other foreign bodies has not been established. Use with caution when injecting in proximity to other implanted dermal fillers.
- Patients who are using substances that can prolong bleeding (such as acetylsalicylic acid, nonsteroidal anti-inflammatory drugs, warfarin and ACE inhibitors) may, as with any injection, experience increased bruising or bleeding at injection sites.
- Recommend the patient to not use any makeup during the 12 hours following the injection treatment and to avoid strenuous exercise and extensive sun or heat exposure within the first 24 hours. Exposure to any of the above may cause temporary redness, swelling, and/or itching at the injection sites.
- Recommend that the patient avoid massaging the implantation area and/or putting pressure on it for a few days following the injection. If nodules appear, patient should

contact the treating physician and follow the instructions, which might include massaging the treated area.

- Use with caution when injecting into the marionette lines and nasolabial folds, do not overcorrect to prevent material migration.
- Use with caution in patients with an active herpes, history of herpes or recent dental treatments or infection.

8. UNDESIRABLE SIDE EFFECTS

The most common side effects include temporary reactions at the treatment site such as erythema, edema, itching sensation, bruising, pain or tenderness to touch. Hematoma, allergic reaction, skin discoloration, nodules, and infection at the injection site. These side effects are consistent with other injectable soft tissue fillers.

Other side effects such hematoma, skin discoloration, allergic reaction, migration, infection, unintentional injection into a blood vessel may lead to vascular occlusion, embolization, vision abnormalities, blindness, stroke, or skin necrosis.

Although most common side effects will resolve within 1 week, some side effects may last for 30 days or longer. If unresolved, the healthcare practitioner should use an appropriate treatment.

Adverse events are reported following the use of soft tissue fillers, including hyaluronic acid fillers with or without calcium hydroxyapatite. Some of these events necessitate counseling and management by the healthcare provider. In certain instances, surgical interventions may be required, such as draining hematomas or necrotic tissue, or removing the implant due to severe allergic reactions, inflammation, hypersensitivity, or infection.

Patients should promptly report the attending medical practitioner about:

- any common adverse event which doesn't resolve within the typical time frame or which worsens.
- any other adverse event.

9. INSTRUCTIONS FOR USE:

- All used devices must be treated as a potential biohazard. Handle and dispose in accordance with standard medical practices and applicable regulations.
- Carefully inspect all parts for damage. Do not use if any faults are suspected.
- HArmonyCa® Lidocaine is a homogenous gel. Carefully inspect the gel before injection. Do not use if particles, discoloration or signs of separation are visible.
- Patients should be instructed to abstain from use of makeup in the area to be treated for 12 hours before and after the procedure.
- Subsequent treatments may be required to obtain optimal results. Allow for at least seven days between treatments, to enable effective evaluation of the implantation outcome.

a) Prior to treatment

- The patient's medical history should be obtained, and the patient should be fully apprised of the indications, contraindications, warnings, precautions, treatment responses, adverse reactions, and method of administration.
- Discuss all potential risks of soft tissue filler injections with their patients prior to treatment and ensure that patients are aware of any residual risks, contraindications, and undesirable side effects.
- The area to be treated should be disinfected thoroughly prior to the injection.
- It is possible, if necessary, to use concurrently a local or local-regional anaesthetic or ice to the injection site. In this case, the instructions for using these products must be followed.
- Check the expiry date on the product label. Do not use if expiry date printed on the package has passed.
- In the event that the content of a syringe shows signs of separation or if there is any damage to the syringe (e.g., cracked or broken syringe barrel, open syringe cap or plunger stopper), do not use the syringe.

b) Needle attachment to Syringe (see Fig 1)

Use of the 27G ½" (thin wall) needles supplied with the device is recommended. It is advisable to use 25G needles or 27G thin-wall needles in case a needle replacement is needed. Needle occlusion may occur more frequently if smaller diameter needles are used. Larger diameter needles may lead to higher frequency of adverse events caused by skin puncture, such as pain and edema, and therefore should not be used.
For multiple injections it is recommended to use 27G thin-wall needles.

Depending on the healthcare practitioner's preferred injection technique, it is possible to use 22G sterile cannula (please see below the cannula reference).

Material	Number Description
SGC-22050	TSK STERIGLIDE 22G 50mm

- Contraindications, Warnings, Precautions and Instructions defined for the needle in this leaflet apply also to the cannula referenced above if used with this product.

1. Remove tip cap - Remove syringe tip cap by holding the luer-lock and screwing the tip cap off as shown in **1**.
2. Insert needle - Hold the syringe body and firmly insert the hub of the needle (provided in the product package) into the Luer-lock end of the syringe.
3. Tighten the needle - Tighten the needle by turning it firmly in a clockwise direction (see **2**) until it is seated in the proper position as shown in **3**. If the position of the needle cap is as shown in **4**, it is not attached correctly. Continue to tighten until the needle is seated in the proper position.
4. Remove the needle cap - Hold the syringe body in one hand and the needle cap in the other. Without twisting, pull in opposite directions to remove the needle cap as shown in **5**.

- A new injection needle must be used for each syringe. Never transfer needles between patients.

c) Injection procedure

- Prior to injecting, depress the plunger rod until the product flows out of the needle. Inject the product slowly and apply the least amount of pressure necessary to extrude the product.
- After needle insertion and before injection, it is recommended to slightly withdraw the plunger to aspirate and verify the needle is not intravascular.
- If the needle is blocked, do not increase the pressure on the plunger rod. Instead, stop the injection and replace the needle. Never try to straighten a bent needle; safely dispose and replace it. Failure to comply with these precautions could cause a disengagement of the needle, and/or product leakage at Luer-lock level, and/or increase the risk of vascular compromise.
- Stop the procedure immediately if vascular puncture is suspected.
- Superficial injection or deposition of large volumes of the implant may result in discoloration, nodules or ischemia at the skin surface.
- Recommended techniques are described below; however, the treating HCP should use his/her clinical experience to determine the treatment technique.

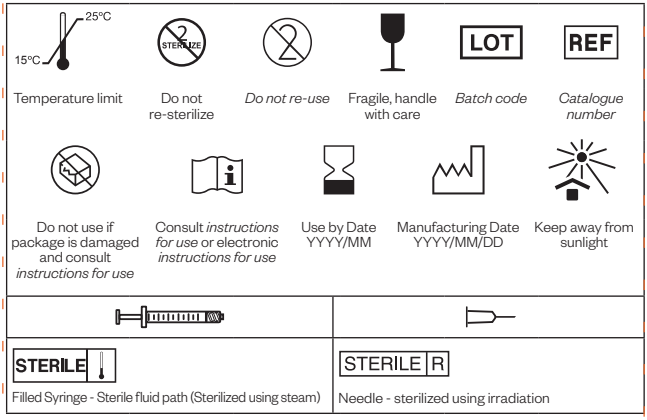
Inject the gel by applying mild continuous pressure on the plunger rod, while slowly withdrawing the needle, thus forming a single uniform thread of injected gel inside the tissue (linear threading technique). When correcting deep folds, several threads should be layered in parallel lines beneath the fold. If larger volumes are required, such layers can be deposited on top of each other, the threads of each layer are perpendicular to those in the underlying layer (cross hatching technique).

- Substantial mechanical resistance to the injection of the implant may be resolved using the following measures: First, horizontally relocate the needle; second, inject from a different entry point; third, replace the needle or even the syringe.
- Stop injection before pulling the needle out of the skin to avoid gel leakage into superficial skin layers.

- If blanching occurs at any time during the injection, the injection should be stopped, and appropriate action taken such as massaging the area until it returns to its normal colour.
- The degree and duration of the correction depend on the character of the defect treated, the tissue stress at the implant site, the depth of the implant in the tissue, and the injection technique. The amount injected will depend on the areas that are to be corrected based on the experience of the healthcare practitioner.
- A touch-up treatment (for achieving optimal correction) and/or a repeat treatment (for maintaining optimal correction) with this product might be required. It is recommended to wait until treatment site side effects are resolved.
- After completing the injection, gently massage the treated area to ensure even distribution of the gel and to mold the gel to the tissue contour.
- After use, treatment syringes and needles are biohazards and/or sharp devices. Handle and dispose of these items in accordance with local procedures and regulations.
- If overcorrection has occurred, firmly massage the area to obtain optimal results.
- Patient should be informed that the injected material may be palpable for a long period after treatment.

9. STORAGE:

- Store between 15°C and 25°C.
- Keep away from sunlight.



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10. IMPORTED BY:

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