RADIESSE® (+) LIDOCAINE

INJECTABLE IMPLANT

INSTRUCTIONS FOR USE

DESCRIPTION

RADIESSE® (+) Lidocaine injectable implant is a sterile, latex-free, non-pyrogenic, semi-solid, cohesive implant. The principle component is synthetic calcium hydroxylapatite suspended in a gel carrier that consists primarily of water (sterile water for injection USP), glycerin (USP), sodium carboxymethylcellulose (USP), and 0.3% lidocaine hydrochloride. The gel is dissipated in vivo and replaced with soft tissue growth, while the calcium hydroxylapatite remains at the site of injection. The lidocaine provides short-term local anesthetic effect. The result is long-term yet non-permanent restoration and augmentation. The typical duration of effect is 6 months, although RADIESSE® (+) Lidocaine injectable implant has been shown to be effective for up to one year in some subjects. Additional injections (touch-ups) may be performed, but only after sufficient time has passed to evaluate the patient (See INDIVIDUALIZATION OF TREATMENT section).

RADIESSE® (+) Lidocaine injectable implant (1.5cc) has a calcium hydroxylapatite particle size range of 25-45 microns and should be injected with a 25 gauge outer diameter (O.D.) to 27 gauge inner diameter (I.D.) needle with a standard Luer fitting.

INTENDED USE

RADIESSE® (+) Lidocaine injectable implant is intended for plastic and reconstructive surgery, including deep dermal and sub-dermal soft tissue augmentation of the facial area and dorsum of the hands.

INDICATIONS

RADIESSE® (+) Lidocaine injectable implant is indicated for

- the treatment of nasolabial folds
- the augmentation of cheeks
- the treatment of marionette lines
- the treatment of jawline
- the hand augmentation to correct volume loss in the dorsum of the hands
- the restoration and/or correction of the signs of fat or volume loss (lipoatrophy) in the facial area and for rejuvenation of the hands fat loss (lipoatrophy) in people with human immunodeficiency virus.

TARGET TREATED POPULATION

Adult patients regardless of gender of all ethnicities and all Fitzpatrick skin types with respect to indications and contraindications stated in the instructions for use.

For hand augmentation and for treatment of the jawline the clinical data for Fitzpatrick skin types V and VI are limited.

INTENDED USER

RADIESSE® (+) Lidocaine injectable implant should be used by healthcare practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.

CONTRAINDICATIONS

- RADIESSE® (+) Lidocaine injectable implant is contraindicated in the presence of acute and/or chronic inflammation or infection when these involve the area to be treated.
- Contraindicated for patients with severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies
- Not to be used in patients with known hypersensitivity to any of the components.
- RADIESSE® (+) Lidocaine injectable implant is not intended to be used in patients with known hypersensitivity to lidocaine or anesthetics of the amide type.
- RADIESSE® (+) Lidocaine injectable implant is contraindicated in patients prone to developing inflammatory skin conditions or those patients with a tendency for developing hypertrophic scars and keloids.
- Do not implant in the epidermis or use as a skin replacement. Implantation into the epidermis or superficial dermis could lead to complications such as fistula formation, infections, extrusions, nodule formation and induration.

- RADIESSE® (+) Lidocaine injectable implant is not intended to be used for the correction of glabellar folds and nose area. A higher incidence of localized necrosis has been associated with glabellar and nose injections. Complications indicate that forceful injection into superficial dermal vessels of the glabellar or nose area could cause retrograde movement into the retinal arteries resulting in vascular occlusion.
- RADIESSE® (+) Lidocaine injectable implant is contraindicated in the presence of foreign bodies such as liquid silicone or other particulate materials.
- RADIESSE® (+) Lidocaine injectable implant should not be used in areas where there is inadequate coverage of healthy, well vascularized tissue.
- RADIESSE® (+) Lidocaine injectable implant should not be used in patients with systemic disorders which cause poor wound healing or will lead to tissue deterioration over the implant.
- RADIESSE® (+) Lidocaine injectable implant is contraindicated for patients with bleeding disorders.

WARNINGS

- Introduction of RADIESSE® (+) Lidocaine injectable implant into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft tissue fillers, for example inject the RADIESSE® (+) Lidocaine injectable implant slowly and apply the least amount of pressure necessary. Rare but serious adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate healthcare practitioner specialist should an intravascular injection occur.
- Implant should not be injected into organs or other structures that could be damaged by a space occupying implant.
- Do not overcorrect (overfill) the injection site as the soft tissue volume is expected to increase within several weeks as the treatment effect of RADIESSE® (+) Lidocaine injectable implant occurs.
- Implant should not be implanted in patients while the patient is on an aspirin regimen or while taking other medications that could inhibit the healing process.
- Implant should not be implanted in infected or potentially infected tissue or in open cavities because infection or extrusion may occur. A significant infection may result in damage or loss to the skin overlying the implant. Hematomas or seromas may require surgical drainage.
- Use of RADIESSE® (+) Lidocaine injectable implant in patients with active skin inflammation or infection in or near the treatment area should be deferred until the inflammatory or infectious process has been controlled.
- In the event of a hypersensitivity or allergic reaction, a significant inflammation or infection may occur requiring the removal of the implant.
- Some injectable implants have been associated with hardening of the tissues at an injection site, migration of particles from an injection site to other parts of the body and/or allergic or autoimmune reactions.
- As with any implant material, possible adverse reactions that may occur include, but are not limited to, the following: inflammation, infection, fistula formation, extrusion, hematoma, seroma, induration formation, inadequate healing, skin discoloration and inadequate or excessive augmentation.
- Safety and performance during pregnancy, in breastfeeding females, or in patients under 18 years old has not been established.

SPECIFIC WARNINGS RELATED TO INJECTIONS INTO HANDS

- Special care should be taken to avoid injection into veins or tendons in the hand. Injection into tendons may weaken tendons and cause tendon rupture. Injection into veins may cause embolization or thrombosis.
- Injection into the hand may cause adverse events that last for more than 14 days. Refer to adverse events sections for details.
- Injection in the dorsum of the hand may result in temporary difficulty performing activities (48% of study patients reported this adverse event). Fitzpatrick Skin Types IV-VI may have an increased risk in difficulty performing activities (68% of Fitzpatrick Skin Types IV-VI reported this event).
- RADIESSE® (+) Lidocaine injectable implant may cause nodules, bumps or lumps in the dorsum of the hand (12% reported this event) and can last up to one year.
- Injection into patients with very severe loss of fatty tissue with marked visibility of veins and tendons has not been studied. The safety and effectiveness in this patient population has not been established.
- Possible acute carpal tunnel syndrome or exacerbation of pre-existing compressive median neuropathy in the wrist may occur. Volumes over 3cc of RADIESSE® (+) Lidocaine injectable implant per hand in a treatment session have not been studied. Increased bruising is associated with higher volume injection. Re-treatment with RADIESSE® (+) Lidocaine injectable implant of volumes greater than approximately 1.6cc per hand in a treatment session can result in increased adverse events (redness, pain, swelling, and difficulty performing activities).

PRECAUTIONS

- In order to minimize the risks of potential complications, RADIESSE® (+) Lidocaine injectable implant should only be used by healthcare practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
- In order to minimize the risks of potential complications, healthcare practitioners should fully familiarize themselves with the product, the product educational materials and the entire package insert.
- Healthcare practitioners are encouraged to discuss all potential risks of soft tissue injection with their patients prior to treatment and ensure that patients are aware of signs and symptoms of potential complications.
- As with all transcutaneous procedures, RADIESSE® (+) Lidocaine injectable implant injection carries a risk of infection. Infection may necessitate attempted surgical removal of RADIESSE® (+) Lidocaine injectable implant. Standard precautions associated with injectable materials should be followed.
- Patients who are using medications that can prolong bleeding, such as aspirin or warfarin, may, as with any injection, experience increased bruising or bleeding at the injection site.
- The calcium hydroxylapatite (CaHA) particles in RADIESSE® (+) Lidocaine injectable implant are radiopaque and are clearly visible on CT Scans or mammograms and may be visible in standard, plain radiography. Patients need to be informed of the radio-opaque nature of RADIESSE® (+) Lidocaine injectable implant, so that they can inform their primary care health professionals and/or radiologists. In a radiographic study of 58 patients, there was no indication of RADIESSE® injectable implant (without lidocaine) potentially masking abnormal tissues or was interpreted as tumors in CT Scans. As with all transcutaneous procedures, RADIESSE® (+) Lidocaine injectable implant injection carries a risk of infection. Standard precautions associated with injectable materials should be followed.
- RADIESSE® (+) Lidocaine injectable implant requires soft tissue for easy percutaneous injection. Scar tissue and significantly compromised tissue may not accept the implant appropriately.
- Infection requiring treatment may occur at the injection site. If such infection cannot be corrected, it may become necessary to remove the implant.
- Injection related reactions, including bruising, erythema, swelling, pain, itching, discoloration or tenderness, may occur at the site of the injection. These usually resolve spontaneously within one to two days after the injection.
- Nodule(s) may form requiring treatment or removal.
- Irregularity of the implant may occur which may require a surgical procedure to correct.
- Do not over-inject the area to be treated. In extreme cases site rupture could occur. RADIESSE® (+) Lidocaine injectable implant can be easily added in subsequent injections, but cannot be easily removed.
- The RADIESSE® (+) Lidocaine injectable implant injection procedure, like similar injection procedures, has small but inherent risks of infection and/or bleeding. The usual precautions associated with percutaneous injection procedures should be followed to prevent infection.
- **Do not re-sterilize.** RADIESSE® (+) Lidocaine injectable implant is supplied sterile and non-pyrogenic in a sealed foil pouch and is intended for single patient, single treatment use only.

  The foil pouch should be carefully examined to verify that neither the pouch nor the syringe has been damaged during shipment. Do not use if the foil pouch is compromised or the syringe has been damaged. Do not use if the syringe end cap or syringe plunger is not in place. There is a small amount of moisture normally present inside the foil pouch for sterilization purposes; this is <u>not</u> an indication of a defective product.
- To help avoid needle breakage, do not attempt to straighten a bent needle. Discard it and complete the procedure with a replacement needle.
- Do not recap used needles. Recapping by hand is a hazardous practice and should be avoided.
- The safety of RADIESSE® (+) Lidocaine injectable implant with concomitant dermal therapies such as epilation, UV irradiation, radiofrequency, ablative or non-ablative laser, mechanical or chemical peeling procedures has not been evaluated in controlled clinical trials.
- No studies of interactions of RADIESSE® (+) Lidocaine injectable implant with drugs or other substances or implants have been conducted.
- Universal precautions must be observed when there is a potential for contact with patient body fluids. The injection session must be conducted with aseptic technique.
- If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with RADIESSE® (+) Lidocaine injectable implant, there is a possible risk of eliciting an inflammatory reaction at the implant site. This also applies if RADIESSE® (+) Lidocaine injectable implant is administered before the skin has healed completely after such a procedure.
- Injection of RADIESSE® (+) Lidocaine injectable implant into patients with a history of previous herpetic eruption may be associated with reactivation of the herpes virus.
- Safety of RADIESSE® injectable implant (without lidocaine) beyond 3 years in the face and 1 year in the hands has not been investigated in clinical trials.
- Care should be taken to determine the risk verse the benefit for patients with congenital methemoglobinemia with glucose-6-phosphate dehydrogenase deficiencies, and with patients who are receiving concomitant treatment with methemoglobin-inducing agents.

SPECIFIC PRECAUTIONS RELATED TO INJECTIONS INTO HANDS

- Use of RADIESSE® (+) Lidocaine injectable implant in the dorsum of the hand in patients with diseases, injuries or disabilities of the hand has not been studied. Care should be taken when treating patients with autoimmune disease affecting the hand, hand implants, Dupuytren's contracture, history of hand tumor, vascular malformations, Raynaud's disease and patients at risk for tendon rupture.
- Use of RADIESSE® (+) Lidocaine injectable implant in the dorsum of the hand may result in significant swelling of the dorsum of the hand. Patients should be instructed to remove jewelry (rings) before treatment and until swelling has resolved to avoid compromise of finger circulation.
- The effects of RADIESSE® (+) Lidocaine injectable implant injection on hand function are uncertain.
- Safety of RADIESSE® (+) Lidocaine injectable implant injected into the dorsum of the hand in patients under 26 years old and over 79 years old has not been studied.

ADVERSE EVENTS

The patients must be informed that as with any implant material possible adverse reactions may occur.

Adverse events seen in a clinical trial with RADIESSE® (+) Lidocaine injectable implant were generally expected, mild in nature, and short in duration.

The following adverse events were reported during clinical trials performed with the RADIESSE® injectable implant (without lidocaine): ecchymosis, edema, erythema, nodule, pain, pruritus, soreness, tenderness, numbness, contour irregularity, lumps, irritation, rash, needle jamming, discoloration, hardness, headache, scab, tightness, blood shot eyes, black eye, abrasion, spot, nerve sensitivity, dry, burning sensation, warm, stretched, pimple, flushed, feverish, ear running, backed-up salivary gland, firmness, hearing loss, and puffiness.

The following adverse events have been identified during post-approval use of RADIESSE® injectable implant (without lidocaine). Because they are reported voluntarily from a population (including from literature) of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to RADIESSE® injectable implant (without lidocaine) These events have been chosen for inclusion due to the combination of their seriousness, frequency of reporting, or potential causal connection to RADIESSE® injectable implant (without lidocaine):

infection (incl. biofilm formation), cellulitis, impetigo, loss of effect, product displacement/migration, allergic reaction, anaphylaxis, hives, rash, pruritus, urticaria, angioedema, inflammation, necrosis, granuloma, nodules, induration, erythema, skin discoloration (including hypo- and hyperpigmentation), dissatisfaction, pustule, skin pallor, hair loss, paresthesia, ptosis, pain (incl. mastication pain), headache, swelling, asymmetry, abscess, herpetic infection including herpes simplex and herpes zoster, hematoma, blanching, blistering, dizziness, festoons, flu-like symptoms, nausea, Guillain-Barre syndrome, tachypnea, ischemic reaction, lymphoid hyperplasia, lymphatic obstruction, pericarditis, scarring, sensitivity to cold, vascular occlusion/obstruction, vascular compromise, ocular ischemia, diplopia, visual impairment/blindness, facial muscle paralysis, Bell's palsy. syncope, chewing problems, erosion, injection site cyst, injection site warmth, aggravation of preexisting conditions, superficial vein prominence, vasculitis, nerve injury, nerve compression, xanthelasma, anxiety, laceration, purpura, calcinosis, capillary fragility, contact dermatitis, dysphagia, dyspnoea, ear pain, eye pain, eyelid function disorder, hypoesthesia, nerve damage, vesicles, lip disorder, mouth ulceration, muscle twitching, nasal congestion, nasopharyngitis, neoplasm, rhinorrhea, exfoliation, fissures, wounds, sneezing, toothache, vomiting.

Patients with specific ethnic characteristics, e.g. Asian population, should be informed of a higher risk of tissue reactions, e.g. inflammatory reactions, pigmentary disorders, post-inflammatory hyperpigmentation (PIH), scarring, and keloid formation upon cutaneous injury.

The following interventions have been reported: antibiotics, anti-inflammatories, corticosteroids, antihistamines, analgesics, massage, warm compress, excision, drainage, and surgery. This information does not constitute and is not intended to be medical advice, a recommendation on how to treat an adverse event or an exhaustive list of possible interventions. Physicians should evaluate each case on an individual basis, and independently determine, based on their professional experience, what treatment(s) are appropriate, if any, for their patients.

INDIVIDUALIZATION OF TREATMENT

Before treatment, the patient's suitability for the treatment should be assessed. The outcome of treatment will vary between patients. In some instances additional treatments may be necessary depending on the size of the defect and the needs of the patient. Additional injections may be performed, but only after sufficient time has passed to evaluate the patient. The patient should not be re-injected sooner than seven days after the previous treatment.

DIRECTIONS FOR USE

GENERAL

The following is required for the percutaneous injection procedure:

- One RADIESSE® (+) Lidocaine 1.5cc injectable implant syringe(s).
- Appropriate size needle(s) with Luer lock fittings. The preferred size is a 25 gauge outer diameter (O.D.) to 27 gauge inner diameter (I.D.) or larger needle with a standard Luer fitting. Use of needles smaller in diameter than 27 gauge I.D. may increase the incidence of needle occlusion.

1. Prepare patient for percutaneous injection using standard methods. The treatment injection site should be marked by a surgical marker and prepared with a suitable antiseptic.
2. Prepare the syringes and the injection needle(s) before the percutaneous injection. A new injection needle may be used for each syringe, or the same injection needle may be connected to each new syringe for same patient treatment.

3. Remove foil pouch from the carton. The pouch can be opened and the syringe dropped onto the sterile field when required. *There is a small amount of moisture normally present inside the foil pouch for sterilization purposes; this is not an indication of a defective product.*

4. Peel or twist apart the needle packaging to expose the hub. For use of needles other than the needle(s) provided with this package, follow the directions provided with the needle(s).

5. Remove the Luer syringe cap from the distal end of the syringe prior to attaching the needle. The syringe can then be twisted onto the Luer lock fitting of the needle taking care not to contaminate the needle. Discard needle package. **The needle must be tightened securely to the syringe and primed with RADIESSE® (+) Lidocaine injectable implant.** If excess implant is on the surface of the Luer lock fittings, it will need to be wiped clean with sterile gauze. Slowly push the syringe plunger until the implant material extrudes from the end of the needle. If leakage is noted at the Luer fitting, it may be necessary to tighten the needle or to remove the needle and clean the surfaces of the Luer fitting or, in extreme cases, replace both the syringe and the needle.

6. Locate the initial site for the implant. Scar tissue and cartilage may be difficult or impossible to inject. Avoid, if at all possible, passing through these tissue types when advancing the injection needle.

NOTE: Do not inject into a blood vessel.

7. The depth of the injection and the amount injected will vary depending on the site and extent of the restoration or augmentation. RADIESSE® (+) Lidocaine injectable implant should be injected sufficiently deep to prevent nodular formation at the surface of the skin or ischemia of the overlying tissue.

8. **DO NOT OVERCORRECT THE INJECTION SITE.** Use a 1:1 correction factor. Mold or massage the injected implant periodically during the injection process to maintain a smooth contour of the implant. A maximum of 10 ml RADIESSE® (+) Lidocaine injectable implant is recommended as yearly dose. The dose may be adapted according to the patient's indication, tissue, age, injection depth and technique for implantation.

9. If significant resistance is encountered when pushing the plunger, the injection needle may be moved slightly to allow easier placement of the material. If significant resistance is still encountered, it may be necessary to pull the needle entirely out of the injection site and try again in a new position. If significant resistance continues to persist, it may be necessary to try a different injection needle. If this is not successful, replace the syringe and injection needle.

10. Advance the needle bevel down at approximately a 30° angle to the skin into the sub- dermis to the starting location. [Refer to additional instructions below for treatment of facial areas.] Carefully push the plunger of the syringe to start the injection and slowly inject the implant material while withdrawing the needle, placing a line of material in the desired location. Continue placing additional lines of material until the desired level of augmentation is achieved. The thread of implant material should be completely surrounded by soft tissue without leaving globular deposits. The injected area may be massaged as needed to achieve even distribution of the implant.

INJECTION PROCEDURE FOR HAND AUGMENTATION

1. Prepare patient for percutaneous injection using standard methods. Have the patient wash both hands with soapy water producing friction for 5-10 minutes and then prepare hands with suitable antiseptic. The treatment injection site may be marked for planned injection sites. Jewelry should be removed prior to injection and until post-procedure swelling has resolved.

2. Using the syringe of RADIESSE® (+) Lidocaine injectable implant fitted with the injection needle, slowly push the syringe plunger until RADIESSE® (+) Lidocaine injectable implant extrudes from the end of the needle performing aspiration before bolus injection to avoid intravascular injection. If leakage is noted at the Luer fitting, wipe it clean with sterile gauze. It may be necessary to tighten the needle, remove the needle and clean the surfaces of the Luer fitting or, in extreme cases, replace both the syringe and the needle.

3. A new injection needle may be used for each syringe, or the same injection needle may be connected to each new syringe for same patient treatment.

4. Locate the initial site for injection. Patients are to receive injections in the dorsum of the hands between the 1st and 5th metacarpals. Injection should initially occur between the 2nd and 4th metacarpals, taking care not to inject close to the metacarpophalangeal joints. If necessary to achieve optimal correction, injection is also allowed between the 1st and 2nd and 4th and 5th metacarpals.

5. Skin tenting should be performed to separate the skin from vascular and tendinous structures by using the thumb and forefinger of the non-injecting hand to lift skin over the dorsal aspect of the hand being treated.

6. Advance the needle between the subcutaneous layer and superficial fascia with the syringe parallel to the dorsum of the hand. Carefully push the plunger of the RADIESSE® (+) Lidocaine injectable implant syringe to start the injection and inject the RADIESSE® (+) Lidocaine injectable implant material in small boluses, 0.2 – 0.5cc/bolus. No more than 0.5cc should be injected per bolus. The number of boluses will vary depending on the extent of treatment desired. No more than 3cc of RADIESSE® (+) Lidocaine injectable implant (2 syringes) will be injected per hand.

7. If significant resistance is encountered when pushing the plunger, the injection needle may be moved slightly to allow easier placement of the material or it may be necessary to change the injection needle.

8. Immediately after injection, cover the injection site with a sterile 4x4 gauze and have patient sit on this hand while the contralateral hand is being injected. This warms the RADIESSE® (+) Lidocaine injectable implant making it more malleable for later massaging.

9. Treat the contralateral hand in the same manner as described in steps 2 through 7 above.

10. Immediately after injection of the contralateral hand, cover the injection site with a sterile 4x4 gauze and have the patient sit on this hand.

11. While the contralateral hand is warming, remove the gauze from the hand that was initially injected, have the patient make a fist with this hand, and gently massage the dorsum of the hand until RADIESSE® (+) Lidocaine injectable implant has been evenly spread across the dorsum remaining distal to the wrist crease and proximal to the metacarpophalangeal joints.

12. Use a 1:1 correction factor. No overcorrection is needed.

TREATMENT OF FACIAL INDICATIONS

1. Insert needle with bevel down at approximately a 30° angle to the skin. The needle should slide into the deep dermis to the point where you wish to begin the injection. This should be easily palpable with the non-dominant hand.

2. Apply slow continuous even pressure to the syringe plunger to inject the implant as you withdraw the needle, leaving behind a single thin thread or strand of implant material. The thread of implant material should be completely surrounded by soft tissue without leaving globular deposits.

3. Individual threads of implant material should be placed parallel and adjacent to each other, and layered when deeper folds are corrected. As an option, the threads can be cross layered in a deeper plane for structural support.

4. After injection, use the index finger and thumb to smooth the areas and better distribute the implant in case of any slight nodular deposition of material.

PATIENT COUNSELING INFORMATION

The patient should be instructed in appropriate post-procedural care, which may include the following, to promote normal healing and avoid complications.

- Apply cool compresses to areas of injection for approximately 24 hours.
- Avoid the sun, tanning (ultraviolet) lights, sauna and intense facial treatments post procedurally.
- Massage the area gently if palpable nodules become present.
- Promote facial rest for one week by encouraging patients to limit talking, smiling and laughing.
- Inform the patient that postoperative swelling and numbness are common. Swelling will usually resolve within 7 to 10 days, but may persist for several weeks. Numbness should resolve within 4 to 6 weeks.

HOW SUPPLIED

RADIESSE® (+) Lidocaine injectable implant is provided sterile and non-pyrogenic in a syringe packaged in a foil pouch and boxed for convenient storage.

Each unit consists of one pre-filled syringe containing 1.5cc of RADIESSE® (+) Lidocaine injectable implant.

Each syringe unit with needle convenience pack consists of one pre-filled syringe containing 1.5cc of RADIESSE® (+) Lidocaine injectable implant and a Terumo K-Pack II with two 27 gauge thin wall injection needle(s).

The degree of accuracy of syringe graduations is ±0.025cc. Do not use if packaging and/or syringe are damaged or if the syringe end cap or syringe plunger is not intact.

The contents of the syringe are intended for single patient, single treatment use only and cannot be re-sterilized. Re-use may compromise the functional properties of the device and/or lead to device failure. Re-use may also create a risk of contamination of the device and/or cause patient infection or cross-infection including but not limited to transmission of infectious disease(s) and blood transfer between patients. All of which, in turn, may lead to patient injury, illness or death.

STORAGE

Packaged RADIESSE® (+) Lidocaine injectable implant should be stored at a controlled room temperature between 15°C and 25°C (59°F and 77°F). Do not use if the expiration date has been exceeded. The expiration date is printed on the product labels.

DISPOSAL

Used and partially used syringes and injection needles could be biohazardous and should be handled and disposed of in accordance with facility medical practices and local, state or federal regulations.

WARRANTY

Merz North America, Inc. warrants that reasonable care has been exercised in the design and manufacture of this product.

Please note that the handling and storage of this product, as well as factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Merz North America, Inc.'s control can directly affect the product and the results obtained from its use.

SYMBOLS

	Legal Manufacturer		Not Made with Natural Rubber Latex
	Article number		Consult instruction for use
	Batch number		Do not use if package is damaged
	Use-by date: YYYY-MM		Do not re-use the product
	Caution, consult instruction for use		Do not resterilize
	Sterilized using ethylene oxide		Storage temperature limitation
	Sterilized using steam		Needle

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Instructions how to use the patient implant card

An implant card is provided with RADIESSE® / RADIESSE® (+) Lidocaine which must be completed by the physician according to the below instructions and provided to the patient after injection.

1. Carefully remove the back cover page of the IFU at the perforation provided
2. Cut out the patient implant card on the intended line (scissors symbol)
3. Fold the patient implant card along the line so that the text is on the outside when folded
4. Fill the patient implant card and add the product label with the information below after the treatment is completed.

Number	Symbols	Details
1		Patient name
2		Date of implantation
3 – 4		Name and address of the physician
5		Number of injections
6		Total volume injected
7		Injection site(s)
8	Product label	*Please stick here the peel-off product traceability label you can find on the Radiesse® / Radiesse® (+) Lidocaine pouch.*

5. Hand over the completed patient implant card to the patient after all information is filled.

<u>Important information to be provided to the patient</u>

Instruct the patient to keep the patient implant card with her/him and to present it to her/his physician in case of other appointments. Information about previous treatment must be presented to the physician before treatment!

fold

Implant Card

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For patients: please read the patient information leaflet for more important information at https://merzaustralia.com.au/patientinformation/aesthetics/products/ or by scanning the QR code.
For HCPs: please refer to the above webpage on how to complete this patient implant card.

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