RENÚ®CALCIUM HYDROXYLAPATITE VOCAL FOLD IMPLANT

INSTRUCTONS FOR USE

DESCRIPTION

RENÚ® Calcium Hydroxylapatite Vocal Fold Implant is a sterile, semi-solid, cohesive implant. The principle component of RENÚ® Calcium Hydroxylapatite Vocal Fold Implant is synthetic calcium hydroxylapatite. The semi-sold nature is created by suspending the calcium hydroxylapatite particles in a durable high yield strength thixotropic gel. The aqueous gel carrier consists of sodium carboxymethylcellulose, glycerin, and a phosphate buffer. The carrier resorbs *in vivo*, so that the calcium hydroxylapatite remains at the site of implantation, providing a scaffold for local tissue infiltration. This cellular infiltrated hydroxyapatite scaffold provides the long-term restoration and augmentation.

INTENDED USE / INDICATIONS

RENÚ® Calcium Hydroxylapatite Vocal Fold Implant is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue-bulking agent. RENÚ® Calcium Hydroxylapatite Vocal Fold Implant injection augments the size of the displaced or deformed vocal fold so that it may meet the opposing fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication.

CONTRAINDICATIONS

- Contraindicated in the presence of acute and/or chronic inflammation or infection when these involve the area to be treated.
- Contraindicated in the presence of foreign bodies, such as liquid silicone or other particulate materials.
- Contraindicated in patients with inadequately controlled malignancy or rapidly advancing disease when these involve the larynx or upper respiratory tract.
- Contraindicated in bilateral laryngeal paralysis and vocal disorders of psychogenic or emotional origin.

WARNINGS

- Special care should be taken when injecting soft tissue fillers to avoid injection into blood vessels/vasculature. Rare but serious adverse events associated with intravascular injection of soft tissue fillers have been reported. Associated complications can be serious and may be permanent. Complications can include stroke, temporary scabs, platelet aggregation, vascular occlusion, infarction, hemolysis, embolization, embolic phenomena, necrosis, ischemia, cerebral ischemia or cerebral hemorrhage leading to stroke. Immediately stop the injection if a patient exhibits any of the following: changes in vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion or unusual pain during or shortly after treatment. Patients should receive prompt medical attention and possibly evaluation by an appropriate health care practitioner should an intravascular injection occur.
- Airway obstruction may result from aggressive vocal fold injection, over-injection, or laryngeal edema from trauma and manipulation of the larynx. Under no circumstance should excessive force be used to overcome resistance during injection, since sudden and uncontrolled over injection may occur. Airway obstruction following vocal fold injection can occur immediately, or at any time up to seven (7) days following injection. Airway obstruction can often be prevented by minimizing laryngeal trauma and manipulation during the injection and can be treated by administering intraoperative and postoperative steroid treatment.
- RENÚ should not be injected into the airway. Confirm placement of needle tip visually before initiating the injection.
- With any implant materials, possible adverse reactions that may occur include, but are not limited to the following: inflammation, infection, fistula formation, inadequate healing, , vocal fold paralysis, breathing difficulty, swelling of throat, implant extrusion, poor phonatory function post injection, permanent hoarseness due to inadequate or excessive augmentation.
- Do not inject superficially. Implantation could lead to complications such as infections, extrusion, tissue erosion, nodule formation and induration.
- Viable tissue is required for effective injection. Scar tissue, cartilage, and significantly compromised tissue may not respond to treatment. If possible, avoid passing through these tissue types when advancing the injection needle.
- Should not be injected into organs or other structures which could be damaged by space occupying implant. Some injectable implant devices have been associated with hardening of the tissues at an injection site, migration from an injection site to other parts of the body, and/or allergic or autoimmune reactions. Based on clinical usage, animal studies, and supporting literature, this has not been observed nor is it expected with RENÚ.
- Do not overcorrect (overfill) a deficiency because the depression should gradually improve within several weeks as the treatment effect of RENÚ occurs (see INDIVIDUALIZATION OF TREATMENT). Inject the product slowly and apply the least amount of pressure necessary.
- There have been published reports of tissue necrosis associated with the use of CaHA based injectable implants.
- Injection procedure reactions have been observed consisting mainly of short-term (i.e., < 7days) bruising, redness and swelling.

PRECAUTIONS

- Therapy should be delayed at least six (6) months following the onset of vocal fold paralysis and/or until an adequate trial of voice rehabilitation has been given.
- Vocal fold injections of RENÚ should only be performed by physicians who have appropriate training, experience with diagnostic and therapeutic otolaryngology procedures including vocal fold injection, are knowledgeable about the anatomy at and around the site of injection, and after fully familiarizing themselves with the product and the entire package insert.
- Do not bend or attempt to straighten a bent 24-gauge needle; discard it and replace with a new needle**.** Renú Transoral Needles have a malleable 16G cannula, however care should be taken to avoid placing undue pressure upon or bending any portion of the 24G needle to avoid needle breakage.
- Do not over-inject the RENÚ into the tissue. RENÚ can be easily added in subsequent injections but cannot be easily removed. Inject the product slowly and apply the least amount of pressure necessary. In extreme cases site rupture could occur.
- In some cases, initial treatment with RENÚ may not be effective and additional injections may be indicated.
- RENÚ injection procedure and the associated instrumentation procedures have small but inherent risks of infection and/or bleeding like similar minimally invasive procedures. The patient may experience slight discomfort during and following the procedure. The usual precautions associated with vocal fold procedures should be followed.
- As with any surgical or implantation procedure, Renú carries a risk of infection. Care should be taken during injection of Renú to avoid infection.
- RENÚ is supplied sterile in a sealed foil pouch and is intended for **single use only**. Do not store partially used syringes for later use. Reuse of a syringe or needle at a later time or on multiple patients, could be biohazardous and pose a risk of contamination and infection.
- **Do not re-sterilize**; re-sterilized device safety and performance has not been validated.
- The foil pouch should be carefully examined to verify that neither the pouch nor the RENÚ 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 has been displaced.
- Use of needles smaller than 25G increase the incidence of needle occlusion.
- Safety and efficacy of Renú has not been evaluated when an anesthetic is mixed into the product prior to injection.
- If significant resistance is encountered when pushing the plunger, under no circumstance should excessive force be used to overcome resistance since the injection needle may disconnect from the Renú syringe. It may be necessary to try a different needle or replace both the syringe and needle.
- The CaHA particles of the injectable implant are radiopaque and are clearly visible on CT Scans and may be visible in standard, plain radiography. In a radiographic study of 58 patients, there was no indication that CaHA based injectable implants potentially masked abnormal tissues or were interpreted as tumors in CT Scans. Patients need to be informed of the radiopaque nature of CaHA based injectable implant so that they can inform their primary care health professionals as well as radiologists.
- The safety of RENÚ in patients with increased susceptibility to keloid formation and hypertrophic scarring has not been studied.
- Safety and efficacy of RENÚ during pregnancy, in breastfeeding or lactating females, or in patients under 18 years has not been established.
- 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.
- Universal precautions must be observed during the injection procedure.
- The injection session must be conducted with aseptic technique.

- After use, treatment syringes and needles may be potential biohazards. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements.
- No studies of interactions of RENÚ with drugs or other substances or implants have been conducted.
- Health care practitioners are encouraged to discuss all potential risks of the soft tissue injection with each patient prior to treatment to ensure that patients are aware of signs and symptoms of potential complications.
- Suboptimal RENÚ injection can occur and may require surgical removal. Excessive injection resulting in persistent over-medialization may occur. Although a rare complication, superficial injection into the subepithelial space can also occur. Partial or total removal of the implant can be performed following standard surgical techniques including through phonomicrosurgery operative techniques.
- The RENÚ vocal fold injection procedure has a small but inherent risk of infection. Post injection infections which do not respond to standard medical treatment are uncommon. However, if an infection is unresponsive to treatment and removal of the implant is determined to be required, partial or total removal of the implant can be performed following standard surgical techniques including through phonomicrosurgery operative techniques.
- Patient movement during the RENÚ injection procedure may cause superficial injection into the subepithelial space. Although a rare complication, partial or total removal of the implant can be performed following standard surgical techniques including through phonomicrosurgery operative techniques. Confirm placement of needle tip visually before initiating the injection.

PHYSICIAN TRAINING

Injections of RENÚ® Calcium Hydroxylapatite Vocal Fold Implant should only be performed by physicians who have experience with diagnostic and therapeutic otolaryngology procedures including vocal fold injection.

INDIVIDUALIZATION OF TREATMENT

Medical examination including medical history and diagnostic testing should be conducted to determine if the patient is an appropriate candidate for treatment with RENÚ® Calcium Hydroxylapatite Vocal Fold Implant. The outcome of treatment with RENÚ® Calcium Hydroxylapatite Vocal Fold Implant may vary between patients. In some patients, additional treatments may be necessary to improve and/or maintain the level of response. If symptoms persist after treatment, 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. Typical correction can be expected to last from 9 to 18 months.

DIRECTIONS FOR USE:

PERCUTANEOUS VOCAL FOLD INJECTION

The following is required for the vocal fold injection procedure:

- RENÚ® Calcium Hydroxylapatite Vocal Fold Implant syringe(s)
- Appropriate sized needle(s)
- Nasopharyngoscope

CAUTION: Universal precautions must be observed during the injection procedure.

CAUTION: The injection session must be conducted with aseptic technique

1. Prepare the syringe(s) of RENÚ® Calcium Hydroxylapatite Vocal Fold Implant, injection needles(s), and nasopharyngoscope equipment before the surgical injection using facility medical practices for a nasopharyngoscope examination. A new injection needle may be used for each syringe or the same injection needle may be connected to each new syringe. **In all cases, when the injection needle is attached to the syringe, the needle must be tightened securely to the syringe (the needle must be tightened until the squared section of the needle's Luer fittings contacts the syringe) and be primed with RENÚ® Calcium Hydroxylapatite Vocal Fold Implant.**

CAUTION: The foil pouch should be carefully examined to verify that neither the pouch nor the RENÚ 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 has been displaced.

CAUTION: RENÚ is supplied sterile in a sealed foil pouch and is intended for **single use only**. Do not store partially used syringes for later use. Reuse of a syringe or needle at a later time, or on multiple patients, could be biohazardous and pose a risk of contamination and infection.

CAUTION: Do not re-sterilize; re-sterilized device safety and performance has not been validated.

2. Remove foil pouch from the carton. The pouch can be opened and the syringe of RENÚ® Calcium Hydroxylapatite Vocal Fold Implant placed onto the sterile field when required. **NOTE:** ***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.***

CAUTION: Health care practitioners are encouraged to discuss all potential risks of soft tissue injection with each patient prior to treatment to ensure that patients are aware of signs and symptoms of potential complications

3. Prepare patient for nasopharyngoscopy and anesthetize using standard methods. Local anesthesia is not required but may be utilized at the injection site.
4. Remove the Luer syringe cap from the distal end of the syringe prior to attaching the needle. The injection needle can then be twisted onto the Luer lock fitting of the syringe of RENÚ®Calcium Hydroxylapatite Vocal Fold Implant.
5. **The needle must be tightened securely to the syringe and primed with RENÚ®.** If excess RENÚ® Calcium Hydroxylapatite Vocal Fold 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 RENÚ® Calcium Hydroxylapatite Vocal Fold Implant extrudes from the end of the injection needle. If leakage is noted at the Luer fitting, it may be necessary to remove the needle and clean the surfaces of the Luer fitting or, in extreme cases, replace both the syringe and the injection needle.
6. Place the nasopharyngoscope to precisely visualize the needle position and RENÚ® Calcium Hydroxylapatite Vocal Fold Implant volume during augmentation.

7. RENÚ® Calcium Hydroxylapatite Vocal Fold Implant should be injected lateral to the thyroarytenoid muscle.

WARNING: Viable tissue is required for effective injection. Scar tissue, cartilage, and significantly compromised tissue may not respond to treatment. If possible, avoid passing through these tissue types when advancing the injection needle.

8. Extend the patient's neck if possible and identify the following external landmark: the cricoid and inferior border of the thyroid cartilage and thyroid notch. Because the superior surface of the vocal fold lies at approximately half the distance between the superior notch and the inferior border of the thyroid cartilage, injection is placed below this level but above the inferior thyroid cartilage margin. Transcartilaginous injection is used unless cartilage calcification prevents it, in which case needle placement is through the cricothyroid membrane.

WARNING: RENÚ should not be injected into the airway. Confirm placement of needle tip visually before initiating the injection.

WARNING: Special care should be taken when injecting soft tissue fillers to avoid injection into blood vessels/vasculature. Rare but serious adverse events associated with intravascular injection of soft tissue fillers have been reported. Associated complications can be serious and may be permanent. Complications can include vision abnormalities/impairment, blindness, stroke, temporary scabs, platelet aggregation, vascular occlusion, infarction, hemolysis, embolization, embolic phenomena, necrosis, ischemia, cerebral ischemia or cerebral hemorrhage leading to stroke, permanent scarring of the skin, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following: changes in vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance (blanching) of the skin, or unusual pain during or shortly after treatment. Patients should receive prompt medical attention and possibly evaluation by an appropriate health care practitioner should an intravascular injection occur.

WARNING: Do not overcorrect (overfill) a deficiency because the depression should gradually improve within several weeks as the treatment effect of RENÚ occurs (see INDIVIDUALIZATION OF

TREATMENT). Inject the product slowly and apply the least amount of pressure necessary.

CAUTION: Do not over-inject the RENÚ into the tissue. RENÚ can be easily added in subsequent injections but cannot be easily removed. Inject the product slowly and apply the least amount of pressure necessary. In extreme cases site rupture could occur.

9. With needle location visually confirmed through nasopharyngoscope, slowly push the plunger shaft of the RENÚ® Calcium Hydroxylapatite Vocal Fold Implant syringe to start the injection.
10. After the initial injection, the patient should be asked to phonate and cough to disperse RENÚ® Calcium Hydroxylapatite Vocal Fold Implant. Additional RENÚ® Calcium Hydroxylapatite Vocal Fold Implant is injected until the vocal folds touch during phonation at a position midway between the anterior commissure and the vocal processes.

WARNING: Airway obstruction may result from aggressive vocal fold injection, over-injection, or laryngeal edema from trauma and manipulation of the larynx. Under no circumstance should excessive force be used to overcome resistance during injection, since sudden and uncontrolled over injection may occur. Airway obstruction following vocal fold injection can occur immediately, or at any time up to seven (7) days following injection. Airway obstruction can often be prevented by minimizing laryngeal trauma and manipulation during the injection and can be treated by administering intraoperative and postoperative steroid treatment.

CAUTION: If significant resistance is encountered when pushing the plunger, under no circumstance should excessive force be used to overcome resistance since the injection needle may disconnect from the Renú syringe. It may be necessary to try a different needle or replace both the syringe and needle.

11. Some tissue planes may be difficult to inject. If significant resistance is encountered when pushing the plunger, pull back the injection needle about one (1) to three (3) millimeters (with the needle still in the vocal fold tissue) and push the plunger again slowly. If significant resistance is still encountered, it may be necessary to pull the needle entirely out of the injection site and inject in a new position.
12. The number of injection attempts is at the discretion of the treating physician and must take into account the patient's tolerance of the procedure and discomfort.

CAUTION: After use, treatment syringes and needles may be potential biohazards. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements.

13. Dispose of the opened syringes, as well as used injection needles.
14. Instruct the patient to not use his/her voice for three days so as to minimize any potential extrusion of the implant through the injection site.

CAUTION: The RENÚ vocal fold injection procedure has a small but inherent risk of infection. Post injection infections which do not respond to standard medical treatment are uncommon. However, if an infection is unresponsive to treatment and removal of the implant is determined to be required; partial or total removal of the implant can be performed following standard surgical techniques including through phonomicrosurgery operative techniques.

15. A course of antibiotics may be prescribed, as appropriate.

ORAL VOCAL FOLD INJECTION

The following is required for the vocal fold injection procedure:

- RENÚ®Calcium Hydroxylapatite Vocal Fold Implant syringe(s)
- Appropriate sized needle(s)
- Nasopharyngoscope

CAUTION: Universal precautions must be observed during the injection procedure.

CAUTION: The injection session must be conducted with aseptic technique

1. Prepare the syringe(s) of RENÚ® Calcium Hydroxylapatite Vocal Fold Implant, injection needle(s), and nasopharyngoscope equipment before the surgical injection using facility medical practices for a nasopharyngoscope examination. A new injection needle may be used for each syringe or the same injection needle may be connected to each new syringe. **In all cases, when the injection needle is attached to the syringe of RENÚ® Calcium Hydroxylapatite Vocal Fold Implant , the needle must be tightened securely to the syringe (the needle must be tightened until the squared section of the needle's Luer fittings contacts the syringe) and be primed with RENÚ® Calcium Hydroxylapatite Vocal Fold Implant.**

CAUTION: The foil pouch should be carefully examined to verify that neither the pouch nor the RENÚ 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 have been displaced.

CAUTION: RENÚ is supplied sterile in a sealed foil pouch and is intended for **single use only**. Do not store partially used syringes for later use. Reuse of a syringe or needle at a later time or on multiple patients, could be biohazardous and pose a risk of contamination and infection.

CAUTION: Do not re-sterilize; re-sterilized device safety and performance has not been validated.

2. Remove foil pouch from the carton. The pouch can be opened and the syringe of RENÚ® Calcium Hydroxylapatite Vocal Fold Implant placed onto the sterile field when required. **NOTE:** ***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.***

CAUTION: Health care practitioners are encouraged to discuss all potential risks of soft tissue injection with each patient prior to treatment to ensure that patients are aware of signs and symptoms of potential complications.

3. Prepare patient for nasopharyngoscopy and anesthetize using standard methods. Local anesthesia is not required but may be utilized at the RENÚ® Calcium Hydroxylapatite Vocal Fold Implant injection site.
4. Remove the Luer syringe cap from the distal end of the syringe prior to attaching the needle. The injection needle can then be twisted onto the Luer lock fitting of the syringe.

CAUTION: Do not bend or attempt to straighten a bent 24-gauge needle; discard it and replace with a new needle. Renú Transoral Needles have a malleable 16G cannula, however care should be taken to avoid placing undue pressure upon or bending any portion of the 24G needle to avoid needle breakage.

5. **The needle must be tightened securely to the syringe (until the squared section of the needle's Luer fitting contacts the syringe) and primed with Renú.** If excess RENÚ® Calcium Hydroxylapatite Vocal Fold 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 RENÚ® extrudes from the end of the injection needle. If leakage is noted at the Luer fitting, it may be necessary to remove the needle and clean the surfaces of the Luer fitting or, in some cases, replace both the syringe and the injection needle.

WARNING: RENÚ should not be injected into the airway. Confirm placement of needle tip visually before initiating the injection.

WARNING: Special care should be taken when injecting soft tissue fillers to avoid injection into blood vessels/vasculature. Rare but serious adverse events associated with intravascular injection of soft tissue fillers have been reported. Associated complications can be serious and may be permanent. Complications can include vision abnormalities/impairment, blindness, stroke, temporary scabs, platelet aggregation, vascular occlusion, infarction, hemolysis, embolization, embolic phenomena, necrosis, ischemia, cerebral ischemia or cerebral hemorrhage leading to stroke, permanent scarring of the skin, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following: changes in vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance (blanching) of the skin, or unusual pain during or shortly after treatment. Patients should receive prompt medical attention and possibly evaluation by an appropriate health care practitioner should an intravascular injection occur.

WARNING: Do not overcorrect (overfill) a deficiency because the depression should gradually improve within several weeks as the treatment effect of RENÚ occurs (see INDIVIDUALIZATION OF TREATMENT). Inject the product slowly and apply the least amount of pressure necessary.

CAUTION: Do not over-inject the RENÚ into the tissue. RENÚ can be easily added in subsequent injections but cannot be easily removed. Inject the product slowly and apply the least amount of pressure necessary. In extreme cases site rupture could occur.

WARNING: Viable tissue is required for effective injection. Scar tissue, cartilage, and significantly compromised tissue may not respond to treatment. If possible, avoid passing through these tissue types when advancing the injection needle.

6. Place the nasopharyngoscope to precisely visualize the needle position and RENÚ® Calcium Hydroxylapatite Vocal Fold Implant volume during augmentation. With needle location visually confirmed through nasopharyngoscope, slowly push the plunger shaft of the syringe to start the injection. RENÚ® Calcium Hydroxylapatite Vocal Fold Implant should be injected lateral to the thyroarytenoid muscle.
7. After the initial injection, the patient should be asked to phonate and cough to disperse RENÚ® Calcium Hydroxylapatite Vocal Fold Implant throughout the vocal fold. Additional RENÚ® Calcium Hydroxylapatite Vocal Fold Implant is injected until the vocal folds touch during respiration at a position midway between the anterior commissure and the vocal processes.

WARNING: Airway obstruction may result from aggressive vocal fold injection, over-injection, or laryngeal edema from trauma and manipulation of the larynx. Under no circumstance should excessive force be used to overcome resistance during injection, since sudden

and uncontrolled over injection may occur. Airway obstruction following vocal fold injection can occur immediately, or at any time up to seven (7) days following injection. Airway obstruction can often be prevented by minimizing laryngeal trauma and manipulation during the injection and can be treated by administering intraoperative and postoperative steroid treatment.

CAUTION: If significant resistance is encountered when pushing the plunger, under no circumstance should excessive force be used to overcome resistance since the injection needle may disconnect from the Renú syringe. It may be necessary to try a different needle or replace both the syringe and needle.

8. Some tissue planes may be difficult to inject. If significant resistance is encountered when pushing the plunger, pull back the injection needle about one (1) to three (3) millimeters (with the needle still in the vocal fold tissue) and push the plunger slowly again. 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.
9. The number of injection attempts is at the discretion of the treating physician and must take into account the patient's tolerance of the procedure and discomfort.

CAUTION: After use, treatment syringes and needles may be potential biohazards. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements.

10. Dispose of the opened syringes, as well as used injection needles.
11. Instruct the patient to not use his/her voice for three days so as to minimize any potential extrusion of the RENÚ through the injection site.

CAUTION: The RENÚ vocal fold injection procedure has a small but inherent risk of infection. Post injection infections which do not respond to standard medical treatment are uncommon. However, if an infection is unresponsive to treatment and removal of the implant is determined to be required; partial or total removal of the implant can be performed following standard surgical techniques including through phonomicrosurgery operative techniques.

12. A course of antibiotics maybe prescribed, as appropriate.

RENÚ®CALCIUM HYDROXYLAPATITE VOCAL FOLD IMPLANT

General Information

HOW SUPPLIED

RENÚ® Calcium Hydroxylapatite Vocal Fold Implant is provided in a foil pouch that contains one sterile, 1.5 cc syringe pre-filled with sterile RENÚ® Calcium Hydroxylapatite Vocal Fold Implant. Do not use if packaging and/or syringe are damaged or if the syringe end cap or syringe plunger have been displaced. The contents of the syringe are intended for single patient use only and cannot be re-sterilized.

STORAGE

RENÚ® Calcium Hydroxylapatite Vocal Fold Implant should be stored at a controlled room temperature between 15° C and 32° C (59° F and 90° F). The expiration date when stored properly is two years from date of manufacture. Do not use if the expiration date has been exceeded.

Upon receipt of shipment, check the packaging to ensure that the packaging is intact and there has been no damage from shipment.

WARRANTY

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

THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ITS PARTICULAR PURPOSE.

Handling and storage of this product as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Cytophil's control directly affect the product and the results obtained from its use. Cytophil's obligation under this warranty is limited to the replacement of this product and Cytophil shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this product. Cytophil, Inc. neither assumes, nor authorizes any person to assume for Cytophil, Inc. any other or additional liability or responsibility in connection with this product.

Manufactured by:

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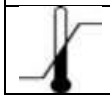
RENÚ® is a registered trademark of Cytophil, Inc.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

	Manufacturer
	Catalog number
	Batch code
	Use by date
	Temperature limit

	Do not resterilize
	Do not reuse
	Do not use if package is damaged
	CAUTION: Consult accompanying documents
	Sterilized using steam or dry heat