RENÚ TRANSORAL NEEDLE INSTRUCTIONS FOR USE (IFU)

DESCRIPTION
The Renú Transoral Needle is comprised of a 304 stainless steel 24ga x 0.398" (0.6 x 10mm) needle with a 17-degree needle point, a 304 stainless steel 16ga (1.7mm) cannula, and a female Luer design nickel-plated brass hub.

INTENDED USE / INDICATIONS
The Renú® Transoral Needle is a single use, sterile device to be used as an accessory to the Cytophil Renú Product Family. The Renú Transoral Needle is indicated to assist in the minimally invasive vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue-bulking agent. **The Renú Transoral Needle is to be used with Cytophil, Inc. products only.**

RENÚ® Transoral Needle General Information

HOW SUPPLIED
The Renú Transoral Needle is a single use, sterile device provided in a Tyvek® pouch that contains one Renú Transoral Needle with a protective sheath that is contained within a secondary protective tube with endcaps. Upon receipt of shipment, check the packaging to ensure that the packaging is intact and there has been no damage from shipment. Do not use if packaging and/or needle are damaged. The Renú Transoral Needle is intended for single patient use only and cannot be re-sterilized.

EXPIRATION
The expiration date when stored properly is two years from date of manufacture. Do not use if the expiration date has been exceeded.

CONTRAINDICATIONS
- Contraindicated in the presence of acute and/or chronic inflammation or infection when these involve the area to be treated.
- Contraindicated in patients with inadequate coverage of healthy, well vascularized tissue.
- Refer to the Renú product IFU for additional contraindications associated with the Renú implant and/or the injection procedure.

WARNINGS
- RENÚ should not be injected into the airway. Confirm placement of needle tip visually before initiating the injection.
- 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.
- Injection procedure reactions have been observed consisting mainly of short-term (i.e., < 7days) bruising, redness and swelling.
- Refer to the Renú product IFU for additional warnings associated with the Renú implant and/or the injection procedure.

PRECAUTIONS
- Vocal fold injections using the Renú Transoral Needle 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.
- The 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 injection procedures, should be followed.
- The Renú Transoral Needle is supplied sterile in a sealed Tyvek® pouch and is intended for **single use only**. Do not store used needles for later use. Reuse of a 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 Tyvek® pouch should be carefully examined to verify that neither the pouch nor the Renú Transoral Needle has been damaged during shipment. Do not use if the Tyvek® pouch is compromised or the needle has been damaged.
- If significant resistance is encountered during needle priming or during the injection procedure, under no circumstance should excessive force be used to overcome resistance since the injection needle may disconnect from the Renú syringe and/or over injection of the implant may occur. It may be necessary to try a different needle or replace both the syringe and needle.
- 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.
- Refer to the Renú product IFU for additional precautions associated with the Renú implant and/or the injection procedure.

ORAL VOCAL FOLD INJECTION DIRECTIONS FOR USE

The following is required for the vocal fold injection procedure:
- RENÚ® Implant syringe(s)
- Renú Transoral Needle
- Nasopharyngoscope

1. Refer to the Renú product IFU for associated Renú implant and/or the injection procedure instructions.

CAUTION: Universal precautions must be observed during the injection procedure.
CAUTION: The injection session must be conducted with aseptic technique.

2. Prepare the syringe(s) of RENÚ®, Renú Transoral 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 of RENÚ®, 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®.**

CAUTION: The Tyvek® pouch should be carefully examined to verify that neither the pouch nor the Renú Transoral Needle has been damaged during shipment. Do not use if the Tyvek® pouch is compromised or the needle has been damaged.
CAUTION: The Renú Transoral Needle is supplied sterile in a sealed Tyvek® pouch and is intended for **single use only**. Do not store used needles for later use. Reuse of a 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.

3. Remove the Tyvek pouch from the carton. Open the pouch and remove the plastic tube containing the needle. Remove the end cap nearest to the needle luer fitting and remove the needle from the tube. Finally, remove the needle from its protective sheath. Place the needle onto a sterile field, when required.
4. The 16 gauge portion of the Renú Transoral Needle may be bent to suit injection needs.

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. Prepare the patient for nasopharyngoscopy and anesthetize using standard methods. Local anesthesia is not required but may be utilized at the RENÚ® injection site.
6. Remove the Luer syringe cap from the distal end of the Renú syringe. If excess RENÚ® is on the surface of the Luer-loc fittings, it will need to be wiped clean with sterile gauze.

Twist the Renú Transoral Needle onto the Luer-loc fitting of the Renú syringe. **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.WARNING**: RENÚ should not be injected into the airway. Confirm placement of needle tip visually before initiating the injection.
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.

7. Place the nasopharyngoscope to precisely visualize the needle position and RENÚ® injection volume during augmentation. With needle location visually confirmed through nasopharyngoscope, slowly push the plunger shaft of the syringe to start the injection. RENÚ® should be injected lateral to the thyroarytenoid muscle.

CAUTION: If significant resistance is encountered during needle priming or during the injection procedure, under no circumstance should excessive force be used to overcome resistance since the injection needle may disconnect from the Renú syringe and/or over injection of the implant may occur. 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 used Renú Transoral Needle and opened syringes.
11. A course of antibiotics maybe prescribed, as appropriate.

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, Inc.'s obligation under this warranty is limited to the replacement of this product and Cytophil, Inc. shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this product. Cytophil neither assumes, nor authorizes any person to assume for Cytophil, Inc., any other or additional liability or responsibility in connection with this product.

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REF	Catalog number
LOT	Batch code
EC REP	Authorized representative in the European community
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STERILE R	Sterilized using irradiation
2 STERILIZE	Do not resterilize
2	Do not reuse
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