

Prolaryn[®] Gel

Injectable Implant

INSTRUCTIONS FOR USE

DESCRIPTION

Prolaryn[®] Gel is a sterile, latex-free, non-pyrogenic injectable material consisting of a buffered aqueous formulation of USP grade pharmaceutical excipients consisting of sterile water, phosphate buffer, sodium carboxymethylcellulose and glycerin. Glycerin, sodium carboxymethylcellulose and phosphate buffer are listed in 21 CFR 182 as Generally Recognized as Safe (GRAS), Sections 182.1320, 182.1745 and 182.6285 respectively.

Prolaryn[®] Gel 1.0cc can be injected with a 30 gauge needle or larger with a standard luer fitting.

INDICATIONS FOR USE

Prolaryn[®] Gel is indicated as a resorbable implant material to aid in surgical reconstructions as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation. Prolaryn[®] Gel is a temporary implant and resorbs within a period of 3-6 months.

IMPLANT MODE OF ACTION

Prolaryn[®] Gel injection augments the size of the displaced or deformed vocal fold so that it may meet in the midline of the opposing fold for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication.

CONTRAINDICATIONS

- Contraindicated in the presence of foreign bodies, acute inflammation, infection, inadequately controlled malignancy or rapidly advancing disease when these involve the laryngeal or upper respiratory tract.
- Contraindicated in bilateral laryngeal paralysis and vocal disorders of psychogenic or emotional origin.

WARNINGS

- Should be used only by trained otolaryngologists or experienced head and neck surgeons.
- Should not be injected into blood vessels. Injection into blood vessels may cause platelet aggregation, vascular occlusion, infarction, embolic phenomena or hemolysis.
- Requires viable tissue for effectiveness. Scar tissue and significantly compromised tissue may not coapt appropriately. Patients who have had multiple surgeries may not be appropriate candidates for bulking injection treatment.
- Use during pregnancy has not been established.

PRECAUTIONS

- Do not over inject the vocal fold. Prolaryn[®] Gel can be easily added in subsequent injections but cannot be easily removed. In extreme cases site rupture could occur.
- Lack of effect is possible. In some cases, initial treatment with Prolaryn[®] Gel may not be effective and additional injections may be indicated.

- The Prolaryn® Gel injection procedure and the associated instrumentation procedures have small, but inherent risks of infection and/or bleeding like similar otolaryngology procedures. The patient may experience slight discomfort during and following the procedure. The usual precautions associated with otolaryngology procedures, specifically vocal fold injection, should be followed.
- Care should be taken with the injection of Prolaryn® Gel, as with any surgical or implantation procedure, to avoid infection during the injection procedure.
- Prolaryn® Gel is supplied sterile and non-pyrogenic in a sealed foil pouch. Intended for single use only. **Do not re-sterilize or store partially used syringes for later use.**
- 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 are not in place or have been removed.

PHYSICIAN TRAINING

Injections of Prolaryn® Gel should only be performed by physicians who have experience with diagnostic and therapeutic otolaryngology procedures including vocal fold injection.

POST MARKET SURVEILLANCE

The following adverse events have been identified during post-approval use of Prolaryn® Gel. Because they are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal connection to Prolaryn® Gel. These events have been chosen for inclusion due to a combination of their seriousness, frequency in reporting, or causal connection to Prolaryn® Gel: dyspnea, pruritus, and cough.

INDIVIDUALIZATION OF PATIENT TREATMENT

Medical examination including medical history and diagnostic testing should be conducted to determine if the patient is an appropriate candidate for treatment with Prolaryn® Gel. The outcome of treatment will 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.

DIRECTIONS FOR USE:

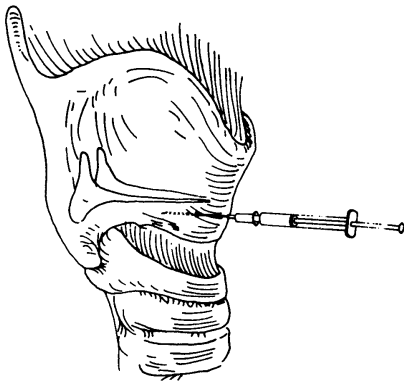
PERCUTANEOUS VOCAL FOLD INJECTION

The following is required for the vocal fold injection procedure:

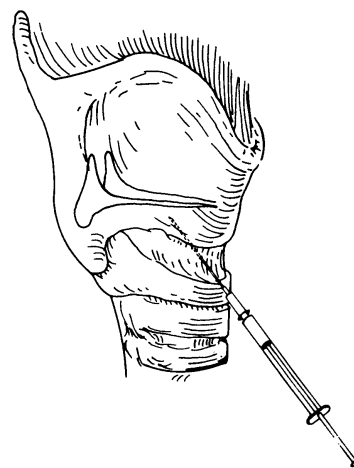
- Prolaryn® Gel syringe(s)
- Appropriate size needle(s) {Provided}
- Nasopharyngoscope

1. Prepare the syringe(s) of Prolaryn[®] Gel, injection needles(s), and nasopharyngoscope equipment before the surgical injection. A new injection needle may be used for each syringe or the same injection needle may be connected to each new syringe. **In all circumstances, when the injection needle is attached to the syringe of Prolaryn[®] Gel, the needle must be tightened securely to the syringe and be primed with Prolaryn[®] Gel.** Prepare nasopharyngoscope equipment using facility's medical practices for a nasopharyngoscope examination.
2. Remove foil pouch from the shipping box. 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.*
3. Prepare patient for nasopharyngoscopy and anesthetize using standard methods. No anesthesia is required at the injection site.
4. Remove the Luer syringe cap (on 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. **The needle must be tightened securely to the syringe and be primed with Prolaryn[®] Gel.** Slowly push the syringe plunger until Prolaryn[®] Gel extrudes from the end of the 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 needle.
5. Place the nasopharyngoscope to precisely visualize needle position during augmentation.

LOCATION AND DIRECTION OF NEEDLE PLACEMENT FOR TRANSCUTANEOUS INJECTION



[A] Through thyroid cartilage.



[B] Through cricothyroid membrane.

6. Extend the patient's neck if possible and identify by 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.

NOTE: Do not inject into a blood vessel.

7. Prolaryn[®] Gel should be injected lateral to the thyroarytenoid muscle. With needle location visually confirmed through the nasopharyngoscope, slowly push the plunger shaft of the syringe to start the injection. Prolaryn[®] Gel is injected in a sublamina propria plane. After the initial injection, the patient should be asked to phonate and cough to disperse Prolaryn[®] Gel throughout the vocal fold. Additional Prolaryn[®] Gel is injected until the vocal folds touch during respiration at a position midway between the anterior commissure and the vocal processes.
8. Some tissue planes may be difficult to inject. If significant resistance is encountered when pushing the plunger shaft, the injection needle should be pulled back about one (1) to three (3) millimeters (with the needle still in the vocal fold tissue) and the plunger shaft slowly pushed 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. 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.
9. Used and partially used syringes and used injection needles could be biohazardous and should be handled and disposed of in accordance with facility medical practices and local, state or federal regulations.

ORAL VOCAL FOLD INJECTION

The following is required for the vocal fold injection procedure:

- Prolaryn[®] Gel syringe(s)
 - Appropriate size needle(s) {Provided}
 - Nasopharyngoscope
1. Prepare patient for nasopharyngoscopy and anesthetize using standard methods. Local anesthesia is not required but may be utilized at the injection site.
 2. Prepare the syringe(s) of Prolaryn[®] Gel, injection needle(s), and nasopharyngoscopic equipment before the surgical injection. A new injection needle may be used for each syringe or the same injection needle may be connected to each new syringe.
 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. 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. The needle must be tightened securely to the syringe and primed with Prolaryn[®] Gel. Slowly push the syringe plunger until Prolaryn[®] Gel 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.
 5. Place the nasopharyngoscope to precisely visualize the needle position and Prolaryn[®] Gel volume during augmentation.
 6. Position injection needle for oral vocal fold injection. Prolaryn[®] Gel should be injected lateral to the thyroarytenoid muscle.

NOTE: Do not inject into a blood vessel

7. With needle location visually confirmed through the nasopharyngoscope, slowly push the plunger of the syringe to start the injection. After the initial injection, the patient should be asked to phonate and cough to disperse Prolaryn[®] Gel throughout the vocal fold. Additional Prolaryn[®] Gel is injected until the vocal folds touch during phonation at a position midway between the anterior commissure and the vocal processes.
8. Some tissue planes may be difficult to inject. If significant resistance is encountered when pushing the plunger, the injection needle should be pulled back about one (1) to three (3) millimeters (with the needle still in the vocal fold tissue) and the plunger slowly pushed 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. 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.
9. Used and partially used syringes and used injection needles could be biohazardous and should be handled and disposed of in accordance with facility medical practices and local, state or federal regulations.

HOW SUPPLIED

Prolaryn[®] Gel is provided sterile and non-pyrogenic in a pre-filled syringe containing 1.0cc of Prolaryn[®] Gel packaged in a foil pouch. The individual pouched unit is packaged in a kit configuration (contains more than one part number) with appropriate size needle(s).

The contents of the syringe are intended for single patient, single treatment use only and cannot be re-sterilized.

STORAGE

Prolaryn[®] Gel should be stored in its unopened, sealed package at a controlled room temperature between 15°C and 32°C (59°F and 90°F). Do not use if packaging and/or syringe are damaged or if the syringe end cap or syringe plunger shaft are not intact. Do not use if the expiration date has been exceeded. The expiration date is printed on the product labels and is based on storing the product as described above.

DISPOSAL

Used and Partially used syringes and injection needles could be biohazardous and should be handled and disposed of in accordance with facility's 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.

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

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