
CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE

INDICATIONS FOR USE

The *LATERA Absorbable Nasal Implant* is indicated for supporting upper and lower lateral nasal cartilage.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS

- Presence of an active infection at the implantation site.
- Patients known or suspected to have an allergy to PLA or absorbable materials.

WARNINGS

- Intended for single use only. Do NOT re-sterilize and/or reuse.
- Do not use the device if the integrity of the sterile packaging has been compromised or a loss of sterility is suspected.
- Improper patient selection, surgical site preparation, or implantation may potentially cause device failure and/or adverse reactions.
- The *LATERA Absorbable Nasal Implant* is not intended to replace normal healthy bone or cartilage.
- Subsequent infection may require Implant removal.
- Do not expose the *LATERA Absorbable Nasal Implant* to high temperatures and do not use if package temperature indicator shows exposure to temperature above 38 °C.

POSSIBLE ADVERSE EFFECTS

Adverse reactions typical to surgically implanted materials may occur. These include:

- Inflammatory foreign body reaction, foreign body sensation, pain or discomfort, infection, and extrusion.
- Excessive activity, trauma, or loading may lead to bending, fracture, loosening, and/or migration of the Implant.
- Implants placed near the skin surface may be palpable or cause skin irritation.
- Temporary hematoma from cannula insertion.

PACKAGING

- **STERILE:** The *LATERA Absorbable Nasal Implant* is sterilized with electron beam radiation. Do not use if the package is open or damaged.
- *The Accessory Delivery Device and Implant Positioning Guide* are sterilized with electron beam radiation. Do not use if the package is open or damaged.
- **IMPLANT STORAGE:** Store in a cool, dry location at or below 30 °C.
- **ACCESSORY DELIVERY DEVICE STORAGE:** Store in a cool dry place.
- **SINGLE USE:** The *LATERA Absorbable Nasal Implant, Accessory Delivery Device and Implant Positioning Guide* are intended for single patient use only. The *Accessory Delivery Device* may be used to deliver multiple *LATERA Absorbable Nasal Implants* to a single patient in a single clinical setting. Do NOT re-sterilize and/or reuse.

DEVICE DESCRIPTION

The Spirox® *LATERA Absorbable Nasal Implant* system is composed of the *LATERA Absorbable Nasal Implant* (Implant) and the *Accessory Delivery Device* (Delivery Device). An *Implant Positioning Guide* is provided to serve as an external visual planning aid prior to Implant placement.

The Implant is predominantly cylindrical in shape with a diameter of 1 mm and an overall length of 24 mm with a forked distal end for anchoring and features on the proximal end for increased flexibility. The Implant is composed of Poly (L-lactide-co-D-L-lactide) 70:30 copolymer which is absorbed in the body over a period of approximately 18 months. The Implant is provided in a plastic tray with a slidable lid. The Implant is depicted in **Figure 1** below.

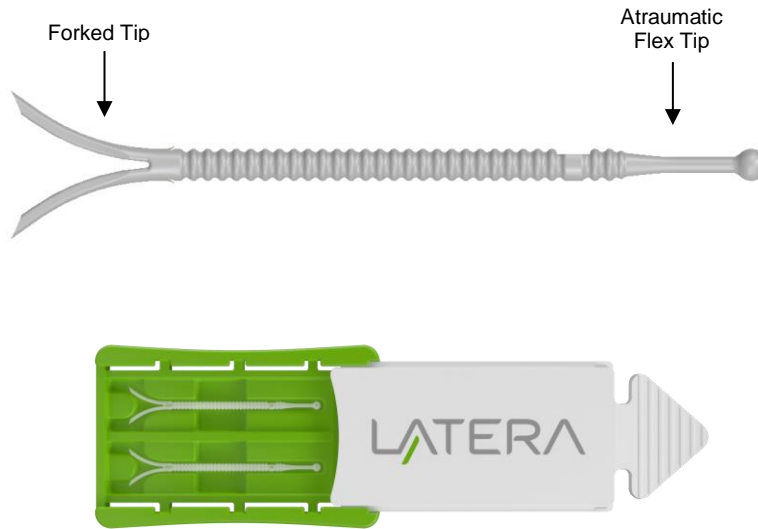


Figure 1: LATERA Absorbable Nasal Implant and Packaging

NOTE: Implant image representative, actual implant appearance may vary

The Delivery Device is a single use device composed of an inner shaft, an outer handle with a push rod, a deploy button, an open button and a 16 gauge delivery cannula with a protective cover. The inner shaft includes an implant loading port which enables the loading of the Implant and may include graphics to indicate the open position. The inner shaft transitions between the open position and the cannula to collapse the implant forks within the cannula inner lumen and prepare the Implant for deployment. The outer handle includes deploy and open buttons that lock and release the handle from these respective positions. The outer handle also includes a push rod that shuttles the implant from the implant loading port to a ready position for deployment. The Implant Positioning Guide is packaged with the Delivery Device and is provided as an aid to the physician for planning the procedure and identifying the target Implant location. The Delivery Device and the Implant Positioning Guide are shown in **Figure 2** below.

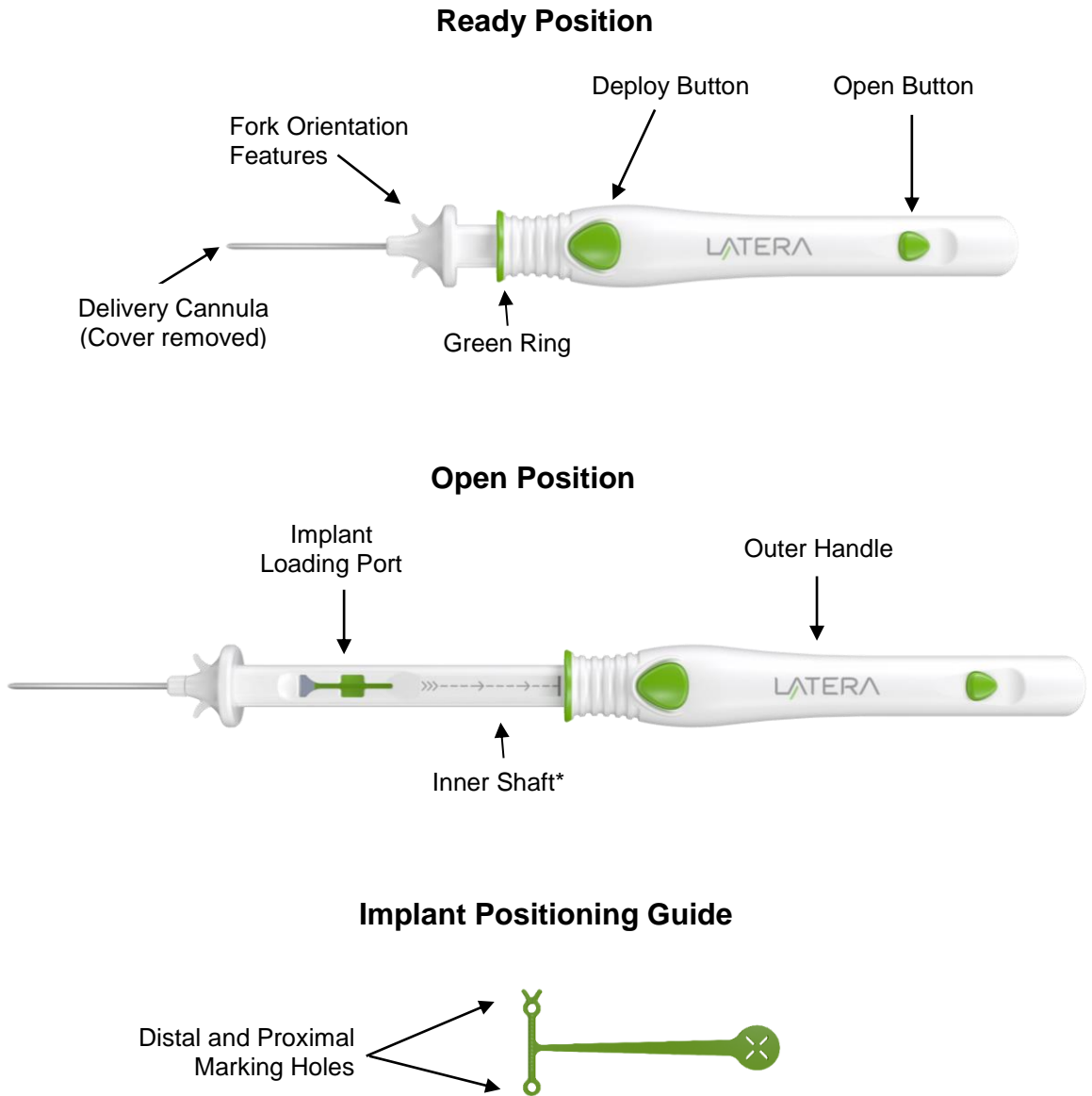


Figure 2: Delivery Device and Implant Positioning Guide

*NOTE: Some Delivery Devices will not include the graphics shown on the Inner Shaft.

COMPATIBILITY

- The *LATERA Absorbable Nasal Implant* is compatible with the *Accessory Delivery Device*. The *Accessory Delivery Device* should be used for proper insertion of the *Absorbable Nasal Implant*.

INSTRUCTIONS FOR USE

Implant Target Location and Device Preparation:

1. Standard surgical procedures should be used to prepare the site for implantation (e.g. cleaning, disinfection, anesthetic, etc.)
2. Prior to implantation, identify the target Implant location and cannula insertion trajectory. The forked distal tip of the Implant should be positioned adjacent and across the maxilla bone and the cylindrical portion of the Implant should be positioned to support the upper and lower lateral cartilage as shown in **Figure 3**.

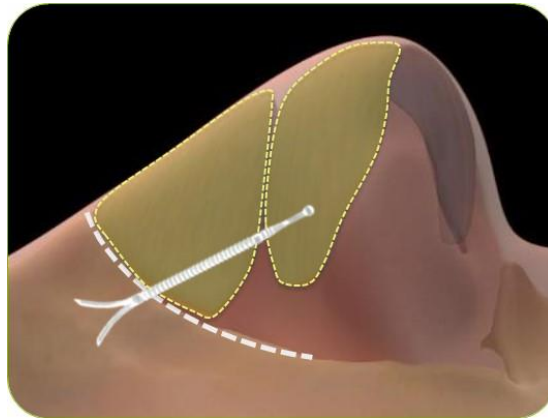


Figure 3: Example Implant location showing support of upper and lower lateral cartilage and position of Implant forks across maxilla bone to cartilage transition (dashed line).

3. Use the Implant Positioning Guide to mark the surgical trajectory as shown in **Figure 4** using a standard surgical pen. The holes provided on the Implant Positioning Guide allow for marking the base of Implant forked tip and the spherical end of the atraumatic proximal tip. The distal mark correlates to the final position of the cannula tip prior to Implant delivery.

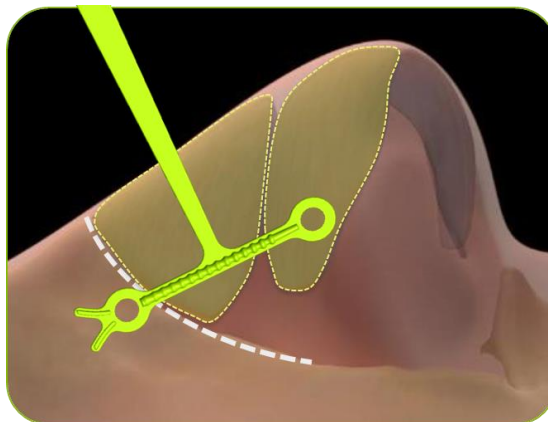


Figure 4: Implant Positioning Guide superimposed on upper and lower lateral cartilage

4. Retract the outer handle of the Delivery Device by gripping the distal flange of the inner shaft, holding the open button in the depressed position and gently pulling until the push rod is clear of the implant loading port. On devices with inner shaft graphics, the green ring will be proximal to the solid black line graphic when the push rod is clear of the implant loading port. Continue to retract the outer handle fully until the pushrod is clear of the implant loading port.

- Using sterile surgical forceps transfer the Implant from the plastic tray to the implant loading port of the Delivery Device as shown in **Figure 5**.



Figure 5: Delivery Device with Implant Loaded

- Slowly advance the outer handle until the outer handle locks into the ready position to advance the Implant into the delivery cannula. While advancing, watch the implant load into cannula inner lumen. This positions the Implant at the tip of the cannula in the ready position. Proper implant loading and handle positioning is shown in Figure 6 below.

Note: If the deploy button is pressed prematurely and the outer handle is advanced too far, the Implant may exit the delivery cannula. If this should happen, completely advance the outer handle so the forks exit the cannula. Carefully remove the Implant from the cannula and repeat the setup process from Step 4.

Proper Cannula Advancement and Implant loading

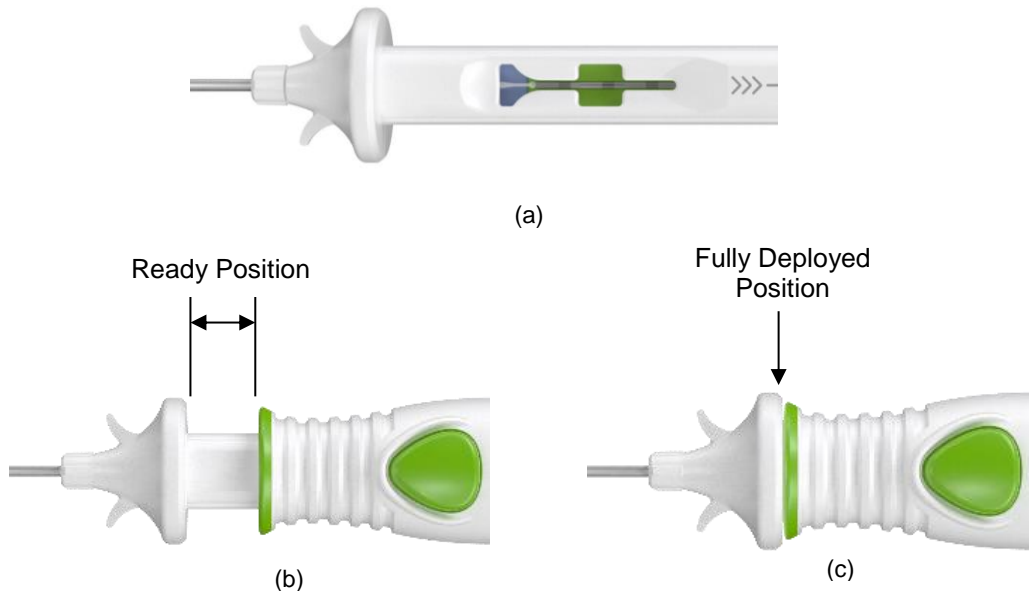


Figure 6: Images showing (a) Proper Cannula advancement and Implant Loading, (b) Delivery Device Ready Position, (c) Delivery Device Deployed Position

Implant Delivery:

- Under direct visualization, the delivery cannula is inserted through the nasal vestibular lining of the lateral wall within the nasal cavity near the margin of the nostril. A small conventional scalpel incision at the target cannula entry location may be optionally created to ease cannula puncture. Approximate Delivery Device orientation and cannula trajectory is shown in **Figure 7** below.

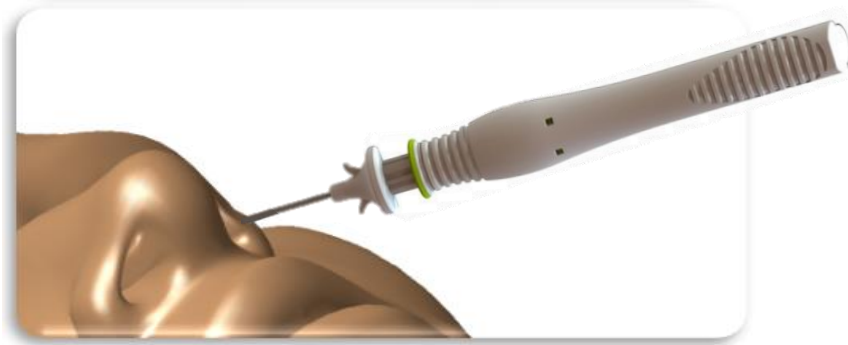


Figure 7: Approximate Delivery Device orientation relative to nasal anatomy

- Identify the cannula insertion point, **Figure 8(a)** below, to provide the maximum distance between the cannula insertion point and the target position of the proximal tip of the Implant to ensure the Implant is fully embedded within the tissue, **Figure 8(b)** below.

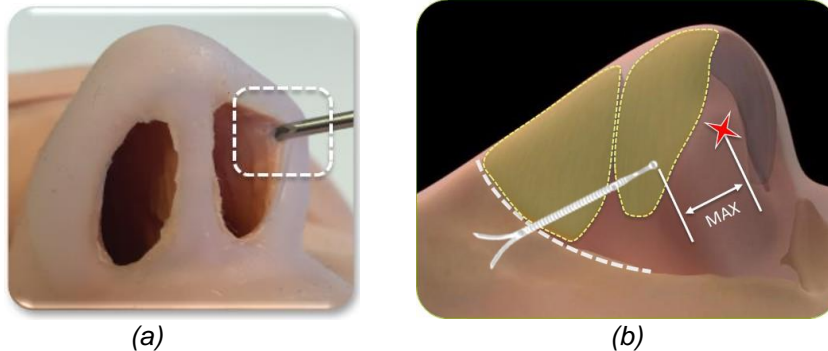


Figure 8: Images showing (a) approximate caudal cannula pierce position in the vestibular lining at the margin of the nostril and (b) the distance intended to be maximized between cannula pierce point and the proximal tip of the Implant

- The cannula should pass along the center of the thickness of the lateral wall to avoid piercing medial through the mucosa or lateral through the skin as it traverses the wall to the target location.
- When the cannula reaches the bony cartilaginous junction, the cannula is passed over the maxillary bone to the target depth.
- If the nasal tissue has compressed or bunched-up during cannula insertion, relax the tissue to its native position. Verify that the cannula is inserted deep enough such that the tip of the cannula is positioned over the maxilla bone. An example of appropriate cannula position within the nasal lateral wall is shown in **Figure 9** below.

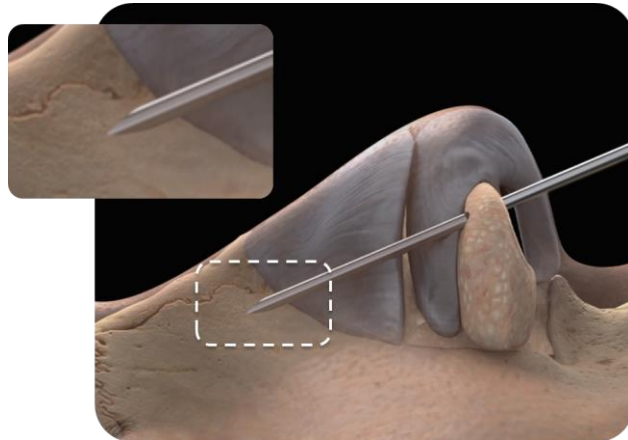


Figure 9: Cannula at target depth mid-thickness within the lateral wall structure. The intended position of the cannula tip and cannula are shown in the magnified views

12. The Implant forks will expand to their original shape as they exit the cannula tip in the orientation they are loaded. Using the Implant fork orientation features on the distal end of the Delivery Device as a reference for fork orientation, verify that the Delivery Device rotation about its axis is appropriate to deliver the forks parallel to the underlying bone.

CAUTION: The Implant forks diverge as they engage with the tissue; orientation of the forks must be controlled by orienting the Delivery Device to prevent forks from piercing towards skin surface.

13. When the cannula is in the appropriate location and orientation, the deploy button can be depressed and released and the outer handle can be carefully advanced to the deployed position. Keep fingers proximal to the green ring when deploying the implant. Cannula may be stabilized with off-hand while deploying, if desired. The Implant forks are driven approximately 4 mm into the tissue beyond the distal tip of the cannula when deployed. The Implant delivery process is shown in **Figure 10** below.

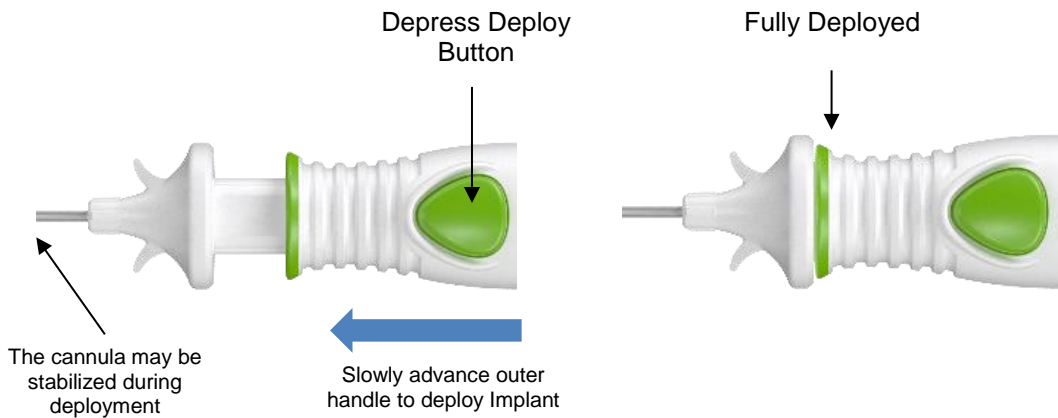


Figure 10a

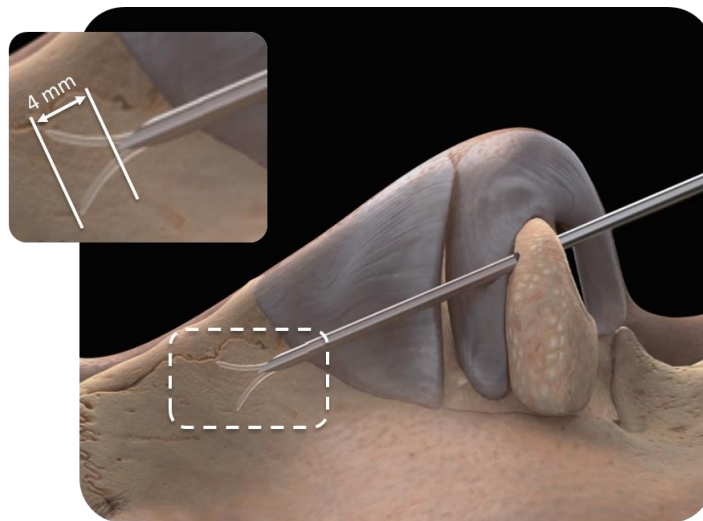


Figure 10b

Figure 10: Images of the Delivery Device proximal end and cannula positioned within the lateral wall showing Implant deployment process including: (a) Actuation of the Delivery Device outer handle and (b) Implant forks expanded approximately 4 mm distal to the cannula tip after deployment.

CAUTION: The forks will advance approximately 4 mm beyond the tip of the cannula when deployed. This should be accounted for in determining the extent of cannula advancement.











CAUTION: Do not hold the inner shaft of the delivery device while deploying. Applying all distal pressure to the outer handle ensures minimal Delivery Device movement during deployment.

14. Following deployment, slowly withdraw the cannula from the tissue. Take care to not alter the angle or rotational orientation of the Delivery Device while withdrawing or the Implant could be dislodged.
15. After complete withdrawal, visually examine the insertion site to ensure the Implant is not exposed and is fully embedded within the tissue. Do not compress or fold the lateral wall to visualize the insertion site. The insertion site may be optionally closed by conventional suture techniques.
16. If multiple implantation attempts are required, a second insertion should utilize a different pierce point within the mucosa and follow a different cannula trajectory.
17. Counsel the patient to avoid manipulation of the nose during the acute healing period (e.g., Week 1: do not pinch or blow nose; Weeks 1-2: avoid strenuous activity; Weeks 1-4: do not place objects inside of nose).

DISPOSAL

The *Accessory Delivery Device* should be disposed of in a biohazard sharps disposal container. The *Implant Positioning Guide* and the *LATERA Absorbable Nasal Implant* container may be disposed of along with standard medical waste.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING

STERILE	R	Sterilized using Irradiation		Keep Away from Sunlight
LOT		Batch Code		Do Not Re-Use
REF		Catalog Number	Rx ONLY	On Order of Physician Only
		Manufactured For		Date of Manufacture
		Use By		Consult Instructions For Use
		Contents of Package/Box		Upper Limit of Temperature
		Keep dry		Do not use if package is damaged

TRADEMARKS AND PATENTS

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Consult a list of patents covering this product at www.spiroxmed.com.